9. APPENDICES

A. Childhood TB Deskguide
B. Monitoring tool
C. Ethical clearance letter
Assess for TB if a child presents with:
“Prolonged or Unexplained illness of more than 2 weeks” with one or more of the following:
• Cough more than three weeks
• Fever (usually low grade at evening)
• Enlarged cervical lymph nodes
• Failure to thrive
• Known contact of smear-positive adult TB case
• X-rays suggest TB
• Signs of slow onset meningitis
HISTORY AND EXAMINATION

TB usually presents with a slow onset; illness. Adolescents and some older children present in a similar way to adults, while younger children often have non-specific symptoms and signs.

The following are suggestive of TB:

Close contact of a TB case, smear positive?

Chest
- Cough > 3 weeks unremitting and not improving?
- Sputum?
- Shortness of breath?
- Unilateral wheeze? dulness?

Systemic
- Fever > 2 weeks? not high? sweating at night?
- Malnutrition or failure to gain weight? (PCM – gd.3)
  not responded to 1 month dietary plan?
- Low immune status? pertussis/ measles (in last 6 months)?
- Lymph nodes cervical enlarged? painless? matted?
  abscess? discharge?
- BCG scar absent?

Meningitis
- Headache? vomiting? irritability? lethargic?
- Neck stiffness? bulging fontanel? coma?

Abdominal
- Chronic diarrhea?
- Distended abdomen? mass? ascities?

Bones and joints
- Unilateral swelling/ joint tenderness? (slow onset)
- Backache? stiffness, lump? deformity? limp?
INVESTIGATE AND INTERPRET

Cough may be soft and sputum may be swallowed, if encouraged the child may cough out sputum.

Sputum smear for AFB – positive or negative

- Guide, give lab request form "TB05" and send to laboratory
  - If two sputum smears found positive, no further investigation for TB
  - If only one or none positive (see page 3)

If a child, with encouragement, fails to produce sputum, or smears found negative, then:

- Explain and give "Investigation slip", and send the child for following investigations.

Tuberculin skin test (TST) – Induration (mm)

- Read after 48 – 72 hour
- Positive TST: Non-contact ≥ 10mm and contact cases ≥ 5

Chest X-rays (AP view)
(see illustrations in Annexures-4)

<table>
<thead>
<tr>
<th>Suggestive of TB</th>
<th>Non-specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Milary mottling</td>
<td>o Ill-defined opacity/ infiltrate</td>
</tr>
<tr>
<td>o lymphadenopathy – para-tracheal, tracheal or mediastinal</td>
<td>o Marked bronchovascular marking</td>
</tr>
<tr>
<td>o consolidation - no response to antibiotics</td>
<td></td>
</tr>
</tbody>
</table>

Histology (cervical L.N or granuloma)

- If biopsy is found positive for AFB, no further investigation for TB. OR
- Caseating granulomatous lesions

Other investigations e.g. lumbar puncture if meningeal signs, and aspirate if ascites.
DECIDE – The Diagnosis

Decide on examination findings and investigation results
- If smears found positive, declare & manage TB.
- The matrix below helps in diagnosis on the basis of multiple features i.e. clinical, histological, radiological, etc.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &lt; 2 yrs</td>
<td></td>
</tr>
<tr>
<td>Close contact in last 2 years</td>
<td>TB</td>
</tr>
<tr>
<td>BCG scar Absent</td>
<td></td>
</tr>
<tr>
<td>Low immune status</td>
<td>Yes</td>
</tr>
<tr>
<td>PCM grade&lt;3 Yes</td>
<td></td>
</tr>
<tr>
<td>Physical examination findings</td>
<td>Suggest TB Strongly suggest TB</td>
</tr>
<tr>
<td>Chest X-ray Non-specific</td>
<td></td>
</tr>
<tr>
<td>Tuberculin skin test 5 - 10 mm</td>
<td>Suggest TB &gt; 10 mm</td>
</tr>
<tr>
<td>Granuloma Non-specific</td>
<td></td>
</tr>
<tr>
<td>Who measles &amp; whooping cough in the last 3 - 6 months</td>
<td>TB</td>
</tr>
</tbody>
</table>

Note: See description of conditions in Annexure 2.

