

# HIV MARKET IMPACT MEMO



March 2025

This is a special edition of the Clinton Health Access Initiative's HIV Market Impact Memo, a brief highlighting the significant risks facing global HIV markets and the broader implications for HIV service delivery in low- and middle-income countries (LMICs) following disruptions and withdrawal of USG funding and uncertainty about the future funding landscape. Data presented is from a CHAI request to 14 countries and is valid as of March 2025. Updates will be made on an ongoing basis, given the rapidly shifting funding and procurement landscape. Countries' degree of impact depends on their reliance on PEPFAR in addition to other funding sources; further analysis is required as the situation evolves.

## Background

Cuts, delays, and uncertainty around global HIV funding exposed vulnerabilities across the HIV cascade. Beyond commodities, service delivery constraints—including human resource shortages and implementation limitations—threaten the ability of programs to ensure that essential HIV products reach those who need them most.

These critical gaps underscore the need for **urgent action** to mitigate supply chain fragility and address service delivery challenges to protect the **continuity of HIV services worldwide** and **avert preventable deaths**.

**PEPFAR Support**

- 20.6M** PEPFAR-Supported People Living with HIV
- \$736M** Total Procurement Budget (2024, USD)
- 370K** PEPFAR-Supported Workforce

## Country-Level Commodity and Client Impacts

### Prevention

Severe Disruptions

**4 countries**

at risk of stockout of oral PrEP alongside extensive service delivery disruptions. CAB-LA introduction severely disrupted in several countries.

### Testing

Moderate to Severe Disruptions

**10 countries**

at risk of stockout of early infant identification commodities. Medium-term risk to adult testing products.

### Advanced HIV Disease

Severe Disruptions

**10 countries**

at risk of stockout of AHD commodities, which will result in preventable AIDS-related deaths.

### Treatment

Moderate Disruptions

**8 countries**

at risk of stockout of adult or pediatric ARVs. Ongoing pediatric product introductions in jeopardy.

### Monitoring

Severe Disruptions

**13 countries**

at risk of stockout of viral load (VL) commodities, which could result in increased drug resistance and onward HIV transmission.

## Supply Impacts

### PEPFAR Procurement



**30-35% of ARV revenue** for the major Indian generic producers comes from PEPFAR-funded ARVs. PEPFAR spent **\$283M on ARV procurement** in FY24.



**US\$55M** value of stock currently in supplier warehouses at risk of cancellation or non-payment, posing a significant risk to business operations, cash flows, and return on investment.

