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Department of Health Research

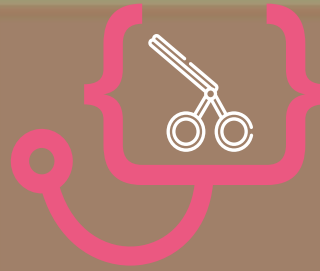
Ministry of Health and Family Welfare, Government of India



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# STANDARD TREATMENT WORKFLOWS *of India*

SPECIAL EDITION ON  
PAEDIATRIC AND  
EXTRAPULMONARY TUBERCULOSIS

**PARTNER**



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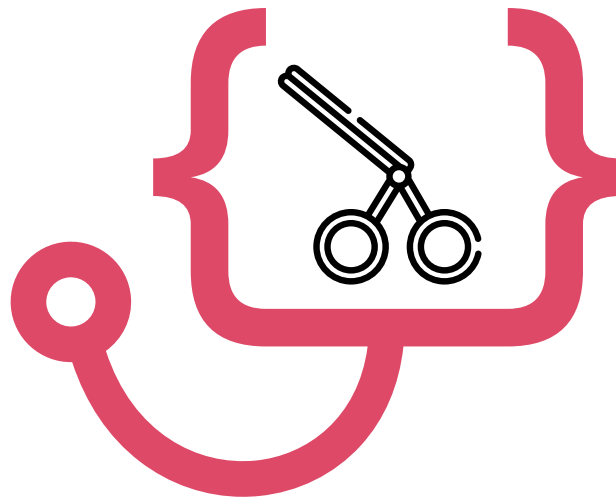
Central TB Division  
Ministry of Health and Family Welfare  
Government of India

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STANDARD  
**TREATMENT**  
WORKFLOWS  
*of India*

Special Edition on  
Paediatric and  
Extrapulmonary Tuberculosis



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- **CONTRIBUTORS**

# INTRODUCTION

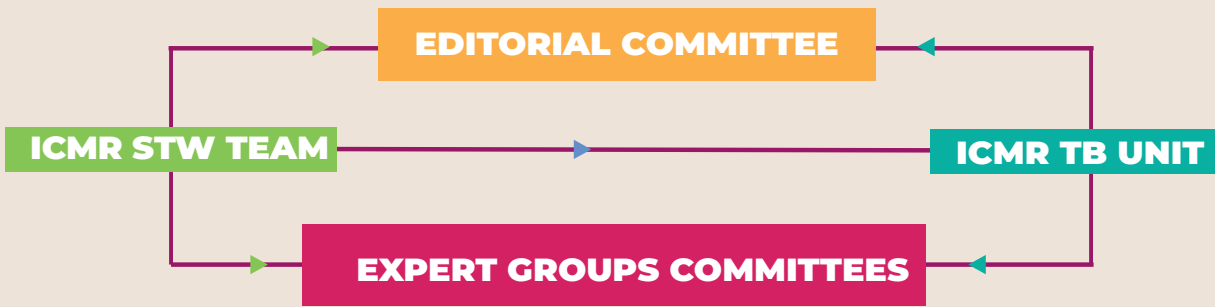
## GOAL

To empower the primary, secondary and tertiary care physicians/surgeons of all specialties towards achieving the goal of TB elimination by increasing detection of Paediatric TB and Extrapulmonary TB with disease management protocols and pre-defined referral mechanisms.

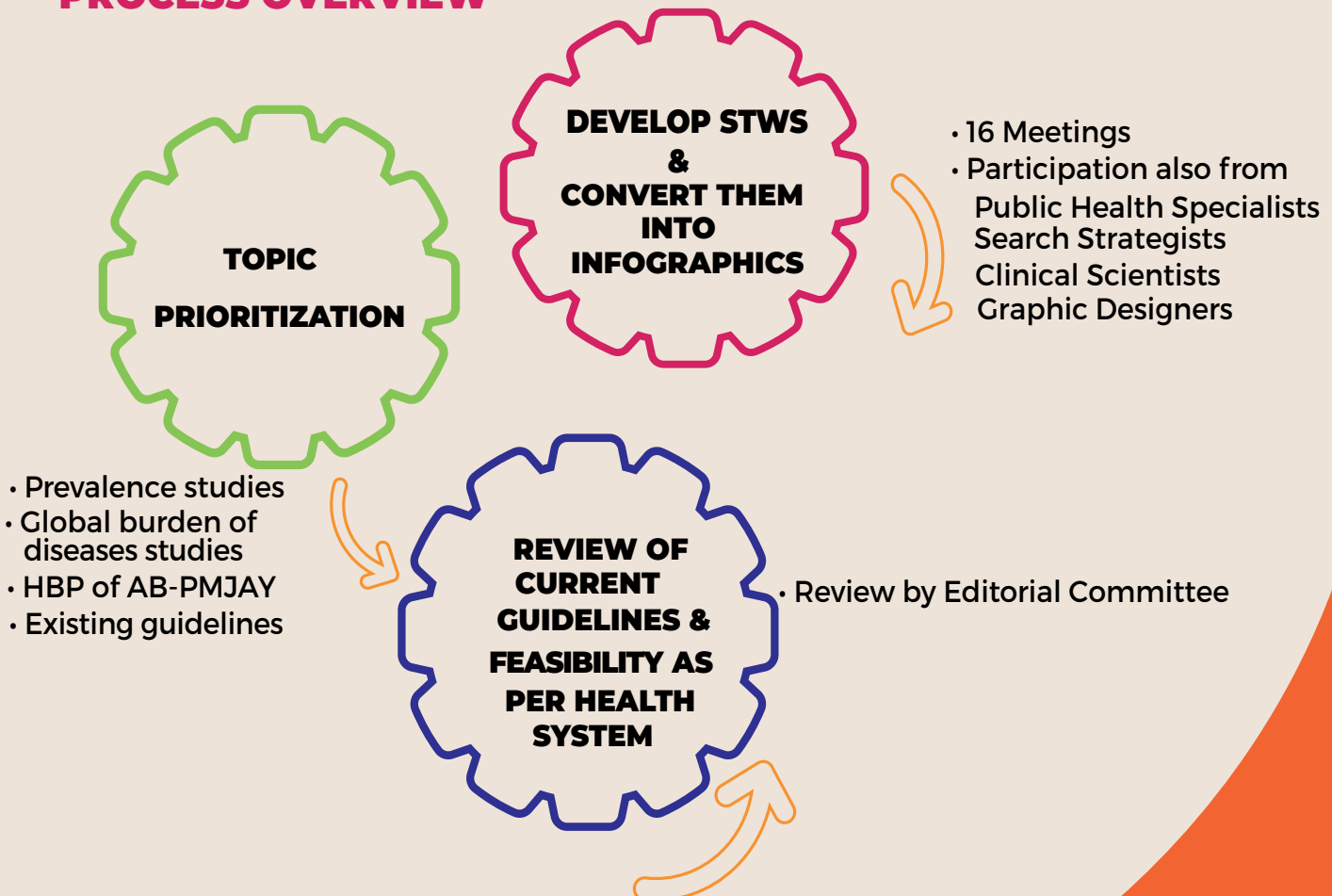
## OBJECTIVES

- To formulate comprehensive algorithms for detection and management of Paediatric and Extrapulmonary TB at primary, secondary and tertiary level health care system
- To improve implementation of the National TB Elimination Programme guide lines by doctors working in peripheral health care and also guide the National Programme to put resources optimally for the management of these conditions

## METHODOLOGY



## PROCESS OVERVIEW





# **Paediatric Tuberculosis**



# Standard Treatment Workflow (STW) for the Management of PAEDIATRIC ABDOMINAL TUBERCULOSIS ICD-10-A18.31

## WHEN TO SUSPECT?

- Presence of Fever >2 weeks
  - Anorexia
  - Unexplained weight loss\* or no weight gain in last 3 months
  - History of contact with TB patient
  - With one or more of following
    - › Recurrent/chronic abdominal pain in presence of red flag signs
    - › Abdominal distension/mass
    - › Altered bowel habits
- \*Constitutional symptoms may or may not be present in suspected case of Abdominal TB



## CLINICAL FEATURES SPECIFIC TO TYPE OF ABDOMINAL TB

| PERITONEAL TB   | VISCERAL TB (LIVER, SPLEEN, PANCREAS)   |
|---|---|
| <ul style="list-style-type: none"> <li>• Abdominal pain, distension</li> <li>• Fever</li> <li>• Weight loss</li> </ul>  | <ul style="list-style-type: none"> <li>• Abdominal pain</li> <li>• Fever</li> <li>• Jaundice</li> <li>• Weight loss</li> <li>• Anorexia</li> <li>• Hepatomegaly</li> <li>• Splenomegaly</li> <li>• Hepatic abscess</li> <li>• Palpable abdominal lump</li> <li>• Abnormal LFTs</li> </ul> |
| NODAL TB  |   |
| <ul style="list-style-type: none"> <li>• Pain abdomen</li> <li>• Fever</li> <li>• Palpable abdominal lump</li> </ul>  |   |
| INTESTINAL TB   |   |
| <ul style="list-style-type: none"> <li>• Recurrent intestinal colic</li> <li>• Altered bowel habits</li> <li>• Chronic diarrhoea</li> <li>• Partial/complete intestinal obstruction</li> <li>• Weight loss, anorexia</li> <li>• Palpable abdominal lump</li> <li>• Lower gastrointestinal bleeding</li> </ul> |   |

## EXAMINATION FINDINGS

- Anthropometry
- General physical & systemic examination
- Look for peripheral LAP, ascites, hepatosplenomegaly, doughy feel of abdomen, palpable abdominal lump, visible peristalsis

### RED FLAGS

- Pain abdomen waking child from sleep
- Chronic, severe, or nocturnal diarrhea
- Gastrointestinal blood loss
- Localized distension or mass

## INVESTIGATIONS

### ESSENTIAL

- Ultrasound abdomen

### SPECIFIC FINDINGS

- Abdominal LN : measuring >15 mm in short axis, conglomerate and/or central necrosis
- Omental/mesenteric thickening >15 mm with increased echogenicity
- Ileocaecal wall thickening

### NON SPECIFIC FINDINGS

- Intraabdominal fluid (free or loculated) or Inter-loop ascites
- Ascitic fluid with multiple septations
- Abdominal LAP with SAD <15 mm in absence of red flag signs

### Ascites

#### Essential

- If exudative ascites, ascitic fluid for NAAT, TB culture
- No role of ADA

#### Enlarged Abdominal LN (SAD>15 mm)

#### Desirable

- USG guided Abdominal LN-FNA for cytology, NAAT, TB culture

#### Optional

- USG/CT guided core biopsy of LN for histology, NAAT, TB culture

### Intestinal involvement

#### Desirable

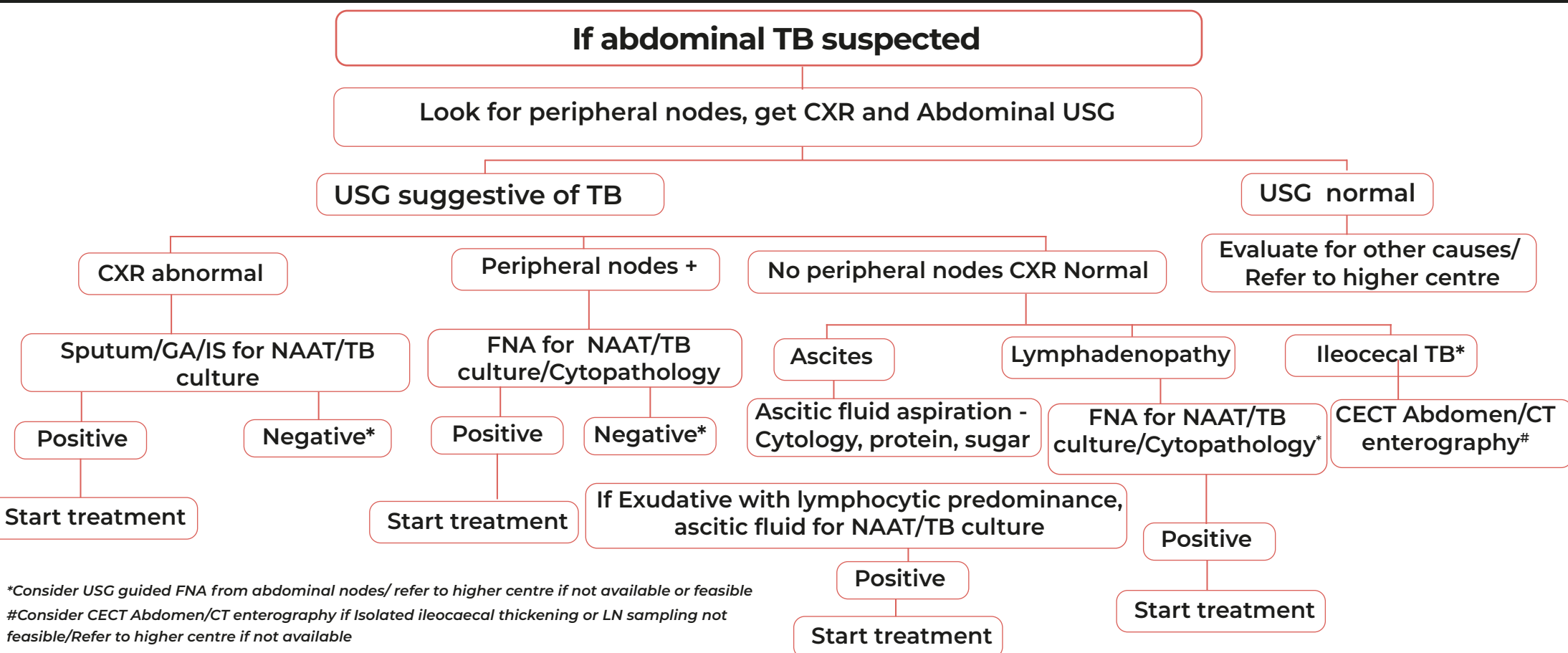
- If Ileocaecal thickening with enlarged nearby LN
- USG guided Abdominal LN-FNA for cytology, NAAT, culture
- Isolated ileocaecal thickening/LN sampling not feasible
- CECT Abdomen/CT enterography

#### Optional

- Ileocolonoscopy, tissue biopsy (HPE, NAAT)
- Laparoscopy, tissue biopsy for HPE, NAAT

- Chest X Ray
- sputum/GA/IS (If CXR abnormal) for NAAT, TB culture
- Ascitic fluid (If present) for cytology, protein & albumin
- Peripheral LN-FNA (If size >2 cm) for cytology, NAAT, TB culture

## DIAGNOSTIC ALGORITHM



## MANAGEMENT

### TREATMENT

- Start treatment & follow-up as per NTEP
- ATT for 6 months (2HRZE + 4HRE)
- Pyridoxine supplementation- 10 mg/day
- Steroids- not useful & not recommended
- Supportive treatment- Management of SAM/Malnutrition as per national guidelines
- Surgical treatment:
  - › Acute intestinal obstruction, Bowel perforation
  - › Persistence of obstructive symptoms despite conservative management & ATT
- DO NOT start Empirical ATT with isolated:
  - › Recurrent/Chronic abdominal pain without red flag signs
  - › Chronic diarrhoea without proper evaluation
  - › Failure to gain weight

### MONITORING

- **Assessment of response to treatment:**
  - › Clinical follow up - every month during treatment & after that every 3 months
  - › Radiologically by USG - At the end of treatment or if worsening or non response to treatment
  - › Microbiological - If worsening or non response to treatment
- **Pointers towards DR TB investigation:**
  - › Non response to treatment or Worsening or deterioration of constitutional symptoms after initial improvement. Consider possibility of Inflammatory Bowel disease after ruling out Crohn's disease
- **Obstructive symptoms may persist or worsen despite treatment with ATT**
- **Monitor for**
  - › Adherence to treatment (ATT)
  - › Adverse drug reactions- ATT induced

### WHEN TO REFER?

- Diagnosis is uncertain & additional investigations are required
- Acute intestinal obstruction or bowel perforation
- DR TB
- No response to appropriate treatment
- Oral drug (ATT) intolerance/cannot be given

## ABBREVIATIONS

|   |                                    |  |                                  |
|---|------------------------------------|--|----------------------------------|
| ATT- Antitubercular treatment               | E- Ethambutol                      | IS- Induced Sputum                       | R- Rifampicin                    |
| CECT- Contrast Enhanced Computed Tomography | FNA- Fine Needle Aspiration        | LAP- Lymphadenopathy                     | SAD- Sagittal Abdominal Diameter |
| CT- Computed Tomography                     | GA- Gastric Aspirate               | LN- Lymph Node                           | SAM- Severe Acute Malnutrition   |
| CXR- Chest X-Ray                            | H- Isoniazid                       | MGIT- Mycobacteria Growth Indicator Tube | USG- Ultrasonography             |
| DR-TB- Drug Resistant tuberculosis          | HPE- Histopathological Examination | NAAT- Nucleic Acid Amplification Test    | Z- Pyrazinamide                  |

## REFERENCES

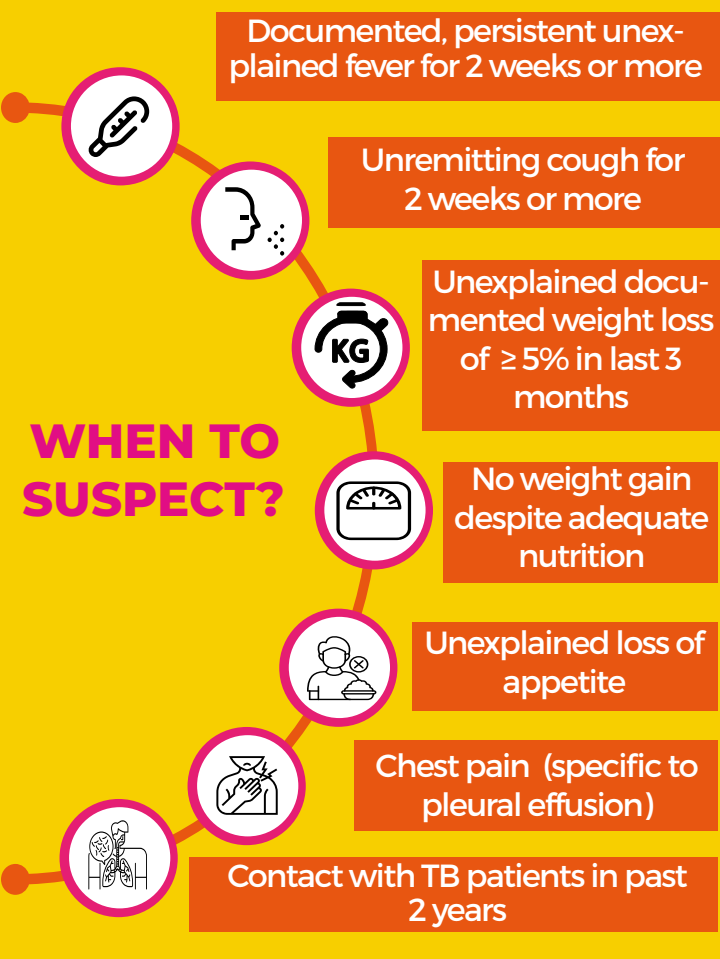
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# Standard Treatment Workflow (STW) for the Management of PAEDIATRIC INTRATHORACIC TUBERCULOSIS (PULMONARY, PLEURAL, MEDIASTINAL) ICD-10-A15



### EXAMINATION

- Temperature, Weight, Mid Arm Circumference (MAC), Lymphadenopathy, cold abscess, discharging sinus
- Chest examination findings depend upon underlying pathology like consolidation, pleural effusion etc.

