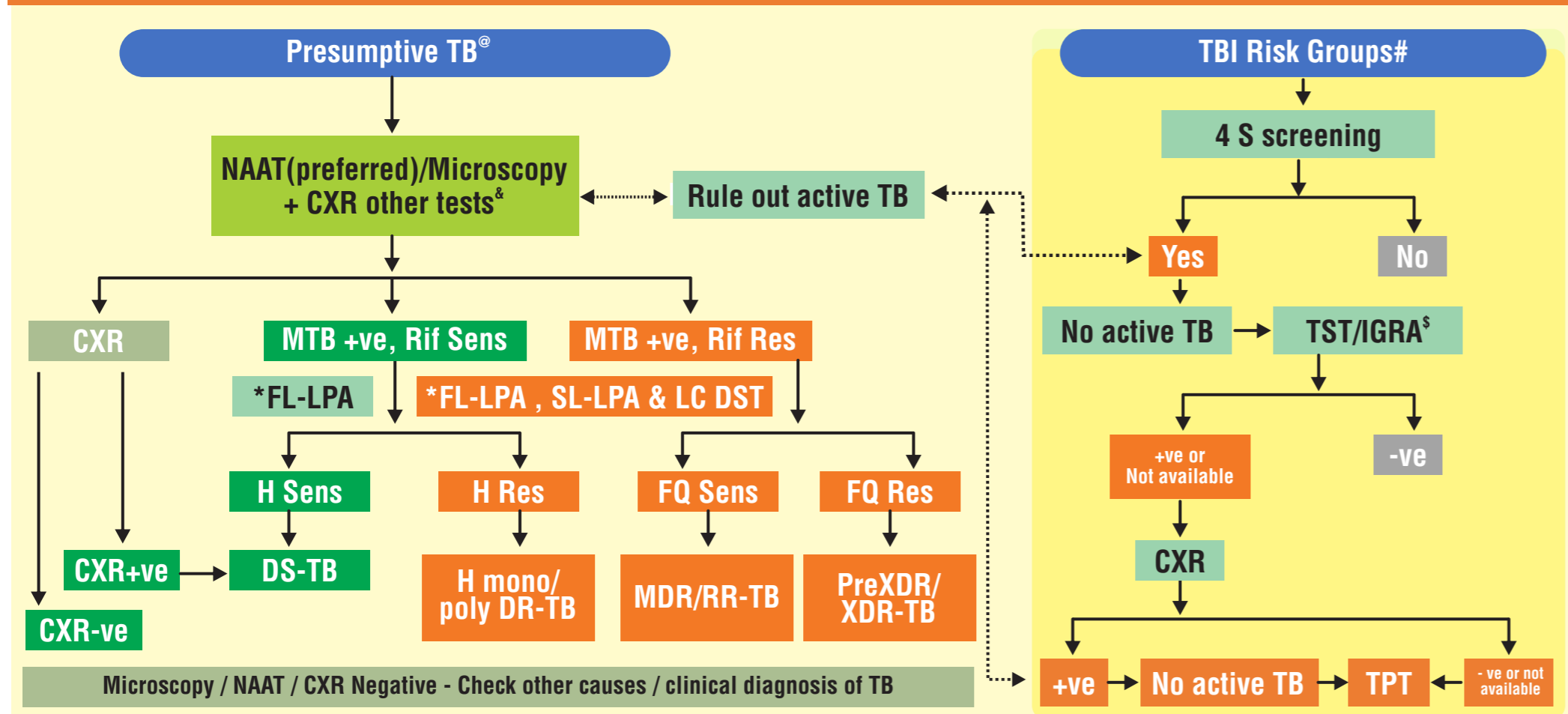


NATIONAL TUBERCULOSIS ELIMINATION PROGRAMME (NTEP) AT A GLANCE

Comprehensive Clinical Management Protocol of Tuberculosis

Integrated Management Algorithm for TB disease and TB infection (I)

