

Getting PrEP Rollout Right This Time:

Lessons from the Field



Executive Summary:

Thirteen years after oral PrEP's introduction, global uptake remains slow, with just over 9 million initiations—falling short of UNAIDS' 2025 targets. While HIV infections are declining in some regions, others are experiencing increasing epidemics. Despite challenges, lessons from oral PrEP and CAB rollout have strengthened health systems for scaling up longer-acting (LA) PrEP.

This analysis, conducted across seven countries before the January 2025 US foreign aid freeze, identifies urgent actions to sustain momentum. US foreign aid cuts are severely impairing PrEP delivery, jeopardizing remarkable progress made in the last 20 years. In the wake of this disruption, it is vital that efforts to mobilize and sustain an effective HIV response learn from the past and reach UNAIDS' targets for 2030 by incorporating these insights into future planning.



Regulatory Approval & Normative Guidance

- Most countries require WHO Prequalification to trigger regulatory approval.
- Approval processes face inefficiencies, including delays influenced by policymakers' perspectives.
- Accelerating approvals requires multi-stakeholder collaboration and process refinement.



Planning & Budgeting

- Balancing sustainability with product choice remains a challenge.
- High costs, supply chain delays, and lack of transparency slow product introduction.
- While countries aim for financial independence, initial donor support is crucial, as domestic funds prioritize treatment over prevention.



Stakeholder Engagement

- Inconsistent multi-stakeholder engagement limits progress.
- Greater private sector and youth involvement is needed.
- Communities lack awareness of the product introduction pathway despite being key stakeholders.



Demand Generation

- Civil society organizations (CSOs) play a key role in reducing stigma and tailoring PrEP messaging.
- Supply shortages, limited healthcare provider training, and funding gaps hinder demand generation.



Supply Chain Management

- Existing procurement and M&E systems help but are strained by economic and infrastructure challenges.
- Limited supply may require some populations to be prioritized, risking further stigma.



Health Service Delivery

- Rural areas, youth, and LGBTQI communities face inequities in access.
- Nationally standardized training models, including train-the-trainer and virtual training, are being adopted.
- Human resource and commodity constraints remain, requiring targeted solutions.



Research, Monitoring & Evaluation

- Implementation studies in public health settings support data-driven rollout.
- Many countries are integrating new PrEP indicators into updated M&E systems and Electronic Medical Records (EMRs).

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Implications of US Foreign Aid Freeze on Report Findings

Key Area	Pre-Freeze (Before Jan 2025)	Post-Freeze (After Jan 2025)	Impact
PrEP Service Delivery	Expanding, though inequities existed for key populations & rural communities.	84% of partners reported disruptions; key population (KP) service sites closing.	Widening inequities, increasing HIV incidence, shrinking access to prevention tools.
Product Introduction & Scale-Up	CAB & DVR regulatory approvals and rollout in progress.	US-funded procurement of CAB was paused, with studies serving over 11,000 participants suspended.	Many countries now lack sufficient stock to continue planned scale-up.
Supply Chain & Procurement	Persistent gaps in the supply chain. Delayed product approvals and stockouts affecting access to PrEP.	PEPFAR procurement and usage stopped; supply crisis for CAB and increasing reliance on limited Global Fund and domestic resources.	PrEP stockouts are imminent, disrupting patient continuity and impeding new initiations.
Human Resources for Health	Ongoing provider training and capacity-building efforts to deliver new PrEP services.	Healthcare worker layoffs, with 17% of nurses in Kenya, 20% in Zambia, and 43% in Malawi forced to stop working.	PrEP service delivery undermined by staff shortages, increasing workload burdens and impeding availability.
Demand Generation & Community Engagement	Demand generation & community engagement underfunded, with challenges in stigma reduction and community awareness.	Most community-led HIV prevention efforts—including CSO engagement and demand generation activities—are suspended.	Lower awareness, increased PrEP stigma, and reduced uptake among key populations.
Research, Monitoring & Evaluation (M&E)	Ongoing studies to generate evidence and guide policy and improve PrEP rollout strategies.	Multiple studies suspended, undermining data-driven decision-making and limiting efforts to develop supportive policies.	Countries will struggle to monitor program effectiveness and make evidence-based decisions, and will lack information to justify investments in PrEP scale-up.
Alternative Funding & Private Sector Engagement	Heavy reliance on external funding; governments exploring long-term financial sustainability plans.	Urgent shift towards Global Fund & private sector involvement.	Rapid policy shifts may be required to integrate PrEP financing into national budgets. This will take time and require significant government commitment.

Introduction, Methods and Limitations

Background and Purpose

With the introduction of next-generation PrEP products, including the [Dapivirine Vaginal Ring](#) (DVR), injectable [Cabotegravir](#) (CAB) and [Lenacapavir](#) (LEN), the [Dual Prevention Pill](#) (DPP), and other [Multi-purpose Prevention Technologies](#) (MPTs), it is vital to assess market needs and ensure rollout is swift and equitable. Applying lessons from the rollout of oral PrEP, CAB, and DVR is critical to inform the Product Introduction Pathway for emerging PrEP options and support a more efficient, coordinated, and community-centered approach to delivery.

AVAC undertook a qualitative landscaping analysis to identify actionable lessons and recommendations across seven countries, Brazil, Kenya, Nigeria, South Africa, Vietnam, Zambia, and Zimbabwe, exploring themes of:

1. Successes and challenges with daily oral PrEP introduction and scale-up and what can be done differently for new PrEP products.
2. Public health system readiness for the introduction and scale-up of new PrEP products.
3. Considerations for improving and accelerating PrEP regulatory approval, normative guidance, demand generation, stakeholder engagement, and health systems strengthening.

Methodology and Limitations

Rapid Desk Review

A review of 59 scholarly journal articles, conference meeting reports, consultation summaries, Country Operational Plans (COPs), media resources, and health webpages over a minimum of seven countries (Brazil, Kenya, Nigeria, South Africa, Vietnam, Zambia, and Zimbabwe) assessed current knowledge in PrEP uptake, lessons on LA PrEP products, and implications for LA PrEP in relevant country settings. Interviews with PrEP experts bolstered the research, uncovering further insights and sharpening recommendations for the future of LA PrEP.

Key Informant Interviews








Key informant interviews (KIIs) in Brazil, Kenya, Nigeria, South Africa, Vietnam, Zambia, and Zimbabwe offered country-level context on the introduction and scale-up of oral PrEP and how those lessons can be applied to new PrEP products. A total of 26 KIIs consisted of Ministry of Health (MoH) officials, implementing partners, and civil society leaders. The majority were involved in LA PrEP introduction, including the DVR and CAB. Conducted from November 2024 to early January 2025, the KIIs preceded the US foreign aid freeze. Thematic analysis was applied to qualitative transcripts (Dedoose, version 9.2.014). While findings can only be strictly attributed to the participating countries, ***we observed numerous points of convergence and data saturation suggesting the findings might be applicable in other settings.***

Country Selection Criteria

Availability of data on PrEP and PrEP uptake in-country, according to [AVAC's Global PrEP Tracker \(GPT\)](#), determined which countries were included in the analysis. Parameters included: oral PrEP approval year, CAB and DVR regulatory status, ongoing or planned studies for long-acting PrEP (LA PrEP), reported number of cumulative PrEP initiations as of Q1 2024, and the state of PrEP scale-up in-country (Table 1).

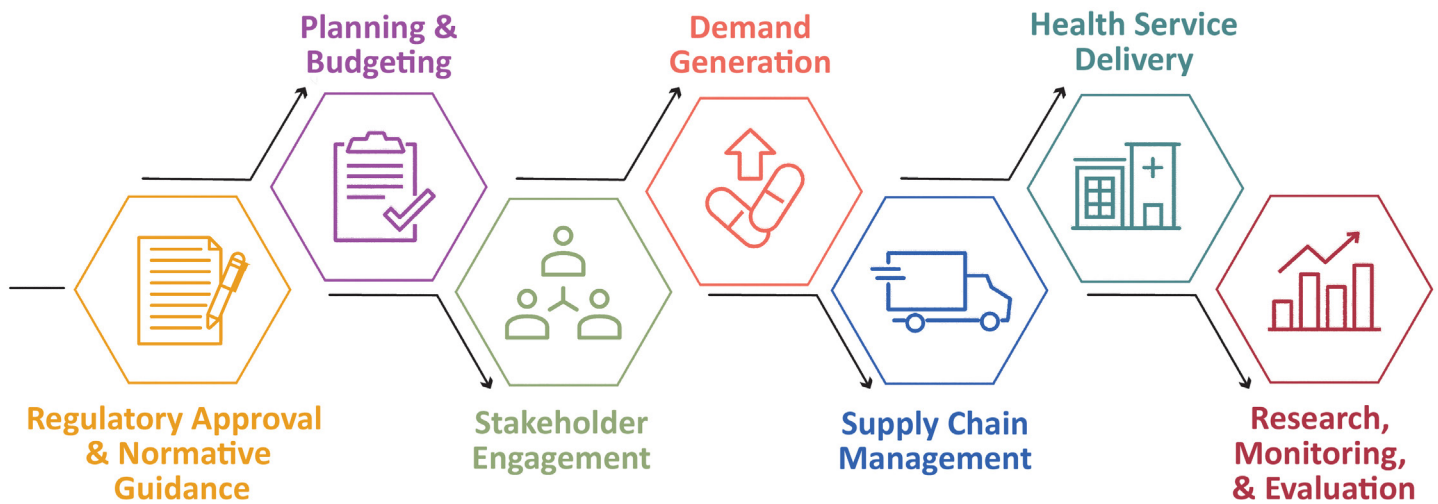
To assess the status of LA PrEP in diverse contexts, countries in Africa, Asia, and Latin America were selected. State of PrEP scale-up in-country was categorized by (1) early scale-up (2019 or earlier) versus recent scale-up (2020 or later) and (2) rapid versus steady growth in PrEP initiations. While approval of CAB and DVR was not required for inclusion, countries had to be planning on introducing at least one LA product and/or submitting them for regulatory review.

