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

PEPFAR Laboratory Priorities in Country Operational Plan (COP) 2021

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ASLM January 2021 LabCoP ECHO Session

17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS

PEPFAR 2021 Country and Regional Operational Plan (COP/ROP) Guidance for all PEPFAR Countries

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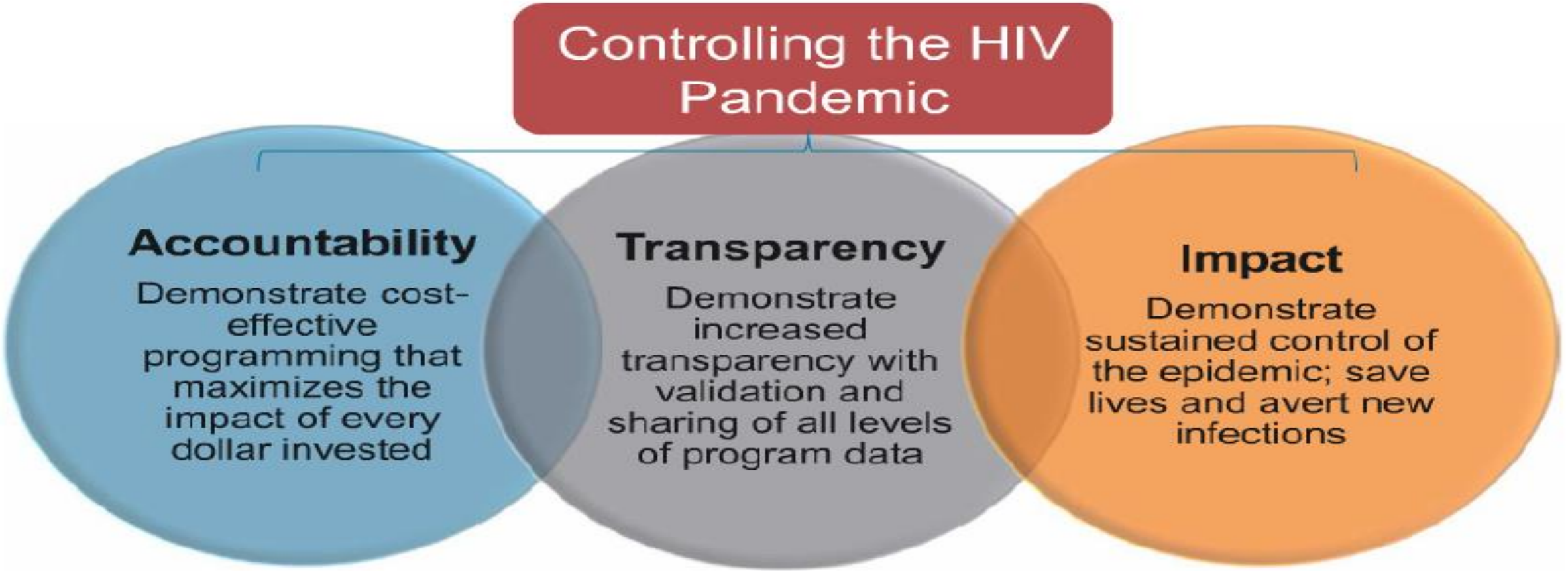
Order of Presentation

- PEPFAR's Guiding Principles and Latest Global Results
- Case Finding/HIV Serology
- Viral Load Testing Coverage and Suppression
- 2 Months Early Infant Diagnosis (EID)
- TB Diagnostics for Adults and Children
- Recommended Strategies to Address Gaps
- COVID-19 Adaptations

PEPFAR' 3 Guiding Principles



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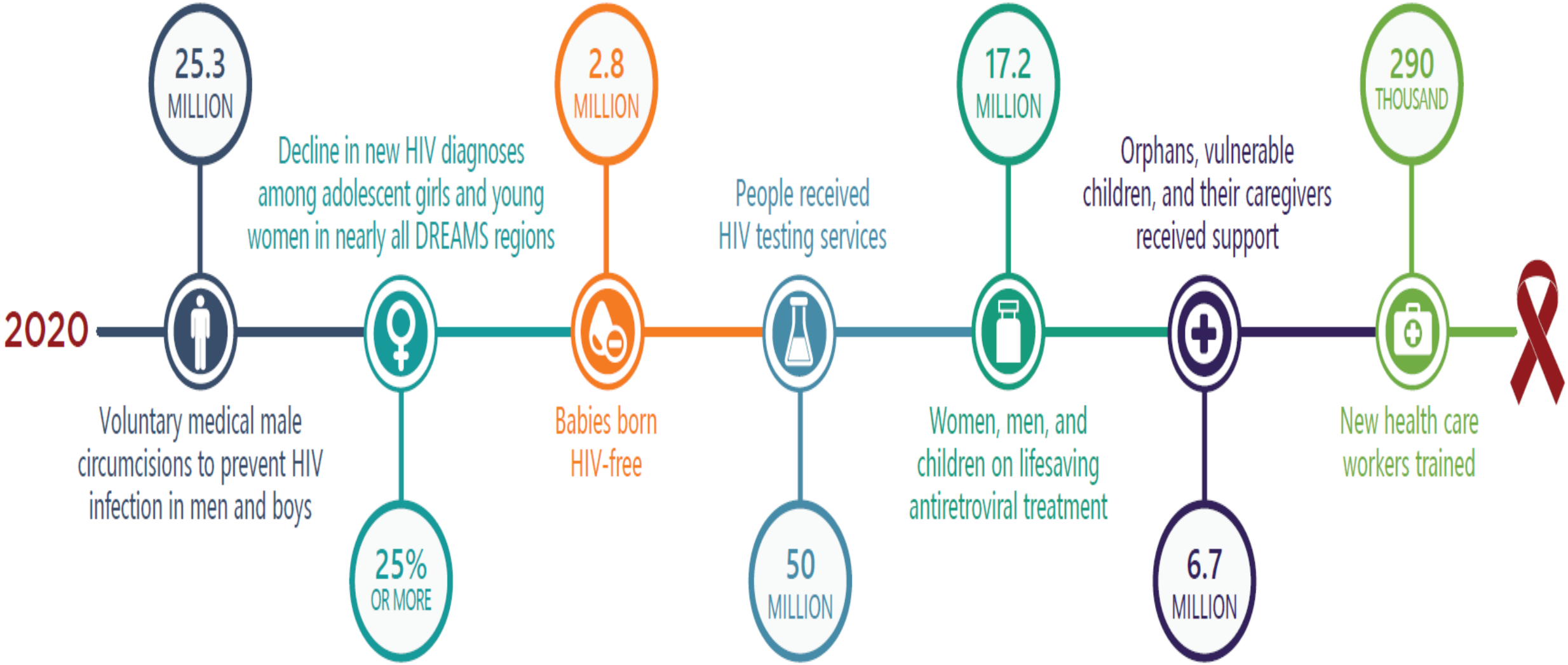
Active Program and Partner Management

