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2025 HIV MARKET REPORT

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The state of HIV treatment, testing, and prevention in low- and middle-income countries

Gates Foundation

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Foreign, Commonwealth & Development Office

DISCLAIMER

The data sources primarily used for analysis in the report include Clinton Health Access Initiative (CHAI) country teams, Ministry of Health counterparts, stakeholder resources and conversations (e.g. Global Fund, PEPFAR, UNAIDS, Unitaid, WHO, and civil society partners), and published research. CHAI has taken precautions to verify the information shared in the report. However, the analysis in the report is not exhaustive, and the responsibility for the interpretation and use of the material lies with the reader. The mention of specific companies or products does not imply CHAI's endorsement or recommendation.

ACKNOWLEDGMENT

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Cover images, clockwise from the top: A lab technician at a clinic in Nigeria; a child attends a clinic in Tanzania; a healthcare worker takes stock at a hospital in Lao PDR

HIV Market Report
CONTENTS

ACRONYMS

3HP	Three months of weekly rifapentine and isoniazid
3TC	Lamivudine
5FC	Flucytosine
ABC	Abacavir
AGYW	Adolescent girls and young women
AHD	Advanced HIV disease
AIDS	Acquired immunodeficiency syndrome
ANC	Antenatal care
API	Active pharmaceutical ingredient
APWG	ARV Procurement Working Group
ART	Antiretroviral therapy
ARV	Antiretroviral
ATV/r	Atazanavir/ritonavir
AZT	Zidovudine
BIC	Bictegravir
bNAb	Broadly neutralizing antibodies
CAB	Cabotegravir
CAB-LA	Long-acting cabotegravir
CAB-ULA	Ultra-long-acting cabotegravir
CATS	Community Adolescent Treatment Supporters
CHAI	Clinton Health Access Initiative
CIFF	Children's Investment Fund Foundation
CLHIV	All children living with HIV
CM	Cryptococcal meningitis
COP	Country Operational Plan
CrAg	Cryptococcal antigen
CROI	Conference on Retroviruses and Opportunistic Infections
CRP	Collaborative registration procedure
CSF	Cerebrospinal fluid
DALY	Disability-adjusted life years
DBS	Dried blood spot
DOR	Doravirine
DRV/r	Darunavir/ritonavir
DSD	Differentiated service delivery
DTG	Dolutegravir
EFV	Efavirenz
EID	Early infant diagnosis
EXW	Ex-Works
FDC	Fixed-dose combination
FTC	Emtricitabine
GA	Generic-accessible
GC7	Global Fund Grant Cycle 7
GC8	Global Fund Grant Cycle 8
GHSC-PSM	Global Health Supply Chain Program - Procurement and Supply Management
HBV	Hepatitis B virus
HCW	Healthcare worker
HIV	Human immunodeficiency virus
HIVST	HIV self-testing
HPV	Human papillomavirus
HTAP	Health Technology Access Program
INH	Isoniazid
INSTI	Integrase strand transfer inhibitor
ISL	Islatravir
KP	Key population
L-AmB	Liposomal amphotericin B
LAT	Long-acting treatment
LEN	Lenacapavir
LFA	Lateral flow assay
LMIC	Low- and middle-income country

LPV/r	Lopinavir/ritonavir
LTFU	Loss to follow-up
MADE	Manufacturing to Accelerate Diagnostic Excellence
MedSuRe	Medicines Supply Resilience
MMD	Multi-month dosing
MoH	Ministry of Health
MoU	Memorandum of understanding
MTCT	Mother-to-child-transmission
NDSRI	Nitrosamine drug substance-related impurity
NNRTI	Non-nucleoside reverse transcriptase inhibitor
NRTI	Nucleoside reverse transcriptase inhibitor
NRTTI	Nucleoside reverse transcriptase translocation inhibitor
NVP	Nevirapine
OI	Opportunistic infections
pALD	Pediatric ABC/3TC/DTG
pDRV/r	Pediatric darunavir/ritonavir
pDTG	Pediatric dolutegravir
PEPFAR	US President's Emergency Plan for AIDS Relief
PI	Protease inhibitor
PLHIV	People living with HIV
PMTCT	Prevention of mother-to-child transmission
POC	Point-of-care
PPC	Prepaid-in-charge
PQ	Prequalification
PrEP	Pre-exposure prophylaxis
pTAF	Pediatric tenofovir alafenamide fumarate
RDT	Rapid diagnostic test
RMEA	Regional Manufacturing for Equitable Access
RPT	Rifapentine
RPV	Rilpivirine
SAHPRA	South African Health Products Regulatory Authority
SWO	Stop work order
QALY	Quality-adjusted life years
TAF	Tenofovir alafenamide fumarate
TB	Tuberculosis
TDF	Tenofovir disoproxil fumarate
THRIVE	Transforming Advanced HIV Disease CaRe in LMICs through ComprehensiVe and Equitable Access
TLD	TDF/3TC/DTG
TPT	Tuberculosis preventive therapy
UNAIDS	Joint United Nations Programme on HIV/AIDS
US FDA	US Food and Drug Administration
USG	United States Government
USP	US Pharmacopoeia
VL	Viral load
WHO	World Health Organization
Wits RHI	University of the Witwatersrand Reproductive Health and HIV Institute
ZAMRA	Zambia Medicines Regulatory Authority (ZAMRA)

Introduction

The 16th edition of CHAI's annual HIV Market Report expands this year to include a focus on the ongoing impact of the foreign aid cuts, building on the two Market Impact Memos released earlier this year. This report analyzes trends in HIV prevention and treatment (see Box 1).

New data from 14 CHAI-supported countries show that after major drops in access in Q1, recovery is limited and uneven, and warning signs abound despite some rebound in service delivery.

A healthcare worker in Nigeria provides pediatric HIV medication and counseling

Across the HIV treatment and prevention cascades, more people living with and at risk of HIV in the first half of 2025 are:

UNTESTED

3.4 MILLION
fewer adults tested for HIV

24,000
fewer infants tested for HIV

UNDIAGNOSED

22 PERCENT
decline in new HIV diagnoses due to a reduction in testing among the most vulnerable, highest-risk people

8 PERCENT
decline in people living with HIV receiving CD4 tests to diagnose advanced HIV disease

UNPROTECTED

2,000
fewer infants and children with HIV started on life-saving medication

37 PERCENT
reduction in PrEP initiations for people at risk of HIV

UNTREATED

26,000
fewer infants and children on antiretroviral medications

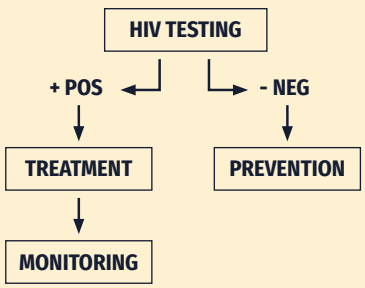
5 PERCENT
reduction in adults starting antiretroviral medications

UNSUPPRESSED

10 PERCENT
increase in people living with HIV disengaging from treatment

Box 1: HIV Prevention and Treatment Cascades

Public health impact in HIV prevention and treatment depends on fully functional programs at every step of the "cascade" of services provided to people living with and at risk of HIV. This cascade starts with HIV testing. People who are HIV negative and at risk are offered pre-exposure prophylaxis (PrEP) and other HIV prevention options. Those who are positive are offered antiretroviral treatment (ART). People initiated on PrEP or ART only benefit from the medication if they have access to it and continue taking it as prescribed. The final stage in the cascade measures PrEP continuation for HIV negative people and viral load in people living with HIV.



If these trends persist, countries will likely face:

- **Increased child mortality due to undiagnosed and un- or under-treated HIV infection**
- **Increased rates of new HIV infections**
- **Increased progression to severe disease and death among people living with HIV**
- **Increased challenges in realizing the game-changing benefits of lenacapavir for PrEP**

Described below, each of these predictions will be refined with continued data collection and analysis, followed by an analysis of the shifts in financial resources available for the HIV response. This report is made possible through collaboration with countries confronting major challenges preserving service delivery while navigating an ever-evolving funding landscape.

More Babies and Young Children with HIV Undiagnosed and Untreated Due to Foreign Aid Cuts

Children are being disproportionately affected by disruptions in 2025 compared to adults. Trends show continuing challenges in rapidly diagnosing children, starting them on treatment, and keeping them on treatment. Without these critical tests and rapid access to treatment, 50 percent of HIV-positive children will die before they turn two and 80 percent will die before they turn five.

Figure 1. Infants Tested for HIV Across Five Countries (EID)

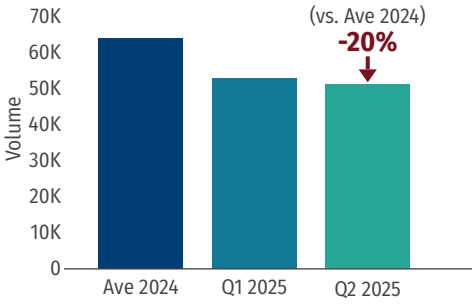


Figure 2. Children Starting HIV Treatment Across Nine Countries

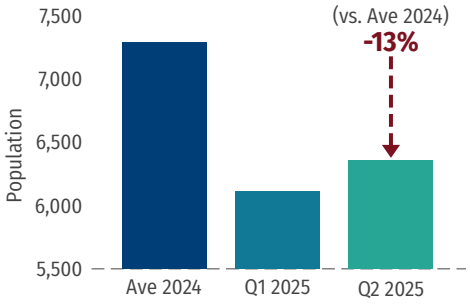
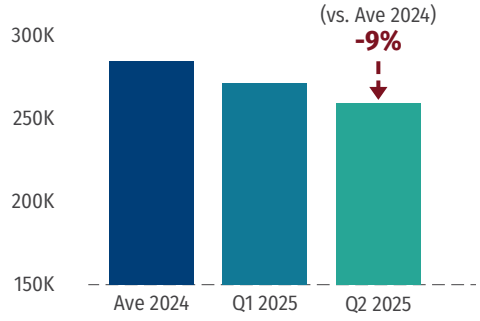


Figure 3. Total Children on HIV Treatment Across Nine Countries



- **Fewer babies at risk of HIV are being tested.** Early infant diagnosis (EID) for babies is **20 percent** below expected levels across five countries—24,000 fewer tests in the first half of 2025. That means thousands of newborns may miss the critical window for fast diagnosis and timely treatment, when delays can be deadly. (Figure 1)
- **Fewer babies and young children living with HIV are starting treatment.** Among those that are diagnosed, rates of treatment initiation have decreased **13 percent** compared to the 2024 average. This amounts to 2,000 fewer children living with HIV starting treatment in the first half of 2025. (Figure 2)
- **Over 26,000 babies and young children living with HIV who were on HIV treatment have fallen out of care so far in 2025**. (Figure 3)

Mothers in Zambia attend a postnatal clinic

Increased Disengagement From and Delayed Start of PrEP and ART, Raising Potential for More Avoidable HIV Infections

Data from countries show declines at almost every stage of the HIV treatment and prevention cascade. These declines could lead to surges in new HIV infections, as discussed in the prevention section, and to increased rates of severe disease and death for people living with HIV, as discussed in the advanced HIV disease (AHD) section. When testing drops, people do not know their status and cannot access the services they need. People at risk of HIV are more likely to acquire the virus, as they lack PrEP or other prevention options. People with HIV are less likely to start and stay on ART. Without medication, the amount of HIV in the blood increases, and people are more vulnerable to illness and more likely to transmit the virus.

KEY FINDINGS:

HIV Testing

- The number of HIV tests conducted is down **eight percent** across nine countries, corresponding to 3.4 million missed tests in the first half of 2025.
- Across seven countries, new HIV diagnoses declined **22 percent**. This corresponds to over 24,000 missed HIV diagnoses so far in 2025.
- **A decline in testing among the most vulnerable, highest-risk people.** The data show an eight percent drop in tests. Positive test counts did not decline by eight percent; rather, they decreased by 22 percent. This gap suggests that the testing that reaches people at the highest risk is being lost—this includes community-based and outreach services. A decline in new diagnoses does not automatically mean that infections are going down. In this context, it likely means that the people most vulnerable to HIV infection are no longer able to get tested.

Figure 4. Total HIV Tests Across Nine Countries

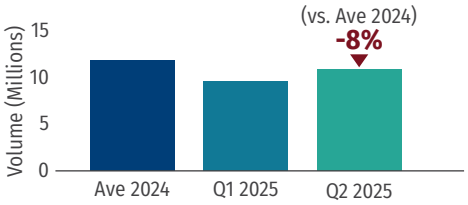
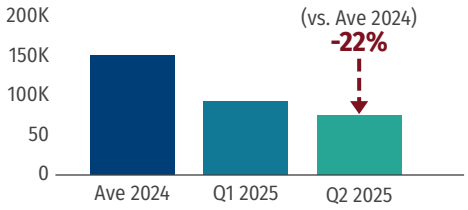


Figure 5. Total HIV Positive Test Results Across Seven Countries



PrEP

- By Q2 2025, **37 percent** fewer people were starting oral PrEP compared to 2024 averages. This corresponds to **more than 250,000 individuals at increased risk of HIV acquisition** in these countries who are not accessing PrEP in the first half of 2025.

HIV Treatment

- Across 10 countries, **five percent** fewer adults began HIV treatment in Q2 than expected, a decline of 25,000 people since the start of the year.
- Data from eight countries show a **10 percent** increase in the number of adults living with HIV who are no longer in care, also known as loss to follow-up. **This corresponds to at least 10,000 people who may have lost access to lifesaving ART in the first half of 2025.**

Figure 6. Number of People Starting Oral PrEP Across 10 Countries

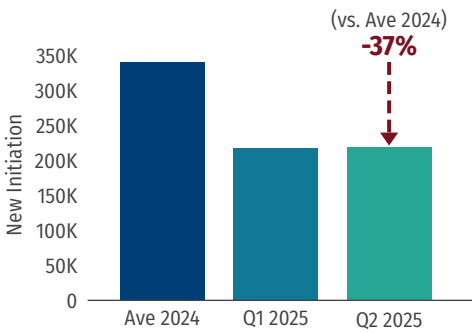


Figure 7. Adults Starting HIV Treatment Across 10 Countries

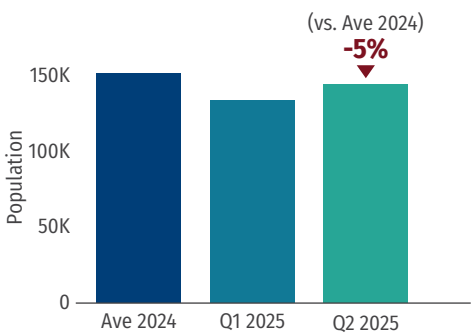
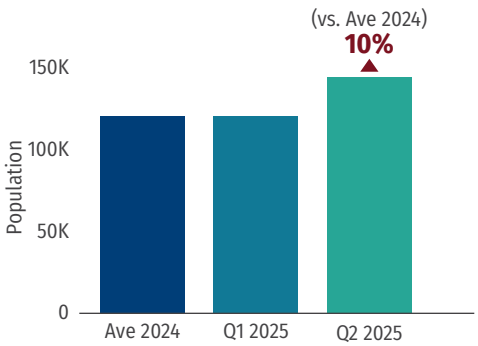


Figure 8. Adults Disengaging from HIV Treatment Across Eight Countries



People With Advanced HIV Disease Go Undiagnosed and Under-Treated With Potential for Increased Severe Disease and Death

Figures 7 and 8 show decreases in the numbers of people living with HIV who start and stay on antiretroviral drugs. Without treatment, the amount of HIV in the body (known as the viral load) can quickly increase, making the person sicker and more likely to pass the virus to others. **People living with HIV who are not on treatment are more vulnerable to progressing to advanced HIV disease (AHD) including developing a range of opportunistic infections, which can require complex treatments.** AHD is diagnosed with a CD4 cell count which is a key indicator of immune system health. People with a CD4 cell count below 200 are considered to have AHD. Data from the first half of 2025 show declines in CD4 testing and availability of essential treatments, meaning that people living with AHD are being missed and are not starting lifesaving treatment.

KEY FINDINGS:

- Across six countries reporting on CD4 tests administered, **41,000 fewer** people received this test for AHD in the first half of 2025, compared to the 2024 average, corresponding to an **eight percent** decrease.
- **Seven out of nine (78 percent)** countries reporting on supplies had less than a six-month stock of point-of-care CD4 tests. This means fewer of the sickest patients are being screened for advanced HIV disease on time for comprehensive care packages and preventable deaths.

Figure 9. Total CD4 Tests Across Six Countries

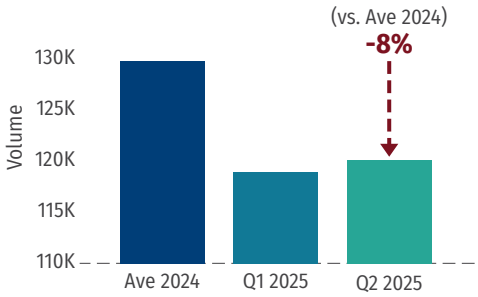
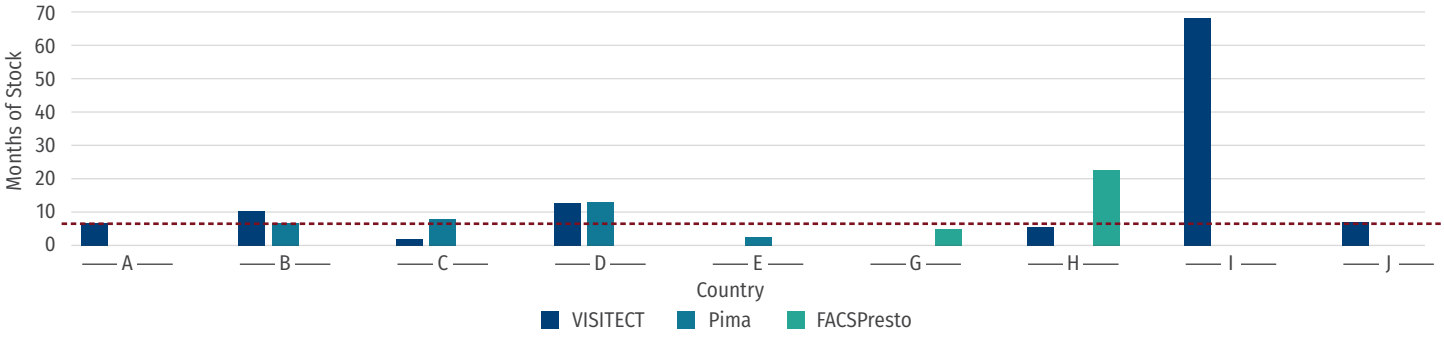


Figure 10. Country Stock Status of Rapid CD4 Tests



- **Cryptococcal meningitis**—a serious brain infection—is the second biggest killer of people living with HIV. The drugs to treat it are 5-flucytosine (5FC) and liposomal amphotericin B (L-AmB). More countries are reporting **less than six months' stock** of 5FC and L-AmB in Q2 2025 compared to Q1 2025. Shortages of these and other AHD treatment commodities could lead to increased mortality among people with AHD.

Figure 11. Country Stock Status for AHD Treatment Commodities (5FC, L-AmB, and INH/RPT)

AHD Treatment Commodities	Countries reporting < 6 months of stock in Q1 2025		Countries reporting < 6 months of stock in Q2 2025
5FC	33%	Worsened +10%	43%
L-AmB	20%	Worsened +9%	29%
INH/RPT	29%	Improved -29%	0%

AHD treatment commodities at a clinic in Kenya

Increased Challenges and Potential Opportunities in Realizing the Game-Changing Benefits of Lenacapavir for PrEP

As a novel six-monthly injectable PrEP product, lenacapavir (LEN) has transformative potential to accelerate PrEP uptake and curb new infections—but more investment is needed to support delivery at scale. The groundbreaking generic deals (see Box 2) make LEN affordable in 120 low- and middle-income countries around the world, and CHAI and partners are working to support rapid scale-up of LEN programs starting with product manufactured by Gilead Sciences, then moving to generics when they become available in 2027.

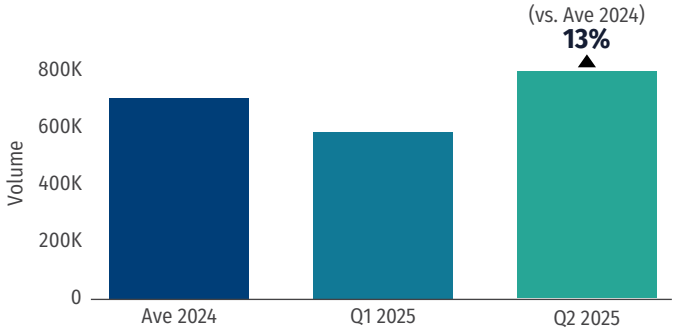
However, the funding disruptions and declines in access described in this report mean that many countries will face additional challenges in realizing the game-changing benefits of LEN for PrEP.

Even before 2025, PrEP coverage was far below the total need of those at risk, and for what is required to reach epidemic control. UNAIDS estimates that at least 20 million people will need to be on PrEP by 2030 to achieve epidemic control—a 10-fold increase from 2024. These major gaps in access to critical HIV prevention services will result in even more HIV infections.

As shown in Figures 4, 5, and 6, overall testing, testing in highly vulnerable communities, and PrEP initiations have all dropped. **These trends put the promise of LEN in peril.** Without testing in communities with high rates of HIV, and without stable PrEP services that allow choice between delivery mechanisms (oral, injectable, etc.), LEN rollout will falter.

Despite these trends, there is also reason for hope and persistence. Declines are stabilizing, and overall testing has started to rebound. The use of HIV self-tests is up 13 percent by Q2 2025 compared to 2024 quarterly averages. **This points to countries attempting to offset declines in conventional testing with a less labor-intensive option that eases workforce strain** due to funding cuts. HIV self-testing is a proven approach for reaching people in need of testing and for the first time, WHO prequalified HIV self-tests are now available for less than US$1.00.

Figure 12. Total HIV Self-Tests Distributed Across Seven Countries



▶ **A 13 percent increase in HIV self-test distribution in Q2 compared to 2024 averages amounts to over 30,000 additional HIV self-tests distributed so far in 2025.**

Box 2: CHAI and Partners Secure Generic Price for Lenacapavir

Six-monthly injectable lenacapavir (LEN) holds the potential to transform HIV prevention—but only if widely and affordably available. Earlier this year, two agreements made under Gilead Science's voluntary license helped bring that potential to reality, with generic manufacturers announcing a price of US$40 per person per year for LEN (exclusive of oral loading dose) across 120 low- and middle-income countries (LMIC).

$40
per year across
120
low- and middle-income countries

In September, Dr. Reddy's Laboratory, Unitaid, CHAI, and Wits RHI announced a collaboration that will bring generic injectable LEN to market at US$40 per person per year in 2027. The announced partnership includes provision of financial, technical, and regulatory support to Dr. Reddy's Laboratory to ensure rapid development and LMIC availability. Importantly, as part of a multi-partner, multi-supplier strategy, the Gates Foundation likewise announced a partnership with Hetero Labs to produce injectable LEN at the same $40 annual price, backed by a volume guarantee. Together, these deals position generic LEN for rapid, affordable scale, in support of individual and epidemic HIV prevention goals, once available.

A healthcare worker prepares a rapid HIV test in Nigeria

Foreign Aid Cuts

Less Foreign Aid, More Confusion, and Less Information on the Impacts of Cuts

Many models and projections describe the short- and medium-term impacts of the 2025 shifts in the HIV funding landscape. **Working with Ministries of Health, communities, development partners, and donors, CHAI is assessing how country data align with or diverge from these scenarios and headline global trends, drawing on both existing and emerging analyses.** Granular, country-level, ground-truthed reporting will be essential to defining strategies that sustain HIV and broader health services over the long term.

