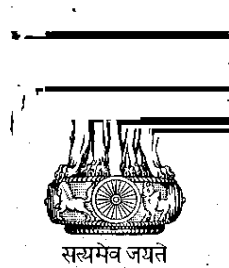


REVISED NATIONAL TB CONTROL PROGRAMME



**Central TB Division  
Directorate General of Health Services  
Ministry of Health and Family Welfare  
Nirman Bhavan, New Delhi-110 011**

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## DEFINITIONS: THE REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

### CASE DEFINITIONS

#### **Pulmonary tuberculosis, Smear-positive**

TB in a patient with at least 2 initial sputum smear examinations (direct smear microscopy) positive for AFB,

**Or:** TB in a patient with one sputum examination positive for AFB and radiographic abnormalities consistent with active pulmonary TB as determined by the treating MO,

**Or:** TB in a patient with one sputum specimen positive for AFB and culture positive for *M. tb*.

#### **Pulmonary tuberculosis, Smear-negative**

TB in a patient with symptoms suggestive of TB with at least 3 sputum examinations negative for AFB, and radiographic abnormalities consistent with active pulmonary TB as determined by an MO, followed by a decision to treat the patient with a full course of anti-tuberculosis therapy,

**Or:** Diagnosis based on positive culture but negative AFB sputum examinations.

#### **Extra-pulmonary tuberculosis**

TB of organs other than the lungs, such as the pleura (TB pleurisy), lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, tubercular meningitis, tuberculoma of the brain, etc.

Diagnosis should be based on one culture-positive specimen from the extra-pulmonary site, or histological evidence, or strong clinical evidence consistent with active extra-pulmonary TB followed by an MO's decision to treat with a full course of anti-TB therapy.

Pleurisy is classified as extra-pulmonary TB. A patient diagnosed with both pulmonary and extra-pulmonary TB should be classified as pulmonary TB.

### TYPES OF CASES

#### **New**

A patient who has never had treatment for tuberculosis or has taken anti-tuberculosis drugs for less than one month.

#### **Relapse**

A patient declared cured of TB by a physician, but who reports back to the health service and is found to be bacteriologically positive.

#### **Transferred in**

A patient who has been received into a Tuberculosis Unit/District, after starting treatment in another unit where he has been recorded.

#### **Treatment After Default**

A patient who received anti-tuberculosis treatment for one month or more from any source and who returns to treatment after having defaulted, i.e. not taken anti-TB drugs consecutively for two months or more.

#### **Failure**

A smear-positive patient who is smear-positive at 5 months or more after starting treatment. Failure also includes a patient who was initially smear-negative but who becomes smear-positive during treatment.

#### **Chronic**

A patient who remains smear-positive after completing a retreatment regimen.

#### **“Other”**

Patients who do not fit into the above-mentioned categories. Reasons for putting a patient in this category must be specified.

### TREATMENT OUTCOMES

#### **Cured**

Initially smear-positive patient who has completed treatment *and* had negative sputum smears, on at least two occasions, one of which was at completion of treatment.

#### **Treatment completed**

Sputum smear-positive case who has completed treatment, with negative smears at the end of the initial phase but none at the end of treatment.

**Or:** Sputum smear-negative TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.

**Or:** Extra-pulmonary TB patient who has received a full course of treatment and has not become smear-positive during or at the end of treatment.

#### **Died**

Patient who died during treatment, regardless of cause.

#### **Failure**

Smear-positive case who is smear-positive at 5 months or more after starting treatment. Also, a patient who was initially smear-negative but who became smear-positive during treatment.

