Annual ARV Buyer Seller Summit Schedule

Virtual | Tuesday, 13 October to Thursday, 15 October 2020

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.

TIME	TOPIC	SPEAKERS/MODERATORS	SLIDE PAGES
Day 1: INTEGRATE: Engaging across National Regulatory, Program Implementation, and Manufacturing Stakeholders			
Virtual Buffer 5:30 EST			
6:00 EST 12:00 CET 15:30 IST 20 minutes	**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**	
6:20 EST 12:20 CET 15:50 IST 55 minutes	**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)** - 5 min Video - 25 min Question and Answer	Mr. Cathal Meere, *Pharma Sourcing Manager, The Global Fund*	**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*	**SLIDE #21 - 67**
	Overcoming Barriers to Importation (T7) **Impact of COVID-19 on Logistics** **Shelf-life Recommendations for Importation of Health Commodities**	**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 #68 - 107**

Day 2 – UPDATE: Procurement Forecast and View towards Changing Guidelines			
Virtual Buffer from 5:30 EST			
6:00 EST 12:00 CET 15:30 IST	**18 Month Consolidated Forecast (W1)**	Mr. Chirag Rajpuria, *Associate Specialist for Principal Recipient Services, The Global Fund*	**SLIDE #108 - 130**
6:15 EST 12:15 CET 15:45 IST 90 minutes	**Individual Highlights for Each Procurement Channel (W2-W8)**	Dr. Charles Lwanga, *Program Management Specialist - Pharma, USAID|Kenya* Ms. Tsion Tsegaye Gizaw, Procurement Contract Management Expert*, Ethiopia Pharmaceuticals Supply Agency* Dr. Rashid Settaala-Gava, *Program Director, Medical Access Uganda Limited* Ms. Khadija Jamaloodien, *Director of Affordable Medicines, Republic of South Africa* Mr. Zafar Yuldashev, *Procurement Specialist, United Nations Development Programme* Ms. Uranchimeg Badarch, *Specialist, Strategic Sourcing Pharmaceuticals*, *The Global Fund* Mr. Alan Pringle, *Global Supply Chain Director, Chemonics International (GHSC-PSM)* **Moderated by Mr. Chirag Rajpuria, The Global Fund, and Dr. Jeffrey Samuel, USAID**	**SLIDE #131 - 208**
7:45 EST 14:45 CET 17:15 IST 15 minutes	**U.S. Food and Drug Administration's Registration of Antiretroviral Drugs under the PEPFAR Program (W9)**	Dr. Sanjana Mukherjee, *Public Health Policy and Regulatory Research Fellow, Office of Commissioner, United States Food and Drug Administration*	**SLIDE #209 - 222**
Coffee/Bio Break from 8:00 EST (15 minutes)			
8:15 EST 14:15 CET 17:45 IST 45 minutes	**Updates from WHO:** **Pediatric Treatment and Infant Prophylaxis (W10)** **Update from WHO: Adult Treatment (W11)** **Question and Answer**	Dr. Martina Penazzato, *Pediatric HIV Lead, World Health Organization* Dr. Marco Vitoria, *Medical Officer for HIV Treatment and Care, World Health Organization* **Moderated by Mr. Martin Auton, The Global Fund**	**SLIDE #223 - 274**
9:00 EST 15:00 CET 18:30 IST 15 minutes	**Update on Performance of APWG (W12)**	Mr. Wesley Kreft, *Co-Chair, Procurement Consortium of Antiretroviral Procurement Working Group*	**SLIDE #275 - 283**

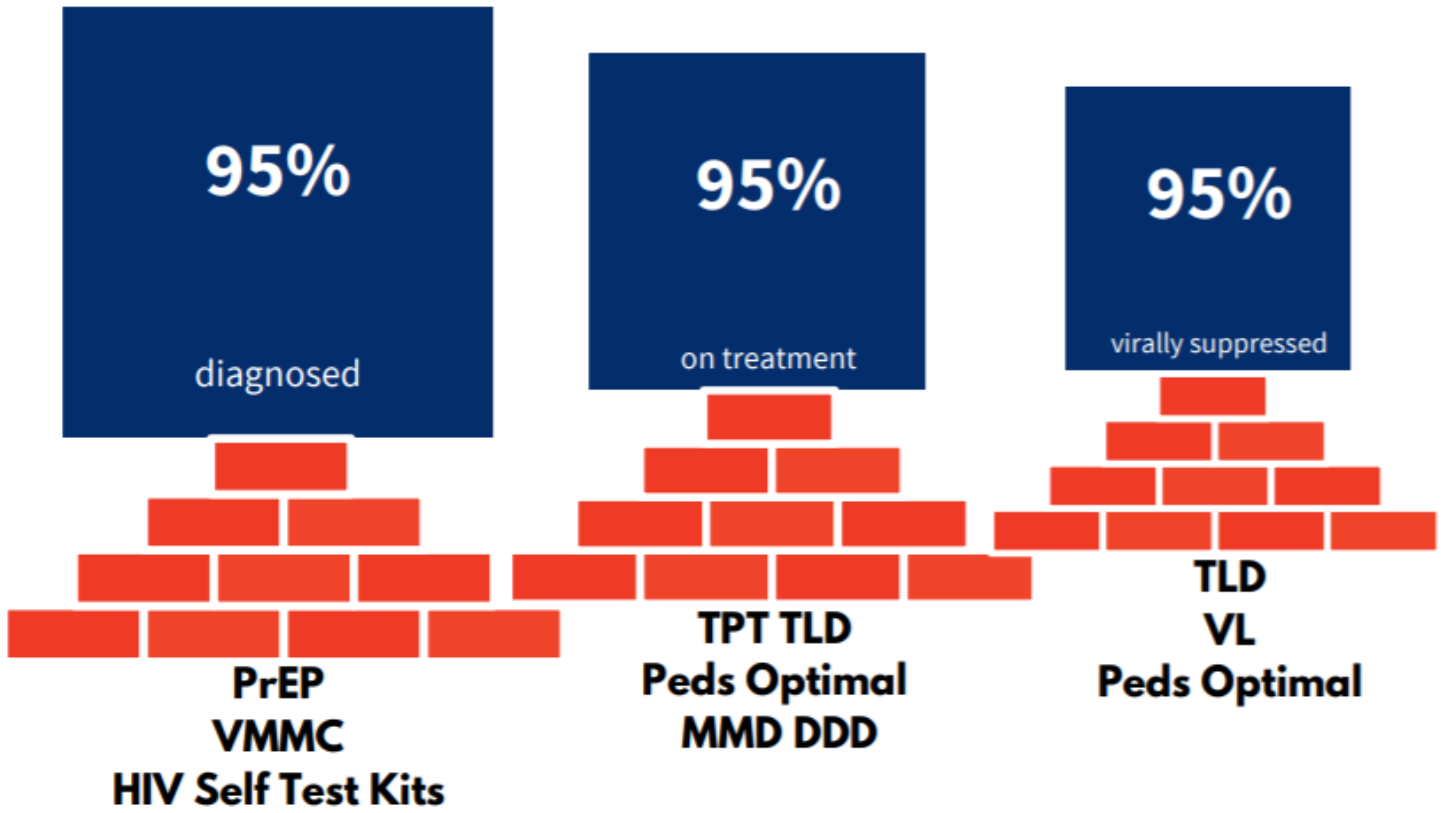
- 9:15 EST 15:15 CET 18:45 IST 45 minutes	**PEPFAR Priorities (W13)** **30 Minute presentation followed by Question and Answer** **(Representatives from the Department of State/Global AIDS Coordinator)**	Mr. Leonard Kosicki, *Senior Technical Adviser for Health Commodities, Department of State/Global 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**	**SLIDE #284 - 310**
Day 3 – EVOLVE: Optimizing Joint Programmatic and Procurement Response			
Virtual Buffer 7:30 EST			
Parallel Sessions on Programmatic and Procurement Considerations			
8:00 EST 14:00 CET 17:30 IST 60 minutes	**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*	**SLIDE #311 - 349**
	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*	**SLIDE #350 - 369**
9:00 EST 15:00 CET 18:30 IST 45 minutes	**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*	**SLIDE #370 - 384**
	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*	**SLIDE #385 - 409**
Coffee/Bio Break from 9:45 to 10:00 EST (15 minutes)			
10:00 EST 16:00 CET 19:30 IST 30 minutes	**Closing Remarks (R5)**	**Ambassador Deborah L. Birx, MD** **U.S. Global AIDS Coordinator & U.S. Special Representative for Global Health Diplomacy**	

Annual ARV Buyer Seller Summit

The Importance of Integration and Coordination between MOH and NMRA

INTEGRATE. UPDATE. EVOLVE.

How commodity availability and accessibility impacts the 95-95-95



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Patient Centric Approach to ARV Access to Achieve Virologic Suppression

MMD, DDD, and Adult ARV Treatment Optimization

	MMD	MMD	DDD
Dispensation (in months)	6MMD	6MMD	1M or 2M supply
Distribution Method	Clinics	DDD channels	DDD channels
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

	MMD		DDD
Dispensation (in months)	3MMD to 6MMD	3MMD to 6MMD	1M or 2M supply
Distribution Method	Clinics	DDD channels	DDD channels
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

Question

1. What is the process for engagement between the Ministry of Health and the National Medicines Regulatory Authority?

Question

2. What is the process for engagement between the Ministry of Health and the National Medicines Regulatory Authority?

Question

3. What advice would you offer ARV manufacturers who are submitting new applications?

Question

4. What resources from the USFDA would be helpful to NMRA in expediting the review of new applications?

Question

5. How often are the national treatment guidelines updated? What are some opportunities for alerting the MOH on the latest information from WHO?

Question

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?

Question

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?

Question

8. What strategies can we employ to support adolescents and men as they are the most difficult patient subgroups to reach?

ANNUAL ARV BUYER SELLER SUMMIT 2020

TUESDAY OCTOBER 13TH 2020

The Global Fund

UNITE TO FIGHT

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

The Global Fund | UNITE TO FIGHT

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

INTEGRATE. UPDATE. EVOLVE.

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

2020 ARV SUMMIT

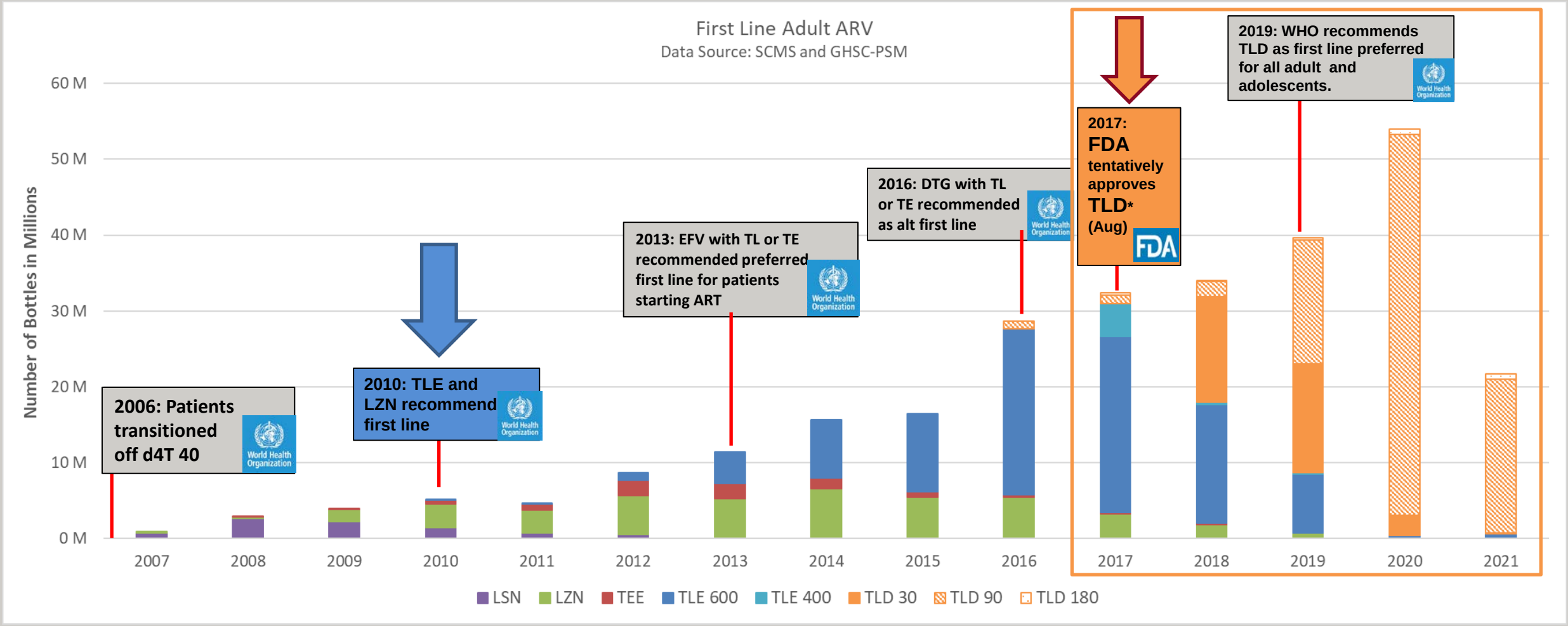
Transition Management Breakout Session

Messai Belayneh, Pharmaceutical Adviser

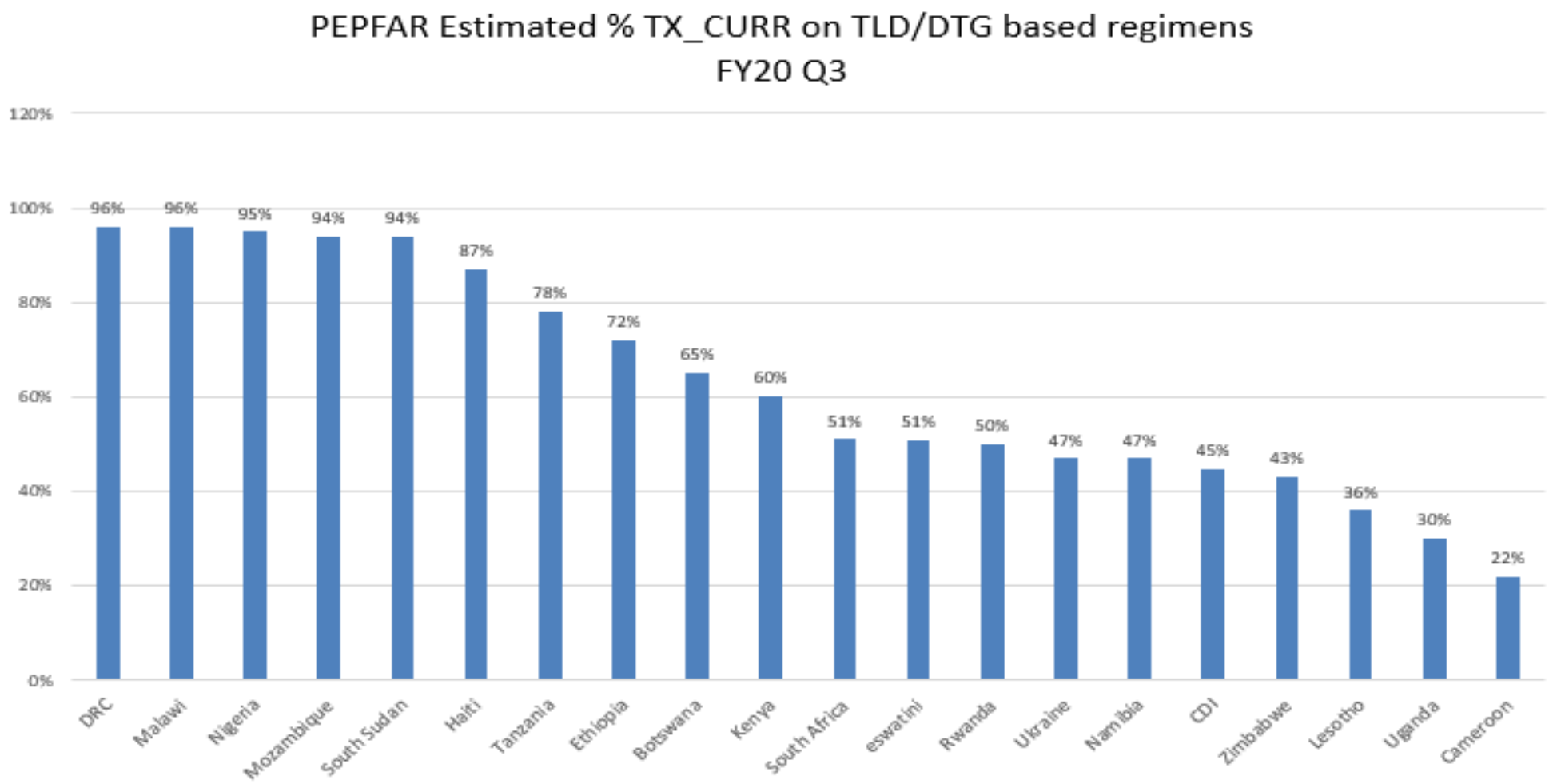
USAID, Office of HIV/AIDS, Division of Supply Chain for Health

Pace and Magnitude of Adult First Line Transitions

(As of October 5, 2020)



TLD TRANSITION PROGRESS



Data Source: PEPFAR OU Slide Presentations for Q3 POART. Estimated % Tx_CURR on TLD/DTG based regimens derived from data presented in OU presentations

TLD Transition progress: Challenges Observed

Common Reasons stated for TLD Transition Delays		
Policy	Delays in inclusion into guidelines and validation at national level	Reliance on VL results for transition
Information Dissemination	MOH has not solidified or communicated clear transition plans and guidance	Conflicting messages related to childbearing eligibility to TLD has delayed scale up
Training	Clinicians hesitant to prescribe new ARV / lack of knowledge and sensitization	Some clinicians still hesitant to prescribe TLD for women of childbearing age
Supply Chain	Shortage of optimal ARV in country	Elevated stock of legacy drugs
	Inefficiencies in Last Mile distribution (often related to delayed processing and distribution of stock from warehouse to facilities.)	Delayed TLD deliveries due to COVID related global supply chain disruptions
Data visibility	Data reporting challenges leading to inadequate tracking of transition rate	

Other ONGOING and UPCOMING TRANSITIONS

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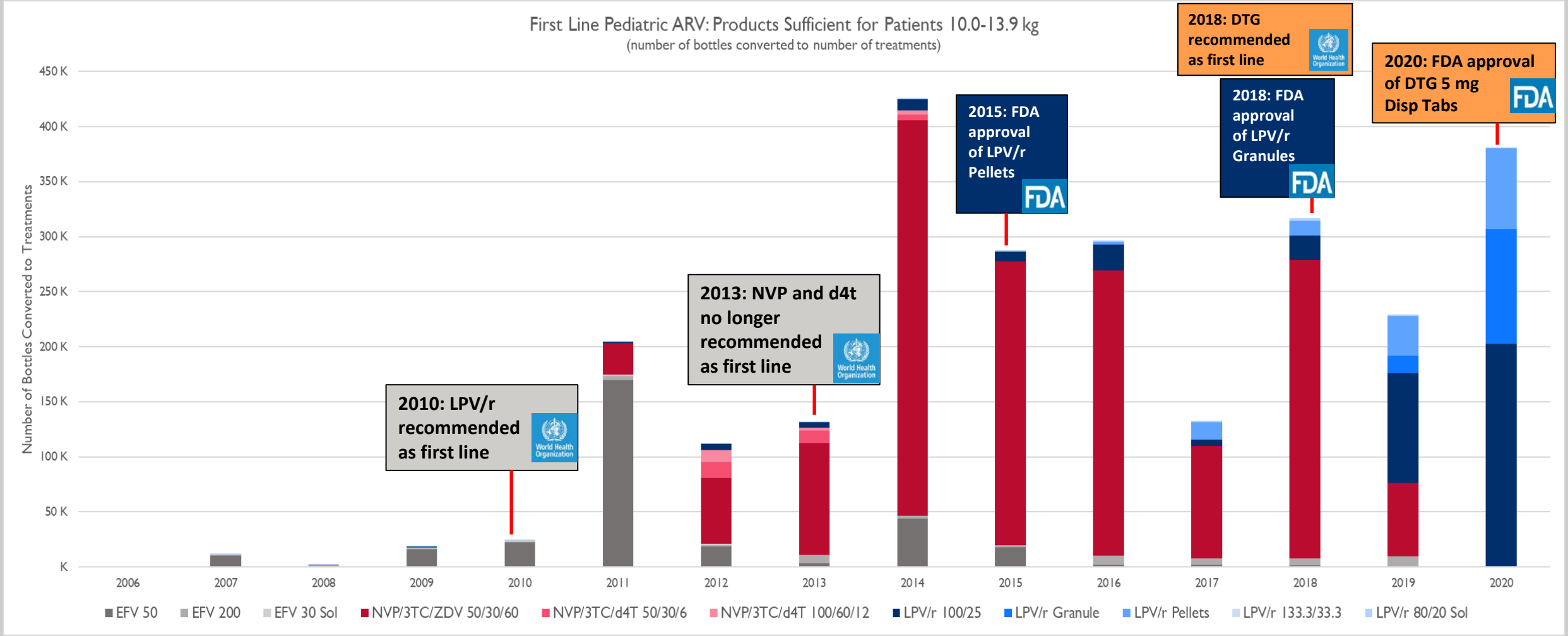
Pace and Magnitude of Pediatric ARV Transitions



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

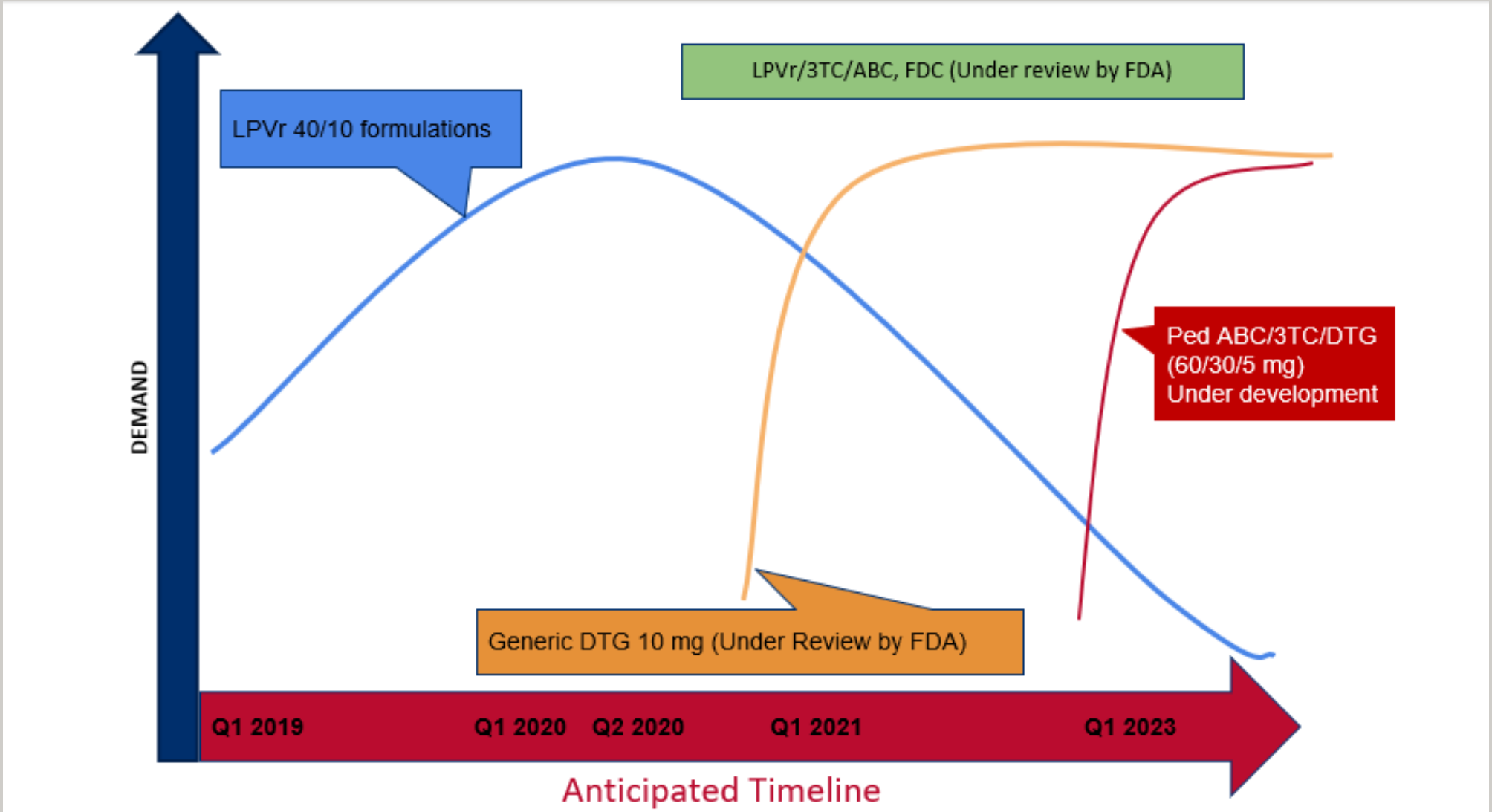
- As new pediatric DTG dosing recommendations and pediatric DTG formulations become available (DTG 5 mg dispersible tablet (DT) and **DTG 10 mg scored** DT), **these should be promptly taken up by programs** and made available to younger and smaller children

https://www.state.gov/pepfar-cop-20-plan-guidance-public-comment

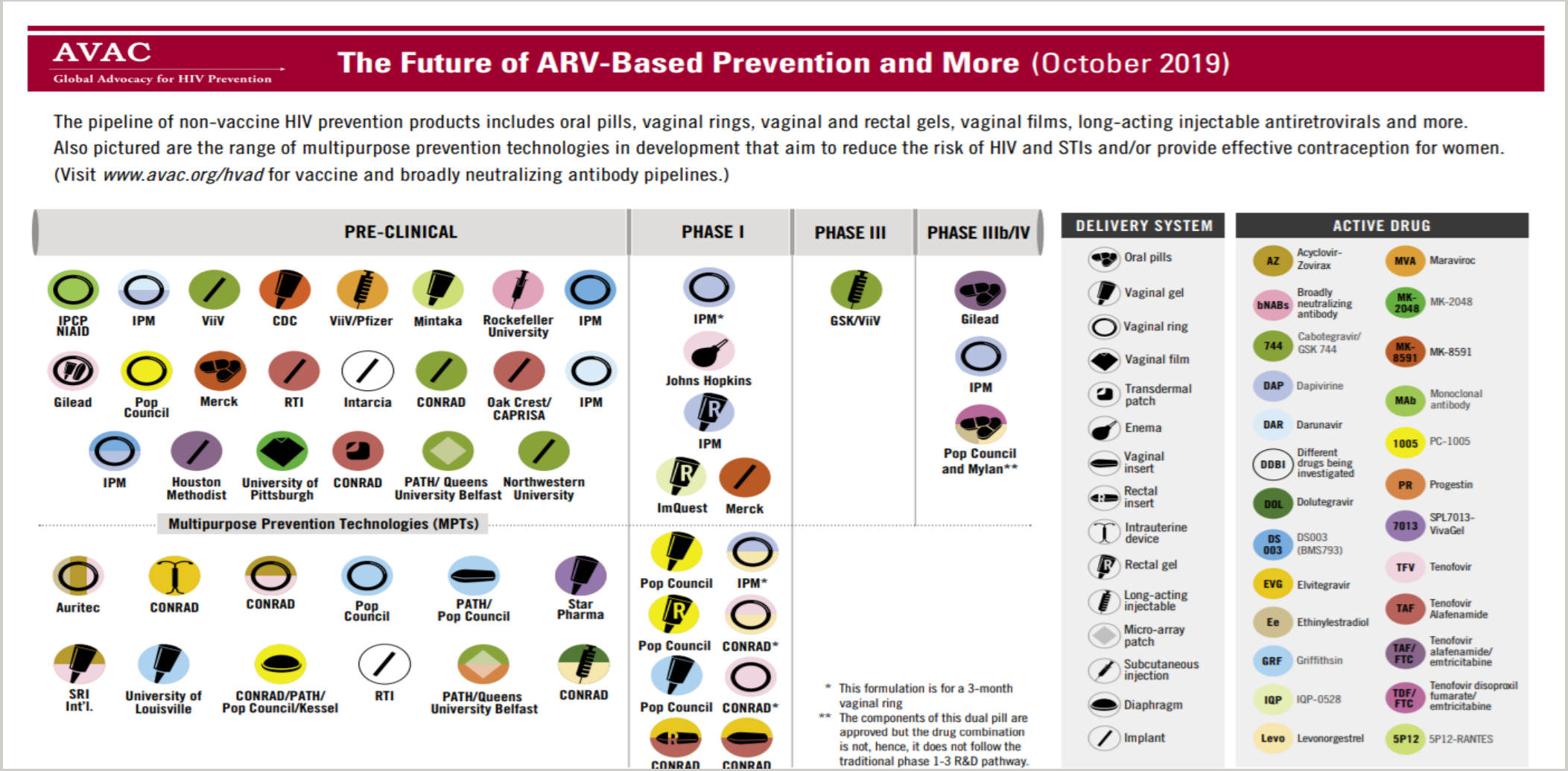
PED ART VIDEO

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



PrEP



https://www.avac.org/sites/default/files/infographics/AVAC4301D_ARVpipeline_R11.pdf

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?

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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

Transitions for PLHIV undertaken by Ministry of Health-Uganda

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."

Most Read Most Commented

Princess Katrina-Sarah Ssangalyambogo engaged?
08 October 2020

Uganda is now open to the world, says Museveni
06 October 2020

Uganda's Cheptegei breaks 10,000m track world record
07 October 2020

Law firm disowns lawyer in Kibalama case
04 October 2020

MP Nsereko sued over sh2.9b botched land deal
04 October 2020

TODAY'S PAPER

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 in to 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

Daily Monitor NEWS BUSINESS OPED SPECIAL REPORTS MAGAZINES SPORTS

"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.

COVID-19 Pandemic

Ugandan HIV-Positive Volunteer Goes Distance to Deliver ARVs

By Halima Athumani
April 27, 2020 01:57 PM

Trump Holds Large White House Event After COVID-19 Hospitalization

Europe Confronted With Second Coronavirus Outbreak

Series of Failures Keeps Coronavirus Spreading in US, Experts Say

US News | Press Freedom | VOA News on Iran | COVID-19 Pandemic | Editorials

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 o 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-

Stock Out of ARVs

The Observer

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 Basudde 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.

No	Challenges	Mitigation Measures
8	Screening for DTG eligibility (Pregnant women, women of reproductive age, HIV/TB, Children) - Training, Tools	Within a year, new recommendations released to guide use DTG in other groups (Pregnant women, HIV/TB, Children)
2	Tagging use of DTG to other program areas (access to family planning services)	With support from IPs access to FP products has increased
3	Use of DTG in aging population and mature programs - Increasing risk of NCDs	MOH/NDA strengthen pharmacovillance and ADR reporting
4	Adverse events (Hyperglycaemia, Erectile dysfunction) - INH/DTG co-administration (Liver injuries) - Glucose strips	MOH/NDA strengthen pharmacovillance and ADR reporting Delayed introduction of INH by 3 months
5	Accelerated transition against limited stock causing stock outs	Phased transition by level of care against pre determined rx targets,

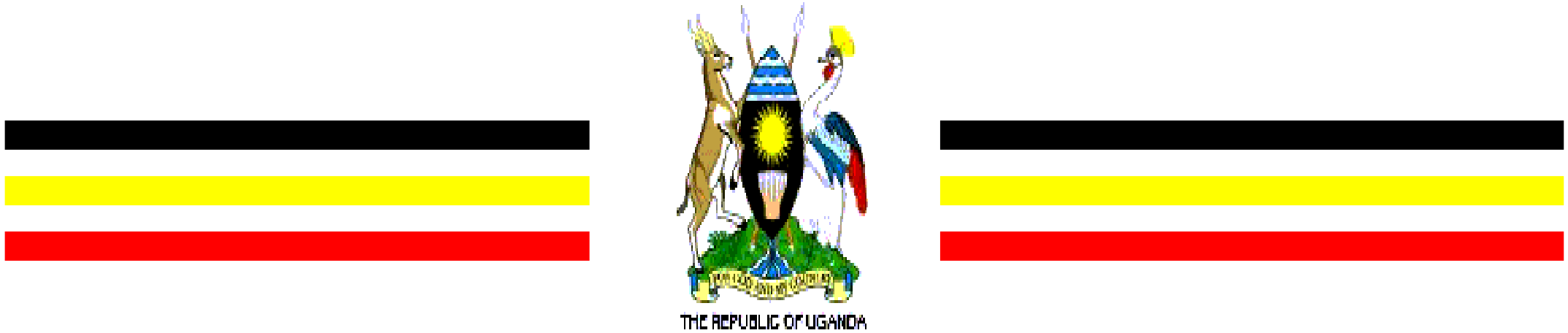
No	Challenges	Mitigation Measures
6	Wastage of Legacy regimens	Where possible cancellation of pipeline, redistribution , mop up of stock.
8	Manufacturers preparedness (Wastage of API for NVP, EFV, AZT/3TC for both adults and children	
1	Knowledge gaps among health care workers	Routine mentorship and coaching Scenario-based short SOPs
2	Multi Month Drug refills of legacy regimen due to COVID	Line listing, use of ART optimization stickers, called back children, motorcycle rider or health worker drug deliveries
3	VL testing; missed opportunities, overdue for testing or dropping off the IAC cascade	National pediatric CQI Line listing, VL camps, phone or home IAC,
4	Poor administration of medicines by caregivers	Dispensing messages for health care workers & a caregiver literacy material developed
	Stakeholder Management	

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-maleficience
   - ⇒ 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

Background

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

Phase 1	• Started in July 2019 • Involving all Health facilities in NMS Zones 4 and 5
Phase 2	• Started in May 2020 • PNFP health facilities in all the regions
Phase 3	• Planned to start in Oct 2020 • Involving the rest of the Public health facilities (In Zones 1,2&3)

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

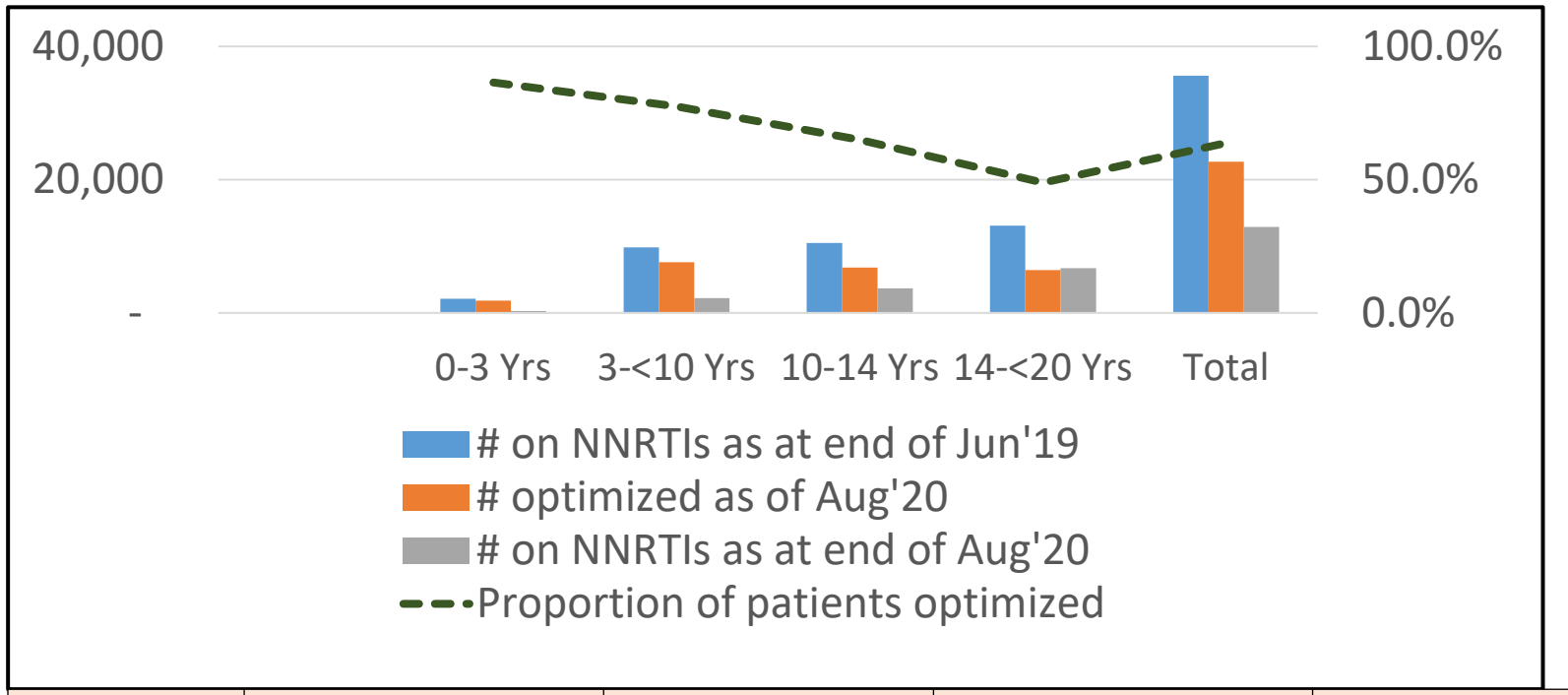
- **Check-list** was used to identify eligible children for optimization at the health facilities

- 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

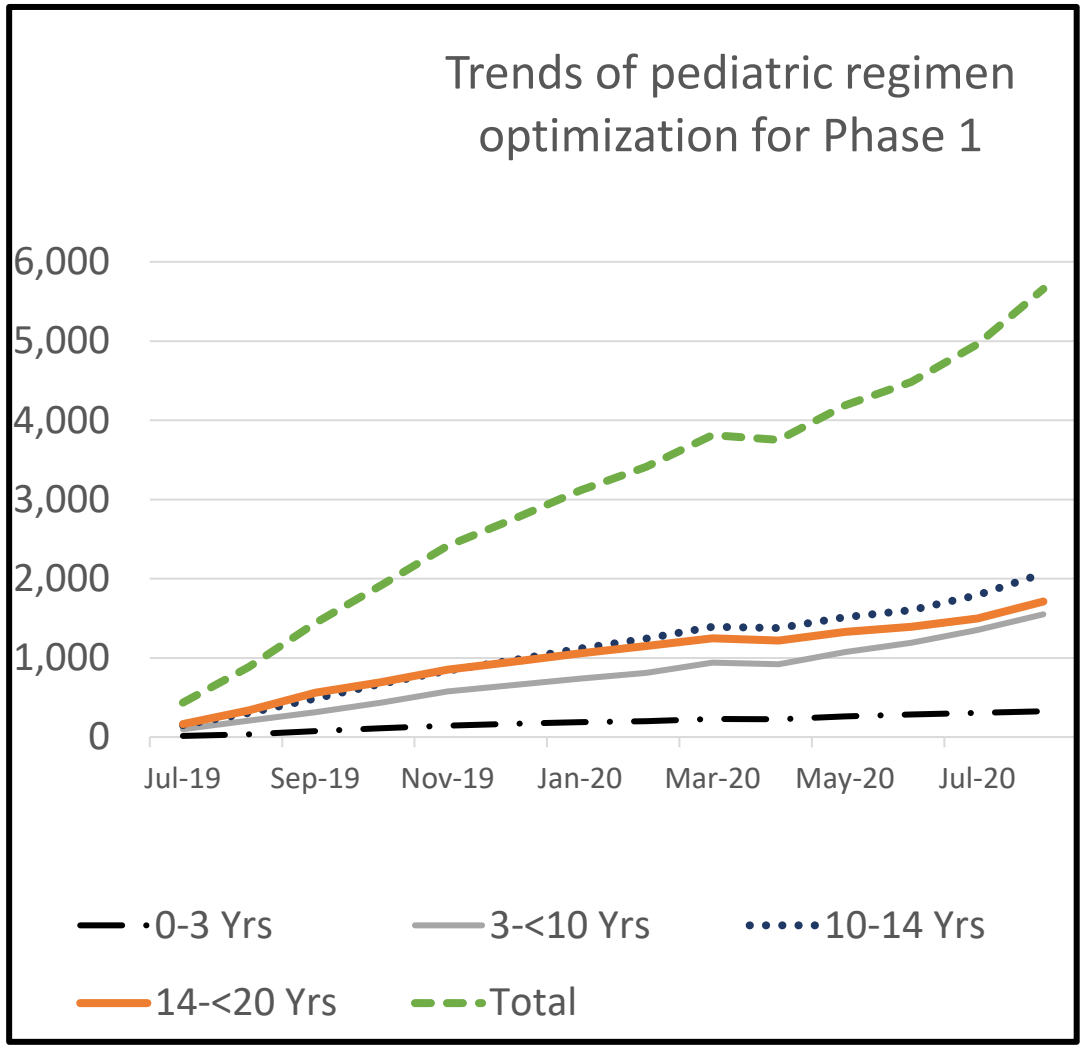
Status of pediatric regimen optimization as at end of Aug'20

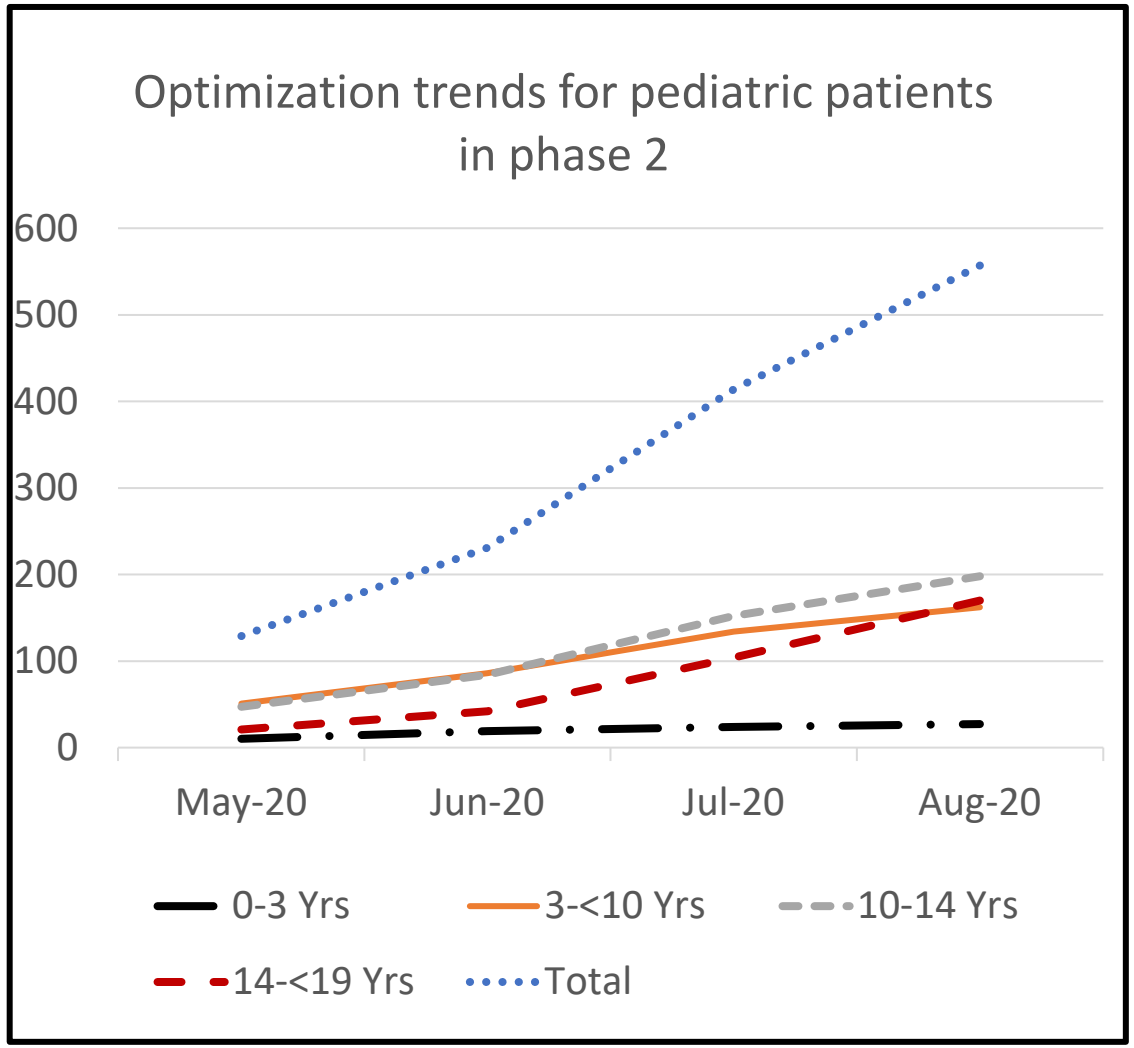


Age Category	# on NNRTIs as at end of Jun'19	# optimized as of Aug'20	# on NNRTIs as at end of Aug,20	Proportion of pts optimized
0-3 Yrs	2,102	1,818	284	86%
3-<10 Yrs	9,849	7,629	2,220	77%
10-14 Yrs	10,497	6,818	3,679	65%
14-<20 Yrs	13,114	6,416	6,698	49%
Total	**35,590**	**22,681**	**12,909**	**64%**

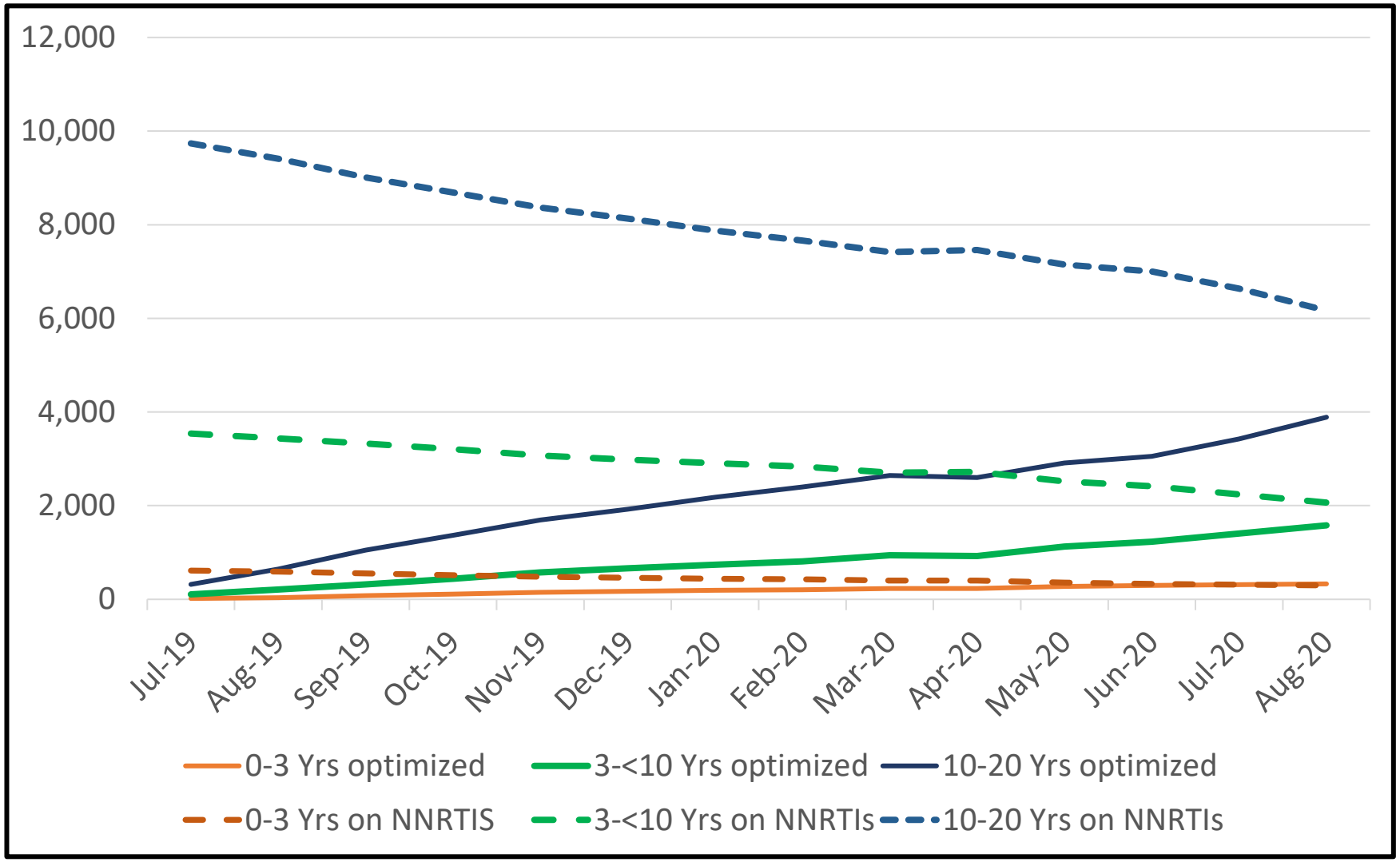
64% of the **paediatric** patients optimized to either DTG or LPV/r based regimen.

Trends of pediatric regimen optimization for phase 1&2





Pediatric patients on NNRTIs and those optimized for phase 1&2



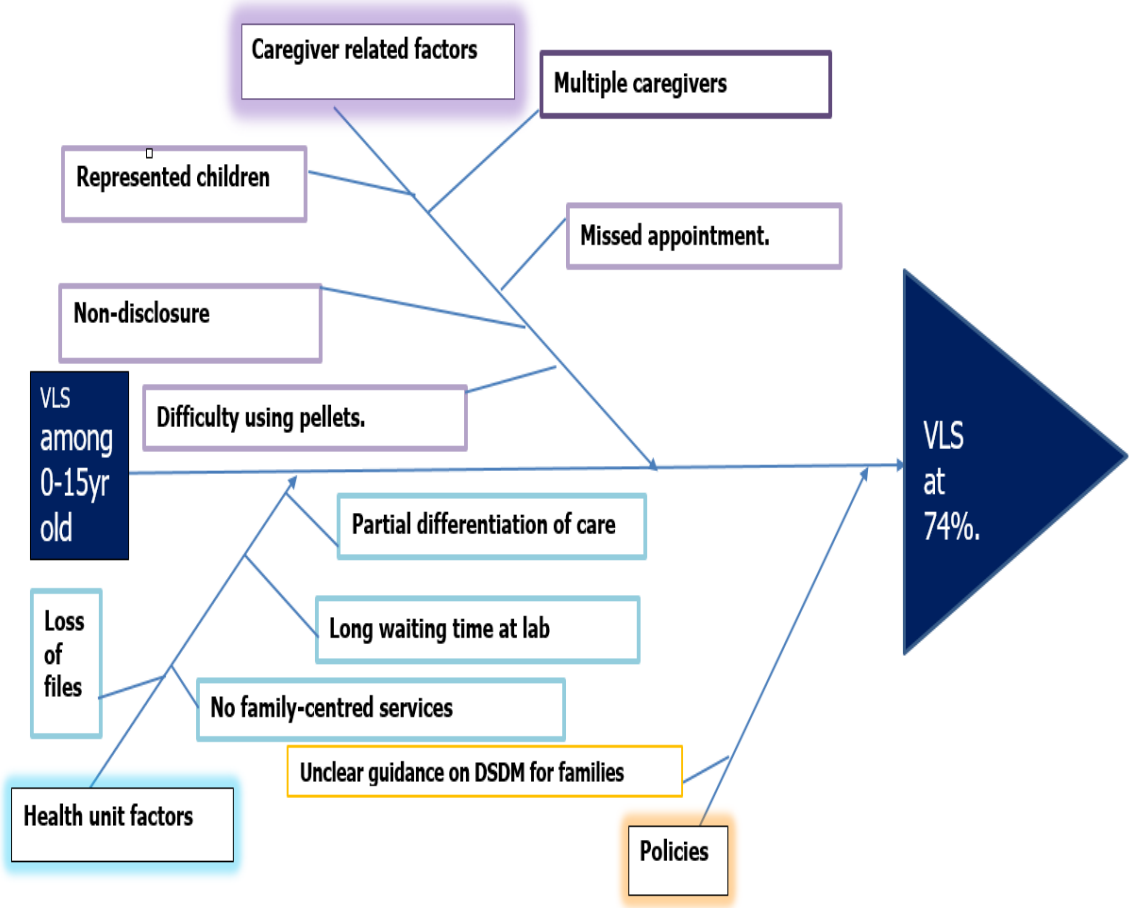
22,681 (64%) children optimized to DTG and LPV/r regimens as at the end of Aug'20.
Children in the age group 10-15 years on NNRTI's to be optimized to TLD following roll out of the 2020 HIV guidelines

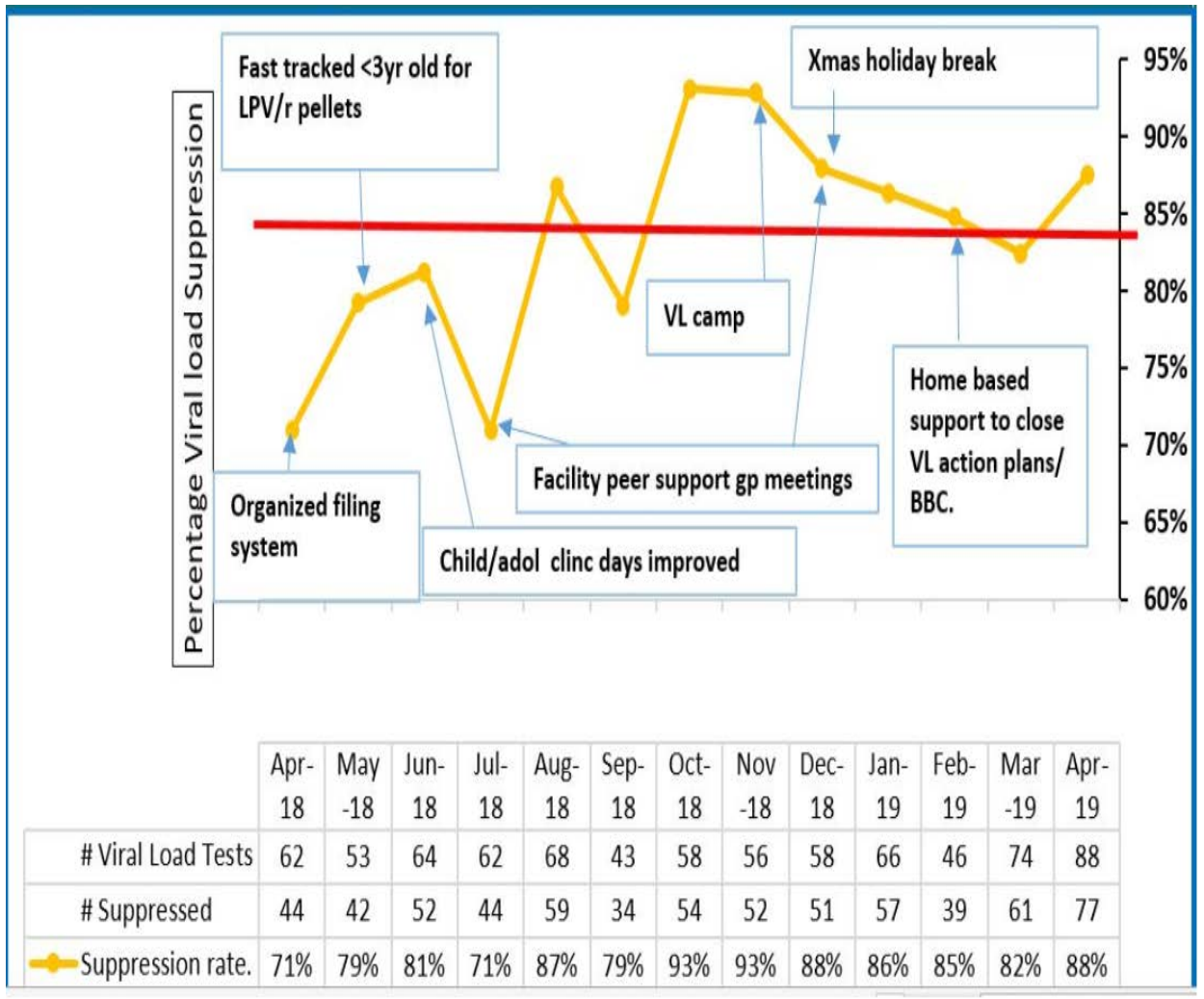
Barriers and Mitigating strategies

	Challenges	Mitigation strategies
1	Inadequate stock of optimal regimens	Phased implementation Stock redistribution by sub-national partners
2	Knowledge gaps among health care workers	Routine mentorship and coaching Scenario-based short SOPs
3	Multi Month Drug refills of legacy regimen due to COVID	Line listing, use of ART optimization stickers, called back children, motorcycle rider or health worker drug deliveries
4	VL testing; missed opportunities, overdue for testing or dropping off the IAC cascade	National pediatric CQI Line listing, VL camps, phone or home IAC,
5	Poor administration of medicines by caregivers	Dispensing messages for health care workers & a caregiver literacy material developed

CQI ON VL AT FPRRH

FIGURE2: FISH BONE ANALYSIS OF THE ROOT CAUSES OF SUBOPTIMAL VIRAL LOAD UPTAKE AT FPRRH IN MARCH 2018.





	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19
# Viral Load Tests	62	53	64	62	68	43	58	56	58	66	46	74	88
# Suppressed	44	42	52	44	59	34	54	52	51	57	39	61	77
Suppression rate.	71%	79%	81%	71%	87%	79%	93%	93%	88%	86%	85%	82%	88%

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

Children's Foundation

BIPAI Baylor International Pediatric AIDS Initiative

BCM Baylor College of Medicine

Texas Children's Hospital

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

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PEPFAR

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health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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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?

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Overcoming Barriers to Importation

INTEGRATE. UPDATE. EVOLVE.

