

Lessons From Oral PrEP Programs

And Their Implications for Next Generation Prevention



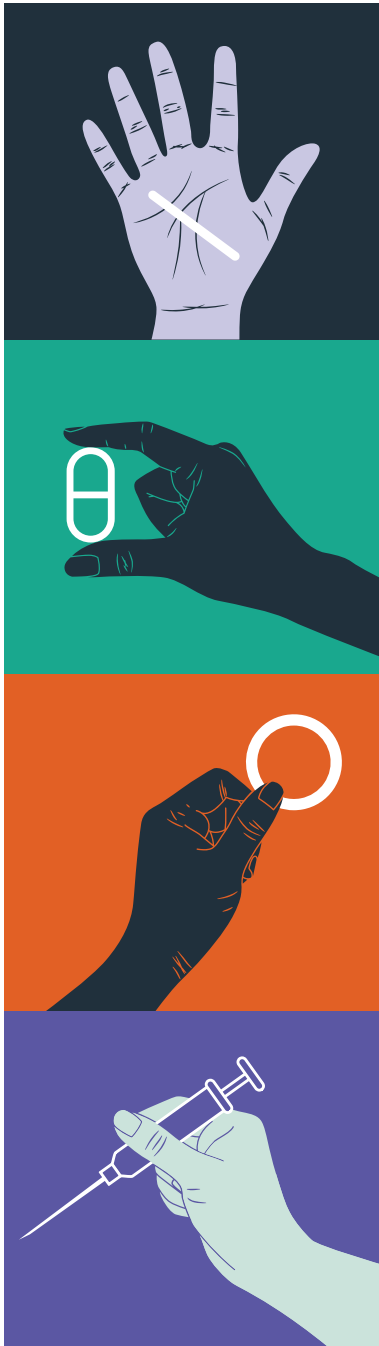
**HIV Prevention
Market Manager**

Accelerating Product Introduction
Informing Product Development
Reducing Time to Impact



Supported by the Bill & Melinda Gates Foundation

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And Their Implications for Next Generation Prevention



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Acknowledgments

The HIV Prevention Market Manager (PMM), led by AVAC and The Clinton Health Access Initiative (CHAI) with funding from the Bill & Melinda Gates Foundation, works with partners to expand the portfolio of HIV prevention options and ensure appropriate products are available, accessible and used. Since 2016, the PMM has generated key insights into HIV prevention programming, centering the people who most need, want and can use prevention, including the identification of motivators and barriers to product use and adherence. PMM has also supported evidence-based PrEP implementation in multiple countries and catalyzed solutions to improve HIV prevention delivery and monitoring of PrEP impact. PMM isn't about a specific HIV prevention product; it's about paving the way for more robust and comprehensive options; accelerating their delivery; and reducing time to impact.

This PMM report outlines insights from a decade of experience with oral PrEP programs that offer key lessons for developing and delivering HIV prevention products so that they reach those who could most benefit. PMM also developed an accompanying suite of issue briefs¹ that highlight key lessons covering monitoring and evaluation, generating demand, improving delivery, and reframing risk.

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Executive Summary

Global PrEP uptake has slowly increased, but barriers to use persist

Over a decade has passed since oral pre-exposure prophylaxis (PrEP) for HIV was first shown to be safe and effective – and nine years since the first regulatory approval and six years since the World Health Organization (WHO) recommended it for use among all people at substantial risk of HIV acquisition. By the second quarter of 2021, more than 1.3 million people had initiated PrEP globally. This represents important progress, but still falls well short of the UNAIDS global target of three million people accessing PrEP by the year 2020. Challenges related to individual reactions to the product (among both potential users and providers) and motivation to seek HIV prevention; low community awareness of PrEP; health system bottlenecks; and underlying structural barriers have all contributed to this slower-than-hoped-for introduction.

The emergence of the COVID-19 pandemic at the end of 2019 has also significantly impacted global health systems and disrupted HIV prevention services and programs, including PrEP delivery as well as care and treatment services.

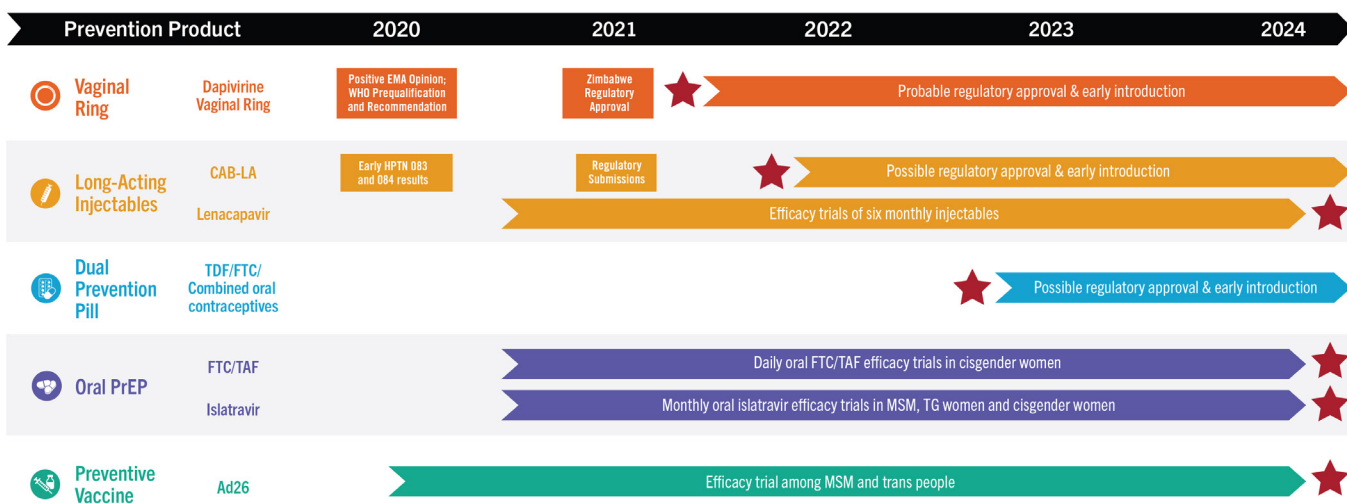
HIV biomedical prevention options are expanding

Despite these challenges, the future of HIV biomedical prevention is bright and rapidly evolving. The next five years could usher in an unprecedented era of PrEP dynamism and innovation. On the immediate horizon are the Dapivirine Vaginal Ring (DVR), which the WHO recommended in January 2021 as an additional prevention choice for women at substantial risk of HIV acquisition, and injectable cabotegravir (CAB-LA), which two efficacy trials demonstrated to be safe and effective in 2020.

Further out is an array of promising candidates including long-acting oral pills, longer-acting rings and injectables, multi-purpose prevention technologies (MPTs), vaccines and antibodies. If and when this expanded range of pipeline products proves safe and effective, and is approved by regulatory authorities, the number of PrEP options would expand considerably. These additional choices – including some that offer greater discretion than a daily oral pill – could encourage more people who are vulnerable to HIV to find a PrEP method that works well for them.

Years Ahead in HIV Prevention Research

Time to Market



Source: AVAC

Lessons from oral PrEP can inform future product introduction and scale-up

Oral PrEP offers valuable implementation lessons that can be applied to accelerate evidence-informed rollout of next-generation HIV prevention products and improve access for those who need and want HIV prevention options – when, where, and how they need them. For example:



- **Pill size, dosing schedule, branding and packaging affect demand for PrEP and continued use:** HIV prevention is often not a top priority among those at risk of HIV infection, making convenience and avoidance of stigma critically important to engage new users and sustain ongoing use. Experience with oral PrEP shows that many people find it difficult to take a pill every day. Others are reluctant to take PrEP when it's packaged like HIV antiretroviral therapy (ART), fearing they will encounter HIV-related stigma. Product developers should work with users early on to learn about their preferences related to packaging and delivery mechanisms, and develop new products that reflect user demand for simplified, easy-to-use regimens while accounting for regulatory requirements.



- **Introduction of PrEP 'for certain populations' may increase stigma and act as a barrier:** Family, partners, peers, and the wider community strongly influence individual decisions about whether to use PrEP. To reduce stigma, normalize PrEP use and better support people to use PrEP effectively, demand creation communications must address the broader community as well as potential users.



- **Peer approaches can increase demand:** In oral PrEP, peer approaches have proven to be effective demand creation and social support strategies across populations and locations in both community and facility settings. As new products are introduced, peer approaches should be central to efforts to increase awareness, address misinformation or mistrust, drive up demand, and promote effective use of PrEP.



- **Many users prefer to access PrEP in non-clinical settings:** Some groups who may benefit most from PrEP, including men who have sex with men (MSM), adolescent girls and younger women (AGYW), sex workers and transgender populations, prefer to access PrEP via community-led and community-based settings such as drop-in centers that offer comprehensive HIV prevention services.



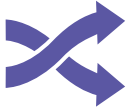
- **Excessive medical requirements and monitoring can discourage PrEP use:** Users of oral PrEP have emphasized the need for simpler PrEP initiation and delivery. Rigid risk-assessment algorithms, long waits at the clinic for refills, and arduous clinical monitoring requirements can make it unnecessarily difficult for users to start and stay on PrEP. Simplifying PrEP delivery can also enable a wider range of providers to prescribe and dispense PrEP and thus accelerate access to HIV prevention services.



