Country experience of programmatic implementation of TPT for contacts of DR-TB patients

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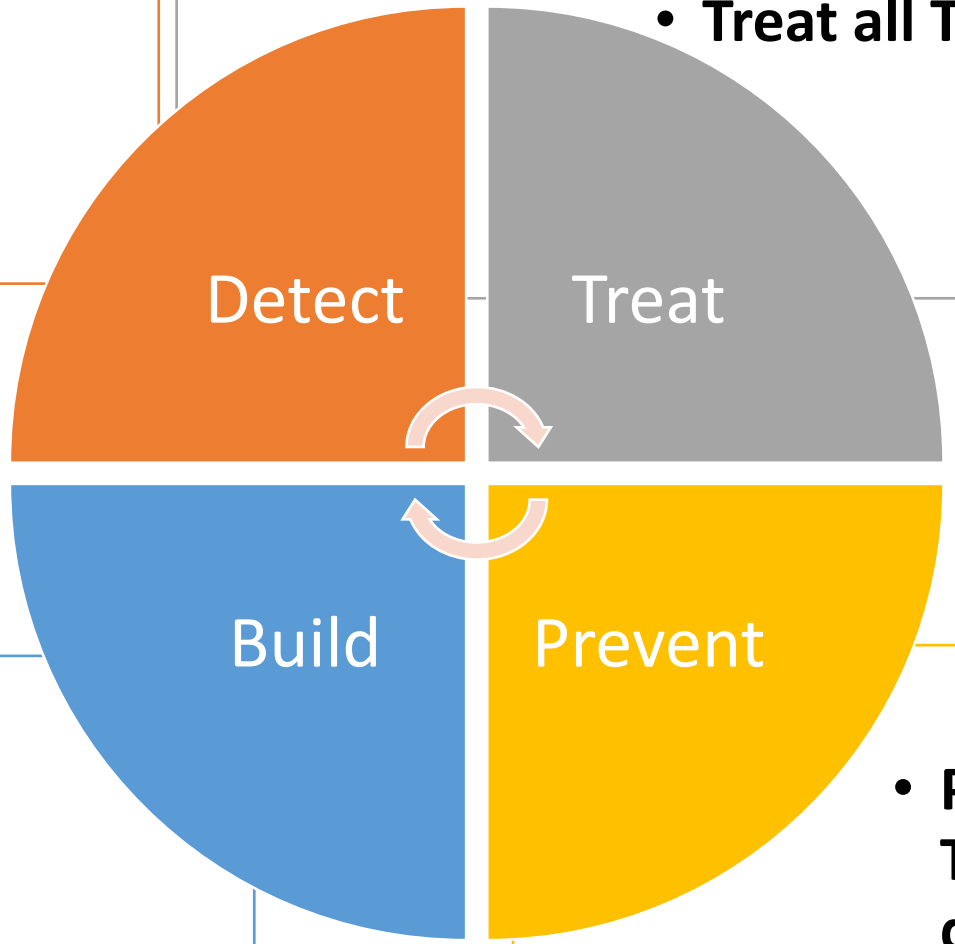
National Strategic Plan (2017-25) for Ending TB in India

- **Identify all TB including in private sector**

- **Treat all TB with quality drugs**



- **Build supportive system and policies**

- **Prevent the emergence of TB infection, breakdown to disease and recurrence**

Key TB Prevention Activity under NTEP

TB Preventive Treatment (TPT)

- Programmatic management of TPT

Vaccination

- BCG at birth (coverage – 89%)
- Adult BCG Vaccination (programmatic study)

Airborne Infection Control (AIC)

- AIC in hospital and high-risk zones
- AIC in community

National TB Preventive Treatment policy

Target groups for TPT

People living with HIV/AIDS (PLHIV)

All household and close contacts of Pulmonary TB patients

Other risk groups ⚠

- Person on dialysis, immunosuppressive, silicosis, transplant recipients
- Smoker,
- Alcoholics,
- Malnourished,
- Diabetes,
- Prisoners,
- Health care workers

Strategy	**Rule out active TB → TPT**	**Rule out active TB → TBI test → TPT**
Regimen options	**1HP**	**3HP, 3RH**
	6H	
	TPT in contacts of DR-TB (6Lfx and 4R)	

Key milestones and activities

Till 2018
Policy of TPT only in PLHIV and contacts <5yrs (6H)

Nov'20 - Apr'21
- Pilot introduction of TPT in a State with 6H and 3RH regimen

Aug'- Dec'21
- **National Guidelines for PMTPT**
- **Introduction of TPT in contacts of DR-TB in 12 states**