PEPFAR Latest Global Results



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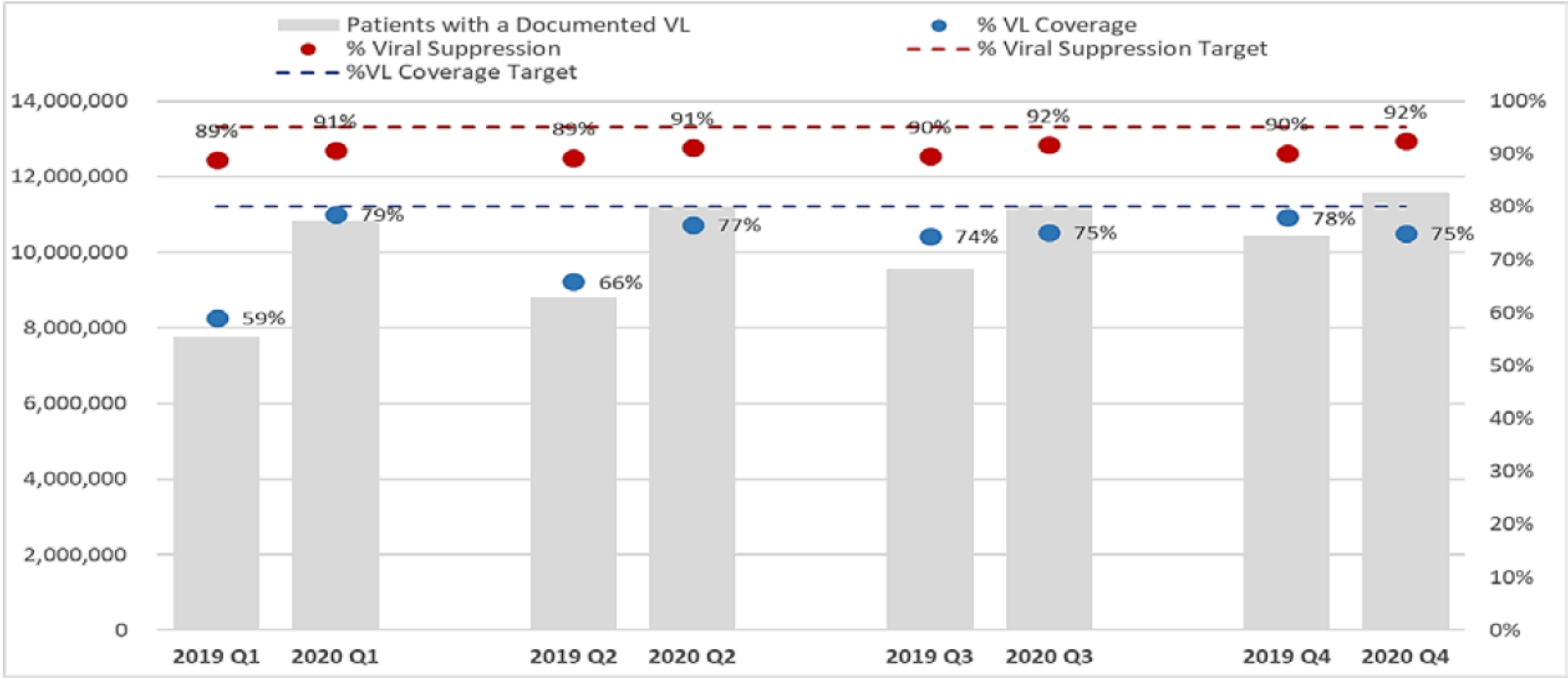
PEPFAR Lab Support for Case Finding

HIV Serology

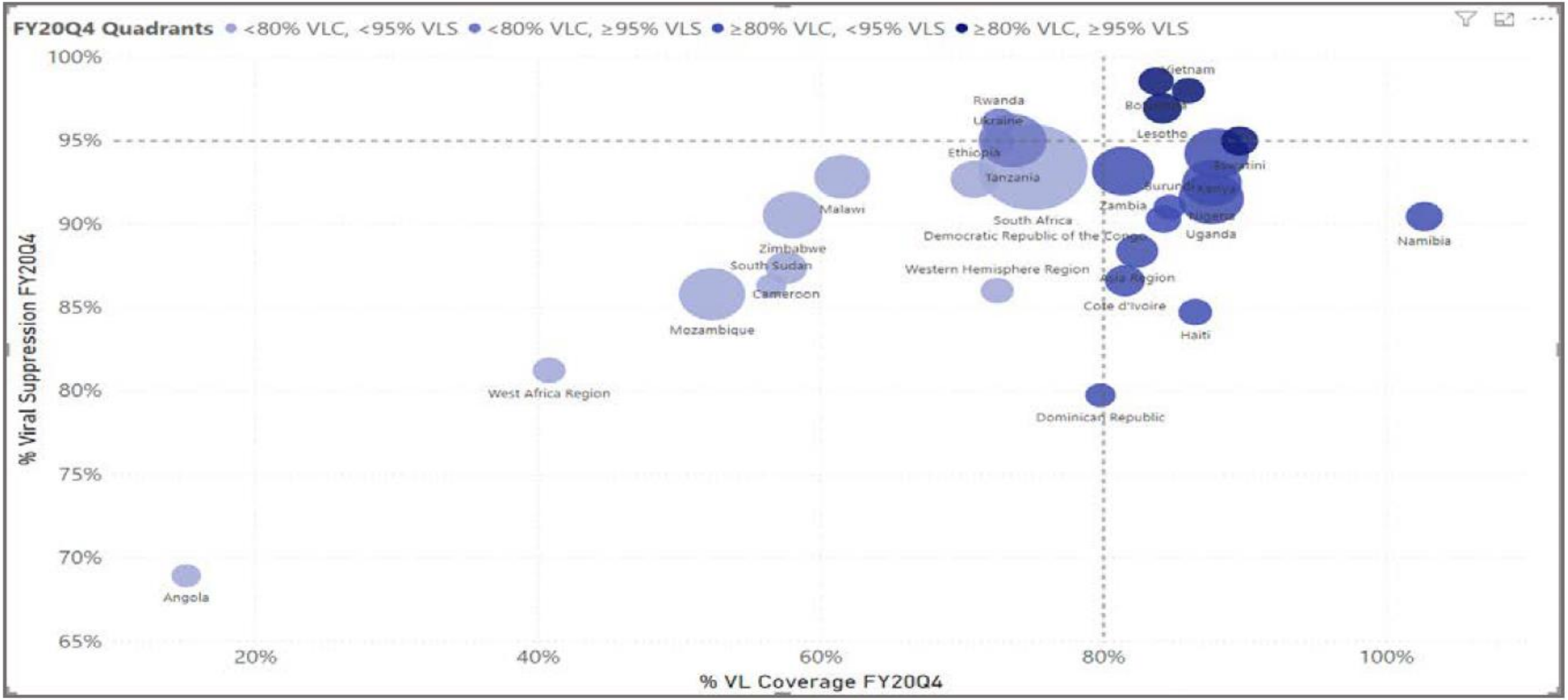
- HIV Rapid Testing
- HIV Rapid Testing Continuous Quality Improvement (HIVRTQCI)
- HIVST
- HIV Recency Testing
- Pre-Exposure Prophylaxis (PrEP)

