

# HIV MID-YEAR MARKET MEMO

JUNE 2021

Introducing the fifth edition of CHAI's **HIV Mid-Year Market Memo**, a brief that covers the latest trends in the HIV space in LMICs since the publication of CHAI's annual [HIV Market Report](#) in September 2020.

For questions reach out to Zack Panos (zpanos@clintonhealthaccess.org)

## UNAIDS 2025 Targets

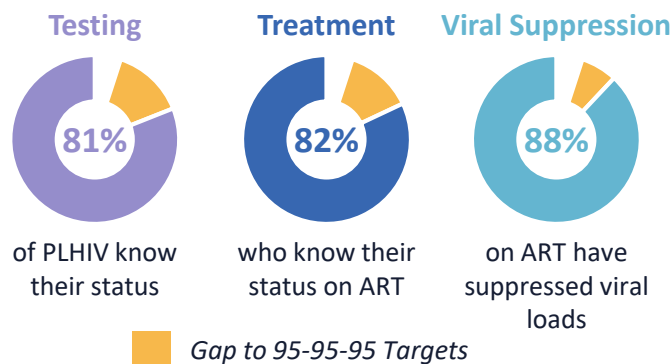
UNAIDS has adopted a new [Global AIDS Strategy](#) outlining **strategic directions** and **priority actions** to be implemented by 2025 to get the HIV response on-track to end AIDS by 2030.

**95%**  
of PLHIV know  
their status

**95%**  
who know  
their status on  
ART

**95%**  
on ART have  
suppressed  
viral loads

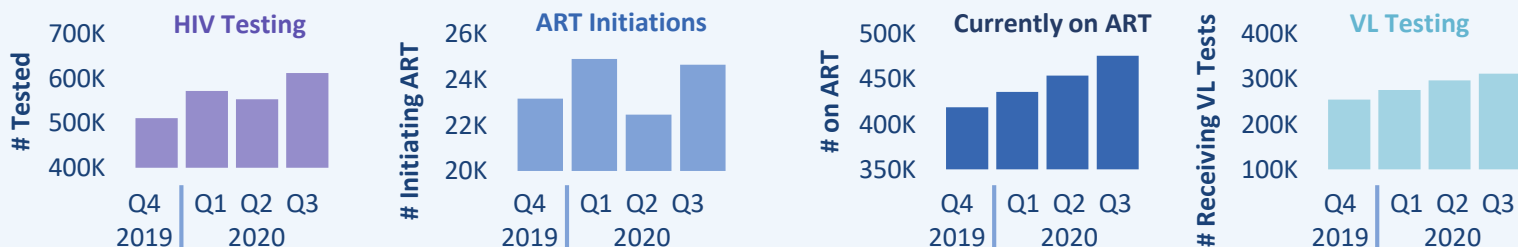
## Global Progress Toward the 95-95-95 Targets (as of Dec. 2019)



## COVID-19 Impact on HIV Services

### HIV Testing and Treatment Services

→ Data from 1,000+ ICAP health facilities in 11 countries in sub-Saharan Africa (see charts below) showed a **transient effect of the COVID-19 pandemic** on HIV services followed by a **rapid recovery**, demonstrating remarkable HIV program resilience

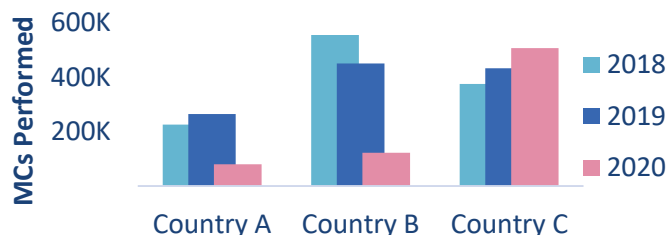


### Voluntary Medical Male Circumcision (VMMC)

→ VMMCs decreased in some southern African countries in 2020, highlighting the importance of **active demand generation** and **outreach** impacted by lockdowns

→ In others, although there were not VMMC campaigns in 2020, they **did not limit VMMC demand generation** and service delivery resulting in increased male circumcisions