**INTERPRETATION:**

<table>
<thead>
<tr>
<th>Score</th>
<th>Interpretation</th>
<th>Suggested Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 2</td>
<td>Unlikely TB</td>
<td>Investigate other reasons of illness.</td>
</tr>
<tr>
<td>3 - 4</td>
<td>Possible TB</td>
<td>- Do not treat for TB, - Manage the presenting symptom(s), - Monitor monthly the condition(s) for 3 months, using scoring chart.</td>
</tr>
<tr>
<td>5 - 6</td>
<td>Possible TB</td>
<td>- Investigate and exclude other causes of illness, then - Register and treat for TB.</td>
</tr>
<tr>
<td>7 or more</td>
<td>Probable TB (confirm, if possible)</td>
<td>- Register and treat for TB.</td>
</tr>
</tbody>
</table>
CATEGORISE – New or Re-treatment Case

Ask and check if child has ever taken:

- TB treatment, for how long? Can verify records?
- Streptomycin (powder/dry) injections, for what? for how long? tablets/syrups which made urine color red? for what? for how long?
- A child diagnosed as TB case is categorized into "new" and "retreatment", on the basis of his previous intake of anti-TB drugs for four weeks or more.
- If found Not to have taken anti-TB drugs for 4 weeks or more in the past, then categorize and manage the child as category-I TB case.

PRESCRIBE DRUGS & INFORM ATTENDANT (PARENT)

- Prescribe drugs using tables on desk guide page 4 & 5
- Complete clinical details on the TB Treatment Card (TB01)
- Give appointment in one month, but if very ill consider admission or give early appointment.
- Explain the key points on TB and its treatment:
  - TB diagnosis, curable, treatment is for 6/8 months, and is free.
  - Symptoms should improve, if not improving come back anytime. If more ill, urgently return
  - Stress importance of daily treatment, supervision by parent and
- Send to the DOTS Facilitator for further education and registration.
# PRESCRIBE TB DRUGS

## Category 1 Regimen

Dosage with 3 FDCs: 2 FDCs & Individual Drugs in children

<table>
<thead>
<tr>
<th>Patient</th>
<th>Daily Intensive Phase 2 Months</th>
<th>Daily Continuation Phase 4 months</th>
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</thead>
<tbody>
<tr>
<td>Body weight</td>
<td>RHZ (60/150mg)</td>
<td>RH (60/300mg)</td>
</tr>
<tr>
<td>Kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 – 8</td>
<td>1 tab</td>
<td>1 tab</td>
</tr>
<tr>
<td>9 – 12</td>
<td>2 tabs</td>
<td>1 tab</td>
</tr>
<tr>
<td>13 – 16</td>
<td>2 tabs</td>
<td>1 tab</td>
</tr>
<tr>
<td>17 – 20</td>
<td>3 tabs</td>
<td>1 tab</td>
</tr>
<tr>
<td>21 – 24</td>
<td>3 tabs</td>
<td>1 tab</td>
</tr>
<tr>
<td>25 – 30</td>
<td>4 tabs</td>
<td>1 tab</td>
</tr>
</tbody>
</table>

*The dosage should be double-checked by the Specialist*

For Children < 5kg b.w.; dosages of the drugs to be calculated by the Specialist

H=Isoniazid, R=Rifampicin, Z=Pyrazinamide, E=Ethambutol, S=Streptomycin
## Category II Regimen

Dosage with 3 FDCs, 2 FDCs & Individual Drugs in children

<table>
<thead>
<tr>
<th>Patient Body Weight (Kg)</th>
<th>Daily Intensive Phase 3 months</th>
<th>First 2 months</th>
<th>Daily Continuation Phase 5 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>RHZ (60/30/150mg)</td>
<td>RH (60/60mg)</td>
<td>E* (400mg)</td>
</tr>
<tr>
<td>5.0 - 8.0</td>
<td>1 tab</td>
<td>1/2</td>
<td>150 mg</td>
</tr>
<tr>
<td>9.0 - 12</td>
<td>2 tabs</td>
<td>1 tab</td>
<td>1/2</td>
</tr>
<tr>
<td>13.0 - 16</td>
<td>2 tabs</td>
<td>1 tab</td>
<td>1/2</td>
</tr>
<tr>
<td>17.0 - 20</td>
<td>3 tabs</td>
<td>1 tab</td>
<td>1/2</td>
</tr>
<tr>
<td>21.0 - 24</td>
<td>3 tabs</td>
<td>1 tab</td>
<td>1/2</td>
</tr>
<tr>
<td>25.0 - 29</td>
<td>4 tabs</td>
<td>1 tab</td>
<td>1/2</td>
</tr>
</tbody>
</table>

* The dosage should be double-checked by the Specialist.