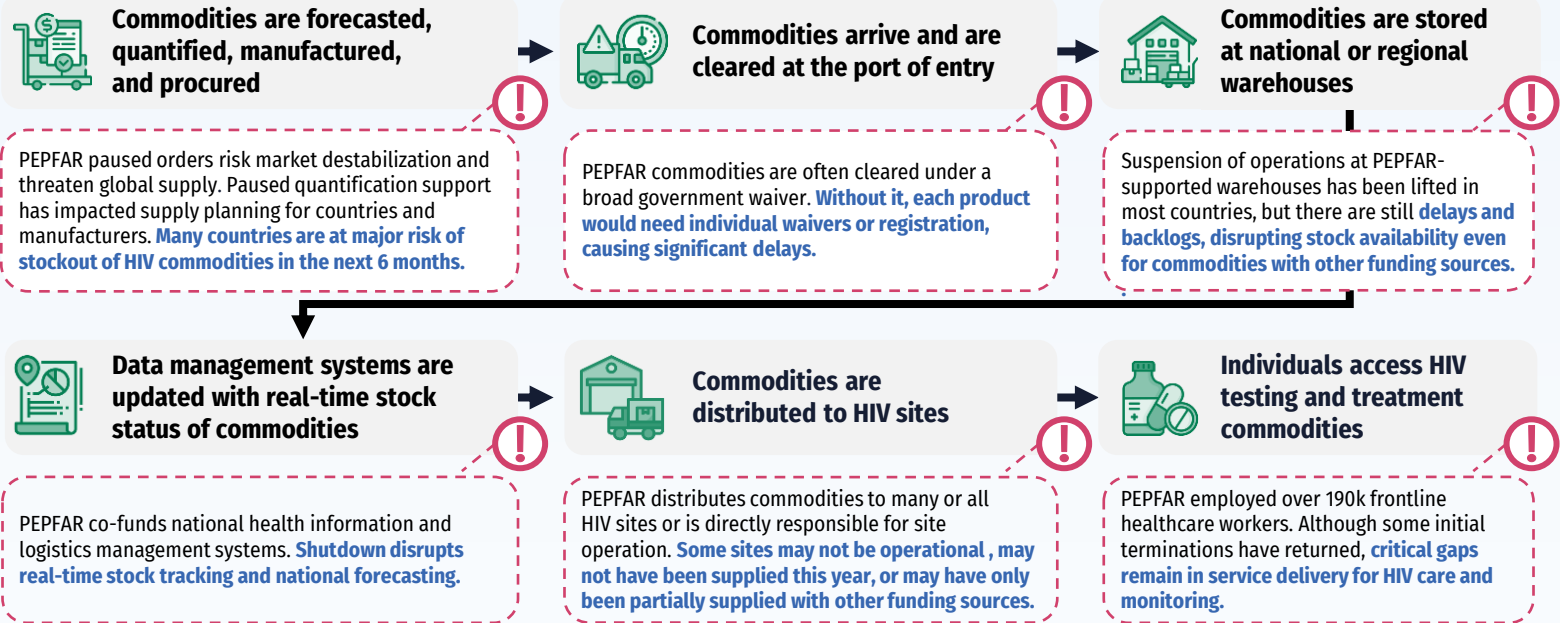
### Key Impacts of Uncertain Funding Outlook

- 1** Increased risks related to access pricing, and potential supplier decisions to exit certain markets, which would threaten current access, particularly for low volume/single-supplier products.
- 2** Heightened risks for suppliers to participate in market shaping efforts due to uncertainty.
- 3** Increased risk of stock-outs and delays in ongoing transitions to optimal formulations and new product adoptions, such as pediatric ALD (pALD).

### Mitigation Strategies

- Strengthen collaboration and communication between governments, donors, and suppliers to reduce risks, prioritize sustainable access, and ensure suppliers remain committed to the HIV market.
- Consider supplier needs during funding transition planning to maintain a stable marketplace and safeguard progress.

# Critical Gaps Across the Supply Chain



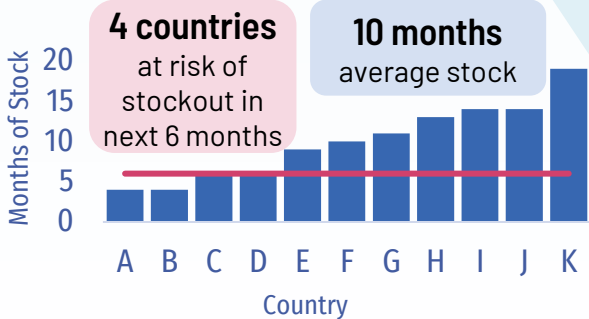
Every step along the supply chain has been impacted by the PEPFAR funding freeze.

*Illustrative example (not exhaustive)*

## Prevention

### Oral PrEP

Stock Status: Oral PrEP



Even where stock is available centrally, **PrEP access at facilities is limited** due to:

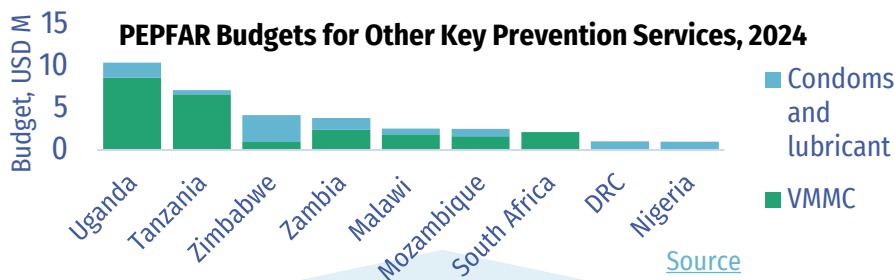
- Deprioritization of last-mile distribution
- Constrained population focus among many implementers (USAID waiver only covered PrEP for pregnant and breastfeeding women)
- Closure of key distribution points (e.g. key population-focused drop-in centers, adolescent and youth-focused channels, and community-based delivery)
- Reduced numbers of trained PrEP providers

