PEPFAR HIV/TB Laboratory Capacity Building

Linda M. Parsons, Ph.D.
International Laboratory Branch
Division of Global AIDS (GAP)
Centers for Disease Control and Prevention
Atlanta, GA, USA
Bush signs expansion of US global AIDS programmes

President George W. Bush on Wednesday signed into law a big expansion of U.S. efforts to fight AIDS in Africa and elsewhere, warning that defeating this scourge requires an unprecedented investment over generations.

The measure, which won final congressional passage last week, calls for the United States to spend $48 billion over the next five years to help treat and prevent AIDS, tuberculosis and malaria in sub-Saharan Africa and elsewhere. The measure more than triples the $15 billion Congress initially funded for the first five years of the program, which began in 2003. It extends and expands an existing effort to bring life-extending drugs to people infected with the human immunodeficiency virus, or HIV, which causes AIDS.
PEPFAR’s goal is to strengthen laboratory capacity as integral part of health systems

**Mission:** To build **sustainable integrated** laboratory capacity to provide **quality** diagnostic tests for **effective** implementation of prevention, surveillance and treatment programs across diseases (**HIV, TB, OIs**)
Association of TB and HIV

- HIV epidemic has led to huge increases in the incidence of TB in the affected countries
- Treatment complicated by negative interactions of HIV and TB drugs
- Increases in smear-negative pulmonary TB in HIV-infected
- TB more difficult to diagnose in HIV co-infected, smear-negative patients
  - Reduced pulmonary cavity formation
  - Reduced sputum bacillary load
  - More frequent involvement of the lower lobes
  - Exceptionally high mortality rate
Percentage of tested TB patients who are HIV-positive

<table>
<thead>
<tr>
<th>Region</th>
<th>% of Notified TB Patients Tested for HIV</th>
<th>% of Tested TB Patients HIV-Positive</th>
<th>% of Estimated HIV-Positive TB Casesa</th>
<th>% of Identified HIV-Positive TB Patients Started on CPT</th>
<th>% of Identified HIV-Positive TB Patients Started on ART</th>
<th>Regional Distribution of Estimated HIV-Positive TB Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFR</td>
<td>22</td>
<td>52</td>
<td>25</td>
<td>78</td>
<td>39</td>
<td>85</td>
</tr>
<tr>
<td>AMR</td>
<td>32</td>
<td>15</td>
<td>54</td>
<td>84</td>
<td>76</td>
<td>3.0</td>
</tr>
<tr>
<td>EMR</td>
<td>1.4</td>
<td>6.1</td>
<td>4.0</td>
<td>17</td>
<td>16</td>
<td>0.9</td>
</tr>
<tr>
<td>EUR</td>
<td>46</td>
<td>1.7</td>
<td>41</td>
<td>54</td>
<td>45</td>
<td>1.8</td>
</tr>
<tr>
<td>SEAR</td>
<td>4.1</td>
<td>18</td>
<td>40</td>
<td>66</td>
<td>33</td>
<td>5.6</td>
</tr>
<tr>
<td>WPR</td>
<td>2.7</td>
<td>6.9</td>
<td>12</td>
<td>66</td>
<td>35</td>
<td>3.2</td>
</tr>
<tr>
<td><strong>Global</strong></td>
<td><strong>12</strong></td>
<td><strong>27</strong></td>
<td><strong>26</strong></td>
<td><strong>78</strong></td>
<td><strong>41</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

a Including estimated HIV-positive TB cases in countries which did not provide information on testing.

Africa has 79% of the global total TB cases arising in people with HIV.

TB is responsible for the majority of deaths of patients co-infected with HIV in SubSaharan Africa.
Objective:
Building laboratory capacity in countries with high burdens of HIV and TB
What approaches are used to build lab capacity?

- Work with in-country government ministries and national and international public and private partners
- Establish and implement National Strategic Plans for Laboratories
- Use an integrated disease-wide approach
- Standardize laboratory systems through certification and accreditation
- Establish public private partnerships
Major Challenges in Strengthening Laboratory Systems to Support Global Health HIV/TB/Malaria Programs

1. Human capacity
   - Limited number of trained and skilled personnel
   - Lack of adequate training programs

2. Infrastructure
   - Inadequate supply of electricity and water
   - Physical infrastructure
   - Lack of equipment, supply chain management for consumables and reagents, and maintenance

3. Lack of policies, advocacy, and leadership
   - Lack of laboratory systems
   - No governmental standards for laboratory testing
   - Vertical programs for different diseases

