Overview of Drug Resistant TB in India and National Scale up of MDR TB Diagnosis and Treatment

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New Delhi

Facing the Reality of Multidrug Resistant Tuberculosis: Challenges and Potential Solutions in India
April 18th – 19th 2011, New Delhi, India
TB Burden in India

- India is highest TB burden country
- Annual 2 million incident cases
- Estimated prevalence of 3 million cases
- Annual deaths due to TB 280,000
- ~5% of TB patients also HIV-positive

Source: WHO Geneva; WHO Global TB Report 2010
## MDR TB in India

- India has 2nd highest MDR-TB burden in the world after China
- Est. MDR TB emerging annually – **99,000 (73,000 in S+ve)**
- Population-based drug resistance surveillance in 3 states shows low MDR prevalence in new cases

<table>
<thead>
<tr>
<th>State (survey year)</th>
<th>Population</th>
<th>MDR among new cases</th>
<th>MDR among previously-Rx cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gujarat (2007–08)</td>
<td>56 million</td>
<td>2.4%</td>
<td>17.4%</td>
</tr>
<tr>
<td>Maharashtra (2008)</td>
<td>108 million</td>
<td>2.7%</td>
<td>14.0%</td>
</tr>
<tr>
<td>Andhra Pradesh (‘09)</td>
<td>86 million</td>
<td>1.8%</td>
<td>11.8%</td>
</tr>
</tbody>
</table>
Second-line drug resistance among MDR TB patients

- Population-based data very limited
- Gujarat state drug resistance surveillance
  - N=219 MDR cases detected
  - FQ resistance=24%, KM=3%
  - XDR=3% among MDR
  - all 7 XDR TB cases previously-treated, none among ‘new’ MDR cases
‘Over the counter’ drugs in any pharmacy
“DOTS Plus” in India
(Programmatic Management of MDR TB)
Guidelines and Strategies
DOTS Plus (PMDT) under RNTCP

- DOTS-Plus activities approved under RNTCP Phase II PIP (2006-11)
- DRS in Gujarat and Maharashtra (2005-06)
- National DOTS-Plus Committee formed (2005)
- DOTS Plus Guidelines developed (2006)
- National Lab Scale-up Plan for establishment of a network of accredited labs for diagnosis
- Uninterrupted supply of quality assured second line anti-TB drugs
- Information systems and data management

DOTS-Plus is an integral component of RNTCP to manage MDR-TB to be implemented through India’s public health and programme infrastructure
RNTCP response to MDR TB

Prevention
• Sustained high-quality DOTS implementation
• Promote rational use of anti-TB drugs
• Implement infection control measures

Stopping transmission
• Improve laboratory capacity: Diagnosing MDR-TB
• Effective treatment of MDR-TB patients
• Initiation and rapid scale up of MDR-TB services
• Evaluate the extent of second-line anti-TB drug resistance and management strategies
RNTCP: Vision and Objectives

• Vision
  – To provide universal access to quality diagnosis and treatment for all TB patients in the community

• By 2015
  – Early detection of at least 90% of all TB patients in the community, including HIV-associated TB
  – Initial screening of all smear-positive TB patients for drug resistant TB
  – Offer of HIV Counseling and testing for all TB patients
  – Successful treatment of at least 90% of all new TB patients and at least 85% of all previously-treated
  – Promote rational use of anti TB drugs
Strategy to Scale-up Lab services

• Scale up number of culture and DST laboratories nationwide to at least 43 by 2013

• Increase throughput per laboratory by
  – Investment in sputum processing capacity
  – Introduction of high-throughput molecular DST
  – Establish automated liquid culture systems
  – Strengthen specimen transport systems & electronic results reporting

• Strengthen reference labs

• Establish and scale-up training capacity

• Engage private sector and medical college contractual laboratory services
Strategy to scale up treatment services

• Strengthened human resource capacity
  – DOTS plus coordinator in every district
  – Additional staff at labs and DOTS plus sites

