EMERGING SOLUTIONS: ADVOCATE COLLABORATIVE MODEL

Peggy Devine[1, 2], Nola Hylton[1], Meredith Buxton[1], Laura Esserman[1]

UCSF Breast SPORE[1], CISN [2]

ABSTRACT

EMERGING SOLUTIONS. ADVOCATE COLLABORATIVE MODEL
Peggy Devine [1,2], Laura Esserman MD, MBA [1], Nola Hylton PhD [1]
University of California, San Francisco (UCSF) [1], Cancer Information & Support Network(CISN)[2]

Introduction: In today's clinical trial arena, interest in accrual and retention is extremely high among investigators. A 2001 study by Lara et al, at Davis University, reported that the consent process, with its legalistic and confusing forms, is itself a barrier to patient participation. Patients are in emotional and intellectual overload after a breast cancer diagnosis and are often not up to the task of understanding complicated consent forms.

Description: To address this problem, patient advocates with the UCSF Breast SPORE created explanatory letters about specific clinical trials. UCSF Investigators and SPORE advocate, Ms. Devine, expanded the idea into an advocate component for the multi-site "I SPY TRIAL" sponsored by the Cancer & Leukemia Group B (CALBG), the American College of Radiology Imaging Network (ACRIN) and the National Cancer Institute (NCI) SPORE. Educational materials developed by advocates to clarify the study were used with patients undergoing consent. We will refer to this as example 1.Further projects in this area were continued by CISN, a Non-profit organization founded by Ms. Devine. Example 2: CISN principals are currently working with the American College of Surgery Oncology Group (ACOSOG) and UCSF researchers to assess the impact of clinical trial decision aids (educational materials plus decision analysis support) to improve the quality of the informed consent process. A companion randomized study using decision aids for women who are undecided about enrolling in an upcoming ACOSOG study is now in development. Example 3: collaboration between CISN, ACRIN and the Coalition of National Cancer Cooperative Groups has been completed and a study update/reminder newsletter will soon be sent to over 18,000 patients in an attempt to improve retention rates for a screening study with a 7-year follow-up period.

Summary: Example 1: work was done informally but has been well received by most stakeholders. We are in the process of tabulating survey data to better document their impact. Example 2: we will formally document the impact of educational/decision aid support during the clinical trial consent process. Example 3: we will attempt to document retention rates by comparing with historical data.
Conclusions: Although this work provides a bold new blueprint for advocate involvement in the informed consent process, there is much work yet to be done. Patient-centered, study specific, educational materials included as part of the informed consent process may enhance patient literacy, improve patient satisfaction, and advance public trust in the research enterprise, leading to responsible increased accrual and retention. CISN is committed to continuing this work.

INTRODUCTION

ACRIN, CALGB, and SPORE are collaborating in a multi-center trial of serial imaging and biopsy for women with tumors at least 3 cm in size who undergo neoadjuvant chemotherapy, entitled the CALGB, InterSPORE, ACRIN **"I SPY TRIAL"**. MRIs and biopsies are being performed at 4 time points over the course of a patient's therapy. This trial provides the opportunity for the molecular characterization of tumors and the measurement of tumor response to therapy and change in tumor size and biology using MRI.

Since this trial asked newly diagnosed women to come in for 2 to 3 non-treatment MRIs and biopsy cores, the study PIs felt that advocates might be an asset to both the PIs and the trial participants and might improve patient accrual, retention, and satisfaction. The project was brought to the UCSF breast SPORE advocate core (BSAC) to develop.

This model for patient-centered educational support materials to accompany the consent form is now being utilized by others, including CISN. This work would never have taken place without the vision and support of the I-SPY TRIAL PI laura Esserman.

DESCRIPTION: With examples of interventions

Advocate involvement in all stages of a large national clinical trial can be an asset to both the study PI's and the patients enrolled, resulting in:

* Increased patient recruitment, accrual and retention
* Patient satisfaction and compliance

EXAMPLE 1: "I SPY" TRIAL

I. Assistance with the IRB process:

A. Consent forms: The consent form was modified (e.g., information was presented in a bulleted rather than paragraph format) at the suggestion of the advocates to clarify the requirements and expectations. Cancer patients are in shock when they are asked to read consent forms. Short bulleted statements are more readily understood than long statements in paragraph form.