Countries reckon with huge blows to testing, care, and treatment for infants and children

Without continued PEPFAR programs, models predict that by 2030, an additional 1 million children will become infected with HIV, 500,000 additional children will die of AIDS, and there will be 2.8 million more children orphaned by AIDS. **Country data on declines in early infant diagnosis, treatment initiation, and support in care are dire warnings that these projections could become realities.** These risks are especially acute in the first years of life, when children with HIV face very high mortality without timely diagnosis and treatment. Early warning data also point to fragile supply of pediatric antiretroviral and testing commodities in several countries, suggesting that service disruptions may increasingly be compounded by stock risks. **Together, these trends signal a heightened risk of reversals against global pediatric HIV targets and efforts to eliminate mother-to-child transmission.**

Our data suggest that an increasing proportion of these children will die without an HIV diagnosis, a further failure of the health system and a barrier to accurate assessment of the impact of aid cuts.

WHAT TO WATCH IN 2026:

- **Diagnosis and treatment gaps for infants and children:** Ministries of Health, pediatric HIV programs, and partners should monitor infant and child testing volumes and coverage, pediatric ART initiation, and retention in care together to understand where service disruption is driving missed diagnoses and delayed treatment, and focus available resources where children are most at risk, including finding children who have already fallen out of care.
- **Pediatric commodity security:** Building on CHAI's early stock-status signals, Ministries of Health, procurement units, and partners should closely track pediatric treatment and testing stock levels, pipeline, and supplier performance, intervening early to prevent stockouts, avoid backsliding from optimal child-friendly formulations and regimens, and maintain continuity of care.

Aid Cuts Devastated PrEP and Testing for Highly Vulnerable Communities

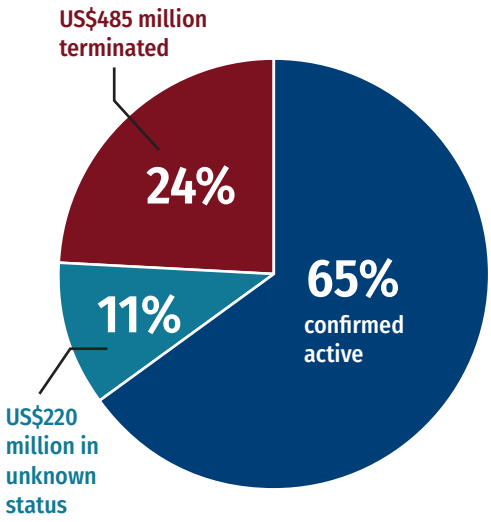
The scale of US government award terminations impacting HIV, tuberculosis, and malaria programs has been difficult to quantify with precision, as no official tally of cancelled US Agency for International Development (USAID) mechanisms has been released, nor have country programs clearly outlined which activities covered by cancelled awards have resumed in whole or in part with other external or domestic resources. At the same time, **PEPFAR has ceased all public-facing data sharing**, ending the routine quarterly data reviews both in countries and globally through online resources. Triangulating available information on cancelled awards, country data on service delivery, and reports on the robustness or challenges of data collection, CHAI and partners find:

Because PEPFAR funded data collection, data cleaning, and analysis in many countries, these core activities have slowed or stopped altogether, seriously impacting the ability of programs to plan and respond to the needs of patients.

- **Worst-case scenarios for adult HIV treatment may have been averted—for now.** Projections of impact on ART have used available information on award cancellation to extrapolate to treatment risk. Approximately 24 percent of USAID's FY25 PEPFAR awards were terminated by August 2025, representing US$485 million, with an additional US$220 million (11 percent) in unknown status. Terminated awards are estimated to affect timely ART delivery for 2.3

million people living with HIV globally (1 in 10 PEPFAR patients), with nearly 80 percent of at-risk treatment concentrated in South Africa, Uganda, India, and Eswatini, where some countries retained less than 25 percent of their planned programming resources. **While countries report a 10 percent increase in disengagement from treatment, as well as drops in initiation that have severe consequences for individuals and health systems, we have not yet recorded disruptions of the magnitude of worst-case scenarios.** Explanations for this include the high proportion of ART services provided with support from the US Centers for Disease Control and Prevention (CDC), which did not lose its PEPFAR funding when USAID was eliminated; Ministry of Health resilience and adaptation of government clinics to absorb clients; community mobilization; and lags in data collection that may be concealing greater shortfalls—or increases in re-engagement in care.

Figure 13. Total US$2.04 Billion USAID budget for PEPFAR



- **Prevention and testing services have suffered catastrophic losses.** Prevention and testing programs faced severe cuts: terminated awards would have been responsible for approximately 31 percent of planned HIV testing targets (6.8 million tests), 39 percent of PrEP initiation goals (390,000 initiations), and 700,000 planned VMMC procedures. CHAI country data confirm the huge impact of US withdrawal of resources for oral PrEP for most populations, with major reductions in PrEP initiations. We also see warning signs that HIV testing services are no longer reaching the most vulnerable populations. Countries have moved to expand the use of HIV self-tests; however, major challenges remain, particularly for early infant diagnosis. **PEPFAR's announcement of support for lenacapavir (LEN) introduction affirms its commitment to expanding access to innovative, long-acting HIV prevention; however, community-based testing and PrEP services that will be the backbone of LEN introduction will need to be rebuilt.**

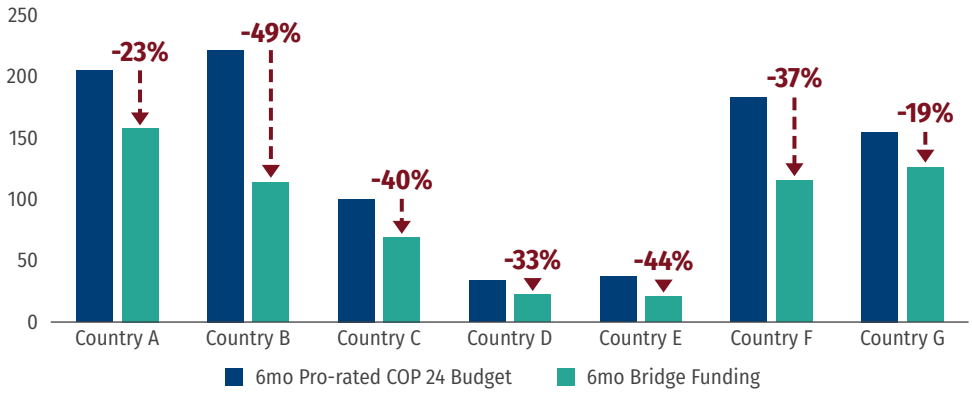
WHAT TO WATCH IN 2026:

- **Reliable country, regional, and global data are essential:** Country-led initiatives to stabilize and secure data infrastructure, and to re-establish a baseline for timely data collection, analysis, and sharing will be critical to understanding impacts and targeting mitigation.
- **Targeted attention to well-defined gaps:** With constrained resources to recover lost ground in testing and reaching vulnerable groups—while also introducing innovations like lenacapavir—countries and partners should shift from modeled projections to estimates of actual impact on the highest-risk populations to guide prioritization and program design.

Countries Challenged to Procure, Program, and Budget with Unprecedented Uncertainty

- **PEPFAR Bridge Plan reduces country funding through March 2026.** CHAI quantified funding reductions from the US government by comparing the resource envelopes for the six months of Bridge funding provided to PEPFAR country programs to the comparable prorated amount from FY2024. Bridge funding covers October 1, 2025 to March 31, 2026. **These countries are heavily reliant on PEPFAR funding for their HIV response and saw an average cut of 35 percent to their funding envelopes**

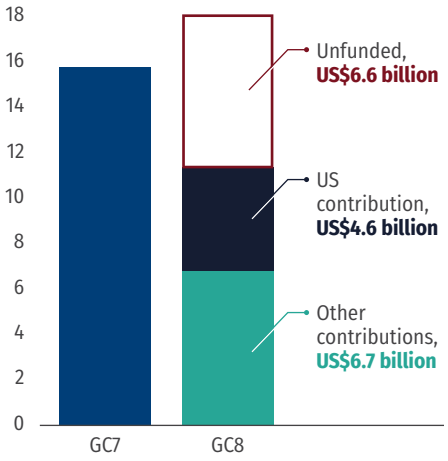
Figure 14. PEPFAR Bridge Funding Compared to Pro-rated COP24 Budgets in Seven Countries (US$ million)



for this transitional period. As this report was being finalized, these and other countries across the region were entering negotiations with the US government for Memoranda of Understanding (MoU), bilateral agreements covering two to five years of programmatic support. The sum for these agreements reflects money not yet appropriated by the US Congress. **Indicative budgets in all countries reflect substantial decreases.** Major questions remain about the implementation arrangements for the MoUs, including which partners will receive funds, whether existing arrangements for supply chain and service provision will be preserved, and how the funding will be distributed across the health areas covered in the agreements (polio immunization, maternal health, malaria, tuberculosis, HIV, and global health security). Notably, the MoU template restricts national governments from including multilateral financing in calculations of domestic resource allocations, a condition that further complicates country-level planning and budgeting.

- **Global Fund secures US$11.3 billion in replenishment—boosted by US$4.6 billion US pledge—but falls short of US$18 billion goal.** Countries also face uncertainty about funding from the Global Fund to Fight AIDS, TB and Malaria, which completed a reprioritization process for the current Grant Cycle 7 (GC7) in September, resulting in an average 12 percent reduction for HIV funding. The Global Fund's Eighth Replenishment Summit, held on November 21, 2025, closed with pledges of US$11.3 billion for the 2027–2029 GC8 period—below both the US$18 billion target and the US$15.7 billion raised previously for GC7. **However, the United States pledged up to US$4.6 billion, subject to a 2:1 match—23 percent less than its US$6 billion pledge for GC7 but substantially higher than the levels signaled in recent budget proposals, easing some of the worst fears of a sharp US retrenchment.** The United Kingdom's GC8 pledge is also down 15 percent relative to its previous contribution. As of late November 2025, three of the largest GC7 donors—France, Japan, and the European Commission, which together pledged nearly US$3.4 billion in the previous cycle—had yet to confirm their GC8 pledges and are expected to do so in 2026. **Taken together, early pledges point to a significant, though less severe than initially feared, reduction in overall Global Fund resources for GC8—on the order of 10–20 percent compared to GC7**. GC8 application materials are expected to be shared with countries by the end of 2025, with specific allocation letters expected in late February or early March 2026, leaving countries with limited visibility on final envelopes as they make critical planning decisions for HIV programs.

Figure 15. Global Fund GC8 Replenishment Progress as of November 2025 (US$ billion)



- **Beyond program budgets, these shifts have direct implications for commodity security.** PEPFAR and the Global Fund currently finance and procure a large share of HIV treatment, diagnostic, and prevention commodities. As envelopes shrink, governments are expected to finance and directly procure more of these commodities themselves. **This transition carries risk.** To date, countries have benefited from two large purchasers (PEPFAR and the Global Fund) that consolidate demand and run large, coordinated tenders that secure low prices, ensure product quality, and enforce supplier performance.

In the absence of a pooled procurement or coordination mechanism, more fragmented, domestically financed procurement could raise prices, weaken supplier accountability, and increase the likelihood of stockouts.

WHAT TO WATCH IN 2026:

- **Country-level coordination and multistakeholder engagement will be essential:** Ministries of Finance, Health, and Environment working closely with impacted communities, private sector partners, implementing partners, and other stakeholders can develop holistic, costed strategies.
- **Commodity security and supply chain resilience:** Ministries of Health, procurement units, and supply chain partners should coordinate to closely track stock status, lead times, and supplier performance across HIV and related health areas, intervening early to prevent stockouts, enable rapid adoption of the best products available, and stabilize vulnerable markets.

HIV PREVENTION

With 1.3 million new HIV infections globally in 2024, HIV prevention remains significantly off track from global goals and acutely vulnerable to US Government (USG) and other foreign aid shifts.[i]

- Access to primary prevention interventions—including oral pre-exposure prophylaxis (PrEP)—declined drastically in 2025. While many countries in Q2 of this year saw a moderate rebound from the Q1 drop, oral PrEP initiations remain 37 percent below 2024 levels.
- Even before 2025, PrEP coverage was well below the level needed for epidemic control, so these reductions are a major setback.
- Despite these challenges, the introduction of lenacapavir (LEN), a six-monthly injectable PrEP option, represents a transformative opportunity.

A nurse gives a health talk to women at a clinic in Nigeria

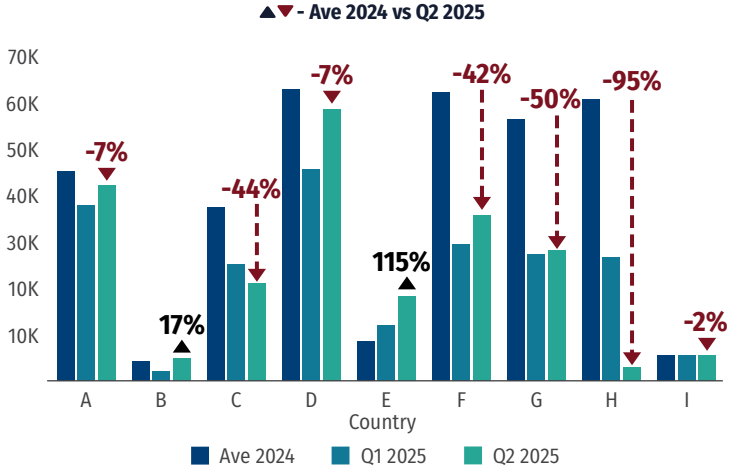
Over 250,000
missed PrEP initiations in 2025

Quarterly Oral PrEP Initiations

Initiations are down **37 percent** compared to 2024 averages across nine countries, despite rebounds from Q1 in two countries. This represents more than **250,000 missed initiations** in these countries alone. Extrapolated across all low- and middle-income countries (LMICs), this is more than **600,000 missed new initiations**, likely resulting in thousands of preventable infections.

Four of nine countries (44 percent) reported less than six months of stock for at least one PrEP product; in some contexts, central-level stock is inaccessible or at risk of expiry while other settings face shortages.

Figure 16. Quarterly Oral PrEP Initiations



Countries with a significant proportion of oral PrEP procured via the Global Fund or domestic funding retained relatively secure supply in 2025; programs relying more heavily on PEPFAR face greater risk given the lack of restarted oral PrEP orders.

Reductions are driven by myriad factors: human resource constraints (including major cuts to community outreach and peer cadres), supply chain disruptions, and the closure of delivery channels or termination of PrEP services in delivery channels that remain active.

The February 2025 PEPFAR waiver excluded oral PrEP except for pregnant and breastfeeding women—a group representing fewer than 60,000 total initiations and only **two percent** of 2024 PrEP initiations across PEPFAR countries—leaving most programs disrupted.[ii,iii] While 2025 saw significant declines in oral PrEP initiations, the scale of reductions does not suggest that PrEP access was fully limited to pregnant and breastfeeding women. Facility-level interpretation of the waiver varied, and while no population restriction has been communicated for LEN, USG policy on oral PrEP remains unclear in many areas.

Supply chain disruptions correlate to the steepest declines, including contexts where oral PrEP stock remained inaccessible in warehouses without the ability to distribute.

Major PrEP Supply Chain Disruptions:

- PEPFAR has not resumed oral PrEP orders, so countries rely on the Global Fund or domestic procurement only
- Commodities are inaccessible in USG-operated warehouses
- PrEP commodities can no longer be distributed by USG supply chain partners

Long-acting Cabotegravir (CAB-LA) Injectable

Early market-building efforts for injectable PrEP with CAB-LA have been severely disrupted by funding cuts:

- PEPFAR planned to procure the vast majority of ViiV's LMIC supply in 2024 (342,000 doses, 75 percent of ViiV supply), but most of this planned procurement was never delivered to countries, as orders were not yet placed when the January 2025 US foreign aid freeze was enacted. As of November 2025, PEPFAR indicated to countries that they will not restart any CAB-LA procurement.
- By November 2025, only seven countries had procured CAB-LA through the Global Fund.
- Total LMIC CAB-LA initiations remain below 20,000.

Several countries receiving LEN in 2025/2026 are also delivering CAB-LA, including Eswatini, Kenya, Lesotho, Malawi, Mozambique, Nigeria, Uganda, Zambia, Zimbabwe. Countries' strategies for delivering both injectables vary, with some planning to phase out CAB-LA and others planning to deliver both injectable options.[iv]

LENACAPAVIR

Named *Science*'s "breakthrough of the year," LEN has the potential to transform the HIV response and rapidly curb new infections.[v]

This will only be possible with widespread access to a sustainable, secure supply of affordable generic versions. In September 2025, breakthrough generic deals unlocked a pathway to affordable quality-assured access to LEN. This was the result of a comprehensive multi-partner, multi-supplier strategy to enable access to a game-changing HIV product.

Historic Breakthrough for Generic LEN

- CHAI, in partnership with Unitaid and Wits RHI, entered into a comprehensive access agreement with Dr. Reddy's Laboratories that makes generic LEN injections available at US$40 per person per year, at launch, in **120** LMICs.
- The Gates Foundation simultaneously established a partnership with Hetero Labs for the same US$40 annual price per patient.
- The expected time to market of generic products is 2027, pending regulatory approvals.
- Under these deals the one-time oral loading dose (required to rapidly reach protective coverage levels in the body) will be available for <US$17.
- Importantly, however, these "at launch" access prices are just the beginning. The aim of these partnerships is also to support innovative approaches to reduce the costs of producing LEN and achieve economies of scale through increased volumes, both of which enable further price reductions.

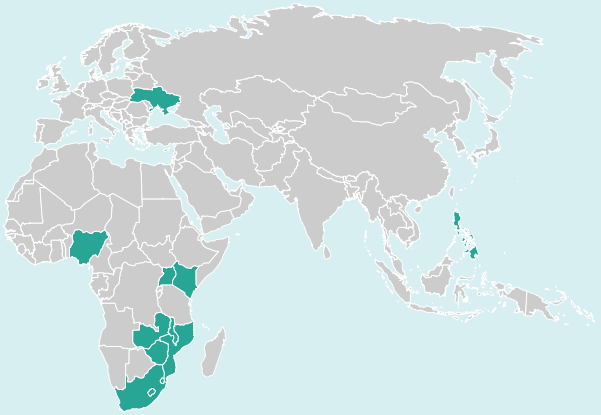
"The ability to protect someone for six months with a single injection, at the same cost as the currently available daily pills, is truly transformational. This partnership marks a remarkable breakthrough and a fundamental shift in what's possible for HIV prevention."

– President Bill Clinton, Board Chair and Co-Founder of CHAI

Announcement of the lenacapavir deal with Dr. Reddy's Laboratories in New York

With US Food and Drug Administration (FDA) approval of the innovator (Gilead Sciences) LEN product in June 2025 and the release of World Health Organization (WHO) guidelines in July 2025, key country-level market preparation is now underway. With support from the Global Fund and PEPFAR, 12 countries are set to introduce Gilead's LEN in 2025-2026, less than one year after high-income country availability.[vi] Early market building with Gilead's product will be critical for supporting a rapid pivot to scale once generic LEN is available. While significant increases to HIV prevention budgets will be needed to generate economies of scale and achieve epidemic control, this landmark set of deals securing at launch access pricing and supply, alongside related demand-side progress, marks major steps toward real-world impact for millions at risk of HIV.

Figure 17. Map of 12 Countries Introducing LEN in 2025-26



PEPFAR

- US Department of State announced a commitment to reach up to 2 million people with LEN by 2028, co-funded with the Global Fund.
- No population restrictions exist for LEN delivery (unlike oral PrEP under PEPFAR's waiver).
- Rollout will focus on high-incidence, concentrated epidemics such as those in the Ukraine and Philippines, in addition to African countries with generalized epidemics through collaborations with the Global Fund.

Global Fund

- Supporting 1.27 million LEN doses under under Global Fund Grant Cycle 7 (GC7), with 76 percent channeled to South Africa.
- Earliest LEN rollout planned for December 2025 (Eswatini and Zambia); others by Q1 2026.
- Global Fund-supported LEN early adopters are prioritizing existing oral PrEP delivery channels and expanding to community-based, pharmacy, and private sector delivery.

Figure 18. Countries receiving LEN through PEPFAR and/or Global Fund

	Eswatini	Kenya	Lesotho	Malawi	Mozambique	Nigeria	Philippines	Uganda	Ukraine	South Africa	Zambia	Zimbabwe
Global Fund	✓	✓	✓		✓	✓		✓		✓	✓	✓
PEPFAR	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓

Figure 19. Regulatory Timeline for Lenacapavir PrEP

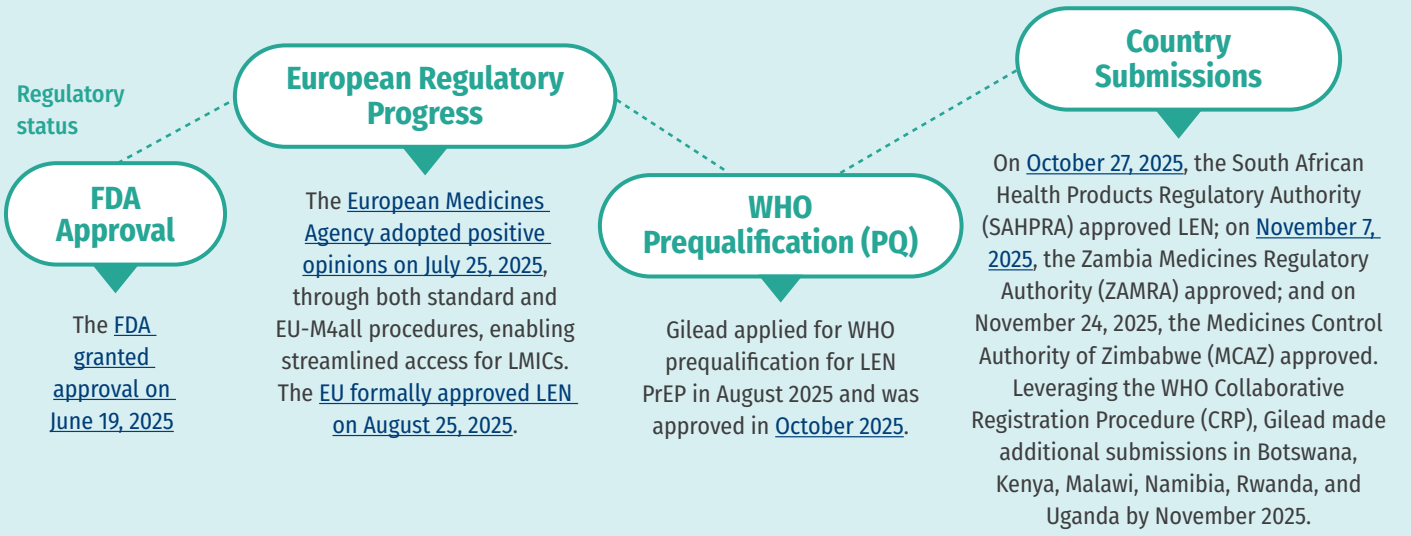
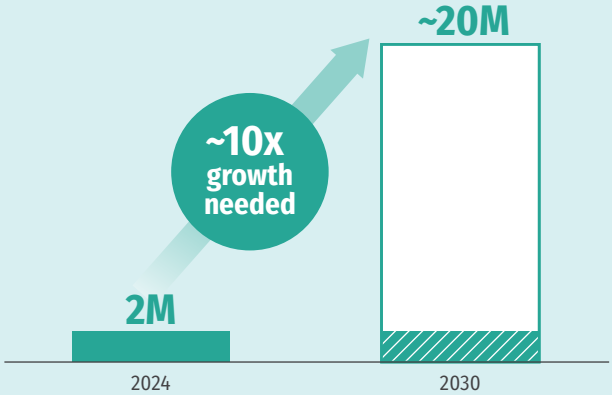


Figure 20. PrEP Coverage Needed to Reach UNAIDS Epidemic Control Targets (Person-Years)



Outlook

Impact is not guaranteed, but the tools now exist to ensure success. Increasing PrEP access through additional delivery channels is crucial for reaching the scale needed for epidemic control. New UNAIDS targets show the need to reach nearly 20 million annual person-years on PrEP by 2030 to achieve epidemic control—a **10-fold increase** in the current PrEP market. With generic market entry expected in 2027, it will be critical to implement the health system changes needed now for delivery at scale.

