ANNEXURES
&
APPENDIX

Annexure -1

Ziehl-neelsen staining procedure

1. A new unscratched slide is selected and the slide is labelled with the Laboratory Serial Number with a diamond marking pencil.
2. A smear is made from yellow purulent portion of the sputum using a broom stick. A good smear is spread evenly, 2 cms x 3 cms in size and is neither too thick nor too thin. The optimum thickness of the smear can be assessed by placing the smear on a printed matter. The print should be readable through the smear. Smear preparation should be done near a flame. This is required, as six inches around the flame is considered as a sterile zone which coagulates the aerosol raised during smear preparation.
3. The slide is allowed to air dry for 15–30 minutes.
4. The slide is fixed by passing it over a flame 3–5 times for 3–4 seconds each time.
5. 1% filtered carbol fuchsin is poured to cover the entire slide.
6. The slide is gently heated with carbol fuchsin on it, until vapours rise. Do not boil.
7. Carbol fuchsin is left on the slide for 5 minutes.
8. The slide is gently rinsed with tap water until all free carbol fuchsin stain is washed away. At this point, the smear on the slide looks red in colour.
9. 25% sulphuric acid is poured onto the slide and allowed to stand for 2–4 minutes.
10. The slide is gently rinsed with tap water and tilted to drain off the water.
11. A properly decolourised slide appears light pink in color .If the slide is still red, sulphuric acid is reapplied for 1–3 minutes and then rinsed gently with tap water.The back of the slide is wiped clean with a swab dipped in sulphuric acid,
12. 0.1% methylene blue is poured onto the slide and left for 30 seconds. Then theslide is rinsed gently with tap water and allowed to dry.
13. The slide is examined under the binocular microscope using x40 lens to select the suitable area and then examined under x100 lens using a drop of immersion oil.
14. The results are recorded in the Laboratory Form and the Laboratory Register.
15. The slides are inverted on a tissue paper till the immersion oil is completelyabsorbed. Xylene is not to be used for cleaning the slides, as it may give falseresults at repeat examination after storage.
16. All positive and negative slides are stored serially in the same slide-box untilinstructed by the supervisor.
17. All contaminated materials are disinfected as per guidelines before discarding.

Grading of smears

The table below depicts information on grading and the number of fields to be examined in different situations:-

Examination finding	No. of fields examined	Grading	Result
No AFB in 100 oil immersion fields	100	0	Neg
1-9 AFB per 100 oil immersion fields	100	Scanty*	Pos
10-99 AFB per 100 oil immersion fields	100	1+	Pos
1-10 AFB per oil immersion field	50	2+	Pos
More than 10 AFB per oil immersionfield	20	3+	Pos

*Record actual number of bacilli seen in 100 fields – e.g. “Scanty 4”

Annexure -2

Fluorescence staining procedure

Smear Preparation-

- Mark a new, clean, grease free slide with laboratory number
- Pick the purulent portion of the sputum using the crushed end of the broom stick
- Prepare smear in an oval shape in the centre of the slide(3x2cm), for good spreading of sputum firmly press the stick perpendicular to the slide and move in small concentric circles
- Thorough spreading of sputum is very important; it should be neither too thick nor too thin. Prior to staining, hold the smear about 4-5 cm over a piece of printed paper, if letters cannot be read, it is too thick.
- Allow smear to air dry at room temperature
- Heat fix by passing the slide over flame 2-3 times for about 2-3 seconds each time. (Do not heat or keep the slide stationary over the flame or for too long or else it will be scorched)

Staining

Arrange slides in serial order on staining bridge, with smear side up, at a distance of at leastone cm between every slide

1. Flood the slide with filtered 0.1% Auramine solution
2. Do not heat
3. Keep the staining reagent for at least 20 min; make sure that the smear area iscontinuously covered with Auramine by adding more if needed
4. Rinse with water and drain
5. Apply decolourising solution, 0.5% acid alcohol for 3 minutes
6. Gently rinse with water until the macroscopically visible stain has been washed awayand drained
7. Flood smear with 0.5% potassium permanganate solution for 1 minute. Time iscritical because counter staining for longer time may quench the acid fast bacillifluorescence.
8. Gently rinse with water and drain
9. Air dry on a slide rack away from sunlight. If they are not read immediately placethem in slide box.

Reading

- Keep stained smears in the dark (box or folder), and read on the same day of staining as the fluorescence is prone to fading with time.
- To be able to focus with ease, better to read first a positive control smear stained by auramine O
- Use the objective 20x for focusing and read the slide using 40X objective (avoid using oil and immersion 100X objective, inexperienced readers should ask confirmation from a supervisor)
- Scan the stained smear systematically from one side to the other, for one length of the smear
- Acid-fast bacilli appear bright yellow against the dark background material.
- Store the slides in a slide box following the Laboratory Register Number as they will be needed for EQA. Do not write the result on the slide.

Grading of smears

The table below depicts information on grading and the number of fields to be examined in different situations:-

200-250x magnification: 1 length = 30 fields = 300 HPF	**400x magnification: 1 length = 40 fields = 400 HPF**	**Grading**	**Result**
No AFB per 1 length	No AFB per 1 length	0	Neg
1-29 AFB per 1 length	1-19 AFB per 1 length	Scanty*	Pos
30-299 AFB per 1 length	20-199 AFB per 1 length	1+	Pos
10-100 AFB per 1 field on average	5-50 AFB per 1 field on average	2+	Pos
More than 100 AFB per 1 field on average	More than 50 AFB per 1 field on average	3+	Pos

Annexure 3

Specimen collection and Transport of samples to C & DST laboratory (including CBNAAT laboratory)

Specimen Collection

An often-overlooked problem is that of obtaining adequate good quality specimens at theperipheral laboratories. Unless specimens are collected with care and promptly transported tothe laboratory under temperature control, diagnosis may be missed, and the patient couldmiss the chance to be detected and put on the correct treatment. A good sputum specimenmay literally make the difference between life and death, and allow containment of thedisease and prevent spread to others in the family and community.

The Laboratory technician needs to explain the process of collecting “a good quality sputumspecimen” and avoid using vernacular terminologies that convey the meaning as salivainstead of sputum. In addition though the general guideline for collection of sputa is one spotand one morning, this does not preclude from collecting 2 spot specimens that need to becollected with a gap of at least one hour (60 minutes) if the patient is coming from a longdistance or there is a likelihood that the patient may default to give a second specimen.

A good sputum specimen consists of recently discharged material from the bronchial tree,with minimum amounts of oral or nasopharyngeal material. Satisfactory quality implies thepresence of mucoid or mucopurulent material. Ideally, a sputum specimen should have avolume of 3-5ml. The patient must be advised to collect the specimen in a sterile container(falcon tube) after through rinsing of the oral cavity with clean water.

Specimens should be transported to the laboratory as soon as possible after collection. Ifdelay is unavoidable, the specimens should be refrigerated up to 1 week to inhibit the growthof unwanted micro-organisms.

Specimen transportation to culture-DST laboratories

Fresh sputum samples will need to be transported from the DMC to the RNTCP-certified CDSTlaboratory in cold chain within 72 hours. Ideally an agency (courier /

speed post) with apan district presence should be identified for this purpose. Two innovative models forspecimen collection and transport using fresh samples in falcon tubes to be transported incold chain using gel packs and their technical specifications have been developed by Gujarat(from peripheral DMCs) and Andhra Pradesh (from high burden DMCs at TUs/DTCs).

All states and districts should establish sample transport system in cold chain irrespective ofthe time taken for transport considering the hot climatic conditions in most of the statesduring most of the year. An appropriate courier / speed post service with pan district presenceshould be identified and contracted by the DTO of every district for prompt transport of thespecimen cold box on the same day from the DMC linked to the courier / speed post office inthe locality to the assigned RNTCP-certified C-DST laboratory.

The following points are critical for the collection of fresh sputum samples at DMCs:

- The falcon tubes and the 3 layer packing materials like thermocol box, ice gel pack (pre-freezed at -20 degree for 48 hours), request for C-DST forms, polythene bags, tissue paper roll as absorbent, para-film tapes, brown tape for packaging box, permanent marker pen,labels, bio-hazard sticker, scissors, spirit swab etc. should be supplied to the DMCs forcollection of sputum through the DTO.
- The falcon tubes should carry a label indicating the date of collection of the samples andthe patient’s details like name, date of sample collection, name of DMC/DTC, Lab. No:-XYZ, specimen A or B
- The Lab technicians at DMCs should be trained to carefully pack the sputum samples in thecold box to avoid spillage of the samples.
- The LT of DMC issuing the falcon tubes to the patients should also give clear instructionsto the patients on correct technique of collection of the sputum. Also the date of issue of thefalcon tubes to the patient should be recorded.
- The LT of the DMC should ensure that the request for C-DST form is packed in a separateplastic zip pouch and placed in the cold box before sealing the lid of the box. Also, the biohazardsymbol should be pasted on the external side of the cold box along with the labelindicating the postal address of the RNTCP-certified C-DST Lab assigned.

- The LT of the DMC should promptly inform the sample transport agency like a courier /speed post service, speed post or a human carrier to collect and transport the samples

As per the national guidelines for biomedical waste management the containers used fortransporting sputum samples to the RNTCP-certified laboratory should be labelled with a “BIO-HAZARD” sticker.

For every presumptive DR TB referred by the MO-DMC, the date of referral and transport ofsputa samples to the Culture & DST laboratory should be entered in the “Remarks” columnof the respective DMC Lab register and the TB notification register**.** Alternatively the presumptive DR-TB patients referred to nearby DMCselected for sample collection and transport for C-DST may be provided two falcon tubes bythe concerned DMC LT/MO and instructed on collecting two samples (one early morningand one supervised spot). These samples will be taken by the patient / relative to the DMCselected for sample collection for C-DST from where these will be packed in cold boxes andtransported to the RNTCP-certified laboratory for culture and DST. Once the sputum hasbeen transported to the RNTCP-certified laboratory, the p should return tocontinue their RNTCP DOTS treatment.

Standard Operative Procedure for collection, transport and processing and inoculation of Extra-pulmonary specimens

1. *Introduction:*

Mycobacteria may not be suspected as the causative agent of an extra pulmonary disease because the chest X-ray or the tuberculin test is negative or both. However, based on clinical symptoms and because mycobacteria can infect almost any organ in the body, the laboratory should expect to receive a variety of extra pulmonary specimens such as body fluids, surgically excised tissues, aspirates or draining pus and urine.

Extra pulmonary specimens are divided in to two groups based on the site and mode of collection and the extent of contamination.

- Aseptically collected specimens, usually free from other microorganisms (sterile) **–** fluids like spinal, pleural, pericardial, synovial, ascitic, blood, bone marrow, tissues (lymph node, tissue biopsies) and fine needle aspirates (FNAs)
- Specimens contaminated by normal flora or specimens not collected aseptically (not sterile) **–** gastric lavage, bronchial washings, urine , pus and stool (in case of disseminated TB in HIV infected patients and infants)

2. *Collection of extra pulmonary specimens*

Body fluids (spinal, pleural, pericardial, synovial, ascitic, bone-marrow) should be aseptically collected in a sterile container by the physician using aspiration techniques or surgical procedures. Specimens should be transported to the laboratory as quickly as possible.

2.1 Pleural fluid

Considered a suboptimal specimen as tubercle bacilli are mainly in the pleural wall and not within the fluid. The minimum volume for pleural fluid required for processing for culture is 20**–**50ml. The fluid is collected using pleural tap or thoracocentesis.

2.2 Pericardial fluid

Should be collected using ultra sonogram

2.3 Blood

Blood as a specimen for isolating *M. tuberculosis* should be generally discouraged for the low diagnostic yield and high possibility of contamination with respect to the technique required for its culture. However, if there are specific indications when a physician suspects disseminated TB in a HIV infected patient, blood can be collected provided, the culture systems for recovery of

mycobacteria is available in that laboratory (BacTAlert, MB Bact or MycolyticF medium on BACTEC 9050 systems)

2.4 Tissues

The aseptically collected tissues are placed by the physician in sterile containers preferably without fixatives or preservatives. If the specimen is to be shipped, it should be protected from drying by adding sterile saline or ideally in selective Kirchner's liquid medium and maintaining a temperature of 4- 15^{0}C. Specimens should be transported to the laboratory as quickly as possible.

2.5 Swabs

Swabs are always sub optimal specimens and not recommended because of risk of infection for specimen collector. They may be useful in children and patients who cannot produce sputum or may swallow it. A sterile absorbent cotton swab should be used for collection. The best time for the collection is early morning before food and drinks are taken. The swab should be placed in a screw capped container containing normal (0.9%) saline to prevent drying. Swabs except for laryngeal swabs or from discharging sinus should be avoided.

2.6 Urine

Among specimens expected to be contaminated, urine is the most common. To minimize excessive contamination of urine specimens, special instructions for collecting urine with adequate cleansing of external genitalia to prevent contamination by commensals should be given. Early morning sample should be collected in 500 ml screw capped sterile containers. Once received in the laboratory, urine must be immediately processed or centrifuged and the pellet refrigerated for further processing. As excretion of tubercle bacilli in urine is intermittent, three early morning specimens must be collected on different days.

2.7 Bronchial secretions

Other respiratory specimens that can be submitted to the laboratory for mycobacteria culture are bronchial secretions (minimum volume: 2- 5ml) and bronchial alveolar lavage (BAL) (minimum volume of 20 – 50 ml). Trans-bronchial and other biopsies should be collected under sterile conditions and placed in 0.5-1.0 ml of sterile normal (0.9%) saline to prevent drying during transportation to the laboratory.

2.8 Gastric Lavage

In children, who rarely produce sputum, the aspiration of the early morning (gastric content) may be used for TB diagnosis. This is done as an inpatient procedure. This should be transported immediately to the lab and processed (nor more than 4 hours) to prevent the killing action of the acid content in the gastric lavage on the tubercle bacilli. In the event of delay, the sample can be neutralised using 1-2 ml of sterile 10 % sodium bicarbonate solution depending on the volume of gastric aspirate. Trisodium phosphate at a final concentration of

25% can be used but it may affect the viability of tubercle bacilli with prolonged storage.

NOTE:

- Samples for culture should **never be** collected in formalin.
- If histo pathological examination is required, two samples should be collected
- No preservative should be used for any extra-pulmonary specimen for culture. Necessary instructions are to be given to the concerned staff for sending the biopsy specimen in normal saline for culture and NOT IN FORMALIN as it will kill the bacilli.
- Extra pulmonary specimens should never be collected or transported in CPC.

3. TRANSPORTATION OF EXTRA PULMONARY SPECIMENS

As for pulmonary samples, extra pulmonary specimens will need to be transported in cool boxes which maintain temperatures below 20^0C for specimens to be compatible for solid, liquid culture systems as well as molecular methods. Triple packing system should be utilised for transportation. All precautions that are followed for transporting pulmonary samples should be followed. For sending material across international or state boundaries this container may have to be packed in the same way with an additional outer container; in such cases, special administrative arrangements with postal authorities and/or airlines may be necessary.
When sending out specimens or when receiving them, check that:

- Request forms are located separately from the specimen containers
- Containers are labelled not on the cap but on the wall of the container
- Each transport box has an accompanying list which identifies the specimens and the patients; the information on the specimen containers should correspond to that on the accompanying list.
- Accompanying list contains the necessary data for each patient
- Date of dispatch and particulars of the health centre are on the accompanying list.

3.1 Specimens and request forms

All specimen transported to the laboratory must be accompanied by the request form for C & DST in hard and soft copy formats (See C & DST request form). For quality control reasons, the tests must be performed only upon written request of authorized persons and oral requests without follow up written instructions should not be allowed. It is also important that specimen request forms are kept separate from the specimens themselves. Forms that have been contaminated by specimens should be sterilized by autoclaving. If mistakes in filling request forms and labelling of specimens are found, reject specimens and do not register them. Document the arrival of specimens in the laboratory and note any delays in

delivery in the remarks column of the specimen register and on the report form, particularly for negative/contaminated results. The packaging material should be autoclaved before discarding.

4. REGISTRATION OF SAMPLES

4.1 Receipt of incoming specimens

For safety and work-flow reasons, specimens should be received in the office area of the laboratory and delivery boxes should be opened using all the applicable biosafety procedures inside the lab.

To minimize risk of infection, the following procedures should be applied:

1. The specimen package received should be opened only in a biosafety cabinet which may be located in a small area within the reception or in the culture room, as they could potentially be MDR or XDR Tuberculosis. (DO NOT OPEN ON AN OPEN BENCH AT THE LAB RECEPTION)
2. Before opening the packet, inspect the delivery box for signs of leakage; if there is gross leakage evident, discard the box by autoclaving or burning; do not try to open and retrieve any specimen.
3. If on gross inspection there is no leakage, disinfect the outside of the delivery box using cotton wool or paper towels saturated with a suitable disinfectant (5% phenol)
4. Open carefully and check for cracked or broken specimen containers or leakage within the packaged container. If there is minimal leakage without any gross loss of specimen, they may be processed with an asterix that leakage was noted on receipt. (This will assist in identifying reasons for contamination used in lab performance indicators). In case of gross leakage, with only very little sample being available, accept the sample and process after carefully making a note of the same – as extrapulmonary specimens are precious and repeat collection may not be possible.
5. Check labelling of specimens with individual identification numbers and correspondence with numbers on the accompanying list or Clinical information forms (CIF) that are accompanying the specimens.
6. Disinfect the inside of the delivery box, wash hands after handling specimen containers
7. Autoclave the packaging material before discarding.
8. Assign unique lab serial number to each patient.
9. Evaluate the quality of specimens and make a note as to volume (in case of fluids), leakage, blood mixed etc. Always register the incoming specimen in the laboratory register; each specimen receives a serial number that should be used to label every test for the specimen. Other data that should be reported on the laboratory register are: the date of the receipt of the specimen, patients name, age, sex and address, the name of the referring health centre, the reason for DST. The signature (with the name in capitals) of the person requesting the examination should always be present.

4.2 Decontamination of extra pulmonary samples

Most of the extra pulmonary specimens are paucibacillary in nature. Hence, they require milder decontamination. When using solid culture for primary isolation of tubercle bacilli from these specimens, it is preferable to use multiple media including one liquid medium made selective by the use of specific antibiotics that inhibit the growth of other micro organisms. The media include, LJ, LJ with sodium pyruvate (LJ–P) and selective liquid Kirchner's medium (SK). Sodium pyruvate facilitates the growth of *M. bovis*. Antibiotics incorporated in the liquid medium include polymixinB, amphotericin B, carbenicillin and trimethoprim (PACT) and vancomycin.

Preparation of media

LJ MEDIUM WITH SODIUM PYRUVATE

LJ medium is enriched with 0.5% sodium pyruvate. In the preparation of the mineral salt solution, glycerol is omitted and 8.0g sodium pyruvate is added for every 600 ml. This is added to 1 litre of egg fluid, mixed well and distributed.

SELECTIVE KIRCHNER'S MEDIUM (For culture of extra-pulmonary specimens**)**

Disodium hydrogen phosphate, $Na_2HPO_4.12H_2O$, A.R.	19.0 g (7.5g of anhydrous salt)
Potassium dihydrogen phosphate, KH_2PO_4, A.R.	2.0 g
Magnesium sulphate, $MgSO_4.7H_2O$, A.R.	0.6 g
Sodium citrate	2.5 g
L-asparagine	5.0 g
Casein hydrolysate (Bactocasitone)	0.5 g
Glycerol	20.0ml
Phenol Red, 0.4% solution	3.0 ml
Distilled water, to	1 litre

Check pH to 6.9 – 7.2

Autoclave at 15 lbs/15 minutes

Then add aseptically the following:

Polymyxin B (20,000 units)	31 mg
Carbenicillin	100 mg
Trimethoprim	10 mg
Amphotericin B, solubilised	10 mg

Dissolve the above in 5 ml sterile distilled water before addition

Also, add sterile calf serum 100 ml

Mix the above carefully and distribute, under sterile conditions, in 10 ml amounts. Check sterility by overnight incubation at 37^{o}C and store in the cold.

5. CULTURE BY SOLID CULTURE METHODS

5.1 CSF and pericardial fluid

Smear:

1. Label a clean dry slide with the lab number and place the slide and the sample container inside the cabinet
2. Mix well and aseptically remove one loopful of the fluid and place in the centre of the slide; close the container and allow the drop to air-dry
3. Place one more drop of the CSF on the same spot and let dry.
4. Place the third drop after processing the sample as below:

Culture:

Culture of CSF is done in two steps:

1. Direct inoculation in media 2. Inoculation after decontamination

Direct

1. Place one loopful of CSF on to one slope each of LJ and LJ-P
2. Add 0.2 ml of CSF in to one bottle containing SK medium
3. Label the set as 'A'

Decontamination

1. Add 1ml of 5% H_2SO_4 to CSF
2. Mix well and let stand for 15 minutes
3. Fill the container with sterile distilled water and centrifuge at 3000 x g for 15 minutes
4. Aspirate the supernatant carefully without disturbing the deposit or discard carefully in to a disinfectant bin containing 5% phenol or any other mycobactericidal solution
5. Inoculate one slope each of LJ and LJ-P with one loopful of deposit for each slope
6. Transfer the remaining deposit in to one bottle of SK
7. Label the set as 'B'
8. Incubate both set A and B at 37^{o}C

5.2 BAL

1. Make a direct smear
2. Process using 5% H_2SO_4 as in CSF
3. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit using 5mm twisted wireloop
4. Transfer the remaining deposit in to one bottle of SK
5. Incubate the slopes and SK medium at 37^{o}C

5.3 Gastric Lavage

1. Gastric Lavage should be processed immediately upon arrival in the lab to prevent the killing action of the gastric pH (due to HCl) on the tubercle bacilli
2. Make a direct smear and process by modified Petroff's method
3. Place one drop of the final pellet on the direct smear
4. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
5. Transfer the remaining deposit in to one bottle of SK
6. Incubate the slopes and SK medium at 37^{o}C

5.4 Tissue / Biopsy

1. Ideally, biopsy specimens should be collected and transported in SK medium
2. Carefully place the tissue inside a sterile petriplate inside the BSC
3. Using sterile scissors and forceps, cut the tissue in to tiny pieces
4. Transfer to a sterile tissue grinding tube – add a little water to the petriplate to facilitate transferring
5. Add sterile distilled water to the tube (not more than 5 ml)
6. Homogenise using a sterile Teflon grinding rod using a foot operated tissue grinder
7. Make a direct smear from the homogenate
8. Centrifuge the homogenate at 3000 x g for 15 minutes
9. Decant the supernatant carefully in to the disinfectant bath
10. To the deposit add 1 ml of sterile distilled water
11. Add one drop to the direct smear, air dry, fix and stain
12. To the remaining pellet, add 1ml of 5% H_2SO_4
13. Proceed as for CSF
14. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
15. Transfer the remaining deposit in to one bottle of SK
16. Incubate the slopes and SK medium at 37^{o}C, along with the SK medium used for transporting

5.5 Fine Needle Biopsy specimen

1. Fine needle specimens should be collected and transported only in SK medium or any other liquid medium
2. The medium is incubated as such at 37^{o}C, since only a very tiny piece of the tissue is obtained as sample

If the sample is received without SK

1. Add the contents of two SK medium bottles to the specimen
2. Shake vigorously and let stand for 10 minutes
3. Divide the medium in to two aliquots and incubate both at 37^{o}C

5.6 Pus

1. Make a direct smear, air dry, fix and stain

2. If the pus is thick or purulent, process by modified Petroff's method using 4% NaOH
3. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
4. Transfer the remaining deposit in to one bottle of SK
5. Incubate the slopes and SK medium at 37°C
6. If the pus is thin or dilute, proceed with decontamination using 5% H_2SO_4
7. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
8. Transfer the remaining deposit in to one bottle of SK

5.7 Urine / Ascitic fluid

1. Distribute the entire specimen in to 20 or 40 ml volumes in Universal containers / Falcon tubes inside a BSC
2. Centrifuge at 3000 x g for 15 minutes

Process the supernatant and deposit independently as follows:

Supernatant:

3. Aspirate carefully 1ml of the top layer from each tube and pool
4. Process by 5% H_2SO_4 as for CSF
5. Transfer 1ml of the final supernatant on to two bottles of SK each – Label the set as DSS (Decontaminated Supernatant Supernatant)
6. Decant the supernatant carefully in to the disinfectant bath
7. From the deposit transfer about 0.2 ml and the remaining in to 2 bottles of SK respectively – Label as DSD (Decontaminated Supernatant Deposit)

Deposit:

8. Pool all the deposit in to one tube
9. Process using 5% H_2SO_4 as for CSF
10. Inoculate two slopes each of LJ and LJ-P with one loopful of deposit for each slope
11. Transfer the remaining deposit in to one bottle of SK

5.8 Swabs:

If two swabs are available, use one for smear and one for culture; if only one is available do only culture

1. Immerse the swab in 5 ml of 4% H_2SO_4 for 1 minute
2. Transfer the swab to another tube containing 5 ml of 4% NaOH
3. Directly inoculate two slopes each of LJ, LJ-P
4. Transfer the swab finally to a tube containing SK medium
5. Incubate all tubes at 37°C

5.9 Culture Reading

1. Read all cultures used for isolating *M. tuberculosis* from extrapulmonary specimens every week for up to 8 weeks using the same methodology used for pulmonary samples
2. If the solid media show typical growth report immediately after confirmation

3. Read SK medium up to 6 weeks
4. MTB appears as whitish granular or flaky growth that settles down at the bottom
5. If the SK medium shows growth or contamination (in the form of turbidity) within 6 weeks, decontaminate as sputum by modified Petroff's method and inoculate deposit on LJ medium alone and read up to 8 weeks
6. Even if the SK medium shows no growth within 6 weeks, proceed with decontamination using modified Petroff's method and inoculate deposit on LJ medium alone and read up to 8 weeks
7. If LJ shows typical MTB growth within 8 weeks, report immediately after confirmation
8. Report as negative only after LJ completes 8 weeks (a total of 14 weeks)

6. Processing of extra pulmonary samples for MGIT960

Isolation of M. tuberculosis by MGIT system requires the final inoculum to be in an ideal condition that will not interfere with the fluorescence.

