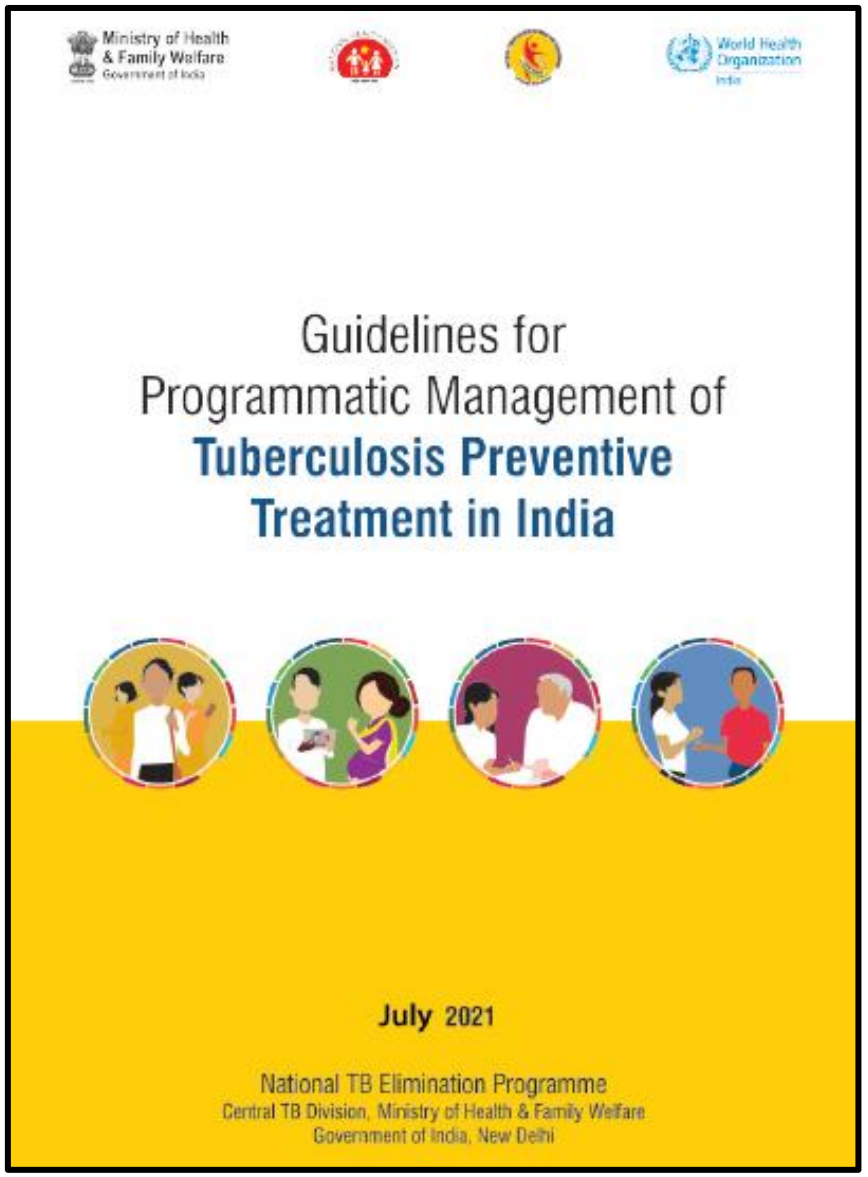


India's TBSTs & IGRAs Experience

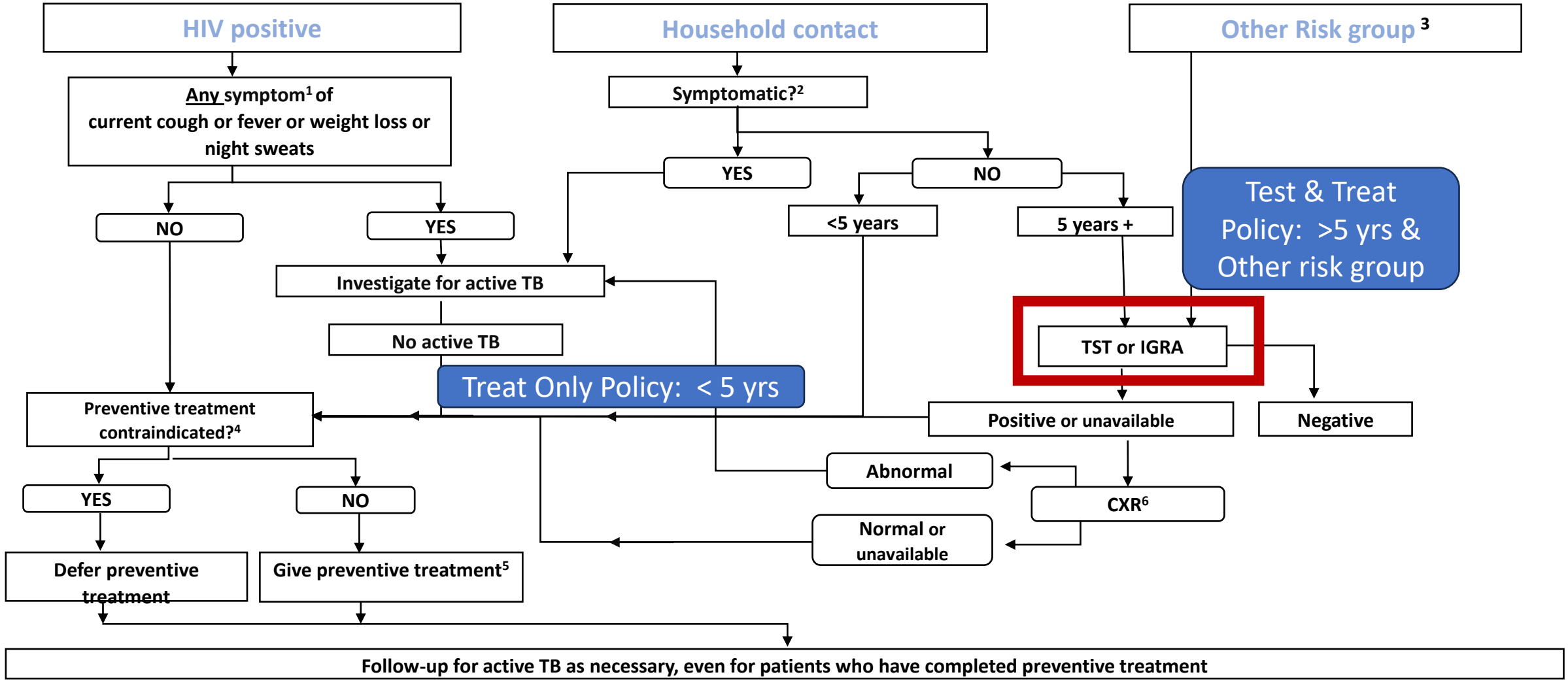
Dr Nishant Kumar

Joint Director (Public Health)

National TB Elimination Programme (NTEP)

Central TB Division, Ministry of Health & Family Welfare, Government of India

Under the NTEP- Algorithm for TB screening and TPT



Other Risk Group for TPT:

Expansion of this risk group in December 2024 under the 100 Days Intensified TB Campaign

- Anti TNF,
- Bronchial Asthma,
- Cancer,
- Cardiovascular disorder,
- COPD, COVID recovered pt,
- Diabetes,
- Dialysis,
- HTN,
- Health care worker
- Lactating mother,
- Liver transplant,
- Migrant,
- Miner
- Palliative care,
- Pt on immunosuppressant,
- Pregnancy,
- Prison,
- Silicosis,
- Transplant,
- Undernourished/ Malnourished (BMO< 18.5 kg/m2)
- Workplace settings (coal, sandblasting. Brick Klin, Tea garden worker, construction site worker, congregate settings),
- Attendees of de-addition centre,
- Person exposed to indoor air pollution,
- Marginalized population at risk of HIV, LGBTQAI++,
- Substance abuse(alcoholic, IV drug users)
- Tobacco/smoker,
- Tribal (particular vulnerable tribal group and Non particular vulnerable tribal group)
- Illegal immigrant,
- Urban slum

Options of tests for TB infection

	TST	IGRA	Cy-Tb
Sensitivity	High	High	High
Specificity	Low in BCG vaccinated	High even in BCG vaccinated	High even in BCG vaccinated
Ease of use	Field friendly, complex test interpretation	Requires lab and infrastructure	Field friendly, single cut-off allows simple test interpretation
Cost of test	Low	High	Low
Manufacturing	Complex, old products	Complex, multiple components	Robust with high yield, well defined and completely characterised
Special populations			
Children	Affected by young age	Affected by young age	More robust
PLHIV	Requires info on HIV status	Affected by HIV and low CD4 count	More robust with low CD4

