NO PREVENTION, NO END
ACKNOWLEDGEMENTS

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IN MEMORIAM

Bonnie Mathieson 1945-2018

This year’s report is dedicated to the tremendous, irrepressible and irreplaceable Bonnie Mathieson. Mathieson passed away suddenly, just after retiring from her position at the National Institutes of Health where, for three decades, she championed AIDS vaccine research, rallied support for young investigators and showed all who knew her what it meant to work with passion and rigor. Bonnie was the consummate advocate, explaining complex science to any and all who had questions. With her broad grin and irrepressible excitement, she improved our work and often infused it with joy. In her long and illustrious career, Mathieson served as head of a laboratory focused on T cells and innate immunity at the NCI-Frederick Cancer Research Facility. She was a Program Officer in the Vaccine Branch, Division of AIDS, NIAID developing many funding streams for research on HIV vaccines, immunology and pediatric AIDS. As the Chair of the HIV/AIDS Vaccine Coordinating Committee at the Office of AIDS Research, she spearheaded the budgeting, planning and review of the US agenda for this work. In these and other positions and as friend, mentor, ally and source of inspiration, she kept focus on what still matters most: sustaining science, nurturing new researchers and keeping up the work to find an HIV vaccine until the search is done. We miss her every day.
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A note on the cover: AVAC gratefully acknowledges the International AIDS Society, which supplied the image of the march at AIDS 2016 in Durban, South Africa that was adapted for the front and back covers. We acknowledge the power of the people who stood in the streets that day and those who put their bodies on the line every day in the name of justice and the right to health. These and other images in the Report seek to convey the art and beauty in the struggles.
Two Years and Counting

A Letter from the Executive Director

In just about 24 months, the world will arrive at the deadline for the UNAIDS “Fast Track” goals for ending the epidemic. The primary fast-track goal for HIV prevention is a reduction in new diagnoses from roughly 2,000,000 a year, to less than 500,000. There’s no chance this goal will be achieved. In July 2018, days before the biennial International AIDS Conference, UNAIDS released its annual state-of-the-epidemic report and declared a “prevention crisis.” That’s the bad news. There’s a lot of bad news around today though. Here at AVAC, we’re concerned that the true implications of this missed target haven’t sunk in. Simply put, the tremendous gains in the fight against HIV made to date are all in peril due to failures in primary prevention. This is due, in no small part, to the demographic shift known as the “youth bulge” or “wave”. In many HIV-endemic countries, there are or soon will be twice as many young people as there were when the epidemic started. At the same time, epidemics driven by drug use in Eastern Europe and Central Asia are out of control. The US epidemic is disgracefully unchecked. This is not a theoretical coming storm. It is a landscape-altering hurricane, just off the shore.

![AVAC’s “3D” View of the World: 2018 and beyond](image)
No Prevention, No End

This is not the time for panic or denial. Action is a must. And here is where the good news lies: the reasons why the world is going to miss the target are obvious and can be tackled. This year’s AVAC Report is dedicated to diagnosing the problem and proposing actionable solutions.

Hasn’t AVAC done this before? Yes and no. As we discussed in 2014, in our report Prevention on the Line, the primary prevention targets set by UNAIDS and adopted by countries the world over have, for several years, been buried pages into UNAIDS’ annual reports. Even with the advent of the Global HIV Prevention Coalition, which has revitalized primary prevention planning structures at the country level, there has been limited allocation of new resources to close persistent funding gaps. As we described in our 2017 report, Mixed Messages, there is a gap between rhetoric and practice, and between countries’ priorities and the possibilities given budget envelopes and funder priorities.

There is also a messaging gap. The true scope of the prevention crisis is hard to convey without also casting doubt on the significant progress to date in expanding access to treatment leading to virologic suppression, scaling up VMMC and more. US government investment in research and implementation related to HIV outpaces any other nation in the world and is essential to the global response. Historically, congressional support has been bipartisan and enthusiastic. A message that conveys the stakes as well as the successes is tough to find. A message that does this and also includes the need for research is even more complex.

With this year’s Report, we don’t waver from prior analysis. Instead we try to get specific and practical. The crisis is coming, the message is clear. Here’s our proposal for exactly what to do and why.

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1 For this and all previous AVAC Reports visit www.avac.org/avac-report.
2 For more information see: https://hivpreventioncoalition.unaids.org/.

**AVAC Report 2018: No Prevention, No End—At-a-Glance**

### 1: NO DEMAND CREATION, NO IMPACT

**THE PROBLEM:** Today’s primary prevention and treatment strategies need new approaches to “demand creation”. While there’s innovation in this field, it’s applied unevenly across interventions. Data gaps on the costs and cost-effectiveness of demand-side thinking are pervasive; the funding gap for primary prevention makes this necessary work seem like a luxury.

**THE RISK:** The perfect can become the enemy of the good. The risks in arguing for intentional and thoughtful introduction plans are that access gets slowed down in pursuit of an unattainable ideal and that expectations of the program design approach are overinflated.

**THE PATH TO A SOLUTION:** Understand not everyone can do demand creation. It’s a science, not a set of slogans. This is true for treatment; it’s the bedrock of primary prevention. Find the people who can do it, the programs that have done it before and work with them to do it consistently. Reaching the right people is more important than reaching all people. Limited resources should be allocated to tailored demand-side thinking.

### 2: NO CHOICE, NO PREVENTION

**THE PROBLEM:** Informed choice is easy to advocate for and hard to implement. Cost, provider time and public health priorities can all work against investment in services that offer and support choice in strategies.

**THE RISK:** Embracing informed choice in biomedical prevention is tricky. There isn’t enough money for primary prevention basics like male and female condoms and VMMC. Advocating for more choices such as PrEP, multiple testing approaches, etc. means finding ways to do more with existing resources and also demanding additional funds.

**THE PATH TO A SOLUTION:** Identify, cost and adapt best practices in informed choice programming and monitoring from family planning and HIV programs as part of planning for new biomedical tools.

### 3. NO RADICAL ACTION, NO END

**THE PROBLEM:** There is a primary prevention crisis. The emphasis on ART-based programs to reduce incidence has drawn attention and funds from primary prevention for too long; the 2020 global target for incidence reduction will be missed.

**THE RISK:** So much has been accomplished in the fight against AIDS; so much is left to do. Emphasizing failure can hurt morale and momentum, yet so can over-promising and failing to deliver.

**THE PATH TO A SOLUTION:** Tailor today’s prevention approaches to specific communities and contexts; sustain research and prepare for results. ART scaled up in the context of flat funding by finding efficiencies; biomedical prevention hasn’t nearly done the same. Accountability mechanisms for implementing effective primary prevention must be built into GFATM, Global HIV Prevention Coalition activities and PEPFAR COPs and at the same time champions of primary prevention can prepare the world for research results and future trials.
First: fund real, rigorous demand creation for primary prevention strategies. In Section One, we assert that there is a science to ensuring that people who most need prevention or treatment are reached with messages that are accurate, resonate and prompt action. There are promising signs that this science is seen as valuable. The US government, the Bill & Melinda Gates Foundation and some additional country governments are prioritizing “demand-side thinking”, work that needs to be expanded and made routine; it’s the key to making primary prevention work.

Another focus this year is choice. In Section 2, we argue that without choice there is no end to the epidemic, and then go on to explain exactly what we mean, what is and isn’t known, where to spend money and time, and why.

Choice matters because of questions like these:

- How does a woman at risk of HIV choose between contraceptive methods when one or more of them have a possibility of increasing her risk of getting HIV?
- How does a woman living with HIV and of child-bearing age, who is struggling to adhere and wants an easier regimen, make a choice about using dolutegravir, a powerful, well-tolerated antiretroviral that may increase risk of a birth defect that occurs very early in pregnancy?
- How does an African man who has sex with other men decide whether to comply with the health provider’s request for the names and contact details of his or her sexual partners?
- How does a person at substantial risk of HIV decide between condoms, oral PrEP, and weigh the offer of assisted partner testing or couples counseling—or choose all three?

It is expensive to build, staff and supply programs that allow people to answer these questions. Events from the past year—discussed in Section Two—show that it is even more costly not to act.

The title of this letter, *Two Years and Counting*, is a nod to the titles of AVAC’s annual reports for the first several years of our existence. Taking inspiration from US President Bill Clinton’s 1997 speech that committed the US to developing an AIDS vaccine within 10 years, we called our annual reports “Nine years and counting…” and so on, stopping in 2003 with “Four years and counting…”.

We didn’t stop because we gave up, but because we felt it was important to calibrate expectations and lay out agendas that would maintain momentum for as long as needed. We still feel that way, and we’re excited that the “Two Years and Counting” deadline takes us close to the anticipated release date of the results of a major HIV vaccine efficacy trial, along with data from trials on long-acting injectable PrEP and antibody-mediated prevention. As we discuss in the final section of this Report, these data will emerge at almost the exact same time that the deadline for the 2020 Fast Track prevention targets (see Fig 14, p. 33) will pass with most unmet.

