

By 2020, UNAIDS predicted massive declines in HIV incidence. Incidence isn't dropping worldwide. Widespread treatment is essential, but it isn't enough. UNAIDS' primary prevention targets won't be met by a long shot.

NOW WHAT?



ANNUAL REPORT 2019

Acknowledgements

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In Memoriam

Those killed for their sexual orientation or gender expression in 2019

Hate has no place in our world. But it stalks and claims some of us every day. This year's AVAC Report is dedicated to some of the many LGBT individuals who were murdered in 2019 for living their truths. As our comrade, South African AIDS activist Yvette Raphael has said, "Where people see statistics, I see the faces of my friends." Each of these individuals had a name and is sorely missed by friends. Here are a few of those we mourn: Marielle Franco (Brazil), Uyinene Mrwetyana (South Africa), Ssemugoma Fahad, Ssebunya Julius and Brian Wasswa (Uganda). In the US—where at least 19 transgender people of color have been murdered in 2019: Dana Martin, Jazzaline Ware, Ashanti Carmon, Claire Legato, Muhlaysia Booker, Michelle "Tamika" Washington, Paris Cameron, Chynal Lindsey, Chanel Scurlock, Zoe Spears, Brooklyn Lindsey, Denali Berries Stuckey, Tracy Single, Bubba Walker, Kiki Fantroy, Jordan Cofer, Pebbles LaDime "Dime" Doe, Bailey Reeves, Bee Love Slater, Jamagio Jamar Berryman, Itali Marlowe and Brianna "BB" Hill. And many more of our brothers and sisters worldwide. Say their names.

Manasseh Phiri (1958-2019)

On April 12, 2019, the world lost a staunch HIV advocate who was a dear friend and partner to many on the AVAC team. Zambian-born Manasseh Phiri was a doctor, writer and radio journalist, activist, advocate, mentor and farmer. He managed this long list of roles with passion, courage, wisdom, intelligence and humor. He was a champion for African-led responses to HIV, from research to program design, and never lost sight of the need to do more to find strategies for the next generation. Once, when asked about "what kept him awake at night" regarding AIDS, he replied that he thought of his grandson and the work that remained to be done to keep his generation safe. Dr. Phiri was remarkably candid about male circumcision—including his own—and about learning to move beyond personal comfort zones to do good activism. A staunch ally of LGBT folks, like those mentioned at left, Phiri also spoke about the ways that culture and tradition had affected him adversely when it came to working with "key populations". This is the kind of powerful honesty and self-reflection that made him a role model to so many of us. He will be missed, but his influence lives on with so many of us.

Table of Contents

The Honest Answer: A letter from the Executive Director	2
Now What? AVAC's top three priorities for 2020—and beyond	8
1 NOW: Enact bold, activist, visible leadership on HIV from the grassroots to Geneva	9
Box: Trends in Government Spending on Health Worldwide: Unfinished business	10
Box: What? Leadership. How? Fearless, evidence-based, activist-aligned actions	11
Dear “Generation Now”	12
Box: AIDS and Climate Justice Activism	14
Dear Winnie Byanyima, UNAIDS Executive Director	15
2 NOW: Use today's evidence to guide tomorrow's prevention targets	19
Research Targets: Time for the spotlight	26
Box: PrEP Scale-Up Agenda Checklist	30
Prevention and Global Leadership: Time for new targets, sustained investment resources and technical excellence	32
3 NOW: Double down on multilayered prevention approaches	35
Box: One Woman, Many Choices: After ECHO, the work continues	37
Box: A “3-D” Agenda for Multilayered Prevention	39
Not the End—Just the Beginning: AVAC's commitments for 2020 and beyond	42
About AVAC—Many Approaches, One Message: Prevention Matters	44

FIGURES

1. AVAC's “3D” View of the World: 2019 and beyond	2
2. UNAIDS Fast-Track Targets: The plan and the progress	3
3. Declines But Not a Decisive Effect of the Intervention: Key results from “universal test and treat” trials	18
4. A Generic and Unifying HIV Prevention Cascade Framework	21
5. Visualizing Multisectoral Prevention: The DREAMS program theory of change	22
6. Monitoring Primary Prevention: What to look at and why it matters— for oral PrEP and more	24
7. What Gets Measured Matters: PrEP monitoring varies widely by country, funder and normative agency	25
8. HIV Prevention Research, Development and Implementation Pipeline in 2020— and Beyond	27
9. Biomedical HIV Prevention Trials: Results, milestones and more	29
10. Total and Additional Users of Modern Contraception, 2012-2019	36

TABLE

1. Universal Test and Treat (UTT) Trial Results	5
2. Metrics for Epidemic Transition: A glossary	34



The Honest Answer

A letter from the Executive Director

“Now what?”

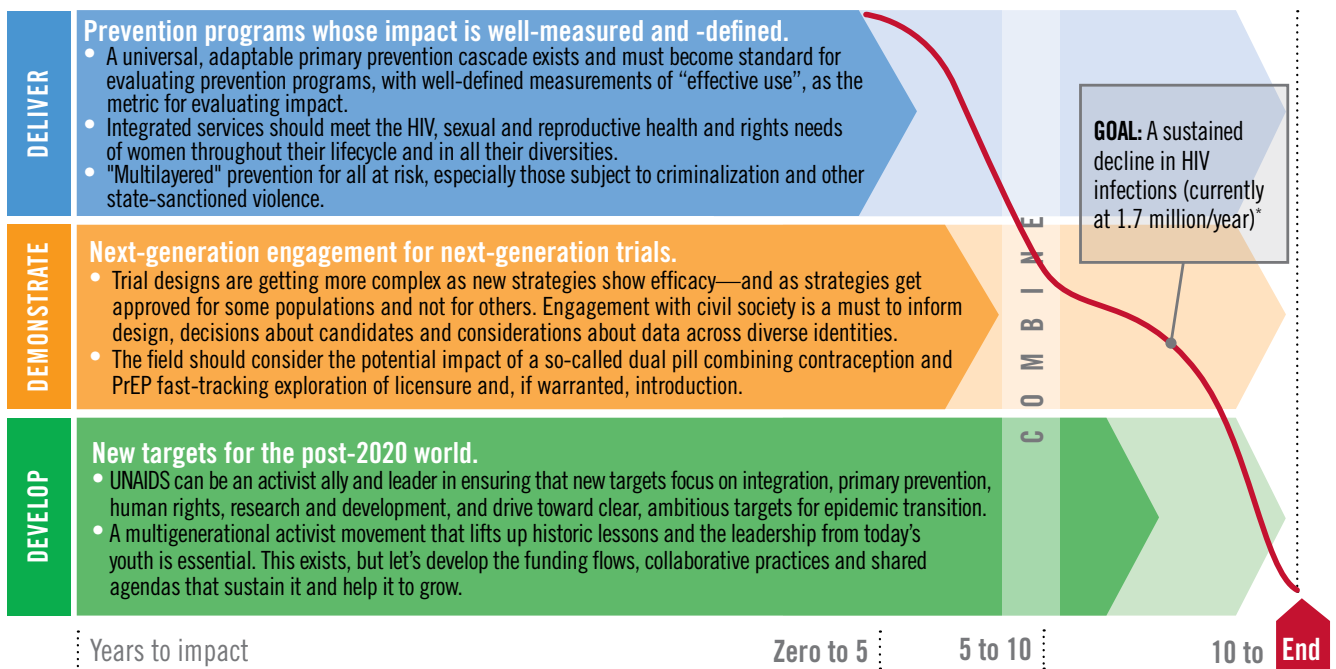
It’s been a challenging year as new data have confirmed, with greater clarity, the distance left to go in addressing global and local HIV epidemics.

Midway through 2019, a range of trials brought new data on the potential and limitations of biomedical strategies in the global HIV response. The data weren’t surprising, but they made some serious obstacles clearer than they have been before. Community-wide testing followed by ART for people living with HIV has health benefits for the individual and reduces incidence by around

30 percent. That’s both invaluable and insufficient to end epidemic levels of new diagnoses. 2019 also brought fresh data from the ECHO trial, data on HIV risk in young women, and their unmet need for integrated sexual and reproductive health and HIV. This clarity comes as the world nears the 2020 deadline UNAIDS has set for reducing new infections to fewer than 500,000 per year worldwide.

2020 is also the deadline for critical milestones in the contraceptive field. FP2020—the global partnership focused on tracking and expanding

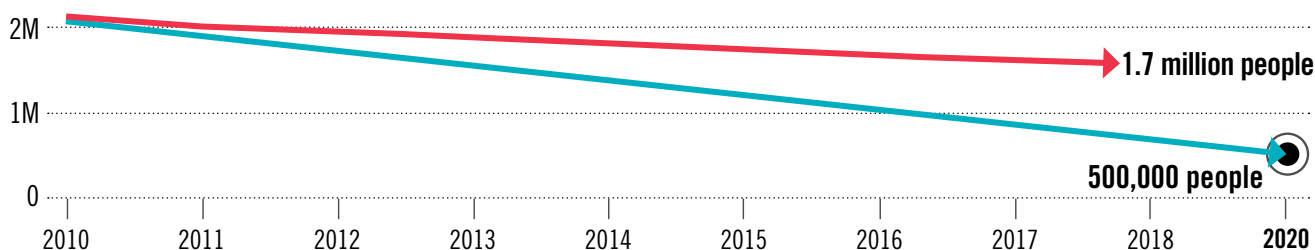
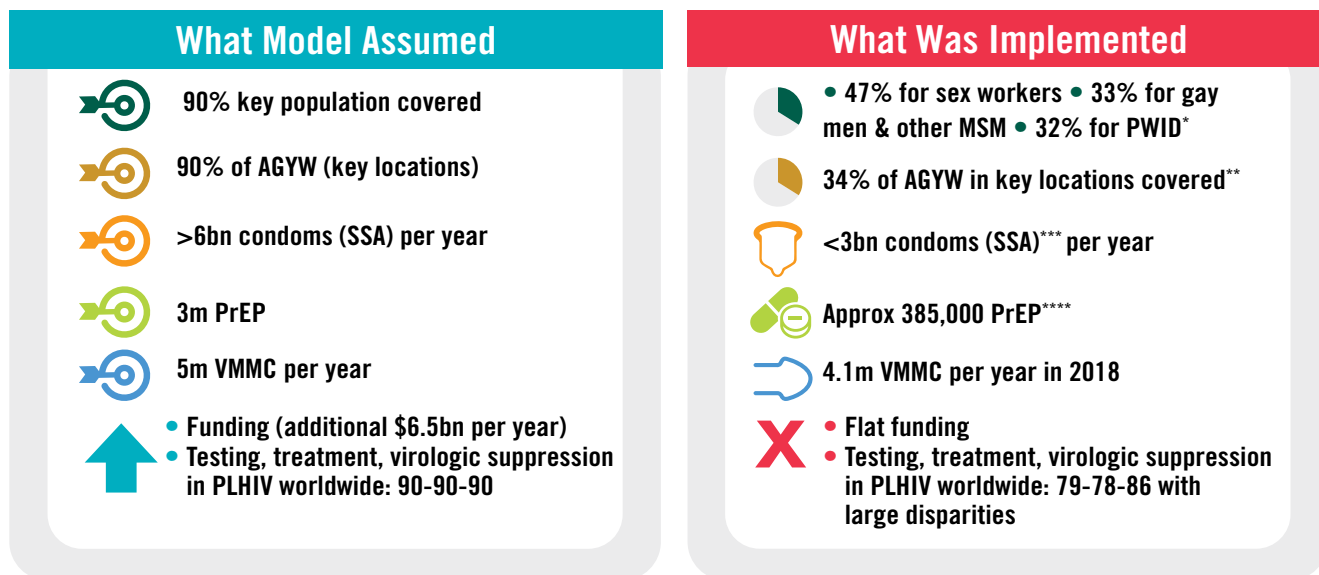
FIGURE 1 AVAC’s “3D” View of the World: 2019 and beyond



* 2019. UNAIDS. *Global AIDS update 2019 — Communities at the centre*. Accessible at: <https://www.unaids.org/en/resources/documents/2019/2019-global-AIDS-update>.

FIGURE 2 **UNAIDS Fast-Track Targets: The plan and the progress**

The most widely-known UNAIDS Fast-Track goals were the 90-90-90 targets focused on diagnosing people with HIV, linking them to ART and supporting them to achieve virologic suppression. But these were only part of what the UNAIDS modelers said was needed to reduce new HIV diagnoses to 500,000 per year; the model also included significant scaling up of primary prevention including the targets listed below. There are gaps across the board, which helps explain how the world fell short of the hoped-for reduction in new HIV diagnoses.



* Average coverage in Global Prevention Coalition (GPC) countries with available estimates: 47% for sex workers, 32% for men who have sex with men, 31% for people who inject drugs. Coverage in countries that are not reporting is likely lower. Quality of data varies greatly.
 ** Interim indicator until data on percent of young women at higher risk reached with effective prevention interventions can be measured.
 *** Condom use with non-regular partners in 19 GPC countries in Africa was on average 62% for men and 47% for women against a 90% target.
 **** The UNAIDS Fast-Track model called for three million individuals in specific countries. These figures reflect global PrEP coverage.

Source: Global HIV Prevention Working Group. Personal communication. 6 November 2019.

contraceptive coverage and choice—had hoped to see 120 million additional users of modern contraception (compared to 2012), and all projections say that target won't be met either.

Now what?

The answer that you'll find in this report is: sustain the investment, do the more difficult things that have been put off, measure those things, modify the approaches, repeat. It's easy

to say, hard to do and there are unknowns at every step. But there is hope: much of what needs to be done involves approaches that are, in many respects, familiar. We need not reinvent the wheel, just reorient the direction of the field.

First: How exactly did this “Now what?” moment arrive? By way of research results. The best trials are not necessarily the ones that bring hoped-for conclusions. They are the ones that catalyze action—whether because of a positive

finding or because the data drive home the need for action on an unsolved problem. This year, a set of studies brought problems with reducing incidence into sharp relief.

In July 2019, three major trials of universal test and treat (UTT) strategies presented results (see page 5 for a summary). They were, in a way, a test of the degree to which the test, treat and suppress targets—the most high-profile of the UNAIDS “Fast-Track Goals”—could drive down new HIV infections.

At an individual level, undetectable viral load means zero transmission to sexual partners.

Undetectable equals untransmissible (U=U)—

Access to HIV treatment in rights-based programs that support people to start and stay on medication that suppresses the virus is a human right and an ethical imperative.

along with PrEP—has the potential to change stigma, reduce or remove fear associated with sex, and shift conversations about HIV criminalization. This is undisputed. These trials sought to look at

the population-level impact of ART as prevention.

The International AIDS Conference in 2018 brought an early look at these data¹; one year later, the studies' results were published in the *New England Journal of Medicine*.²

The UTT strategies all achieved increases in population-level viral suppression over short time frames, with three of the four studies exceeding the UNAIDS target of 73 percent of people with

HIV having undetectable viral load. As the table on page 5 shows, in two of the four trials (Ya Tsie and PopART) this intervention package reduced HIV incidence relative to a control arm consisting of “business as usual”—meaning HIV testing, outreach and linkage to antiretroviral therapy all delivered according to national guidelines. There was no difference in HIV incidence between the arms in the SEARCH and TasP³ trials.

