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13. ABSTRACT *(Maximum 200 Words)*

This grant helped create an interdisciplinary center where the integration of physicians across disciplines has led to an improvement in the management of patients. We see an increase in clinical trial accrual, more attention at the time of diagnosis and fewer numbers of follow-up visits. We created extensive educational materials and a framework for patient-physician collaborative decision-making. A database links clinical information and clinical research. There are programs based on disease stage (prevention to metastatic care) and a longitudinal program for disease management. Project 3 has developed a method to project life expectancy and impact of therapeutic interventions to use as a decision making tool for all patients and for tumor board conferences. We have successfully integrated clinical trials into all stages of breast cancer treatments. Our program volume has grown from 150 patients per month to 1000 patients per month, and from 3 active clinical trials to 33 active clinical trials. We successfully completed a lifestyle intervention and personal support clinical trial showing that women adjust better when they receive psychosocial intensive intervention around the time of their diagnosis. A number of publications are detailing our achievements under this grant.

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A New Vision For Integrated Breast Care
Year 4/5

Introduction

In year four and its subsequent no-cost extension, which for the purpose of clarity we will call year 5, the work of this grant has been essentially completed. However, the foundation which we able to lay through this center grant will expand into a continuingly growing structure, and the programs which were started here will be branched out, assuming that continuing funding can be procured.

As in the past, we have organized the body of the report by presenting separate progress reports from each core. Some highlights include:

Both aims of Project One has been fully and satisfactorily completed, and two manuscripts have been published to describe the results.

Project 2 has resulted in numerous manuscripts, abstracts and presentations. The most important achievement may be the fact that the research has formed the foundation of a new clinical program that is now being offered to women with breast cancer.

Project 3 also will go on to continue as a new program of the Breast Care Center. Our research under the DOD grant has been foundational in establishing the criteria to develop a continuous risk model for patients with early stage breast cancer. While the unexpected difficulties facing us delayed the practical application of the research gained to date, we now have the tools to accomplish this goal in the near future.

Project 4 also has been developed into an ongoing program at the Breast Care Center and has garnered high marks from our patients. The Program for Collaborative Care, as it is now called, is run by a full-time staff member and offers Consultation Planning and Consultation Recording to all patients with a new diagnosis of breast cancer to help them with their treatment decisions.

Similarly, our Pilot Project A will now continue under separate funding in the form of a number of programs which have extended the goals of the original project.

Beyond its tasks of fulfilling the administrative needs of the grant, our Administrative Core has continued to publish the Breast Care Center newsletter to great acclaim (see appendix). Owing to its popularity, we will strive to continue publishing it and are in the process of seeking funding for this purpose.

The CQI Core has continued to define outcome measures that resulted in improved effectiveness and efficiency, especially in terms of data collection. Based on the work that was done in years 1-3 and decisions reached through a series of retreats, a structure was formulated that is described in greater detail in this report and the appendix..

The Informatics Core has developed a comprehensive clinical database (BCCDB) of over 2900 patients. As we describe in this report, this database provides a rich source of demographic and clinical information that is useful for both patient care and outcomes research.

Finally, the Education Core has built educational materials for the diverse needs of the BCC patients. These materials have been the foundation of patient education for the past five years, and will continue to meet the needs of our patients beyond the funding of the grant. The design of these materials allows for individualizing written materials and the timing of their receipt appropriate to the treatment plan.

In the following pages and the extensive appendix, you will find all the details and many practical examples of the results of our work.

Administrative and Continuous Quality Improvement (CQI) Cores

Introduction/Administrative 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. During the grant period of years 4/5, the work of the Administrative Core included:

- 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
- administrative supervision of staff and facilities at the off-campus research offices at 2299 Post.

Special focus was given to the publication of the UCSF Breast Care Center Newsletter, which is now published tri-annually. The latest issue is attached as an appendix. This newsletter, which was funded by the DOD grant until the end of year 4, has become an acclaimed tool for patient contact and information. Pending further funding, the intent is to widen both publication and publish the newsletter quarterly to be able to disseminate more up to date medical information among our patient population.

Continuous Quality Improvement (CQI) Core

During years 4/5, the Continuous Quality Improvement Core continued to define outcome measures that resulted in improved effectiveness and efficiency, especially in terms of data collection. Based on the work that was done years 1-3 and decisions reached through a series of retreats, a structure was formulated that is outline in the following pages.

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.

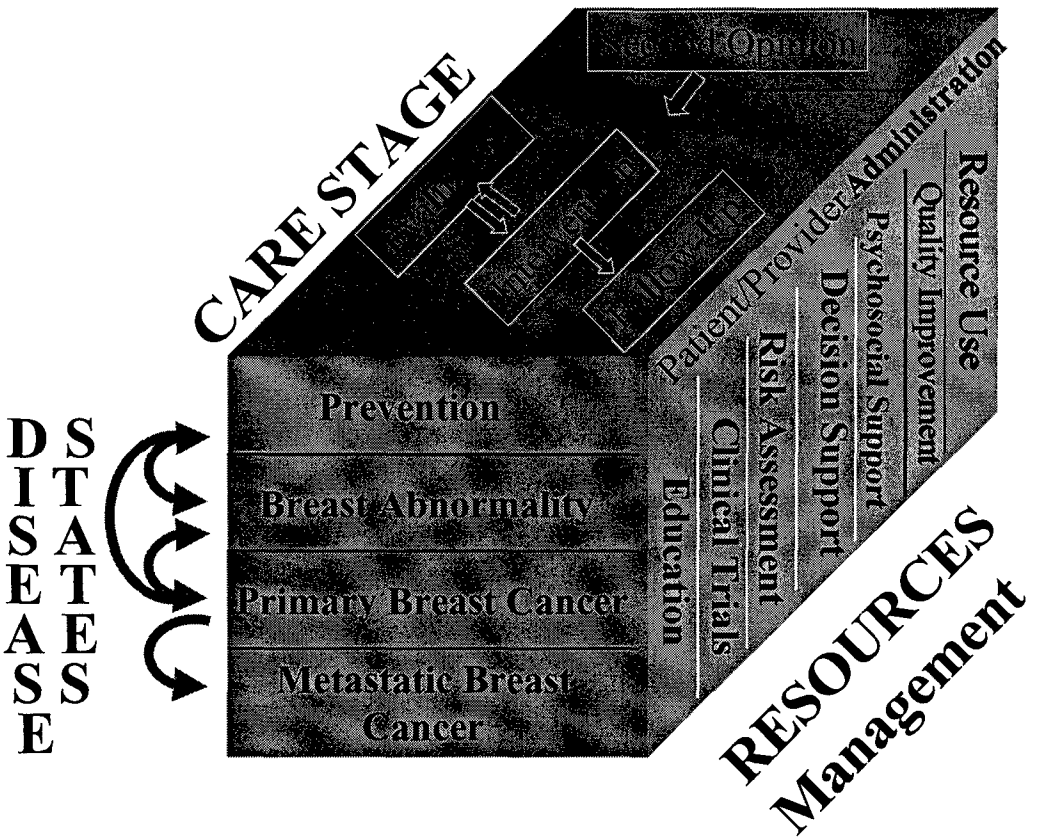
- Issues involved in working with and incentives for private sector companies in the clinical trial arena.

- Business process reengineering issues faced in implementing a clinical trials database.

Patient Focused Care
Service Modules

Figure 1: States and Stages of Care

Every patient who comes to the UCSF Carole Franc Buck Breast Care Center comes in to one of our programs, depending on their "disease state." Figure 1 summarizes the states and stages of care. Based on a patient's state, we have organized resources in the areas of education, psychosocial support, and decision support. Every patient will make choices that depend on their assessed risk and available clinical trials. *We also need to understand the outcome of our interventions and evaluations and the resources expended to achieve a given result, and input from our patients on the quality of our services. Our goal is to set up a model to continuously improve what we do.*



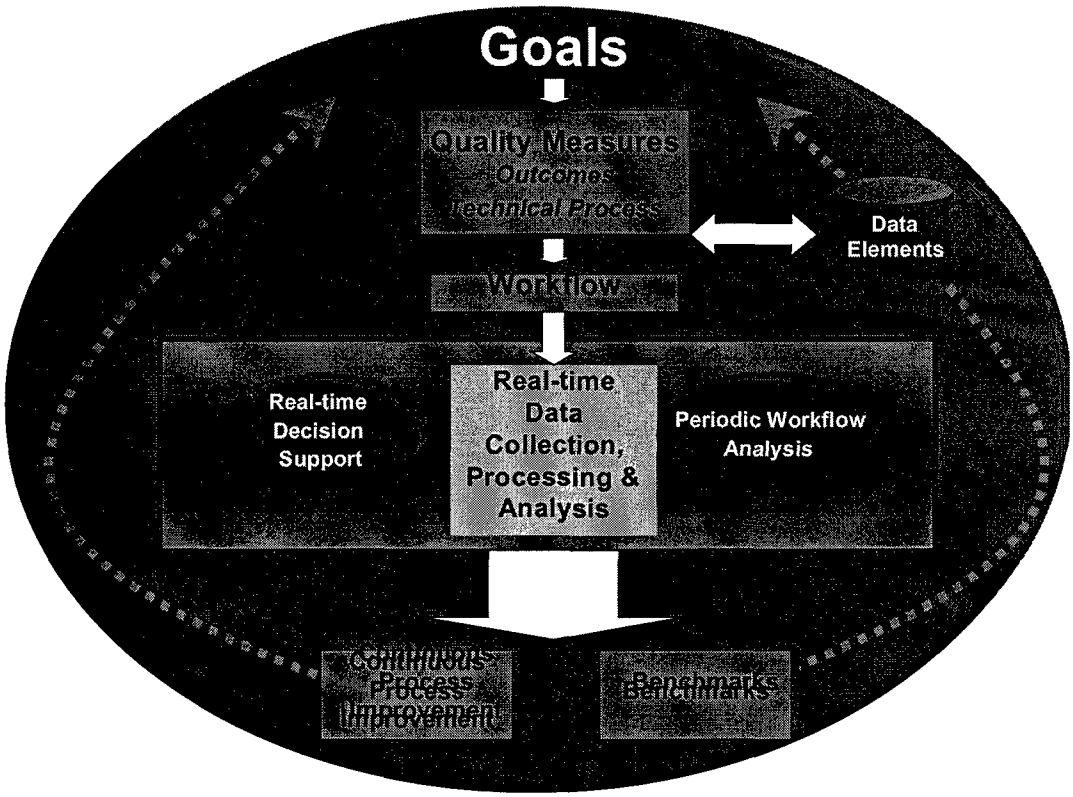
For each of the disease states, we have worked with our team to develop quality measures and define opportunities to coordinate patient services and care as shown in figure 1. Pulling all of the necessary services together to deliver a diagnosis or treatment plan in a single visit is not feasible unless there is sufficient volume to support the process. Once there is volume of patients, the specialties can be brought together with the express purpose of delivering the best service in the most caring and humane environment, while finding new ways to improve the technical process. The opportunity to consolidate services around patient needs has led us to develop

several programs designed to meet our patients' goals as well as our program goals of finding new and better ways to treat and prevent breast cancer.

Quality and Outcome Measures

In order to truly set up a systematic quality improvement program, it is essential to embark on the process of defining goals of care, outcomes of importance, the process of care, and quality measures for those processes. In order to assess our performance, we have to define ways to periodically review performance. However, there will also be information that should inform our decision making and will best be available at the point of care. Our process for evaluating our performance starts as shown in figure 2.

Figure 2: Quality Evaluation Process



Ensuring Consistency of Service and Quality for All Patients Regardless of Provider

Traditionally, the practice of medicine proceeds without communication among individual practitioners, even if they are members of the same practice. Often, each practitioner might offer clinical trials in which they are involved (in an academic setting), and, if they collect data, it is usually what they individually might feel is important. Internal competition among providers is common. A particular patient's access to clinical trials depends upon which practitioner they see. When a patient sees several practitioners, even in the same group, they are often given very

different projections of outcome and benefit, and practitioners are often not aware of the range of outcomes that are presented.

In contrast, the creation of a program results in a comprehensive, integrated approach to breast cancer diagnosis and treatment with consistency among providers. This means that practitioners must meet to agree on the portfolio of clinical trials in which the clinic will participate, as well as the data to be collected and the key quality indicators to be analyzed. Considerable effort and investment in group learning is required. Consensus is required around possible outcomes without therapy and associated risks and benefits with therapy, based on evidence from the literature, so that any patient who comes through the program will receive similar information and be given similar choices, regardless of provider (1997; Hensley, Schuchter et al. 1999; Smith, Davidson et al. 1999; Hillner, Ingle et al. 2000; Recht, Edge et al. 2001). As a result, all providers succeed as the clinic succeeds and patients are provided access to all clinical trials and clinic services regardless of specialist seen.

Group Consensus

For every disease state, practitioners and patients felt we needed:

- The most up-to-date information, designed to support decision making guidelines
  - Meta-analyses
  - Aggregate data on practice patterns
  - Decision models
- Systems for data collection to drive:
  - Improvement in the process of care
  - Improvement in understanding of cancer progression
  - Improvement in quality of life
  - Improvement in survival after breast cancer
- Clinical Trials
  - National trials
  - Investigator-initiated trials
- A Better Understanding of Strategies and Resources to Treat Cancer in context of other life issues (social, medical)

Patient Education

At the core of our educational services for patients is the principle that patients' educational needs and learning styles are diverse and that the needs change over the continuum of care. Within the UCSF Cancer Center, there is a strong collaborative relationship between the Cancer Resource Center (CRC) and the Carol Franc Buck Breast Care Center(CFBBCC). All BCC patients receive a brochure and are encouraged to visit the CRC, which is a library and community resource information and referral resource. A three-ring binder with individualized content is given to the patient either by the physician at the time of diagnosis or by the nurse in concert with the preoperative visit or with the chemotherapy teaching visit. There is a skeleton content in the binders and the binder is then built based on the treatments chosen. Patients whose

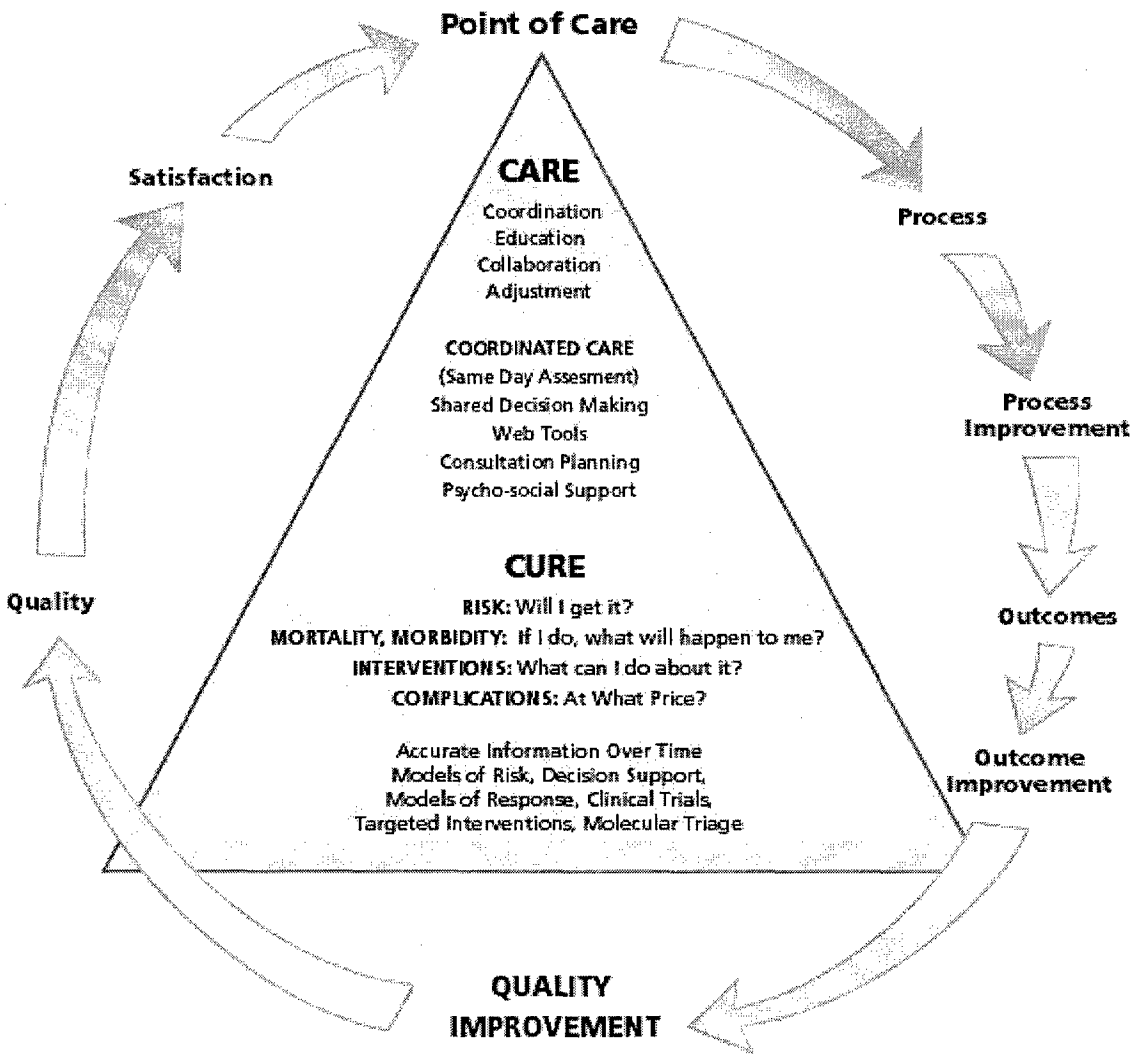
first therapeutic modality is surgery have a ninety minute pre-operative visit with a nurse in the practice. This visit includes a review of pre and postoperative instructions from preoperative logistics through recovery and self-care. It also includes identification of unresolved issues and questions about the diagnosis, treatment decision making and information about breast cancer. In addition, patients are given information about relevant clinical trials if they should choose to participate. Patients are offered both a one-time evaluative consult with a clinical psychologist and participation in our collaborative care program for support in the treatment decision making process. Prior to the initiation of chemotherapy as a treatment modality, each patient meets with a nurse or nurse practitioner for a one-hour chemotherapy teaching session. There are printed materials that are added to the binder with individualized treatment dependant information. Individual providers are educating patients throughout the course of their treatment, in person, by telephone, by email. There is a BCC website (http://breastcarecenter.ucsfmedicalcenter.org/) that provides copies of the information individualized for patients. Dr.Tripathy has been spearheading a community education forum, a once per month topical conversation designed to be of use to breast cancer patients. The core faculty of the BCC provide community education on a regular basis. The plan for the upcoming year is to expand the accessibility of our patient education by collaborative work with members of diverse communities to develop translated and culturally competent and sensitive educational materials for monolingual non-English speaking patients. Our goal is to begin with materials in Spanish, Russian and Chinese as these are the most common languages spoken by our patients.

Clinical Trials

Developing Trials tailored to molecular characteristics, response, and stage

Areas of scientific focus include:

- Prevention and risk stratification using tools developed at UCSF such as phenotypic analysis of cell cycle dysregulation and telomeric crisis and gene copy number abnormalities using array comparative genomic hybridization
- MRI imaging to define anatomy and other tumor characteristics such as vascularity and response to therapy on serial assessments
- Immunological approaches, particularly HER2/*neu* targeting
- Growth factor receptor (HER2/*neu*, EGFR) signal modulation
- Liposomal and immunoliposomal drug delivery systems
- Anti-angiogenic and protease inhibitory therapeutics
- Complementary approaches including herbal/botanical agents for symptom management and anti-cancer indications, and integrated lifestyle interventions following diagnosis and treatment
- Collaborative shared patient-physician decision-making



Point of Care Paradigm Diagram

Patients care about CURE foremost, but they also care about the CARE they receive, how it is delivered, the value it has, and the price (complications, morbidity, indirect cost, and out of pocket cost) they must pay. The type of care likely affects the outcome of care (Hillner, Smith et al. 2000; Esserman LJ 2001; Ljung BM 2001), but how much is unknown. The point is to define the critical outcomes and processes of care, to establish quality measures, and benchmarks, and a dynamic process by which we can rapidly learn and improve. This approach is distinct from the guideline process which is more static and does not incorporate a mechanism for feedback or patient collaboration on decision making. Our approach focuses on the point of care as the ideal place to capture information and foster education, learning, change, and improvement. The system we propose also frees us from the constraint of measuring quality and outcomes with what is available in research and claims databases. It allows us to start first by defining goals of care, quality measures and targets for improvement. With that as a guide, we can develop decision support, data models, data collection tools, feedback algorithms, process improvement

protocols, better and more focused clinical trials, and mechanisms to integrate translational research more quickly into care. Automated ways of measuring change will enable us to shorten the learning cycle. The result will be the creation of a system where learning and improvement is an integral part of care delivery.

Personnel Changes

Tad Lacey, MBA, MPH,. worked with the CQI Core through June of 2000. Tad was able to assist with the database development project and lead the faculty through multiple sessions in order to define the goals and/or targets of therapy for each of the disease states. Cheryl Ewing, MD, Assistant Professor of Surgery, joined the Breast Care Center faculty in January of 2001. Although Dr. Ewing came to the BCC when the grant was in it's final stages, her background in CQI has assisted the team in carrying out the ongoing CQI effort. Her biosketch is attached as an appendix.

Conclusion

Identification and implementation of quality measures is important not only for internal CQI purposes but also as a means for performance measurement by various stakeholders, including patients, health plans, accrediting organizations, and purchasers. As an important part of the goals for year 4, the CQI Core attempted to define and implement outcome measures for the spectrum of breast cancer care that met the following criteria:

- Measures that are relevant to patient care and clinically useful.
- Measures that could be collected at the time of the patient encounter.
- Measures that are representative of important areas of patient care for breast cancer, such as administrative functioning of the Breast Care Center, surgical care, medical evaluation and treatment, pathological diagnosis, access to clinical trials, and patient satisfaction.
- Measures that could be compared to benchmarks as valid assessments of quality.
- Measures that could serve as building blocks for systems of performance measurement sponsored by accrediting organizations (JCAHO, NCQA), health plans, employers, and consumer organizations.

As described in the DOD report for year 3, several measures were developed and considered for implementation for CQI and reporting purposes, including time from patient intake to diagnosis, surgical re-excision rates, use of adjuvant chemotherapy in patients with metastatic breast carcinoma, cancer to biopsy rates, counseling regarding available clinical trials, and patient satisfaction surveys. During year 4, the redesigned clinical assessment tool was implemented to improve administrative efficiency and improve data collection for targeted measures, such as access to clinical trials (numerator = number of patients enrolled in clinical trials, denominator = number of patients offered appropriate clinical trials). Despite the availability of improved forms for data collection, implementation of quality measures in the Breast Care Center proved to be difficult for the CQI Core for a variety of reasons. Barriers included variation in practice styles by different clinicians resulting in incomplete data collection, increased time requirements for

both patients and clinicians, the difficulty in designing appropriate measures that were feasible, methodologically sound and represented important aspects of patient care, the lack of an electronic medical record system that could be used at the point of care, incomplete benchmark data for comparisons, and insufficient administrative and research personnel for data collection, collation, and tracking.

In summary, the CQI Core achieved many of the year 4 goals in regard to improving processes of care within the patient focused care service modules. Developing and implementing outcome measures that are relevant to patient care, can be easily collected and reported, and are true assessments of quality of care is an important, long-term goal in the improvement breast cancer care. Rather than retrospective data collection by accrediting organizations and health plans, the CQI Core attempted to design prospective quality measures from the delivery system point of view. The field of performance measurement is in its infancy*, and further progress will require improved information systems with decision support, outcome tracking, clinical trial linkages, and feedback on performance using appropriate benchmarks. Research should be directed at improving methods for developing measures that are clinically useful in patient care yet can be sufficiently flexible to be adapted for measurement at other levels, such as by health plans, Medicare, purchasers, or consumers. The experience of the CQI core suggests that this is feasible in an integrated, patient-focused delivery system and will be accelerated by improvements in the science of measurement and by better information systems.

*Eddy, David M., "Performance Measurement: Problems and Solutions." Health Affairs 1998, Vol. 17, No. 4 (July-August), pp. 7-25.

Informatics Core

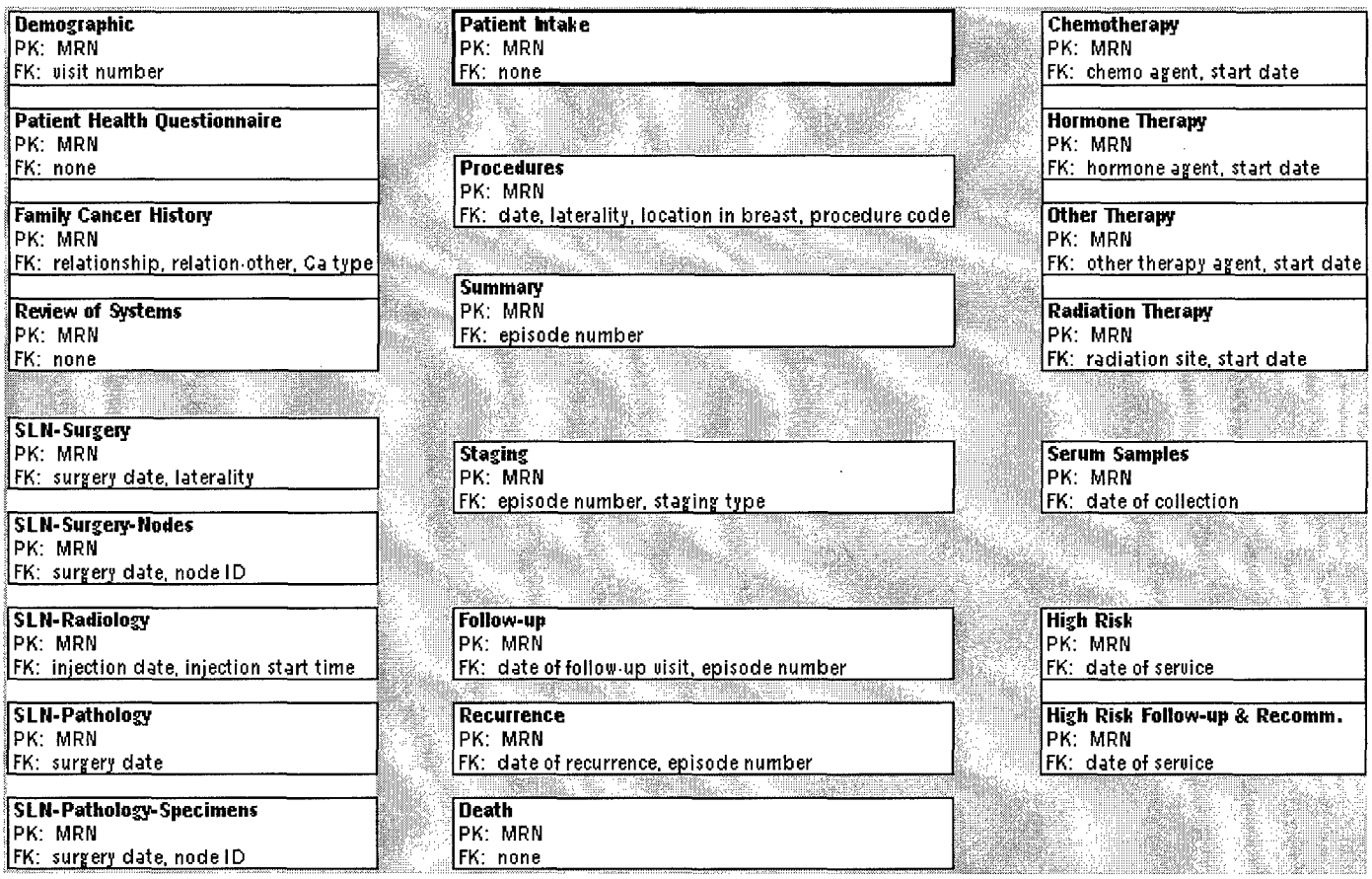
Statement of Work

Introduction

The Informatics Core of the UCSF Breast Care Center (BCC) has developed a comprehensive clinical database (BCCDB) of over 2900 patients. As we describe in this report, this database provides a rich source of demographic and clinical information that is useful for both patient care and outcomes research.

Breast Care Center Database (BCCDB): Data elements/data dictionary

A fundamental aspect of any database is the database design, which encompasses both the data tables and the data elements (i.e., the individual data fields). The BCCDB, written in Microsoft Access 97 and Visual Basic, has undergone continual refinement over several years, and its data tables can be represented by the following figure:



In the figure, each rectangle represents a data table. The "PK" is the primary key, or main data element that is used to identify each entry in the table uniquely. The "FK" is the foreign key, which is used to link the data in one table to the data in another data table. This design, which is fundamental to a relational database, allows for database integrity of the BCCDB, in which, for example, multiple entries for the same patient cannot be inadvertently created.

The database chart also shows data tables for SLN (Sentinel Lymph Node) and High Risk data. These tables represent another important accomplishment of the Informatics Core. Specifically, two specialized databases were created by the Core to serve the highly specialized needs of two groups of BCC patients: patients who underwent sentinel lymph node testing, and patients who met the criteria for high risk of

breast cancer. Initially created as standalone databases, they have now been merged into the primary BCCDB.

Data Acquisition

The Informatics Core has been very successful in developing data entry forms and online data screens to populate the BCCDB. As a result, we now have the following number of patient records in the BCCDB:

DATA TABLE NAME	# OF ENTRIES
patient inquiries	956
patient intake	2930
clinic intakes only	840
demographic	1062
patient health questionnaire	876
review of systems	593
family cancer history	656
procedures	411
chemo	107
hormone	155
radiation	134
other therapy	8
staging	325
follow-up	2111
recurrence	56
summary	331

The data table names correspond to the database design figure above. As can been seen, the BCC clinic staff have entered initial patient intake information on over 2900 women. Of these, over 800 have had additional detailed information such as a complete patient health questionnaire entered into the BCCDB. Follow-up on over 2000 patients has been recorded in the BCCDB. Additionally, as part of a new clinical feature of the BCCDB, a summary record has been created for over 300 patients, and this information is provided in a report to the BCC physicians when they are seeing the patient. This powerful feature of the BCCDB allows clinicians to have up-to-date information in an easy-to-read, summary format for the patients they are treating. An example of a patient summary report is provided below.

Patient Outcomes

As described above, the BCCDB contains follow-up information on over 2000 patients. The database also contains details of procedures performed on over 400 patients, as well as selected treatment information.

Because the BCCDB is a relational database written in Access 97, all of its data elements can be queried and reported on easily. Thus, for example, demographics data can be combined with staging, treatment, and follow-up data to produce an age- and stage-based report of treatment results.

Conclusion

The BCCDB is a rich data source for clinical care and outcomes research at the UCSF Breast Care Center. Detailed descriptions of BCCDB reports and database forms, tables, and elements can be found in the Appendix.

Education Core

Summary

Year 4/5 of the grant enabled the Education Core to complete on-going projects and implement systems to continue our programs beyond the funding of the grant. Assuring the sustainability of our educational programs was a priority in this final year. We focused on systematizing our programs and materials, so that regardless of changes in personnel, hospital structure, or clinic location, the work completed with this grant funding will continue to serve all of the patients of the UCSF Carol Franc Buck Breast Care Center (BCC) for years to come.

Breast Cancer Educational Materials (see appendix)
(Please note: The 3-ring binders themselves are not included. We have included examples from each topic, not the entire content, to avoid excess weight and volume. Full binders are available on request.)

The members of the Education Core built educational materials for the diverse needs of the BCC patients. These materials have been the foundation of patient education for the past five years, and will continue to meet the needs of our patients beyond the funding of the grant. The DOD grant enabled us to build a strong foundation for patient education by enabling the staff to develop materials covering the spectrum of educational needs. The design of these materials allows for individualizing written materials and the timing of their receipt appropriate to the treatment plan. We also reviewed materials and found ways to systematize our programs. Patients who have surgery as their first treatment modality have a 90 minute pre-operative visit with a nurse. The educational binder, either given at diagnosis by the physician or at the time of the preoperative visit by the nurse, is individualized by inserting the relevant modular pieces. For patients receiving neoadjuvant chemotherapy, they are scheduled for a 60 minute visit with the nurse practitioner, it is there that the educational binder is received. Each subsequent therapy is accompanied by educational materials. The binder is supplemented by pamphlets, including the California State Guide required by statute to be given to all patients undergoing breast cancer treatment. We expanded our access to patient education by helping to develop the BCC website as well. Although our major focus was to assist women who have been diagnosed with breast cancer, we also developed materials to meet the specific concerns of women at high risk for breast cancer. In the future, we hope to expand our educational program for women in our developing programs for follow up care and metastatic breast cancer.

Develop
Within year 4/5, we have produced new materials on additional topics related to breast cancer diagnosis, treatment and recovery. We developed materials on breast reconstruction including decision making for breast reconstruction, TRAM Flap, latissimus dorsi flap and implants, post-operative exercises, radiation therapy, follow-up care, and other issues related to breast cancer, including the impact of breast cancer on sexuality, menopause, and osteoporosis.

Review and Revise

A large part of the development process in year 4/5 was to review and revise existing materials developed in previous years and to incorporate the final printed versions into clinical use. Our multi-disciplinary team of surgeons, medical oncologists, radiation oncologists, radiologists, pathologists, advanced practice nurses, and clinic administration reviewed our materials. The process of completing this collaborative review resulted in standardizing clinical education.

Systematize

The final step in the process of systematizing was to restructure our existing patient education folders into a modular binder system. This system enables us to personalize patient education binders to the specific needs of each woman. The components of the binder are:

Surgery: includes information on lumpectomy/reexision, lumpectomy with axillary lymph node dissection, sentinel lymph node dissection, mastectomy, Jackson-Pratt drains, post-operative exercises, post-surgical resource sheet, and breast reconstruction.

Chemotherapy: includes an orientation to the Infusion Center, a chemotherapy guideline with instructions and tips for symptom management, anti-nausea information, wig/hat/scarf resources, and specific drug information sheets

Radiation Therapy: includes an introduction to radiation therapy at UCSF as well as a skin care information sheet

Hormonal Therapy: includes an introduction to hormonal therapy and specific drug information sheets

Emotional Support/ Resources: includes information on supportive care and educational services at the BCC and the Ida and Joseph Friend Cancer Resource Center, collaborative care, and a list of breast cancer related websites

Follow-up Care: includes an introduction to the Follow-Up Program, a summary of our follow-up care practices based on the American Society of Clinical Oncology (ASCO) follow-up guidelines, and finally a copy of the ASCO guidelines

Healthy Lifestyle: includes information on self-care, nutrition, hydration, exercise, meditation, guided imagery, and sexuality

Clinical Trials: includes an introduction to our clinical trials program, letters from our patient advocacy core, and a current list of open clinical trials at the BCC

Complementary and Alternative Medicine: includes an introduction to program, a current list of open CAM trials at the BCC, and information on traditional Chinese medicine as a holistic treatment for breast cancer

Other Topics: includes information on lymphedema, menopause, osteoporosis, and any other topic that needs to be added

Each woman will only receive the information that is relevant to her clinical situation. As she progresses through her care at the BCC, the providers will add the information needed. For example, only when a woman is finished with all of her treatments and is beginning her long-term follow-up care will she receive the Follow-Up module of the binder.

In addition to the above materials that we have developed, the pockets of every binder will include:

"A Woman's Guide to Breast Cancer Diagnosis and Treatment" developed by the California Department of Health Services and mandated by law
NCCN/ACS "Breast Cancer Treatment Guidelines for Patients"
National Cancer Institute's "Taking Part in Clinical Trials: What Cancer Patients Need to Know"
"Don't Fear It, Fight It" brochure on clinical trials developed by the BCC
BCC newsletter
Friend to Friend brochure—Friend to Friend is the UCSF Cancer Center boutique
"UCSF Clinical Cancer Center Supportive Care Guide" developed by the Ida and Joseph Friend Cancer Resource Center

High Risk Program

We also developed a binder of information for the newly developed UCSF High Risk Program. The information in this binder includes:

- Introduction to the UCSF High Risk Program
- NCI's Overview of breast cancer prevention
- Lifestyle: which includes information on self care, nutrition, hydration, meditation, and guided imagery
- Clinical Trials:
- National Cancer Institute's "Taking Part in Clinical Trials: Cancer Prevention Studies What Participants Need to Know"
- Overview of National Cancer Institute supported breast cancer prevention trials
- NCI's Questions and Answers about Hormone Replacement Therapy
- NCI's Questions and Answers about Tamoxifen
- NCI's Preventative Mastectomy
- Information on the UCSF Cancer Risk Program
- Breast self-exam brochure
- Nutrition and Cancer Prevention information

Translation

We have not completed our translation of the educational binder into our three target languages: Russian, Spanish and Chinese. We are in the process of developing a collaborative relationship with the Breast Clinic at San Francisco General Hospital (the county hospital), a major component of which is to develop educational materials that are culturally competent and available in a range of languages to meet our populations' needs. It became clear, in the process of preparing information to translate, that it would be shallow and not meet patients' needs to merely translate the English to other languages. The work of making our educational materials

culturally and linguistically relevant is not done and remains a major unmet goal for the future. At this time, paid, professional translators are available for the above discussed educational sessions and we use the very few translated materials that we have.

Website (see appendix)
A major project within the year 4/5 of the Education Core was to assist in the development and production of the new BCC website. Education Core staff helped design the structure of the site in order to insure easy assess to information. The site is live and the address is: www.ucsfbreastcarecenter.org

The site is an important addition to our patient education resources, because a significant subset of our population relies on the Internet for information. The Education Core and BCC staff recognize the role the Internet plays in patient education and health research, therefore, we have made our materials available via the web. Our site is also an excellent resource for the community at large, as women with breast cancer, family members, friends, and members of the local, national, and international breast cancer community are now benefiting from our materials.

Advocates
The Education Core met regularly with the BCC Advocacy Core. This group of fifteen patients has been influential in reviewing our educational materials and programs. They serve as a patient advisory committee for the BCC and are helping to increase community outreach specifically around the issue of clinical trials. They have written a letter describing clinical trials from a patient's perspective, and this is included in the patient education binder. They have also written two separate letters describing specific trials and the importance of participating in them. The advocates will continue to be consulted on educational projects and will maintain an active role in the BCC as they offer an important perspective.

Outcomes Measures (See appendix for evaluation tool)
We have obtained results from the appended evaluation tool for 40 patients in year 4/5. We are continuing to use the evaluation tool in an ongoing way to evaluate the efficacy of the educational intervention. We recognize that this evaluation tool does not directly measure patient learning, but measures patient satisfaction and perception of learning from the educational session with the advanced practice nurse and the educational binder.
Summary results have been added to appended evaluation form, but in summary, the majority of the patients who returned surveys rated the information received as very good or excellent, as geared to appropriate level of complexity of information, and had a positive experience of the nursing visit intervention. Important comments included a request for more language specific information, more time with the nurse to ask questions and some expression of overwhelm at the amount of information. The bulk of the feedback was positive.

Continuity of Care
Over the course of the last two years, UCSF and Stanford have implemented a process of undoing their institutional merger. The inpatient facilities of the Mount Zion(MZ) site, after a time of being closed, have reopened with a new post surgical unit for breast surgery patients, excluding those who require intensive care unit level care. These institutional changes and challenges have complicated designs for continuity of care. However, with the advent of the

newly opened post surgery unit, continuity of care, including education of nursing and resident staffs, has improved greatly. Standardized post operative orders (appendix) were written collaboratively to both guide practice and make appropriate clinical interventions with patients more available in a timely way.

Professional Literature Bank

We have revised the system to build our professional literature bank. In previous years of the grant, we built a literature bank with hard copies of the articles. We found that it was not useful to providers, as it was cumbersome and difficult to maintain. We then moved to an online literature bank, which we built from weekly searches done by the staff of the UCSF/Mount Zion library. However, the number of articles we were receiving from these searches was overwhelming-- over one hundred articles per week on breast cancer. It was too difficult and time consuming to review these articles, choose which ones were the most pertinent, and then to put the results of the search into an Endnote file. This year, we are revising the search to only include certain journals, review articles, and meta-analyses. The format of the file has also changed, and can be sent in an Endnote-ready form. Providers who request to be included in the list can receive the searches directly from the library. Our original intent, to have the core staff of the Breast Care Center manage and review all of the incoming literature has been unsuccessful. It is simply too time consuming and was underutilized. We have maintained access to the library generated searches and we continually are working to update core literature for students at all levels. As we now have a surgery fellow in our practice, the members of the education core will work collaboratively with the surgery fellow to update our core literature available to students.

The Ida and Joseph Friend Cancer Resource Center(CRC)

The Education Core staff works closely with the Resource Center staff to promote patient education and to provide the resources to support patients through the process of diagnosis, treatment and recovery. Services include books, videotapes, audiotapes, newsletters, information searches for patients and family members using Medline, the Internet, and other healthcare resources. The CRC also offers support groups and other programs like yoga, dance, and diverse educational seminars. The center is open Monday-Friday from 8:30AM-5:00PM, is open to the public, and all programs and services are free of charge. There were between 180 and 223 patient visits per month to the CRC in 1997; this has grown to between 526 and 1010 patient visits per month in the year 200. Approximately, one third of the patient visits are estimated to be breast cancer patients. An Education Core staff member's office was in the Resource Center to promote continuity of care, to share educational materials and to serve as a liaison between the Resource Center and the BCC. Now that we no longer have a paid staff person in that combined role, the advanced practice nurse serves on the Resource Center Advisory Committee and the collaborative work has been sustained. The Resource Center staff is a team participant on the joint educational project with the county hospital.

Peer Support Program (see appendix for PSP brochure)

The Peer Support Program developed out of the Breast Care Center's Patient Navigator Program. The Peer Support Program offers cancer patients the opportunity to speak with veteran patients – others who have already "been there". It also offers veteran patients the opportunity to share with others the knowledge and insight gained from their cancer experience. By doing so, they are able to connect with others in a rewarding and constructive way.

The goals of the program are to match cancer patients to veteran patients in order to provide individual support, reduce feelings of isolation, anxiety, and fear, assist in the development of coping skills and to help navigate the health care experience.
The program is open to any cancer patient at any stage of the disease, and at any point during the cancer experience. The volunteers are patients who have lived with cancer and who want to help others. Patients are matched with a volunteer according to what criteria they consider most important – be it age, diagnosis, treatment, language, gender, ethnicity, religion, or familial status. Requirements to be a volunteer include being at least one year past original diagnosis, and to go through an extensive screening and training process. The training process includes a four-hour training session with presentations from Cancer Center psychologists, nurses, Education Core and Resource Center staff.
There have been two training sessions this year, one in the fall and one in the spring. Forty-five volunteers have completed the training, and twenty-five of those are breast cancer volunteers. The Education Core staff is responsible for the outreach, screening, intake, training of these volunteers as well as the matching, and follow-up of all these breast cancer volunteers with patients. Approximately thirty-five breast cancer matches were made this year. The program is off to a very successful start and we are already planning another training in September.

Community Outreach and Education

Another focus during year 4/5 was on community outreach and education. This was done in different ways, and to diverse audiences. The demographics, awareness levels about breast cancer, and topics varied. However, the goals of all of our outreach efforts were similar: to educate both lay and professional populations about the various aspects of breast cancer screening, prevention, diagnosis, and treatment.

Education Core staff were involved in coordinating "Town Hall Meetings" in underserved communities of San Francisco, including the Bayview Hunters Point and Sunnydale. These are largely low-income African-American neighborhoods. The staff worked with the Department of Public Health, Breast Cancer Early Detection Program, American Cancer Society, and local community organizations to plan the forums. The goal was to increase awareness about breast cancer, educate about the importance of screening, and reduce barriers of access to quality health care among underserved women. Attendance was between 100 and 150 people at all three events, largely African-American women.

Education Core staff also presented educational programs to various professional groups and organizations, including the Women's Cancer Resource Center, Charlotte Maxwell Complementary Clinic, Breast Cancer Early Detection Program, and various groups of UCSF physicians and staff. Topics of these programs included general breast health, breast cancer screening, improving clinical breast examination skills, communication and collaboration, and decision making after a breast cancer diagnosis. We also represented the BCC and distributed educational materials at professional conferences including the American Association for Cancer Research.

The Education Core also participated in larger community events to educate and raise awareness about breast cancer. The San Francisco Race for the Cure is an annual event, with 12,148

patients, survivors, and supporters participating this year. The BCC had a booth with educational materials, information, and BCC physicians available to answer questions. Women's Health 2000 is a conference put on by UCSF Women's Health. Over 450 women attended the event, and BCC staff gave presentations, taught breast self-exam techniques, and distributed educational information at the BCC booth. Saks Fifth Avenue had a three-day event to raise money for breast cancer, and we provided all of the educational materials, information, and staff for this event as well. We also provided the educational support for events at the U.S. Post Office honoring the breast cancer stamp, the Taste for the Cure (a BCC fundraiser), BMW of San Francisco and various health fairs throughout the year. Finally, Education Core staff also coordinated the BCC's program for "Take Our Daughters to Work Day." This outreach to twenty young girls, aged 9-12, was a unique way to educate them about health in general.

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 4/5

Aim 1
This project is completed. The data analysis is completed, and a manuscript is in the process of being published (see reportable outcomes).

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 has been completed. Four hundred fourteen women responded to the follow-up telephone survey (85% of eligible women).

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 have been completed.

Task 5 - Data Analysis:
We have completed data cleaning and data analysis.

Aim 2
This Aim has been completed. A manuscript is in the process of being published (see reportable outcomes).

Key Research Accomplishments

- Completed all data collection for this project. Four hundred eighty-eight women agreed to participate and have completed the baseline telephone survey.
- 85% of these women completed the follow-up survey.
- The chart abstraction has been completed.
- Data cleaning has been completed
- Data analysis has been completed. Two manuscripts have been published.

Reportable Outcomes

Manuscripts

- Haas J, Kaplan C, McMillan A, Esserman L. Does Timely Assessment Affect the Anxiety Associated with an Abnormal Mammogram Result? (Journal Of Women's Health & Gender-Based Medicine, Vol. 10, no. 6, July/Aug. 2001)

- Ljung BM, Drejet A, Chiampi N, Jeffrey J, Chew K. Diagnostic Accuracy of Fine Needle Aspiration Biopsy is Determined by Physician Training (Cancer Cytopathology, Vol. 93, Issue 5, 25 August, 01)

Project 2
Psychosocial Program

This program was 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 (CAM 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 was 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 through 4 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. Our original idea was to have a wait-list control group, consisting of women who would not receive the intervention immediately, but would wait for 12 weeks. They would serve as the control group and would be followed during the time period that the intervention group was conducted, but would not receive the intervention until after that group was finished. We were not able to have traditional wait-list control groups, because of difficulty in recruiting (see below), and women's lack of interest in waiting for a group.

We finished running the interventions and collected post, six-month and one-year data in Year 4-5 (with the exception of the medical data, information is still being gathered). In total, 181 women participated in the program. Both interventions were found to be associated with improved quality of life (CAM, p=..008; Standard, p=.006), decreased depression (CAM, p=.004; Standard, p=.02), decreased anxiety (CAM, p=.0003; Standard, p=.02)and increased "spiritual well-being" (CAM, p=002; Standard, p=.003). At baseline, very high correlations were noted between measures of quality of life, mood, and spiritual integration. At the end of the intervention, the CAM group showed higher satisfaction (p=.006) and fewer dropouts (p=.006)compared to the standard group. Better outcomes in quality of life in the CAM group were associated with lower initial fighting spirit (r=-.39, p=.001),greater helplessness/hopelessness (r=.37, p<.01), higher depression (r=.34, p<.01), and lower initial spiritual integration (r=.27, p=.05). While long-term changes in quality of life, mood, etc. can be examined, it will not be possible to examine changes in health care utilization, as this data was to be provided from another project in the overall grant, which was not able to collect the data. In addition, medical data which was to have been furnished in part by another project on the overall grant, has been difficult to collect. Efforts are still being made to collect this data.

Some preliminary results of the pre-post and six-month data were presented at the following conferences: 1) the Fifth World Congress on Psycho-Oncology held in Melbourne, Australia, Sept. 3-7, 2000; 2) the Pan-American Congress of Psychosocial Oncology, in New York October 1999, 3) the annual meetings of the Society of Behavioral Medicine, in Nashville, TN in March

2000 and in Seattle March 2001; and 4) at the Era of Hope meeting in Atlanta, GA in June 2000. A further talk will be held at the annual meeting of the American Psychological Association, in San Francisco, August 2001.

The first paper from this project has been submitted to the journal Psychosomatics. Further papers are in the works. A second paper that is almost ready for submission looked at a subset of the women, those who manifested full or partial post-traumatic stress disorder (PTSD) at baseline. There were 24 women in the CAM group (26%) and 17 women in the standard group (19%) who met the criteria for full or partial PTSD. At baseline, women with PTSD symptoms were significantly younger that women without PSTD symptoms ($p<.02$), and there was no significant difference in time since diagnosis. Women with PTSD also had a significantly lower quality of life ($p<.0001$) including spiritual well-being ($p<.0001$) and greater emotional distress ($p<.0001$) at baseline than the women who did not exhibit a significant amount of PTSD symptoms. The women with PTSD also reported being more fatalistic about their cancer ($p=.007$), feeling more helpless/hopeless ($p<.0001$), more anxious ($p<.0001$) and used both emotional expression ($p<.0001$) and affect regulation ($p=.03$) as a way to cope with their cancer. They also used more avoidance coping than the women without PTSD ($p<.0001$). Women with PTSD also reported significantly more re-experiencing, avoidance, and arousal symptoms ($p<.0001$ for each symptom cluster). Women with PTSD symptoms also felt less sexually attractive than the women with low PTSD symptoms ($t=4.75$, $p<.0001$), worried more about the effects of stress on illness ($t=-5.02$, $p<.0001$), and felt that the illness was a form of punishment ($t=-2.27$, $p=.02$).

At the end of the intervention, the women in the standard group had more significant decreases in distress and increases in quality of life than did the women in the CAM group. Both groups had significant decreases in overall PTSD symptoms. Both groups also had significant decreases in avoidance. However, only the women in the Standard group had significant changes in re-experiencing and arousal symptoms. The number of women with PTSD symptoms also decreased by the end of the interventions. Among the women who had been classified as having partial or full PTSD at baseline, there was a reduction of 94% among the women in the Standard program, as compared to a 72% reduction among the women in the CAM group. This difference was significant ($X^2=3.9$, $p=.05$). The women in the Standard group also had greater increases in quality of life, whereas the CAM group had significant increases in Functional Well-Being only ($p<.05$). The Standard group had significant changes in Emotional Well-Being ($p<.01$), Functional Well-Being ($p<.01$), the additional items subscale ($p<.05$), Spiritual Well-Being, Faith and Assurance ($p<.01$), Meaning and Peace ($p<.05$) and overall quality of life (FACIT all, $p<.01$). The women in the Standard group also had significant decreases in anxious preoccupation ($p<.01$) but not in any of the other adjustment styles. They also used significantly less emotional discharge after the intervention ($p<.05$). This paper is being finalized for submission to General Hospital Psychiatry.

Other accomplishments not on SOW not reported earlier:
Team Building and thematic exploration exercises were conducted. The team met in a "process group" every three weeks to discuss any programmatic or interpersonal issues that may have

affected the delivery of care, including the end of the program. We have also had a once per year daylong "staff retreat".

We continued with our two clinical psychology doctoral research assistants. One of these students presented a paper and the other a poster at the annual meeting of the Society of Behavioral Medicine in Seattle, March 2001 (Klein, Levine, & Targ, 2001; Klein, Rundel, Levine & Targ, 2001). Two of our former graduate students completed their dissertations based on our data (see Reportable Outcomes). One of these dissertations (examining the role of spiritual well-being in quality of life of women with breast cancer) was presented as part of a symposium held at the annual meeting of the American Psychological Association meeting in Washington, DC in August 2000 (Cotton, Levine, Bressler, Heide, & Targ, 2000). It also served as the core of an article that appeared in the journal Psycho-Oncology in 1999 (Cotton, Levine, Fitzpatrick, Dold, & Targ, 1999). The other dissertation (an examination of the role of fatalism viewed instead as acceptance of breast cancer) was presented as a poster at the Fifth World Congress on Psycho-Oncology, held in Melbourne, Australia, Sept. 3-7, 2000 (Fitzpatrick et al. 2000).

Key Research Accomplishments

What may be considered as most important, a clinical program has spun off from the research and is being offered to women with breast cancer. The program is continuing the 12-week format as well as offering three-day retreats. The director for this program one of the psychologists involved in the grant: Carol Kronenwetter, Ph.D.

Problems

1. Data: We have had problems collecting medical data. Much of this is due to lack of centralized records. Specific physician's offices have to be contacted.

Reportable Outcomes

Abstracts

Klein, A., Levine, E.G., & Targ, E. (2000). Differences in psychosocial well-being between lesbian and heterosexual women with breast cancer. Annals of Behavioral Medicine, 22, (supplement), 44.

Klein, A., Levine, E. G., & Targ, E. (2001). The relationship between perceived health and psychosocial well-being among women with breast cancer. Annals of Behavioral Medicine, 23 (supplement). 72.

Klein, A., Rundel, M., Levine, E. G., & Targ, E. (2001). Breast cancer in survivors of child abuse: Psychosocial well-being and treatment considerations. Annals of Behavioral Medicine, 23 (supplement). 72.

Levine, E. G. & Targ, E. (2001). Predicting amount of meaning and purpose in life of women with breast cancer. Annals of Behavioral Medicine, 23 (supplement). 63.

Levine, E. G. & Targ, E. (2001). Change in post-traumatic stress symptoms following psychosocial treatment for breast cancer. Annals of Behavioral Medicine, 23 (supplement). 123.
Levine, E.G., & Targ, E. (2000). Differences in psychological status of older and younger newly diagnosed women with breast cancer. Annals of Behavioral Medicine, 22, (supplement), 61.

Levine, E.G, Targ, E. et al. (2000). A comparison of alternative-mind/body and support interventions for women with breast cancer. Annals of Behavioral Medicine, 22, (supplement), 127.

Rundel, M., Levine, E.G., & Targ, E. (2000). Use of alternative medicine by women with breast cancer. Annals of Behavioral Medicine, 22, (supplement), 65.

Presentations:

Cotton, S. P., Levine, E. G., Bressler, J, Heide, F., & Targ, E. (2000). Spirituality, Quality of Life, and Psychological Adjustment to Breast Cancer. Presented at the annual meeting of the American Psychological Association, Washington, D.C., August 2000.

Fitzpatrick, C. M., Levine, E. G., Heide, F., Zelman, D., & Targ, E. (2000) Re-examining the construct of fatalism in women with breast cancer: Stoic resignation versus spirituality focused acceptance. Presented at the Fifth World Congress of Psycho-Oncology, Melbourne, Australia, September 3-7, 2000.

Levine, E.G, Targ, E., Stone, B. M., & Kronenwetter, C. (2000). A comparison of complementary and traditional psychosocial treatment for breast cancer. Presented at the Fifth World Congress of Psycho-Oncology, Melbourne, Australia, September 3-7, 2000.

Levine, E.G, Tario, J. D., & Targ, E (2000) Reduction of hopeless/helpless coping style in women with breast cancer. Presented at the Fifth World Congress of Psycho-Oncology, Melbourne, Australia, September 3-7, 2000.

Targ, E. (2000). Spirituality and medicine: a psychospiritual in April at the UCSF Conference on Alternative and Complementary Medicine.

Targ, E. (2000). Spirituality and psychiatry. Half-day presentation in March at the Trinity Church Conference on Spirituality and Medicine in Connecticut.

Targ, E. (2000). Spirituality and group psychotherapy approach in catastrophic illness. Presented in May at the annual meeting of the American Psychiatric Association.

Project 3
Breast Cancer Patient-Specific Outcome and Decision Making Project

Project Summary

The original intent of this project was to develop a continuous risk model for patients with early stage breast cancer based on standard factors of age and tumor characteristics. We are accomplishing this using an artificial neural network regression model trained to provide individual patient continuous probability disease-specific predictions (probability) of survival and recurrence. These predictions are patient-specific and therapy-specific so patients can compare the efficacy of each treatment. The program allows post surgical patients to compare the benefit of adjuvant hormonal, chemotherapy, and combinations of these treatments over time, and we will evaluate its utility and effectiveness on patient decision-making. This is a modular program that can grow and become more refined in time with improved outcome modeling, better estimates of treatment benefits such as HER2/neu, radiation therapy, bisphosphonates, etc. One important component is an accurate description of treatment toxicities that would be treatment and patient-specific. The lack of calibration of risks of mortality and recurrence prior to adjuvant therapy has been recognized. We have assessed three large databases (Turku, Duke, and San Antonio) from which to establish our individual estimates of risk and benefit of adjuvant therapy broken down by age, ER status and treatment, but have found large discrepancies in their predictive value. Using actual patients at the Breast Cancer Tumor Board, three Internet assessment tools were accessed to determine predictive values for adjuvant treatment. Two of these tools represented population models (CancerHome™ and Adjuvant!™) and one represents results of clinical trials (CancerFacts™). As the enclosed table shows, the three tools were at significant variance from one another. For this reason, we have been reluctant to begin counseling patients until a stable database can be found. Both the author of Adjuvant!™ and the present investigators were concerned that the San Antonio model may have been skewed toward larger tumors and later stage patients, based as it was on the SEER, a population based registry. Our search at this time points to the Oxford Overview analysis and we are currently engaged in procuring it for our use. As a more immediately available tool, we now have obtained from Dr. Peter Ravdin an updated version of the program Adjuvant!™ which is different from prior versions in that it is modeled using a larger SEER database with several assumptions regarding the proportion of patients who have received specific adjuvant therapy. This updated version has been piloted (see attached abstract).

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

Task 1: An artificial neural network was developed by Dr. Harry Burke. It was based on the Finnish database, a large, natural history database, with well described treatments and long term follow-up; and the Duke database, consisting of 3600 patients treated at the Duke University

Medical Center between 1979 and 1993. Mortality estimates and 5 and 10 year recurrence estimates were derived from the Oxford Overview. A video designed to give patients basic information regarding adjuvant treatments for breast cancer was developed by Dr. Al Mulley of Harvard University and revised based on focus groups of advocates and patient testimonials at UCSF. **[Complete]**

Task 1b: Develop toxicities database from literature of published cooperative group studies for both hormone (Tamoxifen) therapy and chemotherapy (AC and CMF). **[Complete]**

Task 1c: Develop written patient background information on adjuvant therapy and format to describe absolute benefits attributable to adjuvant therapy and conditional life expectancy estimates customized for the individual patient. The Patient Booklet contains additional information on how predictions were derived, breast cancer background information, the latest information on new treatments, and will be updated at each visit for up to five years. In addition, the effect of the information on the patients, including its effect on their decision making, will be prospectively assessed.**[Complete]**

Task 2: Finalize pre- and post-viewing questionnaires to capture patients' preferences, comprehensibility, satisfaction with decision and other standard measures (quality of life, etc.). All questionnaires, including risk perceptions, treatment choices, hypothetical scenarios, comprehensibility and a new demographic attitudinal survey are finalized. **[Complete]**

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

Task 3: All assessment tools have been finalized and the pilot study has been approved by UCSF Committee on Human Research (CHR). The method for disseminating the patient information has changed to computer format from CD-ROM. The patient population is all new patients with early stage (I and II) breast cancer, post surgery and radiation who have not yet had adjuvant therapy. Patients who agree to be part of the study will fill out the demographic information questionnaires as well as questionnaires that explore their understanding of their hypothetical risk of recurrence and death due to their cancer, both before and after their initial office visit with an oncologist. Patients will be given their information booklet at the time of their intake exam. Arm I booklets will contain information on the probability of disease recurrence as well as ten year estimates of mortality. Arm II booklets will include this information as well as graphic information on time gained (in years and months) due to treatment (See attached). Post visit questionnaires will measure any change in attitude regarding therapy due to the differences in the two arms. Once we have successfully completed the pilot project, we plan to implement the program by obtaining risk and recurrence estimates for new patients who have completed their surgery and radiation and are considering adjuvant therapy. This will take place at the weekly New Patient conference where adjuvant options for patients are evaluated. This information will be in graphic form and will become a part of the patient's chart (See attached). Currently, the risk and recurrence estimates are being used as a tool at the weekly Breast Cancer Tumor Board, to

help medical oncologists provide their patients with recurrence and mortality data that can help them make decisions on adjuvant treatment.

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). We 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. Clinicians participating in this project will have access to their own patients for quality analysis/control purposes and to the contents of the database, subject to IRB approval. We plan to pilot an Internet version of this tool as a separate project to supplement our data analyses.

Reportable Outcomes

1. Development of an artificial neural network regression model to provide individual post surgical patient continuous probability disease-specific predictions of survival and recurrence.
2. Development of table for medical complications due to Tamoxifen use.
3. Development of side effects table for CMF and AC chemotherapy.

Publications:
Tripathy, D. *Breast Cancer Advocacy in Clinical Care.* Breast Disease 10(5,6), 1998, pp. 3-14.

Project Personnel

Debasish Tripathy, M.D.	Principle Investigator
Hope Wallace	Project Coordinator (year 1)
Fern Hassin	Project Coordinator (years 2-4)
Beth Brown	Research Assistant (years 2-3)
Lauren Metzroth	Research Assistant (year 4)

List of Appendices

- Patient Survey
- Protocol and Informed Consent for pilot project
- Patient information on chemotherapy and hormone therapy
- Recurrence and mortality graphs for pilot project
- Toxicity table for chemotherapy
- Medical complications table for tamoxifen
- Reprint on breast cancer advocacy
- Abstract of Adjuvant!™ program
- Tables on 5 and 10 year recurrence estimates

Project 4
Program for Collaborative Care

The goal of Project 4 is to improve the quality of 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, as well as an integrated structure and process, to help patients and physicians manage medical consultations where treatment decisions are made. Our approach to developing these tools is to engage patients and physicians in the design and implementation, to be sure that the interventions we create actually provide value for those they are intended to help. This report documents the progress we have made in program implementation, the refinement of our tools, and the scope of our training. It also highlights directions for future research we have identified.

In 1999, through research funded by the DOD, we established the Program for Collaborative Care and hired a full-time staff member to implement and manage the program. The Program currently offers Consultation Planning and Consultation Recording to all patients with a new diagnosis of breast cancer who need to make treatment decisions in a scheduled consultation with a BCC surgeon or medical oncologist. We have since provided Consultation Planning and Consultation Recording for 310 patients at the Breast Care Center between September 1999 and August 2001.

We have refined and improved our tools for Consultation Recording, based on the qualitative feedback from patient and physician focus groups. We identified three key issues to improve the effectiveness and utility of Consultation Records: comprehensive, standardized presentation of diagnostic information, streamlined estimates of risk reduction assessments for each treatment option, and visual aids to capture patient preferences. We developed and piloted Decision Guides, which are a standardized template that highlights critical diagnostic, risk assessment, and patient preference information (see appendix). Decision Guides are currently used as the standard Consultation Record for four medical decision settings: surgery, DCIS, reconstruction, and adjuvant therapy options.

One of our future goals at the Program for Collaborative Care is to diffuse these methods to more clinical settings. We have applied to the National Institutes of Health to conduct a multi-site clinical trial to test the efficacy of establishing Programs for Collaborative Care in two sites with diverse populations, to assess how decision support tools improve patient outcomes such as anxiety, distress, and decision quality.

We have developed a three-day course curriculum, a handbook, and skill exercises to train Consultation Planners. We have conducted 6 training sessions in the past 18 months, and have established a satellite program offering Consultation Planning at the UCSF Cancer Resource Center, to meet patient demand and evaluate the effectiveness of the tools in a drop-in setting. We have begun a weekly Consultation Planning mentoring group at the Cancer Resource Center, to transfer skills and discuss practical issues. As our experience grows, we intend to develop a similar training program for Consultation Recording, and have begun preliminary work on a

comprehensive training manual that will combine theory, methods, skill exercises, and implementation suggestions for both methods.

Another future research goal is to expand the Program for Collaborative Care to improve patient-physician interaction, treatment decision-making, and quality of life for women with metastatic breast cancer. We are currently conducting a needs assessment and evaluation of current practices to identify ways to adapt Consultation Planning and Consultation Recording for the metastatic setting, and to create additional interventions for physicians, patients, and their families around difficult end of life communication issues. We plan to incorporate psychological counseling and family support, Consultation Planning and Consultation Recording, advance directives, and additional decision-making tools into the standard of metastatic oncology care.

Key Research Accomplishments for Years 4 and 5 of Project 4 (8/15/99-8/14/00 and 8/15/00-8/14/01):

1. Hired a full time manager of the Program for Collaborative Care in September 1999. The manager began to integrate Collaborative Care (Consultation Planning and Consultation Recording) into clinic workflow and provide decision support to all BCC patients facing upcoming surgery or oncology decisions.

2. Expanded the use of Collaborative Care methods to three surgeons and five oncologists in the Breast Care Center.

3. We have worked with 310 patients using Collaborative Care tools since October, 1999.

4. Conducted 2 focus groups with patients in Collaborative Care program to assess patient satisfaction and get feedback on web based decision support/patient education tools currently under development.

5. Conducted physician evaluation meetings to assess usefulness of tools and identify areas for improvement. The qualitative data generated from these focus groups will be used to revise and improve tools and metrics for future use at the BCC.

6. Began ethnographic pilot study of current clinical practices in the metastatic setting to develop ways to adapt Collaborative Care tools and methods with psychological support interventions for women with metastatic breast cancer and their families.

7. Developed a three-day course curriculum, a handbook, and skill exercises to train Consultation Planners. We are developing a similar manual and training program for Consultation Recording.

8. Conducted 6 training sessions in the past 18 months, and have "graduated" 25 new Consultation Planners who use these methods at 7 different sites in Northern California, including the UCSF Cancer Resource Center. We have begun a weekly Consultation

Planning mentoring group at the Cancer Resource Center, to transfer skills and discuss practical issues.

9. Developed and piloted Decision Guides, a refined and improved version of Consultation Records. Decision Guides are standardized templates used during medical consultations, which succinctly capture critical diagnostic information, estimated risks of recurrence for treatment options, treatment option side effects and cosmetic implications, patient preferences, and next steps after decisions have been reached. The Program for Collaborative Care currently uses Decision Guides in the surgical, medical oncology, DCIS, and reconstruction settings.

10. Developed and wrote grant to National Institutes of Health, to conduct multi-site clinical trial testing efficacy of The Program for Collaborative Care at Ohio State University and Alta Bates Cancer Center in Oakland, CA.

Reportable Outcomes

Manuscripts

Sepucha K, Belkora J, Tripathy D, Esserman LJ. Building Bridges Between Physicians and Patients: Results of a Pilot Study Examining New Tools for Collaborative Decision-Making in Breast Cancer. J Clin Oncol 2000 18: 1230-1238.

Aviv C, Sepucha K, Belkora J, Esserman L. Using Action Research to Improve Collaboration Between Breast Cancer Patients and Physicians: Creating the Program for Collaborative Care. Research in The Sociology of Health Care, Vol. 19: Changing Consumers and Changing Technology in Health Care and Health Care Delivery, edited by Dr. Jennie Jacobs Kronenfeld. London: Elsevier Press. In press as of August 2001.

Belkora, J., Sepucha, K., Mutchnick, S., Aviv, C., Esserman, L. Consultation Planning: A Template for Oncology Consultations and Decision-Making. *Oncology Nursing Forum.* Submitted August 2001.

Abstracts

Sepucha K., Belkora J., Tripathy D., Esserman LJ. (1999) Building Bridges Between Physicians and Patients: Tools for Collaborative Decision-Making in Breast Cancer. San Antonio Breast Cancer Symposium, abstract 547.

Sepucha K., Belkora J., Esserman LJ, Tripathy D, Aviv C. (2000) Improving Decision-Making Between Physicians and Patients with Breast Cancer. Department of Defense "Era of Hope" Conference.

Presentations

Sepucha, K. and Belkora, J. Training Weekend for Collaborative Care Methods: Presentation for 3 Bay Area breast cancer advocacy organizations, September 10, 1999

Aviv, C. Lecture Presentation at Beth Israel Cancer Center Supportive Services, New York, NY, November 1999

Belkora, J. and Aviv, C. Lecture Presentation at UCSF Health Psychology Seminar, April 18, 2000

Aviv, C. Lecture Presentation at California Breast Cancer Research Early Detection Program CME course, June 3, 2000.

Aviv, C. Lecture Presentation at Bay Area Breast Cancer Forum, "Involving Patients in Decision-making: A Collaborative Care Model," June 21, 2000.

Aviv, C. Lecture Presentation at American Sociological Association and Society for Study of Social Problems, August 2000.

Aviv, C. Lecture Presentation to UCSF Cancer Resource Center, "How to Make the Most of Your Doctor's Visit," October 2000.

Aviv, C. Lecture Presentation and Training for UCSF Cancer Resource Center Volunteer Program, "Consultation Planning Quickstart," April 2001.

Aviv, C. Lecture and Training, "How to Integrate Consultation Planning into your Breast Cancer Advocacy Project," Arcata CA, May 2001.

PILOT A

Introduction

The project's principal aim has been to characterize barriers to enrollment to breast cancer-related clinical trials that exist from the standpoint of both patients at a time they would typically be eligible for trials as well as care providers that specialize in breast cancer. Based on these results, outreach and educational strategies tailored to overcome these barriers were devised and implemented. The effects of these strategies were measured by reassessing barriers via a repeat survey to patients and caregivers at year 4 and by tracking trial enrollment from years 1 though 4. Special themes of this project included the focus on minority and underserved populations in terms of the assessment of barriers as well as outreach and education. Additionally, attitudes about trials in the area of alternative medicine were assessed given the high use of alternative medicine in the San Francisco Bay Area and a series of trials in alternative medicine currently open at our center. Tools that capitalized on an active advocacy network, the Internet and collaborations with civic organizations were instituted as described below. Numerous projects that will now continue under separate funding have been launched; these will continue new extended and focused goals or the original project.

Project Summary

The first 5 tasks involved developing, piloting and finalizing the patient questionnaire and clinical database to track, identify and follow the trial-eligible subset. The current protocol and informed consent to survey and follow patients is shown in the appendix.

Tasks 1 and 2 – Development and completion of demographic and clinical forms to identify patients eligible for clinical trials and enrollment onto trials. These forms have been developed and used to identify patients who are at a point that they are eligible for most trials (new diagnosis of cancer, new recurrence or progression of disease). A modified version is now being expanded to capture data on all new patients. The initial patient survey examining barriers to clinical trials covered beliefs/attitudes, trial design, toxicities, cost, convenience and alternative medicine.

Task 3 - A large mailing list of care providers (mostly physicians) providing specialized breast cancer care in the San Francisco Bay Area was assembled – this included medical oncologists, surgical oncologists, radiation oncologists, radiologists, pathologists, psychologists and nurse practitioners. The number on the list is currently about 180; it is maintained and expanded in order to communicate information about clinical trials, and could also serve as a resource for future surveys and trial network development.

Task 4 - The initial physician survey (as well as the modified one from the open ended questions was developed and is shown in the appendix. The number of care provider surveys returned was 67 out of 150, a ratio that is comparable to physician surveys in the area of cancer care. Detailed data on mean scores and associations with care provider subsets are shown in the appendix.