- **Trained providers at different levels can broaden access and relieve the burden on health professionals:** Provider training has been critical to the delivery of oral PrEP, but it's been largely relegated to nurses who are certified to provide ART, limiting where people can access PrEP. Authorizing a wider range of providers in family planning, STI and HIV testing clinics where people seek preventative services should be prioritized. Different cadres of providers can support different elements of PrEP provision: for example, peers and other lay providers may be best suited to offer PrEP information and counseling, especially because potential PrEP users may find these providers more accessible and easier to confide in than medical professionals. Shifting these services to lay providers, with adequate remuneration, can also help reduce the burden on the facility-based health workforce, who can then focus on the clinical aspects of prescribing and dispensing PrEP medications.



- **Coordinating demonstration projects and implementation research is important to shorten the time between product approval and availability:** While scores of oral PrEP demonstration projects were funded and started in the years following proof of efficacy, there was little coordination among funding and implementing agencies. Studies risked duplicating efforts, while national and international decision-makers were forced to wade through multiple findings to inform policies and programs. In response, the Biomedical Prevention Implementation Collaborative (BioPIC²) was founded to help donors, researchers and implementers apply lessons learned from the introduction of oral PrEP, and quickly share new findings that all stakeholders can adapt as needed.



- **The concept of effective PrEP use and measures of PrEP impact need to be redefined:** Oral PrEP discontinuation rates are high, especially among young people. While many users need additional support to stay on PrEP while they remain at risk for HIV, in some cases users cycle off and on oral PrEP because their risk for HIV has changed. When new options become available, some people may also choose to switch methods as their circumstances or relationships change. PrEP guidelines, messaging, monitoring and evaluation (M&E) indicators should be reassessed to reflect this new, broadened understanding of how PrEP may be used effectively.

This report documents these and other lessons learned from oral PrEP introduction and the implications for the rollout and use of future HIV prevention products. These lessons are broken out into three categories: **Demand** Generation; **Delivery**; and the use of **Data**-to drive and enable decision-making. Taken together, they offer a roadmap that countries, implementers, donors and product developers can use to help maximize the impact of PrEP by ensuring that existing and new products are available, accessible, and acceptable and used effectively by those who need them.



Successful PrEP implementation at scale will require improvements in all three areas – demand generation, delivery, and collection and use of data for decision-making – with experiences in each area informing the others.

Summary of Lessons Learned From Oral PrEP

Demand Generation

Globally, there was a lag between the introduction of oral PrEP and the application of demand-side thinking and human-centered design to understand user preferences.

With more product options, programming and messages that prioritize the preferences of potential users (around issues such as pill size, packaging, dosing schedule, etc.) will become critically important, especially as people may not only use one product, as seen with oral PrEP, but switch between different products.

Lessons from Oral PrEP	Implications for New Products	Call to Action
<p>Issues such as pill size and packaging may impact uptake and continued use</p>	<p>Product developers and researchers should engage users early to learn about their preferences related to prevention options</p> <p>A more diverse range of products from short and long-acting as well as an array of systemic and locally-acting methods and multi-purpose technologies will help to expand access and reach greater numbers of people with HIV prevention services</p>	<p>Engage users to learn about their preferences and develop new products that reflect user demand for simplified regimens</p> <p>Work with product developers earlier in R&D process to inform product development and packaging decisions</p>
<p>Introduction of PrEP ‘for certain populations’ may increase stigma and act as a barrier to uptake for people at increased HIV risk</p>	<p>Funding for PrEP should not be earmarked exclusively for specific populations, as this can limit how and where PrEP is delivered</p> <p>To reduce stigma, normalize PrEP use and better support people to use PrEP effectively, demand creation communications must address the broader community as well as potential users themselves. Providers can focus on personalized counseling to ensure informed choice and client understanding of product safety, efficacy and other attributes</p> <p>Community-level communications should focus on creating demand for HIV prevention generally</p> <p>User-centered market segmentation strategies can be used to develop tailored messaging for key populations</p>	<p>Donor priorities should reflect funding to scale-up PrEP and promote HIV prevention awareness irrespective of product category</p> <p>Employ mass media campaigns, media engagement and community advocacy to reinvigorate PrEP messaging within a general HIV prevention framework</p> <p>Build on existing community mobilization for related issues, i.e., HIV testing, PMTCT, family planning, etc., to increase acceptance of HIV prevention</p> <p>Invest in research to understand user behavior and engage end users to co-create social marketing demand generation approaches that resonate with people’s lifestyles</p> <p>Apply Good Participatory Practice³ to implementation as well as research</p> <p>Adequately fund community engagement including community, national and global advisory groups of stakeholders and PrEP users</p>

Lessons from Oral PrEP	Implications for New Products	Call to Action
<p>Peer approaches can increase demand and have proven to be effective demand creation and social support strategies across populations and locations in both community and facility settings</p>	<p>Adapt, improve and scale up promising and effective peer approaches such as PrEP ambassadors or champions, peer navigators, peer educators and buddy systems</p>	<p>Build peer demand approaches into implementation planning for new products</p> <p>Invest in building capacity for peer mobilizers so they are able to effectively counter myths and misconceptions among their community networks</p>
<p>Users prefer empowerment messaging</p>	<p>While early messaging for new products should focus on product attributes and HIV prevention efficacy, demand creation should evolve to build user empowerment frameworks that resonate with people's lifestyles</p>	<p>Work with end users to develop demand creation messages that focus on empowerment and integration into user lifestyles</p> <p>Adapt the PrEP Communications Accelerator⁴ to develop evidence-based demand generation for new products and specific populations</p> <p>Develop decision-making tools to help individuals understand and navigate a growing number of HIV prevention options</p>
<p>Providers are critical gatekeepers</p>	<p>An expanded menu of PrEP options will require both clinical and communication capacity training for providers to accommodate and offer a range of new products to clients</p> <p>A provider messaging pivot from efficacy and risk to empowerment and client-centered counseling is needed to encourage uptake of new products</p>	<p>Identify and build awareness, clinical and counseling capacities in pre- and in-service trainings that are relevant to new products</p> <p>Train a range of providers across different delivery platforms to ensure an adequate pool of providers ready to promote and prescribe PrEP at facilities and in community settings</p>

Delivery

Initially, oral PrEP was prescribed and provided primarily through health facilities, but there's been a growing recognition that PrEP scale-up is contingent on simplifying PrEP delivery and providing client-centered care. Today, PrEP is often offered using a range of differentiated service delivery (DSD) approaches such as community-based services, peer delivery and telehealth approaches aimed at getting PrEP to those who need it, when they need it, how and where they want it delivered.

Lesson from Oral PrEP	Implications for New Products	Call to Action
<p>Many people prefer to access PrEP in non-clinical settings</p>	<p>Introduce new products within differentiated service delivery (DSD) platforms relevant to each population and context</p> <p>A combination of facility and community-based settings are needed and likely to reach a broader range of potential PrEP users</p>	<p>Support implementation research to identify and offer PrEP services at a range of sites where key populations are comfortable seeking care such as mobile clinics, safe spaces, pharmacies, home delivery and to generate evidence on the viability, acceptability and effectiveness of diverse delivery channels to influence policymakers and regulators</p> <p>Strengthen the capacity of and scale-up community and peer-led PrEP services to deliver PrEP</p> <p>Fund and scale up effective and promising delivery channels and innovations, including mHealth tools to provide users and potential users with PrEP information, reminders, counseling and support services</p>
<p>Excessive medical requirements and monitoring can discourage PrEP use</p>	<p>Demedicalize and simplify PrEP delivery to suit user preferences, improve client experience, and reduce the burden on health care providers.</p>	<p>Streamline and shorten risk assessments and ensure that individuals interested in taking PrEP are not prematurely screened out</p> <p>Use evidence from oral PrEP on delivery and user behavior to review and revise country guidelines for PrEP delivery in community and other non-clinical models such as peer distribution, mHealth and task shifting</p> <p>Advocate for multi-month distribution of PrEP medication and simplification of clinical monitoring in global and national guidelines</p> <p>Support implementation research to explore the potential of HIV self-testing as well as self-care in the context of new methods, including self-administration of injectable PrEP</p>

Lesson from Oral PrEP	Implications for New Products	Call to Action
<p>PrEP can be offered together with other related services to reach more potential users</p>	<p>Integration of new PrEP products into SRH, family planning, STI, hormonal therapy and other services can help meet the needs of key populations and optimize resources</p>	<p>Identify and offer PrEP in conjunction with health services that key populations are already using</p> <p>Strengthen and adapt health systems to support PrEP integration into existing service delivery points.</p> <p>Strengthen linkages to social services that support an individual to overcome structural barriers that may impede ongoing access to PrEP</p>
<p>Trained providers at different levels can broaden access and relieve the burden on health professionals</p>	<p>Identify and build capacity of a range of providers (including support and other staff who may not actually be prescribers) who support PrEP use and who can connect and establish rapport with users</p> <p>Work with regulators and scientists to generate data that allows non-medical providers (community and peer-led) to initiate and support product use</p>	<p>Advocate for task shifting of PrEP prescription and dispensing beyond ART-trained nurses and to train lay providers to provide counseling and outreach</p> <p>Integrate provider trainings into the introduction plan of new products as they come to market, with funding for both initial provider training (pre- or in-service) and ongoing mentorship and support</p> <p>Ensure that trainings cover both clinical requirements and empathy-building to rapidly build a critical mass of providers who can offer PrEP and support users as new products become available</p> <p>Identify and invest in providers who may serve as PrEP champions among their peers as well as among potential PrEP users</p>
<p>As PrEP programs mature, formal standards for service delivery and assessing quality of care and client satisfaction are important</p>	<p>Routine assessment of PrEP programs embedded in national mechanisms for assessing service quality is needed</p> <p>Evaluating current PrEP programs to identify successes as well as gaps could help strengthen the delivery platform for future products</p>	<p>Establish Quality Assurance and Quality Improvement (QA/QI) programs to assess program strengths and gaps as well as user experiences</p> <p>Develop QA/QI and M&E tools for use by community-based and peer-led providers and integrate into community-led monitoring efforts</p>

Data for Decision-Making and -Enabling Environments

Evidence of PrEP’s reach and impact is collected at the site level, where it can be used to improve client services, and at the national level, where it can be used to inform national guidelines and funding decisions. The introduction of oral PrEP reveals gaps in each area that should be addressed to accelerate the movement of new products, from proof of efficacy to implementation at scale. These include gaps in the ability of existing monitoring and evaluation systems to measure the overall reach and impact of PrEP. With the introduction of new products, it will be even more important to develop indicators that track the overall reach and impact of PrEP as well as the different contributions of specific methods for specific populations.