### Annual VMMC Performance in Three Southern African Countries, 2018-2020

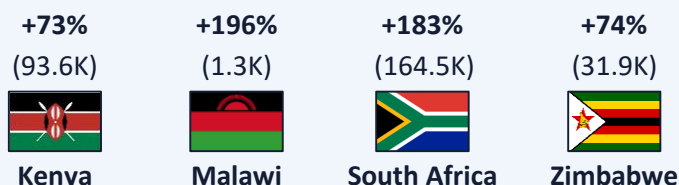


### Oral PrEP

Throughout the pandemic, many oral PrEP programs continued to scale up, aided by **virtual demand generation**, **multi-month dispensing**, and **community-based delivery**

→ There have been **~790K cumulative oral PrEP initiations** in LMICs as of publication, including **~420k in 2020 alone**

### Oral PrEP Program Growth, Q4 2019 - Q4 2020 (Cumulative Oral PrEP Initiations as of Q4 2020)



## Test Smart

### HIV Diagnosis

**NEW** **NEW** **2 New HIV self-tests** approved by GF ERPD **US\$1.99 EXW** price available for the **Mylan HIVST** in 135 countries as a result of a **Unitaid**-led agreement

<b>CheckNOW</b> (Abbot)	<b>EXACTO</b> (Biosynex)	<b>Sure Check HIVST</b> (Chembio Dx)	<b>Mylan HIVST</b> (Viartis/ Atomo)	<b>INSTI HIVST</b> (bioLytical Labs)	<b>OraQuick HIVST</b> (OraSure)	<b>Blood-based</b>
ERPD	ERPD	WHO PQ	WHO PQ	WHO PQ	WHO PQ	<b>Saliva-based</b>

### Updated WHO Guidelines (2021)

- Strong recommendation** for the use of POC NAT to diagnose HIV in infants and children < 18 months
- Strong recommendation** for task sharing of specimen collection and POC testing with non-laboratory personnel
- Conditional recommendation** for POC viral load testing to monitor treatment among PLHIV on ART

### Priority Populations for POC VL Testing

- Pregnant & breastfeeding women
- Patients with AHD and OIs
- Infants, children & adolescents
- Suspected treatment failure
- Patients re-entering care
- Repeat VL after a 1<sup>st</sup> elevated VL

## Treat Right by Addressing Advanced HIV Disease (AHD)

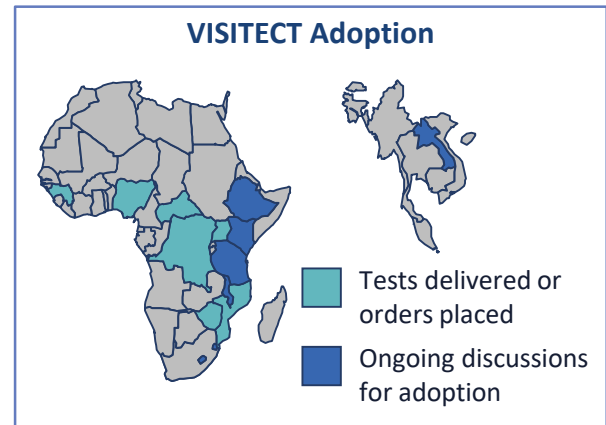
### CD4 Testing

**VISITECT**, a groundbreaking, device-free same-day CD4 test is available for procurement at a price of **US\$3.98 EXW** per test in over 130 LMICs.

- Almost **100K** VISITECT CD4 tests have been ordered
- PEPFAR 2021 COP guidance recommends VISITECT CD4 LFA as an inexpensive CD4 testing option



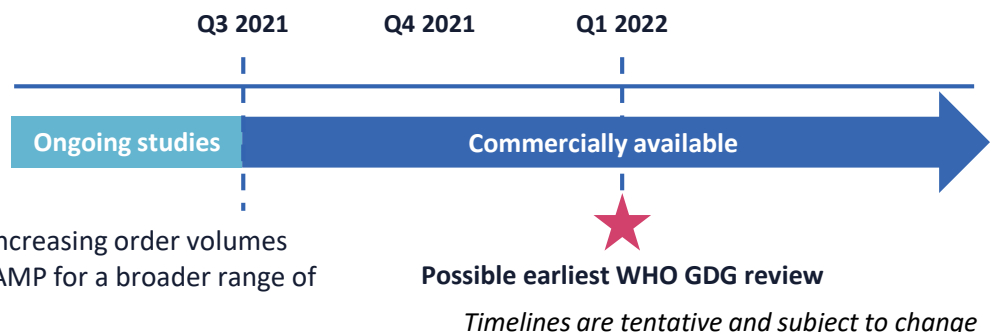
*“This and other CD4 point of care approaches with similar characteristics and implementation considerations should be given highest priority” -PEPFAR COP Guidance 2021*



### Tuberculosis (TB) Diagnosis

**SILVAMP**, a urine-based TB LAM test with improved sensitivity over existing options, is currently in development by Fujifilm.