Jan'22 - Jul'22
- **Pan country role out (194 dist.by GF + Phased scale-up in rest of the districts)**
- Pilot introduction of 3HP with support of WHO-India and GF

2023
- **Domestic procurement** of 5 million courses of 3HP and Cy-Tb each
- Introduced **incentives @Rs. 250 for TPT support**

Aug-Dec'22
- Recommended for scale-up and integration of TPT in at-risk groups during ACF

Jan-Oct 2024
- **Complete transition to 3HP** in HHC and at-risk individual
- **1HP TPT in PLHIV**
- Ni-kshay based monitoring
- **TPT in DR-TB continued in 12 + 4 states**
- Nutritional support to HHC of TB Patient through the crowd funding model

Testing for TB infection

- Options under NTEP: TST (PPD RT 23) or IGRA or Cy-Tb test (antigen-based skin test)
- Recommendation: Testing for TB infection if HHC >5years and other risk groups integrated with ACF
- Model of implementation: in-house testing or end-to-end service procurement for IGRA
- Transition to Cy-Tb:
  - ICMR conducted efficacy and safety study of Cy-Tb use and recommended for programmatic utilization
  - Approval of regulatory authority of India (CDSCO) for use of Cy-Tb
  - Assessment of requirement
  - Domestic procurement of 5 million test doses
  - Capacity building of last mile health care worker
  - Implementation through health system approach
  - Monitoring through digital system (Ni-kshay)

Programmatic experience of implementation

- Variable positivity between IGRA and TST because of non-standardized TST and variable reading
- Training and skill required in health care worker for reading of TST / Cy-Tb.
- Leverage on general health system for storage in cold chain, administration and reading after 48-72 hrs.

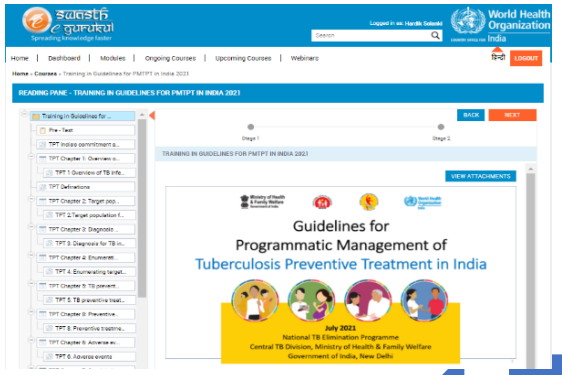
TPT in HHC of DR-TB

NTEG recommendation: To be in Initiated in limited geographies (12 states) to gain experience and expansion as per recommendation of National Technical Expert Group

Target population	Strategy	TPT options
• **Contacts of DR-TB** ○ Contact of MDR/RR-TB (FQ susceptible) or	Testing for TBI and TPT after ruling out TB disease	• 6Lfx (6 months of daily levofloxacin)
○ Contact of isoniazid mono/poly resistant TB (R susceptible)		• 4R (4 months of daily rifampicin)

**TPT should not be deferred in case of non-availability of testing for TB infection in HHC >/=5yrs*

Scale-up processes for programmatic implementation of TPT in contacts of DR-TB



Informed decision in NTEG

Scale-up plan

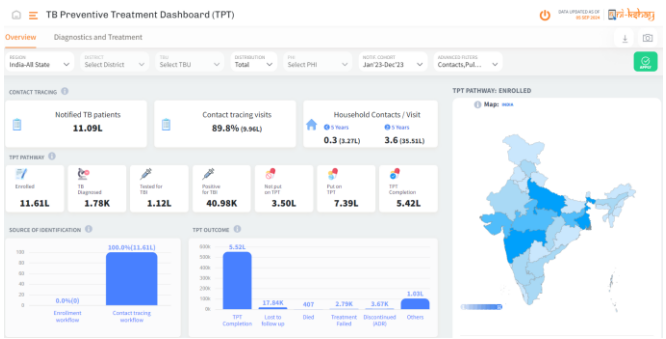
- Identification of geographies
- Logistics requirement