INTERVENTIONS Cont.

II. Development of educational materials for eligible trial participants:

Cancer patients are in a state of shock after receiving their diagnosis. Despite this, they are asked to make choices about treatment, tissue donation, and participation in clinical trials. It is our contention that if patients have a clear understanding of a clinical trial they are more likely to enroll. The following educational materials were developed to aid potential study participants in understanding the study.

A. Woman-to-Woman Note (WWN): A letter that explains the trial in lay language

Woman to Woman: MRI & Marker Study Information

Dear Patient,

There is no way to prepare for the shocking news " You have breast cancer." You are probably asking yourself "what do I do now?" As breast cancer survivors, we have experienced the same shock and asked the same question. We understand how many decisions must be made and how overwhelming it feels.

Unfortunately, as you explore your options, you will quickly find out that there is no "answer book." One of your choices may include a "clinical trial." While this may sound a bit intimidating, it is simply a study that carefully tests new ways to prevent, diagnose, treat or research diseases like breast cancer. We understand that you have been given information on the MRI and Marker study. *This letter is written with the hope that it will help you understand the study better.*

What is the MRI & Marker Study about?

UCSF has opened an important research study with other Cancer Centers for women, who with their physician, have decided to get chemotherapy before surgery (this is called neoadjuvant). The purpose of this study is to carefully monitor (or track) how your tumor will respond to the chemotherapy you are getting. This is actually important because at the present time your Doctor cannot tell you whether your tumor responds to chemotherapy. Your treatment and care are not affected in any way because there is no treatment in this particular study. *Women who participate will help make a difference for future women by providing new facts about how a tumor responds to chemotherapy.*

There are two different ways that patients are followed in the MRI & Marker study

The first way is with MRI scans to monitor the change in tumor growth. MRIs create different (and sometimes better) images of tissue in a breast than mammography. Information from these images will be reviewed to see if MRI can consistently and accurately find out who will respond to chemotherapy, even very early on in treatment. The information learned from this research may help future women who are not responding to their treatment. These women could then stop chemotherapy and move to another form of treatment. *This will save time and spare women from possible side effects of a treatment that is not helping.*

The second way, the marker study, is tracking actual changes in tissue. This tissue will be obtained from your breast with a core biopsy (you will have three biopsies). This portion of the study may provide clues on how individual tumors respond to treatment. Currently almost everyone receives chemotherapy because it is not known who needs it. *With new markers, the hope is that only women who will benefit from chemotherapy will receive it.*

You are not Alone

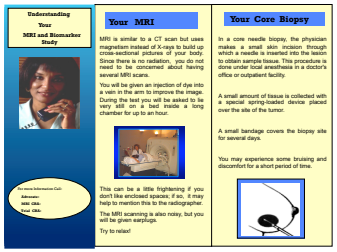
You have made a good decision in coming to this Breast Care Center. For additional information about this clinical trial, please call ..... To talk to a breast cancer survivor call: .....

Wishing you the best,

Peggy Devine,

Deborah Collyar; H.L. Ittner; Linda Vincent; Jodi Alboi; Siri Gomberg; Caroline Marks; Chira Chen; Louise Hyneman; Bambi Schwartz

B. Trial brochure: Explains core biopsies and MRIs. Pictures of each procedure are included to ease women's fears of the unknown.



Understanding Your MRI and Biomarker Study

Your MRI

MRI is similar to a CT scan but uses magnetism instead of X-rays to build up cross-sectional pictures of your body. Since there is no radiation, you do not need to be concerned about having several MRI scans.

You will be given an injection of dye into a vein in the arm to improve the image. During the test you will be asked to lie very still on a bed inside a long chamber for up to an hour.

This can be a little frightening if you don't like enclosed spaces. If so, it may help to mention this to the radiographer.

The MRI scanning is also noisy, but you will be given earplugs.

Try to relax!

Your Core Biopsy

In a core needle biopsy, the physician makes a small skin incision through which a needle is inserted into the lesion to obtain sample tissue. This procedure is done under local anesthesia in a doctor's office or outpatient facility.

A small amount of tissue is collected with a special spring-loaded device placed over the site of the tumor.