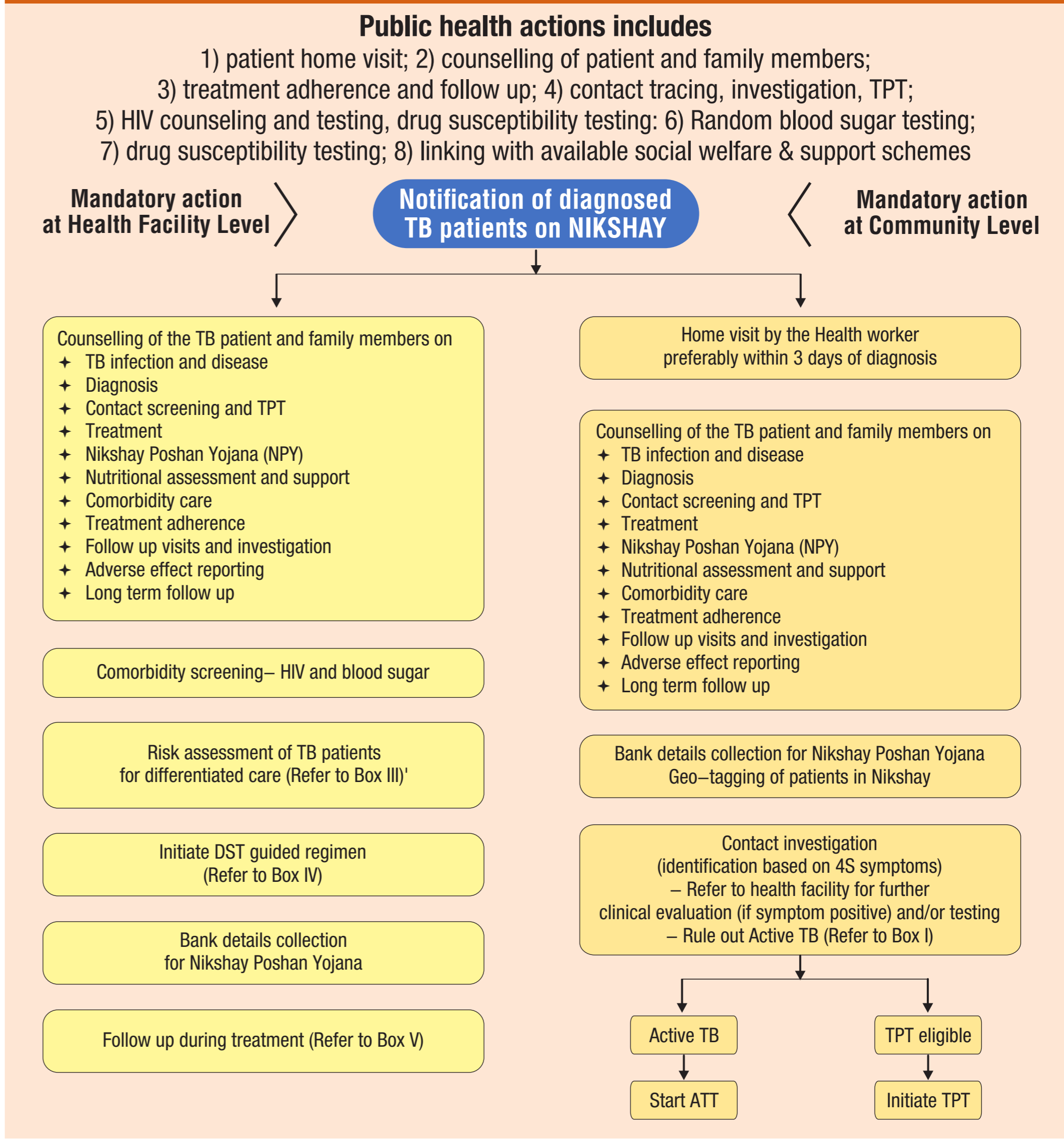


* one or more of the following is positive – In adults, Cough > 2 weeks, fever > 2 weeks, significant weight loss, night sweats, hemoptysis. In children persistent fever and/or cough > 2 weeks, loss of weight/no weight gain and/or history of contact with infectious TB cases. For Extra pulmonary, presence of organ specific symptoms and signs like swelling of lymph nodes, pleural effusion, Gastro-intestinal symptoms, pain and swelling in joints, neck stiffness, disorientation etc. and/or constitutional symptoms like significant weight loss, persistent fever > 2 weeks, night sweats.
 † Other tests: Body fluid examinations, Histopathology (FNAC, Biopsy), Radiology (X-ray, CT Scan, MRI), USG. NAAT must be offered to all patients found positive on smear microscopy.
 ‡ LPA (First and Second Line), Liquid culture on fresh specimen and isolate for DST for Moxifloxacin, Linezolid, Pyrazinamide and in future for Clofazimine, Bedaquiline and Delamanid (further details in PMDT guidelines in India 2021)
 § PLHIV, all contacts of bacteriologically confirmed pulmonary TB index patient, other risk groups (silicosis, immuno-compromised, organ transplant, hemodialysis, anti TNF-therapy, etc).
 ¶ For all risk groups except PLHIV, child contacts under 5 yrs.

