

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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- **People:** placed at the center to understand what they want, need and will use
- **Products:** collaborate with developers to accelerate product introduction and inform product design and development
- **Programs:** build a community of practice amongst implementers that learns what works and what doesn't and course correct in real time
- **Policies:** understand and provide the evidence, data and information needed to guide faster decision-making



All in order to accelerate delivery, inform product development, and reduce time to impact

PMM aims to shorten the time from 'we know a prevention product works' to 'it's in the field and protecting the people who need it most.'

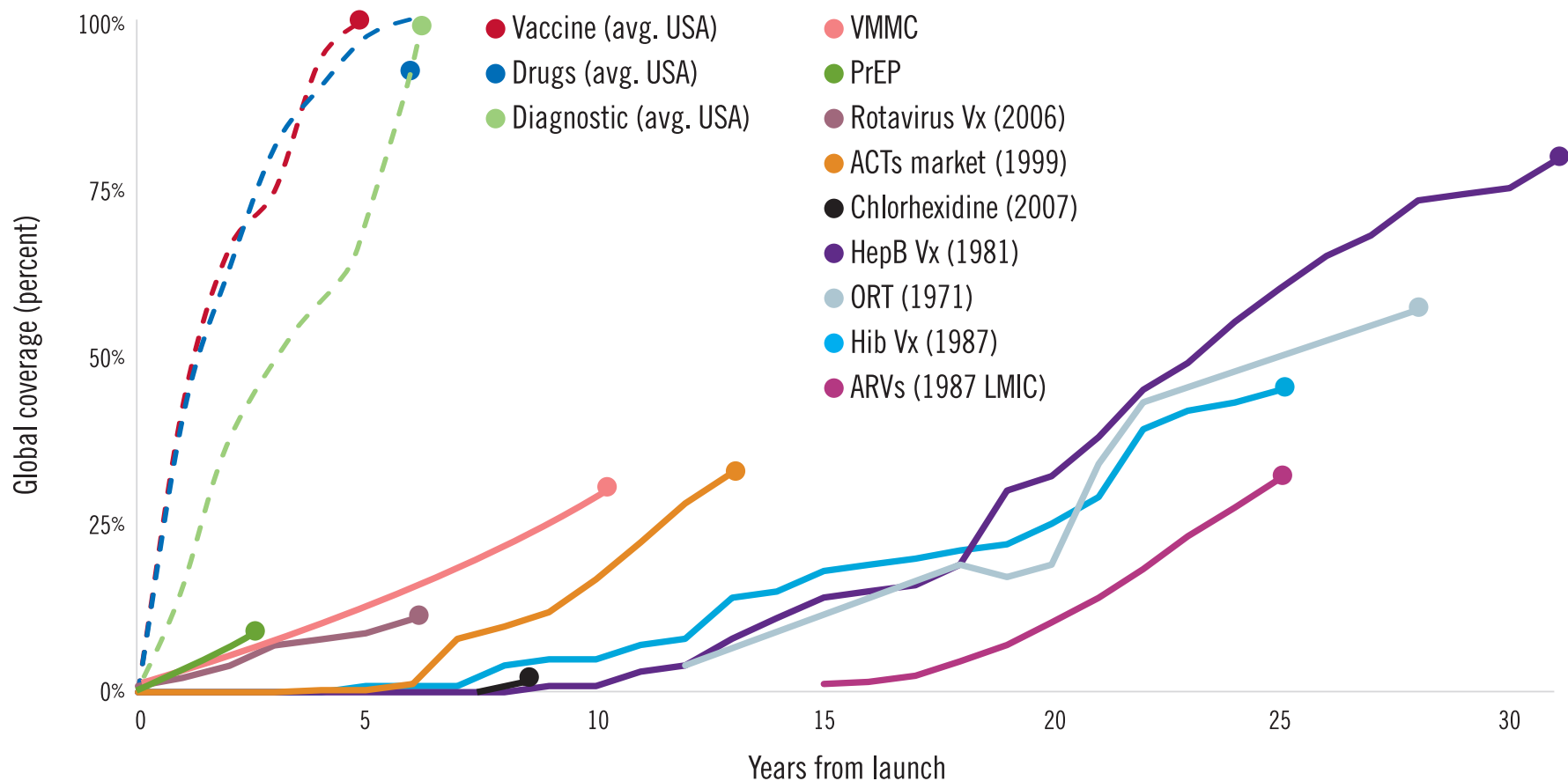


Avoiding Historic Delays with New Prevention Options

Full impact of recent advances—including voluntary medical male circumcision and oral PrEP—delayed by years because of limited advance planning for roll-out. Practical challenges included:

- Limited research to identify and understand potential users.
- Lack of coordinated plans for demonstration projects (e.g., many small studies of PrEP; not big or consistent enough to draw right conclusions).
- Few tools for country-level decision makers (e.g., estimated costs or impact of investments).
- Slow recognition of the importance of and investments in strategic demand creation.

PMM currently working to surmount these challenges for oral PrEP—and to help spur the advance planning needed to avoid delays with next-generation options in the pipeline.



Product launch year is shown in parentheses.
LMIC = Lower- and middle-income countries

Figure courtesy of Dana Hovig, Bill & Melinda Gates Foundation.