So is this good news, bad news or what? (Now what?) The first step to understanding what these trials show is understanding that they were markedly different in their designs.

Perhaps the most important difference between the trials is that all of the communities in SEARCH and TasP—the two trials that did not see a difference in incidence between the intervention and control arms—received universal testing at the start of the study. The SEARCH team has looked at its data and thinks that incidence went down by roughly 30% in both of its trial arms after roughly 90 percent of the communities received HIV testing, and saw major increased in virologic suppression among PLHIV. The two trials that offered universal testing only in the intervention arm saw reduced incidence in that arm compared to the control. Universal testing seems to have impacted incidence, in the context of expanded ART eligibility.

The message isn't to massage the data until you get what you want. It's that testing is critical, and community-wide approaches are a powerful tool for prevention and treatment. This runs counter to the current emphasis on index testing and the “yield” of HIV-positive people, and also has implications for rollout of self-testing. It suggests that a close look at the community-based research and rollout agenda for testing must be a top priority in the post-2020 epidemic response.

¹ AIDS 2018. WEAX01 AIDS 2018 Co-Chairs Choice session. <http://programme.aids2018.org/Programme/Session/164>.

² Hayes, Donnell et al. 2019. *Effect of Universal Testing and Treatment on HIV Incidence—HPTN 071 (PopART)*. *N Engl J Med*. 381:207-218. DOI: 10.1056/NEJMoa1814556. Makhema, Wirth et al. 2019. *Universal Testing, Expanded Treatment, and Incidence of HIV Infection in Botswana*. *N Engl J Med*. 381:230-242. DOI: 10.1056/NEJMoa1812281. Havlir, Balzer et al. 2019. *HIV Testing and Treatment with the Use of a Community Health Approach in Rural Africa*. *N Engl J Med* 2019; 381:219-229 DOI: 10.1056/NEJMoa1809866.

³ Iwuji, Orne-Gliemann, Larmarange, et al. 2018. *Universal test and treat and the HIV epidemic in rural South Africa: a phase 4, open-label, community cluster randomised trial*. *Lancet HIV* 2018;5(3):e116-e125.

TABLE

1**Universal Test and Treat (UTT) Trial Results**

As the table below shows, the two trials that offered community-wide testing in both arms (SEARCH, TasP) did not find a difference in incidence between the arms. One explanation may be that the expanded access to testing and linkage in both arms had an impact in both intervention and control communities. The two trials that only provided universal testing in the intervention arm identified differences in incidence between that arm and the control arm.

There were other differences between the four UTT trials. As described below, PopART was the only trial with urban and peri-urban communities.

UTT Trials	Design Elements				Results
	Intervention Arm(s)	Control Arm	Number of communities, locations	Community-wide testing	Difference in incidence between intervention and control arms
PopART	Annual home-based HIV testing with linkage to HIV care and treatment at local health facility, with ART initiation either on diagnosis (Arm A) or according to local treatment guidelines (Arm B). Midway through trial, national guidelines changed and ART became available on-demand to people on Arm B.	Communities received local standard of care for HIV testing, linkage, ART initiation. Local ART guidelines expanded to universal eligibility during the trial.	21 urban or peri-urban communities in South Africa and Zambia.	Intervention arm only.	Results of pre-specified analysis: 30% decrease in Arm B—universal testing plus ART per national guidelines, compared to Arm C—standard of care. Statistically significant. <i>Post hoc</i> : Analysis of incidence in the two intervention arms (A and B) versus C found a 20% incidence reduction, with statistical significance.
SEARCH	Baseline HIV and multidisease testing plus annual testing, eligibility for universal ART and patient centered care.	Baseline HIV and multidisease testing and national guideline-restricted ART. Local ART guidelines expanded to universal eligibility during the trial.	32 rural communities in Uganda and Kenya.	Both arms.	No difference.
TasP	Repeat rapid HIV testing during home-based visits every six months plus immediate offer of ART.	Repeat rapid HIV testing during home-based visits every six months, standard of care ART initiation. Local ART guidelines expanded to CD4<500 during the trial.	22 rural communities in KwaZulu Natal, South Africa.	Both arms.	No difference.
Ya-Tsie	HIV testing and counseling, linkage to care, ART (started at higher CD4 count than national standard of care) and increased access to male circumcision services.	Communities received local standard of care for HIV testing, linkage, ART initiation. Local ART guidelines expanded to universal eligibility during the trial.	30 rural or periurban communities in Botswana.	Intervention arm only.	Results of primary analysis: 30% decrease in HIV incidence in intervention, compared to control arm; not statistically significant. <i>Post hoc</i> results: sensitivity analyses and models applied analysis found the same decrease, with statistical significance.

Across the trials and their differing approaches, the data were fairly consistent: over a three-year period, any approach that started with universal testing led to a roughly 20-30 percent drop in incidence compared to control arms without the testing push at the outset, in the context of rapidly expanding ART eligibility and high levels of uptake. It's likely that this incidence reduction would grow over time—three years is a very short timeframe for measuring epidemic shifts.

So yes, it is good news. But for much of the period that these trials happened, there were stakeholders who suggested that treatment as prevention could turn around the HIV epidemic. This includes UNAIDS, whose decision to launch Fast Track with the 90-90-90 targets alone (primary prevention targets followed roughly a year later) created the impression that meeting these treatment milestones would lead to “epidemic control”. By the time UNAIDS began to highlight the unmet needs in primary prevention, the conflation of 90-90-90 and the end of AIDS was, in some places, complete.

These trials undo that conflation. They show what's possible and what still needs to be done with other strategies and by other means.

Let's be clear: access to HIV treatment in rights-based programs that support people to start and stay on medication that suppresses the virus is a human right and an ethical imperative. Also, a 30 percent incidence reduction is a substantial achievement. It's clear evidence that scaling up ART needs to be done, in its own right and as a part of effective prevention.

But 30 percent incidence reduction won't get countries, communities or the world to epidemic control or “transition” (see page 34). While there are places in the world where incidence is declining, there are no countries in which the decline has approached 75 percent. In Eastern Europe and Central Asia, new diagnoses are skyrocketing.

Today, to be young, female, black and having sex in a high prevalence sub-Saharan setting is to be at risk of HIV and to be unlikely to remain in a PrEP program.

What's been done to date is inadequate. The number of young people in sub-Saharan Africa has increased dramatically—as it has worldwide. With such large numbers of youth, even with a modest decrease in incidence, the absolute numbers of new HIV infections in this age group will be similar to, or even larger than, annual rates earlier in the epidemic. Without prevention that fits into the lives of young people living with and at risk of HIV, there is no end to epidemic levels of new infections.

Another facet of this “Now what?” moment is the most recent research showing just how persistent these failures are for women, particularly young women in East and Southern Africa. In June 2019, the ECHO trial of contraception and HIV risk released its results. ECHO participants were not recruited on the basis of individual risk factors for HIV, meaning they were not asked about number of partners, engaging in sex work, history of STIs etc. Instead, ECHO simply enrolled women who were sexually active and seeking contraception in high prevalence settings. And yet, incidence amongst these women was 3.8 percent across the trial populations and reached as high as six percent in one of the trial sites in South Africa.

ECHO drove home the enormous unfinished business of meeting women's contraceptive and HIV needs at the same woman-centered service sites. Unfortunately, the response to the results from many quarters, was, essentially, “Phew, now there's no need to shift the approach to contraceptives.”

The vibrant, African-led coalition of women's health advocates that AVAC collaborates with did not share this pure relief. In Section Three, you'll find our post-ECHO women's health agenda.

PrEP initiation in ECHO was quite low. And the information that has emerged from PrEP programs is that much more needs to be done for the strategy to fit into women's lives. At the IAS 2019 Conference in Mexico City, data from implementation projects aimed at encouraging adolescents to start and stay on daily oral PrEP showed that while many start, substantial numbers of them do not continue.⁴ This pattern isn't new, but the projects—which reflected the thoughtful youth-friendly and youth-led design of groups like the Desmond Tutu HIV Foundation—were among the most innovative adolescent-focused efforts to date.

Today, to be young, female, black and having sex in a high prevalence sub-Saharan setting is to be at risk of HIV and to be unlikely to remain in a PrEP program. To be a gay or transgender person in Africa or the US—and many other places around the world—is to be at risk of being murdered, harrassed or physically violated at the hands of police. People who use drugs are criminalized, excluded from care, denied human rights and access to highly effective harm-reduction strategies. Authoritarianism is on the rise and that is bad for communities, public health and the planet.

Now what, indeed?

In the HIV field, it's time to face these additional realities:

- Much of what has been taken to scale are biomedical interventions implemented without the wraparound structural, social, cultural and political shifts that make it possible for people to use strategies to prevent and treat HIV.
- Multisectoral approaches that seek to reduce HIV risk and promote health by working at

the level of education, economics, culture, rights and biomedical strategies are widely recognized to be essential for HIV prevention yet inconsistently programmed at scale. So is voluntary medical male circumcision (VMMC), which is still fighting for prevention funds even in the context of a concerted focus on “finding men”.

- HIV prevention monitoring and evaluation has been steadily improving, but new insights aren't moving into widespread application, nor are they having impact quickly enough. The world has known for some time that incidence wasn't going down in all places, and groups like the Global Prevention Coalition and the HIV Modeling Consortium have, with UNAIDS, worked hard to define what to measure and what to aim for in the next set of goals. But that work hasn't moved from theory to practice. Countries can start to use current data systems today to estimate incidence reduction and assess, more directly, the impact of HIV prevention programs and investments.

If you look closely, that list of realities is also a list of solutions: the ones we've laid out on the next page.

This year's *AVAC Report* is written for everyone on the front lines of this fight who believes that curiosity and commitment will win the day so long as we're honest about what we know and what we don't, and so long as we listen to the answers that matter most, from the people most affected by and at risk of HIV. Together, we can and will answer the question, “Now what?”—not once, but again and again. With each honest answer, we can change the world.



Mitchell Warren
Executive Director, AVAC

⁴ See, for example, the results from the CHAMP study (<https://aidsinfo.nih.gov/news/2566/prep-use-high-but-wanes-after-three-months-among-young-african-women>), which mirror data from national programs (see prepwatch.org).

Now What?

AVAC's top three priorities for 2020—and beyond

1

NOW

**Enact bold, activist, visible leadership
on HIV from the grassroots to Geneva.**

From the head of UNAIDS, to African houses of parliament, to civil society coalitions: take uncompromising stances, demand accountability, speak out for intersectional issues of race, gender, class and climate. This work needs to be funded, full-throttle and fearless. In Section One, we lay out what we hope these leaders will take on.

2

NOW

**Use today's evidence to guide
tomorrow's prevention targets.**

The world is going to miss the 2020 incidence-reduction target not because it tried everything and failed, but because many things didn't get funded or evaluated and fixed when needed. Prevention impact can be achieved and measured. Let's not waste any more time. In Section Two, we identify the interlinked suite of approaches and terms that should be used to set and measure the next generation of prevention targets.

3

NOW

**Double down on multilayered
prevention approaches.**

Let's try a new term to address old siloed problems. Multilayered prevention involves multipurpose strategies (think contraception and HIV prevention) embedded in multisectoral strategies (think policy reform, community norms changing, economic empowerment and more). Only layered approaches like these will drive incidence down. In Section Three, we lay out work for UNAIDS, FP2020 and a new set of targets—including goals for the research pipeline—that are shared by HIV and sexual and reproductive health and rights fields.

1

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Letters to Leaders: Why now?

AIDS isn't over, and AIDS activists know it. The lessons we have from the history of the power of acting up and fighting back are made fresh every day by new risks, new bold statements, new examples of people claiming space. This section contains letters to the people with the power to shape the future. First is a letter to young HIV-focused advocates who are already getting to work. We don't think of them as "next generation", but as "Generation Now"!

Next is a letter to Winnie Byanyima, the new Executive Director of UNAIDS. Byanyima is just one of the visible, global leaders on HIV and health who we hope will show strong activism in the coming year.

A note, here, about the history of activist leadership at UNAIDS: some of the agency's most impactful moments have come when its leaders called out others in power on inaction and bad policy. Around the world, and especially in Africa,

Trends in Government Spending on Health Worldwide: Unfinished business

In 2019, the World Health Organization released "Public Spending on Health: A closer look at global trends" (https://www.who.int/health_financing/documents/health-expenditure-report-2018/en/), which contained the first-ever comparable measures of primary health spending in low- and middle-income countries. It also looked at allocations across diseases and interventions. The report provides a baseline for discussions about government financing for health, including specific diseases and universal health coverage. Here are some key findings.

WHAT?

In low-income countries:

- Economic growth and increased public spending hasn't translated into more money for health:
 - Public spending on health in 2016 was US\$9 per capita—just 22 percent more than it was in 2000.
 - Public spending on health as a share of GDP decreased from 7.9 percent to 6.8 percent in 2016.

In all countries:

- Preventive interventions and primary care are low priorities for governments:
 - Less than 40 percent of public spending is for primary care (versus inpatient care, medicines and medical supplies).
 - Preventive care is 11 percent of public spending on health and 12 percent of the total.

NOW WHAT?



Low-income countries should strive to make investments in health commensurate with growth in GDP, with full acknowledgement of the unforeseen factors and ongoing structural issues that affect developing economies.

Prevention and primary care are under-prioritized yet essential for UHC and a sustainable HIV response. Prioritization and funding from donors and governments is key.

UNAIDS plays a critical role in standing with and for LGBT individuals when they are attacked and persecuted. UNAIDS has also often shown powerful activism in speaking up for audacious targets for resources, commodities and donor and recipient-country commitments. As the box on the preceding page notes, low-income country governments haven't increased general health investments, even as GDP has climbed. That's not a matter of HIV crowding out funding—as the WHO itself suggests in its report⁵—and it often reflects grave realities: famine, conflict or natural disasters. But in some cases, it reflects countries

prioritizing other things besides the health of their own people. Nor can donors expect countries to pay for HIV programs and Universal Health Coverage (UHC) overnight. Global leaders and country governments should not pit health initiatives against each other. We're looking for leadership from WHO Director-General Tedros Adhanom, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria Peter Sands and US Global AIDS Ambassador Deborah Birx among many others. Byanyima is the newest in this cohort. She's a powerful woman—and we hope that when she takes action, others will follow her lead!

WHAT?

Leadership.



What we say is important; so is how we say it. The AIDS field requires activist leaders who do not mince words and do not accept promises without following up. Activists demand accountability. We don't have to agree on everything to be in solidarity.

HOW?

Fearless, evidence-based, activist-aligned actions.

