Large-scale introduction of new diagnostics: India Experience

C. N. Paramasivan
Head of TB Programme - FIND India & SE Asia
cn.paramasivan@finddiagnostics.org

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Background

• RNTCP PMDT Vision is to promptly diagnose and effectively treat all DR TB patients through decentralized DST and PMDT services

• Next 5 years (2012-2017), RNTCP expects to treat
  - 160,000 MDR-TB; and
  - 4,100 XDR-TB cases
RNTCP PMDT Vision: Plan of PMDT service expansion

- **2011**
  - ✅ Introduce RNTCP PMDT services in all 35 states (achieved)

- **2012**
  - ✅ Complete geographical coverage for PMDT services
  - ✅ DST for *all* smear-positive re-treatment TB cases at diagnosis

- **2015**
  - ✅ + DST for *all* smear negative TB (re-treatment) cases & any HIV TB case registered under RNTCP
  - ✓ Start at least **40,000** MDR cases on treatment annually by **2017** (through 120 DR TB Centers)
National Laboratory Scale up Plan (NLSP)

- Integrating contributions from
  - National resources &
  - with donor resources - UNITAID and Global Fund R9

- Activities
  - Enhanced sputum processing capacity
  - Nationwide availability of rapid DST
  - Nationwide availability of sufficient culture capacity (solid + liquid)
  - Engage with laboratories from other sectors
  - Strengthen HR capacity at select labs

- > 60 labs to contribute to PMDT scale-up
  - 43 culture & DST sites identified in NLSP for introduction of LPA and 33 sites for introduction of LC

Source: Guidelines for PMDT in India - May 2012
Support to 43 Labs under NLSP

- Funding support
  - March 2010 - EXPANDx TB
  - September 2011 - Global Fund

- EXPANDx TB
  - Supply of equipment and consumables
    - LPA - 40 sites
    - LC - 31 sites
  - Technical assistance through FIND India

- WHO through EXPANDx TB
  - Established International Centre of Excellence in Laboratory Training (ICELT) at NTI, Bangalore (January, 2011)
    - All national training courses (LPA, LC & Lab Biosafety)
Support to 43 Labs under NLSP...2

- GFATM
  - Equipment and consumables additionally to 3 LPA and 2 LC sites
  - Provision of additional HR in a phased manner
  - Specimen processing equipment and consumables to improve lab throughput
  - Onsite technical support and long term mentoring (travel, HR, etc.)
  - Rapid specimen referral, transportation and reporting for all 43 sites
  - Up gradation of 20 Intermediate Reference Laboratories (IRLs) for LC readiness
Support to 43 Labs under NLSP... 3 for Infrastructure support

<table>
<thead>
<tr>
<th></th>
<th>LPA</th>
<th>BSL3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Source</strong></td>
<td><strong>Sites</strong></td>
<td><strong>Source</strong></td>
</tr>
<tr>
<td>State / NRHM / Institute</td>
<td>24</td>
<td>State / NRHM / Institute</td>
</tr>
<tr>
<td>USAID</td>
<td>12</td>
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</tr>
<tr>
<td>GFATM</td>
<td>7</td>
<td>GFATM</td>
</tr>
</tbody>
</table>
Introducing Rapid Diagnostics - Processes

**Lab Assessment**
- Layout, approval by CTD and NRL
- Required Civil work
- Timelines of Key Activities with responsible level

**Infra-structure**
- Bidding Process through UNOPS
- Up gradation of 3 Clean rooms for LPA
- Up gradation of Negative Pressure Room (TB Containment Lab)

**Procurement & Supply**
- ‘Lead time’ in accordance with time line and progress
- Custom Clearance, Road Permit

**Trainings**
- National Level at ICELT
- On Site Training

**Proficiency Testing**
- Handholding (CTD, NRL, Regional Microbiologist)
- Internal and External Concordance for LPA
- Retesting and PT for LC

**Service Delivery**
- Certification, if the lab achieves the desired concordance
- Testing samples of DR TB suspects
- Panel Testing / Annual Proficiency Testing
## Progress of LPA Labs

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infrastructures in place</td>
<td>31</td>
</tr>
<tr>
<td>Equipment and consumables supplied</td>
<td>31</td>
</tr>
<tr>
<td>Functional for patient care under PMDT</td>
<td>26</td>
</tr>
<tr>
<td>In the process of certification</td>
<td>5</td>
</tr>
<tr>
<td>To start proficiency testing after onsite training</td>
<td>2</td>
</tr>
<tr>
<td>Infrastructure to be developed and LPA items to be provided in 2012</td>
<td>7</td>
</tr>
</tbody>
</table>
# Progress of LC Labs

