

Bringing Patient Centered Best Practices to Your Company: Accrual & Retention in Clinical Trials

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Industry June 29, 2007

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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.



Clinical Trial Accrual & Retention

My Experience:

- ✓ **7 yrs on UCSF protocol review committee**
- ✓ **7 yrs member of ACOSOG / ACRIN**
- ✓ **3 yrs co-chair Summit Series on C.T.**
- ✓ **7 yrs with CISN**
- ✓ **1 yr faculty member at Vail workshop**

We hire expert consultants



Overview

- ❖ **The Problem**
- ❖ **Background Data**
- ❖ **Reality**
- ❖ **Solution strategies**

THE PROBLEM:

- ❖ The consent form (ICD)
- ❖ The consent process
- ❖ Minimal training for site CRAs
- ❖ This problem results in:
 - Low accrual
 - Compliance & retention issues

THE PROBLEM

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

Patient Diagnosed: Shock & Fear

✓ Less Complicated Legal Form

✓ Graphic Handouts

Industry

Better Staff Training

Better Utilization of Time

✓ Fewer Cultural Disparities

✓ More Minorities Represented

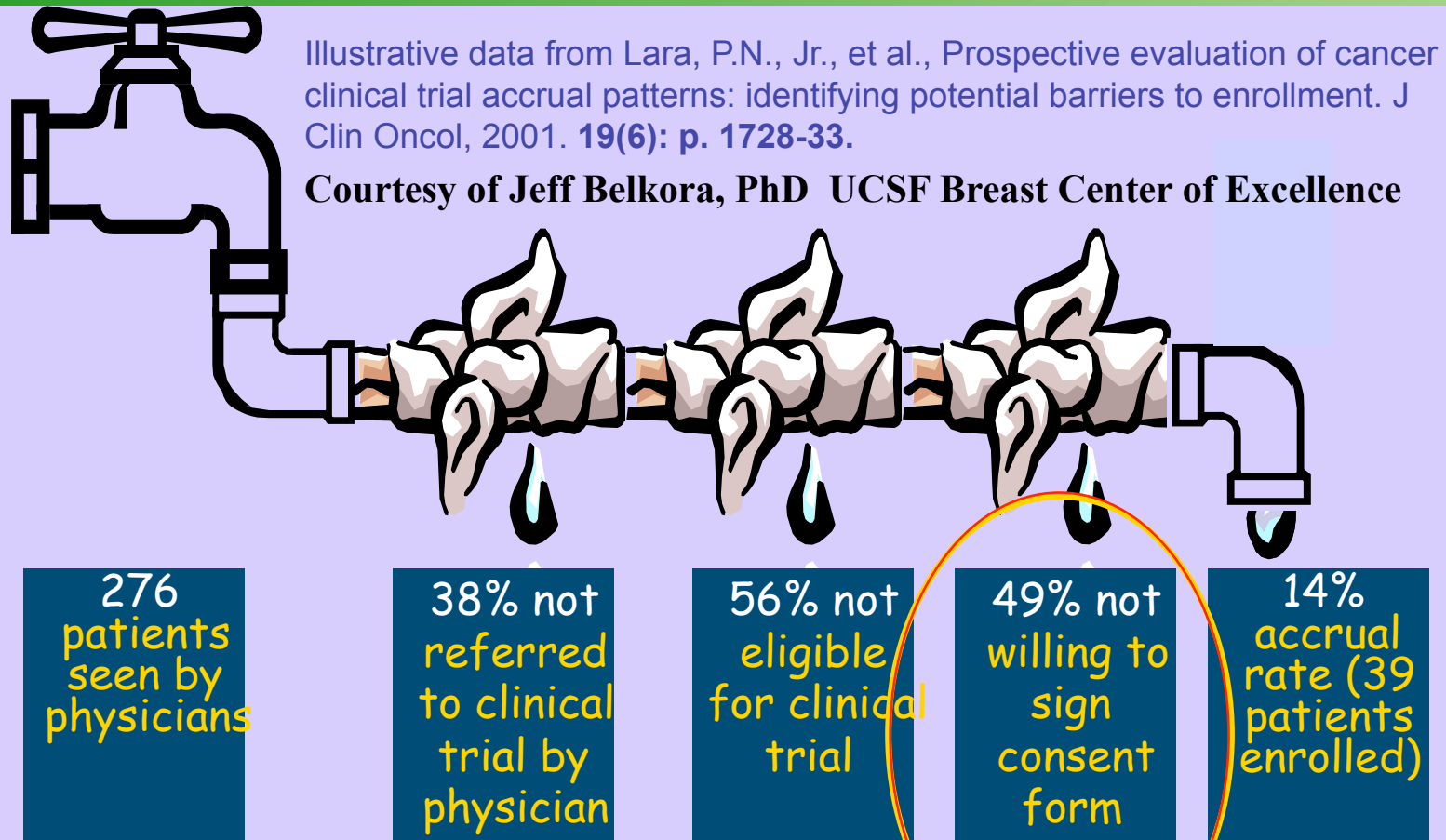


**Interactive Informed
The Choice Process**



THE DATA:

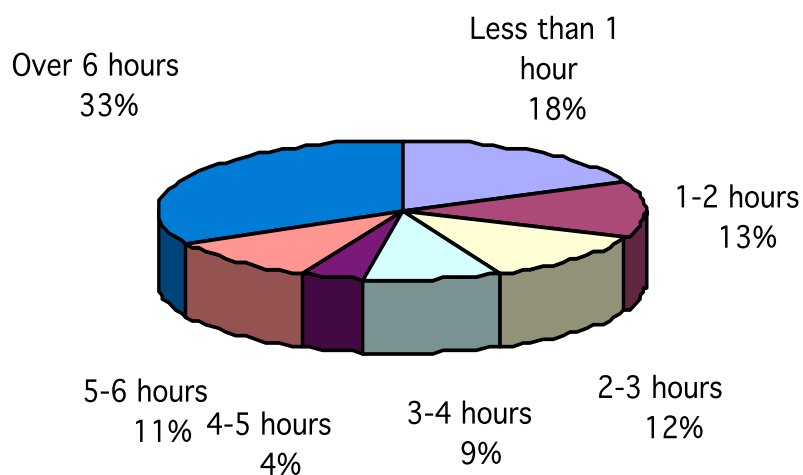
The Leaky Pipe of C. T. Participation



THE DATA:

Summit Series on Clinical Trials Questionnaire

How many hours is the psychosocial training?



67%

of those polled had

< 6 hours

of psychosocial
training

THE REALITY:

SHOCK



FEAR

Slides courtesy of A.P.



THE REALITY:

❖ Patients will have recently received a cancer diagnosis.

They may experience the following emotions:

Shock

Fear

Anger

Overload

Denial

Despondency

Defeat

Betrayal

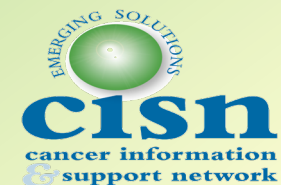
Discouragement

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: Emotional Overload

Cancer Diagnosis

Fear →
Shock →
Sadness /
depression →
Anger →
Denial →

Non Compliance
Identity
Prior stressors
Coping style

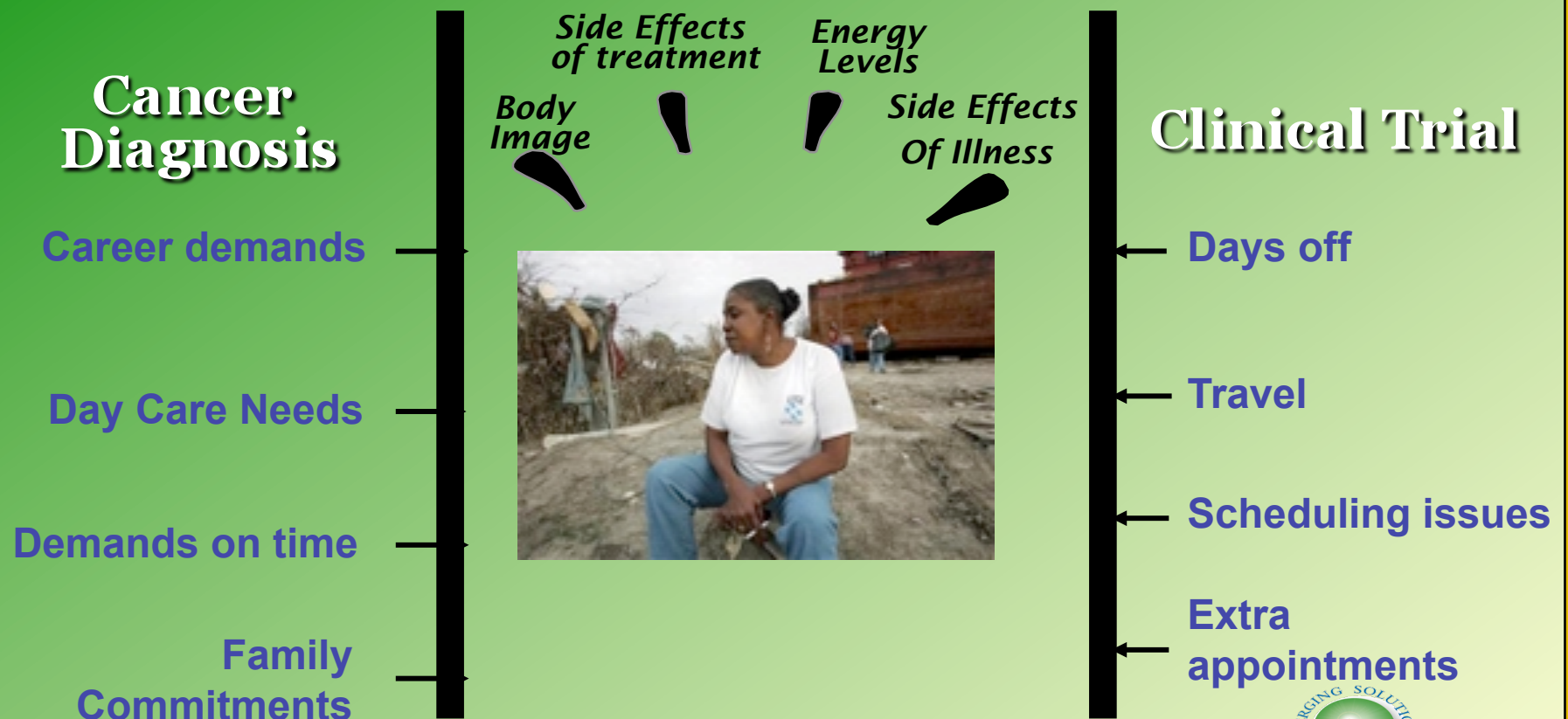


Life/Death?

Clinical Trial

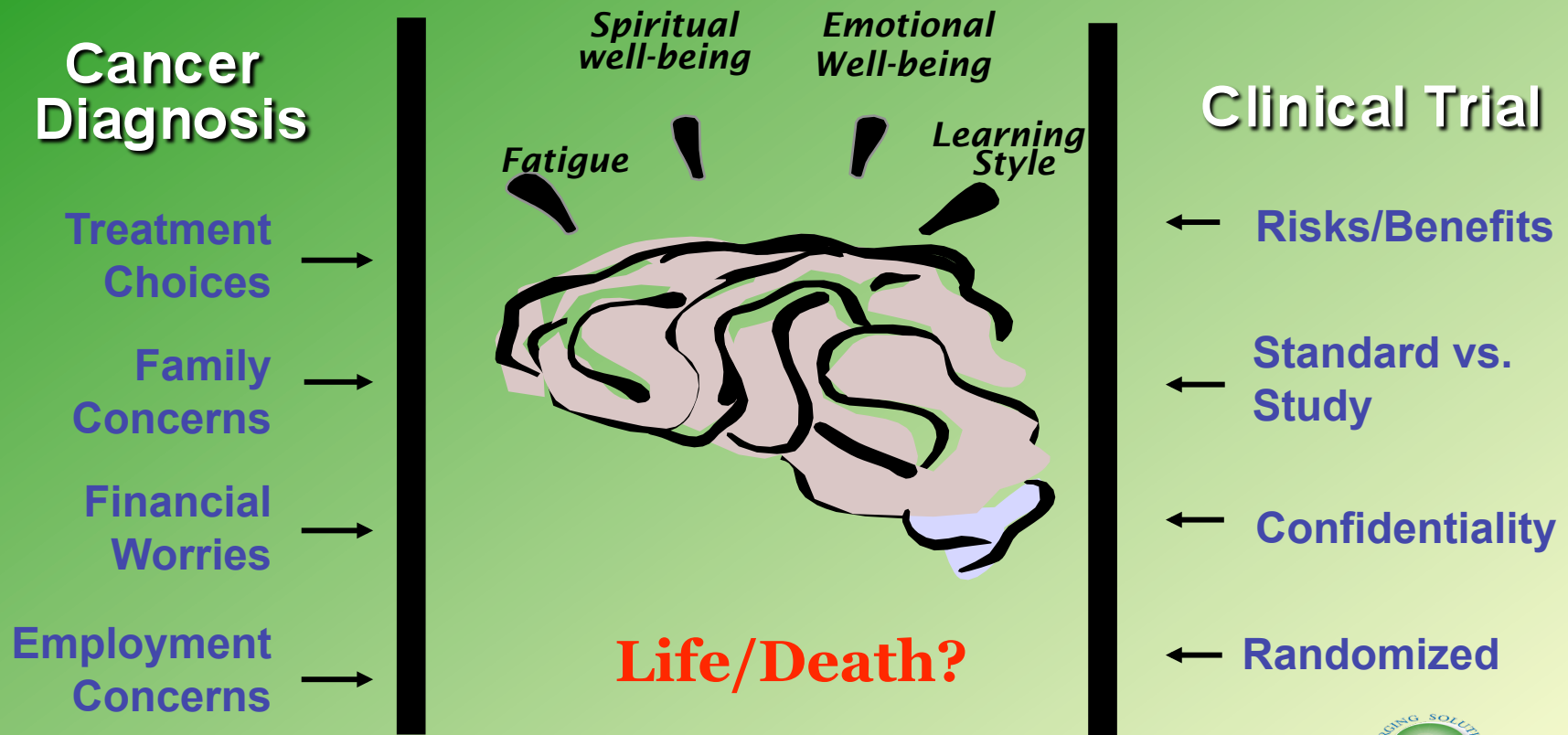
← Confused
← Unable to process
← More people to
interact with
← Unknowns
← Need for more
support