Strengthening VL Testing Coverage and Suppression

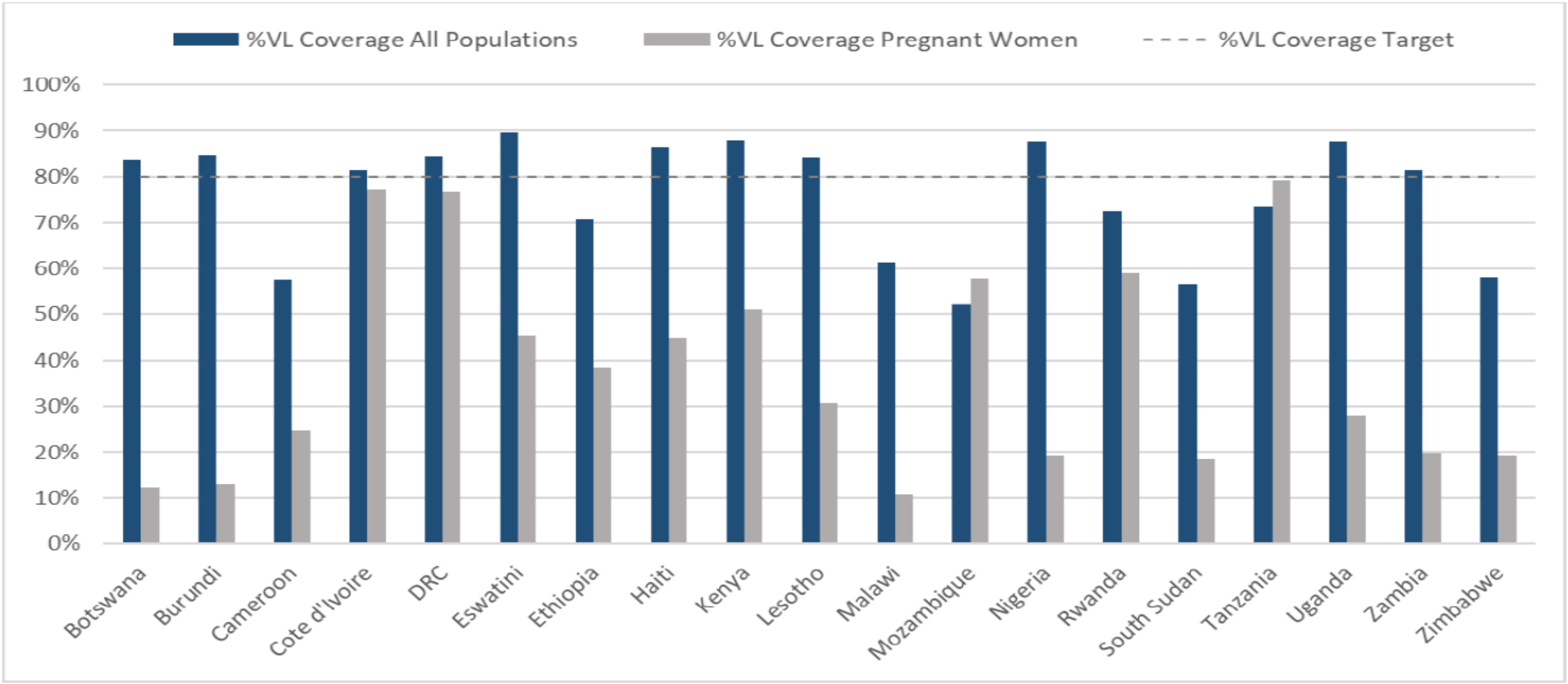
Decrease in Overall VL Testing Coverage from FY20Q1 to Q4 (All OUs) due to COVID-19



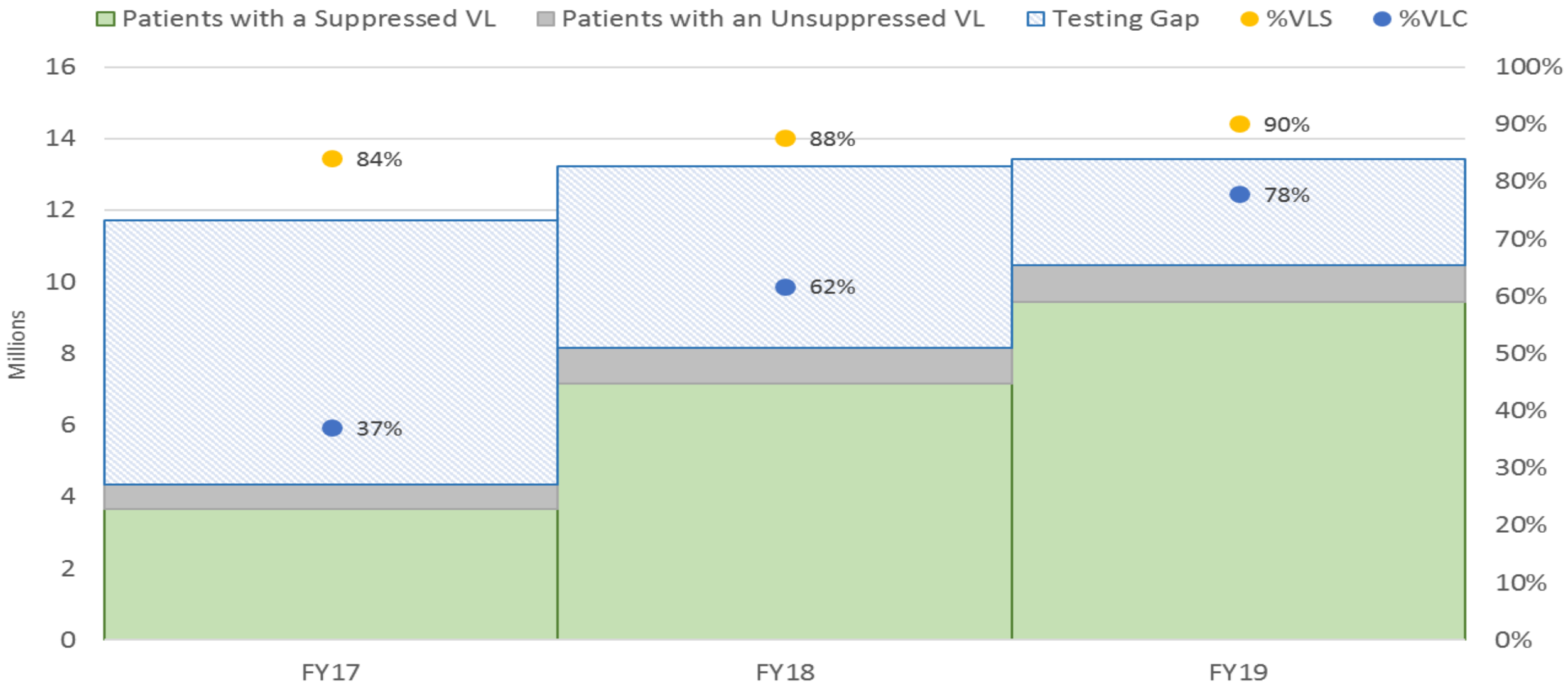
FY20Q4: Only four OUs have achieved both ≥80% VL Coverage & ≥95% Viral Suppression



