Ethical Issues in HIV Prevention

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Background

- From a scientific and public health perspective, primary HIV prevention research, as well as research with those acutely infected and with established infections, should focus predominantly on communities and groups with high HIV incidence.

- Although research is crucially important for groups at heightened risk of HIV, the design and conduct of HIV prevention research with vulnerable populations worldwide continues to raise considerable ethical challenges, particularly in social contexts marked by poverty, weak healthcare infrastructures, inequity, discrimination and stigma.

What has been done for prevention? …

- Increased patient access to antiretroviral treatment, including treatment to prevent mother-to-child HIV transmission, particularly in developing countries with high HIV incidence.

- ‘Provider-initiated’ HIV testing policies have become more commonplace, increasing the number of persons who know their HIV status.

- Prevention research successes:
  - male circumcision, as three randomised controlled trials in Uganda, Kenya and South Africa indicated that circumcision produced a 60% reduction in HIV transmission risk from women to men.

What has been done?

- less successful are but promising are
  - HIV prevention trials of vaccines,
  - microbicides,
  - Diaphragms

- Halted Interventions
  - Trials on pre-exposure prophylaxis in Cambodia and Cameroon were halted prematurely after complaints from community groups, accusations from activist organisations and unfavourable media coverage.

Ethical Issues…

Ethical obligations towards:

- study participants who become HIV positive during a trial
- involvement of vulnerable groups, particularly adolescents, intravenous drug users (IDU) and pregnant women
- non-research participants, such as male partners in microbicide trials
- ancillary care responsibilities of researchers towards research participants
- responsiveness of research to local health priorities
- the use of novel approaches to develop, monitor and evaluate informed consent processes.

Ethical Issues

- This can be looked at the different phases of research:
- Before
- During and
- After research.

[HIV Prevention Trials Network (HPTN); Rennie and sugarman, 2010]

Ethical Issues Before research

- Ensuring high-quality scientific and ethical research
- Setting research objectives and priorities
- Engaging communities
- Building local capacity and partnerships
- Ethical issues in study design
- Consent, assent, permission and re-consent
- Addressing vulnerabilities
- Ethical review of research

…. During research

- Standard of prevention
- Standards of care and treatment
- Independent data safety and monitoring

….. After research

- Disseminating research results
- Sustaining capacity building and infrastructure into the future
- Continuing care for research participants
- Provision of successful research interventions

Standard of prevention….

- Standard of prevention refers to the package of HIV prevention products or services that will be offered to those who participate in HPTN research. [HPTN ethics guidance]

Ethical consideration

- While it is important, on scientific grounds, for research participants to be at risk of exposure to HIV, there is a wide ethical consensus that they must be provided with effective means to protect themselves from acquiring the virus.

- Ethical discussions therefore revolve around the precise content of the ‘prevention package’, beyond a minimum of HIV voluntary testing and counselling, HIV and sexually transmitted disease risk reduction and the provision of male and female condoms.

Standard of prevention

- ‘Researchers, research staff, and trial sponsors should ensure, as an integral component of the research protocol, that appropriate counselling and access **to all state of the art HIV risk reduction methods** are provided to participants throughout the duration of the biomedical HIV prevention trial’ (guidance point 13).

VERSUS

- The new HPTN ethics guidance takes a less categorical and more pragmatic position. It defines the necessary conditions for an acceptable prevention package within HIV prevention research as those services: known to be
  - effective in preventing HIV transmission;
  - Practically achievable as a standard in the local setting;
  - Reasonably accessible by those screened or enrolled in HIV prevention.

Concerns about standard of prevention

- Research studies creating inequities by providing participants with comprehensive prevention services unavailable to local communities and unfeasible to integrate into local health systems.
- Some prevention services (such as male circumcision) may be culturally inappropriate for some communities,
- Insisting on ‘state of the art’ prevention in every context may compromise the real-world significance of the data, and the production of irrelevant research is both a scientific and ethical concern.
- A tension between the ideal to improve local standards of care and treatment and practical obstacles researchers face when pursuing this ideal.

Suggestions

- Pragmatic approach that recognises that HIV prevention research must be conducted according to the highest ethical standards, but
- at the same time realises that , lofty ethical aspirations will not have a meaningful social impact if they cannot be applied in the concrete research settings and the political, social, economic, cultural and regulatory contexts in which they are embedded.

Provision of successful research interventions

Some key questions to be answered regarding 'post-trial access':

- who will be financially and logistically responsible for providing the intervention?
- Who will gain access to the intervention (participants, communities or others) ?
- for how long will access be provided?

Requirements suggested

- researchers to develop a 'post-study access plan' and integrate it in their study protocols before their research begins.
- researchers to start planning for access to successful interventions as early as possible, to modify plans as research unfolds, and to develop an explicit post-study access plan if a beneficial intervention is identified.
- participants should be regularly informed about developments with regard to post-study access,
- ongoing stakeholder and community consultation is crucial to the appropriate sharing of benefits after research is over.
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Continuing care for research participants….

- What obligations do HIV prevention researchers have when a research participant, despite being provided with the 'prevention package', becomes HIV positive during the course of the study?

Arguments /Suggestions

- Some researchers involved in HIV research and ethics argue that with the increase in access to antiretroviral treatment and care services around the world, there is a 'consensus' that those who seroconvert during a trial should be guaranteed access to care and treatment.

- Others claim that, on closer inspection, this obligation has no rational or ethical basis, because the provision of treatment cannot be justified by a principle of reciprocity or claims of research-related injury.

Continuing care for research participants

- While investigators should ensure that study participants do not experience discontinuity of care and treatment, research projects cannot reasonably be expected to act as substitutes for local health systems.

- If, in the worst case scenario, it is highly unlikely that local health services will be able (or willing) to assume care and treatment for those who seroconvert during a HIV prevention study in the foreseeable future, researchers may wish to consider alternative study sites.

  – moving HIV prevention studies to better resourced settings may itself perpetuate or exacerbate existing inequities,

Engaging communities

- HPTN working definition of ‘community’, as the group of people who will participate in, or are likely to be affected by or have an influence on the conduct of research.

- What are the ethical issues?
  - Community engagement