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PEPFAR Update Point-of-Care Viral Load: Pregnant and Breastfeeding Women

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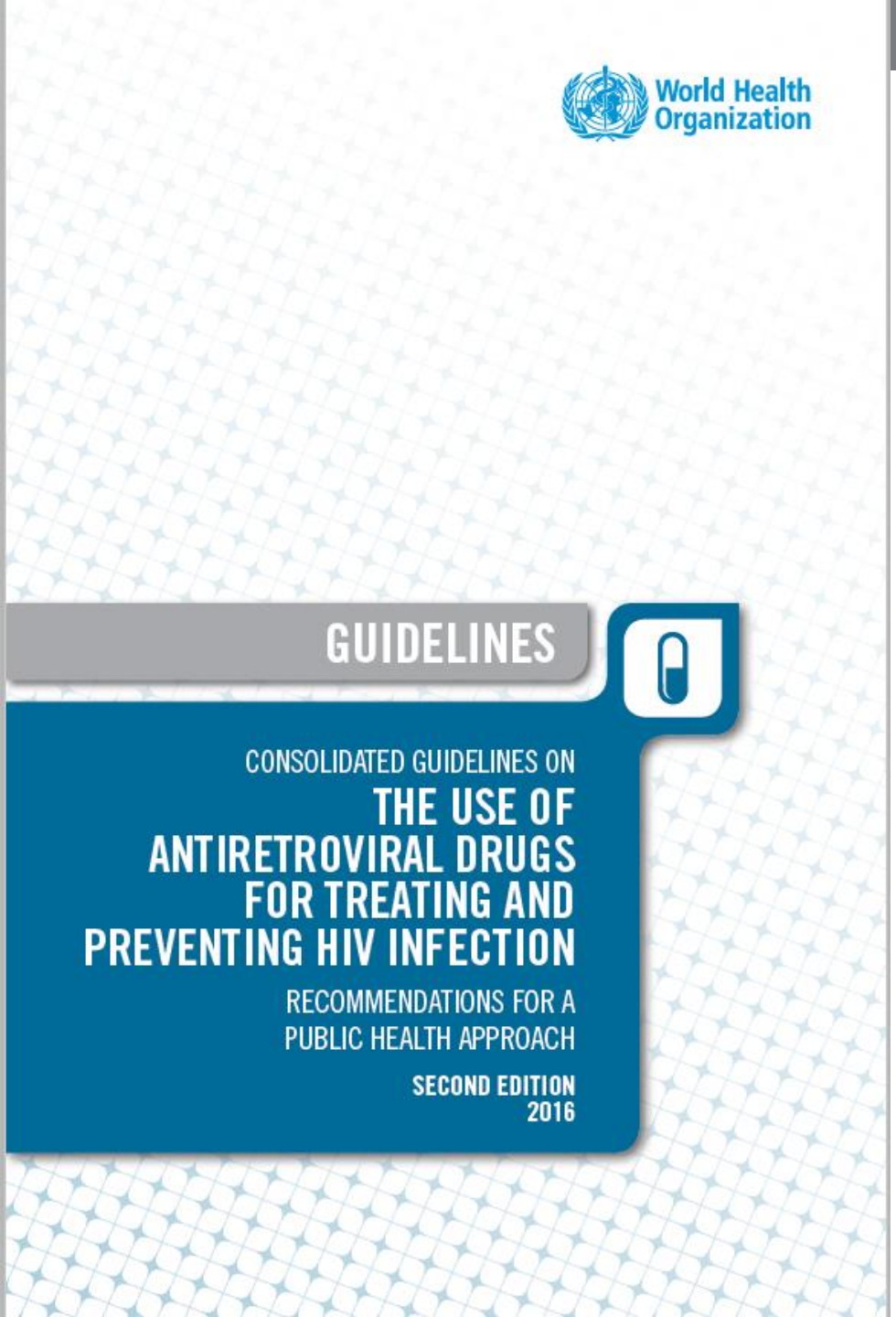
Outline

- Guidance for VL Testing for Pregnant and Breastfeeding Women
- Status of VL testing for Pregnant and Breastfeeding Women in PEPFAR
- PEPFAR Short Term Task Team for POC VL for PBFW Implementation
- PEPFAR-supported study on POC VL in postpartum mothers
- Next Steps for POC VL for PBFW

