Informed Consent: Principles and Problems

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Informed Consent: Law and Ethics

- Law is about duty – these are the things everyone MUST do.
- Ethics is about aspiration – these are the things that you should do to be an outstanding person.
- There are reasons that law should not demand too much of us – think Prohibition

What is this Informed Consent Stuff about?

- Law
  - requires disclosure
  - does not require understanding
- Ethics
  - calls for dialogue
  - Mutual participation in decision making

What disclosure does informed consent require?

- the **nature** of the proposed procedure
- the **purpose** of the procedure
- the **risks**
- the **benefits**
- any **alternatives** to the proposed procedure

What do we Disclose about Clinical Research?

- The primary purpose of research is to gather valid data that will provide an answer to an important research question
- Both legally and ethically, we are required to make that clear.

Contrasting Clinical Trials and Ordinary Treatment

- Treatment
- Individualized Tx decisions
- Physician selects Tx for pt. benefit
- Other treatments used if thought helpful
- Dosage adjusted for maximum benefit
- Tx chosen to be effective

- Clinical Trials
- Randomized assignment
- Physician blinded
- Restrictions on other treatments
- Limited adjustment of dosage
- Use of placebos

These are Important Limits

- Researchers do not impose these limitations lightly
- They are essential for gathering generalizable data
- Research staff often monitor care better
- Nonetheless, these are important risks that subjects should consider when enrolling

The Therapeutic Misconception (TM): A Definition

The ***therapeutic misconception*** occurs when a research subject fails to grasp the distinction between clinical research and ordinary treatment and attributes therapeutic intent to research procedures

The Discovery of TM

- Paul Appelbaum and I were interviewing and taping subjects who were in clinical trials
- Woman was getting all the details right
- Could not believe that her doctor would randomize treatment

An Empirical Study of TM

- Paul Appelbaum, Tom Grisso and I set out to describe the frequency and the correlates of TM
- 243 subjects, 44 different studies, 2 sites
- Semi-structured interviews
- Education averaged 14.2 years
- Most in phase III clinical trials

Measuring the Therapeutic Misconception

- Text of interviews is coded for two features:
  - the belief that the treatment would be individualized to the subject
  - an unreasonable assessment of benefit (i.e. one precluded by the design of the study)
- Found 62% of a sample of research subjects met one criterion or both

Understanding of Risks

- Critical Interview Question:

"What, if any, are the risks or disadvantages of being in this study"

- Coded entire text for statements about risks and disadvantages
- Looked only at clinical trials N=149

Risk Codes

- Risk inherent in Research Design
- Risk inherent in Experimental Treatment (i.e. side effects)
- Risk of Routine Treatment
- Incidental Disadvantages
- Risks Minimized or Partially Denied
- Complete Denial of Risk

Results: Denial

- 18.8% denied any risks or disadvantages
- 14.7% were in partial denial or minimized risks; e.g., I hope there aren't…. They could make mistakes… the treatment could be wrong but I assume they[will] correct [it]"

Risks of Treatment

- 8.7% of sample reported only risks associated with standard care
- Largest group (36.2%) reported side effects of the experimental intervention
- These subjects had no apparent awareness of risks associated with the design of clinical trials

Risks of the Research Design

- 18.1% of subjects reported some awareness of the risks involved with the research design
- Examples:
  - 11 subjects expressed some concern about possibly getting a placebo (including 4 who reported other concerns about clinical trials)
  - 4 subjects expressed concerns about the double blind design.

Three Possible Interpretations

- Subjects are incompetent – Not all subjects
- Poor or deceptive disclosures
- Subjects are confused by their expectations that they will be treated as patients
- Needed: New techniques of disclosure focusing on the implications of the research methods for subjects' care.