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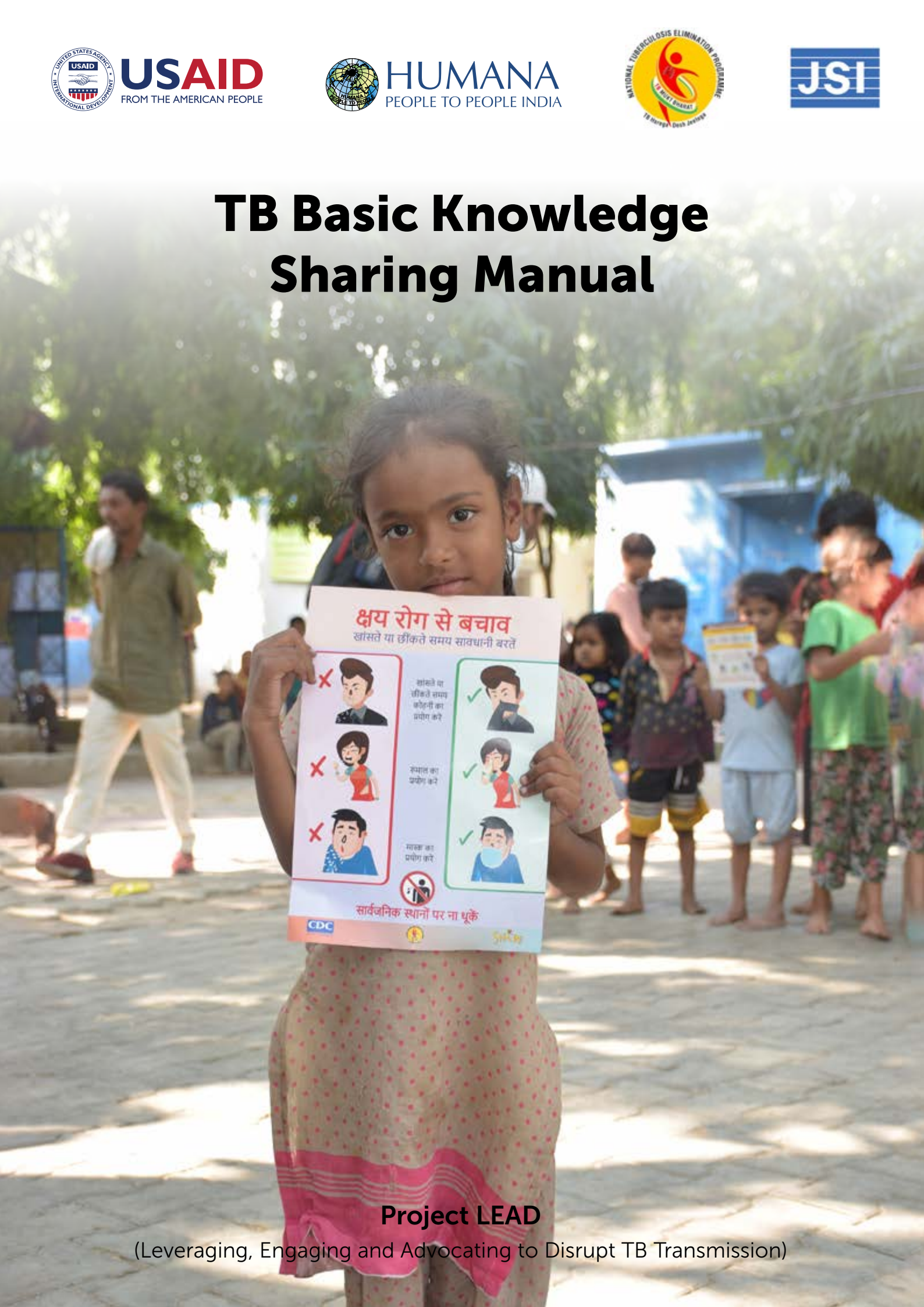
TB Basic Knowledge Sharing Manual



Project LEAD

(Leveraging, Engaging and Advocating to Disrupt TB Transmission)

TB Basic Knowledge Sharing Manual

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ACKNOWLEDGMENT

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OBJECTIVE

- To train the project staff and field officers of project LEAD on technical aspects of TB and TB programmes.
- To utilize the manual for other TB trainings of HPPI.

List of Content

CHAPTER ONE

BASIC TECHNICAL KNOWLEDGE OF TUBERCULOSIS, ITS DIAGNOSIS AND TREATMENT

What is Tuberculosis?

Tuberculosis or TB (in short form) is a disease caused by a germ (bacteria) named Mycobacterium Tuberculosis.

TB usually affects the lungs, but it can affect any part of the body except hair, teeth, and nails.

TB germs are widespread in the environment. Many of us may be carrying the TB germs inside our body in an inactive state. When the body immune system, which protects us from the diseases, becomes weak, the TB germs in the body become active and cause the TB disease.

Men are more affected by TB than women – the reason is not clear. Children constitute about 13% of all TB cases.

TB is a curable and preventable disease.

Types of Tuberculosis/TB

There are two types of TB according to the sites of the body which get affected by TB

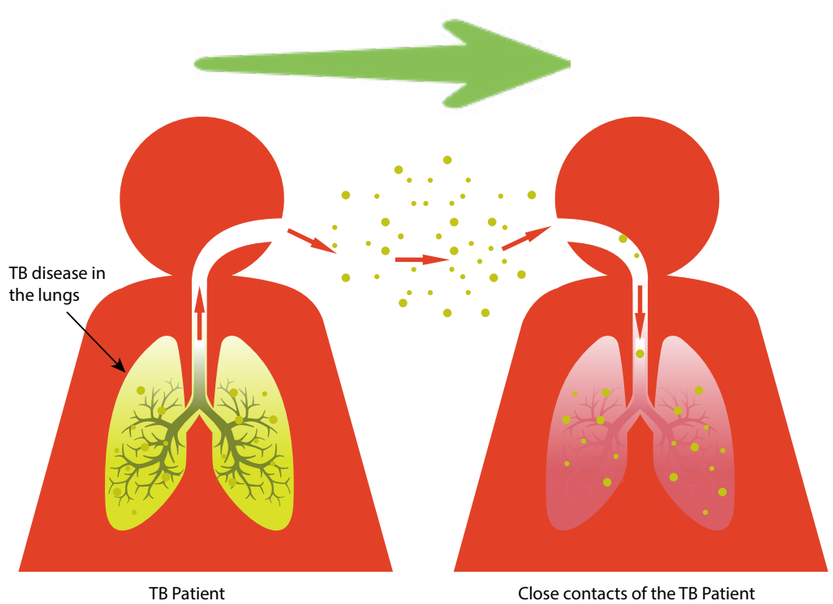
1. Pulmonary TB: - TB of the lungs, which is 80% of all TB cases
2. Extra-Pulmonary TB: - TB of any other organs of the body (other than lungs), like bones, joints, kidneys, lymph nodes, larynx, intestine, brain, which is 20% of all TB cases

There are two types of confirmation of TB according to diagnosis.