Global Guidance for Viral Load Testing for Pregnant and Breastfeeding Women



Viral Load Testing Guidance

- Routine viral load monitoring can be carried out at 6 months, 12 months and then every 12 months thereafter if the patient is stable on ART
- Viral failure is defined as two consecutive high viral load measurements (>1000 copies/mL) within a 3-month interval, with adherence support between measurements, after at least 6 months of starting a new ART regimen

Pregnant Women:

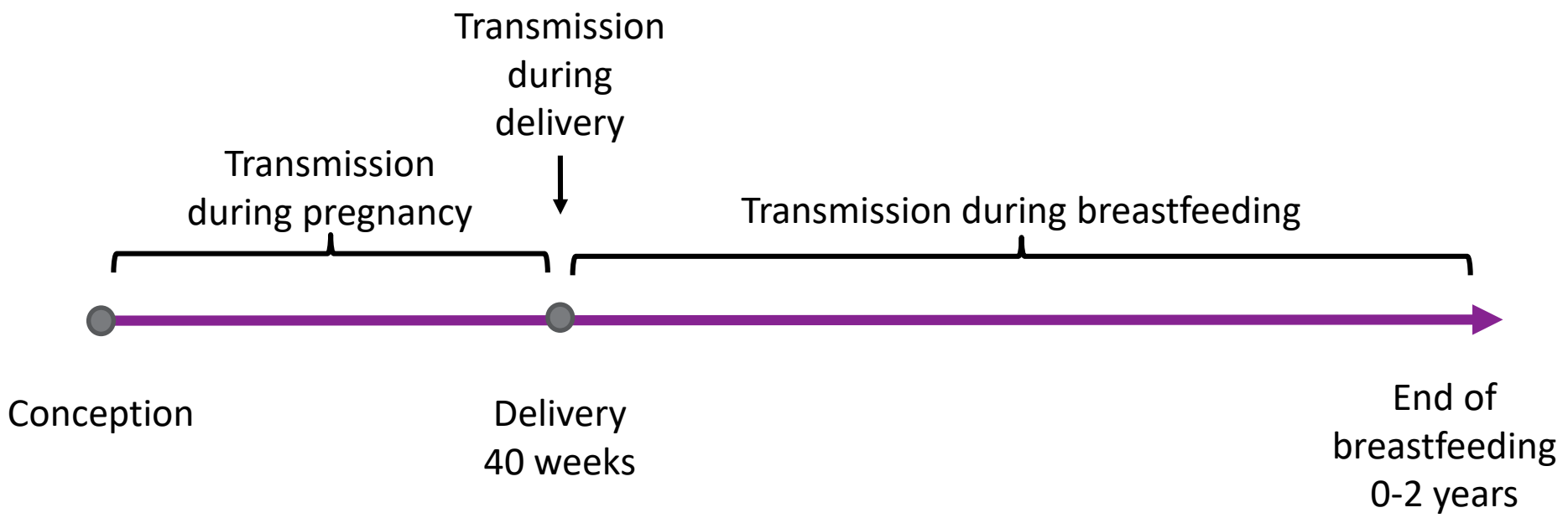
- Recommended to prioritize viral load testing for pregnant and breastfeeding women, especially around the time of delivery, as sustained viral suppression is critical to prevention of transmission to the child
- VL conducted 4 weeks prior to delivery may be used to target enhanced infant prophylaxis

