

# Keys to Optimal Informed Consent

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**This Training is the sole property of CISN and is not for distribution**

**This Training has been conducted at Mayo, SoCRA and ACRIN cooperative Group**

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# CISN

## Mission Statement:

- ❖ Provide cancer patients with information & support.
- ❖ Build bridges between all groups involved with cancer research, treatment, care and advocacy.

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# Learning Objectives

**At the completion of this training you will be able to:**

- ❖ **Identify barriers to enrollment/patient satisfaction from the patient perspective**
- ❖ **Use tools to work more effectively with patients**
- ❖ **Recognize learning styles and tailor approach accordingly**

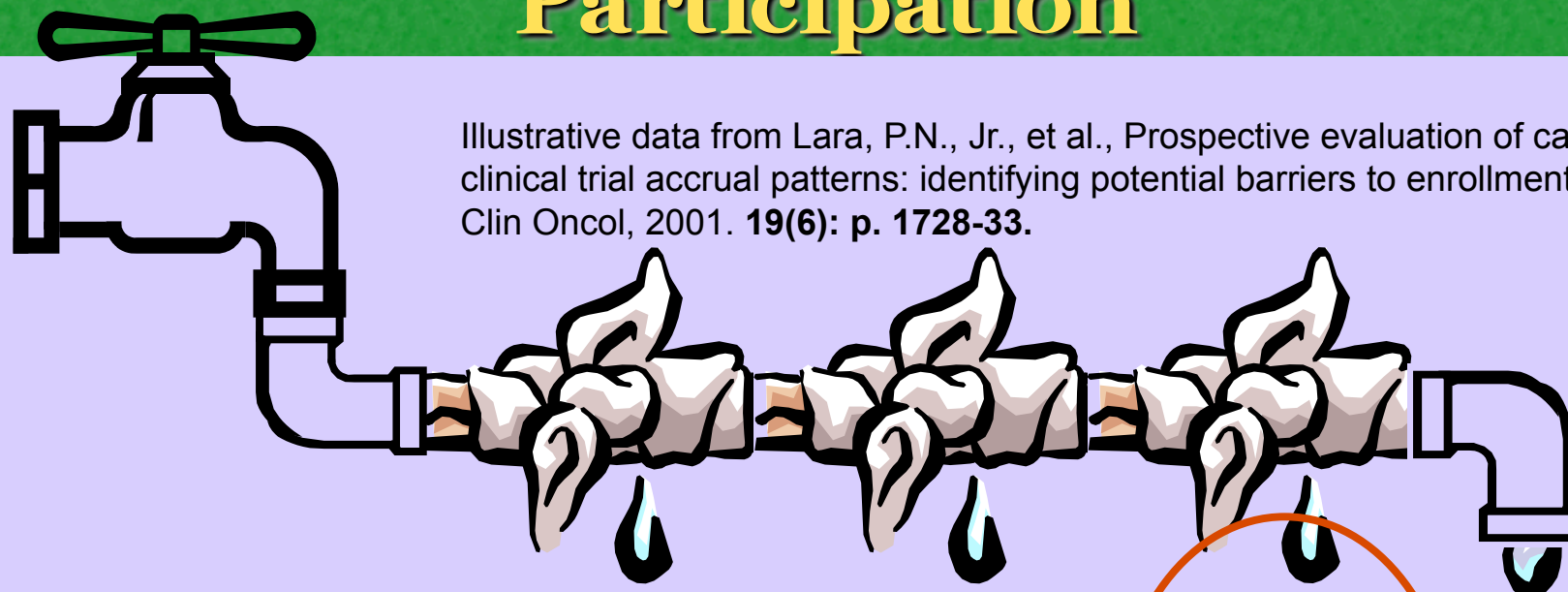


# Overview

- ❖ Background Data
- ❖ Reality
- ❖ Solution strategies



# The Leaky Pipe of Clinical Trial Participation



Illustrative data from Lara, P.N., Jr., et al., Prospective evaluation of cancer clinical trial accrual patterns: identifying potential barriers to enrollment. J Clin Oncol, 2001. 19(6): p. 1728-33.

