

HIV PREVENTION MARKET MANAGER

Accelerating Product Introduction
Informing Product Development
Reducing Time to Impact



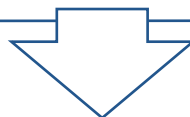
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PMM isn't about a specific HIV Px product.

It's about paving the way for more robust and comprehensive options.

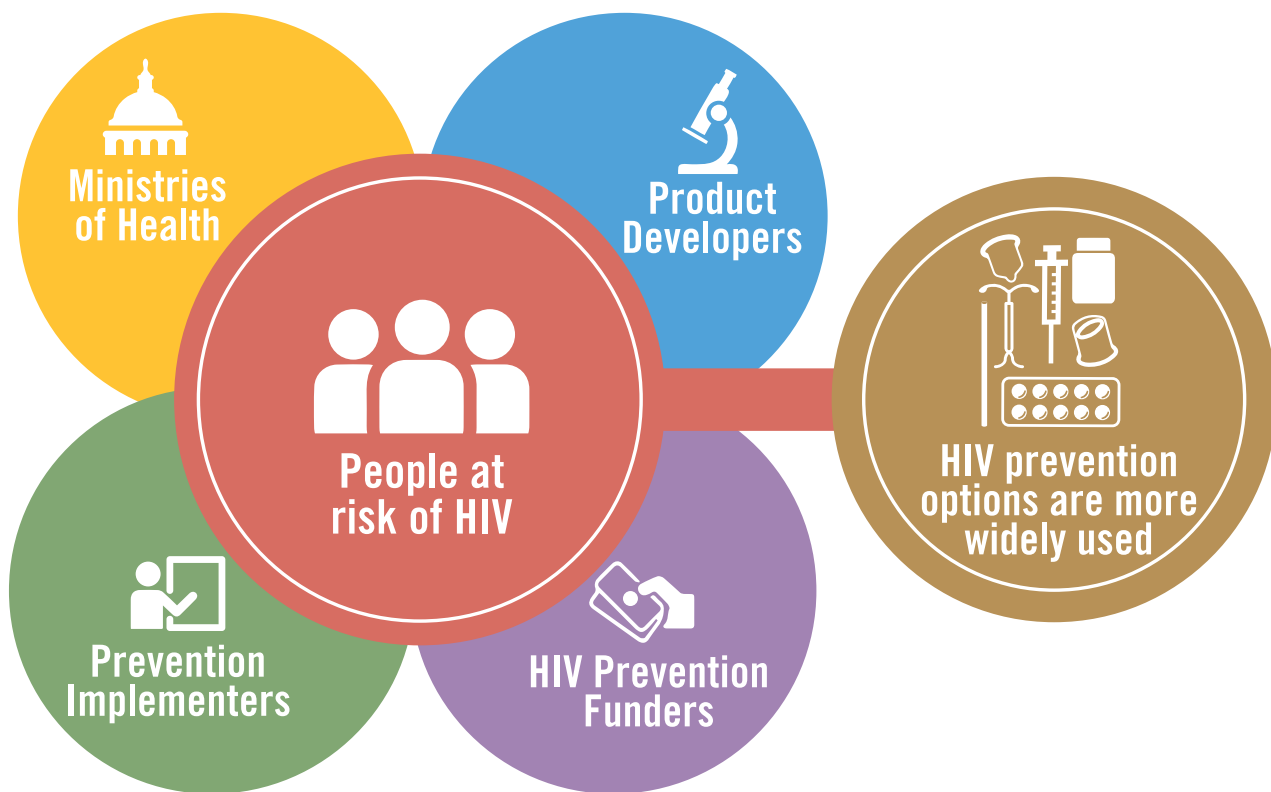
- **People at risk of HIV are the center of PMM's work.** PMM engages affected communities to understand the needs, preferences and the challenges they face in taking up and using HIV prevention options.
- PMM contributes to **more rapid and strategic introduction and scale-up of oral pre-exposure prophylaxis (PrEP)** in four priority countries—**Kenya, Malawi, South Africa and Zimbabwe.**
- PMM analyzes lessons from all facets of the oral PrEP experience 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.




