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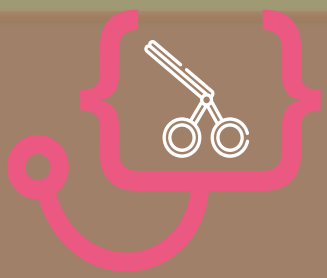

STANDARD TREATMENT WORKFLOWS *of India*

SPECIAL EDITION ON PAEDIATRIC AND EXTRAPULMONARY TUBERCULOSIS

PARTNER

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

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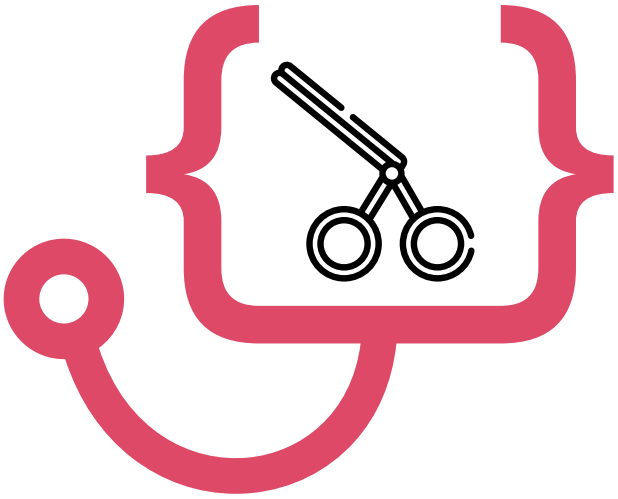

STANDARD TREATMENT WORKFLOWS *of India*

Special Edition on Paediatric and Extrapulmonary Tuberculosis

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These STWs have 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**) for more information.

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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

TOPIC PRIORITIZATION

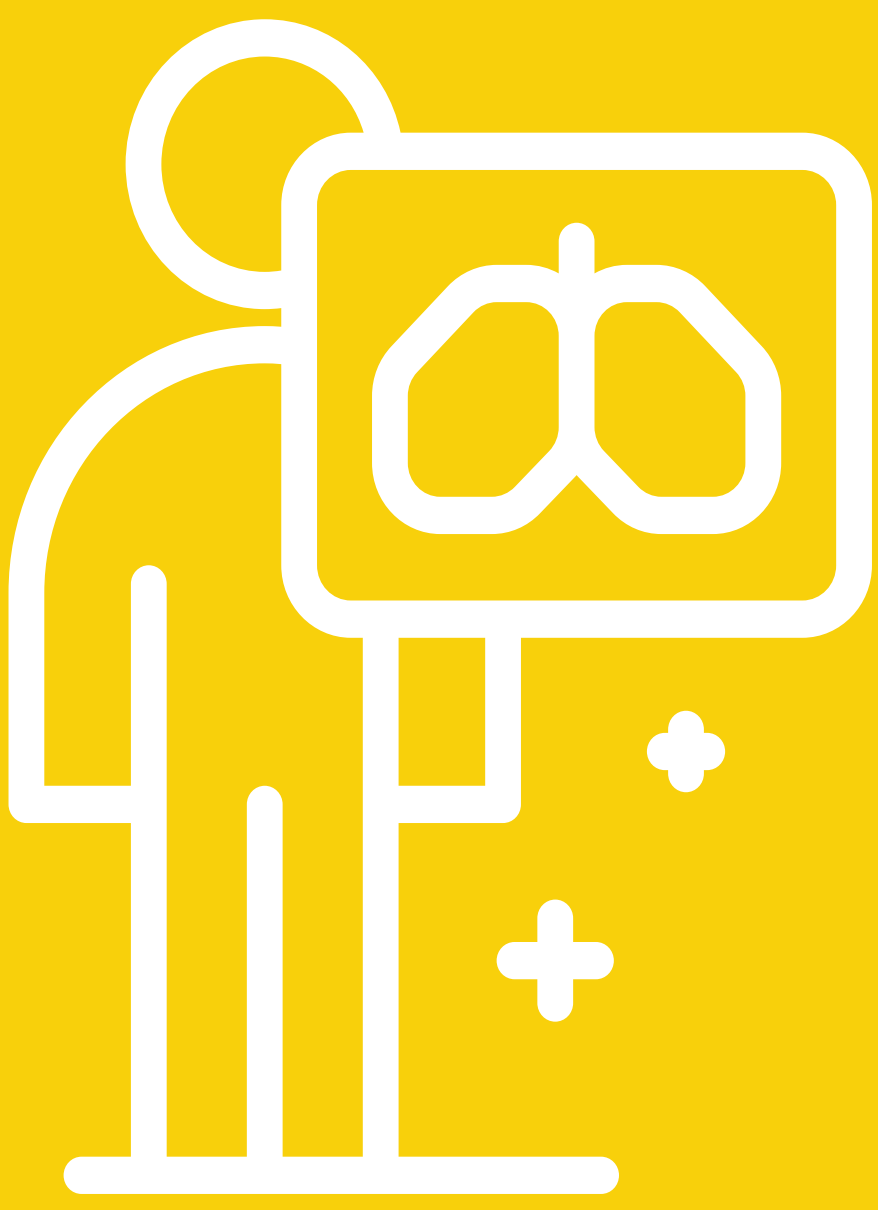
- Prevalence studies
- Global burden of diseases studies
- HBP of AB-PMJAY
- Existing guidelines

DEVELOP STWS & CONVERT THEM INTO INFOGRAPHICS

- 16 Meetings
- Participation also from
  - Public Health Specialists
  - Search Strategists
  - Clinical Scientists
  - Graphic Designers

REVIEW OF CURRENT GUIDELINES & FEASIBILITY AS PER HEALTH SYSTEM

- Review by Editorial Committee



Investigations & Treatment

March/2022

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

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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

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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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 CLD or Cirrhosis

- Start ATT
- Counsel about symptoms of ATT Hepatitis

No

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	No need for urgent ATT
• 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	• 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 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
Bilirubin	**< 2 mg/dl**	**2-3 mg/dl**	**>3 mg/dl**
Albumin	**>3.5 gm/dl**	**2.8-3.5 gm/dl**	**<2.8 gm/dl**
INR	**<1.7**	**1.7-2.2**	**>2.2**
Ascites	**Absent**	**Slight**	**Moderate**
Encephalopathy	**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) Stable Liver disease	9 months of therapy with HRE **OR** 2 months of therapy with HRE followed by 7 months of HR
Child B Cirrhosis (Score 7-10) 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) Very advanced liver disease	No hepatotoxic drug 18 to 24 months treatment using a combination of ETH, FQL, cycloserine & aminoglycoside/ capreomycin
In Acute hepatitis	Avoid hepatotoxic drugs ATT with non-hepatotoxic drugs if urgent ATT required Wait till improvement in liver function if no urgent need of ATT

ABBREVIATIONS

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

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