### Objective:
To engage with industry on improving future demand visibility and working to improve the way buyers and sellers interact and work together to improve performance and efficiency.

<table>
<thead>
<tr>
<th>TIME</th>
<th>TOPIC</th>
<th>SPEAKERS/MODERATORS</th>
<th>SLIDE PAGES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Day 1: INTEGRATE: Engaging across National Regulatory, Program Implementation, and Manufacturing Stakeholders</strong></td>
<td><strong>Virtual Buffer 5:30 EST</strong></td>
<td></td>
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</tbody>
</table>
| 6:00 EST      | Welcome Remarks                                                      | Mr. James Maloney, Deputy Office Director, Office of HIV/AIDS, USAID  
Mr. Rahul Singhal, Chief Risk Officer & Acting Head Supply Operations, The Global Fund  
Dr. Anban Pillay, Deputy Director-General, South Africa National Department of Health | SLIDE #5 - 16 |
| 6:20 EST      | The Importance of Integration and Coordination Between Ministry of Health and National Medicines Regulatory Authorities (T4) | Dr. Aibek Bekbolotov, Deputy Director of the National AIDS Center, Kyrgyz Republic  
Ms. Tadala Hamisi-Mengezi, Pharmaceutical Supply Chain & Logistics Officer for Malawi Ministry of Health  
Mr. Taiye Ologun, Nigeria Federal Ministry of Health, Director of Procurement Supply Management  
Ms. Khadija Jamaloodien, Director of Affordable Medicines, South Africa National Department of Health  
Dr. Agai Kherubino Akec, Deputy Director for Treatment, Care and Support, South Sudan Ministry of Health  
Mr. Ambwene Mwakalobo, Head Pharmaceutical and Laboratory Services, Tanzania Ministry of Health, Community Development, Gender, Elderly and Children [TBC]  
Dr. Eleanor Namusoke-Magongo, Senior Program Officer, Uganda AIDS Control Program  
Dr. Emmanuel Mubanga, Assistant Director of Pharmaceutical Services, Zambia Ministry of Health  
Ms. Heran Gerba, Director General, Ethiopian Food and Drug Authority  
Dr. Abdella Kasso Rari, Director of Medicine Registration and Licensing Directorate, Ethiopian Food and Drug Authority | SLIDE #5 - 16 |
Ms. Clarisse Irasabwa, Acting Head of Department, Product Assessment and Registration, Rwanda Food and Drugs Authority
Dr. Mwesigwa Denis William, Director Inspectorate and Enforcement, Uganda National Drug Authority [TBC]

Moderated by Dr. Christine Malati, USAID and Mr. Bill Coggin, CDC

7:15 EST  
13:15 CET  
16:45 IST  
30 minutes

Manufacturing Insights (T5)  
Mr. Cathal Meere, Pharma Sourcing Manager, The Global Fund  
- 5 min Video  
- 25 min Question and Answer

SLIDE #17 - 20

Coffee/Bio Break from 7:45 to 8:00 (15 minutes)

Parallel Sessions on Program Bottlenecks

8:00 EST  
14:00 CET  
17:30 IST  
90 minutes  
With moderator determined breaks

Transition Management, considering waste management and formulary management (T6)  
Dr. Messai Belayneh, Pharmaceutical Adviser, Supply Chain Technical Branch, USAID (Moderator)  
Mr. Taiye Ologun, Nigeria Federal Ministry of Health, Director of Procurement Supply Management  
Ms. Pamela Achii, Health Products Management Specialist, Uganda Ministry of Health  
Mr. Steven Tula, Logistics Coordinator-Pharmaceutical Services, Tanzania Ministry of Health, Community Development, Gender, Elderly and Children [TBC]  
Dr. Emmanuel Mubanga, Assistant Director of Pharmaceutical Services, Zambia Ministry of Health

Overcoming Barriers to Importation (T7)  
Impact of COVID-19 on Logistics

Dr. Jeffrey Samuel, Health Equity Fellow, Supply Chain Technical Branch, USAID (Co-Moderator)  
Mr. Daniel Kiesa, Senior Advisor for Market Intelligence, Supply Chain Technical Branch, USAID (Co-Moderator)  
Mr. Cathal Meere, Pharma Sourcing Manager, The Global Fund  
Ms. Rebecca Logan, Country Programs Manager, Chemonics International (GHSC-PSM)  
Mr. Ramesh Rajeswaran, Procurement and Logistics Director, IBM (GHSC-PSM)

Mr. Adrian Barojas, Technical Advisor, FHI 360 (GHSC-QA)  
Dr. Abdella Kasso Rari, Director of Medicine Registration and Licensing Directorate, Ethiopian Food and Drug Authority  
Dr. Mwesigwa Denis William, Director Inspectorate and Enforcement, Uganda National Drug Authority  
Mr. Ambwene Mwakalobo, Head Pharmaceutical and Laboratory Services, Tanzania Ministry of Health, Community Development, Gender, Elderly and Children [TBC]

SLIDE #21 - 67

SLIDE #68 - 107
## Day 2 – UPDATE: Procurement Forecast and View towards Changing Guidelines

### Virtual Buffer from 5:30 EST

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Speaker</th>
<th>Slide</th>
</tr>
</thead>
<tbody>
<tr>
<td>6:00 EST</td>
<td>18 Month Consolidated Forecast (W1)</td>
<td>Mr. Chirag Rajpuria, <em>Associate Specialist for Principal Recipient Services, The Global Fund</em></td>
<td>#108-130</td>
</tr>
<tr>
<td>7:45 EST</td>
<td>U.S. Food and Drug Administration’s Registration of Antiretroviral Drugs under the PEPFAR Program (W9)</td>
<td>Dr. Sanjana Mukherjee, <em>Public Health Policy and Regulatory Research Fellow, Office of Commissioner, United States Food and Drug Administration</em></td>
<td>#209-222</td>
</tr>
</tbody>
</table>

### Coffee/Bio Break from 8:00 EST (15 minutes)

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Speaker</th>
<th>Slide</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:15 EST</td>
<td>Updates from WHO: Pediatric Treatment and Infant Prophylaxis (W10)</td>
<td>Dr. Martina Penazzato, <em>Pediatric HIV Lead, World Health Organization</em></td>
<td>#223-274</td>
</tr>
<tr>
<td></td>
<td>Update from WHO: Adult Treatment (W11)</td>
<td>Dr. Marco Vitoria, <em>Medical Officer for HIV Treatment and Care, World Health Organization</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Question and Answer</td>
<td><em>Moderated by Mr. Martin Auton, The Global Fund</em></td>
<td></td>
</tr>
<tr>
<td>9:00 EST</td>
<td>Update on Performance of APWG (W12)</td>
<td>Mr. Wesley Kreft, <em>Co-Chair, Procurement Consortium of Antiretroviral Procurement Working Group</em></td>
<td>#275-283</td>
</tr>
</tbody>
</table>

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**Note:**
- 18 Month Consolidated Forecast (W1) is presented by Mr. Chirag Rajpuria, *Associate Specialist for Principal Recipient Services, The Global Fund*.
- Individual Highlights for Each Procurement Channel (W2-W8) features presentations by various experts from different organizations.
- U.S. Food and Drug Administration’s Registration of Antiretroviral Drugs under the PEPFAR Program (W9) is presented by Dr. Sanjana Mukherjee, *Public Health Policy and Regulatory Research Fellow, Office of Commissioner, United States Food and Drug Administration*.
- Updates from WHO include discussions on Pediatric Treatment and Infant Prophylaxis (W10) and Adult Treatment (W11), with Dr. Martina Penazzato, *Pediatric HIV Lead, World Health Organization*, and Dr. Marco Vitoria, *Medical Officer for HIV Treatment and Care, World Health Organization*, respectively.
- The Update on Performance of APWG (W12) is presented by Mr. Wesley Kreft, *Co-Chair, Procurement Consortium of Antiretroviral Procurement Working Group*.
### PEPFAR Priorities (W13)

**30 Minute presentation followed by Question and Answer**  
*(Representatives from the Department of State/Global AIDS Coordinator)*

- Mr. Leonard Kosicki, *Senior Technical Adviser for Health Commodities, Department of State/Global AIDS Coordinator*
- Dr. Katy Godfrey, *Senior HIV Care and Treatment Technical Adviser*
- Dr. Rachel Golin, *Acting Senior Pediatric Technical Adviser*
- Dr. Teeb Al-Samarrai, *Senior Technical Adviser for TB/HIV and Index Testing*

*Moderated by Dr. Ritu Pati, CDC*

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**Day 3 – EVOLVE: Optimizing Joint Programmatic and Procurement Response**

**Virtual Buffer: 7:30 EST**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Details</th>
<th>SLIDE #</th>
</tr>
</thead>
</table>
| 8:00 EST   | **Product Specifications and Documentation (R1)** | Ms. Lindabeth Doby, *Senior MIS Adviser, Supply Chain for Health Division, USAID (Moderator)*  
Ms. Rachel Smith, *Data Analyst, IBM (GHSC-PSM)*  
Ms. Tarang Verma, *Senior Manager-International Marketing, Hetero Labs Limited*  
Ms. Yeshialem Bekele, *Traceability Office Coordinator, Ethiopian Food and Drug Authority*  
Mr. Scott Dubin, *Senior Adviser for Supply Chain Private Sector Engagement, Supply Chain Management Branch, USAID*  
Mr. Pete Alvarez, *Sr. Director Identification and Master Data, GS1* | #311 - 349 |
| 9:00 EST   | **Multi-Month Dispensing (MMD) & Decentralized Drug Distribution (DDD) (R2)** | Ms. Meaghan Douglas, *Supply Chain Monitoring and Evaluation Technical Adviser, Supply Chain Management Branch, USAID (Moderator)*  
Ms. Ashley Greve, *Supply Chain Adviser, Supply Chain Management Branch, USAID* | #350 - 369 |
| 10:00 EST  | **Vendor-Managed Logistics (R3)**     | Ms. Julia Bem, *Chief, Supply Chain Management Branch, USAID (Moderator)*  
Ms. Ashley Greve, *Supply Chain Management Branch, USAID*  
Mr. Dan Kiesa, *Supply Chain Technical Branch, USAID* | #370 - 384 |
| 11:00 EST  | **PrEP (R4)**                         | Dr. Messai Belayneh, *Pharmaceutical Adviser, Supply Chain Technical Branch, USAID (Moderator)*  
Dr. Sangeeta Rana, *Chief, Biomedical Prevention Branch, USAID*  
Ms. Ashley Vij, *Research Portfolio Adviser, Research Division, USAID*  
Dr. Shannon Allen, *Senior Technical Adviser, Microbicide Branch, USAID* | #385 - 409 |

**Coffee/Bio Break from 9:45 to 10:00 EST (15 minutes)**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Details</th>
<th>SLIDE #</th>
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</table>
| 10:00 EST  | **Closing Remarks (R5)**             | Ambassador Deborah L. Birx, MD  
U.S. Global AIDS Coordinator & U.S. Special Representative for Global Health Diplomacy |         |
The Importance of Integration and Coordination between MOH and NMRA

INTEGRATE. UPDATE. EVOLVE.
How commodity availability and accessibility impacts the 95-95-95

- 95% diagnosed
  - PrEP
  - VMMC
  - HIV Self Test Kits
- 95% on treatment
  - TPT
  - TLD
  - Peds Optimal
  - MMD
  - DDD
- 95% virally suppressed
  - TLD
  - VL
  - Peds Optimal
Patient Centric Approach to ARV Access to Achieve Virologic Suppression
MMD, DDD, and Adult ARV Treatment Optimization

<table>
<thead>
<tr>
<th>Dispensation (in months)</th>
<th>MMD</th>
<th>DDD</th>
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<tbody>
<tr>
<td>6MMD</td>
<td>6MMD</td>
<td>1M or 2M supply</td>
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</table>

<table>
<thead>
<tr>
<th>Distribution Method</th>
<th>MMD</th>
<th>DDD</th>
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<tbody>
<tr>
<td>Clinics</td>
<td>DDD channels</td>
<td>DDD channels</td>
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</table>

Patient Group: Adult Treatment Optimization (TLD or TLE400)
Patient Centric Approach to ARV Access to Achieve Virologic Suppression
MMD, DDD, and Pediatric ARV Treatment Optimization

<table>
<thead>
<tr>
<th>Dispensation (in months)</th>
<th>MMD</th>
<th>DDD</th>
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<tbody>
<tr>
<td>3MMD to 6MMD</td>
<td>3MMD to 6MMD</td>
<td>1M or 2M supply</td>
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<tr>
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<tr>
<td>Clinics</td>
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</table>

**Patient Group: Pediatric Treatment Optimization**

Availability of DTG 10 #90 and DTG 10 #180 will support expeditious implementation of 3MMD for CLHIV aged 2 to 5 and 6MMD for CLHIV aged greater than 5. PEPFAR COP21 DRAFT Guidance
1. What is the process for engagement between the Ministry of Health and the National Medicines Regulatory Authority?
2. What is the process for engagement between the Ministry of Health and the National Medicines Regulatory Authority?
3. What advice would you offer ARV manufacturers who are submitting new applications?
4. What resources from the USFDA would be helpful to NMRA in expediting the review of new applications?
5. How often are the national treatment guidelines updated? What are some opportunities for alerting the MOH on the latest information from WHO?
6. WHO issued a recommendation regarding the use of months of remaining shelf life at the point of importation as opposed to percentage. What in your opinion on the WHO recommendation and the feasibility of implementing this approach based on an assessment of risk?
7. What advantages have you seen in your programs as a result of the introduction of multi month scripting and multi month dispensing? What are some of the challenges?
8. What strategies can we employ to support adolescents and men as they are the most difficult patient subgroups to reach?
Key Message

- The Global Fund procurement strategy focuses on a **robust upstream supply chain** as part of a supplier risk strategy including but not limited to:
  - Diversified API and KSM sourcing strategies
  - Safety stock levels for starting materials and finished products closely aligned with demand

- Global Fund will continue to work on **improving the 12-18 months forecasting** window and **increase the focus on the PO frequency and PO time dimension**
- This will support manufacturers and buyers to plan more accurately, **ensuring supply continuity and competitive pricing**... benefits which can then be passed on to programs
COVID UPdate

- The Industry **continues to function well** despite lockdowns and supply constraints
- There have been **some price increases** due to raw material and API cost increases
- Some ARV products are facing **delays of up to 60 days** due mainly to workforce/manpower constraints & supply delays
- **Changes to shipping channels** have led, in some cases, to supply delays and increased cost

- **A big thanks** goes out to our suppliers for their diligence in keeping their people safe and continuing to deliver life saving drugs to our missions.
- Thanks also for their **close engagement** during this difficult time and their **open and timely communications**.
Thank you
Annual ARV Buyer Seller Summit

Shifting to New and Improved Treatment regimens: Lessons Learned from the TLD Transition (T6)
Shifting to New and Improved Treatment regimens: Lessons Learned from the TLD Transition

2020 ARV SUMMIT
Transition Management Breakout Session

Messai Belayneh, Pharmaceutical Adviser
USAID, Office of HIV/AIDS, Division of Supply Chain for Health
Pace and Magnitude of Adult First Line Transitions
(As of October 5, 2020)

2006: Patients transitioned off d4T 40

2010: TLE and LZN recommended first line

2013: EFV with TL or TE recommended as alt first line

2016: DTG with TL or TE recommended as alt first line

2017: FDA tentatively approves TLD* (Aug)

2019: WHO recommends TLD as first line preferred for all adult and adolescents.

2020: TLD transitioned off ART

2021: Pace and magnitude of adult first line transitions continue to evolve
PEPFAR Estimated % TX_CURR on TLD/DTG based regimens

FY20 Q3

Data Source: PEPFAR OUI Slide Presentations for Q3 POART. Estimated % TX_CURR on TLD/DTG based regimens derived from data presented in OUI presentations.
### TLD Transition progress: Challenges Observed

<table>
<thead>
<tr>
<th>Common Reasons stated for TLD Transition Delays</th>
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<tbody>
<tr>
<td><strong>Policy</strong></td>
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<tr>
<td>Delays in inclusion into guidelines and validation at national level</td>
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<tr>
<td><strong>Information Dissemination</strong></td>
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<tr>
<td>MOH has not solidified or communicated clear transition plans and guidance</td>
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<tr>
<td><strong>Training</strong></td>
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<tr>
<td>Clinicians hesitant to prescribe new ARV / lack of knowledge and sensitization</td>
</tr>
<tr>
<td><strong>Supply Chain</strong></td>
</tr>
<tr>
<td>Shortage of optimal ARV in country</td>
</tr>
<tr>
<td>Inefficiencies in Last Mile distribution (often related to delayed processing and distribution of stock from warehouse to facilities.)</td>
</tr>
<tr>
<td><strong>Data visibility</strong></td>
</tr>
<tr>
<td>Data reporting challenges leading to inadequate tracking of transition rate</td>
</tr>
</tbody>
</table>
Other ONGOING and UPCOMING TRANSITIONS
Pace and Magnitude of Pediatric ARV Transitions

First Line Pediatric ARV: Products Sufficient for Patients 10.0-13.9 kg
(number of bottles converted to number of treatments)

- 2010: LPV/r recommended as first line
- 2013: NVP and d4t no longer recommended as first line
- 2015: FDA approval of LPV/r Granules
- 2018: FDA approval of LPV/r Pellets
- 2018: DTG recommended as first line
- 2020: FDA approval of DTG 5 mg Disp Tabs

Source: SCMS and GHSC-PSM Historic and Current Orders
PEDIATRIC TRANSITION

- Programs should also anticipate the availability of fixed dose combination of ABC/3TC/LPV/r (30mg/15mg/40mg/10mg “4-in1” granules) as pediatric ART optimization plans are being developed, refined and implemented.

- As new pediatric DTG dosing recommendations and pediatric DTG formulations become available (DTG 5 mg dispersible tablet (DT) and DTG 10 mg scored DT), these should be promptly taken up by programs and made available to younger and smaller children.

https://www.state.gov/pepfar-cop-20-plan-guidance-public-comment
While the video includes ARVs from several companies, the use of this product does not equate to promotion, endorsement, nor favor of said company’s product line by the speaker, the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), the United States Agency for International Development (USAID), or the United States Government.
Product Life Cycle of New Pediatric Formulations

- **LPVr 40/10 formulations**
- **LPVr/3TC/ABC, FDC (Under review by FDA)**
- **Ped ABC/3TC/DTG (60/30/5 mg) Under development**
- **Generic DTG 10 mg (Under Review by FDA)**
PrEP

The Future of ARV-Based Prevention and More (October 2019)

The pipeline of non-vaccine HIV prevention products includes oral pills, vaginal rings, vaginal and rectal gels, vaginal films, long-acting injectable antiretrovirals and more. Also pictured are the range of multipurpose prevention technologies in development that aim to reduce the risk of HIV and STIs and/or provide effective contraception for women.

(Visit www.avac.org/hvad for vaccine and broadly neutralizing antibody pipelines.)

TPT

• Pending sufficient production of product, 3HP Regimens will replace IPT for TPT for adults and adolescents

• 3HP Regimens will be available to the field as:
  – RFP/INH FDC OR
  – INH + RFP singles rifapentine-based regimens (e.g. 3HP) will be the preferred PEPFAR regimen for TPT for adults and adolescents.
What lessons have we learned, and how can we be successful in future transitions?
Transition Management

Successes, Best Practices And Challenges Observed With New ARV Regimen Introduction And Transitions

Pamela Achii
Health Products Management Specialist
Ministry of Health Uganda
Oct 13 2020
Uganda has undertaken various transitions in light of the recommendations received from WHO;

These include:

- Transition of eligible Adult PLHIV to DTG based regimens (Sept’18-Dec’19)
- Optimization of children to LPV/r and DTG based regimens (Jul’19-date)
- Transition of Women of Reproductive age to DTG (Jul’20-date)
Guideline development

Following release of WHO guidance with recommendations to transition regimens to optimal regimens the following steps are taken:

- **Step 1**: Recommendations from WHO are presented to the relevant committees putting into consideration Uganda’s context i.e. ART sub committees, National ART advisory committee and Senior Management for adoption.

- **Step 2**: Upon adoption of the recommendations; Efforts are then undertaken to update and develop the HIV care and treatment guidelines incorporating the new recommendations.

- **Step 3**: Updated HIV care and treatment guidelines are then forwarded for approval by the different committees i.e. ART sub committee, National ART Advisory Committee and Senior Management.

- **Step 4**: Health facility staff are trained on the updated HIV care and treatment guidelines. Health facilities implement the HIV care and treatment guidelines.
New cheaper, safer HIV drug to be availed in September

By Taddeo Bwambale  Added 28th June 2018 11:27 AM

“The drug is more efficacious; it achieves faster viral load suppression and it is less prone to resistance.”
Successes With Transition TO New Regimens (24 Months)

1. Manufacturer readiness. This allowed for immediate transition
2. Availability of technical support from international agencies to support country adaptation of guidelines (WHO/ Global Fund/ PEPFAR)
3. Funding availability
4. FDC, once a day pill similar to existing formulations of TLE
5. Multi month dispensing /for 30 and 90 packs (3 to 6 months)
6. Therapeutic efficacy of the medicine and benefits to pregnant women. Fewer babies being born positive
7. Acceptability among population
Best Practices

- Supply chain readiness should determine and drive the pace of transition
  - Product selection is inline with rx regimens
  - Forecasting and supply planning should take into consideration existing formulations
  - Assess whether there are medicines at risk of wastage as a result of the transition
  - Value of stock at risk of wastage
  - Early procurement
  - Update of tools
  - Training

- Phased transition allows leaning and improvement of the transition process
  ⇒ Adjustment of the supply plan that ensures stock security

- Clear communication
  ⇒ Categories eligible for transition (Patient /facility)
  ⇒ Timing, targets
  ⇒ What to do with legacy regimens
  ⇒ Reporting adverse events and pharmacovigilance
Best Practices

- Track transition and create feedback mechanism
  - No of patients and categories transitioning
  - Monitoring rate of dissemination of guidelines
  - Monitoring the rate of transition
  - Monitoring the consumption of new formulations/transitioned to medicines plus other medicines affected by the transition
  - Tracking the potential wastage in circumstances where there is stock at risk of wastage

- DSD allowed for fast track refill reducing waiting time

- Once a year VL monitoring reduced facility level congestion

- Where possible, consider children in the transition (Paediatric friendly formulations)
Challenges
People with HIV report side-effects from new drug

Monday November 11 2019

“Some clients are reporting pre-diabetic symptoms and a few others are reporting impotence. They would prefer to go back to their old regimens,” Ms Oker said.

Ms Erinah (not real name) said she had been using duovir-N for about eight years without any reactions until she was started on DTG in January. She said after taking the new drug for a week, she developed spots on her arms and legs, an itching skin, loss of appetite and weight.

“I have moved from hospital to hospital to see that I am put back on my old drugs but this has not been possible. I had been energetic until they changed my drugs in January. I have lost weight. My lips are all burnt. They tell me government has stopped stocking the old ARVs,” Ms Erinah told Daily Monitor.

Duovir-N is a combination of three ARV drugs; Lamivudine, Zidovudine and Nevirapine. Ms Dora Kiconco, the executive director of Uganda Network on Law, Ethics and HIV/Aids (Uganet), told Daily Monitor that they had received information from various people living with HIV who had experienced negative effects but instead government officials were ignoring the complaints, insisting it is a mindset change.
KAMPALA, UGANDA - Amid a three-week suspension of public and private transport in Uganda due to the coronavirus, some HIV-positive Ugandans have struggled to get hold of needed antiretroviral medications. Noticing a higher risk for HIV patients with compromised immune systems, health worker Simon Bukenya jumped on his bicycle and began making home deliveries, even going long distances to do it.

Simon Peter Bukenya has been living with HIV for 30 years and understands the importance of taking antiretroviral drugs.

A lockdown due to the coronavirus has stranded Ugandans in need of medical attention, including people who are HIV-positive.

Bukenya says on a daily basis, he bicycles more than 80 kilometers to deliver medications to those who need them.

He says he started with three patients, and word of his services spread after he posted a notice on Facebook.

