India's Contribution in Rolling out Newer and Rapid Diagnostics towards PMDT Scale-up

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FIND and Partners Symposium
43rd Union World Conference on Lung Health
November 2012

Partnering for better diagnosis for all

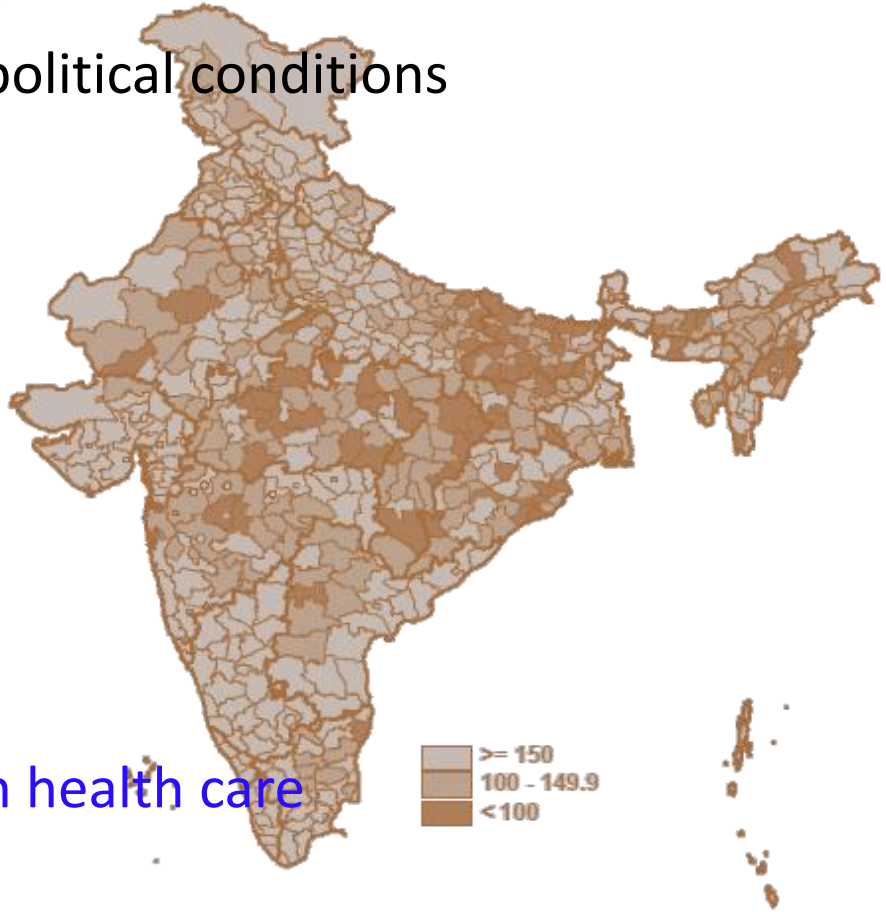
Contents

- India: Profile and TB notification
- RNTCP PMDT: Vision and Expansion Plan
- FIND India: Activities
- Laboratory Scale up : Plan, Process, Resources
- PMDT : Status of Implementation
- What else has been done?
- What further needs to be done?

India: Profile and TB notification

INDIA :

- 7th largest country (3,287,263 sq km)
- 2nd most populous (1,210 million)
- Diverse socio-economic, cultural, political conditions
- 30 states and 5 Union Territories
- 640 administrative districts
  - 662 RNTCP reporting districts
  - 2698 TB units (TUs)
  - 13,039 DMCs
- 5,924 sub-districts & 7,936 towns
- 12,760 Govt. hospitals
- Large unregulated private sector in health care



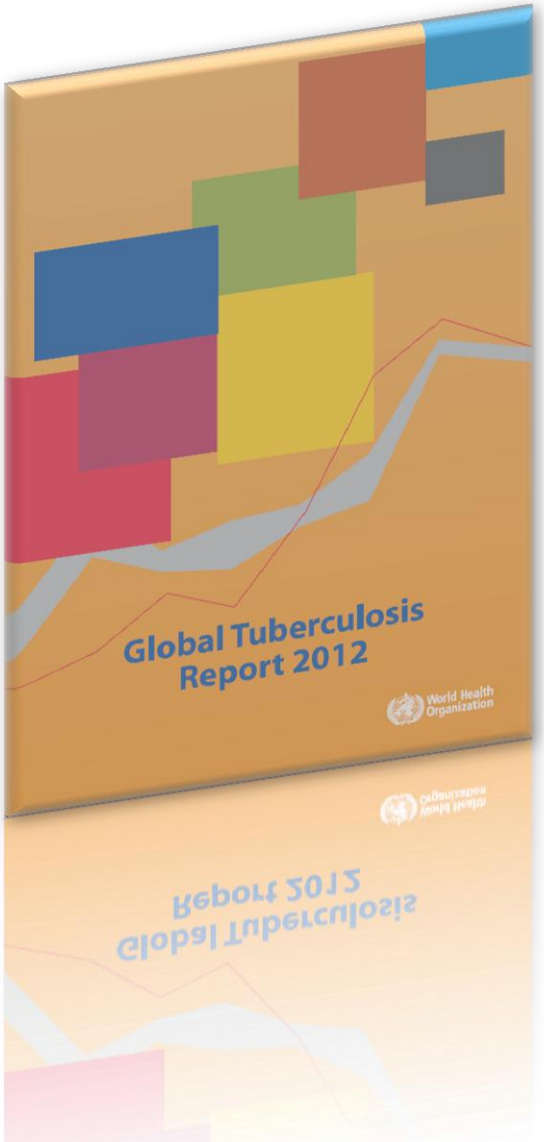
Source: TB India 2012 Annual Report, http://tbcindia.nic.in/pdfs/TB%20India%202012-%20Annual%20Report.pdf

India TB case notifications 2011

Smear-positive	**642,321**
Smear-negative	340,203
Extra-pulmonary	226,965
Total new	1,211,441
Total retreatment	304,431

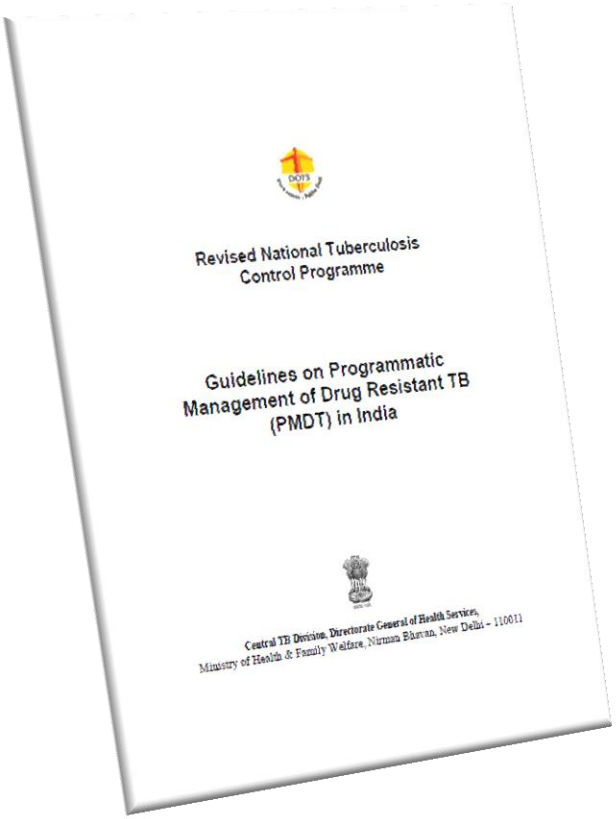
Estimates of MDR-TB burden 2011@	**New**	**Retreatment**
MDR-TB cases	21,000 (15,000-27,000)	45,000 (40,000-50,000)