- Bacteriologically confirmed: When TB is diagnosed by detecting the germ or its genetic materials in the body, we call it a bacteriologically confirmed TB.
- Clinically diagnosed: When TB is diagnosed by other means, like clinical symptoms, findings of Chest X-Ray (CXR), family history, etc., but not by detecting the germ or its genetic materials in the body, we call it clinically diagnosed TB.

How is TB transmitted from one person to others?

PwTB	Close contacts (households, workplaces, hospitals)
When a patient of Pulmonary TB (TB of the lungs) coughs, sneezes, shouts or spits, he/she throws TB germs out in the air in the form of small droplets. Healthy persons around or close to the PwTB inhale those droplets and TB germs enter their lungs.	• Not everyone inhaling TB germs from the air gets TB disease. • TB disease doesn't occur immediately after exposure the TB germs but chances of getting TB remains highest during the first two years of exposure. • TB germs can remain inside our body lifelong, being inactive and without producing active TB. This is called latent TB or TB infection. • Active TB or TB disease can develop later in life when body immunity to fight the TB germs becomes weak and the germs become active inside the body and cause the disease.



Important lessons to learn.

- You might have TB germs in your body but in inactive form. You are healthy like the rest. We call it latent TB infection. Around 40% of India's population are estimated to have TB infection without active disease. There are specific medications to treat latent TB infection.
- If the body immunity becomes weak the inactive TB germs inside the body become active and cause the active TB disease. You must take medicines urgently to treat and cure TB disease in that condition.
- Remember, treatment of latent TB infection and treatment of active TB disease are different.
- Most importantly, a person suffering from active TB disease must cover his/her mouth properly during cough, sneezing or talking. This prevents the discharge of millions of TB germs from the mouth to the air and protects the people living in close contact of a person with TB from getting those germs in their bodies by inhaling them from the air. This is how you can prevent transmission of TB germs from one person to the other.

- Please remember that a PwTB stops discharging TB germs to the surrounding environment after 2-3 weeks of starting the treatment for TB. Therefore, it is very important to detect the PwTB early and start their treatment early. This would stop the TB germs from spreading through the air.

How does a child get TB?

A child gets TB in the same way as an adult, which is by inhaling TB germs/bacteria that are released into the air by someone with active TB. The source of infection for children is usually an adult in their household who has active TB, is coughing and is infectious, but not on treatment. There have also been occasional instances of children being infected in a communal setting such as a school. The source of infection can be either another TB-affected child or an adult.

Once the TB bacteria have been inhaled by a small child, they can directly reach the lungs, because in children the respiratory organs are small and yet to be fully developed. The bacteria can multiply and then spread through the lymph vessels to nearby lymph nodes. The child's immune response against TB comes into action a few weeks after this primary infection. In most children their immune responses stop the TB bacteria from multiplying further although they may continue to be dormant (latent or inactive) bacteria.

However, in some cases the child's immune system fails to stop the multiplication of the bacteria, and TB disease then develops. The risk of progression to TB disease is greatest when the child is less than four years old, and to a lesser extent when they are less than ten years old. There is also a greater risk of progression in children who have a compromised immune system, for example because they are HIV positive.

Overall, the chance of progression to active TB in small children is greater than in adults as they don't have a fully developed immune system.

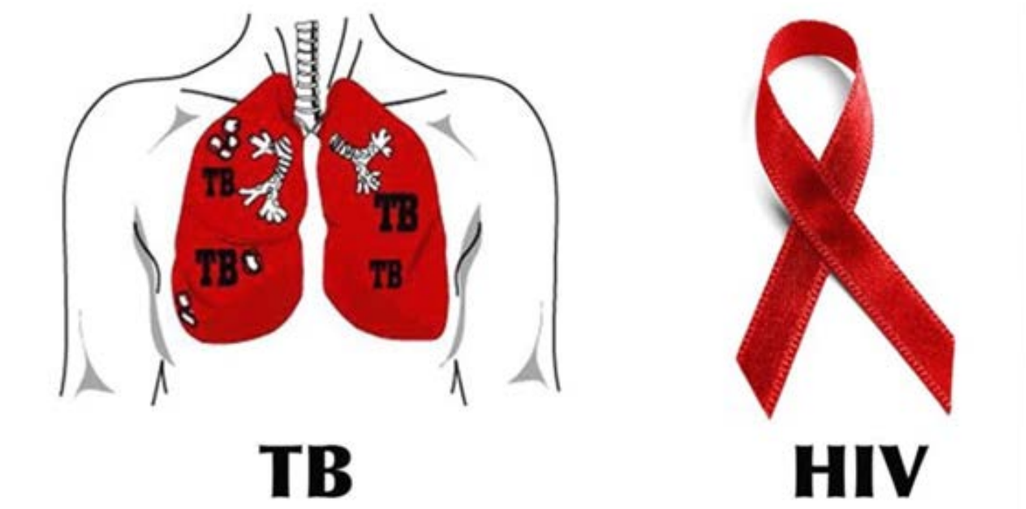
Children who develop TB disease usually do so within two years of first being infected. A small number of older children develop TB later, either due to reactivation following a period when the TB bacteria have been dormant, or because of reinfection.

Children who are at greater risk of getting TB include:

- A child who lives in the same household as a person who has been recently diagnosed with active pulmonary TB
- A child less than 5 years old
- A child with HIV infection or other disease which reduce body immunity
- A child with severe malnutrition and underweight.

What factors can lower body immunity and invite TB?

HIV (Human Immunodeficiency Virus) – If someone is infected with HIV, he or she has a much higher chance of getting TB infection and/or disease.



Other factors -

- Malnutrition
- Diabetes Mellitus
- Smoking and drug addiction
- Usage of steroid medicines, people suffering from chronic ailments and on anti-cancer drugs (cancer patients) for a long time.