Table 1. Country Selection Criteria

Country	Oral PrEP Approval Year	CAB Regulatory Status	DVR Regulatory Status	# of Planned or Ongoing LA PrEP Studies	Cumulative PrEP Initiations as of Q1 2024	Regional PrEP Uptake Ranks as of Q1 2024	Scale-Up Status & Growth Type
Brazil 	2017	Approved	Not Submitted	2	166,563	Highest cumulative PrEP uptake in Latin America & Caribbean	Recent scale-up (2022); Rapid growth
Kenya 	2015	Under Review	Approved	6	481,376	5th highest cumulative PrEP uptake in sub-Saharan Africa	Early scale-up (2017); Steady growth
Nigeria 	2017	Approved	Under Review	N/A	585,349	4th highest cumulative PrEP uptake in sub-Saharan Africa	Recent scale-up (2021); Rapid growth
South Africa 	2015	Approved	Approved	31	1,323,845	Highest cumulative PrEP uptake in sub-Saharan Africa	Early scale-up (2018); Rapid growth
Vietnam 	2015	Under Review	Not Submitted	1	75,748	Highest cumulative PrEP uptake in Asia	Early scale-up (2018); Rapid growth
Zambia 	2017	Approved	Approved	2	697,980	2nd highest cumulative PrEP uptake in sub-Saharan Africa	Recent scale-up (2020); Rapid growth
Zimbabwe 	2017	Approved	Approved	4	293,245	9th highest cumulative PrEP uptake in sub-Saharan Africa	Early scale-up (2019); Steady growth

Analysis

Findings were thematically analyzed and sorted into the six key stages of the Product Introduction Pathway (Figure 1). In addition, findings are analyzed by country, with case studies illustrating challenges, opportunities, and recommendations for PrEP product introduction in each country.



Limitations

We aimed to conduct at least three KIIs with diverse HIV expertise from each country (government official, civil society representative, and PrEP implementer), but this was not possible in every country. In Vietnam, we conducted two KIIs. We were unable to interview policymakers in Vietnam and Brazil. In Nigeria, we were unable to interview a PrEP implementer. All interviews were completed prior to the stop work orders and foreign aid freeze enacted by the new US administration in January 2025. Therefore, the effects of these policies on PrEP services and funding have not been captured.

Findings and Insights

The findings from this analysis offer critical insights into the introduction and scale-up of pre-exposure prophylaxis (PrEP) across seven countries, identifying key challenges and opportunities along the product introduction pathway. Despite significant progress in expanding access to PrEP, countries continue to encounter persistent barriers related to regulatory approval, service delivery, demand generation, stakeholder engagement, and sustainable financing. These findings, categorized under seven key themes—Regulatory Approval and Normative Guidance, Planning and Budgeting, Stakeholder Engagement, Demand Generation, Supply Chain Management, Health Service Delivery, and Research, Monitoring, and Evaluation—highlight the complexity of PrEP implementation and emphasize the need for multi-stakeholder collaboration, targeted capacity-building, and adaptive strategies to ensure equitable access to HIV prevention.



Regulatory Approval and Normative Guidance

Key Insights and Challenges

- **WHO pre-qualification is considered essential when approaching country regulatory bodies.** The WHO typically adapts national guidance by country.
- Most countries **develop national guidelines for new PrEP products** to ensure consistent implementation and inform procurement planning.
- **PrEP technical working groups (TWGs) in countries** are involved in adapting WHO guidance. TWG's typically include MoH, implementing partners, the private sector, and civil society (including populations who may benefit from the product such as young people and KPs). Researchers and other technical partners offer expert presentations and provide answers to questions from TWG members.
- Regulatory approvals would be improved by **better coordination and facilitation**. Inefficiencies slow down regulatory approval, but approvals can be expedited through proactive efforts.
- Product introduction is often tied to policymakers' personal value systems and/or political will. In countries with strong **political will for HIV prevention**, the introduction of new PrEP products is welcomed, while in others, conservative leadership can cause bottlenecks with product introduction, demand generation, and service delivery.

Zimbabwe made history as the first national regulatory agency in the world to approve the DVR, and later became the first African nation to authorize CAB for HIV prevention. Several strategies employed by Pangaea Zimbabwe (Pangaea) contributed to these early approvals:

- **Proactive Regulatory Engagement:** Pangaea alerts the Medical Control Authority of Zimbabwe (MCAZ) about upcoming submissions, allowing for early preparation and faster approvals.
- **Facilitating Evidence-Based Decision-Making:** Pangaea organizes research presentations to help the MoH assess new HIV prevention tools and prepare for large-scale rollout.
- **Collaborative Policy Adaptation:** Pangaea works with policymakers and implementing partners to tailor global guidance for national use.

“Where studies have been conducted in-country, product adoption is easier because stakeholders are already familiar with it. Researchers should engage the Ministry early and disseminate findings throughout the study to ensure government involvement. Unlike oral PrEP, which required extensive demonstration projects due to uncertainties, newer prevention products like CAB and Lenacapavir may not require as many pilot studies since lessons from oral PrEP have streamlined the introduction process.”

— PrEP Implementer, Kenya

Recommendations for New Product Introduction and Scale-Up

- **Early engagement with MoH is crucial.** Creating awareness and knowledge of the product can significantly accelerate a country’s readiness for product introduction while under regulatory review. If a country participated in the clinical trial of a new product, it is beneficial to engage MoH early and share findings to fast-track guidance development. Implementing partners can produce data to support the inclusion of specific populations in national guidelines (such as adolescents or pregnant and lactating people).
- **Global or regional approvals of new products simplify work for local regulators.** For example, Zimbabwe reviewed South Africa’s guidance on oral PrEP and adapted it. Similarly, Kenya did not participate in DVR studies but reviewed global outcomes and approved the DVR on that basis.
- **A global advisory mechanism on product introduction** can be a platform to share experiences and best practices for accelerated regulatory approvals.
- **Regulatory approvals are facilitated and expedited:**
 - When regulatory authorities have **sound knowledge of the new product before receiving the dossier.** Annual meetings with MoH and the regulatory authority post-international science meetings (e.g., IAS conference) could routinely provide a platform to share the latest evidence of new products coming to market soon.
 - When technical partners **alert the regulatory authority to anticipate the dossier.**
 - If **MoH brings the dossier to the regulatory authority** rather than a product developer, who will face a more challenging pathway to prove efficacy, cost-effectiveness, and pricing. Relationship and credibility building between MoH and regulatory authorities are important.
 - If product developers increase responsiveness to queries from the regulatory authority.
 - With a history of participation by the regulatory authority in the clinical trial of the new product.



Planning and Budgeting

Key Insights and Challenges

- **Product effectiveness, cost, and anticipated impact on the health system** are critical factors in country planning for introduction and scale-up.
- **Product price considerations are significant.** Questions around affordability can delay a product from being added to a country's essential medicine list, which in turn delays product introduction and scale-up. Improving transparency in pricing is critical.
- **Countries are grappling with how to balance sustainability with choice in HIV prevention products.** The high cost of new PrEP technologies means that countries are unlikely to consider all new PrEP products for introduction and scale-up. For example, with two LA injectable products coming to market, countries will likely focus on choosing the option that is least burdensome to the client and the health system.
- Delays in the product supply chain add unpredictability, extend timelines, and undermine country readiness to scale-up. In addition, **country uncertainty about the sustainability** of product supplies leads to MoH hesitation in the rollout of a product. For example, countries have no clear plan for purchasing the DVR after donor funding ends, and currently availability is limited to study site communities, raising concerns about future demand and sustainability.
- **Sustainability plans** for HIV prevention by country are influenced by PrEP product costs. Scale-up of new PrEP products is not feasible without initial donor support. Within limited resource settings (low- and middle-income countries, or LMICs), domestic funding prioritizes antiretroviral treatment (ART) programs. While countries experience demand for PrEP, some do not yet budget for it.

Vietnam's Progress Toward Sustainable PrEP Financing

Since introducing PrEP in 2015, Vietnam has made significant strides in expanding access. While initial rollout was supported by PEPFAR and the Global Fund, the long-term sustainability of PrEP financing remains a key focus. To address this, the country is actively developing domestic funding mechanisms, including:

Exploring Co-Pay Models: PrEP is not currently covered under Vietnam's health insurance system. To establish a sustainable payment model, stakeholders have initiated discussions on implementing a co-pay system that balances affordability with long-term financing needs.

Transitioning Payment Models: Currently, 90% of PrEP financing comes from PEPFAR and the Global Fund. Vietnam is working closely with these partners and the MoH to shift to a mixed approach that offers PrEP at a sliding scale based on ability to pay, supported by donors who will offset the cost. This strategy is informed by a comprehensive market analysis that considers sustainability within Vietnam's decentralized provincial health system.

"Even if PEPFAR or the Global Fund were no longer available, the country has sustainability plans in place. Stakeholder engagement is key to ensuring proper documentation, feedback from state-level actors, and leveraging government resources to maintain continuity of services."

