Px Wire A Quarterly Update on HIV Prevention Research

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AVAC's Take

Messages matter. In the midst of tumult linked to hateful speech in so many parts of the world, this simple fact bears repeating. It's certainly been on our minds here at AVAC, as activists and advocates fighting for social justice, and as we think through what the key takeaways were from July's International AIDS Society Conference in Paris. The primary value of the IAS meetings may be to frame the messages for the world about the state of the epidemic. If that's the case, then advocates have their work cut out for them.

There was mixing and matching aplenty—at a time when clear, courageous speech should be the order of the day. A new PrEP dosing schedule could work for men but not for women. We're in the what US National Institutes of Health Division of AIDS head Carl Dieffenbach calls the "golden age of prevention" but, as the centerspread shows, research investment is slowly declining. Data from Swaziland suggesting that the 90-90-90 goals of testing, treating and achieving virologic suppression in people living with HIV are possible, and can reduce HIV incidence, got substantial attention too. There's been progress, as UNAIDS touted in its annual state of the epidemic report, but non-ART prevention is lagging, as are treatment programs in many parts of the world and, especially, for many key populations. This part of the story wasn't clearly told. Who should clarify? Activists and advocates, of course. Here's a roundup of IAS 2017 and a snapshot of the HIV prevention resource tracking report to help set the record straight. —AVAC

Data Dispatch

S'il vous PrEP?

Perhaps unsurprisingly, given its "new kid on the block" status, oral PrEP was everywhere at IAS 2017. The World Health Organization (WHO) set the tone early, just before the conference kicked off, with the launch of their implementation tool for PrEP. The tool includes 11 modules to support PrEP implementation among a range of populations in different settings. These modules and additional tools to support PrEP introduction are available online at www.prepwatch.org.

Presenting in their backyard, the French Ipergay team showed that, in gay men and other men who have sex with men (MSM), what they call "on-demand" PrEP, reduces HIV risk compared to those not using PrEP. On-demand PrEP refers to those who take it in response to their sexual activity rather than on a daily basis. The protection from on-demand PrEP extended even to those who have sex less frequently. Ipergay's researchers made the case using a sub-analysis of participants who'd reported using no more than 15 pills/month and reported that they systematically or often used PrEP when having sex. Since the regimen involves four tablets (two pills 2-24hrs before sex, one pill within 24hrs after sex and another within 48hrs), people in this group were having sex four or fewer times a month. Initial Ipergay efficacy data didn't specify how often participants were having sex; for those having sex multiple times a week, an intermittent schedule would work out to more or less daily dosing. The new sub-analysis, which was designed to get at the efficacy in participants having sex relatively infrequently, found no new HIV diagnoses in this subgroup. These data support the argument that this type of dosing has a place in the oral PrEP landscape. Advocates everywhere have to help clarify: these data only apply to men who have sex with men. There are no data that this before-and-after-sex regimen works for women who are at risk via vaginal exposure. In fact, a presentation from Bob Grant showed that the data in support of PrEP for women is strong but that protection against vaginal exposure looks to require 6-7 doses per week. There is accumulating evidence that men's and women's bodies and tissues process drugs differently—so caution is warranted. For women, daily oral PrEP is the thing to demand.

On the programming side, there was a lot of talk and focus on the "end user", which is usually public-health and marketing speak for people who use PrEP. The "end user" (i.e., the person who uses HIV prevention) matters a great deal for PrEP. The highest individual and public health impact will come from reaching people most at risk of acquiring HIV and encouraging their correct and consistent use for as long as they remain at high risk. Impact will be tied to successful targeting of the strategy to people who need it most and who access it in programs that support usage over time. Voluntary medical male circumcision (VMMC) achieves impact differently. It is a one-off procedure that is recommended for all men aged

AVAC Global Advocacy for HIV Prevention

Investment in HIV Prevention Research & Development

Funding in 2016

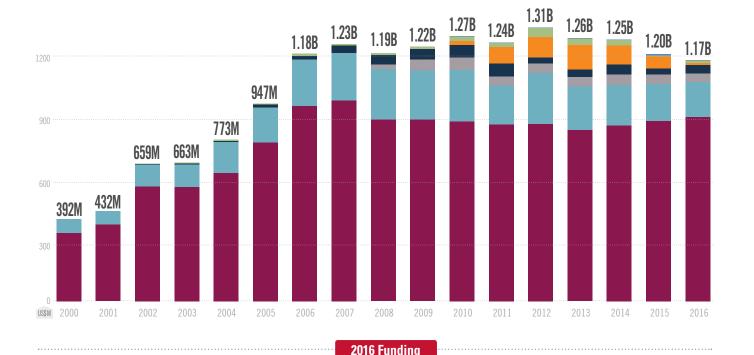
Investment priorities: Funding innovation in a challenging global health landscape

Funding for HIV prevention research and development (R&D) is crucial for continued innovation in the field. Tracking this investment—its volume, direction and sources makes it possible to identify opportunities and gaps, hold the global community accountable to its promises, and sustain forward momentum in the fight to end the epidemic.

The Resource Tracking for HIV Prevention Research & Development Working Group uses a comprehensive methodology to track investment trends in the research and development of biomedical HIV prevention options. The full report, covering 2000-2016, is available at www.hivresourcetracking.org.

Trends in HIV Prevention Research and Development Selected Report Key Findings

In 2016, reported funding for HIV prevention R&D decreased by 3.5% from US \$1.20 billion in 2015 to US\$1.17 billion. This signals the lowest annual investment in HIV prevention R&D in more than a decade.