### INVESTIGATIONS

#### Essential

- Chest x-ray
  - TB suggestive: Hilar/ paratracheal lymph nodes, fibrocavitary disease, Miliary pattern
  - Non Specific : effusion, consolidation, bronchopneumonia, other shadows etc.
- Sputum/Induced Sputum/Gastric Lavage/ Aspirate /pleural fluid for NAAT
- Smear examination (if NAAT unavailable)
- If facilities exist, send aliquot of sample for culture, if NAAT negative for MTB
- Pleural tap\*: Gross, Cytology, Biochemistry, NAAT, MGIT/LJ, ZN if NAAT not available
- \*\*If can't be done at primary level then refer

#### Desirable

- Chest x-ray of family members

#### Optional (to be done in institutions)

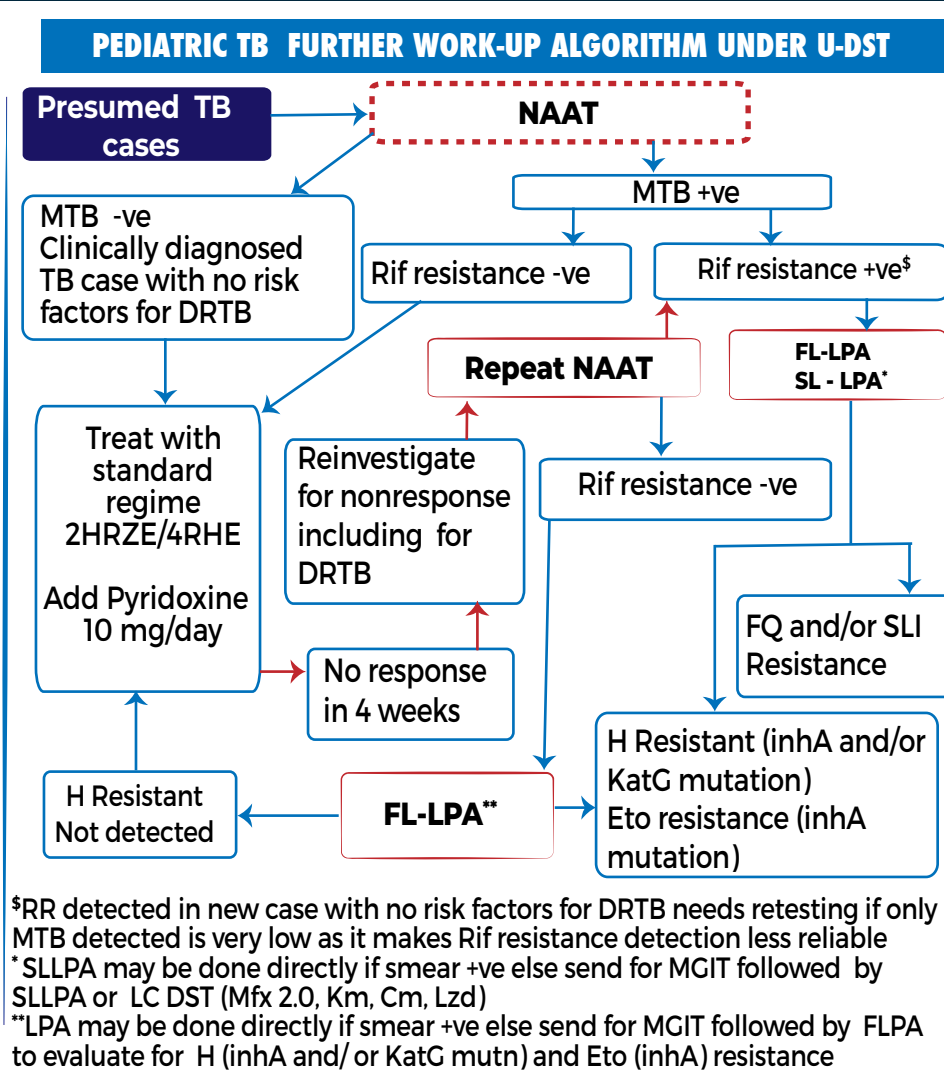
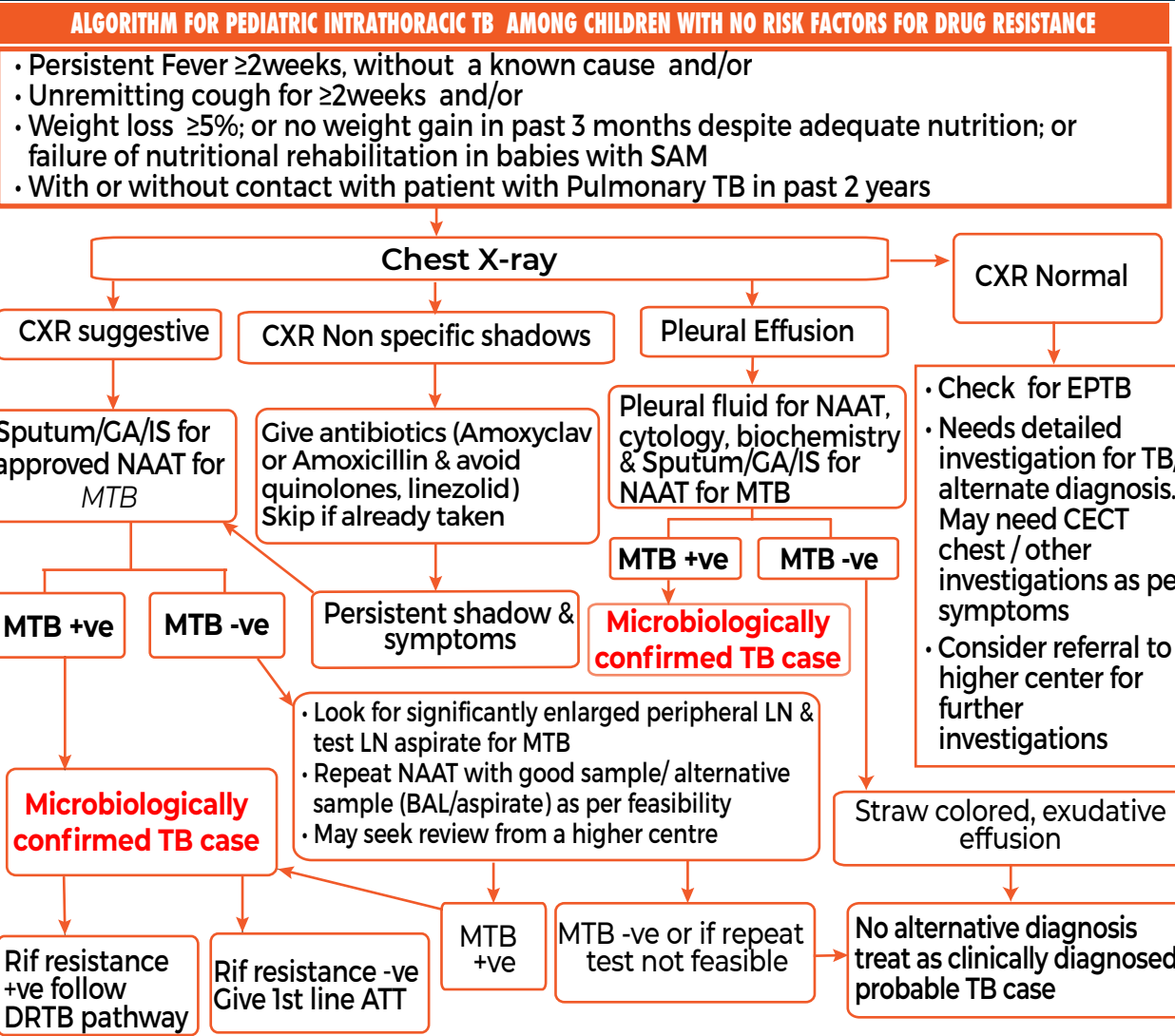
- CECT scan
- Pleural Biopsy (caseating granulomas with Langerhans giant cells, epithelioid cells & lymphocytes)
- Image guided (USG/CT) mediastinal LN biopsy
- Bronchoscopy & BAL

#### DO NOT DO

- TST/Mantoux test
  - Overemphasized, supportive only
  - Not to diagnose TB or to start ATT on basis of +ve TST ONLY
- Serological tests- IGRA (Quantiferon/Quantiferon-Gold etc)
- Pleural fluid ADA

**Do HIV testing for all cases with TB**

## DIAGNOSTIC ALGORITHM



| TYPE OF PATIENTS   | TB TREATMENT REGIMENS |
|--|-----------------------|
| Microbiologically confirmed RS Pulmonary TB  | 2HRZE + 4HRE          |
| Clinically diagnosed Pulmonary TB  |                       |
| Drug sensitive previously treated TB (recurrent, failure, treatment after default) |                       |

**\*DR TB algorithm-DST**

| DRUG             | Dose                                 |
|------------------|--------------------------------------|
| ISONIAZID (H)    | 7-15 mg/kg (maximum dose 300mg/day)  |
| RIFAMPICIN (R)   | 10-20 mg/kg (maximum dose 600mg/day) |
| PYRAZINAMIDE (Z) | 30-40 mg/kg (maximum 2000mg/day)     |
| ETHAMBUTOL (E)   | 15-25 mg/kg (maximum 1500mg/day)     |

| WEIGHT BAND | Number of tablets (dispersible FDCs) |   |                    |   |
|-------------|--------------------------------------|---|--------------------|---|
|             | Intensive phase                      |   | Continuation phase |   |
|             | HRZ                                  | E | HR                 | E |
| 4-7 kg      | 1                                    | 1 | 1                  | 1 |
| 8-11 kg     | 2                                    | 2 | 2                  | 2 |
| 12-15 kg    | 3                                    | 3 | 3                  | 3 |
| 16-24 kg    | 4                                    | 4 | 4                  | 4 |
| 25-29 kg    | 3 + 1A*                              | 3 | 3 + 1A*            | 3 |
| 30-39 kg    | 2 + 2A*                              | 2 | 2 + 2A*            | 2 |

\*A=Adult FDC (HRZE = 75/150/400/275; HRE = 75/150/275)

- Consider steroids in miliary TB with hypoxia, Endobronchial TB
- Prednisone dose 2 mg/kg daily or Dexamethasone 0.6 mg/kg/day for 4 weeks
- Reduce dose gradually over next 4 weeks before stopping
- Pyridoxine 10 mg/day for 6 months
- Nutritional support
- Treat co-morbid conditions: HIV, SAM

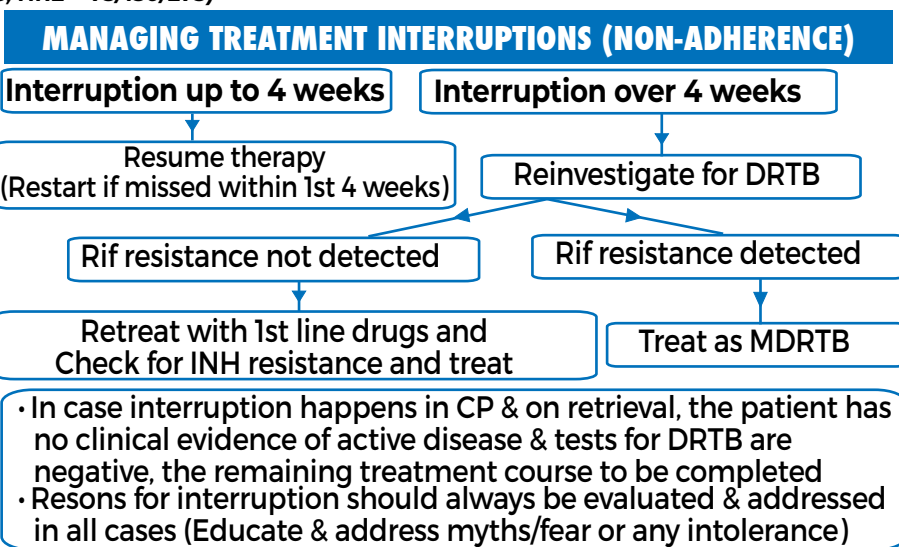
### MONITORING

**When to assess**

- 2 weeks: For adherence, correct dose, combination & tolerance to drugs
- Then every month till completion of treatment

**What to assess**

- Appropriateness of therapy:
  - Correct combination, acceptance/tolerance
  - Counsel about need to complete & not miss on doses (Inform, if doses are missed)
- Response to therapy:
  - Clinical (symptoms, adverse effects, weight, dose revision)
  - X-ray at end of therapy
  - Do X-ray for worsening at any time OR slow resolution OR persistent symptoms at end of IP
  - NAAT is not appropriate follow up tool for monitoring progress of disease
  - Smear examination at end of treatment (to declare outcome)
  - Repeat microbiological test (smear, MGIT, NAAT) at end of IP & at end of therapy, if still symptomatic or any deterioration/failure to respond
- After treatment completion, follow up patients clinically at end of 6, 12, 18 & 24 months



## ABBREVIATIONS

|   |                                       |   |                                       |  |
|---|---------------------------------------|---|---------------------------------------|--|
| ADA: Adenosine Deaminase                                | DRTB: Drug resistant TB               | FQ: Fluoroquinolones                                  | IS: Induced sputum                    | RIF: Rifampicin                        |
| BAL: Broncho-alveolar lavage                            | DST: Drug sensitivity test            | GA: Gastric aspirate                                  | LN: Lymph node                        | SAM: Severe acute malnutrition         |
| CBNAAT: Cartridge-based Nucleic Acid Amplification test | EPTB: Extra-pulmonary TB              | H: Isoniazid  | MAC: Mid Arm Circumference            | SLI: Second line injectables           |
| CECT: Contrast enhanced CT                              | ETO: Ethionamide                      | HIV: Human Immunodeficiency virus                     | MTB: Mycobacterium Tuberculosis       | SL-LPA: Second line - Line probe assay |
| CP: Continuation phase                                  | FDC: Fixed dose combination           | HRZE: Isoniazid; Rifampicin; Pyrazinamide; Ethambutol | NAAT: Nucleic acid amplification test | TST: Tuberculin skin test              |
| CT: Computed tomography                                 | FL-LPA: First line - Line probe assay | IGRA: Interferon Gamma Release assay                  | PPD: Purified Protein Derivative      | USG: Ultrasonography                   |
|   |                                       |   |                                       | ZN: Ziehl Neelson                      |

## REFERENCES

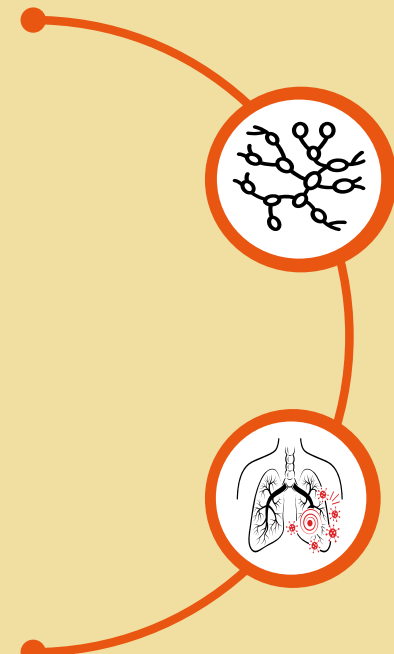
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- Guidelines for Programmatic Management of Drug Resistant Tuberculosis in India March 2021. National TB elimination programme, Central TB Division, Ministry of Health & Family Welfare, Government of India <https://tbcindia.gov.in/showfile.php?lid=3590> Last access on 06 March, 2022.

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# Standard Treatment Workflow (STW) for the Management of PAEDIATRIC LYMPH NODE TUBERCULOSIS

## ICD-10-A18.2



### WHEN TO SUSPECT?

- Persistent enlargement of lymph node for >2 weeks in one or more areas in cervical/axillary/inguinal regions
  - › Size > 2 cm or matted lymph nodes ± chronic sinus
- With/without associated systemic symptoms: fever, cough, poor appetite, weight loss
- With no evidence of recent scalp/skin lesions of draining area

**TB is unlikely if: the lymphnodes are few, small (< 2 cm) and are persistent for a long time (months to years) without any systemic symptoms**

### INVESTIGATIONS

#### Essential

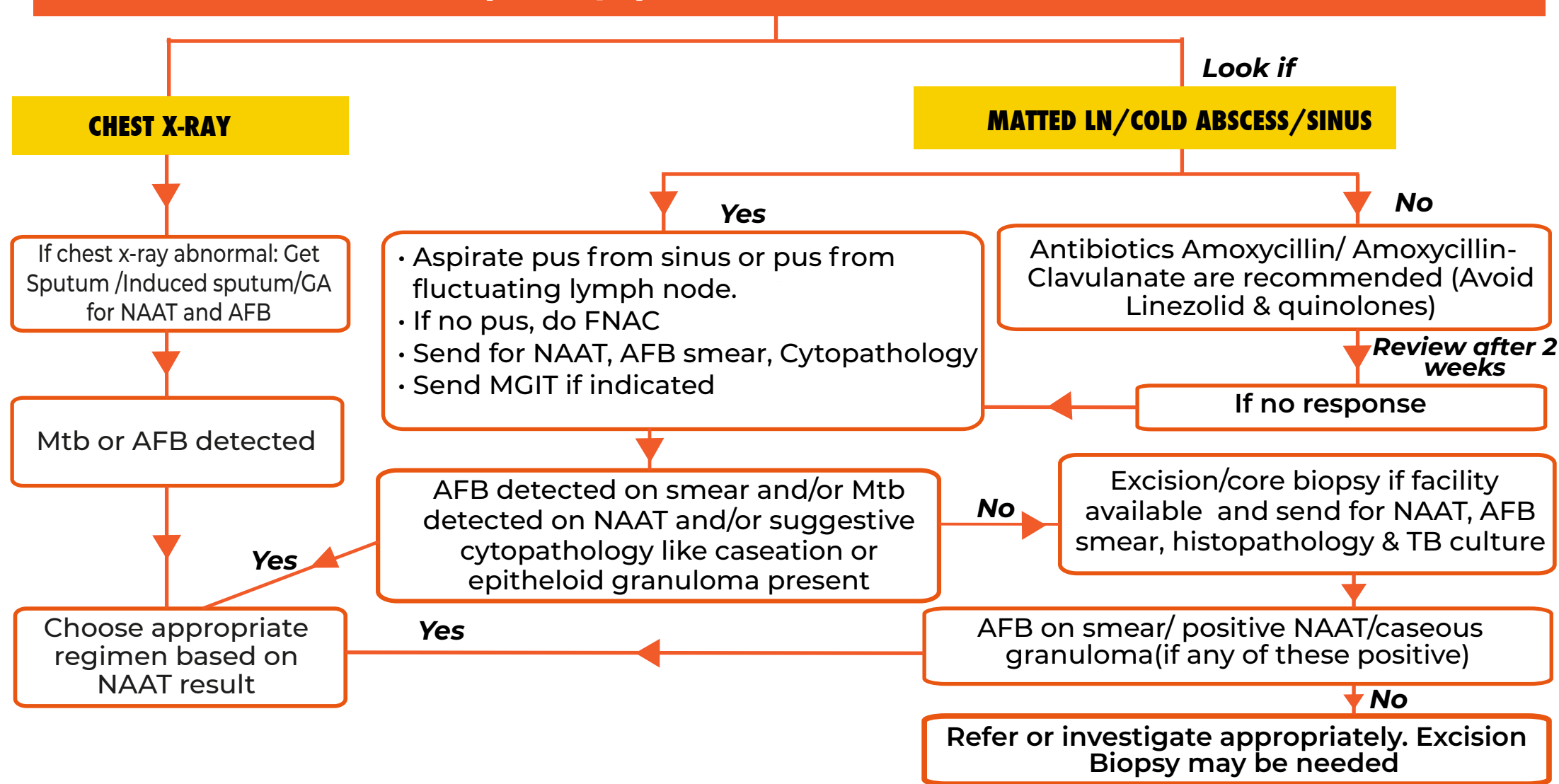
- **Lymphnode aspirate:**
  - › Send for NAAT (also MGIT culture, particularly if the patient is at risk of DRTB)
  - › Smear for AFB

#### Desirable

- Lymphnode cytopathology (If NAAT and smear negative)
- Lymphnode Biopsy (Core/Excision)
- Chest X-ray
- Hemogram with peripheral smear
- Cytopathology

## DIAGNOSTIC

### Peripheral Lymph node > 2cm in one or more sites



## TREATMENT AND MANAGEMENT

### TREATMENT AND RESPONSE

- Treatment should be started and follow-up should be conducted as per NTEP guidelines
- Treat with 2 HRZE + 4 HRE (standard doses) if new case & Rifampicin resistance not detected or not known
- If retreatment case or any other risk factor for DRTB, detailed & swift investigations for DRTB are advised before starting treatment
- Disappearance of constitutional symptoms with decrement or no increment in lymph node size suggests response to treatment
- Increment in lymph node size with disappearance of constitutional symptoms may suggest paradoxical reaction, provided drug resistance has been ruled out
- Increment in lymph node size without disappearance of constitutional symptoms suggests drug resistant TB/alternate cause



- Do not treat for TB based on only positive mantoux test or FNAC suggestive of reactive lymph node with negative NAAT/AFB on smear
- Children with disappearance of constitutional symptoms with no increase in lymphnode size at the end of 6 months therapy, can be kept on follow-up with no extension of therapy

### WHEN TO REFER TO AN EXPERT?

- Diagnosis is not established with FNAC/NAAT
- Surgical facility is not available to do excision or core biopsy
- DR is suspected due to any reason including non-response and the facility for DRTB testing are not available
- If there is any pointer towards possible malignancy e.g. skin or mucosal bleed or significant pallor or generalised adenopathy irrespective of the size or associated hepato-splenomegaly

### BCG LYMPHADENITIS

- Age is usually < 2 years
- Axillary and or supraclavicular lymphnode on the same side as BCG vaccination (usually given on the left)
- No systemic symptoms in immunocompetent children
- Treatment:
  - Wait and watch if small
  - If large and suppurative, repeated aspiration or rarely incision and drainage is required