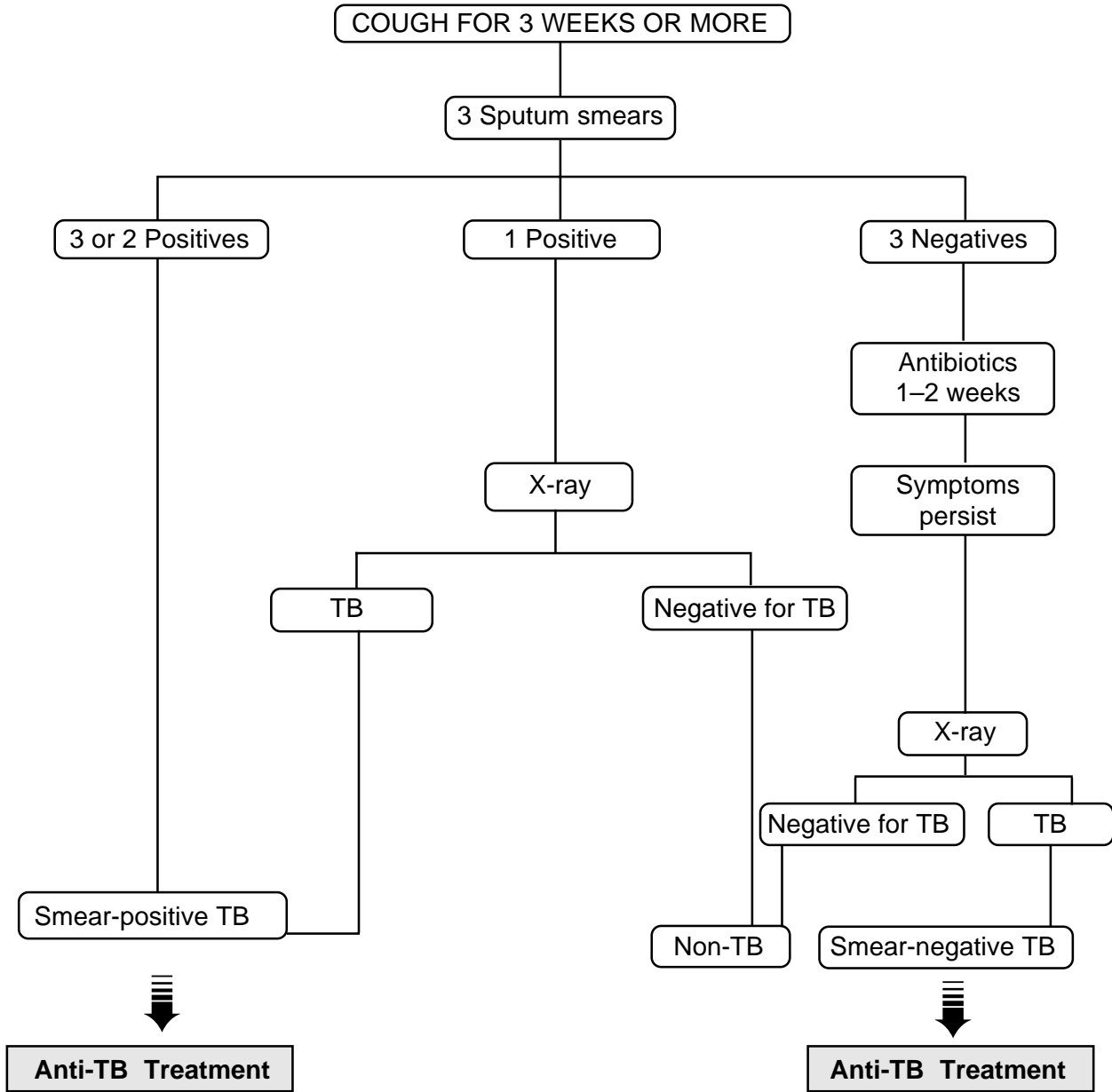
#### **Defaulted**

A patient who, at any time after registration, has not taken anti-TB drugs for 2 months or more consecutively.

#### **Transferred out**

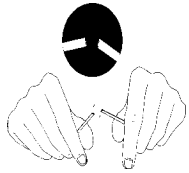
A patient who has been transferred to another Tuberculosis Unit/District and his/her treatment results are not known.

# DIAGNOSIS



## Key steps in the preparation and staining of smears

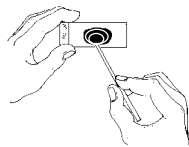
### Step 1



Break a broomstick into two



Pick up the large, yellow purulent portion of sputum



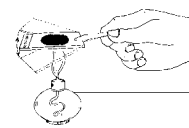
Spread evenly onto 2/3 of central portion of the numbered slide

### Step 2



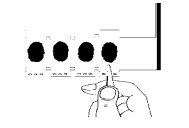
Air-dry the slide for 15–30 minutes

### Step 3

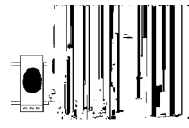


Fix the dry slide by heating briefly 3–5 times for 3–4 seconds each time

### Step 4

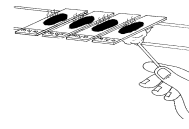


Place the slides in serial order on the staining rack



Stain the slides with 1% carbol fuchsin

### Step 5

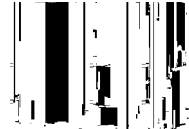


Heat the slides from underneath until vapours rise

### Step 6

Let the slides stand for 5 minutes

### Step 7



Rinse the slides with tap water



Drain off excess water

### Step 8



Decolourize with 25% sulphuric acid and let it stand for 2–4 minutes (repeat, letting stand for 1–3 minutes, if necessary)

### Step 9



Rinse away excess stain with tap water



Drain off the water

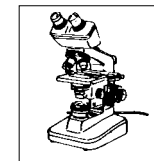
### Step 10



Counterstain with 0.1% methylene blue and let stand for 30 seconds



Gently rinse the slides with tap water, drain the water off, and allow the slide to dry