6.1 Pus and other muco-purulent specimens

1. Thick pus of volume >10 ml is decontaminated using the NALC – NaOH method as sputum
2. If the volume is < 10 ml, either aliquot and process only 10 ml by NALC – NaOH method or concentrate the initial volume by centrifugation for 15 – 20 minutes and resuspend the pellet in 5 ml of sterile distilled water. If the pus is too thick, add about 50-100 mg of NALC powder; mix well and decontaminate using NaOH. Resuspend the final pellet in buffer to reduce the pH
3. If the pus is not thick, decontaminate using 2-4% NaOH. The concentration of NaOH can be changed based on the expected level of contamination in the specimen which depends on the site of collection

6.2 Gastric aspirates

1. Distribute the volume in smaller aliquots and centrifuge the tubes at 3000 x g
2. Pool the deposits, add 5ml distilled water and decontaminate it using NALC-NaOH or 2-4% NaOH

6.3 Bronchial washings

1. Process using NALC-NaOH like sputum
2. If the specimen is >10 ml in volume, process the whole specimen.
3. If <10ml, concentrate the specimen by centrifugation (3000x g, 15-20 minutes)
4. Add 5 ml sterile water to the pellet and decontaminate as for sputum

6.4 Laryngeal swabs

1. Transfer the swab into a sterile centrifuge tube and add 2 ml sterile water.
2. Add 2 ml of NaOH-NALC solution and mix well in a vortex mixer.

3. Let stand for 15 minutes. Remove the swab with forceps, squeezing the liquid out of the swab and discarding it.
4. Fill the tube with phosphate buffer and mix
5. Centrifuge at 3000xg for 15-20 minutes.
6. Discard the supernatant fluid and resuspend the sediment in 1-2 ml sterile buffer. Use this suspension for smear and culture.

6.5 Tissue

1. Homogenize the tissue in a tissue grinder with a small quantity of sterile saline or water (2-4 ml).
2. Decontaminate the homogenized specimen using NALC-NaOH procedure as in sputum.
3. Resuspend the sediment with phosphate buffer
4. If the tissue grinder is not available, use a mortar and pestle.
5. Tissue may also be placed in a Petri dish with sterile water (2-4 ml) and be torn apart with the help of two sterile needles.

6.6 Urine

Isolation of mycobacteria from urine specimens using MGIT has not been validated.

1. Aliquot the entire volume in several centrifuge tubes
2. Concentrate the specimen by centrifugation for at least 20-25 minutes
3. Resuspend the pellet in each tube with 1-2 ml of sterile water and pool together
4. Decontaminate using 4% NaOH as for sputum

6.7 Other body fluids (CSF, synovial fluid and pleural fluid)

As these fluids are collected usually under aseptic conditions, they require only milder decontamination

1. If the specimen volume is more than 10 ml, concentrate by centrifugation at about 3000x g for 15-20 minutes
2. Liquefy thick or mucoid specimens prior to centrifugation by adding NALC powder (50-100 mg).
3. Resuspend the sediment in about 5 ml of saline
4. Mix and decontaminate as for sputum

6.8 Blood

Isolation of mycobacteria from blood specimens by MGIT 960 has not been evaluated thoroughly. A few published studies have used blood after lysis centrifugation. Ideally BACTEC Myco/F Lytic medium is recommended for isolation of mycobacteria from blood samples.

Institution **Laboratory name** Location Head/Responsible person	Standard Operating Procedure (SOP) Specimen processing of CSF, lymph nodes and other tissues for Xpert MTB/RIF	Code: Version: no. Date: of release Page: **1** of **7**

Content

	Compiled by	Examined by	Approved by	Replaced	New version
Name				Code:	Code:
Date					
Signature					
Laboratory area:		No of copies:	Reason for change:		

1. Scope

This SOP describes methods of specimen processing CSF, lymph nodes and tissues for testing in the Xpert MTB/RIF assay and for purposes of culturing *Mycobacterium tuberculosis* culture on solid and / or liquid media.

2. Definitions and abbreviations

BSC : biological safety cabinet
CSF: cerebrospinal fluid
ID: patient's specimen identification, usually laboratory number
LJ: Löwenstein–Jensen
NTP: national tuberculosis programme
PBS: Phosphate buffer 0.067 mol/ litre, pH 6.8
RCF: relative centrifugal force

3. Procedure

3.1 Principle

WHO has issued policy recommendations for the use of Xpert MTB/RIF in the diagnosis of extrapulmonary TB and rifampicin resistance detection

- Xpert MTB/RIF should be used in preference to conventional microscopy and culture as the initial diagnostic test in testing **cerebrospinal fluid specimens** from patients presumed to have TB meningitis (strong recommendation given the urgency of rapid diagnosis, very low quality of evidence);

- Xpert MTB/RIF may be used as a replacement test for usual practice (including conventional microscopy, culture, and/or histopathology) for testing of specific non-respiratory specimens (**lymph nodes and other tissues**) from patients presumed to have extrapulmonary TB (conditional recommendation, very low quality of evidence).

For CSF specimens, Xpert MTB/RIF should be preferentially used over culture if the sample volume is low or additional specimens cannot be obtained, in order to reach quick diagnosis. If sufficient volume of material is available, concentration methods should be used to increase yield;

Individuals presumed to have extrapulmonary TB but with a single Xpert MTB/RIF - negative resultshould undergo further diagnostic testing and hence processing of tissue samples (lymph nodes and other tissues) for Xpert MTB/RIF should include a decontamination step to enable samples to be concurrently cultures

Pleural fluid is a suboptimal sample for the bacterial confirmation of pleural TB, using any method. A pleural biopsy is the preferred sample.

These recommendations do not apply to stool, urine or blood, given the lack of data on the utility of Xpert MTB/RIF on these specimens.

3.2 General considerations

Important points about specimen processing procedures

- Process all specimens as soon as possible, for an optimal culture recovery of MTB. Longer transport should not affect Xpert positivity
- Ensure that the Xpert MTB/RIF cartridge and any culture media to be inoculated are labelled correctly and clearly.
- **Tissues must be processed within a BSC** given the risk of aerosol production while grinding and homogenizing samples.
- **CSF samples are paucibacillary** and can be processed using the same precautions as for sputum EXCEPT when concentrated by centrifugation
- It is important to use Safe Working Practices to avoid contamination by bacteria other than tubercle bacilli and especially cross-contamination by tubercle bacilli from other specimens.
- When sufficient sample is available, culture should be performed concurrently
- Samples requiring decontamination must have the exposure time to decontamination reagents strictly controlled.
- **Decontaminate samples** for culture using either 4% NaOH or NaOH-NALC **depending on usual practice** in the laboratory. The example below uses 4% NaOH.

3.3 Specimen processing

The Xpert MTB/RIF assay can be used directly for CSF specimens and homogenised extrapulmonary samples (lymph node biopsies and other tissues) or on decontaminated specimens if culture is performed concurrently.

Whenever possible, specimens should be transported and stored at 2 to 8°C prior to processing (a maximum of 7 days).

3.3.1 Lymph nodes and other tissues (for Xpert MTB/RIF only)

1. Cut the tissue sample into small pieces in a sterile mortar (or homogenizer / tissue grinder) using a clean, sterile pair of forceps and scissors
2. Add approximately 2ml of sterile phosphate buffer (PBS)
3. Grind tissue/PBS-solution with a mortar and pestle (or homogenizer / tissue grinder) until a homogeneous suspension is obtained
4. Transfer approximately 0.7 ml of homogenized tissue sample to a sterile conical, screw-capped tube using a transfer pipette

NOTE: Avoid transferring any clumps of tissue which have not been properly homogenized.

5. Add a double volume of Xpert MTB/RIF Sample Reagent (1.4 ml) to 0.7 ml of homogenized tissue using a transfer pipette
6. Vigorously shake 10 to 20 times or vortex for at least 10 seconds
7. Incubate for 10 minutes at room temperature, and again shake the specimen vigorously 10 to 20 times or vortex for at least 10 seconds
8. Incubate the sample at room temperature for an additional 5 minutes
9. Using a fresh transfer pipette, transfer 2ml of the processed sample to the Xpert MTB/RIF cartridge
10. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

3.3.2 Lymph nodes and other tissues (Non-sterile collections – Xpert MTB/RIF and culture)

1. Cut the tissue sample into small pieces in a sterile mortar (or homogenizer / tissue grinder) using a clean, sterile pair of forceps and scissors
2. Add approximately 2ml of sterile phosphate buffer (PBS)
3. Grind tissue/PBS-solution with a mortar and pestle (or homogenizer / tissue grinder) until a homogeneous suspension is obtained
4. Use a sterile transfer pipette to add the suspension into a 50ml conical tube
5. Add an equal volume of 4% NaOH and tighten the screw-cap
6. Vortex thoroughly to homogenise the suspension
7. Stand for 15 minutes at room temperature.
8. Fill the tube to within 2 cm of the top (e.g. to the 50-ml mark on the tube) with PBS
9. Centrifuge at 3000*g* for 15 minutes
10. Carefully pour off the supernatant through a funnel into a discard can containing 5% phenol or other mycobacterial disinfectant
11. Re-suspend the deposit in approximately 1-2 ml PBS
12. Use another sterile transfer pipette to inoculate deposit into liquid media and/or onto two slopes of egg-based medium labelled with the sample ID number.
13. Label a Xpert/MTB/RIF cartridge with the sample ID

14. Using a transfer pipette, transfer approximately 0.7 ml of homogenized tissue sample to a conical, screw-capped tube for the Xpert MTB/RIF.

NOTE: Avoid transferring any clumps of tissue which have not been properly homogenized.

15. Using another transfer pipette, add a double volume of Xpert MTB/RIF Sample Reagent (1.4 ml) to 0.7 ml of homogenized tissue.
16. Vigorously shake 10 to 20 times or vortex for at least 10 seconds
17. Incubate for 10 minutes at room temperature, and again shake the specimen vigorously 10 to 20 times or vortex for at least 10 seconds
18. Incubate the sample at room temperature for an additional 5 minutes
19. Using a fresh transfer pipette, transfer 2ml of the processed sample to the Xpert MTB/RIF cartridge
20. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

3.3.3 Lymph nodes and other tissues (Sterile collection – Xpert MTB/RIF and culture)

1. Cut the tissue sample into small pieces in a sterile mortar (or homogenizer / tissue grinder) using a clean, sterile pair of forceps and scissors.
2. Add approximately 2ml of sterile phosphate buffer (PBS)
3. Grind tissue/PBS-solution with a mortar and pestle (or homogenizer / tissue grinder) until a homogeneous suspension is obtained and adjust to a final volume of approximately 2ml with PBS
4. Transfer the suspension with a sterile transfer pipette to a 50ml conical tube
5. Use a another transfer pipette to inoculate suspension into liquid media and/or onto two slopes of egg-based medium labelled with the sample ID number
6. Label an Xpert/MTB/RIF cartridge with the sample ID
7. Transfer approximately 0.7 ml of homogenized tissue sample to a conical, screw-capped tube for the Xpert MTB/RIF using a transfer pipette

NOTE: Avoid transferring any clumps of tissue which have not been properly homogenized.

8. Transfer a double volume of Xpert MTB/RIF Sample Reagent (1.4 ml) to 0.7 ml of homogenized tissue using a transfer pipette

9. Vigorously shake 10 to 20 times or vortex for at least 10 seconds
10. Incubate for 10 minutes at room temperature, and again shake the specimen vigorously 10 to 20 times or vortex for at least 10 seconds
11. Incubate the sample at room temperature for an additional 5 minutes.
12. Using a fresh transfer pipette, transfer 2ml ml of the processed sample to the Xpert MTB/RIF cartridge
13. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

3.3.4 CSF

The preferred processing method for CSF in Xpert MTB/RIF depends on the volume of sample available for testing.

NOTE. Blood stained and xanthochromic CSF samples may cause false negative Xpert MTB/RIF results

More than 5 ml of CSF

1. Transfer all of the sample to a conical centrifuge tube and concentrate sample at 3000*g* for 15 minutes
2. Carefully pour off the supernatant through a funnel into a discard can containing 5% phenol or other mycobacterial disinfectant
   NOTE: Decanting concentrated CSF should be performed within a BSC
3. Re-suspend the deposit to a final volume of 2ml with Xpert MTB/RIF sample reagent.
4. Label an Xpert/MTB/RIF cartridge with the sample ID
5. Using a fresh transfer pipette, transfer 2ml ml of the concentrated CSF sample to the Xpert MTB/RIF cartridge
6. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

1-5 ml of CSF (including blood-stained or xanthochromic samples)

1. Add an equal volume of the CSF to the sample reagent
2. Add 2ml of the sample mixture directly to the Xpert MTB/RIF cartridge
3. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

0.1-1ml of CSF

1. Re-suspend the CSF to a final volume of 2 ml with Xpert MTB/RIF sample reagent.
2. Add 2ml of the sample mixture directly to the Xpert MTB/RIF cartridge
3. Load the cartridge into the GeneXpert instrument as per manufacturer's instructions

Less than 0.1ml

1. Insufficient sample for testing in the Xpert MTB/RIF assay

4. Related documents

1. Xpert MTB/RIF system for the diagnosis of pulmonary and extrapulmonaryTB and rifampicin resistance in adults and children. A pre-publication version of the policy guidance may be accessed at: http://www.stoptb.org/wg/gli/assets/documents/WHO Policy Statement on Xpert MTB-RIF 2013 pre publication 22102013.pdf

2. The full Expert Group meeting report is available at: http://www.stoptb.org/wg/gli/assets/documents/Xpert%20Meeting%20Report%2024102013%20%20Pre%20publication%20FINAL.pdf

Revised National TB Control Programme

Instructions for administering Purified Protein Derivative (PPD):

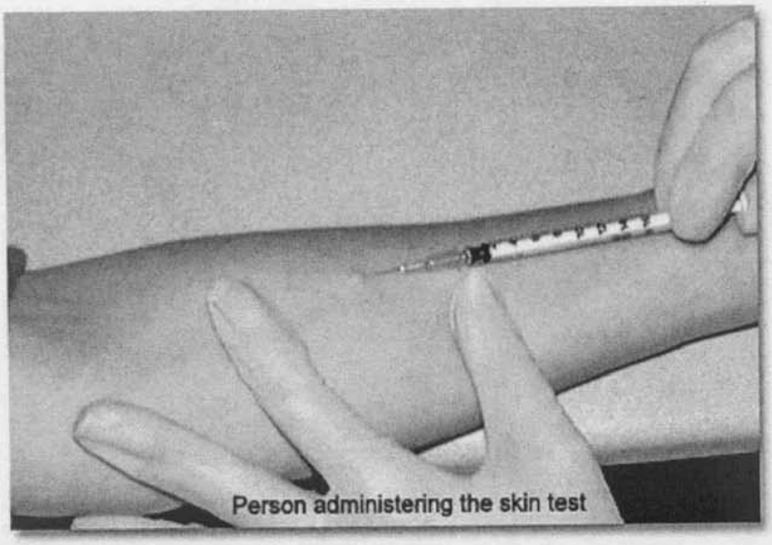
Supplies needed:

- Vial of tuberculin – 1tuberculin units (TU) purified protein derivative (PPD) 1.5 ml solution
- Single-dose disposable tuberculin syringe
- 2x2 gauze pads or cotton balls
- Alcohol swabs
- Puncture-resistant sharp disposal container
- Mantoux Tuberculin Skin Test Record Form
- Appointment cards
- Gloves

Preparation before administration:

- Purified protein derivative (PPD) solution must be kept refrigerated at 2-8°C (DO NOT FREEZE)
- To avoid fluctuations in temperature, do not store on the refrigerator door
- Read the vial label to ensure that the correct solution and tuberculin unit (TU) strength have been selected
- Check the expiration date and the date that the vial was opened. The vial should be discarded if it has been open for more than 30 days or the expiration date has passed. The vaccine vials comes in a pack of ten in a box which also has the vaccine vial monitor (VVM) indicator. All the vials should be taken from a single box, the vaccine vials should not be taken if the VVM on the box has changed its color or if it has crossed the expiry date.
- Select a well-lighted area for administering the test. Have all the equipment and supplies on hand
- Introduce yourself to the patient
- Verify that the correct patient receives the test
- Ask the patient if he/she has any allergies
- Review the patient's tuberculin skin test history. Inquire about documentation of previous tuberculin skin test results
- Provide patient education to answer questions, address fears, and ease anxieties. Discuss the purpose of the test, testing procedure, and the time frame for returning to have the test read. If the patient cannot return 48-72 hours after the test to have the indurations measured and evaluated, do not administer the test. Instead, schedule another time that is more convenient for the patient

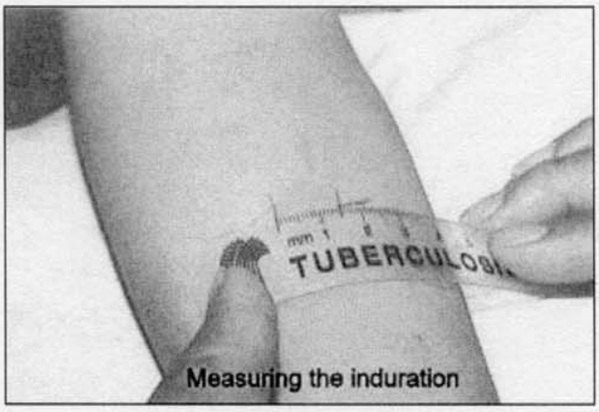
Administration of Skin Test: (Syringes must be filled immediately prior to administration)



Person administering the skin test

- Wash your hands with soap and water
- On a firm, well-lighted surface, expose the patient's arm and slightly flex at the elbow. The injection should be replaced on the palm-side-up surface of the forearm, about 2 to 4 inches below the elbow. Avoid areas of skin with veins, sores, rashes, scars, or excess hair
- Wear the gloves
- Clean the injection site with an alcohol swab, using circular motion beginning in the center and working your way outward. Allow the site to dry completely before injection
- Wipe the top of the vial with a new alcohol swab and allow it to dry thoroughly
- Fasten the needle tightly on the syringe by holding the cap and twisting it onto the tip of the syringe. Remove the needle cap and make sure that the needle bevel is facing up
- Hold vial between your thumb and fingers and insert the needle through the stopper. Inject air into the empty space, not the solution, in the vial
- Invert the vial. With the tip of the needle below the fluid level in the vial, draw out slightly more than 0.1 ml of solution
- Remove the needle from the vial. Hold the syringe in an upright position and gently tap the syringe to break up any air bubbles
- Expel all air from the syringe and excess solution from the needle, leaving exactly 0.1 ml of tuberculin solution in the syringe
- Stretch the skin taut over the injection site to provide a surface that is easy for the needle to penetrate. This can be accomplished by stretching the skin between the thumb and index finger or grasping the patient's forearm and gently pulling the skin from under the arm
- Hold the syringe between your thumb and index finger with the needle bevel facing up and the syringe parallel to the forearm

- With the needle against the patient's skin, insert the needle slowly at a 5 to 15 degree angle, just below the surface of the skin (you should be able to see the bevel of the needle just below the skin surface)
- Release the stretched skin and hold the syringe in place. Slowly inject the tuberculin solution, forming a 6 to 10 mm wheal (pale, raised area with distinct edges; has orange peel appearance and does not disappear immediately)
- If no wheal forms or if it is less than 6 mm in diameter, repeat the test approximately 2 inches from the original site or on the opposite arm
- Remove the needle without massaging or pressing the area and immediately discard the used syringe in the sharps container
- If minor bleeding occurs, use a 2x2 gauze pad or cotton ball to dab the injection site
- Do not cover the site with an adhesive bandage as it could cause irritation
- Wash your hands
- Record the following information on the record-keeping form: the date, time, location of injection site, name of manufacturer, lot number, and expiration date of PPD solution, name of person administering the skin test
- Inform the patient that mild itching, swelling, or irritation is normal and usually goes away within 1 week
- Explain how to care for the injection site: avoid scratching the site, keep the site clean and dry, and avoid creams, lotions, or adhesive bandages
- Inform the patient that it is important to return within 48 to 72 hours to have the test result read
- Give the patient a written appointment to return for the skin test reading



Measuring the induration

Annexure 7

Setting- specific screening strategy

Urban Slums

Urban slum dwellers are at higher risk of developing TB due to overcrowding, poor basic health services infrastructure and their health seeking behaviour. Health is not a priority for them and risk of TB transmission is high in slums. Urban slum-dwellers require focussed efforts and support from the tuberculosis programme.

Intensified case finding efforts in these areas can include:-

- House to house, periodic symptom screening of all the mapped urban slums to actively screen for presumptive TB cases.
- Liaising with NUHM, NPSP and other departments delivering health care services in urban slums for mapping and line listing of providers
- Utilization of Urban slum schemes as in the revised NGO-PP partnership guidelines.

Household and Close Contacts of TB

Household contact:- *A person who shared the same enclosed living space for one or more nights or for frequent or extended periods during the day with the index case.*

Close contact:- *A person who is not in the household but shared an enclosed space, such as a* ***social gathering****,* ***workplace*** *or facility, for extended periods in a day with the index case.*

-Since the transmission can happen from the index case to the contact any time (before the diagnosis of TB or during the treatment) all contacts must be evaluated. In case of Pulmonary Tuberculosis, it is recommended that contact screening is conducted for household and close contacts

It is important to screen household and close contacts for TB as they are more prone to get infected with TB. Some of them may be asymptomatic and others may ignore these symptoms. Chest X-ray screening should be done for all the contacts. Symptom screening should be done whenever X-ray facility is not available.

- The index case should be interviewed as soon as possible after diagnosis (generally within 1 week) to elicit the names of household and close contacts. Data from the contact investigation should be collected in a standardized format and should routinely be evaluated. (Information to be recorded in the treatment card)
- Reverse contact tracing should be done for all paediatric TB patients.

Health Care Workers

Health care workers are at greater risk of getting TB infection and also at a higher risk of getting active disease. The National Airborne Infection Control guidelines advocate Health Care worker Surveillance as a component of the Hospital / Health facility Infection Control Plans.

- Pre placement screening and routine annual screening with Chest radiography of all the health care workers is strongly recommended.
- If Health care worker surveillance is an existing policy in the health institution, facility or department then chest X-ray screening may be added on to the protocol.
- Healthcare workers presenting with symptoms of TB should be evaluated.

Malnourished Children

Malnutrition is a strong risk factor for progression from TB infection to disease among children. As per the TB management guidelines in the paediatric population issued by RNTCP, all malnourished children are eligible for TB screening and diagnostic evaluation.

- Active screening for TB symptoms with chest X-ray as the screening tool (or symptom screening if X- ray is not available) should be undertaken among children with malnourishment that attend any health facility .
- Engage and collaborate with Nutritional Rehabilitation Centres for routine screening of TB in malnourished children attending these centres.
- Regular symptomatic screening of malnourished children attending the Anganwadi centres.

Antenatal Clinics/MCH clinics

Antenatal clinic attendee rates are very high in the country as the RCH programme receives high priority and is a leading public health programme in the country. Screening pregnant women for TB in MCH clinics provides an exceptional opportunity to identify and reach women in need of TB case diagnosis as a majority of women access health care during pregnancy at least once. Strengthening linkages between maternal health and TB management can contribute to the reduction of maternal and newborn mortality too.

- TB Symptoms screening must be undertaken for all mothers attending the antenatal clinics at every visit and those who are symptom screen positive must be immediately linked to the nearest laboratory for early TB diagnosis and decision on TB treatment initiation.

Prison inmates

Predisposing factors such as overcrowding, long-term close contact with inmates and lack of easy access to adequate health services may lead to high rates of TB transmission in prisons. Duration of stay of inmates in the prison is unpredictable and turnover is also high, resulting in undiagnosed or delayed diagnosis of TB.

The intensified case finding activity should include:

- Symptom screening at **Entry;** when prisoners enter the prisons.
- **Periodic mass screening** with chest X-ray. If chest x-ray is not available then symptom screening should be done.

Patients with Co morbidities

Patients with chronic illness like malignancy, on dialysis, on immune-suppressants, long term steroids have higher risk of tuberculosis - Symptom screening for TB should be done on all patient visits to the health facilities for follow up examinations

Patients with past history of TB

Chances of TB relapse or recurrence is higher in people with a past history of TB. Efforts to actively screen for TB symptoms in this group could be a high case yielding activity. The programme now advocates that all TB cases after successful completion of treatment need to be followed up for a period of one year after with follow up examinations at 6^{th}, 12^{th},$18^{th}$and 24^{th}month.

- Active symptom screening by health staff may be undertaken by visiting the homes of those patients at prescribed intervals
- House to house visits may be undertaken of all patients notified and treated by private sector to screen for TB symptoms at prescribed intervals.

Occupational high risk group

Several occupations increase risk for tuberculosis. It is known that thousands of workers and local residents are exposed to hazardous silica levels during stone crushing operations and suffer from silicosis, lung cancer, and other lung diseases. Other occupations include coal and other mining works, tobacco (bidi rolling) and carpet weaving. Vulnerable and socially marginalised groups including tribal communities, children and migrant population are often working in these industries that do not have access to routine health services. Active case finding efforts in these groups will help to identify those suffering from TB early.

- Screening should be done by X-ray and in case X-ray is not available then symptom screening should be done by holding periodic health camps.

Congregate Settings

People in settings like transit camps, night shelter, old age home, orphanages and de addiction centres may have ill ventilated and unsanitary environment and hence, at higher risk of developing tuberculosis.

- In all such congregated settings Symptom screening should be done by holding periodic health camps.

Hard to Reach Areas

People living in difficult, hard to reach and inaccessible areas like certain Tribes or indigenous population delay seeking health care for their symptoms. They are also dependent on local informal providers and traditional healers as their first points of contact for health care, which can lead to delay in diagnosis. Periodic active screening programmes must be planned and implemented to detect TB cases early in this population

- Symptomatic screening may be done by holding periodic health camps or even by house to house survey

- Mobile medical units equipped with microscopes and digital X-ray machines available under NHM can be used.
- Sputum collection centres must be planned and established in strategic locations with the help of local NGOs

Missed cases in health system

Opportunity should not be missed to diagnose TB among people who approach health facility for any other illness. Systems should be strengthened and actively monitored so as to ensure all presumptive TB cases are identified timely and are referred for diagnostic evaluation

- Establish sputum collection centres in all the primary health centres which do not have DMC
- Enhancing the skills of MOs by providing special training package on interpretation of X-ray.
- Wherever X-ray &histo-pathological/FNAC services are not available then outsourcing these services should be done.