Task 5 – A finalized patient survey after piloting on patients and breast cancer advocates is shown in the appendix. One hundred and fifty surveys were administered and tabulated in the final half of year 1. The refusal rate was under 5%. Detailed data on mean scores and associations with patient subsets are shown in the appendix. We expanded Task 5 to include an Internet version of our patient survey as well as a similar attitudinal questionnaire for individuals without breast cancer. These are available on the Breast Care Center site as well as on our website. Responses downloaded from these sites will be analyzed to help us gather demographic information as well as attitudes toward preventive, complementary and alternative medicine. The Internet version of the survey is shown in the appendix

Interim analysis of the patients and care provider survey results was presented in abstract form at ASCO 1998 (appendix). Updated result summary (presented at the DOD Era of Hope Meeting in June 2000) is shown in the appendix.

Tasks 6 through 8 involved the development and implementation of tools for awareness and outreach about clinical trials based on the barriers to patients and care providers identified in Year 1. Initially, we focused our efforts on minority outreach by creating and distributing flyers, posters and brochures to physician offices, mammography centers, and support groups. One of the education and outreach tools developed and maintained as part of Tasks 6-8, is the monthly Bay Area Breast Cancer Forum, initiated in January 1997, which continues to be a very popular part of our outreach. These topics are shown in the appendix and summaries of each session is available on our website at www.ucsfbreastcarecenter.org . Each month we host approximately 45 people for dinner and discussion of topics of interest in breast cancer research. We plan to expand these forums onto the Internet using an audio stream and an interactive question and answer session that will reach a greatly expanded audience. Audio or video conferencing will also be considered and we currently have secured private unrestricted educational grant funding to begin this process. We are continuing monthly clinical trials updates to caregivers during weekly Tumor Board and are making clinical trials lists available to community care providers.

The clinical trials component of our website continues to grow in content and interest for the community. It includes forum minutes, monthly newsletter articles, comprehensive listing of UCSF/BCC Clinical Trials, and annotated websites of interest. One very popular addition has been the Glossary which has been copied and used as a resource by many cancer centers in the Bay Area, at other sites throughout the country and online. We are initiating an Internet mechanism by which patients can match themselves to available clinical trials. After accessing the site, patients will fill in key patient and disease variables. Investigators will be able to query the database of patient information to locate patients eligible for IRB approved trials.

Other tools targeting specific barriers included a moderated panel discussion in December 1998, entitled "Beating the Odds of Breast Cancer: How Can Research Help?", 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, 15 copies of the video have been sent to community agencies as part of their individual programs to foster clinical trials. Other presentations are listed under "Reportable Outcomes".

Technical Objectives 9-12: Measure Outcomes of Intervention

Task 9: Months 36-40: Mail surveys to care providers and tabulate results. Surveys to 160 physicians has been done over 3 rounds of mailing and 59 physicians responded. Physician responses results and analysis with respect to provider variables (eg. type of practice, discipline), along with comparisons to the year 1 results are shown in the appendix.

Task 10: Months 36-48 Reinitiate collection of tracking data of new patients. We are continuing to track new patients, as well as patients who progress, in order to monitor eligibility for clinical trials. Administration of surveys to eligible patients identified through our Patient Tracking System began on schedule in October, 1999. To date, 75 patients have been surveyed. Final patient surveys will be analyzed when the target number is reached within two months, and an interim analysis is shown in the appendix, along with comparisons to the year 1 survey. With our new initiative using online questionnaires, results will be batched and analyzed to determine shifts or changes in attitudes that will allow us to develop trials that are novel and relevant to patient concerns. We have begun to insert requests for patient participation in website questionnaires in information sent from the Breast Care Center as well as providing flyers and information at cancer related events like the Race for the Cure or the Alternative Medicine Symposium held each fall at UCSF.

Task 11: Statistical analyses. Our biostatistician will analyze the data from both patients and physicians relative to the questions surveyed as well as a comparison of Year 1 to Year 4. Whereas the comparison of physician responses from Year 1 to Year 4 is possible as the majority of those queried are from the same mailing list, the patients will be sequentially analyzed as to their attitudes over time. The patients queried in Year 1 will be different patients from those queried in Year 4, except that they are all at a place in their treatment when they would consider enrollment in a clinical trial. See the appendix.

Task 12: Formulate recommendations, publication of results. Once the attitudes of patients and care providers are evaluated, they will be compared to the actual clinical trial accrual in the final year of the project. Our data indicate a positive accrual pattern:

Year	#Patients on Trials
1997	21
1998	44
1999	92
2000	123

Analysis with respect to trends based on the interventions will be possible as well as trends that may be due to extraneous factors such as changes in protocol portfolio or patient population.

Key Research Accomplishments

- Identification of patient and physician barriers to enrollment to clinical trials in the domains of cost, convenience, side effects, quality of care, randomization process and alternative medicine

- Identification of barriers as they pertain to specific characteristics of patients and care providers

• Reporting on changes over time in patient and physician attitudes as well as actual trial accrual in our Center over time following the development and implementation of the following targeted tools:

- Design and dissemination of educational material for outreach to minority and underserved populations
- Monthly patient forum (see presentations) and physician clinical trial update seminars
- Internet site for clinical trials update
- Update sessions to care providers on clinical trials and mechanisms for enrollment

• New initiatives to overcome barriers to trial enrollment, especially in under-represented patient groups

- Internet-based survey
- Patient-driven Internet-based clinical trials matching project
- Satellite Bar Area Breast Cancer Forum (Oakland/Berkeley area)
-

Reportable Outcomes

Informatics and Databases

1. Development of patient clinical database to determine trial eligibility
2. Development of Bay Area Breast Cancer specialist care providers
3. Patient clinical and outcome data

Presentations:

1. December 1998, moderated panel discussion entitled "Beating the Odds of Breast Cancer: How Can Research Help?", 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, 15 copies of the video have been sent to community agencies as part of their individual programs to foster clinical trials.
2. 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.
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.
4. A talk entitled "Harmony and Health", presented at Women's Health 2000, UCSF, March 18, 2000.
5. Represented UCSF at the launch of the Breast Cancer Media Outreach Campaign to the Chinese Community in the San Francisco Bay Area", May 12, 2000, San Francisco's Chinatown.
6. Monthly forum on special topics aimed at breast cancer survivors, advocates, families, clinicians and investigators – topics are listed below

Publications and Abstracts:

1. Tripathy, D, Patel, K, Brown, B, Chernyukhin, N, Wallace, H, Hassin, F, MacMillan, A, and Esserman, L. *Physician and Patient Barriers to Enrollment on Breast Cancer Clinical Trials.* Proc. Am. Soc. Clin. Oncol. 17:178A, 1998
2. Tripathy D. Breast Cancer Advocacy in Clinical Care. Breast Disease 10:3-14, 1998.
3. Sepucha KR, Belkora JK, Tripathy D, Esserman LE. Building bridges between physicians and patients: Results of a pilot study examining new tools for collaborative decision making in breast cancer. J Clin Oncol 18(6):1230-1238, 1999
4. Tagliaferri M, Cohen I, Tripathy D. The role of complementary and alternative medicine in the treatment of early stage breast cancer. Seminars in Oncology 28:121-134, 2001.
5. Tripathy D, Hassin F, Brown B, et al. Patient and Physician Barriers to Enrollment on Breast Cancer Clinical Trials. DOD Meeting – Era of Hope, Atlanta, GA June 8-11, 2000

Project Personnel

Debasish Tripathy, M.D.	Principal Investigator
Hope Wallace	Project Coordinator (year 1)
Fern Hassin	Project Coordinator (years 2-4)
Kiran Patel, M.D.	Research Assistant, Database administrator (years 2-3)
Beth Brown	Research Assistant (years 2-3)
Lauren Metzroth	Research Assistant (year 4)

List of Appendices

- Patient Survey and Follow-up Protocol and Consent Form
- Care Provider Survey
- Final Patient Survey
- Current Internet version of patient survey
- ASCO Abstract on interim patient and care provider survey results
- Summary of patient and care provider survey final results (presented at the DOD Era of Hope Meeting in June 2000)
- Detailed interim results of year 4 care provider and patient questionnaires, comparisons to year 1
- Bay Area Breast Cancer Forum Topics

COMPLETE LIST OF PUBLICATIONS & OTHER REPORTABLE OUTCOMES DURING WHOLE GRANT PERIOD 1996-2001

Manuscripts

Project 1

Haas J, Kaplan C, McMillan A, Esserman L. Does Timely Assessment Affect the Anxiety Associated with an Abnormal Mammogram Result? Journal Of Women's Health & Gender-Based Medicine, Vol. 10, no. 6, July/Aug. 2001

Ljung BM, Drejet A, Chiampi N, Jeffrey J, Chew K. Diagnostic Accuracy of Fine Needle Aspiration Biopsy is Determined by Physician Training Cancer Cytopathology, Vol. 93, Issue 5, 25 August, 2001

Project 2

Cotton S, Levine EG, Fitzpatrick CM, Dold KH, Targ, E. Exploring the relationships among spiritual well-being, quality of life, and psychological adjustment in women with breast cancer. Psycho-Oncology 8:429-438, 1999

Project 3

Tripathy, D. Breast Cancer Advocacy in Clinical Care. Breast Disease 10(5,6), 1998, pp. 3-14.

Project 4

Sepucha K, Belkora J, Tripathy D, Esserman LJ. Building Bridges Between Physicians and Patients: Results of a Pilot Study Examining New Tools for Collaborative Decision Making in Breast Cancer, J Clin Oncol 2000 18: 1230-1238.

Aviv C, Sepucha K, Belkora J, Esserman L. Using Action Research to Improve Collaboration Between Breast Cancer Patients and Physicians: Creating the Program for Collaborative Care. The Sociology of Health Care, Vol. 19: Changing Consumers and Changing Technology in Health Care and Health Care Delivery, edited by Dr. Jennie Jacobs Kronenfeld. London: Elsevier Press. In press as of August 2001.

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. (abstract)

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. (abstract)

Klein, A., Levine, E.G., & Targ, E. (2000). Differences in psychosocial well-being between lesbian and heterosexual women with breast cancer. Annals of Behavioral Medicine, 22, (supplement), 44.

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. (abstract)

Levine, E. G. & Targ, E. (1999). A comparison of complementary and traditional psychosocial treatment for breast cancer. Psycho-Oncology, 8, (6), 14 (Abtr.).

Levine, E.G., & Targ, E. (2000). Differences in psychological status of older and younger newly diagnosed women with breast cancer. Annals of Behavioral Medicine, 22, (supplement), 61.

Levine, E.G, Targ, E. et al. (2000). A comparison of alternative-mind/body and support interventions for women with breast cancer. Annals of Behavioral Medicine, 22, (supplement), 127.

Rundel, M., Levine, E.G., & Targ, E. (2000). Use of alternative medicine by women with breast cancer. Annals of Behavioral Medicine, 22, (supplement), 65.

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 (abstract)

Cotton, S. P., Levine, E. G., Bressler, J, Heide, F., & Targ, E. (2000). Spirituality, Quality of Life, and Psychological Adjustment to Breast Cancer. Presented at the annual meeting of the American Psychological Association, Washington, D.C., August 2000.

Project 4

Belkora J, Fehling, M., Cushing (Sepucha) K, Lamping S., Esserman LJ. Consultation Planning: A New Tool for Visit Preparation." San Antonio Breast Cancer Symposium 1997, abstr .

Belkora J, Sepucha K, Aviv C. Mindful Collaboration: How to Help Clients Prepare for Collaborative Meetings about High-Stakes, High-Risk Decisions. INFORMS Annual Conference, November, 1999

Sepucha K, Belkora J, Tripathy D, Esserman LJ. Building Bridges Between Physicians and Patients: Tools for Collaborative Decision Making in Breast Cancer. San Antonio Breast Cancer Symposium Dec. 1999, abstr 547.

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.

Sepucha K., Belkora J., Esserman LJ, Tripathy D, Aviv C. (2000) Improving Decision-Making Between Physicians and Patients with Breast Cancer. Department of Defense "Era of Hope" Conference.

Pilot A

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

Tagliaferri M, Cohen I, Tripathy D. The role of complementary and alternative medicine in the treatment of early stage breast cancer. Seminars in Oncology 28:121-134, 2001.

Tripathy D, Hassin F, Brown B, et al. Patient and Physician Barriers to Enrollment on Breast Cancer Clinical Trials. DOD Meeting – Era of Hope, Atlanta, GA June 8-11, 2000

Presentations

Project 2:

Cotton, S. P., Levine, E. G., Bressler, J, Heide, F., & Targ, E. (2000). Spirituality, Quality of Life, and Psychological Adjustment to Breast Cancer. Presented at the annual meeting of the American Psychological Association, Washington, D.C., August 2000.

Levine, E.G., & Targ, E. A comparison of complementary and traditional psychosocial treatment for breast cancer. Pan American Congress of Psychosocial and Behavioral Oncology, New York, October 1999.

Levine, E.G., & Targ, E. A comparison of complementary and traditional psychosocial treatment for breast cancer. Presented at the Pan American Congress of Psychosocial and Behavioral Oncology, New York, October 1999.

Levine, E.G, Targ, E., Stone, B. M., & Kroenewetter, C. (2000). A comparison of complementary and traditional psychosocial treatment for breast cancer. Presented at the Fifth World Congress of Psycho-Oncology, Melbourne, Australia, September 3-7, 2000.

Levine, E.G, Tario, J. D., & Targ, E (2000) Reduction of hopeless/helpless coping style in women with breast cancer. Presented at the Fifth World Congress of Psycho-Oncology, Melbourne, Australia, September 3-7, 2000.

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

Targ, E. (2000). Spirituality and medicine: a psychospiritual in April at the UCSF Conference on Alternative and Complementary Medicine.

Targ, E. (2000). Spirituality and psychiatry. Half-day presentation in March at the Trinity Church Conference on Spirituality and Medicine in Connecticut.

Targ, E. (2000). Spirituality and group psychotherapy approach in catastrophic illness. Presented in May at the annual meeting of the American Psychiatric Association.

Project 4

Sepucha, K. and Belkora, J. Training Weekend for Collaborative Care Methods: Presentation for 3 Bay Area breast cancer advocacy organizations, September 10, 1999

Aviv, C. Lecture Presentation at Beth Israel Cancer Center Supportive Services, New York, NY, November 1999

Belkora, J. and Aviv, C. Lecture Presentation at UCSF Health Psychology Seminar, April 18, 2000

Aviv, C. Lecture Presentation at Breast Cancer Research Early Detection Program CME course, June 3, 2000.

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Aviv, C. Lecture Presentation at American Sociological Association and Society for Study of Social Problems, August 2000.

Aviv, C. Lecture Presentation to UCSF Cancer Resource Center, "How to Make the Most of Your Doctor's Visit," October 2000.

Aviv, C. Lecture Presentation and Training for UCSF Cancer Resource Center Volunteer Program, "Consultation Planning Quickstart," April 2001.

Aviv, C. Lecture and Training, "How to Integrate Consultation Planning into your Breast Cancer Advocacy Project," Arcata CA, May 2001.

Pilot A:

Ongoing monthly Bay Area Breast Cancer Forum to educate researchers, healthcare providers, patients, families and advocates about advances in clinical trials.

Talk entitled: "Excluded No More: Why Participating in Clinical Research is Important for You and All Women", presented at Women's Health 2000,.

"Update on Research Resources" presented at the Minority Health Research Panel in Alameda, CA. on April 23, 1999.

December 1998, moderated panel discussion entitled "Beating the Odds of Breast Cancer: How Can Research Help?", 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, 15 copies of the video have been sent to community agencies as part of their individual programs to foster clinical trials.

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A talk entitled "Harmony and Health", presented at Women's Health 2000, UCSF, March 18, 2000.

Represented UCSF at the launch of the Breast Cancer Media Outreach Campaign to the Chinese Community in the San Francisco Bay Area", May 12, 2000, San Francisco's Chinatown.

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". Degree granted June 17, 2000.

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". Degree granted June 17, 2000.

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."

Other Reportable Outcomes

Project 3

1. Development of an artificial neural network regression model to provide individual post-surgical disease-specific predictions of survival and recurrence.
2. Development of table for medical complications due to Tamoxifen use.
3. Development of side-effects table for CMF and AC chemotherapy.

Pilot A

Informatics and Databases:

1. Development of patient clinical database to determine trial eligibility
2. Development of Bay Area Breast Cancer specialist care providers
3. Patient clinical and outcome data

CONCLUSION

The DOD Center grant allowed the creation of an interdisciplinary center, where the providers function as a team to serve the needs of our patients. The integration of physicians across disciplines has led to significant improvements in the management of patients. This is turn has led to an increase in clinical trial accrual, more attention at the time of diagnosis and decision making, and fewer and a more appropriate number of follow-up visits, as well as greater patient satisfaction.

Through the support of the grant, we created extensive educational materials, all of which are web accessible, and a new framework for involving patients and physicians in a collaborative decision making process. We created a database that serves to link clinical information and clinical research. We created programs to serve the needs of patients based on the stage of their breast problem (prevention to metastatic care) and a longitudinal program for disease management. For example, we have demonstrated that a team of expert providers can minimize interventions and maximize cancer diagnosis and streamline the process, so that the diagnostic process takes no more than 1-2 days and the total number of surgical interventions is minimized.

We are currently in the process of automating work flow to manage the tasks better for both providers and patients. We have used Project 3 to develop a method to review all new patients and project life expectancy, impact of breast cancer and therapeutic interventions to use as a decision making tool for all patients. We also use it as a teaching tool for tumor board conference. We have generated an environment that successfully integrates clinical trials into all stages of breast cancer treatments.. Our program volume has grown from 150 patients per month to 1000 patients per month, and from 3 active clinical trials to 33 active clinical trials. We successfully completed a lifestyle intervention and personal support clinical trial and showed that women adjust better in the long run when they receive more psychosocial intensive intervention around the time of their diagnosis.

The DOD center grant has been instrumental in the creation of a vibrant center, has led to the creation of new decision making and educational tools, many publications, and several submissions for new center and investigator-initiated grants.

Carol Franc Buck
BREAST CARE CENTER newsletter
• SUMMER 2001 •
Appendix A

TALKING SPACE

Dr. Esserman (right) in conversation with Resource Director Keren Stronach.

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

We are now settled into our new space on the 2nd floor of the UCSF Comprehensive Cancer Center at 1600 Divisadero Street. It is great to be able to just walk around the corner in order to consult with the pathologists, the radiologists, the genetic counselors, or any of our clinicians from all of the specialties. Our surgical procedures are being performed at Mt. Zion hospital, where our patients can get the personal touch they are accustomed to. At last, most of the pieces of our clinical concept are in place.

Over the coming months, you will notice some changes in the way we organize follow-up appointments. Because so many of the questions and problems that arise after treatment involve menopausal symptoms and quality-of-life issues, we are excited that Dr. Mindy Goldman has joined our team. Mindy is a gynecologist with a special interest in issues of concern to breast cancer survivors.

Rather than have several appointments with many different providers, we will assign everyone to one provider after a year out from treatment. The purpose of this is to teach patients what to look for, make sure no one is worrying unnecessarily about symptoms, make certain patients are getting the appropriate studies, and identify side effects or symptoms that we can make better. If problems arise, patients will immediately see the most appropriate clinician on their designated team.

We also will be hosting two 2-hour sessions with all of our providers, which will be open to any of our patients to come and ask questions. We hope that you will all feel free to come and take advantage of these sessions. We find that many patients have similar questions and would benefit from hearing what others are asking about.

Our goals are to give our patients the best care, make sure they do not have excessive appointments or wait times, and systematically track complications and outcomes. As you know, we are committed to the team concept at the Breast Care Center, where every one of us has the same goals for your recovery and care.

We hope you enjoy this issue of the newsletter. If you have questions or topics you would like us to write about, please contact Sarah Paris at (415) 885-7323 or sarah.paris@ucsfmedctr.org. We are especially looking for more stories from our patients' point of view. ■

NEW CLINICAL TRIAL : THE SOY-TAMOXIFEN PREVENTION TRIAL

by Laura J. Esserman, MD, MBA

Measuring the long-term impact of specific drugs on the development of breast cancer can take years or even decades and cost millions of dollars. In this study, we are instead going to look at markers of risk to see whether drugs like tamoxifen or natural substances like soy can affect these markers.

What is a biologic marker of risk? It is different from risk factors. Risk factors refer to characteristics that are more common in women who have a particular disease. In the case of breast cancer, known risk factors include a family history of cancer, a history of alcoholism, early age of menarche (time of starting menstruation), late menopause, no children or late child bearing. However, about half of the women who get breast cancer do not have any of these risk factors. Furthermore, risk factors are often conditions that cannot be influenced, so they do not help us to design prevention studies.

Biologic markers, on the other hand, can often be changed. They can be measured, and we are just beginning to understand which ones are meaningful for predicting breast cancer risk. One marker that has emerged is breast density. This can be measured by mammography as well as by other studies. It is something that can be changed. Another marker that looks very promising is the finding of atypical or abnormal cells from some kind of breast biopsy or from ductal lavage (getting fluid from the milk ducts). Yet another marker may be the serum hormone levels. These may be important not only in predicting who is at higher risk for breast cancer but who is likely to benefit from therapies such as tamoxifen.

Our Soy-Tamoxifen Trial is designed to see whether soy or tamoxifen, when taken for 6 months, can change breast density or the types of cells that are found in the breast ducts. We are also going to draw blood to measure serum hormone levels to hopefully help us to figure out whether some women benefit more than others from soy or tamoxifen.

This first study is for premenopausal women with dense breasts who are at higher risk for developing breast cancer. Women who participate will have a 50% chance of being assigned to soy, a 25% chance of being given tamoxifen, or a 25% chance of being given a placebo. The study will go on for only 6 months, after which participants are free to pursue whatever therapy they choose.

There is a great need to get more information on how soy works. Many people assume that it prevents breast cancer, but this is not yet proven. Please call our Prevention Program at (415) 353-7029 for more information or if you would like to participate in one of our prevention studies. ■

OUR DIGITAL MAMMOVAN- FIRST IN THE WORLD

by Meridithe Mendelsohn

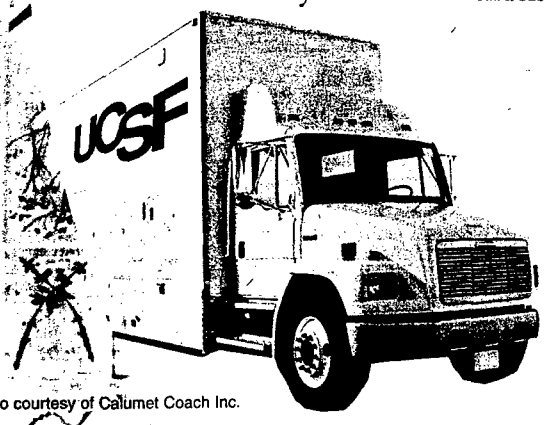


Photo courtesy of Calumet Coach Inc.

Many of our patients still remember the old UCSF mammovan, which the Department of Radiology operated from 1985 to 1998 in order to provide a mobile mammography service. The van was retired in 1998 due to financial hardship brought about by changes in mammography availability and in the reimbursement rules of managed care.

Medicare reimbursement rates for mammography remain low, while costs per mammogram are increasing. Recent studies found that access to mammography services is a problem for a significant number of women. Many smaller mammography sites are closing. The Breast Care Center has been fundraising for over a year to put a new, state-of-

the-art digital mammography van into service to increase the accessibility of mammograms for underserved women in our area. Through our own fundraisers, such as "Taste for the Cure", and through the generous contributions of the organizations listed below, as well as many individual donors, we were able to raise all the funds needed to buy the van and begin our first year of operation. Our new digital mammography van will be equipped with the latest technology from General Electric. It will begin service early this summer. This will be the first digital mobile mammography van in the world!

Our mobile mammography program will provide a much needed public health service to both uninsured and under-insured women. The program will be coordinated through the collaborative efforts of the Breast Care Center and a consortium of community groups and state-funded early-detection and treatment programs. Our mobile mammography van program will include a comprehensive tracking system that monitors the result of screenings and the outcome of recalls for abnormal mammograms.

In its first year, the UCSF mammovan will focus on providing breast cancer screening services to low income and minority women of all ages in San Francisco, starting in Bay View/Hunter's Point and the Western Addition. Our intention is to build and implement the system here and then to extend the model to neighboring counties in subsequent years. During the initial year, the van is slated to perform approximately 2,500 screening mammograms In subsequent years, the van will provide over 5000 mammograms per year to women all over the Bay Area.

A big thank-you to the Gap Foundation, whose extremely generous grant enabled us to purchase the van and the equipment. We also wish to thank the following organizations for their support of the Mammovan project: Mount Zion Health Fund, The Komen Foundation/ Kristi Yamaguchi's Always Dream Foundation, The Vadasz Family Foundation, Universal Care/Strike Out Breast Cancer, Aetna, Cinlexico Foundation, Lifetime, Jones International Networks/KRTY, Crow Canyon Women's Golf Association, Shorenstein Hays/Mama Mia Productions, Peninsula Charitable Events, Oxygen, and Chicks, Cheers and Charities. Generous in-kind support was provided by AT&T Broadband and the American Cancer Society. ■

"SMART PROBE" TO BE TESTED AT BCC

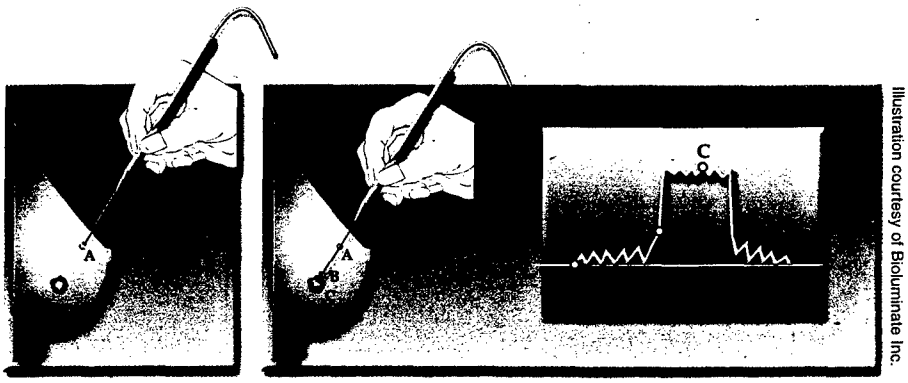


Illustration courtesy of Bioluminate Inc.

The pain associated with biopsies and the anxiety while waiting for the results might soon be avoided, thanks to a new, minimally invasive diagnostic tool; a needle probe designed to distinguish between normal and cancerous tissue.

"Smart Probe" is a new biopsy tool designed to assist with more accurate breast cancer detection. It has been developed by San Jose-based BioLuminate, Inc, in partnership with Lawrence Livermore National Laboratory. The technology was licensed from NASA and was originally designed to analyze soil samples on other planets. The probe removes no tissue, yet it is hoped that it will achieve accuracy levels comparable to fine needle aspiration and surgical biopsies in detecting cancerous cells.

The "Smart Probe" would be used after a mammogram or physical exam has detected a possible malignant lump. It will be inserted into the tissue and guided to the suspicious region. Its needle is smaller than the

[CONT. ON NEXT PAGE]

[SMART PROBE CONT.]

needle used in routine blood tests, so no or very little anesthetic would be necessary. Sensors on the tip of the probe measure optical, electrical and chemical properties that are thought to differ between healthy and cancerous tissues. Tissue measurements are made in real time, in both normal and suspect tissue. The results will be displayed instantly on a computer screen.

The first clinical tests of the "Smart Probe" are going to be held this Summer at selected sites in Northern California, including our Breast Care Center. Says BCC Director Dr. Laura Esserman: "The 'Smart Probe' is an exciting combination of several technologies. We hope it will allow us to simplify the evaluation of breast lumps and abnormal mammograms. This is early in the process, and a lot of hard work lays ahead, but the potential is there for a tool that will really help patients and their physicians."

The company is targeting the year 2003 for a commercially available product. If early studies show promise, the "Smart Probe" could also be used on prostate, lung, colon, cervical and brain cancer patients to detect malignancies and to deliver and monitor treatment. ■

INTRODUCING DR. CHERYL EWING

Photo: Marina Kenzer

We are very happy to welcome Dr. Cheryl Ewing at the Breast Care Center as an Associate Clinical Professor of Surgery.

Dr. Ewing completed her residency at Saint Joseph Hospital (Univ. of Michigan Affiliate) and her surgical oncology fellowship at the University of Chicago. After her fellowship, she joined the faculty at the University of Chicago as an Assistant Professor of Surgery. She became a member of the Comprehensive Breast Program, where she was eventually appointed as Director. She has written a number of articles and a book chapter on breast disease and treatment. Dr. Ewing was the Principal Investigator at the University of Chicago for the NCI-sponsored Breast Cancer Prevention Trial (P1), and she has participated in basic science research evaluating the relationship of oncogenes in colon cancer.

Dr. Ewing then moved to Santa Fe, N.M. to join a private practice group. Continuing her interest in breast diseases, she was particularly active in promoting standards of excellence for breast cancer surgery and for volunteer service. Her wide experience in breast surgery includes skin-sparing mastectomy and sentinel lymph node biopsy for breast cancer and melanoma.

Feeling eager to return to an academic environment, she was happy to respond to our recruitment and join the Breast Care Center. Among her strong clinical interests are breast cancer risk, prevention, and early detection. She is also interested in establishing a lymphedema program at the Cancer Center for the treatment of cancer-related, secondary lymphedema and to investigate the many unanswered questions related to lymphedema. We look forward to adding this much needed service to our program and will tell you more about it in our next newsletter.

Dr. Ewing believes in providing the highest standard of care to patients, and to include patient education and compassion in her care. As her colleagues in Chicago told us, we are very lucky to get her. We are thrilled that she joined our team and is contributing not only her skills and expertise, but her great energy and ever present smile! ■

RECENT FINDINGS IN BREAST CANCER DRUG RESEARCH:
Commentary on the San Antonio Breast Cancer Symposium 2000

by Debu Tripathy, M.D.

A number of new drugs were discussed in December in San Antonio:
Aromatase Inhibitors- Hormonal therapies control cancer growth in advanced breast cancer. However, there didn't seem to be a clear "winner", until a new class of drugs, called aromatase inhibitors, were developed. These drugs were initially designed to bring estrogen levels down in postmenopausal women. It is in these women that higher levels of estrogen carry a risk for the development of new cancer, or of recurrence in those that have already developed cancer. Aromatase inhibitors suppress the enzyme that converts androgens to estrogens. Once the ovaries stop making estrogen, the body still produces it, largely from fatty tissue, where this enzyme is present. Therefore, aromatase inhibitors work well to reduce estrogen production in postmenopausal women. These drugs have been approved for patients who are no longer responding to tamoxifen. They carry relatively little risks, and the side effects are mild (some hot flashes). A series of studies have been done to compare aromatase inhibitors to tamoxifen as a first-line therapy for advanced breast cancer. They showed a significant difference in response and duration of response in favor of aromatase inhibitors.

The next step will be to see if using aromatase inhibitors can help lower the risk of recurrence for early-stage breast cancer when given instead of or in addition to tamoxifen. These are being done with all of the aromatase inhibitors already approved for advanced breast cancer in the United States, anastrozole (Armidex), letrozole (Femara), and exemestane (Aromasin).

Endostatin- Out of 20 patients treated, preliminary results show no response to Endostatin. This is an anti-angiogenic drug which inhibits the formation of blood vessels, which are necessary for tumors to grow. The great recent promise of anti-angiogenic drugs has not been realized in humans, although Judah Folkman at Harvard has had some great success in animal models. VEGF (vascular endothelial growth factor) is a molecule in the body that triggers the formation of blood vessels. An antibody to VEGF has been tested in trials of breast, lung and colon cancer with some fleeting success to date - about 10% of patients had transient responses. A new study will compare chemotherapy alone with chemotherapy plus VEGF antibody. The strategy of combining anti-angiogenic agents with existing therapies is likely to yield better results than we have had to date with the angiogenic drugs alone.

Iressa- Growth factor receptors, like HER2/neu, are proteins that sit on the surface of cells, and are important in cell-to-cell communication. When these growth factors go awry, they can sometimes lead to abnormal growth and ultimately to cancer. The HER2/neu oncogene is present in abnormal amounts in 20 to 30% of breast tumors. By attacking the growth factor receptor with an antibody, in this case Herceptin, one can stop the abnormal process in patients whose tumors make HER2/neu. Other growth factor receptors may respond in the same way as HER2/neu, and pharmaceutical companies are doing research to find them. One is now in clinical trials. An inhibitor of the epidermal growth factor receptor (EGFR) named "Iressa", it has been found to be effective in the treatment of lung cancer, but is also being looked at for breast cancer. Iressa will also be tested in combination with Herceptin in an attempt to dually block the two receptors EGFR and HER2/neu.

Meanwhile, the controversy over **Taxol** continues: At the current time, we must assume that anyone with positive lymph nodes may derive some benefit from Taxol. The benefit appears to be less if the tumor is estrogen receptor (ER) positive, but we can't exclude the possibility of a benefit even in these cases. If the patient is ER positive and has only a few positive nodes, the benefits of Taxol are unclear. If the patient is ER negative and has many nodes, Taxol may actually lower the recurrence risk by as much as 5 to 10% over five years. Women with negative nodes should not be given Taxol outside of clinical trials. ■

THE BOOKSHELF

Dear Stranger, Dearest Friend
by Laney Katz Becker

Dear Stranger, Dearest Friend is an intimate portrait of two complete strangers who become soul mates across hundreds of miles. The novel tracks the e-mail relationship between Lara, a sophisticated New Yorker and Susan, a steady, no-nonsense Midwesterner. Lara logs on to a breast cancer board in a panic after discovering a lump. Susan, a breast cancer survivor, writes back to her. What begins as a chance encounter on the Internet develops into a very special relationship. As their e-mail messages run back and forth, Susan and Lara begin to talk of husbands and children, dreams and fears, the daily cycle of success and setback. When a devastating crisis arises, the two woman are there for each other, through tragedy and triumph. Their emotions and humor as they solve each new problem makes this a highly readable book for anyone. Laney Katz Becker has taken the scary subject of breast cancer and put it into the bite-size pieces of information. ■

CALENDAR

The Bay Area Breast Cancer Forum

This is a monthly gathering of health care providers, researchers, patients, patient advocates, friends and families. Topics are varied, but the emphasis is on clinical trials and research. The meeting takes place on the second Wednesday of the month in Conference Room 1 on the 3rd Floor of the new UCSF Comprehensive Cancer Center at 1600 Divisadero. At 6:00pm, there is a light dinner; from 6:30-8:00pm a discussion led by Dr. Debu Tripathy. Please contact Fern Hassin at (415) 885-3738 for more information.

Pain Management Discussion - May 28, 2001

Carole Grubb, Clinical Psychiatric Nurse, and Dr. Catherine Bowman, Psychologist, from the UCSF/Mount Zion Pain Management Clinic will be leading a discussion on chronic pain and how it affects different aspects of life. The discussion will take place at the Ida and Joseph Friend Cancer Resource Center on 2356 Sutter Street. Topics will include:

- *Gaining a sense of control and empowerment over your pain.*
- *How stress management is related to chronic pain.*
- *Depression resulting from feelings of helplessness or lack of control, and how to avoid it.*
- *Biofeedback and other stress management tools.*

Acupuncture

The Breast Care Clinic is currently offering acupuncture to all patients. Our acupuncturist, Beverly Burns, MS, LAc, is available on Tuesday mornings from 8am to 12pm. Beverly specializes in alleviating a variety of symptoms as well as the side effects of chemotherapy and radiation through acupuncture.

The initial session with Beverly is 90 minutes and each follow-up visit is 60minutes. Payment is due at the time of service, although billing sheets are available for insurance reimbursement purposes. If you would like more information or wish to schedule an appointment, call the Breast Care Clinic at 353-7070 and ask for Sonia. ■

LINKS IN THE CHAIN

www.cancersupportivecare.com

A team which includes UCSF Cancer Center oncologist Dr. Ernest Rosenbaum and Stanford psychologist David Spiegel established a cancer supportive care site to help cancer patients face issues such as fear, isolation, anxiety, depression, fatigue and pain. The Cancer Supportive Care website was started in May 1999, and it has been providing education and support to a world-wide audience. The main goal of the CSCP is to improve the quality of life for cancer patients through a rehabilitation program, to help reduce side-effects of cancer and cancer therapy, and to help patients regain physical and functional status.

An overview course discusses information, including how to use the

Internet and a review of psychological problems, nutrition, exercise, reduction of fatigue and pharmacological control of treatment side-effects.

Educational classes and workshops discuss patients needs. Topics include coping with cancer, depression, will to live, sleep problems, intimacy and sexuality, nutrition, pain control and how to reduce fatigue.

www.friend2friend.org
Shop on-line at the brand new website of "Friend to Friend", the specialty giftshop at the UCSF Comprehensive Cancer Center. "Friend to Friend" offers books, cards, hats, sleep wear, and many other gift items designed for the special needs of cancer patients.

www.cancer-pain.org
The Association of Cancer Online Resources (ACOR), the largest online community of cancer patients, has launched a new website, Cancer-pain.org, to provide cancer patients with the education and support they need to obtain effective relief from pain.
Cancer-pain.org features sections on the causes of pain, breakthrough cancer pain, pain treatment options, and tools to help cancer patients communicate effectively with physicians about their pain. The web site also has a complete list of medications available to treat pain, information about complementary and alternative methods of pain control, and a section devoted to the special needs and issues of caregivers. In addition, Cancer-pain.org has an interactive section where patients and caregivers can exchange information.

The Natural Pharmacist / www.tnp.com
The Natural Pharmacist is a commercial but quite user-friendly site that is helpful for patients seeking background information about alternative treatments, especially herbs and supplements. It it one of the better sites of its kind on the net; for instance, it provides references and information on double-blind randomized trials, rather than just anecdotal findings.
However, the site does not provide a lot of information about possible interactions between, for instance, chemotherapy and herbs. It is very important that you inform your doctor and/or your pharmacist when you take herbs or supplements and that you ask them about possible interactions. ■

QUESTIONS FROM OUR PATIENTS

Q: My doctor prescribed tamoxifen to reduce the risk of a recurrence. What are the benefits and side-effects?

A: The hormone estrogen can accelerate the growth of breast tumors. Tamoxifen is an anti-estrogen that mimics estrogen. Tamoxifen has been shown to reduce the recurrence of breast cancer, reduce the chances of cancer spread or metastasis, and reduce the development of cancer in the opposite breast. Although tamoxifen does not cure advanced breast cancer, the medication can control cancer growth for some time and improve the quality of life

In addition to blocking the effects of estrogen, tamoxifen also has estrogen-like effects on other parts of the body. Some of these are positive, while others may be problematic. Due to its estrogen-like activity and cholesterol-lowering effects, tamoxifen may decrease heart problems, especially after menopause. In addition, tamoxifen can increase bone density and reduce osteoporosis and bone fractures.

Tamoxifen may cause hot flashes. It can also speed up endometrial cell growth in some women and contribute to the risk of uterine cancer. That risk is low, 1.5% after 5 years. It is almost always caught early and is found because women develop vaginal bleeding. Routine monitoring with annual PAP smears is recommended.

Tamoxifen may also increase the risk of stroke and of developing a blood clot in the leg or lung. Patients with a history of these problems should not be on tamoxifen. ■

SOME FACTS AND FIGURES ABOUT CANCER CLINICAL TRIALS

The NCI PDQ Database

The most comprehensive database of cancer clinical trials is the National Cancer Institute's PDQ® database, accessible through the NCI Web site CancerNet (http://cancernet.nci.nih.gov)

PDQ includes most trials sponsored or conducted by NCI. It also includes many cancer trials sponsored by pharmaceutical companies, medical centers, and other groups. It lists both active studies (currently enrolling patients) and those closed to enrollment.

In December 2000, PDQ contained about 1,800 active trials, of which approximately 1,200 are sponsored or conducted by NCI. Of those, about 110 are for breast cancer.

You can search PDQ on the Internet by the kind of cancer, the phase of the trial, the type or "modality" of treatment (e.g., chemotherapy, vaccine therapy), the sponsorship of the trial, and other search criteria. You can also request a search of PDQ by calling NCI's Cancer Information Service at 1-800-4-CANCER.

Some NCI-sponsored trials may not appear in PDQ because it is not mandatory for investigators to submit trials to the database. Trials missing from PDQ include some of the trials funded through NCI grants or contracts and some taking place at NCI-designated cancer centers.

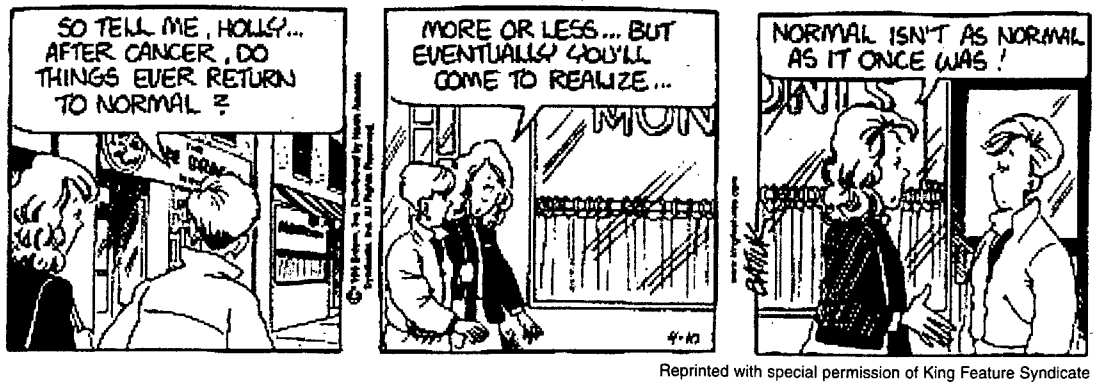
Some NCI-designated cancer centers maintain lists of their own clinical trials on their Web sites. You can check the list of the clinical trials at the UCSF Cancer Center on the Internet at http://cc.ucsf.edu/trials/index.html

Older People in Clinical Trials

Several studies have found that older people are under-represented in clinical trials. Women over 65 make up 56.5 percent of all patients with the more common cancers (lung, breast, colorectal, ovarian, pancreas), but they account for only 25.9 percent of patients in group trials for these diseases.

Experts have suggested several possible explanations:

- Research focuses on aggressive therapies, which may be thought unacceptably toxic to the elderly.
- Older people more often have other health problems (co-morbidities) or have had an earlier cancer that bar them from trials.
- Few trials are specifically designed for older patients.
- Physicians, patients and family members may think that older patients are less likely to benefit from and less able to tolerate aggressive treatment.
- Older patients are more likely to be diagnosed with advanced-stage disease, and more trials are designed for early-stage disease.
- Older patients may be less aware of medical developments and less likely to seek out clinical trials.
- There is a lack of financial, logistic and social support for participation of older patients in trials. ■



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FROM THE ADVOCATES
MEMBER SPOTLIGHT: BAMBI SCHWARTZ

by Linda Vincent

One way for breast cancer patients to help others with the disease is to become an advocate; an activist on behalf of other patients. Our San Francisco Advocacy Core (SFAC) has many dedicated volunteers. One of them, Bambi Schwartz, made headlines last year when she went to Japan to climb Mt.Fuji with other American and Japanese breast cancer survivors.

Bambi Schwartz has developed a patient outreach program at a San Francisco medical center, and she was invited to help develop and implement Mayor Willie Browns Breast Cancer Summit Meeting in 1996, as well as a conference on sexuality and intimacy in breast cancer in 1998.

Photo: Myra J. Bicknell

Bambi Schwartz with prayer flags on Mt. Fuji.

Bambi has been a tireless advocate for the SFAC. For the last four years, she has worked as a community representative on the UCSF Institutional Review Board of the Committee on Human Research, which reviews research protocols twice a month. She is an advocate member of the Epidemiology and Biostat Core, the Mammography Registry, and the Human Tissue Bank and Immuno-Pathology Core. Her involvement with the Epidemiology Core has led to invitations from the Core Director, Dr. Virginia Ernster, to attend a number of conferences.

Bambi continues to educate herself on many aspect of breast cancer. She is a graduate of Project LEAD, a program of the National Breast Cancer Coalition to provide science and medical education to patient advocates, and she has gone back to LEAD for refresher courses in 1997 and 1998.

The San Francisco Advocacy Core

There are many opportunities to be involved in patient advocacy at UCSF. The San Francisco Advocacy Core (SFAC) is open to all whose lives have been affected by breast cancer and who are willing to learn and pass on their knowledge. Advocates who volunteer for the SFAC are actively involved in research and treatment issues. They meet on Wednesday mornings to attend the Breast Oncology Program (BOP) scientific lectures.

SFAC is part of the UCSF SPORE program. SPORE is the acronym for Special Program of Research Excellence. It is a program that began in 1992 as a result of an advocate's conversation with the then head of the National Cancer Institute (NCI). NCI SPORE grants are disease-oriented; currently, there are six breast, two gastro-intestinal, three lung, four ovarian, and three prostate/genito-urinary SPORE research programs in cancer research institutions throughout the U.S. The aim is to translate basic scientific knowledge into clinical trials as quickly as possible. Researchers involved with SPORE enlist support and input of patient advocates at every step, from the laboratory bench to treatment. ■

For more information, please contact Peggy Devine at (415) 502-2986 /pdevine@cc.ucsf.edu

THANK YOU FOR YOUR SUPPORT

We wish to thank the following benefactors for contributions received since the last newsletter appeared (October 2000 - March 2001). The list includes special contributors to the Mammovan project, including donations made at "Taste for the Cure 2000".

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Brenda Solorzano
Takashi and Fumiko Tagawa
Irving and Jeanne Tapper
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Kim Wallace
Allen and Kathleen Weiner
Jonathan Wong
In Memory of Reshma Lalchandani:
Melanie and James Gerace
Mary-Ann Hudson
Nick and Anila Lacuani
Raj Lalchandani
Jane Lee
Norman and Caroline Macleod
Rodney Morgan
Earsh Nandkeshwar
Maha Osman
Dave and Sonica Singhal
Nancy Wood
In Memory of Gilda Loew:
Hugo and Maria Villar-Voukelatos

25-99
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Aki Baccus
Dean Ballback
Robert and Lynda Balzan
Marcela Barajas
Nellie Bates
Cynthia Beach
E.A. Blackmar
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Susan Wolfe
David Woon
Robin Zammas
In Memory of Olive Goodman:
Valerie, Ben and Family Asaro
Julia Capella
Edward and Rosalie Frink
Mary Mills
Dorothy Mitcheletti
Ernest & Elvira Ronzani
Mary and Peter Stafforini
Gemma Zunino
In Memory of Reshma Lalchandani:
Vlasta and James Adams
Nicholas and Joanne Arcuri
David and Susan Benson
Debra and Andrew Carroll
Sal and Harriet Cefalu
Michele Cielecki
Edward and Tricha Diaz
Geoffrey and Eileen Knoerzer
Klara Marent
Lowell and Susan McAdam
Robert and Laura Mechler
Naghmeh Peseschkian
In Memory of Gilda Loew:
Wesley and Mary Asher
Paige Mader
Ping Huang
Gunther Perdigao, M.D.
David and Susan Benson
Michele Cielecki
Sal and Harriet Cefalu
Edward and Tricha Diaz
Debra and Andrew Carroll
Geoffrey and Eileen Knoerzer
Lowell and Susan McAdam
Robert and Laura Mechler
Naghmeh Peseschkian

Carol Franc Buck BREAST CARE CENTER newsletter *Editor:* Sarah Paris *Design:* Greta Berger *Printed by*: UCSF Reprographics

PATIENT PORTRAIT: A STRONG SENSE OF FAITH

by Jeffery Stoia

One Sunday morning in August, 40-year-old Anne Abruzzini woke up to feel a lump in her right breast. Her husband felt it, too. The night before, in a dream, she had been describing a pain in her breast to a young, blonde woman wearing a white lab coat. She didn't recognize the woman, although months later they would meet.

First thing Monday, Anne was in her gynecologist's office. He sent her for a mammogram and to see a surgeon nearby. The appointment was for Friday afternoon, and at 5:00 p.m. she was the last patient in the office. He wanted to send her home. She pressed him to do a biopsy. Ten days later, the surgeon told her she had cancer. He was surprised at her calm. The tumor was large, he said; he urged her to have a mastectomy right away.

Anne didn't want a mastectomy. She went to an oncologist for a second opinion. In the examining room next to hers, she overheard his conversation with a teenage girl having chemotherapy. "I didn't even know what an oncologist was," she said. "But the girl was crying and throwing up. The doctor was matter-of-fact, talking with the mother."
"When I'm sick," Anne told her husband, I want someone compassionate, someone who cares."

Since she was a child, Anne says, she has had a strong sense of faith– a question-and-answer relationship with God, in which she always knew her questions would be answered. Her engineer husband calls her "an independent thinker."

From hours of reading in libraries and bookstores, she realized her cancer would kill her in a year and a half if not treated. Three qualities were essential to her in a doctor: excellent training, faith in God, care and compassion.

A physician Anne knew recommended Dr. Laura Esserman. When Anne met her, she felt Dr. Esserman was the woman she had seen in her dream. There was an instant sense of familiarity. "It was as if I'd heard all her questions before," Anne said. "It was a very comforting feeling."

Together they came up with a plan. Mastectomy was ruled out. A course of chemotherapy shrunk the tumor until it could be excised in December. When the margins weren't clear, a second operation was necessary in January.

"The worst part was the chemotherapy," Anne recalled. "I lost my hair and my memory. I looked like a mangled dog. It slowed down the oxygen flow to my brain, so I had trouble concentrating. I would drive in to the city and park my car in the garage, and then forget what it looked like. I would put a sun hat on the back seat window so I would know which car was mine."

After the second operation, Anne and her husband left the hospital, stopped for a sandwich and got back to their hotel, where she noticed she was bleeding.

"I called Laura, who was in the middle of another operation. I could hear her say, 'Get her in here right away.'" I couldn't have anesthesia, because I'd had something to eat, but I stayed very still, in spite of the pain. Laura sang to me in Spanish."

Today, Anne is cancer-free. She is grateful for her supportive family - her husband and two sons, 14 and 10, 14 and 10 – and for the care she received at the Breast Care Center. "God brought me to the right people," she said. "If you don't reach out, He won't interfere. He know when you're ready for help." ■

% of Tested Patients Positive for Mutations [35%] (manuscript in prep)

Resources/Tools to Improve Service
Model to Predict Likelihood of Developing Estrogen Positive Breast Cancer (Complete)
Clinical Trial to test above model (in progress)
Surrogate Markers of Breast Cancer Development (Breast Density,Atypical Lavage)-in progress

Development of Tailored Risk Assessment based on Lavage, Estradiol Levels
Trial Development for above (in process)
Additional Personnel to participate in High Risk Program (perform lavage)
Point of Care Information Systems with Decision support, Outcome Tracking, Clinical Trial linkages, and feedback on performance (benchmarks)

Forms on following pages:
Intake
Health Questionnaire
Patient Concerns
- Exam and Assessment Form (including Breast Map for Patient)
- Clinical Trial and Next Step form

Educational Brochure

Same Day Assessment Program

Goals
- Rapid assessment of diagnostic abnormality
- Minimize number of procedures necessary to diagnose cancer/assure benign
- High sensitivity (identify cancers when present)
- High specificity (avoid biopsies when cancer not present)
- Minimize use of operating room use for diagnostic procedures
- Integrate Diagnostic Procedures with Cancer Treatment Procedures
- Coordinate Care so that Patient Seamlessly moves to appropriate treatment
- Immediate Support for New Diagnoses of Breast Cancer
- Refine Follow-up based on Triple Assessment Score

Service Program/ Processes/ Forms
Identify Patients with Birads 4 or 5 (Inside/Outside) who require recall
Identify Patients with Birads 5 who need Evaluation and Biopsy
Notification of Abnormal Mammogram within 3 days
Recall coordinated with Assessment and Biopsy
Establish Same Day Clinic sessions so that maximum time to wait for assessment is 3 days from notification of screening abnormality
Same Day Assessment Intake: Make sure old films, prior biopsy reports have been obtained if any
Same Day Assessment Process:
- Exam by NP/surgeon
- Joint review with radiologist

- Core Biopsy, U/S biopsy/ Palpable directed FNA available same afternoon
  Preliminary diagnosis of Mammographic and Palpable Abnormalities same day

Final diagnosis of abnormalities within 24 hours of first visit
Appointments for discussion/ New Diagnosis available that day or next day (MD judgement)

Analytic Models
Gail Risk
Family History Risk Models
Birads Classification
Triple Assessment

Quality Measures/Benchmarks
Mammography
Cancer detection rate

% DCIS	[25%]
% T1a (≤0.5cm)	[5%]
% T1b (>0.5cm, ≤1.0cm)	[15%]
% T1c (>1.0 cm)	[25%]
% T2 or greater	
% Node Negative	[85%]
% Node Positive (cytokeratin only, H&E positive)	[<25%, <15%]
Recall Rates	[7% Incident Round; 4% Prevalent Round]
Cancer to Biopsy Rate	[35-40% Core]
Successful Needle Localization	[98%]

Cytology:

Cancer to Biopsy Rate	[25-30%]
Minimize Insufficient Diagnoses	[<10%]
Minimize False Negative (return with cancer within 1 year)	[<5%]

Integrated Program

Excisional Cancer to Biopsy Rate	[90%]
Identify Patients who could forego further biopsy	[20%]
24 hour diagnosis for pt. with mammogram Birads 4 or 5	[85%]
Minimize Total Procedures for Cancer Diagnosis (past screen)	[1.5]

Resources/ Measures Identified to Improve Service
More technologists to improve throughput (QI process initiated)
Touch preps of core biopsies
Improved communication with Primary Providers to inform them of service
Process Improvement Project to Improve Pathology Turnaround time for cores
(See pathology tracking form)
MRI coil and Clinical Trials study time on MRI at Breast Center Site
Analysis Tools:

a) Define Triple Assessment Score (Score of 1-3 each based on Exam, FNA/Core, Mammogram: Benign, Indeterminate, Malignant)
b) Develop reproducible clinical assessment tool (done, see form)

Create Cytology/Radiology/ Surgery Integrated Database and Data Elements to capture quality measures

Point of Care Information Systems with Decision support, Outcome Tracking, Clinical Trial linkages, and feedback on performance (benchmarks)

Forms

Standard Health History

Same Day Assessment Physical Exam and Assessment Form

(Database in Development)

Same Day Assessment Intake Form

In development (Structured U/S summary form/ Cytology Summary Form)

Primary Cancer Treatment

Goals

- Assess breast cancer recurrence and mortality risk in context of overall health
- Assess whether patients benefit from genetic testing
- Discuss likely outcome based on data from each patient's cancer
- Differentiate Risk of Mortality from Local Recurrence Risk
- Optimize Decision Quality and Empower Patients to Participate Fully
- Offer choices to patients and explain range of outcomes associated with each choice
- Use Collaborative Decision Making Tools to Improve Pt Participation in Decisions
- Minimize Side Effects from: (Improve Treatment Related Quality of Life)
- Chemotherapy: nausea, mucositis; delays from neutropenia; infections; hospitalizations
- Surgery: lymphedema, acute post-operative pain; chronic pain; poor mobility; dissatisfaction with surgical procedure (adjustment)
- Hormone Therapy: hot flashes, thromboembolic events; uterine cancer
- Radiation: skin burns; myositis
- Prepare patients for realistic recovery times from surgery and chemotherapy
- Set Appropriate expectations for Cosmetic Results
- Improve Tailoring of Treatment
- Specificity (identify who will not benefit from Chemotherapy, radiation, surgery)
- Sensitivity (identify who will derive maximal benefit from therapy)
- Encourage Clinical Trial Development
- Establish Portfolio of Correlative Science Trials
- Refine and develop surrogate markers for recurrence (micrometastases, pathologic and MRI response, immune function).
- Develop Expertise in New and Experimental Ductal Access Techniques
- Identify all Appropriate Clinical Trials for each patient
- Accrue Patients to Appropriate Clinical Trials
- Put Disease in Perspective and Help Patients Return to Full, Rich Life

DCIS (additional)

- Identify Patients with Multifocal DCIS
- Minimize Surgical Interventions for Definitive Diagnosis

- Improve non-surgical options, tailoring of treatments
- Introduce preventive strategies, neoadjuvant treatments in early stage
- Develop surrogate markers for response to non-surgical interventions
- Develop surrogate markers for risk of progression

Service Program Work Flow/Process

Coordinate care for patient with 1st phone call

- Ensure all information is ready and available for providers at time of visit
- Schedule Consultation Planning for Patients with 2nd opinion, or who want it

Overall Health Questionnaire: Assess competing health risks, Menopausal Status

Summarize Known Factors About Case

Breast Exam and creation of Breast Map (records density, masses etc)

Identify Patients at Greater Than 10% risk of Having Genetic Predisposition to Br Ca

Identify Patients who would be Appropriate for Neoadjuvant Therapy

- Introduce oncologist that day
- Schedule chemoteaching
- Schedule psychologist visit
- Schedule nurse specialist visit

Consultation Recording When Available

Clinical Trial Eligibility assessment/ Discussion and offer of participation Schedule Surgical Procedure and Complete Pathology Tracking, Trials Workflow

- Surgery Scheduling
- Pathology Review if outside
- Identify Markers to be performed based on prior biopsy
- Identify which trials have been discussed
- Schedule appointment with clinical nurse specialist
- Schedule appointment with psychologist
- Schedule appointment with other specialists (plastic surgery, XRT) as needed
- Schedule missing diagnostic tests
- Schedule appointment with surgical preparation unit
- Coordinate all appointments

Follow-up Schedule Delineated

Confirm Participation in Pre and Peri Operative Clinical Trials

Post Surgery Visit to Discuss Results

- Enter critical data elements into electronic form to database
- Automated generation of risks of recurrence, death, benefit of therapy from ADJUVANT

New Patient Conference (all MDs: surgery, radiation therapy, oncology)

- Review projections from ADJUVANT
- Arrange Oncology visit within three days
- Arrange Radiation Therapy visit within 7 days
- Identify patients at psychological risk

For patients with Chemotherapy

- Chemoteaching
- Set Schedule

Follow-up Schedule Delineated (See Follow-up Program)

Optional Services
Ductal Lavage
Ductoscopy
Cancer Risk (Genetic) Counseling (BRCA Pro, Shattuck Eidens)
Nutrition Counseling
Chinese Herbal Consultation, Acupuncture
Art for Recovery
Support Groups
Personal Support and Lifestyle Intervention Group

Education
Breast Cancer biology and risk factors
Personal Breast Cancer Notebook
(all information is on web, patients get personalized binder with web sites, nutrition, etc.)
Consultation Plan (Structured, transcribed Consultation Summary)
Clinical Trial Information and Informed Consent
Collaborative Care

Analysis Models
Family Breast Cancer Risk: Shattuck Eidens; BRCA Pro; Couch
ADJUVANT Model
Guidelines
National Cancer Centers Network (NCCN)
American Society of Clinical Oncology (ASCO)

Outcome/Quality Measures/Benchmarks
Surgical technique
Minimize hematoma rate
Mastectomy [3%]
Lumpectomy (modest, significant) [20/5%]
Minimize infection rate
No reconstruction (oral Antibiotics, IV Antibiotics) [5%,1%]
Reconstruction (Flap, Flap+Implant, Implant) [5%, 8%, 20%]
Maximize Sentinel Lymph Node Identification [95%]
Minimize Lymphedema Rate
SLN [2%]
ALN [15%]
Total Surgical Procedures
Invasive [1.3]
DCIS [1.9]

Reconstructive Surgery
Use of immediate reconstruction with
Mastectomy [60-70%]
Satisfaction with Result (Hi, Modest or better) [60%, 85%]

Flap loss	[0%]
TRAM complete recovery by 4,6,12 weeks	[80%,90%,100%]
Regret	[5%]

Breast Conservation Rates

▪ With EIC	[50%]
▪ Without EIC	[80%]

5 yr Recurrence with Breast Conservation (expected, based on choice)

▪ With Radiation (Age <50/50-69/≥70)	[10%/4%/1%]
▪ Without Radiation(Age <50/50-69/≥70,Tam)	[35%/15%/6%]

Diagnostic (Pathology) Turn Around Time

FNA 24 hr	[95%]
Biopsy 24/48	[50%,100%]
Lumpectomy 3 day/ 5 day/ 7 day	[40%, 70%, 95%]
Mastectomy 3day/ 5 day/7 day	[30%, 50%, 95%]
ER/PR 7 day	[100%]
Her-2/neu 7 day /12 day	[60%, 95%]

Chemotherapy

Moderate, Severe Nausea	[20%, 5%]
Moderate, Severe Mucositis	[5%, 1%]
Neutropenia that causes delay in therapy	[15%]
Infections	[5%]
Hospitalizations	[2%]
Fatigue after Chemotherapy (collaborate with M. Dod's Trial)	

Radiation

Myositis	[20%]
Skin Burns, severe	[2%]
Satisfaction with Cosmetic result	[95%]
Radiation after Lumpectomy	
< 50 years	[95-100%]
50-69 years (ER+/ER-)	[70/90%]
> 70 years (ER+/ER-)	[30/40%]

Program

Satisfaction with service, information	[80%]
% Who Experience Reduction in Anxiety	[50%]
Clinical Trial Accrual	[70%]
Calibration of Physicians	[90%]
predicting same outcomes for given clinical case, same range of benefit from Rx	
Depression	TBA
Adaptation	TBA

Resources/Tools to Improve Service

Study to determine best methods of presenting risk of recurrence, death to patients (time gained, increased probability of survival, decreased probability of death)
Clinical Trial to test above model (in progress)
Study to measure plastic surgery outcomes and satisfaction (in progress)
Develop Standard psychological Measures
Neoadjuvant Trials
Point of Care Information Systems with Decision support, Outcome Tracking, Clinical Trial linkages, and feedback on performance (benchmarks)

Forms on following pages:

Intake
Health Questionnaire
Exam and Assessment Form
Surgery Scheduling and Pathology Tracking Form
ADJUVANT Output (risk of recurrence, death, benefit of therapy)
Summary Data Form (All therapy)
Chemotherapy Flow Sheet
Educational Introduction (Welcome to the Carole Franc Buck Breast Care Center)
Collarborative Care

Data Elements (Patient Surgery and Pathology Data)

Outcome Measures

Follow-Up Program for patients with breast cancer (In Development)

Goals

- Assess complication rates of treatment, interventions
- Identify and treat complications and track impact of interventions
- Identify and treat (refer) patients with treatable conditions that impact quality of life, breast cancer outcomes and track impact of interventions
- Side effects of menopause (hot flashes, vaginal dryness, osteopenia, etc)
- Identify rates of Clinical Depression
- Identify Patients with Difficulty in breast cancer Adjustment
- Coordinate follow-up care
- Use most efficient and effective resources for follow-up
- NPs for routine follow-up
- MD for specific problems
- Provide Forums with all MDs/Patients to address common concerns, research advances

Service Program/Forms/Process

Follow-up visit
Breast Exam and creation of Breast Map (records density, masses etc)
Clinical Trial Eligibility assessment/ Discussion and offer of participation

Follow-up Exam Schedule Delineated

Optional Services
Cancer Risk (Genetic) Counseling (BRCA Pro, Shattuck Eidens)
Nutrition Counseling
Ductal Lavage
Ductoscopy
Referral for Diagnostic Services (see same day assessment program)
Personal Support and Life Style Intervention Program

Education
Methods to manage Menopausal Symptoms
Others in Development:
- How to Identify Symptoms of Recurrence and What to Report to Your Doctor
- Life After Breast Cancer

Data Analysis Models
Quality Of Life Tools:
- NSABP Symptom Checklist (Ganz 1995; Day 1999)
- WHI Sleep Disturbance Checklist
- FACT B
- MOS Sexual Problems Measure (Watts 1991)

Outcome/Quality Measures/Benchmarks -- CURRENTLY IN DEVELOPMENT

Recurrence	
Local	
Systemic	
Satisfaction with service, information	[80%]
% Who Experience Reduction in Anxiety	[90%]
Clinical Trial Accrual	[20%]
Generation of New trials	2 per year
Fatigue	
Satisfaction with Body Image	
% of Patients with Depression (by CES-d)	
who get intervention (Radloff 1977)	[80%]
Change in Self Reported Exercise Level (# times/week)	[25%]
Change in Self Reported Eating habits (?)	
Lymphedema:	
% with symptoms who get treated	[90%]
% with treatment who improve	[25%]

Resources/Tools to Improve Service
Link to SEER data to improve tracking of outcomes
Point of Care Information Systems with Decision support, Outcome Tracking, Clinical Trial linkages, and feedback on performance (benchmarks)

Forms on following pages:
Follow-Up Symptom Check List
NSABP Symptom Check List
MOS Sexual Problems Measure
Sleep Disturbance Scale
CES-d (Depression Scale)
Follow-Up Exam Form
Follow-Up and Recurrence Data
In-depth Measures
Patient Concerns
Exam and Assessment Form (including Breast Map for Patient)
Clinical Trial and Next Step form
Educational Brochure

Metastatic and Supportive Care (In Development)

Goals of Care

- Identified need to reduce variation in use of support interventions
  - Growth factor
  - Appetite stimulants
  - Pain Medications
- Need to improve methods for consistently addressing end of life questions and issues
- Should be discussed explicitly early in treatment
- Appropriate Use of and Referral to Hospice
- Explicitly develop goals of care based on response to each new agent used
- Match therapies and toxicity with Goals of Care
- Improve organization is needed in staging work-ups to decrease cycle time
- Problems in radiology with getting comparative films
- Problems with biopsy results
- Rapid scheduling of radiology and rapid results turnaround (patients identified this as a major issue, even though MDs were not concerned biologically)

Quality Benchmarks
Time from last chemotherapy to death: Time from Metastatic Diagnosis to Death [0.1]
Use of Home Care Services
Use of Hospice Services
Number of Chemotherapy Treatments
Clinic Visits Over Time
Clinical Trial Accrual
Satisfaction with Care Survey
Pain Control (Excellent/Modest) [85%/95%]
Patient Satisfaction with Decision Making

Resources/Tools to Improve Service
Link to SEER data to improve tracking of outcomes

Tools, Protocols to Improve Communication between patients in physicians (study open to adapt consultation planning methods)

Models to predict time to progression (based on time from initial diagnosis, response to first therapy)

Point of Care Information Systems with Decision support, Outcome Tracking, Clinical Trial linkages, and feedback on performance (benchmarks)

Cheryl Ewing
Biographical Sketch

Provide the following information for all Principal Investigator(s) and Co-Principal Investigator(s).

NAME	POSITION TITLE
Cheryl A. Ewing, M.D.	Assistant Clinical Professor of Surgery, University of California, San Francisco

EDUCATION/TRAINING

INSTITUTION AND LOCATION	DEGREE (*if applicable*)	YEAR(s)	FIELD OF STUDY
University of Michigan; Ann Arbor	BS	1974	Zoology
Wayne State University	MD	1983	Medicine
St. Joseph Mercy Hospital; University of Michigan	Resident	1983-1988	Surgery
University of Chicago	Fellow	1988-1991	Surgical Oncology

RESEARCH AND PROFESSIONAL EXPERIENCE: Include in a 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.**

Professional Experience

1983-1996 Director, Multidisciplinary Breast Cancer Program; University of Chicago
1991-2000 Ass't Professor of Surgery; University of Chicago
1996-1/2001 Private Practice; St. Vincent Hosp., Santa Fe, NM (Gen. and Surg. Oncol.)
2001-present Associate Adjunct Prof. Surgery; UCSF

Honors and Awards

American Association of Cancer Research Travel Award
Women in Medicine Profession Development Travel Award
1992 Young Surgical Investigator Travel Award – American College of Surgeons
Teaching Award - September 2000 instruction in Family Practice Resident Lafamilia Clinic/University of New Mexico.

Research Interests

- Utilization of molecular biology techniques, genomic loci abnormalities previously identified in breast cancers can be evaluated in pre-malignant and malignant breast and then correlation made to location, race, patient's age and histologic grade
- Development of a Lymphedema Program to determine risk factors for upper extremity lymphedema following breast cancer surgery and to investigate prevention methods, and quality analysis of evaluation and treatment methodology

Journal Articles

Ewing, C., Goldberg, R., and Michelassi, F.: Locally Invasive Rectosigmoid Cancer. Postgraduate General Surgery 3(2):57-59, 1991
Michelassi, F., Ewing, C., Vannucci, L., et al.: Prognostic Significance of Ploidy Determination in Rectal Cancer, Hepato-Gastroenterology 39(3):222-225, 1992

SEMINARS & PRESENTATIONS (Selected)

Seminar- "Women and Cancer – Fighting Fear with Fact" – Right Direction. Chicago, IL, 1992
International Seminar – Breast Cancer, 1992 – New Dilemmas In An Old ," Sponsor, U.of Chicago,
Women's Symp.: "What Women Need to Know about Breast Cancer" – U. of Chicago, 1992.
"Breast Conservation as an Alternative Treatment for Breast Cancer" – Grand Rounds – St Catherine's Hospital, East Chicago, Indiana, January 20, 1993.
"Update on Detection and Treatment of Breast Cancer" – Grand Rounds – Methodist Hospital, Merrillville, Indiana, May 5, 1994.
"Striving For Excellence In Mammography" – Eastman Kodak, Chicago, IL; 1994.
"Diagnosis and Management of Breast Cancer," Grand Rounds; U.Chicago OB-GYN; 1994
"Breast Cancer: Evolving Strategies in Diagnosis and Treatment" – McAuley Cancer Center, Ann Arbor, Michigan, November 22, 1994.
" Ductal and Lobular Carcinoma In-Situ and Minimally Invasive Breast Cancer;"Advances in Surgery, Review Course, Chicago, Illinois, June 13, 1995.
"The Challenge of Breast Cancer" – sponsor, National Cancer Institute and The Susan G. Komen Breast Cancer Foundation, October 2, 1995.

Motion Pictures

Ewing, C., Zachary, L. – "Segmental Mastectomy With Immediate Partial Reconstruction: An Alternate to Mastectomy in Women With Small Breasts" – American College of Surgeons, Annual Clinical Congress program: General Surgery Motion Picture Session, New Orleans, Louisiana, October 24, 1995, 1997.

BOOK CHAPTERS

Ewing, C. – "Management of Minimally Invasive and Non-Invasive (In-Situ) Carcinoma of the Breast" – book chapter for Mastery of Surgery 3rd Edition (Published 1997).

ABSTRACTS:

Ewing, C., Gottlied, L., Zachary, L. – "The Diagnosis of Breast Cancer with Fine Needle Aspiration or Core Biopsy Will Maximize the Cosmesis of Skin Sparing Mastectomy", submitted to The Society of Surgical Oncology.
Hansen, N., Cambronero, E., Arenas, R., Ewing, C. – "Needle Localization Breast Biopsies: Does An Incomplete Excision Preclude Breast Conservation?" , submitted to The Society of Surgical Oncolology.