Poverty, migration, unhealthy lifestyles in congested environments (slums and prisons), poor access to health services, gender inequity, and low-quality healthcare are driving forces of TB transmission.

Points to remember

- The people with TB who have more extensive damages and cavity formation in the lungs due to TB spread much greater number of germs in the air during cough and sneezing, so the risk of their close contacts getting infected by them is greater.
- The duration of contact with the PwTB is also important. The more time one spends in the close vicinity of a PwTB, the greater the risk of getting infected by TB.
- The risk of TB infection is >25 times higher among the contacts of bacteriologically confirmed PwTB compared to the general populations.
- TB germs remain in the air for a much longer period in closed, damp environments with no sunlight; therefore, people who stay in such environments, like congested slums, migratory colonies, dormitories and prisons cum correction homes, are at much greater risk of TB infection in the presence of a PwTB among them .
- Active TB – The TB disease where the person develops visual symptoms and signs of TB with damage of the lungs or other body organs and needs early treatment.
- Latent TB – TB infection or presence of inactive TB germs in the body of a healthy person, who does not require treatment for TB disease. But latent TB/TB infection can also be treated to reduce breakdown of TB infection to active TB. Treatment of active TB and latent TB are NOT THE SAME.

What are the symptoms of TB?

The symptoms of TB are,

- Persistent cough for more than 2 weeks
- Persistent fever for more than 2 weeks
- Chest pain
- Shortness of breath
- Blood in sputum
- Weight loss
- Loss of appetite
- Fatigue
- Evening rise of temperature
- Night sweats
- Symptoms of Extra-Pulmonary TB depend on the affected site

(Source: www.shutterstock.com)

Symptoms of Tuberculosis in small children

- Many children (up to half) will not have any symptoms in early stage of TB.
- Those who do are likely to have:
  - A low-grade fever (38°C) which continues over weeks rather than days
  - Cough which persists for two weeks or more
  - Associated loss of appetite, difficulty to thrive, irritability, night sweats, difficulty in breathing.
  - Swelling of neck-glands (glandular TB)

Points to remember in the case of TB in children

- TB in small children most of the time implies an undetected PwTB (adolescent or adult) in the family as a close contact.
- It is critical to screen all family members and close contacts well if a small child of the family is diagnosed with TB.

Symptoms of TB in people living with HIV & AIDS (PLHIV):

The screening of the **4-Symptom Complex** is critical to diagnose active TB in PLHIV. If any one of the symptoms is present in PLHIV, please test the person for TB urgently.

PLHIV (Adult)	PLHIV (Children)
Current cough	Current cough
Fever	Fever
Weight loss	Poor weight gain
Night sweats	Contact with a TB case

Points to remember.

An adult or child with TB symptom/s is called a presumptive TB case or TB symptomatic. Terminology like 'TB suspect' is no more in use to indicate people with TB symptoms.

All presumptive TB cases should go through the TB tests urgently as per NTEP algorithm, without delay, in their local health facilities.

For PLHIV and children the test of choice for TB diagnosis is Genexpert.

TB is not transmitted by a PwTB in conditions like,

- Sharing food, dishes, and utensils
- Sharing towels and linens, or other materials
- Handling food
- Shaking hands
- Using public toilets
- Blood transfusion and casual contact
- TB doesn't transmit from one generation to the other as a hereditary disease
- TB doesn't take place due to a curse of God or heinous acts in previous lives – these are myths about TB

Critical lessons

- TB bacteria can stay alive both in air and surface (ground).
- Not everyone inhaling TB germs from the air gets TB disease.
- TB disease does not occur immediately after inhaling (exposure to) the TB germs but the risk of getting active TB remains highest during the first t.wo years of exposure.
- TB germs can remain inside our body lifelong, being inactive.
- TB disease can develop later, even in much older phase of life in life when the body's immune system becomes weak and the TB germs inside the body then become active to produce the disease.

What is TB screening?

This is an exercise to detect the presumptive TB cases.

How TB Screening is done

- Screening of general population – symptomatic screening
- Screening by chest X-ray – It is done for people living in congregated settings like prisoners, slum dwellers and household contacts of PwTB.
- The best screening is a combination of symptomatic screening and chest X-ray

Screening approaches

- Screening in general population: Symptom screening or abnormal X-ray findings
- High-risk population/KVP: Modified symptoms (cough/fever any duration) plus X-ray

What we should do after screening: Test presumptive TB cases at the health facilities using standard TB diagnostic tests

Candidates of TB diagnostic tests

1) Persons with TB symptoms
2) CXR showing abnormal findings, suggestive of TB
3) Old PwTB who didn't complete treatment

How is TB diagnosed?

TB is diagnosed by the following confirmatory tests.

1) **Sputum microscopy –** Visualizing TB bacteria under the microscope with staining
   - Binocular microscopy
   - LED microscopy
2) **Sputum culture –** Help TB bacteria to grow their colonies in a suitable culture medium. Culture is the best diagnostic test of TB. We call it gold standard test.
3) **Rapid Molecular test –** detect genetic materials of the TB bacteria
   - Genexpert
   - Truenat
   - LPA (Line Probe Assay)

The tests like LPA or culture are used on later stage to detect TB bacteria which are resistant to different TB drugs. They are not primarily/first used to diagnosed TB.

The advantage of tests like Genexpert/Truenat is, besides detecting the bacteria, they can additionally tell us if the bacteria is resistant to Rifampin, the most potent medicine which is used to treat TB.

All these tests confirm presence of TB bacteria in the body, hence TB disease.

What body samples are generally tested for the diagnosis of TB?

- Sputum – most common
- Stool – in children
- Other tissues and body-fluids – to diagnose Extra-Pulmonary TB
- These specimens can be used for NAAT

Bio-marker test to diagnose TB (just for your information):

Most diagnostic tests for tuberculosis (TB) rely on sputum samples, which are difficult to obtain and have low sensitivity in immunocompromised patients, patients with disseminated TB, and children, thus delaying treatment initiation. The World Health Organization (WHO) calls for the development of a rapid, biomarker-based, non-sputum test capable of detecting all forms of TB at the point-of-care to enable immediate treatment initiation. Lipoarabinomannan (LAM) is the only WHO-endorsed TB biomarker that can be detected TB germs in urine, an easily collected type of sample.

Details about TB diagnosis

To diagnose TB, we generally examine the sputum samples of presumptive TB cases in the health facilities.

