Current Diagnostic and Treatment Guidelines of RNTCP – What Physicians Must Know

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The Revised National TB Control Programme (RNTCP) that applies DOTS strategy was launched in India in 1997, after extensive field-testing for technical and programmatic feasibility. The programme was expanded in a phased manner to cover the entire country in 2006. Since its inception, the programme has initiated more than 12.8 million patients on treatment, thus saving nearly 2.3 million additional lives. In 2010, RNTCP has achieved the NSP CDR of 71% and treatment success rate of 87% which is in line with the global targets for TB control. The success of DOTS in India has contributed substantially to the success of TB control in the world. [1]

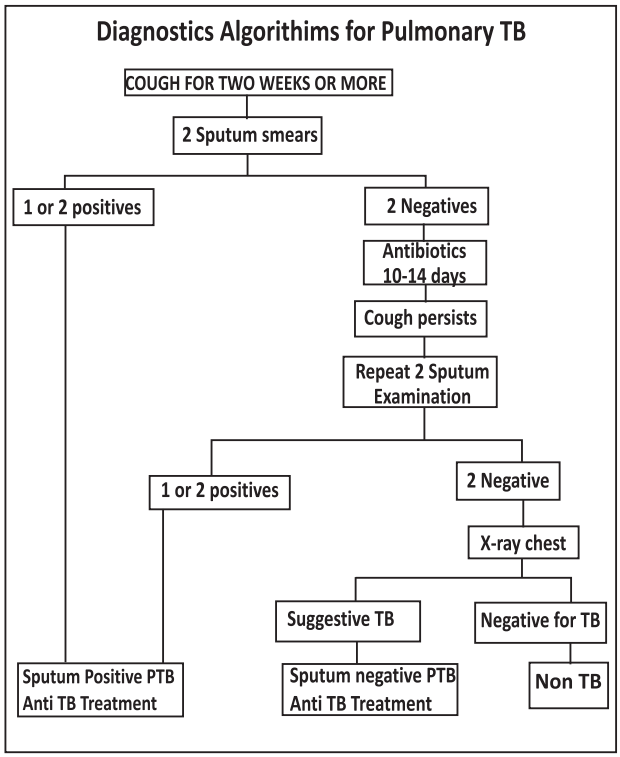
Changes in diagnostic guidelines:

In October 2008, RNTCP National Laboratory Committee recommended following changes in the diagnostic criteria of smear positive pulmonary tuberculosis: [2]

- 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 smear positive pulmonary tuberculosis (Sm +ve PTB)

In view of these changes, the laboratory committee also strongly recommends that Central TB Division, along with the National Reference Laboratories and Intermediate Reference Laboratories, take adequate steps to maintain the full range of External Quality Assurance (EQA) activities in all the RNTCP designated microscopy centres across all states and districts.

Physicians should follow new diagnostic algorithm for diagnosis of pulmonary TB in adults and children to maintain uniformity in diagnosis.



Patients in whom both specimens are smear-negative, while giving symptomatic treatment and broad-spectrum antibiotics for 10 - 14 days; antibiotics such as fluoroquinolones (ciprofloxacin, ofloxacin, etc.), rifampicin or streptomycin, which are active against tuberculosis, should not to be used. Most patients are likely to improve with antibiotics if they are not suffering from TB.

Patients suspected of having extra-pulmonary TB, and patients who are contacts of sputum smear-positive patients, should have their sputum examined for AFB if they have cough of any duration.

Basis of the diagnostic change:

How early can smear positive patients be diagnosed in programme setting? Internationally TB suspect is any person with cough for more than 2 weeks

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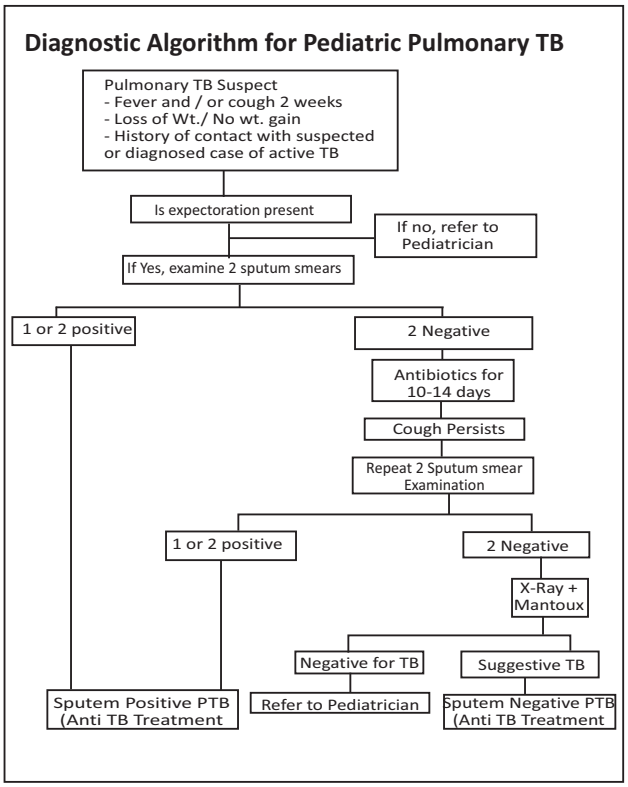

