Ethical Issues in Microbicide Research

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Preview

- What is a microbicide
- What are ‘some’ of the ethical issues in microbicide research.
  - Research in developing countries
  - Women’s & Men’s Health
  - Clinical Trials
- Why did I pick this topic to build my academic career?
Goal of this talk

● To simply list ethical issues that come up.
  – These issues are of ethical nature depending on what ethical system you wish to apply.

● To Inform you about microbicides
HIV and Women

- 34-47 million infected
- 60% in Sub-Saharan Africa
- 17 million women
- 2.3 Million children infected
- 14,000 infections a day
- 2 Million died last year
- Rate of infection in African young women can be 3X higher than male cohort
Vulnerability of Women

- HIV/AIDS has a women’s face
- Gender inequality sustains and nurtures the pandemic in women
- Physiological vulnerability
- Social vulnerability
- Vulnerable to sexual violence
- Resulting is disproportionate numbers of infections in women
What is a Microbicide?

- An topically applied intra-vaginal drug or drug delivery device that prevents the spread of sexually transmitted diseases
- Gel or a vaginal ring

Microbicides could provide women with a method, which they control, to prevent them from being infected with HIV. A microbicide that is 40% effective and used 50% of the time could stop the pandemic.
HIV

- 100 nm particle bound by host bilayer
- Negative zeta potential -35 mV
- Infects cells of the mononuclear phagocyte system
  - blood monocytes and tissue macrophages, T lymphocytes, B lymphocytes, dendritic cells
- An infected person has every possible single point mutation occurring DAILY
Woman-controlled topical vaginal microbicides

- Lack of a vaccine spurred efforts in women controlled prophylactic measures
- Vaginally applied drug delivery systems to create a high local concentration of antiviral agents to prevent early transmission events.
- Microbicide=Antiviral agent + Delivery Vehicle
- Gels (once per day), Intravaginal Rings (once per month)
- Microbicide mechanisms of action
  - Prevent viral binding with the host cells
  - Disrupt viral life cycle
  - Preventive barrier to transport of virus
- 5 microbicides in clinical trials ‘anionic polymers’
It’s a very interesting seemingly trivial but important scientific obstacle that many if not most of the microbicides have the problem that the irritation with the local application tends to override the anti-microbial effect and there have been a number of very disappointing failures of the use of microbicides.
Microbicide Community

- Governments
- NGO’s
- Advocates
- Clinicians
- Researchers
- Charitable Foundations
- Small companies
- Users
- What about men?

Giving Women Power Over AIDS Exhibit

Experience the story of Martha, one of some 11 million AIDS orphans in sub-Saharan Africa, by walking in the footsteps of a family in Zimbabwe struggling with the rampant AIDS pandemic.

http://www.global-campaign.org/exhibit.htm
Physiology

Vagina

Microbicide

Cervix

Os

Semen

Potentially millions of infected cells
Vaginal Rings

- Monolithic
- Reservoir

References:
Ethical Issues of working in developing countries

● (Respect for others) Sense that uneducated people are stupid and can’t control their reproductive health

● (Understanding) You have to come to an understanding and acceptance of other cultures
  – Dry sex practices
  – Importance of children w/r to a woman’s standing in her culture

● But yet the dilemma is that microbicides may require some of these practices to change
Ethical Issues of working in developing countries

- Covert use and the impact on men (social harm to relationships)
- Large clinical trials and what it means to give ‘informed consent’
- Long term availability of effective products to the communities that they were tested on.
Other Ethical Issues

- What do you do with people who seroconverted to HIV+ during the clinical trial?
- Use of placebo and condom only arms in the clinical trial.
- Microbicide primate research when the macaque vagina is so different from the human
- Testing microbicides during pregnancy
- Bias of the field towards women.
  - “The philosophy underlying microbicide trials relates to the empowerment of women to protect themselves from a life-threatening disease in settings where they are unable to negotiate safe sex. Given this rationale, it seems almost antithetical to consider obtaining agreement or consent from male partners.” (Moodley, BMC Medical Ethics, 2007)
But...women are often not empowered

- Property rights
- Inheritance rights after the death of the father
- Unacknowledged economic contribution
- Sexual cruelty
Business

- Do patents help or hurt the field.
  - No patent on a technology makes it freely available
  - But if it is not patented then a large or mid size pharmaceutical company will never pick these products up and make them available particularly in the US.

- Non-profit Pharma companies
  - IPM, One-world Health, Chemists without Borders
Thank You