Here are some of our top priorities for leaders working on HIV and health justice today:

- Appeals, both public and private, to heads of state in HIV-endemic and hyperendemic countries to end harmful policies and immediately increase their contributions to domestic health and HIV specifically.
- New targets that, if met, will result in massive reductions in AIDS deaths and new HIV infections, with budgets attached.
- Visible, solidarity with cisgender women and girls in all their diversity, lifting up their call for services and societies that reflect and respect all their needs.
- Staunch support for gay men, transgender people and all those criminalized and stigmatized because of sexual orientation and gender identity.

⁵ Xu, Soucat et al. 2019. *Public Spending on Health: A Closer Look at Global Trends*. WHO. https://www.who.int/health_financing/documents/health-expenditure-report-2018/en/.

Dear “Generation Now”:

We’re talking to you: AVAC partners, Fellows, ROAR members, COMPASS coalition comrades, along with all the other young and emerging activists worldwide, including the many we haven’t met, who know that our bodies and our planet are on the line.

If you’ve been anywhere near an AIDS presentation in the past year, chances are you’ve heard about the “youth bulge”. Maybe you thought: Wow, that’s an unflattering phrase. Or: Hey, that’s me. Or: Why is the speaker who is talking about youth so old? Maybe you thought: If there are so many of us, why isn’t the work getting any easier? Why is there still so much to do? All of those thoughts are fair.

We’re living in a perilous time. Authoritarianism is rising, economies are struggling, education and employment aren’t

Today’s research trials could find prevention strategies for your youngest siblings—or future children—to use when they become sexually active.

keeping up, access to basic health care is improving in some places and not in others. And in the midst of it all, HIV isn’t going away. Now what?

First of all: please keep on doing what you do so well. You’ve

questioned WHO, country governments and researchers about the implications of the ECHO trial result, rallied slow-moving governments to do more, faster to bring PrEP to adolescent girls and young women, and asked the hard questions about how research trials are conducted and designed.

Next: we hope you will continue to put the focus on the future you want to see. As your peers and friends, the leaders of the Climate Strike (see box, pg. 14), have said so eloquently, today’s leaders are accountable to the world’s youth. The same is true regarding HIV. Choices are being made right now about which experimental products to test, which concepts to shelve, which existing strategies to

implement at-scale, all of which impact you and your communities. Today’s research trials could find powerful prevention strategies for your youngest siblings—or future children—to use when they become sexually active. With your power and vision, you can catalyze social movements to ensure that children come of age in societies that honor their minds and bodies, their freedom from coercion, their right to choice. We want and need you to continue to lead this work. And we hope you’ll take on some of the critical questions that the HIV field is facing today.

On research:

- Are you and your peers being asked your opinions, treated like experts and engaged throughout the research process? If not, what needs to change to create the research engagement structures you want and need? In 2019, we cheered on the AfroCAB, a self-organized group of activists, primarily people living with HIV, as they did an exceptional job of holding the WHO accountable for its recommendations around the antiretroviral dolutegravir. The AfroCAB is now widely recognized as a civil society group that must be consulted on critical issues. There are a range of groups in East and Southern Africa that play roles like this in the HIV prevention space, yet these groups aren’t always considered essential to have at the table. That’s starting to shift, and we think 2020 is the year to secure decisive change.
- Generation Now says it like no one else: women and girls and all people need to be seen as whole humans by a health system that is centered around their needs. Can you help drive a new, transformative agenda that links contraception, sexual and reproductive health and rights and HIV prevention? We hope so!

As you can see in the timeline on page 27, the coming year could bring results from trials

of antibody-mediated prevention, a recommendation on the vaginal ring from the European Medicines Agency, the launch of new trials and approaches—and more. You've got enormous energy and yet still probably agree that if we take each trial individually and weigh each against the others, we'll be worn thin and the story will get fragmented. Can you lead the discussion about the principles needed to guide all of this work? These principles might include:

- 1 Equity in access that starts with equity in investments in research such that relevant data on safety and efficacy are gathered for all bodies at risk of or living with HIV. We need to know how things work for men and women, cis- and transgender alike.
- 2 Accuracy on the part of product developers and funders in describing new strategies including the risks and benefits compared to existing ones, and likely time to market. These groups must also work with civil society to make decisions about advancing products in the pipeline.
- 3 Responsiveness from research funders, governments and other partners to civil society's clear demand for good-enough strategies now and innovation in the future. Research resources need to go to things that can get to public health programs sooner *and* those that will take more time.
- 4 A funded commitment to program design. No product works unless people can get it and use it. For primary prevention, good programs start by learning who people are and how they make decisions. This human-centered-design approach is underfunded and not yet considered core HIV prevention business.

On implementation:

- You are the implementation experts. You live and breathe the realities of today's approaches

every day. You know that not all AGYW programs are created equal and not all programs for sex workers or men who have sex with men or people who inject drugs are truly community-based, bias-free and meeting milestones for preventing or treating HIV. It's up to you to ask hard questions of the people paying for and providing prevention services. These might include some of the questions listed here:

- How do you measure how many prevention services a single person is receiving in a program that seeks to “layer” biomedical, social and structural interventions?
- What evidence do you have that a service is reducing HIV risk or improving health outcomes for people living with HIV?
- How did you come up with your messages and which segments of the population (e.g., within groups of adolescents, young men, sex workers) are they aimed at?
- How many peers do you have working in your program, what are they paid and what is their job description?

Demand that the work gets done—and only take it on yourself if it's part of your activist plan.

- Demand that the work gets done—and only take it on yourself if it's part of your activist plan. One of the ways that activist power gets diluted is when we take on tasks that may or may not be on the critical path to a goal. Does a funder or implementer want you to deliver services, assess capacity, sit on a technical working group, monitor their own programs? Increasingly, civil society is being asked to do all of these things. And while they are important, this can also be a way of co-opting activist time and energy that's needed for bold work. Some of that work may involve taking on the implementers who are offering you work and funding. Here are some things to consider:

- If you're doing community-led monitoring, (i.e., visiting sites to collect information on what's working well or not), are you planning how you will act immediately on any urgent findings via meetings, social media, demonstrations or other tactics? Have you made it clear to your partners and your funders that monitoring and action go hand in hand?
- If you've been asked to create messages for a campaign, what's your in-house expertise? Do you have a clear sense of what the current best practice is for human-centered design, and can you lead on this or ensure that the team includes a group with that essential expertise?
- If you've been asked to be on a technical working group, what decisions will that group be making? Who will chair it—will you? What power does it have, and if the power to effect change lies elsewhere, what influence can it exert?

These are some of the questions we ask ourselves every day at AVAC and in the coalitions we work with. These also might not be your questions. As your influence and power grows, we hope you'll be as critical and choosy and focused as you can be—and already are. That's one of the profoundly rewarding things about working on HIV/AIDS: every victory has been won by people who set the terms for saving their own lives and the lives of people they loved and then wouldn't back down. We all draw strength from that. You're next.

You're now!



AIDS and Climate Justice Activism

2019 saw remarkable youth-led leadership for climate justice. This includes Irsa Hirsi, a leader of the US Youth Climate Strike, who claims climate justice as an issue for people of color, pointing out that America's racial inequities extend to the impacts of environmental degradation. It also includes Greta Thunberg, who told the US Congress that "science tells of unspoken human sufferings, which will get worse and worse the longer we delay action—unless we start to act now." The health of the planet and the health of the community and the individual are intertwined. Here are two examples of global demands that, if met, could drive the agenda for climate justice and HIV.

- **Ensure that existing and new donors fund, without restriction, direct action, activism and advocacy.** Direct action works. People who put the time and energy into planning strategy and taking risks need to be compensated. Networks need to be sustained and expanded so that insights flow across fields and between generations. Yet the current global development arena is fragmented, with resources from more private-sector investors and from countries that don't have a clear human-rights agenda. In a survey of more than 90 development stakeholders published early in 2019, the majority voiced concern about "closing civil society space" around the world.⁶ Funders can and must step in with resources for groups that take risks and demand accountability.
- **Build research and scientific literacy for everyone.** Thirty years ago, people living with the virus mastered immunology, virology and the details of clinical trial design in order to build a movement to save their lives. Today's young leaders are doing the same thing with climate science. No one needs an advanced degree to master the concepts that are critical to crafting an agenda for revolutionary change. But they do need education that's free, accessible and high-quality. All children, of all genders, need and deserve this.

⁶ Ingram G and Lord K. 2019. *Global Development Disrupted: Findings from a survey of 93 leaders*. Brookings Institute. <https://www.brookings.edu/research/global-development-disrupted-findings-from-a-survey-of-93-leaders/>.

Dear Winnie Byanyima, UNAIDS Executive Director:

Welcome to your new role as the Executive Director of UNAIDS. We are part of the fourth decade of the AIDS epidemic. We are part of the transnational networks of people living with HIV and their allies who fight for their rights and their lives every day. We have been waiting for you. There is urgent work to be done, as there has been every day of these past four decades, and as there will be until epidemic levels of new HIV diagnoses are, at long last, history. Putting a comprehensive, ambitious agenda forward for addressing unmet goals in HIV prevention could be the most important thing you do this year. When UNAIDS led on ART targets, the world changed. We urge you to build on UNAIDS' history of linking commodities needs and human rights to make a clarion call for massively-scaled primary prevention. We need you to drive expanded access to prevention that works for people.

Here at AVAC, we are the current team at an organization that has focused, for 25 years, on the unfinished business of HIV prevention. Over this time, we have seen the epidemic both change and

stay the same. We have seen UNAIDS leadership move in and out of activist stances. Today, the world needs you to take approaches supported by the UTT trials to scale, get today's primary prevention to all the people who need it, and put prevention research targets in the global conversation, while continuing to fight for treatment for all.

It's the nature of HIV to intersect with other issues: when you take it on, you take on the world as it is and the work of making it as it should be. In that spirit, we share our wish list for you. Here it is in brief:

- 1 Shape the global approach to HIV and Universal Health Coverage (UHC).**
- 2 Speak the truth about stigma.**
- 3 Do—and support—the work to redistribute power.**
- 4 Balance the ledgers for prevention.**
- 5 Lift up women's voices.**

1 Shape the global approach to HIV and Universal Health Coverage (UHC).

UHC and a fierce HIV response are not contradictory objectives, but reinforcing, synergistic goals. You can be the leader who shows how this works. Specifically:

Stand up for true “shared responsibility”.

We urge you to be the leader who calls on heads of state—privately and in public—and secures

new commitments from countries at all income levels. The call for UHC is coming at a time when global resources for HIV have declined. As a number of leading AIDS activists pointed out in early 2019,⁷ there are ways that UHC, if properly implemented, could sustain and strengthen the fight against HIV. But there are also ways that UHC could undermine hard-won gains. UHC is supposed to be government-led and -provided. Yet there are a range of HIV-related investments that don't fit neatly into government health

⁷ Pages R et al. 11 April 2019. *HIV and the High-Level Meeting on Universal Health Coverage: What's at stake?* POZ. <https://www.poz.com/article/hiv-high-level-meeting-universal-health-coverage>.

budgets. These include CSO- and NGO-led services for stigmatized and marginalized groups and recruitment of lay cadres that may not be part of the formal government health workforce. These and other innovations cannot be lost or phased out in the name of "country ownership". It's essential that external aid continue at levels that do not leave gaps, even as countries increase their investment in both HIV and UHC. The worst-case scenario for shared responsibility is that it is used as an excuse for donor retreat or exit, leaving national governments to rely on health insurance schemes that exclude the poorest citizens and/or cut back on key components of a comprehensive AIDS response.

Now is the time for governments to review the domestic HIV response and identify core elements—from multisectoral prevention to peer cadres—that are supported by external funding and not easily absorbed into a UHC model. Then take steps to ensure that this funding is secure—including funding from external sources and, incrementally, from domestic commitments.

Now is the time for funders—including domestic governments—to step up and fill the HIV funding gap. It is not a matter of the epidemic remaining at status quo if the gap isn't filled. Demographic shifts mean progress can and will be rolled back without these resources. Funders must pay now to save lives and resources down the line.

2 *Speak the truth about stigma.*

The UNAIDS director has a uniquely powerful role to play in championing universal, stigma-free health care. The ongoing impact of stigma, criminalization and discrimination toward people living with and at risk of HIV is undeniable and, while the response is incomplete

and imperfect, stigma-reduction is understood to be essential. So, please lift up the undone work in HIV. Bear witness to the horrific, ongoing brutality against women, gay people, transgender people, people of color, migrants, prisoners, refugees, people who use drugs and others. Champion and direct your country offices to collaborate with civil society groups in measuring stigma, demanding action and providing services with dignity. Help to broaden this stigma work to other contexts. Stigma exists in every health care setting; it drives people away from all kinds of care. The WHO shows worrisome signs that stigma is in its blindspot when it comes to UHC. Its latest evaluation of global trends in public spending on health care is willfully ignorant of the reasons why some middle-income countries are receiving substantial aid to combat HIV/AIDS. Some middle-income countries receive aid—often to NGOs and not government facilities—because the state has abdicated its responsibility to marginalized groups. Please call on WHO to clearly and consistently factor in not just income level but the nature of the epidemic, the country's stigma index and its legal and policy environment in future analyses of disease-specific aid.

3 *Do—and support—the work to redistribute power.*

HIV/AIDS activists have won unprecedented access to and influence in spaces where health policy and budget decisions are made. Maintaining this access is a daily fight in the context of HIV. The space isn't and won't be granted without a struggle in the context of UHC or other diseases. You can work with civil society, government leaders and colleagues to call out and refuse tokenistic approaches to involving civil society. Please use your influence with heads of state to ensure that civil society access to and

influence in UHC-focused processes is robust, complete and inclusive. Please lift up, be seen with, listen to and support autonomous, self-convening, independent civil society forums led by and for those impacted by the decisions made and most likely to be excluded from formal dialogue.

4 *Balance the ledgers for prevention.*

The WHO's latest evaluation of global trends in public spending on health care found preventive care to be just 11 percent of public health spending and 12 percent of global health spending.⁸ In the powerful UNAIDS *Prevention Gap* report of 2016,⁹ your agency identified a gap in spending: most countries are not meeting the “quarter for prevention” threshold, and many donors, such as PEPFAR, only reach it when they count HIV testing (regardless of whether the person tested is linked to services) as well as prevention of vertical transmission. Twenty-five percent for prevention is a minimum for HIV—and could be an aspirational goal for UHC, as well. Calls for spending on today's prevention should go hand in hand with a clear message on the need to maintain funding for research on new strategies.

