

## AVAC's Take

Mark your calendars, prepare your statements and figure out whether you prefer the “clap” or “wave” emoji, because the theme for this year’s World AIDS Day is “Hands Up for HIV Prevention”. At AVAC, all hands are up as this important theme comes at a critical moment for HIV prevention on two major fronts: research and implementation. We’ve devoted space in this issue of *Px Wire* to developments in both arenas—with a spot in our centerspread on the findings from the most recent report from the Resource Tracking for HIV Prevention R&D Working Group, which counts global contributions to prevention research. All in favor of keeping the funding robust, reliable and adequate to the challenge of bringing the epidemic to an end? Raise your hand! —AVAC

## At A Glance

### PrEP popping up in guidelines: What to do when it happens to you

The third quarter of 2016 saw all sorts of language about oral PrEP appear in draft or finalized guidelines throughout east and southern Africa. In June, South Africa formally launched its national PrEP program with clinics that serve sex workers but will also provide the strategy to anyone who asks for PrEP. In July, Kenya launched its new *Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV Infections in Kenya* with oral PrEP fully integrated. And ministries in Namibia, Uganda, Zambia and Zimbabwe are among those that began to draft language around PrEP.

Does all of this mean there’s going to be more PrEP in sub-Saharan Africa in the near future? Not exactly. Here’s what we’ve learned from working with advocates in countries where discussions are underway.

#### ▶ **The process of updating ART guidelines is propelling PrEP into country documents.**

The most recent WHO guidelines on the use of antiretrovirals (ARVs) for treatment and prevention recommend the immediate offer of ART for all people living with HIV. This “test and offer” approach is the cornerstone of most models for ending the epidemic and countries are under pressure from many stakeholders to

swap out their old guidelines—which may have used a CD4-cell-count threshold to guide initiation—for the new ones. Since PrEP is included in the current WHO ARV guidelines, some countries are also including it in their national adaptations. This has happened in Botswana and Lesotho and may soon happen in other countries.

#### ▶ **Guidelines aren’t the same as guidance.**

PrEP is popping up in national guidelines that set the broad strokes for country programs. But fewer countries have developed PrEP guidance—the more detailed, intervention-specific roadmap for implementing who should get PrEP, what tests and counseling messages should go with it and how clinicians should approach monitoring and supporting people who are taking it. Some countries are updating their ART guidelines and developing PrEP guidance at the same time. Others have done the former but aren’t taking action on the latter, which means there’s very little happening on the ground. So a key question for advocates tracking in-country progress is: What’s the status of standalone PrEP guidance?

#### ▶ **Guidance language on who gets PrEP can get tricky.**

Perhaps the most important thing for advocates is to help guide the language on who should be offered PrEP. While the WHO states that PrEP should be made available to “anyone at substantial risk of HIV”, countries are taking various approaches to narrowing down the eligibility criteria. In some places, advocates have seen PrEP recommended for “serodiscordant couples”. This could work if the term “serodiscordant couples” applied to HIV-negative people who might have sex with someone living with HIV. But typically this term is applied only to people in a regular partnership with someone who has a different serostatus, which leaves too many people without access to PrEP. This type of language may also raise questions about why the partner living with HIV isn’t offered ART immediately.

One alternative, naming specific risk groups with documented high incidence such as men who have sex with men, and adolescent girls and young women, can also be tricky. In some regions cultural norms demand that adolescent girls and young women abstain from sex, and MSM aren’t supposed to even exist. Yet these are the precise populations who must have access to PrEP if the strategy is going to have impact. Kenya’s approach is worth studying—their guidelines, which list risk behaviors rather