- Launch price of **US\$7** may decrease with increasing order volumes and following WHO GDG approval of SILVAMP for a broader range of indications outside of PLHIV



For tools to support the introduction of AHD products, see the AHD toolkit at

<http://www.differentiatedcare.org/Resources/Resource-Library/Global-Advanced-HIV-DiseaseToolkit>

## Treat Right with Optimal ARVs for Adult Patients

### TLD and DTG (50 mg)

>10M patients on TLD/DTG in 1L and 2L in LMICs

~300M 30 pack equivalents of TLD procured since 2017

→ Access to **DTG in 2L** should be a priority, including **switching existing stable 2L patients** on protease inhibitors (PIs)

### DRV/r (400/50 mg)

→ Best PI option for patients failing a DTG-based 1L regimen

→ Expected to be available shortly at a comparable price to LPV/r

→ Guideline adoption critical to allow rapid access

### NADIA Trial Results

- 1 **TDF/3TC can be recycled in 2L**, which could have implications for 2L sequencing
  - WHO guidelines have not been updated and **further research is needed** prior to implementation
- 2 **DTG and DRV/r equally effective in 2L**, even in presence of high-level resistance to NRTIs
  - Re-emphasizes the importance of 2L switching to DTG and DRV/r (for those unable to take DTG)

## Service Delivery Optimization

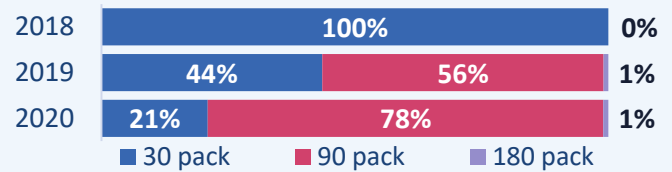


6MMD associated with **better retention in care** and **lower provider costs** in [INTERVAL trial](#) in Malawi and Zambia



Updated WHO guidelines recommend PLHIV stable on ART should be offered refills of **3-6 months**, preferably 6 months

### TLD Orders by Pack Size (as seen by the APWG)



## Treat Right with Optimal ARVs for Pediatric Patients

### Pediatric Dolutegravir (pDTG)

→ DTG-based ART was **superior to standard of care** in children and adolescents starting 1L or 2L at 96-weeks in the [ODYSSEY trial](#)

### DTG (10 mg) Dispersible Scored Tablets



**2 suppliers with US FDA tentative approval** (Viatris and Macleods) and no capacity or supply challenges anticipated



Through a [Unitaid](#) pricing agreement, available at **EXW US\$4.50/90 pack** for all public procurers for use in the 121 countries covered in ViiV's license for pDTG with the MPP



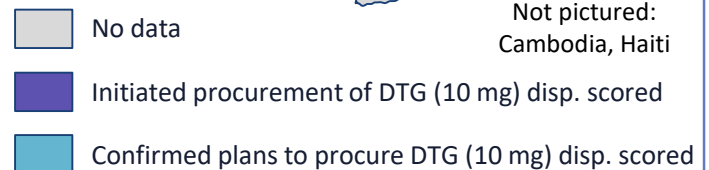
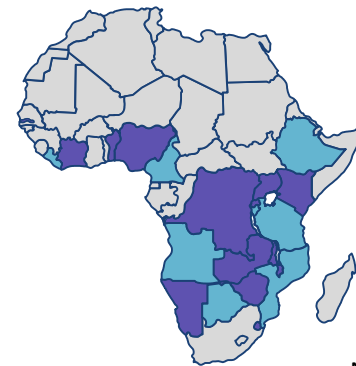
PEPFAR, via COP guidance, expects **rapid adoption** with a full transition within 12 months of first shipment



**Confirmed catalytic procurement deliveries** in Nigeria, Uganda, and Zimbabwe as of publication with expected widespread adoption imminently

