The Laboratory System Community of Practice (LabCoP)

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Outline

LabCoP Framework
What are we doing?
Who are we working with?

LabCoP Theory of Action
How are we achieving our goals?

The tools
What are the instruments and resources developed?
The LabCoP Framework
THE VIRAL LOAD CONTINUUM...

1. PLHIV Eligible for VL Tests
2. Tests Requested
3. Samples Collected
4. Samples Transported
5. Tests Performed
6. Results Returned
7. Results Utilized

....AND THE LAB SYSTEMS THAT SUPPORT IT

- Quality Management Systems
- Laboratory Information Systems
- Policy & Regulation
- Sample Referral
- Infrastructure
- Biosafety & Biosecurity
- Supply Chain & Equipment
- Workforce

OUTCOMES

- Patients with VL suppression referred to less intense models of care
- Patients with elevated viral load referred to intensified adherence counseling, resuppressed, or changed to 2nd Line

THE STAKEHOLDERS INVOLVED

- Implementing Partners
- Policy Makers
- Civil Society
- Clinicians
- Program Managers
- Laboratory Staff
LabCoP Theory of Action
LabCoP THEORY OF ACTION

AIM: TO FACILITATE THE IMPROVEMENT OF LABORATORY SYSTEM FUNCTIONS AND ACCELERATE THE SCALE-UP OF HIV VIRAL LOAD TESTING FOR IMPROVED PATIENT OUTCOMES

DEFINING KEY STEPS IN VL CASCADE AND LAB SYSTEMS → ASSESSMENTS OF VL CASCADE AND NATIONAL LAB SYSTEMS → PRIORITIZING CHALLENGES → IDENTIFYING BEST PRACTICES → "COMMUNITY OF PRACTICE" OF NATIONAL LABS, CLINICAL, CIVIL SOCIETY STAKEHOLDERS → NATIONAL OPERATIONAL PLANS → IMPLEMENTATION OF BEST PRACTICES AND ONGOING QI → NATIONAL BUDGETS, GF FUNDING CYCLES, PEPFAR COPs

OUTCOMES

- Increased access to viral load testing
- Improved patient outcome
- Increased laboratory systems functionality

ASLM
AFRICAN SOCIETY FOR LABORATORY MEDICINE
LabCop Tools and Resources

1- The viral load testing cascade self assessment scorecard
The HIV viral load testing cascade self-assessment tool

- Standard tool to assess the national VL testing program, designed as a scorecard with color coded results

- 6 domains of the testing cascade and systems:
  - Demand creation
  - Specimen collection and processing
  - Sample transport
  - Laboratory testing
  - Results utilization
  - Leadership & management

- One section to quantify the national VL testing cascade.
Results at baseline among the 11 LabCoP countries: common areas of weaknesses

- Demand creation
  - LMS for result delivery
  - Notification of abnormal results
  - TAT (>20 days)
  - Sample transport
  - Result utilization
- Skilled lab personnel
- Equip. maintenance
- Biosafety & Waste Mgm’t
- Demand creation
- Scale-up plan/M&E framework
- Viral Load Testing
  - Quality Mgm’t:
    - QMS
    - EQA
- Specimen Mgm’t
- Assigned unit focal person for VLT
- National protocols

- Network optimization
  - Coverage
  - Turnaround time
  - Efficiencies
- Result utilization
- Waste management

Prioritization and focus for better planning
Country-specific weaknesses: example of Ethiopia

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<tr>
<th>Domain 1: demand creation</th>
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<tr>
<td>- Develop National strategy or procedure on demand creation</td>
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<td>- Strengthen strategy for awareness creation initiatives to PLHIV and stakeholders</td>
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<th>Domain 2: Specimen collection and processing</th>
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<tr>
<td>- Develop a national protocol for sample management and enforce it at facility level</td>
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<td>- Conduct COI activities to reduce the rate of specimen rejection</td>
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<th>Domain 3: Sample transportation</th>
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<td>- Further improve the sample transportation system to integrate other types of specimen for other diseases.</td>
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<td>- Improve the TAT time of test results across the sample referral network</td>
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<th>Domain 4: HIV testing</th>
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<td>QMS:</td>
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<td>- Work towards all VLT labs to be at least SLIPTA audited and certified, and finally accredited</td>
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<td>- Improve on innovative approaches for sharing VL test results from the lab to clinic for HN C&amp;T</td>
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<td>Waste management</td>
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<td>- Develop and disseminate national biosafety manual</td>
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<td>Supply chain and equipment</td>
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<td>- Develop a national plan for equipment maintenance</td>
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<td>- Increase workforce capacity for equipment maintenance</td>
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<th>Domain 5: Results utilization</th>
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<td>- Develop: standardized strategies and processes for referring patients</td>
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<th>Domain 6: Leadership and management</th>
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<td>- Strengthen the Unit or TWG responsible for national lab system strengthening</td>
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<td>- TWG to develop an M&amp;E plan or framework for the scale up of VL</td>
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Educate the PLHIV to increase demand for VLT

Expand QMS to all laboratories doing VLT, Move towards country-coordinated SLIPTA programmes
LabCoP tools and Resources

2- The strategic decision tool
The strategic decision tool

- Identify, summarize and categorize all useful best practices into strategic interventions across the prioritized areas for improvement, through
  - Country to country exchanges
  - Input from Subject matter expert and stakeholders

- Use the strategic decision tool to propose intervention in country action plan
From strategic decision tool to action plans to funding