Follow-up Patient
Customer Service Survey

Data entry cells are highlighted in BLUE
Fixed cells are highlighted in GREY
Results cells are highlighted in YELLOW

1. I have been a patient at the BCC:

Total no of responses	Study Date	Less than 1 year		1 year		2 years		3 years		4 years		4 years+		Check Total
81	Q2 99		13%		18%		25%		25%		4%		16%	100%
33	Q1 00	16	48%	5	15%	6	18%	2	6%	2	6%	2	6%	100%
100	Date 3		0%		0%		0%		0%		0%		0%	0%
100	Date 4		0%		0%		0%		0%		0%		0%	0%
100	Date 5		0%		0%		0%		0%		0%		0%	0%
100	Date 6		0%		0%		0%		0%		0%		0%	0%
100	Date 7		0%		0%		0%		0%		0%		0%	0%
100	Date 8		0%		0%		0%		0%		0%		0%	0%
100	Date 9		0%		0%		0%		0%		0%		0%	0%
100	Date 10		0%		0%		0%		0%		0%		0%	0%

2. How many times on the average are you seen a year?

Total no of responses	Study Date	1-2		3-4		5-6		7-8		9-10		11-15		16+		Don't know/ N/A		Check
81	Q2 99		81%		14%	0	2%		1%		0%		1%		0%	0	0%	100%
33	Q1 00	9	27%	8	24%	5	15%	1	3%	2	6%	3	9%	2	6%	3	9%	100%
100	Date 3		0%		0%		0%		0%		0%		0%		0%		0%	0%
100	Date 4		0%		0%		0%		0%		0%		0%		0%		0%	0%
100	Date 5		0%		0%		0%		0%		0%		0%		0%		0%	0%
100	Date 6		0%		0%		0%		0%		0%		0%		0%		0%	0%
100	Date 7		0%		0%		0%		0%		0%		0%		0%		0%	0%
100	Date 8		0%		0%		0%		0%		0%		0%		0%		0%	0%
100	Date 9		0%		0%		0%		0%		0%		0%		0%		0%	0%
100	Date 10		0%		0%		0%		0%		0%		0%		0%		0%	0%

3a. When I leave a message for a nurse/doctor, my call is returned within a reasonable period of time.

Total no of responses	Study Date	N/A		Agree		Somewhat agree		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		16%		73%		6%		4%		1%			100%
33	Q1 00	7	21%	19	58%	5	15%	2	6%	0	0%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

3b. I expect a call back within:

Total no of responses	Study Date	30 minutes		1-2 hours		Same day		Next day		Don't know/ N/A		NOT APPLIC		Check Total
81	Q2 99		3%		11%		65%		21%		0%			100%
33	Q1 00	2	6%	7	21%	16	48%	5	15%	3	9%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

4. When I call the BCC, I am able to speak with someone within a reasonable amount of time without waiting on hold.

Total no of responses	Study Date	N/A		Agree		Somewhat agree		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		7%		71%		11%		5%		6%			100%
33	Q1 00	8	24%	16	48%	8	24%	1	3%	0	0%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

5. I have too many appointments at the BCC.

Total no of responses	Study Date	N/A		Agree		Somewhat		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		22%		4%		4%		0%		71%			100%
33	Q1 00	9	27%	0	0%	3	9%	2	6%	19	58%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

6. The Front Desk staff were courteous and acknowledged me in a timely manner.

Total no of responses	Study Date	N/A		Agree		Somewhat agree		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		1%		92%		6%		1%		0%			100%
33	Q1 00	1	3%	32	97%	0	0%	0	0%	0	0%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

7. I found the overall appearance of the clinic satisfactory and was comfortable in the waiting area.

Total no of responses	Study Date	N/A		Agree		Somewhat agree		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		2%		95%		2%		0%		0%			100%
33	Q1 00	1	3%	30	91%	2	6%	0	0%	0	0%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

8. I was comfortable with the amount of time that I waited to see the doctor.

Total no of responses	Study Date	N/A		Agree		Somewhat agree		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		2%		95%		2%		0%		0%			100%
33	Q1 00	1	3%	16	48%	7	21%	5	15%	4	12%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

9. After arriving for my appointment, I waited:

Total no of responses	Study Date	0-30 min		31-45 min		46-60 min		1-1½ hours		2+ hours		Don't know/ N/A		Check Total
81	Q2 99		85%		10%		3%		1%		1%		0%	100%
33	Q1 00	19.5	59%	4.5	14%	3.5	11%	2.5	8%	2	6%	1	3%	100%
100	Date 3		0%		0%		0%		0%		0%		0%	0%
100	Date 4		0%		0%		0%		0%		0%		0%	0%
100	Date 5		0%		0%		0%		0%		0%		0%	0%
100	Date 6		0%		0%		0%		0%		0%		0%	0%
100	Date 7		0%		0%		0%		0%		0%		0%	0%
100	Date 8		0%		0%		0%		0%		0%		0%	0%
100	Date 9		0%		0%		0%		0%		0%		0%	0%
100	Date 10		0%		0%		0%		0%		0%		0%	0%

10. I was kept informed of any delays during my visit.

Total no of responses	Study Date	N/A		Agree		Somewhat agree		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		45%		41%		6%		3%		5%			100%
33	Q1 00	8	24%	12	36%	7	21%	3	9%	3	9%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

11a. When I have tests/labs done, I am informed about the results within a reasonable period of time.

Total no of responses	Study Date	N/A		Agree		Somewhat agree		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		19%		66%		14%		0%		1%			100%
33	Q1 00	9	27%	14	42%	6.5	20%	1.5	5%	2	6%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

11b. My definition of a reasonable amount of time is:

Total no of responses	Study Date	Same day		24 hours		48 hours		72 hours		Don't know/ N/A		NOT APPLIC		Check Total
81	Q2 99		12%		31%		18%		15%		24%			100%
33	Q1 00	12	36%	9	27%	3	9%	4	12%	5	15%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

12. The process for making future appointments and other testing arrangements was simple and expedient.

Total no of responses	Study Date	N/A		Agree		Somewhat agree		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		5%		78%		14%		3%		1%			100%
33	Q1 00	3	9%	25	76%	5	15%	0	0%	0	0%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

13. I am able to access the BCC staff as my need arises between visits.

Total no of responses	Study Date	N/A		Agree		Somewhat agree		Somewhat disagree		Disagree		NOT APPLIC		Check Total
81	Q2 99		12%		71%		14%		3%		1%			100%
33	Q1 00	9	27%	18	55%	5	15%	1	3%	0	0%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

14. I would rate my overall satisfaction with today's visit as:

Total no of responses	Study Date	Excellent		Good		Fair		Poor		Don't know/ N/A		NOT APPLIC		Check Total
81	Q2 99		79%		18%		1%		1%		0%			100%
33	Q1 00	16	48%	10	30%	1	3%	0	0%	6	18%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

15a. I would rate my overall satisfaction with the FRONT DESK STAFF (RECEPTIONISTS) as:

Total no of responses	Study Date	Excellent		Good		Fair		Poor		N/A		NOT APPLIC		Check Total
81	Q2 99		71%		21%		6%		0%		1%			100%
33	Q1 00	20	61%	13	39%	0	0%	0	0%	0	0%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

15b. I would rate my overall satisfaction with the MEDICAL ASSISTANT as:

Total no of responses	Study Date	Excellent		Good		Fair		Poor		N/A		NOT APPLIC		Check Total
81	Q2 99		60%		9%		1%		3%		27%			100%
33	Q1 00	16	48%	9	27%	0	0%	0	0%	8	24%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

15c. I would rate my overall satisfaction with the NURSE as:

Total no of responses	Study Date	Excellent		Good		Fair		Poor		N/A		NOT APPLIC		Check Total
81	Q2 99		58%		8%		3%		1%		30%			100%
33	Q1 00	21	64%	9	27%	0	0%	0	0%	3	9%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

15d. I would rate my overall satisfaction with the DOCTOR as:

Total no of responses	Study Date	Excellent		Good		Fair		Poor		N/A		NOT APPLIC		Check Total
81	Q2 99		82%		6%		0%		0%		12%			100%
33	Q1 00	22	67%	6	18%	1	3%	0	0%	4	12%			100%
100	Date 3		0%		0%		0%		0%		0%			0%
100	Date 4		0%		0%		0%		0%		0%			0%
100	Date 5		0%		0%		0%		0%		0%			0%
100	Date 6		0%		0%		0%		0%		0%			0%
100	Date 7		0%		0%		0%		0%		0%			0%
100	Date 8		0%		0%		0%		0%		0%			0%
100	Date 9		0%		0%		0%		0%		0%			0%
100	Date 10		0%		0%		0%		0%		0%			0%

Detailed Description of BCCDB: Patient Summary

As described above, the BCCDB is used in all aspects of the BCC clinical process. One of the most valuable recent additions has been the patient summary report, which provides the clinician with the germane summary information needed before seeing a BCC patient. This summary report lessens the need for the clinician to search through either the chart or the online UCSF clinical information system for critical diagnostic and treatment information during the patient visit.

The following is an example of an actual patient summary report (with identifying information altered):

JANE DOE **MRN 9999999** **Age today:** 59 Printed on 7/30/01
Date of initial cancer diagnosis: 4/9/99

Comorbidity:

Episode #1

Date	Procedure	Laterality
4/9/99	9. Partial mastectomy with_axillary lymph node dissection_including re-excision	Left

Non-Invasive Disease

Histology DCIS:	Yes	Grade:	3
Tumor size DCIS (cm):		Comedo:	Yes
	unknown	Histology LCIS:	No
Multifocal:	Yes	Tumor size LCIS (cm):	
Margin assessment (mm):			
	unknown		

Invasive Disease

Tumor size cumulative dimension:			
Tumor size (cm):	2.00	Nuclear grade:	3
		Mitotic Grade:	
Multifocal:	No	Architecture:	
Lymphovascular invasion:	Yes	Overall SBR Score-Inv. Cancer:	
Dermal lymphatic invasion:	unknown	Total number nodes:	12
Margin assessment (mm):		Total number positive nodes:	2
	unknown	Largest metastasis (mm):	9.0
Histology:	1. Ductal carcinoma	Number SLNs:	0
Extensive intraductal component:	unknown	Number of positive SLNs:	0
Associated with Paget's disease:	unknown	Extracapsular extension:	unknown

Markers

ER Result:	positive	50% MODERATE TO STRONG
PR Result:	positive	50% WEAK
HER2 Result:	0	HERCEPTEST(DAKO)
HER2 Amplif:		
HER2 Copy #:		

Notes:
MARGINS ARE PRESUMED OK AFTER SECOND SPECIMEN. EACH METASTAliC AXLLARY NODE WAS LESS THAN 1 CM BUT THERE WAS EXTENSION INTO THE AXILLARY FAT. XXXXXX STAGED PATIENT AS STAGE 2A. DR. XXXXXX STAGED PATIENT AS STAGE 2A (T1, N1, M0). BUT DR. XXXXXX STAGED PATIENT AS 3B (T1, N3, M0). THERE WAS A SUSPICIOUS MEDIASTINAL NODE AT TIME OF SURGERY BUT WAS NOT BIOPSIED. SURGERY DONE AT XXXXXX.

Therapy	Start Date	End Date		
chemotherapy	4/30/99	7/2/99	Setting	Adjuvant
			AC	
			# of cycles:	4
			Days in cycle:	21
			Patient response:	6. Not Applicable (adjuvant)
radiation	8/12/99	9/22/99	Setting:	Adjuvant
			Site:	5. Mediastinal left
			Dose:	4930
radiation	8/12/99	9/22/99	Setting:	Adjuvant
			Site:	4. Axillary left
			Dose:	4930
radiation	8/12/99	9/22/99	Setting:	Adjuvant
			Site:	3. Supraclavicularleft
			Dose:	4930
radiation	8/12/99	9/22/99	Setting:	Adjuvant
			Site:	1. Breast left
			Dose:	4930
hormone	9/11 /99	Setting:	Adjuvant	
	day unknown		Tamoxifen	
			Dose:	20
			Patient response:	6. Not Applicable (adjuvant)

Staging

4/9/99	T1	N1	MO	IIA	pathological

Last follow-up prior to report print date: 7/23/01

Provider: XXXXXX, XXXXXX
Current menopausal status: post
Diagnosis: distant recurrence
Status: progressive
On other hormone therapy: yes

Detailed Description of the BCCDB: Forms, Data Tables, and Data Elements

Using forms that correspond to the above data tables, data are acquired for the BCCDB as follows:
- The Patient Intake form is completed by intake staff in the clinic.
- The Demographic form is completed by the data entry assistant using the hospital's IDX registration system.
- The Patient Health Questionnaire, Review of Systems, and Family Cancer History forms are completed by the patient.
- The Procedures form is abstracted from the patient chart and/or pathology report(s) by the data manager.
- The Chemotherapy, Hormone Therapy, Radiation Therapy, and Other Therapy sections of the Therapies form are abstracted by the data manager from the patient chart.
- The Summary form is abstracted from the patient chart and/or pathology report(s) by the data manager, with the exception of some fields that require the physician's judgment.
- The Follow-up and Recurrence form is completed by the physician at each follow-up visit and includes staging.

The following table lists all the data tables and data elements (data fields, keys) in the BCCDB. Accompanying each field is a description of the possible data values, as well as comments where appropriate.

BCCDB DATA ELEMENTS

Legend:
* Denotes Primary Key (Links tables) (medical record number)
\# Denotes Secondary Key (Allows for multiple entries within a table)

Attribute Description	Value	Notes
Patient Intake		
Serial Number	auto-number in Patient Intake	for filing hard copies of patient forms
Intakedate	Date	**>01/01/2001 (for new year error prevention-change every new year)**
Apptdate	Date	= or > intake date (or null)
ApptTime		
Requested MD	picklist	
Scheduled MD	picklist	
Lastname		
Firstname		
*UCSF Medical Record Number	8 digit number	
DOB	Date	required; <01/01/1990
Sex	Female/Male/Unknown	required
SSN		
Homephone		
Workphone		

Surgery-patient type	1. surgery patient-new dx of breast cance seeking surgery at BCC 2. surgery patient- new dx of breast cancer seeking second opinion 3. surgery patient- high risk 4. surgery patient- history of breast cancer seeking F/U care 5. surgery patient- history of benign breast disease seeking F/U care 6. surgery patient- breast lump 7. surgery patient- abnormal mammogram 8. surgery patient- other 9. surgery patient-ductal lavage	Per Laurel Bray-Hanin 11/28/2000
Surgery patient-notes		
Primary reason for initial appointment	1. patient discovered breast lump 2. MD/care provider discovered breast lump 3. abnormal mammogram 4. breast edema 5. pain in breast 6. nipple discharge/bleeding 7. breast redness/rash 8. nipple retraction 9. dimpling of breast skin 0. other	Per Laurel Bray-Hanin 11/28/2000: Applies only to new surgery patients.
primary reason laterality	right;left;both;no;unknown	
mammogram-month	01-12	
mammogram-day	01-31	
mammogram-year	1950-2009	
mammogram-where performed		
mammogram-result		
Oncology-patient type	1. oncology patient-new diagnosis of breast cancer seeking treatment 2. oncology patient-new diagnosis of breast cancer seeking second opinion 3. oncology patient-local recurrence 4. oncology patient-new metastatic seeking treatment 5. oncology patient-metastatic breast cancer second opinion 6. oncology patient-metastatic breast cancer seeking access to clinical trial	
Oncology patient-describe		
Laterality	right;left;both;distant mets;no;unknown	feeds into the same field as for Surg. pt.
accomp feature-patient discovered lump	right;left;both;no;unknown	applies to all patients; how diagnosed
accomp feature-MD discovered lump	right;left;both;no;unknown	
accomp feature-abnormal mammogram	right;left;both;no;unknown	
accompanying feature-breast edema	right;left;both;no;unknown	
accompanying feature-pain in breast	right;left;both;no;unknown	
accompanying feature-nipple discharge	right;left;both;no;unknown	
accomp feature-nipple discharge color	clear;green;brown;red;yellow;blue;other (type in)	
accompanying feature-breast redness/rash	right;left;both;no;unknown	
accompanying feature-nipple retraction	right;left;both;no;unknown	
accomp feature-dimpling on breast skin	right;left;both;no;unknown	
accompanying feature-other	right;left;both;no;unknown	
date of first clinical sign of abn or cancer-month	01-12	
date of first clinical sign of abn or cancer-yea	1950-2009	

date of histologic diagnosis-month	01-12	
date of histologic diagnosis-year	1950-2009	
had prior breast biopsies	right;left;both;no;unknown	
had breast cancer	yes/no checkbox	
had breast cancer-year	4-digit	
had breast cancer-describe		
had fibercystic disease	yes/no checkbox	
had fibercystic disease-year	4-digit	
had fibercystic disease-describe		
had cysts	yes/no checkbox	
had cysts-year	4-digit	
had cysts-describe		
had fibroadenoma	yes/no checkbox	
had fibroadenoma-year	4-digit	
had fibroadenoma-describe		
had chronic mastitis	yes/no checkbox	
had chronic mastitis-year	4-digit	
had chronic mastitis-describe		
had nipple discharge	yes/no checkbox	
had nipple discharge-year	4-digit	
had nipple discharge-describe		
had abnormal biopsy	yes/no checkbox	
had abnormal biopsy-year	4-digit	
had abnormal biopsy-describe		
family hx of cancer	mother's side;father's side;both sides;sibling;none;no response	
family hx of cancer-describe		
ReferredMD		
Insurance		
Medical group if HMO		
Subscriber		
Subscriber SSN		
Claims address		
Group #		
pt to bring ins auth	yes/no checkbox	
referral or $150 deposit	yes/no checkbox	
pt to FedEx records prior to appt	yes/no checkbox	
pt to bring records to appt	yes/no checkbox	
no records to bring	yes/no checkbox	
new patient packet sent	yes/no checkbox	
other stipulation/arrangement	yes/no checkbox	
notes		
Patient Inquiries		**Created 12/12/2000**
No appointment scheduled	1. Second opinion surgical, no opening 2. Second opinion oncology, no opening 3. Breast abnormality, non-urgent, no opening 4. Breast abnormality, urgent, no opening 5. Seeking follow-up care, no opening 6. Needs surgery, no opening 7. Needs oncology treatment, no opening 8. Will call back 9. Patient did not return phone calls	Per Laurel Bray-Hanin
# Inquirydate	Date	**>01/01/2001 (for new year error prevention-change every new year)**
Intakedate	Date	**>01/01/2001 (for new year error prevention-change every new year)**
Apptdate	Date	= or > intake date (or null)

ApptTime		
Requested MD	picklist	
Scheduled MD	picklist	
# Lastname		
# Firstname		
UCSF Medical Record Number	8 digit number	
DOB	Date	<01/01/1990
Sex	Female/Male/Unknown	
SSN		
homephone		
workphone		
Surgery-patient type	1. surgery patient-new dx of breast cance seeking surgery at BCC 2. surgery patient- new dx of breast cancer seeking second opinion 3. surgery patient- high risk 4. surgery patient- history of breast cancer seeking F/U care 5. surgery patient- history of benign breast disease seeking F/U care 6. surgery patient- breast lump 7. surgery patient- abnormal mammogram 8. surgery patient- other 9. surgery patient-ductal lavage	Per Laurel Bray-Hanin 11/28/2000
Surgery patient-notes		
Primary reason for initial appointment	1. patient discovered breast lump 2. MD/care provider discovered breast lump 3. abnormal mammogram 4. breast edema 5. pain in breast 6. nipple discharge/bleeding 7. breast redness/rash 8. nipple retraction 9. dimpling of breast skin 0. other	Per Laurel Bray-Hanin 11/28/2000: Applies only to new surgery patients.
primary reason laterality	right;left;both;no;unknown	
mammogram-month	01-12	
mammogram-day	01-31	
mammogram-year	1950-2009	
mammogram-where performed		
mammogram-result		
Oncology-patient type	1. oncology patient-new diagnosis of breast cancer seeking treatment 2. oncology patient-new diagnosis of breast cancer seeking second opinion 3. oncology patient-local recurrence 4. oncology patient-new metastatic seeking treatment 5. oncology patient-metastatic breast cancer second opinion 6. oncology patient-metastatic breast cancer seeking access to clinical trial	
Oncology patient-describe		
Laterality	right;left;both;distant mets;no;unknown	feeds into the same field as for Surg. pt.
accomp feature-patient discovered lump	right;left;both;no;unknown	applies to all patients; how diagnosed
accomp feature-MD discovered lump	right;left;both;no;unknown	
accomp feature-abnormal mammogram	right;left;both;no;unknown	
accompanying feature-breast edema	right;left;both;no;unknown	

accompanying feature-pain in breast	right;left;both;no;unknown	
accompanying feature-nipple discharge	right;left;both;no;unknown	
accomp feature-nipple discharge color	clear;green;brown;red;yellow;blue;other (type in)	
accompanying feature-breast redness/rash	right;left;both;no;unknown	
accompanying feature-nipple retraction	right;left;both;no;unknown	
accomp feature-dimpling on breast skin	right;left;both;no;unknown	
accompanying feature-other	right;left;both;no;unknown	
date of first clinical sign of abn or cancer-month	01-12	
date of first clinical sign of abn or cancer-yea	1950-2009	
date of histologic diagnosis-month	01-12	
date of histologic diagnosis-year	1950-2009	
had prior breast biopsies	right;left;both;no;unknown	
had breast cancer	yes/no checkbox	
had breast cancer-year	4-digit	
had breast cancer-describe		
had fibercystic disease	yes/no checkbox	
had fibercystic disease-year	4-digit	
had fibercystic disease-describe		
had cysts	yes/no checkbox	
had cysts-year	4-digit	
had cysts-describe		
had fibroadenoma	yes/no checkbox	
had fibroadenoma-year	4-digit	
had fibroadenoma-describe		
had chronic mastitis	yes/no checkbox	
had chronic mastitis-year	4-digit	
had chronic mastitis-describe		
had nipple discharge	yes/no checkbox	
had nipple discharge-year	4-digit	
had nipple discharge-describe		
had abnormal biopsy	yes/no checkbox	
had abnormal biopsy-year	4-digit	
had abnormal biopsy-describe		
family hx of cancer	mother's side;father's side;both sides;sibling;none;no response	
family hx of cancer-describe		
ReferredMD		
Insurance		
Medical group if HMO		
Subscriber		
Subscriber SSN		
Claims address		
Group #		
pt to bring ins auth	yes/no checkbox	
referral or $150 deposit	yes/no checkbox	
pt to FedEx records prior to appt	yes/no checkbox	
pt to bring records to appt	yes/no checkbox	
no records to bring	yes/no checkbox	
new patient packet sent	yes/no checkbox	
other stipulation/arrangement	yes/no checkbox	
notes		
DEMOGRAPHIC (currently abstracted from IDX)		
*UCSF Medical Record Number	8 digit number	
Patient Account/Visit Number	10 digit number	
Alias		

Ethnic Group	Hispanic Non-Hispanic Unknown	
Race	Asian/Pacific Islander Black Native American/Eskimo/Aleut Other Russian Emigre Other Israeli White Unknown	
Language	Amharic Arabic Armenian American Sign Language Bulgarian Cambodian Cantonese English Farsi French German Hebrew Hindu Hmong Italian Japanese Korean Laotian Mandarin Mien Other Polish Punjabi Russian Spanish Tagalog Tigrinya Unknown Urdu Vietnamese	
Marital Status	Divorced Legally Separated Married Single Widowed Unknown/Declined to State	

Religion	Apostolic Assembly of God Bahai Baptist Black Muslim Buddhism Catholic Christian Church of Christ Church of God Church of Scientist Congregational Episcopal Evangelical Greek Orthodox Islam Jehovah's Witness Jewish Lutheran Mennonite Methodist Mormon Nazarene Not Available/Not Asked No Religion/Declined to State Other Pentecostal Protestant Presbyterian Quaker Reformed Russian Orthodox Seventh Day Adventist	
Patient Home Address		
Patient Home City		
Patient Home State	picklist	
Patient Home Zip Code		
Patient Employer		
PATIENT HEALTH QUESTIONNAIRE		
Date of Service	Date	< Today's date
*UCSF Medical Record Number		
Main reason for visit?		
Past Medical History:		
Alcoholism	Yes/No/no response	
Anemia	Yes/No/no response	
Arthritis	Yes/No/no response	
Asthma/Bronchitis/Emphysema	Yes/No/no response	
Bleeding/Bruising/Blood Disorder	Yes/No/no response	
Depression/Emotional Problems	Yes/No/no response	
Diabetes	Yes/No/no response	
Drug Abuse/Alcohol Dependency	Yes/No/no response	
Epilepsy/Seizures	Yes/No/no response	
Hay Fever/Sinus Problems	Yes/No/no response	
Heart Disease	Yes/No/no response	
Hepatitis	Yes/No/no response	
High Blood Pressure	Yes/No/no response	
Immune Disorders	Yes/No/no response	
Intestinal Problems	Yes/No/no response	

Kidney Disease	Yes/No/no response	
Liver Disease	Yes/No/no response	
Lung Disease	Yes/No/no response	
Psychiatric	Yes/No/no response	
Skin Disease	Yes/No/no response	
Stroke	Yes/No/no response	
Stomach Ulcers	Yes/No/no response	
Thyroid Disease	Yes/No/no response	
Tuberculosis	Yes/No/no response	
Had cancer other than breast cancer?	Yes/No/no response	
Other Cancers:		NCCN standards (moot early 2000)
Bladder/Kidney	Yes/No/no response	to be deleted (not on form)
Colorectal	Yes/No/no response	to be deleted (not on form)
Invasive Cervical	Yes/No/no response	to be deleted (not on form)
Leukemia	Yes/No/no response	to be deleted (not on form)
Lung	Yes/No/no response	to be deleted (not on form)
Lymphoma	Yes/No/no response	to be deleted (not on form)
Melanoma	Yes/No/no response	to be deleted (not on form)
Mouth/Throat	Yes/No/no response	to be deleted (not on form)
Ovarian	Yes/No/no response	to be deleted (not on form)
Thyroid	Yes/No/no response	to be deleted (not on form)
Uterine	Yes/No/no response	to be deleted (not on form)
Chemotherapy	Yes/No/no response	
Radiation Therapy	Yes/No/no response	
Surgery	Yes/No/no response	
Hormone Therapy	Yes/No/no response	
Other major illnesses		
Other previous hospitalizations/surg/inj		
Had prior breast surgery or biopsies?	Yes/No/no response	
If yes, laterality/proced/date/result		
If yes, second laterality/proced/date/result		
If yes, third laterality/proced/date/result		
Had breast cancer?	Yes/No/no response	
Chemotherapy-Breast Cancer	Yes/No/no response	
Chemotherapy Br Ca-Date		
Surgery-Breast Cancer	Yes/No/no response	
Surgery Br Ca-Date		
Radiation Therapy-Breast Cancer	Yes/No/no response	
Radiation Therapy Br Ca-Date		
Hormone Therapy-Breast Cancer	Yes/No/no response	
Hormone Therapy Br Ca-Date		
Medications		
Taking vitamins or herbs?	Yes/No/no response	
If yes, list vitamins/herbs		
Allergies		
Do you exercise regularly?	less than 1 x per week 1x per week 2x per week 3x per week more than 3x per week	
Psychotherapy or counseling?	Yes/No/no response	
Psychiatric hospitalization?	Yes/No/no response	
Taken medication for psychiatric condition?	Yes/No/no response	
What medicine?		
Ever participated in support group?	Yes/No/no response	
Gynecologic History		These fields are from the Dana Farber form. WS changed hyst/ov ones 8/00.

At what age did you have your first period?	Younger than 11/ 11/12/13/14/15/16/Older than 16	
How many times have you been pregnant?	1-15	
How many miscarriages have you had?	1-9	
How many abortions have you had?	1-9	
How many live births have you had?	1-15	
If you have children, what was your age at your first full-term pregnancy?		
Have had a period within the last 6 months?	Yes/No/no response	
If yes, regular or irregular?	Regular/Irregular/no response	
Have NOT had a period for more than 6 months—natural menopause (no abdominal surgery)?	Yes/No/no response	
At what age did you stop having periods due to menopause?		
Have NOT had a period for more than 6 months—caused by chemotherapy of radiation therapy?	Yes/No/no response	
At what age did you stop having periods due to therapy?		
Have NOT had a period for more than 6 months—but have been pregnant or breastfeeding?	Yes/No/no response	
Have had a hysterectomy?	Yes/No/Not Sure/no response	
Date of hysterectomy		
Have had any ovaries removed?	No/One/Two/Not Sure/no response	
Date of ovary removal		
Do you, or have you ever used, birth control pills?	Yes/No/Not Sure/no response	
If so, for how many years? (If you used them for less than one year, enter 1 in box.)	Number of year(s)	
If so, birth control pills beginning at what age?		
Have you ever used, or do you use, estrogen or estrogen replacement therapy?	No, never/Yes, currently/Yes, in the past/no response	
If you used estrogen currently or in past, wha form of estrogen do/did you use? Check all that apply.	pill/patch/vaginal cream/other/no respons	
How many total years have you used estrogen replacement? (If you have used it for less than one year, enter 1 in the box.)	Number of year(s)	
At what age began estrogen replacement?		
What was the approximate date of your last pelvic exam (internal female exam)- Month/Year	text	NCCN requirement
Patient Social History		
Marital status	single/married/partnered/divorced/ widowed	
Who currently lives in your home?		
Education level-select one that best describes your educational level	Some grade school Some high school High school graduate Vocational or technical school beyond high school Some college or associate's degree College Graduate or professional school Other	NCCN Requirement
Other-education level		NCCN requirement
Current occupation		

What is your current employment status?	Employed 32 hours or more per week Employed less than 32 hours per week Full time student Part time student Part time student, and also employed less than 32 hours per week Homemaker On medical leave Disabled Unemployed and/or seeking work Retired Other	NCCN requirement
Other-employment status		
Have you ever smoked?	Yes, but only in the past Yes, currently No, never no response	NCCN requirement
If you have ever smoked, on average, how many packs per day did you smoke, or do you currently smoke?	never smoked less than _ pack per day _ pack per day 1 pack per day 1 _ packs per day 2 packs per day more than 2 packs per day no response	NCCN requirement
At what age did you start smoking?		NCCN requirement
At what age did you stop smoking?		NCCN requirement
Have you ever or do you currently drink alcohol?	Yes, but only in the past Yes, currently No, never no response	NCCN requirement
How many alcoholic beverages (beer, wine, mixed drinks, etc.) do you consume weekly?	None Less than 1 drink per week 1-4 drinks per week 5-9 drinks per week 10-19 drinks per week more than 19 drinks per week no response	NCCN requirement
Do you use recreational drugs?	Yes/No/no response	
Type of recreational drugs		
Frequency of use		
Research questions:		
Spanish/Hispanic Origin	Yes/No/no response	NCCN requirement
Race/Ethnicity	Caucasian/White African American Asian or Pacific Islander American Indian, Lusatian, or Eskimo Unknown Other (Please specify) no response	
Ashkenazi Jewish Decent	Yes/No/Unknown/no response	NCCN requirement
Did anyone in your immediate family have cancer?	Yes/No/NA/no response	
Physician signature	picklist including "not signed"	physician accountability
Data entry date	date	implemented 10/20/2000
QC by LT	date	
QC by WS date	date	01/01/2000=yes (prior to date implementation on 10/20/2000)

REVIEW OF SYSTEMS		
QC by LT	Date	
QC by WS	Date	
Date of Service	Date	
*UCSF Medical Record Number		
1. Good general health lately	Yes/No/no response	
2. Recent weight changes	Yes/No/no response	
3. Recurrent fevers, chills, sweats	Yes/No/no response	
4. Fatigue	Yes/No/no response	
5. Stress	Yes/No/no response	
6. Pain	Yes/No/no response	
7. Wear glasses/contact lenses	Yes/No/no response	
8. Blurred or double vision	Yes/No/no response	
9. Change in vision	Yes/No/no response	
10. Glaucoma	Yes/No/no response	
11. Change in hearing	Yes/No/no response	
12. Ringing in the ears	Yes/No/no response	
13. Recent nose bleeds	Yes/No/no response	
14. Chronic sinus problems	Yes/No/no response	
15. Mouth sores	Yes/No/no response	
16. Bleeding gums	Yes/No/no response	
17. Frequent sore throats	Yes/No/no response	
18. Voice changes	Yes/No/no response	
19. Hoarseness	Yes/No/no response	
20. Asthma or wheezing	Yes/No/no response	
21. Breathing problems	Yes/No/no response	
22. Chronic cough	Yes/No/no response	
23. Chest pain or angina	Yes/No/no response	
24. Shortness of breath	Yes/No/no response	
25. Palpitations	Yes/No/no response	
26. Swelling of feet, ankles or hands	Yes/No/no response	
27. Blood clots	Yes/No/no response	
28. Varicose veins	Yes/No/no response	
29. Change in appetite	Yes/No/no response	
30. Severe heartburn	Yes/No/no response	
31. Bleeding ulcers	Yes/No/no response	
32. Frequent nausea/vomiting	Yes/No/no response	
33. Frequent diarrhea	Yes/No/no response	
34. Constipation/painful bowel movement	Yes/No/no response	
35. Black or bloody stools	Yes/No/no response	
36. Rectal bleeding	Yes/No/no response	
37. Abdominal pain	Yes/No/no response	
38. Headaches	Yes/No/no response	
39. Numbness or tingling sensations	Yes/No/no response	
40. Weakness or paralysis	Yes/No/no response	
41. Change in memory or concentration	Yes/No/no response	
42. Blood in the urine	Yes/No/no response	
43. Burning with urination	Yes/No/no response	
44. Change in force of strain when urinating	Yes/No/no response	
45. Sexually transmitted disease	Yes/No/no response	
46. Change in sexual function or interest	Yes/No/no response	
47. Prostate trouble (men)	Yes/No/no response	
48. Scrotal masses (men)	Yes/No/no response	
49. Abnormal uterine bleeding (women)	Yes/No/no response	
50. Uterine tumors (women)	Yes/No/no response	
51. Pain/problems with periods (women)	Yes/No/no response	

52. Birth marks	Yes/No/no response	
53. Recurrent rashes	Yes/No/no response	
54. Changing moles	Yes/No/no response	
55. Skin cancer or melanoma	Yes/No/no response	
56. Non-healing wounds	Yes/No/no response	
57. Breast pain or lump	Yes/No/no response	
58. Change in hair or nails	Yes/No/no response	
59. Memory loss or confusion	Yes/No/no response	
60. Nervousness	Yes/No/no response	
61. Depression	Yes/No/no response	
62. Change in sleep	Yes/No/no response	
63. Other	Yes/No/no response	
64. Joint stiffness or pain	Yes/No/no response	
65. Muscle pain or cramping	Yes/No/no response	
66. Weakness of muscles or joints	Yes/No/no response	
67. Back pain	Yes/No/no response	
68. Difficulty walking	Yes/No/no response	
69. Heat or cold intolerance	Yes/No/no response	
70. Excess thirst or urination	Yes/No/no response	
71. Low resistance to infection	Yes/No/no response	
72. Frequent cold or flu	Yes/No/no response	
73. Environmental allergies	Yes/No/no response	
74. Easy bruising	Yes/No/no response	
75. Frequent bleeding	Yes/No/no response	
76. Enlarged lymph nodes	Yes/No/no response	
FAMILY CANCER HISTORY		
*UCSF Medical Record Number		
#Relationship to Patient	Sister Brother Daughter Son Mother Father Granddaughter Grandson Maternal Uncle Paternal Uncle Maternal Aunt Paternal Aunt Maternal Grandfather Paternal Grandfather Maternal Grandmother Paternal Grandmother Other	Highlight "Other" and type in the relationship if not on the list.

#Type of cancer	Bladder/Kidney Breast Invasive Cervical Colon Colorectal Leukemia Liver Lung Lymphoma Melanoma Mouth/Throat Ovarian Pancreatic Prostate Skin/Basal Stomach Thyroid Uterine Other no response	
Additional type of cancer		for addit. "type" entries, same relative
Age at diagnosis		
Age of relative		
If deceased, age at death		
QC by LaDorotha	yes/no checkbox	
QC by WS	yes/no checkbox	
PROCEDURES		
*UCSF Medical Record Number		
Abstractor initials	text	
Abstraction date	date	implemented 10/20/2000
Episode	first Br Ca diagnosis new breast primary (contralateral) local/regional recurrence distant recurrence	
Date of initial cancer diagnosis	Date	
Episode number		for sequencing episodes and linking data for reports
Recurrence date	Date	
Recurrence site #1		
Recurrence site #2		
Recurrence site #3		
Recurrence site #4		
#Date of Procedure	Date	> 01/01/1970 and < today's date
Procedure date incomplete	text	Incomplete month/day defaults to 01. Text note about what's missing.
#Laterality	Left/Right/distant mets	
#Location in breast	1. upper 2. lower 3. inner 4. outer 5. upper-inner 6. upper-outer 7. lower-inner 8. lower-outer 9. axillary node 10. central 11. diffuse 12. unknown 13. not applicable	

Pre-Operative Dx	1. Breast lump/mass 2. Cyst 3. Fibroadenoma 4. Breast abscess 5. Axillary mass 6. Abnormal mammogram 7. Nipple discharge 8. DCIS 9. LCIS 10. Paget's disease 11. Carcinoma NOS (includig positive FNAs) 12. Invasive ductal carcinoma 13. Invasive lobular carcinoma 14. Mixed carcinoma 15. Atypical (on FNA) 16. no known pathology 0. other	Not a pathologic diagnosis; taken from operative notes
Post-Operative Dx	1. Breast lump/mass 2. Cyst 3. Fibroadenoma 4. Breast abscess 5. Axillary mass 6. Abnormal mammogram 7. Nipple discharge 8. DCIS 9. LCIS 10. Paget's disease 11. Carcinoma NOS (includig positive FNAs) 12. Invasive ductal carcinoma 13. Invasive lobular carcinoma 14. Mixed carcinoma 15. Atypical (on FNA) 16. no known pathology 0. other	Not a pathologic diagnosis; taken from operative notes
Surgeon	picklist	

#Procedure Code	0. Other 2. Excisional breast biopsy non-guided 3. Excisional breast biopsy image guided 4. Incisional breast biopsy NOS 5. Any surgical breast biopsy NOS 6. Core biopsy non-guided 7. Core biopsy image guided 8. Partial mastectomy without axillary lymph node dissection, incl. re-excision 9. Partial mastectomy with axillary lymph node dissection, incl. re-excision 10. Subcutaneous mastectomy with or without axillary lymph node dissection 11. Mastectomy without axillary lymph node dissection (includes prophylactic mastectomy) 12. Mastectomy with axillary lymph nod dissection (modified radical) 13. (there is no #13 choice) 14. Radical mastectomy with dissection of majority of pectoralis major with axillary lymph node dissection 15. Extended radical mastectomy plus internal mammary node dissection 16. Mastectomy NOS 17. Axillary lymph node dissection 18. Regional sites dissection 19. Reconstruction: Implant alone 20. Reconstruction: Tram flap w/ or w/o implant 21. Reconstruction: Latissimus w/ or w/o implant 22. Axillary lymph node biopsy 23. Supraclavicular lymph node biopsy 24. Sentinel lymph node biopsy 25. Metastatic site biopsy 26. Nipple or breast skin biopsy 27. Cyst aspiration 28. FNA (breast) 29. FNA (axilla) 30. FNA (supraclavicular lymph node) 31. FNA (other) 32. Major duct excision/duct exploration 33. Skin biopsy 34. Mastopexy 35. Nipple aspirate	
Clinical Pathology Number		
Benign Disease		
Benign disease?	Yes/No	
Histology-Benign 1	1. Fibrocystic changes 2. Fibroadenoma 3. Intraductal Papilloma 4. Lobular/ductal hyperplasia no atypia 5. Lobular/ductal hyperplasia w/atypia 6. Sclerosing adenosis 0. Other	

Histology-Benign 2	1. Fibrocystic changes 2. Fibroadenoma 3. Intraductal Papilloma 4. Lobular/ductal hyperplasia no atypia 5. Lobular/ductal hyperplasia w/atypia 6. Sclerosing adenosis 0. Other	
Histology-Benign 3	1. Fibrocystic changes 2. Fibroadenoma 3. Intraductal Papilloma 4. Lobular/ductal hyperplasia no atypia 5. Lobular/ductal hyperplasia w/atypia 6. Sclerosing adenosis 0. Other	
Cytology	1. adenocarcinoma 2. atypia 3. other 4. benign	
Non-Invasive Disease		
Histology DCIS	Yes/No/unknown	
Tumor size (cm) DCIS largest dimension		
Tumor size (cm) DCIS cumulative dimension		
Tumor size unknown	Unknown	"Unknown" if checked on form; blank if not checked; to facilitate report
Multifocal	Yes/No/unknown	
Margin Assessment (mm)		Closest margin in mm (0=positive margin) <1 mm = 1 mm
Margin Assessment text	negative/positive/widely clear/unknown	
Location of closest margin	0. Multiple 1. Anterior 2. Posterior 3. Medial 4. Lateral 5. Deep 6. Superior 7. Inferior 8. NA unknown	
Grade	1/2/3/unknown	
Necrosis	Yes/No/unknown	
Cribriform	Yes/No/unknown	
Solid	Yes/No/unknown	
Papillary	Yes/No/unknown	
Comedo	Yes/No/unknown	
Calcifications	Yes/No/unknown	

Van Nuys Score		The Van Nuys Prognostic Index is calculated as follows: Each tumor is assigned a total score from 3 to 9, which is the cumulative score from three different categories: size: 15 mm or less=1 16-40 mm=2 41 mm or greater=3 margin: 10 mm or greater=1 1-9 mm=2 < 1 mm=3 grade: nuclear grade 1 or 2 without necrosis=1 nuclear grade 1 or 2 with necrosis=2 nuclear grade 3=3 The clinical significance of this classification system is that if the score is 3 or 4, the patient can probably be adequately treated with excision only. If the score is 5, 6, or 7, they may also benefit from radiation. Scores of 8 or 9 merit consideration of mastectomy.
Van Nuys Score unknown	Unknown	"Unknown" if checked on form; blank if not checked; to facilitate report
Histology LCIS	Yes/No/unknown	
Tumor size (cm) LCIS largest dimension		
Tumor size (cm) LCIS cumulative dimension		
Tumor size unknown LCIS	Unknown	"Unknown" if checked on form; blank if not checked; to facilitate report
Invasive Disease		
Tumor size (cm) I largest dimension		
Tumor size (cm) I cumulative dimension		
Tumor size I unknown	Unknown	"Unknown" if checked on form; blank if not checked; to facilitate report
Multifocal I	Yes/No/unknown	
Lymphovascular Invasion	Yes/No/unknown	
Dermal Lymphatic Invasion	Yes/No/unknown	
Margin Assessment I (mm)		Closest margin in mm (0=positive margin) <1 mm = 1 mm
Margin Assessment I text	negative/positive/widely clear/unknown	
Location of closest margin I	0. Multiple 1. Anterior 2. Posterior 3. Medial 4. Lateral 5. Deep 6. Superior 7. Inferior 8. NA unknown	

Histology I	1. Ductal carcinoma 2. Lobular carcinoma 3. Ductolobular carcinoma 4. Medullary carcinoma 5. Mucinous carcinoma 6. Tubular carcinoma 7. Papillary carcinoma 8. Mixed histology 9. Unknown 10. Undifferentiated carcinoma 11. Adenocarcinoma, metastatic 0. Other	
Extensive intraductal component (EIC, > 25% DCIS)	Yes/No/unknown	
Associated with Paget's Disease	Yes/No/unknown	
Nuclear Grade	1/2/3/unknown	
Mitotic Grade	1/2/3/unknown	
Architecture	1/2/3/unknown	
Overall SBR Score-Invasive Cancer	3: well differentiated 4: well differentiated 5: well differentiated 6: mod differentiated 7: mod differentiated 8: poorly differentiated 9: poorly differentiated unknown	3-5, well differentiated 6-7, mod differentiated 8-9, poorly differentiated
Total Number Nodes		
Total Number Nodes unknown	Unknown	
Total Number Positive Nodes		Must be =< Total Number Nodes
Total Number Positive Nodes unknown	Unknown	
Largest metastasis (mm)		xx.x mm
Largest metastasis unknown	Unknown	
Largest Node	less than 2 cm greater than or equal to 2 cm unknown	to be replaced by the above, 9/21/00
Extracapsular Extension	Yes/No/unknown	
Number of Sentinel Lymph Nodes		Must be =< Total Number Nodes
Number of Sentinel Lymph Nodes unknown	Unknown	
Number of Positive Sentinel Lymph Nodes		Must be =< Number of Sentinel Lymph Nodes
Number of Positive Sentinel Lymph Nodes unknown	Unknown	
ER Date		=< Date of Procedure
ER Result	negative positive not performed pending unknown	
ER text		
PR Date		=< Date of Procedure
PR Result	negative positive not Performed pending unknown	
PR text		
HER2 Date		=< Date of Procedure

HER2/neu	0 1+ 2+ 3+ positive negative not performed pending unknown	
HER2/neu amp	amplified/not amplified	
HER2/neu copy #		
HER2 text		
Ki 67 Date		=< Date of Procedure
Ki 67	positive negative low intermediate high not performed pending unknown	
Ki 67 test		
notes		like if tumor size is reported as a range (largest value is entered, note range)
Data entry date	date	implemented 10/20/2000
QC by WS date	date	01/01/2000=yes (prior to date implementation on 10/20/2000)
SUMMARY DATA		**in use June 2000**
*UCSF Medical Record Number		
Abstractor initials	text	
Abstraction date	date	implemented 10/20/2000
Episode	first Br Ca diagnosis new breast primary (contralateral) local/regional recurrence distant recurrence	
Date of initial cancer diagnosis	Date	
#Episode number		for sequencing episodes and linking data for reports
Laterality	right/left/distant mets	
Location in breast	1. upper 2. lower 3. inner 4. outer 5. upper-inner 6. upper-outer 7. lower-inner 8. lower-outer 9. axillary node 10. central 11. diffuse 12. unknown	
Cytology	1. adenocarcinoma 2. atypia 3. other 4. benign	
Non-Invasive Disease		
Histology DCIS	Yes/No/unknown	
Tumor size (cm) DCIS		
Tumor size unknown	Unknown	"Unknown" if checked on form; blank if not checked; to facilitate report

Multifocal	Yes/No/unknown	
Margin Assessment (mm)		Closest margin in mm (0=positive margin) <1 mm = 1 mm
Margin Assessment text	negative/positive/widely clear/unknown	
Grade	1/2/3/unknown	
Comedo	Yes/No/unknown	
Histology LCIS	Yes/No/unknown	
Tumor size (cm) LCIS		
Tumor size unknown LCIS	Unknown	"Unknown" if checked on form; blank if not checked; to facilitate report
Invasive Disease		
Tumor size (cm) I		
Tumor size I unknown	Unknown	"Unknown" if checked on form; blank if not checked; to facilitate report
Multifocal I	Yes/No/unknown	
Lymphovascular Invasion	Yes/No/unknown	
Dermal Lymphatic Invasion	Yes/No/unknown	
Margin Assessment I (mm)		Closest margin in mm (0=positive margin) <1 mm = 1 mm
Margin Assessment I text	negative/positive/widely clear/unknown	
Histology I	0. Other 1. Ductal carcinoma 2. Lobular carcinoma 3. Ductolobular carcinoma 4. Medullary carcinoma 5. Mucinous carcinoma 6. Tubular carcinoma 7. Papillary carcinoma 8. Mixed histology 9. unknown 10. Undifferentiated carcinoma 11. Adenocarcinoma, metastatic	
Extensive intraductal component (EIC, > 25% DCIS)	Yes/No/unknown	
Associated with Paget's Disease	Yes/No/unknown	
Nuclear Grade	1/2/3/unknown	
Mitotic Grade	1/2/3/unknown	Added from Procedures 6/18/2001 per LJE
Architecture	1/2/3/unknown	Added from Procedures 6/18/2001 per LJE
Overall SBR Score-Invasive Cancer	3: well differentiated 4: well differentiated 5: well differentiated 6: mod differentiated 7: mod differentiated 8: poorly differentiated 9: poorly differentiated unknown	3-5, well differentiated 6-7, mod differentiated 8-9, poorly differentiated Added from Procedures 6/18/2001 per LJE
Total Number Nodes		
Total Number Nodes unknown	Unknown	
Total Number Positive Nodes		
Total Number Positive Nodes unknown	Unknown	
Largest metastasis (mm)		xx.x mm
Largest metastasis unknown	Unknown	
Number of Sentinel Lymph Nodes		
Number of Sentinel Lymph Nodes unknown	Unknown	
Number of Positive Sentinel Lymph Nodes		
Number of Positive Sentinel Lymph Nodes unknown	Unknown	
Extracapsular Extension	Yes/No/unknown	
ER date		

ER Result	negative positive unknown not performed	
ER text		
PR date		
PR Result	negative positive unknown not performed	
PR text		
HER2/neu	0 1+ 2+ 3+ positive negative not performed pending unknown	
HER2/neu amp	amplified/not amplified	
HER2/neu copy #		
HER2 text		
Data entry date	date	implemented 10/20/2000
QC by WS date	date	01/01/2000=yes (prior to date implementation on 10/20/2000)
STAGING		
*UCSF Medical Record Number		
#Episode number		for sequencing episodes and linking data for reports
Date of staging	Date	
Date of staging incomplete	text	Incomplete month/day defaults to 01. Text note about what's missing.
Laterality	right/left/distant mets	
Staging Category	1st presentation at UCSF 1st cancer full work-up (pathologic)	not in use now, per DT & SH
Staging Method	AJCC Cancer Staging-5TH Edition	Can add other methods; not in use
T	TX T0 Tis T1 T2 T3 T4	
N	NX N0 N1 N2 N3	
M	MX M0 M1	

Stage	0 I IIA IIB IIIA IIIB IV	
Staging type	pathological (default); clinical	
CHEMOTHERAPY		
QC by WS	yes/no checkbox	
*UCSF Medical Record Number		
Episode number		for sequencing episodes and linking data for reports
Setting	Neo-adjuvant Adjuvant Metastatic	
Chemo regimen	AC CAF CMF CMFVP cytoxan FAC Pamidronate taxol taxotere VATH Vinorelbine high dose chemo stem cell infusion	Debu said CAF differs from FAC.
#Chemo agent	Adriamycin/Doxorubicin Cisplatin Carboplatin Cyclophosphamide/Cytoxan Epirubicin Etoposide Fluorouracil/5-FU Gemcitabine High dose chemotherapy Liposomal Adriamycin (Doxil) Methotrexate Mitoxantrone Pamidronate Stem cell infusion Taxol/Paclitaxel Taxotere/Docetaxel Thiotepa Velban Vinorelbine Other (double-click & type name)	lookup table
Route	PO IV IT IP IA combo unknown	
Dose/M2		
Total Dose		
#Chemotherapy treatment start date	Date	> 01/01/1984 and < today's date
Chemotherapy treatment start date incomplet	text	Incomplete month/day defaults to 01. Text note about what's missing.

Chemotherapy treatment end date	Date	< today's date
Chemotherapy treatment end date incomplete	text	Incomplete month/day defaults to 01. Text note about what's missing.
Number of cycles	number	
Days in cycle	number	
Oncologist		ever-changing list
Patient Response	1. Progression 2. Stable 3. Response 4. Response then progression 5. Mixed 6. Not Applicable (adjuvant)	
HORMONE		
QC by WS	yes/no checkbox	
*UCSF Medical Record Number		
Episode number		for sequencing episodes and linking data for reports
Setting	Neo-adjuvant Adjuvant Metastatic	
#Hormone agent	Arimidex Buserelin Goserelin Examestane Letrozole Lupron Megace Oophorectomy, surgical Raloxifene Tamoxifen Toremifine Other (double-click & type name)	lookup table
Route	PO IV IT IP IA unknown	
Dose		
#Hormone Treatment Start Date	Date	> 01/01/1984 and < today's date
Hormone Treatment Start Date incomplete	text	Incomplete month/day defaults to 01. Text note about what's missing.
Hormone Treatment End Date	Date	< today's date
Hormone Treatment End Date incomplete	text	Incomplete month/day defaults to 01. Text note about what's missing.
Medical Oncologist		ever-changing list
Patient Response	1. Progression 2. Stable 3. Response 4. Response then progression 5. Mixed 6. Not Applicable (adjuvant)	
OTHER THERAPIES		
QC by WS	yes/no checkbox	
*UCSF Medical Record Number		
Episode number		for sequencing episodes and linking data for reports

Setting	Neo-adjuvant Adjuvant Metastatic	
#Other therapy agent		Should we have a picklist?
Other therapy route	PO IV IT IP IA unknown	
#Other therapy Start Date	Date	> 01/01/1984 and < today's date
Other therapy Start Date Inc Text	Text	Incomplete month/day defaults to 01. Text note about what's missing.
Other therapy End Date	Date	< today's date
Other therapy End Date Inc Text	Text	Incomplete month/day defaults to 01. Text note about what's missing.
Patient Response	1. Progression 2. Stable 3. Response 4. Response then progression 5. Mixed 6. Not Applicable (adjuvant)	
RADIATION		
QC by WS	yes/no checkbox	
*UCSF Medical Record Number		
Episode number		for sequencing episodes and linking data for reports
Setting	Neo-adjuvant Adjuvant Metastatic	
#Site of radiation therapy	1. Breast 2. Chest wall 3. Supraclavicular 4. Axillary 5. Mediastinal 6. Other (list)	
#Laterality	right/left/distant mets	
Total Dose		
#Radiation therapy start date	Date	> 01/01/1984 and < today's date
Radiation therapy start date incomplete	text	Incomplete month/day defaults to 01. Text note about what's missing.
Radiation therapy end date	Date	< today's date
Radiation therapy end date incomplete	text	Incomplete month/day defaults to 01. Text note about what's missing.
Radiation boost given	yes;no;unknown	
Type boost	None Electrons External beam Implants	
Rads of boost		
Radiation Oncologist		ever-changing list
FOLLOW-UP		
*UCSF Medical Record Number		
#Follow-up date		from Date of Service on patient label; required;< or = Date()

#Provider	Benz, Christopher Dollbaum, Charles Esserman, Laura Ewing, Cheryl Hwang, Shelley Leong, Stanley Margolis, Lawrence Park, John Rugo, Hope Tripathy, Debu unknown not collected at this time	added 01/16/2001 for accurage tallying; required
#Episode number		
Laterality	right;left;distant mets	
Second opinion	yes;no	for abstractor
Current Menopausal Status	pre post uncertain	
completed all surgery for this cancer	yes	for abstractor
completed chemotherapy	yes	for abstractor
completed radiation therapy	yes	for abstractor
completed hormone therapy	yes	for abstractor
changed Stage IV therapy	yes	for abstractor
On chemotherapy	yes/default is null	
On tamoxifen only	yes/default is null	
On other hormone therapy	yes/default is null	
On radiation therapy	yes/default is null	
On other therapy	yes/default is null	
Diagnosis	no prior breast cancer diagnosis r/o breast cancer first breast cancer diagnosis new breast primary (contralateral) local/regional recurrence distant recurrence local/regional AND distant recurrences	
Status	not applicable NED stable progressive responding	
Recurrence detected	no/pending/yes	
Data entry date	date	01/01/2000=dummy (prior to required date implementation on 01/25/2001)
QC by WS date	date	01/01/2000=yes (prior to date implementation on 10/20/2000)
RECURRENCE **(subform in Summary and Follow-up)**		
*UCSF Medical Record Number		
#Episode number		>1
Laterality	right;left;distant mets	a double-check?
#Recurrence date		
Recurrence date incomplete	day unknown month/day unknown month/day/year unknown	Incomplete month/day defaults to 01.
Recurrence type	new breast primary (contralateral) local/regional recurrence distant recurrence	
Mode of dx clinical exam date		
Mode of dx radiographic date		
Mode of dx biopsy date		

Mode of dx other date		
Site 1 of recurrence	1. left breast 2. right breast 3. chest wall, left 4. chest wall, right 5. supraclavicular, left 6. supraclavicular, right 7. axillary, left 8. axillary, right 9. bone 10. brain 11. liver 12. lung 13. skin 14. cervical nodes, right 15. cervical nodes, left 16. mediastinum 17. meningeal 18. pleura 19. pericardium 20. peritoneum 21. mesenteric 22. periaortic nodes 23. pelvic nodes 24. uterus 25. ovaries 26. marrow 0. other (list)	
Site 1 of recurrence date		
Site 2 of recurrence	same as above	
Site 2 of recurrence date		
Site 3 of recurrence	same as above	
Site 3 of recurrence date		
Site 4 of recurrence	same as above	
Site 4 of recurrence date		
Site 5 of recurrence	same as above	
Site 5 of recurrence date		
HIGH RISK		
*MRN		
*Date of service		**>01/01/2001 (for new year error prevention-change every new year)**
Referring physician		
Weight		
Height-feet		
Height-inches		
Income		
Migraine headache	yes;no;unknown;no response	
LMP		
Take synthroid	yes;no;unknown;no response	
LowBMD/osteoporosis	yes;no;unknown;no response	
DVT without pregnancy	yes;no;unknown;no response	
DVT with pregnancy	yes;no;unknown;no response	
Date of last mammo		
Annual screening mammogram	yes;no;unknown;no response	
Monthly breast self exam	yes;no;no response	
Date of last pap smear		
Older than 50, date of last fecal occult blood		
Older than 50, date of last flex sig/colonoscopy		
5 servings fruits/vegs	Yes;No;Not Sure;No response	

beans & legumes?	Yes;No;Not Sure;No response	
3 whole grains daily	Yes;No;Not Sure;No response	
limits red meat	Yes;No;Not Sure;No response	
limits pickled, etc	Yes;No;Not Sure;No response	
limits high fat foods	Yes;No;Not Sure;No response	
cooks majority from scratch	Yes;No;Not Sure;No response	
sources of drinking water	tap water predominantely;filtered water predominantely;bottled water predominantely	
chemical exposure during job	Yes;No;Not Sure;No response	
If yes chemical, explain		
Hx of radiation of chest wall	Yes;No;No response	
Alcohol drinks per day	0;1;2;3;4;5;6;7;8;9;10;More than 10	
General risk assessment	option button (click for Yes)	
Surveillance options	option button (click for Yes)	
Current breast problem	option button (click for Yes)	
Family history concern	option button (click for Yes)	
Prophylactic surgery	option button (click for Yes)	
Other breast concerns	option button (click for Yes)	
Other breast concerns-explanation		
Menopause concerns	option button (click for Yes)	
Hormone replacement therapy	option button (click for Yes)	
Heart disease	option button (click for Yes)	
Alzheimer	option button (click for Yes)	
Nutrition	option button (click for Yes)	
Exercise	option button (click for Yes)	
Smoking	option button (click for Yes)	
Stress	option button (click for Yes)	
Other women's concerns	option button (click for Yes)	
Other women's concerns-explanation		
Other Ca	option button (click for Yes)	
Chemoprevention	option button (click for Yes)	
Gail index-5 year		
Gail index-Lifetime		
BMI		
HIGH RISK FOLLOW-UP AND RECOMMENDATIONS		
*MRN		
*Date of service		**>01/01/2001 (for new year error prevention-change every new year)**
Mammogram annually	checkbox	
Mammogram bi-annually	checkbox	
Clinical breast examination annually	checkbox	
Clinical breast examination bi-annually	checkbox	
Breast sonogram	checkbox	
Breast sonogram-explain		
Breast MRI	checkbox	
Breast MRI-explain		
Basic BSE training	checkbox	
MammaCare training	checkbox	
Pelvis ultrasound with Doppler probe annually	checkbox	
Pelvis ultrasound with Doppler probe bi-annually	checkbox	
Pelvic examination	checkbox	
Screening colonoscopy	checkbox	
Flexible sigmoidoscopy	checkbox	
Skin screening	checkbox	

Chemoprevention-prevention	checkbox	
STAR trial	checkbox	
Tamoxifen	checkbox	
Soy	checkbox	
Nutrition consultation	checkbox	
Smoking cessation	checkbox	
Alzheimer's Disease-family history	checkbox	
Menopausal symptoms-HRT	checkbox	
Menopausal symptoms-Soy	checkbox	
Menopausal symptoms-Effexor or other SSR	checkbox	
Menopausal symptoms-Megace	checkbox	
Osteoporosis prevention-Family history	checkbox	
Osteoporosis prevention-Known low BMD	checkbox	
Osteoporosis prevention-Increase weight-bearing exercise	checkbox	
Osteoporosis prevention-Increase Ca# intake	checkbox	
Osteoporosis prevention-BMD	checkbox	
Cardiovascular disease-Family history	checkbox	
Cardiovascular disease-GRT	checkbox	
Cardiovascular disease-Increase exercise	checkbox	
Cardiovascular disease-Fasting lipid profile	checkbox	
Clinical trial-Soy/Tam	checkbox	
Clinical trial-MRI	checkbox	
Clinical trial-NAF	checkbox	
Follow-up appointment given-Yes	checkbox	
Follow-up appointment in approximately how many months		
Follow-up appointment given-No; Patient to call for appointment	checkbox	
Seen by NP (Jill, Marylou)	checkbox	
Seen by CC (Jennifer)	checkbox	
Seen by Cancer Risk	checkbox	
Seen by MD	pull-down list	
Comments		
Follow-up Recommendations given or sent to patient	date	**>01/01/2001 (for new year error prevention-change every new year)**
Profile given or sent to patient	date	**>01/01/2001 (for new year error prevention-change every new year)**
Follow-up Recommendations sent to MD	date	**>01/01/2001 (for new year error prevention-change every new year)**
Profile sent to MD	date	**>01/01/2001 (for new year error prevention-change every new year)**
Letter sent to MD	date	**>01/01/2001 (for new year error prevention-change every new year)**
SERUM SAMPLES		
*MRN		
*Date of collection	date	
Sample ID	text	
Number of samples banked	number	
Number of samples released first	number	
Date samples released first	date	
Number of samples released second	number	
Date samples released second	date	
Number of samples released third	number	
Date samples released third	date	
Number of samples released fourth	number	
Date samples released fourth	date	

DEATH		
*MRN		
Deceased	yes	
Date of death	text	for partial dates
Cause of death	text	to be refined
SLN-Surgery		
*MRN		
Surgeon		
Surgery date		
Anesthesia		
Injection type		
Laterality		
Injection location cm		
Injection location clock		
Antibiotics		
Blue dye injected		
Volume		
Dilution		
Injection start time		
SLN basin incision time		
First SLN excision time		
SLN basin incision closed		
Intraoperative complications		
Breast procedure		
Needle loc used		
SLNDBeforeAfter?		
Neoprobe type		
Collimator used		
PatologyReportDate		
PathologyReportNumber		
SLN-Surgery-Nodes		
MRN		
Surgery date		
Accession number		
Node ID		
Laterality		
Skin count		
In vivo count		
Ex vivo count		
Bed count		
Blue score		
SLN-Radiology		
MRN		
Nuclear medicine physician		
Injection date		
Injection start time		
Imagedate		
Image start time		
Time interval to visualization		
Injection type		

Laterality		
Injection location cm		
Injection location clock		
Radioactive tracer		
Dose injected		
Volume injected		
Pinhole technique		
Total number marked SLNs		
Total number channels		
Lymph node basin		
SLN-Pathology		
MRN		
Accession number		
Surgery date		
Surgery type		
CALND refused?		
Total number of SLNs		
Total number of positive SLNs		
CALND total number of nodes		
CALND total number of positive nodes		
Size of largest metastasis		
Method of detection		
SLN-Pathology-Specimens		
MRN		
accession number		
surgery date		
node ID		
length of metastasis		
width of metastasis		
greatest dimension of metastasis		
number of tumor cells		
extranodal extension		
subcapsular invasion		
cortical invasion		
medullary invasion		
metastasis seen clearly on H&E		
metastasis seen only by IPOX		
hilum present		
hilar invasion		
number of metastases		

Appendix F

Welcome

Welcome to the UCSF Carol Franc Buck Breast Care Center (BCC). We want to provide you with the highest quality of care. Please let us know what we can do to help you get the information, support and guidance you need.

We continue to hear from women with breast cancer how difficult the period following a new diagnosis can be. It is important that you know there are many people and resources available to help you through this time. We, the staff of the UCSF Carol Franc Buck Breast Care Center, want to provide both care and support to you through this difficult time.

General Information

This binder is designed to provide basic information regarding breast cancer, as well as additional information about the resources available to you. The binder is not meant as a substitute for communication with your doctor(s) and nurse(s). This information is given as a supplement and certainly cannot replace personal interaction.

How to find more information

The Ida and Joseph Friend Cancer Resource Center is located at 2356 Sutter Street on the first floor, between the cafe and boutique. There is a library of books, videotapes, audiotapes, and other resources for you to check out, and the staff can perform information searches for you. They can also assist you to use the Internet to find further information and resources. The Resource Center can also refer you to many available support programs, including support groups, a Peer Support Program, Art for Recovery, Tai Chi, dance therapy, and one-to-one psychological counseling.

Research

We will always ask you to fill out evaluations/surveys in order to help us design programs to best suit your needs. Because UCSF is a research institution, you may be asked to participate in one or more of the new programs at the BCC. We want you to know that although we invite your participation in these programs, it is not mandatory and if you choose to decline, this will NOT affect the quality of care you receive.

We recognize that you may have many questions and concerns, and we want to make sure we address them. Please feel free to ask us because we are here to help you.

Sincerely,

Your caregivers at the UCSF Carol Franc Buck Breast Care Center

General information for the BCC

- Office hours are Monday through Friday 8A.M. - 12:00 noon and 1P.M. - 5P.M. After hours a physician is on call for emergencies.
- Please allow at least 72 hours for all prescription refills. Have your pharmacy fax the request to our office. For new prescriptions, please call the office and ask to speak with a nurse.
- You should plan to arrive 15 minutes early for all appointments. This allows you time to complete any necessary paperwork and to check in with the front office before your appointment.
- If you have any tests done at non-UCSF facilities, you will be responsible for bringing the results and any radiology films to your appointments.

If you are on chemotherapy:

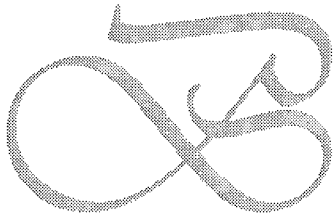
- On the first day of each cycle of chemotherapy you will stop in the lab to get blood drawn 1/2 hour prior to your appointment with your nurse practitioner.
- During treatment, if you are not feeling well, please call us as soon as possible. If we direct you to come in, it is important that you come as soon as possible so we can evaluate and do necessary tests within normal work hours. If it is after 4:00 P.M., you may be directed to the emergency room at the UCSF Parnassus campus.

Insurance:

- If you change your medical insurance during your care at the Breast Care Center, it is your responsibility to notify the front office and provide a copy of your new insurance card.
- If you have an HMO insurance plan, then you will be responsible for obtaining an authorization or referral for each appointment at the BCC.
- If you are unable to provide a referral or authorization, you will be responsible for all charges associated with your appointment.

Disability paperwork:

- If you are out of work for an extended time due to surgery or illness, you may be eligible for disability benefits. These benefits usually are partial compensation for the wages lost while you were unable to work. Please contact your employer or benefits department to find out what your disability benefits are.
- All disability forms will require either a statement or the completion of forms by your physician. You will need to allow 7-10 working days for our office to complete the physician portion of the forms.



Breast Cancer Related Web Sites

Breast Cancer Information:

UCSF Carol Franc Buck Breast Care Center	http://breastcarecenter.ucsfmedicalcenter.org
UCSF Breast Care Center Clinical Trials	http://bcc-ct.his.ucsf.edu
Cancer Links: Links to many breast cancer sites	http://www.cancerlinks.org
CancerNet from National Cancer Institute (includes PDQ)	http://cancernet.nci.nih.gov
ASCO Patient's Guide to Follow-Up Care for Breast Cancer	http://www.asco.org/people/rs/html/breast/f_patguidebr.htm
Community Breast Health Project (CBHP)	http://www.med.stanford.edu/CBHP
Oncolink	http://oncolink.upenn.edu
Breast Cancer Lighthouse	http://commtechlab.msu.edu/CTLprojects/breastcancerlighthouse/
Breast Cancer Network (BreastCancer.Net), an online newsletter	http://www.breastcancer.net/bcn.html
Breast Reconstruction	http://www.cancerbacup.org.uk/info/breast-reconstruction.htm
CancerGuide - Steve Dunn's Cancer Information	http://cancerguide.org
Celebrating Life: A Site for African American Women with Breast Cancer	http://www.celebratinglife.org
Clinical Trials Search: PDQ	http://cancertrials.nci.nih.gov/
Cancer Supportive Care Guide	http://www.cancersupportivecare.com/
The Breast Gene and BRCA1 2 3 Information	www.ncgr.org/gpi/bc_pg_front.html

The Program for Collaborative Care

"I'm in information overload!"

"What questions should I ask my doctor?"

"How can I remember everything my doctor and I talk about?"

What is the Program for Collaborative Care?

Collaborative Care was designed to support patients and physicians as you navigate complex decisions together in breast cancer treatment. Our research has shown that Collaborative Care can help alleviate some of the confusion, anxiety, and fear people often feel in the treatment decision-making process.

Consultation Planning helps you map out your questions and concerns before an upcoming consultation with a breast cancer specialist. We work with you to identify key questions you'd like to ask, and provide a printed flowchart, called a Consultation Plan. Both you and your physician get a copy of the Consultation Plan, which guides the conversation about your options. A Consultation Planning session takes about an hour, usually right before your appointment with a physician.

Consultation Recording provides support during the consultation between you and your doctor. We create an agenda for the meeting, create a flowchart of the discussion, and facilitate the conversation. You receive a copy of the flowchart, called a Consultation Record, at the end of the discussion. This helps alleviate confusion, outlines clear next steps for your care, and identifies who is responsible for each step.

The Program for Collaborative Care was designed to:

- Help you get the answers you need to understand your diagnosis and treatment options
- Give you the confidence to make informed decisions
- Provide the support to move forward in your breast care

Who Can Benefit from Collaborative Care?

Anyone who is scheduled for an upcoming consultation with a breast cancer specialist, surgeon, or oncologist can participate in the Program for Collaborative Care. This is a free, voluntary program provided by the Carol Franc Buck Breast Care Center.

How to Reach the Program for Collaborative Care:

For more information, or to schedule an appointment, please call Caryn Aviv at 415.353.7726.

This program was designed through the research of Dr. Jeff Belkora and Dr. Karen Cushing Sepucha of Stanford University.

Follow-Up Program

UCSF Carol Franc Buck Breast Care Center

Welcome to the Follow-Up Program. On behalf of the staff at the UCSF Carol Franc Buck Breast Care Center (BCC), we want to introduce you to the long-term follow-up program. The team of physicians at the BCC have designed this program to meet the needs of all patients who are a year out from their cancer diagnosis, who are at high risk for breast cancer and have had a year of stable exams, or who have been treated for other related breast problems.

Why a new follow-up program?

After the first year of treatment, many women find themselves wondering: Now what do I do? Who will have the time to answer all of my questions? How do I make sure I continue with appropriate follow-up care? Will someone call to tell me the latest findings reported in the news and how these discoveries apply to me? How should I expect to feel in the upcoming years? Should I be seeing the specialists (surgeons, oncologists, radiotherapists, etc.) several times a year?

Our program allows us to develop better ways to get information to you and to learn more about what happens to each of you. The information we learn from you will be used to advise women properly about what to expect after treatment for breast cancer. We invite you to help teach us what is important to you as you make decisions. That way we can learn what women's concerns are, which will enable us to better address your needs. We feel this program may allow a better and more systematic exchange of information, a greater ability to accurately track your situation, and offer new treatments or clinical trials that are appropriate for you.