“There's even a client that called me and sent me a WhatsApp, when she had gotten herpes zoster, and she's home,” said Bukenya. “She's breastfeeding, she has a two-months...
ARV stock-outs kill more Ugandans

April 11, 2018    Written by Zurah Nakabugo

Richard Echoku, 54, is one of many HIV-positive Ugandans on second-line antiretroviral treatment, having failed to respond to first-line drugs.

“They tested my viral load several times, but it was not suppressing yet I was taking the drugs,” Echoku told The Observer. “However, doctors realized I was not taking my medicine on time especially during stock-outs. Sometimes I could miss getting drugs in hospital for some days,” he said.
COVID–19: HIV positive people abandon ARVs due to hunger

By Elvis Basude
Added 28th April 2020 11:16 AM

Food insecurity is today emerging as a key barrier to ARV adherence among people living with HIV, and as a contributor to ARV treatment interruptions.
<table>
<thead>
<tr>
<th>No</th>
<th>Challenges</th>
<th>Mitigation Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>8</td>
<td>Screening for DTG eligibility (Pregnant women, women of reproductive age, HIV/TB, Children) - Training, Tools</td>
<td>Within a year, new recommendations released to guide use DTG in other groups (Pregnant women, HIV/TB, Children)</td>
</tr>
<tr>
<td>2</td>
<td>Tagging use of DTG to other program areas (access to family planning services)</td>
<td>With support from IPs access to FP products has increased</td>
</tr>
<tr>
<td>3</td>
<td>Use of DTG in aging population and mature programs - Increasing risk of NCDs</td>
<td>MOH/NDA strengthen pharmacovillance and ADR reporting</td>
</tr>
<tr>
<td>4</td>
<td>Adverse events (Hyperglycaemia, Erectile dysfunction) - INH/DTG co-administration (Liver injuries) - Glucose strips</td>
<td>MOH/NDA strengthen pharmacovillance and ADR reporting Delayed introduction of INH by 3 months</td>
</tr>
<tr>
<td>5</td>
<td>Accelerated transition against limited stock causing stock outs</td>
<td>Phased transition by level of care against predetermined rx targets,</td>
</tr>
<tr>
<td>No</td>
<td>Challenges</td>
<td>Mitigation Measures</td>
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</tr>
<tr>
<td>6</td>
<td>Wastage of Legacy regimes</td>
<td>Where possible cancellation of pipeline, redistribution, mop up of stock.</td>
</tr>
<tr>
<td>8</td>
<td>Manufacturers preparedness (Wastage of API for NVP, EFV, AZT/3TC for both adults and children)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Knowledge gaps among health care workers</td>
<td>Routine mentorship and coaching</td>
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<td></td>
<td></td>
<td>Scenario-based short SOPs</td>
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<tr>
<td>2</td>
<td>Multi Month Drug refills of legacy regimen due to COVID</td>
<td>Line listing, use of ART optimization stickers, called back children, motorcycle rider or health worker drug deliveries</td>
</tr>
<tr>
<td>3</td>
<td>VL testing; missed opportunities, overdue for testing or dropping off the IAC cascade</td>
<td>National pediatric CQI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Line listing, VL camps, phone or home IAC,</td>
</tr>
<tr>
<td>4</td>
<td>Poor administration of medicines by caregivers</td>
<td>Dispensing messages for health care workers &amp; a caregiver literacy material developed</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stakeholder Management</td>
<td></td>
</tr>
</tbody>
</table>
Recommendations

1. **WHO/FDA**
   - Product safety
   - Efficacy, Quality (Equity in regulation), aspire to deliver quality across the board
   - Early engagement of manufactures to ensure stock security given that many countries transition at the same time
   - Product design (Packaging, multi month packaging) should be guided by in country operational studies. Do we have any results yet?

2. **Development partners (AIDS development partners)**
   - Non-maleficence
   - Filling funding gaps
   - Consider national context, mindful of cultures, values and additional costs

3. **Governments**
   - Leadership and governance including having significant stake at WHO/FDA (create a protectives stealth)
   - Economic analysis
   - Funding
   - Policy development

4. **Manufactures**
   - Quality
Recommendations

1. Manufactures
   1. Quality, compliance to pharmacopeia standards
   2. Post Market surveillance and product recall
   3. Shelf life
   4. Lead time
Pediatric ART Optimization: Experience from Uganda

Dr. Eleanor Namusoke Magongo

Team Lead Pediatrics & Adolescent HIV Care and Treatment

Ministry of Health
Uganda has been optimizing ART for children since 2014

2014: Zidovudine/Lamivudine (AZT/3TC) to Abacavir/Lamivudine (ABC/3TC)

2016: Introduction of Lopinavir/ritonavir pellets (LPV/r)

52.2% of children aged 3-10 years were still receiving AZT/3TC/NVP as first-line ART by June 2018.

Current ART optimization strategy (July 2018 to date) is to transition children with viral load (VL)< 1000 copies/ml from;

1. AZT/3TC to ABC/3TC
2. Nevirapine or Efavirenz to LPV/r pellets/tablets or DTG-containing first-line ART.
Phases of the paediatric ART regimen optimization in Uganda

Pediatric regimen optimization for children aged 3-10 years was phased;

- Due to **challenges of stocks for LPV/r 100/25mg** caused by global shortage of LPV/r 100/25mg tablets
- To ensure that children already taking LPV/r 100/25mg do not experience treatment interruptions during the transition period

### Phases of pediatric optimization for CLHIV aged 3-10 years

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Started in July 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Involving all Health facilities in NMS Zones 4 and 5</td>
</tr>
<tr>
<td>Phase 2</td>
<td>Started in May 2020</td>
</tr>
<tr>
<td></td>
<td>PNFP health facilities in all the regions</td>
</tr>
<tr>
<td>Phase 3</td>
<td>Planned to start in Oct 2020</td>
</tr>
<tr>
<td></td>
<td>Involving the rest of the Public health facilities (In Zones 1,2&amp;3)</td>
</tr>
</tbody>
</table>

Phase 3 delayed due to low stock levels of ABC/3TC 120/60mg caused by delays in delivery of shipments for ABC/3TC 120/60mg due to API challenges for ABC.
Methods

• Using data from the national reporting system (DHIS-2) & web-based ART ordering system (WAOS), supply chain planning was done

• Standard operating procedures & job aides were developed

• Check-list was used to identify eligible children for optimization at the health facilities

• These were transferred to the line listing tool for tracking
Methods

• Weekly national planning meetings; pediatric ART optimization task force

• Cascaded trainings and post-training mentorships conducted

• ART optimization indicators incorporated into the weekly PEPFAR surge dashboard to monitor implementation

• Weekly optimization meetings with implementing partners to monitor progress
# Status of pediatric regimen optimization as at end of Aug’20

## Proportion of patients optimized

<table>
<thead>
<tr>
<th>Age Category</th>
<th># on NNRTIs as at end of Jun’19</th>
<th># optimized as of Aug’20</th>
<th># on NNRTIs as at end of Aug,20</th>
<th>Proportion of pts optimized</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-3 Yrs</td>
<td>2,102</td>
<td>1,818</td>
<td>284</td>
<td>86%</td>
</tr>
<tr>
<td>3-&lt;10 Yrs</td>
<td>9,849</td>
<td>7,629</td>
<td>2,220</td>
<td>77%</td>
</tr>
<tr>
<td>10-14 Yrs</td>
<td>10,497</td>
<td>6,818</td>
<td>3,679</td>
<td>65%</td>
</tr>
<tr>
<td>14-&lt;20 Yrs</td>
<td>13,114</td>
<td>6,416</td>
<td>6,698</td>
<td>49%</td>
</tr>
<tr>
<td>Total</td>
<td>35,590</td>
<td>22,681</td>
<td>12,909</td>
<td>64%</td>
</tr>
</tbody>
</table>

64% of the paediatric patients optimized to either DTG or LPV/r based regimen.
Trends of pediatric regimen optimization for phase 1&2

Trends of pediatric regimen optimization for Phase 1

Optimization trends for pediatric patients in phase 2
22,681 (64%) children optimized to DTG and LPV/r regimens as at the end of Aug’20.
Children in the age group 10-15 years on NNRTI’s to be optimized to TLD following roll out of the 2020 HIV guidelines
<table>
<thead>
<tr>
<th>Challenges</th>
<th>Mitigation strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Inadequate stock of optimal regimens</td>
<td>Phased implementation</td>
</tr>
<tr>
<td></td>
<td>Stock redistribution by sub-national partners</td>
</tr>
<tr>
<td>2  Knowledge gaps among health care workers</td>
<td>Routine mentorship and coaching</td>
</tr>
<tr>
<td></td>
<td>Scenario-based short SOPs</td>
</tr>
<tr>
<td>3  Multi Month Drug refills of legacy regimen due to COVID</td>
<td>Line listing, use of ART optimization stickers, called back children, motorcycle rider or health worker drug deliveries</td>
</tr>
<tr>
<td>4  VL testing; missed opportunities, overdue for testing or dropping off the IAC cascade</td>
<td>National pediatric CQI</td>
</tr>
<tr>
<td></td>
<td>Line listing, VL camps, phone or home IAC,</td>
</tr>
<tr>
<td>5  Poor administration of medicines by caregivers</td>
<td>Dispensing messages for health care workers &amp; a caregiver literacy material developed</td>
</tr>
</tbody>
</table>
CQI ON VL AT FPRRH

Figure 2: Fish Bone Analysis of the Root Causes of Suboptimal Viral Load Uptake at FPRRH in March 2018.
What did we do different during the lock down

- **Home based intensive adherence counseling**
  - 86% VL re-suppression rates

- **Phone Counseling**
  - To reduce waiting time at clinic

- **Home delivery of ARV’s**
  - Ensure continued supply of ARV’s
Summary of Key Points

- The key barrier to ART optimization for children has been inadequate stock of optimal drugs.
- Continuous mentorship with simplified SOPs is needed to operationalize treatment optimization guidelines for children at facility level.
- Dispensing messages for health care workers & caregiver literacy materials are important to ensure programs and individuals realize the benefits of optimal regimen.
# Acknowledgements

- Ministry of Health
- Pediatric TWG & ART optimization task force
- CHAI Uganda
- PEPFAR Uganda
- UNICEF Uganda

- WHO Global team
- Health care providers
- Caregivers of the children
- Baylor Uganda for the 2 slides included in the presentation
References

• Poster at AIDS 2020
• Uganda Consolidated Guidelines for HIV Prevention, Care and Treatment

• Contacts: Dr. Eleanor Namusoke Magongo
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  ❖ Phone: +256772692628 (WhatsApp) or +256752692629
  ❖ Skype: Eleanor Namusoke Magongo
  ❖ Twitter: @MagongoEleanor
  ❖ Linkedin: Eleanor Namusoke Magongo
1. What has been the most challenging part of the TLD transition in each of the OUs? What has been a success of the TLD/past transitions?

2. Can you give example of how have you overcome some challenges during past transitions?
3. How are you preparing for upcoming transitions, particularly the pediatric transition?

4. Where are you in the process and what do you plan to differently or similarly leaning on lessons learned from past transitions?
5. What requests do you have from ARV manufacturers, donors, multilateral organization to improve ARV regimen transitions management?
6. Can you share any experience on challenges and/or successes from past and/or ongoing transitions? (please introduce yourself and your role/organization)

7. What requests do you have to National Aids Programs, Donors/Procurers, ARV manufacturers and/or the HIV community at large to improve ARV transitions management?
Overcoming Barriers to Importation
Speakers/Moderators

Jeffrey Samuel, Health Equity Fellow, Supply Chain Technical Branch, USAID

Daniel Kiesa, Senior Advisor for Market Intelligence, Supply Chain Technical Branch, USAID

Cathal Meere, Pharma Sourcing Manager, The Global Fund

Rebecca Logan, Country Programs Manager, Chemonics International (GHSC-PSM)

Ramesh Rajeswaran, Procurement and Logistics Director, IBM (GHSC-PSM)

Adrian Barojas, Technical Advisor, FHI 360 (GHSC-QA)

Dr. Mwesigwa Denis William, Director Inspectorate and Enforcement, Uganda NDA

Dr. Abdella Kasso, Director of Medicine Registration and Licensing Directorate, Ethiopian FDA

Mr. Ambwene Mwakalobo, Head Pharmaceutical and Laboratory Services, Tanzania MOH
Agenda

• Welcome (5 minutes)
• Impact of COVID-19 on Logistics (25 minutes)
• Questions & Answers (10 minutes)
• Break (5 minutes)
• Shelf-Life Recommendations for Importation (20 minutes)
• National Stakeholder Perspectives (10 minutes)
• Questions & Answers (10 minutes)
• Conclusion (5 minutes)
Impact of COVID-19 on Logistics

Rebecca Logan, Country Programs Manager, Chemonics International (GHSC-PSM)
Ramesh Rajeswaran, Procurement and Logistics Director, IBM (GHSC-PSM)
Logistics activities were constrained significantly at both origin and destination over the duration of the pandemic

<table>
<thead>
<tr>
<th>OCEAN</th>
<th>AIR</th>
<th>TRUCK</th>
<th>ALL TRANSPORT</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reefer container shortages at various locations</td>
<td>• Cancellation of passenger flights significantly impacted capacity</td>
<td>• Continental and in-country border regulations and movement restrictions—testing, quarantines, lock-downs</td>
<td>• Transit, port of entry, and government staffing constraints resulting in severe congestion, as well as customs clearance, inspection, and waiver delays</td>
</tr>
<tr>
<td>• Vessels quarantined at various destination ports</td>
<td>• Rates were extremely volatile and went up by as much as 400%</td>
<td>• Driver concerns and availability</td>
<td></td>
</tr>
<tr>
<td>• Carrier blanking and capacity adjustments will continue in Q3</td>
<td>• Flight operators optimized capacity to ensure viability</td>
<td>• Intra-India restrictions impacted availability of drivers and trucks and/or their movement</td>
<td></td>
</tr>
</tbody>
</table>
Logistics activities were constrained significantly at both origin and destination over the duration of the pandemic.

Data source: https://www.flightradar24.com/blog/indian-aviation-the-road-ahead/
GHSC-PSM’s goal during the pandemic was to avoid and/or minimize supply chain disruptions and took an enterprise-wide approach to manage the impact of the pandemic.

- Established Covid-19 management task force in early February
- Received USAID approval to
  - incur higher freight costs within pre-established limits
  - deliver products irrespective of committed dates (Requested Delivery Date or Agreed Delivery Date)
- Achieved closer coordination between GHSC-PSM, USAID Mission, and Ministries of Health that facilitated timely movement of commodities through
  - expedited import duty waivers
  - validated availability of warehouse storage and securing “surplus” capacity in-country to allow for early deliveries from the central warehouse to lowest point in the supply chain
  - worked with government officials and USAID Missions to obtain essential personnel designations and secure safe passage for commodities crossing regional and international borders by land
  - leveraged in-country inventory more effectively to compensate for logistical delays, e.g., realignment of product among issuance sites and expedited movement of commodities to service delivery points
- Leveraged charters that enabled consolidation and delivery of products
- Collaborated with the Global Logistics Continuity Working Group (led by Logistics Cluster, WFP) to identify possible synergies for logistics
GHSC-PSM implemented new tools, processes, and reports with an aim to move product closer to end destinations sooner, deliver commodities with higher remaining shelf life, and optimize limited cargo and storage space.

**LOGISTICS AND CLEARANCE RISK ANALYSIS TOOL**
Updated weekly based on input from 3PLs, country offices, market insights

**LOGISTICS MILESTONE TRACKER**
Updated weekly to identify hotspots across the logistics processes

**SHIPMENT COMMUNICATION TOOL**
Updated weekly to identify shipments that can be expedited based on collaboration with Field Offices and Missions
Positive Impact of actions taken (and likely to continue)

- Of the delivered adult and pediatric orders impacted by Covid-19, GHSC-PSM has delivered over 85% of those orders early or on-time
- Some countries that have consistently been able to expedite waivers
- Increased uptake of multi-month dispensing
- Expanded availability of decentralized drug distribution
1. What is the required remaining shelf life (RSL) for health commodities in your country?
   a. 85%
   b. 80%
   c. 75%
   d. < 75%
   e. Not sure
2. How often are waivers available for importation of health commodities that do not meet minimum RSL
   a. Never
   b. Occasionally, but not often
   c. Frequently
   d. Always
3. What is your perspective on shipping products that have RSL < 85%  
   a. Not worth the effort  
   b. Indifferent  
   c. Happy to serve the countries
Shelf-life Recommendations for Importation of Health Commodities

2020 Annual ARV Buyer Seller Summit

Mr. Adrian Barojas, Technical Advisor, FHI 360
Dr. Mwesigwa Denis William, Director Inspectorate and Enforcement, Uganda National Drug Authority
Dr. Abdella Kasso Rari, Director of Medicine Registration and Licensing Directorate, Ethiopian Food and Drug Authority
Mr. Ambwene Mwakalobo, Head Pharmaceutical and Laboratory Services, Tanzania Ministry of Health, Community Development, Gender, Elderly and Children
Supply chain shelf-life regulations for health commodities

Background:

• Countries regulate the importation of medical products (pharmaceuticals, vaccines and medical devices, including in-vitro diagnostics) by limiting the shelf-life (SL) of incoming goods to a minimum amount.

• Many countries require a minimum percentage of the remaining shelf-life (RSL) at the time of importation.
Supply chain shelf-life regulations for health commodities

Problem Description:

• In many instances current regulations have proven to hinder importation of life saving medical products and adversely impact patient access.

• Consumption patterns in many countries often times require far less SL than the those mandated by regulations requiring a minimum percentage SL (ex. 75% RSL).

• Many countries have made significant improvements in forecasting and supply chain management.

• Rejection of products due to the requirement of a minimum percentage of RSL may contribute to stockouts.
Supply chain shelf-life regulations for health commodities

<table>
<thead>
<tr>
<th>Maximum SL</th>
<th>75% RSL</th>
<th>80% RSL</th>
<th>85% RSL</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 months</td>
<td>18 months</td>
<td>19.2 months</td>
<td>20.4 months</td>
</tr>
<tr>
<td>36 months</td>
<td>27 months</td>
<td>28.8 months</td>
<td>30.6 months</td>
</tr>
<tr>
<td>48 months</td>
<td>36 months</td>
<td>38.4 months</td>
<td>40.8 months</td>
</tr>
<tr>
<td>60 months</td>
<td>45 months</td>
<td>48 months</td>
<td>51 months</td>
</tr>
</tbody>
</table>
Supply chain shelf-life regulations for health commodities

Problem Description – Challenges for 90/90/90:

• Lack of patient access will not allow:
  • 90% of people living with HIV to know their status
  • 90% of to enroll in Antiretroviral Treatment (ART)
  • 90% of to have viral suppression
  • Significant impediment to reaching global HIV targets
CASE STUDY:
ANTIRETROVIRALS (ARVs)

Data provided by the USAID Global Health Supply Chain – Procurement Supply Management
The need for flexibility in shelf life due to limited availability

• USAID maintains stock at regional distribution centers (RDCs)
  - Lopinavir/Ritonavir (48 month SL) & Tenofovir/Lamivudine/Dolutegravir (24 month SL)
    ▪ Limited availability in global market & access remains challenge at national level
    ▪ Significant value in holding stock
    ▪ Manufacturing and shipping would require a minimum of 6-9 months additional lead-time
      o In case of LPV/r upwards of 20 months due to supply constraints
  - Products with 50% shelf life can significantly increase access and prevent stockouts
    ▪ LPV/r = 24 months provides significant time for consumption
    ▪ TLD = 12 months; 1st line treatment in many countries
The need for flexibility in shelf life to incentivize introduction of products with longer shelf life

- Current regulations do not incentivize products with longer shelf life
  - Atazanavir + Ritonavir 300 mg/100 mg Tablet
  - Multiple eligible products with varying SL (24 and 36 months)

<table>
<thead>
<tr>
<th>Maximum SL</th>
<th>75% RSL</th>
<th>80% RSL</th>
<th>85% RSL</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 months</td>
<td>18 months</td>
<td>19.2 months</td>
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<tr>
<td>36 months</td>
<td>27 months</td>
<td>28.8 months</td>
<td>30.6 months</td>
</tr>
</tbody>
</table>
The need for flexibility in shelf life to incentivize introduction of products with longer shelf life

• The 36 month SL product will be rejected in countries with a requirement of 75% RSL at importation for having anywhere in the range of 18-27 months of RSL.

• The competitor product that has a 24 month SL can easily import their product while having 18 months RSL.

• Incentivizes procurement of products that will not face importation barriers, rather than the products that give the supply chain more actual months of stock to move the product through to patients.
CASE STUDY:
HIV Rapid Diagnostic Test Kits (RTKs) and Viral Load (VL) Reagents

Data provided by the USAID Global Health Supply Chain - Rapid Test Kits Program
The need for flexibility in shelf life to incentivize introduction of products with longer shelf life

- Brand A” & “Brand B” are picked up from the manufacturer for shipment with 15 months SL
- “Brand A” = 92% RSL
- “Brand B” = 74% RSL
The need to reduce reliance on exceptions

- 53% of most commonly delivered VL products would **not** meet 75% RSL requirement
- Potential inconsistencies in granting exceptions, which may hinder patient access

Source: GHSC-PSM Memo issued to USAID OHA “Diagnostics Shelf Life Background and Recommendations”
Annex 8

Points to consider for setting the remaining shelf-life of medical products upon delivery

1. Introduction
2. Scope
3. Glossary
4. The need for recommendations
5. Remaining shelf-life

References
Further reading
Appendix 1 Example of minimum remaining shelf-life of medical products
Updated WHO Guidelines

• Annex 8 of the WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fourth report

• Scope includes pharmaceuticals, vaccines and medical devices (including in vitro diagnostics and reagents/components).
  - Includes donations
  - Excludes “kits” (ex: VMMC kits)

Updated WHO Guidelines

• Recommends risk assessment to be conducted at national level:
  - Needs assessment, type of product (e.g. pharmaceutical, IVD), timepoints along supply chain, storage/transport conditions, stock rotation....