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)

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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

OCEAN

- Reefer container shortages at various locations
- Vessels quarantined at various destination ports
- Carrier blanking and capacity adjustments will continue in Q3

AIR

- Cancellation of passenger flights significantly impacted capacity
- Rates were extremely volatile and went up by as much as 400%
- Flight operators optimized capacity to ensure viability

TRUCK

- Continental and in-country border regulations and movement restrictions– testing, quarantines, lock-downs
- Driver concerns and availability
- Intra-India restrictions impacted availability of drivers and trucks and/or their movement

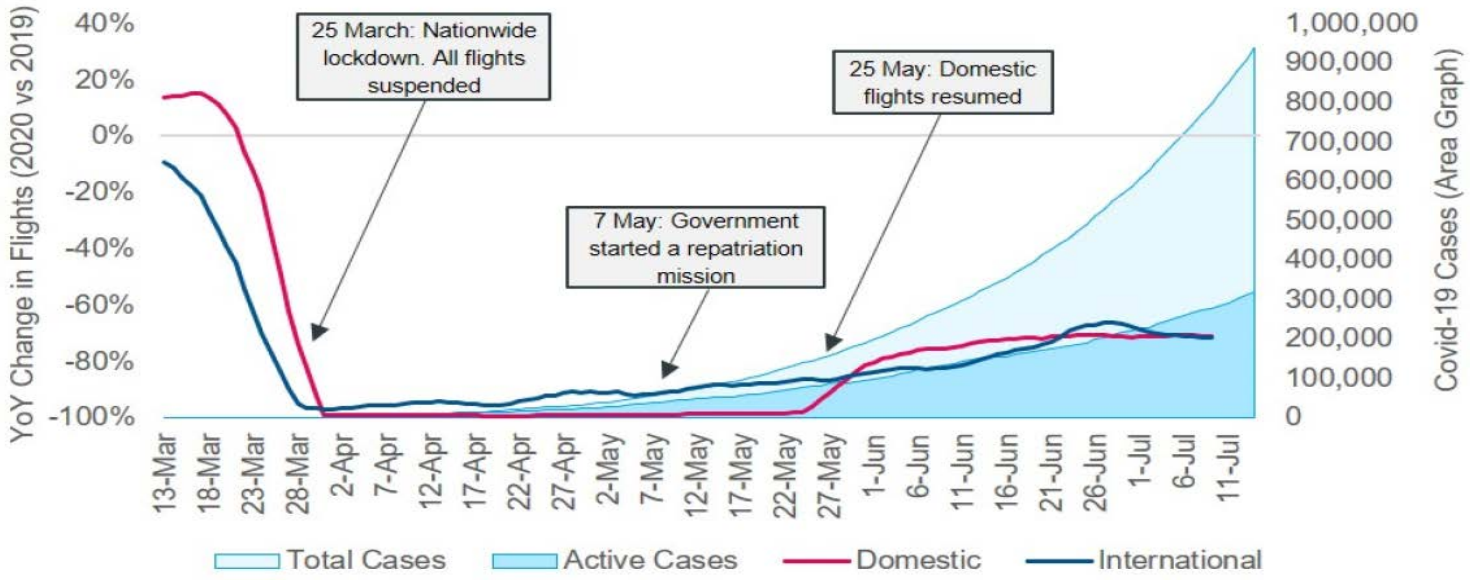
ALL TRANSPORT

- Transit, port of entry, and government staffing constraints resulting in severe congestion, as well as customs clearance, inspection, and waiver delays

Logistics activities were constrained significantly at both origin and destination over the duration of the pandemic

DELAYS AT UGANDAN BORDER

Loss of air capacity out of India



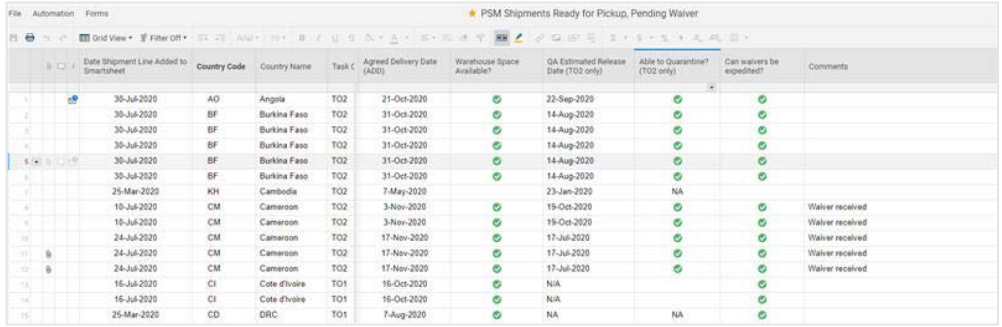
Data source: https://www.flightradar24.com/blog/indian-aviation-the-road-ahead/

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.

Country	Country Clearance Risk	Logistics Risk	# PO / Lines	Truck Imports	# PO / Lines	Air Imports	# PO / Lines	Ocean Imports
CD	3	3		N/A	77 ↑	Limited flights ex. EU / IN	98 ↑	Customs delay
MZ	2	2	8 =	Open	1 =	Limited flights	25 ↑	Open
NG	2	3		N/A	42 ↑	Charter + Freighter Flights	29 ↑	Port backlog
RW	1	2		Border clearance issues	18 ↓	Limited flights (freighters)	9 ↑	Open
TZ	3	2		N/A	7 ↓	Limited flights ex. EU / IN	32 ↓	Open
UG	2	2		Border clearance issues	12 ↓	Limited flights (freighters)	16 ↓	Open
ZM	2	3	4 =	Border clearance issues	26 ↑	Limited flights ex. EU / IN	11 ↑	Open



LOGISTICS AND CLEARANCE RISK ANALYSIS TOOL

Updated weekly based on input from 3PLs, country offices, market insights

LOGISTICS MILESTONE TRACKER

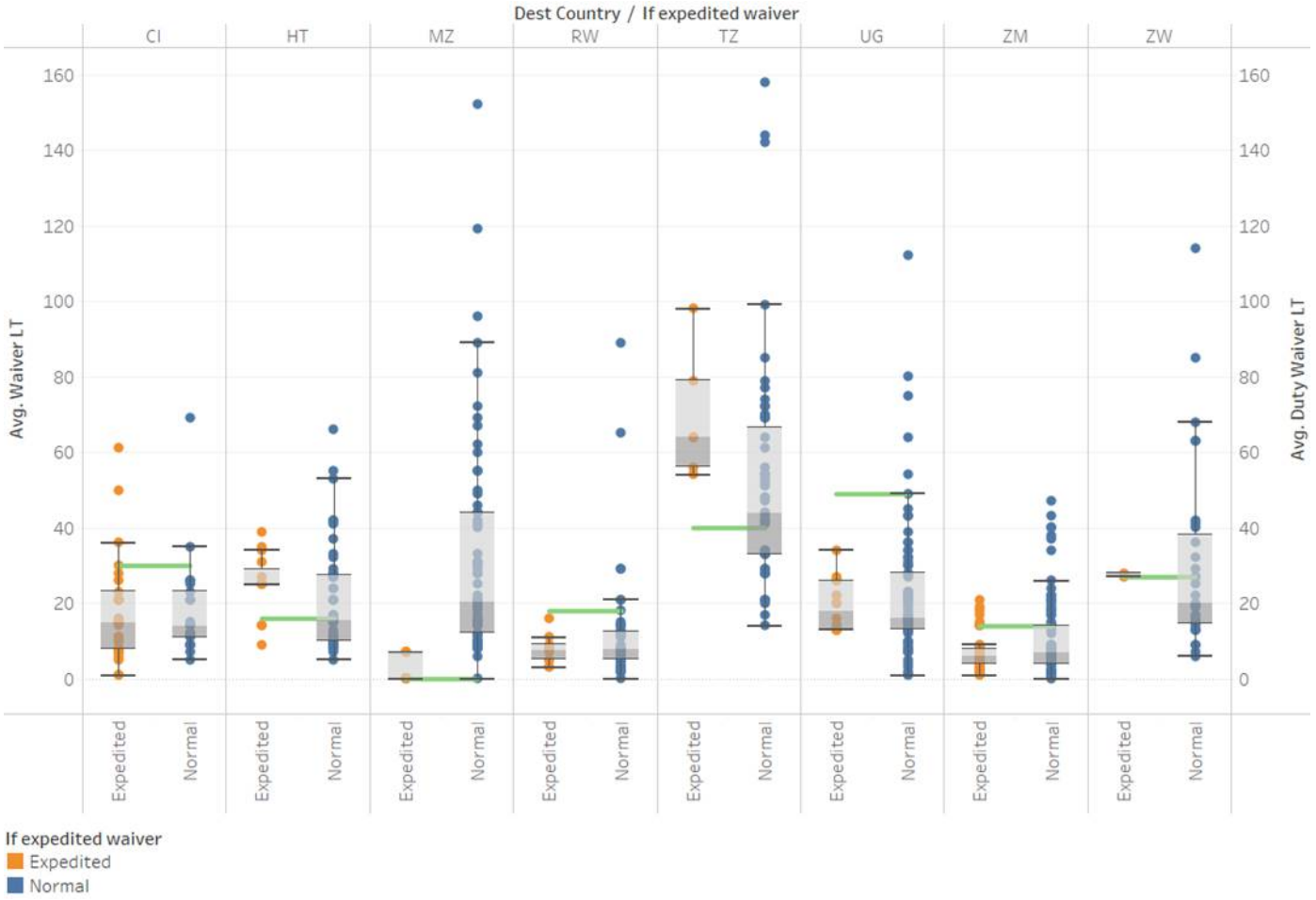
Updated weekly to identify hotspots across the logistics processes

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



Poll Question

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

Poll Question

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

Poll Question

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

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Shelf-life Recommendations for Importation of Health Commodities

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

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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

Maximum SL	75% RSL	80% RSL	85% RSL
24 months	18 months	19.2 months	20.4 months
36 months	27 months	28.8 months	30.6 months
48 months	36 months	38.4 months	40.8 months
60 months	45 months	48 months	51 months

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

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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
      - 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)

Maximum SL	75% RSL	80% RSL	85% RSL
24 months	18 months	19.2 months	20.4 months
36 months	27 months	28.8 months	30.6 months

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

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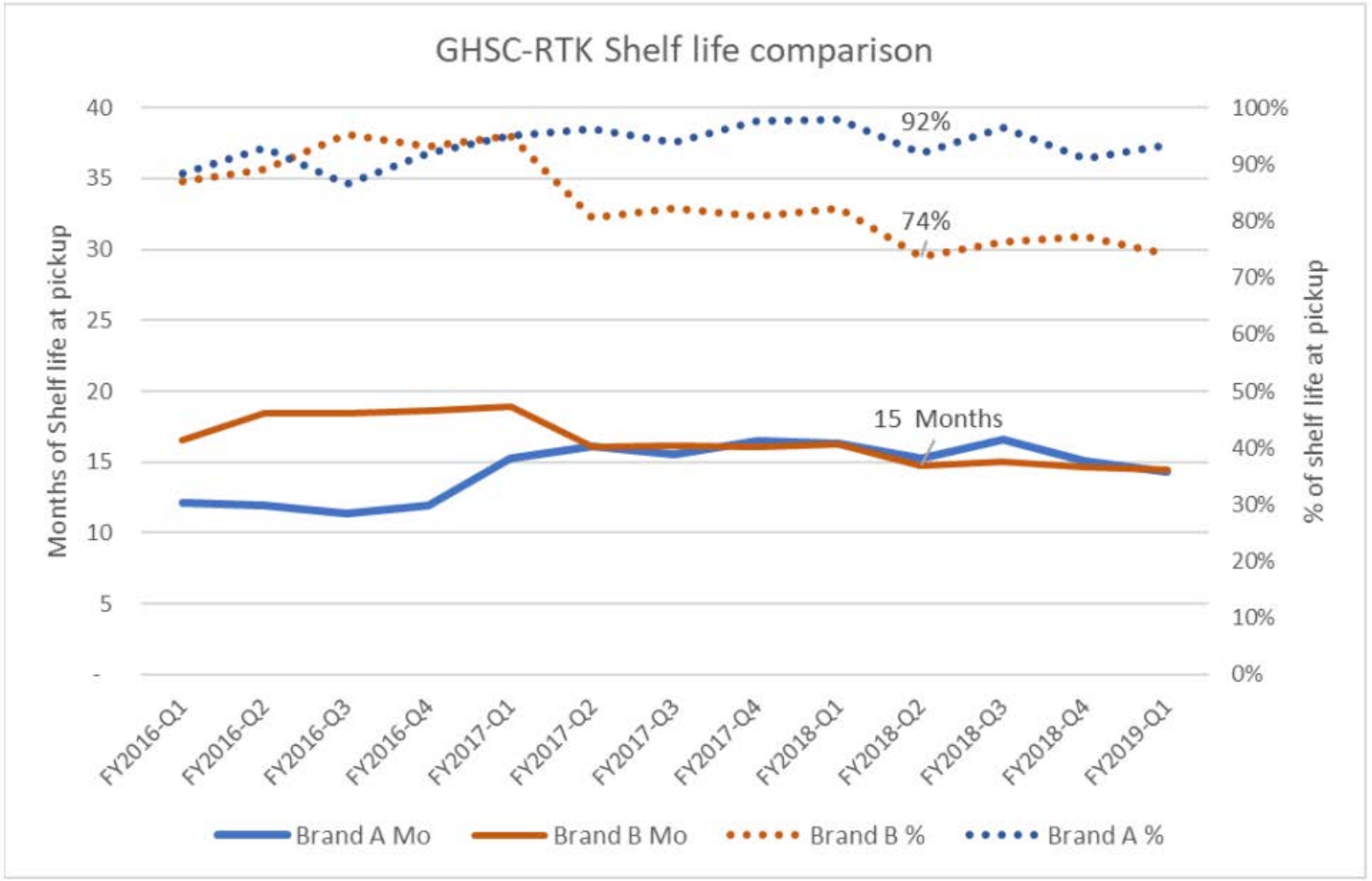
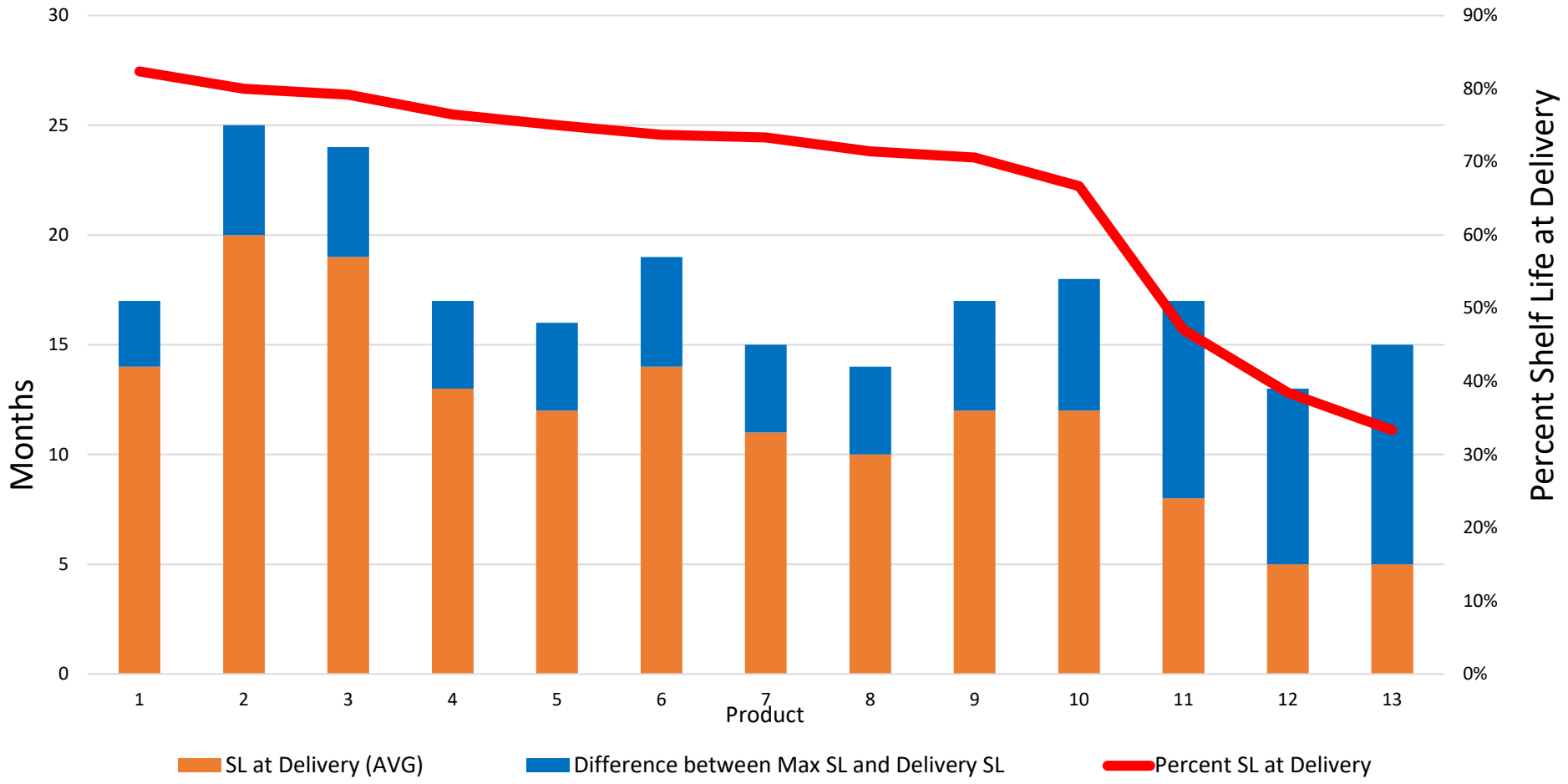
The need for flexibility in shelf life to incentivize introduction of products with longer shelf life



- Brand A" & "Brand B" are picked up from the manufacturer for shipment with 15 months SL
- "Brand A" = 92% RSL
- "Brand B" = 74% RSL

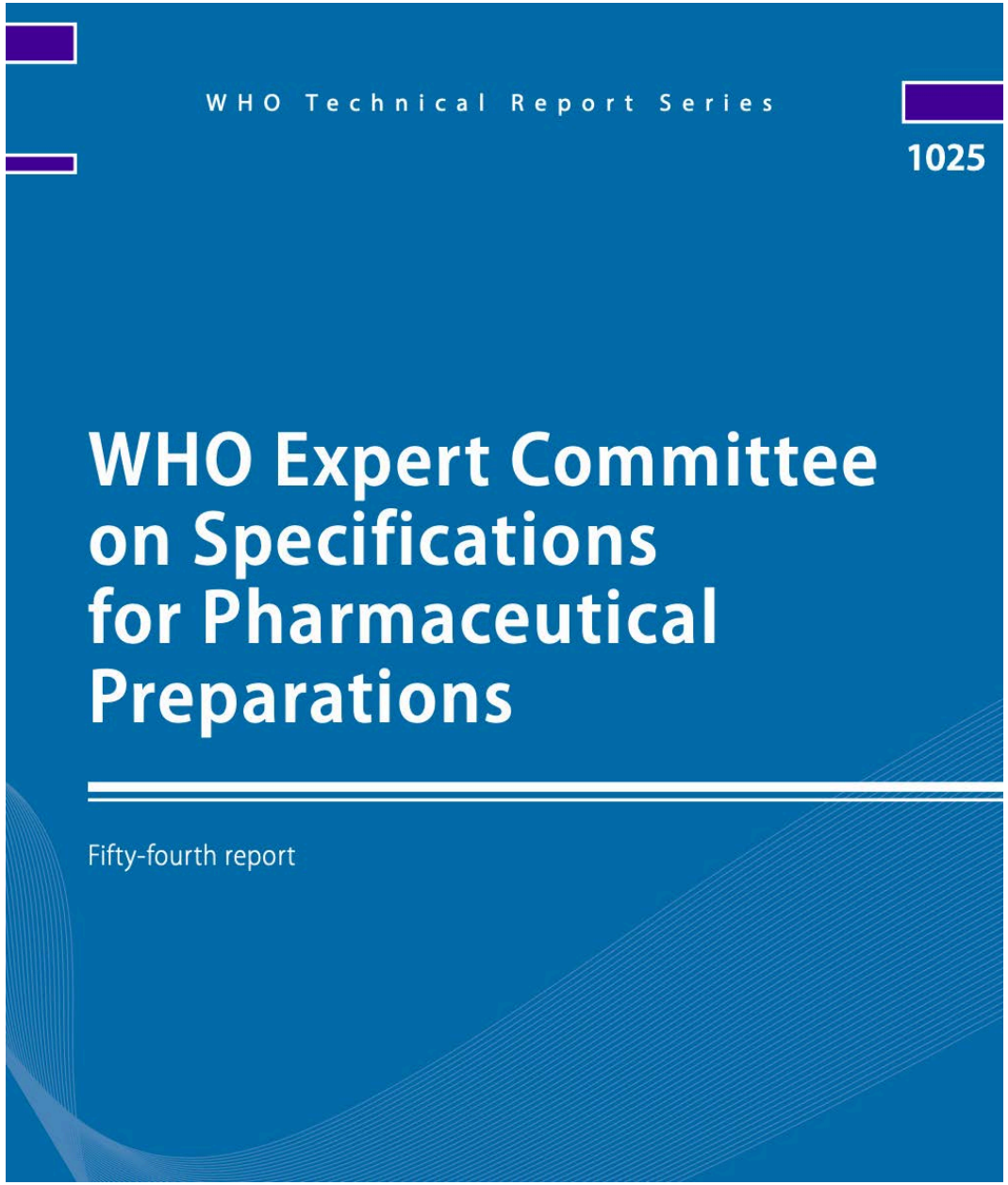
Source: GHSC-RTK Quarterly Report – FY2019-Q3

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

WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report (WHO Technical Report Series, no. 1025, Annex 8 available at: https://www.who.int/publications/i/item/978-92-4-000182-4

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)

WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report (WHO Technical Report Series, no. 1025, Annex 8 available at: https://www.who.int/publications/i/item/978-92-4-000182-4

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

WHO Expert Committee on Specifications for Pharmaceutical Preparations: fifty-fourth report (WHO Technical Report Series, no. 1025, Annex 8 available at: https://www.who.int/publications/i/item/978-92-4-000182-4

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

Total shelf-life (TSL)	RSL at time of dispatch from manufacturer's premises	RSL at time of delivery at port of entry of country	RSL at time of delivery at end-user level
48 months < TSL ≤ 60 months	40 months	30 months	12 months
36 months < TSL ≤ 48 months	30 months	24 months	12 months
24 months < TSL ≤ 36 months	20 months	15 months	6 months
12 < TSL ≤ 24 months	9 months	7 months	3 months
TSL ≤ 12 months	Special arrangements and conditions apply		

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)

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

Perspective from Uganda National Drug Authority

Perspective from Uganda NDA

NATIONAL DRUG AUTHORITY
Safe Drugs Save Lives

- 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

NATIONAL DRUG AUTHORITY
Safe Drugs Save Lives

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

Perspective from Uganda NDA

NATIONAL DRUG AUTHORITY
Safe Drugs Save Lives

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

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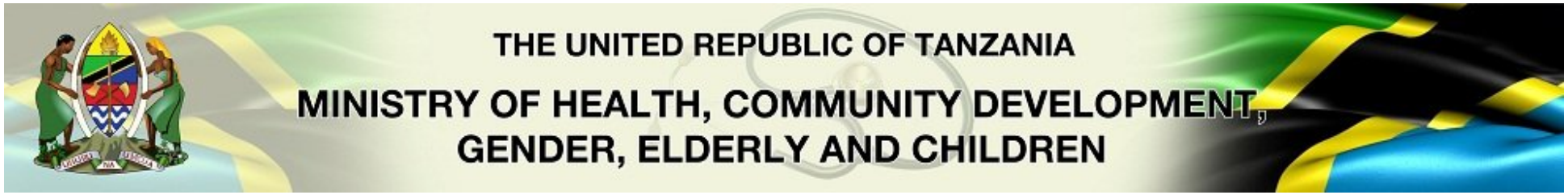
Ethiopian Food and Drug Authority

Perspective from Ethiopian Food and Drug Authority



Perspective from Tanzania Ministry of Health, Community Development, Gender, Elderly and Children

Poll Question

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

Poll Question

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

INTEGRATE. UPDATE. EVOLVE.

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**

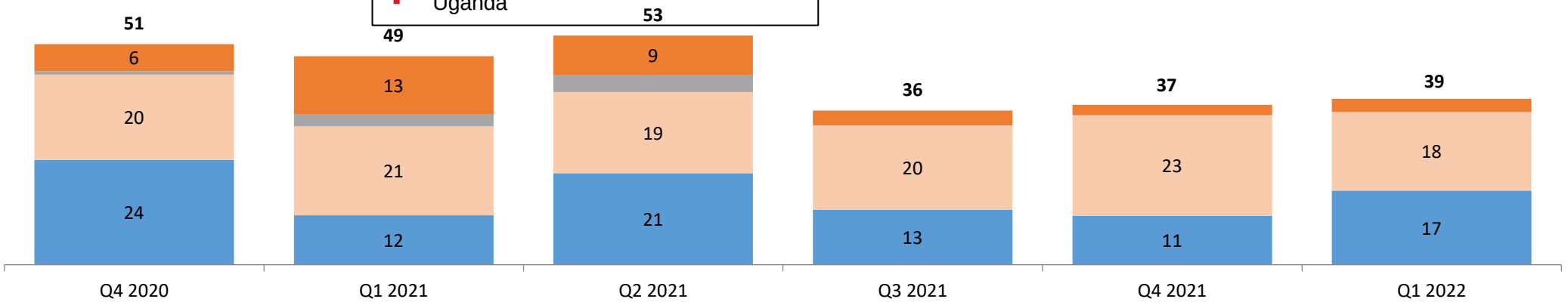
Total ARV Forecast

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 Arica
- Tanzania
- Uganda
- Zambia
- Zimbabwe

- 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



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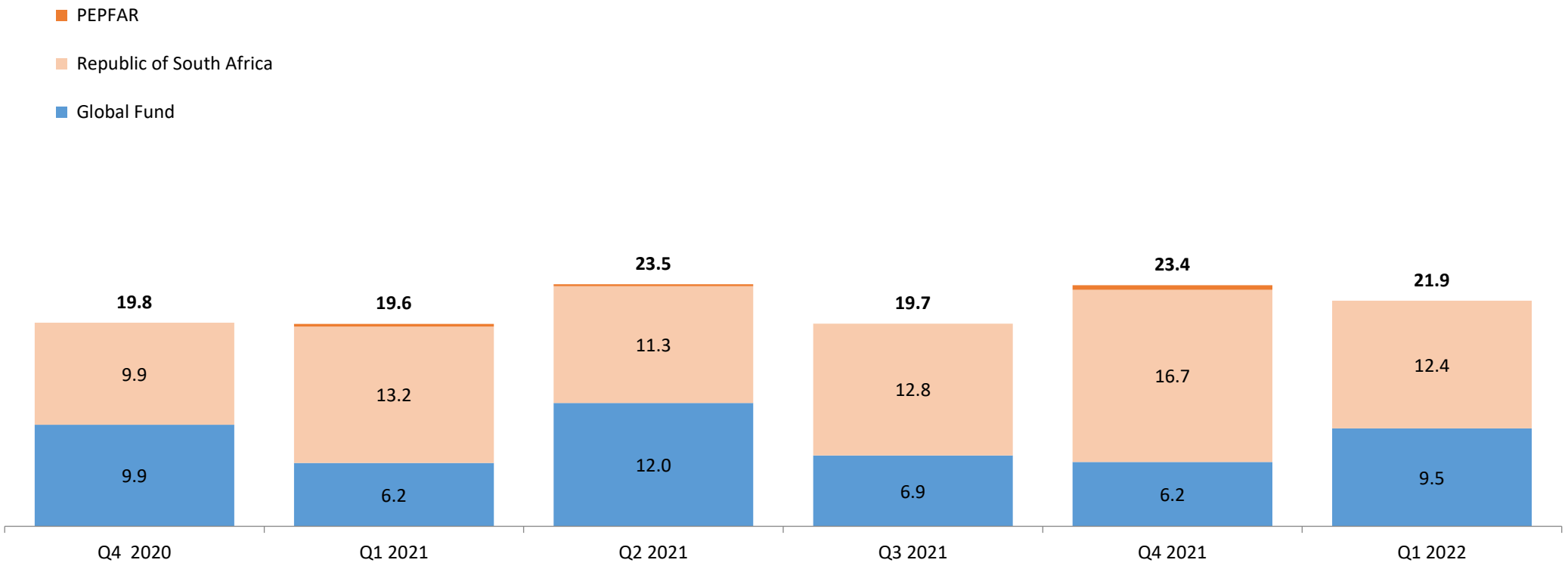
These slides contain a conservative estimate for demand management between the four programs. As such, there may be future volumes not yet financially committed or confirmed.

SOURCE: PEPFAR, Government of Kenya, The Global Fund, South Africa

TLD, 30 Tabs

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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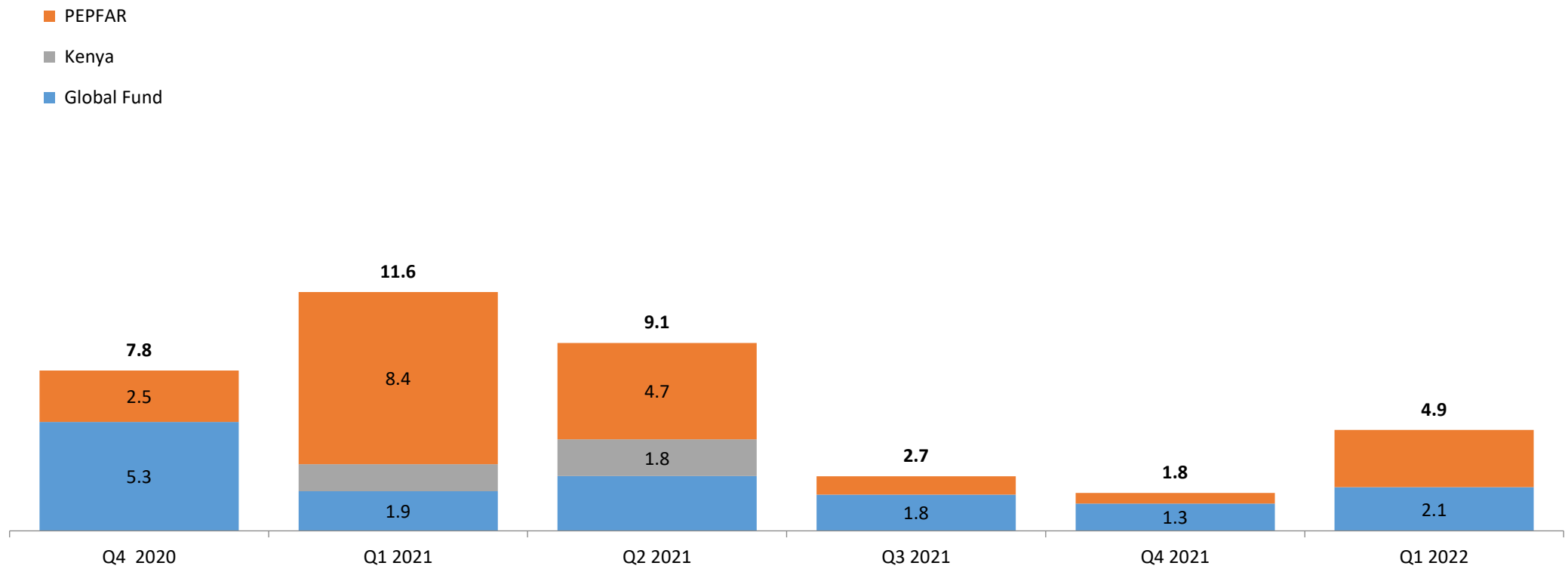
SOURCE: PEPFAR, Government of Kenya, The Global Fund, South Africa

TLD, 90 Tabs

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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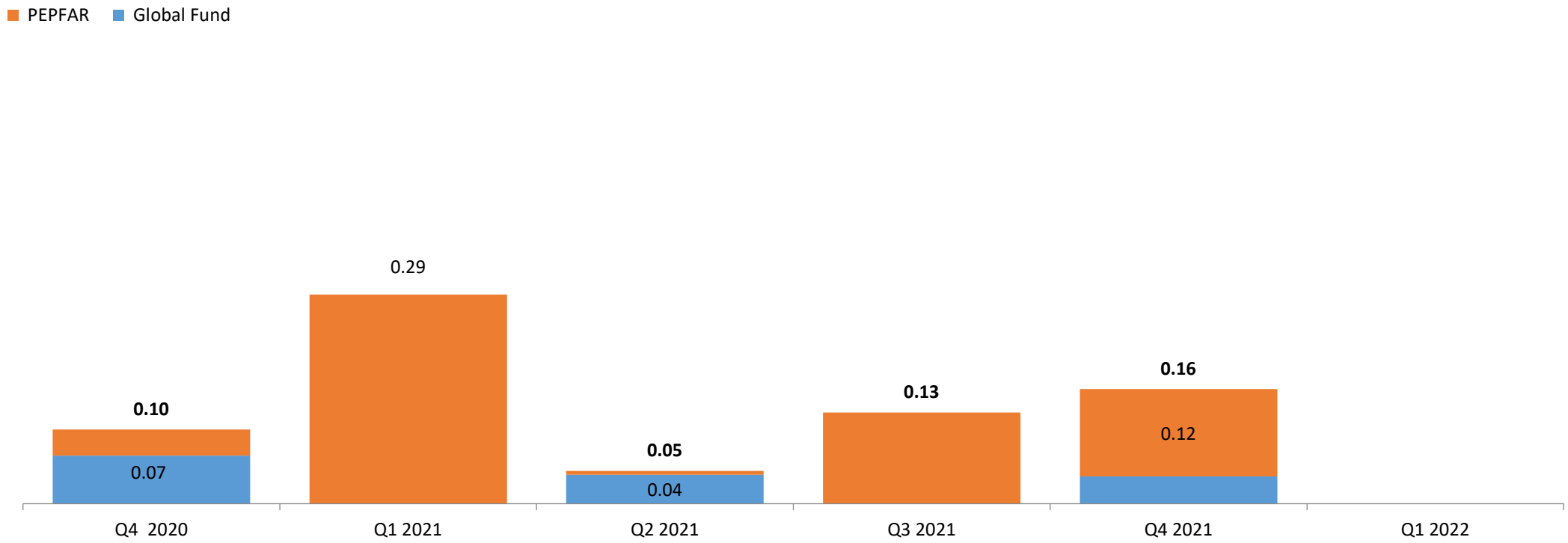
SOURCE: PEPFAR, Government of Kenya, The Global Fund, South Africa

TLD, 180 Tabs

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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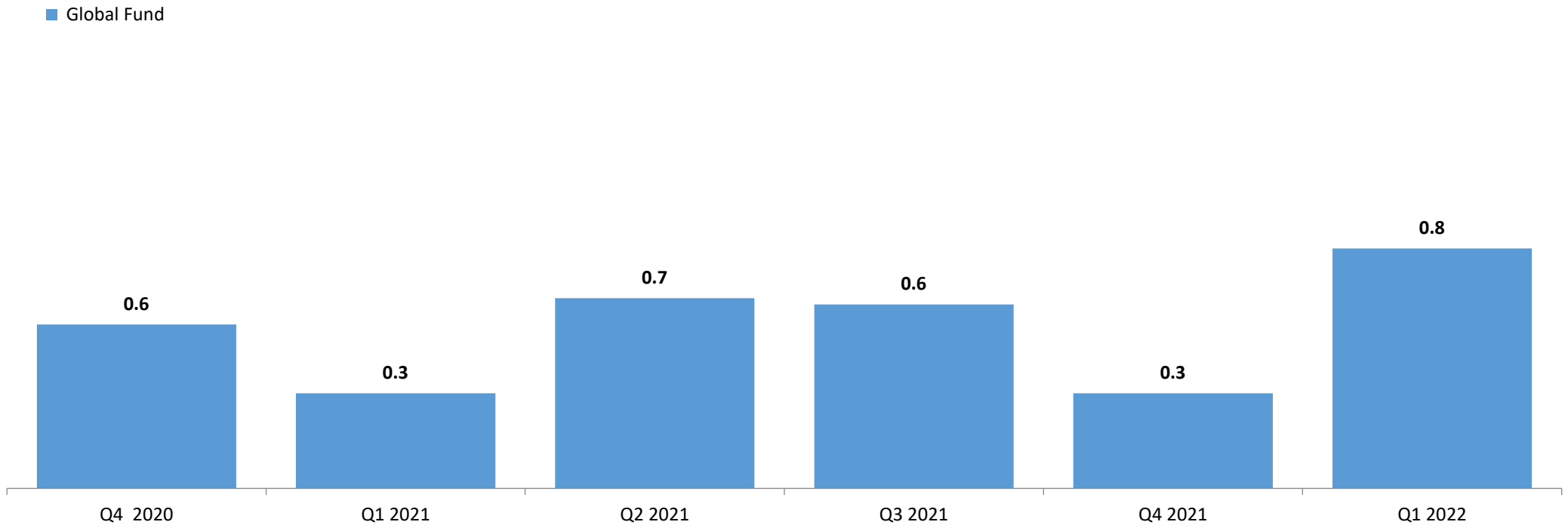
TLE 400, 30 Tabs

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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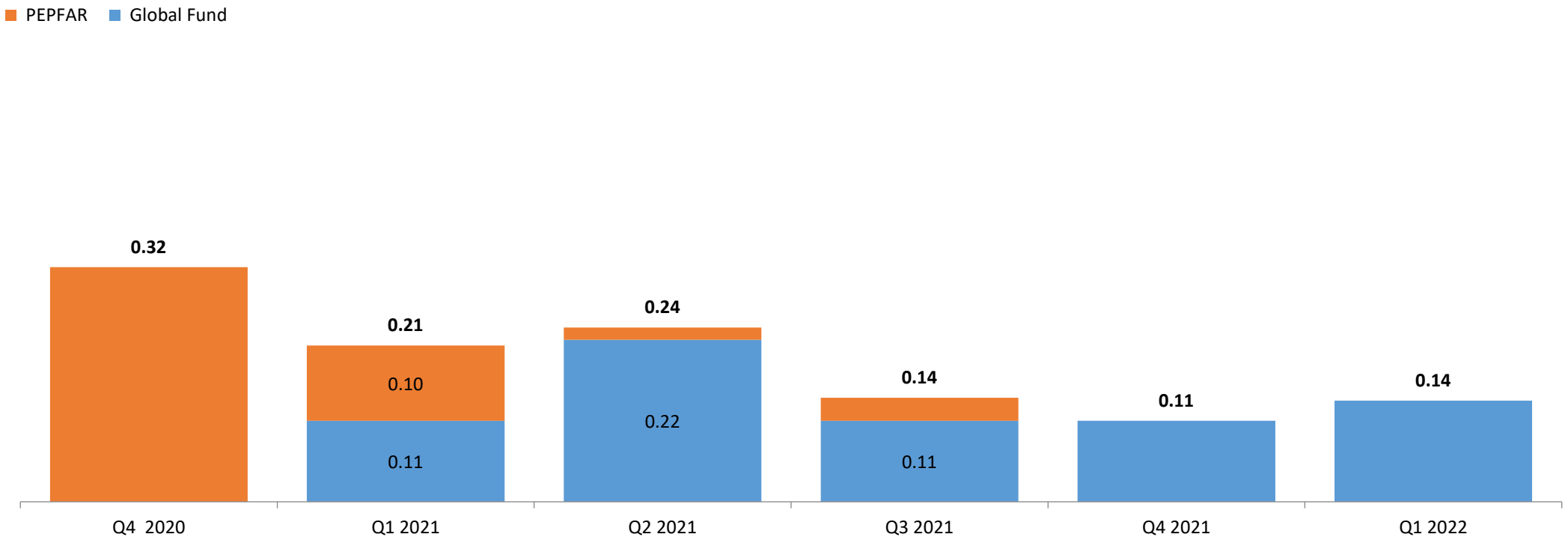
TLE 400, 90 Tabs

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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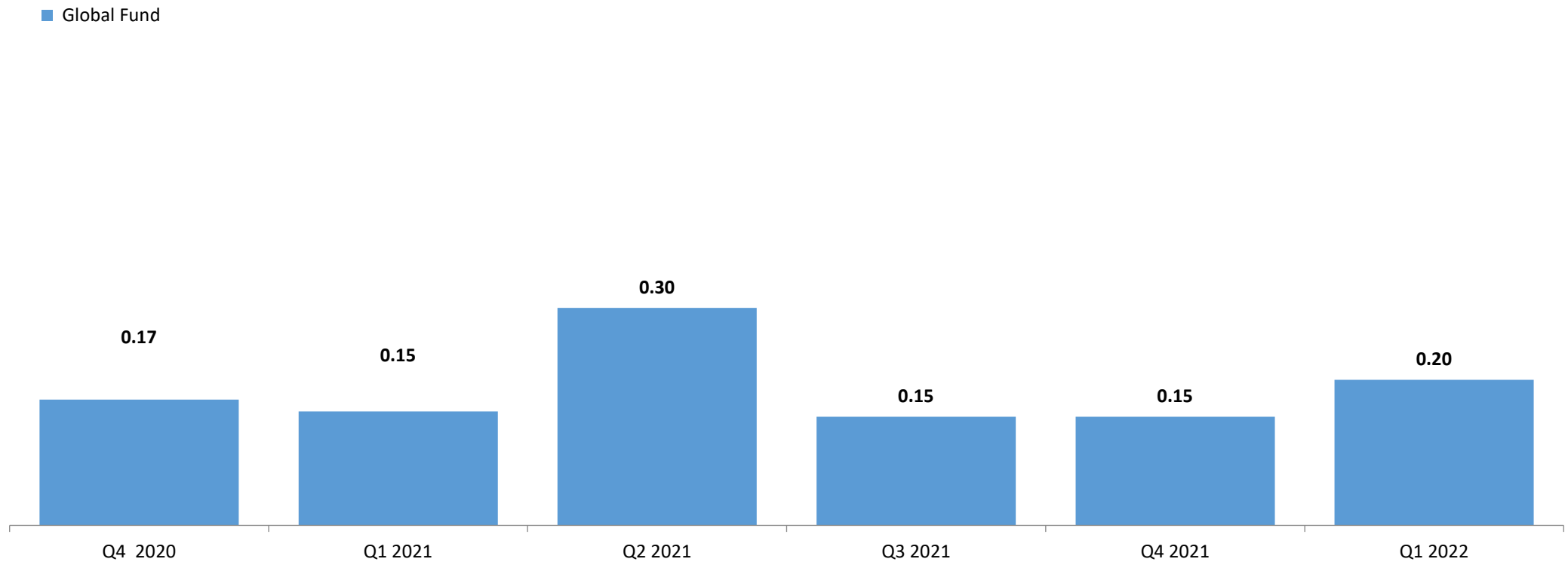
SOURCE: PEPFAR, Government of Kenya, The Global Fund, South Africa

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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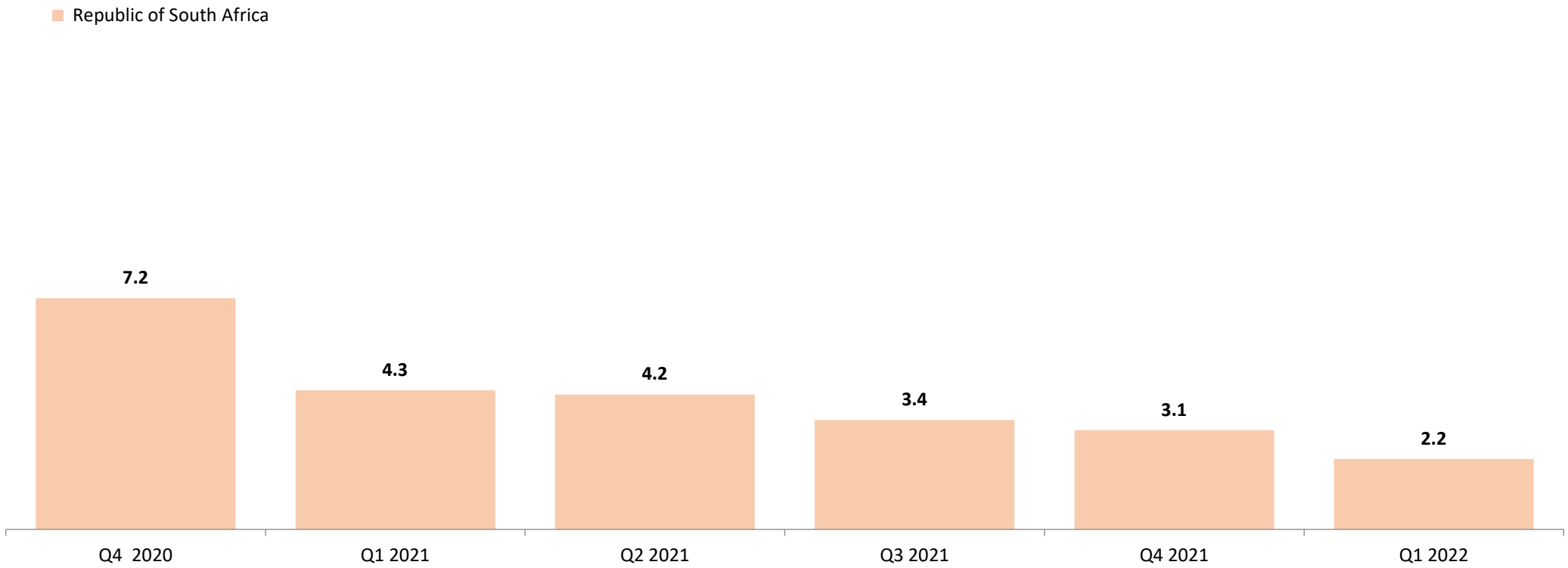
SOURCE: PEPFAR, Government of Kenya, The Global Fund, South Africa

TEE

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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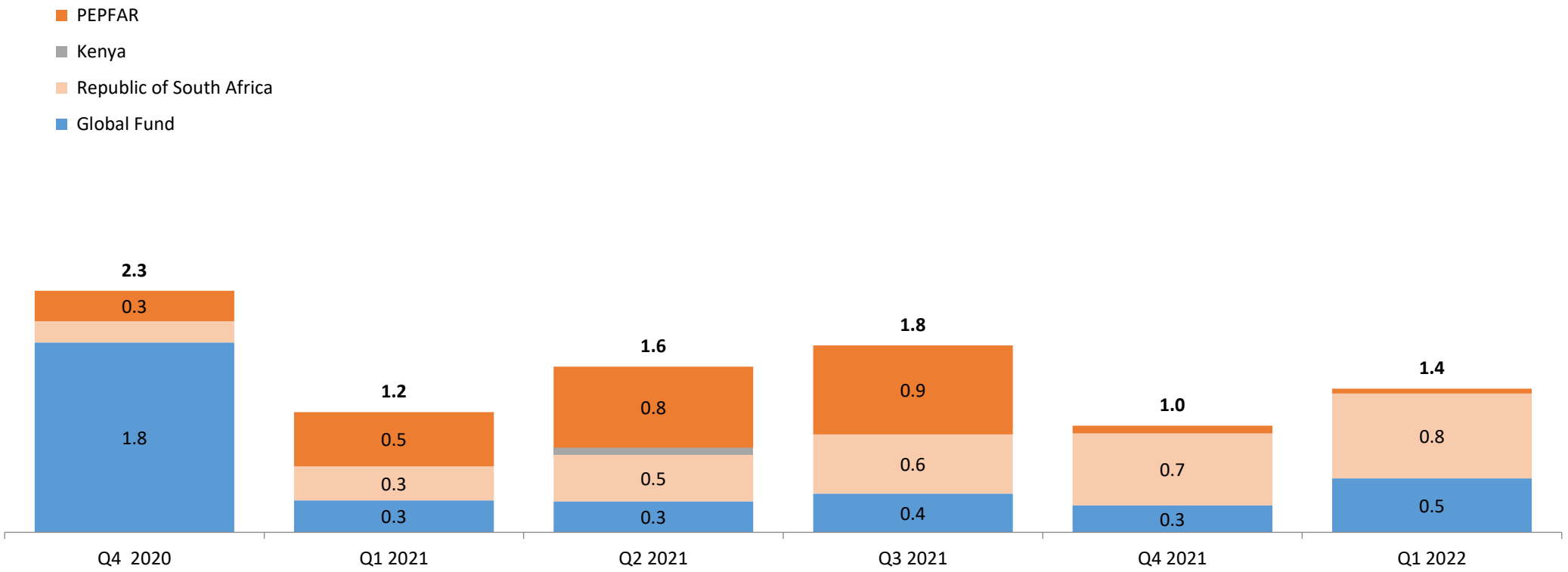
SOURCE: PEPFAR, Government of Kenya, The Global Fund, South Africa

DTG 50, 30 Tabs

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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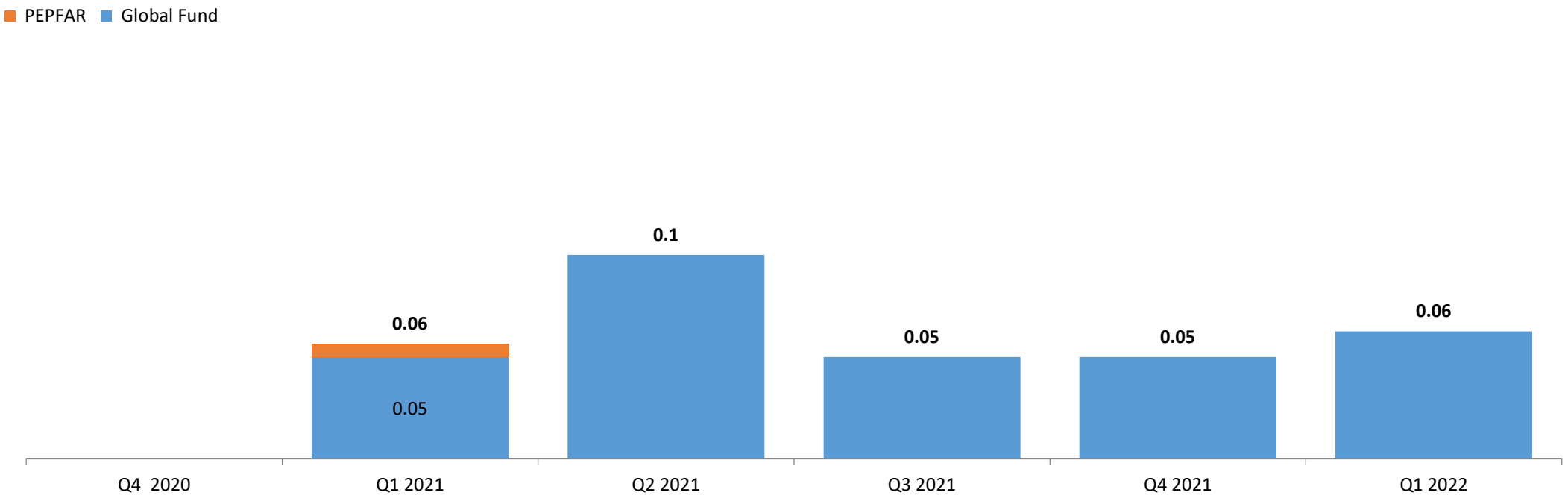
DTG 50, 90 Tabs

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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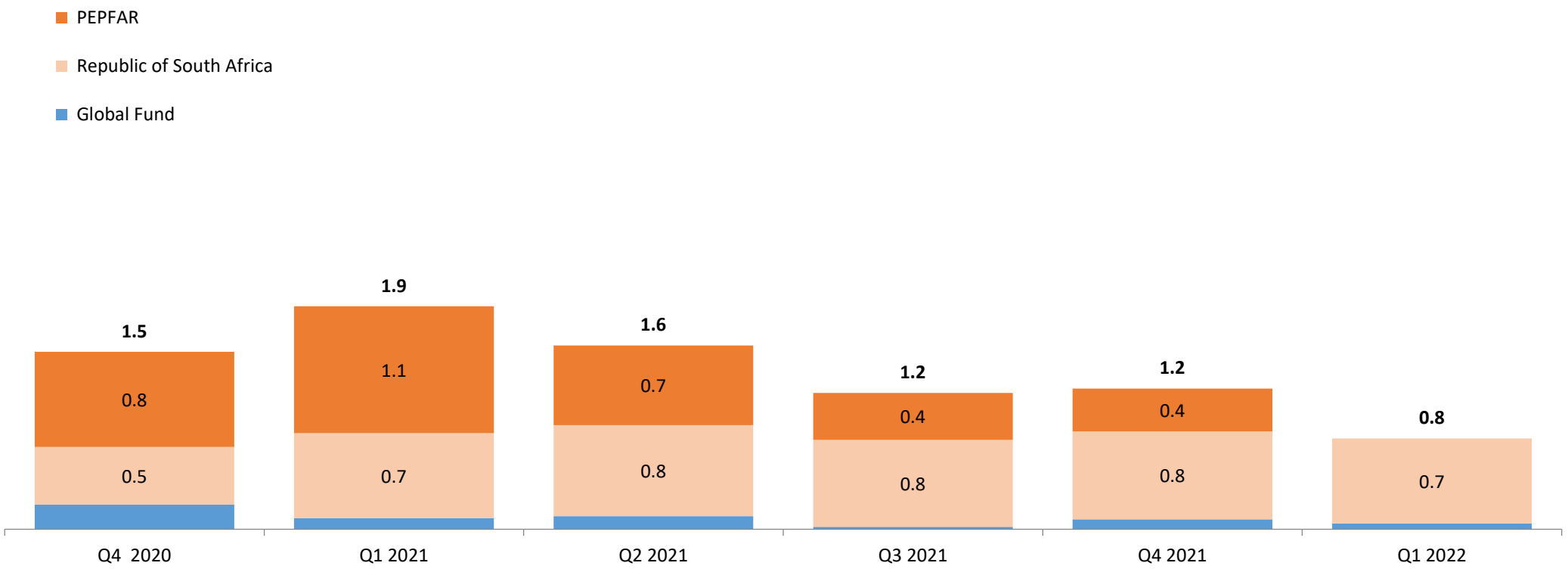
TDF/FTC 300/200

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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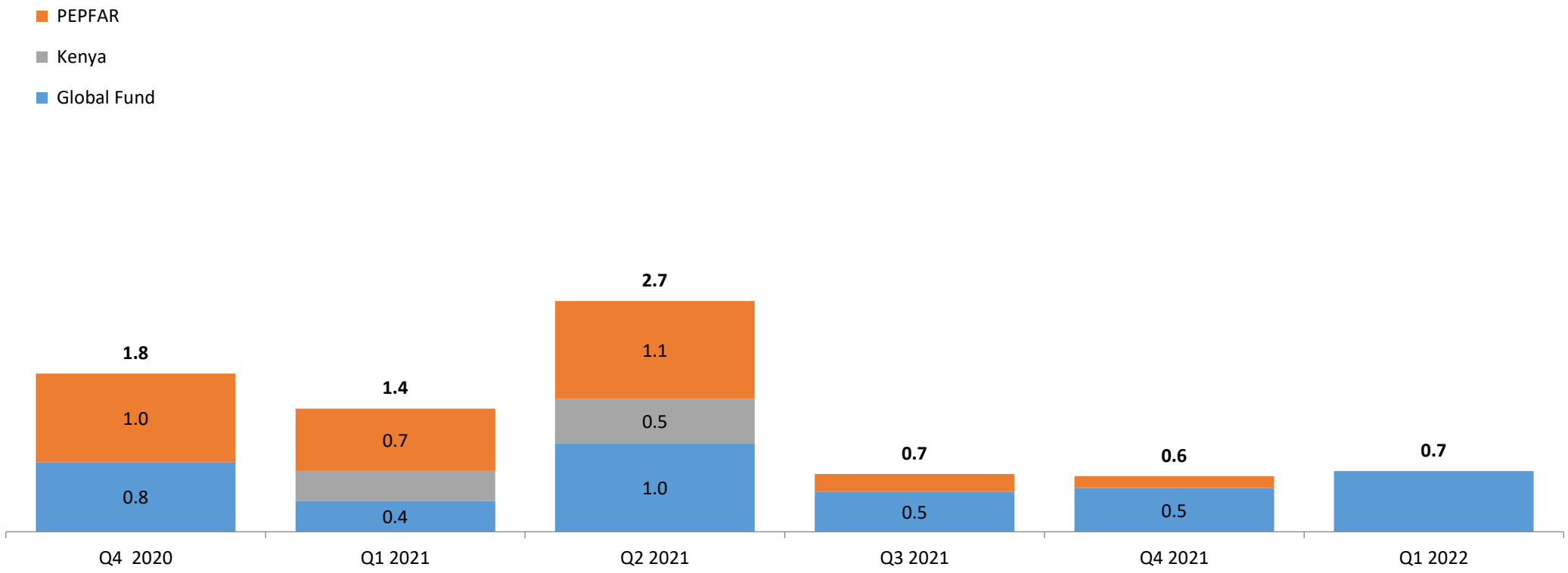
TDF/3TC 300/300

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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3TC/AZT 150/300