The HIV Prevention Research & Development Spectrum

Currently available



HIV treatment for people living with HIV



Oral PrEP with TDF/FTC



Male & Female Condoms



Voluntary medical male circumcision



Syringe exchange programs

In regulatory review



Davipirine vaginal ring



Oral PrEP with F/TAF

In development: Efficacy trials Under way



Long-acting injectable



Preventive vaccines



Broadly neutralizing antibodies

In development: Various pre-clinical and clinical



Long-acting Oral PrEP



Combo Oral PrEP/OC



Long-acting implants



Preventive vaccines



Broadly neutralizing antibodies



Inserts



Multipurpose vaginal ring



Patches



Inserts

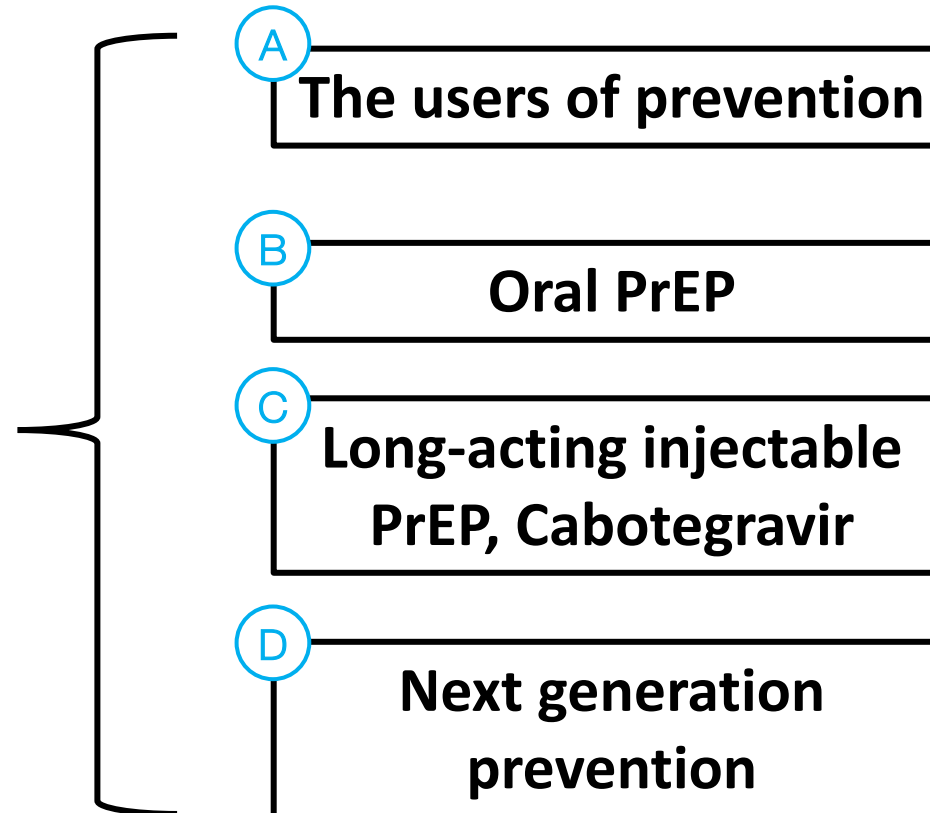


Enema

The approach



The landscape





A

THE USERS OF PREVENTION



The Challenge

Even the safest, most effective prevention options only work if they get used by individuals in need.



The Risk

Product developers and funders could develop new options that are not wanted or used by the people who need them most.



**PMM Response/
Progress**

Initiate innovative behavioral economics and human-centered design project to provide in-depth understanding of HIV prevention needs, wants, challenges and opportunities

- Qualitative data identified nuanced insights that prevention is embedded within a journey of relationship management and healthy sexual routines
- Developed a journey framework, or map, that recognizes the usual linear understanding of prevention behavior was not accurately representing reality
- Quantitative data identified discreet and identifiable segments



**By end
of 2020**

- Disseminate findings and support policymakers, implementers and communities to use findings to improve programming of and increase access to products.
- Feasible, research-based tools that enable program implementers to reach and serve priority population segments
- Identify best messages and messengers for each segment to support their px journeys
- Segment-specific information to support adoption and adherence of current and future products
- Identify product preferences for segments to improve product introduction and market sizing.



B

ORAL PREP



The Challenge

Shown to be safe effective in 2010 and first approved for use in 2012, oral PrEP has been slow to reach people at greatest risk and provide impact against the epidemic. Multiple demonstration projects were implemented, but major questions remain unanswered.