On the matter of titles, we chose No Prevention, No End for this year’s Report both because the message is true, and because of its link to the powerful activist chant, “No Justice, No Peace,” often heard in the US at rallies against police brutality. The same forces of racism and inequality that enable state-sanctioned violence against black and brown Americans also drive the US epidemic, especially amongst transgender women and same-gender loving men. This structural violence is at work in Africa, Europe—it is the global scourage of hate that we fight every day, with all the love and joy we can muster.

Mitchell Warren
Executive Director, AVAC
While it is important to celebrate hard-won victories in the fight to diagnose and treat people living with HIV, it’s equally critical to acknowledge the global failure to slow significantly the rate of new infections. This imperils global efforts to bring the epidemic under control. Now is the time to bring all of today’s tools to bear, while also accelerating the development of new technologies and approaches. This is the only course of action if the world is serious about averting new diagnoses and drastically reducing the burden on health systems of an HIV epidemic that remains on slow boil, three decades on.

HIV incidence remains largely unchecked among sub-Saharan African adolescent girls and young women and key populations, including gay and other men who have sex with men, transgender women and people who inject drugs. Over 40 percent of new cases of HIV occur in these populations, with explosive epidemics in Russia, Eastern Europe and Central Asia. In Africa, initiatives to diagnose and treat the adult men over 24 living with HIV so that their risk of onward transmission is also reduced are underway, but nascent. These are the men who most often pass the virus to adolescent girls and young women, so reaching them is essential. But so is investing in primary prevention for women and girls, recognizing that increasing their agency is key. It’s hard work, but it must be done. Put simply, the gains of the past decades’ work to slow the HIV epidemic could be wiped out if primary prevention is not put in place today, and research is not sustained for tomorrow.

The title of this year’s AVAC Report, *No Prevention, No End*, borrows humbly from a rallying cry of US movements seeking racial justice and an end to state-sanctioned violence against Black people: No Justice, No Peace. We argue that there can be no end to AIDS as public health threat without preventing new HIV infections.

For us, prevention means biomedical, structural and behavioral interventions that are interwoven, not separate strands. It means doing things that work at the scale where individuals and communities and countries benefit. It means understanding that nine-year old girls cannot protect themselves from rape or sexual violence and that when you close clinics that provide comprehensive sexual and reproductive health services you deny women and girls the right to choose if, when and how they become pregnant and to control their own bodies and their own future. It means understanding that gay and bisexual men and transgender women can’t and won’t access the tools and knowledge they need to protect themselves from HIV unless there is a profound shift in the pervasive homophobia and transphobia that drives public policy in too many communities and precludes the provision of non-judgmental sexual health services. And it means understanding that people who inject drugs must be freed from persecution and criminalization if they are to protect themselves from HIV, hepatitis, and other health risks.

The stakes of failing to act on this knowledge have never been higher.

The AVAC Board of Directors
The future of new and existing biomedical prevention options depends on investment in “demand creation”, a term that has been around for a long time and is increasingly becoming a buzzword in discussions about HIV services. The problem with buzzwords is that they can mean everything and nothing. Demand creation encompasses many things, and always will. But there’s a minimum set of pieces that should be considered, if not in place, and often isn’t. We think the future depends on defining—and doing—demand creation right.
First, what is demand creation? Well, demand is what people do when they want something—at least some people, in some cultures. It’s a capitalist-inflected word, to say the least, and it presumes that people can act freely which, in fact, they often can’t because of laws, stigma, the threat of violence or discrimination. It’s a phrase that can seem tone deaf to human rights abuses. Yet, it’s also commonly used and so we’re noting the issues and living with the lexicon in this section.

Demand is different from need. Lots of people who need things don’t demand them. Adolescent girls don’t see themselves as being at risk of HIV. Adult men living with HIV don’t regularly take to the streets to get on ART and achieve virologic suppression. So demand creation could also be described as the science of awakening a sense of interest in the people who do need a given product. At its best the product itself reflects what people want. HIV prevention can’t always do that, but it can still do a lot—as this section describes.

Finally, demand creation is the antidote to the “if you build it, they will come” approach that posits people will come for a service or strategy just because it’s good for their health or their pocketbooks.

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**Towards a Demand Creation Cascade**

Many countries report low initiation and continuation of PrEP. This doesn’t mean people don’t want the product. They might not want the program that’s offering it; or they might not be being reached. A “demand-creation cascade” such as the one proposed here for PrEP is one way to evaluate the program and the product. It would measure how many people received the full suite of demand-side activities the program hopes to deliver at a given stage. The precise set of steps would depend on the service-delivery design and strategy in question.

![Diagram of Demand Creation Cascade]

There are many groups working on different types of prevention cascades today—broadly and for specific interventions like PrEP. This cascade, developed by AVAC, builds off of that work.
A brief history of demand creation and HIV

When the HIV response started in earnest in the late 1980s, fear was a primary motivator for many government-sponsored public health campaigns. By contrast, communities sought to create messages that emphasized self-protection and self-care and, in some cases, sexual pleasure in the context of a frightening new virus. Once antiretroviral drugs became available, messages shifted in places where people had access. If you had HIV, you should find out so that you could start care and, eventually, treatment, and live.

There were many variations on these campaigns but they were often broad, public health-oriented efforts, aimed at reaching large swaths of people, regardless of their risk. For example, in the US, a law against referencing homosexuality in US-funded public information meant that national HIV messages didn’t speak to gay men, transpeople or queers at all.

Demand creation today: Evolving thinking, unevenly applied

More than 30 years into the epidemic the era of one-size-fits-all public health campaigns is over, if it ever truly existed. At this year’s International AIDS Conference in Amsterdam, plenary speaker Ndaku Kilonzo said about Kenya’s decision to develop a “Prevention Revolution Roadmap” to tailor packages to geographies and populations, “In 2014, we recognized that the ‘spray and pray’ one-size-fits-all approach applied generically for HIV interventions was not delivering on the required results for prevention.”

One-size-fits-all doesn’t work for treatment these days either. The current treatment guidelines recommend offer of ART to a person on the same day that he or she receives an HIV-positive diagnosis. The message to come for testing if you’re sick so you can get better no longer applies to everyone. Many people are no longer on their deathbeds when they start ART. There’s an increasing push for demand creation around ART and viral load access, so that people who achieve undetectable status are aware and can use that information as inspiration and reassurance. Men are a particular focus of this work; adolescents and young people are another.

The success of today’s ART and primary prevention programs depends on demand
creation that is well-resourced and –conducted. Investments by the US government, the Bill & Melinda Gates Foundation (including work that AVAC is a part of, see pages 14-15), and other partners reflect this reality. But for a concept that’s been around for a long time, the precise components of demand creation are awfully fuzzy. The first task for advocates is to get clear on what we’re demanding in the first place.

Demand creation—or “demand-side” thinking, a phrase some practitioners prefer—involves the collection and analysis of high-quality information about the mindset of the potential client or user of a strategy. Human-centered design, a discipline within demand-side thinking, uses this information to identify different groups of users, or segments, and then maps their “journeys” to product use. At first glance, demand-side thinking and human-centered design (see page 20 for expanded definitions) can look a lot like socio-behavioral research, which also tries to understand people and their preferences and beliefs through qualitative or hybrid qualitative-quantitative methods.

A recent paper by Betsy Tolley (reference in Fig 4) compared human-centered design and socio-behavioral research. Some of the key differences, as summarized in Figure 4, involve the speed with which the work is conducted, the design and use of research protocols, and the explicit application of private sector-derived concepts regarding markets, users, preferences and mindsets. Tolley, whose long history with SBR makes her something of an ideal informed skeptic about demand-side work writes, “During product introduction, the development and rapid testing of messages, materials, and

**FIG. 4** Comparison of Traditional Socio-Behavioral Research and Human-Centered Design Approaches

The table below comes from an article by Betsy Tolley, which contrasts human-centered design (HCD) with “traditional socio-behavioral research” (SBR). It resists over-simplification like: “HCD looks for solutions, SBR looks for theories”, while also giving a sense of the differences between formal, protocol-driven SBR and a commerce- and private sector-derived methodology, now proving its worth in public health.

<table>
<thead>
<tr>
<th><strong>TRADITIONAL QUALITATIVE SBR</strong></th>
<th>VS</th>
<th><strong>HUMAN-CENTERED DESIGN RESEARCH</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Overall objective</strong></td>
<td>Generate information and theories about behaviors that could be used to inform design or intervention goals</td>
<td>Arrive at new solution-based immersive experience of end-user and context</td>
</tr>
<tr>
<td><strong>Recruitment</strong></td>
<td>Priority on defining participants, categories to ensure data saturation</td>
<td>Priority on identifying a wide range of experiences using rapid, flexible processes</td>
</tr>
<tr>
<td><strong>Proximity to field</strong></td>
<td>Immersion by researchers, often “behind the scenes”, to reduce participants’ “reactivity”</td>
<td>Immersion by multidisciplinary research team, allowing for immediate feedback</td>
</tr>
<tr>
<td><strong>Data capture</strong></td>
<td>Audio-recordings and verbatim transcriptions preferred</td>
<td>Field notes and rich media assets preferred</td>
</tr>
<tr>
<td><strong>Synthesis of findings</strong></td>
<td>Step-by-step “auditable” process, with emphasis on scientific rigor</td>
<td>Rapid and iterative review of data to generate creative insights</td>
</tr>
<tr>
<td><strong>Outputs &amp; dissemination</strong></td>
<td>Text to convey the content with dissemination in peer-reviewed journals and other forms</td>
<td>Rich media collateral and a toolkit of assets that facilitate empathetic ideation</td>
</tr>
</tbody>
</table>

Using HCD to Solve a Problem, Part 1: Defining the problem

To understand low uptake of voluntary medical male circumcision (VMMC) in Zimbabwe, researchers surveyed nearly 2,000 men aged 15-29 in 2013 and realized there was a big gap between intention and action. A team in Zambia did similar work.