- Develop evidenced-based action plans to address prioritized areas

  11 action plans addressing demand creation and results utilization

- Linkage the plans to **existing funding and implementation** opportunities and mechanisms:
  - PEPFAR country operational plans (COP)
  - Global Fund planning or reprogramming cycles
  - National budgets

- OGAC and CDC Headquarter and country team have supported the inclusion of demand creation and result utilization in COP19
LabCoP tools and Resources

3- The LabCoP cookbook of recipes
Example of the Result utilization Recipe

Knowledge co-creation and dissemination within the LabCoP

Knowledge, solutions, tips and various good ideas are summarized into practical guidelines at the attention of multidisciplinary team (not only laboratory)

Guidelines from CDC, WHO, etc...
Critical Result Notification

Critical laboratory test results, in this case (ULI), must be immediately flagged and communicated to clinicians and multidisciplinary teams for immediate action. These systems should be optimized at the site level to match the local context and resources. Several simple approaches have been found to be highly effective, including:

- Use of a separate ULI register
- Mobile texting
- Reports designed to highlight ULI (e.g., color coding, unique tagging, symbols)
- Using stickers on charts
- Labeling results with ‘urgent’ or ‘ASAP’, or other methods to separate linkage of results with action.
- Receipt of a phone call between receipt of critical result to time clinician action is taken.

Standard Operating Protocol

Development of a guide or standard operating procedure (SOP) for reporting ULI and/or other laboratory results, and monitoring its implementation facilitates the sustainable delivery of results. Engagement of clinicians, nurses, laboratory staff, and recipients of care in the development of SOPs helps to ensure they are practical and feasible at the site level.

Timely Result Review and Interpretation

Clinicians should review, review, and interpret test results based on national/local patient management guidelines. Key innovations to support timely and accurate use of ULI test results include:

- Critical result notification systems and SCRs ensure clinicians and multidisciplinary teams see results and prioritize them appropriately.
- Training, ongoing supportive supervision, and development of job aids support appropriate action – whether VI is unequivocal or equivocal.
- Routinely review of patient management by site-level multidisciplinary teams should include assessment of VI-guided interventions.
- Routinely review of program-level data at the health facility and program levels (see Section 4, Monitoring and Evaluation below).

Connection of Results, Clinicians, and Patients

Once results have been reviewed by a clinician, prompt action to connect results, clinicians, and patients is required. In some settings, patients receive timely follow-up appointments after VI specimen collection, i.e., they are scheduled for VI results review within 2-3 weeks. In this context, a systematic review is needed to make sure those appointments occurred and the lab has been cleared. In other settings, a VI result requires attending an urgent appointment with a patient. In either case, understanding the current process is the first step towards improving it. At many facilities, this is complicated, as processes may be implicit or unclear. It may not be clear who is responsible for each step. Additionally, what is actually happening may be very different from what is supposed to happen. Experiences show that:

- Develop a process map with site staff and clinicians to enhance program manager’s ability to identify gaps and opportunities for improvement.
- Review data on an ongoing basis, whether in the context of routine M&E or quality improvement activities, to identify what proportion of patients receive results within the appropriate timeframe.

Appropriate and Timely Clinical Services

The World Health Organization and national guidelines generally recommend that patients with VI (and other infections for VI stabilization) be referred to DDS services, although these vary substantially between and within countries. Guidelines also recommend that patients with VI receive 3 D+C sessions within approximately 3 months, followed by a repeat VI test and either referral for DDS (if suppression) or referral to a new ART regimen (if persistent VI, not documented).

- ULI management should be guided by step by step 50%, including systems and tools to support FAC.
- Site and regions can adapt existing ULI toolkits, such as the one developed by ICHR at Columbia University (see Resources on next page).

Case Managers

Assigning case managers to VI clients helps to improve linkage care. Case managers make periodic contact with patients to ensure linkage to care and conduct standard visits and coordinate the care needed.
Knowledge co-creation and dissemination within the LabCoP

**Demand creation**
1. Waste management – CDC ILB
2. Management of unsuppressed patients – L. Vojnov - WHO
3. Public Private Partnerships – Ravi – CDC ILB
4. Laboratory network Optimization - Jason & Matt – USAID/ PSM

**Sample collection**
1. S. Baptiste (ITPC) Mozambique
2. Moses Super Charger Uganda

**Sample transport**
1. C. Kiyaga (ASLM) Kenya Uganda

**Test performed**
1. P. Fonjungo (CDC ILB) Convent. testing

**Result returned**
1. P. Riley (CDC ILB) LARC

**Result utilization**
1. M. Rabkin (ICAP) Kenya Malawi

**Policy & regulation**
- 9 Countries

**Sample referral**
- POC VL & EID
- J. Sacks(CHAI) Zimbabwe Malawi
- J. Lemaire(EGPAF) 9 Countries

**Supply chain & equipment**
- Quality management systems
- Workforce
- Lab Information Systems

**Sample referral**
- Policy & regulation
- Supply chain & equipment
LabCoP can also assist partners in disseminating their own resources
• The waste management training package

• The Laboratory African Regional Collaborative (LARC)

• The CDC viral load and EID testing scorecard

This will be part of the phase 2 of the LabCoP project

• Face to face meeting Oct 22-24, Addis, Ababa
  • Assessment of country action plans and progress
  • Enhanced engagement of civil society and recipients of care to support the demand and correct utilization of test results
  • New lab system strengthening topics beyond VLT
    • diagnostic testing
    • evidence-based optimization of lab networks

• Expansion to Francophone regions??
Thank You

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