@ provisional



RNTCP PMDT: Vision and Expansion Plan

RNTCP Vision for PMDT


Revised National Tuberculosis Control Programme

Guidelines on Programmatic Management of Drug Resistant TB (PMDT) in India

Central TB Division, Directorate General of Health Services, Ministry of Health & Family Welfare, Nirman Bhavan, New Delhi – 110011

CHAPTER 3: NATIONAL PLANNING FOR UNIVERSAL ACCESS TO QUALITY DIAGNOSIS AND TREATMENT OF MDR TB

"The RNTCP PMDT Vision is to promptly diagnose and effectively treat all TB patients with drug-resistant TB, **through decentralized DST and PMDT treatment services** integrated into RNTCP. Given the complexity, scale and cost, a **phased approach** has been developed, focusing first on those most likely to have drug-resistant TB. Realizing this vision will **require more laboratory capacity, more second-line drugs, infrastructure and manpower**"

Source: Guidelines on PMDT in India, http://www.tbcindia.nic.in/pdfs/Guidelines%20for%20PMDT%20in%20India%20-%20May%202012.pdf

Five Components of PMDT

1. Sustained political and administrative commitment
2. Diagnosis of MDR-TB through quality-assured culture and drug susceptibility testing
3. Appropriate treatment strategies that utilize second-line drugs under proper management conditions
4. Uninterrupted supply of quality assured Second line anti-TB drugs
5. Recording and reporting system designed for PMDT services that enable performance monitoring and evaluation of treatment outcome

Source: Guidelines on PMDT in India, http://www.tbcindia.nic.in/pdfs/Guidelines%20for%20PMDT%20in%20India%20-%20May%202012.pdf

RNTCP Plan of PMDT service expansion

'Specific objectives are to:

- By end 2012, complete nationwide geographical coverage of access to basic MDR TB diagnostic and treatment services;
- By 2012-13, expanded access to 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, nationwide access to MDR-TB diagnosis and treatment for all smear positive TB (re-treatment or new) cases registered under RNTCP before or early during their treatment
- RNTCP expects to treat about 1,60,000 MDR-TB and 4,100 XDR-TB cases over the next 5 years (2012-2017)'

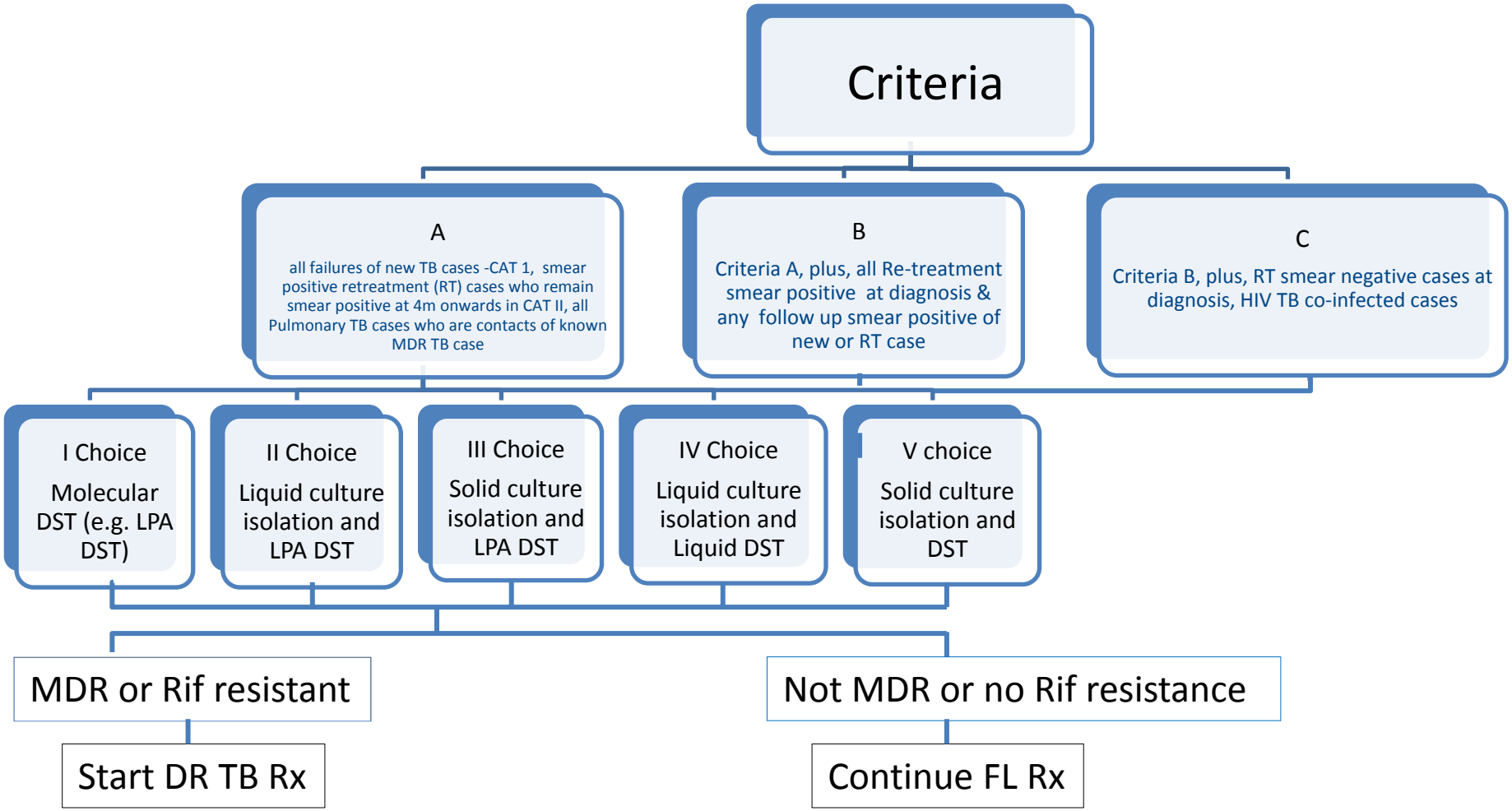
Source: Guidelines on PMDT in India, http://www.tbcindia.nic.in/pdfs/Guidelines%20for%20PMDT%20in%20India%20-%20May%202012.pdf

Drug Resistant TB Suspect Definition

Current PMDT Guidelines (May 2012)

- **Criteria A:**
  - all failures of new TB cases - CAT 1
  - smear positive retreatment (RT) cases who remain smear positive at 4month onwards in CAT II
  - all Pulmonary TB cases who are contacts of known MDR TB case
- **Criteria B:** Criteria A, plus,
  - all Re-treatment smear positive at diagnosis, and
  - any follow up smear positive of new or RT case
- **Criteria C:** Criteria B, plus,
  - RT smear negative cases at diagnosis, and
  - HIV TB co-infected cases

India MDR TB Diagnostic Algorithm



FIND India: Activities

FIND India activities: An Overview

2007	2008	2009	2010

- Establishment of FIND/ India and FIND CTD MoU signed

Demonstration Studies :

- LED FM: 3 Supervisory sites & 9 study sites
- Cepheid Manual NAAT, 2 centers

Collecting evidence for scale up (2008):

- LPA: 7 sites
- MGIT DST & MTB Speciation by lateral flow assay: 3 sites
- NTP approved the results & requested FIND to continue OR studies at the sites till funding from EXPAND TB and TGF R9 is available

Scale up and impact projects:

- Implementation of new technologies in DOTS-Plus sites
- FIND as a;
  - A partner in EXPAND-TB project
  - Sub-recipient of GF R9
- Impact will be measurable after 3 years from 43 sites

FIND India activities: An Overview

2011	2012

Collecting evidence for scale up :

- RNTCP-FIND-WHO CBNAAT study
  - To collect evidence on the feasibility and potential impact of introducing CBNAAT-based **TB** diagnosis **and Rifampicin resistance** detection at TU level
  - 18 Sub district level sites (TB Units) in 13 states