• Deviations should be justified and ensure:
  - Stock will be consumed prior to expiry
  - Reaches end-users with adequate remaining shelf-life

The policy allows for flexibility dependent upon consumption rates

Example of the minimum remaining shelf-life (RSL; at the time of dispatch and upon delivery) of medical products, based on the outcome of risk assessment

<table>
<thead>
<tr>
<th>Total shelf-life (TSL)</th>
<th>RSL at time of dispatch from manufacturer’s premises</th>
<th>RSL at time of delivery at port of entry of country</th>
<th>RSL at time of delivery at end-user level</th>
</tr>
</thead>
<tbody>
<tr>
<td>48 months &lt; TSL ≤ 60 months</td>
<td>40 months</td>
<td>30 months</td>
<td>12 months</td>
</tr>
<tr>
<td>36 months &lt; TSL ≤ 48 months</td>
<td>30 months</td>
<td>24 months</td>
<td>12 months</td>
</tr>
<tr>
<td>24 months &lt; TSL ≤ 36 months</td>
<td>20 months</td>
<td>15 months</td>
<td>6 months</td>
</tr>
<tr>
<td>12 &lt; TSL ≤ 24 months</td>
<td>9 months</td>
<td>7 months</td>
<td>3 months</td>
</tr>
<tr>
<td>TSL ≤ 12 months</td>
<td>Special arrangements and conditions apply</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Benefits of a Months-Based RSL Importation Policy include the following

1. Increases the efficiency of global public health supply chains to help ensure patients do not receive expired products
   • Incentivizes manufacturers to file for longer SL
   • Removes potential preferences of procuring lower SL products
   • Aligns practices in supply chain management of (stock on hand in terms of months of supply) with import regulations
   • Decrease use of exceptions and allow for more predictable importation process
Benefits of a Months-Based RSL Importation Policy include the following

2. Provide flexibility in importation requirements to improve patient access to life-saving commodities and avoid stockouts
   • Provide products immediately to resolve potential stock issues
   • Through distribution from RDCs or direct from stock available at the manufacturer/vendor
Recommendations

• Advocate for implementation as per the WHO Technical Series Report
  - National
  - Regional – RECs
  - Continental level via AMRH

• Review regulations and begin process of updating
  - All levels (National and RECs)
Fake text
Perspective from Uganda NDA

• Importation of medicines and other pharmaceuticals in Uganda is controlled by a regulation

• Medicines and other pharmaceuticals can only be imported if their remaining shelf life is 75% or above at the time the products enter the country

• Medicines entry the Uganda as donations must have at least one year remaining calculated from the date the medicine is allowed in the country

• Vaccines and other biological products imported for the purpose of donation must have ¾ quarters of its stated shelf life, remaining at the time the product is allowed in the country
Perspective from Uganda NDA

Additional parameter to use is risk assessment

• The type of disease to be treated using the imported products

• Assess and avoid counterfeit/superimposed labels that hide the actual expiry dates of the product

• Consideration should be given to donated drugs to avoid damping, vaccines and other biological should be considered since they normally have shorter shelf life – in Uganda, they are allowed with at least 75% SL

• Attention should be given to Medicines containing control substances, as expiry dates may not limit misuse
The feasibility of implementing the risk assessment in Uganda

• Risk assessment can be implemented by the National Medical stores and other big importer of medicines like the faith based organizations

• It is also important to consider MOH-clinical services departed that are greatly affected by availability, access and quality of medicines on the market

• It is therefore visible to consider the remaining shelf life in months other than the percentage but this requires changing the regulation
Perspective from Tanzania Ministry of Health, Community Development, Gender, Elderly and Children
1. What is your understanding of the WHO recommendations on shelf life?
   a. Only allow 90% RSL on health commodities
   b. Implement a sliding scale approach based on percentage of RSL
   c. Implement a sliding scale approach based on months of RSL
   d. RSL is not important and should not be considered
Poll Question

2. Specific to the context of your country, would a months-based shelf life importation policy increase access to medical products
   a. Strongly agree
   b. Agree
   c. No difference
   d. Disagree
   e. Strongly disagree
3. Specific to the context of your country, what is the realistic timeline for changing to a months-based shelf life importation policy?
   a. Within a year
   b. Between 1-2 years
   c. Between 2-3 years
   d. Between 3-4 years
   e. Longer than 4 years
The Global Fund, PEPFAR, and Republic of South Africa Demand Management Data: 18-Month Consolidated Forecast

October 2020 | Virtual
Caveats and limitations of the current visibility

- **Conservative estimates** based on currently confirmed orders and firm demand
- Prepared based on **data currently available** to GHSC-PSM, The Global Fund, South Africa, Kenya, CDC Maul, UNDP, and Ethiopia
- **Preliminary estimates for discussion and planning** – not final purchase commitments
- **May not yet fully capture lead times** between order placement at manufacturer and in-country delivery
- **Tenth joint** consolidated procurement **forecast**
Total ARV Forecast

Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of Packs, millions

- Burkina Faso
- Cameroon
- Cote d’Ivoire
- Congo DRC
- Ethiopia
- Ghana
- Kenya
- Malawi
- Mozambique
- Nigeria
- South Africa
- Tanzania
- Uganda
- Zambia
- Zimbabwe

- PEPFAR
- Kenya
- Republic of South Africa
- Global Fund

- TLD
- TLE 400
- TLE 600
- TEE
- DTG 50
- TDF/ FTC 300/200
- TDF/3TC 300/300
- 3TC/AZT 150/300
- ABC/3TC 600/300
- ABC/3TC 120/60
- ATV/r 300/100
- LPV/r 200/50
- LPV/r 100/25
- LPV/r 40/10 pellets/granules
- NVP 100 ml susp
- DTG 10 mg DT

DISCLAIMER: This is an initial version of the forecast, and may contain inaccuracies – please refer to caveats and data limitations on slide 1. These slides contain a conservative estimate for demand management between the four programs. As such, there may be future volumes not yet financially committed or confirmed.

Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

- **PEPFAR**
- **Republic of South Africa**
- **Global Fund**

<table>
<thead>
<tr>
<th>Quarter</th>
<th>PEPFAR</th>
<th>Republic of South Africa</th>
<th>Global Fund</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4 2020</td>
<td>9.9</td>
<td>9.9</td>
<td>9.9</td>
</tr>
<tr>
<td>Q1 2021</td>
<td>13.2</td>
<td>6.2</td>
<td>6.2</td>
</tr>
<tr>
<td>Q2 2021</td>
<td>12.0</td>
<td>11.3</td>
<td>11.3</td>
</tr>
<tr>
<td>Q3 2021</td>
<td>6.9</td>
<td>12.8</td>
<td>12.8</td>
</tr>
<tr>
<td>Q4 2021</td>
<td>6.2</td>
<td>16.7</td>
<td>16.7</td>
</tr>
<tr>
<td>Q1 2022</td>
<td>9.5</td>
<td>12.4</td>
<td>12.4</td>
</tr>
</tbody>
</table>

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Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

PEPFAR
Kenya
Global Fund

Q4 2020: 7.8
Q1 2021: 11.6
Q2 2021: 9.1
Q3 2021: 2.7
Q4 2021: 1.8
Q1 2022: 4.9

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TLD, 180 Tabs

Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

- **PEPFAR**
- **Global Fund**

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**SOURCE:** PEPFAR, Government of Kenya, The Global Fund, South Africa
TLE 400, 30 Tabs

Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

Global Fund

0.6  0.3  0.7  0.6  0.3  0.8

Q4 2020  Q1 2021  Q2 2021  Q3 2021  Q4 2021  Q1 2022

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AS OF 2 OCT 2020
Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

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**TLE 600, 90 Tabs**

**Consolidated Demand Outlook**
Q4 2020 – Q1 2022, Number of packs, millions

*Some volumes may manifest in orders for packs of 30.*

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**SOURCE:** PEPFAR, Government of Kenya, The Global Fund, South Africa
Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

- Republic of South Africa

Q4 2020: 7.2
Q1 2021: 4.3
Q2 2021: 4.2
Q3 2021: 3.4
Q4 2021: 3.1
Q1 2022: 2.2

AS OF 2 OCT 2020

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### Consolidated Demand Outlook

**Q4 2020 – Q1 2022, Number of packs, millions**

<table>
<thead>
<tr>
<th>Quarter</th>
<th>PEPFAR</th>
<th>Kenya</th>
<th>Republic of South Africa</th>
<th>Global Fund</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4 2020</td>
<td>2.3</td>
<td>0.3</td>
<td>0.3</td>
<td>1.8</td>
</tr>
<tr>
<td>Q1 2021</td>
<td>1.2</td>
<td>0.5</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Q2 2021</td>
<td>1.6</td>
<td>0.8</td>
<td>0.5</td>
<td>0.3</td>
</tr>
<tr>
<td>Q3 2021</td>
<td>1.8</td>
<td>0.9</td>
<td>0.6</td>
<td>0.4</td>
</tr>
<tr>
<td>Q4 2021</td>
<td>1.0</td>
<td>0.7</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>Q1 2022</td>
<td>1.4</td>
<td>0.8</td>
<td>0.5</td>
<td>0.3</td>
</tr>
</tbody>
</table>

**Source:** PEPFAR, Government of Kenya, The Global Fund, South Africa

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DTG 50, 90 Tabs

**Consolidated Demand Outlook**
Q4 2020 – Q1 2022, Number of packs, millions

<table>
<thead>
<tr>
<th>Quarter</th>
<th>PEPFAR</th>
<th>Global Fund</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q4 2020</td>
<td>0.05</td>
<td>0.06</td>
</tr>
<tr>
<td>Q1 2021</td>
<td>0.06</td>
<td></td>
</tr>
<tr>
<td>Q2 2021</td>
<td></td>
<td>0.1</td>
</tr>
<tr>
<td>Q3 2021</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Q4 2021</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>Q1 2022</td>
<td>0.06</td>
<td></td>
</tr>
</tbody>
</table>

**AS OF 2 OCT 2020**

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**SOURCE:** PEPFAR, Government of Kenya, The Global Fund, South Africa
**Consolidated Demand Outlook**

Q4 2020 – Q1 2022, Number of packs, millions

- **PEPFAR**
- Republic of South Africa
- Global Fund

**Q4 2020**
- PEPFAR: 1.5
- Republic of South Africa: 0.8
- Global Fund: 0.5

**Q1 2021**
- PEPFAR: 1.9
- Republic of South Africa: 1.1
- Global Fund: 0.7

**Q2 2021**
- PEPFAR: 1.6
- Republic of South Africa: 0.7
- Global Fund: 0.8

**Q3 2021**
- PEPFAR: 1.2
- Republic of South Africa: 0.8
- Global Fund: 0.4

**Q4 2021**
- PEPFAR: 1.2
- Republic of South Africa: 0.8
- Global Fund: 0.4

**Q1 2022**
- PEPFAR: 0.8
- Republic of South Africa: 0.7
- Global Fund: 0.7

**AS OF 2 OCT 2020**

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Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

- PEPFAR
- Kenya
- Global Fund

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Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

- PEPFAR
- Kenya
- Republic of South Africa
- Global Fund

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ABC/3TC 600/300

Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

- PEPFAR
- Kenya
- Republic of South Africa
- Global Fund

Q4 2020 – 1.3
Q1 2021 – 0.8
Q2 2021 – 1.2
Q3 2021 – 0.8
Q4 2021 – 0.9
Q1 2022 – 1.0

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Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

ABC/3TC 120/60, 30 Tabs*

*Some volumes may manifest in orders for packs of 60.

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Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

- **PEPFAR**
- **Kenya**
- **Global Fund**

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**SOURCE:** PEPFAR, Government of Kenya, The Global Fund, South Africa
LPV/r 200/50

Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

PEPFAR
Kenya
Republic of South Africa
Global Fund

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AS OF 2 OCT 2020
LPV/r 100/25

Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

- PEPFAR
- Kenya
- Republic of South Africa
- Global Fund

0.7
0.8
0.8
0.6
0.3
0.4
0.3
0.1
0.1
0.3
0.2
0.1
0.1
0.3
0.2
0.1
0.1
0.3
0.2
0.1
0.1

Q4 2020 | Q1 2021 | Q2 2021 | Q3 2021 | Q4 2021 | Q1 2022
---|---|---|---|---|---
0.7 | 0.8 | 0.8 | 0.6 | 0.3 | 0.4


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LPV/r 40/10 Capsules/Granules – Consolidated Demand Forecast Outlook

Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

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NVP 100 ml Oral Suspension

Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

- PEPFAR
- Kenya
- Republic of South Africa
- Global Fund

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**SOURCE:** PEPFAR, Government of Kenya, The Global Fund, South Africa
Consolidated Demand Outlook
Q4 2020 – Q1 2022, Number of packs, millions

PEPFAR

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Annual ARV Buyer Seller Summit
2020

Kenya Presentation
Dr. Charles Lwanga, Program Management Specialist – Pharma USAID/Kenya
Outline

• Country HIV/AIDS Landscape
• Treatment Optimization
• FY20/21 Projections
• Procurement and Supplier Performance Management
• COVID-19 Impact on the supply chain and risk mitigation measures
Country HIV/AIDS Landscape

Kenya (2019)

1.5m people living with HIV
4.5% adult HIV prevalence (ages 15-49)
42,000 new HIV infections
21,000 AIDS-related deaths
75% adults on antiretroviral treatment*
63% children on antiretroviral treatment*

*All adults/children living with HIV

Source: UNAIDS Data 2020
KENYA
Progress towards 90 90 90 targets (all ages)

- 90% Aware of their HIV status
- Of which 82% On HIV treatment
  - 74% of all people living with HIV
- 92% Virally suppressed
  - 68% of all people living with HIV

Source: UNAIDS Data 2020

www.avert.org
Patient scale up

No. of Patients ('000)

- Dec-19: 1,062
- Jan-20: 1,077
- Feb-20: 1,080
- Mar-20: 1,093
- Apr-20: 1,107
- May-20: 1,138
- Jun-20: 1,159
- Jul-20: 1,179
- Aug-20: 1,189
**Treatment Optimization**

**Adult ARV optimization**
- Transition to TLD with preference to MMD pack of 90s
  - 63% of all adult patients on TLD
  - No new procurements of TLE
- Shift to ATV/r as preferred Protease Inhibitor for adult patients

**Paediatric ARV optimization**
- On-going transition to LPV/r for paeds <20kgs and DTG for paeds ≥20kg
- NVP phaseout almost complete, ↓ number of paed patients on EFV (ABC/3TC+EFV)
- Introduction of DTG 10mg for paeds 4+ weeks and weigh 3+ kg?
- Pead 4-in-1 formulation? May not be critical?
Trend - TLD Transition

TDF + 3TC + EFV
TDF + 3TC + DTG

## FY20/21 Requirements

<table>
<thead>
<tr>
<th>Products</th>
<th>2020</th>
<th>2021</th>
<th>Total FY 20/21</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q4</td>
<td>Q1</td>
<td>Q2</td>
</tr>
<tr>
<td>Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 30 Tablets</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets</td>
<td>-</td>
<td>1,320,200</td>
<td>1,781,500</td>
</tr>
<tr>
<td>Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 180 Tablets</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Emtricitabine/Tenofovir 200/300mg tablet 30</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Lopinavir/Ritonavir 200/50 mg Tablet, 120 Tablets</td>
<td>216,775</td>
<td>-</td>
<td>176,860</td>
</tr>
<tr>
<td>Lopinavir/Ritonavir 40/10 mg Pellets</td>
<td>43,865</td>
<td>-</td>
<td>60,000</td>
</tr>
<tr>
<td>Nevirapine 10mg/ml oral suspension 100ml</td>
<td>35,711</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets</td>
<td>-</td>
<td>200,000</td>
<td>482,700</td>
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<tr>
<td>Lopinavir/Ritonavir 100/25 mg Tablet, 60 Tablets</td>
<td>125,000</td>
<td>-</td>
<td>128,700</td>
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<tr>
<td>Atazanavir/Ritonavir 300/100 mg Tablet, 30 Tablets</td>
<td>391,196</td>
<td>503,707</td>
<td>526,130</td>
</tr>
<tr>
<td>Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets</td>
<td>-</td>
<td>347,157</td>
<td>522,125</td>
</tr>
<tr>
<td>Dolutegravir 50 mg Tablet, 30 Tablets</td>
<td>-</td>
<td>-</td>
<td>67,600</td>
</tr>
<tr>
<td>Abacavir/Lamivudine 600/300mg tablet 30</td>
<td>-</td>
<td>149,821</td>
<td>137,650</td>
</tr>
<tr>
<td>Abacavir/Lamivudine 120/60mg, dispersible, 30 Tablets</td>
<td>-</td>
<td>375,057</td>
<td>-</td>
</tr>
<tr>
<td>Tenofovir/Lamivudine 300/300mg Tablet, 30 Tablets</td>
<td>522,125</td>
<td>-</td>
<td>347,157</td>
</tr>
</tbody>
</table>
Procurement

Procurement process is dependent of funding mechanism

GoK
- Conducted in accordance to the Kenya Public Procurement and Disposal Act (PPDA)

Global Fund
- Principal Recipient is the National Treasury with obligations set out in the grant agreement and the Procurement and Supply chain Management (PSM) guide
- Procurement conducted in accordance to the Kenya PPDA

PEPFAR
- Procurement done through KEMSA Medical Commodities Programme (KEMSA MCP)
- Procurement conducted in accordance to USAID Federal Acquisition Regulations (FAR) and ADS 312

Issues
- Non-adherence to contracted delivery timelines
- Delays in submission of docs required for application of IDF, import permits and tax waivers
- Requirement for pre-shipment inspection- Now suspended
Supplier Performance and Risk Management

• Split of awards-ratio dependent on past performance, price and risk
• Supplier appraisal tool in place
• Penalties for delayed deliveries
• Performing firms to gain in splits of awards
COVID-19: Impact and Mitigation

- Production delays
- Delays in deliveries/challenges with in-bound logistics
- Increased shipping/freight costs

Mitigation
- Contingency plan developed
- Enhanced engagement with suppliers to plan and track deliveries
- Call-down of most stocks pending with suppliers
- Accelerated move to transition all patients on treatment to MMD 3-6 months
- Early initiation of FY20/21 orders
Ethiopia’s update on HIV program and procurement

October 13-15, 2020

Ms. Tsion Tsegaye Gizaw
Procurement Contract Management Expert
Ethiopian Pharmaceuticals Supply Agency
• HIV prevalence - 0.9% (EDHS 2016)
• Annual New infections estimate in 2019 - 21,486
• Annual AIDS related deaths in 2018 - 11,423

• Ethiopia is a Federal State having nine regional states and two City Administrations
• In 2017, total projected population: 94,351,001 (CSA 2017)
Treatment updates in HIV Program

NVP phase out for adult and pediatrics, full shift to DTG containing regimens, Pediatrics treatment optimization

- **TLD** – Preferred for all clients including women of reproductive age, introduction of 30, 90 and 180 packs
- Pediatrics >70% on AZT/3TC/NVP based regimens shifted to optimal regimens
- **ABC/3TC/LPV/r** – children <10 years and <20kg
- **ABC/3TC/DTG** - children <10 years and >20kg
- Dual **AZT and NVP prophylaxis** for HIV exposed infants

3rd line treatment started at selected 36 hospitals
- Darunavir (DRV) - 600mg – Tablet
- Darunavir (DRV) - 75mg – Tablet
- Dolutegravir (DTG) - 50mg – Tablet
- Ritonavir (RTV) - 100mg – Tablet
- Ritonavir (RTV) - 25mg – Tablet

**DSD Models**
- ASM
- FTR
- UHEW managed CAG
Budget for HIV/AIDS Program

- ARV treatment is provided at 1304 ART sites and 2176 PMTCT sites
- The source of finance is The Global Fund and also USAID
- The Principal Recipient of the fund is Federal HIV/AIDS Prevention and Control Office-Ethiopia (FHAPCO)
- Program management is done by MoH Ethiopia
- Procurement is effected by Ethiopian Pharmaceutical Supply Agency (EPSA)
- Commodity forecasting is done annually for 3 consecutive years with one year supply plan.
- The budgeted amount by the GF have been utilized

HIV/AIDS Budget July 2016 to June 2021
Current ARVs Procurement for 2020/21

- EPSA Spot Tender: 3,115,627.06
- EPSA Framework: 29,530,472.53
- GF-PPM: 1,367,417.95
- GHSC-PSM: 2,123,344.50

- 5,000,000.00
- 10,000,000.00
- 15,000,000.00
- 20,000,000.00
- 25,000,000.00
- 30,000,000.00
- 35,000,000.00
Product specific procurement Expenditure proportion 2020/21

- 24.3% TLD90
- 32.0% TLD180
- 9.6% ATV/r
- 6.7% TLD30
- 6.5% TLE400
- 2.4% DRV75
- 2.0% DRV600
- 1.9% DTG50
- 0.7% TLD30
- 0.6% TLD180
- 0.3% TLD90
- 0.1% TLE400
- 0.1% ZL/60/30
- 0.02% LPV/r 40/10
- 0.02% RTV100
- 0.02% ZL/150/300
- 0.02% NVP susp
- 0.02% LPV/r 123
- 0.02% ABC300
- 0.02% ZL/150/300
- 0.02% 3TC
Long term framework agreements

• EPSA have established long term framework agreement for ARVs for a contract period of Dec-18 to Dec-21

• Eight suppliers have been part of the framework agreement for selected 17 ARVs. For most line items award have been shared among two to three bidders by 60% - 25% - 15% or 60% - 40% ratio

• Additional Framework agreement for TLE400 and TLD90 for a contract period of June-20 to June-22 - to three bidders by 60% - 25% - 15% proportion

• EPSA have reviewed the performance of each supplier yearly
<table>
<thead>
<tr>
<th>Challenges</th>
<th>Mitigation Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most challenges due to</td>
<td>Contract and LC extension</td>
</tr>
<tr>
<td>Delayed delivery</td>
<td>Continuously revise supply planning and map suppliers status</td>
</tr>
<tr>
<td>API price increment which in turn resulted in contract cancellations</td>
<td>Redistribution among regional hubs and health facilities</td>
</tr>
<tr>
<td>Contract cancellations</td>
<td>Strong coordination and follow-up</td>
</tr>
<tr>
<td>Repetitive LC extensions which are having huge charges on suppliers</td>
<td>Agreement with ESL, EAL to work with copy documents and payment will be processed later</td>
</tr>
<tr>
<td>Not being able to submit original documents on time</td>
<td>Incorporating other procurement mechanisms like GF-PPM and GHSC-PSM</td>
</tr>
<tr>
<td>Unwillingness to supply non economic quantities</td>
<td></td>
</tr>
</tbody>
</table>
Planned Activities

- New long term framework agreement contract for ARVs for 2022-2025
- Improving suppliers performance review
- Improved contract management
- Continuous follow-up of GF grant management
- Good supplier relationship
- Country specific ARV suppliers forum
Thank you!!!
Antiretroviral medicines: Large Buyers & Sellers Forum

Rashid Settaala
MAUL
September 2020
Outline

01 Introduction

02 Procurement planning process

03 Procurement Strategy

04 Changes to guidelines/regimens

05 Key milestones
Procurement Planning Process

Procurement Plan Reviews

- Monthly procurement planning meeting
  - Review of stock position by item (MOS)
  - Target inventory is 3 - 6 months i.e. 3 months for stock on hand and 3 months on order
- Monthly national commodity security meetings Led by MOH

Procurement Process

- Procurement guidelines
  - MAUL’s Procurement policies and Procedures manual
  - CDC FAR Guidance
  - NDA regulatory framework
Procurement planning process...