Administrative approval

- Assessment of financial implication
- Resource allocation

Capacity building

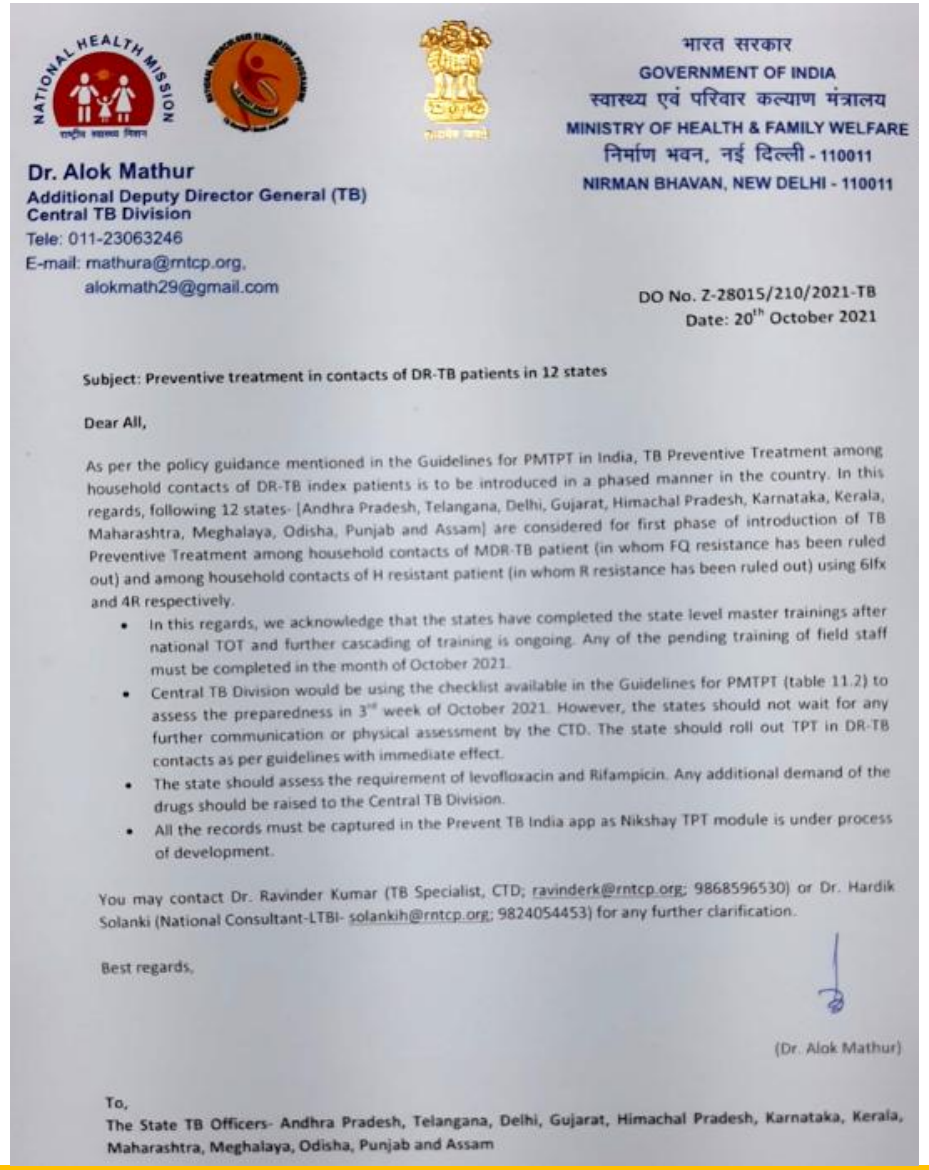
- Virtual (WHO's Swasth e-gurukul
- Physical



System capacity

- Ensure continued supply
- Allocation of entire course to the treatment supporter
- Ni-kshay TPT dashboard based on learnings from Prevent-TB app

Selection of implementation geographies



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Subject: Preventive treatment in contacts of DR-TB patients in 12 states

Dear All,

As per the policy guidance mentioned in the Guidelines for PMTPT in India, TB Preventive Treatment among household contacts of DR-TB index patients is to be introduced in a phased manner in the country. In this regards, following 12 states- [Andhra Pradesh, Telangana, Delhi, Gujarat, Himachal Pradesh, Karnataka, Kerala, Maharashtra, Meghalaya, Odisha, Punjab and Assam] are considered for first phase of introduction of TB Preventive Treatment among household contacts of MDR-TB patient (in whom FQ resistance has been ruled out) and among household contacts of H resistant patient (in whom R resistance has been ruled out) using 6lfx and 4R respectively.

- In this regards, we acknowledge that the states have completed the state level master trainings after national TOT and further cascading of training is ongoing. Any of the pending training of field staff must be completed in the month of October 2021.
- Central TB Division would be using the checklist available in the Guidelines for PMTPT (table 11.2) to assess the preparedness in 3rd week of October 2021. However, the states should not wait for any further communication or physical assessment by the CTD. The state should roll out TPT in DR-TB contacts as per guidelines with immediate effect.
- The state should assess the requirement of levofloxacin and Rifampicin. Any additional demand of the drugs should be raised to the Central TB Division.
- All the records must be captured in the Prevent TB India app as Nikshay TPT module is under process of development.

