Big Data Real People

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AVAC gratefully acknowledges many friends and colleagues in government, industry, academia and the advocacy community who shared their expertise and advice as we researched and prepared AVAC Report 2016: Big Data, Real People.

AVAC Report 2016: Big Data, Real People was written by Emily Bass, with coordination and research by Deirdre Grant in collaboration with AVAC staff and board members. Invaluable input came from many external partners as well. Special thanks to Albert Berces, Chris Collins, Anjali Desai, Karl Dehne, Geoff Garnett, Geoff Graham, Tim Hallett, Emily Hayman, Brian Honermann, Katharine Kripke, Donna Lomangino, Craig McClure, Emmanuel Njeuhmeli, Michael Northrup, Karen O’Malley, Jacob Potter, Jason Reed, Helen Rees, Julie Samuelson, Sarah Schlesinger, Bill Snow, Todd Summers, Maaya Sundaram, Steve Wakefield and Irum Zaidi.

AVAC is dedicated to the ethical development and global delivery of new and proven HIV prevention options. This publication and AVAC’s ongoing policy, advocacy and outreach work are made possible through the dedicated labor of AVAC advocates and support from amfAR, the Bill & Melinda Gates Foundation, the International AIDS Vaccine Initiative, the International Partnership for Microbicides, M-A-C AIDS Fund, UNAIDS, UN Women, Until There’s a Cure Foundation, the United States Agency for International Development (USAID), WHO and many generous individuals who have become AVAC members and contributors through the Combined Federal Campaign (CFC). AVAC does not accept funding from the pharmaceutical industry.

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It is with profound sorrow and deep gratitude that the AVAC team dedicates this year’s AVAC Report to Ward Cates. Willard “Ward” Cates was a distinguished scientist and President Emeritus of FHI 360. He was also, and above all, a friend, mentor, collaborator and advocate extraordinaire. His enthusiasm and warmth was matched only by his commitment to the causes he worked on: reproductive health, the prevention and treatment of HIV, contraception and the all-important intersections of these fields. Ward was an unflagging supporter of the Duke University basketball team, and while team AVAC doesn’t dunk, we do absolutely know what Ward’s team spirit felt like. His love and appreciation shaped us all. His belief in the work of securing health and justice for all people, particularly girls and women, inspired us all. Ward’s memory will keep us on the court, pushing into overtime—and always smiling—until there is victory in this work.

One of the occupational hazards of working in HIV/AIDS and so-called global health (which often means health in less-wealthy nations) is uncaptioned photos of the beneficiaries of programs. There are many pictures in many places of black and brown women and children and sometimes men. These pictures tell a story. They bring need to life. But when they leave out the name, location, age and context of the individual, they sometimes do a disservice to the overall response which depends on specificity, strategy and respect for each individual. The hands pictured throughout this Report belong to members of the AVAC family including: Emily Bass, Jacqueline Borodan, Manju Chatani-Gada, Emily Donaldson, Micky Hingorani, Micheal Ighodaro, Angelo Kaggwa-Katumba, Adriel Kaggwa-Katumba (age six months), Laura Lazar, Mitchell Warren and Alysha White.
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Big Data. What do these words mean to you? Chances are, if all the AVAC Report readers got together in a room (which we would love) and arranged themselves by their understanding of the term, we would be all over the place. It hasn’t seized the attention of many people working on the front lines of the HIV response. Nevertheless, the concept and its applications are starting to shape the landscape of countries with persistent epidemics.

What about prevention data? What do these words mean to you? Is it the measure of new cases of HIV? Is it coverage of HIV testing? Is it the percentage of people on antiretroviral therapy (ART) who have achieved virologic suppression? Chances are, AVAC Report readers would name these types of information and many others, too. We would also be largely in agreement about the enormous gaps in data regarding the size, needs and best approaches for reaching many key groups including adolescent girls and young women, gay men and other men who have sex with men, transwomen—and others.

In this Report, we take a look ahead at both Big Data and prevention data. Big Data is a term on the horizon—a bigger deal in the broader development sphere than in the HIV response. We are looking at how this concept relates to HIV because HIV and global health as a whole can do much better at keeping up with broader development trends. At the same time, we are focusing in on HIV prevention data because it is not possible to end the epidemic without doing much better as soon as possible.

Let’s take each of these topics separately. First, Big Data. The term refers to extremely large data sets that can’t be analyzed or processed by traditional systems. Big Data refers to both the quantity of information and the techniques that have evolved to turn this information into insights.

There are three reasons why Big Data are relevant to HIV.

1. Big Data are a big part of the conversation about how to track progress towards and even meet the Sustainable Development Goals (SDGs)—and the success of the HIV response.

depends on its integration into this effort. As the UN Data Revolution Group wrote in its 2014 report on Big Data, *A World That Counts*, achieving the SDGs will require “a significant increase in the data and information that are available to individuals, governments, civil society, companies and international organizations to plan, monitor and be held accountable for their actions.” Funders focused on development progress are making big grants to high-tech companies specializing in bottom-up data collection. What these will yield remains to be seen, but the success of development programs will almost certainly be measured using Big Data—so advocates need to understand what’s being counted and by whom.

2 **Big Data, in the most traditional and literal sense, are fueling new discoveries in HIV vaccinology and related fields.** Advocates have to understand why these matter in order to keep up the demand for sufficient funding for basic science research.

3 **“Big Data” is the rallying cry and rationale for geographic, population- and individual-level targeting of HIV/AIDS resources by funders and implementers.** This isn’t necessarily Big Data but rather highly detailed data on rates of new HIV diagnoses, clinic performance, who lives in households, income, education and more. These data help guide decisions and funding, but they’re only as good as the systems used to collect them and those systems are still very weak. So advocates need to understand the strengths and weaknesses of data-driven decision-making that’s shaping our world.

Prevention data, which are the primary focus of the Report, are essential to meaningful changes in the epidemic. Yet everywhere we look, whether it is reports from countries, PEPFAR or GFATM, the data are sorely lacking. The power of Big Data—new approaches, massive data sets—won’t matter if basic questions about who is receiving what sorts of prevention services and with what levels of impact remain unanswered.

<table>
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<th>Strategy</th>
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| Antibodies                | • Passive immunization trials are looking at safety and efficacy of the VRC01 antibody in Africa and the Americas.  
                           | • Other antibodies and trials to follow.                                |
| HC/HIV risk               | • ECHO trial of DMPA (Depo Provera), copper IUD and Jadelle implant launched Q4 2015.                           |
| Long-acting injectable ARV| • Two Phase III trials of cabotegravir are planned to start over the next 12 months.                           |
| Multipurpose prevention technologies | • 60- and 90-day contraceptive+dapivirine and 60- and 90-day contraceptive+tenofovir vaginal rings are furthest ahead in development.  
                           | • More formulations (e.g., films, inserts) are in development.         |
| Oral PrEP                 | • Tenofovir-based daily PrEP is safe and effective and is rolling out in many countries.  
                           | • WHO recommends it for all at substantial risk, September 2015.      |
| Preventive vaccines       | • The efficacy trial HVTN 702 builds on previous success—planned launch in Nov 2016.  
                           | • Janssen Ad26/mosaic candidate—possible efficacy trial in 2017.      
                           | • Other candidates are in development.                                 |
| Rectal gel                | • First Phase II completed. Reduced glycerin tenofovir gel is safe, well-tolerated. Mixed feedback on applicator and ease of use.  
                           | • Other candidates and delivery systems are in development.            |
| Vaginal gel               | • Tenofovir gel is not being pursued based on data from trials to date.  
                           | • Other candidates and delivery systems are in development.            |
| Vaginal ring              | • Two trials show modest protection with dapivirine ring; key differences among age groups. Open-label extension trials planned/underway.  
                           | • Other rings for prevention of HIV and/or pregnancy and other STIs are in development. |

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1 HIV Prevention Research Status Report (July 2016)

So there’s actually no surprise in the findings—rather, there’s a warning. We as advocates and activists need to make sure that everyone and everything that counts is counted. The world needs to act on the gaps, whether that is a gap in information, e.g., data on adolescent girls and young women or gay men and other men who have sex with men, or a gap demonstrated by information, e.g., the challenges with retention in Option B+ programs.

In mid-July, days before the International AIDS Conference, UNAIDS issued its first Prevention Gap Report detailing the gaps and challenges in current non-ART prevention. This is needed and overdue leadership and AVAC looks to continued action from UNAIDS and other stakeholders.

For the past 30 years, HIV/AIDS activists have been at the forefront of understanding data, demanding action and seeking to safeguard ethics and human rights throughout. In many ways there’s nowhere else that we should be other than on the front lines of a data revolution, ensuring that facts and bytes and floods of information are “ground-truthed”—confirmed by the lived realities of the people in question and turned into good questions and strategic actions owned by people on the front lines.

That’s why our report theme is Big Data, Real People—because there’s no success via information if that information isn’t connected to, and informed and owned by individuals who can question it, act on it and who will, at the end of the day, be the revolution.

Mitchell Warren
Executive Director, AVAC

Unfortunately, as AVAC Report was being finalized, we received a painful reminder of the consequences of these gaps. The UNAIDS Global AIDS Update on the state of the epidemic found that there was no decline in new cases of HIV for the 2010–2015 time period. The current UNAIDS “Fast-Track” goal calls for a reduction to no more than 500,000 new annual diagnoses by 2020. With these trends, that’s absolutely not going to happen.

Could data have predicted this? Why yes, they could. During the time period in question, annual numbers of voluntary medical male circumcisions remained relatively constant—and then dipped in 2015, an alarming trend that is way off pace for current global goals. Viral load access crept ahead, but in some places where this diagnostic was available, there were still low rates of virologic suppression, which is key for maximizing treatment’s prevention benefit. Also during this time period, rates of funding for civil society and rights-focused organizations plummeted, criminalization of gay people and people living with HIV intensified in many parts of the world, and the promise of PrEP for some individuals at high risk was all but ignored.

Four Problems with Data Points for HIV Prevention:

1. The data are not sufficiently broken down.
2. Data are missing for many of the people most in need of prevention.
3. The data aren’t there to measure prevention progress.
4. Data driving basic science to new breakthroughs need sustained funding.

*For possible solutions, see Executive Summary, page 6.