4. Need for better coordination of partner support
The Maputo Declaration on Strengthening of Laboratory Systems – January 2008

Call on national governments to **support laboratory systems as a priority through implementation of a national strategic laboratory plan.**

Call on national governments with support of their donors and partners to **develop national strategic laboratory plans** that **integrate laboratory support for the major diseases** of public health importance including HIV, tuberculosis, and malaria.
Development and Implementation of a National Laboratory Strategic Plan

- Goal – to establish national quality assured networks of tiered laboratory services

  - Engage country and partners in discussions
  - Form coordinating and technical committees
  - Develop Strategic Plan
  - Implement Strategic Plan
  - Review and evaluate progress
National System of Tiered Laboratories

National Reference Laboratory

Regional Reference Laboratories

Referral Hospitals

Primary Hospital

Health Centers

Senior Health Scientists

Specialists
Senior Technologists
Program Officers

Doctors
Nurse Practitioners
Medical Assistants
Communication is a 2-way street!

Referrals to the National Reference Lab from District and Peripheral Labs

EQA oversight of District and Peripheral Labs by the National Reference Lab

EQA: site supervision, retesting, proficiency testing
Essential Components of a National Laboratory Strategic Plan

- Establish minimum standards for laboratory testing
  - Policies for accreditation of labs and facilities
- Develop strategies for workforce development and retention
- Link tiered integrated laboratory services
- Ensure continuous supply of laboratory commodities
- Establish program for facility and equipment maintenance
  - Provision of safe work environments
- Establish roles, responsibilities and accountability
- Establish targeted health goals that will provide indicators of success
### Development of National Strategic Laboratory Plan in PEPFAR Countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Engaged in Discussion</th>
<th>Coordinating &amp; Technical Committees Formed</th>
<th>Strategic Plan Developed</th>
<th>Strategic Plan Implemented</th>
<th>Strategic Plan Progress Reviewed &amp; Evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cote d’Ivoire</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethiopia</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guyana</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kenya</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesotho*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mozambique</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nigeria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rwanda</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swaziland*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uganda</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vietnam</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Non-focus country*
The Lab Strategic Plan
Train is on the Move!
Kenya’s strategy towards integration of laboratory services

- Established a Laboratory Interagency Coordinating Committee (Lab ICC):
  - Membership from HIV, TB, Malaria, IDSR--etc
- Developed and implemented one integrated laboratory policy and strategic plan
- Develop integrated laboratory request and report form – to be rolled out soon
- Established a Central Data Unit with linkages to the Microbiology, TB, HIV labs
- Launched and integrated laboratory curriculum for in-service training
TB, HIV, Malaria - Integrated Training Center, Zaria, Nigeria
An Integrated Approach for Strengthening Laboratory Infrastructure in Ethiopia

Reference Laboratory for HIV, TB, Malaria and Avian Influenza at Ethiopian Health and Nutrition Research Institute (EHNRI) in Addis Ababa
- Strengthening the tiered lab system
- Integrating TB, Malaria and HIV
  - with involvement of multiple partners
Tiered Laboratory Networks In Ethiopia

- NRL = National Reference Lab
- DHL = District Hospital Labs/Health Centers
- RRL = Regional Reference Lab

CDC

Map of Ethiopia with various laboratory network connections.
Establishment of the African Centre for Integrated Laboratory Training (ACILT)

- 1-3 week standardized trainings in hands-on laboratory techniques
- Located on campus of NICD in Johannesburg – start up September 2008
- Courses based on country needs assessments
  - TB culture and DST
  - DNA PCR for Early Infant Diagnosis of HIV
  - Laboratory Management
  - Commodities Management
  - Biosafety and Laboratory Infrastructure
The Power of Partnerships –
Public Private Partnerships are Critical for Laboratory Strengthening Efforts

New Public-Private Partnership to Strengthen Laboratory Systems

In a pioneering public-private partnership, the U.S. President’s Emergency Plan for AIDS Relief (Emergency Plan and Company) will support services in African countries (TB).

Through this five-year, public partnership, the Emergency Plan and Company will support services in African countries (TB).

Abbott Fund partners with Tanzania MOHSW, CDC, APHL, D4O to modernize labs

$18 Million PEPFAR partnership with Becton Dickinson
Conclusions

Cornerstones for strengthening laboratory capacity

- Coordinate partner efforts and build synergies
- Develop sustainable lab systems via lab strategic plans
- Avoid parallel laboratory systems
- Promote integrated Infectious Diseases Laboratories
- Encourage Public Private Partnerships
Thank you