Examine the slides under the microscope

## **STAINING METHOD**

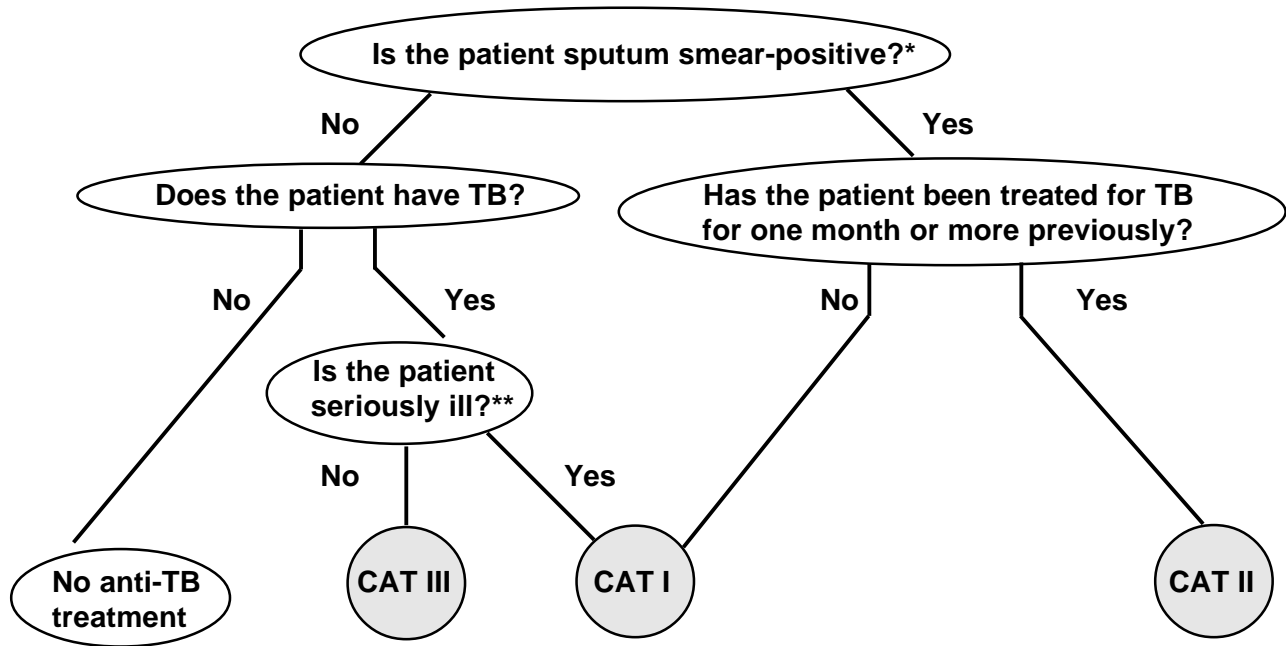
### **Ziehl–Neelsen staining**

1. Select a new unscratched slide and label the slide with the Laboratory Serial Number.
2. Spread sputum on the slide using a broomstick.
3. Allow the slide to air dry for 15–30 minutes.
4. Fix the slide by passing it over a flame 3–5 times for 3–4 seconds each time.
5. Pour filtered carbol fuchsin to cover the entire slide.
6. Gently heat the slide with carbol fuchsin on it until vapours rise. Do not boil.
7. Leave carbol fuchsin on the slide for 5 minutes.
8. Gently rinse the slide with tap water until all free carbol fuchsin stain is washed away.
9. Pour 25% sulphuric acid onto the slide.
10. Let the slide stand for 2–4 minutes.
11. Rinse gently with tap water. Tilt the slide to drain off the water.
12. If the slide is still red, reapply sulphuric acid for 1–3 minutes and rinse gently with tap water.
13. Pour 0.1% methylene blue onto the slide.
14. Leave methylene blue on the slide for 30 seconds.
15. Rinse gently with tap water.
16. Allow the slide to dry.
17. Examine the slide under the microscope using x40 lens to select the suitable area and then examine under x100 lens using a drop of immersion oil.
18. Record the results in the Laboratory Form and the Laboratory Register appropriately as per the table given below:

<b>Examination</b>	<b>Result</b>	<b>Grading</b>	<b>No. of fields to be examined</b>
More than 10 AFB per oil immersion field	Pos	3 +	20
1–10 AFB per oil immersion field	Pos	2 +	50
10–99 AFB per 100 oil immersion fields	Pos	1 +	100
1–9 AFB per 100 oil immersion fields	Scanty	Record exact number seen	200
No AFB in 100 oil immersion fields	Neg	0	100

19. Store all positive and negative slides until instructed by the supervisor.
20. Disinfect all contaminated material before discarding.

## TREATMENT



\* Patients with extra-pulmonary TB should receive Category III treatment unless they are seriously ill, in which case they should receive Category I treatment.

\*\* Examples of seriously ill patients are those suffering from meningitis, disseminated TB, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications, smear-negative pulmonary TB with extensive parenchymal involvement, intestinal and genito-urinary TB.