Ways of Understanding Big Data

There are so many ways to think about “Big Data” that some of the earliest experts in the field are now suggesting the term may eventually be set aside in favor of terms and phrases that are more precise. Here are some specific types of data that are often discussed in the context of “Big Data for Development”:

• The “digital exhaust” of cell phone usage—patterns of use—who’s got them, where they are, where they move over time, the use of mobile money apps to send and receive money, even the contents of text messages.

• Large amounts of information provided by individuals via cell phones, rapidly compiled to give rapid or real-time maps of conditions, e.g., sexual violence in the midst of post-election violence in Kenya in 2007-2008, the precise location of forest fires in Indonesia, new malaria diagnoses and stockouts of medications in Uganda.

• Anonymized analysis of internet searches to identify issues, views, questions and potential public health issues (e.g., outbreaks of flu).

There are many more examples that are featured throughout this Report. In addition, here are a few key aspects of Big Data:

Big Data can still be biased.

One way of using Big Data is to approach a huge data set with no preconceived notions and to use analytic tools to identify patterns of association, and possible hypotheses. As we discuss on page 30, scientists are looking at the full complexity of vaccine-induced immune responses to figure out how, precisely, a vaccine provides protection. But there’s often a human element to selecting questions or generating data points. Big Data can also be biased insofar as it answers the questions that are asked of it. As common as cell phones are, not everyone has reliable access, so studies of digital exhaust or crowd-sourced data aren’t bias-proof.

Big Data can pose risks to individuals that have to be weighed against potential benefits.

There are enormous risks in collecting and making accessible data about people’s private, potentially stigmatized or illegal behaviors. The biomedical prevention field has been at the forefront of evaluating biometric identifiers, like fingerprints, which could be used to link records to people as they move from place to place. In a standard approach, these identifiers are transformed via computer into unique codes so that what is stored and accessible is not the fingerprint itself but a unique data code tied to the fingerprint. That’s a layer of safety, but not a fail-safe against the data being unscrambled and used to identify people. In many ways, the use of fingerprints gets to the core of what is most promising and perilous about this “Big Data” moment. The world has more tools than ever to track what an individual is doing in terms of accessing health care, moving from place to place and so on. That’s a good thing for public health, and on page 10 we highlight one approach to portable records, but there are also privacy concerns that require caution.

Big Data can provide false impressions.

This is true for both “Big Data” and more traditional data sets. Analyzing internet searches to predict flu outbreaks has led to over-estimates of the severity of epidemics. In traditional data, there are problems too. For example, in the case of ART delivery, patients may drop out of one clinic and present at another clinic. They may decide not to disclose their prior test results if they think that this will help them to get enrolled at the new clinic. So a new diagnosis is registered along with misleading data points. The patient will be marked as “lost” to follow-up at the first clinic, and as “newly diagnosed, new on therapy” at the new program, even though he or she had been on treatment before. A clinic located in a relatively stable area might seem to have good coverage and retention numbers because it is adjacent to an area of underserved, mobile people who just don’t show up on the radar (and thus don’t get counted). If they did, that same clinic’s numbers might not look as good.

Big Data presents big opportunities.

There is a lot that should trigger caution, but there’s also much to embrace about Big Data. We are nearing—or already at—a point where people will be able to track where development aid goes not just by country but by district and province. This is a great tool for increasing accountability. And we are also at a point where there are enough high-impact prevention tools that it makes sense to start talking about targeting and layering within specific geographies and populations. Big Data will help guide these decisions and measure the outcomes.
This year’s AVAC Report takes on one of the most urgent issues facing biomedical HIV prevention today: gaps in the type and quality of data collected on prevention for HIV-negative people. Globally, the number of new HIV infections is not declining. In the places where gains have been made, continued progress is not guaranteed. Fixing core problems with how prevention data are collected and reported is key to slowing the rate of new cases of HIV.

Data points in HIV prevention correspond to real people with specific needs that change over time. AVAC Report 2016 argues that today’s prevention data don’t reflect these real people in nearly enough detail. Much of the data on services offered to people who test HIV-negative is inadequate. Countries, funders and implementers report on “people reached” with referrals and condoms, yet data on who is being reached—particularly among key populations—are inadequate. And in the era of strategies such as VMMC (voluntary male medical circumcision) and PrEP (pre-exposure prophylaxis) that have direct impact on HIV risk, reports on referral rates are unacceptable. The new prevention data paradigm should provide detailed information on who is being reached and track linkages to evidence-based tools.

Changing the approach to HIV prevention data means assessing and adapting relevant “Big Data” approaches that analyze enormous data sets to identify new correlations. It also means adapting systems that have existed for decades to reflect new prevention tools and goals.

AVAC Report 2016: Top-line recommendations

**Measure what matters for combination prevention.**
- Understand, measure and report on the risk level of people testing HIV-negative.
- Create and measure linkages to evidence-based prevention for people at substantial risk.
- Use a “Prevention Data Dashboard” to track progress and adjust accordingly.

**Do better for adolescent girls and young women.**
- Map and rationalize investments in research and programming to ensure impact.
- Put adolescent girls and young women in control of core aspects of data collection.
- Build platforms for a range of services, not product-specific programs.

**Put research on the “fast-track” and countries at the center.**
- Build research timelines into global rhetoric and national strategies on ending the epidemic.
- Ensure that epidemiological data inform research priorities.
- Make national research plans for meeting the needs of specific population segments.
How to Fix the Four Major Problems with Data for HIV Prevention

1. The data are not sufficiently broken down.
   - Countries need to be resourced and supported to collect and report data on services financed/implemented by age, gender, income status, key population status and more. Donors can support this with resources and requirements for such data.
   - Civil society must work across agendas (e.g., women and girls, key populations) to develop specific, actionable demands of all stakeholders that lead to collection and presentation of actionable, high-quality, disaggregated data.

2. Data are missing for many of the people most in need of prevention.
   - GFATM and PEPFAR have pledged to improve the quantity, quality and consistency of data gathered on key populations. These promises need to be kept, with fast-paced information-sharing and action taken in countries that are not prioritizing resources based on the data.
   - Funding cuts to civil society groups need to be reversed and the potential for “Big Data”-based systems (e.g., using data delivered by cell phone or collected by lay people) should be explored as part of supporting these groups to document their communities.

3. The data aren’t there to measure prevention progress.
   - Global and national stakeholders must implement a coordinated overhaul of prevention indicators and analyses such that linkages, uptake and adherence are all captured, and prevention measures consisting solely of “people reached” are abandoned.
   - “Prevention Data Dashboards” at the country and funder levels must be realized to help ensure accountability and accuracy in tracking progress on incidence reductions.

4. Data driving basic science to new breakthroughs need sustained funding.
   - Maintain funding for basic science so that there are resources for innovation, including data-driven approaches that look across large data sets for clues to guide vaccine design.
   - Map and engage in the ethical and methodological issues impacting the demand for and design of future HIV prevention trials. Countries will need additional tools to bring the epidemic to an end—and they must be at the center of decision-making.

TOP PRIORITY
HIV Prevention Data Dashboards

In 2016, there is no justification for prevention data to be as patchy and mysterious as they are. HIV testing is not, in and of itself, a prevention service. However, HIV testing linked to impactful services is. Comprehensive prevention is not just condoms, referrals for STI treatment and possible counseling about voluntary medical male circumcision (VMMC) or PrEP. It includes male and female condoms, condom-compatible lubricant, STI treatment and documented linkages to the most appropriate and needed services, including VMMC, ART for partners living with HIV, PrEP, opportunities to build social capital, financial support, harm reduction and much more. The global rhetoric agrees, but the reporting system tells a different story. Linkages aren’t documented and program components aren’t well-defined. Some indicators, such as “people reached with prevention messages”, exist unchanged from what they were 20 years ago.

Let’s link rhetoric and reporting through the piloting and widespread adoption of HIV Prevention Data Dashboards that reorganize existing indicators into “cascade”-style readouts of the services obtained by people testing HIV-negative. Of eligible men testing negative, how many are getting circumcised? Of individuals at substantial risk, how many receive a PrEP prescription, refills and repeated HIV-negative tests?

A dashboard is a visual display of the critical information needed to achieve objectives; consolidated and arranged so that the information can be easily monitored. To see what a Prevention Data Dashboard could look like, turn the page.
Prevention Data Dashboards: A key tool for impact on the epidemic

There is increasing emphasis on measuring the testing “yield” of new HIV positive diagnoses and linkages to ART. But there is no comparable approach to the “prevention yield”—the number of eligible HIV-negative people linked to evidence-based strategies. “Prevention Dashboards” could change this. Many relevant data are already available; they just aren’t systematically collected and clearly presented. Some elements, like reliable indicators of risk status for subsets of some populations, need to be defined. Elements that are not as easily quantified, like legal, social and structural factors, need to be addressed in separate tracking systems as well. Still, piloting dashboards will illuminate gaps, uses and further needs. UNAIDS has changed the conversation about ART for PLHIV by publicizing broad targets, emphasizing new indicators, securing global and national buy-in and reporting out on progress. If UNAIDS could do for other forms of prevention what it has done for ART for PLHIV, it would be an enormous contribution. If not, other stakeholders will need to step in. The global community, governments and funders all need these dashboards or equivalent shifts in their conceptualization of HIV prevention programming and evaluation.

Note: Data in charts are for illustrative purposes only.

Who is getting tested?

Positive
At risk
Low risk

Where?

• VMMC centers
• Self-test
• Health fair/campaign
• Key population service center
• Clinical trial sites
• Antenatal clinic and other locations

Who needs prevention?

Treatment cascade

Linked
In care
Suppressed

For each intervention—e.g., VMMC, PrEP, condoms, combination prevention—need to track who is eligible, reached and participated

What prevention is offered and used?

Supplied/offered
Accepted intervention
Adherence
Effectiveness

* Not all interventions require adherence, e.g., VMMC

What’s the impact?

Readouts from prevention and treatment cascades could be combined to give a sense of progress toward prevention overall. These could be developed for any key population for which there is adequate data or for a nation or program. The Dashboard wouldn’t answer all the relevant questions, but it would offer a valuable snapshot and tool to track progress toward global and national targets for incidence reduction.
Across the globe, countries are aligning with UNAIDS’ “90-90-90” framework for testing, treating and achieving virologic suppression in people living with HIV. National plans reflect and refer to these targets and so do data reports. Information on rates of testing, antiretroviral treatment (ART) uptake, retention and increasingly, virologic suppression, provide a broad-strokes picture of progress and challenges.