Feasibility and Evaluation Study:

- TB LAMP Study aims at
  - -determining TB LAMP performance in MCs and demonstrating the operational feasibility and cost-effectiveness of using TB LAMP at MCs for enhanced detection of smear-negative TB
- Three study sites in India:
  - Rural Sites in Wardha, Sevagram and Hinganghat

DST Scale-up :

- 12 CB-NAAT sites under EXPANDx TB project to supplement the routine DST capacity for PMDT scale up

LPA Demonstration Study: Preparedness for LPA
(No. of sites:7; Pop. Covered:34.8 Million)

- 1454 patients with both LPA and LJ DST results, in 3 IRLs (Hyderabad, Nagpur, Ahmedabad)

Sensitivity	97%
Specificity	99%
PPV	99%
NPV	98%

- LPA PT protocol developed, field tested and found acceptable
- LPA as the primary MDR TB diagnostic tool in PMDT under RNTCP

Laboratory Scale up : Plan, Process, Resources

Revised Laboratory Scale-up plan

- Technical Working Group formulating the revised scale-up plan considering
  - Technology (Solid, liquid and Molecular),
  - HR requirement at laboratories
  - Workload of diagnosis and follow up specimens
- Committee on Identification of two additional NRLs
- Priority list of laboratory for Second line DST in liquid culture based upon the performance and infrastructure
- Engaged private / medical college contractual lab services
- Revision of Laboratory Scale-up Plan being done by National Laboratory Committee to address future needs

Source: CTD Presentation on PMDT Update, Annual Lab Network Meeting, Kolkata, Oct.12

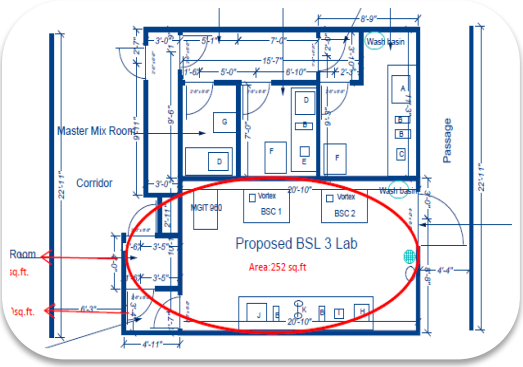
WHO approved diagnostic options

Year	Technology	Turnaround time	Sensitivity gain
Before 2007	ZN microscopy Solid Culture	2-3 days 30-60 days	Baseline
2007	Liquid Culture Rapid speciation	15-30 days	+10% compared to LJ
2008	Line Probe Assay (1st line, Rif & INH)	2-4 days	At this time for S+ only
2009	LED-based FM	1-2 days	+10% compared to ZN
2010	Integrated NAAT (TB, Rif)	120 minutes	+40% compared to ZN

PMDT - Choice of Diagnostic Technology

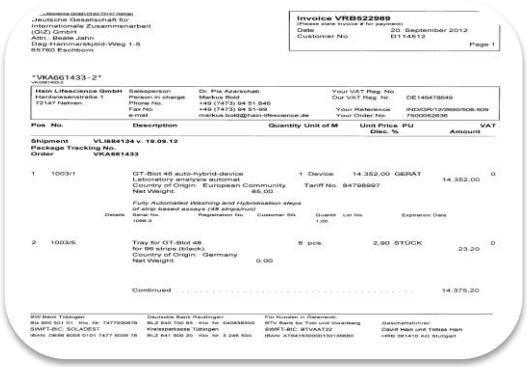
MDR Diagnostic Technology	Choice
Molecular DST (e.g. CBNAAT or LPA DST)	First
Liquid culture isolation and LPA DST	Second
Solid culture isolation and LPA DST	Third
Liquid culture isolation and Liquid DST	Fourth
Solid culture isolation and DST	Fifth

Establishment of Rapid Diagnostics



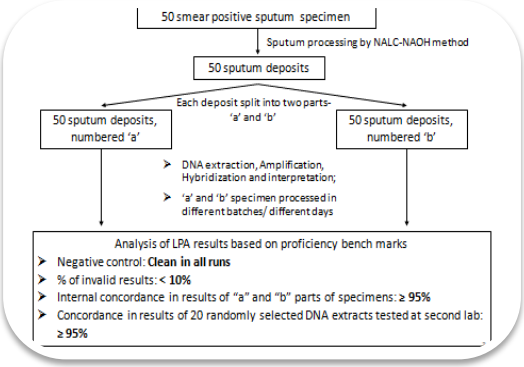
Lab Assessment

Infra-structure



Procurement & Supply

Trainings



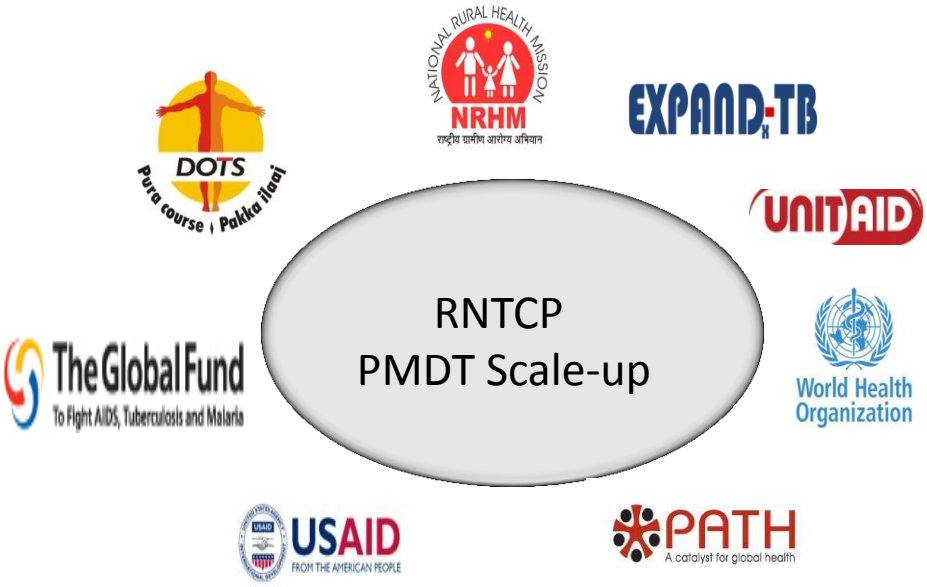
Proficiency Testing

Service Delivery

Resources available for labs in PMDT

Support for Infrastructure			
Source	**LPA**	**LC**	**CBNAAT**
State / NRHM / Institute	24	14	30
USAID	12	1	-
GFATM	7	18	-
Total	**43**	**33**	**30**

Support for Equipment & Consumables			
Source	**LPA**	**LC**	**CBNAAT**
EXPANDx TB	40	31	12
The Global Fund	3	2	-
WHO	-	-	18
Total	**43**	**33**	**30**



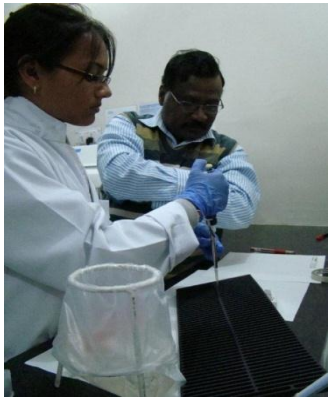
Establishment of Rapid TB Diagnostics : TGF Support




Activity	**LPA Labs (n=43)**	**LC Labs (n=33)**
Up-gradation	-	20
Additional HR	43, in phased manner	
Specimen processing equipment and consumables	43	
Onsite technical support and long term mentoring	43	
Rapid specimen referral, transportation and reporting	43	