### Expected breakup of 135 cases under RNTCP

New smear-positive : New smear-negative 50 : 50  
 New smear-positive (CAT I) : Retreatment smear-positive (CAT II) 50 : 25 (initially)  
 New smear-positive : Extra-pulmonary 50 : 10  
 Non-seriously ill smear-negative : Seriously ill smear-negative 40 : 10  
 Non-seriously ill extra-pulmonary : Seriously ill extra-pulmonary 8 : 2

Treatment	Smear-positive	Smear-negative	Extra-pulmonary	Total
Category I	50	10 (seriously ill)	2 (seriously ill)	62
Category II	25	Nil	Nil	25
Category III	0	40	8	48
<b>Total</b>	<b>75</b>	<b>50</b>	<b>10</b>	<b>135</b>

TREATMENT REGIMEN			SPUTUM EXAMINATIONS FOR PULMONARY TB			
Category of treatment	Type of patient	Regimen <sup>†</sup>	Pre-treatment sputum	Test at month	IF: result is	THEN:
Category I	New sputum smear-positive	2(HRZE) <sub>3</sub>	+	2	-	Start continuation phase, test sputum again at 4 and 6 months <sup>‡</sup>
					+	Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months <sup>‡</sup>
	Seriously ill sputum smear-negative Seriously ill extra-pulmonary <sup>††</sup>	4(HR) <sub>3</sub>	-	2	-	Start continuation phase, test sputum again at 6 months <sup>‡</sup>
					+	Continue intensive phase for one more month, test sputum again at 3, 5 and 7 months <sup>‡</sup>
Category II	Sputum smear-positive Relapse <sup>†††</sup> Sputum smear-positive Failure <sup>†††</sup>	2(HRZES) <sub>3</sub> 1(HRZE) <sub>3</sub>	+	3	-	Start continuation phase, test sputum again at 5 and 8 months
					+	Continue intensive phase for one more month, test sputum again at 4, 6 and 9 months
Category III	Sputum smear-negative, not seriously ill Extra-pulmonary, not seriously ill	2(HRZ) <sub>3</sub> 4(HR) <sub>3</sub>	-	2	-	Start continuation phase, test sputum again at 6 months <sup>‡</sup>
					+	Re-register the patient and begin Category II treatment <sup>‡</sup>

† The number before the letters refers to the number of months of treatment. The subscript after the letters refers to the number of doses per week. H: Isoniazid (600 mg), R: Rifampicin (450 mg), Z: Pyrazinamide (1500 mg), E: Ethambutol (1200 mg), S: Streptomycin (750 mg). Patients who weigh more than 60 kg receive additional rifampicin 150 mg. Patients more than 50 years old and those who weigh less than 30 kg receive streptomycin 500 mg. 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.

†† Examples of seriously ill extra-pulmonary TB cases are meningitis, disseminated TB, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal TB with neurological complications and intestinal and genito-urinary TB.

††† In rare and exceptional cases, patients who are sputum smear-negative or who have extra-pulmonary disease can have Relapse or Failure. This diagnosis in all such cases should always be made by an MO and should be supported by culture or histological evidence of current, active tuberculosis. In these cases, the patient should be categorized as 'Other' and given Category II treatment.

‡ Any patient treated with Category I or Category III who has a positive smear at 5, 6 or 7 months of treatment should be considered a Failure and started on Category II treatment afresh.

## MEDICATION

Medication	Dose (thrice a week)	Number of pills in combipack
Isoniazid	600 mg	2
Rifampicin	450 mg*	1
Pyrazinamide	1500 mg	3
Ethambutol	1200 mg	3
Streptomycin	0.75 g**	—

\* Patients who weigh 60 kg or more are given an extra 150 mg dose of rifampicin

\*\* Patients over 50 years of age and those who weigh less than 30 kg are given 0.5 g of streptomycin

### Phases and duration of treatment

Category	Duration (number of doses)		Total
	Intensive phase	Continuation phase	
CAT I	8 weeks (24 doses)	18 weeks (54 doses)	26 weeks (78 doses)
CAT II	12 weeks (36 doses)	22 weeks (66 doses)	34 weeks (102 doses)
CAT III	8 weeks (24 doses)	18 weeks (54 doses)	26 weeks (78 doses)

### Duration of treatment if sputum smear is positive at 2/3<sup>†</sup> months

Category	Duration (number of doses)		Total
	Intensive phase	Continuation phase	
CAT I	12 weeks (36 doses)	18 weeks (54 doses)	30 weeks (90 doses)
CAT II	16 weeks (48 doses)	22 weeks (66 doses)	38 weeks (114 doses)

<sup>†</sup> CAT I—positive at 2 months    CAT II—positive at 3 months

## MANAGEMENT OF PATIENTS WHO INTERRUPT TREATMENT

Management of patients who were **smear-negative** at diagnosis  
and who interrupt treatment

Treatment received before interruption	Length of interruption	Do a sputum smear examination	Result of sputum smear examination	Outcome	Re-registration	Treatment
<b>Less than 1 month</b>	Less than 2 months	No	—	—	—	Resume treatment and complete all doses
	2 months or more	Yes	Negative	—	—	Resume treatment
			<b>Positive</b>	Default	New	Begin CAT I afresh
<b>More than 1 month</b>	Less than 2 months	No	—	—	—	Resume treatment and complete all doses
	More than 2 months	Yes	Negative	—	—	Resume treatment and complete all doses
			<b>Positive</b>	Default	Treatment After Default	Begin CAT II treatment afresh