—CSO Representative, Nigeria

Recommendations for New Product Introduction and Scale-Up

- **Generate country-specific (real-world setting) evidence** to estimate demand and cost-effectiveness for country government consideration.
- **Budgeting for PrEP introduction** should include costs for awareness campaigns, demand generation, updated M&E systems, preparing the public health system, and extensive training for healthcare providers.
- **Multiple generic manufacturers in multiple geographic regions are needed to improve affordability.** Lengthy technology transfer processes for large-scale production of new products are a concern, while regional manufacturing is also essential to ensure access to PrEP is reliable and consistent. Some advocate for a centralized supply chain to aid in negotiating for better prices, either within a specific country or across a region.
- **Sustainability plans in LMICs** should include:
 - **Taxpayer levies** contributing to the HIV fund (Brazil's HIV program is entirely domestically funded); however, currently countries are using these funds primarily for ART.
 - **National medical schemes** to cover PrEP costs.
 - Exploring **Differentiated Services Delivery (DSD)**, including **private sector** (pharmacy) models with a **PrEP-user co-pay option**. Implementation of DSD will need a **significant initial demand generation investment** to encourage people to invest in their health through HIV prevention products.
 - The Global Fund **PrEP matching funds mechanism**, a catalytic fund designed to incentivize countries to allocate more resources to PrEP in Global Fund priority countries.



Stakeholder Engagement

Key Insights and Challenges

- Given the fast-moving pace of the HIV prevention field, urgent issues are constantly emerging related to product introduction, policies, normative guidance, and more. Some countries have **faced challenges engaging various stakeholders frequently enough** to stay on top of pressing issues.
- **Continuous education and information sessions** on HIV prevention, particularly in clinic settings, have been lacking in some contexts.
- **Youth are usually not engaged** in discussions about HIV prevention and HIV prevention strategy development.
- **Communities are lacking awareness** not only about the benefits and availability of PrEP, but also about the complexities of getting a product from trial to public access. Communities must be partners throughout the entire journey of product introduction, from regulatory approval to M&E.

Brazil's Collaborative Approach to Scaling-Up PrEP

In 2017, Brazil became one of the first countries in Latin America to introduce oral PrEP. Despite challenges—including high costs, conservative societal views, and logistical barriers in a vast country—Brazil's strong civil society networks have played a pivotal role in advancing HIV prevention efforts.

- **Civil Society Leadership:** CSOs play a key role in pushing for HIV prevention innovations and shaping national policies. The MoH has made substantial investments in civil society, recently allocating significant funding to support HIV/AIDS-focused NGOs.
- **Government Support:** The MoH engages early and continuously with CSOs and healthcare providers, funds their participation in global HIV discussions, and ensures they are capacitated to support PrEP rollout.
- **Global Cooperation:** Leveraging its leadership in organizations like Unitaid and UNAIDS, Brazil advocates for simplified health targets and shares best practices globally.

"We are constantly negotiating with civil society on priorities, timing, and feasibility of adopting new innovations. The Ministry of Health includes civil society in all major committees—National Commission of HIV/AIDS, National Committee of Civil Society Organizations, and National Committee of Health Service Providers—ensuring strong participation in public health policymaking. Civil society pushes the government to adopt innovations, but the challenge lies in determining affordability and timing, rather than demand creation."

—PrEP Implementer, Brazil

Recommendations for New Product Introduction and Scale-Up

- **Multi-stakeholder involvement** in regular meetings **should assess progress, share lessons learned or feedback, address challenges, and update implementation and messaging strategies.** Planning and coordination for these meetings should be inclusive and operate at both national and global levels. Stakeholders should include implementing partners, CSOs, government agencies, UN agencies, WHO, etc.
- Sharing lessons or feedback can include **measures of impact, scalability, and sustainability** to improve program implementation.
- Global and national coordination can prevent competitive and siloed implementation, focused on impactful and scalable advocacy and demand generation initiatives. **International actors, such as Unitaid and UNAIDS, should convene platforms** that promote cooperation across all stakeholders.
- **Use educational briefings** to ensure all stakeholders understand the process of adopting a product, including submissions, reviews, policymaking, and guideline adoption and implementation. This includes capacity-building, information-sharing, and transparency among implementing partners, MoH, and civil society.
- **CSOs' involvement is essential.** Early engagement of CSOs can provide stakeholders with unique and essential feedback and ground expectations. Leverage CSO insights and advocacy capabilities in working group meetings and decision-making at every level of the product introduction pathway. When engagement with CSOs is infrequent, urgent issues are identified late and become a barrier to rollout.
- **Actively engage young people and KPs** in discussions about HIV prevention and new PrEP products. Address their specific needs.
- **Early engagement of the private sector** and pharmacies is crucial for new product rollout (i.e. injectable LA PrEP).
- **Stakeholder engagement needs budget allocation.**



Demand Generation

Key Insights and Challenges

- Oral PrEP introduction and scale-up faced **initial low awareness and stigmatizing misconceptions**, limiting adoption. Stigma was fuelled by offering oral PrEP to specific population groups in demonstration projects. In response, countries are **combining CSO engagement and demand generation efforts** to reduce stigma. MoHs now collaborate with implementing partners and stakeholders to understand target populations' preferences for PrEP delivery and messaging.
- Initial **inconsistent support** to nurses and healthcare workers in countries led to inconsistent oral PrEP offerings.
- Resources, like [Journey Mapping](#), are used to **deliver appropriate messages** at different points along PrEP users' decision-making and healthcare engagement journey and **serve as counselling tools**.
- Demand creation is hampered by **inadequate supply** (for example, delays in CAB supply have made implementers reluctant to promote it amongst potential beneficiaries).
- **Insufficient funds, inconsistent demand generation efforts, and out-of-date or misaligned messaging** lead to lower demand for PrEP.
- **Youth, adolescents, and other KPs are vulnerable**, despite having a high PrEP need, due to a lack of knowledge about PrEP.
- Governments tend to not proactively provide **education about PrEP** to the general public, and especially for new PrEP products. National PrEP programs, if they exist, usually do not have a demand generation component.

Enhancing PrEP accessibility and uptake in Zambia

As the first African country to integrate CAB into national programming, Zambia has demonstrated strong political commitment to HIV prevention. While PrEP scale-up has been successful, uptake among vulnerable populations remains a challenge due to stigma, misinformation, and limited demand creation. To address this, Zambia is implementing:

- **Targeted Outreach:** A mix of social media campaigns, peer-led models, and media integration tailored to different populations and locations.
- **Stakeholder-Driven Awareness:** Engaging KPs and adolescents and young people to share information within their networks.
- **The Zambia Ending AIDS Campaign:** A nationwide effort using social media, facility posters, radio, and TV to promote PrEP awareness.
- **Collaborative Demand Generation:** Led by the MoH, civil society, and implementing partners to ensure broad reach.

“We learned earlier on that demand generation is a key component of product introduction. We learned that it’s also not about the person who’s taking that product, but their influences, their partners, their significant others, their parents, their guardians, and whoever they live with in that household—they need to be aware of what’s happening so that products are not stigmatized.”

—PrEP Implementer, Zimbabwe

Recommendations for New Product Introduction and Scale-Up

- **Continuous HIV prevention literacy and awareness sessions** in public health clinics. Demand generation partly occurs through healthcare providers. Therefore, providers need training and support to understand new products and who may benefit from them, based on a human-centered approach to service delivery.
- **National campaigns, including status-neutral (U=U) messaging, led by the government** are perceived as the most successful in creating demand for PrEP, with messages tailored to resonate with local populations. This includes creating Information, Education, and Communication (IEC) materials that appeal to focus populations. Demand generation materials rolled out at the national level and spearheaded by MoH foster trust and buy-in from healthcare workers, who can provide products to clients and support clients to demand products they may need.
- **Community-led initiatives**, including AVAC fellowships, improve messaging and acceptance of PrEP by tailoring demand creation initiatives to local populations and languages.
- **Multiple options for HIV prevention can lead to higher demand** and uptake, similar to the success seen in family planning programs after the increase in product variety.
- **Innovative delivery** is suggested, including digital platforms, peer-led models, and integrating PrEP messaging into popular media.
- Both **integrating PrEP with other services and decentralizing PrEP delivery increase accessibility and demand** in populations that may not be frequenting public health facilities for HIV prevention.



Supply Chain Management

Key Insights and Challenges

Existing Procurement and Distribution Systems are in Place

- Public health systems in multiple countries (e.g., Kenya) are leveraging existing supply chain infrastructure for new PrEP products, ensuring a smoother rollout.
- Countries are updating M&E systems to track supply and demand.
- Site readiness assessments are needed for injectable PrEP (e.g., infrastructure, laboratory systems, and supply chain).

Supply Limitations and Inequitable Distribution

- CAB is in limited supply, leading to prioritization for key and vulnerable populations (e.g., female sex workers, gay, bisexual and other men who have sex with men, adolescent girls and young women), potentially reinforcing stigma.
- Rural areas have fewer access points for PrEP, with urban centers prioritized for new product introduction. This will likely widen disparities in access.

Regulatory Barriers

- Some countries (e.g., Vietnam) require clinics to obtain new facility licenses before administering injectable PrEP, creating bottlenecks in rollout.

Concerns on Stock Stability

- Healthcare providers express concerns about insufficient supplies of new PrEP products, fearing clients may be forced to switch due to stockouts.
- Some countries have adopted measures like adjusting testing algorithms during HIV test stockouts or allowing multi-month PrEP dispensation to ensure continuity of care.

