Implementing Reproductive Health Research Guidelines in Ethics Review

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Background

National and International Research Guidelines in Ethics Review have been established to ensure greater adherence to ethical research practices in reproductive health.

Despite these safeguards, however, traditional research approaches often continue to raise difficult and important ethical questions.
Structure of presentation

- Case presentation
- Identify difficult and important ethical question
- Systematic analysis of such questions to ensure that study participants are protected

- **Standard 7**: Ethical basis for decision-making in research ethics committees
  1. Scientific design and conduct of study
  2. Risks and potential benefits
  3. Selection of study population and recruitment of research participants
  4. Inducements, financial benefits, and financial costs
  5. Protection of research participants’ privacy and confidentiality
  6. Informed consent process
  7. Community considerations
Reproductive Health

- A state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity, in all matters relating to the reproductive system, and to its functions and processes.
- Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so.

1994 International Conference on Population and Development, Cairo
When paradigms collide

Research can yield valuable information

Difficulties in implementation because of sensitive issues
Scientific design and conduct of study

• **Case:**
  – A study to examine whether and how women involved in the sex trade negotiate condom use by their male partners.

• **Ethical Question:**
  – Was the study justified in using a form of participant-observation that depended on deception?
Scientific design and conduct of study

• The research would produce reliable information on the views of these women about HIV/AIDS, their sexual practices, and their condom negotiation skills, and that this information would provide a basis for better policy-making.

• The research method breaches the ethical code – the fake customers had misled research participants.
Risks and potential benefits

• **Case:**
  – Behavioral research to study adolescent sexual and reproductive health.

• **Ethical Question:**
  – Is obtaining reliable and valid information about these behaviors worth the stigma of participation and breach of confidentiality?
Risks and potential benefits

• In cultural contexts where sexual activity outside of marriage is censured, enrolling participants and eliciting truthful responses are especially problematic.

• In such contexts, innovative data collection techniques that use audio-CASI (computer assisted self-interview) methods can reduce the stigma of participation, ensure privacy, and improve participants' reporting (Mensch et al., 2003).
Selection of study population and recruitment of research participants

• **Case:**
  – The development and testing of a vaccine against the human papillomavirus (HPV).

• **Ethical Question:**
  – Is the application of the principle of justice in the selection of young female participants, many of whom were minors and participated with parental consent and shared both the risk and potential benefits of the research, appropriate?
Selection of study population and recruitment of research participants

• The application of the principle of justice seemed appropriate in the HPV vaccine studies.
• Participants have been recruited and selected in a fair and equal manner.
• Special protections were provided to younger participants in the HPV trial by obtaining informed consent from their parents and by providing them with regular health checkups over time.
• The larger issues of justice now facing the study is the cost and availability of effective treatments.
Inducements, financial benefits, and financial costs

• Case:
  – Breastfeeding and mother-to-child HIV transmission.

• Ethical Question:
  – Does the provision of free clinic visits every 2 weeks and free medication constitute a form of undue inducement to participate?
Inducements, financial benefits, and financial costs

• Whenever possible, HIV Prevention Trial Network (HPTN) researchers are directed to seek ways to improve local access to care rather than contribute to the creation of a dual standard that privileges research participants and the potential for undue inducement (FHI, 2003).

• The guidance stresses the desirability of seeking resources and building capacity for that care so that access can be maintained once the research ends.
Protection of research participants’ privacy and confidentiality

• Case:
  – Case-control study of vasectomy and prostate cancer.

• Ethical Question:
  – Is it ethically acceptable to gain access to the medical records of patients without first asking their permission?
Protection of research participants’ privacy and confidentiality

• It has been proposed by many authorities that explicit consent should be obtained from each patient before his or her medical records can be used and require all research that needs access to personal medical records to be submitted to an ethics committee.

• These position would seriously impair an entire category of research and another set of guidelines has been proposed.

• The guidelines encourage the use of medical records for research and ensure that such use can be made in a confidential manner without causing harm (Wald et al., 1994).
Informed consent process

• **Case:**
  – Clinical trials to assess the efficacy of potential vaginal microbicides to prevent sexual transmission of HIV.

• **Ethical Question:**
  – How informed is consent in vulnerable populations?
Informed consent process

• In an effort to improve comprehension and voluntary participation, researchers at the Population Council and their colleagues in South Africa developed an educational video as part of a comprehensive approach to the informed-consent process that also included a study booklet and the informed consent form (de Kock et al., 2005).

• Based on the formative research undertaken in an earlier safety trial conducted at some of the same sites, the Population Council heeded the request of women to create a video to show them what study participation would be like, so as to familiarize them with procedures that they had never experienced, such as a pelvic exam or an HIV test.
Community considerations

• Case:
  – HIV prevention research in resource-limited countries.

• Ethical Question:
  – What constitutes an appropriate standard of health care for participants in HIV prevention trials?
Community considerations

• Participatory methodologies enabled effective partnerships between researchers, participant representatives and community stakeholders to be developed and facilitated local dialogue and consensus on what constitutes a locally-appropriate standard of care in the context of a vaginal microbicide trial in this setting (Vallely et al., 2009).