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.

**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)

- **81%** of PLHIV know their status
- **82%** who know their status on ART
- **88%** on ART have suppressed viral loads

**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.

**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.

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**Test Smart**

**HIV Diagnosis**

- **CheckNOW** (Abbot) **NEW**
- **EXACTO** (Biosynex) **NEW**
- **Sure Check HIVST** (Chembio Dx)
- **Mylan HIVST** (Viatris/Atomo)
- **INSTI HIVST** (bioLytical Labs)
- **OraQuick HIVST** (OraSure)

**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

**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** VISTECT 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

**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

**Coming Soon!**

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**VisiteCT Adoption**

- Tests delivered or orders placed
- Ongoing discussions for adoption

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

**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

**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)**

<table>
<thead>
<tr>
<th>Year</th>
<th>30 pack</th>
<th>90 pack</th>
<th>180 pack</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>100%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>2019</td>
<td>44%</td>
<td>56%</td>
<td>1%</td>
</tr>
<tr>
<td>2020</td>
<td>21%</td>
<td>78%</td>
<td>1%</td>
</tr>
</tbody>
</table>

**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)

**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](https://www.newhivdrugs.org/featured-product-pdtg)

**Select Country Adoption of MMD for Children**

<table>
<thead>
<tr>
<th>Country</th>
<th>Age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eswatini</td>
<td>&gt;2yrs</td>
</tr>
<tr>
<td>Tanzania</td>
<td>&gt;5yrs</td>
</tr>
<tr>
<td>Uganda</td>
<td>all ages</td>
</tr>
<tr>
<td>Zambia</td>
<td>&gt;2yrs</td>
</tr>
</tbody>
</table>
**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

**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

See updated WHO guidelines for other implementation considerations and evidence gaps including **efficacy in young women and cost**.

**Acronyms Used**

- 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
- ERPD: Expert Review Panel for Diagnostics
- EXW: Ex works
- FTC: Emtricitabine
- GF: Global Fund
- HIVST: HIV self-testing
- HPTN: HIV Prevention Trials Network
- 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

**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

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