EpiC / RISE

Key considerations: Long-acting PrEP introductions

Introduction

New long-acting PrEP options, such as injectable cabotegravir and lenacapavir, offer an important opportunity to achieve HIV PrEP targets, meaningfully impact HIV incidence, and advance epidemic control. Early implementation suggests that these products can expand the overall prevention market rather than merely shifting current PrEP users to another option.

This document draws on early lessons to outline key considerations for HIV programs to accelerate long-acting PrEP introduction and scale-up while ensuring access to all individuals at risk of HIV acquisition.

Two principles should guide every stage of long-acting PrEP introduction and scale-up: **meaningful community engagement** from planning throughout implementation, and a **product-neutral approach** that positions each new option within a broader PrEP/prevention framework to allow innovations to be quickly incorporated into country HIV programs.

Development of policy, guidelines, and implementation plans

These first steps set the foundation for introduction and rollout, serving as critical opportunities to establish effective coordination among all stakeholders.

1. Establish a multistakeholder coordination committee to guide introduction.

With the government in the lead, the committee should meet frequently (e.g., weekly) during planning and early implementation, then scale down as maturity is attained or merge with existing prevention forums in country such as a PrEP technical working group; include regulatory authorities, implementers, researchers, community representatives, and other key stakeholders; and oversee development of a **phased implementation plan**, with dedicated subcommittees for guidelines development, service delivery, training, monitoring and evaluation, supply chain monitoring, and demand generation. **Clear leadership, roles, responsibilities, and accountability mechanisms** should be defined across all workstreams. Representation from communities to share lived experiences is crucial in informing early planning and setting strategies.

2. Incorporate product-neutral planning.

Policies, guidelines, and implementation plans should be designed to **accommodate future long-acting HIV prevention products,** including through private sector and other community-informed distribution channels, to minimize the need for substantial revisions and to promote consistency across prevention programs as additional options become available.

3. Engage regulatory authorities early to accelerate product approvals and registration.

Identify opportunities to **expedite regulatory review and product introduction** through existing accelerated pathways or obtaining regulatory waivers pending full regulatory approval where appropriate. Planning should anticipate both originator and future generic products to support a smooth transition as markets evolve and supply expands.

Demand and supply planning

Efficient implementation and optimized impact require continuous strategic supply planning.

4. Use data-driven forecasting and planning.

Tools, such as PrEP-it SHIPP, are available to inform site selection, commodity allocation, coverage targets, and resource requirements. During the initial phases of introduction, **prioritize populations and geographic areas** with the highest HIV incidence and unmet prevention needs, including through community engagement, **to maximize impact**. Introduction plans should be phased and grounded in realistic assessments of supply availability, financing, and implementation capacity.

5. Continuously monitor demand and supply to ensure commodity security.

Routinely monitor uptake, continuation rates, and consumption patterns and **establish active stock monitoring and redistribution mechanisms** to optimize available supplies while availing options. Plan for annual forecasting and procurement cycles with at least six months lead time for procurement and importation. Work closely across agencies to expedite import processes and availability of stock in country.

Service delivery models

To maximize uptake and continuation, service delivery models should make PrEP easy to access, convenient to use, and responsive to client preferences and needs.

6. Differentiate client-centered service delivery models that improve access to PrEP options.

Where feasible, **clients should have access to and information on all available PrEP options** at service delivery points to support method selection and switching. Service delivery models should be determined with the community and may include integration within antenatal care, maternal and child health services, and testing and treatment clinics for sexually transmitted infections and HIV; public and private health facilities; community-based services; pharmacies; mobile outreach; and telemedicine.

7. Plan for operational requirements when decentralizing long-acting PrEP services.

Decentralized delivery models require careful consideration of required workforce, infrastructure, testing requirements, and data systems as well as clear roles and responsibilities across cadres of providers, including those who offer follow-up care. Implementation should ensure adequate space, privacy, referral pathways, and integrated data systems that enable care continuity and seamless client tracking across service delivery points.

Provider training

Building provider confidence and ensuring high-quality service delivery require ongoing capacity strengthening.

8. Provide continuous training and support.

Adapt and leverage existing training materials, job aids, and tools to prepare providers on stigma-free, client-centered product administration, HIV testing requirements, PrEP options counseling, follow-up, adverse event management, and method switching. For injectable products, particular attention should be given to injection technique. Ongoing and frequent mentorship and supportive supervision, informed by community feedback, should complement training to reinforce knowledge and start soon after launch for consistent service delivery, and address challenges as they emerge. This can taper as maturity is attained.

Awareness and demand generation

Targeted awareness and demand generation empowers individuals to choose the HIV prevention option that best fits their lives and should continue even when product supply is limited.

9. Promote informed PrEP options with targeted audience-centered communication strategies.

Position injectable PrEP within the broader prevention options framework; product-specific messaging may unintentionally undermine uptake of other effective PrEP options. Communication strategies should be guided by communities and a clear understanding of the target audience, the desired action, and why it matters to them. Key strategies include stakeholder mapping, co-created messages and materials, validated approaches, community champions, and communication channels tailored to different audiences. Proactive media engagement can build awareness, promote accurate information, shape public perception, and address misconceptions.

Monitoring and evaluation

Leverage existing data systems to support continuous learning, improvement, scale-up, and sustainability.

10. Adapt, don't duplicate.

Integrate long-acting PrEP into existing product-disaggregated HIV prevention monitoring, reporting, and patient information systems, including community-led monitoring where available, and include indicators to guide further scale-up, including side effect monitoring and pharmacovigilance.

11. Differentiate PrEP products in the data and closely monitor during early implementation.

Ensure data systems can distinguish between PrEP products and capture the information needed for client-centered, longitudinal continuation, switching, and re-engagement tracking. Data systems should enable ad hoc analyses and evidence generation to evaluate long-term impact and sustainability. Conduct routine data reviews with community partners during rollout to identify and address gaps, refine forecasts, and guide program adjustments.

Sustainability

Plan for sustainability in early stages to support long-term impact and successful scale-up.

12. Determine budget impact and cost-effectiveness to plan for sustainability.

Strategize to generate the evidence and data needed by multiple actors to inform budgeting, prioritization, and resource allocation decisions to optimize available resources, align investments across donors and domestic financing, and sustain future scale-up and differentiation of service delivery and long-term local ownership, while engaging communities.

For more information, please contact epicproject@fhi360.org and info@jhpiego.org.

This resource is made possible by the generous support of the United States Government. The contents are the responsibility of the EpiC and RISE projects and do not necessarily reflect the views of the United States Government. EpiC is a global cooperative agreement (7200AA19CA00002) led by FHI 360 with core partners Right to Care, Palladium International, and Population Services International (PSI). RISE is a global cooperative agreement (7200AA19CA00003) led by Jhpiego.