### Long-Acting Cabotegravir (CAB-LA)



**CAB-LA introduction has been severely disrupted** (PEPFAR purchased 95% of ViiV's LMIC CAB-LA supply in 2024). While PEPFAR-donated vials have been distributed to 12 countries for introduction and/or studies, the largest donation (>230K doses to South Africa) was not completed, others are inaccessible in central warehouses, and all are impacted by service delivery disruptions. **Only 6 countries** placed orders through the Global Fund as of early January.

### Other Prevention Services



Voluntary medical male circumcision (VMMC) and condom/lubricant access has been reduced or paused in PEPFAR-supported countries.

**9 countries** received \$1M+ in support for VMMC, condoms, and lubricants in 2024

Reduced access to PrEP and other prevention services will contribute to a **surge in new infections** – key populations and young people are among the most vulnerable across PEPFAR countries.

# Testing

## Early Infant Diagnosis (EID)

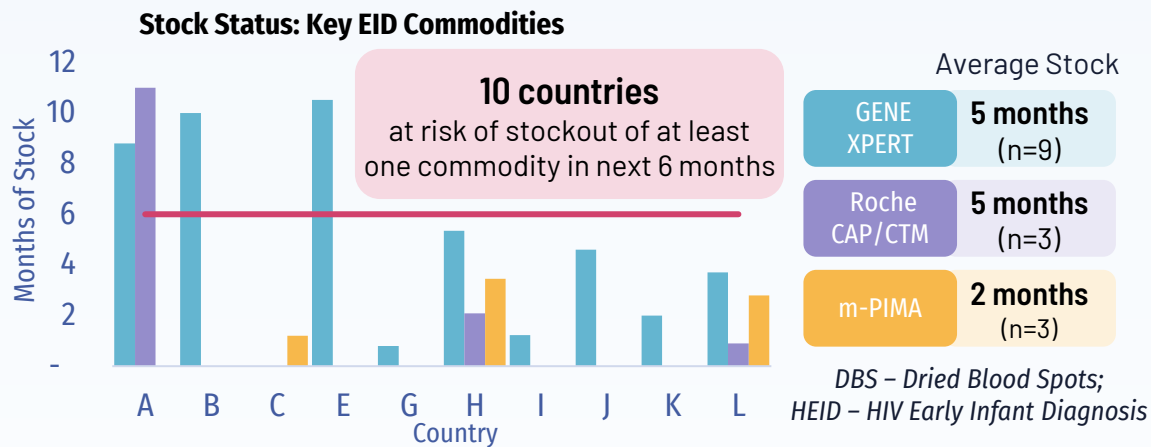
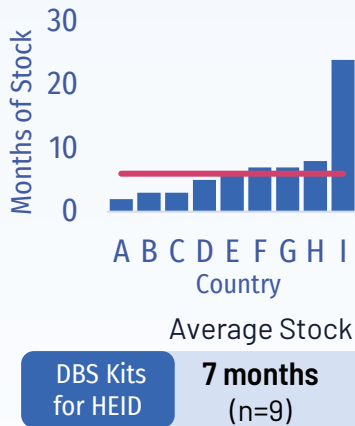


EID is a critical process for detecting HIV infection early in newborns and infants born to pregnant women living with HIV, enabling rapid access to lifesaving treatment.



Stock levels for critical EID commodities are at **high immediate risk** with some already stocked out and others facing stock out in less than 3 months.

Ensuring access to EID services is essential for reducing pediatric HIV-related morbidity and mortality. 50% of children **die before the age of two** if they are not identified and initiated on treatment.