\*NAAT or AFB smear positivity can not differentiate between BCG and MTB

## ABBREVIATIONS

AFB: Acid fast bacillus

BCG: Bacille Calmette Guerin vaccine

DR: Drug resistant

FNAC: Fine needle aspiration cytology

HRZE: Isoniazid; Rifampicin; Pyrazinamide; Ethambutol

MGIT: Mycobacteria Growth Indicator Tube

NAAT: Nucleic acid amplification test

NTEP: National TB Elimination Programmet

TB: Tuberculosis

## REFERENCES

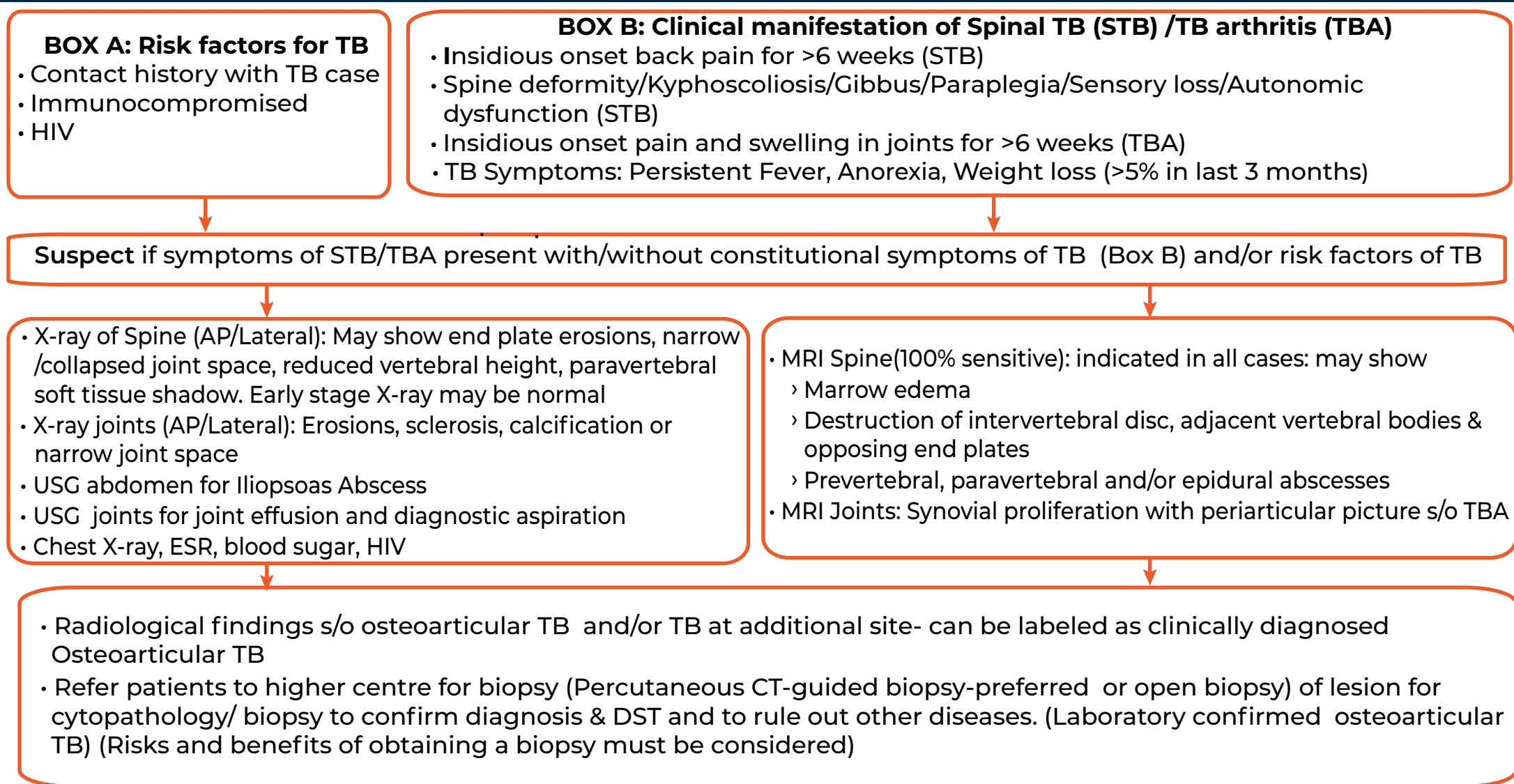
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# Standard Treatment Workflow (STW) for the Management of PAEDIATRIC OSTEOARTICULAR TUBERCULOSIS ICD-10-18.0

|                        | <b>POTT'S SPINE<br/>(COMMONEST, 50% OF OSTEOARTICULAR TB)</b>   | <b>DACTYLITIS<br/>(SHORT BONES)</b>   | <b>ARTHRITIS<br/>(LARGE JOINTS-HIP/KNEE COMMONEST)</b>  |
|------------------------|---|---|---|
| <b>WHEN TO SUSPECT</b> | <ul style="list-style-type: none"> <li>Insidious onset back pain for &gt;6 weeks (Commonest thoracic &gt; lumbar &gt; cervical)</li> <li>Localized/Referred root pain</li> <li>TB Symptoms: Fever/anorexia/weight loss</li> <li>CNS complications like Paraparesis (20-50%), cauda equina syndrome, paraspinal muscle wasting, severe pain</li> <li><b>Examination:</b> Local tenderness/deformity</li> </ul>   | <ul style="list-style-type: none"> <li>Swelling of short tubular bones of hands &amp; feet (Proximal phalanx or metacarpals of index/middle/ring fingers are commonly affected)</li> <li>In children multiple or consecutive bones are involved, compared to a single bone in adults</li> <li>May present without pyrexia or signs of inflammation</li> </ul>   | <ul style="list-style-type: none"> <li>Insidious onset joint pain, swelling</li> <li>Monoarticular arthritis</li> <li>Commonly associated with pulmonary or lymph node TB</li> </ul>  |
| <b>INVESTIGATION</b>   | <p><b>ESSENTIAL</b></p> <ul style="list-style-type: none"> <li><b>X-ray Spine</b> <ul style="list-style-type: none"> <li>In early stage X-ray may be normal</li> <li>May show end plate erosions, joint space narrowing/collapse, decreased vertebral height, paravertebral soft tissue shadow</li> </ul> </li> <li><b>MRI Spine preferred, if not feasible do CT</b> <ul style="list-style-type: none"> <li>Marrow edema</li> <li>Destruction of intervertebral disc, adjacent vertebral bodies &amp; opposing end plates</li> <li>Pre/para vertebral or epidural abscess</li> </ul> </li> <li><b>Sputum/GA for NAAT, MGIT/LJ (if CXR abnormal)</b></li> <li><b>FNAC</b> (if peripheral lymphnodes enlarged) for Cytology, NAAT &amp; MGIT/LJ</li> </ul> <p><b>DESIRABLE</b></p> <ul style="list-style-type: none"> <li>Image guided (USG/CT) aspiration of abscess (if feasible) for NAAT &amp; MGIT/LJ.</li> </ul> | <p><b>ESSENTIAL</b></p> <ul style="list-style-type: none"> <li><b>Plain X-ray of involved parts</b> <ul style="list-style-type: none"> <li>Diaphyseal expansile lesion</li> <li>Periosteal reaction is uncommon</li> <li>Healing is by sclerosis (usually gradual)</li> </ul> </li> <li><b>X-ray film of chest</b> <ul style="list-style-type: none"> <li>Sputum/GA for NAAT &amp; MGIT/LJ, if CXR abnormal</li> </ul> </li> <li><b>FNAC</b> (if peripheral lymphnodes enlarged) for Cytology, NAAT &amp; MGIT/LJ</li> </ul> <p><b>DESIRABLE</b></p> <ul style="list-style-type: none"> <li>Image guided (USG/CT) aspirate from involved bones for NAAT &amp; MGIT/LJ.</li> </ul> | <p><b>ESSENTIAL</b></p> <ul style="list-style-type: none"> <li><b>Plain X-ray:</b> A triad of X-ray abnormalities (Phemister's triad) includes                             <ul style="list-style-type: none"> <li>Peri-articular osteoporosis</li> <li>Peripherally located osseous erosion</li> <li>Gradual joint space narrowing</li> </ul> </li> <li>Early stage synovitis &amp; arthritis imaging may show wide joint space due to effusion</li> <li>Bony ankylosis development is rare in TB arthritis in contrast to Pyogenic arthritis</li> <li><b>USG/ MRI of joint</b></li> <li><b>X-ray film of chest</b></li> <li><b>Sputum/GA for NAAT, MGIT (if CXR abnormal)</b></li> <li><b>FNAC</b> (if peripheral lymphnodes enlarged) for Cytology, NAAT &amp; MGIT/LJ</li> </ul> <p><b>DESIRABLE</b></p> <ul style="list-style-type: none"> <li>Image guided (USG/CT) aspirate from joint fluid for NAAT &amp; MGIT/LJ.</li> </ul> |

## DIAGNOSTIC ALGORITHM



## MANAGEMENT

### TREATMENT & MONTORING

- Start treatment for microbiologically /Lab confirmed TB and probable TB
- Regimen : 2HRZE + 10HRE (Standard doses) + Pyridoxine 10 mg/day
- Follow up every month during treatment & subsequently every 3 months: Pott's spine with X-ray or MRI & Tubercular dactylitis or arthritis with plain X-ray
- Monitor on each visit :
  - Symptomatic improvement, weight gain, side effects of medicines
  - Microbiology : sputum/GA if CXR abnormal at end of IP. Site samples like aspiration of pus from lesions including psoas abscess (if worsening of symptoms/poor response)
- Imaging: MRI/CT/X ray of affected parts: at end of treatment or early if worsening

#### Surgical Indications in Potts Spine

- Progressive neurological deficit
- Paraplegia of recent onset or severe paraplegia
- Persistent pain with spinal instability
- Spinal deformity-severe kyphotic deformity at presentation, or in children (<10 years of age) at high risk of progression of kyphosis with growth after healing of disease

### WHEN TO REFER

- Suspected osteoarticular disease if essential investigations are not available
- Diagnosis (microbiological or probable) not established by investigations
- Surgery needed: imaging suggest compressive myelopathy, motor deficits
- No improvement with appropriate treatment
- DR TB : diagnosed or high suspicion

**Confirm microbiologically in all cases, if possible, before ATT**

### OTHER INFORMATION

- In case of synovial fluid or cold abscess aspiration (against gravity), send samples for confirmation of TB in following 3 ways
  - Two dry slide for demonstration of AFB (ZN staining)
  - Two samples in formalin for histopathological examination
  - Two samples in saline for culture followed by DST and/or NAAT
- Confirmed cases to undergo HIV/blood sugar testing/parent counselling \*MGIT/LJ (if MGIT not available)

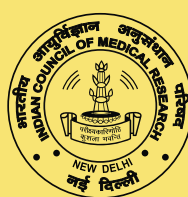
## ABBREVIATIONS

|                                |  |  |  |
|--------------------------------|--|--|--|
| <b>AFB:</b> Acid fast bacillus | <b>DST:</b> Drug Sensitivity Test            | <b>HRZE:</b> Isoniazid; Rifampicin; Pyrazinamide; Ethambutol | <b>NAAT:</b> Nucleic Acid Amplification Test |
| <b>AP:</b> Antero-Posterior    | <b>ESR:</b> Erythrocyte Sedimentation Rate   | <b>IP:</b> Intensive Phase                                   | <b>s/o:</b> Suggestive of                    |
| <b>CT:</b> Computed Tomography | <b>FNAC:</b> Fine Needle Aspiration Cytology | <b>LJ:</b> Lowenstein Jensen                                 | <b>STB:</b> Spinal TB                        |
| <b>CXR:</b> Chest X-ray        | <b>GA:</b> Gastric Aspirate                  | <b>MGIT:</b> Mycobacteria Growth Indicator Tube              | <b>TBA:</b> TB Arthritis                     |
| <b>DR:</b> Drug Resistant TB   | <b>HIV:</b> Human Immunodeficiency Virus     | <b>MRI:</b> Magnetic Resonance Imaging                       | <b>USG:</b> Ultrasonography                  |
|                                |  |  | <b>ZN:</b> Ziehl Neelson                     |

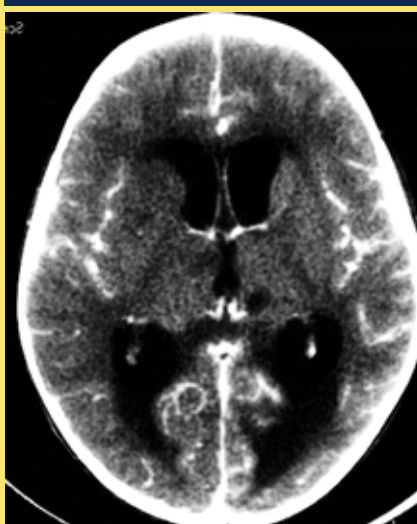
## REFERENCES

- National TB Elimination Programme, Central TB Division. Training Modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India. <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last access on 12 March, 2022.
- Guidelines for programmatic management of drug resistant tuberculosis in India March 2021. National TB Elimination Programme, Central TB Division, Ministry of Health & Family Welfare, Government of India accessed at <https://tbcindia.gov.in/showfile.php?lid=3590> Last access on 12 March, 2022.
- Sharma SK, Ryan H, Khaparde S, Sachdeva KS, Singh AD, Mohan A, et al., Index-TB guidelines: guidelines on extrapulmonary tuberculosis for India, Indian J Med Res. 2017;145(4):448-6

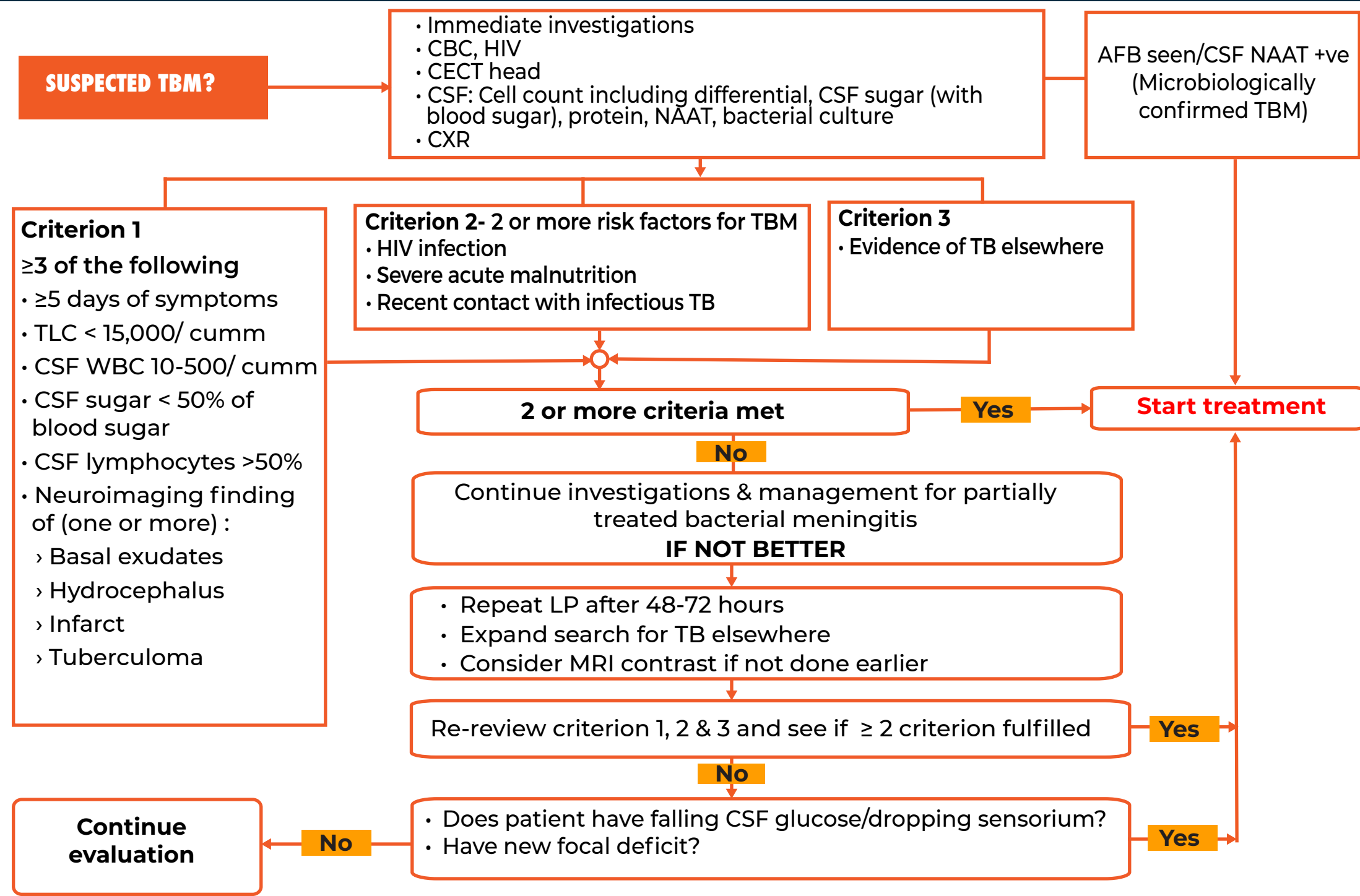




# Standard Treatment Workflow (STW) for the Management of PAEDIATRIC TUBERCULAR MENINGITIS ICD-10-A17.0

| WHEN TO SUSPECT?   | EXAMINATION   | INVESTIGATIONS  | NEUROIMAGING IN TB   |
|--|---|---|--|
| <ul style="list-style-type: none"> <li>Fever with one or more of the following                             <ul style="list-style-type: none"> <li>Headache</li> <li>Vomiting</li> <li>Seizures</li> <li>Irritability/Lethargy/Drowsiness</li> <li>Loss of function e.g. recent onset deviation of eyes/mouth and/or weakness of arm/leg and/or altered mentation</li> <li>Malaise, Anorexia, Weight loss</li> </ul> </li> <li>Symptoms are usually of 5 to 7 days duration with insidious onset, particularly with history of exposure to infectious TB in past 2 years</li> </ul> | <ul style="list-style-type: none"> <li>Assessment of sensorium*</li> <li>Full/bulging anterior fontanelle</li> <li>Meningeal irritation- Neck stiffness, Kernig's sign &amp; Brudzinski's sign</li> <li>Examine eye, if feasible for papilloedema/ choroid tubercles/ optic atrophy</li> <li>Cranial nerves</li> <li>Motor system including power, reflexes &amp; plantar responses</li> <li>Peripheral lymph nodes</li> <li>Chest examination for signs of pulmonary involvement</li> </ul> <p><i>*Use any standardized scale including Glasgow Coma scale/ AVPU scale</i></p> | <p><b>Essential</b></p> <ul style="list-style-type: none"> <li>CBC</li> <li>CSF examination                             <ul style="list-style-type: none"> <li>Cell count and differential</li> <li>Sugar (with simultaneous blood sugar)</li> <li>Protein</li> <li>NAAT*</li> <li>MGIT culture</li> <li>Bacterial culture</li> </ul> </li> <li>HIV</li> <li>Contrast enhanced CT scan of head</li> <li>CXR</li> <li>Gastric lavage/ Induced sputum in patients where CXR is abnormal and CSF NAAT is negative</li> </ul> <p><i>*ICMR/NTEP approved NAAT test, use 3-5 ml CSF if possible</i></p> <p><b>Desirable</b></p> <ul style="list-style-type: none"> <li>MRI brain with contrast when CECT head is not contributory</li> </ul> <p><b>Optional</b></p> <ul style="list-style-type: none"> <li>CSF cryptococcal antigen</li> <li>Contrast CT chest/abdomen to look for extracranial sites of infection</li> </ul> |  <p><b>CECT showing</b></p> <ul style="list-style-type: none"> <li>Hydrocephalus (ventricular dilatation)</li> <li>Thick basal exudates</li> <li>Tuberculoma</li> </ul> |

## DIAGNOSTIC ALGORITHM



## TREATMENT

- Treatment should be started & follow-up to be done as per NTEP guidelines
- Anti TB drug regimen**
  - 2 HRZE and 10 HRE (in appropriate doses)
  - Pyridoxine 10 mg/day
- Corticosteroids**
  - Prednisolone 2 mg/kg/day for 4 weeks & then taper over 4 weeks\*
  - Slower taper needed in some patients

*\*Equivalent dose of another steroid formulation may be used either injectable/oral*
- Other supportive therapy**
  - Care of unconscious child
  - Nasogastric feeding, if indicated
  - Anti edema measures (mannitol/hypertonic saline/glycerol/acetazolamide)
  - Anticonvulsants, if seizures
- Surgical therapy, if indicated**
  - External ventricular drain
  - VP shunt
- Cases should be managed at least at a district hospital**
- Early referral to Medical College/ higher centre to be considered if**
  - Unresponsive child/rapid deterioration indicating need for intensive care
  - No diagnosis after initial evaluation
  - Surgical treatment needed
  - MDR TB meningitis
  - No improvement/deterioration after 2-4 weeks of treatment
- Need for ICU care**

## ABBREVIATIONS

|   |   |  |                            |
|---|---|--|----------------------------|
| AFB: Acid-fast Bacillus                     | CXR: Chest X-ray                                      | MDR: Multi-drug Resistant                | TB: Tuberculosis           |
| CBC: Complete Blood Count                   | HIV: Human Immunodeficiency Virus                     | MGIT: Mycobacteria Growth Indicator Tube | TBM: Tubercular Meningitis |
| CECT: Contrast Enhanced Computed Tomography | HRZE: Isoniazid; Rifampicin; Pyrazinamide; Ethambutol | MRI: Magnetic Resonance Imaging          | TLC: Total Leucocyte Count |
| CSF: Cerebro-spinal Fluid                   | ICU: Intensive Care Unit                              | NAAT: Nucleic Acid Amplification Test    | VP: Ventriculo-peritoneal  |
| CT: Computed Tomography                     | LP: Lumbar Puncture                                   | NTEP: National TB Elimination Programme  | WBC: White Blood Cells     |

## REFERENCES

- National TB Elimination Programme, Central TB Division. Training Modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last access on 05 March, 2022.
- Guidelines for Programmatic Management of Drug Resistant Tuberculosis in India March 2021. National TB Elimination Programme, Central TB Division, Ministry of Health & Family Welfare, Government of India <https://tbcindia.gov.in/showfile.php?lid=3590> Last access on 05 March, 2022.