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



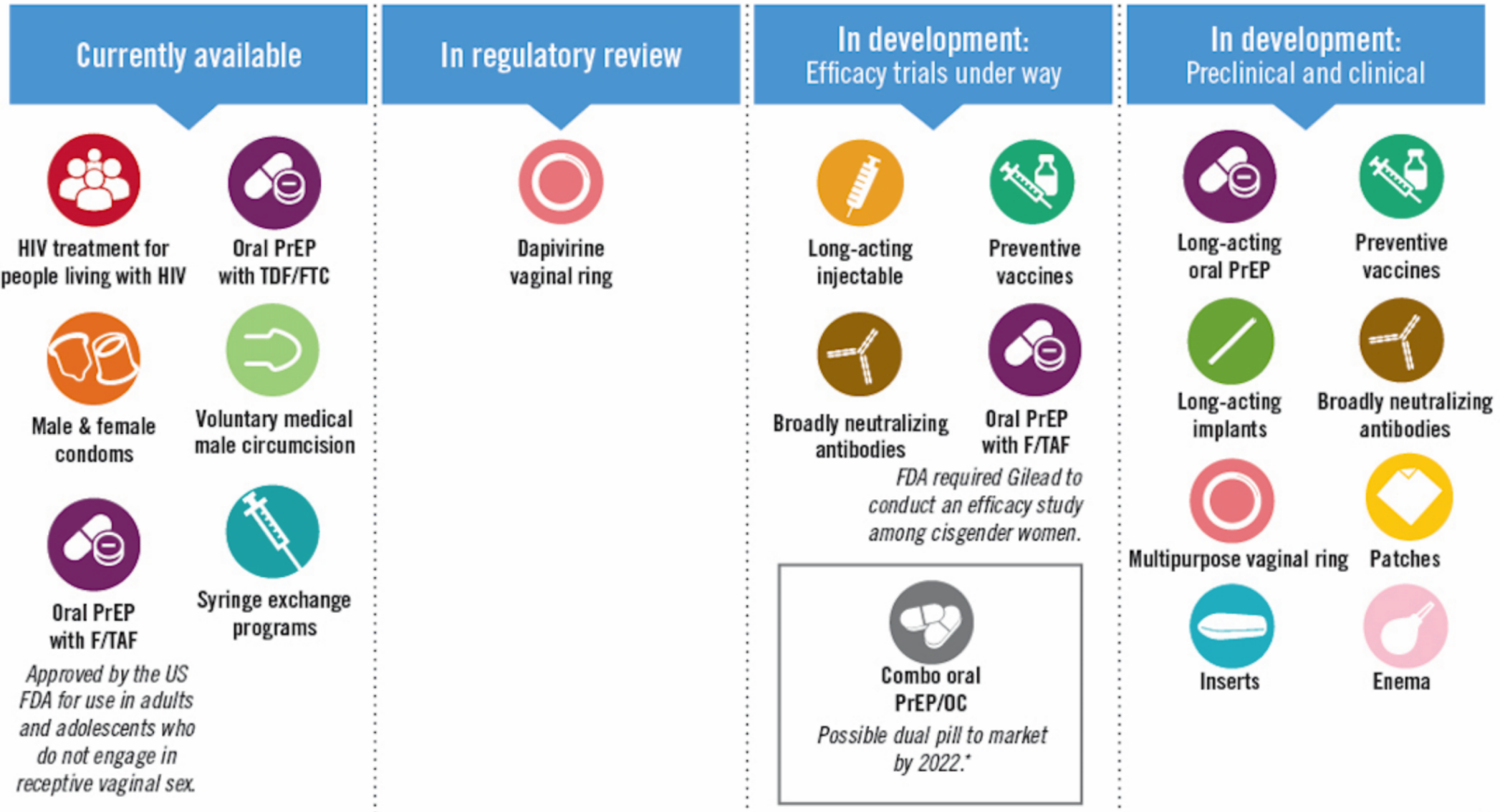
How our work informs HIV prevention from research through roll-out



-  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.



The pipeline for HIV Px products is expanding, but requires coordination especially as more products become available.

