

Funders Concerned About AIDS (FCAA)

Game Changers in HIV Prevention: A Funders' Briefing

The last 12 months have delivered an abundance of exciting headlines in the area of HIV/AIDS prevention: the first microbicide study (**CAPRISA 004**) to demonstrate a reduction in HIV/AIDS infection among women; the first evidence of **pre-exposure prophylaxis (PrEP)** reducing HIV infection risk (**iPrEx**); and finally, the recent results of the **HPTN Study 052** showing a 96% reduction in HIV transmission by the early initiation of antiretroviral treatment (ART). In response to these developments FCAA brought HIV/AIDS grantmakers and key stakeholders together on April 14th, 2011 for a webinar focused on the latest scientific advances in, and the funding landscape for, HIV prevention and research. Co-sponsored by **AVAC** and the **M.A.C AIDS Fund**, the discussion featured **Mitchell Warren** and **Emily Bass** of AVAC; **Dr. Robert Grant** of the **Gladstone Institute of Virology and Immunology, University of California, San Francisco**; **Dr. Zeda Rosenberg**, of the **International Partnership for Microbicides (IPM)**; and **Dr. Reuben Granich**, of the **World Health Organization (WHO)**.

"Funding, not science, is now the obstacle. It's really about taking technology we know works and making sure there are many different ways to deliver it, and as rapidly as possible."

Zeda Rosenberg,
IPM

Moderator Mitchell Warren opened the conversation with a reminder of the innovative use of antiretrovirals (ARVs) over the course of the epidemic: first in HIV treatment, in post-exposure prophylaxis, and in the prevention of vertical transmission. Recent successes, for example, in the prevention of vertical transmission – where public and private sector support has yielded an increase of ARV coverage from 15% in 2005 to 53% in 2009 among pregnant women living with HIV in low-and middle-income countries - demonstrate how science can evolve with the right combination of political commitment and financing. How do we now translate recent research results and opportunities into impact, and into infections averted to game change the course of this epidemic? Speakers were asked to address this question, as well as to discuss how grantmakers at all levels of giving can impact the delivery of these tools in the future.

Top 10 Considerations for Funders

1. **Support both the research of products close to market to confirm trial results, and the acceleration of access to the product as soon as it is licensed.** First revealed at the 18th International AIDS Conference in July 2010, the results of the CAPRISA trial showed promising rates of HIV prevention (39% efficacy) when tenofovir gel was used twice within 12 hours before and after sex, as well as an unexpected 51% efficacy rate against HSV-2 (genital herpes). As CAPRISA was a single study, ongoing confirmatory studies are currently being conducted (or are planned) to support the regulatory dossier for the product, including looking at both the use of tenofovir on a daily basis, as well as the oral use of tenofovir and Truvada® (combination of tenofovir and emtricitabine drugs). In November 2010 the results of the iPrEx study revealed that individuals at high risk for HIV infection who took a once-daily oral Truvada® experienced a 44% reduction of HIV infection compared to those receiving a placebo pill. While there are many ongoing tenofovir-based oral PrEP trials taking place in different countries and populations - such as heterosexual couples and injection drug users - defining new strategies to improve PrEP use will be an essential aim of the next phase of iPrEx, the open label extension (OLE). Using previous trial sites around the globe, iPrEx OLE will seek to find out if more people will take PrEP if they know it is effective, as well as to collect more information on long-term safety issues.
2. **Fund trials of other products and formulations to completion.** For IPM, that includes a Phase III efficacy trial (starting in 2011) to test if the dapivirine ring is effective in reducing the risk of HIV infection in women. This long-acting, monthly ring would allow for more consistent

"We are having this conversation at a remarkable time, one of the most interesting times scientifically and yet at one of the most challenging times economically"

Mitchell Warren,
AVAC

“What prevention needs right now is a grassroots mobilization of people to think about how they use these new opportunities to keep themselves free of HIV. And I think the people we need to lead that are young people.”

**Robert Grant,
Gladstone Institute**

Where is Funding Today?

In 2009, internationally focused U.S.-based HIV/AIDS funders disbursed \$150.6 million to HIV/AIDS-related research – a decrease of nearly \$50 million from 2008. If you look at the same set of funders without the Bill & Melinda Gates Foundation (the world’s largest private HIV/AIDS funder), that figure drops to \$7.8 million. Within the U.S., domestically focused funders disbursed \$33.6 million to research. •

In 2010 the total global investment – including commercial, public and philanthropic support - in research and development reached \$1.9 billion for four key prevention options: preventive HIV vaccines, microbicides, pre-exposure prophylaxis (PrEP) using ARVs and operations research related to male circumcision. ••

• U.S. Philanthropic Support to Address HIV/AIDS in 2009. FCAA, November 2010.