Program Adaptation and Innovation

Despite this challenging context, global and national commitment to prevention remains strong and—given sufficient funding—LEN can unlock significant impact. Examples of program resilience and re-design include:

- **Nigeria:** The government is expanding provider training on key population (KP)-sensitive PrEP delivery to reactivate one-stop-shops in partnership with communities, CHAI, and other technical partners.
- **Uganda:** The Ministry of Health (MoH) is investigating novel community-based delivery channels for PrEP, including potentially leveraging community retail pharmacy drug distribution points to close access gaps.
- **Zambia:** The MoH is planning to generate evidence on community-based LEN delivery, leveraging contraception delivery models and infrastructure.

Healthcare workers review program data at a hospital in Nigera

PEPFAR AND GLOBAL FUND SIGNALS

- PrEP has remained a strong focus during the GC7 reprioritization. However, major reductions are expected in Global Fund Grant Cycle 8 (GC8), raising sustainability concerns. GC7 cuts have already resulted in decreased budgets for HIV self-testing (HIVST) and voluntary medical male circumcision (VMMC).
- All six countries accessing the Children's Investment Fund Foundation (CIFF)/Global Fund PrEP Matching Fund maintained financial matching commitments and programmatic targets for GC7.
- PEPFAR's PrEP funding remains uncertain. LEN procurement and distribution is planned, but broader prevention support is expected to be limited. Draft memorandums of understanding (MoUs) for the US bilateral agreements released and reported on in November 2025 do not include any prevention-related metrics.

WHAT TO WATCH

- **PrEP enrollment:** MoHs, partners, and civil society organizations should monitor service delivery adaptations against historic oral PrEP numbers to gauge effectiveness in recovering and expanding service delivery. To reach epidemic control, PrEP markets will need to grow substantially, far surpassing even pre-2025 volumes.
- **LEN rollout readiness:** Country approvals must translate into uptake, with trained staff and consumables, and early demand. Coordination across MoHs, funders, partners, and civil society will be key to success.
- **Last-mile capacity and channels:** MoHs and communities should monitor KP and adolescent girls and young women (AGYW) access points (drop-in centers, outreach, pharmacy/community drug dispensing points); closures or slow restarts will limit initiations among the most vulnerable populations.
- **PEPFAR & policy posture:** Countries should watch for an oral PrEP procurement restart or guidance change. Prolonged restrictions on oral PrEP (vs. LEN's broader scope) will further constrain access to HIV prevention commodities.

HIV Prevention Pipeline

MK-8527

- Merck's once-monthly oral PrEP candidate has advanced to Phase 3 trials (ExPrESSIVE-10 and 11) following favorable Phase 2 safety data presented at IAS 2025.[vii] As a nucleoside reverse transcriptase translocation inhibitor (NRTTI), it offers a resistance profile distinct from capsid-inhibitor lenacapavir and could provide a simpler, oral alternative alongside injectable long-acting options. Primary endpoints for both trials are expected in October 2027.

12-month LEN (Gilead)

- **July 2025:** PURPOSE 365 study (Phase 3) is underway
- **Q3 2028:** Anticipated primary study completion

Dual Prevention Pill (DPP, Viatris)

- **November 2024:** DPP was included in the Expression of Interest (EOI) for WHO PQ
- **January 2025:** Viatris submitted DPP dossier for the WHO PQ
- **2025:** Viatris filing registration for 47 countries
  - Priority 1 countries include Botswana, Kenya, Malawi, Mozambique, Namibia, Nigeria, South Africa, Tanzania, Uganda, Zambia, and Zimbabwe.
- **Q1 2026:** WHO expected to convene a guidelines development group for guidance on the DPP

Logistics officers in Lao PDR receive medical supplies

CAB four-month injection

- **December 2024:** Phase 2b registration trial (EXTEND 4M study) on four-monthly intramuscular injection of ultra-long-acting cabotegravir (CAB-ULA) started
- **Q3 2026:** Anticipated primary study completion

Three-month Dapivirine Vaginal Ring (DVR)

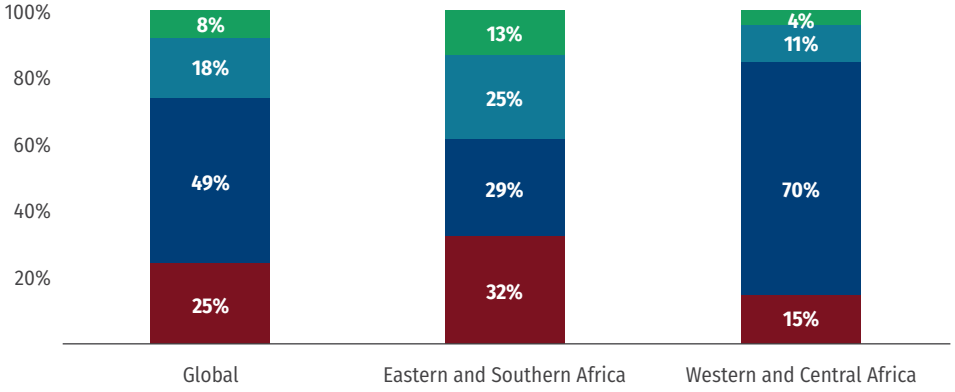
- In 2024, CIFF and the Global Fund announced an early market access vehicle for the 1-month ring, with the aim of bridging more affordable access through the 3-month DVR. However, as of mid-2025, less than a third of the available 150,000 rings had been ordered, raising questions about demand for the product.
- Kiara Health three-month DVR development and manufacturing: MoU signed with the Population council in 2024 to manufacture the ring in South Africa but, as of November 2025, development has not yet advanced. AVAC forecasts to have 323,000 three-month rings manufactured by 2026.

Prevention of Mother-to-Child Transmission (PMTCT)

According to the 2025 UNAIDS report, about half of all new HIV infections in children came from mothers who did not receive antiretroviral therapy (ART) during pregnancy or breastfeeding.[viii] This varies by region, with maternal HIV acquisition driving mother-to-child (MTCT) transmission in Eastern and Southern Africa.

A healthcare worker in Tanzania counsels a mother during a postnatal visit

Figure 21. Reasons for Mother-to-Child Transmission



Long-acting HIV prevention tools present a critical opportunity for pregnant and breastfeeding women, especially given the historically low use of daily oral PrEP in this population. A South African study found that among pregnant and breastfeeding AGYW tested for HIV, less than one in five were offered PrEP, yet two-thirds started when offered.[ix]

This highlights the unmet need within current service delivery models, and the importance of tailored, country-specific approaches and innovative ways to reach women where they are, particularly as health resources become more constrained.

WHO Guideline Update on Infant Prophylaxis

In addition to strengthening prevention options for mothers, the 2025 WHO HIV guidelines simplify infant prophylaxis to reduce vertical transmission.[x] This provides an opportunity to reduce procurement, implementation complexity, and cost, similar to the guideline simplification for pediatric HIV treatment.

- For high-risk infants, a short-course combination of abacavir (ABC), lamivudine (3TC), and dolutegravir (DTG) is now preferred for enhanced potency (considered presumptive treatment unless HIV infection can be ruled out). Breastfed infants who complete the three-drug regimen should follow with single-drug prophylaxis for the rest of breastfeeding or until the mother is virally suppressed, with nevirapine (NVP) as the preferred option.
- For low-risk infants, single drug prophylaxis for six weeks is recommended, with NVP as the preferred option and DTG or 3TC as alternatives.

HIV TESTING

HIV testing is critical for timely diagnosis and treatment initiation, re-engagement into care, and linkage to prevention.

- Testing volumes are still **8.4 percent lower** than 2024 averages across reporting countries, despite some recovery in Q2 after initial disruptions in Q1 2025.
- Testing at antenatal care (ANC) has been **less impacted** than general testing so far, and countries also appear to be increasing HIVST to compensate for decreases in conventional testing capacity.

A healthcare worker in Uganda conducts an HIV test

- However, the number of new diagnoses remains **22 percent lower** than 2024 averages, 2.5 times greater than the decline in overall testing. This is because funding disruptions disproportionately impacted testing services for higher-risk populations who are more likely to test positive, as these strategies have historically been partner driven.

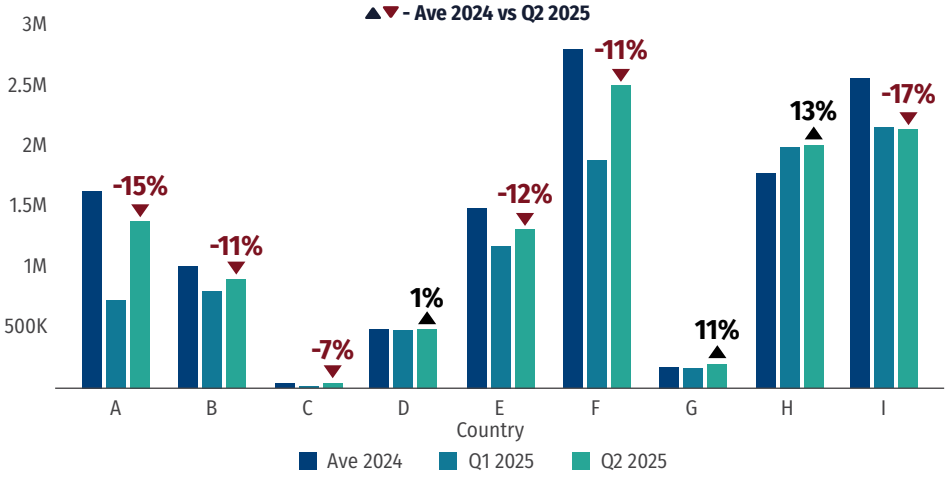
Countries are at a pivotal moment to protect access to testing, make up for critical disruptions in treatment initiation to-date, and sustain progress in the HIV response moving forward.

Over 24,000
missed HIV diagnoses so far in 2025

Quarterly HIV Rapid Tests Run

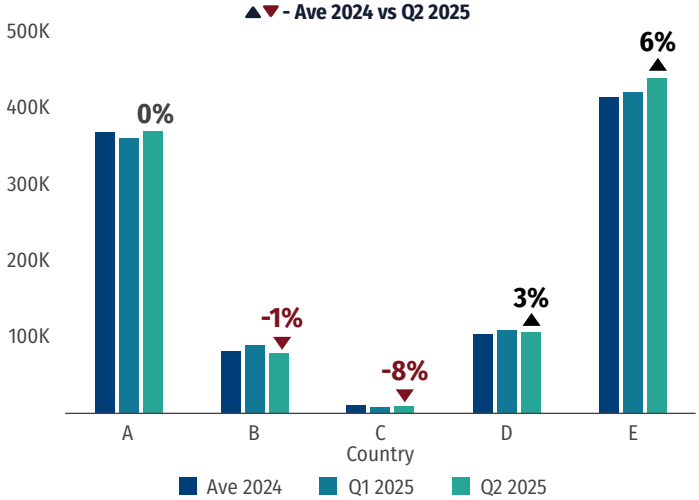
HIV testing has rebounded significantly in the last quarter, by **14 percent**, but is still down by **8.4 percent** across countries by the end of Q2 2025, amounting to **3.4 million fewer tests this year**. This rebound reflects the resumption of PEPFAR-supported service delivery under USG waivers and country-level responses. However, the shortfall from 2024 figures suggests significant service delivery challenges persist.

Figure 22. Quarterly HIV RDT Volumes at All Entry Points



Quarterly HIV Rapid Tests Run at Antenatal Care Facilities

Figure 23. Quarterly HIV RDT Volume at ANC Facilities



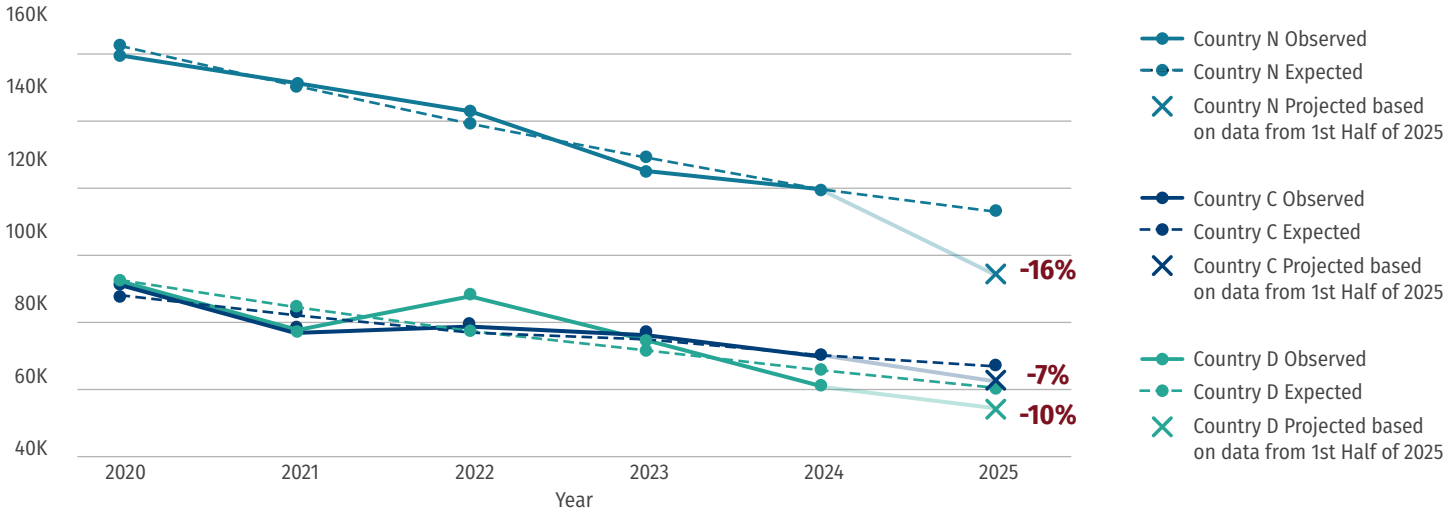
Among countries reporting data, HIV testing at ANC appears less impacted, with most countries maintaining ANC testing volumes in Q2 2025. ANC services are often more integrated in many counties, with non-HIV-specific staff, such as midwives, delivering testing services. These staff are more likely to be government funded, which helped insulate ANC testing from immediate service disruption as many MoHs positioned ANC testing as a high priority in the national health agenda. For instance, in one country where stocks of HIV tests were low, remaining stocks were prioritized for ANC. On the other hand, another country reported an **eight percent** decline, which suggests varied levels of service delivery challenges across countries.

Quarterly HIV Positive Test Results

Countries report **22 percent** fewer people diagnosed with HIV compared to 2024 averages. This decline in new diagnoses is greater than the drop in overall testing (8.4 percent). While new diagnoses were already trending downward before the funding disruptions, CHAI analysis in three Southern African countries based on data for first half of 2025 shows diagnoses in 2025 are projected to be 7–16 percent below historical trends. This likely reflects constrained testing access rather than epidemiological improvement, as PrEP and treatment disruptions would be expected to increase new infections and positive diagnoses. Applied across the seven reporting countries, this represents more than **24,000** missed diagnoses just in the first half of 2025. This could indicate that testing disruptions are disproportionately impacting higher-risk clients who are more likely to test positive. Many of these clients are reached through more resource-intensive strategies like network testing and services for KPs, which have historically relied on PEPFAR support and may be challenging for national systems to absorb.

Figure 24. Quarterly HIV Positive Results

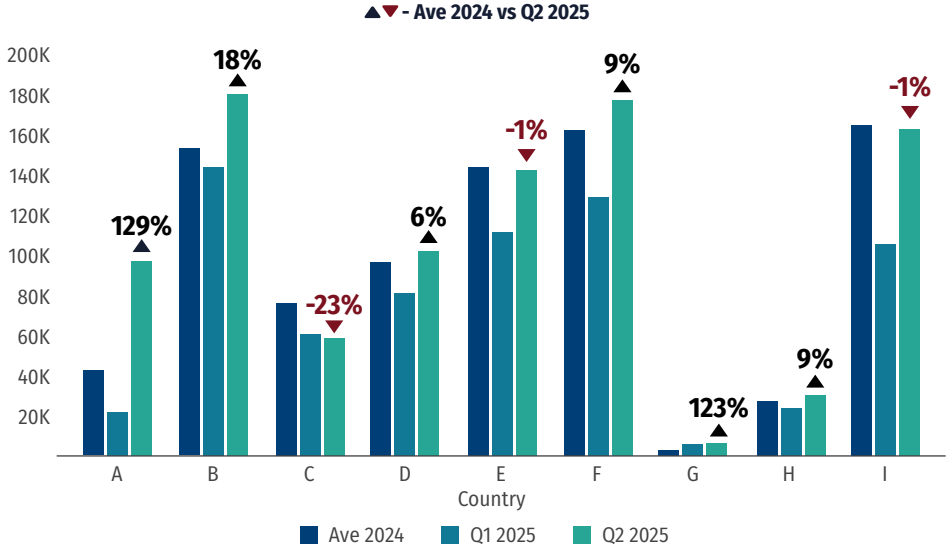
Figure 25. Comparison of Observed and Expected HIV-Positive Test Outcomes (2020–2025)



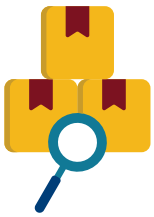
Quarterly HIVST Distributed

HIVST distribution in Q2 surpassed 2024 averages by **13 percent**. This could indicate that countries are leveraging HIVST to mitigate reductions in provider-administered testing due to staffing shortages. The availability and adoption of lower-priced HIVST products will make this approach more feasible moving forward.

Figure 26. Quarterly HIVST Distributed



HTS Stocks Data



Stocks of HTS commodities are improving on average but

7 of 11 (64 percent)

countries still reported less than six months stock of at least one HTS commodity. Interruptions of any of the three rapid diagnostic tests (RDTs) used in testing algorithms can compromise algorithm accuracy and delay diagnosis and linkage to treatment.

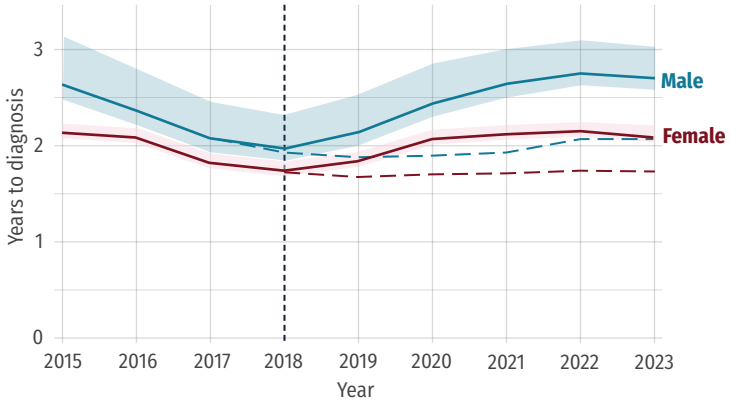
HIV Rapid Test by Algorithm Position	Average Stock
A1	6.3 months (n=11)
A2	7.4 months (n=10)
A3	11.5 months (n=8)

Cost Savings to Ensure Access to Testing

Preliminary modeling with data from sub-Saharan Africa shows the impact of access to testing on time to diagnosis, a critical metric given the impact on individual client health and onward transmission. It is estimated that a **16 percent decline in testing across 33 countries between 2017 and 2023 increased the time to HIV diagnosis** for men and women by eight and four months, respectively.[xi]

Increased time to diagnosis drives higher incidence, mortality, and long-term costs.

Figure 27. Pooled Median Time to Diagnosis in Countries with a Decline (2015-2023)



Given rapidly declining and uncertain funding, it will be critical for countries to maximize impact of available resources to sustain access to testing:

- **HIVST:** HIVST is poised to be a critical enabler, as widespread distribution can increase access to testing while introducing significant efficiencies and cost savings.[xii] This is particularly critical as Ministry cadres must absorb partner-supported HTS delivery. As seen in the ANC testing data above, integration may help sustain HIV service delivery, but there are critical questions on how to define and operationalize this, including measures to prevent additional strain on an already overwhelmed healthcare workforce. HIVST can reduce healthcare worker (HCW) time per test by more than 50 percent, making it an important tool to support long-term shifts in service delivery models.

109

countries with HIVST policies implemented as of January 2025

Lower-priced products allow countries to increase procurement within constrained commodity budgets and expand access with more limited HCW capacity. This is a critical tool as countries work to rebound from disruptions.

  - Modeling using routine data in Uganda, Kenya, Zambia, Lesotho, and South Africa showed HIVST distribution resulted in 0.6 to six additional HIV positive diagnoses per 100 HIVST distributed.[xiii]
  - ART-specific analysis in Kenya demonstrated 6.7 additional ART initiations per 100 HIVST distributed.

This modeling reinforces existing evidence on the effectiveness of using HIVST to reach PLHIV that results in them starting or restarting lifesaving treatment.

HIVST procurement has historically been limited by just a few high-cost commodity options (two to three times more expensive than the cost of conventional RDTs). The market is increasingly diversifying. In addition to two high-quality blood-based products for US$1.50 and US$1.00 ex-works (EXW) that WHO PQ'd in 2022 (Abbott and Wondfo, respectively), two new products are now available.

- **InTec HIVST:** WHO PQ'd InTec's blood-based Advance Quality HIV Self-Test in August 2025 and is now available for US$0.90 EXW. This is the first test to be available for less than US$1.
- **Wantai BioPharm HIVST:** WHOPQ'd the first HIV urine antibody rapid diagnostic self-test kit by Wantai BioPharm in April 2025. Pricing is expected to be US$2 EXW for bulk packaging, and US$4 EXW for individually packaged tests.

- **Lower priced RDTs:** HTS commodity budgets are driven by the first test in the algorithm (A1), which most countries procure at US$0.80 EXW. The WHO recommends countries adopt low-cost, PQ'd HIV RDTs (as low as US$0.53 EXW per kit) as A1 in their algorithm to realize urgently needed cost savings while maintaining a three-test algorithm.
- **4th Generation HIV Ag/Ab RDTs:** Some countries are considering 4th generation RDTs. These could potentially identify acute HIV infection by detecting p24 antigens, which present earlier in infection, in addition to antibodies. Antibodies are detected by all HIV RDTs, including 3rd generation tests, currently in use. However, growing evidence on the only WHO PQ'd 4th generation rapid HIV test shows low p24 antigen sensitivity, limiting potential benefits to HIV programs.
  - A forthcoming systematic review by the WHO (cited in the WHO's 2025 HTS PrEP guidance[xiv]) found that the 4th generation RDT had a pooled sensitivity of 50 percent among acute infections, dropping to **25 percent** among PrEP users.
  - Studies in Eswatini and Mozambique also indicated poor performance identifying acute HIV infection (**0 to 20 percent** sensitivity).[xv,xvi]

For example, in a country that screens 5 million people each year, a **lower-priced A1 commodity** could save US$1.85 million annually (**41 percent** of A1 costs). These savings could be redirected to expand testing coverage and support other essential services.

This evidence indicates that this product would not substantially increase detection of acute HIV infection and does not support prioritizing this product over high quality, lower cost RDTs.