Lesson from Oral PrEP	Implications for New Products	Call to Action
<p>Advanced planning and coordination for introduction is important to shorten the time between product approval and availability</p>	<p>Understanding key elements related to the delivery of new HIV prevention methods early on, including cost, delivery channels and demand generation strategies, is critical to ensure rapid and equitable access to new products</p> <p>As new PrEP products reach the market in the next few years, implementers can accelerate scale-up by applying lessons learned from the introduction of oral PrEP (and ART and SRH) and quickly sharing results of new research so that all stakeholders and projects can adapt as needed</p>	<p>Governments and funders should ensure that approval of future demonstration projects is contingent on clear articulation of the way each proposed project complements and adds to existing or ongoing evidence</p> <p>Develop, resource and apply introduction planning and coordination models that are adaptable to products and contexts</p> <p>Leverage knowledge, infrastructure and capacity created through existing programs such as those delivering oral PrEP, SRH services or ART for rapid introduction of new products</p> <p>Ensure implementation research includes flexible approaches to respond to emerging evidence as well as integration of new products as they become available.</p> <p>Develop curricula, resources and tools that can be quickly adapted for new products and contexts</p> <p>Commit to greater coordination across partners and implementation research efforts to align indicators and outcomes and allow for comparison across contexts</p>
<p>Implementation research should be designed to address real-world questions and challenges</p>	<p>Early input from community members, implementers and policymakers is needed to ensure that studies answer the right questions.</p> <p>An orientation toward implementation over research can help studies adapt as circumstances change</p> <p>Study enrollment overall and by key population needs to be large enough to provide meaningful results</p>	<p>Engage a range of actors in implementation research from the outset: community members and advocates and potential users, as well as experts in implementation, service delivery, new product introduction, and socio-behavioral research</p> <p>Design implementation research to be nimble and responsive to changing external circumstances and mirror real-world conditions</p> <p>Invest in acceptability studies and implementation research at scale</p>

Lesson from Oral PrEP	Implications for New Products	Call to Action
<p>Information collected about PrEP users is not sufficiently disaggregated</p>	<p>More detailed data is needed to assess the impact of PrEP among different populations, assess gaps in programming and identify ways to expand access to new methods</p>	<p>Disaggregate user data (by client or facility) by population group, age, pregnancy or breastfeeding status at both the implementation level and the national level</p> <p>This is easier where electronic medical records are available and patients can be assigned unique IDs</p>
<p>A broader definition of effective PrEP use that permits a shift from measuring continuation to measuring PrEP impact is needed</p>	<p>As new options become available, users may continue to cycle on and off PrEP products, switch between products or discontinue use. This should not necessarily be viewed as an adherence failure but – when done intentionally and safely – as a form of sustained use</p>	<p>Review guidelines to incorporate cycling on and off PrEP as HIV risk changes</p> <p>Fund evaluations and implementation science to document PrEP use across products, the reasons for switching and discontinuation and improve programs based on the evidence</p> <p>Consider the family planning model to assess PrEP’s reach and impact, irrespective of specific products</p>
<p>Greater transparency in pricing and commodity costs is needed for impact modeling and to determine cost-effectiveness</p>	<p>Understanding the comparative benefit and cost-effectiveness of different products will enable prioritization earlier in clinical development and as products are rolled out</p>	<p>Standardize which elements are included in PrEP costs and collect more comprehensive data on the costs of commodities and service delivery, so that models can make comparisons across products</p> <p>Share methodologies, tools and costing inputs to assess cost-effectiveness</p>
<p>Many PEPFAR-funded countries still have parallel M&E and data reporting systems that require integration with national HMIS</p>	<p>Build consensus on targets and key indicators and harmonize M&E and reporting systems to decrease the reporting burden on programs and service providers, especially as new product options expand</p>	<p>Harmonize and simplify data systems to minimize burden on providers and health systems</p> <p>Review HMIS and M&E systems and capacities and strengthen electronic data systems as part of country preparedness and planning for new product introduction</p> <p>Pilot more meaningful indicators at country level to influence the adoption of better measures of PrEP impact on reducing HIV incidence</p> <p>Strengthen triangulation of data collected through national HMIS, community PrEP programs, community monitoring and population-based or surveillance surveys to help validate trends and provide meaningful insights on program performance</p>

Introduction

Global PrEP uptake has slowly increased, but barriers to use persist

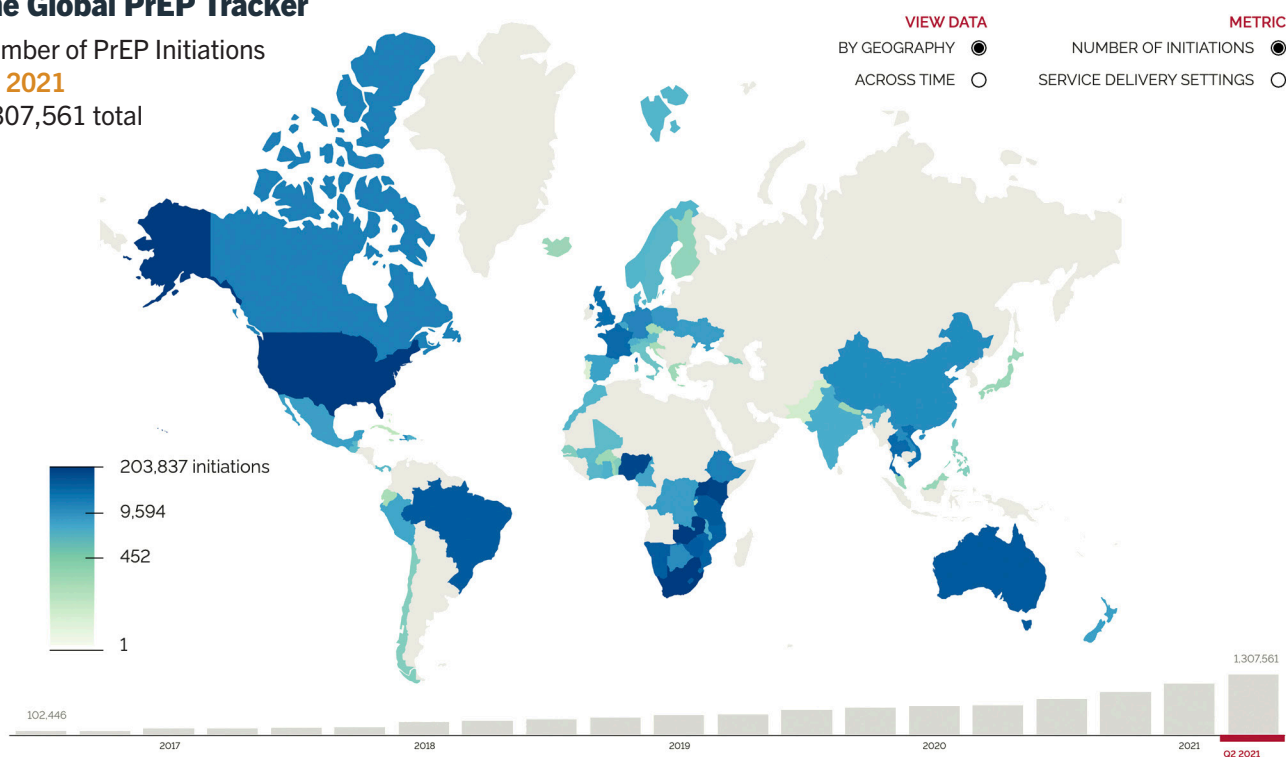
Over a decade has passed since oral pre-exposure prophylaxis (PrEP) for HIV was shown to be safe and effective — and nine years since the first regulatory approval and six years since the World Health Organization (WHO) recommended it for use among all people at substantial risk of HIV acquisition. By the middle of 2021, more than 1.3 million people had initiated PrEP globally. While the largest number of new PrEP users were in the United States, PrEP initiation in sub-Saharan Africa expanded from 4,154 people in 2016 to over 840,000 by the second quarter of 2021.⁵ Recent research has also demonstrated that PrEP can effectively reduce HIV acquisition among people using the method, even with modest levels of uptake.⁶

The Global PrEP Tracker

Number of PrEP Initiations

Q2 2021

1,307,561 total



Source: <https://data.prepwatch.org/>

Despite this progress, however, the world fell far short of the UNAIDS global target of three million people accessing PrEP by the year 2020, due to multiple barriers to PrEP uptake, access and continued use.⁷ Challenges related to individual preferences and circumstances, low community awareness of PrEP, health system bottlenecks and underlying structural barriers have all contributed to this slower-than-hoped-for expansion.