National at ICELT and Onsite Lab Trainings for PMDT

2010 - 2012			
Level	**Training (number)**	**Number trained**	**No. of sites**
National (ICELT)@	24	116	56
Onsite#	115	1,270	55



@ National (ICELT)

Liquid Culture
LPA including updates for V2
Biosafety
LPA TOT
CBNAAT

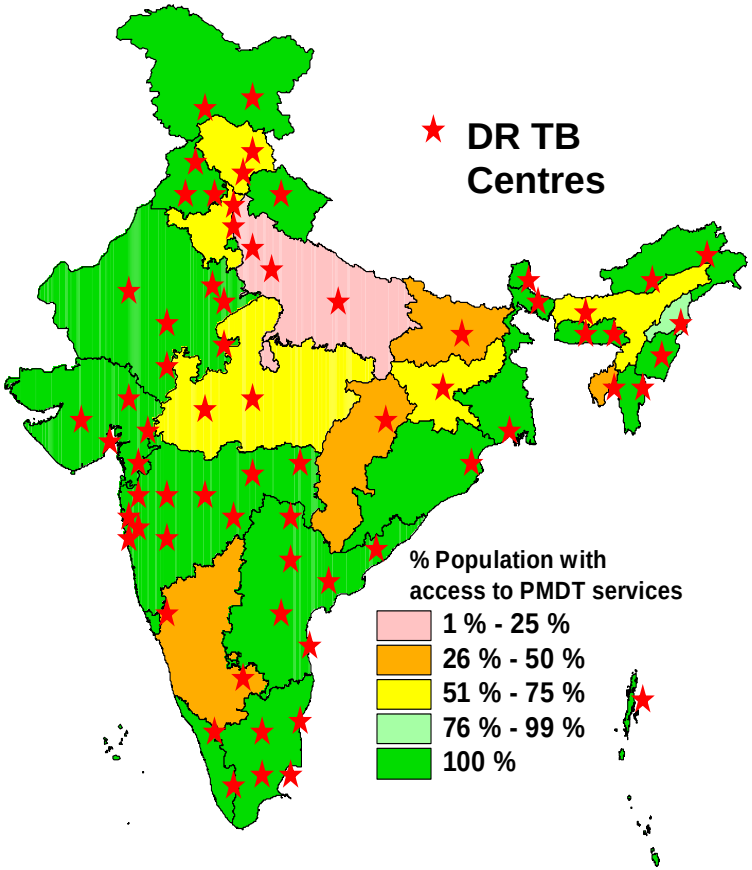
 # Onsite

Liquid Culture
LPA including updates for V2 & GT Blot 48
RNTCP Field staff training
CBANAAT

PMDT : Status of Implementation

Status of PMDT Services (Sep ’12)

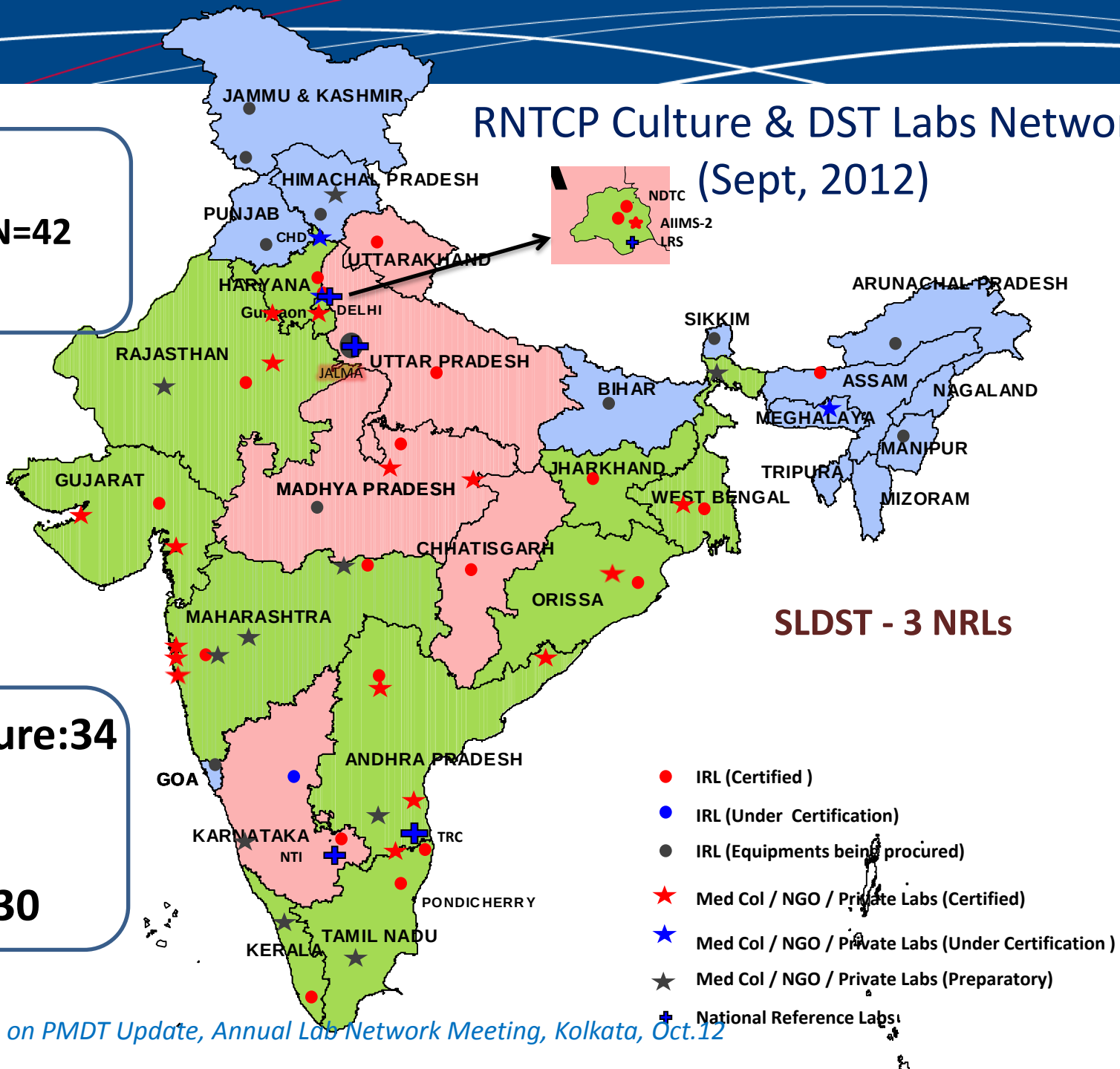
- PMDT Services introduced in Aug 2007
- All 35 State/UTs have introduced PMDT services of which 24 have achieved complete geographical coverage
- Access to DST 864 million (71%) in 507 districts
- 71 DR-TB Centers are functional (70% in Medical Colleges)



Source: Presentation on PMDT Update, Annual Lab Network Meeting, Kolkata, Oct.12

RNTCP Culture & DST Labs Network (Sept, 2012)

