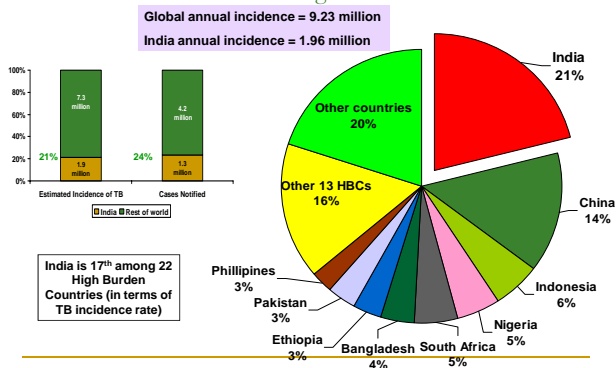


## Challenges towards up-scaling MDR TB under RNTCP

Dr L. S Chauhan  
Deputy Director General (TB)  
Central TB Division, Nirman  
Bhavan, New Delhi

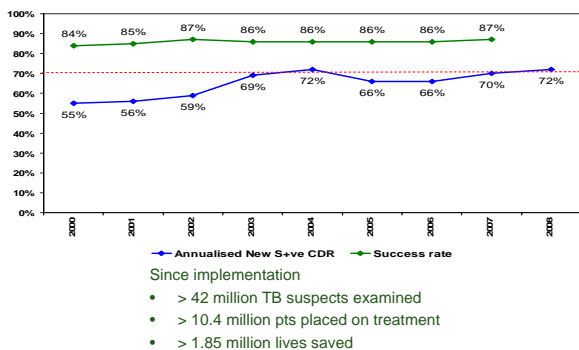


India is the highest TB burden country accounting more than one fifth of the global incidence



Source: WHO Geneva; WHO Report 2009: Global Tuberculosis Control; Surveillance, Planning and Financing

## Key achievements of RNTCP



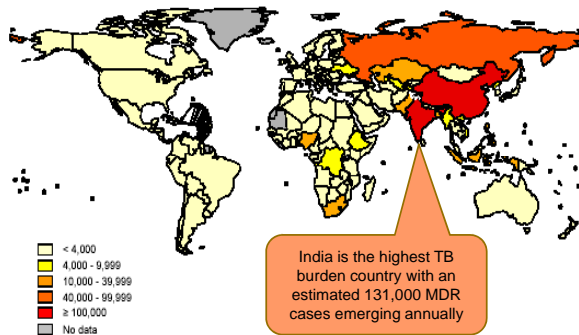
Achievements in line with the global targets

## Challenges to TB Control

- Wide variations in capacity of Health Systems across the country ([Map](#))
- Burden due to TB-HIV Co-infection
- Ensuring adherence of treatment for migratory population
- Large and unregulated Private Sector
- Limited availability of new rapid diagnostic tools, drugs and vaccine
- Drug Resistance**



## Global burden of MDR TB\*



\* WHO Global TB Report 2009



## Drug resistance TB in India

- Prevalence of MDR
  - India has the highest MDR TB burden in the world
  - As per Drug resistance surveys (DRS) done in Gujarat and Maharashtra (2005-06) prevalence of MDR is
    - <3% in new TB cases and 12-17% in previously treated cases though low translates into large absolute numbers
    - As per WHO estimates 131,000 MDR (56000 detectable cases) cases emerged in India in 2007
- XDR-TB has been reported in India though the data is limited and non-representative



## Causes of drug resistance

- Essentially a man made phenomenon
- Inadequate Regimens
  - Irrational use
  - Inappropriate combinations
  - Sub-optimal doses and duration
- Inadequate supply or poor quality of drugs
- Inadequate drug intake