Recommendations for New Product Introduction and Scale-Up

Leverage Existing Supply Chains for Efficiency

- Expand procurement and distribution networks used for oral PrEP to include new PrEP formulations.
- Target facilities already delivering oral PrEP for CAB and subsequent LEN rollout to streamline integration.

Prioritize Equitable Distribution

- Develop a distribution plan that includes rural and underserved areas to prevent widening disparities.
- Expand community-based PrEP distribution (e.g., mobile clinics, private pharmacies).

Enhance Site Readiness Assessments

- Conduct infrastructure and laboratory assessments before rolling out injectable PrEP to ensure facilities meet requirements.

Regulatory Streamlining

- Work with MoHs to pre-emptively address regulatory hurdles.

Stock Stability and Forecasting

- Strengthen supply forecasting to prevent stockouts, ensuring that once clients initiate PrEP, they can maintain continuity.
- Consider multi-month PrEP dispensing (for applicable products) and stock monitoring at a national level.



Health Service Delivery

Key Insights and Challenges

PrEP Counselling and Literacy Are Limited

- Many health facilities do not include PrEP choice counselling, reducing uptake and leading to early discontinuation.
- Low community PrEP literacy also contributes to limited demand.

Integration with Existing Health Services Improves Uptake

- In Brazil, PrEP uptake is higher when integrated into sexual health services, where people already seek care (e.g., STI treatment).
- PrEP counselling should be included in services for STIs and family planning to broaden reach.
- Increasing concern about STIs amongst PrEP users can be addressed with expanded counselling and STI screening.

Innovation in Delivery Improves Access

- Community-based PrEP distribution, virtual clinics, and peer PrEP champions have been effective in increasing access and demand.
- Where approved, HIV self-testing (HIVST) for oral PrEP initiation/continuation is freeing up healthcare providers.

Provider Readiness and Training Are Essential

- Sensitization of providers before product introduction helps ensure enthusiasm and preparedness.
- Train-the-trainer and virtual mentorship (e.g., Zambia's TeleEcho) are some of the models to strengthen provider capacity.
- Available PrEP options have different restrictions, the greatest limitation being where CAB can be delivered.

Increased Workload for Healthcare Providers

- Healthcare providers are concerned about additional workload due to more frequent clinic visits required for CAB compared to oral PrEP.
- Some countries, e.g. Kenya, are considering expanding oral PrEP at the community level to free up clinic capacity for CAB and potentially LEN.

Stigma and Safe Spaces Matter

- LGBTQI individuals and young people continue to lack access to safe, non-stigmatizing service delivery environments.

Lessons from PrEP Pilots

- Piloting new PrEP products in a variety of contexts helps refine delivery strategies.
- Use learnings from CAB rollout to prepare for LEN as an effective staged approach.

Preparing Providers for New PrEP Methods in Nigeria

Nigeria launched oral PrEP in 2020 and achieved rapid scale-up, reaching over **700,000** initiations by **2024**. The **National AIDS, Viral Hepatitis, and STIs Control Programme (NASCP)** now aims to build on this momentum by introducing CAB in 2025, reinforcing its commitment to offering **PrEP choice**. To ensure a smooth rollout, NASCP has taken a **proactive approach to provider readiness**:

- **Early Sensitization of Healthcare Providers:** Providers across Nigeria, including those in states not part of the initial pilot, were sensitized on CAB ahead of time. This **generated enthusiasm** for long-acting methods, as many providers recognized that **pill burden remains a key barrier** to adherence.
- **Readiness Assessments:** Following the sensitization, provider readiness assessments were conducted to evaluate the capacity of healthcare facilities to deliver CAB.
- **Virtual Capacity Building: The ECHO platform**, a virtual community of healthcare providers, is being leveraged to provide continuous education and mentorship on PrEP provision.
- **Diverse Pilots:** CAB is being piloted in **Lagos (South) and Gombe (North) states**, ensuring the product is tested in **varied geographic and social contexts** before broader rollout.

“South Africa focuses so much on the public sector that we miss the private sector. Young people access morning-after pills easily at pharmacies, but for PrEP, they have to wait all day at a government clinic. We are missing an opportunity to provide PrEP at the right moment. Accessing PrEP in government facilities is stigmatized. Young people say nobody gives them PrEP with a smile; instead, they are asked a million questions that demoralize them.”

—CSO Representative, South Africa

Recommendations for New Product Introduction and Scale-Up

Expand and Strengthen PrEP Counselling

- Develop simplified decision-making tools for healthcare providers to support PrEP counselling.
- Integrate PrEP choice messaging into STI and family planning services and counsel and screen for STIs when offering PrEP.

Expand Delivery Models

- Expand differentiated and de-medicalized delivery approaches, including pharmacy-based PrEP access and mobile clinics.
- Increase the use of peer PrEP champions to build demand and improve retention.

Improve Provider Training and Capacity Building

- Offer provider mentorship through virtual training (e.g., ECHO platform in Nigeria, TeleEcho in Zambia).
- Introduce phased training models, starting with providers already experienced in PrEP delivery.

Reduce Provider Workload and Optimize Clinic Flow

- Scale up HIVST for oral PrEP initiation/continuation to reduce provider burden.
- Task-shift oral PrEP and DVR delivery to staff to allow clinical providers to focus on CAB, or LEN in the future.

Ensure Youth- and Key Population-Friendly Services

- Create non-stigmatizing PrEP service environments.
- Empower community members to distribute PrEP, similar to ART models.

Strategic PrEP Pilots for Maximum Impact

- Pilot new products in a range of geographic and social settings.
- Use phased introduction of new products (e.g., Brazil's approach of using CAB to prepare for LEN).



Research, Monitoring, and Evaluation

Key Insights and Challenges

- **Implementation studies must ensure three unique aspects:** 1) Generate evidence for real-world settings, 2) Identify, track, and model costs to inform accelerated timelines in the real world, and 3) Use findings as a springboard to advance PrEP advocacy and literacy efforts at country level.
- Amid limited supply of newer PrEP products, countries follow **data-driven rollout**. This data are diverse and can be derived geographically (e.g., based on big cities and/or HIV incidence data), by population (e.g., focusing on KPs), or impact-driven (e.g., rollout in facilities with current high numbers of PrEP users).
- Most countries are in the process of migrating to electronic health data systems with indicators for new PrEP products already included. Countries review indicators annually and to assess readiness for new product rollout.
- Robust, centralized health data systems support accurate measure of PrEP products and other commodities in the supply chain.
- Key indicators in PrEP introduction and scale-up:
 - PrEP uptake by product, age, and population is currently tracked in countries.
 - PrEP continuation overall and per PrEP method is of high interest to countries with multiple systems and indicators used to understand this outcome. This indicator includes understanding reasons for product switching and discontinuation.
 - Number of people with an HIV positive test result while on PrEP (or recently exposed to new PrEP products) is of interest to countries for tracking potential drug resistance and its impact on HIV treatment programs.

Strengthening PrEP Quantification, Monitoring, and Provider Support

Zimbabwe has established a structured and data-driven approach to PrEP programming, ensuring effective quantification, monitoring, and provider support.

- **Quarterly Quantification for PrEP Scale-Up:** The Ministry of Health and Child Care (MoHCC), in collaboration with the Department of Pharmaceutical Services and implementing partners, conducts a quarterly quantification process. This involves analyzing PrEP usage by demographic groups to inform MoHCC's decision-making on product quantification during scale-up. The process also influences budgeting, policies, supply chain management, and service delivery strategies.
- **Leveraging the PrEP-it Tool:** Zimbabwe adapted this tool to evaluate service delivery costs per person, estimate additional expenses for introducing new products into the health system, and track how individuals initiate and discontinue PrEP use.
- **Annual Indicator Reviews:** The country conducts annual reviews of PrEP indicators to assess their effectiveness in capturing national PrEP uptake and need. These indicators are refined based on lessons learned and emerging insights from major scientific conferences such as IAS and AIDS, ensuring that M&E systems remain relevant and evidence-based.
- **Continuous Coaching and Mentorship:** Ongoing provider support is prioritized to support uptake of new PrEP methods. Supervision follow-ups address provider concerns and build confidence, ensuring high-quality service delivery.

Brazil, on the other hand, has developed robust, centralized data systems to track the distribution and usage of HIV medications, ensuring efficient national monitoring and oversight.

- **Integrated Data Systems for Medication Distribution:** Brazil's logistics system, C-Clone, monitors the nationwide distribution of HIV medications, ensuring streamlined supply chain management.
- **Surveillance of PrEP and HIV Treatment:** The C-Cell system tracks CD4 counts and viral load data, providing critical insights into the national HIV response. All PrEP and HIV medication dispensation in public pharmacies is recorded within these systems, ensuring comprehensive surveillance and realtime data availability.

Recommendations for New Product Introduction and Scale-Up

- **Electronic Surveillance Systems and Electrical Medical Records (EMRs):** Most countries are transitioning from paper based to electronic health surveillance systems with a focus on centralizing data. It is important to digitize all data accurately and fully for a sustainable transition to a digital health system.
- **Manually revise or pre-program indicators** for LA PrEP prior to introduction and/or scale-up in-country.
- **Define what “PrEP Need” is,** how it can be accurately tracked, and how it can be leveraged to enact real-world change

Conclusions

- Most countries are well on their way to addressing the most pressing gaps in their health systems to support an efficient product introduction pathway for new PrEP products.
- Countries continue to plan and discuss financial sustainability.
- Communities continue to be proactively educated about the benefits of PrEP.
- Countries continue to collaborate with CSOs to actively reduce stigma associated with PrEP and package messaging and counselling based on end-user preferences.
- Addressing healthcare provider needs, including comprehensive training, continues to be a top priority for countries.
- Data-driven rollout of PrEP is a key priority for countries, resulting in great support for implementation studies and developing relevant data indicators to update M&E.
- Most countries are capable of leveraging existing product procurement and distribution systems and have either already updated their M&E systems or are proactively migrating to EMRs.