Evaluation Process (4 stage Evaluation Process)

- **01 Preliminary Stage**
  - Legal and statutory compliance

- **02 Technical Stage**
  - Product registration (USFDA & NDA)
  - Manufacturing capacity

- **03 Financial Stage**
  - Price
  - Lead time

- **04 Supplier Performance**
  - OTIF
  - Quality
  - Price

Key Features
- Eligibility to only prequalified suppliers
- Price Benchmarking and Negotiations involved
- Best evaluated bidder on quality, price, lead time and past performance
Challenges

- Increased lead times in the face of COVID-19
- Limited number of USFDA approved suppliers for certain commodities e.g. NVP suspension, LPV/r 40/10mg pellets
- Frequent changes of guidelines – supply disruption
Procurement Strategy

MAUL’s COP 20 Procurement Strategy

- **Cost competitiveness**: Price benchmarking, bi-annual negotiations, expedited prequalification of new entrants, preference for direct procurement from manufacturers, Cartonless packs, MMD packs

- **Supplier performance**: OTIF with a target of 90%

- **Risk management**: Maintaining a well-diversified supplier base, meeting the PEPFAR quality requirements, QC testing, splitting of orders amongst suppliers, consideration of non-cost factors

- **Stakeholder engagement**: Information sharing amongst donors and with MoH - stock status, forecast, price

- **Segmented sourcing process** for Adult and Paediatric ARVs

- **Online ordering**: using the MAUL eProcurement system (MePS) to increase efficiency and visibility
Changes to guidelines/Formulations

Major Transitions of the 2020 Uganda ART guidelines

- **Transitioning pregnant women and adolescent mothers to DTG based regimens:**
  - Virally suppressed pregnant women on TLE to be maintained on the same ART regimen until 6-9 months after delivery
  - Virally suppressed pregnant women on 2nd line ART with ATV/r or LPV/r to be maintained on the same ART regimen until 6-9 months after delivery

- **Transitioning 2nd line adult patients to DTG based regimens:**
  - LPV/r transition commenced in September 2020 and to end by May 2021
  - ATV/r transition to commence in January 2021 and end by September 2021
Changes to guidelines/formulations…

Product phase in and phase out

❖ **New products (Phase in):**
  - TLE 400 – for 1<sup>st</sup> line patients that may not tolerate DTG but are using TDF+3TC and Pregnant women and breast feeding women currently stable on TLE-600.
  - TDF+FTC for PrEP clients

❖ **PEPFAR Disallowed ARVs (Phase out):**
  - LPV/r 200/50mg
  - NVP based regimens (apart from NVP suspension for eMTCT)
  - Adult 2<sup>nd</sup> line NRTIs - ABC+3TC, AZT+3TC and TDF+3TC
  - TLD 30s and TLE-400 30s
Key milestones 2020 / 2021

1. Adopt full capacity for the eProcurement System
   - ARV suppliers are onboarded onto the eProcurement system
   - ARV tenders managed through the system
   - The system has led to improved the procurement process through:
     i. Enhanced data visibility and transparency
     ii. Increased efficiency
     iii. Improved record management
     iv. Enhanced internal controls
     v. Increased standardization

2. Timelines for tenders 2020 / 2021
   - ARV procurement using framework contracts with six monthly review
3. Scale up of MMD packs

- MAUL to streamline the procurement of MMD packs (90’s) for TLD and TLE 400mg
- MAUL to adopt other measures to improve total cost of ownership through bulk purchases and consolidation while ensuring that there is emphasis on EOQ
Republic of South Africa

Ms Khadija Jamaloodien
Affordable Medicines Directorate

ARV Large Buyer Seller Summit
October 2020
Summary

• Overall ARV availability remains high in SA, above 90%
• ARV supplier performance has been a concern, with over-reliance on a smaller subset of suppliers to cope
• TLD transition has accelerated
• 2021 does carry uncertainty, as transitions of 2\textsuperscript{nd} line adult patients and children receive focus
• A new ARV tender will be advertised in 2021, for award in 2022
Our progress on growing patients on treatment has been impacted by COVID-19

People living with HIV (PLHIV) is growing, but at a slower rate

- Source: Thembisa 4.3 model

Department of Health has reviewed its growth targets to reach 6m in Mar-22

- Source: NDoH

- COVID impact has slowed TROA growth
- 6m target shifted to March 2022
Status of transition to dolutegravir based regimens

South Africa has >2m patients on TLD

• TEE suppliers were already struggling before COVID, due to their non-adherence to target stock levels
  – NDoH had to move to “rationing” TEE to manage stock across the country
• Slow TLD uptake in Q1, followed by increases in Q2 and Q3
  – >7m packs of TLD dispensed in Q3 2020
• Despite eight contracted TLD suppliers, the NDoH now has to secure alternative sources of TLD in the short term
  – Zero stock at suppliers, as all available TLD delivered immediately using weekly “rationing” process
  – ~4 weeks of cover in provinces versus target of 8-12 weeks
• DTG50 pace remains slow as focus has been on 1st line, but expected to increase in 2021
Weeks of cover on TLD remains too low

TEE Has finally reached target level after 10 months

TLD High demand expected for holiday dispense drops weeks of cover

Source: Team analysis; TEE/TLD profile based on TROA reaching 6m in Mar-22
Adults on main 1st line ARTs; TLD has overtaken TEE

OUTLOOK FOR 2021

TLD and TEE patient estimates

Source: Team analysis; TEE/TLD profile based on TROA reaching 6m in Mar-22
## Regimen trends: 2\textsuperscript{nd} line adults

<table>
<thead>
<tr>
<th></th>
<th>Patient estimate</th>
<th>Comment</th>
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<tr>
<td>AZT/3TC+LPV/r</td>
<td>~250,000</td>
<td>LPV/r volumes expected to reduce, but based on clinician adherence to</td>
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<td>communication from HIV Programme on 2\textsuperscript{nd} line patient transition to DTG 50</td>
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<tr>
<td>AZT/3TC+DTG</td>
<td>~50,000</td>
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<tr>
<td>AZT/3TC+ATV/r</td>
<td>~10,000</td>
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<tr>
<td>TDF/FTC+LPV/r</td>
<td>~6,000</td>
<td>Stable volumes expected</td>
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<td>TDF/FTC+ATV/r</td>
<td>~250</td>
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<tr>
<td><strong>Total</strong></td>
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Regimen trend: 1\textsuperscript{st} line children

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<tr>
<td>ABC/3TC+EFV</td>
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<td>Expectation that EFV &amp; LPV/r will be replaced by DTG 50</td>
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<tr>
<td>ABC/3TC+LPV/r</td>
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<tr>
<td>ABC/3TC+DTG</td>
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<td>AZT/3TC+NVP</td>
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<td>Stable volumes expected</td>
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<td>ABC/3TC+ATV+r</td>
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<td>Exploring ATV/r combination</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>~160,000</strong></td>
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</table>
Paediatric and PMTCT

Nevirapine will remain as an important treatment component in SA

• WHO treatment of HIV in neonates:
  – Nevirapine (solution)
    • Indicated in SA’s PMTCT programme as well as HIV treatment in the neonate
  – Raltegravir – not preferred in South Africa due to:
    • Complex administration (numerous steps required)
    • Low genetic barrier to resistance and risk of creating resistance to Dolutegravir

• SA will continue to procure NVP solution for PMTCT programme and HIV treatment of the neonate
# TLD / TEE demand plan

**Note**: Q4 demand higher due to dispensing to cover holiday period.

*Excludes requirement to build required stock levels in provinces and at suppliers (ADDITIONAL 10m TLD packs required over Oct-20 to Mar-21)

<table>
<thead>
<tr>
<th>Calendar period</th>
<th>Q4 – 2020</th>
<th>Q1 – 2021</th>
<th>Q2 – 2021</th>
<th>Q3 – 2021</th>
<th>Q4 - 2021</th>
<th>Q1 - 2022</th>
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<tr>
<td>'000s of 28-count packs</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>TLD patient demand</td>
<td>9 905*</td>
<td>8 229*</td>
<td>11 318</td>
<td>12 787</td>
<td>16 693</td>
<td>12 373</td>
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<tr>
<td>TEE patient demand</td>
<td>7 165</td>
<td>4 312</td>
<td>4 182</td>
<td>3 395</td>
<td>3 077</td>
<td>2 183</td>
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Source: TLD transition team
NDoH selection and procurement processes

Current HIV tender active from July 2019 to June 2022

- Expect that new tender will be advertised in H2 2021
- ARV Guidelines will be influenced by clinical evidence, which will impact demand and tender forecasting
Conclusion

• NDoH is working to improve its planning process and budgeting process
• Suppliers to ensure they maintain their stock levels in South Africa as per the special requirements and conditions of contract
• Supplier performance will influence the awards in the new tender

Looking forward to better integration, continued innovation, and evolution of how we work together for the benefit of our patients
THANK YOU
Annual ARV Buyer Seller Summit

UNDP Procurement Update

ZAFAR YULDASHEV,
Procurement Specialist, GF HIST, Copenhagen

14 October 2020
Denmark
UNDP Portfolio overview

UNDP Global Health Procurement and Supply Chain Management Overview

$330 Million USD - 2019 Health Procurement Expenditure Delivered

+37 Countries in Health Procurement Advisory and Support

COVID 19 - Emergency procurement support 100 + countries

Top 5 Countries: South Sudan, Angola, Uzbekistan, Burundi, Zimbabwe
ARV VOLUMES

- **Total value ARVs 2018**: $129,684,800
- **Total value ARVs 2019**: $81,784,700
- **Total value ARVs 2020**: $......
- **Projection of value 2021**: $110,000,000
Top 5 ARV Products 2019

1. Dolutegravir/Lamivudine/Tenofovir, 50+300+300 Tab
   - Revenue: $44,471,557.46

2. Atazanavir/Ritonavir, 300mg+100mg-30 Tab BT
   - Revenue: $59,377,595.65

3. Lamivudine/Zidovudine, 150mg+300mg-60 Tab BT
   - Revenue: $5,381,290.82

4. Abacavir/Lamivudine, 600mg+300mg-30 Tab BT
   - Revenue: $5,302,096.21

5. Efavirenz/Lamivudine/Tenofovir, 600+300+300mg-30 Tab BT
   - Revenue: $4,945,365.93
Framework Agreements

Strategic procurement partnerships with other UN Agencies

- MoU with UNICEF
  Pharmaceuticals: paediatric ARVs, anti-malaria medicines, vaccines, LLINs

- MoU with UNFPA
  Health products: reproductive health commodities

- GDF - Stop TB Partnership with UNOPS
  Pharmaceuticals: 2nd Line TB medicines
Framework Agreements (cont)

**LTAs with Manufacturers and Procurement Agencies (consolidators)**

- ARVs, TB, HEP C, NCDs and other essential medicines
- Medical devices including diagnostic kits
- Health Equipment
- Laboratory equipment and consumables (reagents, cartridges)

**Auxiliary Services**

QC Lab testing, Freight forwarding services, Insurance, provision of data loggers etc.
Optimizations

• QA Policy and Centralization of procurement
• Quarterly tenders
• E-tendering
• Online platform
• Planning
• Tracking of delivery
• KPI Monitoring
<table>
<thead>
<tr>
<th>Product description</th>
<th>Strength</th>
<th>Dosage form</th>
<th>Type of packaging*</th>
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<tr>
<td>Abacavir</td>
<td>300 mg</td>
<td>Tablet</td>
<td>Bottle HDPE: 60</td>
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<tr>
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<tr>
<td>Lamivudine/Tenofovir disoproxyl fumarate</td>
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<td>Nevirapine</td>
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<tr>
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<td>Tablet</td>
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## Preliminary data

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<th>PRODUCTS</th>
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<td></td>
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<td>Efavirenz/Lamivudine/Tenofovir DF 400/300/300 mg Tablet, 30 Tablets</td>
<td>323</td>
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</tr>
</tbody>
</table>
THANK YOU!!!

zafar.yuldashev@undp.org

UNDP Global Fund Health Implementation Support Team
Key contacts here today

Lin (Roger) Li
Senior Manager,
Strategic Sourcing

Cathal Meere
Manager, Pharmaceuticals
Strategic Sourcing

Uranchimeg Badarch
Category Lead, ARVs
Strategic Sourcing

Martin Auton
Senior Manager,
Principal Recipient Services

Chirag Rajputia
Associate Specialist,
Principal Recipient Services
This presentation outlines:

- Implementation of the 2018-2021 ARV strategy
- 2020 supplier performance
- 2021 forecast and priorities
- Global Fund COVID-19 response
The Global Fund disbursed US$3.5 billion* across 150 countries to fight HIV, TB, Malaria and strengthen health systems in 2019

**HIV in 2019:**
- 133 million HIV tests taken; HIV-positive people with knowledge of their status increased from 71% in 2015 to 82% in 2019. Global target: 90% by 2020.
- People living with HIV with suppressed viral load increased 41% in 2015 to 59% in 2019. Global target: 73% by 2020.
- 718,000 HIV-positive mothers received medicine to keep them alive and prevent transmitting HIV to their babies in 2019; coverage increased from 44% in 2010 to 85% in 2019. Global target: 100% by 2020.

**TB in 2019:**
- 5.7 million people received lifesaving treatment for tuberculosis in 2019.
- TB treatment coverage increased from 48% in 2010 to 65% in 2018
- Treatment success rate reached 85% in 2017. Global targets for coverage and treatment success rates: 90% by 2025.

**Malaria in 2019:**
- 160 million mosquito nets were distributed to protect nearly 320 million people from malaria.
- 11 million pregnant women received preventative therapy, 124 million cases of malaria treated
- 243 million suspected cases tested for malaria.

* including regional grant
Key ARV strategy achievements in 2020

**Supplier Collaboration:** managed through pricing strategy roadmaps enabling more for less
- Alternate WHO recommended regimens implemented: 1\textsuperscript{st} & 2\textsuperscript{nd} line
- Better formulations for children-granules, dispersible tabs
- Price reductions for 1\textsuperscript{st} line regimen

**Rapid Supply Mechanism:** improved ability to respond to ARV stock-outs e.g.
- Within 1 month from request to in-country delivery through vendor managed inventory

**Annual Committed Volumes:**
- Covering the 3 years tender period with quarterly updates on next order

**Increased Engagement:** with other large buyers, partners and other Global Fund procurement channels
- Contract terms extended to other buyers
- Procurement approaches evolving to include stronger performance based contract implementation & more non-price factors
- Expanded scope of ARV Procurement Working Group: Including more partners & also adult products

**Innovation:**

supporting efforts to stimulate innovation; accelerate the adoption of new and/or cost-effective products
Implementation of ARV strategies: emphasis on value creation through Supplier Relationship Management and cross-disease strategy

- **Spot tender (before 2014)**
- **Performance Based Approach (2015-2017)**
  - Focus on the strategic areas of 2nd phase of Market Shaping Strategy implementation
  - Enhance supplier performance management matrix
  - Deployment of supply risk mitigation criteria
  - Increase supply visibility and promote best practices
  - Establishing direct suppliers relationships with originators
- **Value creation through SRM (2018-2021)**
- **Cross-disease strategy (end 2021-onwards)**
  - Implement cross-disease pharma strategy, including ARVs & ANTMs
Leveraging impact through increased partner collaboration

• From July 2015, PAHO leveraging Global Fund long term agreements (LTAs) for procuring ARVs through the Strategic Fund
• Close collaboration with UNITAID and PEPFAR on new product introduction

Partnership

- Vendor performance
- Supply assurance for low volume products
- Access to products allocated to TGF for emergency requests
- Best value for money
- Best practice sharing

Added value

- Maximize use of LTAs: framework agreements
- Increase ARV demand visibility
- Transition/adoptions of new products
- Build on country capacity building

Economy of scale

- Contract Supplier Management
- Harmonize Quality Standards & Quality Assurance
- Transparency in tendering process
- Smoothen product transition

Effectiveness

- From July 2015, PAHO leveraging Global Fund long term agreements (LTAs) for procuring ARVs through the Strategic Fund
- Close collaboration with UNITAID and PEPFAR on new product introduction

Leveraging impact through increased partner collaboration
2020 supplier performance at the end of Q3

- TGF ARV Strategy includes active supplier performance management with a greater focus on
  - Supply security
  - OTIF (on-time-in-full delivery)
  - Responsiveness-longer lead-times are factored in OTIF performance and responsiveness
  - Shorter lead-times
  - VMI (Vendor Managed Inventory)
  - Stock visibility for low volume products
  - Mitigate risk of stock-outs

- Communication with suppliers is particularly critical during the COVID crisis

**Supplier OTIF** (on-time-in-full delivery) with target 90% and **responsiveness** (target 80%)
55 million monthly ARV* packs estimated for 2021 delivery through GF PPM

More than 90% tenofovir-based FDCs = cartonless for POs placed in 2020

*Tenofovir-based first-line triple FDC 80%

ABC/3TC paed. 5%
DTG 50 mg 3%
LPV/r paed. 1%
LZ adult 1%
LPV/r adult 2%
ATV/r adult 2%
ABC adult 2%
Others 1%

*more detailed forecast for 2021 will be published in November 2021

Looking Ahead: 2021 Global Fund focus areas during the COVID pandemic

Supply continuity: ensuring continued supply & long term sustainability for strategic medicines, including ARVs

Facilitate collaboration: between key partners & suppliers to balance supply & demand, drive innovation and smoothen new product uptake

Leverage supply synergies: across disease areas through a combined tender for ARV, anti-malaria medicines and other strategic medicines

New grant making and implementation: ensuring a smooth transition from 3 year grants that end this year to the new 3 year grants being finalized for implementation starting early next year
Global Fund and Partners aligned to ensure supply of critical COVID-19 products

1. **Diagnostics**
   - **In-scope products (focused on tests):**
     - COVID PCR tests
     - Instruments
     - Testing software
     - Swap & extraction kits
   - **Partners involved:**
     - WHO Dx Consortium

2. **PPE**
   - **In-scope products:**
     - Health equipment such as:
       - Face masks / shields
       - Protective clothing
       - Gloves
       - Goggles
   - **Partners involved:**
     - UNICEF

3. **Therapeutics**
   - **In-scope products:**
     - Approved therapeutics (e.g., Dexamethasone)
   - **Partners involved:**
     - ACT-A Therapeutics Pillar

4. **Oxygen**
   - **In-scope products:**
     - Oxygen therapy (e.g., ventilators)
     - Oxygen concentrators
   - **Partners involved:**
     - UNICEF

**Partner collaboration**
- Continuing to leverage our **Partnerships** (e.g., WHO Consortium and ACT-A across Dx, Tx and the Health Systems Connector) – a few specific examples:
  - Gates Foundation and others are working to reserve capacity of antigen rapid tests (Ag RDTs)
  - Collaborating with UNICEF to procure Ag RDTs and Dexamethasone

**COVID procurement by the numbers:**
- Procured **2M+** diagnostic tests (Abbott & Cepheid) as part of WHO Dx Consortium (**+1M** since July)
- Made available **~$170M** for PPE through C19RM, which countries are procuring locally and via PPM (UNICEF)
- Preparing to procure **up to $50M** in antigen RDTs (**~10M tests**) for low- & middle-income countries globally

---

1 EUL: Emergency Use Listing; EUA: Emergency Use Authorization by US FDA
Antiretrovirals

Lifesaving antiretroviral medicines (ARVs) are vital for HIV programs and account for nearly 40% of the Global Fund’s Pooled Procurement Mechanism annual spend. Our Market Shaping Strategy and our position as one of the largest global buyers of ARVs guide our commitment to facilitating healthy, balanced and sustainable markets.

We collaborate with implementing partners and other large buyers to consolidate information, understand the demand landscape and share improved forecasts. Working with partners through the multiagency ARV Procurement Working Group allows us to coordinate order cycles and promote optimal products. Quality-assured ARVs and other medicines used in HIV programs are available through the Pooled Procurement Mechanism on our online purchasing platform, wambo.org. We publish current reference prices and the Procurement and Delivery Planning Guide with up-to-date indicative lead times:

• Pooled Procurement Mechanism Reference Pricing: ARVs (download in English)
HELP US SAVE
16 MILLION
MORE LIVES.

STEP UP
THE FIGHT

THANK YOU
ARV Supply Chains in 2020

Using data to create resilience and increase responsiveness

Alan Pringle
Global Supply Chain Director
GHSC-PSM has delivered enough antiretrovirals (ARVs) to provide 9.4 million patient-years of HIV treatment over the life of the project, including 908 thousand patient-years of treatment in Q3.

To date, GHSC-PSM has delivered more than 4.4 million bottles of tenofovir, lamivudine, dolutegravir (TLD) to 13 countries, which would provide more than 4.7 million patient-years of treatment.

Multi-month dispensing packages of TLD first-line treatment accounted for 88 percent of all quantities delivered in Q3.

A total 39 countries procured HIV/AIDS medicines and commodities and received health supply-chain systems strengthening with HIV/AIDS funding.

Thanks to multi-month dispensing (MMD) patients have likely saved more than 6.4 million trips in Q3 to the pharmacy and 20 million over the life of the project.

GHSC-PSM brought improved product visibility into HIV commodities in 103 central and regional warehouses in 22 PEPFAR countries and 11,642 health facilities in 11 PEPFAR countries.

In Q3, 9 countries procured 2.8 million viral-load tests to support scale-up of patient viral-load testing, while viral-load and early infant diagnosis contracts have generated $6.2 million in savings in Q3.
Greater use of data enabled early risk identification and risk mitigation

**ORDER MONITORING TOOL**
Increased supplier touchpoints and frequent order status updates allowed for the consolidation of data to quickly identify regional supply risks.

**SUPPLY PLAN & ORDER VISUALIZATION TOOL**
Layering country forecast data with up-to-date order status data enabled the prioritization of deliveries to eliminate stock risks and support MMD.

**LOGISTICS MILESTONE TRACKER**
Tracking the availability and movements of air and sea freight on a weekly basis highlighted regional trends and pinpointed where 3PL or field support would be required to expedite delivery.
Analytics identified a need for rapid additional procurements to support accelerated MMD

MULTI-MONTH SIMULATION TOOL
The MuMS tool consolidates stock, consumption, and shipment data and allows PEPFAR country offices to run their own MMD simulations and work with Ministry of Health staff to agree on disbursement strategies.
Analytics identified a need for rapid additional procurements to support accelerated MMD

SUPPLIERS RECEIVED ADDITIONAL FIRM ORDERS TO SECURE SUPPLIES AND TOP UP SUPPLY NATIONAL SUPPLY CHAINS

Quickly turning forecasted demand into firm orders at the onset of COVID helped suppliers make investments in raw materials, ensuring a better continuation of supply.
Upcoming release
QAT—Modernized analytical planning tool to enhance national & global decision making

- Open source web-based software with automatic updates and offline capability
- Enhanced analytics and rapid mapping of sub-national, national and global scenarios
- Evaluates multiple data sets e.g. packaging sizes, shelf life, budget, inventory turns etc.
- Platform agnostic deployment that allows data gathering and analysis at any location
- Data exchange and integration capability e.g., ERP, control towers, and LMIS systems
- Role based access permissions with version control and archiving
ARV Supply Chains in 2020—Bent but not broken by COVID-19

ARV On-Time Delivery %: COVID Impacted & Standard OTD

- Standard OTD
- COVID Impacted OTD

<table>
<thead>
<tr>
<th>Year</th>
<th>Standard OTD</th>
<th>COVID Impacted OTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020-01</td>
<td>98%</td>
<td>98%</td>
</tr>
<tr>
<td>2020-02</td>
<td>93%</td>
<td>92%</td>
</tr>
<tr>
<td>2020-03</td>
<td>92%</td>
<td>92%</td>
</tr>
<tr>
<td>2020-04</td>
<td>94%</td>
<td>80%</td>
</tr>
<tr>
<td>2020-05</td>
<td>98%</td>
<td>92%</td>
</tr>
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<td>2020-06</td>
<td>91%</td>
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<tr>
<td>2020-07</td>
<td>94%</td>
<td>83%</td>
</tr>
<tr>
<td>2020-08</td>
<td>88%</td>
<td>87%</td>
</tr>
</tbody>
</table>
THANK YOU!
U.S. Food and Drug Administration’s Registration of Antiretroviral Drugs under the PEPFAR Program

Annual ARV Buyer Seller Summit 2020

Sanjana Mukherjee, PhD., MSc.
Public Health Policy and Regulatory Research Fellow
U.S. Food and Drug Administration
October 14, 2020
Background: FDA’s role in the PEPFAR program

• FDA reviews HIV drugs for use by PEPFAR in partner countries

• “Tentative approval” process is used for drugs that cannot be marketed in the U.S. because of patents or exclusivities but meet all of FDA’s safety, efficacy, and quality requirements

• Two types of drugs are made available:
  - New drugs (NDA) – modifications to formulations, strengths, or combinations of previously approved drugs – but those not available in the U.S. (e.g., TLD)
  - Generic drugs (ANDA) – exact copies of drugs approved for use in the U.S. (e.g. tenofovir DF 300 mg).

• FDA typically expedites review of PEPFAR applications to ensure patients get access to essential ARVs as quickly as possible
Objectives

Two major research questions:

1. An evaluation of FDA’s program to register HIV drugs for PEPFAR use:
   - Trends in submission and approval of ARVs
   - Reasons why FDA issues Complete Response Letters (CRLs)
   - Associations between CRLs and time-to-registration

2. Impact of FDA-reviewed PEPFAR products on global access
   - Extent to which WHO and the Global Fund use ARVs reviewed by FDA for quality reliance
   - Potential duplication of ARV review efforts by FDA and WHO

For complete methodology and results refer to the following peer-reviewed manuscripts:

1. Chahal HS et al. Impact of the US Food and Drug Administration registration of antiretroviral drugs on global access to HIV treatment, *BMJ Global Health* 2018;3:e000651

Part 1 Methods: FDA’s program to register HIV drugs for PEPFAR use

Study Design

- Dec 1, 2004 - May 31, 2018
- NDA (new drugs) and ANDAs (generic drugs) submitted under PEPFAR program
- Registered = Approved/Tentatively Approved

Inclusion and Exclusion Criteria

- Inclusion Criteria:
  - Registered for PEPFAR use
  - Received CRL
  - Withdrawn after registration or CRL
  - Pending status
- Exclusion Criteria:
  - Withdrawn or canceled before any regulatory action*
  - Review process unbegun
  - Refuse-to-file applications

Data Sources and Extraction

- Internal FDA databases:
  - DARRTS
  - CDER Informatics Platform
- Variables collected and analyzed:
  - Type of application (NDA /ANDA)
  - Population (Adult/Pediatric)
  - Drug Type
  - Current Regulatory Status
  - CRL’s issued and reasons
  - Time to registration
Findings: Trends in Submission of ARV Applications for PEPFAR

- Decreasing trend in overall number of PEPFAR application submissions since the peak between 2005 and 2008
  - 23% applications submitted were for pediatric ARV formulations or strengths

- Single molecule drug applications (49%) were most common; however, since 2011, 61% of the submissions have been for fixed-dose combinations (FDCs)

- Overall, 62% of submitted PEPFAR applications were copies of existing drugs (ANDAs), 38% were modifications to existing drugs (NDAs)
Findings: Reasons for Complete Response Letters (CRLs)

- 37% (95/260) applications received >1 CRL
  - Total of 264 reasons for issuance of CRLs identified

- Number of CRLs per application ranged between 1 to 6.