## Funding in 2015

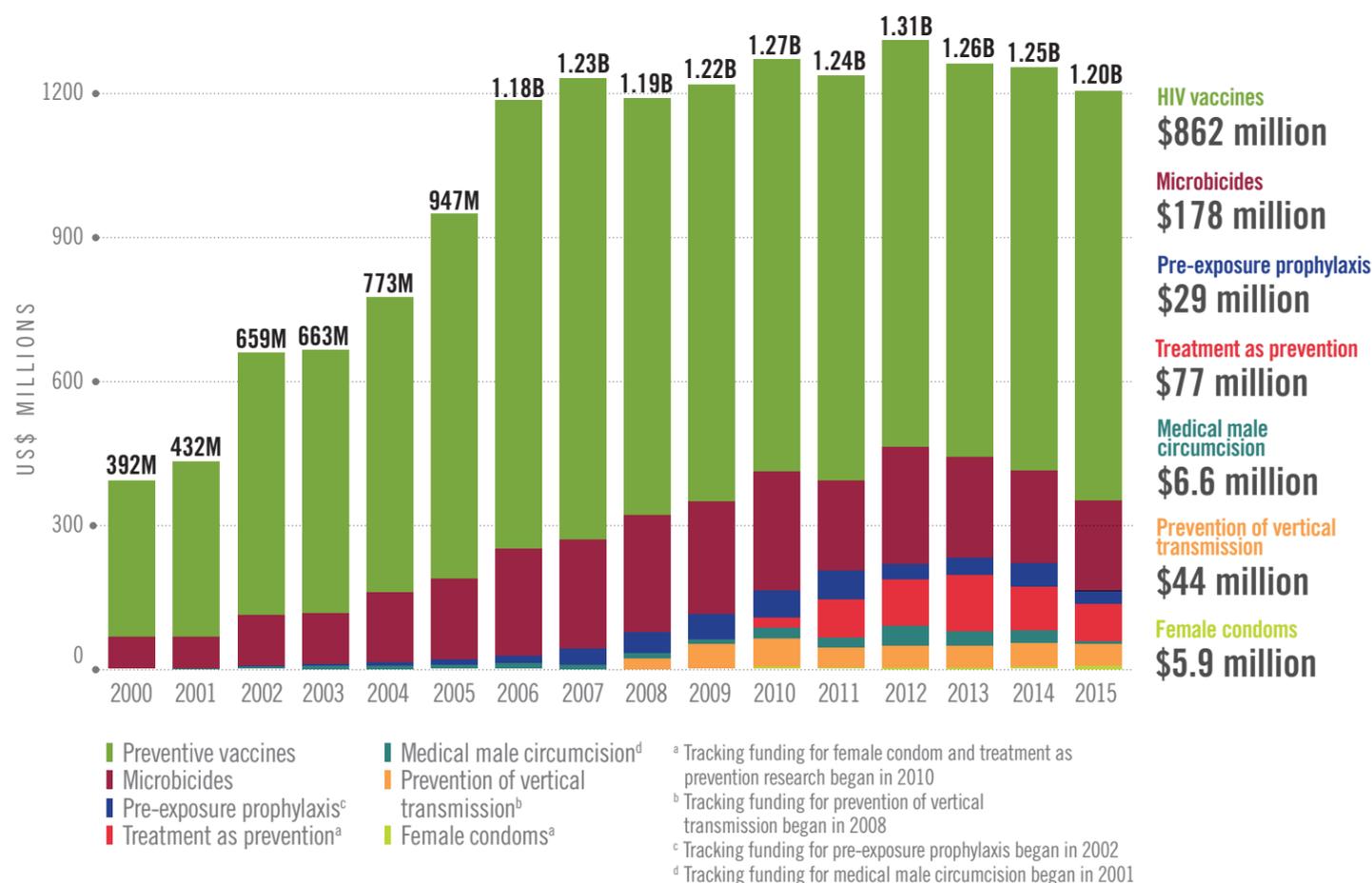
### Investment priorities in an evolving global health and development landscape

Funding for HIV prevention research and development (R&D) is crucial for continued innovation in the field. Tracking this funding, 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 and 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 2000-2015, will be available at [www.hivresourcetracking.org](http://www.hivresourcetracking.org) on October 19.

## Global HIV Prevention R&D Investments by Technology, 2000–2015 (US\$ millions)

In 2015, global funding for HIV prevention R&D declined slightly, from US\$1.25 billion in 2014 to US\$1.20 billion in 2015. This continues a decade of roughly flat funding. The US public sector remained the largest global contributor at US\$850 million, and together with the Bill & Melinda Gates Foundation, the largest philanthropic funder, constituted 81 percent of all funding.

