Improving Informed Consent

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Overview

- Conceptual model
- Evaluating quality
- Towards improvement

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Two Senses of Consent

- Autonomous authorization
- Social rules of consent

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The Process of Informed Consent

- Threshold
  - Decision making capacity
  - Voluntariness
- Information
  - Disclosure
  - Understanding
- Authorization

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Evaluating the Quality of Consent

- Older persons
- Adults
- International comparison

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Older Persons Structured Literature Review

- Searches in 10 electronic databases
- Included primary research data specifically on informed consent and involved older persons in the sample
- Articles abstracted

Sugarman J, McCrory DC, Hubal RC. *J Amer Ger Soc* 1998; 46: 517-524.

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Aspects of Consent
(99 articles; 289 research questions)

ASPECT	N
Recruitment	60
DMC	21
Voluntariness	6
Disclosure	30
Understanding	139
Consent forms	7
Authorization	11
Policies	13
Other	2

Sugarman J, McCrory DC, Hubal RC. *J Amer Ger Soc* 1998; 46: 517-524.

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Results

- Diminished understanding of informed consent information was associated with older age and fewer years of education
- Studies of disclosure suggest strategies to improve understanding
  - Formats
  - Procedures

Sugarman J, McCrory DC, Hubal RC. *J Amer Ger Soc* 1998; 46: 517-524.

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Annotated Bibliography
Methods

- 9 electronic databases (inception-12/97)
- Inclusion criteria
  - Primary data or systematic review
  - One or more aspects of consent
  - Adults
- Articles abstracted and entered into a database

Sugarman J, et al. *Hastings Center Report* 1999; 29: S1-S42.

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Annotated Bibliography
Results

- 377 articles
- 3,173 hypotheses
- Annotated bibliography assembled
- Most examine disclosure and understanding

Sugarman J, et al. *Hastings Center Report* 1999; 29: S1-S42.

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International Comparison

- Systematic review of assessments of understanding and/or voluntariness
- Literature: 1966-2010; 47 studies included
- Findings
  - Comprehension varies across participants
  - Comprehension of randomization and placebo controls is worse than other information
  - "Participants in developing countries appear to be less likely to say they can refuse participation in or withdraw from a trial and are more likely to worry about the consequences of refusal or withdrawal"

Mandava A, et al. *J Med Ethics* 2012; 38:356-65.

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Broad Lessons

- Incomplete comprehension of informed consent has been documented in multiple settings
- Literacy, the research setting, and the approach used to obtain consent seem to affect comprehension
- Comprehension is a necessary but insufficient component of the informed consent process

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Towards Improvement

- Background
- Formal reviews
- Metrics for assessing quality
  - QuIC
  - BICEP
- Comparing approaches
- Testing an intervention

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Background

- Quizzing during informed consent to assess/ensure understanding is commonplace
  - Developed *ad hoc*
  - Multiple methods
  - Time of assessment varies
  - No clear threshold for adequacy
- There is no "gold standard" for assessing comprehension of informed consent
- Robust metrics assess the 'quality of informed consent' and not simply understanding

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Interventions to Improve Understanding

- Systematic review of interventions directed at improving understanding of informed consent
- Literature 1966-2004; 42 trials included
- Findings
  - Multimedia and enhanced forms with limited effect
  - Study team member or neutral educator spend time appeared most promising
- No single method of assessing understanding was used across trials

Flory J, Emanuel E. *JAMA* 2004;292:1593-601.

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Low Literacy

- Systematic review of modifications of IC were tested to improve comprehension in low literacy populations
- MEDLINE 1966 to November 2011, supplemented
- Six met eligibility criteria; 1 randomized
- Spending more time talking was most effective, but this derives from 1 study

Tamariz et al, *J Gen Intern Med* 2012; 28: 121-6.

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Quality of Informed Consent (QuIC)

- Rigorously developed to assess the quality of informed consent in cancer clinical trials
- General elements, but some are sensitive to trial phase
- Includes close-ended items including "objective" and "subjective" measures of understanding

Joffe SL, et al. *J Natl Cancer Inst* 2001; 93: 139-47.

