How to Help Write a Good Consent Form: MOVING FROM INFORMED CONSENT to INFORMED CHOICE

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C3 ASCO advocate training
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FOCUSING on the PATIENT

Science Focus
- Introduction
- Study Objectives

Clinical Focus
- Treatment Plan
- Drugs
- Pathology Review
- Molecular Assessment

Patient Focus
- Schema
- Selection of Patients
- Informed Consent
- Recruitment Plan
- Communication Plan

Design Focus
- Randomization
- Measurement of Effect
- Study Parameters
- Statistical Considerations

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EMERGING SOLUTIONS
cancer information & support network
OBJECTIVES

• Learn what constitutes a good consent
  – Make recommendations to improve the .. consent form

• Learn what constitutes a good accrual plan
  – Make recommendations for ........

• Learn what constitutes a good communication plan
  – Make recommendations for ........

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APPROACH

• Background
  – What the process looks like today

• Why we need to be involved

• Learn to review and construct a good consent form
  – Use both …. and IMPACT form
    • Content
    • Format
    • Additional materials

• Today: focus on the form (always use the NCI 2004 template)

• Will discuss a good accrual & communication plan
  – Make recommendations
What 5 Things Would Patients Need to Know About Study Before Enrolling

- We will re ask this at the end of this section
  - Write down your thoughts as we go
This Is Not What You Want

INFORMED CONSENT!

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All PATIENTS ARE THE SAME

• They have just received devastating health information.

• Cancer has been diagnosed or recurred.
EACH PATIENT IS UNIQUE

- Learning Style
- Age
- Ethnicity
- Family
- Career
- Values
- Other
The Informed Consent Process

- **Mandatory Process**
  - Focus is on the consent form not on the process
  - Developed by committee with focus on liability and research needs
  - Does “human subject protection” guarantee “human subject” comprehension?

- **Reality in the research trenches**
  - Form development delegated to staff with minimal infrastructure and funding
  - Medical professionals have little training, few patient ed materials and little time

- **Patient Perspective**
  - Cancer diagnosis = patient overload
  - IC is patient’s only knowledge of the trial

*Emerging Solutions*

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Patient Diagnosed: Shock & Fear

Very Complicated Legal Form

Few Graphic Handouts

Inadequate Staff Training

Not Enough Time

Cultural Disparities

Minorities Under Represented

The PERFECT STORM
An INTERACTIVE INFORMED CHOICE PROCESS

Patient Diagnosed: Staff very sensitive

Patient Diagnosed: Shock & Fear

Less complicated consent form

Very Complicated Legal Form

Few Graphic Handouts

Inadequate Staff Training

Not Enough Time

Cultural Disparities

Minorities under Represented

Patient-centered graphic handouts
Where Do Advocates Come In?

Researchers (bench)

Advocates can be the bridge
For all translational research

Patients (bedside)
Collaboration is Always Better
Problems With Consent Documents

- Used as legal & not educational tool
- Too long and too complicated
- Reading level too high
- Not geared to minority concerns
- Lack of summary page, schemas, tables, calendars and graphics

Slide courtesy of Ralph Kennedy
What Constitutes a Good Consent Form

- Ethical disclosure
  - Tells patient what the study is about
  - Tells patient what standard of care is
  - Makes all study requirements clear (calendar flow-chart)
  - Makes all risks for standard vs study clear (Table)
  - Reading level at 6th grade
  - Formatted correctly
  - Understandable

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What Constitutes a Good Consent Form

- Ethical disclosure
  - Explains this is a research study
- Patient can:
  - drop out,
  - discuss with your family,
  - take your time
- Informs patient about:
  - costs,
  - confidentiality,
  - injury,
  - other choices
IS There Ethical Disclosure in this study?

- **Yes** – all information has been disclosed BUT not all information is clear

- We do not know anything about the process from reading the form
What Constitutes a Good Consent Form

- Ethical disclosure
  - Explains this is a research study
  - You can drop out, discuss with your family, take your time
  - Costs, confidentiality, injury, other choices
- Tells patient what the study is about
- Tells patient what standard of care is
- Makes all study requirements clear (calendar flow-chart)
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Does this study clearly tell the patient what the study is about?