Unfortunately, there's nothing like this available for non-ART prevention. Neither broad-strokes information nor granular details are available about progress toward providing impactful prevention for people who test HIV-negative—a number that is increasing significantly every year as programs

**Big Data That Deliver**

**Measure what matters for combination prevention**

Inadequate information on prevention is hampering progress and hurting the people who most need access to services. Doing better with data is a big part of the solution.

- Understand, measure and report on the risk level of people testing HIV-negative.
- Make and measure linkages to evidence-based prevention for people at substantial risk.
- Use a “Prevention Data Dashboard” to track progress and adjust accordingly.
scale up to reach testing goal. For example, annually updated PEPFAR guidelines require reporting on a number of service delivery items in each PEPFAR country. Two prevention indicators—KP_PREV (Key populations prevention) and PP_PREV (priority populations prevention)—measure the provision of a minimum package of services for their respective populations. These indicators are heavily reliant on referral reporting but do not have a means of tracking the success of such referrals. Additionally, disaggregated data on the categories of services being provided—such as provision of condoms and lubricant—are not provided through PEPFAR's data dashboards or data sets.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) is also missing the chance to collect and act on key data. In April 2016, GFATM delayed approval of the Key Performance Indicators (KPIs) that will guide the next GFATM Strategy from 2017 to 2022. The good news is that the proposed indicators will measure aspects of gender-specific programs and programs for key populations. However, even when approved, the indicators will be for internal use only by the Board and reporting on KPIs will not be shared with civil society beyond those on the Board. The GFATM approach to linking investment to impact on prevention is to take credit for reductions in incidence in countries in which they work. The reports do not identify the programs or interventions that might have contributed to specific activities trends. While the GFATM has acknowledged its limitations, including in transparency, it hasn’t clarified plans to change it. There is an evolving landscape, but it requires commitment and investment. A recent report found that only five percent of Fund resources went to data collection, data systems and analytic activities.⁶

After the HIV Test: Targets and progress in making and measuring linkages

What happens after a person receives her HIV test result? If it’s positive, there is a well-defined set of steps that are measured and reported at national and global levels. While data on the “treatment cascade” don’t tell the whole story of the choices and challenges involved in starting and staying on ART, they provide a strong framework for measuring progress. Yet if a person is HIV-negative, the next steps are poorly defined, monitored and tracked. Non-ART prevention cascades have different characteristics, but they must be defined and used to catalyze a prevention revolution.

**Test**

- **HIV-negative**
  - Fewer than 500,000 new HIV diagnoses
  - Missing targets, tracking and evidence for engaging HIV-negative individuals at risk
  - Globally, no decrease in new diagnoses (2.1 million per year)

**Linkage to prevention services**

- **Prevention Toolbox**: VMMC, PrEP, condoms, harm reduction
- **Test Retention in services**
  - 27 million VMMCs
  - Three million people on PrEP
  - 90% of key populations access combination HIV prevention
  - 12 million VMMCs projected by end of 2016; pace must increase
  - Limited PrEP access
  - Major gaps in harm reduction services

**Retention in services**

- **Ongoing counseling, support & outreach**

**Adherence support**

- **Support adherence, repeat HIV Testing**

**HIV-positive**

- 90% of people living with HIV know their status
- Testing is scaling up
- More women than men are being reached
- Innovation is needed

**HIV CARE (Pre-ART)**

- Pre-ART care was the designation for services provided until a person reached the CD4 cell count, clinical threshold or started ART. Under new WHO guidelines, this is no longer recommended.

**HIV positive ART**

- 90% of known people with HIV on ART
- 17 million people living with HIV on ART out of a global total of 37 million

**Undetectable**

- 90% of known people with HIV on ART have detectable viral load
- Access to viral load remains limited
- Data on virologic suppression are often lacking

Some of the most informative prevention data are those that report on a service with a known direct impact—e.g., VMMC, PrEP, eMTCT or harm reduction. Behavior change communication, male and female condoms and STI treatment are all important foundations of prevention programs, but a report that shows how many people received these things can’t be used to quantify likely reductions in incidence. Some people take condoms and use them consistently, others don’t. STI treatment has shown a prevention benefit in some studies but not in others. So condom provision and STI referral data can’t be used as proxies for prevention impact in the same way that VMMC can, or that PrEP could be if indicators included adherence, retention and repeat HIV testing.

Governments, implementers and funders should still track and report on spending on all types of prevention programs, but all of these data should not be treated as equal. Using data collected in the “Prevention Data Dashboard” approach that AVAC is proposing, a plausible guesstimate of prevention impact could be made by looking solely at strategies with predictable, direct impact on the risk of HIV transmission or acquisition.

The world isn’t moving quickly enough in this direction. PEPFAR, GFATM and national governments are all tracking VMMC and service uptake and outcomes for programs preventing perinatal transmission. But overall, both PEPFAR and GFATM are continuing to employ a “people reached” approach to prevention data, which reveals next to nothing about the impact that the services have had on the lives and HIV risk of the people in question.

The world simply can’t go on collecting and reporting data on prevention in this way. Now is precisely the moment to make some major course corrections. Heading into 2017, there is an increasing emphasis on the first “90” target—testing—and, within that, a focus on identifying people living with HIV. The percentage of people
who test positive is sometimes termed the “testing yield.” This term has merit insofar as it emphasizes the importance of reaching people who are already living with HIV and can benefit from antiretroviral therapy (ART). But what about those who are HIV-negative? How and why should national planners prioritize HIV prevention for people who are HIV-negative, if yield is defined solely in terms of HIV diagnoses?

The best way to answer this question is to define, fund and implement a concept of prevention yield for HIV-negative people. Putting this concept into action would mean tracking individuals as they move through the system, gathering data at multiple stages to see how well referrals work, what service uptake is and where there is drop-off. This is a standard way of conceptualizing ART, from positive test result through to virologic suppression. The same should be done for prevention interventions. For example, for men in the age bands targeted for VMMC (with reports on how many of these men were referred to VMMC and how many underwent the procedure); and for PrEP (with measures of how many people who tested HIV-negative and were eligible were referred for, started and stayed on PrEP).

Right now there are some but not all of the necessary tracking systems in place to measure prevention yield. VMMC programs gather age and HIV status information, but national testing figures aren’t presented in a way that allows easy analysis of the total portion of those tested who were eligible and went for the procedure. (They show how many men sought VMMC but not how many of the total number of men tested were in the priority age band for the procedure and, of these, how many underwent VMMC.) PEPFAR has recently added a PrEP indicator that will track individuals initiated on PrEP, but it hasn’t incorporated any indicators of individual level of risk, retention or impact, e.g., returning for refills, testing HIV-negative on repeat visits and so on. To be fair, these indicators aren’t yet well defined—but there’s no question that they will be needed.

There are other challenges, too. Prevention for HIV-negative people doesn’t mean providing the

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**Key Populations and Data Gaps**

In too many countries and communities around the world key populations, including gay men and other men who have sex with men (MSM), transgender women, sex workers and people who inject drugs are subject to what Johns Hopkins researcher and advocate Stefan Baral terms “the data paradox,” meaning that “there is the least amount of data characterizing the needs of gay men and other MSM in the most stigmatizing settings.” Gathering information on the size, needs, priorities and structure of LGBTQ communities is complex insofar as researchers and governments may not be trusted. But there is a wealth of examples of evidence-generating partnerships that do have buy-in and leadership from the communities in question. This includes innovative work involving KEMRI and local MSM groups in Kilifi, Kenya, research developed by and for MSM in Malawi in partnership with CEDEP, work with LGBTQ people in Nigeria by The Initiative for Equal Rights (TIER), and many other projects. This research, which generates information on population size, risk and needs can and must be prioritized. National governments and funder/implementer partners also have to do far better. PEPFAR and GFATM should work to ensure that there are treatment and prevention “cascade” data broken down by key populations in quarterly and annual reports. Where data do not exist, new and innovative approaches to gathering it via partnerships with civil society should be implemented. All of this must happen in the context of a larger fight to remove legal frameworks for discrimination and violence against key populations. But the existence of such laws cannot be used as an excuse for inaction or inadequate data.
same kinds of services to all of the people who test HIV-negative. Prevention has to be targeted, and the denominator—the size of the group that the efforts are trying to impact—varies and is often poorly defined. Some of the people who test HIV-negative may not be at substantial risk, so an investment in linking them to high-impact prevention like PrEP may not be warranted. People can move through “seasons of risk” in their lives—different times of year or different ages. Thus, there’s fluctuation within this group of HIV-negative people that just doesn’t exist in the treatment cascade for people living with HIV.

These challenges can be better understood and possibly overcome by looking at different kinds of data on prevention than are routinely collected and presented today. To standardize and systematize analysis of prevention impact, data need to do the following:

- **Classify testing** as home-based, stand-alone (at a site solely providing testing) or at site providing PrEP, VMMC, antenatal care, ART or other services. The numbers of tests administered in the stand-alone category should go down every year, while the numbers in categories linked to innovation and connection to services should go up. It will be particularly important to understand the role of self-testing strategies in reaching men, who test less frequently than women, and in PrEP users, who will require periodic HIV tests while using PrEP.

- **Report linkages to evidence-based interventions.** Did the person who was HIV-negative go on PrEP? Did he or she come back for follow-up HIV testing and refills on schedule? Did he undergo VMMC? Did he or she leave with condoms and lube, and what sort of supply was provided?

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**Talking About Revolutions: Definitions of data-driven change**

**Defining the data revolution**

- An explosion in the volume of data, the speed at which data are produced, and the range of subjects on which there is data, coming from new technologies such as mobile phones and the internet.
- A growing demand for data from all parts of society.

**Defining the data revolution for sustainable development**

- The integration of these new data with traditional data to produce high-quality information that is more detailed, timely and relevant for many purposes and users, especially to foster and monitor sustainable development.
- The increase in the usefulness of data through a much greater degree of openness and transparency, avoiding invasion of privacy and abuse of human rights from misuse.
- Ultimately, more empowered people, better policies, better decisions and greater participation and accountability leading to better outcomes for people and the planet.