The follow-up program

Mary Lou Ernest, our lead nurse practitioner, will head up the follow-up team. Mary Lou has over twenty years of experience working in oncology and has focused on breast cancer for the last five years. Some of her interests include alternative therapies, nutrition, and education. These interests, combined with her expertise in breast care, allow her to take a holistic and comprehensive approach to patient care. A year after diagnosis, you will enter the follow-up program and meet with Mary Lou to create a follow-up plan together. Your plan will include regular breast exams, necessary screening tests, at least one appointment with our nutritionist, information on exercise and other lifestyle changes, and a schedule of future appointments and screening exams. You will also get a list of symptoms to look for and written advice on when you should call the BCC. If there are any problems identified by you and the nurse practitioner, you will automatically be seen by your physician.

Getting the Right Information to You

Dr. Laura Esserman and Dr. Debu Tripathy, along with the rest of the team of physicians, will lead monthly follow-up discussions groups to review any new findings in the literature or newspapers. In your individual appointment with Mary Lou you have the opportunity to address your personal medical needs. Our objective in these forums is to create an atmosphere where both you and the physicians can share information and ideas. During the monthly sessions, Dr. Esserman, Dr. Tripathy or other caregivers will be available for any individual questions.

We hope that this program decreases your waiting times and enables us to make sure the physicians are more readily available for any new problems that arise. Having a follow-up program also enables the BCC physicians to be available to new patients you refer to our practice. We welcome your comments, questions, and suggestions! Thank you.

– The BCC Staff

Follow-Up Care for Breast Cancer Patients

After patients have completed treatment for early stage breast cancer, one of the common questions is "How should I best be monitored?" At the current time, the standard approach for monitoring patients is for them to be seen for a physical exam and a review of symptoms anywhere from every 3-6 months for the first 2-3 years, then every 6 months until year 5, and annually thereafter. You should also continue to have annual mammograms of the other breast. In some cases following a lumpectomy, we may recommend a mammogram of the involved breast every 6 months for 2-3 years and then yearly thereafter. We also ask you to report any new or unusual symptoms so that we can determine whether any further testing needs to be done.

In terms of screening for the spread of breast cancer (metastases), the routine use of chest x-rays and blood tests for patients who have no symptoms is generally not recommended. The reason for this is that even though these tests may pick up a recurrence at an earlier moment, it is not clear that the earlier institution of therapy for advanced breast cancer will ultimately lead to a better long term result. This is because when patients have metastatic recurrence, the focus of therapy is to keep the cancer under control but our ability to cure cancer is limited. Furthermore, screening tests such as x-rays and blood tests can also appear abnormal when in fact there is no spread of cancer and it may require more invasive testing, such as a biopsy, to sort this out. For these reasons, most expert panels have concluded that at the current time, these types of screening tests for spread of cancer are not warranted.

Please refer to the ASCO Guidelines for a more detailed explanation of the latest recommendations for following patients after treatment for early stage breast cancer.

Self-Care and Recovery
Introduction to Lifestyle Change

There are as many breast cancer stories as there are women with breast cancer. There is no single right way to heal, to feel better, to cope or to change one's life. What seems to be important is to spend some time learning about which ways of healing and feeling better are the best match for you.

There are no clear cause(s) of breast cancer, and therefore, no proven ways to prevent the disease or its recurrence. This can provoke uncertainty, fear and anger. It is this fear of the unknown and people's passion to find causes that fuels breast cancer advocacy and research. Even though there is no proof, there are some principles of healthier living which, at the very least, help people to feel less ill. At their best, these principles may help improve your health, energy level and overall sense of well being.

There is ongoing research in progress examining lifestyle issues, such as diet, exercise, support, and stress management. At UCSF we are examining whether or not a diet low in fat and high in vegetables, fruits and fiber can reduce recurrence rates for breast cancer, whether participation in support groups (and what kinds) can improve survival, whether or not exercise can reduce fatigue and whether or not Chinese herbs (and which ones) can reduce chemotherapy side effects. You may have or may in the future participate in studies like this to help answer these questions.

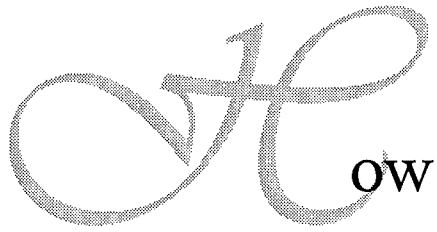
As of now, we do not have answers. However, given the evidence that does exist, and the experience of women who feel better when taking good care of themselves, we want to highlight some recommendations to help you to shape your individual recovery plan.

Imagine a process of self-inventory:

- What are my self-care skills? Do I take care of me last? What advice would I give me if I were my best friend, sibling, or child?
- How am I eating? Am I dieting, feeling deprived, sneaking "junk," feeling guilty about eating the "wrong" stuff, feeling confused about what are the right and wrong foods to eat? Do I drink enough water?
- Do I sleep well? Can I sleep well? What interrupts sleep and rest?
- Do I smoke cigarettes? Do I drink excessive alcohol?
- What are the stressors in my life? What can I change? What can I respond to differently?
- Do I move my body? In which ways of moving do I feel the most pleasure? How, when and where do I fit it in my life?
- What is making me feel badly? What are the barriers to changing that?
- What do I love? What moves me and gives my life meaning? Do I make room or time for that which gives my life meaning? What stirs my creative juices?

Lifestyle change is not a written prescription that never changes. It is a dynamic process that is often in crisis and flux throughout breast cancer diagnosis and treatment. The first and biggest step is to care enough about yourself to care for you. This is self-care.

We at the Carol Franc Buck Breast Care Center hope to provide you with information and support that will enable you to explore ways of feeling better. You can teach us what works for you. This will enable us to hold your experience and communicate your teachings to other women with breast cancer.



How Research Studies Work

Here is some general information about how "clinical trials," the term physicians use to describe research studies, are conducted. Research studies are essential to the goal of curing breast cancer, but they require many participants in order to learn what will help more women. We are providing this information with the hope that it will encourage you to consider a research study, and help doctors to treat women with breast cancer or those at increased risk more effectively.

Recent advances, particularly in detection, therapy, and side effect management have helped more women with breast cancer live longer. Yet despite these advances, over 177,000 women will be diagnosed with breast cancer this year and 44,000 women will die. Less than 50% of the women treated for breast cancer with surgery, radiation, and/or chemotherapy will ever have recurrences, but we don't feel that figure is low enough. There are still many questions:

- *How do we truly prevent breast cancer?*
- *How do we find and treat breast cancer before it's big enough to see?*
- *Which therapies should be used for different kinds of breast cancer?*
- *What is the best way to use these therapies?*
- *How do we identify sub-groups of women who benefit from a particular therapy?*
- *How do we accurately and sensitively determine a woman's response to therapy?*
- *Why do some cancers metastasize (move to other sites) and others don't?*

You can plan an important role in helping to answer these questions by considering a research study. Each study follows a plan called a "protocol." Most trials enroll patients at multiple locations. Each location must get approval to host a study from an "Institutional Review Board" (IRB) or "Committee for Human Research" (CHR) before they can offer it to you. This committee makes sure that you are not being asked to take unnecessary risks. A separate "Data Safety and Monitoring Committee" then tracks the study's progress to make sure it's done well.

Before you enroll in a research study, a person will describe the study to you in language that you can understand, including possible risks and benefits. This is called "informed consent." Please ask all the questions that will help you understand why your doctors are doing the study and what you will be expected to do. Keep asking until you feel comfortable about participating.

Your questions might include:

* *What exactly is the procedure or treatment and is it safe?*
* *How does it compare to the "standard" procedure?*
* *Who might benefit from this study?*
* *How much of my time will it take compared to "standard" procedures?*
* *How much will it cost?*
* *What are my other options?*

A Letter to Breast Cancer Patients & Survivors

Hello,

As breast cancer patient advocates, we understand how confusing it is to be diagnosed with breast cancer and be faced with the many options regarding treatment. You may also have been asked to participate in a research study. Because of this, we want to share with you how new advances for breast cancer are developed and how you can take part in the process.

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. These studies are critical because there is still so much that isn't known about this disease.

There are many active research areas in breast cancer. In the table below, we list several of them and give examples of specific study topics for each:

Research Area	Examples of Study Topics
• How to prevent breast cancer	• Nutrition, exercise, environment, drugs
• How to detect cancer early	• Blood tests, digital mammography
• How to treat cancer more effectively	• Lumpectomy, new ways to give radiation and chemotherapy, gene therapy, vaccines
• How to treat side effects	• Anti-nausea drugs, acupuncture
• How to prevent recurrences	• Drugs, diet, life-style choices
• How to help patients live with cancer	• Support groups, imagery, alternative medicine

There are advantages and disadvantages to participating in a clinical trial. Advantages might include receiving treatment that is not commercially available, receiving more thorough 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. UCSF shares this belief and is working hard to provide options for each of their breast cancer patients. If you are interested, UCSF can provide a list of clinical trials that might fit your particular needs at the UCSF Breast Care Center or at other sites in the Bay Area.

We want you to make the best decision for your particular condition. If you want information about a specific clinical trial, please call the clinical trials manager at the UCSF Breast Care Center (see phone list). We also invite you to learn more about cancer research, and how you can help by contacting Deborah Collyar at Collyar@worldnet.att.net or Peggy Devine at (415) 502-2986.

Complementary and Alternative Medicine Program (BCC - CAMP)

Our Mission

The UCSF/Mt. Zion Breast Care Center Complementary and Alternative Medicine Program is dedicated to designing and conducting scientific studies to assess the value of non-conventional modalities in treating breast cancer and improving the general health of women with breast cancer **or with breast cancer risk**. Modern medicine has made great strides in early detection, reducing rates of recurrence and enhancing quality of life; however, a fully effective breast cancer treatment remains to be found.

Complementary and Alternative Medicine (CAM) encompasses a broad range of healing modalities including acupuncture, herbs, naturopathy, homeopathy and mind/body intervention. These forms of alternative treatment, as well as many others, have gained widespread appeal, particularly here in the San Francisco Bay Area, despite the lack of well documented treatment benefits. The BCC-CAMP strives to create new research methodologies to examine healing practices that have evolved within different cultures and medical traditions. Our goals are to make our research results available and accessible, to educate the community and health care providers and to provide high-quality integrative care. We are committed to attaining the best possible outcomes for women with breast cancer.

Current Studies

*** A Study to Assess the Efficacy, Feasibility, and Toxicities of Chinese Herbal Therapy (CHT) to Alleviate the Side Effects of Chemotherapy for Breast Cancer.**

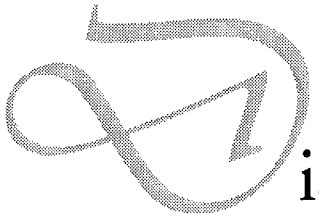
Women eligible to participate in this study have been diagnosed with early stage breast cancer and will be receiving doxorubicin (Adriamycin®) and cyclophoshamide (CYTOXAN) (AC) chemotherapy. Women in this study will be taking a formula of 21 Chinese herbs or a placebo formula, starting ten days before their first AC treatment. Patients' progress and side effects will be followed closely by our research team.

*** A Pilot Feasibility and Efficacy Study Assessing Tibetan Medicine for Metastatic Breast Cancer.**

Women with clinical evidence of asymptomatic or minimally symptomatic metastasis who have discontinued both hormonal and chemotherapy as well as any other investigational or herbal agents (for at least 3 weeks before the start of their regimen) may be eligible for this trial. This study is not placebo-controlled. All women who participate will receive a combination of Tibetan herbal formulae.

*** Pilot Registry of Breast Cancer Patients Using Traditional Chinese Medicine (TCM).**

This study will enroll 15 patients with asymptomatic or minimally symptomatic metastatic breast cancer who are only using TCM and track their outcome over the course of a year. Participants will receive individualized courses of treatment as prescribed by their TCM practitioners. They will have regular physical exams and laboratory work at the Breast Care Center, assessment of their tumor status and will complete questionnaires regarding their physical health and quality of life.



isability Benefits

Obtaining Disability Benefits

If you are out of work for an extended time due to surgery or illness, you may be eligible for disability benefits. These benefits usually are partial compensation for loss of wages while you are unable to work. Depending on your employer and benefits, you may be eligible for either private disability and/or state disability benefits. Prior planning, when possible, is crucial to ensuring that you receive the benefits to which you are entitled.

Please contact your employer or benefits department to find out more about your specific disability benefits. All forms for disability will require either a statement or completed forms from your physician. **You will need to allow 7-10 working days for our office to complete the physician portion of the disability forms.**

If you are having surgery, at your pre-operative visit, please discuss the anticipated length of time that you will be unable to work following surgery with your physician. In most cases, if the initial time off is not sufficient, additional time may be requested. If you are going to be off work due to an extended illness or to complete treatment, please discuss the amount of time you will need to be off work with your physician. **You will need to collaborate with your physician regarding the length of your disability.** This should be done prior to the completion of the disability forms. A nurse in the Breast Care Center (BCC) coordinates the completion of all disability paperwork with the BCC physicians.

If you require any assistance understanding your disability benefits or completing the forms, please let us know and we will be happy to assist you. There are also other resources regarding disability in the Bay Area. The Ida and Joseph Friend Resource Center on the first floor of 2356 Sutter Street can help you obtain this information and help answer other questions you may have.

Since many people are entitled to state disability insurance benefits we are including specific information about the program. We also have state disability forms in the Breast Care Center.

State Disability Insurance Benefits

The State Disability Insurance Program (SDI) was set up to partially compensate loss of earning due to illness or injury. The program is paid for through payroll deductions, and the maximum duration of benefits is 52 weeks.

Basic Eligibility:

An individual is considered disabled on any day on which she or he cannot perform regular work because of a physical or psychological condition.

Eligibility Criteria:

To receive SDI benefits, you must meet all of the following criteria:

- Be unable to perform your regular work.
- Have a wage loss because of a disability.
- Be under the care and treatment of a doctor who certifies that you are disabled.
- Be disabled for at least 8 calendar days.
- File a timely claim. A claim must be filed within 41 days of the first payable day of disability

Menopause:

How to Handle the Side Effects

Breast cancer treatment often causes women to enter menopause prematurely. The change in hormone levels and estrogen depletion caused by stopping hormone replacement therapy or undergoing chemotherapy or hormonal therapy can trigger side effects commonly associated with menopause. Although each woman reacts to therapy individually, certain side effects are common. We hope this information will provide you with useful tips to help you manage any side effects that you may be experiencing. Before implementing these management strategies, please discuss your specific symptoms with your physician or nurse and ask any questions you may have. If you are seeing a complementary or alternative medicine practitioner, please let us know what you are using so we can incorporate the information into your care plan.

Hot Flashes:

Hot flashes are probably the most common side effect of menopause. Triggers include spicy foods, caffeine, alcohol, tight clothing, heat and stress. Try to avoid these things as best you can if your hot flashes are bothersome. Foods, like soy products (soymilk, tofu, soynuts) and flaxseeds (either ground or in oil form), have been shown to reduce hot flashes in some women. Experiment with these in your diet if possible. We have helpful written materials on soy products and how to incorporate them into your diet.

Hot flashes tend to be worse at night, but a few simple things can make you more comfortable:

- Wear cotton pajamas and sleep with a fan on in a cool room
- Use cotton flannel or "t-shirt" sheets to absorb moisture
- Keep a change of sheets and pajamas close to your bed so that you can change them quickly if they are wet from perspiration
- Take a warm bath or shower before bed

The relaxation response, which includes deep abdominal breathing, has been shown to have many beneficial health effects, including minimizing hot flashes. It will help you stay calm and possibly avoid or reduce the severity of a hot flash. Try to take long, slow, deep breaths, 7-8 breaths per minute if possible, when you feel a hot flash coming on. Continue to do so for 15 minutes.

Daily exercise may also reduce hot flashes. Aerobic exercise for at least 20-30 minutes a day, at least 3 times a week is our recommendation. Aerobic exercise includes walking, running, swimming, biking or any other exercise that keeps your heart rate elevated for an extended time period. We have an information sheet describing aerobic exercise that will be helpful for you. If you do not have a regular exercise program already, please consult with your physician or nurse to see what type of exercises may be best for you.

There are prescription medications that provide a benefit to some women. A current example is venlafaxine (Effexor®). This medication is an anti-depressant, and in low doses, can also decrease the frequency and severity of hot flashes.

Sleep Disturbances:

Hot flashes can interrupt a healthy night sleep, and insomnia is common. Some tips to help you avoid insomnia include:

- Only go to bed when you are tired.
- Only sleep while in bed (do not read, eat or watch television).

The Carol Franc Buck Breast Care Center


ABOUT THE BREAST CARE CENTER


COMPREHENSIVE SERVICES


CANCER RESEARCH & CLINICAL TRIALS


THE PATIENT GUIDE TO BREAST CARE


NAVIGATING YOUR PATH TO BREAST CARE

THE PATIENT GUIDE TO BREAST CARE

A diagnosis of breast cancer is often paired with difficult sensations, emotions and responses including fear, shock, numbness and disbelief, anger, betrayal, grief and sadness. In the midst of this emotional trauma, information must be gathered, often a new language of medical terms learned, treatment choices must be understood and difficult decisions must be made. Women often report being overwhelmed or at least intensely challenged to make sense of the medical maze.

Information can help. Emotional support can help. It is important during the stressful time of a new diagnosis to give some thought to how you learn and how you can most easily receive emotional support. Who in your life can be present to help to gather information, hear medical conversations? If you are doing the data gathering yourself, what support do you need from breast cancer clinicians?

This section of our web page is designed to provide you with general information about breast cancer and its treatment.

We see the information here as a starting point to help you begin to understand the range of terminology, procedures, and treatments associated with breast care and breast cancer. With information such as this, we hope, as a patient, you will be more enabled to participate with your doctor in planning the best possible treatment; or as a friend or family member, you will be better able to support someone close to you who has been diagnosed with breast cancer. This section is intended as a source of information and educational resource to assist you in the dialogue with your physician. This information does not replace the expertise and clinical judgment of your physician. Each patient's situation must be evaluated individually by a medical team. It is important to discuss all information regarding your breast health and treatment options with your physician.

Carol Franc Buck Breast Care Center: Education Evaluation

Prior to your treatment for breast cancer our plan is that you meet with a nurse who describes what to expect over the course of your treatment. Hopefully, you were also given an educational packet. We are interested in your feedback about these materials.

1. Did you meet with a nurse prior to your treatment at the Breast Care Center?

   Yes.....1
   Yes, I met with a nurse, but it was after my treatment.....2
   Yes, I spoke with a nurse by telephone..... 3
   No..... 4

2. Did you receive materials describing your diagnosis and treatment options?

   Yes.....1
   No.....2

3. Did you receive materials describing resources available to you at the UCSF Cancer Center?

   Yes.....1
   No.....2

4. The materials included information about cancer support groups and resources available at the Cancer Center and in the community. Did you use any of these services?
   Yes.....1
   No 2

   Please describe the programs or resources you used?

   _____

5. Thinking about the information you received at the Breast Care Center how would you rate the following:

(circle one number on each line)	**Excellent**	**Very Good**	**Good**	**Fair**	**Poor**	**N/A**
a. The clarity and helpfulness of the information provided in the materials describing your diagnosis and treatment?.....	**1**	**2**	**3**	**4**	**5**	**6**
b. The clarity and helpfulness of the information provided in the presurgery printed instruction sheets?	**1**	**2**	**3**	**4**	**5**	**6**
c. The clarity and helpfulness of the information describing what you needed to do after your surgery?.....	**1**	**2**	**3**	**4**	**5**	**6**
d. The clarity and helpfulness of the information describing post-surgery exercises?	**1**	**2**	**3**	**4**	**5**	**6**
e. Overall, rate the educational materials you received.	**1**	**2**	**3**	**4**	**5**	**6**

Education Evaluation (continued)

6. Overall, how would you rate the level of information contained in the materials you received: Was the level...

   Too basic.....1
   Appropriate.....2
   Too complex...3

7. Overall, how much did you benefit from the pre-surgery meeting with the nurse?

Extremely	1	
Quite a bit	2	
Somewhat	3	(Circle one number)
A little bit	4	
Not at all	5	

8. Which of the following sources of information:

(please circle all answers that apply)	Did you use?	Would you recommend to others?
From a doctor?	1a	1b
From a nurse?	2a	2b
From friends or family members?	3a	3b
From breast cancer survivors	4a	4b
From hospital or community based resource centers?	5a	5b
From hospital or community based support groups?	6a	6b
From magazines or journals?	7a	7b
From a website/internet?	8a	8b
Other, please describe _____	9a	9b

9. Any other comments or suggestions?

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MASTECTOMY/RECONSTRUCTION POST-OPERATIVE BREAST SURGERY ORDERS

CHECK ORDERS TO BE IMPLEMENTED

1. Admit to: Attendings: Resident Pager:
2. Diagnosis: ☐ Breast Cancer ☐ Prophylaxis, + family history ☐ Other _____
3. Operation: ☐ Mastectomy and TRAM ☐ Mastectomy and Latissimus Dorsi flap ☐ Other _____
4. Condition: ☐ Stable ☐ Other _____
5. Vital Signs: q2˚x2, q 4˚x4, then q 8˚
   no blood pressure on arm of surgery, if bilateral axillary dissection, blood pressure from leg
6. Drug Allergy:
7. ☐ Left Arm ☐ Right Arm Lymphedema prevention: No IV, blood pressure, injection or blood drawn
   ☐ Bilateral: Blood pressure on leg, IV site blood draw site
8. Notify M.D. if Temperature > 101.5˚F (38˚C), HR < 50 or > 100, BP < 90 systolic or > 100 diastolic,
   JP drain output > 100 cc/2hr
9. Diet: ☐ POD #1: NPO ☐ Other _____
   ☐ POD #2: Clear diet as tolerated ☐ Other _____
   ☐ POD #3: Regular diet as tolerated
10. Activity: Bed position: Head of bed at 30˚-45˚, Hips flexed at 30˚
    ☐ POD #1: Up in chair BID. Patient to walk bent over at waist for 5 days
    ☐ POD #2: Ambulate to door x 2
    ☐ POD #3: Ambulate down hallway x2
    ☐ POD #4: Ambulate around floor x 3
    ☐ Patient to use walker as needed
    ☐ Other _____
11. Drain(s):
    ☐ Strip & empty JP q4° x 2 then q8° and record volume.
    ☐ Patient and family education regarding drain care, emptying, and recording before discharge
    ☐ No JP drain
    ☐ Foley catheter to gravity
    ☐ D/C Foley

Signature _____ **M.D. #** ___ ___ ___ ___ ___ **Time** _____ **Date** _____ **Pager #** _____

FLAG CHART TO INDICATE NEW ORDER **Checked by** _____ **R.N. Time** _____ **Date** _____

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DATE	TIME

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LOCATION DATE

MASTECTOMY/RECONSTRUCTION POST-OPERATIVE BREAST SURGERY ORDERS

CHECK ORDERS TO BE IMPLEMENTED

12. ☐ Ice pack to axilla prn

13. Intravenous Fluids:

☐ D51/2NS + 20 mEq/L KCl @, 100 cc/hr until tolerating po ☐ Other

☐ Heparin lock IV when tolerating po

13. Pain Control:

☐ Epidural (see Epidural orders) written by Anesthesiology team

☐ If pain ≥ 3/10 call Anesthesiology team to adjust Epidural

☐ If pain > 5/10 for over 6 hours, add PCA (see PCA orders) & notify Anesthesiology team

☐ PCA (see PCA orders)

14. Medications:

ANTIBIOTICS ☐ Cefaxolin (Ancef) 1 gram IV q 6°

☐ Cephalexin (Keflex) 500 mg PO qid when IV is D/Ced

PAIN ☐ Rofecoxib (Vioxx) 50 mg po q 24° when tolerating po

☐ Oxycodone Hydrochloride (OxyContin) 10 mg po Q 8° prn pain, when tolerating po

☐ Ibuprofen (Motrin) 600 mg po q4° prn pain when tolerating po

☐ Hydrocodone bi tartrate 5 mg and 500 mg acetominophen (Vicodin) 1-2 tablets po q4° prn moderate pain when tolerating po

☐ D/C Hydrocodone bi tartrate 5 mg and 500 mg acetominophen (Vicodin) if ineffective and start Oxycodone hydrochloride 5 mg and acetominophen 325 mg (Percocet)

☐ Oxycodone hydrochloride 5 mg and acetominophen 325 mg (Percocet) 1-2 tablets po q 4° prn pain, when tolerating po

☐ *Acetaminophen 650 mg po q4° prn headache or T > 101 °F (38°C)

***NOTE:** Total Acetaminophen (present in Vicodin & Percocet) dose not to exceed > 4 grams/day

☐ Ketorlac (Toradol) 15 mg IV q6° prn pain x 72 hours starting post op day #1

☐ Morphine 2-4 mg IV q3-4° prn severe pain and if Vicodin/Percocet insufficient

NAUSEA ☐ Lorazepam (Ativan) 0.5 mg IV, q6° prn; Ativan 1 mg po q 6° po or sl prn nausea/muscle spasm when tolerating po

Signature _____ **M.D. #** ___ ___ ___ ___ ___ **Time** _____ **Date** _____ **Pager #** _____

FLAG CHART TO INDICATE NEW ORDER

Checked by _____ **R.N. Time** _____ **Date** _____

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MASTECTOMY/RECONSTRUCTION POST-OPERATIVE BREAST SURGERY ORDERS

CHECK ORDERS TO BE IMPLEMENTED

Medications Continued:

NAUSEA (cont.)	☐	Lorazepam (Ativan) 1 mg IV, q 6° prn; Ativan 1 mg po q 6° po or sl prn nausea/muscle spasm when tolerating po
	☐	Droperidol (Inapsine) 0.625 mg Q 4° prn nausea if Lorazepam (Ativan) ineffective
INSOMNIA	☐	Zolpidem tartrate (Ambien) 5-10 mg po qhs prn insomnia
	☐	Temazepam (Restoril) 15-30 mg po qhs prn insomnia
CONSTIPATION	☐	Docusate sodium (Colace) 100 mg po qhs when taking po
	☐	Magnesium hydoxide (Milk of Magnesia) 30 cc po q4h prn constipation
	☐	Bisacodyl (Dulcolax) 1 tablet po q12° prn constipation
OTHER	☐	
	☐	
	☐	
	☐	

15 . DISCHARGE PLANNING

- ☐ Discharge to Home Care
  - ☐ RN to assess for signs / symptoms of infection
  - ☐ RN to assess pain control, use of pain medications
  - ☐ RN to instruct patient /caregiver regarding care of Jackson Pratt drains
  - ☐ RN to assess for constipation
  - ☐ RN to assess need for homehealth aide for help with bathing
  - ☐ RN to assess patient/ family coping and need for community resource referrals
  - ☐ Other

Signature _____ **M.D. #** ___ ___ ___ ___ ___ **Time** _____ **Date** _____ **Pager #** _____

FLAG CHART TO INDICATE NEW ORDER

Checked by _____ **R.N. Time** _____ **Date** _____

707121-2C (12/00) ORIGINAL - MEDICAL RECORD COPY YELLOW - NURSING COPY

Cancer is so limited:

It cannot cripple love

shatter hope

corrode faith

eat away peace

destroy confidence

kill friendship

shut out memories

silence courage

invade the soul

reduce eternal life

quench the spirit

and lessen the power of resurrection.

ANONYMOUS

The Ida & Joseph Friend
CANCER RESOURCE CENTER
UCSF Comprehensive Cancer Center
2356 Sutter Street, First Floor
San Francisco, CA 94143-1725

415.885.3693 PHONE
415.885.3701 FAX

MONDAY - FRIDAY
9AM - 5PM

http://cc.ucsf.edu/crc
crc@ucsfmedctr.org

The Ida & Joseph Friend Cancer Resource Center is supported by grants and donations. If you would like to make a donation, please send it to the address listed above.

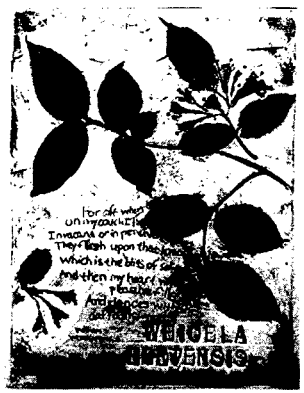
The Ida & Joseph Friend

CANCER RESOURCE CENTER

Supporting wellness and the healing process

Our mission statement...

The Cancer Resource Center



supports wellness and the healing process by providing patients, their families and the community with information related to cancer, including treatment options, clinical trials, emotional support and community resources. Our library includes a significant collection of books, videotapes and audiotapes, as well as access to the Internet and several excellent health-related databases. The Resource Center staff will research cancer-related topics for people living with cancer. In addition, the Resource Center hosts a variety of support groups, exercise classes, monthly workshops, and directs people to appropriate community resources.

All Resource Center programs are free to anyone living with cancer.

We are supported solely by grants and donations. For more information, please call 415.885.3693.

Our goals are to...

- Support people with cancer and their loved ones as they navigate the period of diagnosis, treatment, and recovery.
- Provide a wide range of services that speak to the diverse needs of cancer patients.
- Support effective information gathering and decision-making to increase both participation and a sense of control.
- Foster a sense of community among people affected by cancer.
- Link patients and their loved ones to community resources.

Our client feedback...

"I sincerely appreciate all your help and support. You provide a great support system and service to those of us going through a difficult situation.... I am grateful." CANCER SURVIVOR

"You have created a wonderful setting, rich with resources and warmth." SOCIAL WORKER

"The library has been invaluable to me. The personnel running the library are very knowledgeable and helpful in providing information." CANCER SURVIVOR

Our services include...

- Information and resources on cancer, treatment options, clinical trials, complementary therapies, pain management, and stress reduction.
- Lending library of books, videotapes, and audiotapes.
- Support groups and peer support.
- Benefits and health insurance counseling.
- Gentle yoga, dance therapy, exercise, and restorative movement classes.
- Smoking cessation program.
- Peggy Huddleston's "Prepare for Surgery, Heal Faster™".
- Fatigue management workshops.
- Making the most of your doctor visit.
- Meditation, visualization, and writing workshops.
- Nutrition counseling and workshops.
- Referrals to community resources.
- Free brochures and pamphlets.
- Monthly workshops on cancer-related topics.
- Coffee, tea, and a comfortable place to sit and relax.

If you would like to speak with a veteran cancer patient, please call the

CANCER RESOURCE CENTER

at 415.885.3693.

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Speak with someone who's "been there"...

Peer Support Program

connecting those whose lives have been affected by cancer

Although each patient's experience is unique, many individuals find it helpful to speak with someone who has had or is currently in a similar situation. The Peer Support Program offers cancer patients the opportunity to speak with veteran patients – others who have already "been there".

The Peer Support Program also offers veteran patients the opportunity to share with others the knowledge and insight gained from their cancer experience. By doing so, they are able to connect with others in a rewarding and constructive way.

The goals of the program are to match cancer patients to veteran patients in order to

- Provide individual support.
- Reduce feelings of isolation, anxiety, and fear.
- Assist in the development of coping skills.
- Help navigate the health care experience.
- Increase a sense of hope in dealing with cancer.

What do the Peer Support Volunteers offer?

Although our pre-screened volunteers cannot dispense medical advice, they are a wonderful source of special support, comfort and practical information. They are empathetic listeners who are able to answer your questions drawing from their own personal experiences.

How can the Peer Support Program help me?

Talking with someone who has lived with cancer can often be comforting and can help to reduce feelings of anxiety and isolation you may feel during the initial period of diagnosis.

Who is eligible for this program?

Our program is open to any cancer patient at any stage of the disease, and at any point during your experience. This program is offered free of charge.

Who are the people who serve as volunteers?

Our volunteers are caring people who have lived with cancer and who want to help others. They are at least one year past their original diagnosis, and have been through an extensive screening and training process.

How are patients matched up with volunteers?

After contacting the Cancer Resource Center, we will match you up with a volunteer according to what criteria you consider most important – age, diagnosis, treatment, language, gender, ethnicity, religion, or family.

How can I take part in the program?

If you would like to speak to a peer, or become a volunteer yourself, please call the Cancer Resource Center at 415.885.3693.

Appendix G

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Does Timely Assessment Affect the Anxiety Associated with an Abnormal Mammogram Result?

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Word count: 1,987

Abstract

Anxiety following an abnormal mammogram result can be substantial. We examined whether the time to the first diagnostic test was associated with anxiety. We surveyed 449 women at two and eight months following an abnormal mammogram result, and we reviewed their medical records. Twenty-six percent of women reported being very anxious about their abnormal mammogram result at the time of the time of the two-month interview, and 22% reported persistent anxiety after eight months. After adjustment, the number of days until the first diagnostic test was not associated with anxiety at the two-month interview. By the second interview, women who received their first diagnostic test within the first week were significantly more anxious, as were women who did not receive their first test for at least 60 days following their results. Further work is needed to ascertain how to minimize the anxiety associated with the evaluation of an abnormal mammogram.

Keywords: quality of care, mammography

Background

While the effectiveness of mammography for the early detection of breast cancer has been well documented,[1-4] mammography is associated with a substantial risk of an abnormal result.[5, 6] Most women who receive an abnormal result do not have breast cancer.[6] Receiving an abnormal mammogram result can cause considerable anxiety, decline in mood, and decreased daily function.[7-13] The effects of anxiety related to an abnormal result on subsequent adherence with mammography is uncertain.[14-16]

Our goal was to examine what factors are associated with significant anxiety among women who receive an abnormal mammogram result. In particular, we were interested in examining whether the time until the first diagnostic test is associated with level of anxiety following an abnormal result.

Methods

Setting

Women were recruited from two participating mammography facilities in San Francisco. The Institutional Review Board of each institution approved the study. Both of these facilities perform over 19,000 mammograms each year.

Patients

Since the goal of the study was to examine factors associated with anxiety among women who had received an abnormal mammogram result, we included women who had recently received a mammogram result that required further evaluation (i.e., the results were indeterminate, aroused a suspicion of cancer, or if there was a recommendation for non-routine follow-up including additional or magnification views, mammography within the following twelve months, ultrasound examination, fine needle aspiration, or biopsy).[6] This mammogram was considered the "index" mammogram. Women were initially identified by reviewing the mammogram reports from the participating sites. Women were eligible for the study if they: (1) were English- or Spanish-speaking, (2) had a functioning telephone, and (3) could hear well enough to participate in a telephone survey.

Data collection

Eligible women were sent an informational letter about the study, and were asked to return an "opt-out" postcard if they did not wish to participate. Attempts were made to contact women who did not return a post-card by telephone to complete a "baseline" telephone survey within six – eight weeks of their index mammogram. Women who agreed to participate in the

baseline survey were also contacted for a "follow-up" telephone survey seven – eight months after their index mammogram. Medical records were abstracted using a standard form that collected information about the type of subsequent evaluation, the date of subsequent tests and the results.

Analytic variables

The dependent variables for this analysis were a woman's self-reported anxiety about her breast problem. At the time of each survey, women were asked to rate their anxiety on a three-point scale (very anxious, somewhat anxious, not at all anxious).[10] Because we were interested in looking at factors associated with significant anxiety, this information as dichotomized as very anxious versus less anxious.

The principal independent variable of interest was the time to the first reported diagnostic test resulting from the abnormal mammogram. This time interval was calculated as the number of days between the index mammogram and the first relevant procedure reported by the woman in either survey or noted in the medical record. Women who had not yet received any further diagnostic evaluation by the time of the follow-up survey were assumed to have a time to the first diagnostic test of greater than 60 days. Diagnostic tests included in this measure were: additional mammography, ultrasound, cyst aspiration, fine needle aspiration, core biopsy or surgical biopsy.

Other patient-reported independent variables examined included: age, race, history of a prior abnormal mammogram, history of a prior breast biopsy, family history of a first degree relative with breast cancer, current breast lump, a prior diagnosis of cancer, and a new diagnosis of breast cancer following the index mammogram result. Mammogram results were classified

according to the classification scheme developed by the American College of Radiology.[17] This information was obtained from the medical record review was also examined as an independent variable.

Statistical analysis

The analysis was based on women who responded to the baseline survey. Descriptive statistics were used to examine the association between potential independent variables and the outcomes of interest. Generalized estimating equations were used to control for the effect of intra-site clustering in the multivariate models.[18] Since the multivariate models were descriptive, independent variables were selected based on *a priori* decisions or significant univariate associations. Women with an initial test between 15 – 60 days were chosen as the reference group for this comparison in the multivariate models.

Results

Response Rates

Of the 797 women who were eligible to participate, 488 (61.2%) completed the baseline telephone survey, 171 (21.5%) refused to participate and 138 (17.3%) could not be reached by phone after at least ten attempts. Of the 488 women who completed the baseline survey, 414 women (85% of eligible women who completed the first survey) completed the follow-up survey. 39 women were deleted after data collection because they did not fit the initial eligibility criteria (i.e., they had a normal index mammogram result). The final sample was therefore 449 women.

Description of the Study Sample

Table 1 displays the characteristics of the study sample. 63.3% of participants were post-menopausal. Many of these women had a prior evaluation for an abnormal mammogram, and more than a third had received a breast biopsy. Almost 30% had received a previous cancer diagnosis.

Anxiety about Abnormal Mammogram Result

Women expressed a high level of anxiety following the result of an abnormal mammogram: 26.2% reported being very anxious at the time of the baseline survey and 22.4% reported being very anxious at the time of the follow-up survey. Forty-two women (9.4% of the overall sample) reported persistently high anxiety at both interviews.

Type of Subsequent Evaluation and Outcome

Of the 449 women in the sample, 175 (39.0%) received an evaluation that included a follow-up mammogram, 209 (46.6%) received an ultrasound, 151 (33.6%) received a fine needle aspiration, 126 (28.1%) underwent a core or surgical biopsy. Women received a median of 2 additional diagnostic tests (Table 1). Breast cancer was diagnosed in 53 (11.8%) of women within two months, and in 64 (14.3%) women within eight months. Half of the women received follow-up evaluation within a week of their index mammogram. In contrast, over a quarter of the women (26.5%) did not receive follow-up within 60 days.

Factors Associated with Significant Anxiety

As shown in Table 2, older women were less anxious at the time of the baseline survey, but there was no difference in anxiety by age at the time of the follow-up survey. Women who had already experienced an evaluation for an abnormal mammogram were initially more anxious, but this anxiety was diminished by eight months. Women who had a prior breast biopsy were significantly more anxious at both times. Women with greater anxiety at the time of the initial survey were more anxious at the time of the follow-up survey. Women who received a diagnosis of cancer as a result of their evaluation were more anxious at the time of the follow-up survey. Time to the first diagnostic test was not associated with a woman's level of anxiety at the time of the initial survey. Both women with an initial test within the first week of the index mammogram and those with an initial test more than 60 days after the index mammogram were significantly more anxious after eight months.

Discussion

Our work suggests that the timing of the evaluation for women with an abnormal mammogram result may affect the anxiety that these women experience. Ameliorating anxiety following an abnormal mammogram is important, since high levels of anxiety may affect role function and perhaps affect subsequent adherence.[10, 14-16] Given the substantial number of women who receive an abnormal mammogram result, further study is needed to determine how to best alleviate the anxiety associated with this common clinical scenario.

Our sequential surveys suggest that substantial anxiety remains over an eight-month period for many women who receive an abnormal mammogram result. These results are

consistent with what has been reported by others. Lerman et al. reported that 47% of women without breast cancer reported substantial mammography-related anxiety three months following an abnormal mammogram result.[10] Eighteen months after a screening mammogram, 29% of women with a false positive mammogram report anxiety about breast cancer compared with 13% of women with a normal result.[9] In a prospective study that adjusted for level of anxiety before the mammogram, women with an abnormal result had significantly higher levels of anxiety than women with a normal mammogram at one month.[13]

Our findings about the effect of the timing of further diagnostic evaluation are preliminary. Women who received an initial test within the first week of an abnormal mammogram result were significantly more anxious eight months after their index mammogram, although their anxiety was not elevated two months after their index mammogram. Conversely, women who received an initial evaluation more than 60 days after their index mammogram were also more anxious. These results suggest that some women may need some time to make informed decisions about the best course of action, but that prolonged uncertainty without further testing is also associated with persistent anxiety.

The appropriate time for follow-up of an abnormal mammogram result has not been determined. Prior studies have used definitions of "timely" follow-up of an abnormal mammogram result of 8 – 12 weeks.[19-22] This definition is based on the assumption that a 12-week delay in the diagnosis of breast cancer is unlikely to affect survival.[23-25] While a 12-week delay may not affect survival for many women, this delay may be associated with persistent, and perhaps unnecessary, anxiety.

Our findings suggest that women who have had a prior breast biopsy generally have greater anxiety following an abnormal mammogram result. This is not surprising since women

who have had a prior breast biopsy are at an increased risk for breast cancer.[26] A prior abnormal mammogram result increased anxiety at baseline, but was negatively associated with anxiety at follow-up. It is possible that these women respond to their initial anxiety by getting information and support, and therefore become less anxious with time. Women with a family history of breast cancer were less anxious at the time of the eight-month follow-up than women without a family history. This finding suggests that a woman's perception of her risk of cancer may differ from her actual risk. Not surprisingly, a new diagnosis of breast cancer was associated with anxiety following an abnormal mammogram. Prior research suggests that minority women may have significantly longer time to resolution of an abnormal mammogram result.[21] Our results did not demonstrate ethnic differences in anxiety.

The affect of anxiety on subsequent adherence to cancer screening is unclear. Anxiety about breast cancer has been associated with reduced participation in subsequent mammography screening.[27] Yet, other work has suggested that worry about breast cancer does not affect either the intention to obtain recommended screening or subsequent adherence.[10, 11, 14] The differences in these findings may be related to differences in the level of anxiety. One study suggests a curvilinear relationship between anxiety and the performance of breast self-examination (BSE) – women with high and low levels of worry about breast cancer were less likely to perform BSE compared with women with moderate levels of worry.[14]

Our study has several limitations. We focused on the time to the first documented breast-related test or procedure. We cannot judge whether the evaluation performed was appropriate for a woman's clinical circumstance. Since our data is observational, we cannot conclude a causal relationship between the timeliness of evaluation and the level of anxiety. We examined women with any abnormality requiring further evaluation. This definition has been

used by others.[5, 6, 28, 29] Finally, we recruited women from two sites in San Francisco. Our findings may not be generalizable to other settings.

Abnormal mammogram results are more common in the United States than in many other countries.[1] Since the acceptance and utilization of mammography in the United States is increasing,[30] it is particularly important to understand anxiety following an abnormal result so that interventions can be devised, and systems of care improved, to minimize anxiety.

Acknowledgements

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Table 1: Description of the Sample

N = 449	
Age:	
Less than 50 years	159 (35.5%)
50 – 65 years	209 (46.7%)
More than 65 years	80 (17.9%)
Race:	
White	328 (74.0%)
Non-white	115 (26.0%)
Education:	
High school graduate or less	68 (15.2%)
Some college or college graduate	221 (49.3%)
Some post-graduate education	159 (35.5%)
Breast cancer risk factors:	
First degree family history	94 (21.2%)
Prior abnormal mammogram	209 (47.1%)
Prior history of breast biopsy	152 (33.9%)
Current breast lump	109 (24.4%)
Index BIRAD score	
Probably benign abnormality	347 (77.3%)
Suspicious abnormality	76 (16.9%)
Highly suggestive of malignancy	26 (5.8%)
Prior diagnosis of cancer	132 (29.6%)
Number of days until the first diagnostic test:	
0 – 7 days	226 (50.3%)
8 – 14 days	54 (12.0%)
15 – 60 days	50 (11.1%)
Over 60 days	119 (26.5%)
Median number of additional tests (range):	2.0 (0 – 12)

Site:	
A	209 (46.5%)
B	240 (53.5%)

The following variables had missing data:
Age (n = 1); Race (n = 6); Education (n = 1); Family history of breast cancer (n = 5);
Prior abnormal mammogram result (n = 5); Current breast lump (n = 3);
Prior diagnosis of cancer (n = 3).

Table 2: Factors Associated with being Very Anxious about their Breast Problem

	Baseline Survey §		**Follow-up Survey §**	
	Unadjusted Rate	Adjusted Odds Ratio * (95% CI**)	Unadjusted Rate	Adjusted Odds Ratio * (95% CI **)
Age:				
< 50 years	51 (32.3%)†	–	36 (27.5%)	–
50 – 60 years	40 (26.5%)	0.85 (0.64 – 1.12)	28 (21.2%)	0.68 (0.34 – 1.35)
> 60 years	24 (18.5%)	**0.48 (0.37 – 0.62)**	19 (17.8%)	0.69 (0.32 – 1.50)
Race:				
White	81 (25.2%)	0.91 (0.72 – 1.15)	58 (21.5%)	0.73 (0.72 – 0.74)
Non-white	31 (27.7%)	–	23 (24.2%)	–
Prior Abnormal Mammogram:				
Yes	54 (26.1%)	**1.27 (1.14 – 1.43)**	31 (17.6%) †	**0.52 (0.40 – 0.68)**
No	60 (26.4%)	–	51 (26.7%)	–
Family History:				
Yes	22 (23.9%)	0.88 (0.77 – 1.01)	13 (16.9%)	**0.79 (0.65 – 0.95)**
No	93 (27.2%)	–	70 (24.3%)	–
Prior breast biopsy:				
Yes	59 (39.9%) ‡	**2.36 (1.55 – 3.58)**	44 (33.3%) ‡	**1.38 (1.02 – 1.76)**
No	56 (19.2%)	–	39 (16.4%)	–
Current breast lump:				
Yes	26 (24.5%)	**0.66 (0.47 – 0.95)**	25 (27.2%)	1.04 (0.63 – 1.71)
No	88 (26.6%)	–	57 (20.7%)	–
Index BIRAD score:				
Probably benign abnormality	87 (25.7%)	–	64 (22.3%)	–
Suspicious abnormality or highly suggestive of malignancy	28 (28.0%)	0.68 (0.41 – 1.12)	19 (22.9%)	**0.67 (0.45 – 0.99)**

Prior diagnosis of cancer				
Yes	39 (30.5%)	1.23 (0.89 – 1.72)	33 (30.0%)	1.49 (0.77 – 2.87)
No	76 (24.6%)	–	50 (19.4%)	–
Anxiety at the time of the baseline survey:				
Very	–	–	42 (43.8%) ‡	**3.68 (3.51 – 3.86)**
None – somewhat	–	–	40 (15.0%)	–
Breast cancer diagnosed by time of baseline survey:				
Yes	27 (52.9%) ‡	2.37 (0.84 – 6.72)	–	–
No	88 (22.7%)	–	–	–
Breast cancer diagnosed by time of follow-up survey:				
Yes	–	–	27 (46.6%) ‡	**1.99 (1.31 – 3.02)**
No	–	–	56 (18.0%)	–
Number of days until first diagnostic test:				
0 – 7 days	66 (29.9%) †	0.99 (0.94 – 1.04)	57 (29.1%) †	**2.40 (1.55 – 3.70)**
8 – 14 days	17 (31.5%)	1.11 (0.98 – 1.25)	9 (20.9%)	1.35 (0.71 – 2.56)
15 – 60 days	14 (29.3%)	–	6 (14.3%)	–
> 60 days	18 (15.5%)	0.54 (0.29 – 1.01)	11 (12.4%)	**1.19 (1.06 – 1.34)**

§ Analysis of baseline survey based on 439 women who answered the question about level of anxiety. Analysis of follow-up survey based on 370 women who answered the question on level of anxiety.
* Adjusted for Age, Race, Prior abnormal mammogram, Prior breast biopsy, Prior cancer diagnosis, Current breast lump, Index BIRAD score, Number of days until first diagnostic test and site of care. Analysis of follow-up survey data also adjusted for baseline level of anxiety.
** 95% Confidence Intervals.
† $p < 0.05$
‡ $p < 0.005$

CANCER
CYTOPATHOLOGY

Diagnostic Accuracy of Fine-Needle Aspiration Biopsy is Determined by Physician Training in Sampling Technique

Britt-Marie Ljung, M.D.[1]
Anne Drejet, M.D.[2]
Nona Chiampi, M.D.
Juli Jeffrey, M.D.[3]
William H. Goodson III, M.D.[4]
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BACKGROUND. Fine-needle aspiration biopsy (FNAB) has been used with variable success as a diagnostic test for benign and malignant breast lesions. The goal of this study was to examine the effects of training physicians in the fine-needle aspiration sampling-technique on the diagnostic accuracy of FNAB of palpable breast masses. The settings for this study were private physicians' offices and university clinics of primary care physicians, surgeons, and cytopathologists.

METHODS. We reviewed 1043 consecutive FNAB specimens of the breast obtained during 1 year (1992): 729 FNABs were performed by formally trained physicians (at least 150 FNABs performed previously under supervision during fellowship training or the equivalent) who had done at least 100 FNABs during the year; 314 FNABs were performed by physicians without formal training who had done a median of only 2 FNABs during the year (range, 1–43 FNABs). All FNAB specimens were reviewed microscopically and evaluated for cellularity and type of material present, for diagnostic accuracy, and for the rate of surgical intervention. A minimum of 2 years of follow-up was obtained by matching all cases to the population-based Northern California Cancer Registry. FNAB specimens were correlated with histologic specimens when they were available.

RESULTS. Using FNAB, the formally trained physicians missed 2% of cancers, whereas the physicians without formal training missed 25%. Among the patients with benign lesions seen by the formally trained physicians, 8% went on to surgery, whereas 30% of those seen by physicians without formal training did so. Specimens obtained by the formally trained physicians were significantly more cellular and were significantly less likely to be nondiagnostic.

CONCLUSIONS. FNAB, when performed by physicians who are well trained in the technique, 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 adequate training, FNAB is often misleading and potentially harmful. ***Cancer (Cancer Cytopathol)* 2001;93:263–268.**
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KEYWORDS: physician training, fine-needle aspiration biopsy, palpable mass, breast carcinoma.

Fine-needle aspiration biopsy (FNAB) is a well-established, apparently simple, and rapid technique for diagnosing palpable masses.[1] The breast is commonly sampled by this method throughout Europe. However, in the United States, there has been considerable skepticism regarding the efficacy of FNAB for the diagnosis of carcinoma of the breast. This has been based on the relatively poor performance of FNAB in the community setting. Giard and Herman[2] reviewed 29 reports on FNAB of palpable breast lesions and found

wide variability in the diagnostic sensitivity and specificity for carcinoma of the breast. They concluded that the effectiveness of FNAB depends on the expertise of the physicians involved.

To determine if the poor performance of FNAB reflects inadequate physician training in FNAB sampling techniques, we undertook this study of a large series of consecutive FNABS. In this study, we examined the effect of training in sample procurement on the accuracy of FNAB in diagnosing benign and malignant breast masses. Physicians who had received formal training in FNAB technique were compared with those who had no formal training, using the cytologic cellularity and diagnostic accuracy of FNAB samples obtained by the two groups.

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: University of California at San Francisco (UCSF) Moffitt-Long, UCSF Mount Zion, and California Pacific Medical Center. Cases were identified by searching the computerized databases of the respective pathology departments. Charts were reviewed only when 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 FNAB had failed to detect the tumor.

Information on the training status of all the physicians was collected, and the number of breast FNABs performed by each physician during 1 year was tabulated. The results obtained by physicians who had been formally trained in FNAB technique were compared with the results obtained by physicians who had not been formally trained in FNAB. The formally trained physicians had completed fellowship training in cytopathology or the equivalent, during which they had performed at least 150 FNABs under the supervision of an experienced practitioner of the technique. The physicians without formal training had read a description of the technique, attended a lecture, observed another physician perform the procedure a few times, or had performed a small number of FNAB procedures ($\leq$ 10) under the supervision of an experienced practitioner.

The slides of all 1043 FNABs were reviewed and reinterpreted by an experienced cytopathologist (B.M.L.) who was aware of the clinical presentation but had no knowledge of the original diagnosis or the identity of the physician who had performed the biopsy. For quality control purposes, a subset of 104 cases was reviewed independently by two observers (B.M.L. and T.R.M.). 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 conference sponsored by the National Cancer Institute on uniform approaches to FNAB of the breast.[3] 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, we made a judgment 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, then the specimen was deemed nondiagnostic because the cytologic findings were inconsistent with the clinical finding. However, 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 deemed diagnostic.

Complete follow-up was available in all cases. 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. 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% of all breast carcinomas that have been diagnosed in the region. A minimum of 2 years of

follow-up was available in all cases. The reason for not submitting the remaining 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. However, the surgical outcome was known in all of these cases, and all 78 cases were included in the analysis.

The definition of cancer missed by FNAB in this study was a benign or nondiagnostic FNAB followed within 2 years by carcinoma 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.

Statistical Analysis

We used a two-sided test to compare differences in tumor size and patient age for patients seen by formally trained physicians versus physicians without formal training. A 2 × 2 table was used to compare diagnostic sensitivity and frequency of cancer in FNAB categories. We used contingency-table analysis to compare the cellularity of samples obtained (determined by microscopic reinterpretation) and the accuracy of diagnosis (determined by case review and follow-up). Logistic regression was used to compare the rate of false-negative findings obtained by formally trained physicians with the rate obtained by physicians who had no formal training. This method of analysis allows for heterogeneity in false-negative rates among the practitioners within the two groups, and this method can be used to test for the influence of other factors, such as the total number of FNABs attempted during the year of investigation by each practitioner. Agreement between the two pathologists who independently reviewed a subset of 104 cases for diagnosis and cellularity was assessed with the kappa statistic.[4]

RESULTS

Formally Trained Physicians

Seven hundred twenty-nine of the FNAB specimens were collected by 7 physicians who had been formally trained in FNAB sampling technique and who had performed at least 100 FNABs of various body sites, including the breast, during the 1-year study period. Three had completed a fellowship in cytopathology lasting at least 1 year, and two had had extensive one-to-one training under the supervision of a physician who was 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 7 physicians performed at least 150 FNABs during their training. Each biopsy specimen collected by the two physicians in training 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 formally trained physicians, six were cytopathologists, and one was a surgeon. The cytopathogists, but not the surgeon, applied quick stain (toluidine blue) to at least some of their samples. No specific data on use of this staining were available. This practice might have affected the rate of diagnostic samples.

Physicians without Formal Training

Three hundred fourteen of the specimens were collected by 69 physicians who had not had formal training in FNAB sampling technique. These physicians performed a median of 2 FNABs during the year of investigation (range, 1–43 FNABs). The 3 busiest physicians in this group were surgeons, who performed 28, 35, and 43 FNABs. There were 24 primary care physicians, 21 surgeons, 21 gynecologists, 2 pathologists, and 1 radiologist. None of the physicians without formal training used quick stain to assess the adequacy of their samples.

Study Population

Consecutive FNAB specimens (n = 1043) from 927 patients were analyzed. There was no significant difference in the mean age or tumor size between patients seen by formally trained physicians (n = 729) and those seen by physicians without formal training (n = 314). The mean ages (±standard deviation [SD]) in the 2 patient groups were 56.6 ± 16.1 (range, 33–88 yrs) and 62.7 ± 15.8 years (range, 37–91yrs), and the mean tumor sizes (±SD) were 2.9 ± 2.1 cm (range, 0.9–10 cm) and 2.3 ± 1.6 cm (range, 0.7–7.8 cm), respectively. In three cases from each group, tumor size could not be ascertained.

Cellularity of FNAB Specimens

Table 1 compares the samples obtained by the formally trained physicians with those obtained by the physicians without formal training, regardless of whether the lesion was benign or malignant. Generally, samples obtained by the formally trained physicians had much more abundant cellularity and were markedly less likely to be nondiagnostic ($P < 0.0001$). In addition, the formally trained physicians obtained a

TABLE 1
Cellularity of the FNAB Samples as Determined by Microscopic Review[a]

Sample cellularity[b]	No. formally trained physicians (%)	No. physicians without formal training (%)
Benign masses		
Abundant	238 (35.3)	20 (7.5)
Moderate	110 (16.3)	37 (13.1)
Scant	185 (27.4)	84 (31.6)
Nondiagnostic	16 (2.4)	109 (41.0)
Cysts	126 (18.7)	16 (6.0)
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

[a] Six samples of benign masses were unavailable for microscopic review; information in these cases was extracted from the reports.
[b] The cellularity of samples obtained by formally trained physicians was significantly higher than that of samples obtained by physicians without formal training ($P < 0.0001$ by contingency-table analysis).

TABLE 2
FNAB Diagnosis Determined by Microscopic Reinterpretation

FNAB diagnosis	No. formally trained physicians (%)	No. physicians without formal training (%)
Benign masses[a]		
Benign[b]	487 (72.1)	103 (38.7)
Malignant	0 (0)	0 (0)
Atypical	46 (6.8)	13 (4.9)
Nondiagnostic[c]	16 (2.4)	134 (50.4)
Benign cysts	126 (18.7)	16 (6.0)
Total	675	266
Malignant tumors[d]		
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

[a] $P = 0.0001$ comparing diagnosis of benign masses by formally trained physicians versus physicians without formal training (contingency-table analysis).
[b] Includes varying degrees of epithelial cellularity and some cases of fat only, and depends on the clinical findings.
[c] Includes specimens that did not explain the clinical findings; most had scant or no epithelial component.
[d] $P = 0.0013$ comparing diagnosis of malignant tumors by formally trained physicians versus physicians without formal training (contingency-table analysis).

much higher percentage of samples that resulted in a definitive (and correct) benign diagnosis ($P < 0.0001$) (Table 2). Importantly and significantly, 30% (73 of 266) of the benign lesions sampled by the physicians without formal training were referred for surgical excision, whereas only 8% (60 of 675) of the benign lesions sampled by the formally trained physicians were so referred (30% vs. 8%; $P < 0.0001$).

Independent review of a subset of 104 cases by 2 observers resulted in excellent agreement[4] in both diagnosis (86.5%; kappa statistic, 0.78) and cellularity (85.4%; kappa statistic, 0.80). The diagnostic differences were minor. In 9 of the 13 cases, 1 observer felt that the specimen was benign with scant cellularity, and the other felt it was nondiagnostic. In no case did one issue a malignant diagnosis and the other a benign diagnosis.

Sensitivity of FNAB for Breast Cancer

Table 3 compares the sensitivity for the 102 (9.8%) malignancies included in the 1043 FNABs in this study; 89 (89%) of these 102 were recognized as atypical (suspicious for cancer) or diagnosed as cancer by FNAB. Most notable is the striking difference in sensitivity for breast carcinoma diagnosis: 98% for the formally trained physicians versus 75% for physicians without formal training ($P = 0.0014$). None of the 54 cancers among the FNABs collected by the formally trained physicians was missed because of sampling errors, compared with 11 of the 48 cancers collected by the physicians without formal training (Table 3). One cancer in each group was missed because of erroneous microscopic interpretation.

Among the 69 physicians without formal training, 3 performed significantly more procedures (28 to 43 each) than the others. Together, they failed to diagnose 4 out of 15 cancers encountered (sensitivity, 74%), a proportion similar to the proportion for the other 66 physicians in this group. Testing based on logistic regression confirmed that, within the formally trained and untrained groups, the sensitivity of FNAB showed no significant heterogeneity and was not affected by the number of FNABs each physician contributed to this study (data not shown).

Microscopic reinterpretation resulted in only two significant revisions. In both cases, the diagnosis was changed from benign to suspicious for cancer, and subsequent histologic examination showed carcinoma. In one of these cases, only a few atypical cells were present. In the other, a moderate number of epithelial cells were collected from a cystic lesion; these cells were obscured by high numbers of inflammatory cells in an unusually darkly stained filter preparation.

DISCUSSION

This study shows that physicians with formal training in FNAB sampling technique achieved much more accurate diagnostic results than did physicians without such training. Using FNAB, the formally trained

TABLE 3
Original FNAB Diagnosis of 102 Breast Carcinomas Included in the Study

Physician	Cancer or atypical by FNAB	False-negative or nondiagnostic	Sensitivity	Sampling error	Interpretive error
Formally trained	53	1	98%[a]	0	1
Without formal training	36	12	75%	11	1

[a] $P = 0.0014$ versus physicians without formal training (chi-square test).

physicians missed only 2% of malignant lesions, whereas the physicians without formal training missed 25% (Table 3). This difference was entirely due to errors in sampling the lesion rather than in interpreting the specimen. In patients with benign lesions, only 8% of those biopsied by formally trained physicians went on to surgery, whereas 30% of those biopsied by physicians without formal training did so. In addition, the specimens collected by the formally trained physicians were of much higher cellularity and significantly less likely to be nondiagnostic (Table 2; $P < 0.0001$). Formally trained physicians submitted a larger percentage of cysts for microscopic interpretation. The reason for this was a difference in practice pattern between the two groups. The physicians without formal training frequently discarded cyst fluid when they had a low degree of concern for cancer, clinically and by macroscopic inspection of the fluid.

Our findings suggest that formal training in FNAB sampling techniques has a major positive effect on the diagnostic accuracy of the procedure. 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.[5] Jowell et al.[6] 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.[7] found substantial variance in diagnostic accuracy in detecting breast carcinoma and concluded that additional specialized education, better-defined diagnostic criteria, and examination of performance were required to improve diagnostic accuracy.

Few previous studies have systematically examined factors that affect the accuracy of FNAB. These factors, which include the number of needle passes done and the target size[8] as well as the importance of training in the microscopic examination of the samples,[9] have had considerably less effect on the accuracy of FNAB diagnosis than has formal training in FNAB sample procurement, as shown in the present study. Lee et al.[10] found that a single operator performing a larger number of FNABs had a markedly lower rate of nondiagnostic specimens than physicians in the same community performing only a few FNABs. Others have found similar trends. Training in sample procurement was not recorded in these studies. Before the present study, and to our knowledge, there had been no report of a systematic analysis of the effect on diagnostic accuracy of physician training in FNAB sampling technique.

The formally trained physicians performed at least 100 FNABs during the 1-year study period, whereas the physicians without formal training performed a median of 2 FNABs. Only 3 of the physicians without formal training had performed 28 or more FNABs during the study period. Thus, the effect of FNAB caseload on diagnostic accuracy in our study could not be evaluated adequately. However, the sensitivity (11 of 15 or 74%) for cancer was no higher for these 3 physicians than for the remaining physicians without formal training who performed fewer FNABs.

FNAB is a well-established and very successful diagnostic procedure in many European centers, where FNAB samples of palpable targets typically are collected and interpreted by cytopathologists with formal training in sampling technique. In the U.S., however, most of such samples are collected and prepared by surgeons and primary care physicians who do not have formal training in sampling technique. The samples are then forwarded to a pathology laboratory for processing and interpretation. This study shows that FNAB sample procurement by physicians who lack formal training results in unacceptably high rates of nondiagnostic specimens and of missed cancers. The resulting lack of sensitivity of FNAB in many U.S. centers is most likely the reason for the recent decline in use of this low-cost, low-morbidity, rapid, and potentially accurate diagnostic technique.[11] It is being replaced by more invasive and more expensive alternatives including open biopsies and large-core biopsies, and, in some cases, clinical follow-up by periodic palpation, which has relatively low sensitivity and specificity for carcinoma of the breast.

One solution to the problem of substandard FNAB results is to train a number of physicians well enough so that they can achieve a reliable diagnosis in greater than 95% of cases with a minimal false-negative rate. In our experience, such training entails sampling 150–200 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. Conversely, 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. In our opinion, it is not productive to implement "mini-training programs" in which residents perform 10 to 20 FNABs during their residency. Such training may give the trainees the false impression that they have been adequately trained when, in fact, training on substantially greater numbers of FNABs is necessary. Many who undergo such mini-training will use the technique briefly, be discouraged, and turn to other diagnostic methods that are more expensive, have a higher morbidity, or both.

In summary, when performed by appropriately trained physicians, FNAB is a cost-effective, highly accurate diagnostic technique with very low morbidity. Our data support a model for the triage of palpable breast masses utilizing FNAB performed by formally trained physicians. Conversely, performance of FNAB by operators without formal training is not supported and potentially may be harmful to patient outcome in an unacceptably high proportion of cases. Delay in treatment resulting from an incorrect diagnosis could allow for significant tumor growth and potentially lead to metastasis and thus a poorer prognosis for the patient. In conclusion, we suggest that FNAB be concentrated in well-trained hands to provide the benefit of high-quality, rapid, minimally invasive FNAB diagnosis to the maximal number of patients.

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Project 2
Selected Abstracts

A comparison of alternative-mind/body and support interventions for women with breast cancer. Levine, E.G, Targ, E. et al. (2000). Annals of Behavioral Medicine, 22, (supplement), 127.

Psychological adjustment to cancer can influence a variety of important issues, including quality of life, psychological well-being, and physical morbidity. Various interventions have been developed to decrease the amount of psychological morbidity associated with the disease and to assist breast cancer patients to improve their quality of life. However, direct comparisons have not been made between traditional interventions such as support groups and groups which focus on complementary practices in coping with cancer.

In this clinical trial 150 women with breast cancer were randomized to participate in either a 12-week traditional support group or an integrated group which combines yoga, meditation, dance, imagery, health information, and support in a single intervention. Long-term data for 65 women show that women in both groups reported significant improvements in quality of life and mood after the intervention, with benefits sustained until at least three months after the end of the intervention. The women in the integrated group showed significant changes at the end of the intervention, with continued improvements at three months post-intervention in: overall quality of life and mood, emotional well-being, functional well-being, spiritual well-being, anxiety, depression, vigor, and confusion. Improvements in the support group over all three time periods were seen only for: emotional well-being, functional well-being, and vigor. These results suggest that an integrated program is at least as beneficial as a traditional support group, and produces long-lasting effects.

Change in post-traumatic stress symptoms following psychosocial treatment for women with breast cancer. Levine, E. G., Targ, E., Stone, B. M, & Kronenwetter, C. (2000b) Psycho-Oncology, 9 (5 Supplement), 27.

The diagnosis of cancer is a traumatic experience, which may result in post-traumatic stress symptoms, such as arousal, re-experiencing the diagnostic process and arousal. Change in post-traumatic symptoms was assessed in 105 women with breast cancer who participated in either a standard support group or an integrated program using support, yoga, meditation, movement and imagery. At baseline 30 women were classified as having significant PTSD symptoms (at or above the 75%ile of the entire sample). In addition, 30 women reported significantly higher re-experiencing symptoms, 28 had high avoidance symptoms, and 33 reported high arousal. After the 12 week sessions, significant decreases were seen in all four areas, with the number of women rated as having significant PTSD decreased to 12 women. The number of women having

high re-experience symptoms fell from 30 to 12, while the number of women who reported high avoidance fell from 28 to 12, and the number of women who reported being highly aroused decreased from 33 to 16. For the entire sample, overall PTSD symptoms were significantly reduced (F=16.56, p=.0001). Significant decreases were also observed in re-experiencing (F=11.38, p=.0011), avoidance (F=7.22, p=.0087), and arousal (F=12.71, p=.0006). There were no differences between the two interventions. These results indicate that PTSD symptoms can be prevalent among women with breast cancer, and that psychosocial interventions can be effective in reducing this type of distress.

*Reduction Of Hopeless/Helpless Coping Style In Women With Breast Cancer..*Ellen G. Levine, James D. Tario, & Elisabeth Targ, Reduction of hopeless/helpless coping style in women with breast cancer. Psycho-Oncology, 9 (5 Supplement), 32.

Some researchers have suggested that the coping style of helplessness or hopelessness is unchangeable, and that they are related to poorer immune function and survival of cancer. The purpose of this study was to measure the extent of Helpless/Hopeless (H/H) coping style of women with breast cancer (n=127) before and after participation in a support group as part of, or exclusive of a mind/body integrated program. The participants completed the Mini-Mental Adjustment to Cancer Scale (Mini MAC) before the interventions started (mean time from diagnosis = 14 months) and after completion of the intervention.

The H/H scores of women in both groups improved over the twelve week intervention period. Although there were no differences in improvement between the groups, the decrease over time was significant (F = 6.39, p=.01). The mean H/H score prior to participation for both groups was 12.53 (SD=3.78) and 11.44 (SD=3.45) after completion. At baseline 24 women had high H/H scores. At the end of the twelve week programs only 16 remained in the high H/H group, 14 women changed from the high to the low group, and 6 changed from low to high H/H, while 107 women did not change H/H status. The number of women changed from high H/H to low was significantly greater than the number of women who changed from low to high (chi2 =22.7. p<.0001). These results suggest that psychosocial interventions can reduce feelings of helplessness and hopelessness. Further research will explore change in H/H over longer periods of time.

Differences in Psychosocial Status of Older and Younger Newly Diagnosed Women with Breast Cancer. Ellen G. Levine, Ph.D., M.P.H. (presenter), Elisabeth Targ, M.D. Breast Cancer Personal Support and Lifestyle Intervention Trial, University of San Francisco/California Pacific Medical Center

It has been suggested that older women cope differently with breast cancer than younger women. This study is part of a larger study of the efficacy of an alternative psychosocial intervention for breast cancer. Women who were newly diagnosed with breast cancer (n=142) completed measures of quality of life and psychosocial distress as part of the larger study. 84% were caucasian, 9% Asian American, 5% African American, and 2% Latina. The women were divided into two groups, based on the median split of age (age 49). Older women reported significantly higher vigor, emotional well-being, functional well-being, spiritual well-being, and overall quality of life than younger women. Older women were significantly more fatalistic/accepting of their disease. In contrast, younger women were significantly more hopeless, anxious, depressed, and angry and reported more post-traumatic symptoms than older women, (affect regulation, avoidance, re-experiencing, and arousal). No differences were seen between the groups on coping style or adjustment to cancer. These results suggest that while women of all ages may cope with a new diagnosis of cancer in different ways, younger women tend to be more distressed and report poorer quality of life than older women. As more and more younger women are being diagnosed with breast cancer, attention should be paid to the amount of psychological distress experienced by younger women, without overlooking psychosocial issues that may arise among older women as well. Interventions using groups specifically for younger women and for all ages of women should be studied and compared.

Re-examining the construct of fatalism in women with breast cancer: Stoic resignation versus spiritually focused acceptance. Fitzpatrick, C. M., Levine, E. G., Heide, F., Zelman, D., & Targ, E. (2000). Psycho-Oncology, 9 (5 Supplement), 90.

The present study sought to re-examine a specific type of adjustment to cancer known as Fatalism, which has been characterized by "the appraisal of cancer as a minor threat", "perceived lack of control over the outcome of one's illness", and "acceptance of the outcome". Current research on this construct has found mixed results, but has typically identified Fatalism as a negative construct which is associated with negative outcomes, such as increased mortality. Nonetheless, we hypothesized that fatalistic adjustment, as measured by the Mental Adjustment to Cancer Scale - short form (Watson et al., 1994) might actually be associated with better mood, quality of life, and feelings of control, as well as a sense of spirituality. The participants in the present study were 120 women diagnosed with primary and metastatic breast cancer (mean age = 49). Results revealed that Fatalism was strongly correlated with spirituality and engagement in an active religious practice, as well as several outcome measures, such as higher quality of life and less depression and anxiety. Contrary to the original definition, adopting a fatalistic attitude was significantly associated with feelings of control and acceptance. Finally, a simultaneous multiple regression analysis revealed that a combination of Spirituality, Fighting Spirit, Active Cognitive Coping, and low Distress significantly predicted 49% of the overall adjusted variance for Fatalism. In sum, despite the commonly held view of fatalistic adjustment, Fatalism appears to be associated with increased acceptance, spirituality, and feelings of control, and can have positive, health-affirming effects for those dealing with cancer.