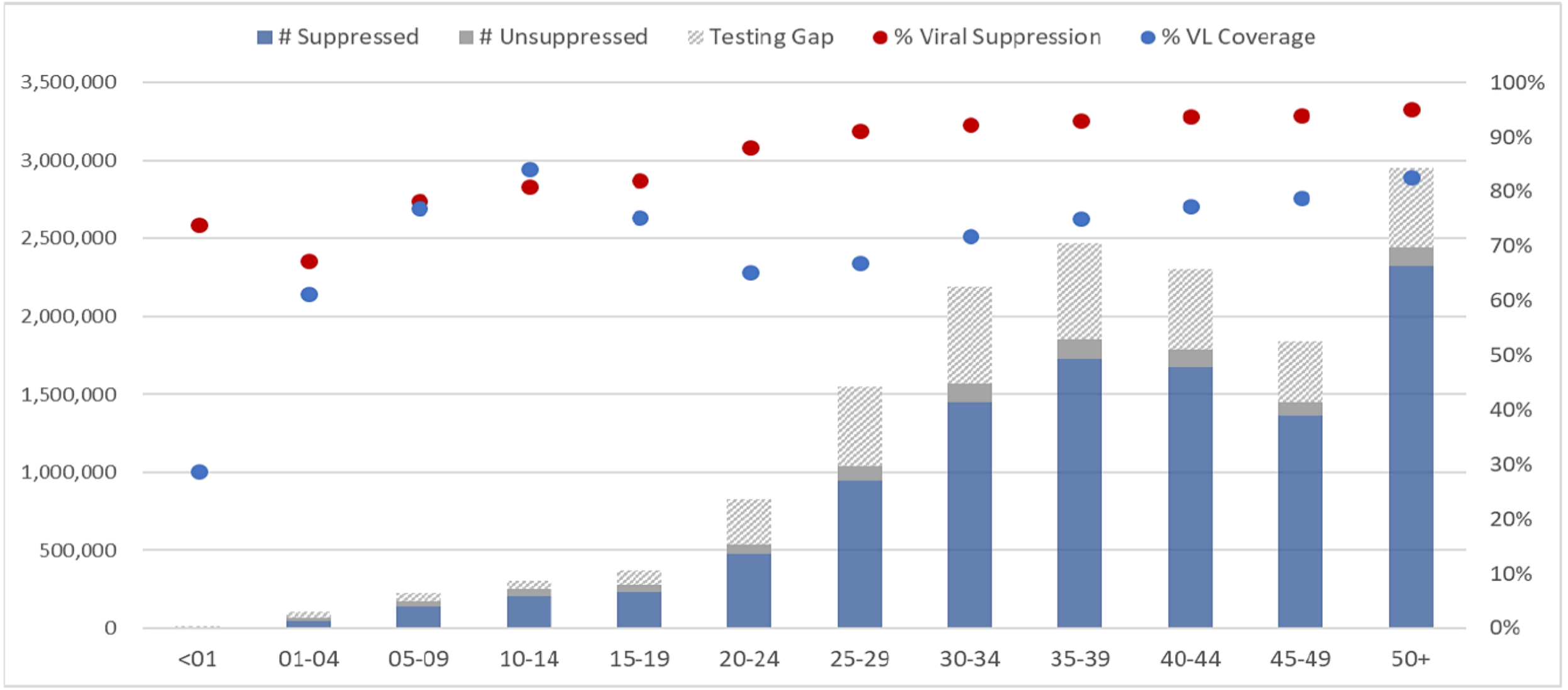
FY20Q4: Pregnant Women VLC Compared to General Population



Trends in VL Outcomes, FY17Q4 - FY19Q4, all Operating Units



FY20Q4: Low VL testing coverage and suppression among infants, children and adolescents