Certified : N=42

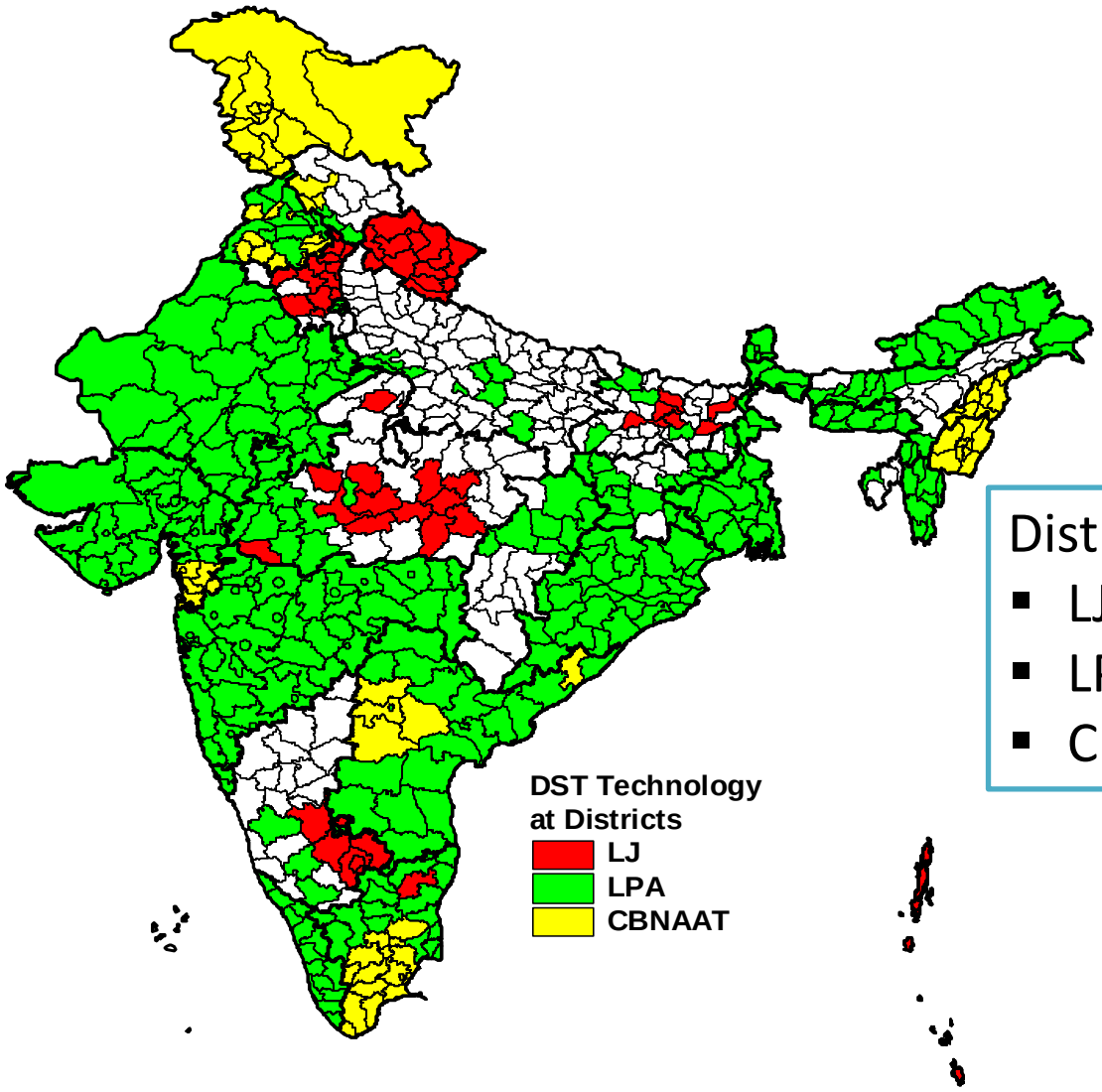


SLDST - 3 NRLs

Solid culture:34
LPA: 29
LC: 10
CBNAAT: 30

Source: Presentation on PMDT Update, Annual Lab Network Meeting, Kolkata, Oct.12

No. of districts covered for DST (Sept, 2012)