**Defining the data revolution for HIV**

- Breakthroughs in basic science via systems biology approaches that analyze vast quantities of information to generate hypotheses and explanations in new ways.
- Use of fine-grained geographic information down to the site and individual level to make decisions about where to spend money (or not) and what to do (or not).
- A potentially empty promise that can’t and won’t be fulfilled until yawning gaps in information about marginalized and stigmatized groups are filled in ways that respect and protect individual rights and privacy.
Were connections made to social and economic support services? VMMC is particularly important because, as discussed on page 16, it consistently ranks as the highest impact, most cost-effective strategy to add in key African locations with low male circumcision coverage. And sadly, in most countries, coverage is still far from the target of 80 percent among men ages 15 to 29. What’s more, annual procedures performed in some high-priority countries declined between 2014 and 2015.

• **Provide a framework for quantifying the prevention benefit from virologic suppression** as part of the overall prevention effort. ART is counted as treatment, but 90-90-90 is the backbone of the prevention strategy for reducing new cases of HIV to less than 500,000 by 2020. Other interventions play a role—UNAIDS has a whole raft of non-ART prevention targets (see page 18)—but many countries are explicitly naming the ART-related goals without making reference to other prevention targets. AVAC would like to see this focus expand. We would also argue that, since the prevention benefit depends wholly on virologic suppression, that countries that do not have substantive viral load programs cannot claim, as some do, to be on the road to epidemic control based on the numbers of people on ART. Universal access to ART is essential; it should be the goal if not the reality. But reality should also be measured. Readouts of levels of virologic suppression give a sense of where and how ART programs and programs focused on HIV-negative individuals need to be improved.

• **Link data to facility-level ownership and action.** The most impactful data are the ones that trigger action, and many of the most impactful actions happen at the level of a facility or a sub-national unit (district or province). People at these levels are often responsible for collecting raw data, but they don’t routinely receive analyses in real time and don’t always have the power to act on the findings. This can change as part of intentional investment in strengthening human resources along with infrastructure for data collection. By many accounts, when field-level staff have access to and the ability to act on data from their programs, the level of data collection also improves. It is an ideal virtuous cycle.

Finally, the success of the Prevention Data Dashboard depends on global and national frameworks for epidemic control that afford appropriate priority to non-ART strategies: VMMC programs should be a top priority in all countries, and PrEP introduction should not be far behind. The scale and scope of VMMC and PrEP differ quite a bit right now and that’s okay. What is critical is to redefine “yield” as the number of all people linked to the services that can readily and reliably keep them healthy for a long, long time.
The data from trials of voluntary medical male circumcision (VMMC) for HIV prevention remain the biggest prevention news of the 21st century so far. AVAC isn’t inclined to pit prevention strategies against one another—and we’re also not a fan of hyperbole—but VMMC, which is the single most effective one-off intervention an HIV-negative man can use to reduce his own HIV risk, makes us want to say attention-grabbing things. That’s because VMMC continues to fight for its fair share of attention, funding and prioritization in the global response.

The past 12 months have been a notable time for VMMC. UNAIDS included the strategy in its non-ART prevention targets. The new VMMC target is 27 million additional circumcisions by 2021. PEPFAR also released a new target of 11 million cumulative circumcisions by the end of 2016 and 13 million by the end of 2017.

So, are things going well? Not exactly. Annual numbers hover the vicinity of 2.5 to 3 million. There has not been a surge in the rate of scale-up since 2014. In fact, the pace has slowed down. WHO reports that there were roughly 20 percent fewer procedures in 2015 compared with the year before.* Yet the new UNAIDS target requires roughly five million procedures per year between now and 2020. This simply isn’t possible based on pace to date.

Additional resources need to be sought and committed by national governments and the GFATM. VMMC needs to be tracked as part of Prevention Data Dashboard (see page 8). The following steps are also key:

- **Data on and messaging about VMMC needs to get much, much clearer.** PEPFAR, national governments and WHO/UNAIDS all track annual numbers of VMMCs performed. PEPFAR tracks its own procedures and reports on national totals; WHO/UNAIDS report on national totals that include PEPFAR. But the numbers come out at different times and sometimes reflect different trends. There isn’t a clear sense of where there are problems and where there is progress—and AVAC takes responsibility for working even harder to sort out the figures and identify gaps and areas for action. AVAC also insists that messages to country stakeholders about how to position VMMC remain clear and consistent—in terms of the minimum service delivery package and the rationale for pursuing high-coverage goals. While VMMC can be the foundation for a platform of services, particularly for young men, it is highly impactful as a one-off procedure and the successes to date have hinged on campaigns that saturate specific geographies and then move on. In 2016, we’ll be watching closely to ensure that countries get clear messages about the models to invest in to reach the new ambitious targets.

* **No one should be being turned away from VMMC programs.** HIV treatment programming reflects the need to reach people when they ask for services, not ask them to come back when they (the clinic or program) are ready.

- **Generate funding estimates and gap analyses.** It is much harder than it should be to understand the global price tag and funding shortfall for VMMC. WHO/UNAIDS has in the past released its strategic framework without messaging regarding funding—and as AVAC Report went to press was preparing to do so again. PEPFAR doesn’t work with countries to quantify funding gaps left by its prioritization of specific geographies and ART coverage goals.

- **PEPFAR can’t pay for all of the VMMC procedures that need to happen in a country.** There has to be a clear, coordinated approach to identifying the gaps left by any single program-funding source as matched against ambitious national goals.

- **Country-level budgets for VMMC should not be disproportionately reliant on PEPFAR central funding.** If you’re running a household, a business or a large-scale HIV program, you need to know your budget in order to plan. The budget for PEPFAR programs is determined during the process of finalizing the annual Country Operational Plan (COP). Programs with targets matched to funds in the COP know what they’re expected to do and what resources they will have on an ongoing basis. A windfall can make a difference, and can help achieve some great things, but it doesn’t support good planning. PEPFAR central funds—which come out of a fund administered in Washington, DC—are, in some ways, a windfall-type resource. Central funds aren’t allocated on the COP funding cycle, they aren’t predictable, and they aren’t guaranteed. Right now this is happening with VMMC and central funds. Since the increase in funding in 2016 is coming solely from central funds, it is essential that PEPFAR find ways to streamline funding disbursal such that identification of new partners, launch of new campaigns and other programmatic activities aren’t adversely impacted.

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Not on Track: The slow pace of VMMC scale-up

UNAIDS 2021 fast-track target: 27 million between 2016-21 (41 million total by 2021)

VMMC 2012-16 framework target: 20.8 million

Current trajectory
Trajectory towards 2021 target
Cumulative progress
Targets

The Global VMMC Gap

41 M total by 2021
27 M procedures in 5 years to stay on track
+21 M additional procedures by 2021
+6 M additional procedures based on 2011-2016 target from WHO/UNAIDS Joint Strategic Action Framework
14 M Total procedures projected by 2016

www.malecircumcision.org.
**UNAIDS 2016–2021 Strategy: What does it say about prevention?**

This graphic shows core components of the current UNAIDS strategy. It seeks to achieve three strategic milestones by 2020: an end to HIV-related discrimination, fewer than 500,000 new cases of HIV and fewer than 500,000 deaths from AIDS. It has ten targets (below) and eight strategic areas. We’ve included the description of the strategic area specific to combination prevention.

### Targets

1. Ninety percent of people (children, adolescents and adults) living with HIV know their status, 90% of people living with HIV who know their status are receiving treatment and 90% of people on treatment have suppressed viral loads.

2. Zero new HIV infections among children, and mothers are alive and well.

3. Ninety percent of young people are empowered with the skills, knowledge and capability to protect themselves from HIV.

4. Ninety percent of women and girls live free from gender inequality and gender-based violence to mitigate the risk and impact of HIV.

5. Ninety percent of people living with, at risk of and affected by HIV, who are in need, benefit from HIV-sensitive social protection.

6. Overall financial investments for the AIDS response in low- and middle-income countries reach at least US$30 billion, with continued increase from the current levels of domestic public sources.

7. Ninety percent of women and men, especially young people and those in high prevalence settings, have access to HIV combination prevention and sexual and reproductive health services.

8. Twenty-seven million additional men in high-prevalence settings are voluntarily medically circumcised, as part of integrated sexual and reproductive health services for men.

9. Ninety percent of key populations, including sex workers, men who have sex with men, people who inject drugs, transgender people and prisoners, as well as migrants, have access to HIV combination prevention services.

10. Seventy-five percent of people living with, at risk of and affected by HIV, who are in need, benefit from HIV-sensitive social protection.

### UNAIDS “Result Area” on Combination Prevention and Key Populations

**Tailored HIV combination prevention services are accessible to key populations, including sex workers, men who have sex with men, people who inject drugs, transgender people and prisoners, as well as migrants.**

- Combination prevention services are adequately resourced and available, tailored to populations, locations and interventions with maximum impact.

- Outreach and new media inform and create demand for the use of traditional and new prevention technologies, including condoms and pre-exposure prophylaxis.

- Three million people go on pre-exposure prophylaxis annually, focused particularly on key populations and people at high risk in high-prevalence settings.

- People who inject drugs can access clean needles and syringes, as well as opioid substitution therapy and other evidence-informed drug dependence treatment.

- Migrants, refugees and crisis-affected populations have access to HIV-related services.

- People living with HIV and other key populations are meaningfully engaged in decision-making and implementation of HIV prevention programs.
Big Data That Demonstrate
Do better for adolescent girls and young women

There are more data on HIV prevention for adolescent girls and young women than ever before. This information won’t clarify action plans or achieve impact without changes—today.

- Map and rationalize investments in research and programming to ensure impact.
- Put adolescent girls and young women in control of core aspects of data collection.
- Build platforms for a range of services, not product-specific programs.

Epidemic levels of HIV can’t be stopped without addressing the needs of adolescent girls and young women, particularly in sub-Saharan Africa. This is true both because of the high incidence rates—four–nine percent in recent trials—in this population, and because this population is growing. In what population scientists call a “youth bulge”, there are roughly 30 percent more young people (ages 10 to 29) in sub-Saharan African today than there were when the epidemic first emerged. Prevention for young people, particularly young women and girls, is of paramount importance.