- Deficiencies in manufacturing processes was the most common reason (44%) for issuance of CRL

- 55% (52/95) received registration after addressing deficiencies

### CRL Reasons, No. (%)

<table>
<thead>
<tr>
<th>Variable</th>
<th>1 CRL</th>
<th>2 CRLs</th>
<th>3 CRLs</th>
<th>4 CRLs</th>
<th>5 CRLs</th>
<th>6 CRLs</th>
<th>Total Reasons for CRLs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing and chemistry</td>
<td>67 (44)</td>
<td>23 (37)</td>
<td>15 (60)</td>
<td>5 (45)</td>
<td>4 (40)</td>
<td>1 (33)</td>
<td>115 (44)</td>
</tr>
<tr>
<td>Labeling</td>
<td>36 (24)</td>
<td>18 (29)</td>
<td>4 (16)</td>
<td>1 (9)</td>
<td>2 (20)</td>
<td>1 (33)</td>
<td>62 (23)</td>
</tr>
<tr>
<td>Facility inspection</td>
<td>24 (16)</td>
<td>18 (29)</td>
<td>4 (16)</td>
<td>5 (45)</td>
<td>3 (30)</td>
<td>NA</td>
<td>54 (20)</td>
</tr>
<tr>
<td>Bioequivalence</td>
<td>18 (12)</td>
<td>3 (5)</td>
<td>2 (8)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>23 (9)</td>
</tr>
<tr>
<td>Biopharmaceutics</td>
<td>6 (4)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>6 (2)</td>
</tr>
<tr>
<td>Missing facility</td>
<td>1 (1)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Packaging</td>
<td>1 (1)</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Risk evaluation and mitigation strategy&lt;sup&gt;a&lt;/sup&gt;</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>1 (10)</td>
<td>1 (33)</td>
<td>2 (1)</td>
</tr>
<tr>
<td>Total</td>
<td>153 (59)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>62 (24)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>25 (10)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>11 (4)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>10 (4)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>3 (3)&lt;sup&gt;c&lt;/sup&gt;</td>
<td>264 (100)</td>
</tr>
</tbody>
</table>

Findings: Association of CRLs on Time to Registration

- Median registration time
  - All applications = 10 months (IQR: 7 – 17.5 months)
  - Without CRLs = 9 months (IQR: 5.5 – 12 months)
  - With at least 1 CRL = 22 months (IQR: 14 – 38 months)

- Registration Time: inclusive of all review time – from application submission to FDA to registration. This time can include multiple review cycles and time for applicants to respond to FDA questions related to review.

Part 1 Conclusions

• Shift towards FDC products observed

• A decrease in PEPFAR applications submitted annually since beginning of PEPFAR

• Efforts to develop better, easier-to-use pediatric-specific therapies are needed

• FDA issued CRLs to applications that had deficiencies. CRLs were issued for multiple reasons including:
  ➢ Deficiencies in manufacturing processes and facilities

• To improve applications, applicants can:
  ➢ Request FDA advice/feedback on application issues prior to submission using existing processes
Part 1 Limitations

- Did not assess whether FDA-registered products are being actively manufactured or procured

- Did not conduct an in-depth analysis of technical reasons for issuing CRLs

- Results of this study cannot be generalized to other drugs reviewed by FDA
  - Study only focused on FDA’s PEPFAR program
Part 2 Methods: Impact of FDA-reviewed PEPFAR products on global access

Study Design

- Dec 1, 2004 to March 20, 2017
- Registered and active status = Approved/Tentatively Approved

Inclusion and Exclusion Criteria

- Inclusion Criteria
  - Registered for PEPFAR use and in active status

- Exclusion Criteria:
  - Withdrawn or rescind after registration

Data Sources and Extraction

- Internal FDA databases:
  - DARRTS
  - CDER Informatics Platform

- WHO/PQP public list

- Global Fund’s public ARV Pharmaceutical Products (v. 132)
Findings: One-way reliance on FDA PEPFAR ARVs by WHO and Global Fund

- 87% (194/224) of FDA-registered ARVs appeared on WHO/PQP and/or Global Fund ARV lists though direct or indirect reliance

- % FDA-registered ARVs listed by WHO and Global Fund through one-way reliance:
  - WHO/PQP list: 45% (100/224)
  - Global Fund List: 79% (178/224)

- Of the 124 FDA-registered ARVs not included on WHO/PQP list through one-way reliance:
  - 66 products underwent both WHO Prequalification and FDA registration

Part 2 Conclusions

• In addition to PEPFAR, other global health agencies such as the Global Fund and WHO may rely on FDA-reviewed drugs for quality assurance to enhance their respective formularies

• There is potential duplication of efforts between FDA and WHO

• FDA, WHO, and applicants should explore methods to make efficient use of limited resources
  ➢ CRP-Lite Pilot Program
Part 2 Limitations

• FDA, WHO/PQP, Global Fund lists updated frequently
  ➢ Lists as of March 20, 2017 were used for analysis

• Did not analyze those ARVs which are on WHO/PQP and Global Fund list but are not registered by FDA

• Did not analyze whether drugs are being actively manufactured and procured
Questions?

For complete methodology and results refer to the following peer-reviewed manuscripts:

1. Chahal HS et al. Impact of the US Food and Drug Administration registration of antiretroviral drugs on global access to HIV treatment, *BMJ Global Health* 2018;3:e000651


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Pediatric Treatment and Infant Prophylaxis

Martina Penazzato MD, MSc, PhD
Paediatric HIV lead, WHO-HQ Geneva
Presentation outline

• Background
• Treatment guidelines and introduction of new formulations
• Postnatal prophylaxis
• Priority pediatric formulations
2016-2020 strategy had two commitments for children: We missed them both.
Despite high levels of PMTCT coverage new child infections persist

Figure 2. Percentage coverage of pregnant women reached with antiretroviral therapy and number of children acquiring HIV, focus countries, 2010–2019

Note: the 2020 targets are for all countries and not just the focus countries. Globally, 85% of pregnant women were receiving antiretroviral therapy in 2019 and 150,000 children acquired HIV. Source: UNAIDS epidemiological estimates, 2020.
Final transmission rates over 10% in 13 of 21 countries

About 50% of new infections are during breastfeeding
Pediatric ART is still far behind adult coverage in 17 of 20 focus countries

**Figure 9.** Antiretroviral therapy coverage among people aged 0–14 and 15+ years for 20 focus countries, 2019

Data for Botswana were not available at the time of publication.
Even among children on treatment, viral load suppression is lower than among adults on treatment.

**Figure 14.** Viral load suppression among people aged 0–14 and 15+ years receiving antiretroviral therapy by age group and country in 15 focus countries, 2019.

Good progress on policy uptake in most countries but implementation is requiring time and efforts as a result of COVID-19 disruptions.

Table 2. Policies related to HIV treatment for children

<table>
<thead>
<tr>
<th>Country</th>
<th>Dolutegravir first line for children ≤20 kg</th>
<th>Lopinavir first line for children &lt;20 kg</th>
<th>Multi-month dispensing, 3 or 6 months</th>
<th>Point-of-care early infant diagnosis policy</th>
<th>Virological testing at nine months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angola</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Botswana</td>
<td>√</td>
<td>√</td>
<td>*</td>
<td>x</td>
<td>Partial</td>
</tr>
<tr>
<td>Burundi</td>
<td>√</td>
<td>*</td>
<td>√</td>
<td>x</td>
<td>*</td>
</tr>
<tr>
<td>Cameroon</td>
<td>√</td>
<td>√</td>
<td>&gt;2 years</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Chad</td>
<td>√</td>
<td>*</td>
<td>√</td>
<td>*</td>
<td>Partial</td>
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<tr>
<td>Côte d'Ivoire</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>Partial</td>
</tr>
<tr>
<td>Democratic Republic of the Congo</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>Eswatini</td>
<td>√</td>
<td>√</td>
<td>&gt;2 years</td>
<td>√</td>
<td>√</td>
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<tr>
<td>Ethiopia</td>
<td>√</td>
<td>√</td>
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<td>√</td>
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<td>Malawi</td>
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<td>Mozambique</td>
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<td>x</td>
<td>√</td>
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<td>√</td>
<td>*</td>
<td>x</td>
<td>√</td>
</tr>
<tr>
<td>South Africa</td>
<td>√</td>
<td>√</td>
<td>&gt;5 years</td>
<td>x</td>
<td>√</td>
</tr>
<tr>
<td>United Republic of Tanzania</td>
<td>√</td>
<td>√</td>
<td>&gt;5 years</td>
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<td>Zimbabwe</td>
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<td>√</td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
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</table>

* not available
Treatment
### WHO 2018 recommendations and guidance

<table>
<thead>
<tr>
<th>NEONATES</th>
<th>CHILDREN</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preferred</strong></td>
<td><strong>ABC+3TC+DTG</strong></td>
</tr>
<tr>
<td>AZT+3TC+RAL&lt;sup&gt;1&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td><strong>Alternatives</strong></td>
<td>ABC+3TC+LPV/r</td>
</tr>
<tr>
<td>AZT+3TC+NVP</td>
<td>ABC+3TC+RAL&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Special circumstances&lt;sup&gt;3&lt;/sup&gt;</strong></td>
<td>ABC (or AZT)+3TC+EFV</td>
</tr>
<tr>
<td>AZT+3TC+LPV/r</td>
<td>ABC (or AZT)+3TC+RAL</td>
</tr>
<tr>
<td></td>
<td>AZT+3TC+RAL</td>
</tr>
<tr>
<td></td>
<td>AZT+3TC+NVP</td>
</tr>
</tbody>
</table>

<sup>1</sup> For the shortest time possible, until a solid formulation of LPV/r or DTG can be used.

<sup>2</sup> For age and weight groups with DTG approved dosing (50 mg adult tablet from 20 kg TLD can be used in adolescents weighing more than 30 kg) and where LPV/r is not available.

<sup>3</sup> In cases where no other alternatives are available.
DTG below 20 kg dosing is now available and NO FURTHER guidance is needed on the formulations (including BD for children on TB Tx)
TAF now an option for NRTI backbone

- Improved durability and sequencing (more favourable resistance profile)
- Reduction in adverse impact on bone and renal health
  - Bone accretion throughout childhood with peak in puberty
  - Multiple factors impacting bone health including nutrition, HIV and HIV treatment
- Children co-infected with HBV (~8-10% among children with HIV in SSA) are not receiving treatment for Hep B.
- Adult formulations of TAF can be used in children over 25 kg
### WHO 2018 recommendations for 2nd and 3rd line*

<table>
<thead>
<tr>
<th>Population</th>
<th>1st line</th>
<th>2nd line</th>
<th>3rd line</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Children</strong></td>
<td>2 NRTI + LPV/r</td>
<td>2 NRTIs + DTG**</td>
<td>DRV/r + DTG**** ± 1-2 NRTIs Where possible consider optimization using genotyping</td>
</tr>
<tr>
<td></td>
<td>2 NRTIs + EFV</td>
<td>2 NRTIs + DTG***</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 NRTI + DTG</td>
<td>2 NRTIs + (ATV/r or LPV/r)</td>
<td></td>
</tr>
</tbody>
</table>

* Optimized NRTI backbone should be used: AZT following TDF or ABC failure, and viceversa.

**This applies to children for whom approved DTG dosing is available. RAL should remain the preferred 2nd line for those children for whom approved DTG is not available.

***This applies to children for whom approved DTG dosing is available. ATV/r or LPV/r should remain the preferred 2nd line for those children for whom approved DTG is not available.

****DTG based 3rd line following use of INSTI must be administered with DTG BD.
We already encourage transition to optimal regimens

Goal of transition
• Improve outcomes
• Harmonization
• Simplification
• Supply security

Children eligible for transition
• Already on ART
• Clinically stable (defined as per national guidelines)
• Prioritize children on NNRTI based regimen

<table>
<thead>
<tr>
<th>Current regimen</th>
<th>Weight</th>
<th>Optimal regimen for transition</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT/3TC/NVP</td>
<td>&lt;20 kg</td>
<td>ABC/3TC/LPv</td>
<td>If still stable these can be transitioned to DTG when they reach 20 kg</td>
</tr>
<tr>
<td>AZT/3TC/EFV</td>
<td>20-30kg</td>
<td>ABC/3TC/DTG</td>
<td>If still stable these can be transitioned to TLD when they reach 30 kg</td>
</tr>
<tr>
<td>ABC/3TC/NVP</td>
<td>&gt; 30kg</td>
<td>TLD</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Current regimen</th>
<th>Weight</th>
<th>Optimal regimen for transition</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC/3TC/EFV</td>
<td>&lt;20 kg</td>
<td>No change until reach 20 kg unless treatment failure occurs</td>
<td>Of value once reached 20 kg when DTG can be used so that OD administration is preserved.</td>
</tr>
<tr>
<td></td>
<td>20-30kg</td>
<td>ABC/3TC/DTG</td>
<td>If still stable these can be transitioned to TLD when they reach 30 kg</td>
</tr>
<tr>
<td></td>
<td>&gt; 30kg</td>
<td>TLD</td>
<td>-</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Current regimen</th>
<th>Weight</th>
<th>Optimal regimen for transition</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC/3TC/LPv</td>
<td>&lt;20 kg</td>
<td>No change until reach 20 kg unless treatment failure occurs</td>
<td>Important to ensure use of tablets as soon as possible to reduce pill burden. Transition from AZT/3TC/LPv to ABC/3TC/LPv can also be considered to reduce pill burden</td>
</tr>
<tr>
<td>AZT/3TC/LPv</td>
<td>20-30kg</td>
<td>ABC/3TC/DTG</td>
<td>If still stable these can be transitioned to TLD when they reach 30 kg</td>
</tr>
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<td>&gt; 30kg</td>
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</tbody>
</table>

VL monitoring good practice but no pre-condition for transition
**Goal of transition**
- Improve outcomes
- Harmonization
- Simplification
- Supply security

**Children eligible for transition**
- Already on ART
- Clinically stable (defined as per national guidelines)
- Prioritize children on NNRTI based regimen

**VL monitoring good practice but no pre-condition for transition**

### Table: Current regimen and Optimal regimen for transition

<table>
<thead>
<tr>
<th>Current regimen</th>
<th>Weight</th>
<th>Optimal regimen for transition</th>
<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AZT/3TC/NVP</strong></td>
<td>&lt;20 kg</td>
<td>ABC/3TC/LPVr</td>
<td>If still stable these can be transitioned to DTG when they reach 20 kg</td>
</tr>
<tr>
<td><strong>AZT/3TC/EFV</strong></td>
<td>20-30 kg</td>
<td>ABC/3TC/DTG</td>
<td>If still stable these can be transitioned to TLD when they reach 30 kg</td>
</tr>
<tr>
<td><strong>ABC/3TC/NVP</strong></td>
<td>&gt; 30 kg</td>
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</tr>
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</table>
NEW DRAFT - Transition to optimal regimens

Goal of transition
• Improve outcomes
• Harmonization
• Simplification
• Supply security

Children eligible for transition
• Already on ART
• Clinically stable (defined as per national guidelines)
• Prioritize children on NNRTI based regimen

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<th>Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT/3TC/NVP AZT/3TC/EFV ABC/3TC/NVP ABC/3TC/EFV</td>
<td>&lt;30 kg</td>
<td>ABC/3TC plus DTG</td>
<td>As long as above 3 kg AND 4 weeks</td>
</tr>
<tr>
<td></td>
<td>&gt; 30kg</td>
<td>TLD</td>
<td>-</td>
</tr>
<tr>
<td>ABC/3TC/LPVr AZT/3TC/LPVr</td>
<td>&lt;30kg</td>
<td>ABC/3TC plus DTG</td>
<td>-</td>
</tr>
<tr>
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<td>&gt;30kg</td>
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VL monitoring good practice but no pre-condition for transition
Goal of transition

- Improve outcomes
- Harmonization
- Simplification
- Supply security

Children eligible for transition

- Already on ART
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- Prioritize children on NNRTI based regimen

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<tr>
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<td>ABC/3TC plus DTG</td>
<td>As long as above 3 kg AND</td>
</tr>
<tr>
<td>AZT/3TC/EFV</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>ABC/3TC/NVP</td>
<td>&gt; 30kg</td>
<td>TLD</td>
<td></td>
</tr>
<tr>
<td>ABC/3TC/EFV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABC/3TC/LPVr</td>
<td>&lt;30kg</td>
<td>ABC/3TC plus DTG</td>
<td><strong>Key rationale: Transition out of NNRTI and use of once daily regimen with FDC as soon asap</strong></td>
</tr>
<tr>
<td>AZT/3TC/LPVr</td>
<td>&gt; 30kg</td>
<td>TLD</td>
<td><strong>Key rationale: Use once daily FDC as soon asap</strong></td>
</tr>
</tbody>
</table>

VL monitoring good practice but no pre-condition for transition
DELIVERING BETTER TREATMENT TO CHILDREN IN NEED

LET’S STOP ACCEPTING THAT IT’S OK TO HAVE LOWER STANDARDS FOR CHILDREN

WHO Guidelines have taken very seriously treatment optimization of children and we should join forces to make sure these guidelines are adopted and adapted as soon as possible despite COVID19 pandemic:

No new recommendations needed, now is time for action!

01 Phasing out of NNRTI based regimens is urgently needed

02 DTG plus ABC/3TC is the preferred regimen for 1st line across age groups

03 DTG with optimized backbone preferred for 2nd line across age groups

04 LPVr solid formulations should be used where DTG not available

05 2021 will allow us to fully implement WHO recos for children: plan in advance

WHO Guidelines have taken very seriously treatment optimization of children and we should join forces to make sure these guidelines are adopted and adapted as soon as possible despite COVID19 pandemic:

No new recommendations needed, now is time for action!

DELIVERING BETTER TREATMENT TO CHILDREN IN NEED
“Yes, introduction of new products has historically taken time and availability has been a problem but it doesn’t have to be that way.”

**NEW OPTIONS AVAILABLE**
- DTG 10 mg scored tablets and 4IN1 approved at the same time: **DTG preferred**
- 4IN1 important alternative

**CURRENT STATUS OF OPTIMIZATION**
Ongoing optimization efforts should not be delayed waiting to better products and need to continue

**TRANSITION PLANS**
Different scenarios for transition might be considered depending **current status of optimization and stocks** (transition of stable kids still a unclear).

**TOXICITY MONITORING**
Importance to set up **active toxicity monitoring** to ensure we scale up safely new products.

“Each country will need to develop a national transition plan which is tailored to the context and capacity of the HIV programme but the goal should be the same: get better formulations to children and their families.”
Scenario Considerations

Given the anticipated near-simultaneous market entry of these paediatric products, countries should consider introduction implications, with the primary focus being adopting a child-centric approach and expediting access to DTG 10mg.

When assessing the appropriate timing of new product introductions, considerations should be made for:
- All children should be transitioned to the preferred 1L regimen (DTG 10mg) when possible
- LPV/r 4-in-1 will have a place alongside for patients who cannot tolerate DTG
- The timelines associated with regimen transitions and the capacity to implement multiple product transitions
- Stock on hand and pipeline orders placed for existing 2-in-1 (LPV/r) formulations
- The consideration of procurement and programmatic simplification benefits of using 4-in-1 FDC

Courtesy of Caroline Middlecote (CHAI)
Next steps on DTG

• ECHO session October 6th
• ODYSSEY results to be shared with WHO
• PAWG to reconvene by the end of the year to discuss transition table
• Narrative to be included in new ARV guidelines for release in Q1-2 2021
  • New transition table
  • Some notes on administration
Postnatal prophylaxis
**Simplified approach to assessing risk at delivery**

High Risk Infants are born to women that...

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Are identified as HIV positive in the postpartum period</td>
</tr>
<tr>
<td>2</td>
<td>Acquire HIV infection during pregnancy or breastfeeding</td>
</tr>
<tr>
<td>3</td>
<td>Where VL is available, have a VL &gt; 1,000 copies/ml at delivery or in the last 4 weeks of pregnancy</td>
</tr>
<tr>
<td>4</td>
<td>Where VL is not available, have been on ART for less than 4 weeks at delivery</td>
</tr>
</tbody>
</table>
At DELIVERY

HIV+ Mother on ART

Is a VL result available from no more than <4 weeks before delivery?

YES: VL >1,000

HIGH RISK

YES: VL <1,000

LOW RISK

NO

Has she been on ART for >4 weeks prior to delivery?

YES

LOW RISK

NO

HIGH RISK

Known HIV+ Mother not on ART

Woman identified HIV+ post nata tally

ePNP: identification of high risk infant
Summarizing ePnP recommendations

ART for the mother

ART should be **initiated urgently** in all pregnant and breastfeeding women as the **most effective way to prevent MTCT is to reduce maternal VL.**
TABLE 4. NVP doses for prophylaxis beyond 12 weeks

<table>
<thead>
<tr>
<th>Infant age</th>
<th>Dosing of NVP</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 to 12 weeks</td>
<td>20 mg once daily</td>
</tr>
<tr>
<td>12 weeks to 6 months</td>
<td>20 mg once daily</td>
</tr>
<tr>
<td>6 to 9 months</td>
<td>30 mg once daily</td>
</tr>
<tr>
<td>9 months to end of BF</td>
<td>40 mg once daily</td>
</tr>
</tbody>
</table>

Under review by PAWG to ensure simplification and optimization of existing solid formulations.
Countries policies on ePNP (May 2018)

- Guidelines being updated between 2018 and 2019
- Implementation started in Kenya.
  - To be started in Sept 2018 in Mozambique.

- Unchanged GL
  - Angola
  - Cameroon
  - Chad
  - Côte d’Ivoire
  - Ethiopia
  - Malawi

- ePNP adopted for all HEI
  - Botswana
  - Ghana
  - Namibia
  - Nigeria
  - South Africa
  - Tanzania
  - Uganda
  - Zambia
  - Zimbabwe

- ePNP adopted for HR infants
  - Kenya
  - Mozambique
  - Swaziland

Updated assessment ongoing
Priority products for investigation and development
DRVr (120/20 mg): critical formulation to use a PI in 2nd and 3rd irrespective of regimens history (dosing and ratio confirmed).

DTG (10 mg scored): key product to expand DTG-based regimens to children as young as 4 weeks.

DTG/ABC/3TC (5/60/30 mg): critical formulation to provide preferred first line in FDC (dosing and ratio now confirmed).

XTC/TAF and XTC/TAF/DTG: remains desirable for full harmonization in the future (dosing and ratio to be clarified as TAF investigation plans are completed).
MK8591 and Doravirine were considered of interest and active review of investigation plans is encouraged.

bNabs: Potential use for postnatal prophylaxis and early Tx, with potential for enhancing HIV-specific immune response, and reduction of reservoir.

Long Acting: Treatment of infants and children with current formulations (ie CAB/RPV) is unlikely but could represent a suitable opportunity for prevention in neonates and treatment of adolescents.