PEPFAR AND GLOBAL FUND SIGNALS

PEPFAR COP25 planning:

USG resumed orders of HTS commodities within existing funding earlier this year. HIV testing is included within life-saving activities for PEPFAR Bridge plans, which explicitly include diagnostic commodities. The scope of support for human resources to deliver HTS and any funding past March 2026 are unclear.

Global Fund:

Planned procurement of HTS commodities was largely protected within GC7 reprioritization. Both future procurement and support to service delivery are at risk, given significant expected cuts to GC8.

WHAT TO WATCH

- **Diagnosis trends and testing volumes:** MoHs and partners should track quarterly HIV tests and new HIV-positive results against historical baselines, disaggregated by age, sex, geography, and population, to detect where clients are being missed and whether rebounds in testing reflect true recovery.
- **High-yield testing strategies:** Programs should monitor performance of community-based testing, index/partner testing, KP–specific services, and HIVST to ensure high-yield approaches are maintained despite workforce and funding disruptions.
- **PMTCT and pediatric case-finding:** MoHs and implementing partners should closely monitor HIV testing coverage in ANC, maternity, and child health platforms; declines should trigger rapid corrective action given the risk to PMTCT progress and missed pediatric diagnoses.
- **Financing and policy environment:** Governments, donors, and civil society should track GC8 allocations, domestic financing, and changes in national HIV testing guidelines to safeguard budgets for commodities and implementation, and sustain targeted testing volumes

Triple Elimination

HIV screening at ANC has remained relatively stable through recent disruptions, underscoring the continued prioritization of PMTCT by countries. Many countries are advancing integrating HIV screening in ANC with syphilis and hepatitis B (HBV) as part of 'triple elimination' programming.

The WHO Triple Elimination targets for 2030 aim to eliminate MTCT of all three infections by integrating prevention, testing, treatment, and vaccination within maternal and child health platforms.

Emerging triple HIV, syphilis, and HBV RDTs offer a practical tool to accelerate simultaneous screening and advance elimination goals across all three diseases—simplifying testing workflows, improving linkage to treatment and vaccination, and optimizing limited resources.

In 2025, WHO PQ'd Abbott's ANC Panel, while products from SD Biosensor and Intec are expected to achieve PQ by 2028. These products have varying formats suited to diverse health system contexts. Additional suppliers are expected to finalize designs and launch triple tests over the next three to five years.

A healthcare worker in India provides counseling on triple elimination

Lessons from the dual HIV/syphilis RDT rollout, which closed syphilis screening gaps but took nearly a decade to scale, highlight the importance of aligned policy, product readiness, financing, and early implementation evidence for accelerated adoption. Successful introduction and uptake of triple tests will require similar alignment of the enabling environment elaborated in CHAI's HIV/Syphilis-Dual RDT Market Brief. Further reflections and implementation considerations will be detailed in CHAI's Integrated Screening Market Brief (December 2025), part of the Triple Elimination Market Series.

Figure 28. Overview of Available and Anticipated Triple Combination RDTs for HIV, Syphilis, and Hepatitis B

NAME	ABBOTT ANC PANEL	INTEC ADVANCED QUALITY COMBO TEST	SD BIOSENSOR STANDARD Q TRIPLE TEST
Total lanes	3	2	1
Sample volume	~250 µL capillary blood	~90 µL capillary blood	~20 µL capillary blood
Buffer	1 buffer; 1 drop strip	1 buffer; 1 drop strip	1 buffer; 1 drop strip
Time to result	20-25 minutes	15-20 minutes	20-25 minutes
Sensitivity percent/ Specificity percent (manufacturer provided)	▶ Determine HIV Early Detect • p24 Antigen – 88/99.7 • HIV ½ Antibody – 100/99.9 ▶ Determine Syphilis TP – 99.6/99.7 ▶ Determine HBsAg2 – 98.4/99.5	▶ HIV1/2 – 100/99.6 *(n=1,329; 86 positive)* ▶ Syphilis TP – 100/100 *(n=1,329; 86 positive)* ▶ HBsAg – 99.3/100 *(n=300 samples; 150 positives*	▶ HIV1/2 – 100/100 *(n=250 samples; 50 positives)* ▶ Syphilis TP – 100/100 *(n=250 samples; 50 positives)* ▶ HBsAg – 100/100 *(n=250 samples; 50 positives)*
WHO PQ	Obtained July 2025	Anticipated by Q4 2027	Anticipated by Q2 2028
Other considerations	4th generation HIV test	Lane 1 - Dual HIV/Syphilis Lane 2 – HBsAg	

Regional Manufacturing of Diagnostics

Regional manufacturing may offer opportunities to increase supply security and regional self-sufficiency. In December 2024, WHO approved the addition of a Nigeria-based packaging and shipping site (Colexa Biosensor Ltd./Codix Pharma Group) for the WHO PQ'd STANDARD Q HIV ½ Ab 3-Line test. This marks the first African packaging of a WHO PQ'd HIV rapid test. In May 2025, WHO and the Medicines Patent Pool announced the first sublicense under SD Biosensor's non-exclusive, transparent license to Codix Bio to develop and manufacture RDTs, initially for HIV. WHO and the Global Fund are supporting rapid verification studies of regionally packaged/manufactured RDTs under the Next Generation Market Shaping Strategic Initiative to accelerate adoption of low-cost, quality-assured diagnostics.[xvii]

A box of Standard Q HIV rapid tests

Unitaid Regional Manufacturing for Equitable Access (RMEA):

- Unitaid launched two US$50 million programs to strengthen African diagnostics and pharmaceutical manufacturing capacity. Manufacturing to Accelerate Diagnostic Excellence (MADE), led by PATH, supports manufacturers in Kenya, Nigeria, Senegal, and South Africa to produce cost-competitive HIV and malaria RDTs for regional and global markets. Another program, Medicines Supply Resilience (MedSuRe) Africa, led by US Pharmacopoeia (USP), enhances active pharmaceutical ingredient (API) manufacturing collaboration and regional bioequivalence testing capacity for HIV and malaria treatments.

WHO:

- WHO's Health Technology Access Program (HTAP) facilitated SD Biosensor's 2023 sub-licensing agreement with Medicines Patent Pool for African RDT manufacturing, which resulted in Colexa Biosensor's STANDARD Q HIV 1/2 Ab 3-Line Test receiving WHO approval for production in Nigeria in December 2024.
- WHO's 3rd World Local Production Forum (April 2025) delivered four recommendations to strengthen regional manufacturing of essential medical supplies: aligning national and regional priorities, promoting health financing partnerships, advancing AI and digitalization across value chains, and supporting environmentally sustainable production initiatives.[xviii]

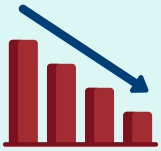
PEDIATRIC HIV

HIV service disruptions are having a profound impact on children, exacerbating existing gaps in testing and treatment outcomes compared to adults.

A healthcare worker dispenses pediatric ARVs in Zimbabwe

- In 2024, there were **1.4 million children living with HIV (CLHIV).**[i] Approximately 55 percent were on ART (compared to 78 percent of adults), leaving just under half still in need of treatment. We have the tools required to close these gaps, and ending preventable deaths from HIV in children was within reach.
- However, the foreign aid cuts threaten to undo years of these hard-won gains:
  - Lifesaving medications, already purchased by US taxpayer-funded programs, have never been delivered, arrived months late, or were left stranded just miles away from dying children.
  - 20 percent fewer infants were tested and 13 percent fewer children initiated ART compared to 2024 averages in surveyed countries. This is more than twice the reduction in ART initiations as seen in adults.
- **Without deliberate and urgent action, CLHIV will face preventable and unnecessary deaths.** A USG funding withdrawal could result in an estimated 350,000 additional deaths, and half of the children will die before their second birthday without rapid access to treatment.

Pediatric ART initiations down
13 percent

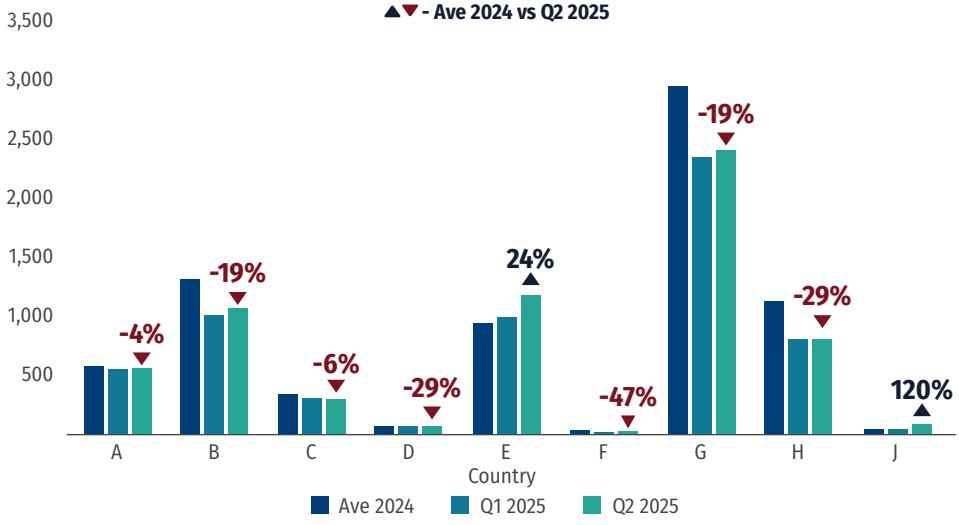


EID testing down
20 percent

Quarterly New Pediatric ART Initiations

Compared to 2024, countries reported an average of **13 percent** fewer children newly initiated on ART by Q2 2025, which translates to 2,000 fewer children starting treatment than last year. This is likely driven by reductions in healthcare workers (HCWs) needed to facilitate testing and treatment initiation, leading to delayed or missed opportunities for diagnosis and linkage. The declines in ART initiations paint a stark picture of health systems under strain.

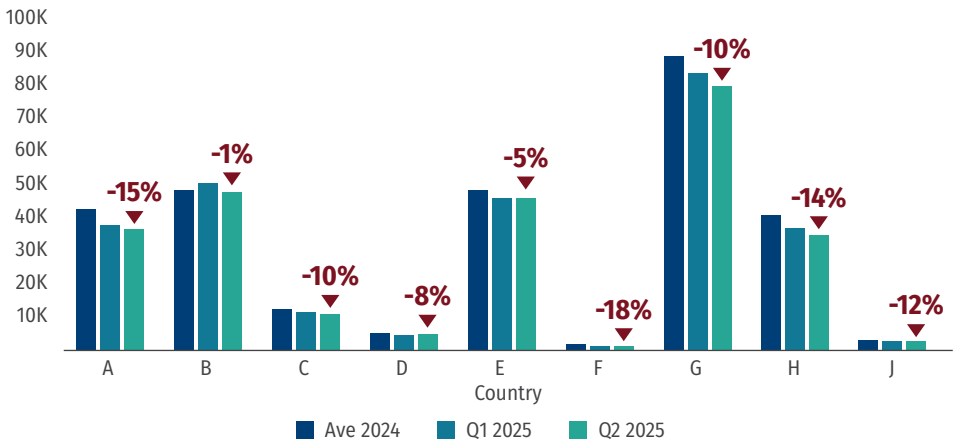
Figure 29. Quarterly New Pediatric ART Initiations



Quarterly Total Children on ART

All countries are reporting declines in the number of children on ART. Q2 2025 totals were **nine percent** below the 2024 quarterly average, extending Q1 decreases, and translating to 26,000 fewer children on ART compared to the 2024 quarterly average. These declines in children are **four to five times greater** than what would be expected from aging-out and baseline attrition alone. This contrasts with the number of adults on ART, which has remained less affected.

Figure 30. Quarterly Total Children on ART
▲▼ - Ave 2024 vs Q2 2025



This suggests reduced pediatric initiations and/or retention challenges are likely driven by loss of access due to the foreign aid cuts. As HIV services are rapidly merged into general health services, families are struggling to navigate where to access care. **HCW numbers have fallen**, while remaining staff face heavier workloads and less time for specialized pediatric support. Community outreach programs, such as peer support, care navigation, and follow-up for children lost to care, have also been sharply reduced.

At the same time, the loss of technical assistance has left major gaps in data analysis and monitoring. With fewer staff able to track pediatric outcomes, it is becoming harder to identify where children are being lost and take swift action to bring them back into care.

PEDIATRIC HIV CASE STUDIES

Community programs supporting CLHIV are at severe risk with funding disruptions, yet these programs could deliver outsized impact to children and families. Two case studies from Zimbabwe and Nigeria highlight their value:

Zvandiri CATS Program Delivers High Value for Adolescent HIV Care

Community outreach programs are at risk with tightening HIV budgets, but evidence shows that peer support remains a powerful way to engage and keep children and adolescents in care. For example, the Zvandiri Community Adolescent Treatment Supporters (CATS) peer-to-peer psychosocial support program for adolescents is a **highly cost-effective model**, delivering benefits on adherence, viral suppression, and mental health among youth living with HIV.[xix] A recent economic assessment of the Zvandiri CATS program in Zimbabwe found that scaling it nationally from 2025 to 2035 would cost US$21.6 million but generate US$24.4 million in net financial benefit, driven by an estimated US$31.7 million in averted treatment costs and US$14.3 million in averted testing costs.[xx]

THRIVE: Community-Led Interventions Reach Pediatric Advanced HIV Disease

In Benue State, Nigeria, a 14-year-old girl lay critically ill at home until an Advanced HIV Disease (AHD) Champion under the Unitaid-funded THRIVE project mobilized neighbors and HCWs to raise emergency funds and bring her to care. Diagnosed with AHD, she received lifesaving treatment thanks to the swift, collective action of her community. Meanwhile, in Makurdi, another 14-year-old became a young mother and nearly abandoned her baby out of fear and despair. A AFROCAB community visit identified this risk, prompting an AHD Champion to step in to offer empathy, practical support, and a path back to care. These **community interventions are saving lives**, ensuring no one is left behind. Read the full blog post to learn more about how communities are rewriting the story of pediatric AHD care under the THRIVE project.

A parent in Malawi prepares HIV medication for their child

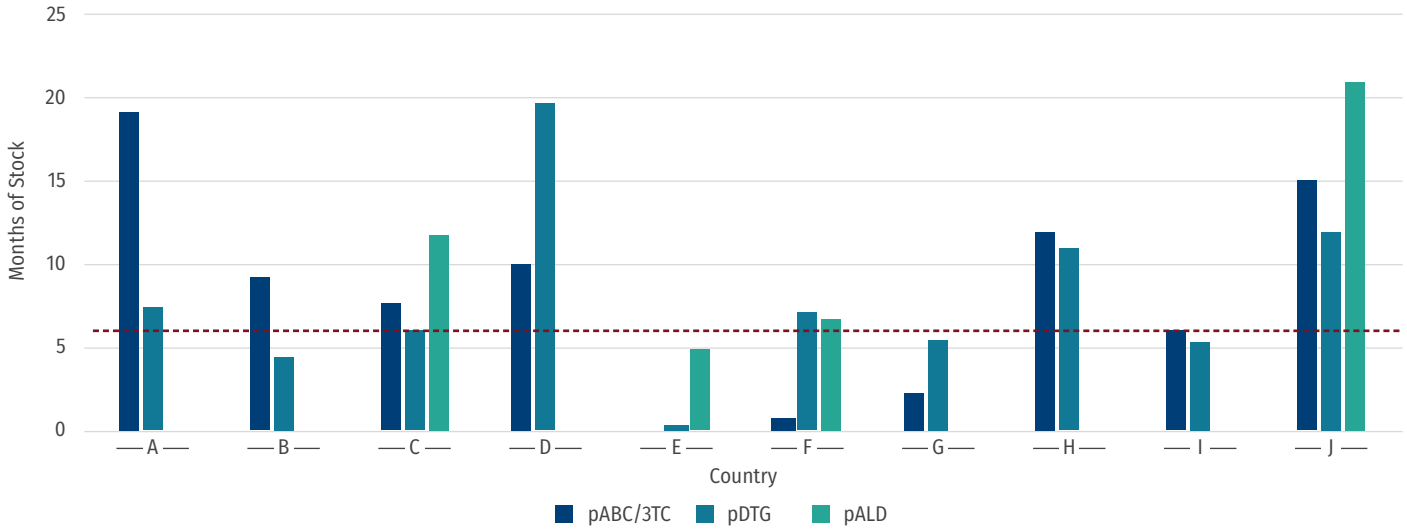
Stock Status: ARVs

6 of 10 (60 percent) countries reported less than six months' stock of at least one pediatric treatment commodity.

At least one country experienced a national stockout of pediatric ABC/3TC/DTG (pALD).

Pediatric Formulation	Average Stock
pABC/3TC	8.2 months (n=10)
pDTG	8 months (n=10)
pALD	8.9 months (n=5)

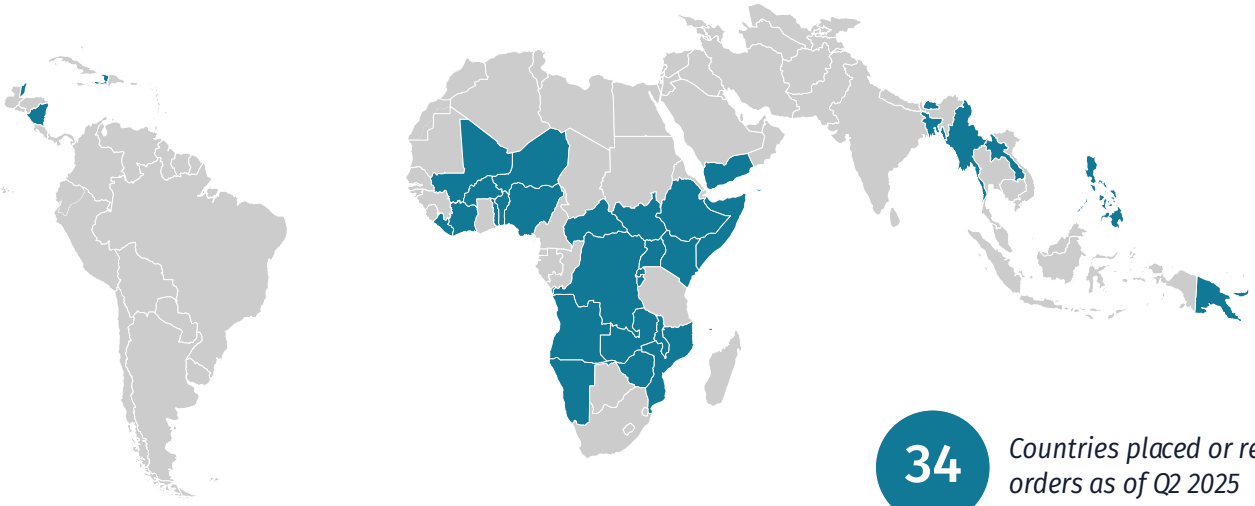
Figure 31. Stock Status: Key Pediatric ARVs



pALD Adoption

Pediatric ALD (pALD) is a dispersible fixed-dose combination (FDC) of ABC/3TC/DTG (60/30/5 mg) recommended for children at least four weeks of age and ≥ 3kg.[ix] This is the first ever pediatric FDC to include DTG, providing the complete WHO-recommended first-line regimen for children in one convenient pill that is dispersed in water. As of Q2 2025, generic pALD demonstrates accelerating global market penetration, with active supply chains established across 34 countries, regulatory approvals secured in 18 countries, and pending submissions in 20 others. The Global Fund is also supporting technical assistance to MoHs to accelerate pALD adoption and implementation planning in a number of countries.

Figure 32. pALD Adoption Map as of June 2025



34 *Countries placed or received orders as of Q2 2025*

4 *Generic suppliers*

We expect additional countries to file and begin planning for transition to pALD in 2026. The pace of transition will largely be driven by existing stocks of pediatric dolutegravir (pDTG) in each country once pALD has been registered. In that way, countries will be able to avoid any wastage of existing stocks.

pALD Implementation Insights

While product adoption has been strong, close attention is required to maintain stable supply chains and ensure smooth transition to pALD. To accelerate adoption and rollout, key considerations include:

- **Fast-tracking adoption** by leveraging existing national recommendations for DTG-based regimens to enable timely policy updates and procurement decisions.
- **Driving smooth transition** by capturing early rollout lessons and guiding evidence-based forecasting and quantification.
- **Reinforcing prescriber education and community literacy** including awareness that pALD is the same medicine in a simpler form and clarity on co-administration considerations with tuberculosis (TB) treatment.
- **Strengthening pharmacovigilance and clinical oversight** as pediatric HIV services are integrated into general healthcare platforms.

Two pharmacists at a hospital in Cambodia holding bottles of pALD

WHO's 2025 Update Simplifies Pediatric HIV Treatment

- **DTG**–based regimens are now preferred from birth, with **pALD** (ABC/3TC/DTG 60/30/5 mg) recommended for children from four weeks of age (≥ 3 kg).[ix] This is the first FDC for infants this young, further expanding access to highly effective drugs and easing dosing and supply planning.

- WHO also advises **phasing out zidovudine (AZT)** and **retaining abacavir (ABC)** in initial and subsequent regimens after failure, reflecting ABC's stronger resistance profile, supporting improved adherence and smoother transitions to once-daily tenofovir disoproxil fumarate (TDF)-based regimens once eligible.*[xxi]

DTG-based regimens now cover nearly all ages, enabling major formulary simplification. Pediatric formulations procured dropped from 24 in 2022 to 18 in 2024 (25 percent reduction) but could now be streamlined further to just 8 to 10 formulations.[xxii] This can reduce procurement complexity, shipping and storage costs, and the risk of stockouts.

** A combined analysis of ODYSSEY and CHAPAS-4 studies showed that AZT performs worse than ABC, even in presence of ABC resistance at baseline (significantly less treatment failures)—recommended to recycling ABC instead of AZT.*

Early Infant Diagnosis

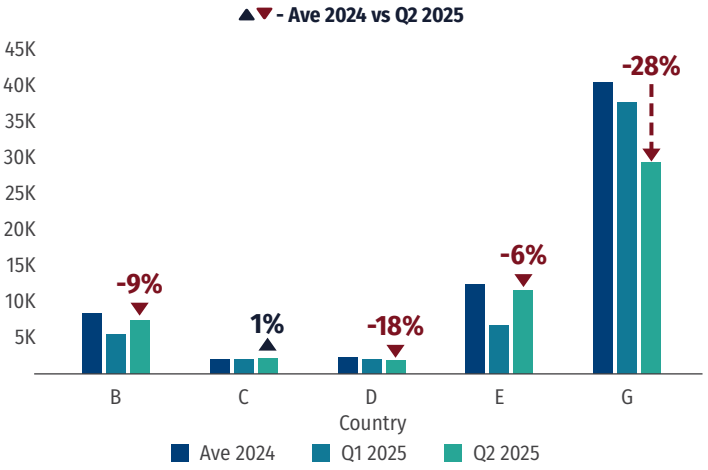
Early infant diagnosis (EID) is a cornerstone of PMTCT and the gateway to timely treatment for children under 18 months. When infants are not tested and linked to care quickly, treatment is delayed and mortality rises sharply. With **funding disruptions** and **service slowdowns** this year, access to EID itself is at risk—**putting one of the most vulnerable populations in jeopardy** of missed identification and preventable deaths.

A healthcare worker in Tanzania collects a DBS sample for EID testing

Quarterly EID Tests Run

Countries are now reporting **20 percent fewer** tests compared to 2024 averages, resulting in **more than 24,000 fewer infants tested**. This signals concerning missed opportunities to diagnose and link infants, most of whom will die without treatment. These declines are likely driven by interruptions in test kit distribution and availability, reduced support for test sample collection, transport, and processing, and reduced data review capacity, impeding efforts to rapidly identify and respond to gaps. Reduced HCW capacity to trace and test infants heightens the risk of preventable deaths.