Consolidated Demand Outlook

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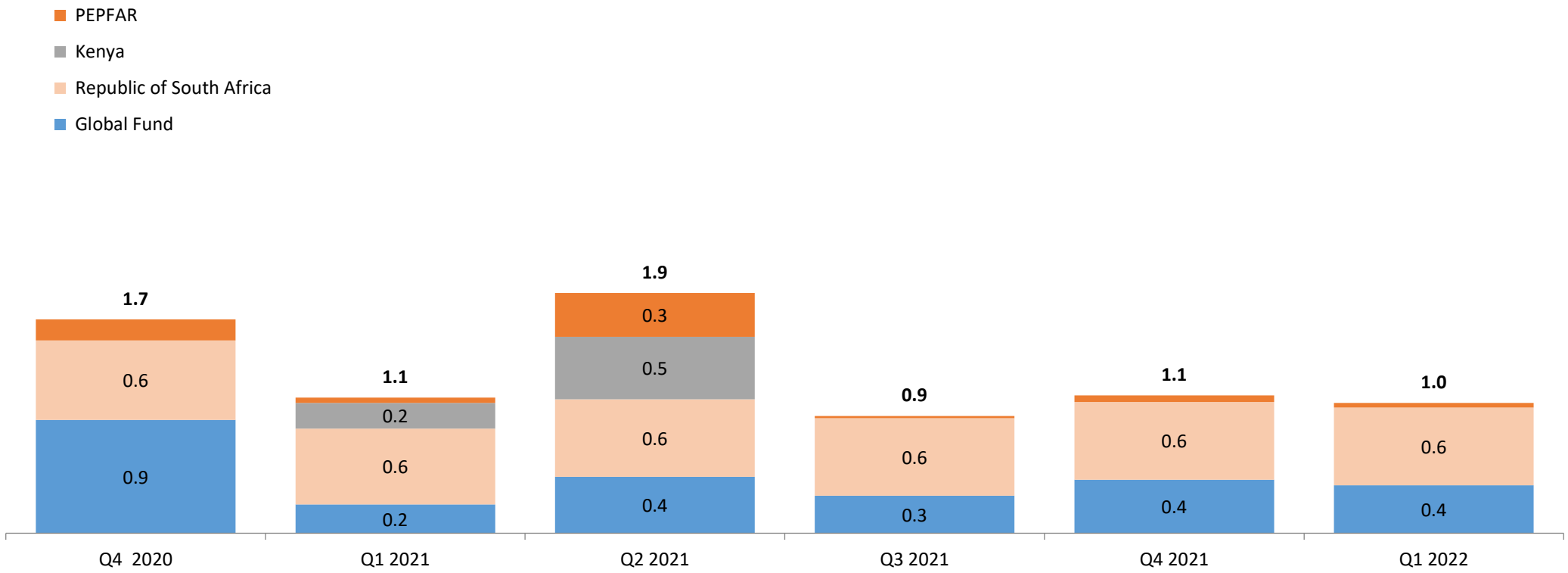

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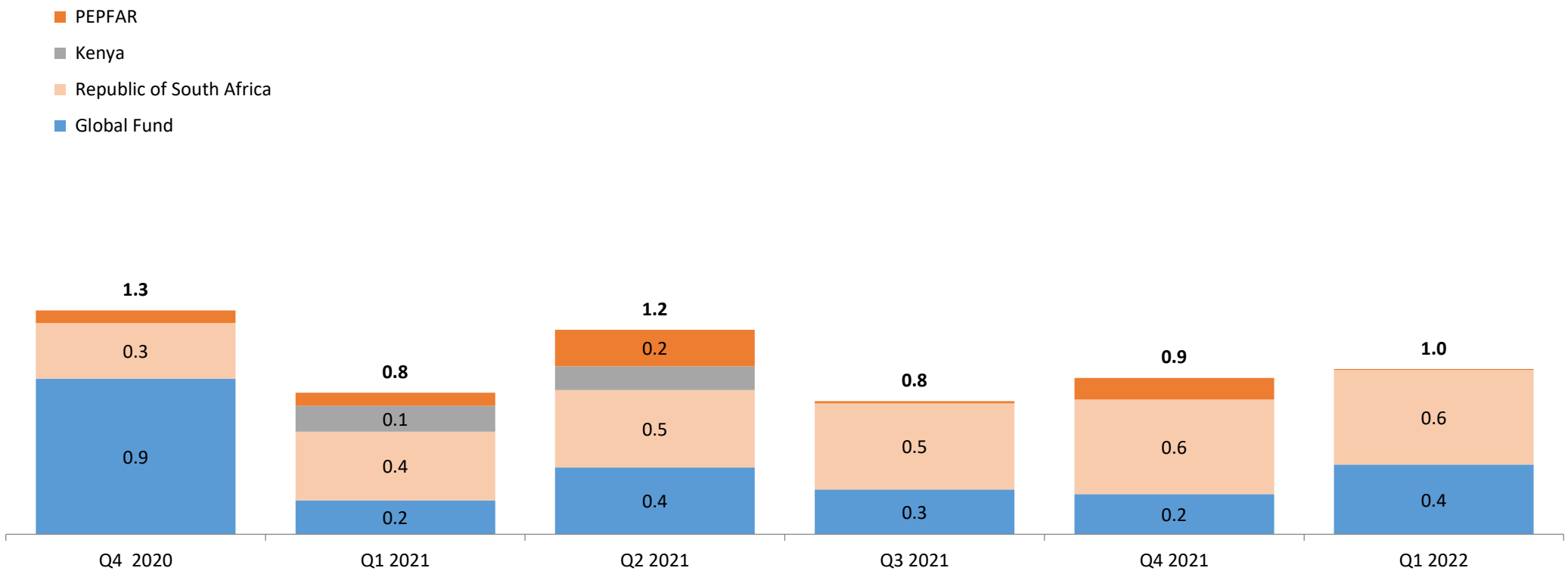
ABC/3TC 600/300

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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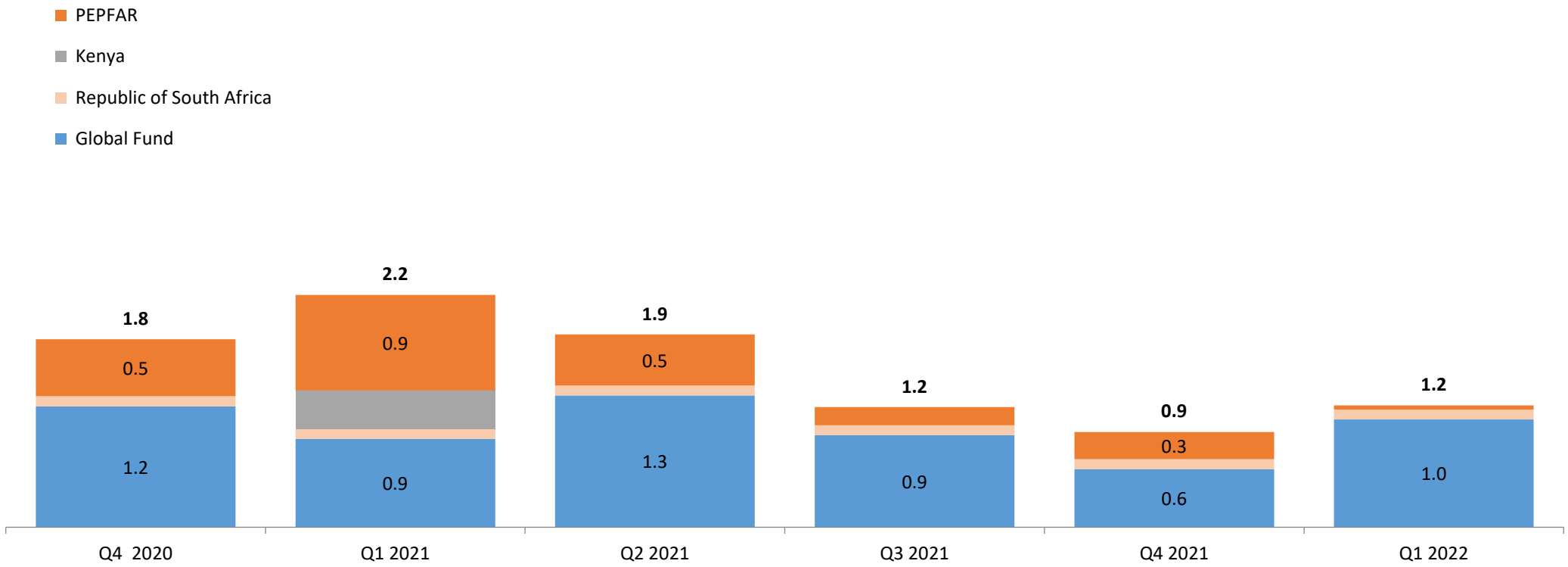
SOURCE: PEPFAR, Government of Kenya, The Global Fund, South Africa

ABC/3TC 120/60, 30 Tabs*

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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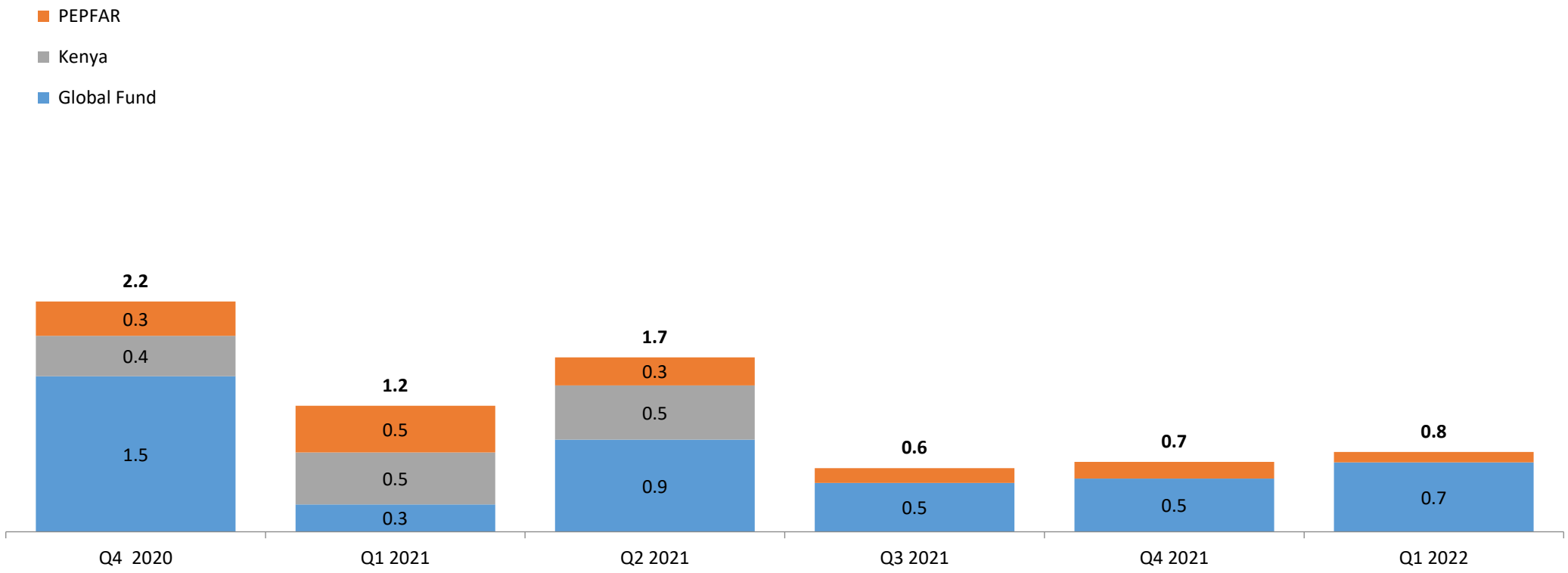
ATV/r 300/100

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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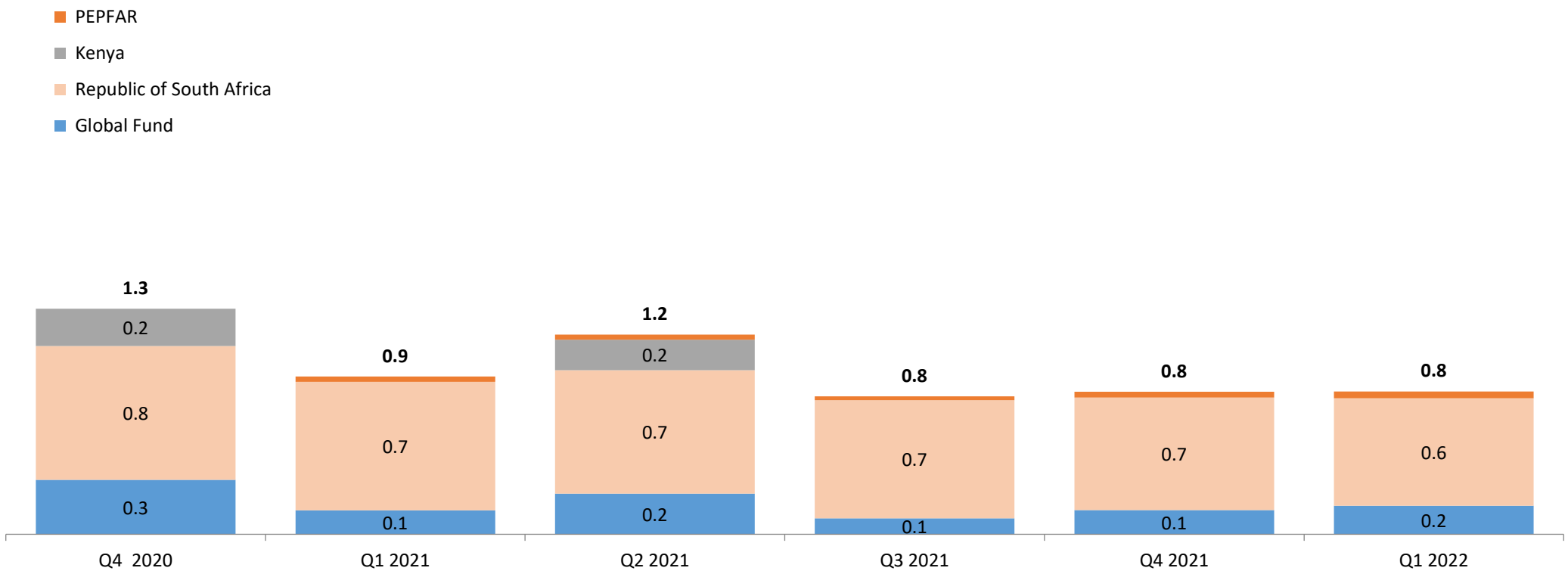
LPV/r 200/50

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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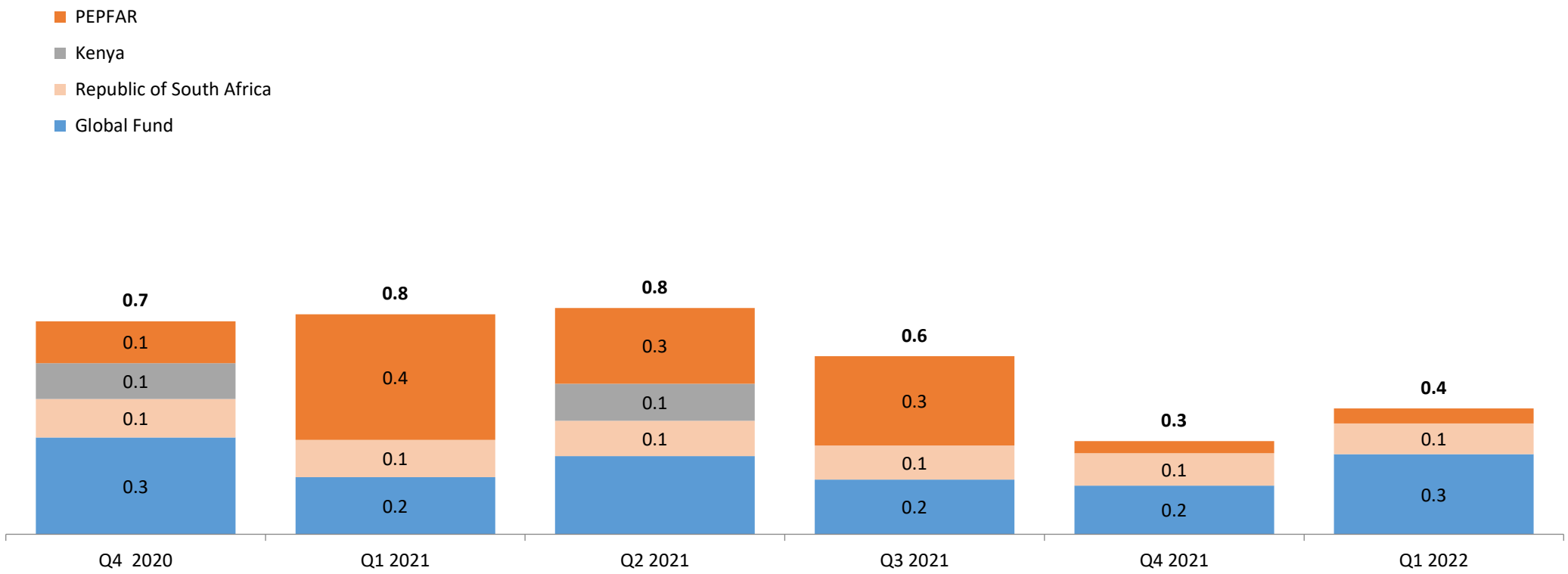
LPV/r 100/25

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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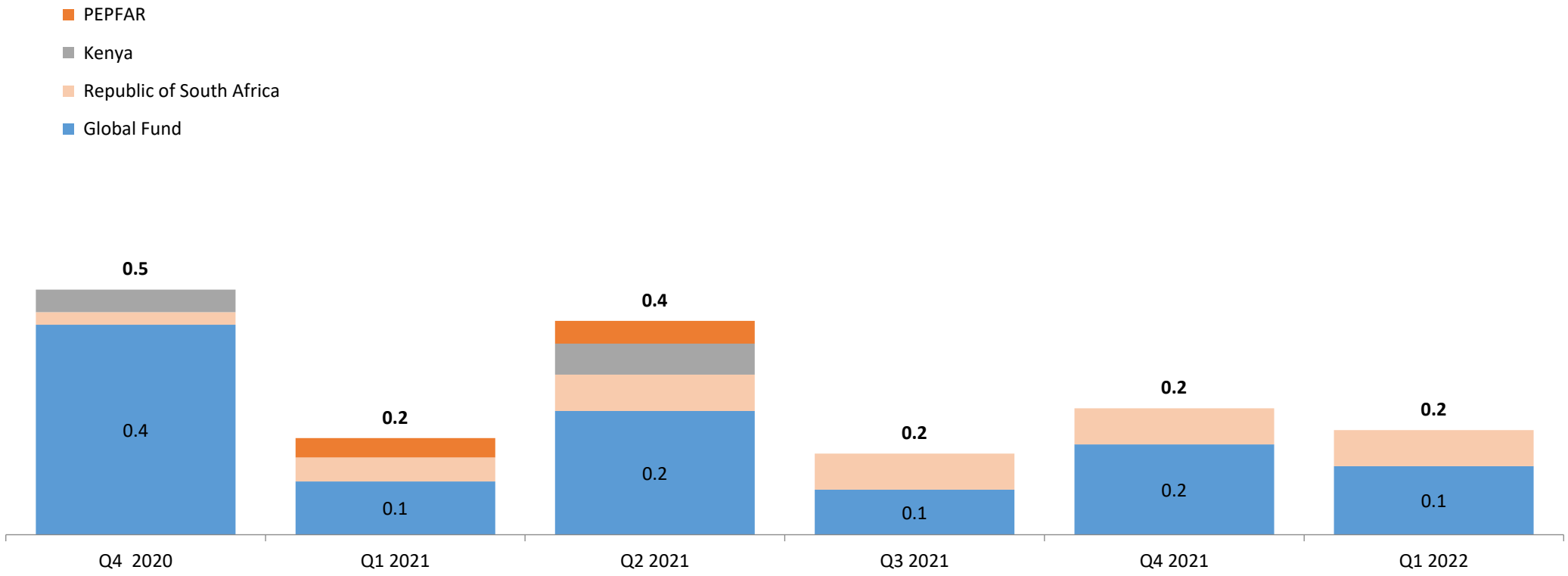
LPV/r 40/10 Capsules/Granules – Consolidated Demand Forecast Outlook

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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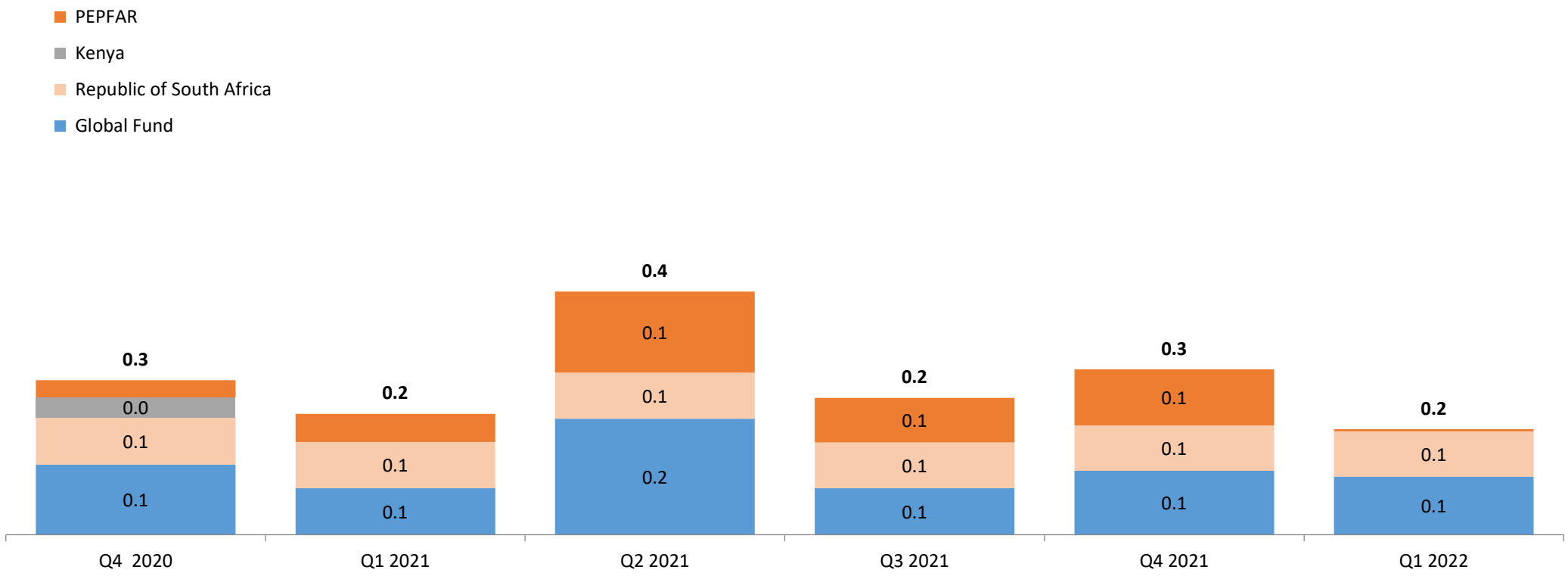
NVP 100 ml Oral Suspension

Consolidated Demand Outlook

Q4 2020 – Q1 2022, Number of packs, millions



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DTG 10 DT, 90 Tabs

Consolidated Demand Outlook

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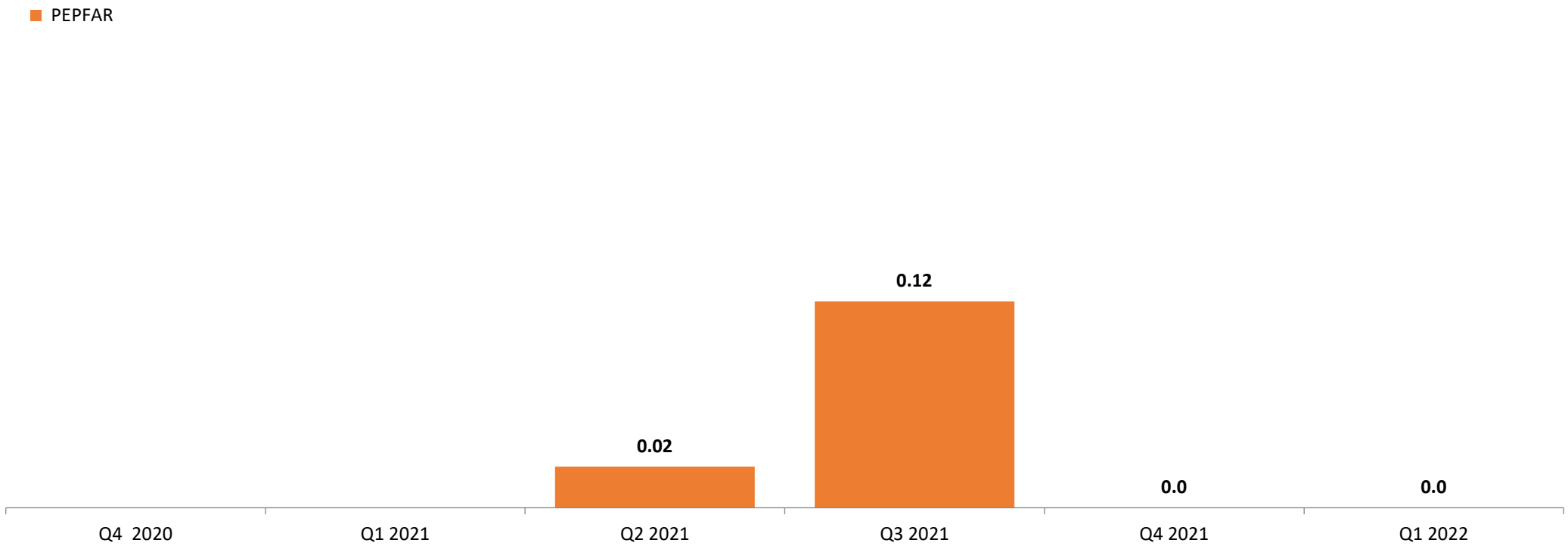

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Annual ARV Buyer Seller Summit 2020

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/AID Landscape

Kenya (2019)

1.5m people living with HIV

4.5% adult HIV prevalence (ages 15-49)

42,000 new HIV infections

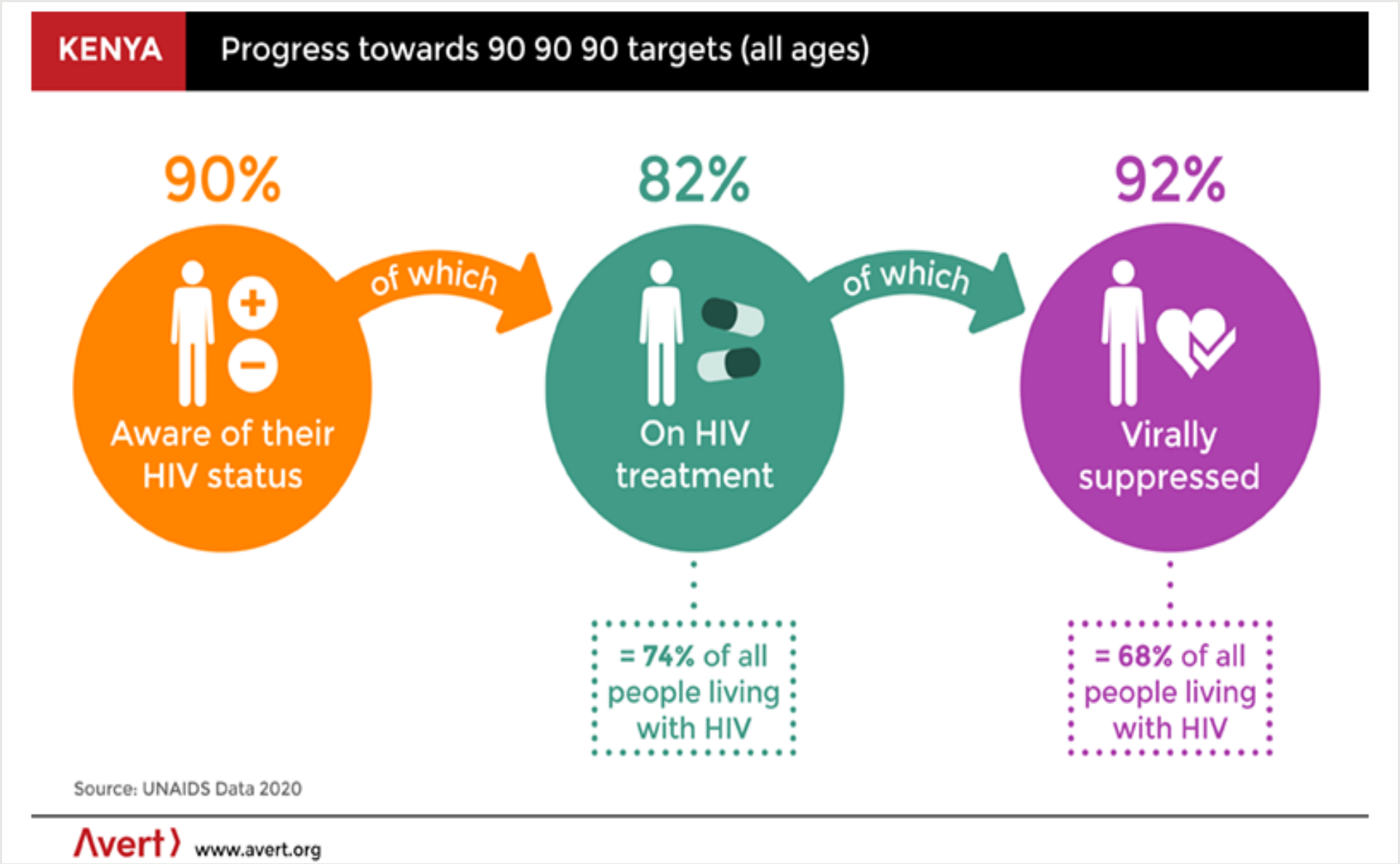
21,000 AIDS-related deaths

75% adults on antiretroviral treatment*

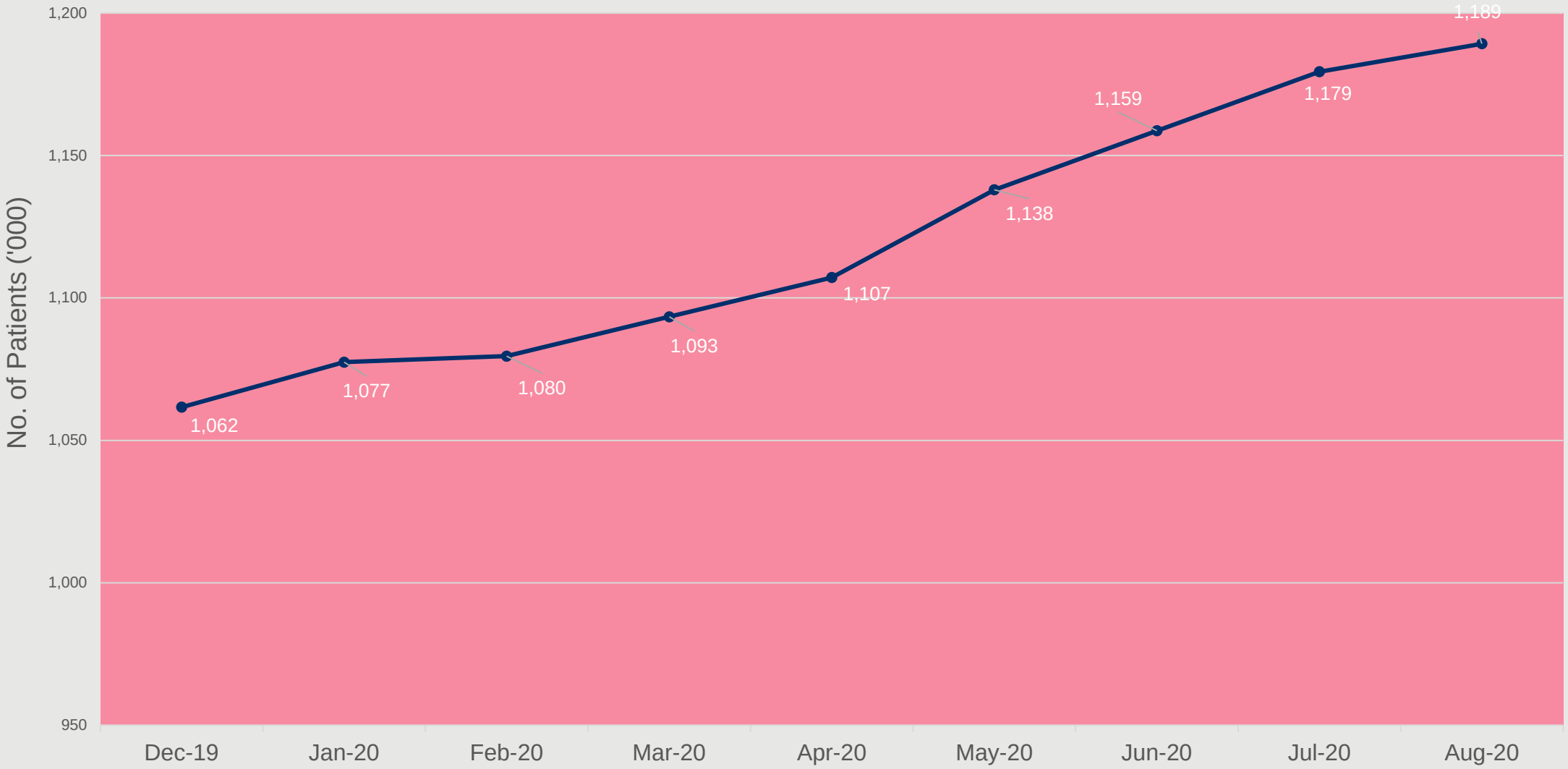
63% children on antiretroviral treatment*

*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
of which
92%
Virally suppressed
= 68% of all people living with HIV
Source: UNAIDS Data 2020
Avert
www.avert.org

Patient scale up



Treatment Optimization

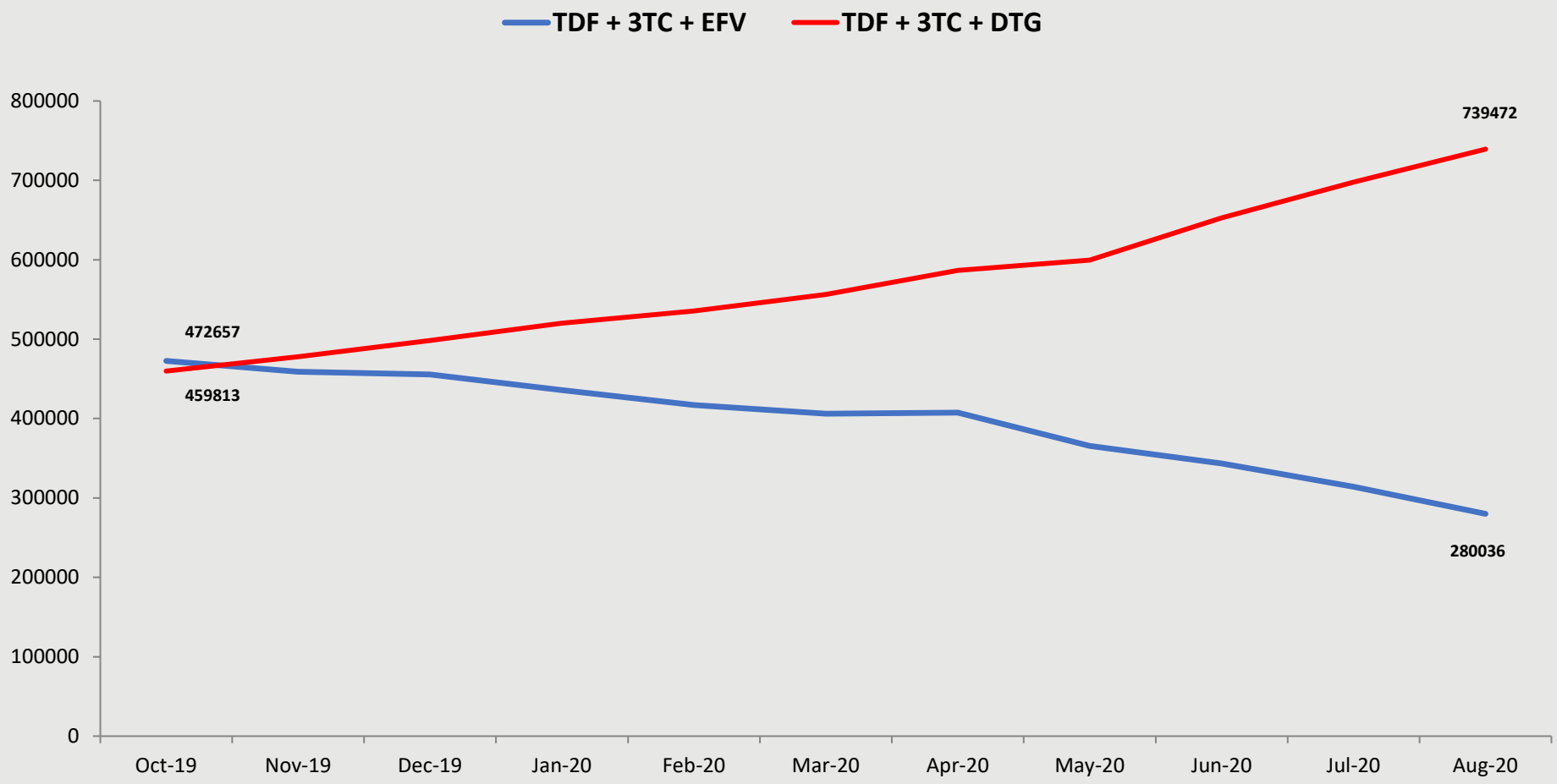
Adult ARV optimization

- 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



FY20/21 Requirements

Products	2020	2021		Total FY 20/21
	Q4	Q1	Q2	
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 30 Tablets	-			-
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets	-	1,320,200	1,781,500	3,101,700
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 180 Tablets	-	-	-	-
Emtricitabine/Tenofovir 200/300mg tablet 30	-	-	-	-
Lopinavir/Ritonavir 200/50 mg Tablet, 120 Tablets	216,775	-	176,860	393,635
Lopinavir/Ritonavir 40/10 mg Pellets	43,865	-	60,000	103,865
Nevirapine 10mg/ml oral suspension 100ml	35,711	-		35,711
Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets	-	200,000	482,700	682,700
Lopinavir/Ritonavir 100/25 mg Tablet, 60 Tablets	125,000	-	128,700	253,700
Atazanavir/Ritonavir 300/100 mg Tablet, 30 Tablets	391,196	503,707	526,130	1,421,033
Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets	-	347,157	522,125	869,282
Dolutegravir 50 mg Tablet, 30 Tablets	-	-	67,600	67,600
Abacavir/Lamivudine 600/300mg tablet 30	-	149,821	137,650	287,471
Abacavir/Lamivudine 120/60mg, dispersible, 30 Tablets	-	375,057	-	375,057
Tenofovir/Lamivudine 300/300mg Tablet, 30 Tablets	522,125		347,157	869,282

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

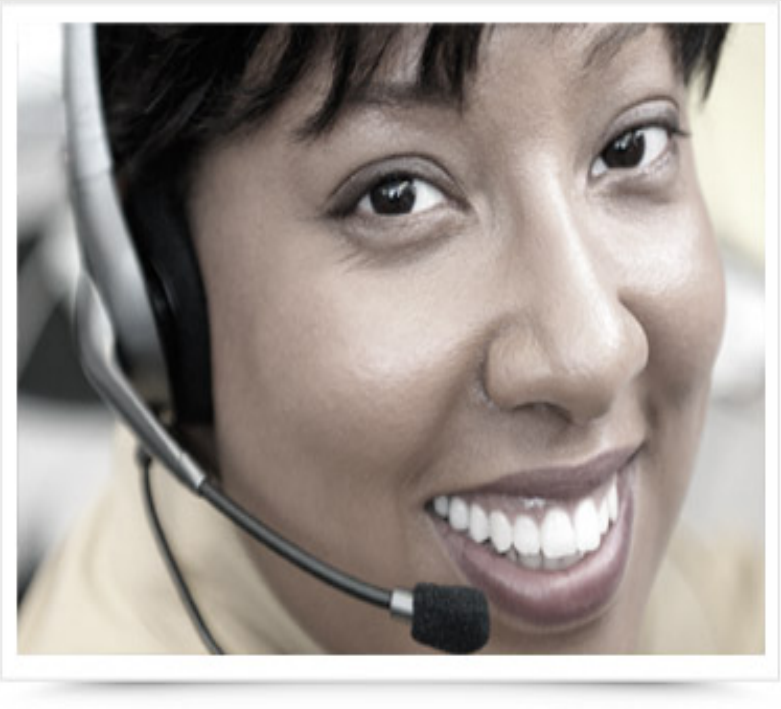
- Procurement done through KEMSA Medical Commodities Programme (KEMSA MCP)
- Procurement conducted in accordance to USAID Federal Acquisition Regulations (FAR) and ADS 312

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

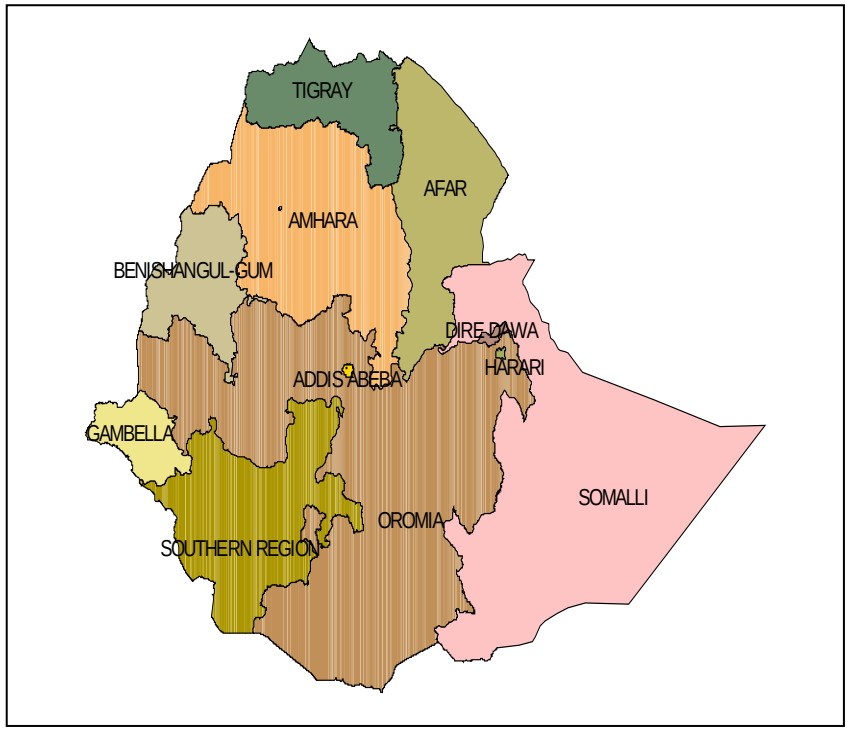
Mitigation

- 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



- Ethiopia is a Federal State having nine regional states and two City Administrations
- In 2017, total projected population: 94,351,001 **(CSA 2017)**

- HIV prevalence - 0.9% ,(EDHS 2016)
- Annual New infections estimate in 2019 - 21,486
- Annual AIDS related deaths in 2018 - 11,423

Clients on ART	Jun-20	Jun-21	Jun-22	Jun-23	Jun-24
Total Adults and Pediatric	**518,845**	**549,265**	**560,041**	**570,817**	**581,593**
Total Adults	**497,082**	**526,226**	**536,550**	**546,874**	**557,198**
Adult 1st line	472,998	500,309	510,125	519,940	529,756
Adult 2nd line	22,369	23,680	24,145	24,609	25,074
Adult 3rd line	1,640	1,737	1,771	1,805	1,839
Total Pediatrics	**21,763**	**23,039**	**23,491**	**23,943**	**24,395**
Pedi 1st line	18,871	19,928	20,268	20,608	20,948
Pedi 2nd line	2,829	2,995	3,054	3,113	3,171
Pedi 3rd line	63	116	169	222	275

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

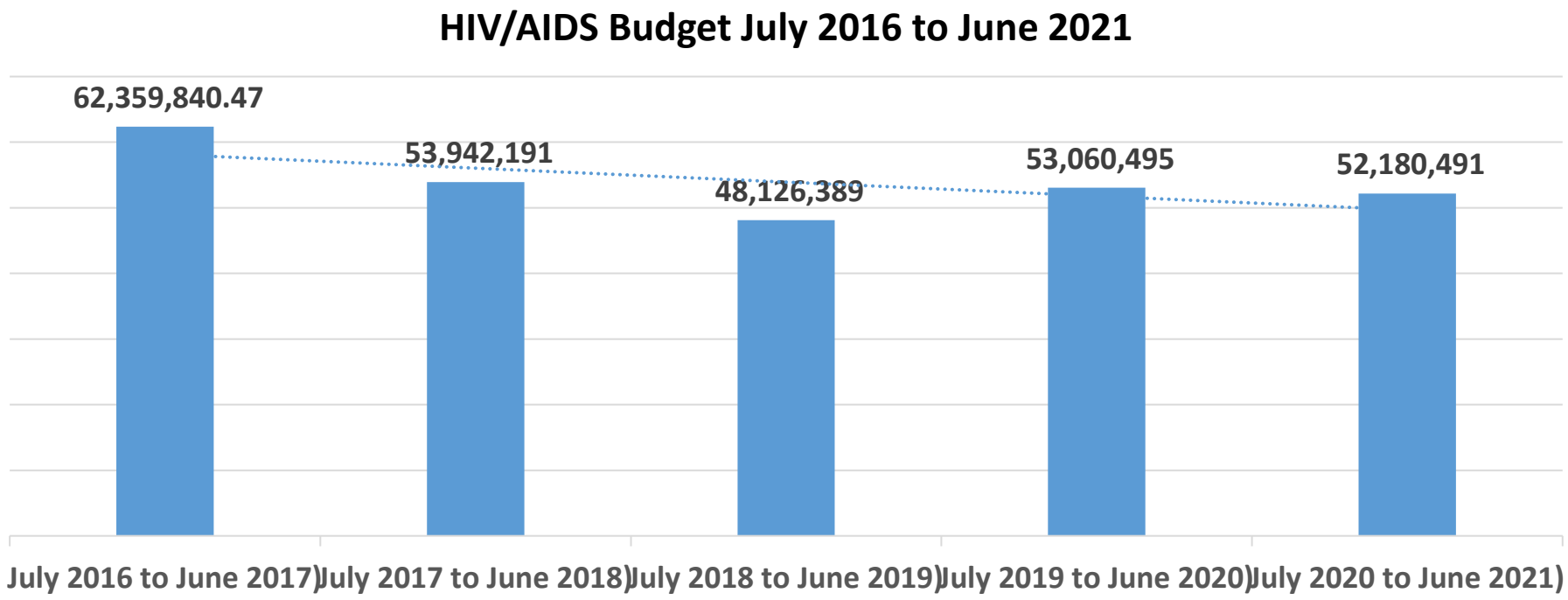
- Darunavir (DRV) - 600mg – Tablet
- Darunavir (DRV) - 75mg – Tablet
- Dolutegravir (DTG) - 50mg – Tablet
- Ritonavir (RTV) - 100mg – Tablet
- Ritonavir (RTV) - 25mg – Tablet

DSD Models

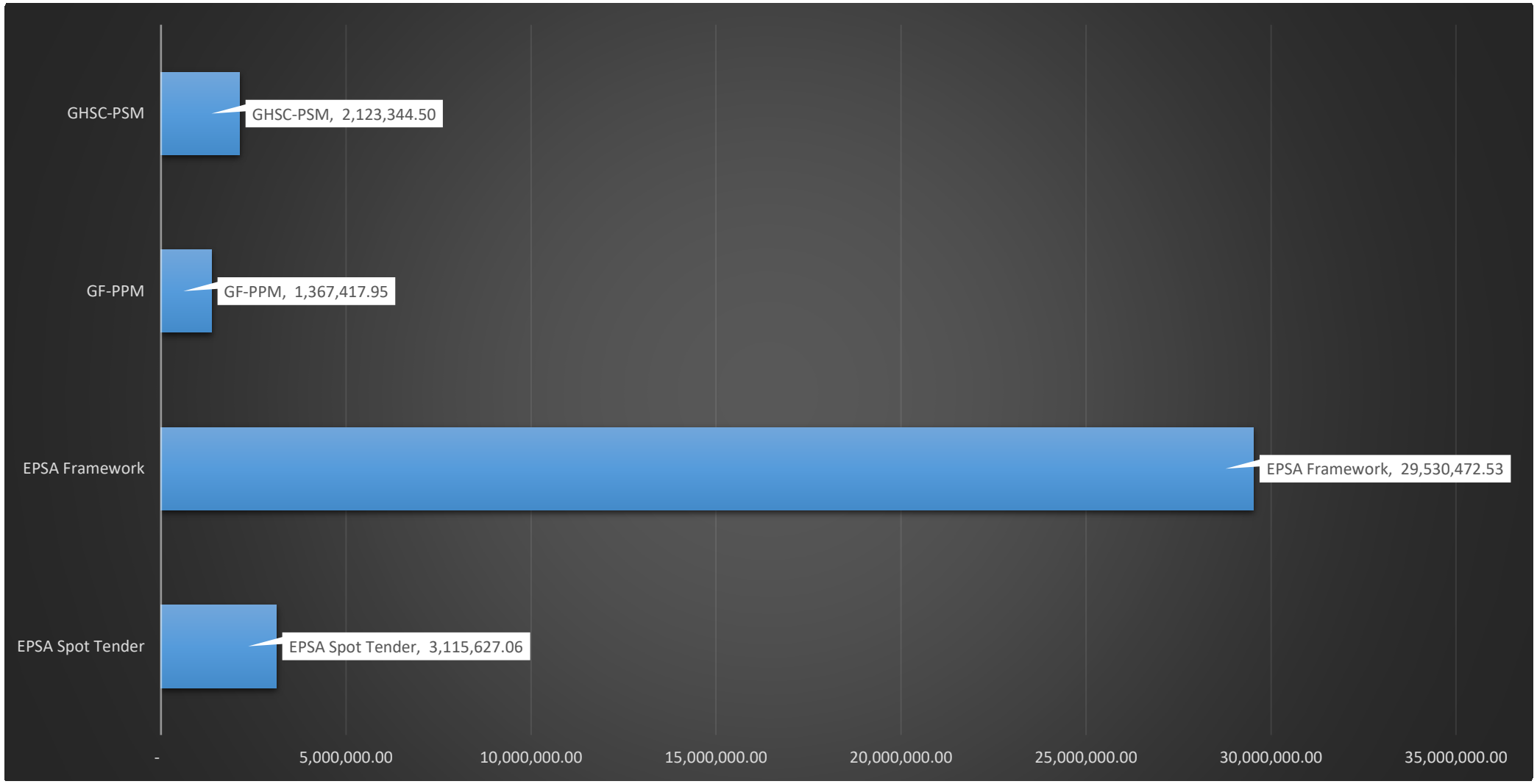
- ASM
- FTR
- UHEW managed CAG

Budget for HIV/AIDS Program

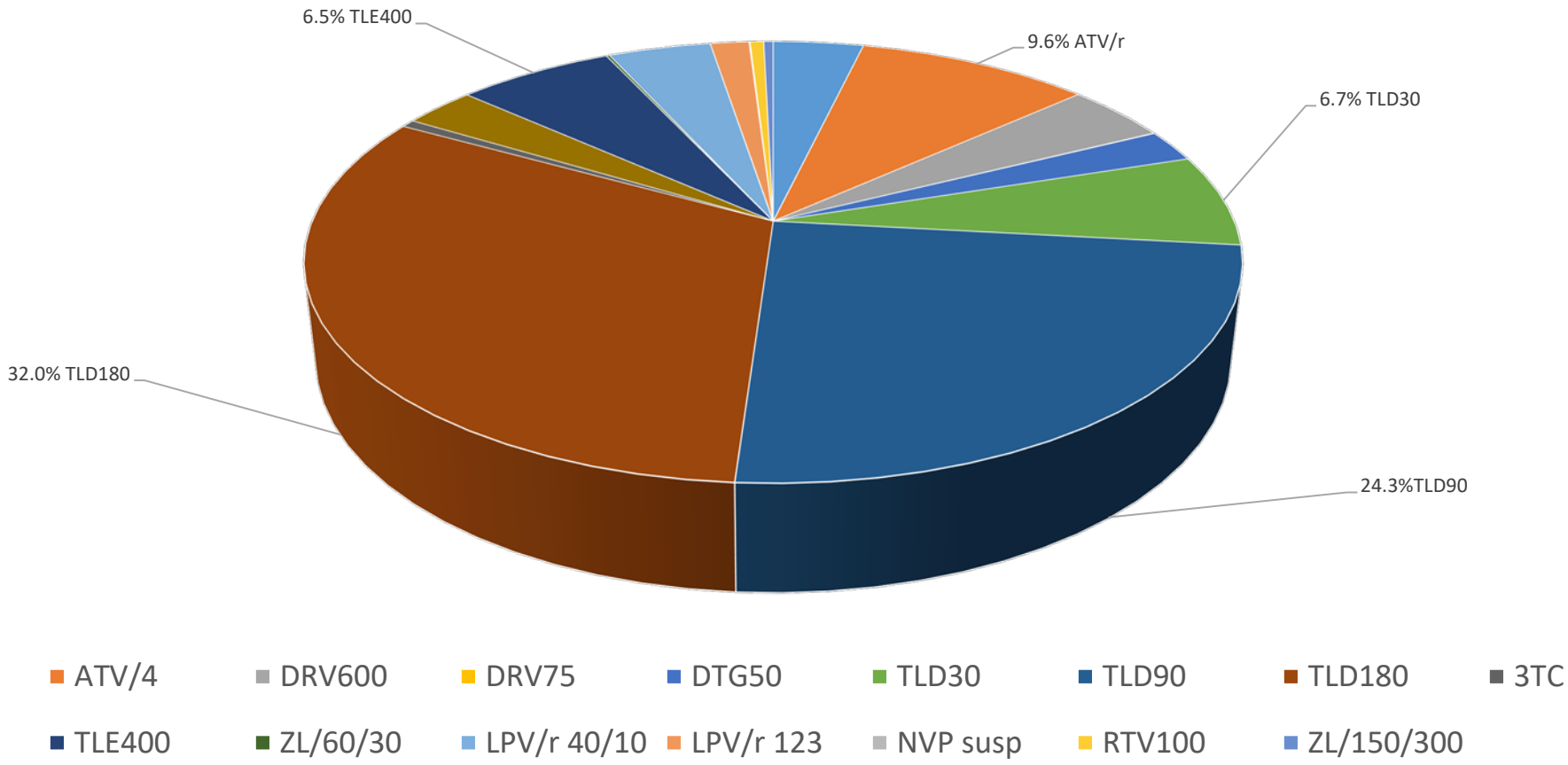
- ARV treatment is provided at 1304 ART sites and 2176 PMTCT sites
- The source of finance is The Global Fund and also USAID
- The Principal Recipient of the fund is Federal HIV/AIDS Prevention and Control Office-Ethiopia (FHAPCO)
- Program management is done by MoH Ethiopia
- Procurement is effected 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



Current ARVs Procurement for 2020/21



Product specific procurement Expenditure proportion 2020/21



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

Challenges

- Most challenges due to
- Delayed delivery
- API price increment which in turn resulted in contract cancellations
- Contract cancellations
- Repetitive LC extensions which are having huge charges on suppliers
- Not being able to submit original documents on time
- Unwillingness to supply non economic quantities

Mitigation Strategies

- Contract and LC extension
- Continuously revise supply planning and map suppliers status
- Redistribution among regional hubs and health facilities
- Strong coordination and follow-up
- Agreement with ESL, EAL to work with copy documents and payment will be processed later
- Incorporating other procurement mechanisms like GF-PPM and GHSC-PSM

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!!!

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health for a better life.

