MD SEMINAR

RNTCP

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GLOBAL & INDIAN SCENARIO

- In 2002 estimated 8.8 million new cases of TB, globally
- 3.9 million sputum smear positive,
- One fifth of the global TB cases in India
- 1.8 million new cases every year
- 0.8 million smear-positive cases
- 4 lakh deaths occur from TB every year.
- Every Day, in India
  more than 5000 develop TB disease
  more than 1000 people die of TB
  (2 deaths every 3 minutes)
- TB kills more adults in India than any other infectious disease.
- Peak incidence in economically productive age group of 15-60 years.

TUBERCULOSIS CONTROL IN INDIA

- National TB Control Programme (NTP) 1962
- RNTCP – 1993

NTP

- Launched in 1962
- District tuberculosis control programme
- Managerial weakness
- Over reliance on x ray
- 30% cases diagnosed
- Of them 30% completing treatment
- Non standardized treatment
- Lack of report on outcome

LAUNCH OF RNTCP

- Failure of NTP
- GOI – WHO revised strategy for control of TB in India
- RNTCP application of WHO – DOTS launched in 1993

CHALLENGES FOR RNTCP

- The general health service often does not function optimally.
- A large and mostly unregulated private sector provides a substantial proportion of outpatient care, and this care is of inconsistent quality.
- The level of socioeconomic development can have a major effect on program performance.
- Ensuring the quality of drugs is difficult.

OBJECTIVES OF RNTCP

- Primary aim – achieve a cure rate of 85% of new sputum smear positive patients.
- RNTCP shifts the responsibility for cure from the patient to the health system
- 70% detection of new sputum smear positive cases – but only if the cure rate of already detected patients is > 85%

DOTS – 5 COMPONENTS

- Political and administrative commitment
- Good quality diagnosis, primarily by sputum smear microscopy
- Uninterrupted supply of good quality drugs
- Directly observed treatment (DOT)
- Systematic monitoring and accountability

STRUCTURE OF RNTCP

- Central TB Division
- State level
- District level
- Sub-district level

  Tuberculosis Unit (TU)

  Medical Officer-Tuberculosis Control (MO-TC)

  Senior Treatment Supervisor (STS)

  Senior TB Laboratory Supervisor (STLS)

STRUCTURE OF RNTCP

- Designated Microscopy Centre

  Tertiary / Secondary level health care institutions

  Block PHCs / other equivalent institutions

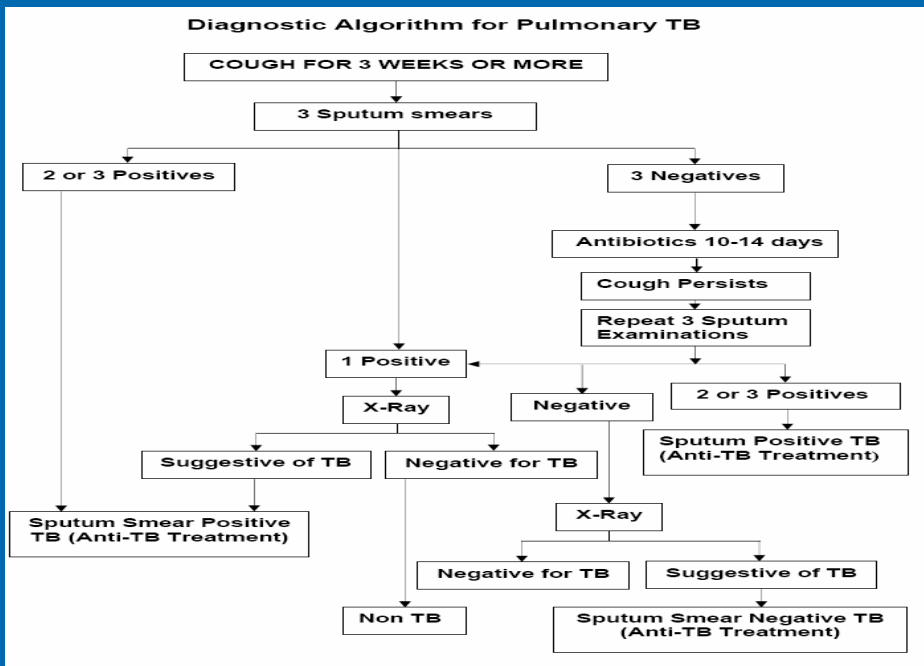
  Caters to a population of 1 lakh (0.5 lakh in hilly, tribal and difficult areas)

  60 -100 new adult outpatient attendance per day

  The laboratory technician must be examining an average of at least 3 – 5 smears and not more than 20 – 25 smears per day.