This isn’t news. PEPFAR, the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and national governments are all adjusting their plans and
Big Data, Fine Resolution: A pilot project on mapping women’s welfare

In low and lower-middle income areas in a given country, there are greater differences in women’s welfare than there are between countries. So knowing national statistics for, say, maternal morbidity or childhood stunting (a symptom of malnourishment) doesn’t tell us where to focus programs.

Satellite imagery that provides high-resolution pictures of our planet and its inhabitants is one component of Big Data. A collaborative project between Data2X (data2x.org, a new initiative focused on filling data gaps affecting women and girls) and Flowminder is pairing high resolution maps with gender disaggregated data on literacy, income and maternal health. The output is a detailed map that shows the spatial distribution of the population and these indicators of welfare and well-being. The pilot will be expanded based on information regarding feasibility and cost. See page 24 for more on data gaps in women and girls.

High-resolution geospatial mapping has a wide array of uses, including improved resource allocation and donor coordination. This is one way to begin to rationalize activities.


making new investments in hopes of providing the types of services that can help keep adolescent girls and young women safe, healthy, strong and in control of their bodies—choosing when and how they have safe and pleasurable sex, when they get pregnant and when they use the contraceptive method of their choice.

In fact, there is so much happening in relation to adolescent girls and young women that it can feel a bit chaotic. In the realm of biomedical HIV prevention, there are an ever-increasing number of focus-group discussions being conducted to understand how to use PrEP in this population. In parallel, there are myriad projects—whether via PEPFAR’s DREAMS Initiative, South Africa’s new national youth-focused campaign or GFATM-supported programs—focused on reaching and serving girls and young women with social and structural interventions. And that’s just in the HIV sphere. Looking at tobacco control, sexual and reproductive health and poverty-reduction programs, there are entire worlds of research and results related to these uniquely resilient and vulnerable young people.

In spite of all this activity, what is striking today is how many questions remain about the lives, needs, preferences and opportunities for reaching different segments of this broad population. That’s the paradox of research. It can generate lots of data without necessarily clarifying anything. In the coming year, one of the top priorities for the HIV prevention field is to take steps to ensure that the data that are being generated on adolescent girls and young women are put to good use and that the remaining gaps are rapidly filled.

There are a number of steps that need to be taken by funders, implementers and national governments to make this a reality.

- **Be specific and strategic in defining population segments to reach.** The phrase *adolescent girls* and *young women* is so broad as to be nearly meaningless. For starters, the age range captured by this phrase differs by countries and regions and is defined in different ways (age of legal majority, puberty, etc). Then there is the matter of difference within age groups. Every girl in the world should have access to comprehensive sex and sexuality education, as well as a full range of choices for preventing pregnancy, HIV and STIs. But targeted HIV prevention need not be delivered to every girl...
or young woman. There are specific demographic characteristics that can impact HIV risk, including but not limited to age, education, marital status, income and legality (e.g., migrants and refugees, sex workers etc.) that impact HIV risk.

Right now, countries funded through the PEPFAR DREAMS initiative, which is focused on reducing incidence in adolescent girls and young women, are deploying a range of approaches to segment and stratify the risk (or the risk profile) of these young people. These approaches need to be catalogued and evaluated based on the degree to which they reach the most at-risk girls and young women with a range of needed, impactful services. This should happen across programs via a collaboration between UNAIDS, governments, PEPFAR, GFATM and the Bill & Melinda Gates Foundation and should be used to develop a library of resources on reaching and providing combination HIV prevention for different segments of the population, or “end users”.

- **Map who is investing in what and where.** Ensure that the right questions are being asked in the right places. Resources should be reallocated where there is duplication or inefficiency.

- **Put adolescent girls and young women in control of core aspects of the data-collection enterprise.** One of the tenets of the “data

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**A Cycle of Transmission in South Africa**

*Researchers at the Africa Centre in South Africa used genetic analysis of HIV to understand the cycle of transmission of HIV in one part of the country. Men and women in each of these age groups have distinct health and prevention needs.*

**Very young women acquire HIV from men who are, on average, 8 years older**

**Women at high risk of HIV**
Mean age: 18 years (range: 16-23 years)

**Women with high HIV prevalence**
Mean age: 26 years (range: 24-29 years)

**Men and women > 24 years usually acquire HIV from similarly aged partners**

**Male populations with high HIV incidence**
Mean age: 27 years (range: 23-35 years)

**When teen women reach their mid-20s, they continue the cycle**

designed and led studies over participatory methodologies—and complex requirements for securing funding that exclude many grassroots groups and front line individuals.

- **Ensure country-owned data are disaggregated by age and gender.** It’s not possible to evaluate programs targeting men or women, boys or
girls without age and gender disaggregated data. Pilot programs and demonstration projects almost always collect and report this information, but there are major gaps in what is reported by national governments. Investments in national statistics centers, data management systems, and health facility-based approaches to collecting and using the information are all key. These are health-systems strengthening activities that don’t necessarily get attention in population-focused programming. AVAC proposes that UNAIDS put forward a common baseline framework for disaggregation and secure endorsement from funders and governments alike. This would benefit gender-based programming and programming for key populations (see page 14).

- **Adopt gender-specific indicators tailored to the lifecycles of girls and women, bridging health, development and more.** As described on page 24, there are major gaps in the quality, quantity and reliability of data regarding the well-being of girls and young women. In addition to ensuring disaggregation of the data that are collected, it’s necessary to prioritize investment in a core set of indicators that can help track the overall well-being of girls and young women throughout their lives.

In the coming year, AVAC will work with existing and new partners to ensure that many steps related to mapping research and funding, identifying gaps and sharing outcomes, are taken. We will work as we have always done, via advocacy, coalitions and publications that share information and strategic analysis. We will also be taking on the responsibility of making some of these things happen, through a new body of work focused on bringing coordination and strategy to the implementation of new biomedical tools. For more, see page 39 and visit avac.org.

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**Let’s Leave This Behind**  
**Gender binaries and competition for resources**

In the past year, as focus has rightly been placed on the needs of adolescent girls and young women, some stakeholders have suggested that men are being left behind. This offers a perfect example of data that prompt counterproductive action. Men aren’t being left behind. Both men and women, and boys and girls, are underserved in different ways. There are class, race and gender-expression components to this, as well as the specific sets of issues facing transwomen and transmen, who for too long have been lumped together with gay men and other men who have sex with men. Different bodies have different issues. This doesn’t mean that there can’t be programs that specifically, intelligently and proactively focus on cis- or transgender men and, by the same token, on women in all their diversity. But when the rhetoric pivots on the notion that one group has been left behind—the unspoken corollary being that the other group has gotten ahead—no one flourishes. So let’s check the binaries at the door.
The quality, quantity and detail of data on the world’s women and girls is severely lacking. Without improvements in the type of information about broad and HIV-specific indicators, it is not possible to design good programs, track progress and make comparisons between and within countries. Once available, data on education, employment and overall health outcomes can be mined for associations with HIV risk. In this way, HIV prevention can be better tailored to find and meet the needs of the women and girls who need it the most.

**Broad Data Needs for Women and Girls**

**How many are there?**
- Birth registries

**How are they educated?**
- Rates of school completion
- Learning outcomes
- Transition rates to higher education or employment

**How do they meet basic needs/spend their time?**
- Unpaid work
- Informal employment
- Earnings
- Asset ownership

**What is their overall health and well-being?**
- Mental health
- Disease burden
- Adolescent health
- Utilization of health services
- Experience of violence and more

These and other indicators are not routinely collected and disaggregated for women and girls. Looking globally, when these data are collected, there are issues with the quality, level of detail and comparability between countries. So it’s difficult to interpret, make international comparisons and get a complete global picture. Having these type of data provides a foundation for research to identify indicators that are proxies for HIV risk and other forms of vulnerability. These, in turn, can be used to guide HIV programming and answer specific questions such as those shown here.


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**Data gaps related to HIV prevention for HIV-negative women and girls**

- Who needs prevention?
  - What are the known characteristics of the most at-risk adolescent girls and young women based on information from PrEP demo projects, trials, DREAMS, etc.?

- What do they need?
  - What are the facilitators and barriers to accessing various types of prevention services?

- How should programs find them?
  - What are the best practices for identifying at-risk individuals?

- How do they use it?
  - For those accessing PrEP, what are the barriers to adherence?
  - For those accessing strategies to build social capital (girl-only spaces, training, etc.) what are barriers and facilitators to completing programs and using skills to improve their well-being after completion?

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**Data gaps related to women and girls’ experiences with ART**

- After initiation, what influences retention in care or decisions to stop taking ART, and what facilitates or inhibits adherence (at the individual, facility and societal level)?

- What does the treatment “cascade” of initiation, retention, adherence and virologic suppression look like in women from marginalized populations or partners of men who are at increased risk (such as female sex workers, transgender women, women who inject drugs or whose partners inject drugs and wives/female partners of men who have sex with men), who face high levels of stigma and discrimination that impede their access to treatment?
**FIGURE 11**

Demographic Shift in Southern Africa: 10- to 29-year-olds

- **30%** more girls and young women since the beginning of the epidemic

Due to a “youth bulge” that is particularly pronounced in sub-Saharan Africa, there are far more young men and women today than there were at the beginning of the epidemic. Today, high rates of HIV in young women remain unchecked, and there are more young women than ever. If prevention isn’t effectively targeted to this population, early gains in the fight against the epidemic will be reversed.


**FIGURE 12**

Picking up the Pace: A global look at PrEP introduction

The numbers in the large circles represent global totals, many of which took years to achieve, while the smaller circles represent changes in just a nine-month span (Oct. ’15 – Jun. ’16). In sub-Saharan Africa, many of the implementation studies are in female sex workers—leaving gaps in research on men who have sex with men, adolescent girls and young women, and other groups in need.