Patient Perspective at Diagnosis: Physical Overload



Life/Death?

Patient Perspective at Diagnosis: Cognitive Overload



Slide developed by Jeff Belkora, PhD, UCSF and CISN

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



All Patients Are The Same

- ❖ They have just received devastating health information.
- ❖ Cancer has been diagnosed or recurred.



Each Patient Is Unique

- ❖ Learning Style
- ❖ Coping Style
- ❖ Age
- ❖ Ethnicity
- ❖ Family
- ❖ Career
- ❖ Values / Beliefs
- ❖ Other



POSSIBLE SOLUTIONS

- ❖ **CISN Input on the Consent Form (ICD / PED)**
- ❖ **CISN Developed Educational Materials**
- ❖ **Decision Support**
 - ❖ **Educational Materials**
- ❖ **CRA Training**

The Consent Form (ICD / PED)

- ❖ **6-8 Grade Reading Level**
- ❖ **Formatting**
- ❖ **Study Requirements clear**
- ❖ **Other Options Clear**



The Consent Form (ICD / PED)

6-8 grade reading level

❖ Techniques to Use

❖ The Flesch-Kincaid grade level index / or the smog readability formula

❖ 14-17 words/sentence; 139-147 syllables/100 words

❖ Is “readability” the same as “understanding” ¹

❖ Concept words; category words; value judgment word

❖ Clear Writing Tips ²

❖ Word substitution lists ³

¹ Hochhauser, M., IRB: Ethics & Human Research 25, no. 5 (2003):7-10

² Kripalani, S., Texas Medicine, 91(8), 40-45

³ Hilts, L. & Krilyk B. J. (1991). Write readable information to educate.

The Consent Form (ICD / PED)

Formatting ¹

❖ **Techniques to use:**

- ❖ Use font size of 12 or greater
- ❖ Use fonts with “tails”, like GRAMMOND, CENTURY or COPPER PLATE LIGHT
- ❖ Bullet all study requirements
- ❖ Make sure all headings are bolded
- ❖ Make sure all risks are bulleted
- ❖ Use short paragraphs
- ❖ Lots of white space



¹ courtesy of Ralph Kennedy

The Consent Form (ICD / PED)

Study Requirements are clear

- ❖ **Techniques to use: What is required**
 - ❖ **Treatments**
 - ❖ **Tests**
 - ❖ **Extra visits**
 - ❖ **How does that fit into daily life**
 - ❖ **Graphic flowchart ¹**

The Consent Form (ICD / PED)