# **Adult Extrapulmonary Tuberculosis**



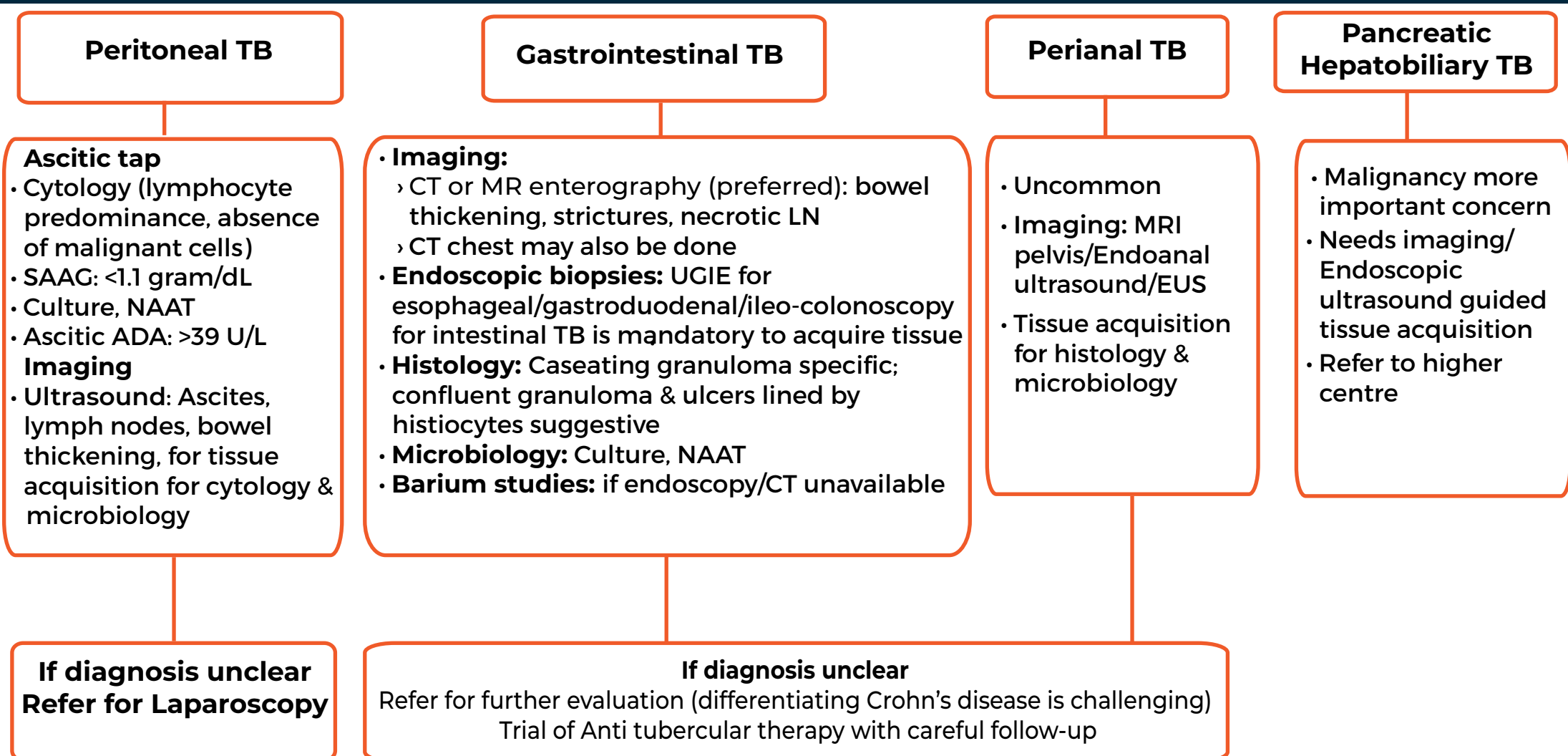
# Standard Treatment Workflow (STW) for the Management of ADULT ABDOMINAL TUBERCULOSIS ICD-10-A18.3

## WHEN TO SUSPECT

Any organ in abdominal cavity, including gut lumen & peritoneum may be affected

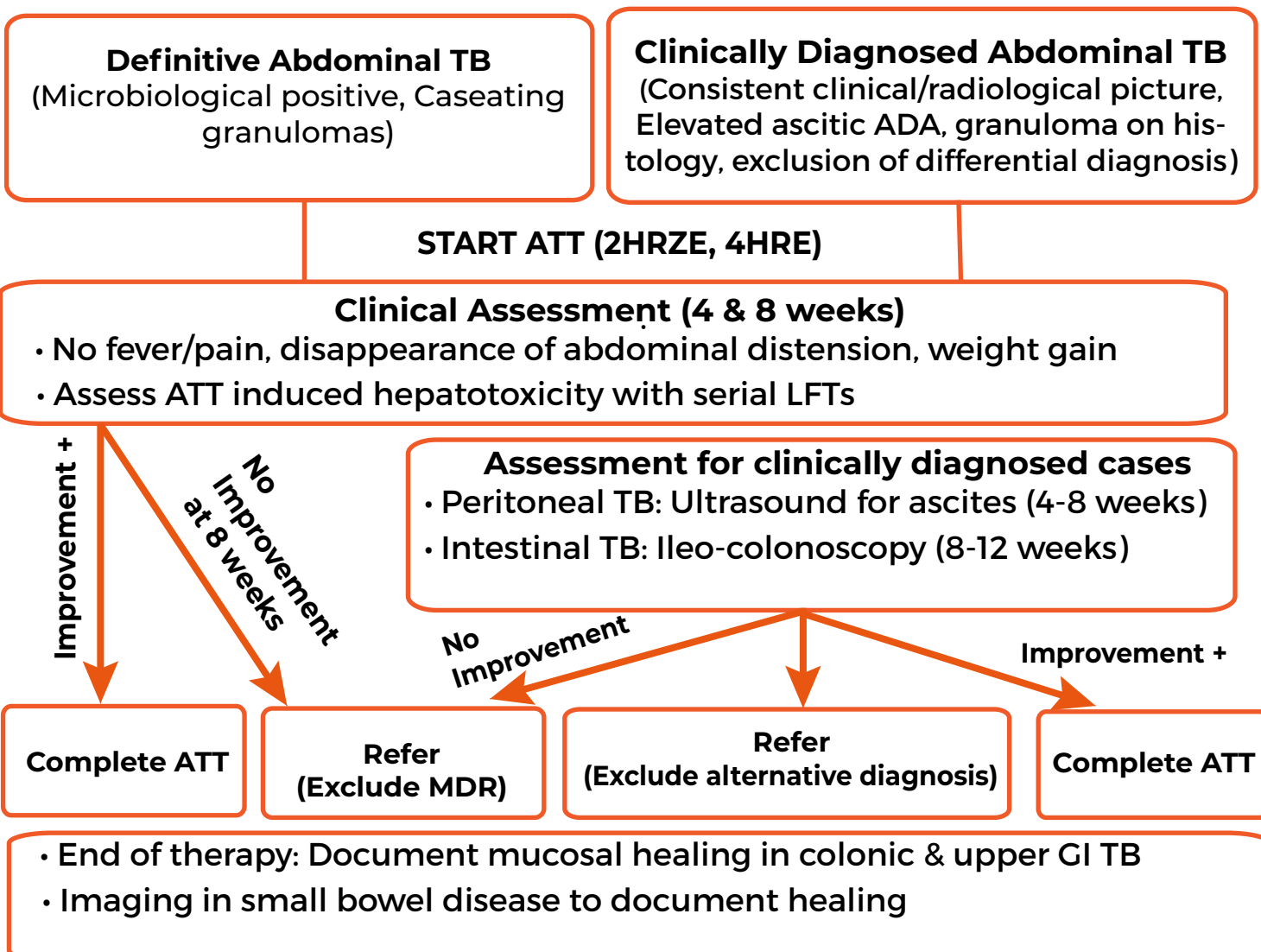
| PERITONEAL  | INTESTINAL   | ESOPHAGEAL   | GASTRO-DUODENAL  | PERIANAL   | PANCREATIC   | HEPATO-BILIARY  |
|---|--|--|--|--|--|---|
| <ul style="list-style-type: none"> <li>Abdominal distension</li> <li>Pain abdomen</li> <li>Fever</li> </ul> | <ul style="list-style-type: none"> <li>Recurrent intestinal colic</li> <li>Partial/ incomplete intestinal obstruction</li> <li>Chronic diarrhoea</li> <li>Weight loss</li> <li>Palpable mass abdomen</li> <li>Lower gastrointestinal bleeding</li> </ul> | <ul style="list-style-type: none"> <li>Dysphagia</li> <li>Odynophagia</li> <li>Hematemesis</li> <li>Constitutional symptoms</li> </ul> | <ul style="list-style-type: none"> <li>Gastric outlet obstruction</li> <li>Gastrointestinal bleed</li> </ul> | <ul style="list-style-type: none"> <li>Simple/ Complex peri-anal fistula</li> <li>Persistent discharge</li> <li>Fistulae which recur after multiple surgeries</li> </ul> | <ul style="list-style-type: none"> <li>Abdominal pain</li> <li>Obstructive jaundice</li> <li>Dilated pancreatic or bile duct with (peri)-pancreatic mass or cyst</li> <li>Constitutional symptoms</li> </ul> | <ul style="list-style-type: none"> <li>FUO</li> <li>Hepatomegaly</li> <li>Jaundice</li> <li>Elevated ALP</li> <li>SOL</li> <li>Hepatic abscess</li> </ul> |

## EVALUATION FOR SUSPECTED ABDOMINAL TUBERCULOSIS



**HIV & blood sugar test should be done in all suspected patients as per NTEP guidelines**

## FOLLOW UP



## TREATMENT:

- Start treatment & follow-up as per NTEP guidelines
- 1st line treatment for adults & children with abdominal TB: 2HRZE/4HRE
- Extend duration of treatment in cases of inadequate response
- Refer for surgical management for complications [intestinal obstruction (due to strictures), perforation]. Consider endoscopic dilatation for treatment for accessible strictures
- Refer for biliary drainage in case of Jaundice due to biliary obstruction (hepatobiliary obstruction/pancreatic TB)

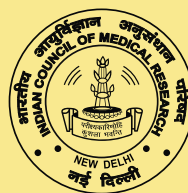
## ABBREVIATIONS

|                                |   |   |  |
|--------------------------------|---|---|--|
| ADA: Adenosine Deaminase       | FUO: Fever of Unknown Origin                          | MR: Magnetic Resonance                  | Rif: Rifampicin                        |
| ALP: Alkaline phosphatase      | GI: Gastro-intestinal                                 | Mtb: Mycobacterium Tuberculosis         | SOL: Space occupying Lesion            |
| ATT: Anti-Tubercular treatment | HRZE: Isoniazid; Rifampicin; Pyrazinamide; Ethambutol | NAAT: Nucleic Acid Amplification Test   | SAAG: Serum Ascites Albumin Gradient   |
| CT: Computed Tomography        | LFT: Liver function tests                             | NTEP: National TB Elimination Programme | UGIE: Upper gastrointestinal endoscopy |
| EUS: Endoscopic ultrasound     | MDR: Multi-drug resistance                            |   |  |

## REFERENCES

- National TB Elimination Programme, Central TB Division. Training Modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India. <https://tb-cindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last access on 08 March, 2022.
- Guidelines for programmatic management of drug resistant tuberculosis in India March 2021. National TB Elimination Programme, Central TB Division, Ministry of Health & Family Welfare, Government of India accessed at <https://tbcindia.gov.in/showfile.php?lid=3590> Last access on 08 March, 2022.





## Standard Treatment Workflow (STW) for the Management of ADULT LYMPH NODE TUBERCULOSIS ICD-10-A18.2

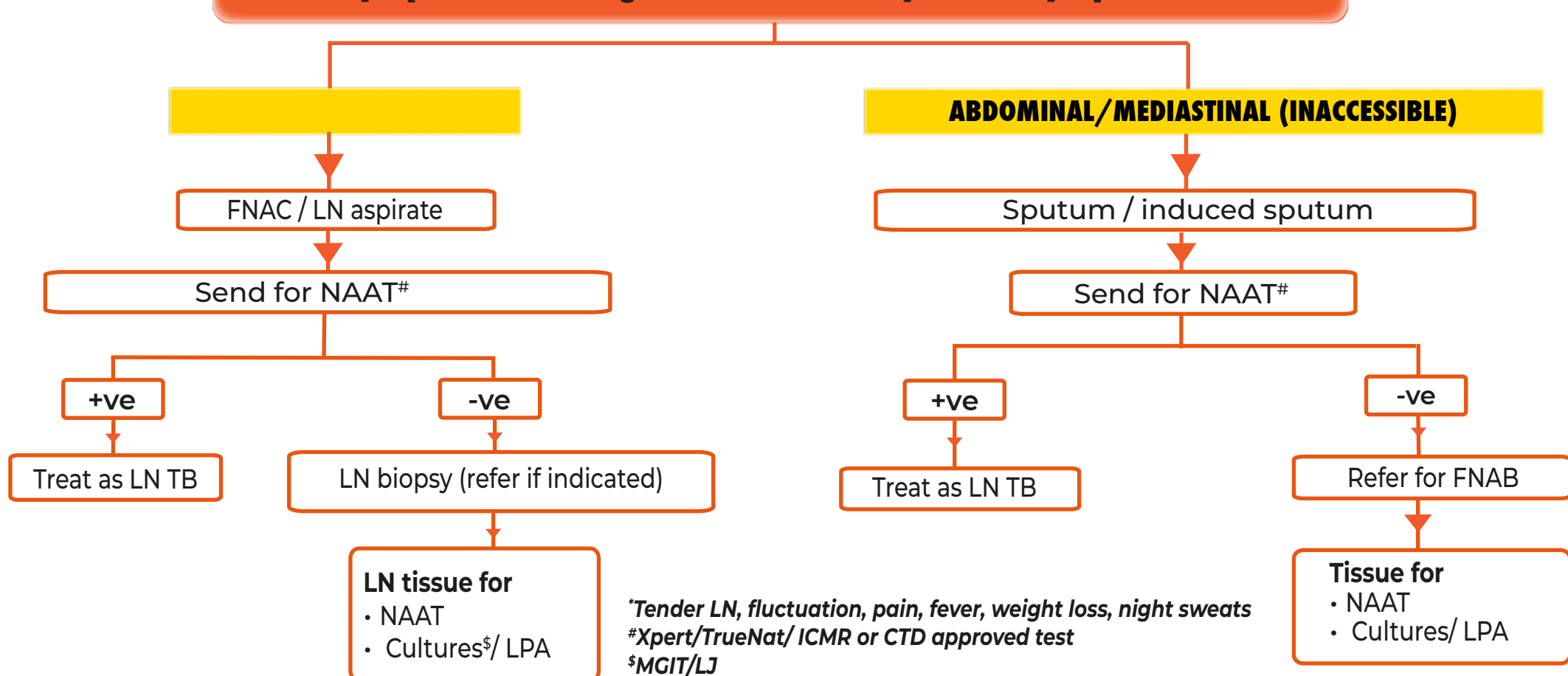
### WHEN TO SUSPECT?

#### WHEN TO SUSPECT?

- Swelling (>1 cm) in neck, armpit or groin (>2 cm) +/- redness, fluctuation, sinus discharge
- May or may not be associated with fever, weight loss, night sweats or cough
- History of similar swelling in the past / past history of tuberculosis
- History of contact with a patient with a diagnosis of TB

### DIAGNOSTIC ALGORITHM

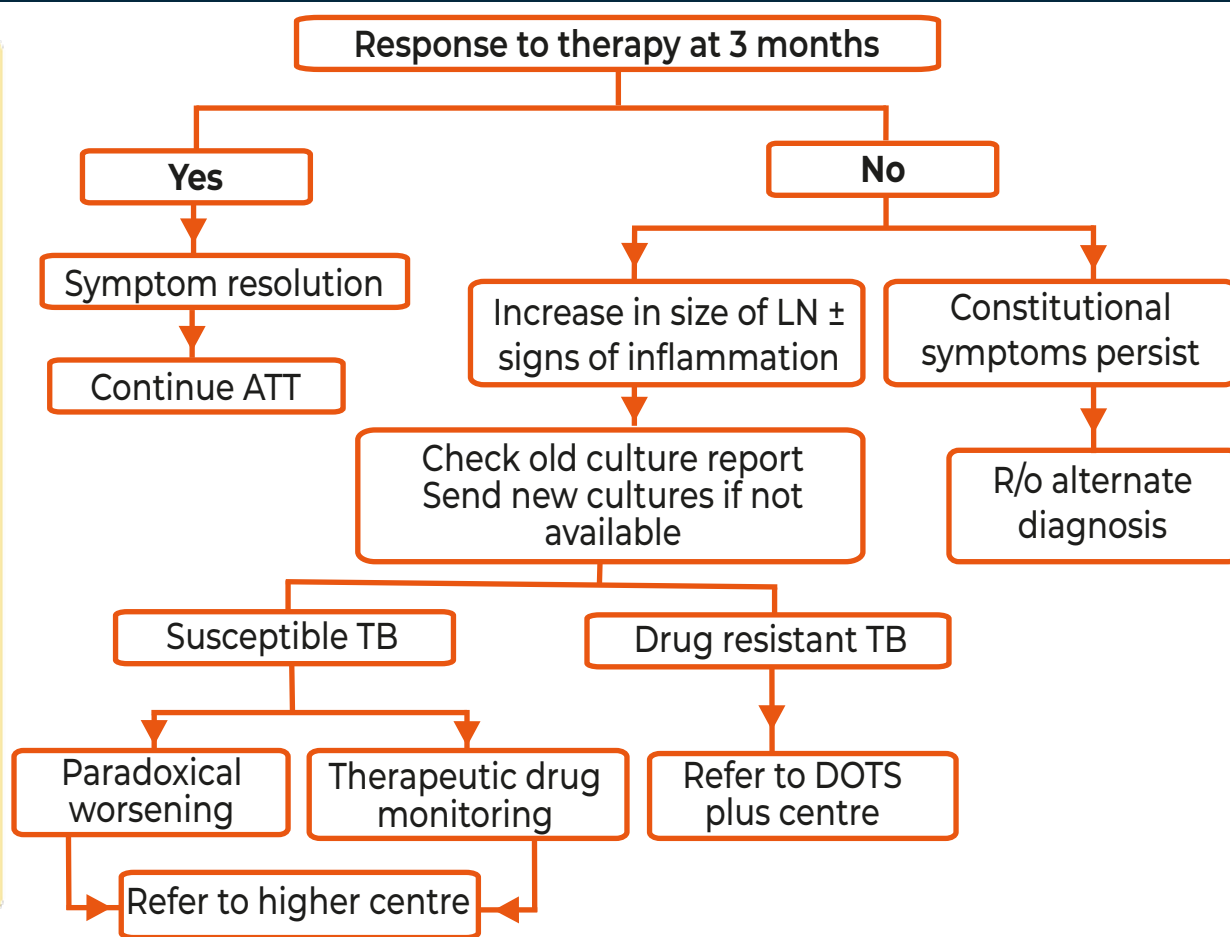
#### Lymphnode enlargement > 1cm ± systemic symptoms\*



#### Treatment : As per NTEP Guidelines

### ASSESS RESPONSE TO THERAPY AT 3-4 MONTHS

- Resolution:** Decrease in size of LN with settling of systemic symptoms
- Delayed response -Paradoxical reaction:** Increase in size of LN or new signs of inflammation (up to 3 months of starting treatment) OR appearance of new LN at same/other site
- May require tissue cultures, if not done, to rule out treatment failure/resistance
- Therapeutic drug monitoring to ensure adequate drug levels
- If cultures reveal susceptible TB it is likely due to paradoxical worsening: May require anti-inflammatory agents (inaccessible)/ surgical removal (accessible)



#### COMPLICATIONS

- Abscess formation
- Rupture may lead to sinus formation

#### REFER TO HIGHER CENTRE IF

- Non responders
- Needs treatment for Drug Resistance
- Large Nodal Mass/Abscess requiring surgical intervention

#### BCG LYMPHADENITIS

- Age is usually < 2 years
- Axillary and/or supraclavicular LN on same side as BCG vaccination (usually given on left)
- No systemic symptoms in immunocompetent children
- Treatment:**
  - Wait & watch if small
  - If large & suppurative, repeated aspiration or rarely incision & drainage is required

NAAT/AFB smear positivity can not differentiate between BCG & MTB

#### ABBREVIATION

|  |  |  |  |
|--|--|--|--|
| <b>ATT:</b> Anti Tubercular Treatment                | <b>FNAB:</b> Fine Needle Aspiration Biopsy   | <b>LPA:</b> Line Probe Assay                     | <b>NTEP:</b> National TB Elimination Programme |
| <b>BCG:</b> Bacille Calmette Guerin                  | <b>FNAC:</b> Fine Needle Aspiration Cytology | <b>MGIT:</b> Mycobacterial Growth Indicator Tube | <b>PCR:</b> Polymerase Chain Reaction          |
| <b>CTD:</b> Central TB Division                      | <b>LJ:</b> Lowenstein Jensen                 | <b>MTB:</b> Mycobacterium Tuberculosis           | <b>TB:</b> Tuberculosis                        |
| <b>DOT:</b> Directly Observed Treatment Short-course | <b>LN:</b> Lymph Node                        | <b>NAAT:</b> Nucleic Acid Amplification Test     |  |

#### REFERENCES

- National TB Elimination Programme, Central TB Division. Training Modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India. <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last accessed on 11 March, 2022.
- Guidelines for programmatic management of drug resistant tuberculosis in India March 2021. National TB Elimination Programme, Central TB Division, Ministry of Health & Family Welfare, Government of India. <https://tbcindia.gov.in/showfile.php?lid=3590> Last accessed on 11 March, 2022.
- Gaikwad P, Samuel VM, Rupali P. Tb or not Tb. Paradoxical response and the role of selective lymphadenectomy in tuberculous cervical lymphadenitis. Indian J of Applied Research, October 2016; Vol 6(10): 40-43.
- Alsultan A, Peloquin CA. Therapeutic drug monitoring in the treatment of tuberculosis: an update. Drugs, 2014 Jun; 74(8):839-54. Erratum in: Drugs. 2014 Jun; 74(9):2061.