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

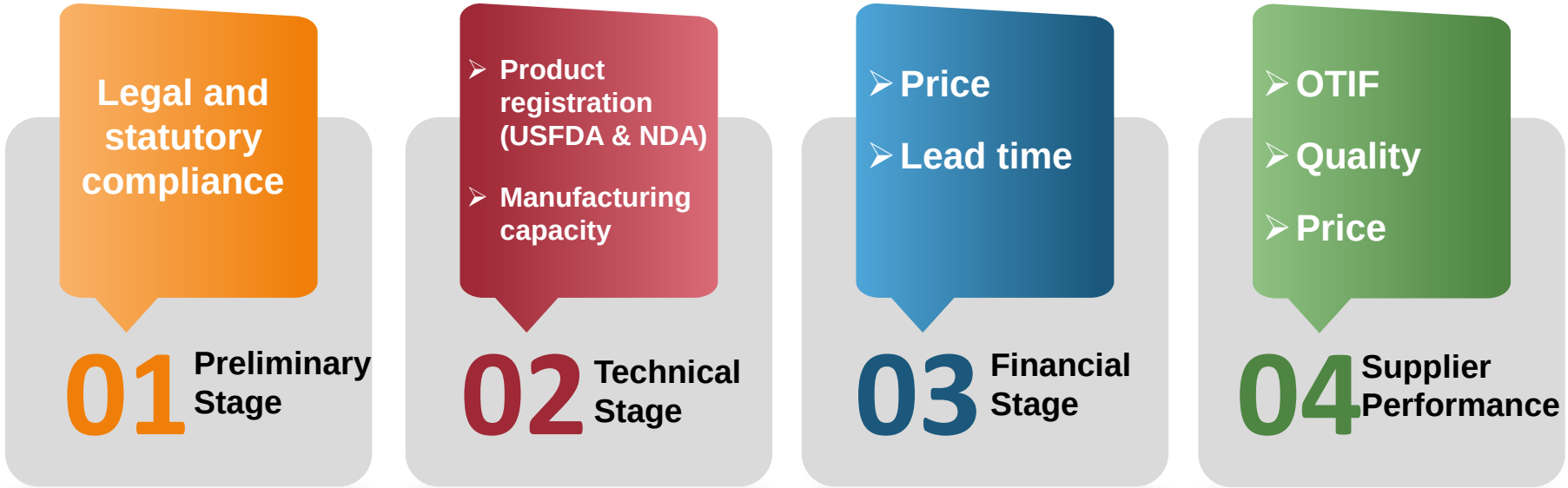
- Monthly procurement planning meeting
  - Review of stock position by item (MOS)
  - Target inventory is 3 - 6 months i.e. 3 months for stock on hand and 3 months on order
- Monthly national commodity security meetings Led by MOH

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)



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 1st line patients that may not tolerate DTG but are using TDF+3TC and Pregnant women and breasting 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 2nd 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

Key milestones 2020 / 2021

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 top improve total cost of ownership through bulk purchases and consolidation while ensuring that there is emphasis on EOQ


THANK
YOU
GRACIAS
ARIGATO
SHUKURIA
DANKSCHEEN
BIYAN
SHUKRIA
TINGKI
YAQHANYELAY
TASHAKKUR ATU
SUKSAMA
EKHMET
MEHRBANI
GRAZIE
PALDIES
KOMAPSUMNIDA
MAAKE
GOZAIMASHITA
EFCHARISTO
JUSPAXAR
BOLZÏN
MERCI

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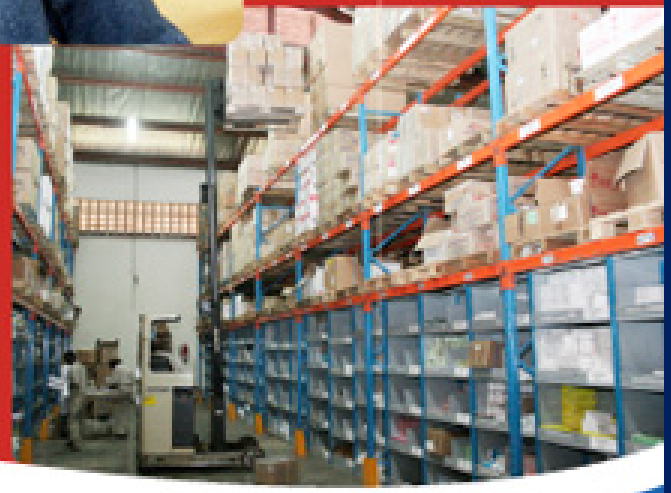
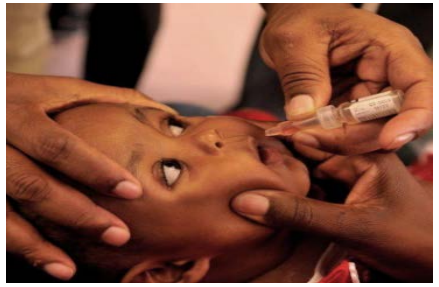


ARV Large Buyer Seller Summit



Republic of South Africa

Ms Khadija Jamaloodien
Affordable Medicines Directorate

ARV Large Buyer Seller Summit
October 2020

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

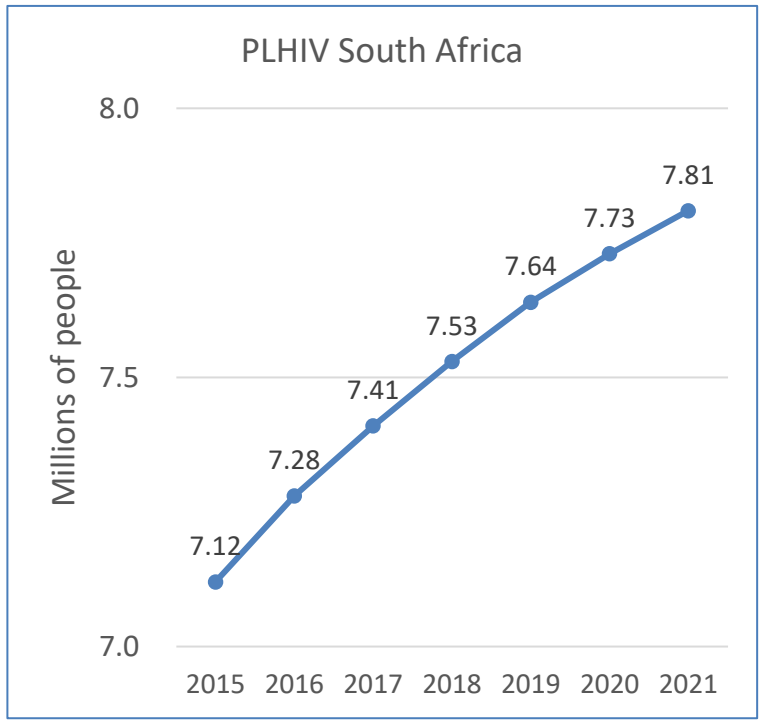
2030 NDP

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 2nd line adult patients and children receive focus
- A new ARV tender will be advertised in 2021, for award in 2022

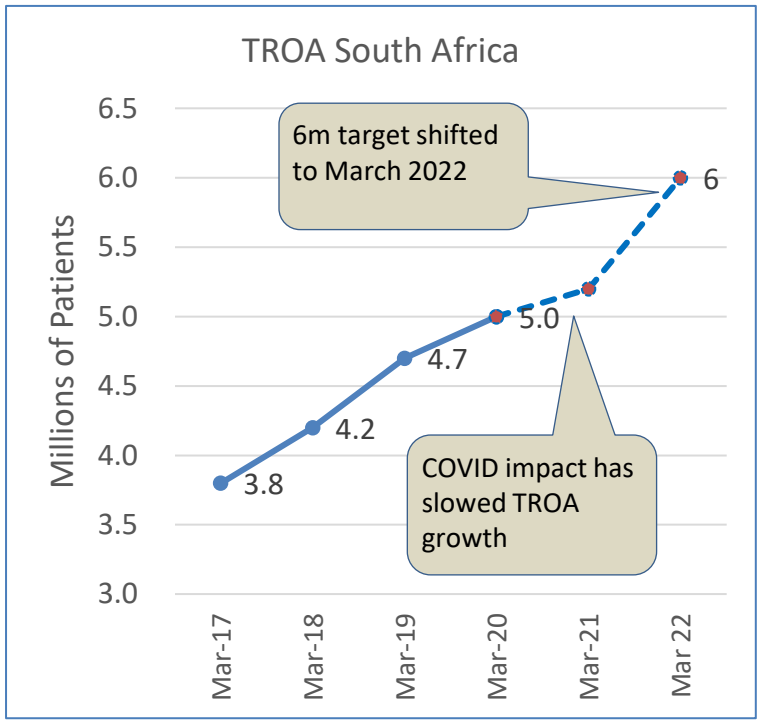
Our progress on growing patients on treatment has been impacted by COVID-19

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



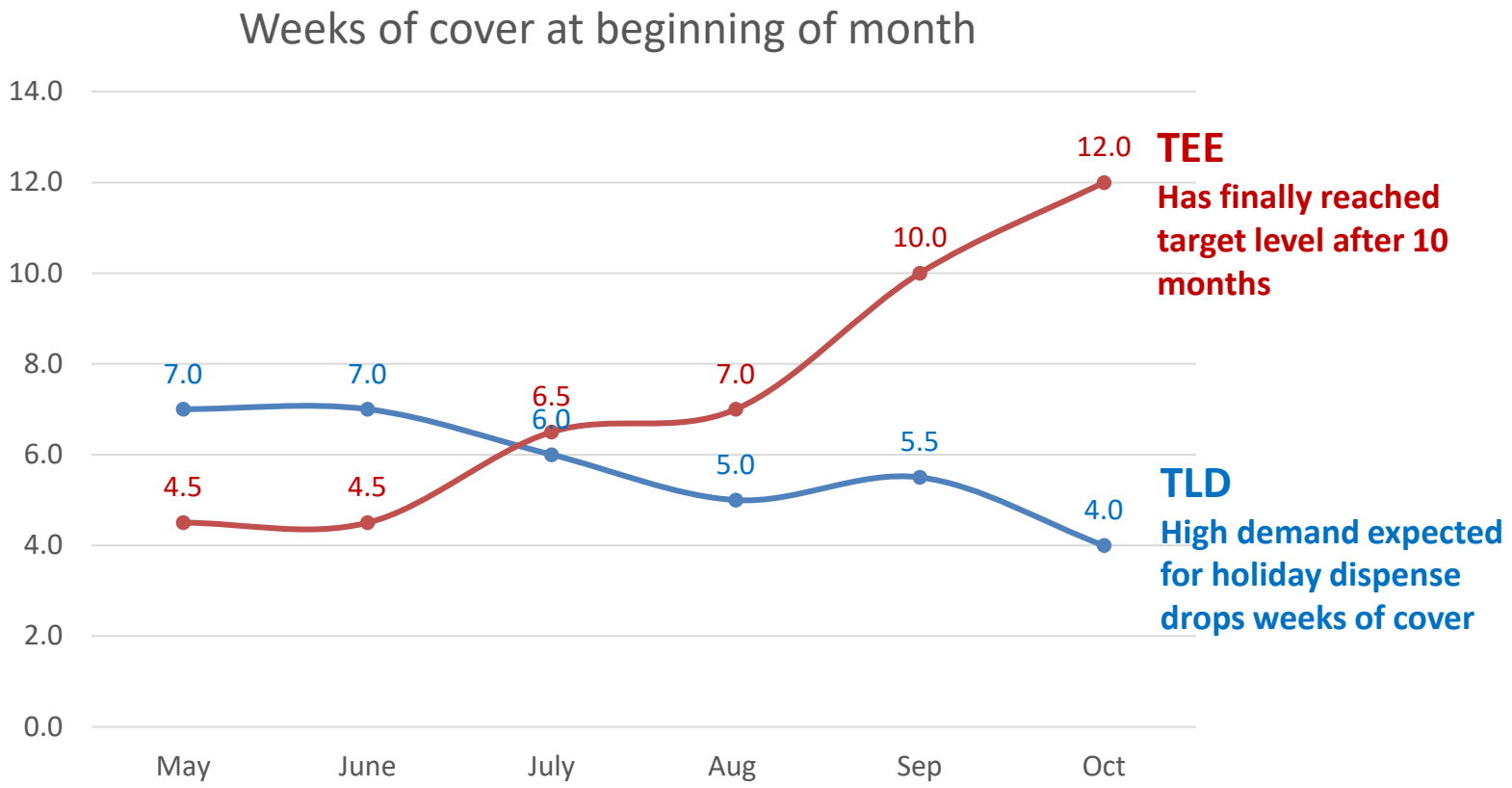
Source
- NDoH

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

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Department:
Health
REPUBLIC OF SOUTH AFRICA

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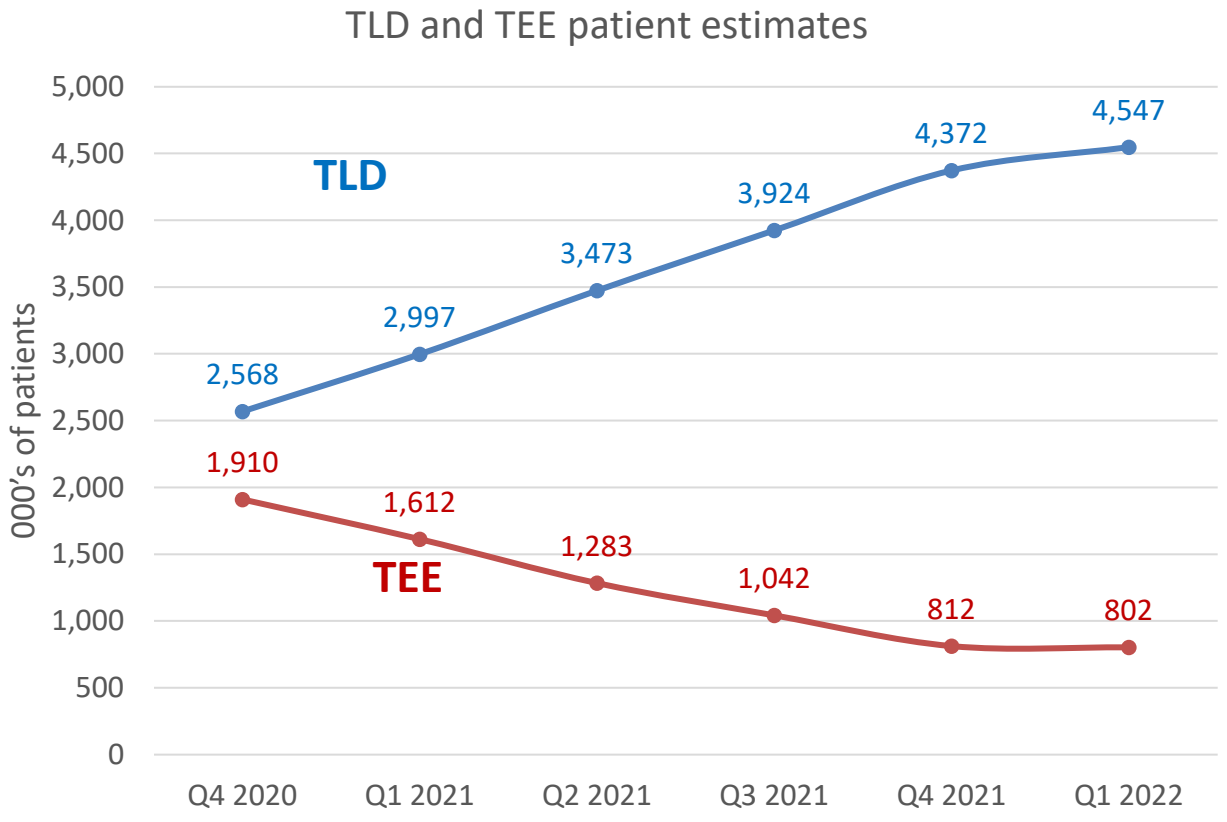
Adults on main 1st line ARTs; TLD has overtaken TEE

OUTLOOK FOR 2021



Source: Team analysis; TEE/TLD profile based on TROA reaching 6m in Mar-22

Regimen trends: 2nd line adults

	Patient estimate	Comment
AZT/3TC+LPV/r	~250,000	LPV/r volumes expected to reduce, but based on clinician adherence to communication from HIV Programme on 2nd line patient transition to DTG 50
AZT/3TC+DTG	~50,000	
AZT/3TC+ATV/r	~10,000	Stable volumes expected
TDF/FTC+LPV/r	~6,000	
TDF/FTC+ATV/r	~250	
Total	**~320,000**	

Regimen trend: 1st line children

	Patient estimate	Comment
ABC/3TC+EFV	~90,000	Expectation that EFV & LPV/r will be replaced by DTG 50
ABC/3TC+LPV/r	~45,000	
ABC/3TC+DTG	~2,000	
AZT/3TC+NVP	~6,000	Stable volumes expected
ABC/3TC+ATV+r	~3,000	Exploring ATV/r combination
Total	**~160,000**	

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Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

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

WHO Interim Guidelines: Updated recommendation on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV. December 2018

TLD / TEE demand plan

Calendar period	**Q4 – 2020**	**Q1 – 2021**	**Q2 – 2021**	**Q3 – 2021**	**Q4 - 2021**	**Q1 - 2022**
'000s of 28-count packs						
TLD patient demand	9 905*	8 229*	11 318	12 787	16 693	12 373
TEE patient demand	7 165	4 312	4 182	3 395	3 077	2 183

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)

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

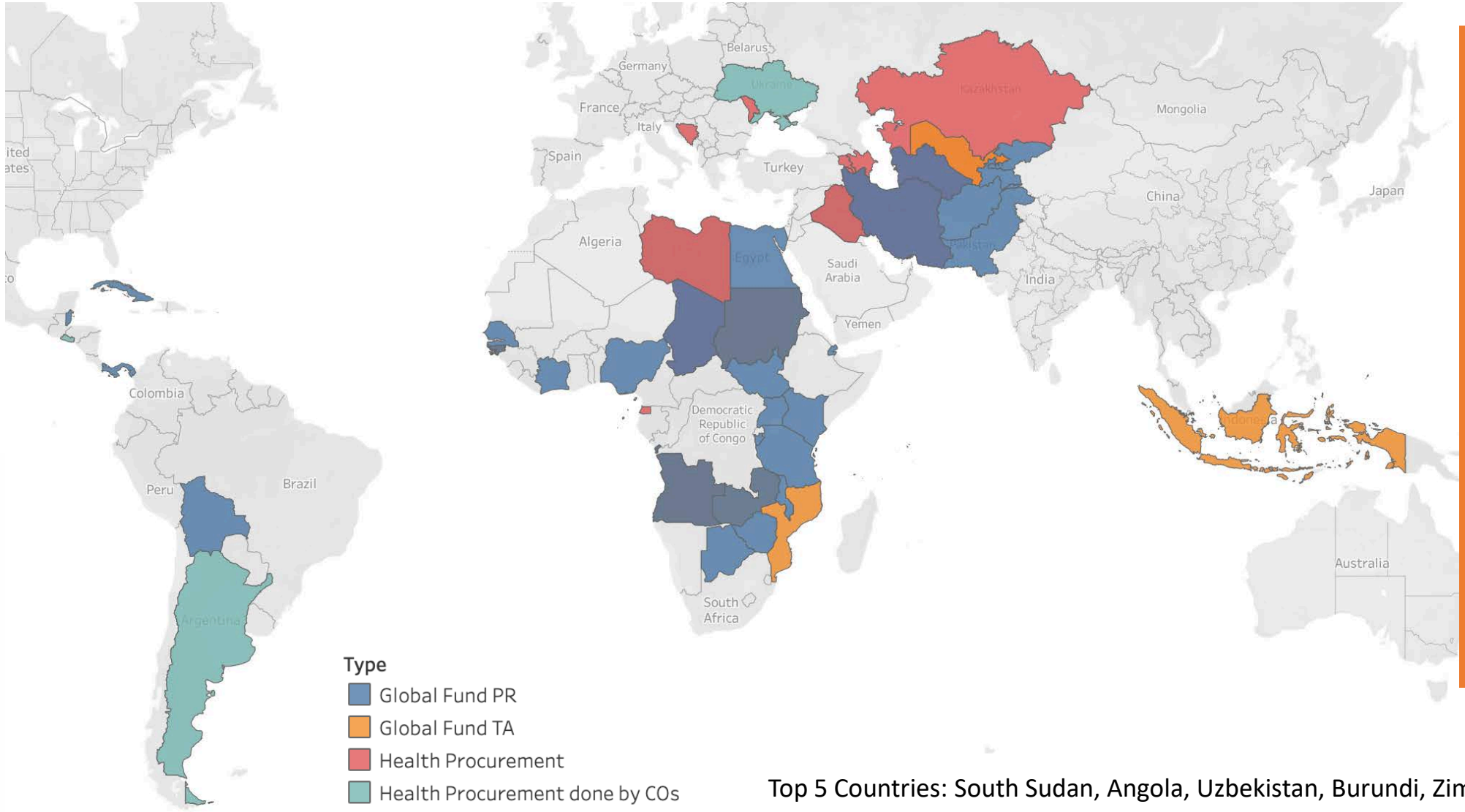
Empowered lives.
Resilient nations.

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

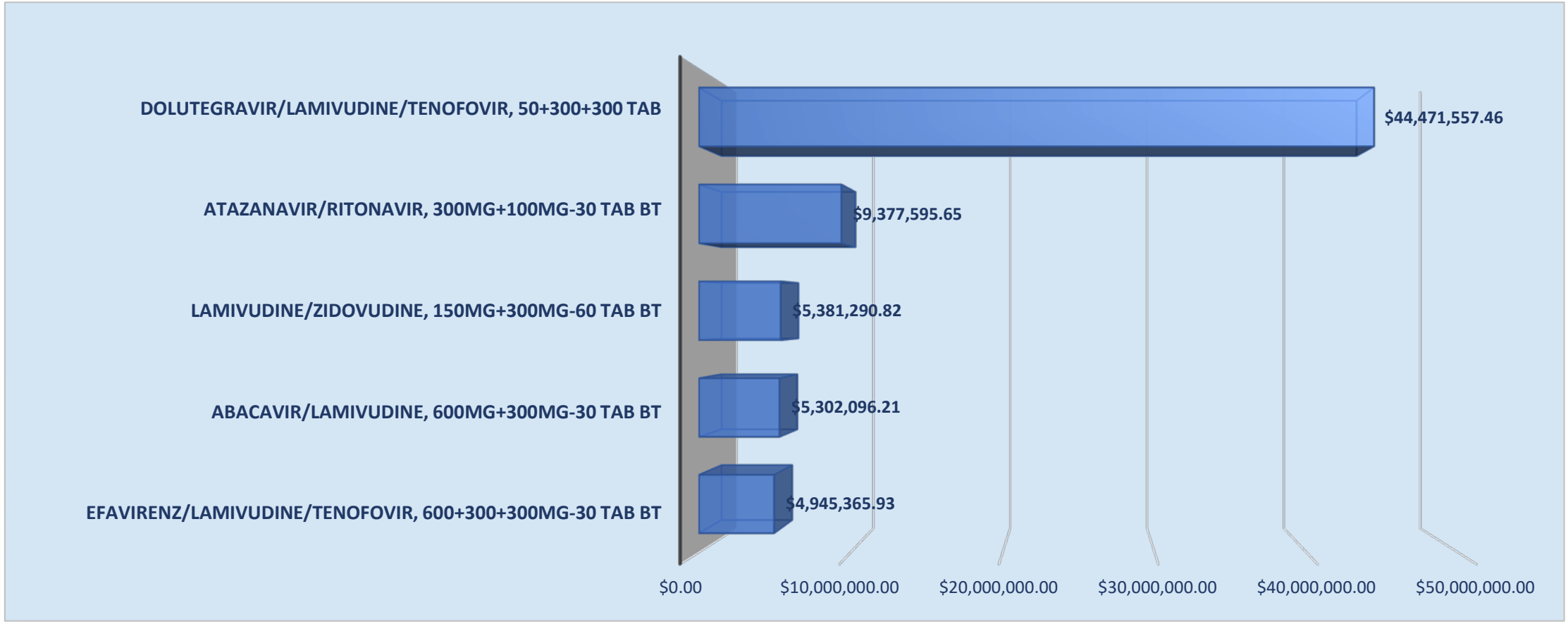
COVID 19 - Emergency procurement support
100 + countries

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

ARV VOLUMES

Total value ARVs 2018	Total value ARVs 2019	Total value ARVs 2020	Projection of value 2021
$129.684.800	**$81.784.700**	**$.....**	**$110.000.000**
2018	2019	2020	2021

Top 5 ARV Products 2019



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

DocuSign

Go Green. Go Paperless.

List of products covered by LTAs

Product description	Strength	Dosage form	Type of packaging*
Abacavir	300 mg	Tablet	Bottle HDPE: 60
Abacavir/Lamivudine	600 mg + 300 mg	Tablet	Bottle HDPE: 30
Atazanavir/Ritonavir	300 mg + 100 mg	Tablet	Bottle HDPE: 30
Darunavir	600 mg	Tablets	Bottle HDPE: 60
Dolutegravir /Lamivudine/Tenofovir disoproxyl fumarate	50mg+300mg+300mg	Tablet	Bottle HDPE: 30
Dolutegravir /Lamivudine/Tenofovir disoproxyl fumarate - cartoon less**	50mg+300mg+300mg	Tablet	Bottle HDPE: 30
Dolutegravir /Lamivudine/Tenofovir disoproxyl fumarate	50mg+300mg+300mg	Tablet	Bottle HDPE: 90
Dolutegravir /Lamivudine/Tenofovir disoproxyl fumarate - cartoon less**	50mg+300mg+300mg	Tablet	Bottle HDPE: 90
Dolutegravir	50 mg	Tablet	Bottle HDPE: 30
Darunavir/Ritonavir	400 mg + 50 mg	Tablet	Bottle HDPE: 60
Darunavir/Ritonavir	400 mg + 50 mg	Tablet	Bottle HDPE: 120
Efavirenz	600 mg	Tablet	Bottle HDPE: 30
Efavirenz/Emtricitabine/Tenofovir disoproxyl fumarate	600 mg + 200 mg + 300 mg	Tablet	Bottle HDPE: 30
Efavirenz/Emtricitabine/Tenofovir disoproxyl fumarate	600 mg + 200 mg + 300 mg	Tablet	Bottle HDPE: 90
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate	400mg+300mg+300mg	Tablet	Bottle HDPE: 30
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate - cartoon less*	400mg+300mg+300mg	Tablet	Bottle HDPE: 30
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate - cartoon less*	400mg+300mg+300mg	Tablet	Bottle HDPE: 90
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate	600 mg + 300 mg + 300 mg	Tablet	Bottle HDPE: 30
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate - cartoon less*	600 mg + 300 mg + 300 mg	Tablet	Bottle HDPE: 30
Efavirenz/Lamivudine/Tenofovir disoproxyl fumarate - cartoon less	600 mg + 300 mg + 300 mg	Tablet	Bottle HDPE: 90
Emtricitabine/Tenofovir disoproxyl fumarate	200 mg + 300 mg	Tablet	Bottle HDPE: 30
Lamivudine	150 mg	Tablet	Bottle HDPE: 60
Lamivudine/Nevirapine/Zidovudine	150 mg + 200 mg + 300 mg	Tablet	Bottle HDPE: 60
Lamivudine/Tenofovir disoproxyl fumarate	300 mg + 300 mg	Tablet	Bottle HDPE: 30
Lamivudine/Zidovudine	150 mg + 300 mg	Tablet	Bottle HDPE: 60
Lopinavir/Ritonavir*	200 mg + 50 mg	Tablet (heat stable)	Bottle HDPE: 120
Nevirapine	200 mg	Tablet	Bottle HDPE: 60
Raltegravir	400 mg	Tablet	Bottle HDPE: 60
Ritonavir	100 mg	Tablet	Bottle HDPE: 30
Tenofovir disoproxyl fumarate	300 mg	Tablet	Bottle HDPE: 30
Abacavir/Dolutegravir/Lamivudine	600 mg + 50 mg + 300mg	Tablet	Bottle HDPE: 30

Preliminary data

PRODUCTS	2021				2022
	Q1	Q2	Q3	Q4	Q1
Efavirenz/Lamivudine/Tenofovir DF 600/300/300 mg Tablet, 30 Tablets	7,028				13,340
Efavirenz/Lamivudine/Tenofovir DF 600/300/300 mg Tablet, 90 Tablets					
Efavirenz/Lamivudine/Tenofovir DF 400/300/300 mg Tablet, 30 Tablets	323				588
Efavirenz/Lamivudine/Tenofovir DF 400/300/300 mg Tablet, 90 Tablets					
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 30 Tablets	2,158,990	3,587,954	2,885,540	1,350,870	3,576,155
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets					28,293
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 180 Tablets					
Dolutegravir 10mg, 90 Tablets					
Emtricitabine/Tenofovir 200/300mg tablet 30	75,338	71,565		64,367	24,612
Lopinavir/Ritonavir 200/50 mg Tablet, 120 Tablets	46,193	28,393		21,258	48,945
Lopinavir/Ritonavir 40/10 mg Granules	15,924	22,765		41,097	23,497
Lopinavir/Ritonavir 40/10 mg Pellets					
Nevirapine 10mg/ml oral suspension 100ml		22,765		14,532	
Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets		101,491	123,201		161,973
Lopinavir/Ritonavir 100/25 mg Tablet, 60 Tablets	840			33,685	43,625
Atazanavir/Ritonavir 300/100 mg Tablet, 30 Tablets	2,463	233,818	210,221	139,334	229,836
Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets	38,901	177,515	144,167		302,864
Dolutegravir 50 mg Tablet, 30 Tablets	160,200		224,809	109,997	106,930
Dolutegravir 50 mg Tablet, 90 Tablets					
Abacavir/Lamivudine 600/300mg tablet 30	3,194		66,980	39,973	162,140
Abacavir/Lamivudine 120/60mg, dispersible, 30 Tablets	329,562	222,361	303,127	37,356	314,243

THANK YOU!!!

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Global Fund update and priorities. Antiretroviral Large Buyers and Sellers Forum 2020

12 - 15 OCTOBER 2020

The Global Fund

Key contacts here today

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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:

- 20.1 million people on antiretroviral therapy for HIV. Coverage increased from 48% in 2015 to 67% in 2019. Global target: 81% by 2020.
- 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: 1st & 2nd line
- Better formulations for children-granules, dispersible tabs
- Price reductions for 1st 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

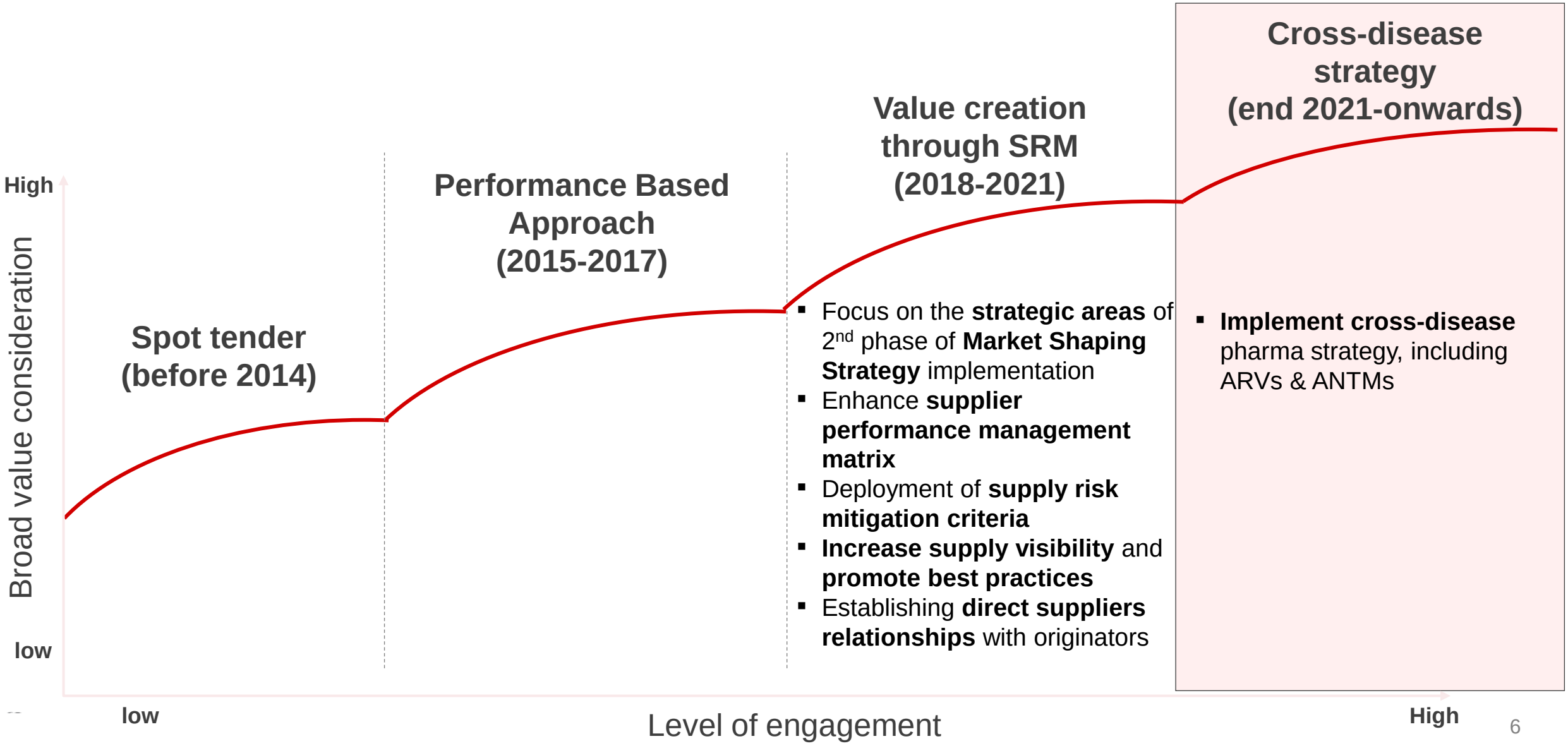
Increased Engagement: with other large buyers, partners and other Global Fund procurement channels

- 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



Leveraging impact through increased partner collaboration

USAID FROM THE AMERICAN PEOPLE

PAHO STRATEGIC FUND

The Global Fund

Unitaid

Partnership

- 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

Added value

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

Economy of scale

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

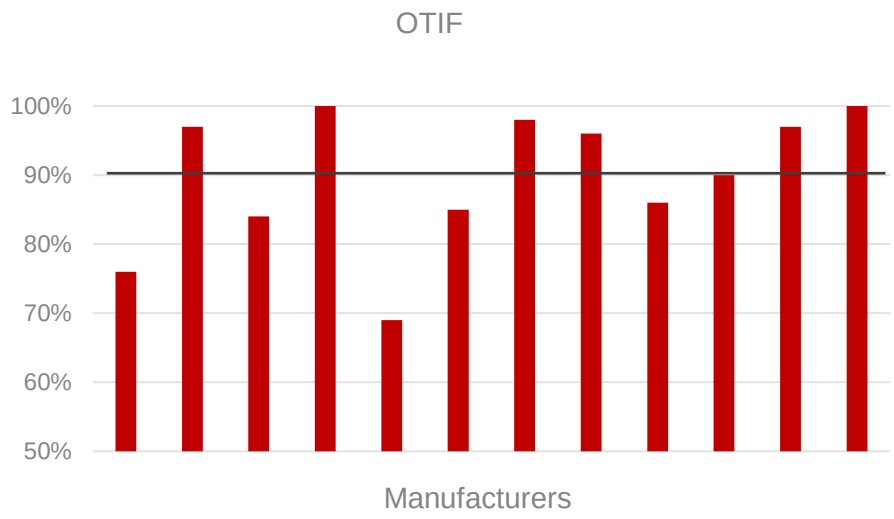
Effectiveness

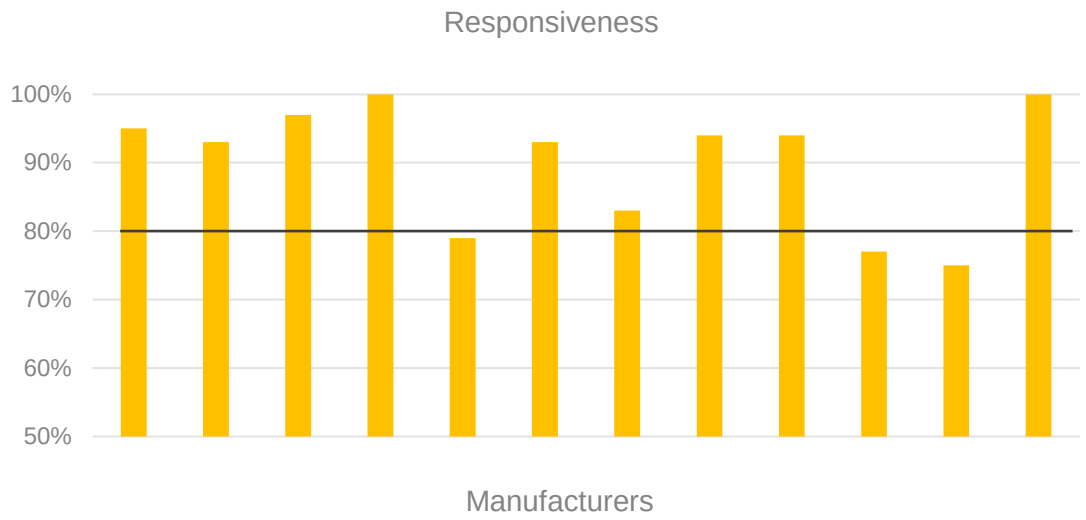
- ✓ Contract Supplier Management
- ✓ Harmonize Quality Standards & Quality Assurance
- ✓ Transparency in tendering process
- ✓ Smoothen product transition

2020 supplier performance at the end of Q3

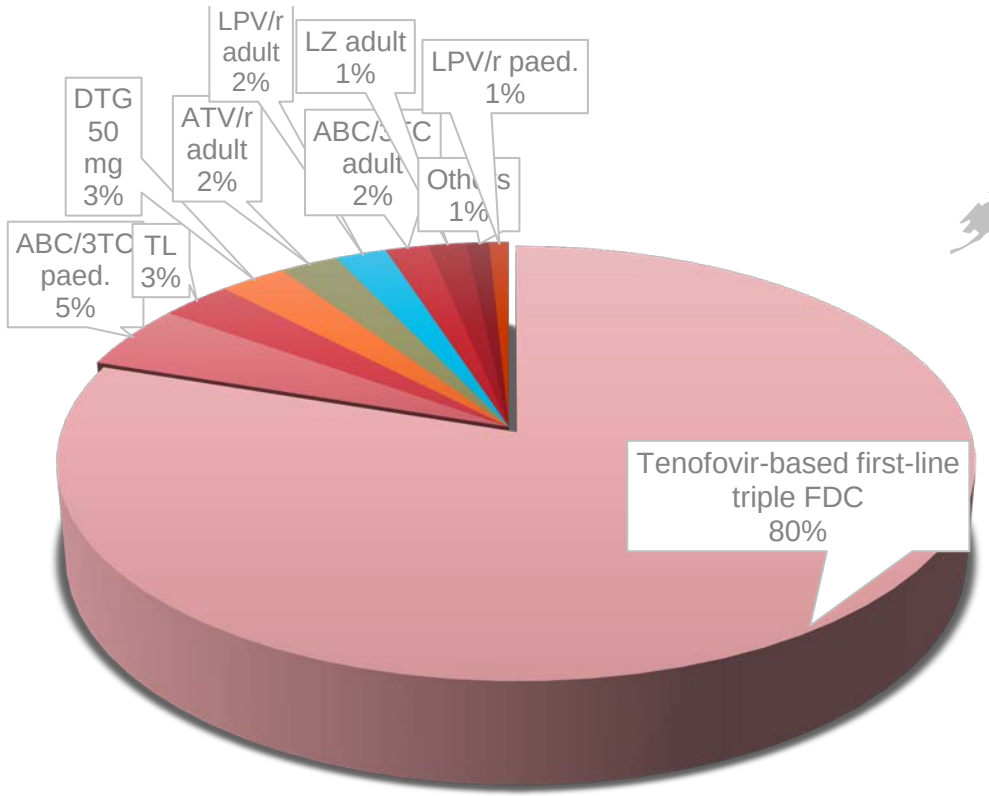
- TGF ARV Strategy includes active supplier performance management with a greater focus on
  - Supply security
  - OTIF (on-time-in-full delivery)
  - Responsiveness-longer lead-times are factored in OTIF performance and responsiveness
  - Shorter lead-times
  - VMI (Vendor Managed Inventory)
  - Stock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

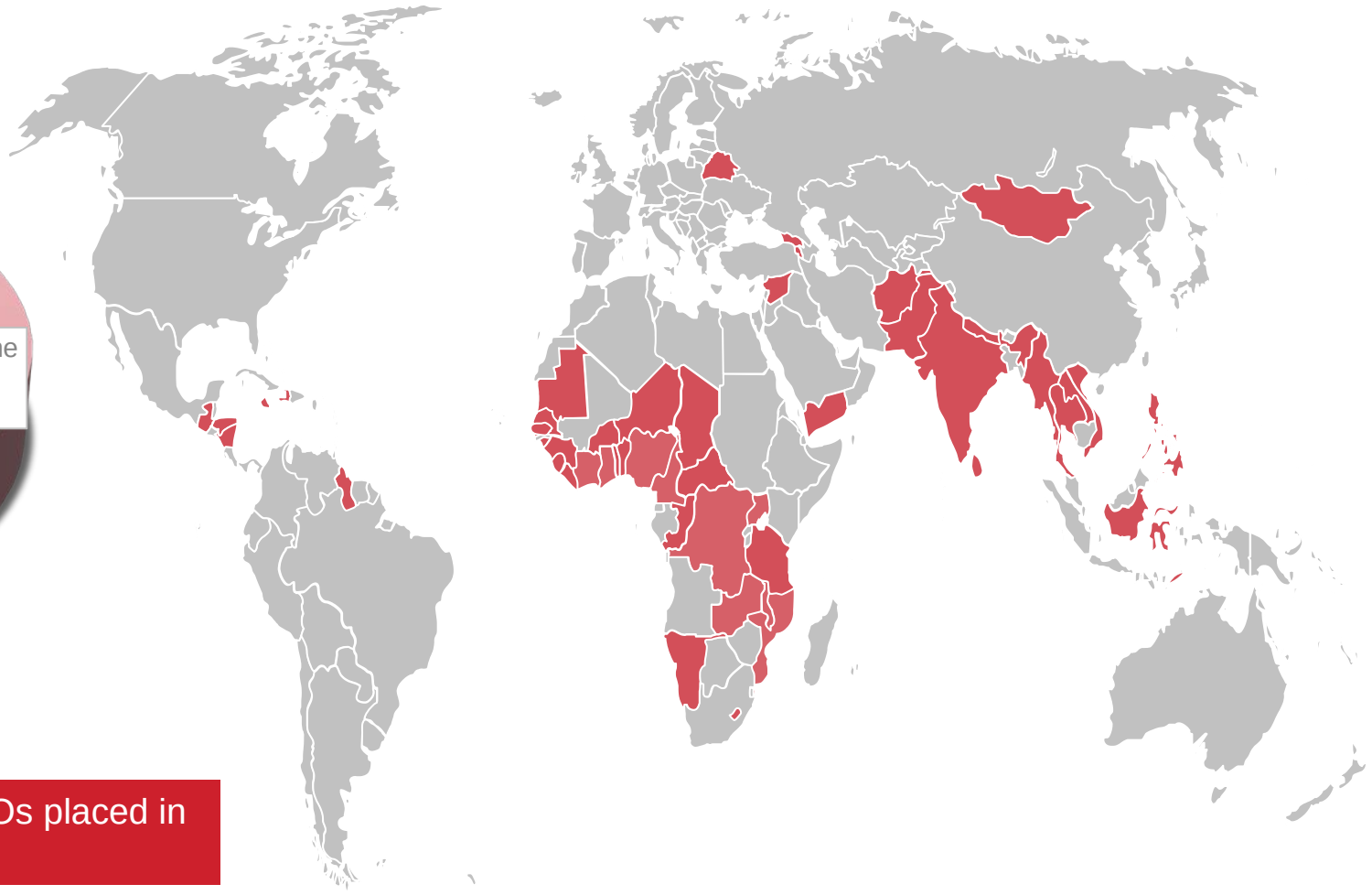
Supplier OTIF (on-time-in-full delivery) with target 90% and **responsiveness** (target 80%)





55 million monthly ARV* packs estimated for 2021 delivery through GF PPM





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

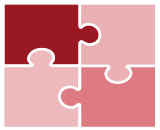
*more detailed forecast for 2021 will be published in November 2021

Afghanistan, Armenia, Belarus, Benin, Burkina Faso, Cote d'Ivoire, Cameroon, Cape Verde, Central African Republic, Chad, Comoros. Congo, Congo DRC, Fiji, Gambia, Georgia, Ghana, Guatemala, Guinea, Guyana, Haiti, Honduras, Indonesia, Jamaica, Laos, Lesotho, Liberia, Malawi, Mali, Mauritania, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Nicaragua, Niger, Nigeria, Pakistan. Philippines, Senegal, Sierra Leone, Sri Lanka, Syrian Arab Republic, Tanzania, Thailand, Timor-Leste, Togo, Uganda, Vietnam, Yemen, Zambia

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

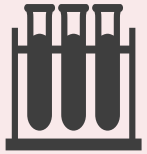
New grant making and implementation: ensuring a smooth transition from 3 year grants that end this year to the new 3 year grants being finalized for implementation starting early next year

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

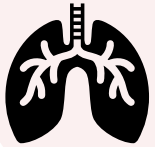
In-scope products:
Approved therapeutics (e.g., Dexamethasone)

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

More information: https://www.theglobalfund.org/en/sourcing-management/health-products/antiretrovirals/

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.

4.6 MILLION

PEOPLE RECEIVING ARV TREATMENT PROCURED THROUGH THE POOLED PROCUREMENT MECHANISM IN 2019

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

USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

34 Country/Regional Offices

3 Regional Distribution Centers

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.

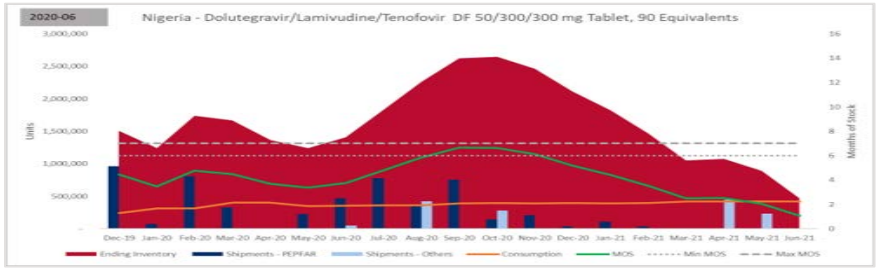
In Q3, 9 countries procured **2.8 million viral-load tests** to support scale-up of patient viral-load testing, while viral-load and early infant diagnosis contracts have generated **$6.2 million in savings** in Q3.

Greater use of data enabled early risk identification and risk mitigation

Product	Commited GAD	Estimated GAD	Current GAD	Difference Estimated vs Current	Reason for Delay	Delay Description
Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets	9/25/2020	9/25/2020	9/6/2020	-19	Not Applicable	Order will be ahead of schedule
Lamivudine/Zidovudine 150/300 mg Tablet, 60 Tablets	7/7/2020	7/7/2020	9/21/2020	76	Supplier/Manufa	Zidovudine API challenge
Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets	7/13/2020	7/2/2020	7/2/2020	0	Not Applicable	No change
Emtricitabine/Tenofovir DF 200/300 mg Tablet, 30 Tablets	3/10/2020	3/31/2020	3/31/2020	0	Not Applicable	No change
Abacavir/Lamivudine 600/300 mg Tablet, 30 Tablets	5/15/2020	5/15/2020	5/15/2020	0	Not Applicable	No change
Abacavir/Lamivudine 600/300 mg Tablet, 30 Tablets	8/15/2020	8/15/2020	8/30/2020	15	Supplier/Manufa	QA Release Delay
Abacavir/Lamivudine 600/300 mg Tablet, 30 Tablets	3/15/2020	4/15/2020	5/15/2020	30	Supplier/Manufa	Delay to plant closure for COVID
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 180 Tablets	3/31/2020	3/31/2020	5/20/2020	50	Supplier/Manufa	Delay to plant closure for COVID
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 180 Tablets	3/31/2020	3/31/2020	5/15/2020	45	Supplier/Manufa	Delay to plant closure for COVID
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets	3/5/2020	3/5/2020	6/5/2020	92	Supplier/Manufa	Delay to plant closure for COVID
Dolutegravir/Lamivudine/Tenofovir DF 50/300/300 mg Tablet, 90 Tablets	3/5/2020	3/5/2020	6/5/2020	92	Supplier/Manufa	Delay to plant closure for COVID
Lamivudine 10 mg/mL Solution w/ Syringe, 240 mL	4/7/2020	4/7/2020	6/10/2020	64	Supplier/Manufa	Delay to plant closure for COVID
Lamivudine/Tenofovir DF 300/300 mg Tablet, 30 Tablets	3/20/2020	3/20/2020	6/15/2020	87	PSM Request	GAD pushed due to country shutdown (COVID)

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.

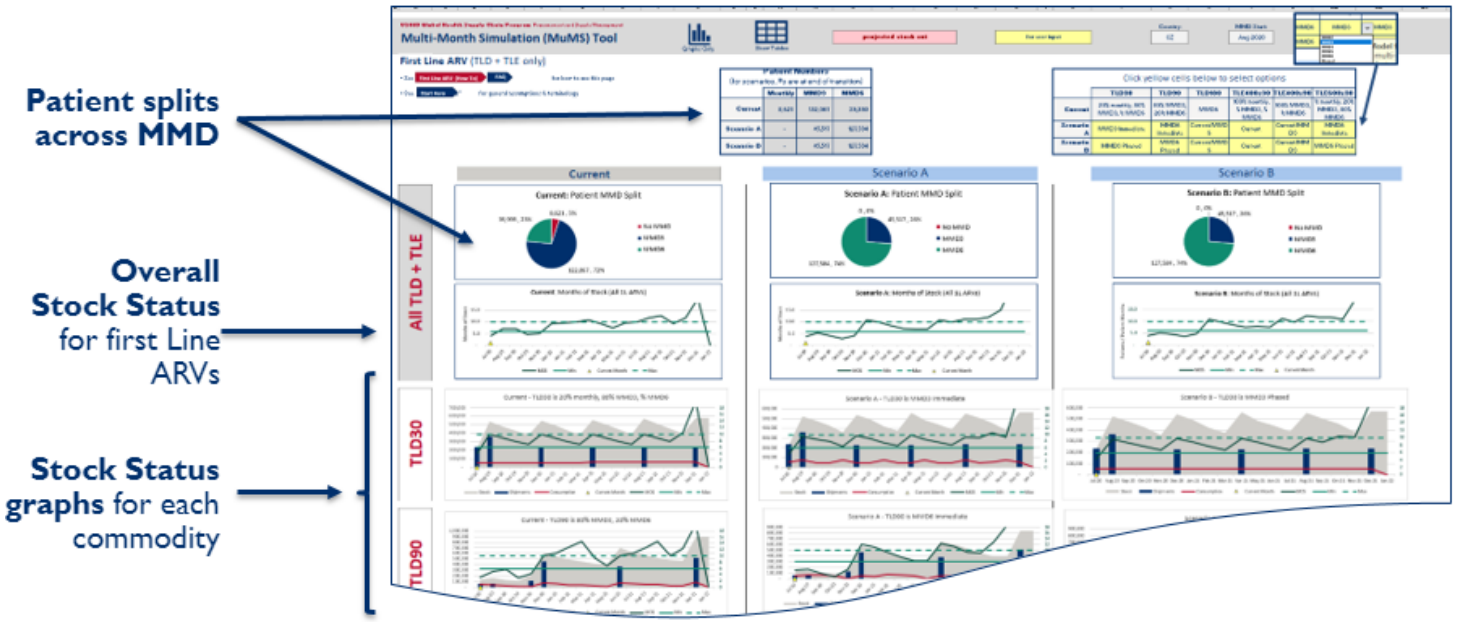
LOGISTICS MILESTONE TRACKER

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 (MuMS) Tool

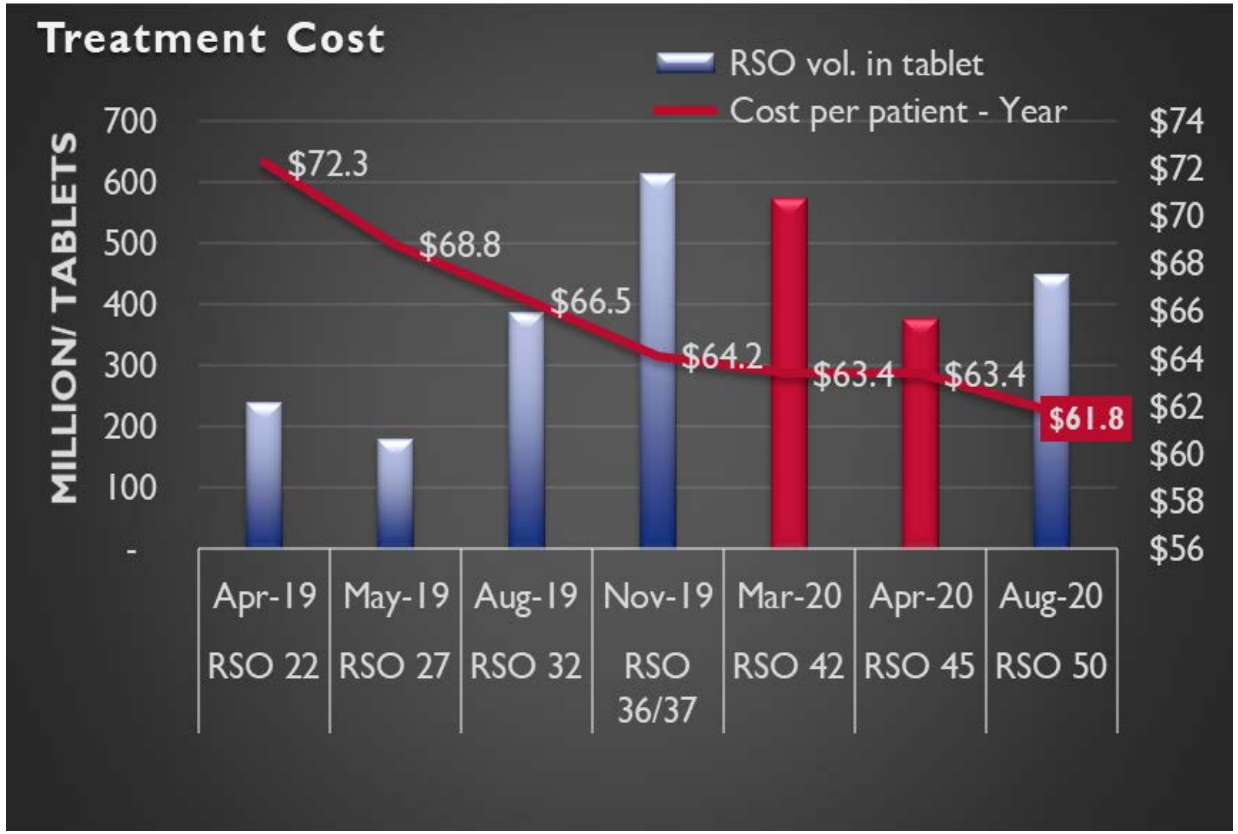
Tool Outputs



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



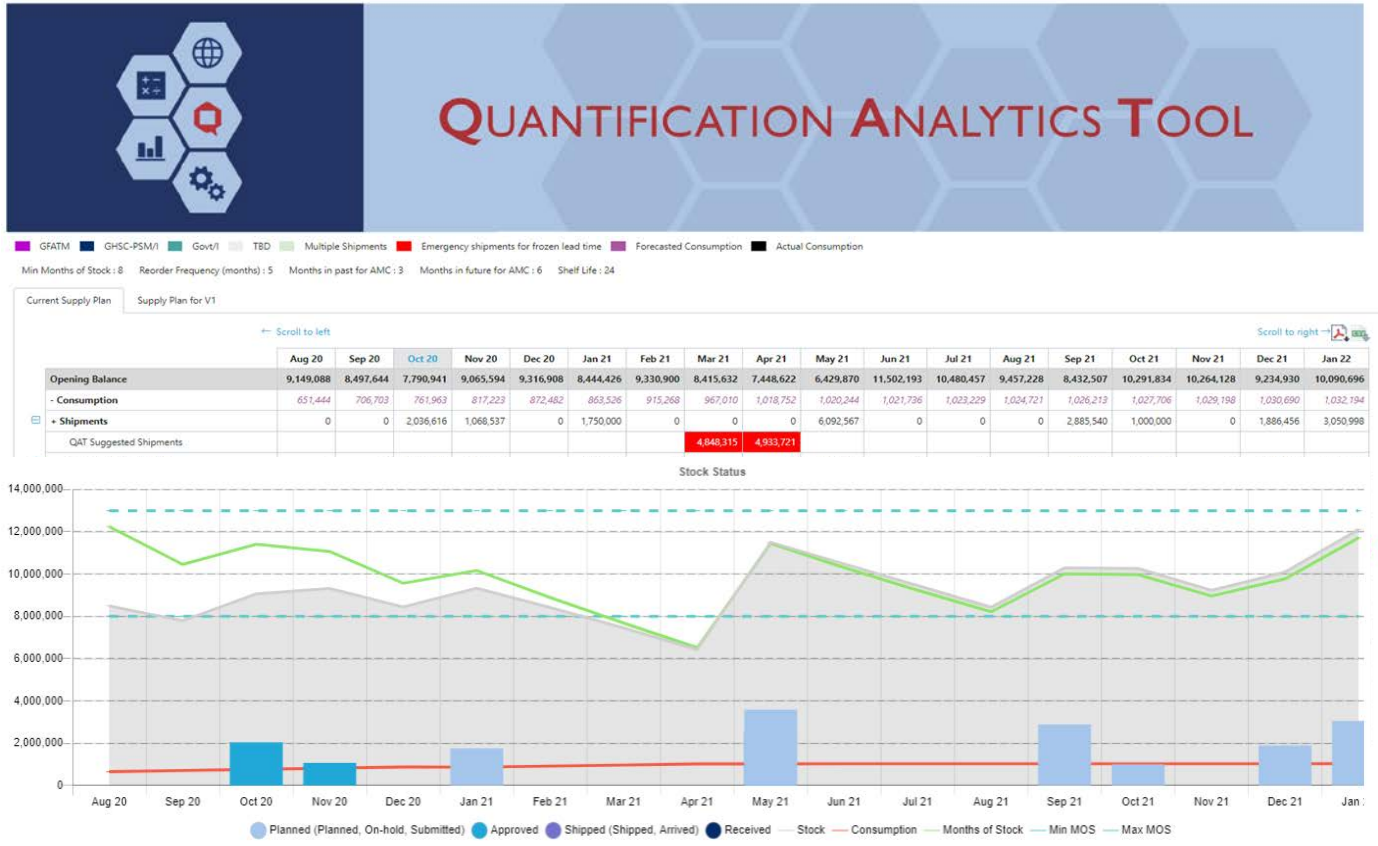
SUPPLIERS RECEIVED ADDITIONAL FIRM ORDERS TO SECURE SUPPLIES AND TOP UP SUPPLY NATIONAL SUPPLY CHAINS

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.