Other Options Are Clear

- ❖ Techniques to use
 - ❖ List other options
 - ❖ Not just standard of care
 - ❖ Compare clinical trial & standard of care ¹
 - ❖ Better distinction between risks and benefits
 - ❖ side by side comparison chart ²

¹ Hochhauser, M., "The Informed Consent Form: Document Development", Drug Information Journal, 34 (4) 1309-1317 (2000)

² CISN

Need: Educational Materials

- ❖ **Too many elements to process** ¹
 - ❖ **14 required, 6 optional + 5 HIPPA**
 - ❖ Decision to participate may be based on what patient is able to process and understand
- ❖ **Omission neglect:** You can't use what you don't see ^{1, 2}
 - ❖ **Consent Forms do not compare standard vs. study**

¹ **Hochhauser, M.**, "Applying Consumer Psychology to Subject Recruitment", actmagazine.com

² **F.R. Kardes and D.M. Sanbonmatsu**, "Ommision Neglect, the importance of Missing Information," *Skeptical Inquirer*, 27(2) 42-46 (2003)

Need: Educational Materials

❖ Learning Styles Matter¹

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

¹ Adapted from: Teachers Make The Difference by Susan Kovalik

Need: Educational Materials

❖ The Visual Learner:

- ❖ **Learns best from visual images (sight – show a picture or graphic illustration)**
- ❖ **Usually attentive and make direct eye contact**
- ❖ **Has difficulty understanding / learning when instruction is (only) oral**
- ❖ **Notices details**

¹ Adapted from: Teachers Make The Difference by Susan Kovalik

Need: Educational Materials

- ❖ Study Schema (graphic) ^{1, 2}

- ❖ Calendar Format

- ❖ Clear / color coded

- ❖ Study Brochure ^{2, 3}

- ❖ Address possible hurdles

- ❖ Randomization

- ❖ Placebo

- ❖ What makes this “different”

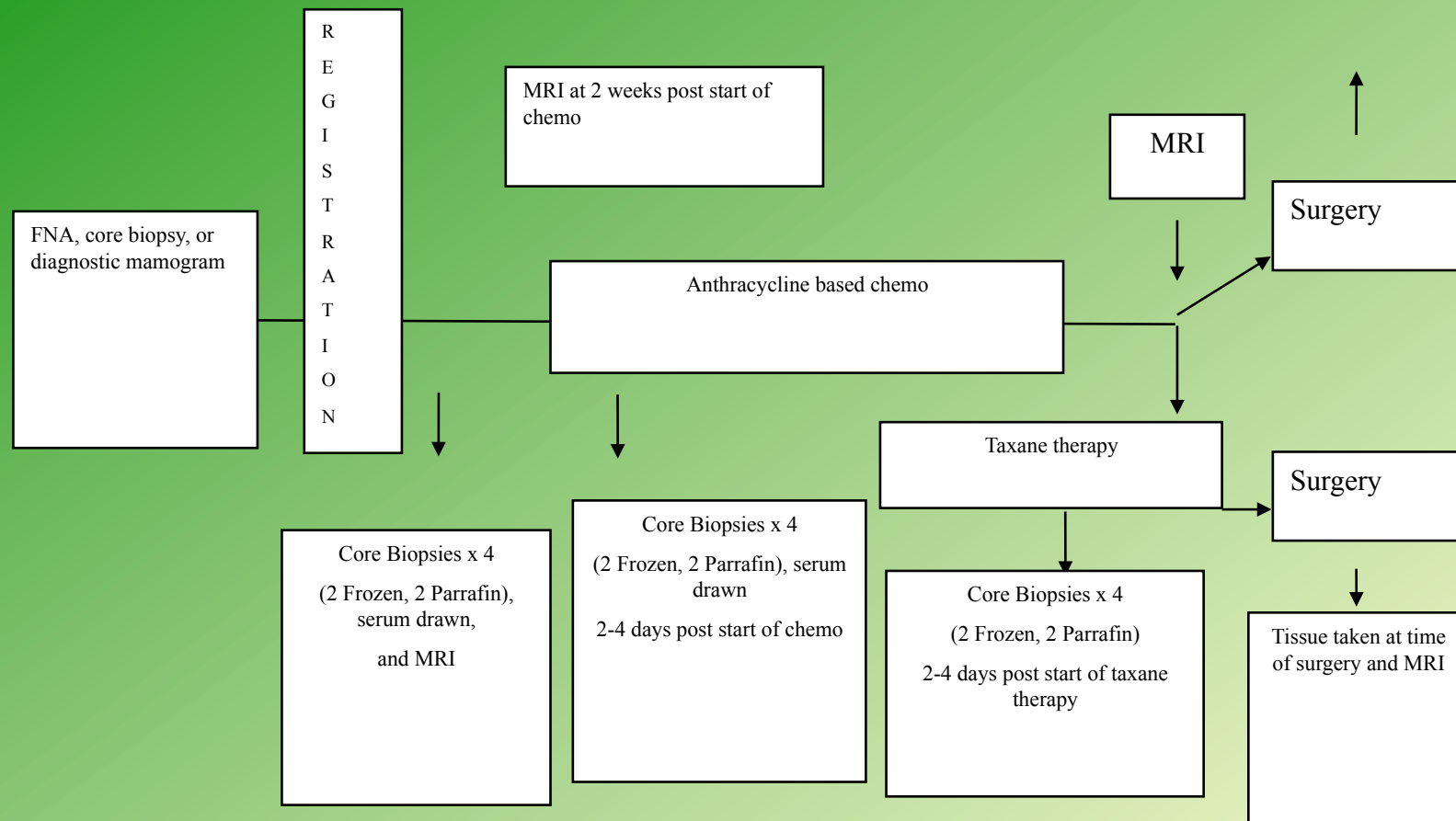
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education materials. Oncology Nursing Forum, 23 (8)