• DOTS Plus site growth
  – 120 DOTS Plus sites across the country (10 million pop)
  – Upgraded to national airborne infection control standards

• Advocate with Indian Drug Manufacturers with GDF support
  – Adhere to WHO Prequalification and GDF QA systems
  – Develop SLD production plans with National drug demand in view

• Integrated national on-line electronic recording and reporting system
  (E-TB Manager Brazil Model being adapted by MSH)

• Advocate rational use of anti-TB drugs (FQ in respiratory cases)
MDR TB diagnosis – current approach

• MDR suspect criteria
  – All TB patients failing first-line regimen
  – All previously-treated patients smear-positive at the end of extended intensive phase or later (CAT II)
  – Smear-positive contacts of known MDR cases

• DST at accredited laboratory
  – LPA – if available – is preferred DST method
  – Treatment started on basis of RIF resistance only (RIF mono-resistance rare)
DOTS Plus – Model of care

**CULTURE - DST LAB**

**DOTS PLUS SITE**
(IN-PATIENT FACILITY)

**DISTRICT**

**HEALTH FACILITY**
(PHI)

**MDR CASE**

Follow up protocol
• Physical exam
• Culture
• Kidney function

**SPUTUM SAMPLE**

Initial hospitalization followed by ambulatory care

**RESULT**

**MDR SUSPECT**

• Cat I failure
• Cat II sm+ at 4 months of Rx
• Contacts of MDR cases
RNTCP DOTS-plus decentralized and integrated care model

**DOTS Plus Site**
1 per 10 million pop.
Medical college, inpatient MDR ward
- Initial ~1 week hospitalization.
- Remaining care ambulatory unless inpatient care or specialist consultation needed.

**District level**
~1.5–4 million pop.
Coordinates MDR case-finding, follow-up exams, reporting.

**Health facility**
Manage minor side effect
Supervise DOTS provider
Most patient care done at local level by routine health staffs and programme staff.

**DOTS provider**
Local health facility, paramedical ‘village’ doctor, private provider, community volunteer
MDR TB Treatment regimen

• Standardized treatment algorithm: “Category 4”
  – Intensive phase (6-9 months): Kanamycin, Levofloxacin, Cycloserine, Ethionamide, PZA, Ethambutol
    • If 4\textsuperscript{th} month culture-positive, treatment continued till culture-negative
  – Continuation phase (18 months): Levofloxacin, Cycloserine, Ethionamide, Ethambutol
  – PAS is used as a substitute drug in case of intolerance
  – Daily DOT (Kanamycin is given 6/7 days throughout IP)
  – Three weight bands to simplify drug logistics
    • 16-25 Kg; 26-45 Kg and >45 Kg

RNTCP CATEGORY IV regimen: 6 (9) Km Ofx (Lvx) Eto Cs Z E / 18 Ofx (Lvx)Eto Cs E
Drug logistics

• Quality-assured drugs from international procurement
  – GLC procurement
  – GoI procurement - ICB

• Supply line
  – Loose drugs supplied to State drug stores
  – Repackaged at State Drug Stores into monthly IP or CP packs, 3 per box
  – Supplied to the districts and downwards
  – Loose drugs provided at DOTS Plus sites

• Logistics and reporting on consumption integrated with first line drugs
Status of DOTS Plus in India
DOTS Plus Status (Dec ’10)- 1

- Initiated in 2007 in Gujarat and Maharashtra
  - Expanded in a phased manner
- 12 States are implementing basic DOTS Plus services in some districts
- Cumulative, till Dec 2010
  - 19,178 MDR suspects examined
  - 3605 patients initiated on treatment
- 6 States to initiate services shortly
- Remaining States to initiate basic services by end 2011
• 288 million (24%) population of India have access to DOTS Plus Services
• 141/658 (21%) of districts with MDR diagnostic and treatment services available
• Hyderabad initiated the pilot of suspect criteria B (all S+ RT cases) in Jan ‘11
## Diagnosis & Treatment Initiation Status of MDR TB – Year 2007 to 2010

