9. APPENDICES

A. Childhood TB Deskguide
B. Monitoring tool
C. Ethical clearance letter

APPENDICE-A Childhood TB deskguide

DESK GUIDE (Draft)

MANAGEMENT OF TUBERCULOSIS IN CHILDREN

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? dullness?

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)

Suggestive of TB	Non-specific
○ Miliary mottling ○ lympadenopathy – para-tracheal, tracheal or mediastinal ○ consolidation - no response to antibiotics	○ Il-defined opacity/ infiltrate ○ Marked broncho-vascular marking

Histology (cervical L.N or granuloma)

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

Other investigations e.g. lumber 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

Condition	Scores				
	1	2	3	4	5
Age	< 2 yrs				
Close contact in last 2 years	TB patient S –ve		TB patient S +ve		
BCG scar	Absent				
Low immune status	Yes				
PCM grade-3	Yes		Not improve		
Physical examination findings		Suggest TB		Strongly suggest TB	
Chest X-ray	Non-specific	Suggest TB			
Tuberculin skin test	5 – 10 mm		> 10 mm		
Granuloma	Non-specific				TB
H/o measles & whooping cough in the last:	3 – 6 months	< 3 months			

Note: See description of conditions in Annexure-2.

INTERPRETATION:

Score	Interpretation	Suggested Actions
0 – 2	Unlikely TB	Investigate other reasons of illness
3 – 4	Possible TB	-Do not treat for TB -Manage the presenting symptom(s) -Monitor monthly the condition(s) for 3 months, using scoring chart
5 – 6	Possible TB	-Investigate and exclude other causes of illness, then -Register and treat for TB
7 or more	Probable TB (confirm, if possible)	-Register and treat for TB

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 I Regimen				
Dosage with 3 FDCs, 2 FDCs & Individual Drugs in children				
Patient	Daily Intensive Phase 2 Months			Daily Continuation Phase 4 months
Body weight	RHZ	RH	E*	RH
Kg	(60/30/150mg)	(60/30mg)	(400 mg)	(60/30mg)
5 – 8	1 tab		¼	1 tab
9 – 12	2 tabs		½	2 tabs
13 – 16	2 tabs	1 tab	¾	3 tabs
17 -20	3 tabs		1	3 tabs
21- 24	3 tabs	1 tab	1	4 tabs
25 -29	4 tabs		1 ¼	4 tabs

**** 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						
Patient	Daily Intensive Phase 3 months			First 2 months	Daily Continuation Phase 5 months	
Body weight	RHZ	RH	E*	S*	RH	E*
Kg	(60/30/150mg)	(60/30mg)	(400mg)	1G/2.5 ml	(60/30mg)	(400mg)
5 - 8	1 tab		¼	100 mg	1 tab	¼
9 - 12	2 tabs		½	150 mg	2 tabs	½
13 - 16	2 tabs	1 tab	¾	200 mg	3 tabs	¾
17 - 20	3 tabs		1	250 mg	3 tabs	1
21- 24	3 tabs	1 tab	1	300 mg	4 tabs	1
25 -29	4 tabs		1 ¼	350 mg	4 tabs	1 ¼
** 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,

Ethambutol only in over 5 years. In the over 5 years, arrange regular visual acuity and red-green discrimination 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:

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

- **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

Unless re-occurred due to an acute

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 cared 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 para/tracheal, or mediastinal;
- miliary mottling

Annexure-3

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:

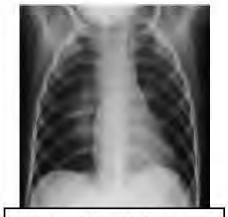
Return after default: A child returns to treatment after interrupting treatment for two or more months.

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.

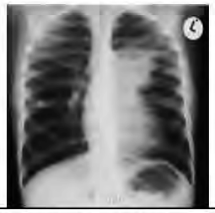
Others: Patients who do not fit in the above mentioned types such as patients known to have taken TB drugs for more than 4 weeks from outside the programme.

Annexure-4

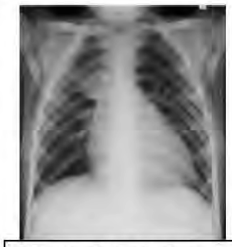
Illustrations: Typical X-rays Findings



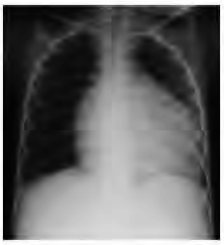
Uncomplicated hilar lymph gland enlargement on the right-hand side



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

Item	Minimal Stock Level	Stock available	Stock Replenishment		Comments/Required Action
			Supplied	To Arrange	
Scoring form (PPA)	1 pad				
Contact tracing letter	1 pad				
Growth chart	20 cards				

B. DRUG

Drugs	Minimal Stock Level	Stock available	Stock Replenishment		Comments/ Required Action
			Supplied	To Arrange	
RHZ	20 patients				
RH	20 patients				
Weighing Scale	1				
PPD					

C. STAFF AVAILABILITY

Category	Staff		Comments/ Required Action
	#Available	#Trained	
Pediatrician			
DOTS Doctor			
DOTS Facilitator			
Lab. Person			

D. CASE MANAGEMENT PRACTICES Hospital: _____ Month under review:_____

OPD (FR3)	Lab. (TB 04)			PPD		Scoring form		Registration (TB 03)					Case management (TB01)				
Number Examined (last month)								Number of children registered					Pt who started their intensive phase during month under review			Absentee patients (TB01)	
Attendee	TB suspects		Patient					Smear Positive			Smear Negative	Both				#	Action taken
	AFB tested	Found positive	Follow-up	PPD administered	PPD positive	# administered	# attached (TB01)	New	Re-treatment (cat 2)	Total (cat1 & 2)	New	Pre-reg referral	Correct regimen	Correct Dose	Rx. 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

Main Gaps	Agreed Action	Responsible	Dead line	Remarks
Inputs				
Case management				
Laboratory functioning				

Prepared by: _____ Counter signed by: _____

APPENDICE-C Ethical clearance letter

BY LEOPARDS

National Bioethics Committee (NBC) Pakistan

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

Dated: 15th Feb. 2008.

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

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