Original Co-operative group Study Schema



Neoadjuvant MRI Correlative Science Trial Procedure Time Line

Timeline Events:

- Point 1:** Mammogram
- Point 2:** MRI #1
- Between 2 and 3:** Core Biopsy #1, Serum sample
- Point 3:** Core Biopsy #2, MRI #2
- Between 3 and 4:** 48 hrs after AC starts (24-96 hrs)
- Point 4:** 2 weeks after AC starts
- Point 5:** MRI #3
- After Point 5:** Mammogram

Chemotherapy Schedule:

- Start AC:** Cycle 1 (Date)
- Cycle 2:** (Date)
- Cycle 3:** (Date)
- End AC:** Cycle 4 (Date)

Other Events:

- Patient:** (Date)
- Mammogram:** (Date)
- SURGERY Date:** (Date)
- O.R. Tissue Specimens:** (Date)
- Start TAXANE see page 2:** (Date)

Legend:

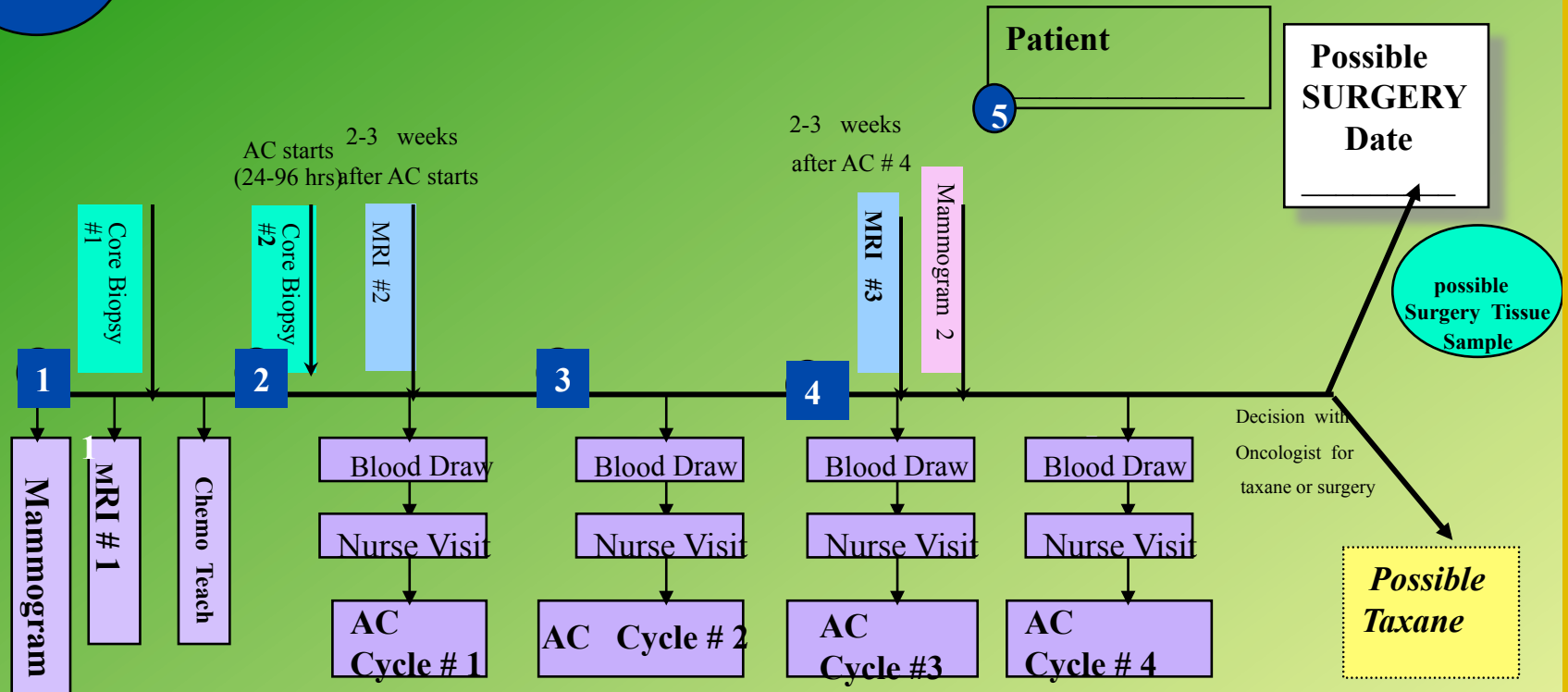
- AC Chemo dates:** (Purple box)