![Diagram showing percentage of men aware, interested, intending, and circumcised.]

Using HCD to Solve a Problem, Part 2: Understanding the client

In Zambia and Zimbabwe, researchers identified multiple different “types”, including champions, scared rejectors and more. They then prioritized a subset of categories for outreach based on the size of the segment, risk, potential for becoming advocates, and likelihood of uptake, such as the three listed below.

- **Enthusiasts**: 21% - Large potential for uncircumcised men, high commitment, dissonance issues
- **Neophytes**: 19% - Large potential, knowledge gaps, addressing knowledge gap is relatively easy
- **Embarrassed / Rejecters**: 16% - Moderate potential, low commitment, embarrassed, afraid—need social support

Using HCD to Solve a Problem, Part 3: Strategies derived from HCD research

Finally, the HCD research was used to guide specific messages for each target segment. Counselors received training and support on how to use simple questions to identify which type of man they were speaking to, and then tailored their approach, while communications campaigns provided broad messages based on men’s feedback.

- **Segmentation**
- **Honest communication about pain and procedure**
- **Targeted messaging**
- **Improve client experience**
- **Advocacy (e.g., messages about sexual appeal)**
- **Information on demand**

These data come from research activities in Zambia and Zimbabwe funded by the Bill & Melinda Gates Foundation, implemented by IPSOS Healthcare and PSI. For a write up of findings, see Sgaier et al. eLife 2017;6:e25923. DOI: https://doi.org/10.7554/eLife.25923.
VMMC, which has generated roughly a decade of demand creation activities fitting virtually all definitions, has recently yielded some much-discussed models (see Fig 5 on previous page).

The problem is that the lessons learned from VMMC and the dynamic discourse around HCD and demand-side thinking are not routinely applied. This is also the case when it comes to applying SBR to clinical research. Advocates don’t need to know everything about these evolving terms, or to choose one approach over another, but we do need to understand that demanding thorough, well-designed demand creation early on in product introduction, or as soon as a problem has been identified, is essential for success in biomedical primary prevention. And that when we demand these things, we shouldn’t necessarily take up the task of providing the answers.

**Demand creation and advocacy: Necessary, not the same**

Demand creation is not civil society advocacy. When civil society demands something—which it often does—that is neither an example nor the result of demand creation. In the earliest years of VMMC, AVAC—which did and does a great deal of advocacy around the need to scale up the policies and budgets needed to deliver VMMC—was often asked about getting more men to go for the procedure. At that time, we were solely working as advocates. There was expertise on staff in social marketing, but we saw our role as working in coalition to ensure action on guidelines and funding, including investments in good communications and demand creation.

Today AVAC actually does work in the demand-creation space (see pages 14-15). We also work as advocates and are concerned by the reliance on underfunded civil society partners as the demand-creation team for new interventions, irrespective of whether these partners have experience with the critical components of demand creation.

This doesn't mean civil society can be excluded from demand-creation processes. Involvement is essential, not just as focus group participants but as experts on technical advisory groups.

However, when a civil society group, coalition or constituency is tasked with primary responsibility for messaging or demand creation it should be a red flag. Far too often, civil society is asked to lead on things that program implementers don’t want to or aren’t able to spend real money on.

### Cutting to the chase: Lessons on demand creation from VMMC

In the past few years, communicators, scientists, program staff and civil society stakeholders working on demand creation for VMMC have provided valuable examples of what these pieces look like in action.

With VMMC, the first five years of most countries’ programs showed low levels of coverage. As Emmanuel Njeuhmeli, the USAID senior biomedical prevention advisor who oversaw the agency’s work on VMMC for many years, has said of the early VMMC programs, “There was less focus at that time on creating demand for services as we were very cautious about not going against the local culture. Rather, the program just followed the natural demand that existed […]”

Importantly, this low level of initial demand never imperiled the program. It just propelled the search for better strategies. VMMC rolled out with strong support from the US government, so the budget was there, as were targets. Since VMMC reduces risk of HIV in males of all ages, the target was a percentage of all males within a specific age range. Many countries developed national plans, often with the assistance of grants from funders like the Bill & Melinda Gates Foundation.
Foundation and/or technical support from the World Health Organization. Some of these conditions are different from the ones that apply for PrEP today—as we discuss starting on page 18.

For VMMC, a jump in the numbers of men coming for the procedure coincided with the infusion of funds for demand creation that came starting around 2014. Lots of issues triggered the attention: the age range of males coming for the procedure, lackluster demand, underutilized capacity and more.

Whether there is precise cause and effect is a matter of debate among VMMC implementers. In that sluggish first half-decade, countries came around to championing the benefits of VMMC, developed political will and became more invested in the intervention. However, it is also the case that the investments in demand creation did help increase uptake and identify the challenges and opportunities for reaching men in the age bands where the procedure would have the most public health impact. This happened because funders and implementers decided that boosting demand for VMMC was a priority and were willing to invest in a range of research, including investigations of men's needs, desires and motivators. This willingness to explore the nuances of experience, without necessarily knowing what form the final demand-creation strategy will take is critical, and hard to do with rigid funding cycles and pre-set deliverables.

For VMMC, this work ultimately generated insights that helped improve uptake in target age bands in some cases, and to sustain programs in other places where early geographies and communities had reached saturation level.

Many insights focused on the “journey” that different types of men—grouped on the basis of formative research—go through to decide whether to undergo VMMC. The figures on page 11 show the outcomes of one example of this work.

VMMC has also yielded some of the only information about the cost of demand-creation activities in a programmatic setting. Surprisingly, these figures

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### Key Questions for Advocates to Ask About Demand Creation Plans

- Who is developing the demand creation approach, what is the methodology budget, timeline?
- What is their expertise and do they have respect for and empathize with the people they are hoping to influence?
- How are the views, needs and desires of the people using the product or service being solicited and incorporated?
- How is the demand-creation work being iterated on during the life of the program and measured so that successes are built upon and failures captured so that they are not repeated?
- Is there a comprehensive understanding of demand creation or do people just limit demand creation to mass media interventions?
- What are the relevant technical advisory groups within and outside of government that are linked up with the demand creation approach?
- How is the work connecting to other initiatives with relevant expertise?
- Do the group(s) leading the demand-creation work understand that not all civil society groups are made up of “end-users” of a given product; that civil society needs to be engaged not only in focus-group discussions but as architects of programs and engines of accountability?
Human-Centered Design: Part of AVAC’s Expanded Work on Product Introduction

Over the past three years, AVAC has undertaken a new body of work focused on product introduction. This work complements the advocacy that remains central to our identity and mission. Across all our work, we seek to ensure timely availability and widespread coverage of efficient, effective and affordable HIV prevention options. Our product introduction work focuses specifically on these four key areas: (1) Understanding the products’ users, (2) Compiling and analyzing market data,

Laying the Groundwork:
- Develop project goals
- Build consortiums
- Immersion

Turning Insights Into Interventions:
- Initial field work
- Documentation
- Analysis & synthesis
- Communicate findings
- Choosing a focus
- Strategic planning
- Ideation & prototyping
- Field testing
- Revision / iteration
- Finalize designs
- Implementation

BARRIERS & RISKS
- Lack of process transparency & inconsistent communication
  When HCD teams “go dark” it causes significant anxiety to stakeholders outside the HCD team. Stakeholders need detailed documentation and frequent updates to be able to explain and advocate for the work during and after the project.

- Overwhelmed and under-resourced country offices
  Country offices aren’t always given enough background information or hours to successfully manage/participate in HCD activities. It’s also risky to participate if resources and performance indicators don’t support HCD goals.

- Losing track of feasibility and sustainability
  It can sometimes seem like designing clever solutions is prioritized over designing ones that are feasible to implement and can be sustained long-term.

HOW TO MITIGATE
- Avoid the “black box” effect
- Ensure the right resources & performance measures are in place
- Revisit feasibility and resource allocation as interventions take shape
(3) Sharing information, (4) Bringing effective prevention options to those who need them. We are presently in the midst of a two-year collaborative research project called “Breaking the Cycle of Transmission”, which is using human-centered design to improve approaches to delivering HIV prevention options amongst adolescent girls and young women. At the outset, AVAC and collaborators began by mapping out stages in the human-centered design process, which is new for many stakeholders. The table below is one output from this work—for more visit https://www.avac.org/product-innovation-availability.

