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AUTHORITY
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AD _____

Award Number: DAMD17-96-1-6260

TITLE: A New Vision for Integrated Breast Care

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REPORT DATE: September 1999

TYPE OF REPORT: Annual

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

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Form Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE September 1999	3. REPORT TYPE AND DATES COVERED Annual (15 Aug 98 - 14 Aug 99)	
4. TITLE AND SUBTITLE A New Vision for Integrated Breast Care		5. FUNDING NUMBERS DAMD17-96-1-6260	
6. AUTHOR(S) Laura J. Esserman, MD			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of California San Francisco, California 94143 -0962 e-mail: laura.esserman@medcenter.ucsf.edu		8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012		10. SPONSORING / MONITORING AGENCY REPORT NUMBER	
11. SUPPLEMENTARY NOTES			
12a. DISTRIBUTION / AVAILABILITY STATEMENT Distribution authorized to U.S. Government agencies only (proprietary information, Sep 99). Other requests for this document shall be referred to U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, Maryland 21702-5012.			12b. DISTRIBUTION CODE
13. ABSTRACT (Maximum 200 Words) During the third year of "A New Vision for Integrated Breast Care", we have launched many of the programs designed during the first two years: We have successfully launched our same-day assessment, and follow-up programs, which have streamlined care, made our clinic more efficient, and deliver better services to our patients. We will evaluate our same-day assessment program using the same tools that we are using to assess abnormal mammograms in Project 1. In Project 4, we have added to our tool set, so that it consists of consultation planning and consultation recording. This type of tool will be merged with Project 3, which will be producing tailored Kaplan-Meier plots to describe the benefits of adjuvant chemotherapy. Forms and data content has been organized, and we are basing the data elements on national standards (where they exist) or developing them with other groups. We have successfully integrated clinical trials into every stage of care. Educational packages are available for most types of patients we see at the clinic. In the near future, our redesigned website will include all of the educational material, as well as on-line scheduling and communication. Staff and patient-satisfaction is at an all time high.			
14. SUBJECT TERMS Breast Cancer Center			15. NUMBER OF PAGES 204
			16. PRICE CODE
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Limited

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)
Prescribed by ANSI Std. Z39-18
288-102

FOREWORD

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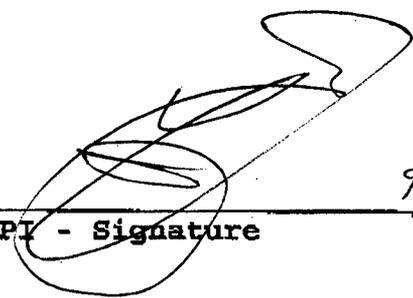
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A New Vision For Integrated Breast Care Year 3

Introduction

A great deal has been accomplished during the past year. This introduction serves to highlight some of our successes and discuss the challenges we face. We have organized the body of the report by presenting separate progress reports from each core and project, including the year's goals, what was accomplished, and what is planned for the fourth year.

We are especially pleased with the progress of Project 4. We have added to our tool set, so that it consists of consultation planning (CP) and consultation recording (CR). CP is a technique in which we capture and organize the patient's concerns. CR is the organization of the consultation itself, using a collaborative framework for discussion that includes the establishment of facts, a review of the CP, outline of options and consequences of interventions, the resolution from the discussion, and the next steps to take. This whole process is captured and recorded on a single sheet of paper that can be given to the patient and placed in the medical chart. Karen Sepucha refined this entire process and completed a pilot trial as her PhD dissertation, which was received very enthusiastically. We are enormously excited by this development and have presented it at meetings and grand rounds, as well as submitting it as a manuscript to the Journal of Clinical Oncology. We have just hired a full-time person, Caryn Aviv, to continue the work, and we are planning a large scale trial. This is just the kind of tool we need to merge with Project 3, which will be producing tailored Kaplan-Meier plots to describe the benefits of adjuvant chemotherapy.

By the end of the grant period, we believe we will have a complete package of tools that facilitate the process of "collaborative care." By that, we mean consistent means for evaluating concerns, describing options, representing risks and benefits, and capturing the conversation in a format that is easy for patients to understand and review. The process facilitates patient-participation and can be used by all physicians in the practice.

We have also made considerable headway in the organization of care by defining our programs around "disease states", so that we can utilize resources most efficiently and maximize value to patients. We have identified 6 such states: high risk, same-day evaluation, treatment of primary breast cancer, follow-up, metastatic care, and second opinion. We have successfully designed programs around same-day assessment and follow-up, which has streamlined care, made our clinic more efficient, and delivers a better package of services to our patients. We will evaluate our same-day assessment program using the same tools that we are using to assess abnormal mammograms in Project 1. We are currently designing our comprehensive high-risk program and the associated clinical trials and will be seeing our first patients for that program in October.

Developing the infrastructure for informatics has been most challenging. Forms and data content have been organized, and we are basing the data elements on national standards (where they exist) or developing them with other groups. Integrating the data forms, completing the process-flow analysis, and integrating the package is a much more exhaustive task. There is a formidable barrier of resources required to automate the forms in a usable fashion so that data can be entered at the point of care. Forming partnerships to develop systems is necessary. We have just been successful in garnering a grant from the Life Sciences Informatics program of the University of California to develop such a system.

We have successfully integrated clinical trials into every stage of care and now have over 25 clinical trials open at the Breast Care Center. Our accrual has gone up and we have worked with our breast cancer advocate group to develop introductory letters about clinical trials and also to explain specific trials. Abbreviated versions of these letters were published in our reconceived newsletter (appendix A). Our accrual has improved from less than 5% of patients on trials to over 25% of new patients on trials.

Our educational packages are now available for most types of patients we see at the clinic. We are currently designing our website to include all of the educational material as well as to plan for on-line scheduling and communication in the future. We are planning to conduct our first on-line survey this fall, and launch the full Breast Care Center website in October.

We have reconceived our newsletter with a more professional format and much wider distribution (appendix A). The newsletter includes information to our patients about program changes, new research findings, clinical trials, new staff, support groups and resources. Our first edition was sent out in July of this year, and we have received an overwhelmingly positive response.

We have completed improvements to the physical space and have planned our new clinical floor at the new Cancer Center (currently in construction) so that all services will be available on the same floor. The Breast Care Center has been instrumental in completing our story garden, which includes a wall of over 580 tiles etched with patient stories, a redesigned, beautiful garden, a new resource center, and a boutique with prostheses and wigs.

All of these changes have helped us to coalesce and work well as a team. Principles of enlightened management, where problems are analyzed, discussed with staff, and collectively solved, have helped to keep the program unified, even as we have doubled our physician staff and patient volume. Patient-satisfaction is at an all time high, and we have not had one turnover in our front office staff in two years.

Administrative Core and Continuous Quality Improvement (CQI) Core

The Administrative and CQI Cores continue to be closely integrated. The work of the Administrative Core directly supports the outcomes targeted by the CQI Core.

Administrative Core

Activities that are primarily administrative included in Year 3:

- administration of all subcontracts and consultation agreements
- a close working relationship with the UCSF Contracts & Grants office to ensure compliance with all rules and regulations
- organization of the monthly PI meetings and the quarterly meetings of all the grant participants, as well as participation in the CQI packaging subgroup
- organization of and data gathering for the physician time-tracking (CQI) project
- administrative supervision of staff and facilities at the off-campus research offices at 2299 Post
- creation of the new Breast Care Center newsletter which is being sent to over 2000 patients and providers (appendix A)
- organization of a lecture at UCSF's Herbst Hall by Stanford Professor and organizational expert Dr. Jeffrey Pfeffer (appendix B).
- Currently, the core is working on the speaker program for this next grant year. Among the speakers we will be inviting is Dr. Michael Roizen, chair of anesthesia at the University of Chicago and a preventive gerontologist who developed the Real Age program, which is based on over 25,000 studies on aging. His insights into the mechanisms of aging and how to remain more vital will be of great benefit not only to our patients but to the whole UCSF community.
Other possible future speakers include:
 - Dr. Michael Abel, CEO of Brown & Toland Medical Group and expert on the economics of outcomes and CQI
 - Dr. Laszlo Tabar, Director of Mammography at Falun Central Hospital in Sweden and an international expert on mammography trials.

CQI Core

Introduction

Over the course of Year 3, the CQI Core has concentrated its energies on continuing to pursue the following objectives:

- Enable the collection of information that doctors and patients need to better understand the outcomes of interventions. This will enable their decision-making regarding treatment options
- Standardize forms and procedures
- Improve availability of new patient appointments
- Improve efficiency
- Improve cost effectiveness
- Gather information electronically. These will enable the establishment of baselines so that necessary improvements can be made and monitored over time

The main focus of our efforts this year has been to develop and implement the Same Day Assessment Program and the Follow-up Program. Models have been derived from these programs that are pertinent and applicable to other new and existing programs.

Statements of Work for Year 3

- Choose clinical and medical outcome measures and business process measures to be used as the "report card" for the Breast Care Center. These measures must reflect the needs of the patients, the physicians, health plans and employers.
- Establish a patient navigator program.
- Create a new follow-up program.
- Hold a series of forums to address quality issues in the eyes of the patient.
- Identify a hierarchy of values for patients and providers regarding treatment decision making.
- Create survey instruments for staff and MDs to fill out regularly to identify areas where improvement is needed.
- Develop a CQI time study and process improvement study for the time it takes to perform a wire localization.
- Create patient satisfaction surveys.
- Coordinate all surveys and activities.

Patient Focus Groups

To date, two patient focus groups reviewing service needs and performance have been held. Patients have been recruited by direct telephone solicitation and invited to attend a one-time group to discuss their experiences as patients at the Breast Care Center (BCC). For the most part, patients have been receptive to this idea and, if they have been unable to attend the group, have been willing to discuss their views on the telephone. The most difficult problems in recruitment to groups has been reaching women on the telephone as opposed to answering machines and finding a time that suits their schedules.

Recruitment for further focus groups will follow a plan of offering two potential times for participation, an evening and a day group, and offer a stipend of \$25 to each patient for their participation.

The procedure in the groups has been to allow a range of topics to surface. Questions from this leader have been open-ended and broad in order to facilitate a discussion about aspects of service and care at the Center. Women in the groups have understood that their comments are confidential and that their input will be used to answer basic questions: What kind of service and care are we giving at the Center, and how can we make it better?

The topics discussed in the groups fell into several general categories: procedural problems and successes (e.g., making an appointment, waiting time, referrals to other resources); relationship and contact with MD's and support staff, including nurses, administrative assistants, psychosocial staff; availability and access to information; coordination of service with other important services; and the physical environment. While the patients' comments included a wide range of issues, a few consistent themes emerged. On the whole patients want to be heard, understood, and received by their physicians and the staff at the Center in a personal and caring fashion with attention to the details of their experiences. They also want organized and easy access to information and referral sources outside the center. Professional, thorough treatment and collaboration with their physicians is another significant concern.

In general, the patients note that the Breast Care Center has succeeded in these areas. However, there is room for improvement and patients made specific suggestions which will be helpful in the further development of our services. For example, one patient noted that there is no "official welcoming to the BCC" while another noted that the infusion center staff was "wonderful." A number of patients have suggested that the BCC's way of helping patients access information is spotty. For example, they suggested a monthly newsletter, more advertising of services, and that the folder of information for new patients was intimidating and might be reexamined.

In sum, the focus groups are producing valid suggestions for consideration. Following the completion of the study, a summary and more thorough examination of results will be available.

Report Card

The Packaging Subcommittee has continued to meet during year 3. They have been working on the definition of quality measures related to breast cancer care that are relevant to performance measurement data sets being developed by purchasers, health plans, and accrediting bodies. The goal of this subcommittee is to focus on delivery system measures that can be the building blocks of performance measurement data sets such as NCQA, HEDIS or JCAHO ORYX. If these measures are methodologically sound and represent the spectrum of breast cancer care, then they could be adopted as a valid assessment of quality and provide clinical and financial incentives for further improvement in patient care.

A measure of time from intake to diagnosis was considered and felt to be problematic. BCC chart reviews done by Grant Coordinator Sarah Paris revealed that of all new patients less than 50% have no diagnosis. The rest of the patients present to the BCC for treatment and/or second opinions. Within the remaining sample of new patients without a diagnosis, the biggest obstacle was a missing intake date. The forms are currently being revised to address this problem.

As a measure of the quality of surgical care at the BCC, it was decided to test the feasibility of assessing surgical re-excision rates using both manual and on-line chart reviews. A sampling of charts were identified and reviewed by Wade Aubry, MD, who directs the Packaging Committee. A total of 77 charts were reviewed (28 manually and 51 electronically). The charts included all patient records including data from other providers. The electronic records included histories and physicals, operative reports and pathology reports, but not outpatient visit notes. In most cases, the electronic pathology reports alone were sufficient to determine the diagnosis and reason for repeat excision. Operative reports were useful in some cases. Findings and preliminary conclusions are as follows:

- Approximately half of the patients had a benign diagnosis, and approximately 30% had re-excision for invasive CA or DCIS.
- Some patients were treated elsewhere or were lost to follow-up.
- Core biopsies frequently have positive margins, followed by excision.
- A common reason for re-excision was DCIS. More input from the CQI group is needed as to whether DCIS should be treated the same or differently from invasive CA. Not including DCIS would reduce the sample size significantly.
- On-line reviews proceeded more quickly and could be performed by a trained clinical assistant with clear guidelines; however, there would always be gray areas that would require physician review. This process could be integrated into the overall information systems to facilitate analysis.

- Denominator population would need to be defined clearly in terms of which patients to exclude (such as benign diagnosis, core biopsies, re-excision following excision at another facility, and potentially, DCIS).
- Literature review by the Packaging Subcommittee needed to determine benchmark rates. Integrate guidelines established for "report cards" by the National Comprehensive Cancer Network.
- Re-excision rates can be measured using the database and may potentially reflect the quality of surgical care if methodologic issues can be addressed and resolved.

At the last Packaging Subcommittee meeting, we considered measures of medical oncology care for breast cancer with the assistance of BCC oncologist John Park, MD. The oncology patient population can be generally divided into two groups: primary cancer patients and metastatic cancer patients. Different measures would likely be required for each population. At the BCC, the larger group is the primary cancer patient population. When considering survival rates, however, 5-year rates are needed in this group, while 2-year rates may be valid (and yield more data in the short term) in patients with metastatic breast cancer. Another key issue is that patient populations must be evenly matched in terms of performance status in order to permit comparisons across groups or institutions. Measures other than median or overall survival that may be appropriate in these patients include access to clinical trials (participation, counseling, number of trials offered) quality of life surveys, and recurrence (3-year) after adjuvant therapy. One of these measured will be tested for feasibility as was done for the surgical excision rate. The status of the FACCT measures should also be determined. This will involve coordination with Pilot A.

The re-excision measure data will continue to be collected over Year 4. The metastatic measure data collection will commence within the first quarter of Year 4.

Time tracking study

As part of our effort to improve patient care and clinical efficiency, an in depth time study was performed in the Breast Care Center. The study involved measuring the different amounts of time that patients wait (i.e. waiting to be escorted to an exam room, waiting for the doctor in the exam room, etc.)

The resulting data was analyzed and discussed at the BCC faculty meeting. Areas of improvement were identified and specific interventions mapped out to shorten waiting time for patients. These interventions will be implemented within the first quarter of Year 4.

Patient Navigator Program

After months of preparation, the Patient Navigator Program was ready to begin in September of 1998. Volunteer navigators had been trained, a manual written and a mechanism for referral established. Since September, the program has been presented to 27 newly diagnosed breast cancer patients during consultation with the BCC psychologist, with written information about the program provided. Of the 27 patients, no one has expressed an interest in the program. In addition, one patient was referred by a practitioner. This patient wanted the name of another patient to call who had been through the type of reconstructive surgery that they were seeking.

The sheer number of women diagnosed with breast cancer in the Bay Area may mean that most women already know someone who has had the disease. Several women indicated that they spoke with a friend of a friend, etc. Patients in the BCC may be more sophisticated and able to "navigate" the system on their own. This, coupled with the many

organizational improvements in the BCC over the last 3 years, may mean that there is not a great need for patient navigators.

It is clear that there continues to be a need for a phone list, so that patients may speak with others who have had specific types of treatment. To that end, a database will be created. This database will include women who are willing to speak with others regarding some aspect of their experience. This would limit the interaction to phone contact. The database will be implemented for clinic patients reflecting the service in the clinic.

Patient Satisfaction

Two survey instruments were developed and implemented this year. One is strictly for new patients to the BCC, the other is for follow-up patients. Results will be tabulated and reviewed every 6 months (appendix C).

Additionally, a survey was done by the larger organization looking at patient satisfaction with the FNA services (appendix D).

Staff Satisfaction

Based on staff satisfaction surveys and discussion at staff meetings, two interventions were designed to increase job satisfaction. These activities were chosen as methods to develop team relationships and help the staff deal with personal issues that arise as an outcome of working with cancer patients.

One of the objectives of the BCC is to maintain a very low level of staff absenteeism and turnover, so that patients feel a sense of continuity with the staff. If the staff members feel that they are part of the team, they are less likely to miss work or leave for other job opportunities.

The first intervention was designed by the Art for Recovery Program Director, Cindy Perlis. She had the team complete several small projects that involved expressing their emotions through working with color and paper. She asked the staff to depict "how it feels to work in the BCC".

The second project was an off-site activity that occurred at a ceramics studio. The staff each drew a name of another staff member out of a hat and made a mug specifically for that person. After the mugs were fired, they gave the mug to the person that it was created for. This activity gave the staff a chance to be together without the workday interruptions and be creative together. They learned new things about each other.

Same Day Assessment Program (Appendix E)

In order to improve access for patients, a "Same Day Assessment Program" was developed and implemented by the clinical staff and the CQI analyst. This program is designed to facilitate and streamline the process for patients who have an abnormal mammogram or a breast lump. The outline of the program is as follows:

- A patient calling the BCC with a breast lump or an abnormal mammogram to schedule an appointment is scheduled with a surgeon on the day that this program is available.
- The patient sends or brings all relevant data (i.e. previous mammograms, medical records) to the appointment.
- A breast exam is performed and records are reviewed.
- All of the patients films are reviewed and the case discussed at a noon conference that includes the surgeon, the radiologist, the radiology technician, the BCC nurse

coordinator. Recommendations are made. Based on the findings from the exam and review of the records, the patient is scheduled for further diagnostic testing (i.e. Fine Needle Aspiration, stereotactic core) during that afternoon.

- A return appointment is made for the patient within the next 48 hours.
- The patient is phoned if the result is negative and does not need to return for their appointment the next day.
- If the result is positive, the patient will keep the appointment and come in to discuss next steps with the surgeon.
- Data is collected on the day of the program.

The SDAP began in October 1998. So far, the program operates one day a week. Within the next 6 months, the program will expand to 2 days per week. The trial period is close to completion, so problems in the system have been identified and improvements implemented.

The following data elements are collected:

- Fine needle aspiration(FNA) (date of test, patient, test ordered, test result, patient birth date, physician ordering test)
- Core biopsy
- Stereotactic core biopsy
- Stereotactic FNA
- Ultrasound
- Ultrasound guided FNA
- Screening mammograms
- Diagnostic mammograms
- Clinical impression
- Excisional biopsy
- Surgeries
- Benign follow-up from biopsy
- Time for definitive diagnosis
- Time for test results to be received
- Flow path for all patients included in program

A cost analysis of the program is underway. The costs that are being tracked and analyzed are related to all services provided to patients of the SDAP (i.e. imaging, pathology, laboratory, surgery).

Follow-up Program (Appendix F)

The next program which was implemented in year 3, is the Follow-up program. The main objective of this program is to increase accessibility for patients. Up to 80% of patients seen by the BCC physicians are coming for follow-up care. A designation of "follow-up" means that they are at least one year away from their cancer diagnosis and are deemed cancer-free. By freeing the physicians' time, particularly the surgeons, more new patients can be seen. Another objective, was to decrease the number of visits for each patient. By chart review, it was determined that some patients have come to the BCC as frequently as 30 times in one year. The premise is that by carefully managing the course of follow-up care, patients will be better served by minimizing visits to the BCC.

Initializing this program meant sending letters to patients who meet the follow-up criteria to inform them of the shift in the pattern of care and assure them that if there was any question about their care, their physician would be available. The next step was to begin scheduling this group of patients with Nurse Practitioners instead of physicians. A flyer was created

to inform/remind patients of the monthly forum that was developed particularly for this patient group to give the patients some access to their physician(s) through this venue.

A survey tool will be implemented in October 1999 to ensure patient satisfaction with this program.

Patient Outcome Measurement Tools

Under the leadership of Deborah Lubeck, PhD, the assessment tools for tracking patient outcomes have been selected and scheduled for implementation. The most difficult task was to determine the points at which patients could consistently receive the surveys. Once this was established, the implementation could begin. The categories that will be measured are general health domains, disease specific measures, problems and symptoms, and overall satisfaction (appendix G).

CQI Tracking Log

A log was designed and implemented that outlines all CQI projects underway in the BCC. The log delineates the description of the project, the goal, what is being measured and how it is being measured.

Personnel Changes

Carrie Sanders, CQI Analyst, has left the university. Her activities have been taken over by Tad Lacey, MBA, MPH, a consultant with an extensive background in healthcare CQI development that will lend itself well to the accelerated effort of the database project. Tad Lacey will assume the role of principal investigator of the CQI Core. He most recently worked for Healthcon Corporation which specializes in reengineering work processes in the realm of health care. This work complemented his already existing work process reengineering, change management and health care strategy experience, gained while a management consultant with Arthur Andersen (appendix H).

Hope Rugo, MD, Assistant Clinical Professor of Medicine, has joined the BCC staff as a clinical oncologist. Hope's focus will be working with Tad to develop a process outline for specific CQI initiatives directed towards patients with metastatic disease. Hope has an extensive background in hematology/oncology. She most recently was part of the Bone Marrow Transplant service. She will offer her services at no charge to this Grant.

Conclusion: Goals for Year 4

- Establish goals of therapy and analysis of outcomes for each of the 6 program modules.
- Identify intended versus unintended variations in patterns of care, with a focus on metastatic breast cancer treatment.
- Work with Informatics Core to make sure data collected and analysis will support tasks 1 & 2.
- Physician focus groups will be conducted in order to continue the work which analyzes quality standards through the eyes of the various stakeholders. Patient focus groups will continue, as well.

- The template derived from bringing up the Same Day Assessment Program will be applied to the next set of new programs:
 - High Risk Clinic
 - New Patient Program for Oncology
- The costing model begun in Year 3 for the Same Day Assessment Program will be completed and applied to the other programs.
- As the clinical database work is defined and completed by the Informatics Core, the CQI core will provide necessary data, assist in the process mapping activities, review the deliverables and make recommendations, and generally serve as a liaison between Management Science Associates(MSA) and the BCC to ensure that continuous quality improvement techniques are utilized.
- Measure BCC physician satisfaction again, following interventions.
- Develop data collection methods for tracking specimen pathology in conjunction with MSA.
- Monitor CQI tracking log, enabling all staff to utilize the information on-line.
- Implement selected measures and continue collection of data already in progress for the report card in order to ultimately present a data set that will describe the elements of the packaging recommendations.
- Publication and Presentation Plan for Year 4
- Clearly delineated patient disease states and related services with goals of care and required data analysis.
- Costs of care associated with disease states by visit type and stage.
- Issues involved in working with and incentives for private sector companies in the clinical trial arena.
- Business process reengineering issues faced in implementing a clinical trials database.

Informatics Core

Statement of Work

In efforts to serve all the research projects and other cores of the UCSF Breast Care Center, the Informatics Core has established the foundation for a comprehensive clinical communications system. Common databases have been designed and programmed to support both clinical and research activities. The communications infrastructure is in place and the staff is migrating to a standard set of desktop software to support electronic mail, Internet/World Wide Web access and other computing needs. Tasks completed this year have positioned us to accomplish our goal of creating real-time data collection and data analyses that support the clinic's goals of care.

Common Data Elements/Data Dictionary

The Informatics Core has continued its efforts to define the critical data elements necessary to the day-to-day process of caring for patients with breast disease. A crucial part of this effort has been the process of standardizing data elements common to information systems used in breast cancer clinical care and research. In this regard, the Informatics Core has collaborated with the National Comprehensive Cancer Network (NCCN, a consortium of 18 U.S. cancer centers that UCSF recently joined), which has developed a comprehensive data dictionary of breast cancer-related data elements for use in clinical care and in assessing patient outcomes. We have used the NCCN data dictionary to guide the development of the BCC clinical database, described in more detail below.

We are also collaborating with Dr. John Silva of the NIH and the Defense Advanced Research Projects Agency, who is developing a data dictionary for breast cancer clinical trials that will also have broader applicability to routine clinical care. This data dictionary is available on the World Wide Web, and we are evaluating the appropriate way to incorporate these data elements into BCC information systems.

To assist us in evaluating the NCCN and NCI data standards, we have been fortunate to work with Qing Yan, M.D., an internist from China who is currently a UCSF graduate student in Medical Information Science. In conjunction with other members of the Informatics Core and with BCC clinicians, Dr. Yan is actively reviewing these data elements, and she has already modified components of BCC databases to use the NCCN data standards.

BCC Forms And Databases

Several data collection forms and databases have been developed by the Informatics Core and have been used by various groups within the BCC. Patient and physician satisfaction forms, used by the BCC clinic administration, have been designed to be machine-scannable with the TeleForms scanning software package. Additional scannable forms include a patient intake form developed with the clinic administration. This form, and non-scannable health questionnaire, surgical summary, and pathology summary forms, are in the process of being entered into the BCC database, which resides in Microsoft Access on an NT Server in the BCC. This database is currently being managed by Dr. Yan, mentioned above, who has also worked with BCC clinicians to refine a patient summary form that will be printed at each patient visit.

Additional databases developed in FileMaker Pro by Dr. Kiran Patel, formerly of the BCC, and by Ms. Liz Bogen, a consultant, include a Tibetan medicine database and an alternative medicine database. These two projects have been led by Dr. Debu Tripathy. Both of these databases have accumulated data on significant numbers of patients.

BCC Web Site

The BCC Web site development began with the clinical trials component. Ms. Fern Hassin has kept the content of the Web site current, and Dr. Ellyn Cohen is providing Web site maintenance. We have now contracted with Ms. Jennifer Melnick to design an expanded Web site that covers all BCC clinical services.

Collaboration With Other Cores

The Informatics Core has provided significant support to the Psychosocial Core, which recently moved to a newly renovated site at UCSF. We helped them upgrade their hardware and network to afford them full Internet connectivity.

The Web site activities mentioned comprise part of the work of the Education Core. The Informatics Core has continued to provide them the hardware and software to develop this site.

The Informatics Core has worked closely with the CQI Core by providing systems for data analysis. Dr. Jerry Miller has developed a data analysis system on a VAXStation that has been used to analyze the data collected in the Same Day Assessment Program database, also developed by the Informatics Core. Dr. Miller's system is also being used to analyze breast cancer datasets from outside institutions.

Future Plans

The Informatics Core will continue all the projects described above.

Additional collaborations have been planned with the BCC and the MSA (Management Sciences Associates) data management consulting group to develop more complex databases for use in breast cancer care. Dr. Qing Yan will play an important role in working with MSA to develop breast cancer database models that are compatible with similar efforts underway at the NCI and the NCCN.

This collaboration will include the design of automated data collection tools which will be based on the workflow of the clinic. The process and workflow analyses forming the basis for this system is being conducted by the CQI core. The CQI and Informatics teams will in turn define all information needs based on process. The subsequently resulting system will support the clinic workflow and goals of care delivery.

Dr. Miller will expand his collaborations to include analysis of UCSF breast cancer databases maintained by the UCSF Breast Oncology Program.

New personnel

In addition to Qing Yan, M.D. and Ellyn Cohen, Ph.D., we have hired LaDorotha Thomas as our data assistant. Mrs. Thomas is responsible for scanning, entering, and the QA of data in our clinical and research databases. Since the resignation of our programmer in the spring of 1999, programming responsibilities have been shared by Dr. Yan, Dr. Goldman, and programmers from MSA. We recruited for a new full-time programmer and at this time have extended an offer to our candidate of choice. We anticipate her employment to begin September 1999.

Education Core

The Education Core had a very successful year. Once again, we set ambitious goals and, with few exceptions, were able to accomplish them. We introduced beneficial educational programs for both breast care patients and providers. In addition to expanding our services, we were able to build on our experiences from the previous two years and incorporate new ideas to improve existing programs. All of our work was done in an effort to integrate the most advanced educational services into the clinical care at the UCSF Carol Franc Buck Breast Care Center.

Year Three:

1. Our main goal in year three was to develop a tool to measure the effectiveness of our educational interventions. With the help of outcomes specialists, we were able to develop a tool, pilot its use, and then implement the measure throughout the system. In this way we were able to gather the data needed to evaluate our programs.
2. Multiple personnel changes in the CQI team made it more of a challenge to analyze and improve upon weaknesses in the educational component of clinical care. We are committed to doing this in year four, and feel that with the new team in place that we will be able to do so.
3. Over the past two years we have worked hard to develop specific educational materials for the BCC patients. In an effort to keep those materials as updated as possible, we reviewed each piece, and revised them based on changes in our system. We will continue to review our information in year four, as we are confident that this review process helped us improve our materials.
4. With the help of a BCC surgeon, we were able to introduce standardized post-operative orders for the surgical staff and residents. Although implementing these standardized orders continues to be a challenge, we are committed to educating the staff about the proper post-operative care of breast cancer patients.
5. We built information packets for our patients who are undergoing biopsy procedures, who are newly diagnosed with breast cancer, or who are undergoing the Tram Flap procedure in years one and two of the grant. This year, we revised the information in these packets in order to guarantee patients receive the most updated and beneficial information. In an effort to expand this successful piece of our program, we also built patient information packets for patients starting chemotherapy. The nurse practitioner meets with each patient before beginning the chemotherapy and gives her the packet at this point as part of the educational consultation.
6. As we continue to build our educational materials and programs, we want to develop informational packets for patients undergoing radiation therapy at UCSF. This is one project that we will accomplish in year four, as we were unable to finish this during year three. The preliminary meetings and work we did during year three will enable us to implement this project at the beginning of year four.
7. We worked with a leading surgeon to help us develop informational materials for women undergoing the sentinel node biopsy. As this procedure is still experimental, our patients have many questions about the process as well as the implications of the results. Our materials are written to explain many of these questions.

8. The BCC started a Follow-Up Program in year three for patients who are in long term care. All of these women are at least one year post-treatment, so they have different needs than those women who are in active treatment. We developed a packet of information to support the educational needs of women in the Follow-Up Program. This includes information about diet, exercise, lifestyle changes, and recommendations for care based on the American Society of Clinical Oncology guidelines.

9. The goal of Project III of the DOD Grant is to develop a program to quantify a patient's specific risk of recurrence as a way to help made decisions about adjuvant therapy. One aspect of this is to have patient educational materials explaining the program and it's goals. Patients need to understand their specific situation based on the latest clinical information, but they also need a context through which to understand this data. Our materials aim to provide the foundation of knowledge needed to participate in this cutting edge treatment decision making program.

10. We compiled an extensive literature bank for providers in year two. However, we do not feel that the providers are utilizing this hard copy literature bank. We shifted our focus to continue to build an on-line literature bank for providers instead. We feel that the on-line version of the bank may be utilized more, as providers have a limited time to sort through hard copies. We will work to organize this on-line literature bank in year four to maximize it's utility for our providers.

11. One goal we have had throughout this grant, and will continue to in year four, is the translation of patient education materials into foreign languages. The BCC has a large population of Russian speaking patients, as well as Spanish and Chinese speakers, and so we need to provide materials to support their educational needs. We were successful in having some materials translated and will continue to have our most updated information translated as well.

12. As we develop and acquire new materials about the various aspects of breast cancer, we work to make the BCC staff aware of these new educational pieces. We continually update the patient education file cabinet, and inform the staff through the weekly staff newsletter, and periodic updates. In this way, we are working to insure that all staff members know the latest information, and where to find it.

13. Part of our objectives in the Education Core is to support the continuing education of the providers. One way that we have done this is to bring in expert speakers on specific topics related to breast cancer. For example, an expert on osteoporosis spoke to the group about how bone health impacts breast cancer treatment. We will continue to bring in these experts during year four to cover topics like lymphedema and fertility and breast cancer. With the help of these experts, we hope to produce specific educational materials on these topics.

14. We continue to build our library of books, video tapes, and audiotapes for patient use. New resources are introduced constantly, and we strive to have the most current resource library.

15. We work with Resource Center staff and DOD Grant Coordinator to highlight new resources in various ways including the new BCC newsletter, BCC staff weekly updates, and the "Book of the Month" program. This way, we can advertise the new resources that we have and encourage the patients to utilize all of our education and support services.

16. Another area on which we focused this year was community outreach. We were involved in a number of very successful events, including a "Town Hall Meeting on Breast Cancer" in an underserved San Francisco community, as well as the "Race for the Cure." We attended numerous health fairs to distribute breast cancer information including "Women's Health 2000" a day long conference sponsored by UCSF. We are participating in all of these events next year, and are committed to expanding our outreach even further in year four.

17. We have not been documenting the community outreach in a systemic manner. In year four, we hope to document and more importantly to evaluate the programs in which we participate. This will enable us to measure the amount of outreach in which we are involved, as well as to compare the impact of the various outreach programs.

18. We developed a one year Patient Navigator Program through the BCC last year. Based on that pilot program, we worked with the staff of the Cancer Resource Center to develop a cancer center wide Peer Support Program. We are interviewing potential peer support volunteers at this time, and will conduct a volunteer training in September. Matching patients and peer support volunteers will begin after the training. We will also include the evaluation of the program and the volunteers as an important quality assurance component.

19. The BCC has an active core of patient advocates. We meet regularly with the advocates to get feedback about our educational programs and materials. Getting comments from our patient's perspective assures that our work is beneficial to our specific population. In year four, the patient advocates and the Education Core will work together to improve educational outreach about clinical trials.

20. Staying current on the latest research is an important task for the members of the Education Core. Our patients demand that we be aware of the latest advances and current issues. In an effort to do so, we attended conferences and community events on a host of topics related to breast cancer.

Year Four:

The work we did in years one through three built a strong foundation upon which we can meet the educational needs of patients and providers. We are committed to continuing the programs we established, and will expand our development as well. The following is a list of additional goals for year four:

1. To review, to revise, and to improve existing BCC sponsored patient education materials, including the development of design as well as content
2. To revise existing outcomes measures to accurately assess educational interventions
3. To implement tracking system for pre-surgery, one month post-operative, and one year post-operative evaluations
4. To establish a packet of information specific to issues of metastatic cancer
5. To explore the development of lymphedema clinical and educational care in collaboration with the Stanford Lymphedema Center
6. To prioritize continuity of care in an effort to identify and implement clinical changes including those related to patient and provider education

7. To standardize post-operative orders
8. To develop packets of information for radiation therapy, and for women with metastatic cancer
9. To develop educational materials to support the High Risk Program
10. To work with the patient advocates to increase outreach for clinical trials, for example, including an educational letter describing the importance of clinical trials

Our major focus in year four will be the production of lasting educational materials. This involves developing a standardized design, as well as continuing to revise the content. We want to insure that patients will benefit from the work of the Education Core for many years after the grant by having these types of materials available.

Education Core: Statements of Work Year Three

The Education Core once again revised the Statements of Work to reflect the changes in goals and objectives made during year three. We will continue to adapt these statements based on the experiences from the previous three years, as well as from patients, provider, and staff needs. Our hope is to provide the highest quality educational programs and materials to our specific population.

Year Three:

1. To improve on tracking and evaluation of new and existing programs
2. To work with Continuous Quality Improvement team to identify and implement clinical changes including those related to patient and provider education
3. To review and revise existing BCC sponsored patient education material
4. To standardize the post-operative orders for surgical staff and residents
5. To build information packets for patients about chemotherapy
6. To build information packets for patients about radiation therapy
7. To write and review an information sheet on the new sentinel node biopsy procedure
8. To develop educational materials for the BCC Follow-Up Program
9. To develop educational materials to support Project III
10. To make an abbreviated list of the most pertinent articles from the literature bank for use by new surgical and medical residents, medical students, staff, and highly sophisticated patients
11. To coordinate translation of educational materials into Spanish, Russian, and Chinese.
12. To educate Breast Care Center staff about new patient education materials
13. To coordinate professional educational session about specific clinical aspects of breast cancer
14. To increase resources/ patient education materials in the Resource Center
15. To work with Resource Center staff and DOD Grant Coordinator to highlight new resources in various ways including the new BCC newsletter, BCC staff weekly updates, and the "Book of the Month" program
16. To be involved with community events related to breast cancer, for example local Town Hall meetings and "Race for the Cure", and to provide educational materials at these events
17. To document community outreach and evaluate the various types of outreach being offered
18. To develop a Peer Support Program in conjunction with the Cancer Resource Center

19. To work with the Patient Advocacy Core regarding educational issues
20. To attend conferences regarding breast cancer research and clinical issues

Year Four:

1. To review, to revise, and to improve existing BCC sponsored patient education material, including development of design as well as content
2. To revise existing outcomes measures to accurately assess educational interventions
3. To implement tracking system for pre-surgery, one month post-operative, and one year post-operative evaluations
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Our major focus in year four will be the production of lasting educational materials. This involves developing a standardized design, as well as continuing to revise the content. We want to insure that patients will benefit from the work of the Education Core for many years after the grant by having these types of materials available.

Project 1
Evaluating Cost Effectiveness
in the Diagnosis of Breast Abnormalities

Project Summary

This program consists of two aims:

1. A cross-sectional survey and medical record review of women who have received an abnormal mammogram result at two large mammography facilities in San Francisco. The purpose of this project is to examine factors that are associated with differences in the quality of care that women receive after receiving an abnormal mammogram result.
2. A review of consecutive fine needle aspiration specimens of palpable breast lesions linked to Cancer Registry Data. The purpose of this project is to examine the effects of provider training and experience on the diagnostic accuracy of the specimens.

Tasks Completed during Year 3 and Anticipated During Year 4

Aim 1

Significant progress has been made towards completing this project. By task:

Task 1 - Recruitment:

We have completed recruitment for this project. Four hundred eighty-eight women agreed to participate and have completed the baseline telephone survey.

Task 2 - Follow-Up Survey:

The follow-up survey will be completed by 10/1/99. To date, 312 women have completed the follow-up survey (follow-up response rate 84.6% to date).

Task 3 - Development of Data Entry Database/ Task 4 - Medical Record Review:

The development of the data entry database has been completed and has been in use. The medical records of women who are participating in the study are being reviewed around the time of the follow-up survey. They will therefore also be completed by 10/1/99.

Task 5 - Data Analysis:

We have begun some preliminary data cleaning on the data from the baseline telephone survey. The final analysis will be initiated once the follow-up survey and the medical record abstraction is complete. The table following summarize some preliminary data from the baseline survey.