Use of alternative medicine by women with breast cancer. Rundel, M., Levine, E.G., & Targ, E. 2000Annals of Behavioral Medicine, 22, (supplement), 65.

Recent studies have found that women with breast cancer who use alternative therapies are more distressed than those who do not. We studied 168 women entering a research intervention study of a holistic program of alternative behavioral strategies (i.e., yoga, meditation, guided imagery and nutrition). The median age of participants was 49. The ethnic background of participants was 85% Caucasian, 8% Asian American, 5% African American, and 2% Latina. At entry to the study, 47 women had never used alternative therapies, 52 women had started an alternative treatment after surgery, 55 women were using alternative methods continuously for a variety of reasons, and 14 had used alternative therapies in the past but not currently.

The women who started using alternative therapies after surgery, and those who had used them both before and after surgery, reported lower quality of life (QOL) on the FACT-B scale than women who had never used them. Those who used alternative treatments before and after surgery also reported greater levels of anxiety and overall distress. None of the groups reported significantly higher or lower levels of depression. Analysis was also done on QOL and levels of distress, depression, and anxiety for users of each type of alternative treatment. Women who used acupuncture and herbs had lower QOL than those who did not ($t=2.60$, $p=.01$). Women who used body therapies had lower levels of depression ($t=2.28$, $p=.02$) and anxiety ($t=2.6$, $p=.01$). Women who had meditated had higher levels of anxiety ($t=2.01$, $p=.04$) and overall distress ($t=2.04$, $p=.04$). The results concur with other research findings that women who use alternative therapies to cope with breast cancer surgery may have overall lower QOL than women who do not use alternative therapies. However there are differences in levels of QOL and distress among users of different alternative modalities. Differences between these groups of women may be useful in treatment planning, and psychosocial and medical assistance.

Differences In Psychosocial Well-being Between Lesbian and Heterosexual Women With Breast Cancer. Klein, A., Levine, E.G., & Targ, E. Breast Cancer Personal Support and Lifestyle Intervention Trial, University of California, San Francisco/California Pacific Medical Center. (2000). Annals of Behavioral Medicine, 22, (supplement), 44.

The lack of research on lesbian health is a concern for both medical and mental health providers. One-hundred-forty-two women completed measures of quality of life and psychosocial distress as part of a research trial evaluating the efficacy of a psychosocial intervention for breast cancer. Breast cancer patients were divided into two groups based on self-disclosure of heterosexual ($n=13$) versus homosexual identity ($n=13$). Between the two groups, participants were matched for age and stage of disease. Median age of participants was 49. The ethnic background of participants was 84% Caucasian, 9% Asian American, 5% African American and 2% Latina. The

two groups did not differ on measures of social well-being. No significant differences were found between the groups on reports of happiness with partners. However, heterosexual women reported a significantly higher level of functional well-being ($F=7.6$, $p=.01$), emotional well-being ($F=4.64$, $p=.03$) and overall quality of life ($F=8.7$, $p=.003$) than lesbians. Heterosexual women adopted more of a fighting spirit approach to coping with breast cancer ($F=5.37$, $p=.02$). More lesbians assumed a helpless/hopeless coping strategy ($F=11.65$, $p=.0008$). Lesbians also reported a significantly higher incidence of depression ($F=11.38$, $p=.001$) and anxiety ($F=9.84$, $p=.002$), fatigue ($F=7.76$, $p=.006$), anger ($F=15.18$, $p=.0002$) and confusion ($F=6.46$, $p=.01$). Finally, lesbians endorsed more post-traumatic symptoms than heterosexual women ($F=5.11$, $p=.02$). Further qualitative analyses revealed that 60% of the lesbians experienced physical and/or sexual abuse before the age of 15. Differences were not found between the groups on spirituality measures. Despite our small sample size, these results indicate that in response to a breast cancer diagnosis, lesbians experience strikingly higher levels of distress and lower quality of life than heterosexual women. More research is necessary in response to the amount of psychological distress experienced by lesbians with breast cancer.

A Comparison Of Complementary And Traditional Psychosocial Treatment For Breast Cancer.
Ellen G. Levine, Ph.D., M.P.H., Elisabeth Targ, M.D. Brook M. Stone, LCSW, and Carol Kronenwetter, Ph.D. California, Pacific Medical Center and University of California-San Francisco

Psychological adjustment to cancer can influence a variety of important issues, including quality of life, psychological well-being, and physical morbidity. Various interventions have been developed to decrease the amount of psychological morbidity associated with the disease and to assist breast cancer patients to improve their quality of life. Although complementary oriented interventions have become popular, direct comparisons have not been made between traditional interventions such as support groups and groups which focus on complementary practices in coping with cancer. Nor have groups using complementary therapies been adequately assessed.

In our clinical trial 72 women with breast cancer were randomized to participate in either a 12-week traditional support group or a more intensive/integrated group which combines yoga, meditation, dance, imagery, health information, and support in a single intervention. Post intervention data showed that women in both groups reported significant improvements in physical well-being ($F=13.80$, $p=.009$) and emotional well-being ($F=9.74$, $p=.004$). Significant decreases were also seen in depression ($F=4.80$, $p=.04$), with increases in vigor ($F=4.04$, $p=.05$), and a non-significant improvement in overall mood ($F=3.76$, $p=.06$) in both of the intervention groups. However only the traditional support group showed significant increases in social well-being ($F=7.69$, $p=.009$). In addition, the women in the intensive group reported being more satisfied with their experience than the women in the support group. These results suggest that while an integrated program may not be more effective than a traditional support group, women's "self-percived" satisfaction may relate to issues other than mood and functional well-being.

Factor Analysis Of The Mini-Mental Adjustment To Cancer Scale In Women With Breast Cancer. Ellen G. Levine, Ph.D., M.P.H., Cory Fitzpatrick, M.A., Janelle Eckhardt, Ph.D., Sian Cotton, M.A., and Elisabeth Targ, M.D., California Pacific Medical Center and California School of Professional Psychology

The concept of adjustment styles to cancer such as fighting spirit, and helplessness/hopelessness, 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. We present a factor analysis of the short version of the Mental Adjustment to Cancer (MAC) scale, the Mini-MAC. Data from 87 women with breast cancer were used to factor analyze the scale, and to correlate the subscales with those of another coping scale, the Index of Coping responses. The factor analysis identified seven factors with Eigen values above 1.0. The factors were then rotated to develop a five factor model, consistent with the number of subscales in the Mini-MAC. Results show that the Mini-MAC subscales of Anxious Preoccupation and Avoidance were delineated correctly in the factor analysis. The factor loadings for Helpless/Hopeless was less consistent with the original subscale, but still highly correlated ($r=.99$ $p<.000$). Interestingly, the factor loadings for Fighting Spirit and Fatalism were not consistent with the original subscale structures, although they were still highly correlated with them (Fighting Spirit $r=.89$, $p<.0000$; Fatalism $r=.92$, $p<.0000$). The two subscales were significantly but modestly correlated with each other ($r=.32$, $p=.003$). In addition, Fighting Spirit was significantly correlated with coping styles of logical analysis ($r=.38$, $p=.0004$), information seeking ($r=.40$, $p=.0002$), problem solving ($r=.34$, $p=.002$), and avoidance ($r=.27$, $p=.01$). Fatalism was also significantly correlated with logical analysis ($r=.39$, $p=.0002$), information seeking ($r=.45$, $p=.0000$), problem solving ($r=.42$, $p=.0001$), and affective regulation ($r=.36$, $p=.0008$). These results suggests that although the factor structure of the Mini-Mac holds up with this sample, the concepts of Fighting Spirit and Fatalism seem to be similar and should be developed further.

Predicting amount of meaning and purpose in life of women with breast cancer. Levine, E. G. & Targ, E. (2001).. Annals of Behavioral Medicine, 23 (supplement). 63.

A diagnosis of cancer is a crisis, physically, emotionally, and existentially. At this time women may re-evaluate their lives, and think about their own purpose in life. This study sought to examine predictors of meaning and purpose in life among 159 women who had either been newly diagnosed with a breast cancer, had a recurrence of their cancer or had metastatic disease. Meaning and purpose was significantly correlated with: age, physical well-being, social well-being, functional well-being, emotional welll-being, having a sense of faith and assurance, fighting spirit, helplessness/hopelessness, anxious preoccupation, fatalism, avoidance, logical analysis, information seeking, problem solving, affect regulation, emotional discharge,

avoidance, anxiety, depression, anger, vigor, fatigue, confusion, spiritual practice, spiritual growth, a sense of embracing life, and overall spirituality. There wsa no significant relationship between meaning and purpose and time since diagnosis. A simultaneous multiple regression found that 67% of the variance in meaning and purpose was accounted for by a combination of physical well-being, functional well-being, having sense of faith and assurance, fighting spirit, vigor, overall distress, spiritual growth, and embracing life ($F=40.82$, $p<.0001$). These results suggest that women who feel able to continue their daily lives both physical and emotionally, who have a fighting spirit, are spiritual and also have an active spiritual practice have a greater sense of meaning and purpose in the world. Promoting a sense of meaning and purpose may be very useful in helping women adjust to having cancer and yet go on with their lives. Women who are able to fell that there is a purpose to their life may feel less distressed, and may be able to recover physical and functional well-being soon after their diagnosis and treatment for cancer.

Breast cancer in survivors of child abuse: Psychosocial well-being and treatment considerations. Klein, A., Rundel, M., Levine, E. G., & Targ, E. (2001). Annals of Behavioral Medicine, 23 (supplement). 72.

Research shows that victims of trauma experience greater psychological distress and lower quality of life upon a cancer diagnosis than those patients who have no history of trauma. This study examined two groups of women with breast cancer. One group (N=22) identified themselves as survivors of physical, sexual, or emotional abuse as children. The other group (N=63) indicated that they had not suffered from child abuse. All women participated in a 12-week psychosocial intervention, including group support, meditation, movement, and health education. Mean age was 49, and mean time since diagnosis was 14.5 months. At initial assessment before the intervention, women who had suffered ongoing abuse showed significantly worse quality of life, $x^2(1, N=80)=4.34$, $p=.04$, greater overall distress $x^2(1, N=79)=6.01$, $p=.01$, and more depression $x^2(1, N=79)=5.24$, $p=.02$ than those who had not been victims of abuse. No significant differences were found among the groups on measures of coping strategies or symptoms of post-traumatic stress disorder. In the first assessment immediately following the intervention, the two groups did not significantly differ on any of the measures. However, upon follow up one year after the intervention, the survivors of child abuse once again showed greater overall distress $x^2(1, N=45)=4.06$, $p=.04$ than those who had not suffered abuse. This study suggests that women with breast cancer who were victims of child abuse may be in greater need of psychosocial support. It also shows that while such interventions are effective, the benefits diminish over time, and so ongoing support may be indicated.

Study ID #_____

Drs. Laura Esserman and Debu Tripathy of the UCSF Breast Care Center are conducting a survey to understand factors that impact upon how women with breast cancer make decisions about their health. If you choose to participate in this study, please answer each of the following questions as best you can.

Participating in this survey is voluntary. The answers you give are confidential. If you have any questions regarding this study, you can contact Fern Hassin at (415) 885-3738. If for any reason you do not feel comfortable expressing your concerns to Ms. Hassin, you may contact the UCSF Committee of Human Research at (415) 476-1814.

A. Information About You.
We would like to ask you some questions about you and your health. Your answers will help us better understand you.

A.1. What is your date of birth? Month _____ Year _____

A.2. Were you born in the United States?
- ❑ Yes
- ❑ No

A.3. What is you current zip code? _____

A.4. What is your racial/ethnic identification?
- ❑ Black/African American
- ❑ Chinese
- ❑ Filipina
- ❑ Hawaiian
- ❑ Indian-subcontinent
- ❑ Japanese
- ❑ Korean
- ❑ Latina/Hispanic
- ❑ Native American
- ❑ Pacific Islander
- ❑ Thai
- ❑ Vietnamese
- ❑ White
- ❑ Other
- ❑ Unknown

A.5. What is your current relationship status?
- ❑ Married
- ❑ Living with a partner
- ❑ Divorced
- ❑ Widowed
- ❑ Single

A.6. What is the highest level of education you have completed?
- ❑ 11th grade or less
- ❑ High school graduate
- ❑ Associate degree
- ❑ College graduate
- ❑ Master's degree
- ❑ Doctorate

A.7. What is you current employment status?
- ❑ Full time (32 hrs or more/wk)
- ❑ Part time (fewer than 32 hrs/wk)
- ❑ Not employed for pay, but seeking work
- ❑ Not employed for pay and not seeking work
- ❑ Retired
- ❑ Disabled

A.8. What is your annual family income?

- ❑ Less than $19,999
- ❑ $20,000 to $49,999
- ❑ $50,000 to $74,999
- ❑ $75,000 to $149,999
- ❑ Over $150,000

A.9. How do you pay your medical bills?

- ❑ Pre-paid insurance (HMO)
- ❑ Fee-for-service insurance
- ❑ Medicare
- ❑ Medi-Cal
- ❑ VA, Military
- ❑ Self-Pay

A.10. How would you rate your past health compared to that of other women your age?

❑ Excellent ❑ Good ❑ Average ❑ Poor

A.11. How would you rate your current overall health compared to that of other women your age with breast cancer?

❑ Excellent ❑ Good ❑ Average ❑ Poor

A.12. Do you have children?

- ❑ Yes – How many: _____ Please list their ages: ____, ____, ____, ____, ____, ____
- ❑ No

A.13. Are you the primary caregiver for dependent children?

❑ Yes ❑ No

A.14. Are you the primary caregiver for any adults?

❑ Yes ❑ No

A.15. Do you have any of the following health conditions at this time? (Check all that apply)

- ❑ High blood pressure
- ❑ Heart disease
- ❑ Osteoporosis (bone loss)
- ❑ Other cancer plus breast cancer
- ❑ Rheumatoid Arthritis
- ❑ Osteoarthritis
- ❑ Depression
- ❑ COPD
- ❑ Diabetes
- ❑ Kidney disease

A.16. How was your breast cancer discovered?

- ❑ Mammogram
- ❑ Breast examination in doctor's office
- ❑ Self examination
- ❑ My husband/partner discovered it
- ❑ Other; please specify: _____

A.17. Have you undergone treatment for your breast cancer that involves complementary and alternative medicine?

- ❑ No
- ❑ Have, but not currently
- ❑ Would consider
- ❑ Never

A.22. How would you describe your participation in your medical care for breast cancer?

- ❑ I have done everything my doctors have advised
- ❑ I have done some of what my doctors have advised
- ❑ I have done none of what my doctors have advised

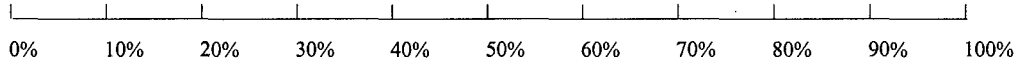
B. Adjuvant Therapy Risk Estimates and Treatment Preferences (Pre-Doctor's Visit)

This set of questions asks for your perceptions regarding your treatment options and your satisfaction with the information you have received.

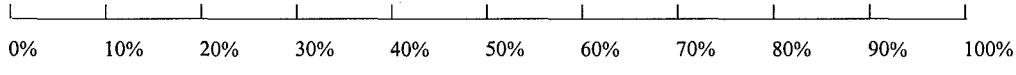
You will be presented imaginary situations about your health. You are to identify your beliefs regarding the chance of that situation occurring in a certain time period. On each scale presented below, please circle a percentage to represent the chance you feel of that situation happening to you.

B.1. The chance of my breast cancer returning or spreading within the next 10 years after having:

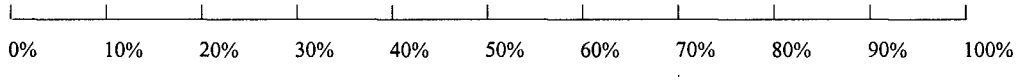
surgery



surgery and chemotherapy

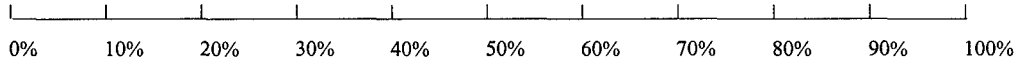


surgery and hormonal therapy

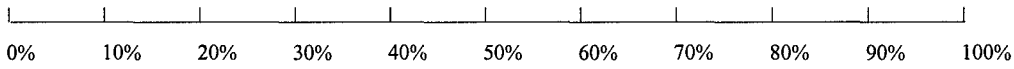


B.2. The chance that I will die from my breast cancer within the next 10 years after having:

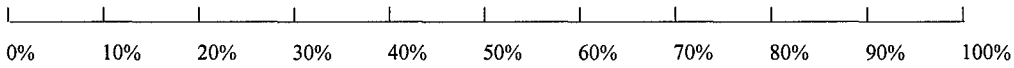
surgery



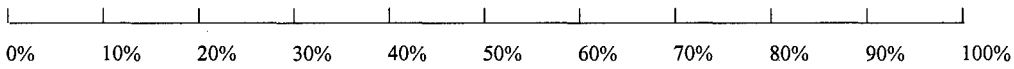
surgery and chemotherapy



surgery and hormonal therapy



surgery, chemotherapy and hormonal therapy



B.3. What is your understanding of the level of the side effects for each of the treatments listed below? Please check the box corresponding to the level of side effects you would expect to experience.

Treatment	No side effects	Mild side effects	Moderate side effects	Severe side effects
1. Chemotherapy				
2. Hormonal therapy				
3. Chemotherapy and hormonal therapy taken together				

B.4. Do you feel knowledgeable about the effects of chemotherapy on your risks of recurrence and dying from breast cancer?

❑ Yes ❑ No

B.5. Do you feel knowledgeable about the effects of hormonal therapy on you risks of recurrence and dying from breast cancer?

❑ Yes ❑ No

B.6. Do you feel knowledgeable about the effects of chemotherapy and hormonal therapy on your risks of recurrence and dying from breast cancer?

❑ Yes ❑ No

C. Scenarios of Benefit with Chemotherapy (Pre-Doctor's Visit)

Chemotherapy is sometimes recommended for the treatment of early stage breast cancer. We are interested in understanding how you make decisions about whether or not to undergo chemotherapy.

In the box below, information has been provided about chemotherapy to assist you in completing the next set of questions.

Description of typical chemotherapy:

Typical chemotherapy is given every 3 or 4 weeks for approximately six months. Chemotherapy treatment requires checking blood counts at least every 2 weeks. Chemotherapy is generally given in a medical clinic.

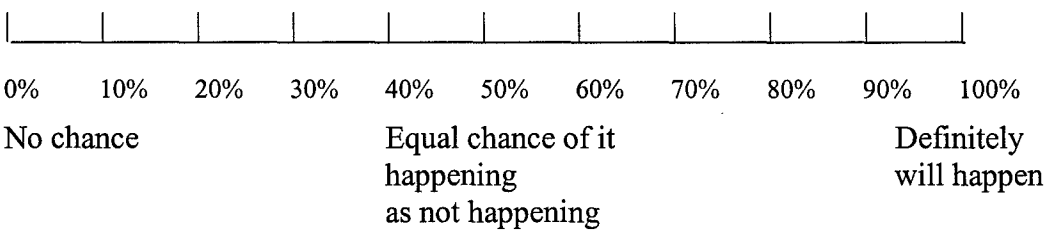
A list of side effects associated with chemotherapy:

Nausea and vomiting: Usually mild (2 or more episodes each cycle). It is usually, but not always, well controlled by medicine.
Fatigue: Worst for 2 or 3 days each cycle, but sometimes more severe.
Hair Loss: Its severity can depend on regimen, but usually complete hair loss.
Low blood counts: Can result in transfusions, infections and even hospitalization (necessary in 1 out of every 20 patients treated).
Rare blood cancer: Chemotherapy can cause a rare form of blood cancer (1 out of every 500-1000 patients treated).
Heart Problems: Can cause weaknesses of heart; heart problems in 1 out of every 200 cases.

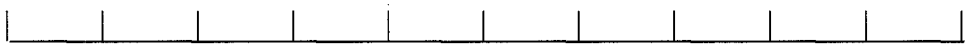
C.1. Based on your risk of recurrence with surgery alone, what is the smallest amount of risk reduction necessary for you to choose chemotherapy?
_____%.

On each scale presented below, please circle a percentage that represents your answer.

C.2. If your chance of recurrence within ten years without chemotherapy was 20% what reduction in risk of recurrence would you look for as a benefit in order to choose chemotherapy?



C.3. If your chance of recurrence within ten years without chemotherapy was 50% what reduction in risk of recurrence would you look for as a benefit in order to choose chemotherapy?



0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

No chance — Equal chance of it happening as not happening — Definitely will happen

C.4. If chemotherapy added additional months or years of life, what would you need to add in order to choose chemotherapy?

_____ Months _____ Years

C.5. The following best reflects my treatment decisions at this time:

- ☐ I am completely undecided
- ☐ I am leaning towards no therapy after surgery
- ☐ I am leaning towards chemotherapy only after surgery
- ☐ I am leaning towards hormonal therapy after surgery
- ☐ I am leaning towards chemotherapy and hormonal therapy after surgery

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Please **STOP** completing this survey at this time!

You are to wait to complete the next set of questions until **AFTER** your visit with your UCSF/Mount Zion Health Care providers.

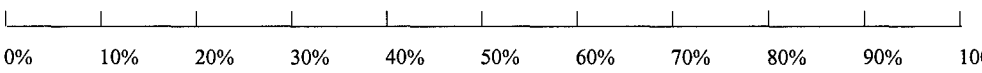
After you have had your consultation please continue with the survey questions.

D. Adjuvant Therapy Risk Estimates and Treatment Preferences (Post-Doctor's Visit)

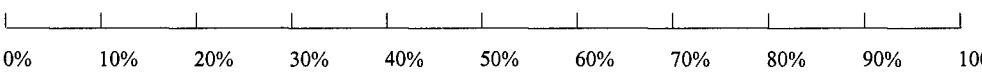
This set of questions asks for your perceptions regarding your treatment options and your satisfaction with the information you have received.

You will be presented imaginary situations about your health. You will be asked to identify your beliefs regarding the chance of that situation occurring and in a certain time period. On each scale presented below, please circle a percentage to represent the chance you feel of that situation happening to you.

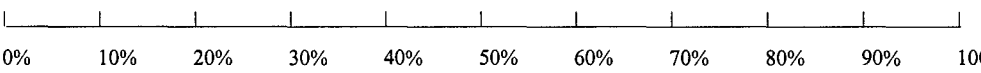
D.1. The chance of my breast cancer returning or spreading within the next 10 years after having surgery (with no other treatment) is:



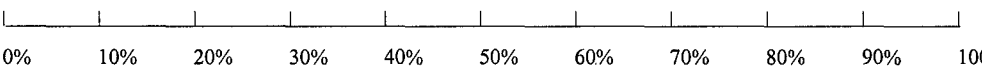
D.2. The chance of my breast cancer returning or spreading within the next 10 years after having surgery and chemotherapy is:



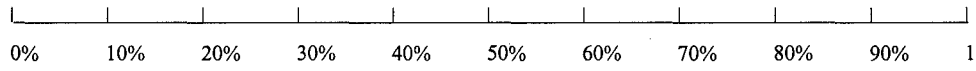
D.3. The chance of my breast cancer returning or spreading within the next 10 years after having surgery and hormonal therapy is:



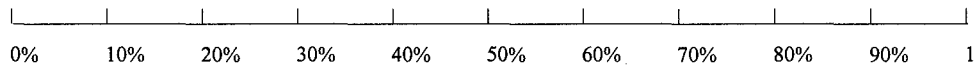
D.4. The chance of my breast cancer returning or spreading within the next 10 years after having surgery, chemotherapy and hormonal therapy is:



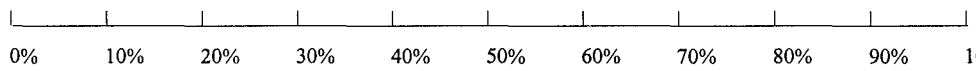
D.5. The chance that I will die from my breast cancer within the next 10 years after having surgery (with no other treatment) is:



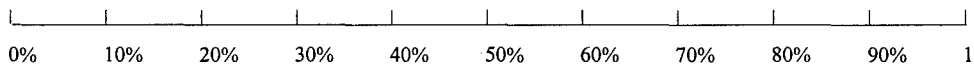
D.6. The chance that I will die from my breast cancer within the next 10 years after having surgery and chemotherapy is:



D.7. The chance that I will die from my breast cancer within the next 10 years after having surgery and hormonal therapy is:



D.8. The chance that I will die from my breast cancer within the next 10 years after having surgery, chemotherapy and hormonal therapy is:



D.9. What is your understanding of the level of the side effects for each of the treatments listed below? Please check the box corresponding to the level of side effects you would expect to experience.

Treatment	No side effects	Mild side effects	Moderate side effects	Severe side effects
1. Chemotherapy				
2. Hormonal therapy				
3. Chemotherapy and hormonal therapy taken together				

D.10. Do you feel knowledgeable about the side effects of chemotherapy on your risks of recurrence and dying from breast cancer?

❑ Yes ❑ No

D.11. Do you feel knowledgeable about the side effects of hormonal therapy on your risks of recurrence and dying from breast cancer?

❑ Yes ❑ No

D.12. Do you feel knowledgeable about the side effects of chemotherapy and hormonal therapy on your risks of recurrence and dying from breast cancer?

❑ Yes ❑ No

D.13. Would participate in a breast cancer research study (clinical trial) where the study treatment is at least as good as standard treatment?

❑ Yes ❑ No ❑ Don't know

D.14. Would you participate in a breast cancer research study (clinical trial) where the study treatment is at least as good adjuvant therapy?

❑ Yes ❑ No ❑ Don't know

D.15. Would you participate in a breast cancer research study (clinical trial) where the study treatment is at least as good "salvage" therapy?

❑ Yes ❑ No ❑ Don't know

E. Scenarios of Benefit with Chemotherapy

Chemotherapy is sometimes recommended for the treatment of early stage breast cancer. We are interested in understanding how you make decisions about whether or not to undergo chemotherapy.

In the box below, we have provided information about chemotherapy to assist you in completing this next set of questions.

Description of typical chemotherapy:

Typical chemotherapy is given every 3 or 4 weeks for approximately six months. Chemotherapy treatment requires checking blood counts at least every 2 weeks. Chemotherapy is generally given in a medical clinic.

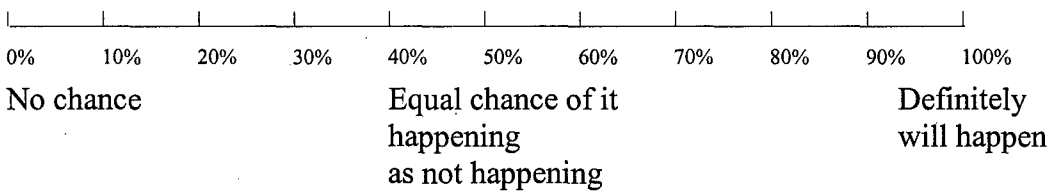
A list of side effects associated with chemotherapy:

Nausea and vomiting: Usually mild (2 or more episodes each cycle). It is usually, but not always, well controlled by medicine.
Fatigue: Worst for 2 or 3 days each cycle, but sometimes more severe.
Hair Loss: Its severity can depend on regimen, but usually complete hair loss.
Low blood counts: Can result in transfusions, infections and even hospitalization (necessary in 1 out of every 20 patients treated).
Rare blood cancer: Chemotherapy can cause a rare form of blood cancer (1 out of every 500-1000 patients treated).
Heart Problems: Can cause weaknesses of heart; heart problems in 1 out of every 200 cases.

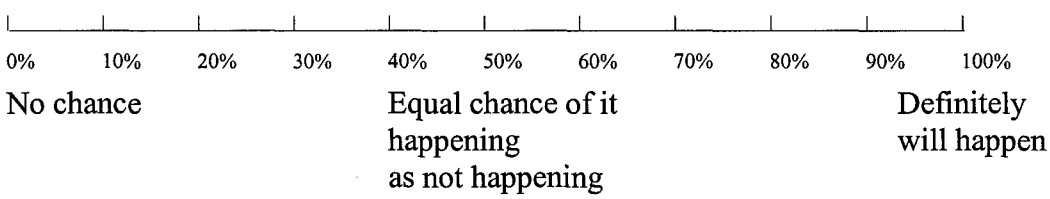
The following questions ask you how much you need chemotherapy to decrease your risk of cancer recurrence in a 10 year period in order for you to take chemotherapy? On each scale presented below, please circle a percentage to represent your answer.

E.1. Based on your risk of recurrence with surgery alone, what is the smallest amount of risk reduction necessary for you to choose chemotherapy?
_____%.

E.2. If your chance of recurrence within ten years without chemotherapy was 20% what reduction in risk of recurrence would you look for as a benefit in order to choose chemotherapy?



E.3. If your chance of recurrence within ten years without chemotherapy was 50% what reduction in risk of recurrence would you look for as a benefit in order to choose chemotherapy?



E.4. If chemotherapy added to the average amount of life someone in your situation would have, how much time gained would you feel necessary in order to choose chemotherapy?

_____ Months

_____ Years

E.5. The following best reflects my treatment decisions at this time:

- ❑ I am completely undecided
- ❑ I am leaning towards no therapy after surgery
- ❑ I am leaning towards chemotherapy only after surgery
- ❑ I am leaning towards hormonal therapy after surgery

I am leaning towards chemotherapy and hormonal therapy after surgery

F. Risk Estimates and Treatment Preferences (Post-Doctor's Visit)

Please answer the following questions about the written booklet and the graphs outlining your personal risks of recurrence and dying from your breast cancer.

Written Booklet

F.1. Is the information in the booklet useful?

❑ Yes ❑ Somewhat ❑ No

F.2. How would you rate the amount of information in the booklet?

❑ Too much ❑ Enough ❑ Not enough

F.3. How much of the information presented in the booklet was new to you?

❑ All of it ❑ Half of it ❑ None of it
❑ Most of it ❑ Some of it

F.4. Was the information in the booklet outlining the side effects of chemotherapy and hormonal therapy useful?

❑ Yes ❑ Somewhat ❑ No

F.5. How much of the information in the booklet outlining the side effects of chemotherapy and hormonal therapy do you understand?

❑ All of it ❑ Half of it ❑ None of it
❑ Most of it ❑ Some of it

F.6. Has your perceptions of the side effects of chemotherapy changed after viewing the booklet?

❑ Yes ❑ Somewhat ❑ No

F.7. Has your perceptions of the side effects of hormonal therapy changed after viewing the booklet?

❑ Yes ❑ Somewhat ❑ No

F.8. Has your perceptions of the side effects of chemotherapy taken with hormonal therapy changed after viewing the booklet?

❑ Yes ❑ Somewhat ❑ No

F.9. Did the booklet impact upon your treatment decisions?

❑ Yes (Please continue to next question)
❑ Somewhat
❑ No

F.9a→If Yes – Please describe how it affected your decisions?

_____

_____

_____

Graphs

F.10. Was the information on the graphs useful?

❑ Yes ❑ Somewhat ❑ No

F.11. How would you rate the amount of information on the graphs

❑ Too much ❑ Enough ❑ Not enough

F.12. How much of the information presented on the graphs was new to you?

❑ All of it ❑ Half of it
❑ Most of it ❑ Some of it ❑ None of it

F.13. Was the information on the graphs outlining the effects of chemotherapy and hormonal therapy useful?

❑ Yes ❑ Somewhat ❑ No

F.14. How much of the information on the graphs outlining the effects of chemotherapy and hormonal therapy do you understand?

❑ All of it ❑ Half of it ❑ None of it
❑ Most of it ❑ Some of it

F.15 Has your perceptions of the side effects of chemotherapy changed after viewing the graphs?

❑ Yes ❑ Somewhat ❑ No

F.16. Has your perceptions of the side effects of hormonal therapy changed after viewing the graphs?

❑ Yes ❑ Somewhat ❑ No

F.17. Has your perceptions of the side effects of chemotherapy taken with hormonal therapy changed after viewing the graphs?

❑ Yes ❑ Somewhat ❑ No

F.18. Did the graphs affect your treatment decisions?

❑ Yes ❑ Somewhat ❑ No

F.18.a. →If Yes – Please describe how it affected your decisions?

_____

_____

F.19. Has your perception of your risk of recurrence and risk of dying from breast cancer changed after viewing the booklet and the graphs?

- ❑ Yes
- ❑ Somewhat
- ❑ No

F.20. How would you rate your risk of recurrence and your risk of dying from breast cancer after viewing the booklet and graphs?

- ❑ Higher than I thought
- ❑ Same as I thought
- ❑ Lower than I thought

F.21. How would you rate the side effects of therapies after viewing the booklet and graphs?

- ❑ Worse than I thought
- ❑ Same as I thought
- ❑ Less severe than I thought

F.22 Did the booklet and graphs help you think of questions to ask your doctor?

- ❑ Yes
- ❑ Somewhat
- ❑ No

F.23. Did the material present one treatment more favorable compared to the others?

- ❑ Yes (Please continue to next question)
- ❑ Somewhat
- ❑ No

F.23.a→If Yes – Which therapy?

_____

_____

_____

F.24. How much of your questions or concerns were answered by us?

- ❑ All
- ❑ Most
- ❑ Some
- ❑ None
- ❑ Didn't have any questions or concerns

Thank you for your cooperation with this study.

University of California, San Francisco

Assessment of a Shared Decision Making Program and Written Materials for Decisions about Adjuvant Therapy for Early Stage Breast Cancer: A Pilot Feasibility Study

1. STUDY AIM, BACKGROUND, AND DESIGN

- To use a graphic display and written materials to provide estimates in the risk of recurrence and death and the effects of adjuvant hormonal therapy and chemotherapy on these risks after surgery for early stage breast cancer.
- To assess the feasibility of administering this program to patients following surgery for early stage breast cancer.
- To assess the effect of this program on patient preferences regarding the use of adjuvant therapy, on the quality and satisfaction with patient's decisions, and on their attitudes and willingness to participate in clinical trials.

Background

An increasing number of women are being diagnosed with breast cancer, and a higher proportion of these cases are of early stage.[1] The effect of adjuvant chemotherapy or endocrine therapy for early stage breast cancer has been extensively studied in randomized trials as well as a meta-analysis, showing approximately 20-25% relative reductions in the annual odds of death due to adjuvant chemotherapy or endocrine therapy.[2-3] Furthermore, this benefit appears to be independent of stage of disease, hence, the absolute benefit (absolute reduction in the risk of recurrence or death) is proportional to the overall risk of recurrence or death. For example, if a relative reduction in the risk of recurrence of 30% is afforded by chemotherapy, and a patient with a low risk tumor carries a 10% chance of recurrence at 5 years, then the absolute benefit for this patient would be .30 x .10 = a 3% reduction in the risk of recurrence at 5 years. This simple formula may not hold true for higher risks due to the fact that annual reductions cannot be extrapolated over many years, but computer-derived approximations can be utilized in this case.

When women make decisions about adjuvant therapy, it is difficult to systematically provide risk estimates as well as the projected benefit that may be derived from adjuvant hormonal therapy or chemotherapy. In fact, physicians are not consistent in their estimation of risk based on standard prognostic factors[4] and tend to overestimate the benefits of adjuvant therapy.[5] With randomized trials confirming small but statistically significant risk reductions even for patients with low risk node-negative breast cancers[6-8], guidelines are now calling for the use of hormonal therapy or chemotherapy for such patients.[9] However, these guidelines do not take into account different preferences that women may have in choosing potentially toxic treatment for relatively small gains. In one study where women were surveyed after receiving chemotherapy, there was a large variation in the amount of risk reduction that would be necessary in order to embark on therapy when given several hypothetical situations, although on average, women chose treatment for relatively small gains.[10]

Significance – The shared decision making program (Appendix C) and written materials (Appendix B) will describe the benefits of adjuvant chemotherapy and hormonal therapy based on a summation of the literature of adjuvant clinical trials for patients having undergone surgery for early stage breast cancer. Side effects of treatment will also be presented. An individualized assessment projection of recurrence and death risk will be provided and thus, the benefits (absolute reductions in the risk of recurrence in 10 years) can be estimated for a given individual. Estimates of the median time gained (additional years of life) can also be made. This study will therefore examine the feasibility and effect of the program on patients perception of risk and preferences for therapy as well as their willingness to participate in clinical trials. Such a study will provide insight into the optimal way information needs to be presented so that patients can make choices that accurately reflect their risks, expectant benefits and tradeoff of toxicities from adjuvant therapies.

Study Design – One part of the study will assess perceptions of patient's risks and preferences for adjuvant therapy following surgery for early stage breast cancer and the effect of a Shared Decision Making program on patient's perceptions, preferences, and willingness to participate in clinical trials. The other part will be two-armed, in which subjects will be randomized to receive information regarding time gained as a result of adjuvant treatment for early stage breast cancer.

2. **SUBJECT POPULATION** - Patients with early stage breast cancer (Stage I and II) seen at UCSF and Mount Zion will be eligible to participate. Total Number: 20 patients will be recruited in 2-3 months.

Eligibility Criteria

Patients who have undergone surgery (mastectomy or partial mastectomy) for early stage (I, II) breast cancer. Staging information including tumor size and lymph node involvement must be available. No chemotherapy or hormonal therapy should have been started.

Exclusion Criteria

- Necessity for further surgery to complete staging
- Inability to provide informed consent
- Potential of undue psychological distress at viewing the program

3. **PROCEDURES**

Possible participants will be recruited from patients seen at UCSF. After a review of initial clinical data, eligible patients will be identified. These patients will be informed of the basic nature of the study, and will be asked for informed consent. Basic demographic, disease stage information, and information on clinical co-morbidity will be kept on all patients. For those refusing to participate, the process that is used for standard decision making at each site will be followed.

Participating patients will be asked to fill out questionnaires about their medical health, personal history, understanding of their condition, the risks of recurrence and death, and their willingness to participate in clinical trials (see Appendix A at the end of this summary).

Patients will next be given written materials explaining adjuvant therapy (Appendix B) and shown graphs detailing risks of recurrence and death due to breast cancer, as well as the lowering of these risks that could be expected from hormonal therapy or chemotherapy using the Adjuvant!™ program[11] (see Appendix C at the end of this summary). All cases will be reviewed by the PI (Dr. Tripathy) and collaboratively by the Breast Care Center medical oncology team to ensure the risk estimates fall within a range that would be equivalent to that which would be discussed as part of standard consultative care. Benefits will be defined by the Adjuvant!™ Program (see Appendix D at the end of this summary). They will also read information about side effects of chemotherapy and hormonal therapy (see Appendix B at the end of this summary). They will then be randomly assigned to see or not see an additional estimate of time gained from the use of adjuvant therapy (half of the people on this study will see this information). Randomization will be done using a computerized random generator in blocks of 10. Finally, they will be asked to complete a written survey to assess their understanding of the materials they have reviewed (see Appendix A at the end of this summary).

Patients will have the chance to have any part of the program explained to them in greater detail. They will be free to make any decisions about their therapy and can use the information provided to them as they please.

Statistical considerations. Feasibility will be described as the percentage of patients who were asked to participate that declined as well as those that consented to participate and did not complete the program. Reasons for declining or not completing the program will be tabulated and exploratory correlations with baseline demographic factors will be done. Patient questionnaire answers will be expressed as the mean and standard deviation on a 1-5 scale, or % yes/no, or as an average on a continuous 0-100% scale depending on the question (refer to questionnaires). Comparisons of scores between patients randomized to see the time gained estimates and those who did not view those estimates will be done using (Chi square or t-test). The principal comparison will be of the scores describing the benefits necessary for the patient to choose adjuvant therapy (see questions D1-3 and F1-3 on Appendix A). Since there are no estimates known of the differences in these groups, a formal sample size calculation cannot be made, but may be estimated following this pilot study.

4. RISKS AND DISCOMFORTS

- Filling out questionnaires and receiving information about recurrence and death risks may cause some anxiety.

- No extra costs will be incurred by patients for participating in this trial.
- Participation in research may involve a loss of privacy. The patient's records will be kept as confidential as possible. No individual identities will be used in any reports or publications resulting from this study.

5. BENEFITS

Patient may receive no benefit from being in this study. The information from the program may make it easier for the patient to make a decision about the treatment. It may help women to understand adjuvant therapy benefits and risk and to make better decisions.

6. CONSENT PROCESS AND DOCUMENTATION

All patients who choose to participate in this study will sign a Committee on Human Research approved consent prior to beginning study treatment. The patient will be given a signed copy of the consent and the original copy will be a part of the permanent medical record.

7. QUALIFICATIONS OF INVESTIGATORS

Principal Investigator is Debasish Tripathy, M.D., Associate Clinical Professor of Medicine, Division of Hematology/Oncology. Co-investigators include: Laura Esserman, M.D., Associate Professor of Surgery, Hope Rugo, M.D., Associate Clinical Professor, Division of Hematology/Oncology and John Park, M.D., Assistant Adjunct Professor of Medicine.

8. REFERENCES

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Consent to be a Research Subject

Assessment of a Shared Decision-Making Program and Written Material for Decisions about Adjuvant Therapy for Early Stage Breast Cancer

PURPOSE AND BACKGROUND:

Dr. Debasish Tripathy and associates are conducting a research study to determine how patients understand the risks of breast cancer recurrence (return or spread of cancer) and the risk of dying from breast cancer after undergoing surgery for breast cancer at early stage (cancer in the breast or breast and lymph nodes under the arm only). Treatment after surgery for early stage breast cancer (adjuvant therapy) may include hormonal therapy or chemotherapy. Adjuvant therapy is treatment given after surgery to lower the risk of recurrence or death. Different people with early stage breast cancer have different risks of recurrence and death. They also get different amounts of risk reduction with adjuvant therapy. This study is designed to look at the effects of a shared decision-making program, using written material and graphs, that explain patients' risks and the benefits of adjuvant therapy as well as the side effects of therapy. This program is based on information from previous clinical trials and patient registries and therefore the risks and benefits of treatment may not be precise. The information is individualized for each patient based on the patient's age and tumor characteristics. This study will also examine patients' perceptions and treatment choices when the information is presented as time gained (in years and months) from adjuvant treatment. I am being asked to participate in the study because I have breast cancer and I am at a point where I will be making decisions about adjuvant treatment following surgery.

PROCEDURES:

If I decide to participate in the study, I understand that the following will happen:

1. I will be asked to fill out one questionnaire that will include information about my medical health, personal history, understanding of my condition, my perceptions on risks of recurrence and treatment preferences, and my willingness to participate in clinical trials. This will take about 45 minutes.

2. I will read material and see a graph explaining my estimated risks of recurrence and death from breast cancer, as well as the lowering of these risks that could be expected from hormonal therapy or chemotherapy. I will also read information about side effects of chemotherapy and hormonal therapy. I will either see or not see an additional estimate of time gained from the use of adjuvant therapy. Since this is a double-blind randomized trial, it means that I will be randomly assigned to either receive or not receive the information on "time gained" from the use of adjuvant therapy (Half the people on this study will see this information.) Neither I nor my doctor will be able to select or even know which treatment I receive. This is so that bias in the study is minimized.

3. I will be asked to complete one written survey to assess my understanding of the material I have reviewed which will take approximately 15 minute.

RISKS AND DISCOMFORT:

I may feel anxious or nervous about some of the materials presented even if I am not part of the study randomized to receive "time gained" information. Additionally, the estimates of prognosis and effectiveness of therapy are based on large population studies and might not acurately reflect my specific situation.

BENEFITS:

I may receive no benefit from being in this study. The information from the graphs and written might may make it easy for me to make a decision about my treatment, and may benefit future patients.

FINANCIAL RISKS:

I will not be charged or incur any cost for partcipating in this study.

ALTERNATIVE:

I may decide not to participate in this study and still have all the benefits and risks of adjuvant therapy explained to me. My treatment options and treatment will not be affected.

REIMBURSEMENT:

I will not be reimbursed for participating in this study.

QUESTIONS:

I will have a chance to have any part of the program explained to me in greater detail. I will be free to make any decisions about my therapy and I can use the information provided to me as I please.

The investigator who signed below has discussed this study with me and I have been given the opportunity to ask questions. If I have further questions regarding this study, I should contact Fern Hassin at (415)885-3738. If for some reason I do not want to call Ms. Hassin, I may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. I may reach the Committee office between 8:00 a.m. and 5:00 p.m. by calling (415)476-1814 or by writing Committee on Human Research, P.O. Box 0962, University of California, San Francisco, CA 94143.

CONSENT:

Participation in research is voluntary. I have the right to withdraw from the study at any time, and withdrawing will not jeopardize my future medical care. My participation may be ended at any time with or without my consent. If I wish to participate, I should sign below. I have read and been given a signed copy of the consent form.

_____

Print Name

_____

Signature of Subject Date

_____

Signature of Person obtaining Consent Date

UCSF Carol Franc Buck Breast Care Center: A Personalized Approach to Adjuvant Therapy Decision Making

This information is designed to help you understand your individual chance of a breast cancer recurrence and of survival. We believe that this information will help you make your adjuvant therapy decisions. Adjuvant therapy is post-surgery treatment designed to kill any remaining breast cancer cells. We recognize that each woman is different, and believe this tailored approach will give you the information you need to make the best choice(s) for you.

What are we doing?

With the help of the latest information technology, we are able to use continuously updated clinical information, based on many large databases of women with breast cancer, to give you your most accurate risk assessment. The program is designed to estimate your chance of recurrence, and your estimated life expectancy based on your possible treatment choices. During your consultation, your physician will enter specific information about your clinical situation into a computer. Based on the information entered the program will calculate your chance of recurrence and survival from 1-10 years after surgery. Your physician will explain this information and its meaning in greater detail during your consultation. We believe that this information can help to guide you to make the best individual decision.

What are we asking you to do?

By now, you have already filled out one questionnaire. You will be asked to fill out another questionnaire at the end of your physician consultation, and another one again in six months. We will gain valuable knowledge about how this information affected your decision making about adjuvant therapy. More specifically, we are looking at the effect of the information on your choice of therapy, your opinions of the information and manner of presentation, and changes in your knowledge and understanding after receiving the information. We appreciate you taking time to fill out these questionnaires. Your experience may be helpful to women in the future.

Understanding Risks

In order to understand the chance of recurrence, there are a few points we would like to clarify. A recurrence of cancer is when cancer returns to the same or different area of your body. When cancer spreads from one part of the body to another it is called a metastasis. The stage (I to IV) of your breast cancer, determined by tumor size, presence or absence of cancerous lymph nodes and cancer metastasis or spread, can group you with women of the same stage of breast cancer to predict potential future outcome. With use of the

computer and additional information about your cancer we can improve our ability to predict the effect of each potential treatment on your chance of recurrence and survival.

What does it mean to talk about your chance of recurrence and survival? Every person has a set of factors that are related to the disease process, for example, tumor size. Using data from a large number of woman with breast cancer we have been able to determine what each factor means in terms of a woman's chance of recurrence and survival. When we combine all of these factors we get the best estimate of a woman's chance of recurrence and survival. A woman's chance of recurrence and survival can be anywhere from 0% to 100% and those percentages change as we look into the future. We can look at data up to 10 years into the future.

This program will help give estimates for four considerations important in decision making. The most important medical factors used to predict the chance of recurrence include tumor size, lymph node involvement, growth rate, and whether or not your tumor grows in response to the hormones estrogen and/or progesterone. Your physician will enter all of this information into the computer program. The computer will then calculate values for your specific chance of recurrence, and your estimated life expectancy based on whether or not you choose an adjuvant therapy.

- You chance of recurrence and survival with local therapy only (surgery with or without radiation therapy).

- A comparison of the benefit of hormone therapy, chemotherapy, and both hormone and chemotherapy.

Adjuvant Therapy

The goal of adjuvant therapy is to reduce the risk of a recurrence. The two types of systemic adjuvant therapy used in breast cancer treatment are chemotherapy and hormonal therapy.

Chemotherapy is a treatment aimed at killing or disabling cancer cells. It is a systemic treatment, meaning that it affects all cells within the body. Many clinical trials have shown that chemotherapy reduces the risks of a recurrence of breast cancer and thereby lowers the risk of dying of breast cancer. Different combinations of drugs are given depending on the nature of your cancer. There are many chemotherapy agents that have shown activity in breast cancer. In the setting of a new diagnosis chemotherapy may be given before surgery (neoadjuvant) or after surgery (adjuvant). Two common drug combinations are Adriamycin-Cytoxan (AC) given by intravenous injection over 3 months, once every three weeks for four cycles, and Cytoxan-Methotrexate-Fluouracil (5-FU), also referred to as CMF, which is given over 6 months. Methotrexate and 5-FU are given by intravenous injection in days 1 and 8 of each month; Cytoxan may be given by intravenous injection on days 1 and 8 or orally on days 1-14.

Each of these drugs has particular side effects, but the most common side effects overall are fatigue, nausea/vomiting, hair loss, and potential for increased infection risk. Drug information sheets on the chemotherapy drugs are available for you to read. There are individuals who tolerate chemotherapy well and others who have a more difficult time. Please speak with your doctor or nurse regarding side effects, as there are ways to help manage them.

The presence of estrogen can promote tumor growth in some breast cancer patients. Hormonal therapy is a treatment that blocks estrogen from hormone receptors, thus inhibiting tumor growth. It is usually given in the form of Tamoxifen (Nolvadex) for five years. Studies have not shown an increased benefit of using this type of hormonal therapy for more than five years. There are many risks and benefits associated with the use of Tamoxifen. In addition to being shown to reduce breast cancer recurrence rates, Tamoxifen use has been shown to help prevent osteoporosis and lowers lipid production in post-menopausal women. However, it also has significant side effects that must be considered as well, including a small increased risk of endometrial (uterine) cancer, development of blood clots, increased risk for cataracts, experience of menopausal symptoms (including hot flashes and vaginal dryness), despite the fact that many women continue to menstruate.

It is important to consider both the risks and the benefits of taking any medication before beginning treatment. Your physician and nurse will give you educational materials and describe the details of both chemotherapy and hormonal therapy in greater detail.

Questions

We have included a list of questions that can help you analyze how you make decisions. These were designed to help you identify your own needs, and to communicate these needs to your physician. We also encourage you to consider the values we have listed below, as they can significantly impact decision making as well.

Questions to ask yourself about how you make decisions:

- How do I learn? (discussion, reading, Internet, etc.)
- Who do I want to be included in my decision making process?
- What information do I need to make a decision?
- How willing/unwilling am I to take risks?
- In the past, what has helped me to make a decision?
- What are my prior thoughts and/or experiences regarding chemotherapy and/or hormonal therapy?
- What do I believe works for my own healing? (research proven therapy, experimental treatments, "eastern" or "western" philosophies, complementary, alternative, etc.)

Individual Values Affecting Treatment Decisions:

- Different cultural meaning(s) of illness, cancer, and healing
- Spiritual or religious beliefs
- The opinions and needs of children, family members, friends
- Desire to become pregnant in the future
- Lifestyle (travel, athletic/recreational activities)
- Profession
- Beliefs about chemotherapy and radiation treatments
- Impact of other illnesses on your general well-being

Important Information for Chemotherapy Infusion Patients

Appointments

Once you have met with your oncologist and a decision has been made as to what therapy you will take, you will meet with a nurse practitioner. Your nurse practitioner will review your chemotherapy schedule, potential side effects, and answer any questions you may have. During your chemotherapy treatment, you will be seen by the nurse practitioner who will stay in close contact with your oncologist. Your oncologist will stop in on your appointment approximately every other cycle to follow-up with you directly.

On the first day of each cycle of chemotherapy you will stop in the lab to get blood drawn 1/2 hour prior to your appointment with your nurse practitioner. The nurse practitioner will go over side effects and do a physical exam looking for signs of infection or toxicity. If your blood counts are normal, you will be sent to the Infusion Center for treatment.

Each office visit at both the Breast Care Center and the Infusion Center must be scheduled. You can call the Breast Care Center (oncology/chemotherapy number) and the Infusion Center number to schedule your respective appointments. All appointments must be scheduled in advance as drop in appointments are not allowed.

The Infusion Center schedules the last appointment at 3:00 pm. Therefore, you should always plan to have your appointment at the Breast Care Center no later than 1:00 pm. This way you will have enough time to be seen in the Breast Care Center and still have your infusion.

During Treatment

During treatment if you are not feeling well, please call the Breast Care Center as soon as possible. If we direct you to come in, it is important that you come as soon as possible so that we can evaluate and do necessary tests within normal working hours. If it is after 4:00pm, you may be directed to the emergency room at the UCSF Parnassus campus.

Thank You

We appreciate this opportunity to work with you and will do all that we can to make this as comfortable as possible.

Anti-Nausea Medication

When you are receiving chemotherapy you may experience problems with nausea or vomiting. Our goal is to prevent nausea all together or at least control it as best we can. It is much easier for you to complete your chemotherapy regime if we can minimize your side effects. Sometimes this means you have to take other medications that can also cause side effects. There are several medications that you can use. How and when you use them depends on your individual situation. In other words, what works for others may not work for you. Either way, there are different ways to deal with your nausea, and we will help you find what works best for you. Our recommendations are also different depending on which chemotherapy agents you are receiving. Some chemotherapy agents are known to cause more nausea than others.

The anti-nausea medications include prochlorperazine (Compazine®), lorazapam (Ativan®), dexamethasone (Decadron®), ondansatron (Zofran®), granisetron (Kytril®), and dolasetron (Anzemet®). All of these medications work well for nausea, but you will find certain ones work best for you. All the nausea medications come in varying dose forms and have different side effects, which will be covered below. If you take one type of anti-nausea medication and still feel nauseated, you can use a different one. It usually takes 45 minutes for a medication to start working. For example, if you took a Compazine® at 8 A.M. and you were still nauseated at 9 A.M., you may take Ativan®, Zofran®, Kytril® or Anzemet®.

Dosages and Side Effects:

1. Prochlorperazine (Compazine®) is usually ordered in 10-mg tablets or 25-mg rectal suppositories. If you take a prochlorperazine pill you must wait 6 hours before taking any more prochlorperazine. If you use a rectal suppository you must wait 12 hours before taking any more prochlorperazine. If you are feeling nauseated, it is sometimes hard to swallow a pill and you may do better with a suppository.

   Prochlorperazine usually causes sleepiness and you should not drive while taking it. In some people it can cause other symptoms, such as jitteriness, tight jaw or other muscle tightness. If you experience these symptoms you should take Benadryl 25-mg which is an antihistamine that you can buy over the counter. If you have those symptoms once, you will have them every time you take prochlorperazine. Benadryl will also make you sleepy, so you should not drive while using it.

2. Lorazapam (Ativan®) can be swallowed or placed under the tongue. You can take this medication every 4-6 hours. This medication can also make you very drowsy, so do not drive while taking it. You can try breaking the tablet in half and see if you get the same control of your nausea with less drowsiness. Ativan® is also used for anxiety and can become addictive.

3. Dexamethasone (Decadron®) is a cortisone-like medicine that is given intravenously (IV) or orally prior to patients getting Adriamycin®/Cytoxan® therapy. We sometimes also use it in pill form for 2-3 days after receiving Adriamycin®/Cytoxan® to help treat anticipatory nausea or vomiting. Dexamethasone should be taken with food as it can irritate your stomach. You also may find you are very excitable, have a lot of energy or have trouble sleeping the days you use it. You may also experience facial flushing which may last several days.

4. Some of the newer anti-nausea medications include Ondansatron (Zofran®), Granisetron (Kytril®), or Dolasetron (Anzemet®). They work differently than the other medications for nausea and may be used in your care as well. They do not cause drowsiness, but can cause headaches and constipation. If you get a headache from them, you need to stop taking them and let us know. Sometimes if we switch you to another drug, you will not get a headache from it. These medications are new, quite expensive and are not always covered by your insurance. Each ondansatron costs $20-$25, dolasetron $35-$40 per pill, and granisetron $40 per pill. We order these medications in small numbers because of cost. If your insurance does not cover them, you may not want to fill the prescription. If your insurance provides limited coverage, you may find it effective to use them in the morning when you want to be alert and then use Compazine® or Ativan® in the afternoon or evening.

Alternatiave Anit-Nausea Approaches:

- Acupressure wristbands (Reliefband®) are available at most pharmacies - you may find these helpful. These last 6 days and cost about $50.00.
- Peppermint tea helps some patients.
- Ginger tea made with fresh ginger has a natural anti-nausea property: Cut 2 quarter sized pieces - steep this in steaming water for 25 minutes.
- Saltines in the morning, prior to eating, have been helpful for some patients.

Nausea Related to Cytoxan®, Methotrexate®, and 5-FU (CMF)

If you are on CMF chemotherapy you may need to take anti-nausea medication during the 14 days you take Cytoxan®. Sometimes changing the time of day you take your Cytoxan® helps decrease your nausea. Either way, you will be given prescriptions for anti-nausea medications. You may find that taking them on a schedule helps. If you are nauseated take one, and then wait 45 minutes to 1 hour before eating to see if that relieves the nausea. Some people have no nausea, and so may not need to take anti-nausea medications at all.

Nausea Related to Adriamycin®/Cytoxan® (AC)

If your therapy is Adriamycin®/Cytoxan® you will be given a prescription for Zofran® or Kytril®. You need to fill that prescription and bring the medication with you the day you start therapy. You will take the pill 1 hour prior to your chemotherapy. When you get to the Infusion Center they will then give you intravenous Decadron®. Once you leave the Infusion Center, we recommend that you take either Compazine® or Ativan® 6 hours after the chemotherapy even if you are not nauseated. If you awaken in the middle of the night and it has been more than 6 hours since you took either Compazine® or Ativan®, take the anti-nausea medication at that point as well. The next morning we also recommend you take one of your anti-nausea medications and wait 30-45 minutes before eating. You may need to take scheduled anti-nausea medications for 24-48 hours or longer after your chemotherapy. Some patients have minimal nausea, while others have nausea around 4-6 days after chemotherapy. If your nausea occurs later, we will continue to work with you to control it.

Day number	When to take anti-nausea medications	Medication
Day 1	1 hour prior to chemotherapy	Zofran® or Kytril®
Day1	6 hours after chemotherapy	Compazine® or Ativan® (even if not nauseated)
Day 2	30-45 minutes before breakfast	Zofran® or Kytril®
Day 2 and on	take on schedule only if needed	

Other Chemotherapy Agents

The other chemotherapy agents include Herceptin®, Taxol®, Taxotere®, Doxil®, Navelbine® and Capecitabine (Xeloda®). These agents, for the most part, cause significant nausea less frequently than CMF or AC. We will usually give you a prescription for Compazine® or Ativan® in case you get nauseated. Please call us if you experience nausea.

Adriamycin® (Doxorubicin) Cyclophosphamide (Cytoxan®) "AC"

How do these drugs work?

These are "chemotherapy" drugs that prevent division of DNA and growth of cancer cells and may also injure normal cells that grow fast such as blood cells, hair follicles, cells that line the mouth, stomach, and intestines.

Common side effects

- Lower numbers of white blood cells (which fight against infection), red blood cells (which carry oxygen) platelets (which help blood clot). A low number of these cells may lead to infection, anemia, and bleeding
- Nausea, vomiting
- Hair loss
- Metallic taste (when Cytoxan® is given)
- Mouth sores and throat irritation
- Fatigue
- Premature menopause (stopping of menstrual periods, which is often permanent)

Less common side effects with your type of chemotherapy

ADRIAMYCIN®

- Sensitivity to sunlight
- Skin and tissue damage may occur to the area in which Adriamycin® is given, if the drug leaks out of the vein into the tissue
- Dry skin and blistering to areas previously treated by radiation
- Heart muscle weakness (also called cardiomyopathy)
- Watery, sore eyes
- Skin rash and itching

CYCLOPHOSPHAMIDE

- Bladder bleedingand irritation
- Nasal stuffiness, sneezing, watery eyes (when Cytoxan® is given)
- Dizziness, confusion, agitation
- Yellowing of skin and/or eyes
- As with any drug, other side effects that were not mentioned may occur

General concerns

- Report vomiting or nausea that is not relieved with anti-nausea medication.
- Immediately report any fevers of 101° or higher, with or without chills
- Report nose bleeds, gum bleeding, or any unusual bruising
- Avoid direct sunlight. Wear sunscreen and sunglasses for protection
- Ask your nurse about special mouth rinses to prevent mouth sores
- Ask your doctor about a birth control method for you
- Report any symptoms which are unusual for you

Other concerns with your type of chemotherapy

ADRIAMYCIN®

- Your urine may turn pink or red up to 2-3 days after the drug is given to you. This is not blood and is not harmful.
- Report to the nurse immediately any redness, swelling, or discomfort along the injection site.
- Report chest discomfort or pain.

CYCLOPHOSPHAMIDE

- Drink 8-10 glasses of fluid each day for two days after your treatment. Urinate often (about every 2 hours while awake). Drinking fluids and urinating often will help prevent any bladder irritation.
- Report nasal stuffiness while getting the drug.
- Immediately report blood in urine or painful urination.

Cyclophosphamide (Cytoxan®) "CMF"
Methotrexate (MTX)
Fluorouracil (5-FU)

How do these drugs work?

These are "chemotherapy" drugs that destroy cancer cells and may also kill normal cells which grow fast such as blood cells, hair, cells that line the mouth, stomach, and intestines.

Common side effects

- Lower numbers of white blood cells (which fight against infection), red blood cells (which carry oxygen), platelets (which helps blood clot). A low number of these cells may lead to infection and bleeding
- Nausea, vomiting, and diarrhea
- Hair thinning and hair loss
- Mouth & throat irritation and sores
- Irritation of the eyes
- Metallic taste and taste changes in general
- Skin reactions: rash, itchy skin, discoloration
- Fingernail splitting or darkening
- Watery or dry eyes, eye discomfort
- Menopause symptoms —hot flashes, dry vaginal mucosa
- Fatigue

Less common side effects with your type of chemotherapy

CYCLOPHOSPHAMIDE

- Bladder bleeding and irritation
- Nasal stuffiness, sneezing, watery eyes (when Cytoxan® is given)
- Dizziness, confusion, agitation
- Yellowing of skin and/or eyes
- As with any drug, other side effects that were not mentioned may occur

METHOTREXATE

- Sensitivity to light
- Difficulty breathing
- Swelling of legs and feet
- Yellowing of skin and/or eyes
- Liver irritation and elevated liver function tests

FLUOROURACIL

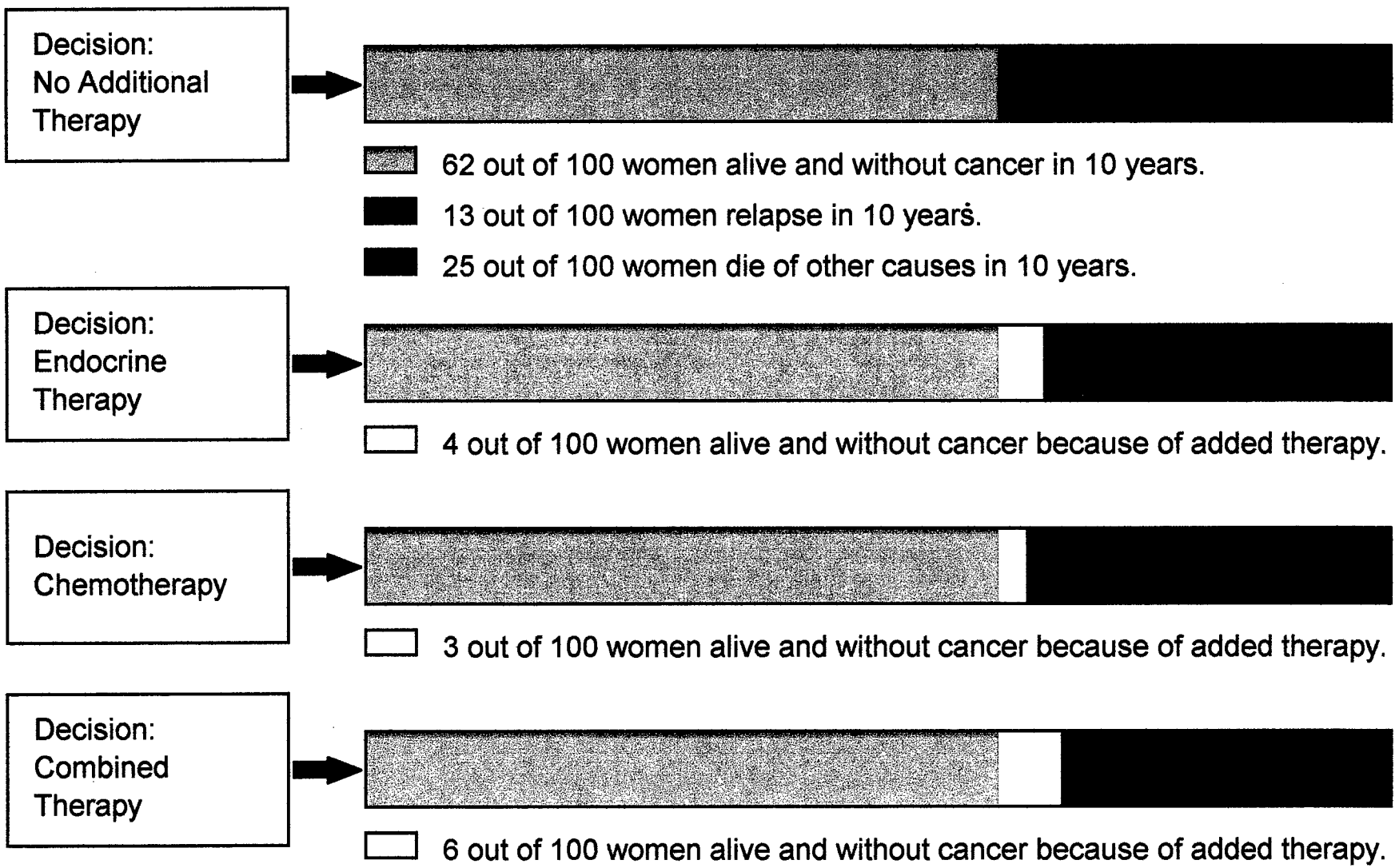
- Sensitivity to light
- Mild depression
- Difficulty with balance and walking
- Rare blood clots causing chest pain, heart attack, or stroke

As with any drug, other side effects that were not mentioned may occur

General concerns

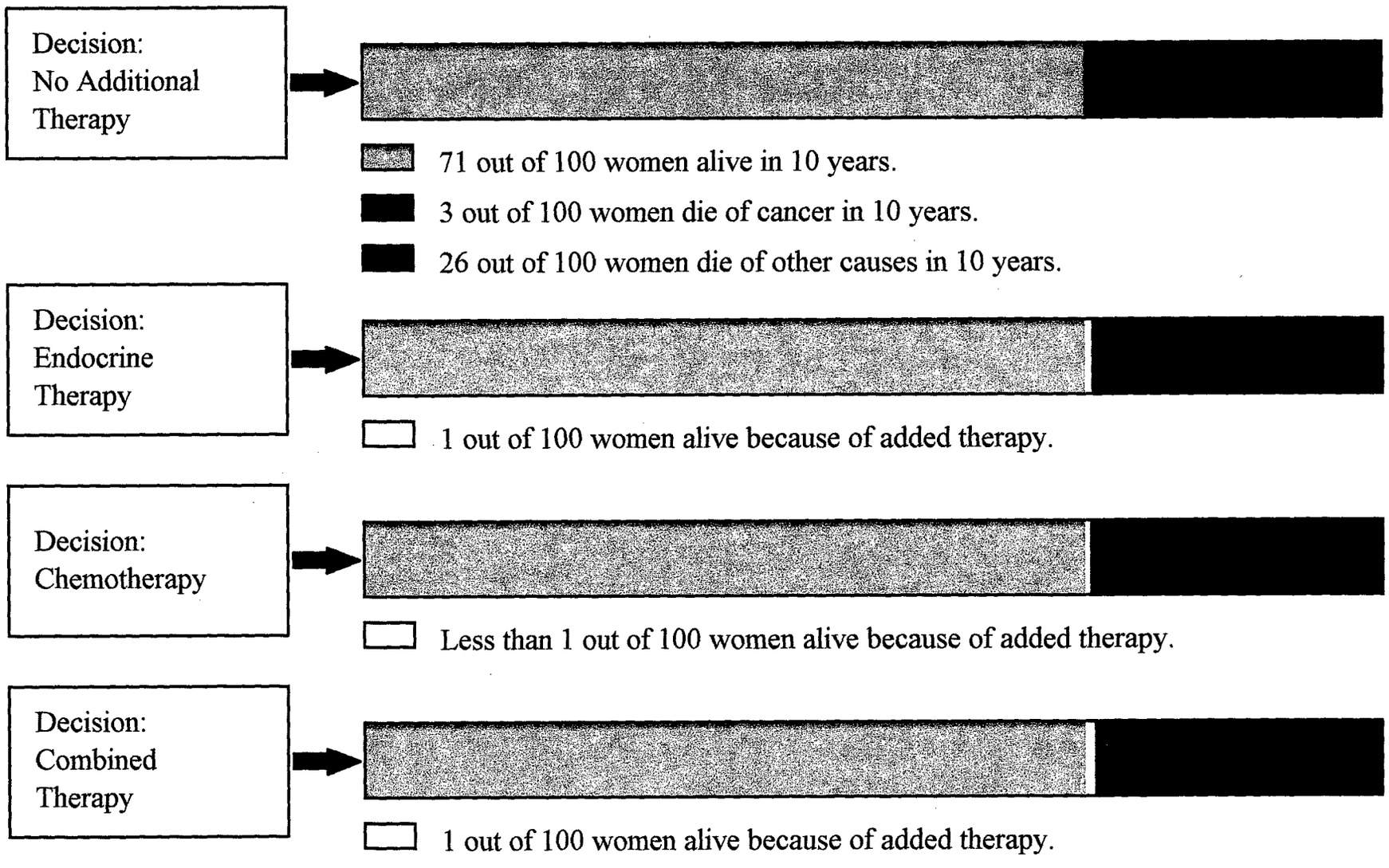
- Report vomiting or nausea that is not relieved with anti-nausea medication.
- Immediately report any fevers of 101° or higher, with or without chills.
- Report nose bleeds, gum bleeding, or any unusual bruising.
- Report more than 5 watery stools a day.
- Avoid direct sunlight. Wear sunscreen and sunglasses for protection.
- Ask your nurse about special mouth rinses to prevent mouth sores.
- Ask your doctor about a birth control method for you.
- Report any symptoms which are unusual for you.