### Understanding and Increasing Impact:

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<thead>
<tr>
<th>BARRIERS &amp; RISKS</th>
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<td><strong>Piloting</strong></td>
<td><strong>Build a more robust picture of impact</strong></td>
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<td><strong>M&amp;E (intervention output)</strong></td>
<td><strong>Tailor deliverables for specific audiences</strong></td>
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<td><strong>Scaling</strong></td>
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<td><strong>M&amp;E (project impact)</strong></td>
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<td><strong>Communicate findings</strong></td>
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<td><strong>Broader dissemination</strong></td>
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<td><strong>Broader application</strong></td>
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- **Measurement fails to capture behavioral change**
  The existing measures used to communicate ROI are often too focused on simple uptake measures to capture behavioral change. This and other meaningful HCD impacts can get lost in translation.

- **Deliverables aren’t easy for outside audiences to pick up & understand**
  While much HCD research exists and is open to be shared, audiences may not know where to find it, and don’t often have the resources, expertise or desire to use insights developed by other firms.
AVAC’s take on milestone events and impact on VMMC numbers. Cause and effect is open to interpretation.

FIG. 7 Annual Number of Voluntary Medical Male Circumcisions, 2008-2017


aren’t calculated separately or included in estimates of cost-effectiveness and impact. A recent study from the South African CAPRISA team4 shows how simple analysis and adjustment of demand-creation activities can be tied to changes in cost and impact on uptake.

From success to struggle: Condoms and demand creation

Demand creation investment also has to be preserved over the long haul. When it isn’t, healthy programs falter. This is agonizingly apparent with condom programming, so much so that UNAIDS has identified a “condom crisis” within the prevention crisis it also highlighted.

When condoms were first introduced as HIV prevention—and were the only biomedical tool available—many countries and funders invested substantially in a robust condom marketplace that included free public brands, socially marketed subsidized condoms and private-sector choices.

The advertising and demand-creation campaigns for socially marketed brands were innovative and country-driven. At their peak, socially-marketed

Tailored approaches to different “segments” of a population, without leaving out community and context. Messages about various prevention and treatment approaches need to be tailored to reach specific segments of the population—with a finer degree of specificity than ever before. It is not a matter of reaching adolescent girls or sex workers with PrEP but of finding those at highest risk within these populations. The interventions—which might include peer outreach, media campaigns and tailored counseling—that might persuade a man who does day labor and sleeps in a hostel with little privacy, to initiate ART the same day he receives an HIV-positive test result, might be different from what a professional man in an urban center would need. If there is too much tailoring the target group can get stigmatized, so information and access for others in the community is important too.

Costed and quantified approaches to primary prevention-focused peer navigators and lay cadres that are integrated with similar approaches in other programs. 2018 may be the year of the low-paid “volunteer” or “peer” or “low-level cadre” health worker. These groups of workers are the key for just about everything: testing, linkage to care, adherence support, championing PrEP and much more. The number of terms used in this paragraph are just a handful of the many different categories thrown around by countries and implementing partners. At times it seems like the future of the HIV response depends on an unpaid workforce made up of people living with or at risk of the virus—and, except for the “unpaid” part, it does. Program design has to tackle the roles, compensation and standardized training and support for these cadres to create demand and support choices about primary prevention and ART.

Breakdown of costs for demand creation by prevention intervention and “yield” in national and implementer budgets. At the 2018 regional planning meetings for PEPFAR programs, many countries committed to robust demand-creation programs focused on viral load and the individual and public health benefits of undetectable status, known commonly as U=U. But when it came down to checking whether there was enough money to make good on these commitments, the budget lines for demand creation and communication work often seemed inadequate. And that was just in the context of U=U. Scant resources for primary prevention can scare people off of looking at the costs of doing specific activities thoroughly and well, but that just makes for shoddy programs and less incentive to spend more. Putting demand-creation budget lines into programs and tracking that spending along with performance must be done by PEPFAR and national governments as well as programs.
Demand creation investment also has to be preserved over the long haul. When it isn't, healthy programs falter. This is agonizingly apparent with condom programming.

condom programs provided 20-25% of condoms and covered approximately 15-20% of total global need. Today, of the 32 major social-marketing programs, only a dozen remain—and that number is going down. In countries like Burkina Faso, the rollback of a social-marketing program coincided with an increase in new HIV diagnoses.⁵

**Daily oral PrEP: The most demanding strategy to date?**

To work, demand creation needs to be systematic and sustained, and reviewed for iterative improvements on an ongoing basis. It also needs to be situated in the larger context: it isn't a solution to societal or structural flaws. Nowhere is this more apparent than with daily oral PrEP.

Based on the most recent data presented at the International AIDS Conference, the largest and highest-risk population in need of PrEP—adolescent girls and young women—either isn’t starting or isn’t staying on daily oral PrEP. In one Kenyan study, less than half of all sex workers and MSM came back for their one-month visit after initiating PrEP. For adolescent girls and young women in the same study, the figure was less than a third. After six months, retention rates stood at 15% for MSM and 10% for AGYW.⁶

Kenya launched its program with intentional, audience-specific design, so the problem can’t be traced solely to the approach to demand creation. Instead, one of the largest barriers to PrEP uptake may be that adolescent girls and young women have limited agency to choose to use the product and/or may not consider themselves at risk of HIV. In this instance, a major structural and societal issue—the gender inequities that drive the epidemic—are also hindering PrEP uptake.

Many people who need PrEP the most are the ones who can’t or don’t want to negotiate condom use, who don’t know for sure that their partner living with HIV is monogamous and virologically suppressed, who have insecurity in housing, income or personal safety. In these contexts, it can be difficult to choose or consistently use any product—pill, injection or ring.

The critical step for oral PrEP programs now is to look at what’s been learned, iterate the demand-creation activities accordingly and document the demand-creation cascade (see Fig 3, p. 8) to understand who’s being reached with which components of a package designed to promote HIV prevention, with PrEP as one option. PEPFAR’s DREAMS program for AGYW is making strides to documenting “layering”—the number of adolescent girls and young women reached with multiple interventions—and this work could inform routine measurement of demand cascades. That won’t solve issues with young women’s agency, but it will help the strategy, and other HIV prevention messages, reach incrementally more adolescent girls and young women than it has to date.

The information across multiple prevention and treatment strategies is clear: peers and lay counselors make a major difference in rates of uptake and retention. Perhaps more than any other prevention strategy, PrEP depends on strategic engagement and fair remuneration of frontline peers, “champions” or adherence supporters. These cadres are called different

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things in different places—community health workers, peer educators, etc.—but whatever the name, they need to be adequately compensated and integrated into demand-creation programs. There is substantial evidence showing that mass media, e.g., a billboard, is important to legitimize a product or raise awareness, but the interpersonal communication element is crucial in giving people the information they need.

This work isn’t a given and, in many places, it isn’t happening. Save for Kenya, South Africa and Zimbabwe, there are few African countries with national plans inclusive of multi-year targets and overall program costs and demand-creation campaigns designed to reach people who need PrEP most. There are smaller efforts supported by specific PEPFAR implementing partners, but fewer national-level communications and demand-creation campaigns before PrEP hits the shelves in clinics. Uganda, for example, has had a PrEP program for nearly two years and has not yet released any communications materials.

The ideal approach would be for countries to prioritize thoughtful user-led and –embedded demand creation for daily oral PrEP from the outset, with funders attaching conditionality to PrEP dollars so that this is a need-to-have element, and countries holding implementers to account for investing in comprehensive programs, not just putting pills on shelves.

This will not only buoy programs and set them up for success, it will also help improve size estimates for those in need. A successful PrEP program for sex workers or men who have sex with men or adolescent girls and young women will be one that is welcoming, affirming and offers a range of services that are easy to get to or meet people where they are. It can serve as a way to bring identified key and vulnerable populations into contact with services and incentivize others to seek services. This is a virtuous cycle of information feeding programming, rather than the vicious one of no good estimates, no targets, no budget, no real program.

FIG 8 Anatomy of a Target

It’s been four years since AVAC advanced these criteria for effective targets in our 2014/15 Report, Prevention on the Line. Then, we identified targets that have advanced the field and ones that have fallen short. Today’s prevention crisis exists in part because the primary prevention targets set by UNAIDS didn’t meet these criteria. Targets for primary prevention are still essential, but they won’t get met without demand creation work, such as we describe in this section. It’s not too late to recalibrate resources and commitment.

- Resourced
- Audacious
- Achievable
- Measurable
- Accountable
- Political Support
- Collective Priority

Targets without sufficient resources are empty promises. Set the price tag, raise the resources and don’t ask countries to do more with less.

The best goals redefine possible. There were 50,000 people in low-income countries on ART in 2003. The 3 by 5 target changed the world.

Effective targets reflect evidence and experience. AIDS science is evolving. We can’t set a deadline for finding a cure. But we can aim high with research milestones.

Quantification is key. Prevention targets need to be tied to impact including incidence and other validated, indirect measures.

Setting a target means taking responsibility for mobilizing resources, tracking progress and sharing data.

Country-level support is key. Goals that originate in Geneva won’t go anywhere without endorsement by leaders in hard-hit countries.

No one, including scientists, can set targets on their own. Civil society, policy makers and politicians all need to buy in.
Activities by individuals or groups aimed at influencing decisions within political, economic and social institutions and systems. The distinction between activism and advocacy is often a matter of tactics—direct action, street protests and other forms of escalating disruption are associated with activism.