## HIV Testing Services (HTS)

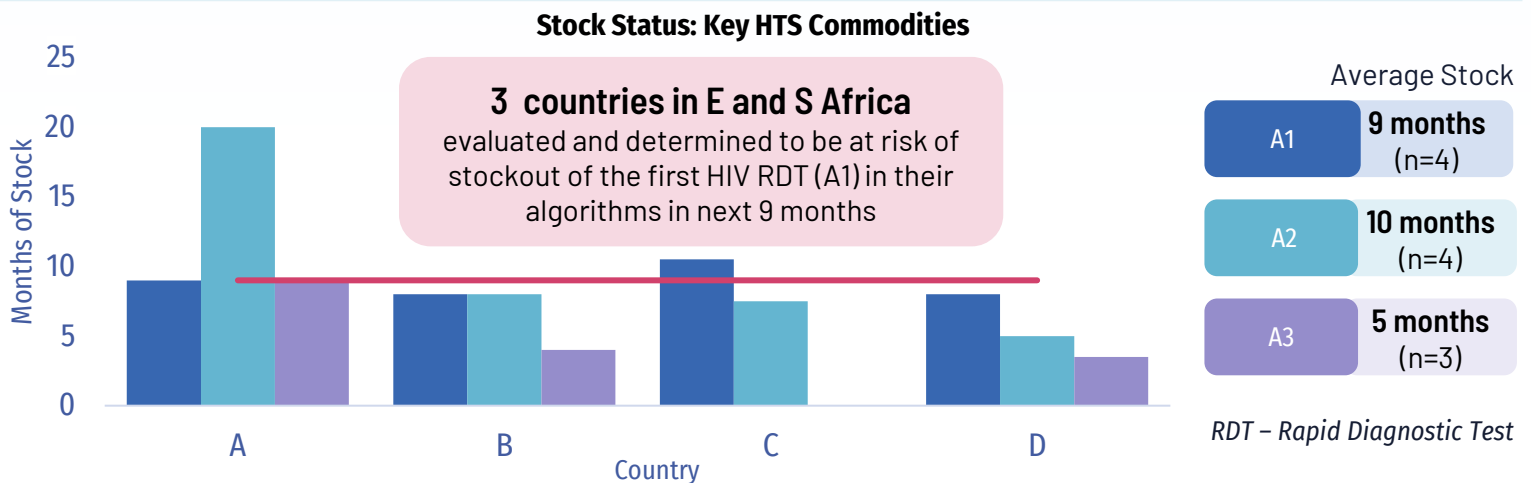


HTS includes a range of strategies to identify individuals living with HIV or at risk of HIV infection and link them to treatment or prevention services.



**Moderate risk of stockouts** for HIV RDTs later this year, with countries having the lowest stocks of A2 and A3.

Interrupted access to testing services and commodities risks delayed diagnosis and initiation on treatment, impacting health outcomes and increasing HIV transmission.



Large-scale terminations of healthcare workers (HCWs) in high-burden countries expected to **significantly impact HIV Testing Services**, which often rely on implementing partners or USG-funded cadres, particularly in the highest-burden areas. In one country, USAID funding cuts led to the termination of 53% of HTS-focused HCWs, leaving massive gaps in access to testing even when commodities are available.



According to WHO, **countries can consider leveraging HIV self-tests** as a cost-effective and efficient approach for increasing access to HTS, with WHO-prequalified HIV self-tests **available for as low as US\$1 ex-works (EXW)**. This is a critical tool to maintaining access to HTS considering the HCW gaps.

