Revised National Tuberculosis Control Programme (RNTCP)

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Problem Statement of TB in India

• India accounts for nearly $1/4^{th}$ of global burden of TB (2010).

• **Mortality**: 26 per 1 lac population.

• **Prevalence (old + new cases)**: 256 per 1 lac population.

• **Incidence (new cases only)**: 185 per 1 lac population.
Millennium Development Goals

• **Goal 6:** “Combat HIV/AIDS, malaria and other diseases”
  – **Target 8:** “By 2015, to have halted and begun to reverse the incidence of malaria and other major diseases...”
  
    • **Indicator 23:** between 1990 and 2015 to halve prevalence of TB disease and deaths due to TB
    
    • **Indicator 24:** to detect 70% of new infectious cases and to successfully treat 85% of detected sputum positive patients
## Evolution of TB Control in India

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1950s-60s</td>
<td>Important TB research at TRC and NTI</td>
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<tr>
<td>1962</td>
<td><strong>National TB Programme (NTP)</strong></td>
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<tr>
<td>1992</td>
<td>Programme Review&lt;br&gt;  • only 30% of patients diagnosed;&lt;br&gt;  • of these, only 30% treated successfully</td>
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<tr>
<td>1993</td>
<td><strong>RNTCP</strong> pilot began</td>
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<td>1998</td>
<td>RNTCP scale-up</td>
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<tr>
<td>2000</td>
<td>&gt;30% of country covered</td>
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<tr>
<td>2004</td>
<td>&gt;80% of country covered</td>
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<tr>
<td>2006</td>
<td>Entire country covered by RNTCP</td>
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National Tuberculosis Control Programme

• NTCP was started in 1962 with aim to detect cases at the earliest & treat them.
• However,
  – Treatment success rate : unacceptably low
  – Death & default rate : high
Need For Revised Strategy

• in 1992, nation wise review was conducted with assistance of SIDA & WHO.
  – NTP suffered from managerial weakness
  – Inadequate funding
  – Over-reliance on X-rays for diagnosis
  – Frequent interrupted supplies of drugs
  – Low rates of treatment completion.

• In 1993, GoI decided to give a new thrust by revitalizing NTP.
• RNTCP thus formulated
Revised National Tuberculosis Control Programme

• Objectives of RNTCP:

1. To achieve and maintain a **cure rate of at least 85%** among newly detected infectious (new sputum smear positive) cases

2. To achieve and maintain **detection of at least 70%** of such cases in the population.
Revised strategy:

1. Augmentation of organizational support at centre and state level.
2. Use sputum testing as primary method of diagnosis.
3. Standardized treatment regimen.
4. Ensuring regular, uninterrupted supply of drugs.
5. Emphasis on training, IEC, operational research & NGO involvement.
6. Increased budget outlay.
Components of DOTS:

1. Political will ensures financial support and sustainability.
2. Case detection with the help of quality assured sputum smear microscopy.
3. Regular and uninterrupted supply of drugs
   - *patient wise boxes*
4. Directly observed treatment
   - *direct observation while patient is getting treatment.*
5. Systemic monitoring and accountability.
Structure of RNTCP at State level

State TB Cell

District TB Centre

Nodal point for TB control

One/ 5 lakh (2.5 lakh in hilly/difficult/tribal area)

Tuberculosis Unit

One/ lakh (0.5 lakh in hilly/difficult/tribal area)

Microscopy Centre

DOT Centre

STO, Deputy STO
MO, Accountant,
IEC Officer, SA, DEO

DTO, MO-DTC, LT,
DEO, Driver

MO-TC
STS, STLS

MO, LT

DOT Provider – MPW,
NGO, PP, Comm Vol
Recommendation of the RNTCP National Laboratory Committee (Oct 2008)

- Strongly recommended that RNTCP changes diagnostic criteria of Smear +ve PTB as below:
  - **TB suspect** is any person with cough for 2 weeks, or more
  - Number of specimen required for diagnosis is 2, with one of them being a morning sputum
  - **One specimen positive out of the two** is enough to declare a patient as Sm+ PTB
Basis of changes

• The revised definition of a new sputum smear positive pulmonary TB case is based on the presence of at least one acid-fast bacillus (AFB) in at least one sputum sample in countries with a well functioning EQA system.