The emergence of the COVID-19 pandemic at the end of 2019 also significantly impacted global health systems and has disrupted HIV prevention services and programs, including PrEP delivery, as well as care and treatment services.

HIV biomedical prevention options are expanding

Despite these challenges, the future of HIV biomedical prevention is bright and rapidly evolving. New approaches, insights and mechanisms gleaned from oral PrEP can help ease introduction of future products and address persistent delivery challenges.

At the end of 2020, daily oral pills were the only approved and available biomedical PrEP option for all populations.⁸ Then, in January 2021, the WHO recommended that the Dapivirine Vaginal Ring (the ring) be offered as an additional prevention choice for women at substantial risk⁹ of HIV acquisition as part of combination prevention approaches.

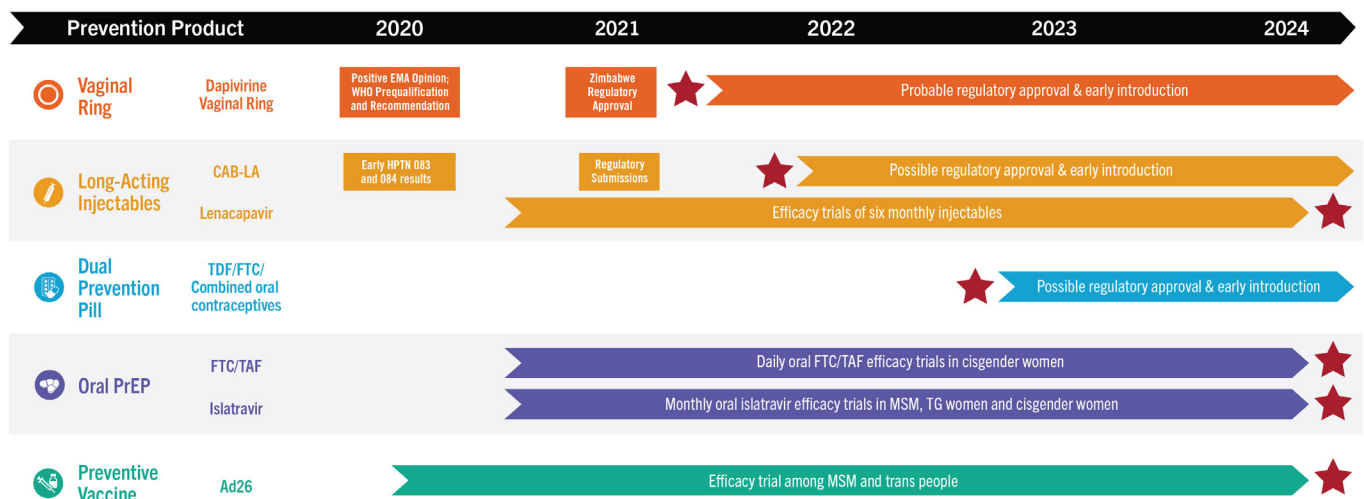
The ring is worn inside the vagina, where it slowly releases the antiviral medication dapivirine. Every 28 days it is replaced by a new ring. The WHO recommendation, along with a positive scientific opinion by the European Medicines Agency (EMA) that came earlier in 2020, set the ball rolling for in-country regulatory approvals and planning for introduction of the ring. The timeline for these processes varies by country but is expected to be completed in most priority countries in 2021.

In addition, long-acting injectable Cabotegravir for PrEP (CAB-LA) was recently demonstrated to be safe and effective in two efficacy trials.¹⁰ CAB-LA given every two months demonstrated highly effective HIV prevention among men who have sex with men (MSM) and transgender women in the HPTN083 study.¹¹ In the HPTN 084 study among cisgender women in sub-Saharan Africa, CAB-LA was also found to be safe and superior to daily oral FTC/TDF for HIV prevention.¹² With these positive results, countries can begin preparations for introduction of CAB-LA by drawing on oral PrEP lessons. ViiV, the developer of CAB-LA, is submitting data to the US Food and Drug Administration on a rolling review and has stated its plan to submit to other regulatory agencies later in 2021 and 2022, with possible initial approvals as early as 2022.¹³

The next five years could usher in an unprecedented era of dynamism and innovation for HIV, with an array of promising HIV options on the horizon including long-acting oral pills, longer-acting rings and injectables, multi-purpose vaginal rings and oral pills, vaccines and antibodies.

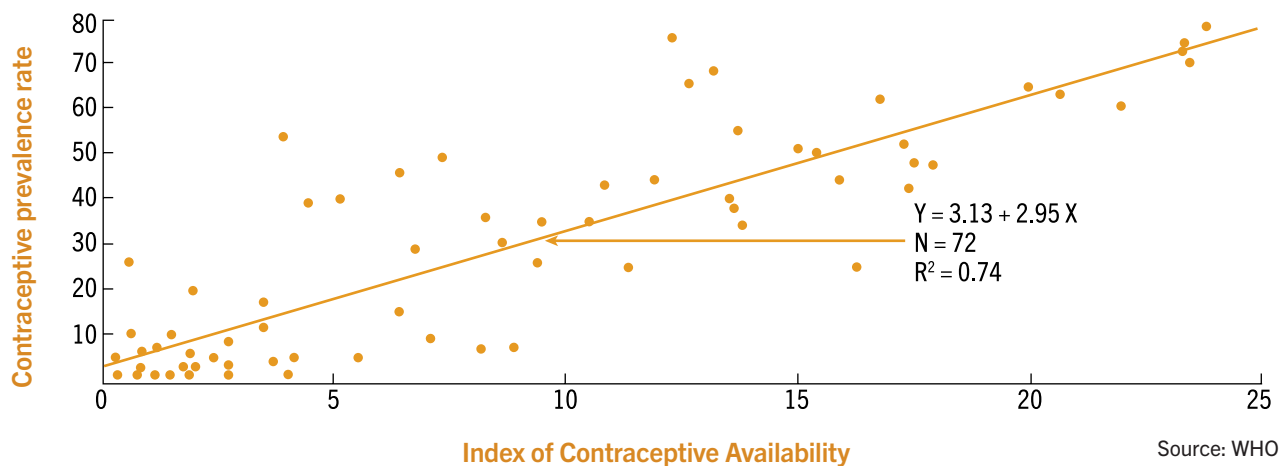
Years Ahead in HIV Prevention Research

Time to Market



Source: AVAC

If and when this expanded range of pipeline products proves safe and effective, and is approved by regulatory authorities, the number of PrEP options – and hopefully users – could expand considerably. Experience with family planning suggests that a greater choice of methods increases contraceptive prevalence, extends user persistence on a chosen method, and improves overall health outcomes.¹⁴



Source: WHO

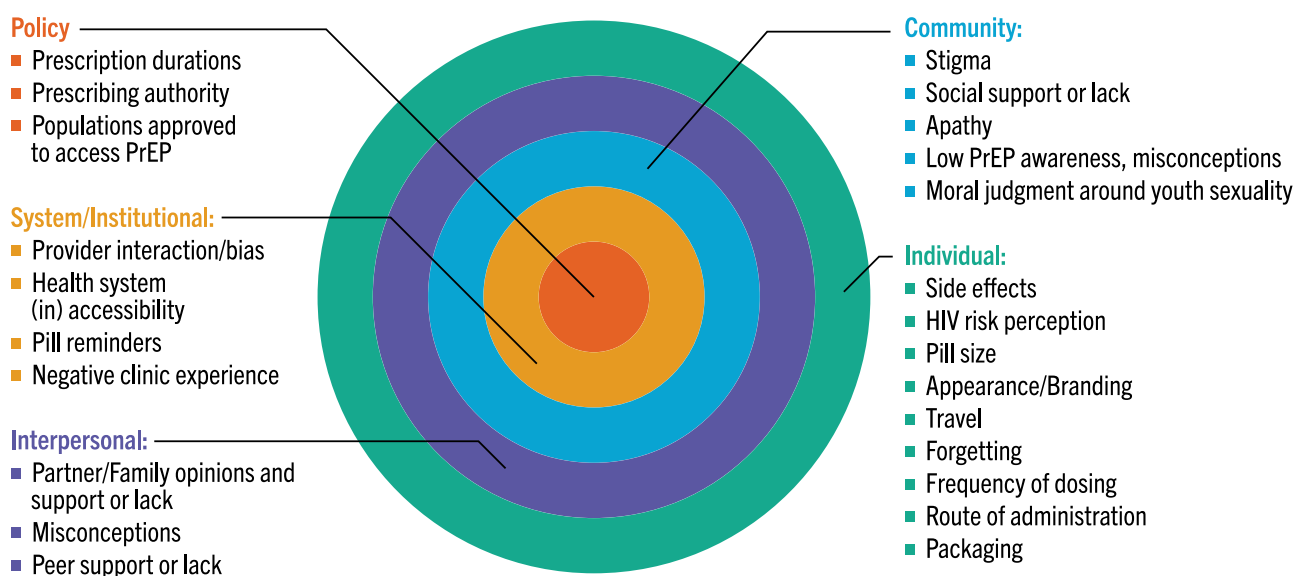
Lessons from oral PrEP can inform future product introduction and scale-up

The expansion of biomedical prevention options also brings with it myriad challenges to product delivery and implementation, including those associated with the complexity of introducing multiple products within a short time frame and how to support effective use to achieve impact.

Oral PrEP offers valuable implementation lessons that can be applied toward introduction of all these impending and potential future biomedical HIV prevention products. The field has the opportunity to implement rapid, evidence-informed rollout, and to improve access to next-generation biomedical products to those who need them – when, where, and how they need them.