**276  
patients  
seen by  
physicians**

**38% not  
referred to  
clinical trial  
by physician**

**56% not  
eligible for  
clinical  
trial**

**49% not  
willing to  
sign  
consent  
form**

**14%  
accrual  
rate (39  
patients  
enrolled)**

**Awareness**

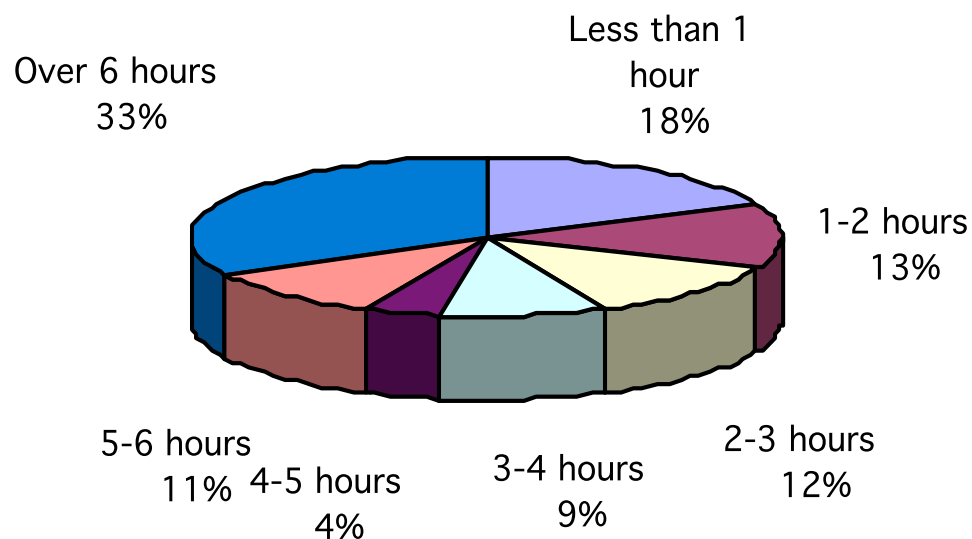
**Design**

**WG6**

Courtesy of Jeff Belkora, PhD UCSF Breast Center of Excellence

# Results of Summit Series on Clinical Trials Questionnaire

**How many hours is the psychosocial training?**



**67%**  
of those polled had  
**< 6 hours of  
psychosocial  
training**



**Patient Diagnosed: Shock & Fear**

**Very Complicated Legal Form**

**Few Graphic Handouts**

**Incomplete Staff Training**

**Not Enough Time**

**Cultural Disparities**

**Minorities Under Represented**



**The PERFECT STORM**

# Exercise to Elicit Emotional Response

**View slides**

**Recall the emotions attached to the experience**



# Emotions triggered



Slide courtesy of A.P.

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# Emotions Triggered



# FEAR

Slide courtesy of A.P.

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# Emotions Triggered

**Your patients will have recently received a cancer diagnosis.**

**They may experience the following emotions:**

**Shock**

**Fear**

**Anger**

**Overload**

**Denial**

**Despondency**

**Defeat**

**Betrayal**

**Discouragement**

**Hypersensitivity**

**Stoicism**

**Loss of control**

**You will need to communicate new, complicated information through this maze of emotions & individual learning styles**



# Patient Perspective at Diagnosis: Cognitive Overload

## Cancer Diagnosis

Treatment  
Choices

Family  
Concerns

Financial  
Worries

Employment  
Concerns

*Spiritual  
well-being*

*Emotional  
Well-being*

*Fatigue*

*Learning  
Style*



**Life/Death?**

## Clinical Trial

← Risks/Benefits

← Standard vs.  
Study

← Confidentiality

← Randomized

Slide courtesy of Jeff Belkora, PhD, UCSF  
in collaboration with CISN

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# Patient Perspective

## Decisional Conflict

*(North American Nursing Diagnostic Association)*

- ❖ The uncertainty about which course of action to take when choice among competing actions involves risk, loss, regret or challenge to personal health.