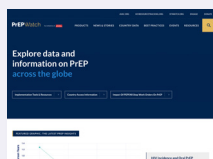
However, issues remain:

- Current regulatory approval processes tend to be mired in inefficiencies and policymakers' personal value systems in most countries, which slow down or halt product availability for end users.
- Countries are grappling with high PrEP costs by endeavouring to balance sustainability with HIV prevention product choice. Lack of transparency from manufacturers, delays in the product supply

chain, and a potential lack of donor support to at least initiate PrEP product scale-up are currently barriers to product introduction.

- While stakeholder engagement is quickly becoming a key priority for countries, engagement with the private sector and youth remains a gap. Budget allocations for the purpose of stakeholder engagement tends to not be prioritized and lack of product introduction knowledge within the community hinders efficient stakeholder feedback.
- Inefficient funds for demand generation, limited provider capacitation on counselling for LA PrEP, and inadequate product supply have led to hesitation in demand generation.
- Unequal societal distribution of PrEP and infrastructure challenges continue to hinder holistic, population-level service delivery. A widening gap in resources could further exacerbate this population inequality and risk reviving PrEP-use stigmatization.
- Existing human resource and commodity constraints continue to challenge healthcare provider capacitation and concerns.
- Countries' current health systems have discerningly incorporated lessons learned from oral PrEP scale-up. Most countries are aware of the strength and weaknesses of their health systems and the majority are also working on addressing the gaps they can control. Successful scale-up of new PrEP products will rely on not only resolving inefficiencies within their health system but also strengthening neighboring and global health systems that impinge on countries' abilities to successfully and safely care for those in need of HIV prevention services.

Additional Resources



[PrEPWatch](#)



[Getting Rollout Right: Lessons Learned from Oral PrEP Programs](#)



[Global PrEP Tracker](#)



[Coalition to Accelerate Access to Long-Acting PrEP](#)



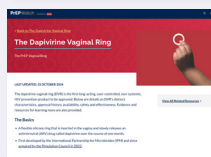
[PEPFAR Stop Work Order Tracker](#)



[Injectable Lenacapavir for PrEP](#)



[Injectable Cabotegravir for PrEP](#)



[Dapivirine Vaginal Ring](#)



[MK-8527](#)



[Dual Prevention Pill](#)

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- Zambia Ministry of Health
- Zimbabwe Ministry of Health and Child Care
- ZIMTTECH

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Country Case Studies PrEP Introduction and Scale-Up

The following pages reflect findings from a country-specific analysis of PrEP introduction and scale-up, offering a detailed examination of successes, challenges, and adaptive strategies across Brazil, Kenya, Nigeria, South Africa, Vietnam, Zambia, and Zimbabwe. While countries demonstrate notable progress in expanding PrEP access, persistent barriers such as regulatory inefficiencies, supply chain disruptions, limited funding for demand generation, and gaps in healthcare provider capacity continue to hinder equitable access. The analysis underscores the importance of context-driven, multi-stakeholder collaboration and strategic planning to achieve sustainable HIV prevention.

Brazil



PrEP Introduction & Scale-Up

Executive Summary: In 2017, Brazil became one of the first countries in Latin America to introduce oral PrEP. High costs, conservative societal views, and logistical difficulties posed challenges to rollout. PrEP implementation was initially concentrated in cities at a few specialized sites for key populations. More than 80% of PrEP users in Brazil are gay men. Transgender women and sex workers have limited access despite also being focus populations. To better reach those in need, in 2023, PrEP began to be offered to anyone who feels at risk based on self-assessment. In 2024, Brazil expanded PrEP into primary healthcare settings. CAB is now being scaled up, starting in large cities, and the health system is preparing for the introduction of LEN.

Key Insights

- **Structural Barriers Hinder Access:** While the public health system provides free access to health care, economic challenges, such as transportation costs, poverty, and fear of stigma hinder access to PrEP services for key populations, especially in the north, a poorer region of the country.
- **Sustainability is a Challenge:** Brazil's PrEP program is fully funded by the national government, and HIV treatment comprises nearly all the HIV program's budget. The MoH relies on licensing and low pricing of PrEP products, and will be selective about which new products to introduce.
- **Strong MoH Partnerships Smooth Introduction:** Regulatory agencies, civil society, and implementers influence national guidelines and rollout plans, making them key collaborators for MoH.
- **New Products Must be Cost-Effective Relative to Other Options:** Because CAB is not recommended for those with silicone implants due to CAB's required intramuscular injection, coupled with no generic manufacturing agreement in place and high cost, MoH is unlikely to invest heavily in CAB.

Key Implications

- **More Efforts are Needed to Reach those Most Vulnerable to HIV:** PrEP users are primarily older, male, and white, but data show HIV incidence is increasing among people who are younger, male, and Black/mixed race. Providing PrEP in community and primary healthcare settings could better reach populations with high need (e.g., adolescents).
- **Replicate Strategies that are Working:** São Paulo has decreased new HIV infections in part by providing a high number of PrEP services, high level of outreach, and differentiated delivery such as vending machines. Settings with higher rates of HIV benefit from innovative strategies such as these.
- **Data Systems are Ready:** Robust surveillance and linkages between the public health system and pharmacies should make it easy to track new products.
- **LEN Introduction is a Priority:** Initial rollout of injectable PrEP will prioritize key populations (GBMSM, transgender women, sex workers) in large cities, and expand to smaller cities and rural areas after. Gilead plans to file for regulatory review of LEN in 2025.

Best Practices & Recommendations – Supply Side

Regulatory & Normative Guidance

- MoH can expedite product approval by submitting a dossier to Anvisa, the national regulatory authority, which they did for oral PrEP. The process is easier for MoH due to its strong relationships and credibility with regulatory agencies compared to the industry, which faces a tougher pathway to prove efficacy, cost-effectiveness, and pricing.
- After initial approval, the dossier goes to the Committee for Incorporation of New Technology (Conitec) for an evaluation of data, evidence, cost, and potential savings.
- Cost-effectiveness of new products is a key factor in approval. MoH decides if there is funding to purchase the product. CAB, for instance, is currently very expensive.

Planning & Budgeting

- Brazil's PrEP program is funded by the government, with no external donors, and PrEP is free for users. The program faces challenges related to the high cost of new drugs.
- Licensing and pricing are key to keeping the PrEP program sustainable. Economic restrictions and funding cuts make it difficult to sustain the current program.
- Brazil needs LEN priced below \$600/year to be cost-effective. Negotiations with Gilead are ongoing. Brazil is also engaged with UNAIDS in a campaign for affordable pricing for oral PrEP (to \$40).
- Plans to implement injectable PrEP begin in 27 state capitals, where most new infections are concentrated.



Research, Monitoring, and Evaluation

- Medicines are only available through the government, ensuring strong surveillance.
- Brazil has robust data systems for monitoring distribution and surveillance, which will be adapted for new technologies like injectable PrEP.
- Brazil uses a model that has shown that three people on PrEP for every new HIV case leads to a decrease in the epidemic.
- Implementation project data can prompt changes to national guidelines (e.g., PrEP15-19 study pushed for adolescent KPs in guidelines) and inform scale-up.

Best Practices & Recommendations – Demand Side

Health Service Delivery

- Training healthcare providers to reach key and vulnerable populations with PrEP is a challenge. Many clinics lack the human resources to offer PrEP due to a focus on HIV care/treatment. Providers are not well-informed about PrEP and there is some resistance to incorporate new methods.
- Clinics serving sex workers and transgender women focus on gender-affirming care and contraceptive services, while STI prevention and PrEP are less of a concern. Offering other SRH services can support PrEP introduction and scale-up.
- Aim to drastically increase PrEP coverage by offering HIVST and PrEP via telehealth, vending machines, and other decentralized and innovative settings.

Demand Generation

- PrEP messaging has not reached target populations effectively. Vulnerable adolescents (a focus population with high PrEP need) often have little knowledge of PrEP. Refine messaging to reach these populations without stigmatizing them.
- PrEP is free in Brazil, but demand creation strategies are limited. Need to include demand creation strategies in national programs.
- Demand creation relies on websites, with little use of other media sources. Some influencers and doctors talk about PrEP on social media. Diversify the media channels and personnel used to create demand.
- For injectable PrEP, engaging communities and primary health care services is crucial to avoid restricting these methods to specific populations.

Stakeholder Engagement

- Strong CSOs play a crucial role in Brazil's HIV response, which has always involved the government and civil society working together.
- The public health system does not traditionally have close partnerships with private companies. Start forging sustainable relationships with the private sector.
- CSOs push the government to adopt new innovations. But how to incorporate and deliver a range of innovations, which are often expensive, is unresolved. Discuss, generate data-driven scenarios, and strategize how to adopt and incorporate these innovations.
- MoH invests in civil society, recently allocating a significant amount of money to finance HIV/AIDS NGOs in Brazil.



