


Evidence in Research Ethics

Locating, Gathering, and Using Data to Solve Ethical Problems



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Overview

1. Why we need empirical evidence in research ethics
2. Examples of useful data in substance abuse research
3. Challenge of finding relevant data: Example from review of the journal *AIDS* (2005/2006)
4. Challenge of gathering relevant data: Example from HIV prevention study
5. Conclusions



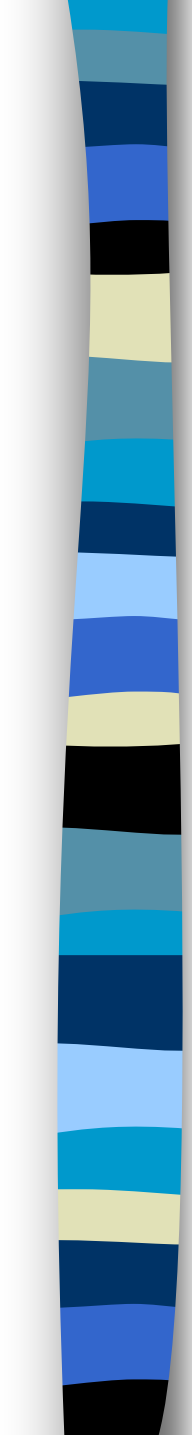
Criteria for Evaluating the Ethics of a Study

- Emanuel, Wendler, Grady (2000). Review of major codes of ethics yielded 7 requirements for ethical research
 1. Value--enhance health or knowledge
 2. Scientific validity
 3. Fair subject selection
 4. Favorable risk-benefit ratio
 5. Independent review
 6. Informed consent
 7. Respect for enrolled subjects--privacy protection, ability to withdraw, safety monitoring



The Need for Empirical Data

- We need data in assessing when we've met the 7 ethical requirements:
 - What processes enhance understanding of consent information?
 - Which methods of de-identification best protect the confidentiality of data?
 - What benefits do a specific group seek?
 - Do payments cause participants to ignore risks?
- For a detailed research agenda see: Sieber (2004), *Ethics&Behavior*, 14(4)
- A venue for publication: *JERHRE*



Examples of Useful Data from the Field of Substance Abuse

- Based on Anderson & DuBois' (2007) review article based on searches of:
 - Medline; ETHX; PsychInfo; Sociological Abstracts
 - Snowballing
- Review of theoretical literature followed by empirical studies on themes like consent, privacy, benefits, harms, justice
- Studies examined from 1960's through Sept 2005



Comprehension in SA Research

3 Studies of IDUs enrolling in HIV vaccine trials:

- Fureman et al 1997: pamphlet and video tape increased knowledge; effect of video tape remained after 1 month
- Harrison et al 1995: High level of comprehension
- MacQueen et al (1999): High level of comprehension; higher after group educational session



Financial Incentives

- Festinger et al 2005: random assignment of financial incentives. Low perception of coercion across groups; higher payments and cash increased follow up attendance
- Reynolds et al 2000: Cash incentive increased enrollment across all groups (low/high income; employed/unemployed)
- Fry & Dwyer (2001): Reported reasons for enrolling in a study including economic gain as well as altruism and activism



Administration of Alcohol

- Six studies identified from 1973-2000:
 - No study found that experimental administration of alcohol led to increased quantity or frequency of drinking following the study
 - Small samples: Total n of 117 across all studies



Administration of Cocaine

- Kaufman et al 2000: experimental exposure to cocaine had no adverse health effects; no altered use of cocaine
- Elman et al 2001: experimental infusion of cocaine did not increase frequency of cocaine use or severity of addiction



Justice in Research

- Carroll et al 1999:
 - Compared participants in 2 cocaine trials to clients in outpatient clinical setting
 - Participants more likely to be young, White, on public assistance, with employment problems
- Gorelick et al 1998:
 - Reviewed studies of cocaine treatment studies to national survey of people seeking treatment
 - Research participants are like others seeking treatment, except for race: Participants are predominantly White--all White in 25% of cases
- Consider evolving notion of justice in research, from protection to inclusion (McCarthy 1998, King 1998)



Gaps

- Effects of using placebo in clinical trials
- Therapeutic misconception and rates of treatment seeking
- Understanding and impact of certificates of confidentiality
 - Only 1 study addressed confidentiality
 - McCrady & Bux (1999) found most researchers had a policy of breaching confidentiality to report abuse and suicidality, but some did not inform participants of this



Finding Data: The Challenge of Hidden Research

- We may speak of “hidden” research on research ethics in 3 senses:
 1. Journal Choice: studies are not published in research ethics journals such as JERHRE, IRB, Ethics & Behavior, or Accountability in Research
 2. Keywords: Studies are published with no ethics keywords. Hard to find using a database such as Medline or PsychInfo
 3. Research aims: Studies may shed light on ethical questions, but these questions are not engaged in the studies’ aims or discussions



