Px Wire: A Quarterly Update on HIV Prevention Research

AVAC
Global Advocacy for HIV Prevention

Volume 6 | No. 3
July–September 2013

AVAC's Take

Combination prevention is all about connecting distinct interventions into a single package of services. In late May, the World Health Organization (WHO) prequalified PrePex, a nonsurgical device for voluntary medical male circumcision (VMMC). In mid-June, researchers from the US Centers for Disease Control and Prevention, the Bangkok Metropolitan Administration and the Thailand Ministry of Public Health announced a positive result from the long-running Bangkok Tenofovir Study of daily oral tenofovir as PrEP for HIV prevention in people who inject drugs. And in early July, the WHO issued new guidelines on antiretrovirals (ARVs) for treatment and prevention recommending antiretroviral treatment (ART) for all HIV-positive people with CD4 cell counts of 500 or below.

What links a plastic ring, a pill for prevention and a document that adds 19.2 million people to those needing ART worldwide? They all currently face issues of implementation. For each strategy, three major questions are: What is the next step? Who will take it? How and when will the views of people living in impacted areas and communities be sought and used to guide relevant decisions?

Each of these developments puts a spotlight on the gap between what a normative agency does and what happens on the ground. WHO prequalification is just the first step in delivering devices to countries implementing VMMC. It will be up to countries to act on the new ARV guidelines. And the Thai PrEP trial data are just the latest confirmation that daily oral tenofovir-based PrEP works when taken consistently. These data that come at a time when there is still little clarity about the suite of demonstration and pilot projects that are needed to build on the WHO guidance on PrEP that was issued almost exactly a year ago. In the intervening 12 months, activity on new demonstration projects has been slow, and there still isn't a shared agenda that could help countries' decision-making processes.

The history of the AIDS response holds examples of new guidelines that don't necessarily translate into action and impact. It's relatively new territory for prevention research advocates, who have long focused on the swift and ethical implementation of trials. Today we have to continue that research-oriented work—see this issue's centerfold for the latest information on investments in HIV prevention research globally—while also acting as implementation advocates to ensure that the complicated challenge of rolling out combination prevention and treatment stays on track. With no new HIV prevention efficacy trial results expected until late 2014, now is the time to turn our attention to the specific next steps dictated by the past quarter's developments.

PrePex Circumcision Ring: Defining price, managing expectations

We don't yet know the exact price of the PrePex device—the first nonsurgical device to receive WHO prequalification for voluntary medical male circumcision. Prequalification signals that the device has met international regulatory standards and clears the way for donors and governments to purchase the device for public health programs. On a recent AVAC webinar discussing device development, Tzameret Fuerst, Co-Founder and President of PrePex manufacturer Circ MedTech said that the company was in "daily conversations" with PEPFAR and other donors and implementing partners about the price of the device, which has been previously quoted at approximately US$20. Plans for bulk procurement could bring that number down but initial costing studies have shown that at this price PrePex would be comparable to surgical VMMC. For advocates, it's critical to track pricing developments, urging that cost be set so that non-surgical VMMC is affordable and sustainable. At the same time, it's key to manage expectations of what this, or any device, can and cannot do to simplify the procedure, save funds and increase uptake.

Bangkok Tenofovir Study: Looking back and moving forward

What happens when a trial that was launched and conducted amidst controversy and community concern ends with a positive result? When the