PrEP Introduction & Scale-Up

Executive Summary: Kenya approved oral PrEP for HIV prevention in 2017, becoming one of the first African countries to integrate it into its national HIV prevention strategy. This approval followed successful demonstration projects and clinical trials, leading to a scale-up across approximately 2,500 health facilities where PrEP is administered, with over 550,000 initiations to date. However, retention issues, the unavailability of HIV testing kits for initiating clients, and difficulties in reaching vulnerable populations remain a challenge. Additional PrEP technologies, such as CAB and DVR, have since been introduced through implementation science and national programs to expand HIV prevention choices.

Key Insights

- **PrEP Uptake and Barriers:** Initial PrEP uptake has been higher among key populations, with challenges in reaching adolescent girls and young women due to funding priorities and stigma.
- **Collaborative Rollout Success:** Kenya's successful PrEP introduction benefited from collaboration with the MoH, using existing infrastructure and a standardized training approach.
- **Sustainability and Funding:** Kenya is developing a sustainability plan for HIV services, including PrEP, focusing on increasing domestic funding and improving product accessibility.
- **Demand Generation Challenges:** Demand generation for PrEP has been inconsistent, with a reliance on donor funding, and stigma remains a significant barrier to widespread uptake.
- **Regulatory and Stakeholder Engagement:** Active involvement of stakeholders and the MoH during product research and approval supported adoption and scale-up of new HIV prevention methods.

Key Implications

- **Targeted Efforts for Adolescents:** To improve PrEP uptake among adolescents, targeted awareness campaigns and service delivery outside HIV clinics are necessary.
- **Service Delivery Diversification:** Expanding PrEP delivery to more accessible locations like community pharmacies and family planning clinics can help reduce stigma and increase access for various populations.
- **Commodity shortages:** Restricted supplies of HIV testing kits and PrEP products can disrupt PrEP use, emphasizing the need for effective supply chain management, strategic procurement, and robust monitoring systems to ensure consistent access and provider confidence.
- **Comprehensive Training for Providers:** Health providers require ongoing training to support uptake and choice among PrEP methods.
- **Increased M&E and Data Use:** Strengthening M&E systems will be critical for tracking PrEP uptake, continuation, and effectiveness, especially with new product rollouts.

Best Practices & Recommendations – Supply Side

Regulatory & Normative Guidance

- The product developer submits an application to the Pharmacy and Poisons Board (PPB) for review, with approval depending on the developer's responsiveness and the PPB's workload.
- Researchers should engage the Ministry throughout their studies to ensure smooth adoption of new products. Kenya's regulatory process supports engagement. Additionally, involving and supporting communities in advocating for the product can expedite the approval process.
- Research institutions can address remaining questions for product introduction, while development and implementing partners generate evidence for national scale-up, with the TWG at the national level discussing policy issues.



Planning & Budgeting

- Governments must determine practical, feasible options and ensure access for all in need.
- Kenya is developing a sustainability plan for HIV services, including PrEP, by increasing domestic funding to 50% and securing affordable commodities through procurement and manufacturer negotiations.
- Including products in national programming and other real-world settings helps assess actual product use beyond studies, informing discussions on choice, resource allocation, and cost coverage.
- Government policies support the introduction of new products, and the health sector is ready to deliver them using existing systems.

Research, Monitoring, and Evaluation

- Data collection and reporting systems are in place, with efforts to adopt or update EMRs, define an indicator for PrEP need, and revise M&E tools to include DVR and CAB.
- Implementation science studies may precede national scale-up, focusing on ease of use, acceptability, and potential side effects within the population.
- Data is collected by population, age, and product, including switching data, while seroconversions on PrEP are monitored to track HIV drug resistance.
- Monitoring is done to ensure clients receive high-quality services and help identify service delivery issues.

Best Practices & Recommendations – Demand Side

Health Service Delivery

- About 2,500 facilities offer oral PrEP with trained staff and M&E tools, but capacity building is needed to help providers adapt to new methods and counsel effectively.
- Efforts are underway to make PrEP more accessible outside health facilities, including through peers, family planning centers, outpatient facilities, pharmacies, and community spaces, with a focus on reaching younger populations and reducing facility traffic.
- Providers are concerned about having sufficient commodities and avoiding stockouts of new products.

Demand Generation

- Demand generation begins after product procurement, provider training, and system readiness, with efforts like mass and print media planned to avoid overwhelming demand before availability.
- A dedicated subcommittee developed materials for oral PrEP, monitored progress, and led awareness efforts, with the national launch generating excitement.

Stakeholder Engagement

- Kenya's TWG actively involves stakeholders, including civil society, community organizations, private sector workers, and regulators, in scaling up new products. They participate in discussions on products, guidelines, and policies, their inputs contribute to inclusive and effective decision-making from inception to monitoring.
- There is a need for broad stakeholder engagement, including policymakers, to ensure they understand the transition to injectable PrEP/ARVs.



PrEP Introduction & Scale-Up

Executive Summary: Nigeria launched oral PrEP in 2020 and scaled up quickly, reaching over 700,000 initiations by 2024. Though PrEP was rolled out to all populations, uptake so far has been mostly limited to key populations. This rapid scale-up has been attributed to careful planning and constant engagement with a variety of internal and external stakeholders. The National AIDS, Viral Hepatitis, and STIs Control Programme (NASCP) hopes to build on the success of PrEP to date by introducing injectable cabotegravir (CAB) for PrEP in 2025.

Key Insights

- **Nigeria is a Large and Culturally Diverse Country:** Regions have different cultural and religious norms, and this impacts the level of stigma associated with KPs and HIV more generally.
- **Awareness of PrEP Varies with Risk Perception:** There is high PrEP awareness amongst KPs, but lower awareness amongst sero-different couples and the general population, who may not feel they are at risk.
- **Oral PrEP is Popular, but Comes with Challenges:** Users struggle with pill burden and side effects which can lead to discontinuation.
- **Users are Price Sensitive:** Free services have higher uptake.
- **Stakeholders Need to be Brought Along for the Journey:** NASCP credits the success of early PrEP rollout to good collaboration with stakeholders, including all levels of government and the national regulator, KP groups, and local influencers such as traditional leaders.
- **WHO is a Trusted Source of Information:** Decisions on new product introduction and M&E indicators are influenced by WHO recommendations.

Key Implications

- **Pilot New Interventions in a Variety of Contexts:** CAB for PrEP is being introduced in one northern and one southern state to understand context-specific best practices.
- **Adapt Materials for the Audience:** Demand generation and IEC materials need to be adapted for local context and for different populations who may have different levels of risk perception.
- **Choice has the Potential to Improve Uptake:** Providers are excited about the prospect of CAB, for its potential to overcome challenges such as pill burden and unintended PrEP disclosure via the pill bottle.
- **Sustainability Should Be Considered from the Start:** Though some new products may be introduced free of charge, users are told they will need to pay in the future to manage their expectations.
- **Engage Stakeholders Regularly:** Quarterly PrEP subcommittee meetings ensure continued buy-in from stakeholders at all levels.
- **Leverage WHO Expertise:** WHO tools and recommendations can provide a starting point for decision-making.

Best Practices & Recommendations – Supply Side

Regulatory & Normative Guidance

- To help move PrEP products through the approvals process, NASCP works closely with the national regulatory authority, the National Agency for Food and Drug Administration and Control (NAFDAC), including paying some inspection costs.
- The ECHO platform, a virtual community of healthcare providers offering continuing education and mentorship, is being used to build provider capacity in PrEP provision.

Planning & Budgeting



- The federal government's sustainability plans include informing clients that subsidized PrEP will later cost money.
- Selecting which products to scale-up is based on WHO recommendation, effectiveness, and funding, and less so on user demand.
- CAB pilots are planned for Gombe and Lagos states in early 2025, and the government plans to assess readiness of providers and communities in other states to roll out later in the year.

Best Practices & Recommendations – Demand Side

Health Service Delivery

- Acceptance of oral PrEP is very high, though users are price-sensitive and free services have significantly higher uptake.
- Providers were successfully sensitized on CAB in advance, even in states that were not part of the pilot, and then assessed on readiness to deliver PrEP.
- Providers believe CAB can help users overcome both pill burden and stigma associated with having a pill container.
- NASCP is looking forward to offering PrEP choice, including both CAB and LEN.

Demand Generation

- Demand generation materials, including IEC materials and provider job aids, are designed and targeted for specific KP groups.
- Demand generation is seen as an integral part of new product introduction, materials for CAB were developed even before the pilot was due to start.
- In addition to users, the wider community is sensitized, including traditional leaders.
- Channels for messaging include social media and speeches at diverse institutions.

Stakeholder Engagement

- Though states have their own health commissioners, there is “one health system” with the national government leading the process of PrEP rollout and bringing all relevant stakeholders on board.
- Engagement with both the state and local government authority (LGA) has been key, and built on relationships established to roll out PMTCT.
- PrEP subcommittees meet quarterly; these include UN agencies, WHO, government agencies, NAFDAC, NACA, NASCP, and KP groups including sex workers, people who use drugs, and trans populations.



PrEP Introduction & Scale-Up

Executive Summary: Since beginning PrEP rollout in 2016, South Africa has made significant progress in expanding PrEP access by integrating it into national guidelines and public healthcare facilities. However, barriers such as stigma, segmentation of programming for KPs, financial constraints, and regulatory delays have hindered widespread uptake. The country's ability to influence global pricing and access to HIV prevention products can inform strategic planning for sustainable funding beyond donor support. Continued efforts to enhance demand generation, streamline service delivery, and strengthen stakeholder engagement are essential for ensuring equitable access. Moving forward, a focus on affordability, decentralized distribution, and youth-friendly services will be key to scaling up PrEP effectively.