### Cumulative Status

<table>
<thead>
<tr>
<th></th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MDR TB Suspects</strong></td>
<td>309</td>
<td>62</td>
<td>1511</td>
<td>7333</td>
</tr>
<tr>
<td><strong>MDR TB Cases Detected</strong></td>
<td>109</td>
<td>308</td>
<td>1981</td>
<td>1175</td>
</tr>
<tr>
<td><strong>MDR TB Cases Initiated on Rx</strong></td>
<td>62</td>
<td>190</td>
<td>2967</td>
<td>2178</td>
</tr>
</tbody>
</table>

- **MDR TB Suspects**: Total of 19,178 suspects were identified from 2007 to 2010.
- **MDR TB Cases Detected**: A total of 5,365 cases were detected, which is approximately 28% of the total MDRTB suspects.
- **MDR TB Cases Initiated on Rx**: A total of 3,605 cases were initiated on treatment, which is approximately 67% of the total MDRTB cases detected.
Involvement of other sectors

• Successful partnership established with Private sector, NGOs, MCs and civil society partners under DOTS Plus in implementing states

• Laboratory Services:
  – 9 other sector C-DST labs accredited (BPRC-Hyderabad, PD Hinduja-Mumbai, CMC-Vellore, SMS-Jaipur, RMRCT (ICMR)-Jabalpur, JJ Hospital-Mumbai, Choitram – Indore, BMHRC – Bhopal and DFIT Nellore)
  – 8 other sector C-DST labs near accreditation (PGI Chandigarh, AIIMS-New Delhi, QUEST- Gurgaon, SRL-Mumbai, Gurgaon & Kolkata, RMRC Port Blair & Dibrugarh)
  – FIND support for LPA/Liquid Culture for 43 labs under EXPAND TB Project

• Treatment Services:
  – 14/20 (70%) functional DOTS Plus Sites are located in Medical Colleges
  – Enhance social support & vocational rehabilitation provided through NGOs (supported by Elli Lily &Co. and GLRA)
  – Under GF R9, Civil Society Partners – The Union and World Vision to support RNTCP prevent emergence of DRTB through improved access to quality DOTS services

• Scale up Planning:
  – FIND extended support by aligning their work-plans to national scale-up plan
  – Independent external validation of National Plan by Clinton Foundation (with WHO)
PMDT expansion plans

RNTCP DOTS Plus Vision
....way forward
RNTCP DOTS Plus Vision:

• By 2011, RNTCP Category IV services will be introduced in all states with complete geographical coverage by 2012

• By 2013, access to laboratory based quality assured MDR-TB diagnosis and treatment for
  – all smear positive re-treatment TB cases and
  – new cases who have failed an initial first-line drug treatment

• By 2015, access to MDR-TB diagnosis and treatment for all smear positive TB (new and re-treatment) cases registered under RNTCP

• RNTCP plans to initiate at least 30,000 MDR cases on treatment annually by 2013
Laboratory Scale-up Plan

- 43 laboratories to be established & strengthened
  - Enhanced sputum processing capacity (staff, centrifuges, BSC)
  - Solid culture and DST capacity in all lab units
  - Line Probe Assay (LPA) in all laboratories
  - Liquid culture in 33 laboratories

<table>
<thead>
<tr>
<th>Element</th>
<th>2010-11</th>
<th>2011-12</th>
<th>2012-13</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhance sputum processing capacity</td>
<td>12</td>
<td>+13</td>
<td>+18</td>
<td>43</td>
</tr>
<tr>
<td>Establish LPA</td>
<td>12</td>
<td>+13</td>
<td>+18</td>
<td>43</td>
</tr>
<tr>
<td>Establish liquid culture systems</td>
<td>13</td>
<td>+9</td>
<td>+11</td>
<td>33</td>
</tr>
<tr>
<td>Expected annual DST capacity</td>
<td>35,000</td>
<td>80,000</td>
<td>144,000</td>
<td>220,000</td>
</tr>
</tbody>
</table>