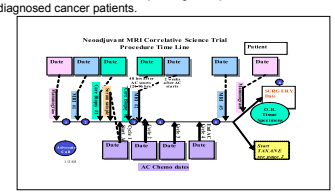
A small bandage covers the biopsy site for several days.

You may experience some bruising and discomfort for a short period of time.

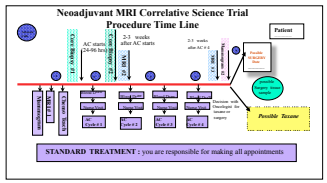
Interventions Cont.

II. Development of educational materials for eligible trial participants

C. Trial procedure flowchart: A color-coded flowchart was developed to help patients understand their time and procedure commitment. This is also being used as a study calendar. It is important to have visual charts available when explaining complicated information to newly diagnosed cancer patients.



D. A standard treatment vs. study procedures flowchart: A comparison flowchart was also developed because patients where having a difficult time understanding the difference between standard treatment and study expectations. The **standard treatment information is presented below the line**, printed on paper and slipped into a clear sheet protector. This flowchart is shown to the patient. The CRC then slips the study procedures (printed on a clear transparency) into the sheet protector, **study procedures are above the line**.



III. Peer support throughout length of the trial: Each trial participant is partnered with a study volunteer. The peer volunteer has received study -specific training, as well as peer support training. The peer volunteers make calls to remind the patient of upcoming procedures and to provide support.

By offering these reminders and support, the advocates may help the study and the patients to comply better with study procedures.

For this program to be successful, it takes the cooperation of all members of the research team. PIs and clinical research coordinators (CRCs) become partners with the advocates at their respective sites.

INTERVENTIONS Cont.

EXAMPLE 2: UCSF / ACOSOG / CISN Decision Aid Collaboration

Example 2 takes the idea that patient centered educational materials may have an impact on accrual, retention and patient survival and combines it with the concept that providing decision support further improves these outcomes and moves the project into a randomized research study.

This study is being developed and may be a companion study to an ACOSOG study.

EXAMPLE 3: CISN / ACRIN Collaboration

A newsletter was developed to remind participants in a 5 year lung screening study to continue to have their yearly screen. This is a specific piece focused on improving retention in a multi year screening study, these types of studies suffer from dropping retention which then confounds the data.

SUMMARY

The I SPY TRIAL collaboration was the first ever effort to incorporate an advocate component into an existing multi-site study. Leading the way in this effort was the study PI Laura Esserman from UCSF and the ACRIN PI, Nola Hylton also with UCSF.

This idea has been embraced by others and will serve as an example for how to better serve patients by forming collaborations between academia and patient advocates.

ACKNOWLEDGMENTS

Example 1:

The advocate component for the I SPY study would not be successful without the support and cooperation of the study PIs, the project manager, the advocates, the research nurses and the CRCs at each site. We would therefore like to acknowledge the following people:

The lead study PIs - Laura Esserman and Nola Hylton.

The lead site PIs - Lisa Carey, Angie DeMichele, Helen Krontiras, Minetta Liu and Leslie Montgomery.

The project manager - Meredith Buxton, originally Kathy Hwang.

The MRI coordinator - Lorna Beccaria: **The advocate manager** - Peggy Devine.

The volunteer site advocates - Robin Hutchison, Linda Katz, Nora Carbine, Gayle Becker, Peggy Devine, Jo Ellen Lezotte, Susi Lewis and Judi Allen.

The study nurses and CRCs - Jessie Gibbs, Nneka Emenyonu, Hillary Robbins, Lauren Sherman, Rachael Sherron, Tara Holiday, Amanda Tweed, Lynn Werner, Valerie Kracke, Tori Amos, Jane Fey, Carolina Montalvo, Cathleen Cooper, Jen Torres, Jenny Crawford, Ann Gallagher and Anita Sarcone.

The CALGB data manager - Eleanor Leung; **The ACRIN data managers** – Sophia Sabina and Deb Harbison

We would especially like to thank and honor those women who have enrolled in this study.

Example 2: UCSF Jeff Belkora PhD, ACOSOG, CISN

Example 3: ACRIN, Coalition of National Cooperative Groups, CISN