Caribbean Laboratories – Resourcing for Sustainability

UWI Health Economics Unit - Conference on the Economy
Presentation by Valerie Wilson
Caribbean Med Labs Foundation
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Overview

• Background – CMLF – Global Fund Project
• Caribbean Laboratory Services:
  – Importance
  – Achievements
• Challenges to SUSTAINABILITY of service
• Remedial interventions
Caribbean Med Labs Foundation

• Not-for-profit non-governmental organisation
• Established in 2008
• Mission:
  To promote and support the achievement of quality laboratory services in accordance with appropriate standards, through advocacy, resource mobilisation, collaboration, research and education
CMLF Activities under GF R9 Project

• Strengthening of regional and national networks to support HIV related services:
  – Assessments of laboratory services
  – Development of national laboratory strategic and network development plans
  – Training and quality systems improvement support
  – Laboratory Information Management improvements
  – Development of national laboratory policies to guide and sustain laboratory improvement efforts
Value for Money

• Approximately **5% of the national health budget** in most countries is expended on laboratory services

• **Laboratory data influences 70% of clinical decisions**
  – NCDs (diabetes, cancer, heart disease, etc.)
  – Communicable diseases (HIV, TB, dengue, ChikV, etc.)
For the past 15-20 years:

- Major investments (> $20 M) in laboratory services – regional and international agencies and donors
- Major emphasis on expanding scope, access and quality building strategies
- Ministers and Officials:
  - Endorsement of strategies – commitment to:
    - Licensing
    - Strategic Plans
    - Sustainable Funding
- BUT........
"My question is: Are we making an impact?"

We need to measure impact!
Role of Laboratory Services in meeting 90-90-90 targets

• **Testing** is the **first point** of access to the continuum of care and is **central and critical to the achievement of each of the 90-90-90 targets**

• Laboratory services underpin all aspects of HIV programmes:
  – Identifying individuals infected with HIV (first 90)
  – Providing CD4 - initiation patients on treatment (second 90)
  – Identifying viral suppression through monitoring VL (third 90)
  – Identifying opportunistic infections such as TB, and sexually transmitted infections to ensure appropriate interventions.
  – Monitoring safety of patients on treatment - biochemistry and haematology
  – Identifying drug resistance in treatment failures
Regional CHALLENGES

- Small Region
- Small fragile economies
- Slow Progress in achieving and sustaining Lab Quality Improvement
- Finding new strategies for sustainable improvement
Some Startling Realities!
Gov't pays big for wrong diagnosis

The Government has agreed to compensate a woman with just under $9 million for a misdiagnosis that she was HIV-positive. But that is not enough for 28-year-old Karen Reid, who suspects that medication she was treated with nine years ago might have affected her baby, who was born blind, as she was pregnant at the time.

2005 POSITIVE.
SECOND TEST 2007 – NEGATIVE.
SHAME, PAIN, LOSS OF RELATIONSHIP
State Lab mistakenly declared eight mothers HIV positive - Treatment initiated (2015)
## Variation Laboratory vs Pharmaceutical Costs

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Laboratory Reagents</td>
<td>5-10%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory Supplies</td>
<td>5-15%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmaceuticals – AZT/3TC/NVP</td>
<td>28.6%</td>
<td>76.2%</td>
<td></td>
</tr>
<tr>
<td>Pharmaceuticals Lopinavir/Ritonavir</td>
<td>13%</td>
<td>83%</td>
<td></td>
</tr>
</tbody>
</table>
HIV Rapid Testing – Country A

<table>
<thead>
<tr>
<th>Laboratory Resources – 10 Sites</th>
<th>Cost US$ per annum</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA Co-ordinator Salary*</td>
<td>27,823</td>
</tr>
<tr>
<td>Test Kits</td>
<td>18,000</td>
</tr>
<tr>
<td>Supplies</td>
<td>5,000</td>
</tr>
<tr>
<td>Training</td>
<td>1,000</td>
</tr>
<tr>
<td>TOTAL</td>
<td>51,823</td>
</tr>
</tbody>
</table>

- *QA Co-ordinator oversees quality of testing at sites and at the laboratory
- All funding for this rapid testing programme is provided by extrabudgetary funding
- Funding ends in 2015
- Laboratory budget cut by 10% for period 2012-2015
Laboratory Service Pattern for 2012 – Country B

<table>
<thead>
<tr>
<th>Quarters</th>
<th>Numbers of Patient Accessioned</th>
<th># of Tests Done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan – March 2012</td>
<td>13,848</td>
<td>87,578</td>
</tr>
<tr>
<td>April – June 2012</td>
<td>12,349</td>
<td>72,968</td>
</tr>
<tr>
<td>July - Sept 2012*</td>
<td>9,569</td>
<td>37,719</td>
</tr>
<tr>
<td>October - Dec 2012</td>
<td>10,969</td>
<td>64,896</td>
</tr>
<tr>
<td>TOTALS</td>
<td>46,735</td>
<td>263,181</td>
</tr>
</tbody>
</table>

- Reagent stockouts and equipment downtime due to unpaid invoices and lack of equipment service contracts
## Laboratory Financial Status – Country B

<table>
<thead>
<tr>
<th>YEAR</th>
<th>INCOME EC$</th>
<th>FEES TO PRIVATE LABS EC$</th>
<th>OUTSTANDING DEBT EC$</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>750,000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>500,000</td>
<td>74,025 for hospital in patients</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td></td>
<td>103,995 – owed at end 2013</td>
<td>675,000</td>
</tr>
</tbody>
</table>