DIAGNOSIS

- The most common symptom of pulmonary TB is persistent cough, usually with expectoration
- 2-3% of new adult outpatients in a general health facility
- 10% of TB suspects are expected to have sputum smear positive pulmonary TB
- Three sputum specimens
- SPOT - EARLY MORNING - SPOT.



SPUTUM EXAMINATION

Examination finding	Result as recorded	Grading	No. of fields examined
> 10 AFB per oil immersion field	Positive	3+	20
1–10 AFB per oil immersion field	Positive	2+	50
10–99 AFB per 100 oil immersion fields	Positive	1+	100
1–9 AFB per 100 oil immersion fields	Positive	Scanty*	100
No AFB in 100 oil immersion fields	Negative	Negative	100

TREATMENT

Factors that determine the regimen

- Disease classification
- Type of case
- Sputum result
- Severity of illness
- History of previous treatment

DISEASE CLASSIFICATION

- **Pulmonary tuberculosis**

a. Smear-positive patient

- A patient with at least 2 initial sputum smear examinations positive for AFB
- Or: one sputum positive for AFB and radiographic abnormalities
- Or: one sputum positive for AFB and culture positive for M. tuberculosis.

b. Smear-negative patient

- Symptoms suggestive of TB with at least 3 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO, followed by a decision to treat the patient with a full course of anti-TB therapy;
- Or: culture positive for M. tuberculosis but sputum smear examinations negative

DISEASE CLASSIFICATION

Seriously ill smear-negative PTB

- Miliary TB
- Extensive parenchymal infiltration
- Co-infection with HIV
- Pulmonary disease with cavitations
- All forms of pediatric sputum smear negative pulmonary TB except primary complex

DISEASE CLASSIFICATION

Extra Pulmonary Tuberculosis

- This includes TB of organs other than the lungs.
- Patients who have both pulmonary and extra-pulmonary TB are classified as having pulmonary tuberculosis.

Seriously ill EPTB	Not seriously ill EPTB
• Meningitis • Pericarditis • Peritonitis • Bilateral or extensive pleural effusion • Spinal TB with neurological involvement • Intestinal • Genito-urinary • Co-infection with HIV • All forms of pediatric extra-pulmonary TB other than lymph node TB and unilateral pleural effusion are considered to be seriously ill	• Lymph node • Pleural effusion (unilateral) • Peripheral joints

TYPES OF PATIENTS

- **New:** A TB patient who has never had treatment for TB or one who has taken anti-TB drugs for less than one month.
- **Relapse:** A TB patient who was declared cured or treatment completed by a physician, but who reports back to the health service and is now found to be sputum smear-positive.
- **Treatment after default:** A TB patient who received anti-TB treatment for one month or more from any source and returns to treatment after having defaulted, i.e., not taken anti-TB drugs consecutively for two months or more, and who is found to be sputum smear-positive.

TYPES OF PATIENTS

- **Failure:** Any TB patient who is smear-positive at 5 months or more after starting treatment. Failure also includes a patient who was treated with Category III regimen but who becomes smear-positive during treatment.
- **Transferred in:** A TB patient who has been received for treatment in one Tuberculosis Unit, after starting treatment in another unit (TU) where (s)he has been registered
- **Chronic:** A TB patient who remains smear positive after completing a re-treatment regimen.
- **Others:** TB patients who do not fit into the above mentioned types. Reasons for putting a patient in this type must be specified.

ESSENTIAL ANTITUBERCULAR DRUGS

Essential drug (abbreviation)	Recommended dosage (dose range) in mg/kg	
	Daily	3 times weekly
isoniazid (H)	5 (4–6)	10 (8–12)
rifampicin (R)	10 (8–12)	10 (8–12)
pyrazinamide (Z)	25 (20–30)	35 (30–40)
streptomycin (S)	15 (12–18)	15 (12–18)
ethambutol (E)	15 (15-20)	30 (20-35)
thioacetazone (T)	2.5	NA

RATIONALE OF TREATMENT

3 main properties of anti-TB drugs:

- Bactericidal activity
- Sterilizing activity
- Ability to prevent resistance

Type of TB Bacilli	Effective Drugs
Extra-cellular rapidly multiplying	Rifampicin, Isoniazid Streptomycin, Ethambutol
Extra-cellular intermittently multiplying/semi-dormant	Rifampicin
Intra- and extra-cellular acidic environments intermittently multiplying/semi-dormant	Pyrazinamide
Dormant	No drug