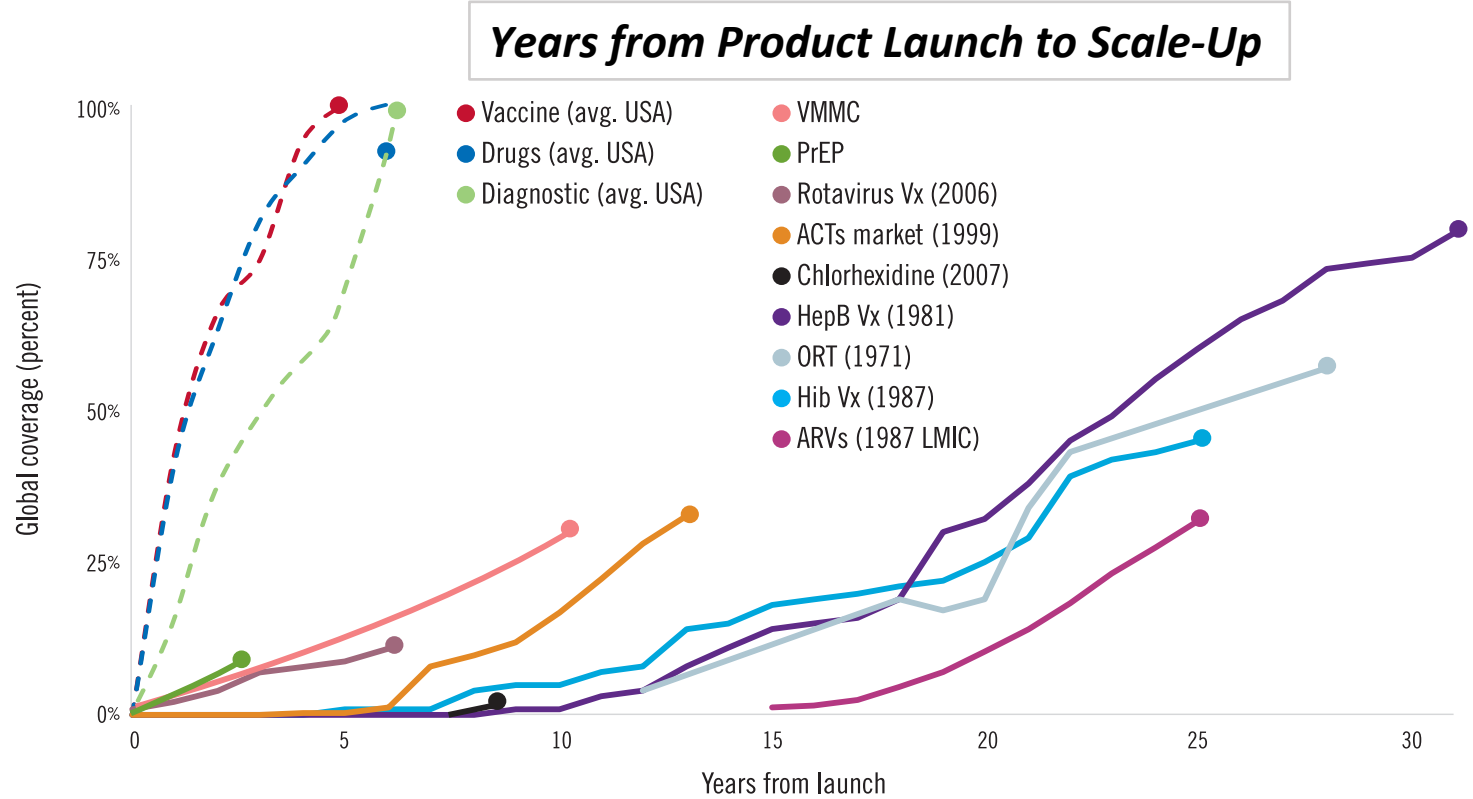


PMM works to resolve challenges for oral PrEP— and help spur advanced planning to avoid delays with next-generation options in the pipeline.

The full impact of recent advances (including VMMC and oral PrEP) were delayed by years because of limited advance planning.

