



Emerging Solutions: Cancer Information & Support Network Collaborative Advocate Model

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ABSTRACT

Background: In today's clinical trial arena interest in accrual and retention is extremely high among investigators. Although there have been various efforts to determine the literacy of prospective research participants, until recently no one knew why patients unfamiliar with the logistics and nuances of the research enterprise had difficulty making decisions about the risks and benefits of clinical trial participation.

The founder of CISN, a grassroots organization promoting awareness and action, spearheaded the advocacy effort to bridge the research gap and make patient-centered educational material a priority in the clinical trial informed consent process. She began on a small scale at UCSF where patient advocates with the UCSF Breast SPORE, created explanatory letters about specific clinical trials. Since then, her work developed into an advocate component for the MRI Correlative Science clinical trial 15007, sponsored by CALBG, ACRIN, NCI and funded by UCSF. This work was presented as abstract #335 at last years San Antonio Symposium. CISN principals are currently working with UCSF researchers to study the impact of patient-centered materials on the quality of informed consent with ACOSOG and on a small-scale project with ACRIN to create an educational piece for an upcoming study. Although these studies provide a bold new blueprint for advocate involvement in the informed consent process, there is much work yet to be done.

Hypothesis: Educational materials designed with advocate input to enhance the informed consent process may increase patient literacy, improve patient satisfaction, and advance public trust in the research enterprise, leading to responsible increased accrual and retention.

Methods: CISN is introducing the medical community to an array of issues affecting patients considering participation in clinical trials: lack of literacy about research requirements; tissue donation; understanding the informed consent process; the importance of meaningful and full disclosure to patients, and strategies for promoting research integrity.

CISN works closely with academic, government, and industry researchers to help ensure that advocates are integrated into the clinical trial process in a way that will add value to both patients and clinicians. Unique educational materials are being developed to capture the acceptance of the patient. These include, but are not limited to: Woman-to-Woman Notes clarifying the study; brochures detailing medical procedures; flow-charts delineating timelines, newsletters, and research requirements, and clinical /placebo distinctions.

Discussion: Over the past several years' advocates have been integrated into the research setting. What is their role in the future and how can they help set new paradigms and models for informed consent? We address these issues and present various strategies that might be applied to other Cooperative Group trials so as to bridge the research gap, move research forward, and adopt the best course that serves the needs of the community, researchers, and patients.

CISN Goals

Transmit:

Emerging advances in cancer research, diagnosis and treatment by bridging the gap between industry, academia and the public.

Foster:

Public awareness and literacy about the importance of medical research.

Guide:

Enhancements in company infrastructure and organizational framework to better reflect the needs of the public.

CISN Contention

Difficulties Patients experience during clinical trial consent:

- I. Being in cognitive & emotional overload
- II. A 20-30 page legal document to read and sign
- III. Very little educational and decision support structure to assist them

It is our contention that if patients have clear educational information and support during the clinical trial consent process, their understanding my lead to higher satisfaction about the process, with possible secondary results of increased accrual and retention rates.

Examples of CISN products: UCSF breast SPORE

CISN principals have been involved in the following projects:

- I. Cooperative Group clinical trial (SPORE /CALGB/ACRIN) 150007

A suite of educational materials were developed to aid potential 150007 study participants in understanding the study and were used by the clinical research coordinators (CRCs) during the consent process. These materials grew out of a UCSF advocate SPORE project and were funded by UCSF.

The following are two examples:

A. A study specific trial brochure was developed:

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

Understanding Your MRI and Biopsy

Your MRI

MRI is similar to a CT scan but uses computer 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 harmful X-ray 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 cylinder for up to an hour.

A small bandage covers the biopsy site for several days.

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

Your Core Biopsy

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

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

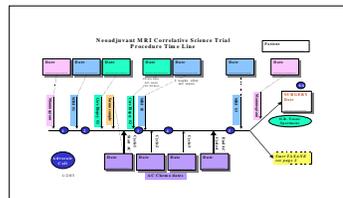
This can be a little frightening if you don't see the procedure. For a more help to mention this to the radiographer.

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

Try to relax!

CISN Examples Cont. : UCSF

B. 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.



Results to date for 150007

- * ~ 72% of patients eligible for the study have enrolled in the study
- * 100% Retention rate

This is much higher than historical averages.

Examples of CISN Products: ACRIN

- I. CISN received an advocate grant from the NCI Coalition of National Cooperative Groups, to design a clinical trial accrual or retention piece for ACRIN. Below is one article in a newsletter that is being developed to thank and remind National Lung Screening Trial 6654 participants about their yearly screen.

Every Star Matters

Remember to mark your NLSST screening test in your 2005 calendar. As an NLSST participant you will receive a screening test once a year for three years. Remember these tests are provided at no cost to you! You also will complete questionnaires about your health every six months during the remaining years of the study. By getting your yearly screen and returning your questionnaires, you will help us answer the following important questions:

Who should be screened for lung cancer?

- ★ How often should the screen occur?
- ★ Is screening for lung cancer effective?
- ★ Which screening tool is most effective?

Example of CISN Products: ACOSOG / UCSF / Pfizer

I. CISN principals have joined forces with Jeff Belkora, PhD, the Director of Decision Services at UCSF, to bring decision aids to the clinical trial consent process. The low participation rate of all cancer patients in clinical trials has been a concern for several decades. Our review of the literature suggests that informed consent is an area of significant attrition.

We will design decision aids to assist patients undergoing consent for an upcoming ACOSOG clinical trial. Those patients who are undecided about enrolling in the ACOSOG study, will be referred to our companion decision aid study.

(see Belkora, Devine, Buxton SABCS poster # 2053 for more specifics)

NEW DIRECTIONS

- I. CISN will reach out to other groups to continue their collaborative model for bridging the gap between industry, academics and the public.
- II. CISN will bring the importance of clinical trials to the public through a planned website provided by Cancer Information and Support Network.
- III. CISN will prepare and distribute customized educational materials (fact sheets, brochures, newsletters and flowcharts). Topics will include but are not limited to tissue and clinical trial issues.
- IV. CISN will help identify and assist in creating "best practice" tools. We will assist partners in preparing patient centered consent forms while maintaining all NCI and Industry required components.
- V. CISN will foster public awareness and literacy about the importance of medical research.

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 3. Thank you to UCSF's Jeff Belkora and Meredith Buxton for their collaboration in the decision aid study.
 4. Thank you to the Coalition of National Cancer Cooperative Groups & ACRIN for the NLSST Newsletter
 5. Thank you to Susan Samson and Candace Brady for their contributions to CISN.
 6. Thank you to Pfizer for their support of the ACOSOG project.
 7. Thank you to Genentech for their support in an Ovarian Study CISN is developing materials for
- We would especially like to thank and honor those women who have enrolled in clinical trials**