DOTS Strategy adopted by RNTCP addresses all these issues



## RNTCP Response to MDR/XDR-TB

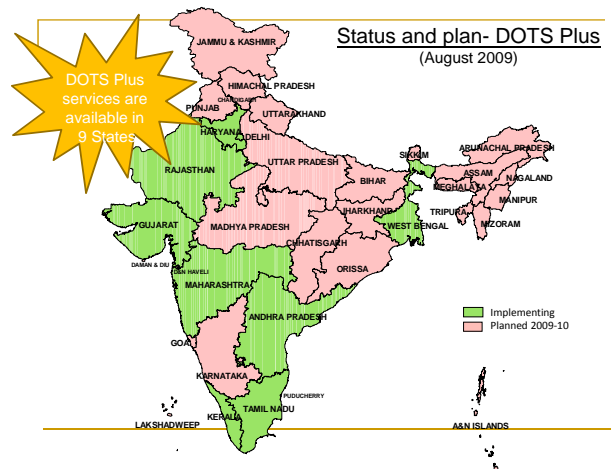
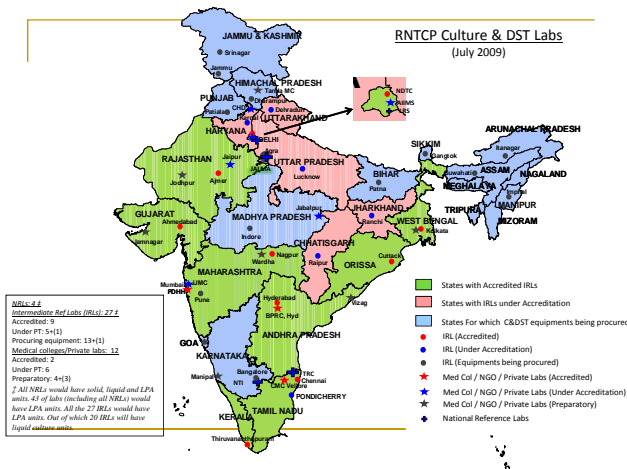
- Prevention of drug resistance through sustained high-quality DOTS implementation
  - Promote rational use of anti-TB drugs in the country
- Improve laboratory capacity: Diagnosing MDR-TB
- Effective treatment of MDR-TB patients through implementation of RNTCP DOTS Plus (Category IV services)
- Evaluate the extent of the threat of second-line anti-TB drug resistance and management of XDR-TB



## Status of RNTCP DOTS Plus services

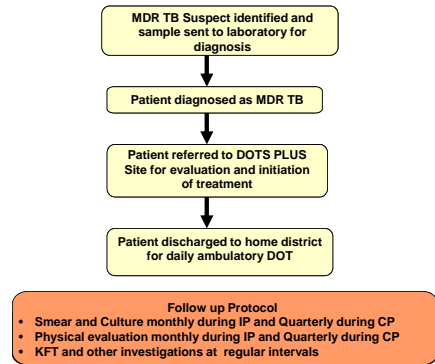
## Status of RNTCP Category IV services

- National level DOTS-Plus Committee established in 2005 and meeting regularly
- RNTCP DOTS-Plus Guidelines developed and available from 2006
- First MDR-TB suspects enrolled in March 2007 and first MDR patients initiated treatment in August (Gujarat) and Sept (Maharashtra) 2007
- Lab status
  - RNTCP has 12 (9 Govt + 3 private) laboratories accredited; 5 under accreditation process
- MDR-TB treatment on-going in 9 states with >650 patients on treatment
  - Gujarat, Maharashtra, Andhra Pradesh, Kerala, Delhi, Haryana, West Bengal, Tamil Nadu and Rajasthan
- On-going research into newer more rapid diagnostic tests



## Programmatic management of MDR TB

### Patient flow under DOTS Plus



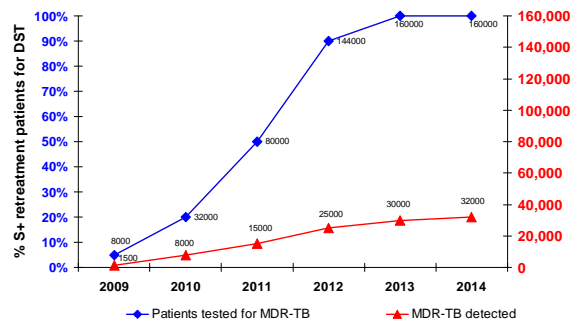
## DOTS Plus Vision

### RNTCP DOTS Plus Vision .....

- By 2010, RNTCP Category IV services introduced in all states with complete geographical coverage by 2012
- By 2012, 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 2012-13



## Multi-year plan for patients to be tested for MDR-TB and number of MDR-TB cases to be detected



\*Based on RNTCP 2012 goal of MDR diagnosis for all S+ retreatment patients.

## Strategies for achieving the vision

- Enhancing the laboratory capacity
  - ~ 43 laboratory units to be established
  - Introduction of rapid diagnostics
    - Molecular DST and liquid culture system
  - Purchase services from private/NGO laboratories
- Scaling up treatment services
  - Identification of DOTS Plus sites (~120 sites)
  - Uninterrupted supply of adequate quality assured second line drugs
  - Provision for daily DOT



## Challenges in achieving the vision

## Ensuring quality DOTS services

- Administrative Commitment
  - TB programme perceived as a vertical programme
    - Involvement of general health system staff is poor
  - TB programme is not given priority during review meetings
  - Restricted administrative and financial powers of the programme managers in some states/districts
- Vacancies of key staff
- Suboptimal involvement of NGOs and Private practitioners