Annexure 8

Enhanced enables and incentives under programme are given below:

Item	Existing norm	Proposed by MoHFW and approved by MSG
Existing Incentives		
Revision of incentives to Community DOT provider providing treatment support to Category I TB patients	250/- for completed course of treatment	Rs1000/- for the completed course of treatment
Revision of incentives to Community DOT provider providing treatment support to Category II TB patients	250/- for completed course of treatment	Rs1500/- for the completed course of treatment
Revision of incentives to Community DOT provider providing treatment support to Drug Resistant TB patients	Rs.2500/- for completed course of treatment (Rs.1000/- at the end of IP and Rs 1500/- at the end of CP)	Rs.5000/- for completed course of treatment. (Rs.2000/- at the end of IP and Rs 3000/- at the end of CP)
Incentives to patient in tribal and difficult areas	Rs.250/patient and one attendant	Rs 750/patient and one attendant
Incentive to volunteers for sputum sample transport in tribal and difficult areas	Rs.200/month/volunteer. If less than one visit per week then Rs 100/ month	Rs.25 per sample transported to the DMC
Travel cost to MDR TB patient/suspect to DRTB centre (outside district)	Actual travel cost using any public transport	Up to Rs 1000/visit/patient restricted to actuals by a public transport
Travel cost to MDR TB patient/suspect to DRTB centre (within district)	Actual travel cost using any public transport	Up to Rs 400/visit/patient restricted to actuals by a public transport
New Incentives		
Transportation cost for co-infected TB -HIV patient travel	NIL	Up to Rs.500/patient for only the first visit restricted to actuals by a public transport
Incentive related to Injection prick	NIL	Rs.25/injection prick

Annexure 9

Ready Reckoner for General Practitioners

Important general instructions:

1. Ensure that patient completes full course of anti-TB therapy
2. Side effects of anti-TB drugs can be an important cause of patient stopping medication, especially with second line drugs.
3. Prevention and early detection of side effects are needed
4. Alcohol, smoking and use of illicit drugs increase side effects
5. Relevant history, clinical examination and lab tests are important to evaluate risk factors and diagnosis of side effects at an early stage
6. For contraception, ask patient to seek advice from family health center as oral contraceptives are less effective with some anti-TB drugs
7. Educate, counsel and reassure patients for self-limiting side effects
8. For side effects and serious side effects, take immediate action and refer patient to specialist / tertiary center; as suggested below
9. Report serious side effects to PvPI center (Procedure for reporting: Call your nearby PvPI center and provide complete information about side effects. Contact details of the nearest PvPI center are: Name of the Centre - _____; Contact no: _____; National toll free number: **1800 180 3024**)
10. Advice nutritious diet to TB patients
11. Advice patients about respiratory hygiene and provide information on preventing spread of TB (using facemask, tissue paper and cover face)

ADRs with anti-TB drugs, their prevention and management:

ADRs	Diagnosis	Suspect Drug(s)	Differential Diagnosis / Other causes	Prevention	Management
Nausea and Vomiting	Clinical, based on complaints by patient	All oral anti-TB drugs	Hepatitis	Take anti- TB medication with banana	Symptomatic management. Exclude hepatitis / hepatoxicity
Rash, urticaria	Clinical	All anti-TB drugs	Steven Johnson syndrome, Anaphylactic reaction, Exfoliative dermatitis, Herpes infection	Seek past history of allergy before starting treatment and as applicable.	If rash involves <10% body surface area (BSA) and is not associated with mucous membrane involvement, treat with anti-histaminics. Stop suspect anti-TB drug and refer patient to specialist if indicated. Desensitization can be attempted. If it fails, substitute the suspect drug with alternate drug
Diarrhea	Clinical	All oral anti-TBdrugs	Bacterial dysentery Amoebic dysentery, Malabsorption syndrome, Pseudomembranous colitis	Use of clean and potable water for drinking, washing hands before eating and drinking any thing	AdviceOral Rehydration Solution (ORS)200 ml, after each loose stool. Check for infective causes.
Liver enzymes- SGOT/ SGPT increased (up to 2xULN)	Increase of liver enzymes after starting anti-TB drugs	Frequent & Severe: PZA INH RIF Rare: EMB Ethionamide FQs PAS Cycloserine	Viral hepatitis – rule out by negative serological tests for A, B, C and E. Alcoholic hepatitis - AST:ALT > 2:1 with history of alcohol intake Amoebic liver abscess – Ultrasound / CT to detect cystic lesions / abscess	Up to 2xULN is not serious. DIH reported in 8-30% of patients. Cannot be prevented. Avoid simultaneous administration of other hepatotoxic drugs. It can worsen to severe hepatitis, which can be prevented by monitoring	Usually drugs are not withdrawn. Check for other potential hepatotoxic agents e.g. alcohol

			Mass in ultrasound/CT→ Liver biopsy to rule out Hepatoma	of LFT in high risk patients every 15 days & taking appropriate action if liver enzymes increase.	
Hepatitis (Severe)	ALT/ AST >3×ULN with symptoms of Nausea, vomiting, anorexia, jaundice, dark colored urine OR ALT/ AST >5×ULN without symptoms	Frequent & Severe: PZA INH RIF Rare: Ethionamide PAS Cycloserine Clarithromycin Clofazimine Imipenem-cilastatin	Investigate as above to rule out: Viral hepatitis Alcoholic hepatitis - Amoebic liver abscess Hepatoma	Early detection of raised liver enzymes to prevent worsening & reduce associated morbidity & mortality	Management includes withdrawal of potential causative drugs & supportive treatment. Later, when enzyme levels return to normal, then gradually reintroduce the drugs. (Refer to flowcharts)
Exfoliative and allergic dermatitis	Clinical based on symptoms- Pruritus, widespread erythema and epidermal sloughing	Frequent: FQs Rare: RIF PAS Cycloserine linezolid Amoxicillin-clavulanate clarithromycin Clofazimine	Asteatotic Eczema Contact Dermatitis, Drug-Induced Bullous Disorders Drug-Induced Photosensitivity Nummular Dermatitis Perioral Dermatitis Phytophotodermatitis	Early detection and management can prevent worsening	Topical hydrocortisone or oral antihistamines may be helpful to control pruritus. Anti-TBmedications should not be discontinued unless an equally effective drug is available for substitution. Refer to specialist if indicated.
Stevens-Johnson and Toxic epidermal necrosis	Clinical based on total body surface area (BSA)involvement of more than 10% and/ or mucous membrane	Rare: INH RIF EMB FQs Amoxicillin-clavulanateclari	Staphylococcal scalded skin syndrome Irradiation – History of radiation Trauma - History Progressive systemic sclerosis (scleroderma) –	Early detection and management can prevent worsening	Immediate drug withdrawal and referral to specialistis recommended. Reintroduction is not recommended. Supportive therapy like antihistamines, anti-inflammatory agents may be helpful in the meantime.

	involvement	thromycin imipenem-cilastatin	ANCA antibodies		
Psychosis (Severe)	Symptoms of Hallucinations, paranoia, suicidal or abnormal thoughts or actions	Frequent & Severe: Cycloserine Frequent: INH Rare: RIF, FQs Clarithromycin Clofazimine Imipenem-cilastatin	Post-traumatic Stress Disorder, Delusional disorder, Schizophrenia, Schizophreniform Disorder	Careful monitoring. Psychiatric counseling at the start of treatment in patients at risk of psychiatric disorders.	Refer to specialist for further evaluation.Consider suspectdrug withdrawal. Refer to specialist.
Peripheral neuropathy	Clinical symptoms of Burning and paresthesia in extremities. Electromyography (nerve conduction studies)for confirmation	Frequent: INH Rare: EMB FQs PAS Ethionamide Cycloserine Linezolid (Severe)	Neuropathy due to high dose of pyridoxine Diabetic neuropathy Peripheral demyelinating disease	Supplementing the anti-TBdrugs with Pyridoxine 5-10 mg orally once a day if patient is on INH, Pyridoxine 50 mg per day with Linezolid and with every 250 mg Cycloserine.	Check for Pyridoxine compliance. Give paracetamol / NSAIDsto alleviate pain. Drug withdrawal is not indicated. Start Pyridoxine 100 mg per day. If no response, increase dose of Pyridoxine to 200 mg. Refer to specialist if no response or if patient is taking Linezolid.
Ototoxicity/ Hearing loss/ Deafness	Symptoms-Tinnitus, vertigo, Loss of balance and equilibrium. Audiometry for confirmation	Frequent & Severe: AGs Rare: Linezolid clarithromycin imipenem-cilastatin	Ear wax, otitis media, Traumatic hearing loss, Meniere's disease Acoustic neuroma	Monitoring of early symptoms can prevent permanent ear damage	Consider withdrawal of the suspect drug. Refer to specialist for further evaluation
Optic neuritis	Vision loss, Peri-ocular pain, Dyschromatopsia(disorder of color vision). Based on	Frequent & Severe: EMB Rare: PAS	Brain Tumor, Giant cell arteritis, Retinal detachment, Multiple sclerosis, Closed-angle glaucoma,	Regular ophthalmologic examination	Consider withdrawal of the suspect drug. Refer to specialist for further evaluation

	symptoms and ophthalmic examination for confirmation	Ethionamide Clofazimine Linezolid (severe)	Cataract, Macular degeneration, Diabetic retinopathy		
Immune Nephrotoxicity	Serum creatinine >2×baseline. Presence of Auto-antibodies in the blood is confirmatory	RIF, especially when restarted after stopping for few weeks	Urinary tract infection, Post streptococcal glomerulonephritis, Minimal change disease, Rapidly progressing glomerulonephritis	Patients should be counseled not to stop and restart rifampicin randomly,on their own	Consider drug withdrawal and refer tospecialist.
Flu Syndrome	By symptoms-Chills, malaise, dry cough, shortness of breath, loss of appetite, body aches and nausea	Frequent: RIF(specially with intermittent regimen)	Viral infections: Influenza, Dengue Fever: Dengue NS1 antigen test positive	Patients on daily regimen have reported lower frequency and less severe flu as compared to the patients on intermittent regimen	Oral antihistaminic and paracetamol, according to the symptoms
Arthralgia / arthritis	Joint pain, swelling involving one or more joints, High uric acid levels. Demonstration of tophi crystals in joint is confirmatory of Gout	Frequent & Severe: PZA Rare: EMB INH	Osteo-arthritis Rheumatoid arthritis	Early diagnosis and management can prevent progression and can improve quality of life	Therapy with paracetamol / NSAIDs can be used for pain relief as needed / Colchicine can be given in gout.
Thrombocytopenia	Blood platelet count <50000 mg/dl indicates thrombocytopenia, Drug induced thrombocytopenia is diagnosed by excluding other causes of	Frequent & Severe: RIF FQs Rare: INH EMB PZA AGs	Dengue hemorrhagic fever – Dengue NS1 antigen test positive Malaria – Peripheral blood smear, malaria antigen test Liver Cirrhosis – Liver biopsy Thrombotic Thrombocytopenic Purpura	Patients should be advised not to skip the doses of anti-TB drugs as the incidence of drug-induced thrombocytopenia has been reported to be higher when the drug is not taken continuously	Manage with platelet transfusion and consider withdrawal of suspect drug. It is important to remember that anti-TBdrugs can cause thrombocytopenia.

	thrombocytopenia	PAS Ethionamide Cycloserine Amoxicillin-clavulanate Clarithromycin Imipenem-cilastatin Linezolid	– Blood picture showing thrombocytopenia and hemolytic anemia with clinical symptoms Acute Leukemia – Bone marrow examination	As such thrombocytopenia cannot be prevented.Regular monitoring of platelet levels can facilitate early detection & thus, reduce the associated morbidity & mortality	
Leucopenia	Leucocyte count less than 2000/mm^3 Neutropenia: Absolute neutrophil count less than 1000/mm^3 Routine blood counts	<u>Rare:</u> INH EMB RIF FQs AGs Ethionamide Linezolid Amoxicillin-ClavulanateClarithromycin Imipenem-cilastatin	Typhoid, malaria, dengue, Rickettsial infections, HIV, thyroid disorders, aplastic anemia, rheumatoid arthritis, vitamin B12 or folate deficiency, mineral deficiencies of copper and zinc etc. Bone marrow diseases: Myelodysplastic syndrome, leukemia, Autoimmune disorders: SLE Bone marrow damage or suppression Drugs like: Clozapine, Valproate, Lamotrigine, Interferons, and Bupropion.	Monitoring of the complete blood count as indicated, will help in early identification. Avoid simultaneous administration of other drugs that can cause leucopenia.	If the total leucocyte count is <2000/ mm^3 or absolute neutrophil count < 1000/mm^3. **Refer the patient to specialist as this is serious.**
Nephrotoxicity	Serum creatinine more the twice the baseline with symptoms of Oliguria, Appetite loss, General ill feeling and fatigue	<u>Frequent & Severe:</u> **AGs** <u>Rare:</u> Linezolid	Chronic renal failure, Alcoholic ketoacidosis, Diabetic ketoacidosis, Metabolic acidosis, Urinary tract infection	Dose adjustment in patients with pre-existing renal disease, monitoring of renal function as indicated	Dose adjustment in patients with pre-existing renal disease. In cases of lack of response consider drug withdrawal and refer to specialist.

Hyperglycemia	Fasting blood sugar more than 160 mg/dl with polydypsia, polyphagia, polyuria.	Rare: RIF INH FQs Moxifloxacin Clofazimine	Hyperglycemia: Uncontrolled diabetes mellitus, Impaired glucose tolerance	Regular Blood sugar monitoring in high risk patients can help in early detection.	Individualized diet, exercise, patient educationand glucose-lowering therapies.
Hypoglycemia	Blood sugar less than 55 mg/dl with weakness, palpitation, loss of consciousness, seizures.	Rare: INH Ethionamide Clarithromycin	Hypoglycemia: Prolonged starvation, Pheochromocytoma, Cushing's syndrome	Regular Blood sugar monitoring in high risk patients for early detection	In case of severe hypoglycemia, withhold all hypoglycemic medications. Glucose to be given orally or I.V. as appropriate.
Hypothyroidism	TSH level >10 mIU/L with tiredness, increased sensitivity to cold, weight gain, constipation, depression, lethargy	Rare: PAS Ethionamide Cycloserine	Hypothyroid Goitre - TSH levels high Myxoedema - Hashimotos thyroiditis – Anti-thyroid antibodies Riedels thyroiditis - Antibodies	Early diagnosis, followed by prompt treatment can help to preventworsening.	All patients with TSH >10 mIU/L, whether symptomatic or not, should be started on Levothyroxine
Pseudomembranous colitis	Watery diarrhoeawith or without blood, associated with stomach cramps and highfever,stool examination	Frequent & Severe: Amoxicillin-clavulanate ClarithromycinI mipenem-cilastatin Linezolid Rare: RIF FQs	Viral diarrhea Bacterial diarrhea, Amoebic dysentery Malabsorption syndrome – Chronic condition accompanied with weight loss	Judicious use of antibiotics, use of probiotics	Vancomycin and metronidazole are effective. Refer to specialist. Consider withdrawal of the suspect drug.

Gynaecomastia	Clinical symptoms and biopsy	Rare: INH RIF Ethionamide	Lipomas, dermoid cysts, sebaceous cysts, ductal ectasia, hematomas, and fat necrosis FNAC will provide the clear diagnosis	Resolves after stopping anti-TB drugs	Reassure patient and in severe cases, withdraw suspect drug.
Pellagra-like syndrome	Based on clinical symptoms of Dementia, Dermatitis and Diarrhea	Rare: INH Ethionamide	Chronic alcoholism – Malnutrition Amino acid imbalance - Hypoalbuminemia	Supplementation with nicotinamide and pyridoxine	Check for compliance. Increase the dose of nicotinamide and pyridoxine if required.
QT prolongation Torsade de pointes Arrhythmia	QTc≥ 501 ms on at least two separate ECGs and or arrhythmia on ECG	Rare: FQs Moxifloxacin Clofazamine Linezolid Clarithromycin	Hypokalemia, Metabolic acidosis, Atrial fibrillation, atrial flutter, ventricular arrhythmia, Paroxysmal supraventricular tachycardia	ECG of patient on FQs as and when indicated	Refer to specialist for management

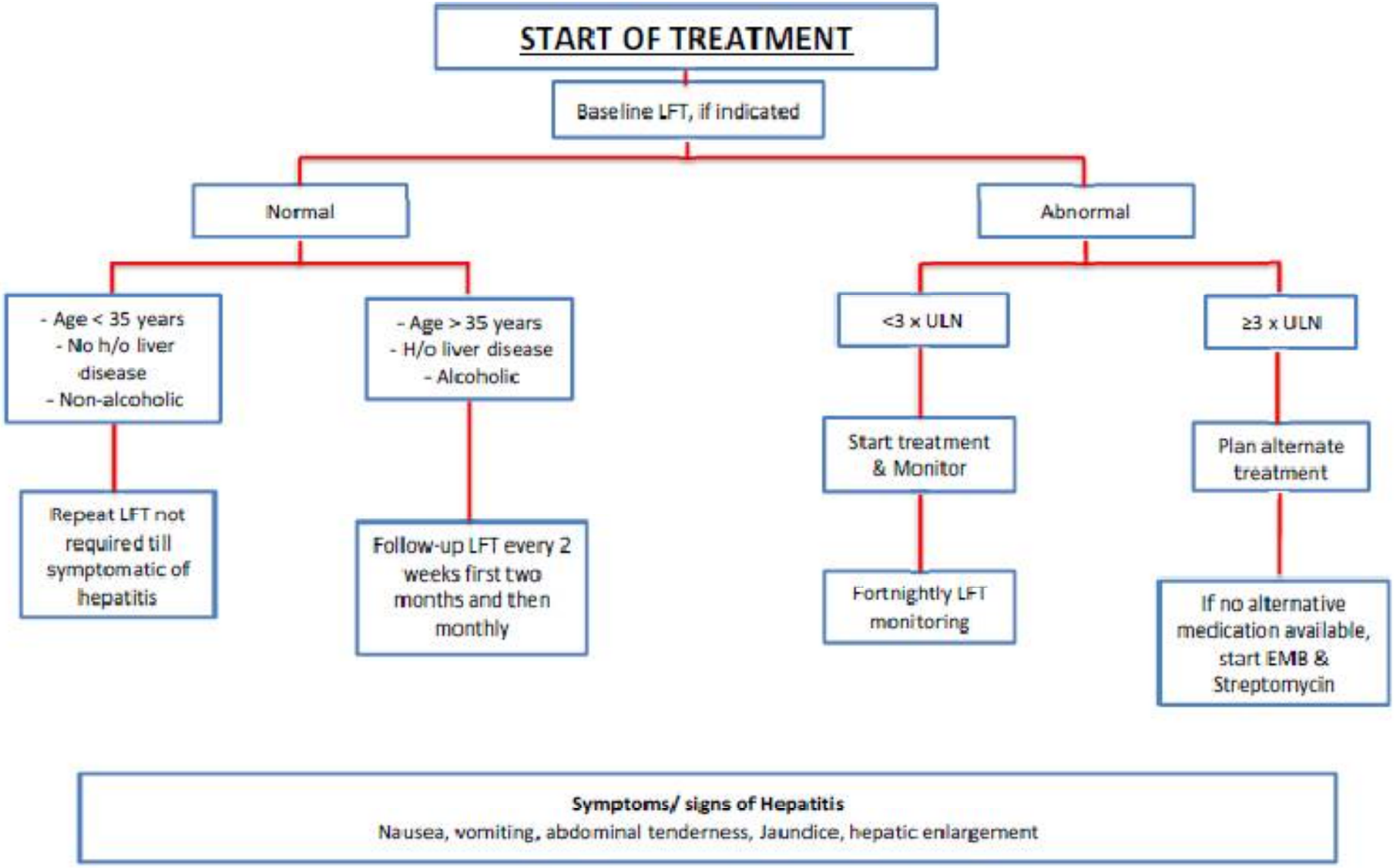
Pancreatitis, Peptic ulcer, Depression, Encephalopathy, Pneumonitis, Myopathy, Rhabdomyolysis, Congestive cardiac failure, Pericarditis have also been reported **rarely**with anti-TBdrugs.Peripheral neuropathy, anemia, thrombocytopenia, leucopenia and optic neuritis with Linezolid (2nd line drugs) can be sever and need immediate referral to specialist.
Frequent: Seen in 1-10% patients
Rare: Seen in less than 1% patients

Laboratory tests for TB patients:

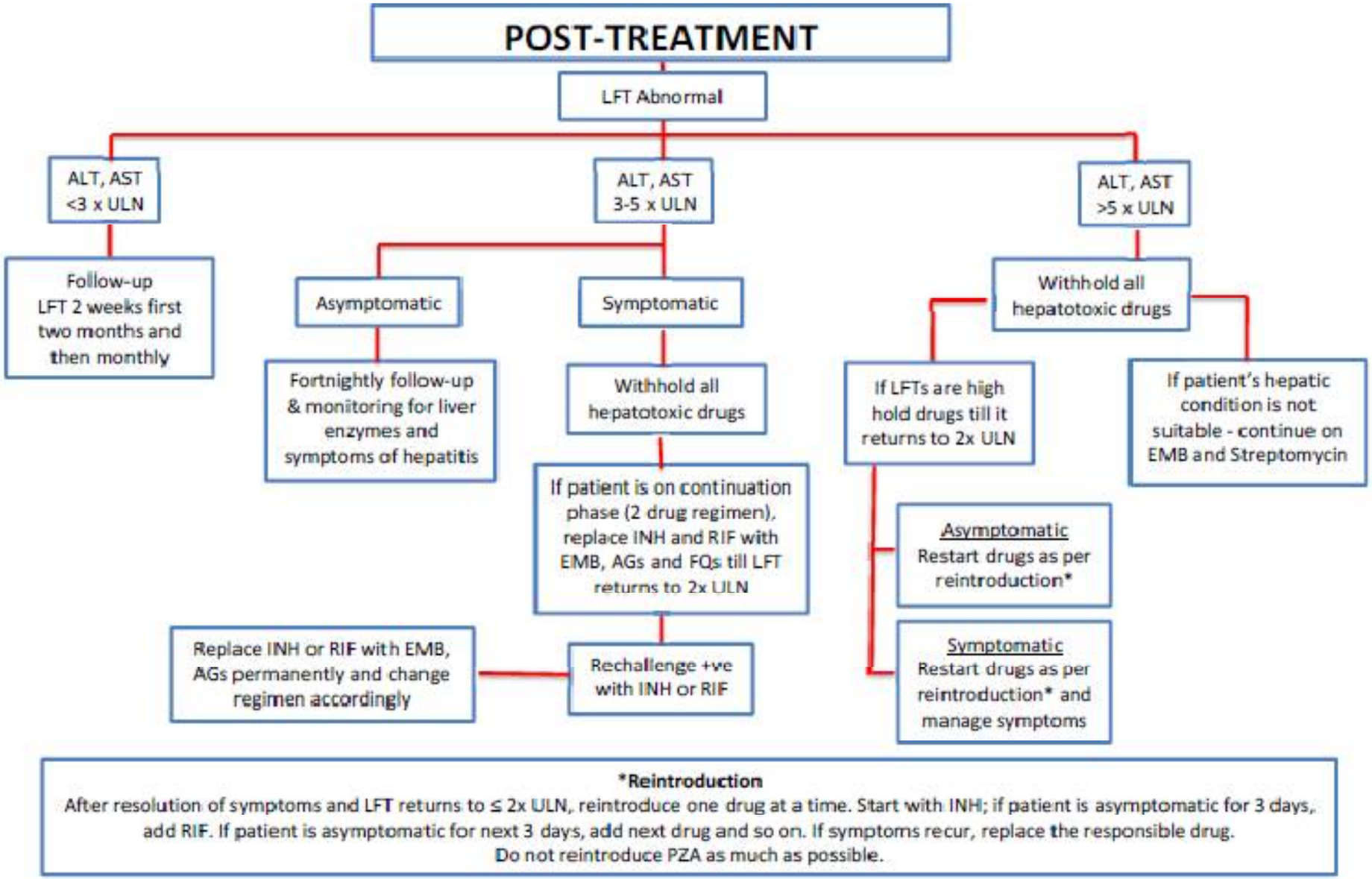
Time points	Laboratory tests
Baseline (Before initiating treatment if indicated)	1. LFT (ALT, AST, Serum bilirubin) 2. RFT (Serum creatinine, Blood Urea, Urine routine and microscopy) 3. Complete blood count, peripheral smear and Hb 4. Blood glucose: Fasting and post-prandial (Random in non-diabetics) 5. Total serum proteins, Albumin and Globulin 6. Serum uric acid 7. Serum electrolytes 8. Thyroid function tests (T3, T4 and TSH) 9. Ophthalmologic examination 10. Psychiatric consultation (before starting Cycloserine) 11. In females: Urine pregnancy test and USG of abdomen and pelvis
After 1.5 months	Ophthalmologic examination (for patients taking Ethambutol), if indicated
After 2 months of treatment as indicated	Tests 3 to 8 mentioned at the baseline will be repeated. Ophthalmologic examination: If EMB is stopped at or before 2 months, not required. If EMB is continued and ophthalmologic examination was not performed at 1.5 months, then it should be done.

Tests to be performed at 2 months will be repeated at 4 and 6 months if and as and when indicated.

Algorithm for the Management of Hepatitis: Flowchart 1:



Algorithm for the Management of Hepatitis: Flowchart 2



Warning symptoms for some serious adverse reactions:

Warning Symptoms	For Medical officer / General practitioner (GP): When to refer the patient
• Rash • Skin lesions on oral cavity, nose	If mucous membranes are involved OR rash is more than 1/10th of body surface area without mucous membrane involvement OR associated with fever and generalized swelling (edema); **refer to specialist / tertiary care center immediately.**
Pain in eye/s, Blurring of vision and Disturbance in color vision	Indicates **Eye toxicity.** **Refer the patient to specialist for evaluation.**
Loss of hearing / Diminished hearing, Ringing in the ears, Dizziness and Loss of balance	Indicates **Ear toxicity**. **Refer the patient to specialist** for evaluation.
Puffiness of face, Swelling over feet and Oliguria, Anuria	Indicates **Kidney toxicity**. Treat the symptoms and**refer the patient to specialist for evaluation.**
Hallucinations, Seeing abnormal things and Suicidal or abnormal thoughts or actions	Indicates **Psychiatric disturbances.** **Refer the patient to specialist** for evaluation.

Absolute contraindications of anti-TBdrugs:(Benefit – Risk) have to be carefully assessed.