Figure 33. Quarterly EID Test Volumes

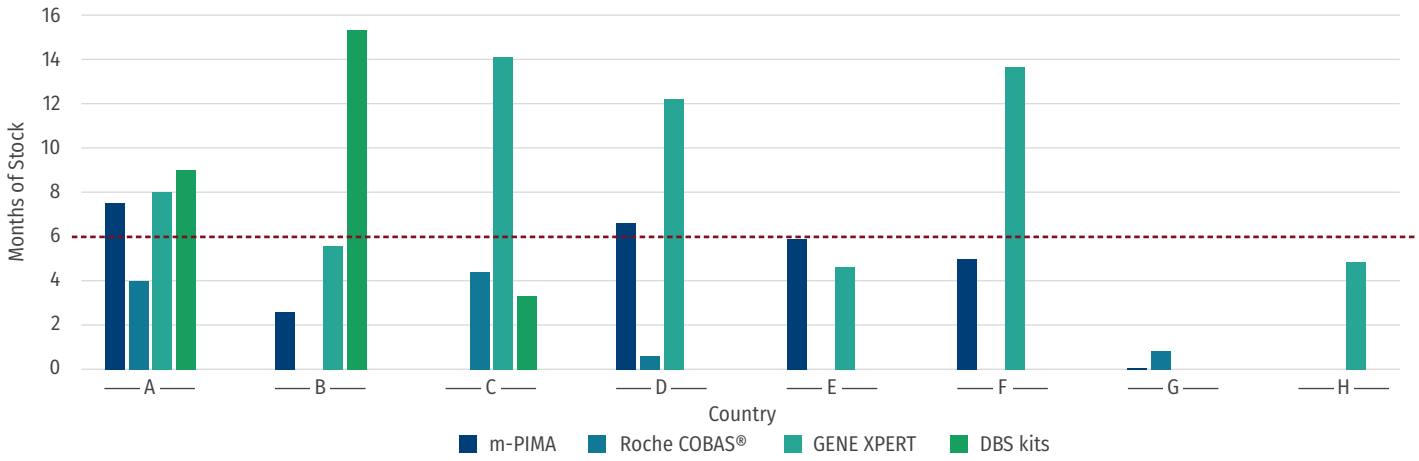


Stock Status: EID Commodities

All eight (100 percent)
countries reported less than six months of stock of at least one EID commodity

EID commodities	Average Stock
m-PIMA	4.6 months (n=6)
Roche COBAS	2.5 months (n=4)
GENE XPERT	9 months (n=7)

Figure 34. Stock Status: Key EID Commodities



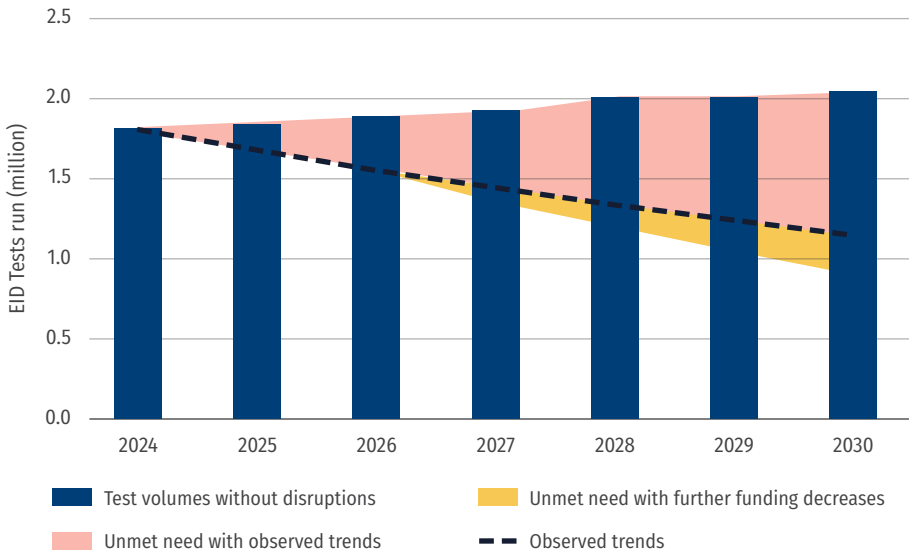
EID Forecast

In 2024, estimated EID volumes in LMICs remained at **1.8 million** and reached only 61 percent of infants in need.[xxiii] Regional disparities remained pronounced, with a particular coverage gap in West and Central Africa (31 percent) compared to higher rates in Eastern and Southern Africa.

A recovery to service delivery back to 2024 levels would lead to an increase in demand to **2 million** tests per year by 2028. But if the 2025 disruptions persist, demand could fall below **1.5 million** by 2027, with further declines if funding for EID service delivery drops even more. This could impact market health and current pricing for EID commodities.

The forecast below combines both point-of-care (POC) and conventional EID testing. Limited data availability remains a barrier to accurate forecasting of POC testing, though historical trends show its increasing use to accelerate diagnosis and treatment initiation.

Figure 35. LMIC EID Test Demand Actuals and Forecast with Funding Disruptions



The blue bars in Figure 35 show the progress in testing coverage without funding disruptions, while the observed disruption scenario (black dotted line) models a compound growth rate based on observed decline in testing across 14 countries following the foreign aid cuts. With additional funding cuts expected, the EID testing uptake is projected to decrease by **50 percent** by 2030. Without adequate resources, a growing number of infants will be left undiagnosed and at risk of preventable death.

PEPFAR AND GLOBAL FUND SIGNALS

- The America First Global Health Strategy prioritizes ending MTCT in select high-burden geographies, with a focus on maintaining critical pediatric HIV commodities (ARVs and EID) and frontline costs in the short-term.
- Community-based service delivery—including peer-led programs and support to help pregnant and breastfeeding women start and stay on ART or PrEP—is not prioritized for full, continued funding by USG. In addition, the PEPFAR DREAMS program, which focused on AGYW, has been eliminated, leaving this vulnerable population without tailored peer support or linkage to contraception and PMTCT services for safe, healthy pregnancy and delivery.

WHAT TO WATCH

- **Numbers of children on ART:** MoHs and partners should closely monitor numbers on treatment and loss to follow-up (LTFU). Where cohorts decline, surge tracing, re-engagement, and community support to bring children back to care.
- **pALD rollout and supply:** Countries and donors should ensure uninterrupted stocks and ensure disciplined phase-in of pALD to allow rapid transition while preventing unnecessary wastage of existing commodities. Sharing clear demand signals with suppliers will help ensure supply security.
- **EID testing:** MoHs and partners should monitor and prioritize testing volumes, commodity supply (dried blood spot (DBS) kits, POC cartridges) kits, and ensure rapid turnaround time and treatment initiation to prevent missed or delayed diagnoses.
- **Key enablers:** Funding cuts, staff losses, weaker data systems, and rapid integration into general services risk leaving children behind. Countries should prioritize testing, tracing, re-engagement, and reliable access to child-friendly treatment to avert a dangerous setback. Innovations that leverage digital health, AI tools, and focused community outreach can help countries retain focus on children with fewer resources.

Pediatric ART Pipeline Update

- **BIC/LEN:**
  - Phase 2/3 clinical study is underway to evaluate safety and tolerability of daily oral bictegravir with LEN (BIC/LEN) among children and adolescents living with HIV ages between 2 to 17 years with no prior INSTI resistance.
- **pTAF:**
  - In June 2025, the FDA approved a pediatric formulation of tenofovir alafenamide (pTAF) with emtricitabine (FTC) (15/120mg) for children 14 to 25kg. The formulation is a solid oral non-dispersible fixed dose combination of 15mg TAF and 120 mg FTC. Based on findings from the CHAPAS-4 study, WHO guidelines now recommend TAF/FTC for children for use in subsequent regimens after failing initial treatment.[xxiv]

A healthcare worker in Lao PDR dispenses ARVs

- **pDRV/r:**
  - The WHO now recommends darunavir/ritonavir (DRV/r) as the preferred boosted protease inhibitor (PI) for children who may require a subsequent regimen if they fail on a DTG-based regimen. DRV/r is more efficacious and has a higher barrier to drug resistance than atazanavir/ritonavir (ATV/r) and lopinavir/ritonavir (LPV/r), previously recommended as part of the subsequent treatment regimen. Programs should plan for transition as pediatric DRV/r formulations, including the forthcoming dispersible FDC, complete regulatory review.
  - In June 2024, Laurus Labs submitted a US FDA new drug application for a dispersible pediatric DRV/r FDC (120/20 mg). During review, the FDA issued updated nitrosamine guidance (September 2024) and a ritonavir-specific notice (October 28, 2024) identifying a newly characterized nitrosamine drug substance-related impurities (NDSRI) and recommending testing of all ritonavir-containing products. As a result, the pDRV/r review was paused while Laurus implements the new requirements and generates additional data. This is a class-wide issue affecting all ritonavir products (including innovator) and does not imply a deficiency of the pDRV/r dossier. Laurus plans to resubmit once the newly required data are available, with timelines dependent on completion of these assessments.

Pediatric Long-Acting Pipeline

- **CAB/RPV:**
  - The interim study result of the Phase 1/2 CRAYON study demonstrated comparable results on monthly intramuscular CAB+RPV injection in children 20 to 40 kg.[xxv]
  - The Phase 3b CROWN study is evaluating the efficacy and safety of two-monthly CAB+RPV injection in adults and adolescents aged 12 years and older with detectable viral loads (VLs). Primary completion is expected in December 2026.
- **LEN + Optimized background regimen (OBR) injection:**
  - Ongoing Phase 2 trial, evaluating safety, tolerability, and efficacy of twice-yearly LEN with OBR among children and adolescents living with HIV up to 17 years and at least 35 kg began in March 2025 with expected primary completion date of June 2026.

ADULT TREATMENT

Following the 2025 funding cuts, countries report dual pressures of declining treatment initiations and increasing loss to follow-up (LTFU) among existing clients.

- The immediate priority is locating and re-engaging individuals who lost access to care due to funding disruptions, while expanding differentiated service delivery (DSD) models to stabilize coverage.
- Without urgent action, treatment cascade gaps will drive increased transmission and preventable mortality.

A healthcare worker in Lao PDR stocks ARVs

ART initiations down
5 percent
from 2024

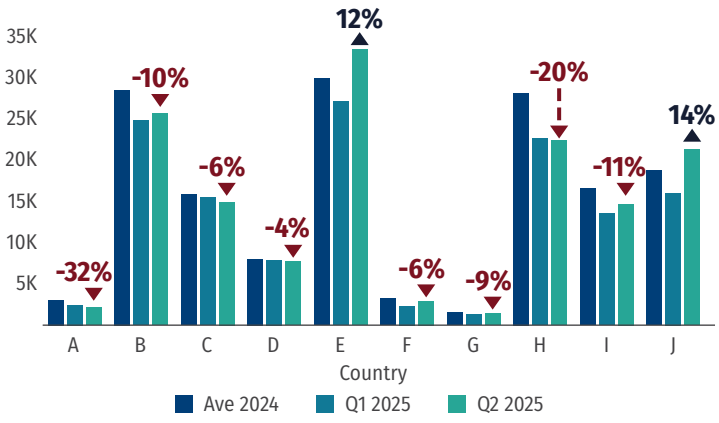
Loss to follow-up
up 10 percent
from 2024

Quarterly New Adult ART Initiations

Adult initiations declined **five percent** in Q2 2025 across 10 countries compared to the 2024 quarterly average, representing nearly **25,000 fewer** clients starting treatment than expected. This likely reflects the reduced HIV testing and HIV positive diagnoses documented in the HIV testing section. However, there are indications in at least two countries that catch-up efforts were made in Q2 to initiate individuals who may have been deferred from initiation in Q1, suggesting early signs of program adaptability to service disruptions.

Figure 36. Quarterly New Adult ART Initiations

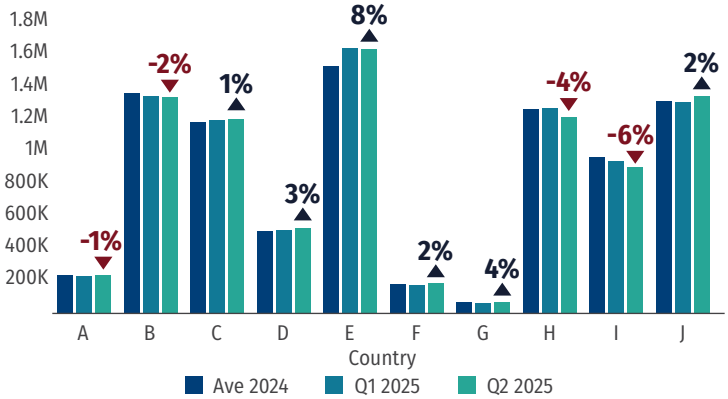
▲▼ - Ave 2024 vs Q2 2025



Given year-on-year declines of approximately 10 percent in ART initiations over the last three years, a mid-year five percent decrease may appear consistent with this trend. However, 2025 is not a normal year; HIV-positive results are down 22 percent and LTFU up 10 percent, indicating a reduced diagnosis pipeline and increased churn out of care. It is possible that initiations in the first half of 2025 were buoyed by backlog clearance and re-starts recorded as new initiations as key services recovered after the initial stop work order (SWO) in Q1. **Without further recovery in case-finding and retention, initiations in the second half of 2025 are likely to fall below trend.**

Figure 37. Quarterly Total Adults on ART

▲▼ - Ave 2024 vs Q2 2025



Quarterly Total Adults on ART

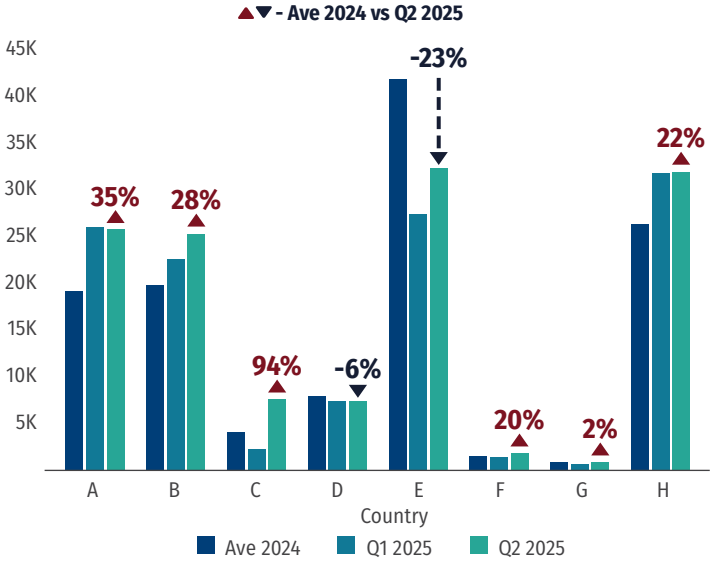
Net growth in ART cohorts is mixed across countries. An average increase of only **0.6 percent** across 10 countries is lower than the expected growth of one percent. In the four countries reporting declines, this amounts to more than 135,000 adults no longer in care in 2025. **However, growth greater than one percent in six others suggests resilience through the first half of the year.** It will be critical to monitor cohort size if challenges with LTFU and new diagnoses persist.

Quarterly Adults Lost to Follow-Up

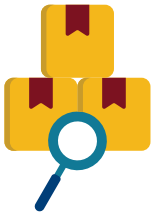
LTFU has increased by **10 percent** on average compared to 2024 quarterly averages. This means **10,000 additional clients dropped out of treatment in the first half of 2025 alone**. This is consistent with the wider stalled ART growth, as the number of new and re-engaging PLHIV is being offset by higher LTFU in several settings. This is a concerning trend and shows that countries continue to face challenges in providing essential services that enable clients to remain in care.

Immediate emphasis should be on retention and rapid re-starts, increased follow-up within communities to identify and reengage those who are LTFU, multi-month dosing (MMD), and support for affected drop-in centers that provided convenient access to ART for many stable patients.

Figure 38. Quarterly Adults in HIV Care Lost to Follow-Up



Stock Status



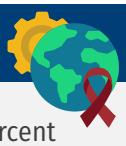
Overall, adult first-line ARV stock levels remain stable across most countries. However,

4 of 10 (40 percent)

countries reported less than six months' stock of at least one other adult treatment commodity.

Key Adult ARVs	Average Stock
TLD	11.8 months (n=10)
DTG	11.3 months (n=10)

PEPFAR AND GLOBAL FUND SIGNALS



- Through the America First Global Health Strategy and draft MoUs, the US has committed to covering 100 percent of commodities and frontline HCW costs in FY2026 at levels that are the same or higher than those from FY2024. However, these commitments do not appear to extend to community-based ART delivery, peer-led linkage and retention, defaulter tracing, and other community-based services that keep people connected to care. As a result, large portions of the treatment delivery ecosystem in many countries will be left unfunded or underfunded in the near to medium term while new arrangements and approaches are defined.
- These gaps could be compounded by reductions in community-based activities following the Global Fund GC7 Reprioritization.
- Further reductions in funding post-PEPFAR Bridge plans and for Global Fund GC8 allocations highlight the need for close coordination between countries, PEPFAR, and the Global Fund to mitigate against current and future gaps in critical treatment services.

WHAT TO WATCH

- **Treatment cohort dynamics:** National programs and partners should track cohort trends, new ART initiation, time-to-initiation, and discontinuation rates to understand how funding disruptions affects treatment coverage and identify where mitigation is most urgent.
- **Program efficiency:** MoHs and partners should identify and evaluate efficiencies in service delivery to inform context-appropriate scale-up decisions. Cost, workload, and outcomes should all be measured to decide which models to maintain or expand and where to leverage private sector engagement as part of the service mix.
- **Community-based services:** Funding cuts disproportionately affected community programs that drive adherence, retention, and viral suppression (e.g. peer support and tracing). Programs, in partnership with community-based and other civil society organizations, should develop and scale models that can reach clients with limited resources to sustain treatment coverage.

CASE STUDY

"I Thought It Was the End—But It Was the Beginning"

Stella's Story of Hope and Healing

Stella Machuma and her now-healthy child in their home in Kenya

When Stella Machuma tested HIV-positive during ANC in Bugoma, Western Kenya in 2023, she could not accept it. Because she felt healthy, the diagnosis did not seem real. ***"I thought maybe it was a mistake,"*** she recalls. Despite counseling, she declined treatment and stopped returning to care.

After delivery, nurses urged immediate treatment for both Stella and her newborn son. However, fear and stigma kept her from accepting care. Her son tested positive, yet she walked away when lifesaving treatment could have begun. The missed opportunity to take advantage of the critical post-natal window for linkage to pediatric HIV treatment had devastating effects on Stella's son.

Without ART, her child's health collapsed. ***"He couldn't sit, crawl, or move. He was always sick."*** With her husband gone and no support, Stella grew isolated and overwhelmed. By the time she returned to the hospital, her son was extremely ill with tuberculosis.

Only then, more than a year after giving birth, were both finally linked to ART. ***"I apologized for rejecting care,"*** she says. ***"The nurse listened instead of judging."*** With treatment, her son slowly grew stronger. ***"Before, he couldn't move. Now he runs."***

Stella's story reflects a broader pattern: too many caregivers leave facilities overwhelmed or afraid, with no community system to bring them back. Adult treatment disruptions do not occur in isolation. When caregivers disengage from care, children are often left behind too, directly driving pediatric HIV infections, LTFU, and preventable deaths. For infants with HIV, these interruptions are deadly. Half die before age two without treatment.

Funding disruptions are deepening these gaps. In just five countries, more than 24,000 infants missed an EID test in the first six months after aid reductions, and the gap continues to grow.

Projects like THRIVE, funded by Unitaid and led by CHAI with AFROCAB and Penta, work to reverse this trend by ensuring that children and caregivers are found, linked, and retained in treatment, starting in pregnancy and continuing through every post-natal visit. AFROCAB's community-based work is especially critical for reaching families like Stella's and ensuring that no one, and no child, is left behind.

Adult ART Forecast

ART coverage surpassed 25 million adults in generic accessible (GA) LMICs in 2024, with **97 percent** on DTG-based regimens (Figure 39).[xxvi] This demonstrates a complete transition to optimized treatment across GA LMICs. CHAI forecasts DTG use to remain steady through 2028, with minimal efavirenz (EFV) use restricted to patients unable to tolerate DTG and marginal NVP or protease inhibitor (PI) use persisting in select contexts.

While impressive, it is important to note a slower growth rate in treatment coverage as case identification of undiagnosed PLHIV becomes more challenging, which will be compounded by reduced resources for testing.

Figure 39. Adult INSTI/NNRTI/PI Use Actuals and Forecast in GA LMICs

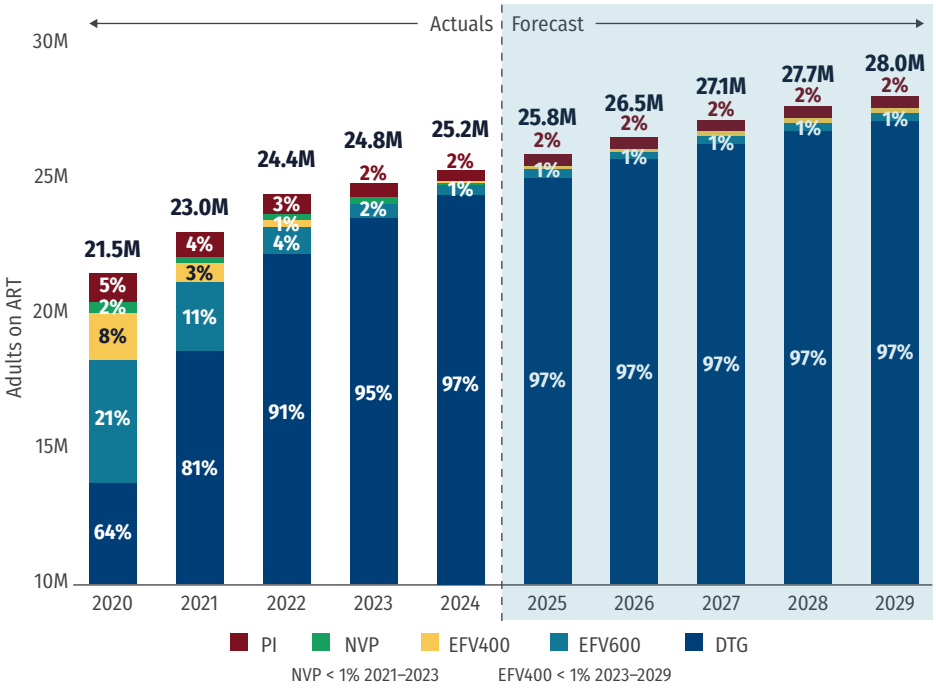
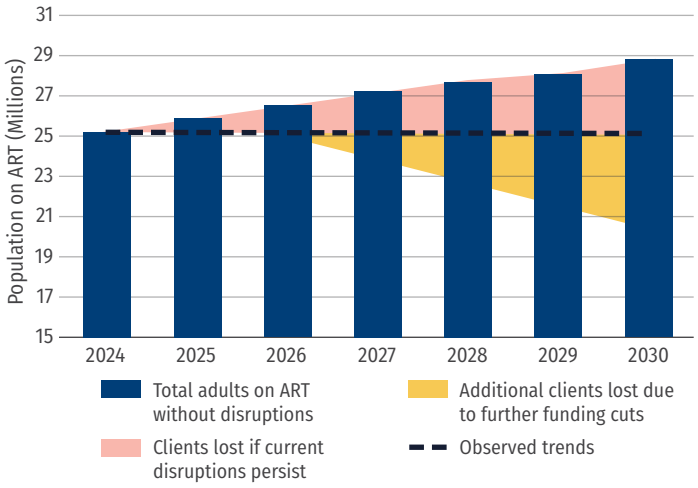


Figure 40. Total Adults Living with HIV on ART Actuals and Forecast with Funding Disruptions



The forecast illustrates projected trends in the number of adults receiving treatment in LMICs between 2024 and 2030 under varying scenarios. The ideal scenario (Figure 39 and blue bars in Figure 40) shows a steady growth in treatment coverage, assuming sustained funding for ART initiation and retention programs. However, the black dotted line projects the impact of observed disruptions in the first half of 2025, such as decline in treatment initiation and increase in number of clients lost to follow-up. If these trends persist, ART cohort growth could stall. Even worse, further disruptions could reverse growth completely, marking the first ever worldwide decline in the number of people on lifesaving ART.