Advocacy is not demand creation. When civil society groups are asked to be partners in service delivery, such as by staffing drop-in centers or holding education events, they do so as experts. But their participation in this work does not mean that they cede their right to do advocacy and activism to hold funders, governments and program implementers accountable. With shrinking funding for civil society activism, many groups take on demand-creation work and can feel torn about challenging policies and programs tied to their funders. Groups are pulled into areas where they may or may not have the expertise—all PLHIV are not experts in human-centered design—and away from the areas where they and others have essential skills and leadership. Expanding the resource allocation for true accountability-focused advocacy and activism is key, as is ensuring that groups who do partner in demand-creation work can do critical watchdogging and advocacy without fear of lost funds.

The activities undertaken to raise awareness about a strategy and that, if successful, lead people who need the strategy to seek it out. These activities could include peer educators, information fairs, mass-media campaigns, radio programs, school, church or community-based outreach, one-off or recurring events and many other approaches.

Demand creation is not necessarily reflective of human-centered design. A demand-creation strategy can be and often is based on what’s been done in the past, what’s worked in the past (these are not the same thing), what fits within the project or program budget, or what’s considered acceptable by political leaders, policy makers or implementers.

A specific approach to designing demand-creation strategies, often undertaken with an emphasis on better defining difference within a group of people, such as men or adolescent girls and young women, who might be the desired users of a strategy. Its results are not guaranteed. It can yield actionable insights that boost uptake of products among key groups, but it can also be time-consuming, expensive and unforgiving of shortcuts.

Socio-behavioral research is a qualitative approach used to explore and describe human attitudes and behaviors and to generate theories that could be tied to design or intervention goals. Beyond addressing immediate intervention goals, however, SBR is about building the evidence base and contributing to new scientific knowledge. Its common features include a research protocol that is approved by ethics and/or institutional review boards and a theoretical framework guiding the work.
Choice is a dangerous word in public health these days. It’s always been politically loaded, but it’s been even more risky since January 23, 2017, when the Trump Administration implemented a vastly expanded version of the Global Gag Rule (GGR), a statute historically implemented by Republican US presidents restricting foreign NGO recipients of US funding from speaking about, referring women for, or advocating for expanded access to abortion. Previous versions of the GGR applied only to foreign recipients of US family-planning funds. The Trump Administration’s GGR applies to foreign recipients of all global health funds. The International AIDS Conference brought documentation of its pernicious effects. It is already causing services to close, reproductive-health coalitions to falter due to confusion about allowable activities, and imperiling women’s health and lives as unsafe abortions and poor outcomes from unplanned pregnancies take their toll.¹ Curtailing choice—especially when that choice is when and how to become pregnant or to remain pregnant—is dangerous.

¹ Bound and gagged: Exposing the impact of the expanded Mexico City policy. AIDS 2018. Available at: http://programme.aids2018.org/Programme/Session/130.
To fight back, all champions of women’s health and HIV prevention need to use the word choice frequently, passionately and strive to protect the programs women and girls most need. This is true in terms of direct resistance to the misogynist, anti-science politics at play in the expanded GGR.

It is also true in other contexts, including primary prevention, antiretroviral treatment and contraceptive programming. Indeed, it is no exaggeration to suggest that the future of biomedical HIV prevention depends on the field assuming a leadership role as a champion of and expert on informed choice.

As the graphic above depicts, informed choice, in the context of health care, encompasses elements including but not limited to information, staffing, commodities, and time and space for conversation that, when assembled, allow an individual to make the health decision that is right for him or her.

The term “informed choice” is frequently used in the context of family planning programs (see p. 29) and was used with regards to HIV in the context of the WHO guidelines for infant feeding by women living with HIV. First issued in 1991 and updated many times over the years, these guidelines are among the most conflicted of HIV policy documents. They were first issued at a time when women with HIV who were not on ART had to choose between breastfeeding and formula feeding, knowing both options carried health risks for their babies.

The implementation of the WHO infant-feeding guidelines, in their various forms, has provided a wealth of information about how the concept of choice has been understood, implemented and ignored by providers, funders, governments, women and their families. As one study from
Senegal found, when WHO began to recommend antiretroviral treatment for all pregnant women living with HIV, the related shift away from formula feeding as an option had a range of consequences. Social and organizing spaces for women living with HIV had emerged at the community centers where they were instructed to go to pick up formula. Removing infant feeding meant an end to these spaces; so the loss of choice was also a loss of community and agency. The author writes, of formula-based programming, “It introduced women caught in medically-defined relationships to a type of biosociality they could assert in associations, without necessarily becoming an ‘expert’ [...]” It wasn’t the specific option, but the framework that supported choice that mattered. Single-option approaches, while supported by science, can feel over-medicalized and undermining of clients’ agency. Still, informed choice is not simple. Many studies have documented all the ways that informed choice is challenging to implement and measure due to provider biases, varying degrees of training, limited time per client and so on.

Yet today, most biomedical prevention programs are only just beginning to grapple with the complexities. Countries and implementers consider the provision of PrEP or VMMC or condoms, but rarely all of these options together. The research arena is also siloed, with leaders often advocating for a specific approach rather than effective prevention by whatever means work best for a person at a given moment in his or her life. It can be tempting to think that the right prevention option might allow for a large-scale, single-strategy push. But history says otherwise.

Put affirmatively, there is an opportunity today to reverse a decades-long tradition of foot-dragging, penny-pinching and corner-cutting when it comes to HIV and contraceptive services, and to fully embrace a human- and choice-centered approach to delivering services.

Choice and Contraception: Rings as a real choice

In August 2018, the US Food and Drug Administration approved the first contraceptive ring that can be worn vaginally for up to a year. “Annovera”, developed by the Population Council, is a flexible silicone ring that contains synthetic hormones that prevent conception. (A similar ring, containing the ARV dapivirine, is under regulatory review with a decision pending in the coming year (see Fig 14, p. 33).) The contraceptive ring developers have lauded this approach as being the first contraceptive providing year-long protection wholly under a woman’s control—a reference to the fact that women can insert and remove the ring themselves. Vaginal rings are also in development as multi-purpose prevention technologies that contracept and reduce the risk of HIV or other STIs (see Fig 16, p. 37). Both family planning and HIV prevention programs will need to incorporate rings as a choice sooner or later. This advance is a great chance to build collaborative programming, including with civil society, which has raised concerns that messages about the new one-year ring could prompt confusion about other discrete methods that also provide long-term protection.

What does this mean, exactly? In Section One, we talked about the need to invest in demand-side thinking: ensuring that people’s mindsets, ideas, preferences and decision-making “journeys” inform the messages, products and services offered to them. At a very simple level, adding “informed choice” to this approach means that, at the end of the journey, people have more than...
Choice and HIV Testing: Can a “high-yield” focus uphold human rights?

Early in 2018, the US AIDS program, PEPFAR, declared that 30 percent of all new HIV diagnoses in its testing programs should come from index testing, an approach that relies on individuals to provide the names and contact information of sexual and needle-sharing partners and children who may have been exposed. The program then uses this information to trace and test these contacts, without revealing the source of the information.

Data from index-testing programs show high “yield”, meaning a greater proportion of newly identified positives versus other testing approaches. But advocates are concerned that yield could come at a cost of confidentiality about HIV status and/or about aspects of a person’s life such as same-sex partners or sex work. Data from couples-based index testing don’t show that the strategy increases the risk of violence, but couples programs are different from the index testing being rolled out today, which puts gay people, sex workers and other marginalized groups in a position of potentially coerced disclosure of contacts and, by extension, identity. This has raised real concern about human rights abuses that could be triggered by index testing that’s overly focused on yield, not on informed consent. Monitoring and measuring adverse outcomes of these programs is essential, as is documenting how many people opt out of index testing, since this is a proxy for people having the right to choose.

Our bodies, our choice: Women’s fight for dolutegravir

Recent developments demonstrate just how critical it is to budget for and design programs that are platforms for a range of options, not a single strategy. Consider dolutegravir (DTG), an antiretroviral that is well-tolerated, powerful and has a highly favorable resistance profile. DTG is such a good drug that many countries are planning to or have already switched to DTG as a first-line option, replacing efavirenz, which can cause tough side effects in the first weeks and months of use.

Yet the momentum behind the transition to DTG came to a whiplash-inducing pause in mid-May 2018. That’s when WHO issued a statement, based on data from a cohort of women in Botswana, indicating that DTG might increase the risk of neural tube defects (NTD) in infants born to women living with HIV who were on DTG-based regimens at the time of conception, compared to women using efavirenz. The risk of an NTD is within the very early weeks of pregnancy (through about day 28), so women on DTG who are in later stages of pregnancy, or who start DTG while pregnant, would not face that risk or need to switch.

In response, several African countries moved swiftly to adapt the WHO statement, with proposed guidance that DTG only be offered to women over the age of 49 (i.e., women who were less likely to become pregnant). This move prompted outrage from women living with HIV who were on DTG-based regimens at the time of conception, compared to women using efavirenz. The risk of an NTD is within the very early weeks of pregnancy (through about day 28), so women on DTG who are in later stages of pregnancy, or who start DTG while pregnant, would not face that risk or need to switch.