Options for Adjuvant Therapy



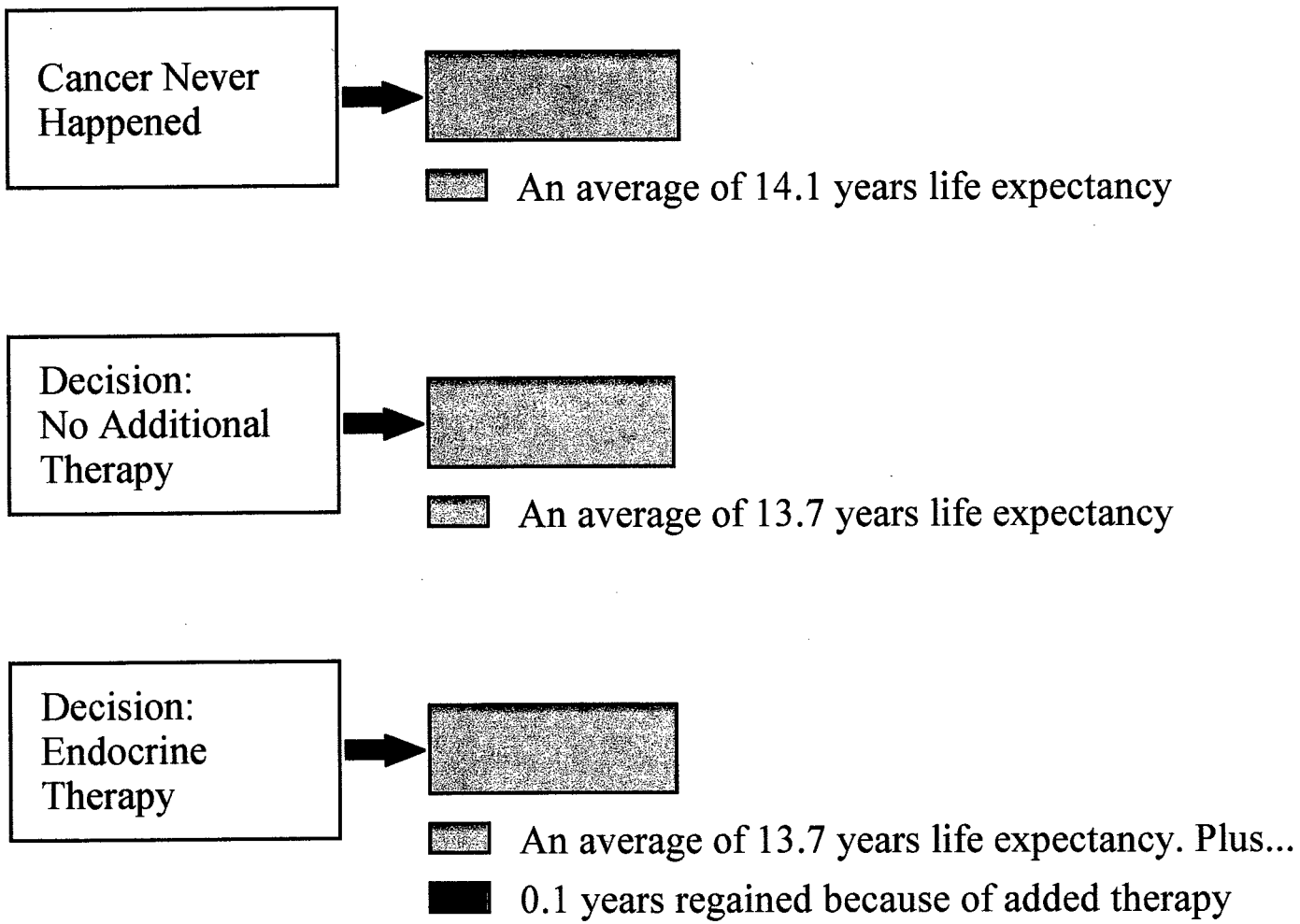
Age: 74 Tumor Size: 0.6 - 1.0 cm Nodes Involved: 0 ER Status: Positive Hist. Grade: Grade 2 Chemotherapy Method: Overview 98 (Derived Anthra)

Options for Adjuvant Therapy



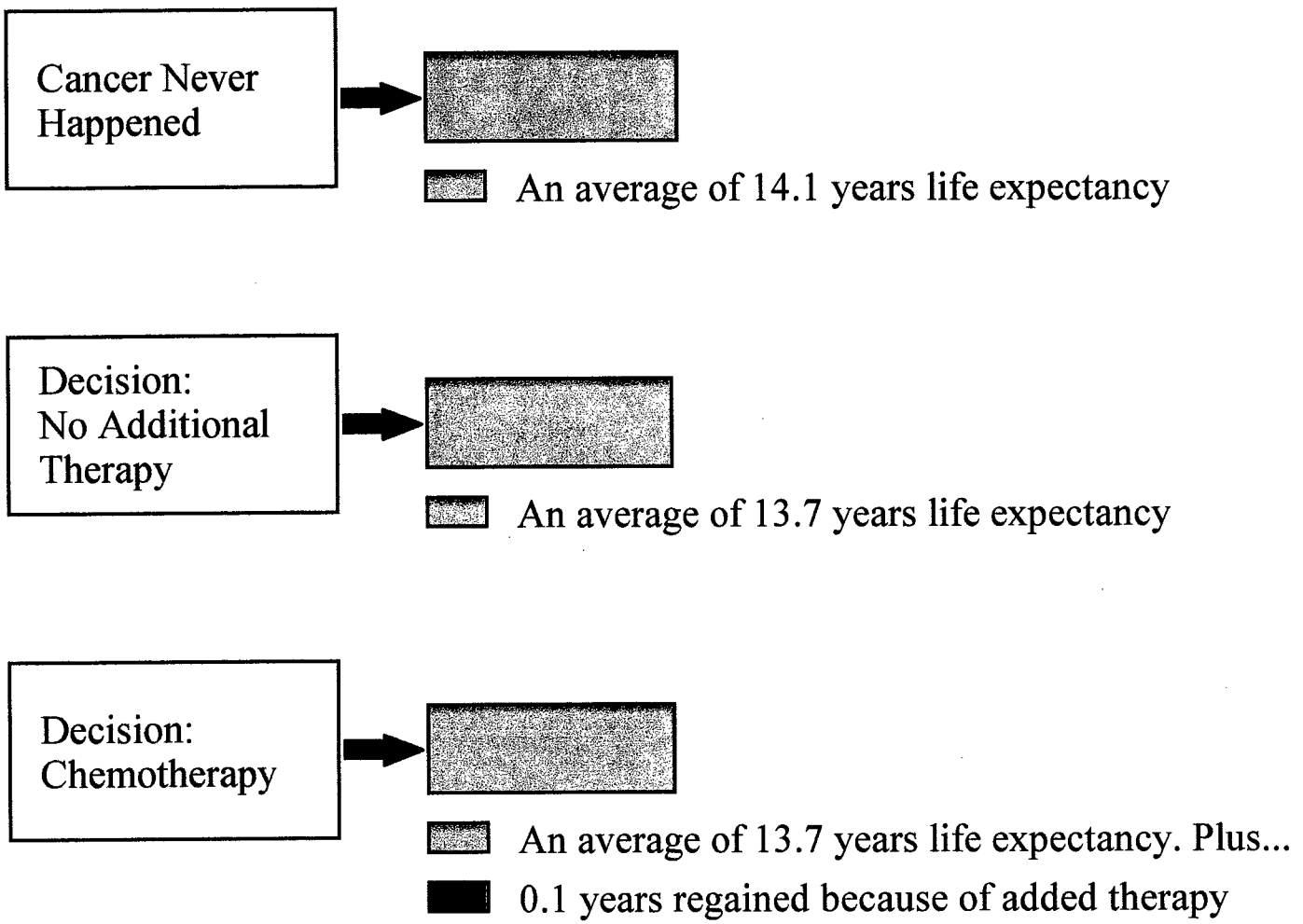
Age: 74 Tumor Size: 0.6 - 1.0 cm Nodes Involved: 0 ER Status: Positive Hist. Grade: Grade 2 Chemotherapy Method: Overview 98 (Derived Anthra)

Projected Life Expectancy (Endocrine Therapy)



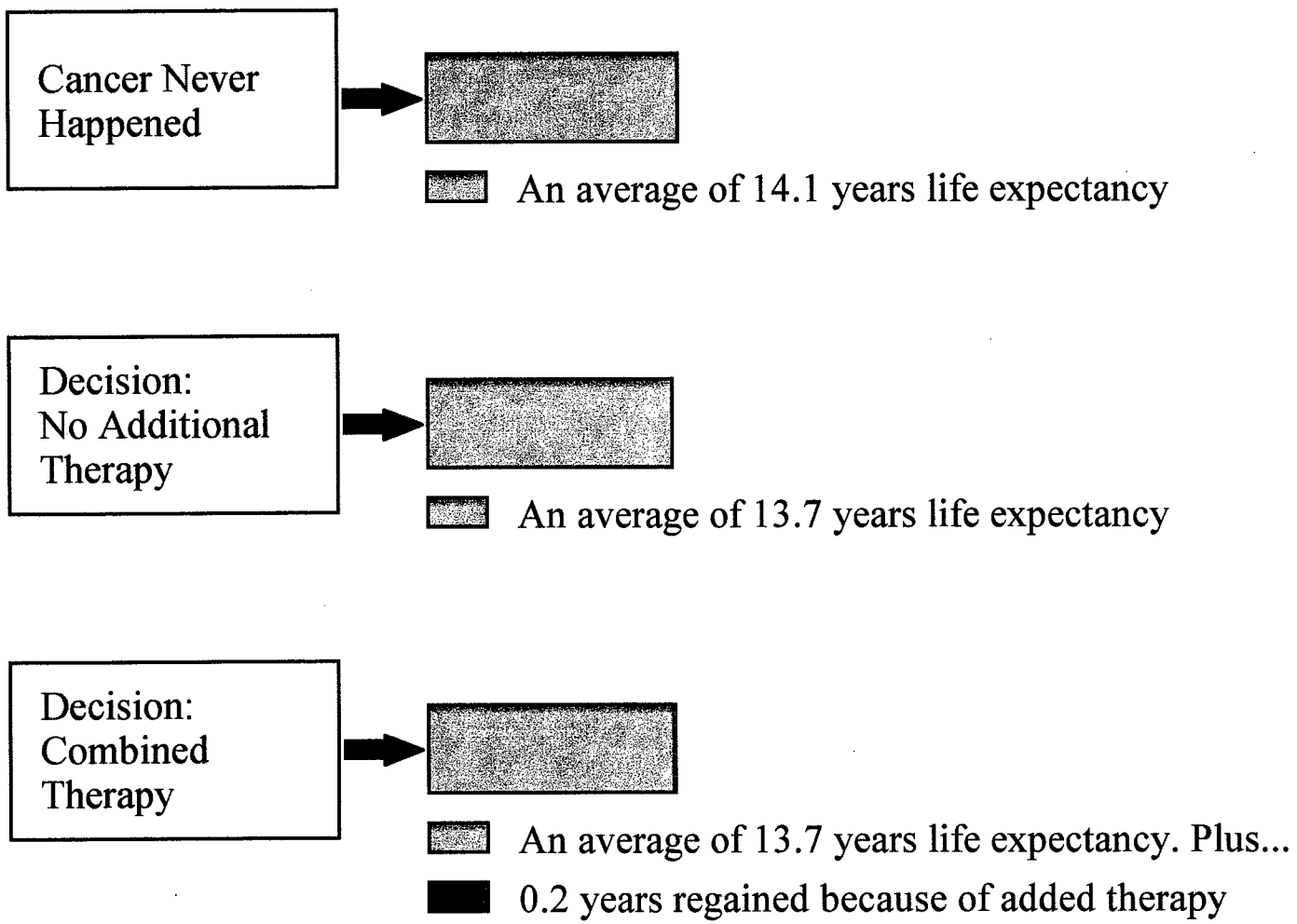
** These are estimates only and are based on many assumptions including the assumption that the effectiveness of therapy for breast cancer and other major diseases stays the same.

Projected Life Expectancy (Chemotherapy)



** These are estimates only and are based on many assumptions including the assumption that the effectiveness of therapy for breast cancer and other major diseases stays the same.

Projected Life Expectancy (Combined Therapy)



** These are estimates only and are based on many assumptions including the assumption that the effectiveness of therapy for breast cancer and other major diseases stays the same.

Toxicity Table for Chemotherapy in Breast Cancer
(in percent)

Symptom	CMF (n=1054)	AC (n=2256)
WBC		
Moderate	10.2	3.9
Severe	0.2	0.7
Infection		
Severe	0.6	1.4
Life Threatening	0.6	1.1
Death	0.0	0.0
Nausea & Vomiting		
Mild	50.6	*49.9
Severe	8.1	34.9
Diarrhea	3.1	2.1
Mouth Sores Interfering with Eating	*3.1	*1.3
Hair Loss		
Mild	29.1	*3.1
Pronounced	24.8	*89.4
Cystitis	*1.8	0.3
Early Menopause		
Less than 40 years old	31-38	13.0
Greater than 40 years old	81-89	57-63

*Denotes statistical significance

Medical Complications with Tamoxifen Use (average annual rate per 1000 patients)						
	Tamoxifen			Placebo (no Tamoxifen)		
N=13388	test participants = 6681			placebo group = 6707		
Medical Complications	< 49	all ages	> 50	< 49	all ages	> 50
Blood Clots						
Stroke	0.3	1.45	2.2	0.39	0.92	1.26
Temporary Stroke	0.3	0.73	1.01	0.39	0.96	1.32
Pulmonary Embolism travelling	0.2	0.69	1	0.1	0.23	0.31
to the lung						
Deep vein thrombosis	1.08	1.34	1.51	0.78	0.84	0.88
Uterine (Endometrical)Cancer	1.21	*2.3	4.01	1.09	*.91	0.76
follow up 66 months later		13			0.54	
Cataracts		4.72			3	
follow up 66 months later		*24.82			*21.72	
Fractures	1.98		5.76	2.24		7.27
Symptoms						
	test participants = 6466			placebo group= 6498		
Depression						
No		65.40%			65.40%	
Slightly		15.60%			16.10%	
Moderately		10.10%			9.50%	
Quite a bit		5.10%			5.40%	
Extremely		3.70%			3.60%	
Vaginal discharge						
No		44.80%			65.20%	
Slightly		26.20%			21.80%	
Moderately		*16.60%			*8.50%	
Quite a bit		*9.30%			*3.30%	
Extremely		*3.10%			*1.20%	
Hot flashes						
0-15		19.40%			31.40%	
16-22		14.10%			18.20%	
23-29		21.80%			21.70%	
30-36		*28.10%			*18.60%	
>36		*17.60%			*10.10%	

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Breast Cancer Advocacy in Clinical Care

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ABSTRACT: Although still in a continual state of evolution, breast cancer advocacy has come of age in the last few years. Advocacy is a very broad term that can be defined as the viewpoint of a breast cancer patient or survivor, or a viewpoint that is fully patient centered. In the area of clinical care and research, a cooperative atmosphere has developed that has required a close working relationship and understanding of cultures between advocates and those in the professional medical care and research communities. Interaction with patients and decision makers, which reflects individual values and preferences, requires a firm knowledge of medical outcomes; in this way, the advantages and disadvantages of a screening, diagnostic, or treatment plan can be analyzed. Moreover, a clear communication strategy needs to be in place to convey these concepts to patients and to elicit their individual choices and concerns. The development of optimal, shared decision making will require ongoing innovations in all these areas, and some are now being piloted and tested in the areas of screening, prevention, and treatment. The role of advocacy in research has likewise involved a sharp learning curve from both sides. Multiple models of mutual education, exchange of ideas, and the conversion of this interaction into research strategies are now in place in many settings. The intent of such interaction is to move forward with discovery and clinical application in a way that forces a rethinking and innovation of approaches but emphasizes proper scientific methodology. Patient-focused themes of relevance to patients with breast cancer, timely translation to the clinic, and a broader scope of research and ideas are all being integrated into the scientific review process. An emphasis on advocacy issues, along with stepwise scientific progress, will be essential in the new era of rapid technology development, clinical testing, and adoption into the standard of patient care.

BREAST CANCER ADVOCACY IN CLINICAL CARE

There is a clear and momentous shift in the mode of interactions between patients and physicians, and the area of breast cancer represents a leaning edge in this transition. The term advocacy can be used to broadly define the role of patients and those whose interests represent patients' direct points of view in the area of clinical care, health policy, and research. The growth of advocacy in the area of breast cancer stems from several key factors. There has been a need to peruse a lengthening list of diagnostic and therapeutic options as technology has advanced and created several choices, many with individual pros and cons. Patient participation in these choices is a growing trend, particularly in younger and well informed populations. Managed health care has created limitations in these choices and has forced the need to demonstrate more clearly the relative effectiveness and cost-benefit ratios of prevention, screening, and treatment options. Managed care has also shifted financial burdens to patients and providers of care, necessitating a greater awareness among both patients and physicians of the importance of rigorous decision making. Finally, the growing interest of health related matters in the mainstream media, and the explosive growth of information technology, mainly via the Internet, has thrust every development in breast cancer into a wide and unfiltered forum of patients, health care providers, journalists, and researchers.

Why has the field of breast cancer been a fertile ground for advocacy? Present are all

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the elements of a fearsome and common disease, hyperacute awareness, and a high percentage of affected individuals who are young and desire control over information and decisions. The current and past decades witnessed a similar phenomenon with the AIDS epidemic, with the advent of prophylactic antibiotic and remittive retroviral and protease therapies. Many of the same circumstances for advocacy and activism were present in the area of breast cancer; in fact, many of the features have been borrowed, intentionally and unintentionally, from the AIDS model. On the other hand, several unique features have distinguished the breast cancer advocacy movement as it relates to clinical care and research.

- Access to information and partnership in decision making in screening, prevention, and treatment, both on an individual basis as well as in public policy.
- Partnership in research with a focus on direct relevance to cancer and rapid translation to the clinical setting.
- Humanistic and holistic approaches (and, in general, a broadened horizon of view) to care and research, along with the development of new models of clinical care and research paradigms that would improve our understanding in this area.
- Improved access to standard and investigational care.

These themes will be illustrated in three key areas of advocacy — clinical decision making, public policy, and research.

ADVOCACY IN CLINICAL DECISION MAKING

Two clinical decision making tools are described that attempt to integrate an advocacy point of view in a collaborative process. One of these is a *Shared Decision Program* for patients with early stage breast cancer who are beginning to be counseled about adjuvant therapy (typically hormonal therapy and chemotherapy). The other is a process termed *Collaborative Care*, a facilitated consultation planning and intervention program that allows patients to be partners in the decision making process by first developing an agenda that reflects their individual concerns. Both of these projects have been developed out of needs that were identified in clinical practices, with input from the advocacy community. Ongoing advocate involvement in project development, clinical trials to validate and refine these tools, and in the future directions of improved models of decision making will be critical to individualizing care in a both scientific and humanistic way.

Shared Decision Making

One of the most common situations through which an individual with newly diagnosed breast cancer must pass is the determination of the optimal surgical approach and adjuvant system therapy for early stage breast cancer. A majority of breast cancer cases are diagnosed at early stage, and for most patients, breast conserving surgery with radiation is an option to mastectomy. Decisions for the type of surgery is often solicited in a hurried fashion when the burden of evidence suggests that one or even several weeks to make a choice of the type of surgery, as well as the surgical or multidisciplinary team, is acceptable. A decision board that was developed to help clinicians inform patients about the benefits and risks of breast irradiation following lumpectomy was assessed in a comparative study (1). This tool, consisting of written material and visual aids, provided the patient with detailed information about her choices (breast irradiation or not), outcomes (breast cancer recurrence and survival), probability of those outcomes, and quality of life associated with treatment and outcome. After consultation with the clinician, material comprehensibility and treatment choices of patients using the decision board were compared to those of patients who did not use the tool. Overall understanding was similar except for an increased

understanding of the lack of survival benefit in node-negative cases and the fact that radiation could not be repeated. Only 70% of patients in the no-decision board group felt they were offered a choice as opposed to 97% in the decision board group. These findings suggest that an interactive educational tool can enhance the standard consultative sessions and result in a better satisfaction with choices.

The use of systemic adjuvant therapy with either tamoxifen, chemotherapy, or both is being recommended increasingly as clinical trials are now showing benefits even in patients at low risk for recurrence (2,3). The use of adjuvant therapy poses many tradeoffs between benefits in terms of the reduction in risk or recurrence and mortality versus short- and long-term side effects of tamoxifen and chemotherapy. This is especially true in lower risk situations, such as node-negative cancer. Historically, these types of decisions would rest primarily in the hands of physicians who relied on their own experience, published literature, and the opinions of experts and consensus panels. When patients have been queried after already receiving adjuvant chemotherapy, the average benefit to be gained that would justify chemotherapy was very small, between 1% and 2% reduction in five-year recurrence risk (4). However, making tradeoffs between the benefits and risks of therapies in some situations may involve personal preferences or values that would vary among individuals. Furthermore, evidence indicates that oncologists usually overestimate the benefits of adjuvant therapy (5). Most patients do not receive quantitative benefits and they themselves have an inflated estimation of the adjuvant benefits of treatment (6).

The process of bringing the patient (and advocates) into this arena can be termed *shared decision making*. Three challenges posed by this process revolve around obtaining accurate estimates of the following:

- Baseline risks, that is the risk of recurrence and mortality at defined time points, such as 5 and 10 years, that would be expected in the absence of any therapy given after surgery. These estimates, which can be obtained from various databases from single institutions, large randomized studies, or cancer registries, tend to vary depending on the source. Furthermore, it is difficult to accurately individualize these estimates for the numerous characteristics such as age, tumor stage, pathological grade, and hormone receptor status as well as new biological tumor assays such as HER2/*neu* oncogene expression level.
- Accurate and reliable quantitative benefits derived from adjuvant hormonal therapy, chemotherapy, and a combination of the two. The most comprehensive dataset derived from randomized clinical trials of adjuvant therapy is the Early Breast Cancer Trialists' Group Overview (2). These estimates, too, need to be individualized for age and tumor hormone receptor status, factors known to affect the degree of benefit of chemotherapy and hormonal therapy, respectively.
- Short- and long-term side effects of therapy. Short-term side effects that are well defined clinical syndromes such as mucositis, nausea, and vomiting are generally included in published trials. However, other side effects that are difficult to measure, such as cognitive changes and alterations in ovarian functioning or sexuality, have not been sufficiently characterized to be included in quantitative decision making models.

Using the above information, it is possible to generate simple models of individualized baseline risks, benefits of adjuvant therapy, and side effects so that patients can make decisions about the tradeoffs of benefits versus side effects for their particular situation. An example is provided in Figure 1. A similar bar graph can be contructed to reflect mortality probabilities and the changes in these due to therapy. This method depicts the risk and

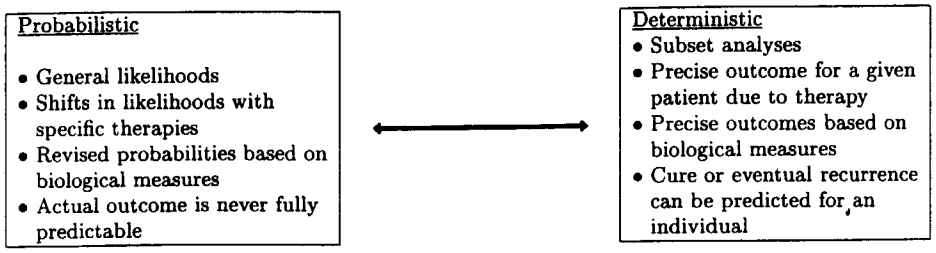

Fig. 2. Dichotomy between a probabilistic and deterministic view.

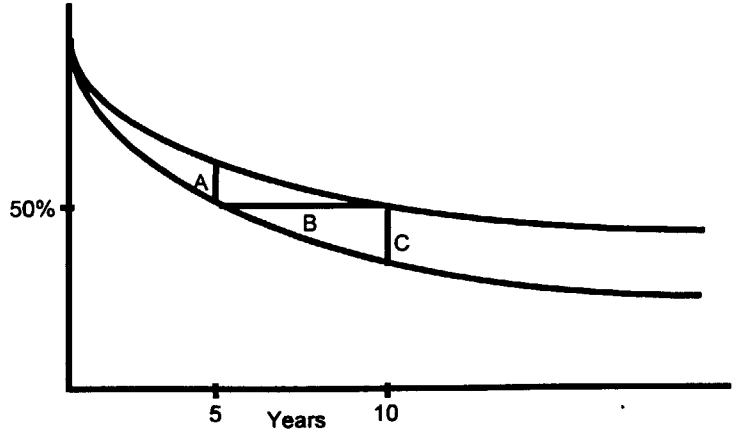

Fig. 3. Decrease in risk versus time gained: two ways of looking at the same outcome curves. If the vertical axis represents the proportion free from recurrence or death, the upper curve patients undergoing a given adjuvant therapy, and lower curve those receiving no therapy, then the difference in risk at 5 and 10 years is given by lines A and B, while the "average time gained" is given by line C.

perience is primarily probabilistic in regard to outcomes in breast cancer and the effects of treatment. Another way to express an adjuvant benefit is the average time gained either free from recurrence or mortality due to recurrence (Figure 3). Estimates of the average time gained free from recurrence or mortality are not commonly reported in clinical trials, due to their wide confidence intervals, and they are felt to be less reliable. Even data from the overview analysis may not provide sufficiently narrow confidence intervals. However, the estimates of time gained (distance B, Figure 3), may be interpreted very differently from the differences in recurrence or mortality at 5 and 10 years (distances A and B), even though they describe the very same curves and clinical outcome data. Whether or not these estimates result in different patient preferences, comprehensibility, and satisfaction in decision making needs to be tested prospectively.

There is an ongoing effort to individualize clinical outcomes and responses to therapy based on individual traits and on characteristics of the primary tumor. Only in fields with very predictable outcomes and cures with therapy, such as the treatment of simple bacte-

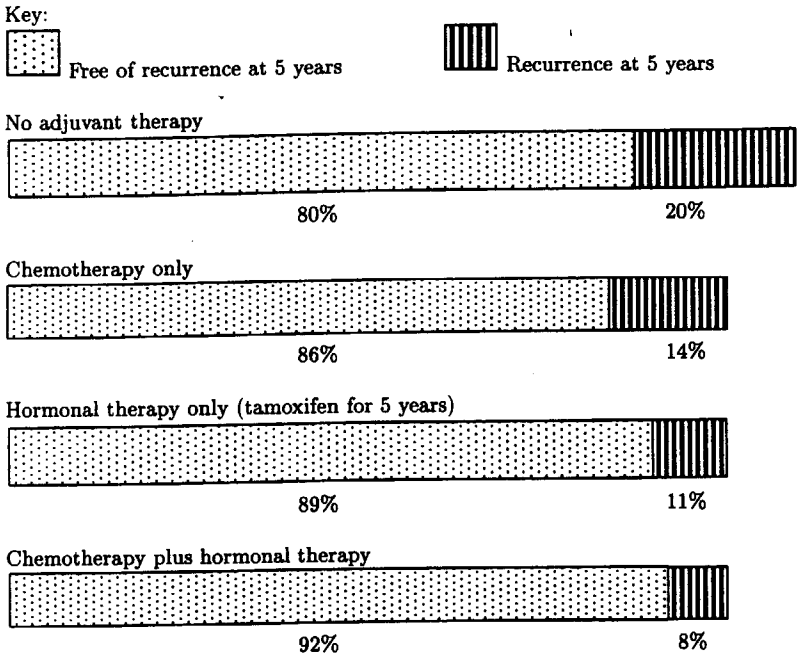

Fig. 1. Likelihood of risk of recurrence at 5 years. 45 year old woman with 2.5 cm, node-negative, hormonal receptor-positive invasive ductal carcinoma. Changes in the risk of recurrence based on a baseline risk of 20% recurrence without any therapy at 5 years and a relative reduction of 30% with combination chemotherapy and 45% with tamoxifen hormonal therapy.

changes in risk afforded by therapy in graphical form that is easy to understand. It is based on baseline risk assessments based on age and tumor stage, as well as relative reduction in the odds or recurrence and death afforded by hormonal therapy and chemotherapy. A personal computer-based method of presenting these data has been piloted in patients about to undergo adjuvant therapy and has been found useful in decision making (7). However, this remains a probabilistic model, and many users may find it difficult to reconcile a statistical view versus one that is immediately predictive of their situation (deterministic).

The feedback we have received from the advocacy community in the San Francisco Bay area regarding this model reflects the duality of the information on adjuvant benefits. On one hand, the probabilities are felt to be helpful since they represent a set of numbers that can be agreed upon by many clinicians; therefore, patients feel that there is at least agreement in the absolute benefits attributable to therapy. On the other hand, there is frustration that the deterministic view, or the attempt to synthesize all this information to predict the actual outcome for a given patient based on therapy, is simply not possible (nor is it ever likely to be given the random component of biological systems). The dichotomy between a probabilistic and deterministic view is shown in Figure 2.

The current state of science and clinical ex-

Table 1
New features for Refined Shared Decision-Making Program

Revised Baseline Risk Estimates and Benefits of Therapy Based on
Histologic grade
HER2/*neu* expression status
Longer term estimates (15 years)
Long term effects of therapies
Cognitive function
Sexual function
Osteoporosis
Heart disease
Other malignancies
Revised Estimates of Therapies
Adjuvant radiation therapy effects on distant recurrence and mortality
New data on bisphosphonates in reducing oseoporosis and recurrence risk
Effects of newer chemotherapy (taxanes)

Table 2
Individual values affecting Treatment Decisions

Desire to Preserve Fertility
Dependent Children or other Family Members
Lifestyle (Travel, Athletic/Recreational Activities)
Profession
Beliefs about Cytotoxic and Radiation Treatments
Concerns about Relationships with Spouse, Family Members, and Friends
Underlying Morbidity or Predisposition (Cardiac Disease, Depression)

rial infections, can more deterministic models be developed. However, further additions to the Shared Decision Program shown in Table 1 will allow for refinements in risk estimates and effects of therapies. While the Shared Decision Model will be probabilistic in nature, these can serve as a guide rather than a rigid road map. Table 2 illustrates some of the individual values we have identified from focus groups that would be applied in trading off the benefits derived from therapy when an individual case is run through the Shared Decision Program. Piloting of this Shared Decision Program will be necessary, followed by formal trials assessing the utility, comprehensibility, and most importantly, the impact of decision making and long-term satisfaction with decisions for adjuvant therapy.

Collaborative Care

The term *collaborative care* refers to the process of planning consultative and treatment discussion sessions with the active participation of the patient under the direction of a trained facilitator. Most visits to the physician's office are dictated by a clinical agenda with an emphasis on treatment options. The physician and office staff generally do not have the training or resources to integrate specific patient's concerns or values into this process, and the trend toward shorter office visits and more complex decision making create a higher level of uncertainty and apprehension. The advocacy movement has been instrumental in highlighting the problems that women face in the consultative process. Shortly after a cancer diagnosis, patients are expected to acquire and process much technical information and, in many cases, are asked to make difficult choices about their therapy. Not only do they lack information on the nuances of different treatment approaches, the results of clinical trials, and the side effects of treatments, but they are not able to prioritize their concerns to methodically query the physician or to obtain

relevant information. Efforts are underway to pilot a systematic consultation planning session and to assess the value of an agenda for the consultation created by the patient and facilitator, with the production of a detailed consultation record done in real time with feedback from the consulting physician. Many of the items that are highlighted are generated by the patients, but some are also suggested based on previous input from patients and advocates who have already experienced this situation. Attention to evidence-based medicine and Shared Decision is employed as well and integrated into the discussion plan. Preliminary results show collaborative care can impact on decision quality and satisfaction with the consultation (8).

Collaborative care, coupled with good decision support tools and attention to individual concerns, is an approach that has been driven by patients and patient advocacy. An optimal decision making process would combine accurate outcomes data tailored as much as possible to an individual patient, with a care provider team that uses patient-guided consultation along with standardized educational and informational approaches. We expect that this process will undergo a continuous quality improvement loop over time. The ultimate goal is to present high quality and standardized information in a way that is relevant and meaningful to the specific patient being counseled and is delivered in a consistent and efficient manner. This program will be measured by the amount of time spent by the staff, the number of follow-up visits, questions needed by the patient, and the long-term satisfaction with the consult and the decisions made.

ADVOCACY IN PUBLIC POLICY

Two general issues that affect a significant proportion of the population have been at the center of controversy and attention from providers and consumers of health care. One is the burgeoning area of inherited predisposition for breast cancer and the process of genetic counseling, genetic testing, and the appropriate use of the results of genetic tests (9). The other is the more established field of mammographic screening for which ample data already exists from numerous randomized trials showing a mortality reduction, but ongoing controversy remains as to the appropriate age to begin screening (10).

Inherited Predisposition to Breast Cancer, Genetic Counseling and Genetic Testing

The science of cancer genetics has moved at a very rapid pace, yet the clinical applicability, as well as the ethical, moral, and legal implications of this field, will always lag behind. Until reliable prospective data associated with genetic testing and interventions based on genetic testing results are available, it is generally accepted that these activities should all occur in the context of investigational protocols and the requisite informed consent process. The elements of informed consent are being formalized with open communication among professional organizations such as the American Society of Clinical Oncology and the American Society of Human Genetics, and governmental agencies and advocacy groups (11). Nevertheless, decisions regarding surveillance, lifestyle modifications, pharmacological prevention, and surgical prophylaxis will need to be discussed with patients despite the paucity of data. As information slowly accumulates, specific models may emerge to provide individualized benefits and risk tradeoffs (12), similar to the process described for adjuvant therapy. Advocates will be in the interesting position of driving the development of these models as well as serving as subjects and sounding boards for their testing and eventual utilization. Due to the strong participation of advocate groups, policies in the area of genetic predisposition and genetic testing will be based upon qualitative

and quantitative research exploring patients preferences, psychological factors, quality of decision, and the more customary indices of clinical outcomes and cost-benefit analyses. Standardized guidelines and policies will undoubtedly follow, which may allow for flexibility depending on individual preferences and needs. Protection against job and insurance discrimination and privacy laws are being enacted at the local and federal levels. In most cases, active advocacy is represented. Given the relative youth of the field of cancer genetics, the role of patient advocacy has been very evident from the basic science to the clinical relevance and applicability, as well as policy setting and the law.

Advocacy in Mammographic Screening Recommendations

Clear reductions in breast cancer mortality of 25–30% has been attributable to mammographic screening. In most trials, this benefit has been confined to women over age 50, even though mammographically detected cancers in younger women tended to be of lower stage and associated with an improved outcome. However, a meta-analysis of trials did show an apparent relative reduction in mortality, in the range of 15–20%, for women aged 40–49 (13). The absolute reduction in mortality in the younger age group, however, is much smaller because of the lower prevalence of disease. Based on these and other data, a recent Consensus Development Panel sponsored by the National Institutes of Health has recommended screening for women over 40 with an emphasis on individualized decision making (14,15). This highlights the necessity to tailor recommendations when tradeoffs must be made between the benefits of screening and the harms caused by false positive mammographic results. One single institution series conducted over a 10-year period estimated a cumulative false positive rate of close to 50% and observed a biopsy rate of 19% in that period of time (16). In younger women, many fewer cancers are going to be detected at the cost of many normal procedures including biopsies — a point rarely discussed with patients when a plan to begin mammographic screening is formulated. Hence, a model for informed and shared decision making with input from the scientific, social/legal, and advocacy sectors is highly desirable in the area of screening mammography. To this end, an Internet-based information tool regarding the pros and cons of mammographic screening has been developed in conjunction with the advocacy community (http://mammography.ucsf.edu/inform/index.cfm). This program also has a built-in questionnaire covering patients concerns, preferences, and demographics to better understand the spectrum of all these aspects and learn how to better individualize education and decision making for mammographic screening.

ADVOCACY IN RESEARCH

The design and conduct of scientific inquiry and research in the field of breast cancer has become much more interactive, bridging the gap between the disciplines of basic and applied biology, epidemiology, clinical research, and clinical outcomes. The ascent of advocacy and lay interest in the research process has been accompanied by many struggles involving the education of constituents to become active partners. Differences in opinion exist not only on specific issues but on the philosophical and conceptual foundations upon which we should be combating breast cancer. Initially, communications between the advocacy and research communities were confrontational with diverging opinions (see Table 3). One example of differing viewpoints was the advocacy community's belief that the conventional research establishment was not interested in studying environmental causes of breast cancer such as industrial chemicals, pesticides, and electromagnetic fields. Many investigators countered that retrospective epidemiological studies did not generally support

Table 3

Perceptions of Advocacy from the Research Community	Perceptions of Researchers from the Advocacy Community
Lack of understanding of the biological and clinical problems	Failure to understand the impact and urgency of the clinical problem
Lack of understanding of research methodology and diligence required	Inability to develop creative methods to hasten the research process
Fixation on unfounded causative factors and unproven treatments	Limited scope of inquiry and fear to depart from current lines of investigation
Misunderstanding of funding limitations and peer-review grant process	Prioritize professional advancement and have other conflicts of interest
Less likely compromise	Complacency with the status quo

these associations although some have admitted that these study designs could not sufficiently reject such hypotheses. Funding agencies are now interested in soliciting research in the area of epidemiology and etiology and an accompanying increase in publications in this area. The large cultural gap between these sectors has narrowed and, while it is always evident in many forums, areas of consensus have been expanding. This has led to more productive exchanges and even cooperative projects, and several samples follow.

New Mechanisms for Funding Research in Breast Cancer

An effort spearheaded by advocate and academic leaders, and ultimately championed by members of Congress, was the allocation of additional funds for breast cancer research to be administered by the Department of Defense. There was a clear mission to develop an innovative review process that rewarded collaboration and risk-taking and discouraged applications which could be readily funded by existing mechanisms such as the National Cancer Institute (NCI). Every year, specific themes are highlighted and these have included cancer etiology, population-based research, cancer genetics and predisposition, and translational therapeutically oriented projects. The two tiered review process consists of a scientific study section with administrative and advocate representation that assigns an initial priority score. The second review (Consensus Panel) can reprioritize funding based on programmatic goals, special needs (such as minority and underserved population-targeting), novel therapeutics, and direct relevance to ultimately improving the outlook of breast cancer. The Consensus Panel is composed of scientists, clinicians, representatives from the Army, public policy experts, and patient advocates. The intent of this process is to have a type of merit review that differs from that of the NCI or even the American Cancer Society. The ultimate goal will be assessed in future years, and the mileposts will be the degree of innovation, new directions and unique resources, and a rapid timeline to deployment in the clinical setting.

The NCI was also directed to expand breast cancer research requests for applications and to develop new funding mechanisms that stressed translational goals. One of the programs that is now in its sixth year of existence is the Specialized Program for Research Excellence (SPORE), with 6 centers currently funded in the area of breast cancer. SPOREs for other common cancer types also exist and the overall program may be further expanded. The SPOREs emphasize collaborations between disciplines, translational objectives, and interactions with advocacy, the community and other researchers. Each of the Breast SPOREs now have an active advocacy network although the modes of interaction vary from one to another. This experiment of advocacy as a part of a large academic

research program is likely to evolve over time and hopefully will serve as a model for the patient interest perspective to be reflected in research and public policy in other areas of medicine.

Advocacy-led Projects and Interactions with Research

Within the SPORE, several models for advocacy partnerships with research have been developed. At some of the SPOREs, advocates play a key role in steering committees, review of developmental projects, and in some cases, have their own projects. One project at the University of California at San Francisco SPORE, in conjunction with Partners in Research (PAIR), has developed a Clinical Trials Directory for the San Francisco Bay Area and is conducting focus groups on clinical trials participation. Active participation at scientific meetings and retreats has led to enhanced education for advocates, a new viewpoint for investigators (especially those that are laboratory-based), and a revised emphasis on many projects. One example has been to develop outreach mechanisms to enhance enrollment to clinical trials, especially in underserved populations. One study requiring volunteers with metastatic breast cancer to submit to a bone marrow biopsy had important scientific aims that would understandably be very difficult to study since it required an invasive and uncomfortable procedure. This study was supported by the advocacy community and subsequent enrollment was adequate to rapidly complete accrual, due mostly to subjects having heard about the trial through the advocacy network. A new initiative to create a tissue resource and registry for protein and genetic analysis of breast carcinoma in situ involving all 6 SPOREs has a built-in advocacy education and outreach effort for awareness and participation for any individual diagnosed with in situ carcinoma since a rate of case accrual will be essential for this effort. It is now routine for the SPORE discussions and projects to include the following:

- Pre- or post-conference summation for advocates given by investigator (or postdoctoral fellow)
- Mechanisms to move project toward an efficient and rapid clinical application
- Inclusion of advocates in Steering Committees and retreats
- Advocacy representation at national SPORE meeting (including plenary talk or poster presentation of advocacy-led projects)
- Plans for dissemination of information on projects and research results

The Role of Advocacy in Clinical Trials

The importance of clinical trials not only to further our knowledge regarding novel and established therapies is self evident, but to patients and advocates, these also are felt to provide better treatment alternatives in individual cases. Admittedly, the likelihood that a new Phase I drug would have a significant impact in someone with refractory advanced breast cancer is rather small. Nevertheless, fair and equal access to new agents is not the rule given the small number of centers performing such trials and the lack of a central information clearinghouse and referral service. As promising new agents move to efficacy (Phase III) trials, there are similar limitations as well as narrow eligibility criteria. During the Phase II and III Herceptin™ (humanized anti-HER2/*neu* antibody, Genentech, Inc.) trials, there was concern in the advocacy community that many women with no other treatment options were being denied access to this drug due to eligibility requirements. A series of meetings between project leaders at Genentech, Inc. and both national and San Francisco Area advocates led to the development of an expanded access study that had minimal eligibility and followup requirements. This provided many women the opportunity to receive treatment prior to full approval by the FDA and still retain some scientific value to the trial itself. Paradoxically, the

increased access uncovered new problems as the supply of drug, still being made at a pilot facility, was limited and required the use of a lottery. Many members of the advocacy community then joined Genentech in supporting the lottery system as the only fair mechanism, but all sides agreed that this problem should be addressed in future drug development. The efficient and rapid development of new therapeutics will undoubtedly pose as many new problems and solutions ranging from only partial activity, determining the appropriate population in which effectiveness will be seen, and obtaining timely outcomes data to satisfy third party payer as usage of new drugs expands. The NCI plans to overhaul the cancer clinical trials information system to make it more comprehensive, user friendly and effective in terms of reaching more patients and increasing trial participation and broad population representation.

SUMMARY

In summary, the role of advocacy in clinical care and research is relatively new and undergoing evolution. The gap between care providers and patients in the attitudes, expectations, and methods of assessment and treatment has closed slightly due to innovative study tools and methods of interaction. In both public policy and research, a growing expertise from the advocacy community has begun to pay off with the development of consensus, collaboration, and even joint projects. The NCI has listed 13 areas of emphasis in breast cancer research, and one of these is "to assure that all basic and clinical research and communication efforts reflect and address patient and survivor needs and concerns." This process is irreversible and represents a true democratization in the breast cancer field. Along with the established scientific principles of inquiry, a reinvention of the discovery process with an advocacy viewpoint will greatly help in the challenges ahead.

ACKNOWLEDGEMENTS

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Abstract 555

Results of a Randomized Trial of a Computerized Decision Aid "Adjuvant!" to Present Tailored Prognostic Information to Stage I-III Breast Cancer Patients.

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We have developed a decision aid to help strengthen the role of the patient in the decision making process. Decision aids can provide the physician with more accurate information to guide decision making. Our decision aid provides a method of estimating the benefit of different adjuvant treatment options for individual patients based on prognostic information. We report on the results of a randomized trial of a decision aid to help newly diagnosed breast cancer patients, in conjunction with their physicians, make adjuvant therapy decisions. A Decision Guide that presents specific prognostic information to breast cancer patients in the form of colored bar graphs has also been developed. These bar graphs are tailored to each woman using our newly developed computer program Adjuvant!. The Adjuvant! program uses a life table analysis technique and factors in natural mortality in addition to excess mortality due to breast cancer. Estimates of breast cancer mortality are based on SEER data. Estimates of treatment efficacy are largely derived from the 1998 meta-analysis of breast cancer adjuvant therapy clinical trials.

A randomized trial of the decision aid was conducted with 400 patients and their medical oncologists (n=45) in two distinct geographic regions, Cleveland, OH, and San Antonio, TX. Physicians were randomized to receive either the output produced by Adjuvant! or no output. Patients received either the individualized Decision Guide produced by the Adjuvant! program or a generic brochure about adjuvant therapy. The presentation will report the results of the clinical trial of Adjuvant! and its impact on: 1) treatment decisions, 2) patient understanding of treatment and prognostic information, 3) patients' immediate satisfaction with the decision, 4) patients'decisional regret. We also present a cost-utility analysis comparing standard decision-making with decision-making aided by the Adjuvant! program and the presentation of the Decision Guide.

5 YEAR RECURRENCE RISK ESTIMATES														10 YEAR RECURRENCE RISK ESTIMATES			
CancerHome					Adjuvant				Cancer Facts					Adjuvant 2			
Patient	No Tx	Hormone	Chemo	H+C	No Tx	Hormone	Chemo	H+C	No Tx	NeoAdj	Syst. Tx	Sx Only	Sx+XRT	No Tx	Hormone	Chemo	H+C
RE	45%	34%	34%	24%	33%	17%	25%	25%	36%	54%	NA	25%	32%				
LS	48	36	37	26	17	8	6	5	40	57	NA	32	25				
LM	56	44	44	33	43	15	9	20	40	52	NA	32	35				
RF	12	8	9	6	17	9	25	11	40	NA	74	32	25	25	16	25	14
JP	40	30	30	23	20	10	17	9	40	NA	75	32	32	32	18	29	16
PMM	35	26	27	19	18	15	16	12	38	42	74	32	26	32	19	28	16
DD	32	24	24	15	18	15	16	12	35	42	74	25	31	48	35	41	28
SDC	58	45	46	35	17	12	15	11	31	35	NA	10	23	52	30	46	27
KLS*	63	51	50	40	8	8	6	6	35	NA	NA	21	30	20	20	15	15
NK*	62	51	50	39	8	8	5	5	36	NA	NA	21	30	20	20	14	14
RM*	83	74	72	62	28	28	19	19	31	NA	NA	20	22	48	48	33	33
TB	29	22	22	16	8	6	7	6	32	35	NA	20	22				
BN	30	21	21	15	14	11	11	8	40	50	NA	32	30				
KO	44	34	34	25										55	32	43	24
JAT	6	4	4	3										10	6	8	5
CI	43	35	33	25										57	41	43	30
(* denotes ER-, all others ER+)																	

(PR) 10 Year Recurrence Risk Estimates				
Patient	No Tx	Hormone	Chemo	H+C
KK	11	6	8	4
RF	25	16	25	14
JP	32	18	29	16
PMM	32	19	28	16
DD	48	35	41	28
SDC	52	30	46	27
KLS	20	20	15	15
NK	20	20	14	14
RM	48	48	33	33
JAT	10	6	8	5
VN	53	31	47	28
KO	55	41	43	30
CI	57	41	43	30
PS	54	33	43	24
FM	67	67	54	54
LJ	42	42	32	32
RC	35	19	26	14
AM	66	40	60	37
CP	18	9	13	7
CM	56	32	43	24
MP	55	32	43	24
NL	35	19	26	14
GE	11	6	9	5
TT	25	17	18	12
AB	55	32	43	24
LS	53	32	48	28
HM	64	40		36
KW	10	5	8	4
FP	9	5	8	4
SH	39	22	34	19
MA	56	42	48	35
MM	53	53	42	42
DS	13	8	11	6

(HB) 10 Year Recurrence Risk Estimates			
No Tx	Hormone	Chemo	H+C
31	22	22	16
23	16	17	12
63	50	50	38
49	38	38	28
62	49	49	38
61	48	48	37
47	40	36	30
44	38	33	28
70	63	58	51
12	9	9	6
63	49	50	38
69	56	56	44
68	57	55	45
95	88	89	78
99	98	97	96
48	37	37	28
93	85	86	74
73	60	60	48
53	43	41	32
82	69	70	56
87	76	77	63
57	44	45	34
30	21	22	15
46	37	35	25
73	59	59	46
57	43	44	33
83	72	72	59
19	13	13	9
19	13	14	10
69	55	56	43
94	88	88	78
95	90	89	80
40	29	30	21

Building Bridges Between Physicians and Patients: Results of a Pilot Study Examining New Tools for Collaborative Decision Making in Breast Cancer

By Karen R. Sepucha, Jeffrey K. Belkora, Debasish Tripathy, and Laura J. Esserman

Purpose: To present the results of a pilot study testing an intervention designed to improve the quality of medical consultations between breast cancer patients and physicians and, in particular, to report the effects of the intervention on the quality of treatment decisions, the quality of communication, and the satisfaction of patients and physicians.

Patients and Methods: We enrolled 24 predominantly white, well-educated, early-stage breast cancer patients who were facing local or systemic treatment decisions in a sequential, controlled trial. All patients received a visit preparation session before the consultation in which a trained researcher helped patients organize their questions and concerns. In the control, a researcher observed the consultation. In the intervention, a researcher helped create an agenda, facilitated the discussion, and created a record of the consultation in real time. Valid and reliable surveys measured the quality of treatment decisions and satisfaction with the consultation.

Results: Patients in the intervention achieved significantly higher final decision quality scores compared with control patients (median score, 14 v 10, respectively; $P = .008$) and a significantly higher level of intersubjective agreement with their physicians about decision quality (Cohen's kappa, 0.49 v 0.285, respectively; $P < .0001$). Consultation recording methods did not affect the length of time required for the consultation.

Conclusion: Consultation recording methods provide a promising innovation for medical consultations. Further studies are warranted to broaden the findings, assess impacts on the quality of decisions, cost, and health, and develop practical ways to integrate consultation recording methods into clinics.

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TRADITIONALLY, PHYSICIANS have been trained to assess a clinical situation and create a treatment plan for their patients. However, the role of the physician as primary analyst and decision-maker is changing. Many patients want to participate in decisions about their care, and increasingly, physicians are trying to accommodate them. In this new paradigm, physicians' roles are evolving into that of educator and collaborator.

Patients and physicians face many challenges sharing responsibility for decisions. One study of over 1,000 breast cancer patients found that only 42% believed they had achieved their preferred level of participation.[1] The lack of patients' participation may be problematic; studies indicate that breast cancer patients want to participate in their medical decisions, and further, that those who are able to participate in decision making have better psychosocial and health outcomes.[2-4]

Sharing responsibility for decision making requires good communication during medical consultations. Unfortunately, studies show the majority of patients and physicians do not receive special training in communication or collaborative decision-making skills.[5-10] Poor communication has been linked to dissatisfaction, conflict, and worse outcomes for patients. Studies suggest that these patients tend to change physicians,[11,12] to initiate complaints and malpractice suits against physicians,[13] and not to adhere to medical treatment plans.[14,15]

Several researchers have designed seminars and programs to improve the communication skills of physicians. Programs teach clinicians how to interview patients to elicit medical history,[16] how to establish rapport,[17,18] and how to elicit and address patients' questions.[5,19,20]

Other researchers have designed interventions to improve the communication skills of patients. These visit preparation interventions seek to increase patients' comfort and confidence when communicating with their physician.[9,21] We created a similar intervention, consultation planning, that prepares breast cancer patients to articulate their questions and concerns during consultations (Belkora et al, manuscript submitted for publication). Visit preparation interventions have been linked to improved health outcomes in chronic disease management, such as diabetes and peptic

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ulcer disease. However, the main health outcome measure, compliance, does not apply in acute diseases such as breast cancer.

The tools and training that help patients and physicians communicate are important, but alone they may not be sufficient to help patients and physicians effectively collaborate. In breast cancer, patients and physicians make treatment decisions soon after the diagnosis, when patients are experiencing a great deal of stress and anxiety.[22,23] Studies suggest that patients suffering from stress and anxiety are not able to comprehend a lot of information.[24] Moreover, studies have shown that the cancer clinicians, in particular, suffer from burnout, stress, and psychiatric disorders as a result of the constant exposure to death and dying and the lack of training to address emotional issues.[25,26]

In a few short visits, breast cancer patients and their physicians must overcome emotional barriers, bridge the distance between their views, and agree on a course of action. We wanted to help patients and physicians engage in collaborative decision making and improve the quality of their communication without overloading or overwhelming them. Therefore, we focused on ways to improve the quality of the critical consultations between diagnosis and treatment.

We translated standard meeting facilitation processes that have been well validated in the business community to the medical consultation.[27] Then, we qualitatively integrated decision analysis to structure the discussion about treatment decisions and action science to promote open communication.[28-30] This is not the first attempt to translate techniques commonly used in other industries to the field of medicine. Berwick et al[31,32] have successfully brought methods for quality improvement, data management, and other business processes to improve the effectiveness and quality of health care.

We developed consultation recording to structure the outpatient consultation for decision making. Using a framework to improve the quality of medical interactions is not new. The subjective objective assessment plan note was introduced to standardize the medical interview examination and assessment.[33] The literature does not include standard metrics to measure the quality of decision making and track how it changes over time. Rather, standard metrics measure satisfaction with decisions or decision-making style.[34,35] Thus, we also developed and tested new metrics to measure the impact of these methods.

Our hypothesis was that consultation recording would increase the quality of treatment decisions, the satisfaction with the consultation, and the amount of agreement between patients and physicians. Higher decision quality and higher agreement should reduce the need for multiple consultations. As a result, we also hypothesize that consultation recording should reduce the number of follow-up visits before treatment begins. In this article, we report the results of a pilot study comparing consultation recording intervention with consultation planning alone.

PATIENTS AND METHODS

Setting and Patient Sample

We recruited patients from the University of California, San Francisco Carol Franc Buck Breast Care Center (San Francisco, CA) from June 1998 through November 1998. Eligible patients had a diagnosis of breast cancer (or ductal carcinoma-in-situ), could read and speak English, and were consulting one of two physicians, a surgeon or a medical oncologist, about treatment. We identified patients through the scheduling system and through physician referral.

Study Design

We chose a sequential, controlled trial design for this study to minimize the anticipated learning effects of the two physicians. Twelve patients were enrolled onto the control arm, and 12 patients were enrolled onto the intervention arm. Both physicians saw a comparable number of patients in each group. The short enrollment period was meant to minimize any confounding factors that might be expected in a sequential trial.

One investigator trained in consultation recording methods administered both the control and the intervention conditions. Because it was impossible for either the investigator or the physicians to be blind to the intervention, precautions were taken to ensure that the interventions were administered without bias favoring either group. First, the investigator consistently emphasized to patients that different methods for intervening were being tested and that their candid assessment was most important. Second, the investigator encouraged specific patient and physician behaviors (eg, providing examples and asking questions) but did not tell the patients or physicians of the potential impacts on satisfaction or other outcomes. Third, the researcher emphasized that the patients' evaluations would remain anonymous (in particular, that the physicians would not see the patients' responses) to help patients feel comfortable answering candidly.

The study was performed under the approval of the University of California, San Francisco, Committee on Human Research, and all patients reviewed and signed an informed consent. Patients completed surveys indicating their current desire for participation in decisions and assessment of decision quality. This was followed by a 30-minute consultation planning session for all patients, at which time a researcher created a flow chart of the patients' specific questions and concerns. Consultation planning methods have been validated as a means to help breast cancer patients prepare for medical visits and have been described in detail elsewhere.[7,36,37] Then, patients repeated the surveys indicating their perceptions of decision quality.

Before the consultation, the physicians completed a short questionnaire indicating their level of preparedness. After the consultation, the patients and physicians filled out a satisfaction questionnaire and repeated the decision quality survey. The diagram in Fig 1 outlines the sequence of the study. Patients follow the top sequence, and physicians follow the bottom sequence. The squares indicate the interventions and the circles represent the metrics that we administered before and after these activities.

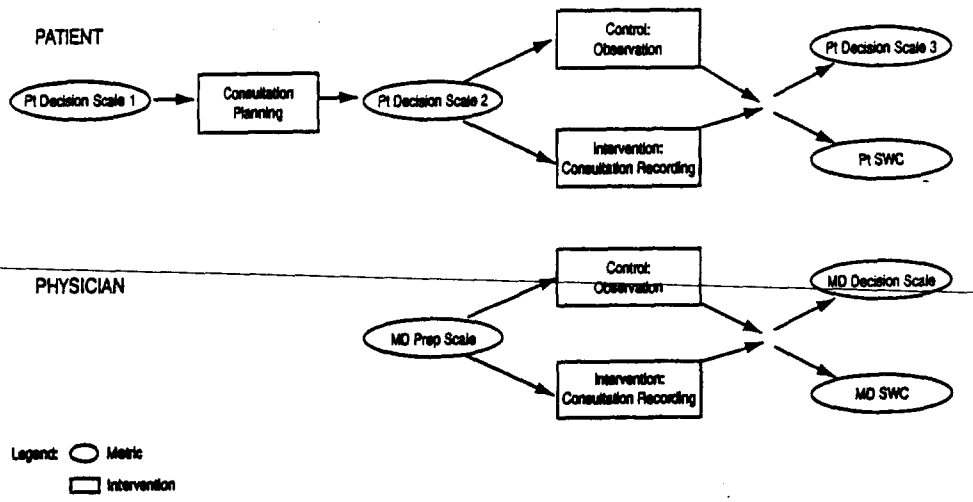

Fig 1. Trial protocol for patients and physicians.

Intervention: Experimental Group

Consultation recording is a five-step intervention: contracting, agenda, mapping, commitments, and debriefing. A trained researcher led patients and physicians through the five steps. First, in the contracting phase, patients and physicians discussed how they wished to share decision-making responsibility. Second, the patients and physicians set an agenda. We created a generic structure for the consultation. The physicians shared the agenda (Table 1) with patients at the beginning of the consultation.

Third, the researcher facilitated the progression through the agenda and recorded the main points of the discussion. During this mapping phase, the researcher asked questions designed to prompt physicians and patients to give examples and provide reasoning for their views. The researcher also periodically paraphrased the consultation record that she was creating using Inspiration software (Inspiration Software Inc, Portland, OR). Patients would be encouraged to ask questions during each item, and the physician or researcher would check the patient's understanding before moving ahead. For example, before listing the treatment alternatives, the researcher would ask the patient to share her understanding of the diagnosis to check that it was accurate.

Fourth, the researcher helped the patients and physicians make clear commitments for the next steps that need to be taken. Finally, in the debriefing phase, the researcher, physician, and patient reviewed the printed summary of the consultation. We used the structure in Table 1 to organize the medical consultation and the consultation record. The record pictured in Fig 2 reflects the detailed discussion for one of the patients in the intervention arm of the trial. The text captures statements from the physician and the patient. The arrows connect lines of reasoning and related items. The headings (in bold) are the agenda topics, and the discussion of each agenda item is summarized underneath. The boxes highlight decisions that have been made and the next steps that have been agreed on by both the patient and the physician.

Table 1. Generic Agenda for a Decision-Making Focus in Medical Consultations

1. Physical examination and review medical history
2. Explain diagnosis
3. List the treatment alternatives
4. Describe the consequences
5. Elicit patient's preferences
6. Generate treatment plan
7. Review next steps

Control Group

We designed the control condition to provide a comparison in which a researcher observed the consultation but did not participate unless asked to by the patient or physician.

Measurement of Impact: Baseline and Outcome Measures

Decision Quality Scale, a 10-item Likert scale, measures the quality of a decision based on the six elements of decision quality from decision analysis.[38] Patients filled it out three times, before any intervention (Patient Decision Scale 1), after the consultation planning session (Patient Decision Scale 2), and after the consultation (Patient Decision Scale 3). The survey asks patients to agree or disagree to statements such as, "I am having difficulty making decisions about treatment," "I have a thorough understanding of the medical diagnosis," and "My doctor and I agree on a treatment strategy." We have demonstrated the reliability (Cronbach's alpha coefficient, 0.77) and validity of this scale.[39] Scores range from −20 to 20, with higher scores indicating higher decision quality.

The MD Decision Scale, a modified version of the Decision Quality Scale, was completed by physicians after the consultation and used to measure the amount of agreement between patients and physicians. This scale asks physicians to agree or disagree to statements such as, "This patient is having difficulty making decisions about her treatment," "I know what is important to this patient for these decisions," and "This patient and I agree on a treatment strategy."

The University of California San Francisco Satisfaction with Consultation Scale (SWC), completed after the consultation by both patients (Pt SWC) and physicians (MD SWC), is a seven-item Likert scale. Specifically, the scale focuses on communication and meeting dynamics in statements such as "It was easy for me to voice my questions and concerns" and "I was not able to talk as much as I wanted to during this consultation." We have demonstrated the reliability (Cronbach's alpha coefficient, 0.9) and validity of this scale for patients. Scores range from −14 to 14, with higher scores indicating

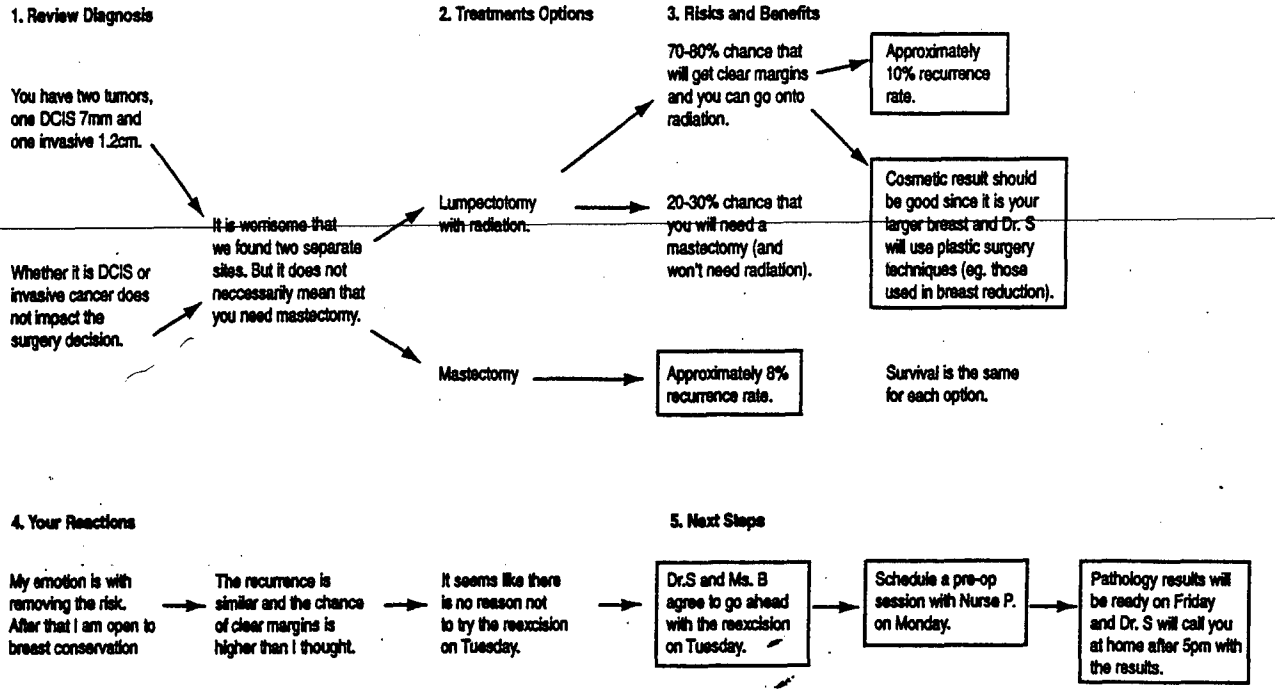

Fig 2. Example of a consultation record. All identifying information has been removed to protect the patient's and the physician's privacy.

higher satisfaction. The researcher timed each consultation and reviewed medical charts to document the number of subsequent consultations with the physician before treatment.

Statistical Analysis

We used nonparametric statistics to analyze the ordinal survey data. We used a one-tailed Wilcoxon rank sum test to analyze the Likert scores, and the pre- and postintervention differences for the Patient Decision scale and the Pt SWC scale.[40] We used Cohen's kappa (κ) to measure the amount of agreement between patients and physicians on the Decision Scale.[41] We used a two-tailed Wilcoxon rank sum test to analyze the difference in length of consultations and number of consultations. Because this is such a small sample, in addition to reporting the statistics, we present the complete data as much as possible.

RESULTS

A total of 24 patients were recruited, 12 in the control arm and 12 in the intervention condition. The patients in each group had comparable baseline characteristics. As listed in Table 2, the sample was predominantly white, well-educated, early-stage breast cancer patients. Even though the samples were small, the similarity between the two groups allows for comparisons.

We did not detect a difference in the Patient Decision Scale 1 or the Patient Decision Scale 2 scores for the control group compared with the intervention group. Further, the consultation planning intervention did not significantly affect the Patient Decision Scale scores. The median score on the Patient Decision Scale 1 compared with the Patient Decision Scale 2 for the pooled sample did not differ significantly (4 v 3.3, respectively; $P = .42$).

We did find that breast cancer patients, in general, were confused about decisions. Before the consultation, less than 20% of the patients in the study agreed or strongly agreed to the statements, "I understand what could happen after each medical treatment alternative," "It is clear to me which

Table 2. Demographics for Pilot Study

Patient Group	No. of Patients	White Patients (%)	Patients With at Least Partial College Education (%)	Patients With Early-Stage Breast Cancer (%)	Age ± SD (years)
Control	12	91	100	83	48 ± 6.7
Intervention	12	83	89	82	47 ± 6.9

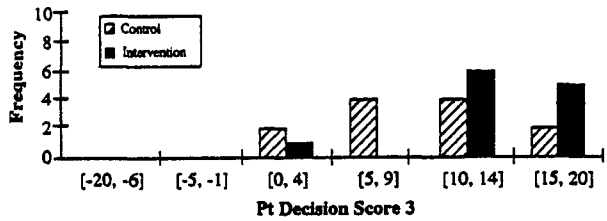

Fig 3. Distribution of decision quality scores after consultation (Patient Decision Scale 3).

treatment alternative is best" and "My doctor and I agree on a treatment strategy." However, more than 80% of patients agreed or strongly agreed with the statement, "I understand what could happen without any further medical treatment."

Patients Achieve Higher Decision Quality With Consultation Recording

After the consultation, patients in both arms demonstrated an increase in decision quality. Compared with the control group, the intervention group achieved a significantly higher median score on the Patient Decision Scale 3 (9.5 *v* 13, respectively; estimated difference, 3.5; $P = .008$). Figure 3 shows the distribution of Patient Decision Scale 3 scores for the intervention and the control groups.

The data also suggest that the mean increase in decision quality is larger in the intervention group than in the control. The mean change, Patient Decision Scale 3 minus Patient Decision Scale 2, is 9.7 points for the intervention and only 6.6 points for the control, for an estimated difference of 3.1 ($P = .057$). Figure 4 plots the change in decision quality score for each patient in the intervention and the control conditions.

Patients and Physicians Achieve Higher Agreement With Consultation Recording

We also measured the amount of agreement between patients and physicians on aspects of the decisions. We compared the physician's response with the statement, "This patient is having trouble making decisions" with the patient's response to the statement "I am having trouble making decisions." The stronger the agreement, the higher the inferred quality of communication during consultations.

For the control group, the strength of agreement was fair, with a κ coefficient of 0.28 (n = 10, 95% confidence interval [CI], 0.24 to 0.32). For the intervention sample, the strength of agreement was moderate, with a κ coefficient of 0.49 (n = 10, 95% CI, 0.44 to 0.53). Thus, the intervention group achieved significantly higher intersubjective agreement, with an estimated increase in κ of 0.205 over the control group (SE = 0.031, $P < .0001$).[41]

Patients Are More Satisfied With the Consultation

The data from the SWC scale suggests that patients' satisfaction is higher with the intervention than with the control. The median Pt SWC score is 11 for the intervention group versus 7 for the control group, for an estimated difference of 4 ($P = .073$). Further, in Fig 5, we see that 75% of patients in the intervention group scored 10 or higher on the SWC scale, whereas less than 17% of the control scored 10 or higher.

Physicians' Like Consultation Recording

We had difficulty consistently administering the physician preparation survey because of the busy provider schedules. Further, the physicians remarked that the statements on the SWC survey did not accurately reflect those issues that were important to them. As a result, we stopped administering the physician preparation and MD SWC surveys and plan to revise them for future use. Informally, the physicians reported that they did not feel that the presence of the researcher interfered with establishing a relationship with their patients.

Impact on Costs

Because this was part of a research study, patients were not charged for this service. The intervention did not

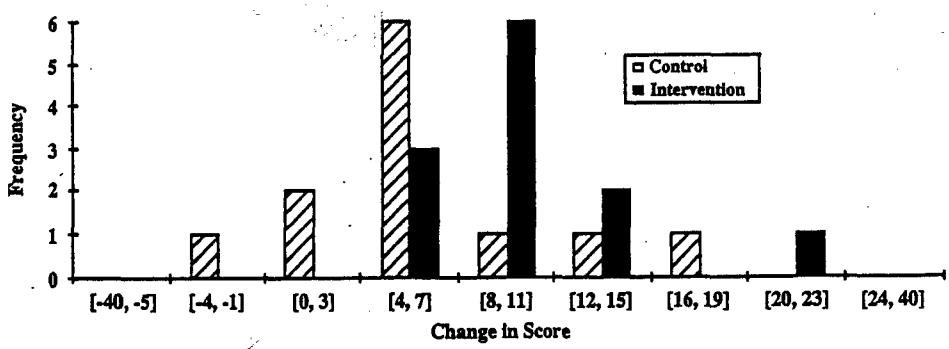

Fig 4. Change in decision quality score for patients (Patient Decision Scale 3 – 2).

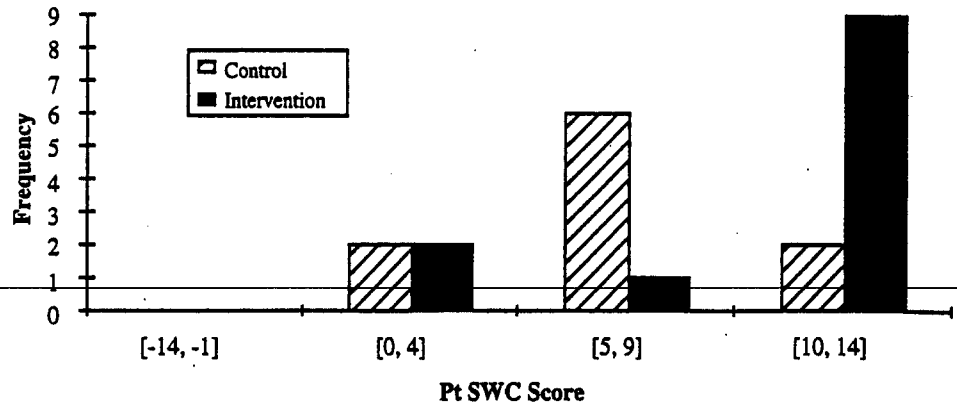

Fig 5. Patient's satisfaction with consultation (Pt SWC).

significantly change the time in consultation (mean time in consultation, 50.9 minutes for the control group [n = 9] *v* 52.9 minutes for the intervention group [n = 10], which was not a statistically significant difference. On average, patients took an additional 0.375 consults in the control group (n = 8) compared with 0.125 in the intervention group (n = 8) (estimated difference, 0.25 visits; 95% CI, 0.22 to 0.75), which was not a statistically significant difference. Four patients in each group were seeking second opinions (not treatment) and were not counted as part of this calculation. The intervention did not significantly increase the time in consultations or significantly affect the number of follow-up consultations before treatment.

DISCUSSION

Many breast cancer patients are actively seeking involvement in their care.[42,43] There has been an explosion of information in the popular press and on the Internet supporting this change. Breast cancer patients find articles covering a broad range of topics from the latest experimental therapies to complementary medicine techniques.[44-46] Unfortunately, the information and recommendations from these sources are not always up to date and do not apply to all patients. As a result, many patients become confused and overwhelmed, especially when their physicians contradict what the patients have read or heard.