This STW has been prepared by national experts of India with feasibility considerations for various levels of healthcare system in the country. These broad guidelines are advisory, and are based on expert opinions and available scientific evidence. There may be variations in the management of an individual patient based on his/her specific condition, as decided by the treating physician. There will be no indemnity for direct or indirect consequences. Kindly visit our web portal ([stw.icmr.org.in](http://stw.icmr.org.in)) for more information.

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# Standard Treatment Workflow (STW) for the Management of ADULT MUSCULOSKELETAL TUBERCULOSIS ICD-10-A18.0



## WHEN TO SUSPECT?

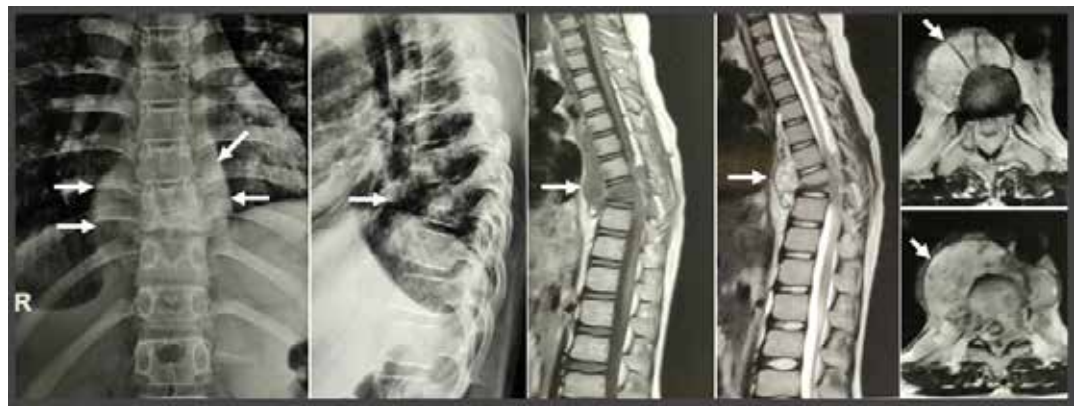
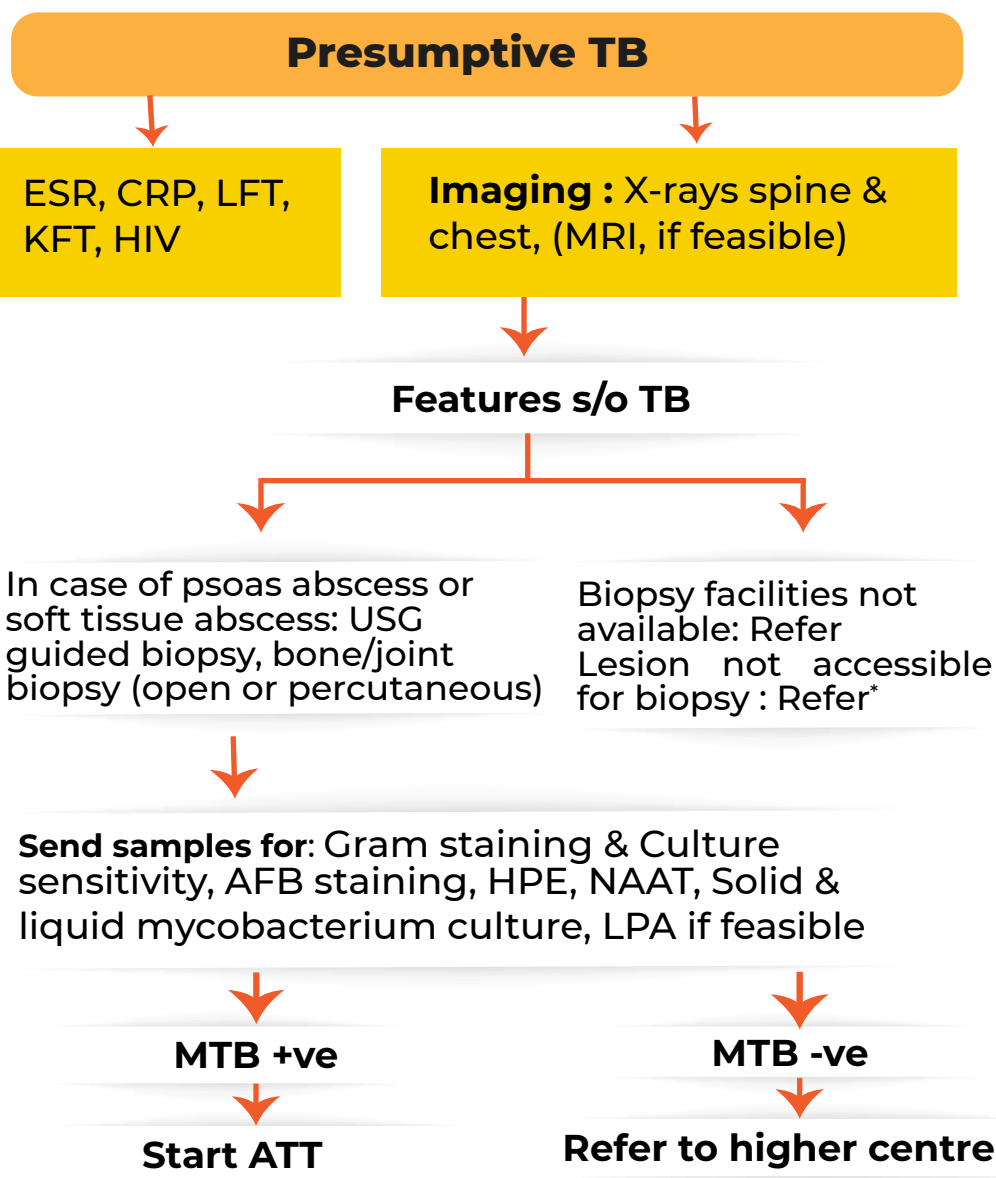
### SPINE TUBERCULOSIS

- Persistent localized pain in spine region >6 weeks, night pains
- Local tenderness/cold abscess
- Recent onset deformity in the back
- Recent neurological deficit (better to refer\*)
- Persistent heaviness around the waist/Girdle pain
- Fever, cough, weight loss & night pains
- History of close contact with TB

### OTHER JOINTS/BONES

- Persistent localized pain & swelling >6 weeks
- Mono-articular joint involvement
- Discharging sinus (+/-)
- Fluctuant swelling with or without inflammation
- Painful restriction of involved joint movements
- Wasting around the area
- Fever, cough, weight loss & night pains
- History of close contact with TB

## DIAGNOSTIC ALGORITHM



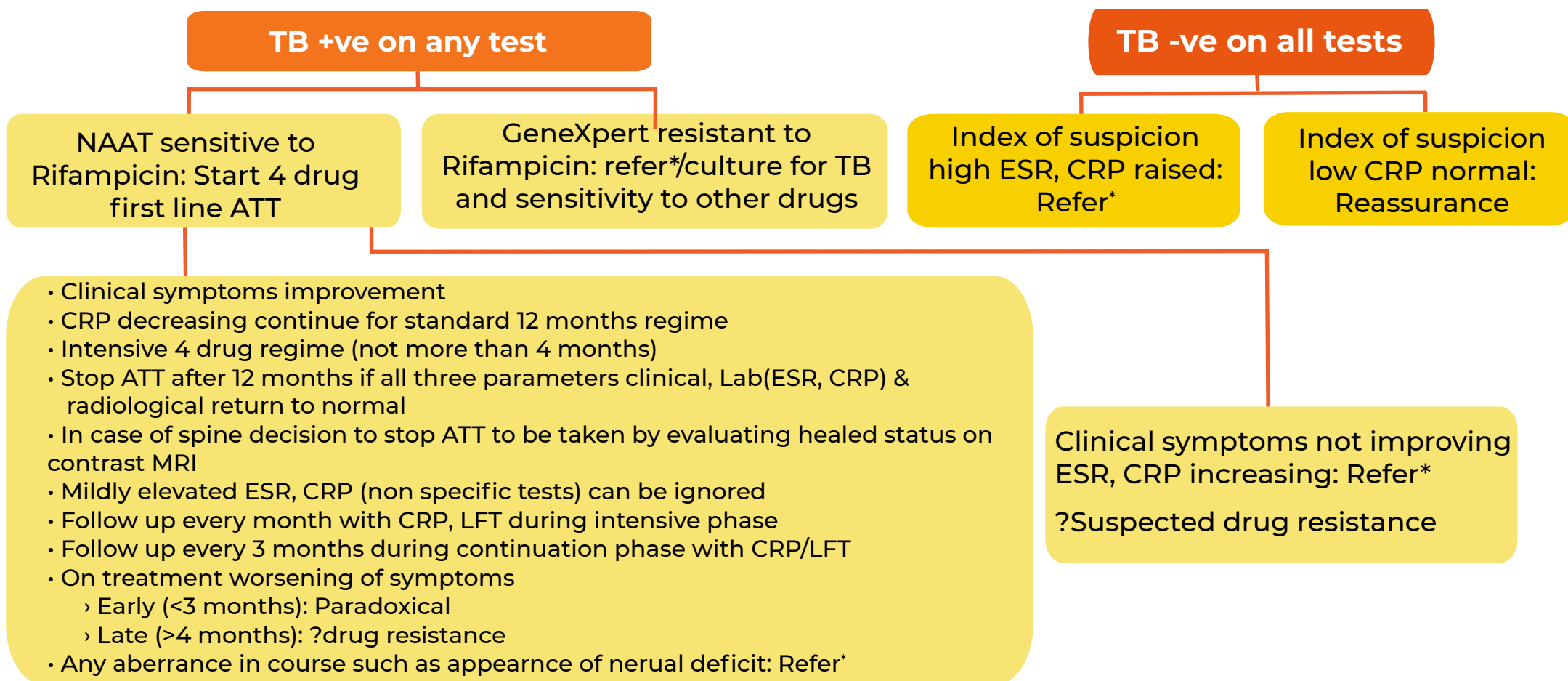
Paravertebral shadow    Obliterated disc space & bone loss in X-rays    T<sub>1</sub>WI and T<sub>2</sub>WI images bone edema with VB destruction    T<sub>2</sub>WI septate pre/para vertebral abscess in MRI

### Findings S/o TB

- **X-ray findings(spine):**
  - › Regional Osteopenia
  - › Decreased/obliterated disc space
  - › Vertebral erosions +/- reduced vertebral height
  - › Paravertebral shadow
- **MRI findings (Spine):**
  - › Contagious VB involvement with relatively preserved disc
  - › Pre & paravertebral septate collection (Abscess)
  - › Epidural encroachment +/- intraosseous abscess
- **X-ray & MRI Finding (extraspinal):**
  - › Regional osteoporosis with bone destruction on X-rays
  - › Inflammation of bone(T1WI & T2WI) +/- abscess on MRI

## TREATMENT

Treatment should be started & follow-up should be conducted as per NTEP guidelines  
The following algorithm provides additional guidance for follow-up



\*Refer to higher centre where advanced diagnostic, & therapeutic facilities including surgical procedures are available.

## ABBREVIATIONS

AFB: Acid-fast Bacillus  
ATT: Anti-Tubercular Treatment  
CRP: C-Reactive Protein  
ESR: Erythrocyte Sedimentation Rate

HIV: Human Immunodeficiency Virus  
HPE: Histopathological examination  
KFT: Kidney Function Tests  
LFT: Liver Function Tests  
LPA: Line Probe Assay

MRI: Magnetic Resonance Imaging  
NTEP: National TB Elimination Programme  
TB: Tuberculosis  
USG: Ultrasonography  
VB: Vertebral body  
WNL: Within Normal Limits

## REFERENCES

1. National TB Elimination Programme, Central TB Division. Training Modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last accessed on 10 March, 2022.
2. Guidelines for programmatic management of drug resistant tuberculosis in India March 2021. National TB Elimination Programme, Central TB Division, Ministry of Health & Family Welfare, Government of India <https://tbcindia.gov.in/showfile.php?lid=3590> Last accessed on 10 March, 2022.



# Standard Treatment Workflow (STW) for the Management of ADULT PERICARDIAL TUBERCULOSIS ICD-10-A18.84

## WHEN TO SUSPECT

### SYMPTOMS

- Cough, fever, breathlessness or pleuritic chest pain
- May be associated with weight loss, night sweats or difficulty lying down
- Past history or a history of contact with a patient with a diagnosis of tuberculosis
- Examination reveals tachycardia, increased jugular venous pressure, hepatomegaly, ascites, & peripheral edema
- A pericardial friction rub and distant heart sounds present on cardiovascular examination
- If clinical picture +/- heart US suggest pericarditis or pericardial effusion refer for echo-cardiogram

## COMPLICATIONS

**Constrictive pericarditis:** Clinical signs for recognition include

- Kussmaul's sign (lack of an inspiratory decline in jugular venous pressure)
- Elevated & distended jugular veins with a prominent Y descent (second inward deflection of internal jugular pulse due to diastolic inflow of blood into the right ventricle)
- Pericardial knock (rare)

**Cardiac tamponade:** Clinical signs include

- Sinus tachycardia
- Hypotension with a narrow pulse pressure
- Elevated JVP jugular venous pressure
- Muffled heart sounds
- Pulsus paradoxus (a decrease in systolic blood pressure by >10 mmHg on inspiration)
- Ascites

**Other complications:**

- **Myopericarditis:** Abnormal ejection fraction with evidence of myocarditis and pericarditis (elevated cardiac enzymes & ST elevation on ECG)
- **Effusive constrictive pericarditis:** Mixed clinical picture. Main clue is elevated JVP clinically & right atrial pressure on ECHO in spite of removal of pericardial fluid

### Essential tests:

- Chest X-ray
- ECG
- Echocardiogram

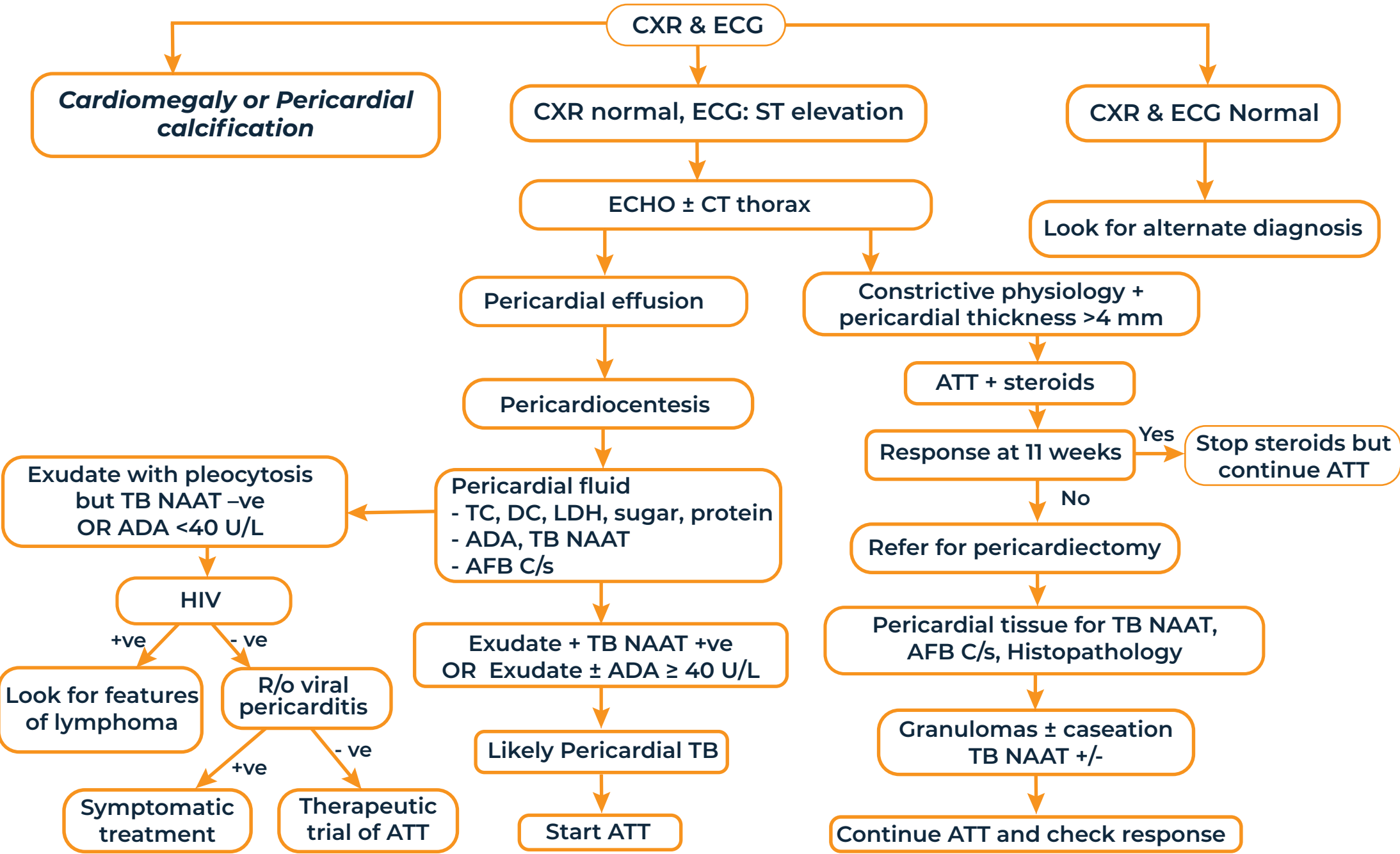
### INVESTIGATION

#### Desirable:

- Cardiac enzymes
- CT/MRI of Thorax
- Pericardiocentesis
- Pericardial biopsy

## DIAGNOSIS

### SUSPICION OF PERICARDIAL TUBERCULOSIS



## MANAGEMENT

### TREATMENT

- Antitubercular therapy is advised as per NTEP
- Steroids are recommended in large pericardial effusions, prominent pleocytosis & pericardial fluid with high inflammatory markers or early constriction
- Give Prednisolone 60 mg/day for 4 weeks, 30 mg/day for 4 weeks, 15 mg/day for 2 weeks & 5 mg/day for 1 week
- Total duration of systemic steroids is 11 weeks

### NON RESPONSE TO STEROIDS & ATT

- Should prompt a referral to a specialist center for confirmation of diagnosis
- Should prompt an evaluation for alternative causes of effusio-constrictive pericarditis: viral infections, systemic lupus erythematosus, primary effusion lymphomas or pericardial malignancies
- Non response of cardiac symptoms to anti-tuberculous therapy cardiac surgical evaluation may be required

## ABBREVIATION

ADA: Adenosine Deaminase  
ATT: Antituberculous Therapy

CXR: Chest X-ray  
ECG: Electrocardiogram  
ECHO: Echocardiogram

JVP: Jugular Venous Pressure  
NTEP: National Tuberculosis Elimination Programme  
TB: Tuberculosis

## REFERENCES

1. National TB Elimination Programme, Central TB Division. Training Modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India accessed at <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last access on 15 March, 2022.
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# Standard Treatment Workflow (STW) for the Management of ADULT PLEURAL TUBERCULOSIS ICD-10-A15.6

## WHEN TO SUSPECT?



**HISTORY**

- Fever
- Pleuritic chest pain
- Cough
- Breathlessness
- Anorexia
- Weight loss
- History of TB contact

