STANDARD TREATMENT WORKFLOW (STW)

Drug Sensitive-TB Treatment as per NTEP

Rajendra Prasad Joshi, Sanjay Kumar Mattoo
Central TB Division, Ministry of Health and Family Welfare

CORRESPONDING AUTHOR
Dr Rajendra Prasad Joshi, Central TB Division, Ministry of Health and Family Welfare
Email: ddgtb@rntcp.org, ddgtb.mohfw@gov.in

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Department of Health Research
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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:**
  1. 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
  2. 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

Drugs	Doses
Isoniazid (H)	5 mg/kg daily (4 to 6 mg/kg)
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

	Number of tablets (FDCs)

Special considerations for Adult TB Meningitis

- Intensive Phase: 2 months of RHZE or RHZS
- Continuation phase: 3 drugs-RHE for at least 10 months*
- 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

Special considerations for Adult abdominal TB

- 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

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Weight category	Number of tablets (FDCs)	
	Intensive Phase H: 75mg; R: 150 mg; Z: 400 mg; E: 275 mg)	Continuation Phase H: 75mg; R: 150 mg; E: 275 mg)
25 to 34 kg	2	2
35 to 49 kg	3	3
50 to 64 kg	4	4
65 to 75 kg	5	5
> 75 kg	6	6

- Fixed Dose Combinations (FDCs) refer to products containing two or more active ingredients in fixed doses, used for a particular indication(s)
- In NTEP, for Adults: 4-FDC (given in IP) consists of HRZE and 3-FDC (given in CP) consists of HRE
- During treatment if weight of the patient increases by > 5 kg and crosses the next weight band then patient should be given the next higher weight band FDC drugs

Special considerations for Adult TB Meningitis

- Intensive Phase: 2 months of RHZE or RHZS
- Continuation phase: 3 drugs-RHE for at least 10 months*
- 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 a single morning dose
  - › Discharge on oral steroids on tapering doses for total duration of 8-12 weeks
  - › 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

*treatment duration may be increased in some cases as per the clinician decision

Special considerations for Adult abdominal TB

- 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)

Special considerations for intra-ocular TB

- **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 Uveitits expert

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

1. Dispersible FDC, flavoured
   - Rifampicin 75 mg + Isoniazid 50 mg + Pyrazinamide 150 mg
   - Rifampicin 75 mg + Isoniazid 50 mg
2. Dispersible Loose drugs
   - Ethambutol 100 mg
   - Isoniazid 100 mg

Weight Band	Number of tablets (dispersible FDCs)			
	Intensive phase		Continuation phase	
	HRZ	E	HR	E
	50/75/150	100	50/75	100
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

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)

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

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

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