- **52** Implementation studies planned, ongoing, completed globally
- **16** Implementation studies in Africa
- **9** Regulatory approvals
- **13** National strategies
- **2+** Global recommendations
- **2** In development

For the latest version please visit [www.avac.org/infographic/prep-pace](http://www.avac.org/infographic/prep-pace).
The PrEP landscape has shifted dramatically since mid-2015, with recognition by the World Health Organization that PrEP should be available for all individuals at substantial risk of HIV, inclusion in the UNAIDS Fast Track Targets (see page 18) and adoption by a growing list of countries (see prepwatch.org for the most current information). At the same time that daily oral PrEP has begun to roll out, the dapivirine vaginal ring is moving into open-label access trials after initial positive efficacy findings from two trials (see page 28 for results). But is all of this change having an impact on adolescent girls and young women (AGYW)—some of the people who need it most? Here, it’s still very early days, but the landscape looks like this:

• **Selective scale-up of PrEP, largely focusing on female sex workers.** The World Health Organization recommends oral TDF-based PrEP for all individuals at substantial risk of HIV and further defines that risk as a situation where incidence is three percent or higher per year. A substantial proportion of AGYW fall into this category, but right now, the main focus of PrEP rollout in sub-Saharan Africa is sex workers. South Africa launched its national PrEP program in sex workers in mid-2016. Female sex workers are also the focus of the programs being introduced by five of the ten PEPFAR DREAMS countries. (The other five PEPFAR DREAMS countries included daily oral PrEP in their original plans though some may add PrEP via additional “innovation” grants.)

Female sex workers must have access to comprehensive prevention including PrEP. However, a singular focus on PrEP for female sex workers—without a multi-year plan for expanding and evaluating PrEP effectiveness for adolescents and young women in all their diversity—could trip up PrEP uptake for women and girls who need it. After all, interventions like the hepatitis B vaccine, which was first introduced as a tool for gay men and other MSM in some places, was subsequently not well accepted in the general population. There is limited information today about how to deliver PrEP to AGYW, for whom even basic youth-friendly health services are virtually non-existent. So in some places it makes sense to start with sex workers, for whom there are dedicated clinics. But a plan for diversifying PrEP offerings is still needed.

• **Dapivirine ring access is in the works via open-label studies.** In early 2016, two trials of the dapivirine ring showed modest efficacy, particularly in women 24 and older. The next step is open-label extension (OLE) trials to better understand how the ring works for women now that efficacy is understood. In an ideal world, the ring would be an additional option, alongside oral PrEP. The two products are on different timelines, but there are chances in some countries to understand both of them together. Right now, these are mainly missed opportunities, as the map on page 22 shows. In an era of limited resources, countries literally cannot afford to sidestep the opportunity to learn which products women prefer and why. The ring, which is still an investigational product, cannot be added to PrEP sites and OLE sponsors have said referrals for oral PrEP will be made in countries where it is available. But this leaves gaps in access and is an inefficient way to gather information. Oral PrEP should be available on-demand in all of the OLE locations.

IPM, the ring’s developer, is aiming to submit a dossier for licensure in early 2017. OLE trial results will be used to inform introduction if the ring is approved—and the world must plan for this. But it’s also important to scale up broader platforms that can deliver multiple different strategies, including daily oral PrEP.

**Key Points**

**To-do list for governments, funders and implementers:**

• Make sure PrEP gets offered to all who need it, including, but not only, female sex workers.

• Move fast, with ways to assess impact and inefficency of programs that provide multiple services (e.g., cash transfers, social assets plus biomedical tools).

• End tokenistic, late and under-supported engagement of the vibrant adolescent girls and young women who are the targets but not the leaders of many programs today.
Big Data, Real People

Here are some specific elements for stakeholders to track:

- **Ensure that the emphasis is on developing platforms, rather than product- or intervention-specific programs.**
  No one wants a world in which there is PrEP in one district, the dapivirine ring in another, and a flourishing set of girl-only spaces in yet another. And today's programs are, for the most part, striving to provide comprehensive care and services. But there can be big gaps between a health facility and what a girl-only space needs in terms of staff, the messages delivered and the physical space requirements. Now is the time to ensure that data on “layering” (providing a number of services to the same young person) are collected and analyzed as swiftly as possible. Some of those data could come from the impact studies tied into DREAMS. There also needs to be a government-driven coordination of efforts so that no single product enters trials or the public health realm in a vacuum.

- **Revamp the approach to collecting and analyzing social and behavioral data in randomized controlled trials (RCTs) and open-label extensions.**
  In this way, insights that might inform program design can be gathered and disseminated as quickly as possible. Why, in 2016, are we still scratching our heads about young women’s vaginal practices, sexual behavior, etc.? It’s not only because there are unanswered questions; it’s also because there are unmined data and sources of expertise, including young women themselves who remain remarkably absent from the planning, implementation and advisory mechanisms set up to bring services to them. This starts during research, including RCTs, in which social and behavioral data are collected but not analyzed or acted upon in anything close to real time. This allows confusion to set in regarding issues such as, for example, the terms used to query anal sex, or the barriers to use that might be related to living situations (e.g., living with parents or not, sharing a room etc.). This information emerges after the efficacy data are already in—at a point at which they might inform implementation, yes, but after they might help redirect trial conduct. This isn’t just about RCTs for women-controlled prevention. In the realm of implementation science, there is a real issue with trials of test-and-start treatment strategies and combination prevention that do not report some of the service-delivery findings that might be implemented immediately, even while the trial’s primary question is pursued—without jeopardizing the rigor of the study.

- **Develop plans to introduce diverse daily oral PrEP programs.**
  For the past five years, AVAC has used a “3-D” model to conceptualize the biomedical HIV prevention arena (see page 6). It’s a framework that recognizes the importance of delivering what is available today, while demonstrating the effectiveness of emerging strategies and continuing to develop new, innovative tools. In the past, we’ve categorized different interventions under different “D”s, but when it comes to women in all their diversity, the reality is that oral PrEP fits into both the “deliver” (get it out there) and “demonstrate” (prove it works, then scale up) categories. Programs that deliver PrEP are already being launched, but these won’t provide information on how PrEP fits into the lives of the most vulnerable AGYW. That answer will come from programs that demonstrate whether and how the intervention can be used as part of a comprehensive package of services that includes opportunities to build social and financial capital, support for staying in school, norms-changing work aimed at families and communities and absolute insistence on a legal framework that safeguards the rights of the girl-child and woman.

Finally, and perhaps most importantly, it is essential to:

- **Provide adequate, reliable accessible resources for civil society groups truly working at the grassroots.**
  The best-intentioned donor-developed programs for resourcing civil society are structured in a way that may put resources out of reach for many small organizations. They simply don’t meet the funding requirements or can’t assemble the type of documentation needed to qualify as applicants. In this era of dwindling civil society funding, women are doing what they have always done: operating out of their living rooms, using per diems to pay their health bills and the bills of the people they love and scrounging for airtime to get on the next conference call. These are exactly the lives that PrEP needs to fit into, and they are a long way away from organizations headquartered in the US, UK or elsewhere in the developed world. Agenda-setting is underway; let’s also set criteria for who should be engaged, what that engagement looks like and what percentage of leadership and resources should be assigned to truly local, women-powered organizations. This is a cross-cutting recommendation for many disciplines, but we’ll leave it here because it is so important in the context of ongoing work to create programs to find the right girls.
# Dapivirine Vaginal Ring Results

<table>
<thead>
<tr>
<th>Study</th>
<th>The Ring study (IPM 027), International Partnership for Microbicides</th>
<th>ASPIRE (MTN-020), Microbicide Trials Network</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study design and enrollment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td>Long-term safety and effectiveness</td>
<td>Safety and effectiveness</td>
</tr>
<tr>
<td><strong>Study design</strong></td>
<td>Double-blind randomized placebo controlled with 2:1 randomization (active: placebo)</td>
<td>Double-blind randomized placebo controlled with 1:1 randomization (active: placebo)</td>
</tr>
<tr>
<td><strong>Enrollment</strong></td>
<td>Total: 1959 women, ages 18-45; active arm: ~1300</td>
<td>Total: 2629 women, ages 18-45; active arm: ~1325</td>
</tr>
<tr>
<td><strong>Regulatory requirement</strong></td>
<td>3000 women on dapivirine ring for at least one year follow-up; 1500 women on dapivirine ring for two year follow-up</td>
<td></td>
</tr>
<tr>
<td><strong>Participant follow-up</strong></td>
<td>Two years + six weeks following ring discontinuation</td>
<td>Minimum one year + four weeks following ring discontinuation</td>
</tr>
<tr>
<td><strong>Research sites</strong></td>
<td>Seven IPM research center partners in South Africa and Uganda</td>
<td>Fifteen MTN research centers in Malawi, South Africa, Uganda, Zimbabwe</td>
</tr>
</tbody>
</table>

## Results

| |  |
| **Overall results** | 31% effective, confidence interval 1-51 |
| **Secondary analysis that excluded data from two sites with lower retention and adherence** | 37% effective, confidence interval 12-56 |

### Results by age stratification (post hoc analysis)

| |  |
| **Women over 21 years of age** | 37% effective, confidence interval 3.5-59 |
| **Women 18-21 years of age** | No statistically significant effect |

### HIV incidence

| |  |
| **Overall** | 4.1% among women in active arm  
6.1% among women in placebo arm |
| | 3.3% among women in active arm  
4.5% among women in placebo arm |

Results announced at CROI 2016

2015 | 2016 | 2017 | 2018 | 2019
---|---|---|---|---
The Ring study (IPM 027) Results released Q1, 2016 | DREAM (IPM OLE) Expected to start Q3 2016 |
ASPIRE (MTN-020) Results released Q1, 2016 | HOPE (MTN-025) Expected to start Q3 2016 |

### Safety and PK studies (data to be used in regulatory submission)

- Efficacy trials
- Move to open label
- Open-label extension studies
- Additional Ring research
- Regulatory
- Related

### Additional data

2017 anticipated submission of a product dossier to European, US and South African regulatory agencies  
Approvals, WHO guidance?  
African country-level submissions and approval processes  
Earliest introduction

Daily oral PrEP introduction, including to young women in countries where ring is being investigated
Put research on the “fast-track” and countries at the center

Pursuit of research breakthroughs is happening in parallel to the ending-AIDS effort—it’s time to integrate and anticipate the synergies.

- Build research timelines into global rhetoric and national strategies on ending the epidemic.
- Ensure that epidemiological data inform research priorities.
- Make national research plans for meeting the needs of specific population segments.