**EXAMINATION**

- Dullness to percussion
- Decreased/absent breath sound

### INVESTIGATIONS

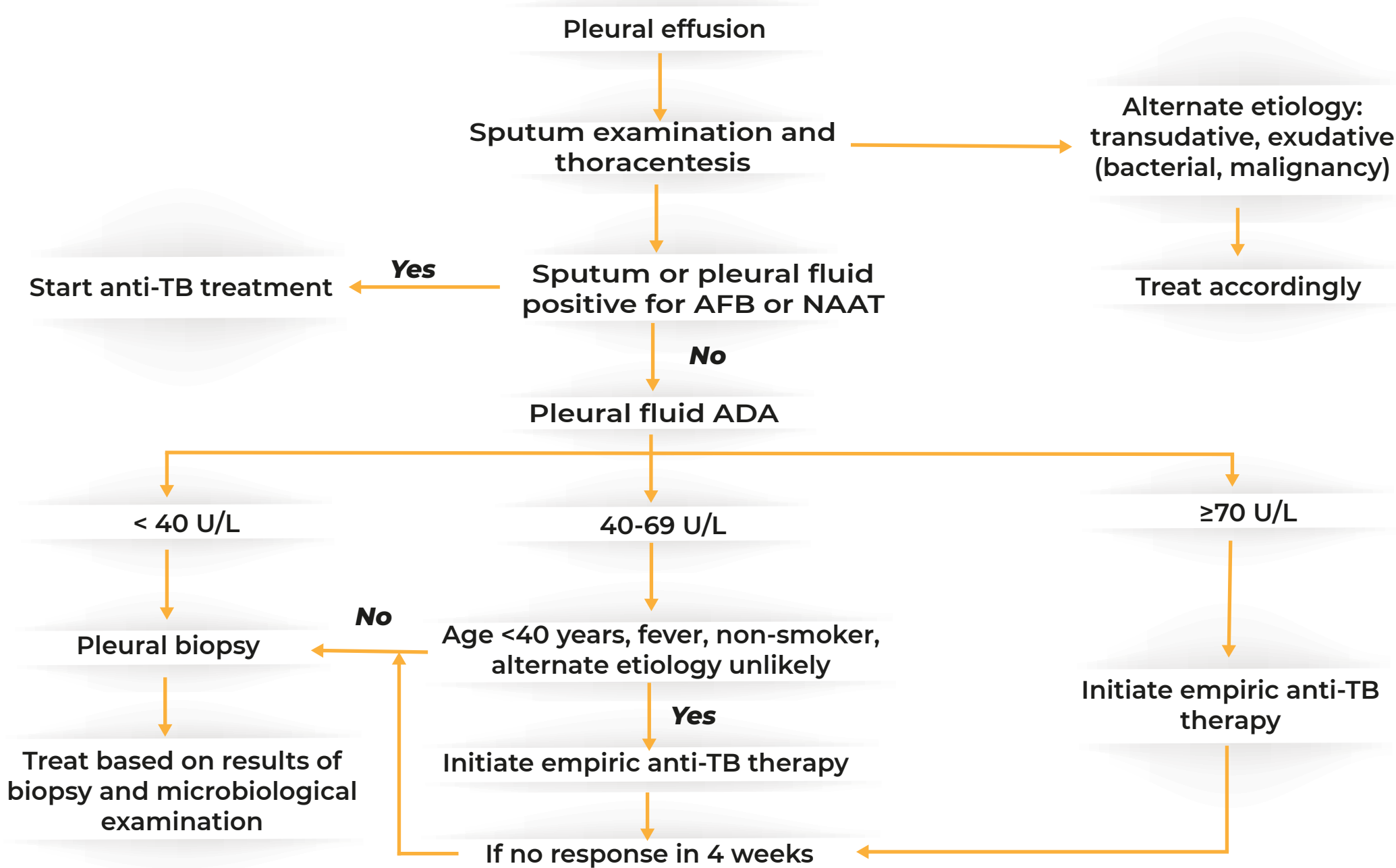
**ESSENTIAL**

- CXR (to confirm pleural effusion)
- Sputum for AFB/NAAT
- Refer immediately for pleural tap
- Thoracentesis (ultrasound-assisted)
- Pleural fluid analysis :
  - › Cell count (total and differential)
  - › Protein
  - › Glucose
  - › Gram stain
  - › Bacterial cultures
  - › Stain for acid-fast bacilli
  - › Adenosine deaminase (ADA)
  - › NAAT
  - › Cytology evaluation

**DESIRABLE**

- CT chest (before pleural biopsy)
- Pleural biopsy (image-guided/thoracoscopic) (If diagnosis is uncertain)
- Histopathology
- MGIT

## DIAGNOSTIC



## MANAGEMENT

### TREATMENT AND RESPONSE

- As per NTEP
- Therapeutic pleural tap can be done under ultrasound assistance if the effusion is large, and the patient is breathless

### WHEN TO REFER?

- Facility for ultrasound assistance is not available
- Diagnosis is not established after thoracentesis and facilities for pleural biopsy is not available
- Drug-resistant TB is detected: according to NTEP
- Worsening pleural effusion on follow up

### FOLLOW UP

- Most patients who respond to treatment will have improvement in their general condition by 2 weeks, and significant improvement in pleural effusion by 4-8 weeks
- Disappearance of constitutional symptoms with decrease in pleural effusion suggests responsiveness to treatment
- Increase in pleural effusion can suggest
  - › Paradoxical reaction or
  - › Drug-resistant TB or
  - › Alternative etiology
- A follow up CXR at 4-8 weeks after starting ATT is useful to assess progress

## ABBREVIATIONS

**ADA:** Adenosine Deaminase  
**AFB:** Acid-fast Bacilli  
**ATT:** Anti Tubercular Treatment

**CT:** Computed Tomography  
**CXR:** Chest Radiograph  
**MGIT:** Mycobacterial Growth Indicator Tube

**NAAT:** Nucleic Acid Amplification Test  
**NTEP:** National Tuberculosis Elimination Programme  
**TB:** Tuberculosis

## REFERENCES

1. National TB Elimination Programme, Central TB Division. Training modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last access on 11 March, 2022.
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# Standard Treatment Workflow (STW) for the Management of ADULT TUBERCULAR MENINGITIS

**ICD-10-17.0**

## SUSPECT TBM WITH FOLLOWING CLINICAL FEATURES

- Fever (Duration of 5 days or more<sup>#†</sup>)
- Headache & Vomiting
- Altered sensorium
- Cranial nerve palsy
- Hemiparesis/any limb weakness
- Seizures
- Neck pain and stiffness

## ALWAYS ENQUIRE FOR ASSOCIATED FEATURES

- Constitutional symptoms
- Active TB elsewhere
- Past history of TB & ATT
- Contact with TB patient
- HIV seropositivity
- Low socio-economic status
- High endemic area

<sup>#</sup>This is to increase sensitivity for diagnosis of TBM. The duration could be variable from days to weeks to months.  
<sup>†</sup>Clinical judgement & evaluation of other conditions is also required as fever can be associated with headache in other medical conditions. Delaying work up for meningitis is not recommended.

## IF TBM SUSPECTED

Refer to a centre where facility of evaluation (at least Lumbar puncture & CT scan) is available.

## EVALUATION AT CENTRE OF CARE

### CLINICAL HISTORY & EXAMINATION

- Symptoms type & duration, onset & progression
- Headache, altered sensorium, focal deficits
- Neck rigidity, Kernig's sign
- Cranial nerve palsy
- Fundus examination - papilledema

### LABORATORY EVALUATION

- CBC, ESR, CRP
- LFT, RFT, Electrolytes
- Blood sugar, HIV
- Chest X Ray- PA view
- USG whole abdomen
- Mantoux (optional)

### IMAGING

- NCCT/CECT head- Preferred as initial investigation
- MRI brain (and spine if indicated) in selective cases

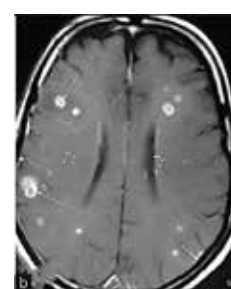
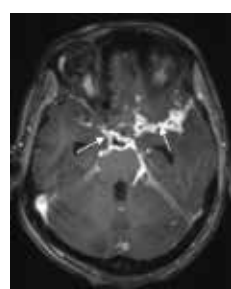
### CSF

- Mandatory- Should be sent for essential analysis (Box 1)
- Prudent to perform CT head prior to CSF in presence of papilledema & /or focal deficits

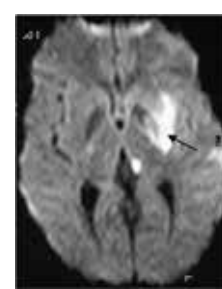
### COMMON NEUROIMAGING FINDINGS IN TBM



Basal exudates and Hydrocephalus



Tuberculomas



Infarction



Arachnoiditis



Pott's spine

### CSF EVALUATION\*

**01**

#### ESSENTIAL

- Cell count & type
- Protein
- Sugar (& Corresponding blood sugar)
- NAAT
- Grams stain
- Bacterial culture
- AFB stain
- AFB culture/sensitivity
- India Ink\*\*
- Cryptococcal antigen\*\*

\*CSF samples should be sent to the lab as soon as possible for examination of cells, protein, sugar and cytology.  
 \*\*Cryptococcal meningitis should be excluded wherever possible as it is a close differential diagnosis of TBM.

<sup>#</sup>In ideal settings, it may be prudent to exclude a diagnosis of carcinomatous meningitis.

<sup>†</sup>Especially in patients with HIV.

**02**

#### DESIRABLE

- Fungal smear & culture
- Cytopathology<sup>#</sup>

**03**

#### OPTIONAL

- Wet mount
- VDRL
- Toxoplasma PCR<sup>†</sup>
- Viral PCR

If some tests are not available at site, store sample in sterile container, keep in refrigerator & transport in icebox to other facility

### CSF FINDINGS IN TBM AND OTHER MENINGITIS

| MENINGITIS TYPE   | CELL COUNT   | PREDOMINANT CELL TYPE                           | PROTEIN                   | SUGAR    | SPECIFIC TESTS FOR CONFIRMATION                    |
|-------------------|--------------|---|---------------------------|----------|--|
| <b>Tubercular</b> | Usually <500 | Lymphocytic<br>Neutrophilic in some acute cases | High                      | Low      | AFB smear & culture<br>NAAT* <sup>‡</sup>          |
| <b>Pyogenic</b>   | In thousands | Neutrophilic                                    | Moderately High           | Very low | Gram stain, culture                                |
| <b>Fungal</b>     | Variable     | Lymphocytic                                     | High                      | Low      | India Ink, Fungal Culture,<br>Cryptococcal antigen |
| <b>Viral</b>      | 50-500       | Lymphocytic                                     | Normal to marginally high | Normal   | PCR for specific virus                             |

\*A negative NAAT result does not rule out TBM. The decision to give ATT should be based on clinical features and CSF profile.

<sup>‡</sup>NAAT: Xpert/TrueNat

### MANAGEMENT

#### ANTI-TUBERCULAR TREATMENT

- Intensive Phase: 2 months of RHZE or RHZS
- Continuation phase: 3 drugs: RHZ<sup>#</sup> for at least 10 months<sup>†</sup>

#### STEROIDS

- Preferably Dexamethasone 0.4 mg/kg/day intravenously in 3-4 divided doses during hospital stay
- If not feasible, give oral Dexamethasone 0.4 mg/kg/day in divided doses or oral Prednisolone 1 mg/kg/day in single morning dose
- Discharge on oral steroids on tapering doses for a total duration of 8-12 weeks

<sup>#</sup>treatment duration may be increased in some cases as per the clinician decision

<sup>†</sup>This is as per strong recommendations of concerned specialty experts in view of high toxicity of Ethambutol on TBM. These recommendations have been sent to NTEP

### FOLLOW UP

- Regular follow up is essential every month for at least first 3 months & can be increased thereafter till treatment is stopped
- Monitor liver function tests & any other features of drug toxicity
- Observe for clinical improvement or any deterioration
- Closely observe for development of any complications

### SUSPECT COMMON COMPLICATIONS

- Hydrocephalus and raised ICP:** Worsening of headache with vomitings and/or altered sensorium
- Optico-chiasmatic arachnoiditis:** Complaints of vision loss in one or both eyes with or without headache
- Myelitis and or arachnoiditis:** Development of paraparesis or quadriparesis with/without sensory disturbances, bladder involvement
- Epidural abscess/Pott's spine:** Complaints of back pain and/or weakness in one/ both lower limbs/ bladder/ bowel disturbances
- Tuberculoma:** Seizures, new onset focal focal deficits, worsening headache
- Seizures:** Consider tuberculoma/electrolyte or metabolic imbalance/ cerebral infarction
- Cerebral infarction and stroke:** Sudden onset weakness of one half of body, new onset confusion, altered mental status, seizures
- Hyponatremia, SIADH:** Persistent or worsening mental status

### ABBREVIATIONS

ATT: Antitubercular therapy  
 CBC: Complete Blood Count  
 CECT: Contrast Enhanced CT  
 CRP: C Reactive Protein  
 CSF: Cerebrospinal Fluid

E: Ethambutol  
 ESR: erythrocyte sedimentation rate  
 H: Isoniazid  
 ICP: Intracranial pressure  
 LFT: Liver function tests

MRI: Magnetic resonance imaging  
 NAAT: Nucleic Acid Amplification Test  
 NCCT: Non-contrast CT  
 NTEP: National TB Elimination Programme  
 PCR: Polymerase Chain Reaction

R: Rifampicin  
 RFT: Renal function tests  
 S: Streptomycin  
 SIADH: Syndrome of inappropriate antidiuretic hormone  
 TBM: Tubercular meningitis  
 Z: Pyrazinamide

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This STW has been prepared by national experts of India with feasibility considerations for various levels of healthcare system in the country. These broad guidelines are advisory, and are based on expert opinions and available scientific evidence. There may be variations in the management of an individual patient based on his/her specific condition, as decided by the treating physician. There will be no indemnity for direct or indirect consequences. Kindly visit our web portal ([stw.icmr.org.in](http://stw.icmr.org.in)) for more information.  
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# Standard Treatment Workflow (STW) for the Management of **CUTANEOUS TUBERCULOSIS** ICD-A18.4

## ETIOLOGY

- M.tuberculosis
- M.bovis
- NTM
- BCG (rarely)

### WHEN TO SUSPECT

- Presence of ulcer or discharging sinus over lymph node, bone & joints
- Persistent asymptomatic reddish/reddish brown lesion of >6 months duration which may show scarring
- Persistent warty or verrucous lesion of >6 months duration

### OTHER FEATURES

- Extracutaneous involvement
- Lymph node & lungs involvement
- Other organ systems involvement (bones, GIT & CNS)

### TYPES OF CLINICAL DISEASE

- Primary Inoculation tuberculosis
- Tuberculosis verrucosa cutis
- Lupus vulgaris
- Scrofuloderma
- Acute miliary tuberculosis
- Orificial tuberculosis
- Metastatic tuberculous
- Abscess (tuberculousgumma)
- Normal primary complex-like reaction
- Postvaccination
- Perforating regional adenitis
- Lichen scrofulosorum
- Papulonecrotictuberculid
- Facultative tuberculids
- Nodular vasculitis & Erythema nodosum



Lupus Vulgaris



Lupus Vulgaris



Scrofuloderma



Scrofuloderma



Verrucous TB



Verrucous TB

## INVESTIGATION

### INVESTIGATIONS

- **Histopathology:** Granulomas with epithelioid histiocytes & Langerhans - type giant cells
- **FNAC:** If indicated
- **IGRA/PCR:** Not recommended for diagnosis

### SCREENING FOR SYSTEMIC INVOLVEMENT

- **Examination:**
  - › Lymph node to be examined (FNAC)
  - › Other organ system can be done if indicated
- **Essential:**
  - › Chest X-ray
  - › FNAC from the indurated part of lesion
- **Desirable:**
  - › Histopathology
  - › Culture from biopsy sample (Not swab)

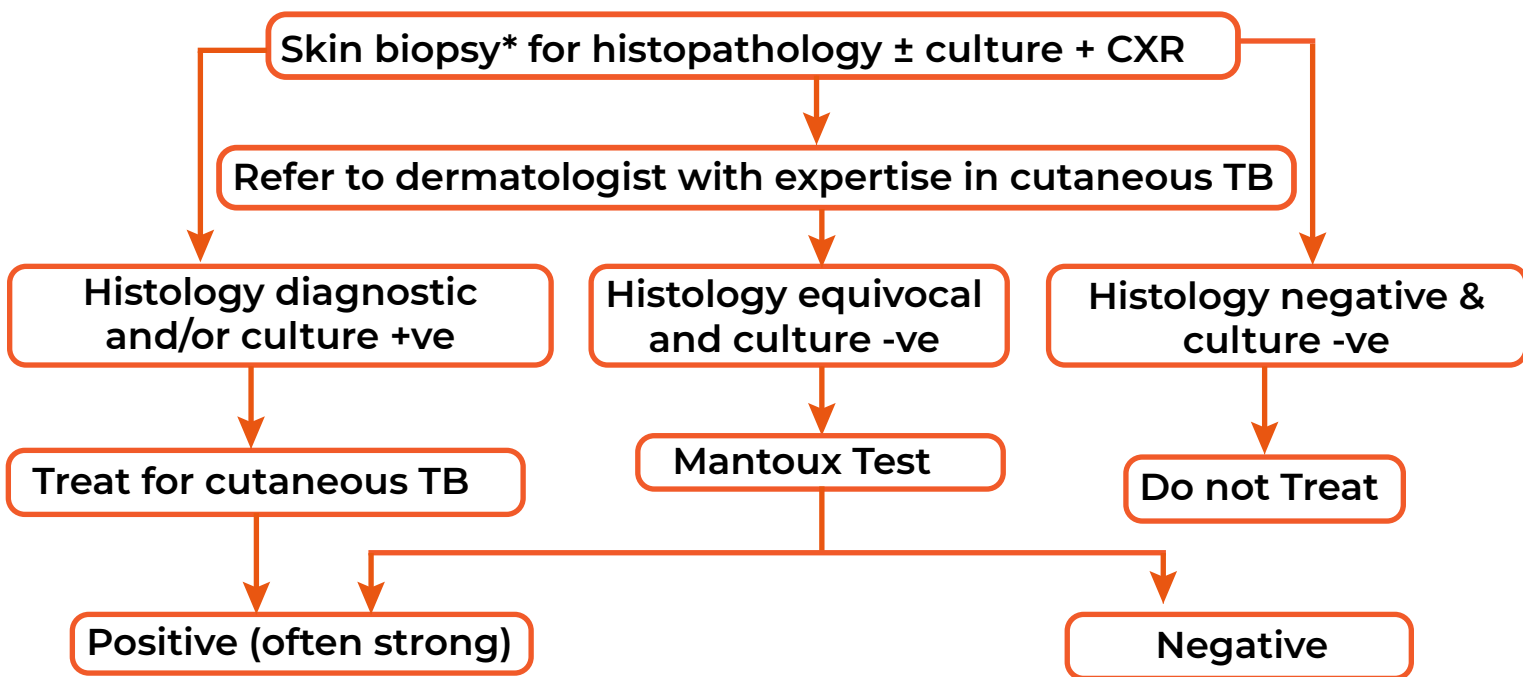
### CASE DEFINITION

- A) Confirmed case:**
  - › M.tuberculosis complex identified by either culture or NAAT or histology shows typical morphology
  - › Full course of ATT which led to complete clearance of lesions
- B) Probable case:**
  - › Typical skin lesion with no positive features/investigation as mentioned above (A)

## DIAGNOSTIC ALGORITHM

### Suspected TB case based on presence of clinical signs

- Ulcers/discharging sinuses over sites of LN, bones & joints
- Persistent, asymptomatic raised reddish/reddish brown lesion of >6 months' which may show scarring at one end
- Persistent, warty skin lesion of >6 months'



• **Strong clinical suspicion**  
› Start ATT

\*FNAC can be done if facilities for skin biopsy are not available

## MANAGEMENT

### TREATMENT

- Similar to Pulmonary TB as per NTEP
- DR -TB to be kept in mind
- No role of steroids, oral or topical, in management of CT

### FOLLOW UP

- 1st follow-up after 4-6 weeks; majority improves
- If no response after 8 weeks
- Alternate diagnosis/DR-TB; refer to higher centre

## ABBREVIATION

ATT: Anti-Tubercular treatment  
BCG: Bacille Calmette Guerin vaccine  
CNS: Central Nervous system  
CT: Cutaneous Tuberculosis  
CXR: Chest X-ray

DR-TB: Drug resistant Tuberculosis  
FNAC: Fine needle aspiration cytology  
GIT: Gastro-intestinal tract  
IGRA: Interferon Gamma Release assay  
LN: Lymph node

NAAT: Nucleic acid amplification test  
NTEP: National TB Elimination Programme  
NTM: Non-Tuberculous Mycobacterium  
PCR: Polymerase chain reaction test  
TB: Tuberculosis

## REFERENCES

1. National TB Elimination Programme, Central TB Division. Training Modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last access on 15 March, 2022.
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## Standard Treatment Workflow (STW) for the Management of **FEMALE GENITAL TUBERCULOSIS** ICD-10-A18.17

### WHEN TO SUSPECT?



#### SUSPECT

Consider following symptoms in history :

- H/O infertility (primary or secondary)
- Chronic lower abdominal or pelvic pain
- Amenorrhoea or other menstrual disturbances
- Abnormal vaginal discharge
- Constitutional symptoms of TB (low grade fever, weight loss etc.)
- Other symptoms related to extra-genital TB (abdominal, CNS, bone and lymph nodes etc.)

In addition, standard investigations for TB to be carried out

#### Clinical Examination

- General Physical Examination
- Pelvic Examination (cervical growth, uterine size and mobility, adnexal tenderness & mass)

#### Abdominal and Pelvic USG (TVS)

- Uterus, adnexa & pelvis to be evaluated preferably by transvaginal scan
- Endometrial cavity & vascularity to be looked carefully with colour Doppler

#### Specific Investigations

- Endometrial sampling or biopsy with Pipelle device or Karman cannula (4 mm) for microbiological & histopathological examination
- Endoscopy :
  - › Hysteroscopy & laparoscopy to evaluate uterus, adnexa & other pelvic organs along with lower abdomen
  - › Laparoscopic biopsy from peritoneum or abdominal/pelvic lesions
- MTB diagnosis from biopsy specimen (endometrium & other tissues) by
  - › Smear microscopy (AFB smear) & culture
  - › Gene Xpert or other NAAT
  - › HPE of biopsy specimen

### DIAGNOSIS

#### SUGGESTIVE FINDINGS IN FGTB

##### Imaging and Radiological

- HSG : to be avoided in acute phase  
Findings : blocked fallopian tubes, usually cornual; tobacco pouch appearance of the tubes; beaded tubes; filling defect in the uterine cavity (Asherman syndrome)
- USG : cogwheel appearance of tubes; uterine cavity may show thin diffuse endometrium with irregular borders
- CT/MRI : can be used for tubo-ovarian mass

##### Endoscopy

- **Hysteroscopy** : To look for tubercles, pale endometrium & endometrial adhesions
- **Laparoscopy** : Direct visualization of tubercle like lesions on the uterus, tubes and other pelvic organs including peritoneum, & caseous nodules

#### FEMALE GENITAL TB (STEPWISE DECISION)

- Clinical history
- General physical and pelvic examination
- Pelvic ultrasound
- HSP as indicated in infertility HSG

**Definite FGTB needing ATT if any of the following tests are positive**

- AFB microscopy positive
- AFB culture positive
- Gene Xpert or other NAAT +ve
- Histopathological demonstration of epithelioid granuloma

**Probable FGTB needing ATT if any of following positive**

- Clinical findings/suspicion of TB with tubo-ovarian masses on imaging studies
- Clinical findings/suspicion of TB with laparoscopic findings of beaded tubes, caseous nodules, tubercles, adhesions, hydrosalpinx & pyosalpinx etc.
- Clinical findings/suspicion of TB with hysteroscopic findings of tubercles, caseous nodules, pale endometrium, intrauterine adhesions etc.

