Informed Consent

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Overview

- The evolution of informed consent
- The process of informed consent
- Obtaining evidence about informed consent

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The Evolution of Consent

For Medical Treatment

- Patient litigation
- Laws and regulations

For Research

- Early consent practices
- Infamous research

Medical Treatment and The Right to Liberty

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages." *Schloendorff*

Early Consent Practices for Research

- Sometimes recognized as important for research with volunteers
  - Not necessarily free and voluntary
  - Lack of consent central to the problems in a litany of infamous experiments
- Not typically recognized as relevant for patients enrolled in research

Two Senses of Consent

- Autonomous authorization
- Social rules of consent

Faden and Beauchamp

Autonomous Authorization

- Arises from a littered history
- Respect for persons/autonomy
- Liberty interests

Social Rules

- Consent of minors
- Special forms
- Witnesses

The Process of Informed Consent

- Threshold
- Information
- Consent

Threshold

- Decision making capacity
- Voluntariness

Information

- Disclosure
- Understanding

Content of Disclosure

- Nature of the proposed intervention
- Procedures and alternatives
- Potential risks and benefits
- Assurance that participation is voluntary
- Protection of confidentiality

Information

- Disclosure
- Understanding

Authorization

- An indication of agreement
- Consent forms
  - Consistent with disclosure
  - Readable

An Empirical Imperative

- Clinical research is predicated on the notion that we need data to determine 'truth' and facilitate sound decision-making
- Ironically, methods of clinical research, including those designed to protect participants such as informed consent, are introduced without data regarding safety or efficacy
- Where relevant we need to evaluate these protections as we would any proposed clinical intervention

Controlled Clinical Trials 1999; 20:187-193

Advisory Committee on Human Radiation Experiments

- Uncover the history of human radiation experiments between 1944 and 1974
- Examine cases of released radiation into the environment for research purposes
- Identify the ethical and scientific standards for evaluating these events
- Make recommendations to ensure that whatever wrongdoing may have occurred in the past cannot be repeated

ACHRE's Empirical Projects

- Review federal agency policies
- Examine contemporary research documents and consent forms
- Interview patients receiving out-patient medical care about their understanding of and attitudes towards medical research

Methods

- Part 1: Brief Survey
  - Interviewed 1,882 patients
  - From medical oncology, cardiology, and radiation oncology waiting rooms
  - Included 16 hospitals and 5 cities around the U.S.
  - To determine beliefs and attitudes about medical research and to ask if they were, or ever had been, participants in medical research
  - Paid $5.00

Methods

- Part 2: In-Depth Interview
  - Interviewed 103 patients
  - All reported in Brief Survey that they were or had been in medical research
  - To determine reasons for joining research and to describe their research experiences
  - Paid $25.00

Demographics
Total Respondents = 1,882
(Response rate = 94.7%)

Age > 59		53%
White		80%
African American		16%
High School Graduates	54%	
College Graduates	25%	

Terms	Unproven Treatment (%)	Better Off? (%)	Greater risk? (%)
Medical Experiment	52	11	70
Medical Research	16	61	10
Medical Study	23	34	11
Medical Research	40	23	60
Clinical Investigation	23	26	24
Medical Research	40	42	46
Clinical Trial	27	28	31
Medical Research	35	37	35

IRB 1998;20:1-7.

EQUIC Study Chairs

- Phil Lavori, PhD
- Jeremy Sugarman, MD, MPH, MA

Goals

- Create, field test, and validate an independent, real-time measure of the quality of informed consent encounters in actual clinical trials
- Develop specific interventions directed at improving the quality of informed consent
- Test interventions in CSP trials

Expert Advisory Committee

- Membership
  - Paul Appelbaum, MD
  - Marguerite Hayes, MD
  - Robert Pearlman, MD, MPH
- Findings
  - Independent measurement
  - Results confidential
  - Evaluate IC process and not experience
  - Not-interfere with research process
  - Minimal burden
  - Practical and simple

EQUIC-Development Phase

- Telephone interview after “parent” study consent
- Brief Informed Consent Evaluation Protocol (BICEP)
- Substrate for all subsequent EQUIC studies