• The reduction of the number of specimens to be examined for screening of TB cases from three to two, in places where workload is very high and human resources are limited.
Diagnostic Algorithms for Pulmonary TB

COUGH FOR 2 WEEKS OR MORE

2 Sputum smears

1 or 2 Positives

2 Negative

Antibiotics 10-14 days

Cough persists

Repeat 2 Sputum Examination

1 or 2 Positives

Sputum Positive PTB Anti TB Treatment

Sputum negative PTB Anti TB Treatment

Negative for TB

2 Negative

X-ray chest

Suggestive of TB

Non TB
## Revised Categories

<table>
<thead>
<tr>
<th>Treatment groups</th>
<th>Type of patient</th>
<th>Regimen</th>
<th>Intensive phase (IP)</th>
<th>Continuation phase (CP)</th>
</tr>
</thead>
</table>
| **New (Cat I)**        | • New sputum smear positive  
                          • New sputum smear negative  
                          • New extra-pulmonary  
                          • New others            | 2 H3R3Z3E3       | 4 H3R3               |
| **Previously treated (Cat II)** | • Smear positive relapse  
                               • Smear positive failure  
                               • Smear positive treatment after default  
                               • Others              | 2 H3R3Z3E3       | 5 H3R3E3             |
Quality Assurance

• RNTCP Lab network has three levels:
  – National Reference Laboratories
    • NTI Bangalore
    • TRC Chennai
    • LRS New Delhi
  – Intermediate Reference Laboratories
    • State level
  – Network of Designated Microscopy Centers (>11,000)
    • Includes microscopy centers in medical colleges
    • One DMC covers a population of about 1 lakh
    • Provide quality assured acid-fast sputum smear microscopy services
RNTCP External Quality Assessment

Components

• Panel testing
• On-site evaluation
• Random blinded rechecking of routine slides
External Quality Assessment activities of RNTCP

**Onsite Evaluation**
- By NRL team - Once a year
- By IRL team, once a year
- By DTO once a month, By IRL team once a year
- By STLS once a month, By DTO once a quarter
- By IRL team during annual visit (sample of)

**Panel testing**
- NRL
- By IRL team, once a year
- Intermediate Ref. Lab
- By IRL team, once a year
- DTC
- TB Unit
- DMC

**Blinded Cross-checking**
- By NRL team - Once a year
- Blinded rechecking at district level by STLS of slides collected from DMCs
- Monthly random collection of routine slides from DMCs
Reporting Procedure

**On-site evaluation reports**
- a. Detailed checklist (NRL, IRL, TU)
  - b. Summary report
- ii. Quarterly Programme Management report

**Panel testing reports**
- During on-site evaluation

**RBRC reports**

Quarterly programme management report

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CTD

Quarterly & yearly reports

Quarterly programme management report (% of DMCs with high false errors)

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EQA Periodic Reporting

NRL

OSE-Yearly

Quarterly & yearly reports

IRL

OS-Yearly

Monthly & Quarterly reports

DTC

Monthly EQA-OSE & RBRC

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DMC

DMC

DMC

TU

DMC

DMC (50,000–100,000 population)
HIV & TB

• HIV co-infection strongest known risk factor for the progression of latent TB infection to active TB disease

• Estimated 7-10% annual risk of reactivation, with 60% lifetime risk (cf. 10% lifetime risk in TB infected, non-HIV infected individual)

• Conversely, TB amongst the most common causes of morbidity and mortality in people living with HIV/AIDS

• Immune response to TB bacilli increases HIV replication leading to a rapid progression of HIV disease

• Optimal access to DOTS will significantly reduce morbidity and mortality in PLWHA
TB/HIV collaborative activities

• TB/HIV Action Plan - implemented by RNTCP and NACP jointly, focusing on:
  – Training of service providers
  – Service delivery linkages (ICTC-RNTCP Cross-referrals)
  – Monitoring
  – Information, Education, and Communication

• Implementation started:
  – in 2001, in 6 high HIV prevalent States (population 311 million)
  – expanded in 2004, to 8 additional States (population 323 million)
TB/HIV collaborating activities