## MANAGEMENT OF PATIENTS WHO INTERRUPT TREATMENT

Management of **New smear-positive** cases who interrupt treatment (Category I)

Treatment received before interruption	Length of interruption	Do a sputum smear examination?	Result of sputum smear examination	Outcome	Re-registration	Treatment
Less than 1 month	Less than 2 weeks	No	—	—	—	Continue CAT I*
	2–7 weeks	No	—	—	—	Start again on CAT I**
	8 weeks or more	Yes	Positive	Default	New	Start again on CAT I**
			Negative	—	—	Continue CAT I*
1–2 months	Less than 2 weeks	No	—	—	—	Continue CAT I*
	2–7 weeks	Yes	Positive	—	—	1 extra month of intensive phase of CAT I
			Negative	—	—	Continue CAT I*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start on CAT II**
			Negative	—	—	Continue CAT I*
More than 2 months	Less than 2 weeks	No	—	—	—	Continue CAT I*
	2–7 weeks	Yes	Positive	Default***	Other	Start on CAT II**
			Negative	—	—	Continue CAT I*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start on CAT II**
			Negative	—	—	Continue CAT I*

\* A patient must complete all **24 doses** of the initial intensive phase. For example, if a patient has to **continue** his previous treatment and he took 1 month of treatment (12 doses) before interrupting, he will have to take 1 more month (12 doses) of the intensive phase treatment. He will then start the continuation phase of treatment.

\*\* A patient who must 'start again' will *restart treatment from the beginning*.

\*\*\* Although this patient does not strictly fit the definition of default, default most closely describes the outcome of this patient, although at re-registration they should be categorized as 'Other'.

## MANAGEMENT OF PATIENTS WHO INTERRUPT TREATMENT

Management of **retreatment smear-positive** cases who interrupt treatment (Category II)

Treatment received before interruption	Length of interruption	Do a sputum smear examination?	Result of sputum smear examination	Outcome	Re-registration	Treatment
<b>Less than 1 month</b>	Less than 2 weeks	No	—	—	—	Continue CAT II*
	2–7 weeks	No	—	—	—	Start again on CAT II**
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start again on CAT II**
			Negative	—	—	Continue CAT II*
<b>1–2 months</b>	Less than 2 weeks	No	—	—	—	Continue CAT II*
	2–7 weeks	Yes	Positive	—	—	1 extra month of intensive phase of CAT II
			Negative	—	—	Continue CAT II*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start again on CAT II**
			Negative	—	—	Continue CAT II*
<b>More than 2 months</b>	Less than 2 weeks	No	—	—	—	Continue CAT II*
	2–7 weeks	Yes	Positive	Default**	Other	Start again on CAT II
			Negative	—	—	Continue CAT II*
	8 weeks or more	Yes	Positive	Default	Treatment After Default	Start again on CAT II
			Negative	—	—	Continue CAT II*

\* A patient must complete all **36 doses** of the initial intensive phase.

\*\* Although this patient does not strictly fit the definition of default, default most closely describes the outcome of this patient, although at re-registration they should be categorized as 'Other'.

## TREATMENT OF CHILDREN

### Dosages for children

Drugs	Therapy per dose (thrice a week)
Isoniazid	10–15 mg/kg
Rifampicin	10 mg/kg
Pyrazinamide	35 mg/kg
Streptomycin	15 mg/kg
Ethambutol*	30 mg/kg

\* Should not be given to children below 6 years of age

### How to proceed with preventive chemotherapy in children under 6 years of age who were in contact with a smear-positive case

IF:	AND:	THEN:	
The child has symptoms of tuberculosis	an MO determines (preferably in consultation with a paediatrician) that the child has tuberculosis	a full course of anti-tuberculosis treatment (CAT III) should be given.	
The child does not have symptoms of tuberculosis	a tuberculin test is <b>not</b> available	the child should receive preventive chemotherapy for 6 months (isoniazid daily—5 mg per kg body weight).	
	a tuberculin test is available	the child should receive 3 months of INH preventive chemotherapy and a tuberculin test should then be done.	
		IF:	THEN:
		The child's induration to the tuberculin test is less than 6 millimetres in diameter	stop the preventive chemotherapy and give BCG vaccination (if not previously vaccinated).
The child's induration to the tuberculin test is 6 millimetres or more in diameter	continue isoniazid preventive chemotherapy for another 3 months.		

