

From Technical to Tactical

HIV Prevention Options and Philanthropy

ONE-SHEET REPORT

On May 29, 2008, **Funders Concerned About AIDS (FCAA)** and the **AIDS Vaccine Advocacy Coalition (AVAC)** co-hosted a teleconference titled **"From Technical to Tactical: HIV Prevention Options and Philanthropy."** Mediated by **Mitchell Warren**, Executive Director of AVAC, the teleconference focused on rectal and vaginal microbicides—substances designed to thwart HIV infection at its earliest stages by killing the virus or blocking its initial fusion with target cells. **Dr. Sharon Hillier** of the **Magee-Women's Research Institute** gave a short presentation on microbicide development, and **Jim Pickett** of **International Rectal Microbicides Advocates (IRMA)** followed with a discussion of advocacy. The teleconference addressed current challenges to the advancement of this vital preventive technology, with an eye to clarifying how private funders might contribute meaningfully to the field. At least 18 representatives from philanthropic organizations dialed in to the call. This One-Sheet Report summarizes the key facts, insights and issues that were discussed.

Microbicides

Research into vaginal microbicides has come a long way since clinical trials in the early 1990s first assessed the ability of over-the-counter agents such as Nonoxynol-9 to block HIV infection. The first presenter on the call, Dr. Sharon Hillier, noted that the failure of those studies and tests on the first generation of microbicides (often gels filled with charged molecules thought to block viral fusion and applied prior to sex) led to a sea change in how HIV microbicides are devised and tested. Today, she said, scientists are investigating dozens of novel concepts in microbicides—including antiretroviral drugs as active ingredients—and they are just beginning to devise more targeted ways to inhibit viral fusion based on the unique molecular biology of HIV. They are also rethinking how such agents might be delivered. Rather than focusing solely on gels applied before sex, researchers are considering everything from tablets to injections to intrauterine devices as mechanisms for microbicide delivery. Importantly, clinical researchers today are also working more closely with the communities in which new products are tested. Many researchers are doing a much better job of explaining their clinical trials to participants, and readily take suggestions from advocates and community leaders about how the trials might best be designed. Such measures have not only helped attenuate suspicions within communities about the intent of researchers testing microbicides, Hillier said, but also have helped to improve the quality of clinical trials.

Yet, as Hillier pointed out, "we will have solved only half the problem even if we develop a vaginal microbicide," since it isn't clear that such agents would necessarily protect against transmission during anal-receptive intercourse, a practice that is far more common among heterosexuals than is generally believed. Somewhere between 76% to 90% of gay men and men who have sex with men (MSM) practice anal intercourse, and about half the time do not use condoms. However, surveys done in places as culturally distinct as Pune, India and Pittsburgh, Pennsylvania, have found that more than one in five women report participating in anal intercourse. Among heterosexuals, unprotected anal sex is almost the rule, not the exception, noted the second presenter on the call, Jim Pickett. All this is ample cause for concern. "An act of unprotected receptive anal intercourse, is five to 80 times more likely to result in HIV transmission than an act of unprotected vaginal intercourse," said Pickett.

A limited understanding of rectal immunology has certainly held back research in the field. Both Hillier and Pickett felt that the stigma associated with anal sex has contributed as well. But things seem to be changing, if slowly. For one thing, said Hillier, researchers are far more open to the possibility that rectal microbicides can be both developed and tested in clinical trials. Indeed,



it has become common practice now for candidate vaginal microbicides to be tested for safety in the rectum. The Microbicide Trials Network, which is supported by the National Institutes of Health (NIH), and in which Hillier participates as a principal investigator, will soon be moving forward on two clinical trials specifically assessing the use of antiretroviral drug-based gel products as rectal microbicides. At the same time, she said, scientists are studying gut immunology with greater intensity to lay the groundwork for future development of such agents.

Such changes can help funders find funding opportunities in microbicide development. Almost all of the current public financing for microbicide research and clinical development—97%—comes from the US Government, which, according to the Global Campaign for Microbicides, contributes roughly \$142 million to the effort. The total global investment in this arena came to \$227 million in 2007. By IRMA's reckoning, the portion of that funding going specifically into rectal microbicides adds up to \$7 million a year, an amount that, though higher than it was in previous years, remains less than adequate. According to Pickett, almost five times that amount is needed to maintain a viable research pipeline. The money currently dedicated to microbicide development overall each year is barely a fraction of what would be needed to bring even a single product to market. Few organizations, however, have the financial wherewithal to support drug development, and thus far, funders have been reluctant to put microbicides, especially rectal microbicides, on their agendas.

But there are concrete ways funders can help. For example, NIH support for community outreach efforts is typically tied to specific clinical trials. Since informed community participation is such a vital part of any clinical trial, funders could help underwrite more expansive programs to disseminate information about HIV prevention, microbicides and clinical trials within the communities that host such research.

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Furthermore, both presenters stressed that even small sums can go a long way, especially in the advocacy arena. Pickett noted that the largest contributions made to IRMA topped out at \$25,000—not much in terms of drug development, but more than sufficient to support its various efforts at advocacy. With this funding, IRMA was able to make several small grants, many of which were considerably less than \$1,000, to help people from all over the world attend its biennial conference in Delhi in February 2008. Small donations can also be used to help fund reports crucial to effective advocacy.

Finally, funders can provide valuable resources toward more widespread acceptance of microbicides. Pickett suggested, for instance, that a better understanding of the geography and practice of anal receptive intercourse could help reduce the stigma associated with the practice. Hillier, meanwhile, pointed out that much work needs to be done to illuminate what kinds of microbicidal products are most likely to be used consistently by average people, and what sorts of marketing strategies would make their use—and conversations about their use—an acceptable part of the public discourse.

For more information on microbicides, check out these websites:

hivresourcetracking.org

Go here to find data on annual investments in the research and development of, among other things, preventive HIV vaccines and microbicides, and cash-flow into HIV/AIDS-related policy development and advocacy

mtnstopshiv.org

The website of the Microbicide Trials Network is a storehouse of information on clinical trials of microbicides and their place in combating the AIDS crisis

rectalmicrobicides.org and irma-rectalmicrobicides.blogspot.com

The IRMA website and blog focus on advocacy and research for rectal microbicides

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AS A NETWORK OF MORE THAN 1,500 PHILANTHROPIC GRANTMAKERS ENGAGED IN THE FIGHT AGAINST HIV/AIDS, FUNDERS CONCERNED ABOUT AIDS (FCAA) WORKS TO MOBILIZE PHILANTHROPIC LEADERSHIP, IDEAS, AND RESOURCES TO END THE HIV/AIDS EPIDEMIC AND TO ADDRESS ITS SOCIAL AND ECONOMIC CONSEQUENCES.



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