Table 1 – Demographics of the Sample (n = 488)

Age:	
< 50 years	36%
50 – 65	47%
> 65	18%
Race:	
White	73%
Asian	13%
Other	14%
Education:	
High school or less	15%
Some college	50%
Graduate education	35%
Post-menopausal	63%
Family history of breast cancer (1 st degree)	20%
Health Insurance:	
None	1%
Site of mammogram:	
UCSF	49%
CPMC	51%
Clinical breast lump	23%
Evaluation following index mammogram (categories not mutually exclusive):	
Consultation with primary care provider	30%
Consultation with surgeon	32%
Magnification views	23%
Ultrasound	41%
Needle biopsy	24%
Open biopsy	15%
Outcome of evaluation at the time of the baseline survey:	
Cancer	15%
Benign	74%
In progress	12%
Woman's rating of the overall quality of her care:	
Excellent	60%
Good	36%
Poor	4%

Aim 2

This Aim has been completed. A draft of a manuscript is currently under review. This has been included (appendix I).

Year 4

Aim 1

Task 1 - Recruitment:
Completed.

Task 2 – Follow-up Survey:

The follow-up survey will be completed by 11/1/99.

Task 3 – Development of Data Entry Database/ Task 4 – Medical Record review:

The medical records of women who are participating in the study are being reviewed around the time of the follow-up survey. They will therefore also be completed by 11/1/99.

Task 5 - Data Analysis:

Final data analysis will be completed between 11/1/99 and 4/30/00.

Task 6 – Dissemination

A draft manuscript will be prepared in the Spring, 2000. Abstracts will be submitted to national meetings.

Conclusion

Aim 1 is moving towards the completion of the data collection phase and beginning on the data analysis phase. We believe that this project will yield important information about variation in the management of women with an abnormal mammogram, and the effect of this variation on patient satisfaction and subsequent adherence with screening recommendations. Aim 2 has been completed. There have been no personnel changes.

PROJECT 2

Psychosocial Program

This program is a randomized clinical trial comparing the effectiveness of two psychosocial interventions, a standard support group versus an integrated program incorporating complementary techniques such as yoga, meditation, imagery and dance along with a psycho-spiritual support group. Participants are being randomly assigned to the groups, and measures are gathered at baseline, three months, six months, and one year following study entry.

The overall purpose of this project is to compare an individualized vs. an integrated/intensive support program for women with breast cancer. In year 1 we set up the structure for the project and began to address the goals for the project. Years 2 and 3 continued the work on the goals for the project, which are to directly compare the two approaches (i.e., changes in psychological distress coping, quality of life, etc.), explore which women do better with which type of intervention, and examine long term outcomes such as time to progression, survival, costs, quality of life, etc.

Year 3

The original statement of work for this program is delineated by the tasks below. Tasks 1 and 2 have been completed. Tasks 3 and 4 are in progress.

Task 1:

Set up clinic for research, Months 1-3

- a. Hire secretary and social worker.
- b. Purchase computer, printer, phones.
- c. Ensure availability of group leaders.
- d. Prepare assessment packets for patients to complete.
- e. Ensure that physicians are aware of the psychosocial program.
- f. Write information package describing the program and the interventions available.
- g. Set up procedure for inputting data into database-coordinate with Informatics Core.

Task 2:

Initial assessment and treatment of patients, Months 4-16

- a. Begin patient entry into research program. Assessment of women as they enter program.
- b. Piloting of data collection mechanisms
- c. Piloting of intervention groups.
- d. Conduct follow-up assessments as the interventions are completed.

Task 3:

Aim 1: One-year follow-up, Months 17-18

- a. Collect one-year medical data from data base in order to complete Aim 1.
- b. Collect one-year follow up for all women in the program (assess psychological status, coping style and quality of life) in order to complete Aim 1.
- c. Determine number of women who participated in the interventions.
- d. Perform analyses of data collected to address Aim 1.

We began to collect 1 year follow-up data, on schedule, in Month 17. So far one year follow-up data has been collected on the first two of seven cohorts (n=36) and will continue for one year after

completion of the planned study interval. No analysis will be done until at least 50% of the projected data is available.

Task 4:

Testing Aims 2-3, Months 17-44

- a. Add wait-list control groups. Begin to randomly assign women to immediate or wait-list groups.
- b. Continue baseline and post-intervention assessments.
- c. Continue yearly assessment of all women entered in the program.

We have not been able to have traditional wait-list control groups, because of difficulty in recruiting (see below). We have had a wait list group out of necessity (women waiting for a group to start), rather than by randomization. Many women have not been able to join the next cohort, because of time restrictions (e.g., the next cohort runs in the afternoon, and they can only come in the evening), medical issues (e.g., a woman was waiting to have a stem cell transplant done), and no more room in that particular cohort. We are continuing to gather post intervention from the women, and for the women who are on the wait list, we gather information at the beginning of their waiting period, and again when the group starts (as well as follow-up data after the group ends).

Other accomplishments not on SOW:

1. Team Building and thematic exploration exercises are ongoing. Because the focus of the Integrated program is to create an emotionally holding and safe environment, program staff participate in a number of exercises to help them develop better awareness of their own personal responses to the issues the women are exploring. These have included discussions on personal views and fears about death and dying, breast cancer in general, body image, and values. In addition the team meets in a "process group" every three weeks to discuss any programmatic or inter-personal issues that may be affecting the delivery of care. Once per year the entire staff participate in a day-long "staff retreat", again for the purpose of improving staff communication, morale, and understanding of their personal reaction to patient issues.
2. We were approved as a practicum site for graduate level students from the California School of Professional Psychology-Alameda. While we have had a series of students who assist with the research (interviewing of women, collecting data, co-leading groups, etc.), we also had two clinical practicum students who conducted patient screening, intakes, and co-lead groups. Two of our other graduate students presented aspects of this research at the annual meeting of the Society of Behavioral Medicine in March 1999, and are conducting their dissertations using data from the program. One dissertation is examining the construct of fatalism in women with breast cancer. The other is an examination of the role of spiritual well-being in quality of life of women with breast cancer. This latter research has spawned an article which has been accepted by the journal Psycho-Oncology for publication this year. Two more graduate students have joined the research team, and hope to be able to conduct their dissertations through our program as well. In addition, two other presentations at the Society of Behavioral Medicine meeting focused on preliminary results from the study. Abstracts of all of the presentations are attached.
3. We were approved as a practicum site for Social Work interns through the Mount Zion Medical Center. One social work student from UC Berkeley spent last year training in the Integrated program.
4. We have been approved as a clinical rotation site for Psychiatry residents at both UCSF and CPMC. Two fourth year psychiatry residents have participated with the program over the last 12 months, and one has been subsequently hired by the program as part-time staff leading groups and doing individual psychotherapy and medication evaluations.

5. Training seminars and case meetings were devised for the above students/interns and were successfully received.

Problems

1. Recruitment. Recruitment continues to be our biggest problem. In order to recruit more program participants, we have opened up enrollment to woman who meet the study criteria from institutions other than CPMC and UCSF. We have recruited through doctors offices, other cancer centers, advocacy groups, the UCSF cancer center website, and through public service announcements. It may be that the study is lacking in participants for two reasons:

- a) Women do not want to be randomized. Several women have called stating that they are only interested in the integrated program.
- b) Women cannot attend at the times the groups are offered.

Summary of Year 3

We have spent the third year with continued implementation of an entirely new and different program for women with breast cancer for comparison with a group representing the community standard. Data collection is continuing, as is the data analysis. The women who have entered our program so far have been pleased with the center, the program, and the group that they have been randomized to. Initial data shows that both of the interventions resulted in significant improvements in positive mood and quality of life. Despite the rigor and time intensity of the Integrated program, both of the interventions have been shown to be feasible, both for the staff and for the patients. It is still not clear of the benefits of the programs over the long term. This will be examined in year 4.

Plans for Year 4

1. Continuation of recruitment and running of groups, including efforts to attract more minority women;
2. Analysis of the first 100 women who have gone through the program (Aim 1), including immediate pre-post changes and longer term (6 months, 1 year) changes;
3. Depending upon the results of the analyses eliminating the randomization aspect of the research and begin to study the choices that women make for complementary treatment (Aim 2);
4. Presenting data at various scientific meetings (e.g., Society of Behavioral Medicine)
5. Submission of papers to referred journals;
6. Continue to collect follow-up data;
7. Continue to train students/interns/residents.
8. Program per-patient cost analysis to determine resources required to deliver these services on an ongoing basis
9. Compare outcome measures to data compiled on women who attend the Breast Care Center at UCSF who do not join the program.

Staff Changes

As expected, we have had changes in research assistants, as our current research assistants graduate or leave for internship. We have lost three graduate students because of graduation or move for internship. However, we have two first-year graduate students who have started to work with us. We have also hired a data manager. The rest of the staff have not changed.

PROJECT 3

Breast Cancer Patient-Specific Outcome and Decision Making Project

The goal of this project is to develop a physician/patient Shared Decision Making Program (SDP) to assess patients' risk of recurrence and mortality from breast cancer, and determine absolute benefits of adjuvant hormonal therapy and chemotherapy using available institutional databases and data from large controlled clinical trials. The project includes the following tasks: finding common ways to represent risk of recurrence to patients which incorporate the latest clinical and research evidence; and testing patients' perceptions of risk and how it influences their choices when the representation is made in terms of time and probability of disease recurrence. The project will provide breast cancer patients with individualized empirical outcome information in the context of the physician-patient relationship, and it will assess how the provision of such information changes a patient's knowledge, attitudes and choices of treatment options.

The lack of calibration of risks of mortality and recurrence prior to adjuvant therapy was identified. For this reason we held a Calibration Conference with Dr. Ravdin and Dr. Don Berry in order to establish defined time points at which to express benefits. We determined these to be 5 and 10 years for both risk of recurrence and risk of mortality. In addition, agreement was required on the interpretation of several key large new studies, as well as the 1995 World Overview analysis of adjuvant therapy benefits. We chose the relative risk reduction estimates from the Overview analysis, deciding to break these down by age, ER status, and treatment. The resulting program will provide unique graphs for each patient, with baseline risks described as a continuous equation based on tumor size and nodal status. While these studies revealed significant new estimates of benefit from adjuvant therapy, the accuracy of these estimates was questioned. The original information from the San Antonio database seemed to have problems functioning as a clinical trial database in that patients selected tended to have worse outcomes; estimates were not reflective of the general population. The SEER data was studied but was found to have no staging or treatment data. We therefore developed a risk model based on data derived from a Finnish database (every woman with breast cancer in Turku, Finland from 1945 to present, treated with surgery alone), and a database from Duke University (entire set consists of 3600 patients with breast cancer treated at Duke University Medical Center between 1979-93). We will expand to include other databases (i.e., UCSF) as they become available. Dr. Harry Burke, an Associate Professor of Medicine at New York Medical College, Valhalla, New York, has joined the project, replacing Dr. Peter Ravdin. Dr. Burke has extensive experience working with empirical data sets. He has eight years of experience working with survival analyses and outcomes research, primarily in breast cancer (Biosketch appendix O).

Technical Objectives 1-2:

Obtain Recurrence and Mortality Estimates. Develop Graphic and Written Additional Tools for the Shared Decision Program (SDP)

Tasks 1 and 2:

Comparative survival and recurrence by treatment over time

Using the best available data, an artificial neural network regression model will be trained to provide individual post surgical patient continuous probability disease-specific predictions (probability) of survival and recurrence. These predictions will be patient-

specific and therapy-specific to allow patients the ability to compare the efficacy of each treatment. The program will allow patients to compare the benefit of adjuvant hormonal, chemotherapy, radiation treatment and combinations of the three treatments over time. All patients will receive this information. We have developed the first pilot model using a subset of the Duke database and have begun to run several scenarios. This model seems to perform well although is unstable in certain clinical scenarios. The Finnish and UCSF databases will be modeled next and combining databases will be attempted. We expect better performance as larger databases are incorporated.

Comparative conditional life expectancy by treatment

Conditional life expectancy provides the following information: "given that the patient has lived to age X1, and that her life expectancy would have been age X2 without breast cancer, and that she will live to age X2 less Y years with untreated (except for surgery) breast cancer, what is the benefit of each treatment?" "How much does each treatment reduce the Y years lost to breast cancer?" Conditional life expectancy estimates are based on all cause mortality. Therefore its calculation requires two data sets (or one data set with both types of information): (1) data set with prognostic factors and disease specific mortality and (2) data set with comorbidities and competing risk mortality. These data are available on the general population through the National Institutes of Health, and will be obtained by Dr. Burke. The predictions of these two data sets are combined to create the conditional life expectancy estimates. Half the patients will be randomly assigned to intervention.

Conditional life expectancy information can be presented in three ways: (1) age benefit (estimated age of death), (2) years benefit (estimated years added from no additional treatment), and (3) percent benefit (percentage of the way from age if no additional treatment to age if no breast cancer). One or more of these explanations can be provided to determine which explanation provides the most meaningful information to patients. Initially, we plan to test estimated years benefit and percentage benefit and ask the patient to determine which is most useful.

Comparative side effects by treatment over time

Using the best available side effect data, an artificial neural network regression model will be trained to provide individual patient continuous probability predictions (probability) of side effects for each treatment. These predictions will be patient-specific and therapy-specific. All patients will have received surgery. The program will allow patients to compare adjuvant hormonal, chemotherapy, radiation treatment and combinations of the three treatments in terms of which side effects will occur and when. This data on toxicities has never before been presented in the context of benefits. We will need to pay particular attention to the recent literature on acute toxicities, such as nausea, vomiting and hair loss may be overestimated by as much as 30% if using data that does not reflect new drug therapy. Side effects can be presented either numerically, in pie or bar graphs. The exact method is not important as the information presented does not show trends. It will need piloting with focus groups to identify which method patients prefer. Within the scope of this project, we will accomplish this task by compiling common short and long term side effects from tamoxifen as well as common chemotherapy regimens (AC, CMF, AC--> Taxol) based on published toxicity rates from large cooperative group clinical trials. This will be shown on the patient-specific booklet (see below) concurrent with the baseline risk and benefit estimates.

Patient-specific booklet

The three predictions (survival and recurrence, side effects, and life expectancy in those patients randomized to receive it) will be integrated into a patient-specific booklet. This booklet is being developed by the *Education Core* of the DOD grant, to be given to patients by their physician during the course of the physician-patient interaction. The booklet will be automatically customized by a computer program for each patient, with standardized data elements for prognosis provided by the *Informatics Core*, using the artificial neural network. In addition to the predictions, the booklet will contain information regarding how the predictions were derived as well as the general limitations in how to apply statistical data on individual decision-making, the physicians and nurses taking care of the patient, breast cancer background information, prognosis, treatment, the latest clinical information, and references that provide more detailed information related to what was presented in the booklet. At each visit the patient will receive a new booklet with updated predictions (including conditional survival and recurrence estimates, i.e., given that she has lived five years, what is her ten year survival probability) and updated breast cancer information. Over time each patient will have a library of booklets. This library of individualized booklets will allow her to better understand the course of her disease and its treatment.

Technical Objective 3: Viewing of Revised SDP with Pre- and Post-Assessment Tools and Testing on Patients with Early Stage Breast Cancer

Task 3:

Although the basic approach to analysis has changed, as well as the method for the disseminating the information (modified from CD-ROM format to computer generated patient information booklet), the study plan remains essentially unchanged: the project will recruit patients with early stage (Stage I and II) breast cancer who have undergone surgery and radiation but who have not received adjuvant therapy. Patients who agree to participate in the two-armed study will complete questionnaires on demographic information as well as those that explore patients' understanding of their hypothetical risk of disease recurrence and mortality due to their breast cancer. These surveys will be administered at the pre- and post-office visit. Patients will have an intake exam with an oncologist, be provided with their unique patient information booklet (including information on probability of recurrence (Arm 1) or probability of recurrence and time gained (conditional life expectancy) from treatment (Arm 2)). Post visit questionnaires will ascertain any change in patients' attitudes regarding adjuvant therapy due to the differences in the two arms.

The conditional life expectancy information and patient-specific booklets will be prospectively evaluated to determine the optimal way to present the information. In addition, the effect of the information on the patients, including its effect on their decision making, will be prospectively assessed. The assessment will include, but not be limited to, the following:

1. The effect of individualized outcome information on patients' choice of therapy.
2. The effect of patient attributes on decision making.
3. Any changes in patients' attitudes toward the information that was presented, method of presentation, and overall satisfaction with its contents.
4. Changes in patients' knowledge and understanding as a result of the information received.
5. Track quality of life measures, profile mood states, and correlate patient responses.

We will compare quantitative scores for patients viewing survival statistics with those that did not. We will also look for relationships among baseline clinical variables such as age, family history, dependent children, and menopausal status.

We will continue to provide each patient with new and updated medical information at each visit for the duration of their care. The effect of providing medical information over time to patients must be assessed. Therefore we will follow patients and observe their true outcomes. In addition, by using follow-up interviews and questionnaires, we will assess changes in patients' attitudes based on their retrospective assessment of their prior decision, perhaps integrating it with consultation planning. Certain parts of this project can be accomplished during the course of the DOD grant. These include obtaining larger databases, testing predictions for their accuracy, and measuring the impact on patients. Other portions, including roll out and links to Tumor Bank and SPORE Registry may become protocols for future grants.

Related Work/Plans for Year 4:

1. The patient booklet will be completed by the beginning of year 4.
2. Pre- and post-viewing questionnaires are finalized.
3. New demographic/attitudinal questionnaire is being finalized.
4. Toxicity database is being finalized.
5. With assistance from the *CQI/Informatics Core*, the project will develop a database to capture patient prognostic factors, predictions, and follow-up information. This database has the potential to function as a tumor registry and it will provide an electronic medical record that can be accessed by clinicians from any location at any time (it can be integrated into an electronic medical record). It will also contribute information to a database of basic and clinical research. Clinicians participating in this project will have access to their own patients for QA/QI control purposes and to the contents of the database (subject to IRB approval and certain conditions).
6. Over time, this project has the potential to be expanded to incorporate other prognostic markers (such as HER2/neu) and in addition to the benefits of other treatments, i.e., radiation. Beginning with the Duke and Finnish databases (part of the basis for our projections), we will expand to include other databases as they become available.
7. Given the significant delays in developing models for recurrence and mortality as well as calculating patients-specific benefits and the change in formats (from videodisk to CD-ROM to patient booklet), we will need to accrue patients over a larger base using collaborating institutions (Alta Bates, Marin General, California Pacific Medical Center and Kaiser Medical Centers in Northern California, all current network partners in the UCSF Bay Area Breast Cancer SPORE). This will allow us to enroll the requisite number of patients (n=200) in a shorter time frame.
8. We plan to pilot an Internet version of this tool as a separate project to supplement our data analyses. Other projects, outside the scope of this grant, including roll out and links to Tumor Bank and SPORE Registry will become projects for future grants.
9. Topics for possible publications include:
 - (1) Using retrospective data to project real survival (rather than "ideal" clinical trial survival).
 - (2) Comparing treatments within subpopulations that have never been assessed by a clinical trial.
 - (3) Comparing survival analysis with the artificial neural network approach to other methods of risk estimation (i.e., recursive partitioning, regression analyses).

PROJECT 3

Revised Statement of Work

Technical Objectives 1-2: Obtain Recurrence and Mortality Estimates. Develop Graphic and Written Additional Tools for the Shared Decision Program (SDP)

Task 1 Artificial neural network based on Finnish and Duke databases along with Oxford Overview relative risk reductions in recurrence and mortality from adjuvant therapy. Absolute benefits (mortality and recurrence at 5 and 10 years) and conditional life expectancy estimates will be derived - **Completed**

Task 1b (new) Toxicities database from literature of published cooperative group trials - **Completed**

Task 1c (new) Develop written patient background information on adjuvant therapy and format to describe absolute benefits attributable to adjuvant therapy and conditional life expectancy estimates - **to be completed by 9/1/99**

Task 2 Finalize pre and post viewing questionnaires to capture patients' preferences, comprehensibility, satisfaction with decision and other standard measures (quality of life, Profile of Moods State) - **Completed**

Technical Objective 3: Viewing of Revised SDP with Pre and Post Assessment Tools and Testing on Patients with Early Stage Breast Cancer

Task 3 Enrollment of patients - **9/30/99 through 8/30/00**

Technical Objectives 4-6: Analysis and Interpretation of Data

Task 4 Tabulate data from questionnaires, patient preferences, and download data from SDP (levels of query). **8/30/00**

Task 5 Statistical analyses on all pre/post tools. **8/30/00**

Task 6 Recommendations for final revisions of SDP (remaking SDP outside scope of project). Preparation of publication. **8/30/00**

Project 4

Collaborative Care Facilitation

Introduction

In Year 3, the Project 4 team improved and extended upon the work done in years 1 and 2. Karen Sepucha developed and piloted new methods and metrics for Consultation Recording, Jeff Belkora created a prototype decision support system, and Stephanie Lamping developed a comprehensive training program that was used to successfully train four BCC staff members in Consultation Planning.

We established the Program for Collaborative Care at the BCC and Consultation Planning, the first service offering, is available for all BCC patients. The Oncology Roundtable featured Consultation Planning in its Innovations in Breast Cancer Care as an example of best practices for decision making in breast cancer care (appendix P). The BCC is currently hiring a fulltime Project Manager for the Program for Collaborative Care to ensure that we can provide these valuable services to patients at the BCC and continue to extend and improve the offerings.

I. Metrics

A. Coordinate with other projects and cores regarding cost and other outcomes assessment.

During Year 3, Karen Sepucha met with investigators in the other cores and participated in multiple meetings with others at the BCC to create a standard set of metrics for patients. Karen used a subset of the health outcome metrics in the six-month follow-up for the Consultation Recording pilot study.

B. Validate the UCSF Satisfaction with Consultation Scale and the OYM Decision Clarity Scale.

During Year 3, Karen tested the OYM Decision Clarity Scale (DCS) and the UCSF Satisfaction with Consultation Scale (SWC). Karen published a review of the survey in the Community Breast Health Project's quarterly newsletter to solicit feedback from patients. A reprint of the article is included (appendix Q).

The DCS survey is acceptable and reliable as determined by a sample of 60 breast cancer patients. On average, the survey took less than 5 minutes to fill out. The survey was highly acceptable to patients with less than 1% missing data. The responses were well distributed across all response categories indicating a lack of a floor or ceiling effect. The survey meets the standards for reliability (Cronbach's alpha >0.70), with an alpha coefficient of 0.77.

The SWC survey is acceptable and reliable as determined by a sample of 30 breast cancer patient. The SWC is short and easy to administer. It is highly acceptable to patients, as indicated by less than 1% missing data and a lack of floor or ceiling effect. The survey is highly reliable as measured by a Cronbach's alpha of 0.9.

II. Facilitation Processes

A. Advance the theory of Consultation Recording.

By November, we had recruited 24 patients and closed the pilot study. After completion enrollment, Karen focused her efforts on analyzing the data and publishing the positive results. Karen wrote up a comprehensive account of the methods, metrics, theory and pilot results for her dissertation in March. An abstract from the study was accepted for a poster session at the Annual Conference of the American Society for Clinical Oncology (ASCO) in April. In addition, Karen and Dr. Esserman presented the study results at Surgery Grand Rounds at UCSF/Mt. Zion in April. Finally, she completed a manuscript on the Consultation Recording pilot study and submitted it to a leading medical journal in July.

To supplement the pilot data, Karen administered a six-month follow-up program in which she achieved 75% response rate from patients. This data has been analyzed and an abstract has been accepted for a poster session at the 22nd Annual San Antonio Breast Cancer Symposium.

In Year 3 we focused on getting the research ready for publication, and in Year 4, we plan to create training modules to supplement the Consultation Planning training program, and extend the Consultation Recording services to larger population of physicians. A copy of the ASCO abstract is included (appendix R).

B. Integrate Consultation Planning and Recording with OnTRAC (Oncology Treatment Risk Analysis Clarification) assessments.

Stephanie Lamping created a comprehensive training program for Consultation Planning. Using the materials, we trained four fulltime employees at UCSF in the methods. These Consultation Planners are able to offer these services to all patients at the BCC during the week. In addition, we used the program to train nurse coordinators at the University of Utah Hospitals and Clinics and the Kaweah Delta Cancer Care Program and volunteers at the Community Breast Health Project.

The OnTRAC system prototype is still waiting for the data in order to move forward. As a result we are too early in the product development to create a training program.

III. Decision Analysis Methods

We developed a prototype OnTRAC (Oncology Treatment Risk Analysis Clarification) decision support system for breast cancer. The system has five core areas: Demographics, Health State Definitions, Preferences, Treatment Risks, and Analysis. Demographics section provides the interface between the patient database and OnTRAC's evidence-based predictive model. Health State Definitions area helps patients clearly describe what they mean by good, average and poor health states. Preferences section quantifies each patient's attitude toward time tradeoffs with their health states. Treatment Risks area physicians use research and data to quantify the patient's chances of achieving the health states. Finally, Analysis calculates which treatment offers the best prospects for health based on the patient's preferences and the medical evidence.

We have included screen shots from the pilot of the ONTRAC software (appendix S) in order to provide a feel for the software and interface. Moving forward, we need to wait until the CQI Core and the Informatics Core have prepared the database of patients so that we can populate the Demographics section. Once the database is ready, then we can test the system in a pilot study and work to integrate the service into our current offerings. In

addition, we will benefit from the results found in Project III through incorporating more meaningful ways of presenting risk to patients.

Changes to Statement of Work/Personnel

We made a few changes to the statement of work for Year 3. First, the development of the OnTRAC system was put on hold due to the problems encountered by the CQI Core in securing and preparing the patient database. Second, we also held up spreading the use of Consultation Recording methods with other physicians in favor of preparing publications and getting a good understanding of the data and what we could learn from the pilot study.

In May, Stephanie Lamping ended her participation on the project in order to get married and move to Michigan. She contributed greatly to the Consultation Planning training and handed off the training materials to Jeff and Karen. She might be available in the future to participate in training seminars and publications.

Conclusion

We had another successful year developing and implementing methods for Collaborative Care Facilitation at the BCC. In particular, we have a comprehensive training program for Consultation Planners, we have positive results from a pilot of Consultation Recording methods, and we have trained personnel handling Consultation Planning for any BCC patient.

Moving forward our biggest challenge is to identify personnel to continue extending and implementing methods and tools for collaborative care at the BCC.

Plan for Year 4

Due to the solid foundations that have been laid in Years 1-3, we plan to withdraw from the project in Year 4 in order to allow the BCC to hire a fulltime person to manage the Program for Collaborative Care. This person's job will include overseeing the Consultation Planning services and developing Consultation Recording and other collaborative tools for use at the BCC.

Project 4

Statement of Work, Year 3

The goal of Project 4 is to improve the quality of medical decisions in the treatment of breast cancer. To do this, we focus on improving the quality of medical consultations between breast cancer patients and physicians. We have created tools and metrics to help patients prepare for upcoming consultations, and most recently, recently tools for patients and physicians to manage consultations. These tools improve communication and understanding between patients and physicians through structuring the conversations. Our approach to developing these tools is to engage patients and physicians in the design and implementation. In this way, we can be sure that the interventions we create actually help those they are intended to help. This report documents the progress that we have made developing new interventions, testing and refining validated interventions and highlights directions for future research.

1. 1998-1999 Project 4 Workplan

Collaborative Care Facilitation requires quality assurance metrics, facilitation processes, and decision analysis methods. On Your Mind's purpose in our Project 4 subcontract is to conduct the basic research and development that will advance the state of the art in these three areas. Dr. Jeff Belkora will direct this effort, at an overall level of 23 days (10% time). Karen Sepucha will staff the project at a level of 76 days (33%), along with Stephanie Lamping at 58 days (25%). All staff will require a few additional days, not on these tasks, for coordination.

I. Metrics

A. Coordinate with other projects and cores regarding cost and other outcomes assessment.

- Coordinate with Project 3 - review metrics and subject population for overlap in recruiting patients (Sepucha: Due 1/31/99)
- Coordinate with Informatics - coordinate automated data collection especially new patient intake, review potential to generate medical history for patients, link with OnTRAC system (Sepucha, Belkora, Lamping: Due 3/1/99)
- Coordinate with Psychosocial - review health related outcomes, stress, etc. and link with collaborative care patient population (Sepucha, Lamping: Due 6/1/99)
- Design health outcomes metrics for CCF (Sepucha, Lamping: Due 9/30/99)
- Deliverables: suite of outcome measures for Collaborative Care Facilitation.

B. Validate the UCSF Satisfaction with Consultation Scale and the OYM Decision Clarity Scale.

- Report on validity of OYM Decision Clarity Scale for CBHP newsletter (Sepucha: Due 10/15/98)
- Report on validity of UCSF Satisfaction with Consultation Scale for a (CBHP) newsletter (Sepucha: Due 11/31/98)
- Report on reliability of OYM Decision Clarity Scale and UCSF Satisfaction with Consultation Scale (Sepucha, Lamping: Due 11/31/98)
- Prepare accounts for peer-review publication (Sepucha, Lamping: Due 3/31/99)
- Deliverables: Research reports, submitted for publication, accounting for the validity and reliability of OYM Decision Clarity Scale and UCSF Satisfaction with Consultation Scale.

II. Facilitation Processes

A. Advance the theory of Consultation Recording.

- Report on pilot study for CR (Sepucha: Due 12/15/98)
- Collaborate with new patient coordinator on medical doctor preparation for consultations (Sepucha: Due 1/31/99)
- Expand use of Consultation Recording methods with new surgeons and other medical doctors (Sepucha: Due 3/1/99)
- Report on Consultation Recording methodology (Sepucha: Due 3/1/99)
- Import method to tumor board (Sepucha: Due 6/1/99)
- Develop generic training module for physicians and facilitators (Sepucha 9/30/99)
- Deliverables: Research reports, submitted for publication, connecting Consultation Recording to theories of Critical Reflection; in-service training for Tumor Board participants.

B. Integrate Consultation Planning and Recording with OnTRAC (Oncology Treatment Risk Analysis Clarification, see Arthur Vining Davis workplan) assessments.

- Provide training in Consultation Planning methods (Lamping: Due 12/15/98)
- Train Consultation Planners in Consultation Recording method (Sepucha: Due 4/1/99)
- Coordinate with Jerry Miller to develop OnTRAC assessment training materials (Belkora, Lamping, Sepucha: Due 4/1/99)
- Integrate training modules into a single training program (Belkora, Lamping, Sepucha: Due 6/1/99)
- Deliverables: Instruction manual for Collaborative Care Facilitators.

Decision Analysis Methods

- Populate OnTRAC with outcomes data prepared by the CQI Core.
- Develop preference- and evidence-based risk assessment tool (Belkora, Lamping: Due 12/31/98).
- Design pilot study and obtain IRB approval (CQI Core).
- Oversee the provision of Consultation Planning, Consultation Recording and preference- and evidence-based risk assessment to 10 pilot study participants (Belkora, Sepucha, Lamping, & CQI Core: Due 6/30/99)
- Report on pilot study findings to Department of Defense Grant participants (Belkora, Sepucha, Lamping: Due 9/30/99)
- Deliverables: a pilot study of 10 patients whose care is facilitated by the application of Consultation Planning and Recording followed by quantitative risk analysis.

PILOT A

Introduction

As we near the end of year three, the objectives of Pilot A continue to be to increase patient enrollment on clinical trials by informing minority and other women and their caregivers about trials and improving access to information about clinical trials in breast cancer. We have accomplished technical objectives 1-5 and completed a survey of 150 patients who are at a point in the clinical pathway where they are typically eligible for clinical trials. This required the development and use of our Patient Tracking System database to identify patients who were eligible to receive our survey. This database is updated weekly, and provides the staging information necessary to identify patients' eligibility for clinical trials. Seventy five clinicians from the San Francisco Bay Area specializing in breast cancer care also completed a separate survey. These surveys examining barriers and facilitators of clinical trials covered several domains (beliefs/attitudes, trial design, toxicities, cost, convenience and trials in alternative medicine), and have been presented in abstract form (Tripathy D, Patel K, Brown B, et. al.: *Physician and Patient Barriers to enrollment on breast cancer clinical trials*. Proc Am Soc Clin Oncol 17:178A, 1998 -- enclosed with last year's report). A manuscript is in development. We have expanded task 5 to include a modified patient survey regarding clinical trials for use over the Internet. After patient advocates and patients reviewed our pilot questionnaire, we revised the survey and resubmitted to the Institutional Review Board for approval. Having received approval to use the questionnaire on the website, we have converted to an html format and are ready to add it to the Breast Cancer Clinical Trials website (see appendix T). A secondary questionnaire for individuals without breast cancer has also been developed which will allow us to gather demographic information as well as attitudes toward preventive, complementary and alternative medicine. Responses will be downloaded from the Web page server and analyzed.

Technical Objectives 6-8: Education and Outreach Tools

Task 6: Months 12-18: Develop written and oral material for patients and caregivers. Arrange and post seminars.

Task 7: Months 15-18: Distribute caregiver and patient written material. Place written material on the Breast Care Center Home Page.

Task 8: Months 18-36 Seminars for caregivers and patients.

Progress Report:

Task 6

We have used our Patient Tracking System database to identify patients who were eligible to receive our survey of patients' opinions regarding barriers to clinical trials. This database is updated weekly, and provides the staging information necessary to identify patients' eligibility for clinical trials. We have administered, received and tabulated the results of 150 patient questionnaires, and the resulting abstract was published in the Proceedings of ASCO, 1998. The final manuscript based on this abstract is ready for submission to the Journal of Clinical Oncology. After patient advocates and patients reviewed our pilot questionnaire, we revised the survey and resubmitted to the Institutional Review Board for approval. Having received approval to use the questionnaire on the website, we have converted to an html format and are ready to add it to the Breast Cancer Clinical Trials website. A secondary questionnaire for individuals without breast cancer has also been developed which will allow us to gather demographic information as well as attitudes toward preventive, complementary and alternative medicine. We continue to update and make available to physicians at the Breast Care Center the Clinical Trials Flow Chart which lists all ongoing clinical trials here at the Center. This chart is also accessible from our website. A Protocols Book has recently been completed which outlines all clinical trials at the BCC according

to objectives, eligibility and consent and is available to all physicians at the Center. We are continuing monthly clinical trials updates to caregivers during weekly Tumor Board and are making clinical trials lists available to care providers in the community. A new, comprehensive Glossary has been added to our website, as well as a Bibliography section which includes informative articles that relate to the monthly Forum topic. We present updated information on protocols at monthly meetings in the Breast Care Center as well as via mailed booklets in addition to Internet listings.

Task 7

During the third year we began our outreach seminars which include a slide presentation in English, Spanish or Russian, depending on the patient population. In addition to the presentation on clinical trials, educational materials which we have developed or appropriate materials developed by others are distributed at these gatherings. A talk entitled "Excluded No More: Why Participating in Clinical Research is Important for You and All Women" was presented at Women's Health 2000, UCSF on March 20, 1999, utilizing materials developed by this program. We hope that the information we elicit from these gatherings will lead to the design and initiation of trials which will be of greater interest to patients, so that we may increase participation in subgroups with traditionally low recruitment. We continue to distribute posters and brochures (developed in the second year) to mammography centers, senior centers, support groups, clinics, and resource centers.

Task 8

The Bay Area Breast Cancer Forum continues to be a very popular part of our outreach. Our gathering of health care providers, patients, advocates, families, and interested public and staff meets monthly from October to June discussing current topics in breast cancer research. Dr. Debu Tripathy is the moderator. We host approximately 45 people for dinner and discussion, with a mailing list of 350. A direct outgrowth of the Forum was the December 1998 moderated panel discussion entitled "Beating the Odds of Breast Cancer: How Can Research Help?". The panel consisted of a physician, two minority health care representatives, a patient advocate/breast cancer survivor, and an ethicist. It addressed the barriers to clinical trials for diverse and underrepresented populations of women. The discussion was lively and informative. It was videotaped for use throughout the community to further our educational outreach program. To date, 14 copies of the video have been sent to community agencies as part of their individual programs to foster clinical trials. We discussed the video at the Minority Health Research Panel, sponsored by the Cancer Information Service at the County of Alameda Conference Center on April 23, 1999 (appendix U).

The Breast Care Center Clinic Trials Website (<http://bcc-ct.his.ucsf.edu>) continues to grow in content and interest for the community. It includes Forum minutes, monthly newsletter articles, comprehensive listing of UCSF/BCC Clinical Trials, comprehensive glossary, and annotated websites of interest. It provides links to major breast cancer sites: Cancerlink.com, www.acor.org/Cancerlist, www.comprehend.com/Cancerlist, www.saklan.com/Cancerlist. We have also been listed on major search engines like AltaVista, Yahoo!, Snap.com, aol.com, InfoSeek, and WebCrawler, etc. Our newest additions are the two new on-line patient questionnaires for breast cancer patients and those without cancer diagnosis. As an extension to this aim (under separate funding) we are initiating an Internet-based mechanism for patients to match themselves to available clinical trials. Patients (in some cases with volunteer help) would access the Web site and fill in the patient query forms fields of key patients and disease variables. Protocols from an increasing number of sources (initially UCSF, then PDQ, then others) would be embedded along with eligibility criteria and a search engine developed for matching patients based on their eligibility (and search restrictions such as "non-chemotherapy"). Drill down options for more protocol details and contact information will be available for all protocols. We are finalizing the fields (matching them to NCI-mediated emerging database standards) and have begun fundraising for this project and we plan for this effort to be spearheaded by patients and patient advocates with the guidance of our Center.

Conclusion

We have completed an assessment of barriers to clinical trial enrollment from both providers and patients, and have analyzed the data and written a manuscript to determine important barriers as they pertain to specific care providers/patients subsets. Our education and outreach program to patients and care providers is continuing more broadly than originally planned. We are focusing our efforts on minority outreach by creating and distributing flyers, posters and brochures to physician offices, mammography centers, support groups, anywhere that our target audience may see them. We have participated in community panels to provide broad exposure to our outreach. We have created a website which is linked to many breast cancer information and support sites where patients and families can get information regarding ongoing clinical trials at UCSF. Evening information forums will continue, with additional slide presentation evenings devoted to the importance of clinical trials for the underserved in our communities. As our baseline clinical trial enrollment is already more than double the national average, we are in need of these expanded programs to further improve this number, and to provide us with the information we need to develop trials that are more interesting and relevant to patient concerns.

Presentations:

1. A talk entitled "Excluded No More: Why Participating in Clinical Research is Important for You and All Women" was presented at Women's Health 2000, UCSF on March 20, 1999.
2. December 1998 moderated panel discussion entitled "Beating the Odds of Breast Cancer: How Can Research Help?". It addressed the barriers to clinical trials for diverse and underrepresented populations of women. It was videotaped for use throughout the community to further our educational outreach program. To date, 14 copies of the video have been sent to community agencies as part of their individual programs to foster clinical trials.
3. "Update on Research Resources", presented at the Minority Health Research Panel, sponsored by the Cancer Information Service at the County of Alameda Conference Center on April 23, 1999.

Technical Objectives 9-12: Measure Outcomes of Intervention

Task 9: Months 36-40: Mail and surveys. Tabulate results. We plan to initiate this in October, 1999 on schedule. We will use our current system to again identify patients at a point where they are typically eligible for clinical trials. Care provider surveys will again be mailed.

Task 10: Months 36-48: Reinitiate collection of tracking data of new patients. Additionally, after 50 responses, we will begin to analyze the demographic data received from the website questionnaires

Task 11: Statistical analyses.

Task 12: Formulate recommendations, publication of results.

