

An Analysis of the History of Reproductive Health Clinical Trials in South Africa

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Outline

History of SA Reproductive Health

Background of Clinical Trials

Current Microbicide Trials

History of Reproductive Health

- Contagious Diseases Law No. 12 (1895)
- Spread of tuberculosis in early 1900's
- First case of AIDS in South Africa diagnosed in 1982
- AIDS was not properly treated due to its prevalence in low-income communities
- AIDS Stigma: Seen as a behavioral problem

During Apartheid

- Birth/Death rates not required for black community
- Infant mortality rates in black communities 6-7x the rate of whites
- Government encouraged small family size (1970's)
- AIDS: Afrikaner/American Invention to Deny Sex
- AIDS origin linked to tribal ceremonies

U.S. Record

“As decolonization movements throughout the Third World demanded national autonomy, the United States replaced colonialism with development.”

-Laura Briggs Reproducing Empire: Race, sex, science, and US imperialism in Puerto Rico

- Birth Control testing in Puerto Rico
- ABC method and PEPFAR
- Global Gag Rule (Mexico City Policy)

Why is a female-controlled option necessary?

“Barriers to introducing condoms include the woman’s reluctance to raise the issue of trust and fidelity in the relationship and concerns about the male partner’s reaction to condoms. Additionally, power discrepancies found in many heterosexual relationships and the cultural dictates around the role of women in sexual encounters may leave women unable or unwilling to engage in condom negotiation.”

-Janet S. Moore

“Female Controlled Prevention Technologies”

Types of Clinical Trials

- HIV Vaccine Trials
 - First ever clinical trial of an HIV vaccine developed in South Africa was launched in Cape Town, July 2009
- Microbicide Trials
- Mother-to-Child Transmission

Microbicide Clinical Trials

What is it?

Gel, cream, film or suppository designed to prevent the spread of sexually transmitted infections, including HIV

Why are microbicides unique?

- Colorless, odorless, and tasteless
- Bi-directional
- Contraceptive and non-contraceptive options
- Vaginal and rectal microbicide options

NOTE: Microbicides are being created as a condom supplement, not intended as a replacement. Microbicides are aimed to be used in conjunction with a condom or when the option of a condom is unavailable.

Benefits of Microbicide Trials

- HIV Screening

Medical Research Council in Durban has screened over 14,000 women for HIV

- Counseling in native language

- Community referrals (for both participants and supportive male partners)

Unique Ethical Issues

- Partner Consent
- Contraceptive Hierarchy
- Informed Consent
 - Role Plays and Comprehension Tests

According to a study completed in 2004, a microbicide which was used by 20% of sexually-active individuals in 73 low-income countries could prevent 2.5 million new HIV infections over 3 years, even if only 60% effective

Alliance for Microbicide Development

Suggestions/Improvements

- Allow benefits to continue for a period of time following the closure of the trial (especially if closing unexpectedly)
- All trials should use local infrastructure whenever possible
- NGO vs. Pharma (Change in FDA policy from Helsinki to GCP regarding placebo group treatment)

How does this effect you?

- Effects of HIV reach into all other clinical trials fields, as well as the greater community at large
- Highlights unique ethical issues surrounding gender when females are primary candidates

'Umuntu Ngumuntu Ngabantu.'

"A person is a person, through other persons."

"I am because you are, and you are because we are."

'My humanity is caught up, is inextricably bound up, in what is yours. –Archbishop Desmond Tutu