The UNAIDS Fast Track Goals for ending the HIV epidemic set a 2020 milestone of no more than 500,000 new cases of HIV. In the Global Status Update, which came out in June 2016, the news was sobering. The world hasn’t even crossed the starting line when it comes to reducing new cases of HIV. That figure is holding steady at roughly 2.1 million per year. In this context, it is impossible to ignore the need for better prevention today and continued research for innovation in the future.
As sobering as the global incidence estimate is, there is reason for optimism. PrEP is rolling out, as is viral-load monitoring to evaluate whether ART is being optimized for individual benefit and prevention. And VMMC numbers have crossed the 10 million mark, though there is still much work to be done.

So we do expect to see prevention progress in the coming years, especially in countries where the epidemic is driven by sexual transmission. (This Report acknowledges and does not seek to do justice to the urgent agenda for protecting the rights and health of people who inject drugs.)

Now is the time to fit biomedical HIV prevention research into comprehensive prevention plans tied to national targets for incidence reduction. UNAIDS much-needed, long overdue Prevention Gap Report 2016 doesn’t address the need for additional research. Advocates have an essential role to play in ensuring that research and development are put on the “Fast-Track” agenda that UNAIDS and much of the world is using.

But here are some specific areas to track and take action on, depending on context.

- **Investment of time and resources in stakeholder engagement.** No country can plan an efficacy trial today and expect smooth conduct and clear results without intensive stakeholder engagement. This must go beyond consultations or CAB meetings, and include ongoing, honest conversations both trial communities and advocates about trial objectives, progress and challenges. In countries like South Africa, which is hosting a range of efficacy trials (see Table 2, page 32), it is essential that governments, research funders and other stakeholders invest in and require use of the Good Participatory Practice (GPP) framework.

- **Step up domestic financing of HIV research as part of a comprehensive response.** Calls for
bring the gaps in prevention coverage into focus. These gaps should be used to drive national research agendas. Perhaps it is a question of a population with an unmet need, or a successful service delivery model that is adaptable to some products. Whatever the variables, countries need to be supported in looking at prevention progress and challenges alongside the research pipeline, in making strategic investments and in prioritizing trials for the national context. This only works in a context where all groups are seen and valued—including key populations.

- **Make national research plans for meeting the prevention needs of populations where incidence has gone down and where it remains high.** Why is research needed in both groups? Because the impressive gains that can be made using today’s tools may prove reversible for (at least) two reasons: first, the nature of the interventions and second, the changing demographics in the hardest-hit countries. With the exception of voluntary medical male circumcision, today’s tools require user commitments for months or years (e.g., condoms, daily oral PrEP and the vaginal ring)

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**Unnecessary Confusion on Hormonal Contraception and HIV: WHO must act now**

The question of whether specific contraceptive methods, particularly the injectable progestogen-only method known as DMPA or Depo-Provera, affect women’s risk of HIV is complex and, for the moment, unanswered. Fortunately, the three-arm ECHO trial that is evaluating DMPA, the Jadelle implant and the copper IUD has begun, with recruitment underway in the majority of its sites. Unfortunately, the WHO has added to the complexity with a layer of completely preventable confusion. This dates back to October 2015, when WHO surprised many stakeholders with a “clarification” of its existing technical guidance on hormonal contraception and HIV. The clarification reversed the position of the guidance—which was reviewed and developed by experts in the field—on some key issues. A wide range of advocates and service providers asked WHO to remove the statement and issue a document in alignment with the technical note. After five months, in April 2016, WHO said that it would. But since then, representatives have publicly backpedaled from this commitment. The confusion caused by the statement—no longer on the website—must be corrected, as WHO has promised. Failure to do so jeopardizes the effort to secure a full, informed choice within a wide range of options for all women.
normative agencies. These should be designed to enable governments to define unmet needs and prevention niches and to allocate programming and research funds accordingly.

These mid- and long-term goals for country-level action need to be complemented by even more coordination among trial sponsors and implementer involved in the remarkable array of planned or ongoing efficacy trials focused on injectable prevention (e.g., vaccines, passive immunization and long-acting injectable ARVs). As described in Figure 14 at right, there are more efficacy trials in vaccine-related strategies than at any other point in the history of the field. The success of both these specific trials and of the strategies they may identify depends on collaborative work that puts countries at the center, as opposed to specific products, trials or research groups. Done well, this short-term management of messages, expectations and trial launches will help countries assume an even greater degree of ownership of mid- and long-term HIV prevention research agendas.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Trial</th>
<th>Product</th>
<th>Number</th>
<th>Population</th>
<th>Status (start-end)</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibody</td>
<td>HVTN 704/HPTN 085</td>
<td>VRC01 antibody, infused every two months</td>
<td>2,700</td>
<td>Men and transgender persons who have sex with men</td>
<td>Enrolling: Apr. 2016–Sept. 2020</td>
<td>Brazil, Peru, US</td>
</tr>
<tr>
<td>Antibody</td>
<td>HVTN 703/HPTN 081</td>
<td>ALVAC/gp120 MF59 adjuvant boost, five doses over 12 months</td>
<td>1,500</td>
<td>Sexually active women</td>
<td>Enrolling: May 2016–Jul. 2020</td>
<td>Botswana, Kenya, Malawi, Mozambique, Tanzania, South Africa, Zimbabwe</td>
</tr>
<tr>
<td>Preventive HIV vaccine</td>
<td>HVTN 702</td>
<td>CABG-12-020 adjuvant boost; five doses over 12 months</td>
<td>5,400</td>
<td>Sexually active heterosexual women and men</td>
<td>Projected start Nov. 2016–End 2020</td>
<td>South Africa</td>
</tr>
<tr>
<td>Long-acting injectable</td>
<td>HPTN 083</td>
<td>Cabotegravir injections every two months</td>
<td>4,500</td>
<td>Men and transgender persons who have sex with men</td>
<td>Projected start Q3/4 2016; OR projected end June 2020</td>
<td>~40 sites in North and South America, South Africa and Asia</td>
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<tr>
<td>Long-acting injectable</td>
<td>HPTN 084</td>
<td>Cabotegravir injections; schedule to be confirmed, either every two or three months</td>
<td>TBD</td>
<td>Sexually active women</td>
<td>Potential start in 2017</td>
<td>Southern and East African countries TBD</td>
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<tr>
<td>Preventive HIV vaccine</td>
<td>TBD</td>
<td>Ad26/MVA boost</td>
<td>TBD</td>
<td>TBD</td>
<td>Potential start in 2017</td>
<td>US, Latin American, Southern and East African countries TBD</td>
</tr>
</tbody>
</table>

For the latest trial updates visit www.avac.org/pxrd.

or for life (ART). These strategies can help cut rates of new HIV cases, but it’s not clear whether they can sustain these reductions.

**Prioritize investment in research infrastructure.**

As we’ve said throughout the Report, systems for collecting and sharing data are key. Countries can and should push partners to funnel resources toward the creation of platforms that make it easier to track clinical trials and share data within countries. In addition, regulatory capacity must be strengthened so that local Institutional Review Boards (IRBs) can evaluate proposed research for its scientific value, design and ethics and can also determine what is most needed in a given country’s context.

**Decision-making tools and product profiles must be available for country stakeholders including governments and civil society.** This should include “best guess” or “moving target” descriptions of candidates in the pipeline. Product developers can generate these, as can other stakeholders such as research funders and
Time for a Surge in Vaccine Advocacy

As the figure below shows, the next two years will bring more vaccine-related efficacy trials than the world has seen in roughly seven years. Back then, there were ongoing daily oral PrEP and microbicide trials, too. Today, the biomedical prevention efficacy trials landscape is dominated by vaccines and related strategies, like antibody-mediated prevention (AMP). These trials are happening with a complex and changing prevention backdrop. Daily oral PrEP is rolling out in countries where vaccine and AMP trials are taking place, though not all sites have yet finalized plans for whether PrEP will be offered to participants. These same trials are articulating broad and site-specific messages about how these new strategies would fit in. The time-honored message, “The world needs an AIDS vaccine”, is still true, but it sounds different when there are other tools and (hopefully) more on the way. And it’s not clear whether the world needs passive immunization of broadly neutralizing antibodies (bNAb)s as a public health tool, or whether these trials are primarily to build scientific knowledge. Advocates have already given feedback that early messages about AMP as a coming prevention tool for women did not feel accurate or well-calibrated. Trial sites and staff are grappling with these messages, but much of the work needs to be done by civil society who are given the chance to think through, challenge and communicate about the trials and concepts that are underway or on the horizon. AVAC is proud to be working with a group of leading advocates who are playing this role. The Vaccine Advocacy Resource Group (VARG)—a team of 11 HIV prevention advocates from countries significant to vaccine research—is tracking key issues and committed to holding scientists accountable. We will be working with the VARG and other partners to build out this work in the coming year. Visit www.avac.org for more news.