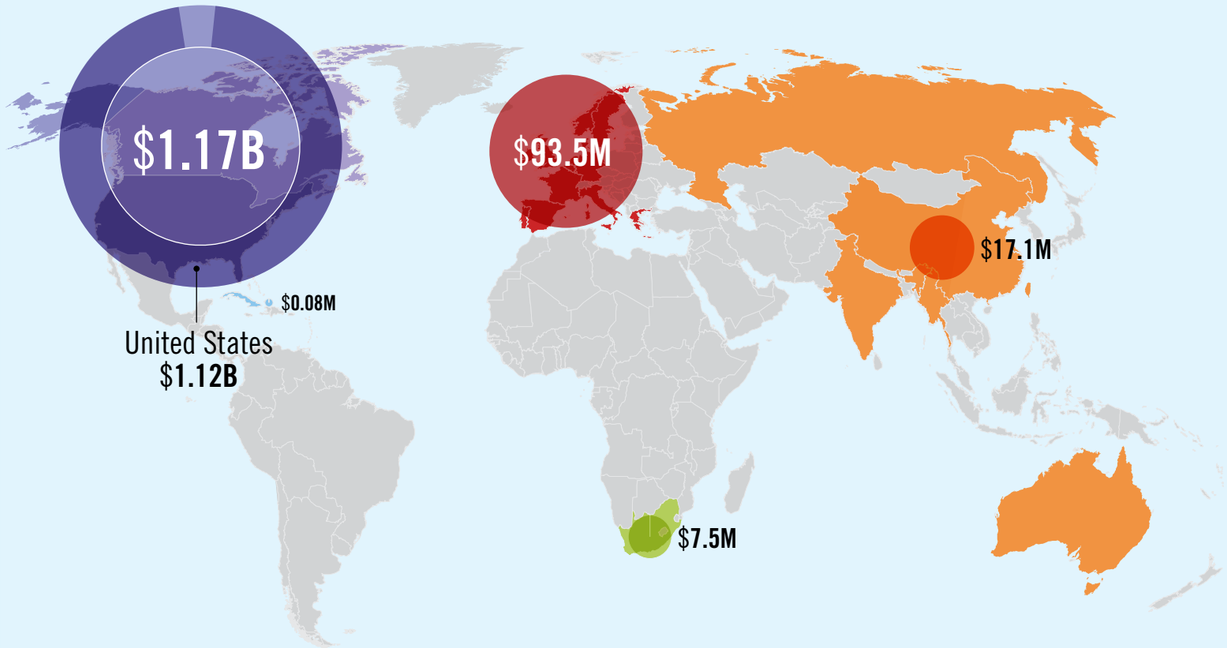
Continues on back

From Research to Reality: Investing in HIV Prevention Research in a Challenging Landscape

Data compiled by the HIV Vaccines & Microbicides Resource Tracking Working Group
www.hivresourcetracking.org

HIV Prevention R&D Global Investment by Region in 2012

Public, philanthropic and commercial sector funding from countries investing in HIV prevention R&D*



** Information collected includes funding from those agencies, organizations and companies within countries that responded to the Working Group's annual survey, or where public information sources of funding were available.*

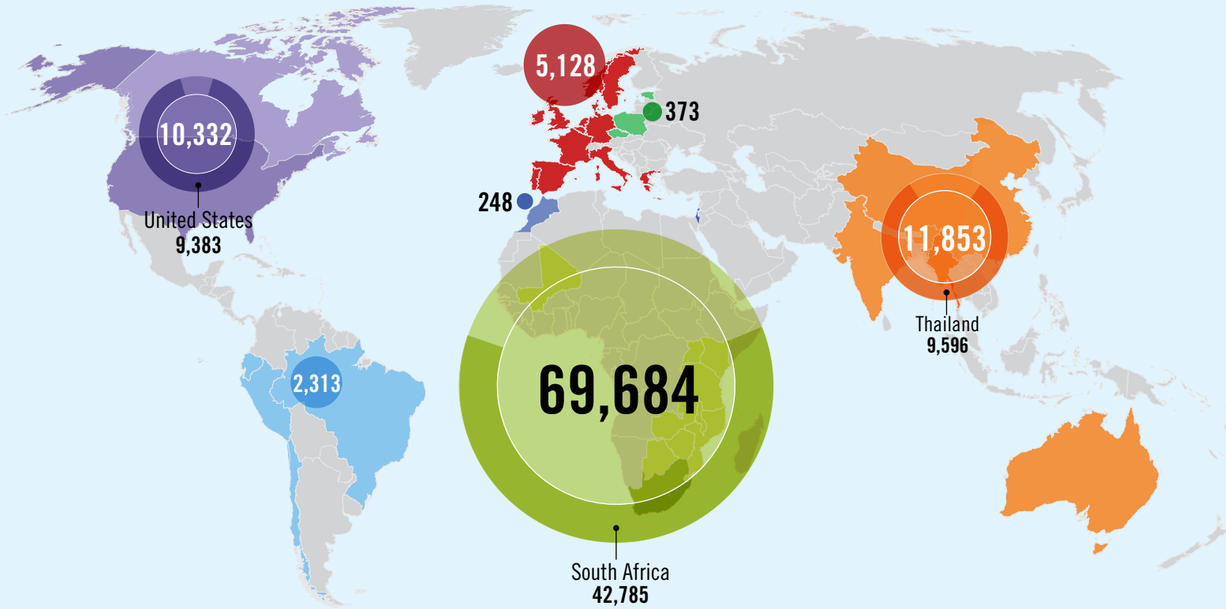
North America	
Canada	US$**45.4M**
US	US$**1.12B**
Latin America and the Caribbean	
Cuba	US$**0.08M**
Western and Central Europe	
Belgium	US$**2.6M**
Denmark	US$**1.8M**
France	US$**16.0M**
Germany	US$**2.4M**
Ireland	US$**2.5M**
Italy	US$**0.2M**
Netherlands	US$**19.6M**
Norway	US$**2.1M**
Spain	US$**4.0M**
Sweden	US$**1.6M**
Switzerland	US$**3.4M**
United Kingdom	US$**37.3M**
Southeast Asia, East Asia and Oceania	
Australia	US$**6.0M**
China	US$**7.0M** (est.)
India	US$**1.8M**
Japan	US$**1.7M**
Russia	US$**0.1M**
Taiwan	US$**0.48M**
Sub-Saharan Africa	
South Africa	US$**7.5M**

