Global Campaign News – Issue #49
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Welcome to the biweekly *Global Campaign News*! The *Global Campaign News* is a forum for international exchange on microbicide activities and information with an aim to build a more informed and integrated movement for microbicide development and other prevention options against HIV and STDs. This and previous issues of GC News are available online at http://www.global-campaign.org/gcnews.htm

In this issue:

GCM and AVAC issue public statement on Tenofovir Trials

Global

In response to recent controversy over the halting of clinical trials of Tenofovir as a "once a day" pill to prevent HIV in uninfected individuals in Cambodia and Cameroon, the Global Campaign for Microbicides and the AIDS Vaccine Advocacy Coalition issued a public statement on Friday February 18th 2005. The statement lays out our plans to investigate the concerns put forward by activists but argues that some of the statements circulating in the press have been inflammatory and not evidence based. We argue that simply objecting to existing trial designs and shutting down trials is not a solution. We must, instead, proceed with the much harder job of shaping a research standard we can support and then demanding that trials be designed and adequately funded to meet that standard.

A full copy of the statement is available at: http://www.global-campaign.org/clientfiles/TDF-Feb2005.pdf

Trials of BufferGel and PRO2000/5 begin in Philadelphia and Durban

Research

A large, multisite trial designed to examine the safety and preliminary effectiveness of two candidate microbicides to prevent HIV infection has opened to volunteer enrollment. The trial, sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, represents a partnership among various research institutions in Africa and the United States.

The first volunteers were enrolled this week at sites in Durban, South Africa, and at the University of Pennsylvania in Philadelphia. Enrollment will begin shortly at sites in four additional African countries--Malawi, Tanzania, Zimbabwe and Zambia. Approximately 3,220 women will be enrolled in the trial, which is expected to last approximately 30 months.

"This is the first microbicide safety and effectiveness trial of this magnitude to be conducted by NIAID," says Roberta J. Black, Ph.D, Topical Microbicide Team Leader in NIAID's Division of AIDS. "It is a critical trial evaluating two topical microbicides with differing mechanisms of action," she adds.

The microbicides to be tested are BufferGel and PRO 2000. Produced by Indevus Pharmaceuticals, Lexington, MA, PRO 2000 has shown activity against HIV and other STIs in both laboratory and animal testing. It is believed to act by inhibiting the entry of HIV and other pathogens into body cells. BufferGel, a product of ReProtect, Inc., Baltimore, MD, boosts the natural acidity of the vagina in the presence of semen, which normally neutralizes the vaginal environment. An acidic environment inactivates HIV as well as other pathogens.

Each woman in the trial will be placed at random into one of four equally sized groups. One group will use BufferGel before each act of sexual intercourse, one group will use PRO 2000, one group will use a placebo gel, and the final group will not use any gel. In addition, all participants will receive condoms and extensive prevention counseling at each clinic visit.

The trial is one of numerous studies conducted through NIH's HIV Prevention Trials Network (HPTN), which is funded by NIAID, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse and the National Institute of Mental Health. More information about this study (HPTN 035) is available at www.hptn.org/index.htm. The protocol chair of the study is Salim Abdool Karim, MBChB, Ph.D, of the University of KwaZulu-Natal in Durban, South Africa. *News releases, fact sheets and other NIAID-related materials are available at http://www.niaid.nih.gov.*

New issue brief available on Condoms – "Setting the Record Straight"

Research

Numerous groups in the U.S have called into question the effectiveness of condoms at preventing the sexual transmission of HIV infection. To address the resulting public confusion on the topic, amfAR has produced a new easy to read, two-page issue brief that summarizes the evidence related to condom effectiveness for the prevention of HIV/AIDS. To access the two page brief in PDF format, visit: http://www.amfar.org/cgi-bin/iowa/programs/publicp/record.html?record=21

U.S. National Black HIV/AIDS Awareness Day on February 7th

North America

Source: Kaisernetwork.org Daily HIV/AIDS Report, February 8, 2005.

Monday, February 8th marked the fifth annual National Black HIV/AIDS Awareness Day, which was sponsored by the Community Capacity Building Coalition, a consortium of national minority-focused groups supported by CDC through the National Minority AIDS Initiative. The CCBC includes: Concerned Black Men, the Health Watch Information and Promotion Service, the Jackson State University-Mississippi Urban Research Center, the National Black Alcoholism and Addictions Council and the National Black Leadership Commission on AIDS.

The goal of National Black HIV/AIDS Awareness Day is to urge African Americans to "get educated, get tested and get involved" with HIV/AIDS activities in their communities. Special events on the day included no-cost HIV testing, prayer breakfasts, town hall meetings and memorial services. Events were being held in cities across the country, including Atlanta, Baltimore, Chicago, Cleveland, Dallas, Detroit, Houston, Los Angeles, Miami, New Orleans, New York, Philadelphia and Washington, D.C.