Key Insights

- **Stigma and Segmentation Hinder Uptake:** Efforts to reach key and vulnerable populations, including young people and sex workers, are limited by stigma and the way HIV prevention services are structured.
- **Financial Constraints Threaten Sustainability:** Donor funding plays a critical role in HIV prevention, but long-term sustainability is uncertain due to budget cuts and lack of domestic funding plans.
- **Pricing Delays New Products:** The cost of new HIV prevention products, including injectables and DVR, has slowed their adoption, requiring strong negotiation strategies and a focus on affordability.
- **Community Engagement is Crucial for Demand Generation:** A lack of national campaigns and public education on PrEP has led to poor awareness and uptake, highlighting the need for grassroots and mass media initiatives.
- **Health System Readiness and Integration Gaps Exist:** Overcrowded facilities, long wait times, and inadequate healthcare provider training create barriers to efficient PrEP delivery and uptake.

Key Implications

- **Policy and Funding Diversification is Needed:** A shift toward domestic funding sources and pooled donor contributions will be essential for long-term sustainability.
- **Service Delivery Must Be Expanded and Decentralized:** Integrating PrEP into youth-friendly spaces, community-based services, and primary healthcare will increase access and uptake.
- **Regulatory Processes Must Be Streamlined:** Faster approval mechanisms and price negotiations for new prevention products will be critical for timely access and affordability.
- **National-Level Demand Creation Strategies Are Urgent:** Broad public education and media campaigns should be implemented to increase HIV prevention literacy and normalize PrEP use.
- **Stronger Stakeholder Coordination is Essential:** Government, civil society, and donors must align efforts to avoid program duplication and ensure an efficient, well-resourced HIV prevention strategy.

Best Practices & Recommendations – Supply Side

Regulatory & Normative Guidance

- Prepare for a successful regulatory approvals process by engaging policymakers, regulators, and communities early in clinical trials, ensuring a shared understanding of timelines, evidence needs, cost considerations and affordability, and regulatory pathways.
- Ensuring updated, inclusive guidelines that reflect user choice to allow for broad access beyond KP groups can also reduce stigma.
- A national platform with a multi-level governance structure, like the South African National AIDS Council (SANAC), can support effective policy alignment across government, civil society, and the private sector.

Planning & Budgeting

- An over-reliance on donor funding undermines sustainability, limiting long-term access to HIV prevention products. Diversifying funding and budgeting domestic funds for HIV prevention services is needed.
- High costs hinder the introduction and scale-up of new prevention methods like injectables and the vaginal ring. A centralized supply chain, regional manufacturing, and pooled resources can reduce costs and improve access.
- Facilities with high PrEP uptake should be prioritized for injectables.
- A sustainability framework is needed, with better collaboration among donors, government, and private sectors.
- National guidelines for new HIV prevention products are in place, with PrEP included in essential medicine lists.



Research, Monitoring, and Evaluation

- Need to track the uptake of PrEP as well as differentiate based on the type of PrEP product (oral, DVR, CAB).

Best Practices & Recommendations – Demand Side

Health Service Delivery

- PrEP access should be non-stigmatizing and include youth-friendly zones.
- Empower young people to distribute PrEP, similar to ARV peer distribution.
- Facilities need better trained providers, reduced wait times, and community-based PrEP distribution.
- Primary healthcare centers face staffing challenges, and community-based organizations should be leveraged to improve HIV prevention access.

Demand Generation

- Community education is key to improving HIV prevention literacy, reducing PrEP stigma, and increasing demand.
- Ongoing HIV prevention education in clinics is necessary.
- A national strategy, with broad public messaging, is needed to boost awareness of PrEP, and other biomedical prevention, and support adherence.
- HIV prevention should align with treatment efforts, including U=U messaging. Integration of services for HIV and SRH is key.

Stakeholder Engagement

- Continuous HIV prevention education is needed, especially in clinics and underserved regions.
- Young people should be involved in discussions and strategy development for HIV prevention.
- Strong advocacy through local organizations and the South African AIDS Council is crucial for government buy-in and product adoption.
- Involve regulators, policymakers, and communities early in the trial process to build relationships and prepare for success.



PrEP Introduction & Scale-Up

Executive Summary: Vietnam has made significant strides in scaling up PrEP since its introduction in 2015, with strong community support and government commitment leading to the development of national guidelines and strategies. Key population organizations played a crucial role in service delivery, and innovative approaches like tele-PrEP and mobile services improved access. However, the limited availability of PrEP outside PEPFAR-supported provinces, concerns about sustainable funding, and regulatory hurdles for new products like injectable PrEP remain a challenge. Efforts are ongoing to integrate PrEP into the broader healthcare system, secure domestic funding, and streamline the regulatory process to ensure long-term access and success.

Key Insights

- **Successful Scale-Up with Community Involvement:** Vietnam's PrEP expansion was driven by strong community support, national strategy development, and international collaboration, making it the highest-enrolling PrEP program in the Asia-Pacific region.
- **Funding and Sustainability Challenges:** While initial PrEP rollout was supported by PEPFAR and the Global Fund, long-term sustainability remains uncertain, requiring a shift towards domestic funding and co-payment models.
- **Regulatory and Infrastructure Barriers:** The introduction of new PrEP products, especially injectables, faces delays due to complex regulatory approval processes, gaps in infrastructure and healthcare provider readiness.
- **Innovative Service Delivery Models:** Mobile PrEP, tele-PrEP, and community-led clinics have improved access, particularly for MSM and transgender populations, but expansion beyond PEPFAR-funded provinces is still limited.
- **Data-Driven Decision-Making:** Vietnam has established a centralized data management system for tracking PrEP enrollment and continuation, providing valuable insights for monitoring, evaluation, and future HIV prevention strategies.

Key Implications

- **Sustainability Planning is Urgent:** Vietnam must develop domestic funding mechanisms to sustain PrEP services and reduce over-reliance on PEPFAR and Global Fund support.
- **Regulatory Reform is Needed for New Products:** Streamlining the approval process for long-acting PrEP options will be critical to expanding HIV prevention efforts.
- **Expanding Access Beyond Key Populations:** While initial efforts focused on MSM and transgender communities, scaling up PrEP to a broader population will require additional investment, infrastructure, and demand-generation campaigns.
- **Strengthening Healthcare Provider Engagement:** More comprehensive training, ongoing mentorship, and addressing provider hesitations about PrEP (including concerns about side effects) are needed.
- **Enhanced Integration with STI and Primary Care Services:** To maximize effectiveness, PrEP programs should be linked with STI screening and other sexual health services in both public and private healthcare settings.

Best Practices & Recommendations – Supply Side

Regulatory & Normative Guidance

- PrEP introduction in Vietnam involves multiple agencies, including the MoH, the Vietnam Administration of HIV/AIDS Control (VAAC), and the Drug Administration of Vietnam (DAV).
- In-country trials are no longer required for products that have been approved by the Australian national regulator, but there has been regulatory gridlock following the Covid-19 pandemic.

Planning & Budgeting

- PrEP is not included in Vietnam's health insurance, prompting discussions on co-payment models. Additionally, cuts in PEPFAR and Global Fund support highlight the need for domestic PrEP funding. Currently, around 90% of PrEP funding comes from donors, with efforts to balance free, subsidized, and commercial PrEP.
- Vietnam's decentralized funding system (63 provinces) complicates local funding efforts, while the commercial sector aims to lower oral PrEP costs through volume guarantees.



Research, Monitoring, and Evaluation

- All PrEP data in Vietnam is managed by the government, including PEPFAR and Global Fund data.
- PrEP sites must report data through a unified software system, analyzed by VAAC's Monitoring & Evaluation team.
- Data is not reported separately to donors but can be requested from the government for program use.
- The existing data management system is prepared for the introduction of injectable PrEP.

Best Practices & Recommendations – Demand Side

Health Service Delivery

- Facilities must meet strict certification, licensing, and registration requirements, without limiting access to public and general clinics.

Demand Generation

- Past efforts primarily targeted MSM, shaping messaging and outreach strategies. However, campaigns have expanded to transgender communities as well.
- KP organizations drive demand generation using TikTok, small-scale events, and personal testimonials.
- Outreach to transgender women is important to address the frequent concerns about oral PrEP's interaction with feminizing hormones.
- Technical assistance is provided in non-PEPFAR provinces for support on demand creation.

Stakeholder Engagement

- Consultations organized by VAAC with community leaders occur about once a year. It would be helpful to increase their frequency to address urgent issues promptly.
- VAAC collects feedback for programming, which provides a channel between the government and communities.
- There are mechanisms through PEPFAR programs or the Global Fund where community members can raise concerns.



