Laboratory Procurement and Supply Chain Considerations

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Overview

• Harmonization and Standardization
• Laboratory Network Systems Approach
• Product selection
• Understanding price
• Forecasting and procurement
• Maintenance challenges
• POC integration
• Discussion
Maputo and Freetown Declarations (2008/2015)

• Prioritization of laboratory system coordination by developing national laboratory policies, establishing departments of laboratory systems within ministries of health, and calling upon donors and partners to support national governments in this effort.

• Define and establish the minimum test offerings required at each level of an integrated, tiered laboratory network:
  – Diagnostic instruments, equipment, and human resources

• Prioritize supply chain systems and maintenance and service contracts for laboratory-based equipment at all levels of the laboratory network.
### Harmonization and Standardization approach

<table>
<thead>
<tr>
<th>Process</th>
<th>Involvement</th>
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<tbody>
<tr>
<td><strong>Phase I</strong></td>
<td><strong>Policy stakeholders, implementers, clinicians, program, procurement, biomedical engineers, laboratorians (all levels)</strong></td>
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<tr>
<td>Testing profile defined by tiered level</td>
<td>1. Clinical, program, and laboratory engagement – existing review and refinement of testing services</td>
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<tr>
<td><strong>Phase 2</strong></td>
<td><strong>Procurement, biomedical engineers, laboratorians (all levels)</strong></td>
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<tr>
<td>Testing methodologies defined</td>
<td>2. Informed testing protocols – influenced by existing HR, infrastructure, and instrumentation</td>
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<td>1. Instrument coverage defined</td>
<td>3. Evidence based instrument reduction process*</td>
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<td>2. Instrument evaluation criteria defined</td>
<td><strong>Ancillary equipment needs established by tier</strong></td>
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<td>3. Instrument selection process defined</td>
<td><strong>Human resource demands established by tier</strong></td>
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<tr>
<td>4. Evidence based selection established by tier</td>
<td>4. Define minimum ancillary equipment needs based on testing methodology and instrument selection</td>
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<tr>
<td><strong>MOH approval and policy dissemination</strong></td>
<td>5. Define minimum human resource requirements based on testing methodology and instrument selection</td>
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*Evidence based approach: Review of existing instrument specifications, national laboratory quantification data (service statistics, consumption, and demographic data), instrument inventories, and commodity distribution data. Can be used to establish site level demand and existing instrument utilization, as well as instrument testing contributions by brands to inform selection.
Laboratory network systems

**Lab**
- Platforms
- Sample collection
- Staffing & Training
- Quality Assurance
- Result Return

**Logistics**
- Forecasting & Procurement
- Reagent Storage & Cold Chain Distribution
- Maintenance
- Sample Transport

**Clinical**
- Provider Training
- Patient /Community Education
- Systems for Sample Collection, Results Return, Documentation, Interpretation/Utilization, QA/Mentorship

**M&E**
- Forms & Registers
- M&E System (LIS, Logistics & Clinical) Integration
PEPFAR VL/IVT Scale Up Strategy: Network Approach

• Understanding the national laboratory network and supportive systems (agnostic of disease type or program area) to inform efficient and effective program growth and instrument expansion.
  – Requires baseline mapping of the laboratory network and systems, identification of functional instruments, and current utilization rates.

• An all-inclusive per test cost structure spread across all instruments of the same brand within the network and available to all stakeholders to include:
  – Cost options that account for existing instruments with new contract models (eg. Leasing and rentals) that facilitate network expansion;
  – Inclusive service and maintenance;
  – Data solutions for patient result transmission, instrument/user performance;
  – Additional technology & support (training, barcoding, sample processing);
  – Enhanced commodity management strategies to ensure reagent availability;
### Procurement challenges

- Adherence to established approved instrument lists
- Procurement coordination and visibility
- In-country vendor capacity
- Lack of adherence to supply plans and making adjustments
- Aligning instrument deployments with commodity needs
- Protocol transitions
  - Commodities and software roll-out
Product selection considerations

• Is the instrument nationally approved?

• Fit for purpose? Environmental, capacity, technical complexity needs

• Site readiness?

• Incountry vendor support, capacity, and performance?

• Existing instrument types and past experience?

• Umbrella maintenance contracts?

• What are the longer term investment needs over short term costs (S&M, training, commodities, cold chain, etc.)

• Is reagent rental/bundling an option?
Understanding price:

- Significant variation in commodity pricing (comparing apples to apples);
- Global access pricing vs. Local vendor procurement;
- Demand – volume of testing;
- Amortization of instruments included in price;
- Reagent bundling (inclusive service and maintenance);
- Single brand platform use limits price negotiations;
- **A need to focus on an ‘all-in’ cost;**
- **Revisit and renegotiate agreements.**
Challenges associated with forecasting

- Quickly changing guidelines and system adjustments
  - Test and start, CD4 transitions, MMS, rapid VL scale-up
- No historical data for new programs – unknown uptake, system limitations and capacity
- Use of demographic/target based forecasts, traditionally overestimate commodity demands
- Rapid instrument deployments and network expansion
- High level of instrument diversity and failures
- M&E (LIMS/LMIS) systems are required to capture testing uptake to inform adjustments to supply plans
Forecasting: Forlabtool.com

• New version in development
Maintenance challenges:

- Limited data use to inform maintenance strategies;
- Limited coordination and alignment in instrument management strategies (lease vs. purchase);
- Agreements are many times not negotiated system wide;
- Adherence to contracts are not normally monitored, nor is vendor performance;
- There is limited capacity and consistency in managing and negotiating maintenance contracts;
- Vendor capacity can quickly be exceeded with rapid instrument scale-up;
- Spare part availability and ability to import.
POC integration considerations:

- Alere Q – new technology, no historical data associated with instrument lifespan and a clear understanding of maintenance strategy
- GeneXpert – existing TB challenges with maintenance – new strategy required!
- Site appropriateness and the need to understand conventional network impact
- There is a need for robust data feeds to monitor commodity replenishment and instrument failures
- Ensure a coordinated POC introduction strategy (program, laboratory, logistics)
POC integration considerations: commodity shifts
Recommendations

• Ensure alignment of laboratory policies, treatment guidelines, and minimum service packages

• Planning and procurement must be coordinated among agencies and donors in country

• Development of and adherence to policy criteria for placement of additional machines or higher throughput platforms

• Seek a systems/network approach where possible to inform network maintenance and expansion

• Data is key to effective asset management

• Seek reagent rental / bundling of services (including connectivity) into contracting as a priority
Thank you