The Risk

Oral PrEP as an intervention could be dismissed prematurely—not because the product doesn't work, but because programs were not strategically designed or implemented.



PMM Response/ Progress

- Create a real-time community of practice, with policy makers and implementation partners to capture and analyze data to identify and address the critical barriers to use—and impact
- Catalytic support to governments in priority countries for policy development, program design, and monitoring.



By end of 2020

- Clear understanding of what works—and doesn't—in oral PrEP programs, to inform scale-up and the introduction of next generation products
- Drive consensus among stakeholders on definitions and approaches to address continued use of oral PrEP.
- Develop strategy to address provider challenges.
- Identify effective demand-creation interventions and approaches for integrating oral PrEP and family planning services.



C

LONG-ACTING INJECTABLE CABOTEGRAVIR (CAB-LA)



The Challenge

Experience from oral PrEP rollout and from previous global health product introductions demonstrate the challenges with uncoordinated planning for product introduction and the resulting delays in delivering public health impact.



The Risk

Even if shown to be safe and effective in clinical trials, introduction of CAB-LA will be delayed and/or not reach those in greatest need.



**PMM Response/
Progress**

- Established the Biomedical Prevention Implementation Collaborative (BioPIC).
- BioPIC developing a comprehensive, coordinated product introduction agenda and access strategy in parallel with clinical trials and ahead of their completion.
- While focused on CAB-LA, PMM is working with IPM and the OPTIONS Consortium to collaborate on planning for the dapivirine vaginal ring.



**By end
of 2020**

- Identify research-to-rollout challenges, outlining what is still needed to be known to efficiently rollout CAB-LA.
- Iterate on plan, especially as new data becomes available, that identifies critical activities, timing, resources and stakeholder roles and responsibilities to fill gaps.
- Leverage CAB-LA as an example to develop and fine-tune an overarching product introduction framework that is adaptable for any future product.

