

Coordinating Implementation Science: Taking Stock of PrEP Evidence

AVAC/BioPIC and WHO

19 March 2024, 10am EDT

Background/Rationale

The PrEP landscape has evolved significantly since oral PrEP was first approved by the US Food and Drug Administration in 2012, both in terms of scale – with over 6.2 million oral PrEP initiations taking place by the end of 2023 – and range – with two types of oral pill, a two-month injectable, and a one-month vaginal ring currently available, and a six-month injectable and combined PrEP/oral contraceptive pill in late stage development. A priority within the field has been addressing evidence gaps, particularly through implementation science, to facilitate the efficient scale up of new PrEP options. As the field of biomedical HIV prevention enters this new phase of increased choice and scale, now is a critical time to take stock of the available evidence and its application and to identify remaining evidence gaps impacting the field's ability to scale up a multi-product PrEP market.

This Think Tank provided an opportunity to both review existing evidence and identify priority evidence gaps so that these can be explored and addressed further in future Think Tanks. Evidence and best practices generated through these future Think Tanks will be used to update relevant PrEP tools such as the [WHO's PrEP Implementation Tool](#) as well as inform programmatic scale up.

Meeting Objectives:

1. Discuss how to effectively incorporate available PrEP evidence and best practices into programming/service delivery.
2. Identify and prioritise remaining PrEP evidence gaps, including those to be addressed at future Think Tanks.
3. Identify tools that require updating to facilitate PrEP scale up.

Proven Strategies

Though the scale-up and implementation of oral PrEP has varied across countries and populations, [several key lessons](#) have consistently emerged, including:

- **Risk of HIV acquisition** changes over time so PrEP use may change accordingly, and users who self-identify as at risk for HIV may not fit into traditional risk categories.
- **Demand generation** is an integral part of PrEP delivery, should be tailored to different audiences, and should focus on positive, empowering messaging.
- **Demedicalised** service delivery is often preferable to users.
- **Monitoring and evaluation** systems should be simplified and harmonised to allow collection of high quality data to truly measure the impact of PrEP and understand who is (and is not) using PrEP.

Effectively Scaling up PrEP Choice: What do we know, what do we do with that insight, and what do we still need to know?

Category	What do we know?	What to do with these insights?	What do we still need to know?
Policy, Budgeting, and Planning	Governments may be influenced into action by neighbours, e.g. in approving new guidelines	Build political will to swiftly approve new products, guidelines, and policies to facilitate PrEP delivery	How to develop effective strategies to induce governments to take ownership of PrEP delivery
	Defining and costing what success looks like can support governments to budget for PrEP effectively Governments will be more likely to fund PrEP if its impact can be clearly demonstrated	Build political will to fund PrEP delivery	How to define and cost “successful” PrEP delivery How to package compelling data to demonstrate the impact of PrEP to date
	Effective coordination amongst implementers, donors and the government from the implementation research phase facilitates a successful scale-up	Promote both vertical coordination- between government and implementers- and horizontal coordination- amongst service delivery channels	How to ensure coordination happens from the start and continues throughout
Supply Chain	A consumer choice-based quantification system can respond to user preference, lead to less wastage, and be less costly for governments Tools like PrEP-it can be used to aid in quantification in response to user preference	Ensure sufficient supply in country for a PrEP method mix that reflects user preference	User preferences for PrEP method mix How to move governments from a “push” system to consumer choice-based procurement
Service Delivery	Pilots have demonstrated successful oral PrEP delivery via community-based facilities, mobile facilities, pharmacies, and other novel channels	Implement effective PrEP delivery via a wide range of channels to meet the needs of users	How to deliver PrEP choice via non-traditional channels at scale, especially when different methods require different levels of provider engagement
	Elements of oral PrEP delivery, including counselling, prescribing, and dispensing, have been successfully task-shifted across a variety of contexts	Continue to task-shift PrEP delivery to community settings, including peer-led delivery, to widen access	How to get government buy-in for continued task-shifting Feasibility of task-shifting for injectables and vaginal rings