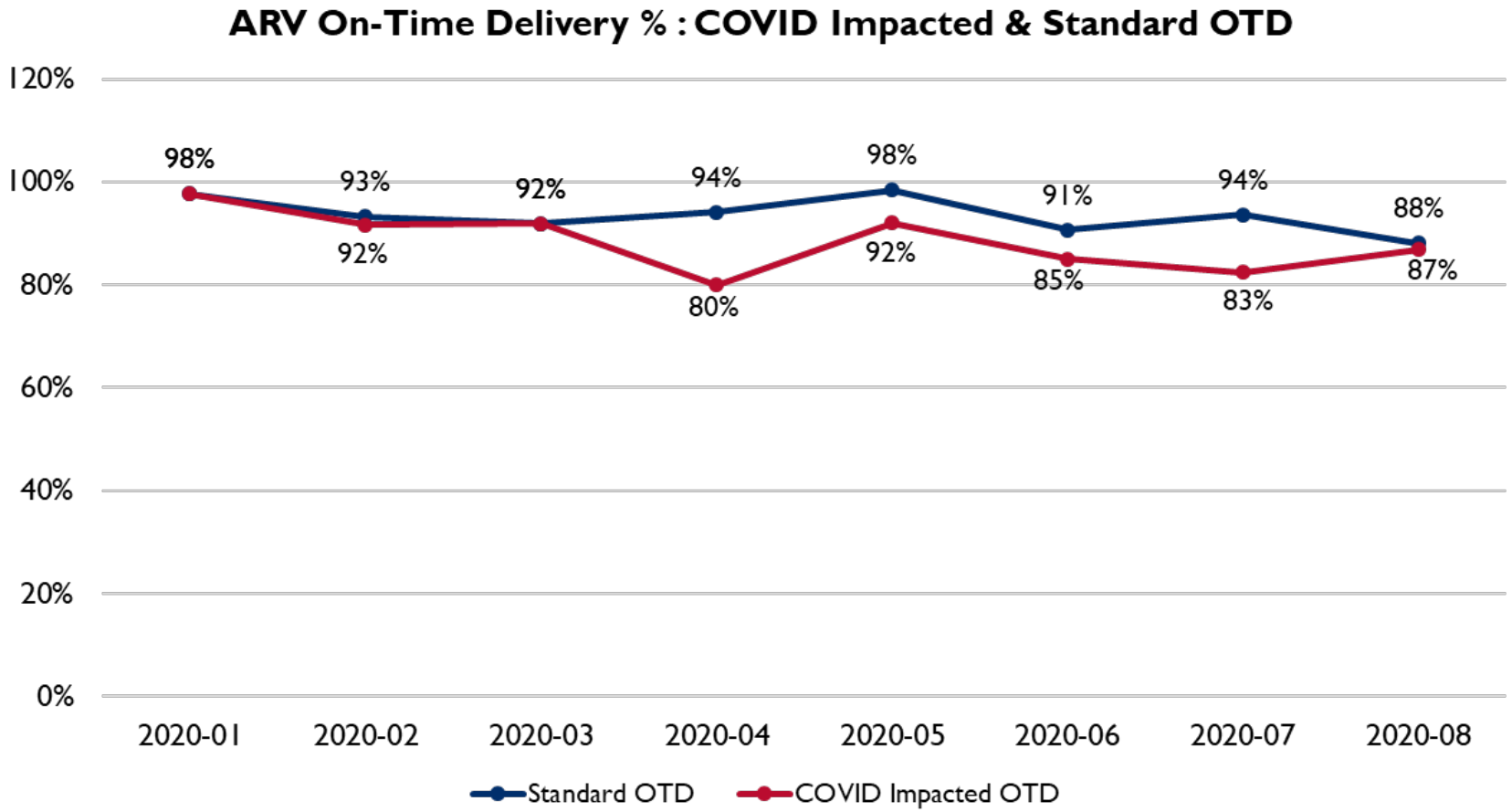
Upcoming release

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



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

2. Chahal HS *et al. An Evaluation of US Food and Drug Administration's Program to Register HIV Drugs for Use in Resource-Constrained Settings*, JAMA Network Open. 2019;2(11):e1915787.doi:10.1001/jamanetworkopen.2019.15787

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

U.S. FOOD & DRUG ADMINISTRATION

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

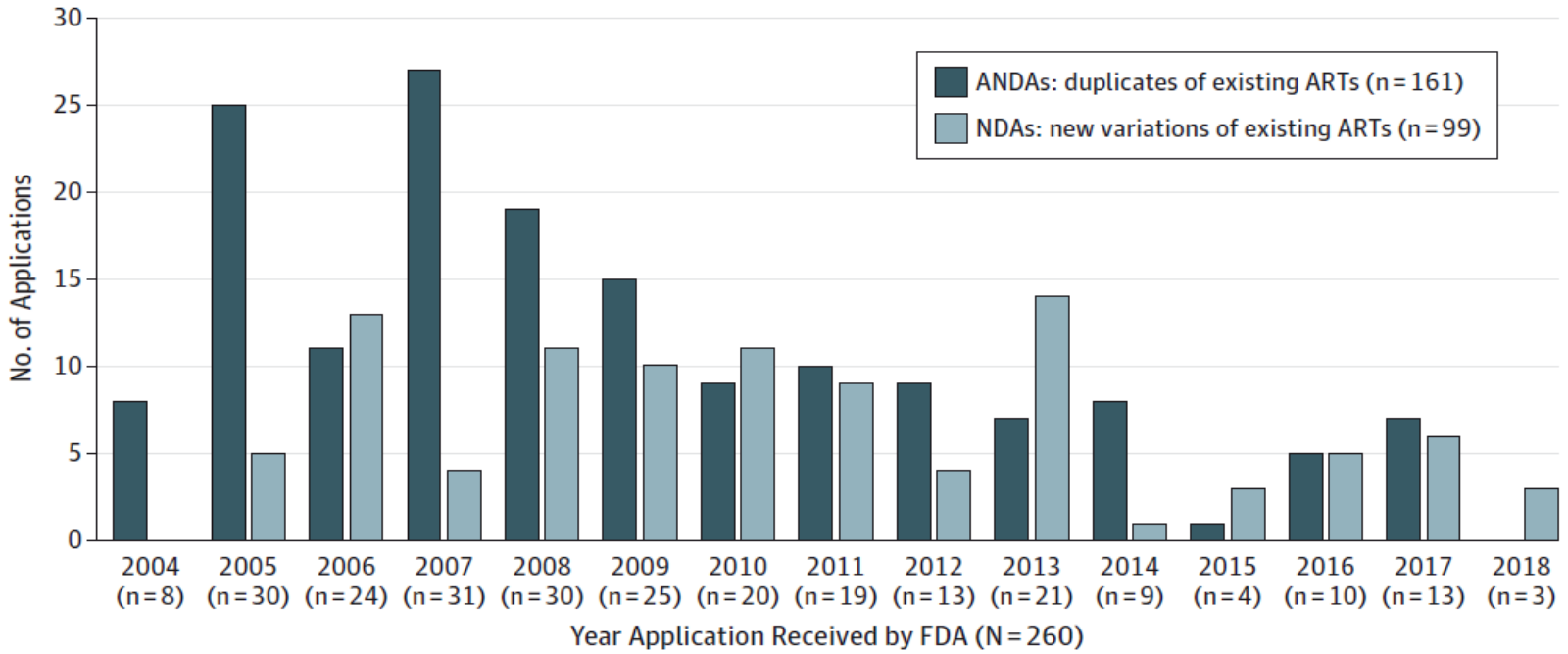
- Inclusion Criteria:
  - Registered for PEPFAR use
  - Received CRL
  - Withdrawn after registration or CRL
  - Pending status
- Exclusion Criteria:
  - Withdrawn or canceled before any regulatory action*
  - Review process unbegun
  - Refuse-to-file applications

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

Figure 1. US President's Emergency Plan for AIDS Relief Applications Submitted to the US Food and Drug Administration (FDA) Since 2004, by Application Type



The data for 2018 are partial, up to May 2018. Applications are shown regardless of current regulatory status. ANDA indicates Abbreviated New Drug Application; ART, antiretroviral therapy; and NDA, New Drug Application.

Source: Chahal HS *et al.* JAMA Network Open. 2019;2(11):e1915787.doi:10.1001/jamanetworkopen.2019.15787

- 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)

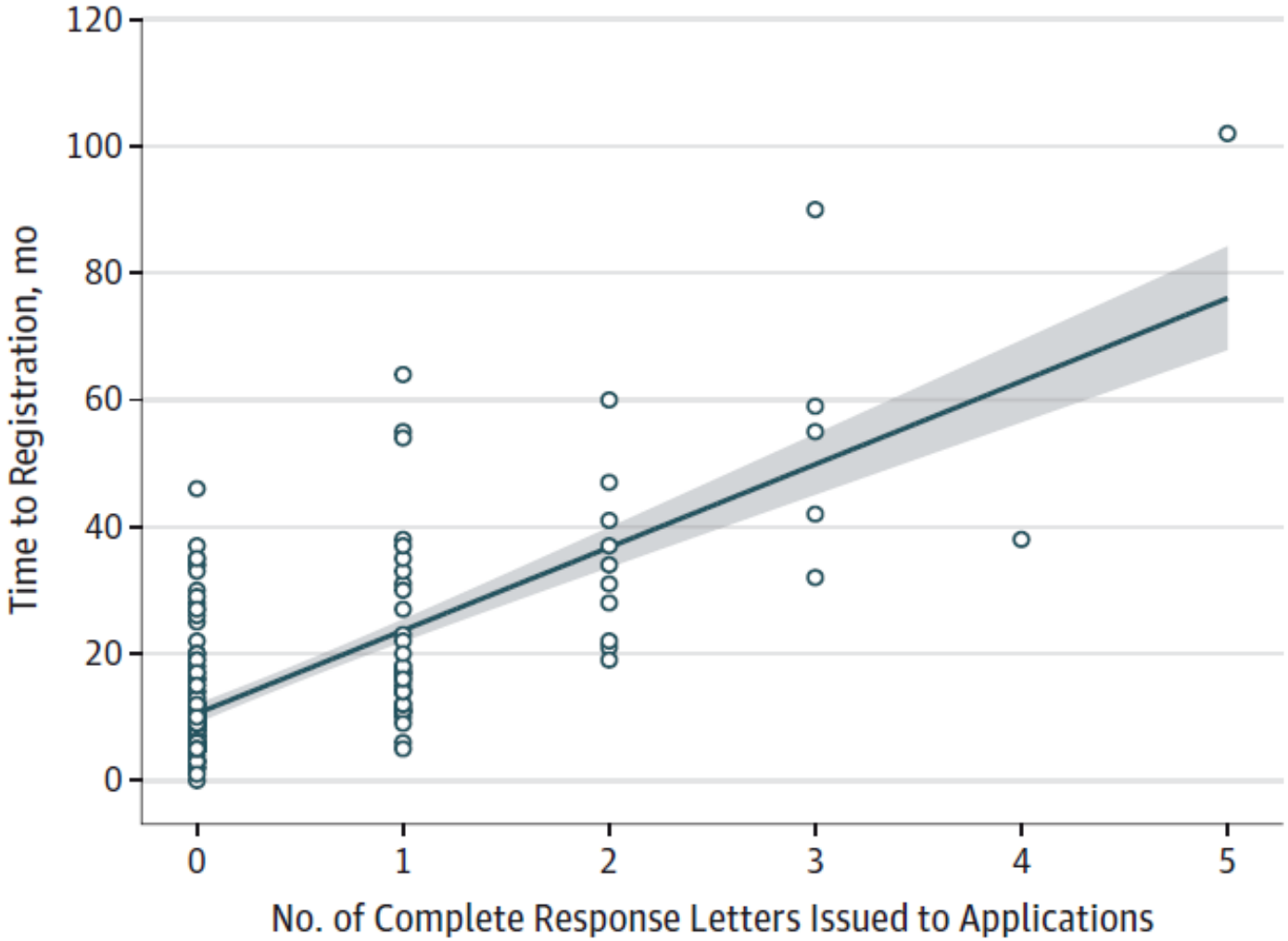
Variable	CRL Reasons, No. (%) 1 CRL	2 CRLs	3 CRLs	4 CRLs	5 CRLs	6 CRLs	Total Reasons for CRLs
Reasons for issuing a CRL							
Manufacturing and chemistry	67 (44)	23 (37)	15 (60)	5 (45)	4 (40)	1 (33)	115 (44)
Labeling	36 (24)	18 (29)	4 (16)	1 (9)	2 (20)	1 (33)	62 (23)
Facility inspection	24 (16)	18 (29)	4 (16)	5 (45)	3 (30)	NA	54 (20)
Bioequivalence	18 (12)	3 (5)	2 (8)	NA	NA	NA	23 (9)
Biopharmaceutics	6 (4)	NA	NA	NA	NA	NA	6 (2)
Missing facility	1 (1)	NA	NA	NA	NA	NA	1 (<1)
Packaging	1 (1)	NA	NA	NA	NA	NA	1 (<1)
Risk evaluation and mitigation strategy[d]	NA	NA	NA	NA	1 (10)	1 (33)	2 (1)
Total	153 (59)[c]	62 (24)[c]	25 (10)[c]	11 (4)[c]	10 (4)[c]	3 (3)[c]	264 (100)

Source: Chahal HS *et al.* JAMA Network Open. 2019;2(11):e1915787.doi:10.1001/jamanetworkopen.2019.15787

- 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

Findings: Association of CRLs on Time to Registration

Figure 3. Complete Response Letters Issued to Applications



- 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.

Source: Chahal HS *et al.* JAMA Network Open. 2019;2(11):e1915787.doi:10.1001/jamanetworkopen.2019.15787

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

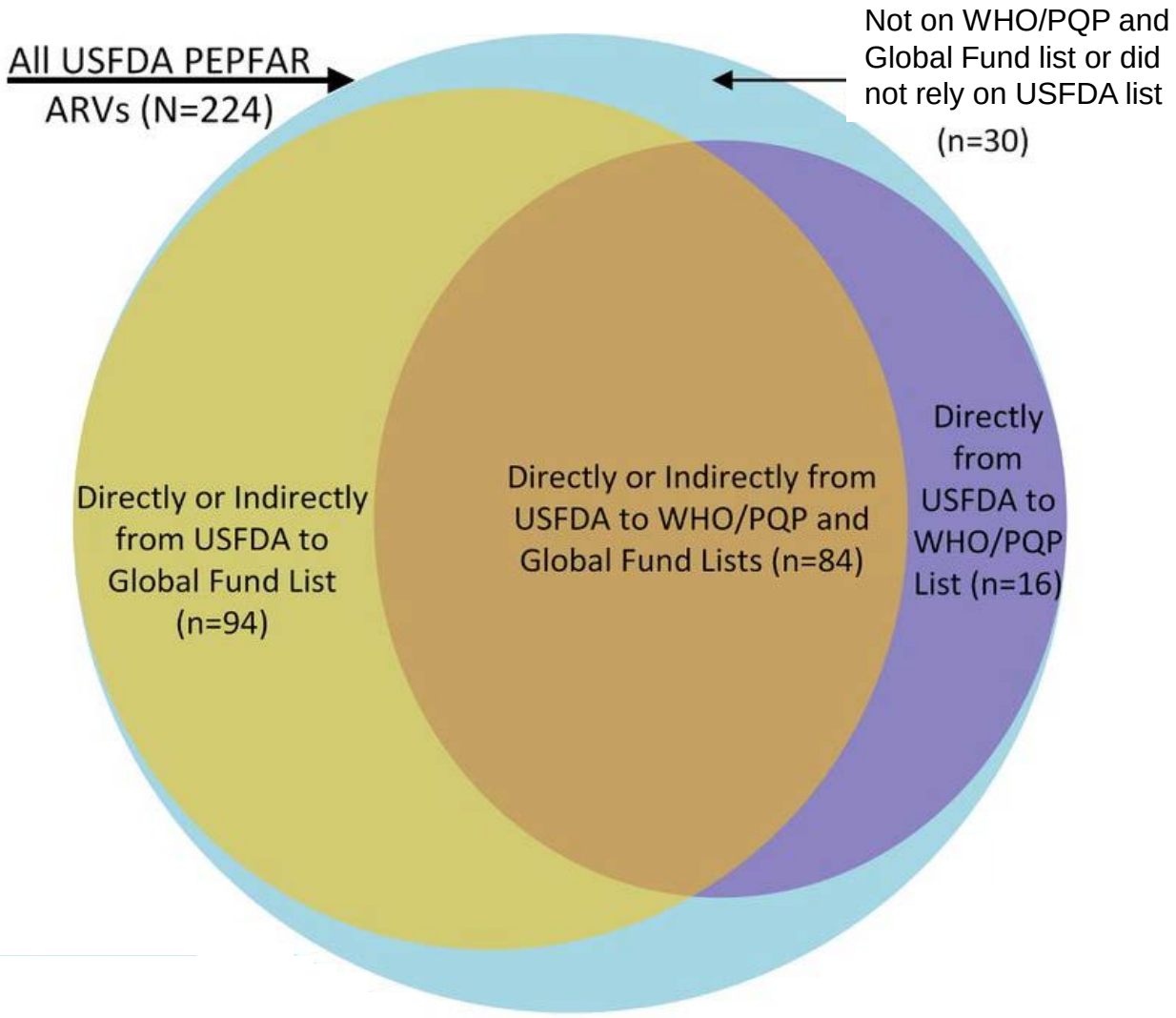
Part 2 Methods: Impact of FDA-reviewed PEPFAR products on global access

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

- Inclusion Criteria
  - Registered for PEPFAR use and in active status
- Exclusion Criteria:
  - Withdrawn or rescinded after registration

- 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

Source: Chahal HS *et al. BMJ Global Health* 2018;**3:**e000651.

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 (https://www.fda.gov/news-events/fda-brief/fda-brief-fda-announces-pilot-program-world-health-organization-expedite-review-hiv-drug)


U.S. FOOD & DRUG ADMINISTRATION

Home / News & Events / FDA Newsroom / FDA In Brief / FDA In Brief: FDA announces pilot program with World Health Organization to expedite review of HIV drug applications

FDA In Brief: FDA announces pilot program with World Health Organization to expedite review of HIV drug applications

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November 30, 2018

Media Inquiries

Alison Hunt
240-402-0764

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

2. Chahal HS *et al. An Evaluation of US Food and Drug Administration's Program to Register HIV Drugs for Use in Resource-Constrained Settings*, JAMA Network Open. 2019;2(11):e1915787.doi:10.1001/jamanetworkopen.2019.15787

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Pediatric Treatment and Infant Prophylaxis

World Health Organization

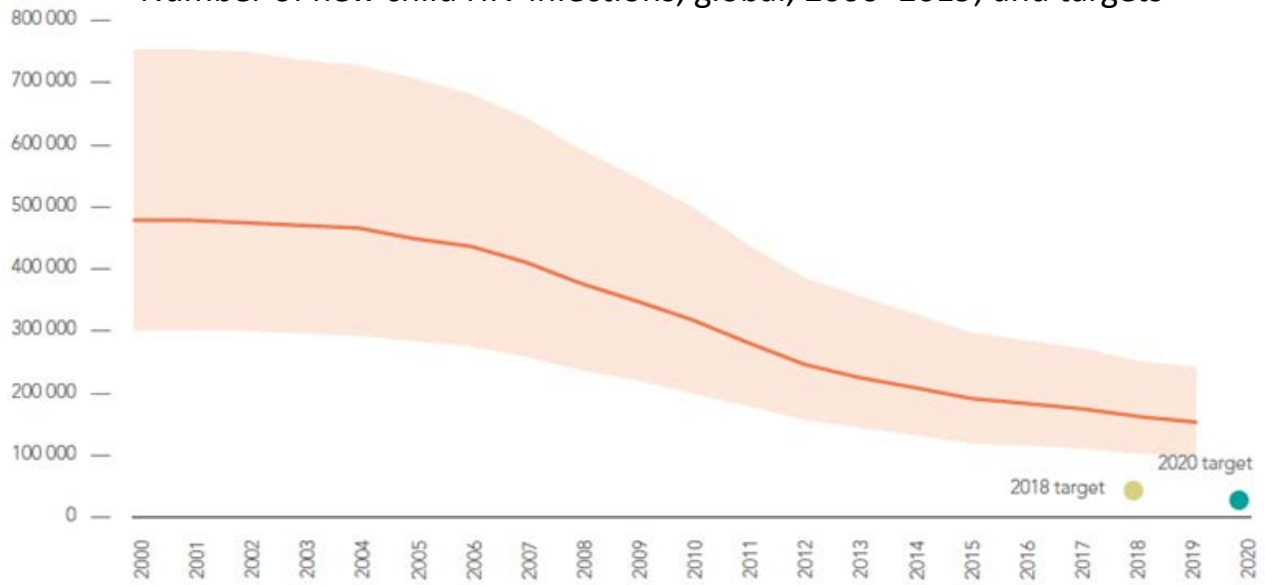
Martina Penazzato MD, MSc, PhD
Paediatric HIV lead, WHO-HQ Geneva

Presentation outline

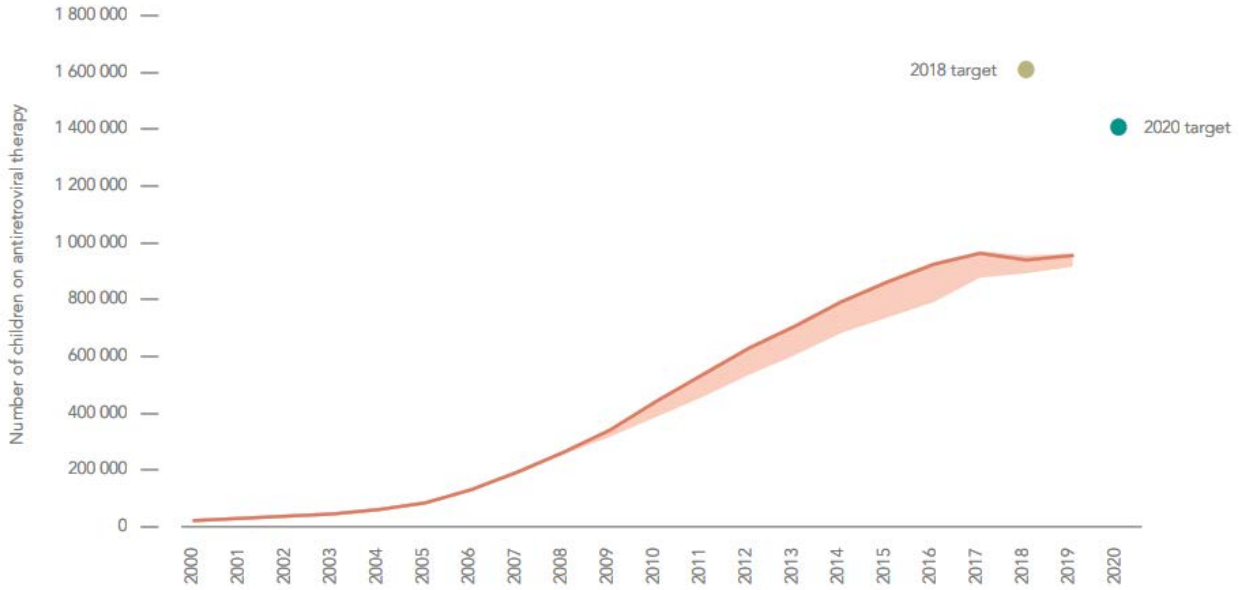
- Background
- Treatment guidelines and introduction of new formulations
- Postnatal prophylaxis
- Priority pediatric formulations

2016-2020 strategy had two commitments for children: We missed them both

Number of new child HIV infections, global, 2000–2019, and targets



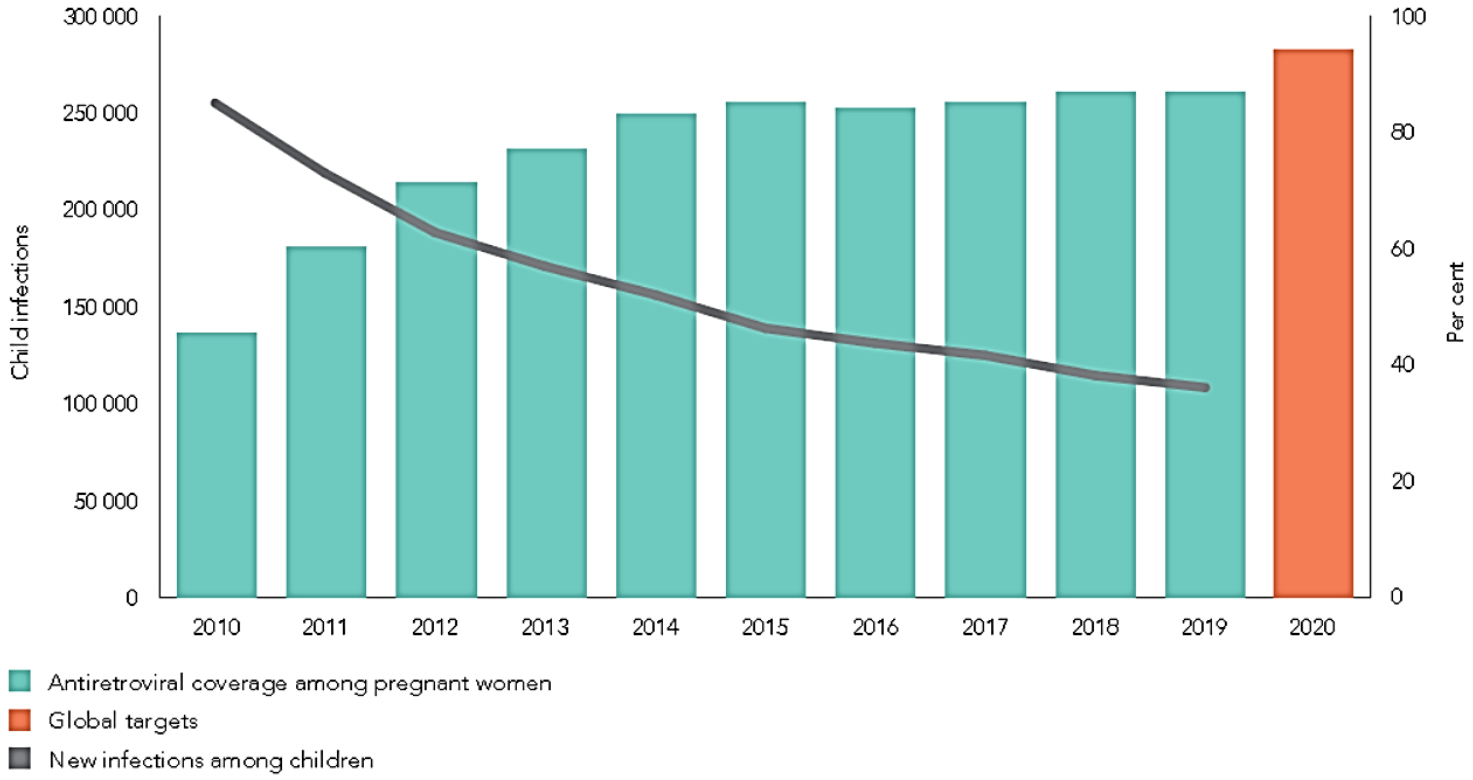
Number of children accessing antiretroviral therapy, global, 2000–2019 and targets



Source: UNAIDS epidemiological estimates, 2020 (see https://aidsinfo.unaids.org/); UNAIDS Global AIDS Monitoring, 2020 (see https://aidsinfo.unaids.org/).

Despite high levels of PMTCT coverage new child infections persist

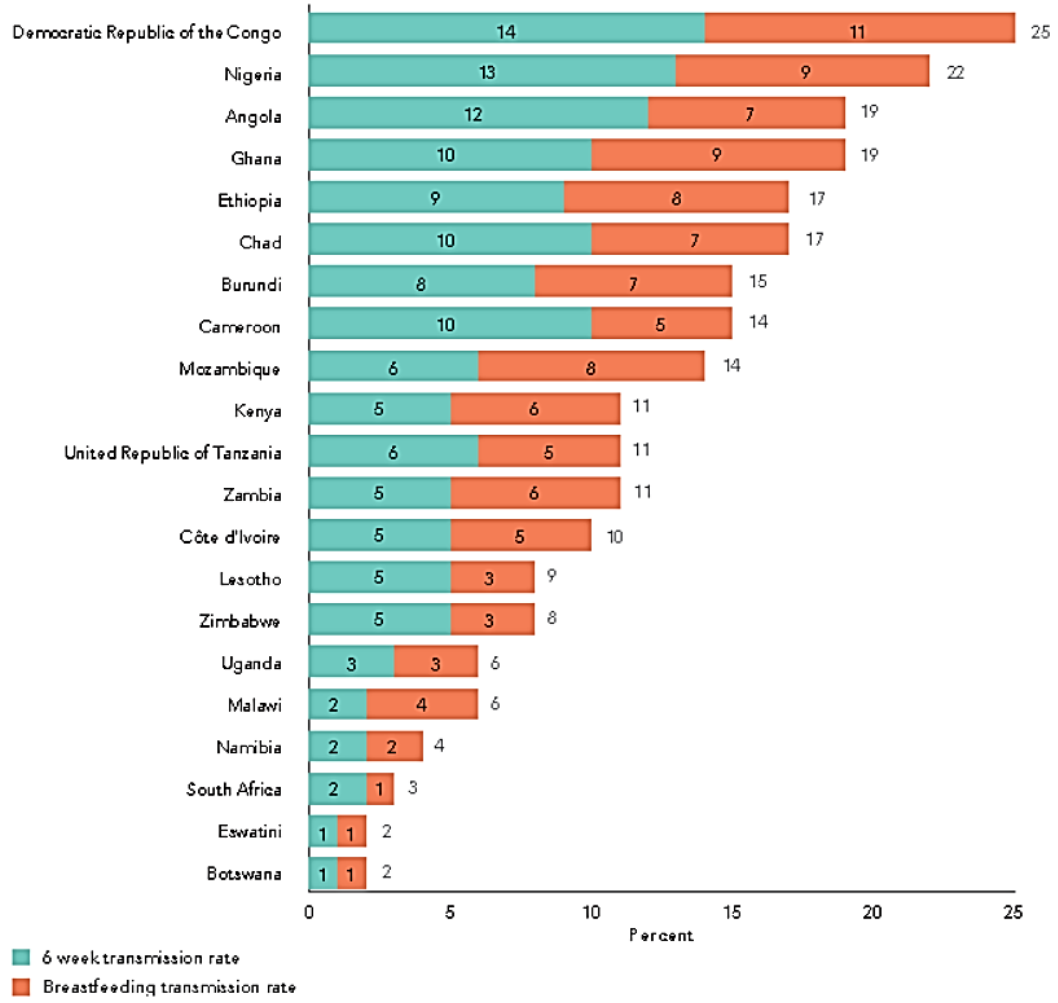
Figure 2. Percentage coverage of pregnant women reached with antiretroviral therapy and number of children acquiring HIV, focus countries, 2010–2019



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

Figure 4. Six-week vertical transmission rate and final transmission rate in the focus countries, 2019

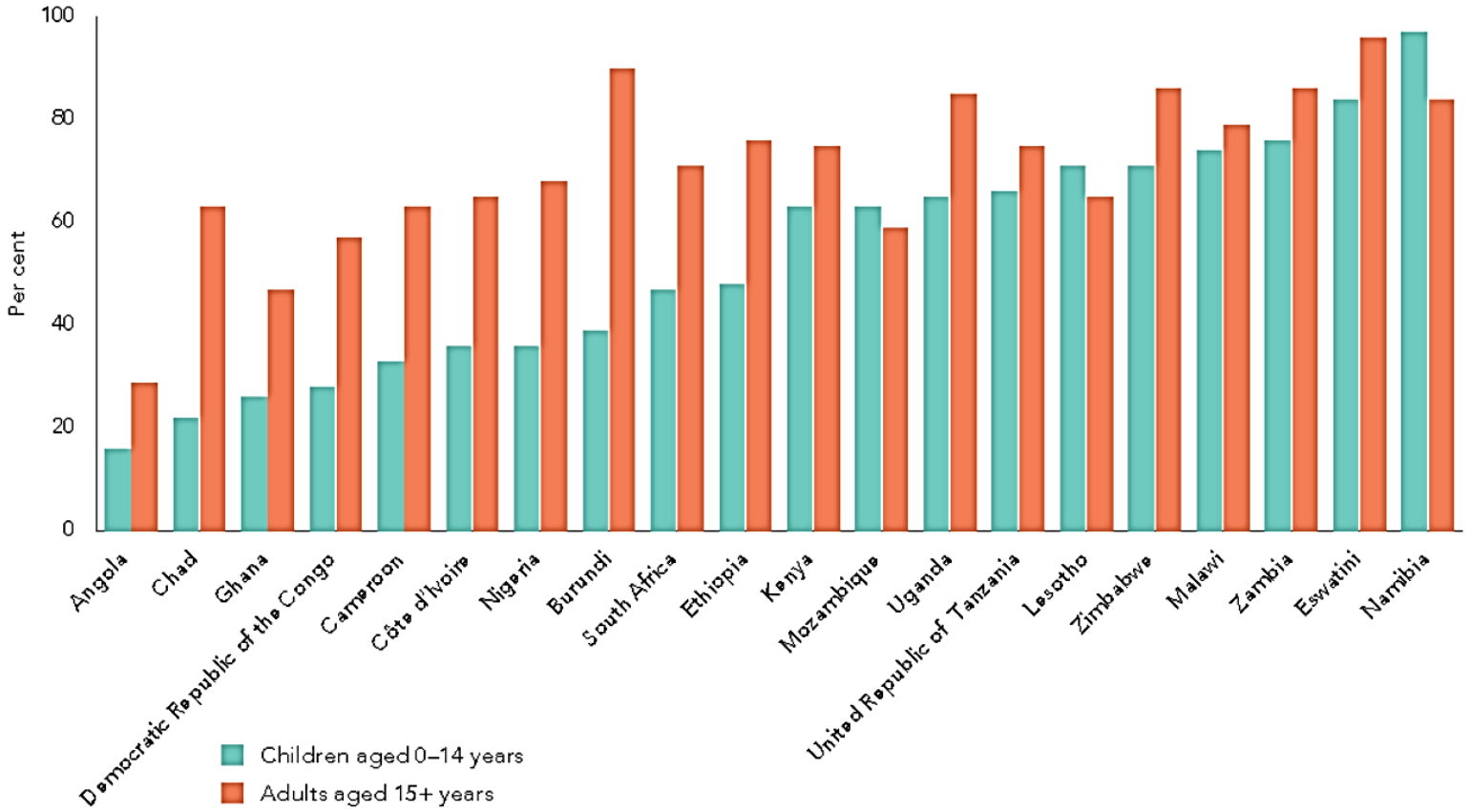


Source: UNAIDS epidemiological estimates, 2020.

About 50% of new infections are during breastfeeding

Pediatric ART is still far behind adult coverage in 17 of 20 focus countries

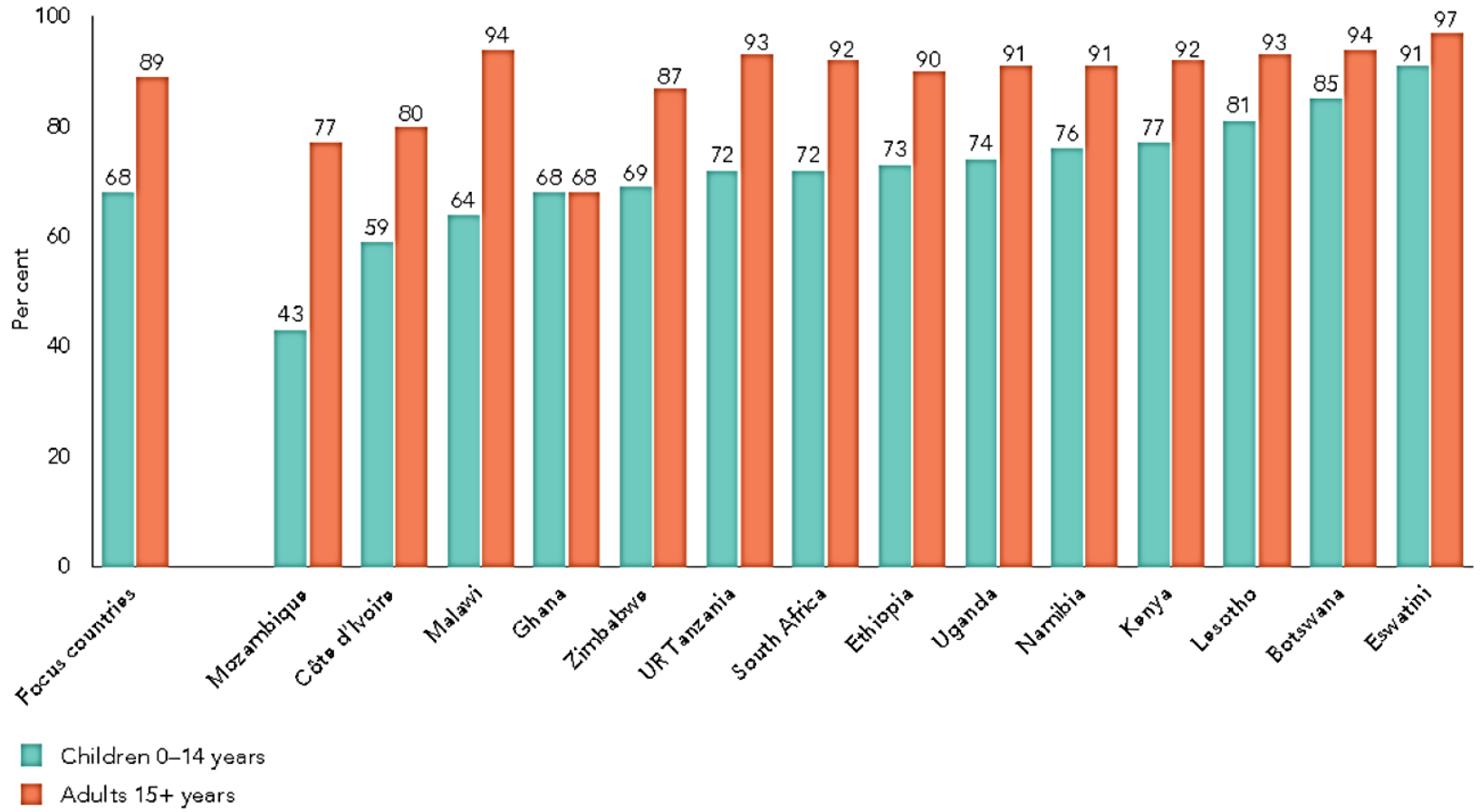
Figure 9. Antiretroviral therapy coverage among people aged 0–14 and 15+ years for 20 focus countries, 2019



Data for Botswana were not available at the time of publication.
Source: UNAIDS epidemiological estimates, 2020.

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



Source: UNAIDS epidemiological estimates, 2020.

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

Country	Dolutegravir first line for children ≥20 kg	Lopinavir first line for children <20 kg	Multi-month dispensing, 3 or 6 months	Point-of-care early infant diagnosis policy	Virological testing at nine months
Angola	√	√	√	√	√
Botswana	√	√	*	x	Partial
Burundi	√	*	√	x	*
Cameroon	√	√	>2 years	√	√
Chad	√	√	*	√	Partial
Côte d'Ivoire	√	√	√	√	Partial
Democratic Republic of the Congo	√	√	√	√	√
Eswatini	√	√	>2 years	√	√
Ethiopia	√	√	√	√	√
Ghana	√	√	*	√	√
Kenya	√	√	√	√	√
Lesotho	√	√	√	√	√
Malawi	√	√	√	√	√
Mozambique	√	√	>2 years	√	√
Namibia	√	√	√	x	√
Nigeria	√	√	*	x	√
South Africa	√	√	>5 years	x	√
United Republic of Tanzania	√	√	>5 years	√	√
Uganda	√	√	*	√	√
Zambia	√	√	>2 years	√	√
Zimbabwe	√	√	√	√	√

* not available
Source: UNAIDS National Commitments and Policy Instrument, 2020 (see http://lawsandpolicies.unaids.org/) and supplemented with data submitted to the World Health Organization.

Treatment

WHO 2018 recommendations and guidance

Move away from NNRTI-based regimens

Introduce DTG as soon as possible

Use the most potent non-NNRTI option

	NEONATES	CHILDREN
Preferred	AZT+3TC+RAL[1]	**ABC+3TC+DTG[2]**
Alternatives	AZT+3TC+NVP	**ABC+3TC+LPV/r** ABC+3TC+RAL[1]
Special circumstances[3]	AZT+3TC+LPV/r	ABC (or AZT)+3TC+EFV ABC (or AZT)+3TC+RAL AZT+3TC+LPV/r AZT+3TC+RAL AZT+3TC+NVP

[1] For the shortest time possible, until a solid formulation of LPV/r or DTG can be used

[2] **For age and weight groups with DTG approved dosing (50 mg adult tablet from 20 kg TLD can be used in adolescents weighting more than 30 kg)**
and where LPV/r is not available

[3] In cases where no other alternatives are available

World Health Organization

POLICY BRIEF – JULY 2020

CONSIDERATIONS FOR INTRODUCING NEW ANTIRETROVIRAL DRUG FORMULATIONS FOR CHILDREN

World Health Organization · CLINTON HEALTH ACCESS INITIATIVE · Elizabeth Glaser Pediatric AIDS Foundation · 15 ICAP · medicines patent pool · unicef · DNDi · MÉDECINS SANS FRONTIÈRES · Unitaid

Dosing of optimal pediatric ARVs

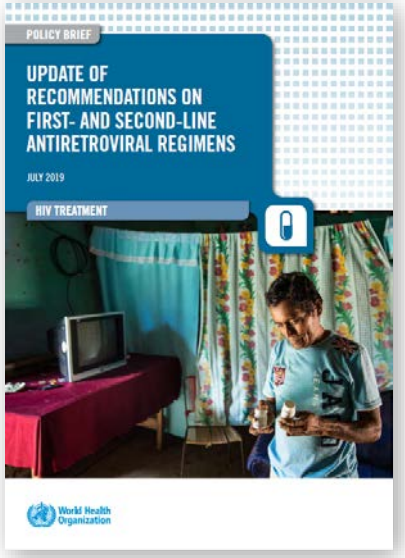
Formulation	3–5.9 kg		6–9.9 kg		10–13.9 kg		14–19.9 kg		20–24.9 kg		25–29.9 kg		≥30 kg	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
ABC/3TC 120/60 mg scored dispersible tablet	1		1.5		2		2.5		3		1 adult tab (600/300 mg)		1 adult tab (600/300 mg)	
LPV/r 40/10 mg pellets (capsules)	2	2	3	3	4	4	5	5	6	6	–		–	
LPV/r 40/10 mg granules (sachets)	2	2	3	3	4	4	5	5	6	6	–		–	
LPV/r 100/25 mg tablets	–	–	–	–	2	1	2	2	2	2	3	3	3	3
4-in-1 ABC/3TC/LPV/r 30/15/40/10 mg (capsules)	2	2	3	3	4	4	5	5	6	6	–	–	–	–
DTG 5 mg dispersible tablets*	1		3		4		5		–		–		–	
DTG 10 mg scored dispersible tablet	0.5		1.5		2		2.5		–		–		–	
DTG 50 mg tablet	–		–		–		–		1		1		1	
TDF/3TC (or FTC)/DTG 300/300 (or 200)/50 mg tablet	–		–		–		–		–		–		1	

* This dosing was reviewed and confirmed by the Pediatric ARV Working Group on June 19, 2020.

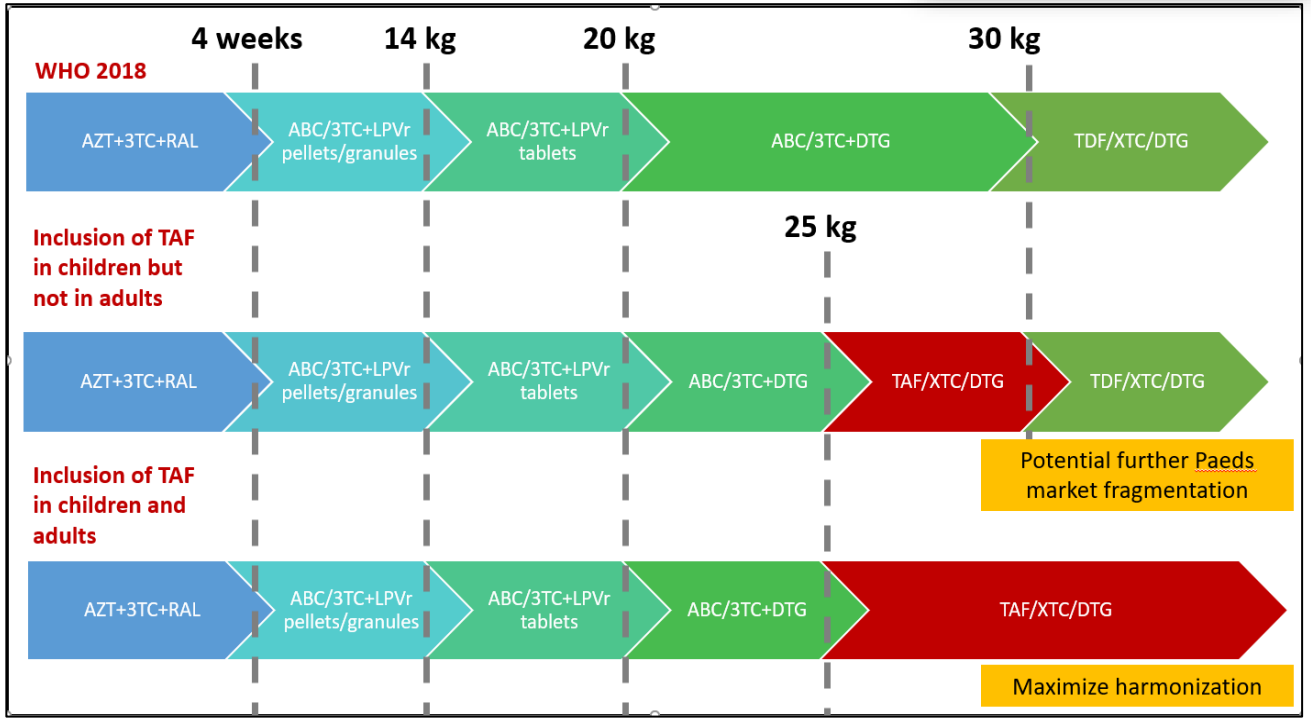
DTG below 20 kg dosing is now available and NO FURTHER guidance is needed on the formulations (including BD for children on TB Tx)

World Health Organization

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



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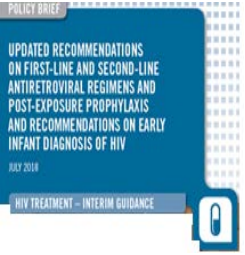

WHO 2018 recommendations for 2nd and 3rd line*

Population	1st line	2nd line	3rd line
Children	2 NRTI + LPV/r →	2 NRTIs + DTG**	DRV/r + DTG**** ± 1-2 NRTIs Where possible consider optimization using genotyping
	2 NRTIs + EFV →	2 NRTIs + DTG***	
	2 NRTI + DTG →	2 NRTIs + (ATV/r or LPV/r)	

* **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.

World Health Organization

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

VL monitoring good practice but no pre-condition for transition

Current regimen	Weight	Optimal regimen for transition	Considerations
AZT/3TC/NVP AZT/3TC/EFV ABC/3TC/NVP	<20 kg	ABC/3TC/LPVr	If still stable these can be transitioned to DTG when they reach 20 kg
	20-30kg	ABC/3TC/DTG	If still stable these can be transitioned to TLD when they reach 30 kg
	> 30kg	TLD	-
ABC/3TC/EFV	<20 kg	No change until reach 20 kg unless treatment failure occurs	Of value once reached 20 kg when DTG can be used so that OD administration is preserved.
	20-30kg	ABC/3TC/DTG	If still stable these can be transitioned to TLD when they reach 30 kg
	> 30kg	TLD	
ABC/3TC/LPVr AZT/3TC/LPVr	<20 kg	No change until reach 20 kg unless treatment failure occurs	Important to ensure use of tablets as soon as possible to reduce pill burden. Transition from AZT/3TC/LPVr to ABC/3TC/LPVr can also be considered to reduce pill burden
	20-30kg	ABC/3TC/DTG	If still stable these can be transitioned to TLD when they reach 30 kg
	> 30kg	TLD	-

World Health Organization

Should we extend this approach to children <20 kg?

Goal of transition

- Improve outcomes
- Harmonization
- Simplification
- Supply security

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AZT/3TC/NVP AZT/3TC/EFV ABC/3TC/NVP	<20 kg	ABC/3TC/LPVr	If still stable these can be transitioned to DTG when they reach 20 kg
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ABC/3TC/EFV	<20 kg	No change until reach 20 kg unless treatment failure occurs	Of value once reached 20 kg when DTG can be used so that OD administration is preserved.
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	> 30kg	TLD	
ABC/3TC/LPVr AZT/3TC/LPVr	**<20 kg**	**No change until reach 20 kg unless treatment failure occurs**	**Important to ensure use of tablets as soon as possible to reduce pill burden. Transition from AZT/3TC/LPVr to ABC/3TC/LPVr can also be considered to reduce pill burden**
	20-30kg	ABC/3TC/DTG	If still stable these can be transitioned to TLD when they reach 30 kg
	> 30kg	TLD	-

World Health Organization

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

Current regimen	Weight	Optimal regimen for transition	Considerations
AZT/3TC/NVP AZT/3TC/EFV ABC/3TC/NVP ABC/3TC/EFV	<30 kg	ABC/3TC plus DTG	As long as above **3 kg AND 4 weeks**
	> 30kg	TLD	-
ABC/3TC/LPVr AZT/3TC/LPVr	<30kg	ABC/3TC plus DTG	
	>30kg	TLD	-

VL monitoring good practice but no pre-condition for transition

World Health Organization

NEW DRAFT-Transition to optimal regimens

Goal of transition

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- Simplification
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Children eligible for transition

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Current regimen	Weight	Optimal regimen for transition	Considerations
AZT/3TC/NVP AZT/3TC/EFV ABC/3TC/NVP ABC/3TC/EFV	<30 kg	ABC/3TC plus DTG	As long as above **3 kg AND**
	> 30kg	TLD	-
ABC/3TC/LPVr AZT/3TC/LPVr	<30kg	ABC/3TC plus DTG	Ongoing discussion within PAWG: agreement in the vision for full transition to DTG but no urgency to do so if they are on an effective regimen like ABC/3TC/LPVr (awaiting ODYSSEY results)
	>30kg		

Key rationale: Transition out of NNRTI and use of once daily regimen with FDC as soon asap

Key rationale: Use once daily FDC as soon asap

VL monitoring good practice but no pre-condition for transition

World Health Organization

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**

World Health Organization

PROACTIVELY PLANNING FOR CHANGE

ACCELERATION CAN HAPPEN IF WE START WORKING ON IT NOW!

"Yes, introduction of new products has historically taken time and availability has been a problem but **it doesn't have to be that way"**

1 CURRENT STATUS OF OPTIMIZATION

Ongoing optimization efforts should not be delayed waiting to better products and need to continue

2 NEW OPTIONS AVAILABLE

DTG 10 mg scored tablets and 4IN1 approved at the same time: **DTG preferred**

! 4IN1 important alternative

3 TRANSITION PLANS

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

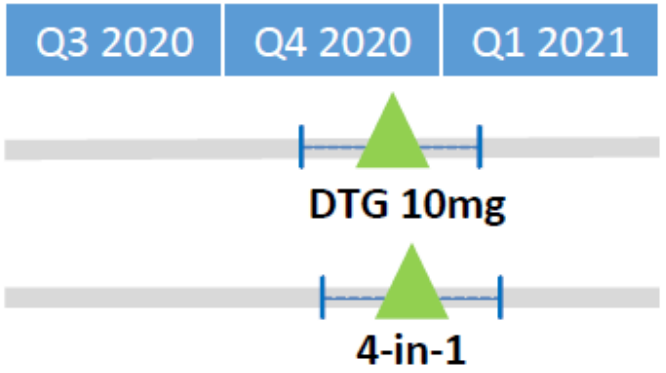
4 TOXICITY MONITORING

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"

World Health Organization

Regulatory Approval Timelines



Transition Scenario 1: Multiple simultaneous product transitions	Transition Scenario 2: Focus on DTG access with staggered 4-in-1 introduction when appropriate
• DTG as preferred in all children over 4 weeks of age • 4-in-1 as alternative in children who do not tolerate DTG and also cannot swallow tablets • Simultaneous introduction	• DTG as preferred in all children over 4 weeks of age • LPV/r 2-in-1 as alternative in children who do not tolerate DTG and also cannot swallow tablets • Consider substituting the 4-in-1 for the 2-in-1 when ready

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

Session 1: 6 October 2020 –Considerations for introducing new ART drug formulations for children

Session 2: 3 November 2020 – Package of Care for children and adolescents with Advanced HIV disease: STOP AIDS

Session 3: 1 December 2020 –Towards Comprehensive Care for children and adolescents living with HIV

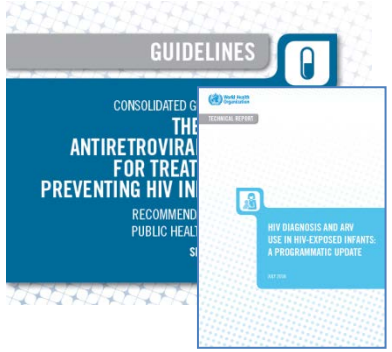
Postnatal prophylaxis

Simplified approach to assessing risk at delivery

High Risk Infants are born to women that...

1	Are identified as HIV positive in the postpartum period
2	Acquire HIV infection during pregnancy or breastfeeding
3	Where VL is available, have a VL>1,000 copies/ml at delivery or in the last 4 weeks of pregnancy
4	Where VL is not available, have been on ART for less than 4 weeks at delivery

World Health Organization



ePNP: identificaton of high risk infant

At DELIVERY

Known HIV+ Mother not on ART

HIV+ Mother on ART

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

Woman identified HIV+ post natally

YES: VL >1,000

YES: VL <1,000

NO

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

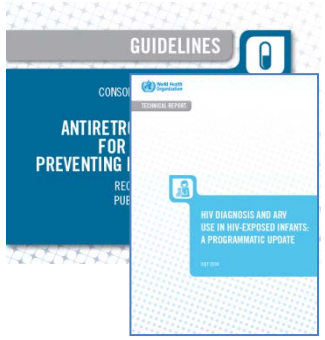
YES

NO

HIGH RISK

LOW RISK

HIGH RISK



Summarizing ePNP recommendations

FORMULA FEEDING

AZT/NVP

Birth or identificaton

6 wks

12 wks

BREAST FEEDING

AZT/NVP

AZT/NVP or NVP alone

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**.

Dosing and formulation options for infant enhanced and prolonged prophylaxis

TABLE 4. NVP doses for prophylaxis beyond 12 weeks

Infant age	Dosing of NVP
6 to 12 weeks	20 mg once daily
12 weeks to 6 months	20mg once daily
6 to 9 months	30mg once daily
9 months to end of BF	40mg once daily

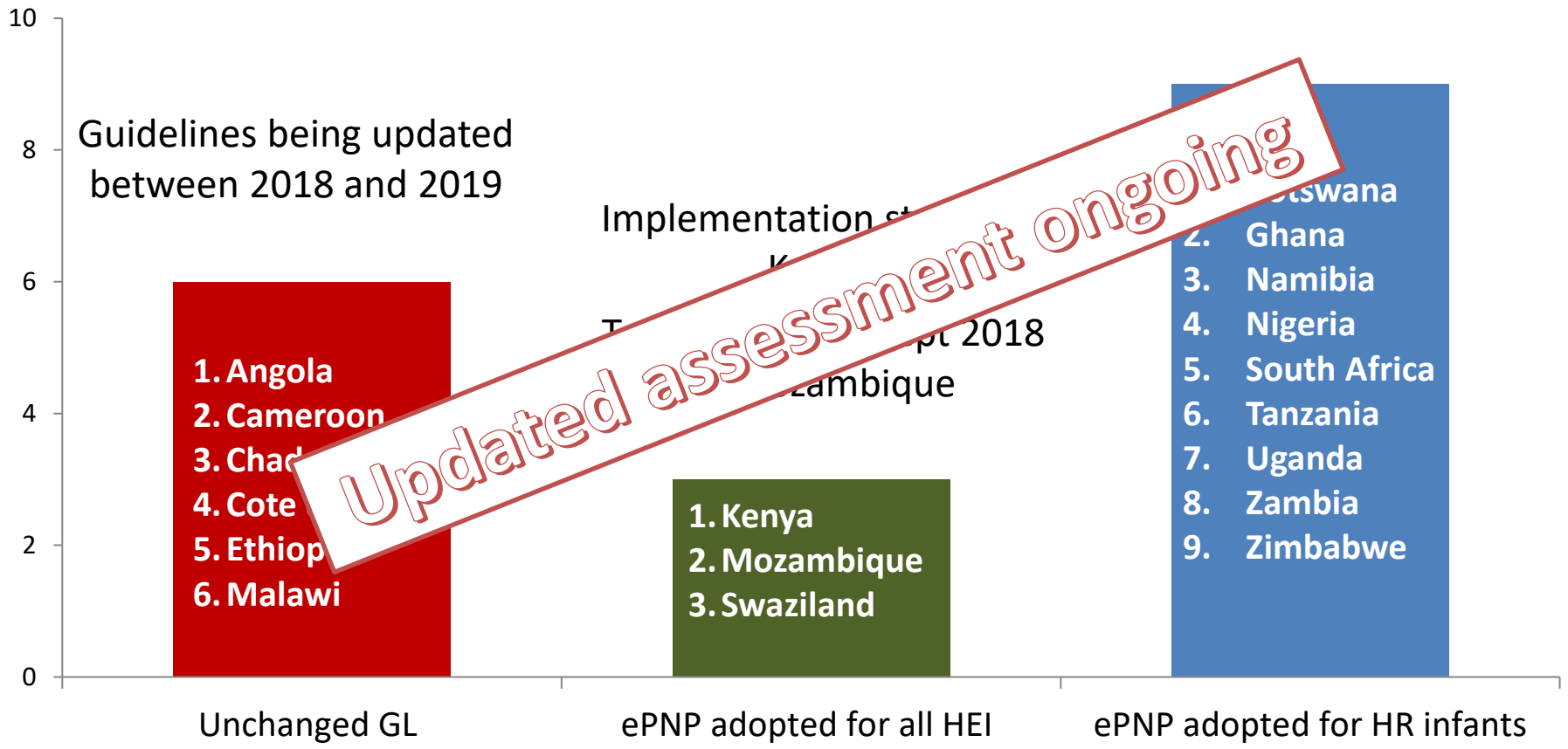
Under review by PAWG to ensure simplification and optimization of existing solid formulations

Dosage forms	Dose 0-6 weeks AZT plus NVP	Dose 6-12 weeks AZT plus NVP	Dose 6-12 weeks NVP only	Comments
Syrups AZT 10mg/ml NVP 10mg/ml	AZT dose 1.5ml (15mg) twice daily	AZT dose 6ml (60mg) twice daily	NVP dose 2ml (20mg) once daily	– Accurate dosing for all drugs (included for low birth weight newborns) and one type of formulation for the whole 12-week period – Costly to procure and transport syrups – Difficult to hide in the home – Supplier availability may be limited – Might be acceptable where most women of childbearing age are well controlled on ART and numbers of high-risk infants is low, but would not be the best option for a program that chooses to treat all infants as high risk
	NVP dose 1.5ml (15mg) once daily	NVP dose 2ml (20mg) once daily		
Syrups and single drug tablets AZT 60mg NVP 50mg	AZT dose 1.5ml (15mg) twice daily	AZT dose 1 tab (60mg) twice daily	NVP dose ½ tab (25mg) once daily	– Combines accuracy of syrup dosing in the first 6 weeks and the ease of tablets from 6 to 12 weeks – Challenges of syrups as before – ½ a tab of NVP represents a slight overdose of NVP (25mg vs 20mg)
	NVP dose 1.5ml (15mg) once daily	NVP dose ½ tab (25mg) once daily		
FDC	¼ tab (15mg AZT, 7.5mg 3TC, 12.5mg NVP) twice daily	Unsuitable	Not applicable	– Difficult to quarter a FDC accurately: caregivers should use the first quarter in the morning and the second quarter in the evening in order to keep daily dose accurate – 3TC not part of the recommended prophylaxis regimen – Cannot use FDC during weeks 6 to 12 without giving 5 times more than the recommended daily NVP dose
FDCs and single drug tablets	¼ tab (15mg AZT, 7.5mg 3TC, 12.5mg NVP) twice daily	AZT dose 1 tab (60mg) twice daily	NVP: ½ a 50mg tablet once daily	– Combines ease of FDC with single drug tablet for the second – Challenges of FDC as above
		NVP dose ½ tab (25mg) once daily		

Remarks:

- It should be noted that unlike for NVP, there is no specific prophylaxis dose for AZT. The recommended dose is the same as that used for treatment - 15 mg twice daily for term infants in the first six weeks of life, increasing to 60mg twice daily from week 6 to week 12.
- When presumptive treatment is administered, age-appropriate regimens and dosing should be used as illustrated in current WHO treatment guidelines[10].