- National, State and District level coordination committees to monitor linkages
- Guidelines and training material developed jointly
- On-going training of staff on TB/HIV
- Cross-referral between ICTC and DOTS services developed, piloted and implemented
- Involvement of NGOs and PPs
- Collaborative IEC activities
- Joint monitoring of activities
Treatment of TB in HIV

- TB can be successfully treated even in HIV-infected pts.
- But, cannot alone prevent people from dying of AIDS
  - In addition to TB treatment, ART and CPT needed for those eligible
- DOTS is the treatment of choice
- Intermittent SCC is effective
  - National policy is to provide RNTCP Cat-I to new cases and Cat-II to re-treatment cases
- Higher relapse rates have been observed especially in those treated with non-Rifampicin containing regimen
  - Whether true relapse or re-infection?
- Drug interactions between Rifampicin and ARVs
  - National policy is to start ART after completing anti-TB treatment, or modify ART by replacing Nevirapine with Efavirenz for the duration of TB treatment
Likely impact of HIV on TB in India?

• **Scenario without RNTCP**
  
  – HIV would increase TB prevalence (by 1%), incidence (by 12%), and mortality rates (by 33%) between 1990 and 2015

• **Scenario with RNTCP**
  
  – Expect substantial reductions in prevalence (by 68%), incidence (by 41%), and mortality (by 39%) between 1990 and 2015

• Nationally, RNTCP should be able to reverse the increases in TB burden due to HIV but, to ensure that TB mortality is reduced by 50% or more by 2015, HIV-infected TB patients should be provided with antiretroviral therapy in addition to the recommended treatment for TB
Pediatric Tuberculosis

• Related to adult TB

• Can occur at any age

• Disease develops within one year of infection
  – Younger, earlier = ↑ disseminated

• PTB : EPTB :: 55 : 45

• PTB paucibacillary, usually sp-neg
Diagnostic Algorithm for Pediatric Pulmonary TB

Pulmonary TB Suspect
- Fever and / or cough 2 weeks
- Loss of wt/No wt gain
- History of contact with suspected
  Or diagnosed case of active TB

Is expectoration present?

If no, refer to Pediatrician
If yes, examine 2 sputum smears

1 or 2 Positives
2 Negatives
Antibiotics 10-14 days
Cough Persists
Repeat 2 Sputum smear Examinations

1 or 2 Positive
2 negative
X-ray + Mantoux
Negative for TB
Sputum-Negative PTB
(Suggestive of TB)
Refer to Pediatrician

Sputum-Positive PTB
(Anti-TB Treatment)
Treatment of Pediatric TB

- DOTS
- Categorization – SAME
- Doses per kg body weight
- Drugs to be made available as combi-packs in patient wise boxes, linked to child's weight (6-10kg, 11-17kg, 18-25kg, 26-30kg)
- PWB – being made available
  - PC13 yellow (6-10kg)
  - PC14 orange (11-17kg)
  - Prolongation pouches
    - Pink (18-25 kg)
    - Gray (26-30 kg)
MDR-TB and DOTS-Plus

• MDR-TB is a lab diagnosis, NOT a clinical one

• MDR-TB levels of less than 1% to 3% in new cases and of 12% in re-treatment cases.

• Emergence of resistance to Rifampicin in only 2% of patients, despite a high level (8%) of initial resistance to Isoniazid, either alone or in combination with other anti-TB

• Quality assured laboratory facility for culture and Drug Susceptibility Test must be available (NB: 2 – 4 months delay before DST results seen)
• RNTCP Cat IV treatment is a 24 month standardized 2nd-line regimen given under daily DOT:
  – 6 Km Ofx Eto Cs Z E / 18 Ofx Eto Cs E

• MDR-TB patient admitted to indoor facility at DOTS-Plus site for up to 1 month for:
  – pre-treatment assessment;
  – initiation of Category IV treatment after decision of DOTS-Plus site committee;
  – monitoring tolerance to treatment regimen;
  – counseling and health education to patient and family;
  – developing linkages to district services; and
  – contact tracing
Achievements of RNTCP

- Treatment success rate: 25% (1998) to 88% (2010)
- Death rate: 29% (1998) to 4% (2010)
- 662 DTCs
- 2,698 TUs
- 13,039 DMCs
- 1,971 NGOs
- > 10,894 Private practitioner
- 297 Medical colleges
- > 13,000 peripheral laboratories
Thanks....