Finally, we will measure attitudes of both patients and care providers as well as actual clinical trial accrual in the final year of the project. Analysis with respect to trends based on the interventions will then be possible. We will also seek out reasons for trends that may be due to extraneous factors such as changes in protocol portfolio and other facilitators not related to the interventions in this project.

Year 3

Conclusion

The challenges of integration are many. Keeping the faculty communication clear and the desire for group success among a growing staff strong requires constant attention. All of our programs are of great value individually, but the integration of every segment is challenging. We are learning to reorganize and consolidate information to avoid overload. We are striving to streamline care and offer cutting edge trials and innovative communication tools, as well as to measure the value of what we do. To accomplish all these goals at the same time is not an easy task. The solution we are piloting is to measure some things some of the time, rather than trying to measure the impact of each tool all of the time.

Finally, finding the proper combination of data elements for the patient follow-up program, where we are capturing medical outcomes, psychological outcomes, and complications of interventions in a routine manner, is essential, but quite difficult. It is especially important to have outcome data on the different domains: physical function, social function, biological function (recurrence), and psychological function, if we want to assess the impact of our life-style and collaborative care interventions. This is a priority for us, and we are piloting these measures now. We hope to have an extensive baseline that will enable us to determine a minimal set of information to collect for programs that are interested in tracking these outcomes.

Another challenge has been to identify the true costs of running an interdisciplinary program in a large, merged medical center environment. The health care environment is constantly changing and therefore poses great obstacles to developing stable models for cost, independent of departments or hospitals reimbursements. We are halfway through this model and intend for this to be complete and able to generate useful monthly data by the end of the grant period.

We have enjoyed our work this year and look forward to completing the tasks we have set forth.

LIST OF KEY RESEARCH ACCOMPLISHMENTS
AND REPORTABLE OUTCOMES
FOR YEAR 3, ENDING AUG. 14, 1999

KEY RESEARCH ACCOMPLISHMENTS

Project 1:

- Completed recruitment for this project. Four hundred eighty-eight women agreed to participate and have completed the baseline telephone survey.
- To date, 312 women have completed the follow-up survey (follow-up response rate 84.6% to date).
- The development of the data entry database has been completed and has been in use.
- We have begun some preliminary data cleaning on the data from the baseline telephone survey. The final analysis will be initiated once the follow-up survey and the medical record abstraction is complete. Preliminary data from the baseline survey has been reported in table form.

Project 2:

- Performed a pilot comparison of two 12-week breast cancer coping interventions suggesting that, while a semi-structured support group was satisfactory to participants, an intensive lifestyle change and support program emphasizing psychospiritual issues was better received.
- Determined that positive coping styles correlate positively with optimistic tendencies and negatively with feelings of helplessness, hopelessness, and avoidance.
- Research resulted in approval as a practicum site for the California School of Professional Psychology-Alameda. We were also approved as a clinical rotation site for Psychiatry residents at both UCSF and CPMC.

Project 3:

- Developed artificial neural network regression model to provide individual post surgical patient continuous probability disease-specific predictions of survival and recurrence.

Project 4:

- Expand the use of Consultation Recording methods: Based on promising results of Consultation Recording from the pilot study published in a leading peer-reviewed journal (JCO), we expanded the use of collaborative care facilitation. Currently, two surgeons and four oncologists in the Breast Care Center use collaborative care facilitation in their consultations.

Pilot A:

- Administered, received and tabulated results of 150 patient and 70 physician questionnaires regarding attitudes and barriers to clinical trials.

REPORTABLE OUTCOMES

Manuscripts

Project 1:

- Ljung BM, Drejet A, Chiampi N, Jeffrey J, Chew K. Diagnostic Accuracy of Fine Needle Aspiration Biopsy is Determined by Physician Training (in submission)

Project 2

- Cotton, S.P., Levine, E.G., Fitzpatrick, C.M., Dold, K. H., & Targ, E. (in press). Exploring the Relationships among Spiritual Well-Being, Quality of Life, and Psychological Adjustment In Women with Breast Cancer. *Psycho-Oncology* (in press).

Abstracts

Project 2

- Carey, M. S., Levine, E. G. Hoffman, D., Zelman, D., & Hardin, K. (1999). Coping styles of breast cancer patients and spouses: The effect on patient's psychological well being and quality of life. *Annals of Behavioral Medicine*, 21 (Suppl.), 132.
- Fitzpatrick, C. M., Targ, E., Cotton, S. P., Dold, K. H., & Levine, E. G. (1999). Psychological adjustment, spirituality, and "New Age Guilt" in women with breast cancer. *Annals of Behavioral Medicine*, 21 (Suppl.), 138.
- Eckhardt, J. R., Levine, E. G., Targ, E. F., Zelman, D., & Ruzek, J. (1999). Coping style and PTSD symptoms among women with primary breast cancer. *Annals of Behavioral Medicine*, 21 (Suppl.), 46.
- Levine, E. G., Fitzpatrick, C. M., Eckhardt, J., Cotton, S., & Targ, E. (1999). Factor analysis of the Mini-Mental Adjustment to Cancer Scale in women with breast cancer. *Annals of Behavioral Medicine*, 21 (Suppl.), 156.
- Levine, E. G., Targ, E., Stone, B. M., & Kronenwetter, C. (1999) A comparison of complementary and traditional psychosocial treatment for breast cancer. *Annals of Behavioral Medicine*, 21 (Suppl.), 156.
- Zelman, D., Levine, E. G., Hoffman, D., Olkin, R., & Carey, M. (1999). Family interaction models of coping in chronic illness: From research to intervention. *Annals of Behavioral Medicine*, 21 (Suppl.), 104.

Project 4:

- Sepucha K, Belkora J, Tripathy D, Esserman LJ. Consultation Recording Methods to Improve Collaborative Decision-Making in Breast Cancer. American Society of Clinical Oncology's Annual Conference May 1999, abstr 1621.

Presentations

Project 2:

- Targ, E. Lecture presentation at University of Florida Arts and Medicine Program, February, 1999
- Targ, E. Lecture presentation at the Twentieth Annual Conference of the Society of Behavioral Medicine, March 1999.
- Targ, E. Lecture presentation at American Psychiatric Association, Washington DC, May, 1999
- Targ, E. Lecture presentation at Congress of Comprehensive Cancer Care, Washington DC June, 1999
- Targ, E. Lecture presentation at Institute of Noetic Sciences Annual Conference, Orlando, July 1999

Pilot A:

- Talk entitled: "Excluded No More: Why Participating in Clinical Research is Important for You and All Women", presented at Women's Health 2000, UCSF, March 20, 1999.
- "Update on Research Resources" presented at the Minority Health Research Panel in Alameda, CA. on April 23, 1999.
- Ongoing monthly Bay Area Breast Cancer Forum to educate researchers, healthcare providers, patients, families and advocates about advances in clinical trials.

Products/Informatics

Project 3:

- Developed patient specific booklet which will be automatically customized by computer program to include: prognosis predictions, breast cancer background information, treatment, and the latest information on clinical trials.
- Pre- and post-viewing questionnaires have been finalized.
- New patient survey which gathers quality of life and demographic information has been developed.
- Toxicity tables for side effects of chemotherapy and hormone therapy have been finalized.

Pilot A:

- Modified patient survey which gathers demographic data as well as attitudes toward preventive and complementary medicine has been placed on the Clinical Trials Website.
- Breast Care Center Clinical Trials Flow Chart continues to be updated and made available to physicians and is on our website.
- Continuing monthly clinical trial updates to caregivers during weekly Tumor Board and making clinical trials lists available to care givers in the community.
- Comprehensive Glossary has been added to the Website.
- Slide presentation seminars presented in English, Russian and Spanish with posters and brochures developed in year 2 distributed at these gatherings.
- Videotape of moderated panel discussion entitled "Beating the Odds of Breast Cancer: How Can Research Help?", addressing barriers to clinical trials for diverse and underserved populations of women, has been distributed to community agencies.

Degrees Obtained

Project 2:

- Janelle Eckhardt, Ph.D., Clinical Psychology, California School of Professional Psychology- Alameda, CA. Dissertation: "Coping Style and Symptoms of Post Traumatic Stress Disorder Among Women With Primary Breast Cancer."
- Sian P. Cotton, Ph.D., Clinical Psychology, California School of Professional Psychology- Alameda, CA. Dissertation: "Exploration of the relationship between spirituality and quality of life in women with breast cancer".
- Cory. M. Fitzpatrick, Ph.D., Clinical Psychology, California School of Professional Psychology- Alameda, CA. Dissertation: "Re-examining the construct of fatalism in women with breast cancer: Stoic resignation versus spirituality focused acceptance.

Project 4:

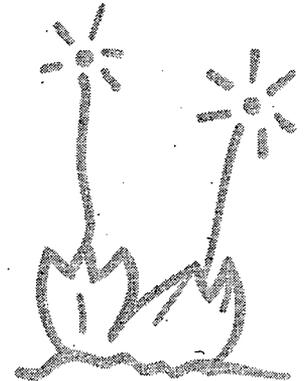
- Karen Sepucha, Ph.D. in Engineering-Economic Systems and Operations Research, Stanford University. Dissertation: "Consultation Recording Methods to Facilitate Collaborative Decision Making in Breast Cancer."

BREAST

CARE CENTER newsletter



A MOMENTOUS YEAR IN BREAST CANCER RESEARCH



Laura J. Esserman, MD, MBA
Director, Carol Franc Buck Breast Care Center

Welcome to the first issue of *Breast CARE Center Newsletter*, the newsletter of the Carol Franc Buck Breast Care Center at the UCSF Cancer Center. Many of you have asked for a summary of the most important news in the field of breast cancer. You've also asked to be informed of new programs at the BCC. In response, we have created this publication, which we will send out twice a year. Each issue will include summaries of important studies, programs and seminars at our Center, a Question & Answer column ("Analyze This!"), and various information of interest to our patients.

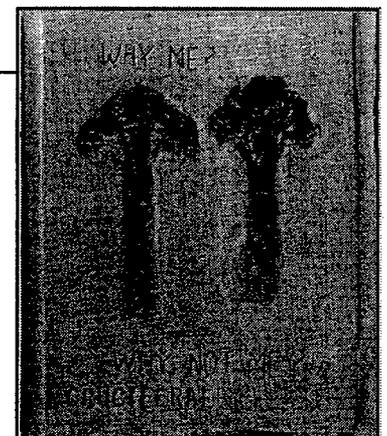
This issue features a review of last year's most newsworthy breast cancer research findings. Debu Tripathy summarizes the news from the San Antonio Breast Cancer Conference, featuring updates on Tamoxifen and Herceptin. Henry Kuerer reports findings from a study on Neoadjuvant Therapy in which he was involved, and Stanley Leong explains the importance of the sentinel lymph node. Other articles concern clinical trials and our own research.

We hope you enjoy the information in this newsletter. Your feedback is very much appreciated -- for suggestions and comments please contact the editor sarah_paris@quickmail.ucsf.edu / phone (415) 885-7323. Thanks!

HEALING TILES & STORY GARDEN

Shown here is one of the 550 "healing tiles" that line the entrance hallway of the Cancer Center. Each tile has been created by a patient, family member, or caregiver and contains a personal message or story, accompanied by images of plants from the garden or botanical remedies with their scientific and common names.

For more info on upcoming garden or tile projects for the Cancer Center, please contact the Ida and Joseph Friend Cancer Resource Center at 885-3693.



The drug Tamoxifen has been making headlines in the last year. The good news is that Tamoxifen will reduce the short-term risk of getting breast cancer and the chance of a DCIS recurrence, as well as breast cancer in the opposite breast (see Debu Tripathy's article on page 6). However, it also leads to a small increase in the risk of uterine cancer in woman who are post-menopausal. The important lesson here is one we have learned throughout breast cancer research: The relative benefit is not nearly as important as the absolute benefit. While tamoxifen can reduce your risk of getting breast cancer, in either breast or at a metastatic site, you must understand your original risk and how much benefit this treatment will bring you.

The same applies in relation to the news about prophylactic mastectomy. A report from the Mayo Clinic showed that prophylactic mastectomy reduced the risk of getting breast cancer by over 90%. Again, how much benefit you would receive from such a procedure would depend on your risk. If you have a hereditary mutation for breast cancer, and your lifetime risk of developing breast cancer is somewhere between 60% and 85%, a 90% risk reduction would be far more important than if your lifetime risk is somewhere around 5%.

Another drug in the headlines was Taxol, which promises a 20% relative reduction in the risk of recurrence, especially if the tumor is hormone-receptor negative. The trial results are early, and we will hear more about them in the next years. Once again, it is not the relative risk but the absolute risk reduction that is important. This is something you need to discuss with your physician, or you can bring your questions to our monthly "office hours" sessions (see page 9). ■

Laura Esserman, MD, MBA
(*excerpted from a talk at Women's Health Grand Rounds at UCSF/Mt. Zion*)

The diagnosis of DCIS (ductal carcinoma in situ) is increasingly common due to today's advanced, mammographic technology. DCIS is microscopic cancer, confined to cells lining the milk ducts of the breast. While it is non-invasive, a significant proportion (30-50%) will probably progress to invasive cancer, if left untreated. The current therapy, which is generally the same as for invasive cancer, is effective but traumatic and expensive. For many patients, therapy other than surgical excision is probably unnecessary. The problem is, we have no clear idea which ones. The challenge is to establish a framework for decision-making that allows treatment tailored to the different types of DCIS and the extent of the disease. Individual risk can then be matched to treatment recommendation. The table below shows some of the statistics:

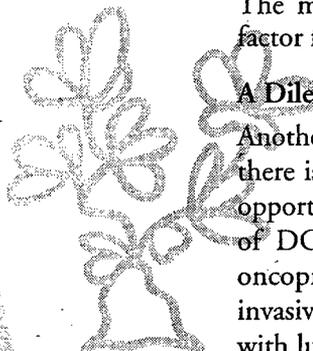
	Lo-grade DCIS	Hi-grade** DCIS
No Further Treatment	10% (5%*)	25% (12.5%)
With Radiation	5% (2.5%)	12% (6%)
With Radiation & Tamoxifen	3% (1.5%)	8-10% (4-5%)
Tamoxifen Only***	5% (2.5%)	12-15% (6-7%)
Mastectomy	1%	1%

* risk for recurrence to be invasive cancer.
** risk for low-grade DCIS may eventually be as high as for high-grade DCIS, but only after 10-20 years.
*** Tamoxifen also reduces the risk of breast cancer in the opposite breast from 5% to 2.5%.

The margin of normal tissue around the DCIS should also be a factor for decision-making (NEJM 1999).

A Dilemma Becomes an Opportunity

Another factor in DCIS is that because the cancer is not invasive, there is *no urgency* to intervene. This presents us with a window of opportunity to try out novel strategies, such as vaccines. Over half of DCIS lesions over-express a genetic marker, the HER2/neu oncoprotein. These lesions are the most likely to progress to invasive cancer in the first five years after diagnosis, if treated only with lumpectomy. In my laboratory at the Cancer Center, we are in the process of testing various potential HER2/neu vaccines. We are planning to start a phase I/II clinical trial next Spring to test a cell vaccine currently being developed. Patients will be vaccinated and followed for 3 months prior to surgical excision. We will use Magnetic Resonance Imaging (MRI) to demonstrate the extent of DCIS before and after treatment to assess the efficacy of the vaccines. ■





Henry M. Kuerer, MD

joined the Breast Care Center last year after completing a fellowship in breast surgical oncology at the M.D. Anderson Cancer Center. He has a special interest in the surgical management of breast cancer in women who have received chemotherapy before undergoing surgery. He is also strongly committed to helping women who have just been diagnosed with breast cancer to make sound treatment decisions based on their personal needs and to successfully adhere to the best and most appropriate treatments for their conditions. Dr. Kuerer will be helping to organize new trials at the Breast Care Center for women with stage III breast cancer.

NEOADJUVANT CHEMOTHERAPY ALLOWS FOR LESS RADICAL SURGERY FOR BREAST CANCER

In a new study, we found that chemotherapy that is given before surgery (called "neoadjuvant chemotherapy") sometimes caused the tumor in the breast to completely disappear. This could potentially eliminate the need for radical surgery for these patients.

Until now, there has been limited research on a woman's response to neoadjuvant chemotherapy.

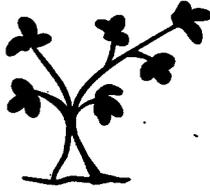
The study was done between 1989 and 1996. A total of 372 women (median age 47 years) with locally advanced breast cancer, who had not undergone breast surgery, participated in two clinical trials, during which they received four cycles of doxorubicin-based neoadjuvant chemotherapy treatment. Forty-three women (12 percent) had no evidence of cancer after receiving chemotherapy.

Says Dr. Kuerer: "Our study also found that the five-year overall and disease-free survival rates were significantly higher for those patients with no evidence of cancer than for those women whose tumors were not completely eliminated after receiving the neoadjuvant chemotherapy." However, it's important to realize that there is still a risk of recurrence, even for patients with no evidence of cancer after neoadjuvant chemotherapy."

The advantage of neoadjuvant chemotherapy is not only that it shrinks the tumor and allows for less radical procedures, but also that we can determine within three to four months to what degree a patient responded to the chemotherapy that was given. If a woman does not respond well to chemotherapy, we can start her on another treatment immediately, or we can proceed with surgery.

Traditionally, chemotherapy has been administered to cancer patients after surgery, and doctors had no way of determining for sure whether or not a particular treatment was actually effective. The sooner the effectiveness of a treatment can be assessed, the better a woman's chance of survival.

Dr. Kuerer performed this study with a team of researchers at the M.D. Anderson Cancer Center. The full results were published in the February 1, 1999 issue of the Journal of Clinical Oncology (www.jco.org). ■



INTRODUCTION TO THE PROGRAM FOR COLLABORATIVE CARE

by Karen Sepucha, Ashley Parsons, and Carrie Sanders

The goal of our new Program for Collaborative Care is to ease communication between patients and physicians so you can make better treatment decisions. The program has several components: One is to make sure we know what is of greatest concern to you. The next is to find better ways to communicate the risks and benefits of various treatments when there is uncertainty. Treatment decisions can be very complex and confusing, so it is very important that communication between patients and physicians is clear and concise. We are developing ways to structure your consultation when you have important decisions ahead of you, then give you a summary of the discussion when you leave.

Consultation Planning, the first step, is ready to be provided to our patients free of charge. During a typical session, a Consultation Planner helps create a flow-chart of a patient's questions and concerns. Patients then take a print-out with them to their appointment to share with their doctor.

Over the past year, we have worked with 61 patients with breast cancer in Consultation Planning sessions. Their ages ranged from 31 to 79, and their diagnoses varied in severity from Stage 1 to Stage 4. These women were making treatment decisions, such as on the type of surgery (including the type of reconstruction) and the type of chemotherapy.

For example: Ms. A came to the BCC for a second opinion. She told us, "I scheduled an appointment here because I have gotten conflicting diagnoses, and I do not know which information to trust. I am frustrated with the lack of coordination and communication among my treatment team." Ms. A was anxious to make a decision and move forward with treatment. She felt Consultation Planning would help her communicate her priorities during her consultation at the BCC.

The figure below is the Consultation Plan we created for Ms. A. Each Consultation Plan is a unique picture of what is on an individual patient's mind. The arrows connect related questions and concerns, and the numbers reflect the priority of these items, according to this patient.

Dr. Esserman reviewed the Consultation Plan before seeing the patient and during the consultation. "I like having a Consultation Plan, because it helps me figure out where the patient is and what is important to her. I cannot find these things in the medical chart". For any number of reasons, patients sometimes don't raise all of their concerns during their office visit.

Whatever decisions you face when scheduling an appointment, a Consultation Planning session can help you prepare and stay focused during your consultation. The Consultation Planners at the BCC are available for appointments, which take between 45 and 60 minutes. If you would like to schedule an appointment for a Consultation Planning session before your next medical appointment, please call the Front Desk at 885-3700.

If you have questions about Consultation Planning or wish to share an experience making decisions about treatment, please call Karen Sepucha at (415) 885-7228 x2 or e-mail her at karen@onyourmind.com. Your input is appreciated!

Our fall newsletter will feature information about the next step in Collaborative Care, Consultation Recording. ■

CONSULTATION PLAN FOR DR. ESSERMAN AND MS. A

One surgeon recommended mastectomy based on the tumor size

I would like to make the decisions about treatment but want to strongly consider the doctor's opinion.

One surgeon said that breast conservation was an option for me

I am confused with the differing opinions. Do you feel I am a good candidate for a lumpectomy?

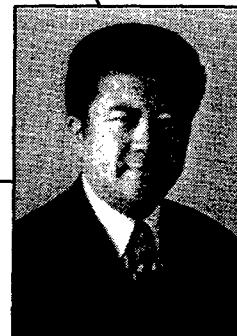
I have concerns about the side effects from radiation. Does it damage my lungs and heart?

I want to maximize my survival. I have two young children.

If breast conservation is an option, that's what I would choose.

ROLE OF SENTINEL LYMPH NODES IN BREAST CANCER

by Stanley P. L. Leong, MD., FACS



The sentinel lymph node received its name because it is the first node that is invaded by metastatic cells. The concept of the sentinel lymph node has been well-studied in melanoma and is now being applied to breast cancer. The standard treatment for patients with primary invasive breast cancer is the surgical excision of the primary tumor, either through a lumpectomy or a mastectomy, and the removal and dissection of all or most lymph nodes. However, this can result in complications for the patient, such as lymphedema (swelling) of the arm. If an analysis of the sentinel lymph node proves to be a reliable indicator of whether or not metastatic cells have progressed as far as the lymphatic system, then the removal of further lymph nodes could be avoided.

At the Breast Care Center, the sentinel lymph node program began in January of 1998. Our goal is to decrease post-operative problems for women who do not need an axillary lymph node dissection, yet provide appropriate treatment for those who have sentinel lymph nodes involved with disease.

Reference: Leong SPL. The role of sentinel lymph nodes in human solid cancer. In: DeVita, VT, Hellman S and Rosenberg SA. eds. Cancer Principles and Practice of Oncology Updates Vol 12(4). Philadelphia: Lippincott-Raven; 1998:1-12.

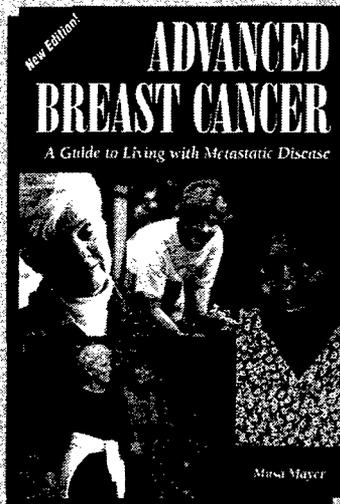
IN THE NEWS THE BONE MARROW CONTROVERSY

Early study results show that undergoing bone marrow transplantation does not appear to improve the survival of women with metastatic disease. There may be a group of women with a great response to chemotherapy that might benefit; this needs to be looked at in the context of a clinical trial. For women diagnosed with stage II/III disease (many positive nodes), bone marrow transplantation seemed to improve survival modestly, in the range of 7%. However, this came at a cost: the complications were significantly higher; in the largest trial, the mortality was high (7%). The critical factors that determine complications are the combination of drugs (regimen) used for the transplant, and where it is performed. At very experienced, high-volume treatment centers, trials show a mortality of 1% or less.

Bone marrow transplantation cannot be considered the standard of care for women with high-risk or metastatic disease; but further investigation will continue through clinical trials at high-volume centers with demonstrated low mortality rates. In our next newsletter, we will devote a longer article to bone marrow transplantation.

More on Bones: Clodronate, a bisphosphonate drug that promotes bone growth and prevents bone destruction, may also reduce the risk of developing new bone metastases, as shown in 2 out of 3 recent European studies. Results from one of the studies suggest that it might even reduce the risk of developing other metastases. These studies are controversial, but extremely intriguing, and will be followed up by national trials. This is a very exciting new area of research, and we will keep you updated on further developments. ■

THE BOOKSHELF



This newest edition of Musa Mayer's book "Advanced Breast Cancer: A Guide to Living with Metastatic Disease" (formerly entitled: Holding Tight, Letting Go) is reissued as part of a series of "Patient-Centered Guides". And indeed, this is an excellent resource for patients and their care-givers, with much practical information, sound advice, and many stories of real patients and their experiences.

While many other books on breast cancer focus on newly diagnosed patients and on the issue of being a "survivor", this book acknowledges the reality that for some breast cancer patients, the disease will reoccur. All aspects involved in such a recurrence are covered here, including coping with the news, making informed treatment decisions, managing side effects, getting emotional support and finding new ways to keep hope alive and discover meaning in adversity. ■



Debu Tripathy, MD
*Director of Clinical Research
& Breast Oncology
Carol Franc Buck Breast Care Center*

ADVANCES IN RESEARCH

Several important advances were covered at the San Antonio Breast Cancer Symposium held in December of 1998.

Tamoxifen

Findings from the NSABP P01 Prevention Trial now confirm that in the short term (over about 5 years), patients who are at high risk for getting breast cancer can reduce their risk by almost one half by taking tamoxifen. Based on this information, the Food and Drug Administration has approved tamoxifen as a drug that can lower the short-term incidence of breast cancer.

It is important to recognize that tamoxifen may not in reality be preventing cancer. In the opinion of most scientists, breast cancer takes as many as 5 to 15 years to develop. Therefore, it is likely that what tamoxifen is doing is actually treating established breast cancers that are microscopic and undetectable.

There are many questions about the long-term effects of tamoxifen prevention and the optimal time for a woman to take it. Trials showed a higher risk of uterine cancer, blood clots, and the development of cataracts, especially in women over 50. So even though tamoxifen can now be prescribed as a "prevention" drug, it remains unclear for which women the benefits of the treatment will actually outweigh the risks.

There is a trial planned to compare tamoxifen to raloxifene as a preventive agent for breast cancer. Raloxifene has the advantage that it may not increase the risk of uterine cancer.

HER2/neu

Reports in San Antonio included further information on the HER2/neu genetic marker and its use to identify who might benefit from different types of therapy -- hormonal or chemotherapy -- for early stage breast cancer.

Patients whose tumors overexpressed HER2/neu (i.e., made high amounts of the protein encoded by the HER2/neu gene) seem to benefit more from the chemotherapy Adriamycin. A study of older women compared tamoxifen alone to a regimen of tamoxifen and Adriamycin-containing chemotherapy. Results suggested that only patients whose tumors overexpressed HER2/neu obtained significant benefits from the addition of chemotherapy.

Herceptin

Further presentations included an update from the clinical trials using Herceptin, the HER2/neu antibody. In one trial, women received Herceptin as the only treatment if they had metastatic breast cancer which overexpressed HER2/neu and which had progressed after one or two chemotherapy regimens. 14% of the 222 women had a response. It remains unclear why a majority of women do not respond to Herceptin, but certainly for those that do respond, there is a clinical benefit, even though the responses were temporary.

Another randomized trial compared chemotherapy alone to chemotherapy with Herceptin, also for women with metastatic, HER2/neu-positive breast cancer. This study showed convincingly that the addition of Herceptin improved the effectiveness of chemotherapy. The average time after which patients had progression of their tumor was significantly prolonged. The number of patients who had a response in the first place was also improved, and the one-year survival was improved.

These changes were not as dramatic as one would like to see, but clearly demonstrate the biological effectiveness of Herceptin at least in some women.

The important message is that though we don't have a cure yet, we are seeing the beginning of success for treatments which actually target the genetic and biochemical pathways of cancer. In the coming years, we will explore many other strategies. These include drugs that target angiogenesis (the formation of blood vessels that tumors require to grow); drugs that boost the immune system (such as vaccines), and drugs that actually introduce or alter the expression of a specific gene. It will take not only laboratory research but large and well-conducted clinical trials to move potential biological therapies towards a major impact in breast cancer.

For more details, check out the Breast Care Center Clinical Trials website at <http://bcc-ct.his.ucsf.edu> ■

BREAST CARE CENTER STAFF

Left to right: Annette Ramos, *Medical Assistant*; Laurel Bray, *Practice Manager* (kneeling); Sabrina Taylor, *Front Office* (standing); Claudia Castro, *Front Office*; Michelle Jones, *Front Office*; Sonia Stallworth, *Front Office*; Christine Del Rosario, *Medical Assistant*; Jenny Aquino, *Front Office*. Not depicted: Sandra Rodriguez, *Front Office*, and Mary Garlin, *Surgery Scheduler*



Carol Franc Buck

BREAST CARE CENTER
newsletter

Editor: Sarah Paris

Design: Greta Berger, Pharos Interactive, LLC

Printed by UCSF Reprographics

This newsletter is funded by DOD
Grant DAMD 17-96-1-6260

"A New Vision For Integrated Breast Care"

ANALYZE THIS!

Our next newsletter will feature a patient Q & A column... Please send us your questions, and we'll publish a selection along with the answers in the fall issue. Questions can be sent to Sarah Paris, UCSF Box 1728, San Francisco, CA 94143, e-mail: sarah_paris@quickmail.ucsf.edu

FROM THE ADVOCATES

The two sidebars on this page are excerpts from letters written to patients by former patients who have become advocates in the fight against breast cancer.

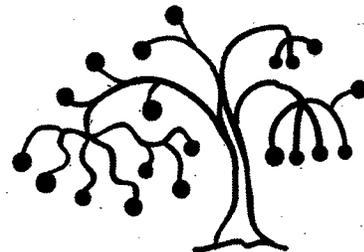
For the full text of these letters, please contact Deborah Collyar at Collyar@worldnet.att.net, or at (925) 736-8155; or Peggy Devine at pdevine@pacbell.net, or at (415) 502-2986.

Clinical Trials

Virtually all of the improvements in cancer care have occurred because of something called a "clinical trial." The term "clinical trial" may sound a bit intimidating, but it is simply a research study that carefully tests new ways to prevent, diagnose, or treat diseases like breast cancer. There are advantages and disadvantages to participating in a clinical trial. Advantages might include receiving treatment that is not commercially available, undergoing more rigorous follow-up care, or experiencing treatment that is given in a more effective way than with standard therapies. Disadvantages might include more doctor visits, additional tests, or increased costs (although such costs are usually covered by the trial budget or by insurance).

We believe it is important for you to understand all of your options as you decide upon a treatment plan. We want you to make the best decision for your particular condition and invite you to learn more about cancer research. If you want information about a specific clinical trial, please call Liz Wieland at the UCSF Breast Care Center at (415) 353-7213. ■

LINKS IN THE CHAIN



Selected links of interest to our patients (for a comprehensive list of websites please check the "links" section of the Cancer Resource Center site below):

<http://cc.ucsf.edu/crc> - the Ida & Joseph Friend Cancer Resource Center at the UCSF Cancer Center

<http://bcc-ct.his.ucsf.edu/> - the Breast Care Center's Clinical Trials website.

www.ucsf.edu/ocim/ - website of the Osher Center for Integrative Medicine at the UCSF/Mount Zion. The Center's mission is to search for the most effective treatments for patients by combining non-traditional and traditional approaches that address all aspects of health and wellness - biological, psychological, social and spiritual.

www.cancerlinks.org - one of the most comprehensive, organized and user-friendly sites, with links to numerous topics related to cancer.

www.breastcancer.net - provides very complete information on breast cancer: current news articles, indexed reference articles, support groups, treatment options, and related websites.

www.canceranswers.org - what makes this site unique are the personal stories and artwork in support of women receiving treatment for breast cancer.

www.cancersupportivecare.com - information for patients and caregivers on topics such as Nutrition, Exercise, Pain Control, Sexuality, and Spirituality.

www.noah.cuny.edu - the N.Y. Public Library, City University of N.Y., and the N.Y. Academy of Medicine have joined forces to produce the ultimate resource on cancer and other diseases. Primary devoted to educating underserved populations, the website is totally bilingual (English and Spanish), and includes exhaustive information on breast cancer clinical trials, diet, diagnosis, prevention, causes, risk factors about cancer, and even includes questions to ask your physician. ■

CALENDAR



Monthly Office hours

with Drs. Laura Esserman, Debu Tripathy,
and other BCC and visiting MDs

These are open discussion sessions for our patients to discuss concerns and ask questions on important topics, such as hormone replacement, herbal medicine, exercise and nutrition, and new treatments. They are open Q & A sessions, where patients can bring up issues specific to them. The sessions are geared towards patients in follow-up care.

"Office Hours" are held Monday evenings from 5:15pm to 6:15 pm at the Resource Center on the First Floor of the Cancer Center. The following dates have been set for 1999:

July 19
August 23
September 13
October 11
November 8



Bay Area Breast Cancer Forum

Sessions are open to the public. Upcoming dates for the BABCf are September 7, October 13, and November 10. Topics for discussion may include hormonal therapy, diet & exercise, sexual problems, and environmental factors. For more information, please contact Fern Hassin at 885-3738



October is Breast Cancer Awareness Month!

1999 San Francisco Race for the Cure: **October 17, 1999**
on-line information at www.racefortheure.com
If you'd like to be on our BCC team for next year, please contact Sarah Paris @ (415) 885 7323 or sarah_paris@quickmail.ucsf.edu to be put on our list.

In conjunction with the Race, we are planning to organize "Taste for the Cure", a gourmet event featuring celebrity chefs. Please check back with us as the date gets closer for more information! ■



FEATURED

Clinical Trial at the BCC:
The Micrometastasis Study

Micrometastasis (MM) occurs when cancer cells break loose from their original tumor site and circulate in the bloodstream. This process goes undetected until the cells invade other organs and grow large enough to cause symptoms. Our study will test three ways of detecting micrometastasis, and will study the relationship between MM and clinical outcome.

This study will help to achieve the following:

- improve care for future patients
- learn more about how to predict whether breast cancer will spread and whether a woman needs chemo or hormonal therapy
- predict which cancers will respond to different types of therapy
- find potential genetic markers for metastasis

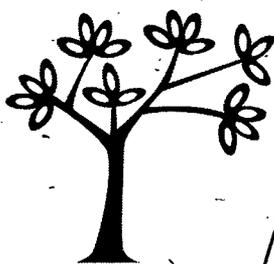
If we find a reliable, easy method of detecting circulating cells (MM) in the blood and bone marrow, we can, in the future:

- tailor therapy
- use mm to follow response to therapy
- follow the genetic markers for MM

The "Micrometastasis Study" is open to any woman who has been diagnosed with breast cancer, but has not yet had breast cancer surgery. It will necessitate having a bone marrow aspiration during surgery, while under anesthesia. A decision to participate or not in this study will not affect the quality of care you receive from UCSF.

Although you may not experience a direct benefit from participating in this study, your willingness to donate bone marrow will help researchers in their efforts to treat breast cancer more effectively in the future.

If you want information about this or other clinical trials, please call Liz Wieland at the UCSF Breast Care Center at (415) 353-7213. ■



SUPPORT GROUPS AT THE BCC

RECRUITING

Personal Support and Lifestyle Intervention Trial of UCSF and CPMC. Women with breast cancer are invited to participate in a research program studying the benefits of two types of psychosocial and lifestyle interventions on well-being and quality of life. Women will be asked to participate in one of two groups, both lasting for 12 weeks. Interested people can call the program at 885-7877.

Young Adults with Cancer Support Group 1st and 3rd Monday of each month, 5:30-7:30 pm. To register or for more information, contact Keren Stronach, MPH at the Cancer Resource Center, 885-3693.

Support Group for Husbands & Significant Others 1st and 3rd Tuesday of each month, 6:30-8:30 pm, Cancer Center. To register or for more information, contact Andrew Kneier, PhD, 885-7585.

UCSF/Mt. Zion Department of Psychiatry offers the following support groups to cancer patients. To register, or for more information, contact Debra Marks, PhD, 415-885-3770.

-Family & Friends Support Group - A group for family members and friends of people dealing with cancer.

-DCIS - 12-week support group for women with Ductal Carcinoma In Situ.

The Cancer Support Community is an 11 year-old free-standing community-based agency. UCSF/Mount Zion is proud to co-sponsor the groups situated at Mount Zion.

-African American Group 1st and 3rd Monday of each month, 6-8 pm at the YWCA, 1830 Sutter St. Contact Jane Gainer 765-7677, 207-5958 pager.

-Breast Cancer Support Group For more information contact Carol Kronenwetter, PhD 885-3785.

-Cantonese Support Group 1st and 3rd Sat., Chinatown District, Health Center, 1490 Mason St., SF. To register, or for more information, call 788-2131.

-Family and Friends Support Group Meets on the 2nd and 4th Friday of each month, 12-1:30 pm. To register or for more information, call Carol Kronenwetter, PhD 885-3785.

-General Cancer Support Group - all stages Wednesdays 5:30-7:30 pm, Resource Center. Contact Carol Kronenwetter, PhD 885-3785.

-Group for Children Whose Parents Have Cancer To register or for more information, call 788-2131.

-For Support Groups in other languages contact the Resource Center, 415-885-3693

Ida and Joseph Friend Cancer Resource Center Programs and Services:

Exercise Class for Cancer Patients

Tuesdays, 12:15-1:45 pm and Thursdays, 9:45-11:15 am, Mount Zion Cardiac Care Gym, first floor, room C101. Entrance is at 2200 Post at Scott. To register, please contact the Resource Center at 885-3693 and Kathleen Dzuber at 510-597-1189.

Restorative Movement

Wednesdays, noon - 1:00 pm in Mount Zion Cardiac Care Gym, first floor, room C101. Entrance is at 1600 Divisadero. For more information, contact the Resource Center at 885-3693.

Gentle Yoga Class

Thursdays, 12:15 - 1:30 pm. Mount Zion Medical Building, 1701 Divisadero. Registration required. To register, contact the Resource Center at 885-3693.

Individual and Couple's Counseling

Individual and couple's counseling/psychotherapy with a sliding scale fee can be arranged by calling Debbie Marks, PhD, at 885-3770.

Support for Russian-Speaking Women and Their Family Members

Raya Smail, MA, (Russian-speaking) at 831-4339.

Smoking Cessation & Relapse Prevention Course

A month-long course, Wednesdays, 5:30 -7 pm. To register, contact the Resource Center at 885-3693.

Art for Recovery

Mondays & Thursdays at the Cancer Center Infusion Center, 2nd floor, or by appointment. Contact Cindy Perlis, 885-7221.

Healing Garden and Tile-Making Workshops

Call the Resource Center for more information at 885-3693.

Look Good, Feel Better

Workshops to improve appearance during chemotherapy. Call the Resource Center for dates and locations at 885-3693.

Spiritual Counseling and Guidance

Chaplains are available in the department of Pastoral Care to provide patients with spiritual counseling and guidance, and to assist in coping with bereavement. Please call 353-7681.

The Cancer Resource Center contains books and audio tapes & video tapes which may be checked out by the public. The Center can help you locate information about your condition, treatment options, nutrition, pain management, stress reduction or other health matters. All Resource Center support groups and activities are free. Stop by and visit us at 2356 Sutter Street, First Floor or call us at (415) 885-3693. Web page: <http://cc.ucsf.edu/crc> ■



**NUTRITION
CONSULTATIONS**

Now Available in the

Breast Care Center

with registered dietitian

Alison Horton

One Hour Consult Can Include:

- dietary assessment
- current information about diet and breast cancer
- information on phytoestrogens in soy
- answers to your nutrition questions
- supplementation needs
- weight loss suggestions

To book an appointment with

Alison, simply ask the Breast

Care Center front desk staff.

or call the Breast Care Center

at 885-3700

FOR OPPORTUNITIES
VOLUNTEERS!