Dr. Anthony Fauci, director of NIH's National Institute of Allergy and Infectious Diseases, said in a statement on Monday that while National Black HIV/AIDS Awareness Day is only "part of a critical effort encouraging individuals to get tested, educated and involved in HIV research activities," it is "an opportunity to educate our communities about research progress in the areas of prevention, care and treatment options and the importance of research to find new treatment regimens, microbicides and vaccines" (NIH release, 2/7). Several newspapers around the country have published articles covering events that took place to mark National Black HIV/AIDS Awareness Day. Links to additional articles are available at:
http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=28033

Rectal microbicide acceptability study ongoing in Boston

Research

Founded in Boston in 1971 as a free clinic, Fenway Community Health has developed into the largest provider of medical and mental health care and community health education for lesbians, gay men, bisexuals and transgender individuals in New England. Fenway also operates one of the nation's first community-based HIV research programs and has been conducting long-term epidemiological, behavioral and clinical research since 1985.

Under the leadership of Dr. Kenneth Mayer, Fenway Community Health was named an HIV Prevention and Treatment Network (HPTN) site by the National Institutes of Health in July 2000, after previously serving as the

home of the New England HIVNET trials unit. In collaboration with Miriam Hospital, Women and Infants' Hospital and Brown University in Providence, Rhode Island, Fenway has conducted clinical microbicide research to assess the safety, tolerability and acceptability of BufferGel, PRO 2000/5, PMPA Gel and Cellulose Sulfate as vaginal microbicides. In addition, Fenway has worked with our Rhode Island collaborators as well as YRG Care, an NGO in Chennai (Madras), India, to conduct microbicide acceptability research.

At present, the Fenway is in the second year of a partnership with the HIV Center for Clinical and Behavioral Studies at the New York State Psychiatric Institute and Columbia University to conduct the Topical Rectal Microbicide Acceptability study. The study is lead by Principal Investigator Dr. Alex Carballo-Diéguez at Columbia University and Co-Principal Investigator Dr. Mayer at the Fenway, and is funded by the National Institute of Child Health and Human Development.

The Topical Microbicide Acceptability study is designed to explore issues relevant to the acceptability of rectal microbicide products. One of the persistent questions raised with respect to rectal microbicides is what volume will be necessary to apply in order to provide effective HIV protection. Some microbicide developers have suggested that as much as 50-ml may be required. Additionally, besides gels, suppositories are the most frequently used vehicles to deliver medication intrarectally. The study uses placebo gels and suppositories similar to investigational microbicide products to explore attitudes and opinions concerning microbicide acceptability.

One arm of the study will enroll two cohorts of men who have sex with men (MSM). The first cohort will participate in an in-depth interview concerning anal sex practices and knowledge of microbicides. They will then rate the acceptability of different volumes of a placebo gel, starting with a 5-mL dose and increasing in 15-ml increments to a 50-mL dose. After the volume escalation, the participants will rate the acceptability of the highest volume they found acceptable when used in conjunction with receptive anal sex with a regular sexual partner. The second MSM cohort will rate the acceptability of two potential methods of delivering a microbicide product – a set volume of placebo gel (determined by the volume that the majority of the first MSM cohort found acceptable) and a placebo suppository – when used in conjunction with receptive anal sex. All participants in the two cohorts are counseled in safer sex practices and instructed to use condoms when rating the placebo products used in conjunction with receptive anal sex.

Although many HIV-prevention studies have been conducted on a variety of issues with MSM, women who have anal sex remain a hidden, stigmatized, and understudied population at high risk of HIV infection. To advance the scientific knowledge in this field, the other arm of this study will consist of preliminary exploratory research with women concerning anal sex practices and rectal microbicide acceptability. The study will enroll a cohort of women with a recent history of unprotected anal intercourse and elicit, through one-on-one in-depth interview, the psychological, social, and cultural factors associated with anal sex. The interview will also assess the women's attitudes, intention to use, and preferences concerning rectal microbicides.

Participants in all three cohorts are compensated for their participation in the Topical Microbicide Acceptability study; individuals may contact (617) 927-6450 if they are interested in participating. For more information about the study, please contact the Principal Investigator, Alex Carballo-Diéguez, at (212) 543-5969.

Circumcision Decreases Risk of HIV but Not Other STIs

Research

Excerpt from notice: Reuter's Health News Release on Medscape, January 25

Even though male circumcision seems to reduce the incidence of HIV, the procedure appears to have no effect on susceptibility to other sexually transmitted infections (STIs), according to a study conducted in Uganda.

It thus appears that "the preputial mucosa is an important target tissue for HIV, but probably not for other STIs," Dr. Ronald Gray, at Bloomberg School of Public Health in Baltimore, and colleagues report in the December 3rd issue of AIDS.

In the Rakai cohort, Dr. Gray's group found a 9.5% prevalence of HIV infection in 803 circumcised men versus 15.0% in 4352 uncircumcised men. The incidence was 1.1 per 100 person years and 1.8 per 100 person-years, respectively, among men followed at 10-month intervals ($p = 0.03$).

However, there were no significant differences between the groups in the prevalence of genital ulcer disease, genital discharge and dysuria, or in the incidence of gonorrhea, Chlamydia, syphilis, or herpes simplex virus 2. "Circumcision seems to be almost uniquely protective against HIV infection but not other STIs," Dr. Gray told Reuters Health.

More information is available at http://www.medscape.com/viewarticle/498165?src=mp with the complete findings in the December 3, 2004 edition of AIDS 2004;18:2428-2430.

We welcome your input and contributions for future issues! Correspondence can be addressed to info@global-campaign.org.

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