## POSSIBLE SIDE-EFFECTS OF ANTI-TUBERCULOSIS DRUGS

Symptom	Drug (abbreviation)	Action to be taken
Drowsiness	Isoniazid (H)	Reassure patient
Red–orange urine/tears	Rifampicin (R)	Reassure patient
Gastrointestinal upset	Any oral medication	Reassure patient Give drugs with less water Give drugs over a longer period of time (e.g. 20 minutes) Do not give drugs on empty stomach If the above fails, give anti-emetic if appropriate
Burning in the hands and feet	Isoniazid (H)	Give pyridoxine 100 mg/day until symptoms subside
Joint pains	Pyrazinamide (Z)	If severe, refer patient for evaluation
Impaired vision	Ethambutol (E)	STOP ethambutol, refer patient for evaluation
Ringing in the ears	Streptomycin (S)	STOP streptomycin, refer patient for evaluation
Loss of hearing	Streptomycin (S)	STOP streptomycin, refer patient for evaluation
Dizziness and loss of balance	Streptomycin (S)	STOP streptomycin, refer patient for evaluation
Jaundice	Isoniazid (H) Rifampicin (R) Pyrazinamide (Z)	STOP treatment, refer patient for evaluation

**In all cases of jaundice, anti-tuberculosis drugs should be stopped immediately and the patient referred for evaluation.**

## SUPERVISORY VISITS

Category of supervisor	Methodology of supervision	Number of supervisory visits
<p>DTO/MO (DTC)</p>	<p><b>Interview</b> the MO-TC, MO I/C of PHC-CHC, STS, STLS and the person incharge of anti-TB drug storage.</p> <p><b>Random interview</b> of patients and community leaders.</p> <p><b>Inspection</b> of records of the TU, PHC and CHC, and stock of anti-TB drugs and laboratory consumables.</p> <p><b>Random checking</b> of the microscopy centre and sub-centre.</p>	<p>To visit all TUs every month, all CHCs and Block PHCs in the district every quarter, one sub-centre from each Block PHC area and a proportion of tribal sub-centres every quarter.</p>
<p>MO-TC (Tuberculosis Unit)</p>	<p><b>Interview</b> the MO I/C BPHC/CHC/PHC. <b>Random interview</b> of patients and community leaders.</p> <p><b>Random checking</b> of the microscopy centre and sub-centre stock of anti-tuberculosis drugs and laboratory consumables.</p>	<p>To visit at least once every quarter all CHCs/BPHCs/PHCs, microscopy centres, and a proportion of sub-centres.</p>
<p>STS</p>	<p><b>Interview</b> MPHS and MPWs at the PHC sub-centre. <b>Inspect</b> records, Tuberculosis Treatment Cards and Tuberculosis Laboratory Register.</p> <p><b>Random interview</b> of patients.</p>	<p>To visit all PHCs and CHCs every month and all sub-centres every quarter.</p>
<p>STLS</p>	<p><b>Inspect</b> all microscopy centres and laboratory records.</p>	<p>To visit all microscopy centres in the jurisdiction of the TU at least once a month.</p>

## SUMMARY OF KEY INDICATORS AND POSSIBLE ACTIONS

Quarterly Report	Indicator	Possible Actions
<b>New and retreatment cases</b>		
<b>Expected:</b> New smear-positive cases: 40–85/100 000	Calculated annualized incidence of New smear-positive cases is less than 40/100 000	Ensure that chest symptomatics in all facilities undergo sputum smear examination (at least 2% adult outpatients).  Ensure that three sputum smear examinations are being done on all chest symptomatics.  Ensure that sputum smear microscopy is being done correctly (5%–15% positivity among patients examined for diagnosis). Intensify review of slides read as smear-negative, particularly those of patients placed on treatment.  Ensure that all smear-positives in the Laboratory Register are recorded in the Tuberculosis Register.  Ensure that sputum smear microscopy is accessible to patients throughout the assigned area, with trained laboratory technicians in place.
	Calculated annualized incidence of New smear-positive cases is more than 85/100 000	Ensure that active case-finding is not being done in any area.  Ensure that sputum smear microscopy is accurate. Ensure review of slides of smear-positive patients.  Ensure that only patients who reside in the area are being treated.
<b>Expected:</b> Retreatment smear-positive cases are 50% of New smear-positive cases in initial years of RNTCP implementation	Retreatment cases are less than 40% of New smear-positive cases	Ensure that accurate history-taking is being done at all levels. Patients must be questioned carefully about prior treatment for tuberculosis from any source. It should be explained to patients that only if they provide accurate information can the most effective treatment be given.  Make sure that definitions are being applied correctly. Any smear-positive patient treated in the past for more than one month and has defaulted for more than two months, should receive the retreatment (CAT II) regimen.
	Retreatment cases are more than 70% of New smear-positive cases	Ensure that active case-finding is not occurring. With active case-finding, many 'old' TB cases are reported.  Ensure that history-taking is accurate and definitions are being correctly applied.  Ensure that new symptomatic patients undergo three sputum smear examinations for acid-fast bacilli (AFB).
<b>Expected:</b> At least 50% of all New pulmonary cases will be smear-positive	Among New pulmonary cases, proportion which are smear-positive is less than 40%	Ensure that over-diagnosis of sputum smear-negative patients is not occurring on account of over-reliance on radiography. No patient should begin treatment without having three sputum smear examinations done.  Ensure that three sputum smear examinations are being done on all chest symptomatics.  Ensure that sputum smear microscopy is being done correctly. Consider review of slides of smear-negative patients placed on treatment.