VL Monitoring in PBFW

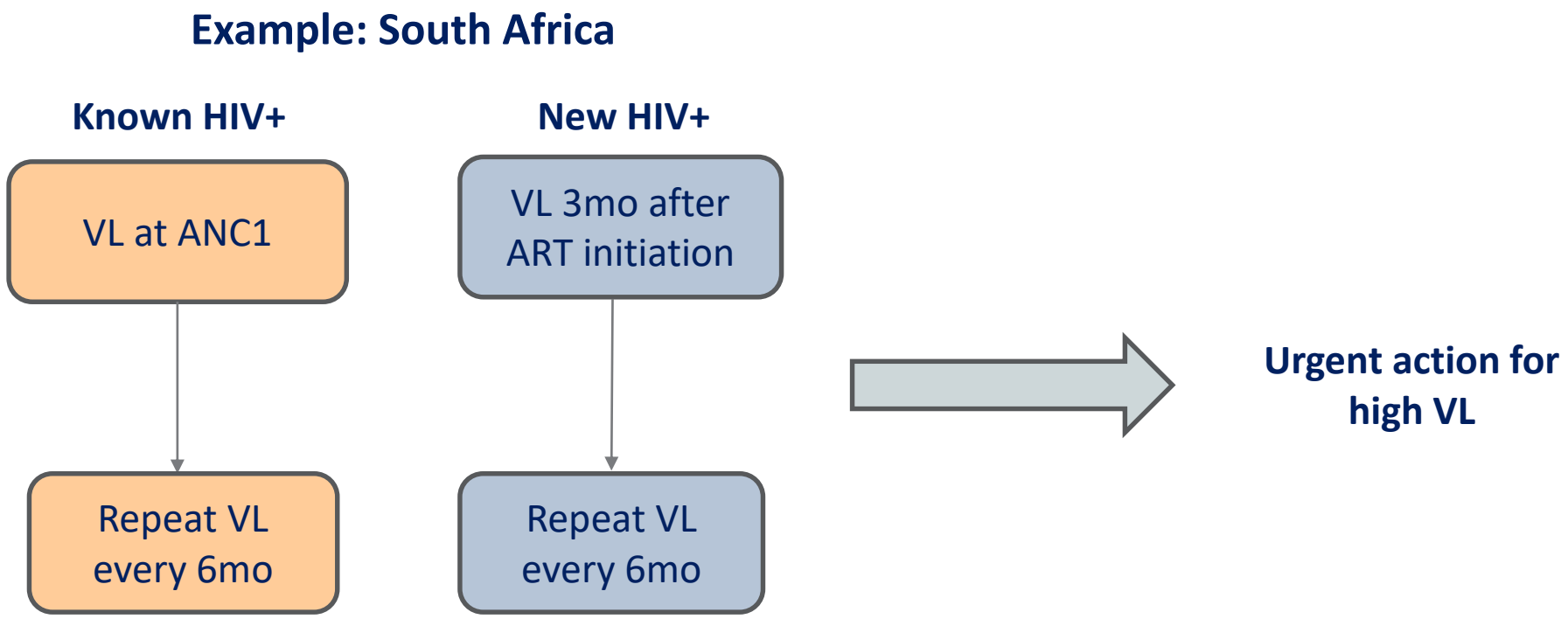
- High maternal HIV viral load is the most predictive factor for mother-to-child transmission of HIV
- Evidence suggesting that ART adherence may be inadequate during pregnancy & breastfeeding
- Increased transmission risks with each additional week of high viral load during pregnancy

Prompt return of results and early action on high viral loads in this population is essential for prevention of maternal disease progression and prevention of mother-to-child transmission.