Drug	Absolute contraindications	Reason
Rifampicin	With Saquinavir and Ritonavir	Potential for hepatotoxicity is increased. Rifampicin is CYP3A4 inducer and can decrease Saquinavir level and effect
Ethambutol	Optic neuritis	Ethambutol can cause optic neuritis
Pyrazinamide	Acute porphyria Gouty arthritis Hepatic diseases	Pyrazinamide can precipitate acute porphyria Can inhibit excretion of urates Can cause drug induced hepatitis
Neomycin Kanamycin, Tobramycin, Amikacin, Capreomycin, Streptomycin	Concurrent use of two aminoglycosides With potent diuretics e.g. Furosemide Soon after use of anesthetics and muscle relaxants	Can potentiate nephrotoxicity Can potentiate ototoxicity Can result in respiratory paralysis
Levofloxacin, Ofloxacin, Moxifloxacin	History of tendon disorders	Associated with risk of tendinitis and tendon rupture
Ethionamide	Severe hepatic impairment	Risk of worsening
Cycloserine	Epilepsy, Psychiatric illness-Depression, Severe anxiety, Psychosis Severe renal insufficiency	Can precipitate seizures Can lead to severe psychosis and depression Can lead to Cycloserine toxicity
Clarithromycin	With Pimozide, Astemizole With Lovastatin or Simvastatin Hypokalemia and in patients with prolonged QT interval	Risk of QT prolongation Can cause rhabdomyolysis Risk of further QT prolongation
Imipenem	With Valproic acid and Probenecid	Decrease in valproic acid concentration and Increase in plasma levels of imipenem
Linezolid	With Monoamine oxidases A or B inhibitors (e.g. phenelzine, isocarboxazid, selegiline, moclobemide) within two weeks	Risk of MAO inhibition leading to serotonin syndrome

Algorithm for reintroduction of anti-TB drugs - To be done by experts only:

Adverse drug reaction	Advice on reintroduction
Hepatotoxicity	• Reintroductionafter liver enzyme returns to ≤ 2 X ULN
Ocular toxicity	• Main suspect drug is EMB • Reintroduction of Ethambutol is not recommended
Immune mediated Nephritis	• Main suspect drug is RIF • Reintroduction with RIF is not recommended
Non serious cutaneous ADRs -no mucous membrane involvement or less than 10 % of BSA.	• After withholding all drugs reintroduce one drug at a time
Serious Cutaneous adverse drug reactions - mucous membrane involvement or more than 10 % of BSA.	• Reintroduction is not recommended (applies for all anti-TBdrugs).
Immune thrombocytopenia	• Main suspect drug is RIF • Reintroduction with RIF is not recommended
Gynecomastia	• Symptoms takes long time to resolve (4-12 month) hence usually reintroduction is not required.
Aplastic Anemia	• Main suspect drug is INH • Reintroduction with INH is not recommended
Nephrotoxicity	• Main suspect drugs are AGs. • AGs can be reintroduced at low doses after the renal function returns to normal.
Ototoxicity	• Main suspect drugs are AGs. • Reintroduction of AGs is not recommended.
Cardiac arrhythmias including Torsede pointes (TdP)	• Main suspect drugs are FQs. • Reintroduction with FQs is not recommended.
Diarrhea	• Reintroduction is recommended with one drug at a time every fourth day, once diarrhea is resolved
Seizures	• Main suspect drugs are FQs. • Reintroduction with FQs is not recommended.
Psychosis	• Main suspect drugs iscycloserine. • Reintroduction with cycloserine can be done at low dose but if symptoms recur than completely discontinue the drug.

Stepwise increase in the dosage for Reintroduction

1. Reintroduction of anti-TB drugs:

Drug	Day 1	Day 2	Day 3
Isoniazid	50 mg	Full dose	Full dose
Rifampicin	75 mg	300 mg	Full dose
Pyrazinamide	250 mg	1000 mg	Full dose
Ethionamide / Prothionamide	125 mg	250 mg	Full dose
Fluoroquinolones	50 mg	200 – 250 mg	Full dose
Cyclosporine	125 mg	250 mg	Full dose
Ethambutol	100 mg	500 mg	Full dose
PAS	1 g	4 g	Full dose
Capreomycin	125 mg	500 mg	Full dose
Kanamycin	125 mg	500 mg	Full dose
Amikacin	125 mg	500 mg	Full dose

If the test dose of any drug causes a reaction, discontinue this drug, unless it is deemed essential to the regimen. If that is the case, desensitization can be considered.

2. Reintroduction of the drugs should be in hospitalized patients.

3. In patients with severe rash,dose increment should be slower than stated above.

4. For key drugs, Isoniazid, Rifampicin, Ethambutol, detailed desensitization protocol with very small dose and method of dosage preparation is available on the website (http://www.who.int/topics/tuberculosis/en/)

Commonly used ancillary medicines:

Management of adverse reaction often requires use of ancillary medicines to reduce or lessen side effects. Below is list of indications and commonly used medicines for management of adverse reactions.

Indication	Drugs
Nausea, vomiting, Stomach upset	Domeperidone, metoclopramide, prochlorperazine, promethazine, ondansetron
Heartburn, indigestion and acidity	H2-blockers (ranitidine etc.), proton pump inhibitors (omeprazole, pantoprazole etc) Antacid syrups and the antacids if prescribed should be takenat least 2 hours apart from anti-TB drugs
Oral candidiasis	Fluconazole, clotrimazole lozenges, nystatin suspension
Diarrhoea	ORS sachets
Prophylaxis of neurological complications of cycloserine and isoniazid	Pyridoxine (vitamin B6)
Musculoskeletal pain, Arthralgia, headaches	Give paracetamol / ibuprofen / aspirin/ diclofenac. If caused by fluoroquinolones, refer tospecialist immediately. Tendonitis can progress to tendon rupture.
Cutaneous reactions, itching	Hydrocortisone cream, calamine lotion
Systemic hypersensitivity Reactions	Antihistamines (diphenhydramine, chlorpheniramine, dimenhydrinate) Systemic corticosteroids (prednisone, prednisolone, Dexamethasone) are reserved only for very severe reactions
Bronchospasm	Inhaled beta-agonists (salbutamol, albuterol, etc.), inhaled corticosteroids (beclomethasone, etc.)
Hypothyroidism	Levothyroxine
Electrolyte wasting	Potassium and magnesium replacement therapy (oral formulations)
Depression	Selective serotonin reuptake inhibitors (fluoxetine, sertraline), tricyclic antidepressants

	(amitriptyline)
Severe anxiety	Lorazepam, diazepam, clonazepam
Insomnia	Any hypnotic
Psychosis	Haloperidol, thorazine, risperidone (consider benzotropine or biperiden to prevent extrapyramidal Effects), Buromazine, thioridazine
Seizures	Phenytoin, carbamazepine, valproic acid, phenobarbital
Peripheral neuropathy	Amitriptyline, gabapentin
Vestibular symptoms	Meclizine, dimenhydrinate, prochlorperazine, Promethazine

Ready Reckoner for Health Worker

Annexure 10

Important general instructions:

Common side effects of anti-TB drugs and their management

1. Ensure that patient completes full course of anti-TB therapy
2. Side effects of anti-TB drugs are important cause of patient stopping medication
3. Prevention and early detection of side effects are needed
4. Alcohol, smoking and use of illicit drugs increaseside effects
5. Relevant history, clinical examination and lab tests are important to evaluate risk factors and diagnosis of side effects at an early stage
6. For contraception, ask patientto seek advice from family health center as oral contraceptives are less effective with some anti-TB drugs
7. Educate, counsel and reassure patients for self-limiting side effects
8. Side effects and serious side effects requiring immediate action ⟶ **refer patients to Medical officer**
9. Report serious side effects to PvPI center (Procedure for reporting: Call your nearby PvPI center and provide complete information about side effect. Contact details of the nearest PvPIcenter are: Name of the Centre **-** _____;Contact no: _____;

   National toll free number:**1800 180 3024**)
10. Advice nutritious diet to TB patients
11. Advice patients about respiratory hygiene and provide information on preventing spread of TB (use facemask, tissue paper and cover face)

Ready Reckoner for Health Worker

Table 1: Some common and rare side effects of anti-TB drugs are as follows:

Common (Seen in 1-10% patients)	Rare (Seen in less than 1% patients)
Nausea, Vomiting, Gastritis, Hepatitis, Hypersensitivity reactions, Cutaneous reactions	Flu like syndrome, Peripheral neuropathy, Ocular toxicity, Dysglycemia, Gynaecomastia, Hypothyroidism, Joint related side effects, Tendinopathy and tendinitis, Myelo-suppression, Anaemia, Thrombocytopenia, Psychosis, Seizures, Prolongation of QT interval

Table 2: Symptoms, causative drugs and action to be taken by Health worker:

Symptoms	Which drugs cause	Action by Health Workers
Upper abdominal pain - Frequent	All oral anti-TB drugs	Indicates **gastritis.** Advise patients to increase fluid intake. Patients should not take antacids / acid lowering agents together with first line anti-TB drugs as it reduces the absorption of drugs. **Refer to Medical Officer**
Nausea, vomiting	All oral anti-TB drugs	Reassure patient. Advice patient to take drugs embedded in a banana. Give drugs with less water and over a longer period of time (e.g. 20 minutes). However, later in the day, patients should take sufficient water. **If above measures fail, refer to Medical Officer.**
Nausea, vomiting with yellowness of skin and dark colour urine	Mainly by Pyrazinamide, Rifampicin and Isoniazid	Indicates**Liver toxicity** **Refer to Medical officer urgently**
Loose motions frequency >4 times, liquid stools	Mainly by PAS, Ethionamide, Isoniazid, Rifampicin, Ofloxacin, Levofloxacin,	Counsel patients on food and personal hygiene. Advice 200 ml Oral rehydration solution (ORS) after every loose

	Moxifloxacin	stool to maintain hydration. **Refer to Medical officer**
Loose motions associated with dryness of skin and mouth, decreased urination, tiredness and sunken eyes	Same as above	Indicates**Dehydration(Serious)** **Refer to Medical officer urgently**
Itching / Rashes	Mainly by Ethambutol, Rifampicin, Streptomycin	Reassure patient **If rash persists, refer to Medical Officer**
Itching / Rashes involving very large body area or present in mouth, nose associated with swelling and fever	Mainly by Ethambutol, Rifampicin, Streptomycin	Indicates systemic involvement (**Serious**) **Refer to Medical officer urgently**
Tingling /burning /numbnessin hands and feet	Mainly Isoniazid, Cycloserine	Check that patient is taking Pyridoxine. **Refer to Medical officer.**
Pain in Joints	Mainly Pyrazinamide	Paracetamol can be given if only 1-2 joints are involved. Reassure patient that it is a self-limiting condition. If > 2 joints are involved or pain is not relieved, **refer to Medical officer.**
Impaired vision: Pain, Blurring of vision, Disturbance in color vision	Mainly Ethambutol	Indicates**Eye toxicity**. **Refer to Medical officer urgently**
Flu-like syndrome: Chills, dry cough, shortness of breath, loss of appetite, body ache, malaise	Mainly Rifampicin	Reassure patient. If not controlled, refer patient to **Medical Officer** for evaluation.
Swelling of face or legs, less or no urine	Amikacin, Kanamycin, Capreomycin, Streptomyin	Indicates**Kidney toxicity**. **Refer to Medical officer urgently**

Ready Reckoner for Health Worker

Seeing abnormal things, change of thoughts, suicidal thoughts	Mainly Cycloserine	Indicates **Psychiatric disturbances.** **Refer to Medical officer urgently**
Tiredness, lethargy, headache, giddiness, pale look, palpitations	Mainly Linezolid, Isoniazid, Rifampicin, Pyrazinamide, Ofloxacin, Levofloxacin, Moxifloxacin	Indicates**Anemia.** Patients can be advised rest in DOTS center post-dosing to avoid giddiness. Advice patients on nutrition Refer **to Medical Officer** for evaluation.
Ringing in ears, Loss of hearing, dizziness and loss of balance leading to recurrent fall	Mainly Streptomycin, Amikacin, Kanamycin, Capreomycin	Indicates**Ear toxicity.** **Refer to Medical officer urgently**
Slowness of activities, swelling of face, swelling in neck, disproportionate weight gain	Mainly PAS and Ethionamide	Indicates **Thyroid involvement.** **Refer to Medical officer urgently**
Pain and swelling in muscles and Tendons, difficulty in movement	Ofloxacin, Levofloxacin and Moxifloxacin	Indicates **Tendonitis** **Refer to Medical officer urgently**
Seizure: Convulsion	Isoniazid, Cycloserine, Ofloxacin, Levofloxacin, Moxifloxacin	**Refer to Medical officer urgently**
Orange and reddish color of urine sweat, phlegm (sputum), saliva or tears may be noticed. As this is quite common with rifampicin and reassure patients.		

Annexure 11

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reactions by healthcare professionals

CDSCO
Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India,
FDA Bhavan, ITO, Kotla Road, New Delhi
www.cdsco.nic.in

(AMC/ NCC Use only
AMC Report No.
Worldwide Unique no.

A. Patient Information

1.Patient Initials _____	2.Age at time of Event or date of birth ----------	3. Sex ☐M ☐ F 4. Weight ____Kgs

12. Relevant tests / laboratory data with dates

B .Suspected Adverse Reaction

5. Date of reaction stated (dd/mm/yyyy)
6. Date of recovery (dd/mm/yyyy)
7. Describe reaction or problem

13. Other relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

14. Seriousness of the action
- ☐ Death (dd/mm/yyy)____
- ☐ Life threatening
- ☐ Hospitalization-initial or prolonged
- ☐ Disability
- ☐ Congenitial anomaly
- ☐ Required intervention to prevent permanent impairment / damage
- ☐ Other (specify)

15. Outcomes
- ☐ Fatal
- ☐ Continuing
- ☐ Recovering
- ☐ Recovered
- ☐ Unknown
- ☐ Other (specify)____

C.Suspected medication(s)

S.No	8. Name (brand and /or generic name)	Manufacturer (if known)	Batch No./ Lot No. (if known)	Exp. Date (if known)	Dose used	Route used	Frequency	Therapy dates (if known give duration)		Reason for use of prescribed for
								Date started	Date stopped	
i.										
ii.										
iii.										
iv.										

Sl.No As per C	9. Reaction abated after drug stopped or dose reduced					10. Reaction reappeared after reintroduction				
	Yes	No	Unknown	NA	Reduced dose	Yes	No	Unknown	NA	If reintroduced dose
i.										
ii.										
iii.										
iv.										

11. Concomitant medical product including self medication and herbal remedies with therapy dates (exclude those used to treat reaction)

D. Reporter (see confidentiality section in first page)

16. Name and Professional Address :_____
_____
Pin code : _____ E-mail _____
Tel. No. (with STD code): _____
Occupation _____Signature _____

17. Causality Assessment

18. Date of this report (dd/mm/yyyy)

ADVICE ABOUT REPORTING

- **Report adverse experiences with medications**
- **Report serious adverse reactions. A reaction is serious when the patient outcome is:**

  - death
  - life-threatening (real risk of dying)
  - hospitalization (initial or prolonged)
  - disability (significant, persistent or permanent
  - congenital anomaly
  - required intervention to prevent permanent impairment or damage

- **Report even if:**

  - You're not certain the product caused adverse reaction
  - you don't have all the details, however, point nos. **1, 5, 7, 8, 11, 15, 16 & 18** (see reverse) are essentially required.

- **Who can report:**

  - Any health care professional (Doctors including Dentists, Nurses and Pharmacists)

- **Where to report:**

  - Please return the completed form to the nearest ***Adverse drug reaction Monitoring Centre (AMC)*** or to ***National Coordinating Centre***
  - A list of nationwide AMCs is available at: http://cdsco.nic.in/pharmacovigilance.htm

- **What happens to the submitted information:**

  - Information provided in this form is handled in strict confidence. The causality assessment is carried out at Adverse Drug Reaction Monitoring Centres (AMCs) by using WHO-UMC scale. The analyzed forms are forwarded to the National Coordinating Centre through the ADR database. Finally the data is analyzed and forwarded to the Global Pharmacovigilance Database managed by WHO Uppsala Monitoring Center in Sweden.

  - The reports are periodically reviewed by the National Coordinating Centre (PvPI). The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines.

  - The information is submitted to the Steering

interventions that may be required.

Reaction Reporting Form

For VOLUNTARY reporting
of suspected adverse drug reactions by
health care professionals

Central Drugs Standard Control Organization
Directorate General of Health Services,
Ministry of Health & Family Welfare, Government of India
FDA Bhawan, ITO Kotla Road, New Delhi – 110002
www.cdsco.nic.in

Pharmacovigilance Programme of India for Assuring Drug Safety

(PvPI)

***National Coordinating Centre*,**
Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare,
Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201 002.Tel.:0120-2783400, 2783401, 2783392, FAX: 0120-2783311
E.mail: ipclab@vsnl.net

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not ex-
and will not disclose the reporter's identity in response to a request from the public. **Submission of a report does not constitute**

caused or contributed to the reaction.

Annexure 12 A

Line-List Of Persons Referred From ICTC To RNTCP

REPORTING MONTH: YEAR NAME OF ICTC: NAMEOF DISTRICT:

	TO BE COMPLETED BY ICTC COUNSELLOR							***TO BE COMPLETED BY the STS***					
1	***2***	***3***	***4***	***5***	***6***	***7***	***8***	***9***	***10***	***11***	***12***	***13***	***14***
Sr. No.	*PID NO*	*Complete Name & Complete Address*	*Age*	*Sex*	*HIV status (R / NR / Unknown)*	*Date of referral to RNTCP*	*Name of facility referred to*	*Is patient diagnosed as TB –Yes or No*	*If diagnosed as TB, specify type of TB and basis of diagnosis*	*Is patient initiated on RNTCP treatment*	*Date of Starting Treatment*	*TB No.*	*Remarks*
	Sign of Counsellor *Date of completion:*					*Sign of MO- ICTC*		*Name of the TU:* *Signature of STS* *Date of Completion:*			*Signature of DTO/CTO/MO-TU*		

Basis of diagnosis – Microbiologically confirmed, Clinically diagnosed

Type of TB – Pulomary, Extrapulomary

Annexure 12B

ICTC TB-HIV monthly report

REPORTING MONTH: _____ *YEAR _____*

NAME OF ICTC:_____ *DISTRICT:_____*

I. TOTAL NUMBER OF GENERAL CLIENTS ATTENDING ICTC:

a) Total no. of clients who attended ICTC in the month (excluding PPTCT clients)	

II.REFERRAL OF PRESUMPTIVE TUBERCULOSIS CASES FROM ICTC TO RNTCP

	HIV positive	HIV Negative
a) No. of persons presumptive diagnostic services		
b) Of the referred presumptive TB patients, No. diagnosed as having:		
(i) Pulmonary TB (Microbiologically confirmed)		
(ii) Pulmonary TB (Clinically diagnosed)		
(iii) Extra-Pulmonary TB (Microbiologically confirmed)		
(iv) Extra Pulmonary (Clinically diagnosed)		
c) Out of above (b), diagnosed TB patients, number receiving RNTCP treatment		

Signature of Medical Officer – In charge ICTC*Name of Medical Officer In-charge ICTC*

HIV-TB Line List (Referrals)

Annexure 13 A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	19	20	20	21
Date of Registration in HIV Care *(dd/mm/yyyy)*	HIV Registration Number	Name	Date of Birth (or Age)	Sex (M/F/TG)	Contact Number	Address - Block, District, State	Status at the time of referral (Pre-ART/ART)	ART Number *(If on ART at time of referral)*	Symptoms Present[1] *(You can select more than one symptoms)*	Whether any past history of TB? (Y/N)	Date of referral for TB Examination (dd/mm/yyyy)	Type, Name of facility where referred to *(Give code and name of all facilities)*[2]	Date of sample	Testing details		Drug Resistance status[4] Mention drug to wich the TB resistant to	Type of TB diagnosed[5]	Date of final diagnosis (dd/mm/yyyy)	If drug resistant TB, then date of referral to DRTB center? (dd/mm/yyyy)	Name of DRTB center where the patient has been referred for treatment	Date of starting ATT (dd/mm/yyyy)	Type of treatment (Category I/II/IV/V)	TB Number / NIKSHAY ID	Place of registration
														Type of test & Result[3] *(Enter all test results)*	Date of test (dd/mm/yyyy)										

Note:

1. (A)Cough of any duration, (B)Low grade fever, (C)Weight Loss, (D)Night sweats, (E)Lymph Nodes, (F) Anorexia, (G)Others: Specify
2. (A)DMC, (B)CBNAAT, (C)DST, (D)Radiology, (E)Histopathology, (F)ART Center, (G)Others
3. For type of test details enter code of test and corresponding test results
   (c)Invalid*(d)Error*(e)No result* (*not conclusive results, need repeat test), (ii)CBNAAT (Rif Resistance) - (a)RR(b)RS(c)Indeterminate, (iii)Smear- (a)Positive(b)Negative
   (iv)Culture-(a)Positive(b)Negative,
   (vii)TST (for children under 5 years of age)-(a)Positive(b)Negative, (viii)Others (Specify)-(a)Positive(b)Negative
4. (i)First Line DST-RIF only/INH only/RIF and INH, (ii)Second Line DST-Ofloxacin, Capreomycin, Kanamycin, Ethambutol, Levofloxacin, Moxifloxacin
   Microbiological diagnosis through Culture, CBNAAT, Smear, TST and histopathology & **Clinical** diagnosis through X-Ray, USG etc. Kindly pick the relevant code from below -
   Microbiologically Microbiologically confirmed), (iv)Extra Pulmonary TB (Clinically diagnosed)

Annexure 13 B

3 b. HIV/TB -Intensified TB Case Finding				
TB Diagnosis & Treatment				
(From Completed HIV/TB Line-List- 1 month prior to reporting month)				
3b.1) Number of PLHIV attending ART Centre during the month (Pre ART and ART)				
3b.2) Out of above number of PLHIV screened for 4 symptoms				
3b.3) Out of above, number of PLHIV with presumptive TB (those with anyone/more symptoms out of 4S)				
3b.4) Out of above,number of PLHIV with presumptive TB referred from ART centre for TB diagnosis				
3b.5) Out of above, number of PLHIV with presumptive TB, tested for TB diagnosis				
3b.6) Out of the above number of PLHIV diagnosed as having TB :		**In Pre ART Care at time of TB diagnosis**	**Already on ART at time of TB diagnosis**	**Total**
	(i) (Microbiologically confirmed)			0
	(ii) Pulmonary TB (Clinically diagnosed)			0
	(iii) (Microbiologically confirmed)			0
	(iv) Extra Pulmonary (Clinically diagnosed)			0
3b.7) Total PLHIV Diagnosed with TB		0	0	0
3b.8) Out of **(3b.7)**,, number of TB patients receiving RNTCP treatment				
3b.9) Out of **(3b.7)**,, number of TB patients receiving Non-RNTCP treatment				
3b.10) Out of **(3b.7)**, number of TB patients with RRTB (Rif Resistant TB)				
3b.11) Out of **(3b.10)**, number of TB patients with RRTB (Rif Resistant TB) receiving Cat IV treatment				
3 c. Treatment of HIV in HIV TB co-infected PLHIV				
(From the HIV- TB register data -2 months prior to reporting month)				
3c.1) Total number of TB patients enrolled in HIV/TB register 2 months prior to reporting month				
3c.2) Out of **(3c.1)** number of TB patients initiated on CPT				
3c.3) Out of **(3c.1)** number of TB patients initiated on ART				
3 d. IPT Status (From Master Line List of Reporting Month)				
3d.1) Number of PLHIV newly initiated on IPT during this month				
3d.2) Number of PLHIV completed IPT during this month				

HIV TB Register (Confirmed)

Annexure 13 C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Date of Registration in HIV Care *(dd/mm/yyyy)*	HIV Registration Number	Name	Date of Birth (or Age)	Sex (M/F/TG)	Contact Number	Address - Block, District, State	From where the patient has been referred? (Pick appropiate code and provide name of facility)[1]	Testing details		Drug resistant Status	Type of TB diagnosed[5]	Date of final diagnosis	Patient category[4]	If DRTB, then date of referral to DRTB center	Date of anti TB treatment (ATT) initiation	If not initiated on ATT , reason for the same[9]	Type, Name of facility for TB treatment[6]	Weight band[7]	Type of treatment (Category I/II/IV/V)	NIKSHAY Number/ TB Number/ PMDT Number *(if applicable)* **Any one of these**	Date of treatment completion	If patient faced any side effects please mention (A)Toxicity (B)Others: Specify	If discontinued, date of discontinuation and reason for discontinuation[8]	Treatment outcome[9]	Is the patient on CPT? (Y/N)	Date of ART initiation	ART Registration Number	CD4 Count (A)Baseline (B)At the time of diagnosis (C)At the time of completion *(Provide all three counts)*		If not initiated on ART, reason for the same[10]	Remarks
								Type of test & Result[2] *(Enter all test results)*	Date of test																				Count	Date		

Note:

1.(A)Referred by ART center for TB diagnosis, (B)Referred by ICTC for TB diagnosis, (C)K/C/O TB referred by RNTCP to ICTC (D)Referred from private practioner/Other

2. For type of test details enter code of test and corresponding test results

(c)Invalid*(d)Error*(e)No result* (* not conclusive results, need repeat test) (ii)CBNAAT (Rif Resistance) - (a)RR(b)RS(c)Indeterminate, (iii)Smear - (a)Positive(b)Negative

(iv)Culture-(a)Positive(b)Negative,(v)First Line DST-RIF only/INH only/RIF and INH,(vi)Second Line DST-Ofloxacin, Capreomycin, Kanamycin, Ethambutol, Levofloxacin, Moxifloxacin

(vii)TST (for children under 5 years of age)-(a)Positive(b)Negative,(viii)Others (Specify)-(a)Positive(b)Negative

Microbiological diagnosis through Culture, CBNAAT, Smear, TST and histopathology & **Clinical** diagnosis through X-Ray, USG etc. Kindly pick the relevant code from below -

Microbiologically confirmed), (iv)Extra Pulmonary TB (Clinically diagnosed)

Microbiologicall)

Retreatment Others

6. (A).ART center (B) RNTCP, (C)Private institution, (D) DRTB, (E)Others

7.(A) <25kg, (B)25-39kg, (C)40-54kg, (D)55-69kg, (E) >70Kg

8.(A)Death, (B)LFU, (C)Transferred out, (D)Side effects, (E)Others: Specify

9.(A)Cured, (B)Treatment completed, (C)Died, (D)Treatment failure, (E) Lost to follo up, (F) Transfer out, (G)Switched over to MDR TB treatment(H)Others: Specify