The sputum samples are tested,

- Under simple or LED microscope by a special staining process to see the presence of the TB germs (bacteria) in the sputum samples. If TB germs are seen under the microscope the patient has TB disease.
- In special culture media to see if the TB germs can grow there. If growing, TB disease is confirmed.
- With highly sophisticated, recent tests like Genexpert or LPA or Truenat, which can detect genetic materials of TB germs in the sputum samples or other body fluids. If present we become sure about TB.

If TB in a person is diagnosed by any of these tests, where presence of TB germ or its genetic materials is confirmed in sputum samples, we call it bacteriologically confirmed TB.

Sometimes, especially when TB germs can't be detected in sputum samples, TB is also diagnosed by a combination of

- Symptoms of the patients which are suggestive of TB
- History of exposure to PwTB within the family
- History of TB and intake of TB medication
- Abnormal findings on chest X-ray including the finding in MRI (Magnetic Resonance Imaging), CT scan (Computerized Topographic scan) and USG (Ultra- Sonography)

If TB in a person is diagnosed by these, we call it clinically diagnosed TB.

Extra-Pulmonary TB is diagnosed mostly by biopsy[1] = FNAC (Fine Needle Aspiration Cytology is a method of biopsy used to diagnose TB in glands of the necks, mostly in children)

[1] Biopsy: the removal of some tissues from somebody's body in order to find out about a disease that he/she may have

What is universal DST (Drug Susceptibility test)?

Universal drug susceptibility testing (DST) of TB: Tests used universally, at the primary healthcare level to diagnose TB, RR TB and MDR-TB, using rapid genotypic tests (cartridge-based nucleic acid amplification test CBNAAT - and line probe assay - LPA). UDST is done to rule out of drug resistance in every person with TB right after their TB diagnosis or at the time of their treatment initiation.

RR-TB: Rifampicin Resistant

MDR-TB: Multi-Drug Resistant TB

NAAT

1. CBNAAT: Cartridge Based Nucleic Acid Amplification Test
2. LPA: Line Probe Assay

Points to remember regarding Chest X-ray (CXR)

- Chest X-ray is not a TB confirmatory test.
- A personal with abnormal X-ray will be considered as a presumptive TB case. He/she should be evaluated with bacteriologically confirmation test if not done prior If not confirmed bacteriologically, and still considered as a TB case on clinical ground, it is known as clinically diagnosed TB. This means, Chest X-ray tells us if the patient is a presumptive TB case or not.
- Chest X-ray tells us if the patient is a presumptive TB case or not, although abnormal X-ray findings in symptomatic people along with other factors like family history/past history of TB and co-morbidities like HIV, diabetes, chronic lung diseases help to reach the clinical diagnosis of TB (clinically diagnosed TB).
- A person with TB suggestive signs in chest X-ray must be tested by a standard TB diagnostic test.
- Same principles are applicable to the chest CT scan

Portable X-ray machines: Essentially, a portable X-ray machine is an X-ray unit that's smaller than a fixed one and can be moved. It allows radiographers, vets and dental professionals to take X-ray images of patients without having to call them into a special lead-lined room.

Digital X-ray machines: Digital X-ray machines are like the digital cameras we have today. They still use X-rays as the standard X-ray machines; the only difference is that their sensors are connected to a computer and not a film. This enables modern X-ray to capture clearer and more accurate images as compared to its predecessor.

Point-of-care TB screening by using AI[2]-enabled portable, digital X-ray devices: The highly effective futuristic TB screening tool would be an AI-enabled, portable and digital chest X-ray solution which can be readily used in TB surveillance3, prevalence survey, and screening of the KVP (Key and Vulnerable Population) at the Point-of-Care4 settings. This can be performed in the community as well as in primary healthcare set-ups where the findings of the X-ray will be aided and interpreted near-accurately by the AI software without the presence of a specialist radiologist, and the result will be known at the spot. Such a screening approach will improve the yield of presumptive TB cases during community-level screening. The presumptive cases can also be tested upfront by using portable rapid molecular testing devices like Truenat in the field to reach the diagnosis of TB and Drug-Resistant TB on the spot.

Treatment Initation For DSTB :

Please remember, the treatment of TB must be initiated within 7 days of the diagnosis. The NTEP (National TB Elimination Program of India) targets more than 90% of the newly diagnosed TB patients (all types) to be initiated on treatment within 7 days of their diagnosis.

Initial lost-to-follow up: The people with TB who are not initiated on treatment after the diagnosis of TB, which can be due to,

1) Denial of TB diagnosis/doubt on TB diagnosis
2) Stigma
3) Fear of discrimination
4) Visit to other healthcare providers for re-consultation.
5) Lack of knowledge, education, and risk perception on TB of the PwTB
6) Improper and inadequate pre-test counselling of the patient at the healthcare facility
7) Migratory, mobile, and homeless people who have, in general, poor access to healthcare facilities.
8) PwTB addicted to alcohol and drugs.
9) Peer or family pressure to avoid taking anti-TB medications.
10) Wrong contact particulars provided by the patient by which he/she can't be tracked and retrieved on treatment initiation.
11) Systemic issues like wrong diagnosis, re-diagnosis.

Key activities of treatment initiation:

- A patient diagnosed with TB must be brought to the health facilities for registration and treatment initiation. Target: 0% Initial lost-to-follow up (for all TB projects of HPPI)
- Registration: Allotment of TB number (unique for every patient who are put on treatment)
- Along with treatment initiation at the health facilities, get the PwTB tested for
  - HIV
  - Diabetes and other comorbidities
  - Rifampicin resistance/Universal DST
- Bring the HH contacts of the PwTB to the health facility for screening and initiation of TPT (TB Preventive Treatment) OR visit the households of the PwTB, screen all the household contacts symptomatically and bring the symptomatic contacts to the health facilities for immediate TB diagnostic tests.

Please remember the primary principles of treatment

- Daily treatment regimen
- The Category II regimen is no longer used
- FDC – Fixed Dose Combination is used
- Dose depends on weight of the patient

Treatment of DSTB

DSTB is treated by the following drugs as shown below. Drugs used to treat DSTB are called First-line drugs (FLDs)

The FLDs are

i. Rifampicin/R
ii. Isoniazid/H
iii. Pyrazinamide/Z
iv. Ethmabutol/E

Treatment are given in two phases:

Intensified phases / LP = first 2 months

Continuation phase /CP = last 4 months

Streptomycin injection is not routinely used. It is used for a limited number of complicated TB cases, if decided by the doctor/Medical Officer

What is FDC (Fixed Dose Combination)?