RATIONALE OF TREATMENT

Intermittent use – rationale:

- Equally efficacious in intermittent dosing
- Facilitates observation
- Reduces costs and convenience
- "Lag period" phenomenon

RATIONALE OF TREATMENT

Intensive Phase (IP)

- Rapid killing of bacilli.
- Shorter duration of infectiousness (≤ 2 weeks)
- Rapid smear conversion (80% – 90%) after 2 to 3 months of treatment.
- Each dose in this phase should be directly observed

Continuation Phase (CP)

- Eliminates most residual bacilli
- Reduces failures and relapses.
- Low numbers of bacilli and less chance of drug resistant mutants.

CATEGORIES OF TREATMENT

Category of Treatment	Type of Patient	Regimen*
Category I	New sputum smear-positive Seriously ill** new sputum smear-negative Seriously ill** new extra-pulmonary	$2H_3R_3Z_3E_3$+ $4H_3R_3$
Category II	Sputum smear-positive Relapse Sputum smear-positive Failure Sputum smear-positive Treatment After Default Others***	$2H_3R_3Z_3E_3S_3$ + $1H_3R_3Z_3E_3$ + $5H_3R_3E_3$
Category III	New Sputum smear-negative, not seriously ill New Extra-pulmonary, not seriously ill	$2H_3R_3Z_3$ + $4H_3R_3$

- Patients in Categories I and II who have a positive sputum smear at the end of the initial intensive phase receive an additional month of intensive phase treatment
- Patients who weigh 60 kg or more receive additional rifampicin 150 mg.
- Patients who are more than 50 years old receive streptomycin 500 mg.
- Patients who weigh less than 30 kg, receive drugs as per body weight.

FOLLOW UP EXAMINATION

Category	Pre-treatment sputum	Test at month	If result is	Then…
Cat I	Positive	2	Neg	Start continuation phase, test sputum again at 4 and 6 months
			Pos	Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months
	Negative	2	Neg	Start continuation phase, test sputum again at 6 months
			Pos	Continue intensive phase for one more month, test sputum again at 3,5 and 7 months
Cat II	Positive	3	Neg	Start continuation phase, test sputum again at 5 and 8 months
			Pos	Continue intensive phase for one more month, test sputum again at 4,6 and 9 months
Cat III	Negative	2	Neg	Start continuation phase, test sputum again at 6 months
			Pos	Re-register the patient and begin Category II treatment

TREATMENT OUTCOME

- **Cured:** Initially sputum smear-positive patient who has completed treatment and had negative sputum smears, on at least two occasions, one of which was at the end of treatment.
- **Treatment Completed:** A sputum smear-positive patient who has completed treatment, with negative smears at the end of IP but none at the end of treatment, **OR**
- A sputum smear-negative patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment, **OR**
- An EP TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.

TREATMENT OUTCOME

- **Died:** Patient who died during the course of treatment, regardless of the cause of death.
- **Failure:** Any TB patient who is smear-positive at 5 months or more after starting treatment, **OR**
- A patient who was treated with Category III but who becomes smear-positive during treatment.
- **Defaulted:** A patient who has not taken anti-TB drugs for 2 months or more consecutively after starting treatment.
- **Transferred out:** A patient who has been transferred to another TB Unit or district and for whom the treatment result (outcome) is not known.

QUALITY ASSURANCE

- An effective quality assurance (QA) system for sputum smear microscopy is an integral part of RNTCP.
- QA is a total system consisting of
  - ✓ Internal quality control(IQC),
  - ✓ Assessment of performance using external quality assessment (EQA) methods
  - ✓ Continuous quality improvement (QI) of laboratory services.

FEATURES UNIQUE TO RNTCP

Public-private mix projects

- Private Practitioners (PPs) are the first "point of contact"; necessary to "partner" with NGOs and private health care providers.
- Officially prescribed guidelines for the involvement of NGOs(2001) and private practitioners (2002).
- To date, 800 NGOs & 5,000 PPs involved in RNTCP activities.