Challenges included:

- Limited research to identify and understand potential users
- Lack of coordination for demo projects
- Few tools for country-level decision makers (e.g., estimated costs or impact of investments)
- Failure to invest in strategic demand creation



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

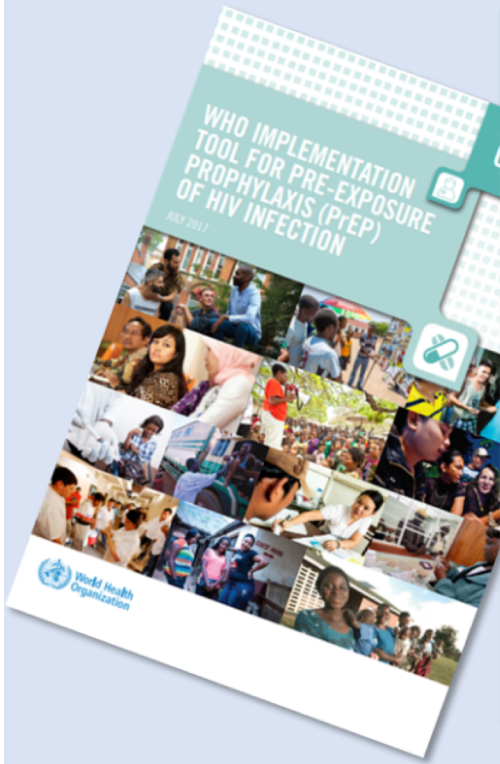
Figure courtesy of Dana Hovig, Bill & Melinda Gates Foundation.

While drugs, diagnostics, and vaccines typically scale within the first two years of launch in developed countries, they often take decades to scale in lower- and middle-income countries.







When PMM began in 2016, no countries in sub-Saharan Africa had introduced oral PrEP and national PrEP programs did not exist

- In Q4 2015, WHO recommended that TDF-containing oral PrEP should be offered as an additional prevention choice for people at substantial risk of HIV as part of combination HIV prevention approaches



- The PMM initiated work to **accelerate introduction of oral PrEP and ensure lessons from PrEP roll-out** inform future prevention programming.

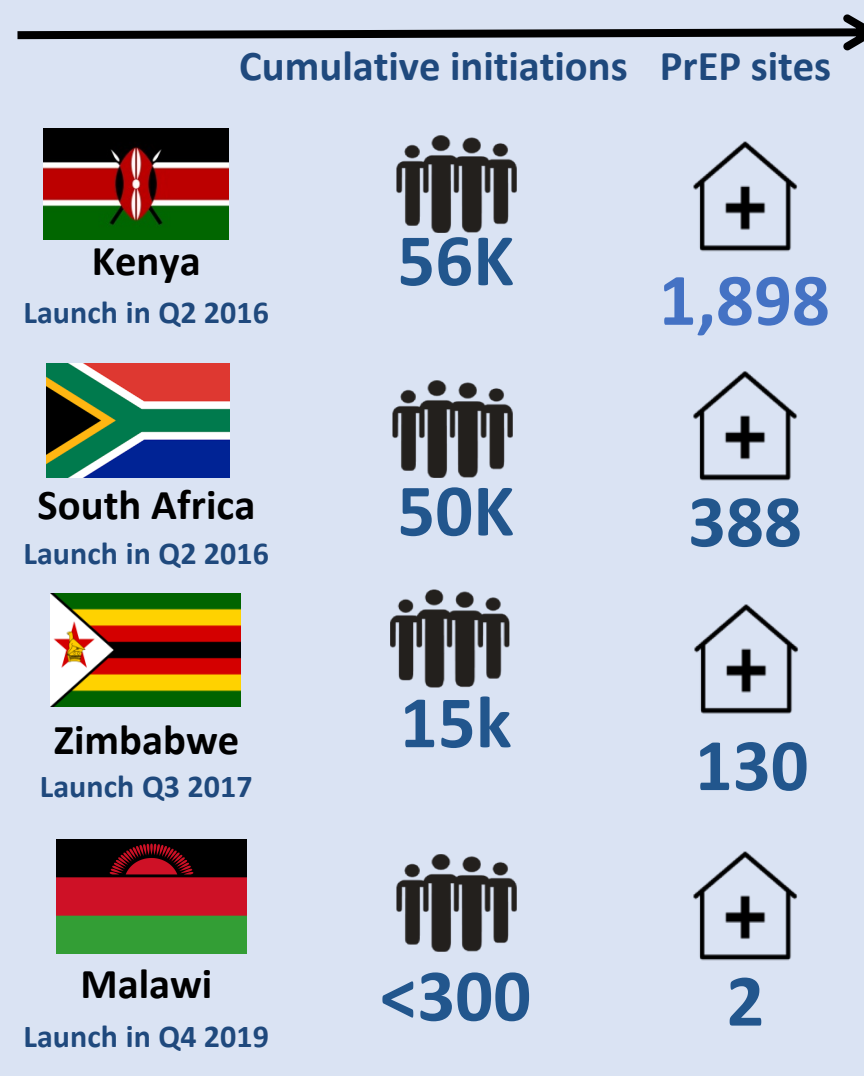
- In 2016, PMM focus countries were:
 -  **South Africa:** Strong national HIV response; historical early adopter
 -  **Kenya:** Strong national Tx and VMMC program; historical early adopter
 -  **Zimbabwe:** Strong MOH support for Px but very limited resource envelope
 -  **Malawi:** Limited resource envelope but has recently prioritized exploring PrEP as an option