Fixed Dose Combinations (FDCs) refer to products containing two or more active FLDs in the following forms and used in NTEP for the treatment of the PwTB

- For Adults - 4-FDC (given in IP) consists of HRZE and 3-FDC (given in CP) consists of HRE
- For pediatric: 3-FDC + E dispersible (IP) and 2 FDC + E dispersible (CP

What are the advantages of FDCs?

- Simplicity of treatment
- Increased patient acceptance
- Fewer tablets to swallow
- Prevents 'concealed' irregularity
- Increased health worker compliance
- Fewer tablets to handle, hence quicker supervision of DOT
- Easier drug management
- Reduced use of monotherapy
- Lower risk of misuse of single drugs
- Lower risk of emergence of drug resistance
- Easier to adjust dosages by body weight
- Reduce recurrence

Why are 4 drugs to be taken together ?

- It has been scientifically proved that the combination of 4 drugs treat the TB best and enhances the cure by acting against naturally occurring resistant bacterial strains
- It minimizes relapse of TB and drug-resistance
- How the 4 drugs work:
  - Isoniazid works by preventing the TB bacteria from forming their own protective covering that prevents their damage
  - Rifampicin inactivates a bacterial enzyme (RNA-polymerase) which is required by TB bacteria to make essential proteins and to reproduce.
  - Together, they kill the bacteria and eradicate the infection.
  - Ethambutol and pyrazinamide on the other hand, work by slowing the growth of these bacteria.

How is TB treated?

Please remember, TB is a fully curable disease, if the treatment can be completed successfully, along with the treatment of other comorbid conditions like HIV and diabetes, if they are present.

For treatment purposes the PwTB are further categorized into -

- **New:** Someone to be treated for the first time for TB OR someone treated for TB previously for less than one month
- **Previously treated:** Already treated for TB in the past or more than one month.
  - **Relapse/Recurrence:** Had TB before, put on treatment, got cured from TB after successful treatment completion but became sputum positive again
  - Relapse can be due to
    - **Re-infection:** Fresh bout of infection with same or different strain of TB germs
    - **Reactivation:** The dormant strain which caused the TB disease earlier becomes active and produces the disease again
  - **Lost-to-follow up:** Had TB before, put on treatment, but remained without medication for more than one month.
  - **Treatment Failure:** Had TB before, put on treatment, but remained sputum positive after 5 months of treatment.
  - ***Please remember that previously treated patients are much more prone to Drug- Resistant TB***
  - ***Both New and Previously treated patients are treated with the first-line drugs unless diagnosed as Drug resistant TB.***

AND

- **Drug Susceptible TB (DSTB):** Person diagnosed with drug-susceptible (DSTB)TB are treated with first-line drugs/FLDs (Roughly 95% of total patients)
- **Drug Resistant TB (DRTB):** Persons diagnosed with drug-resistant TB (DRTB) are treated with second-line drugs/SLDs (Roughly 5% of total patients)

We will describe the treatment part separately for DSTB and DRTB.

- 4-Drug FDC should be taken on an empty stomach or with little breakfast (morning)
- Vitamin B6/Pyridoxine should be taken daily during the entire period of TB treatment to prevent/ minimize damage of the nerves which is caused mostly by Isoniazid

[2] AI – Artificial Intelligence
[3] Surveillance: Disease surveillance is an information-based activity involving the collection, analysis, and interpretation of large volumes of data originating from a variety of sources. The information collated is then used in several ways to evaluate the effectiveness of control and preventative health measures.
[4] Point-of-Care Testing: Point-of-care testing (POCT) is a form of testing in which the analysis is performed where healthcare is provided close to or near the patient.

Treatment Regimen for DSTB (NTEP)		
Type of TB	**Intensive phase (IP)**	**Continuation phase (CP)**
New Patient / Previously treated	2HRZE (2 months treatment)	4HRE (4 months treatment)

Treatment is given in two phases:

- Intensive phase (IP) 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.
- Continuation phase (CP), 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 may be extended by 12-24 weeks in certain forms of TB like CNS TB, Skeletal TB, Disseminated TB etc. based on clinical decision of the treating physician on case to case basis. Extension beyond 12 weeks should only be on recommendation of specialists.

Please remember, Injection Streptomycin (S) is not routinely used to treat PwTB. It is only used at the discretion of the doctors/Medical Officers who treat the PwTB. In general, streptomycin injection is only used in case of complicated forms of TB (TB meningitis, miliary TB), but not used in most other forms of TB.

The doses of TB drugs depend on the body weight of the person with TB. For adults the following daily dosage schedule (as per weight bands)

Daily Dose Schedule for Adults (as per weight bands)

Weight Category	Number of tablets (FDCs)	
	Intensive Phase HRZEE	Continuation Phase HRE
	75/150/400/275	75/150/275
25-34 kg	2	2
35-49 kg	3	3
50-64 kg	4	4
65-75 kg	5	5
> 75 kg	6	6

(Doses of injection Streptomycin is only calculated in case it is prescribed by the doctor/Medical Officer, otherwise not)

Drug Dosage for Pediatric TB

Weight Category	Number of tablets (dispersible FDCs)			Inj. Streptomycin
	Intensive Phase		Continuation Phase	
	HRZ	E	HRE	
	50/75/150	100	50/75/100	mg
4-7 kg	1	1	1	100
8-11 kg	2	2	2	150
12-15 kg	3	3	3	200
16-24 kg	4	4	4	300
25-29 kg	3 + 1A	3	3 + 1A	400
30-39 kg	2 + 2A	2	2 + 2A	500