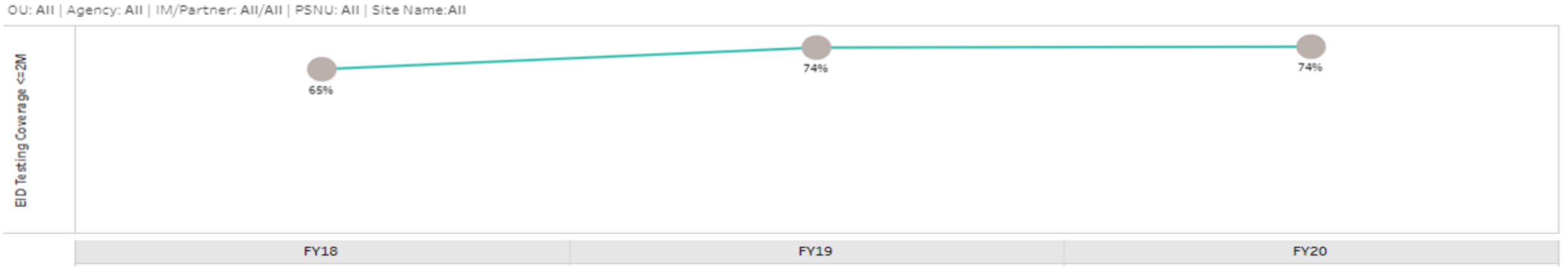


Strengthen 2 Months EID

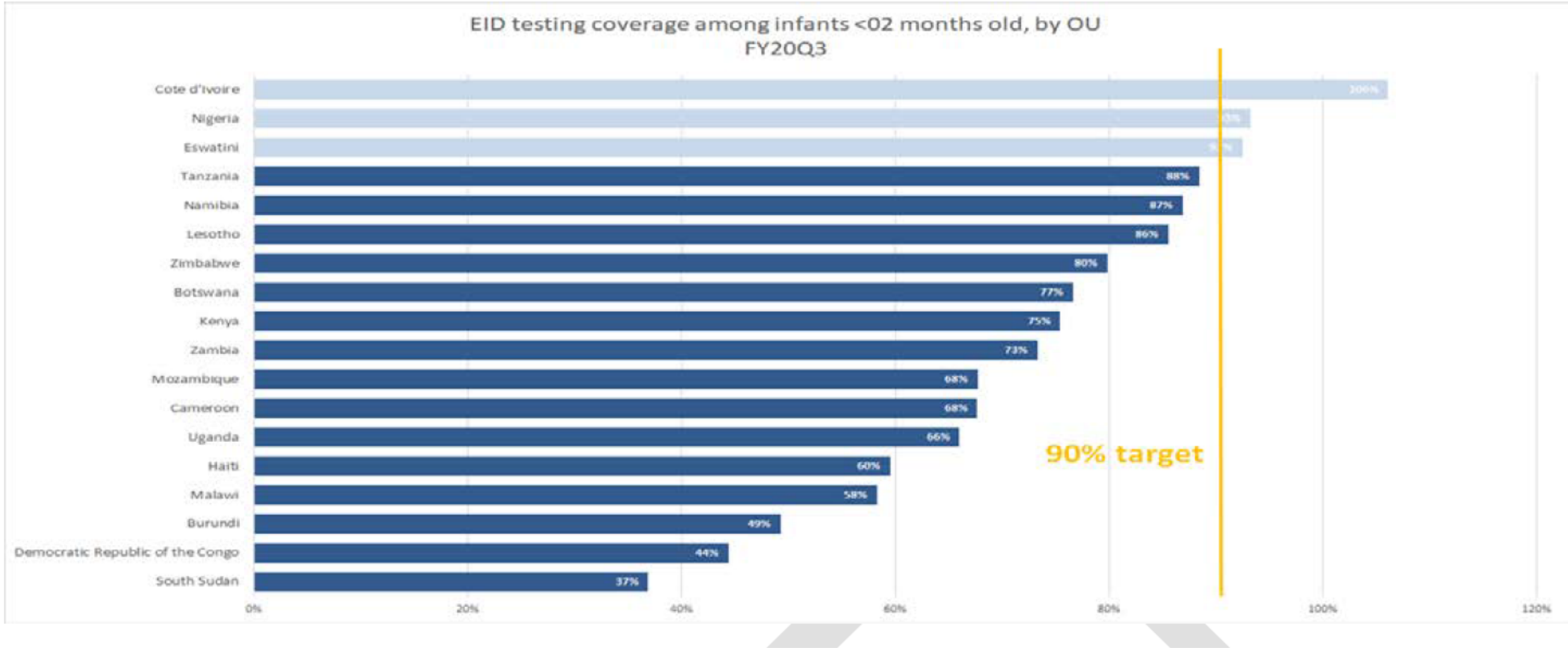
Minimal Impact COVID-19 on EID testing coverage FY20Q1 to Q3

EID 2 month testing coverage quarterly trends

EID 2 month testing coverage cumulative trends



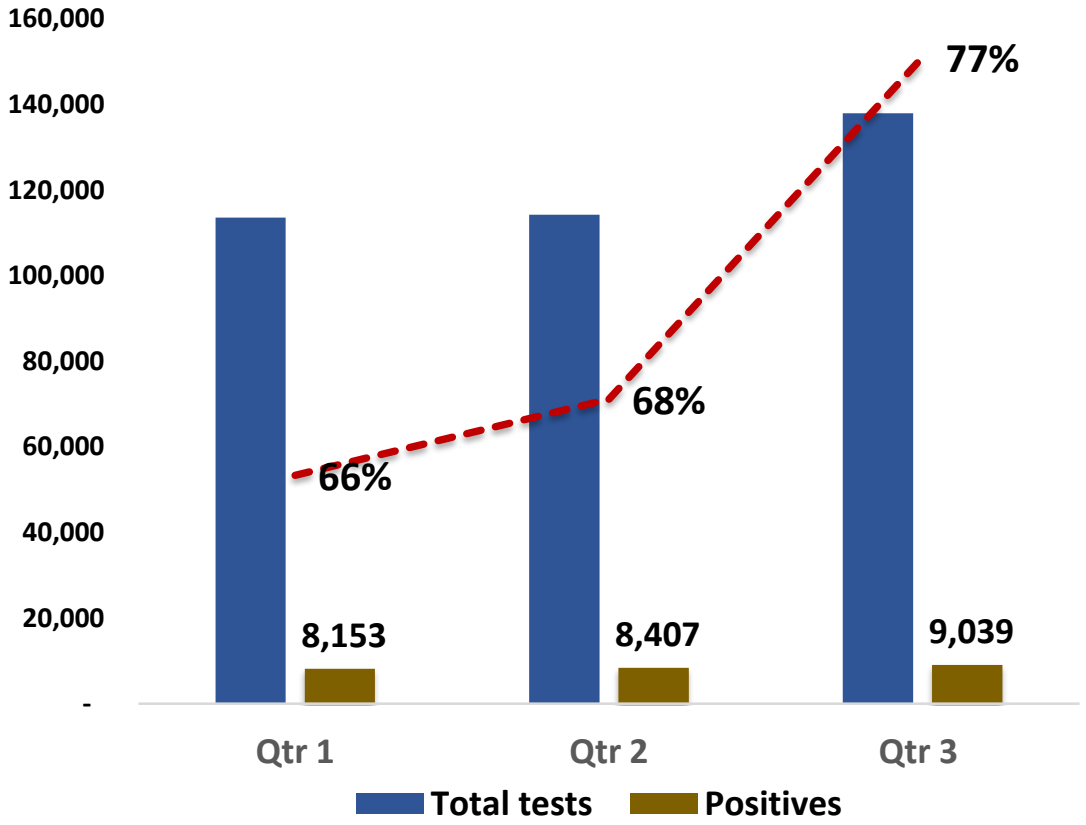
FY20Q4: EID testing coverage among infants <2 months old by OU