Overall lab budget $1.6 M EC – not assigned to the lab
No Chemistry tests offered by the laboratory since September 2013
Reagent and material costs increase by 2.5 – 5% annually
# National Lab in Country X

Financial Challenges Impacting Access to Services

<table>
<thead>
<tr>
<th>TEST</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4</td>
<td><strong>Interrupted</strong></td>
<td><strong>Interrupted</strong></td>
</tr>
<tr>
<td>CBC</td>
<td>Uninterrupted</td>
<td>Uninterrupted</td>
</tr>
<tr>
<td>VIRAL LOAD</td>
<td>Uninterrupted</td>
<td><strong>Interrupted</strong></td>
</tr>
<tr>
<td>GC</td>
<td><strong>Interrupted</strong></td>
<td>Uninterrupted</td>
</tr>
<tr>
<td>Syphilis</td>
<td>Uninterrupted</td>
<td>Uninterrupted</td>
</tr>
<tr>
<td>Liver Function Test</td>
<td><strong>Interrupted</strong></td>
<td><strong>Interrupted</strong></td>
</tr>
</tbody>
</table>
## International Health Regulations: Laboratory

<table>
<thead>
<tr>
<th>Component Core Capacity</th>
<th>Country Level Indicator</th>
<th>&lt;1 - Foundational</th>
<th>1 Inputs and Processes</th>
<th>2 Outputs and Outcomes</th>
<th>3 Additonal Achievements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy and coordination of laboratory services</td>
<td>Coordinating mechanism for laboratory services</td>
<td>A laboratory focal point identified for coordinating laboratory services</td>
<td>A national Plan of Action - essential functions of labs, minimum standards and licensing/registration</td>
<td>Up to date policies disseminated specifying minimal requirements</td>
<td>Regulatory authorities are designated within the country (regional?)</td>
</tr>
<tr>
<td>Policy to ensure quality of laboratory capacity (licensing, accreditation, biosafety level, etc.)</td>
<td>National laboratory quality standards/guidelines</td>
<td>National or international external quality assessment schemes for diagnostic laboratories</td>
<td>All diagnostic laboratories are certified according to international or national standards</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Framework for National Laboratory Policy

• Endorsed by meeting of CMOs in April 2014
• Endorsed by COHSOD - Health September 2014:

Model Regional/Sub-Regional Policies and Legislation: National Laboratory Policy Framework (CMLF)

• **Endorsed** the Regional Laboratory Policy Framework; and
• **Requested** Member States to provide leadership at the national level to support adaptation and implementation of the National Laboratory Policy Framework.
National Laboratory Policy Components

• Situation Analysis
• Mission and Vision
• Essential elements of the national laboratory policy should include:
  – Laboratory Governance and Network Structure (Coordination and Monitoring)
  – Quality Management Systems (Efficiency, Licensing)
  – Laboratory Support Systems (Procurement, Maintenance, Safety and Biosafety)
  – Information and Data Management (LIS→HIS)
National Policy Consultations

- 2014-2015: CARICOM-PANCAP GF CMLF Project
  - Belize
  - Suriname
  - 6 OECS countries (Antigua & Barbuda, Dominica, Grenada, St. Kitts and Nevis, St. Lucia, St. Vincent & The Grenadines)
  - Montserrat
  - Barbados
  - Jamaica
  - Guyana
  - Bahamas (planned)

Collaboration with PAHO HIV Office - 2014
- 4 OCTs – Anguilla, Cayman Is., St. Maarten, Turks and Caicos Is
28th COHSOD of Health Ministers 2015

- **Noted and Congratulated** countries for the progress made in developing national laboratory policies with facilitation by CMLF;

- **Commited** to provide leadership at the national level to support adoption and implementation of the National Laboratory Policy – critical to meeting IHR requirements and to ensuring reliable and sustainable national laboratory services

- **Committed to ensuring** that the required quantum of human and financial resources are allocated to secure consistent, uninterrupted, reliable testing and information generation by laboratories, given the evidence that while only approximately **5% of the national health budget** in most countries is expended on laboratory services, **laboratory data influences 70% of clinical decisions.**
Implications for the future

• Labs need to:
  – Provide quality service
  – Manage costs and wastage effectively – track real COSTS
  – Engage in outcomes research to show lab impact on patient health & cost of care

• Governments and Administrators recognise:
  – Labs are NOT a ‘cost-item’ and their value cannot be measured in whether lab testing makes a profit
  – One wrong result can reverberate across the entire health system and cost more than the annual laboratory budget
  – Labs are an investment that make good business and economic sense – impact on patient in-stay and recovery, increase in national productivity, growth and development
At Regional Level

- Advocate with governments to secure and sustain laboratory budgets
- Negotiate joint pricing for common lab supplies
- Advocate for adoption of national laboratory policies
- Continue to emphasise quality of laboratory services and support laboratories to improve quality
- Support laboratory costing studies to provide data for action
The Risks of ignoring the signs...

- Stock-outs
- Equipment down-time
- Suspension of testing
- Loss of clinical services
- Loss of PH capacity
- Vulnerability to disease outbreaks
- Inability to meet international health mandates
- Loss of tourism market share
- Higher national health costs
- Declining productivity & economic viability
We need to know that while labs are invaluable in this economically challenging and competitive time, CHANGE is critical.
Thank-you