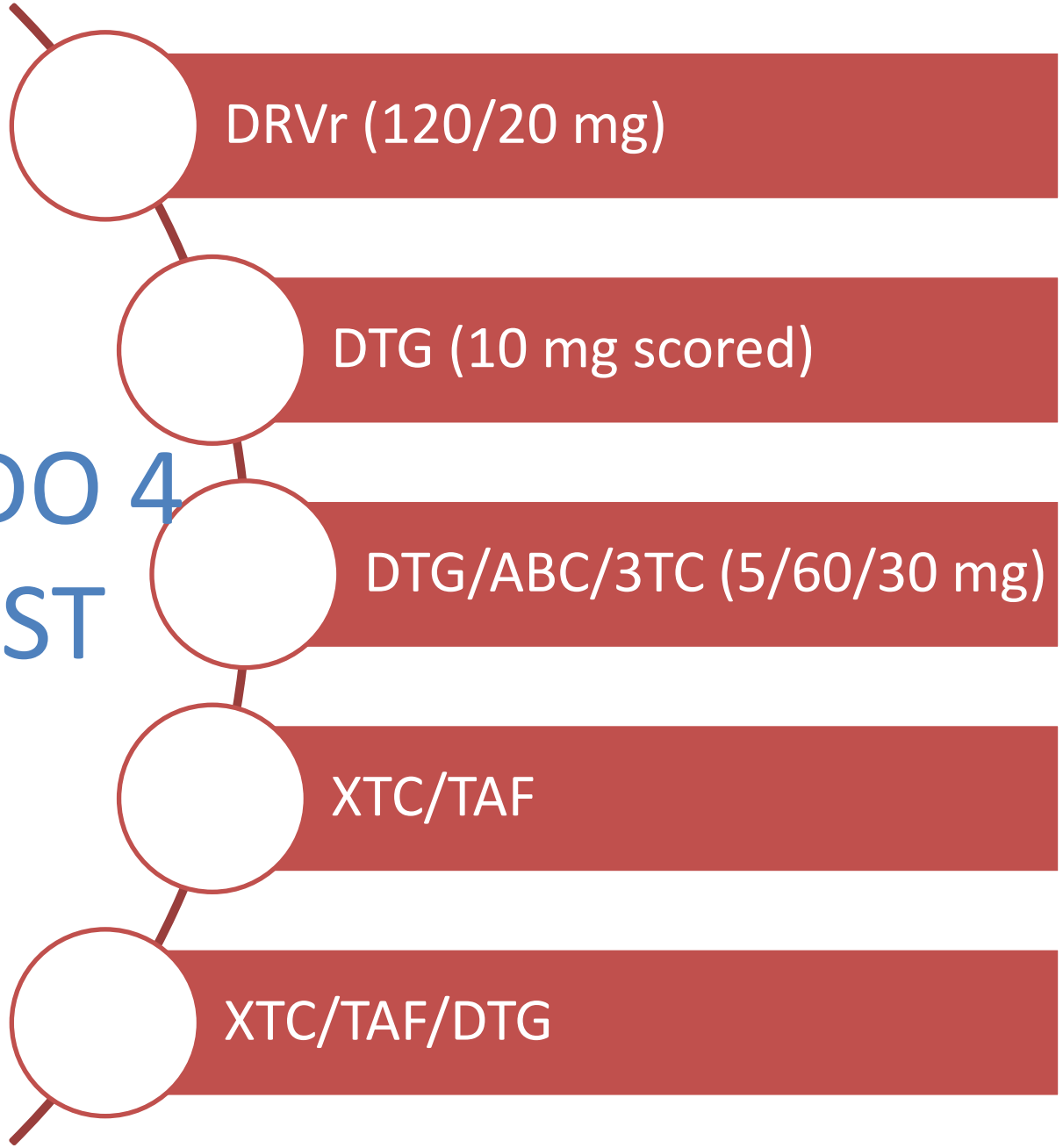
Countries policies on ePNP (May 2018)



World Health Organization

Priority products for investigation and development

PADO 4 LIST



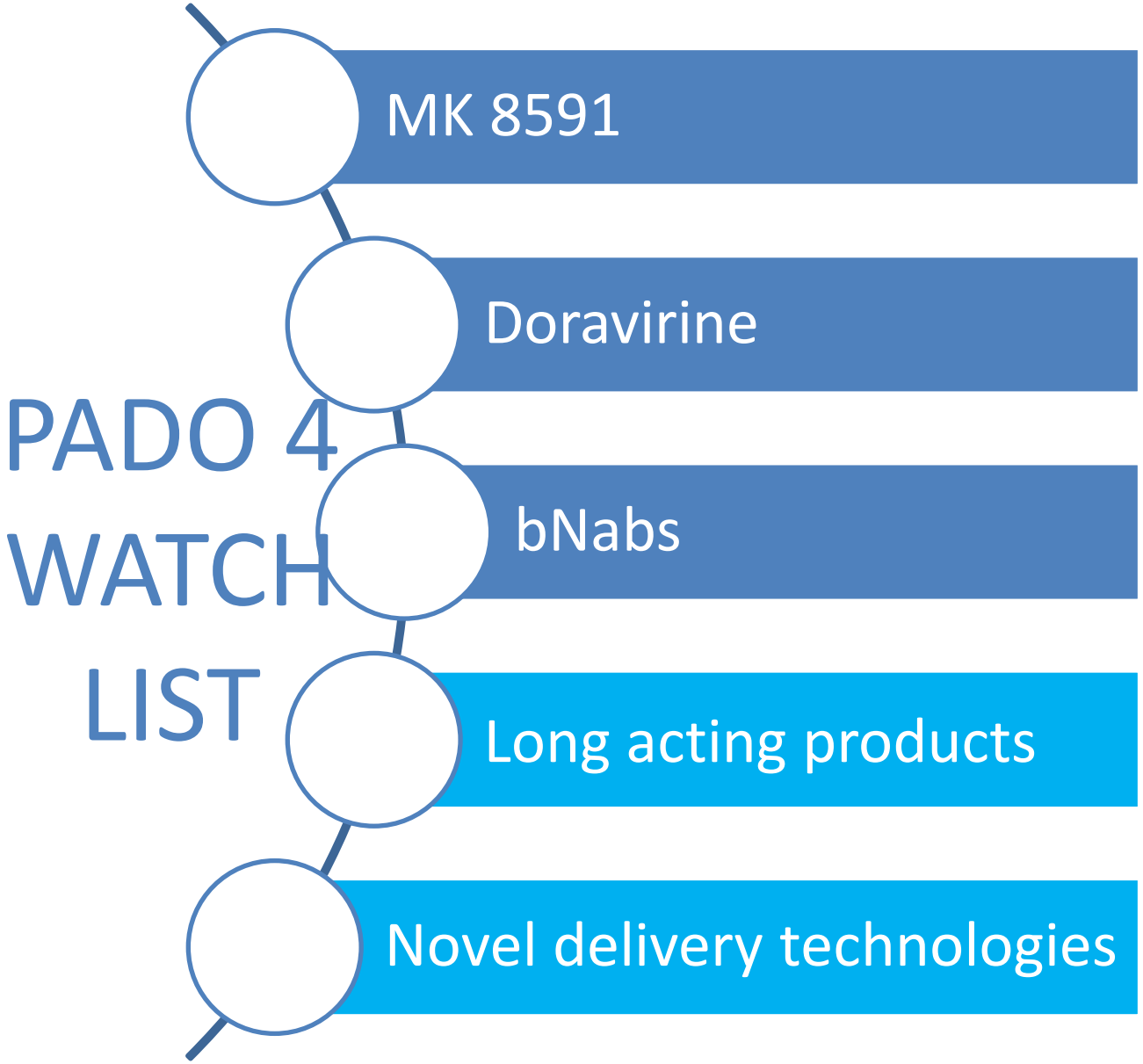
DRVr (120/20 mg): critical formulation to use a PI in 2nd and 3rd irrespective of regimens history (dosing and ratio confirmed).

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).

World Health Organization



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.

World Health Organization

Global Accelerator for Paediatric Formulations (GAP-f) webinar

Better Medicines for children in need

26 October – 14:00 CET | 09:00 ET | 18:30 IST

Registration link: https://bit.ly/3drDZFI

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/

www.who.int/hiv/pub/research-dev-toolkit-paediatric-arv-drug-formulation/en/

Update from WHO: Adult ART Guidelines

Marco Vitoria

WHO/HHS Department

Annual ARV Buyer Seller Summit

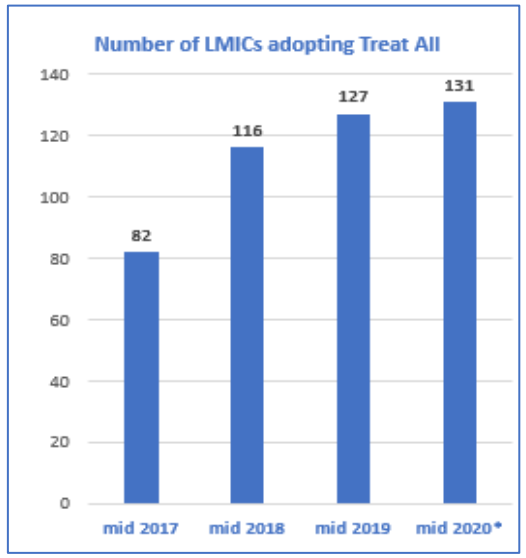
October 2020

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

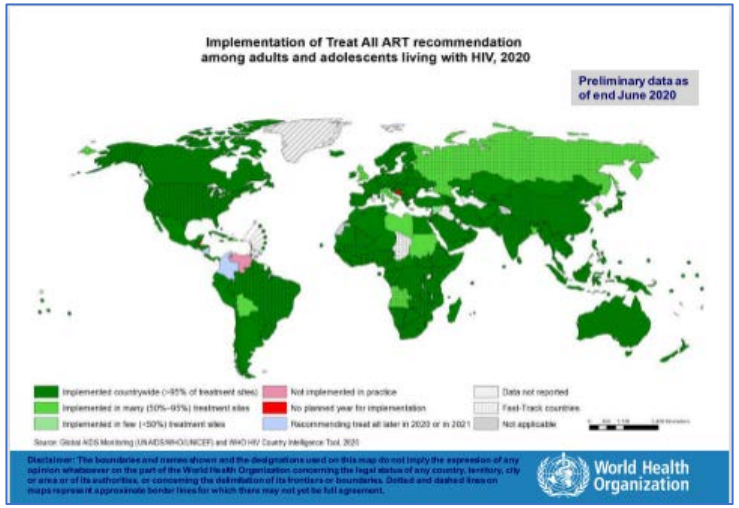
HIV TREATMENT HAS EVOLVED

Evolution of the uptake of major ARV treatment policies in LMICs

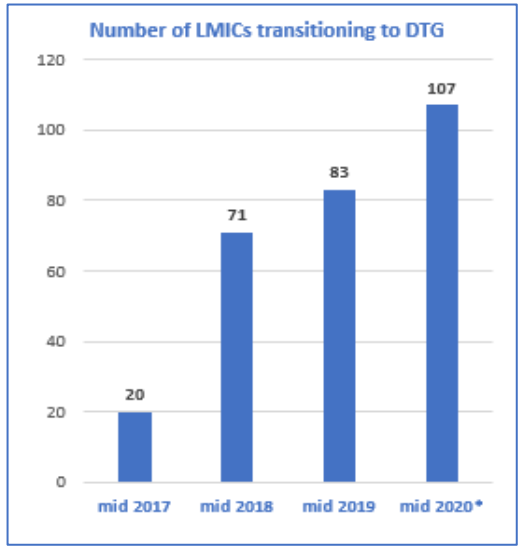
Treat All



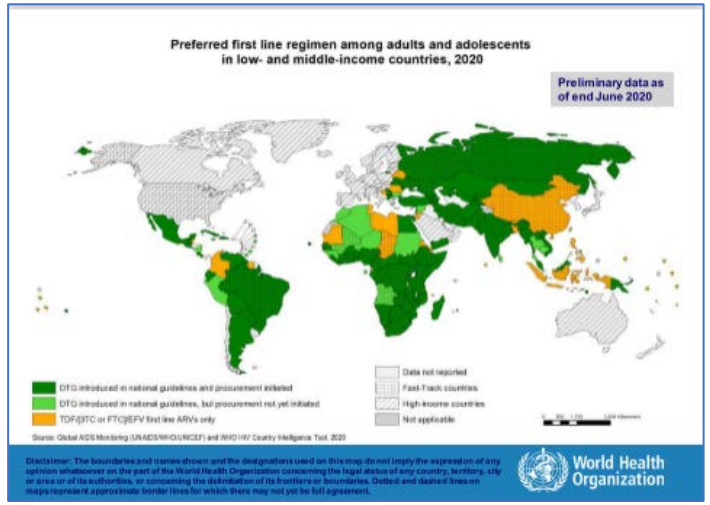
131 LMICs adopted Treat All (96%)



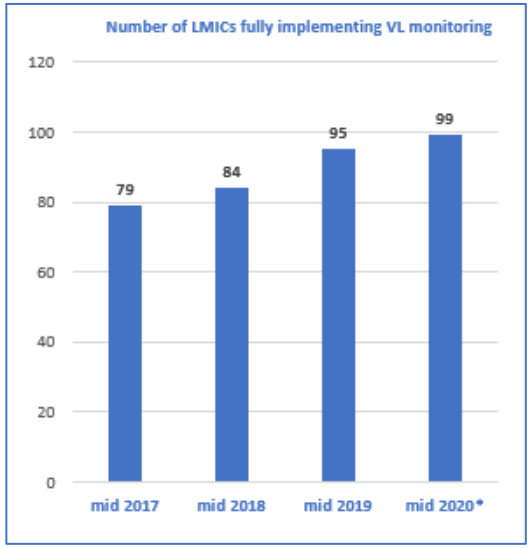
DTG transition



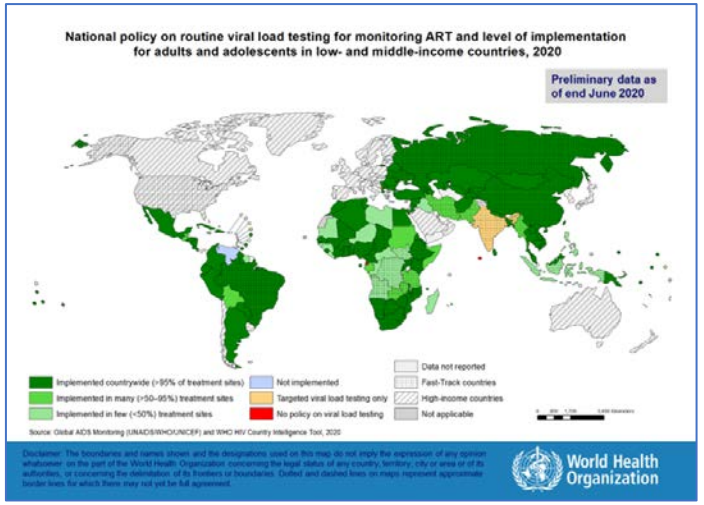
107 LMICs adopted DTG regimens (78%)



Routine VL monitoring



99 LMICs adopted VL monitoring (72%)



* Preliminary data

2019 ARV recommendations at a glance

WHAT TO USE IN 1ST LINE

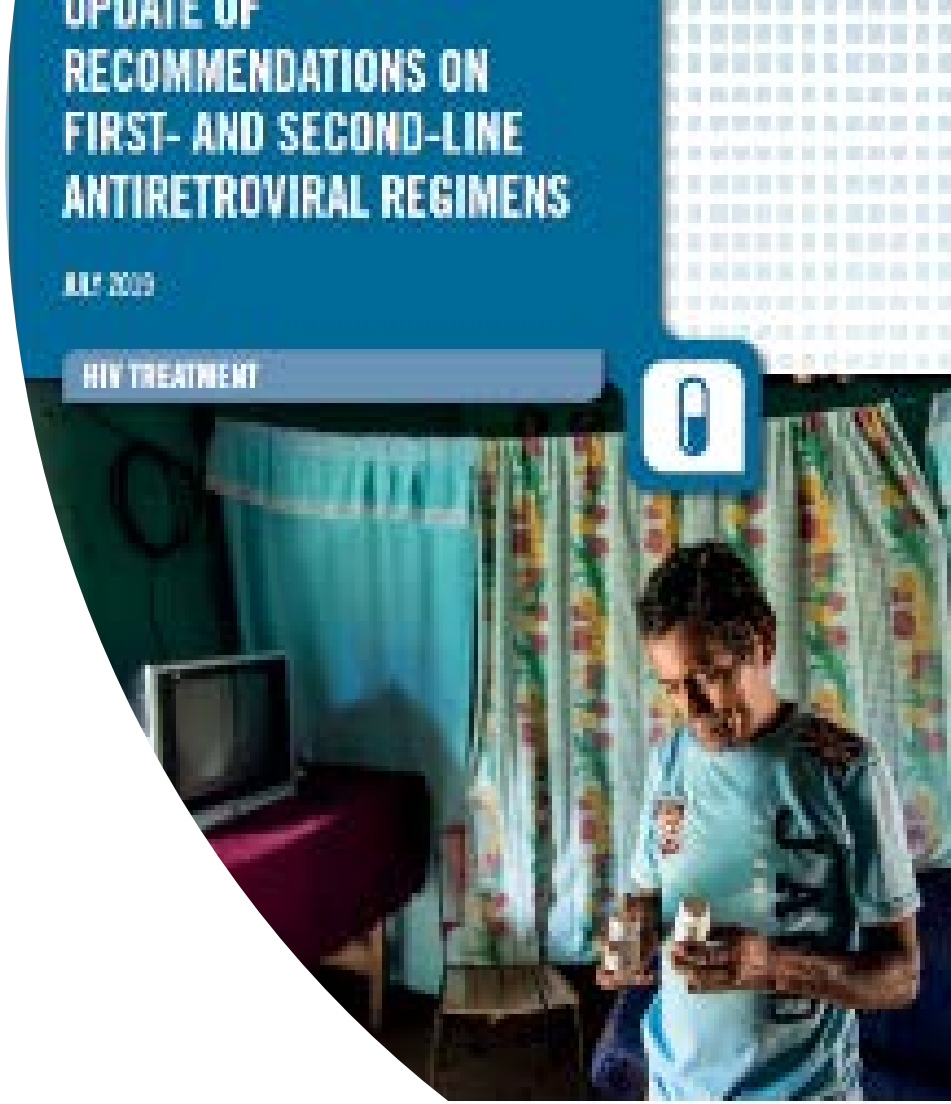
- ✓ TLD as preferred regimen in 1st line ART for all PLHIV (with approved DTG dose)
- ✓ TLE400 as alternative 1st line option. TLE600 in special circumstances
- ✓ Switching of stable patients using suboptimal regimens is recommended. Switching those on TLE with supressed VL should be considered

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



World Health Organization

Safety and Efficacy of DTG and EFV_{600} in 1st line ART (PICO 1 A)
(summary 2019 WHO Sys Review & NMA)

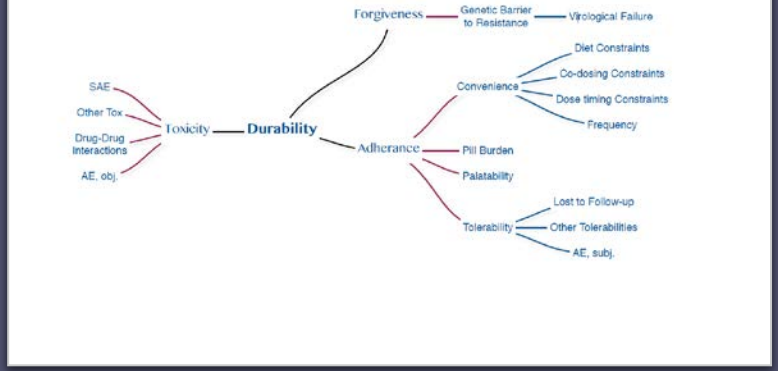
	major outcomes	DTG vs EFV_{600}	quality of evidence
Efficacy outcomes	Treatment discontinuation (any or due AEs)	DTG better	high
	Viral suppression (4-96 weeks), viral suppression at delivery (PW), transmission (PW)	DTG probably better	high to moderate
	CD4 recovery (24-144 weeks)	DTG probably better	high to moderate
	Mortality	comparable	low
Tolerability, safety & resistance outcomes	Neuropsychiatric AEs (any grade), depression (grade 3 or 4), dizziness (any grade)	DTG probably better	moderate to low
	Sleep disorders (any grade)	comparable	very low
	Body weight gain	EFV probably better	moderate
	NTD	EFV may be better	low
	HIVDR (overall, NRTI or anchor drug)	DTG probably better	high to moderate

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

World Health Organization

DTG as preferred option in 1st line: improved efficacy and durability when compared with EFV

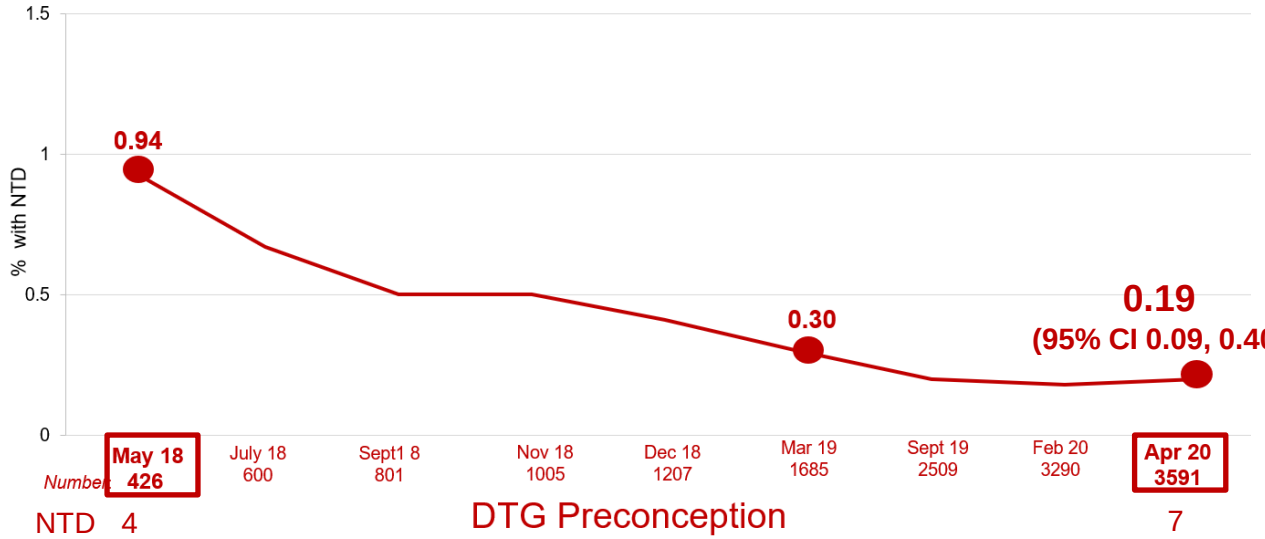
- Better than EFV in the majority of critical outcomes (high/moderate quality of evidence)
- Rapid viral load suppression
- Once daily and well tolerated
- High genetic barrier to resistance
- Few drug interactions
- Single and fixed-dose generic formulations
- Lower price in LMICs
- Risk of neural tube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

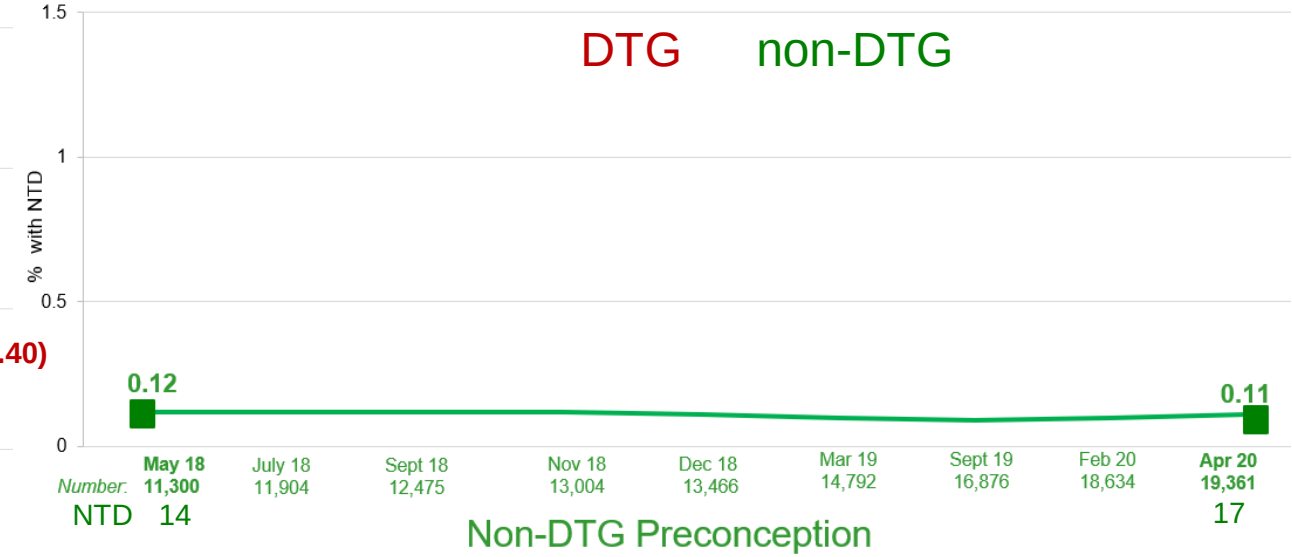


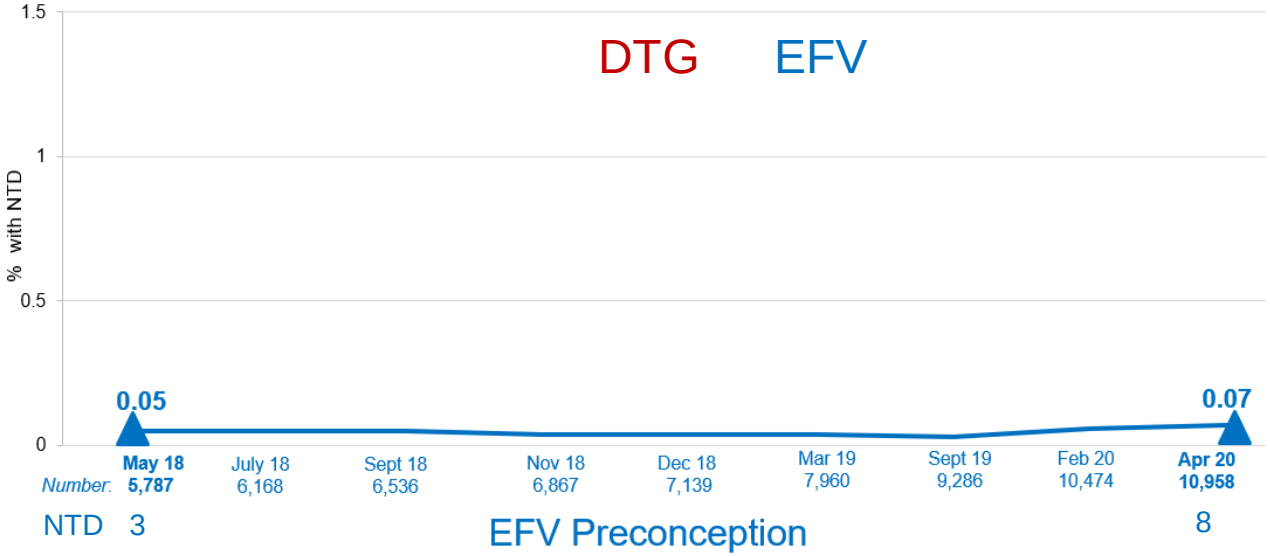
World Health Organization

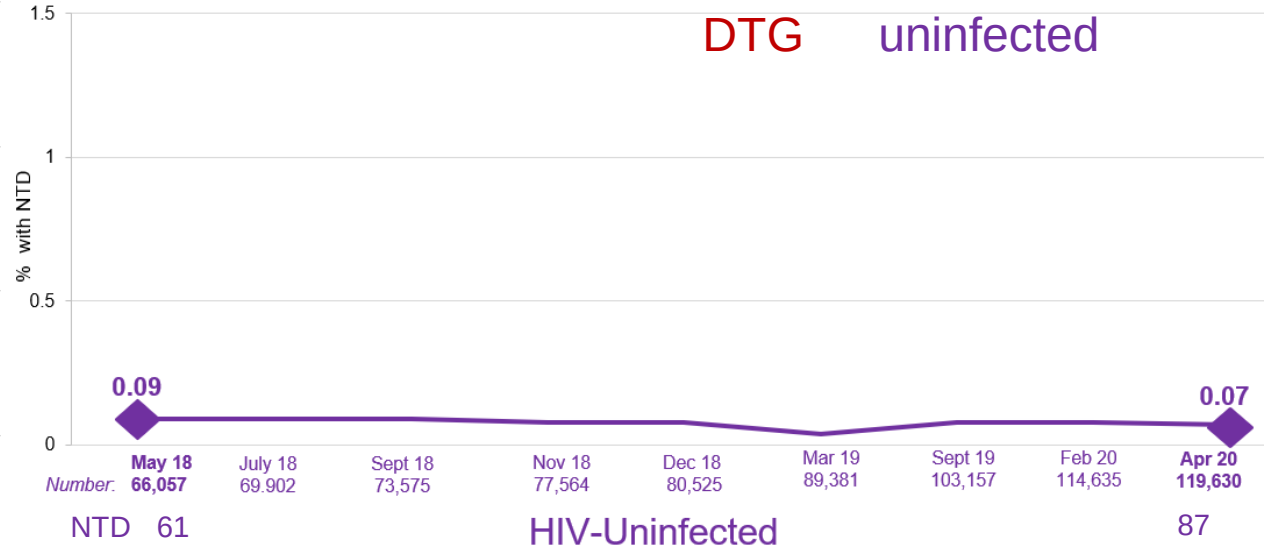
Tsepamo: Evolution of NTD Prevalence with Preconception DTG

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



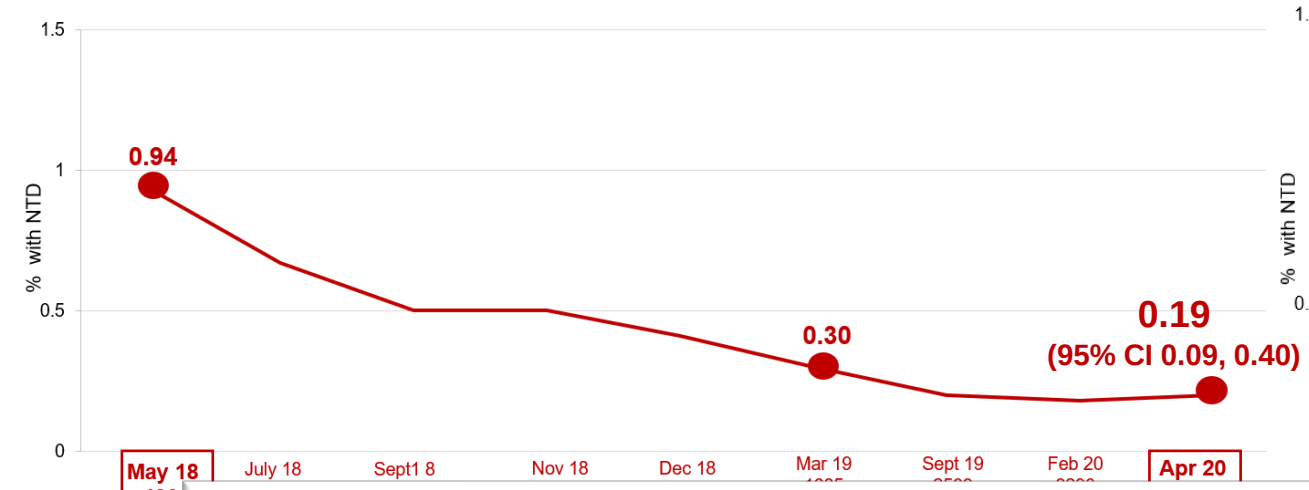


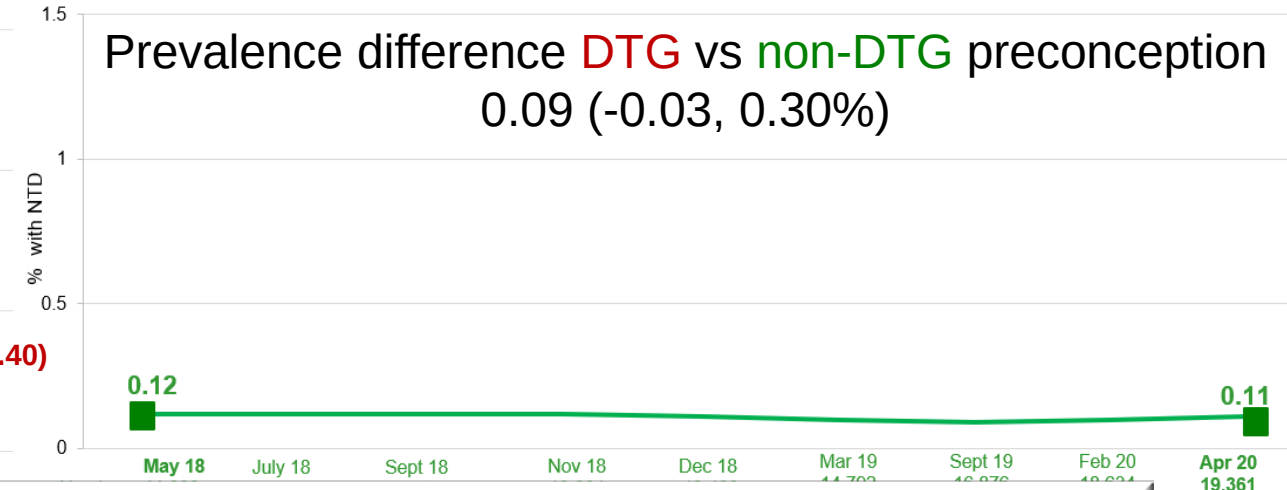




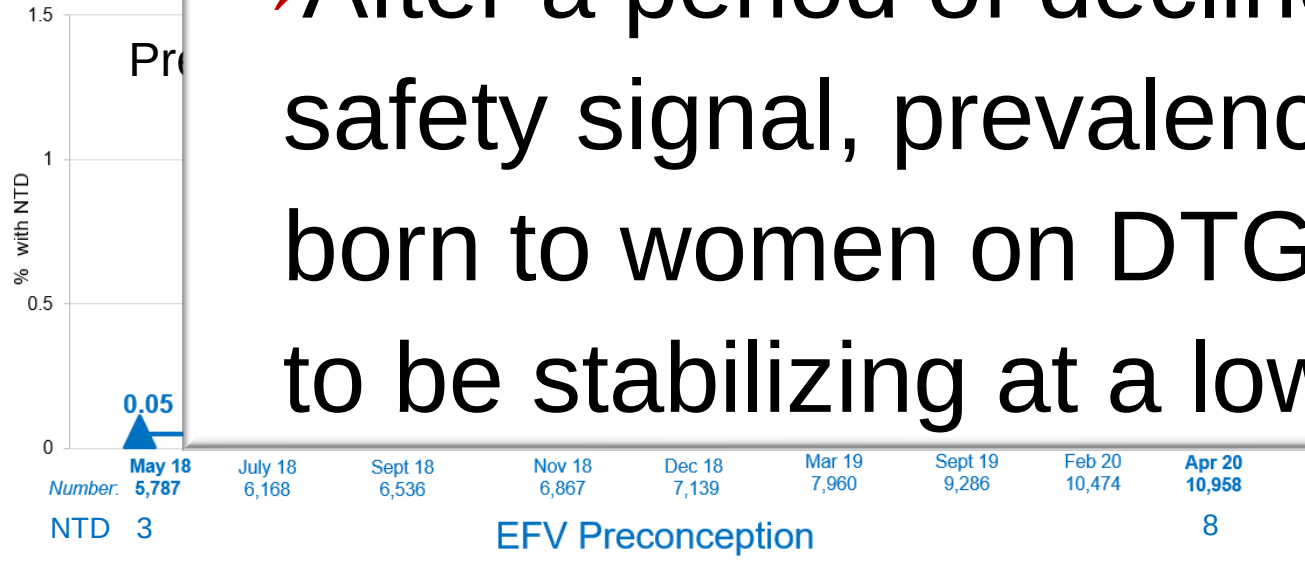
Tsepamo: Evolution of NTD Prevalence with Preconception DTG

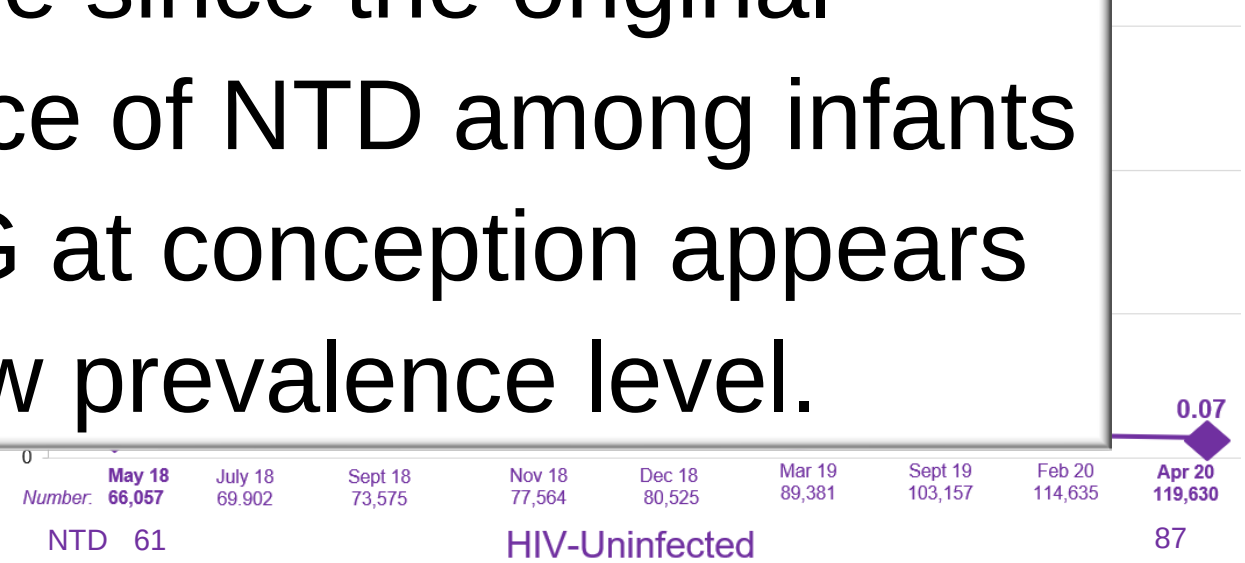
Zash R et al. IAS Virtual July 2020 Abs. OAXLB0102



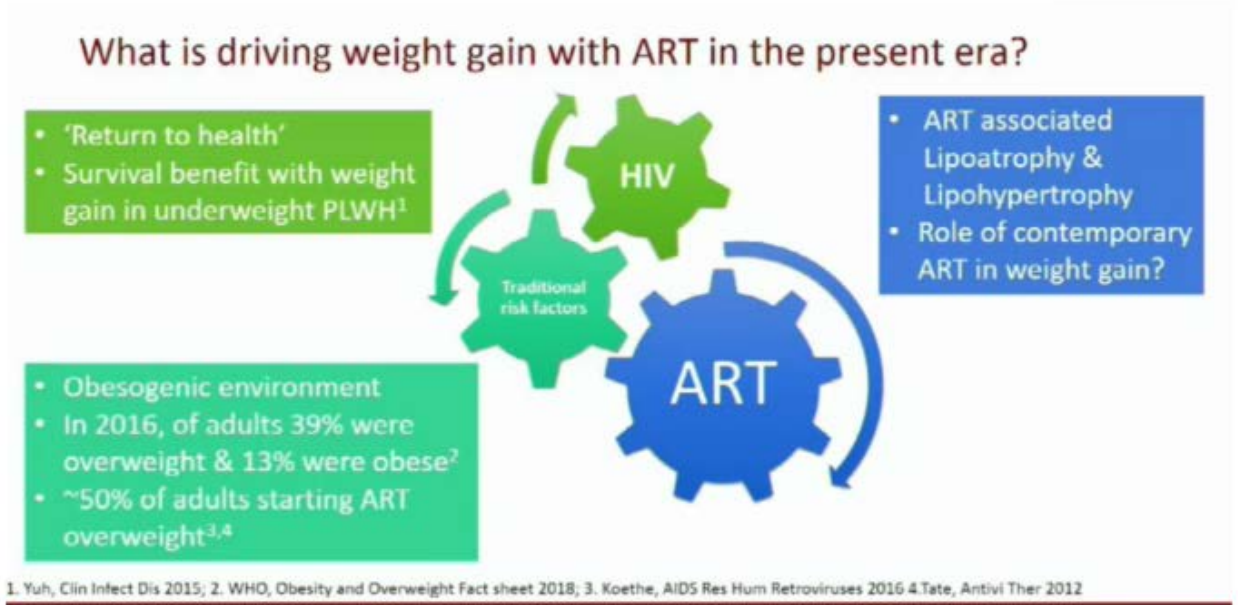


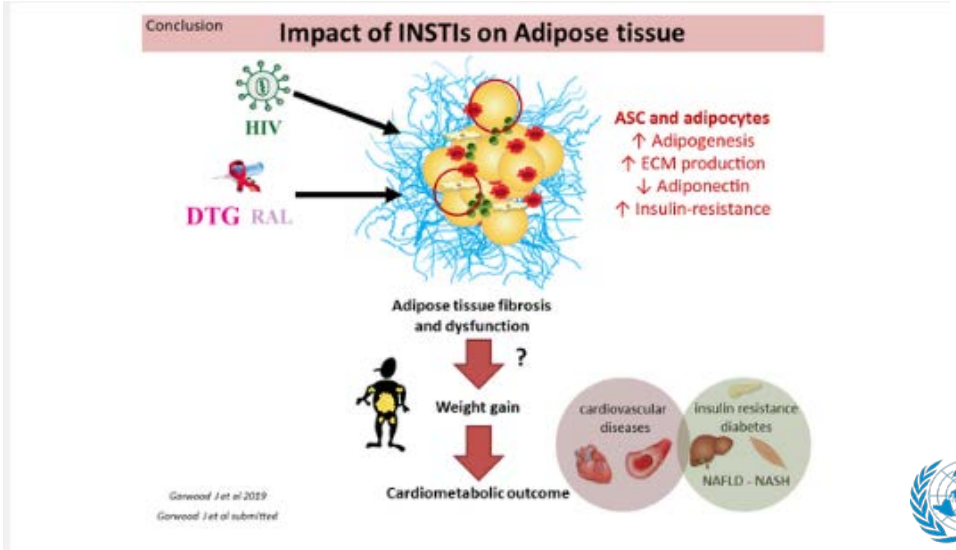
→After a period of decline since the original safety signal, prevalence of NTD among infants born to women on DTG at conception appears to be stabilizing at a low prevalence level.

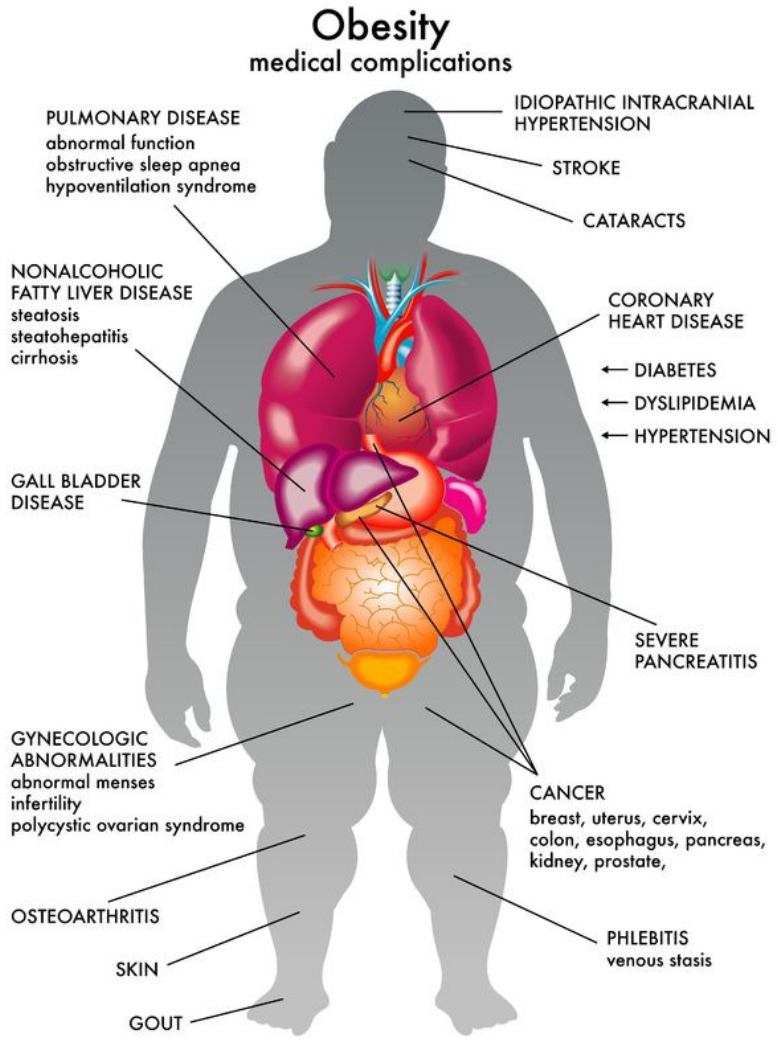




INSTI and new story of weight gain among PLHIV







World Health Organization

Safety and Efficacy of EFV_{400} and EFV_{600} in 1st line ART (PICO 3)

(summary 2019 WHO Sys Review & NMA)

	major outcomes	EFV_{400} vs EFV_{600}	quality of evidence
Efficacy outcomes	Treatment discontinuation (due AEs)	EFV400 better	high to moderate
Efficacy outcomes	Viral suppression (48-96 weeks), VL suppression if baseline > 100,000 (48 weeks)	comparable	moderate
Efficacy outcomes	CD4 recovery (24-96 weeks)	comparable	moderate
Efficacy outcomes	Mortality	comparable	low
Tolerability, safety & resistance outcomes	Neuropsychiatric AEs (any grade), depression (grade 3 or 4), dizziness (any grade), sleep disorders (any grade)	comparable	low to very low
Tolerability, safety & resistance outcomes	Body weight gain	comparable	low
Tolerability, safety & resistance outcomes	Treatment related adverse events	EFV400 better	moderate
Tolerability, safety & resistance outcomes	HIVDR (overall, NRTI or anchor drug)	comparable	very low

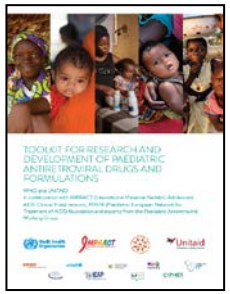
Reference: Steve Kanters, For WHO ARV GDG, 5-7 June 2019

World Health Organization

TLD transition at a glance (adults and adolescents)

Treatment transition scenario	Preferred approach	Comments
DTG in people living with HIV initiating ART		
Adults and Adolescents[a]	Initiate TLD	• Potential risk of neural tube defects among infants exposed to DTG during the conception period • Women not using or accessing contraception or who want to be pregnant can use DTG or EFV based on informed choice of the risks and benefits of each regimen
Pregnant/Breastfeeding women[b]	Initiate TLD	• Possibility of conception during breastfeeding remains
TB co-infection	Initiate TLD (DTG dose adjustment needed).	• DTG 50 mg BD if rifampicin in TB regimen
DTG in people living with HIV already using first-line regimen		
Clinical/immunological failure or VL non-suppressed	Switch to AZT+3TC + DTG (or PI/r[c])	• There is no evidence to support the efficacy of DTG when used in combination with an inactive NRTI backbone. • Provide adherence support.
Viral load suppressed	Substitution to TLD regimen may be considered according to national recommendations.	• Substitution should be considered in the context of drug supply and patient choice • Substitution may confer new side-effects and interfere with adherence • DTG regimens may be more durable in the long term
Clinically/immunologically stable[d] and VL unknown	Prioritize VL testing or consider other programmatic or clinical indications for decision for substitution to TLD	• No evidence to support the efficacy of DTG when used in combination with an inactive NRTI backbone • provide adherence support
Clinically/immunologically stable[d] on suboptimal first-line ARV regimens	Substitute to TLD	• Substitution may confer new side-effects. • Provide adherence support

WHO support to countries for implementation of active toxicity monitoring and safe introduction of DTG and other new ARVs – guidance, tools and technical assistance

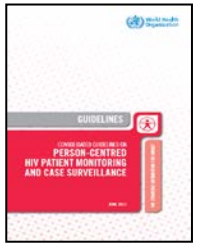


Toolkit with PV module for children

General population inc. children & adolescents

Guidance and tools inc. WHO ARV toxicity monitoring implementation tool and training materials

new indicators for toxicity in routine monitoring



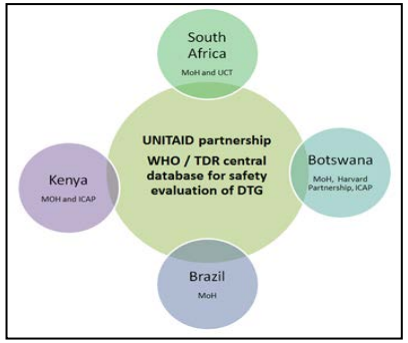
WHO global databases

Generic DTG ADR notification form

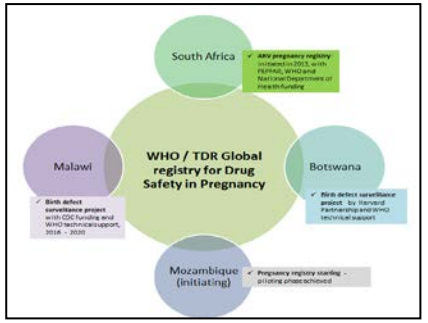
Pregnant women

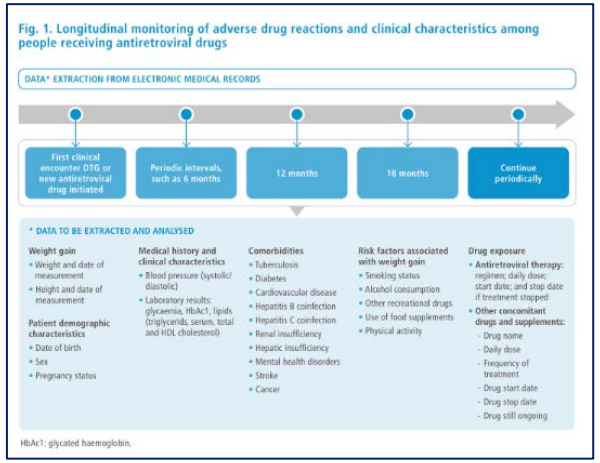
Pregnancy & birth defect registry tools

WHO global ARV toxicity monitoring database



Central registry for drug safety in pregnancy





https://www.who.int/publications/i/item/9789240007901

World Health Organization

Safety and Efficacy of TAF vs TDF (PICO 4)

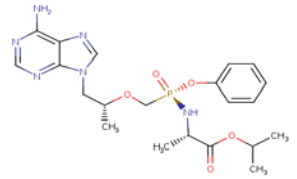
(summary 2019 WHO Sys Review & NMA)

	major outcomes	TAF vs TDF	quality of evidence
Efficacy outcomes	Viral suppression (24-96 weeks)	comparable	high to moderate
	CD4 recovery (24-96 weeks)	comparable	low
	Mortality	comparable	low
Tolerability, safety & resistance outcomes	Discontinuations (AEs), overall SAEs, overall AEs, treatment related SAEs	comparable	moderate
	Protection effect renal function markers (creatinine, eGFR) at 24-96 weeks	TAF probably better	high to moderate
	Protection effect bone lab markers (BMD) at 24-96 weeks	TAF probably better	high
	Any lab abnormalities (grade 3 or 4)	TAF probably better	moderate
	Cholesterol levels(grade 3 or 4)	TDF probably better	moderate
	Body weight gain	TDF probably better	moderate
	HIVDR (overall, NRTI)	comparable	low

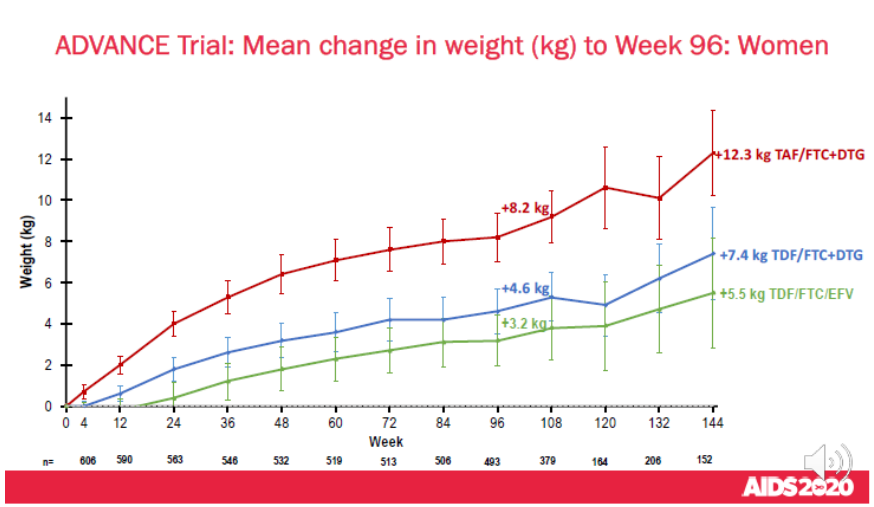
Reference: Steve Kanters, For WHO ARV GDG, 5-7 June 2019

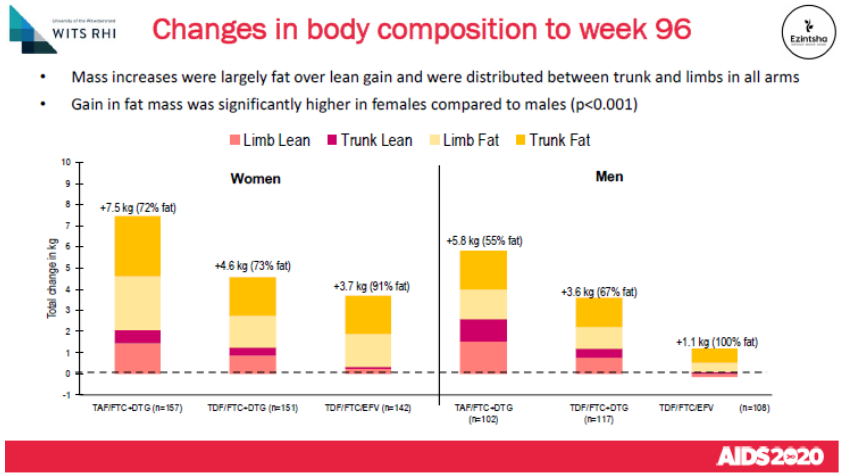
World Health Organization

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 2nd line ART (PICO 2)

(summary 2019 WHO Sys Review & NMA)