KEY

- North America
- Latin America and the Caribbean
- Western and Central Europe
- Eastern Europe
- Middle East and North Africa
- Southeast Asia, East Asia and Oceania
- Sub-Saharan Africa

** Countries by region follow UNAIDS regions and countries available at www.unaids.org/en/regionscountries/countries/*

HIV Prevention R&D Trial Participants by Region in 2012*



** Approximation. Where data on total participants by country is not disaggregated by country, total figures are divided among countries where trial sites are located.*

The HIV Vaccines & Microbicides Resource Tracking Working Group, comprised of AVAC, the International AIDS Vaccine Initiative (IAVI), and the Joint United Nations Programme on HIV/AIDS (UNAIDS), uses a comprehensive methodology to track annual research and development (R&D) investment trends in biomedical HIV prevention. Information collected in previous years has been used by the Working Group and others to monitor levels of effort, analyze the significance of investment trends and assess the impact of public policies aimed at accelerating scientific progress towards new prevention tools against HIV.

HIV PREVENTION OPTION	TOTAL INVESTMENT 2012
Preventive Vaccines	US$847 million
Microbicides	US$245 million
Pre-Exposure Prophylaxis	US$31 million
Adult Male Circumcision	US$42 million
Treatment as Prevention	US$98 million
Total 2012*	US$1.31 billion

** The Working Group defines HIV prevention R&D as including funding for: preventive HIV vaccines, microbicides, pre-exposure prophylaxis, treatment as prevention, adult male circumcision and prevention of vertical transmission. The Working Group also tracks annual investment in HSV-2 vaccine, female condom, HIV cure and therapeutic HIV vaccine R&D—these amounts are not included in the HIV prevention R&D total.*

Px Wire: A Quarterly Update on HIV Prevention Research | Volume 6 | No.3 | July–September 2013

Continued from front

Bangkok Tenofovir Study announced its finding of a 49 percent overall prevention benefit, the conclusion of the trial brought up fresh discussion on its beginning and how it was run over its eight-year history. In the weeks after the announcement, the Thai Drug Users Network (TDN), Thai AIDS Treatment Action Group (TTAG) and the Treatment Action Group issued a statement that said, in part, "While TTAG is glad for any evidence of reduced HIV transmission among people who inject drugs, this trial failed to promote basic ethical practices and patently ignored community concerns. In our opinion, the trial serves as a 'worst practice' example of community engagement, failing to ensure participant access to a comprehensive prevention package in a placebo trial, and ignoring other issues we tried to raise to researchers at the outset."

The concerns raised about the trial were one impetus for the development of the *Good participatory practice guidelines for biomedical HIV prevention trials* that were first published in 2007 and updated in 2011. These guidelines—informed by community input—map out key activities and best practices for stakeholder engagement and have been put to use in several large-scale trials to date. The guidelines also lay out best practices for stakeholder engagement during the results dissemination and post-trial access stages. As this issue went to press, the Thai NGO Coalition on AIDS (TNCA) and various civil society partners convened a community dialogue to discuss the results with key Thai government officials—an activity that is part of a broader initiative to develop a national community advisory board in Thailand.

New WHO Treatment Guidelines: Putting individual choice at the heart of combination prevention

The new WHO guidelines on the use of ARVs have triggered a global debate about the feasibility of, and scientific rationale for, expanding ART eligibility criteria to CD4 cell counts of 500 and below. Continued advocacy and engagement in this conversation is needed to ensure that treatment fulfills its promise as a prevention option.

Combination prevention is the best way to begin to end the epidemic; implementing a range of options is also the best way to meet the needs of individuals living with or at risk of HIV. Sustained advocacy from research to rollout is essential to ensure that the element of choice—and of changing needs across the life cycle—is preserved.

Recently Released

Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection – Earlier, safer and simpler antiretroviral therapy is needed, *www.who.int/hiv/pub/guidelines/arv2013/download/en/index.html*

From Research to Reality: Investing in HIV Prevention Research in a Challenging Landscape – Highlights funding trends, opportunities and challenges for HIV prevention R&D, *www.hivresourcetracking.org*

WHO Prequalification of Male Circumcision: PrePex – *www.who.int/diagnostics_laboratory/evaluations/PQMCdevices_list/en/*

Not to be Missed

September 8-11: United States Conference on AIDS, *New Orleans, Louisiana, www.iasociety.org*

September 22-24: IAPAC/BHIVA Conference, *London, England, www.bhiva.org/IAPAC-2013.aspx*

October 7-10: AIDS Vaccine 2013, *Barcelona, Spain, www.vaccineenterprise.org/conference/2013*

About AVAC

Founded in 1995, AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of HIV biomedical prevention options as part of a comprehensive response to the pandemic.

To receive regular updates via email sign up at *www.avac.org/mailinglists*.

423 West 127th St., 4th Floor • New York, NY 10027 USA
Telephone + 1 212 796 6423 • *www.avac.org*