D NEXT-GENERATION PREVENTION

 The Challenge	Multiple products are currently in early-stage development, including multiple implants, other novel delivery systems, and combination products.
 The Risk	Product developers and funders could develop new options that do not fully respond to the preferences and realities of the people who need them most.
 PMM Response/ Progress	<ul style="list-style-type: none">• Ensure that oral PrEP lessons and end-user insights are compiled, analyzed and disseminated as field-wide assets.• Provide product- and category-specific information to developers with early-stage products to inform understanding of overall market and improve decision-making.
 By end of 2020	<ul style="list-style-type: none">• Work with multiple developers early in the development process to ensure products meet needs of potential users.• Develop market forecasts and work with modelers to estimate cost and impact of introducing new options.• Anticipate unique challenges that each product will need to resolve—and which challenges will not be addressed by new products.



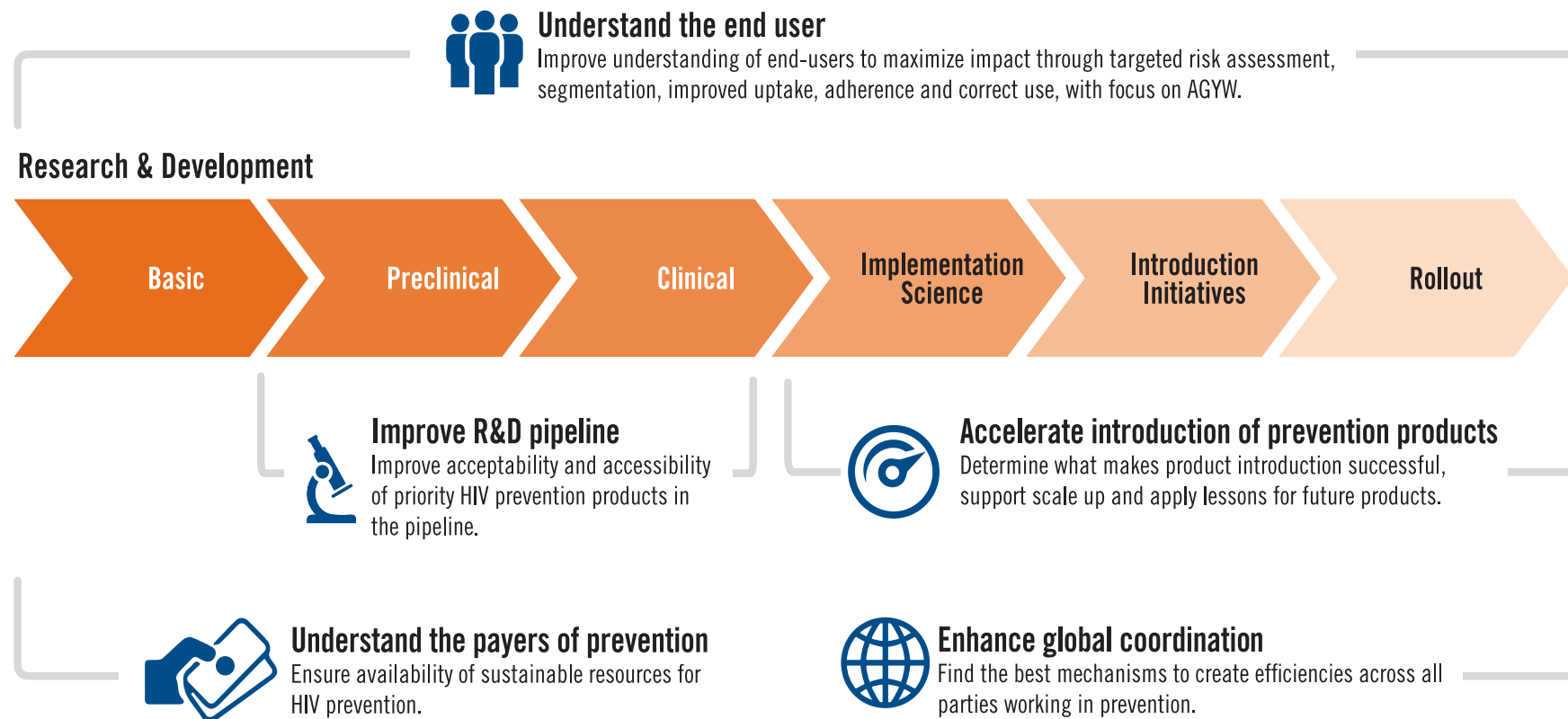
PMM's work is not about any single HIV prevention product. It's about paving the way for introduction of a more robust and comprehensive mix of options from which people can choose.