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QuIC Part A: Objective

- 20 items
  - Scoring dependent on trial phase
- Responses
  - Disagree
  - Unsure
  - Agree

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QuIC Part B: Subjective

- 14 items
- "When you signed the consent form to participate in your clinical trial"
- 5-point Likert Scale
  - I didn't understand this at all (1)
  - I understood this very well (5)

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QuIC Modified

- Part A modified, tested and used in assessing understanding during three mock informed consent processes for HIV prevention research in Malawi
- Response options changed to: "true"; "not true"; and "unsure"

Corneli AL, et. al. *AIDS Behav* 2012;16:412-21.

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BICEP

- Telephone interview after "parent" study consent
- Intended to be used to assess interventions to improve the quality of consent

Sugarman J, et al. *Clinical Trials* 2005; 2:1-8.

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BICEP Interview

1: Did you get all the information you needed to make a good decision about participating in [Parent Study]?
2: Did you sign a consent form to participate in [Parent Study]?
3: Did you feel any pressure to participate in [Parent Study]?
4: Suppose that you had decided not to participate in [Parent Study], do you think that would have made any difference to your regular medical care?
5: What are the benefits to you for participating in [Parent Study]?
6: What are the risks to you for participating in [Parent Study]?

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BICEP Interview

7: Were you satisfied with the informed consent process?
8: As a result of participating in [Parent Study], what are the main things you will have to do differently than if you were not participating?
9: What is the primary purpose of [Parent Study]?
10: Can you tell me when the [Parent Study] ends?
11: When can you stop participating in the [Parent Study]?
12: I have been trying to learn about your impressions of the informed consent process for [Parent Study]. Is there anything else you would like to tell me about?

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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"

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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

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"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

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"When can you stop participating in the [Parent Study]"

Code for clear appreciation of voluntariness	Percent
Yes	55
No	45

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IC Aggregate Score (Mean=8.23; sd=1.17)

1. Having all the information needed
2. Recall of signing the form
3. No pressure to participate
4. No consequences to medical care of non-participation
5. Identifying an aspirational benefit
6. Being completely or somewhat satisfied
7. Study addresses a research question
8. Research is directed at an outcome ultimately benefiting others
9. Not reporting the that the research was directed toward an outcome ultimately to benefit self
10. Clear appreciation of voluntary participation

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TM Aggregate Score (Mean 1.62; SD=.93)

- Mentioning a direct benefit from participation
- Believing that the research is ultimately aimed at benefiting the self
- Not endorsing an aspirational benefit
- Not reporting that the primary purpose is to addresses a research question
- Not believing that the research is aimed at ultimately benefiting others

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Lessons

- BICEP is well-tolerated, by participants and staff
- BICEP imposes minimal burden
- 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

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Comparing Approaches

- Forced choice approaches lead to higher scores than open-ended measures
- Cultural appropriateness of measurement approaches should be considered

Lindegger G, et al. *J Acquir Immune Defic Syndr* 2006; 43:560-6.

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EQUIC-SM

- Aim to develop and test the effectiveness of a self-monitoring "check-list" (the SMQ) to be used by the person obtaining informed consent
- Assumes that persons obtaining informed consent have sufficient knowledge, interest and ability to obtain meaningful informed consent, but that in the context of a busy clinical environment the process or parts of it may be treated superficially

Lavori P, Wilt T, Sugarman J. *Clin Trials* 2007; 4: 638-649.

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Methods

- Parent studies recruited
- Sites recruited and cluster randomized to Control or Experimental arm (SMQ)
- Following informed consent for the parent trial, participants asked for oral consent to complete the BICEP
- Interviewers were masked with respect to site assignment
- Person obtaining consent in the Experimental arm completes the SMQ and faxed it to the coordinating center

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Respondents

- 943/1049 agreed to participate
- 83-100% agreement rates across studies
- 938 BICEP interviews completed

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Results

- Mixed effect analysis reveals a non-significant (and near zero) negative effect of SMQ on the ICAS (P=0.73, effect= -0.034, std err= 0.099) and TMAS (P=0.97, effect = -.005, std err = 0.137) after adjusting for parent study and including a random effect for site.
- The permutation test shows a total P-value=0.89 for the observed -0.04 ICAS effect (0.49 in the left tail and 0.40 in the right) and a total P-value=0.91 for the observed TMAS score of 0.04 (0.39 in the left tail and 0.52 in the right).

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Discussion

- Sample too heterogeneous?
- Underpowered?
- Invalid or unreliable measures?

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Implications

- There is room for improvement in the quality of consent
- It is possible to field randomized trials of informed consent
- Not all interventions, however plausible, are effective underscoring the need to for empirical testing of approaches

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