WHO Treatment Guideline Updates: Preferred and Switch Regimens

- **DRV/r as preferred boosted PI if needed:** Elevating this best-in-class PI option with its high resistance barrier and tolerability will improve durability and optimize PI regimens for national programs.
- **Tenofovir backbone: TDF or tenofovir alafenamide fumarate (TAF) + 3TC or FTC preferred for initial and subsequent ART in adults, adolescents, and children ≥30 kg, even after prior TDF or AZT exposure.** This enables nucleoside reverse transcriptase inhibitor (NRTI) recycling, reducing reliance on AZT and allowing programs to streamline sequencing and procurement. This recommendation also comes with potential gains in cost dosing frequency since AZT-based backbones have higher costs and are taken twice daily compared to tenofovir.
- **DTG/3TC dual regimen (simplification switch) for virologically suppressed adults/adolescents without active HBV infection.** Botswana and Brazil introduced the dual regimen, and more LMICs may follow. Programs will need to consider the requirements for HBV screening and VL-informed transitions prior to adoption. Emcure and Cipla have secured tentative US FDA approvals for their DTG/3TC products.
- **Long-acting CAB/rilpivirine (RPV) (switch) for virologically suppressed adults/adolescents without active HBV.** Offering injectables expands options for people who struggle with daily oral adherence but requires reliable visit schedules and injection-service readiness (e.g. cold chain).

Long-Acting HIV Treatment

Recent developments in long-acting treatment (LAT) are reshaping the global HIV response, particularly for the significant challenges in adherence and retention. The latest WHO recommendation for long-acting cabotegravir and rilpivirine (CAB/RPV) injection for treatment, emerging evidence on CAB/LEN combinations, and ongoing development of new candidates demonstrate growing feasibility of LAT use in LMICs.

- A modeling analysis found that the introduction of injectable CAB/LEN could reduce the number of virally unsuppressed PLHIV by 17 percent, HIV mortality by 19 percent, and decrease MTCT transmission by 18 percent. The analysis also predicted that at US$100 per patient per year, the regimen is likely cost effective in all settings, highlighting the opportunity for long-acting ART to transform outcomes for people unable to sustain daily oral therapy.[xxvii]

The findings highlight the opportunity for long-acting ART to transform outcomes for people unable to sustain daily oral therapy, if pricing, supply, and delivery models can be aligned for equitable access.

- **CAB/RPV:** Phase 3b CARES study reported non-inferior clinical outcomes among participants receiving two-monthly CAB/RPV injection in comparison to an oral treatment group at 96 weeks.[xxviii] Viral suppression (<50 copies/ml) stood at **97 percent** in both study arms.
- **GS-1720:** Phase 2 clinical trials (WONDERS-1 and WONDERS-2) investigating the safety and efficacy of an oral weekly regimen of GS-1720 (INSTI) and GS-4182 (LEN pro-drug) were put on hold by the FDA on June 10, 2025 due to decreases in CD4 and lymphocyte counts among subset of participants.
- **Multi-day oral ARVs**
  - Phase 2a and Phase 2b proof-of-concept trials for **VH-184** and **VH-499** respectively showed successful viral suppression among PLHIV.[xxix,xxx]
- **LEN** as treatment:
  - **LEN + GS-3242:** Gilead has announced GS-3242; a phase 1 Integrase strand transfer inhibitor candidate as the preferred partner drug with LEN for twice-yearly treatment of HIV. Phase 1 results on GS-3242 are expected to be presented in 2026.
  - **LEN/TAB/ZAB:**
    - FDA granted Breakthrough Therapy Designation in January 2025
    - A Phase 2 trial on 6-month injection of oral LEN with two broadly neutralizing antibodies (bNAbs), teropavimab (GS-5423, TAB) and zinlirvimab (GS-2872, ZAB), is expected to complete in 2029.
  - **LEN/ISL (Gilead and Merck)**: Two Phase 3 clinical trials (ISLEND-1 and ISLEND-2 studies) on safety of once-weekly oral LEN/ISL combination are underway, with expected primary completion in April 2026 for both trials.
- **Islatravir (ISL):**
  - The FDA accepted the New Drug Application for **Merck's daily doravirine and islatravir (DOR/ISL)** in July 2025 with a potential target action date of April 28, 2026. This would become the first FDA-approved two-drug HIV regimen without an integrase inhibitor if approved.
  - **ISL/ULO:** Phase 2b study on switch to Merck's once-weekly oral combination of ISL with investigational non-nucleoside reverse transcription translocation inhibitor ulonivirine (MK-8507) (ISL/ULO 2/200mg) from daily BIC/FTC/TAF began in April 2025. The expected primary completion is August 2027.

Research Updates

BREATHER Plus study evaluated the efficacy of a short-cycle ART (five days on, two days off) in comparison to continuous treatment in HIV-positive adolescents. Significantly higher rates of viral rebound were reported in the intervention arm.[xxxi] This result underscores the need for continued funding and programmatic efforts to improve client retention and re-engagement programs.

Regional Manufacturing

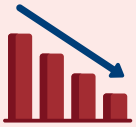
The first procurement of African-made TDF/3TC/DTG (TLD) by the Global Fund occurred in May 2025, with a procurement from Kenya's Universal Corporation. This milestone strengthens regional supply security, reduces import dependence, and advances continental pharmaceutical manufacturing goals.

ADVANCED HIV DISEASE (AHD)

Despite progress in AHD services, many are diagnosed too late, missing critical screening and treatment for tuberculosis (TB) and cryptococcal meningitis (CM), the leading causes of death among PLHIV.

- Foreign aid cuts drove troubling declines in key diagnostics, with CD4 and TB-LAM testing dropping eight and nine percent compared to 2024 averages, leaving tens of thousands without testing.
- Stock security has deteriorated, with 57 percent of countries at risk of stockouts for cryptococcal antigen (CrAg) tests and rising stockout risk for critical treatments like flucytosine (5FC) and liposomal amphotericin (L-AmB).
- Sustaining the AHD package of care requires urgent coordination to reverse these trends, ensure reliable commodity supplies, and maintain focus on AHD as countries assume greater responsibility amid shrinking donor support.

A healthcare worker in Malawi conducts a POC CD4 test



CD4 testing down
8 percent
in 2025

Figure 41. AHD Statistics from the 2025 UNAIDS Report[viii]

1 in 10
AIDS-related deaths were children

25–40%
of PLHIV have AHD, with no change in recent years

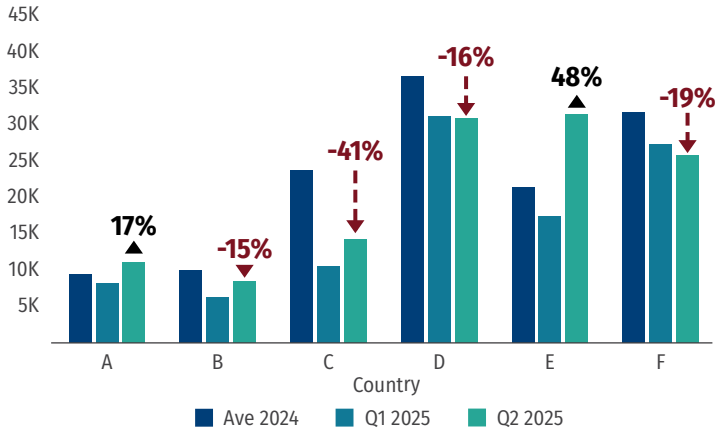
35%
of PLHIV with AHD are men receiving HIV treatment but who do not have a suppressed VL– this population has the highest prevalence of AHD

1 in 5
PLHIV with AHD know their HIV status but are not on ART

1.65x
more likely for men to have AHD compared to women

Figure 42. Quarterly CD4 Test Volumes

▲▼ - Ave 2024 vs Q2 2025



Quarterly CD4 Tests

Across six countries quarterly CD4 testing in Q2 2025 remained **eight percent** lower than the 2024 quarterly average. This translates to more than 41,000 clients who did not receive CD4 testing in these countries alone. Despite improvements from Q1 2025, the stark drop from 2024 underscores the urgent need for sustained efforts to restore testing to levels seen prior to the funding disruptions. One country reported a 48 percent increase in CD4 testing in Q2 2025 compared to 2024, attributed to training additional HCWs during the early phase of the national CD4 testing rollout. Protecting access to CD4 testing is essential as funding cuts threaten the broader HIV care package. Without it, AHD cases will continue to go undetected, with deadly consequences..

Quarterly TB-LAM Tests

Declines in TB-LAM testing volumes were not uniform across countries, indicating that unique country circumstances could be influencing uptake. While one country recorded a decline in Q1 2025 that largely reflects funding-related disruptions, three countries recorded increases in testing volumes. This leaves overall testing levels **nine percent** lower on average across these countries and translates to approximately 4,600 missed clients. However, a small number of reporting countries limits the generalizability of these findings and may amplify the apparent magnitude of change in the overall weighted average.

Figure 43. Quarterly TB-LAM Test Volumes

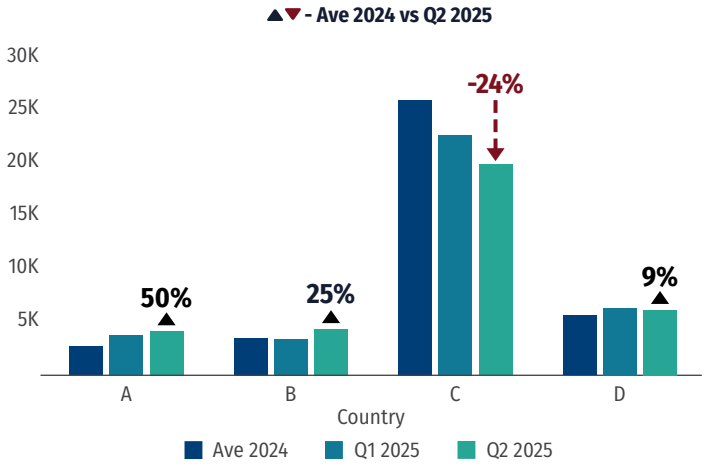
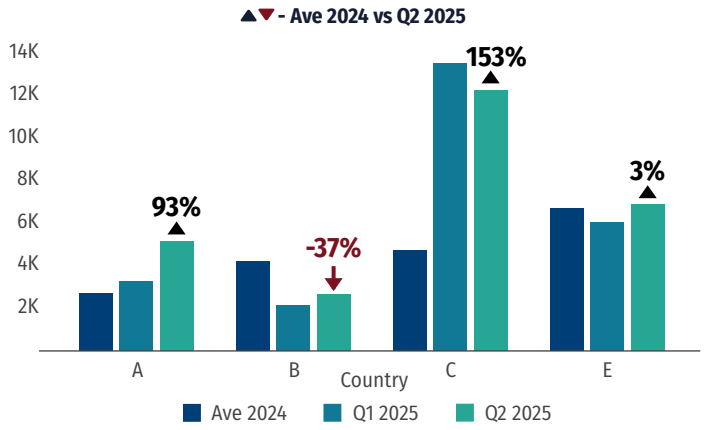
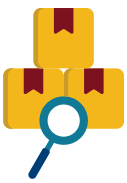


Figure 44. Quarterly CrAg Test Volumes



Quarterly Cryptococcal Antigen (CrAg) Tests

CrAg testing demonstrated notable resilience in 2025, with some countries remaining unaffected by funding disruptions. Overall, CrAg testing recorded a **27 percent increase** in Q2 2025 compared to the 2024 quarterly average, underscoring sustained prioritization of CrAg screening and continued application of WHO staging where CD4 testing remains limited. However, this may not be reflective of the global picture as data is limited and includes countries that are in the early stages of adoption and have been increasing access to CrAg screening during 2024.



Stock Status: OI Screening Commodities

Overall stock levels for CrAg lateral flow assay (LFA) tests worsened between Q1 and Q2 of 2025; **four of seven countries (57 percent)** had less than six months of stock compared with three of six (50 percent) in Q1. In addition, one country reported a national CrAg LFA stockout in August, while another had less than one month of stock remaining in September. In contrast, all six countries indicated sufficient TB-LAM stock in both Q1 and Q2 2025.

CD4 Tests	Average Stock
VISITECT	5.6 months (n=7)
Pima	7 months (n=4)
FACSPresto	13.3 months (n=2)

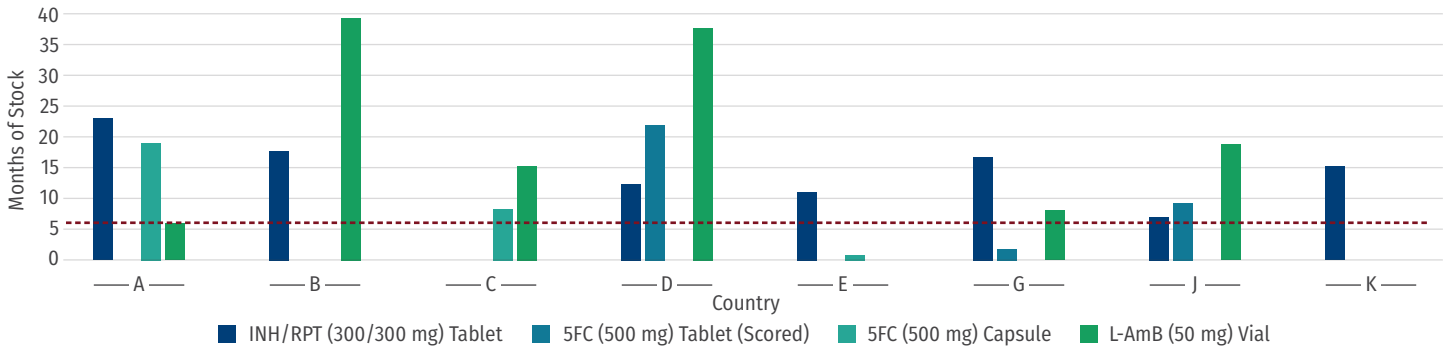
Stock Status: AHD Treatment Commodities

The number of countries at risk of stockout for 5FC and L-AmB for CM increased by 10 and 9 percentage points in Q2 2025 compared to Q1 respectively. Although PEPFAR has resumed treatment commodity orders, supply security challenges persist due to long lead times. On the other hand, the availability of three months of weekly rifapentine (RPT) and isoniazid (INH), also known as 3HP, for TB preventive therapy (TPT) improved by **29 percent** in Q2, with all countries reporting optimal stock levels.

Figure 45. Proportion of Countries at Risk of Stockout of Key AHD Commodities Within the Next Six Months

AHD Commodities	Q1 2025 (%)		Q2 2025 (%)
CrAg LFA Test	50%	Worsened +7%	57%
TB-LAM	0%	No Change	0%
5FC	33%	Worsened +10%	43%
L-AmB	20%	Worsened +9%	29%
INH/RPT	29%	Improved -29%	0%

Figure 46. Stock Status: Key AHD Treatment Commodities



CD4 Market Updates

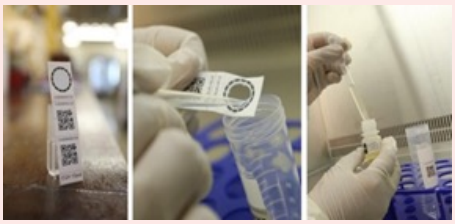
CD4 testing remains critical for identifying and managing AHD in LMICs, yet recent evidence shows declining use and significant unmet need. In many settings, platforms are grossly underutilized, test kits expire, and large proportions of eligible patients still do not receive testing. Despite these challenges, the global community is working to expand access through advocacy, external quality assurance, and innovation in products and service delivery..

Strengthened WHO CD4 Guidance

At IAS 2025, WHO issued **stronger guidance** on the use of CD4 as the preferred method for identifying and managing AHD, particularly on the use of qualitative vs quantitative CD4 testing.[x]

External Quality Assurance (EQA) Program for VISITECT

Through the Unitaid THRIVE and Gates Foundation AHD investments, and in partnership with AccuBio, the manufacturer of VISITECT, the first EQA solution for the VISITECT CD4 LFA is now available from SmartSpot. This follows a successful pilot in Lesotho, Nigeria, and Zimbabwe and provides national programs, donors, and implementing partners with a critical tool to support continuous in-field assessment of test accuracy, result interpretation, training effectiveness, user proficiency, and adherence to test procedures.



Dried tube specimens being run as part of EQA

PROGRAM CHARACTERISTICS:

- **3 EQA cycles** per year, 4 controls per cycle
- **< 1 week Door-to-door delivery** including customs clearance
- **Simple** online result submission
- **6 weeks** ambient stability to date (ongoing, targeting 12 months)
- **ISO/IEC 17043:2023** Accredited
- **Expedited** result reporting
- **6 months** extended stability when stored below -15°C
- **Non-infectious,** dried tube submission

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Rapid Diagnostic Test Reader Solution

TestCard developed a mobile app-based reader that supports quick interpretation and digital capture of RDTs. This technology, which meets 100 percent of WHO's minimum criteria and 90 percent of ideal criteria for readers of RDTs, has the potential to simplify results reading for tests such as the VISITECT, for which interpreting test lines is a known challenge. Under the Unitaid-supported THRIVE project, a real-world feasibility and acceptability assessment is planned in countries where RDT interpretation remains a challenge. While the first use case is VISITECT, the platform is designed to expand to other RDTs in response to the needs and preferences of national programs.

Figure 47. Availability of WHO Prequalified CD4 Testing Platforms and Assays*

▶ Available ▶ Devices discontinued, cartridges available

Use	Brand	Product Type	CD4 Type	Status/Updates
Point-of-Care (POC)	Accubio VISITECT Advanced Disease	Rapid Diagnostic Test	Semi-quantitative (above or below 200 cells/µL)	▶ Available ▶ Shelf-life revised to 12 months, following WHO withdrawal of conditional approval to extend to 18 months
	Abbott Pima	Platform & Cartridges	Quantitative	▶ WHO PQ'd analyzers no longer available for procurement ▶ Continued supply of cartridges and bead standards as well as service and refurbishment of existing analyzers
Conventional	Sysmex Cyflow Counter	Platform & Cartridges	Quantitative	▶ Available, no anticipated changes to platform or cartridges
	Beckman Coulter Aquios CL Flowcytometer	Platform & Cartridges	Quantitative	▶ Available, no anticipated changes to platform or cartridges

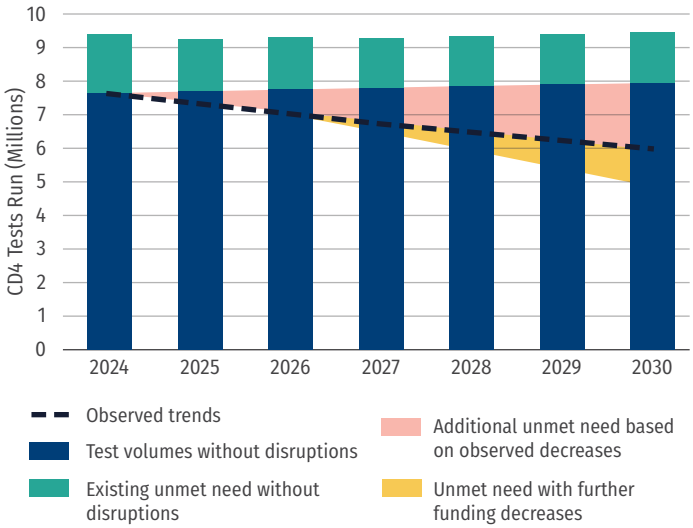
**BD FACSCount and FACSPresto analyzers are no longer available for procurement; however, remaining cartridge stock may still be used, and service support will continue through the end of their shelf life.*

CD4 Forecast

Using data from CHAI-supported countries and Avenir Health, CHAI estimates that about 7.6 million CD4 tests were conducted across LMICs in 2024, with 70 percent conventional and 30 percent POC.[xxxii] Over the next five years, demand is expected to stagnate or decline due to funding constraints that may lower prioritization, procurement, and attention to AHD screening. Even at current levels, a large unmet need persists, particularly for PLHIV not tested when (re)entering care or after unsuppressed VL results.

Because a decline in CD4 count often precedes symptoms, clinical staging alone can miss nearly half of AHD cases, leading to preventable opportunistic infections (OIs) and deaths. Renewed advocacy is critical to keep CD4 testing central to HIV care, as the forecast shows that further funding disruptions could significantly affect testing volumes, access, and program sustainability in LMICs.

Figure 48. CD4 Testing Demand Actuals and Forecast with Funding Disruptions



Cost Effectiveness of the AHD Package of Care in Malawi

In Malawi, a cost-effectiveness analysis found that the WHO-recommended AHD package of care is the most cost-effective intervention for PLHIV among 13 strategies, increasing one-year survival by nearly two percent and quality-adjusted life years (QALYs) by 1.85 percent compared to ART alone, at an incremental cost of just US$580 per QALY gained.[xxxiii]

Adapting Training Methods to Expand Reach in South Africa and Lesotho

In South Africa and Lesotho, CHAI and MoHs used virtual and onsite training models to cost-effectively expand AHD-related clinical training, engaging more than 29,200 participants via webinars in South Africa and demonstrating in Lesotho that an onsite model could train five times as many HCWs as residential training and save up to US$905,000 by 2030.

THRIVE Community-Led Approaches

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Community Interventions:
- Referrals and linkage to care
- AHD screenings
- Community support groups
- Psychosocial support
- Nutrition assessments
- Post-discharge support and home visits

Referrals & Linkages

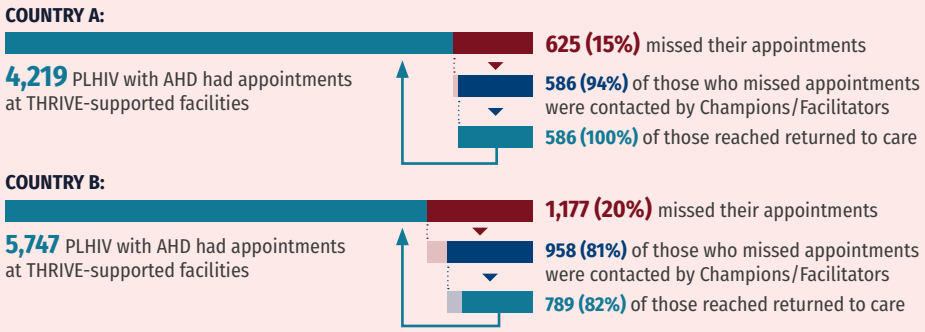
Capacity Building & Sensitization:
- Advocacy
- Awareness campaigns
- STOP AIDS package of care

Referrals & Linkages

Facility Interventions:
- Inpatient and outpatient support
- Adherence counseling
- Support CD4 testing
- Commodity tracking
- Post-discharge follow-up
- Tracking patient LTFU

Figure 49. Follow-Up of Missed Appointments by THRIVE Champions and Facilitators in Two Countries

Missed appointments are often the first sign that a recipient may drop out of care. Champions and facilitators work to prevent that, conducting follow-up visits and phone calls. In August 2025:



Tuberculosis

After COVID-19 waned, TB reclaimed its position as the world's deadliest infectious disease in 2024, with PLHIV up to 16 times more likely to develop active TB, and those with AHD up to 20 times more likely. Despite TB remaining the leading cause of hospitalization and death for PLHIV, only 56 percent of PLHIV and 21 percent of household contacts received TPT, far below the 90 percent coverage target by 2027.[xxxiv,xxxv,xxxvi] PEPFAR had committed to finding two million TB cases and preventing 500,000 TB-related deaths among PLHIV by 2027, supporting 21 high-burden countries to scale AI-assisted screening, while the Global Fund is prioritizing integrated TB/HIV services and shorter regimens. However, funding disruptions in early 2025 have severely impacted service delivery and TPT provision.