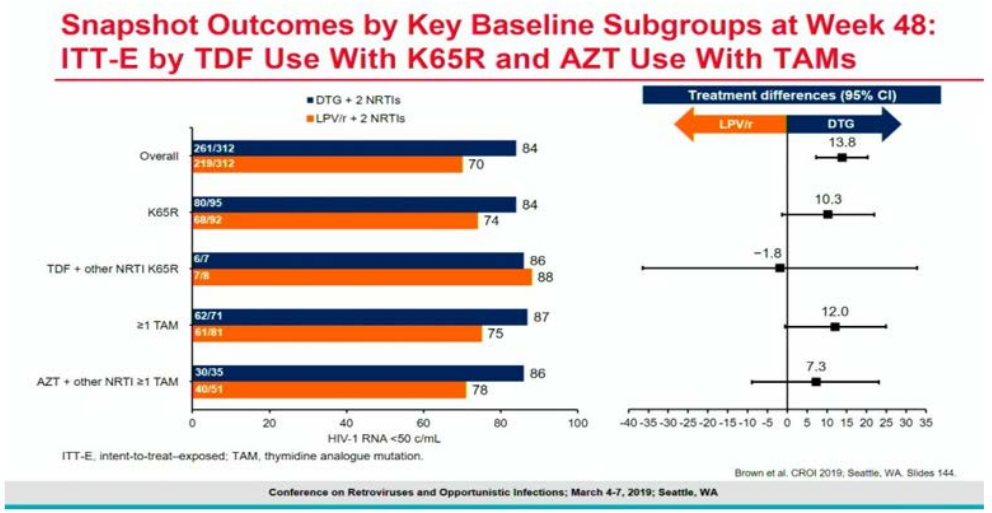
	major outcomes	DTG vs LPVr	quality of evidence
Efficacy outcomes	Viral suppression (4-96 weeks)	DTG better	high
	Viral suppression baseline VL > 100,000 (48 weeks)	comparable	moderate
	CD4 recovery (24-48 weeks)	comparable	moderate
	Mortality	comparable	low
Tolerability, safety & resistance outcomes	Neuropsychiatric AEs (any grade)	comparable	low
	Treatment related SAE	comparable	low
	Treatment emergent AE, related AEs	DTG probably better	high
	Treatment discontinuation (any or due AEs)	DTG probably better	high
	HIVDR (overall)	comparable	very low

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

World Health Organization

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

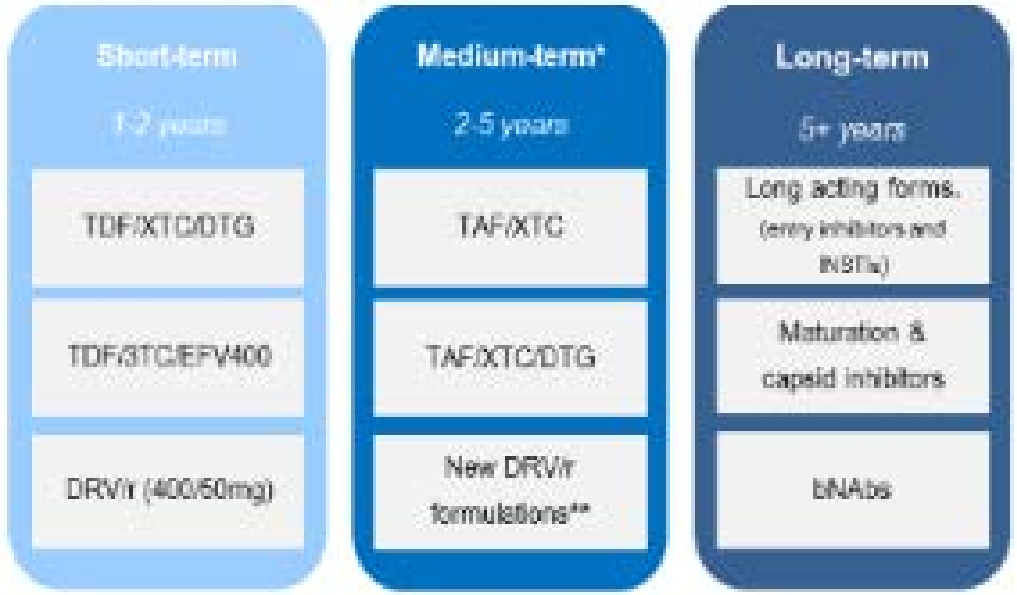
Future role of dual therapy: considerations

- Several studies as " simplification" strategy in ARV supressed 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 (eg: TB, HBV) and baseline resistance, efficacy in advanced disease, efficacy and safety of new drugs

Strategy	Regimens/Agents	Potential Future Implications in HIV Treatment
Long-acting ART	▪ Cabotegravir + RPV ▪ MK-8591 (EFdA) ▪ bNAbs	▪ Long-acting regimens could remove the need for daily pills ▪ May have role in maintenance therapy
Dual therapy	▪ DTG + 3TC or RPV ▪ PI/RTV + 3TC or RAL	▪ Dual therapy regimens might be used in first-line, switch, induction/maintenance, or salvage settings ▪ Could allow treatment simplification, cost savings vs 3+ drug regimens, minimization of DDIs, AEs
Investigational agents	▪ Doravirine ▪ GS-9883 (bictegravir)	▪ Novel agents with potential utility for treatment-naive or switch pts
	▪ Fostemsavir ▪ BMS-955176 ▪ Ibalizumab	▪ Novel agents with potential utility for treatment-experienced pts

Slide credit: clinicaloptions.com

Figure 22: CADO3 Prioritized List of Optimized Products and Formulations for Adults on ART



*Other lower priority products might be considered in the future if the data suggests superiority to existing priorities

**Low dose standard formulations (400/100mg) or standard dose nanoformulations (800/100mg)

Major ART Optimization Studies in Adults and Adolescents (with COVID-19 impact)

Research priority topic	CLINICAL TRIALS: 1ST LINE				CLINICAL TRIALS: 2ND LINE /SWITCHING			
	ADVANCE	NAMSAL	DOLPHIN-2	VESTED	VISEND	NADIA	ARTIST	D2EFT
Safety of DTG and /or TAF periconception and pregnancy			✓	✓				
Changes in body weight/cardiometabolic risk with DTG combined with TAF or TDF	✓	✓	✓	✓	✓	✓	✓	✓
Outcomes from switching from TLE to TLD without VL					✓	✓	✓	✓
Safety and efficacy of DTG and/or TAF in adolescents	✓	✓	✓	✓		✓		✓
Impact of COVID19 pandemic	**No delays**	**No delays**	**No delays***	**+3 months**	**+3 months**	**+3 months**	**No delays**	**+ 6-months**
Time of expected results	**Q2 2021 144 weeks**	**Q4 2020* 144 weeks**	**Q4 2020 144weeks postpartum**	**Q1 2021 96 weeks**	**Q1 2021* *48 weeks**	**Q2 2021* 48 weeks**	**Q2 2021 48 weeks**	**Q4 2021* 48 weeks**

* Some delays in paediatric component of the study is expected

World Health Organization

OBSERVATIONAL STUDIES
(with COVID-19 impact)

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

World Health Organization

Key messages

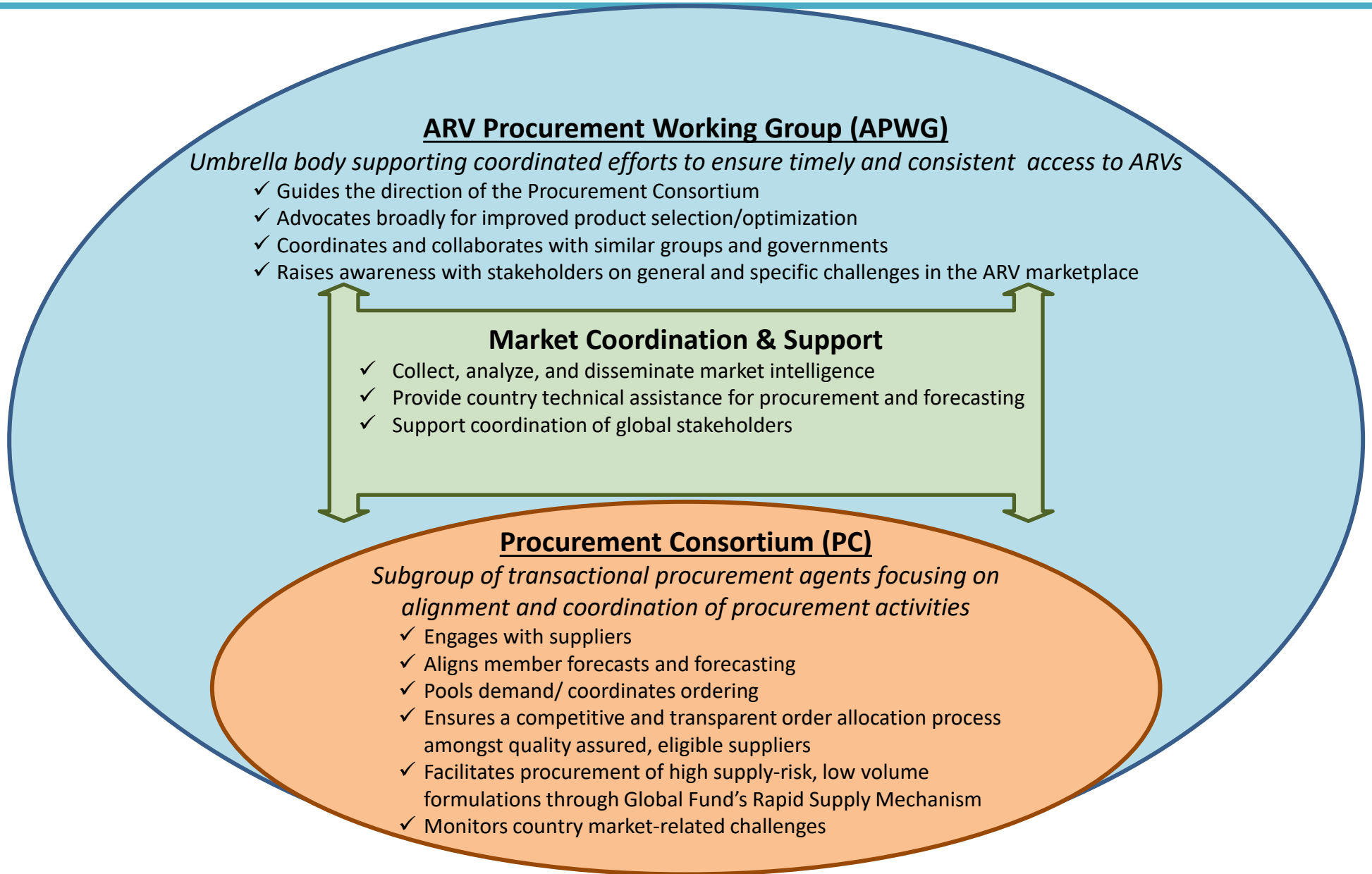
- DTG scale up has been implemented in majority of LMICs, but transition criteria in those well and stable on previous ART still have some knowledge gaps
- The potential association of NTDs and DTG detected in TSEPAMO study was not confirmed, but emerging adverse events as body weight gain and other 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



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

POLICY BRIEF

THE 2018 OPTIMAL FORMULARY AND LIMITED-USE LIST FOR PAEDIATRIC ARVS

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

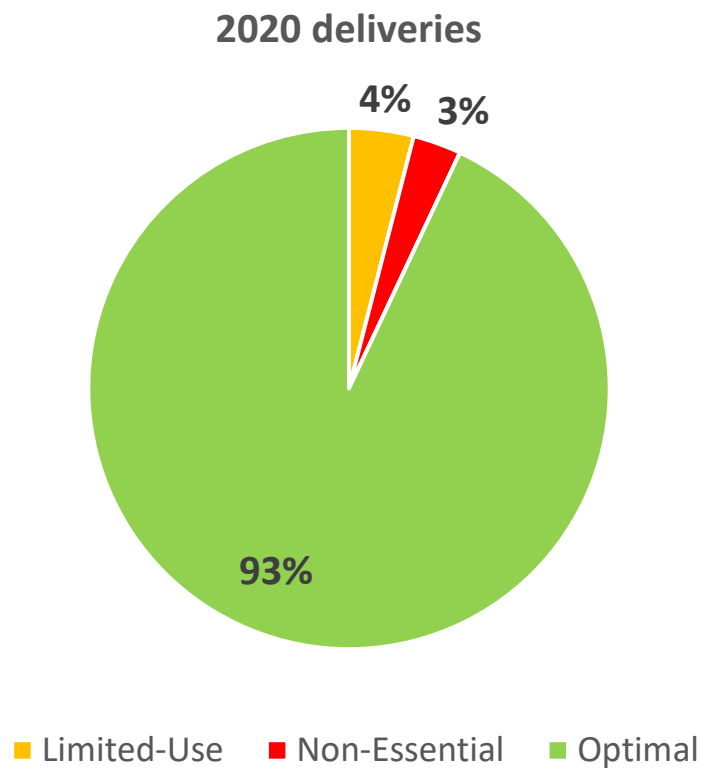
APWG monthly calls with focus on market information, country uptake and supply issues

- 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



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

Limited-Use Formulations	Quantity	%
EFV (200 mg) Tablet (Scored) - 90	474,000	75%
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60	94,000	15%
LPVr (80 mg + 20 mg/ml) Oral Solution	65,000	10%

Non-Essential Formulations	Quantity	%
AZT (50 mg/5 ml) Oral Solution – 240 mL	320,000	56%
ABC/3TC (60/30 mg) Tablet (Disp) - 60	185,000	32%
EFV (200 mg) Capsules - 90	65,000	12%

Quantities are based on orders placed for delivery in 2(

The APWG website includes relevant optimization documents

https://www.arvprocurementworkinggroup.org/home

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

APWG Anticipated Demand Forecast published quarterly

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**

APWG Anticipated ARV Demand Forecast as of September 23, 2020: *By Expected Delivery Quarter*

(total pack volumes across all procurement agents by expected delivery quarter, defined as the quarter in which ARVs are expected to be handed over to the local client according to the respective incoterms. Below orders are listed as "placed" or "to be placed" by the procurement agents.)

Below forecast only includes order data from APWG Procurement Agents: GHSC-PSM, PPM, UNICEF, UNDP, KEMSA, PAHO, EPSA. Forecast data from the USAID ARV Forecast is included in the second table below (row 61 and down), and only includes 'to be placed' orders.

Target Delivery Quarters →	Q4 2020	Q1 2021	Q2 2021	Q3 2021
Optimal Pediatric Products				
ABC/3TC (120/60 mg) Tablet (Disp) - 30	1,771,438	725,350	-	100,131
ABC/3TC (120/60 mg) Tablet (Disp) - 60	20,454	254,240	-	18,900
AZT (50 mg/5 ml) Oral Solution - 100ml	3,532	60,850	-	-
AZT/3TC (60/30 mg) Tablet (Disp) - 60	231,835	60,443	2,789	-
LPV/r (100/25 mg) Tablet (HS) - 60	312,922	416,116	168,329	33,128
LPV/r (100/25 mg) Tablet (HS) - 120	28,033	-	-	-
LPV/r (40/10 mg) Oral Pellet - HS - 120	211,817	72,720	13,104	-
LPV/r (40/10 mg) Oral Granule - HS - 120	285,999	81,288	155,718	-
NVP (50 mg) Tablet (Disp) - 30	50,000	-	-	-
NVP (50 mg) Tablet (Disp) - 60	-	2,598	-	-
NVP (50 mg/5 ml) Oral Solution - 100ml	198,691	199,190	100,105	20,193
RAL (25 mg) Tablet (Scored) - 60	60	45	-	971
Limited-Use Pediatric Products				
3TC (50 mg/5 ml) Oral Solution - 100ml	-	-	-	-
ABC (60 mg) Tablet (Disp) - 60	-	-	-	-
ATV (200 mg) Capsule - 60	6	-	-	-
AZT/3TC/NVP (60/30/50 mg) Tablet (Disp) - 60	-	-	-	-
DRV (75 mg) Tablet - 480	-	-	-	526
EFV (200 mg) Tablet (Scored) - 90	12,462	683	-	627
LPV/r (80 mg + 20 mg/ml) Oral Solution - 160ml	1,073	-	-	-
LPV/r (80 mg + 20 mg/ml) Oral Solution - 5x60ml	14,721	1,940	30	6,506
RAL (100 mg) Granules - 60	1,920	-	-	-
RTV (100 mg) Powder - 30	6,588	-	-	-
RTV (25 mg) Tablet - 30	-	-	-	-
RTV (25 mg) Tablet - 60	-	-	-	-

Latest quarterly demand forecast and other APWG documents can be found here:
https://www.arvprocurementworkinggroup.org/arv-procurement-working-group-documents

Questions


PEPFAR
The Global Fund
Pan American Health Organization
USAID
FROM THE AMERICAN PEOPLE
i+ solutions
universal access to essential medicines
ICAP
COLUMBIA UNIVERSITY
Mailman School of Public Health
CLINTON HEALTH ACCESS INITIATIVE
KEMSA
ECS
Unitaid
EPSA
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
EXPERTISE FRANCE
unicef
DNDi
Drugs for Neglected Diseases initiative
ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION
Réseau
eva
Enfants et VIH en Afrique
IAS
medicines patent pool
MEDECINS SANS FRONTIERES
UNDP
World Health Organization

PEPFAR

U.S. President's Emergency Plan for AIDS Relief

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

17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

Agenda

- Priorities for Adult Treatment
- Priorities for Pediatric Treatment
- Priorities for Tuberculosis Preventive Treatment (TPT)

PEPFAR

U.S. President's Emergency Plan for AIDS Relief

Priorities for Adult treatment

Catherine Godfrey, M.D.

14 October 2020

17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

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

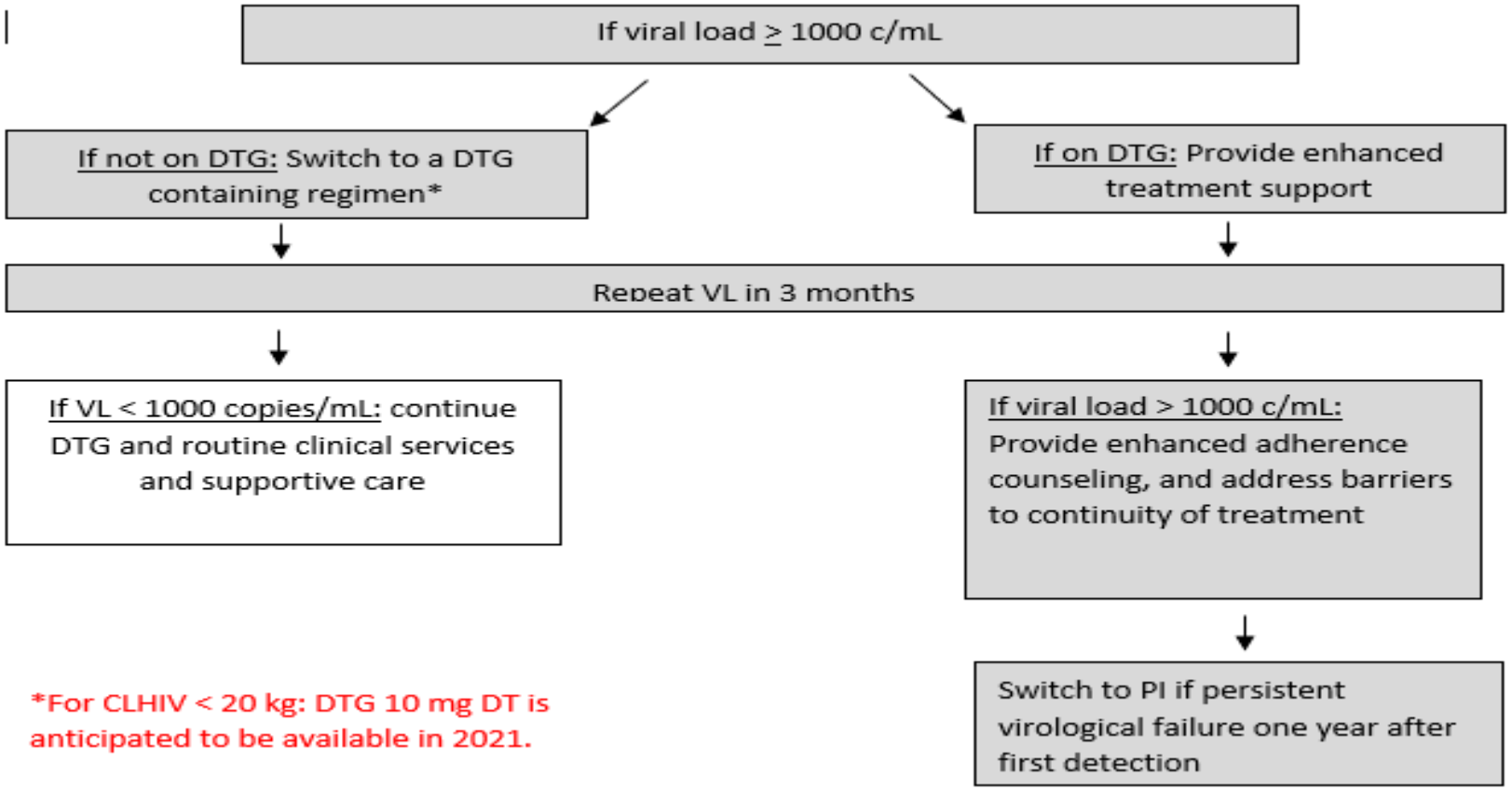
Individuals on TLE and PI based regimens should be switched

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

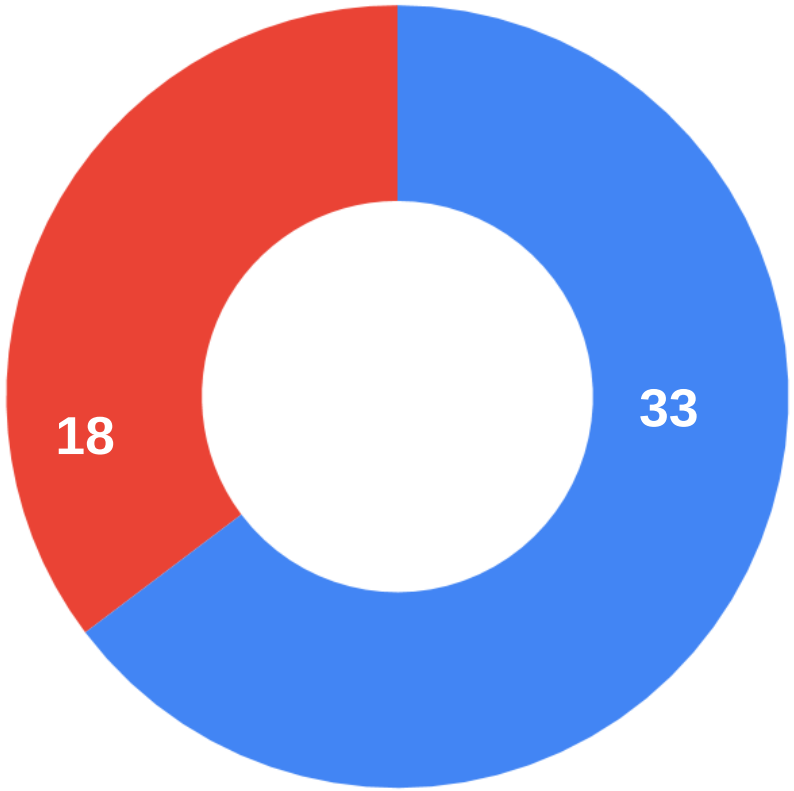
Tenofovir Alafenamide (TAF)

- 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

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

COVID-related Changes to MMD Policy among PEPFAR-supported Countries with Care & Treatment Program

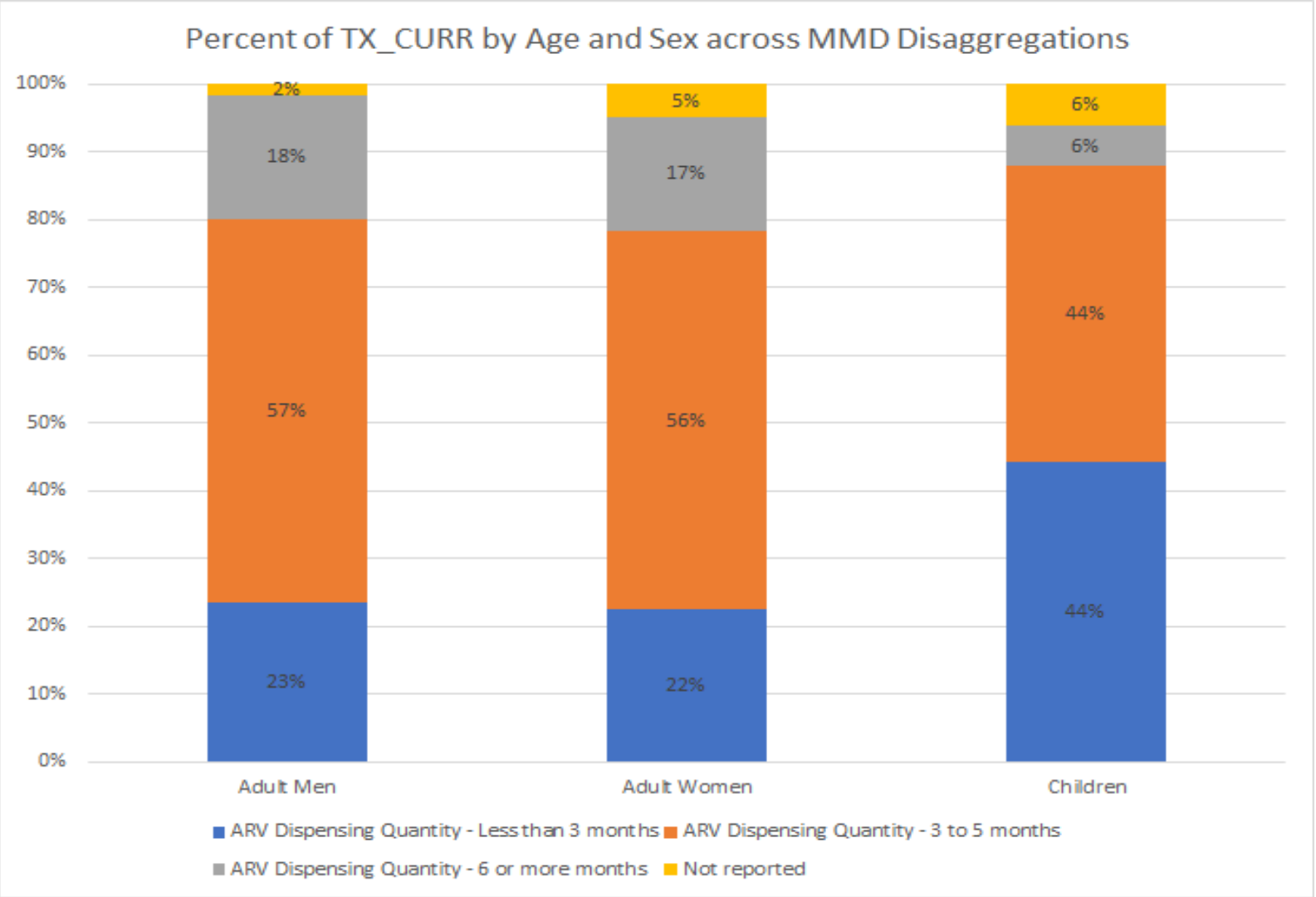


PEPFAR has knowledge or record of 33 of 51 (~65%) PEPFAR-supported countries with C&T programs amending MMD policy or implementation to increase MMD coverage during the COVID-19 response.

PEPFAR countries that changed MMD policies and/or implementation of MMD since 03/2020 due to

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

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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”)

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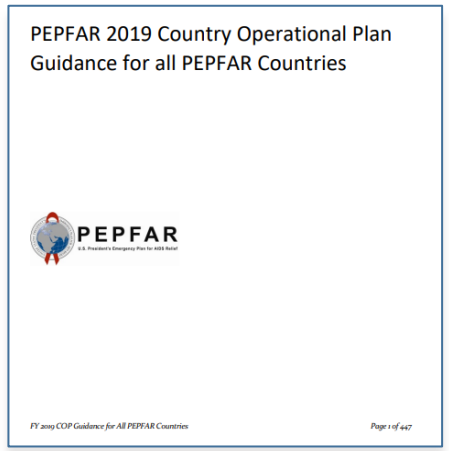
Priorities for Pediatric treatment

Rachel Golin, M.D.

14 October 2020

17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

PEPFAR promotes pediatric ART optimization

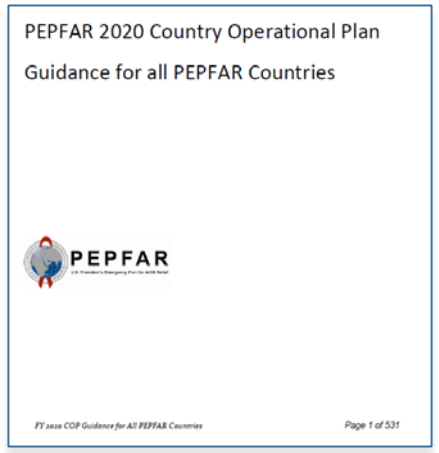

PEPFAR 2019 Country Operational Plan
Guidance for all PEPFAR Countries

PEPFAR

FY 2019 COP Guidance for All PEPFAR Countries Page 1 of 447

"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


PEPFAR 2020 Country Operational Plan
Guidance for all PEPFAR Countries

PEPFAR

FY 2020 COP Guidance for All PEPFAR Countries Page 1 of 531

"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

Table 1. Preferred and alternative first-line antiretroviral therapy regimens

Population	Preferred first-line regimen	Alternative first-line regimen
Children	ABC + 3TC + DTG[a]	ABC + 3TC + LPV/r or RAL[b] TAF + 3TC (or FTC) + DTG[c]
Neonates	AZT + 3TC + RAL[d]	AZT + 3TC + NVP

[a] For age and weight groups with approved DTG dosing.
[b] RAL should be used as an alternative regimen only if LPV/r solid formulations are not available.
[c] For age and weight groups with approved TAF dosing.
[d] Neonates starting antiretroviral therapy with an RAL-based regimen should transition to an LPV/r solid formulation as soon as possible.

Table 2. Preferred and alternative second-line antiretroviral therapy regimens

Population	Failing first-line regimen	Preferred second-line regimen	Alternative second-line regimens
Children and infants	ABC + 3TC + DTG[a]	AZT+ 3TC + LPV/r (or ATV/r[b])	AZT + 3TC + DRV/r[c]
	ABC (or AZT) + 3TC + LPV/r	AZT (or ABC) + 3TC + DTG[a]	AZT (or ABC) + 3TC + RAL
	ABC (or AZT) + 3TC + EFV	AZT (or ABC) + 3TC + DTG[a]	AZT (or ABC) + 3TC + LPV/r (or ATV/r[b])
	AZT + 3TC + NVP	ABC + 3TC + DTG[a]	ABC + 3TC + LPV/r (or ATV/r[b] or DRV/r[c])

[a] For age and weight groups with approved DTG dosing.
[b] ATV/r can be used as an alternative to LPV/r for children older than three months, but the limited availability of suitable formulations for children younger than six years, the lack of a fixed-dose formulation and the need for separate administration of the ritonavir booster should be considered when choosing this regimen.
[c] DRV should not be used for children younger than three years and should be combined with appropriate dosing of ritonavir.

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

PEPFAR's DTG 10 mg Country Readiness Questionnaire (1/2)

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

PEPFAR's DTG 10 mg Country Readiness Questionnaire (2/2)

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

PEPFAR

U.S. President's Emergency Plan for AIDS Relief

Priorities for Tuberculosis treatment

Teeb Al-Samarrai, M.D.

14 October 2020

17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

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

Year	Target	Achievement
FY18	1,900,000	797,418
FY19	2,800,000	1,393,965
FY20	6,300,000	1,382,382
Total	11,000,000	3,573,765

COVID-19 Impact on TPT Uptake

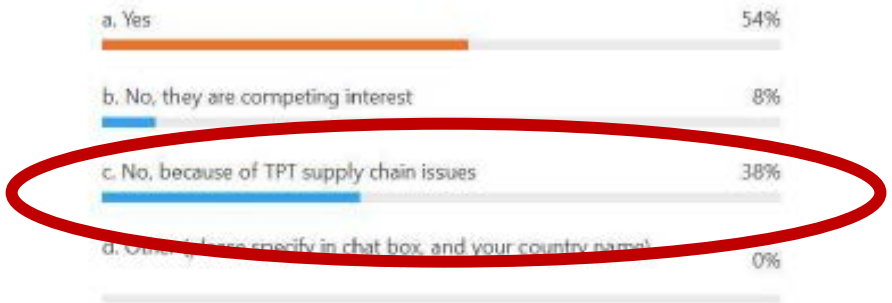
- Declines in patient volume at health care facilities
- Declines in HIV case finding
- TB Programs and staff diverted to COVID-19 response
- Declines in TB case finding
- TPT scale-up significantly impacted
  - Multiple countries at high risk of INH stock-out, limiting MMD
  - Delays in 3HP
- *However,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

Country	MMD TB	MMD TPT
Botswana	N/A	N/A
Cameroon	**Yes**	N/A
Cote d'Ivoire	N/A	N/A
DRC	N/A	N/A
Eswatini	N/A	**Yes**
Ethiopia	**Yes**	No
Haiti	**Yes**	**Yes**
Kenya	**Yes**	**Yes**
Lesotho	**Yes**	**Yes**
Malawi	N/A	Paused TPT
Mozambique	N/A	**Yes**
Namibia	**Yes**	**Yes**
Nigeria	**Yes**	**Yes**
Rwanda	N/A	**Yes**
Uganda	**Yes**	**Yes**
Tanzania	N/A	**Yes**
South Africa	**Yes**	**Yes**
Vietnam	N/A	N/A
Zambia	**Yes**	**Yes**
Zimbabwe	**Yes**	**Yes**

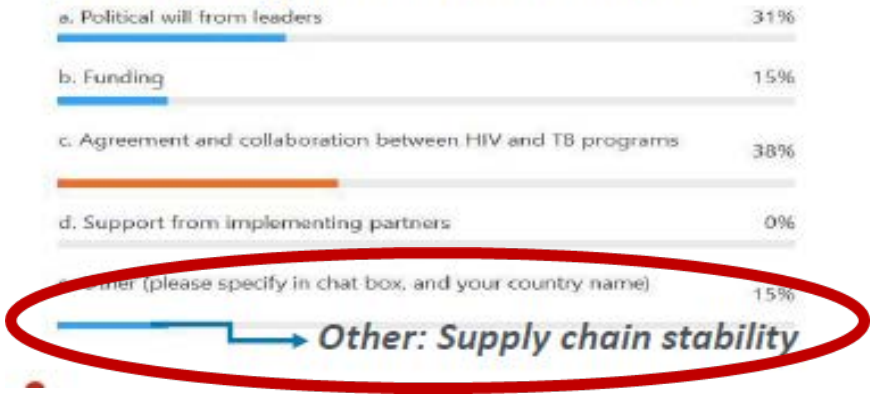
Source: Al-Samarrai T. Scaling up TPT in PEPFAR: Experience and Lessons Learned. Presented at Proceedings of the International AIDS Society; July 2020; On Demand Session: Leveraging Differentiated Service Delivery to Enhance Coverage and Completion of Tuberculosis Preventive Treatment (TPT).

Country Feedback: Integrating TPT into DSD during COVID-19

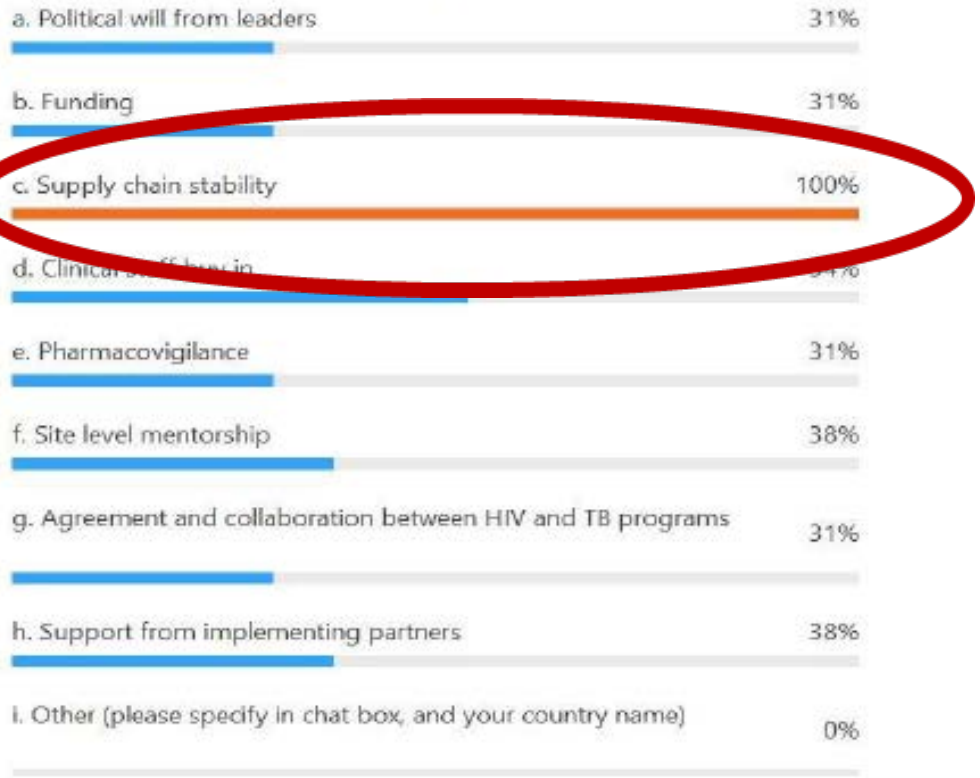
Poll question 1 - *Has the push for MMD for ART helped scale-up integration of TPT into DSD?*



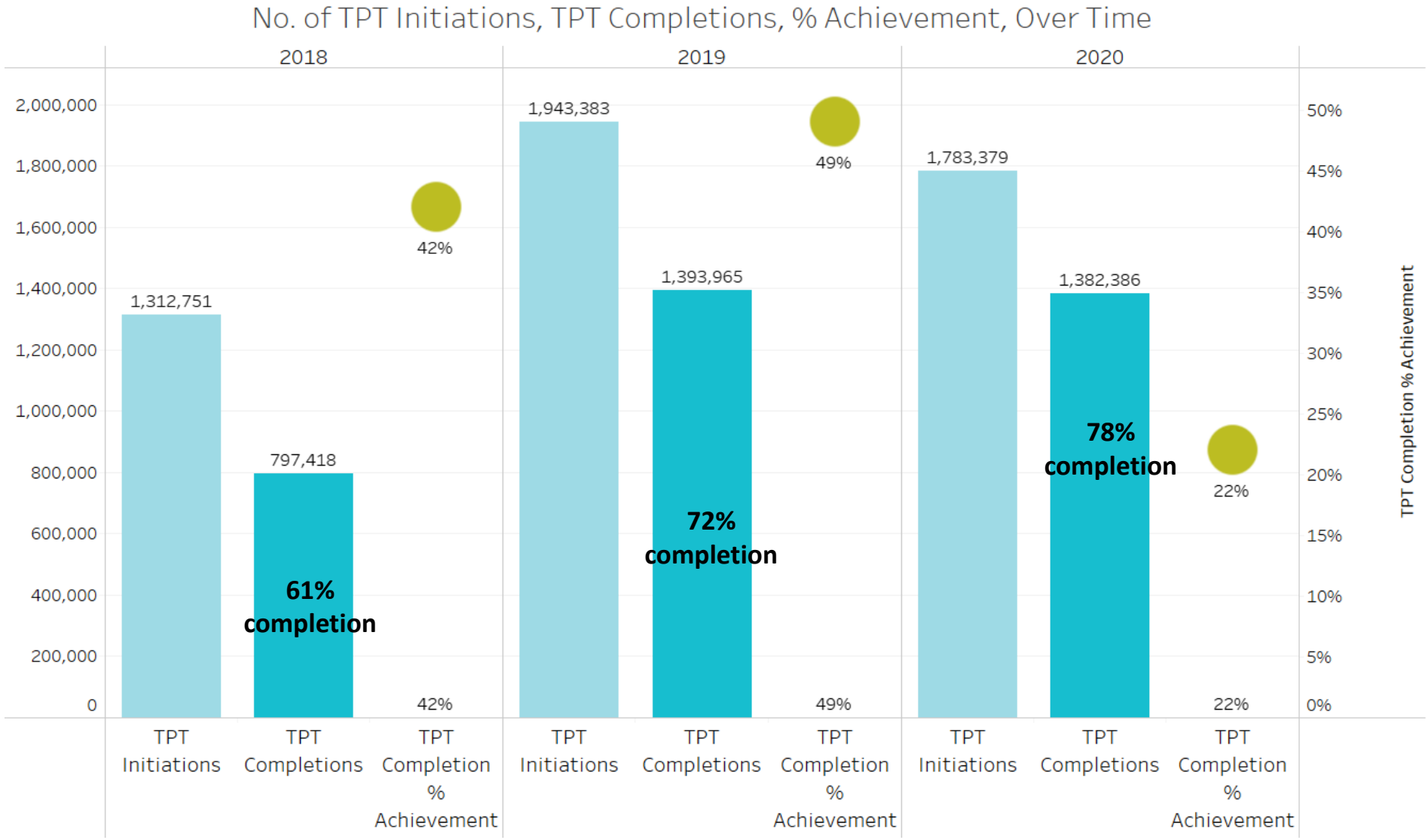
Poll question 2 - *What are the current barriers for integrating TPT into DSD models?*



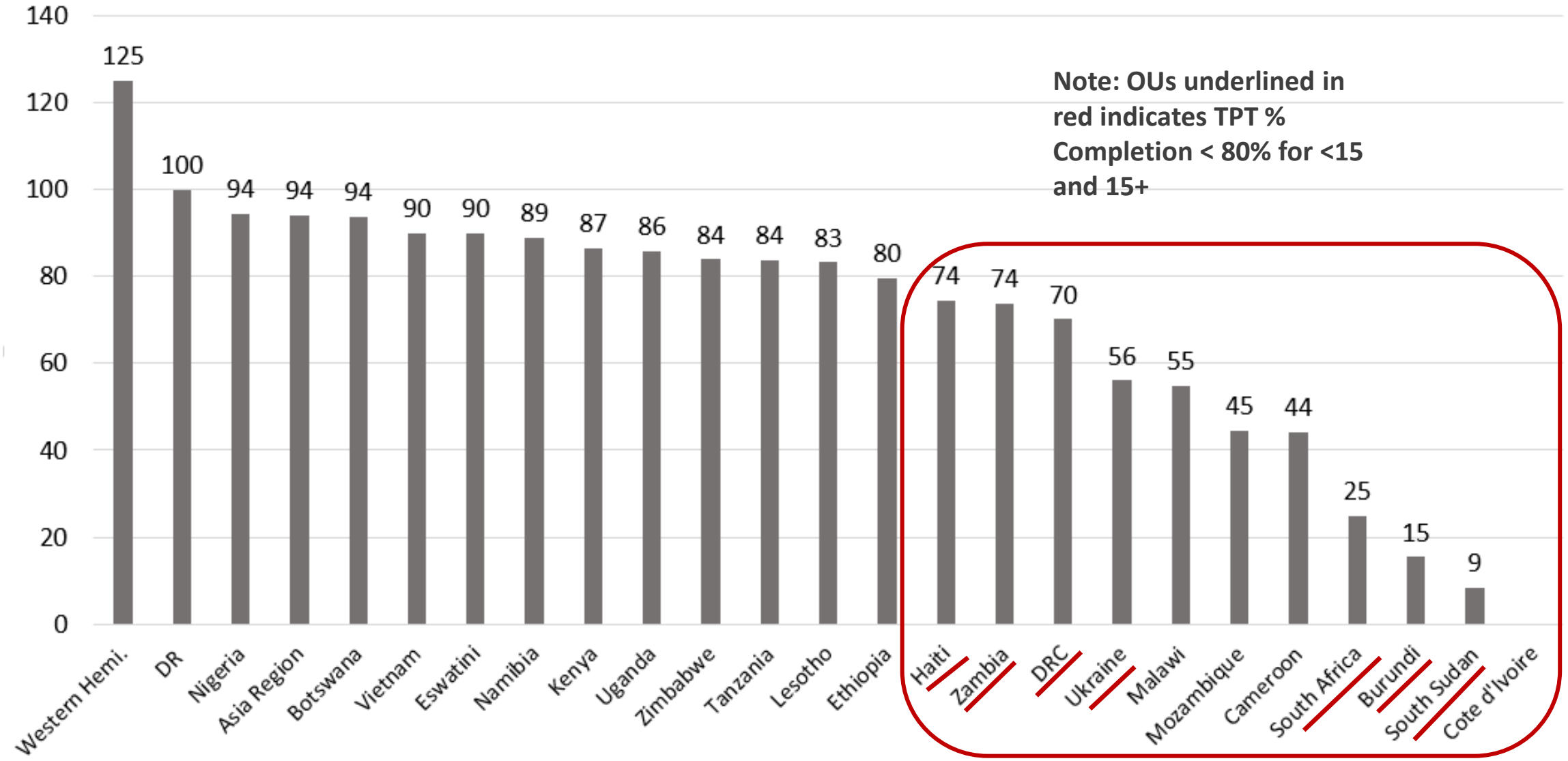
Poll question 3 - *What are the three most important ingredient for integrating TPT into DSD models?*



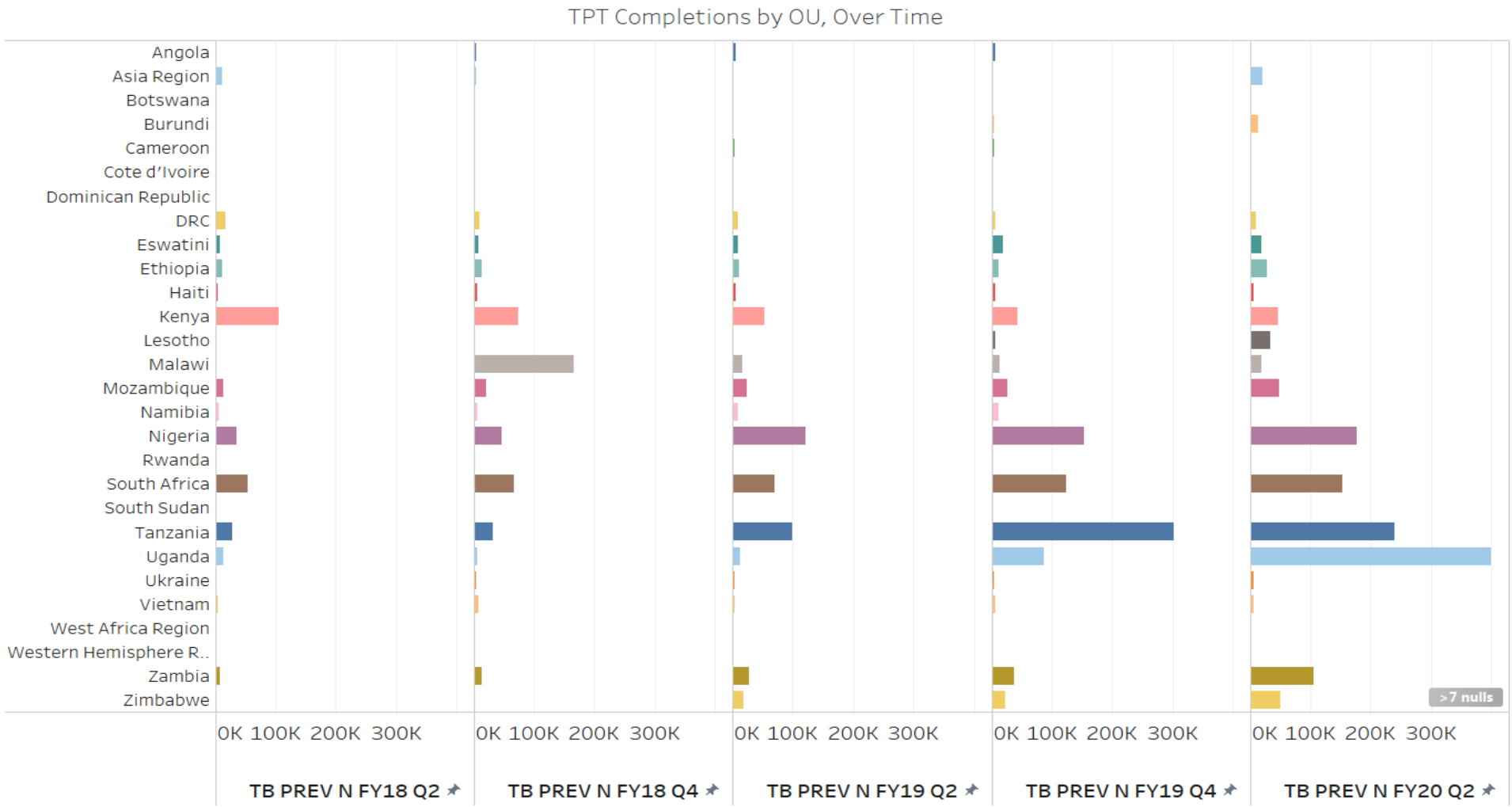
Number of PLHIV completing TPT, 2018-2020 Q2



Percentage of TPT Completion by Country/Region, among <15, FY20 Q2



TPT Coverage in PEPFAR OUs over Time



TB Preventive Regimens for PLHIV

TPT regimen	Adults & adolescents	Children	DTG dose adjustment
INH/B6/Cotrimoxazole daily (180/270 doses)*	6 months (300 mg daily)	N/A	NO
INH +/- B6	300 mg daily	9 months 10-20mg/kg (max dose: 300 mg)	NO
3HP 900mg/900mg weekly	INH: 15 mg/kg (rounded to nearest 50 or 100 mg max: 900 mg)	>2-11 years old INH: 25 mg/kg Rifapentine weight based starting at 10 kg: 300/450/600/750/900 mg	If on efavirenz-based regimen: 50 mg BID (adults)
1HP 600mg/300mg daily x28 days*		>13 years age only	Data pending
4R daily	10 mg/kg (Max dose = 600 mg)	15-20 mg/kg (Max dose = 600 mg) (pending availability in child-friendly regimen)	50 mg BID (adults)
3HR daily	INH: 5 mg/kg (300 mg) Rif: 10 mg/kg (600 mg)	INH:10-20 mg/kg Rifampin: 15-20 mg/kg	50 mg BID (adults)


PEPFAR
U.S. President's Emergency Plan for AIDS Relief
Thank you
17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS


USAID
FROM THE AMERICAN PEOPLE
PEPFAR
ARV Summit - Evolve
Product Description &
Documentation
MOE-2013

CHALLENGE

- 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

Tarang Verma, Hetero

- **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 Dubin, USAID/Supply Chain for Health

- 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)

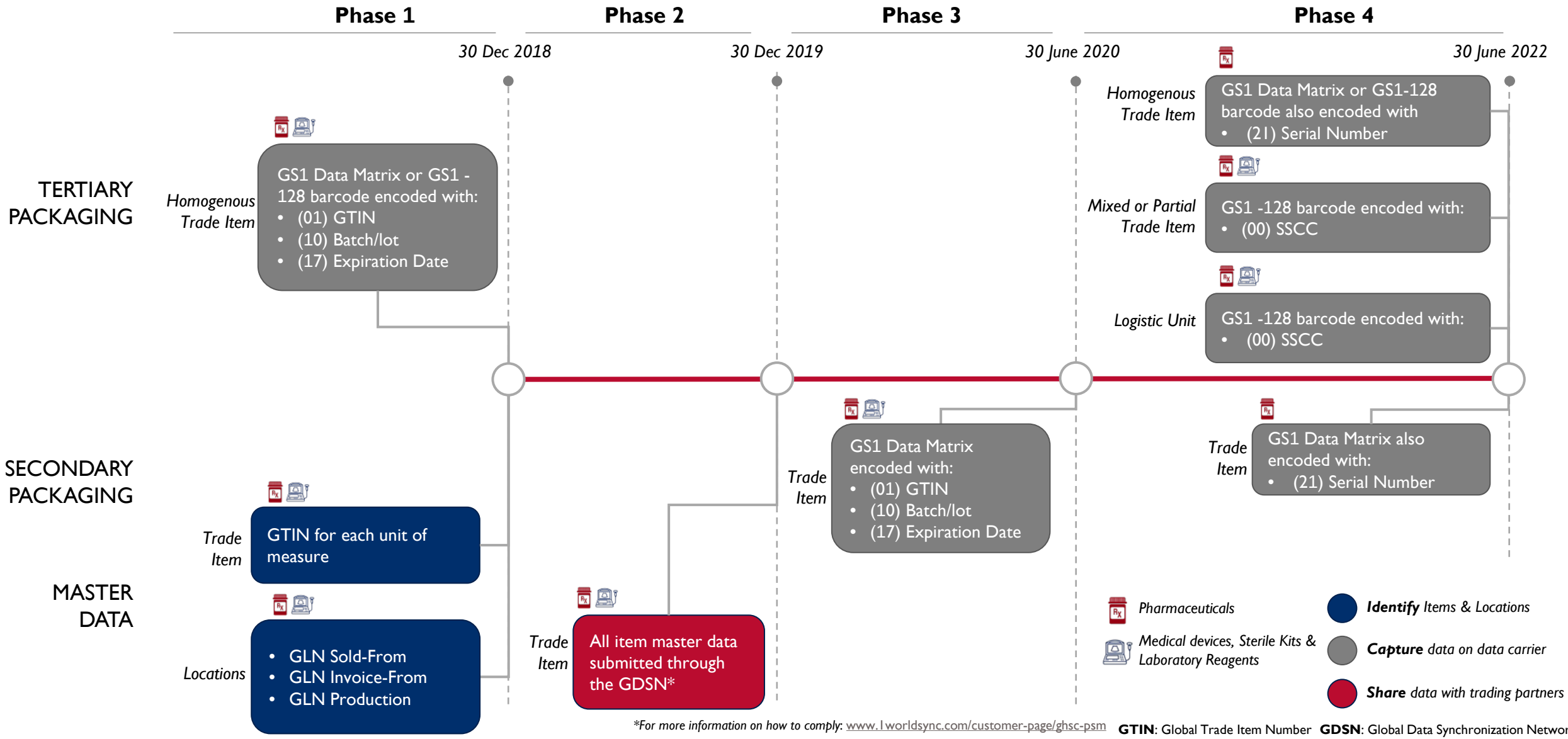
USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM

Procurement and Supply Management

USAID FROM THE AMERICAN PEOPLE

PEPFAR U.S. President's Emergency Plan for AIDS Relief

Global standards requirements for pharmaceuticals, medical devices, sterile kits, and laboratory reagents



*For more information on how to comply: www.1worldsync.com/customer-page/ghsc-psm

For more information on our requirements: http://ghsupplychain.org/globalstandards

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

Joint donor guideline

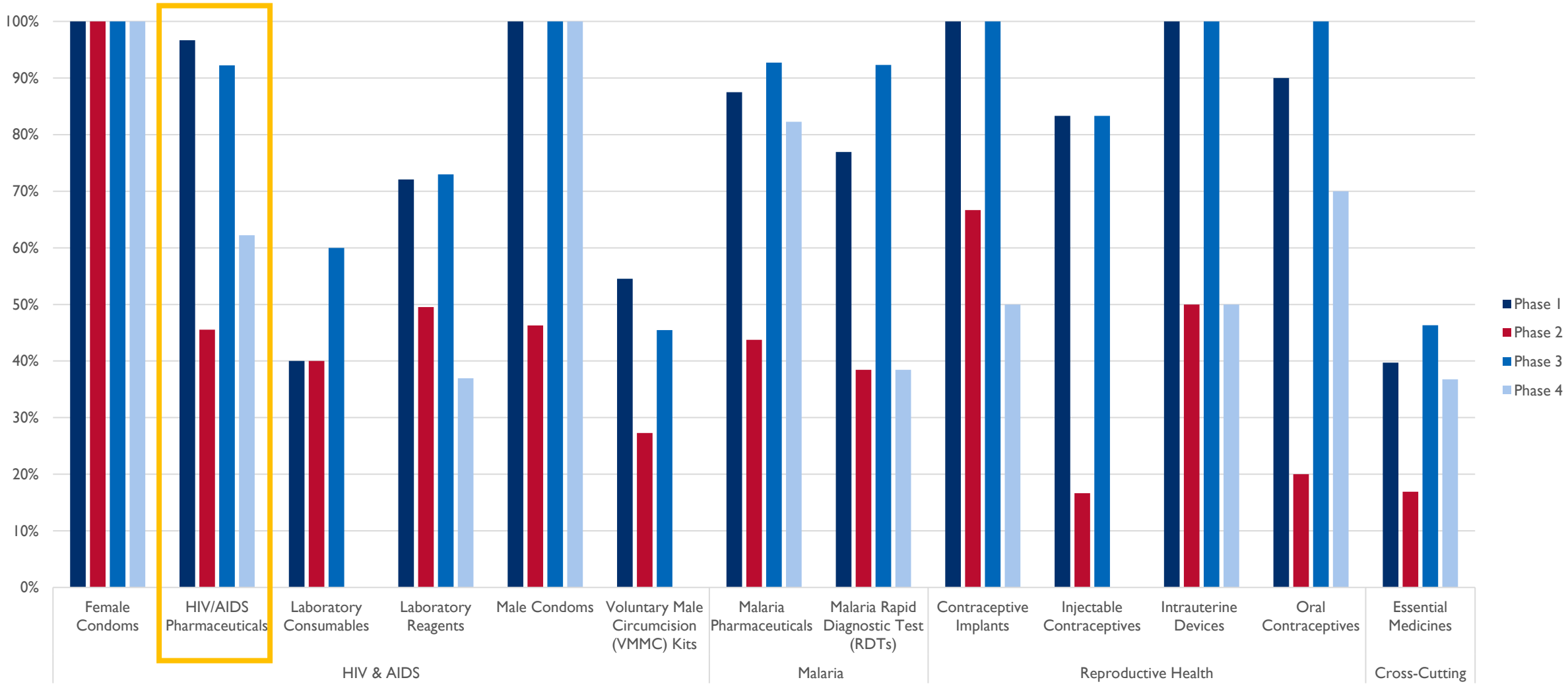
- Single primary reference document for technical requirements to meet requirements for implementation of global standards for product and location identification, labeling, and data exchange
- Endorsed by the Global Drug Facility/StopTB, Global Fund, UNDP, UNFPA, and USAID

Guideline available to download: https://www.ghsupplychain.org/index.php/global-standards-technical-implementation-guideline-global-health-commodities-v21

International procurement agency timelines – pharmaceuticals and vaccines

Agency	Phase 1	Phase 2	Phase 3	Phase 4
Global Drug Facility	31 Dec 2019	31 Dec 2019	30 Jun 2020	30 Jun 2022
The Global Fund	31 Dec 2019	31 Dec 2019	30 Jun 2020	30 Jun 2022
UNDP	Voluntary but preferred			
UNFPA	31 Dec 2019	31 Dec 2020	Voluntary but preferred	
USAID GHSC-PSM	30 Dec 2018	30 Dec 2019	30 Jun 2020	30 Jun 2022

Current compliance in key product categories



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

For questions, please contact:

Rachel Smith

rsmith@ghsc-psm.org

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.