Novel delivery technologies (ie. microneedle patches and gastric residence system): with the potential to simplify administration, and improve adherence.
Welcome and introduction

WHO

Need and response

Being a child in need for treatment when options are limited
A caregiver’s perspective

GAP-f: A coordinated response to the lack of appropriate paediatric medicines
WHO

Operationalization

Prioritization: Guiding alignment with manufacturers
Aurobindo
MPP

Partnering to optimize clinical research and product development: Universal project
PENTA
CHAI

Joining forces to safely roll out new adapted paediatric drug formulations
MOH, Uganda
EGPAF

Building on synergies

Closing the gaps in other disease areas
MMV
GARDP

Catalyzing the mission of GAP-f to fit the needs of the broader paediatric community
ELMA

Promoting innovation

Paediatric drug formulation technology landscape
Unitaid

The bitter blocker project
CHAI
Monel Institute

“Open mic” session: Questions and reflections
Thank you

Happy to take any question

WHO
20, Avenue Appia
1211 Geneva
Switzerland

www.who.int
www.gap-f.org/
www.who.int/hiv/pub/paediatric/aids-free-toolkit/en/
Update from WHO: Adult ART Guidelines

Marco Vitoria
WHO/HHS Department
Annual ARV Buyer Seller Summit
October 2020
### HIV Treatment Has Evolved

<table>
<thead>
<tr>
<th>Treatment parameter</th>
<th>PAST</th>
<th>PRESENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred 1st line (NRTI backbone)</td>
<td>Thymidinic analogues (AZT, d4T)</td>
<td>Non-thymidinic analogues (TDF, ABC, TAF)</td>
</tr>
<tr>
<td>Preferred 1st line (3rd drug)</td>
<td>NNRTIs (NVP, EFV)</td>
<td>INSTIs (DTG)</td>
</tr>
<tr>
<td>Frequency, daily doses</td>
<td>BID (high pill burden)</td>
<td>MID (low pill burden, FDCs)</td>
</tr>
<tr>
<td>Number of preferred 1st line regimens</td>
<td>4-6</td>
<td>1-2</td>
</tr>
<tr>
<td>TB/HIV (preferred ARV option)</td>
<td>2 NRTI + EFV or LPV/r (double dose)</td>
<td>2 NRTI + DTG (double dose)</td>
</tr>
<tr>
<td>Pregnant women (preferred option)</td>
<td>2 NRTI + EFV or bPI</td>
<td>2 NRTI + DTG</td>
</tr>
<tr>
<td>When to start ART</td>
<td>Symptomatic / CD4 criteria (prioritizing sick people)</td>
<td>Any CD4 (immediate treatment)</td>
</tr>
</tbody>
</table>
Evolution of the uptake of major ARV treatment policies in LMICs

- **Treat All**: 131 LMICs adopted Treat All (96%)
- **DTG transition**: 107 LMICs adopted DTG regimens (78%)
- **Routine VL monitoring**: 99 LMICs adopted VL monitoring (72%)

* Preliminary data
2019 ARV recommendations at a glance

WHAT TO USE IN 1ST LINE

- TLD as preferred regimen in 1st line ART for all PLHIV (with approved DTG dose)
- TLE400 as alternative 1st line option. TLE600 in special circumstances
- Switching of stable patients using suboptimal regimens is recommended. Switching those on TLE with suppressed VL should be considered

WHAT TO USE IN 2ND AND 3RD LINES

- DTG as preferred option in 2nd line in those who not used DTG in 1st line
- Boosted PI as preferred option in those who already used DTG in 1st line
- DRV/r as anchor drug in 3rd line, associated with DTG BD (± 1-2 NRTIs as optional)

SPECIAL SITUATIONS

- DTG BD in TB/HIV patients using rifampicin is safe
- TAF as an alternative option in children and in special circumstances in adults and adolescents
## Safety and Efficacy of DTG and EFV₆₀₀ in 1ˢᵗ line ART (PICO 1 A)
(summary 2019 WHO Sys Review & NMA)

<table>
<thead>
<tr>
<th>major outcomes</th>
<th>DTG vs EFV₆₀₀</th>
<th>quality of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment discontinuation (any or due AEs)</td>
<td>DTG better</td>
<td>high</td>
</tr>
<tr>
<td>Viral suppression (4-96 weeks), viral suppression at delivery (PW), transmission (PW)</td>
<td>DTG probably better</td>
<td>high to moderate</td>
</tr>
<tr>
<td>CD4 recovery (24-144 weeks)</td>
<td>DTG probably better</td>
<td>high to moderate</td>
</tr>
<tr>
<td>Mortality</td>
<td>comparable</td>
<td>low</td>
</tr>
<tr>
<td>Neuropsychiatric AEs (any grade), depression (grade 3 or 4), dizziness (any grade)</td>
<td>DTG probably better</td>
<td>moderate to low</td>
</tr>
<tr>
<td>Sleep disorders (any grade)</td>
<td>comparable</td>
<td>very low</td>
</tr>
<tr>
<td>Body weight gain</td>
<td>EFV probably better</td>
<td>moderate</td>
</tr>
<tr>
<td>NTD</td>
<td>EFV may be better</td>
<td>low</td>
</tr>
<tr>
<td>HIVDR (overall, NRTI or anchor drug)</td>
<td>DTG probably better</td>
<td>high to moderate</td>
</tr>
</tbody>
</table>

Reference: Steve Kanters, For WHO ARV GDG, 5-7 June 2019
DTG as preferred option in 1st line: improved efficacy and durability when compared with EFV

- Better than EFV in the majority of critical outcomes (high/moderate quality of evidence)
- Rapid viral load suppression
- Once daily and well tolerated
- High genetic barrier to resistance
- Few drug interactions
- Single and fixed-dose generic formulations
- Lower price in LMICs
- Risk of neural tube defects similar to other ARVs (recent update of TSEPAMO study)
Tsepmo: Evolution of NTD Prevalence with Preconception DTG

Zash R et al. IAS Virtual July 2020 Abs. OAXLB0102

Prevalence difference DTG vs EFV preconception: 0.12 (0.0, 0.32)

Prevalence difference DTG vs non-DTG preconception: 0.09 (-0.03, 0.30)

Prevalence difference DTG vs uninfected: 0.12 (0.01, 0.32)
After a period of decline since the original safety signal, prevalence of NTD among infants born to women on DTG at conception appears to be stabilizing at a low prevalence level.
INSTI and new story of weight gain among PLHIV
## Safety and Efficacy of EFV\(_{400}\) and EFV\(_{600}\) in 1\(^{st}\) line ART (PICO 3)
(summary 2019 WHO Sys Review & NMA)

<table>
<thead>
<tr>
<th>major outcomes</th>
<th>EFV(<em>{400}) vs EFV(</em>{600})</th>
<th>quality of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment discontinuation (due AEs)</td>
<td>EFV(_{400}) better</td>
<td>high to moderate</td>
</tr>
<tr>
<td>Viral suppression (48-96 weeks), VL suppression if baseline &gt; 100,000 (48 weeks)</td>
<td>comparable</td>
<td>moderate</td>
</tr>
<tr>
<td>CD4 recovery (24-96 weeks)</td>
<td>comparable</td>
<td>moderate</td>
</tr>
<tr>
<td>Mortality</td>
<td>comparable</td>
<td>low</td>
</tr>
<tr>
<td>Neuropsychiatric AEs (any grade), depression (grade 3 or 4), dizziness (any grade), sleep disorders (any grade)</td>
<td>comparable</td>
<td>low to very low</td>
</tr>
<tr>
<td>Body weight gain</td>
<td>comparable</td>
<td>low</td>
</tr>
<tr>
<td>Treatment related adverse events</td>
<td>EFV(_{400}) better</td>
<td>moderate</td>
</tr>
<tr>
<td>HIVDR (overall, NRTI or anchor drug)</td>
<td>comparable</td>
<td>very low</td>
</tr>
</tbody>
</table>

Reference: Steve Kanters, For WHO ARV GDG, 5-7 June 2019
<table>
<thead>
<tr>
<th>Treatment transition scenario</th>
<th>Preferred approach</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DTG in people living with HIV initiating ART</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults and Adolescents&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Initiate TLD</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnant/Breastfeeding women&lt;sup&gt;b&lt;/sup&gt;</td>
<td>Initiate TLD</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB co-infection</td>
<td>Initiate TLD (DTG dose adjustment needed).</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DTG in people living with HIV already using first-line regimen</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical/immunological failure or VL non-suppressed</td>
<td>Switch to AZT+3TC + DTG (or PI/r&lt;sup&gt;c&lt;/sup&gt;)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Viral load suppressed</td>
<td>Substitution to TLD regimen may be considered according to national recommendations.</td>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinically/immunologically stable&lt;sup&gt;d&lt;/sup&gt; and VL unknown</td>
<td>Prioritize VL testing or consider other programmatic or clinical indications for decision for substitution to TLD</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinically/immunologically stable&lt;sup&gt;d&lt;/sup&gt; on suboptimal first-line ARV regimens</td>
<td>Substitute to TLD</td>
<td></td>
</tr>
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<td></td>
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<td></td>
<td></td>
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</tbody>
</table>
WHO support to countries for implementation of active toxicity monitoring and safe introduction of DTG and other new ARVs – guidance, tools and technical assistance
# Safety and Efficacy of TAF vs TDF (PICO 4)

(summary 2019 WHO Sys Review & NMA)

<table>
<thead>
<tr>
<th>major outcomes</th>
<th>TAF vs TDF</th>
<th>quality of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral suppression (24-96 weeks)</td>
<td>comparable</td>
<td>high to moderate</td>
</tr>
<tr>
<td>CD4 recovery (24-96 weeks)</td>
<td>comparable</td>
<td>low</td>
</tr>
<tr>
<td>Mortality</td>
<td>comparable</td>
<td>low</td>
</tr>
<tr>
<td>Discontinuations (AEs), overall SAEs, overall AEs, treatment related SAEs</td>
<td>comparable</td>
<td>moderate</td>
</tr>
<tr>
<td>Protection effect renal function markers (creatinine, eGFR) at 24-96 weeks</td>
<td><strong>TAF probably better</strong></td>
<td>high to moderate</td>
</tr>
<tr>
<td>Protection effect bone lab markers (BMD) at 24-96 weeks</td>
<td><strong>TAF probably better</strong></td>
<td>high</td>
</tr>
<tr>
<td>Any lab abnormalities (grade 3 or 4)</td>
<td><strong>TAF probably better</strong></td>
<td>moderate</td>
</tr>
<tr>
<td>Cholesterol levels (grade 3 or 4)</td>
<td><strong>TDF probably better</strong></td>
<td>moderate</td>
</tr>
<tr>
<td>Body weight gain</td>
<td><strong>TDF probably better</strong></td>
<td>moderate</td>
</tr>
<tr>
<td>HIVDR (overall, NRTI)</td>
<td>comparable</td>
<td>low</td>
</tr>
</tbody>
</table>

Efficacy outcomes

Tolerability, safety & resistance outcomes

Reference: Steve Kanters, For WHO ARV GDG, 5-7 June 2019
TAF Considerations

- May be considered for people with established osteoporosis and/or impaired kidney function
- Lower renal and bone toxicity vs TDF based on lab markers (but no difference in clinical outcomes)
- **Common toxicities:**
  - Reports of significant weight gain in clinical trials (ADVANCE)
  - Dyslipidemia more common with TAF
- Co-administration of rifampicin and TAF is contraindicated
- Gaps in TAF evidence base on safety and efficacy in pregnancy and TB-co-infection
Safety and Efficacy of DTG and PIs (LPVr) in 2\textsuperscript{nd} line ART (PICO 2)  
(summary 2019 WHO Sys Review & NMA)

<table>
<thead>
<tr>
<th>major outcomes</th>
<th>DTG vs LPVr</th>
<th>quality of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viral suppression (4-96 weeks)</td>
<td>DTG better</td>
<td>high</td>
</tr>
<tr>
<td>Viral suppression baseline VL &gt; 100,000 (48 weeks)</td>
<td>comparable</td>
<td>moderate</td>
</tr>
<tr>
<td>CD4 recovery (24-48 weeks)</td>
<td>comparable</td>
<td>moderate</td>
</tr>
<tr>
<td>Mortality</td>
<td>comparable</td>
<td>low</td>
</tr>
<tr>
<td>Neuropsychiatric AEs (any grade)</td>
<td>comparable</td>
<td>low</td>
</tr>
<tr>
<td>Treatment related SAE</td>
<td>comparable</td>
<td>low</td>
</tr>
<tr>
<td>Treatment emergent AE, related AEs</td>
<td>DTG probably better</td>
<td>high</td>
</tr>
<tr>
<td>Treatment discontinuation (any or due AEs)</td>
<td>DTG probably better</td>
<td>high</td>
</tr>
<tr>
<td>HIVDR (overall)</td>
<td>comparable</td>
<td>very low</td>
</tr>
</tbody>
</table>

Reference: Steve Kanters, For WHO ARV GDG, 5-7 June 2019
DTG in 2nd line – Considerations

- Main info source: Dawning Study
- Week 48 results showed superior efficacy of DTG vs LPV/r arms
- Response rates were high with DTG arms regardless of pre-existing resistance to one NRTI
- Rates of virologic failure were lower in DTG arms regardless of NRTI resistance patterns and second line background NRTI use
- Very limited data with other PIs (ATV, DRV)
- DTG in 2nd line not recommended if used in 1st line

If NNRTI used in 1st line ⇒ DTG in 2nd line

If DTG used in 1st line ⇒ PI in 2nd line
Future role of dual therapy: considerations

- Several studies as “simplification” strategy in ARV suppressed patients
- GEMINI and PADDLE studies as main references in naive patients
- Already included in some guidelines (EACS, IAS, DHHS) as alternative options in certain situations (simplification, induction/maintenance) but with several considerations
- Not evaluated in LMIC context
- Major challenges: impact of co-infections (e.g., TB, HBV) and baseline resistance, efficacy in advanced disease, efficacy and safety of new drugs
### Major ART Optimization Studies in Adults and Adolescents (with COVID-19 impact)

<table>
<thead>
<tr>
<th>Research priority topic</th>
<th>CLINICAL TRIALS: 1ST LINE</th>
<th>CLINICAL TRIALS: 2ND LINE /SWITCHING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety of DTG and /or TAF periconception and pregnancy</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Changes in body weight/cardiometabolic risk with DTG combined with TAF or TDF</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Outcomes from switching from TLE to TLD without VL</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Safety and efficacy of DTG and/or TAF in adolescents</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
<td>✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Impact of COVID19 pandemic</td>
<td>No delays</td>
<td>No delays*</td>
</tr>
<tr>
<td>Time of expected results</td>
<td>Q2 2021 144 weeks</td>
<td>Q4 2020* 144 weeks postpartum</td>
</tr>
</tbody>
</table>

* Some delays in paediatric component of the study is expected
### OBSERVATIONAL STUDIES
(with COVID-19 impact)

<table>
<thead>
<tr>
<th>research priority topic</th>
<th>TSEPAMO</th>
<th>BEAT</th>
<th>AFRICOS (RV 329)</th>
<th>OBSERVE TLD (ACTG 5381)</th>
<th>EMEDT</th>
<th>DISCO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety of TAF periconception and pregnancy</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changes in body weight/cardiometabolic risk with DTG combined with TAF or TDF</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcomes from switching from TLE to TLD without VL</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Safety and efficacy of DTG and TAF adolescents</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety and efficacy of DTG and /or TAF in young children</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expected impact of COVID19 pandemic</td>
<td>No delays</td>
<td>+ 6 months</td>
<td>+3 months</td>
<td>+ 6 months</td>
<td>+ 3 months</td>
<td>No delays</td>
</tr>
<tr>
<td>Expected results</td>
<td>Q4 2020</td>
<td>Q1 2021</td>
<td>Q1 2021</td>
<td>Q2 2021</td>
<td>Q4 2020</td>
<td>Q1 2021</td>
</tr>
</tbody>
</table>
Key messages

• DTG scale up has been implemented in majority of LMICs, but transition criteria in those well and stable on previous ART still have some knowledge gaps

• The potential association of NTDs and DTG detected in TSEPAMO study was not confirmed, but emerging adverse events as body weight gain and other cardiometabolic effects need to be monitored

• The role of TAF in LMICs context should continue to be limited to special situations until more information on safety become available

• The role of dual therapies and what best options to be combined in LMICs are still uncertain and will be influenced by ongoing/planned ARV optimization studies

• The use of DTG in 2nd line will be influenced by the level/speed of TLE to TLD transition in 1st line.

• NVP use in adults should be rapidly phased out
Annual ARV Buyer Seller Summit: Integrate, Update, Evolve
Update on Performance of APWG
October 14, 2020
WORKING GROUP STRUCTURE

ARV Procurement Working Group (APWG)
*Umbrella body supporting coordinated efforts to ensure timely and consistent access to ARVs*
- Guides the direction of the Procurement Consortium
- Advocates broadly for improved product selection/optimization
- Coordinates and collaborates with similar groups and governments
- Raises awareness with stakeholders on general and specific challenges in the ARV marketplace

Market Coordination & Support
- Collect, analyze, and disseminate market intelligence
- Provide country technical assistance for procurement and forecasting
- Support coordination of global stakeholders

Procurement Consortium (PC)
*Subgroup of transactional procurement agents focusing on alignment and coordination of procurement activities*
- Engages with suppliers
- Aligns member forecasts and forecasting
- Pools demand/coordinates ordering
- Ensures a competitive and transparent order allocation process amongst quality assured, eligible suppliers
- Facilitates procurement of high supply-risk, low volume formulations through Global Fund’s Rapid Supply Mechanism
- Monitors country market-related challenges
APWG role in Optimal Formulary List

• Advice on products to be included in the Optimal and Limited Use list

• Highlight procurement and supply elements for each product

• Initiate conversations with suppliers on production capacity and supply timelines

• Identify products for monitoring via quarterly APWG calls
APWG role in advocating ordering Optimal formularies

• APWG buying organizations only show products on their catalogue that support treatment optimization

• Dialogue with countries to transition towards optimal formularies

• Highlight supply chain and procurement advantages of treatment optimization to countries

• Organize webinars on supply chain related elements of treatment optimization

• Publish recommendation letters for transition to optimal formularies
APWG monthly calls with focus on market information, country uptake and supply issues

• Demand and Supply issues
  ➢ Demand monitoring LPV/r pellets, granules, LPVr 100/25 and Rifapentine
  ➢ No supply issues for high volume Optimal peadiatric products and low volume Adult products
  ➢ Supply issues for oral solutions
  ➢ Supply issues LPV/r pellets, granules and 100/25

• Update on new product initiatives
  ➢ 4-in-1
  ➢ Rifapentine and INH/Rifapentine to support 3HP
  ➢ Flucytosine

• Communication and policy briefs
  ➢ Engagement with suppliers
  ➢ Quarterly forecast to suppliers
  ➢ Updated APWG memo on LPV/r peads
  ➢ APWG webinars for LAC countries
Orders placed by APWG members are mostly for optimal formulations

**Limited-Use Formulations**

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Quantity</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFV (200 mg) Tablet (Scored) - 90</td>
<td>474,000</td>
<td>75%</td>
</tr>
<tr>
<td>AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60</td>
<td>94,000</td>
<td>15%</td>
</tr>
<tr>
<td>LPVr (80 mg + 20 mg/ml) Oral Solution</td>
<td>65,000</td>
<td>10%</td>
</tr>
</tbody>
</table>

**Optimal Formulations**

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Quantity</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC/3TC (120/60 mg) Tablet (Disp) - 30</td>
<td>6,300,000</td>
<td>37%</td>
</tr>
<tr>
<td>LPVr (100/25 mg) Tablet (HS) - 60</td>
<td>3,100,000</td>
<td>18%</td>
</tr>
<tr>
<td>ABC/3TC (120/60 mg) Tablet (Disp) - 60</td>
<td>2,500,000</td>
<td>15%</td>
</tr>
<tr>
<td>NVP (50 mg/5 mL) Oral Solution – 100 mL</td>
<td>1,500,000</td>
<td>9%</td>
</tr>
<tr>
<td>LPVr (40/10 mg) Oral Granule - HS - 120</td>
<td>1,450,000</td>
<td>8%</td>
</tr>
<tr>
<td>LPVr (40/10 mg) Oral Pellet - HS - 120</td>
<td>1,371,000</td>
<td>8%</td>
</tr>
<tr>
<td>AZT/3TC (60/30 mg) Tablet (Disp) - 60</td>
<td>885,000</td>
<td>5%</td>
</tr>
</tbody>
</table>

**Non-Essential Formulations**

<table>
<thead>
<tr>
<th>Formulation</th>
<th>Quantity</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>AZT (50 mg/5 ml) Oral Solution – 240 mL</td>
<td>320,000</td>
<td>56%</td>
</tr>
<tr>
<td>ABC/3TC (60/30 mg) Tablet (Disp) - 60</td>
<td>185,000</td>
<td>32%</td>
</tr>
<tr>
<td>EFV (200 mg) Capsules - 90</td>
<td>65,000</td>
<td>12%</td>
</tr>
</tbody>
</table>

Quantities are based on orders placed for delivery in 2020.
The APWG now has a dedicated website to host all important documents and communications!

Check back often as new documents are released.

The website includes:
- The quarterly demand forecast
- Bi-annual newsletters
- Recorded webinars
- Key recommendations and product guidance documents
- A LPV/r product dashboard
- DTG peds and 4-in-1 supply updates

https://www.arvprocurementworkinggroup.org/home
APWG Quarterly Anticipated Demand Forecast

- Provides summary of **expected orders over 12-18 months** that are visible to APWG members
- Includes pediatrics ARVs, low-volume adult ARVs, and adult products in transition
- Shared **quarterly** (usually third month of each quarter)
- Includes summary of countries that have already placed or are expected to place orders for priority products
- Provides a **breakout of procurement agents sourcing orders** for each member country

Latest quarterly demand forecast and other APWG documents can be found here: [https://www.arvprocurementworkinggroup.org/arv-procurement-working-group-documents](https://www.arvprocurementworkinggroup.org/arv-procurement-working-group-documents)
Questions
PEPFAR Priorities for COP 21

SGAC: Leonard Kosicki
SGAC: Catherine Godfrey, M.D.
SGAC: Rachel Golin, M.D.
SGAC: Teeb Al-Samarrai, M.D.

14 October 2020
Agenda

• Priorities for Adult Treatment
• Priorities for Pediatric Treatment
• Priorities for Tuberculosis Preventive Treatment (TPT)
Priorities for Adult treatment

Catherine Godfrey, M.D.
14 October 2020
Adult treatment priorities

1. Complete DTG transition
2. Approach to treatment failure
3. Needs of specific populations
4. Multi-month dispensing
5. Emphasis on Advanced Disease
TLD transition

All PLH should have access to most convenient drug with the least side effects including women of child-bearing age

• Expanded datasets reassuring about the very low rate of neural tube defects
• One study rates of neural tube defects not greater than background risk

Concerns about the development of obesity

• Data from ADVANCE and NAMSAL trials confirm excess weight gain
• Data from AFRICOS showed a clinically small but statistically significant weight gain
• No excess in metabolic syndromes

All new pts should be started on TLD

Individuals on TLE and PI based regimens should be switched

Rare individuals, intolerant of DTG, may be prescribed TLE (400 mg)
Switching to DTG based therapy

• Goal of ART is virological suppression: should be achievable by all
• Viral load testing encouraged, but not required prior to switch
• If switch when unsuppressed, recommend prioritized viral load
• TLD is preferred second line regimen
Approach to treatment failure

If Viral Load is documented > 1,000 c/ml for more than a year – this small population of patients may be switched to a PI-based regimen

If viral load > 1000 c/mL

If not on DTG: Switch to a DTG containing regimen*

If on DTG: Provide enhanced treatment support

Repeat VL in 3 months

If VL < 1000 copies/mL: continue DTG and routine clinical services and supportive care

If viral load > 1000 c/ml:

Provide enhanced adherence counseling, and address barriers to continuity of treatment

Switch to PI if persistent virological failure one year after first detection

*For CHILD < 20 kg: DTG 10 mg DT is anticipated to be available in 2021.
Tenofovir Alafenamide (TAF)

- Current labeling recommends against its use with rifamycins
- Supported for individuals as an alternative for individuals with renal disease as an alternative to ABC
- Not used in first line
Multimonth dispensing and Decentralized drug delivery
COVID-related Changes to MMD Policy among PEPFAR-supported Countries with Care & Treatment Program

PEPFAR has knowledge or record of 33 of 51 (~65%) PEPFAR-supported countries with C&T programs amending MMD policy or implementation to increase MMD coverage during the COVID-19 response.