Have you ever considered volunteering some of your time? Do you think our efforts here at the BCC are worth supporting? Would you like to gain some hands-on experience in healthcare? Please contact *Merridith Mendelsohn* (415) 885-7558

UCSF

The Carol Franc Buck Breast Care Center
UCSF Stanford Health Care
2356 Sutter Street, Box 1710
San Francisco, CA 94143-1710

Franking Code #2096

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University of California
San Francisco

BREAST

CENTER

• SUMMER 1999 •

THE CAROL FRANC BUCK BREAST CARE CENTER
INVITES YOU TO A TALK AND DISCUSSION PRESENTED BY ·

Jeffrey Pfeffer, Ph.D.

*Thomas D. Dee Professor of Organizational Behavior
Stanford Graduate School of Business*

**Author of "The Human Equation:
Building Profits by Putting People First"**

Friday, January 15, 1999, at 4pm
Herbst Hall, Mt. Zion Hospital, 2nd Floor
1600 Divisadero Street, San Francisco, CA

Please join us after the presentation for wine & hors d'oeuvres
at Ida's Cafe (in the Cancer Center), 2356 Sutter, 1st Floor.

RSVP to Sarah Paris, (415) 885-7323 / sarah_paris@quickmail.ucsf.edu

Jeffrey Pfeffer, Ph.D., is a much sought-after lecturer in both the corporate and academic worlds. He is the author of a number of books on organizational design; his most recent one, "The Human Equation", has earned him abundant praise. Experts in the field declared it "a must-read for every executive" and called him "a paragon of sanity and clarity of thought."

*The talk will focus on why it is critical to the success of any organization to invest in its workforce.
An open discussion will follow.*

*This event is sponsored by DOD Grant DAMD 17-96-1-6260
"A New Vision For Integrated Breast Care".*



30406

Breast Care Center Patient Satisfaction Survey

Version E

We welcome you to the Breast Care Center. To serve you better we ask that you please complete this survey. We encourage your honest opinions so that we may improve the quality of the Breast Care Center and the care we provide. Thank you!

Please use a black pen - This form will be read by a computer.

Shade circles like this: ●

Not like this: ⊗



Appointment Date

 / / 9 9

Age

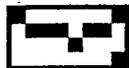
We would like to know what aspects of your care are most important to you. Please rank the following on a scale of 1-6, 1 = most important.

- The expertise of the doctor.
- The expertise of the nurse.
- The availability of direct communication with doctors and nurses.
- The courtesy of the Breast Care Center staff.
- The amount of time that I wait to see the doctor.
- The process for making future appointments and any other testing arrangements(i.e. mammograms, scans).

Today my appointment was with

- | | | |
|---|--|--|
| <input type="radio"/> Christopher C. Benz, MD | <input type="radio"/> Deborah Hamolsky, RN, MS | <input type="radio"/> Debra Marks, PhD |
| <input type="radio"/> Emile Daniel, MD | <input type="radio"/> I. Craig Henderson, MD | <input type="radio"/> Lawrence W. Margolis, MD |
| <input type="radio"/> Charles Dollbaum, MD | <input type="radio"/> E. Shelley Hwang, MD | <input type="radio"/> John Park, MD |
| <input type="radio"/> Mary Lou Ernest, NP | <input type="radio"/> Henry Kuerer, MD, PhD | <input type="radio"/> Debasish Tripathy, MD |
| <input type="radio"/> Laura J. Esserman, MD | <input type="radio"/> Stanley Leong, MD | <input type="radio"/> Nancy Valente, MD |

Comments:



30216

Breast Care Center Patient Satisfaction Survey

Version N

We welcome you to the Breast Care Center. To serve you better we ask that you please complete this survey. We encourage your honest opinions so that we may improve the quality of the Breast Care Center and the care we provide. Thank you!

Please use a black pen - This form will be read by a computer.

Shade circles like this:



Not like this:



Appointment Date / / 9 9 Age

We would like to know what aspects of your care are most important to you. Please rank the following on a scale of 1-6, 1 = most important.

- The expertise of the doctor.
- The expertise of the nurse.
- The availability of direct communication with doctors and nurses.
- The courtesy of the Breast Care Center staff.
- The amount of time that I wait to see the doctor.
- The process for making future appointments and any other testing arrangements(i.e. mammograms, scans).

Today my appointment was with

- | | | |
|---|--|--|
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| <input type="radio"/> Emile Daniel, MD | <input type="radio"/> I. Craig Henderson, MD | <input type="radio"/> Lawrence W. Margolis, MD |
| <input type="radio"/> Charles Dollbaum, MD | <input type="radio"/> E. Shelley Hwang, MD | <input type="radio"/> John Park, MD |
| <input type="radio"/> Mary Lou Ernest, NP | <input type="radio"/> Henry Kuerer, MD, PhD | <input type="radio"/> Debasish Tripathy, MD |
| <input type="radio"/> Laura J. Esserman, MD | <input type="radio"/> Stanley Leong, MD | <input type="radio"/> Nancy Valente, MD |

Comments:

Breast Care Center Patient Satisfaction Survey

Returning Patients (8pts)

Question	Answer	Percent
1. I have been a patient at the Breast Care Center:	Less than 1 year	12.5%
	1 year	17.50%
	2 years	25.00%
	3 years	25.00%
	4 years	3.75%
	More than 4 years	16.25%
	2. How many times on the average are you seen a year:	1 to 2
3 to 4		14.29%
5 to 6		2.38%
7 to 8		1.19%
9 to 11		0.00%
12 to 15		1.19%
16 or more		0.00%
3a. When I leave a message for a nurse/doctor, my call is returned within a reasonable period of time.	N/A	15.66%
	Agree	73.49%
	Somewhat Agree	6.02%
	Somewhat Disagree	3.61%
	Disagree	1.20%
	3b. I expect a call back within:	30 min.
1 to 2 hours.		11.11%
Same day		65.28%
Next day		20.83%
4. When I call the BCC, I am able to speak with someone within a reasonable amount of time without waiting on hold.	N/A	7.14%
	Agree	71.43%
	Somewhat Agree	10.71%
	Somewhat Disagree	4.76%
	Disagree	5.95%

Question	Answer	Percent
5. I have too many appointments at the BBC.	N/A	22.35%
	Agree	3.53%
	Somewhat Agree	3.53%
	Somewhat Disagree	0.00%
	Disagree	70.59%
6. The Front Desk staff were courteous and acknowledged me in a timely manner.	N/A	1.18%
	Agree	91.76%
	Somewhat Agree	5.88%
	Somewhat Disagree	1.18%
	Disagree	0.00%
7. I found the overall appearance of the clinic satisfactory and was comfortable in the waiting area.	N/A	2.35%
	Agree	95.29%
	Somewhat Agree	2.35%
	Somewhat Disagree	0.00%
	Disagree	0.00%
8. I was comfortable with the amount of time that I waited to see the doctor.	N/A	2.35%
	Agree	95.29%
	Somewhat Agree	2.35%
	Somewhat Disagree	0.00%
	Disagree	0.00%
9. After arriving for my appointment, I waited _____ until I met the nurse/doctor.	0 to 30 min.	84.62%
	31 to 45 min.	10.26%
	46 to 60 min.	2.56%
	1 to 1.5 hrs	1.28%
	2+ hrs	1.28%
10. I was kept informed of any delays during my visit.	N/A	45.00%
	Agree	41.25%
	Somewhat Agree	6.25%
	Somewhat Disagree	2.50%
	Disagree	5.00%

UCSF Stanford Health Care
Fine Needle Biopsy Clinic Patient Satisfaction Survey

1. Please rate each of the following:

(circle one number on each line)

	<u>Excellent</u>	<u>Very Good</u>	<u>Good</u>	<u>Fair</u>	<u>Poor</u>
a. The care you received from the doctor who performed your fine needle biopsy	5	4	3	2	1
b. The helpfulness and courtesy of the doctor who performed your fine needle biopsy	5	4	3	2	1
c. The promptness of the care and testing you received	5	4	3	2	1
d. The promptness of the results of your biopsy	5	4	3	2	1
e. The doctor's explanation of the risks and benefits of the fine needle biopsy	5	4	3	2	1
f. Overall, how would you rate the care you received?	5	4	3	2	1

2. Were your questions about the procedure answered satisfactorily?

Yes

No ⇒ What additional information did you need?

3. Did you receive enough information so that you knew what to expect and how to take care of yourself when you left the clinic?

Yes

No ⇒ What additional information did you need?

4. Did you understand the results of your fine needle biopsy?

Yes

No ⇒ What additional information did you need?

5. Based on your experience with this Clinic, would you choose UCSF Stanford again for your medical care?

Yes

No ⇒ Please comment.

6. Would you recommend UCSF Stanford to a friend or family member?

Yes

No ⇒ Please comment.

7. Do you have any other comments about the care that you received at UCSF Stanford Health Care?

FNA Biopsy: Patient Satisfaction Survey Responses

Questionnaires were mailed 3-9 weeks post-procedure to all 115 patients who underwent fine needle aspiration biopsy in the Breast Care Center between February 1 and June 3, 1999. Fifty-nine questionnaires were returned, for a response rate of 51%.

Please rate each of the following:

	Excellent	Very Good	Good	Fair	Poor	No Response
The care you received from the doctor who performed your fine needle biopsy	80% (47)	15% (9)	5% (3)	0	0	0
The helpfulness and courtesy of the doctor who performed your fine needle biopsy	80% (47)	15% (9)	3% (2)	2% (1)	0	0
The promptness of the care and testing you received	68% (40)	20% (12)	7% (4)	0	5% (3)	0
The promptness of the results of your biopsy	67% (39)	10% (6)	10% (6)	9% (5)	3% (2)	(1)
The doctor's explanation of the risks and benefits of the fine needle biopsy	57% (32)	25% (14)	9% (5)	4% (2)	5% (3)	(3)
Overall, how would you rate the care you received?	63% (36)	32% (18)	5% (3)	0	0	(2)

100% of the 59 respondents rated the care they received from physicians as excellent, very good or good. 98% rated helpfulness and courtesy the same way. Promptness of care and testing was rated 95% good to excellent, with 5% rating this aspect as poor. Promptness of biopsy results and the doctor's explanation of risks and benefits were the most problematic areas, as noted in the comments sections, with 13% giving a rating of fair, poor or no response.

Overall care was rated excellent or very good by 95% of those who responded.

	Yes	No	What additional information did you need?
Were your questions about the procedure answered satisfactorily?	98% (58)	2% (1)	No one mentioned anything about risks. (x4) I was not given any info on the procedure until it was being performed.

98% of respondents felt that their questions about the procedure were answered satisfactorily.

	Yes	No	No response	What additional information did you need?
Did you receive enough information so that you knew what to expect and how to take care of yourself when you left the clinic?	93% (54)	7% (4)	(1)	<p>New drugs</p> <p>Patient should have a written explanation of results. I already forgot what I was told verbally.</p> <p>The doctor had a strange look on his face and when I questioned the results, he said "they look funny." He wasn't helpful in helping me to understand exactly what "funny" meant. This caused me a lot of anxiety and distress because I left thinking I had cancer.</p> <p>However, the procedure went very well and was uneventful, so I didn't need any follow-up info!</p> <p>No care instructions given to care for self.</p> <p>Except the first one hurt a lot and kept hurting for about 15 min.</p>

93% of respondents felt that they had received enough information so that they knew what to expect and how to take care of themselves at home. Five patients felt they needed more information.

	Yes	No	No response	What additional information did you need?
Did you understand the results of your fine needle biopsy?	89% (51)	11% (6)	(2)	<p>Although I would like to have had a written report of what the results were.</p> <p>Have not received any paperwork; results were given only by phone. 6 weeks have passed.</p> <p>I did not get complete test results. ER/PR - yes. HER2NEU - no.</p> <p>I just know it was ok. Nothing to worry for now.</p> <p>No cancer cells, but what is the lump?</p> <p>Not totally. I should have written it down so I could research it later and/or discuss it with my doctor.</p> <p>Since the results were "funny" according to the dr. He didn't seem to have words to correctly describe my results.</p> <p>Someone called me, left a message on my machine about "the good news". I returned the call and was never called back.</p> <p>The only thing that made me a bit uneasy was the explanation I received when I asked how the dr. knows that the needle is inside of the mass.</p> <p>Barely. I had to call for results.No one called me. Even then results weren't explained in depth.</p>

Although 89% of respondents reported that they understood the results of their fine needle biopsy, ten patients (17%) wrote comments that expressed concerns with this aspect of care.

	Yes	No	Comments
Based on your experience with this Clinic, would you choose UCSF Stanford again for your medical care?	100% (59)	0	Certainly, because my experience with other doctors there have been very genuine and positive. If I ever have to go through this biopsy again I will ask Dr. Ljung to do it. If I know I can afford it.

	Yes	No	Comments
Would you recommend UCSF Stanford to a friend or family member?	98% (58)	2% (1)	Letting them know it's expensive. Yes for the care but absolutely NOT because of the ridiculous difficulty in making an appointment and getting through your voice mail system.

100% of respondents would choose UCSF Stanford again for hospital care and 98% would recommend to a friend or family member.

OTHER COMMENTS

All my care at the Breast Care Center has been caring and VERY efficient.

At the time of FNA I was lactating and 3 days post FNA I developed mastitis. The doctor on call was not familiar with my condition and appeared quite incompetent. I had to seek my OB/Gyn's help for my condition.

Did not receive explanation of risks and benefits. Would choose again: the best people are always busy so elsewhere not better. There are many services -- therapy, acupuncture, nutrition, counseling -- to gather questions for the doctor, resource library.

Doctor was very matter-of-fact. Gained my confidence.

Dr. Ljung is an exemplary physician. I haven't met many physicians like her.

Dr. Ljung was excellent! A deft technician, extremely humane, and very clear in her explanations.

Dr. Ljung was exceptionally outstanding in every way. She went out of her way to give me all the information she could concerning the results of the biopsy which put my mind at ease. Above all, she made me feel that she really cared and was a truly compassionate human being in addition to being an expert in her field. She is a real credit to her profession. She should be an example to others in the medical profession!!!

Dr. Sudilovsky was very reassuring and professional and I appreciated his caring attitude and his expertise.

Everyone I encountered was friendly, competent and compassionate. You all made a scary procedure practically "pleasant." Thank you, thank you.

I am extremely happy with the care I'm given there. I would recommend UCSF. I am very thankful to all doctors and nurses who helped me. I was so scared, but they were all nice and friendly and gave me good support and advice. And thank you Dr. Daniel, too. You're a good surgeon.

I didn't realize there were any risks. Very genuine, helpful, friendly staff.

I don't like that doctors never take full responsibility for what they're doing. I guess it's all about the doctors making more money. 2 mammograms, 1 sonogram, 3 doctors visits, 1 needle biopsy, and I have been asked to come again so that the surgeon can check it again. Why do you charge so much if you don't know how to interpret all these tests!!!!!!

I don't recall hearing about risks. The initial physical exam with Dr. Kuerer was also excellent. I was nervous, and he completely put me at ease. Both he and Dr. Sudilovsky were very professional, kind and thoughtful.

I first saw a breast care surgeon, who sent me to the clinic in my gown (since I would be seen immediately). When I arrived at the waiting room, I told the receptionist I was there for a biopsy. She saw that I had only the gown on. She told me to sit down and wait and then forgot about me. I felt uncomfortable sitting in the waiting room (which happened to be loud and busy) without my regular clothes on.

I had 2 (one after the other) and the first one really hurt a lot!! I wasn't expecting that. The second one was only about 1/3 as painful. I didn't understand why? Perhaps there's no answer!

I had the same procedure several years ago, also at Mount Zion. I found this second experience to be superior. Also, the speed of the result report was remarkable. Thank you.

I received care in the Cancer Research Center and some advice would be to have staff be extra friendly. I realize life is stressful enough but you have people going in there that are either being treated for cancer or finding out if they have it. Life changing experiences going on- very sensitive time for delicate people. Hello's, smiles and How are you's are great!

I thought the doctors that did the needle insertion were wonderful. But I had to call for results 2 1/2 weeks later.

I'm receiving excellent care from Debbie Hamalsky and Dr. Kuerer as a follow-up at the Breast Care Center.

It took a long time to get official results. Although preliminary results were good, I would have appreciated a faster final result.

Overall I have had very good care at UCSF.

Since my initial diagnosis of breast cancer 1/98 I feel I have received the best of care at all times, mentally and physically.

Thank you for giving me the best care I needed. Thank you to the staff (doctors, nurses, administrative supports) who made me feel at ease during the time I was scared and nervous when I found out I have breast cancer. I'm fine at the moment, everything seems to be going well.

Thanks for asking.

The actual appointment with the doctor was fine. However, I had to wait one and a half hours before seeing her. I only will come back to UCSF because I have limited options with my insurance and I liked my doctor. The service from the staff was slow and unfriendly. I also had to leave 3 messages before being called back with my biopsy results. There must be a way to improve this service!

The assistant Liz was very helpful in explaining things and putting me at ease. It was comforting to have her with me.

The care was excellent but I had to wait for about an hour and a half in the doctor's room before I was seen. I understand the staff may have been busy but I need to make a living as well and I cannot be waiting such an extended period of time to be seen for an appointment.

The doctor and staff were very helpful and supportive. I had to bring my 8 month old baby. They held him and comforted him and me at the same time. Very positive experience.

The doctor was very thorough and sympathetic. I felt confident of his ability to administer the test and evaluate the results.

The doctor was wonderful, compassionate, kind and professional -- very impressive. So was the intern who was there learning/assisting. However, I understood I would be contacted regarding the results within a few days. I waited a week or so and called in for results. Another irritating experience getting through your voice mail system and not knowing whom I should contact. [Also] I don't remember discussion of any risk (from biopsy).

The doctor who ordered the FNB indicated the wrong breast on the chart! I advised the doctor who was performing the fine needle biopsy and he double checked with the doctor.

The doctors took time to listen and they didn't seem rushed. It was very comforting.

The MD and the assistant were friendly, considerate and competent. I wasn't told anything about risks, so I can't comment on that aspect of the questionnaire.

The nurse was very nice and tried her best to make me feel relaxed which was very much appreciated at such a stressful time. Also, the doctor had a very good manner of explaining everything without making me feel like he was in a big hurry like most doctors do. Thanks!

The only major drawback is that my appointment was 2 hours late and 2 hours in total. That's four hours. A bit long don't you think!

The staff displayed sensitivity to the patient. Administrative staff was also very helpful.

Very impressive. Superior to the care I received from my breast care team in New York City.

Very nice doctors; not in a big rush.

Very satisfied with service.

More personal attention regarding results would have been more appropriate. I think I should be contacted when results are in, with time then to make sure I am understanding the significance.

Quality Improvement
6/28/1999

1. Diagnostic tests may be done:
Fine Needle Aspiration,
Stereotactic core biopsy, on
the same day. Or you may be
scheduled for a surgical biopsy
for another day.
2. You will be scheduled to
return in 48 hours for results
of any diagnostic tests.

On average, patients with an
abnormal mammogram should plan
to spend the day at the Breast Care
Center depending on the type of
diagnostic tests done.

Assessment Team

Ernest, Mary Lou RN NP
Nurse Practitioner specializing in Breast
Oncology & teaching Self-Breast Exam.

Esserman, Laura MD, MBA Director
Surgeon specializing in diagnosis and
treatment of breast problems. Director of
the Breast Care Center.

Kearns, Pat RN
Nurse Coordinator of Same Day Assessment
Program.

Hamolsky, Deborah RN, MS
Clinical Nurse Specialist, Breast Care Center.

Hwang, E. Shelley MD
Surgeon specializing in diagnosis and
treatment of breast problems.

Kuerer, Henry MD, PhD
Surgeon specializing in diagnosis and
treatment of breast problems

Leung, Jessica MD
Breast Imaging Clinical Instructor

Ljung, Britt-Marie MD
Pathologist specializing in Fine Needle
Aspiration and breast disease diagnosis.

Maas, Kathryn MD
Breast Imaging Clinical Instructor

Sickles, Edward, MD
Radiologist specializing in Breast Imaging.
Chief, Breast Imaging Section UCSF.

Sudilovsky, Daniel MD
Pathologist specializing in Fine Needle
Aspiration and breast disease diagnosis.

UCSF
CAROL FRANC BUCK
BREAST CARE CENTER

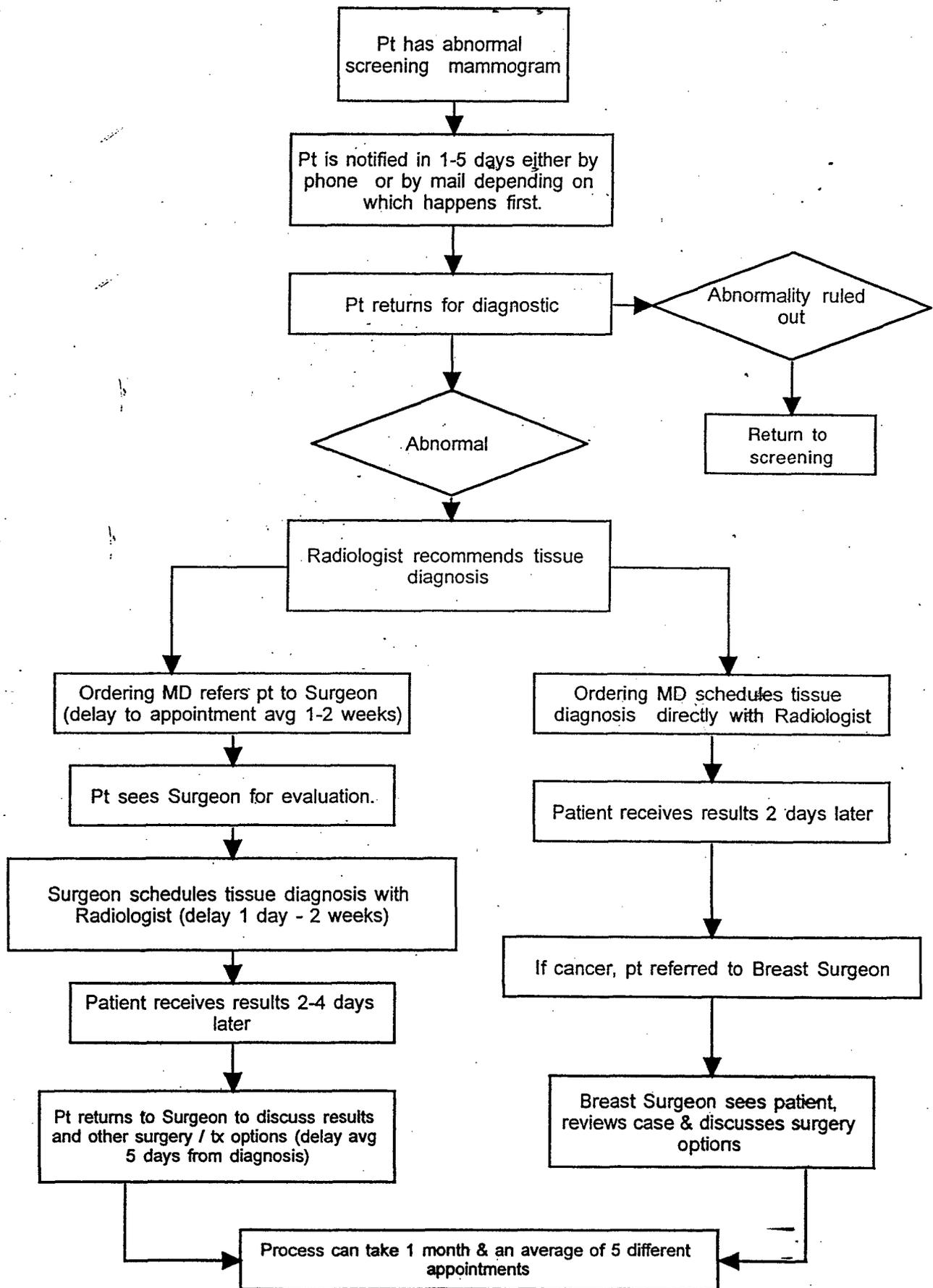
(415) 415-476-5555

2356 Sutter Street, 6th Floor
San Francisco, CA 94115

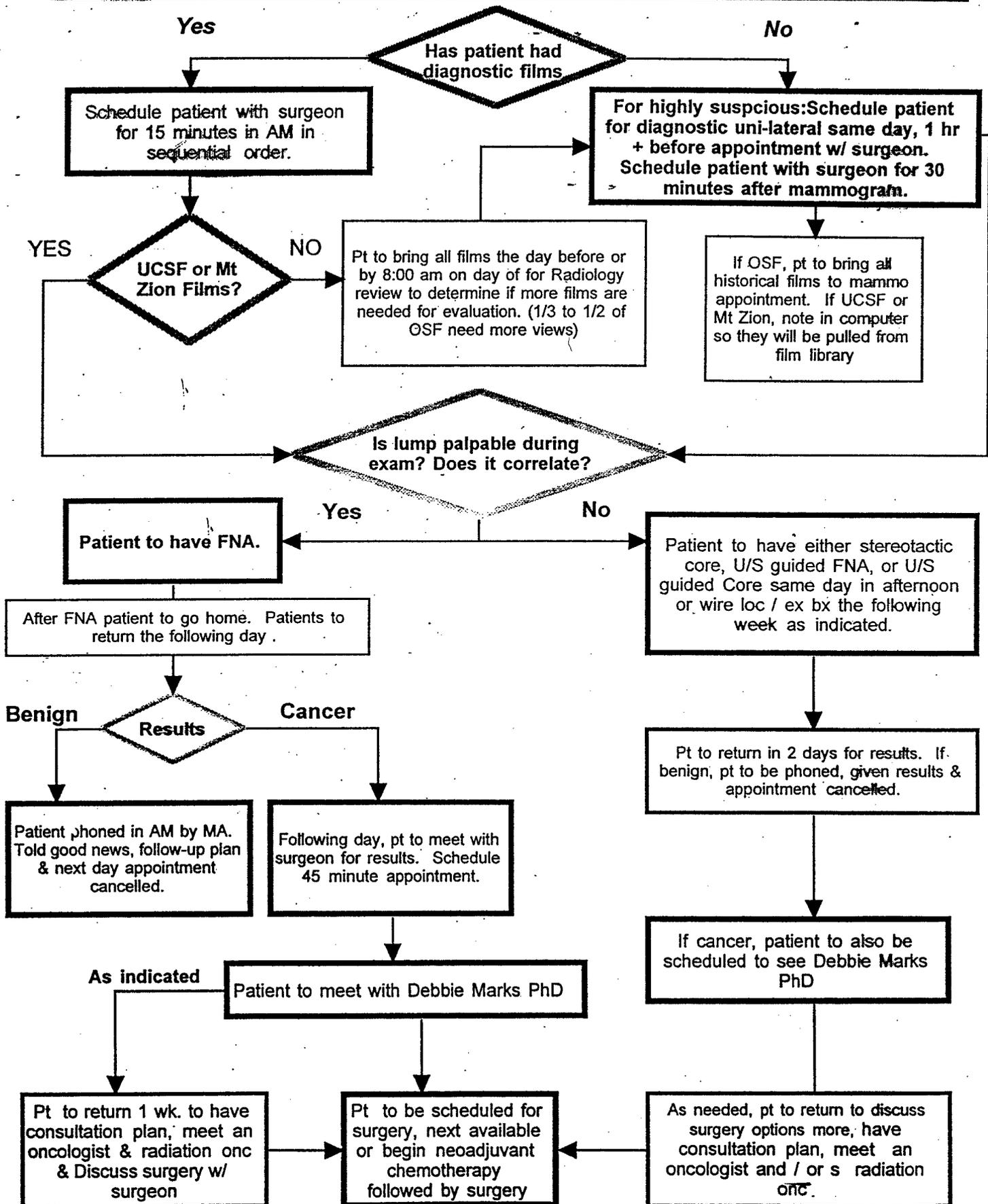
Same Day Assessment Program

*For Diagnosis & Evaluation of
Patients with Breast Lumps &
Abnormal Mammograms*

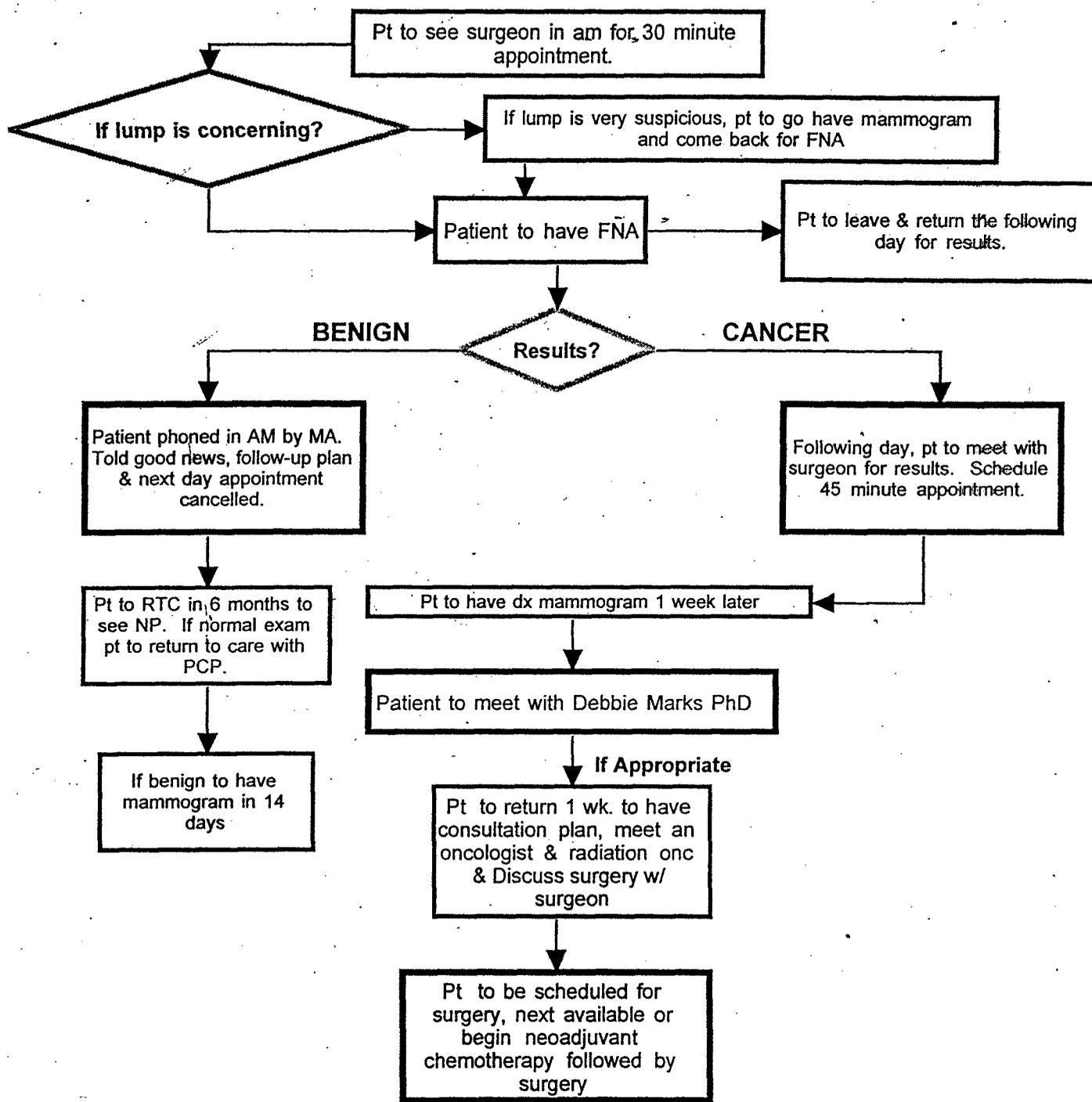
CURRENT SCENARIO ABNORMAL MAMMOGRAMS



SAME DAY EVALUATION PROGRAM ABNORMAL MAMMOGRAMS



SAME DAY EVALUATION PROGRAM: BREAST LUMPS



Physician Interview Outline - Breast Evaluation Program

MD Name _____

Date _____

1. When a patient has an abnormal mammogram, what is your procedure for referral, etc.?
2. How do you think this works? (Good / Bad)
3. What is your optimal scenario for processing patients with abnormal mammograms?
4. When a patient has a breast lump, what is your procedure for referral, etc.?
5. What is your optimal scenario for processing patients with breast lumps?
6. Where do you refer? (Mammograms, Lump evaluation, etc.)
7. Describe our program:
 - a) Quick turn around on Dx (work up 1 day, path 1-2 days)
 - b) Less visits to different offices (radiology, BCC, etc.) = 1 stop shopping
 - c) Coordinated support infrastructure (RN, Ph.D., Path, Radiology, Surgeon) = true interdisciplinary care.
 - d) Improve access for physicians and patients
 - e) Review flow chart
8. Any suggestions for us.
9. Looking to start Nov. 1, 1998. Will send f/u materials.
10. (Get email address, correct mailing address.)

Breast Same Day Evaluation Program
Implementation Time Line

ID	Task Name	September			October			November			December							
		9/30	9/6	9/16	9/26	10/4	10/11	10/18	10/25	11/1	11/8	11/15	11/22	11/29	12/6	12/13	12/20	12/27
1	DAY ORGANIZATION	[Gantt bar spanning 9/30 to 12/27]																
2	Patient Flow	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
3	BOD Patient schedule	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
4	Radiology schedule	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
5	Coordinating calls / patients	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
6	2nd FLOOR	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
7	Painting	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
8	Changing Room	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
9	Waiting Area	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
10	Clean up, Supplies in storage, etc.	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
11	Placement of Mammoviewer	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
12	Reading Room set up / Darkening	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
13	FEEDBACK	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
14	Referral Patterns ref. MDs	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
15	Input Referring MDs	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
16	BCC staff	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
17	DEFINING OUTCOMES	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
18	Measurement	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
19	INFORMATICS	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
20	Data Capture	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
21	Data Standards	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
22	PRICING	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
23	Costing	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
24	Putting together a package	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
25	EXPANSION	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																
26	To other BCC Surgeons & other days	[Gantt bar: 9/16-9/18, 9/26-9/27, 10/4-10/11, 10/18-10/25, 11/1-11/8, 11/15-11/22, 11/29-12/6]																

January 27, 1999

To all of my patients:

I am writing to tell you that beginning February 1, 1999, I am going to be spending more time on breast care center program development and finalizing work on some exciting research. I am finding it increasingly difficult to be available for all of the new patients referred to me with breast cancer, and to also be available to see all of my follow-up patients. I am also aware that there are problems getting in to see me and long waiting times once you are here. Obviously, a better solution is needed!

As most of you know, I am now the Director of the Carol Franc Buck Breast Care Center, and as we have grown in size, I have had to shoulder many more responsibilities and must now devote some attention to program development. I have assembled a highly skilled clinical staff. There are two new surgeons who like myself, specialize in diseases of the breast, Drs. Shelley Hwang and Henry Kuerer. Most of you know our clinical nurses Marylou Ernest and Deborah Hamolsky who have accrued many years of expertise in the field of cancer care and are highly skilled in breast exams and breast care. We have now added Pat Kearns RN to our staff who works primarily to ensure that patient questions and concerns are met. The Breast Care Center is totally committed to your care.

In order to continue to provide the quality of care that we have been striving for, we have just finished designing a comprehensive new program that will deliver coordinated, consistent care to each of you. **We have designed a follow-up program for patients who are a year out from their cancer diagnosis or who are at high risk for breast cancer and have had a year of stable exams.** At your follow-up appointment you will be seeing Mary Lou Ernest, our Nurse Practitioner, who will perform a thorough exam and you will be asked an extensive set of questions. The questions are to help us make sure that you are doing well, and to make sure that we do not miss the opportunity to take care of any side effects of treatment that we can improve. If any problems are detected you will automatically be seen by your physician. **I want to assure you that I will be available for any urgent problems that arise but will not always be available for routine follow-up exams.**

In addition, we will have nutrition and exercise consultation available. Once a month Dr. Tripathy and I will hold sessions open to our patients who wish to come, where we can discuss all of the latest updates and critical issues that any of you may have. We have discovered that often people have issues that are important to them, but that also turn out to be of great interest to others. We believe that this approach will improve care and we are going to try it and evaluate it. In addition, we will have a monthly educational seminar on topics ranging from nutrition, exercise, lymphedema to prevention and cancer risk.

I welcome your input. Please send your comments to me via Laurel Bray-Hanin, our Clinical Practice Manager at laurelb@itsa.ucsf.edu or call her at (415) 885-7607.

Sincerely Yours,

Laura Esserman, MD, MBA, Director
UCSF Carol Franc Buck, Breast Care Center

Monthly Follow-Up Program Office Hours

With Laura Esserman, MD

Mondays

June 14, 1999

July 19, 1999

August 23, 1999

September 13, 1999

October 11, 1999

November 8, 1999

5:15-6:15 PM

2150 Sutter Street, 1st Floor Resource Center



The monthly discussion sessions are designed for people in the follow-up program who are receiving their breast cancer follow-up care at the Breast Care Center.

To help us better prepare answers to some of your questions, please take a moment to let us know any concerns or questions you would like addressed.