As with oral PrEP, the availability of products that prove safe and effective depends on national regulatory approval and guideline processes, while uptake and continued use are influenced by individual, interpersonal and structural factors.

Common Barriers and Motivators of Effective Use



Each of the next-generation products poses unique benefits and disadvantages, depending on an individual's needs and life circumstances. Some products will address barriers attributed to oral PrEP such as daily pill taking, but new challenges will likely emerge. The anticipated challenges related to demand generation, delivery and data-driven decision-making will not be eliminated by any single product either, and may increase with an expanded portfolio of products and options.

Looking ahead, oral PrEP lessons offer a roadmap to inform demand generation, delivery and data for decision-making related to the introduction and scale-up efforts for new and future products. We now know, for example, that empowerment messaging attuned to users' lifestyles supports uptake and continued use of prevention products, while innovative delivery approaches such as mobile services remove hurdles to access.

This report reviews challenges and identifies successful strategies to advance all phases of PrEP programming, from introduction to launch and scale-up. Looking in turn at demand generation, delivery, and data-driven decision-making and -enabling environments, the report addresses the following questions:

1. What worked and where and how can we build on these strategies?
2. What could have been done differently/better?
3. What are the remaining challenges and gaps?
4. What can be adapted, carried over and continued for new products?

The answers to these questions have important implications for PrEP implementation, the direction of donor investments, and national and regional policy decisions.

Lessons on Demand Creation for PrEP



Globally, there was a lag between the introduction of oral PrEP and the application of demand-side thinking and human-centered design to understand and address user preferences. Demonstration projects showed that many people at risk were interested in PrEP and willing to try it, but nevertheless declined it for reasons including fear of side effects, not wanting to be seen with pills or at the clinic, and not wanting to take a pill daily.¹⁵ Adolescent girls and younger women (AGYW) in particular felt they needed to inform their partners or families about PrEP use.

User-centered, user-designed, and dynamic demand creation strategies are needed to overcome these challenges and promote PrEP awareness, uptake and correct use. Some product-related barriers encountered with the rollout of oral PrEP, such as concerns about branding, packaging, side effects and dosing schedules, might have emerged and been addressed earlier if potential users had been engaged in product development. To address other barriers, programs will need to invest in social marketing and strategies such as market segmentation for demand creation communications with different groups of people and implementation contexts, some of which may be product-specific while others are for prevention generally.¹⁶

New PrEP methods such as CAB-LA and the ring will remove the daily pill burden associated with oral PrEP, but these new products may still face many of the other identified challenges related to demand. With more product options, programming and messages that prioritize the preferences of potential users will become critically important, especially as people may not only use one product, as seen with oral PrEP, but switch between different products. The field of behavioral economics offers valuable insights into how the expansion of product choice might affect PrEP user behavior (see sidebar).

In collaboration with Departments of Health in Kwazulu-Natal and Mpumalanga Provinces in South Africa, Final Mile, Upstream Design and Ask Afrika, The HIV Prevention Market Manager used these behavioral health insights to develop and pilot a set of new tools for engaging adolescent girls and young women in HIV prevention.¹⁸

Many lessons have been learned from oral PrEP projects about what works – or not – for oral PrEP demand creation in different populations that can now be applied to the development and introduction of new prevention products. These include:

- **Issues such as pill size and packaging affect demand for PrEP and continued use:** People are generally less willing to tolerate inconvenience or discomfort for a prevention product like PrEP



Pill size, dosing schedule, branding and packaging affect demand for PrEP and continued use



Introduction of PrEP ‘for certain populations’ may increase stigma and act as a barrier



Peer approaches can increase demand

Insights from Behavioral Economics

The field of behavioral economics has offered insights for generating demand for family planning in the context of a range of product options that can also be applied to PrEP demand generation.¹⁷ Some considerations include:

- **Choice Overload:** This is not currently a concern with PrEP, but something to stay aware of as new options become available.
- **Compromise Effect:** Today, the presentation of too few options may impede uptake; at some future point, consumers could potentially be faced with too *many* PrEP options.
- **Framing:** Different presentations of identical information can influence consumer attitudes, so it will continue to be important to conduct market research to identify the message frameworks that are most appealing to groups who could benefit from PrEP.
- **Present-Biased Preferences:** People who are currently healthy can find it difficult to take action, like PrEP use, to protect their future health.
- **Default:** As new options become available, providers should present potential users with a diverse menu of options rather than providing one method, e.g., oral PrEP, or the ring, as the first or preferred option.

than for a treatment or cure. Experience with oral PrEP shows that many people find it difficult to take a pill every day. Others are reluctant to take PrEP when it's packaged like ART, fearing they will encounter HIV-related stigma. End user research shows that a representative sample of AGYW in South Africa would prefer PrEP as a 3-month injectable, although many were also open to the idea of a monthly pill.¹⁹

Implications

- Product developers and providers should engage users early to learn about their preferences and develop new products that reflect user demand for simplified, easy-to-use regimens.

- **Introduction of PrEP “for certain populations” may increase stigma and act as a barrier:** Family, influencers and the wider community strongly influence individual decisions about whether to use PrEP. To reduce stigma, normalize PrEP use and better support people to use PrEP effectively, demand creation communications must address the broader community as well as potential users.

While tailored messaging for key populations is important in peer outreach and in counseling sessions, at the general population level, a broad message about the importance of HIV prevention has been shown to be effective at driving acceptance of PrEP.²⁰ Mass media outreach that positions PrEP as a strategy for stigmatized populations, on the other hand, is likely to attract backlash and discourage people at risk from seeking out prevention options.

Implications

- Mass media campaigns, media engagement and community advocacy should all be employed to create an enabling environment as new products are introduced. These campaigns should focus on general messaging about HIV prevention, with limited product-specific references. Community leaders and peer educators should play a role in developing these materials.²¹
- Community advocacy programs can build on existing efforts to mobilize community support for related issues, such as HIV testing, PMTCT, and family planning.
- As more and different types of products become available, programs will need to invest in social marketing and strategies such as market segmentation for demand creation communications with different groups of people and implementation contexts, some of which may be product-specific and some of which will be creating demand for prevention generally.²²
- Implementers should actualize Good Participatory Practice²³ in implementation as well as research, engaging users, communities and populations as active co-designers of these broader demand creation messages and strategies.
- Adequately fund community engagement including community, national and global advisory groups of stakeholders and PrEP users.

The Jilinde Project

In Kenya, the Jilinde oral PrEP bridge to scale project worked with private sector partners to segment groups of end users by behaviors, attitudes and beliefs—rather than only demographics—and developed messages for each based on the traits they shared. This approach informed investments in messages for each segment around PrEP awareness, uptake, adherence and discontinuation, as well as strategies designed to meet the needs of each segment of end users.²⁴



- **Peer approaches can increase demand:** Peer approaches that use members of a given group to effect change within the group have been widely used as health promotion strategies in different areas of public health. In oral PrEP programs, peer approaches have proven to be effective demand creation and social support strategies across populations and locations in both community and facility settings. Various models of peer approaches – PrEP ambassadors or champions, peer navigators, peer educators, buddy system, etc. – have been implemented in oral PrEP rollout.

Implications

- As new PrEP products are introduced, peer approaches should be central to efforts to increase awareness, address misinformation or mistrust, drive up demand and promote effective use of PrEP. Peer champions who have used oral PrEP may be more credible drivers of demand and effective use by sharing lived experiences. These peer approaches must be built and resourced into implementation planning for new products.
- Investment in capacity building for peer mobilizers is critical, especially at the product introduction and scale-up stage. Experiences with oral PrEP show that if peer mobilizers are not adequately trained and motivated, they may be unable to counter myths and misconceptions with their community networks which can lead to low user uptake and/or discontinuation.

- **Users prefer empowering demand creation messaging:** In the beginning, oral PrEP social marketing and demand creation messaging strongly emphasized increasing understanding of its efficacy as a biomedical HIV prevention product to address personal risk. In the context of HIV information fatigue, HIV stigma and an association of oral PrEP primarily with reducing risk and disease prevention, this messaging has become problematic. Users prefer an empowerment framework and demand creation messages that position oral PrEP within people’s lifestyle.²⁵

While HIV prevention must be integrated into messaging, especially in individual counseling and at PrEP initiation, it should not be the primary entry point to creating demand. For example, AGYW prioritize their relationships over HIV prevention, and leading with health or risk-based communications may not be the most effective way to encourage them to adopt an HIV prevention method.²⁶ Demand generation messages should align with AGYW’s relationship goals and the ways that an HIV diagnosis could negatively impact those goals.

Implications

- Demand creation messaging for new products should evolve over time from one of early information about product characteristics and efficacy in HIV prevention to a focus on additional PrEP benefit – e.g., contributing to reaching one’s dreams and aspirations, being in control of one’s sexuality etc. – that can enhance personal motivation for taking and continuing PrEP.

Breaking the Cycle of Transmission

In partnership with Final Mile and Upstream Design, AVAC conducted a comprehensive human-centered design and behavioral economics project to understand and address HIV prevention among adolescent girls and young women in South Africa. The research included quantitative and qualitative research using a human-centered approach that sought to understand factors that influence their decisions and behaviors with regard to HIV prevention, and to segment AGYW for better-tailored prevention messages.²⁷

The findings revealed that AGYW don’t have a specific HIV prevention journey; they prioritize relationship management, and they overestimate their ability to judge their own and a partner’s risk. The research provides unique insights into how AGYW make decisions about sexual relationships and therefore HIV prevention. Each segment of AGYW has unique motivations and pathways to effective HIV prevention in the context of relationship management. Prevention interventions for AGYW should focus on supporting healthy choices within their relationships and should emphasize positive, self-protective behaviors.