# Advanced HIV Disease (AHD)

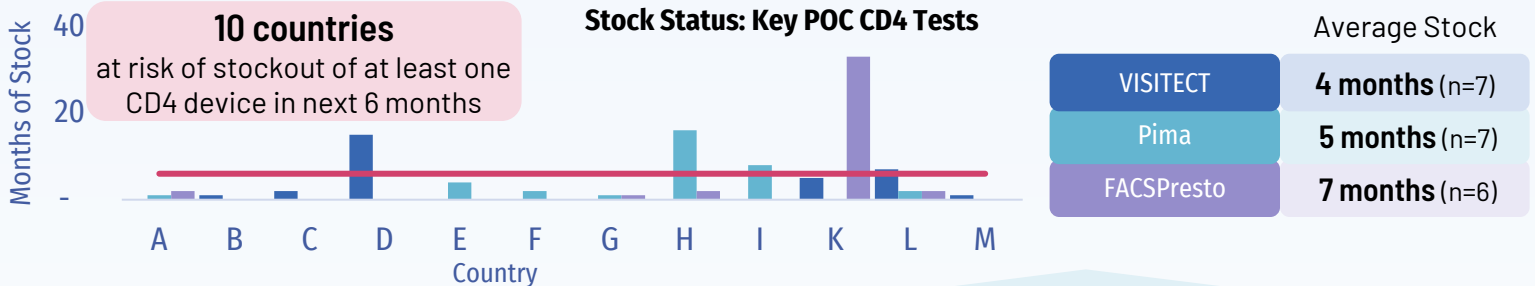
## Commodity Supply Risks



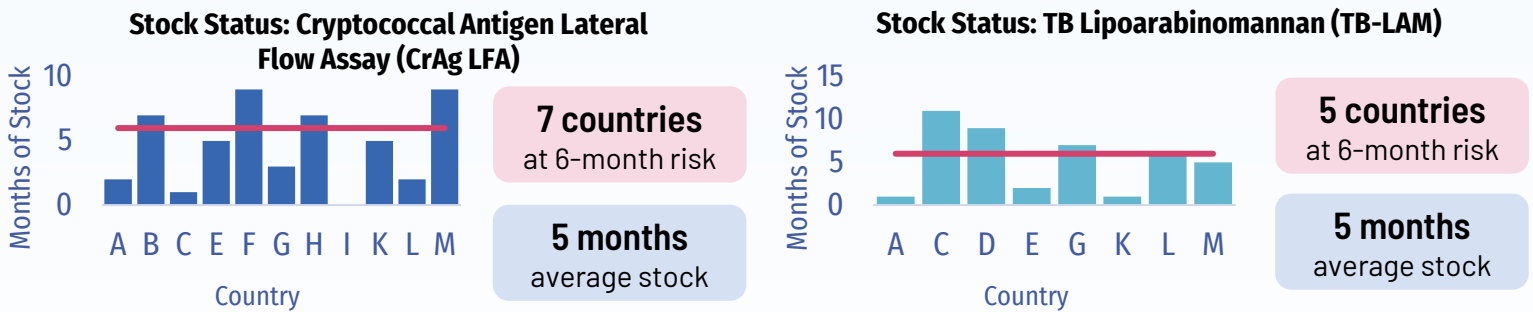
AHD is defined as a CD4 count < 200 cells/ $\mu$ L or the presence of a WHO stage 3 or 4 condition, such as TB and cryptococcal meningitis (CM).



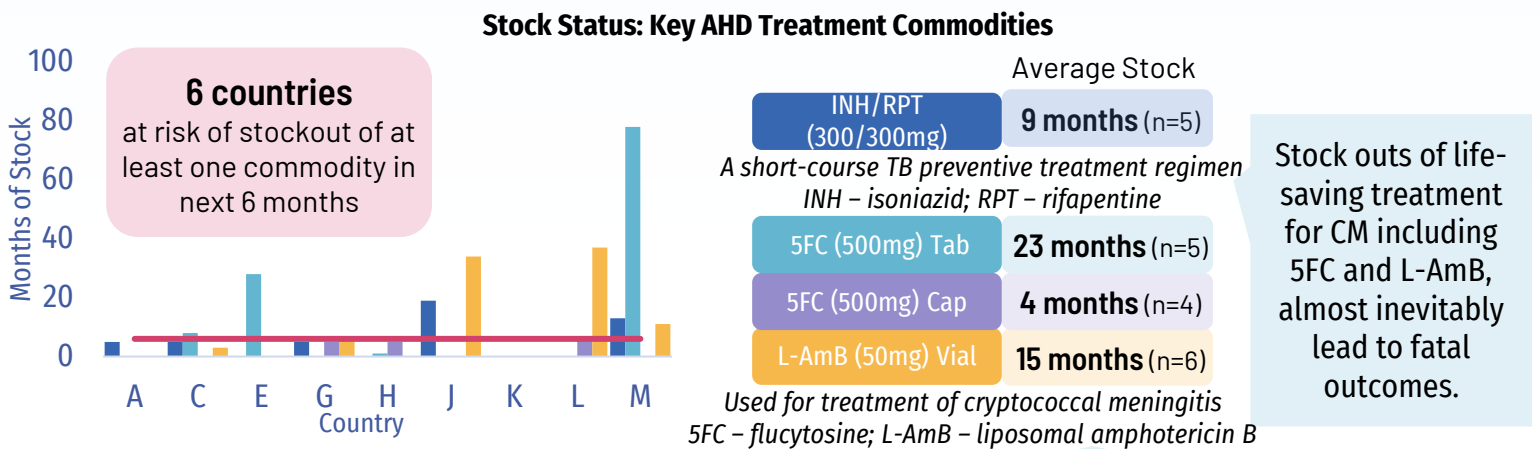
There are **critical immediate gaps** across AHD treatment and diagnostic commodities.