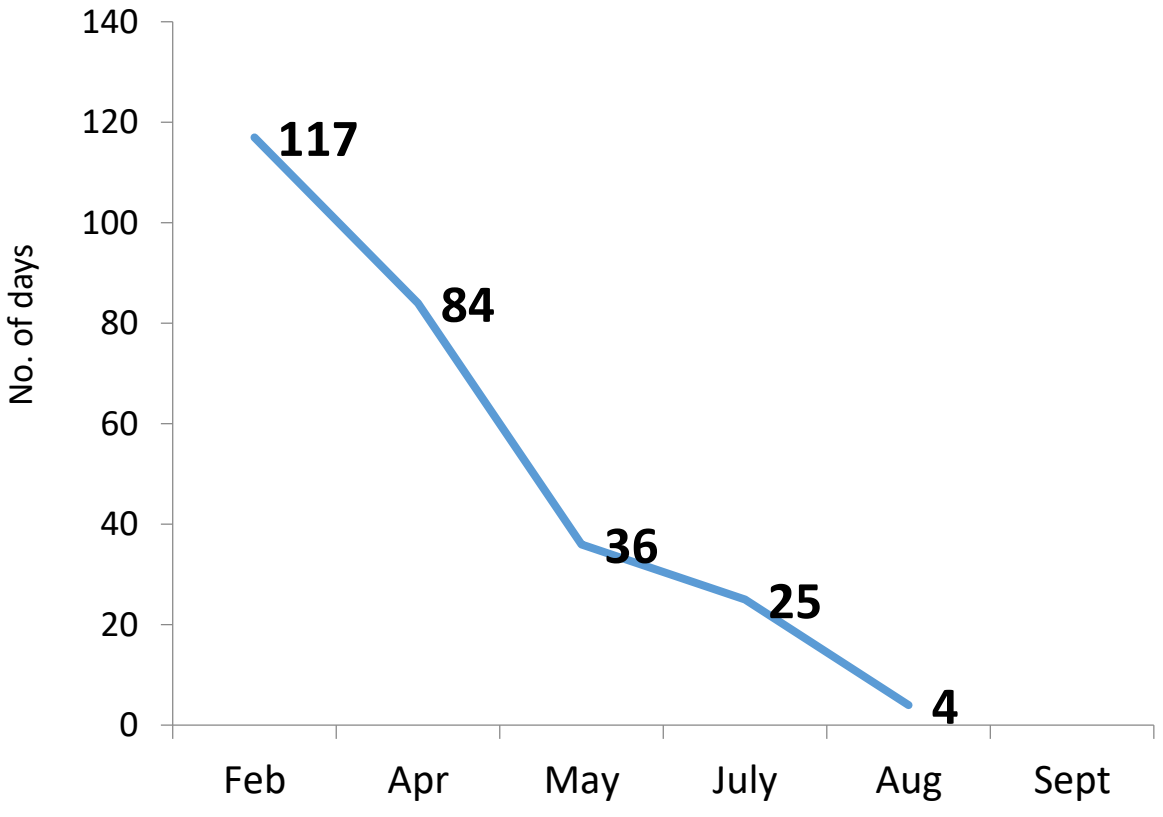
Strengthen TB Diagnosis in Adults, Infants and Children

Efficiency of GeneXpert Utilization FOR TB has improved. Need to improve result utilization – Uganda Example

Increasing trend in Xpert test workload and utilization rate



Average TAT for Xpert repair



1) MOU with Cepheid, 2) Improved TB demand creation, 3) Improved integrated sample transportation, 4) Multiplexing

Recommended Strategies

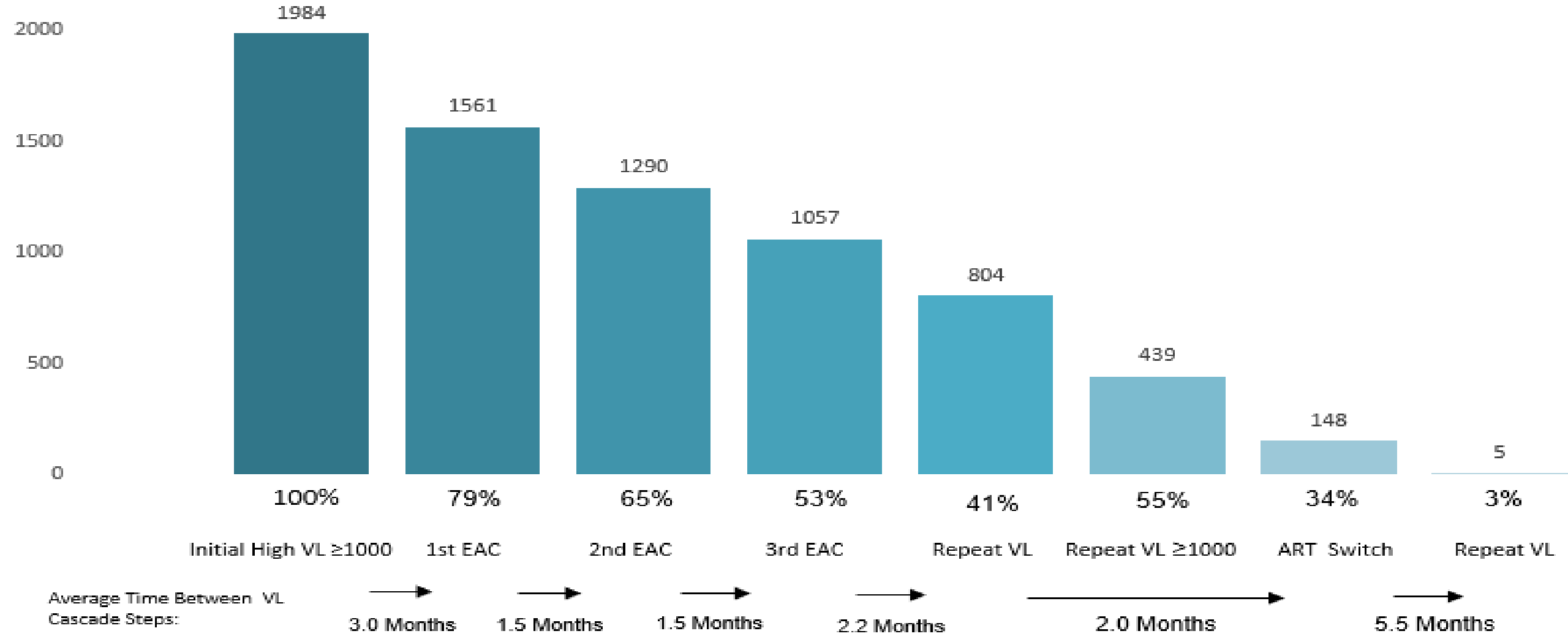
Client-centered Care Approaches

- Community engagement to increase demand for VL testing and EID
- Community/household sample collection
- Improvement in turnaround time and return of all results
- Data systems to alert patients of the availability of their test results
- Use of POC platforms to accelerate testing
- Quick action on non-suppressed VL results
- Last mile delivery of supply chain products

Use Point-of-Care Platforms to Accelerate Testing Coverage

- Viral load testing among pregnant and breastfeeding women
- Viral load testing among infants and children
- Viral load testing among non-suppressed populations
- Early Infant Diagnosis (EID)

Construct High Viral Load Cascade to Address non-suppression-South Sudan example



Improving TB diagnosis

- Rapid molecular diagnostic tests, such as Xpert MTB/RIF Ultra,
- If resistant to rifampicin, consider TB culture and molecular drug susceptibility testing
- Consider use of urine lipoarabinomannan (LF-LAM) assay as a rapid point-of-care diagnostic test for TB
- **Special considerations for TB diagnosis for infants and children, particularly sample types and detection methods**