- **Providers are critical gatekeepers of demand for PrEP:** PrEP uptake is linked to how prepared and receptive providers are to offer PrEP to different groups of people at increased risk for HIV, and how supportive they are while counseling clients. Early provider engagement focused on clinical skills; understanding how PrEP works, eligibility screening of who needs PrEP and clinical monitoring of PrEP users. We now know that provider knowledge, attitudes and biases also influence their willingness to offer PrEP. Human-centered design insights showed that counseling related to oral PrEP is often formulaic and overly focused on risk rather than empowering a client to take charge of their PrEP use journey.²⁸

Implications

- An expanded menu of PrEP options will require changes to current provider capacity development. Early identification and strategies to address provider receptivity or biases towards or against new PrEP products and the populations they serve will be critical toward promoting wider demand. In addition to PrEP knowledge, programs should routinely integrate sensitivity training and values clarification to help address provider bias.
- The first/initial provider interaction may be especially critical for PrEP uptake and continued use.²⁹ In a recent Jilinde Awareness Survey, 32 percent of surveyed individuals in the general population knew about PrEP from a healthcare provider. We know that many PrEP users are introduced to PrEP during clinical visits.³⁰
- Continued training of a wide range of providers across different delivery points, especially in countries with staff shortages and high turnover, will be necessary to ensure an adequate pool of providers who are trained to promote and offer PrEP at facilities and in community settings.

Lessons on PrEP Delivery



Initially, oral PrEP was prescribed and provided primarily through health facilities. Using ARVs for HIV prevention was novel, and guidelines tended to be conservative because there was little evidence about implementation strategies, potential for PrEP impact and the possibility of drug resistance. As a result, PrEP delivery approaches defaulted to treatment models that weren't well suited to the motivations and behaviors of healthy people seeking preventative care.

The emergence of differentiated service delivery (DSD) approaches for PrEP has begun to broaden access and promises to increase PrEP uptake.³¹ These approaches are based on a growing recognition that PrEP scale-up is contingent on simplifying PrEP delivery and client-centered care: getting PrEP to those who need it, when they need it, how and where they want it delivered.

For example, limited access to health facilities may have impeded uptake, especially in the early days of PrEP implementation. Today, in some places, PrEP is successfully offered through community-based services such as those operated by non-governmental and peer-led organizations. These types of community services have demonstrated higher uptake and continued PrEP use compared to health care facility delivery.³²

PrEP is also now sometimes available for purchase through private facilities offering 'fee for services', on the internet and at pharmacies. Peers, rather than providers, may conduct PrEP outreach or drop off medications.³³ In some countries, multi-month refills of PrEP medication help reduce the number of required facility visits to help people stay on PrEP. Text messaging, interactive chats and other mHealth approaches are also being used to support ongoing, effective PrEP use for those who continue to experience HIV risk (see box).

The global COVID-19 pandemic prompted even greater efforts to differentiate service delivery options, including HIV self-testing and the use of mHealth approaches for counseling and support. All these creative approaches offer important models and examples for the ongoing delivery of oral PrEP and the rollout of new methods. Key lessons for delivery include:

- **Many people prefer to access PrEP in non-clinical settings:** Experience with oral PrEP shows that some groups who may benefit most from PrEP, including MSM,



Many users prefer to access PrEP in non-clinical settings



Excessive medical requirements and monitoring can discourage PrEP use



Trained providers at different levels can broaden access and relieve the burden on health professionals

Seasons of Risk

Continued PrEP use – which currently means taking a pill every day, along with regular visits to clinics or other facilities for refills, HIV testing, and other monitoring and counseling – continues to be a challenge across all populations, especially younger people.³⁴ DSD strategies such as those described in this report are promising for supporting continued PrEP use while an individual remains at risk.

Additionally, HIV risk changes over time, as people move in and out of “seasons of risk.” As personal risk changes, discontinuing, cycling on and off, or switching PrEP methods can all be forms of effective use. In the early introduction stages of oral PrEP, adherence messages and metrics followed the example of HIV treatment in stressing the importance of daily medication use into the indefinite future. Low continuation rates were often attributed solely to low demand for a daily oral pill rather than a reflection of how some PrEP users cycled on and off PrEP during varying periods of HIV acquisition risk.

In 2019 and 2020, the HIV Prevention Market Manager and Jhpiego organized Think Tanks to assess the growing evidence that people stop and restart PrEP and identify interventions that promote continuation.³⁵ They found mHealth approaches to be promising across populations and geographies, while younger populations benefitted most from tailored adherence support including regular check-ins and personalized messaging. With the expanding range of PrEP products, messaging should account for, and adapt to, dynamic user behaviors and lifestyles. These include stopping or switching across different products³⁶ and messaging aligned to the needs, preferences and life goals of different segments of populations.

sex workers, AGYW and transgender populations, prefer to access PrEP via community-led and community-based settings such as drop-in centers that offer comprehensive HIV prevention services.^{37,38} If guidelines require that a certain PrEP product be dispensed in a formal health facility, it may still be helpful to offer information and adherence support through a wider range of outlets and channels.

Implications

- Support implementation science to identify and offer PrEP services at a range of sites where key populations who could benefit from the method are comfortable seeking care.
- Strengthen the capacity of community and peer-led PrEP services to deliver PrEP. Community pick-up points, mobile services and peer delivery have all proven to be effective and convenient ways for users to access PrEP supplies. With sufficient training, peers can offer many more types of PrEP counseling and support. In Thailand, for example, key population providers have been trained and certified to legally provide HIV services and in less than two years, they have supported more than 60,000 clients.³⁹
- Fund and scale up effective and promising delivery channels and innovations, including mHealth tools to provide users and potential users with PrEP information, pill reminders, counseling and support services. These may include interactive, bidirectional texts; online risk screening and counseling, automated daily reminders and more.

- **Excessive medical requirements and monitoring can discourage PrEP use:** Users of oral PrEP have emphasized the need for simpler PrEP initiation and delivery. Rigid risk-assessment algorithms, long waits at the clinic for refills, and arduous clinical monitoring requirements can make it unnecessarily difficult for users to start and stay on PrEP. Evidence suggests that less frequent administration of some clinical tests, such as kidney function monitoring, would likely be safe for most PrEP users and reduce expenditures as well as simplifying PrEP continuation for users.⁴⁰

Implications

- Streamline and shorten risk assessments and ensure that individuals interested in taking PrEP are not prematurely screened out.⁴¹ Risk algorithms can miss many people who could benefit from PrEP,⁴² in part because clients may not feel comfortable revealing their sexual history, sexual orientation or relationship status with health care providers.
- Once a client has started and is comfortable with PrEP, consider providing two, three or even six-month pill refills that make it easier for those who find it difficult to visit a facility each month to sustain consistent use. These multi-month distribution (MMD) strategies proved especially important during travel restrictions imposed in response to the COVID-19 epidemic.
- Consider reducing or eliminating clinical requirements, such as creatinine testing, that may not be beneficial for young, healthy populations often using PrEP.
- Explore the potential of HIV self-testing as well as self-care in the context of new methods, including self-administration of injectable PrEP.

- **PrEP can be packaged together with other related services to reach more potential users:** This approach expands delivery platforms, reaching more PrEP users and increasing its potential impact at a population level.⁴³ For example, PrEP has been successfully integrated into family planning services to reach AGYW (PriYA⁴⁴ and POWER⁴⁵ projects), or alongside gender-affirmative hormone treatment for transgender individuals (Tangerine Project⁴⁶). Oral PrEP rollout has also highlighted high rates of prevalent and incident sexually transmitted infections (STIs) among some users and the need to better integrate sexual and reproductive health, STI and HIV prevention services.

Implications

- Identify and offer PrEP in conjunction with health services that key populations are already using, especially family planning, STI and hormone therapy services.
- Strengthen health systems to support PrEP integration into existing service delivery points.
- Strengthen linkages to social services, such as referrals for housing or medical assistance, to reduce underlying barriers to accessing and taking PrEP.⁴⁷ Support for people experiencing intimate partner violence (IPV) is also critically important, as experience with IPV has been linked to PrEP interruptions.⁴⁸

Simplifying PrEP Delivery

Many programs have implemented differentiated service delivery models (DSD) of PrEP delivery that have been scaled up or newly piloted across populations and countries during the COVID pandemic. In sessions at HIVR4P/Virtual 2021⁴⁹ and IAS 2021,⁵⁰ a range of successful DSD examples were shared from key populations, AGYW, and female sex workers programs in Kenya, Thailand, Vietnam and Zimbabwe including the following:

WHEN: From a one-month supply to multi-month dispensing of PrEP

WHERE: From the health or clinical facility as the primary delivery setting to the home, community, mobile, outreach site, safe spaces, multiple multimedia and virtual spaces (e.g., internet, video and telephone) that serve as program settings for PrEP initiation, delivery, information and adherence support.*

WHO: From health care workers as primary providers to PrEP home delivery by community health workers and peers, including peers providing PrEP refills in facilities.

WHAT: From solely giving PrEP information to addressing PrEP literacy, awareness and understanding.