Date: 1/2/03



Advocate
Calls

Example # 2 of Schema



STANDARD TREATMENT : you are responsible for making all appointments

Study timeline developed for UCSF by Peggy Devine

Pre

MRI of the Contralateral Breast

ACRIN Research Study 6667

An ACRIN Research
Study for Women
with a
Recent Diagnosis of
Breast Cancer

*Information for
Participants*

acrin American College of Radiology
Imaging Network

CISN



Post

Breast MRI Study

Imaging your cancer-free breast



Are you a breast cancer
patient with concerns
about your healthy breast?

acrin American College of Radiology
Imaging Network

*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)

Brochure Example:

Developed by CISN



Summary

- ❖ There is a Problem
- ❖ There are patient centered solutions
 - ❖ Input on ICD / PED
 - ❖ Provide educational materials that help explain the study
- ❖ Provide additional training for sites



Resources

- **Medical Matrix** (www.medmatrix.org/index.asp) is a ranked, peer-reviewed, annotated, updated guide and link to clinical resources. It links to (and reviews) patient education resources.
- **Ohio State Un. Medical Center Health Information:**
Provides links to over 1,400 Ohio State Un. Medical Center Patient Education materials. You must agree to the disclaimer statement to view the patient education home page.
- **American Psychological Association.** (1994). Publication manual of the American Psychological Association (4th ed.). Washington, DC: Author.
- **Doak, C. C., Doak, L. G. & Root, J. H. (1996).** Teaching patients with low literacy skills (2nd ed.). Philadelphia, PA: J.B. Lippincott Company.



Resources

- **Doak, L. G., Doak C. C. & Meade, C. D. (1996).** Strategies to improve cancer education materials. Oncology Nursing Forum, 23 (8)
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- **Kripalani, S. (1995, August).** The write stuff: Simple guidelines can help you write and design effective patient education materials. Texas Medicine, 91(8)
- **Rankin, S. H. & Stallings, K. D. (1996).** Patient education: Issues, principles, practices (3rd ed.). Philadelphia, PA: J.B. Lippincott Company.
- **Schrefer, S. (Ed.). (1995).** Mosby's patient teaching tips. St. Louis, MO: Mosby-Year Book, Inc.
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Thank You

- ❖ **Industry**
- ❖ **The Summit Series on Clinical Trials**
- ❖ **My collaborators**
 - Laura Esserman, MD, MBA, UCSF
 - Paula H. Finestone, Ph.D.
 - Jane Perlmutter, Ph.D.
 - Jeff Belkora, PhD, UCSF
 - Ralph Kennedy,
 - SoCRA
 - Mayo Clinic, Rochester
 - ACRIN: RA Committee
 - Advocate Reviewers