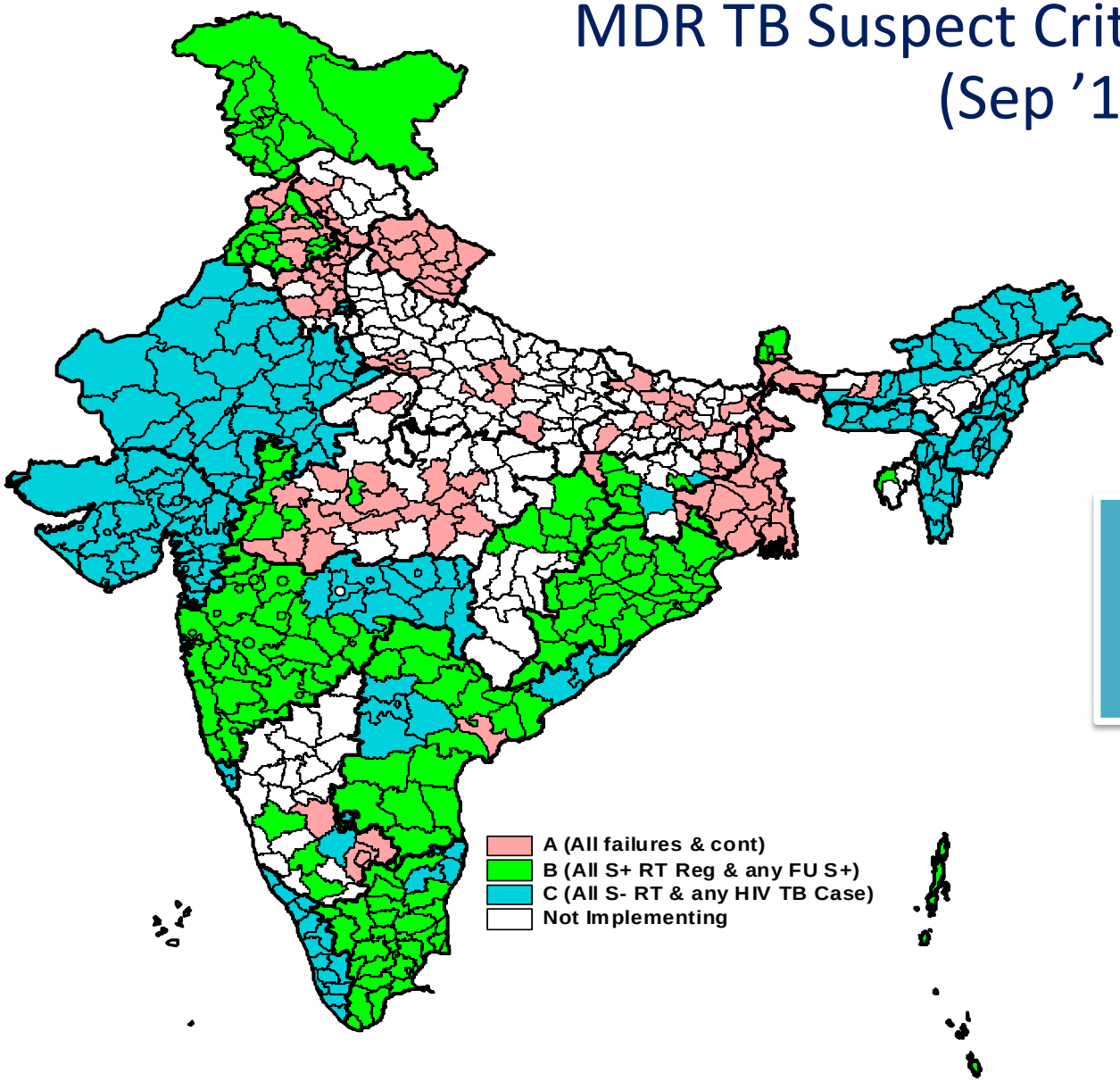


Districts

- LJ - 56
- LPA - 382
- CBNAAT – 69

Source: Presentation on PMDT Update, Annual Lab Network Meeting, Kolkata, Oct.12

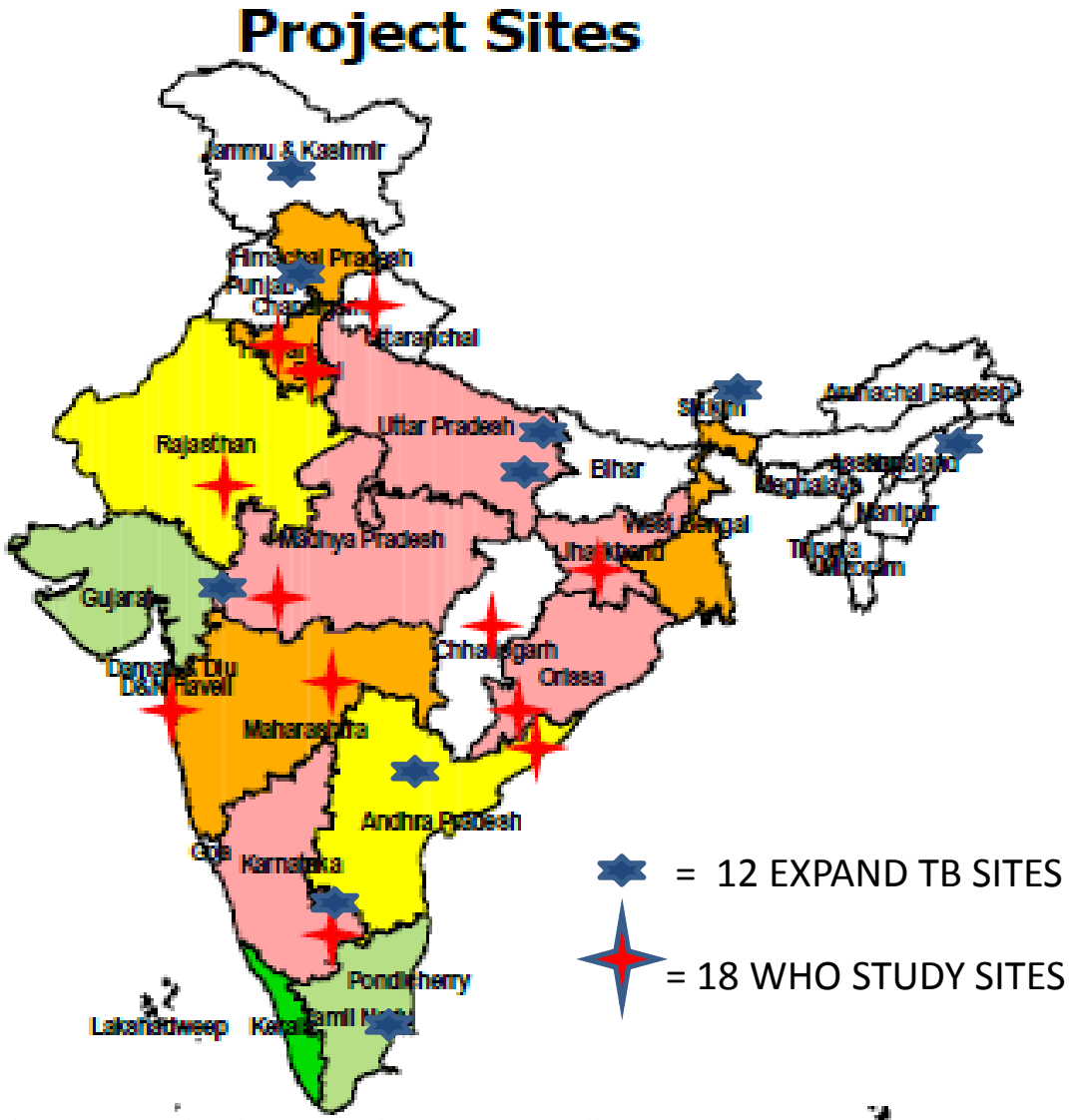
MDR TB Suspect Criteria in districts (Sep '12)



Criteria A - 114
Criteria B - 170
Criteria C - 223

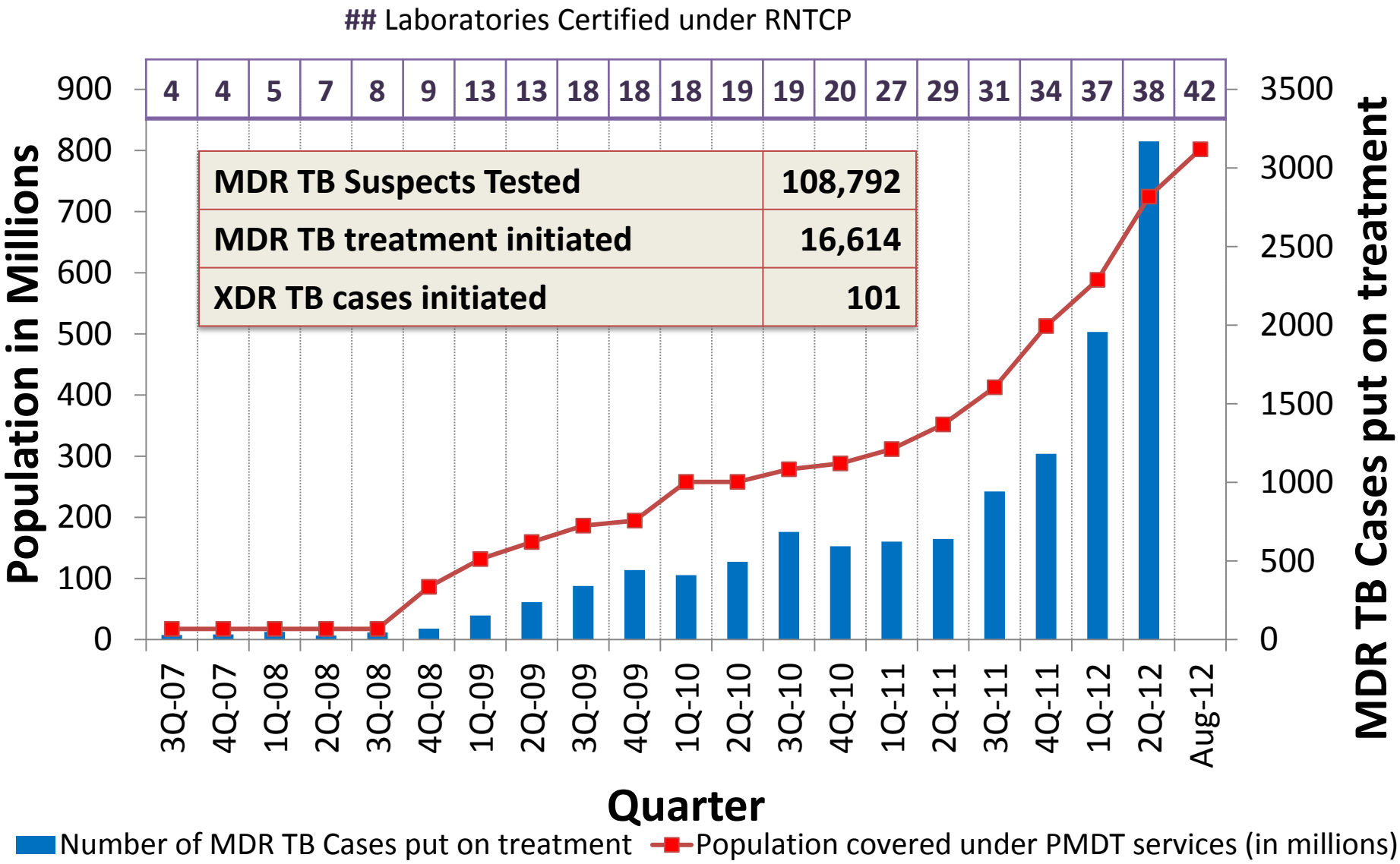
Source: Presentation on PMDT Update, Annual Lab Network Meeting, Kolkata, Oct.12