Cepheid GeneXpert Field Demonstration Study proposed in 2011 - might accelerate the drug demand once Cepheid is programme policy

Source: RNTCP National Laboratory Scale-up Plan 2010, www.tbcindia.org
Plan for patients to be tested and treated for MDR-TB

*Based on RNTCP 2013 goal of MDR diagnosis for all S+ retreatment patients,
Resources for SLD procurement

- Lab scale up to be undertaken with support from
  - UNITAID Expand TB
  - Global Fund –RCC and Rd 9
  - World Bank
  - USAID through WHO

- Second line drugs

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<thead>
<tr>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Global Fund –RCC</td>
<td>800</td>
<td>1200</td>
<td>2450</td>
<td>3500</td>
<td>4250</td>
</tr>
<tr>
<td>World Bank</td>
<td>2350</td>
<td>3450</td>
<td>4550</td>
<td>9000</td>
<td>13250</td>
</tr>
<tr>
<td>UNITAID</td>
<td>4850</td>
<td>5000</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Global Fund Rd 9</td>
<td>-</td>
<td>5350</td>
<td>18000</td>
<td>17500</td>
<td>14500</td>
</tr>
<tr>
<td>Total</td>
<td>8000</td>
<td>15000</td>
<td>25000</td>
<td>30000</td>
<td>32000</td>
</tr>
<tr>
<td>Procurement through GLC</td>
<td>5650 (70%)</td>
<td>11550 (77%)</td>
<td>20450 (82%)</td>
<td>21000 (70%)</td>
<td>18750 (60%)</td>
</tr>
</tbody>
</table>
National DOTS Plus Scale-up Plan, 2011-12
(Operational Plan Developed from State Micro-plans)

Source: Consolidation of State wise DOTS Plus micro-plans developed during the series of meetings with 35 states organized by CTD at New Delhi in November 2010
**Expansion by MDR TB Suspect Criteria.........
......move towards Universal Access**

<table>
<thead>
<tr>
<th>Criteria A</th>
<th>Failures of New Pulm. TB Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Currently used)</td>
<td>Failures and Non-Converters of Smear Positive Re-Treatment Pulm. TB Cases</td>
</tr>
<tr>
<td></td>
<td>Contacts of confirmed MDR TB cases</td>
</tr>
</tbody>
</table>

| Criteria B       | All Smear Positive Re-Treatment Pulm. TB cases registered for treatment |
|------------------| (Relapse, TAD, Failure and Others) |
| (next level)     |                                |

| Criteria C       | All Smear Positive Pulm. TB Cases (New and RT) registered for treatment |
|------------------|                                                                           |
| (universal access) |                                                                      |

Estimations of MDR Suspects and Cases were done using 2009 National Data by districts.
Cumulative Plan for 2011 - 2012

<table>
<thead>
<tr>
<th>Cumulative Plan for</th>
<th>2011 - 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDR TB Suspects enrollment plan</td>
<td>1,33,830 suspects</td>
</tr>
<tr>
<td>MDR TB Cases enrollment plan</td>
<td>25,137 cases</td>
</tr>
</tbody>
</table>
DOTS Plus Coverage by Geography & Suspects Criteria -
As on December 2010

A (140 Districts)
B (1 District)
Planned DOTS Plus Coverage by Geography & Suspects Criteria - As on December 2012
## Summary of Scale up by Geography and Suspects Criteria

<table>
<thead>
<tr>
<th>Active</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>States*</td>
<td>12</td>
<td>35 (100%)</td>
<td>35</td>
</tr>
<tr>
<td>Total Districts</td>
<td>141 (21%)</td>
<td>390 (37%)</td>
<td>605 (92%)</td>
</tr>
<tr>
<td>Criteria A</td>
<td>140</td>
<td>246</td>
<td>319</td>
</tr>
<tr>
<td>Criteria B</td>
<td>1</td>
<td>141</td>
<td>251</td>
</tr>
<tr>
<td>Criteria C</td>
<td>0</td>
<td>3</td>
<td>35</td>
</tr>
</tbody>
</table>