5 *Lift up women's voices.*

Today the news about unmet need among young people, and especially young women, is stark. Contraceptive coverage is climbing in some places and not in others; expansion of contraceptive choice is uneven, as well. Young women who want contraception and live in high-prevalence communities are at

astronomical risk of HIV, but many don't feel that way and so don't have a plan for effective HIV prevention. Others worry about risk but have no access. This isn't a matter of advocating for tools or integration, though that's important, too. We need now—more than at any point in history—a woman leader who ceaselessly, passionately and tirelessly elevates her own and other unapologetically female voices to do what is needed. There is no end to the HIV epidemic without investments in primary prevention and provision of comprehensive sexual and reproductive health and rights programs. Yet there is, at present, a lethal and insidious war on women's lives and bodily autonomy being waged by governments, societies and cultures. This takes the form of the expanded Mexico City Policy, which is eviscerating many groups' budgets and/or ability to integrate contraception and HIV programs. It takes the form of domestic US policy developments that have set American women's rights and ability to access comprehensive sexual and reproductive health services back by decades. It takes the form of “#metoo” harassment and assault perpetrators receiving warning letters and gentle reprimands, of lofty “ending AIDS” goals that overlook the ways that cisgender women with HIV are still often fighting for basic things: decision-making power about trials and products that affect them; data that says what new products do in their bodies, and more. It takes the form of underspending on siloed programs and unmet goals for expanding contraceptive coverage.

We look to you to connect these dots, to change the conversation—and women's lives.

⁸ Xu, Soucat et al. 2019. *Public Spending on Health: A Closer Look at Global Trends*. WHO. https://www.who.int/health_financing/documents/health-expenditure-report-2018/en/.

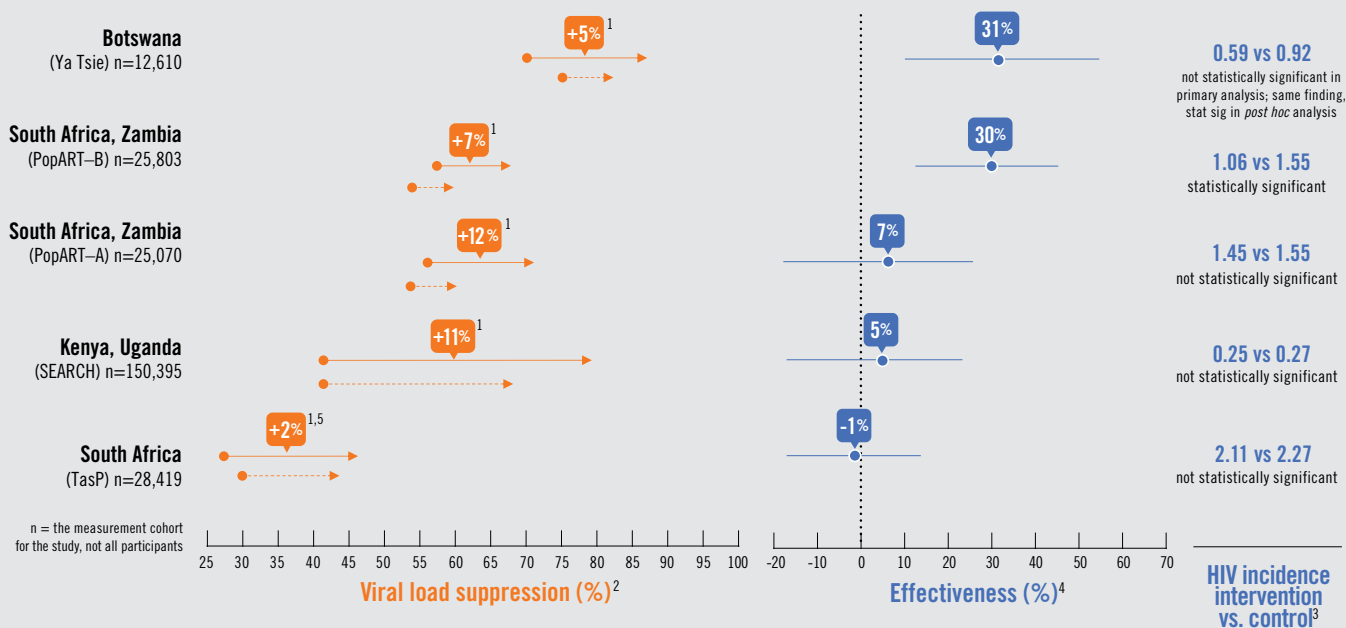
⁹ UNAIDS. 2016. *Prevention Gap Report*. <https://www.unaids.org/en/resources/documents/2016/prevention-gap>.

FIGURE

3

Declines but Not a Decisive Effect of the Intervention: Key results from “universal test and treat” trials

UNAIDS' Fast-Track Goals for ending the epidemic focused on testing 90 percent of people living with HIV, linking 90 percent of those people to ART, and supporting 90 percent of those individuals to reach virologic suppression. The busy figure below summarizes recent research on how reaching these targets impacts incidence. Each orange arrow shows the level of virologic suppression among PLHIV in the community at the start and end of the trial, the pairs of arrows represent different trial arms. The figure in the box above is the absolute difference in suppression between the two arms. For PopART, which had three arms, there are two different comparisons. The longer arrows belong to the intervention arms, which had a greater increase in virologic suppression across the trials. The blue bars show the point estimate for, and confidence interval around, the relative incidence in the intervention arm compared to the control arm. The bottom line: arms with community-wide testing saw incidence drop. Rapid expansion of ART leading to virologic suppression is feasible. This is good news for communities and individuals.



¹ Difference in virologic suppression (<400 copies/mL) between the intervention and control groups at the end of the trial.

² The dot is the virologic suppression percentage at baseline, and the arrow is the virologic suppression percentage at the end of the trial. The figure in the orange box is the absolute difference in suppression between arms.

³ HIV incidence is per 100 person-years.

⁴ The dot and blue box is the point estimate of effectiveness in preventing HIV (relative HIV incidence in intervention versus control arm) and the lines on either side represent the 95% confidence interval.

⁵ Viral suppression at baseline was estimated from baseline ART coverage, assuming 90% of ART patients were virally suppressed.

Adapted from Abdool Karim, S. 2019. *HIV-1 Epidemic Control—Insights from Test-and-Treat Trials*. *N Engl J Med*. 381:286-288. DOI: 10.1056/NEJMe1907279.

2

NO**W**

**Use today's evidence to guide
tomorrow's prevention targets**

The world is going to miss the 2020 incidence-reduction target not because it tried everything and failed, but because many things didn't get funded or evaluated and fixed when needed. Prevention impact can be achieved and measured. Let's not waste any more time.

No Time to Waste

Never has the phrase “hindsight is 2020” had so much resonance. Very soon, the world will arrive at the 2020 deadline previously set for achieving a range of targets that linked to ending epidemic levels of HIV worldwide. Deliver HIV testing so that 90 percent of people living with HIV know their status, make sure that 90 percent of those people are linked to antiretroviral treatment and that 90 percent of them are virologically suppressed. Support three million people at substantial risk of HIV to start and stay on PrEP. Put condoms and lube in the hands (and bedrooms) of everyone who wants and needs them. Reach 27 million additional men with voluntary medical male circumcision from the 2016 baseline of 14 million. Slash stigma, shore up human rights. (For a look at all of the prevention targets, see *AVAC Report 2016*, <https://www.avac.org/infographic/unaid-2016-2021-strategy-what-does-it-say-about-prevention>.)

Not only will the world fall short of individual targets, but, more importantly, the all-important milestone of driving new HIV infections down to 500,000—from an estimated 1.7 million each year—will be missed by a long shot. This doesn't mean that the targets were a bad thing. At AVAC, we love a target that ticks the boxes that we described in our “Anatomy of A Target” in 2015: audacious, achievable, resourced, measurable, accountable, backed by political will and a collective priority (<https://www.avac.org/infographic/turning-targets-impact>). And we think that hindsight can be a powerful tool for recalibrating visions of the future. Here's what the next generation of prevention targets needs to draw on:

1 A universal prevention cascade—with “effective use” as the final step.

In past *AVAC Reports* we have proposed and argued for the use of prevention cascades to track progress in the implementation of key strategies, such as PrEP. We've looked at and adapted a range of cascades. We've also urged PEPFAR to require countries to present a prevention cascade as part of their annual Strategic Direction Summaries. But these efforts have been hindered by the complexity of creating cascades based on HIV-negative populations. You don't need to reach everyone who is HIV-negative, since many of those people are not at risk of HIV. Estimating the size of groups that are at risk can be tricky, especially when it comes to groups that are stigmatized and criminalized. However, even with rough estimates, a cascade-driven approach gives a much better picture of what's working and what needs attention. Now, there's progress to a usable model that needs to make it into the field.

In early 2019, members of the HIV Modeling Consortium (an international group of epidemiologists, statisticians and others who work on modeling that shares ideas, compares projections and develops tools for the field) proposed a unifying framework for a prevention cascade that would measure progress on:

- reaching a target number of people who would benefit from a product;
- identifying, within that group, who wants to use the product (choice is key!);
- measuring who can access that product—comparing coverage with interest; and
- measuring effective use.

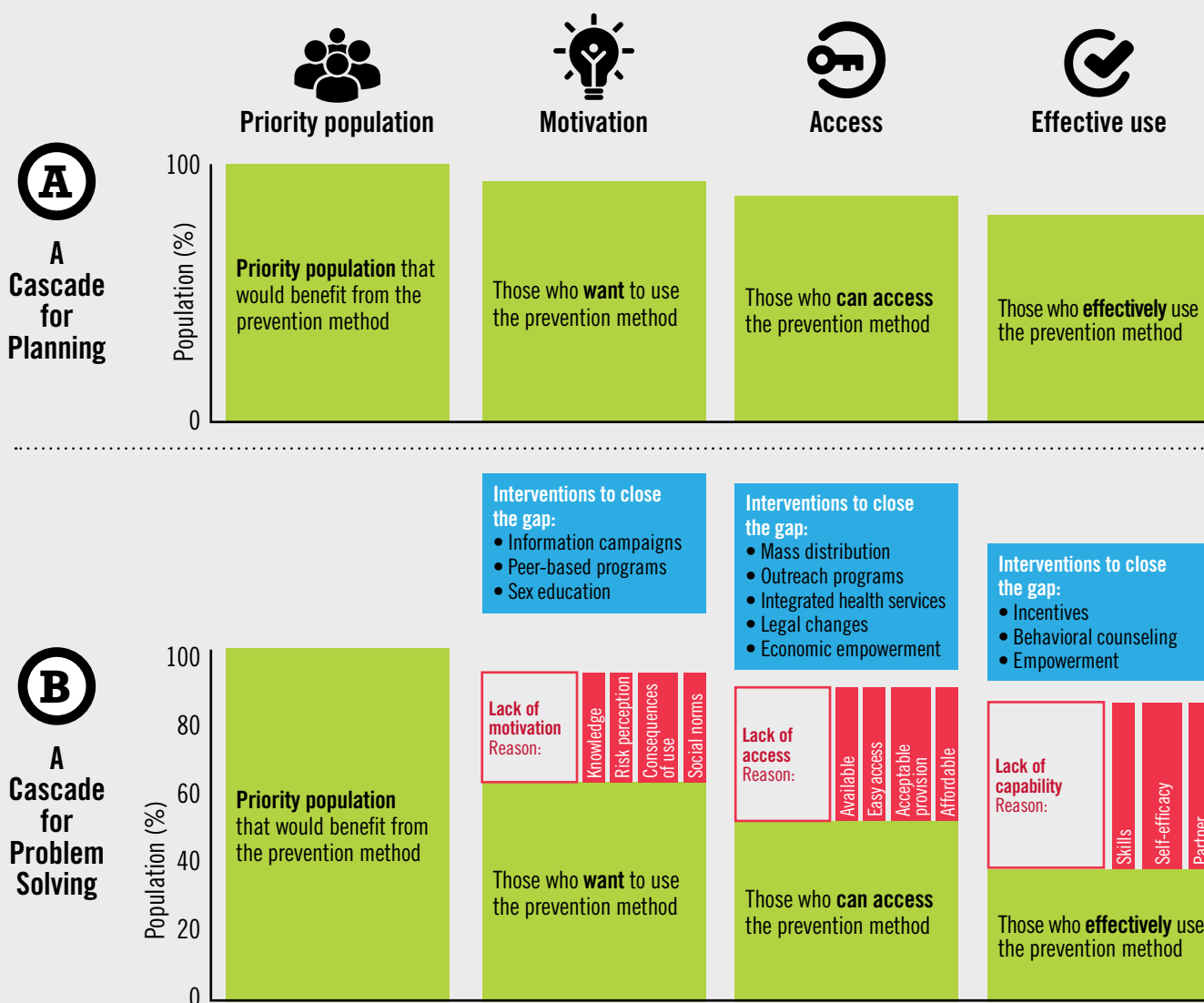
One key feature of this cascade is that it culminates in “effective use” of the strategy. For people living with HIV, ART frequently brings a return to health and, ideally, a normal lifespan. The impact of ART programs is sometimes

FIGURE

4

A Generic and Unifying HIV Prevention Cascade Framework

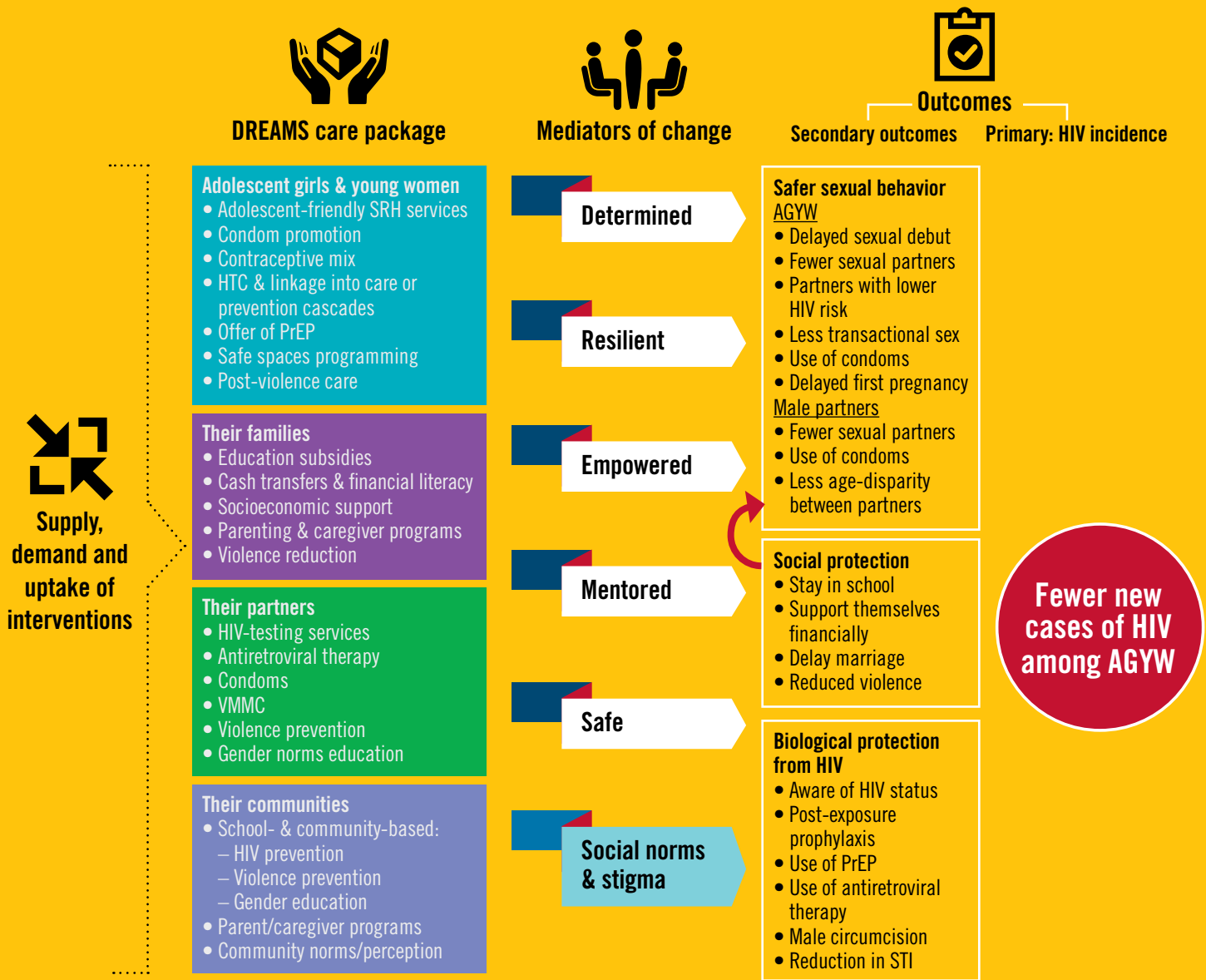
What gets measured matters if and only if that measurement is linked to impact. The most common approaches to evaluating primary prevention don't measure up. They measure commodities but not use. A count of the condoms or PrEP bottles handed to people does not tell you whether the condoms were used, the pills were taken—or even, often, whether the people receiving the commodities were at high risk of HIV. A simple, universal prevention cascade could help change that. The one below, which presumes that HIV testing has happened and is focused on people at risk of HIV, suggests four stages (see A) and then shows how solutions could be tailored to fix the cascade (see B).