PMM created mechanisms and documented learnings to catalyze PrEP introduction and scale-up

- Implementing partners mobilized around support for delivery of oral PrEP with diverse goals and population targets. **PMM was well placed to support Ministries to coordinate the response and establish national policy.**
- Through AVAC and CHAI’s longstanding relationships in-country, the PMM drove several activities required for product introduction and scale-up:
 - ✓ **Enabling PrEP availability** via support around decision-making on drug choice, product registration, annual forecasting, supply chain integration
 - ✓ **Achieving technical and operational consensus around delivery** via development of clinical guidance and national implementation plans
 - ✓ **Setting priorities and coordinating implementation** via establishment of PrEP TWGs to ensure robust dialogue and joint planning, target-setting and review of progress across government and partners
 - ✓ **Capacitating HCWs and public facilities** with tools to provide PrEP
 - ✓ **Enabling data-driven decision-making** by creating M&E systems to track implementation progress and developing new methods to estimate impact
 - ✓ **Identifying and leveraging opportunities for sustainable financing**

Oral PrEP achievements to-date





South Africa

- PMM will continue to support the NDoH with oral PrEP scale-up by supporting effective M&E approaches to understand progress against scale-up targets, linkage with HTS targets, and continued technical assistance for using data to optimize service delivery.



Kenya

- PMM will support NASCOP and other key PrEP partners to set country-level PrEP targets using a methodology launched in 2019, and iterate on it as population size data becomes more reliable in 2020.
- PMM will scale-up use of the electronic ADT platform to provide key insights to understand uptake and continuation trends to-date. The team will analyze continuation trends across various populations and carry out focus group discussions with those who are early discontinuers to understand potential reasons and barriers.



Zimbabwe

- PMM will work with MOHCC and partners to develop a revised national PrEP implementation plan, as well as a standardized PrEP M&E system (harmonizing indicators, tools, and reporting) to comprehensively inform national decision-making and facilitate better coordination of activities.



Malawi

- PMM will focus on documenting learnings from the oral PrEP introduction for future prevention products, and preparing the market and health system to better meet the needs of those in need of HIV prevention options.



Global Coordination

- Catalyze and elevate solutions to optimize and inform HIV prevention delivery through evidence and resource sharing when convening implementers, governments, advocates and developers at global, regional and country levels

People



Demonstrate the impact, scalability and viability of the SA end user work among implementers inside and outside of SA as well as product developers and funders

Programmatic Platforms



Catalyze and support evidence-based optimization of oral PrEP programs and platforms by providing technical assistance to governments, implementers and funders

Pipeline Products



Leverage CAB-LA research and post-trial access strategy to inform and coordinate investments;
Apply lessons learned and adapt BioPIC structure to engage with next-gen px product developers to accelerate product introduction



PMM's 3Ps framework analyzes the prevention landscape to optimize existing programs and accelerate introduction for future products