Point-of-care (POC) CD4 testing is critical for identifying people with AHD by providing same-day results. Without it, missed AHD diagnoses lead to failures to link people to life-saving prevention, screening, and treatment services.



Reduced availability of diagnostic tools for opportunistic infections, alongside reductions in the health workforce, severely impede linkage to essential care for these life-threatening conditions.



**Critical risk of stockouts**, with some settings already facing national-level stock depletion and imminent site-level shortages. Without urgent intervention, **disruptions in the AHD package of care will lead to preventable deaths.**



Paused orders to already fragile AHD markets, which often rely on single-source suppliers and limited manufacturing windows, could have **major impacts on global supply**, including the withdrawal of existing suppliers and deprioritization of new products.



With large-scale terminations of HCWs taking place in many countries, there are **critical gaps in HCW capacity to provide AHD services.**

# Adult Treatment

## Commodity Supply Risks

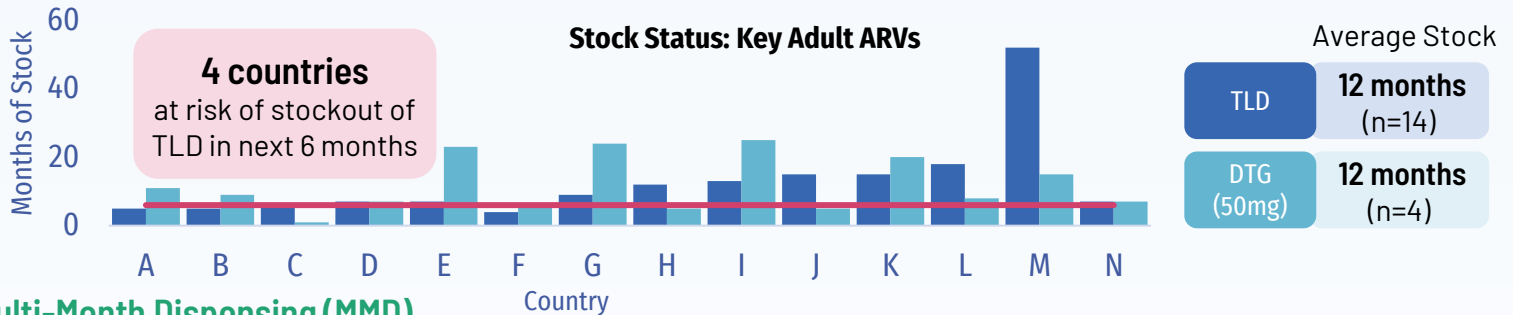


**95%** of adults are on a DTG-based regimen in generic-accessible\* LMICs, the majority on tenofovir/ lamivudine/dolutegravir (TDF/3TC/DTG) (TLD).



**Medium-term risks** to sustaining adult ARV access and preventing mortality, morbidity, and onward HIV transmission.

DTG is a **highly efficacious and well-tolerated** product allowing those suppressed on treatment to live long, healthy lives and prevent HIV transmission.