Adapted from Moorehouse L, Schaefer R et al. July 2019. *Application of the HIV prevention cascade to identify, develop and evaluate interventions to improve use of prevention methods: examples from a study in east Zimbabwe. J Int AIDS Soc. (Suppl 4): e25309.*

FIGURE 5 **Visualizing Multisectoral Prevention: The DREAMS program theory of change**

Below is PEPFAR's own visualization of how its AGYW programs can effect change. It's notable for the definition of a care package that touches on the individual and her community, and for the way it defines a range of outcomes. There isn't anything comparable for PEPFAR's Key Population Investment Fund, which is infusing resources into a range of countries. Some of that funding is going for ART; for primary prevention, a theory of change linked to incidence is a must. AVAC is working with allies in KPIF countries to make this demand.



Birdthistle I, Schaffnit S et al. 25 July 2018. *Evaluating the Impact of the DREAMS Partnership to Reduce HIV Incidence Among Adolescent Girls and Young Women in Four Settings: A Study Protocol. BMC Public Health.* 18(1):912. doi: 10.1186/s12889-018-5789-7.

described in terms of AIDS-related deaths averted, but these deaths aren't actually counted. (Many countries don't have reliable autopsies, and stigma still prevents people from listing AIDS as cause of death.) Instead, the impact on mortality is inferred from the effective use of ART, which is, in turn, inferred by measuring virologic suppression. People living with HIV need to take pills consistently to suppress the virus so "undetectable" is equated with effective use. For primary prevention, the outcome is that people do not get HIV, but it's notoriously hard to prove a negative. "People reached" or "condoms distributed" or even "people started on PrEP" do not equate to effective use, since pills may not be taken, condoms may or may not be used. You can't count commodities to assess primary prevention impact. But there are other measures that can be employed, with many of these using existing or readily-accessible data, as we describe on the next page. These data need to be incorporated into primary prevention cascades that give a better picture of prevention impact.

The best way to find out whether cascades improve delivery and evaluation of primary prevention is to field-test them widely. PEPFAR, the Global Fund, the Global HIV Prevention Coalition and individual countries should begin to collect—and communities demand—these primary prevention data. Problems and proposed solutions should be consistently presented in a version of this universal prevention cascade format.

2 *Well-defined metrics of effective use*

Primary prevention has struggled for years with the ideological and practical problems of efficacy and effective use. Abstinence and condoms are both one hundred percent effective in the context of perfect use, which is both hard to measure and ridiculous to employ as a national prevention strategy. But there's new science—particularly coming from the PEPFAR DREAMS

program and from work on oral PrEP—that provides concrete, scalable approaches to effective-use measurements that, if widely adopted, could build confidence that prevention dollars are going where they'll have the most impact. Here's a look at how effective use is used in different prevention arenas.

- **Defining effective use of multisectoral, layered strategies**

An ongoing evaluation of PEPFAR's DREAMS program, being undertaken by the London School of Hygiene and Tropical Medicine (LSHTM), is collecting and analyzing several different kinds of data to try to tease out where and how DREAMS programs have reduced incidence. This includes interviews with young women engaged in DREAMS, detailed reviews of who received which services, and more. The LSHTM team is also looking at whether there is a "dose-effect" in DREAMS interventions, that is, a link between the number of DREAMS interventions a girl or young woman receives and her declining risk of HIV. This is sophisticated, expensive science—and exactly the kind of impact evaluation that a new program like DREAMS should have. PEPFAR's forthcoming Key Population Investment Fund should build in something similar.

You can't count commodities to assess primary prevention impact.

Intensive impact evaluations can't happen everywhere. So it's equally important to use existing data to estimate impact. PEPFAR is looking at new HIV diagnoses and pregnancy rates among AGYW at antenatal clinics in areas covered by DREAMS over time. These changes are used to infer the program's impact on incidence. Such data are routinely collected and available in all countries. Every country could look at AGYW prevention

programs in this way and identify communities where there is effective use of multisectoral approaches (meaning that these approaches are in place, reaching the right people and having the intended impact) and identify those that report offering these services but do not see impact.

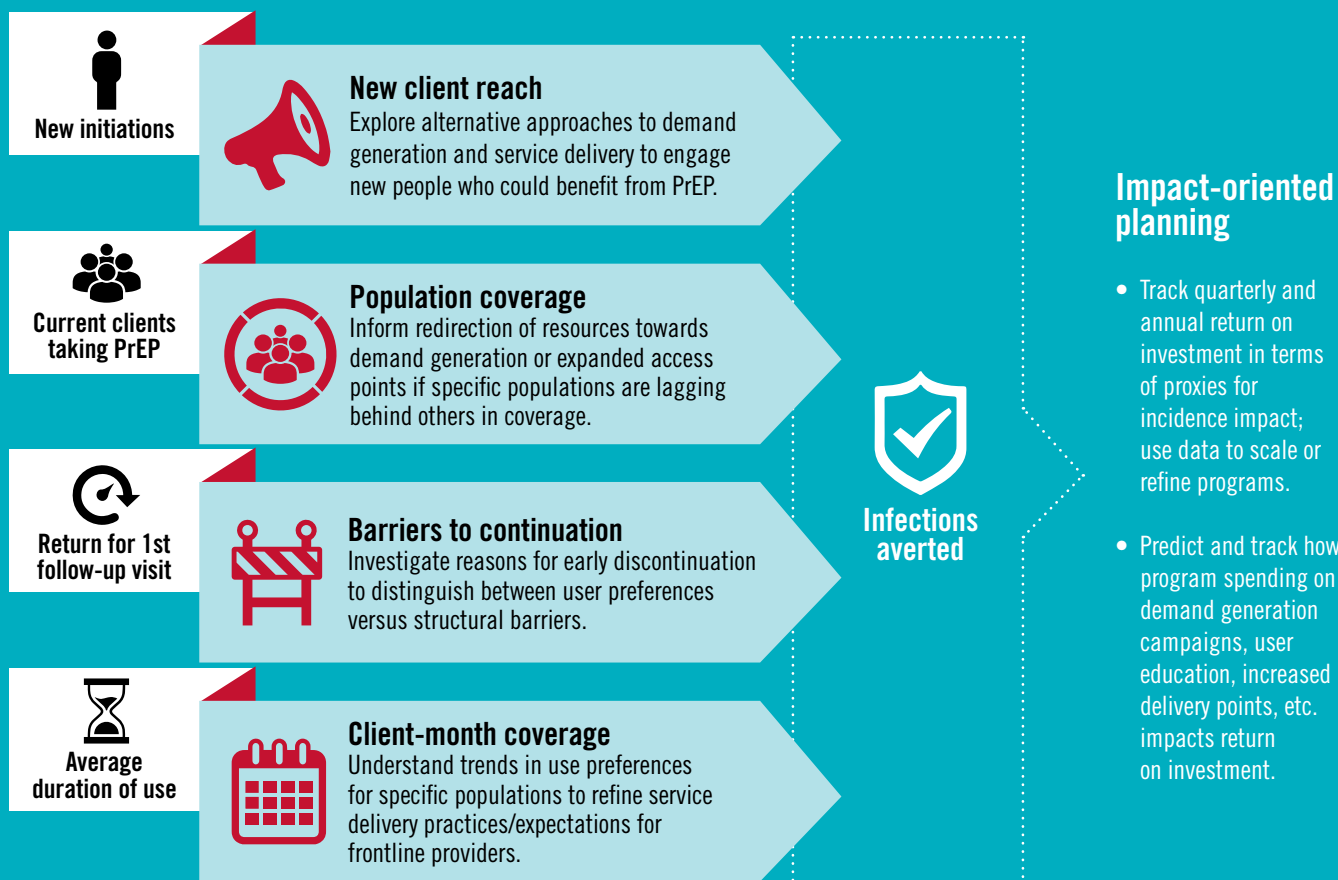
Effective use of a multisectoral strategy requires reaching an individual and a community in different ways: changing norms and economic opportunities and offering

quality health services. This is sometimes called “layering”, and it’s a key element of multisectoral prevention. To ensure that layering is happening, service providers need to ask people about their whole lives and record select information; AGYW- and KP-friendly facilities and drop-in centers could have a standard approach to collecting information on the educational, economic, stigma-related and violence-reduction services a person wants or is receiving. Communities can also help gather this information.

FIGURE

6

Monitoring Primary Prevention: What to look at and why it matters – for oral PrEP and more








These aren't cheap or easy solutions. Data collection can be onerous, and health workers are overburdened. But without an effective use measure that captures layering and multisectoral strategies, AGYW and key population prevention spending may be squandered—as it is all too frequently—on programs with good intentions and little impact.

- **Defining effective use of daily oral PrEP**
As stated in the Executive Director's letter, the initial data coming in from PrEP programs

show that many people who start PrEP don't stay on it. That's especially true for AGYW in sub-Saharan Africa, who need new prevention options. The data are clear, and they point to the need to refine programs, including the integration of contraception and HIV, as we discuss further in Section Three. But in addition to refining programs, it's also important to refine how these programs are evaluated. This isn't a dodge to try to make oral PrEP look better than it is. It's an essential adjustment, reflective of the ways that primary prevention differs from treatment.

FIGURE 7 **What Gets Measured Matters: PrEP monitoring varies widely by country, funder and normative agency**

There is enormous variability in country and funder/normative approaches to tracking PrEP program rollout. Assessments of progress require common, comprehensive measures against and estimates of the parameters below.

	National Oral PrEP Program Indicators			Funder/Normative Guidance Recommendations		
	Kenya	Malawi	South Africa	UNAIDS	PEPFAR	World Health Organization
 New initiations	✓	✓	✓	✓	✓	✗
 Current clients taking PrEP	✗	✗	✗	✗	✓	✓
 Return for 1st follow-up visit	✓	✗	✗	✓	✗	✗
 Average duration of use	✗	✗	✗	✗	✗	✗
 Inferred estimate of infections averted	✗	✗	✗	✗	✗	✗



Research Targets: Time for the spotlight

Well-framed targets shape expectations and support accountability. The lack of clear, public, prevention research-focused targets is holding back the field and the global response. Early moments—such as US President Bill Clinton calling for an AIDS vaccine within 10 years—did not result in a licensed vaccine, but the target catalyzed the field, driving new investments, focus and prioritization. Now, the research pipeline is full and complex. There are more trials, more trial participants and a more diverse array of prevention options in development than ever before. Results from multiple efficacy trials of different approaches—a long-acting injectable, an infused antibody, and two different vaccines—are expected over the next three years. The European Medicines Agency is expected to issue its opinion on the dapivirine ring in 2020; this could provide a discrete, longer-acting HIV prevention option and also serve as the basis for future dual-acting products.

In the longer term, three vaccine efficacy programs are underway (see Figure 8 on the next page). The product development pipeline is booming with combinations of antibodies, multipurpose products, a monthly ARV-based prevention pill, along with films, implants and microneedles (a novel injection approach) and novel vaccine strategies such as the SOSIP trimer to elicit neutralizing antibodies.