Please leave in the box in the waiting room or mail to Laurel Bray, c/o Breast Care Center PO Box 1710, SF CA 94143-1710. Thank You



Long Term Follow-Up Program Proposal
Stage I & II Cancer Patients
High Risk Patients

How things are now

- Average reimbursement for a f/up visit with an MD is approx. \$35 and for a new patient it is \$100
- In physician time they spend approx. 25 minutes, including the exam, dictation, and reviewing the chart and mammos for a f/up visit
- 80% of our patient load is f/up
- Surgeon schedules are booked up to 3 months in advance with f/up visits
- The NP is under utilized, doing duplicate clinical work
- We have no standards in place therefore it takes many more resources to take care of the patients

Long term f/up program

Overview

- Physician director who oversees the program-Henry
- NP program coordinator- which would allow Mary Lou to be an NP3
- Stage I and II patients enter the program at one year post diagnosis
- Program has a standardized set of protocols and a form to be used to collect data
- It would be supplemented by monthly educational sessions
- We would have more funding to allow for a nutritionist, more of Debbie Marks' time, a physical therapist (in the future)-further supplementing the program to make it more comprehensive

What this will change

- It will reduce the number of excessive f/up visits
- It will allow the patients to form a relationship with one main person who they can then feel comfortable coming to with their concerns (NP)
- It will reduce the number of calls patients make to their MDs
- It will reduce staff stress, MDs and front office, as we will have more availability for new patients and patients won't have to wait as long to be seen
- We will be able to collect data from the forms
- We will create a standard of care which will allow us to better track our progress and identify areas for improvement
- It will be more cost effective as we will be seeing more new patients therefore generating more surgical cases
- We will improve referring physician satisfaction
- There will be less duplicate work and fewer dictations for the MDs
- It will map out for patients their five year care plan so they know what to expect

Supporting Data

- The MD Anderson patient satisfaction survey demonstrated the following:
 - overall patients were equally or more satisfied with the care provided with the NP in the long term f/up program
 - they felt that the explanation of tests was more thorough
 - the completeness was better overall
 - their ability to discuss health concerns was higher
- Other well known breast centers such as UCLA have adopted similar programs which supports the use of an NP in managing f/up patients

How our program would differ from MD Anderson

- Patient would enter the program one year from their initial diagnosis
- We will have a supplementary monthly educational program led by the physicians
- We would have a nutritionist, psychologist and a physical therapist on the days when there was a f/up clinic
- We would do QA checks on charts but not have MD sign off on every chart

Beginning Steps

- Agree on a protocol
- Finalize the form and make it scannable
- Develop educational material for patients describing the program
- Develop a letter for existing patients to introduce the program
- Redefining the MA's role
- Map out when and how the clinic will operate (including monthly sessions and ancillary services)
- Set up a cost analysis-tracking system
- Streamline the way we manage patients and patient charts to better utilize our resources

BASELINE QUESTIONS

Domain	Subdomain	Specific Construct	Measure/source	Measurement type	# Items	Time Frame
Biological data	Breast cancer			Administrative		at diagnosis
Health Behaviors	Diet		DOD grant	Q		past year
	Exercise		DOD grant	Q		past year
	Smoking		DOD grant	Q		past year
	ETOH use		DOD grant	Q		past year
	Other substance use		DOD grant	Q		past year
Quality of life	General	General physical and psychological functioning	FACT-B Single general health measure	Q	36	7 days
	Interpersonal	Marital satisfaction	Quality of Marriage Inventory (Norton, 1983)	Q	1	4 weeks
	Psychological functioning	Depression	CESD	Q	6	current
		Cancer fears	Fear of Cancer Recurrence in FACT-B	Q	5	
		Body image	in FACT-B			
	Work functioning	status, time off, bed days, limited activities, usual activities	RA Panel study	Q	6	past year

Post surgery assessment

Domain	Subdomain	Specific Construct	Measure/source	Measurement type	# Items	Time Frame
Biological outcomes	Breast cancer			A		since diagnosis
Quality of life	General	General physical and psychological functioning	FACT-B- Single general health	Q	36	7 days
		Marital satisfaction	Quality of Marriage Inventory (Norton, 1983)	Q	1	4 weeks
Satisfaction with treatment	Interpersonal	Psychological functioning	Depression	Q	6	current
		Cancer fears	Fear of Cancer Recurrence in FACT-B, Kornblith in FACT-B	Q		
		Body image				
		overall satisfaction, satisfaction with choice, cancer relief, bother from side effects	UCSF Prostate cancer study	Q	4	since treatment

Follow up assessments

Biological outcomes	Breast cancer, Cardiac disease, Other body systems			A		past year	
Health Behaviors	Diet		DOD grant	Q		past year	
	Exercise		DOD grant	Q		past year	
Quality of life	Smoking		DOD grant	Q		past year	
	ETOH use		DOD grant	Q		past year	
	Other substance use		DOD grant	Q		past year	
	General	General physical and psychological functioning		FACT-B	Q	36	7 days
		Marital satisfaction		Single general health	Q	36	4 weeks
Interpersonal	Psychological functioning	Mood	Quality of Marriage Inventory (Norton, 1983)	Q	6	current	
		Cancer fears	CESD	Q	65	7 days	
		Body image	Fear of Cancer Recurrence in FACT-B, Kornblith in FACT-B				
	Stress-related growth (1 and 5 year only)		Post-traumatic growth inventory (Tedeschi & Calhoun 1996)	Q	20	since diagnosis	

Follow-up assessments continued

Domain	Subdomain	Specific Construct	Measure	Measurement type	# Items	Time Frame
Patient satisfaction with treatment		overall satisfaction, satisfaction with choice, cancer relief, bother from side effects	UCSF Prostate cancer study	Q	4	since treatment
Service utilization	Medical visits	number, type	NHIS (National Health Interview Survey)	Q	10	past year
	Hospital visits/ER/Outpatient procedures/Institutional care	number, type	NHIS	Q	5	past year
	Diagnostic tests/ treatments used	number, type	NHIS	Q	12	past year
	Medications/devices	type, period	NHIS	Q	4	past year
	Complementary/alternative visits	number, type	NHIS	Q	8	past year

Codes

Measurement type

Q= Patient completed questionnaire

A= Data available from medical database

FACT-B (Version 4)

Below is a list of statements that other people with your illness have said are important. By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

PHYSICAL WELL-BEING

		Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy.....	0	1	2	3	4
GP2	I have nausea.....	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family.....	0	1	2	3	4
GP4	I have pain.....	0	1	2	3	4
GP5	I am bothered by side effects of treatment.....	0	1	2	3	4
GP6	I feel ill.....	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

SOCIAL/FAMILY WELL-BEING

		Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family.....	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness.....	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support).....	0	1	2	3	4
<p><i>Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box <input type="checkbox"/> and go to the next section.</i></p>						
GS7	I am satisfied with my sex life.....	0	1	2	3	4

FACT-B (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

EMOTIONAL WELL-BEING

		Not at all	A little bit	Some- what	Quite a bit	Very much
GE1	I feel sad.....	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse.....	0	1	2	3	4

FUNCTIONAL WELL-BEING

		Not at all	A little bit	Some- what	Quite a bit	Very much
GF1	I am able to work (include work at home).....	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well.....	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun.....	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

FACT-B (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

<u>ADDITIONAL CONCERNS</u>		Not at all	A little bit	Some- what	Quite a bit	Very much
81	I have been short of breath.....	0	1	2	3	4
82	I am self-conscious about the way I dress	0	1	2	3	4
83	One or both of my arms are swollen or tender	0	1	2	3	4
84	I feel sexually attractive.....	0	1	2	3	4
85	I am bothered by hair loss.....	0	1	2	3	4
86	I worry that other members of my family might someday get the same illness I have	0	1	2	3	4
87	I worry about the effect of stress on my illness.....	0	1	2	3	4
88	I am bothered by a change in weight.....	0	1	2	3	4
89	I am able to feel like a woman.....	0	1	2	3	4

SPIRITUALITY SUBSCALE

English		Spanish	
Reliability (Cronbach's coefficient alpha)=0.87		Reliability (Cronbach's coefficient alpha)=0.85	
N=656 English-speaking patients		N=467 Spanish-speaking patients	
Response Categories	Response Categories	Response Categories	
0=not at all 1=a little bit 2=somewhat 3=quite a bit 4=very much		0=nada 1=un poco 2=algo 3=mucho 4=muchísimo	
Item Content	Item Content	Item Content	
1. I feel peaceful.	1. Estoy tranquilo(a).		
2. I have a reason for living.	2. Tengo razones para vivir.		
3. My life has been productive.	3. Mi vida ha sido productiva.		
4. I have trouble feeling peace of mind.	4. Me es difícil tener paz mental.		
5. I feel a sense of purpose in my life.	5. Siento que mi vida tiene sentido.		
6. I am able to reach down deep into myself for comfort.	6. Encuentro apoyo en mí mismo(a).		
7. I feel a sense of harmony within myself.	7. Me siento en paz conmigo mismo(a).		
8. My life lacks meaning and purpose.	8. Mi vida carece de sentido.		
9. I find comfort in my faith.	9. Mi fe me ayuda.		
10. I find strength in my faith.	10. Mi fe me da fuerza.		
11. My illness has strengthened my faith.	11. La enfermedad ha fortalecido mi fe.		
12. I know that whatever happens with my illness, things will be okay.	12. No importa lo que suceda con mi enfermedad, se que todo me ira bien.		

Note: Items 4 and 8 are reversed scored.

Single General Health Item from the SF-36:

1. In general, would you say your health is:

Excellent

Very Good

Good

Fair

Poor

Fear of Recurrence

Listed below are a number of statements concerning a person's beliefs about their own health. In thinking about the past week, please indicate how much you agree or disagree with each statement: Strongly Agree, Agree, Not Certain, Disagree, or Strongly Disagree. Please circle the number of your answer.

	Strongly Agree 1	Agree 2	Not Certain 3	Disagree 4	Strongly Disagree 5
1. Because cancer is unpredictable, I feel I cannot plan for the future.					
2. I will probably have a relapse [recurrence] within the next five years.					
3. My fear of having my cancer getting worse gets in the way of my enjoying life.					
4. I am afraid of my cancer getting worse.					
5. I am certain that I have been cured of cancer.					

Please check the appropriate response for each of the statements as they pertain to you OVER THE PAST WEEK. Please read carefully since some statements are positive and some are negative.

	Rarely or None of the Time (LESS THAN 1 DAY/WK)	Some or a Little of the Time (1 - 2 DAYS/WK)	Occasionally or Moderate Amount of the Time (3 - 4 DAYS/WK)	All of the Time (5 - 7 DAYS/WK)	
I was bothered by things that usually don't bother me.	_____	_____	_____	_____	BOTHERED _____
I did not feel like eating, my appetite was poor.	_____	_____	_____	_____	APPETITE _____
I felt that I could not shake off the blues even with help from my family.	_____	_____	_____	_____	BLUES _____
I felt that I was just as good as other people.	_____	_____	_____	_____	ASGOOD _____
I had trouble keeping my mind on what I was doing.	_____	_____	_____	_____	TROUBLE _____
I felt depressed.	_____	_____	_____	_____	DEPRESSE _____
I _____ that everything I did was an effort.	_____	_____	_____	_____	EFFORT _____
I felt hopeful about the future.	_____	_____	_____	_____	HOPEFUL _____
I thought my life had been a failure.	_____	_____	_____	_____	FAILURE _____
I felt fearful.	_____	_____	_____	_____	FEARFUL _____
My sleep was restless.	_____	_____	_____	_____	RESTLESS _____
I was happy.	_____	_____	_____	_____	HAPPY _____
I talked less than usual.	_____	_____	_____	_____	TALKED _____
I felt lonely.	_____	_____	_____	_____	LONELY _____
People were unfriendly.	_____	_____	_____	_____	UNFRIEND _____
I enjoyed life.	_____	_____	_____	_____	ENJOYED _____
I had crying spells.	_____	_____	_____	_____	CRYING _____
I felt sad.	_____	_____	_____	_____	SAD _____
I felt that people disliked _____	_____	_____	_____	_____	DISLIKED _____
_____ could not "get going."	_____	_____	_____	_____	NOGETGO _____

SATISFACTION WITH TREATMENT

(Currently used in UCSF Prostate Cancer Study)

1. Overall, how satisfied are you with the treatment you received for your breast cancer?
2. Overall, how satisfied have you been with the relief of your breast cancer symptoms?
3. Overall, how satisfied are you with your choice of treatment for your breast cancer?

Response choices for the above three questions are:

Extremely dissatisfied
Dissatisfied
Neither satisfied nor dissatisfied
Satisfied
Extremely satisfied

4. How bothered have you been by the side effects of your breast cancer treatment?

- I have no side effects
- Not at all bothered
- Slightly bothered
- Moderately bothered
- Very bothered
- Extremely bothered
- I have not started treatment yet

Satisfaction with Care

(Disease-Specific Care, with approval from the Arthritis Research Group, UCSF)

1. How would you rate the following aspects of your health care for your breast cancer?
(Response choices: 1=Excellent, 2=very good, 3=good, 4=Fair, 5=Poor, 6=DK/NA)

1. Getting through to your doctor's office on the telephone to get advice?
2. Being able to see your own doctor, or another doctor who is familiar with your medical history?
3. The length of time between making the appointment and the day you can see the doctor?
4. The distance you have to travel to the doctor's office?
5. The time you have to wait in the doctor's office?
6. The information you receive from your doctor?
7. The way the doctor encourages you to ask questions?
8. The way your doctor listens to your concerns?
9. The way your doctors explains your medical condition and treatments?
10. The thoroughness of the doctor/s examination?
11. The way your doctor involves you in treatment and medication decisions?
12. Your doctor's competence

2. Overall, how satisfied are you with the care provided by your primary cancer doctor?

1. Very satisfied
2. Satisfied
3. Dissatisfied
4. Very Dissatisfied
5. DK/NA

We are interested in your use of health care providers in the **PAST 12 MONTHS**. Please record all information whether or not the care was for your breast cancer.

1. Have you seen any health professionals such as a nurse practitioner or any doctor in the PAST 12 months? Please don't include any visits while you were in the hospital or for receiving a medication injection only.

If "YES," record the number of visits for each type of health professional you have seen.

EXAMPLE: 3 Number of visits to a Medical Oncologist (in the PAST 12 months)

a.	_____	Number of visits to a Primary Physician, Internist, or General Practitioner
b.	_____	Number of visits to a Gynecologist
c.	_____	Number of visits to a Medical Oncologist (cancer specialist)
d.	_____	Number of visits to a Radiologist, Radiation Technician/Therapist for treatment
e.	_____	Number of visits to a Mental Health Professional (psychiatrist, psychologist, etc...)
f.	_____	Number of group session with a Mental health Professional
g.	_____	Number of visits to a Nurse Practitioner or Physician's Assistant
h.	_____	Number of visits to a Physical or Occupational Therapist
i.	_____	Number of visits to a Chiropractor
j.	_____	Number of visits to a massage therapist
k.	_____	Number of visits to Other Health Workers (please describe): (For example: nutritionist, social worker, dietitian, or others)
	_____	_____
	_____	_____

In the PAST 12 months, did you stay in the hospital overnight or visit an emergency room for any reason?

If "YES," please describe each hospital or emergency room visit in the PAST 12 months:

Reason for Hospitalization/ Emergency Room Visit	Hospital Information	Admission Date 11/99-6/30/99	# of Days in Hospital
a.	<hr/> <i>Hospital Name</i> <hr/> <i>Hospital Address (Street Name, City, State)</i>	<i>(Month, Year)</i>	
b.	<hr/> <i>Hospital Name</i> <hr/> <i>Hospital Address (Street Name, City, State)</i>	<i>(Month, Year)</i>	

In the PAST 12 months, have you had any outpatient surgeries or procedures?

If "Yes," please describe:

Surgery or Procedure	Date (Month, Year)
a.	/
b.	/

In the PAST 12 months, have you had to obtain any devices to help you in daily activities, such as a cane or walker, or prosthesis?

If "Yes," please indicate whether you PURCHASED or RENTED the device:

Device	Purchased	Rented
a. Drainage supplies.....	<input type="checkbox"/>	<input type="checkbox"/>
b. Prosthesis	<input type="checkbox"/>	<input type="checkbox"/>
c. assistive devices for personal hygiene, such as a raised toilet seat.....	<input type="checkbox"/>	<input type="checkbox"/>
d. Wheelchair/Walkers/Canes.....	<input type="checkbox"/>	<input type="checkbox"/>
e. Special Bras.....	<input type="checkbox"/>	<input type="checkbox"/>
f. Special sleeves	<input type="checkbox"/>	<input type="checkbox"/>
g. assistive devices for personal hygiene, such as a raised toilet seat.....	<input type="checkbox"/>	<input type="checkbox"/>
h. Others (please describe): _____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>

In the PAST 12 months, have you used alternative treatments such as acupuncture, herbal remedies, homeopathic remedies, special diets or other treatments?

If "Yes," please complete:

Type of Treatment	# of Treatments or days of treatment in the past 12 months
a. acupuncture	
b. Chinese herbal remedies (describe) _____	
c. Other herbal remedies (describe) _____	
d. Vitamin/mineral supplements	
e. Diet modification (describe _____)	
f. Exercise program (tai chi, yoga, or other program)	
g. Homeopathy	
h. Other (describe) _____	

In the PAST 12 months (January 1 – June 30, 1999), have you received any injections or intravenous medications (intravenous infusions)?

If "YES," COMPLETE FOR ANY INJECTIONS OR INTRAVENOUS INFUSIONS.

Name of Medication	# of Injections per month	# of Infusions per week	Still taking today? (Circle one)		IF NO, month stopped	# Weeks out of last 12 months on drug
			Yes	No		
a.	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
b.	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
c.	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
d.	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
e. Other (please specify below):	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____
_____	_____	_____	<input type="checkbox"/>	<input type="checkbox"/>	_____	_____

What type(s) of health insurance do you have?

(Please check all that apply.)

- a. None
- b. Medicaid or Other State Assistance
- c. BCRP – insurance specifically for breast cancer patients
- d. Medicare Part A – Medicare insurance for hospital care.
- e. Medicare Part B – Medicare insurance for physician visits and other non-hospital care.
- f. Medicare/HMO – Insurance for people with Medicare who select to join a health maintenance organization (HMO).
Name of HMO: _____
- g. Medigap Insurance – Additional insurance for people covered by Medicare. Medigap policies generally pay the Medicare deductibles and co-insurance.
Name of Supplemental Insurance: _____
- h. Medicare Disability Insurance
- i. Other Public Assistance
- j. Traditional Insurance – Insurance where you may see any physician you choose. Many traditional insurance policies require you to pay coinsurance [a percentage of the charges for each visit] and/or a deductible.
Name of Insurance: _____
- k. Health Maintenance Organization (HMO) - Insurance where you must see a primary care physician (MD) to receive care. In most cases, the primary care MD must authorize visits to specialists or other providers. Primary care MD's are chosen from a list of MD's affiliated with the organization. In most cases, HMO's charge a small co-payment for each visit, but have no deductible.
Name of HMO: _____
- l. Preferred Provider Organization (PPO) - Insurance where you may see any physician (MD) you choose, but you pay a different amount depending on whether or not the MD is affiliated with the organization and whether or not you are referred by your primary care MD.
Name of PPO: _____
- m. Champus or Veterans Administration
- n. Federal Employees Health Benefit Program (FEHBP)
- o. Other (please specify): _____

Baseline Demographics

Please answer the following questions. All of your answers will remain confidential. If you have any questions, please ask the person who gave you this questionnaire. Thank you for your cooperation.

Name: _____ Date: _____

Age: _____ Birthdate: _____ Height: _____ Weight: _____
DOD ID# _____

1. What is your racial/ethnic background? _____

2. Which of the following best describes your relationship status? (Check one)

- Married:
- Living together on a long term basis:
- Widowed:
- Divorced/Separated:
- Never Married:

3. Do you have any children? Yes: No:

If yes, how many? _____ How old are they? _____

4. What is the highest grade you completed in school? (Check one)

- 8th Grade or less:
- Some high school:
- High school graduate:
- Some college:
- College graduate:
- Any post-graduate work:

5. What is your occupation(if retired, from what)? _____

6. What is your average yearly family income? (Check one)

- <\$15,000:
- \$15,000-29,000:
- \$30,000-44,000:
- \$45,000-59,000:
- >\$60,000:

Baseline Demographics (continued)

7. Do you have pain/discomfort at this time? Yes: No:

What do you do to reduce your pain? _____

8: In general, would you say your health is: (Check one)

- Excellent:
- Very good:
- Good:
- Fair:
- Poor:

9. Have you ever participated in any alternative treatments (e.g. acupuncture, biofeedback, yoga, alternative spiritual practice, etc.)? Yes: No:

If yes, what did you do? _____

Did you do this for a certain reason (illness, etc., list)? _____

How long ago? _____

10. Do you smoke? Yes: No: Have you ever smoked? Yes: No:

If yes, when did you quit? _____

11. Do you drink alcoholic beverages? Yes: No:

If yes, how often? Once/week:
 2-3 Times/week:
 3-5 Times/week:
 Every day:

12. Do you use non-prescription drugs such as marijuana, cocaine, etc.? Yes: No:

If no, have you ever used non-prescription drugs? Yes: No:

Baseline Demographics (continued)

13. Do you have a regular exercise routine? Yes: No:

If yes, please describe: _____

If yes, how many days/week do you exercise? _____ days/week.

About how long do you exercise each times? _____

Could also add: Do you follow a special diet? Yes: No:

If yes, please describe: _____

TAD LACEY

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tad@laceymanagement.com 650-520-4802

EXPERIENCE**Healtheon Corporation****Professional Services/Process Improvement Manager**

Santa Clara, CA
1998-1999

- Supported the software deployment activities at six physician and PSO beta sites.
- Major responsibilities included: consultative healthcare expertise, business process flow analysis and process reengineering; workflow analysis and software workflow rule development; end user training and on-going technical and process support.
- Facilitated meetings and developed change management criteria, strategies and documents to ensure software acceptance by end users.
- Wrote and produced software training materials. Helped develop requirements for on-line help and software documentation.

Arthur Andersen—Business Consulting Practice
Senior Healthcare Consultant

Washington, DC
1995-1997

- Served as a management consultant responsible for leadership, project management, quantitative analysis, meeting facilitation and business development.
- Redesigned the Medicare ADR billing process and workflow for the behavioral health practice of a large urban medical center. Identified content to satisfy Medicare billing documentation requirements. Benchmarked current processes against baseline performance indicators; created future targets. Identified and corrected technical errors in electronic bill submission. Designed process reports for performance tracking and management decision support. Trained employees in new ADR billing process.
- Co-leader on a \$21 million Accounts Receivable (A/R) clean-up project for a major academic medical center which resulted in the collection of over \$13 million. Worked within the center's IDX computer system. Developed an Access® database used to identify and segment project priorities. Created Excel® spreadsheet models to quantify financial impact of different collection strategies upon overall A/R. Made presentations to senior management with recommendations for strategic information systems use and overall process improvements.
- Wrote the business plan for a physician group network expansion. Performed detailed strategic, financial, operational, market and competitor analyses. Created financial models used to analyze merger and acquisition opportunities for a hospital's MSO.
- Meeting facilitator and advisor in a reengineering project with targeted savings of \$55 million. Led project teams. Focus areas included support services, materials and change management. Developed employee reduction policies with senior management.
- Designed and wrote business development proposals and external marketing materials.

U.S. Department of Health and Human Services (DHHS)
Special Assistant to the Secretary for Health

Washington, DC
1994

- Speechwriter for the Secretary; prepared over 20 speeches per month. Acted as aide for Secretary while at speaking engagements. Researched and analyzed health care reform plans. Prepared Secretarial briefings; wrote news articles, press releases and statements on health policy and departmental programs for public dissemination.
- Project leader on DHHS project developing Internet capabilities to communicate health policy and to meet long term strategic goals. Helped develop strategic plan. Analyzed technological requirements and limitations; interfaced and coordinated workflow within eight DHHS agencies.
- Interfaced with other DHHS agencies, HCFA and Congressional office staff to research, develop and write health policy statements for press publication.

Palo Alto Medical Foundation
Consultant

Palo Alto, CA
1993-1994

- Wrote business and marketing plans for physician network expansion. Performed market research and internal operational and strategic analyses. Identified internal and competitor strategic competitive advantages, and operational factors affecting financial performance.
- Prepared financial models used to identify and quantitatively support alternative expansion scenarios.

The Gap, Inc.
Store Manager/Assistant Manager

San Francisco, CA
1990-1992

- Managed all the customer service, sales, operations and personnel functions of a \$2.9 million store. Managed and supervised three assistant managers and 25 employees. Trained two sales associates for promotion to manager.

EDUCATION

Walter A Haas School of Business
University of California, Berkeley
Master of Business Administration (MBA)

Berkeley, CA
May 1994

- Concentration: Marketing and Strategic Planning
- *Event Chairman*, MBA Challenge for Charity; *Member*, MBA Consulting and Marketing Club; *Member*, MBA Marketing Club

School of Public Health
University of California, Berkeley
Master of Public Health (MPH)

Berkeley, CA
May 1995

- Concentration: Health Services Management
- *President*, American College of Healthcare Executives Student Chapter

University of California, Los Angeles (UCLA)
Bachelor of Arts in History

Los Angeles, CA
- June 1989

FINE NEEDLE ASPIRATION BIOPSY OF PALPABLE BREAST MASSES:
TRAINING IN SAMPLING TECHNIQUE IMPROVES DIAGNOSTIC ACCURACY

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Running head: IMPROVING DIAGNOSTIC ACCURACY OF FINE NEEDLE ASPIRATION BIOPSY

Word Count (text only): 4056

Acknowledgements:

This work was supported by NCI grants P01 CA44768 and P50 CA58207. Cancer incidence data used in this publication have been collected by the Northern California Cancer Center under contract N01-CN-65107 with the Division of Cancer Prevention and Control, National Cancer Institute, National Institutes of Health, Department of Health and Human Services, and under subcontract 0501-8701-S1132 with the California Public Health Foundation. We thank Elizabeth Tioupine for manuscript preparation and Stephen Ordway for editorial assistance.

ABSTRACT

Background Fine needle aspiration biopsy (FNAB) has been used with highly variable success as a diagnostic test for benign and malignant breast lesions. In this study, we examined the effects of training in the sampling technique and of caseload on the diagnostic accuracy of FNAB of palpable breast masses.

Methods We reviewed 1043 consecutive FNAB specimens of the breast obtained during one year (1992). Seven hundred twenty-nine FNABs were performed by formally trained physicians (at least 150 FNABs performed under supervision during fellowship training or the equivalent) who had done at least 100 FNABs during the year. Three hundred fourteen FNABs were performed by physicians without formal training who had done 43 or fewer FNABs during the year (median, two). All cases were reviewed microscopically and evaluated for the quality, amount, and type of material present, for diagnostic accuracy, and for the rate of surgical intervention. A minimum of two years' follow-up was obtained by matching all cases to the population-based Northern California Cancer Registry. FNAB specimens were correlated with histologic specimens when available.

Results Using FNAB, the trained physicians missed only 2 percent of cancers, whereas the untrained physicians missed 25 percent. Only 8 percent of the patients with benign lesions seen by the trained physicians went on to surgery, whereas 30 percent of those seen by untrained physicians did so. Specimens obtained by trained physicians were of much higher quality and significantly less likely to be nondiagnostic.

Conclusion When performed by physicians who are well trained in the technique, FNAB is a highly accurate, cost-effective diagnostic method that carries minimal morbidity and could replace a large number of surgical biopsies. When performed by physicians without proper training, it is virtually useless, adds cost, and is potentially harmful. We suggest that training opportunities be set up and the procedure concentrated in well-trained hands to provide high-quality FNAB to the maximum number of patients.

INTRODUCTION

The idea of using thin needles to sample lesional tissues is not new. As early as 1847, Khun used a needle to aspirate material for diagnosis of tumors.¹ In 1904, Grieg and Gray detected trypanosomal organisms in needle aspiration biopsy material from the lymph nodes of patients with sleeping sickness.² The first larger series of needle aspirations was reported in 1930 by Martin and Ellis,³ who described 65 needle aspiration diagnoses primarily of neoplastic disease in various body sites. Three years later, Stewart expanded that series to include the cytological findings in 2,500 tumors.⁴ These early studies used needles that were slightly larger than the ones used today, but otherwise the technique was essentially the same. Over the ensuing decades, fine needle aspiration biopsy (FNAB) was used on a limited basis in the United States and Europe.

Over the past twenty years, fine needle aspiration biopsy of many body sites (including the thyroid gland) has enjoyed increasing popularity in the United States. The breast is commonly sampled by this method, and many reports have been published on its use at this site. Giard and Herman's review of 29 such reports illustrates the wide spectrum of results obtained with this procedure.⁵ The sensitivity (ability to detect breast cancer) ranged from 65 percent to 98 percent, and the specificity (ability to rule out malignancy) ranged from 34 percent to 100 percent. Thus, at the high end of this spectrum, FNAB is a highly reliable, cost-effective test comparable to open biopsy.⁶ At the low end, however, FNAB is unreliable and misleading, often rendered as an extra step in a patient's work-up and followed by an open biopsy. In this situation, FNAB often adds cost because it is a redundant procedure.

Currently, there is a trend in the United States to abandon FNAB in favor of larger core needle biopsies, "microbiopsy systems," and traditional open biopsies. Often, ultrasound is used to guide biopsies, even when the lesion is clearly palpable, adding to the cost of patient care. This trend appears to reflect a perception that FNAB is not delivering accurate results. Many clinicians cite the inability of the pathologists to interpret the material, while many pathologists complain that the specimens they receive contain scanty and poorly preserved material. Some have concluded that FNAB inherently is not a good diagnostic tool.

Numerous studies have attempted to identify ways to improve the diagnostic accuracy of FNAB. Some studies have concluded that more experienced practitioners or those with larger caseloads produce fewer nondiagnostic specimens.⁷⁻¹⁰ None of these studies, however, defined or specifically assessed the effects of training in FNAB sampling technique. It may be that physicians who perform more FNABs are also more likely to have received extensive training in the technique. Thus, a larger caseload may not, by itself, explain why the specimens are better. One study showed that specific training and experience in the microscopic interpretation of FNAB specimens produce better results.¹¹ Other studies have looked at the impact of the number of needle passes used¹² and the importance of target size for obtaining a diagnostic specimen.¹³ Several studies have concluded that sampling error accounts for the majority of missed diagnoses.^{8, 14-17}

The goal of this study was to investigate the effect of training in the sampling technique and the effect of case load on the sensitivity and the specificity of FNAB in the diagnosis of benign and malignant breast lesions.

MATERIALS AND METHODS

We retrospectively reviewed 1043 consecutive FNAB specimens of palpable breast lesions from 927 patients. All specimens were collected between January 1 and December 31, 1992, in three San Francisco hospitals: UCSF Moffitt-Long, UCSF Mount Zion, and California Pacific Medical Center. The cases were identified by searching the computerized databases of the respective pathology departments. Charts were reviewed only when needed information could not be obtained from the cytology requisition forms, from the pathology, cytology, and mammography reports, or from the Northern California Cancer Registry Surveillance, Epidemiology, and End Results (SEER) database. The primary information obtained from the charts was tumor size and location (quadrant of the breast). Knowing the location of the tumor within the breast allowed us to

determine if a lump sampled by FNAB was in the same location as the subsequently removed tumor before we concluded that a FNAB had failed to detect the tumor.

Cases collected by physicians who were well trained in FNAB technique were compared with cases collected by physicians who had not had significant training in FNAB. The well-trained physicians had completed fellowship training or the equivalent, having performed at least 150 FNABs under the supervision of an experienced practitioner of the technique. The untrained physicians had read a description of the technique, attended a lecture, observed another physician perform the procedure a few times, or performed a small number of FNAB procedures (10 or fewer) under the supervision of an experienced practitioner. Information about the training status of all the physicians was collected, and the number of breast FNABs performed by each physician during 1992 was tabulated.

All reports and slides were pulled for review. The slides were reviewed and reinterpreted **by an experienced cytopathologist (B-M L)** without knowledge of the original diagnosis. The degree of epithelial cellularity and the presence of nonepithelial components were recorded. The degree of cellularity was defined as follows. When epithelial cells were present in most microscopic fields, the material was considered to be of abundant cellularity; when epithelial cells were easy to find but not present in most microscopic fields, the material was considered to be of moderate cellularity; and when it was necessary to search for epithelial cells, the material was considered to be of scant cellularity. These definitions are in accordance with the recommendations of a National Cancer Institute-sponsored conference on uniform approach to FNAB of the breast.¹⁸ The nonepithelial components present were for the most part fragments of adipose tissue and components of cyst fluid; a few cases of hematoma and fat necrosis were recorded. Significant artifacts affecting the evaluation of the specimens were noted.

Based on the material present on the slides and on the clinical information available in the original cytology request form, a judgment was made as to whether the material was diagnostic or not. For example, if a firm or moderately firm defined mass was described and the slide contained only scant epithelial cells and fragments of adipose tissue, the specimen was deemed nondiagnostic because the cytologic findings were inconsistent with the clinical finding. Similar cytologic material obtained from a soft, ill-defined thickening of the breast and judged to have a low likelihood of being malignant was considered consistent with the clinical finding and was deemed diagnostic.

To determine how many malignant tumors were missed by FNAB, we submitted all 877 cases without surgical follow-up and 77 of the 155 cases with surgical follow-up to the SEER database for matching with reported breast cancers. **The reason for not submitting 78 cases with known surgical outcomes to the SEER registry was the difficulty in obtaining all information required by the registry from one of the hospitals.** SEER is a population-based cancer registry administered by the Northern California Cancer Center which is designated by the California Department of Health Services to collect cancer incidence data. SEER covers all seven counties of the greater San Francisco Bay Area and is estimated to include 98 percent of all breast cancers diagnosed in the region. A minimum of two years' follow-up was available in all cases. The definition of cancer missed by FNAB in this study was a benign or nondiagnostic FNAB followed within two years by cancer in the same quadrant of the breast. Medical charts, pathology reports, and cytology requests and reports were used to correlate the sites of FNABs and subsequently reported cancers.

The statistical significance of differences in tumor size and patient age between patients seen by trained versus untrained physicians was determined by *t* test. The chi-square test was used to compare the sensitivity and frequency of cancer in the various diagnostic categories between trained and untrained physicians. Contingency-table analysis was used to compare the quality of samples obtained (determined by microscopic reinterpretation) and the accuracy of diagnosis (determined by case review and follow-up) by trained versus untrained physicians.

RESULTS

Study Population

There was no significant difference in patient age or tumor size between patients seen by trained physicians and those seen by untrained physicians. The mean age was 56.6 years (range, 33 to 88) in the trained group and 62.7 years (range, 37 to 91) in the untrained group. The mean tumor size was 2.9 cm (range, 0.9 to 10) in the trained group and 2.3 cm (range, 0.7 to 7.8) in the untrained group. In three cases from each group, tumor size could not be ascertained.

Trained Physicians

Seven hundred twenty-nine of the FNAB specimens were collected by seven physicians who were well trained in FNAB sampling technique and who performed at least 100 FNABs of various body sites, including breast, during the study period. Three had completed a formal fellowship in cytopathology lasting at least one year, and two had had extensive one-to-one training under the supervision of a physician experienced and proficient in the procedure. The cytopathology fellowship also provided extensive training in the microscopic interpretation of FNAB specimens. Two physicians were undergoing fellowship training and were supervised closely until they were judged able to operate independently. All seven performed at least 150 FNABs during their training. Early in training, all biopsies were done under direct supervision. Each biopsy specimen was checked microscopically for adequacy by quick stain before the patient was released. As they showed increased proficiency, trainees performed FNABs without direct supervision. However, if the material appeared too scant by quick stain or if technical difficulty was encountered, a senior colleague was immediately called in for consultation. Of the seven trained physicians, six were cytopathologists and one was a surgeon.

Untrained Physicians

Three hundred fourteen of the specimens were collected by 69 physicians who had not had significant training in FNAB sampling technique. These physicians performed a median of two FNABs during the year of investigation (range, 1 to 43). The three busiest physicians in this group were surgeons, who performed 28, 35, and 43 FNABs, respectively. There were 24 primary care physicians, 21 surgeons, 21 gynecologists, 2 pathologists, and 1 radiologist.

Quality of FNAB Specimens

The samples obtained by the trained physicians were of strikingly better quality than those obtained by the untrained physicians, regardless of whether the lesion was benign or malignant (Table 1). Generally, samples obtained by the trained physicians had much more abundant cellularity and were significantly less likely to be nondiagnostic. In addition, the trained physicians obtained a much higher percentage of samples that resulted in a definitive (and reliable) benign diagnosis (Table 2). Significantly, benign lesions sampled by the untrained physicians were almost four times more likely to be referred for surgical excision (30 percent vs. 8 percent).

Missed Cancers

Of 102 cancers included in the 1043 FNABs in this study (9.8 percent), 89 were recognized as atypical (suspicious for cancer) or diagnosed as cancer by FNAB (89 percent). Most notable is the striking difference in sensitivity for breast cancer: 98 percent for trained physicians versus 75 percent for untrained physicians. Eleven of the 13 missed cancers were missed because of sampling errors by the untrained physicians. Two cancers, one in each group, were missed because of erroneous microscopic interpretation. No cancer was missed because of sampling error by the trained physicians (Table 3). The true frequency of cancer, as determined by case review and follow-up, in the various original diagnostic categories is shown in Table 4.

Revised Diagnoses

The microscopic review resulted in 51 revised diagnoses. In two cases, the diagnosis was changed from benign to suspicious for cancer; in both cases, subsequent histologic examination showed carcinoma. In one of these cases, only a few atypical cells were seen. In the other, a moderate number of epithelial cells were collected from a cystic lesion; these cells were obscured by large numbers of inflammatory cells in an unusually darkly stained filter preparation.

The most common change of diagnosis, in 33 cases, was from benign to nondiagnostic. None of these 33 samples came from lesions containing carcinoma. In five cases, the diagnosis was changed from suspicious for cancer to definitive for cancer. Conversely, one case was changed from definitive for cancer to suspicious for cancer. All six cases showed carcinoma upon histologic examination. The remaining revisions of diagnoses were of lesser consequence. Notably, in 45 of 51 revised diagnoses, the epithelial component was either scant or absent. Of the 13 missed carcinomas, 6 were originally diagnosed as benign and 7 as nondiagnostic. Of the 6 specimens from cancers originally diagnosed as benign, 2 had moderately abundant material and 4 had scant epithelium. One of the two cases misinterpreted microscopically contained moderately abundant material and the other one scant material.

DISCUSSION

This study shows that physicians with formal training in FNAB sampling techniques achieve much better results than physicians without such training. Using FNAB, the trained physicians missed only 2 percent of malignant lesions, whereas untrained physicians missed 25 percent. Of the patients with benign lesions, only 8 percent who were seen by trained physicians went on to surgery, whereas 30 percent of those seen by untrained physicians did so. In addition, the specimens collected by the trained physicians were of much higher quality and were significantly less likely to be nondiagnostic. These findings suggest that formal training in FNAB sampling techniques has a major positive effect on the diagnostic accuracy of the procedure, a far greater effect, in fact, than other factors considered in previous reports.

The importance of adequate training is evident in other areas of medicine as well. Primary care physicians, for example, have a much higher rate of false-negative diagnosis of skin cancers than dermatologists.¹⁹ Jowell et al.²⁰ found that gastroenterology fellows could be considered competent in performing endoscopic retrograde cholangiography only after they had performed at least 180 procedures, a much greater number than previously recommended for training. In a study of variability in the interpretation of mammograms by radiologists, Elmore et al.²¹ found substantial variability in diagnostic accuracy in detecting breast cancer. Although impact of level of training or experience was not evaluated in this study, the authors concluded that improving diagnostic accuracy requires additional specialized education, better-defined diagnostic criteria, and examination of performance.

The effect of caseload on diagnostic accuracy in our study was less clear. The well-trained physicians performed at least 100 FNABs during the one-year study period, whereas the untrained physicians performed a median of two FNABs. However, the three busiest untrained physicians in the latter group, who performed between 28 and 43 procedures each, did not achieve a higher sensitivity for cancer than the other untrained physicians, who had smaller caseloads. Of the 15 cancers they encountered, these three physicians missed four (sensitivity, 74%), or 31% of the 13 cancers missed in the study. Thus, a slightly larger caseload alone does not appear to improve the diagnostic accuracy.

Factors Affecting the Accuracy of FNAB

Numerous studies have investigated ways to improve the diagnostic accuracy of FNAB. The factors evaluated include the number of samples collected,^{12,22} the size of the mass,¹³ the use of various sample preparation techniques,²³⁻²⁷ and the use of quick-stain procedures to assess the adequacy of the material collected.²⁸ One report on the impact of the number of samples implied

that diagnostic material would always be obtained if a mass were sampled enough times (approximately 10).¹² However, the data in that report are in agreement with our experience that the first sample provides the best chance for obtaining diagnostic material. Subsequent samples yield diminishing returns because of local bleeding, particularly in the case of small targets, and infinite sampling does not guarantee a diagnostic sample.

