



Global Campaign News January 18, 2002

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.

We welcome your input and contributions. Correspondence can be addressed to info@global-campaign.org. If you would like to unsubscribe to the Global Campaign News, please reply to this e-mail with the subject line: UNSUBSCRIBE.

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Prospects for a Microbicide Pill

Until recently the very definition of the term "microbicide" has included the presumption that such a product would be applied topically in the vagina or rectum. But now a new option may be on the horizon: a microbicide pill.

Recently, the Bill and Melinda Gates Foundation convened a group of experts to explore ethical issues raised by the possible testing of an oral microbicide pill. The experimental compound under consideration, known as Tenofovir (tenofovir disoproxil fumarate), is a potent anti-retroviral drug that has recently been approved by the Food and Drug Administration as an anti-AIDS therapy. Tenofovir works by inhibiting reverse transcriptase, one of the enzymes HIV needs to reproduce within cells. Animal studies suggest that when taken daily, Tenofovir may be able to stop HIV in its tracks before infection can take hold.

The prospect of using Tenofovir as an oral microbicide raises both new possibilities and new questions. All experts agreed that there would be substantial interest in an HIV prophylaxis in pill form. There was concern, however, that all existing safety data in humans are from trials involving HIV-positive individuals. (These studies had to be done to get Tenofovir developed as an AIDS therapy). The group recommended that large scale effectiveness trials of oral tenofovir for prevention be postponed until further safety data can be gathered among non-HIV infected individuals.

Also raised were concerns about the logic and ethics of testing Tenofovir as a "prevention pill" in settings where anti-retroviral drugs are not yet available to individuals living with HIV. (Recall that Tenofovir has been proven effective as a therapy). The group recommended that clinical testing of Tenofovir as a prevention technology take place in

settings where HIV- positive individuals already have access to other anti-retroviral drugs.

Tenofovir (also known as PMPA) is also under investigation in gel form as a possible vaginal microbicide. PMPA gel is scheduled to enter Phase I human safety trials this year among healthy women in New York City, Philadelphia and Providence. Data from primate studies using SIV (Simian Immunodeficiency Virus), a close cousin to HIV, suggest that PMPA gel may help protect the animals from infection even when administered up to 24 hours before or after inoculation with the virus. Such data raise the possibility that a vaginal gel containing PMPA might represent an approach to protection that could be used significantly before intercourse.

The group noted that while many women may prefer an oral rather than a vaginal microbicide, a shift to pill form undermines the "woman" focus of the technology. Some members voiced concern that in settings where women have little economic or social power, shifting from a vaginal to an oral product could increase the likelihood that husbands or others might try to appropriate the pills for therapeutic use.

Overall the group endorsed the importance of the search for a safe and effective "microbicide pill" but recommended that further work be done to resolve outstanding ethical and safety questions before initiating large-scale effectiveness trials. In the meantime, the group recommended accelerating the evaluation of vaginal PMPA gel as an approach to prevention that might offer some of the same benefits as oral Tenofovir (such as long-acting protection) while raising fewer safety and ethical challenges. Lori Heise, Director of the Global Campaign, attended the expert consultation.

Microbicide Clinical Trials Update

Several microbicides are advancing through clinical trials, where products are tested in women and men to evaluate whether they are safe and effective for HIV and STI prevention. Participants at the Alliance for Microbicide Development meeting, held in Washington D.C. on January 8th, learned that ten different microbicides will be in some stage of clinical trials this year.

Any microbicide has to pass through a rigorous series of tests to prove that it is safe and effective before it is approved for people to use. The microbicides that are farthest along in the process are ready for Phases Two and Three, where they will be tested among thousands of people in different sites. Carraguard™, a carrageenan-based product sponsored by the Population Council, will enter a Phase Three trial in South Africa and Botswana this year. A large trial of BufferGel and Pro2000 will begin by collecting expanded data on safety and continue on to evaluate effectiveness (whether the product works). This multi-site trial will take place in India, Malawi, South Africa, Tanzania, and Zimbabwe and is being conducted by the HIV Prevention Trials Network (HPTN), a network of academic researchers funded by the NIH. Many Phase One safety trials are ongoing in the United States, in Los Angeles, Houston, New York, Norfolk, Philadelphia, Pittsburgh, Providence and Seattle. These trials variously collect information about

product safety, acceptability, male tolerance (whether the microbicide is safe for a man's penis), safety for rectal use, and safety for use by HIV-positive women and men.

For more information about products or clinical trials, visit the web page of the Alliance for Microbicide Development, www.microbicide.org to see the complete Clinical Trials Database.

South African Men endorse Microbicides

A study conducted by Gita Ramjee and her colleagues at the Medical Research Council in Durban, South Africa, revealed that more than four-fifths of South African men interviewed (n=243) want their partner to use some form of protection against sexually transmitted diseases (STDs), and most believe that women have a right to protect themselves from infection. The large majority of the men in each interview group (77-87%) would like their partners to use a vaginal microbicide if one became available. According to the analysis, 62% of men surveyed were aware that condom use could prevent HIV infection, but 58% disliked using condoms. Eighty-two percent said they would prefer using microbicides to condoms. Furthermore, data indicated that the men preferred products that did not interfere with their sexual pleasure or increase lubrication in their partner's vagina. The majority of men also said that they would prefer a microbicide that was not contraceptive, reflecting the high social value placed on childbearing in many African countries. (International Family Planning Perspectives 27(4):2001 at <http://www.guttmacher.org/pubs/journals/2716401.html>)

Advocates in Action

The Global Campaign-US has issued a new Hot Flash--an action alert that goes out to its grassroots Campaign Sites and their networks when constituency action is needed. This Hot Flash (copy attached) calls on advocates to phone or e-mail their Representatives and Senators urging them to sign on as co-sponsors of the Microbicides Development Act, legislation now pending in the US Congress. More co-sponsors not only strengthen the bill's chance of passage but also send a message that microbicides must be a part of the US government's overall response to HIV/AIDS. Senator Kerry (Dem-MA), for example, is expected to introduce an omnibus Global HIV/AIDS Bill in the Senate in early 2002. Since Senator Kerry's bill has a good chance of passing, we must ensure that meaningful (not just symbolic) microbicides language is included in it. A sharp rise in the number of Microbicides Development Act co-sponsors would strengthen our ability to negotiate the language we need with Senator Kerry's office.

Internet Discussions

Journalists Against AIDS (JAAIDS) in Nigeria featured a two-week online discussion on vaccines, microbicides, and the female condom in December. The forum served to open discussions on research advances in HIV/AIDS prevention options as well as Nigeria's role and preparedness in further research and development. You can find this discussion at www.nigeria-aids.org.

Bobby Ramakant, key correspondent with the Global Campaign, also has a regular column on the South Asian Women's Forum website called "M-Power" where he talks about women's health and empowerment in India. His last column focused on the AIDS India 2000 conference in Chennai, India in December, which held an exclusive satellite session on microbicides. His column can be found at <http://www.sawf.org/newedit/edit12102001/mpower.asp>.