- ▶ **People at risk of HIV are at the center of everything we do.** With our partners, we engage affected communities directly to understand individual needs, preferences and the challenges they face in taking up and using HIV prevention options. Adolescent girls and young women are a central focus of our work in African countries, because they are at greatest risk for HIV and are historically underserved by HIV prevention efforts.
- ▶ In the near term, a significant outcome of our work is **more rapid and strategic introduction of oral pre-exposure prophylaxis (PrEP)** in four priority countries—Kenya, Malawi, South Africa and Zimbabwe. The rollout of PrEP in these countries shows how complex and challenging implementation can be, with 62 distinct oral PrEP implementation projects: 31 ongoing, 20 planned and 11 completed, with 47 different organizations involved in implementation research.
- ▶ PMM analyzed lessons from all facets of the oral PrEP experience—demand generation to retention strategies to delivery platforms—to **pave the way for faster development and introduction of vaginal rings, long-acting injectables, implants, patches, and others next-generation approaches** that are at various stages in the pipeline.

Driving Product Introduction and Access

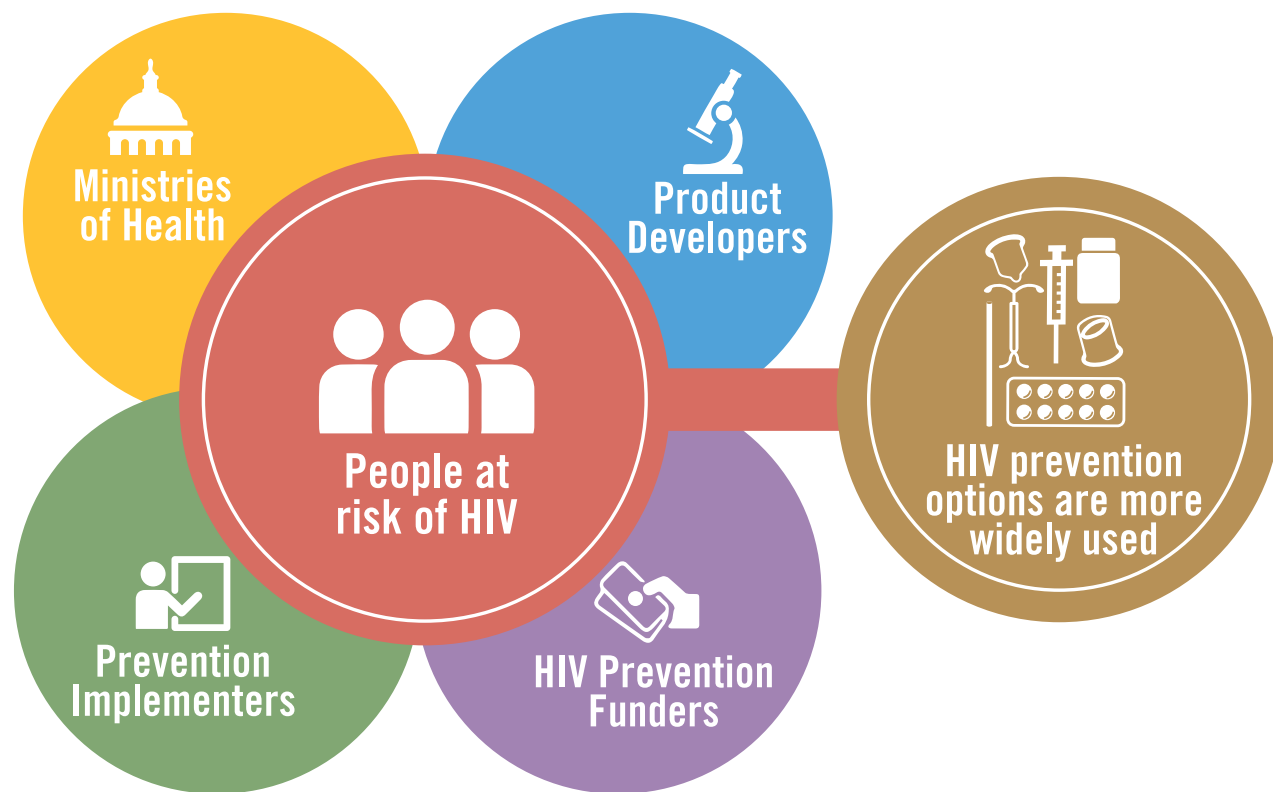
As PMM, AVAC and CHAI are taking our missions further. AVAC has always advocated for **closing critical prevention gaps**. With African and **global partners**, we're stepping beyond advocacy to generate knowledge and tools to **more quickly deliver new advances**:

- Engaging directly with national decision-makers to **identify and overcome delivery hurdles** for PrEP
- Examining the **preferences and experiences** of people at high risk for HIV, so that future tools—long-acting injectables, vaginal rings, bNABs and vaccines—can be optimized to meet their needs





How our work informs HIV prevention from research through roll-out



-  We're learning about the experiences and prevention preferences of adolescent girls and young women, and other high-risk and underserved groups, so future prevention tools can be designed to meet their needs.
-  Product developers better understand the prevention needs of individuals at risk for HIV, and in-country product distribution channels and challenges, to better deliver HIV prevention options that are more likely to be used.
-  Funders can make more thoughtful decisions about their prevention investments when they have confidence that HIV prevention options entering the market can be distributed effectively to, and will be used by, those who need them most.
-  Government decision-makers share what they know with peers and partners in real-time, enabling more informed decisions and make programmatic adjustments.
-  By sharing lessons learned broadly, implementers in any country can modify or develop new systems that support more rapid scale-up and introduction of future HIV prevention options.

-  **Support for rapid policy development and program implementation**
-  **Data for more informed decisions**
-  **Cutting edge market research insights shared in real time**
-  **Informing HIV prevention product development**

See following pages for detail

Support for rapid policy development and program implementation.

In October 2015, less than one month after WHO released its updated PrEP recommendations, PMM was there to provide administrative, technical and knowledge support to the South African government as it began planning for rollout. *On June 1, 2016, South Africa was the first country in sub-Saharan Africa to move from WHO's global guidance on offering oral PrEP to actual implementation, a feat it achieved in just nine months.*

PMM, in partnership with the OPTIONS Consortium and the South African Department of Health, conducted the ACCESS Operations Research Study to assess the first year of the national PrEP program. ACCESS identified factors affecting individual's decisions to initiate, continue, and/or stop PrEP use, and PrEP provider's attitudes and practices. The findings led to immediate programmatic adaptation.



Support for rapid policy development and program implementation

- [Advancing PrEP: Insights to guide introduction and scale-up in South Africa](#)
- Oral PrEP Mapping in [Kenya](#) and [Zimbabwe](#)

PrEPWatch

PrEP Planning A-Z

Oral PrEP is gaining momentum worldwide. More and more countries are approving it for daily use — and global demand is growing!