To confuse matters more, many of the benefits of therapy are often expressed as a relative reduction in the odds of recurrence as opposed to absolute reductions. A physician may inform her patients that chemotherapy will reduce her risk of recurrence by 30%. However, this benefit is variable among individuals. In other words, a woman who has a 30% chance of recurrence will experience a 10% reduction in risk, whereas a woman who has a 10% chance of recurrence will experience a 3% reduction. Patients and physicians need to be clear when referring to relative risk reduction, otherwise patients may be making trade-offs on dissimilar quantities.

Despite the increase in consumerism, many breast cancer patients come to consultations with little or no prior knowledge of breast cancer and want their physicians to choose on their behalf. In breast cancer, many alternatives do not differ in their impact on survival and recurrence, but do have very different side effects. In adjuvant therapy, some patients must trade-off the long-term effects of chemotherapy (eg, infertility and so on) with a small survival difference. Physicians who assume the responsibility for choosing on behalf of their patients need to be able to understand their patients' preferences. With limited time and resources, physicians need to synthesize their patient's detailed medical history along with the relevant evidence from the literature and incorporate their patients' preferences. This is a challenging task to complete in a short visit, even for the most skilled practitioners.

Physicians need to be prepared to handle the diversity of their patients. In particular, physicians need to be able to engage and empower their patients to participate in the consultation in whatever manner is most comfortable for the patient. We developed consultation recording to help physicians function better in this diverse and changing environment.

Consultation recording provides a structured process for decision-making consultations. In the control arm, the patients and physicians did not ask the researcher to participate; as a result, the researcher simply observed these sessions. The results of this pilot study support our hypothesis that active facilitation and recording improves the effectiveness of medical consultations. Patients in the intervention group achieved significantly higher decision quality than those in the control group, without spending more time. Intervention patients also achieved a significantly higher level of agreement with physicians on aspects of decision

quality and a marginally significant increase in satisfaction with the consultation.

Before the study, the physicians were concerned that the presence of a researcher might negatively affect their ability to establish a relationship with their patients. After the study, they reported that they did not feel that the researcher adversely impacted their ability to establish a strong relationship with their patients. In fact, the two physicians felt that the intervention helped them reach a higher level of discussion with their patients and enabled them to get to the heart of issues quicker and more effectively.[39]

The introduction of a simple structure for the consultation and the creation of a written record of the consultation improved the quality of the consultation. The patients in the intervention group did not worry about writing everything down or remembering everything because a record was being created for them. Instead, they were free to listen and ask questions. Similarly, the physicians were confident that the information the patients in the intervention group took away from the consultation was an accurate reflection of what transpired. The patients and the physicians in the intervention were able to accomplish more in the same amount of time.

The introduction of the problem-oriented medical records approximately 30 years ago brought consistency and structure to the medical record.[33] Although some physicians object to the specific structure of the subjective objective assessment plan note, none debate the usefulness of a structure for medical records.[47-49] In this pilot, we tested a new structure for the medical record that also guides the medical consultation. The steps include explain diagnosis, list treatment alternatives, describe consequences, elicit patient's preferences, review decisions, and plan the next steps. The structure of the agenda is similar to steps advocated by Grueninger et al[20] to facilitate patient education in the medical encounter and provides a decision-making focus for the consultation.[28,39]

Consultation recording helped patients and physicians bridge the distance between their views and create a shared understanding. This shared understanding is a necessary component for any method of collaborative decision making. Patients have diverse preferences for decision making, and one strategy for consultations will not satisfy all patients. Instead, physicians need to elicit their patients' preferences and then be flexible to allow patients to participate in whatever way makes them most comfortable.

This pilot study did identify some potential limitations of consultation recording. A formal process does not eliminate the need for high-quality, consistent information. Further, although engaging patients in the decision-making process has been shown to have beneficial emotional impacts, consultation recording does not eliminate the need for psychosocial support. Consultation recording is not a complete solution for patients and physicians.

Future research could usefully explore the applicability of these methods to a larger population of breast cancer patients and physicians. We need to develop new metrics to measure the physicians' satisfaction with the consultation. We also need to explore how to further increase the amount of agreement between patients and physicians, so that instead of only moderate agreement, they achieve high agreement.

To spread these methods to the community at large, we need to demonstrate that consultation recording methods are realistic to implement in a busy clinic with limited resources and limited time. We are currently exploring several opportunities to use resources that are already in place to implement consultation recording methods. Medical students and residents often observe consultations without participating. Giving them an active role in these consultations may increase their learning and enjoyment with the experience.

Some innovative programs across the country use premedical students to create records for emergency room physicians. These programs have found that the premed students cut down on the physician's workload and decrease the liability of the hospital, while gaining valuable clinical experience.[50] Incorporating consultation recording into the medical training of students may enable widespread use of these methods at low cost to hospitals.

The health care system is placing increasing demands on physicians to provide better care faster and at a lower cost. Most industries have struggled with similar challenges, and those organizations that were attentive to the needs of their customers survived.[31] Breast cancer patients increasingly want to participate in decisions about their care. Physicians and hospitals that enable patients to participate will survive and thrive in this new environment. Physicians, too, need to thrive, and studies demonstrate that those oncologists who have the best communication skills are least likely to experience burnout.[25]

Consultation recording is an innovative approach to improving the quality of medical consultations. These methods fill a gap in the period between diagnosis and treatment for breast cancer patients and their physicians. Further studies are warranted to broaden the findings, assess impacts on cost and health, and develop practical ways to integrate them in a busy clinical setting.

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Using Action Research to Improve Collaboration between Breast Cancer Patients and Physicians: Creating the Program for Collaborative Care

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Introduction: Action Research and Breast Cancer Decision-Making

Recently, breast cancer patients have become more eager to actively participate in decisions about their care. The availability of information on the Internet, and the visibility of the breast cancer advocacy movement (Klawiter 1999; Potts 1999), have changed the way breast cancer is addressed in the United States. Most of the exchange between breast cancer patients and physicians occurs during the medical consultation. However, the decision-making in breast cancer has yet to incorporate these broader social changes (Fisher, 1996). In the short time of a consultation, physicians disclose information about the diagnosis, explain alternatives for treatment and present information about the risks and benefits. Patients voice their preferences and disclose information about their history. Somehow, during these rushed, strained, patients and physicians make decisions about treatment.

This paper describes an action research project that aimed to improve the way patients and physicians make decisions about breast cancer. We describe: 1) the current problems breast cancer patients and physicians face as they make decisions about treatment, 2) the process of developing methods to improve the collaboration between patients and physicians, and 3) the transition from action research to implementing a full time clinical program. We use an ethnographic, case study approach to illustrate the social world of breast cancer, to highlight the difficulties in decision-making and to describe the process of conducting action research in a university medical center.

Action research is an interdisciplinary methodology with similarities to participatory sociological research (Hart and Bond 1999; Cancian 1996; McCormick 2000). Action

research emphasizes the formulation, implementation and assessment of interventions in applied settings, and advocates finding a motivated organizational partner who is willing and able to change the status quo. The partnership seeks to render an explanatory account of a problem, invent, practice and implement productive change, and then assess the effectiveness of the intervention. Success of an intervention is determined by the adoption and use of the methods (i.e. is it compelling and practical enough to adopt?). However, biomedicine stipulates that only statistical significance through randomized clinical trials can prove associations between variables, and therefore generate legitimate "results." To address this reality, we used both qualitative methods (ethnographic participant observation, focus groups, in-depth interviews) and a sequential, controlled clinical trial to determine the value of our interventions (Sepucha, Belkora et al. 2000).

Background

We found a willing action research partner in the University of California, San Francisco Breast Care Center (BCC). The director, a practicing surgeon, wanted to explore new tools and methods to improve the decision-making interaction and the quality of decisions. We used action research (Lewin 1951; Hart 1999) and its foundations in critical theory (White 1995) as a guide for generating the important questions, as well as answering them. Although we have been involved in many projects—collaborations in classrooms, rape crisis centers, community resource centers, and other hospital units - this project was the first to focus on with the physicians and patients at the UCSF Breast Care Center from beginning to end.

We focus on the portion of our collaboration that resulted in the intervention called Consultation Recording. In Consultation Recording, a trained researcher facilitates and records the medical consultation. This intervention extends and improves on another intervention called Consultation Planning, also developed by the authors. In Consultation Planning, a trained researcher helps patients prepare for an upcoming medical consultation by organizing their questions and concerns on a flow chart. The Consultation Plan acts as a visual aid or "road map" for the discussion between patients and physicians.

Organizational Context: The Breast Care Center

The Breast Care Center (BCC) is a busy, multidisciplinary clinic that opened in1996. At first it was simply several private practices co-located in a cramped space. Scheduling was a challenge, exam rooms were always double booked, patients had to wait, and physicians seemed to get in each other's way more than they collaborated. The staff and services have since integrated, they have moved into new space that better supports patient care. The ten physicians and three nurse practitioners at the BCC see an average of 9200 patients a year from diverse communities across Northern California.

Every day at the Breast Care Center, patients and their families deal with a potentially life threatening disease and make decisions that have significant impact on their bodies and lives. The diagnosis of breast cancer often comes as a shock. The few days or weeks between receiving the diagnosis and starting treatment are filled are often filled with anxiety, confusion and a sense of a loss of control. Breast cancer is profoundly disruptive

to women's busy lives, as they must quickly assimilate the news, cope with conflicting, emotions, learn more about the disease, and shuttle between different appointments. This emotionally laden organizational context impacted the project's development. We needed to be mindful of the cost (both time and energy) imposed on patients—many of whom were already at their limits. We wanted to minimize the time patients needed to fill out surveys, avoid overloading them with interviews, and develop interventions that were sensitive to their needs.

We began this project with a qualitative analysis of how patients and physicians interacted in decision-making consultations. How did treatment decisions get made? What happened when things went well? What happened when things went poorly? How did patients and physicians communicate, and what prevented them from doing it well? Then we needed to develop an understanding of their goals or ideals for collaborative decision making, and the barriers to achieving the goals. What would be better according to patients? What would be better according to physicians? What prevented them from achieving their goals? What supported them in achieving their goals? What kinds of tools or services would help reinforce the support or overcome those barriers? What kind of constraints (resources, time, organizational) did we need to take into account? Finally, as we tried new interventions, we needed help understanding their impact on the current situation and whether or not we had moved closer to the goals of improving patient-physician communication and collaborative decision-making.

Getting Started: The Social World of Patients and Physicians

To better understand the challenges patients and physicians faced in making treatment decisions, Karen Sepucha immersed herself in the clinic. She followed three doctors around for days, and interviewed them individually about their activities. She also interviewed several nurses and administrative staff, attended tumor board meetings and other physician conferences. In addition, Karen offered Consultation Planning services to patients, developed through an earlier action research project at Stanford University, the BCC and the Community Breast Health Project. Consultation Planning involves an hour-long discussion with patients prior to their appointment with a physician, in which we map out their questions, concerns, and issues into a flowchart (Sepucha, Belkora et al.; Belkora 1997). Then the patient and physician use the Consultation Plan in the medical consultation to clarify questions, discuss all the issues at stake, and come to a decision about treatment.

Throughout this process, we analyzed the interdependencies and relationships in the clinic and explored the following questions: who are the participants? Who are the stakeholders? What decisions are they making? What are the authority relationships? How are resources shared or regulated? What are the channels of communication? What actually happens in those interactions where decisions are made? Mapping these practices was difficult, interpreting and determining what to do was even harder. The clinic setting required an investigation into micro-processes of how patients and

physicians negotiated meaning, as well as more a macro approach to understand how broader social and economic changes affected the delivery of care (Clark 1991).

Through our ethnographic observation, we began to identify and develop the concept of a "decision gap." Physicians had detailed protocols for diagnosing breast cancer, and detailed protocols for treating breast cancer, however they did not have any tools or structure for the period of time between diagnosis and treatment. Patients receive emotionally overwhelming news of a diagnosis and lots of clinical information, but no structured way to sort through their feelings, concerns, and priorities about treatment. During this time patients and physicians make critical decisions that will impact patients' bodies and lives.

The main interaction between patients and physicians during the decision gap occurs during the medical consultation. We began to document these critical consultations more thoroughly and to identify the barriers to productive collaboration. The following case is interpreted from a transcribed interaction between a patient and highlights several problems we observed. [A more in depth discussion can be found in(Sepucha 1999).]

> A patient, Ms. Murphy, is getting a second opinion from an oncologist. She had surgery two weeks ago and now needs to make a decision about adjuvant therapy, but everything she has heard seems to suggest that the decision will depend on her lymph nodes. Thirty minutes after her appointment was scheduled to start, Ms. Murphy wonders if anyone knows that she is waiting. Alone in the room, the knot in Ms. Murphy's stomach keeps growing. She is anxious about what the doctor will say. She is hoping for good news from the pathology report but fears that her cancer has spread.
>
> At 3:25 p.m. Dr. Smith finishes seeing an unscheduled patient and quickly answers two pages. He glances at his schedule to see who is next, a new patient, Ms. Murphy, and then six more patients before 5 p.m. He glances at his watch and begins to flip through her chart and take furious notes. Her history is long and very complex, and to make matters worse, the copies of her records are not in order. With the hope that she can help him piece the history together, Dr. Smith grabs the chart and walks in to greet Ms. Murphy.

After a quick greeting, Dr. Smith immediately starts to ask many specific questions. During this time he barely looks up and instead is flipping back and forth through pages of her medical chart, asking for specific dates and things that have happened, taking notes.

Ms. Murphy wonders why she had to bring her things an hour early if he didn't even read them beforehand. She also was anxious to see if the doctor had her pathology report, so she can learn the status of her lymph nodes. Then she began to worry that he was stalling because it's bad news. After about 15 minutes, Dr. Smith looks up and starts to summarize what he just pieced together of her history. When he pauses, Ms Murphy finally asks a question,

Ms. Murphy: So what about the sentinel node pathology report?
Dr. Smith: All six of the other nodes were negative by microscopy, by looking at them. The special stain on those nodes is pending.
Ms. Murphy: That was supposed to be done today. It was supposed to have been done last Monday and the surgeon called yesterday and told me about the one you just mentioned and the other six were supposed to have been done today. Has anyone called about the pathology report?
Dr. Smith: I don't know. I just spoke to pathology now and we can call them again after we speak.
Ms. Murphy: Yes, that's the whole thing. We need that before we can talk.
Dr. Smith: Well to some extent, yes, it would certainly help us. But I can already tell you, the fact that the sentinel node is involved, it is a little hard to interpret because it is a new test, but nevertheless, it is positive. Currently our best estimate to assess the risk associated with that is to assume that it is the same as if it was positive by any other means.
Ms. Murphy: Now the surgeon spoke very differently about that, so I'm confused. The surgeon said it made no difference, the surgeon said that since there was no gross tumor, that it was as if it was negative.
Dr. Smith: Well that's why I want to stress that we don't know. This whole sentinel node procedure is new. That's when they get the node with the radioactive material and then finding the cancer, with the old technique, which is looking under the microscope or whether finding the cancer with this new technique, this special staining, we really don't know how this fits in.
Ms. Murphy: This is *really* anxiety provoking for me. The surgeon talks about it one way, you talk about it another way there is no definitive information for me here. Does anybody read my chart? Does anybody follow up on these phone calls? Does anybody care?

This scenario highlights several problems we consistently found during medical consultations. First, medical consultations lack some basic standards for a meeting—patients often do not know when consultations will start, or how long they will last. Lengthy waiting times and the uncertainty can create additional anxiety and frustration for patients coping with a recent diagnosis.

Physicians' overbooked schedules leave them barely enough time to read a patient's name on the chart before entering the room, and medical charts are disorganized and often missing important reports. Current standards for "the medical interview" focus on the clinical aspects of the case (Lipkin, Putnam et al. 1995). Medical charts reinforce this by containing only documentation of clinical information intended for other clinicians (e.g. as opposed to a list of patients' questions or descriptions of situations in a language patients can understand). Research suggests that by increasing the time spent reviewing the chart, Dr. Smith risks compromising Ms. Murphy's satisfaction and understanding(Smith, Polis et al. 1981).

Physicians are not the only ones who do not adequately prepare for the consultation. Patients often do not know what questions to ask. Even for patients who know what questions to ask, shyness, defensiveness and confusion can prevent them from interrupting the doctor (Sepucha, Belkora et al.; Roter 1977; Roter 1984) The lack of preparation prevents patients and physicians from voicing their questions and concerns. As a result, it is difficult to clear up confusion and decide on the best course of action.

Not surprisingly, physicians did most of the talking. Doctors spoke rapidly and moved quickly from one issue to another, often slipping into medical jargon. Neither the patients nor the physicians asked many questions, and the if they did, they were often closed questions that did not lead to further elaboration.

Patients did not leave the consultation with a record of the conversation that had been reviewed by the physicians for completeness or accuracy. Occasionally the patients (or a support person accompanying the patient) took notes. It was often unclear what had been decided and who was supposed to do what next. Patients often scheduled follow-up appointments or called the physicians to clarify issues previously discussed. In some cases things fell through the cracks (e.g. tests never got ordered, patients did not get enrolled in clinical trials). Physicians often complained that they needed to repeat the same information over and over to their patients.

From our exploration into the decision gap, three recurring themes emerged. Confusion, poor communication and overload consistently posed barriers for patients and physicians as they tried to make treatment decisions. Figure 1 synthesizes the specific problems and breakdowns that contribute to each of these themes. For example, patients often got confused by having to choose among undesirable alternatives and conflicting recommendations from physicians. Similarly, physicians often got overloaded trying to fill the multiple roles required during the consultation, (e.g. recorder, educator, facilitator, supporter, and expert). Confusion, poor communication and overload are dependent, e.g., a patient who is experiencing overload, is less likely to be able to voice her questions and concerns and communicate productively with her physician.

We shared our emerging analysis with patients and physicians, and reviewed previous consultation plans to see if the issue raised by patients could be linked to confusion, poor communication and overload. Many physicians would read through the summary

descriptions and transcripts, and recognized different aspects of the situation. But most still thought the data described other physicians and other patients, not their own interactions. Documenting these dynamics through audio-tapes and other means was critical, because, with a transcript, they could no longer tell themselves that it was someone else. As we analyzed their situation, they began to see things from a new perspective and became more receptive to the idea of changing their practices.

Consultation Recording Methods

Based on our qualitative analysis, our goal became to create a systematic method to make decisions and promote open, balanced communication between patients and physicians—and to do this without overwhelming or overloading patients and physicians. We wanted to create a process that bridged the gap between the knowledge physicians bring and the knowledge patients bring, in order to foster better interaction and help them create high quality, collaborative decisions during medical consultations.

Even with this focus, it was not immediately clear how to do that. Another breakthrough came when we decided to view the medical consultation as an important meeting. Neither patients nor physicians generally approach medical consultations as meetings, as neither usually schedules them, creates an agenda, or agrees together who is in charge. Medical consultations suffer from many of the unproductive dynamics commonly found in poorly run meetings, such as wheel spinning, layering of topics, defensiveness, and role conflicts (Doyle 1982). We found that during consultations physicians tended to take control of the discussion, repeat the same information, layer topics, interrupt patients, and

dominate. Overwhelmed and scared patients withheld their questions and concerns and withdrew from the discussion during consultations.

We found a simple and promising framework in Doyle and Straus' *How to Make Meetings Work* (1993). Doyle and Straus stress the need for four roles in every meeting. The *facilitator* is responsible for preparation and helps the group work together by making process suggestions (as opposed to content suggestions). The *recorder* publicly documents the ideas and questions that are voiced; the *group leader,* voices his or her concerns and questions and keeps the group focused on the agenda; and the *group members* voice their concerns and questions in a productive manner.

When we envisioned the medical consultation as a meeting with a facilitator and recorder, we saw the potential to improve consultations by reducing overload. A facilitator would help patients prepare for consultations (using Consultation Planning) and would make sure that patient's questions and concerns were addressed adequately. A recorder would free patients (and support person), enabling more attention for listening, understanding, and asking questions. The patient's preparation would help the physician better prepare for the consultation (e.g. if the patient indicates that the results of her pathology report is her number one question, the physician can make sure to track it down before going in). A record of the consultation in language patients can understand would (hopefully) reduce follow- and insure that patients leave with an accurate summary of biomedical information and next steps in their care.

However, as described by Doyle and Straus, the facilitator/recorder role did not provide much explicit help overcoming barriers to communication or making complex decisions. As a result, we used methods and tools from action science, which promotes open communication (Argyris 1993; Action 1996), and decision analysis, which provides structure and methods to evaluate complex decisions (Howard and Matheson 1989; Howard and Matheson 1989; Keeney 1992).

Consultation Recording methods introduced a facilitator/recorder into the consultation to help patients and physicians set an agenda, promote open communication, and create a written record of the consultation for all participants. Consultation Recording (CR) methods follow a five-step process. The flow of a consultation with CR is depicted in Figure 2. The medical chart and the patient's Consultation Plan are inputs to the consultation. Then Patients and physicians progress through the five steps of Consultation Recording.. Then patients and physicians receive a Consultation Record and the physician dictates a note for the medical chart.

The input to, process and output of the medical consultation took the following form: First, before the consultation, a trained facilitator helps patients prepare during a Consultation Planning session. (See Belkora 1997 for more details on Consultation Planning.) The Consultation plan includes details about the *process* patients want to follow to make decisions (e.g. "I want the doctor to make the decision but strongly consider my opinion.). It also articulates statements that detail the *content* patients want addressed such as, "I don't understand my pathology report, do I have invasive cancer or noninvasive cancer?"

During the consultation, the patient, physician and a facilitator proceed through the five phases of Consultation Recording. In the **Contracting** phase, the group agrees on a process and clarifies the roles (including the patient's preference for participation in decisions). In the **Setting the Agenda** phase, the patient and physician agree on a common focus on the content for the consultation. In **Mapping**, the patients and physicians discuss the agenda items. The facilitator intervenes to maintain an open and balanced conversation and records the discussion using flowchart software. For **Commitments**, the facilitator helps the patient and physician explicitly document the decisions that have been made and any next steps, to be done, when, and by whom. During the **Debriefing** phase, the facilitator prints out the Consultation Record, which participants review to make sure they have covered everything on the agenda and in the Consultation Plan. This debriefing helps to close to the meeting, allows the physician to carefully edit any medical information in the Consultation Record, and helps reinforce the commitments and decisions of the group.

The Consultation Record summarizes the discussion. The record structures the salient issues, captures the information relevant to the decision, including choices and probabilities, and connects the reasoning. The records also documents the decisions or commitments that have been made and the next steps that need to be taken. The record is not a lengthy transcription of the conversation, rather it is a one page summary that structures the key information necessary to make and implement treatment decisions.

Experiences working with patients

Before this project, we had approached improving collaborative decision making by helping patients prepare for medical consultations. We helped patients think through their questions and concerns and printed out flow charts, or Consultation Plans, for patients to share with their physicians. Throughout this experience several things became clear. First, patients need help organizing and prioritizing their concerns. Second, information alone is not enough to enable patients to communicate with their doctor or make decisions. Finally the interaction nuances and quality of doctor-patient relationships are important (Sepucha, Belkora et al.) in making and implementing decisions (Goffman 1967; Goffman 1981). However, until we started observing actual consultations of patients who had generated a Consultation Plan, we had little to no data on the impact in the consultation itself. After observing the medical consultation, we realized that preparing patients might not be enough to improve the quality of the collaboration. Although Consultation Recording methods sounded promising, we didn't know how an extra person in the room would impact the consultation, and whether a facilitator would improve or inhibit the consultation.

Karen's first case was difficult emotionally, socially, and medically. It highlights how the context and constraints of patients' lives influence their decision-making process. The patient was squeezed in at the end of a long day. Her appointment started around 6:30 and lasted until a little after 8pm. She was currently living in another country, and unsatisfied with doctors there, who told her she was going to die if she didn't have surgery immediately. She was a single parent, with two young kids who would need to be

relocated if she stayed in the US for treatment. Karen mostly recorded, and felt slightly overwhelmed by the intensity of the conversation. Half of the discussion focused on her lack of support system, her relationship with her ex-husband, job issues and financial concerns surrounding the location of her treatment.

The other half dealt with "medical" issues including describing her medical situation, choices for treatment, and what the risks and benefits of the choices were. Her cancer was advanced and she needed to decide whether she wanted to start treatment with chemotherapy or surgery. Although most breast cancer patients have several weeks to think through their decisions, she needed to start treatment soon. The best choice depended heavily on taking financial and social issues into account.

During the discussion Karen struggled to record all these issues (and connect them to her decision about treatment – which the patient indicated as her main goal for the consultation in her Consultation Plan). Karen only participated in the discussion to check that the medical information she was transcribing was an accurate reflection of the doctors' comments, and did not interrupt to inquire into the patient's understanding. Nor did she ask how certain topics might or might not have been relevant to the decision at hand. Eventually Karen improved at condensing the conversations and actively facilitating the discussions. The concerns about the presence of another person in the room lessened. And the physicians even started adopting some of the methods into their style, by reviewing the CP and asking to set an agenda, and asking for their to-do list before leaving the room.

Negotiating roles

The following discussion explores how emotions, interactions, and relationships were managed in this organizational context. Our experience provides suggestions and clues as to how researchers balance and negotiate multiple roles in a complex setting, how the interaction between researchers and partners changes over time, and how those changes impact the project's development.

Outsider or Insider

Karen's role at the BCC and relationships with the physicians and staff changed dramatically over the course of the project. She is not sure which came first—the change in her internal commitment or the change in the time she spent there. Initially, Karen felt the "distance" that is sometimes advocated in many researcher-subject relationships.. With only a few hours spent at the clinic every week, it was hard to get a good sense for the system and really build a collaborative feel.

Karen decided to become more of a regular presence, which changed the dynamics. . Doctors would pull her into consultations, or ask her to work with their patients. She observed many informal "backstage" conversations, and watched physicians talking in the hallway or the conference room—often right after a disconcerting situation had occurred. As time passed, she felt more invested in process, and connected to the people. Over the course of a few months, she accepted more ownership of the project, and felt a sense of responsibility for the quality of care delivered by the physicians and received by the patients.

Patient's advocate or physician's assistant

Before coming to UCSF, Karen had completed some research projects that we developed in collaboration with a local community resource center. The center was created and staffed mainly by breast cancer survivors, who articulated a powerful critique of the medical establishment, and advocated self-help and patient empowerment. The women at the center repeatedly told horror stories of misdiagnoses, of poor interactions, and of manipulative relationships in their experiences navigating breast cancer treatment.

The BCC showed us another version of the same story. Medicine is a "greedy institution (Coser 1974) that demands enormous commitments of time and energy of its practitioners (Cassell 1998). Physicians had no time for lunch, or even the restroom. We watched them decipher pages of cryptic handwritten notes and lab reports, frantically trying to find missing reports. We saw scheduling mistakes and overbooking, which demanded the impossible task of being in 2 places simultaneously. The physicians were busy, rushed, and constantly worried about time. They came to work early, stayed late, and worked on weekends to return pages, answer emails and attend to their patients' needs.

In this frenetic, complicated place, we also saw emotionally intense moments that occasionally happened when patients and their health care providers truly connected in a time of need (Scheff 1990). A hug or a "doctor's prescription" for a nice dinner or massage could change the relationship. In Karen's volunteer work at the community center, she suddenly found herself sympathizing with doctors and trying to offer some

explanations for some of the seemingly horrible behavior. This shift created ambivalence and internal conflict. Karen felt that her role was to help patients navigate this difficult time, make sure they were prepared and that the physicians answered their questions and concerns. On the other hand, she also felt that her role was to support the physicians so they could develop their abilities to connect with their patients. Often during the consultation, these goals came into conflict. Consultation Recording methods and the reliance on a "neutral" facilitator role did not adequately address this tension. And although the methods did espouse to support both patients and physicians, in practice the facilitation and recording were primarily directed at supporting the patients by making sure they got what they needed from the consultation.

From Research Project to Program Implementation

During Karen's dissertation defense, a professor challenged that the results from the experiment were due to her unique skills and capabilities, something he called "the Karen Effect." We disagreed, believing that the necessary skills to facilitate and record consultations can be taught and learned by others. In 1999, The BCC director decided to create a full time program to implement Consultation Planning and Consultation Recording as a free service for all patients and physicians at the clinic. The following discussion explores how the implementation process unfolded and some of the unanticipated challenges of we encountered to create organizational change.

As an applied qualitative sociologist with experience in community-based and ethnographic research, Caryn Aviv came to the Breast Care Center in September 1999. After a month of observation, she began to work with patients and physicians on a daily

basis. She also kept an ethnographic field journal to record interactions, and the emotional work (Hochschild 1983; Scheff 1990) she experienced with patients, family members, and physicians. Adding a sociologist brought a new perspective and different questions to the project.

In contrast to engineering and decision analysis, sociology begins with different assumptions about the social world (Collins 1992), often uses inductive methods to conduct research (Glaser and Straus 1967), and proposes alternative ways to create and evaluate change (Gottfried 1996). Engineers, using deductive, quantitative research methods, develop practical and efficient improvements to existing systems. Decision analysts strive for clarity and consensus, tend to view decisions as individualistic, rational choices, and often consciously ignore social and historical contexts that drive decision-making.

Qualitative sociological research often aims for "thick description," rich details, and analysis of natural settings, actors, relationships, and processes where power and knowledge are exercised unequally (Smith 1989). Academic sociologists working in this tradition advocate recommendations for structural changes in society, but they often fall short on proposals for practical implementation. Sometimes the goal of qualitative research involves suggesting social change (DeVault 1999; Stacey and Thorne 1985), and sometimes it merely aspires to describe current conditions to improve our understanding of social settings. Applied sociologists take the insights of this discipline, and attempt to create small-scale change within organizations, often using participatory research

methods. The addition of a sociological perspective required a learning curve for all participants, to create a shared understanding of the conditions of the clinic, a common conceptual vocabulary, and agreement on how to move forward with the program.

Despite these disciplinary differences, we saw the traditions of action research and applied sociology as complementary and synergistic. As Caryn observed medical consultations and slowly began to provide collaborative care services, the challenge of transition from research to clinical practice raised several issues. How can we pass along the skills for an emerging, innovative method that combines multiple disciplines How can we integrate a pilot research project into the everyday clinic workflow with busy physicians and anxious patients? We focus on two issues in the implementation process, which have identified new areas to explore as we adapt these methods and improve our decision support tools. One area involves passing along important skills required for effective Consultation Recording. The second concerns the ambiguity and role negotiation of the Consultation Recorder.

Learning Consultation Recording and Facilitation Skills

Initially, Caryn struggled with the practical aspects of Consultation Recording. How can one write the details about a patient's case that physicians thought was most important (which varies from physician to physician), in a way that provides value to the patient? How does one determine what that value might be for patients, whose goals and needs differed from physicians? As she watched doctors and patients interact, Caryn likened Consultation Recording to spear fishing. During a consultation, the flow of information

can rush by quickly, like a swiftly moving stream. Consultation Recorders have to develop sufficient skills to capture succinct chunks of the most vital information, statistics, patient preferences, and commitments - in other words, to carefully watch the stream and to throw their spears effectively to catch the right fish. Simultaneously, Consultation Recorders keep the discussion on track, check for patient understanding, help patients and physicians articulate decisions and outline concrete next steps. Juggling all these communication and writing tasks proved difficult and challenging.

With her background in symbolic interaction and ethnography, Caryn had learned to provide as much detail, nuance, and "thick description" (Geertz 1974, Lofland and Lofland 1995) as possible to understand a social setting. With thick description as her framework, she did not know what to write on Consultation Records that would meet the diverse needs of patients and physicians, and wondered how she could fit everything on one page. Her stated goal was to structure and record decisions, and capture elements of conversations. But she also wanted to richly describe and document interactions, which created unwieldy consultation records and differed from the recording focus. In contrast, the physicians wanted a clean, concise, and succinct Consultation Record that mapped out decision trees. Caryn's early Consultation Records suffered from "too many spears," catching all sorts of fish.

In the early consultation records, the pages were so cluttered it was difficult to know what to focus on. Additionally, the decision patients and physicians made about treatment was assumed, but not explicitly articulated. Sometimes physicians wanted clarity, brevity, and a focus on the presentation of statistical risks, while patients wanted comprehensive

explanation and narrative to understand their choices. After trial and error, we realized Consultation Recorders need to balance and reflect the needs of both patients and physicians. They have to learn what important information needs to be on the record, and how much (or how little) description to include. They also need training and practice to learn the "filtering" skills to identify and address those different needs. One year later, Consultation Records look quite different (Figure 3).

The changes in Consultation Records over time suggest two insights. First, these skills can successfully be passed on. Caryn learned to anticipate standard information physicians give about diagnosis descriptions, surgery and chemotherapy side effects, and recovery. Filling in these "data fields" quickly gives her more time to facilitate and summarize the discussion between patients and physicians about treatment options and preferences. Second, she learned that trying to create a record of thick description hampers her ability to actively facilitate the conversation, and is a more appropriate strategy for a participant observer whose sole focus is to conduct fieldwork. Caryn's Consultation Records reflected the learning curve in filtering, but also in negotiating her role as a facilitator/recorder and ethnographer in the applied setting.

Negotiating Roles

The Consultation Recording model stipulates a neutral role in meeting facilitation (viewing both patients and physicians as participants who need help). Caryn initially found the neutrality stance perplexing and uncomfortable, given her training in medical sociology. That literature extensively documents physician dominance in conversations

(Waitzkin 1997), the reliance on professional distancing strategies of detachment, objectivity, and cultivated neutrality (Foucault 1994; Lupton 1994) and the persistence of inequalities based on age, race, economic class, sexual orientation, and gender (Lorber 1997; Balshem 1993). She questioned the assumption of neutrality, because power relationships between patients and physicians are so inherently unequal, especially when patients are women (West 1993). Given this inequality, shouldn't the Consultation Recorder encourage more patient participation? Shouldn't the Consultation Recorder encourage physicians to listen more, and dominate less?

In addition to these theoretical and ideological questions about negotiating roles, there were pragmatic tasks to address. Karen Sepucha moved across the country. Caryn Aviv was on her own to integrate Consultation Recording and expand the number of physicians who used it, while Karen provided advice and support off-site. How did Caryn want to play the role of the Consultation Recorder, particularly with physicians who had never used the methods? Was she a patient advocate, neutral observer, or physician assistant?

Patients and physicians sometimes seemed to want different things, and Caryn brought more of a patient advocacy model to her work (Aviv 1997). Some physicians asked her to perform administrative tasks that facilitated their work (and increased their appreciation for having someone else in the room), but required her absence from the consultation room during the discussion. Caryn worried that physicians occasionally enlisting her as their assistants blurred the role and detracted from her facilitation and

recording responsibilities. Some patients wanted her to attend all their consultations as a patient advocate even after they had made decisions about treatment. Would working with patients throughout their treatment process dilute the original intent of Consultation Planning and Recording? These questions about role clarification and potential opportunities for more tools and support are areas we will explore in future research as we refine collaborative care methods and train others.

The implementation lessons we learned are twofold. Individuals bring different ideologies, agendas, experiences, and theoretical prisms through which to understand the dilemmas of collaborative decision-making. An additional disciplinary perspective added complexity to the program, but also provided another window through which to critically view the context of decision-making and patient-physician interaction. Second, negotiating a new role, program, and staff member into a busy clinic and the traditional dyad of patient-physician relationships is by no means easy. With a role model (Karen Sepucha) mentoring long distance, Caryn Aviv learned by doing, made mistakes, and solicited feedback. Combining applied sociology and Consultation Recording presented a struggle to blend divergent roles, theoretical frames, and practical approaches. We learned that in order to move from novice to skilled recorder/facilitator, implementation requires building agreement about roles, extensive observation of current conditions, and systematic training in theory, methods, and skills.

Collaborative Care Provides Support for Patients

We currently collect quantitative data from patient surveys that are completed after Consultation Recording, which assess satisfaction with consultation planning and satisfaction with the physician consultation. We have also conducted several focus groups to collect qualitative data and suggestions for program improvement. Our preliminary data suggest that patients strongly appreciate and benefit from the Program for Collaborative Care. Patients have written that they felt relieved another person was in the room to step in when they were feeling lost, overwhelmed, or scared. Others have provided detailed impressions of their experience and suggestions for bringing the program to other breast cancer clinics.

Two patients commented,

> *"I think the most helpful aspect was what's called collaborative care. There's a woman who, before my appointment, she sat with me and asked me a lot of questions [about] what I knew and elicited the information that I had already found out, and then did a flow chart. We went in to see the doctor and she was there and she took notes on her laptop. She reminded me if there were questions that I had forgotten because you do. You know, all of a sudden you're hearing this news from the doctor and you forget what to ask. And then she had a flow chart at the end of all the information that I had been given, so I think that was the most helpful part." Allison S.*

> *"When I had the recurrence, I went to a medical center for a second opinion. I discovered that there is a space in a medical community where a group of people developed a system to support a patient and to listen to a patient and to treat a patient as an individual. That was so surprising, so astonishing to me that in fact it made me stop and realize that there was an absolute another way of being treated in the medical community. That in fact I could get the expertise and the compassion that I needed to take me through whatever choices that I made." Karen H.*

Our data suggest that the Program for Collaborative Care improves the decision-making process for patients by providing timely support and structure to their medical consultations. We plan to create more comprehensive methods to evaluate the Program and assess how we can better meet the needs of patients and physicians, through survey revision, additional focus groups, and other assessment methods.

Collaborative Care as a Disruptive Innovation for Physicians

The physicians' response to the Program for Collaborative Care varied. Currently, two surgeons, four medical oncologists, and one radiation oncologist have used the program in their medical consultations. Reactions to the program have ranged from overt skepticism to indifference to enthusiastic support. We have learned that building consensus about the practical implementation of a new program and its potential benefit is critical to organizational change.

We conducted individual interviews with each physician in May 2000, to assess the implementation process and solicit direct, critical feedback. From the physician perspective, Consultation Planning and Recording methods raises issues of infringing upon professional autonomy, the effectiveness of physicians' interaction skills, and the question of disruptive intrusion into the medical consultation. As Caryn struggled with the Consultation Recorder's role, so did physicians. Some physicians wanted Consultation Recorders to step in frequently to clarify, keep conversations on track, and summarize, while others preferred an observer/recorder who did not interrupt the flow of conversation. Some physicians seemed defensive or irritated when she accompanied

patients into the consultation. One physician said that while Consultation Plans were useful for anticipating patients' questions and concerns, Consultation Recording implied a deficit in her own communication skills. Having a third party, she explained, undermined her authority as a physician and facilitator, and she didn't think she needed it. Consequently, Caryn adapted the level of active facilitation to address physician needs, and in some cases, abandoned facilitation altogether to promote more physician support for the program. While this strategy lessened conflict, she sometimes questioned whether her work actively promoted more collaborative decision-making between physicians and patients.

Consultation Recording requires establishing cooperative relationships with physicians to encourage their participation, while paradoxically challenging their unquestioned authority. To facilitate a productive meeting, Consultation Recorders often need to interrupt, clarify, and reiterate complex information, which can raise the hackles of physicians who might have different ideas about the definition of non-intrusive facilitation. If the Program for Collaborative Care becomes implemented elsewhere, Consultation Recorders need to develop relationships with the physicians, to explain the program, observe diverse interaction styles, and solicit suggestions for how to best meet their particular needs prior to stepping into the Consultation Recording role. They will need to accommodate to individual physicians' needs and interaction styles to work effectively and collaboratively. Variation in physician interaction style requires flexibility, adaptation, and a wider array of tools at their disposal to promote collaborative decisions with patients.

From Implementation Back to Research

After one year of implementation, we have identified several areas for future research to improve our tools and methods for critical medical decision-making consultations, including. These include comprehensive patient support, more physician preparation and logistical support, better tools to record consultations, and better ways to translate clinical evidence into usable patient information. Based on the feedback from physicians, we realize that they need more help to engage patients collaboratively. Consultation Recording is time-intensive, challenging to implement with physicians, and requires significant time and resources to train facilitators. One goal is to improve the quality of collaborative breast cancer treatment decision-making by improving the decision support tools physicians use in their consultations. Future research will focus on how to transition collaborative care to non-facilitated tools and methods, in order to reduce cost, streamline the process, take advantage of new technologies, and promote easy replication.

We have also identified a gap in the decision and emotional support for women with metastatic breast cancer (which has spread to other parts of the body) and their physicians, who often face very different decisions about treatment and end of life issues (Mamo 1999). The culture of medicine and patient's fears about their own mortality pose challenging barriers to openly discussing the risks and benefits of end stage treatment options and feelings about end-of-life issues (Larson 2000; The 2000). Future research will use ethnographic and action research methods to examine how oncologists and patients currently navigate this process, to assess how collaborative care, in conjunction

with new emotional and psychological support interventions, might address the needs of patients, physicians, and families facing metastatic cancer and the dying process.

We have found action research to be a useful approach to the formulation, implementation and assessment of interventions in breast cancer decision-making. Our partnership between researchers and clinicians has yielded fruitful interventions that try to help patients and physicians navigate the complexities of communication, information, and treatment options. Action research provided a framework to describe the challenges patients and physicians face in making treatment decisions. It also helped us develop a viable intervention (Consultation Recording) with a motivated client based on our analysis of patient and physician needs. Finally, we used this approach to implement the intervention into a busy clinic, and to evaluate the transition from research to a full-time program. We identified some key tasks that are necessary to move an action research project from research into practice, to insure successful implementation that sticks. We learned about core skills necessary to train future effective Consultation Recorders, how to identify and recruit patients, how to incorporate physicians, and how to modify our methods to fit physician style. Action research also helped us identify new areas of need for better patient and physician support.

This case study makes two claims. First, an action research framework can successfully help researchers and their clients identify needs, develop and implement interventions, and assess their value in changing the status quo. Our experience suggests that this approach (while by no means easy) helped us address a significant, persistent problem in

health care, changed how patients and physicians interact, and facilitated more collaborative decision-making. Second, action research can create a feedback loop to further identify and address emerging needs in an applied health care setting. If they successfully manage the tensions between academia and organizational needs, sociologists, anthropologists, and other health researchers can pragmatically address important social problems. Action research can be used to expand research projects beyond their initial parameters, sustain research relationships, and affect the way patients and physicians negotiate care in rapidly changing, complex social settings.

Acknowledgements

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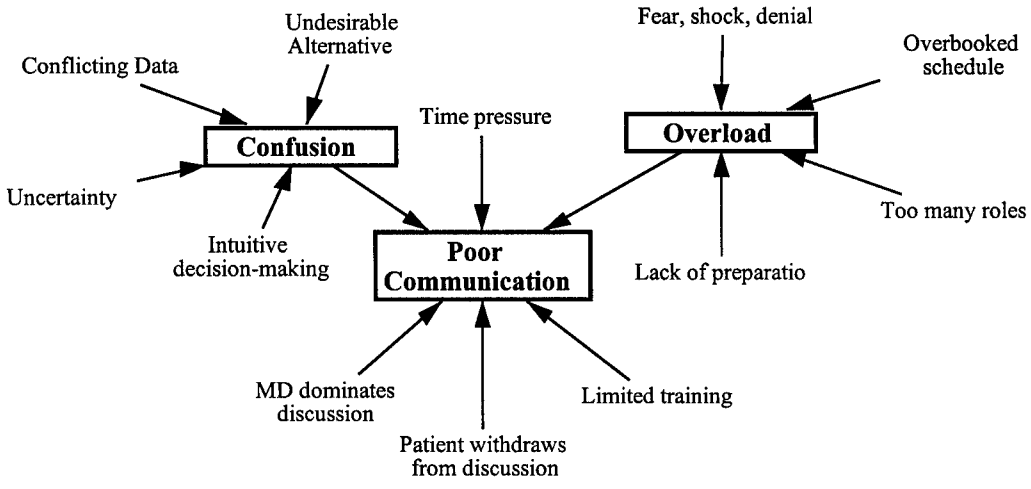

Figure 1: Three main barriers to collaborative decision-making in breast cancer consultations and the factors that contribute to these barriers. [Reproduced with permission from(Sepucha 1999).]

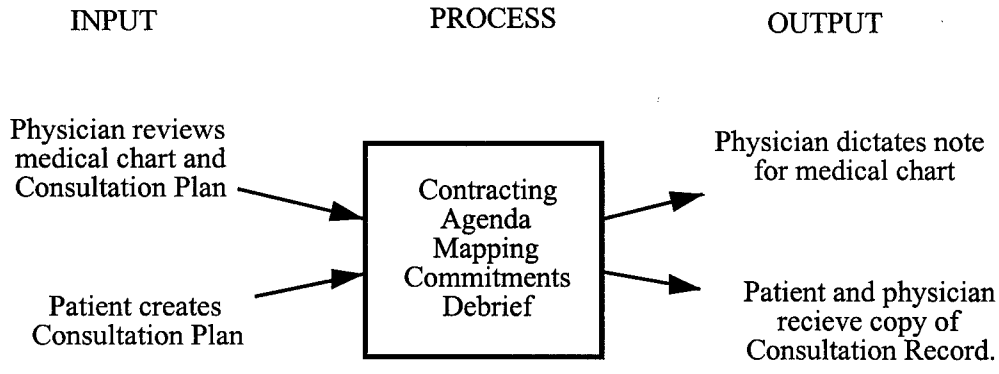

Figure 2: The Flow of a Medical Consultation with Consultation Recording. [Reproduced with permission from(Sepucha 1999).]

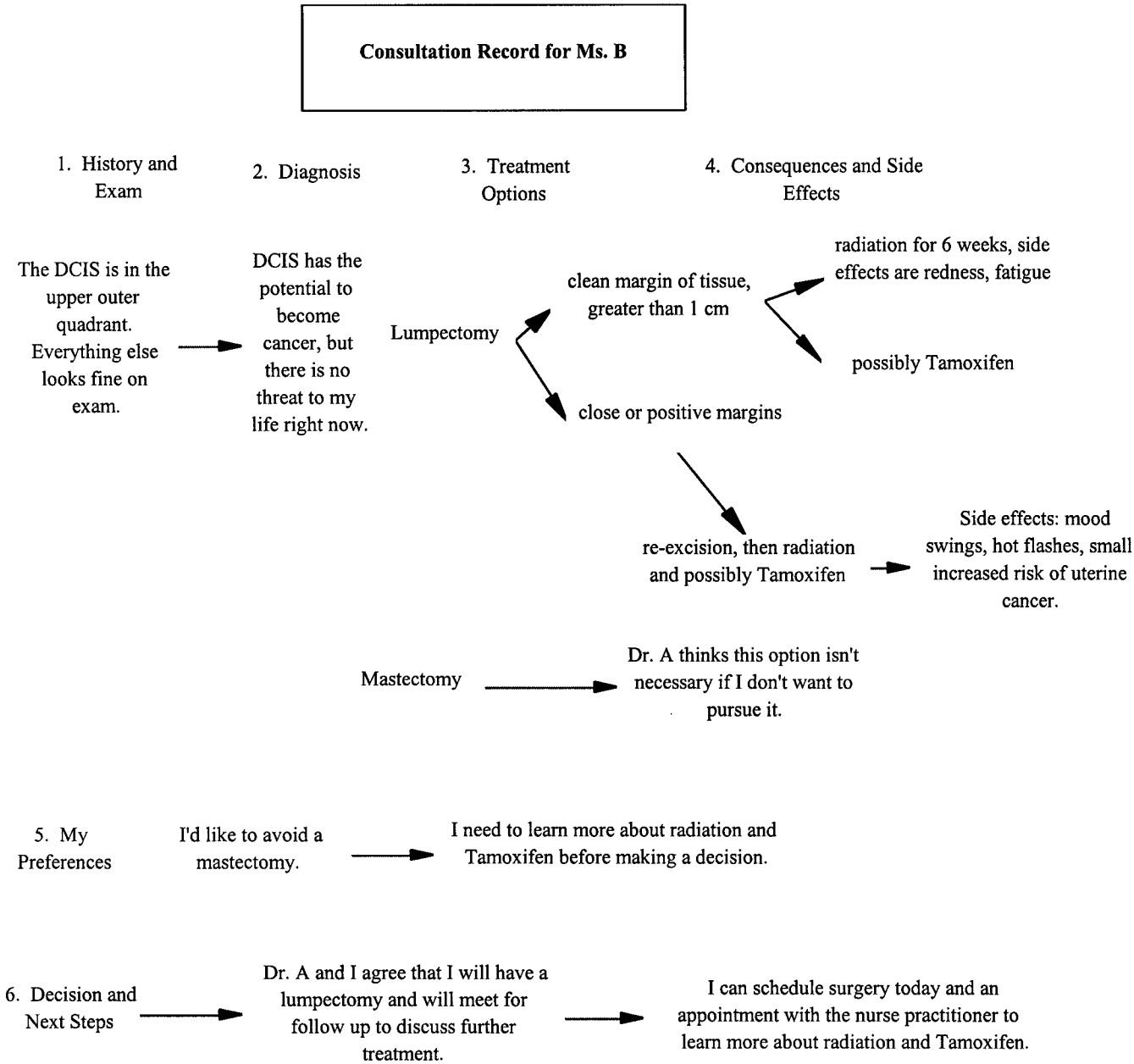

Figure 3: A Consultation Record after One Year of Program Implementation

Clinical Trials In Breast Cancer - A Survey For Patients With Breast Cancer

This survey is being given to patients with breast cancer. It is designed to understand concerns that patients may have about **clinical trials**, or research involving patients. Some questions may not reflect your particular situation. Please answer these questions as best as you can.

Please circle the most appropriate number ranging from **1** (**strongly disagree**) to **5** (**strongly agree**) or place a mark in the last column if you do not know or do not have an opinion about the particular statement. Also indicate how important this issue is **to you** by circling the most appropriate number ranging from **1** (**not important**) to **5** (**very important**). Thank you!

		Strongly Disagree→→→→→→→→Strongly Agree					I Don't Know
1.	I would like to participate in a clinical trial, but would not be able to because English is not my native language. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
2.	I have enough information about clinical trials to make a good decision about being in a trial *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
3.	Clinical trial information is available on the Internet, and I would use it to find out more about available trials. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
4.	Being in a clinical trial would limit my choices for future treatment. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
5.	I will get my needed treatment as soon as possible if I am on a trial. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
6.	In a clinical trial, I am able to see my regular doctors. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
7.	If my doctor does not suggest looking into clinical trials, they are probably not right for me.	1	2	3	4	5	
8.	My doctor may not want me to participate in a trial *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
9.	I may not have all my questions answered if I am in a trial. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
10.	If I am in a trial I, may have to spend extra time having more tests and doctor visits. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
11.	On a clinical trial I may have to spend more money on transportation and childcare and may lose more income due to time away from work than I would on standard treatment. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	

		Strongly Disagree→				Strongly Agree	I Don't Know
12.	If I am in a clinical trial, my insurance company might not cover the cost of my treatment and I might have to pay more money myself. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
13.	I may have more harmful side effects, or become more sick, if I am in a clinical trial than I would with standard treatment. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
14.	I would have more stress if I participated in a clinical trial than if I had standard treatment. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
15.	I would not want to participate in a clinical trial because it would be a constant reminder that I have breast cancer. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
16.	Psychological and quality of life issues would be better addressed on a clinical trial than on standard treatment. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
17.	New drugs and treatments for breast cancer may not be much better than older, standard drugs and treatments. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
18.	If I am in a trial that looks at a new drug, I might have worse side effects. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
19.	If I participate in a randomized study, where I am assigned to one of two or more treatments by chance, my treatment might not be as good as regular treatment. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
20.	I would like to know what treatment I am signing up for and therefore would not want to be randomized, or assigned to one of two or more treatments by chance. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
21.	I would have no control over my medical decisions if I participated in a clinical trial. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
22.	Participating in a clinical trial would make my medical records less confidential. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
23.	The area of alternative medicine (such as holistic, homeopathic or herbal medicines) should be studied in clinical trials. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
24.	There is not enough known about alternative medicine for me to participate in a trial testing alternative medicine. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	

		Strongly Disagree→→→→→→→				Strongly Agree	I Don't Know
25.	I would not want to be in a study of alternative medicine where I would not able to choose my own treatment. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
26.	A clinical trial can test the effects of alternative medicine combined with regular medicine. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
27.	A study with alternative medicine would limit my choices for regular therapy in the future. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	
28.	If I was in a study of alternative medicine, my doctors, friends and family may think I made a bad decision. *How Important is this to you Not 1 2 3 4 5 Very*	1	2	3	4	5	

University of California, San Francisco

96754: Questionnaire about Clinical Trials for Breast Cancer

Consent To Be A Research Subject

PURPOSE AND BACKGROUND

Dr. Debasish Tripathy and associates are conducting a research study to determine how patients feel about clinical trials and the investigation of new treatments for breast cancer. New developments in treatments for breast cancer must be understood and proven through a series of studies called clinical trials. These studies involve giving new treatments to patients and examining the effect on improving patients conditions as well as side effects of treatments. Sometimes, one treatment is compared to another in a kind of trial called a randomized trial where the patient will receive one of two or more treatments and is assigned to their treatment by chance. Neither the patient nor the doctor can choose which treatment will be given in this case. Newer drugs and alternative or traditional medicines also need to be examined in clinical trials before they can be shown to be effective, or found not to work. Most patients with breast cancer do not participate in clinical trials for many different reasons. This study will attempt to find out what those reasons are by asking certain questions to patients with breast cancer. My medical records will be reviewed to see if there is a connection between my condition and the reasons for not participating in clinical trials. I am being asked to participate in this study because I have breast cancer.

PROCEDURES

If I participate in this study, the following events will happen:

1. I will be given a questionnaire about clinical trials that will take about 15 minutes to fill out.

2. My medical records will be reviewed to provide information about my background and my medical health.

RISKS AND DISCOMFORT

Some of the questions in the questionnaires may make me uncomfortable or upset, but I am free to decline to answer any questions I do not wish to, or discontinue my participation at any time.

FINANCIAL RISKS

I will not be charged or incur any cost for participating in this study.

BENEFITS

I will receive no direct benefit from being in this study. It is hoped that the information I and others provide will help to understand some of the concerns patients have about clinical trials.

ALTERNATIVE

I may decide not to participate in this study. My treatment options and treatment will not be affected.

REIMBURSEMENT

I will not be reimbursed for my participation in this study.

QUESTIONS

The member of the staff who signed below has discussed this study with me and I have been given the opportunity to ask questions which have been answered to my satisfaction. If I have any further questions regarding this study, I should contact Dr. Debasish Tripathy at 415-885-3700.

If for some reason I do not want to call the investigators, I may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. I may reach the Committee office between 8:00 a.m. and 5:00 p.m. by calling (415) 476-1814 or by writing: Committee on Human Research, P.O. Box 0962, University of California, San Francisco, California, 94143.

CONFIDENTIALITY

Participation in research will cause a loss of privacy, but my medical records will be kept as confidential as is possible. No individual identities will be disclosed in any report or publication resulting from this work. All or part of my medical records may be reviewed and analyzed by the U.S. Department of Defense (Sponsors of this project), and representatives of the University of California responsible for overseeing research.

CONSENT

Participation in research is voluntary. I have the right to withdraw from the study at any time, and withdrawing will not jeopardize my future medical care. My participation may be ended at any time with or without my consent. If I wish to participate, I should sign below. I have been given a signed copy of the consent form.

_____ _____

Signature of Participant Date

_____ _____

Signature of Person Obtaining Consent Date

I certify that this is an accurate and true translation.

_____ _____

Signature of Translator's Translator's Typed

_____ _____ _____

Address Telephone TELEFAX Number

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S
BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,
2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5) To be told of the other choices I have and how they may be better or worse than being in the study,
6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7) To be told what sort of medical treatment is available if any complications arise,
8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9) To receive a copy of the signed and dated consent form,
10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, Box 0962, University of California, San Francisco, CA 94143.

Call 476-1814 for information on translations.

12\91

Clinical Trials in Breast Cancer - A Survey for Caregivers

This is an anonymous survey being given to care providers that work with patients who may be eligible for clinical trials. We are attempting to identify potential obstacles to accrual to trials based on concerns that caregivers have regarding various issues. Please circle the most appropriate number ranging from **1 (not significant)** to **5 (very significant)** as they apply to your level of concern across the spectrum of past and present clinical trials in breast cancer with which you are familiar.

		Not Significant				Extremely Significant
1.	The control, or standard arm in a controlled trial may offer inadequate therapy for some patients.	1	2	3	4	5
2.	Eligibility criteria for trials are too restrictive.	1	2	3	4	5
3.	Controlled trials may contain an experimental arm that is likely to produce a worse outcome or have worse toxicity without any benefit.	1	2	3	4	5
4.	Important areas of uncertainty in breast cancer treatment are not addressed by clinical trials.	1	2	3	4	5
5.	New approaches being studied in clinical trials are not fundamentally different from current standard care and are not likely to show clinical improvements in breast cancer.	1	2	3	4	5
6.	The clinical trial process is too slow to answer questions as treatment options and new agents emerge.	1	2	3	4	5
7.	New agents may have unacceptable short and long term side effects and clinical trials are not designed to properly assess these side effects.	1	2	3	4	5
8.	New agents may be found to have very small benefits at costs that neither patients nor the health care system in general can afford.	1	2	3	4	5
9.	Clinical trials do not study cost effectiveness.	1	2	3	4	5
10.	Patients may already want treatment with one of the arms and would not want to be randomized.	1	2	3	4	5
11.	Clinical trials may be too inconvenient and time consuming for certain patients.	1	2	3	4	5
12.	The clinical trial process is too stressful for the patient.	1	2	3	4	5
13.	Clinical trials cost too much for the patient.	1	2	3	4	5
14.	Enrolling a patient on a trial can interfere with other aspects of medical care.	1	2	3	4	5
15.	Enrolling a patients on a trial may delay needed therapy for breast cancer.	1	2	3	4	5
16.	Participation in a clinical trial may cause the patient to lose follow-up with or change care from the referring specialist and primary care providers.	1	2	3	4	5
17.	A patient's quality of life may not be reliably measured in a clinical trial.	1	2	3	4	5
18.	Participation in a clinical trial assessing a new agent may limit future treatment options.	1	2	3	4	5
19.	Patients participating in clinical trials may not directly benefit from them.	1	2	3	4	5

		Not Significant				Extremely Significant
20.	Consent forms and protocols may be difficult for many patients to understand.	1	2	3	4	5
21.	Consent forms may be misleading to patients and may not discuss standard treatment options.	1	2	3	4	5
22.	Many patients want to participate, but are not eligible for any clinical trials.	1	2	3	4	5
23.	Enrolling a patient on a trial can take extra staff time and add cost to the practice.	1	2	3	4	5
24.	I do not have enough information on clinical trials readily available to offer trials to all eligible patients.	1	2	3	4	5
25.	The area of alternative medicine (such as holistic, homeopathic or herbal medicines) should be studied in clinical trials	1	2	3	4	5
26	Not enough is known about alternative medicine to yet justify clinical trials in this area.	1	2	3	4	5
27.	Some patients' beliefs in alternative medicine are too strong for them to participate in clinical trials examining this approach.	1	2	3	4	5
28.	Clinical trials may not be able to test standard approaches in conjunction with alternative medicine.	1	2	3	4	5
29.	Clinical trials in alternative medicine may interfere with other aspects of patient treatment and care.					
30.	Participation in a clinical trial with alternative medicine may cause a loss of credibility to the patient and the patient's caregivers.	1	2	3	4	5

Please answer the following demographic questions by circling the correct answer or filling in the blank.

31. How old are you?

25-30 30-35 35-40 40-45 45-50
55-60 60-65 65-70 70 +

32. What is your area of practice/interest?

Nursing Surgery/Surgical Oncology Medical Oncology
Radiation Oncology Reconstruction Surgery Radiology
Pathology General Medicine Lab Research Only
Other (please specify)_____

33. Do you currently counsel patients about clinical trials in any way?

Yes____ No____

34. If yes, how many patients do you counsel in one year? _____

35. If you are a clinician, what is your practice setting?

Academic Practice Private/Outpatient Practice HMO
Hospital Practice

Please answer the following questions.

1. What areas of uncertainty in breast cancer treatment are well represented in clinical trials?

2. What areas of uncertainty in breast cancer treatment are poorly represented in clinical trials?

3. What are the major problems with eligibility criteria in clinical trials?

4. What are the principle administrative problems with clinical trials?

5. What are the principle cost problems with clinical trials?

6. List some major problems with Phase I/II trials assessing new drugs:

7. List some problems and concerns you may have with trials examining alternative medicines:

Physician Attitudes to Clinical Trials

		Overall Mean Score ‡ P	Subgroups Significant Differentials§
Attitudes to Clinical Trials in General			
Issues regraded as impediments			
10	Pt may prefer one arm, refuse randomization	4.1 ***	
23	CT takes staff time	4.0 ***	
11	Inconvenient, time-consuming for some pts.	3.6 ***	
Issues regarded as not being impediments			
15	May delay needed therapy	2.0 ***	Private practice
13	Cost too much for pt.	2.2 ***	
7	Side effects of new agents not assessed	2.3 ***	Older
18	Limits future Tx options	2.3 ***	
16	Patient may be lost to referring MD.	2.4 ***	Private practice
14	Interferes with other aspects of care	2.4 ***	Private practice
24	Not enough information to offer CT	2.5 **	Private practice
6	CT process is too slow to answer questions	2.6 **	
5	New aproaches are not different from standard.	2.6 **	
17	Quality of life not reliably measured	2.7 *	
12	Too stressful for pt.	2.7 *	Private practice
Issues with no significant overall agreement or disagreement			
4	Important areas of uncertainty not addressed	2.7	
19	No direct benefit to patients on CT	2.7	
9	Do not study cost effectiveness	2.8	
21	Consent forms misleading	2.8	Private practice
8	Small benefits or new Tx relative to costs	2.9	
3	Experimental arm may do worse	3.0	
2	Eligibility criteria are too restrictive	3.0	
1	Control arm may offer inadequate Tx	3.1	
20	Consent difficult for pt. to understand	3.2	
22	Many pts. Are willing but not eligible	3.2	Counsel patients
Attitudes to Clinical Trials of Alternative Medicine			
Overall, respondents did not find impediments to CT of Alt. Med.			
Issues regarded as not being impediments to CT of Alt. Med.			
26	Not enough is know to justify CT	2.3	
30	Loss of credibility to pt. and her MD	2.4	Older
28	CT can't test standard along with Alt. Med.	2.6	
Respondents neither agreed nor disagreed on the following			
25	*CT should study Alt. Med.*	2.7	Older, non-HMO
27	Some patient's beliefs are too strong	2.9	
29	Interferes with other aspects of Tx	2.9	Older

For questions printed in *italics*, low scores indicate impediments. In other questions, high scores indicate impediments

‡ Mean response on a scale where 1=Disagree strongly, 5=Agree strongly.

‡ Significant differences from the midpoint (3) are noted by * (P<0.05), ** (P<0.01) or * (P<0.001).**

§ Where a respondent subgroup is listed, there was a significant correlation between an attribute and response to the question.

§ In all cases, the subgroup listed is the one reflecting higher impediment to CT.

UCSF Breast Care Center. Research supported by a grant from the Department of Defense.

Following are the scores of the survey questions given to caregivers listed in order from highest to lowest. The highest possible score was a 5 which meant that the caregiver thought the issue was extremely significant. A score of 1 meant that the issue was not significant.

The left column contains the rank of scores from 1 to 15 (highest to lowest). When questions received the same score, they were given the same rank number and listed in order of how they appeared on the survey. The number in parenthesis is the number of the original question. The next column contains the question that the caregivers scored. The third column is the mean score the question received. The last column indicates how many people answered the question.

Rank (original ? #) / Question given to caregiver		Mean Score / Count	
1 (10)	Patients may already want treatment with one of the arms and would not want to be randomized.	4.1	67
2 (23)	Enrolling a patient on a trial can take extra staff time and add cost to the practice.	4	66
3 (11)	Clinical trials may be too inconvenient and time consuming for certain patients.	3.6	67
4 (22)	Many patients want to participate, but are not eligible for any clinical trials.	3.2	66
4 (20)	Consent forms and protocols may be difficult for many patients to understand.	3.2	66
5 (10)	The control, or standard arm in a controlled trial may offer inadequate therapy for some patients.	3.1	67
6 (2)	Eligibility criteria for trials are too restrictive.	3	67
6 (3)	Controlled trials may contain an experimental arm that is likely to produce a worse outcome or have worse toxicity without any benefit.	3	67
7 (8)	New agents may be found to have very small benefits at costs that neither patients nor the health care system in general can afford.	2.9	67
7 (27)	Some patients' beliefs in alternative medicine are too strong for them to participate in clinical trials examining this approach.	2.9	65
7 (29)	Clinical trials in alternative medicine may interfere with other aspects of patient treatment and care.	2.9	60
8 (9)	Clinical trials do not study cost effectiveness.	2.8	67
8 (21)	Consent forms may be misleading to patients and may not discuss standard treatment options.	2.8	66
9 (4)	Important areas of uncertainty in breast cancer treatment are not addressed by clinical trials.	2.7	67
9 (12)	The clinical trial process is too stressful for the patient.	2.7	67
9 (17)	A patient's quality of life may not be reliably measured in a clinical trial.	2.7	67
9 (19)	Patients participating in clinical trials may not directly benefit from them.	2.7	67
9 (25)	The area of alternative medicine (such as holistic, homeopathic or herbal medicines) should be studied in clinical trials	2.7	66
10 (5)	New approaches being studied in clinical trials are not fundamentally different from current standard care and are not likely to show clinical improvements in breast cancer.	2.6	67
10 (6)	The clinical trial process is too slow to answer questions as treatment options and new agents emerge.	2.6	67
10 (28)	Clinical trials may not be able to test standard approaches in conjunction with alternative medicine.	2.6	64

11 (24)	I do not have enough information on clinical trials readily available to offer trials to all eligible patients.	2.5	66
12 (14)	Enrolling a patient on a trial can interfere with other aspects of medical care.	2.4	67
12 (16)	Participation in a clinical trial may cause the patient to lose follow-up with or change care from the referring specialist and primary care providers.	2.4	67
12 (30)	Participation in a clinical trial with alternative medicine may cause a loss of credibility to the patient and the patient's caregivers.	2.4	65
13 (7)	New agents may have unacceptable short and long term side effects and clinical trials are not designed to properly assess these side effects.	2.3	66
13 (26)	Not enough is known about alternative medicine to yet justify clinical trials in this area.	2.3	66
13 (18)	Participation in a clinical trial assessing a new agent may limit future treatment options.	2.3	67
14 (13)	Clinical trials cost too much for the patient.	2.2	67
15 (15)	Enrolling a patients on a trial may delay needed therapy for breast cancer.	2	66

Appendix Y

University of California, San Francisco

Breast Care Center

Complete a Survey About Breast Cancer Research

Drs. Laura Esserman and Debu Tripathy of The UCSF Breast Care Center are conducting a survey to understand how women with breast cancer feel about clinical trials (research studies) for breast cancer and how women without breast cancer feel about clinical trials for the prevention of breast cancer. This survey will help us to understand the needs of women with and without breast cancer.

If you choose to participate in this survey, please answer each of the following questions as accurately as possible. Participating in this survey is voluntary. The answers you give are confidential. Please **do not** put your name on this survey. You are free to decline participation at any time. If you have any questions regarding this study, you can contact Fern Hassin at fern@itsa.ucsf.edu. If for any reason you do not feel comfortable expressing your concerns to Ms. Hassin, you may contact the UCSF Committee on Human Research: UCSF, CHR, Box 0962, San Francisco, CA 94143, (415)476-1814.

If you have any questions about the data collection service or if you have any problems with the collection forms, please contact help@datstat.com.

Thank you for your participation.

Click the button below to start the survey.

Start the Survey

Home

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SANTA BARBARA • SANTA CRUZ

Drs. Laura Esserman and Debu Tripathy of The UCSF Breast Care Center are conducting a survey to understand how women with breast cancer feel about clinical trials (research studies) for breast cancer. This survey will help us to understand the needs of patients with breast cancer. In order to participate, you must have received a diagnosis of breast cancer.

If you choose to participate in this survey, please answer each of the following questions as accurately as possible. Participating in this survey is voluntary. The answers you give are confidential. Please **do not** put your name on this survey. You are free to decline participation at any time. If you have any questions regarding this study, you can contact Fern Hassin at **fern@itsa.ucsf.edu**. If for any reason you do not feel comfortable expressing your concerns to Ms. Hassin, you may contact the UCSF Committee on Human Research: UCSF, CHR, Box 0962, San Francisco, CA 94143, (415) 476-1814.

A. The first set of questions asks for information about you and your health. The answers to these questions will help us understand who you are.

1) Do you have or have you had breast cancer?

Yes
No

2) How old are you?

20-24
25-29
30-34
35-39
40-44
45-49
50-54
55-59
60-64
65-69
70-74
75-79
80-84
85 and over

3) Were you born in the United States?

Yes
No

4) Where do you live now?

In U.S. - What are the first three digits of your zip code __/__/__
Out of U.S. - What country? _____

5) What is your racial/ethnic identification?

Black/African American
Chinese
Filipina
Hawaiian
Indian-subcontinent
Japanese
Korean
Latina/Hispanic

Native American
Pacific Islander
Thai
Vietnamese
White/European American
Other
Unknown

6) What is your current relationship status?

Married
Living with a partner
Divorced
Widowed
Single

7) What is the highest level of education you have completed?

11th grade or less
High school graduate or GED
years of college (AA)
College graduate (BA, BS)
Master's degree (MA, MS)
Advanced/graduate degree (PhD, JD, MD)

8) What is your current employment status?

Full time (32 hrs or more/wk)
Part time (fewer than 32 hrs/wk)
Not employed for pay, but seeking work
Not employed for pay and not seeking work
Retired

9) What is your estimated total family income from all sources in your household (before taxes) for the previous year (Jan.-Dec. 1998)?

Less than $19,999
$20,000 to $49,999
$50,000 to $74,999
$75,000 to $149,999
Over $150,000

10) How do you pay for your medical bills?

Pre-paid private insurance (HMO)
Military or VA sponsored
Other private insurance
Free care (clinic)
Medicare
Private self pay
Medi-Cal
Other; Please specify: _____

11) How would you rate your current overall health compared to that of other women your age?

Excellent
Good
Average
Poor

12) Have you had a menstrual period during the past 12 months?

Yes
No

13) Do you have children?

Yes - How many: _____, Please list their ages: ____, ____, ____, ____, ____, ____, ____
No

14) Are you the primary caregiver for dependent children or any adults that require care?

Yes
No

15) Do you have any of the following health conditions at this time? (Check all that apply).

Hypertension (high blood pressure)
Osteoporosis
Other cancer in addition to breast cancer
Arthritis
Depression
Heart disease
Diabetes
Other major condition, Please specify: _____

16) When were you diagnosed with breast cancer?

Less than one year ago
1-2 years ago
3-5 years ago
More than 5 years ago

17) How was your breast cancer first detected or discovered?

Mammogram
Breast examination in doctor's office (CBE)
Self examination (BSE)
My husband/partner discovered it
Other; please specify: _____

18) At what stage was your breast cancer when first diagnosed?

Stage I
Stage II
Stage III
Stage IV
Don't know

19) Have you had a recurrence of breast cancer?

Yes
No
Never was in remission

20) What treatments have you undergone for your breast cancer? (Check all that apply).