In response, several African countries moved swiftly to adapt the WHO statement, with proposed guidance that DTG only be offered to women over the age of 49 (i.e., women who were less likely to become pregnant). This move prompted outrage from women living with HIV and their allies who demanded that they be given the choice to take DTG-based regimens—ideally with the offer of effective contraceptives—and that those women who wanted to stay on or switch to efavirenz also be allowed to do so.
Phases of Informed-Choice PrEP Counseling

This flow chart emerged from socio-behavioral research, including surveys and in-depth interviews with Kenyan and South African women. The research team set out with the goal of adapting the informed-choice approach used in family planning programs for use in PrEP, a prime example of fields learning from each other. The result is very clinic-centered; AVAC has added the column at the far right to reflect additional elements. However, it is a step towards much-needed exploration of how to make informed choice a reality in HIV prevention today.

**Introductory phase**

- **The counselor:**
  - Informs client that PrEP is available, explains what it is and asks if client is interested.

- **The client:**
  - Expresses interest in PrEP and proceeds to information phase.
  - Is not interested in PrEP and proceeds to standard HIV risk-reduction counseling.

**Information phase**

- **The counselor:**
  - Explores the client’s current context of risk and preventive behaviors.
  - Educates about what different choices (and combinations) such as PrEP, condoms and ART (leading to viral load suppression for known partners living with HIV) can and cannot do.
  - Encourages client questions and asks questions to ensure comprehension.

- **The client:**
  - Helps the counselor understand her context of risk and preventive behaviors.

**Deliberation and decision-making phase**

- **The counselor:**
  - Helps client apply information to her individual circumstances.
  - Provides information and skills to reduce HIV risk and promote overall sexual health.
  - Supports client in her informed decision.

- **The client:**
  - Considers information and makes a decision about what method(s) are right for her to use.

**Concluding phase**

- The client finalizes her decision.
- The counselor welcomes her to return in the future if she would like to try a different approach.

**Requirements: An advocacy checklist**

- Commodities to support client decisions
- Training and supportive supervision for counselor to assess client risk, provide non-judgmental and supportive space for decision-making
- Staffing levels and compensation that support the time needed for conversation
- Peers to support and enhance choices
- Commitment to revisiting client’s choice(s) over time
- Monitoring and evaluation approaches to measure decision quality and informed choice

Inaction on informed choice: The case of Depo-Provera and similar products

In 2019, the ECHO trial that is asking whether DMPA-IM (depot medroxyprogesterone acetate or Depo-Provera, delivered via intramuscular injection), the copper IUD (intrauterine device) or the Jadelle implant impact women’s risk of HIV, is expected to release results. These data could shape policy and programs, and yet by that time it will have been two years since WHO reclassified DMPA and other progestin-only contraceptives as having a theoretical or possible risk related to women’s HIV acquisition. And it will have been seven years since an earlier classification stipulated that women at high risk of HIV should be informed about the uncertainty related to DMPA and similar products. As African women and their allies have said repeatedly, these classifications should have triggered a substantial investment in programs that provided women with comprehensive information on the

to support informed choice existed when there was little choice in treatment; today, when such choice is possible, these resources are much diminished.

The DTG developments—still evolving as this report went to press—also highlight the ways in which the HIV field has missed opportunities to invest in the studies and data collection needed to inform choice in the first place. As Polly Clayden, veteran HIV activist and expert on women, HIV and pregnancy, wrote in a July 2018 review, “Despite massive global investment, aggressive transition plans—as well as calls for years for more systematic recording of outcomes when women receive ART in pregnancy—few prospective birth registries have been established in other settings that can refute or confirm this finding.”

This type of inaction can make a fallacy of informed choice. If better data are not collected, then the choice will not be any more informed in a year—or ten—than it is today.

Funders don’t always prioritize investment in the types of research that enhance, focus and provide the basis for informed choice. While low-cost compared to clinical trials, the research and information-gathering that should be done to support informed choice often isn’t funded. Here are three examples:

- Pregnancy registries for women on ART aren’t adequate, as the DTG developments have made clear.
- Research into how to convey complex choices to clients and providers is underfunded and not translated from field to field. There is nothing in peer-reviewed literature about counseling women about DMPA and similar contraceptive products in the context of uncertainty about HIV risk, even though that uncertainty is more than eight years old. Contraceptive programs and infant-feeding programs for women living with HIV provide examples but are seldom cited by HIV practitioners.
- The ECHO trial is smaller than its leaders originally proposed, simply because of funding. One of the proposed arms that got dropped was the injectable NET-EN, which contains a different synthetic progestin from DMPA. NET-EN is a potential alternative to DMPA-IM, but its absence from ECHO means that there will be unanswered questions about how different it is from DMPA, if at all.

Research to Inform Choice-Based Programs: Three Gaps

In 2018, the ECHO trial that is asking whether DMPA-IM (depot medroxyprogesterone acetate or Depo-Provera, delivered via intramuscular injection), the copper IUD (intrauterine device) or the Jadelle implant impact women’s risk of HIV, is expected to release results. These data could shape policy and programs, and yet by that time it will have been two years since WHO reclassified DMPA and other progestin-only contraceptives as having a theoretical or possible risk related to women’s HIV acquisition. And it will have been seven years since an earlier classification stipulated that women at high risk of HIV should be informed about the uncertainty related to DMPA and similar products. As African women and their allies have said repeatedly, these classifications should have triggered a substantial investment in programs that provided women with comprehensive information on the different.
No Prevention, No End

Supplies Coalition “advocacy pack” for DMPA-SC talks about the uncertainty related to HIV risk and urges advocates to call for more choices and better integration of HIV and family planning.  

But DMPA-SC is not being systematically rolled out with choices for women who might want a comparably long-acting option or better HIV prevention to offset the uncertainty. By the same token, if ECHO shows that DMPA-IM does exacerbate women’s HIV risk, it is still a totally reasonable and rational choice for some programs to choose DMPA-IM or DMPA-SC as an option, and for some women to choose either as their option.

Will the champions of choice please step up?

As Figure 11 (p. 28) shows, ongoing discussions regarding DTG and hormonal contraception are converging on common areas: the degree to

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**FIG. 10** Contraception and HIV Prevention: A clear picture of women’s needs

A range of scientific models predict that a world without DMPA is bad for women. It’s a discrete, long-acting method that many women want and prefer. But this isn’t a scenario that’s likely to occur unless there’s profound negligence and poor communication.

In many parts of Eastern and Southern Africa—the parts of the world where DMPA use and HIV prevalence are high—the shot is the only long-acting option on the shelf in programs that provide little or nothing in the way of comprehensive HIV prevention. Women need contraception, so this is better than nothing—but not good enough by a long shot.

One woman faces many choices about HIV prevention and contraception. Funders and governments need to move to integrate programs that provide all these services in one place.

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which public health systems and funders trust women to make their own choices, the degree to which those rare systems that do trust women are resourced to procure the products and train the providers in ways that support choice, and the ways in which choice is understood to be about overall health rather than a specific option.

This is the best if not the only context for delivering new biomedical prevention strategies. Many scientists and advocates in the field recognize this and pursue it in their work every day. This is why the biomedical prevention field has the potential to become a leader in informed choice. Done right, this leadership from the biomedical field will build trust among potential users, by demonstrating the clear understanding that the world is organized around people, not products. There are not women who just need HIV prevention or women who just need contraception, nor are there people who only need information on dolutegravir and others who need clarity on DMPA. Products aren’t perfect. The programs that deliver them need to provide full information about risks and benefits in language that’s clear and in the context of choice between options and the integration of services—contraception, HIV prevention, sexual and reproductive health and rights. A good information sheet on dolutegravir or DMPA won’t do the trick because it isn’t an issue-by-issue problem. The need for proactive investment in simple, robust strategies for communicating about and providing choices is essential in all fields.

**FIG. 11 Putting Women* at the Center: Informed choice in 2018 and beyond**

*This graphic uses issues of primary relevance to cisgendered women and does not reflect diversity within those communities. The principles at the center could be adapted to apply to every category of person affected by HIV, including but not limited to transgender women, gay men and other men who have sex with men, heterosexual men and migrants. We also stand firm in the belief that the needs and issues of cisgendered women must be continually and specifically foregrounded as central to any epidemic response.
“It’s time for an integration index,” said South African researcher and women’s health advocate Helen Rees at AIDS 2018. She made the remark at a panel that was a first for the international AIDS Conference: a joint session including FP2020, HIV prevention researchers and civil society activists. FP2020 is a global partnership dedicated to expanding women and girls’ right to decide whether, when and how many children to have. The index Rees proposed would measure the integration of family planning and HIV services in clinics, programs and policies, and could be a meaningful way of tracking a merger that’s essential to ending HIV. In many countries, including South Africa, the young women most at risk of HIV are far more concerned about pregnancy. Services have to be co-located, non-judgemental and centered on choice.

Beth Schlachter, the Executive Director of FP2020, shared some of the ways that FP2020 is working to expand women and girls’ right to control their bodies. Some of FP2020’s indicators could be adapted for HIV prevention and used as the cornerstone of the integration index. Watch for advocacy on this in 2019!