* States with at least 1 district implementing

- Geographical coverage by Mar ’13 for 44 districts from states like MP, PB and NE states
- Some states/districts start directly with suspect Criteria B
Consolidated plan of 66 labs includes 43 planned labs and other private, NGO, ICMR and Medical College labs.
## Lab Capacity v/s Demand – Summary Variation by States

<table>
<thead>
<tr>
<th>States</th>
<th>Self sufficient for Diagnosis</th>
<th>Need Backup for Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self sufficient for</td>
<td>AP*, HR, JH, KE, MP, MH, PD,</td>
<td>BI, CG, DL, GA, GU, HP,</td>
</tr>
<tr>
<td>Follow Up</td>
<td>RJ*, UR, CD</td>
<td>JK, KA, PB, UP, 8NE, 4UTs</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Need Backup for</td>
<td>OR, TN*, WB</td>
<td></td>
</tr>
<tr>
<td>Follow Up</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Will face intermittent deficits in lab capacity

Lab Capacity Back up to be arranged from NRLs, IRLs of adjoining states, Purchase services from Private labs (under RNTCP NGO PP Schemes)
Cumulative Plan for 2011 - 2012

| Drug Envelop (15 months working stock) | 22,222 courses |
| MDR TB Cases enrollment plan          | 24,326 cases  |

Drug deficit in plan: (- 2104 courses)
Challenges - 1

- Delay in establishment and accreditation of laboratories
- Diagnostic delay with conventional method (3-4 months turn around time)
- Special requirements for introduction of newer rapid diagnostics – laboratory infrastructure and training
- Improving efficiency of MDR suspect identification and referral
Challenges - 2

• Efficiently starting treatment on diagnosed MDR TB patients
  – Deaths, refusals with long delay;
  – LPA may reduce this

• Uninterrupted supply of second-line drugs

• Cost escalation (~2,100 $) reduces number of patients

• Extensive training, supervision and monitoring needed at all levels, nationwide

• Dramatic demand on local programme staff for supervision, ensuring treatment adherence and timely follow up
Summary

- Expansion of PMDT / DOTS Plus well-underway in India
- Plans established, resources in place
- Key threats
  - SLD cost, availability, quality and procurement
  - Success of laboratory scale-up
  - Second-line drug resistance
- Electronic Information System being deployed
- After a long time, some successes are visible on the horizon...
Thanks for your attention
Acknowledgements

• National DOTS Plus Committee
• Central TB Division Chief Medical Officers
  — K Sachdeva
  — P Saxena
• State and District RNTCP programme Staffs
• DOTS plus site committees
• Culture and DST laboratory Staff
• WHO
  — P Dewan
  — M Parmar
  — RNTCP medical consultants
• The Union
• FIND-India
## XDR-TB in India

<table>
<thead>
<tr>
<th>Study</th>
<th>Setting</th>
<th>No. of MDR cases</th>
<th>No. Of HIV +ve</th>
<th>Prevalence of XDR-TB (%)</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thomas et al, 2007</td>
<td>Field trial, Chennai</td>
<td>66</td>
<td>Not reported</td>
<td>1 (1.5)</td>
<td>IJT, 2007</td>
</tr>
<tr>
<td>Sharma et al, 2009</td>
<td>AIIMS, New Delhi, tertiary care hospital</td>
<td>211</td>
<td>All HIV-negative</td>
<td>5 (2.4)</td>
<td>IJMR, 2009</td>
</tr>
<tr>
<td>Ramchandran et al, 2009</td>
<td>Gujarat, Field study</td>
<td>216</td>
<td>Not reported</td>
<td>7 (3.1)</td>
<td>IJTLD, 2009</td>
</tr>
</tbody>
</table>
Dosage and Weight Bands