The priorities

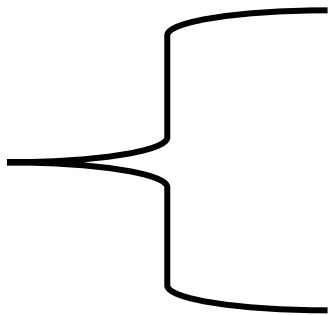
People



Programs



Products



The landscape

A

The users of prevention

B

Oral PrEP

C

Long-acting injectable PrEP, Cabotegravir

D

Next generation prevention

The approach



The Challenge



The Risk



PMM Response/
Progress



By end
of 2020



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

- Initiated innovative behavioral economics and human-centered design projects to provide in-depth understanding of HIV prevention needs, wants, challenges and opportunities
- Found that, for most AGYW, HIV Px is embedded in a journey of relationships and healthy sexual routines
- Developed journey framework that recognizes the standard linear understanding of prevention behavior does not accurately represent reality
- Used quantitative data to outline discreet and identifiable segments



By end
of 2020

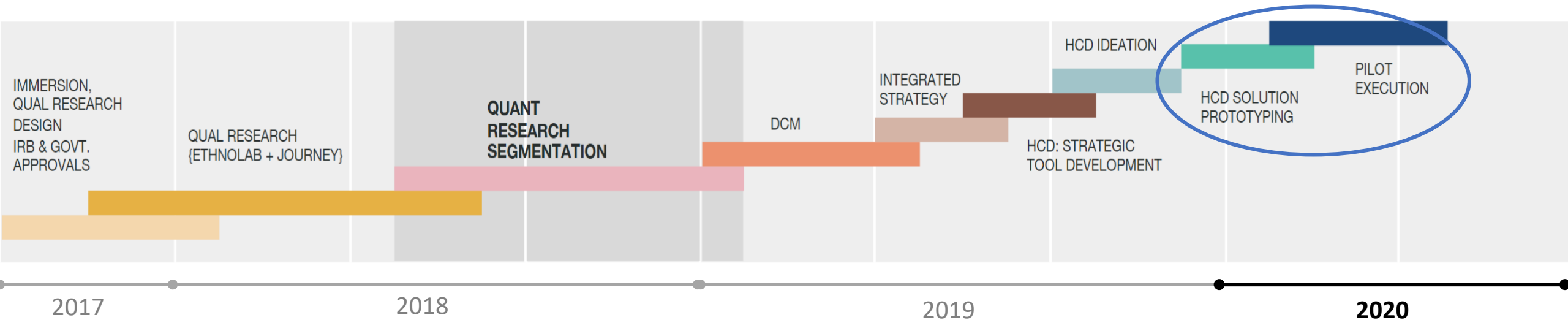
- Design, implement, & evaluate 2 pilot interventions to improve AGYW uptake of HIV Px
- Provide technical assistance to partners to inform and incorporate user insights into program(s)
- Coordinate with regional partners (Kenya, Zimbabwe, and Malawi) to explore scalability and applicability of the research outside of South Africa
- Document and disseminate results and lessons learned to targeted stakeholders through roadshows and sharing of tools and resources





A THE USERS OF PREVENTION

▶ Cutting edge market research insights shared in real time.

PMM relied on behavioral economics and human-centered design to learn how AGYW in South Africa make decisions regarding their sexual health and relationships.

PMM is using the below model, and ideas sourced directly from AGYW, to implement targeted communications using market segmentation to test two pilot interventions aimed at maximizing uptake, adherence, and correct use of prevention products.



B	ORAL PREP
 <p>The Challenge</p>	<p>Shown to be safe effective in 2010 and first approved 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 remained unanswered</p>
 <p>The Risk</p>	<p>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</p>
 <p>PMM Response/ Progress</p>	<ul style="list-style-type: none"> • Catalyzed achievement of >120k cumulative initiations in Kenya, South Africa, Zimbabwe, and Malawi, representing 2/3 of LMIC initiations and 1/3 of global initiations, by providing TA to governments on policy development, program design & implementation, and M&E • Created a real-time community of practice to capture and analyze data to identify and address the critical barriers to use and impact
 <p>By end of 2020</p>	<ul style="list-style-type: none"> • Catalyze scale-up of oral PrEP according to national strategies in Kenya, Malawi, South Africa, and Zimbabwe by developing, providing guidance on, and assisting governments to track and achieve expressed implementation plans (improving/adjusting where needed) • Prepare the in-country environment for rapid introduction of CAB-LA by sensitizing stakeholders to ongoing clinical trials and begin system preparations for rapid introduction in BMGF priority countries



C LONG-ACTING INJECTABLE CABOTEGRAVIR (CAB-LA)