(International Standards for TB Control: 2-3 weeks; World Health Organization: more than 2 wks). Cough for less than 2 weeks has many causes and is unlikely to be TB. In cough for more than 2 weeks, TB is an important cause & in cough for 3 weeks or more, TB is even more common. Programme decision is based on prevalence of cough and TB & Lab workload. Early diagnosis of S+ve PTB reduces transmission, prevents treatment delay, reduces patient's shopping for care, improves treatment outcome & reduces duration of disease and prevalence. [2]

A cross sectional OPD based study at government health facilities in six districts of India concluded that detection of sm+ TB can be substantially improved by changing the screening criterion for sputum microscopy from cough >3 weeks to >2 weeks (Table I). In a cross sectional multi-centric study in different settings in five geographical areas in India; using ⩾ 2 weeks of cough instead of ⩾ 3 weeks as the criteria for screening, there was an overall increase of 58% in chest symptomatic and 23% increase in the detection of smear positive cases. Increase in the workload if 2 smears were done for patients with cough of ⩾ 2

Table I: 55561 OPD pts interviewed weeks were 2 and screened for TB

	Cough ≥2 wks	Cough ≥3 wks
PTB suspects	2210 (4%)	1370 (2.5%)
Sm+veTB	267	182
Positivity	12%	13%
No. of smears per health facility per day (primary and secondary level)	8 and 19	5 and 12

specimens (i.e. 13 to 15) per day for an adult OPD of 150.[4] Thus resultant increase in TB suspects and the reduction of smears per suspect is expected to balance out any impact on laboratory workload.

The diminishing return of serial smears is known from studies that have examined multiple serial specimens (Table II). Studies suggest that each serial smear adds an additional increment in case yield, but the incremental yield gets smaller with each additional examination. Program managers must thus arrive at some optimum that requires the least amount of work (number of smear examinations) to yield a large proportion of cases. [3]

In a systematic review of studies that quantifies the diagnostic yield of each of three sputum specimen; although heterogeneity in such methods and results presented challenges for data synthesis, subgroup analysis suggests that the average incremental yield and/or the increase in sensitivity of examining a

Table II: Yield of smear-positivity (India)

Study	Chest symptomatics	Smear positivity			
		Pos. on any 2	Pos. on any 1	Pos. on 1st or 2nd	Pos. on 3rd
Santha et al 2000	1715	199	209	206	3(1.4%)
Rohit Sarin 2001	7927	NA	1763	1755	8 (<1%)
Gopi et al 2004	7843	895	962	954	8 (<1%)
Thomas et al (TRC), 2008	2560	199	211	210	1(<1%)

third specimen ranged between 2% and 5% (Table III).[5]

Data from Rapid Field Evaluation during 5-9 June 2007, in states with functioning EQA concluded that reducing 3 smears to 2 smears without changing case definition means 12.5% fewer patients classified as smear positive.[2] Thus changing diagnostic criteria to 1 Sm+ve

Table III: Yield and Incremental yield

	Result 1st sputum	Result 2nd sputum	Result 3rd sputum	Incremental yield (%)*
Yield with 1st sputum	pos	irrelevant	irrelevant	85.8%
Incremental yield with 2nd sputum	neg	pos	irrelevant	11.9%
Incremental yield with 3rd sputum	neg	neg	pos	2.3%

out of 2, and screening criteria for OPD from 3 wks cough to 2 wks cough will substantially improve case detection of Sm+ve TB.

Change in treatment guidelines:

In October 2010, based on the recommendations of Joint Monitoring Mission 2009, Meeting of National Experts (NTI, September 2009) and National Task Force for Medical colleges (October 2009); Central TB Division communicated the following changes in RNTCP treatment guidelines:[6]

• Treatment regimens:

For the purpose of treatment, TB patients are classified into two groups, namely, "New" or "Previously Treated", based on the history of previous treatment. CAT III regimen has been discontinued.

Patient wise drug boxes: Drugs are supplied in patient-wise boxes (PWB) containing the full course of treatment, and packaged in blister packs. The PWB have a colour code indicating the two regimens - **Red for "New", Blue for "Previously treated".** There is no **"Green"** box for Cat III regimen.

Physicians should follow above guidelines of RNTCP to maintain uniformity in diagnosis and treatment of TB and thereby genuinely contribute in TB control efforts.

Treatment groups	Type of patient	Regimen	
		Intensive Phase (IP)	Continuation Phase (CP)
New (Cat I)	New Sputum smear-positive New Sputum smear-negative New Extra-pulmonary New Others	$2H_3R_3Z_3E_3$	$4H_3R_3$
Previously Treated (Cat II)	Smear-positive relapse Smear-positive failure Smear-positive treatment after default Others	$2H_3R_3Z_3E_3S_3$ / $1H_3R_3Z_3E_3$	$5H_3R_3E_3$

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