Mother-to-Child Transmission

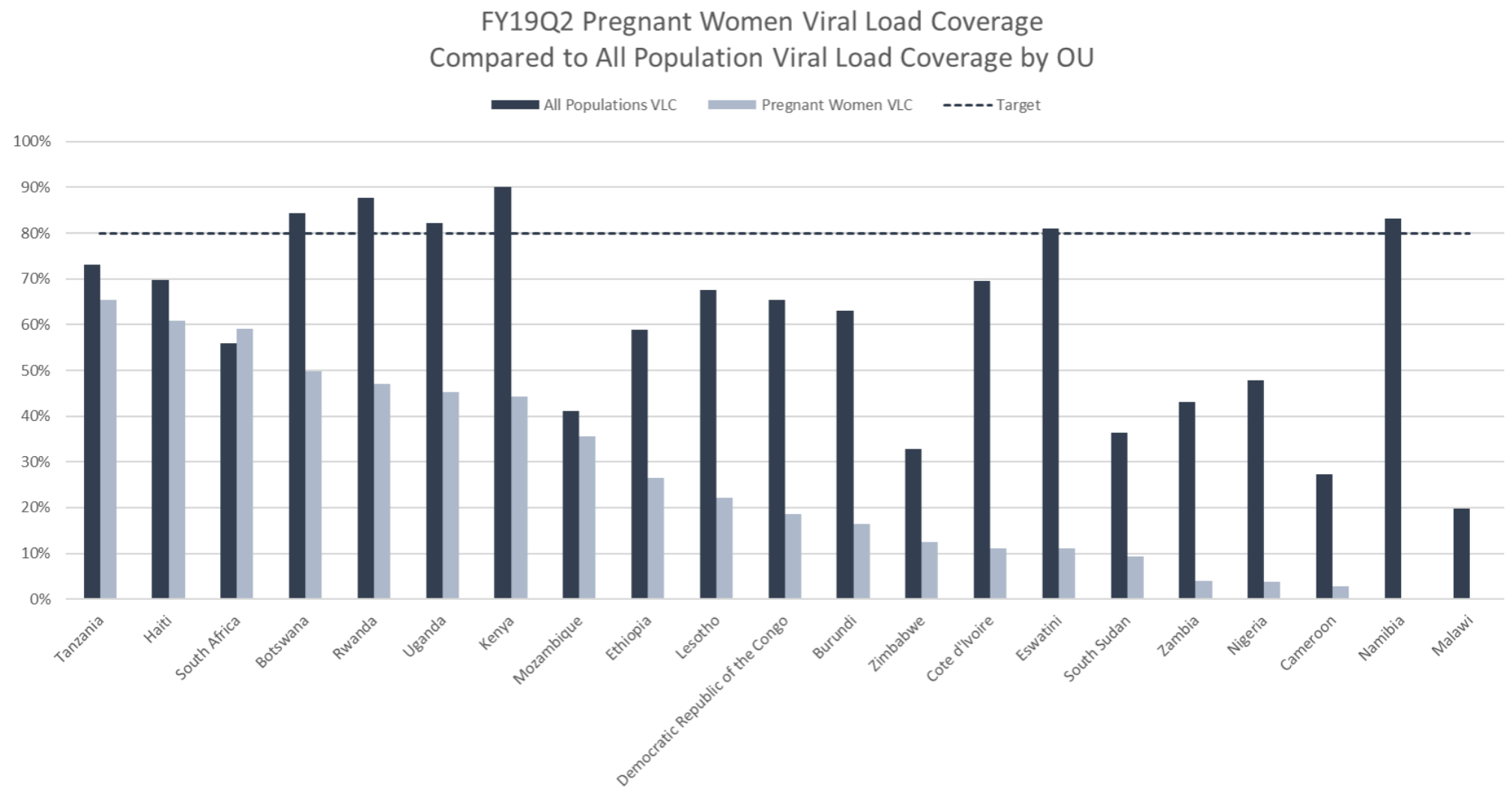


Early Identification of High Viral Loads in PBFW

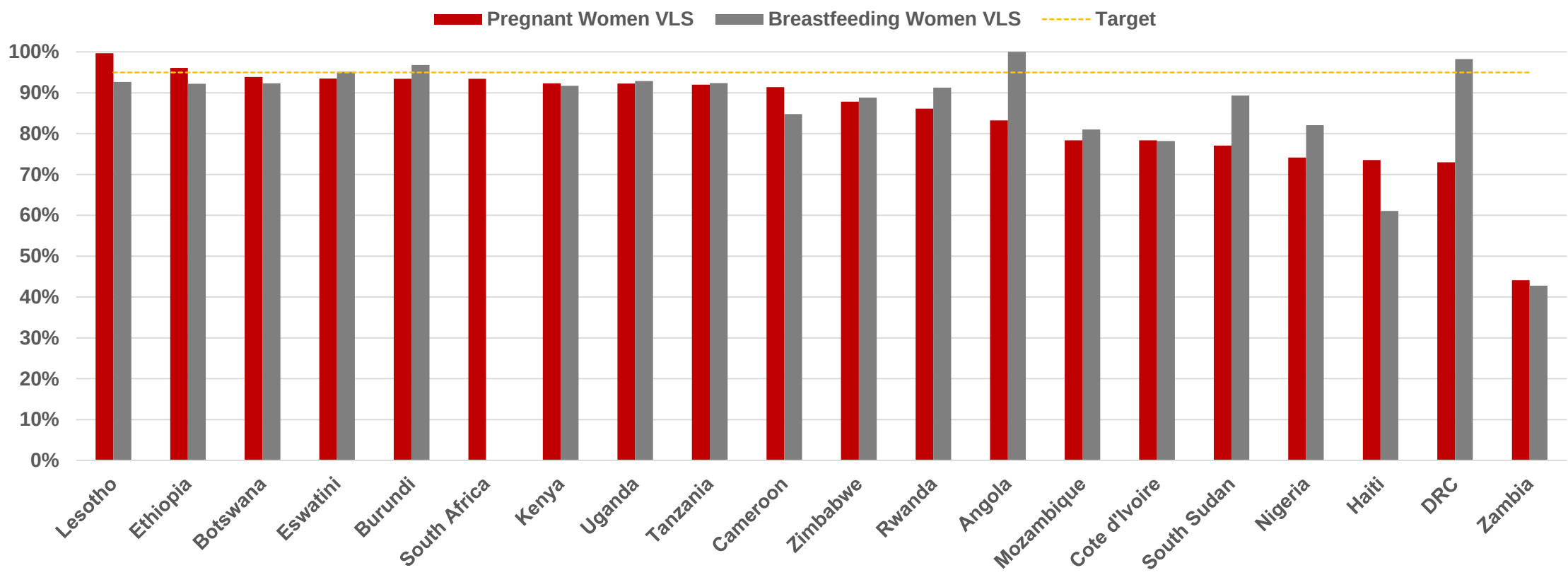


VL Testing: Pregnant & Breastfeeding Women in PEPFAR

PEPFAR FY19 Q2 Viral Load Coverage: Pregnant Women



PEPFAR FY19 Q2 Viral Suppression: PBFW



Status of POC VL for Pregnant and Breastfeeding Women

PEPFAR COP19 Guidance – POC VL for PBFW

- ✓Scale up of VL testing using conventional networks has challenges including long TAT and limited access to VL testing at peripheral or community levels
- ✓To optimize time-sensitive VL among PBFW, PEPFAR programs should plan to use POC for VL testing among PBFW only
- ✓Timely results will increase ability to provide an enhanced infant prophylaxis regimen for exposed infant
- ✓Essential to understand clinic-laboratory network and patient need before placing additional instruments
- ✓The GeneXpert platform can be used for multiple tests: TB, EID, and VL (PBFW)
- ✓Collaborate to strengthen TB/HIV laboratory integration and joint TB/HIV program planning to ensure efficient use of POC platforms

STTT to Support POC VL Implementation in PBFW

- Goal: provide tools and guidance to implementation subject matter experts and country programs to support implementation of POC VL in PBFW

- Objectives:
  1. Summarize current country plans for POC VL implementation
  2. Identify and create tools and guidance, as needed, to support country implementation
  3. Train implementation subject matter experts on POC platforms, considerations, and tools for placement and use of POC VL for PBFW

COP19 - Plans for POC VL in PBFW

Short Term Task Team to Support POC VL in PBFW is currently performing reviewing country plans for POC VL in PBFW. We are compiling information from 21 countries on the following topics:

1. Is there a policy and/or national implementation plan?
2. Are there plans to conduct POC EID and/or POC VL in PBFW in COP19?
3. Are there plans for integration?

Desk Review Completed 7/21 countries

6/7 countries plan on implementing POC EID

3/7 countries plan to implement POC VL for PBFW

1/3 plan to scale-up integrated testing

2/3 discussion ongoing regarding integrated testing

Desk Review Completed to date for: Cameroon, Namibia, Mozambique, Rwanda, South Africa, Uganda, Zimbabwe

Feasibility of Point-of-Care Viral Load Testing in Postpartum HIV-positive Women in South Africa: Interim Results