The Challenge

Experience from oral PrEP rollout demonstrates 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), which developed a CAB-LA introduction strategy to ensure critical planning and preparation occurs in parallel with clinical trials and ahead of their completion
- Leveraging lessons learned regarding new products, PMM is working with CIFF to launch the Dual Prevention Pill (DPP) combining oral contraceptive and oral PrEP



By end
of 2020

- Track and monitor progress against the CAB-LA Strategy and lead public dissemination of v2.0 strategy with communication materials, webinar, and roadshow with key stakeholders
- Use CAB-LA Strategy to conduct preliminary readiness assessment that systematically evaluates health system capacity and policies to anticipate rollout challenges and identify available delivery mechanisms for CAB-LA and draft initial country-specific introduction roadmaps



LONG-ACTING INJECTABLE CABOTEGRAVIR (CAB-LA)



Establishing an innovative mechanism to accelerate access to pipeline products

Oral PrEP Product Introduction Prior to PMM

Without advanced planning and coordination, LMIC introduction of oral PrEP was delayed 4+ year after FDA approval.



Key components of product introduction were not well-timed, causing delays in introduction and scale up.



Due to a complex, fragmented stakeholder landscape, post-approval studies were not designed to answer critical questions.

Future Product Introduction Approach Launched by PMM

To support rapid, successful introduction of HIV prevention products, BioPIC aims to forge a new path forward for future products.



Plan in parallel to clinical trials to shorten the time between regulatory approval and large-scale, phased implementation projects in LMICs.



Coordinate stakeholders in advance to ensure projects are well-designed to provide evidence to quickly build from small pilots to scale.







In partnership with BMGF and ViiV Healthcare, PMM engaged diverse stakeholders from over 80 organizations and 20 countries to compile HIV prevention learnings and to plan ahead for successful introduction of future products.



C

LONG-ACTING INJECTABLE CABOTEGRAVIR (CAB-LA)

Establishing an innovative mechanism to accelerate access to pipeline products

-  Established buy-in on advanced, collaborative planning with 100+ civil society members, donors, researchers, policy makers, normative agencies, and implementers
-  Led extensive working group consultations to develop V1 introduction and access strategy for CAB-LA
-  Finalized CAB-LA need estimate and conducted HRH analysis to inform early introduction
-  Informed Unitaid's long-acting technology investment strategy
-  Catalyzed WHO's regulatory coordination to prepare NDRAs for review
-  Spurred an analogous ClIFF investment to start collaborative planning for a dual HIV prevention-contraceptive pill

A shared introduction and access strategy developed in parallel to clinical trials will ensure activities are well-designed, well-timed, and well-funded to meet the needs of global and country decision-makers.

BioPIC Next Steps



BioPIC will continue to serve as a coordination structure, tracking progress against the strategy and disseminating learnings for CAB-LA and HIV prevention more broadly.



BioPIC will distill learning from the CAB-LA strategy into an adaptable product introduction framework, which will support planning for future products.



D

NEXT-GENERATION PREVENTION



The Challenge

Multiple products are currently in early-stage development, including multiple implants, other novel delivery systems, and multi-purpose prevention technologies (MPTs)



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

- 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

- Engage with pipeline product developers based on shared and specific information needs
- Provide insights from AGYW end user work around preferences and barriers
- Develop a revised governance structure, objectives, and terms of reference for a next-generation (BioPIC)



PMM works to optimize the potential impact of pipeline HIV prevention products by sharing insights and updates with developers.

Developers turn to PMM for critical information and analyses on:



National procurement processes



End user preferences, human centered-design, marketing & communication plans



Health systems capacity



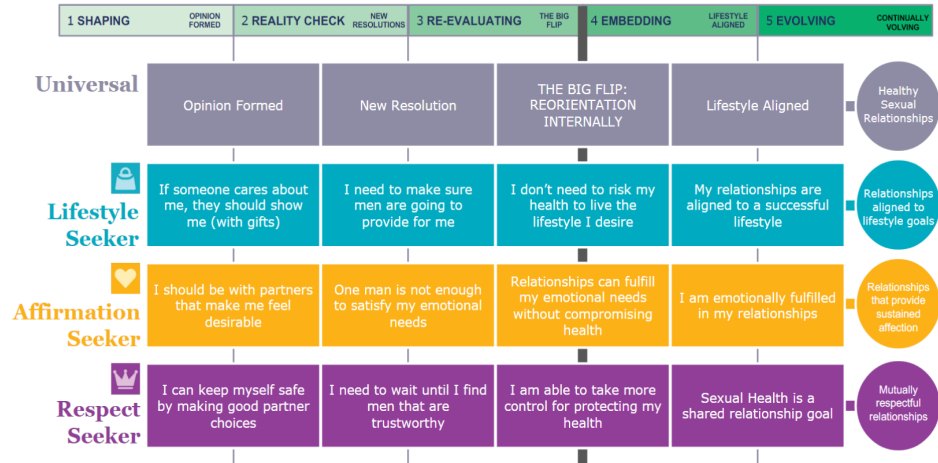
Market sizing and landscaping



Stakeholder engagement



People: AGYW Integrated Qual + Quant Research Presentation



Products: BioPIC Strategy for CAB-LA 2.0

Biomedical Prevention Implementation Collaborative HIV Prevention & Planning for Success

The HIV prevention product pipeline offers exciting potential to curb incidence—but we know from previous products, that achieving impact will be challenging without advanced planning and coordination.

Summary of BioPIC's CAB-LA Strategy:

By involving decision-maker levels across the research-to-culture continuum, BioPIC has developed a product introduction strategy for CAB-LA, which identifies activities critical to product introduction, to rapidly and successfully introduce CAB-LA, stakeholders must work to address the following needs:

- Regulatory Approval & New-market Release:** Ensure global and national bodies have sufficient evidence and safety assurance
 - Plan in advance to obtain safety data for pregnant and breastfeeding women
 - Plan in advance and bolster systems to monitor resistance
 - Conduct research for additional populations not included in clinical trials
 - Support efficient regulatory review and development of normative guidance
- Planning & Buydown:** Establish evidence to understand resource needs and the impact of CAB-LA
 - Model impact on multiple end-points and in different country contexts
 - Build consensus and align methods on indicators, monitoring, and target setting
 - Conduct cost and paper analyses to inform budgeting
 - Coordinate and align procurement
- Delivery & Supply Chain:** Enable programs to quickly move from small projects to scale
 - Conduct delivery channel analyses to identify operational opportunities and barriers prior to early implementation projects
 - Support development of guidance and tools during early implementation
 - Consolidate implementation questions in fewer, larger-scale projects
- Individual Update & Continued Use:** Identify methods to support high uptake and continued use
 - Engage and build community mechanisms to refine program design and implementation
 - Conduct human-centered design research to understand barriers and enablers for providers, communities, and priority populations

Next Steps for BioPIC CAB-LA Introduction and Future Products

BioPIC aims to leverage the shared product introduction strategy for CAB-LA to keep a near path forward for HIV prevention and catalyze more rapid LMIC access to a growing portfolio of products.

BioPIC will continue to serve as a coordination structure, tracking progress against the strategy and disseminating learnings for CAB-LA and HIV prevention more broadly.

BioPIC will distill learning from the CAB-LA strategy into an adaptable product introduction framework, which will support planning for future products.

Programmatic Platforms:

HIV & Sexual and Reproductive Health Integration

Key Learnings from a Multipronged Review of Policies and Evidence

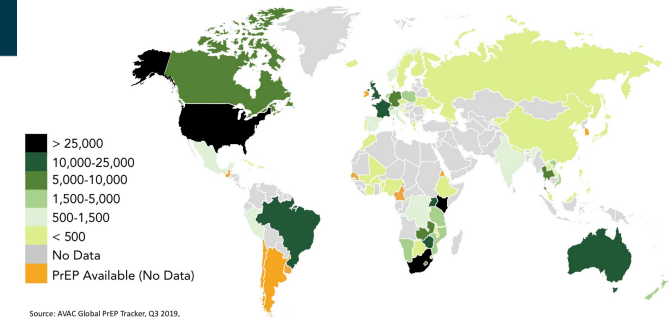


Global Coordination: PrEPWatch's Global PrEP Tracker

Global PrEP Tracker

Download it here!

PrEP Initiations by Country, October 2019



Source: AVAC Global PrEP Tracker, Q3 2019. <https://www.prepwatch.org/country-updates/>

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