HIV Vaccine Research Trials: Past and present

<table>
<thead>
<tr>
<th>Year</th>
<th>VAX003 AIDSVAX</th>
<th>VAX004 AIDSVAX</th>
<th>RV144 ALVAC/AIDSVAX</th>
<th>STEP MRKAD5</th>
<th>Phambili</th>
<th>HVTN 505 DNA-Ad5</th>
<th>VRC01</th>
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<td>16,500</td>
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<td>2,700</td>
<td>1,500</td>
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<td>2,700</td>
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<tr>
<td>2009</td>
<td>2,500</td>
<td>5,400</td>
<td>16,500</td>
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<td>2,700</td>
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<td>5,400</td>
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<td>2011</td>
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<td>2,700</td>
<td>1,500</td>
<td>5,400</td>
<td>TBD</td>
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<tr>
<td>2015</td>
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<td>5,400</td>
<td>16,500</td>
<td>3,000</td>
<td>800</td>
<td>2,500</td>
<td>2,700</td>
<td>1,500</td>
<td>5,400</td>
<td>TBD</td>
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<tr>
<td>2017</td>
<td>2,500</td>
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<td>16,500</td>
<td>3,000</td>
<td>800</td>
<td>2,500</td>
<td>2,700</td>
<td>1,500</td>
<td>5,400</td>
<td>TBD</td>
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<tr>
<td>2019</td>
<td>2,500</td>
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<td>16,500</td>
<td>3,000</td>
<td>800</td>
<td>2,500</td>
<td>2,700</td>
<td>1,500</td>
<td>5,400</td>
<td>TBD</td>
<td></td>
</tr>
</tbody>
</table>
### Biomedical Prevention in 2016—At a glance (July 2016)

#### Prevention Option

**2015** | **2016** | **2017** | **2018** | **2019** | **2020**
---|---|---|---|---|---
Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |

**DEVELOP**

- **GUIDELINES** WHO Guidelines
- **SCALE-UP** Roll out and scale up testing
- **SCALE-UP** Roll out and scale up male and female condoms
- **WHO PQ** Shang Ring WHO PQ & PrePex for adolescents
- **SCALE-UP** Roll out and scale up VMMC

**DEMONSTRATE**

- **GUIDELINES** WHO Guidelines
- **SCALE-UP** Roll out and scale up of immediate offer of ART
- **GUIDELINES** WHO Guidelines
- **SCALE-UP**? Roll out and scale up oral PrEP
- **REGULATORY** MCC approval

**DEMONSTRATION PROJECT RESULTS** Suite of ongoing oral PrEP demonstration projects

**IMPLEMENTATION RESEARCH** VMMC device operations and implementation research

**ASPIRE**

- The Ring Study
  - Move to open label
  - **WHO PQ**
  - **REGULATORY** EMA review
  - **REGULATORY** FDA review
  - **REGULATORY** MCC review

**HPTN 077**

**HPTN 076**

**HPTN 083**

**HPTN 084**

**HPTN 085**

**HVTN 703/HPTN 081**

**EARLY TRIALS** Various early multipurpose prevention technology trials ongoing

**PLANNED OLE**

- HOPE (MTN 025)
- DREAM (IPM 032) pending funding

**PLANNED EFFICACY TRIAL**

- Anticipated HVTN 702 start
- Possible Ad26 start

**SCALE-UP?**

**MARKET ENTRY**

- Earliest market entry

**REGULATORY** African NRAs

**MCC approval**

**EMA review**

**FDA review**

**MCC review**

**PrePex**

**PLANNED OLE**

**PLANNED EFFICACY TRIAL**

Visit www.avac.org/pxrd for trial details and the latest updates.
Conclusion

Big People, Real Data

Whether the lesson is learned in art history class or via selfie trial and error, we all find out, sooner or later, that the stuff in the foreground is the biggest. And the conclusion of this Report is pretty simple: the people impacted by, reacting to, and fighting against HIV, poverty, economic and structural inequalities in the world need to be big—foregrounded in leadership and at the helm of the response. This isn't going to happen if funding levels for civil society keep plummeting, if siloed approaches to funding HIV research and prevention and human rights persist at the donor level and if the pursuit of Big Data doesn't include thoughtful funding, training and support for the workers charged with collecting and responding to it.

Let's take these groups one at a time.

First and foremost: civil society. In the past decade, funding for and recognition of the role of civil society in service delivery, catalytic advocacy and program effectiveness has shrunk. Today, recognition is returning, but funding isn't. Many calls for proposals set thresholds that make it extremely difficult for groups working on the ground to qualify for grants. And as long as this funding and engagement is precarious, the data are going to be either inactionable or inaccurate. Here's the call: fund civil society (big people) in the service of the data that can make an impact on the AIDS response, today, tomorrow and for all time.

Secondly: health workers, data managers and other “on-the-ground” staff. If these individuals don't have the training, mandate and resources to view and react to data, then the information isn't doing its job. The tools that are used to collect data need to fit into the lives of the collectors. They must be simple, adaptable and sturdy. And people need to be trained and paid to watch for trends and act on what they see. This seems like a given, but it isn't. Resources for data management are the sort of “health systems strengthening” activity that can fall by the wayside or become a line item that doesn't translate into reality.

Finally: the people on the front lines of the epidemic. This group encompasses many members of the groups above. It includes trial participants, clients of prevention and treatment programs. It includes the young woman who was born with HIV and is growing into an articulate activist and the man diagnosed in the 1980s who has survived and continues to work until he sees the day when the epidemic is finally over. It's so many different types of people in so many places around the world that they are, well, uncountable. This is the point all of our humanity. Data can get close to it, but at the end of the day, our strength is in our diversity—and that defies quantification.

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When AVAC was founded in 1995, we were called the AIDS Vaccine Advocacy Coalition. Our singular goal was to advance swift, ethical research for a vaccine that was then—and is today—essential to bringing the epidemic to a conclusive end.

Twenty years later, AVAC is still focused on swift and ethical research, but our scope has expanded. Along with vaccines, we advocate for PrEP, microbicides, voluntary medical male circumcision, and more.

And we’ve evolved with the field. As positive results have delivered new tools, AVAC has led the charge for the rapid, strategic rollout of all options needed to end the epidemic.

Through it all, our message has been the same: prevention is the center of the AIDS response. Not just any prevention, but smart, evidence-based, community-owned, rights-based strategies.

AVAC is the only advocacy group working across the full spectrum of biomedical prevention interventions, from early-stage research to large-scale rollout.

We do this work because it’s essential. We are able to do it because of our robust partnerships worldwide. We will keep doing it—with your help—until the epidemic has, finally, come to an end.
Keeping the field on track—no matter what.

We’ve experienced 20 years of breakthroughs and disappointments in prevention research. A vaccine that many had given up on was the first to provide modest protection. One microbicide everyone hoped for didn’t pan out. Male circumcision and PrEP studies overcame skepticism and, together with antiretroviral therapy, paved the way for a prevention revolution. Through it all, AVAC has worked with partners to maintain the field’s focus and press for continued research into an AIDS vaccine, a cure and more.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Phase I</th>
<th>Phase II/IIb</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical trial safety and efficacy</td>
<td>Open-label extension / post-trial access</td>
<td>Demonstration projects</td>
<td>Product introduction</td>
</tr>
</tbody>
</table>

Ending the AIDS epidemic takes comprehensive targets and action.

For the first decade of AVAC’s existence, most prevention advocacy focused on actions to the left of the red arrow above. But with results, come new challenges. We now work on research and on ensuring that products cross the gap between efficacy and real-world use.

Defining the path from research to rollout.

When AVAC was founded, the only biomedical HIV prevention options for adults were male and female condoms. The pathway for introducing any new strategy was largely unmapped. No one knew where the gaps would be—between trial result and country action, between guidance and financial support. Now we do. Over two decades, AVAC has not only identified the gaps; we’ve worked to bridge them, so that products reach people in programs that work—without delay.
Twenty years ago, advocacy for HIV prevention hardly existed. So AVAC helped build a global network of advocates equipped with effective advocacy strategies and the latest evidence. With our support, they are putting prevention on the agenda in countries and communities around the globe.

Through Advocacy Fellows, PxROAR members, coalition-building, strategic convening, training and other support, AVAC partners with stakeholders throughout the world to increase awareness and understanding of the current state of HIV prevention research and implementation. Together, we hold decision-makers accountable and press for smart investments and sound policies in all aspects of HIV prevention.

Creating a global network of prevention advocates.

When the world lacked a plan for ending AIDS, we helped to create one. Now we’re holding global leaders accountable for results—demanding the resources, policies and evidence-based plans needed to deliver all of today’s prevention options to the people who need them, and to plan for the rapid rollout of new options as they emerge.

Demanding action on an agenda to end AIDS.
Managing through controversy.

Communities’ support for prevention research can never be taken for granted—it has to be earned. For 20 years, we’ve helped build trust among researchers, funders and communities to speed the ethical development and rollout of new prevention options. And when controversy threatened to derail those efforts, AVAC provided leadership and resources to help get them back on track.

Driving product introduction and access.

AVAC has always advocated for closing critical prevention gaps. Now we’re taking our mission further. With African and global partners, we’re stepping beyond advocacy to generate the knowledge and tools that countries need to more quickly deliver new advances. We’re engaging directly with national decision-makers to identify and overcome delivery hurdles for PrEP. We’re examining the preferences and experiences of people at high risk for HIV, so that future tools—long-acting injectables, vaginal rings and others—can be optimized to meet their needs.

The Good Participatory Practice (GPP) Guidelines provide trial funders, sponsors and implementers with systematic guidance on how to effectively engage with all stakeholders in the design and conduct of biomedical HIV prevention trials.

Achieving the End of AIDS

The world is talking about ending AIDS. AVAC’s advocacy is dedicated to realizing that vision. To get there we must:

• **Deliver** proven tools for immediate impact.
• **Demonstrate** and roll out new HIV prevention tools.
• **Develop** long-term solutions to end the epidemic.

From research to rollout, evidence drives AVAC’s advocacy. By expanding the evidence base for action, we’re making HIV prevention advocacy more powerful than ever before.
Your gift to AVAC will support our efforts to accelerate the development and delivery of HIV prevention options to men and women worldwide. With your help, we can continue to convene, collaborate and communicate a strong, clear and cohesive vision for HIV prevention today, tomorrow and to end the epidemic.

It will take all of us working together to end AIDS. Please join us.

To learn more about AVAC, including our history, our focus and our team, please visit www.avac.org. And to support this work, please go to www.avac.org/donate.

WEBSITE

www.avac.org

For the latest updates in HIV prevention, visit the AVAC website. It includes our publications as well as comprehensive coverage of the full range of biomedical HIV prevention interventions in an easy-to-use format that is searchable by intervention and by topic.

PUBLICATIONS

www.avac.org/publications

AVAC publications aim to translate the complex issues of biomedical HIV prevention research for a range of audiences. We have materials that explain current scientific issues in simple language, documents that explore the issues of trial participants and affected communities, and a lively blog, P-values, which features voices from across the HIV prevention advocacy arena.

DATABASES

www.avac.org/pxrd, avac.org/resources-search and avac.org/infographics

The AVAC website hosts three searchable databases: one on biomedical HIV prevention research clinical trials, products and sites, one that includes research literacy resources for understanding HIV prevention research and another for infographics.

MAILING LISTS

www.avac.org/mailinglists

The Advocates’ Network is an electronic network for anyone interested in receiving timely updates about developments in the biomedical HIV prevention field.

The Weekly NewsDigest is a compilation of media coverage, published research, policy news and materials on HIV prevention options.

SOCIAL MEDIA

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twitter.com/hivpxresearch
youtube.com/hivpxresearch
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