Introducing PrEP is a complex process, and there's no single mold for an effective program. But this section of PrEPWatch is a great place to start.

This step-by-step framework for scaling up PrEP outlines what's involved for introducing oral PrEP and provides links to tools and resources:

TECHNICAL BRIEF

NOVEMBER 2018

Advancing PrEP: Insights to guide introduction and scale-up

▶ Data for more informed decisions.

PMM worked closely with the Kenyan Ministry of Health's National AIDS & STI Control Programme (NASCO) to support the development of its national PrEP strategy. Specifically, PMM worked to improve data systems so that decision-makers would have a clear snapshot of PrEP uptake. *This research helped drive the decision to make PrEP widely available in Kenya in 2017, through the largest nation-wide oral PrEP program outside of the US, France and Australia.*

PMM also established a robust partnership with the Jilinde project in Kenya to develop a comprehensive, user-centered integrated oral PrEP marketing campaign. Initial demand for oral PrEP was above target, and Jilinde, PMM and many other partners are now exploring factors related to product continuation and how to support ongoing use.

Data for more informed decisions

- [Risk Assessment Tools & the Identification of Individuals at High-Risk of HIV infection in Delivery of Oral PrEP](#)
- [PrEPWatch's Track Global PrEP Use](#)



Global PrEP Tracker

[Download it here!](#)

Risk Assessment Tools and the Identification of Individuals at High-Risk of HIV infection in the Delivery of Oral PrEP

Cutting edge market research insights shared in real time.

PMM is using behavioral economics and human-centered design research to learn more about how adolescent girls and young women in South Africa make decisions and how this might inform better programs and product development. The research recognizes that an individual's needs, desires and motivations change over time, and can help identify effective program design, communications tools and messages to help them make personal, informed HIV prevention decisions. *PMM is providing interim updates on findings to HIV program implementers so they can act on the information as quickly as possible. Full results are anticipated in 2019.*

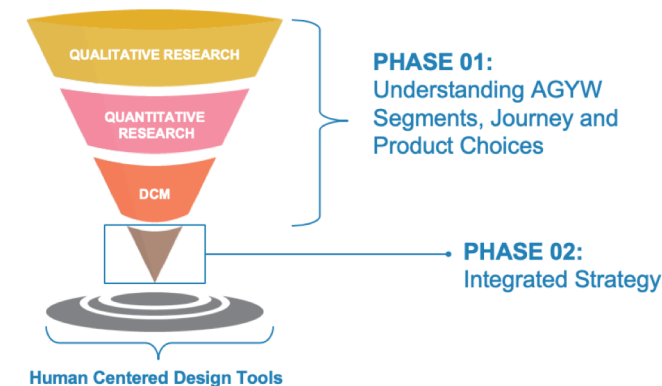
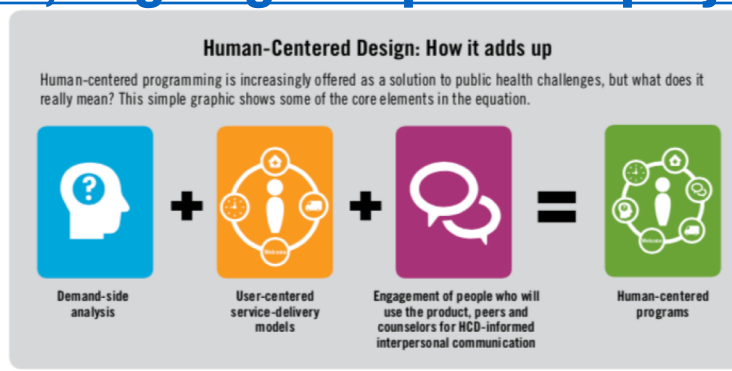
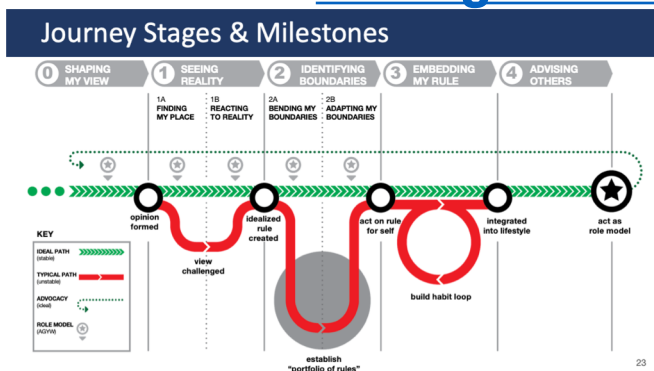
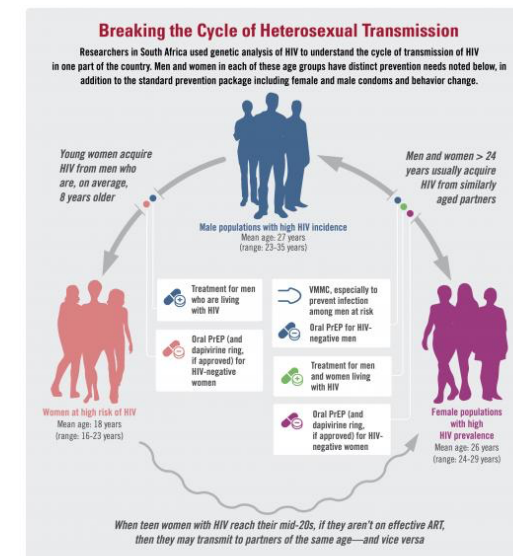
Initial qualitative analysis found that for young women in South Africa, HIV prevention is embedded in a broader context of relationship management and sexual health. A distinct five-phase overarching journey to sexual health was identified through which individuals will navigate in different ways and at different speeds. PMM is now collaborating with implementers to consider application of these findings to programs that can be more responsive and supportive of young women's journey.