## Challenges in diagnosis of MDR TB...

- Delay in establishment of accredited state level laboratories due to administrative reasons
- Sub-optimal functioning of the accredited labs
  - Non-availability of trained manpower
    - Dedicated regular staff in addition to the contractual posts
  - Uninterrupted power supply
- Diagnostic delay with conventional method (3-4 months turn around time)
- Special requirements for introduction of newer rapid diagnostics- laboratory infrastructure and training



## Treatment Challenges

- Long duration of treatment (24-27 months) with second line drugs
  - Toxic, expensive (~2,000 \$ per patient course) and short shelf life
- Treatment given under daily ambulatory DOT
  - Including 6-9 months of injectables
- Availability of DOTS Plus sites (1 per 10 million population)
  - Tertiary care centres with dedicated in-patient facility
  - Trained manpower and facilities for
    - undertaking pre-treatment assessment which include special tests
    - management of severe adverse reactions
- Extensive training, supervision and monitoring needed at all levels
- Ensuring treatment adherence
  - Regular and intensive counseling of patients and family members
  - Timely retrieval of treatment interrupters



## Support required .....

- Expedite the establishment of accredited culture and DST facility in the State
- Constitution of the State DOTS Plus Committee and formulation of action plan
- Ensuring initiation and scale up of DOTS Plus services as per the time lines
  - Achieve complete geographical coverage by 2012
- Ensure treatment adherence
- **Ensure DOTS Plus does not compromise DOTS**
  - **Regular Supervision and Monitoring from the highest level**



## Thank You



## Infection control

- **Challenges**
  - Infection control considered synonymous with waste management
  - Lack of National guidelines on Airborne Infection control in context of TB
  - Overcrowding/lack of space at health facilities
  - Lack of awareness and commitment of hospital administrators
- **Steps taken by RNTCP**
  - National Airborne Infection Control Committee constituted
  - "National guidelines for airborne infection control" under development
  - Provision of support to upgrade IC measures at DOTS-Plus sites and IRLs
  - Collaboration with NACP to ensure infection control measures at ICTCs and ART centres
  - Encouraging Medical Colleges (through Task Force mechanism) to develop and implement infection control measures

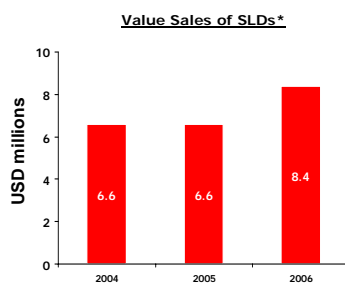


## Promoting Rational use of anti TB drugs

- **Situation**
  - In 2006, 75% of FLDs and almost 100% of SLDs were sold and used outside of RNTCP ([link](#))
- **Challenges**
  - Large unregulated private sector
  - Conflict of Interest
  - Easy availability of anti TB drugs
- **Steps taken by RNTCP**
  - "Chennai Consensus Statement on the Management of MDR-TB outside of RNTCP" developed and disseminated
  - IMA on behalf of RNTCP interacting with MCI for guidelines to all healthcare providers on rational use of anti TB drugs
  - Interactions with office of DCGI to draft guidelines for the regulation of anti TB drugs
  - Encouraging additional manufacturers for pre-qualification



## SLD market in India estimated at USD \$8M



**2<sup>nd</sup> line drugs**  
**Led by Macleods**  
**(#1) and Lupin (#2)**  
**Mainly a private**  
**sector market**  
**Growth between**  
**2005 and 2006**  
**driven by an**  
**increased use of**  
**fluoroquinolones**

\*2<sup>nd</sup> line drugs adjusted to screen out use in other indications  
 Note: Does not include 1<sup>st</sup> line drugs that may be used in 2<sup>nd</sup> line treatment of patients

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Source: ORG-IMS stockist data, RNTCP 2006 Annual Report, Interviews

## Countries that had reported at least one XDR-TB case by September 2009



Argentina, Armenia, Azerbaijan, Bangladesh, Belgium, Botswana, Brazil, Burkina Faso, Canada, China, Colombia, Czech Republic, Ecuador, Estonia, France, Georgia, Germany, India, Iran (Islamic Rep. of), Ireland, Israel, Italy, Japan, Kenya, Latvia, Lesotho, Lithuania, Mexico, Mozambique, Myanmar, Namibia, Nepal, Netherlands, Norway, Oman, Pakistan, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Slovenia, South Africa, Spain, Swaziland, Sweden, Thailand, Ukraine, United Arab Emirates, United Kingdom, United States of America, Uzbekistan, Viet Nam

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**New Smear Positive Case Detection Rate (First Quarter, 2009)**

**Cure Rate by district (First Quarter, 2008)**