**Programs task shifting to the home as a delivery setting should put in place measures to ensure that PrEP users are not exposed to gender and intimate partner violence.*

■ **Trained providers at different levels can broaden access and relieve the burden on health professionals:**

Evidence-informed and context-specific provider training has been critical for the introduction and delivery of oral PrEP.⁵¹ Different cadres of providers can support different elements of PrEP provision: for example, peers and other lay providers may be best suited to offer PrEP information and counseling, especially because potential PrEP users may find these providers more accessible and easier to confide in than medical professionals. Shifting these services to lay providers can also help reduce the burden on the facility-based health workforce, who can then focus on the clinical aspects of prescribing and dispensing PrEP medications.

Implications

- Identify and reach out to the providers who are most likely to offer PrEP services and who appeal most to potential clients. Even if guidelines restrict PrEP prescribing or dispensing to particular cadres of professionals, other providers can conduct outreach, share information, and support ongoing effective use.
- Integrate provider training into the introduction plan of new products as they come to market, with funding for both initial provider training (pre- or in-service) and ongoing mentorship and support. Trainings should cover both clinical requirements and empathy-building to rapidly build a critical mass of providers who can offer PrEP and support users as new products become available.
- Identify and invest in providers who may serve as PrEP champions among their peers as well as among potential PrEP users.⁵²
- Work with regulators and scientists to generate data that allows non-medical providers (community and peer-led) to initiate and support product use.

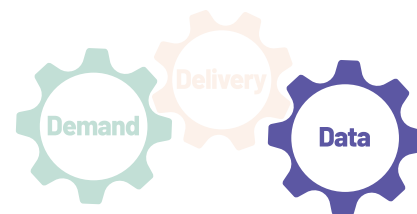
■ **As PrEP programs mature, establishing standards for service delivery and assessing quality of care and client satisfaction is important:**

Tools and metrics to evaluate PrEP care should be embedded into programmatic and national mechanisms to ensure regulatory compliance and support routine assessment of service quality. Ongoing evaluation of oral PrEP programs, identifying successes as well as gaps, can encourage providers to identify potential areas for improvement and help strengthen the delivery platform for future products.

Implications

- Establish Quality Assurance and Quality Improvement (QA/QI) programs to assess program strengths and gaps and improve the user experience
- Develop QA/QI and M&E tools that can be used by community-based and peer providers

Lessons on Data for Decision-Making and -Enabling Environments



Most national PrEP programs remain small, and delivery has progressed slowly even in Africa, where the HIV burden is high. Evidence generated through the oral PrEP rollout can be used to streamline the introduction and scale-up of new products, accelerating the path from evidence to implementation. While significant progress has occurred in the monitoring and measurement of oral PrEP programs, persistent challenges remain that will be relevant to new PrEP products.

Two distinct types of evidence are required. First, demonstration projects and ongoing implementation research can generate important insights into how to support product introduction, generate demand and streamline delivery. Well over 100 demonstration projects were launched to assess and improve the delivery of oral PrEP. Examining the lessons learned from some of these can streamline the introduction of new biomedical prevention products and potentially eliminate the need for additional rounds of demonstration research once new products become available.⁵³

Second, at the national level, the introduction of oral PrEP revealed gaps in the ability of existing M&E systems to measure the overall reach and impact of PrEP. Indicators recommended to monitor PrEP programs were transposed from HIV treatment, even when they were not fully applicable to prevention. These targets created a disproportionate focus on PrEP initiation and did not reflect actual patterns of PrEP use or account for cycling on and off, which is widely observed across many populations and settings. With the introduction of new products, it will be even more important to develop indicators that track the overall reach and impact of PrEP as well as the different contributions of specific methods for specific populations.

Specific lessons learned to date include:

- **Coordinating across projects and programs is important to shorten the time between product approval and availability:** While scores of oral PrEP demonstration projects were funded and started in the years following proof of efficacy, there was little coordination among funding and implementing agencies.⁵⁴ Studies risked duplicating efforts, while national and international decision-makers were forced to wade through multiple sets of findings to inform policies and programs.

The Biomedical Prevention Implementation Collaborative (BioPIC,⁵⁵ see box) was founded to improve coordination for future PrEP products. This includes applying lessons learned from the introduction of oral PrEP, when relevant, and quickly sharing results of new research so that all agencies can adapt as needed. Models that can be rapidly adaptable and applied to new products as they come to market are needed to make all options available and accessible to users in the shortest time possible.



Coordinating demonstration projects and implementation research is important to shorten the time between product approval and availability



The concept of effective PrEP use and measures of PrEP impact need to be redefined

An Adaptable Introduction and Access Mechanism: BioPIC

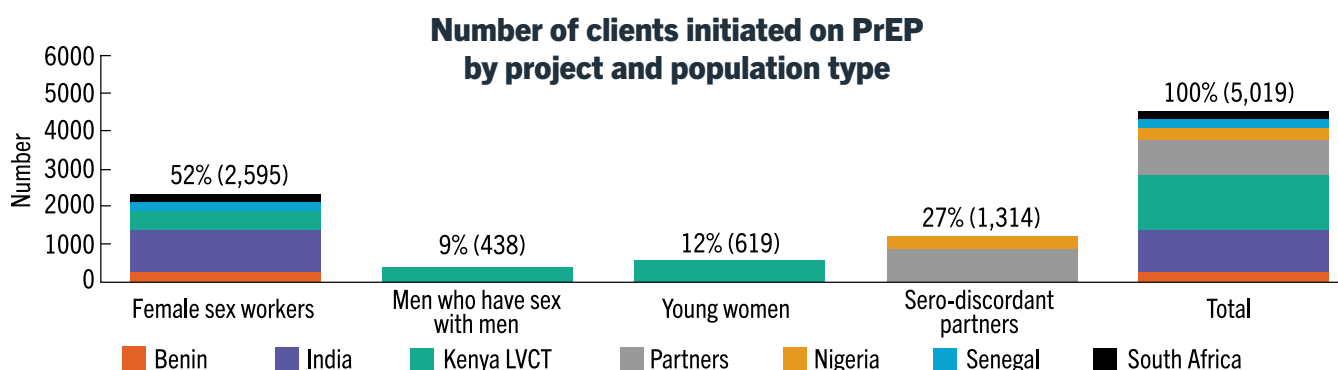
In some low- and middle-income countries (LMICs), oral PrEP impact has been delayed by the absence of coordinated introduction planning efforts to support the move from small projects to scale-up. Looking ahead, advance planning and solid access strategies can optimize the potential benefit of CAB-LA and other emerging products. BioPIC⁵⁶ offers a new mechanism to do this. It's a global multi-stakeholder collaborative approach to support an adaptable product introduction and access strategy that's well suited to the rapidly-changing HIV prevention context. BioPIC aims to ensure advance planning, including activities that are well-designed, well-timed and well-funded to meet the needs of global and country decision-makers. CAB-LA, now awaiting country regulatory approval, is one focal point for the BioPIC framework.



Implications

- Governments and funders should ensure that approval of future demonstration projects is contingent on clear articulation of the way each proposed project complements and adds to existing or ongoing evidence.
- Introduction planning and coordination models should be adaptable to products and contexts.
- Countries should consider leveraging existing knowledge, infrastructure and capacity created through oral PrEP, SRH and ART for rapid introduction of new products, rather than requiring generation of new evidence for each new product through demonstration projects.

- **An implementation mindset helps demonstration projects deliver useful results:** Early input from community members, implementers and policymakers is needed to ensure that studies answer the right questions. Oral PrEP demonstration projects demonstrated the feasibility of initiating clients on PrEP across a range of settings and populations.



However, study questions and findings didn't always align with the topics and issues prioritized by implementers, policy makers and the WHO. By the time PrEP introduction was imminent, policymakers were interested in how to deliver PrEP in communities and identify those who would benefit most from PrEP, patterns of use, and adherence support, among other factors. Because many early demonstration studies were designed as research projects, their protocols made it difficult to quickly adapt to changing circumstances.

Implications

- To speed product introduction, identify and work to answer the most critical questions of WHO and countries considering product scale-up.
- Engage a range of actors in demonstration project design from the outset: community members and advocates, as well as experts in implementation research, service delivery, new product introduction, and behavior.
- Design demonstration projects to be nimble and responsive to changing external circumstances (such as rapidly developing interest in product implementation) and mirror real-world conditions (including clinical and support services that are replicable in rollout).
- Ensure that study enrollment overall and by key population is large enough to provide meaningful results oriented toward national scale-up.

- **Information collected about PrEP users is not sufficiently disaggregated to assess the impact of PrEP among key populations:** In particular, users' pregnancy or breastfeeding status is not typically tracked and will continue to be important as new products, including products intended specifically for women, like the ring, are introduced.

Implications

- Disaggregate user data by population group, age, pregnancy or breastfeeding status at both the implementation level and the national level, to help ensure PrEP is reaching those who could most benefit.

- **A broader definition of effective PrEP use that permits a shift from measuring continuation to measuring PrEP impact is needed:** Stopping and starting PrEP use⁵⁷ can be effective and considered sustained use, based on individual risk and circumstances. Oral PrEP discontinuation rates are high across populations and geographic locations, especially among the younger users – adolescents and young key populations. With a range of options available, users may not only cycle on and off a PrEP product⁸ but switch between products or discontinue use. This should not be viewed as an adherence failure but a form of sustained use. In 2019 and 2020 a global Think Tank⁵⁹ of researchers, implementers, donors and experts made a number of recommendations regarding definitions of continuation and successful use and impact and how best to measure them, including:

Implications

- Review guidelines to incorporate cycling on and off PrEP as HIV risk changes.
- Fund evaluations and implementation science to document PrEP use across products, the reasons for switching and discontinuation and improve programs based on the evidence.
- Consider the family planning model to assess PrEP’s reach and impact, irrespective of specific products. Family planning programs use a “couple-years of protection” indicator based on the volume of contraceptives distributed across a population over a given period of time. A similar measure could be used for PrEP, combining relatively easy-to-collect data points: the volume of PrEP distributed (independent of product, as additional products become available); the average duration of HIV prevention per “dose” (allowing for incorporation of longer-acting methods into the model); and the number of people in a community or geographic area who are at risk for HIV and have an indication for PrEP.