## SUMMARY OF KEY INDICATORS AND POSSIBLE ACTIONS

Quarterly Report	Indicator	Possible Actions
<b>New and retreatment cases (continued)</b>		
<p><b>Expected:</b> No more than 20% of smear-negative/extra-pulmonary patients are considered seriously ill and placed under CAT I</p>	<p>The proportion of smear-negative or extra-pulmonary seriously ill patients included in CAT I is greater than 25%</p>	<p>Ensure that only seriously ill patients are given CAT I treatment. Non-seriously ill smear-negative New patients should receive CAT III treatment.</p> <p>Ensure that sputum microscopy is being done correctly. Consider review of slides of smear-negative patients placed on treatment.</p>
<b>Conversion</b>		
<p><b>Expected:</b> Conversion rate is 90%</p>	<p>Less than 85% of smear-positive CAT I patients are documented to become sputum smear-negative at 3 months</p>	<p>Ensure that Medical Officers, treatment supervisors, and all staff in the programme and at peripheral centres understand the importance of follow-up sputum examinations. Follow-up sputum examinations are the best measure of patient response to treatment. Results of sputum examinations change patient treatment and are critical to programme evaluation.</p> <p>Visit all centres with low rates of sputum conversion and resolve any problems with the help of the staff.</p> <p>Make sure defaulter rates in the first two months are &lt;5%, and that there is not an excess of patients who die or who are transferred out.</p> <p>Visit centres with a low sputum smear conversion rate to discuss with patients and staff about potential reasons. Make sure each centre is aware of their result so that they may take steps to improve performance.</p> <p>Ensure that accurate history-taking is being done at all levels. Patients must be questioned carefully about prior treatment for tuberculosis from any source. It should be explained to patients that only if they provide accurate information can the most effective treatment be given. If previously treated patients are not given the retreatment regimen, they may not respond well to treatment.</p> <p>Make sure that definitions are being applied correctly. Any smear-positive patient treated for more than one month in the past, and with default of more than two months, should receive the retreatment (CAT II) regimen. If previously treated patients are not given the retreatment regimen, they may not respond well to treatment.</p> <p>Ensure that sputum microscopy is accurate. Ensure review of slides of patients who remained smear-positive at the end of the intensive phase.</p> <p>Ensure that every dose of medication is observed during the intensive phase of treatment. Observation sites should be convenient to the patient. The possibility that DOTS is not being strictly followed should be checked by observation, including checking and comparing Treatment Cards with the drugs available in patient-wise boxes.</p>

## SUMMARY OF KEY INDICATORS AND POSSIBLE ACTIONS

Quarterly Report	Indicator	Possible Actions
<b>Treatment outcome</b>		
<b>Expected:</b> Cure rate is 85% or more	Cure rate of smear-positive patients is less than 80%	<p>Visit centres with low cure rates to discuss with patients and staff the reasons and possible solutions. Make sure that each centre is aware of its cure rate so that it can take steps to improve performance.</p> <p>Ensure that accurate history-taking is being done at all levels. Patients must be questioned carefully about prior treatment for tuberculosis from any source. It should be explained to patients that only if they provide accurate information can the most effective treatment be given. If previously treated patients are not given the retreatment regimen, they may not respond well to treatment.</p> <p>Make sure that definitions are being applied correctly. Any smear-positive patient treated for more than one month in the past, with default of more than two months, should receive the retreatment (CAT II) regimen.</p> <p>Ensure that every dose of medication is observed during the intensive phase of treatment, and at least one dose per week in the continuation phase. Ensure return of empty blister packs during weekly collection of drugs. Observation sites should be convenient for the patient.</p> <p>Ensure that health workers are dispensing medication properly as per technical guidelines.</p> <p>Ensure that follow-up sputum smear examinations are being done according to guidelines.</p>
	Cure rate of smear-positive CAT I patients is more than 95%	Check to make sure the report is correct. If it is, consider checking to make sure that reporting and classification of treatment outcomes is being done correctly and that all detected smear-positive patients are registered.
<b>Expected:</b> No more than 3% of smear-positive patients are given the treatment outcome 'complete'	Per cent of New smear-positive patients who are classified as having 'completed' treatment is more than 5%	<p>Ensure that follow-up sputum examinations are being done as per policy. Carefully track this at all New treatment units.</p> <p>Explain to Medical Officers and others the crucial importance of the follow-up sputum examinations.</p> <p>Locate patients who have recently completed treatment and obtain sputum samples for examination.</p> <p>Carefully review all data on patients to ensure accuracy of information and to ensure that treatment is being given under direct observation as per policy.</p>
<b>Expected:</b> No more than 4% New smear-positive patients die during treatment	Per cent of New smear-positive patients who die during treatment is more than 5%	<p>Ensure that every dose of medication is observed during the intensive phase of treatment, and at least one dose per week in the continuation phase. Observation sites should be convenient to the patient.</p> <p>Review information on patients who died to determine the reasons.</p> <p>If patients are presenting for treatment when already moribund, consider ways and means to encourage more prompt referral and diagnosis so that patients can be treated earlier in the course of their TB illness.</p> <p>If all of the above has been done and death rate is still more than 5%, consider evaluation of the prevalence of HIV infection among TB patients, to be done strictly as per policy with safeguards of confidentiality.</p>