**Negative FGTB : No ATT**

- No microbiological, histological, radiological, laparoscopic & hysteroscopic evidence of FGTB

**Menstrual blood should not be used for NAAT.**

### MANAGEMENT

#### TREATMENT

- Treatment of FGTB should be as per NTEP
- Patients requiring specific treatment such as infertility, Asherman syndrome & tubo-ovarian mass etc. should be referred to higher centres

#### FOLLOW UP

**Follow-up of the patient should be flexible depending on the clinical presentation and response to ATT**

- 1 month : Clinical Evaluation (General & Gynaecological)
- 3 months : Clinical Evaluation (General & Gynaecological)
- 6 months : Clinical Evaluation & Investigations (endometrial biopsy, hystero-laparoscopy & USG as needed)

### ABBREVIATION

**AFB:** Acid-Fast Bacilli

**FGTB:** Female Genital TB

**MRI** - Magnetic Resonance Imaging

**PCR:** Polymerase Chain Reaction

**ATT:** Anti-Tuberculosis Therapy

**FNAC:** Fine-needle Aspiration Cytology

**MTB:** Mycobacterium Tuberculosis

**TB:** Tuberculosis

**CNS:** Central Nervous System

**HSE:** Histopathology Examination

**NAAT:** Nucleic Acid Amplification Test

**TVS:** Transvaginal Scan

**CT:** Computed Tomography

**HSG:** Hysterosalpingography

**NTEP:** National Tuberculosis Elimination Programme

**USG:** Ultrasonography

### REFERENCES

1. National TB Elimination Programme, Central TB Division. Training Modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India. <https://tb-cindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last access on 08 March, 2022.
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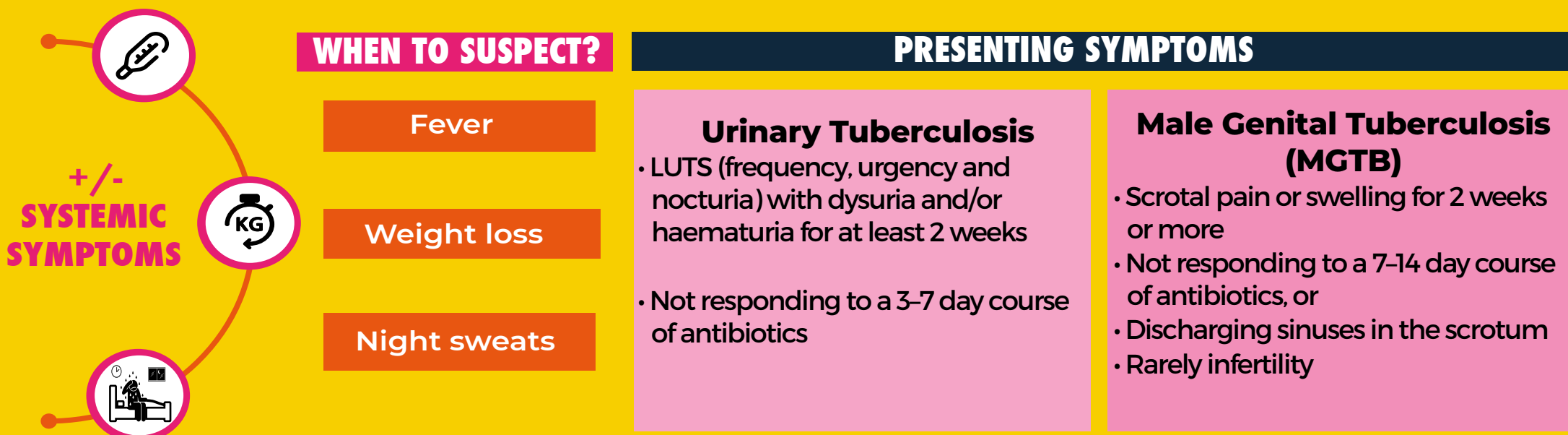
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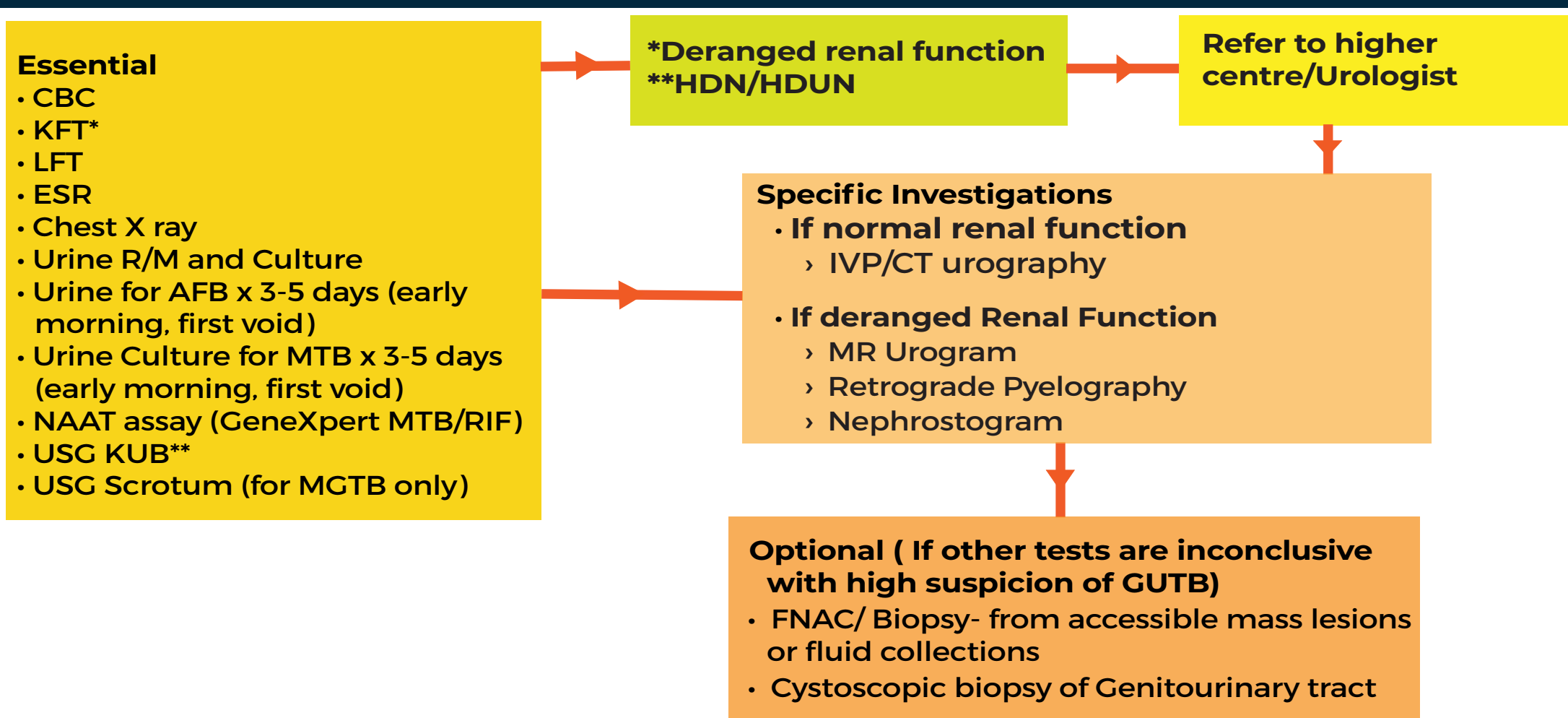




# Standard Treatment Workflow (STW) for the Management of GENITOURINARY TUBERCULOSIS ICD-A18.10



## INVESTIGATION



## TREATMENT

| TYPE OF TB          | TYPE OF REGIMEN                  | DRUGS                              | EXTENSION CRITERIA   |
|---------------------|----------------------------------|------------------------------------|--|
| DRUG SUSCEPTIBLE TB | DS-TB REGIMEN                    | 2 MONTHS H,R,E,Z<br>4 MONTHS H,R,E | Extension packets of infection, concurrent smear positive cavitory pulmonary disease, CNS involvement, Delay in positive cultures converting to negative<br>Duration can be increased up to 9 to 12 months |
| MDR/RR OR XDR-TB    | TREATMENT AS PER NTEP GUIDELINES |                                    |  |

## FOLLOW UP

- At 8 weeks :** Resolution of systemic symptoms, improved urinary symptoms, repeat culture if baseline culture positive
- After completion of ATT:** Repeat culture if baseline culture positive
- Repeat imaging:** If partial or impending ureteric stricture
- Watch for the following complications at each Follow-up visit:**
- Severe LUTS suggestive of small capacity bladder
  - Deteriorating renal function

## ABBREVIATIONS

**ATT:** Anti-tubercular treatment

**CT:** Computed Tomography

**CBC:** Complete Blood Count

**CXR:** Chest X- Ray

**DJS:** Double J Stent

**DS-TB:** Drug Susceptible Tuberculosis

**E:** Ethambutol

**ESR:** Erythrocyte Sedimentation Rate

**H:** Isoniazid

**HDN:** Hydronephrosis

**HDUN:** Hydroureteronephrosis

**IVP:** Intravenous Pyelogram

**LFT:** Liver Function Test

**LUTS:** Lower Urinary Tract Symptoms

**MDR:** Multi Drug Resistant

**MTB:** Mycobacterium Tuberculosis

**MR:** Magnetic Resonance

**NAAT:** Nucleic Acid Amplification Test

**NTEP:** National Tuberculosis Elimination Programme

**RFT:** Renal Function Test

**R:** Rifampicin

**RR:** Rifampicin Resistant

**USG KUB:** Ultrasonography Kidney, Ureter and Bladder

**URINE AFB:** Urine for Acid-fast Bacillus

**XDR:** Extensively Drug Resistant

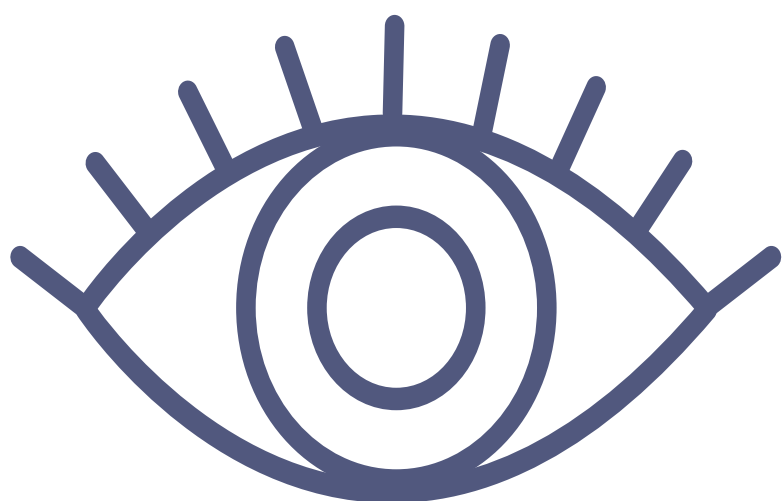
**Z:** Pyrazinamide

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- National TB Elimination Programme, Central TB Division. Training modules for Programme Managers & Medical Officers. Ministry of Health & Family Welfare, Government of India <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last access on 11 March, 2022.
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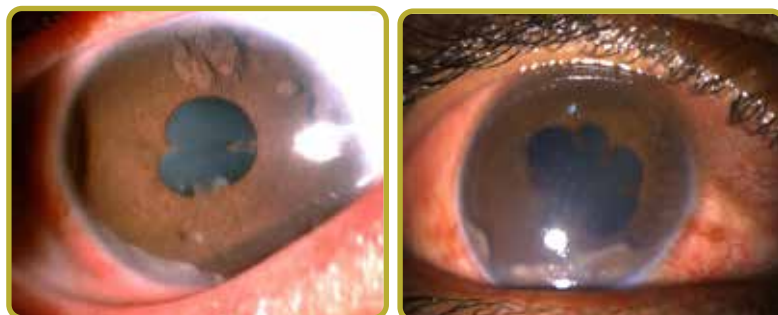


# Standard Treatment Workflow (STW) for the Management of INTRAOCULAR TUBERCULOSIS ICD-10-A18.3



| When to suspect   | Refer to Ophthalmologist for detailed examination   |
|---|---|
| <b>Ocular Symptoms</b> <ul style="list-style-type: none"> <li>• Blurred vision</li> <li>• Redness</li> <li>• Photophobia</li> <li>• Pain in the eye</li> <li>• Floaters</li> <li>• Flashes of lights</li> </ul> | <b>Eye Care facility should have:</b><br><b>Mandatory:</b> Slit lamp, ophthalmoscope (direct or indirect), intraocular pressure assessment device<br><b>Preferred:</b> Fundus camera, Fundus fluorescein angiogram(FFA), Optical Coherence Tomography (OCT) |

Granulomatous anterior uveitis



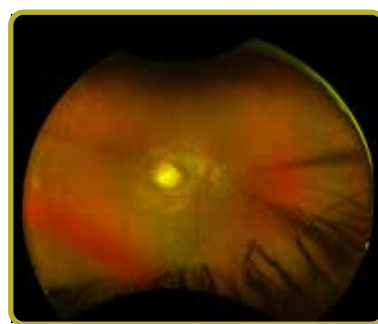
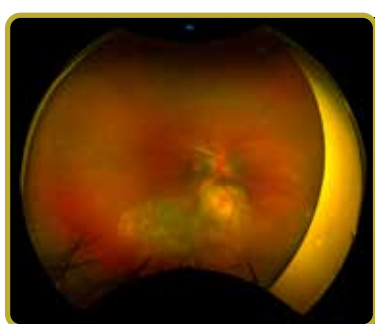
## Examination of the eyes

|   |
|---|
| <b>Clinical signs</b> <ul style="list-style-type: none"> <li>• Assess visual acuity</li> <li>• Anterior chamber cells, Keratic precipitates, Synechiae, Irregular pupil, RAPD</li> <li>• Complicated cataract, high or very low intraocular pressure</li> <li>• Vitritis, Pars plana exudates, Retinal vasculitis, Retinitis, Choroiditis, Optic nerve head swelling</li> </ul> |
|---|

Intermeditate uveitis



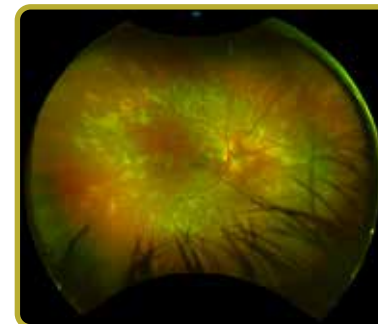
Panuveitis/Posterior uveitis



Retinal vasculitis



Choroiditis



## INVESTIGATIONS

|   |  |   |  |  |  |
|---|--|---|--|--|--|
| <b>Essential:</b><br><b>CXR for healed/active pulmonary TB</b>          | <b>Desirable:</b><br><b>Mantoux Test (standardised tuberculin units):</b> 10 mm induration considered positive | <b>Optional:</b><br><b>CT Chest (if available) for healed/active pulmonary TB</b> | <b>Imaging of eye:</b> Ascertaining diagnosis, extent of disease & follow up, teleconsultation |  |  |
| <b>Investigations to rule out other causes of clinical presentation</b> |  |   | <b>Retinal photographs using fundus camera</b>   | <b>Optical coherence tomography scans (if available)</b> | <b>Fluorescein angiograms (if available)</b> |

## MANAGEMENT

### TREATMENT

- **ATT** : 2 months of RHEZ + 7 months of RH depending on clinical response & side effects to treatment
- Add pyridoxine 10 mg/day
- **Corticosteroids** : Topical steroids eye drops for severe/anterior chamber inflammation
- For treatment in children refer to paediatrician
- Systemic corticosteroids for severe inflammation in consultation with Uveitis expert

### REFERRAL TO HIGHER CENTRE

- Not confident to treat
- Vision threatening
- Non-response to treatment
- Side effects due to treatment
- Atypical reaction

### MONITORING AND FOLLOW UP

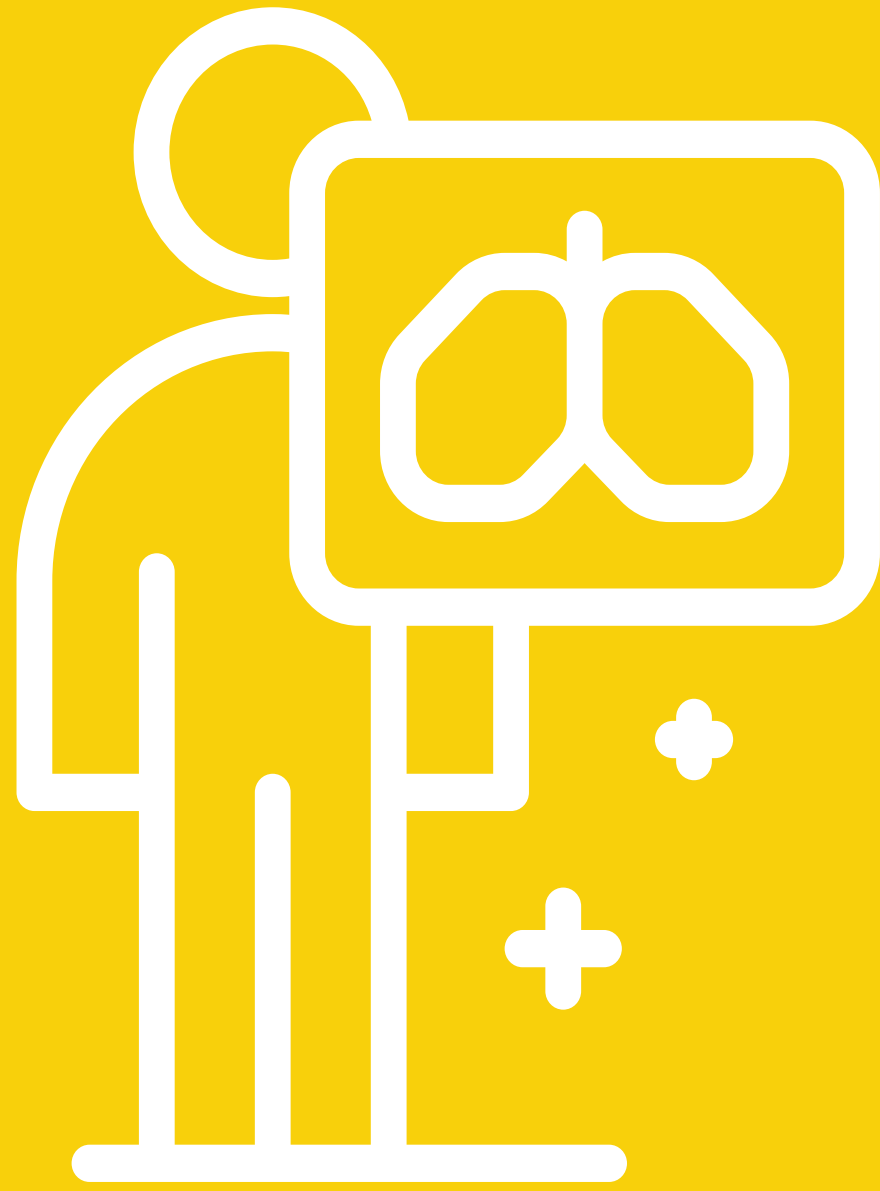
- **Frequency of follow up:** 1-2 weeks in 1st month followed by monthly for 3 months & then 3 monthly
- **Eye:** Clinical grading of inflammation using fundus photographs & OCT scans (if available)
- **Steroids:**
  - › **Topical:** Monitor IOP, cataract and any signs of bacterial/ fungal infection
  - › **Systemic steroids:** Monitor body weight, blood sugar & blood pressure

## ABBREVIATIONS

|                                      |   |  |
|--------------------------------------|---|--|
| <b>ATT:</b> Antitubercular treatment | <b>IOP:</b> Intraocular pressure                | <b>OCT:</b> Optical coherence tomography |
| <b>E:</b> Ethambutol                 | <b>R:</b> Rifampicin                            | <b>Z:</b> Pyrazinamide                   |
| <b>H:</b> Isoniazid                  | <b>RAPD:</b> Relative Afferent Pupillary Defect |  |

## REFERENCES

1. Agrawal R, et al.; Collaborative Ocular Tuberculosis Study Consensus Group. Collaborative Ocular Tuberculosis Study Consensus Guidelines on the Management of Tubercular Uveitis-Report 1: Guidelines for Initiating Antitubercular Therapy in Tubercular Choroiditis. *Ophthalmology*. 2021 Feb;128(2):266-276. doi: 10.1016/j.ophtha.2020.01.008. Epub 2020 Jan 11. PMID: 32115264.
2. Agrawal R, et al.; Collaborative Ocular Tuberculosis Study Consensus Group. Collaborative Ocular Tuberculosis Study Consensus Guidelines on the Management of Tubercular Uveitis-Report 2: Guidelines for Initiating Antitubercular Therapy in Anterior Uveitis, Intermediate Uveitis, Panuveitis, and Retinal Vasculitis. *Ophthalmology*. 2021 Feb;128(2):277-287. doi: 10.1016/j.ophtha.2020.06.052. Epub 2020 Jun 27. PMID: 32603726.