PrEP Introduction & Scale-Up

Executive Summary: Zambia was the first country in Africa to introduce CAB as part of national programming, demonstrating strong political will and commitment to HIV prevention. The country has seen high PrEP initiation and scale-up, driven by effective stakeholder collaborations. However, increasing PrEP uptake among vulnerable populations, misinformation, stigma, discrimination, and inadequate demand creation efforts continue to hinder access. To ensure long-term availability of PrEP, Zambia is developing a sustainability roadmap to strengthen PrEP provision and access

Key Insights

- **Zambia's Successful PrEP Program:** Zambia has a strong PrEP program supported by political commitment and various stakeholders, including CSOs and PEPFAR.
- **Collaborative Effort for New Product Rollout:** The introduction of new PrEP products has been a collaborative effort, with effective coordination among MoH, implementing partners, and CSOs.
- **Awareness and Stakeholder Engagement:** Partners, especially CSOs, play a key role in collaborating with the MoH and the community to raise awareness and promote oral PrEP and other new products.
- **Regulatory and Normative Framework:** Zambia is developing guidelines to include new prevention tools like the DVR and DPP. WHO pre-qualification is key to the process.
- **Sustainability and Cost Considerations:** Zambia prioritizes sustainability and cost-effectiveness in introducing new products. Government is focused on offering prevention options, especially for vulnerable populations, while integrating new products into existing healthcare systems with careful planning and community involvement.

Key Implications

- **Early MoH Involvement:** Early MoH ownership and engagement would have accelerated effective PrEP scale-up in Zambia.
- **Access through Product Choice:** Zambia is prioritizing providing a range of HIV prevention options to ensure access for diverse populations, catering to the lifestyles and needs of end users.
- **Demand Generation:** Significant investment in demand generation is necessary to maximize uptake among those who need prevention, especially in the face of limited funding.
- **Capacity Building for Health Workers:** Continuous capacity building and training for healthcare providers is critical to effectively deliver new HIV prevention products and reduce stigma.
- **Infrastructure Challenges:** Improved infrastructure and supply chain management are needed to ensure the readiness of health facilities and prevent disruptions in service delivery.
- **Decentralization and Demedicalization of PrEP:** Expanding access through decentralized and demedicalized services to communities will improve PrEP coverage, especially in underserved areas.

Best Practices & Recommendations – Supply Side

Regulatory & Normative Guidance

- New products are often piloted in a few facilities to gather data and learn lessons before scaling up.
- Absence of a structured framework for product introduction makes the process reliant on individual policymakers, risking delays. Developing a framework with cross-stakeholder engagement and agreement can expedite the process.
- Strong political will, supported by civil society advocacy and scientific data, helps drive acceptance of new products.
- TWG consultations and strong collaboration among stakeholders helps develop guidelines, review data, and address challenges.

Planning & Budgeting



- The government is prioritizing sustainability by creating a roadmap and reducing reliance on donor support by 2030.
- MoH conducts value chain analyses to evaluate the feasibility and acceptance of new HIV prevention products, by engaging both recipients and healthcare workers.
- Zambia evaluates the cost-effectiveness of new HIV prevention tools, prioritizing those that reduce HIV incidence while offering choice to the target population.
- Products like CAB are resource-intensive due to additional screening costs. Implementers ensure adequate resources and capacity.

Research, Monitoring, and Evaluation

- HIV data in Zambia is collected through health management information systems (HMIS), DHIS2, and national surveys like ZDHS.
- MoH oversees data reporting, from sub-national to national level with support from implementing partners and CSOs.
- MoH to lead coordination efforts with implementing partners to promote collaboration and sharing of lessons learned for scaling up initiatives.
- Priority indicators for monitoring new PrEP products include initiation rates, persistence, reasons for discontinuation, and adverse events, with a focus on understanding impact and improving service delivery.

Best Practices & Recommendations – Demand Side

Health Service Delivery

- Poor site readiness, supply chain issues/inadequate commodities, human resources, and infrastructure issues must be addressed to boost service delivery.
- Government is considering demedicalizing PrEP and using community distribution models.
- MoH, with partners, utilize training and mentorship to equip and sensitize health workers for providing HIV services to KPs, and to reduce stigma and discrimination. One mentorship program, The TeleEcho program, is a platform for sharing experiences and best practices.

Demand Generation

- A mixed approach based on populations and geolocation uses tailored messages delivered through social media campaigns, peer-led models, and other media to reach diverse target populations.
- The Zambia Ending AIDS campaign promotes HIV literacy across prevention and treatment, using social media, posters in facilities, radio programs nationwide, and TV shows featuring PrEP messages.
- Demand generation is carried out by all key stakeholders, including the MoH, implementing partners, and CSOs.

Stakeholder Engagement

- Healthcare workers, CSOs, and communities are informed early about new products to manage expectations and gather feedback.
- MoH acknowledges the role and importance of CSOs and actively involves them in decision-making processes.
- Community engagement and capacity building for healthcare providers and CSOs are key for the successful implementation and acceptance of PrEP programs.



PrEP Introduction & Scale-Up

Executive Summary: Zimbabwe began PrEP dissemination in 2017 and has risen to become one of the top 10 PrEP-providing countries in sub-Saharan Africa. With strong models for PrEP provision models and general support, the country has been proactive addressing gaps in oral PrEP delivery and preparing the country for introducing long-acting PrEP products. The country has committed to improving awareness, destigmatization, and service delivery. Zimbabwe needs to continue on this path, address sustainability issues and supply chain barriers, and balance treatment and prevention priorities.

Key Insights

- **Stigma is Common:** The community is very sensitive to cultural implications associated with PrEP. Broad acceptance of PrEP will require more work to destigmatize HIV prevention and PrEP.
- **PrEP Awareness and Capacitation Need to be Bolstered:** While awareness around PrEP has increased, pockets of the community remain misinformed or unaware. Many healthcare providers are providing PrEP care, but additional training and support is needed to overcome provider hesitation and overburdened staff.
- **TWGs are Vital:** Consisting of diverse stakeholders, including implementing partners, funding partners, civil society, end users, and academics/researchers, findings from TWGs led to improved access to oral PrEP.
- **MoH-Implementing Partner Collaborations are Priority:** The MoH worked with Pangaea Zimbabwe whose research and stakeholder analyses on end user needs, messaging, best service delivery methods, and demand generation, especially as it relates to youth, informed key decisions.

Key Implications

- **Informed Decision Making Requires Support:** Funding for IEC materials and demand generation is necessary as these will support informed decision-making.
- **Sustainable Security of Supply Chains are Needed:** Sustainability is hindered by supply chain uncertainty. For example, women are protected on DVR longer than on oral PrEP. But supply uncertainty and lack of dedicated procurement funds prevent investment in DVR for the population. Assess methods to sustainably ensure supply chain for uninterrupted scale up as donated product supplies, while vital, do not cover PrEP scale up needs.
- **Budgets and PrEP Choice are Conflicting:** While the value of PrEP choice is evident and preferred, many low resource settings do not have the funding to employ it. To prioritize choice requires teamwork, leadership, and shared objectives.
- **HIV Treatment Versus Prevention:** Similarly, limited funding from donors also means treatment will be prioritized over prevention. Budget planning for sustainable prevention is vital.
- **Stigma Differentially Restricts Access to Services:** Rural areas and certain KPs face greater stigma and/or access barriers to PrEP services. Privatization and innovative service delivery channels can help bridge this gap.

Best Practices & Recommendations – Supply Side

Regulatory & Normative Guidance

- Generally, WHO guidance is followed. Additionally, Zimbabwe reviews already developed guidance from other countries and adapts them to fit the Zimbabwe context. This is great collaboration and strengthens regional health systems.
- Normative guidance procedures are triggered when a product developer submits a dossier to the Medical Control Authority of Zimbabwe (MCAZ). If Pangaea Zimbabwe is aware of this submission, they will engage MCAZ early, which shortens review time.
- Guidance development is primarily led by the Ministry of Health and Child Care (MoHCC), but this process requires active involvement and feedback directly from researchers, PrEP implementers, in-country WHO personnel, and policy advocates.

Planning & Budgeting

- Implementation science projects support the MoHCC to gather funding for a possible national program. Zimbabwe is working on sustainability plans to match donations, add DSD, and provide PrEP through the private sector.



Research, Monitoring, and Evaluation

- Implementation science studies prioritize understanding community questions/gaps in research prior to the start of the studies. Studies are structured to address questions and gaps to improve rollout.
- Implementation studies for newer technologies test cost scenarios while the product and delivery models are under development. This informs country decision-making and improves timelines.

Best Practices & Recommendations – Demand Side

Health Service Delivery

- Rural areas and LGBTQI populations have less access to facilities providing PrEP or trained healthcare providers, especially in non-stigmatizing contexts. Alternatively, many populations turn to private pharmacies for access.
- Inadequate counselling messages by healthcare providers and low PrEP literacy in the community have led to low uptake and high discontinuation rates. For example, those presenting with an STI, a high-priority group for intervention, are not always offered PrEP. Integration of SRH services is needed.

Demand Generation

- MoHCC is actively involved in demand generation and ensures materials produced under projects, like OPTIONS or CATALYST, are part of a national campaign to encourage demand.
- The majority of demand generation resources are for the general population, disseminated nationally, and embedded in messages of combination prevention. Additional resources are produced for KPs. This two-pronged approach reduces stigma and provides tailored messages for KPs.
- Zimbabwe used human-centered design to produce a National Communications Strategy that considers both HIV treatment and prevention.
- Zimbabwe has successfully used Journey Mapping, PrEP Champions, status neutral messages about HIV, and the knowledge that PrEP uptake is not only about the client but also the people that influence them, to strategically increase demand.

Stakeholder Engagement

- Zimbabwe has worked with stakeholders to research several questions, beyond clinical trials, associated with PrEP introduction and scale-up. This includes questions about who is best suited to administer PrEP and how.
- District, provincial and/or national meetings allow stakeholders to engage with each other, learn about the state of the field, innovate new collaborations, and share feedback.
- Civil society and community-based organizations raise awareness and provide services in communities.