Consider Hospitalization/ Consultation for presence of any one of the following* (III)

- BMI < 14.0 kg/m²
 - BMI 14.0–15.9 kg/m² AND (bilateral pedal oedema OR inability to stand without support OR no appetite)
 - Severe anaemia (Hb < 7 g/dL) with or without heart failure
 - Unstable vital signs—pulse rate > 100 per minute OR RR > 24 per minute / <12/min OR oxygen saturation < 94% OR systolic blood pressure < 90 mm Hg OR poor performance status (bed-ridden or extremely limited mobility)
 - Complications of PTB—Example, moderate–massive haemoptysis, hydro–pneumothorax
 - Complications of EPTB—Example, altered consciousness, seizures, lower limb paresis/ paralysis, suspected intestinal obstruction or perforation
 - Complications to anti-TB treatment—drug induced hepatotoxicity or seizures
 - Patients with comorbidities who need inpatient care to manage these comorbidities according to the judgement of the treating physician—Example, DM, HIV, liver or renal disease, alcohol addiction/ drug abuse
 - Discretion of the Treating physician based on the clinical scenario of the patient.
- *Technical Guidance For Comprehensive Package for Differentiated Care of TB patients

Public Health Action at Health Facility Level (II)



Treatment Regimens(IV)

Type of TB	Type of Regimen	Drugs	Extension Criteria
Drug Susceptible TB	DS–TB regimen	2 months H, R, E, Z 4 months H, R, E	In certain EP TB cases (Like TB Spine, Bone TB, etc) in consultation with the specialist
H mono/poly DR–TB	H mono/poly DR–TB regimen	6 months Lfx R, E, Z	Extension for 3 months in patients having: ▪ Uncontrolled comorbidity, ▪ Extra Pulmonary TB ▪ Smear positive at the end of 4th month.
MDR/RR and XDR TB	Shorter oral Bedaquiline–containing MDR/RR–TB regimen	(4–6 months) Bdq (6 months), Lfx, Cfz, Z, E, H [†] , Eto/ (5) Lfx, Cfz, Z, E	IP can be extended to 5th or 6 th month based on smear results at the end of 4 th and 5 th month of treatment.
	Shorter injectable containing MDR/RR–TB regimen [no new patient to be started on this regimen from April 2022]	(4–6 months) Mfx [‡] , Km/ Am, Eto, Cfz, Z, H [†] , E/ (5 months) Mfx [‡] , Cfz, Z, E	IP can be extended to 5 th or 6 th month based on smear results at the end of 4 th and 5 th month of treatment
	Oral Longer M/XDR–TB regimen*	(18–20 months) Lfx Bdq (6 months or longer) Lzd# Cfz Cs	If the 5m/4m culture report is negative Linezolid tapered to 300 mgs *For Pre–XDR/XDR–TB patients, duration has to be 20 months with appropriate regimen modification
TB Infection	TB preventive treatment	6H (6 months daily H monotherapy)	
		3HP (3 months weekly P & H – 12 dosages)	
		6Lfx (6 months daily Lfx in contacts of MDR/RR–TB with FQ sensitive index patient)	
		4R (4 months daily R in contacts of H resistant with R sensitive index patient)	

Follow up(V)

Regimen	Clinical + Wt	Smear	Culture	DST	Other Investigations (Bio– Chemical/ Radiological)	Long term FU
Drug sensitive TB regimen	Monthly	End of IP, end of Rx			CXR: End of treatment and as indicated; USG Abdomen if required for EP TB LFT: If required	6 monthly screening followed by testing 2 years by culture
H–mono/poly DR –TB regimen	Monthly	3m – 6/9m	3m, end of treatment (6m and/or 9m if applicable).	As per Guidelines for Program–matic Management of Drug Resistant TB in India 2021	CXR: End of treatment and as per requirement TSH & LFT: When indicated ECG: When indicated Electrolytes: If required	
Shorter MDR/RR –TB regimen	Monthly in IP, Quarterly in CP	3m to 4/6m, SM & LC within 7 days if SM+ at 6m or later	3m, 6m and/or end of treatment if applicable		CXR: End IP, If required TSH & LFT: End IP, If required ECG: 2 wks and monthly for 6 months	
Oral Longer M/XDR–TB regimen	Monthly up to 6/7/8 m Quarterly 7/8/9m	3m to 4/6m, SM & LC within 7 days, if SM+ at 6m or later	Monthly from 3m to 6/7/8m. Quarterly from month 6/7/8m If LC +		CXR: 6 months and end of treatment Electrolytes: if there is QTcF prolongation LFT: Every 3 months TSH: Every 6 months ECG: 2 weeks and monthly for 6 months	

Connecting patients/ citizens with National TB Elimination Programme (NTEP)(VI)

- Notification**
- Private providers notifying TB are paid Rs. 500 on notification and Rs. 500 on successful outcome.
 - Use Nikshay Login credentials for Nikshay Mobile App and Nikshay Dashboard for monitoring.
 - eSanjeevani – a web–based comprehensive telemedicine solution– May also be used for TB related problems.

- Adherence**
- ICT based adherence system: 99DOTS, MERM, VOT
 - Use Nikshay Login credentials for Prevent TB India Mobile App, Nikshay Mobile App and Nikshay Dashboard for monitoring.