For Children < 5 kg b.w., dosages of the drugs to be calculated by the Specialist.

H = Isoniazid, R = Rifampicin, Z = Pyrazinamide, E = Ethambutol, S = Streptomycin.

Ethambutol only in over 5 years. In the over 5 years, arrange regular visual acuity and red-green disc marker checks. If any change, stop the drug.
REGISTER A CHILD TB CASE

- Ask and record full address of patient and contact person details in TB01.
- Record the treatment center in TB01.
- Fill in patient treatment card (TB02), by transferring data from TB01, and also record the date for next follow-up visit.
- Fill in the first part of TB Register (TB03), by transferring data from TB01.
- Transfer district TB number to TB01 and TB02.

ENABLE THE PARENT(S)

With the help of communication tool (flip chart):

- Educate about TB treatment and precautions.
- Direct observation and support by parent and selected treatment supporter
- Identify household contacts for further management.
MANAGE THE HOUSEHOLD CONTACTS

The protocol for screening the household contacts of a child-TB case are as follows:

- All 0 – 5 years old children, regardless of any symptom/ sign suggestive of TB, are brought to the hospital for TB screening.
- All children above 5 years old with symptoms suggestive of TB (i.e. history of cough, fever or weight loss) are brought to the hospital for TB screening.
- All adults with chest symptoms suggestive of TB (i.e. cough more than three weeks) are brought to the diagnostic center for TB screening.

Screen the household members of a child-TB case, as per above protocol, by:

- Interviewing the attendant, enlist the household contacts and decide those who need further screening at the hospital (child) or a diagnostic center (adult).
- Arranging the screening of identified eligible contacts by:
  - Giving attendant a “contact screening slip”
  - Instructing the attendant where, when and how to go for the screening of contacts.
MANAGE THE MONTHLY FOLLOW-UP VISIT
– for all child TB cases

- Check symptoms improving and weight gained
- Ask about new symptoms, and change in vision
  - if change - check visual acuity.

- Ask about the regularity of drugs taken and check the Treatment Supporter Card
  - if good complement, if not ask why and help solving the problem

- If new symptom consider side-effect as follows:

<table>
<thead>
<tr>
<th>Side effect</th>
<th>Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minor Side Effects</strong></td>
<td></td>
</tr>
<tr>
<td>✓ Anorexia, nausea, abdominal pain</td>
<td>Continue anti-TB drugs and give TB drugs last thing at night</td>
</tr>
<tr>
<td>✓ Joint pains</td>
<td>Paracetamol</td>
</tr>
<tr>
<td>✓ Burning sensation in feet</td>
<td>Pyridoxine 10 - 50 mg daily</td>
</tr>
<tr>
<td>✓ Itching of skin</td>
<td>Anti histamine</td>
</tr>
<tr>
<td><strong>Major Side Effects</strong></td>
<td></td>
</tr>
<tr>
<td>✓ Skin rash</td>
<td>If no response, exclude other possible reasons.</td>
</tr>
<tr>
<td>✓ Deafness</td>
<td></td>
</tr>
<tr>
<td>✓ Dizziness (vertigo &amp; nystagmus)</td>
<td>Stop anti-TB drugs. Refer to Pediatric or other Specialist (e.g. Ophthalmologist for visual impairment, potentially related to Ethambutal).</td>
</tr>
<tr>
<td>✓ Jaundice</td>
<td></td>
</tr>
<tr>
<td>✓ Visual impairment (other causes excluded)</td>
<td></td>
</tr>
<tr>
<td>✓ Shock, purpura, acute renal failure</td>
<td></td>
</tr>
</tbody>
</table>

- Deliver and record the drugs for the next month.
- Enter the current and next date of appointment on TB02 & inform.
MANAGE FOLLOW-UP VISIT – 2 & 5/6 Month

If sputum smear positive at diagnosis decisions are based on doing a smear at each of 2, 5/6 months:

- If negative at 2 months, start continuation phase treatment
- If positive at 2 months, continue initial phase treatment for another month and review

If TB diagnosis was made on clinical findings (other than smears) then reassess for TB symptoms:

- Fever and sweating — now absent
- Lethargy — now normal activity
- Weight — gain
- Repeat chest X-ray — improved
- Other TB-associated findings at diagnosis — improved

Decide if these findings have improved or not:

1. Symptoms improved, start continuation phase TB treatment
2. Symptoms not improved or deteriorated:
   - Reassess for another cause of these symptoms, if found treat this diagnosis, and also start continuation phase TB treatment
   - If no other cause found to explain the non-improvement, continue intensive phase treatment for one more month, then
     - Again reassess and, whether or not another diagnosis found, start continuation phase TB treatment.