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of Sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completion of Infrastructure</td>
<td>14</td>
</tr>
<tr>
<td>LC activity ongoing</td>
<td>11</td>
</tr>
<tr>
<td>Certified</td>
<td>6</td>
</tr>
<tr>
<td>In process of certification</td>
<td>5</td>
</tr>
<tr>
<td>Awaiting supply of LC equipment and consumables</td>
<td>3</td>
</tr>
<tr>
<td>Infrastructure development and supply of automated liquid culture equipment and consumables planned in 2012</td>
<td>15</td>
</tr>
</tbody>
</table>
Certified: N=42
- 29 / 43 RNTCP labs
- 13 Additional

SLDST - 3 NRLs

- Solid culture: 34
- LPA: 30
- LC: 10

CB-NAAT: 30

Source: Presentation on PMDT Update, Annual Lab Network Meeting, Kolkata, Oct. 12
Progress - Number of LPA labs reporting

- Q2 2013: 43
- Q1 2013: 35
- Q4 2012: 29
- Q3 2012: 23
- Q2 2012: 19
- Q1 2012: 15
- Q4 2011: 10
- Q3 2011: 4
- Q2 2011: 3
- Q1 2011: 3

Number of LPA labs reporting
Progress: Number of LPA tests conducted/estimated & MDR TB cases detected/estimated by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>LPA tests conducted/estimated</th>
<th>MDRTB cases detected/estimated (LPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>6,677</td>
<td>2,188</td>
</tr>
<tr>
<td>2012</td>
<td>103,904</td>
<td>17,738</td>
</tr>
<tr>
<td>2013</td>
<td>242,945</td>
<td>28,817</td>
</tr>
</tbody>
</table>
Progress: MDR TB Suspect Examination - Actual till 3Q12 / Estimated from 4Q12: 2011-2013

Tests for MDR TB Suspects Examined: Actual upto 3Q12/ Estimated from 4Q12 (LJ+LPA+LC+CBNAAT)
LPA Tests conducted till 3Q12 / estimated from 4Q12 onwards
CBNAAT tests reported till 3Q12/ estimated from 4Q12
Progress: MDR TB cases Detected - Actual till 3Q12 / Estimated from 4Q12: 2011-2013

<table>
<thead>
<tr>
<th>Quarter</th>
<th>2011-Actual</th>
<th>2012-Actual</th>
<th>2012-Estimated</th>
<th>2013-Estimated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2 2011-Actual</td>
<td>704</td>
<td>2609</td>
<td>6470</td>
<td>7237</td>
</tr>
<tr>
<td>Q3 2011-Actual</td>
<td>349</td>
<td>1130</td>
<td>2278</td>
<td>2278</td>
</tr>
<tr>
<td>Q4 2011-Actual</td>
<td>0</td>
<td>538</td>
<td>3663</td>
<td>538</td>
</tr>
<tr>
<td>Q2 2012-Actual</td>
<td>843</td>
<td>1498</td>
<td>4119</td>
<td>774</td>
</tr>
<tr>
<td>Q3 2012-Actual</td>
<td>329</td>
<td>272</td>
<td>4717</td>
<td>964</td>
</tr>
<tr>
<td>Q4 2012-Actual</td>
<td>0</td>
<td>972</td>
<td>7908</td>
<td>964</td>
</tr>
</tbody>
</table>

- Total MDR TB case detection reported till 3Q12 / estimated MDR TB case detection from 4Q12 onwards
- LPA MDRTB case detection reported till 3Q12/ estimated from 4Q12
DST methods in place at various districts in India (Sept, 2012)

DST Technology at Districts
- LJ - 56
- LPA - 382
- CBNAAT - 69

Source: Presentation on PMDT Update, Annual Lab Network Meeting, Kolkata, Oct. 12
Collaboration for increasing Access to Rapid Diagnostics for DR TB

**National Resources**

**State Resources**

**Donor Support**

- World Health Organization
- EXPAND-TB
- UNITAID
- The Global Fund
- USAID
- PATH
Collaboration Working

By end of 2013, these collaborative efforts will result in

- Examination of approximately 250,000 MDR TB suspects using LPA and LC
- Diagnosis of an estimated 46,000 MDR TB cases
Lessons Learnt

- Excellent support and coordination by the CTD
- Relevant technical inputs from National Lab Committee
- Much needed contribution from Partners & Donors (UNITAID, TGF, USAID and others)
- TGF Rd 9 activities supplementing EXPANDx TB support – additional HR, equipment and consumables to improve lab throughput, infrastructure support
- Establishment of National Training Facility – ICELT
- Building team of technical consultants for onsite trainings and handholding
- Team of professionals supporting Procurement and Supply Logistics – at HQ and at country office
- Training of field staff in specimen collection and transportation
Acknowledgement

- Central TB Division, MOH, Government of India
- National Reference Laboratories
- National Laboratory Committee
- Respective States, STDCs and other institutions including participating NGOs and Private Providers
- Partners
- UNITAID
- WHO
- FIND Technical Team

Thank you