Ongoing CBNAAT study details



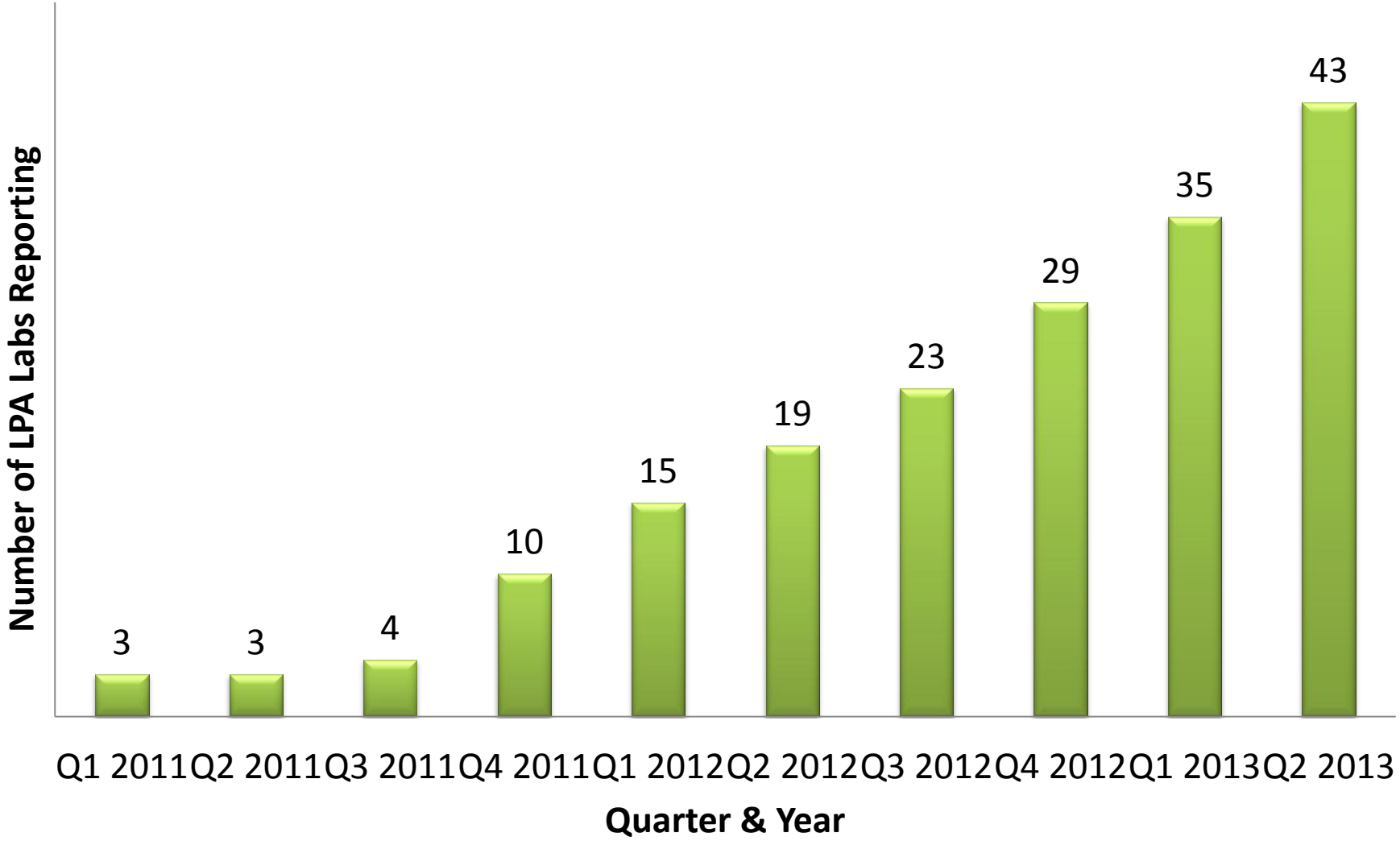
Source: Presentation on PMDT Update, Annual Lab Network Meeting, Kolkata, Oct.12

Population in India covered under PMDT services, Labs Certified and MDR TB cases put on treatment