NB. Once started, even if the initial TB diagnosis is changed, or is uncertain, always complete TB treatment.
RETRIEVE PATIENTS WITH DELAYED VISIT

The DOTS Facilitator will identify the delay of 7 or more days, in collection of medicine, and arrange for retrieval through one or more of the following ways:
- Writing letter, where usually effective, feasible and/or
- Calling by (telephone), where deemed suitable and found feasible
- Other feasible ways, as deemed suitable under local circumstances, such as contacting a LHW or a health worker doing a home visit, etc.

Discuss problems in completing treatment, help to solve them

Explain the importance of continued treatment and give an appointment
DECLARE TREATMENT OUTCOMES

Smear-positive TB

Cured: a smear positive child who has completed the treatment and is smear negative in the last month of treatment and on at least one previous occasion.

Completed: a smear positive child who has completed the treatment and had negative smears at the end of intensive phase, but with no sputum examined at the end of treatment. OR

A smear negative child who has completed the treatment (i.e. 6 months), with improvement in symptoms and signs suggestive of TB.

Failure: a new smear positive child who remained, or became again, smear positive five months or later after commencing treatment.

Transferred out: a child who has been transferred to another TB register to continue treatment.

Died: a child reported to have died of any reason during the course of treatment.

Defaulted: a child who at any time after registration had not collected drugs for consecutive two months or more.
Annexure-1

Child examined for sputum smears and one or none smear is found positive.

If one smear is found positive: Send for X-rays chest

- If X-rays consistent with active pulmonary TB, 
  Declare sputum positive pulmonary TB

- If X-ray not consistent with active pulmonary TB, 
  Give antibiotic for 7 days and re-assess

If all three sputum smears found negative: Give antibiotic for 7 days, clinically assess after 7 days, send for X ray (if req)

- If X-rays consistent with active pulmonary TB, 
  and patient found still ill after taking a full course of antibiotics, 
  Declare sputum negative pulmonary TB

- If X-rays are not consistent with active pulmonary TB, and patient found still ill after taking a full course of antibiotics

  Assess the child for TB, with the help of scoring chart.
Annexure-2

Description of conditions to be assessed for diagnosing childhood TB

Low Immune Status: Includes children with
- malignancies (leukemia, lymphomas),
- immunodeficiency, and
- immunosuppressive therapy such as chronic steroids more than 2 weeks

Protein Calorie Malnutrition grade 3 or below 3% line on child care at not improving after 4 weeks of "adequate" caloric intake

Physical Examination suggestive of TB:
- pulmonary findings (unilateral wheeze, dullness);
- hepatosplenomegaly, ascites

Physical Examination strongly suggestive of TB:
- matted lymphadenopathy;
- abdominal mass; gibbus formation;
- chronic monoarthritis;
- Meningeal findings (bulging fontanel, irritability, papilledema)

Radiological findings

Non-specific:
- ill defined opacity/infiltrates;
- marked broncho-vascular marking

Suggestive of TB:
- consolidation not responding to antibiotic therapy;
- lymphadenopathy paraesophageal, or mediastinal;
- miliary mottling
TB PATIENT CATEGORIES

New (Category-I)
A child diagnosed as TB, has never taken treatment for TB or has taken anti-TB drugs for less than 4 weeks in the past and not registered

Re-treatment (Category-II) smear positive cases only
A child diagnosed as TB, has taken TB treatment for 4 weeks or more in the past. The types of re-treatment may include:

Return after default: A child returns to treatment after interrupting treatment for two or more months.

Treatment failure: A new smear positive patient while on treatment remains or becomes sputum smear positive at the end of 5 months or later. OR Smear negative patient found smear positive at completion of 2 months treatment.

Relapse: A patient declared cured or treatment completed in the past, again has a positive sputum smear.

Others: Patients who do not fit in the above mentioned types such as patients known to have taken TB drugs for more than 4 weeks from outside the programme.
Illustrations: Typical X-rays Findings

- Uncomplicated hilar lymph gland enlargement on the right-hand side.
- Mediastinal lymph gland enlargement with lung infiltration is seen on the left.
- Hilar lymph gland enlargement with infiltration into the surrounding lung tissue.