Resources to help countries create optimized plans for DTG (10 mg) dispersible scored introduction and transition can be found at <https://www.newhivdrugs.org/featured-product-pdtg>

### Current DTG (10 mg) Disp. Scored Adoption (as of Q1 2021)



## Service Delivery Optimization

→ **Updated WHO guidelines now recommend:**



3-6 month dispensing of ARVs for children



Psychosocial interventions for all adolescents and young adults

### Select Country Adoption of MMD for Children

Eswatini



>2yrs

Tanzania



>5yrs

Uganda



all ages

Zambia



>2yrs

## Treat Right with Optimal ARVs for Pediatric Patients

### WHO Optimal Formulary and Limited-Use List (2021)

The WHO released an **updated optimal formulary and limited-use list** in April 2021 intended to support the implementation of WHO-recommended pediatric regimens.

For more information, check out the WHO webinar,

[Update on DTG: Odyssey Trial Results and DTG Introduction](#)

### Summary of Key Changes



**DTG 10 mg disp** added to optimal formulary



**ZLN** removed from limited-use list



**LPV/r oral pellets** moved to the limited-use list



**RAL 25 mg** removed from optimal formulary

## Stay Negative

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

- HPTN 084 (cisgender women) showed an **89% reduction in infections in the CAB-LA arm** compared to oral PrEP
- Updated analysis of the HPTN 083 study (cisgender men and transgender women who have sex with men) confirmed **68% fewer HIV infections with CAB-LA injections**
- ViiV has started a rolling new drug application (NDA) with the US FDA

### Dapivirine Vaginal Ring (DVR)



Updated guidance from the WHO recommends that the DVR may be offered as an **additional HIV prevention choice** (secondary to oral PrEP) for those at substantial risk of HIV as part of **combination prevention approaches**.

- The DVR has WHO PQ and is under review for US FDA and other regulatory approvals

See [updated WHO guidelines](#) for other implementation considerations and evidence gaps including **efficacy in young women and cost**

### Pipeline Prevention Products

- Phase 3 efficacy trials began for Merck's islatravir as once-monthly oral PrEP
- Gilead's Women's HIV Prevention Study (cisgender adolescent girls and young women) has added a **new arm investigating lenacapavir, a six-month injectable PrEP option**, alongside TAF/FTC and is set to begin enrollment in 2021



Check out the [Biomedical HIV Prevention Adaptable Introduction Framework](#) for more on introduction planning for pipeline prevention products and multipurpose technologies

#### Data Sources:

- 1 CHAI's annual data request to 25+ LMICs
- 2 Articles from journals and news outlets
- 3 Supplier and partner market intelligence
- 4 Major conferences and meetings
- 5 WHO guidelines and PEPFAR technical guidance

**1L:** First-line  
**2L:** Second-line  
**3TC:** Lamivudine  
**APWG:** ARV Procurement Working Group  
**ART:** Antiretroviral therapy  
**ARV:** Antiretroviral  
**COP:** Country Operational Plan  
**DRV/r:** Darunavir/ritonavir  
**DTG:** Dolutegravir  
**ERP:** Expert Review Panel for Diagnostics  
**EXW:** Ex works  
**FTC:** Emtricitabine  
**GF:** Global Fund

#### Acronyms Used

**HIVST:** HIV self-testing  
**HPTN:** HIV Prevention Trials Network  
**LFA:** Lateral flow assay  
**LAM:** lipoarabinomannan  
**LMIC:** Low- and middle-income country  
**LPV/r:** Lopinavir/ritonavir  
**MMD:** Multi-month dispensing  
**NAT:** Nucleic acid testing  
**NRTI:** Nucleoside reverse transcriptase inhibitor  
**OI:** Opportunistic infection  
**PLHIV:** People living with HIV  
**POC:** Point of care

**PrEP:** Pre-exposure prophylaxis  
**RAL:** Raltegravir  
**TAF:** Tenofovir alafenamide fumarate  
**TDF:** Tenofovir disoproxil fumarate  
**TLD:** TDF/3TC/DTG  
**VL:** Viral load  
**WHO:** World Health Organization  
**WHO GDG:** WHO Guidelines Development Group  
**WHO PQ:** WHO Prequalification  
**ZLN:** AZT/3TC/NVP