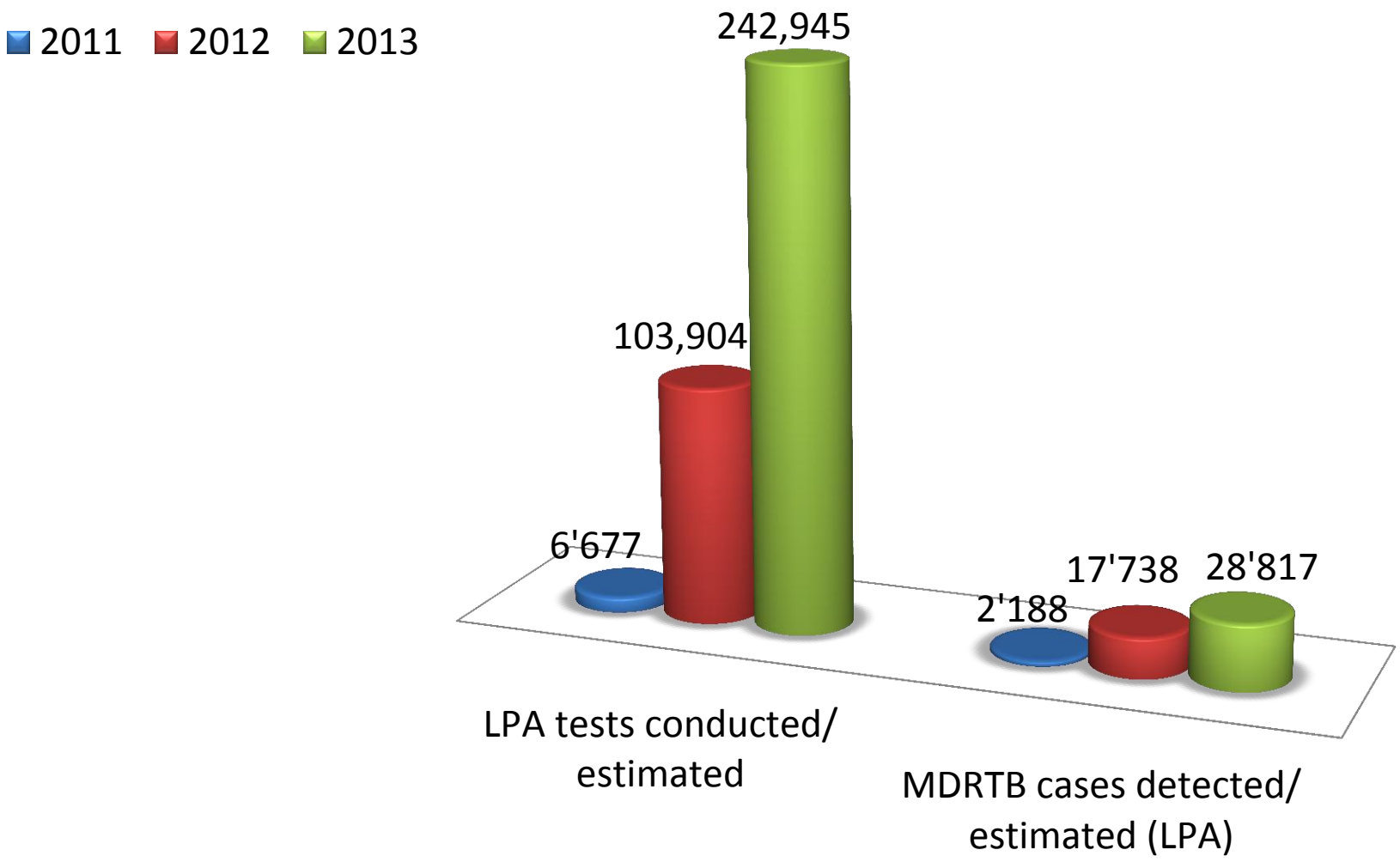


Source: Presentation on PMDT Update, Annual Lab Network Meeting, Kolkata, Oct.12

Progress - Number of LPA labs reporting



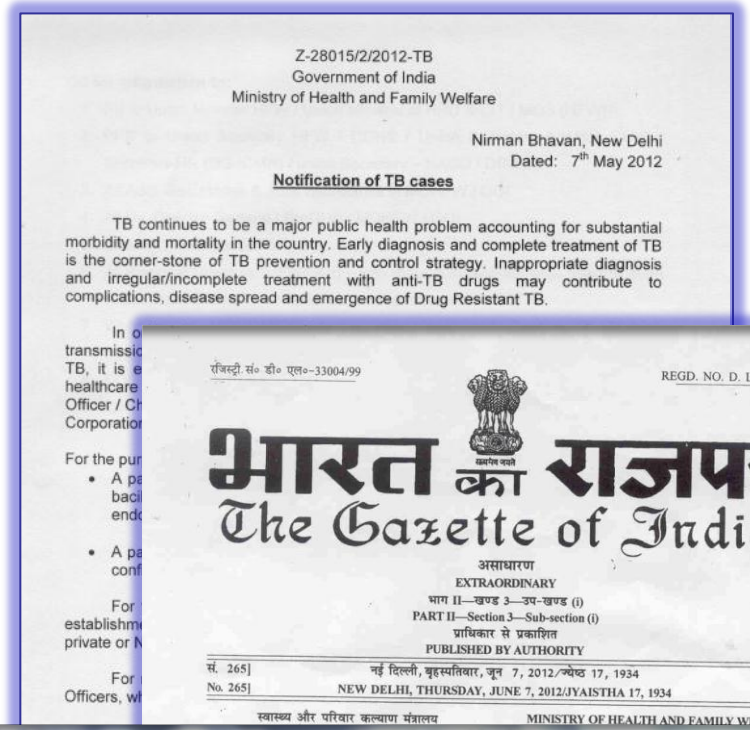
LPA tests conducted and MDR TB cases detected & estimated



What else has been done and what further needs to be done?

What else has been done?

- TB Notification Order, 7th May 2012, Govt. of India, RNTCP
- The Gazette of India - Notification , 7th June 2012; Ban on Serological test kits for TB in India (manufacture, sale, distribution, use and import)
- NIKSHAY - Case Based Web Based Recording & Reporting System



Z-28015/2/2012-TB
Government of India
Ministry of Health and Family Welfare

Nirman Bhavan, New Delhi
Dated: 7th May 2012

Notification of TB cases

TB continues to be a major public health problem accounting for substantial morbidity and mortality in the country. Early diagnosis and complete treatment of TB is the corner-stone of TB prevention and control strategy. Inappropriate diagnosis and irregular/incomplete treatment with anti-TB drugs may contribute to complications, disease spread and emergence of Drug Resistant TB.

रजिस्ट्री सं० डी० एल०-33004/99 REGD. NO. D. L.-33004/99

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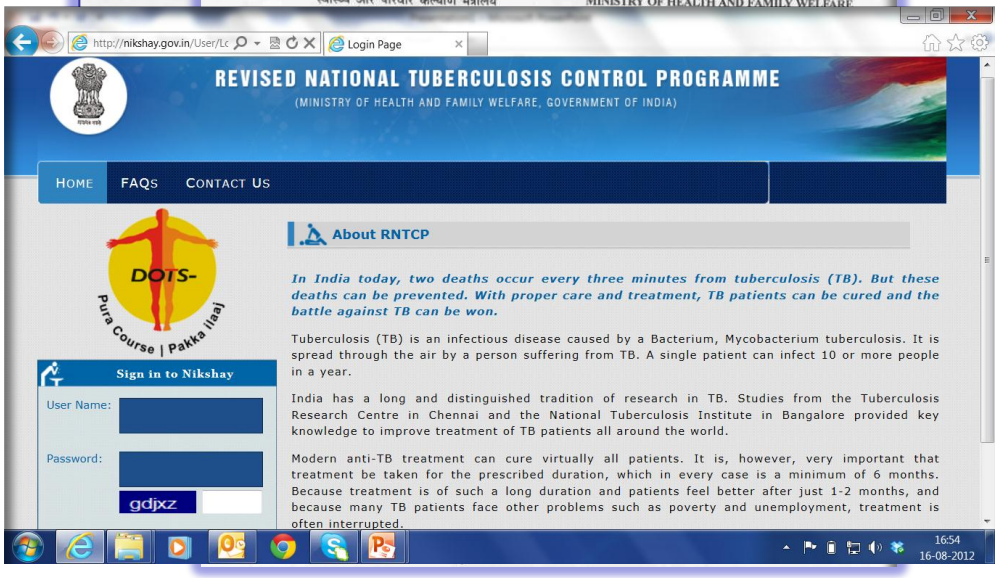

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REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME
(MINISTRY OF HEALTH AND FAMILY WELFARE, GOVERNMENT OF INDIA)

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About RNTCP

In India today, two deaths occur every three minutes from tuberculosis (TB). But these deaths can be prevented. With proper care and treatment, TB patients can be cured and the battle against TB can be won.

Tuberculosis (TB) is an infectious disease caused by a Bacterium, Mycobacterium tuberculosis. It is spread through the air by a person suffering from TB. A single patient can infect 10 or more people in a year.

India has a long and distinguished tradition of research in TB. Studies from the Tuberculosis Research Centre in Chennai and the National Tuberculosis Institute in Bangalore provided key knowledge to improve treatment of TB patients all around the world.

Modern anti-TB treatment can cure virtually all patients. It is, however, very important that treatment be taken for the prescribed duration, which in every case is a minimum of 6 months. Because treatment is of such a long duration and patients feel better after just 1-2 months, and because many TB patients face other problems such as poverty and unemployment, treatment is often interrupted.

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16-08-2012

What further needs to be done?

1. Support states to enhance lab capacity and move all districts towards universal access to DST
2. Extend access to DST in 950 districts by 2017 through any WHO approved rapid diagnostics
3. Monitor implementation of the updated Guidelines for PMDT in India (May ’12)
4. Ensure efficient sputum sample transport system
5. Streamline information management and notification of TB and DR TB from private sector through NIKSHAY
6. Develop capacity of labs to do 2nd line DST in phased manner

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
- Others
- All FIND technical and support staff




Thank you


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Key Facts and Concepts
Success Stories
DOTS-Plus
TB/HIV
IEC Resource Centre
History of TB Control
Patient Treated
015039007
Procurement Info | Calculation | Directory | Related Sites
Lives Saved
2707021
TUBERCULOSIS CONTROL - INDIA
DOTS
The WHO-recommended Directly Observed Treatment, Short Course (DOTS) strategy was launched formally as Revised National TB Control programme in India in 1997 after pilot testing from 1993-1996. Since then DOTS has been widely advocated and successfully applied. ....
More..
-The Stop TB Strategy
-International standards of TB Care
RNTCP
100% coverage under DOTS
Click here to see RNTCP implementation in India
- DDG Letter on Serodiagnostics NEW
- RNTCP Negative Recommendation on Commercially Available Serodiagnostics NEW
- RTI NEW
- NIKSHAY NEW
- TB Notification NEW
- Nodal Officer for TB Notification – contact details NEW
In terms of population coverage, India now has the second largest DOTS (Directly Observed Treatment, Short course) programme in the world. However, India's DOTS programme is the fastest expanding programme, and the largest in the world in terms of patients initiated on treatment, placing more than 100,000 patients on treatment every month. This site provides information about tuberculosis and its control in India.
70% case detection achieved
RNTCP Annual Report 2012 NEW
- Strategic Vision doc of the RNTCP
- Revised Financial Norms NEW
- RNTCP response to challenges of Drug resistance TB in India NEW
- National PMDT Scale-up Plan –
About the RNTCP
In India today, two deaths occur every three minutes from tuberculosis (TB). But these deaths can be prevented. With proper care and treatment, TB patients can be cured and the battle against TB can be won ....
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