But trials are notoriously unpredictable. They don't always start or end when scheduled and the results are impossible to predict in advance—even though it's tempting to try! So a target like “We'll have an AIDS vaccine in 10 years” has been tough to deliver on. But the global AIDS response can and must have process targets that people who aren't steeped in the science can follow and influence. UNAIDS should include these in the next set of milestones to shoot for, and the Global

Prevention Coalition should support country-based discussions of what these targets—and national research agendas—mean in different contexts. Here are the kinds of milestones we'd like to see:

- **By mid-2020: a clear plan for gathering information on F/TAF as PrEP in cisgender women.** The FDA approval of F/TAF for adults and adolescents, excluding those who have receptive vaginal sex, reflected poor guidance on the FDA's part and poor product development planning on the part of Gilead, the maker of F/TAF. Work is now underway to understand what the company's post-approval commitments for further research in cisgender women will look like—and who will decide. In October 2019, the company announced its intention to seek input from “Africa-based” community advisors on key elements of the study, such as site selection, recruitment and ongoing study management. Cisgender women worldwide, and especially in Africa, will be tracking and actively engaging in this process, as will AVAC and our partners. Gilead needs to listen, partner and act with speed. With a new trial slated to start in mid-2020, there is a need for a comprehensive product development plan for F/TAF as PrEP for cisgender women. Product developers, funders and regulators must also act on the lessons from F/TAF such that this type of egregious omission in data collection doesn't happen again—for any population.
- **By early 2020: an ambitious timeline for acting on the results of injectable PrEP:** Stakeholders involved in development of injectable ARVs for prevention need to plan for and commit to executing the critical steps required for regulatory submission, consideration and approval decisions within

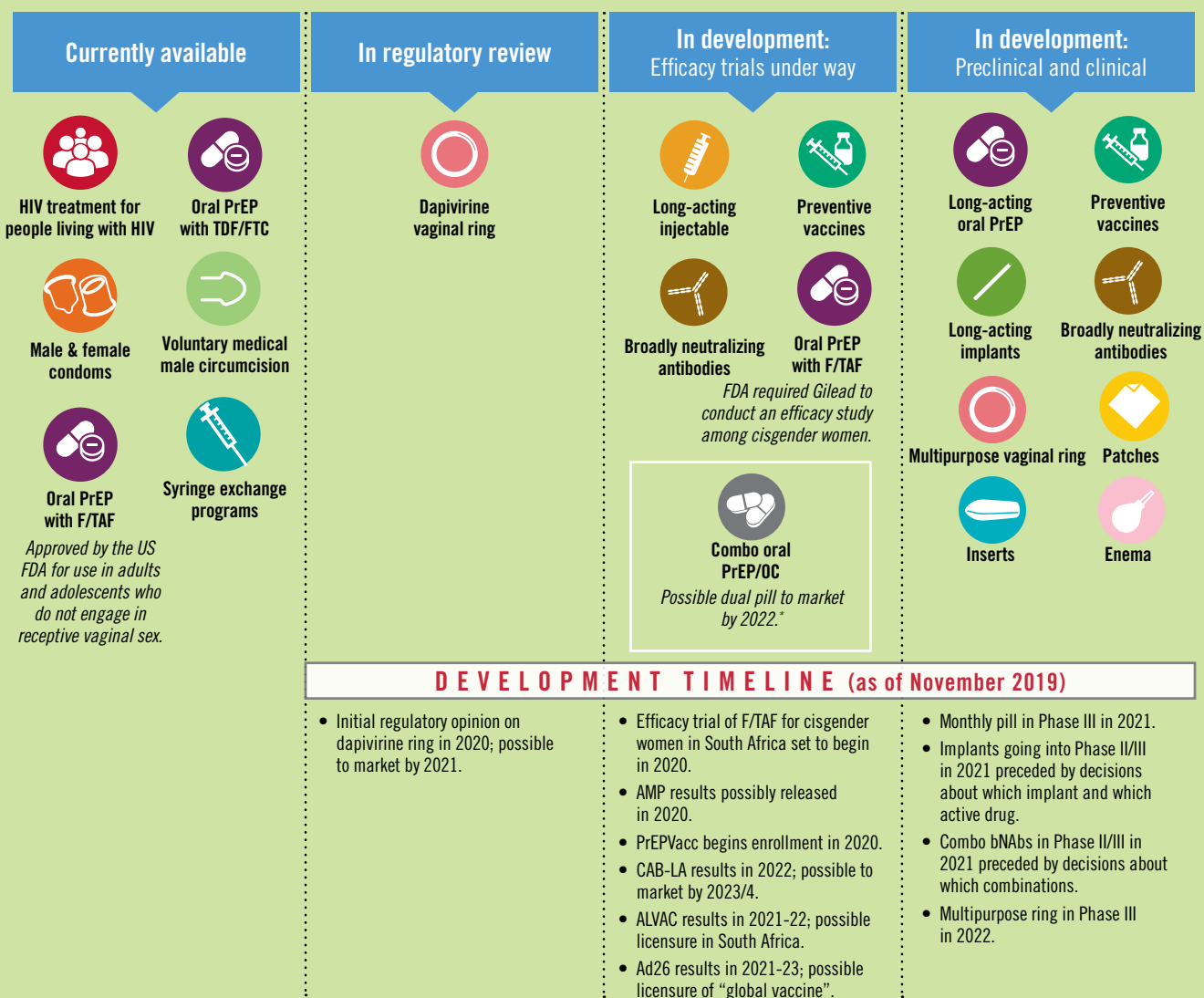
12 months of efficacy data, if positive; introduction plans and initial pilots within 18 months; and introduction in national HIV prevention programs within 24 months. The Prevention Marker Manager, an initiative led by AVAC in partnership with CHAI, convened the Biomedical Prevention Implementation Collaborative (BioPIC) to help make this a reality. The BioPIC has developed a consensus

framework for introducing long-acting injectable PrEP, if it is shown to be safe and effective in the current trials. This framework could also be adapted for other forthcoming products.

- **By (and included in) the 2020 UNAIDS global prevention report: an HIV vaccine target for the 21st century.** There is no need to promise

FIGURE 8 HIV Prevention Research, Development and Implementation Pipeline in 2020—and Beyond

The graphic below shows the wide range of HIV prevention and multipurpose prevention products (MPTs) available and in the pipeline. For a look at the timelines for when efficacy trials will have results, see Figure 13. Products that are “in development” are, for the most part, many years away from regulatory consideration and wide-scale introduction. The exception: combined oral PrEP and oral contraceptives, which could be ready in two to three years, at least five years before the next MPT might come to market.



* Efficacy trials not required; bioequivalency of the two approved products when dosed together may be all that is required.

Additional information on trials and products in development available at www.avac.org/pxrd.

a product to set a target. Set a deadline for consensus in key countries about actions to be taken in the context of different efficacy scenarios for current candidates and lay out milestones for when follow-up research and/or product introduction plans should be in place if there is a positive result. The global spotlight hasn't shone on vaccine research for some time, and with two vaccine candidates in large-scale efficacy trials, the time is now.

- **By 2021: an injectable combination bNAb in efficacy trials.** Antibody-mediated prevention, (AMP), which seeks to use potent, HIV-specific immune responses to protect against infection, could be an alternative or complement to ARV-based injectables. Promising results from the AMP trials of the VRC01 bNAb, which could come as early as 2020, should prompt investment and action on plans that are already underway.
- **By, and released at, the 2020 HIVR4P conference: fieldwide prevention research milestones specific to—and owned by—women, adolescent girls and key populations.** Everyone at risk today—especially women, adolescents, MSM and transgender people—needs biomedical prevention method mix, mirroring the contraceptive field. Contraceptive method mix includes a long-acting method, a short-acting method, an emergency method and a barrier method. In HIV prevention, this could be an ARV-based implant or injectable, oral PrEP or the dapivirine ring, PEP and male and female condoms and lube.
- **By the end of 2020: guiding principles for the next generation of prevention trial designs endorsed and integrated into updated ethics and GPP guidelines.** Primary prevention trial ethics dictate that all people in a prevention trial should receive the best available standard of prevention, even if the strategies are flawed. This poses challenges for the size and design trials of next-generation products. Proposed designs raise questions the field hasn't grappled with before like:
 - Is it ethical to conduct a placebo-controlled trial of a new ARV-based prevention strategy, in which participants are not given PrEP and are enrolled on the basis of their stated preference not to use the strategy?
 - Are there ways that statistical calculations can fill gaps, such as using a hypothetical estimate of what the rate of new HIV diagnoses would be in a given population as the comparator to the observed incidence in that population when a new strategy is introduced?

Both the discussion of and the eventual answers to these questions will shift current norms around regulatory oversight, trial operations and ethics. As of now, there's no clear "right" next-generation design. But it is clear that these decisions can only be made with robust community input. AVAC and our partners know that in order for concerned communities to truly have a say, the processes for engagement need to be well-defined and -funded. There is no room for cutting corners, especially now. Some of the things we will work towards with our partners include:

- Guiding principles about stakeholder engagement that look specifically at when and how a protocol is reviewed by the communities where the trial will take place. GPP currently states that protocol review is a must, but it still isn't always done.
- Independent review boards and ethics committees requiring documentation of engagement with civil society as part of any submission, delaying approval if it's inadequate.
- Civil society could work with researchers to develop principles for various kinds of scenarios for trials—without regard to specific trials.

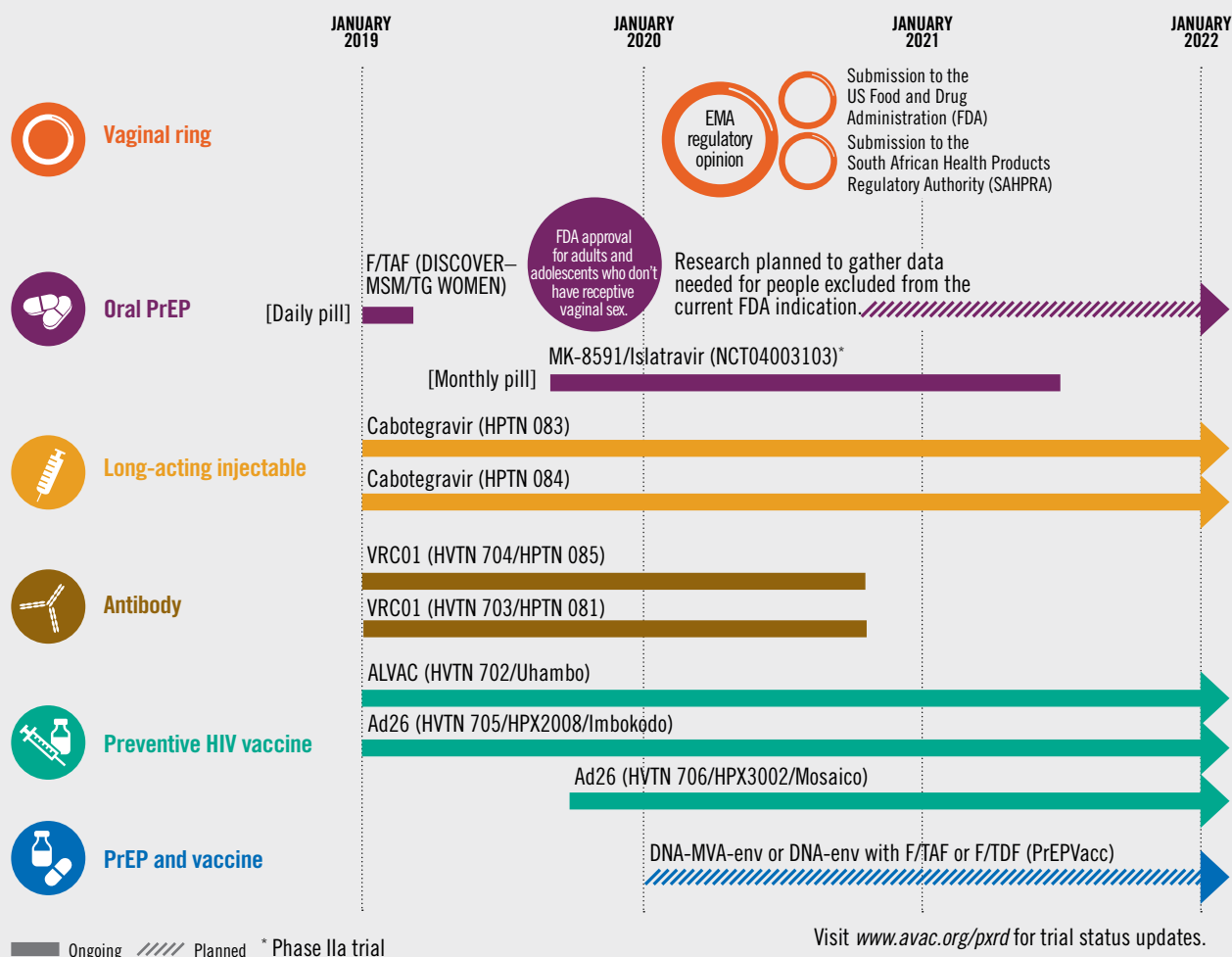
AVAC is already working to ensure that calls for community engagement in complex trials are operationalized, resourced and monitored.

The future of PrEP—both oral PrEP today and the next-generation options of tomorrow—depends as much on fixing the standards by which programs are evaluated as it does on fine-tuning the programs themselves.

People move in and out of times of HIV risk and phases of their lives where an oral pill is the right choice for prevention. Finding the right effective-use measure is key, therefore, to understanding the impact of PrEP investments and making decisions—guided by the prevention cascade—that improve services and use over time. At a 2019 Think Tank on Defining and Measuring Effective Use

of Oral PrEP, a range of stakeholders agreed that, in order to talk about and evaluate effective PrEP use, programs need to have a grasp of the length of time that people stay on PrEP and the intervals between their periods of PrEP usage, and an understanding of the ways that a person’s HIV risk fluctuates over time, as economic, household or other factors change. This isn’t part of PrEP evaluation, which tends to equate a longer time on PrEP with better program performance, and does not look at all closely at fluctuations in levels of risk. Indicators of PrEP use are typically measured by cross-sectional approaches

FIGURE 9
Biomedical HIV Prevention Trials: Results, milestones and more



(e.g., how many people are enrolled in a PrEP clinic on a given day) or client-level longitudinal approaches (e.g., how many people are enrolled in a PrEP clinic on a given day, and how many people come back for a refill one or three or six months later). This approach to measurement is important but not sufficient by itself. It can track how many people come back and who came back, but it doesn't provide information on why someone did stop PrEP—e.g., whether their risk level had changed or whether it didn't work in their lives. So it isn't really getting at core issues about how the program is working.

Now what?

At the 2019 think tank on effective use and PrEP evaluation, a number of recommendations were made that could be adapted by PEPFAR and by countries seeking to better understand the impact of their investments. The proposal is a conceptual shift: what if, instead of measuring the number of clients on a given date and tracking refills, programs were to measure how much PrEP use was occurring across a community at a given moment in time? In other words, what if we take the focus off of a clinic and into the community to measure the “saturation” of PrEP, which could

PrEP Scale-Up Agenda Checklist

WHAT?

Daily oral PrEP works for some people but not for all. It's the only approved woman-controlled strategy that doesn't need to be used at the time of sex. It's effective. It can be discrete. The problem is figuring out how to make it work in people's lives.

NOW

PrEP Funders and Implementers:

- Learn from existing programs and human-centered design projects. Iterate and improve.
- Change the approach to measuring impact—adopting “effective use” based prevention cascade.

Product Developers:

- Evaluate and bring to market a combination PrEP and oral contraception product.
- Use today's PrEP to build platforms for next-generation products such as injectable ARVs.
- Put product introduction plans informed by daily oral PrEP experience in place today for upcoming products.
- Restore trust in the research enterprise by getting F/TAF approved for cisgender women.

UNAIDS:

- Make the “quarter for prevention” funding allocation proposed by UNAIDS a reality, and put more PrEP in more places to begin to saturate communities.

Civil society:

- Don't settle for anything less than PrEP and all biomedical strategies in the context of multilayered prevention offerings.

come from lots of people using it for short periods of time rather than a set number of people starting and staying on it? Right now, this approach is at the hypothesis stage. It seems feasible in low- and lower-middle-income countries, but there are key variables and systems that need to be in place. If there is enough information about PrEP coverage and HIV incidence in the populations using PrEP in a community, then a calculation of community saturation should be possible. Some of the information to support these estimates is readily available; some of it would need to be collected via new indicators.

Countries and communities seeking to understand the best use of prevention dollars also have a vested interest in refining these indicators, and they can make this case to funders, including PEPFAR, which is actively considering how best to measure the impact of PrEP programs. Modifications to current PrEP indicator and monitoring-and-evaluation approaches include:

- Report PrEP_NEW, the current PEPFAR indicator measuring number of people newly initiated on PrEP, on a quarterly basis.

This should include disaggregation by key population status and age.