Clinical Trials 2005; 2:1-8

EQUIC-DP Research Team

- Maryann Boeger, MBA - Program Manager
- Andres Busette - Research Health Scientist
- Carole Cain, PhD – Interviewer
- Eric Crawford - Interviewer
- Robert Edson, MS – Statistician
- Madhulika Gupta, MS – Interviewer
- Phil Lavori, PhD – Co-Principal Investigator
- Patrick Nisco, MA- Interviewer
- Lee Pickett, MS – Interviewer
- Jeremy Sugarman, MD – Co-Principal Investigator
- Carmen Tumialan-Lynas, MS - Interviewer

EQUIC-DP Parent Studies

1. CSP 027 FDG PET
2. CSP 403 Shingles Vaccine
3. CSP 410 FeAST
4. CSP 424 COURAGE
5. CSP 453 HOST
6. CSP 494 PTSD and Women
7. CSP 499 SELECT
8. CSP 719B Latent Prostate

EQUIC-DP Participating Sites

Site	Study	Site	Study
Ann Arbor, MI	CSP 424	Melbourne, FL	CSP 424
Birmingham, AL	CSP 403	Minneapolis, MN	CSP 403
Buffalo, NY	CSP 027	Northport, NY	CSP 403
Durham, NC	CSP 424	Northport, NY	CSP 499
Houston, TX	CSP 410	Northport, NY	CSP 719B
Houston, TX	CSP 424	Reno, NV	CSP 410
Indianapolis, IN	CSP 027	Seattle, WA	CSP 424
Lexington, KY	CSP 410	St. Louis, MO	CSP 499
Mayo Clinic	CSP 424	St. Louis, MO	CSP 719B

13 VAMCs; 1 non-VAMC

EQUIC-DP Enrollment

- Total: 632 interviews completed
- BICEP-1
  - 441 completed
  - 8/21/00-7/31/01
- BICEP-2
  - 191 completed
  - 8/1/01-7/2/02

EQUIC-DP
Site Coordinators' Reports

- 100% patient willingness to participate
- 98.9% "no difficulty with process"
- 99.5% "no difficulty with call"
- 95.4% "no difficulty reaching center"
- 98.4% "no interruption of clinic flow"
- 99.2% "no other difficulties"

Degree of Disruption of Parent Study

- None 66.3%
- Mild 32.8
- Moderate 1
- Severe 0

Incremental Burden

- Site coordinators
  - mean 14.2 min (std dev 9.6)
- Participants
  - mean 10.9 min (std dev 7.8)

Mean Timing of Interviews

- Completion of parent study IC and EQUIC IC: 19.8m (sd 28.0)
- EQUIC IC and initiation of call: 8.4m (sd 11.7)
- Duration of call: 8.8m (sd 3.6)
- Interview length: 7.7m (sd 2.9)

Respondents' Reports about Parent Study IC Process

- 95.1% received "just right" amount of information
- 99.3% remember signing consent form
- 99.8% "felt no pressure to consent"
- 98.4% "made a good decision to participate"
- 89.1% "completely satisfied with the IC process"

Taking a Deeper Look

- Verbatim responses to selected items
  - What is the primary purpose of the [parent study]?
  - When can you stop participating in the [parent study]?
- Coding developed and refined during BICEP-1

“What is the primary purpose of [parent study]?” (n=191)

Code	Percent
• Addresses a research question?	• 80
• Directed at an outcome to ultimately benefit others?	• 59
• Directed at an outcome to ultimately benefit self?	• 6
• Other?	• 1

“When can you stop participating in the [Parent Study]”

Code for clear appreciation of voluntariness	Percent
Yes	55
No	45

Lessons

- BICEP is well-tolerated, by participants and staff
- BICEP imposes minimal burden
- Verbatim coding is reliable
- Patients who consent are uniformly satisfied with the process, but inspection of verbatims reveals considerable room for improvement, especially in the “therapeutic misconception”
- Innovations have scope to work

Next Steps

- EQUIC-SM (Self-Monitoring)
- Consider other uses for BICEP and develop new interventions

Concluding Comments

- *Respect for persons* is manifest in the expectations of a meaningful informed consent process
- Meeting this obligation can be enhanced with the use of data about the consent process

References

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