The study of the importance of the size of the mass concluded that targets smaller than 1 cm or larger than 4 cm are difficult to sample.¹³ One explanation for the difficulty in sampling large breast masses is that some of them are ill-defined lobular carcinomas. Such lesions are difficult to diagnose by FNAB because of the lack of a firm, well-defined area to sample, the admixture of benign components, the abundance of stromal tissue, and the presence of scant small tumor cells often lacking obvious malignant features. Various, usually laborious, techniques, such as routinely rinsing the needle for cell blocks or using other special sample preparations, have been suggested as means to improve yield.²³⁻²⁷ Others have suggested the use of a quick stain to determine if the material obtained is sufficient for diagnosis.²⁸

There are several reasons to use a quick stain at the time of sampling. First, it can show whether enough material has been collected for a subsequent definitive diagnosis. Second, it allows clearly malignant cells to be identified immediately, eliminating the need for additional samples; in the absence of malignant cells, at least two samples should be collected in most cases.¹⁸ Third, it provides in many cases an immediate preliminary diagnosis, and any material needed for special studies can be collected without delay (e.g., for culture of organisms in cases of inflammation). However, using a quick stain will not compensate for poor sampling technique, and obtaining several bad samples is unlikely to yield diagnostic information.

As is amply clear from the studies referenced above, none of the suggested remedies will improve the results of FNAB by more than a few marginal percent. One problem with FNAB is that it appears so easy to perform. However, unlike procedures such as venipuncture and spinal taps, the results of which are immediately obvious (the fluid comes pouring out when the procedure is properly performed), FNAB does not, in most cases, produce obvious confirmation that the specimen is adequate. Thus, good sampling technique is best reinforced by one-on-one training and microscopic examination of the sample. Even at the time of microscopic examination, judging whether a specimen is adequate and representative of the lesion sampled requires experience and knowledge of the clinical presentation of the mass.¹⁸

Because of its apparent simplicity, low cost, and low morbidity, FNAB is often used in a casual fashion. Our findings in this study demonstrate that such use of FNAB produces unreliable results that could seriously harm patients by not revealing the correct diagnosis. Failure to diagnose a tumor is potentially deadly and may expose the physician to liability for malpractice.²⁹ Also, extra costs are incurred by the need for additional redundant tests. Indeed, in our study, the untrained physicians referred almost four times more patients with benign lesions for surgery than the well-trained physicians. One could argue that core biopsies are only a little more expensive than FNAB. Because of their larger diameter, however, core biopsies tend to cause more local bleeding than FNAB. They are also less versatile in that they are less suitable than FNAB for targets in certain anatomical positions (e.g., close to the chest wall or adjacent to vital structures), small superficial targets, and small movable targets in the axillary area.

Studies comparing the accuracy of core biopsies and FNAB for palpable masses are few. One recent study by Ballo and Sneige³⁰ showed that FNAB has a significantly higher sensitivity than core biopsy. In that study, FNABs were collected by well-trained physicians in an FNAB clinic. There are many more studies comparing FNAB and core needle biopsy on nonpalpable lesion requiring guidance.³¹⁻³⁹ There the results vary widely. Generally when well-trained cytopathologists participated in the process, the sensitivity and specificity were similar for both procedures; however, when FNAB was carried out casually, the sensitivity of FNAB in particular was much lower. In one study of mammographically guided FNAB, retraining the physicians who collected the samples, more vigorous sampling, and intraprocedural evaluation of specimens for

adequacy of the material increased the diagnostic sensitivity for cancer from 73 percent to 92 percent.⁴⁰

When carried out by well-trained practitioners, FNAB is not only reliable as shown in this study, it is also highly cost-effective compared with alternative diagnostic procedures such as open biopsy. A number of studies have found substantial savings from avoiding open biopsies for benign lesions and being able to proceed to definitive surgery for cancer without an intermediate open biopsy.^{6,41-43} Thus, FNAB has significant advantages over other techniques, but only when it is properly performed. It is therefore in the best interest of high-quality, cost-effective patient care that practitioners be properly trained in its use.

Increasing the Diagnostic Accuracy of FNAB

In the United States, FNAB is performed primarily by physicians without formal training in sampling technique and with small caseloads, typically fewer than 40 cases per year. The specimens are then sent to a local or distant pathology laboratory for processing and interpretation. As noted above, the diagnostic accuracy thus obtained is highly variable. In Europe, including Scandinavia and France, however, where FNAB has been used extensively since the 1960s with excellent results,⁴⁴⁻⁴⁷ a different approach is usually employed. There the patient with a lump in the breast (or other superficial site) is referred for FNAB in a clinic staffed by cytopathologists specifically trained in both the collection and the interpretation of the sample. The volume of cases is typically high, and staff physicians typically perform an average of at least 50 FNABs per week. In addition, the same physician examines the patient, performs the biopsy, and examines the specimen microscopically, making sure the cytologic findings match the clinical presentation.

Several studies have found lower rates of false-negative diagnosis and/or nondiagnostic specimens when cytopathologists perform the sampling and interpret the specimens than when clinicians perform the sampling and send the specimens to a laboratory.^{8,15,16,44,48} Dixon et al.⁴⁹ showed that the sensitivity of FNAB for breast cancer increased from 59 to 99 percent when the samples were collected by a single experienced physician instead of by many physicians with limited experience.

The results of the present study and the success of the Scandinavian approach to FNAB suggest that the accuracy of the procedure could be significantly improved by formal training in the sampling technique combined with expert interpretation of the samples. In the hands of our well-trained physicians, FNAB had a sensitivity similar to that of frozen section⁵⁰⁻⁵⁶ and approaching that of open biopsy.^{6,57} Using FNAB in conjunction with clinical examination and mammography further improves the sensitivity significantly.⁵⁸⁻⁶³ No palpable mass is too small or too large to be sampled, and rarely are more than two or three samples from a given mass necessary. A quick stain will enable the physician to collect only one sample in most malignant lesions.

A solution to the problem of substandard FNAB results is to train a limited number of physicians well enough so that they can achieve a reliable diagnosis in over 95% of cases with a minimal false-negative rate, 2 to 5 percent depending on the site. In our experience, such training entails sampling 150 to 200 lesions under supervision. A substantial proportion of the cases must be technically challenging for the trainee to develop advanced skills. Such training can be easily organized if a clinic with a large caseload and well-trained physicians is available. On the other hand, it is almost impossible to become well trained if the teachers are physicians who themselves had no significant training and who perform only the occasional FNAB.

It makes good sense to train a given physician to perform FNAB on all superficial body sites since the technique is essentially the same regardless of site. In this fashion, most medical communities can have at least one or two physicians who are able to serve patients in the area. In our opinion, it is not productive to implement "training programs" where residents perform 10 to 20 FNABs during their residency, as some have suggested. Such training will give the trainees the false impression that they have been adequately trained when in fact all they have received is an introduction. Many will use the technique briefly, be discouraged, and turn to other diagnostic

methods that are more expensive or have a higher morbidity or both. Because most surgeons and primary care physicians see relatively few patients who would benefit from FNAB, training all these physicians would not be cost effective and would be logistically difficult if not impossible.

In summary, when performed by appropriately trained physicians, FNAB is a cost-effective, highly accurate diagnostic technique with very low morbidity. When performed by physicians without proper training, it is virtually useless, adds cost, and is potentially harmful. We suggest that training opportunities be expanded and the procedure concentrated in fewer, well-trained hands in order to provide high-quality FNAB to the maximum number of patients.

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TABLE 1. QUALITY OF THE FNAB SAMPLES DETERMINED BY MICROSCOPIC REVIEW.*

SAMPLING QUALITY [†]	TRAINED PHYSICIANS	UNTRAINED PHYSICIANS
Benign masses		
Abundant	238 (35.3%)	20 (7.5%)
Moderate	110 (16.3%)	36 (13.5%)
Scant	185 (27.4%)	84 (31.6%)
Nondiagnostic	16 (2.4%)	109 (41.0%)
Cysts	126 (18.7%)	17 (6.4%)
Total	675	266
Malignant tumors		
Abundant	48 (88.9%)	9 (18.8%)
Moderate	3 (5.6%)	17 (35.4%)
Scant	3 (5.5%)	15 (31.2%)
Nondiagnostic	0 (0%)	7 (14.6%)
Total	54	48

* Quality of the samples is based on review of the material for this study. Six samples of benign masses were unavailable for microscopic review; information in these cases was extracted from the reports.

[†]The quality of samples obtained by trained physicians was significantly higher than that of samples obtained by untrained physicians ($P=0.0001$ by contingency table analysis).

TABLE 2. FNAB DIAGNOSIS DETERMINED BY MICROSCOPIC REINTERPRETATION.

FNAB DIAGNOSIS	TRAINED PHYSICIANS	UNTRAINED PHYSICIANS
Benign masses [‡]		
Benign*	487 (72.1%)	103 (38.7%)
Malignant	0 (0%)	0 (0%)
Atypical	46 (6.8%)	13 (4.9%)
Nondiagnostic [†]	16 (2.4%)	134 (50.4%)
Benign cysts	126 (18.7%)	16 (6.0%)
Total	675	266
Malignant tumors [§]		
Benign	0 (0%)	4 (8.3%)
Malignant	42 (78%)	24 (50%)
Atypical	12 (22%)	13 (27.1%)
Nondiagnostic	0 (0%)	7 (14.6%)
Total	54	48

*Includes varying degrees of epithelial cellularity and some cases of fat only, dependent on the clinical findings.

[†]Includes specimens that did not explain the clinical findings; most had scant or no epithelial component.

[†]P=0.0001 comparing diagnosis of benign masses by trained versus untrained physicians (contingency table analysis).

[§]P=0.0013 comparing diagnosis of malignant tumors by trained versus untrained physicians (contingency table analysis).

TABLE 3. ORIGINAL FNAB DIAGNOSIS OF 102 BREAST CANCERS INCLUDED IN THE STUDY.

PHYSICIAN	CANCER OR ATYPICAL BY FNAB	FALSE-NEGATIVE OR NONDIAGNOSTIC	SENSITIVITY	SAMPLING ERROR	INTERPRETIVE ERROR
Trained	53	1	98%*	0	1
Untrained	36	12	75%	11	1

*P=0.0014 versus untrained physicians (chi-square test).

TABLE 4. TRUE FREQUENCY OF CANCER IN THE VARIOUS ORIGINAL FNAB DIAGNOSTIC CATEGORIES.

FNAB DIAGNOSIS	TRAINED PHYSICIANS	UNTRAINED PHYSICIANS	STATISTICAL COMPARISONS*
Benign (includes cysts)	1/617 (0.2%)	5/154 (3.2%)	P=0.0007
Malignant	42/42 (100%)	20/20 (100%)	NS
Atypical	11/57 (19.3%)	16/29 (55%)	P=0.0124
Nondiagnostic	0/13 (0%)	7/111 (6.3%)	NS

*The chi-square test was used to compare the diagnostic accuracy of FNAB performed by trained versus untrained physicians.

NS, not significant.

SYM 19A COUPLES COPING AND ADHERENCE TO PRESCRIBED LIFESTYLE BEHAVIORS FOLLOWING MYOCARDIAL INFARCTION

Hoffman, Deborah, Yale University Medical School, Department of Psychology

Non-adherence to prescribed self care behaviors following myocardial infarction (MI) is a serious and chronic problem. This study examines the association between marital interaction measures and adherence to post-MI prescriptions in couples an average of six years post-MI.

Male patients and their spouses (N=168, 90% Caucasian) from an outpatient cardiology practice independently completed a measure of the patients' adherence to post-MI prescriptions (a revised version of the Medical Outcomes Study Condition-Specific Recommendations Questionnaire). The adherence measure was independently confirmed by the patient's physician. Couples interactional style measures included the Relationship Focused Coping Scales (Active Engagement and Protective Buffering) and other measures from the Michigan Family Heart Questionnaire. Anger management and control were evaluated via the State-Trait Anger Expression Inventory (STAXI).

Regression analyses showed that patients' use of Active Engagement was significantly and positively associated with adherence in general, as well as with practice of specific prescribed heart-care behaviors, including stress reduction, relaxation, healthy diet and taking prescribed medication (all $p < .05$). Adherence was also positively associated with patient anger control and negatively associated with patient Anger-In and Anger-Out (all $p < .01$).

Unexpectedly, spouse Protective Buffering showed significant bidirectional relationships with the practice of specific prescribed heart-care behaviors. Spouse Protective Buffering was significantly positively correlated with patient stress reduction ($p < .05$) but negatively associated with reports of patient regular exercise, low salt diet and weight loss diet (all $p < .01$).

The findings show that the relationship between couples' interaction style and post-MI adherence is complex. Adherence represents a variety of recovery and health maintenance tasks managed between a couple and within the family. An interactional style of hiding concerns and worries (Protective Buffering) may diminish stress but also fail to encourage other important health behaviors. Taken together with other recent findings on couple anger expression style, these findings suggest that couple anger style, expression of criticism and task allocation of adherence tasks between the couple are fruitful areas for post-MI intervention.

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SYM 19B

FOR RICHER OR POORER, IN SICKNESS AND IN HEALTH: DISABILITY AND MARRIAGE

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This presentation will discuss a model for viewing couples with disabilities. The able-bodied and person-with-a-disability partnership is seen as a cross-cultural relationship. Thus issues of culture, identity, minority status, stigma, and discrimination are critical for understanding such relationships.

Research on key characteristics that influence marriages of people with disabilities will be summarized. These couples vary enormously, according to characteristics of the disability (e.g., stability, degree of impairment, whether cognitive or personality changes occur), of the relationship (e.g., length and strength, age of partners), and of the supportive environment (e.g., extended family, availability of respite care, financial resources). Other factors include the timing of disability onset, the ages and life stage of the couple, the number and ages of children, other minority statuses (e.g., sexual orientation and ethnicity), and the gender of each partner.

There will be a particular focus on the distinction between "pre-injury marriages" and "post-injury marriages." The scant research on this topic will be summarized. When a partnership that forms between two able-bodied people is joined by a disability ("pre-injury marriage"), clinical issues are different from those in which a partnership is formed between an able-bodied person and one who already has a disability, or between two people with disabilities ("post-injury marriages").

The model to be presented argues for integration of the disability into the individual and couple identities. The key differences between this view, and a medical model that views disability as external and foreign to the couple, will be outlined. The model also critiques several prevailing notions of the coping-as-buffer literature. Implications for couples interventions will be summarized.

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SYM 19C

DYADIC COPING AND QUALITY OF LIFE IN WOMEN WITH BREAST CANCER AND THEIR SPOUSES

Levine, Ellen G.; Carey, Michael; & Zelman, Diane C.

For married women with breast cancer, coping as a spousal unit may more strongly predict overall patient adjustment than coping as reported only by the patient. In this study, the relationship between individual and dyadic coping style, marital adjustment, patient mood disturbance and quality of life was examined in women with breast cancer and their husbands (N=80). Couples were interviewed and independently completed measures of cancer coping style (Mini-Mental Adjustment to Cancer Scale), emotional distress (Profile of Mood States) and physical and general quality of life (QOL, Functional Assessment of Cancer-Breast). The sample was 90% Caucasian and primarily middle class. All women had received diagnoses of Stage I or Stage II breast cancer within the last two years.

Patient coping styles (Anxious Preoccupation, Helpless/Hopeless and Fighting Spirit) were strongly associated with patient outcome. Multiple regression analyses show significant relationships between coping style, QOL, and mood disturbance ($p < .001$). Spouse coping styles were also significantly associated with patient outcome. Multiple regression analyses found significant association between Spouse Helpless/Hopeless and Cognitive Avoidance coping style and patient QOL ($p < .01$).

The Dyadic Anxious Preoccupation coping style accounted for 42% of the variance in patient well being ($p < .001$), and Dyadic Helpless/Hopeless coping style accounted for 17% of the variance in Physical QOL ($p < .01$). Patient Total QOL scores were best predicted by Dyadic Helpless/Hopeless and Anxious Preoccupation scores, with over 40% of the variance in total QOL accounted for by these variables (both $p < .001$).

Overall, this study found that dyadic coping style, and dyadic adjustment in general, accounts for patient psychological adjustment over and above that accounted for by patient coping. Psychosocial intervention aimed at increasing quality of life in women with breast cancer should incorporate couples-directed and spouse directed approaches. A number of treatment possibilities are discussed.

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SYM 20

DEVELOPING CULTURALLY SENSITIVE INTERVENTIONS: ENHANCING RECRUITMENT, EFFECTIVENESS, AND RETENTION

Chair: Jasjit S. Ahluwalia, MD, MPH, MS; Participants: Ken Resnicow, PhD, Emory University; Cheryl Gibson, PhD, University of Kansas; Kari Jo Harris, PhD, University of Kansas; Kimber P. Richter, PhD; Discussant: C. Tracy Orleans, PhD, Robert Wood Johnson Foundation

Presenters will provide a theoretical framework for developing culturally sensitive interventions and three examples of how interventions were developed for smoking cessation among African Americans. Examples will draw upon work conducted in urban settings in Kansas, Missouri, and Georgia including a public housing developments, a community health center, and a hospital-based clinic. We will illustrate of how to develop, implement, and evaluate culturally sensitive interventions by discussing projects that are in various stages of development. Researchers will illustrate methods others can use to increase the cultural sensitivity of interventions, including focus groups, pilot testing, advisory boards, site advisors, and strategically locating intervention sites. The discussant will reflect upon and critique the ideas and methods presented. The session will include time for audience questions and discussion.

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SYM 18C MATERNAL ENVIRONMENT INFLUENCES EVOKED FETAL HEART RATE RESPONSES IN HUMAN PREGNANCY*

Pathik D Wadhwa MD PhD (Presenter), Helena Trusczynska PhD, University of Kentucky; Thomas J Garite MD, Manuel Porto MD, & Curt A Sandman PhD, University of California, Irvine.

Previous studies by our group have reported maternal environment during pregnancy exerts a significant influence on infant birth outcomes (length of gestation, birthweight), and that this influence is mediated, in part, by the maternal-placental neuroendocrine axis (Wadhwa et al, 1993, 1996, 1997, 1998). The direct influence of maternal factors on the developing fetus is, however, poorly understood. We performed fetal assessments in a sample of 156 mother-fetus pairs at 31-33 weeks gestation, including: a) fetal biometry and biophysical profile (BPP) using obstetric ultrasound; b) umbilical flow velocimetry using doppler energy; and c) an experimental paradigm to quantify fetal heart rate (FHR) reactivity to a series of ex-utero vibro-acoustic stimuli. Maternal assessments included: a) structured interviews and questionnaires to assess psychosocial and behavioral constructs, b) maternal plasma samples for bioassays of stress hormones (CRH, ACTH, BE, cortisol), and c) medical records to abstract and quantify obstetric risk. To date, results indicate: (a) Significant FHR increase in response to the first few vibroacoustic stimuli with a response decrement to subsequent stimuli, indicating habituation. A two-parameter growth curve (power) model to assess habituation rate accounted for approximately 70% of the variance in FHR response. (b) Baseline FHR and characteristics of the challenge protocol such as inter-trial interval significantly influenced the magnitude of FHR responses; and (c) Maternal medical conditions, fetal sex, umbilical blood flow, placental CRH, and maternal psychosocial stress significantly influenced the pattern of FHR responses. The implications of these findings, which support a role for the prenatal environment in modulating fetal behavior, are discussed within the context of an epigenetic framework for intrauterine development. (*Supported, in part, by NIH grants R29 HD-33506, R01 HD-28413 and P30 HD-28202)

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SYM 18D TYPE OF MATERNAL STRESS INFLUENCES PATTERN OF FETAL GROWTH*

CJ Hobel MD (Presenter), S Gupta MD, Cedars-Sinai Medical Center; S Roesch PhD, C Dunkel-Schetter PhD, University of California, Los Angeles

Maternal stress has been associated with decreased fetal growth. This study examined the effect of type of maternal stress on the pattern of decreased fetal growth. 513 women were administered a stressful life events checklist (objective measure) and a perceived stress scale (subjective measure) at three different gestational ages (GA): T1 (18-20), T2 (28-30), T3 (35-36 weeks). Fetal growth was assessed using ultrasound biometry at each of the intervals. Fetuses were grouped into 3 growth profiles based on the measurements at each time interval: (a) decreased symmetric growth: <40th percentile on all fetal growth parameters (biparietal diameter (BPD), head circumference (HC), femur length (FL), abdominal circumference (AC)); (b) decreased asymmetric growth: <40th percentile for AC but >50th percentile for others; and (c) normal growth. Mean maternal stress differences as a function of fetal growth profile were examined. Significant differences in stress levels as a function of fetal growth profile were evident ($p < 0.05$). Women with both types of decreased fetal growth had significantly higher stress than normals. Women with decreased symmetric fetal growth experienced more perceived stress than normals at T1 ($M = 2.54$ vs. 2.41). They also reported more stressful ruminations about stressful life events than normals ($M = 2.97$ vs. 2.72). Both perceived stress and stressful rumination were a measure of chronicity of stress; the stressful rumination represented repetitive reflections of the perceived stress and the stressful life events. In contrast, women with decreased asymmetric fetal growth had more stressful life events at T1 ($M = 3.47$ vs. 2.04) and T2 ($M = 2.10$ vs. 1.43) than normals. These represented acute events in their lives. They also had less rumination about them. In conclusion, maternal stress was associated with decreased fetal growth. The chronicity of stress present prior to and/or during early pregnancy resulted in decreased symmetric fetal growth of all parameters at mid gestation (T1). Acute stress (stressful life event) during pregnancy caused decreased asymmetric fetal growth (<40th percentile for AC also identified at mid gestation (T1).

(*Supported, in part, by NIH grant R01 HD-29553)

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SYM 18E CEREBRAL BLOOD FLOW VELOCITY IN THE FETUS PREDICTS NEUROBEHAVIORAL ORGANIZATION IN THE NEWBORN*

Eugene K Emory PhD (Presenter); Kim A Bard PhD; Marlyne Israelian MA; & Denise Raynor MD; Emory University.

The purpose of this study was to determine if fetal measures of neurobehavioral integrity were predictive of newborn neurobehavioral organization. Fetal cerebral blood flow velocity (f-cbvf) was measured in the right and left middle cerebral arteries (MCA) using color doppler energy (CDE) in 45 fetuses that varied in gestational age (GA). Since f-cbvf increases with GA, the hypothesis was that total f-cbvf might serve as an index for neurobehavioral maturity. The second hypothesis was that degree of asymmetry (difference in f-cbvf between the left and the right MCA) would provide additional information on neurobehavioral integrity. Neurobehavioral organization was assessed when these subjects were 30-day-old infants with the Neonatal Behavioral Assessment Scale (NBAS). The following cluster scores were obtained: Orientation; Motor muscle; Range of state; State Regulation; Autonomic Nervous System (ANS) Stability; and Abnormal Reflexes. Infants varied in age, ethnic background and sex. Planned hierarchical multiple regressions were used to determine the unique contribution of background variables (ethnicity and sex entered together in the first step) and f-cbvf (total f-cbvf entered second and degree of asymmetry entered third) in the prediction of NBAS cluster scores. Total velocity accounted for a significant amount of unique variance in two clusters: Regulation and Motor. Asymmetry changed with GA, and the degree of asymmetry, after controlling for ethnicity, sex, and total f-cbvf, accounted for a significant amount of unique variance in three clusters: Orientation, Abnormal Reflexes and Range of State. We conclude that, in healthy fetuses, total cerebral blood flow velocity may be useful as a measure of neurobehavioral integrity and that degree of asymmetry between the right and left MCA may add important additional information. The fetus and the newborn infant are dynamic systems, however, these measures of neurobehavioral integrity in the fetus contribute significantly to the prediction of neurobehavioral organization in the newborn.

(*Supported, in part, by NIH grant R01 HD-28382)

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SYM 19

FAMILY INTERACTION MODELS OF COPING IN CHRONIC ILLNESS: FROM RESEARCH TO INTERVENTION

Zelman, Diane C., CSPP-Alameda; Levine, Ellen G., California Pacific Medical Center; Hoffman, Deborah; Yale University School of Medicine; Olkin, Rhoda, California School of Professional Psychology - Alameda & Carey, Michael, Boston University Medical Center

This symposium presents research and theory on the use of family interaction models in the evaluation of family coping in illness, with an emphasis on moving from research data to intervention. In a couples interaction model, the patient and partner or caregiver are seen as a collective unit living and coping with illness, disability and treatment.

The family interaction model builds on and extends the prevailing social support model. The social support model primarily views the patient as recipient of support, and a partner or caregiver as a source of support. Research using the social support model typically considers the benefit of support for the patient and the liabilities of caregiving for the partner, and views the partner as either facilitator or impediment to the patient's coping. In contrast, viewing family interaction during illness as a mediator of quality of life is one way to bridge the gap between behavioral social support research and intervention. By specifying the interactional forces that maintain the family vitality and agency in the face of illness, new intervention possibilities arise.

Each of the three research presentations will discuss one perspective on the association between couple/family interaction and outcome. The first presentation will focus on dyadic measures of coping and and their relationship to quality of life in breast cancer. Next, adherence in couples post-myocardial infarction will be viewed from the couple perspective, with a presentation of research on the relationship between interaction style, anger management and adherence. The final presentation will discuss a minority model of couples with disabilities, summarizing key variables in outcome and contrasting pre- and post-injury marriages. Presenters will translate findings into interventions that maintain the family or couple as focus.

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Psycho-Oncology (in press)

**Exploring the Relationships among Spiritual Well-Being,
Quality of Life, and Psychological Adjustment
In Women with Breast Cancer**

Short Title: Spiritual Well-Being, Quality of Life, and Adjustment In Women with Breast Cancer

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Breast Cancer Personal Support and Lifestyle Intervention Trial

Breast Care Center of University of California, San Francisco

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This study was supported by a generous grant from the U.S. Department of Defense, Grant No.

DAMD17-96-1-6260.

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ACKNOWLEDGMENTS

The authors would like to thank the following people for their involvement and support in this project: Rosalind Benedet, RN, NP, Alison Brady, B.A., Jnani Chapman, RN, Janelle Eckhardt, Ph.D., RN, Deborah Hamolsky, RN, Sylvine Jerome, M.D., Carol Kronenwetter, Ph.D., Diane Neighbor, DTR, Cindy Perlis, M.A., Megan Rundel, B.A., Brook Stone, LCSW, Ragini Vykunta, MBBS, and Laura Esserman, M.D., MBA.

SUMMARY

This study examined the relationships among spiritual well-being, quality of life, and psychological adjustment in 142 women diagnosed with breast cancer who were participating in a larger study designed to compare the efficacy of two psychosocial support programs. Participants were given a set of questionnaires that measured spiritual well-being, quality of life, and adjustment to cancer. Results revealed a positive correlation between spiritual well-being and quality of life, as well as significant correlations between spiritual well-being and specific adjustment styles (e.g., fighting spirit). There was also a negative correlation between quality of life and use of a helpless/hopeless adjustment style, and a positive correlation between quality of life and fatalism. In addition, a combination of demographic variables, spiritual well-being and all five adjustment to cancer styles explained 38% of the variance in quality of life. These findings suggest that spiritual well-being is strongly associated with quality of life and psychological adjustment in women with breast cancer and should thus be considered as part of one's overall treatment plan.

INTRODUCTION

The scientific literature strongly supports the notion that religious commitment can enhance one's health. In a review of over 200 studies, positive relationships were documented between religious commitment and physical and functional status, reduced extent of psychopathology, greater emotional well-being, improved coping, and strengthened social support (Matthews et al., 1993, 1995). Overall, these studies show that religious/spiritual beliefs typically play a positive role in adjustment and greater health (Fitchett, 1996; Larson & Milano, 1995; Matthews, 1997).

Spirituality has been defined by Ross (1995) in terms of three primary areas: meaning and purpose, the will to live, and belief and faith in self, others, and God. It may be that spirituality influences recovery from illness through a deeper understanding of life's meaning or purpose, or an enhanced will to live. This study is the first of a series of studies hoping to further elucidate the ways in which spirituality may influence the healing process and aid clinicians in recognizing the interconnections between mind, body, and spirit.

Spiritual Well-Being (SPWB)

While studies vary in the particular focus they take when addressing concepts such as spiritual well-being (SPWB) and spirituality, SPWB has been defined as incorporating aspects of 1) faith or spiritual beliefs, 2) meaning and purpose, and 3) peace/harmony. SPWB was initially conceptualized as the feeling that one has a relationship with God, oneself, one's community, and the environment, and that these relationships create a sense of wholeness and peace (National Interfaith Coalition on Aging, 1975). It is viewed as a multidimensional construct that

incorporates both existential and religious dimensions (Ellison, 1983). The existential aspect has been operationalized as the extent to which one has a sense of purpose and meaning in life, while the religious aspect focuses more on a sense of relationship with a God or Higher Power (Mickley, Soeken, & Belcher, 1992). This definition of SPWB provides a framework from which to understand both the existential "spirit" realm and the religious "practical" realm of a patient's overall spiritual well-being.

SPWB has been associated with several indicators of well-being, including self-esteem, assertiveness, and meaning/purpose in life (Koenig, 1997; Mickley et al., 1992). Additionally, improved SPWB in cancer patients has been shown to correspond with lower levels of anxiety (Kaczorowski, 1989), good health habits (Kurtz, 1995), hope (Mickley et al., 1992), and higher life satisfaction (Yates, 1981). What is not as clear, however, is the impact of a patient's SPWB on other aspects of her/his well-being, including functional, emotional, physical, social/family well-being, and overall quality of life. Furthermore, the relationship between SPWB and psychological adjustment to cancer has received virtually no attention in the scientific literature.

Psychological Adjustment

Psychological adjustment is often noted as an important construct in the psychosocial oncology literature. While a patient's mental adjustment to cancer may be viewed as an individual process, it has also been defined in terms of categories of adjustment styles when studied in patients with a variety of types of cancers. Two key components of mental adjustment to cancer are: 1) appraisal, or the perception of the implications of cancer, and 2) the resulting reaction, including thoughts and actions to minimize the threat of cancer (Greer & Watson, 1987).

Research by Moorey and Greer (1989) has led them to summarize the variety of individual reactions one might have to a cancer diagnosis into five survival schema: Fighting Spirit, Cognitive Avoidance (Denial), Fatalism, Helplessness/Hopelessness, and Anxious Preoccupation.

A patient's psychological response to cancer, measured three months post-operatively, has been shown to be predictive of disease-free survival. More specifically, women with breast cancer who exhibited Denial or a Fighting Spirit (FS) showed higher rates of disease-free survival at five and ten year follow-ups than women who showed a Helpless/Hopeless (HH) or Stoic Acceptance (Fatalistic) response to cancer (Greer, Morris, & Pettingale, 1979; Pettingale et al., 1985). While many other studies have examined the relationships between different styles of mental adjustment to cancer and other related variables, only recently have researchers begun to explore connections between psychological adjustment styles and SPWB.

Rationale for Present Study

While the relationships among SPWB, QOL, and psychological adjustment for people with cancer have not been studied together, researchers have examined different combinations of these variables. Fitchett et al. (1996) conducted a study which demonstrated that faith and a sense of purpose and meaning in life were strongly associated with higher QOL for persons with cancer and HIV. Similarly, Cohen et al. (1996) found that the existential domain of SPWB was an important predictor of overall QOL for people with various stages of cancer. Riley et al. (1998) reported that among persons with chronic illnesses, the "non-spiritual" group reported lower levels of QOL and life satisfaction compared with the "existential" or "religious" groups. SPWB has also been shown to be independently related to QOL, even when controlling for the influence

of mood, emotional well-being, and social desirability (Brady, Peterman, Fitchett, Mo, & Cella, in press).

While these studies have begun to explore some of the connections between these variables, few conclusions can be drawn. This is primarily due to the fact that the few studies that have been conducted in this area have used different measures of religion and spirituality, making comparisons between these studies difficult. QOL has been studied in relation to variables such as social support, coping, psychological adjustment and health status, yet few studies have directly linked QOL with SPWB (Cohen et al., 1996; Fitchett et al., 1996; Riley et al., 1998). Additionally, existing studies have not examined how different types of psychological adjustment relate to SPWB, used validated measures of SPWB, or studied these constructs together specifically in women with breast cancer, as opposed to cancers in general or other chronic illnesses.

The present study examined the constructs of SPWB, QOL, and psychological adjustment in women with breast cancer as they entered a 12-week psychosocial program that focused on issues of social support and lifestyle change. We hypothesized that there would be a positive correlation between SPWB and QOL. We also hypothesized that SPWB would be negatively correlated with certain psychological adjustment styles, such as Helpless/Hopeless or Anxious Preoccupation, but positively correlated with Fighting Spirit. Furthermore, we predicted that SPWB would be positively associated with QOL, even after controlling for psychological adjustment.

METHODS

Participants

The sample consisted of 142 women diagnosed with invasive breast cancer within the last 18 months, or women with a recurrence or metastatic disease. Exclusion criterion included Ductal Carcinoma In Situ/Lobular Carcinoma In Situ, history of cancer other than a reproductive cancer, and any concurrent life-threatening illness. In order to participate in the study the women had to be fluent in English and able to fill out the questionnaires. Participants were part of a larger grant funded project that compared a standard support group with a holistically oriented support program for women with breast cancer. Recruitment was conducted through local physician's offices, hospitals, and public service announcements. The majority of the sample was Caucasian (84%) and mean time since diagnosis was 14 months. Their mean age was 49 years, ranging from 26 to 78 years old. Fifty-two percent were married/partnered, and 55% had done some post-graduate work. An additional question was asked of each participant: "Do you have an active religious practice?" with the definition of "active religious practice" determined by the participant. Only 35% reported having an active religious practice.

INSERT TABLES 1 & 2 HERE

Measures

The participants completed a battery of questionnaires including an extensive informed consent, a demographic questionnaire, a medical data information sheet, and measures of quality of life, spiritual well-being, spirituality, and psychological adjustment.

The Functional Assessment of Chronic Illness Therapy-Breast (FACIT-B, Cella, 1997) is a quality of life measure that focuses on issues of managing a chronic illness. It is self-administered and ranked on a five point Likert scale. The FACIT-B is comprised of the FACIT-G and nine additional items specifically related to breast cancer. The FACIT-G is the 27-item general version of the FACIT scale that measures four areas of quality of life: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, and Functional Well-Being. The nine breast cancer-specific items include questions related to appearance, sexuality, treatment side effects, and stress/illness. The FACIT-B has good reliability and validity (Cella, 1997). It was validated on a sample of 295 breast cancer patients who were part of a large three-year validation study. Internal consistencies (Cronbach's alpha) on the subscales range from 0.63 to 0.90 (Brady et al., 1997). In addition, the FACIT-G was validated on a sample of 630 patients and also has sound psychometric properties, including concurrent and construct validity, an internal consistency rating of .89, and test-retest reliability coefficients ranging from .82 to .92 (Cella, 1997).

This study also used the 12-item Spiritual Well-Being (SPWB) scale of the FACIT, the FACIT-Sp (Cella, 1997). This scale differs from other measures of spirituality primarily in its focus on the existential and religious aspects of spirituality. It has two subscales including meaning/peace and faith. Items cover issues such as: having a reason to live, finding purpose or meaning in one's life, the ability to find comfort within, finding strength or comfort in one's faith or spiritual beliefs, and the effect the illness has on one's faith. The internal consistency for this measure was .87 (Cella, 1997) and further validity and reliability testing is underway (Brady et al., in press). While this scale includes two subscales, only the overall spiritual well-being score

was examined in the present study in order to focus more closely on the relationships among overall SPWB, QOL, and psychological adjustment.

The Mini-Mental Adjustment to Cancer (Watson et al., 1994), is the shorter version of the MAC scale (Watson et al., 1988), and measures one's attitude toward dealing with cancer. Specifically, it assesses the psychological adjustment styles of Fighting Spirit (FS), Fatalism (FT), Helpless/Hopeless (HH), Anxious Preoccupation (AP), and Cognitive Avoidance (CA). The 29 items are ranked on a four-point Likert scale ranging from (1) Definitely does not apply to me, to (4) Definitely applies to me. Higher scores on these subscales represent higher endorsement of the attitude associated with the particular sub-scale. The MAC has good psychometric properties, and has been validated on samples of cancer patients from England (Watson et al., 1991), the United States (Schwartz et al., 1992), and Spain (Ferrero et al., 1994). Internal consistency is sound, and reliability for the subscales range from .65 to .84 (Watson et al., 1988). Validation of the Mini-MAC is currently underway, and preliminary analyses show that the scale has internal consistencies ranging from .62 (FT) to .85 (HH) (Levine, Fitzpatrick, Eckhardt, Cotton, & Targ, 1999).

The Principles of Living Survey (Thoresen, Bowman, Koopman, Yang, Dubs, & Spiegel, 1995) is a 16-item measure of religious and spiritual beliefs. It includes three subscales: spiritual practices, spiritual growth, and embracing life's fullness. Items cover issues such as: how one's relationship with God or a higher power gives a sense of comfort, specific time commitments to attending services or praying, forgiveness, time spent reflecting on life, feeling joyful and alive, having meaning in life, and seeing death as a normal part of life. Recent inter-item reliability data have found Cronbach's alpha's ranging from .93 for the spiritual practices subscale, .80 for

spiritual growth, and .76 for embracing life's fullness (Thoresen, Bowman, Koopman, Yang, & Spiegel, 1997). As with the SPWB scale of the FACIT-B, only the overall spirituality score was used in the present study in order to examine the association of overall SPWB with overall QOL. Further research by a member of the present research team is underway to investigate the relationships among the subscales of the PLS and those of QOL.

Procedure

Eligibility for the study was determined by trained research assistants who conducted phone screenings. If eligible, women came to the clinic for an initial intake interview with a research assistant, were given the first set of questionnaires, and then randomized into one of two support group programs. Informed consent was collected from participants prior to their entry into the study. Participants filled out questionnaires at four time points: prior to beginning the program, and at 3, 6, and 12-month follow-ups. As mentioned previously, the present study examined baseline data only.

Statistical Analyses

Total baseline scores were calculated for each of the scales and various demographic variables were examined. In addition, bivariate Pearson R correlations among SPWB, QOL, and psychological adjustment styles were examined. Nonparametric Spearman Rho correlations were also performed between QOL and specific demographic variables. Finally, a hierarchical regression analysis was performed to determine how much of the variance in QOL was accounted for by the adjustment styles, spirituality, and SPWB.

RESULTS

Demographic information on the participants in the study is provided in Table 1. The means and standard deviations for the measures are shown in Table 2. Statistical analyses revealed several significant correlations between SPWB, QOL, demographic variables, and psychological adjustment styles (see Table 3).

The analysis began with an examination of the correlation between demographic and health variables and quality of life. Pearson r and nonparametric Spearman Rho correlations were performed between QOL and various demographic variables. Several demographic variables were correlated with QOL. While age was positively correlated with QOL ($r = .32, p = .0001$), time since diagnosis was not significantly associated with QOL ($r = -.03$). Perceived health status was significantly correlated with QOL ($r = -.30, p = .0003$) with higher perceived health related to higher QOL. In addition, being married or partnered was related to higher QOL ($r = -.22, p = .01$) as was having a higher income ($r = .21, p = .01$). Education was not significantly correlated with QOL ($r = .11$) nor was ethnicity ($r = .07$) and therefore they were not utilized in the regression analyses.