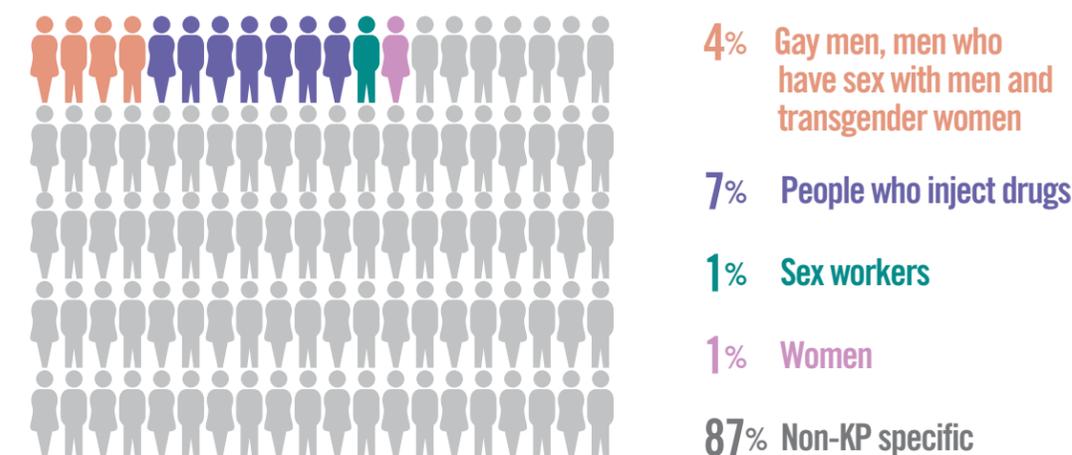


## Trial Participants by Prevention Research Area, 2015

Trial participants receive a standard package of HIV prevention services and care as part of their trial participation. Furthermore, if the product studied in the trial is proven safe and effective, ethical considerations demand that trial populations, and other populations at high risk in the community, are prioritized for access to the new intervention. Given the higher rates of acquisition seen across so-called key populations—members of highly burdened and underserved groups—it is critical to provide access to the research process such that they can participate and reap more immediate benefit of scientific progress. Greater efforts must be made to include key populations in this crucial process for the HIV prevention response to be truly impactful.



## Key Population Representation in Clinical Trials, 2015



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**2016-17: A Percolating Pipeline** — While scaling up access to all treatment and prevention options that currently exist is essential, it is not sufficient. There remains a critical need for additional options. In addition to the introduction of oral TDF-based PrEP and the open-label extension studies of the vaginal dapivirine ring, there are a number of efficacy trials planned or underway (noted below). They're tackling virtually every intervention — from next-generation PrEP in the form of F/TAF, a drug that will soon be tested for efficacy as daily oral PrEP, to long-acting injectables, vaccines and antibody-mediated prevention.

Strategy	Trial	Product	Number participants	Population	Status start-end	Location
 Antibody	<b>HVTN 704/ HPTN 085</b>	VRC01 antibody, infused every two months	2,700	Men and transgender persons who have sex with men	Enrolling Apr 2016–Sept 2020	Brazil, Peru, US
 Antibody	<b>HVTN 703/ HPTN 081</b>		1,500	Sexually active women	Enrolling May 2016–Jul 2020	Botswana, Kenya, Malawi, Mozambique, Tanzania, South Africa, Zimbabwe
 Preventive HIV vaccine	<b>HVTN 702</b>	ALVAC/gp120 MF59 adjuvant boost, five doses over 12 months	5,400	Sexually active heterosexual women and men	Planned Nov 2016–End 2020	South Africa
 Long-acting injectable	<b>HPTN 083</b>	Cabotegravir injections every two months	4,500	Men and transgender persons who have sex with men	Planned Q4 2016–June 2020	~40 sites in North and South America, South Africa and Asia
 Oral PrEP	<b>Discover</b>	Daily F/TAF	5,000	Men and transgender women who have sex with men	Planned Q4 2016–End 2020	Over 90 sites in Canada, Europe and the US
 Long-acting injectable	<b>HPTN 084</b>	Cabotegravir injections; schedule to be confirmed, either every two or three months	TBD	Sexually active women	Potential start in 2017	Southern and East African countries TBD
 Preventive HIV vaccine	<b>TBD</b>	Ad26/MVA boost	TBD	TBD	Potential start in 2017	US, Latin American, Southern and East African countries TBD

than populations, avoid political minefields but recognize that it's behaviors, not identities, that put people at risk. There are also early, anecdotal indications that programs focused on sex workers are deterring some women from starting PrEP. They fear being identified as sex workers by virtue of using PrEP. This is another reason to roll out programs with broad guidance and targeted programming. Advocates can help secure broad access by focusing on risk behaviors, not identities, as the basis for eligibility within in-country guidance.

**▶ It shouldn't be too complicated.**

PrEP is a new tool. It hasn't been delivered at national scale anywhere in the world. And there's a lot to be learned about the best way to offer it safely and sustainably. In order to learn these lessons, PrEP guidance needs to be sensible but not so complex that the strategy becomes difficult to roll out. Creatinine tests for kidney function are nice to have in PrEP programs, but they

shouldn't be a requirement, as this can slow down initiation and isn't the standard in Kenya, for example. Counseling messages should focus on the individual's sense of his or her risk and overall well-being and also support the individual's choice whether to take PrEP. And women who become pregnant while on PrEP should be able to continue PrEP use. This issue was hotly debated at the recent International AIDS Conference—it's time to move ahead with access inclusive of pregnant women.

## 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/subscribe](http://www.avac.org/subscribe).

423 West 127th St., 4th Floor • New York, NY 10027 USA  
Telephone +1 212 796 6423 • [www.avac.org](http://www.avac.org)