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

Controlling the HIV Pandemic

Accountability
Demonstrate cost-effective programming that maximizes the impact of every dollar invested

Transparency
Demonstrate increased transparency with validation and sharing of all levels of program data

Impact
Demonstrate sustained control of the epidemic; save lives and avert new infections

Active Program and Partner Management

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PEPFAR Latest Global Results

- **2020**
  - **25.3 MILLION** Decline in new HIV diagnoses among adolescent girls and young women in nearly all DREAMS regions
  - **2.8 MILLION** People received HIV testing services
  - **17.2 MILLION** Orphans, vulnerable children, and their caregivers received support
  - **290 THOUSAND** New health care workers trained

- **2020**
  - **Voluntary medical male circumcisions to prevent HIV infection in men and boys**
  - **25% OR MORE** Babies born HIV-free
  - **50 MILLION** Women, men, and children on lifesaving antiretroviral treatment
  - **6.7 MILLION**

**17 YEARS OF SAVING LIVES THROUGH AMERICAN GENEROSITY AND PARTNERSHIPS**
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

<table>
<thead>
<tr>
<th>Quarter</th>
<th>% VL Coverage</th>
<th>% Viral Suppression</th>
<th>% VL Coverage Target</th>
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<tbody>
<tr>
<td>2019 Q1</td>
<td>85%</td>
<td>59%</td>
<td>79%</td>
</tr>
<tr>
<td>2020 Q1</td>
<td>89%</td>
<td>66%</td>
<td>77%</td>
</tr>
<tr>
<td>2019 Q2</td>
<td>89%</td>
<td>66%</td>
<td>77%</td>
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<tr>
<td>2020 Q2</td>
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<td>2019 Q3</td>
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<td>75%</td>
</tr>
<tr>
<td>2020 Q3</td>
<td>90%</td>
<td>78%</td>
<td>75%</td>
</tr>
<tr>
<td>2019 Q4</td>
<td>92%</td>
<td>90%</td>
<td>92%</td>
</tr>
<tr>
<td>2020 Q4</td>
<td>92%</td>
<td>92%</td>
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</tbody>
</table>
FY20Q4: Only four OUs have achieved both ≥80% VL Coverage & ≥95% Viral Suppression
FY20Q4: Pregnant Women VLC Compared to General Population

%VL Coverage All Populations | %VL Coverage Pregnant Women | %VL Coverage Target

Botswana | Burundi | Cote d'Ivoire | DRC | Eswatini | Ethiopia | Haiti | Kenya | Lesotho | Malawi | Mozambique | Nigeria | Rwanda | South Sudan | Tanzania | Uganda | Zambia | Zimbabwe

0% | 10% | 20% | 30% | 40% | 50% | 60% | 70% | 80% | 90% | 100%

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

- Patients with a Suppressed VL
- Patients with an Unsuppressed VL
- Testing Gap
- %VLS
- %VLC

FY17:
- 37% Suppressed VL
- 62% Unsuppressed VL
- 84% Testing Gap
- 84% %VLS
- 84% %VLC

FY18:
- 62% Suppressed VL
- 38% Unsuppressed VL
- 88% Testing Gap
- 62% %VLS
- 62% %VLC

FY19:
- 78% Suppressed VL
- 22% Unsuppressed VL
- 90% Testing Gap
- 78% %VLS
- 78% %VLC
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

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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

- Qtr 1: 8,153 Total tests, 8,153 Positives (66%)
- Qtr 2: 8,407 Total tests, 8,407 Positives (68%)
- Qtr 3: 9,039 Total tests, 9,039 Positives (77%)

Average TAT for Xpert repair

- Feb: 117 days
- Apr: 84 days
- May: 36 days
- July: 25 days
- Aug: 4 days

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

Average Time Between VL Cascade Steps:
- Initial High VL ≥1000: 3.0 Months
- 1st EAC: 1.5 Months
- 2nd EAC: 1.5 Months
- 3rd EAC: 2.2 Months
- Repeat VL: 2.0 Months
- Repeat VL ≥1000: 5.5 Months
- ART Switch: 5.5 Months

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

<table>
<thead>
<tr>
<th></th>
<th>Viral Load</th>
<th>EID</th>
<th>TB</th>
<th>COVID-19</th>
<th>HIV serology</th>
<th>COVID-19 serology</th>
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### Serology (Antibody)


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**PEPFAR**

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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.