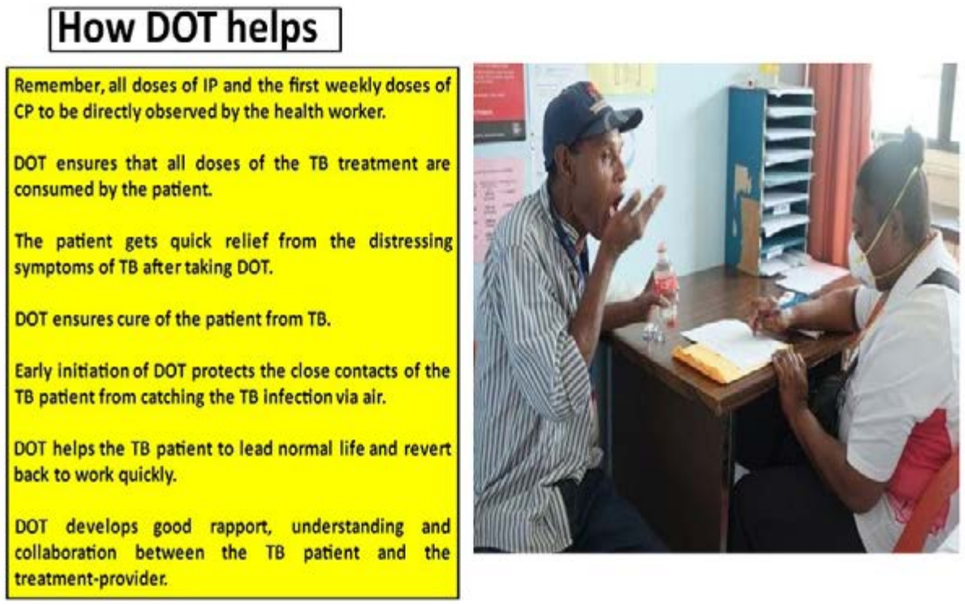
A=Adult FDC (HRZE = 75/150/400/275: HRE=75/150/275)

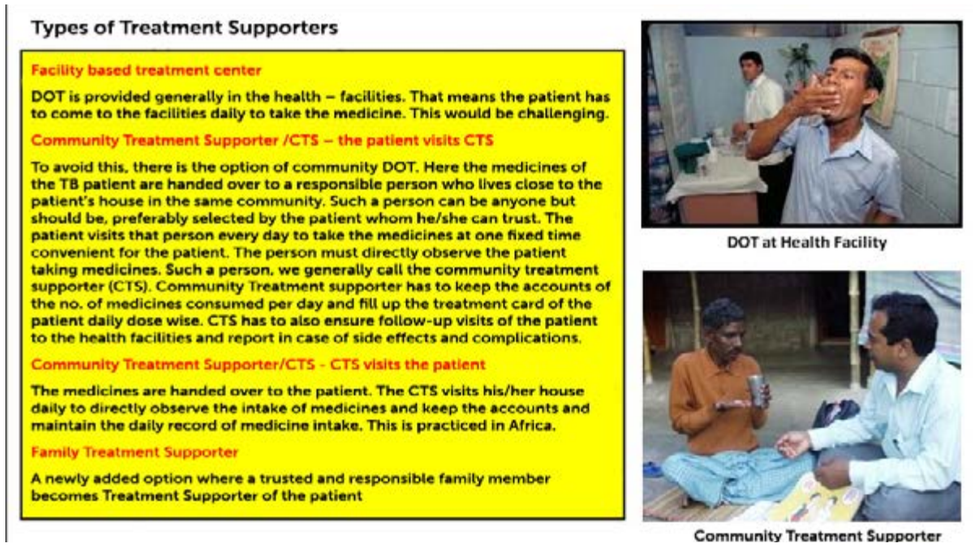
Shorter regimen to treat drug-susceptible TB

The 4-month high-dose, daily rifapentine-moxifloxacin TB treatment regimen was found to be as effective as (noninferior to) the standard daily 6-month regimen in curing drug-susceptible TB disease, according to clinical trial findings. This regimen is not currently available in the NTEP.

Key aspects of DSTB treatment

- TB is a curable illness. It can be cured even in PLHIV.
- TB can't be treated by one or two drugs but multiple drugs. The treatment continues for minimum 6 months up to 9 months or as advised by the doctor.
- The first 2-3 months the patient must take 4-5 medicines on daily basis (we call it intensified phase or IP) and the rest of the months 2 medicines again on daily basis (we call it continuation phase or CP).
- The medicines are to be taken under direct observation of a health worker in the health facility or a community worker in the community during the whole of the intensified phase and for the first weekly dose across the continuation phase. We call it DOT (Directly Observed Treatment).
- Follow-up sputum tests to be done at the end of IP and the end of CP.
- No dose should be missed, and the course should be completed by all means, to get a complete cure from TB and to prevent relapse.
- In case of co-infection with HIV, the TB medication should be started first. The ART should be started afterwards, at least 2-3 weeks later when TB medicines are well tolerated by the patient and to be continued. When the full course of the TB treatment is complete the patient should continue the ART without any break.
- It is important for the patient to go through the follow-up sputum test after the end of TB treatment.
- WHO recommends post-treatment TB Preventive Treatment for the PLHIV who completed TB treatment.





DOT at Health Facility

Community Treatment Supporter

Incentives of Community Treatment Supporter from the NTEP after successful completion of treatment of their PwTB

- A Community Treatment Supporter will receive an incentive of
  1) 1000 INR for DS (Drug Susceptible) TB
  2) 5000 INR for DRTB

How to supervise the activities of the Community Treatment Supporter

- Pill counting from the Patient-wise Box
- Check the treatment card, which is kept with the Community Treatment Supporter, if doses documented tally with the pills consumed from the patient-wise box
- Interview the patient
- Monitor the improvement of the health and well-being of the patient

How do you know that the PwTB is improving through the treatment?

- Gradual disappearance of TB symptoms which will be replaced by positive symptoms like increase of appetite, increase of body weight, etc.
- Absence of TB germs in the sputum samples of the follow-up examinations.

Contact Screening:

All household members of the PwTB (known as Contacts) who stay with him or her should be symptomatically screened for TB. In case of active TB is detected, he or she should be initiated on DOT. We call it contact screening.

- All children below 5 years of age who are the direct contacts of a PwTB and not having active TB disease should be given a 6-months preventive dose of INH. Similarly, PLHIV without active TB disease should also be given the same prophylaxis.
- The NTEP now recommends preventive treatment for all household members of the index TB patients if they don't have active TB.
- We will describe it separately under programmatic management of Latent TB Infection (LTBI)

Side effects of TB medicines

Common side effects of TB medicines that we should know

Minor side-effects – here the patient should continue the medicines without interruption

- Loss of appetite, Abdominal pain, Nausea
- Joint pain
- Sensation of burning in feet
- Red or orange coloration of the urine

Major side-effects – here the patient should visit the doctor of the health facility immediately after the appearance of the side-effects

- Deafness
- Yellowish discoloration of urine, eye, and body
- Visual impairment
- Shock, abnormal urination, skin rashes, body itching
- Psychiatric manifestations, depression, suicidal thoughts/attempts

NTEP's definition of treatment outcome of the PwTB

Treatment Outcomes – standard definitions

Outcome	Definition
Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last month of treatment and on at least one previous occasion
Treatment completed	A TB patient who completed treatment without evidence of failure *but* with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable
Treatment failed	A TB patient whose sputum smear or culture is positive at month 5 or later during treatment
Died	A TB patient who dies for any reason before starting or during the course of treatment
Lost to follow-up	A TB patient who did not start treatment or whose treatment was interrupted for 1 month or more
Not evaluated	A TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit.
Treatment success	The sum of *cured* and *treatment completed*

Source: NTEP

Under what conditions does the TB treatment become difficult and/or ineffective?