In the protocol
- Background and justification
  Hypothesis: hard to dig out
- For Chemo - page 9-10
- For markers – page 5,9-10

In the consent form
- Yes but is it clear?
- For Chemo – Pg 61
- Markers – pg 61
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- Understandable
Does this Study Tell the Patient What Standard of Care Is?

- **In the protocol:**
  - Observation remains an appropriate option

- **In the consent form:**
  - In the side effects / risk section
    - Currently, the standard of care is to receive no chemo
  - **What other options are there?**
    - Choose not to be in study
    - Enter a different study
    - Get no *(further)* treatment – do not mention this is standard of care

Break into groups – rewrite this
What Constitutes a Good Consent Form

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Does this Study Make all Study Requirements Clear?

- What can you learn from the schema?
  - You will be randomized by marker results
  - Chemo names
  - Chemo schedule

- What is not clear?
  - How this translates to your life

Recommendations?

Schema removed due to confidentiality
Example of a patient centered study schema.
Example # 2 of schema

STANDARD TREATMENT: you are responsible for making all appointments

Study timeline developed by Peggy Devine

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Example: Phase 3 Patient Schedule

Slide courtesy of Jane Perlmutter & Peggy Devine

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What Constitutes a Good Consent Form

- **Ethical disclosure**
  - Explains this is a research study
  - You can drop out, discuss with your family, take your time
  - Costs, confidentiality, injury, other choices

- Tells patient what the study is about

- Tells patient what standard of care is

- Makes all study requirements **clear** (calendar flow-chart)

  - Makes all risks for standard vs. study **clear** (Table)

- Reading level at 6th grade

- Formatted correctly

- **Understandable**
Does this Study Make all Risks and Side Effects Clear?

What do you know?

- Side effects of all drugs
- If the hypothesis is wrong you may receive chemo when you didn’t need it

What don’t you know?

- Some long term side effects of chemo: secondary cancers, chemo brain

Recommendations?

Break into groups to rewrite this
### Example: Presenting Side Effects

<table>
<thead>
<tr>
<th>Drug or Test</th>
<th>Name</th>
<th>Standard or Experimental</th>
<th>Common (&gt;10% of patients)</th>
<th>Occasional (3-9% of patients)</th>
<th>Rare (&lt;2% of patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug x</td>
<td>Experimental</td>
<td>• rash</td>
<td>• anemia</td>
<td>• infection</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• fatigue</td>
<td>• nausea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug y</td>
<td>Standard</td>
<td>• hair loss</td>
<td>• low white cell count</td>
<td>• heart damage blood clot</td>
<td></td>
</tr>
<tr>
<td>Blood Draw</td>
<td>Standard</td>
<td>• mild pain</td>
<td>• vomiting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bone Marrow</td>
<td>Experimental</td>
<td>• pain</td>
<td>• infection</td>
<td>• allergic reaction</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• bruising</td>
<td>• hitting a nerve</td>
<td></td>
</tr>
</tbody>
</table>

**Red Bold:** indicates side effects may be permanent, serious or fatal

**Green Italics:** indicates side effects are generally resolved with additional drugs

Plain: indicates other known side effects

*Slide courtesy of Peggy Devine & Jane Perlmutter*

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  - You can drop out, discuss with your family, take your time
  - Costs, confidentiality, injury, other choices

- Tells patient what the study is about

- Tells patient what standard of care is

- Makes all study requirements clear (calendar flow-chart)

- Makes all risks for standard vs study clear (Table)

- **Reading level at 6th grade**

- Formatted correctly

- Understandable
Informed Consent Literacy

Generally:

- Most consent forms are written at 10-16th grade reading level.
  - Use plain English at the 6th - 8th grade level (check in MS Word or use Flesch formula)
  - Don’t use jargon or acronyms
  - Use shorter sentences
  - Omit complex words (use substitution word list)
- Comprehension and recall of consent information is poor – 30% could not recall being in a research study within 10 weeks