<table>
<thead>
<tr>
<th>S.No</th>
<th>Drugs</th>
<th>16-25 Kgs</th>
<th>26-45 Kgs</th>
<th>&gt;45 Kgs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kanamycin</td>
<td>500 mg</td>
<td>500 mg</td>
<td>750 mg</td>
</tr>
<tr>
<td>2</td>
<td>Levofloxacin</td>
<td>250 mg</td>
<td>500 mg</td>
<td>750 mg</td>
</tr>
<tr>
<td>3</td>
<td>Ethionamide</td>
<td>375 mg</td>
<td>500 mg</td>
<td>750 mg</td>
</tr>
<tr>
<td>4</td>
<td>Ethambutol</td>
<td>400 mg</td>
<td>800 mg</td>
<td>1000 mg</td>
</tr>
<tr>
<td>5</td>
<td>Pyrazinamide</td>
<td>500 mg</td>
<td>1250 mg</td>
<td>1500 mg</td>
</tr>
<tr>
<td>6</td>
<td>Cycloserine</td>
<td>250 mg</td>
<td>500 mg</td>
<td>750 mg</td>
</tr>
<tr>
<td>7</td>
<td>PAS (80% w/v)*</td>
<td>5 gm</td>
<td>10 gm</td>
<td>12 gm</td>
</tr>
<tr>
<td>8</td>
<td>Pyridoxine</td>
<td>50 mg</td>
<td>100 mg</td>
<td>100 mg</td>
</tr>
</tbody>
</table>

*In case of PAS with 60% w/v the dose will be increased to 7 gm (16-25 Kg); 14 gm (26-45 Kg) and 16 gm (> 45 Kg)

All drugs to be given as single daily dose.
If intolerance to Eto/Cs/PAS can be divided into 2 doses
Drug logistics

- Preparation of 3 monthly drug boxes
- Ensuring uninterrupted supply
- Strict monitoring because of short shelf life expiry

State Drug Store

3 months drug boxes

DTC and TU

DOTS Plus site

Loose drugs

Domiciliary Treatment by DOT Provider
## Total MDR patients Alive, On Treatment and Culture Negative at 12 months after treatment initiation

<table>
<thead>
<tr>
<th>Cumulative Status</th>
<th>Sum of 12m reg</th>
<th>Sum of 12m alive, on Rx &amp; CN</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDR TB Cases Reg up to 3Q09</td>
<td>984</td>
<td></td>
</tr>
<tr>
<td>MDR TB Cases who are alive, on Rx and Culture Negative at 12 months</td>
<td>549 (56%)</td>
<td></td>
</tr>
</tbody>
</table>

### Graph

![Graph showing the cumulative status of MDR TB cases registered up to 3Q09 and those who are alive, on Rx, and culture negative at 12 months after treatment initiation.](image-url)
Analysis of Poor initial microbiological outcomes in initial PMDT pilot cohort – Summary

• Very high prevalence of FQ resistance in initial MDR treatment cohorts
  – Number small, patients highly treatment experienced, all had failed re-treatment regimen
• Poor 12-month interim outcomes
  – Low initial culture conversion, high re-version
• Ofx resistance, low BMI, and missing 1-week during IP independently associated with initial non-conversion

Source: Solanki RN et al., Association of poor culture-conversion with fluoroquinolone resistance in Gujarat, Western India – Nov ’10
Initial cohort treatment outcomes

- High level of second line drug resistance
- Heavily treatment experienced cohort

Cumulative Status

<table>
<thead>
<tr>
<th>Cumulative Status</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Registered up to 2Q08</td>
<td>137</td>
</tr>
<tr>
<td>Success Rate</td>
<td>59 (43%)</td>
</tr>
<tr>
<td>Death Rate</td>
<td>28 (20%)</td>
</tr>
<tr>
<td>Failure Rate</td>
<td>21 (15%)</td>
</tr>
<tr>
<td>Default Rate</td>
<td>29 (21%)</td>
</tr>
</tbody>
</table>
support for lab scale-up