HETERO GS1 JOURNEY

Virtual Annual ARV Buyer Seller Summit.

Oct 15th'2020

Ms. Tarang Verma.

Sr. Manager, International Marketing.

HETERO

Follow us on:

GS1 Implementation Journey

HETERO

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

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

Objective of Global GS1

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

USA – DSCSA	Since Sep'17
EU – FMD	Since Dec'18
Russia & China	Under Process
USAID (GHSC-PSM)	Phase wise implementation*

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

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

Regulatory compliance & Data integrity

Implement ation Cost

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

Lessons Learnt, Takeaway messages!

- Invest significant time & efforts from initial analysis phase.
- Think GS1 as an “End-to-End process”, don’t cut corners.
- Engage with experienced partner(s).
- Equipment selection plays pivotal role to deliver the best outcome, equipment’s like: scanners, printers, scan devices etc.
- The GS1 requirements across various healthcare systems should be aligned.
- Development of country healthcare systems enabling GS1/Track & Trace

CONCLUSION

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

Its good to be on “Track” which you can “Trace”.

HETERO

Follow us on:


USAID
FROM THE AMERICAN PEOPLE
PEPFAR
SHIPPING DOCUMENTATION
AND LABELING IMPROVEMENT
MOE-2013

CHALLENGE

- 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 Global Language of Business

The GS1 Digital Link Standard in Healthcare

ARV Summit: Product Specifications and Documentation (R1)

Pete Alvarez

15 October 2020

A GS1 Healthcare strategic objective

A single barcode for identification and access to product information

GS1 Healthcare Position Paper on GS1 DataMatrix Implementation

GS1 Healthcare Position Statement on GS1 DataMatrix Implementation

To meet the growing demands of increased data needs and facilitate increased patient safety, the healthcare community is in the position to be the leader in GS1 DataMatrix implementation. To demonstrate support of this leadership position, the GS1 Healthcare community has set a goal of 2015 for implementation of GS1 DataMatrix printing on, and scanning of, Regulated Healthcare Trade Items where the current needs are not being met by other GS1 Data Carriers. While not a binding mandate, the community feels strongly in setting a clear direction to further galvanize the industry and encourage action over and above the many active implementations that exist today.

Global standards for automatic identification provide an opportunity to make the healthcare supply chain safer as well as more efficient and accurate. Healthcare regulators and trading partners have realized that a global, standardized identification system from product manufacture to patient treatment is imperative to comply with the increasing need for product traceability around the world.

The GS1 System, globally endorsed by the healthcare community, is the most widely used trade item identification system worldwide with more than 5 billion transactions per day. Built on a foundation of identification keys (such as the Global Trade Item Number or GTIN) and attributes (such as batch/lot numbers, expiry date, etc.) it is uniquely suited to meet the needs of the global healthcare industry.

Pharmaceutical and medical device identification & marking have very specific needs, including:

- Encoding large amounts of variable or dynamic data (lot number, expiration date, serial number, etc.) at high production speeds
- Direct part marking (e.g. marking on surgical instruments, etc.)
- Efficient marking of irregular packaging for many medical products
- Global legal and regulatory requirements that dictate the placement of data in a bar code symbol
- Traceability requirements for both pharmaceuticals and medical devices

Some of these needs are being met, and will continue to be met, through the use of "traditional" linear bar codes, such as GS1-128 or GS1 DataBar. However, for applications where they are not, GS1 Healthcare has adopted the use of GS1 DataMatrix as the data carrier (bar code symbol) solution.

GS1 DataMatrix is a 2-dimensional (2D) bar code symbology that efficiently meets all of the above needs by:

- **Allowing the encoding and marking** of a greater amount of data within a smaller space
- **Enabling direct part marking** of trade items where labels may not be practical (small medical / surgical instruments)
- **Providing error detection and correction** capabilities to improve the readability of bar codes despite irregular packaging or physical damage to a label

As with the implementation of any forward looking technology, there can be challenges that must be recognized. For GS1 DataMatrix, these could include:

- Upgrades to scanner systems: to read the GS1 DataMatrix symbology, camera-based bar code scanners are required. Linear technology based bar code scanners cannot read 2D bar codes, however camera-based bar code scanners can read both linear as well as 2D bar codes and users should be prepared to see both of these types of bar code symbols. (see the GS1 Healthcare position statement on 2D camera based scanners)
- Updates to printing systems: to print GS1 DataMatrix, particularly on-line, direct to packaging, within production environments, printing systems may need software / hardware updates or replacement
- Updates to IT infrastructure systems: to ensure that dynamic, variable attribute data (lot/batch, expiry, serial number, etc.) is available for encoding in a "real time" packaging environment as well as ensuring that the underlying systems can support the additional data where this is not already implemented

Recognising all of these needs, as well as the potential challenges of implementation, GS1 Healthcare and its global members strongly support the implementation of 2D capable scanners and the adoption of GS1 DataMatrix. A global implementation will not be accomplished without time and effort. The use of the GS1 DataMatrix can facilitate increased automation of data capture in any country without creating trade barriers that could otherwise potentially impact patient care and safety.

Where GS1 DataMatrix can enhance or solve data capture issues, we need to begin or expand implementations and ensure that the infrastructure is in place as we move to the use of 2D Symbols (like GS1 DataMatrix) through the investment in 2D capable scanners. To bring awareness to the industry of the need to consider these practical challenges and to move forward as quickly as practical, GS1 Healthcare urges that new investments in printing and scanning systems throughout the global healthcare market include compliancy to GS1 DataMatrix.

About GS1 Healthcare

GS1 Healthcare is a global, voluntary user community bringing together all Healthcare supply chain stakeholders, including manufacturers, distributors, Healthcare providers, solution providers, regulatory bodies and industry associations. The mission of GS1 Healthcare is to lead the Healthcare sector to the successful development and implementation of global standards by bringing together experts in Healthcare to enhance patient safety and supply chain efficiencies.

GS1 Healthcare members include over 60 leading Healthcare organisations worldwide. For more information about GS1 Healthcare, and to view this paper please visit www.gs1.org/healthcare.

GS1 Healthcare Position Paper on GS1 DataMatrix Implementation - December 2011

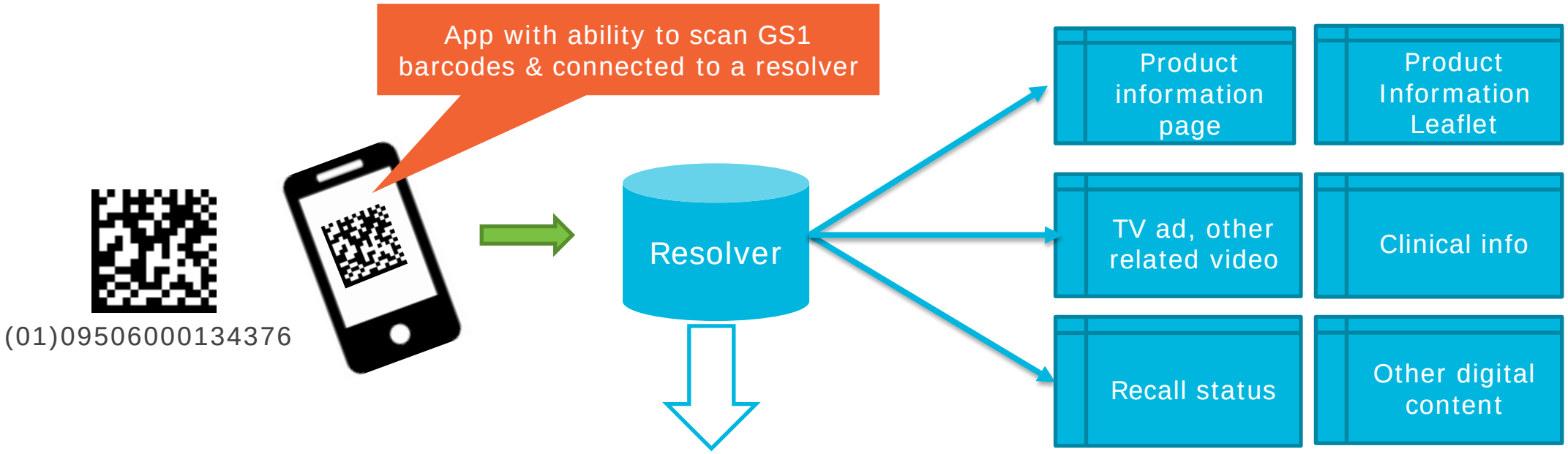
- Allow a single GS1 barcode on a medical products to be scanned and have the user (e.g., consumer, healthcare provider) access the product digital content, complementing the reliance on the label information.
- Drive the efforts towards ONE barcode on medical product packages

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)

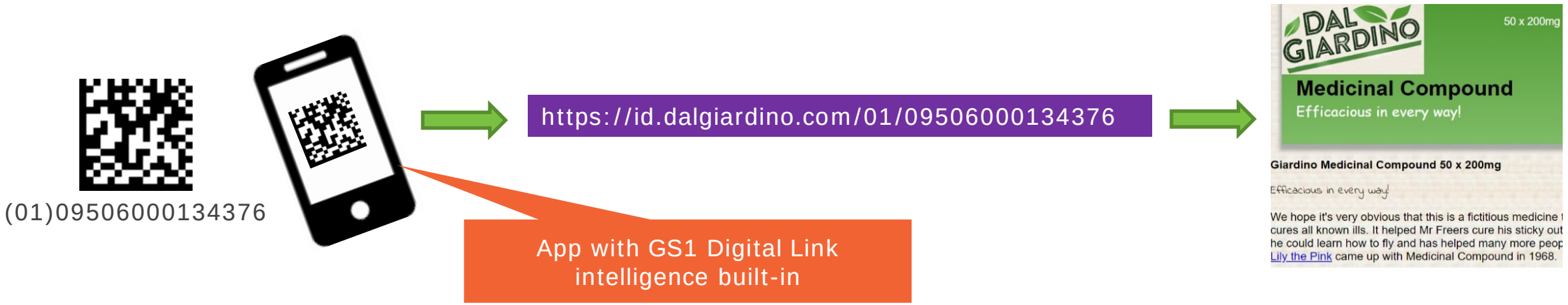
GS1 Digital Link standard with the existing GS1 barcode on the pack:



Link type	Lang	Target URL
gs1:pip	en	https://dalgiardino.com/medicinal-compound/
gs1:pip	ja	https://dalgiardino.com/medicinal-compound/index.html.ja
gs1:epil	en	https://dalgiardino.com/medicinal-compound/pil.html

Single destination (example)

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



- No resolver required to access a single destination.

Contact details

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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

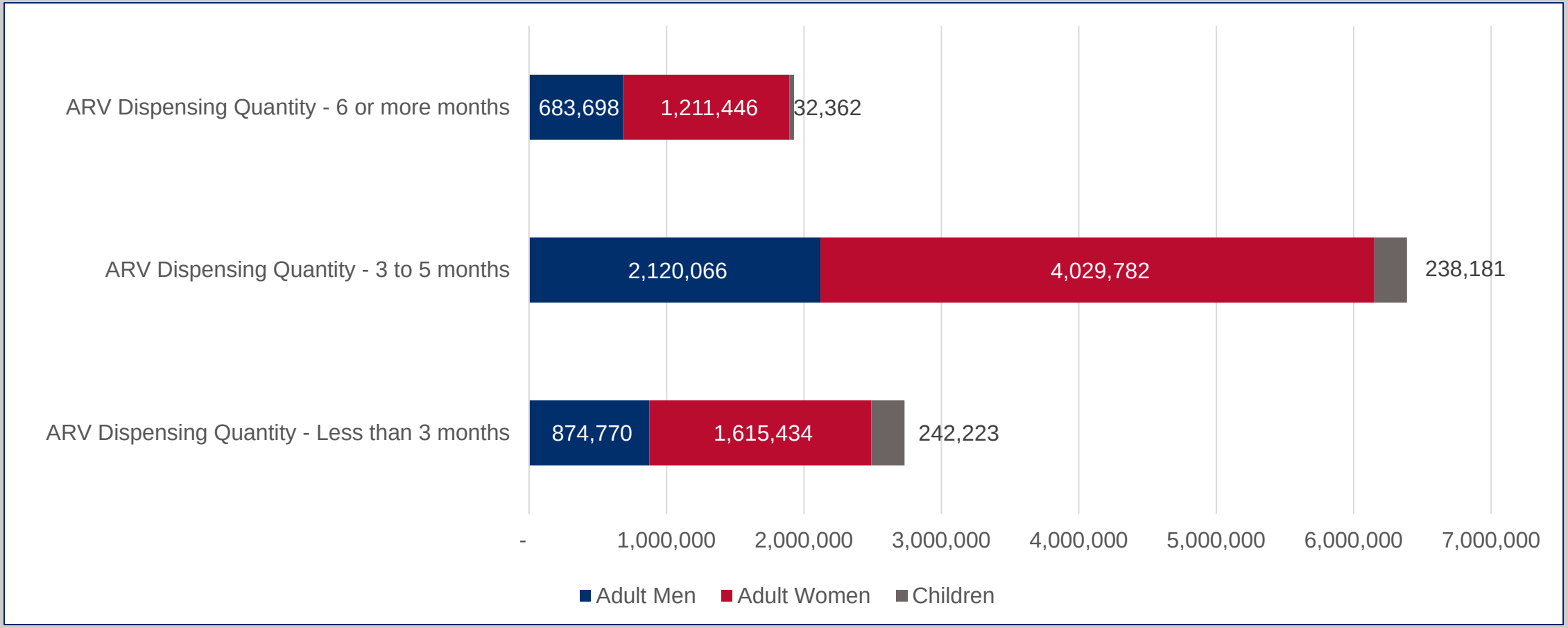
USAID Office of HIV/AIDS, Supply Chain Management Branch

How has supply chain historically impacted the ART patient experience?

- Distribution methods
- Continuous drug availability
- Shelf life
- Packaging
- Labeling
- Marketing and messaging

Photo Credit: CONRAD Website https://www.conrad.org/launchingv/

PEPFAR Multi Month Dispensing Footprint April to June 2020



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

		MMD	DDD
Dispensation (in months)	6MMD	6MMD	1M or 2M supply
Distribution Method	Clinics	DDD channels	DDD channels
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

		MMD	DDD
Dispensation (in months)	3MMD to 6MMD	3MMD to 6MMD	1M or 2M supply
Distribution Method	Clinics	DDD channels	DDD channels
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?

PHOTO CREDIT: TIMOTHY ROSCHE AND DENIS OKIDI LADWAR, GHSC-PSM

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 choice!
  - 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?

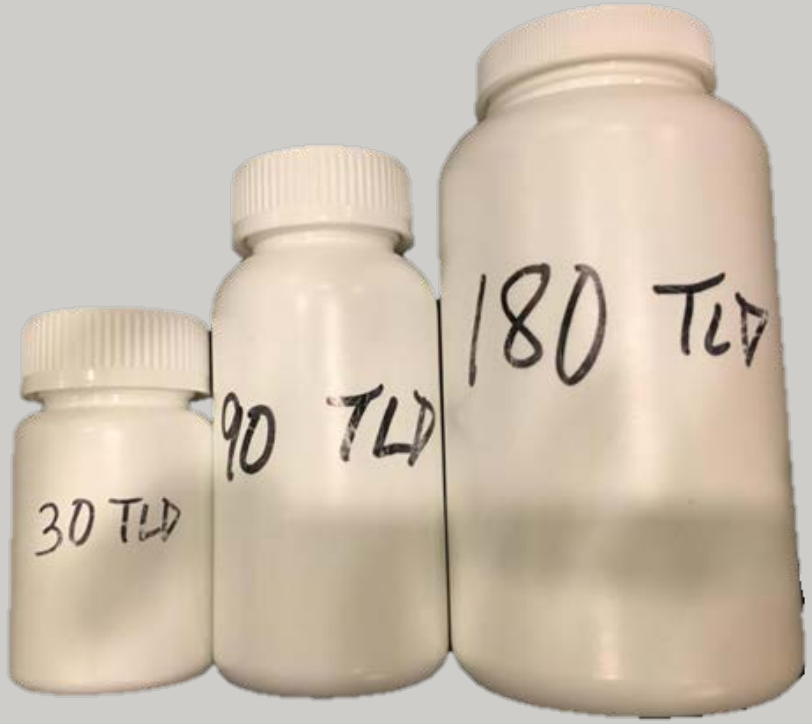


PHOTO CREDIT: CMALATI, USAID

It’s time to hear MORE from you!

Annual ARV Buyer Seller Summit | Virtual

Considering your experience, what are the enabling factors MMD?

INTEGRATE. UPDATE. EVOLVE.

Annual ARV Buyer Seller Summit | Virtual

How can we influence further expansion of MMD?

INTEGRATE. UPDATE. EVOLVE.

Considering your experience, what are the enabling factors DDD?

INTEGRATE. UPDATE. EVOLVE.

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?

INTEGRATE. UPDATE. EVOLVE.

What measures should we take to detect falsification of medicines dispensed at new dispensing sites?

INTEGRATE. UPDATE. EVOLVE.

Questions?

The next patient-friendly innovation...

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

Event # **41115**

Thank you!

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USAID
FROM THE AMERICAN PEOPLE

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

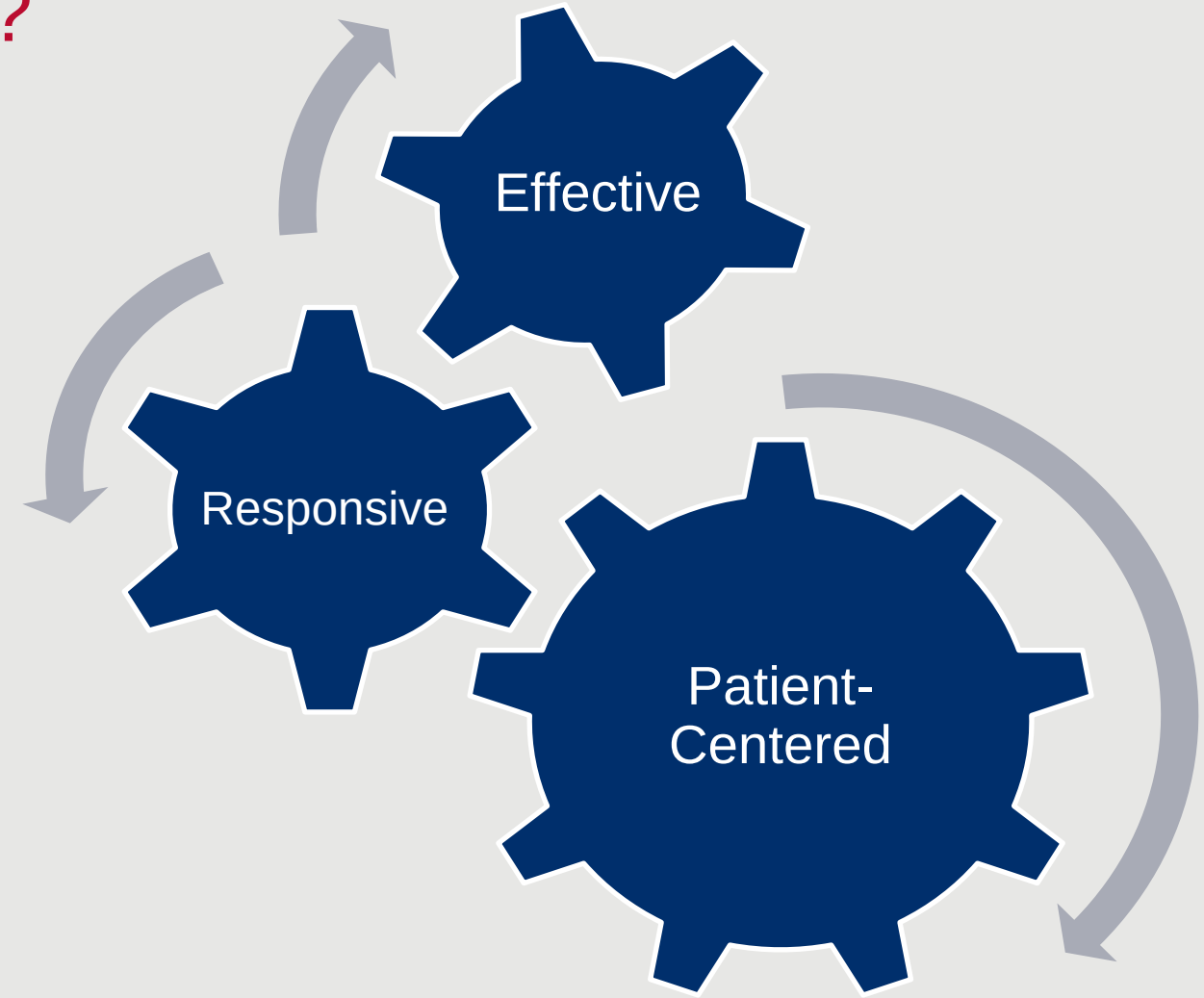
Julia Bem
Supply Chain Management Branch Chief
USAID Office of HIV/AIDS

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?



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

Points of Care

Decentralized Distribution Point

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?

Distributed for Sale via Private Sector Partner or Wholesaler?

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 vender-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

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1. What is the largest barrier to moving toward vendor-led in-country distribution?

INTEGRATE. UPDATE. EVOLVE.

Annual ARV Buyer Seller Summit | Virtual

2. Into how many destination countries have you arranged customs and importation?

INTEGRATE. UPDATE. EVOLVE.

3. Considering a March 2021 delivery, to what level of infrastructure would deliveries be possible? (looking for sustainable, not *ad hoc* solutions)

INTEGRATE. UPDATE. EVOLVE.

4. Which factor will be most important for the success of vendor managed logistics?

(put additional ideas into the chat box!)

INTEGRATE. UPDATE. EVOLVE.

5. In which country would you have the most confidence of managing logistics closest to patient distribution?

INTEGRATE. UPDATE. EVOLVE.

Thank you!

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Dan Kiesa
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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

"These results provide evidence that in generalised epidemic settings, offering universal access to PrEP can reduce HIV incidence."

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

"Just a 25% uptake of PrEP by women in the ECHO study produced a more than 50% fall in the rate of HIV infection."

Rapidly declining HIV infection in MSM in central London

Published Online October 20, 2017 http://dx.doi.org/10.1016/S2352-3018(17)30181-9

In 2016, there were 1·8 million [illegible] HIV infections worldwide. Although the annual [illegible] infections has fallen by 16% sinc[illegible] decline is far too slow to meet [illegible] been increasing since 2007.[6] The reduced incidence in [illegible] and bisexual men was most pronounced in London, [illegible] 29% decrease with an overall [illegible] of 11%.

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

In *The Lancet HIV*, Andrew E Grulich and colleagues[1] describe the rapid roll-out of pre-exposure prophylaxis (PrEP) in New South Wales, Australia (the Expanded PrEP Implementation in Communities–New South [illegible] [EPIC-NSW] study), a setting where the [illegible] suburbs and the rest of New South Wales, but was only 7·3% in the non-gay suburbs of the [illegible] the challenge of [illegible]

Australia On Path To Nearly Eliminate HIV Transmission By 2030 But Prevention Efforts Must Remain Strong, Experts Say

Jul 11, 2019

New York Times: How Australia Could Almost Eradicate HIV Transmissions
t took universal health care, political will, and a health campaign designed to terrify the public, but nea
ur decades into the HIV crisis, Australian researchers say the country is on a path to
nsmissions of the virus vanishingly rare. The fight is not yet won. [illegible]

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

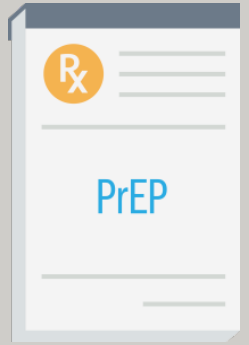
FREE

Dawn K Smith, Patrick S Sullivan, Betsy Cadwell, Lance A Waller, Azfar Siddiqi, Robertino Mera-Giler, Xiaohong Hu, Karen W Hoover, Norma S Harris, Scott McCallister

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

Published: 25 Februa[illegible] 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

USAID Supported PrEP demo studies, CAPRISA-DREAMS and POWER

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

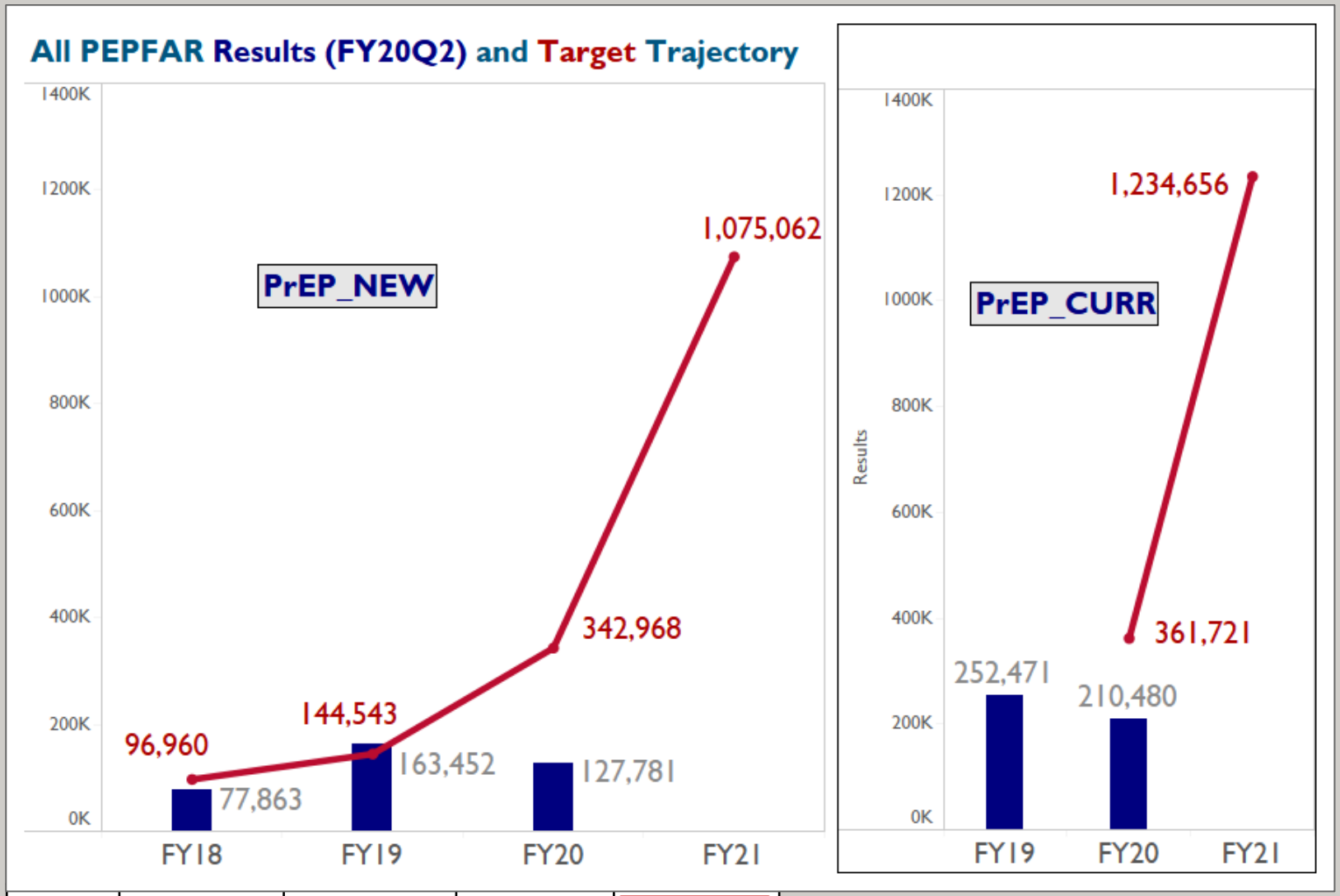
PEPFAR interagency PrEP community of Practice

COP 20
Ambitious goal to reach 1 million new people with PrEP during COP20 implementation

Accelerating from COP19 to COP20

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

Oral PrEP scale-up COP17-20

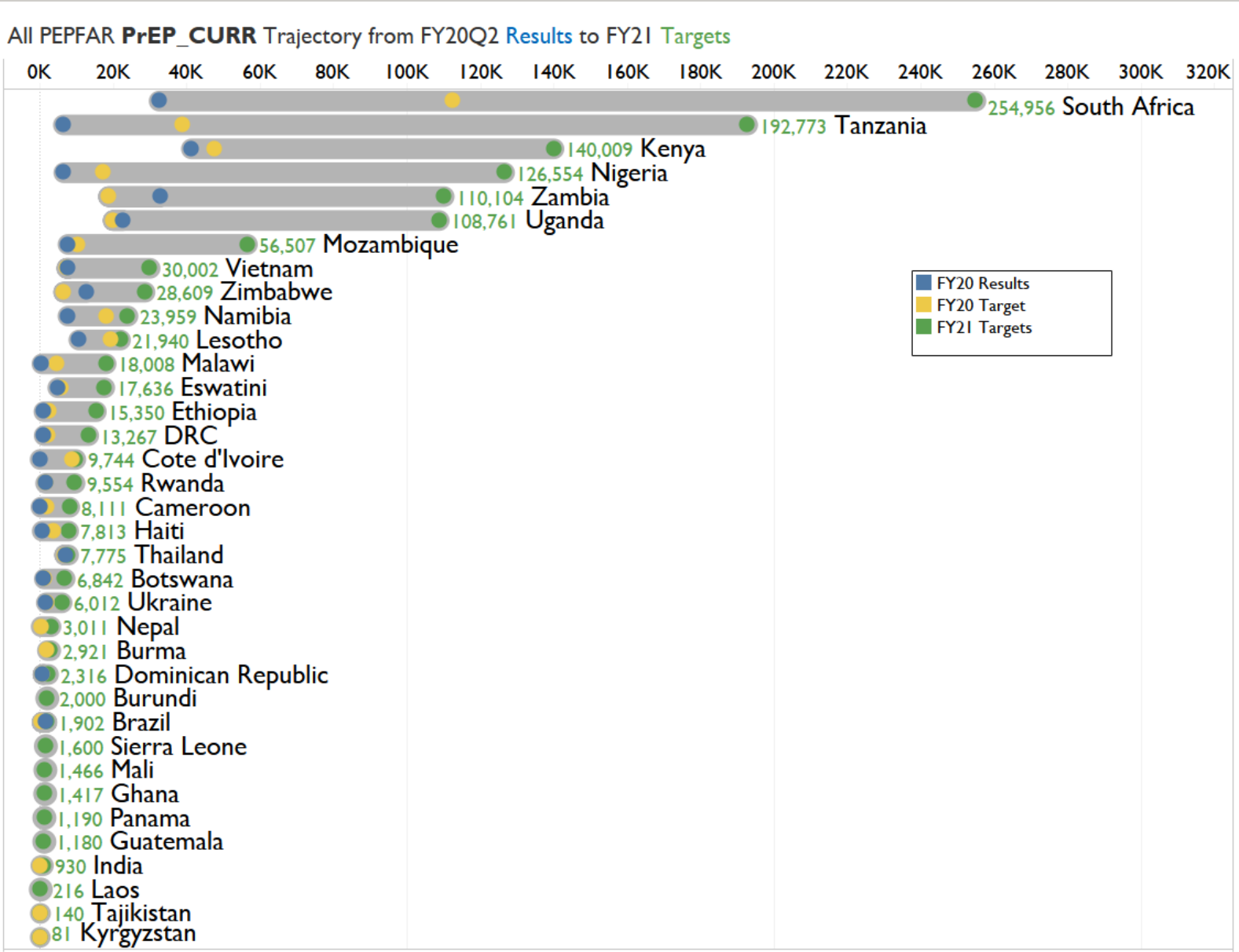


#countries w targets	17	21	29	36

Implementation expanded to **7 additional** countries in COP20

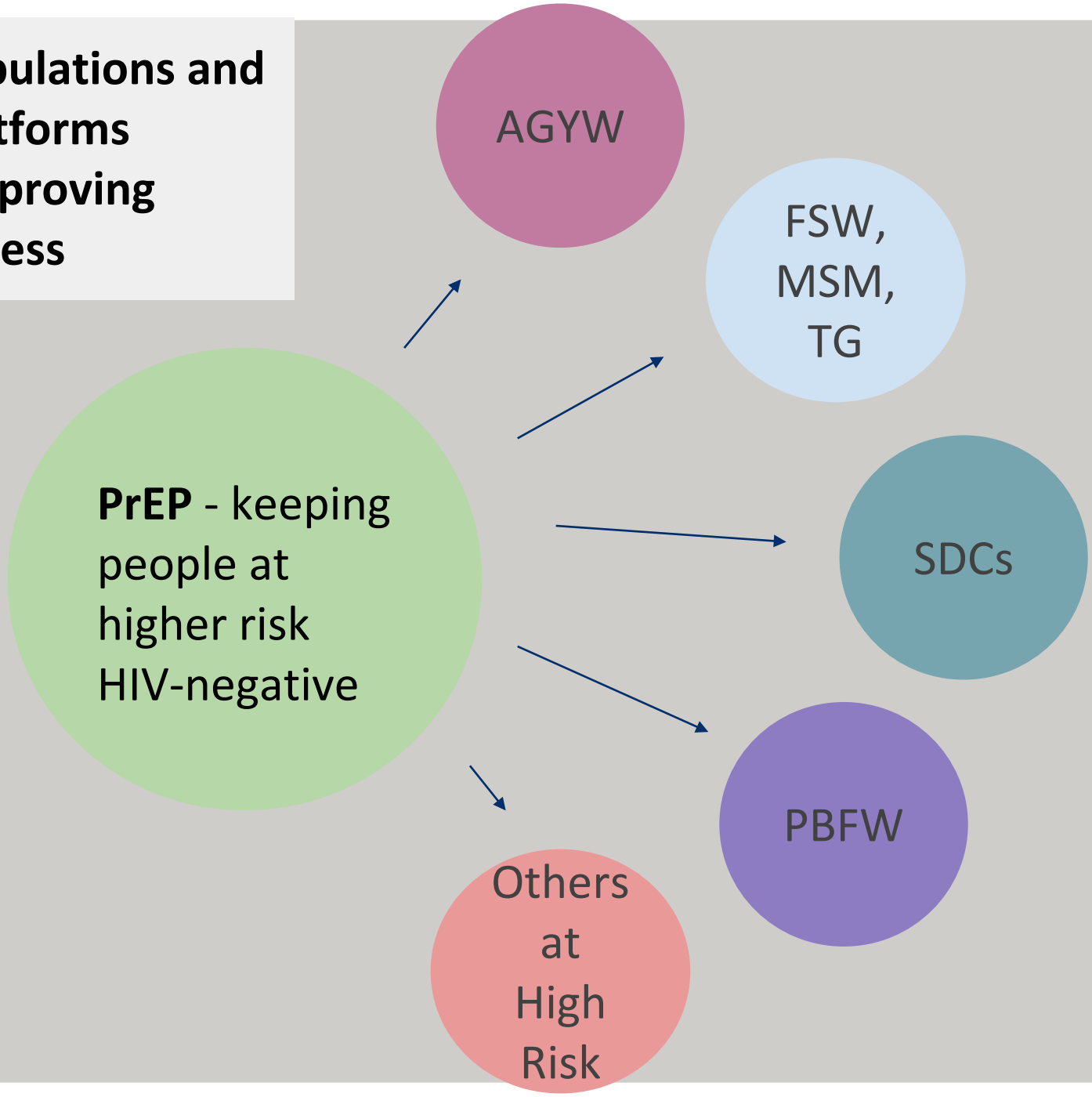
- COP18 PrEP achievement was strong
- COP19 was focused on expanding and building momentum
- COP20 targets require <u>significant program scale-up</u>

Reaching 1 million on PrEP: focus on scaling to saturation and supporting PrEP continuation



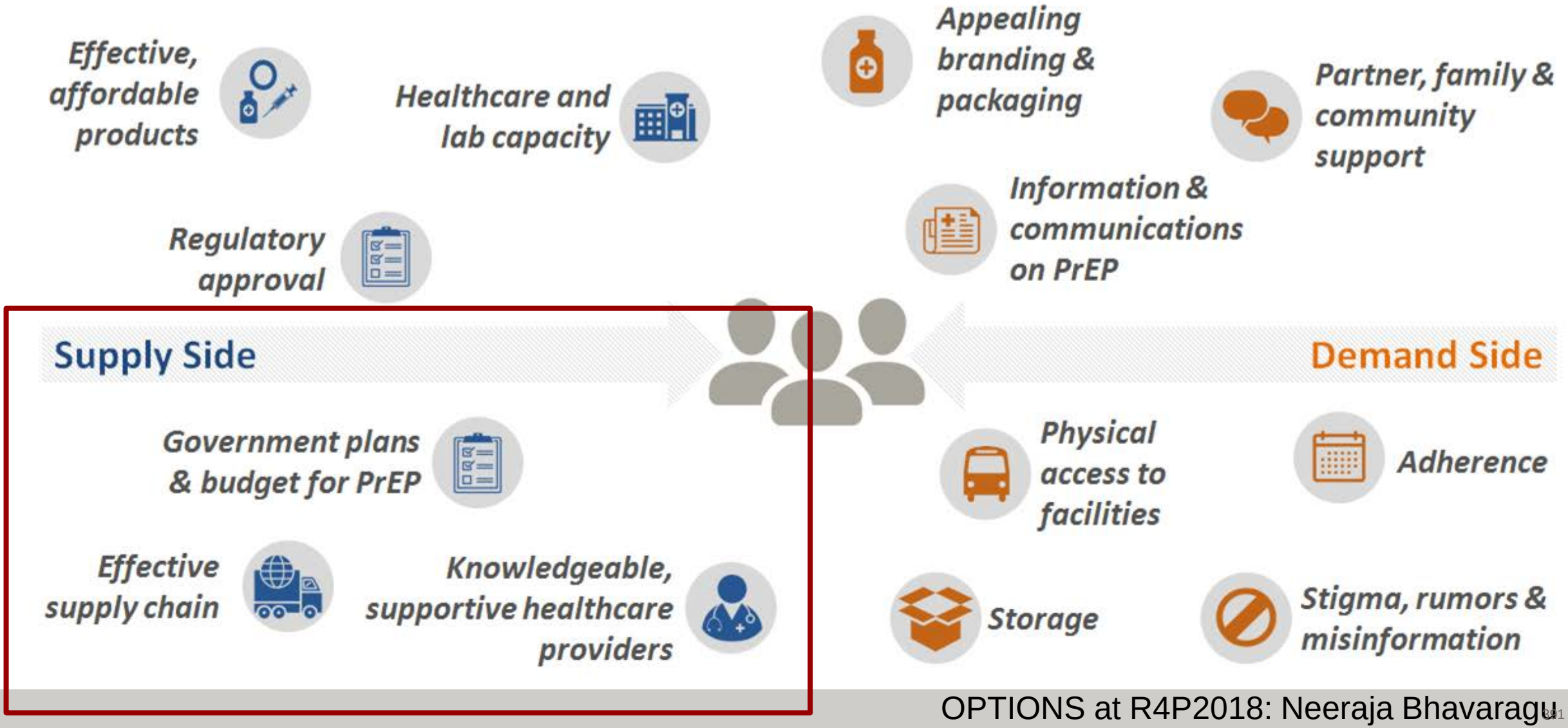
- 14 countries will have to increase number of clients on PrEP by at least 4 fold from COP19-20
- Overall PrEP CURR targets increase 4 fold from COP19-20
- Top 6 countries listed have 75% of PEPFAR PrEP CURR targets

Populations and Platforms -Improving Access



- 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**

Introducing oral PrEP is not easy!



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)

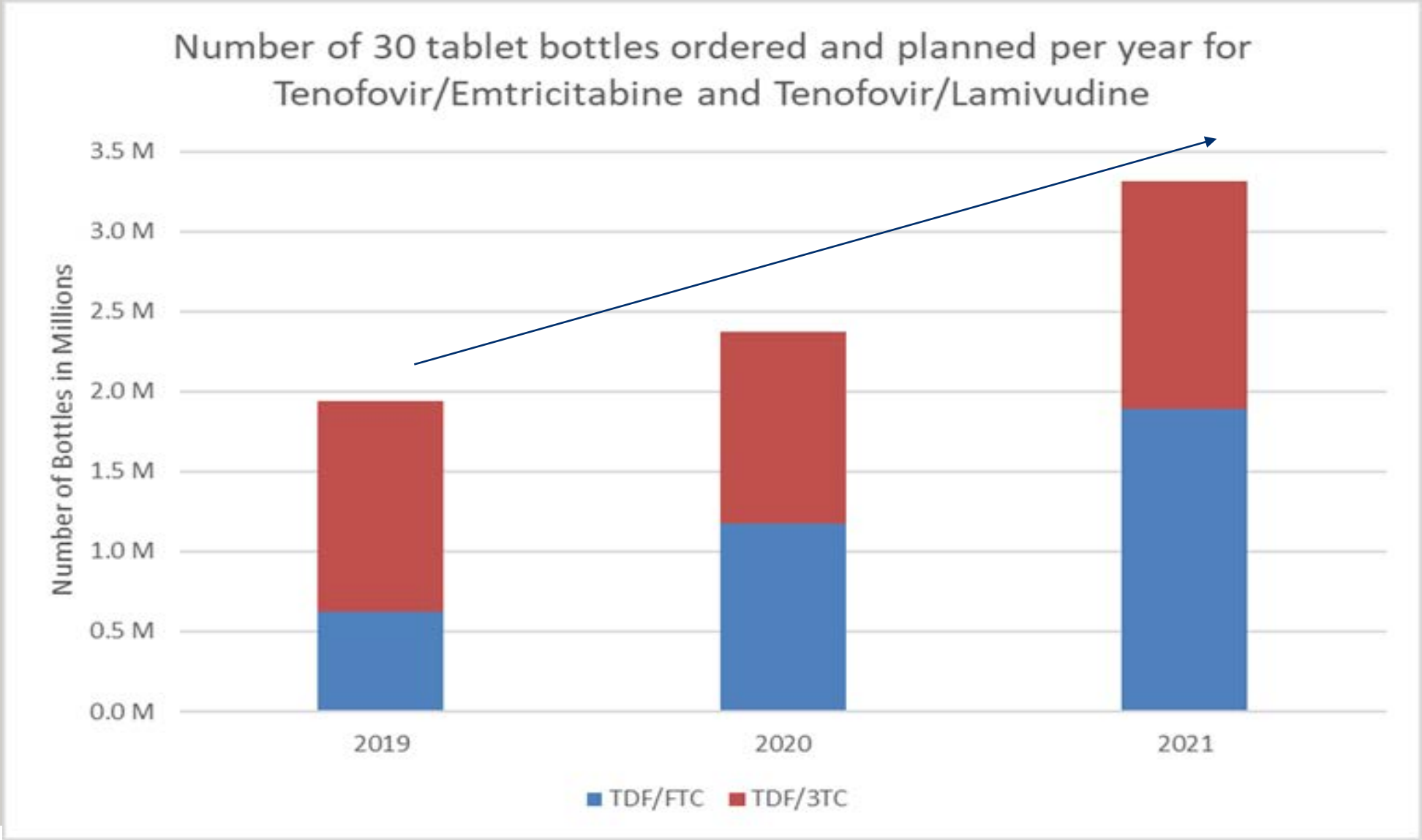
Supply chain opportunities and challenges

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

GHSC-PSM orders (Firm and Planned)

THANK YOU!!!

RCH health fair where PrEP was offered.

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***

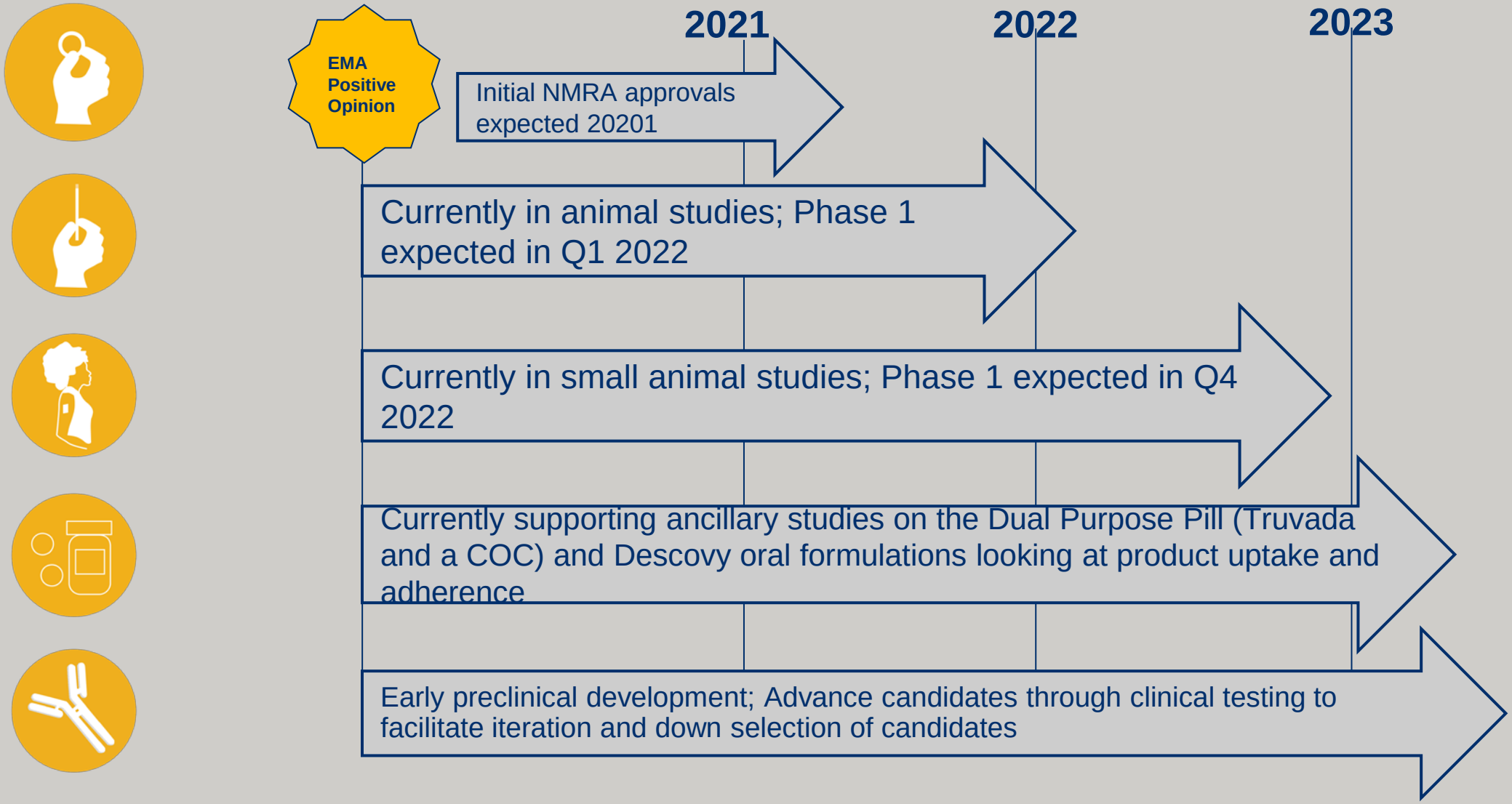
Amplifying Clear and Effective Advocacy for HIV Prevention

- 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



Monthly Dapivirine Vaginal Ring (DVR)


Photo Credit: International Partnership for Microbicides, 2020

- 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

Anticipated FDA and NMRA Timelines

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

EMA Positive Opinion

WHO: Development of Use Guidelines, Issuance of Expression of Interest, and Prequalification by **December, 2020**

WHOPQ

FDA NDA Submission Estimated **December, 2020**

FDA Review

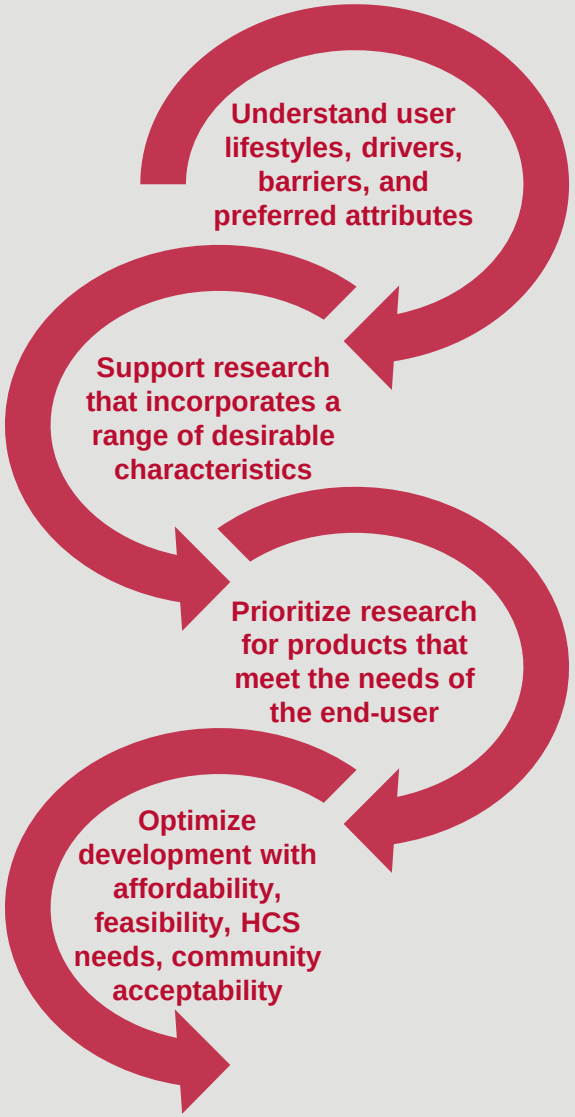
Anticipated FDA Approval Q4 2021

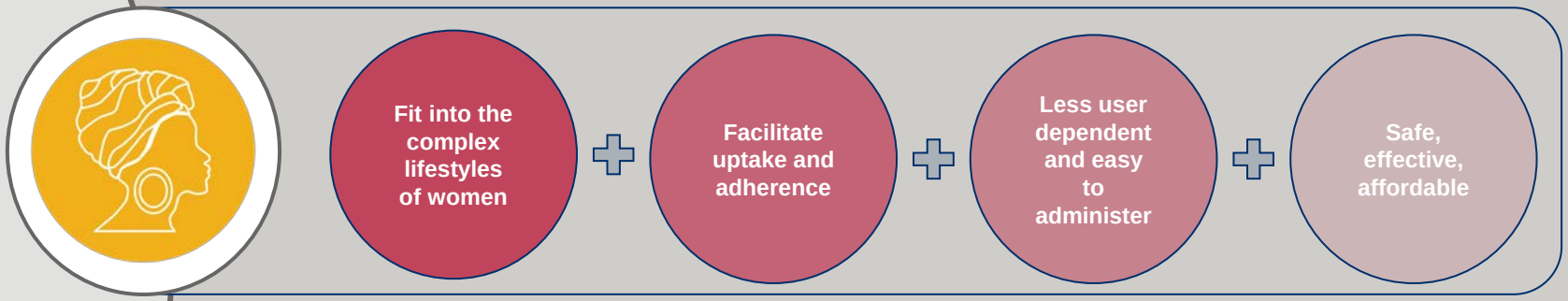
SAHPRA (South Africa) Dossier Submission: WHO Collaborative Review Procedure (CRP)

NMRA Submission

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





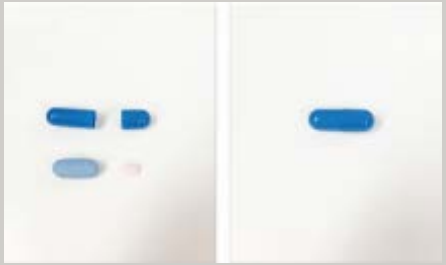
Understand user lifestyles, drivers, barriers, and preferred attributes

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

Dual Prevention Pill for HIV and Pregnancy Prevention	Improved Oral PrEP Formulation for HIV 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)	• Supporting parallel ancillary studies during Phase 3 Descovy trial to determine uptake, acceptability and adherence



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Improved Oral PrEP Formulation for HIV Prevention

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Sub-Q Resevoir 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 Resevoir Implant

- Early preclinical development
- **Biodegradable TAF+Hormone**
- Designed to be used with an existing trocar (HCW required)
- Target dosing: at least 1 yr

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

Understand user lifestyles, drivers, barriers, and preferred attributes

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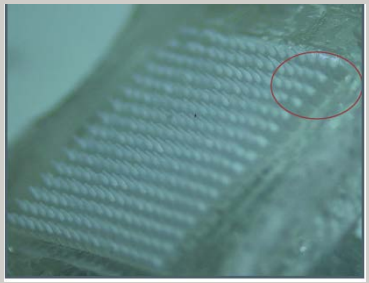
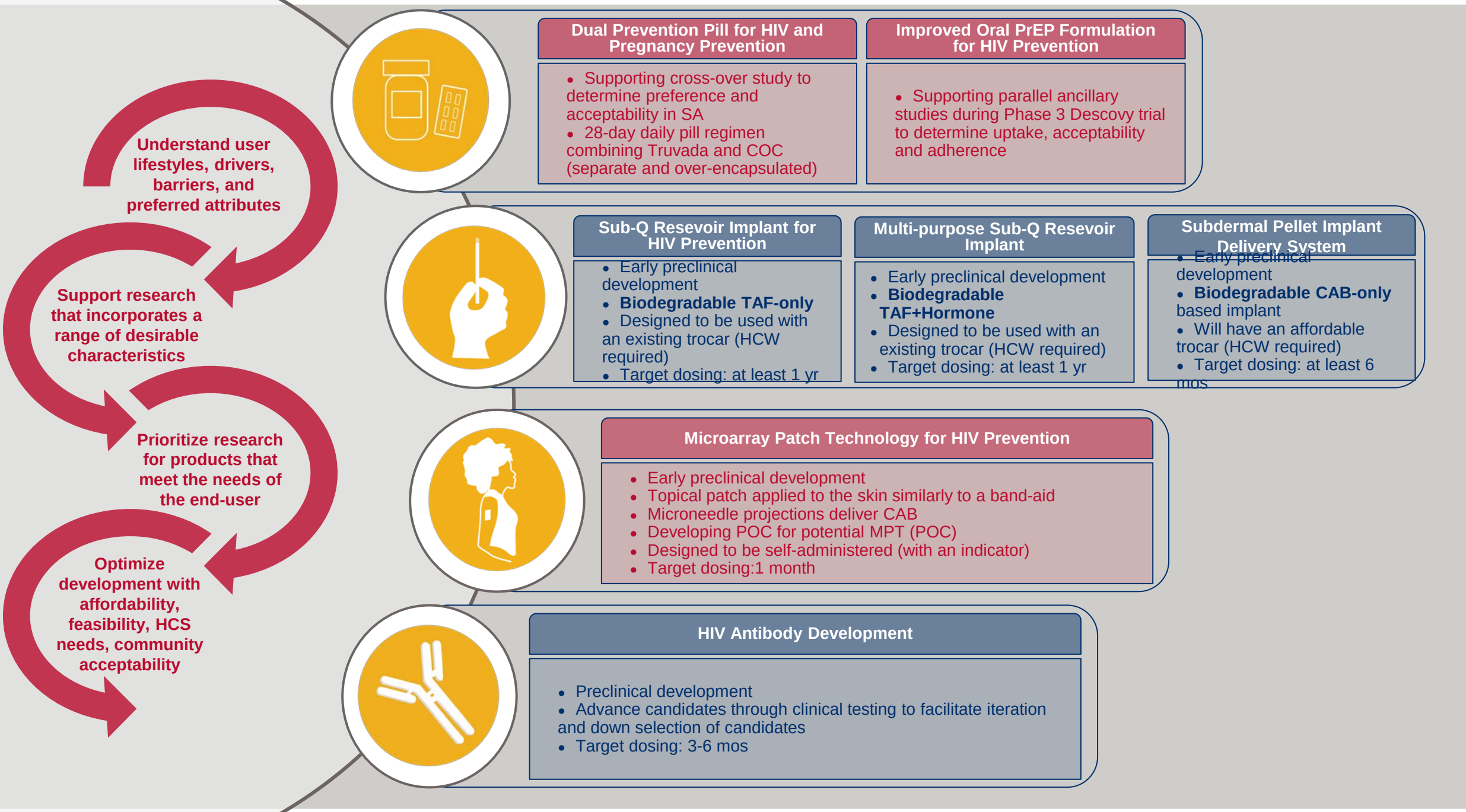
- Will have an affordable trocar (HCW required)
- Target dosing: at least 6 mos

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)
- Target dosing:1 month

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• 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 Resevoir Implant
• Early preclinical development
• Biodegradable TAF+Hormone
• Designed to be used with an existing trocar (HCW required)
• Target dosing: at least 1 yr
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
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)
• Target dosing:1 month
HIV Antibody Development
• Preclinical development
• Advance candidates through clinical testing to facilitate iteration and down selection of candidates
• Target dosing: 3-6 mos

Using Data for Decision Making throughout the Product Development and Access Pathway

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

PATH

RTI INTERNATIONAL

CONRAD
Leaders in Reproductive Health and HIV Prevention

INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

GILEAD

ViiV Healthcare

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Annual ARV Summit By the Numbers

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32 Countries!

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86 Organizations
24 Sellers

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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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