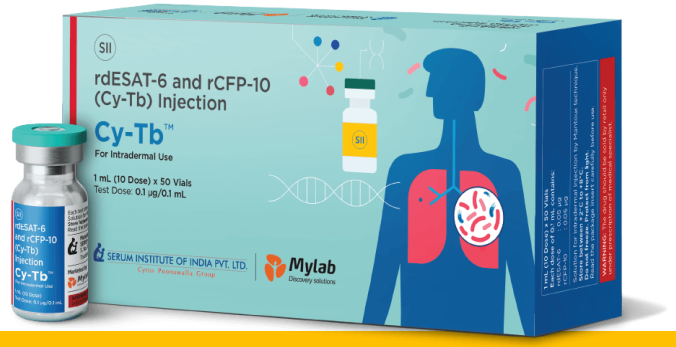
✓ ***PLHIV and Household Contacts < 5years old are offered TPT directly without testing***

Cy-TB in India

- A **new point-of-care skin test** (TB Ag skin test) **for Mycobacterium tuberculosis infection detection**,
- **It's made in India** (Manufactured by Serum Institute of India Pvt. Ltd)
- **Introduced in India in September 2024** under the TB program.
- The **antigens used are rdESAT-6 and rCFP-10**.
- **Advantage: high specificity of 97%,** surpassing traditional tuberculin skin tests due to its use of Mtb-specific antigens.

Its Implementation under the program in India:

- **Procured centrally at national level &** distributed to states in tranches
- Program has **procured 5 million tests** and is distributing it to states in tranches.
- Available for **use of the test in age >/=18 years**.



IGRA in India

- In India, **the Interferon Gamma Release Assay (IGRA), also known as the TB Gold test**, is a **blood test** used to detect tuberculosis (TB) infection.
- It measures the **immune system's response to TB bacteria** (Mycobacterium tuberculosis) in a person's blood, indicating whether they have been infected with TB.
- **Advantage:** It requires only **one patient visit**, unlike TSTs, which require two visits (one for injection and one for reading the results)

Its Implementation under the program in India:

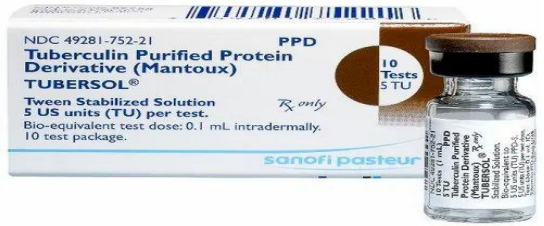
- Program has provision to allocate **state budget for local procurement of IGRA**
- **Procured locally at State level &** distributed to districts as per need
- Available for **use of the test in age >/=5 years**.

TST in India

- TST detects, **reaction to purified protein derivative (PPD) of mycobacterium**
- Also known as the **Mantoux test,**
- **Limitations: low specificity,** requiring two visits**,** and potential for false-positive results due to BCG vaccination or non-tuberculous mycobacteria.
- **Advantage:** It's a well-established test with a **long history of use**, meaning **healthcare providers are generally familiar with its administration, reading, and interpretation.**

Its Implementation under the program in India:

- Program has provision to allocate **state budget for local procurement of TST**
- **Procured locally at State level &** distributed to districts as per need
- Available for **use of the test in age >/=5 years**.



Use of Cy-Tb, IGRA &TST in India

From September 2024 till March 2024

- **39% supplies have been consumed.**

(Among >=18 yrs HHC with pulmonary* TB patients)

In 2023 & 2024

223,994 IGRA tested

(Among >=5 yrs and adult HHC with pulmonary* TB patients)

TST use : In 2023 & 2024

51,211 TST tested

(Among >=5 yrs and adult HHC with pulmonary* TB patients)

Learnings from the programmatic implementation of TB Infection Testing

- **Hesitancy among programme managers and clinicians affecting coverage:** required multipronged advocacy; developed risk communication materials; shared of scientific evidence with doctors
- **Ensuring availability of resources:** Secured sufficient resources (diagnostics, funding)
- **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. Training and re-training of the staff in the field and ensuring digital entries are recorded on real time basis.
- **Concurrent operational research:** to understand challenges and strengthen the programme




THANK YOU