As part of its annual evaluation of progress, FP2020 has developed a trio of indicators to measure rights-based family planning, which it defines as programs that aim to fulfill the rights of all individuals to: choose whether, when, and how many children to have; act on those choices through high-quality sexual and reproductive health services, information, and education; and access those services free from discrimination, coercion and violence.

Core Indicator 14, the Method Information Index (MII), serves as a proxy for quality of counseling and reflects the extent to which women are informed about side effects and alternate methods. The MII is a summary measure constructed from three questions asked of current contraceptive users about the occasion when they obtained their current method:
- Were you informed about other methods?
- Were you informed about side effects?
- Were you told what to do if you experienced side effects?

In 2019, the ECHO trial will release data on whether DMPA or two other contraceptive methods affect women’s HIV risk. These data are most relevant to countries where HIV prevalence and DMPA use are both high. The MII values for some of these countries are shown below.

Core Indicator 15 measures the proportion of women who have received any kind of family planning information in the last 12 months, either from a health worker in a facility or in the field (among both those using and not using contraception).

Core Indicator 16 measures the percentage of women using family planning who made family planning decisions either by themselves or jointly with their husbands or partners. This indicator shows a high level of women’s participation in contraceptive decision-making, yet it is also important to note that in 15 of 35 countries with data, at least 1 in 10 female users reported that they were not involved in such important choices as whether and when to use contraceptives and what method to use.

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Method information index in countries most impacted by uncertainty about DMPA and HIV

The x-axis measures the percent of women who answered “yes” to each individual question; the bar at the top of the graphic shows the percentage of women who answered “yes” to all three questions.


13 Hormonal contraception and HIV risk at the crossroads: What do the latest research, advocacy and program developments mean for women, providers and programs? Proceedings of the AIDS 2018 Conference, 2018 July 23; Amsterdam, Netherlands.
Peers are Primary: Towards a systematic approach to lay cadres

Across treatment and prevention programs, peer navigators, mentor mothers and lay counselors are recognized as essential to good services. Yet many countries don’t have clear schemas for quantifying the number of individuals needed, budgeting for their remuneration and defining the roles and responsibilities that lead to impact. Activists are working to ensure clarity by demanding that governments, funders and implementers take steps to:

- Quantify the need and coverage gap for lay workers supporting HIV and other health services;
- Recognize lay cadres in government human-resources-for-health plans;
- Monitor performance in sites and programs with different types of lay workers;
- Provide updates on investments in human resources for health by cadre as part of all PEPFAR Country Operational Plans, AIDS reviews and other annual surveys.

Defining the peer or lay person’s roles and responsibilities is essential. The graphic below is one example of what a specific job description could look like.

No radical action, no end

3

An end to epidemic levels of new HIV infections—a situation that occurs when the rate of new diagnoses is lower than the rate of deaths from AIDS—is possible. Profoundly, achingly possible. It will take a major course correction in approaches to primary HIV prevention, but it can happen and there are signs that it is already underway.

The concept of differentiated prevention is beginning to gain currency, thanks in no small part to Kenya’s committed and forward-thinking leadership, which undertook a “Prevention Revolution” over four years ago. In a plenary speech at the Amsterdam AIDS Conference, Nduku Kilonzo, Executive Director of Kenya’s National AIDS Control Council, laid out the core elements of such an approach (see Fig 13, p. 32).

THE PROBLEM
There is a primary prevention crisis. The emphasis on ART-based programs to reduce incidence has drawn attention and funds from primary prevention for too long; the 2020 global target for incidence reduction will be missed.

THE RISK
So much has been accomplished in the fight against AIDS; so much is left to do. Emphasizing failure can hurt morale and momentum, yet so can over-promising and failing to deliver.

THE PATH TO A SOLUTION
Tailor today’s prevention approaches to specific communities and contexts; sustain research and prepare for results. ART scaled up in the context of flat funding by finding efficiencies; biomedical prevention hasn’t nearly done the same. Accountability mechanisms for implementing effective primary prevention must be built into GFATM, Global HIV Prevention Coalition activities and PEPFAR COPs and at the same time champions of primary prevention can prepare the world for research results and future trials.
There is a robust pipeline of biomedical prevention options, including vaccines, antibodies, injectable PrEP and multipurpose prevention technologies. As Figure 14 shows, pivotal trials will yield results in the next 24 months; these findings could expand the prevention toolbox, provided that there are platforms—based on today’s strategies—for delivery.

The 2018 International AIDS Conference and *Miles to Go*, the UNAIDS report that preceded it, were also notable for their embrace of human-centered programming. There is now widespread recognition that the only way to address the needs of men, boys, women, girls and key populations is to meet people where they are, with peers trained in interpersonal counseling and communication leading the way.

PEPFAR’s emphasis on site-level data and on expanding investment in indigenous organizations is laying the groundwork for a truly country-owned, data-driven response. Small adjustments to approaches can yield dividends in terms of people coming for services. Such fine-grained analysis of service quality is becoming more common in the context of ART, though there’s still, as UNAIDS would say, miles to go. It hasn’t become the norm for primary prevention.

Condoms—basic and relatively low-tech—played a critical role in the early AIDS response. Use and funding for social marketing for condoms is down, but again, the alarm has been sounded and people are beginning to pay closer attention to the targets, resources and program design for this pillar of primary prevention.

These are the signs of hope to hold onto as we contemplate the world beyond 2020, when prevention targets will be missed and will need to be reset. That world will also be one in which, if present patterns hold, the effects of climate change will be devastatingly palpable. Heat waves, floods and droughts will exacerbate food insecurity and political unrest and propel human migration. This, in turn, will increase individual- and community-level risk with regards to a range of health issues, including HIV. At the same time, global demographics will be even more pronounced than they are right now: the youth “bulge” of 15- to 29-year-old individuals will become a youth “tsunami” (a convergence of climate catastrophe and demographic metaphor that is, sadly, apt). Countries—including the US, where the majority of AVAC staff are based—will continue to test the strength of political activism and resistance against authoritarian regimes.

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**Kenya’s HIV Prevention Revolution Roadmap**

![Kenya’s HIV Prevention Revolution Roadmap](https://hivhealthclearinghouse.unesco.org/sites/default/files/resources/kenya_hiv_prevention_revolution_road_map.pdf)


One problem with HIV prevention agendas is that they either live in an eternal present or in a far-off future. It’s *Work with what we’ve got, which is condoms and VMMC and a little bit of PrEP* or it’s *Nothing can change without an AIDS vaccine*. The future depends on using what’s available, better and more widely, without ever losing sight of what’s in the pipeline.

As the figures below show, in the very same timeframe that the world will miss its critical target for incidence reduction and scale-up of primary prevention, several trials will release results that could change the future. 2020 will be a time of hope and reckoning. But only if the two stories start to be told as one.

Visit [www.avac.org/pxrd](http://www.avac.org/pxrd) for trial status updates.
Coalition provides a platform for countries, including government and civil society. What if these countries banded together and became the activist voice for an HIV response that UNAIDS has been in the past? UNAIDS has been hobbled by its response to the #metoo sexual harassment issue and, prior to that, had been largely silent on primary prevention for years. (While not the focus of this section or Report, AVAC stands in solidarity with the women who have raised their voices for a zero-tolerance approach to sexual harassment of all sorts in all settings.) What if UNAIDS used the frameworks and scorecards available to grade donors and implementers on their commitments to meeting primary prevention goals, if it identified national and regional resource gaps and if it perhaps even added a set of indicators for tracking the impact of trade policies, inaction on climate emissions and criminalization of migration on country-level economic indicators linked to individual and public health?

In the short term, the only outcome might be the enumeration of the gap between rhetoric and reality. But when low- and middle-income countries assert leadership, their partners in the Global North often listen, if only because of the other geopolitical interests—far beyond the scope of HIV—that are at play.

**Anticipating 2020: Talking points on the missed target**

Some people won’t care at all that the world has missed the prevention target; others may decide that major investments in some or all of the HIV response are no longer warranted. Honest analysis can provide fodder for critics. An accurate explanation of why it’s been so difficult to reach adolescent girls and young women, as an example, could reduce confidence that it’s even possible. Yet any retreat in funding or emphasis, particularly for young people, could allow a surge in new diagnoses that overturns decades of work that has kept the surge of new diagnoses in check.

In this context, the prevention-specific beacons of hope will be important but inadequate. The imperative is to take the specific solutions that are at hand for primary prevention and integrate them into a broader agenda for social change and global justice. It is not unlike the imperative facing everyone concerned about climate change: to make as many immediate and local adjustments as possible while working ceaselessly towards radical, revolutionary revision of the way the world works.

It’s time for new thinking and “what if” proposals. At the top of the list: What if the Global HIV Prevention Coalition, which is a UNAIDS-convened effort that comprises the 25 highest-burden countries in the world, along with many other stakeholders, obtained and flexed more muscle than it currently has? The

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**FIG. 15 Public Health is Personal, Pleasurable and Connected**

What gets measured gets funded, the adage goes. What would happen if communities demanded measurements of individual and collective health and well-being that have nothing to do with a retrovirus or a specific sex act, and everything to do with human dignity, comfort and safety in one’s own skin—a comfort that’s hard-fought in racist, sexist, homo– and trans-phobic nations? Imagine a world in which this cascade counted as much as 90-90-90. Let’s work to make it a reality.