**Too much data, delivered too fast, too soon**

**OVERLOAD is the starting point when patients are approached to participate in clinical trials**



# Patient Focus

## Learning Styles:

- ❖ Patients learn best when there is a match between their preferred learning style and the presentation style.
  - ❖ Visual Learner
  - ❖ Auditory Learner
  - ❖ Sensory Learner
  - ❖ Kinesthetic Learner

Adapted from: **Teachers Make The Difference** by Susan Kovalik

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# Myth: All Patients Are The Same



**They have just received  
devastating health  
information.**

**Cancer has been  
diagnosed or recurred.**



# Reality: Each Patient Is Unique



Learning Style

Age

Ethnicity

Family

Career

Values / Beliefs

Other



# Tips to assist you in working with overloaded patients

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# Patient Focused

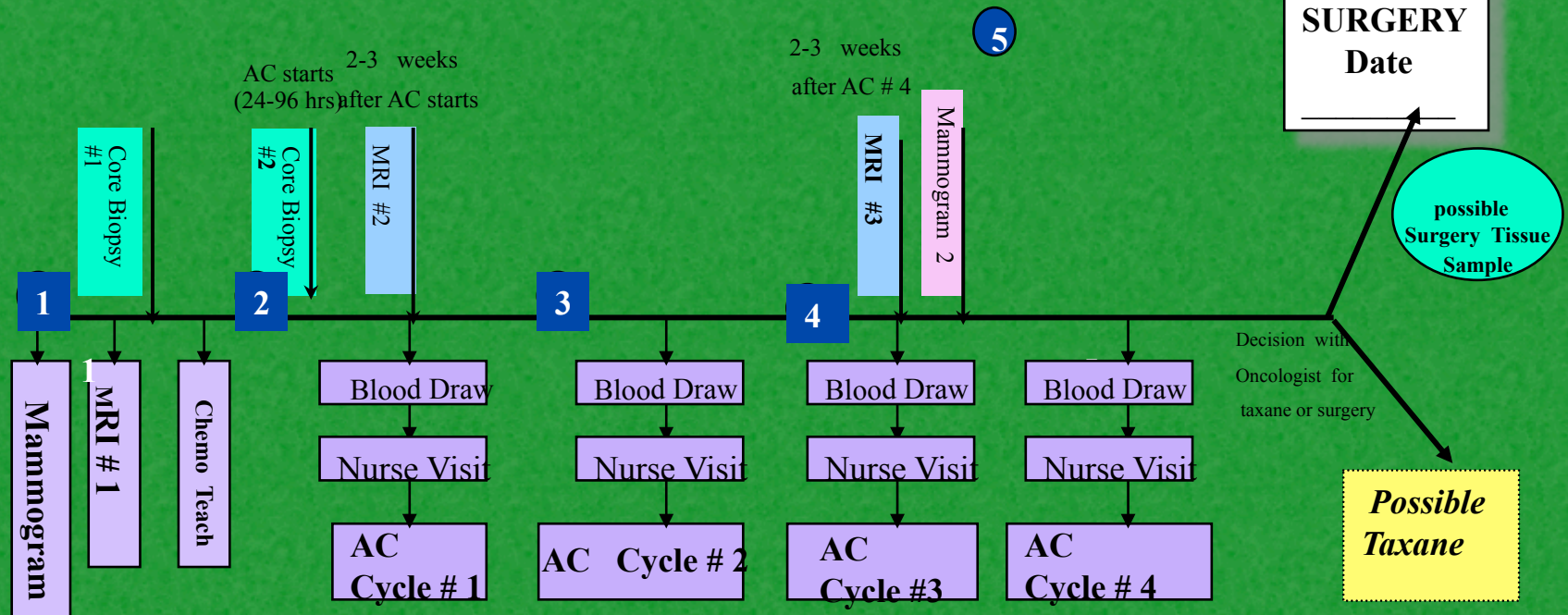
- ❖ Keep it simple
- ❖ Speak slowly
- ❖ Use short sentences
- ❖ Avoid jargon
- ❖ Make sure patient has a basic understanding before they leave the first appointment (and a phone number for questions)