Courtesy IUATLD
This operational guide is based on NTP and WHO childhood TB case management guidelines. This guide, as a decision aid, does not cover all possible situations and/or solutions related with the management of childhood TB. The clinical judgment of the doctor remains the basis for final decision making, and this aid should only be taken as a supplement and not a substitute of the clinical acumen.

Developed by:

- National TB Control Programme Pakistan.
- Association for Social Development
- Center for International Health, Norway
- Nuffield Center for International Health and Development, University of Leeds, UK

Supported by:

- Center for International Health (CIH, Norway)
- Communicable Disease Research Programme (COMDIS, DFID-UK)

NTP CIH COMDIS ASD WHO
APPENDICE-B. Monitoring tool

HOSPITAL CHILDHOOD TB MONITORING TOOL

Name of Hospital ____________________ Catchment Population ____________
Month under reporting ________________ Meeting Date ________________

A. PRINT MATERIALS

<table>
<thead>
<tr>
<th>Item</th>
<th>Minimal Stock Level</th>
<th>Stock available</th>
<th>Stock Replenishment</th>
<th>Comments/Required Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scoring form (PPA)</td>
<td>1 pad</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contact tracing letter</td>
<td>1 pad</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growth chart</td>
<td>20 cards</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

B. DRUG

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Minimal Stock Level</th>
<th>Stock available</th>
<th>Stock Replenishment</th>
<th>Comments/Required Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>RHZ</td>
<td>20 patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RH</td>
<td>20 patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weighing Scale</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPD</td>
<td></td>
<td></td>
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C. STAFF AVAILABILITY

<table>
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<tr>
<th>Category</th>
<th>Staff #Available</th>
<th>#Trained</th>
<th>Comments/ Required Action</th>
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</thead>
<tbody>
<tr>
<td>Pediatrician</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOTS Doctor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DOTS Facilitator</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lab. Person</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### D. CASE MANAGEMENT PRACTICES

<table>
<thead>
<tr>
<th>OPD (FR3)</th>
<th>Lab. (TB 04)</th>
<th>PPD</th>
<th>Scoring form</th>
<th>Registration (TB 03)</th>
<th>Case management (TB01)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number Examined (last month)</td>
<td>Number of children registered</td>
<td>Pt who started their intensive phase during month under review</td>
<td>Absentee patients (TB01)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Attendee</th>
<th>TB suspects</th>
<th>Patient</th>
<th>Smear Positive</th>
<th>Smear Negative</th>
<th>Both</th>
<th>Action taken</th>
</tr>
</thead>
</table>
| AFB tested | Found positive | Follow-up | PPD administered | PPD positive | # administered | Re-treatment (cut 7? | Total cases | Follow-up referral | Correct 
referral | Correct case | Re- Support notes |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 |

Prepared by: ___________________________ Counter signed by: ___________________________
**DOTS REVIEW/PLAN MEETING: HOSPITAL: _______________________; Date: ____________**

**ACTION NOTES**

<table>
<thead>
<tr>
<th>Main Gaps</th>
<th>Agreed Action</th>
<th>Responsible</th>
<th>Dead line</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Inputs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Case management</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Laboratory functioning</strong></td>
<td></td>
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</tr>
</tbody>
</table>

Prepared by: ______________________; Counter signed by: ______________________
APPENDICE-C Ethical clearance letter

National Bioethics Committee (NBC) Pakistan

Ref: PMRC/4-87/07/NBC-ECP-14/ 2989


Dr. Nauman Safdar
Lead Professional
Project Development and Technical Support Unit
Association for Social Development
House-12, Street-48
Sector F-7/4
Islamabad.

Subject: Research Proposal “Childhood Tuberculosis in Punjab, Pakistan: Diagnosis and Outcomes”.

Dear Dr. Safdar,

I am pleased to inform you that the above mentioned project has been cleared by “Research Ethics Committee of National Bioethics Committee”.

Kindly keep the National Bioethics Committee Secretariat update with the progress of the project and submit the final report on completion.

A separate letter will be sent indicating details of fee regarding the ethical clearance of this project.

Yours Sincerely,

Dr. Zulfiqar A. Bhutta
Chairman
Research Ethics Committee

Pakistan Medical Research Council, Shahr-e-Arab, Off Constitution Avenue, Sector G-5/2, Islamabad.
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