5,10. (A)Patient transferred out to other ART center, (B)Patient not reporting for treatment/LFU,(C)Patient died before ATT/ART initiation,(D)Patient taking treatment in the private sector,(E)Others

Annexure 14 A

MONTHLY STOCK STATEMENT (MSS)

(REPORT SHOWING RECEIPTS & ISSUES OF ANTI-TB DRUGS AS AT)

State: State Drug Store:

Sl. No.	Drug	UOM	Opening Balance	Receipts		Total Stores	ISSUES		Balance Stores with DOE
				Receipts During the Month	Drugs Trfd. In		Store Supplied	Drugs Trfd. Out	
(a)	(b)	(c)	(d)	(e)	(f)	(g = d+e+f)	(h)	(i)	[j = g- (h+i)]
1	PC-1 Treatment box for New Cases	PWB							
2	PC-1 D-I Daily regimen treatment Box for New Cases (25-39kg)	PWB							
3	PC-1 D-II Daily regimen treatment Box for New Cases (40-54kg)	PWB							
4	PC-1 D-III Daily regimen treatment Box for New Cases (55-69kg)	PWB							
5	PC-1 D-IV Daily regimen treatment Box for New cases (≥70 Kg)	PWB							
6	PC-2 Treatment box for Re-Treatment Cases	PWB							
7	PC-2 D-I Daily regimen treatment Box for Re-Treatment Cases (25-39kg)	PWB							
8	PC-2 D-II Daily regimen treatment Box for Re-Treatment Cases (40-54kg)	PWB							
9	PC-2 D-III Daily regimen treatment Box for Re-Treatment Cases (55-69kg)	PWB							

Annexure 14 A

10	PC-2 D-IV Daily regimen treatment Box for Re-Treatment Cases (≥70 Kg)	PWB							
11	Prolongation Pouches	Pouch							
12	PC-5 Inj. Streptomycin 750 mg	Vials							
13	PC-5D-I Inj. Streptomycin 500 mg	Vials							
14	PC-5D-II Inj. Streptomycin 750 mg	Vials							
15	PC-5D-III Inj. Streptomycin 1 gm	Vials							
16	Pyrazinamide 750 mg	Tablet							
17	Rifampicin 150 mg	Caps							
18	Rifampicin 450 mg	Caps							
19	Isoniazid 100 mg	Tablet							
20	Ethambutol 800 mg	Tablet							
21	Isoniazid 300 mg	Tablet							
22	PC-13 Pediatrics Drug	PWB							
23	PC-14 Pediatrics Drug	PWB							
24	PC-15 Pediatrics Drug	Pouch							
25	PC-16 Pediatrics Drug	Pouch							

KEY: UOM: Unit of Measurement

Note: In the case of Inj. SM, please maintain stock at the rate of 24 injections for each PC-2 box and 56 injections for each PC-2 D-I/ PC-2 D-II / PC-2 D-III / PC-2 D-IV in stock

QUARTERLY REPORT ON PROGRAMME MANAGEMENT AND LOGISTICS **Annexure 14 B**
DTC Level: Medication

ADULT PATIENT WISE BOX

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution of boxes during Quarter	Stock Transferred Out *	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f) - (g+h)	(j)= (h/3 x 7) - i
PC-1 Treatment box for New Cases	PWBs								
PC-2 Treatment box for Re-Treatment Cases	PWBs								

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution of boxes during Quarter	Stock Transferred Out *	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f) - (g+h)	(j)= (h/3 x 5) - i
PC-1 D-I Daily regimen treatment Box for New Cases (25-39kg)	PWBs								
PC-1 D-II Daily regimen treatment Box for New Cases (40-54kg)	PWBs								
PC-1 D-III Daily regimen treatment Box for New Cases (55-69kg)	PWBs								
PC-1 D-IV Daily regimen treatment Box for New cases (≥70 Kg)	PWBs								
PC-2 D-I Daily regimen treatment Box for Re-Treatment Cases (25-39kg)	PWBs								
PC-2 D-II Daily regimen treatment Box for Re-Treatment Cases (40-54kg)	PWBs								
PC-2 D-III Daily regimen treatment Box for Re-Treatment Cases (55-69kg)	PWBs								
PC-2 D-IV Daily regimen treatment Box for Re-Treatment Cases (≥70 Kg)	PWBs								

Prolongation Pouches and Inj SM

Item	Unit of Measure-ment	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution during Quarter	Stock Transferred Out *	Consumption during the Quarter	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f)-(g+h)	(j)= (h/3 x 7) - i
PC-4 (Prolongation Pouches)	Pouches each with 12 blister strips								
PC-5 Inj. Streptomycin 750 mg	Vials								
PC-5D-I Inj. Streptomycin 500 mg	Vials								
PC-5D-II Inj. Streptomycin 750 mg	Vials								
PC-5D-III Inj. Streptomycin 1 gm	Vials								

Paediatric Patient Wise Boxes (Including PWBs for Adult Patients <30kgs)

ITEM	Unit of Measure-ment	Stock on first day of Quarter	Stock received during the quarter	Stock transferred in	Reconstitution during Quarter	Stock Transferred Out *	Consumption during the Quarter	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)= (c+d+e+f)-(g+h)	(j)= (h/3 x 7) - i
Paediatric PC 13	Paediatric PWB								
Paediatric PC 14	Paediatric PWB								
Paediatric PC 15	Paediatric Prolongation Pouches								
Paediatric PC 16	Paediatric Prolongation Pouches								

RNTCP Loose drugs

ITEM	Unit of Measure -ment	Stock on first day of Quarter	Stock received during the quarter	Stock transf erred in	Stock Transfer red Out *	Consumption during the Quarter	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)= (c+d+e)-(f+g)	(i)= (g/3 x 7) - h
INH 300 mg	Tablets							
INH 100 mg	Tablets							
Rifampicin 150mg	Capsules							
Pyrazinamide 750 mg	Tablets							
Ethambutol 800 mg	Tablets						`	

Annexure 14 C

QUARTERLY REPORT ON PROGRAMME MANAGEMENT AND LOGISTICS

TU Level : Medications

Adult Patient Wise Boxes

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 4) - f
PC-1 Treatment box for New Cases	PWBs					
PC-1 D-I Daily regimen treatment Box for New Cases (25-39kg)	PWBs					
PC-1 D-II Daily regimen treatment Box for New Cases (40-54kg)	PWBs					
PC-1 D-III Daily regimen treatment Box for New Cases (55-69kg)	PWBs					
PC-1 D-IV Daily regimen treatment Box for New cases (≥70 Kg)	PWBs					
PC-2 Treatment box for Re-Treatment Cases	PWBs					
PC-2 D-I Daily regimen treatment Box for Re-Treatment Cases (25-39kg)	PWBs					
PC-2 D-II Daily regimen treatment Box for Re-Treatment Cases (40-54kg)	PWBs					
PC-2 D-III Daily regimen treatment Box for Re-Treatment Cases (55-69kg)	PWBs					

PC-2 D-IV Daily regimen treatment Box for Re-Treatment Cases (≥70 Kg)	PWBs					

Prolongation Pouches and Inj SM

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 4) - f
PC-4 (Prolongation Pouches)	Pouches each with 12 blister strips					
PC-5 Inj. Streptomycin 750 mg	Vials					
PC-5D-I Inj. Streptomycin 500mg	Vials					
PC-5D-II Inj. Streptomycin 750mg	Vials					
PC-5D-III Inj. Streptomycin 1 gm	Vials					

PAEDIATRIC PATIENT WISE BOXES (INCLUDING PWBS FOR ADULT PATIENTS <30KGS)

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 4) - f
Paediatric PC 13	Paediatric PWB					
Paediatric PC 14	Paediatric PWB					
Paediatric PC 15	Paediatric Prolongation Pouches					
Paediatric PC 16	Paediatric Prolongation Pouches					

RNTCP Loose drugs

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 4) - f
INH 300 mg	Tablets					
INH 100 mg	Tablets					
Rifampicin 150mg	Capsules					
Pyrazinamide 750 mg	Tablets					
Ethambutol 800 mg	Tablets				`	

Annexure 14 D

MONTHLY REPORT ON PROGRAMME MANAGEMENT AND LOGISTICS

PHI Level : Medications

Adult Patient Wise Boxes

Item	Unit of Measure ment	Stock on first day of month	Stock received during month	Patients initiated on treatment	Stock on last day of month	Quantity Requested
(a)	(b)	(c)	(d)	(e)	f= (c+d)-e	g= (e X 2) - f
PC-1 Treatment box for New Cases	PWBs					
PC-1 D-I Daily regimen treatment Box for New Cases (25-39kg)	PWBs					
PC-1 D-II Daily regimen treatment Box for New Cases (40-54kg)	PWBs					
PC-1 D-III Daily regimen treatment Box for New Cases (55-69kg)	PWBs					
PC-1 D-IV Daily regimen treatment Box for New cases (≥70 Kg)	PWBs					
PC-2 Treatment box for Re-Treatment Cases	PWBs					
PC-2 D-I Daily regimen treatment Box for Re-Treatment Cases (25-39kg)	PWBs					
PC-2 D-II Daily regimen treatment Box for Re-Treatment Cases (40-54kg)	PWBs					
PC-2 D-III Daily regimen treatment Box for Re-Treatment Cases (55-69kg)	PWBs					
PC-2 D-IV Daily regimen treatment Box for Re-Treatment Cases (≥70 Kg)	PWBs					

Prolongation Pouches and Inj SM

Item	Unit of Measurement	Stock on first day of month (a)	Stock received during month (b)	Consumption during the month (c)	Stock on last day of month (d)= (a+b)-c	Quantity Requested (e) = (c X 2) – d
PC-4 (Prolongation Pouches)	Pouches					
PC-5 Inj. Streptomycin 750 mg	Vials					
PC-5D-I Inj. Streptomycin 500mg	Vials					
PC-5D-II Inj. Streptomycin 750mg	Vials					
PC-5D-III Inj. Streptomycin 1 gm	Vials					

PAEDIATRIC PATIENT WISE BOXES (INCLUDING PWBS FOR ADULT PATIENTS <30KGS)

Item	Unit of Measurement	Stock on first day of Quarter	Stock received during the Quarter	Patients started on treatment	Stock on last day of Quarter	Quantity Requested
(a)	(b)	(c)	(d)	(e)	(f)=(c+d)-e	(g)=(e/3 x 2) -f
Paediatric PC 13	Paediatric PWB					
Paediatric PC 14	Paediatric PWB					
Paediatric PC 15	Paediatric Prolongation Pouches					
Paediatric PC 16	Paediatric Prolongation Pouches					

RNTCP Loose Drugs

Item	Unit of Measurement	Stock on first day of month (a)	Stock received during month (b)	Consumption during the month (c)	Stock on last day of month (d)= (a+b)-c	Quantity Requested (e) = (c X 2) – d
INH 300 mg	Tablets					
INH 100 mg	Tablets					
Rifampicin 150 mg	Capsules					
Ethambutol 800 mg	Tablets					

For MRPML of PHI-level, all information is available from the stock register of the PHI stores.

Annexure 14 E

Monthly Stock Statement for stocks at SDS Level
(To be submitted to CTD each month by SDS)

				Receipts during the month		Issues during the month						
Sr. No.	Nomenclature	A/U	Opening Balance	Receipt from Mfrs	Transfer In / Returns	Qty issued for boxes	Qty Issued to DRTB centre	Transfer Out	Balance Stock	DOM (One row for each drug)	DOE (One row for each drug)	Remarks
			(a)	(b)	(c)	(d)	(e)	(f)	(g)= (a+b+c-d-e-f)			
	Loose Drugs											
1	KANAMYCIN (Km) - 500 mg	Vials										
2	KANAMYCIN (Km) - 1000 mg	Vials										
3	LEVOFLOXACIN (Lfx)-250mg	Tabs										
4	LEVOFLOXACIN (Lfx)-500mg	Tabs										
5	CYCLOSERINE (Cs) -250 mg	Caps										
6	ETHIONAMIDE (Eto) - 125 mg	Tabs										
7	ETHIONAMIDE (Eto) - 250 mg	Tabs										
8	PYRAZINAMIDE (Z) - 500 mg	Tabs										
9	PYRAZINAMIDE (Z) - 750 mg	Tabs										
10	ETHAMBUTOL(E) - 200 mg	Tabs										
11	ETHAMBUTOL(E) - 400 mg	Tabs										
12	ETHAMBUTOL(E) - 800 mg	Tabs										
13	PYRIDOXIN-50mg	Tabs										
14	PYRIDOXIN - 100 mg	Tabs										
15	SODIUM PARA-AMINOSALICYLATE(NA PAS) 4gm Sachets (Box of 250 sachets)	Sachets										
16	SODIUM PARA-AMINOSALICYLATE (NA PAS) 10gm Sachets (Box of 100 sachets)	Sachets										
17	SODIUM PARA-AMINOSALICYLATE (NA PAS)-100gm jars	Box (100g)										
	Substitute Drugs											
18	CAPREOMYCIN (Cm)-750 mg	Vials										
19	CAPREOMYCIN (Cm)-1000 mg	Vials										
20	MOXIFLOXACIN (Mfx)-400mg	Tabs										

No.	Nomenclature	A/U	Opening Balance	Receipt during the month	Qty issued	Closing Balance	D.O.E (One row for each box)
			(A)	(B)	(C)	(D = A+B-C)	
	Monthly Patient Wise Boxes						
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					

Weight Band	**< 16 kg**	**16-25 kg**	**26-45 kg**	**45-70 kg**	**>70 kg**
Number of MDR TB patients initiated on treatment during the month					

Monthly Stock Report for Stocks & Indenting of Cat IV drugs at DR-TB Centre
(To be submitted to SDS/STO by DOTS- PMDT Site)

Monthly Report showing the receipt & Issue of MDR Drugs as on _____Qtr ____ -(month/year) for DRTB Centre ..... DTC _____									
Sr.No	Nomenclature	A/U	Opening Balance	Receipt during the month	Qty issued	Balance Stock	D.O.M (One row for each drug)	D.O.E (One row for each drug)	Qty required
			(A)	(B)	(C)	(D= A+B-C)			(E=C x 2)-D
1	KANAMYCIN (Km) - 500 mg	Vials							
2	KANAMYCIN (Km) - 1000 mg	Vials							
3	LEVOFLOXACIN (Lfx)-250mg	Tabs							
4	LEVOFLOXACIN (Lfx)-500mg	Tabs							
5	CYCLOSERINE (Cs) -250 mg	Caps							
6	ETHIONAMIDE (Eto) - 125 mg	Tabs							
7	ETHIONAMIDE (Eto) - 250 mg	Tabs							
8	PYRAZINAMIDE (Z) - 500 mg	Tabs							
9	PYRAZINAMIDE (Z) - 750 mg	Tabs							
10	ETHAMBUTOL(E) - 200 mg	Tabs							
11	ETHAMBUTOL(E) - 400 mg	Tabs							
12	ETHAMBUTOL(E) - 800 mg	Tabs							
13	PYRIDOXIN-50Mg	Tabs							
14	PYRIDOXIN - 100 mg	Tabs							
15	SODIUM PARA-AMINOSALICYLATE(NA PAS) 4gm Sachets (Box of 250 sachets)	Sachets							
16	SODIUM PARA-AMINOSALICYLATE (NA PAS) 10gm Sachets (Box of 100 sachets)	Sachets							
17	SODIUM PARA-AMINOSALICYLATE (NA PAS)-100gm jars	Box (100g)							
	Substitute Drugs								
18	CAPREOMYCIN (Cm)-750 mg	Vials							
19	CAPREOMYCIN (Cm)-1000 mg	Vials							
20	MOXIFLOXACIN (Mfx)-400mg	Tabs							

Quarterly PMR for stocking & indenting of Cat IV drugs at DTC Level

(To be submitted to CTD & STO/SDS by District) State:DTC:_____Qtr-_____

Cat-IV Regimen - TU Level							
Monthly Patient Wise Boxes							
S.No	**Item**	**UOM**	**Stock on first day of the Qtr**	**Stock received during the Qtr**	**Consumption during the Qtr**	**Stock on last day of the Qtr** (c+d) –e	**Quantity Requested for DTC (e/3 x 5) – f**
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					

Quarterly PMR for stocking & indenting of Cat IV drugs at TU Level

(To be submitted to DTC by DOTS-PMDT implementing TU)D.T.C.TU: _____Qtr-_____

Cat-IV Regimen - TU Level							
Monthly Patient Wise Boxes							
S.No	**Item**	**UOM**	**Stock on first day of the Qtr**	**Stock received during the Qtr**	**Consumption during the Qtr**	**Stock on last day of the Qtr** (c+d) –e	**Quantity Requested for TU (e/3 x 4) – f**
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**	**(g)**
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes					
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes					
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes					
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes					
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes					
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes					
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes					
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes					
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes					
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes					
11	Type-C (Na PAS)	Drug Boxes					

Monthly PMR for stocking & indenting of Cat IV drugs at PHI Level
(To be submitted to TU by DOTS- PMDT implementing PHI)

D.T.C. **TU:** **PHI:** **Month-**

Cat-IV Regimen - PHI Level					
Monthly Patient Wise Boxes					
S.No	Item	UOM	Stock on first Day of the Month	Stock received during the Month	Consumption during the month
	(a)	(b)	(c)	(d)	(e)
1	Type-A (<16 Kg Body Weight Patient)	Drug Boxes			
2	Type-A (16-25 Kg Body Weight Patient)	Drug Boxes			
3	Type-A (26- 45 Kg Body Weight Patient)	Drug Boxes			
4	Type-A (46-70 Kg Body Weight Patient)	Drug Boxes			
5	Type-A (>70 Kg Body Weight Patient	Drug Boxes			
6	Type-B (<16 Kg Body Weight Patient)	Drug Boxes			
7	Type-B (16-25 Kg Body Weight Patient)	Drug Boxes			
8	Type-B (26- 45 Kg Body Weight Patient)	Drug Boxes			
9	Type-B (46- 70 Kg Body Weight Patient)	Drug Boxes			
10	Type-B (> 70 Kg Body Weight Patient)	Drug Boxes			
11	Type-C (Na PAS)	Drug Boxes			

Annexure 15 A

RNTCP Request Card for examination of biological specimen for TB

(Required for Diagnosis of TB, Drug Sensitivity Testing and follow up)

Patient Information			
Patient name		**Age (in yrs):_____**	**Gender: ☐ M ☐ F ☐TG**
Patient mobile no. or other contact no.		**Specimen Date of collection** (DD/MM/YY)_____	**☐ Sputum ☐ Other (specify)** _____
Patient address with landmark		**HIV Status: ☐ Reactive ☐ Non-Reactive ☐ Unknown**	
		Key populations:☐Contact of known TB Patient ☐ Diabetes ☐ Tobacco ☐ Prison ☐ Miner ☐ Migrant ☐ Refugee ☐ Urban slum ☐ Health-care worker ☐Other (specify) _____	

Name referring facility (PHI/DMC /DR-TB Centre /Laboratory/other): **Health Establishment ID (NIKSHAY): _ _ _ _**	**CDL NIKSHAY ID: _ _ - _ _ _ - _ - C - _ _ - _ _ _ _ _** **RNTCP TB Reg No. _____** **Or** ☐ Not Applicable
State: _____ District:_____Tuberculosis Unit (TU): _____	

Reason for Testing:

Diagnosis and follow up of TB	
Diagnosis (NIKSHAY ID_____)	Follow up (Smear and culture)
H/O anti TB Rx for >1 month: ☐ Yes ☐ No	RNTCP TB Reg No _____ NIKSHAY ID:_____
☐ Presumptive TB ☐ Private referral ☐ Presumptive NTM Predominant symptom _____ Duration _____ days	Regimen: ☐New ☐ Previously Treated Reason: ☐ End IP ☐ End CP Post treatment:☐ 6m ☐ 12m ☐ 18m ☐ 24m

Diagnosis and follow up Drug-resistant TB		
Drug Susceptibility Testing (DST)		Follow up (Culture)
☐ Presumptive MDR TB	☐ New ☐ Previously treated ☐ At diagnosis ☐ Contact of MDR/RR TB ☐ Follow up Sm+ve ☐ Private referral ☐ Discordance resolution	PMDT TB No _____ DR TB NIKSHAY ID: _____ Regimen: ☐Regimenfor INH mono/poly resistant TB ☐Regimenfor MDR/RR TB ☐ Modified Regimenfor MDR/RR-TB + FQ/SLI resistance ☐Regimenfor XDR TB ☐ Modified Regimenfor mixed pattern resistance ☐Regimenwith Bedaquiline for MDR-TB Regimen + FQ/SLI resistance ☐Regimenwith Bedaquiline for XDR-TB ☐Regimen with Bedaquiline for failures of regimen for MDR-TB ☐Regimen with Bedaquiline for failures of regimen for XDR-TB ☐Other Treatment ☐month☐ Week :_____
☐ Presumptive H mono/poly		
☐Presumptive XDR TB	☐ MDR/RR TB at Diagnosis ☐ ≥ 4 months culture positive ☐ 3 monthly for persistent culture positives (treatment month _____) ☐ Culture reversion ☐ Failure of MDR/RR-TB regimen ☐ Recurrent case of second line treatment ☐ Discordance resolution	

Test requested:

☐ Microscopy ☐ TST ☐ IGRA ☐ Chest X-ray ☐ Cytopathology ☐ Histopathology ☐CBNAAT ☐ Culture ☐ DST
☐ Line Probe Assay ☐ Gene Sequencing ☐ Other (Please Specify) _____

Requestor Name, Designation and Signature: _____
Contact Number:_____ Email ID:_____

Results: **CDL NIKSHAY ID**Generated: _ _ - _ _ _ - _ - C - _ _ - _ _ _ _ _

Microscopy(☐ZN☐Florescent)							
	Lab Sr. No	Visual appearance	Result				
			Negative	Scanty	1+	2+	3+
Sample A							
Sample B							

Date tested: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

Cartridge Based Nucleic Acid Amplification Test (CBNAAT)

Sample	☐ A ☐ B
M. Tuberculosis	☐ Detected ☐ Not Detected☐ N/A
Rif Resistance	☐ Detected ☐ Not Detected☐ Indeterminate ☐ N/A
Test	☐ Error (Please arrange for fresh sample)

Date tested: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

Culture (☐ LJ☐ LC)

Lab Sr. No	Results			
	Negative	Positive	NTM (write species)	Contamination

Date Result: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

Line Probe Assay (LPA)

☐ Direct ☐ Indirect Lab serial _____

First line LPA

RpoB: — locus control: present absent

WT1: present absent **WT2:** present absent **WT3:** present absent **WT4:** present absent

WT5: present absent **WT6:** present absent **WT7 :** present absent **WT8 :** present absent

MUT1 (D516V): present absent **MUT2A (H526Y):** present absent **MUT2B (H526D):** present absent **MUT3 (S531L):** present absent

KatG: — locus control: present absent

WT1 (315): present absent

MUT1 (S315T1): present absent
MUT2 (S315T2): present absent

InhA:— locus control: present absent

WT1 (-15, -16): present absent **WT2 (-8):** present absent

MUT1 (C15T): present absent **MUT2 (A16G):** present absent
MUT3A (T8C): present absent **MUT3B (T8A):** present absent

Second line LPA

gyrA:-—

locus control: present absent

WT1 (85-90): present absent
WT2 (89-93): present absent
WT3 (92-97): present absent

MUT1 (A90V): present absent
MUT2 (S91P): present absent
MUT3A (D94A): present absent
MUT3B (D94N/Y): present absent
MUT3C (D94G): present absent
MUT3D (D94H): present absent

gyrB:—-

locus control: present absent

WT1 (536-541): present absent

MUT1 (N538D): present absent
MUT2 (E540V): present absent

rrs:—-

locus control: present absent

WT1 (1401-02): present absent
WT2 (1484): present absent

MUT1 (A1401G): present absent
MUT2 (G1484T): present absent

eis:—-

locus control: present absent

WT1 (37): present absent
WT2 (14, 12, 10): present absent
WT3 (2): present absent

MUT1 (C-14T): present absent

Final LPA Interpretation: —

MTB result MTB positive MTB Negative
RIF Sensitive Resistant Indeterminate**INH** Sensitive Resistant Indeterminate
Quinolone Sensitive Resistant Indeterminate**SLID** Sensitive Resistant Indeterminate

Date Result: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

Drug Susceptibility Test (DST) results

Lab Sr. No	1st line drugs						SLI			FQ			Other										
	S	H1	H2	R	E	Z	Km	Cm	Am	Lfx	Mfx (0.5)	Mfx (2)	PAS	Lzd	Cfz	Eto	Cla	Azi					

Date Result: _____ **Date Reported:**_____ **Reported by:**_____
(Name and Signature)

R: Resistant; S: Susceptible; C: Contaminated; – Not done

Other tests for TB diagnosis

Test(Please Specify): _____
Result:_____

Date reported:_____ **Reported by:**_____
(Name and Signature)

REFERRAL SLIP SR NO xxxxx

(Referring health facility copy)

Date: .....Lab referred to : .....
Name of referring HF: .....
Name of Patient: .....
Age: ..... yrs Sex: M / F
Address of patient (with landmarks)

.....

.....

.....
Patient's / Contact person's Mobile number :

_ _ _ _ _ _ _ _ _ _
Kindly tick

- ☐ Cough.....days
- ☐ Fever.....days
- ☐ Loss of weight .....days
- ☐ Night sweat.....days
- ☐ Blood in sputum/ cough.....days

☐ Contact of TB / MDR TB

Stamp of HF Referred by (Name & Sign)

REFERRAL SLIP SR NO xxxxx

(Patient copy)

Date: .....Lab referred to : .....
Name of referring HF: .....
Name of Patient: .....
Age: ..... yrs Sex: M / F
Address of patient (with landmarks)

.....

.....

.....
Patient's/ Contact person's Mobile number :

_ _ _ _ _ _ _ _ _ _
Kindly tick

- ☐ Cough.....days
- ☐ Fever.....days
- ☐ Loss of weight .....days
- ☐ Night sweat.....days
- ☐ Blood in sputum/ cough.....days

☐ Contact of TB / MDR TB

Stamp of HF Referred by (Name & Sign)

REFERRAL SLIP SR NO xxxxx

(Lab Copy)

Date: .....Lab referred to : .....
Name of referring HF: .....
Name of Patient: .....
Age: ..... yrs Sex: M / F
Address of patient (with landmarks)

.....