•• Capitalizing on Scientific Progress: Investment in HIV Prevention R&D in 2010. HIV Vaccines and Microbicides Resource Tracking Working Group. July 2011.

use and thus better protection. The ring can also be developed at low cost (suitable for the developing world) and has the potential for drug combinations.

3. **Fund demonstration projects** to mobilize people and promote adherence to whatever program they choose. Similarly, **funding the addition of a site to an existing study** can also be a relatively less expensive option for new funders, and allows the testing of a new synergy or approach that may be more applicable for your community. For instance, additional funding could expand enrollment in iPrEx OLE to more young men of color, in more cities (eg: New York, Chicago, Atlanta, D.C., Los Angeles, Kilifi, Cape Town, Beijing, etc.), and to assess synergies with PrEP in HIV testing centers, STD clinics, community-based organizations and treatment clinics.
4. **Support individual studies focused on ART in prevention research.** Current evidence shows that viral load (the amount of active HIV in blood) is the single greatest risk factor for HIV transmission, and that ART can lower viral load to undetectable levels. While previous studies have shown that ART lowers HIV transmission by 92%, in May 2011 results of a large multinational clinical study conducted by the HIV Prevention Trials Network (HPTN) found that initiation of ART by HIV-infected individuals reduced the risk of transmitting the virus to their sexual partners by 96%. There are currently a number of other individual studies – including randomized control trials (such as HPTN 052), observational studies and ecological approaches – of ART in prevention taking place around the globe with the potential to yield equally important results, but that are in the need of additional financing.
5. **Foster communication programs on HIV prevention, especially with young people.** What are they saying about sexual health, about violence, about their goals and desires? Such programs can help to find out what youth populations think about what all these tools (HIV Prevention) mean for them. As the global median age of the iPrEx study sample was 25, some of the study’s recruitment strategies could also be used to mobilize youth around HIV prevention more broadly, including: focusing on young innovators, relying on communications and word of mouth (but not mass media), and emphasizing positive messages within campaigns.
6. **Additional research is still needed:** diagnostics; behavioral research, including using behavioral economics to understand sexual decision-making; and biological research such as identifying synergies between PrEP and vaccines.
7. **Support global leadership (such as WHO) to monitor and foster research, as well as the rapid development of guidance as evidence becomes available.** While the new WHO guidelines recommend starting ART for everyone with ≤ 350 CD4 count, support is still needed to develop guidance as new evidence becomes available, as well as to implement guidelines on-the-ground. Support will also help WHO to formulate new ART in prevention policy as a key element of combination prevention efforts.
8. **Support scientific meetings to share best practices, and provide leadership and foster collaboration among researchers.** When scientists come together and collaborate, work moves faster and more efficiently. In addition, supporting the participation of civil society in research and at scientific meetings also ensures the voice and perspective of the most affected communities.
9. **Consider pooling resources with other organizations.** Funding as part of a group or consortium is a way to defray some of the risk while also contributing to a large effort with relatively minor commitment. The iPrEx trial, for instance, was sponsored by the National Institutes of Health, with co-funding from the Bill & Melinda Gates Foundation and drug donation from Gilead Sciences. A recent Huffington Post editorial written by the scientists who led some of these advances (CAPRISA, HPTN study 052) commended the role of public-private partnerships in advancing the science, and noted that this type of continued collaboration will be essential in changing the course of the epidemic.
10. **Funders should note that research trials build the capacity of research centers, communities, and countries.** In addition to infrastructure and staff development, research trial sites also promote community engagement and referral networks for medical care, treatment, and support. The CAPRISA trial community, for instance, was empowered through education and counseling, and the promotion of reproductive health and HIV awareness.

“We need to address the fact that only 40% of people have access to care and treatment who need it, and roughly the same number of people who have HIV know their status. We can only do that through a combination approach to HIV prevention that would hopefully include treatment, PrEP, and microbicides”
Reuben Granich, WHO

FUNDERS CONCERNED ABOUT AIDS

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.

2121 Crystal Drive, Suite 700
Arlington, VA 22202

t: 703.879.0815

f: 703.879.0800

www.fcaaid.org