## Multi-Month Dispensing (MMD)



Dispensing 3–6 months of ARVs at a time reduces costs, saves time, and improves treatment outcomes. Ongoing stock uncertainty has led to rationing in some countries, limiting people to short-term supplies. This results in increased burden on facilities and additional clinic visits, often costing people additional time or money to collect their ARVs. This may impact adherence and viral suppression, resulting in increased treatment failure, higher rates of AHD, and ultimately increases in morbidity and mortality.

# Pediatric Treatment

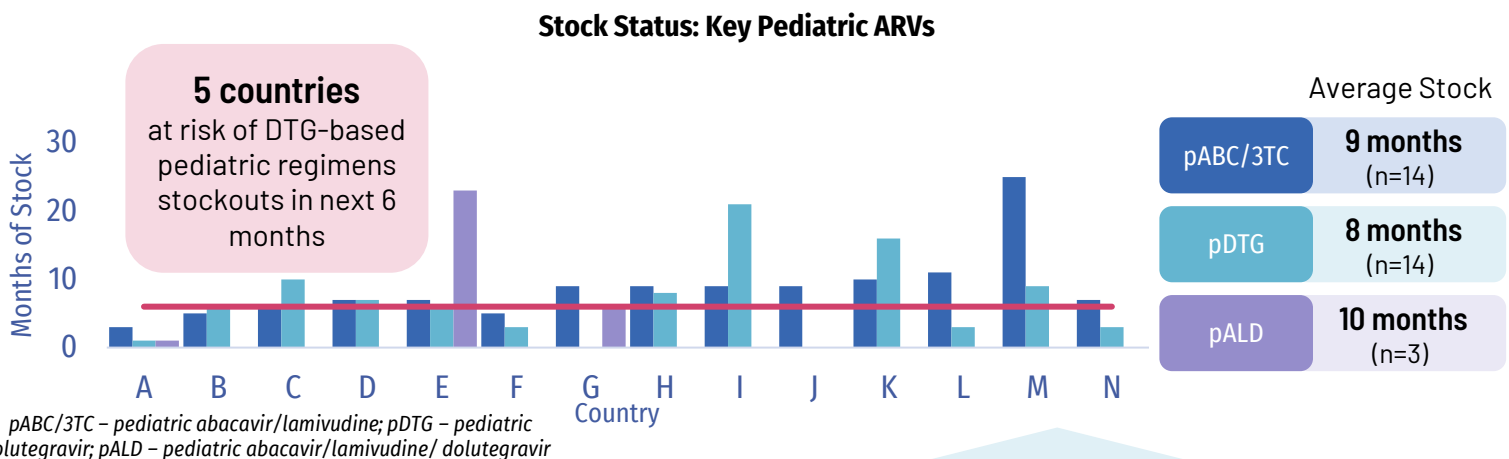
## Commodity Supply Risks



Ongoing introduction of pALD, the WHO-preferred HIV treatment regimen for children, has resulted in lower-than-normal stock of pediatric products.



**pALD introduction is in jeopardy.** At least **7 countries** reported ongoing transitions that are at risk given currently paused orders.



pABC/3TC – pediatric abacavir/lamivudine; pDTG – pediatric dolutegravir; pALD – pediatric abacavir/lamivudine/ dolutegravir

**1 in 5 children** with HIV under one year old who experienced an interruption in treatment **subsequently died**, based on recent data highlighting the **urgency of sustaining access for this vulnerable population.**

\*Generic-accessible' denotes countries where generic manufacturers can register and supply a large proportion of that country's ARVs.