In addition, there was no significant difference in QOL between women who stated that they had an active religious practice and those who stated that they did not ($t = 1.33$). As expected there was a significant negative correlation between overall QOL and HH ($r = -.46, p = .0000$) and between QOL and AP ($r = -.46, p = .0000$) and a positive correlation between QOL and FT ($r = .32, p = .0001$). Surprisingly, QOL was not significantly correlated with FS ($r = .14$) or Avoidance ($r = -.12$), (see Table 3).

As predicted, a positive correlation between SPWB and QOL ($r = .48, p = .00000$) was found. Spiritual well-being was also strongly positively correlated with FS ($r = .46, p = .0000$) and FT ($r = .61, p = .0000$), negatively correlated with HH ($r = -.55, p = .0000$), AP ($r = -.49, p = .0000$), and CA ($r = -.21, p = .02$). Perceived health status was again significantly correlated with SPWB ($r = -.20, p = .02$), with higher perceived health related to higher SPWB. Higher income was also slightly related to SPWB ($r = .17, p = .05$). Neither age, marital status, time since diagnosis, or education level was significantly related to SPWB. However, as expected, having an active religious practice was significantly associated with SPWB ($r = .18, p = .04$).

Weaker associations were seen with the demographic, health, and psychological variables and spirituality. The way in which the PLS was constructed results in a lower score signifying high spirituality. Therefore some the correlations that one would expect to be positive actually are reported as negative. Spirituality was not significantly related to any of the demographic variables. However, strong correlations were seen with spirituality and FS ($r = -.34, p = .0001$), HH ($r = .27, p = .001$), AP ($r = .26, p = .002$), FT ($r = -.54, p = .0001$), but not with avoidance ($r = .16, ns$). As expected, spirituality correlated highly with SPWB ($r = -.58, p = .0001$) but weakly with QOL ($r = -.19, p = .03$).

INSERT TABLE 3 HERE

A hierarchical regression analysis was used to determine how much of the variance in QOL was associated with SPWB and the five psychological adjustment styles (see Table 4). The model was formed by entering the demographic variables first, then the psychological adjustment

scales, and the spirituality scale, with SPWB entered last. When the demographic variables (age, income, marital status, health status) were entered a weak association was found with QOL ($R^2 = .18$). The addition of the psychological variables strengthened the association ($R^2 = .36$), while the inclusion of the spirituality measure did not affect the association ($R^2 = .36$). However, the final addition of SPWB significantly increased the association of the variables with QOL ($R^2 = .38$, F for the entire model = 4.87, $p < .0001$). In this final model, only fighting spirit ($F = 4.04$, $p = .05$), and SPWB ($F = 5.29$, $p = .02$) significantly contributed to the model.

INSERT TABLE 4 HERE

DISCUSSION

With the recent renewal of interest in the spiritual realm and its relationship to healing, questions arise about the nature of the relationships among spiritual well-being, quality of life, and psychological adjustment to cancer. Our results indicate that, in this sample of women with breast cancer, significant relationships were found between spiritual well-being and quality of life. While only 35% of our sample described themselves as having an active religious practice, many of these women reported having high overall Spiritual Well-Being. Regardless of specific religious belief or practice, these women reported feeling that spirituality was an important part of their well-being. Although we cannot determine which came first, improved QOL or higher SPWB, our results indicate that change in one area could potentially influence the other. This study added to the existing literature on health and spirituality by further demonstrating the importance of SPWB in relation to QOL.

In addition, significant associations were observed between SPWB and psychological adjustment styles including Fighting Spirit (FS), Helpless/Hopeless (HH), and Fatalism (FT). Numerous studies have found that spiritual factors influence health status variables, such as improved recovery and pain levels (Oxman, Freeman, & Manheimer, 1995; Pressman et al., 1990; Yates, 1981). Furthermore, psychological adjustment styles which utilize cognitive strategies such as positive thinking, faith, and finding meaning in life (e.g., FS) were related to SPWB. The negative correlation between HH and SPWB is consistent with the studies showing that spirituality is often related to hope or optimism for the future (Fehring, Miller, & Shaw, 1997). In sum, the more "spiritually well" a woman reported she felt, the better her overall QOL and psychological adjustment.

Significant correlations between QOL and Helpless/Hopeless (HH) and Fatalistic (FT) adjustment styles were also found. These findings underscore the importance of hope and acceptance in quality of life. It may be that a person who has accepted her/his illness with a sense of hope for the future would report a higher QOL. It is interesting to note that Fighting Spirit (FS) showed only a small, yet significant, correlation with QOL, which is different than we had predicted. On the other hand, a significant positive correlation was observed between FT and QOL. This correlation might seem unusual given the present definition of fatalism. However, based on the current research it appears that the concept of fatalism may be complex. Although exploration of this finding is beyond the scope of this paper, further research by a member of this team is underway to re-examine this construct. Preliminary findings have revealed that Fatalism seems to be positively related to spirituality and QOL and might be better

construed as a type of acceptance rather than stoic resignation (Fitzpatrick, Levine, Zelman, & Heide, 1999).

In addition, a combination of demographic variables (age, income, marital status, health status), adjustment styles and spirituality were significantly associated with QOL. A person who feels secure financially and socially may be more able to focus on inner experiences which may lead to greater QOL. On further examination, it was found that only fighting spirit and SPWB added significantly to the model. Both fighting spirit and SPWB utilize cognitive strategies such as faith and belief in meaning and purpose in life. It may be that the inner process that is experienced by cognitive strategies such as faith and belief may be more strongly related to quality of life than had been thought before.

Interestingly, different results were obtained from the two spiritually focused measures used in this study, the PLS and the FACIT-Sp. While the scales were highly positively correlated with each other, the size of the correlation suggests that they do not measure the same construct. It may be that the FACIT-Sp measures more internally-based constructs such as meaning, purpose, strength, etc., while the PLS focuses on external factors such as religious practice, forgiveness, and connection to others and nature. The weaker association between PLS and quality of life, as opposed to the strong association between SPWB and QOL, suggests that internally-based SPWB as measured by the FACIT-SP, is a separate and important construct that may influence a patient's QOL. Further studies are being conducted by our team on the nature of the association of the subscales of these measures and QOL. We are also exploring whether certain subscales are more related to adjustment and quality of life than other subscales.

A strength of this study is that three important psychological variables have been incorporated together that have previously not been examined: SPWB, QOL, and psychological adjustment. In particular, the examination of how SPWB relates to the psychological adjustment styles of FT, FS, and HH sheds light on the relationship between psychological adjustment and spirituality. Another strength of this study is the homogeneity of the sample. Through conducting research with a select sample of women with breast cancer, the variance in coping styles that might be evidenced in a more heterogeneous sample is reduced. With the relationships among SPWB, QOL, and psychological adjustment established in this homogeneous group of cancer patients, further studies can now test the generalizability of these theories with other populations.

On the other hand, our small, homogeneous sample does restrict the generalizability of our study to people with other cancers or illnesses. In addition, our sample included women who were highly educated, primarily Caucasian, and from a single geographic area, which may also restrict the applicability of these findings to other populations. Furthermore, the majority of the women who enrolled in this study were interested in alternative medicine, as this is a focus of the larger study. Therefore, many of these women may have more experience in alternative and/or spiritual practices than the general population. Finally, longitudinal studies should be conducted to determine if these relationships are consistent over time and to establish whether a causal relationship exists between SPWB, QOL, and psychological adjustment to cancer.

Living with breast cancer presents women with many challenges, not the least of which is facing the existential dilemmas of pain, suffering, and possible death. All resources, including those spiritual in nature, that encourage healing, adjustment, and a better quality of life for

patients should be addressed in the clinical arena. Future studies, particularly if longitudinal, could further aid in our understanding of the interrelationships between spirituality/religious commitment and health-related outcomes.

Table 1: Demographic Data^a

<u>Variable</u>	<u>N (%)</u>	<u>Mean Value</u>	<u>SD</u>	<u>Potential Range</u>
Age	142	48.94	9.67	26-78
Time since Diagnosis (months)	142	14.49	30.24	
Ethnicity				
Caucasian	109 (84)			
Asian/Pacific Islander	12 (9)			
African-American	7 (5)			
Hispanic	2 (2)			
Marital Status				
Married	63 (44)			
Living Together	12 (8)			
Divorced	35 (25)			
Never Married	32 (23)			
Education				
High School or less	2 (2)			
Some College	24 (17)			
College Graduate	37 (26)			
Post Graduate Work	79 (55)			
Income				

Less than \$15,000	7 (5)
\$15-29,000	20 (14)
\$30-44,000	18 (13)
\$45-59,000	27 (19)
Over \$60,000	68 (48)

Self-Rated Health

Excellent	39 (27)
Very Good	58 (41)
Good	33 (23)
Fair	10 (7)
Poor	2 (1)

Engagement in an Active Religious Practice

Yes	48 (35)
No	90 (65)

a: Due to rounding, not all categories equal 100%

Table 2: Means and Standard Deviations for the FACIT-B, the SPWB scale, the PLS, and the subscales on the Mini-MAC:

<u>Scale</u>	<u>N</u>	<u>Mean Value</u>	<u>SD</u>	<u>Potential Range</u>
1. Quality of Life Scale (FACIT-B)	142	95.86	18.76	11-135
2. Spiritual Well-Being Scale (FACIT-Sp)	130	28.34	9.24	6-48
3. Principles of Living Survey (PLS)	138	43.76	8.64	22-64
4. Psychological Adjustment Scale (Mini-MAC)				
Fighting Spirit	139	12.67	1.92	7-16
Helpless/Hopeless	140	12.59	3.80	8-24
Fatalism	139	14.05	2.67	8-20
Anxious Preoccupation	140	21.52	4.64	8-32
Cognitive Avoidance	139	8.41	2.37	4-15

Table 3: Bivariate Correlations between QOL, SPWB, Spirituality (PLS), Psychological Adjustment, and demographic variables:

	1	2	3	4	5	6	7	8	9	10	11
1. Quality of Life	1.00	.48***	-.19*	.14	-.46***	.32***	-.46***	-.12	.32***	.21**	-.30***
2. Spiritual Well-Being	1.00	1.00	-.58***	.46***	-.55***	.62***	-.49**	-.21**	.05	.17*	-.20*
3. Principles of Living Survey ^a	1.00	1.00	1.00	-.34***	.27**	-.54***	.26**	.16	.01	-.00	-.05
4. Fighting Spirit	1.00	1.00	1.00	1.00	-.35***	.49***	-.09	-.16	-.05	.14	-.22**
5. Helpless/Hopeless	1.00	1.00	1.00	1.00	1.00	-.34***	.70***	.23**	-.26**	-.27**	.22**
6. Fatalism	1.00	1.00	1.00	1.00	1.00	1.00	-.30***	-.04	.17*	-.02	-.10
7. Anxious Preoccupation	1.00	1.00	1.00	1.00	1.00	1.00	1.00	.02	-.29***	-.16	.04
8. Cognitive Avoidance	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	.09	-.16	.18*
9. Age	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	-.00	-.02

10. Income ^b	1.00	-.18*
11. Health Status ^b		1.00

a: Lower scores indicate higher spirituality

b: Spearman Rho

* $p < .05$; ** $p < .01$; *** $p < .001$

Table 4: Hierarchical Regression Analysis of Quality of Life:

Variables	Step 1	Step 2	Step 3	Step 4	Step 5
Age	.28***	.28***	.14	.15	.12
Income	.18*	.14	.12	.10	.07
Ethnic Group ^a	-.33	-.26	-.29*	-.30*	-.26*
Health Status		-.19*	-.14	-.16	-.17*
Fighting Spirit			-.12	-.13	-.16
Helpless/Hopeless			-.22	-.22	-.11
Anxious Preoccupation			-.18	-.16	-.15
Fatalism			.26**	.25*	.16
Cognitive Avoidance			-.04	-.04	.00
Spirituality				-.05	.03
Spiritual Well-Being					.29*

R ²	.18	.21	.42	.43	.44
Adjusted R ²	.16	.19	.37	.38	.38
R ² change	0	.03	.21	.01	.01
Significance of R ² change		.02	.001	.52	.03

* p<.05; ** p<.01; *** p<.001

a: Asian Americans significantly different from other groups on FACIT

Note. Values are standardized betas

Entered using stepwise method

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QUESTIONING THE NOTION OF "NEW AGE GUILT" IN WOMEN WITH
BREAST CANCER: THE INFLUENCE OF ATTRIBUTIONS, PSYCHOLOGICAL
ADJUSTMENT, AND SPIRITUALITY

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Acknowledgments: We would like to acknowledge and thank the following people for their involvement and support in this project: Laura Esserman, M.D., M.B.A, Michelle Baumgartner, O.T.R., Rosalind Benedet, R.N., N.P., Alison Brady, B.A., Jnani Chapman, RN, Janelle Eckhardt, Ph.D., RN, Monique Ewig, B.A., Laurie Garret, Th.M., Deborah Hamolsky, RN, Allison Horton, R.D., Sylvine Jerome, M.D., Adina Klein, B.A., Carol Kronenwetter, Ph.D., Chris Loufborrow, B.A., Diane Neighbor, DTR, Cindy Perlis, M.A., Megan Rundel, B.A., Brook Stone, LCSW, Ragini Vykunta, MBBS, Gerry Wanieski, M.A.

Funded by Grant No. DAMD #17-96-1-6260, U.S. Department of Defense

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** Presented at the Twentieth Annual Conference of the Society of Behavioral Medicine, March 1999.*

ABSTRACT

This study examined the effects of self-blame versus taking responsibility for one's health in order to explore the concept of "New Age Guilt" (NAG) in 114 women with invasive breast cancer. Participants were administered measures of adjustment (Mini-MAC), quality of life (QOL), spiritual well-being (SPWB), mood (POMS), and five questions that assess beliefs about the causation and meaning of illness. Response rates to these questions were as follows: 68% of the women believed that they were "Responsible for how healthy or sick", 91% stated that an "Illness could have a positive effect" on their life, 50% reported that "Being ill was meant to teach" them something, 68% felt that their "Thoughts or emotions could cause" them to have a serious illness, and 16% believed that "Illness can be a form of punishment". Believing an "Illness can have a positive effect" was positively correlated with SPWB and negatively related to poor adjustment styles. Taking "Responsibility for one's health" was associated with higher FS, FT, and seeing "Illness as an opportunity to learn" but not related to distress. These findings are interpreted as refuting the notion that NAG is associated with more distress. Rather, "Taking responsibility" is associated with better adjustment and seeing illness as an opportunity to learn. In addition, searching for meaning in one's illness was associated with higher SPWB, while searching for causation was associated with lower SPWB.

BACKGROUND

- **What is New Age Guilt (N.A.G.)?**

Recent trends in health care have led to the development of NAG, referred to as the belief that one has caused oneself to become ill and which can result in guilt and self-blame. NAG can be viewed as a side effect of the current trend towards focusing on the potential roots of one's illness, personal responsibility for well-being, and the need for lifestyle changes in response to illness.

- **Causation versus Meaning in Cancer**

The search for causation in for one's illness (e.g., believing emotions can cause illness) can result in blaming oneself for becoming ill, whereas the search for meaning (e.g., viewing illness as a teacher) can serve to reframe the impact an illness has on one's life and alter one's sense of well-being.

- **Examples of N.A.G. Self-Comments:**

1. "I developed cancer because I let myself get too stressed"
2. "If I had prayed/meditated regularly I wouldn't have gotten sick"
3. "I got cancer because I have unresolved issues with my mother"
4. "If I had only eaten right and exercised I wouldn't have had a recurrence"
5. "If emotions affect my health, and I'm sick, then my illness must be my fault"

Primary Purpose of the Study: To explore the notion of "New Age Guilt" in a sample of women with breast cancer, to determine the relative influence of assigning meaning versus causation in one's illness, and to test whether taking responsibility for one's health was associated with negative mood.

Research Questions:

1. Is taking responsibility for one's health associated with self-blame or guilt, as expressed through negative mood, feelings of helplessness/hopelessness, and avoidant coping?
2. Is there a differential relationship between Causation versus Meaning in Illness and Spiritual Well-Being (SPWB)?
3. What is the relationship between the belief that an "Illness can be a form of punishment" and SPWB, coping, and mood?

METHODS

Participants

- N = 114

The participants were women with invasive breast cancer diagnosed within the last 18 months, or women with metastatic or recurrent disease

- Mean Age = 50, SD=10

Ethnicity: 85% were Caucasian (N=88), and 14% were Women of Color (N=15)

- Marital Status: 45% were married (N=51), 23% were divorced/separated (N=26), 23% were never married (N=26), and 10% were living with a partner on a long term basis (N=11)
- Household Incomes:
 - 49% had incomes greater than \$60,000 (N=55)
 - 4% had incomes less than \$15,000 (N=5)
- Self-Rated Health: 29% = excellent (N=33), 24% = good (N=27), 39% = very good (N=44), 7% = fair or poor (N=8)

Measures

- MENTAL ADJUSTMENT TO CANCER SCALE (Watson et. al., 1994), measures one's attitudes towards dealing with cancer (Mini-MAC). Subscales include: *Anxious Preoccupation (AP)*, *Avoidance (AV)*, *Fighting Spirit (FS)*, *Fatalism (FT)*, and *Helplessness/Hopelessness (HH)*
- FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY-BREAST (FACIT-B; Cella, 1997) was used to measure overall quality of life (QOL).
- FACIT SPIRITUAL WELL-BEING SCALE (FACIT-Sp; Cella, 1997) was used as a measure of overall Spiritual Well-Being (SPWB).
- PROFILE OF MOOD STATES (McNair et al., 1971) is a measure of depression, anxiety, and overall distress (POMS).
- Five questions were developed to assess beliefs about CAUSATION and MEANING of illness (Targ and Levine).

RESULTS SUMMARY

1. This study found that while seeing "Illness as form of punishment" was associated with higher distress, poorer adjustment, and lower QOL and SPWB, viewing "Illness as having a positive effect" was associated with better coping and higher SPWB.
2. Taking "Responsibility for one's health/illness" was not associated with mood disturbance but was related to higher Fighting Spirit and Fatalism.
3. Also, the questions that related to *Meaning of Illness* were associated with higher SPWB, while the questions relating to *Causation of Illness* were not associated with SPWB.
4. These findings are interpreted as refuting the notion that New Age Guilt is associated with more distress. Rather, taking "Responsibility for one's health/illness" is associated with better coping and not related to distress.
5. Clinical Implications: Supporting patients in finding meaning in, rather than causation of, their illness may result in a greater sense of peace and spiritual well-being.

Table 1. Relationships between Causation and Meaning Questions and Related Variables

1. Believing an illness could have a positive effect on one's life was associated with:

Higher:

Fighting Spirit

Fatalism

Spiritual Well-Being

Lower:

Helplessness/Hopelessness

Anxious Preoccupation

Avoidance

- Plus, viewing "Illness as a teacher", and *not* believing that an "Illness can be a punishment"

2. Believing that one's thoughts or emotions can cause a serious illness was associated with:

- Viewing "Illness as a teacher"
- Believing one is "Responsible for one's health/illness"

3. Believing that an illness could be a form of punishment was associated with:

Higher

Helpless Hopeless

Anxious Preoccupation

Avoidance

Lower

Fatalism

Spiritual Well-Being

Quality of Life

- Plus higher Anxiety, Depression, and Overall Distress
- Plus *Not* believing that "Illness can have a positive effect."

4. Believing that being ill is meant to teach one something was associated with:

Higher Fighting Spirit, Fatalism, and Spiritual Well-Being

- Plus, believing that an "Illness can have a positive effect", that "Thoughts/emotions can cause illness", and that one is "Responsible for one's health/illness".

5. Believing that one is responsible for how healthy or sick they are was associated with:

Higher Fighting Spirit and Fatalism

- Plus, believing that "Thoughts/emotions can cause illness", and that "Being ill is meant to teach one something"

Table 2. Means and Standard Deviations for the Scales and Measures ($N = 115$)

Scale	Mean	Std. Dev.
A. Mini-Mental Adjustment to Cancer Scale (Mini-MAC)		
Fighting Spirit (4)	3.20	.51
Fatalism (5)	2.81	.54
Helpless/Hopeless (8)	1.53	.46
Anxious Preoccupation (8)	2.64	.58
Avoidance (4)	2.08	.61
B. Functional Assessment of Chronic Illness Therapy (FACIT-B)		
Spiritual Well-Being	28.98	9.59
Quality of Life	98.34	16.99
C. Profile of Mood States (POMS)		
Depression	11.58	10.15
Anxiety	11.73	7.83
Overall Distress (range = -21 - 156)	36.53	36.58

Table 3. Response Rates for the Causation/Meaning of Illness Questions

Question	Yes	No
<u>Meaning:</u>		
I believe that an illness can have a <u>positive effect</u> on my life.	91%	9%
I believe that illness can be a <u>form of punishment</u> .	16%	84%
I believe that being ill is <u>meant to teach</u> me something.	50%	50%
<u>Causation</u>		
I believe that my thoughts or <u>emotions can cause</u> me to have a serious illness.	68%	32%
I believe that I am <u>responsible for how healthy</u> or sick I am.	68%	32%

Table 4. Correlations between Specific Attributions and Psychological Adjustment Styles on the MAC

	1	2	3	4	5	6	7	8	9	10
1. Positive Effect on Life	1.00	.02	-.27**	.33***	.01	.29**	-.41***	.31***	-.27**	-.21*
2. Emots. Cause Illness		1.00	.07	.27**	.36***	.01	-.01	.05	-.10	.17
3. Illness as Punishment			1.00	-.03	-.12	-.08	.24*	-.21*	.29**	.24*
4. Illness as Teacher				1.00	.27**	.27**	-.08	.25**	-.06	.01
5. Resp. for Health/III					1.00	.20*	.00	.26**	-.11	.04
6. Fighting Spirit						1.00	-.36***	.47***	-.08	-.21*
7. Helpless/Hopeless							1.00	-.29**	.66***	.32***
8. Fatalism								1.00	-.28**	-.02
9. Anxious Preoc.									1.00	.06
10. Avoidance										1.00

* p<.05, ** p<.01, *** p<.001

Table 5. Correlations between Specific Attributions and Spiritual Well-Being, Quality of Life, Depression, Anxiety, and Distress.

	1	2	3	4	5	6	7	8	9	10
1. Pos. Effect on Life	1.00	.02	-.27**	.33***	.01	.36***	.16	-.18+	-.15	-.11
2. Emots. Cause Illness		1.00	.07	.27**	.36***	-.01	-.12	.15	.09	.12
3. Illness as Punish.			1.00	-.03	-.12	-.30**	-.21*	.22*	.19*	.19*
4. Illness as Teacher				1.00	.27**	.21*	-.05	.04	.06	.03
5. Resp. for Health/III					1.00	.14	-.04	.08	.11	.08
6. Spiritual W.B.						1.00	.48***	-.58***	-.40***	-.52***
7. Quality of Life							1.00	-.69***	-.57***	-.76***
8. Depression								1.00	.80***	.92***
9. Anxiety									1.00	.89***
10. Distress										1.00

* p<.05, ** p<.01, *** p<.001

FACTOR ANALYSIS OF THE MINI-MENTAL ADJUSTMENT TO CANCER SCALE IN
WOMEN WITH BREAST CANCER

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ACKNOWLEDGMENTS

We would like to acknowledge and thank the following people for their involvement and support in this project: Laura Esserman, M.D., MBA, Michelle Baumgartner, O.T.R., Rosalind Benedet, RN, NP, Alison Brady, B.A., Jnani Chapman, RN, Monique Ewig, B.A., Laurie Garret, Th.M., Deborah Hamolsky, RN, Allison Horton, R.D., Sylvine Jerome, M.D., Adina Klein, B.A., Carol Kronenwetter, Ph.D., Chris Loufborrow, B.A., Alex McMillan, Ph.D., Diane Neighbor, DTR, Cindy Perlis, M.A., Megan Rundel, B.A., Brook Stone, LCSW, Gerry Wanieski, M.A., Ragini Vykunta, MBBS,

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Funded by Grant No. DAMD17-96-1-6260, U.S. Department of Defense

BACKGROUND

Adjustment styles to cancer have been shown to be related to the course of the illness. While these constructs have been measured in several ways, not all of the measures have been adequately validated. One of the more commonly used scales is the Mental Adjustment to Cancer Scale (MAC; Watson et al., 1988). The MAC scale was designed from studies which found that certain adjustment styles were used by breast cancer patients. Greer (1991) found that after 15 years women who exhibited either fighting spirit or denial modes of adjustment to breast cancer lived longer than women who exhibited stoic acceptance, anxious preoccupation, or helplessness/hopelessness styles.

The Mini-MAC (Watson et al., 1994) was designed as a refinement to the original MAC. Few validation studies exist for the Mini-MAC. The validation of the Mini-MAC on a sample of women with breast cancer is presented here.

METHODS

Participants and Procedure

The participants were 115 women diagnosed with invasive breast cancer within the last 18 months or women with metastatic disease. Participants were recruited from local hospitals and doctor's offices to participate in a larger study, which involved random assignment to one of two types of support programs: A Life-issues Support Group and an Integrated Support Program. Participants were randomly assigned to one of two groups and given a set of questionnaires to fill out at the start of the program. The data presented is from the baseline assessment of the women.

Measures

1. *Mini-Mental Adjustment to Cancer Scale (Mini-MAC; Watson et al., 1994).*

The Mini-MAC is a shorter version of the Mental Adjustment to Cancer Scale (Watson et al., 1988). It contains 29 items measuring five coping styles: fighting spirit, helpless/hopeless, anxious preoccupation, fatalism, and avoidance.

2. *Index of Coping Responses (ICS; Billings & Moos, 1984; Moos, Cronkite, & Finney, 1990).* This 29-item scale can be analyzed in terms of five main methods of coping (logical analysis, information seeking, problem solving, affective regulation, and emotional discharge).

RESULTS

Demographics:

Mean age: 50 (SD=10)

Ethnic group: 85% (N=88) Caucasian
14% (N=15) women of color

Marital Status: 45% were married (N=51)
23% were divorced/separated (N=26)
23% were never married (N=26)
10% were living with a partner on a long term basis (N=11)

Income: 49% had household incomes of greater than \$60,000 (N=55);
Only 4% had household incomes less than \$15,000 (N=5).

Self-reported health at entry to study:
Excellent: N=33 (29%)
Very good: N=44 (39%)
Good N=27 (24%)
Fair or Poor N=8 (7%).

Factor Analysis:

A non-orthogonal factor analysis resulted in six factors with an Eigen value greater than 1. Therefore, an orthogonal rotation was conducted to create five factor structures in order to correspond with the five adjustment styles on the Mini-MAC:

FACTOR 1

<u>Original Mini-MAC</u>	<u>New Factor</u>
Anxious Preoccupation	
5	5
7	7
9	9
13	12
22	13
25	16
28	21
29	22
	25
	28
	29

(Note: Items 12,16, & 21 also loaded highly on Helpless/Hopeless, consistent with the original structure of the Mini-MAC.)

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FACTOR 2

<u>Original Mini-MAC</u>	<u>New Factor</u>
Avoidance	
11	11
17	17
26	26
27	27

FACTOR 3

<u>Original Mini-MAC</u>	<u>New Factor</u>
Fighting Spirit	
2	1
10	2
18	10
23	23

FACTOR 4

<u>Original Mini-MAC</u>	<u>New Factor</u>
Fatalism	
1	3
3	8
8	19
19	24
24	

FACTOR 5

<u>Original Mini-MAC</u>	<u>New Factor</u>
Helpless/Hopeless	
4	4
6	6
12	9
14	12
15	13
16	14
20	15
21	16
	18
	20
	21

(Note: Item 9 also loaded highly on Anxious Preoccupation, consistent with the original structure of the Mini-MAC.)

Reliability

Chronbach's alpha was performed on the original subscales of the Mini-MAC:

Fighting Spirit: .63
Helpless/Hopeless: .85
Anxious Preoccupation: .84
Fatalism: .62
Avoidance: .79

DISCUSSION

Overall, the Mini-MAC subscales seem to be relatively consistent in this sample, and seem to have concurrent validity based on the Index of Coping Responses. However, while the factor for Avoidance was in total agreement with the original construction of the scale, the factors for Anxious Preoccupation and Helpless/Hopeless were not as consistent with the original Mini-MAC scale. Several items which loaded in the Anxious Preoccupation factor were on the original Helpless/Hopeless subscale, and vice versa. However, many of these items loaded highly on both subscales. Although these two subscales had the highest internal consistency, the factor analysis suggests that these two subscales may need further refinement.

Another interesting discovery was that the item "I am very optimistic" which is on the fighting spirit subscale loaded most highly on the Helpless/Hopeless factor. When one is optimistic, one also tends to be less hopeless, however optimism and it's relationship to helplessness and hopelessness should be explored further.

As expected, fighting spirit correlated highly with the more positive coping styles on the Index of Coping Responses. Fatalism also correlated highly with the more positive coping styles on the ICR, while Helplessness/Hopelessness and Avoidance correlated highly but negatively with the more positive coping styles on the ICR. Anxious Preoccupation correlated highly with avoidance and emotional discharge coping styles, which is consistent with this construct.

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A COMPARISON OF COMPLEMENTARY AND TRADITIONAL PSYCHOSOCIAL
TREATMENT FOR BREAST CANCER

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ACKNOWLEDGMENTS

We would like to acknowledge and thank the following people for their involvement and support in this project: Laura Esserman, M.D., MBA, Michelle Baumgartner, O.T.R., Rosalind Benedet, RN, NP, Alison Brady, B.A., Jnani Chapman, RN, Janelle Eckhardt, Ph.D., RN, Monique Ewig, B.A., Laurie Garret, Th.M., Deborah Hamolsky, RN, Allison Horton, R.D., Sylvine Jerome, M.D., Adina Klein, B.A., Chris Loufborrow, B.A., Diane Neighbor, DTR, Cindy Perlis, M.A., Megan Rundel, B.A., Gerry Wanieski, M.A., Ragini Vykurta, MBBS.

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Funded by Grant No. DAMD17-96-1-6260, U.S. Department of Defense

BACKGROUND

Cancer is a shock, physically, mentally, and spiritually. The treatment for the illness can result in further physical, mental, and emotional difficulties. Cancer can be seen as a "wake up call", a time when one's mortality and the uncertainty of life and quality of life become apparent (Potts, 1996). Therefore, it is not surprising that psychological reactions such as anger, fear, and depression are common when cancer is diagnosed (for reviews on psychological sequelae and adjustment see Glanz & Lerman, 1992; Jacobsen & Holland, 1991; Meyerowitz, 1980). While for many patients, the distress of cancer surgery and treatment declines within one year, it has been estimated that up to 30 percent of women continue to have some disruption in quality of life one year after treatment for breast cancer (Glanz & Lerman, 1992; Irvine, Brown, Crooks, Roberts, & Browne, 1991). One landmark study of 215 cancer patients found that 47 percent of the sample had severe enough psychiatric disorders to be classified by the DSM-III (APA, 1980) and who could have been benefited by a psychosocial intervention (Derogatis, Morrow, & Fetting, 1983). Many factors influence psychological adjustment to cancer and quality of life, including fear (of the future, of the possible loss of a body part [e.g., a breast], of isolation, of pain, etc.), choice of treatments (both conventional and CAM) and the effects of the treatments.

Psychosocial treatment techniques for cancer patients have ranged from psychotropic medications to group, and individual therapies. Various psychosocial interventions have been developed to decrease the amount of psychological morbidity associated with the disease and to assist cancer patients to improve their daily functioning and quality of life. In general, these interventions have been designed in a conventional manner, i.e., that they were mostly designed as traditional psychotherapy "talking" groups. Some of the more effective groups have used supportive-expressive (Spiegel, Bloom, Kraemer, & Gottheil, 1989) or cognitive behavioral techniques (Fawzy et al. 1990). Results of two randomized prospective trials suggest that participation in such groups may be associated with increased survival (Fawzy et al. 1990; Spiegel, et al., 1989). Interestingly, although the Spiegel study involved a year long intervention, the study by Fawzy and his colleagues involved only a six week long intervention and still found significant increases not only in survival but also in immune functioning. Therefore, it may be that shorter interventions may be just as useful as longer interventions, and thus may be more cost-effective.

A criticism of these types of groups is that the traditional type of support group may not adequately facilitate the self-reflection, introspection, or expression of feelings and emotions associated with the illness, treatment, and other sequelae. A group that meets for only an hour to an hour and a half may not provide enough time for shifts into a more introspective part of the person, which could provide for deeper healing. Finally, unlike spiritual or meditative programs for cancer (e.g., Busick, 1989), few of these conventional groups focus on spiritual issues such as self-transcendence to initiate or enhance hope, optimism, and a sense of harmony and wholeness. Therefore, many cancer patients have also looked to mind/body complementary or alternative (CAM) therapies as an adjunct to conventional groups, for a possible cure, or to increase their quality of life.

Many cancer patients search for a venue to express their fears and emotions and to gain a feeling of peace, acceptance of themselves and their situation, and/or a purpose in life. Mind/body CAM therapies such as yoga and meditation have been used for thousands of years to teach peace,

acceptance, and to treat physical illnesses (Shannahoff-Khalsa, 1991). It is estimated that 10-60% of cancer patients use some type of mind/body CAM, mostly as a supplement to conventional cancer therapy (Doan, 1998; Cassileth, Lusk, Strausse, & Bodenheimer, 1984; Eisenberg, Kessler, Foster, Norlock, Calkins, & Delbanco, 1993). Not only do people seek out CAM therapies on their own, a growing number of health professionals are also recommending CAM therapy. A recent survey of 772 Northern California HMO physicians found that 16% are using or recommending guided imagery, 48% are prescribing meditation, and 27% are prescribing movement therapies such as yoga, t'ai chi, or chi gong as adjuvant therapy (Gordon, Sobel, & Tarazona, 1998). Many of these and other complementary or alternative mind/body modalities have been used by cancer patients, and have been reported in case and anecdotal accounts to have beneficial effects (Achterberg & Lawliss 1984; Block, 1997; Doan, 1998; Gray, Greenberg, Fitch, Parry, Douglas, & Labrecque, 1997), although other research has disputed these claims (Cassileth, et al., 1991).

Mind/body CAM modalities are currently used in many formats, including retreats, groups, and individual therapy (Lerner, 1994). CAM therapies emphasize inner knowledge, spiritual growth, and self-transcendence whether offered in a retreat or community setting. Mind/body CAM therapies are used to help individuals to develop a new relationship with fears and anxieties about their illness. However, these therapies have not been studied in much detail with cancer patients (Stoner & Keampfer, 1985).

The purpose of this ongoing study is to compare a traditional support group to an Integrated/intensive support program for women with breast cancer.

RESULTS

Demographics:

Group membership: 23 Life Issues
30 Integrated

Mean age: 48 (SD=9.24)

Ethnic group: 83% (N=43) Caucasian
17% (N=9) women of color.

Marital Status:

45% were married (N=24)
19% were divorced/separated (N=10)
26% were never married (N=14)
9% were living with a partner on a long term basis (N=5)

In addition, women reported having an average of one child.

School: College: n=23 (43%)
Post-college: n=30 (57%)

Income: 44% had household incomes of greater than \$60,000 (N=23);
Only 2% had household incomes less than \$15,000 (N=1).

Self-reported health at entry to study:

Excellent: N=16 (30%)
Very good: N=20 (38%)
Good N=12 (23%)
Fair or Poor N=5 (9%).

METHODS

Participants and Procedure

The participants were 53 women diagnosed with invasive breast cancer within the last 18 months, or women with metastatic disease. Women were recruited from local hospitals and doctor's offices to participate in a study designed to compare two types of support group programs: A Life-Issues Support Group and an Integrated Support Program. Participants were randomly assigned to one of two groups and given a set of questionnaires to fill out at the start of the program and at the end of the 12-week program.

Program

A. *Life Issues Group*: 12-week semi-structured support group. Emphasis in this group is on coping with real life issues, including communicating with friends, family, and medical staff, body image, sexuality, grief, and anger.

B. *Integrated Group*: 12-week intensive lifestyle change and support program with an emphasis on psychospiritual issues, and inner process. Participants meet twice a week for 2 1/2 hours each time.

The Integrated program consists of the following elements:

1. Health and Nutrition (discussion of health issues pertaining to breast cancer such as early menopause, healthy eating, lymphedema, etc.),
2. Movement (dance or yoga)
3. Meditation/Imagery
4. Spiritual Focus support group Semi-structured support group using discussion and imagery to explore issues of meaning and purpose in life, connectedness, forgiveness, dying and healing.
5. Art Studio (staffed by a clinical artist). In this studio they may create with whatever medium they choose, including making quilts for the Breast Cancer Quilt Project.
6. Recommended Daily Practices:
Recommended daily: exercise, low-fat diet, yoga, and meditation or imagery.

Measures

1. *Functional Assessment of Chronic Illness Therapy (FACIT-B)*; Cella, 1997).

Subscales: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being, Functional Well-Being, and additional breast cancer-specific items.

2. *Profile of Mood States* (McNair et al., 1971). Subscales: Anxiety, Depression, Anger, Fatigue, Confusion, and Vigor.

3. *Spirituality*

FACIT-Sp (Cella, 1997), Subscales: Faith and Assurance, Meaning and Purpose.

Principles of Living Survey (Thoresen, et al., 1997). Subscales: Spiritual Practices, Spiritual Growth, and Embracing Life's Fullness.

4. *Satisfaction with the program* : An additional question designed to measuring overall satisfaction with the program was used.

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Fair or Poor N=5 (9%).

RESULTS

Quality of Life

Significant Changes Over Time:

For both groups increases in:

Emotional Well-Being: $F=18.19$, $p<.0001$

Functional Well-Being: $F=9.22$, $p=.004$

Overall Quality of Life: $F=8.35$, $p=.006$

<u>Variable</u>	<u>Pre-Mean (SD)</u>	<u>Post-Mean (SD)</u>	<u>F</u>	<u>p</u>
Physical Well-Being	20.77(4.86)	21.68 (5.47)	1.22	ns
Social Well-Being	19.85 (5.21)	19.79 (4.84)	.11	ns
Emotional Well-Being	13.94 (3.53)	16.25 (3.69)	18.13	.0001
Functional Well-Being	17.78 (5.24)	19.77 (4.86)	9.22	.004
Additional Questions	24.58 (5.93)	24.87 (5.26)	.57	ns
Overall Well-Being	96.69 (15.56)	102.16 (17.89)	8.35	.006

Mood

Significant Changes Over Time:

For both groups:

Tension/Anxiety: $F=6.97$, $p=.01$

Depression: $F=5.86$, $p=.02$

Total Mood Disturbance: $F=5.19$, $p=.03$

<u>Variable</u>	<u>Pre-Mean (SD)</u>	<u>Post-Mean (SD)</u>	<u>F</u>	<u>p</u>
Tension-Anxiety	12.57 (8.36)	9.19 (7.35)	6.97	.01
Depression	11.96 (10.10)	8.20 (9.42)	5.86	.02
Anxiety-Hostility	8.92 (7.14)	7.58 (7.95)	3.06	.09
Vigor	13.58 (6.34)	14.60 (6.14)	1.14	ns
Fatigue	11.06 (7.10)	9.58 (6.93)	1.58	ns
Confusion	8.49 (5.26)	7.24 (5.17)	3.39	.07
Total Mood Disturbance	39.45 (36.23)	27.15 (34.11)	5.19	.03

Spirituality

Significant Changes Over Time:

For both groups:

Spiritual Well-Being: $F=5.58, p=.02$

Embracing Life Fully: $F=4.21, p=.04$

<u>Variable</u>	<u>Pre-Mean (SD)</u>	<u>Post-Mean (SD)</u>	<u>F</u>	<u>p</u>
Spiritual Well-Being				
Total	29.28 (9.41)	31.72 (7.15)	5.58	.02
Principles of Living				
Total	43.61 (7.00)	42.67 (7.31)	1.69	ns
Spiritual Practice	22.66 (4.13)	22.36 (4.02)	2.59	.11
Spiritual Growth	12.10 (2.87)	11.78 (2.84)	1.00	ns
Embracing Life Fully	8.85 (2.51)	8.33 (2.55)	4.21	.04

Satisfaction with the Program

For Integrated: Median=5

For Life Issues: Median=3

Significant difference between the groups:

Wilcoxon Rank Sum=-2.67, $p=.008$

DISCUSSION

These results suggest that while both groups were effective in reducing stress and increasing quality of life, the women in the Integrated group were more satisfied with their experience.