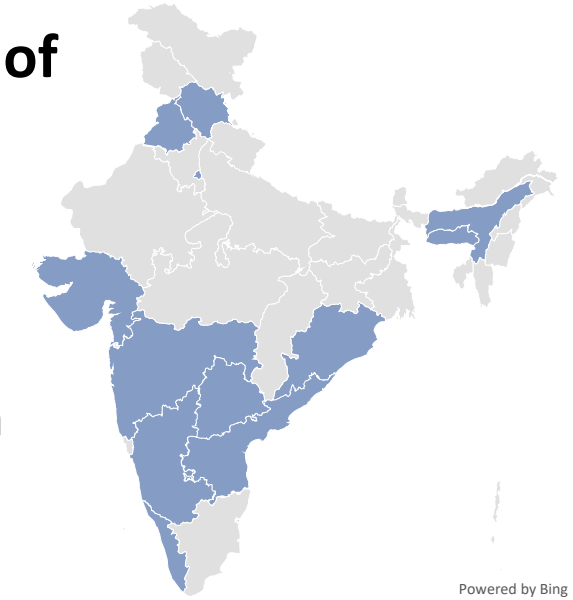
You may contact Dr. Ravinder Kumar (TB Specialist, CTD; ravinderk@rntcp.org; 9868596530) or Dr. Hardik Solanki (National Consultant-LTBI- solankih@rntcp.org; 9824054453) for any further clarification.

Best regards,

(Dr. Alok Mathur)

To,
The State TB Officers- Andhra Pradesh, Telangana, Delhi, Gujarat, Himachal Pradesh, Karnataka, Kerala, Maharashtra, Meghalaya, Odisha, Punjab and Assam

- **Selected 12 states for roll out (57% of India's MDR/RR-TB notification)**
- **Criteria for selecting these states:**
  - Less FQ resistance proportion than national average
  - Network of adequate laboratory capacity for second Line- Line Probe Assay (SL-LPA)
  - Decentralized DR-TB treatment centres
  - Coincide with scale-up of shorter oral BDQ containing regimen for MDR/RR-TB



Coverage and outcome of 6Lfx

Jan 2022 – Dec 2024

3534

Contacts of MDR/RRTB initiated on 6Lfx

Treatment outcomes of individuals initiated on 6Lfx, India (2023)

Treatment outcomes	Contacts of MDR-TB initiated on 6Lfx (%) N = 1770
TPT completed	**1565 (89%)**
Loss to follow-up (LFU)	10 (1%)
TPT discontinued due to toxicity	24 (1%)
TPT failed	21 (1%)
Died	3 (0%)
Not evaluated	147 (8%)

Coverage and outcome of 4R

Jan 2023 – Dec 2024

2432

Contacts of Isoniazid mono/poly resistant TB (Hr-TB)with rifampicin susceptible

Treatment outcomes of individuals initiated on 4R, India (2023)

Treatment outcomes	Contacts of MDR-TB initiated on 6Lfx (%) N = 1424
TPT completed	**1132 (79%)**
Loss to follow-up (LFU)	25(2%)
TPT discontinued due to toxicity	10 (1%)
TPT failed	9 (1%)
Died	2(0%)
Not evaluated	246 (17%)

Learnings from the programmatic implementation

- **Hesitancy among programme managers and clinicians affecting coverage:** required multipronged advocacy; developed risk communication materials; shared of scientific evidence with doctors
- **Role of second line drug susceptibility testing:** expansion of FQ testing coverage in index MDR/RR-TB patients would improve access to 6Lfx; implementation of CBNAAT-XDR in near future
- **Ensuring availability of resources:** Secured sufficient resources (drugs, diagnostics, funding)
- **Adherence monitoring:** high completion rates depend on community involvement and effective adherence monitoring tools.
  - Incentivizing TPT monitoring encouraged uptake. (programme incentivized ~3USD per completion to treatment supporter)
- **Rule out active TB:** quality screening and detection of all risk group using symptoms and/ or CXR followed by upfront NAAT is critical.
- **Digital infrastructure for monitoring:** Develop a robust digital system (like India's Ni-kshay TPT module) to track patient progress, coverage, and outcomes. This ensured real-time data for decision-making and course correction.
- **Concurrent operational research:** to understand challenges and strengthen the programme

Thank you