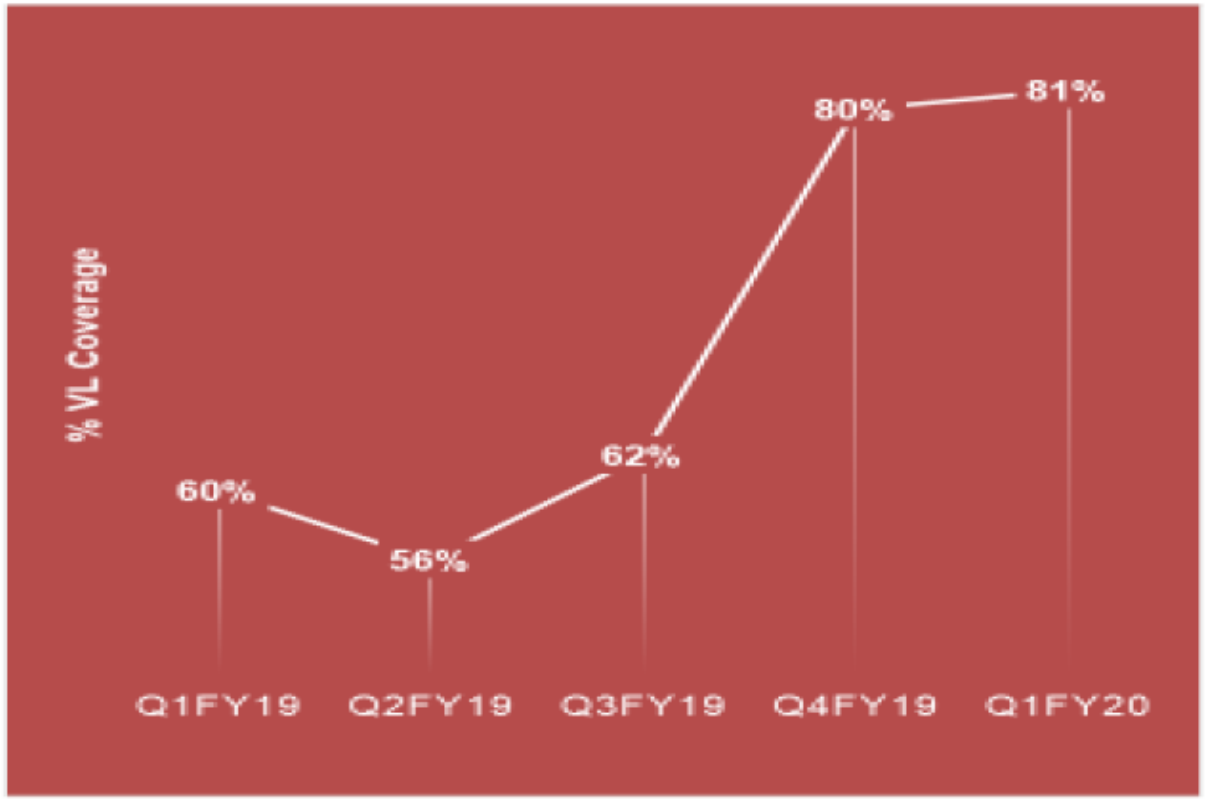
Limited CD4 Testing to Support AHD

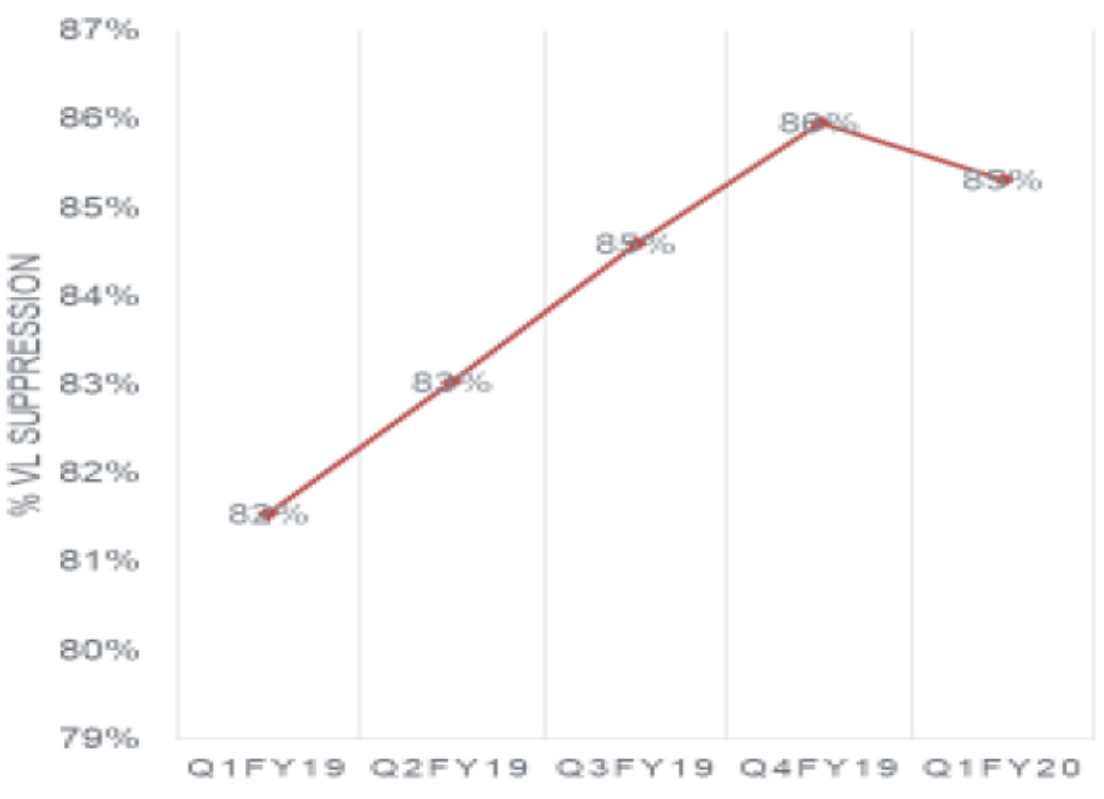
- Not used to determine ART eligibility or monitoring
- Identify individual with advanced HIV diseases (AHD)
- Individuals out of care for more than one year
- Individuals with documented viremia for more than one year
- Regions with suspected or documented AHD >15%

Diagnostic Network Optimization (DNO)