Credit: David Malebranche, Morehouse School of Medicine, USA, Making the Treatment Cascade Work in Key and Vulnerable Populations, AIDS 2018 (Accessible at: http://programme.aids2018.org/Programme/Session/35).
cases at bay. It’s important to clearly explain the specific, surmountable issues that have led to the missed target and with an eye to what can be done next. Some key talking points:

► Constrained resources have forced countries into false choices between primary prevention and prevention derived from people living with HIV achieving and maintaining virologic suppression on ART.

► Human rights are fragile and frequently violated, and in the absence of societies that value women, girls, gay people, people who use drugs, transgender individuals and all other forms of difference, it is very, very hard to provide services that work.

► The strategies that do exist have not been deployed at the scale needed for population-level impact.

► There is no “silver bullet” primary prevention tool: VMMC is simple and powerful, but it is only indirectly beneficial to women; oral PrEP and condoms only work when used correctly and consistently, and each carries unique adherence challenges. The same will apply to the dapivirine ring, if it is approved. Next-generation products may address some of these challenges but will undoubtedly bring different ones. More strategies with different characteristics are needed—not instead of what already exists, but in addition to it.

An agenda for the future, starting today

There are no simple answers but there are some things to try, starting now, that could lay a strong foundation for 2020—and beyond.

► An activist Global HIV Prevention Coalition that uses its platform to hold funders and implementers accountable for meeting the resource needs for a comprehensive primary prevention response.

► A requirement at Global Fund to Fight AIDS, Tuberculosis and Malaria that all countries applying for grants have clear prevention roadmaps and commensurate funding lines, with criteria regarding legal, structural and rights provisions, as well as integration of sexual and reproductive health and rights.

Radical Action on Prevention: How it adds up

The world is poised to lose ground in the fight to control HIV, but it doesn’t have to be that way. The components listed below depend on activists and advocates taking radical action to ensure accountability at every stage.

Set targets that are resourced, audacious, achievable, measurable, accountable, have political support and are a collective priority.

Deliver primary prevention via programs with robust demand creation, a rights-based framework and a commitment to choice.

Sustain investment in basic science, clinical trials for the long haul.

Staying on the path to epidemic control.
Now is the time to build alliances in the trenches. Whatever happens, it is going to be a fight.

- A budgeted “path-to-access” strategy from the funders and implementers of the seven efficacy trials of five different strategies set to release results in 2020–22, which demonstrates when, where and how different options can be layered in. Think of this as the prevention research roadmap that has been missing from the Global HIV Prevention Coalition. It’s a shame it got left out, but the field can do it for itself.

- A sustained commitment to research funding to ensure that upstream products make it into efficacy trials.

- Common cause built by working on broader issues. The 2018 High Level Meeting on Tuberculosis saw alarming pushback against national and global targets, R&D commitments and language affirming access to medications and vaccines. The search for an HIV vaccine is at a pivotal moment, just as funding for vaccine research may be faltering across diseases. An effective preventive vaccine will play a crucial role in conclusively ending the epidemic. Now is the time to build alliances in the trenches. Whatever happens, it’s going to be a fight.

Yes to prevention, yes to shared humanity

“Cascade” is another one of those words-of-the-moment in the HIV response. In an era of fine-grained data and measurable outcomes, the measurement of people met, served, retained and so on is essential. These data are most often presented as a cascade. In nature a cascade is liquid—a small waterfall, typically one of many. It is not a set of steps or pillars but something fluid that changes with the light and the seasons—much like human beings do. Alongside the biomedical cascades, we must therefore imagine and pursue cascades such as the one proposed by David Malebranche (Morehouse School of Medicine), that measures our humanity and care for each other (see Fig 15, p. 34). It is through this work that the HIV response—with all of its scientists, warriors for justice, nasty women, proud gay men, beautiful transgender people, and exhausted yet tireless health workers—will help to realize the type of cascade envisioned 55 years ago by the Reverend Dr. Martin Luther King, Jr. In his letter from a Birmingham jail, he quoted the Prophet Amos, “Let Justice roll down like waters in a mighty stream.” This quote is often cited without context but the full text of the great civil rights leader’s words holds profound resonance today:

The search for a consensus will tend to become a quest for the least common denominator of change. In an atmosphere devoid of urgency, the American people can easily be stupefied into accepting slow reform, which in practice would be inadequate reform. “Let Justice roll down like waters in a mighty stream,” said the Prophet Amos. He was seeking not consensus but the cleansing action of revolutionary change. America has made progress toward freedom, but measured against the goal, the road ahead is still long and hard. This could be the worst possible moment for slowing down.
The Future of ARV-Based Prevention and More (October 2018)

The pipeline of non-vaccine HIV prevention products includes oral pills, vaginal rings, vaginal and rectal gels, vaginal films, long-acting injectable antiretrovirals and more. Also pictured are the range of multipurpose prevention technologies in development that aim to reduce the risk of HIV and STIs and/or provide effective contraception for women. (Visit www.avac.org/hvad for vaccine and broadly neutralizing antibody pipelines.)

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**DELIVERY SYSTEM**
- Oral pills
- Vaginal gel
- Vaginal ring
- Long-acting injectable
- Vaginal film
- Thin film polymer
- Phosphate buffered saline
- Nano-fiber
- Enema
- fast-dissolve insert
- Intrauterine device
- Implant

**ACTIVE DRUG**
- TFV: Tenofovir
- bNABs: Broadly neutralizing antibody
- TDF: Tenofovir disoproxil fumarate
- TAF: Tenofovir Alafenamide
- TVF/FTC: Tenofovir/emtricitabine
- TDF/FTC: Tenofovir disoproxil fumarate/emtricitabine
- ELT: Elvitegravir
- 1005: PC-1005
- MVA: Maraviroc
- RAL: Raltegravir
- MX-8591: MK-8591
- AZ: Aciylovir-Zovirax
- 7013: SPL7013-VivaGel
- Aa: Ascorbic acid
- Ba: Betulonic acid
- DDBI: Different drugs being investigated

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

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

And we’ve evolved with the field. As positive results have delivered new tools, AVAC has 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:
AVAC IN 2018

In the past 12 months, we’ve worked with partners to do more, faster and with greater impact than ever before. As the primary prevention crisis unfolds, and with current gains in epidemic control imperiled, there is no other choice. We did much more than what’s listed below—with a vast range of partners. Please visit avac.org to learn more.

Selected Highlights of Our Work in 2018:

✓ Launched a new North-South coalition focused on data-driven advocacy: The Coalition to build Momentum, Power, Activism, Strategy and Solidarity (COMPASS) Africa brings together activists working on the cutting edge of accountability—and impact-focused campaigns, with work centered in Malawi, Tanzania and Zimbabwe.

✓ Debuted a global PrEP tracker, collected best practices and co-created agendas to accelerate product introduction: AVAC’s product introduction work takes place through the HIV Prevention Market Manager project and the OPTIONS Consortium. Visit prepwatch.org, which features the global PrEP tracker and updates from projects on what works and why. AVAC’s product introduction team is also taking on next-generation products, including injectable PrEP, the dapsivirine ring and ARV implants.

✓ Worked alongside African research advocates to raise voices, awareness and tough issues: Participated in consultations on PrEP as standard of care in upcoming and ongoing trials with our partners in the Coalition to Accelerate & Support Prevention Research (CASPR), the Vaccine Advocacy Resource Group (VARG), dynamic teams of young African women, and in a “GPP Think Tank”. AVAC was privileged to partner with activists committed to keeping research on the right track.

✓ Built primary prevention movements from the ground up: Now in its ninth year, our Advocacy Fellows program has continued to provide a platform for emerging and mid-career advocates to take on tough issues, build skills and expand their reach. Our newer PxROAR programs focus on LGBT Africans working to bridge rights and biomedical agendas—a must in these dangerous times.
To learn more about AVAC, including our history, our focus and our team, please visit www.avac.org. And to support this work, please go to www.avac.org/donate.

**WEBSITES**


For the latest updates in HIV prevention, visit the **AVAC website**. It includes our publications as well as comprehensive coverage of the full range of biomedical HIV prevention interventions and is searchable by intervention and topic.

AVAC also maintains **PrEP Watch**, a clearinghouse for PrEP data, research, cost, access, implementation and advocacy efforts across the globe. It is also home to the **Global PrEP Tracker**, which offers quarterly updates on programs delivering oral PrEP.

**PUBLICATIONS**

www.avac.org/publications

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

**DATABASES**

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

The AVAC website hosts **three searchable databases**: HIV prevention clinical trials (PxRD), research literacy resources, and infographics.

**PODCAST**

www.avac.org/px-pulse

Px Pulse uses interviews, discussion and first-person reflections to explore vital topics confronting the field of HIV prevention research.

**MAILING LISTS**

www.avac.org/mailinglists

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

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

**SOCIAL MEDIA**

facebook.com/hivpxresearch
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