Preventive

US\$ MILLION

prophylaxis

US\$ MILLION

Microbicides

of vertical



Treatment as prevention



medical male

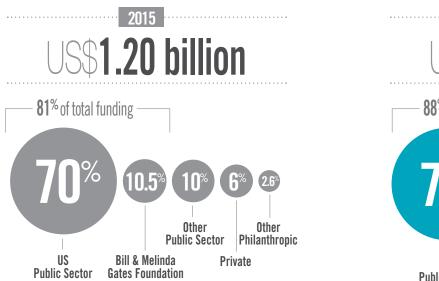
Female

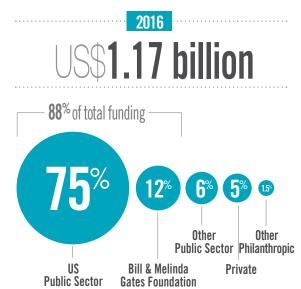
- Tracking funding for female condom and treatment as prevention research began in 2010
- Tracking funding for prevention of vertical transmission began in 2008

- Tracking funding for pre-exposure prophylaxis began in 2002
- Tracking funding for medical male circumcision began in 2001

Intensifying trend towards a small number of large investors

The call for a more diverse base of funders in the prevention R&D landscape is not a new one, but recent trends display greater polarization and a more extreme funding imbalance. Simply put, for every dollar spent on HIV prevention R&D in 2016, 88 cents came from just two donors.





Diminished funding beyond the US public sector

In 2015, public-sector investments outside the US had amounted to US\$119 million, however this number fell to US\$71 million in 2016. Compared to the previous year, Australia, Brazil, India and Japan reduced funding by 42 percent, 50 percent, 74 percent and 42 percent, respectively.



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15-49 in a set of African countries with high HIV and low VMMC prevalence. While VMMC has rolled out with an emphasis on finding subsets of men-e.g., younger men, up to 29 years old—these programs haven't had to assess men's risk on a finer level. That's because it's costeffective and beneficial at a population level to offer the procedure to all men. In Paris, new data confirmed that VMMC has benefits for women too. More than 4700 women from South Africa's KwaZulu-Natal province were asked about their partner's VMMC status in a crosssectional survey. Researchers from the US CDC presented data showing that women who reported a circumcised partner were about 30 percent less likely to have HIV; rates of HSV-2 and HPV were also lower. This type of study has limitations—circumcision can be traditional or medical and there was no way of validating what women were reporting about their partners—but still emphasizes the additional benefits of this key strategy.

Daily oral PrEP isn't a strategy designed for populationlevel coverage but rather for key individuals and communities with persistently high rates of new HIV diagnoses. Therefore, as the Paris presentations reflected, people designing and paying for programs are putting a lot of thought into strategies to identify individuals who could benefit from PrEP—and to support those people in using it correctly and consistently. Since no one wants to be labeled as "high-risk" or "unable to use condoms" or "promiscuous", campaigns about PrEP need to be accurate, clear and non-stigmatizing. In a satellite session, Connie Celum presented formative research showing that messaging focused on empowerment and intimacy is preferred to one centered on risk (see Chicago's PrEP for Love (www.prep4love.com) campaign as a great example of this approach). She also underscored that the places where PrEP is delivered, and even the packaging it comes in, are important too.

Data presented at the *HIV and STIs: The Terrible Lovers* symposia session showed that rates of STIs have been steadily on the rise since 2000. This is relevant to PrEP since it shows that this strategy itself isn't causing people to abandon condoms and acquire STIs otherwise prevented by this latex barrier. One presenter suggested that rollout of PrEP and antiretroviral treatment bring people to healthcare centers, creating new opportunities to diagnose and treat STIs given that "you won't find it if you don't look." This session is an important reminder of the importance of monitoring and treating STIs as part of comprehensive sexual reproductive health and HIV programs.

Self-testing finds the spotlight

Shortly before the conference began, the first HIV self-test was prequalified by the WHO. (WHO prequalification paves the way for countries and international donors to procure a device or medicine.) OraSure Technologies' OraQuick® HIV self-test got this important stamp of approval. Data on use of this self-test was a feature of a number of sessions. Zambian data from the PopART study (HPTN 071) showed that HIV self-testing was popular among men and young people, populations that are still lagging behind in uptake of HIV testing. Young men and women living with HIV are also less likely to be on ART and to have achieved virologic suppression.

In one study in Zimbabwe, among 607 sex workers, just over half opted to self-test (the majority of whom took the self-test in the clinic). Those participants reported that the tests were easy to use, and nearly all of those who had a reactive self-test were linked to post-test services within two weeks. This demonstrates the potential for testing and linkage to care for this highly affected group, although focus-group discussions among female sex workers noted a gap in reaching those who did not attend clinic services. Other studies explored the possibility of "secondary distribution" where partners or peers distributed the self-test kits to others.

The next generation

Phase II studies of both long-acting injectable cabotegravir (CAB-LA) and a vaccine strategy that has the backing of the Janssen pharmaceutical company (industry involvement is a rarity at this stage of vaccine development) were also presented in Paris. Now, both strategies are scheduled to move into efficacy trials starting later this year or in early 2018. These are important additions to the pipeline. For more information see our blog post: www.avac.org/ias-2017-snapshot and our updated pipeline graphic at www.avac.org/percolating-pipeline.

About AVAC



AVAC works to accelerate the development and global delivery of HIV prevention tools. To receive regular updates via email sign up at www.avac.org/signup.

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