.....

.....
Patient's/ Contact person's Mobile number :

_ _ _ _ _ _ _ _ _ _
Kindly tick

- ☐ Cough.....days
- ☐ Fever.....days
- ☐ Loss of weight .....days
- ☐ Night sweat.....days
- ☐ Blood in sputum/ cough.....days

☐ Contact of TB / MDR TB

Stamp of HF Referred by (Name & Sign)

Annexure 15 C

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME
Treatment Card

TB Notification No / NIKSHAY ID _____

State_____ City / District _____ TB Unit _____ PHI _____

Name _____Sex ☐ M ☐ F☐TGAge:____ Occupation_____ Socioeconomic status: APL/ BPL

Complete Address: House No. _____ Road: _____Ward/Village: _____ Town/City: _____ Taluka/Mandal:_____ District:_____

State: _____ Pin code _____ Important landmark:_____ Mobile:- _____Aadhar No. _____Area :Slum/Tribal/Migrant/Refugee

Name andAddress of contact person _____Mobile No. _____

Name of Treatment Supporter _____Designation _____Mobile No.: _____

Initial home visit by _____ Date _____Type of Treatment Adherence – DOT / Family DOT / ICT supported, specify _____ / Other ___

Date of onset of first symptom: Number of health care providers visited before diagnosis for current episode:

Disease Classification

☐ Pulmonary
☐ Extra Pulmonary
Site _____

Type of Patient

☐ New ☐Recurrent
☐ Transfer in ☐ Treatment AfterFailure
☐Treatment ☐ Others, previously treated
After LFU (Specify)_____

Basis of Diagnosis

☐Microbiologically confirmed
☐Clinical TB

Investigations (ZN / FM / CBNAAT / Liquid C / Solid C)	Lab	Lab. No.	Test result	Sample sent to CDST (date)	DST result
Pre-treatment					
End of Intensive Phase					
End of treatment					

H/O of Previous ATT:___ months of treatment___ months since end of last episode
Source of treatment:-❑ Public ❑ Private Previous regimen: _____

Other investigations (if any) with result

HIV related information

HIV Status: ❑Unknown❑Reactive❑NR Date_____ PID_____

CPT delivered on: (1) (2) (3) (4) (5) (6)

Initiated on ART: ☐ No ☐ Yes Date & ART No._____

Diabetes related information

Diabetes Status: ❑Unknown❑Diabetic❑Non-Diabetic

RBS_____ FBS_____

Initiated on ADT: ☐ No ☐ Yes Date & ADT No._____

Other co-morbidity

Details_____

Signature of MO with date _____

	<6yrs	>6yrs
No of household contacts		
No screened		
No with symptoms		
No evaluated		
No diagnosed		
No put on treatment		

No of children less than 6 years given chemoprophylaxis = _____

Name	Wt (Kg)	Dose (mg)	1	2	3	4	5	6

Addiction related information

Current Tobaccouser❑ Yes ❑ No
If yes,❑Smoking❑Smokeless Linked for cessation ❑ Yes ❑ No
If tobacco user, status of tobacco use at end of treatment ❑Quit❑ Not quit

H/o Alcohol intake❑ Yes ❑ No
If yes, linked for deaddiction❑ Yes ❑ No

Date of initiation of intensive phase _____ **Date of initiation of continuation phase** _____

Dosage frequency ❑ Daily ❑ Intermittent Drug formulations ❑ FDC ❑Combipack❑ Loose drugs Drug packaging ❑ PWB ❑ Strips

Weight Band: Adult: ☐ 25-39 Kg ☐ 40-54 Kg ☐ 55-69 Kg ☐≥70 Kg Pediatric: ☐4-7 Kg ☐8-11 Kg ☐12-15 Kg ☐16-24 Kg ☐ 25-39 Kg ☐30-39 Kg

Dosages: FDC / Combipack _____ per day Height_____ (cm)

Loose drugs		H	R	Z	E	S
	Dose					
	Pills					

Mark✓when doses are taken under direct observation, ⊘ when the dose was not observed, O when missed the dose
Record CP from fresh line

Month/ year	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Wt

Retrieval Actions for Missed Doses

Date	By Whom	Whom contacted	Reason for missed doses	Outcome of retrieval action

Details of Adverse events

Date of adverse event	Details of symptoms	Action taken	Duration of management for adverse event	Outcome of adverse event

Post treatment follow up clinical & sputum

Follow up	Clinical	Sputum	CXR	Impression
6 mths of Rx				
12 mths of Rx				
18 mths of Rx				
24 mths of Rx				

Findings _____

Remarks

_____
_____
_____
_____
_____

Nutrition support (if any, give details) _____

Treatment outcome with date: _____ **signature of the MO with date:** _____

TB identity card

Name: _____

Sex ☐ M ☐ F ☐ TGAge:____

Address:_____

_____

_____

Contact No: _____

PHI _____ TU _____ District _____

NIKSHAY ID:_____

Name and designation of treatment supporter:

_____

Contact number and address of treatment supporter:

_____

☐ CPT ☐ ART ☐ Diabetic ☐ Smoker

Date of starting treatment: (DD/MM/YYYY)

Weight Band:

Adult: ☐ 25-39 Kg ☐ 40-54 Kg ☐ 55-69 Kg ☐ ≥70 Kg

Pediatric: ☐4-7 Kg ☐8-11 Kg ☐12-15 Kg ☐16-24 Kg ☐ 25-39 Kg ☐30-39 Kg

Site of Disease

☐Pulmonary
☐Extra pulmonary

Type of Patient

☐New
☐Recurrent
☐Treatment after Lost to Follow up
☐Treatment after Failure
☐Previously treated other
☐Transfer in

Treatment regimen:☐New
☐Previously treated

_____

Smear follow-up results			
End IP		End Rx	
Post Rx Month __		Post Rx Month __	
Post Rx Month __		Post Rx Month __	

Treatment outcome: _____

Date:_____

Appointment dates

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

In case of side effects or queries please contact

Name and contact number:

_____
_____

RNTCP PMDT Treatment Card

NIKSHAY ID	CDL NIKSHAY ID	PMDT NIKSHAY ID	PMDT TB No

Patient's name: _____

Age: _____yrsGender: ☐ Male ☐ Female ☐ Transgender

Address: _____

_____

Marital status: _____

Occupation: _____

Contact No: _____

Name, designation of treatment supporter:_____

_____

Contact no:_____

State:_____District: _____

TB Unit: _____ PHI:_____

Initial home v: Date _____By:_____

DR TB Centre:_____

Reason for Testing	
☐ New ☐ Previously Treated	
☐ Presumptive TB ☐ Private Referral ☐ Presumptive NTM	
☐ Presumptive MDR TB	☐ At diagnosis ☐Contact of MDR/RR TB ☐ Follow up Sm+ve at end IP ☐ Private referral
☐ Presumptive H mono/poly	
☐ Presumptive XDR TB	☐ MDR/RR TB at diagnosis ☐ ≥ 4 months culture positive ☐ 3 monthly, for persistent culture positives (treatment month _____) ☐ Culture reversion ☐ Failure of MDR/RR-TB regimen ☐ Recurrent case of second line treatment

☐ Transfer in from Other DR TB Centre

Name of DR TB Centre _____

PMDT NIKSHAY ID_____

HIV Testing: Date:_____ Result:_____ PID no._____

Date of starting CPT: _____ Date of starting ART:_____

Contact tracing:

No of household contacts				
No of members screened				
No of presumptive TB cases identified				
No of presumptive TB cases evaluated				
No diagnosed with TB				
No of DR-TB diagnosed				

TB Site:☐ Pulmonary ☐ Extra Pulmonary If extra pulmonary, please specify _____

Treatment regimen

☐Regimen for INH mono/poly resistant TB☐Regimen for MDR/RR TB ☐ Modified Regimen for MDR/RR-TB + FQ/SLI resistance ☐Regimen for XDR TB ☐ Modified Regimen for mixed pattern resistance ☐Regimen with Bedaquiline for MDR-TB Regimen + FQ/SLI resistance☐Regimen with Bedaquiline for XDR-TB☐Regimen with Bedaquiline for failures of regimen for MDR-TB☐Regimen with Bedaquiline for failures of regimen for XDR-TB☐Regimen for mixed pattern resistance

Initiation Date: _____

Registration Date: _____

Drugs and Dosages																				
Drugs	H	R	E	Z	mK	mA	mC	xf L	xf M	s C	α E	$ AP	z L d	zf C	x mA vl c	rl C	QDB			
Dose (mg)																				

Patient eligible and consented for BDQ ☐ Yes ☐ No
If No, reason_____

Name & Signature of Treating Physician:_____

DR-TB Centre Committee meetings – dates and decisions

Date	Decision	Duration of indoor stay

Month of Treatment	Culture Results			Other Investigations					
	Date	Lab No	Culture	S. Cr	LFT	ECG*-QTC Interval	CBC/ Platelets	Electrolyte(K, Mg, Ca)	Urine Gravindex
Diagnosis									
1st week									
2nd week									
3rd week									
4th week									
1									
2									
3									
4									
5									
6									
7									
8									
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30									
31									
32									
33									
34									
35									

Patient's Name:_____

Blood Sugar Testing:

Date:_____

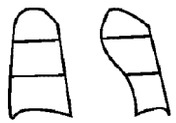
RBS:_____

FBS:_____

ADT*

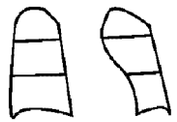
(*write date of starting)

Thyroid Function Test		
Month	Zero	Six
Date		
T3		
T4		
TSH		



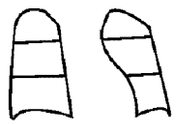
Date of X-ray

Findings_____



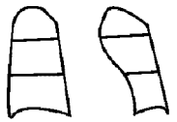
Date of X-ray

Findings_____



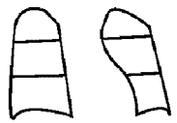
Date of X-ray

Findings_____



Date of X-ray

Findings_____



Date of X-ray

Findings_____

*ECG to be done daily (first two weeks), weekly (for 3 months) then monthly

Patient's name:_____

Initial Weight: _____kgs Height:_____cms

Weight band:

☐<16 Kg ☐ 16-25 Kg ☐ 26-45 Kg ☐ 46-70 Kg ☐>70 Kg

Date of starting intensive phase: _____

Date of starting continuation phase:_____

Details of rchange		
Date	Changed regimen	Reason for change

Drug Susceptibility Testing (DST) Results						
Drug	Date of specimen collection &type of DST (LJ/LC/LPA/CBNAAT)					
	Diagnosis	Month___	Month___	Month___	Month___	Month___
S						
H1						
H2						
R						
E						
Z						
Km						
Am						
Cm						
Lfx						
Mfx (0.5)						
Mfx(2.0)						
Eto						
PAS						
LZD						
CFZ						

ADMINISTRATION OF DRUGS (one line per month) **Patient's Name:_____**

Month/Yr	Day																													Weight in kg
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	

Mark in the boxes: ✓= directly observed; ✓ Unsupervised; = ◯ gs not taken; X=initiation of new box; Recording of CP should start from fresh line.

Month/Yr	Day																													Weight in kg
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	

Mark in the boxes: ✓= directly observed; ✓ = unsupervised; ◯ = drugs not taken; X=initiation of new box; Recording of CP should start from fresh line.

Date of retrieval action	By whom	Who contacted	Reason for missed doses	Outcome of retrieval action

Date of adverse drug reaction	Details of symptoms	Action taken

Treatment outcome	Date	Remarks
Cured		
Treatment completed		
Died		
Failed–Culture non conversion		
Failed – Culture reversion		
Failed – Additional drug resistance		
Failed – Adverse Drug Reaction		
Lost to follow up		
Regimen Change		
In remarks column, provide cause of death, reason for lost to follow up, latest TB no. in case of failure and put on treatment further		

Comments:

_____

_____

_____

_____

Name & Signature of Treating Physician:

_____

Post treatment follow up clinical & sputum				
Follow up	Clinical	Sputum	CXR	Impression
6 months of Rx				
12 months of Rx				
18 months of Rx				
24 months of RX				

RNTCP PMDT TB identity card

Name: _____

Address:_____

_____

_____

Contact No: _____

PMDT TB number:_____

PMDT NIKSHAY ID:_____

DR TB Centre: _____

District: _____

TB Unit: _____

DOT Centre:_____

Name of Treatment Supporter:

_____

Contact Number of Treatment Supporter:

_____

Treatment regimen: ☐ Regimen for H mono/poly resistant TB
☐ Regimen for MDR/RR TB
☐ Regimen for MDR/RR-TB + FQ/SLI resistance
☐ Regimen for XDR TB
☐ Regimen with Bedaquiline for MDR-TB + FQ/SLI resistance
☐ Regimen with Bedaquiline for XDR-TB
☐ Regimen with Bedaquiline for failures of regimen for MDR-TB ± FQ/SLI resistance
☐ Regimen with Bedaquiline for failures of regimen for XDR-TB
☐ Regimen for mixed pattern resistance

☐ CPT ☐ ART ☐ Diabetic ☐ Smoker

Date of starting treatment: (DD/MM/YYYY)

_____

Culture follow-up results			
Month __		Month __	
Month __		Month __	
Month __		Month __	
Month __		Month __	
Month __		Month __	
Month __		Month __	
Month __		Month __	

Treatment outcome: _____

Date:_____

Appointment dates

_____

_____

_____

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_____

In case of side effects or queries please contact

Name and contact number:

_____

_____

REVISED NATIONAL TUBERCULOSIS CONTROL PROGRAMME

Referral / Transferform for treatment Serial Number

*To be filled **in** triplicate. One copy to be sent to the DTO receiving the patient, one copy to the health facility where the patient is referred to, and one copy to the patient*

Name and address of referring health facility _____

Contact Number and e-mail address of referring health facility: _____

Name and address of health facility to which patient is referred _____

_____

Name of patient_____ **Age**_____ **Sex M F TG**

Complete Address_____

_____**Contact no.**_____

Patient detail	
Site of disease ☐ Pulmonary ☐ Extra Pulmonary, Site _____ **Type of Patient** ☐ New ☐ Recurrent ☐ Transfer in ☐ Treatment After Failure ☐ Treatment After LFU ☐ Others, previously treated (Specify)_____ **Basis of Diagnosis** ☐ Microbiologically confirmed ☐ Clinical TB **H/O of ATT:** ___ months of treatment ___ months since end of last episode	**Diagnosis details** Date of diagnosis: __/__/___ Name of laboratory: Type of test: ZN / FM / CBNAAT / Culture Result : _____ TB notification number:_____ **HIV Status:** ☐ R ☐ NR ☐ Unknown **DST Status:** ☐ Rif Sensitive ☐ Rif Resistant ☐ Unknown, if unknown **Sample sent for DST to** _____ Date: __/__/__ **Treatment regimen:** ☐New☐Previously Treated **Date of treatment initiation: :** __/__/__ **Number of doses:**_____

Referred for:

- ☐ Initiation of treatment
- ☐ Adverse drug reaction (give details) _____
- ☐ Transfer out (give details)_____
- ☐ Any other (give details)_____

Name and designation of the referring doctor_____

Date referred

----------✂----------✂----------

Serial Number_____

For use by the health facility where the patient has been referred

Name of receiving health facility_____ Name of TB Unit and District_____

Name of patient _____ TB No (if available)_____

Age_____ Sex M ☐ F ☐ Date of receipt of patient_____

Date of initiation of treatment _____Treatment regimen_____ _____

Result of End IP specimen examination _____ Date of end IP specimen examination _____

Treatment outcome _____Date of treatment outcome _____

Signature_____Designation_____Date_____

This portion of the form has to be sent back to the referring unit as soon as the patient has been initiated on RNTCP treatment

Annexure 15 H

RNTCP PMDT Referral for treatment form

(Fill in duplicate. Send one copy to the concerned facility receiving the patient, and file the duplicate.)
Name and address of referring unit (District TB Centre/DR TB Centre):_____
e-mail address of referring unit: _____
Name of the facility where patient is referred: _____
Name of patient: _____ Age:_____ Gender: _____
Complete address:_____

Patient detail

Disease classification: ☐ Pulmonary
☐ Extra pulmonary (site_____)

Type: ☐ New ☐ Recurrent ☐TA LFU ☐ Failure ☐ Others

Reason for testing:
☐ New ☐ Previously Treated

☐ Presumptive TB
☐Private referral
☐ Presumptive NTM
☐Presumptive MDR-TB
☐ At diagnosis
☐ Contact of MDR/RR TB
☐ Follow up Sm+ve
☐ Private referral
☐Presumptive H mono/poly
☐ Presumptive XDR-TB
☐ MDR/RR TB at diagnosis☐ = 4 months culture positive☐ 3-monthly for persistent culture positives (treatment month _____)☐ Culture reversion☐ Failure of MDR/RR-TB regimen☐ Recurrent case of second line treatment

Latest TB No:_____

Latest regimen:
☐Regimen for INH mono/poly resistant TB
☐Regimen for MDR/RR TB
☐Regimen for MDR/RR-TB + FQ/SLI resistance ☐Regimen for XDR TB ☐Regimen with Bedaquiline for MDR-TB + FQ/SLI resistance
☐Regimen with Bedaquiline for XDR-TB
☐Regimen with Bedaquiline for failures of regimen for MDR-TB±FQ/SLI resistance
☐Regimen with Bedaquiline for failures of regimen for XDR-TB
☐Regimen for mixed pattern resistance

Sputum, culture and DST details

Date of culture result: __/__/___
Date of DST/LPA/CBNAAT result: __/__/___
DST/LPA/CBNAAT result* :
☐ S ☐ H1☐ H2☐ R ☐ E ☐ Z
☐ Km ☐ Am ☐ Cm
☐ Lfx ☐ Mfx (0.5) ☐ Mfx (2.0)
☐ Eto ☐ PAS ☐ LZD ☐ CFZ ☐ ___☐ ___☐___
(* Tick the drugs to which resistance is demonstrated)

DR TB treatment details

PMDT NIKSHAY ID: _____

DR TB Centre:_____

Date of DR TB regimen initiation: : __/__/__

Number of doses:_____

Date of regimen change and details of change: _____
Past exposure to second-line a-ntiTB drugs: Drugs (duration)_____
HIV Status: Pos Neg Not known Date of CPT initiation:_____ Date of ART initiation:_____
Date of referral to DR-TB Centre / DTC: Day _____ Month _____ Year _____

Referred for:
Initiation of treatment
Adverse drug reaction (give details) _____
Transfer out (give details)_____
Ambulatory treatment (if the patient is referred to DTC)
Any other (give details)_____
Name and designation of the referring doctor_____

Reminder for the health facility where the patient has been referred

Please send an e-mail to the referring unit, informing the referring doctor of the date that the above-named pa tient reported at the receivinghealth facility.

Revised National Tuberculosis Control Programme – TB Notification Register Year ____________ PHI__________

TB notification no. (NIKSHAY)	Name (in full)	Age	Sex (M/F/TG)	Complete Address	Pin code	Mobile/Landline Number	Key population#	Type of patient*	Site (P/EP)	Regimen N/PT /Outside RNTCP	Weight at beginning of treatment	Microbiological confirmation test results				Basis of diagnosis other than Microbiological (CXR/Histopatho/ Cytology/ Clinical/ /Other, specify)	HIV Status± (P/N/U)	Diabetes Status^ (D/N/U)	Date of sample sent for DST (NO if not sent, NA if not applicable)	Result of DST@	Status of treatment ***	Date of treatment initiation	Dosage Frequency (Daily / Intermittent)
												Date	Lab Name	Test (ZN / FM / Culture / CBNAAT)	Results of Test#								
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	…………………………			………………………																			
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*** Type of patient (use complete words)**
New, Recurrent, Failure, LFU, Other PT, Transferred in

 # Test of result
For Smear result – Grades for smear positive, NEG for smear negative
For GX result – MTB detected Rif Resistance, MTB detected Rif sensitive, MTB detected Rif Indeterminate, MTB not detected, Error, Invalid, No result
For Culture result – Grades for culture positive, NEG for culture negative

± HIV Status
HIV status as reported before or during TB treatment P – Positive, N – Negative, U – Unknown.

^Diabetes Status
D=Diabetes, N=NonDiabetes, U = Unknown

@ Sensitive= if sensitive to tested drugs, Name of drug if resistant to any – R= Rifampicin, H=Isoniazide, E=Ethambutol, Z=Pyrazinamide, S=Streptomycin Lx=Levofloxacin, Mx=Moxifloxacin, Km=Kanamycin, Cm=Capreomycin

*****Status of treatment-**
1. Initiated on First line treatment in the same Health Facility
2. Initiated on second line treatment in the same Health Facility
3. Initiated on treatment outside Health Facility
4. Treatment initiated outside RNTCP
5. Incomplete/ incorrect address
6. Died
7. Migrated & untraceable
8. Repeat diagnosis
9. Patient already on treatment/ Follow up patient
10. Wrong diagnosis
11. Referred for treatment with pending feedback
12. Other

#Key population
PLHIV/Diabetes/Contact/Miner/Prison inmate/Health worker/Migrant/Refugee/Urban slum/Other, specify_____

Revised National Tuberculosis Control Programme – TB Notification Register Year_____ PHI_____

Follow-up smear examinations										Treatment Outcome#		If HIV-Pos		Post treatment follow up														Treatment supporter details		Remarks
End of IP					End of Treatment Exam									At 6 months Date____				At 12 months Date____				At 18 months Date____				At 24 months Date____						
Date	DMC Name	Smear result	Date of sample collected for DST	Result of DST@	Date	DMC Name	Smear results	Date of sample collected for DST	Result of DST@	Outcome	Date	CPT (y/n) date	ART (y/n) date	Symptoms*	CXR	Smear	Culture	Symptoms	CXR	Smear	Culture	Symptoms	CXR	Smear	Culture	Symptoms	CXR	Smear	Culture	Name	Designation	

Treatment Outcome –
Cured, Treatment Completed, Died, Lost to follow up, Failure, Not evaluated or Treatment change

± **Additional treatments if patient HIV-positive**
Required only for patients known to be HIV positive. If provided by any source during TB treatment, enter "Y" and approximate date. If not provided / unknown, enter "N".
***Symptoms-** Mention predominant system- Cough-C, Fever-F, Haemoptysis-H, Weight loss-W, Night Sweat - N Others-O, No symptoms - NS

Annexure 15J

RNTCP PMDT Treatment Register

Month _____Quarter _____ Year _____ District: _____ C-DST Lab: _____ DR-TB Centre:_____ State: _____

PMDT TB No	PMDT NIKSHAY ID	CDL NIKSHAY ID	Patient's name in full	Gender (M/F/TG)	Age in yrs	Complete address & mobile number	Name of health facility, TU, district	Reason for Testing @	Site of Disease (P/EP)	Type (New, Recurrent , TALFU, Failure, Others)	DST Details																			
											Type (LJ/LC/ LPA/ CBNAAT)	Date of DST	Results																	
													S	H	R	E	Z	Km	Am	Cm	Lfx	Mfx (0.5)	Mfx (2)	Eto	PAS	Lzd	Cfz	_____	_____

@ Presumptive TB – 1; Private referral – 2; Presumptive NTM – 3;

@ Presumptive MDR TB, At diagnosis–4; Contact of MDR/RR TB – 5; Follow up Sm+ve at end IP – 6; private referral – 7; Discordance resolution – 8; Presumptive H mono/poly –9; MDR/RR TB at diagnosis – 10; ≥ 4 months culture positive –11; 3-monthly for persistent culture positives –12; Culture reversion –13; Failure of MDR/RR-TB regimen –14; Recurrent case of second line treatment –15

Type of DR TB Patient RRTB/MDRTB/XDR TB	DRTB Regimen #	Date of Treatment initiation	Culture and DST Results at initiation and during DR TB Treatment (Treatment months)																														TB/HIV Collaborative activities					Final Treatment Outcome	Remarks
			0	3	4	5	6	7	9	12	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36							
			dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy	dd/mm/yy							
			Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Culture	Date of Test	PID No	HIV Status	Date of CPT initiation	Date of ART initiation		

#Cases put on:Regimen for H mono/poly resistant TB–**1**; Regimen for MDR/RR TB –**2**; Regimen for MDR/RR-TB + FQ/SLI resistance –**3**; Regimen for XDR-TB –**4**; Regimen with Bedaquiline for MDR-TB + FQ/SLI resistance–**5**; Regimen with Bedaquiline for XDR-TB–**6**; Regimen with Bedaquiline for failures of regimen for MDR-TB ± FQ/SLI resistance–**7**; Regimen with Bedaquiline for failures of regimen for XDR-TB – **8**; Regimen for mixed pattern resistance – **9**

Annexure 15 K

TB Laboratory Register

Lab. Serial No.	Date of collection of first specimen	Name in Full	Sex M/ F/TG	Age	Complete address (for diagnosis patients) Phone No.	Key Population	Name of referring health facility (PHI/ICTC/ART/Medical College / Private Others, specify)	Reasons for Examination								Type of specimen	Visual appearance	
								Presumptive TB / RE / Presumptive NTM	Predominant symptom & its duration	History of >1 month ATT (Yes/No)	Follow-up						a	b
											Nikshay ID	Regimen New / Previously Treated	Month	Post Treatment follow up month				

Notes

1. a- stands for supervised spot sample, b- stands for early morning sample
2. Remarks column can include date of starting treatment, treatment regimen, TB no., referral details with date, remarks on un blinded rechecking, etc
3. Visual appearance- mention M, B, or S., Mucopurulent, Blood stained or Saliva
4. Predominant symptoms: Cough-C, Fever-F, Haemoptysis-H, Weight loss-W, Night Sweat - N Others-O, No symptoms - NS
5. Key population - ☐Contact of TB/DRTB case ☐ Diabetes ☐ Tobacco ☐ Smoker ☐ Prison inmates ☐ Miner ☐ Migrant ☐ Refugee ☐ Urban slum ☐ Health-care worker ☐Other (specify) _____
6. Sensitive= if sensitive to tested drugs, Name of drug if resistant to any – R= Rifampicin, H=Isoniazide, E=Ethambutol, Z=Pyrazinamide, S=Streptomycin Lx=Levofloxacin, Mx=Moxifloxacin, Km=Kanamycin, Cm=Capreomycin
7. Duration of predominant symptoms should be recorded in days

Results		Date of Result	HIV status (Reactive / Non Reactive / Unknown)	Diabetic status (Diabetic /Non Diabetic / Unknown)	Sample for DST sent (Y/N) with date	DST result (write the drugs to which resistance is demonstrated)	NIKSHAY ID (notification no.)	Treatment initiation details (TB No. & TU details)/ Referral for treatment	Signature	Remarks
a	b									

Annexure 15 L

TB Laboratory Register

Lab. Serial No.	Date of collection of first specimen	Name in Full	Sex M/ F/TG	Age	Complete address (for diagnosis patients) Phone No.	Key Population	Name of referring health facility (PHI/ICTC/ART/Medical College / Private Others, specify)	Reasons for Examination								Type of specimen	Visual appearance	
											Follow-up						a	b
								Presumptive TB / RE / Presumptive NTM	Predominant symptom & its duration	History of >1 month ATT (Yes/No)	Nikshay ID	Regimen New / Previously Treated	Month	Post Treatment follow up month				

Notes

1. a- stands for supervised spot sample, b- stands for early morning sample
2. Remarks column can include date of starting treatment, treatment regimen, TB no., referral details with date, remarks on un blinded rechecking, etc
3. Visual appearance- mention M, B, or S., Mucopurulent, Blood stained or Saliva
4. Predominant symptoms: Cough-C, Fever-F, Haemoptysis-H, Weight loss-W, Night Sweat - N Others-O, No symptoms - NS
5. Key population - ☐Contact of TB/DRTB case ☐ Diabetes ☐ Tobacco ☐ Smoker ☐ Prison inmates ☐ Miner ☐ Migrant ☐ Refugee ☐ Urban slum ☐ Health-care worker ☐Other (specify) _____
6. Sensitive= if sensitive to tested drugs, Name of drug if resistant to any – R= Rifampicin, H=Isoniazide, E=Ethambutol, Z=Pyrazinamide, S=Streptomycin Lx=Levofloxacin, Mx=Moxifloxacin, Km=Kanamycin, Cm=Capreomycin
7. Duration of predominant symptoms should be recorded in days

RNTCP Laboratory Register for Culture, CBNAAT and Drug Susceptibility Testing

Rapid DST Results						Culture Results			Standard DST Results (R/S)																				Reporting of results		
Test performed (LPA/CBNAAT)	Date of receipt & CDL NIKSHAY ID	Valid* (Y/N)	TB † (Y/N)	RIF ‡ (R / S / I / N A)	INH (R/S/NA)	Type (LJ/LC)	CDL NIKSHAY ID	Results §	Type (LJ/LC)	Date of receipt & CDL NIKSHAY ID	Streptomycin	Isoniazid 1	Isoniazid 2	Rifampicin	Ethambutol	Pyrazinamide	Kanamycin	Amikacin	Capreomycin	Levofloxacin	Moxifloxacin (0.5)	Moxifloxacin (2.0)	Ethionamide	PAS	Linezolid	Clofazimine	Other _____	Other _____	Other _____	Date of reporting culture result	Date of reporting DST result	Remarks

* **Valid = Y** if both Amplification Control (AC) band & Conjugate Control (CC) band present; if either are missing, record **N**, and record no additional LPA results for this specimen.