Example: A Review of the Journal *AIDS* (2005 & 2006)

- 7 articles identified that address one of the 7 requirements for ethical research
- None used “ethics” as a keyword; only 1 used a related keywords (patient selection)
- None discussed their findings in ethical terms
- Thus, these are “deeply hidden”--but may be relevant to IRB deliberations, research priorities, and study designs
 - Note: In Am J. Psychiatry and Pediatrics there were more really relevant studies, and keywords were used in most cases



Example: A Review of the Journal *AIDS* (2005 & 2006)

- Gandi et al 2005: Review of NIH-funded HIV RCTs in phase II & III:
 - Underreporting of full list of HIV enrollment criteria in publications and exclusion of certain populations may affect generalizability of trials
- Menzer et al 2005:
 - 10 of 49 patients had drug resistant HIV; 5 of the 10 had minor viral quasi species, which go unidentified in genotypic analyses. These individuals are not identified in research studies
 - Could affect ethics of random assignment and generalizability of results



Example: A Review of the Journal *AIDS* (2005 & 2006)

- Zamani et al (2005)
 - Survey in Tehran found IDUs acquired HIV at higher than normal rate in prisons
 - Info relevant to justifying research with prisoners
- Gardner et al (2005)
 - Found brief intervention by case manager increased visits to an HIV clinician
 - Finding relevant to increasing benefits and compliance within HIV treatment studies



Gathering Data: General Challenges

- Dual expertise needed
- Access to participants (privacy concerns, and collaborative concerns)
- Burdens to participants
- Risks to researchers
- Ethical concepts are difficult to operationalize and measure



Example: Collaboration in an HIV Prevention Study

- DuBois, Cottler, Callahan (In press)
- Benefits:
 - Team: Welcomed data that could elucidate what participants want and facilitate getting good data
 - DuBois: Welcomed access to data from a hard to reach population, chance to ask important questions
- Challenges:
 - Diverging views on experimental vignettes and questions about certificates of confidentiality
 - Needed to avoid duplicating questions on benefits

Results: Consent Process

<i>Do you want...</i>	HC %YES	LC %YES	χ^2
Consent form read aloud by researcher?	88	69	.02
Researcher to test your understanding of consent information?	96	96	NS
Researcher to verify you're not high during consent?	96	89	NS
Prefer friend present during consent?	31	16	NS
Prefer family member present during consent?	40	27	NS
Prefer stranger, unaffiliated with research team, trained to help you understand consent process?	40	31	NS
Researchers to remind you of consent information at each visit?	79	80	NS
To give consent verbally, without signing a form?	10	9	NS



Note on amounts of incentives

- Asked participants how much money was “fair” and “a lot” for participation in a 90-minute study involving a blood draw and interview. Median responses:
 - \$30 “fair”
 - \$100 “a lot”
- Used their actual dollar amounts when inquiring into influence of fair/high payments

Results: Financial Incentives

Question:	HC %YES	LC %YES	χ^2
Should participants be paid for their time?	94	89	NS
Would you be willing to participate for a "fair amount" paid with gift card instead of cash?	88	84	NS
Would others be likely enroll in a study just to receive a large payment?	88	91	NS
Would a large payment would make you ignore risks?	8	16	NS
Should researchers be allowed to offer large payments to encourage participation?	58	56	NS

Results: Different treatment

Question	HC %YES	LC %YES	χ^2
Is it fair to forbid researchers to pay drug users cash?	42	51	NS
Should researchers be allowed to exclude drug users from ordinary clinical trials?	25	16	NS
Is it "right" to exclude prisoners from most research projects?	10	18	NS



ESRAA Conclusions

- Ethical concerns did not affect compliance in the previous HIV prevention study
- Participants did not welcome common protections for vulnerable participants
- Participants want researchers--not friends, advocate, or family members--to ensure comprehension of consent information
- Because attitudes and values will vary across vulnerable participant populations, research ethics “quality improvement” questionnaires are best used routinely in studies



Empirical Research on Ethics: Beyond Polling

- Common criticism of empirical bioethics:
 - It appears to address questions like “Should physician-assisted suicide be permitted” by polling
 - Assumes ethical relativism, assumes majority views should prevail
- Defense of Polling:
 - Descriptive data on attitudes and preference is important when it provides key stakeholders with a much-needed voice
- Beyond Polling:
 - But most empirical bioethics now goes well beyond polling, providing “ethically relevant facts”



Meeting the Need

- Successful research will require:
 - Partnerships:
 - Field-specific researchers (e.g. in SA or HIV) + social scientists/methodologists + ethicists
 - Funding
 - Creativity
- Researchers and IRB members must be encouraged to find and use such data