While this study showed that an Integrated complementary/alternative medicine intervention is as good as a conventional support group, women are more satisfied with a complementary/alternative program.

Differences in the groups may emerge as the sample size grows.

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FF

Principal Investigator/Program Director (Last, first, middle):

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.
Photocopy this page or follow this format for each person.

NAME		POSITION TITLE	
Burke, Harry B.		Associate Professor of Medicine and Oncology	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Chicago	AB	1979	Tutorial Studies
University of Chicago	AM	1980	Divisional Masters
University of Chicago	Ph.D.	1987	Cognitive Science
University of Chicago	M.D.	1988	Medicine

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list, in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. If the list of publications in the last three years exceeds two pages, select the most pertinent publications. **DO NOT EXCEED TWO PAGES.**

APPOINTMENTS

1988 - 1991	<i>Internal Medicine Resident, St. Francis Hospital (Loyola University), Evanston IL.</i>
1991 - 1992	<i>Assistant Professor of Medicine, Division of General Internal Medicine, Medical College of Wisconsin, Milwaukee WI.</i>
1992 - 1994	<i>Assistant Professor of Medicine, Division of General Internal Medicine and Health Care Research, University of Nevada School of Medicine, Reno NV</i>
1992 - 1994	<i>Associate Director, Center for Biomedical Modeling Research, University of Nevada School of Medicine, Reno NV.</i>
1992 - 1994	<i>Director, Ambulatory Care Training Program, Department of Medicine, University of Nevada School of Medicine, Reno NV.</i>
1994 - 1998	<i>Assistant Professor of Medicine, Division of General Internal Medicine, Department of Medicine, New York Medical College, Valhalla NY.</i>
1996 - Present	<i>Director, Bioinformatics, Decision Making, and Health Services Research Group, New York Medical College, Valhalla NY.</i>
1998 - Present	<i>Statistical Director, Division of Oncology, Department of Medicine, New York Medical College, Valhalla NY.</i>
1998 - Present	<i>Director of Clinical Information Systems, Zalmen A. Arlin Cancer Institute, Hawthorne NY 10532.</i>
1999 - Present	<i>Associate Professor of Medicine and Oncology, Department of Medicine, New York Medical College, Valhalla NY.</i>

EDITORIAL POSITIONS

1986 - 1987	<i>Assistant Editor, JAMA-Pulse.</i>
1986 - 1991	<i>Editorial Board, Perspectives in Biology and Medicine.</i>
1994 - 1997	<i>Reviewer, Journal of General Internal Medicine.</i>
1994 - Present	<i>Reviewer, Journal of the National Cancer Institute.</i>
1994 - Present	<i>Reviewer, Cancer.</i>
1996 - 1998	<i>Reviewer, Journal of Clinical Outcomes Management.</i>
1997 - Present	<i>Editorial Board, Journal of the National Cancer Institute.</i>
1998 - Present	<i>Editorial Board, Molecular Urology.</i>
1998 - Present	<i>Reviewer, British Journal of Cancer.</i>
1998 - Present	<i>Reviewer, Oncology.</i>
1998 - Present	<i>Editorial Board, Journal of Urologic Pathology.</i>
1998 - Present	<i>Reviewer, IEEE Transactions on Neural Networks.</i>
1999 - Present	<i>Reviewer, Cancer Detection and Prevention.</i>

SECTIONS AND PANELS

1996 - Present	<i>Chair, National Cancer Institute Working Group for Research on Prognostic Factors and Systems, National Institutes of Health.</i>
1999 - Present	<i>Study Section, Early Detection Research Network, National Cancer Institute, National Institutes of Health.</i>

BOOKS

Burke HB, Henson DE. Prediction in Cancer. Kluwer Academic Publishers, in preparation.

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Burke HB, Hutter RVP, Henson DE. Breast Carcinoma. In P Hermanek, MK Gospadoriwicz, DE Henson, RVP Hutter, LH Sobin (eds), UICC Prognostic Factors in Cancer. Berlin: Springer-Verlag, 1995, 165-176.

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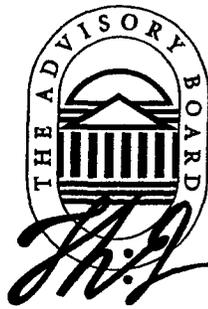
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INNOVATIONS IN BREAST CANCER CARE
VOLUME I



THE NEW SERVICE STANDARD

*Redefining the Patient Experience
in Breast Cancer Care*

ONCOLOGY ROUNDTABLE

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PRACTICE #7: CONSULTATION PLANNING

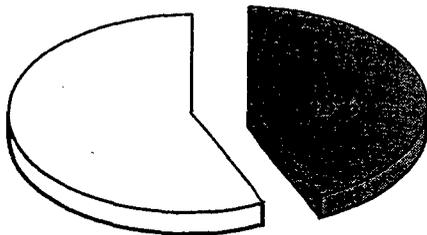
Breast Cancer Patients Perceive Numerous Communication Barriers

The previous two practices dealt with improving communication from the physician's side; for many breast cancer patients, however, the trouble comes on their end. Research suggests that a large number of breast cancer patients have difficulty communicating their needs and feelings to their physicians, a situation that can make an already traumatic experience even more trying.

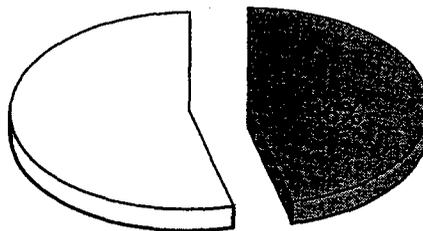
The data presented below suggest the magnitude of the problem. The pie chart to the upper left shows that 43 percent of patients struggle to ask their physician questions. The middle pie chart indicates that 46 percent find it difficult to express their feelings. The pie chart at the bottom right demonstrates that 24 percent of patients have a hard time reporting new symptoms to their physician. For many of these patients, the communication barriers become so difficult to overcome that they simply stop trying. When this occurs, patients leave consultations with unanswered questions, unvoiced concerns and the sense that they are passive observers in their own treatment planning.

Trouble Doing Their Part

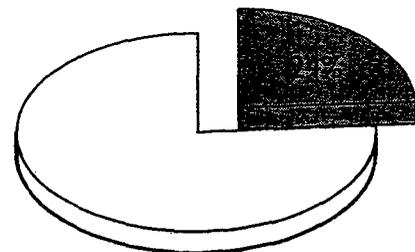
Hard to Ask Doctor Questions



Hard to Express Feelings



Hard to Tell Doctor New Symptoms



Note: n=97.

Source: Lerman C, et al. *Cancer* (1993).

Patients Coached to Participate in Treatment Planning Discussions

Consultation Planning—the final practice for improving the decision-making process—offers a method for helping patients overcome communication barriers and derive greater value from their consultations.

Starting at the bottom left, the process of consultation planning begins with two brief surveys that patients complete immediately prior to their consultation. These two surveys assess patients' comfort level in communicating openly with their physician and seek to quantify how involved patients want to be in their treatment decisions. The consultation planner—typically an existing staff member (a nurse, social worker or volunteer)—evaluates the patient's survey responses prior to the planning visit.

Next, the patient meets with the consultation planner, who helps the patient surface and verbalize her expectations for the upcoming consultation. The planner uses the survey responses not only to explore the questions and concerns that the patient intends to raise, but also to investigate those concerns that the patient is likely to withhold from her physician. Through this process, the consultation planner develops a two-sided list of the patient's concerns, depicted below under Step #2.

ARMING PATIENTS WITH TOOLS



Step #1: Surveying

Step #2: Identifying Concerns

Overcoming Communication Barriers					
	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
1. I'm in information overload	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I know how to talk—not just agree—with Dr.A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I don't know how to question Dr.A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I know what questions to ask Dr.A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I expect to withhold some of my concerns for fear wasting Dr.A's time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I expect to withhold some of my questions for fear Dr.A will think they're stupid	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I expect to withhold some of my questions for fear Dr.A will react defensively	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I expect to withhold some of my questions for fear Dr.A can't admit being ignorant of the answers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I have chosen to consult Dr.A from among several candidate physicians	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I know where I can go for another opinion, if I need	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I am having trouble deciding whether to consult another physician besides Dr.A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I know exactly who else I need to see about my concerns	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Stance Toward Collaboration Scale

How do you wish to participate in your upcoming consultation with your doctor (whom we'll refer to as Dr.A)? Please place a check mark after the one (and only one) statement of the five below that best summarizes your feelings about who should make any decisions that need to be made in the course of your upcoming consultation:

- Dr.A should make the decisions using all that Dr.A knows or can learn, without regard to my opinion.
- Dr.A should make the decisions but strongly consider my opinion.
- Dr.A and I should make the decisions together, on an equal basis.
- I should make the decisions but strongly consider Dr.A's opinion.
- I should make the decisions using all I know or can learn, without regard to Dr.A's opinion.

Thoughts and Feelings	Topics I Expect to Cover
I feel like my treatment has been predetermined without my input.	I am ready to do what is necessary to save my life. Do I need to have a mastectomy?
	Am I a candidate for a lumpectomy?
	I want to go back to work as soon as possible.
	How can I minimize recovery time?

Consultation Planners Help Patients Voice and Prioritize Concerns

Based on the list of the patient's concerns, the consultation planner and the patient jointly create a "map" that organizes and rank orders the issues that are most important for the patient to discuss with her physician (Step #3). A computer software program can be used to facilitate the process and create a printed version of the map for the patient to take with her to the physician visit. At the bottom of this page is a reprint of a typical map, with the patient's concerns linked and ordered by importance.

Step #4, rehearsal and debriefing, consists of a role-play exercise with the consultation planner to ensure that the patient is comfortable asking her questions before she meets with her physician.

Finally, the consulting physician receives a copy of the patient's consultation plan and uses it as a road map to guide the discussion (Step #5). This encourages the physician to share the communication burden, and ensures that he or she is aware of the patient's concerns.

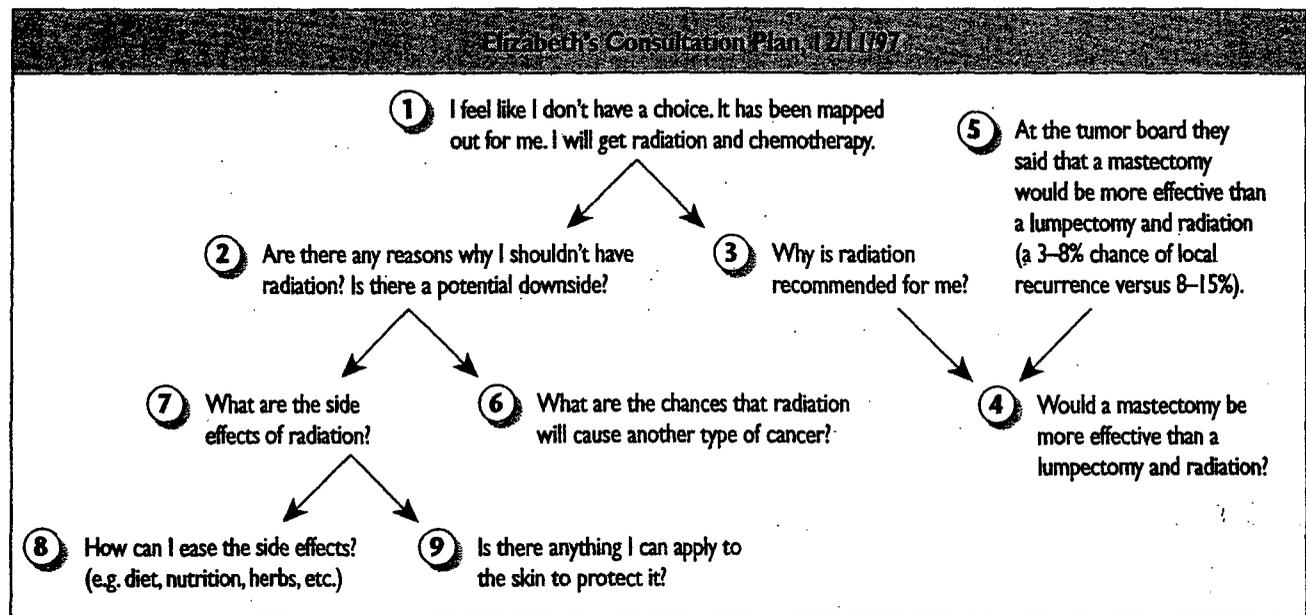
FOR EFFECTIVE CONVERSATIONS



Step #3: Mapping

Step #4: Rehearsal and Debriefing

Step #5: Physician Consultation



Source: On Your Mind, Redwood City, Calif.;
Oncology Roundtable interviews.

Patients Less Inhibited in Conversations with Physicians

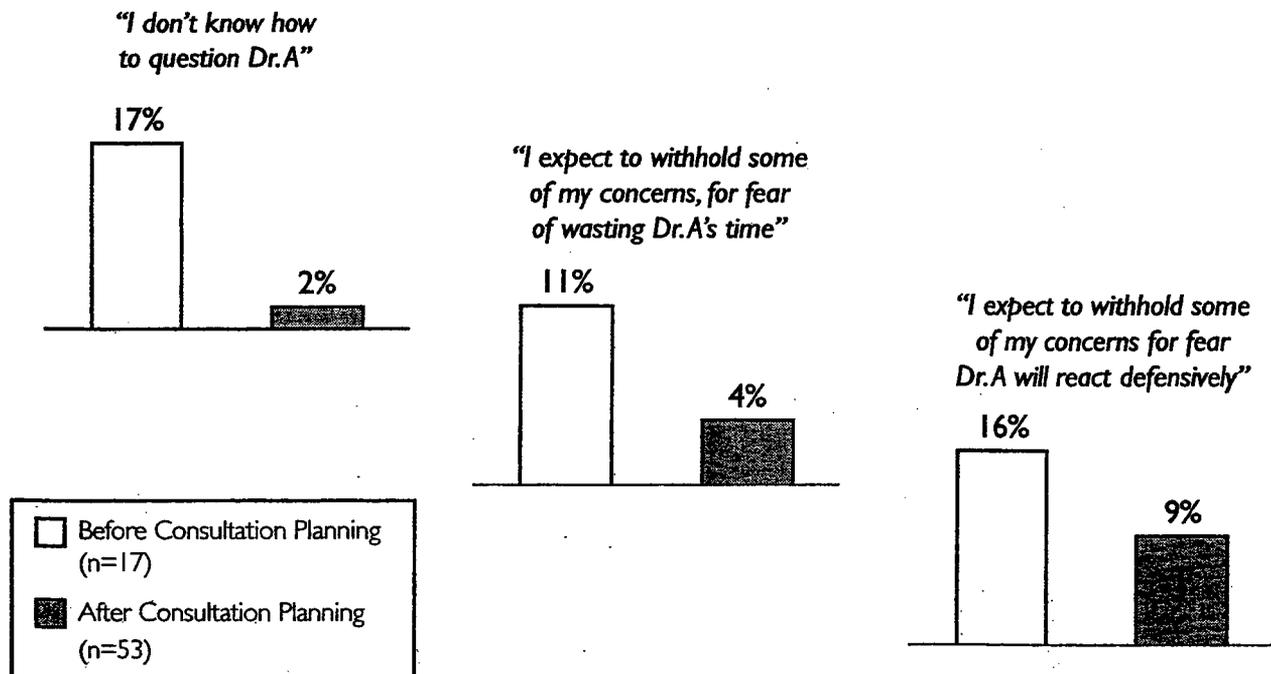
Presented in the charts below are results from a survey (with an admittedly small sample size) comparing patient responses before and after the implementation of consultation planning. As shown by the bars at left, while 17 percent of patients initially felt unsure of how to question their physician ("Dr. A"), only 2 percent of patients expressed this concern after consultation planning was implemented.

In the center bars, 11 percent of patients expected to withhold some of their concerns for fear of taking too much of their physician's time; this number decreased to 4 percent after consultation planning. Finally, the bars at right offer evidence that patients who participate in consultation planning are less likely to withhold those concerns that might make their physician defensive. Taken together, the data suggest that consultation planning is achieving the goal of minimizing barriers to communication between patients and their physicians.

BREAKING DOWN

Patients More Forthcoming

Percentage Agreeing or Strongly Agreeing



Source: On Your Mind, Redwood City, Calif.; Oncology Roundtable interviews.

Patients Overwhelmingly Value Consultation Planning Service

Consultation planning has been in use at the University of California-San Francisco Breast Care Center since 1996, and a pilot project is underway at the University of Utah's Huntsman Cancer Institute.¹ Early results indicate that the service has been extremely popular with patients.

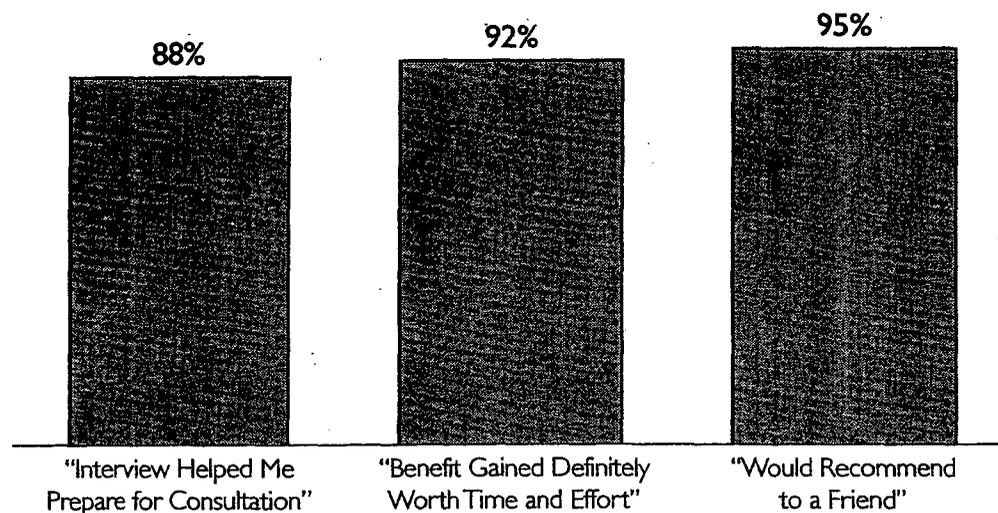
Presented below are the results from a survey of breast cancer patient satisfaction with the consultation planning program. As shown in the bars from left to right, 88 percent of patients felt that the visit with the consultation planner helped prepare them for their physician consultation; 92 percent of patients agreed that the benefit gained was well worth the time and effort they put into the process; and 95 percent of patients would recommend consultation planning to a friend diagnosed with breast cancer.

Practice #7, Consultation Planning, is the last of three practices intended to facilitate the treatment decision-making process for patients by improving the quality of communication and information flow between patients and physicians. In the remaining pages of this section on enfranchising patients, the focus shifts from better communication to better education, with practices to help patients understand their disease and become more comfortable with postsurgical self-care.

COMMUNICATION BARRIERS

Resounding Endorsement

Percentage Agreeing or Strongly Agreeing



¹ Software and training for consultation planning are offered by On Your Mind, Redwood City, California. For more information, contact Dr. Jeffrey Belkora, Vice President, Research & Development, at 650-306-1134 (jeff@onyourmind.com) or Stephanie Lamping at 650-306-1139 (stephanie@onyourmind.com) or visit <http://www.onyourmind.com>.

Source: On Your Mind, Redwood City, Calif.; Oncology Roundtable interviews.

Focus on Consultation Planning:

Are You Ready to Decide?

By Karen Sepucha, Jeff Belkora, Stephanie Lamping, Ashley Parsons, Dr. Laura Esserman

A Tool for Tough Decisions

The path through cancer is filled with difficult and confusing decision points. We want to help patients get clear on which treatment is best for them, help them get the support of family, friends and physicians, and help them reduce anxiety with decision making. We developed a survey to assess a patient's current capacity for decision making, *Are You Ready for Treatment?*. Patients with very high scores on this survey (in the range of 15-20) are usually ready to begin treatment. Those with lower scores may not have fully completed the decision-making process. These individuals may benefit from seeking second opinions, or visiting CBHP or other resources.

Like all surveys, this one is imperfect, but we hope that it will lead respondents to reflect on important aspects of their decisions. Since we would like feedback on this survey as a decision-making tool, we will briefly discuss each item. ♦

Are You Ready For Treatment?

Instructions: Please consider a significant health care decision. For each of the statements below indicate whether you (strongly) agree or disagree. If the statement does not apply to your situation, or you do not understand what it means, check "neither agree nor disagree." Please check only one response for each statement.

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
I am having trouble making decisions regarding my medical care.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I have a thorough understanding of the medical diagnosis.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I understand what could happen without any further medical treatment.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I know of at least two treatment alternatives that are often recommended in cases like this one.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I do not understand what could happen after each medical treatment alternative.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I know what is important to me for this decision.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
It is not clear to me which treatment alternative is best.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My doctor and I agree on a treatment strategy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am comfortable with my level of participation in the decisions about treatment.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am ready to begin treatment to deal with my medical situation.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

To determine your score:

- For items 2, 3, 4, 6, 8, 9, and 10, give 1 point for "agree," 2 points for "strongly agree," subtract 1 point for "disagree," subtract 2 points for "strongly disagree" and score 0 points for "neither agree nor disagree."
- For items 1, 5, and 7, please give 1 point for "disagree," 2 points for "strongly disagree," subtract 1 point for "agree," subtract 2 points for "strongly agree" and score 0 points for "neither agree nor disagree."
- Calculate your total score by adding and subtracting points for each statement. Your total score should fall between -20 and +20.

Consultation Planning: None of many services available to breast cancer patients at CBHP.

This article, written by CBHP volunteers and a surgeon who is also the director of the Breast Care Center at UCSF, describes how a particular tool may help clients assess whether they are ready to make a decision regarding their breast cancer treatment.

What Does Each Item Indicate?

I am having trouble making decisions regarding my medical care. If you are having any difficulty making decisions, do not allow yourself to be rushed or pressured into doing something. Most breast cancer patients can take a few weeks to think through decisions without compromising their health.

I have a thorough understanding of the medical diagnosis. A key ingredient for decision making is understanding your current situation. Be sure to get copies of your medical record and ask your physician to explain all tests and how to interpret the results.

I understand what could happen without any further medical treatment. To compare the benefits of various treatments, you need a baseline. A good baseline is your prognosis with *no* treatment. If your physician says to you, "For you chemotherapy will give a 5 year recurrence rate of about 6-8%," you may evaluate this information differently if your recurrence rate without any treatment is 25 % than if it is 10%.

I know of at least two treatment alternatives that are often recommended in cases like this one. Try to identify several alternatives by asking your physician to recommend a minimally invasive option, an aggressive option and something that falls in between those two. A breast cancer patient with an early stage, hormone receptive tumor might be given these three options: no further therapy (*minimally invasive option*); Adriamycin Cytoxan chemotherapy plus tamoxifen (*aggressive option*); and tamoxifen alone (*a middle option*).

I do not understand what could happen after each medical treatment alternative. You may be considering treatments that provide similar survival benefits, but have very different side effects, duration of treatment and recovery, or cosmetic results. For each alternative, get a clear picture of how this choice will affect your life during treatment, during recovery, and afterward.

I know what is important to me for this decision. Facts alone will not make your decision—you also need to understand how you feel about your choices. A cancer patient once remarked, "If someone had asked me to think about my values while I was making my decision I would've called them crazy. All I wanted was medical facts and information. Now, I realize that both facts and feelings were crucial to my decision."

It is not clear to me which treatment alternative is best. Even with creative alternatives, valid information, and clear preferences, you still may not be able to make a decision. For some people decision-making is an intuitive or even a spiritual

process. We encourage you to integrate the best aspects of rational, intuitive, and spiritual decision-making into your process.

Dr. A and I agree on a treatment strategy. It can be very disconcerting if your doctor does not support your choice of treatment. You must be able to freely share your questions and concerns and to seek other opinions and views. This exchange can deepen your physician's understanding of your particular position.

I am comfortable with my level of participation in the decisions about treatment. You should explore how you want to participate in decisions about your care, realizing that your preferences can change over time. Then share this preference with your doctor. Find a doctor who "fits" well with you, one who enables you to participate in the way you feel most comfortable. You should not begin treatment if you are uncomfortable with your level of participation in the decision-making.

I am ready to begin treatment to deal with my medical situation. Even if you are clear on which treatment is best, and your physician is in agreement, you still need a strong network of family and friends to support you. Most of all, you need to support yourself. Patients who are comfortable and confident with their decisions often do better in treatment and have faster recoveries. ♦

We need your feedback!

The CBHP community has consistently provided comments and suggestions to strengthen our services. We are looking forward to hearing your views on the decision-making tool. In particular, we would appreciate your feedback on the following questions:

1. Does your score reflect your personal assessment of your readiness for decision making? Would you personally benefit (or have benefited) from taking this survey while making treatment decisions?
2. Does the wording of the questions need to be changed to be clearer, if so?
3. What is missing from the survey?

Our hope is to work with our colleagues at UCSF, Stanford Healthcare and at CBHP to create tools that help patients and physicians converge on their preferred treatment. Please give us your feedback by phone (Consultation Planning voicemail 360-326-6299 extension 18) or by e-mail (karen@onyourmind.com). Thank you for your help.

**1999 ASCO Abstract #1621:
CONSULTATION RECORDING METHODS TO IMPROVE
COLLABORATIVE DECISION-MAKING IN BREAST CANCER**

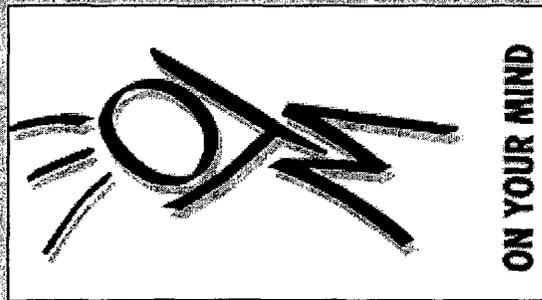
K. Sepucha, J. Belkora, D. Tripathy, L. Esserman; Stanford University, Stanford CA; On Your Mind, Inc., Redwood City, CA; and Breast Care Center, Univ California San Francisco, San Francisco, CA.

Background: Breast cancer patients and physicians make complex, life altering decisions during medical consultations. Breast cancer patients often withhold their questions and concerns during consultations. Physicians have limited time and resources to synthesize their patient's detailed medical history along with the relevant evidence from the literature, and incorporate their patients' preferences. As a result, breast cancer patients and physicians often leave consultations confused, frustrated, and anxious about decisions.

Methods: We developed Consultation Recording methods to increase the effectiveness of consultations. We enrolled 24 breast cancer patients facing local or systemic treatment decisions in a sequential, controlled trial. Patients in both arms received a Consultation Planning session. In the intervention, a trained facilitator helped to create an agenda, facilitate the discussion and create a record of the consultation in real time. In the control, the facilitator observed the consultation. Valid and reliable surveys measured decision quality and satisfaction with consultation. **Results:** Patients in the intervention group reported significantly higher final decision quality (median score 14 versus 10, $p=0.008$) when compared with the control. Patients in the intervention also reported a larger improvement in decision quality (mean increase 9.7 versus 6.6, $p=0.057$) and higher satisfaction with the consultation (median score 11 versus 7, $p=0.073$), both of which are marginally significant even in this small sample. Further, patients and physicians in the intervention achieved a significantly higher level of inter-subjective agreement about their decision quality, (Kappa 0.49 versus 0.28, estimated difference 0.205, $p<0.0001$).

Discussion: Presenting evidence from the literature without overwhelming patients is difficult. Consultation Recording uses standard meeting facilitation tools and processes well validated in the business community which leverage the patient's and physician's time in consultations. These methods enable patients and physicians to combine evidence- and preference-based medicine to maximize decision quality. Good communication during medical visits and collaborative medical decision-making has been linked to such important outcomes as increased health, compliance, and satisfaction. **Conclusion:** Based on the findings, further studies are indicated to replicate these results with other physicians and to assess cost and health outcomes.

Screen Shot from Software Prototype



DPict On-TRAC
Excel Version 0.1

Oncology Treatment Risk Analysis Clarification

Demographics

*Health Status
Determinants*

Preferences

Treatment Risks

Analysis

Track the mix of patients in your practice... feed their demographics into your evidence-based predictive model.

Help your patients define what they mean by good, average, and poor health.

Quantify each patient's attitude towards time tradeoffs among good, average, and poor health states.

Quantify the chances of achieving good, average, and poor health under each of the available treatments.

Calculate which treatment offers the best prospects for health, based on patient preferences and medical evidence. Conduct deterministic and probabilistic sensitivity analysis on evidence & preference assumptions

Screen shot from Software Prototype

	Good	Average	Poor
Work	60 hour weeks, anywhere anytime	40 hour weeks	Halftime
Play	Play tennis, golf, run, swim	Run, swim	Walk
Pain	Mild headaches quarterly	Daily aches from tendinitis or arthritis	On medication
Nausea	Car and boat sickness	Monthly	Weekly
Care for dependents	Hold children, cook daily, clean weekly	Cook weekly, clean monthly	
Significant other	Balanced mutual support	A little needy	
Pets	Horse grooming and stall cleaning daily	Weekly horse care	
Plants	Gardening	Plant-watering	
Appearance	Steady weight	Weight gain, hair loss	
Sexual appetite	Weekly	Monthly	
Sexual functioning	Weekly	Monthly	
Fertility	NA	NA	Infertile
Depression	Only after tragedies	Quarterly	Weekly
Hobbies			
Other			
Driving			

ScreenShot from Software Prototype

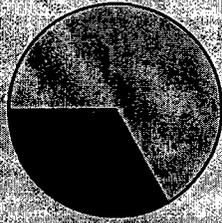
		Probability that health is			Median Time		
		Poor	Average	Good			
CMF	In treatment	10%	40%	50%	0.5	years	
	In recovery	1%	50%	49%	1	years	
	In life	1%	20%	79%	14.50	equivalent "good" years	
AC	In treatment	80%	20%	0%	0.33	years	
	In recovery	75%	20%	5%	1	years	
	In life	70%	25%	5%	14.33	equivalent "good" years	
Tamoxifen	In treatment	10%	40%	50%	5	years	
	In recovery	1%	50%	49%	0	years	
	In life	1%	20%	79%	23.00	equivalent "good" years	

If I had to trade...

I would just be willing to give them up in exchange for... along with...

12 months of average health...
8 months of good health...
4 months of poor health...

Exchanging 1 Average for a Mix of Good and Poor



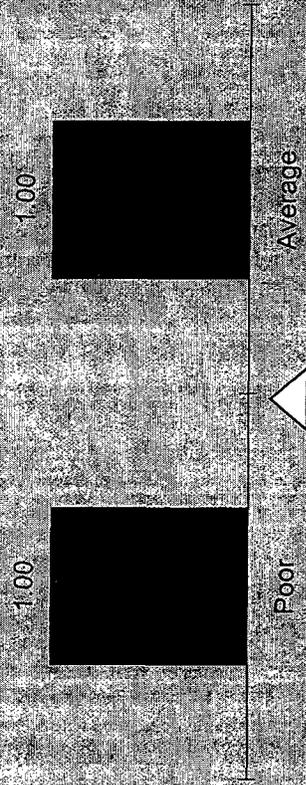
□ Fraction of poor
■ Fraction of good

If I had to trade...

I would just be willing to give them up in exchange for...

12 months of poor health...
12 months of average health...

1 Poor is worth this many Average...



UCSF Breast Care Center Clinical Trials

[Bay Area Breast Cancer Forum](#) | [News Letter](#) | [Breast Cancer Clinical Trials](#) | [Website Links](#) | [Glossary](#)

Welcome to UCSF Breast Care Center Web Site!

Because breast cancer will strike one out of nine women in their lifetime, every woman knows someone with this disease. Advances in diagnostic techniques and therapies have given us modest improvements in survival, but we are still at a loss as to what causes breast cancer, why it spreads, and why it recurs. Can research and clinical trials involving new technology and established practices make a major difference in the future? Our website, focusing on clinical trials and relevant research for individuals, families, and friends of those living with breast cancer, will seek to understand existing barriers and other problems with the current system. Our long term goal is to provide an integrated resource that takes advantage of known strengths and addresses shortcomings in the field. The potential for making a real difference in bringing better trials to the public as quickly as possible can be realized through collaborations, partnerships, and communications between individuals from multiple disciplines, individuals with, and advocates of those with, breast cancer, and the community at large.

Contacts: If you are interested in obtaining more information on specific breast cancer clinical trials offered at UCSF, please call Liz Wieland, clinical trials manager, at (415)353-7213, or e-mail her at elizabew@email.his.ucsf.edu. For comments and/or questions of a more general nature regarding our website, you can e-mail Fern Hassin at: fern@itsa.ucsf.edu.

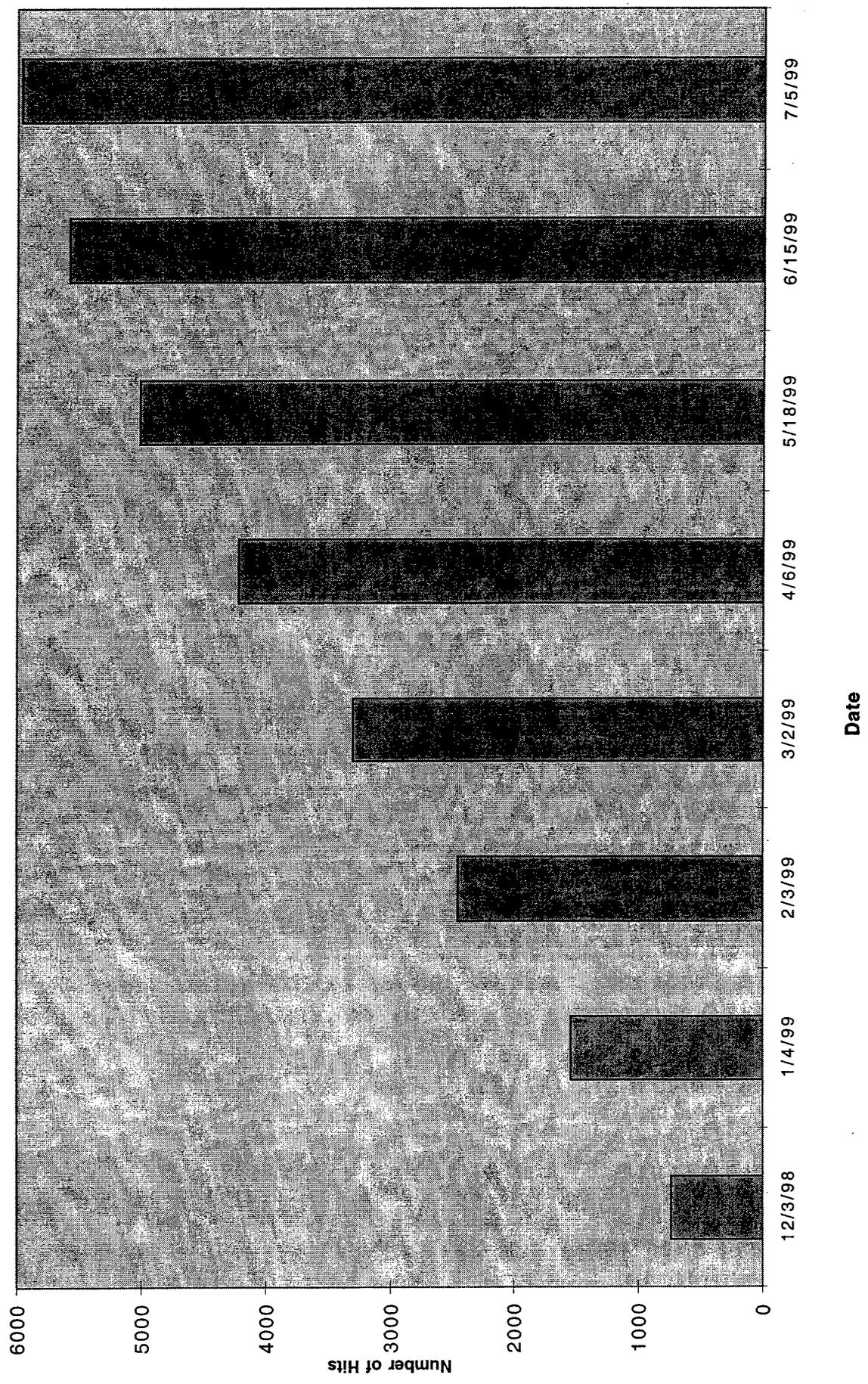
This material was deemed current and factual at the time it was published here. As research progress very quickly and information may change as fast, you should discuss this and all medical information with your health care professional before making any decisions on future treatment options.

(This page has been visited

6874

times.)

Breast Care Center Clinical Trials Website



Minority Health Research Panel
County of Alameda Conference Center
April 23, 1999

~ ~ Schedule ~ ~

12:45 pm

Greetings/Remarks

(Michelle Axel, Outreach Program Manager, Cancer Information Service)

12:55 pm

Overview: CIS Role in Research

(Sharon Davis, Director, Cancer Information Service)

1:15 pm

Minority Health Research Panel Presentation

Christina Perez, Moderator

Coordinator, Office on Minority Health, Region IX

Panelists:

Anna Napoles-Springer, Ph.D.
UCSF, Center for Aging in Diverse Communities
Medical Effectiveness Research Center

Phillip Gardiner, Dr.P.H.
Social and Behavioral Sciences Research
University of California, Office of the President

Ann Chou, M.P.H.
Doctoral student, University of California, Berkeley

Lorraine Provost
Cancer Navigator Program, Highland Hospital

1:55 pm

Question and Answer Period

Christina Perez, Facilitator

2:15 pm

Update on Research Resources

Fern Hassin

UCSF Breast Care Center

Jay K. Harness, MD

UC Davis Department of Surgery, Alameda County Medical Center

2:40 pm

Closing/Evaluation

Refreshments provided by Novartis Oncology, a partner of the National Cancer Institute in Clinical Trials Education
Sponsored by the NCCC's Cancer Information Service in collaboration with Bay Area Tumor Institute,
California East Bay Oncology Nursing Society, Office on Minority Health, Region IX, and
California Department of Health Services Office on Multicultural Health



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)

26 Aug 02

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

SUBJECT: Request Change in Distribution Statement

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


PHYLIS M. RINEHART
Deputy Chief of Staff for
Information Management

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