- PEPFAR countries that changed MMD policies and/or implementation of MMD since 03/2020 due to COVID
- PEPFAR countries that we do not have record of changing MMD policy due to COVID as of 8/31/2020
Q3 Course Age and Sex Distribution on MMD
Advanced HIV Disease
Advanced HIV disease in Adults

Defined as CD4 ≤ 200 or Stage 3 and 4 disease

- Comprises people new to care, and those representing to care

- WHO “package of care” reduces mortality
  - Rapid ART start
  - Cotrimoxazole
  - TB “action” (screening and treatment or TPT)
  - Cryptococcal “action” (screening and treatment vs presumptive treatment)
Priorities for Pediatric treatment

Rachel Golin, M.D.
14 October 2020

17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS
PEPFAR promotes pediatric ART optimization

“For children, PEPFAR supports use of currently preferred regimens in child-friendly formulations and will support rapid introduction of new drugs and formulations for children (e.g., dolutegravir [DTG]) as they become available and recommendations are updated. A regimen containing DTG 50mg is preferred for children weighing at least 20kg. For infants and smaller children, programs should prioritize regimens containing a protease inhibitor such as lopinavir/ritonavir (LPVr) in age-appropriate solid form (pellets or granules) rather than regimens containing nevirapine; programs should also be prepared to move quickly to adopt DTG for infants and younger children as DTG formulations and dosing are established. Finally, programs that are employing testing at or soon after birth, should have pediatric raltegravir available for optimal (preferred over nevirapine) treatment in the first weeks of life, until LPVr regimens can be used.”

- PEPFAR 2019 Country Operational Plan Guidance for all PEPFAR Countries

“In 2019, the WHO updated HIV guidelines119 ensured that children were not left behind in their recommendations to shift optimal ART for all PLHIV away from NNRTIs and toward integrase-strand transfer inhibitor (INSTI)-based regimens, especially DTG-based regimens (see Figures 6.5.1 and 6.5.2). Rapid policy adoption and procurement of optimal pediatric ART regimens should be a priority for all countries. OUs must specify in COP20 current national treatment policies for infants, young children and school-age children and concrete plans with timelines for adopting WHO-recommended ARV regimens and formulations for children. Programs should have already transitioned all infants (other than neonates) and children off NVP-based regimens to LPV/r- or DTG-based regimens. Countries should transition all children from NNRTI-based regimens to LPV/r- or DTG-based regimens by the end of COP19.

- PEPFAR 2020 Country Operational Plan Guidance for all PEPFAR Countries
PEPFAR recognizes the importance of and supports rapid transition to DTG 10 mg DT

Benefits of DTG 10 mg DT:

- DTG has superior efficacy
- Individuals can maintain the same anchor ARV throughout their lifetime (preferred for pediatric 1L and 2L)
- Familiar, child-friendly formulation
- Reduced pill burden compared to pediatric LPV/r formulations
- Alignment of dosing with optimized ABC/3TC backbone for CLHIV weighing 6.0 – 19.9 kg
- Compatible with concurrent TB treatment
- Anticipated to be available in 90-count and 180-count bottle size (180-count bottle will facilitate 3MMD for CLHIV who weigh 10.0 – 13.9 kg)
- Substantial program cost savings compared to pediatric LPV/r formulations with current estimates ranging from $92K to $1.2M per 1,000 CLHIV.
- Streamlines and reduces the number of pediatric ARV regimens a country must maintain

Sources:
WHO’s Policy Brief: Considerations for Introduction New Antiretroviral Drug Formulations for Children (July 2020)
Global Health Supply Chain – Procurement Supply Management, September 2020
The DTG 10 mg Readiness Questionnaire is 2 parts

• Part 1 was sent to countries in August 2020
  • Transition Strategy and Budget
  • National Guideline Updates

• Part 2 will be sent by the end of November
  • Product Registration
  • Stakeholder Engagement
  • Supply Plan
  • Facility Level Uptake
Summary of Readiness Questionnaire Part 1

• 14 PEPFAR operating units have responded
• 4 countries already have DTG 10 mg in National Guidelines!!
  • DRC, Namibia, Nigeria and Zimbabwe
• 14 countries have DTG 50 mg for CLHIV ≥ 20 kg
• Identified need for regimen streamlining
  • Countries report requiring 5 to 35 regimens to treat all CLHIV
• Length of transition to DTG partly dependent upon amount of LPV/r stock in country
  • Between 6 to 12 months
• NVP is still being phased out
• The majority of respondents requested technical assistance with the introduction of DTG 10 mg DT
Priorities for Tuberculosis treatment

Teeb Al-Samarrai, M.D.
14 October 2020
Accelerating TPT Scale Up Across PEPFAR

- In 2018, PEPFAR set ambitious target to **treat all eligible PLHIV with TPT** by FY2021
- Since 2018, more than 3.5 million PLHIV have completed TPT
- Guidance has encouraged integration of HIV & TB/TPT, including TPT integration into DSD models
- In context of COVID-19, rapid integration of TPT and TB treatment for PLHIV into DSD and MMD models
- Nigeria experience highlights successful “kitting” approach which has led to over 90% completion rate
- Targets do not include TPT for household child contacts < 5 yo of PLHIV with TB which remains a priority

<table>
<thead>
<tr>
<th>Year</th>
<th>Target</th>
<th>Achievement</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY18</td>
<td>1,900,000</td>
<td>797,418</td>
</tr>
<tr>
<td>FY19</td>
<td>2,800,000</td>
<td>1,393,965</td>
</tr>
<tr>
<td>FY20</td>
<td>6,300,000</td>
<td>1,382,382</td>
</tr>
<tr>
<td>Total</td>
<td>11,000,000</td>
<td>3,573,765</td>
</tr>
</tbody>
</table>
COVID-19 Impact on TPT Uptake

- Declines in patient volume at health care facilities
- Declines in HIV case finding
- TB Programs and staff diverted to COVID-19 response
- Declines in TB case finding
- TPT scale-up significantly impacted
  - Multiple countries at high risk of INH stock-out, limiting MMD
  - Delays in 3HP
- However, MMD for TPT and TB treatment has expanded (table as of June 2020)

<table>
<thead>
<tr>
<th>Country</th>
<th>MMD TB</th>
<th>MMD TPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Botswana</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Cameroon</td>
<td>Yes</td>
<td>N/A</td>
</tr>
<tr>
<td>Cote d’Ivoire</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>DRC</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Eswatini</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Haiti</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Kenya</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Lesotho</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Malawi</td>
<td>N/A</td>
<td>Paused TPT</td>
</tr>
<tr>
<td>Mozambique</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>Namibia</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Nigeria</td>
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<td>Yes</td>
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<tr>
<td>Rwanda</td>
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<td>Yes</td>
</tr>
<tr>
<td>Uganda</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Tanzania</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>South Africa</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Vietnam</td>
<td>N/A</td>
<td>N/A</td>
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<tr>
<td>Zambia</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Source: Al-Samarrai T. Scaling up TPT in PEPFAR: Experience and Lessons Learned. Presented at Proceedings of the International AIDS Society; July 2020; On Demand Session: Leveraging Differentiated Service Delivery to Enhance Coverage and Completion of Tuberculosis Preventive Treatment (TPT).
Country Feedback: Integrating TPT into DSD during COVID-19

Poll question 1 - Has the push for MMD for ART helped scale-up integration of TPT into DSD?

- a. Yes: 54%
- b. No, they are competing interest: 8%
- c. No, because of TPT supply chain issues: 38%
- d. Other (please specify in chat box and your country name): 0%

Poll question 2 - What are the current barriers for integrating TPT into DSD models?

- a. Political will from leaders: 31%
- b. Funding: 15%
- c. Agreement and collaboration between HIV and TB programs: 30%
- d. Support from implementing partners: 0%
- e. Other (please specify in chat box and your country name): 15%

Poll question 3 - What are the three most important ingredient for integrating TPT into DSD models?

- a. Political will from leaders: 31%
- b. Funding: 31%
- c. Supply chain stability: 100%
- d. Clinical adherence: 15%
- e. Pharmacovigilance: 31%
- f. Site level mentorship: 30%
- g. Agreement and collaboration between HIV and TB programs: 31%
- h. Support from implementing partners: 38%
- i. Other (please specify in chat box and your country name): 0%

Other: Supply chain stability
Number of PLHIV completing TPT, 2018-2020 Q2

No. of TPT Initiations, TPT Completions, % Achievement, Over Time

- 2018:
  - TPT Initiations: 1,312,751
  - TPT Completions: 797,418
  - Completion %: 61%

- 2019:
  - TPT Initiations: 1,943,383
  - TPT Completions: 1,393,965
  - Completion %: 72%

- 2020:
  - TPT Initiations: 1,783,379
  - TPT Completions: 1,382,386
  - Completion %: 78%

PEPFAR
17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS
Percentage of TPT Completion by Country/Region, among <15, FY20 Q2

Note: OUs underlined in red indicates TPT % Completion < 80% for <15 and 15+
# TB Preventive Regimens for PLHIV

<table>
<thead>
<tr>
<th>TPT regimen</th>
<th>Adults &amp; adolescents</th>
<th>Children</th>
<th>DTG dose adjustment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INH/B6/Cotrimoxazole daily</strong> <em>(180/270 doses)</em></td>
<td>6 months (300 mg daily)</td>
<td>N/A</td>
<td>NO</td>
</tr>
<tr>
<td><strong>INH +/- B6</strong></td>
<td>300 mg daily</td>
<td>9 months 10-20mg/kg (max dose: 300 mg)</td>
<td>NO</td>
</tr>
<tr>
<td><strong>3HP 900mg/900mg weekly</strong></td>
<td>INH: 15 mg/kg (rounded to nearest 50 or 100 mg max: 900 mg)</td>
<td>&gt;2-11 years old</td>
<td>If on efavirenz-based regimen: 50 mg BID (adults)</td>
</tr>
<tr>
<td><strong>1HP 600mg/300mg daily x28 days</strong></td>
<td>&gt;13 years age only</td>
<td>Data pending</td>
<td></td>
</tr>
<tr>
<td><strong>4R daily</strong></td>
<td>10 mg/kg (Max dose = 600 mg)</td>
<td>15-20 mg/kg (Max dose = 600 mg) (pending availability in child-friendly regimen)</td>
<td>50 mg BID (adults)</td>
</tr>
<tr>
<td><strong>3HR daily</strong></td>
<td>INH: 5 mg/kg (300 mg) Rif: 10 mg/kg (600 mg)</td>
<td>INH:10-20 mg/kg Rifampin: 15-20 mg/kg</td>
<td>50 mg BID (adults)</td>
</tr>
</tbody>
</table>
Thank you
ARV Summit - Evolve
Product Description &
Documentation
• Product names, descriptions and attributes typically differ in every system and make reconciliation and data exchange extremely difficult.
Long Term Solution

- USAID, donors and stakeholders set requirements related to documentation and labeling information.
Before We Get Started

- Panel Members will present their challenges and lessons learned, then we will open the Question & Answer period
- If you have a question - enter it into the Q&A function on the right side of your session window; please indicate who the question is intended for
- If someone has already asked a similar question, rather than type it again, please ‘like’ their question and it will increase that questions priority
- If you want to verbally ask a question, please use the ‘raise hand’ function. During the Q&A session, we will activate your microphone and camera to allow you to ask your question
- General session chat amongst attendees should happen in the Event Chat
- During some of the panel presentations, a poll might pop up, please feel free to answer; we will review the poll results during the Q&A session
- Enjoy the discussion
GS1 Implementation Panel

- Rachel Smith - GHSC-PSM
- Tarang Verma - Hetero
- Sr Yeshialem Bekele - Ethiopian FDA
- Scott Dubin - USAID/GH/OHA/Supply Chain for Health
- Pete Alvarez - GS1 Global Office
Rachel Smith, GHSC-PSM

- Rachel is a Global Standards Technical Specialist at the USAID Global Health Supply Chain Program – Procurement and Supply Management (GHSC-PSM), where she primarily supports supplier engagement for the implementation of global standards within GHSC-PSM’s global supply chain. In addition to that, she has supported initiatives related to supply chain data visibility, traceability, master data management, and analytics for global health
Ms. Tarang Verma has done Masters (MBA) in International Business. With 10 years’ experience in Antiretroviral Institutional business, she has been taking care of PEPFAR business for more than 9+ years (earlier PFSCM & now GHSC-PSM) together with other global procurement agencies. She is currently working with Hetero as a Senior Manager – International Marketing for past 8½ years. Prior to Hetero she was with Cipla Ltd also in international Marketing. Tarang together with her team oversaw (& still does) the successful Phase wise implementation of GS1 labelling standards for supply of ARVs to GHSC-PSM project under USAID contract.
Sr Yeshialem Bekele, Ethiopian FDA

- Sr Yeshi Bekele is the Traceability Office Coordinator for the Ethiopian Food and Drug Authority
Scott has over 14 years of experience successfully designing, implementing and managing humanitarian, development and diplomatic projects in a host of complex environments in the U.S. and abroad. He is the Senior Advisor for Supply Chain Private Sector Engagement at USAID. He led a cutting edge initiative to utilize drone technology for delivering much-needed medicines, lab samples, blood transfusions and vaccines within hard-to-reach regions of the world and developed a low cost, cloud based, transport management system, called TransIT, for use in low resource settings. Additionally, Scott led a multi country activity to monitor temperature remotely throughout public health supply chains using IoT sensors, and utilize the data collected to improve the quality of medicines received by our customers.
Pete Alvarez, GS1 Global Office

- Pete is Senior Director, Identification and Master Data, Healthcare, he is part of the GS1 Global Office healthcare team. Pete works with the global healthcare industry on the implementation of GS1 standards to help improve medical outcomes, clinical decision making, supply chain efficiency and ultimately patient safety.
Implementation of Global Standards (GS1)

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
Procurement and Supply Management
Global standards requirements for pharmaceuticals, medical devices, sterile kits, and laboratory reagents

**Phase 1**
- 30 Dec 2018
  - GS1 Data Matrix or GS1-128 barcode encoded with:
    - (01) GTIN
    - (10) Batch/lot
    - (17) Expiration Date
  - Homogenous Trade Item

**Phase 2**
- 30 Dec 2019
  - GS1 Data Matrix or GS1-128 barcode encoded with:
    - (01) GTIN
    - (10) Batch/lot
    - (17) Expiration Date
  - Mixed or Partial Trade Item

**Phase 3**
- 30 June 2020
  - GS1 Data Matrix or GS1-128 barcode also encoded with:
    - (21) Serial Number
  - Homogenous Trade Item

**Phase 4**
- 30 June 2022
  - GS1 Data Matrix or GS1-128 barcode encoded with:
    - (21) Serial Number
  - Mixed or Partial Trade Item

**Tertiary Packaging**
- GS1 Data Matrix or GS1-128 barcode encoded with:
  - (01) GTIN
  - (10) Batch/lot
  - (17) Expiration Date

**Secondary Packaging**
- GTIN for each unit of measure

**Master Data**
- GLN Sold-From
- GLN Invoice-From
- GLN Production

**All item master data submitted through the GDSN**

*For more information on how to comply: [www.1worldsync.com/customer-page/ghsc-psm](http://www.1worldsync.com/customer-page/ghsc-psm)
For more information on our requirements: [http://ghsupplychain.org/globalstandards](http://ghsupplychain.org/globalstandards)

**GTIN**: Global Trade Item Number
**GLN**: Global Location Number
**GDSN**: Global Data Synchronization Network
**SSCC**: Serial Shipping Container Code

**Pharmaceuticals**
- Identify Items & Locations
- Capture data on data carrier
- Share data with trading partners

**Medical devices, Sterile Kits & Laboratory Reagents**
- Identify Items & Locations
- Capture data on data carrier
- Share data with trading partners

---

---
Joint donor guideline

• Single primary reference document for technical requirements to meet requirements for implementation of global standards for product and location identification, labeling, and data exchange

• Endorsed by the Global Drug Facility/StopTB, Global Fund, UNDP, UNFPA, and USAID

International procurement agency timelines – pharmaceuticals and vaccines

<table>
<thead>
<tr>
<th>Agency</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNDP</td>
<td>Voluntary but preferred</td>
<td>Voluntary but preferred</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNFPA</td>
<td>31 Dec 2019</td>
<td>31 Dec 2020</td>
<td>Voluntary but preferred</td>
<td></td>
</tr>
</tbody>
</table>
Current compliance in key product categories

- Female Condoms
- HIV/AIDS Pharmaceuticals
- Laboratory Consumables
- Laboratory Reagents
- Male Condoms
- Voluntary Male Circumcision (VMMC) Kits
- Malaria Pharmaceuticals
- Malaria Rapid Diagnostic Test (RDTs)
- Contraceptive Implants
- Injectable Contraceptives
- Intrauterine Devices
- Oral Contraceptives
- Essential Medicines

Phase 1
Phase 2
Phase 3
Phase 4
Benefits to suppliers

- **Product data quality:** Standardized product information ensures that GHSC-PSM is aligned with suppliers regarding items available for procurement, avoiding costly miscommunications.

- **Master data:** Using the GDSN, suppliers can provide and update accurate item data to GHSC-PSM and other trade partners at any time. This allows for a single, definitive source of truth for product master data.

- **Awards:** Suppliers’ GS1 score is incorporated into award decisions as part of past performance.
Next steps

• Close the gap in current compliance
• Phase 4 deadline (serialization)
• Ongoing engagement and data stewardship for new trade items and other data updates
The USAID Global Health Supply Chain Program—Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership. For more information, visit ghsupplychain.org.

The views expressed in this presentation do not necessarily reflect the views of USAID or the U.S. government.

For questions, please contact:
Rachel Smith
rsmith@ghsc-psm.org
HETERO GS1 JOURNEY
Virtual Annual ARV Buyer Seller Summit.
Oct 15th’2020
Ms. Tarang Verma.
Sr. Manager, International Marketing.
GS1 Implementation Journey

1. About HETERO
2. Objective of Global GS1 standards
3. Serialization Implementation status
4. Steps & Challenges
5. Take Away message(s)
6. Conclusion
About Hetero

- 25 years of excellence
- 36 state-of-the-art manufacturing facilities
- 300+ products in portfolio
- Presence in 126+ countries
- 21,000 employees globally
- Largest closely held pharmaceutical company in India
- Among the largest manufacturers of ARV APIs & FDFs in the world
- Asia’s largest SEZ complex for APIs manufacturing at Visakhapatnam, Andhra Pradesh
The objective of Global Track & Trace regulations is to protect patient safety by preventing counterfeit, diversion of products and to ensure product integrity across the complete pharma supply chain.
## Serialization Implementation Status

<table>
<thead>
<tr>
<th>Region</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA – DSCSA</td>
<td>Since Sep’17</td>
</tr>
<tr>
<td>EU – FMD</td>
<td>Since Dec’18</td>
</tr>
<tr>
<td>Russia &amp; China</td>
<td>Under Process</td>
</tr>
<tr>
<td>USAID (GHSC-PSM)</td>
<td>Phase wise implementation*</td>
</tr>
</tbody>
</table>

### Table of Requirements

<table>
<thead>
<tr>
<th>Phase #</th>
<th>Phase Timeline</th>
<th>Labelling Requirements</th>
<th>Packing &amp; Master data</th>
<th>Hetero Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>30-12-2018</td>
<td>GS1 Data Matrix or GS1-128 barcode symbology encoded with:</td>
<td>Tertiary packing</td>
<td>Achieved</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• GTIN</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Batch/lot</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Expiration date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 2</td>
<td>30-12-2019</td>
<td>Provide mandatory and required attribute data via the GDSN</td>
<td>Master Data</td>
<td>Achieved</td>
</tr>
<tr>
<td>Phase 3</td>
<td>30-06-2020</td>
<td>GS1 Data Matrix or GS1-128 barcode symbology encoded with:</td>
<td>Secondary level (Inner pack)</td>
<td>Secondary level - Achieved Primary Level - Achieved</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• GTIN</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Batch/lot</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Expiration date</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Secondary level (Inner pack)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Primary: In case of carton less, on Bottle(Optional; required only when the item is supplied in carton less packaging.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase 4</td>
<td>30-06-2022</td>
<td>GS1 Data Matrix or GS1-128 barcode symbology encoded with:</td>
<td>Primary and Secondary level</td>
<td>In process (by/before oct’21)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• SSCC</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Steps Taken & Challenges faced while implementing GS1

**STEPS TAKEN**

1. Understanding the expectations & requirements of GS1
2. IT Architecture and Infrastructure
3. Artwork modifications
4. Integration with existing packaging-line equipment(s)
5. Multiple packaging configurations on the same line
6. Multiple vendors as part of risk mitigation plan
7. Thorough training to get well versed

**CHALLENGES**

1. Diverse GS1 Regulations
2. Different GS1 standards & interpretations
3. Space constraints on production floor
4. Multiple line-level solution providers and vendor-locking architecture
5. GS1 implementation deadline (without impacting the Production outcome)

Regulatory compliance & Data integrity
Implementation Cost
<table>
<thead>
<tr>
<th>Lessons Learnt, Takeaway messages!</th>
</tr>
</thead>
<tbody>
<tr>
<td>Invest significant time &amp; efforts from initial analysis phase.</td>
</tr>
<tr>
<td>Think GS1 as an “End-to-End process”, don’t cut corners.</td>
</tr>
<tr>
<td>Engage with experienced partner(s).</td>
</tr>
<tr>
<td>Equipment selection plays pivotal role to deliver the best outcome, equipment’s like: scanners, printers, scan devices etc.</td>
</tr>
<tr>
<td>The GS1 requirements across various healthcare systems should be aligned.</td>
</tr>
<tr>
<td>Development of country healthcare systems enabling GS1/Track &amp; Trace</td>
</tr>
</tbody>
</table>
Global Track & Trace is complex in nature but the success mantra is: “Understand what it is, where you are, what you need, involve all necessary functions, build long-term relationship with your solution partner, and take joint responsibility as a team to make this project successful.”
THANK YOU

It's good to be on “Track” which you can “Trace”.

Follow us on: Facebook | Twitter | LinkedIn | YouTube
SHIPPING DOCUMENTATION AND LABELING IMPROVEMENT
Typically there is limited connection between sourcing and the individuals who interact with the commodities down the supply chain.
SOLUTION

- USAID, donors and stakeholders set requirements related to documentation and labeling information.

- Creation of a template to standardize presentation for:
  - Shipping document
  - Pallet
  - Carton
AREAS FOR IMPROVEMENT

● Shipping Document
  ○ The way in which the commodity is packaged (e.g., 10 blister packs per box, 25 boxes per carton)
  ○ The dimensions, weight and value of each level of packaging, from unit to the carton
  ○ Total number of pallets and cartons, with cartons listed by number and corresponding pallet number they are located on

● Carton Labelling
  ○ Number of partial cartons, their carton number (with contents), their pallet location
  ○ The way in which the commodity is packaged (10 blister packs per box, 25 boxes per carton)
  ○ Identifying the number of the carton out of a complete order
    ○ e.g. 15 of 67
  ○ Partial carton should be labeled to easily identify it (red X), with contents listed

● Pallet Labelling
  ○ Identifying the number of the pallet of the total number of pallets
  ○ # of cartons within the pallet
  ○ Expiration
  ○ Product
  ○ RO# and PO# the products coincide with
  ○ Batch #
  ○ Recipient and consignee
  ○ Donor
NEXT STEPS

- Gain input from the private sector and stakeholder
- Finalize list of attributes
- Develop template
- Develop implementation plan
- Add to procurement contracts
The GS1 Digital Link Standard in Healthcare

ARV Summit: Product Specifications and Documentation (R1)

Pete Alvarez

15 October 2020
A single barcode for identification and access to product information

- Allow a single GS1 barcode on a medical products to be scanned and have the user (e.g., consumer, healthcare provider) access the product digital content, complementing the reliance on the label information.
- Drive the efforts towards ONE barcode on medical product packages
Patients, clinical staff & others in healthcare... Need access to digital information about the product

The **GS1 Digital Link** standard unlocks the digital content with a single scan
Multiple destinations (example)

GS1 Digital Link standard with the existing GS1 barcode on the pack:

App with ability to scan GS1 barcodes & connected to a resolver

Resolver

- Product information page
- Product Information Leaflet
- TV ad, other related video
- Clinical info
- Recall status
- Other digital content

<table>
<thead>
<tr>
<th>Link type</th>
<th>Lang</th>
<th>Target URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>gs1:pip</td>
<td>en</td>
<td><a href="https://dalgiardino.com/medicinal-compound/">https://dalgiardino.com/medicinal-compound/</a></td>
</tr>
<tr>
<td>gs1:pip</td>
<td>ja</td>
<td><a href="https://dalgiardino.com/medicinal-compound/index.html.js">https://dalgiardino.com/medicinal-compound/index.html.js</a></td>
</tr>
</tbody>
</table>
Single destination (example)

GS1 Digital Link standard with the existing GS1 barcode on the pack:

(01)09506000134376

https://id.dalgiardino.com/01/09506000134376

App with GS1 Digital Link intelligence built-in

• No resolver required to access a single destination.
Contact details

Pete Alvarez
Senior Director, Identification & Master Data, Healthcare
GS1 Global Office
T  +1 609 557 4547
M  +1 609 462 2625
E peter.alvarez@gs1.org
Thank You

- GS1 Implementation is a journey
- We are working closely to ensure everyone is moving together
- If you ever have a question, please ask! We are learning as we go
TOWARD PATIENT-FRIENDLY ANTIRETROVIRAL THERAPY

THE ROLE OF SUPPLIERS AND THE SUPPLY CHAIN
Moderators

Meaghan O’Keefe Douglas
Supply Chain Measure and Evaluation Advisor

Ashley Greve
Supply Chain Advisor

USAID Office of HIV/AIDS, Supply Chain Management Branch
How has supply chain historically impacted the ART patient experience?