<table>
<thead>
<tr>
<th>Activity</th>
<th>In place</th>
<th>Expand TB</th>
<th>GF Rd 9</th>
<th>GF RCC</th>
<th>GoI/WB</th>
<th>WHO/USAID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid Culture Labs (43)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment</td>
<td>17 Labs*</td>
<td></td>
<td></td>
<td>21* Labs</td>
<td>5 Labs*</td>
<td></td>
</tr>
<tr>
<td>Consumables</td>
<td></td>
<td></td>
<td></td>
<td>2010-15</td>
<td>2010-15</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(8 Labs)</td>
<td>(35 Labs)</td>
<td></td>
</tr>
<tr>
<td>LPA Labs (43)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Equipment</td>
<td>5 labs **</td>
<td>40 Labs</td>
<td>3 Labs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consumables</td>
<td>-</td>
<td>2010-14</td>
<td>2014-15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquid Culture Labs (33)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BSL 3</td>
<td>7# labs</td>
<td>20 labs</td>
<td>6 labs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment</td>
<td>4 Labs</td>
<td>29 Labs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Includes 27 IRLs, 4 NRLs, Govt. Medical College Labs and ICMR labs

**Basic LPA equipment provided through FIND demo project; Other high through put LPA equipment to be provided under Expand TBx

# 4 NRLs and 3 FIND demo project sites;

$ 33 +6 = 39; Not to be provided to NRLs as they are reference site and not service delivery sites
## Partners and areas of support

<table>
<thead>
<tr>
<th>Partners</th>
<th>Area of Support</th>
</tr>
</thead>
</table>
| WHO / USAID               | - TA (Consultants – GDF/CTD/States)  
                           - Procurement (Lab equipments & SLD)  
                           - Evidence building through OR  
                           - National PPM Lab Consultation & National Experience Sharing for Labs                                                                                     |
| World Bank                | - Overall programme management (Infrastructure - IRLs, DP Sites, Stores; HR, Lab consumables, honorarium, PPM, SME etc.)  
                           - Procurement (Lab equipments, consumables & SLD)                                                                                                          |
| Global Fund               | - Overall programme management (8 states)  
                           - Procurement (Lab equipments, consumables & SLD)  
                           - Enhanced lab capacity in 43 labs (with LPA & Liquid Culture[33]) through FIND  
                           - Engaging Civil Society Partners (ACSM) through The Union and World Vision                                                                                   |
| UNITAID                   | - Enhance lab capacity in 43 labs (with LPA & Liquid Culture[33])  
                           - Procurement (Lab equipments, consumables & SLD)                                                                                                          |
| FIND                      | - Introduce New Rapid Diagnositics (LPA, Liquid Culture)  
                           - Enhance lab capacity in 43 labs (with LPA & Liquid Culture[33]) through Expand TB project (with funding from GF)                                          |
| PATH / USAID              | - Support RNTCP in AIC Pilot (incl training of Architects/Engineers)  
                           - Support in up-gradation of Labs to BSL III and installation of equipments  
                           - Organize DOTS Plus Experience sharing workshops for implementing states                                                                                  |
Planning meetings with States

Objectives:
• To articulate the operational strategy to achieve the RNTCP vision for PMDT scale up
• To align state plans with the available resources (CAT IV drugs, and lab capacity) as per the National lab scale up and SLD procurement plan.

Outcome:
• To have a national comprehensive DOTS Plus scale up micro-plan, matched to drug supply and lab capacity, with implications for appraisal and training responsibilities understood by all.
Methods

• Conduct "backfill" drug quantity calculation for the state
• Determine how many new patients can be initiated on Rx by states
  – Using assumptions based on current national experience
  – With timelines for all prep activities (Civil works, staffing, training, appraisals)
• Set out clear timelines (by pending processes) for service initiation by each lab in the states and at what capacity of Culture & DST
• District planning worksheets to
  – match MDR suspects / cases with available lab capacity and drug envelop
  – match each district over time with the right lab and the right suspect criteria
• Determine national training and appraisal needs to meet the scale-up plan for the state
## Assumptions validated by current experience