- Add an indicator to measure the distribution of PrEP (i.e., number of pills/bottles distributed combined with number of individuals prescribed PrEP/population size) as a proxy or initial step in measuring impact based on PrEP coverage.
- Explore with national PrEP technical working groups the potential for piloting an impact indicator based on distribution of pills or bottles in settings where PrEP is sufficiently scaled up.
- Support countries to define and collect data to support evaluation of effective use.
- Support the program evaluations and implementation science to identify the reasons for oral PrEP discontinuation and—if related to program quality—identify effective interventions and strategies to improve the quality of PrEP programs and to better understand episodic or sporadic use.
- PEPFAR should assign a PEPFAR budget code to PrEP, making it possible to monitor investments.



Prevention and Global Leadership: Time for new targets, sustained investment resources and technical excellence

What do global funders and implementers working on the AIDS response need to do post-2020? First and foremost: sustain investments. The most recent replenishment round for the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) met its target of \$14 billion. That's cause for both celebration and vigilance. \$14 billion was a floor—not a ceiling—for what is needed to fund the global fight. PEPFAR's funding is dependent on the whims of an unpredictable US President and it is already stretched thin. The newly-filled coffers could empty quickly if the Global Fund is expected to fill gaps in PEPFAR programs. There are still looming gaps in funding for regional and country-specific HIV programs, which prevent sustained progress and must be filled. Funding for research is also in limbo. 2018 saw a small uptick in resources after five years of declining investment. But that's the smallest net increase since 2003 (for more on research funding visit hivresourcetracking.org). We know investment is tied to evidence of impact and confidence that funds are doing the most needed work. Here are some ways to build that confidence:

GFATM Technical Review Panels must demand high-quality prevention proposals. There is enough evidence from DREAMS about what incidence-reducing layering for AGYW looks like that comparable programs funded by the GFATM can be evaluated with rigor (see pgs. 22-23 for more on this). A project proposing to set up drop-in centers for AGYW without condoms, community change, PrEP and so on isn't proposing DREAMS-like work. That's a single intervention and not a layered package, and it

shouldn't be funded. GFATM can and should do what it can with central resources, too. In 2020, look for a centrally-funded, condom-focused strategy guiding GFATM investments in condom promotion, targeting and measurement.

Advocates should advance a primary prevention agenda that mirrors the epidemic.

We are all advocates—and we all should speak up loud and often for primary prevention and ART services that work for those most in danger of being left behind. Where it's relevant, veteran activists should be sure to step back and let people—particularly young people—from those most-affected groups speak for themselves.

The global funders of HIV, TB and malaria should improve data transparency.

AVAC and partners in the COMPASS coalition (avac.org/compass) have been working with the Global Fund Secretariat to improve the quality and transparency of GFATM data that is collected and shared. We are also working to ensure that community-led monitoring that identifies issues and activates solutions based on local knowledge is explicitly supported in the next round of funding. PEPFAR and the GFATM along with countries should continue to meet demands for detailed, timely, usable data.

Global leadership should advance concise, clearly-defined post-2020 “epidemic transition” metrics.

In 2018, UNAIDS released its sobering “Miles to Go” report on the state of HIV prevention efforts worldwide. It showed pockets of progress and swathes of unchecked incidence.¹⁰ There is a clear need for metrics of progress that capture this heterogeneity. Some

¹⁰ UNAIDS. 2018. *Miles to Go: Global AIDS Update 2018*.

new ones have been proposed; see page 34 for the ideas and their pros and cons, propelling discussion on metrics for epidemic transition and for measuring stigma. We're going to work to catalyze these new metrics by joining with activists and advocates to push for ambitious, measurable and meaningful targets.

Global stakeholders must set ambitious new targets for the post-2020 world. Here are seven suggestions focused on primary prevention of sexual transmission. The same are needed for people who use drugs, and ending stigma and discrimination.

- 1** Ensure that by 2021 there is 100 percent implementation of a prevention cascade framework for evaluating primary prevention interventions at GFATM, PEPFAR and country levels.
- 2** The 2020 PEPFAR Country Operational Plan Guidance and GFATM guidance should contain harmonized technical instructions for developing and implementing multisectoral prevention programs for both AGYW and key populations.
- 3** By the end of 2021, all PrEP funders and stakeholders should adapt new indicators for the evaluation of PrEP impact. One-hundred percent of countries with PrEP programs should also have national PrEP plans that consider how this strategy links to other primary prevention, self-testing, structural and rights-based interventions, and builds platforms for the introduction of the vaginal ring and other next-generation options.
- 4** The condom gap should be closed in all countries by the end of 2025, with the stipulation that the gap isn't closed unless

there are commodities (condoms *and* lube), updated social marketing programs linked to peer and provider training on messaging, and delivery channels to make sure that latex is where it needs to be the most.

- 5** There should be a five-year plan for five new prevention strategies to reach the regulatory stage of product introduction. The research pipeline was left out of the last UNAIDS targets, even though next-generation strategies are critical. Within five years, a dual pill, the dapivirine ring, F/TAF for PrEP, injectable PrEP and possibly an AIDS vaccine could all be arriving at—or possibly even finished with—regulatory consideration. AVAC wants UNAIDS to put research milestones at the foreground of the global response including acting on results and launching next-gen trials.
- 6** Around the world, 2021 should be free of contraceptive stockouts and should see 100 percent of sexual and reproductive health programs in HIV-endemic and hyper-endemic settings offering HIV prevention (including PrEP) to all women.
- 7** All countries and communities that haven't yet reached 80 percent of infants, boys or men targeted by the national prevention plan for VMMC should have funding and strategies in place to meet those goals by the end of 2025.

These suggestions—and many others—need to be backed up with hard targets that reflect modeling, on-the-ground evidence and the centrality of local decision-making. If it isn't named, it won't be pursued. The time to be bold, specific and focused on primary prevention is—NOW.

TABLE

2

Metrics for Epidemic Transition: A glossary

Following the 2016 UN High-Level Meeting on HIV/AIDS, UNAIDS undertook work to derive a better definition of what “epidemic control” might look like and how it might be measured. It turns out that out saying the era of seeking the “end of the AIDS epidemic”—a phrase from a few years back—has come to an end. It’s rhetorically powerful but tricky to pin down what this means. Countries and communities need better, more precise ways to track progress. Funders need this information too, in order to see impact and sustain confidence in the effort. With great global diversity in incidence and mortality rates, worldwide measures obscure progress and challenges. The table below summarizes the work to date on identifying metrics that make sense. Civil society must weigh in on what matters to us, which of these terms is meaningful and how to minimize the potential for manipulation and misinterpretation.

	STATUS	IN PLAIN LANGUAGE	PROS	CONS
Incidence rate per 1,000 uninfected	Existent, one of the Sustainable Development Indicators.	Out of 1,000 people, how many acquired HIV over a given time period (usually a year)?	Compares the number of new infections to total deaths in an HIV population.	Incidence is hard to estimate or routinely measure with confidence.
AIDS-related mortality rate	Existent, widely used.	Out of 1,000 people living with HIV, how many died of AIDS-related causes over a given time period (usually a year)?	Compares the number of new infections to total deaths in an HIV population.	Measures a late-stage indicator of disease response. Many people die of AIDS-related causes yet this isn’t listed as the cause of death, nor is an autopsy performed or a death certificate issued.
Percent change in new infections from 2010 baseline	Adopted at the UN High-Level Meeting.	Are more or fewer people getting diagnosed with HIV compared to ten years ago? This calculates the percent change.	Simple to explain the concept and how it is calculated.	Hard to calculate with confidence. Very few countries have population-wide incidence measures from 2010; incidence is hard to estimate with confidence.
Percent change in AIDS deaths from 2010 baseline	Adopted at the UN High-Level Meeting.	Are more or fewer people dying from AIDS-related causes today, compared to 10 years ago? This calculates the percent change.	Simple to explain the concept and how it is calculated.	Measures a late-stage indicator of disease response. Many people die of AIDS-related causes yet this isn’t listed as the cause of death, nor is an autopsy performed or a death certificate issued.
Ratio of incidence to prevalence (IPR)	Proposed.	Compares the number of new diagnoses with the number of people living with HIV.	Measuring IPR is a clear way to track whether epidemic levels of new diagnoses are still ongoing. It’s considered “highly relevant” to measures of epidemic transition by UNAIDS. An IPR of 0.03 would mean the epidemic will decline over time.	IPR is designed as a population-wide measure, and not to be disaggregated by age, sex, sub-geography.
Ratio of incidence to mortality (MR)	Proposed.	Compares the number of new infections to total deaths in an HIV population.	UNAIDS says this can be used by countries to identify when AIDS-related health care costs can be expected to decline. An IMR of less than one would mean the size of the population of PLHIV is getting smaller, so health costs will go down.	The size of the population of PLHIV can go down for the wrong reasons: AIDS-related illness, TB, lack of access to ART. IMR only works if there’s a measure of access to, coverage of and virologic suppression on ART for PLHIV.

3

NO**W**

Double down on multilayered prevention approaches

Let's try a new term to address old, siloed problems.

“Multilayered” prevention involves multipurpose strategies (think contraception and HIV prevention) embedded in multisectoral strategies (think policy reform, community norms-changing, economic empowerment and more). Only layered approaches like these will drive incidence down.

Every Woman Matters: Integration now

The post-2020 agenda for both HIV and sexual and reproductive health and rights must tackle major, well-known deficits in programming head on, via an emphasis on multilayered prevention. Multi-what? Multilayered. We're proposing this term to encompass both multipurpose prevention options like male and female condoms (which prevent pregnancy and reduce the risk of HIV and other sexually-transmitted infections) and multisectoral strategies that encompass biomedical, behavioral and structural interventions. Does the world need another term? Maybe not. But success in primary prevention depends on finding new ways to talk about and, more importantly, deliver what's needed since the standard approaches are coming up short.

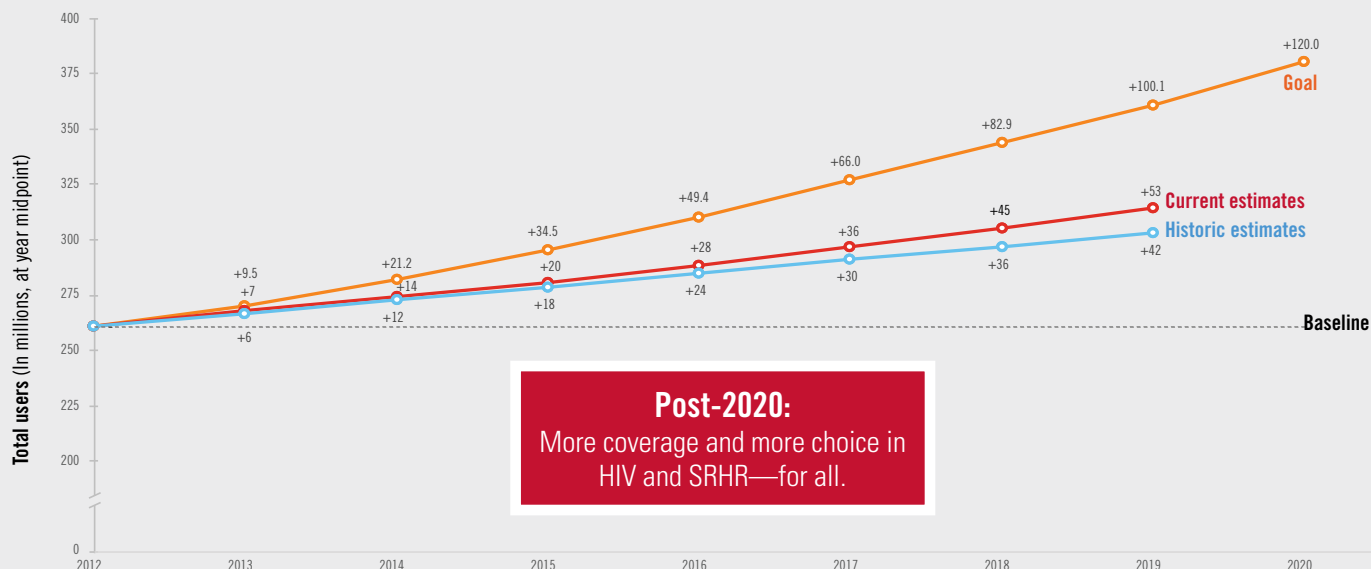
There are many deficits, but they almost all boil down to this: four decades into the epidemic, HIV prevention programs are still designed around the virus, not around people's minds, behaviors and relationships. There are a range of innovative, youth-centered, sex-positive programs out there. But the vast majority of HIV prevention still focuses solely on the retrovirus and what's needed to stop it, without putting as much focus on the bodies it tries to enter or on the communities that we live in.

Our bodies play, work, grow weary, rest and have sex for pleasure and sometimes for survival. They may bear children or they may not. Our genital anatomy may match our gender identity and presentation or it may not. We live in communities that are policed, formally and informally, by authorities—be they law enforcement or local leaders—who do not always support human rights for all. Our communities

FIGURE
10

Total and Additional Users of Modern Contraception, 2012-2019

In November 2019, FP2020 released "Women at the Center: 2018-2019" (<http://progress.familyplanning2020.org/>), its latest progress report from which this graphic is adapted. As its graphic below shows, coverage of modern contraception in the 69 low income countries that partner with FP2020 in tracking progress has increased since 2012, but not at the pace needed to meet the FP2020 goal. The group has also launched a post-2020 vision, and AVAC looks forward to working together towards an integration agenda.



struggle with inadequate housing, insufficient employment and poverty. This is true whether we are living comfortably or on the margins: global inequality affects everyone.

Too many of today's HIV prevention programs and products don't consider these embodied realities: they don't provide contraception to those seeking it or don't have clear and comprehensive information about how a product might interact with hormone replacement therapy (or staff trained to provide services to transgender or gender-nonconforming individuals). Astonishingly, pregnant and breastfeeding women who are HIV-negative do not routinely receive interventions to reduce the risk of HIV or STIs. Daily oral PrEP is not routinely offered to pregnant women in high

prevalence settings, in spite of the fact that there is increased HIV risk associated with pregnancy. In a study of HIV transmission among more than 2,500 serodiscordant couples (in which the male partner was living with HIV and the woman was HIV-negative), a woman's risk of acquiring HIV was increased when she was pregnant compared to when she was not, with the risk increasing throughout pregnancy and reaching a peak during the postpartum period.¹¹ In spite of this, PrEP isn't a standard part of antenatal care, even though the same medications in PrEP would be offered to a pregnant woman if she were living with HIV.

One Woman, Many Choices: After ECHO, the work continues

The ECHO trial was a three-arm study in which women from Eswatini, Kenya, South Africa and Zambia were randomly assigned to one of three contraceptive methods: the Jadelle implant, the copper intrauterine device or DMPA-IM (also known as Depo Provera). The trial measured and compared rates of HIV among women in the trial. Prior to ECHO, DMPA-IM had been classified by the WHO Medical Eligibility Criteria (MEC) grading system as a MEC 2. This grade is given to products for which the benefits outweigh the possible or theoretical risks. ECHO found no substantial difference in HIV risk between women using the different methods. By design, the trial was able to measure, with confidence, an increased risk of about 50 percent relative to the other methods. Smaller increases, i.e., 30 percent or below, would not be detected by the trial. Following ECHO, WHO reclassified DMPA-IM as a MEC 1—use without restriction. AVAC, ICW Eastern Africa, the Civil Society Working Group on HC-HIV, the South African prevention activist group APHA and others are working to ensure that, in the post-ECHO world, women have access to full information, stigma-free services and choice in contraception and HIV prevention.