# Monitoring

## Commodity Supply Risks



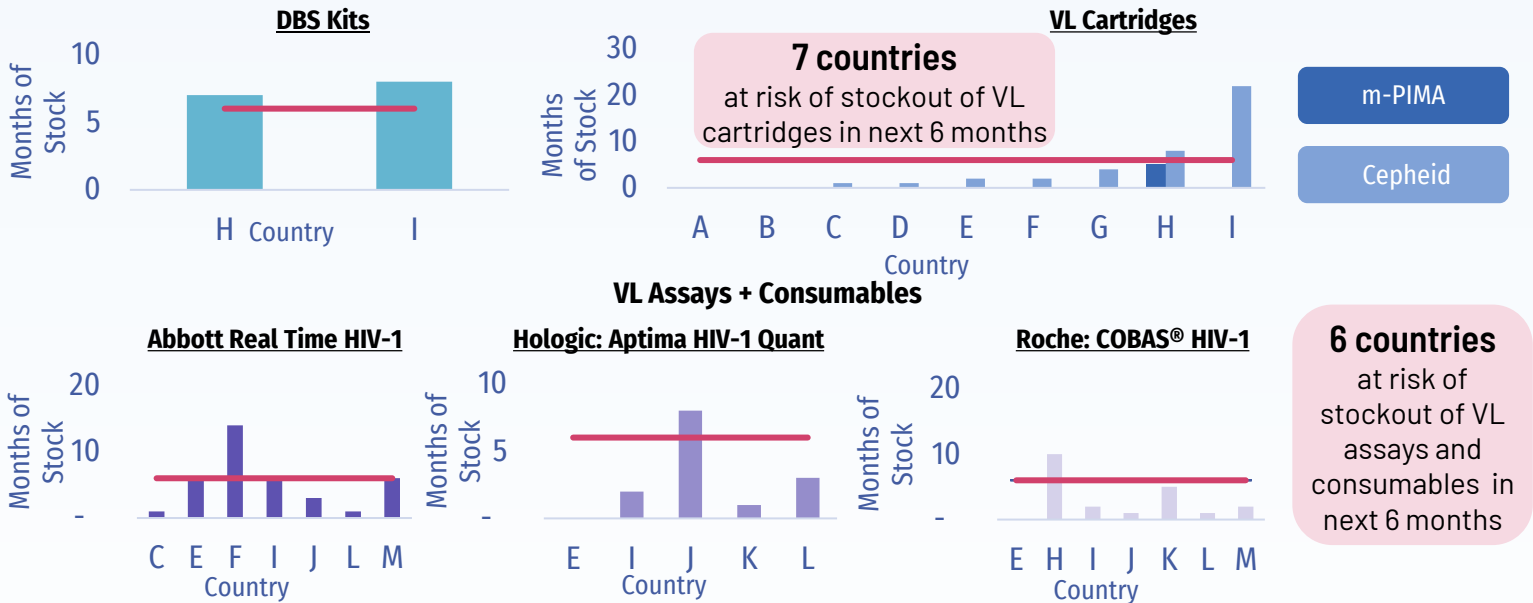
Viral load (VL) monitoring is essential for ensuring viral suppression, detecting failure early, and reducing the risk of HIV transmission.



**Critical stock levels** for many VL commodities including cartridges, assays, and consumables.

Viral load monitoring is critical for detecting treatment failure, linking to enhanced adherence counselling, and switching regimens when required. Reduced access risks **increased drug resistance and onward HIV transmission**.

### Stock Status: Key VL Commodities



# Looking Forward

Financing for the global HIV response is facing a dramatic shift. The current funding cuts threaten to undo years of progress in improving access to lifesaving commodities for people living with and at risk of HIV and in strengthening the HIV commodity markets. Without urgent action and collaboration these hard-won gains are at risk of unraveling. As we look to the future, we need:



### Coordinated Market Mechanisms

Explore development of country- and global-level structures, leveraging existing systems, to support short-term needs and plan for long-term sustainability.



### Shift to Government-Owned Systems

Rebuild HIV systems to prioritize national ownership and integration with existing health systems and supply chain management to ensure long-term self-reliance and stability of HIV services.



### Sustainable Financing

Establish long-term, government-led financing systems that prioritize efficient use of resources to support HIV services.

**As the rebuilding begins in HIV, we must be led by empowered governments to efficiently address key gaps and drive towards greater impact, together.**

# References & Methodology

This memo is based on CHAI market intelligence and PEPFAR data published by [UNAIDS](#). All data valid as of March 28, 2025. Stock status data comes from a CHAI data request to 14 LMICs. Data on HIV testing services is based on information available from 4 countries. For the purposes of data anonymization, country identifiers vary across different sections of the memo but have been kept consistent within each section.



This memo was made possible through the support of Unitaid.