- **Greater transparency in pricing and commodity costs is needed for impact modeling and to determine cost-effectiveness.** Understanding the comparative benefit and cost-effectiveness of different products will enable prioritization earlier in clinical development and as products are rolled out. Cost-effectiveness modeling demands standardization of the elements to be included in PrEP costs, and more comprehensive data on both the cost of commodities and the costs of delivering PrEP. All cost-effectiveness models should be updated and adapted with new data as longer-acting products with different distribution needs and frequency, and future combination prevention methods, become available.

Implications

- Standardize commodities to be costed so that model can make comparisons across products.
- Share methodologies, tools and costing inputs to assess cost effectiveness.

- **Many PEPFAR-funded countries still have parallel M&E and data reporting systems that require integration with national health management information systems (HMIS) to minimize the reporting burden on programs and service providers as new product options expand:**

Implications

- Harmonize and simplify data systems to minimize the burden on providers and health systems.
- Review HMIS and M&E systems and capacities and strengthen electronic data systems as part of country preparedness and planning for new product introduction.
- Strengthen triangulation of data collected through national HMIS, community PrEP programs, community monitoring and Population-based HIV Impact Assessment (PHIA) surveys to help validate trends and provide meaningful insights on program performance.

Conclusion

As additional PrEP options come to market, they could transform the HIV prevention landscape – offering more personalized prevention options, potentially increasing the number of PrEP users, and ultimately contributing to a reduction in HIV incidence. These products must be available, accessible, acceptable and used effectively by those who need them. This means users need access to PrEP supplies, information, counseling and clinical care on their own terms: how, when and where they prefer.

Oral PrEP programs have faced numerous individual, community and structural barriers to success. As this report documents, experience with these programs has also generated promising solutions to such challenges. These solutions include investing in appropriate demand generation efforts that normalize PrEP use within a community-wide HIV prevention framework; delivering PrEP services in more diverse places, through training more providers, and with more attention to quality; and generating and using appropriate evidence to evaluate and improve programs.

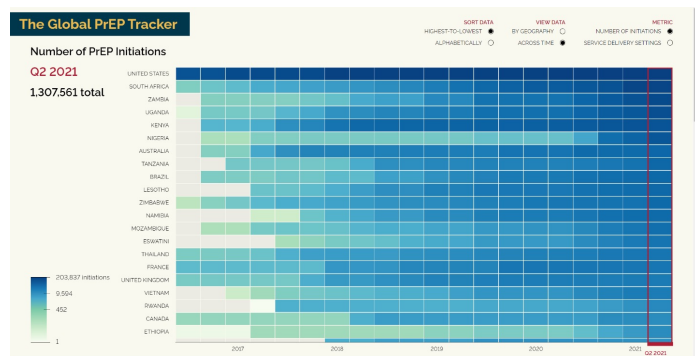
Six years after the introduction of oral PrEP, with promising new tools on the horizon, the world cannot afford to repeat mistakes. There is a unique opportunity to reimagine HIV biomedical prevention and – similar to family planning – to demonstrate the profound effect that providing informed choice can have on increasing overall access to and use of HIV prevention methods. Applying lessons learned through the oral PrEP rollouts early in product design, research, and planning for introduction of new products will achieve more equitable access and significantly expand the impact of future prevention efforts.

Six years after the introduction of oral PrEP, with promising new tools on the horizon, the world cannot afford to repeat mistakes.

Resources

PrEPWatch and the Global PrEP Tracker

Since 2006, AVAC's PrEPWatch (prepwatch.org) has served as a clearinghouse for information on PrEP research, data, cost, access, implementation and advocacy around the world. PrEPWatch includes the Global PrEP Tracker (data.prepwatch.org) a dynamic, map-based tool that allows users to explore trends in oral PrEP use globally as countries introduce and scale up PrEP programs.



Demand Generation

Findings from the Prevention Market Manager's human-centered approach to increase adoption of and adherence to HIV prevention among high-risk adolescent girls and young women (AGYW) are summarized in the following documents:

- [What Women \(and Girls\) Want: Key findings from a review of HIV prevention projects in sub-Saharan Africa](#)
- [Integrated End User Research Qualitative and Quantitative Research Findings](#)
- [Beginning with the end in mind. HIV Prevention: What we think we know about user preference – Plenary presentation at R4P2020, Ram Prasad](#)
- [Breaking the Cycle of HIV Transmission – Final Findings from Pilots](#)

Digital tools such as The PrEP Communications Accelerator (<https://accelerator.prepwatch.org/>) and the B-Wise Platform (<https://bwisehealth.com/>) provide examples of messaging for different populations. These can be adapted for any PrEP formulation.

Building on previous product introduction experience with oral pre-exposure prophylaxis (PrEP) and informed by planning for cabotegravir long-acting injectable (CAB-LA), the [BioPIC Adaptable Product Framework](#) presents an overarching product introduction framework that can be adapted to guide the introduction of future biomedical HIV prevention products.

In addition to this report, the HIV Prevention Market Manager has published four issue briefs highlighting key insights from a decade of oral PrEP programs and their implications for next-generation prevention products, programs and platforms. The briefs provide practical guidance for researchers, implementers, healthcare providers, policy-makers and advocates to improve existing efforts and, as the HIV prevention pipeline is poised to expand with long-acting products, to apply to the next generation of prevention products and programs.



[Reframing Risk in the Context of PrEP](#)



[Generating and Sustaining Demand for PrEP](#)



[Simplifying and Improving PrEP Delivery](#)



[Next Generation M&E for Next-Generation PrEP](#)

Delivery

Literature on health systems needs for PrEP scale-up in sub-Saharan Africa is summarized in Health system adaptations and considerations to facilitate optimal oral pre-exposure prophylaxis scale-up in sub-Saharan Africa. Were DK et al. The Lancet HIV 8(8): E511-E520, August 1, 2021 ([https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(21\)00129-6/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(21)00129-6/fulltext)).

PrEP provider training tools and resources that can be adapted to different contexts are available at <https://www.prepwatch.org/prep-planning/training-materials/>.

In Kenya, the NASCOP and Department of Family Health worked together to assess the integration of HIV prevention with sexual and reproductive health services and identify pathways for greater integration. They shared their findings and discussed next steps at a February 2020 dissemination meeting in Nairobi (<https://www.avac.org/resource/integration-hiv-prevention-and-sexual-reproductive-health-services-kenya>). Similarly, the Ministry of Health and Child Care and the Department of Sexual and Reproductive Health in Zimbabwe conducted an assessment of HIV prevention and SRH services. The findings were shared in July 2020 (<https://www.avac.org/resource/integration-hiv-prevention-and-srh-services-zimbabwe>).

[Easier and Equitable Access to Prep: How DSD Can Help Get Us There](#) provides a succinct overview of PrEP delivery challenges and innovative solutions.

Laws, policies and guidelines that could support or hinder PrEP scale-up are reviewed in Policy Barriers to Provision of HIV Biomedical Prevention Services in sub-Saharan Africa (<https://www.prepwatch.org/resource/policy-barriers-to-provision-hiv-biomedical-prevention-services/>)

Data for Decision Making

Findings from Prevention Market Manager analyses of seven early oral PrEP demonstration projects are available at prepwatch.org (<https://www.prepwatch.org/resource/bmgf-funded-demo-projects/>).

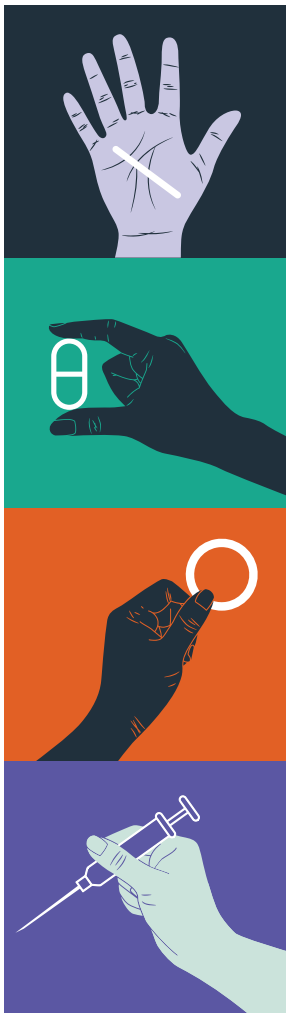
Discussions and conclusions of the Prevention Market Manager / Jhpiego Think Tanks on monitoring and evaluating PrEP use are summarized in the following reports:

- Defining and Measuring the Effective Use of PrEP Think Tank Meeting Report, June 1, 2019 (<https://www.prepwatch.org/resource/prep-think-tank-report/>)
- Evaluating, Scaling up and Enhancing Strategies for Supporting PrEP Continuation and Effective Use, September 20, 2020 (<https://www.prepwatch.org/resource/scaling-up-and-enhancing-strategies-for-supporting-prep/>)

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Lessons From Oral PrEP Programs

And Their Implications for Next Generation Prevention



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AVAC is a non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of new HIV prevention options as part of a comprehensive response to the pandemic. For more information, visit www.avac.org.