† **TB = Y if** M. tuberculosis (TUB) band on LPA strip confirming identity as M. Tb or MTB Detected in CBNAAT, **N** if no TUB band on LPA strip or MTB Not Detected in CBNAAT

‡ **R** = Resistant, **S** = Sensitive, I = Indeterminate, **NA** = no result, judged by no locus control band on LPA strip for *rpo-B* (RIF), or for *inh-A* or *kat-G* (INH) or for *gyr-A* or *gyr-B* for FLQ or *eis* for ETH, or rrs for SLI. In case of CBNAAT, specify for NA, i.e. Error, Invalid, No Result

§ **Negative** = no growth, **Conta** = contaminated, **NTM** = Non-Tuberculosis Mycobacteria/fast grower, **3+** = confluent growth, **2+** = >100 colonies, **1+** = 10–100 colonies; **Sc#**Scanty<10 . Positive culture results should only be reported after identity for *M. tuberculosis* is confirmed with PNB, Niacin, Catalase, Rapid Immunoassay, or other methods.

Annexure 16

Monitoring Indicators

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Estimated incidence rate	Estimated incidence TB cases occurred in a year	Population in lac in year	State wide estimation by DHR	Annually
2	Estimated prevalence rate	Estimated number of TB cases prevalent in a year	Population in lac in year	State wide estimation by DHR	Annually
3	Estimated TB mortality rate	Estimated number of TB cases died due to TB in a year	Population in lac in year	State wide estimation by DHR	Annually
4	Estimated MDR-TB incidence rate	Estimated MDR-TB cases	Population in million in year	State wide estimation by DHR	
5	Estimated HIV-TB case incidence rate	Estimated HIV-TB cases	Population in lac in year	State wide estimation by DHR	
6	Annualized Total TB Case Notification Rate	All forms of TB Cases Notified during specified Period * multiplier to convert it annualized	Population in Lac in year	NIKSHAY	
7	Proportion of estimated incident TB cases notified	Number of TB cases notified	Estimated number of TB cases in a year	NIKSHAY	

8	New TB Case Notification Rate A)MicrobiologicallyConfirmed B)Clinically Diagnosed	Number of New TB Cases Notified during specified Period A) Microbiologically Confirmed B)Clinically Diagnosed	Population in lac in a year	NIKSHAY	
9	Recurrent TB Case Notification Rate A)Microbiologically Confirmed B)Clinically Diagnosed	Number of retreatment TB Cases Notified during specified Period A) Microbiologically Confirmed B)Clinically Diagnosed	Population in lac in a year	NIKSHAY	
10	Number of notified cases of all forms of TB - microbiologically confirmed plus clinically diagnosed, new and recurrent (By Age, SEX, HIV status)			NIKSHAY	
11	Proportion of microbiologically confirmed TB cases notified	Number of microbiologically confirmed TB cases notified	Total number of TB cases notified	NIKSHAY	
12	Presumptive TB Cases Examination Rate	Number of Presumptive TB Cases Examined during specified Period	Population in Lakh during mid of specified Period	NIKSHAY (PMR)	
13	Average time to diagnosis of TB patients from the onset of symptoms	Summation of (difference between date of onset of symptoms and date of diagnosis of TB)	Total number of TB patients diagnosed	E-NIKSHAY	
14	Average time to initiation of treatment from diagnosis	Summation of (difference between date of diagnosis and date of initiation of	Total number of TB patients initiated on treatment	NIKSHAY	

		treatment of TB)			
15	Proportion of New TB Cases with RR/MDR TB	Number of RR/MDR TB Cases diagnosed among New TB Cases during specified Period × 100	Number of New TB Cases Diagnosed during specified Period	NIKSHAY	
16	Proportion of patients reported any ADR affecting treatment during month (partially or complete discontinuation of treatment)	Total number of patients reported any ADR affecting treatment continuation.	Total number of patients on treatment	E- NIKSHAY	
17	Proportion of patients interrupted treatment (missed doses >3 doses) during month	Number of patients missed doses (>3 doses) during month	Total number of patients on treatment	E- NIKSHAY	
18	Proportion of TB patients screened for Diabetes	Number of TB patients screened for Diabetes	Number of TB patients notified	E-NIKSHAY	
19	Proportion of patients diagnosed with Diabetes	Number of TB patients diagnosed with Diabetes	Number of TB patients tested for Diabetes	E- NIKSHAY	
20	Proportion of TB-Diabetes patients linked with diabetes care services	Number of TB-Diabetes patients linked with diabetes care services	Number of TB-Diabetes patients notified	E-NIKSHAY	
21	Proportion of Paediatric Cases among Total TB Cases	Number of Paediatric TB Cases Notified during specified Period × 100	Number of Total TB Cases Notified during specified Period	E-NIKSHAY	
22	Proportion of pulmonary TB patients whose household contacts were screened for TB within one month of initiation of treatment	Number of pulmonary TB patients whose house hold contacts were screened	Number of TB patients registered for treatment one month prior	E- NIKSHAY	
23	Proportion of TB patients diagnosed out of household	Number of TB patients diagnosed during household	Number of household contacts screened for TB	E-NIKSHAY	

	contact screening	contact screening			
24	Proportion of eligible children given chemoprophylaxis for 6 months	Number of eligible children given chemoprophylaxis for 6 months	Number of children eligible for chemoprophylaxis	E-NIKSHAY	
25	Percentage of notified TB cases, all forms, contributed by non-NTP providers - private/non-governmental facilities	Number of TB cases notified by non-NTP providers	Number of TB cases notified in a period	NIKSHAY	
26	Number of TB cases (all forms) notified among key affected populations/high risk groups (HIV, prisoners/ migrants/refugees.IDPs)			E-NIKSHAY	

Interim outcome indicators

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Proportion of microbiologically confirmed patients converted	No. of microbiologically confirmed patients converted at end of 3 months	Total number microbiologically confirmed patients initiated on treatment 3 months prior	NIKSHAY	
2	Proportion of mono- / poly-drug resistant pulmonary TB patients converted	No. of mono- / poly- drug resistant TB patients converted at end of 6 months	Total number of mono- / poly- drug resistant TB patients initiated on treatment 6 month prior	E-NIKSHAY	
3	Proportion of RR/MDR pulmonary TB patients	No. of RR / MDR pulmonary TB patients	Total number RR / MDR pulmonary TB patients	E-NIKSHAY	

	converted at end of 6 months	converted at end of 6 months	initiated on treatment 12 month prior		
4	Proportion of RR/MDR TB patients died by 6 months	No. of RR / MDR TB patients died by 6 months	Total number RR / MDR TB patients initiated on treatment 12 month prior	E-NIKSHAY	
5	Proportion of RR/MDR TB patients lost to follow up by 6 months	No. of RR / MDR TB patients lost to follow up by 6 months	Total number RR / MDR TB patients notified 12 month prior	E-NIKSHAY	

HIV-TB

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Proportion of notified new and recurrent TB patients with documented HIV status	Number of notified new and recurrent TB patients with documented HIV status x 100	Number of new and recurrent TB patients notified	NIKSHAY	
2	Proportion of notified new and recurrent TB patients with documented HIV-positive status	Number of notified new and recurrent TB patients with documented HIV-positive status	Number of new and recurrent TB patientsnotified	NIKSHAY	
3	Proportion of HIV-positive new and recurrent TB patients on ART during TB treatment	Number of HIV-positive new and recurrent TB patients on ART during TB treatment	Number of HIV-positive new and recurrent TB patients notified	NIKSHAY	
4	Proportion of people living with HIV newly enrolled in HIV care and screened negative for TB, started on TB preventive therapy	Number of people living with HIV newly enrolled in HIV care and screened negative for TB, started on TB preventive therapy	Number of people living with HIV newly enrolled in HIV care and screened negative for TB	NACP (Patient visit register / monthly report)	

5	Mortality among HIV-positive new and recurrent TB patients	Number of HIV-positive new and recurrent TB patients died	Number of HIV-positive new and recurrent TB patients notified	NIKSHAY	
6	Risk of TB among health care workers relative to the general population, adjusted for age and sex	Number of TB patients notified per 100,000 health care workers in a year	Number of TB patients notified per 100,000 population in a year		
7	Proportion of people living with HIV in care who are screened for TB in HIV care or treatment settings *1.ICTC/FICTC* *2.ART* *3.TI settings* *4.CSCs*	Number of persons enrolled in HIV care whose TB status was assessed and recorded at their last visit during the reporting period	Number of persons enrolled in HIV care and seen for care during the reporting period	NACP (Patient visit register / monthly report)	
8	Proportion of people living with HIV who are TB symptom screen positive out of those who are screened for TB	Number of people living with HIV found to have anyone of the symptoms suggestive of TB	Number of people living with HIV who were screened for presence of TBsymptoms during their last visit to HIV care or treatment facility	NACP (Patient visit register / monthly report)	
9	Proportion of people living with HIV who are tested for TB out of those who are symptom screen positive	Number of people living with HIV who are investigated for TB	Number of people living with HIV who were TB symptom screen positive during the reporting period	NACP (HIV-TB line list / monthly report)	
10	Proportion of people living with HIV diagnosed with active TB out of those who are tested	Number of people living with HIV diagnosed as having active TB	Number of people living with HIV investigated for presence of active TB during the reporting	NACP (HIV-TB line list / monthly report)	

			period		
11	Proportion of people living with HIV who are started on TB treatment out of those diagnosed as having active TB	Number of people living with HIV started on TB treatment and registered in the TB register	Number of people living with HIV diagnosed to have active TB through intensified TB case finding	NACP (HIV-TB line list / monthly report)	
12	Proportion of people living with HIV having TB symptoms who receive a rapid molecular test (e.g. CBNAAT)as a first test fordiagnosis of TB	Number of people living with HIV having TB symptoms who were investigated using a rapid molecular test (e.g. CBNAAT) as a first test	Number of people living with HIV having TB symptoms identified through intensified case finding at HIV care and treatment facilities during the reporting period	NACP (HIV-TB line list)	
13	Proportion of HIV-positive new and recurrent TB patients detected and notified out of the estimated number ofincident HIV-positive TB cases	Number of HIV- positive new and recurrent TB patients registered during the reporting period	Estimated number of incident TB cases among people living with HIV (with low and high uncertainty bounds)		
14	Proportion of HIV-positive new and recurrent TB patients who receive co-trimoxazole preventive therapy	Number of HIV- positive new and recurrent TB patients notified during the reporting period who are started or continued on co-trimoxazole preventive therapy during TB treatment	Number of HIV- positive new and recurrent TB patients notified during the reporting period	NIKSHAY	
15	Proportion of health care facilities providing services for	Number of health care facilities having	Number of health care facilities evaluated	NIKSHAY	

	people living with HIV that have TB infection control practices	"demonstrable" TB infection control practices that are consistent with international guidelines	for TB infection control practices during the reporting period		
16	Proportion of people living with HIV who complete a course of TB preventive therapy	Total number of persons who completed the course of treatment for latent TB infection during the reporting period	Total number of persons in HIV care who were newly started on treatment for latent TB infection 12 to 15 month earlier	NIKSHAY	
17	Proportion of people living with HIV in care who ever received a course of TB preventive therapy	Number of persons who received at least one complete course of treatment for latent TB infection ever, by the end of the reporting period	Number of persons currently in HIV care at the end of the reporting period	NIKSHAY	
18	Proportion of presumptive TB patients having documented HIV status	Total number of presumptive TB patients who have a documented HIV test result	Total number of presumptive TB patients who are investigated for TB during the reporting period	E-NIKSHAY (PMR)	
19	Proportion of patients having multidrug-resistant or rifampicin-resistant TB with known HIV status	Total number ofmultidrug-resistant and rifampicin-resistant TB patientshaving documentedHIV status	Total number of multidrug- resistant and rifampicin- resistant TBpatients registered duringthe reporting	NIKSHAY	

			period		
20	Proportion of HIV-positive patients treated for multidrug-resistant or rifampicin-resistant TB who are also on ART	Number ofHIV-positive multidrug- resistant and rifampicin- resistant TB patientswhoare onsecond-line TBtreatmentand newlystartedor alreadyonART	Number of HIV-positive multidrug- resistant and rifampicin- resistant TBpatients registered duringthe reporting period	NIKSHAY	
21	Proportion of HIV-positive TB patients on protease inhibitor-based ART regimen receiving rifabutin-containing anti-TB treatment	Number of HIV-positive TB patients on protease inhibitor- based ART who received rifabutin-containing anti-TBtreatment regimen	Number of people living with HIV on protease inhibitor-based ARTwhoare diagnosedas havingactive TBduring thereporting period	NIKSHAY	

Drug resistant -TB

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Proportion of previously treated microbiologically-confirmed cases receiving DST at the start of treatment	No. of previously treated microbiologically-confirmed cases receiving DST at the start of treatment x 100	No. of previously treated TB cases notified	E-NIKSHAY	

2	Proportion of new microbiologically-confirmed cases receiving DST at the start of treatment	No. of new microbiologically-confirmed cases receiving DST at the start of treatment x 100	No. of new TB cases notified	E-NIKSHAY	
3	Proportion of Previously Treated TB Cases with RR/MDR TB	Number of RR/MDR TB Cases diagnosed among Previously Treated TB Cases during specified Period × 100	Number of Previously Treated TB Cases Diagnosed during specified Period	NIKSHAY	
4	Proportion of New TB Cases with RR/MDR TB	Number of RR/MDR TB Cases diagnosed among New TB Cases during specified Period × 100	Number of New TB Cases Diagnosed during specified Period	NIKSHAY	
5	Number of microbiologically confirmed, drug resistant TB cases (RR-TB and/or MDR-TB) notified (By Sex and Age)			NIKSHAY	
6	Proportion of diagnosed MDR-TB patients initiated on treatment	Number of MDR-TB patients initiated on treatment	Number of MDR-TB patients diagnosed	NIKSHAY	
7	Annualized MDR TB case notification rate	Number of MDR TB cases notified in a specified period x multiplier to convert annualized	Population in a year	NIKSHAY	
8	Proportion of estimated MDR TB cases notified	Number of MDR TB cases notified in a year	Estimated number of MDR-TB cases in a year		
9	Proportion of MDR-TB patients tested for second line Drug susceptibility at initiation of treatment	Number of MDR-TB patients tested for second line DST	Number of MDR-TB patients notified	E-NIKSHAY	

10	Proportion of MDR TB cases diagnosed as XDR TB	Number of MDR TB cases diagnosed as XDR	Number of MDR patients notified	NIKSHAY	
11	Proportion of diagnosed XDR TB cases put on treatment	Number of XDR TB cases started on treatment	Number of XDR TB cases diagnosed	NIKSHAY	
12	Proportion of MDR TB cases diagnosed with additional drug resistance	Number of MDR TB cases diagnosed with additional drug resistance	Number of MDR patients notified	NIKSHAY	

Outcome of treatment indicators

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
	Drug sensitive patients				
1	Proportion of TB patients declared **(treatment outcome)** *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	No. of TB cases declared **(treatment outcome)**	Total No. of TB patients registered in a quarter that ended 12 months prior	NIKSHAY	
2	Proportion of patients followed at 6 / 12 / 18 month after completion of treatment	No. of patients followed at 6/12 month after completion of treatment	Total number of patients who had completed treatment 6/12/18 months prior	E-NIKSHAY	
3	Proportion of TB patients **developing recurrence of TB**	No. of TB Patients developing recurrence	Total no. of Notified Patients completed	E-NIKSHAY	

	within 1 year of completion of treatment	of TB within one year of completion	treatment before one year prior		
4	Proportion of HIV-TB patients declared **(treatment outcome)** *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated* **by Age / Sex / HIV status*	No. of HIV-TB cases declared **(treatment outcome)**	Total No. of HIV-TB patients registered in a quarter that ended 12 months prior	E-NIKSHAY	
	Drug resistant TB				
5	Proportion of DRTB Patients declared **(treatment outcome)** *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	No. of DRTB Patients declared **(treatment outcome)**	Total No. of DRTB patients cohort registered 33 months prior	E-NIKSHAY	
6	Proportion of DRTB patients declared **Failure due to** *culture non-conversion at end of IP* *culture reversion in CP*	No. of DRTB cases declared Failure due to **(reason)**	Total No. of DRTB patients cohort registered 33 months prior	E-NIKSHAY	

	Additional drug resistance *Adverse drug reaction*				
	Drug resistance other than MDR				
7	Proportion of DRTB patients declared **(treatment outcome)** *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	No. of DR-TB cases declared cured	Total No. of DR-TB patients registered in a quarter that ended 15 months prior	E-NIKSHAY	

Private sector indicators

Sr. No.	Indicator name	Numerator	Denominator	Source of data	Remarks
1	Proportion of private sector health facilities registered in NIKSHAY (health facility wise) - Single clinic - Multiple - Laboratory	Number of private health registered in NIKSHAY	Number of private health facilities in area	NIKSHAY	
2	Proportion of private sector health facilities notifying TB out of registered (health facility wise) - Single clinic - Multiple - Laboratory	Number of private health facilities notifying TB	Number of private health facilities registered	NIKSHAY	
3	Proportion of TB patients notified from private sector	Number of TB patients notified from private sector	Total number of TB patients notified	NIKSHAY	
4	Proportion of new and recurrent TB patients notified from private sector	Number of TB new and recurrent TB patients notified from private sector	Total number of new and recurrent TB patients notified	E-NIKSHAY	

5	Proportion of microbiologically confirmed among TB cases among total notified cases from private sector	Number of microbiologically confirmed TB patients notified from private sector	Total number of TB patients notified from private sector	NIKSHAY	
6	Proportion of the DRTB patients notified from private sector	Number of DR-TB patients notified from private sector	Total number of DR-TB patients notified	NIKSHAY	
7	Proportion of the pediatric TB patients notified from private sector	Number of pediatric TB patients notified from private sector	Total number of pediatric TB patients notified	NIKSHAY	
8	Proportion of TB patients (notified from private sector) with known HIV status	Number of TB patients (notified from private sector) with known HIV status	Total number of TB patients notified from private sector	NIKSHAY	
9	Proportion of previously treated TB patients (notified from private sector) received DST at the beginning of treatment	Number of previously treated TB patients (notified from private sector) received DST at the beginning of treatment	Total number of TB patients notified from private sector	NIKSHAY	
10	Proportion of new TB patients (notified from private sector) received DST at the beginning	Number of new TB patients (notified from private sector) received DST at the beginning of	Total number of TB patients notified from private sector	E-NIKSHAY	

	of treatment	treatment			
11	Proportion of TB patients declared (treatment outcome) *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	Number of TB patients declared (treatment outcome) *Cured* *Treatment completed* *Successfully treated* *Died* *Failure* *Lost to follow up* *Regimen changed* *Not evaluated*	Total number of TB patients notified from private sector	E-NIKSHAY	

Review meeting Protocol for all Program staff

Level	Type of Review	Chairperson	Participants	Frequency
National	RNTCP performance review	DDG (TB)	STOs	Biannual
	Medical College performance review	DDG (TB)	ZTF members	Annual
	TB-HIV collaborative activities	DDG-TB	Members of National Working Group for TB-HIV collaborative activities	Quarterly
	Laboratory Committee	Chairperson Laboratory Committee / DDG (TB)	Members of Laboratory Committee	Biannual
	National DOTS-Plus Committee	Chairperson National DOTS- Plus Committee / DDG (TB)	Members of National DOTS-Plus Committee	Biannual
	National Technical Working Group (NTWG) for PPM Activities	Chairperson NTWG for PPM Activities / DDG (TB)	NTWG for PPM Activities members	Biannual
	National Operational Research Committee	Chairperson National OR Committee / DDG (TB)	National OR Committee members	Biannual
	National Airborne Infection Control (AIC) Committee Members	National AIC Committee Chairperson / DDG (TB)	National AIC Committee members	Biannual
Zonal	Medical College performance review	ZTF Chairperson	STF members	Annual
	RNTCP Performance Review including one day exclusively for PMDT activities	DDG (TB)	Regional Directors, STOs, DTOs of selected districts	Annual
State	State Health Society Review (RNTCP included as an agenda item)	PS (Health), MD-NRHM	Director Health Services, CMHO , All programme heads in state,	Quarterly

Level	Type of Review	Chairperson	Participants	Frequency
	RNTCP performance review	STO	DTO	Quarterly
	Performance review of Under-performing districts	STO	DTO	Biannual
	Medical college performance review	STO/ STF Chairperson	Nodal Officers from all medical colleges	Quarterly
	State Operational Research Committee Meeting	STO/ STF Chairperson	State OR Committee Members	Quarterly
	State TB-HIV Co-ordination committee meeting	PS (Health)	Members of State TB-HIV Cordination Committee	Biannual
	State Working Group Meeting for HIV/TB collaborative activities	PD-SACS / STO	Members of State Working Group for HIV/TB collaborative activities	Quarterly
	State DOTS-Plus Committee meeting	PS (Health)	State DOTS-Plus Committee members	Quarterly
	Review of RNTCP Accounting	State Accountant	District level Accountant	Biannual Review and One for PIP
	Review of Drug management	State Drug Store Manager	District Drug Storekeepers	Biannual
	Review of data management	State epidemiologist and state Statistical Assistant	District DEO/Statistical assistant	Biannual
	Workshop for Other Sector Health Facilities such as Railways, ESI, CGHS, Mines, etc...	STO	Representatives from Other sector Health facilities	Annual
	Review Meeting of Partners	STO	All Partners	Biannual
District	District Health Society Review (RNTCP included as an agenda item)	District Magistrate / Chairman District Health Society.	CMHO, All programme heads in district, Block Medical Officers, MO-PHIs (infrequently)	Quarterly

Level	Type of Review	Chairperson	Participants	Frequency
	CMHO Monthly Meeting with Block Medical Officers and MO-In charge PHCs (RNTCP included as an agenda item)	CMHO	All Block Medical Officers, MO-In-charge PHC, and Superintendent CHC.	Monthly
	RNTCP performance review	DTO	MOTC, STS and STLS	Monthly
	Medical college performance review	Core Committee Chairman of the respective Medical College	Core Committee Members of the respective Medical College and DTO	Quarterly
	TB-HIV District Coordination Committee meeting	Chairperson of TB-HIV District Coordination Committee	Members of District TB-HIV Coordination Committee	Quarterly
	Review of Drugs and Logistics	DTO and DTC Pharmacist	Pharmacists/Incharge Storekeeper of all TUs and PHIs	Quarterly
	DOTS-Plus site committee meeting	Chairperson/Coordinator DOTS-Plus site	DOTS-Plus site committee members, DTOs / Sr.DOTS-Plus-TB-HIV Coordinator	Monthly
	Workshop with Partners and other sector hospitals such as Railways, ESI, CGHS, IMA, AYUSH, NGOs, External funded projects etc…	CMHO/DTO	Representative from Partners	Biannual
	Review of TB-HIV collaborative activities along with RNTCP monthly meeting	DAPCU/DTO	ICTC/CCC Counsellors, STS,_DOT-Plus-TB-HIV Coordinator	Monthly
Block	Block Level Meeting with MO-In-charge PHI and other staff. (RNTCP included as an agenda item)	Block Medical Officer	MO-I/C-PHC and other staff.	Monthly
PHI	Monthly Meetings with Staff (RNTCP included as an agenda item)	MOIC, PHC	MPHS/ANM/MPW/ASHA	Monthly

Annexure I8 A

TB Notification reporting format for **Laboratory**

Period of reporting: From ...../...../..... To ...../...../.....