## SUMMARY OF KEY INDICATORS AND POSSIBLE ACTIONS

Quarterly Report	Indicator	Possible Actions
<b>Treatment outcome</b>		
<p><b>Expected:</b> Failure: No more than 4% of New smear-positive patients are smear-positive 5 or more months after the start of treatment</p>	<p>Per cent of New smear-positive patients who fail treatment is more than 5%</p>	<p>Ensure that accurate history-taking is being done at all levels. Patients must be questioned carefully about prior treatment for tuberculosis from any source. It should be explained to patients that only if they provide accurate information can the most effective treatment be given. If previously treated patients are not given the retreatment regimen, they may not respond well to treatment.</p> <p>Make sure that definitions are being applied correctly. Any smear-positive patient treated for more than one month in the past, with default of more than two months, should receive the retreatment (CAT II) regimen.</p> <p>Ensure that every dose of medication is observed during the intensive phase of treatment, and at least one dose per week in the continuation phase. Ensure return of empty blister packs during weekly collection of drugs. Observation sites should be convenient for the patient.</p> <p>Ensure that health workers are dispensing medication properly as per technical guidelines.</p> <p>Ensure that drugs are of acceptable quality, that drugs are stored in appropriate conditions, and that they are being used before their expiry period.</p> <p>If all of the above has been done and failure rate remains higher than 5%, consider evaluation of the level of primary drug resistance in the community.</p>
<p><b>Expected:</b> Default rate is less than 5%</p>	<p>Default rate of smear-positive CAT I patients is more than 10%</p>	<p>Visit centres which have the highest default rates and interview staff and patients to determine the efforts made to retrieve patients, the reasons for default and possible solutions. Make sure that centres are aware of their default rate so they can take steps to reduce it.</p> <p>Ensure that patient history is being carefully ascertained, including the address. A visit to patients' homes should be made to verify addresses, and landmarks near the house should be recorded in the Treatment Card. To the greatest extent possible, services should be convenient to the patient in terms of distance, time and staff attitudes.</p> <p>During the visit to the house for verification of address, note the name and address of a person who can be contacted in the event the patient defaults.</p> <p>Ensure that directly observed treatment is being given to patients in the intensive phase and at least one dose per week is being directly observed during the continuation phase.</p> <p>Ensure that each centre is aware of its own default rate so that it can take steps to improve performance.</p>
<p><b>Expected:</b> Transferred out is less than 3%</p>	<p>Percentage of patients who fall under outcome category 'Transferred out' is more than 5%</p>	<p>'Transfer out' can be a way of disguising default. Patients should only be categorized as 'Transferred out' if they have been given a Transfer Form to bring to the jurisdiction to which they are being transferred. Ensure that counterfoils have been received.</p>

## REPORTING

### Due dates for reports from Tuberculosis Units to DTC

Due On	Quarterly Report	Period Covered
7 January 2000	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 October–31 December 1999 1 October–31 December 1999 1 July–30 September 1999 1 October–31 December 1998
7 April 2000	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 January–31 March 2000 1 January–31 March 2000 1 October–31 December 1999 1 January–31 March 1999
7 July 2000	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 April–30 June 2000 1 April–30 June 2000 1 January–31 March 2000 1 April–30 June 1999
7 October 2000	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 July–30 September 2000 1 July–30 September 2000 1 April–30 June 2000 1 July–30 September 1999
7 January 2001	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 October–31 December 2000 1 October–31 December 2000 1 July–30 September 2000 1 October–31 December 1999
7 April 2001	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 January–31 March 2001 1 January–31 March 2001 1 October–31 December 2000 1 January–31 March 2000
7 July 2001	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 April–30 June 2001 1 April–30 June 2001 1 January–31 March 2001 1 April–30 June 2000
7 October 2001	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 July–30 September 2001 1 July–30 September 2001 1 April–30 June 2001 1 July–30 September 2000
7 January 2002	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 October–31 December 2001 1 October–31 December 2001 1 July–30 September 2001 1 October–31 December 2000
7 April 2002	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 January–31 March 2002 1 January–31 March 2002 1 October–31 December 2001 1 January–31 March 2001
7 July 2002	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 April–30 June 2002 1 April–30 June 2002 1 January–31 March 2002 1 April–30 June 2001
7 October 2002	New and Retreatment Cases Programme Management Sputum Conversion Cohort Treatment Outcome Cohort	1 July–30 September 2002 1 July–30 September 2002 1 April–30 June 2002 1 July–30 September 2001

The District TB Officer is to retain one copy for records and send the quarterly reports to the State TB Officer, The National Tuberculosis Institute ('Avalon' 8, Bellary Road, Bangalore 560 003), and the Central TB Division (Nirman Bhavan, Directorate General of Health Services, Ministry of Health and Family Welfare, New Delhi 110 011). All reports to reach Central TB Division by the 24th of the month.