Category	What do we know?	What to do with these insights?	What do we still need to know?
Service Delivery <i>(continued)</i>	Reducing the number of times a user needs to return to a facility, such as by employing multi-month dispensing or conducting follow-up visits remotely, can help increase adherence	Implement multi-month dispensing for oral PrEP where permitted and advocate for policy changes where it is not Develop and build capacity to offer remote follow-up visits	How to scale mhealth solutions to facilitate remote support and follow-up How to effectively use HIV self-testing (HIVST) as part of remote follow-up
	Offering choice increases PrEP coverage HIV prevention can be an entry point for users to access other sexual and reproductive health (SRH) services, and vice versa	Offer a full-service package in a single location- including a range of PrEP methods and other SRH services	How to effectively and sustainably integrate PrEP and new PrEP methods into existing service delivery
	Use of HIVST for PrEP has similar health impacts, costs, and low risk of drug resistance as provider-administered rapid tests , and is recommended by WHO	Utilise self-care solutions, such as HIVST, for initiation and continuation, to widen access	How to effectively scale up HIVST for initiation, continuation, and re-initiation, and the associated costs Which other self-care interventions can be delivered alongside PrEP, such as STI self-tests
Demand Generation	Demand generation works best when it uses empowering messaging to appeal to users' real concerns and desires, and is designed in conjunction with users	Invest in effective demand creation	How to ensure sustained investment in impactful demand generation at scale
	Peer champions can be particularly effective in normalising PrEP with young people, who are strongly influenced by peers	Normalise PrEP and HIV prevention	How to scale demand generation strategies that normalise PrEP with young people, including young key populations
	Lessons learnt from demand generation for voluntary male medical circumcision (VMMC) can be applied and/or adapted to PrEP	Apply learnings from other HIV prevention demand generation strategies such as VMMC	How to apply and scale learnings from other proven demand generation strategies for HIV prevention

Category	What do we know?	What to do with these insights?	What do we still need to know?
Monitoring and Evaluation	<p>When choice is offered, some current oral PrEP users will continue with oral PrEP, others will switch, and new users will choose what they prefer, including oral PrEP</p> <p>Tools such as PrEP-it can be used to help with target setting</p>	Develop and promote widespread adoption of a clear and measurable definition of what successful PrEP coverage looks like, including method mix	<p>What an ideal method mix looks like in different contexts and how to programme choice in response to evidence</p> <p>How to measure continuation</p>
	<p>Modelling to date has shown that CAB for PrEP can be cost-effective at up to twice the cost of oral PrEP</p> <p>Some HIV stakeholders believe that PrEP methods which cost more than oral PrEP are too expensive</p>	Develop reliable cost-effectiveness estimates for all PrEP methods	<p>At what price different PrEP methods can be cost-effective in different contexts</p> <p>How to shift mindsets around the relative costs of different forms of HIV prevention</p>
	<p>Evidence has shown event-driven PrEP may be feasible for cisgender women</p>	Investigate the feasibility of different dosing options for oral PrEP in cisgender women	How to define effective use by cisgender women
	<p>PrEP is more cost-effective if prescribed to people at heightened risk for HIV</p>	Develop and disseminate clear guidance on who PrEP is for in light of constrained supply and finite resources	The minimum amount of information needed to assess risk and offer PrEP
	<p>Modelling has shown that CAB for PrEP introduction could lead to a five to ten fold increase in INSTI resistance</p>	Implement effective monitoring systems for HIV drug resistance (HIVDR)	How to implement effective and sustainable HIVDR monitoring systems for CAB for PrEP users at scale

Next Steps

To address several of these priority evidence gaps, and generate evidence to update the [WHO's PrEP Implementation Tool](#), AVAC and WHO will co-host a series of convenings throughout 2024.

2024 BioPIC Convenings Calendar (subject to change in response to shifting priorities)

Date	Topic	Format
8 February	Insights from EBONI and PILLAR	Think Tank with Implementation Science Community of Practice
19 March	Taking stock of PrEP Evidence	Expert Forum
26 March	Coordinating Modelling and Implementation Science	Think Tank with Implementation Science Community of Practice and Modellers
23 April	Insights from SEARCH	Webinar with SEARCH team
23 May	Scaling up HIV Self Testing for PrEP Initiation and Continuation	Webinar with WHO
May TBD	HIV Testing Algorithms for CAB for PrEP	Expert Forum
27 June	Scaling up HIV Self Testing for PrEP Initiation and Continuation- What else do we need to know to implement this effectively?	Expert Forum
11 July	Monitoring and Evaluation for PrEP Choice	Webinar with Avenir and The Choice Agenda
September TBD	Scaling up Demedicalised and Community-Based Approaches for PrEP in the Era of Integration	Expert Forum
October TBD	Coordinating Modelling and Implementation Science	Think Tank with Implementation Science Community of Practice and Modellers
November TBD	PrEP and Women: Effective Use and Best Practices	Expert Forum
December TBD	What does PrEP choice actually look like?	Think Tank with PrEP Implementation Community of Practice

Resources:

- [WHO's Consolidated HIV Guidelines \(2021\)](#)
- WHO's [Differentiated and Simplified Pre-exposure Prophylaxis for HIV Prevention Update \(2022\)](#)
- [Consolidated guidelines on HIV, viral hepatitis and STI for key populations - 2022 \(who.int\)](#)
- WHO's [Guidelines on Long-acting Injectable Cabotegravir for HIV Prevention \(2022\)](#)
- [WHO's PrEP Implementation Tool](#)
- [Getting Rollout Right: Lessons from Oral PrEP](#) (Prevention Market Manager)
- [Integrated Study Dashboard](#)