Selected Resources from PMM to Support the Field

Cutting edge market research insights shared in real time

- **Breaking the Cycle of Transmission: Increasing uptake and effective use of HIV prevention among high-risk adolescent girls and young women in South Africa: Qualitative & Quantitative findings & segmentation**
- **Human-Centered Design in Global Health & Development: Guidance to Maximize Impact and Mitigate Risk**
- **What we know and don't know about adolescent girls and young women and HIV prevention in sub-Saharan Africa – Mapping findings across completed, ongoing and planned projects**



Informing HIV prevention product development.

In 2018, product developer ViiV, the Bill & Melinda Gates Foundation and PMM established the Biomedical Prevention Implementation Collaborative (BioPIC) to gain input from a range of global stakeholder groups, including civil society, donors, researchers, policy makers, normative agencies, implementers, on a product introduction plan for a long-acting PrEP injectable in development.

Through the BioPIC, PMM is now supporting over 100 global health experts representing the widest array of expertise across the research to rollout continuum to develop a comprehensive, coordinated product introduction agenda and access strategy in parallel with the clinical trials and ahead of their completion. While focused on CAB-LA, PMM is also working with IPM and the OPTIONS Consortium to collaborate on planning for the dapivirine vaginal ring.

Informing HIV prevention product development

- Biomedical Prevention Implementation Collaborative (BioPIC) introduction
- Prevention Pipelines and Planning for Success

Collaboratively Planning For Success

Ideal Scenario for Future Px Products

Mapping decision-maker questions against studies

Planning in parallel with clinical trials

Shared strategy developed by diverse stakeholders



Post-approval studies are well designed to address decision-maker questions



Data from research is well timed to inform decision-making at global and country level



Coordinated stakeholder landscape with roles agreed upon in advance

HIV prevention product pipeline offers exciting potential to curb incidence, but achieving impact will be challenging, and we need to plan ahead

Overview of Critical Pathway Activities