- Patient support**
- Nikshay Poshan Yojana: Rs. 500/month for all TB patients as DBT for nutritional assistance
 - Travel reimbursement for TB patients @ Rs. 750 coming from notifiable tribal areas
 - Treatment supporter incentives @ Rs. 2000 for DS–TB & @ Rs. 5000 for DR–TB patients
 - TB Arogya Saathi Application: Information on TB: Symptoms of TB, Side effects, Health facilities, BMI assessment, Nutrition advice, Social support.
 - Scan and download: TB Arogya Saathi Application
 - Nikshay Sampark (Call Centre): 1800116666– For citizen/patients/care giver (Everyday from 7:00 AM– 11:00 PM)
 - Patients may also take the help of Emergency Response System (ERS) by dialing 108 for emergency services.
 - For any TB related updates and query may refer to Central TB Division website @ <https://tbcindia.gov.in/>

Definitions

- 4S screening:** Screening for 4 symptoms (cough, fever, weight loss and night sweat)
- Contact:** Is any individual who is exposed to a person with active TB disease.
- Contact investigation:** Is a systematic process for identifying previously undiagnosed people with TB disease and TB infection among contacts of an index TB patient and/or other comparable settings where transmission occurs. [Contact investigation consists of identification, clinical evaluation and/or testing and provision of appropriate anti–TB treatment (for people with confirmed with TB) or TB preventive treatment (for those without TB disease)].
- TB preventive treatment (TPT):** Treatment offered to individuals who are considered to be at risk of developing TB disease, in order to reduce that risk. [Also referred to as treatment of TB infection.]
- Tuberculosis infection (TBI):** Is a state of persistent immune response to stimulation by M. tuberculosis antigens with no evidence of clinically manifest TB disease. [There is no gold standard test for direct identification of M. tuberculosis infection in humans.]
- Rifampicin resistant TB (RR–TB):** A TB patient, whose biological specimen is resistant to R, detected using phenotypic or genotypic methods, with or without resistance to other anti–TB drugs. It includes any resistance to R, in the form of mono–resistance, poly–resistance, MDR or XDR.
- Pre–extensively drug resistant TB (Pre–XDR–TB):** TB caused by Mycobacterium tuberculosis strains that fulfil the definition of MDR/RR–TB and are also resistant to any fluoroquinolone.
- Extensively drug resistant TB (XDR–TB):** TB caused by Mycobacterium tuberculosis strains that fulfil the definition of MDR/RR–TB and are also resistant to any fluoroquinolone (levofloxacin or moxifloxacin) and at least one additional Group A drug (presently to either bedaquiline or linezolid (or both)).
- Multidrug–resistant TB (MDR–TB):** A TB patient, whose biological specimen is resistant to both H and R with or without resistance to other first–line anti–TB drugs. MDR–TB patients may have additional resistance to any/all FQ or any other anti–TB drug.

Abbreviations used

Bdq	Bedaquiline	ECG	Electrocardiography	IGRA	Interferon gamma release assay test	NAAT	Nucleic Acid Amplification Test	TPT	TB preventive treatment
BMI	Body Mass Index	EPTB	Extra Pulmonary TB	IP	Intensive Phase	P	Rifapentin	TSH	Thyroid stimulating hormone
Cfz	Clofazimine	Eto	Ethionamide	Km/Am	Kanamycin/Amikacin	PMDT	Programmatic management of Drug resistant TB	TST	Tuberculin sensitivity test
CP	Continuation Phase	FL–LPA	First line Line probe Assay	LC–DST	Liquid Culture Drug Susceptibility Testing	Pre–XDR	Pre extensively drug resistant	USG	Ultra sonography
Cs	Cycloserine	FQ	Fluoroquinolones	LFT	Liver function test	PTB	Pulmonary TB	VOT	Video observed treatment
CXR	Chest X–Ray	FU	Follow up	Lfx	Levofloxacin	R	Rifampicin	XDR	Extensively Drug resistant
DBT	Direct Beneficiary Transfer	H	Isoniazid	Lzd	Linezolid	Rx	Treatment	Z	Pyrazinamide
DM	Diabetes Mellitus	Hb	Haemoglobin	MDR/RR	Multidrug Resistant/ Rifampicin Resistant	SM	Sputum Microscopy		
DR–TB	Drug Resistant Tuberculosis	H [†]	High dose Isoniazid	MERM	Medication Event Reminder Monitors	SL–LPA	Second line Line probe Assay		
DS–TB	Drug Sensitive Tuberculosis	HIV	Human Immunodeficiency Virus	Mfx [‡]	High dose moxifloxacin	TBI	TB infection		
E	Ethambutol	ICT	Information and Communication technologies	MTB	Mycobacterium Tuberculosis				