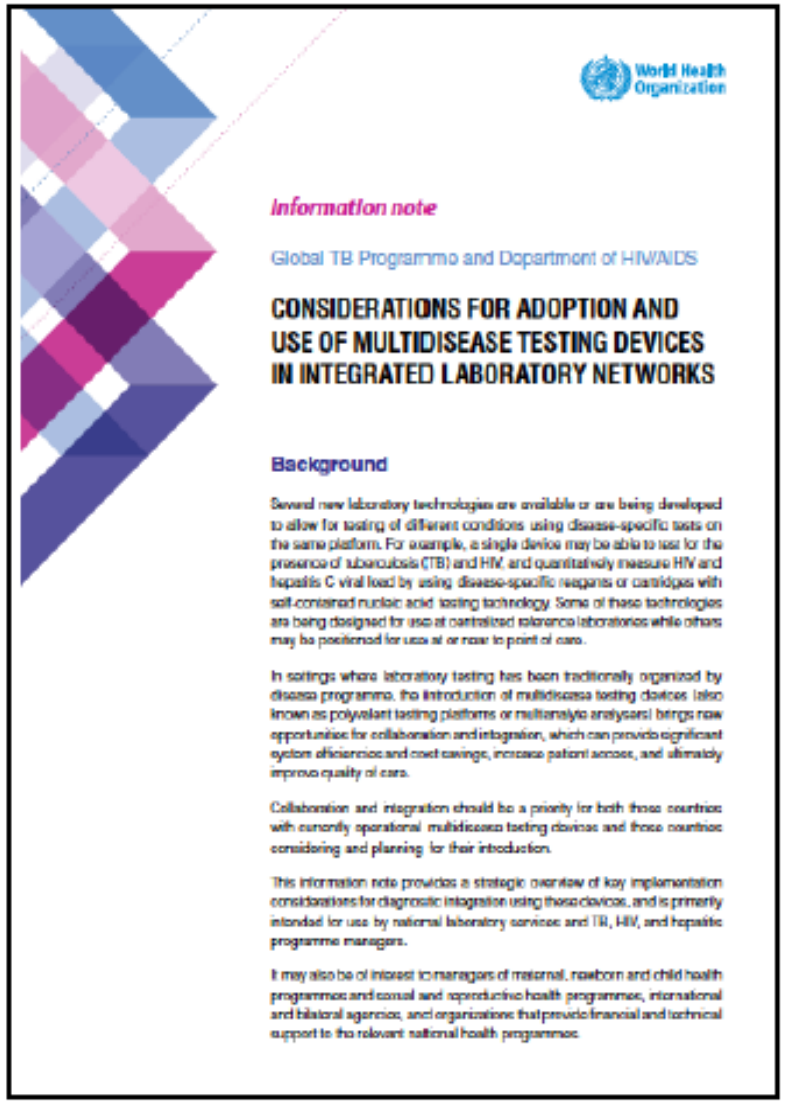
- Increase access to testing
- Increase network efficiencies
- Decrease total cost per test
- More effective allocation of funding
- Create a more competitive and dynamic marketplace

DNO led to Reduction in number of labs, introduction of Mega labs and increase VL TC- Nigeria example





Use Diagnostic Integration Approaches



World Health Organization

Information note

Global TB Programme and Department of HIV/AIDS

CONSIDERATIONS FOR ADOPTION AND USE OF MULTIDISEASE TESTING DEVICES IN INTEGRATED LABORATORY NETWORKS

Background

Several new laboratory technologies are available or are being developed to allow for testing of different conditions using disease-specific tests on the same platform. For example, a single device may be able to test for the presence of tuberculosis (TB) and HIV, and quantitatively measure HIV and hepatitis C viral load by using disease-specific reagents or cartridges with self-contained nucleic acid testing technology. Some of these technologies are being designed for use at centralized reference laboratories while others may be positioned for use at or near to point of care.

In settings where laboratory testing has been traditionally organized by disease programme, the introduction of multidisease testing devices (also known as polyvalent testing platforms or multianalyte analysers) brings new opportunities for collaboration and integration, which can provide significant system efficiencies and cost savings, increase patient access, and ultimately improve quality of care.

Collaboration and integration should be a priority for both those countries with currently operational multidisease testing devices and those countries considering and planning for their introduction.

This information note provides a strategic overview of key implementation considerations for diagnostic integration using these devices, and is primarily intended for use by national laboratory services and TB, HIV, and hepatitis programme managers.

It may also be of interest to managers of maternal, newborn and child health programmes and sexual and reproductive health programmes, international and bilateral agencies, and organizations that provide financial and technical support to the relevant national health programmes.

MOLECULAR DIAGNOSTICS INTEGRATION GLOBAL MEETING REPORT

10–12 JULY 2019, GENEVA, SWITZERLAND

World Health Organization

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE

Unitaid

World Health Organization

MULTI-DISEASE DIAGNOSTIC LANDSCAPE FOR

INTEGRATED MANAGEMENT OF HIV, HCV, TB AND OTHER COINFECTIONS

JANUARY 2018

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Multiplex Use of Platforms for HIV, TB and COVID-19 Testing (FDA EUA)

	Viral Load	EID	TB	COVID-19	HIV serology	COVID-19 serology
1 	✓	✓	✗	✓		
2 	✓	✓	✗	✓		
3 	✓	✗	✗	✓		
4 	✓	✓	✓	✓		
Serology (Antibody)					✓	✓

Current WHO laboratory guidance suggests that COVID-19 testing should be conducted in appropriately equipped **laboratories with BSL-2 facilities**. https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-

Global Request for Proposal (RFP)

- Improved system performance, reduced cost and transparent pricing, and enhanced supply chain security.
- Increase network efficiencies
- Anticipated cost savings is $20 million or more annually
- Fully supported by country ministries of health, GF and other stakeholders
- Incorporate the all-inclusive pricing approaches
- Applied to both centralized and POC instruments, including procurement and use of cartridges.
- Full DNO to ensure full benefits of this innovative initiative.

Biosafety and Waste Management

- Waste management policy at national
- Systems for management and disposal of routine laboratory waste
- Coordination with MOH other stakeholders within the Integrated Diagnosis Consortium (IDC) to address challenging waste management issues.
- Engagement with manufacturers to address the Guanidanium Thiocynate (GTC) issues

Plausible Causes of Low VL Testing as Result of COVID-19 Outbreak

- Lockdown resulting in clinic closure, restricted movements, and fear of COVID-19 infection.
- This impacted sample collection and transport from remote areas to central lab for testing.
- Multiplex use of HIV related platforms for COVID-19 testing
- Diversion of HIV molecular testing staff to support COVID-19 testing
- Global flights restriction
- Major supply chain issues due to several reasons

Suggested COVID-19 Mitigation Strategies

- Consider options for timing and location of specimen collection that allow for social distancing such as:
  - Reduce wait time for sample collection
  - Avoid crowded waiting rooms
  - Schedule and stagger appointments
- Streamline clinic flow so that patients for sample collection do not interact with multiple clinic providers.
- More use of DBS for sample collection out of facilities.
- Reactivate safe sample transport systems.
- Consider more use of mobile testing or point of care services, particularly in the community.

Minimum Program Requirement

VL/EID Scale Up & Diagnostic Network Optimization (DNO)

To address gaps associated with low VL testing coverage among PBFW, low VL testing coverage and suppression among infants, children and adolescents, low 2 months EID coverage, and low TB testing, country programs should develop and implement a DNO approach that shows:

1) complementary use of point of care (POC) and centralized instruments,
2) TB/HIV diagnostic integration,
3) multiplexing, and
4) use of data systems to include SMS to alert patients of the availability of their test results,

Strengthen Global Lab Stakeholders' Coordination

- Integrated Diagnostic Consortium (IDC) Platform
  - Formed in October 2017 with clear TOR
  - The goal of IDC is to enable better coordinated, uninterrupted provision of timely, high-quality diagnostics test results in countries most in need.
- The Vatican Initiative
- African CDC led initiatives
- Implementing partners/local capacity building
- Leadership and ownership from host governments

Thanks to all those who have contributed to the COP21 development process.