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 process of informed consent
• Obtaining evidence about informed consent
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%
<table>
<thead>
<tr>
<th>Terms</th>
<th>Unproven Treatment (%)</th>
<th>Better Off? (%)</th>
<th>Greater risk? (%)</th>
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</tr>
<tr>
<td>Medical Research</td>
<td>35</td>
<td>37</td>
<td>35</td>
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</tbody>
</table>

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

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<tr>
<th>Site</th>
<th>Study</th>
<th>Site</th>
<th>Study</th>
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<td>Melbourne, FL</td>
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<td>Birmingham, AL</td>
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<td>Buffalo, NY</td>
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<td>Northport, NY</td>
<td>CSP 499</td>
</tr>
<tr>
<td>Houston, TX</td>
<td>CSP 410</td>
<td>Northport, NY</td>
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<tr>
<td>Indianapolis, IN</td>
<td>CSP 027</td>
<td>Reno, NV</td>
<td>CSP 410</td>
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<td>CSP 410</td>
<td>Seattle, WA</td>
<td>CSP 424</td>
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<td>Mayo Clinic</td>
<td>CSP 424</td>
<td>St. Louis, MO</td>
<td>CSP 499</td>
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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)

<table>
<thead>
<tr>
<th>Code</th>
<th>Percent</th>
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<tbody>
<tr>
<td>Addresses a research question?</td>
<td>80</td>
</tr>
<tr>
<td>Directed at an outcome to ultimately benefit others?</td>
<td>59</td>
</tr>
<tr>
<td>Directed at an outcome to ultimately benefit self?</td>
<td>6</td>
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<tr>
<td>Other?</td>
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</table>
“When can you stop participating in the [Parent Study]”

**Code for clear appreciation of voluntariness**
- Yes
- No

**Percent**
- 55
- 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