TB Prevention Therapy Market Updates

Macleods has held WHO PQ for its 3HP FDC formulation since May 2022, and an accompanying volume guarantee secured a price of US$14.25 per patient course, establishing a clear benchmark for new suppliers. With WHO PQ of Lupin's 3HP FDC, supplier diversity has increased, and prices have fallen further, to as low as US$11.16 prepaid-in-charge (PPC).[xxxvii]

TPT Research Updates

- **SaDAPT study:** Clinical outcomes of PLHIV with presumptive TB who initiated ART on the same day as diagnosis ("ART-first" arm) were non-inferior to waiting for TB test results ("TB-results-first" arm), the standard of care group, in Lesotho and Malawi.[xxxviii]
- **IMPROVE study:** Initiation of the 1HP regimen—once daily dose of RPT and INH for 28 days—in inpatient settings for adults with AHD and CM at three tertiary hospitals in Uganda showed non-inferior clinical outcomes to an outpatient 1HP initiation at six weeks (standard-of-care), and fewer TB diagnoses within the inpatient arm.[xxxix]
- **IeDEA network study** showed a higher post-treatment mortality rate among children and youth living with HIV (0-24 years) compared to CLHIV without TB history for up to 15 years after treatment completion.[xl]

Cryptococcal Meningitis

CM is a fungal infection of the brain and spinal cord, which is the second-leading cause of death for PLHIV.[xli] Access to diagnostic tools and the lifesaving, WHO-preferred treatment regimen (single high-dose L-AmB administered with 5FC and fluconazole) for CM management remains limited globally. Among eight countries that reported stock status, 50 percent have experienced stockouts or had less than two months of stock available for 5FC in Q2 2025. In addition, only 37.5 percent had stock of both L-AmB and 5FC, the preferred CM management regimens.

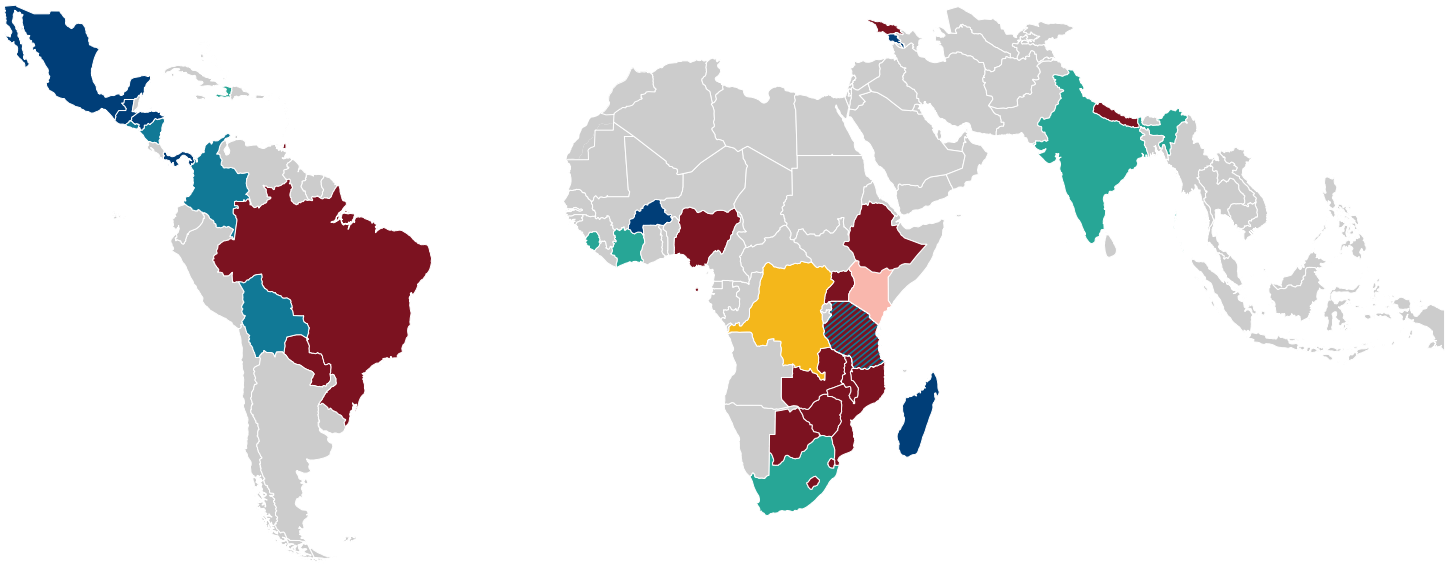
CM Diagnostics Market

Semiquantitative CrAg testing: The first semiquantitative antigen test is now listed by the US FDA for use with serum and cerebrospinal fluid (CSF). At the time of this report's publication, efforts were underway towards attaining CE marking for serum, CSF, whole blood, and plasma.[iv] The test is currently available for procurement.

CM Treatment Market

According to ARV Procurement Working Group (APWG) data, only two additional countries began procuring L-AmB and 5FC in 2024.[xxii] While several high-burden countries in East and Southern Africa have expanded CM treatment programs, progress in other regions remains limited, suggesting that many countries are not yet implementing CM screening and treatment or continue to rely on suboptimal regimens.

Figure 50. 5FC and L-AmB Adoption Map, as of 2024, as Seen by the APWG

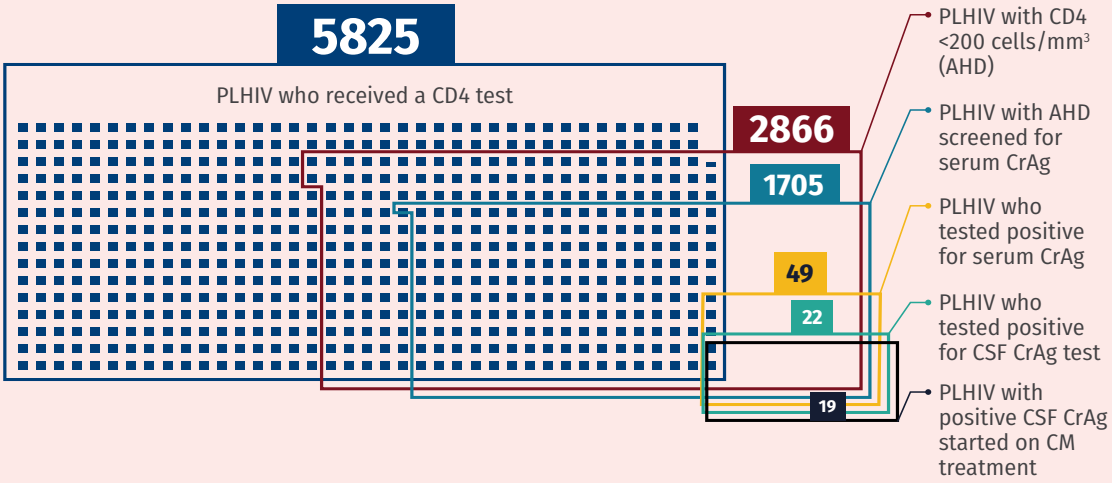


CM SCREENING CASCADE EXAMPLE

Figure 51 shows the 2024 national CM cascade in a CHAI-supported country and demonstrates the dependencies in the elements of the cascade.

For instance, more than 40 percent of PLHIV with AHD did not receive CrAg screening, which indicates substantial missed diagnoses and a serious gap in access to lifesaving CM care.

Figure 51. CM Cascade in a CHAI-Supported Country



CM Research Updates

- **5FC HIV-Crypto study:** A Phase II clinical trial to simplify 5FC administration from every six hours (four times a day dosing) to twice daily is underway in Malawi and Tanzania. If successful, the new sustained release 5FC formulation will reduce dosing frequency and aid adherence during treatment.
- **PLATFORM-CM Trial:** A randomized, open-label platform trial to investigate novel antifungal medicines as part of efforts to identify new and improved regimens for CM management in PLHIV began in early 2025 in Uganda. Currently, the study evaluates the safety and efficacy of two investigational drugs, oteseconazole and Sfu-AM2-19 (AmBisome and fluconazole) in PLHIV, compared to the current standard of care. Even with the current preferred regimen (single L-AmB, 5FC and fluconazole), mortality at 10 weeks of treatment remains high at 24.8 percent. The prospect of new drugs that could further improve survival will be transformational.

PEPFAR AND GLOBAL FUND SIGNALS

- **Anticipated Global Fund GC8 cuts threaten screening, treatment, and service delivery:** The Global Fund's GC7 framework continues to prioritize AHD, including TB and CrAg screening and treatment for CM as part of a comprehensive AHD response. However, cuts anticipated for GC8 threaten both AHD commodity availability and service delivery support as programs look for efficiencies. Commodity gaps and reductions in community-based and facility level activities risk delayed identification and poorer outcomes for people presenting with advanced disease.
- **Essential PEPFAR support for AHD remains uncertain:** USG resumed orders of critical AHD commodities earlier this year after a pause that disrupted supply chains and pushed several countries toward stock outs. The AHD package, including CD4 testing with VISITECT, remains within life-saving activities under PEPFAR Bridge plans, yet support beyond the Bridge period remains unclear.
- **Sustaining AHD requires coordinated investment and national transition:** Donor funding has been central to the scale up of AHD services in recent years, and reductions risk reversing gains for vulnerable PLHIV, including children. Donor support for low-volume, life-saving products such as CrAg LFA, 5FC, and L-AmB has been essential to sustaining the global market and ensuring continued availability for PLHIV.

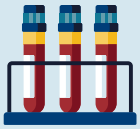
WHAT TO WATCH

- **Sustained focus on AHD programs:** National programs should prioritize AHD services in budgets and implementation plans—including CD4 testing, TB-LAM and CrAg screening, and inpatient AHD care—to prevent service gaps and avoid preventable deaths.
- **Reducing financial burden on clients:** MoHs should ensure consistent availability of AHD commodities and services to prevent out-of-pocket spending and reduce financial burdens for affected households.
- **Market stabilization and procurement coordination:** Donors and governments should sustain demand through pooled procurement mechanisms to mitigate price volatility, ensure supplier participation, and minimize stockout risks. Clear demand signals to suppliers will also be key to ensuring continued market participation.
- **Community outreach for the AHD management:** National programs should maintain community outreach, screening, and retention efforts to reduce LTFU and ensure early identification and management of AHD cases.

TREATMENT MONITORING

Viral load (VL) testing remains essential to confirm treatment is working and to guide timely clinical action, preventing disease progression and onward transmission.

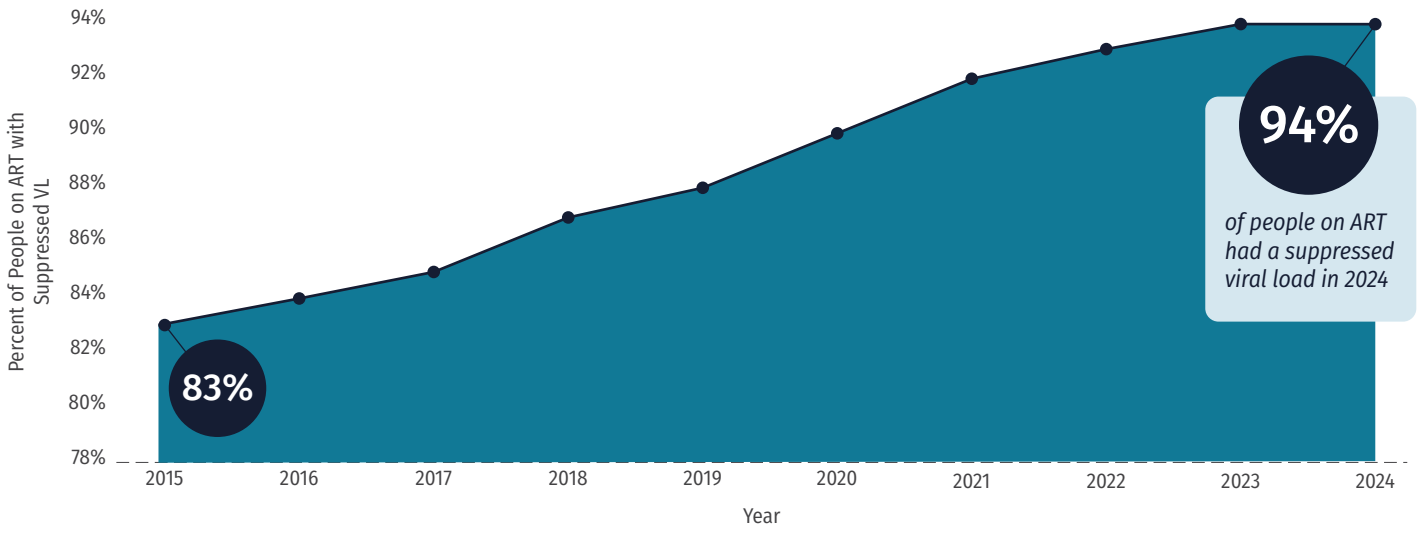
- As countries plan for HIV program sustainability, some are considering adjustments to VL testing schedules to manage tightening resources, especially given the effectiveness and durability of today's HIV treatments.
- Any such changes should be risk-assessed and targeted to safeguard client outcomes and protect the broader diagnostics market.



Over 360,000
missed VL tests in 2025

A lab technician in Kenya runs VL tests

Figure 52. Trends in Treatment Monitoring: Proportion of People on ART with Suppressed VL



Key Treatment Monitoring Highlights

- In 2024, men living with HIV are **13 percent** more likely to have unsuppressed VL than female peers.[i]
- **Only 47 percent** of CLHIV had a suppressed VL, compared to target of 86 percent by 2025, underscoring the need for improved pediatric monitoring and clinical follow-up.[i] However, this target has been achieved for CLHIV on ART, demonstrating the effectiveness of today's treatments.
- Viral suppression continues to be lower among men, KPs, and especially children due to stigma, discrimination, and absent or insufficient resources.
- Women experiencing physical intimate partner violence in the previous year are **nine percent** less likely to be virally suppressed.[i]

A healthcare worker in Kenya collects a blood sample for VL monitoring

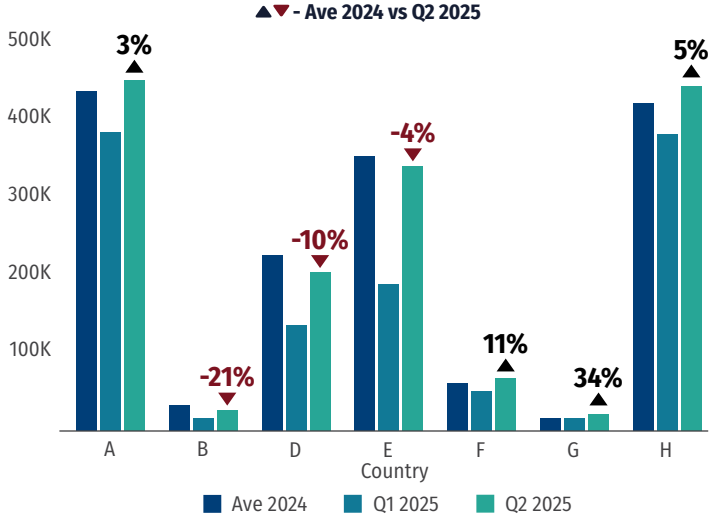
VL Implementation Update

Although 94 percent of people who know their HIV-positive status and are on ART have achieved viral suppression, disruptions in Q1 2025 to lab systems, sample transport, and facility capacity to collect samples weakened monitoring efforts.

Quarterly VL Tests

After a decline in Q1, most countries reported rebounding VL testing volumes in Q2, with many exceeding quarterly averages in 2024. Early signals indicate VL testing has nearly recovered from the 24 percent decline seen in Q1 2025, with Q2 volumes comparable to the 2024 quarterly average. This suggests that mitigation measures to ensure HIV service delivery and lab testing have resolved short-term challenges. However, the observed increase may be due to backlogged sample runs accumulated during the height of the disruptions, given that the drop in Q1 volumes amounted to over 360,000 fewer tests. The true impact of the funding cuts on VL monitoring in 2025 may yet be seen, especially with well recorded impacts on supply chain and referral networks.

Figure 53. Quarterly VL Test Volumes



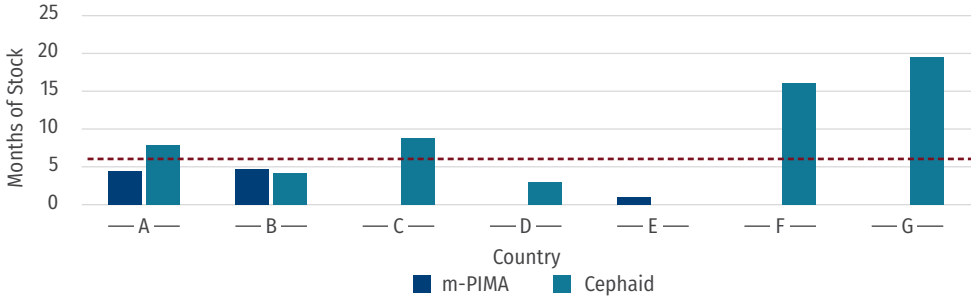
Stock Status: Key Adult ARVs

4 of 7 (57 percent) countries reported less than six months of stock for at least one POC VL cartridge.

7 of 8 (87 percent) countries reported less than six months for at least one VL assay or consumable.

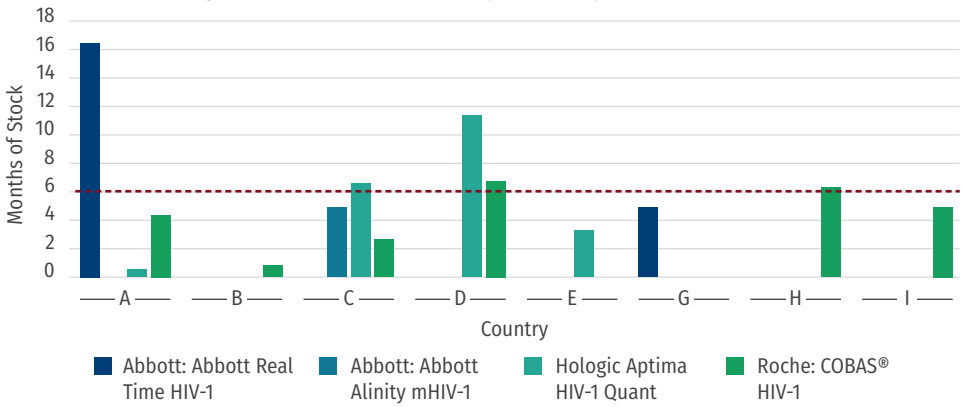
Without adequate VL testing supplies, programs may face delayed detection of treatment failure and missed opportunities to switch clients to alternative regimens, ultimately undermining progress towards HIV epidemic control.

Figure 54. Stock Status: Key VL Catridges



Key VL Catridges	Average Stock
m-PIMA	3.4 months (n=3)
Cepheid	9.9 months (n=6)

Figure 55. Stock Status: Key VL Assays and Consumables



VL Assays and Consumables	Average Stock
Abbott: Abbott Real Time HIV-1	10.6 months (n=2)
Abbott: Abbott Alinity mHIV-1	4.9 months (n=1)
Hologic Aptima HIV-1 Quant	3.1 months (n=7)
Roche: COBAS® HIV-1	4.3 months (n=6)

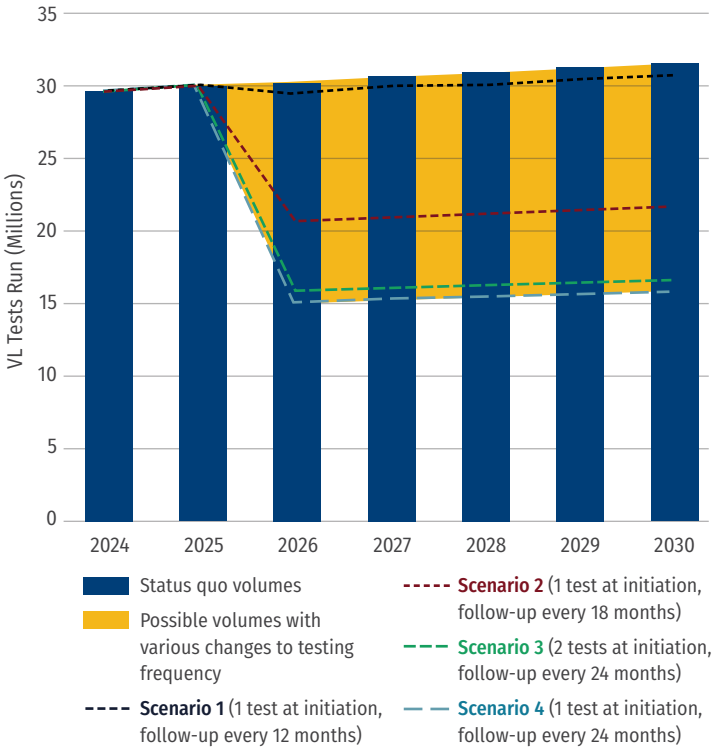
VL Forecast and Implementation Considerations

VL volumes reached a record 29.7 million tests in 2024 and were projected to begin to plateau over the next four years absent new disruptions.[xlii] However, funding uncertainty and potential revisions to VL testing frequency could significantly reshape volumes from 2026 as new USG bilateral MoUs take effect and countries prepare GC8 applications.

The VL forecast illustrates projected changes in volumes in LMICs across testing scenarios. The blue bars show the baseline (status quo) with slow growth tracking ART coverage. The shaded area captures uncertainty from funding disruptions, revisions to testing schedules, and shifts in the number of people on treatment due to other service delivery disruptions (e.g. reduced testing, increased LTFU).

Most countries use a six-month test after ART initiation, a 12-month test, then annual testing. Because existing clients vastly outnumber new initiations, routine annual VL for stable adults drives total volume; changes to this interval have the largest impact, while dropping early tests has only a marginal effect. In the forecast, the shaded band is bounded at the top by status quo testing (no frequency change from 2024) and at the bottom by an immediate switch in 2026 to 24-month intervals for stable adults (approximately 50 percent volume reduction). A shift to 18-month intervals would reduce volumes by roughly **25 percent**. In practice, country choices will likely fall between these bounds, depending on the share of stable clients affected, the pace of roll-out, and exemptions for high-risk groups.

Figure 56. VL Testing Demand Actuals and Forecast with Adjusted Testing Scenarios



To ensure shrinking HIV budgets are directed to highest-impact areas—and to avoid unintended harm—countries and funders considering VL testing schedule adjustments should assess and actively manage:

1. Client outcomes and equity. Model health impacts of any frequency changes, maintaining or intensifying monitoring for higher-risk groups (e.g. children, unsuppressed clients, pregnant/breastfeeding women).

2. System efficiency and cost. Quantify effects on platform utilization, throughput, and unit costs across VL and other molecular programs (e.g. EID). Typical access prices for VL are around US$10 to 13 per test; changes in test volumes can alter cost per test and service contracts.

3. Market health and cross-program effects. Anticipate how lower VL volumes could weaken supplier competition and threaten access or pricing—not only for VL but also for other tests run on the same platform like EID. These increased costs could offset savings from reducing testing frequency if not properly assessed and managed.