http://programme.ias2019.org/Abstract/Abstract/4132

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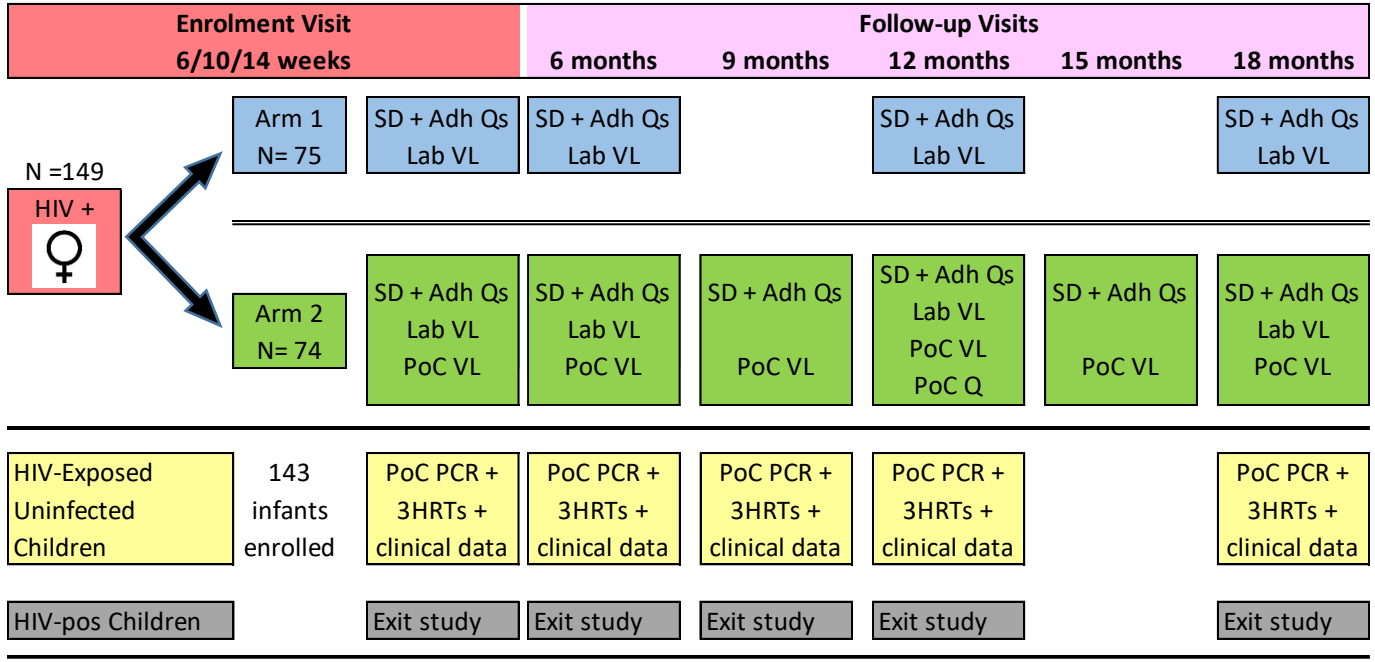
Study Objectives – HIV-positive Postpartum Women

Primary objective:

- Compare viral suppression rates (VL <1000 copies/ml) between HIV-positive postpartum women on first line ART, receiving a package of enhanced VL monitoring including POC VL to those receiving standard of care lab-based VL monitoring specifically:
  - Investigate demographic, clinical, and psychosocial factors associated with viral suppression
  - Describe the barriers and facilitators of implementing viral load POCT in real-world settings by assessing provider's perspectives regarding feasibility and the acceptability of services and their delivery
  - Describe drug-resistance mutations among women with virologic failure in each group



Interim Results

Arm 1 - SOC

- High VL, >1000 copies/mL: 5/75 participants at enrolment
- The median time for laboratory VL results to be available electronically was 2 days (IQR 2-4) and returned to the mother was 45.5 days (IQR: 17-103)
- Three women were high viral loads were not contactable

Arm 2 – POC every 3 months

- High VL, >1000 copies/mL: 11/74 participants at enrolment
- 99% women received POC VL results on the same day as study visit.
- One woman was not contactable to return for a repeat VL

Conclusions based on findings to date:

1) POC VL testing in postpartum women, conducted by field workers and nurses with proper training, monitoring, and CQI is possible with same day results allowing immediate and tailored clinical management of HIV in maternal populations.
2) POC VL testing may reduce challenges experienced with return of laboratory-based results to the patient.
3) These challenges may include establishing telephonic contact, insufficient or inaccurate locator information to conduct home visits, or challenges with participants returning to the clinic for frequent visits.

Next Steps for POC VL in Pregnant and Breastfeeding Women

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Support Country Teams in POC VL Implementation

- Desk review is currently being finalized
- As we begin COP19, engage with country teams to complete landscape review
- Finalize the compilation and creation of tools and guidance as needed to support country implementation
- Train implementation subject matter experts on POC platforms, considerations, and tools for placement and use of POC VL for PBFW

Thank you!

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