# Example # 2 of schema

Advocate  
Calls

Patient



**STANDARD TREATMENT :** you are responsible for making all appointments

*Study timeline developed by Peggy Devine*

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*Are you an ovarian, primary  
peritoneal or fallopian tube  
cancer patient whose tumor  
has become resistant to  
platinum chemotherapy?*

*You may be eligible to  
participate in a new study.*



Clinical Trial Education Series (CTES)

## Example of a CISN designed study brochure

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# Patient Focus

## CRA Final Tips

- ❖ Follow the five steps
- ❖ Keep it simple
- ❖ Set meeting expectations – allow enough time
- ❖ Stay on topic
- ❖ Make information specific and concrete
- ❖ Make ongoing assessments of patient's understanding

From Beck, A.T. & Emery, G. (1985) Anxiety Disorders and Phobias:  
A Cognitive Perspective

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# Thank You

- ❖ SOCRA
- ❖ Mayo Clinic, Rochester
- ❖ ACRIN – CRA committee
- ❖ The Summit Series on Clinical Trials
- ❖ Jeff Belkora, Ph.D., UCSF
- ❖ My collaborators
  - ❖ Paula H. Finestone, Ph.D.
  - ❖ Jane Perlmutter, Ph.D.

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# Appendix

- ❖ URLs
- ❖ Publications

# URL's

- ❖ Susan M. Miller, PhD, Fox Chase Cancer Center [www.fccc.edu/research/pid/miller](http://www.fccc.edu/research/pid/miller)
- ❖ Jeff Belkora, PhD, Decision Services, UCSF Breast Care Program [www.guidesmith.org/home/](http://www.guidesmith.org/home/)
- ❖ Dana-Farber Cancer Institute  
[www.dana-farber.org/res/clinical/trials-info/](http://www.dana-farber.org/res/clinical/trials-info/)
- ❖ Coalition of Cancer Cooperative Groups [www.cancertrialshelp.org/selfStudyGuide/courses/coalition/standardPlatform/standardPlatform.htm](http://www.cancertrialshelp.org/selfStudyGuide/courses/coalition/standardPlatform/standardPlatform.htm)
- ❖ Y-me National Breast Cancer Organization  
<http://www.y-me.org>