Lumpectomy
Mastectomy
Radiation therapy

Hormonal therapy
Chemotherapy
Biological therapy (vaccine, Herceptine™)
Other therapy; please specify: _____
Traditional Chinese medicine (herbs or acupuncture)
Other complementary or alternative medicine; please specify: _____
No treatment at this time
I don't know

21) How would you describe your participation in your medical care for breast cancer?
I have done everything my doctors have advised.
I have done some of what my doctors have advised.
I have done none of what my doctors have advised.

22) Have any of your first degree relatives (mother/sister/daughter/aunt) had breast cancer?
Yes
No

23) Have any of your first degree relatives (male or female parent/sibling/child) had other types of cancer?
Yes
No

24) Have any of your close friends ever had breast cancer?
Yes
No

B. The following questions focuses on what you know or have personally experienced regarding breast cancer clinical trials.

1) I have been asked to participate in a breast cancer clinical trial.
Yes
No
Don't know

2) The following best describes my participation in a breast cancer clinical trial:
I have participated in a breast cancer clinical trial in the past.
I am currently participating in a breast cancer clinical trial.
I declined to participate in a breast cancer clinical trial.
I was interested in a breast cancer clinical trial but was not eligible to participate.
I have never been asked to participate in a breast cancer clinical trial.

3) My doctor would want me to participate in a breast cancer clinical trial.
Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

4) People I am close to would support my participation in a breast cancer clinical trial.

Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

5) **I have a good understanding about what it would be like to participate in a breast cancer clinical trial.**
Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

6) **I would like more information about breast cancer clinical trials that are available for women to join.**
Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

7) **My doctor would no longer be making the main decisions about my care if I participate in a breast cancer clinical trial.**
Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

8) **I will have fewer choices regarding my care if I participate in a breast cancer clinical trial.**
Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

9) **I will have to spend additional time having tests and doctors' visits if I participate in a breast cancer clinical trial.**
Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

10) **I will have to spend more money (due to transportation, child care, and lost income) if I participate in a breast cancer clinical trial.**
Strongly disagree Strongly agree
Disagree
Neither disagree nor agree
Agree

11) My insurance company will not cover the cost of my treatment if I participate in a breast cancer clinical trial.

Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

12) My medical records would be treated less confidentially if I participate in a breast cancer clinical trial.

Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

13) I will receive more comprehensive care if I participate in a breast cancer clinical trial.

Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

14) My standard treatment will be delayed if I participate in a breast cancer clinical trial.

Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

15) If my doctor does not suggest that I participate in a breast cancer clinical trial, taking part in one is probably not right for me.

Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

16) Participation in a breast cancer clinical trial could endanger my health.

Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

17) I will have no control over my medical decisions if I participate in a breast cancer clinical trial.

Strongly disagree
Disagree
Neither disagree nor agree

18) Which factors are most important to you in considering whether or not to participate in a breast cancer clinical trial? Choose all that apply.

The possibility of improving my health
My doctor recommending the study to me
Being paid for participation
Believing in what the researchers are investigating
Not needing to pay money to participate
Receiving a treatment not yet available
Not risking my health by participating
Not needing to spend a lot of extra time
The possibility of helping other women with breast cancer
Receiving payment for my participation
Other; please specify: _____
Don't know

19) Who benefits the most from a breast cancer research clinical trial?

The patient
Physicians treating women with breast cancer
The physician/researcher conducting the clinical trial
The research institution
Women in general
No one benefits

20) How important is research for making progress in treating breast cancer?

Very important
Somewhat important
Not at all important
Don't know

21) Being part of a breast cancer clinical trial would make me feel that I was actively participating in my own health care.

Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly Agree

22) What factors might prevent you from participating in a breast cancer clinical trial? (Choose all that apply).

Time constraints
Lack of child or elder care
Limited transportation options
Poor health
Not feeling well
Concerns about extra or hidden expenses
Language difficulties
Concerns about being hurt in the study
Concerns about confidentiality
Husband/partner would not support participation
Do not trust researchers to look out for patients' well-being

Do not understand the purpose of research
Other; please specify: _____

23) Whom would you look to most in deciding whether or not to participate in a breast cancer clinical trial?

Self
Doctor
Family
Husband/partner
The study contact person
A second opinion doctor
Religious leader
Other; please specify: _____

24) What do you think would be the best way to inform women about breast cancer clinical trials? (Select one).

Brochures/posters
Video
Telephone calls to their home
Presentations
Health care providers
Internet
Newspapers
Direct mail
Radio/TV
Other; please specify: _____

25) "Randomization" means that participants are assigned by chance to one of two or more treatments in a study. Neither study participants nor their physicians are allowed to choose the treatment. Randomization allows researchers to compare the treatments to see which one is better. If you were asked to join a study with randomization, what would you do?

I would join a study with randomization.
I am not sure I would join a study with randomization.
I would not join a study in which I could not choose my study treatment.

26) I would like to know what treatment I am signing up for and therefore would not want to be randomized.

Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

C. "Complementary" or "alternative medicine" includes such treatments as herbs, acupuncture, accupressure, massage, visualization, and other therapies that are not always considered to be part of conventional treatment. The following questions relate to your opinions about complementary or alternative therapies.

1) Complementary/alternative medicine should be studied in breast cancer clinical trials.

Strongly disagree

Disagree
Neither disagree nor agree
Agree
Strongly agree

2) **I would need more information about complementary/alternative medicine before I would participate in a breast cancer clinical trial of complementary/alternative medicine.**
Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

3) **I would not participate in a randomized clinical trial of complementary/alternative medicine.**
Strongly disagree
Disagree
Neither disagree nor agree
Agree
Strongly agree

Type abstract below. Limit: 300 words (excluding abstract title, authors' names, and affiliations).

Appendix 2. Pr

PHYSICIAN AND PATIENT BARRIERS TO ENROLLMENT ON BREAST CANCER CLINICAL TRIALS.

D. Tripathy, K. Patel, B. Brown, N. Chernyukhin, H. Wallace, F. Hassin, A. MacMillan, L. Esserman. The University of California at San Francisco Cancer Center, San Francisco, CA 94143

Fewer than 3% of patients with breast cancer in the U.S. participate in clinical trials, indicating barriers to enrollment both on the side of care providers and patients. Patients with newly diagnosed or progressive breast cancer and physicians who provide care for breast cancer in the San Francisco Bay Area responded to separate surveys covering domains of trial awareness, cost, convenience, risks, potential benefits, and trials in alternative medicine. Patients felt extra time requirements, side effects of new drugs, and reluctance to be randomized are major barriers. Younger patients had more concerns about costs. Worries about insurance coverage were seen in lower income and education groups and confidentiality was a concern in married patients. White patients received more information on the Internet. Non-white patients and those citing a religious preference trusted their doctors to make decisions about trials. English-speaking patients were more concerned about side effects and efficacy of experimental therapy. Physicians identified lack of trial information, patient inconvenience, preference for one treatment arm, office staff time, but not compromise on patient care as important barriers. Younger physicians were more concerned about toxicities of new agents. Medical oncologists compared to other specialists felt a greater restriction of eligibility requirements and were less worried about side effects of new agents. Private practice and non-academic physicians were more concerned about stresses to patients and interference with treatment and referral patterns. Attitudes on trials in alternative medicine were generally positive, especially in younger respondents. Married and higher income patients were more concerned about negative perceptions from family and physicians for participation in alternative medicine trials. Younger physicians had less concern about interference with standard care and loss of patient/physician credibility with participation in alternative trials. Mechanisms to target and address these physician and patient barriers are needed.

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1. FIRST AUTHOR / PRESENTER INFORMATION (please type):

Last Name	First Name	Degree
Tripathy	Debu	MD

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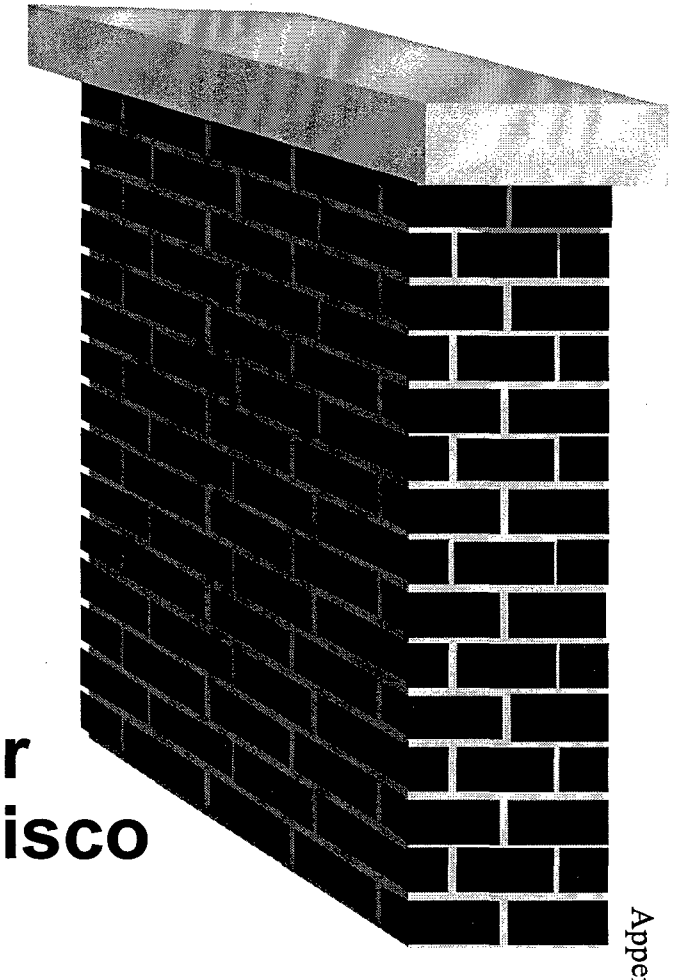
University of California San Francisco

Patient and Physician Barriers to Enrollment on Breast Cancer Clinical Trials

D. Tripathy
F. Hassin
B. Brown
A. McMillan
K. Patel
L. Esserman

Carol Franc Buck Breast Care Center
University of California at San Francisco



Supported by DOD-USAMRMC-DAMD17-96-1-6260

Background

- Most new effective diagnostics and therapeutics provide incremental benefits rather than sweeping improvements
- Controlled clinical trials are necessary to characterize risk/benefit attributable to interventions
- Only 3% of women with breast cancer enroll in clinical trials

Background

Potential or Previously Described Patient Barriers

- Awareness
- Access
- Reluctance to be randomized
- Concerns about toxicities
- Extra time, inconvenience
- Loss of control and MD relationship

Background

Potential or Previously Described Physician Barriers

- Information and access
- Extra staff and office time
- Rigid eligibility criteria
- Concerns about toxicities
- Bias toward standard or experimental arm
- Loss of patient to another center

Hypotheses

- Unique patient barriers to clinical trial enrollment may emerge upon surveying women at a time when they would typically be making decisions about considering a trial
- Breast cancer trial-specific physician barriers may exist
- Attitudes about trials in the area of alternative medicine may differ from those in the conventional area
- Community wide interventions that are tailored to address identified barriers may increase breast cancer trial enrollment

Methods

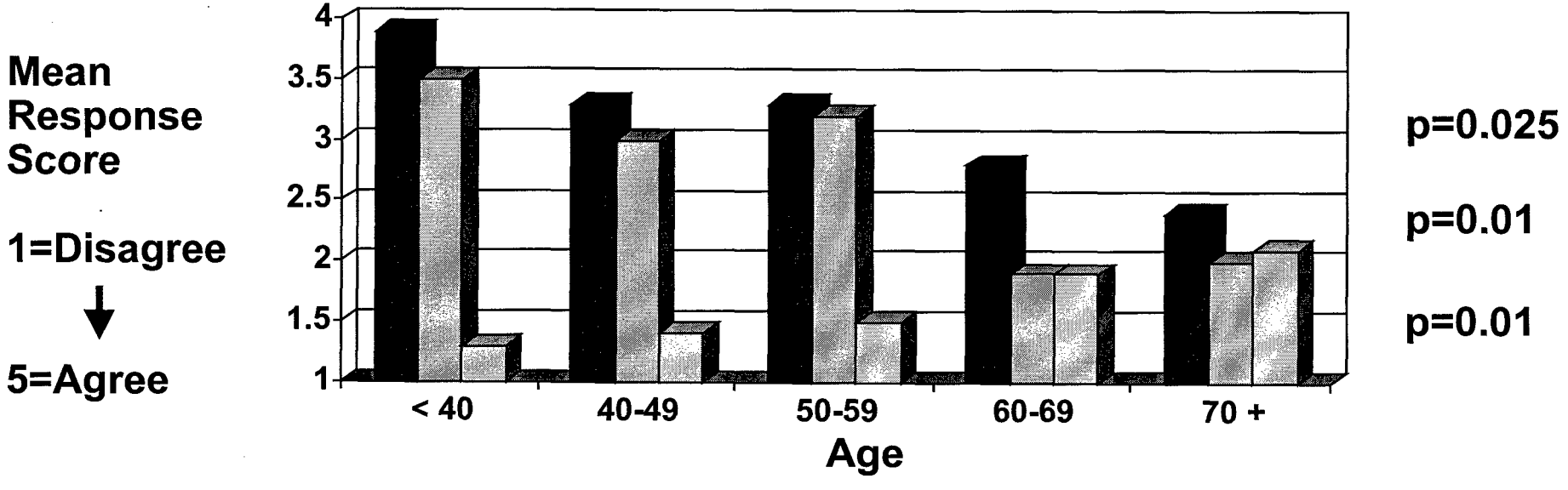
- Survey given to 150 patients at time of new diagnosis of breast cancer, or at recurrence or progression of cancer
- 28 Question survey covers domains of:
  - Information/access
  - Interference with normal medical care
  - Cost and time constraints
  - Side effects and safety
  - Randomization
  - Alternative medicine trials
- 30 Question survey of 150 care providers specializing in breast cancer treatment - similar domains
- Targeted interventions (education/outreach/literature) based on survey results (years 2-4)
- Repeat survey and tracking of trial enrollment (year 4)

Results

- **Major patient barriers**
  - Reluctance to be randomized
  - Side effects of experimental therapy
  - Extra time
  - Information availability and awareness
- **Not felt to be barriers**
  - Interference with established medical care
  - Quality of care
  - Clinical trials in alternative medicine

Differential Barriers Based on Patient Characteristics

- **Younger patients**
  - More concerned about costs
  - Less concerns about trials in alternative medicine
  - More difficulties with transportation and dependent care
  - Less difficulty in obtaining information about trials



Differential Barriers Based on Patient Characteristics

- Non-white patients trusted their physician more to make decisions about trial referral or recommendation
- Non-white patients were more skeptical about experimental benefits over standard

	White	Non-White	p
Trust their MD to refer for trial	2.4	3.8	0.0016
Experimental therapy better than standard	2.6	1.7	0.0089

1 = Disagree ⟶ 5 = Agree

Results
Physician Barriers from 67 Respondents of 150

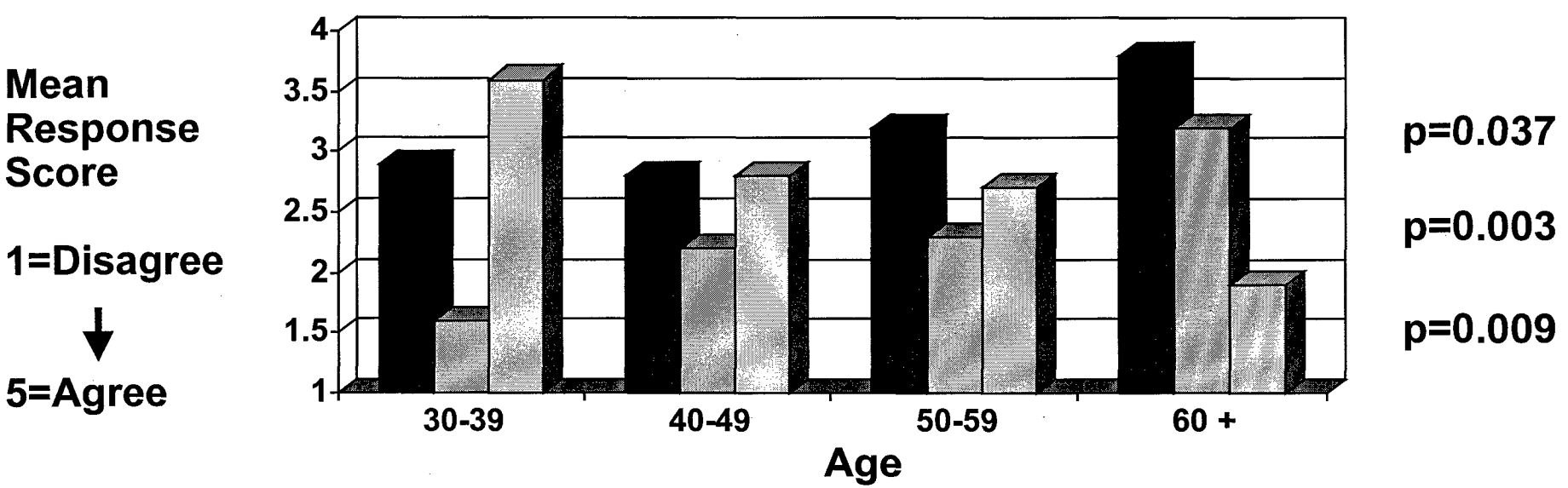
- **Identified as Barriers**
  - Lack of trial information and contacts
  - Preference of one treatment arm in randomized studies
  - Increased office staff time

- **Not felt to be Barriers**
  - Interference with standard care (delay of therapy, future options)
  - Assessment and reporting of side effects
  - Trials in the alternative medicine

Differential Barriers Based on Care Provider Characteristics

Associations with Age

- Older - Felt control arm was inadequate
- Older - More concerned about side effects
- Younger - Agreed on need for trials in alternative medicine



Differential Barriers Based on Care Provider Characteristics
Associations with Practice Setting

	Private	Non-Private (HMO/Acad/Hosp)	
Inconvenient to Patient	3.9	3.4	p = 0.0475
Stressful to Patient	3.2	2.3	p = 0.0004
High Cost to Patient	2.5	1.9	p = 0.05
Interferes with Care	2.9	1.8	p = 0.0001
Delays Therapy	2.5	1.5	p = 0.0002
Loss of Patient Follow-up	2.9	1.9	p = 0.0011
Consent is Misleading	3.2	2.5	p = 0.017

1 = Disagree ⟶ 5 = Agree

Changes in MD Survey from 1997 to 2000
Trend over time

- Less concern that the experimental arm could be harmful
- Less belief that the clinical trials process is stressful on patients
- Less concern the trials in alternative medicine would interfere with normal care
- Less concern the trials in alternative medicine would lower patients' credibility

Survey Conclusions

- Significant barriers exist in a population of patients with breast cancer at a time when they would be eligible for participation in clinical trials
- The process of randomization, concern about side effects and the added time constraints were cited
- Younger patients are more concerned about time and cost constraints
- Generally favorable views on alternative medicine research are held among patients and physicians, especially younger respondents
- Care providers in the private settings are more concerned about side effects, the consent process, interference with care and loss of patients

Targeted Interventions

- Monthly Community "Bay Area Breast Cancer Forum"
- Breast Cancer Research Awareness Poster in mammography suites, resource centers, civic organizations
- Symposium on Research Barriers for Minority and Underserved Populations - videotaped and distributed
- Website (minutes of Forum, clinical trial material, links) - http://bcc-ct.his.ucsf.edu
- Web-based clinical trials-matching program (in development)
- Clinical trials network opportunities for community oncologists

Examples of "Forum" Topics

- Breast Cancer Prevention and Risk Factors
- Preinvasive Breast Cancer
- Research in Immunological Approaches to Breast Cancer
- New Imaging Technology
- Alternative and Complementary Medicine
- Patients/Physician Collaborative Decision-making
- Progress in Adjuvant Therapy
- Neoadjuvant Therapy: Use as a Research Platform
- Research Methodology in Advanced Breast Cancer

- New Satellite Forum Site added to the East Bay (Alta Bates, Summit)
- Interactive Internet Forum under development

UCSF Breast Care Center - DoD Grant (L Esserman)/Pilot A (D Tripathy)
Patient Attitudes to Clinical Trials

This report summarizes the results of two questionnaires on patient attitudes to clinical trials, a baseline questionnaire given around 1997 and a follow-up questionnaire given to a separate group of patients around 2000. Patients were asked to rank their level of agreement or disagreement on a 5-point scale. As appropriate, the answers to some of the questions were reversed in this analysis so that a high score always reflects an impediment to clinical trials.

There were only a few questions where the answers differed in the two years (Table#2) and of these only question 1 remained significant after adjusting for patient characteristics.
There were some significant correlations between answers and patient characteristics, but the very large number of comparisons involved makes P values uninterpretable.

Table#1 gives the overall scores, Table#2 breaks these into the two questionnaires and gives P values for differences.
Table#3 gives summary P values for correlations between answers to the questionnaire and patient characteristics.
Table#4 is an auxiliary table that shows which patient characteristics differed in the two years. Table#5 gives details of these characteristics by year.
Table#6 is another auxiliary table that relates answers to questions to patient characteristics.

Contents

This report has 26 pages.

Patient Attitudes to Clinical Trials

Table#1 - Patient answers

Overall responses

YEAR Both years

Means and P value for midpoint=3	ANS			TEST=3	NOTE
	N	MEAN	STD	MEAN	MEAN
Question					
01) enough CT info	250	2.8	1.4	0.0204	Disagree
02) CT on Internet	240	2.6	1.5	0.0000	Disagree
03) CT limits future Tx	98	2.5	1.5	0.0031	Disagree
04) Tx sooner on CT	206	2.3	1.3	0.0000	Disagree
05) Can see regular MD	207	1.6	1.0	0.0000	Disagree
06) If no CT ref, then CT not right	248	2.8	1.5	0.0526	
07) MD may not want	195	2.4	1.3	0.0000	Disagree
08) unanswered questions on CT	229	2.5	1.4	0.0000	Disagree
09) extra time on tests and visits	232	3.9	1.2	0.0000	Agree
10) spend transport., childcare, lose	220	3.0	1.4	0.4530	
11) insurance may not cover CT cost	90	2.8	1.5	0.1097	
12) more side effects	194	3.0	1.2	0.6972	
13) more stress on CT	225	2.8	1.3	0.0097	Disagree
14) CT a constant reminder of Brca	274	1.8	1.2	0.0000	Disagree
15) Better Psych, QOL on CT	181	2.9	1.3	0.1371	
16) New Tx not better than standard	235	2.4	1.3	0.0000	Disagree
17) new drug side effects	217	3.3	1.1	0.0013	Agree
18) randomized treatment worse than re	233	3.6	1.2	0.0000	Agree
19) Don't want to be randomized	268	4.3	1.1	0.0000	Agree
20) no control on a CT	234	2.5	1.4	0.0000	Disagree
21) CT Loss of confidentiality	228	3.0	1.4	0.7094	
22) alt. med. should be studied	276	1.5	1.0	0.0000	Disagree
23) alt. med. too unknown	249	2.5	1.4	0.0000	Disagree
24) alt. med. can't choose own Tx	244	3.7	1.4	0.0000	Agree
25) CT can test alt. med. with reg. me	235	1.6	0.9	0.0000	Disagree
26) alt. med. limits future Tx	209	1.7	1.0	0.0000	Disagree
27) Bad MD, friends opinion of alt med	238	2.1	1.3	0.0000	Disagree
28) English.not native	83	1.3	1.0	0.0000	Disagree
29) English not native (N/A set to 1)	150	1.2	0.8	0.0000	Disagree
30	150	0.0	0.0	0.0000	Disagree

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#1 - Patient answers

Overall responses

YEAR Both years

Percentages	ANS			ANSWER				
	N	MEAN	STD	1 PCTN	2 PCTN	3 PCTN	4 PCTN	5 PCTN
Question								
01) enough CT info	250	2.8	1.4	22%	22%	25%	13%	16%
02) CT on Internet	240	2.6	1.5	33%	19%	18%	12%	15%
03) CT limits future Tx	98	2.5	1.5	36%	13%	25%	8%	16%
04) Tx sooner on CT	206	2.3	1.3	34%	26%	22%	7%	9%
05) Can see regular MD	207	1.6	1.0	62%	21%	9%	2%	3%
06) If no CT ref, then CT not right	248	2.8	1.5	27%	19%	19%	11%	21%
07) MD may not want	195	2.4	1.3	38%	16%	25%	11%	8%
08) unanswered questions on CT	229	2.5	1.4	32%	23%	18%	12%	13%
09) extra time on tests and visits	232	3.9	1.2	7%	6%	10%	38%	37%
10) spend transport., childcare, lose	220	3.0	1.4	23%	13%	21%	24%	16%
11) insurance may not cover CT cost	90	2.8	1.5	32%	12%	15%	23%	16%
12) more side effects	194	3.0	1.2	11%	22%	34%	20%	11%
13) more stress on CT	225	2.8	1.3	20%	23%	26%	18%	11%
14) CT a constant reminder of Brca	274	1.8	1.2	58%	18%	11%	6%	5%
15) Better Psych, QOL on CT	181	2.9	1.3	20%	11%	39%	14%	13%
16) New Tx not better than standard	235	2.4	1.3	32%	22%	25%	11%	7%
17) new drug side effects	217	3.3	1.1	8%	11%	40%	21%	17%
18) randomized treatment worse than re	233	3.6	1.2	8%	11%	19%	32%	28%
19) Don't want to be randomized	268	4.3	1.1	3%	5%	11%	14%	64%
20) no control on a CT	234	2.5	1.4	35%	22%	15%	13%	13%
21) CT Loss of confidentiality	228	3.0	1.4	21%	16%	24%	19%	18%
22) alt. med. should be studied	276	1.5	1.0	69%	13%	11%	1%	2%
23) alt. med. too unknown	249	2.5	1.4	32%	20%	19%	13%	13%
24) alt. med. can't choose own Tx	244	3.7	1.4	10%	11%	20%	18%	39%
25) CT can test alt. med. with reg. me	235	1.6	0.9	59%	27%	8%	3%	1%
26) alt. med. limits future Tx	209	1.7	1.0	55%	24%	12%	2%	3%
27) Bad MD, friends opinion of alt med	238	2.1	1.3	47%	17%	18%	10%	6%
28) English not native	83	1.3	1.0	86%	3%	3%	.	6%
29) English not native (N/A set to 1)	150	1.2	0.8	92%	2%	2%	.	3%

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#2 - Average answers - significance of differences 1997 to 2000

Question		Mean score 1997	Mean score 2000	P(Year)	Number 1997	Number 2000	P(Yr adj)
Q01	Suff Info	3.21	2.35	0.0000	126	124	0.0129
Q02	Info on Internet	2.71	2.43	0.2241	118	122	
Q03	Limits Choices	2.54	.	.	98	0	
Q04	Treated sooner	2.52	2.13	0.1202	97	109	
Q05	Regular MD	1.65	1.63	0.8278	101	106	
Q06	If MD disagrees	2.61	2.99	0.0364	132	116	0.2170
Q07	MD may not want	2.31	2.40	0.4842	98	97	
Q08	My Q's not answered	2.47	2.56	0.6898	120	109	
Q09	Extra time	3.76	4.11	0.0207	122	110	0.5124
Q10	More money	2.85	3.09	0.2265	110	110	
Q11	Insurance doesn't cover	2.80	.	.	90	0	
Q12	More SE	2.96	2.97	0.8866	96	98	
Q13	More Stress	2.79	2.77	0.9131	117	108	
Q14	Constant reminder	1.78	1.83	0.2764	142	132	
Q15	QoL/Psych	2.76	2.99	0.1589	86	95	
Q16	New not better	2.56	2.18	0.0339	121	114	0.1596
Q17	Worse SE	3.37	3.16	0.1129	108	109	
Q18	Rand not as good	3.59	3.64	0.8888	118	115	
Q19	Don't want random	4.26	4.37	0.2178	137	131	
Q20	No control	2.47	2.49	0.7818	125	109	
Q21	Less confidential	3.07	2.88	0.2966	120	108	
Q22	AM should be studied	1.53	1.54	0.7902	143	133	
Q23	AM less known	2.40	2.68	0.0723	128	121	0.3736
Q24	Can't choose own AM	3.51	3.79	0.1459	123	121	
Q25	CT can test AM SE	1.64	1.56	0.7238	125	110	
Q26	AM limits future Tx	1.69	1.79	0.1645	117	92	
Q27	Others' opinions of AM	2.12	2.10	0.7392	127	111	
Q28	English	1.35	.	.	83	0	
Q29	English (w/o NA's)	1.19	.	.	150	0	

P(Yr adj) is the P value for a difference between years 1997 and 2000, adjusted for ER_OR_PR, Education, Family history of breast cancer and Oral contraceptive use.

Questions 3, 11 and 28/29 were not asked in 2000.

On any question a high answers reflects an impediment to CT
Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#3 - P values for demographics/questions correlations

Associations between questions and demographics

YEAR Both years

P values, association of questions with patient variables	VN				
	AGE	STAGE	EDUCNLEV	N_CHILD	N_PREG
	P_VALUE	P_VALUE	P_VALUE	P_VALUE	P_VALUE
Q					
01) enough CT info			0.0130		
02) CT on Internet					
03) CT limits future Tx	0.0618				
04) Tx sooner on CT					
05) Can see regular MD					
06) If no CT ref, then CT not righ	0.0684		0.0018	0.0355	
07) MD may not want					
08) unanswered questions on CT					
09) extra time on tests and visits			0.0824		0.0179
10) spend transport., childcare, l	0.0110				
11) insurance may not cover CT cos	0.0442				
12) more side effects					
13) more stress on CT					
14) CT a constant reminder of Brca					
15) Better Psych, QOL on CT					
16) New Tx not better than standar					
17) new drug side effects					
18) randomized treatment worse tha		0.0999			
19) Don't want to be randomized					
20) no control on a CT		0.0496			
21) CT Loss of confidentiality				0.0641	
22) alt. med. should be studied					
23) alt. med. too unknown	0.0091	0.0654			
24) alt. med. can't choose own Tx		0.0020			
25) CT can test alt. med. with reg					
26) alt. med. limits future Tx					
27) Bad MD, friends opinion of alt					
28) English not native	0.0547				
29) English not native (N/A set to	0.0445				

P values above 0.1 are not shown

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#3 - P values for demographics/questions correlations

Associations between questions and demographics

YEAR Both years

P values, association of questions with patient variables	VN				
	WHITE	MARRIED	CGRAD	FH_BR_CA	POSTMENP
	P_VALUE	P_VALUE	P_VALUE	P_VALUE	P_VALUE
Q					
01) enough CT info					
02) CT on Internet		0.0669			0.0292
03) CT limits future Tx					
04) Tx sooner on CT			0.0835		
05) Can see regular MD	0.0660				
06) If no CT ref, then CT not righ	0.0005		0.0035	0.0585	
07) MD may not want					
08) unanswered questions on CT	0.0274			0.0271	
09) extra time on tests and visits				0.0475	
10) spend transport., childcare, l					
11) insurance may not cover CT cos					
12) more side effects					
13) more stress on CT		0.0360			
14) CT a constant reminder of Brca				0.0025	
15) Better Psych, QOL on CT					
16) New Tx not better than standar					0.0573
17) new drug side effects					0.0960
18) randomized treatment worse tha	0.0419				
19) Don't want to be randomized					
20) no control on a CT	0.0590				
21) CT Loss of confidentiality		0.0181			
22) alt. med. should be studied		0.0780			
23) alt. med. too unknown	0.0419			0.0083	
24) alt. med. can't choose own Tx	0.0891				
25) CT can test alt. med. with reg					
26) alt. med. limits future Tx				0.0016	
27) Bad MD, friends opinion of alt				0.0523	0.0704
28) English not native	0.0731				
29) English not native (N/A set to	0.0256				

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#3 - P values for demographics/questions correlations

Associations between questions and demographics

YEAR Both years

P values, association of questions with patient variables	VN				
	OC_USE	ER	PR	ER_OR_PR	ERPRBOTH
	P_VALUE	P_VALUE	P_VALUE	P_VALUE	P_VALUE
Q					
01) enough CT info					
02) CT on Internet					
03) CT limits future Tx					
04) Tx sooner on CT					
05) Can see regular MD					
06) If no CT ref, then CT not righ	0.0147		0.0298	0.0877	0.0766
07) MD may not want					
08) unanswered questions on CT	0.0228	0.0124	0.0450	0.0079	0.0513
09) extra time on tests and visits					
10) spend transport., childcare, l					
11) insurance may not cover CT cos					
12) more side effects					
13) more stress on CT					0.0749
14) CT a constant reminder of Brca	0.0272				
15) Better Psych, QOL on CT					
16) New Tx not better than standar					
17) new drug side effects			0.0890		
18) randomized treatment worse tha			0.0601	0.0823	
19) Don't want to be randomized					
20) no control on a CT					
21) CT Loss of confidentiality					
22) alt. med. should be studied	0.0726				
23) alt. med. too unknown	0.0086				
24) alt. med. can't choose own Tx	0.0373				
25) CT can test alt. med. with reg					
26) alt. med. limits future Tx					
27) Bad MD, friends opinion of alt	0.0784				
28) English not native					
29) English not native (N/A set to					

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#4 - P values differences in demographics (1997 vs 2000)

Variable		Mean 1997	Mean 2000	P(Year)	N 1997	N 2000
AGE	Age	52.86	53.16	0.5493	150	147
STAGE	Stage Grouping	1.90	1.91	0.6419	39	100
EDUCNLEV	Educ level	4.62	4.92	0.0608	97	146
N_CHILD	# live births	1.54	1.52	0.9091	124	147
N_PREG	# pregnancies	2.42	2.08	0.5301	132	147
WHITE	White?	0.88	0.81	0.1030	133	145
MARRIED	Married?	0.54	0.56	0.7168	130	147
CGRAD	College Graduate	0.62	0.71	0.1661	97	146
FH_BR_CA	FH of Breast Cancer	0.39	0.28	0.0881	119	144
POSTMENP	Post Menopausal?	0.55	0.58	0.6882	93	145
OC_USE	Ever used oral contr.?	0.74	0.63	0.0922	96	144
ER_OR_PR	ER+ or PR+	0.61	0.80	0.0052	143	71
ERPRBOTH	ER+ and PR+	0.44	0.57	0.1151	143	56

Some variables are ordinal, use means only to establish a trend

Patient Attitudes to Clinical Trials

Table#5 - Demographics 1997, 2000, Overall

Ages of Respondents		YEAR		
		1997	2000	ALL
Age				
<30	%	1%	0%	1%
30-40	%	10%	8%	9%
40-50	%	32%	29%	30%
50-60	%	34%	36%	35%
60-70	%	14%	18%	16%
70-80	%	5%	6%	5%
80+	%	2%	.	1%
Age	Mean	52.9	53.2	53.0
Age	N Obs	150	147	297

Stage		YEAR		
		1997	2000	ALL
Stage Grouping				
In Situ	%	2%	4%	3%
I	%	25%	41%	36%
II	%	58%	28%	36%
III	%	5%	14%	11%
IV	%	7%	13%	11%
Stage	N Obs.	39	100	139

Patient Attitudes to Clinical Trials

Table#5 - Demographics 1997, 2000, Overall

Marital status		YEAR		
		1997	2000	ALL
Married?				
No	%	46%	43%	44%
Yes	%	53%	56%	55%
	N Obs.	130	147	277

Ethnicity		YEAR		
		1997	2000	ALL
White?				
No	%	12%	19%	15%
Yes	%	87%	80%	84%
	N Obs.	133	145	278

Education		YEAR		
		1997	2000	ALL
Educ level				
8th grade or less	%	1%	.	0%
Some high school	%	5%	.	2%
High school graduate	%	12%	15%	13%
Some college or technical	%	19%	14%	16%
College graduate	%	36%	34%	34%
Graduate school	%	25%	36%	32%
EDUC	N Obs.	97	146	243

Table#5 - Demographics 1997, 2000, Overall

Number of children		YEAR		
		1997	2000	ALL
# live births				
0	%	33%	29%	31%
1	%	16%	19%	17%
2	%	26%	31%	29%
3	%	13%	13%	13%
4	%	5%	2%	4%
5+	%	4%	3%	3%
# Children	Mean	1.5	1.5	1.5
# Children	N Obs.	124	147	271

Number of pregnancies		YEAR		
		1997	2000	ALL
# pregnancies				
0	%	24%	20%	22%
1	%	13%	17%	15%
2	%	18%	24%	21%
3	%	16%	19%	17%
4	%	12%	10%	11%
5+	%	13%	8%	11%
# Preg.	Mean	2.4	2.1	2.2
# Preg.	N Obs.	132	147	279

Patient Attitudes to Clinical Trials

Table#5 - Demographics 1997, 2000, Overall

Fam. History		YEAR		
		1997	2000	ALL
FH of Breast Cancer				
No	%	61%	71%	66%
Yes	%	38%	28%	33%
	N Obs.	119	144	263

Menopausal status		YEAR		
		1997	2000	ALL
Post Menopausal?				
No	%	45%	42%	43%
Yes	%	54%	57%	56%
	N Obs.	93	145	238

Use of oral contraceptives		YEAR		
		1997	2000	ALL
Ever used oral contr.?				
No	%	26%	36%	32%
Yes	%	73%	63%	67%
	N Obs.	96	144	240

Patient Attitudes to Clinical Trials

Table#5 - Demographics 1997, 2000, Overall

ER		YEAR		
		1997	2000	ALL
ER				
-	%	42%	24%	36%
+	%	57%	75%	63%
	N Obs.	143	74	217

PR		YEAR		
		1997	2000	ALL
PR				
-	%	52%	37%	48%
+	%	47%	62%	51%
	N Obs.	143	53	196

Positive on ER or PR or both		YEAR		
		1997	2000	ALL
ER+ or PR+				
-	%	39%	19%	32%
+	%	60%	80%	67%
	N Obs.	143	71	214

Positive on ER and PR		YEAR		
		1997	2000	ALL
ER+ and PR+				
-	%	55%	42%	52%
+	%	44%	57%	47%
	N Obs.	143	56	199

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

Age Differences		Age						
		<30	30-40	40-50	50-60	60-70	70-80	80+
	ANS N	ANS MEAN	ANS MEAN	ANS MEAN	ANS MEAN	ANS MEAN	ANS MEAN	ANS MEAN
Question								
01) enough CT info	250	2.7	3.1	2.8	2.8	2.7	2.5	2.3
02) CT on Internet	240	2.3	2.8	2.3	2.5	2.9	2.8	5.0
03) CT limits future Tx	98	1.0	3.3	2.8	2.6	2.4	1.3	3.0
04) Tx sooner on CT	206	2.0	2.3	2.3	2.4	2.2	2.3	2.0
05) Can see regular MD	207	2.0	1.6	1.8	1.7	1.5	1.1	2.0
06) If no CT ref, then CT not right	248	2.0	2.9	2.6	2.6	3.2	3.6	3.0
07) MD may not want	195	2.5	3.2	2.1	2.3	2.5	2.4	2.3
08) unanswered questions on CT	229	2.0	2.6	2.4	2.5	2.6	3.1	2.3
09) extra time on tests and visits	232	4.7	4.2	4.0	4.0	3.7	3.4	2.0
10) spend transport., childcare, lose	220	3.5	3.5	2.9	3.1	2.5	2.7	1.0
11) insurance may not cover CT cost	90	5.0	3.1	3.3	2.4	2.9	2.0	4.0
12) more side effects	194	3.0	3.0	2.8	3.1	2.9	3.0	1.0
13) more stress on CT	225	2.3	2.9	2.8	2.7	2.8	2.8	1.8
14) CT a constant reminder of Brca	274	2.0	1.6	1.8	1.8	2.0	1.8	1.5
15) Better Psych, QOL on CT	181	2.0	2.8	2.8	3.0	2.7	4.3	2.0
16) New Tx not better than standard	235	3.0	2.3	2.4	2.4	2.5	2.5	1.7
17) new drug side effects	217	3.3	3.0	3.2	3.4	3.3	3.4	3.0
18) randomized treatment worse than re	233	4.0	3.7	3.6	3.6	3.5	4.0	4.0
19) Don't want to be randomized	268	5.0	4.0	4.3	4.4	4.1	4.8	5.0
20) no control on a CT	234	2.0	2.3	2.5	2.6	2.4	2.0	3.7
21) CT Loss of confidentiality	228	4.0	2.7	3.0	3.0	2.9	3.4	2.3
22) alt. med. should be studied	276	1.7	1.5	1.4	1.5	1.7	1.7	2.3
23) alt. med. too unknown	249	3.7	2.2	2.4	2.5	2.7	3.3	5.0
24) alt. med. can't choose own Tx	244	3.7	3.5	3.5	3.7	3.8	3.7	4.5
25) CT can test alt. med. with reg. me	235	2.7	1.6	1.6	1.5	1.8	1.4	3.5
26) alt. med. limits future Tx	209	2.0	1.9	1.6	1.7	2.0	1.3	2.7
27) Bad MD, friends opinion of alt med	238	2.3	2.0	2.0	2.0	2.5	2.3	3.0
28) English not native	83	.	1.0	1.2	1.2	2.3	1.0	3.0
29) English not native (N/A set to 1)	150	1.0	1.0	1.1	1.1	1.7	1.0	2.0
30	150	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

Ethnic Group		Ethnic_Group					
		Asian	Black	White	Hispanic	Other	Missing
	ANS	ANS	ANS	ANS	ANS	ANS	ANS
	N	MEAN	MEAN	MEAN	MEAN	MEAN	MEAN
Question							
01) enough CT info	246	2.3	2.9	2.8	3.1	3.5	2.8
02) CT on Internet	237	3.1	2.8	2.5	2.2	1.5	2.1
03) CT limits future Tx	94	1.7	2.4	2.6	1.0	.	3.0
04) Tx sooner on CT	203	2.6	2.0	2.3	1.8	3.0	2.2
05) Can see regular MD	205	1.7	1.2	1.7	1.4	2.0	1.1
06) If no CT ref, then CT not right	244	3.6	3.6	2.6	3.7	1.0	3.3
07) MD may not want	192	2.3	3.1	2.3	2.4	2.0	2.5
08) unanswered questions on CT	225	3.0	2.9	2.4	3.4	1.5	3.2
09) extra time on tests and visits	228	4.1	3.6	3.9	3.0	4.5	4.8
10) spend transport., childcare, lose	216	3.2	2.8	3.0	2.7	4.0	2.9
11) insurance may not cover CT cost	88	1.5	2.5	2.8	.	3.0	3.4
12) more side effects	191	3.4	3.1	2.9	2.8	2.0	3.4
13) more stress on CT	221	3.2	2.1	2.8	3.2	3.0	3.0
14) CT a constant reminder of Brca	271	2.0	1.8	1.8	1.5	3.0	1.6
15) Better Psych, QOL on CT	180	2.7	3.5	2.9	2.0	5.0	2.8
16) New Tx not better than standard	231	2.1	2.1	2.4	2.3	2.0	2.7
17) new drug side effects	214	3.0	2.8	3.3	4.4	3.0	3.7
18) randomized treatment worse than re	230	3.1	3.1	3.7	3.8	4.0	3.6
19) Don't want to be randomized	264	4.4	4.7	4.3	4.5	5.0	4.2
20) no control on a CT	230	2.3	1.4	2.6	3.0	2.5	1.9
21) CT Loss of confidentiality	224	2.7	2.4	3.0	3.0	4.0	2.9
22) alt. med. should be studied	272	1.5	1.4	1.6	1.0	1.0	1.3
23) alt. med. too unknown	246	3.2	2.8	2.4	2.9	2.5	2.4
24) alt. med. can't choose own Tx	240	3.8	4.2	3.6	4.0	3.0	2.8
25) CT can test alt. med. with reg. me	232	1.8	1.5	1.6	2.0	1.5	1.5
26) alt. med. limits future Tx	207	2.0	1.6	1.7	1.5	1.5	1.6
27) Bad MD, friends opinion of alt med	236	1.5	2.5	2.1	1.6	1.0	2.4
28) English not native	81	1.5	1.0	1.2	2.5	1.0	1.4
29) English not native (N/A set to 1)	146	1.3	1.0	1.1	2.5	1.0	1.3
30	146	0.0	0.0	0.0	0.0	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

WHITE Group		White?	
		No	Yes
	ANS N	ANS MEAN	ANS MEAN
Question			
01) enough CT info	234	2.7	2.8
02) CT on Internet	227	2.8	2.5
03) CT limits future Tx	89	1.9	2.6
04) Tx sooner on CT	195	2.3	2.3
05) Can see regular MD	194	1.4	1.7
06) If no CT ref, then CT not right	230	3.6	2.6
07) MD may not want	182	2.6	2.3
08) unanswered questions on CT	213	3.0	2.4
09) extra time on tests and visits	217	3.7	3.9
10) spend transport., childcare, lose	205	2.9	3.0
11) insurance may not cover CT cost	80	2.3	2.8
12) more side effects	182	3.2	2.9
13) more stress on CT	211	2.8	2.8
14) CT a constant reminder of Brca	257	1.8	1.8
15) Better Psych, QOL on CT	171	2.9	2.9
16) New Tx not better than standard	221	2.2	2.4
17) new drug side effects	205	3.1	3.3
18) randomized treatment worse than re	219	3.2	3.7
19) Don't want to be randomized	250	4.5	4.3
20) no control on a CT	219	2.1	2.6
21) CT Loss of confidentiality	213	2.6	3.0
22) alt. med. should be studied	258	1.4	1.6
23) alt. med. too unknown	235	3.0	2.4
24) alt. med. can't choose own Tx	228	4.0	3.6
25) CT can test alt. med. with reg. me	220	1.7	1.6
26) alt. med. limits future Tx	196	1.8	1.7
27) Bad MD, friends opinion of alt med	225	1.9	2.1
28) English not native	73	1.6	1.2
29) English not native (N/A set to 1)	133	1.4	1.1
30	133	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

Marital Status		Married?	
		No	Yes
	ANS N	ANS MEAN	ANS MEAN
Question			
01) enough CT info	232	2.7	2.8
02) CT on Internet	223	2.8	2.4
03) CT limits future Tx	83	2.6	2.5
04) Tx sooner on CT	189	2.5	2.2
05) Can see regular MD	193	1.7	1.6
06) If no CT ref, then CT not right	229	2.8	2.8
07) MD may not want	181	2.3	2.3
08) unanswered questions on CT	212	2.6	2.4
09) extra time on tests and visits	216	3.9	4.0
10) spend transport., childcare, lose	208	2.8	3.0
11) insurance may not cover CT cost	79	2.8	2.7
12) more side effects	180	3.0	2.9
13) more stress on CT	207	3.0	2.6
14) CT a constant reminder of Brca	255	1.8	1.8
15) Better Psych, QOL on CT	168	2.9	2.9
16) New Tx not better than standard	219	2.4	2.3
17) new drug side effects	205	3.4	3.2
18) randomized treatment worse than re	217	3.6	3.5
19) Don't want to be randomized	249	4.4	4.2
20) no control on a CT	215	2.5	2.5
21) CT Loss of confidentiality	209	3.2	2.8
22) alt. med. should be studied	257	1.4	1.6
23) alt. med. too unknown	229	2.5	2.5
24) alt. med. can't choose own Tx	226	3.7	3.6
25) CT can test alt. med. with reg. me	217	1.6	1.6
26) alt. med. limits future Tx	193	1.7	1.7
27) Bad MD, friends opinion of alt med	220	2.0	2.1
28) English not native	74	1.3	1.2
29) English not native (N/A set to 1)	130	1.2	1.1
30	130	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

Age		Age			
		<45	45-50	50-60	>60
	ANS N	ANS MEAN	ANS MEAN	ANS MEAN	ANS MEAN
Question					
01) enough CT info	250	2.9	2.9	2.8	2.6
02) CT on Internet	240	2.5	2.3	2.5	3.0
03) CT limits future Tx	98	2.8	2.9	2.6	2.1
04) Tx sooner on CT	206	2.3	2.3	2.4	2.2
05) Can see regular MD	207	1.7	1.8	1.7	1.4
06) If no CT ref, then CT not right	248	2.9	2.5	2.6	3.3
07) MD may not want	195	2.8	1.9	2.3	2.5
08) unanswered questions on CT	229	2.5	2.5	2.5	2.7
09) extra time on tests and visits	232	4.1	4.0	4.0	3.6
10) spend transport., childcare, lose	220	3.5	2.6	3.1	2.5
11) insurance may not cover CT cost	90	3.2	3.3	2.4	2.6
12) more side effects	194	3.1	2.6	3.1	2.8
13) more stress on CT	225	2.9	2.8	2.7	2.7
14) CT a constant reminder of Brca	274	1.8	1.7	1.8	1.9
15) Better Psych, QOL on CT	181	2.8	2.7	3.0	3.0
16) New Tx not better than standard	235	2.4	2.3	2.4	2.4
17) new drug side effects	217	3.1	3.3	3.4	3.3
18) randomized treatment worse than re	233	3.6	3.6	3.6	3.6
19) Don't want to be randomized	268	4.2	4.4	4.4	4.3
20) no control on a CT	234	2.6	2.3	2.6	2.4
21) CT Loss of confidentiality	228	3.0	2.9	3.0	3.0
22) alt. med. should be studied	276	1.5	1.3	1.5	1.7
23) alt. med. too unknown	249	2.4	2.3	2.5	2.9
24) alt. med. can't choose own Tx	244	3.4	3.6	3.7	3.8
25) CT can test alt. med. with reg. me	235	1.6	1.6	1.5	1.8
26) alt. med. limits future Tx	209	1.7	1.6	1.7	1.9
27) Bad MD, friends opinion of alt med	238	2.1	1.9	2.0	2.5
28) English not native	83	1.1	1.2	1.2	2.0
29) English not native (N/A set to 1)	150	1.1	1.1	1.1	1.5
30	150	0.0	0.0	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

Post menopausal		Post Menopausal?	
		No	Yes
	ANS N	ANS MEAN	ANS MEAN
Question			
01) enough CT info	203	2.7	2.6
02) CT on Internet	194	2.3	2.8
03) CT limits future Tx	66	2.7	2.5
04) Tx sooner on CT	174	2.3	2.4
05) Can see regular MD	169	1.6	1.6
06) If no CT ref, then CT not right	200	2.8	2.9
07) MD may not want	160	2.3	2.5
08) unanswered questions on CT	187	2.3	2.6
09) extra time on tests and visits	185	4.0	3.9
10) spend transport., childcare, lose	180	3.1	2.8
11) insurance may not cover CT cost	60	2.7	2.5
12) more side effects	157	2.8	3.0
13) more stress on CT	183	2.8	2.9
14) CT a constant reminder of Brca	219	1.8	1.8
15) Better Psych, QOL on CT	151	2.9	3.0
16) New Tx not better than standard	188	2.2	2.6
17) new drug side effects	177	3.1	3.4
18) randomized treatment worse than re	188	3.5	3.7
19) Don't want to be randomized	216	4.3	4.4
20) no control on a CT	187	2.4	2.6
21) CT Loss of confidentiality	181	2.9	3.1
22) alt. med. should be studied	221	1.5	1.6
23) alt. med. too unknown	199	2.5	2.7
24) alt. med. can't choose own Tx	199	3.8	3.7
25) CT can test alt. med. with reg. me	190	1.5	1.6
26) alt. med. limits future Tx	165	1.7	1.8
27) Bad MD, friends opinion of alt med	189	1.9	2.3
28) English not native	55	1.3	1.6
29) English not native (N/A set to 1)	93	1.1	1.4
30	93	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

Educational level attained		Educ level			
		No college	Some college	College grad.	Grad. school
	ANS	ANS	ANS	ANS	ANS
	N	MEAN	MEAN	MEAN	MEAN
Question					
01) enough CT info	206	2.8	3.1	2.9	2.4
02) CT on Internet	201	2.5	2.7	2.6	2.4
03) CT limits future Tx	64	2.0	2.9	2.5	2.8
04) Tx sooner on CT	170	1.9	2.3	2.6	2.3
05) Can see regular MD	169	1.6	1.6	1.7	1.7
06) If no CT ref, then CT not right	195	3.4	3.2	2.8	2.4
07) MD may not want	163	2.4	2.4	2.5	2.3
08) unanswered questions on CT	187	2.9	2.1	2.5	2.5
09) extra time on tests and visits	185	3.8	3.6	4.0	4.2
10) spend transport., childcare, lose	182	3.1	3.1	3.1	3.0
11) insurance may not cover CT cost	59	2.6	2.7	3.0	2.9
12) more side effects	155	2.9	2.8	3.3	2.8
13) more stress on CT	182	2.7	2.8	2.9	2.6
14) CT a constant reminder of Brca	224	2.1	1.7	2.0	1.6
15) Better Psych, QOL on CT	152	3.2	2.7	2.8	3.1
16) New Tx not better than standard	192	2.4	2.5	2.2	2.2
17) new drug side effects	176	3.0	3.5	3.4	3.2
18) randomized treatment worse than re	189	3.3	3.4	3.8	3.6
19) Don't want to be randomized	221	4.0	4.3	4.4	4.4
20) no control on a CT	192	2.4	3.1	2.4	2.4
21) CT Loss of confidentiality	184	3.0	3.2	3.0	2.9
22) alt. med. should be studied	226	1.4	1.6	1.6	1.6
23) alt. med. too unknown	203	2.9	2.5	2.5	2.4
24) alt. med. can't choose own Tx	197	3.6	3.9	3.6	3.6
25) CT can test alt. med. with reg. me	192	1.8	1.6	1.6	1.5
26) alt. med. limits future Tx	167	2.0	1.7	1.8	1.6
27) Bad MD, friends opinion of alt med	193	2.3	2.5	2.0	2.0
28) English not native	54	1.6	1.0	1.2	1.5
29) English not native (N/A set to 1)	97	1.4	1.0	1.1	1.2
30	97	0.0	0.0	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Table#6 - Average answers by demographics

YEAR Both years

Stage		Stage Grouping				
		In Situ	I	II	III	IV
	ANS	ANS	ANS	ANS	ANS	ANS
	N	MEAN	MEAN	MEAN	MEAN	MEAN
Question						
01) enough CT info	118	2.3	2.7	2.6	2.5	2.4
02) CT on Internet	122	2.0	2.5	2.9	2.6	2.1
03) CT limits future Tx	26	5.0	2.7	2.2	3.0	1.0
04) Tx sooner on CT	103	3.0	2.1	2.7	2.2	2.0
05) Can see regular MD	97	1.6	1.9	1.8	1.3	1.2
06) If no CT ref, then CT not right	116	2.0	3.2	2.5	2.6	2.7
07) MD may not want	99	3.8	2.4	2.4	2.7	1.9
08) unanswered questions on CT	112	3.8	2.7	2.8	3.1	1.9
09) extra time on tests and visits	111	4.3	3.8	4.0	4.5	4.3
10) spend transport., childcare, lose	107	2.8	3.2	3.1	3.2	3.3
11) insurance may not cover CT cost	23	.	2.3	3.3	2.0	.
12) more side effects	101	2.3	3.2	3.0	3.1	2.9
13) more stress on CT	105	2.0	2.9	2.9	2.7	2.4
14) CT a constant reminder of Brca	128	1.6	1.8	1.9	1.7	1.3
15) Better Psych, QOL on CT	90	4.0	3.0	2.7	3.7	2.8
16) New Tx not better than standard	110	3.0	2.0	2.2	2.6	1.9
17) new drug side effects	105	3.4	3.1	3.3	3.2	2.3
18) randomized treatment worse than re	111	4.4	3.5	3.7	3.5	3.0
19) Don't want to be randomized	124	3.8	4.4	4.2	4.4	3.9
20) no control on a CT	109	3.0	2.6	2.6	2.0	1.7
21) CT Loss of confidentiality	105	2.8	2.8	2.8	2.4	3.5
22) alt. med. should be studied	131	1.4	1.7	1.5	1.6	1.1
23) alt. med. too unknown	115	2.8	2.7	2.3	2.5	1.9
24) alt. med. can't choose own Tx	113	4.5	3.9	3.6	3.6	2.8
25) CT can test alt. med. with reg. me	113	1.3	1.6	1.7	2.0	1.7
26) alt. med. limits future Tx	95	1.5	1.8	1.9	2.3	1.5
27) Bad MD, friends opinion of alt med	117	2.4	2.3	2.0	2.1	1.9
28) English not native	15	.	2.0	1.4	1.0	.
29) English not native (N/A set to 1)	39	1.0	1.4	1.2	1.0	1.0
30	39	0.0	0.0	0.0	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

Family history of Br Ca		FH of Breast Cancer	
		No	Yes
	ANS N	ANS MEAN	ANS MEAN
Question			
01) enough CT info	221	2.7	2.9
02) CT on Internet	214	2.4	2.7
03) CT limits future Tx	79	2.6	2.8
04) Tx sooner on CT	181	2.3	2.4
05) Can see regular MD	183	1.7	1.6
06) If no CT ref, then CT not right	218	2.9	2.5
07) MD may not want	176	2.4	2.2
08) unanswered questions on CT	206	2.7	2.2
09) extra time on tests and visits	203	4.1	3.7
10) spend transport., childcare, lose	196	3.0	3.0
11) insurance may not cover CT cost	70	3.0	2.5
12) more side effects	174	3.1	2.8
13) more stress on CT	199	2.9	2.6
14) CT a constant reminder of Brca	243	2.0	1.5
15) Better Psych, QOL on CT	158	3.0	2.7
16) New Tx not better than standard	208	2.3	2.4
17) new drug side effects	192	3.2	3.5
18) randomized treatment worse than re	206	3.6	3.5
19) Don't want to be randomized	239	4.3	4.3
20) no control on a CT	211	2.6	2.3
21) CT Loss of confidentiality	199	3.0	2.9
22) alt. med. should be studied	242	1.6	1.6
23) alt. med. too unknown	221	2.8	2.3
24) alt. med. can't choose own Tx	218	3.6	3.7
25) CT can test alt. med. with reg. me	211	1.6	1.6
26) alt. med. limits future Tx	184	2.0	1.5
27) Bad MD, friends opinion of alt med	211	2.3	1.9
28) English not native	65	1.4	1.2
29) English not native (N/A set to 1)	119	1.2	1.1
30	119	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

ER status		ER	
		-	+
	ANS N	ANS MEAN	ANS MEAN
Question			
01) enough CT info	189	3.1	2.9
02) CT on Internet	177	2.6	2.7
03) CT limits future Tx	94	2.5	2.6
04) Tx sooner on CT	148	2.3	2.4
05) Can see regular MD	154	1.6	1.7
06) If no CT ref, then CT not right	190	2.8	2.6
07) MD may not want	150	2.4	2.3
08) unanswered questions on CT	174	2.9	2.3
09) extra time on tests and visits	178	3.9	3.9
10) spend transport., childcare, lose	160	3.2	2.9
11) insurance may not cover CT cost	87	2.7	2.9
12) more side effects	149	3.0	3.0
13) more stress on CT	166	2.7	2.9
14) CT a constant reminder of Brca	204	1.8	1.7
15) Better Psych, QOL on CT	131	2.9	2.8
16) New Tx not better than standard	175	2.3	2.4
17) new drug side effects	160	3.4	3.2
18) randomized treatment worse than re	170	3.7	3.5
19) Don't want to be randomized	197	4.3	4.3
20) no control on a CT	174	2.3	2.5
21) CT Loss of confidentiality	169	3.1	2.9
22) alt. med. should be studied	206	1.4	1.6
23) alt. med. too unknown	186	2.3	2.4
24) alt. med. can't choose own Tx	176	3.6	3.5
25) CT can test alt. med. with reg. me	179	1.6	1.6
26) alt. med. limits future Tx	162	1.8	1.6
27) Bad MD, friends opinion of alt med	183	2.0	2.0
28) English not native	79	1.3	1.3
29) English not native (N/A set to 1)	143	1.2	1.2
30	143	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

PR status		PR	
		-	+
	ANS	ANS	ANS
	N	MEAN	MEAN
Question			
01) enough CT info	169	3.0	2.9
02) CT on Internet	159	2.6	2.6
03) CT limits future Tx	94	2.5	2.5
04) Tx sooner on CT	132	2.4	2.5
05) Can see regular MD	139	1.7	1.6
06) If no CT ref, then CT not right	171	2.9	2.4
07) MD may not want	132	2.5	2.2
08) unanswered questions on CT	157	2.8	2.4
09) extra time on tests and visits	162	3.8	4.0
10) spend transport., childcare, lose	143	3.0	3.0
11) insurance may not cover CT cost	87	2.7	2.9
12) more side effects	133	3.0	3.0
13) more stress on CT	151	2.7	3.0
14) CT a constant reminder of Brca	184	1.8	1.8
15) Better Psych, QOL on CT	118	2.9	2.7
16) New Tx not better than standard	155	2.3	2.5
17) new drug side effects	142	3.4	3.1
18) randomized treatment worse than re	153	3.9	3.4
19) Don't want to be randomized	178	4.2	4.4
20) no control on a CT	157	2.3	2.6
21) CT Loss of confidentiality	154	2.9	3.0
22) alt. med. should be studied	186	1.5	1.5
23) alt. med. too unknown	166	2.4	2.3
24) alt. med. can't choose own Tx	161	3.5	3.6
25) CT can test alt. med. with reg. me	162	1.6	1.6
26) alt. med. limits future Tx	144	1.7	1.7
27) Bad MD, friends opinion of alt med	163	2.0	2.1
28) English not native	79	1.3	1.3
29) English not native (N/A set to 1)	143	1.2	1.2
30	143	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

Either ER or PR		ER+ or PR+	
		-	+
	ANS N	ANS MEAN	ANS MEAN
Question			
01) enough CT info	186	3.1	2.9
02) CT on Internet	174	2.7	2.7
03) CT limits future Tx	94	2.6	2.5
04) Tx sooner on CT	145	2.4	2.4
05) Can see regular MD	151	1.7	1.7
06) If no CT ref, then CT not right	187	2.9	2.5
07) MD may not want	147	2.5	2.3
08) unanswered questions on CT	171	3.0	2.3
09) extra time on tests and visits	175	4.0	3.9
10) spend transport., childcare, lose	157	3.2	2.9
11) insurance may not cover CT cost	87	2.6	2.9
12) more side effects	146	3.2	2.9
13) more stress on CT	163	2.8	2.9
14) CT a constant reminder of Brca	201	1.9	1.7
15) Better Psych, QOL on CT	129	2.9	2.8
16) New Tx not better than standard	173	2.2	2.4
17) new drug side effects	157	3.5	3.2
18) randomized treatment worse than re	167	3.9	3.5
19) Don't want to be randomized	194	4.3	4.3
20) no control on a CT	171	2.3	2.5
21) CT Loss of confidentiality	168	3.0	2.9
22) alt. med. should be studied	203	1.4	1.6
23) alt. med. too unknown	183	2.3	2.3
24) alt. med. can't choose own Tx	173	3.6	3.6
25) CT can test alt. med. with reg. me	176	1.6	1.6
26) alt. med. limits future Tx	159	1.7	1.7
27) Bad MD, friends opinion of alt med	180	2.0	2.0
28) English not native	79	1.3	1.3
29) English not native (N/A set to 1)	143	1.2	1.2
30	143	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

Patient Attitudes to Clinical Trials

Table#6 - Average answers by demographics

YEAR Both years

Both ER and PR		ER+ and PR+	
		-	+
	ANS N	ANS MEAN	ANS MEAN
Question			
01) enough CT info	172	3.0	2.9
02) CT on Internet	162	2.6	2.6
03) CT limits future Tx	94	2.5	2.6
04) Tx sooner on CT	135	2.3	2.5
05) Can see regular MD	142	1.7	1.6
06) If no CT ref, then CT not right	174	2.8	2.4
07) MD may not want	135	2.4	2.2
08) unanswered questions on CT	160	2.8	2.3
09) extra time on tests and visits	165	3.8	4.1
10) spend transport., childcare, lose	146	2.9	3.0
11) insurance may not cover CT cost	87	2.7	2.9
12) more side effects	136	3.0	3.0
13) more stress on CT	154	2.7	3.1
14) CT a constant reminder of Brca	187	1.8	1.8
15) Better Psych, QOL on CT	120	2.9	2.7
16) New Tx not better than standard	157	2.4	2.4
17) new drug side effects	145	3.4	3.1
18) randomized treatment worse than re	156	3.8	3.5
19) Don't want to be randomized	181	4.2	4.4
20) no control on a CT	160	2.3	2.6
21) CT Loss of confidentiality	155	2.9	2.9
22) alt. med. should be studied	189	1.5	1.5
23) alt. med. too unknown	169	2.3	2.3
24) alt. med. can't choose own Tx	164	3.5	3.6
25) CT can test alt. med. with reg. me	165	1.6	1.6
26) alt. med. limits future Tx	147	1.7	1.6
27) Bad MD, friends opinion of alt med	166	2.0	2.0
28) English not native	79	1.3	1.3
29) English not native (N/A set to 1)	143	1.2	1.2
30	143	0.0	0.0

Answers to Questions Q01 Q02 Q04 Q05 Q22 Q25 have been reversed so 5=impediment always

- Clinical Trials
- Basic Research
- Patient Perspectives
- Breast Cancer Forum
- Clinical Trials Newsletter
- Patient Questionnaire
- Other Resources
- Glossary

Breast Cancer Forum

Our group sponsors monthly Bay Area Breast Cancer Forums. These forums are held the second Wednesday every month, from 6-8pm in the 3rd floor conference room of the UCSF Comprehensive Cancer Center at 1600 Divisadero Street, San Francisco.

Below are the minutes from the monthly gathering of health care providers, researchers, patients, patient advocates, and families on current issues relating to clinical trials.

2001

January	Making Surgery as Easy, Effective and Informative as Possible
February	Quality of Life After Breast Cancer: How Do We Measure It and Use the Information Effectively?
March	Mammograms: Is a Picture Worth a Thousand Words?
April	When and Why is Radiation Therapy Helpful?
May	The Latest on Tamoxifen and Other Hormone Therapies
June	Demystifying Genetic Risk and Hormone Influences in Breast Cancer

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2000

January	Making Decisions in the Face of Uncertainty
March	Studies in Stage III Breast Cancer: What Can We Learn About Biology and Prognosis
April	Treating Metastatic Breast Cancer: A Philosophical Approach
May	Integrating Research and Individual Patient Preferences into Optimal Decision-Making for Breast Cancer Treatment
June	ASCO 2000: What's New in Breast Cancer Research & Involving Patients in Decision Making: A Collaborative Care Model
October	The Internet: Friend or Foe?
November	Therapy After Surgery: Can We Change Fate? Results of the NCI Consensus Conference
December	What's New in Breast Cancer Research: Commentary on the San Antonio Breast Cancer Symposium, 2000

1999

January	Analyzing the Traditional Chinese Model of Care for Breast Cancer
February	What if I Have a Recurrence? A Revisionist Approach to the Treatment of Breast Cancer
April	Watchful Waiting or Serial Scanning: Which is Better Surveillance for Early Stage Breast Cancer?
May	Lymph Node Status: Do We Really Want to Know?
June	Safe or Toxic: What Are the Short and Long Term Effects of Chemotherapy and Tamoxifen?
October	Lifestyle Choices:How Much Does it Matter?
November	Breast Nipple Aspirate Analysis: A Window to Breast

	Cells, Risk of Cancer and Response to Preventive Measures
December	What's New in Breast Cancer Research: Summary and Commentary on the San Antonio Meeting

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1998

January	Determining Inherited Breast Cancer Risk
February	What's the Latest in Anti-Angiogenesis Therapy for Breast Cancer?
March	Molecular Decision-Making and Therapy: The HER2/neu Example
April	Tissue Research: Hopes and Concerns. How to Read Your Path Report.
May	What is Quality Care? A Patient's Perspective
June	Integrative Medicine for Breast Cancer
October	Adjuvant Therapy for Early Breast Cancer: Individualizing Decisions
November	Treatment Old and New: What Works and What Doesn't
December	Beating the Odds of Breast Cancer: The Role of Research

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1997

January	How to Choose and prioritize
February	Making Decisions About Experimental Therapies
March	Exploring Alternative and Complementary Medicine
April	10 Coping Mechanisms
May	The Future of Science and Technology
June	Developing the Role of the Patient Navigator
September	The Patient Navigator System
October	Overcoming Barriers to Information and Access
November	The Relevance of Optimal Communication
November	The Second Meeting in November
December	The Yin and Yang of Estrogens and Antiestrogens

- Clinical Trials
- Basic Research
- Patient Perspectives
- Breast Cancer Forum
- Clinical Trials Newsletter
- Patient Questionnaire
- Other Resources
- Glossary

CLINICAL TRIALS NEWSLETTER

We publish a regular newsletter focusing on clinical trials and relevant research for individuals, families, and friends of those living with breast cancer. Look for our newsletter to cover the following topics:

- The current status of research and clinical trials - perspectives from patients and advocates, physicians and scientific investigators.
- Barriers to clinical trials enrollment - perceptions of patients and caregivers.
- Promising directions in science and technology for new therapies (vaccines/immunological approaches, growth factor targeting, anti-angiogenesis drugs, gene therapy, and others).
- New discoveries in causes of cancer, prevention, and screening.
- Research in genetic counseling and testing for inherited cancer ask.
- Alternative and complimentary medicine - current practices and opportunities for better understanding through clinical research.
- Psychological and social support.
- Proposed mechanisms for improving information on clinical trials and access to participation.
- Addressing underrepresented populations and underserved areas of investigation.
- Summaries of focus groups and forums held by our group on diverse topics.

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2001

February	Novel Vaccine Study Opens at UCSF
March	Cancer Patients Not Keen to be Test Subjects
April	New Breast Cancer Trial Starting
May	New Clinical Trial: The Soy-Tamoxifen Prevention Trial
June	Gene Sequence May Protect Against Breast Cancer
July	Bone Density May Signal Breast Cancer Risk

2000

January	Alternate Therapies Used by Women with Breast Cancer in Four Ethnic Populations
February	Serious Scientific Misconduct Alleged in Clinical Trial of High-Dose Chemo Plus Bone Marrow Transplant
March	UCSF Part of Major Breast Cancer Prevention Study
May	Cancer Trial Costs Similar to Standard Care Costs
September	Breast Cancer Complementary Support Program Opens

October	Onyx 015 has Broad Application for Treatment of Cancer
November	Cancer Risk Program Available at UCSF
December	A New Clinical Trial for Women with Metastatic Breast Cancer

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1999

January	San Antonio Breast Cancer Symposium Update, 1998
February	Chemotherapy and Heat Combined to Better Target Chest Wall Lesions in Breast Cancer
March	Detecting Breast Cancer Cells in the Blood and Marrow: Which Technology is Better?
April	Preview of Five Studies to Be Presented at ASCO in May, 1999
May	Breast Cancer Vaccine Trial Opens at UCSF
June	Psychosocial Trial Continues Recruitment at UCSF
October	UCSF Breast Cancer Expert Collaborates with Dalai Lama's Doctor in Tibetan Medicine Study

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1998

February	Concerns and Hopes for Tissue Research
March	Alternative and Complementary Medicine Moves Forward at Mount Zion
April	Genetic Aspects of Cancer: Is Testing in Your Future?
May	Breast Center Explores Lifestyle Intervention in Research Trial
August	ASCO Meeting
October	FDA Offers Fast-Track Approval to Herceptin
November	Can Chinese Herbs Reduce the Side Effects of Chemotherapy for Breast Cancer?

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List of Personnel

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DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
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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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