Health Establishment code for TB Notification

Name of the Laboratory :.....

Registration Number:..... Telephone (with STD):.....

...../.....

Mobile number:.....

Complete Address: .....

.....

Sr No	Name of TB Patient (surname first)	Father / Husband's name	Age (yrs)	Sex (M/F/O)	GoI issued identification number *	Complete residential address	PIN number	Patient Phone number	Date of TB Diagnosis	Date of sputum collection	Date of result	Type of Test result (smear microscopy positive / culture positive / MTB on LPA / MTB on Xpert / MTB in FNAC / TB on Histopath/ DST	DST results for each drug tested (R=resistant / S=sensitive/NA=not available) Rif, INH, SM, EMB, Ofx, Km, Eto, Cipro, Capr, etc $							
													Rif	INH	SM	EMB	Ofx	Km	—	—

*** Aadhaar, driving license, voter ID, ration card, PAN no, passport no etc**

Laboratories include those Health Establishments carrying out any of the RNTCP endorsed TB diagnostics

Signature:.....Date: ...../...../.....

Annexure I8 B

TB Notification reporting format for Medical practitioners / Clinics/Hospitals/Nursing homes

Period of reporting: From ...../...../..... To ...../...../.....

Name of the health facility / practitioner :.....(single/Multi)
Registration Number:..... Telephone (with STD):.....
Mobile number:.....
Complete Address: .....

Health Establishment code for TB Notification

...../.....

Sr No	Name of TB Patient (surname first)	Father / Husband's name	Age (yrs)	Sex (M/F/O)	GoI issued identification number *	Complete residential address	PIN no	Patient Phone number	Date of TB Diagnosis	Date of TB treatment initiation	Site of Disease (P / EP)	Patient Type (New TB case/ Recurrent TB case/ Treatment change)	Basis of diagnosis (Smear microscopy / culture / PCR / LPA/ FNAC/Histo-pathology/Clinical exam/X-Ray)	Weight in Kg	Drugs and dosages (in mg) H/R/Z/E/S/ O/K/Cs/Eto/ Levo/Mx/Cpr/ Other (specify)

*** Aadhaar, driving license, voter ID, ration card, PAN no, passport no etc**

Private practitioner / Clinic (single) will include any Health Establishments where TB cases are treated or diagnosed clinically / radiologically and the medical services are provided by single medical practitioner
Hospital / Clinic / Nursing Home (multi-practitioners) will include any Health Establishments where TB cases are treated or diagnosed clinically / radiologically & medical services are provided by more than one practitioner

Signature:.....Date: ...../...../.....

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TB Notification reporting format for
Medical practitioners / Clinics/Hospitals/Nursing homes

Period of reporting: From ...../...../..... To ...../...../.....

Health Establishment code for TB Notification

Name of the health facility / practitioner :.....(single/Multi)

Registration Number:..... Telephone (with STD):.....

...../.....

Mobile number:.....

Complete Address: .....

Patient ID	Patient home visit Done (Y/N)	If Yes, done by	Patient counselling Done (Y/N)	Type of treatment adherence (DOT/ SMS/ Phone/ Nil)	Status of patient (regular/ Not regular / defaulted)	Month at which FU examination done	Status at FU examination (SM/Cult) (Pos/Neg)	Clinical improvement (Yes/No)	No of contacts	No of contact symptomatic	No found to have TB among contact	No of contacts initiated on anti-TB treatment	No of contacts offered chemoprophylaxis	HIV testing offered (No/Neg /Pos)	DST testing offered (No/RIF resistance /RIF sensitive/ Indeterminate)	Treatment Outcome (C/TC /F/D /LTFU/TO /RC)

C=Cured, TC=Treatment Completed F=Failure D=Died LTFU=Lost to FollowUp TO=Transferred Out RC=Regimen Change

This information on page 2 is to be submitted during treatment and after treatment completion with sosupdation in Nikshay with public health action support by local public health staff.

Signature:.....Date: ...../...

Page 2

Financial Reporting requirements under RNTCP at various levels

Annexure 19

Level I-At State TB Cell

	Name of report	Basis of Preparation and Key Checks	Frequency/Timelines	Responsibility	Assisted by	To Whom
1	Financial Monitoring Report(FMR)	• Should be prepared from Book of Accounts • Only actual expenditures to be reported • Proper classification of expenditure/sub heads to be ensured	Quarterly, to be submitted within 21 days from the close of quarter.	STO/ APO	State accountants	FMG NHM , GoI with copy to CTD
2	Statement of Expenditure(SOE)	Consolidated SOE along with individual SOE of STCS, DTCS/MTCS	Quarterly, to be submitted within 21 days from the close of quarter.	STO	State accountants	CTD-MoHFW & State NHM
3	Statement of Fund position	To be submitted with FMR and SOE Should be duly reconciled with FMR, SOE and books of accounts	Monthly	STO	State accountants	CTD-MoHFW & State NHM
4	Utilisation certificate	Should be prepared sanction wise Should be as per Form 19A Final UC should be as per the expenditures certified in audit report	Annual By 31st July along with the audited statements	STO/APO	State accountants	CTD-MoHFW & State NHM
5	Statement confirming State's contribution	Should provide details of instruments indicating the fund transfer to STC through SHS NHM.	Quarterly	STO/APO	State accountants	CTD-MoHFW & State NHM
6	Preparation of Final Accounts	This will be prepared by STC for the purpose of Annual Audit		STO	State accountants	
7	Audited statement of accounts and Audit reports of STC	As per Audit Format given in NRHM Financial Manual	Annual , to be submitted by 31st July of following year	STO	State accountants	CTD-MoHFW & State NHM

- Format of all these will be provided in updated guideline for NRHM Financial Management for state and districts.
- Bank Reconciliation Statement should be submitted on a quarterly basis along with the FMR.
- Executive Summary of concurrent audit report should be submitted on a quarterly basis. This is being carried by NHM.

Level II - at district Level

	Name of report	Basis of Preparation and Key Checks	Frequency/Timelines	Responsibility	Assisted by	To Whom
1	Financial Monitoring Report(FMR)	• Should be prepared from Book of Accounts • Only actual expenditures to be reported • Proper classification of expenditure/sub heads to be ensured	Quarterly, to be submitted within 15 days from the close of quarter.	DTO	District accountant	State/State TB Cell
2	Statement of Expenditure(SOE)	SOE of District TB Cell	Quarterly, to be submitted within 15 days from the close of quarter.	DTO	District accountant	STC
3	Statement of Fund position	To be submitted with FMR and SOE Should be duly reconciled with FMR, SOE and books of accounts	Monthly	DTO	District accountant	STC
4	Utilisation certificate	Should be prepared sanction wise Should be as per Form 19A Final UC should be as per the expenditures certified in audit report	Annual By 21st July along with the audited statements	DTO	District accountant	STC
6	Preparation of Final Accounts	This will be prepared by STC for the purpose of Annual Audit		DTO	District accountant	
7	Audited statement of accounts and Audit reports of DTC	As per Audit Format provided in NRHM financial guidelines	Annual , by 21st July of following year	DTO	District accountant	STC

Guidelines on activities under ACSM

District teams must formulate ways to strengthen the planning and implementation of the programme initiatives listed below reported in the Quarterly Report on Programme Management and Logistics (QRPML). All efforts need to be made to ensure that the outcome of the initiatives listed below contribute to the achievement of programmatic objectives including better case finding, treatment adherence, notification etc.

Activities	Objective
Patient Provider Meetings	Patient support and improving case holding/treatment adherence
Community Meetings	Improving levels of awareness about TB in the community to improve referrals, adherence and address stigma
School-based activities	Improving levels of awareness, referrals
Sensitisation of PPs, NGOs, PRIs, Others	For advocacy, building allies for support, additional resources, improving case finding, case notification etc.
Outdoor Publicity	Improving levels of awareness about TB, referrals, adherence and addressing stigma etc.

Patient Provider Meetings

Facilitators: These meetings are organized by the DOT Provider. STS/ Medical Officer are to conduct these meetings. **Purpose:** The purpose of the meeting is to counsel patients in a group who are on treatment or who are about to begin treatment. This is an opportunity for free interaction between provider and patient and also an opportunity for patients to clarify their doubts, if any.

Target Group: Patients on treatment or who are about to begin treatment. There could be 5- 10 patients (minimum) in each such meetings. *(If there is large number of patients at one centre, small groups of about 10 patients may be made so that better interaction takes place between patients and providers*)

Place: These meeting are to be organized at the health facility. **Duration and Frequency**: These meetings can be organized once a month so that each patient who is on treatment has the opportunity to attend one such meeting during the intensive phase. ***(Frequency of such meeting would be more than one in a month when the number of patients is large at one health facility)***

Each meeting can be for half hour to one hour. The patient may be provided refreshments (tea etc.)

Kindly note that patient provider interaction meetings are additional to and are different from interpersonal communication that provider has with the patient while administering treatment.

Messages for Patients:

1. Basic information about tuberculosis, cough etiquette etc.
2. Importance of completing treatment
3. Side-effects of drugs and how to manage these
4. Importance of follow up sputum examination
5. Prophylaxis for children in the family
6. Do's and don'ts including protective measures, role of nutritious diet etc.

Health Communication Materials: Flip Book; Banner; Posters on TB etc.

Report writing: At the end of each meeting, a report may be prepared stating date and time of meetings, number of patients, name of facilitators and topic covered along with major concerned mentioned by the patients. The report is to be prepared by the STS. The list of patients who attended the meeting may be attached with the report. It may be more convenient to have register at each centre for such meetings and patients can put their name in the same register.

The STS should indicate organization of these meetings in their tour dairy indicating place, number of patients, presence of MO in the meeting and main points discussed in the meetings. These may be submitted by STS to MOTC on a monthly basis for onward submission to DTO to be included in quarterly PMR report.

Community Level Meetings

Facilitators: These meetings are organized by the STS and conducted by the Medical Officer.

Purpose: The purpose of the meeting is to create awareness about signs and symptoms of TB, availability of diagnosis and free treatment in the health facilities, availability of good quality drugs under the direct observation of the DOT provider. Provision of drugs in patient wise boxes, option of community DOT Providers can also be highlighted in these meetings.

Target Group: General public, patients, community leaders/ people's representative including SHGs, NGOs, Community Volunteers, Traditional healers, people practicing other systems of medicine. There should be at least 20-25 people in these meetings.

Place: These meeting are to be organized at the village or block level. These can be organized in the community centre, or any other important place in the community.

Duration and Frequency: These meetings can be organized once a month and each meeting could be for one hour to two hours.

The participants may be provided refreshments (tea/ snacks etc.)

Messages for Patients:

TB signs and symptoms; availability of diagnosis of good quality treatment in the health facility; location of nearest health facility; provision of drugs in patient-wise boxes; Importance of treatment under direct observation; Importance of completing of treatment; option of community DOT providers

(These may be given in the form of discussion, lecture. Street play can also be organized followed by discussion and question answer session)

Health Communication Materials:

Banner; Posters on TB; Pamphlets; mike; exhibition material; audio visual materials where possible

Report writing: At the end of each meeting a report may be prepared stating date and time of meetings, number of persons, name of facilitators and topic covered along with major concerned mentioned by the people. The report is to be prepared by the STS. List of persons who attended the meeting may be attached with the report.

STS should indicate organization of these meetings in their tour dairy indicating place, number of persons, presence of MO in the meeting and main points discussed in the meetings. These may be submitted by STS to MOTC on a monthly basis for onward submission to DTO to be included in Quarterly Report on Programme Management and Logistics (QRPML) or Programme Management Report.

School-based Activities

Awareness generation amongst students and teachers of schools and colleges regarding tuberculosis

Steps for organizing school activities

- ✓ Contact the department of school education at state/district level (whichever applicable) to bring them on board in the fight against TB.
- ✓ Take necessary approvals to enlist schools and colleges in the district.

- ✓ Organize training of trainers (TOT) for school teachers, who can also conduct school activities in a planned and coordinated manner to maximize impact. These can also be done in coordination with the school health programme.
- ✓ Display and distribute appropriate support materials like posters/charts/videos/pamphlets, etc. in local language that may be provided by the state government and for which the prototype may have been prepared by the centre.
- ✓ Help the schools utilize the opportunity innovatively by involving students in group activities like painting competitions, dramas/plays, road shows etc.

The initial visit to the school may include simple messages through quiz contests, games, essay writing, drawing and slogan competitions etc. on TB and related issues. Conclude the event with take home messages and how the students can participate in awareness generation; students and teachers can convey TB related key messages to parents, discuss the issue in the Village Health and Sanitation Committee meetings or with prominent people in the community etc. Some token gifts like pen, pencils, key rings, colour boxes, notebooks etc. can be distributed as prizes to the students.

The subsequent visit to the school/college can be done after 2-3 months to follow up and re-sensitization. Follow up visit should start with a quiz to gauge recall level of the information shared during the previous visit followed by planned activities and distribution of prizes.

In this context, following activities need to be carried out in time bound manner:

1. Issue letter with details from STOs to all the DTOs and municipal health officers, with copy to state/UT Education Director and CTD annually
2. DTO should ensure the preparation of block-wise enlisting of all the schools and colleges in the district to make sure no government/private school/college is missed out. For this purpose, DTOs can seek help from the District Education Officers.
3. Preparation of a detailed district specific action and monitoring plan containing – name of the district and block, name of the school, name of the health functionaries responsible to visit, date of visit, activity planned (specific), resource material required, name of the officials responsible for monitoring (monitoring on random basis covering nearer and remote areas). For this purpose can involve STS, Axshaya project and CBCI functionaries. The action and monitoring plan can be developed block-wise. At least 2 school activities should be monitored on monthly basis.
4. Submission of the district-wise action and monitoring plan by DTOs to the STOs.
5. Submission of the state/UTwise action and monitoring plan by STOs to the CTD.
6. Activity to be undertaken during the month of Aug/Sep 2012 (first visit) and Nov/Dec 2012 (second visit).
7. Submission of the district-wise report on outcome of the activity (covering both the visits) by DTOs to the STOs.

8. Submission of the state-wise report on outcome of the activity (covering both the visits) by STOs to the CTD.

Sensitisation of PRIs, NGOs, PPs etc.

Facilitators: These meetings are to be organized by the District PPM Coordinators/STS in consultation with DTO and other relevant cadres at the District and Sub-District levels.

Purpose: The purpose of these meetings/interactions is to create greater awareness about the need for public action on TB and generate specific commitment from target audience on how they would support TB control and care efforts.

Target Group: Elected representatives under the 3-tier Panchayati Raj System, community leaders, SHGs, NGOs, Community Volunteers etc.

Place: These meetings can be organized at the District, village or block level. These may be done individually, in groups or at any other available forums such as IMA meetings, hospitals/Clinics, NGO forums/offices, Gram Panchayat meetings etc.

Duration and Frequency: Meetings with each of these stakeholders must be organized a minimum one with each group per month. These meetings may be done individually but it is preferable to do this in groups.

Key Messages:

1. Facts about TB
2. RNTCP programme and services
3. The need to support the TB programme for a TB-free India

Health Communication Materials:

Banner, posters on TB, pamphlets, exhibition and audio visual materials where possible

Report writing: At the end of each meeting a report may be prepared stating date and time of meetings, number of persons met, name of facilitators and topic covered along with details of any commitments made by any participant. The report is to be prepared by the District PPM Coordinator/ STS. List of persons who attended the meeting may be attached with the report.

District PPM Coordinator/ STS should indicate organization of these meetings in their tour dairy indicating place, number of persons, presence of RNTCP officials/cadres in the meeting and main points discussed in the meetings. These may be submitted by District

PPM Coordinator to DTO and by STS to **DTO or MOTC** on a monthly basis for onward submission to be included in Quarterly Report on Programme Management and Logistics (QRPML) or Programme Management Report.

World TB Day

The World TB Day is observed each year globally on March 24. In India, numerous events and activities are organized at national, state, district, and community levels to draw public attention to TB as a major health problem and efforts being made under RNTCP for TB care and control. The World TB Day represents a worldwide call to action as well as helps mobilize political and social commitment at the national level. It is necessary to plan it well, to derive maximum benefit. As a major media event, the World TB Day provides a good opportunity to draw attention towards:

1. Good work done under RNTCP
2. Local/regional/national TB scenario to inform and emphasize the urgency
3. Role of different sections of society and service providers to bridge gaps
4. Gaps and what more needs to be done
5. Mobilize support of stakeholders and increase commitment from local leaders/health managers/ administrators to fight TB
6. Attract media attention/coverage to emphasize the urgency of TB control for wider understanding, support, and commitment
7. Co-opt new groups as partners such as businesses, private practitioners etc.
8. NGOs and professional bodies, which are important in the fight against TB

Plan for World TB Day at the start of the year while formulating the District Annual Action Plan and PIP.

Essential reading material:

1. Operational Handbook on ACSM for RNTCP
2. RNTCP Health Communication Strateg

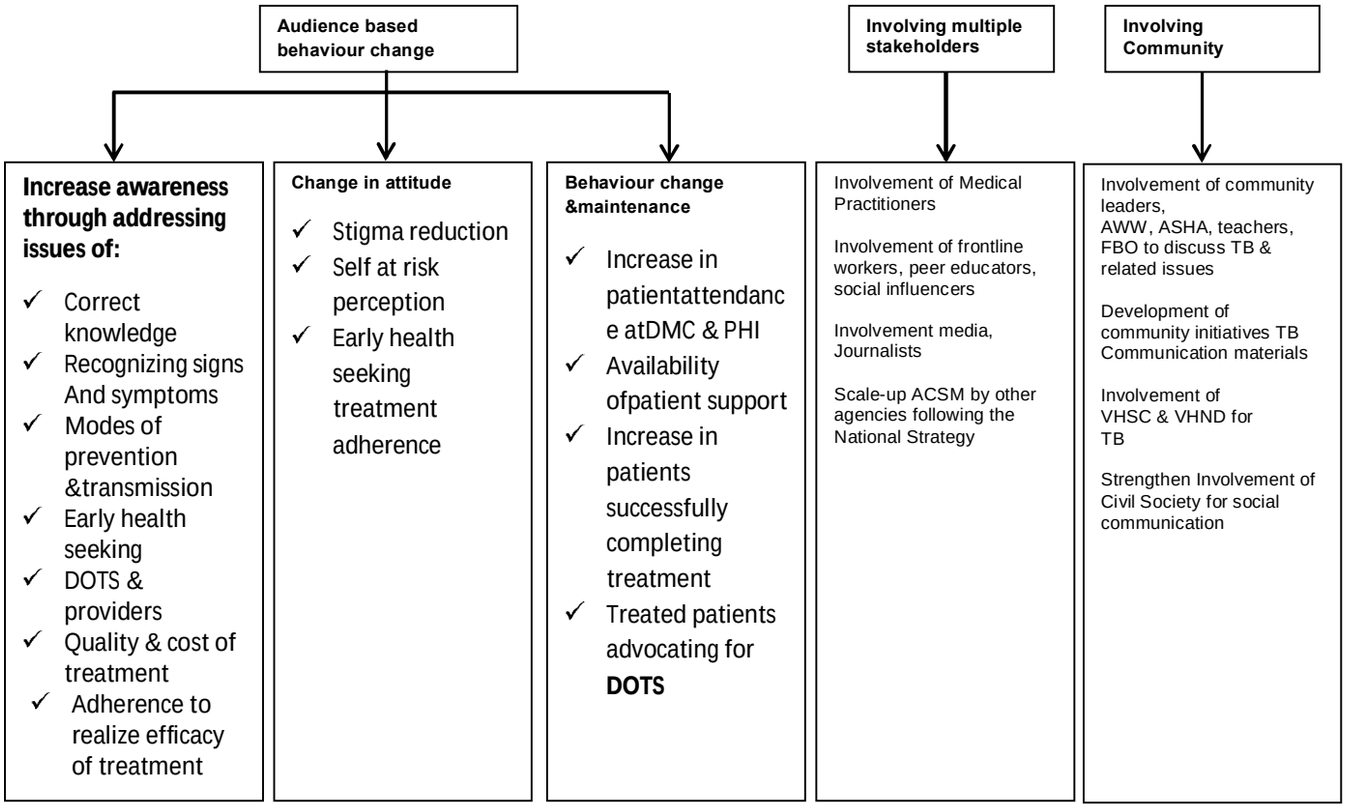
Strategic approach to plan ACSM activities

Strategies are broadly classified in to two groups

For greater demand for early diagnosis and treatment, improvement in thehealth seeking behaviourthrough empowered community structures andother stakeholders, using evidence based BCC strategies will be adopted.

For ensuring supply of quality assured diagnosis andtreatment,enhancement of political will and commitment of policy makers atnational, state and community levelwill be focussed. This will be achievedby effectively engaging with other stakeholders including media, NGOs, patient support groups etc to support advocacy and communication.

The diagram below is an illustration of the broad strategy that would be adopted for designing activities.



Annexure 21

Bio Medical Waste Management

Categories of Bio-Medical Waste- There are 10 categories of the bio medical waste which as tabulated as below-

Option	Treatment & Disposal	Waste Category
Cat. No. 1	Incineration /deep burial	Human Anatomical Waste (human tissues, organs, body parts)
Cat. No. 2	Incineration /deep burial	Animal Waste Animal tissues, organs, Body parts carcasses, bleeding parts, fluid, blood and experimental animals used in research, waste generated by veterinary hospitals / colleges, discharge from hospitals, animal houses)
Cat. No. 3	Local autoclaving/ micro waving/ incineration	Microbiology & Biotechnology waste (wastes from laboratory cultures, stocks or specimens of micro-organisms live or attenuated vaccines, human and animal cell culture used in research and infectious agents from research and industrial laboratories, wastes from production of biological, toxins, dishes and devices used for transfer of cultures)
Cat. No. 4	Disinfections (chemical treatment /autoclaving/micro waving and mutilation shredding	Waste Sharps (needles, syringes, scalpels blades, glass etc. that may cause puncture and cuts. This includes both used & unused sharps)
Cat. No. 5	Incineration / destruction & drugs disposal in secured landfills	Discarded Medicines and Cytotoxic drugs (wastes comprising of outdated, contaminated and discarded medicines)
Cat. No. 6	Incineration , autoclaving/micro waving	Solid Waste (Items contaminated with blood and body fluids including cotton, dressings, soiled plaster casts, line beddings, other material contaminated with blood)
Cat. No. 7	Disinfections by chemical treatment autoclaving/micro waving& mutilation shredding.	Solid Waste (waste generated from disposable items other than the waste sharps such as tubing, catheters, intravenous sets etc.)
Cat. No. 8	Disinfections by chemical treatment and discharge into drain	Liquid Waste (waste generated from laboratory & washing, cleaning , house-keeping and disinfecting activities)
Cat. No. 9	Disposal in municipal landfill	Incineration Ash (ash from incineration of any bio-medical waste)
Cat. No. 10	Chemical treatment & discharge into drain for liquid & secured landfill for solids	Chemical Waste (chemicals used in production of biological, chemicals, used in disinfect ion, as insecticides, etc)

Note-

- Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfections.
- Mutilation/shredding must be such so as to prevent unauthorised reuse.
- There will be no chemical pre-treatment before incineration. Chlorinated plastics shall not be incinerated.
- Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.
- Chemicals treatment using at least 1% hypochlorite solution or any other equivalent chemical reagent. It must be ensured that chemical treatment ensures disinfections.
- Mutilation/shredding must be such so as to prevent unauthorised reuse.
- There will be no chemical pre-treatment before incineration. Chlorinated plastics shall not be incinerated.
- Deep burial shall be an option available only in towns with population less than five lakhs and in rural areas.
- The most essential part of hospital waste management is the segregation of Bio-medical waste. The segregation of the waste should be performed within the premises of the hospital/nursing homes. The colour coding, type of container to be used for different waste category and suggested treatment options are listed below.

COLOR CODING & TYPE OF CONTAINER FOR DISPOSAL OF BIO-MEDICAL WASTE

Colour Coding	Type of containers	Waste Category	Treatment Options as per Schedule 1
Yellow	Plastic bag	1,2,3,6	Incineration/deep burial
Red	Disinfected Container/ Plastic bag	3,6,7	Autoclaving/Micro waving/ Chemical Treatment
Blue/ White translucent	Plastic bag/puncture proof container	4,7	Autoclaving/Micro waving/ chemical treatment and destruction/shredding
Black	Plastic bag	5,9,10 (Solid)	Disposal in secured landfill

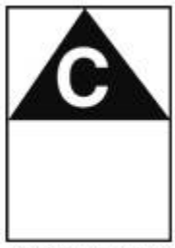
LABEL FOR BIO-MEDICAL WASTE CONTAINERS/BAGS-

Different labels for Bio-medical waste containers and bags shall be required for identification and safe handling of this waste. These labels for storage/transportation of Biomedical waste are as under-

BIOHAZARD SYMBOL
जैविक परिसंकट चिन्ह

BIOHAZARD
जैविक परिसंकट

CYTOTOXIC HAZARD SYMBOL
कोषिकाविष परिसंकट चिन्ह



CYTOTOXIC
कोषिकाविष

LABEL FOR TRANSPORT OF BIO-MEDICAL WASTE CONTAINERS/BAGS

	Day:_____ Month _____
	Year _____
Waste Category No. _____	Date of generation_____
Waste Class	
Waste Description	
Sender's Name & Address	Receiver's Name & Address
Phone No.:_____	Phone No.:_____
Telex No. _____	Telex No. :_____
Fax No. _____	Fax No. :_____
Contact Person _____	Contact Person:_____
In case of emergency please Contact:	
Name & Address:	
Phone No.	

Appendix

Drug dosages for first line anti-TB drugs

Drugs	Adult	Children
Isoniazid	5 mg/kg (4 to 6 mg/kg) daily	10 mg/kg (7-15 mg/kg) daily
Rifampicin	10 mg/kg (8-12 mg/kg) daily	15 mg/kg (10-20 mg/kg) daily
Pyrazinamide	25 mg/kg (20-30 mg/kg) daily	30 mg/kg (30-40 mg/kg) daily
Ethambutol	15mg/kg (12-18 mg/kg) daily	20 mg/kg (15-25 mg/kg) daily
Streptomycin	15 mg/kg (15-20 mg/kg) daily	15 mg/kg (12-18 mg/kg) daily