- Distribution methods
- Continuous drug availability
- Shelf life
- Packaging
- Labeling
- Marketing and messaging
PEPFAR Multi Month Dispensing Footprint April to June 2020

ARV Dispensing Quantity - 6 or more months
- Adult Men: 683,698
- Adult Women: 1,211,446
- Children: 32,362

ARV Dispensing Quantity - 3 to 5 months
- Adult Men: 2,120,066
- Adult Women: 4,029,782
- Children: 238,181

ARV Dispensing Quantity - Less than 3 months
- Adult Men: 874,770
- Adult Women: 1,615,434
- Children: 242,223

Source of Data: PEPFAR's DATIM* TX_CURR_MMD FY20 Q3
PEPFAR Multi Month Dispensing from a Pharmacist

While the video includes ARVs from several companies, the use of this product does not equate to promotion, endorsement, nor favor of said company’s product line by the speaker, the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), the United States Agency for International Development (USAID), or the United States Government.
Patient Centric Approach to ARV Access to Achieve Virologic Suppression
MMD, DDD, and Adult ARV Treatment Optimization

<table>
<thead>
<tr>
<th>Dispensation (in months)</th>
<th>MMD</th>
<th>DDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>6MMD</td>
<td>6MMD</td>
<td>1M or 2M supply</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Distribution Method</th>
<th>MMD</th>
<th>DDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinics</td>
<td>DDD channels</td>
<td>DDD channels</td>
</tr>
</tbody>
</table>

Patient Group: Adult Treatment Optimization (TLD or TLE400)
Patient Centric Approach to ARV Access to Achieve Virologic Suppression
MMD, DDD, and Pediatric ARV Treatment Optimization

<table>
<thead>
<tr>
<th>Dispensation (in months)</th>
<th>MMD</th>
<th>DDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>3MMD to 6MMD</td>
<td>3MMD to 6MMD</td>
<td>1M or 2M supply</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Distribution Method</th>
<th>MMD</th>
<th>DDD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinics</td>
<td>DDD channels</td>
<td>DDD channels</td>
</tr>
</tbody>
</table>

Patient Group: Pediatric Treatment Optimization

Availability of DTG 10 #90 and DTG 10 #180 will support expeditious implementation of 3MMD for CLHIV aged 2 to 5 and 6MMD for CLHIV aged greater than 5. PEPFAR COP21 DRAFT Guidance
What makes MMD and DDD for antiretroviral therapy possible?

Enabling Factors for MMD:
- Little to no chance of adverse drug reactions
- Shelf stable
- Sturdy product packaging (can last for months without disintegrating)
- Larger bottle sizes

Enabling Factors for DDD:
- Same as MMD above
- Vendor Managed Services (VMx)

Other factors?
How do we impact the patient experience through Multi-Month Dispensing and/or Decentralized Drug Distribution?

• **Advantages**
  - Getting refills is cheaper and easier for clients
  - Larger packaging can increase convenience
  - Alternative pick-up locations provide opportunities for easier pickup and more discretion!
  - MMD and DDD can be easier on the manufacturer, PSA, 3PL and Donor partners
  - Reductions in cost
  - Increases in efficiency
  - Cartonless

• **Challenges**
  - Risk of leakage
  - Potential for fraud/resale of product
  - Larger packaging can increase stigma
  - Longer shelf-life is needed at the time of dispensation
  - Data retention can be challenging with DDD

**Other factors missing here?**
What are the opportunities?

Packaging
- Stigma reduction (ex. V-Pack)
- How do we reduce stigma related to the “Big Blue Bottle” or the “rattle?”
- Environmental impact (waste)

Labeling
- Reminders (Package change to include a sticker on the bottle where health care provider can write the date of the next appointment, pick-up or viral load)
- What else?

What are other areas for improvement?
It’s time to hear MORE from you!
Considering your experience, what are the enabling factors MMD?
How can we influence further expansion of MMD?
Considering your experience, what are the enabling factors DDD?
How can we influence further expansion of DDD?

INTEGRATE. UPDATE. EVOLVE.
Particularly with DDD and vendor-managed logistics services, what risk mitigation approaches are needed to avoid product leakage?
What measures should we take to detect falsification of medicines dispensed at new dispensing sites?
Questions?
The next patient-friendly innovation...

https://app.sli.do/event/zwcegsgl

Event # 41115
Thank you!

Meaghan O’Keefe Douglas
Supply Chain M&E Advisor
medouglas@usaid.gov

Ashley Greve
Supply Chain Advisor
agreve@usaid.gov
VENDOR-LED
SOLUTIONS FOR THE
SUPPLY CHAIN OF THE
FUTURE

EXPLORING OPTIONS FOR
VENDOR MANAGED SERVICES
TO ACCOMPANY PRODUCT
DELIVERY
TODAY’S MODERATORS AND SPEAKERS

Julia Bem
Supply Chain Management Branch Chief
USAID Office of HIV/AIDS

Ashley Greve
Supply Chain Advisor
USAID Office of HIV/AIDS

Dan Kiesa
Senior Market Intelligence Advisor
USAID Office of HIV/AIDS

Jack Erbs
Senior Market Dynamics Analyst – HIV/AIDS
Procurement and Supply Management Project (GHSC-PSM)
WHAT DOES THE ARV SUPPLY CHAIN OF THE FUTURE LOOK LIKE?

- Effective
- Responsive
- Patient-Centered
WHAT ROLE WILL PRODUCT SUPPLIERS PLAY IN THE ARV SUPPLY CHAIN OF THE FUTURE?

Manufacturing Site

Global Distribution Center

Vendor Warehouse In-Country

Central Medical Store

Regional Warehouse

Distributed for Sale via Private Sector Partner or Wholesaler?

Manufactured for Pick-Up by Buyer?

Sold with Delivery to Central MoH Warehouse?

Sold from Vendor Warehouse In-Region?

Sales transaction occurs upon Distribution to Patient?

Points of Care

Decentralized Distribution Point

2020 ANNUAL ARV BUYER SELLER SUMMIT: INTEGRATE, UPDATE, EVOLVE
WHAT DOES THE ARV SUPPLY CHAIN OF THE FUTURE LOOK LIKE?

Medicine procurement transactions are necessary. By moving the transaction closer to the patients, can we

- More closely connect the success of procurement with medicine availability to patients
- Simplify the number of transactions between production and medicine consumption
- Enable processes that will, one-day, be more transferrable to host government management
PRINCIPLES OF THE HIV SUPPLY CHAIN OF THE FUTURE

- **PROGRAM CENTERED**
  - Get the medicine to the patient—not the patient to the medicine!
  - Path toward host government oversight of supply chain service and are empowered to engage vendors to best meet the needs of their national program & patients

- **EFFICIENT**
  - Process & metrics that align procurement success with patient access more closely
  - Manufacturing closely informed by product stocks in network
  - Flexibility to consider greatest whole supply chain efficiency when making changes or improvements

- **COMPETITIVE**
  - System of vendor-led services is dependent on increasingly long-term, strategic, and collaborative supplier relationships
  - Consolidated sourcing of product with logistics services adds value to award
BENEFITS OF VENDOR MANAGED SUPPLY CHAINS

- Result-based
- Simpler value-stream between manufacturer and patient can
  - Reduce lead time for key commodities due to fewer transactions and fewer hand-offs
  - Improve product availability
  - Empower innovation for commercial efficiencies
  - Reduce dependency on high inventory levels
- Milestones move closer to patients
  - Sourcing the results in delivery closer to patient can better correlate supply chain success with program success
- Strategic, inventory management contracts can
  - Improve data visibility and forecasting accuracy
  - Simplify ordering process through outsourced planning
  - Reduced order management burden (ultimately) enables transition to host government
BENEFITS OF VENDOR MANAGED SUPPLY CHAINS

- **INCREASED PRIVATE SECTOR MANAGEMENT ALONG VALUE CHAIN**
  - Implementation of vendor logistics globally
  - Options for vendor-led distribution in country

- **INNOVATION**
  - Solutions could be dynamic between recipient country, product, supplier or region
  - We want to hear ideas from you how to evolve the delivery of ARVs to patients
  - Reduce lead time for key commodities due to fewer transactions
GHSC-PSM IS PILOTING D-TERM SHIPMENTS WITH AN EMPHASIS ON DATA VISIBILITY

- The ARV team has identified strategic suppliers to pilot a D-term Program
- These suppliers are leveraging their existing technology and logistics partnerships while exploring new technologies and standards
- Suppliers will be responsible for both delivery and providing data visibility along critical logistics milestones

Benefits of D-term Shipping:
- Places more ownership at the end country level where PSM will facilitate greater interactions between suppliers and Field Offices/Consignees
- Allows suppliers to push out their own solutions and be a more active partner in a customer centric supply chain
- Reduces the dependency on the PSA to coordinate Freight and Logistics
1. What is the largest barrier to moving toward vendor-led in-country distribution?
2. Into how many destination countries have you arranged customs and importation?
3. Considering a March 2021 delivery, to what level of infrastructure would deliveries be possible? (looking for sustainable, not ad hoc solutions)
4. Which factor will be most important for the success of vendor managed logistics? (put additional ideas into the chat box!)
5. In which country would you have the most confidence of managing logistics closest to patient distribution?
Thank you!

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Oral PrEP Scale-up Plans, Opportunities and Challenges

Annual ARV Summit, October 15, 2020

Sangeeta Rana, Branch Chief, Biomedical Prevention, USAID
Robyn Eakle, Senior Advisor, Biomedical Prevention, USAID

Contributors: Allison Kimmel, Chris Obermeyer, Messai Belayneh, Christy Wahle, USAID
Outline

• Background
• Timeline of PEPFAR and USAID PrEP scale up
• COP20 expansion (October 2020 - September 2021)
• Commodity challenges and opportunities
Significant impact on reducing new infections where scaled-up

PrEP prevents an estimated three-quarters of HIV infections in people at risk in large African study

Big drop in incidence, despite low use of PrEP, because people used it when needed.

Gus Cairns | 4 July 2020

Rapidly declining HIV infection in MSM in central London

In 2016, there were 1.8 million worldwide. Although the annual infections has fallen by 16% since then, the rate of HIV infection has been increasing since 2007. The reduced incidence in low-income and non-injected men has been most pronounced in London, with a 20% decrease with an overall change of 11%.

What happens when PrEP is scaled up? Results from EPIC-NSW

In The Lancet HIV, Andrew E Grulich and colleagues describe the rapid roll-out of pre-exposure prophylaxis (PrEP) in New South Wales, Australia (the Expanded PrEP Implementation in Communities-NSW) study setting where the incidence of 7.3% in the non-gay suburbs of the city. The use of PrEP has led to a significant reduction in new infections.

Evidence of an Association of Increases in Pre-exposure Prophylaxis Coverage With Decreases in Human Immunodeficiency Virus Diagnosis Rates in the United States, 2012–2016

Dawn K Smith, Patrick S Sullivan, Betsy Cadwell, Lance A Walter, Azfar Siddiqui, Robertoino Mena-Giler, Xiaohong Hu, Karen W Hoover, Norma S Harris, Scott McCallister

Clinical Infectious Diseases, 21279, https://doi.org/10.1093/cid/ciz1229

Published: 28 February 2019 Clinical Infectious Diseases
Oral PrEP in PEPFAR / USAID

Pre-2015
USAID supported,
CAPRISA 004,
Partner’s PrEP OLE,
Partner’s Demo,
FEM-PrEP & several
demonstration studies

2015
PEPFAR SAB
recommends PrEP
implementation
Some PrEP
implementation in KP programs

2016
COP16 encouraged
stakeholders coordination and PrEP
readiness
Drug procured w/ non-PEPFAR funds
DREAMS sites can initiate PrEP

2017
COP17 guidance allows for
procurement of PrEP ARVs when:
→ Test & START policy initiated
→ VL testing in place
→ multi-month scripting for stable
ART clients

2018
COP18 guidance highlights PrEP as an
evidence based intervention to
accelerate prevention, and outlines target
setting and budgets
Inaugural Plan4PrEP
Learning Collaborative
1st Cost and Impact
models for 13 countries

2019-2020
PEPFAR-wide PrEP
implementation in 29 countries,
targeting > 300,000
new initiations
PEPFAR interagency
PrEP community of Practice

COP 20
Ambitious goal
to reach 1 million new
people with PrEP during
COP20 implementation
### Accelerating from COP19 to COP20

<table>
<thead>
<tr>
<th>COP19</th>
<th>COP20</th>
</tr>
</thead>
<tbody>
<tr>
<td>29 countries with PEPFAR PrEP programming</td>
<td>36 countries with PEPFAR PrEP programming</td>
</tr>
<tr>
<td>342,968 PrEP.NEW, 361,721 PrEP_CURR</td>
<td>1,075,062 PrEP.NEW, 1,234,656 PrEP_CURR</td>
</tr>
<tr>
<td>Many policies and guidelines still focused on populations</td>
<td>Revisions of policies and guidelines to be more inclusive</td>
</tr>
<tr>
<td>Limited provider training (at start)</td>
<td>Expanding provider trainings, including virtual</td>
</tr>
<tr>
<td>New developments in DSD and integration of PrEP services</td>
<td>Expansion/scale-up of DSD in most countries</td>
</tr>
<tr>
<td>Few national demand creation strategies, more limited/ localized</td>
<td>Most countries to build national approaches to demand creation</td>
</tr>
</tbody>
</table>
Oral PrEP scale-up COP17-20

- COP18 PrEP achievement was strong
- COP19 was focused on expanding and building momentum
- COP20 targets require significant program scale-up

Implementation expanded to 7 additional countries in COP20
Reaching 1 million on PrEP: focus on scaling to saturation and supporting PrEP continuation

- 14 countries will have to increase number of clients on PrEP by at least 4 fold from COP19-20
- Overall PrEP CURR targets increase 4 fold from COP19-20
- Top 6 countries listed have 75% of PEPFAR PrEP CURR targets
PrEP should be integrated into multiple service delivery points - primary care, index testing, STI services, ANC, family planning, ART, VMMC (demand creation and/or care)

Opportunity to engage higher risk people in care (prevention and treatment)

DSD critical to supporting client centered services and successful expansion of PrEP

PrEP - keeping people at higher risk HIV-negative
Introducing oral PrEP is not easy!

Supply Side

- Effective, affordable products
- Healthcare and lab capacity
- Regulatory approval
- Government plans & budget for PrEP
- Effective supply chain
- Knowledgeable, supportive healthcare providers

Demand Side

- Appealing branding & packaging
- Partner, family & community support
- Information & communications on PrEP
- Physical access to facilities
- Storage
- Adherence
- Stigma, rumors & misinformation

OPTIONS at R4P2018: Neeraja Bhavaragu
Accelerating PrEP service innovations and adaptations: leveraging responses to COVID-19

- **Pivot to virtual/phone-based support**: phone/WhatsApp to track refills and HIV testing; virtual support groups (e.g., virtual engagement of AGYW); virtual demand creation that directs clients to static clinics; online assessment for HIV risk / PrEP eligibility; telehealth visits with providers and counselors. Pivoting to virtual platforms has supported continuation, and after initial declines, new initiations are coming back up post lockdowns.

- **Reduced contact PrEP service delivery**: determined essential staff; reduced number of clients in facility at same time; strengthened infection control measures; online reservation systems to make appointments for PrEP initiation and refills

- **Enhanced decentralization**: home-based delivery of PrEP; PrEP pick-up at predetermined community pick-up points; HIVST being discussed in some places

- **MMD to extent allowable by national policy with provision for monthly scripting for clients who may not adhere (to converse commodities)**
Supply chain opportunities and challenges

Expand access by bringing PrEP closer to clients building on existing and accelerating new approaches

**Opportunities:**
- Expanding MMD for PrEP
- Innovative service delivery models (e.g. community and home delivery, private pharmacy pick-up, automated vending machines, lockers, etc.)
- Packaging innovations: e.g. V-Kit

**Challenges:**
- Difficult to forecast for PrEP commodity needs given varying and cyclical patterns of use; also other donors contributing to stock
- MMD not always possible due to low stock/lack of planning
- PrEP stock sometimes “lost” in ART stock, used for ART clients
Ensuring continued supply is critical to meeting increasing demand

- This is only for PEPFAR procured ARVs
- GF, local gov’ts, other donors (incl. Gilead) contribute to national commodity stocks
THANK YOU!!!
USAID HIV Prevention Product Pipeline

The USAID Microbicide Program
2020 Annual ARV Buyer Seller

October 15, 2020
Presenters: Ashley Vij and Shannon Allen
Program End-to-End Model for Impact on HIV Incidence: From Research to Access and Use

Getting PrEP Into the Hands of the Most Vulnerable
- Policy and systems approach to expedite and sustain access to oral PrEP
- Innovations in PrEP implementation
- Mitigating unintended consequences of taking oral PrEP

Using End-Users to Maximize the Impact of HIV Prevention Products
- Incorporating preference data from high-risk women to inform product development
- Shaping development decisions through prioritizing cost, features and characteristics, access preferences
- Understanding end-user lifestyles, drivers, barriers/obstacles, preferred attributes

Blazing the Trail for Introduction of Next-Generation HIV Prevention Products
- Fast-tracking product introduction processes (e.g. registration, manufacturing/distribution, supply chains)
- Building on existing service delivery foundations
- Supporting country programs to adopt lessons learned

Catalyzing Development of HIV Prevention Products that Support Adherence
- Supporting research for products that incorporate a range of desirable characteristics
- Prioritizing research for products that meet the needs of the end-user
- Aligning investments with product affordability, feasibility, healthcare system needs, community acceptability, etc

Amplifying Clear and Effective Advocacy for HIV Prevention
- Amplifying the need for new HIV prevention options
- Ensuring that advocates engage, support and critique research
- Holding stakeholders accountable and shortening research to rollout

Impact on PEPFAR Programs
- Reduced HIV incidence among high-risk women
- Applied research-to-use model to help program implementers address major gaps
- Expanded access to currently available prevention products
Timeline of Products and Technologies Currently Supported Under the Program

**July 2020**
- **EMA Positive Opinion**
- Initial NMRA approvals expected 2020

**January 2021**
- Currently in animal studies; Phase 1 expected in Q1 2022

**January 2022**
- Currently in small animal studies; Phase 1 expected in Q4 2022
- Currently supporting ancillary studies on the Dual Purpose Pill (Truvada and a COC) and Descovy oral formulations looking at product uptake and adherence

**January 2023**
- Early preclinical development; Advance candidates through clinical testing to facilitate iteration and down selection of candidates
Monthly Dapivirine Vaginal Ring (DVR)

- Flexible silicone **vaginal ring**
- Slowly releases ARV **dapivirine**
- **Woman-initiated, woman-centered:**
  - Self-inserted monthly
  - Discreet
  - Does not interfere with sex
- First long-acting product to add to prevention method mix in current portfolio
- **Suitable for LMICs**
- Stored at room temperature; **no cold chain**
- **5 Year Shelf Life**
- Potential to combine multiple ARVs, contraception in longer acting rings

Photo Credit: International Partnership for Microbicides, 2020
Anticipated FDA and NMRA Timelines

- **EMA Positive Opinion**
- **WHO: Development of Use Guidelines, Issuance of Expression of Interest, and Prequalification by December, 2020**
- **SAHPRA (South Africa) Dossier Submission: WHO Collaborative Review Procedure (CRP)**
- **NMRA Submission**
- **FDA NDA Submission Estimated December, 2020**
- **FDA Review**
- **Anticipated FDA Approval Q4 2021**
- **Earliest Anticipated NMRA Approvals in Q1/Q2 2021**
Contributing to Reducing HIV Incidence in Women Through Supporting R&D of Safe, Effective and Affordable Microbicides

Understand user lifestyles, drivers, barriers, and preferred attributes

Support research that incorporates a range of desirable characteristics

Prioritize research for products that meet the needs of the end-user

Optimize development with affordability, feasibility, HCS needs, community acceptability

Fit into the complex lifestyles of women

Facilitate uptake and adherence

Less user dependent and easy to administer

Safe, effective, affordable

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**Dual Prevention Pill for HIV and Pregnancy Prevention**
- Supporting cross-over study to determine preference and acceptability in SA
- 28-day daily pill regimen combining Truvada and COC (separate and over-encapsulated)

**Improved Oral PrEP Formulation for HIV Prevention**
- Supporting parallel ancillary studies during Phase 3 Descovy trial to determine uptake, acceptability and adherence
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**Sub-Q Reservoir Implant for HIV Prevention**
- Early preclinical development
- Biodegradable TAF-only
- Designed to be used with an existing trocar (HCW required)
- Target dosing: at least 1 yr

**Multi-purpose Sub-Q Reservoir Implant**
- Early preclinical development
- Biodegradable TAF+Hormone
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**Subdermal Pellet Implant Delivery System**
- Early preclinical development
- Biodegradable CAB-only based implant
- Will have an affordable trocar (HCW required)
- Target dosing: at least 6 mos

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Microarray Patch Technology for HIV Prevention
- Early preclinical development
- Topical patch applied to the skin similarly to a band-aid
- Microneedle projections deliver CAB
- Developing POC for potential MPT (POC)
- Designed to be self-administered (with an indicator)
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HIV Antibody Development
- Preclinical development
- Advance candidates through clinical testing to facilitate iteration and down selection of candidates
- Target dosing: 3-6 mos

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Improved Oral PrEP Formulation for HIV Prevention
- Preclinical development
- Supporting parallel ancillary studies during Phase 3 Descovy trial to determine uptake, acceptability and adherence
Using Data for Decision Making throughout the Product Development and Access Pathway

**Pre-Clinical Research, Clinical Research and Regulation**

**MEASURE**
Characterizing and assessing product leads against Target Product Profiles, demonstrating safety and efficacy, and supporting regulatory approval

**DEMONSTRATE**
Creating real-world evidence and demonstrating potential for program implementation

**INFORM**
Using research to address barriers, inform policies, and facilitate delivery at the country level
Acknowledgements

Questions? Please contact
Ashley Vij - avij@usaid.gov
Shannon Allen - Shallen@usaid.gov
32 Countries!
86 Organizations
24 Sellers
Annual ARV Buyer Seller Summit | Virtual

22% Buyer (Directly engaged in buying)
26% Seller (Directly engaged in selling)
15% National Government
37% ARV Stakeholder (FDA, Clinical USG, Field USG, CHAI, MSF, ICAP, MPP, DNDi, others)
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