# **Investigations & Treatment**





## Standard Treatment Workflow (STW) of MICROBIOLOGICAL WORK-UP FOR ADULT EXTRAPULMONARY TUBERCULOSIS

### LOGISTICS INVOLVED IN SAMPLE COLLECTION AND TRANSPORTATION

- Collect Samples for Microbiological work-up in sterile containers before treatment is started. (Mention date & time of collection)
- Specimens to be sent in sterile saline (NOT in formalin)
- Establish linkages between peripheral centres, District centres and Tertiary centre/medical colleges/ IRL. Specify details of person to be contacted, department and contact number during referrals
- Transportation at 2-8 °C
- Maximum time for transportation in cold chain should be 5 days from time of collection
- Quantity of sample mentioned is only for microbiological work-up. Tests like histopathology, cytology, ADA, glucose, protein, etc will require additional sample
- Microbiological tests for TB (smear, molecular tests, culture) will be performed as per availability and preparedness of site
- PHC and CHC should perform smear microscopy and molecular diagnostic tests. If sample less than 500 µl, refer directly to Tertiary centre/medical colleges/IRL for culture. Residual sample in the needle and syringe used to collect the specimen can be used for smear
- MGIT to be used for culture. However, if MGIT is not available, LJ medium should be used

### REJECTION OF SAMPLES

- Unlabelled samples (All specimens MUST be labelled & have a unique patient identifier)
- Have no collection date indicated
- Insufficient quantity - No specimen in container
- Damaged - Specimen leaked or broken in transit
- Samples greater than 3 days old at room temperature and more than 5 days in refrigeration are unreliable specimens for testing

*Precious samples should be transported to IRL.*

**Diagnostic algorithm of NTEP to be followed in the Microbiology labs**

### MICROBIOLOGICAL GUIDANCE FOR COMMON TYPES OF EXTRAPULMONARY TUBERCULOSIS

**OSTEOARTICULAR/  
MUSCULOSKELETAL**

- Sample: Tissue, pus, synovial fluid
- Sample amount: Biopsy: Specimen material 1 cm x 1 cm biopsies. Any caseous area should be sampled. Add 0.5-2 ml sterile saline to biopsy depending on its size to avoid drying of tissue specimen
- Optimum fluid/pus: 2-3ml.
- Swabs are sub-optimal samples

**PLEURAL**

- Sample: Pleural fluid
- Sample amount: 10-15 ml

**MENINGITIS**

- Sample: CSF:
- Sample amount: 3-5 ml

**LYMPHADENITIS**

- Sample: FNA/ Biopsy
- Sample amount: Specimen material 1 cm x 1 cm biopsy. Add 0.5-2 ml sterile saline to biopsy depending on its size to avoid drying of tissue specimen
- Optimum FNA sample: 2 ml

**UROGENITAL**

- Sample: urine
- Sample amount: Entire early morning urine sample (3-5 days)

**FEMALE GENITAL**

- Sample: Endometrial curettage/biopsy
- Sample amount: Biopsy: Specimen material 1cm x 1 cm biopsies. Any caseous area should be sampled. Add 0.5-2 ml sterile saline to biopsy depending on its size to avoid drying of tissue specimen

**GASTROINTESTINAL**

- Sample: Tissue, pus, peritoneal fluid
- Sample amount: Biopsy: Specimen material 1 cm X 1 cm biopsy (Atleast 6 biopsies for microbiological diagnosis including any caseous area). Any caseous area should be sampled. Add 0.5-2 ml sterile saline to biopsy depending on its size to avoid drying of tissue specimen
- Optimum fluid/pus: 5-10ml

#### Processing:

- Preferably immediately. If not possible- store/transport at 2-8 °C
- *If sample is adequate, attempt molecular testing at that site*
- *If biopsy is not possible or at an inaccessible site, refer patient to the next higher centre immediately where appropriate test can be done*
- *If sample obtained at a centre is inadequate, send directly to nearest Tertiary centre/medical colleges/IRL*

#### Microbiological procedures :

- AFB Smear Microscopy except in GI TB
- NAAT
- Culture (MGIT. If MGIT is not available LJ medium should be used)
- Drug susceptibility testing, if culture is positive

### ABBREVIATIONS

|                              |   |  |
|------------------------------|---|--|
| ADA: Adenosine Deaminase     | FNA: Fine needle aspirate   | PHC: Primary health Centre             |
| AFB: Acid fast bacilli       | LJ medium: Lowenstein Jensen medium   | TB: Tuberculosis                       |
| CHC: Community Health Centre | MGIT: Mycobacteria Growth Indicator tube (Liquid culture medium for mycobacteria) | IRL: Intermediate Reference laboratory |
|                              | NAAT: Nucleic Acid Amplification Tests-Xpert MTB/RIF/TrueNat                      |  |

### REFERENCES

1. National TB Elimination Programme, Central TB Division. Training Modules for programme managers & Medical Officers. Ministry of Health & Family Welfare, Government of India. <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> Last access on 15 March, 2022.
2. Guidelines for programmatic management of drug resistant tuberculosis in India March 2021. National TB Elimination Programme, Central TB Division, Ministry of Health & Family Welfare, Government of India accessed at <https://tbcindia.gov.in/showfile.php?lid=3590> Last access on 15 March, 2022.

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# Standard Treatment Workflow (STW) Guidelines for DRUG SENSITIVE-TB TREATMENT AS PER NTEP

- For all TB patients whether being treated in public or private sector, clinicians should follow Standards for TB care in India guidelines
- In NTEP, the principle of TB treatment (except confirmed DR-TB) is to administer daily FDC of 1st line ATT in appropriate weight bands, under direct observation
- For patients being treated in private sector, FDCs may be provided by NTEP whenever requested

## Regimen for Drug-Sensitive TB cases: 2HRZE/4HRE

- This regimen is for H & R sensitive TB cases and cases where the sensitivity pattern can not be established
- Treatment is given in two phases:**
  - Intensive phase consists of 8 weeks (56 doses) of isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) given under direct observation in daily dosages as per weight band categories
  - Continuation phase consists of 16 weeks (112 doses) of isoniazid, rifampicin and ethambutol in daily dosages. Only pyrazinamide will be stopped in the continuation phase. The CP needs to be extended upto 24 weeks in certain forms of TB like CNS TB, Skeletal TB. In disseminated TB or slow response treating physician may extend on case to case basis.

| Regimen for DS-TB | IP     | CP    |
|-------------------|--------|-------|
| Drugs             | 2 HRZE | 4 HRE |
| Doses             | 56     | 112   |

## ADULT TB TREATMENT

| Drug dosages for first-line anti- TB drugs  |  | Special considerations for Adult TB Meningitis  | Special considerations for Adult abdominal TB   |
|---|--|---|---|
| Drugs   | Doses  |   |   |
| Isoniazid (H)   | 5 mg/kg daily (4 to 6 mg/kg)                                 | <ul style="list-style-type: none"> <li>Intensive Phase: 2 months of RHZE or RHZS</li> <li>Continuation phase: 3 drugs-RHE for at least 10 months*</li> <li>STEROIDS                             <ul style="list-style-type: none"> <li>Preferably Dexamethasone 0.4 mg/kg/day intravenously in 3-4 divided doses during hospital stay</li> <li>If not feasible, give oral Dexamethasone 0.4 mg/kg/day in divided doses or oral Prednisolone 1 mg/kg/day in a single morning dose</li> <li>Discharge on oral steroids on tapering doses for total duration of 8-12 weeks</li> <li>Regular follow up is essential every month for at least first 3 months &amp; can be increased thereafter till treatment is stopped</li> <li>Monitor liver function tests &amp; any other features of drug toxicity</li> <li>Observe for clinical improvement or any deterioration</li> <li>Closely observe for development of any complications</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>Extend duration of treatment in cases of inadequate response</li> <li>Refer for surgical management for complications [intestinal obstruction (due to strictures), perforation]</li> <li>Consider endoscopic dilatation for treatment for accessible strictures</li> <li>Refer for biliary drainage in case of Jaundice due to biliary obstruction (hepatobiliary obstruction/pancreatic TB)</li> </ul>                  |
| Rifampicin (R)  | 10 mg/kg daily (8 to 12 mg/kg)                               |   |   |
| Pyrazinamide (Z)  | 25 mg/kg daily (20 to 30 mg/kg)                              |   |   |
| Ethambutol (E)  | 15 mg/kg daily (12 to 18 mg/kg)                              |   |   |
| Streptomycin (S)*   | 15 mg/kg daily (15 to 20 mg/kg)                              |   |   |
| *Streptomycin is administered only in certain situations, like TB meningitis or if any first line drug need to be replaced due to ADR as per weight of the patient  |  |   |   |
| Pyridoxine may be given at a dosage of 10 mg per day  |  |   |   |
| Weight category   | Number of tablets (FDCs)                                     |   | Special considerations for intra-ocular TB  |
|   | Intensive Phase<br>H: 75mg; R: 150 mg; Z: 400 mg; E: 275 mg) | Continuation Phase<br>H: 75mg; R: 150 mg; E: 275 mg)  |   |
| 25 to 34 kg   | 2  | 2   | <ul style="list-style-type: none"> <li><b>ATT</b> : 2 months of RHEZ + 7 months of RH depending on clinical response &amp; side effects to treatment</li> <li>Add pyridoxine 10 mg/day</li> <li><b>Corticosteroids</b> : Topical steroids eye drops for severe/anterior chamber inflammation</li> <li>For treatment in children refer to paediatrician</li> <li>Systemic corticosteroids for severe inflammation in consultation with Uveitis expert</li> </ul> |
| 35 to 49 kg   | 3  | 3   |   |
| 50 to 64 kg   | 4  | 4   |   |
| 65 to 75 kg   | 5  | 5   |   |
| > 75 kg   | 6  | 6   |   |
| <ul style="list-style-type: none"> <li>Fixed Dose Combinations (FDCs) refer to products containing two or more active ingredients in fixed doses, used for a particular indication(s)</li> <li>In NTEP, for Adults: 4-FDC (given in IP) consists of HRZE and 3-FDC (given in CP) consists of HRE</li> <li>During treatment if weight of the patient increases by &gt; 5 kg and crosses the next weight band then patient should be given the next higher weight band FDC drugs</li> </ul> |  |   |   |

## PAEDIATRIC TB TREATMENT

- Paediatric cases are to be treated under NTEP in daily dosages as per 6 weight band categories
  - Children & adolescents up to 18 years of age weighing less than 39 kg, are to be treated using paediatric weight bands. Those weighing more than 39 kg to be treated with adult weight bands.
- Available paediatric dispersible FDCs and loose drugs
- Dispersible FDC, flavoured
    - Rifampicin 75 mg + Isoniazid 50 mg + Pyrazinamide 150 mg
    - Rifampicin 75 mg + Isoniazid 50 mg
  - Dispersible Loose drugs
    - Ethambutol 100 mg
    - Isoniazid 100 mg

| Drug dosages for first-line anti- TB drugs |                                       |
|--|---------------------------------------|
| Isoniazid (H)                              | 7-15 mg/kg (maximum dose 300 mg/day)  |
| Rifampicin (R)                             | 10-20 mg/kg (maximum dose 600 mg/day) |
| Pyrazinamide (Z)                           | 30-40 mg/kg (maximum 2000 mg/day)     |
| Ethambutol (E)                             | 15-25 mg/kg (maximum 1500 mg/day)     |

| Weight Band | Number of tablets (dispersible FDCs) |   |                    |   |
|-------------|--------------------------------------|---|--------------------|---|
|             | Intensive phase                      |   | Continuation phase |   |
|             | HRZ                                  | E | HR                 | E |
| 4-7 kg      | 1                                    | 1 | 1                  | 1 |
| 8-11 kg     | 2                                    | 2 | 2                  | 2 |
| 12-15 kg    | 3                                    | 3 | 3                  | 3 |
| 16-24 kg    | 4                                    | 4 | 4                  | 4 |
| 25-29 kg    | 3 + 1A *                             | 3 | 3 + 1A *           | 3 |
| 30-39 kg    | 2 + 2A *                             | 2 | 2 + 2A *           | 2 |

\*A=Adult FDC (HRZE = 75/150/400/275; HRE = 75/150/275). It is added in higher weight band categories i.e. > 25 kg as these children may be able to swallow tablets  
Pyridoxine may be given at a dosage of 10 mg per day

- Special considerations for paediatric TB meningitis**
- ATT for paediatric TB Meningitis**
- > 2 HRZE and 10 HRE (in appropriate doses)
  - Corticosteroids**
    - Prednisolone 2 mg/kg/day for 4 weeks & then taper over 4 weeks\*
    - Slower taper needed in some patients
- \*Equivalent dose of another steroid formulation may be used either injectable/oral

- Special considerations for paediatric osteoarticular TB**
- Regimen : 2HRZE + 10HRE
  - Follow up every month during treatment & subsequently every 3 months: Potts spine with X-ray or MRI & Tubercular dactylitis or arthritis with plain X-ray

- Special considerations for paediatric Abdominal TB**
- Steroids- Not recommended
  - Supportive treatment- Management of SAM/Malnutrition as per national guidelines
  - Surgical treatment:
    - Acute intestinal obstruction, Bowel perforation
    - Persistence of obstructive symptoms despite conservative management & ATT
  - DO NOT start Empirical ATT with isolated:
    - Recurrent/Chronic abdominal pain without danger signs
    - Chronic diarrhoea without proper evaluation

## ABBREVIATIONS

|                                       |   |   |                                       |
|---------------------------------------|---|---|---------------------------------------|
| <b>ADR:</b> Adverse drug reaction     | <b>DR-TB:</b> Drug resistant Tuberculosis | <b>H:</b> Isoniazid                                     | <b>R:</b> Rifampicin                  |
| <b>ATT:</b> Anti-Tubercular treatment | <b>DS-TB:</b> Drug sensitive Tuberculosis | <b>IP:</b> Intensive phase                              | <b>S:</b> Streptomycin                |
| <b>CNS:</b> Central Nervous system    | <b>E:</b> Ethambutol                      | <b>MRI:</b> Magnetic Resonance imaging TB: Tuberculosis | <b>SAM:</b> Severe acute malnutrition |
| <b>CP:</b> Continuation phase         | <b>FDC:</b> Fixed dose combination        | <b>NTEP:</b> National TB Elimination Programme          | <b>Z:</b> Pyrazinamide                |

## REFERENCES

1. National TB Elimination Programme, Central TB Division. Training modules for programme managers & Medical officers. Ministry of Health and Family Welfare, Government of India accessed at <https://tbcindia.gov.in/index1.php?lang=1&level=1&sublinkid=5465&lid=3540> on 24 February, 2022.

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# Standard Treatment Workflow (STW) for the Management of ANTITUBERCULAR THERAPY RELATED HEPATITIS

## PATIENT TO BE STARTED ON ATT

### Risk factors for ATT Hepatitis

- History of underlying liver disease (jaundice, ascites, GI bleeding)
- Physical findings suggestive of liver disease (Splenomegaly, ascites, icterus, edema)
- Alcoholism
- Hypoalbuminemia and Malnutrition
- Elevated aminotransferases at baseline
- HIV
- IV drug abuse
- Elderly age

Yes

Evaluate for underlying liver disease  
HBsAg, Anti-HCV, Ultrasound

Chronic Liver disease +

- Intensive education & counselling
- Modified ATT may be needed based on Child Pugh Status
- LFT monitoring

No

No CLD or Cirrhosis

- Start ATT
- Counsel about symptoms of ATT Hepatitis

## START ATT

### Diagnosis of ATT hepatitis Clinical symptoms present

- (abdominal pain, vomiting, unexplained fatigue, yellowing of sclera, altered sensorium)
- AST/ALT increased to 3 times of baseline/ULN
  - Jaundice (Bilirubin 2 ULN)

### No clinical symptoms

- AST/ALT increased to 5 times of baseline/ULN

Exclude viral hepatitis (HBsAg, Anti-HCV, IgM- antiHAV, IgM-AntiHEV, Get PT/INR, Ultrasound liver)

### Stop all hepatotoxic drugs

- Need urgent ATT: Change to non-hepatotoxic drugs (Fluroquinolones, ethambutol & aminoglycosides)
  - No need for urgent ATT: repeat LFT after a week & reintroduce (see later)
  - Non-resolution of LFT abnormalities: exclude alternative causes of liver disease
- Jaundice and coagulopathy/encephalopathy**
- Refer to higher center immediately

### Urgent ATT: life or organ threatening

- Sputum + Pulmonary TB
- TB meningitis or CNS TB
- Pericardial TB
- Any form that is life threatening, eg., Intestinal TB with intestinal obstruction
- Ocular TB
- Joint or Spinal TB

### No need for urgent ATT

- Sputum-ve Pulmonary TB
- TB lymphadenitis
- Tubercular pleural effusion
- Tubercular ascites
- Intestinal TB
- Genitourinary TB
- Bone TB

### REINTRODUCTION OF ATT HEPATOXIC DRUGS

- Reintroduce only if ALT and AST < 2 ULN & normal bilirubin
- Start one drug at a time: helps identify the culprit
- Rifampicin may be introduced at 10 mg/kg dose
- After one week add Isoniazid 5 mg/kg if LFT normal
- After one week add pyrazinamide 25 mg/kg if LFT is normal
- If ATT hepatitis severe (liver failure, coagulopathy or altered sensorium): Pyrazinamide reintroduction may be avoided
- Another approach could be low dose of one drug followed by full dose after three days
- Duration of ATT: count only when full ATT is started

## REINTRODUCTION OF ATT: IF AST AND ALT < 2 ULN

### SEQUENTIAL

Initiate one at a time Rifampicin 10 mg/kg

1 week: repeat LFT

Initiate Isoniazid 5 mg/kg

1 week: repeat LFT

Initiate Pyrazinamide 25 mg/kg

### INCREMENTAL

Initiate Rifampicin 150 mg/day  
Gradually increase dose by day 4

Initiate Isoniazid 100 mg/day at day 8  
Gradually increase dose by day 11

Initiate Pyrazinamide 500 mg/day on day 15  
Gradually increase dose by day 18

### CHILD PUGH (CTP) SCORE

|                       | Score 1    | Score 2       | Score 3    |
|-----------------------|------------|---------------|------------|
| <b>Bilirubin</b>      | < 2 mg/dl  | 2-3 mg/dl     | >3 mg/dl   |
| <b>Albumin</b>        | >3.5 gm/dl | 2.8-3.5 gm/dl | <2.8 gm/dl |
| <b>INR</b>            | <1.7       | 1.7-2.2       | >2.2       |
| <b>Ascites</b>        | Absent     | Slight        | Moderate   |
| <b>Encephalopathy</b> | Absent     | Grade 1-2     | Grade 3-4  |

### HEPATIC ENCEPHALOPATHY GRADE

- **Grade 0:** normal consciousness, personality & neurological examination
- **Grade 1:** restless, disturbances in sleep, irritability or agitated, tremors, handwriting affected
- **Grade 2:** lethargy, disorientation to time, asterixis, ataxia
- **Grade 3:** somnolent & stuporous, disoriented to place, hyperactive reflexes, rigidity
- **Grade 4:** unrousable coma, decerebrate

### ATT SELECTION FOR UNDERLYING LIVER DISEASE

| Child Status   | Suggested ATT  |
|--|--|
| Child A Cirrhosis (Score 1-6)<br>Stable Liver disease          | 9 months of therapy with HRE OR<br>2 months of therapy with HRE followed by 7 months of HR   |
| Child B Cirrhosis (Score 7-10)<br>Advanced Liver Disease       | One hepatotoxic drug regimen can be used: Two months of therapy with INH (or) RIF with ETH & aminoglycoside, followed by 10 months of therapy with INH/RIF & ETH |
| Child C Cirrhosis (Score 11-15)<br>Very advanced liver disease | No hepatotoxic drug<br>18 to 24 months treatment using a combination of ETH, FQL, cycloserine & aminoglycoside/ capreomycin                                      |
| In Acute hepatitis   | Avoid hepatotoxic drugs<br>ATT with non-hepatotoxic drugs if urgent ATT required<br>Wait till improvement in liver function if no urgent need of ATT             |

## ABBREVIATIONS

|                                       |   |   |                                   |
|---------------------------------------|---|---|-----------------------------------|
| <b>ALT:</b> Alanine transaminase      | <b>GI:</b> gastro-intestinal              | <b>HRE:</b> Isoniazid, Rifampicin, Pyrazinamide | <b>LFT:</b> Liver function tests  |
| <b>AST:</b> Aspartate transaminase    | <b>HAV:</b> Hepatitis A virus             | <b>IgM:</b> Immunoglobulin M                    | <b>PT:</b> Prothrombin time       |
| <b>ATT:</b> Anti-tubercular treatment | <b>HBsAg:</b> Hepatitis B surface Antigen | <b>INH:</b> Isoniazid                           | <b>RIF:</b> Rifampicin            |
| <b>ETH:</b> Ethambutol                | <b>HCV:</b> Hepatitis C virus             | <b>INR:</b> International normalized ratio      | <b>TB:</b> Tuberculosis           |
| <b>FQL:</b> Fluoroquinolone           | <b>HEV:</b> Hepatitis E virus             | <b>IV:</b> Intravenous                          | <b>ULN:</b> Upper limit of normal |

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