- Poor adherence to medicines due to side effects, alcoholism, etc
- Resistance to TB-drugs/FLDs
- HIV co-infection
- Diabetes
- Other underlying illnesses of lungs and other body parts
- Chronic malnutrition
- Smoking
- Mental illness, substance abuse
- Chronic liver illnesses like chronic Hepatitis B and C, liver cirrhosis

Treatment of Drug-Resistant TB (DRTB)

What is DRTB?

The TB bacteria becomes resistant to one or more FLDs. We call it drug-resistant TB.

Detailed categorization of DRTB

- Mono-resistant TB: The TB bacteria are resistant to any one of the FLDs
- Multi-Drug resistant TB/MDR: The TB bacteria are resistant to both Isoniazid and Rifampicin with or without being resistant to other FLDs
- Rifampicin resistant: The TB bacteria are resistant to Rifampicin. Rifampicin resistant is included under MDR.
- Isoniazid resistant: The TB bacteria are resistant to Isoniazid
- Poly-resistant TB: The TB bacteria are resistant to more than one FLDs, other than Isoniazid and Rifampicin
- Extensively Drug Resistant (XDR) TB is the worst form of Drug-Resistant TB, where the TB germs turn resistant to the drugs which are used to treat MDR-TB. Less than 50% of MDR-PwTB can successfully complete their treatment. Treatment of XDR -TB is more complicated with poor chance of recovery for the patient

Second-line drugs/SLDs

- When TB bacteria become resistant to FLDs, we treat the patients with drugs known as Second-Line Drugs/SLDs. The most important SLDs are fluoroquinolones (FQs) like Ofloxacin, Gatifloxacin and Moxifloxacin. There are more than 10 SLDs.
- XDR TB (Extensively Drug-Resistant TB): In an already MDR PwTB , where FQ resistance is also detected. So, MDR + FQ resistance = XDR TB
- Names of other important SLDs
  - Bedaquiline
  - Delamanid
  - Linezolid

Please remember

- DSTB can be treated only by using FLDs
- DRTB can be treated with a combination of FLDs (those not resistant) and SLDs, or only by SLDs

Types of drug resistance

- Primary resistance occurs in persons who are initially infected with resistant organisms.
- Secondary resistance, or acquired resistance, develops during TB therapy, because the patient was treated with an inadequate regimen, because the patient did not take the prescribed regimen appropriately, or because of other conditions such as drug malabsorption or drug interactions that led to low serum levels.

Reasons of Drug-Resistant TB

- Genetic mutation of the bacteria (change of genetic material of the bacteria that makes it resistant to specific anti-TB drugs)
- Poorly administered treatment regimen - People do not complete a full course of TB treatment.
- Suboptimal doses of the medicines are prescribed to treat TB
- Health care providers prescribe the wrong treatment (the wrong dose or length of time)

Side effects of TB medicines

DST: Drug Susceptibility Test, means the test which tells us if the TB bacteria is susceptible to an anti-TB drug.

Universal DST: Universal access to rapid DST for at least Rifampicin and further DST for FQs among those who are Rifampicin resistant

Please remember

Injectable medications are not routinely used to treat DRTB patients as per the newer treatment guidelines

Detailed diagnosis of DRTB

- In an ideal situation, a PwTB should go through DST for all available anti-TB drugs (both FLDs and SLDs). However, that is not practically possible as it takes a lot of time to know the results of the susceptibility testing and those tests are very expensive and resource intense.
- So, primarily, we look for resistance to 3 main anti-TB drugs in a newly detected PwTB. 2 of them are FLD (Rifampicin and Isoniazid) and 1 of them is SLD (Fluoroquinolones/FQ).
- Rifampicin – For that we conduct a rapid molecular test like CBNAAT. This can be done at the PHCs by using Genexpert and even at the mobile clinics by using Truenat MTB machines.
- Isoniazid – for that we conduct a test named LPA (Line Probe Assay). This can be done in the reference labs at the higher-level health facilities.
- FQ – If the patient is found to be MDR-TB (resistance to Rifampicin and Isoniazid), he/she is further tested for FQ resistance by using LPA. This can be done in the reference labs at the higher-level health facilities. Resistance to FQ gives us the diagnosis of XDR (MDR + FQ resistance).

Treatment of DRTB – the following cascade of care is generally followed to treat DRTB

- Pre-treatment evaluation/PTE, including screening for HIV and DM
- Treatment initiation – depending on types of resistance
  - Short oral treatment regimen
  - Long oral treatment regimen
  - Customized treatment
  - Pediatric treatment
- Counseling
- Management of adverse drug reactions
- Follow up – sputum culture and clinical examination
- Notification to NIKSHAY
- Contact screening and TPT
- Post-treatment follow-up

Four key WHO-recommended regimens for DRTB treatment (for information only)

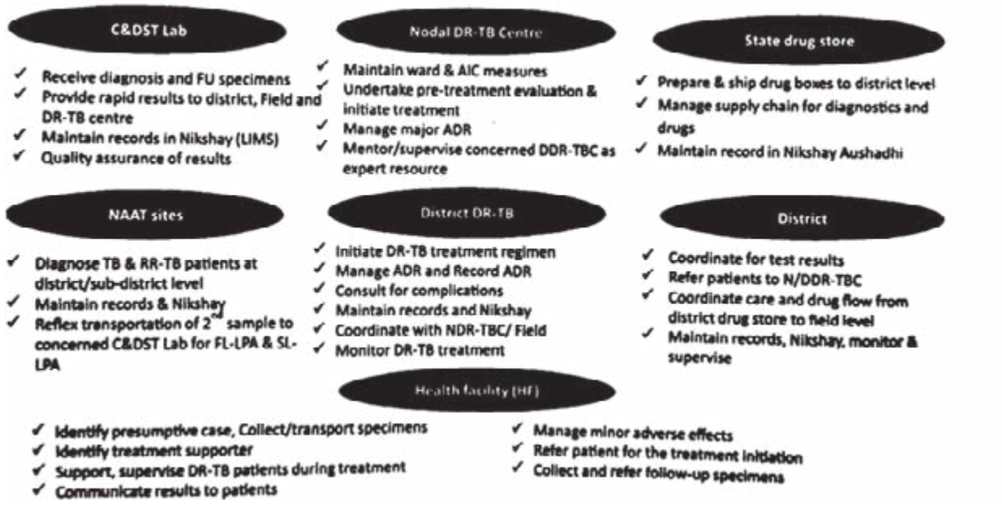
- Regimen for rifampicin-susceptible and isoniazid-resistant tuberculosis, X 6 months
- Shorter all-oral bedaquiline-containing regimen for multidrug- or rifampicin-resistant tuberculosis, X 9-12 months