<table>
<thead>
<tr>
<th>Assumptions of MDR Rates based on Suspect Criteria</th>
<th>All States</th>
<th>Kerala</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDR suspects, from whom diagnostic specimen cannot be collected</td>
<td>20%</td>
<td>7%</td>
</tr>
<tr>
<td>RT end-IP positive who are positive at 4 month, beyond RT Failures</td>
<td>15%</td>
<td>25%</td>
</tr>
<tr>
<td>NSP failures with RIF resistance</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>RT non converters with RIF resistance</td>
<td>50%</td>
<td>25%</td>
</tr>
<tr>
<td>RT failures with RIF resistance</td>
<td>50%</td>
<td>25%</td>
</tr>
<tr>
<td>NSN failures with RIF resistance</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>Number of s+ Contacts per MDR case</td>
<td>33%</td>
<td>33%</td>
</tr>
<tr>
<td>S+ve Contacts of MDR cases with RIF resistance</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>RT type Relapse registered with RIF resistance</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>RT type Failure registered with RIF resistance</td>
<td>50%</td>
<td>30%</td>
</tr>
<tr>
<td>RT type TAD registered with RIF resistance</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>RT type Others S+ve registered with RIF resistance</td>
<td>10%</td>
<td>10%</td>
</tr>
<tr>
<td>NSP registered with RIF resistance</td>
<td>2.5%</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

## Assumptions of Rx drop out rates of diagnosed MDR cases based on Lab test

<table>
<thead>
<tr>
<th>Assumptions</th>
<th>All States</th>
<th>Kerala</th>
</tr>
</thead>
<tbody>
<tr>
<td>LJ/MGIT Culture Diagnosed MDR cases, not initiated on CAT IV</td>
<td>30%</td>
<td>30%</td>
</tr>
<tr>
<td>LPA Diagnosed MDR cases, not initiated on CAT IV</td>
<td>10%</td>
<td>10%</td>
</tr>
</tbody>
</table>
Scale up in Districts/States determined by timelines for...

- C-DST Lab – accreditation or service linkage
- Procurement of Packing material and arranging transport for samples and 3m PWB
- DOTS Plus Site identification, Up-gradation for AIC, Committee formation, Staff training
- Up-gradation of State and District Drug Stores for Storage of SLD
- National and State level Trainings and Appraisals
Strategy to meet the National Training Demands:
1. Develop 4\textsuperscript{th} National DOTS Plus Training Centre at Trivandrum, Kerala
2. Arrange training batches @ 2 per month with batch size ~ 40 (240 trainees / quarter)
3. Identify trainers from experienced states – National Institutes, DP Site Committee, STDC, WHO Consultants apart from CTD facilitators.
4. Training budget from Gujarat, Andhra Pradesh, Kerala and Delhi for National Training in Annual Action Plan 2011-12 to be approved at CTD.
5. Develop annual training calendar and monitor progress

Demand for CTD Training

- 5 National training batches conducted since Dec ‘10
- ~ 320 key staff trained since Dec ‘10
- State teams and Phase 1 districts of all 35 states trained at national level
Strategy to meet the unrealistic CTD Appraisal Demands:

1. Simplify CTD Appraisal format and develop normative guidelines (like CIE)
2. Develop Core Group to conduct Appraisals – STOs, STDC Directors, DP Site Committee, WHO Consultants, External Resources from Partners.
3. Fast-track lab accreditations, civil works for DP Sites (AIC), SDS, DDS and HRD.
4. Ensure State appraisals of all districts and monitor compliance to recommendations before CTD appraisals.
5. Develop CTD appraisal matrix and calendar.
6. Arrange Multiple team of Core Group members to conduct simultaneous appraisals.

Appraisals conducted since 2010:
- Maharashtra – 7 districts
- Andhra Pradesh – 3 districts
- Himachal Pradesh - 2 districts
- Jharkhand – 2 districts
- UP – 1 district