PEPFAR AND GLOBAL FUND SIGNALS

- VL monitoring is included in the COP25 Bridge Plan as part of core lifesaving services and in the draft MoUs being negotiated now between PEPFAR and countries to structure support for two to five years. As such, the percentage of people on ART with virologic suppression is included as a key metric for countries in these MoUs.
- The Global Fund underscored using VL testing for treatment monitoring in GC7 reprioritization. However, the reprioritization guidance did allow countries to consider that for contingency planning, VL may be used less frequently or in a more targeted way than WHO recommends (at six months, 12 months, then annually following ART initiation) to reduce costs under severe budget constraints. Similar enabling guidance is expected for GC8, giving countries implementation flexibility.

WHAT TO WATCH

- **Cohort context and signal quality:** MoHs and in-country stakeholders should continue to track ART initiations, discontinuations, and LTFU so VL volumes are interpreted against the underlying cohort. Comparisons between anticipated VL tests based on cohort size, throughput, and known back-logs can help distinguish true recovery from delayed runs. It is critical to also review disaggregation of those receiving VL testing to identify any emerging disparities among different populations (e.g. children, KP) and specific geographies.
- **Policy shifts and market effects:** Procurers and program managers should carefully weigh the anticipated savings from testing schedule changes against client impact, market health, and knock-on effects for other centralized testing programs like EID, human papillomavirus (HPV), and hepatitis. Clear demand signals for suppliers and early engagement will be key to avoiding any supply-side disruptions and understanding implications of reduced testing volumes.
- **Implementation guardrails:** If testing schedules change, countries should set explicit safeguards, maintaining more frequent monitoring for high-risk clients such as children, pregnant/breastfeeding women, and anyone with recent non-suppression. Strengthening turnaround time and prompt clinical action will remain critical.

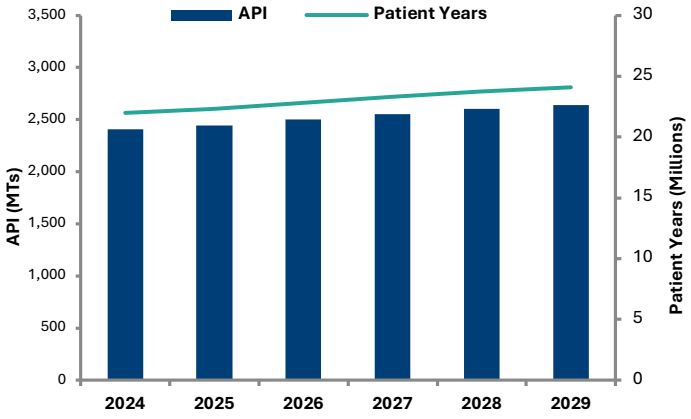
HIV Drug Resistance

Effective and timely treatment monitoring through VL testing is critical to detect early treatment failure and curb the development of HIV drug resistance. The WHO's HIV Drug Resistance Fact Sheet from June 2025 shows DTG resistance is more likely among individuals with extensive treatment histories. In addition, a modelling study of predicted DTG resistance in PLHIV in South Africa indicates an increasing trend of acquired DTG resistance among individuals on failing DTG-based ART regimens, with resistance closely associated with the duration of viremia while on treatment.[xliii] Despite this, DTG continues to deliver strong outcomes, with over 90 percent of patients maintaining viral suppression when adherence is consistent. Even among those unsuppressed, actual observed resistance remains minimal. Resistance to NRTIs, such as TDF or 3TC, can rise sharply when PrEP is started during undiagnosed acute HIV infection.[xliv]

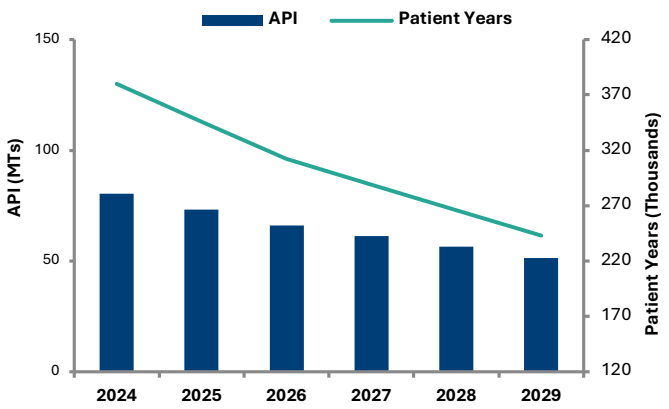
The Central Medical Stores in Malawi recieves a shipment of diagnostic commodities

Appendix A: Forecasted API Demand in GA LMICs

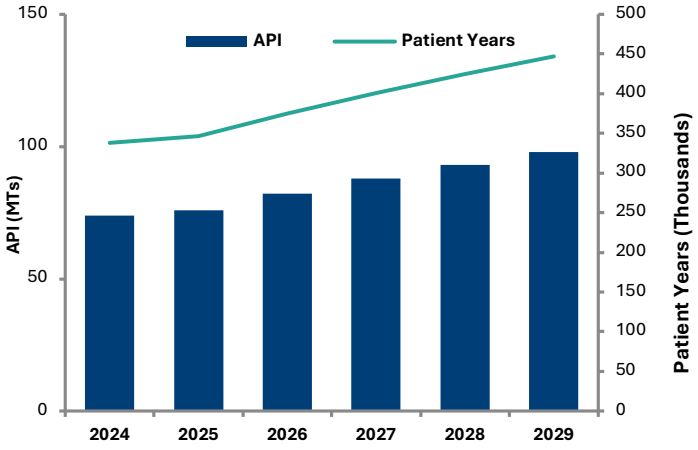
TDF API



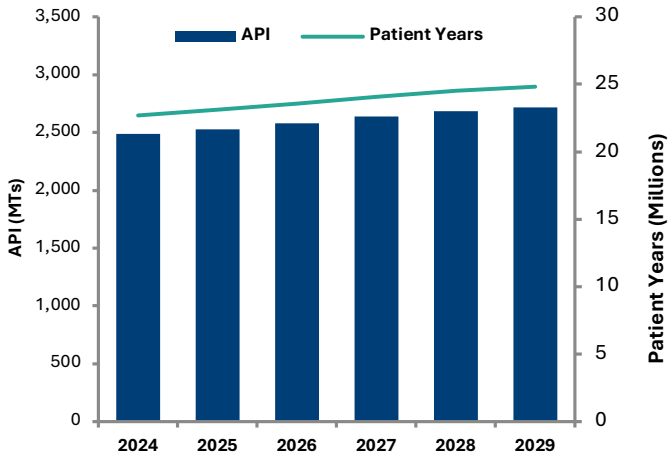
EFV API



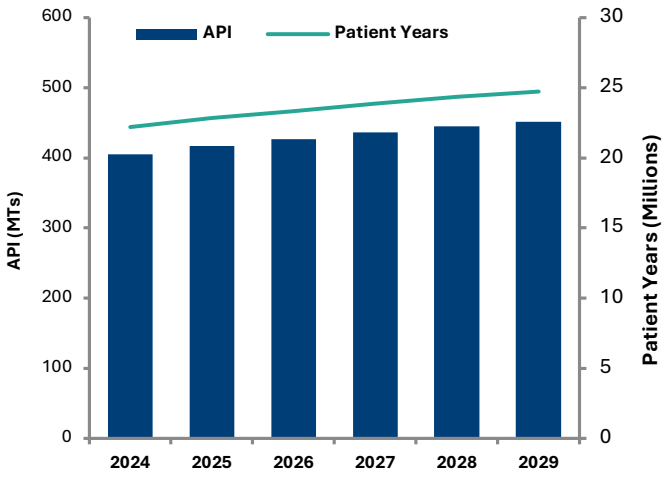
AZT API



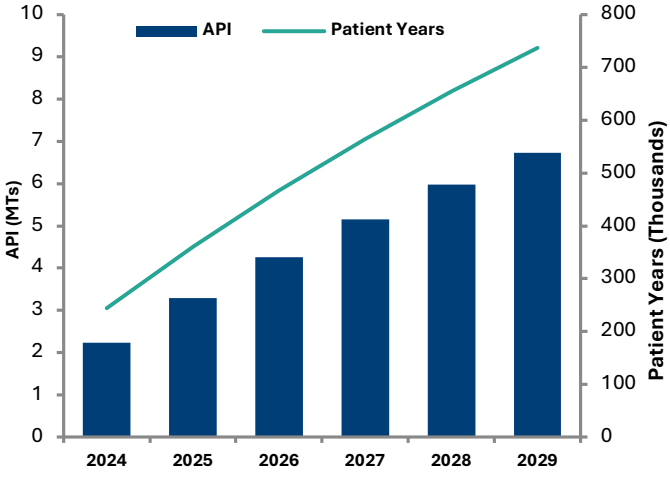
3TC API

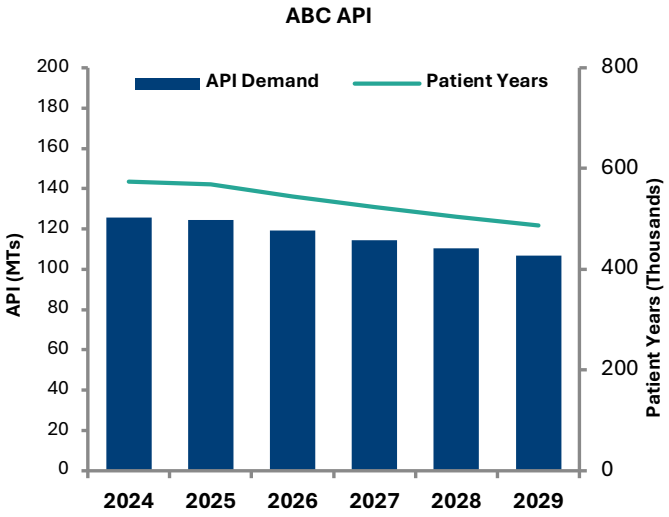


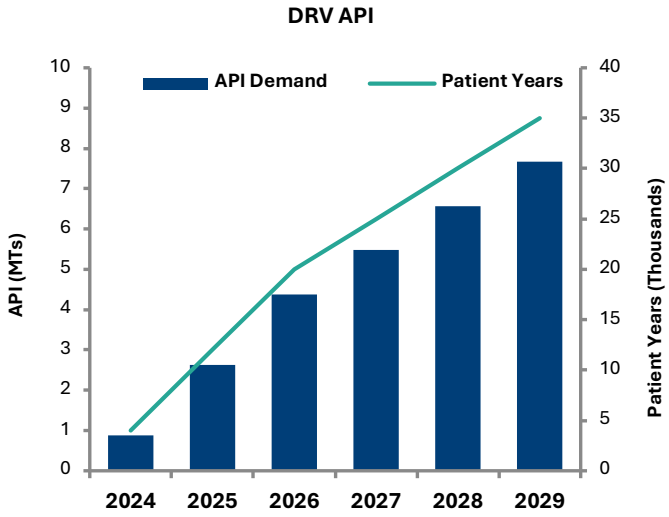
DTG API

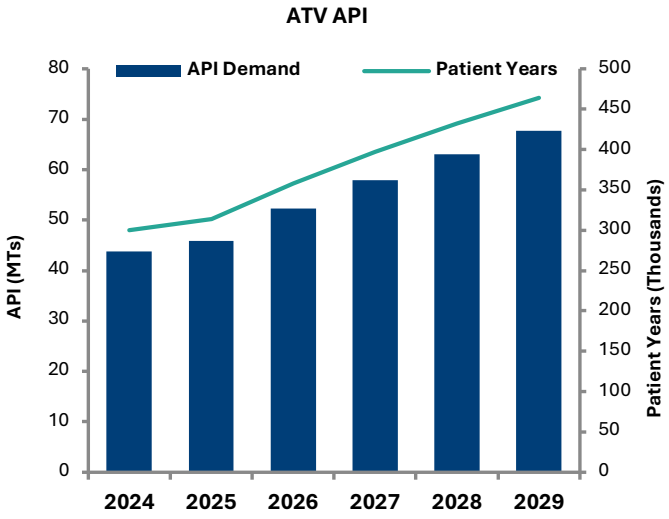


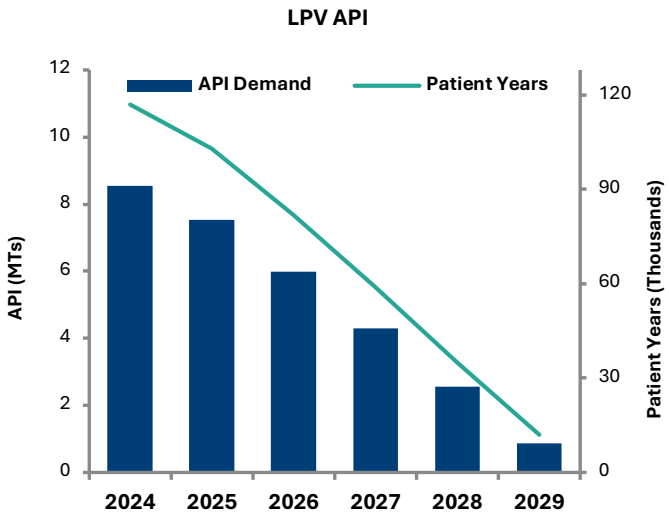
TAF API




ABC API
API Demand
Patient Years
API (MTs)
Patient Years (Thousands)
200
180
160
140
120
100
80
60
40
20
0
800
600
400
200
0
2024
2025
2026
2027
2028
2029


DRV API
API Demand
Patient Years
API (MTs)
Patient Years (Thousands)
10
9
8
7
6
5
4
3
2
1
0
40
35
30
25
20
15
10
5
0
2024
2025
2026
2027
2028
2029


ATV API
API Demand
Patient Years
API (MTs)
Patient Years (Thousands)
80
70
60
50
40
30
20
10
0
500
450
400
350
300
250
200
150
100
50
0
2024
2025
2026
2027
2028
2029


LPV API
API Demand
Patient Years
API (MTs)
Patient Years (Thousands)
12
10
8
6
4
2
0
120
90
60
30
0
2024
2025
2026
2027
2028
2029

Appendix B: CHAI ARV Benchmark Price Comparison List

The table below provides per pack or bottle prices (USD) for key adult and pediatric ARVs. Prices are Ex-Works (EXW).

PRODUCT	PACK SIZE*	GLOBAL FUND PPM PRICE OCT 2025[1]	GHSC-PSM E-CATALOG PRICE OCT 2025[2]	RSA WEIGHTED AVE TENDER PRICE 2025-2028[3]
Adult Products				
ABC/3TC (600/300 mg)	30 tablets	$7.85	$12.35	$5.14
ATV/r (300/100 mg)	30 tablets	$10.50	$10.45	$6.94
AZT/3TC (300/150 mg)	60 tablets	$5.35	$7.00	$3.91
DRV/r (400/50 mg)	60 tablets	$17.50	$27.95	$16.27
DTG (50 mg)	30 tablets	$1.10	$1.21	$1.85
DTG (50 mg)	90 tablets			
LPV/r (200/50 mg)	120 tablets	$17.95		$11.65
RTV (100 mg) heat-stable	60 tablets			$3.91
TAF/3TC/DTG (25/300/50 mg)	30 tablets	$4.75		$3.91
TAF/3TC/DTG (25/300/50 mg)	90 tablets		$14.22	$11.50
TAF/FTC/DTG (25/200/50 mg)	30 tablets	$4.75	$5.43	
TAF/FTC/DTG (25/200/50 mg)	90 tablets		$15.00	
TDF (300 mg)	30 tablets	$2.40	$2.40	$1.33
TDF/3TC (300/300 mg)	30 tablets	$3.00		
TDF/FTC (300/200 mg)	30 tablets	$3.29		
TDF/3TC/DTG (300/300/50 mg)	30 tablets	$2.87		$2.55
TDF/3TC/DTG (300/300/50 mg)	90 tablets	$8.60	$9.16	$7.11
TDF/3TC/DTG (300/300/50 mg)	180 tablets	$17.20	$18.27	
TDF/3TC/EFV (300/300/400 mg)	30 tablets	$4.50		
TDF/3TC/EFV (300/300/400 mg)	90 tablets	$12.75		
TDF/3TC/EFV (300/300/600 mg)	30 tablets	$5.25		$3.40
TDF/FTC/EFV (300/200/600 mg)	30 tablets			$10.59
Pediatric Products				
Optimal Formulary				
ABC/3TC (120/60 mg) disp. scored	30 tablets	$2.70	$2.70	$2.56
ABC/3TC (120/60 mg) disp. scored	60 tablets	$5.35	$5.35	
ABC/3TC/DTG (60/30/5 MG) DISP.	90 tablets	$7.40	$7.55	
ABC/3TC/DTG (60/30/5 MG) DISP.	180 tablets	$13.50	$14.85	
AZT (50/5 mg/ml) oral solution	240 mL bottle	$2.50	$2.00	
AZT/3TC (60/30 mg) disp. scored	60 tablets	$1.90	$1.90	
DTG (10 mg) disp. scored	30 tablets		$1.45	$1.21
DTG (10 mg) disp. scored	90 tablets	$4.00	$4.22	
LPV/r (100/25 mg) heat-stable	60 tablets	$6.40		$3.18
LPV/r (40/10mg) oral granules	120 sachets	$16.9		$11.65
NVP (50/5 mg/ml) oral solution (with syringe)	100 mL bottle	$1.75	$1.75	$0.93
Limited-Use List				
3TC (50/5 mg/ml) oral solution	240 mL	$2.25	$2.15	$1.06
DRV (75 mg)	480 tablets	$65.00		
DRV (150 mg)	240 tablets			
LPV/r (40/10 mg) oral pellets	120 capsules	$17.25		
NVP (50 mg) disp. scored	60 tablets		$1.60	
RAL (100 mg) granules	60 sachets		$57.00	
RTV (25 mg) heat-stable	30 tablets	$3.00		

1) Global Fund Pooled Procurement Mechanism Reference Pricing: ARVs, October, 2025. Link.
2) Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) E-Catalog: ARVs, October, 2025. Link.
Prices represent the latest blended average pricing of actual procurement.
3) Republic of South Africa 2022-2025 Tender, weighted average price across awarded suppliers, 1 USD = 18.73 ZAR exchange rate used per Tender documents.
Ex-Works prices have been calculated by removing 15% VAT and 5% in shipping; prices subject to forex-based adjustments; some pack sizes differ slightly from those listed above, see tender for full details.

** For certain products, pricing on other pack sizes might be available (e.g. multi-month prescription pack sizes). Please refer to relevant price list for more information.*

Appendix C: Notes on Methodology

There are several CHAI analyses from which many figures in this report are derived:

- **ART Patient Forecast:** Each year, CHAI develops a forecast for the total number of patients on ART in generic-accessible LMICs (GA LMICs). 'Generic-accessible' denotes countries where global generic manufacturers can register and supply a large proportion of that country's ARVs. For this purpose, CHAI defines GA countries as those LMICs that are covered under voluntary licenses for generic TDF/TAF, or for where there are no patents. The largest *generic-inaccessible* countries are Brazil, China, Mexico, and Russia.

  CHAI compiles historical data on the number of patients on ART from the UNAIDS AIDSinfo Database. For each country, CHAI assumes that the number of people receiving treatment will increase at the same rate as the linear trend observed in the last four years and will plateau as universal access (under a "Treat All" paradigm) is approached.

  Historical ART coverage rates for GA LMICs are calculated based on data available in the UNAIDS AIDSinfo Database as of October 2025. The numerator and denominator are derived by only including countries with both ART and PLHIV data available for the age category in question (adults vs. children).

- **Adult ARV Demand Forecast:** CHAI collects aggregate country data on patient regimens, formulations used, national guidelines, and anticipated future trends from CHAI country teams and published literature each year. CHAI uses that data, an internally developed forecasting model, and the ART patient forecast to project ARV demand in GA LMICs over the next five years at the global level. CHAI's 2025 ARV demand forecast for current drugs includes data from: Cambodia, Eswatini, Ethiopia, Indonesia, Kenya, Laos, Lesotho, Malawi, Nigeria, South Africa, Tanzania, Uganda, Zambia, Zimbabwe. These countries represent approximately 64 percent of adult patients on ART in GA LMICs in 2024.

- **Diagnostics Forecasts:** CHAI's VL, EID, and CD4 diagnostics forecasts have two primary components: 1) diagnostic testing demand, and 2) diagnostic testing need. While the exact methodology differs slightly between VL, EID, and CD4 tests, the general approach is as follows:

  For *demand*, CHAI collects baseline (2024) testing volumes from CHAI country teams, uses publicly available dashboards, or other sources with supplemental data from Avenir Health and the WHO survey. For CD4 and EID, demand is forecasted by applying historical compound annual growth rates (CAGRs) to baseline data. CHAI forecasts VL demand by assigning countries to one of five growth analogs based on real-world viral load scale-up and hypothetical scenarios. CHAI assigns these analogs based on country intelligence around future scale-up plans. Testing needs are forecasted based on the estimated number of patients each year and country-level testing guidelines for each type of test. The estimated CD4 need is based on 1.1 CD4 tests at initiation (accounting for wastage/retesting) and 1-2 tests for those with an elevated VL result. National guidelines and implementation may differ from these assumptions. Need estimates do not include CD4 testing used for treatment monitoring. For all test types, CHAI forecasts at the country level and then aggregates globally across all LMICs.

  Demand, need, and coverage are estimated at the test level, and not the patient level (i.e., coverage is estimated as the number of tests run divided by the number of tests needed, not the number of patients receiving tests).

- **Funding Disruption Scenario Forecasting:** In response to foreign aid cuts in 2025, CHAI developed scenario-based forecasts for VL, EID, CD4 testing, and ART patients to assess programmatic impact of funding disruptions. The baseline scenario applies linear CAGR projections from historical trends assuming stable funding conditions, while the disruption scenario incorporates H1 2025 reductions in testing and treatment volumes following PEPFAR cuts and Global Fund GC7 reprioritization. The further funding disruptions uncertainty range (shaded areas) models upper and lower bounds using observed 2025 mid-year CAGR under varying PEPFAR Bridge Plan/MoU, Global Fund GC8 Cycle Replenishment, and policy outcomes, quantifying how funding conditions may affect diagnostic access, treatment monitoring, and ART continuity.

- **Measuring Uncertainty in Forecasts:** CHAI applies a standardized approach to estimate uncertainty ranges. These ranges capture plausible upper and lower bounds around each forecast, reflecting variability in underlying data, recent growth trends, and future program performance. For each country, CHAI analyzes the rate of change over the past four years as a CAGR and projects for future growth based on this trend, adjusting for expected slowdowns as full treatment coverage is approached. To account for uncertainty, alternative growth scenarios are modeled assuming faster or slower scale-up and different timelines for reaching peak coverage. At the aggregated level, country-level results are combined to generate regional and global ranges.

- **Stock Status and Implementation Reporting:** Stock status and implementation data presented in the report were collected from 14 countries across sub-Saharan Africa and Southeast Asia and is valid as of October 2025. For the purposes of data anonymization, country identifiers vary across different sections of the memo but have been kept consistent within each section.

  An at-risk status is defined as less than six months of stock on hand, calculated as total national stock divided by average monthly consumption from the previous months. The stocks levels were reported by the countries, and it is unclear whether these figures were adjusted for months with stockouts. No adjustments were made to account for the expected scale-up or funding disruptions. Where a stockout occurred, the team specified the month of occurrence to distinguish no consumption (delayed or missing data) and actual stockouts (confirmed unavailability). CHAI made efforts to validate all data, but accuracy may be impacted by ongoing reporting challenges precipitated by funding constraints.

Appendix D: References

i *UNAIDS, AIDSInfo Database*, Acc. Nov 2025. Link

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