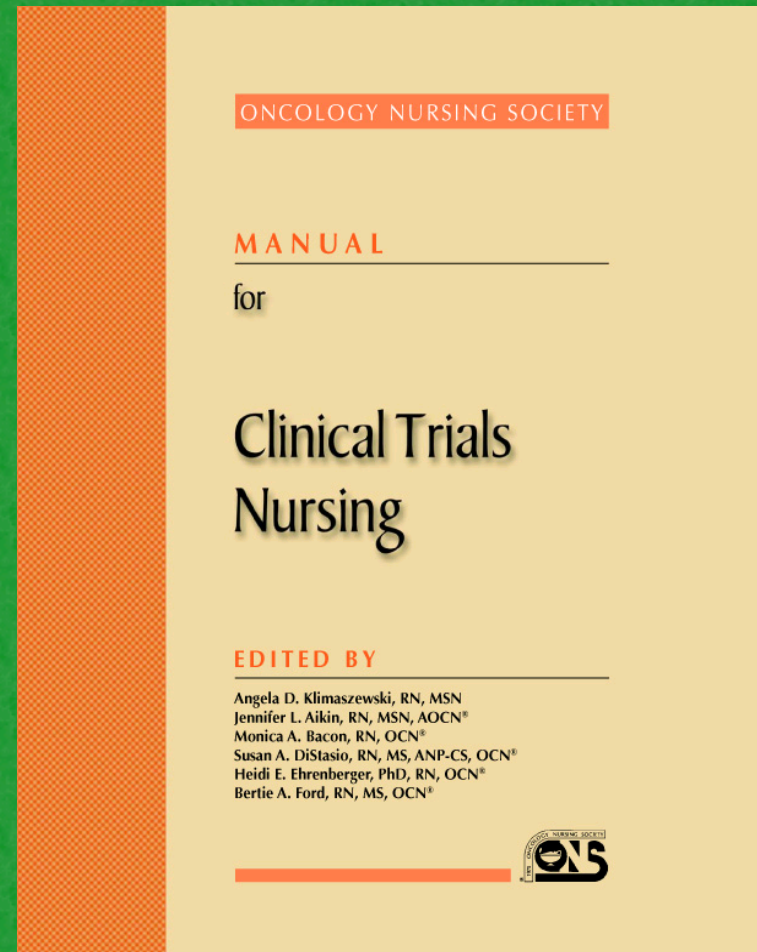
# URL's

- ❖ [www.cancer.gov](http://www.cancer.gov)
- ❖ [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- ❖ [www.centerwatch.com](http://www.centerwatch.com)
- ❖ [www.pharma.org](http://www.pharma.org)
- ❖ [www.ohrp.osophs.dhhs.gov](http://www.ohrp.osophs.dhhs.gov)
- ❖ [www.ctep.info.nih.gov](http://www.ctep.info.nih.gov)
- ❖ [www.ctsu.org](http://www.ctsu.org)



# Resources

- ❖ 60 chapters
- ❖ Address protocol development, promotion and recruitment, eligibility, active treatment, off-treatment follow-up, quality improvement, safety, ethics, data management, information systems, and professional development
- ❖ Spiral bound 380 pages





# Resources

- ❖ Research The Society of Clinical Associates (SoCra)  
<http://www.socra.org/>
- ❖ Association of Clinical Research Professionals (ACRP)  
<http://www.acrpnet.org/>
- ❖ Oncology Nursing Society <http://www.ons.org>



# Publications

- ❖ J. Holland, S. Lewis, *The Human Side of Cancer: Living with Hope, Coping with Uncertainty*, 2001.
- ❖ Neal J. Meropol et al, Perceptions of Patients and Physicians Regarding Phase I Cancer Clinical Trials: Implications for Physician-Patient Communication, *J Clin Oncol* 21:2589-2596. © 2003 by American Society of Clinical Oncology.
- ❖ CK Daugherty, Impact of therapeutic research on informed consent and the ethics of clinical trials: A medical oncology perspective. *J Clin Oncol* 17:1601-1617, 1999
- ❖ *Oncol* 19:3554-3561. © 2001 by American Society of Clinical Oncology.



# Publications

- ❖ P. N. Lara et al, Prospective Evaluation of Cancer Clinical Trial Accrual Patterns: Identifying Potential Barriers to Enrollment, *J Clin Oncol* 19:1728-1733. © 2001 by American Society of Clinical Oncology.
- ❖ Peter M. Ellis, et al, Randomized Clinical Trials in Oncology: Understanding and Attitudes Predict Willingness to Participate, *J Clin Oncol* 19:3554-3561. © 2001 by American Society of Clinical Oncology.
- ❖ James R. Wright et al, Why Cancer Patients Enter Randomized Clinical Trials: Exploring the Factors That Influence Their Decision, *J Clin Oncol* 22:4312-4318. © 2004 by American Society of Clinical Oncology



# Publications

- ❖ Christopher K. Daugherty, Impact of Therapeutic Research on Informed Consent and the Ethics of Clinical Trials: A Medical Oncology Perspective, *J Clin Oncol* 17:1601-1617. r 1999 by American Society of Clinical Oncology.
- ❖ S. Bok , Shading the truth in informed consent for clinical research. *Kennedy Inst Ethics J* 5:1-17, 1995
- ❖ S. Ross , A. Grant , C. Counsell , et al: Barriers to participation in randomized controlled trials: A systematic review. *J Clin Epidemiology* 52:1143-1156, 1999