These are just some of the programmatic issues. A range of structural factors are also well-recognized and unaddressed by most—though not all—prevention programs. These include gender-based violence (physical, psychological, emotional), clinic environments and wait times, laws permitting child marriage and marital rape and expulsion of pregnant girls from school. These, too, can and must be addressed as part of public health programs that seek to help all people live healthy, dignified lives.

HIV prevention still stands apart from sexual and reproductive health and rights-based

¹¹ Mugo N et al. 2011. *Increased Risk of HIV-1 Transmission in Pregnancy: A Prospective Study among African HIV-1 Serodiscordant Couples*. *AIDS*. 25(15): 1887–1895. DOI: 10.1097/QAD.0b013e32834a9338.

programs (SRHR), contraception, and pre- and postpartum health care. Contraceptive programs often stand apart, too, from comprehensive SRHR, focusing on delivering contraception and leaving other issues and needs—including but not limited to abortion and post-abortion care—to other facilities.

As long as HIV prevention programs and products are designed with a sole focus on the virus, and as long as contraceptive programs and products are designed with a sole focus on pregnancy intentions, incidence is going to stay level—or climb.

In East and Southern Africa, recent work guided by human-centered design and focused on adolescent girls and young women (AGYW) confirms what these young women have been saying for years: they're actively concerned about preventing pregnancy, and they take a more passive approach to avoiding HIV. They may try to avoid the virus by choosing partners they believe to be “safe” or going through periods of condom use. They want to go to one location—not many places—to get what they need from providers who don't judge them, berate them for being sexually active or violate their confidentiality.

Women in the ECHO trial—who were not recruited to the trial based on individual risk factors for HIV but who were sexually active, seeking contraception and living in high prevalence communities—had high rates of HIV: 3.8 percent incidence across the trial and up to 6 percent in one of the South African sites.

In these regions, contraceptive prevalence is increasing by about one percent per year. As of 2019, there were 53 million more users of modern contraception than there were in 2012, for a total of 314 million in 69 low-income countries.¹² That's progress, but it's not on track to meet the goal of 120 million additional users in low-income countries by 2020.

Thus, there are coverage gaps for the services women and adolescent girls actively seek and integration gaps (or chasms) at the program level. What women want (contraception) and what they may also need (HIV and STI prevention, sexuality education, cervical cancer screening, prevention and treatment, general health care) isn't available at the same place, at the same time or from the same provider.

So what's needed for multilayered prevention? We propose:

Stakeholders at the country, community, funder and normative agency levels must develop and embrace a “3-D” agenda (Deliver, Demonstrate, Develop) for multilayered prevention—one that incorporates care for women with diverse fertility intentions with HIV and STI prevention. Multipurpose prevention strategies in the pipeline are designed as contraceptives that also reduce HIV and/or STI risk. We propose the phrase “multilayered prevention” to capture the need for these biomedical strategies to be embedded in multisectoral programs that take on structural barriers at the social, community and service-delivery levels. Here's what the 3-D agenda might look like in detail.

DELIVER

- 1 Deliver ambitious targets and funded plans for integrated contraceptive and HIV services based in informed choice.** Impact on HIV incidence and contraceptive uptake will likely be highest when one program offers the choices that women want in both areas. We and our allies have called for integration targets and funded budgets to meet them. In 2020, countries, normative agencies, implementers and funders must work with civil society to meet these needs.

¹² FP2020. 2019. *FP2020: Women at the Center*. familyplanning2020.org.

FP2020 is setting its post-2020 goals and strategy. It has done invaluable work on tracking informed choice in contraceptives. The Global HIV Prevention Coalition, convened by UNAIDS and UNFPA, should—with leadership from Winnie Byanyima (see our letter in Section One) and in collaboration with FP2020—set global integration targets, support country action and make it resoundingly clear that integrated women's health services are essential to ending epidemic levels of new HIV infections.

2 Deliver the most effective triple prevention product at scale: male and female condoms prevent pregnancy, HIV and many STDs.

Many countries have allowed condom programs to fall by the wayside. GFATM is starting to make some central funding available for these programs and should look at all new concept notes to ensure that they address the condom gap, if there is one. An effective response means funding both commodities and delivery strategies,

including social marketing and demand creation strategies, the segmentation of users and the development of targeted messages and materials to reach each segment of the population with what they need and want. (For more on what this entails, see www.avac.org/report2018 for AVAC's human-centered design agenda in *AVAC Report 2018: No Prevention, No End*).

3 Deliver daily oral PrEP for girls and women at risk of HIV.

As we discuss in Section Two, information on challenges and successes in daily oral PrEP delivery to women, girls and key populations must guide the revision of indicators, targets and program models. Young people are starting PrEP when offered, yet few stay on it. Since many people are coming on and off PrEP, it's critical that PrEP programs and funders start to gather information on its community-wide use in order to begin to understand the impact of periodic use. At the same time, the programs that seek to reach young women and adolescents need sustained

A “3-D” Agenda for Multilayered Prevention

DELIVER

- 1 Ambitious targets and funded plans for integrated contraceptive and HIV services based in informed choice.
- 2 The most effective triple-prevention product at scale: male and female condoms prevent pregnancy, HIV and many STDs.
- 3 Daily oral PrEP for girls and women at risk of HIV.

DEMONSTRATE

- 1 The impact of multisectoral prevention for AGYW and key populations.
- 2 A commitment to gathering data on F/TAF for PrEP in women.

DEVELOP

- 1 An ambitious, accelerated approach to the pipeline of dual- and triple-prevention products.
- 2 A prevention research trial infrastructure—including NIH-funded network stakeholder engagement mechanisms—that works for and with women and key populations.

funding and the space to continue to innovate and adapt their approaches. If young people come in the door for PrEP but stay for condoms or counseling or STI treatment, that's all success, and it is essential to build these platforms and put them in place for future products, including, potentially, the dapivirine ring and injectable ARVs.

DEMONSTRATE

1 **Demonstrate the impact of multisectoral prevention for AGYW and key populations.**

PEPFAR's DREAMS initiative is the most systematic multisectoral HIV prevention intervention delivered to date, with programs that seek to measure and report on the layering of different services at the community and individual level. The impact data so far have been calculated by looking at pregnancy and new HIV diagnoses in DREAMS communities, but this is an indirect measure, and it hasn't convinced all stakeholders. The London School of Hygiene and Tropical Medicine is completing its own independent evaluation, which will give additional insight into where and how DREAMS packages reduce incidence. PEPFAR is also funding an evaluation of its Key Population Investment Fund though with a different scope. This work on demonstrating what multisectoral strategies can achieve is key, since at present GFATM-supported DREAMS-like programming is a patchwork of strategies that are well intentioned (like Tanzania's recent GFATM fund reallocation to purchase sanitary napkins) but not necessarily strategic or taken to scale.

2 **Demonstrate a commitment to gathering data on F/TAF for PrEP in women.** In October 2019, the US Food and Drug

Administration (FDA) followed the recommendation of its independent advisory committee and approved a new PrEP drug, called F/TAF, for use in adults and adolescents, with the exception of those who have receptive vaginal sex. This exclusion, which impacts cisgender women and some nonbinary or transgender individuals assigned female at birth, came after the FDA failed to require—and Gilead failed to obtain—comprehensive safety and efficacy data on F/TAF in cis-women, perhaps because they're not a major PrEP market in the US. This omission is the latest entry into the history of scientific research that fails to investigate how drugs work in women's bodies. The FDA's approval letter did stipulate that Gilead was required to conduct a trial to get the answers excluded people need. But it's up to activists and advocates to demand urgent action on a well-funded, community-supported research agenda that generates the information that should have been collected in the first place for F/TAF and needs to be the basis for all products in development.

DEVELOP

1 **Develop an ambitious, accelerated approach to the pipeline of dual and triple prevention products.** There is a robust pipeline for dual-prevention products that could be used in the context of vaginal and anal sex by cis- and transgender women and men. Within this pipeline, there are products like a combined oral contraceptive/PrEP pill that could be introduced within three years and vaginal rings that reduce HIV risk and act as contraceptives. Research hasn't been part of any of the global rhetoric or target-setting leading up to 2020, but it must be. UNAIDS,

FP2020, WHO and governments of countries with epidemic and hyperendemic HIV should, together, set and champion targets for moving products through trials and into programs. Here's what these could look like:

- One new dual-prevention product (the combined oral contraceptive/PrEP pill) introduced in at least three countries within 12 months of licensure.
- Two dual- or triple-prevention products, including both long- and short-acting versions such as a ring and a quick-dissolving film, advanced to efficacy trials by the end of 2022.
- Three next-generation products reflecting user-centered design advancing to efficacy trials by 2025.

2 Develop a prevention research trial infrastructure—including NIH-funded network stakeholder engagement mechanisms—that works for and with women and key populations. For the past two years, AVAC and other civil society partners have been calling on the NIH to ensure that its new clinical research networks fund and support trials of products that people want—e.g., both short- and long-acting approaches to HIV prevention and multipurpose prevention technologies. With the NIH clinical trial networks expected to receive new multiyear grants in 2020, even as a range of trials move toward completion, it is essential that the trial networks make good on the following:

- Using the Good Participatory Practice Guidelines as the central pillar supporting stakeholder engagement in HIV prevention

research trials, starting with protocol review all the way through to results dissemination. This requires funding and budgets that account for in-person meetings with civil society, engagement with advocates within the trial communities and at the global level and much more.

- Pursuing a coordinated, comprehensive, woman-centered research agenda that addresses critical questions about HIV prevention in pregnant and breastfeeding women, incorporates implementation science to guide program design and makes adjustments so that women and girls seek out and return to sites of healthcare.
- Ensuring that data on women in all their diversities—cisgender, transgender, old, young, lesbian, bisexual and straight—are gathered for all products that may be used in those groups.
- Supporting trials that seek to address and strive to transform gender norms (e.g., can a young woman or man finish a trial with a stronger sense of self-worth and the ability to speak about her or his sexual desires?). These trials should test potential products that reflect the preferences and needs of the people for whom they are intended.
- Developing comprehensive product development plans and regulatory packages that include adequate data on women and key populations and plans for the rapid introduction of effective strategies.

If this 3-D agenda is implemented, it will change the course of the epidemic, and women's health, worldwide. Let's aim high!

Not the End—Just the Beginning:

AVAC's commitments for 2020 and beyond

As longtime *AVAC Report* readers know, we develop a “3-D agenda” every year that summarizes our take on the critical advocacy priorities for the field of HIV prevention. Every year, with our partners, we take on these challenges. But, the way that we’ve presented that agenda in the past hasn’t always been clear about what we, as AVAC, are taking on ourselves. So this year, as we near global deadlines and wrestle with the question of “Now what?”, we want to change that—and share our answers with you.

AVAC has a bold agenda for 2020 and beyond. We will work with our partners to influence the post-2020 agenda to ensure that funding for prevention increases and money is directed to the geographies and populations with the most need, and to the most effective interventions. We will continue to build and sustain a global cadre of smart, evidence-based, impact-driven advocates who stand at the front lines of this fight. We will continue to raise our voices for women’s HIV prevention and help craft the global prevention agenda for women. We will ensure civil society perspectives are informing and influencing decision-making on current and next-generation trials and trial designs. We will guide and pressure developers, funders and policy makers to ensure comprehensive plans for all relevant populations for products entering and coming out of the product pipeline in 2020. And we will identify, raise up and advocate for ways to increase uptake and continuation rates for prevention methods through a people-centered lens.

When we look specifically at our calls to action in the *AVAC Report*, here’s what you can look for and expect from us in the coming year:

1

NOW **Leadership**

- We will take our letter to Winnie Byanyima to UNAIDS and the Global HIV Prevention Coalition. We will assemble a delegation of young people, particularly women and key populations, and carry forward the specific requests related to UHC, targets for research and contraceptive-HIV integration.
- We will work at the country level to find ways for activists to use community-led monitoring and analysis of national data to point out programs that work and need to be scaled up and those that are failing. And we’ll lift up those in power who are our allies and hold those who block progress to account.
- We will continue to support and develop a cadre of HIV prevention advocacy leaders through our Advocacy Fellows program, and to grow a powerful activist and advocacy network through our COMPASS and CASPR programs, focusing on accountability from research to rollout.

2

NOW **Targets**

- We will push PEPFAR to lead the way in adopting new approaches to measuring PrEP impact, starting with the Country Operational Plan guidance for FY2020 and work with our civil society partners in the COMPASS coalition—who engage with PEPFAR and national PrEP programs year-round—to raise awareness of what the effective-use agenda is and how to move it forward.
- We will work, with our partners in CASPR, the Prevention Market Manager and other networks to set milestones for the prevention research pipeline, from the launch of trials through to product introduction.
- We will build advocacy power by collaboratively developing and using curricula that explain complex concepts like new trial design, epidemic transition metrics, prevention cascades and effective use. As AVAC has always done, we will make the materials that communities of advocates use to demand action in an ever-changing field.
- We will work with networks to see new research targets secure wide buy-in and public endorsement.

3

NOW **Multilayered prevention**

- With our “multilayered” prevention agenda, we’re advancing a new term and a new set of priorities. This means more work and also more opportunities for true change. We will take the call for multilayered prevention on the road, to see if it catalyzes discussion and fits in with other ongoing activism and advocacy. We will work throughout 2020 to set up the meetings, step up to the mics, and take the stands that can make this a reality.
- Along with our longstanding collaborators throughout East and Southern Africa, we will continue to advance an agenda for multisectoral prevention—including HIV and SRHR integration—in today’s clinical services and research for tomorrow’s multipurpose products.
- We’ll work with advocacy and media partners to contextualize and understand multilayered prevention in their communities and to translate what they learn into context-specific action.
- We will expand our product introduction work to take on the dual contraceptive and PrEP pill, exploring the path to licensure and catalyzing action on introduction plans that would provide a near-term solution and build a platform for future multipurpose prevention options.

Many Approaches, One Message

PREVENTION MATTERS

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, which remains essential to bringing the epidemic to a conclusive end.

Nearly 25 years later, AVAC is still focused on swift and ethical research, but our scope has expanded over time. Along with vaccines, we advocate for PrEP, microbicides, voluntary medical male circumcision, integration of HIV and sexual and reproductive health and rights, and more.

And we've evolved with the field. As positive results have delivered new tools, AVAC has expanded its high-impact advocacy, focusing on programs, policies and payers for HIV prevention at the country level. In recent years, we have also begun work with partners to accelerate access by working to meet the information and planning needs of the global prevention “market”.

Over the years and across all our workstreams, our message is the same: prevention is the center of the AIDS response. Not just any prevention, but smart, evidence-based, community-owned, rights-based strategies. To make this a reality, we focus on:



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