FEATURES UNIQUE TO RNTCP

Involvement of other sectors

- Public sectors outside of the Health Departments e.g. Railways and ESI hospitals, Port hospitals.
- Medical Colleges - sheer number of TB patients treated, role in teaching medical students and other practitioners

FEATURES UNIQUE TO RNTCP

Collaboration with National AIDS Control Programme

- Infection with HIV- risk factor for progression to active TB among adults.
- Joint Action Plan between RNTCP and the AIDS Programme implemented for collaborative activities (2001), initially in the 14 states of highest HIV prevalence,

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INDIAN EXPERIENCE OF DOTS

- More than doubles the accuracy of TB diagnosis
- Cuts down TB deaths by seven fold
- Doubles the cure rate
- Reduces the incidence and prevalence of TB
- Helps in alleviating poverty by saving lives, reducing the duration of illness and preventing new infectious cases
- Improves the quality of care and overcomes stigma
- Prevents treatment failure and the emergence of MDRTB

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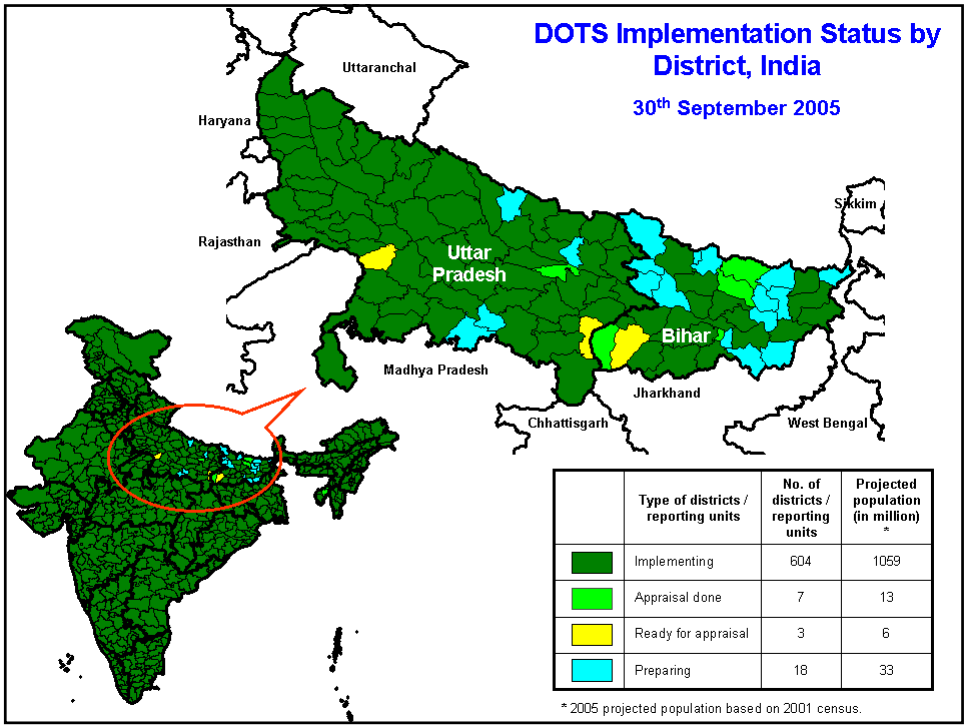
ACHIEVEMENTS OF RNTCP



ACHIEVEMENTS OF RNTCP

- Over 100,000 patients being put on treatment each month, the RNTCP, in terms of patients treated, is the largest DOTS programme in the world.
- Full nation-wide coverage by 2005- the fastest expansion of any DOTS programme in the world, without any compromise on the quality of services provided
- In 2004, the case detection rate was 78% - 75% with cure rate maintained at 85%, WHO targets met.

ACHIEVEMENTS OF RNTCP

- Over 3.5 million patients provided free diagnosis and treatment under the RNTCP.
- Resulted in over 6 lakh additional lives saved

Indian J Tuberc 2005; 52: 1-4

CHALLENGES FOR RNTCP IN THE FUTURE

- Shortage of staff – rapid expansion – redistribution of current staff
- Upgradation of existing TB laboratories and creation of new microscopy centres to strengthen the TB laboratory network
- Recent study – initial bacillary load can influence sputum conversion rates and treatment outcome of new smear positive patients treated by DOTS.

- Sputum conversion – 3+ were 62% & 81% at 2 & 3 months,
  1+/2+ were 77% & 89%
- Cure rates 76% vs 85%
- Failure rates 7.7% vs 4.5%

Indian J Chest Dis Allied Sci 2005

- Treatment of MDR cases – DOTS PLUS –
  DRS surveys & establishment of quality assured culture & drug sensitivity testing (DST) lab facility in large states +
  provision of second line drugs for resistant cases