This study

- Microsoft word test – 6th grade reading level ~
- Use word substitution list

*Slide courtesy of Ralph Kennedy*
What Constitutes a Good Consent Form

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  - Costs, confidentiality, injury, other choices

- Tells patient what the study is about

- Tells patient what standard of care is

- Makes all study requirements clear (graphic flow-chart)

- Makes all risks for standard vs study clear (Table)

- Reading level at 6th grade

  - Formatted correctly
  - Understandable
Formatting The Document

Generally

– 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

Slide courtesy of Ralph Kennedy

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SUMMARY

- Consent process discussed in protocol:
- Consent form
  - Ethical disclosure:
    - Explains this is a research study
    - You can drop out, discuss with your family, take your time
    - Costs, confidentiality, injury, other choices -
  - Tells patient what the study is about:
  - Tells patient what standard of care is:
  - Makes all study requirements clear (calendar type flow-chart):
  - Makes all risks for standard vs study clear (Table):
  - Reading level at 6th grade:
  - Understandable
What 5 Things would Patients need to know about this Study before Enrolling

- What does this study ask me to do?
  - If I don’t want to know if I was high-risk – don’t enroll
  - If I absolutely want chemo - don’t enroll
  - If I absolutely don’t want chemo – don’t enroll

- How does this differ from standard of care?

- Side effects of chemo- short and long term

- This is a research study – as likely to be true as not

- Other
I'm pooped... what say we have a little paper jam in tray two?
Stuff to do when you have cancer...
#16: Use a Nerf Ball™ to see if your oncologist has a sense of humor.
An Effective Accrual Plan

- A Well designed study
- A well written consent form
- Developed before the study opens

- Staff
  - Strategies to reach community doctors
  - Training: psychosocial aspects of diagnose on patient

- Patients
  - Education materials

- Communities
  - Community outreach
  - Strategies to reach under represented communities
Developed before the study opens

• NO indication of this
An Effective Accrual Plan

- Developed before the study opens

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"Perhaps you'd like to read this informative booklet, So - You've Just Woke Up From Cryogenic Suspension and Now You're a Disembodied Head In a Jar."
Old Style vs. New Style

MRI of the Contralateral Breast

A CRIN Research Study 6667

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

Information for Participants

Breast MRI Study

Imaging your cancer-free breast

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

Don’t use words people don’t understand

Add a picture

Ask a question

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Understanding Your MRI and Biomarker Study

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

Try to relax!

Your MRI

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.

For more Information Call:
Advocate: MRI CRA: Trial CRA:
Patient Focused Brochure Developed for Genentech

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.

Ask a question

Add A Picture

developed by Peggy Devine
Example: Phase 3 Patient Schedule

Week

Treatment

Tests

0 4 8 12 16

Ex  Ex  Ex  Ex  Ex

Std  Std  Std  Std  Std

Blood  Blood

Physical CT, Blood, Biopsy

Physical CT, Blood, Biopsy

Physical CT, Blood, Biopsy

Slide courtesy of Jane Perlmutter & Peggy Devine

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An Effective Accrual Plan

- Developed before the study opens
- Staff
  - Strategies to reach community doctors
  - Training: psychosocial aspects of diagnose on patient
- Patients
  - Education materials
- Communities
  - Community outreach
  - Strategies to reach under represented communities
How to Reach Out to Under Represented Communities

- Use the leaders already established in the community
- Develop new leaders from within the community
- Partner with: academic / cancer or community centers / non profits
- Go into:
  - Schools
  - Churches
  - Beauty parlors / barbershops

Recommendations?
A Good Communication Plan

- **Developed before the study is activated**
- **Pre study**
  - Work with advocates
  - Work with non profits representing that organ site
  - Work with community leaders and other established groups
- **During Study**
  - Continue above
  - Send yearly thank you's to patients
  - Create a website for PI’s, staff and pt’s to access
- **Post Study**
  - Send final pt thank you
  - Report of findings
  - Reminder to check website
I Know That This Feels Like A Stretch
No Patient Should Feel Stuck Like This
There are Times When advocates Feel Under Appreciated

BUT
don’t take it seriously
Together we can make a difference, Thank You