- Longer regimens for multidrug- or rifampicin-resistant tuberculosis, X 18 months
- The bedaquiline, pretomanid and linezolid (BPaL) regimen for multidrug-resistant tuberculosis with additional fluoroquinolone resistance, X 6-9 months

How to prevent/minimize drug resistance

- Early diagnosis of TB (all types), early treatment initiation and successful treatment completion by a strong NTP
- Strengthen counselling and health education to ensure treatment adherence
- Reduction of stigma and discrimination related to TB
- Strengthen ADR (adverse drug reaction) management
- Minimize out-of-pocket expenditure
- Facilitate civic amenities like issuance of Aadhaar card and bank account, linkage to social welfare schemes
- Special care for those who become chronic lost-to-follow-up, previously-treated PwTB, and co-infected (TB-HIV) patients

Programmatic management of DRTB (PMDT) – the NTEP structure



Treatment of latent TB infection (LTBI)

What is latent TB Infection?

- Latent – Inactive
- TB – TB bacteria
- Infection – Presence in the body
- LTBI is the presence of inactive TB bacteria in the body, which cannot produce TB disease in normal conditions or under a strong immunity.
- A healthy person can very well have LTBI, but no TB disease.
- In a community where the TB burden is high, many people have LTBI, but they don't suffer from active TB disease, as their immunity is strong.

Who are vulnerable to LTBI?

- The household and close contacts of the index PwTB (mostly, Pulmonary TB)
- People living with HIV and AIDS
- People with weak body immunity

Why should we treat LTBI?

Because,

- LTBI can produce active TB disease when the body immunity becomes weak in conditions like,
  - HIV infection
  - Under-nutrition
  - Diabetes
  - Drug addiction and alcoholism
  - Presence of cancer, chronic kidney diseases
  - Patients who are taking drugs like steroids, anti-cancer drugs for a long time

Please remember

By treating LTBI, we can reduce the chances of the conversion of TB infection to active TB disease.

And this helps in reducing the number of new PwTB and subsequently the TB incidence, which is critical to achieve TB elimination.

Treatment of latent TB: Treatment of LTBI is known as **TB Preventive Treatment or TPT Who will be the most eligible candidates of TPT?**

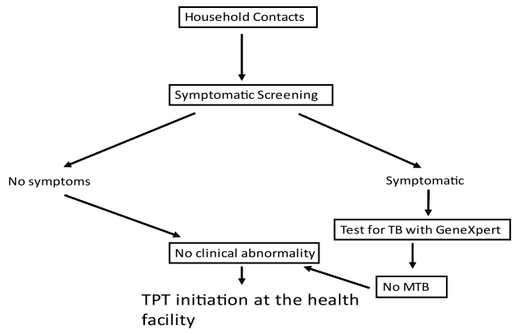
- All household contacts of the index Pulmonary PwTB
- PLHIV

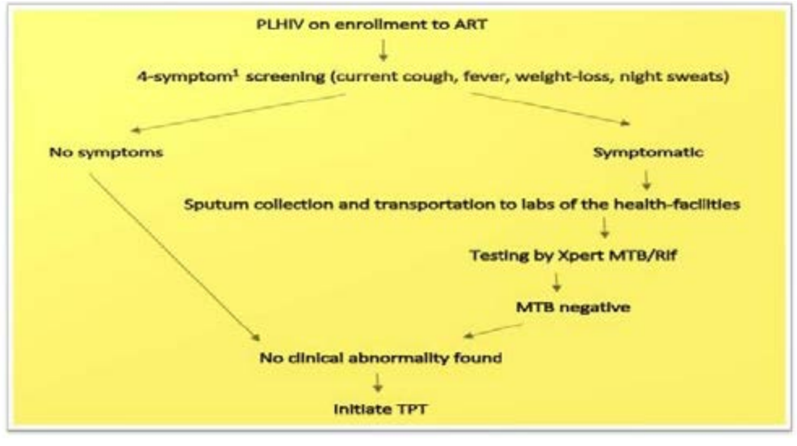
Please remember, that the candidates of TPT shouldn't suffer from active TB. This can be ensured by compulsory and meticulous screening of all those eligible candidates for the presence of TB symptoms, and testing them for TB if symptoms are present, preferably by rapid molecular test (already described before). The screening of the household contacts is known as contact screening as mentioned before.

Please remember, if the person suffers from active TB, but is not diagnosed for that, and given TPT, that will be extremely harmful for the person. Therefore, TB screening is very critical before initiating TPT.

TPT Algorithm – household contacts

Algorithm for TPT initiation among household contacts (for field operation)





Standard treatment regimens of TPT

- INH - Daily X 6 months (180 doses) – the regimen in use in the NTEP (6INH)
- Rifampicin – Daily X 4 months (4R)
- Isoniazid plus rifampin – Daily X 3 months (3HR)

Shorter treatment regimen in NTEP

- 3HP (Isoniazid plus Rifapentin) – Weekly dose X 3 months (12 doses) – under trial
- 1HP (Isoniazid plus Rifapentine) – Weekly dose X 1 month (4 doses) – under trial

TPT for HH contacts of the DR PwTB – under trial

International guidelines have recently proposed fluoroquinolones for tuberculosis preventive therapy (TPT) in DR-TB contacts, although the available evidence is low quality. The pooled data from small observational studies suggest that a fluoroquinolone-based TPT is safe, effective, and cost-effective as a preventive treatment in DR-TB contacts.

Please remember

- After initiation of treatment, successful completion of treatment of LTBI is very important.
- The most challenging part is to convince a healthy contact to take medicines and complete the course, especially its long course like 6INH

How to ensure completion of TPT for all HH contacts (poor evidence at present)

- Thorough education on TPT to the HH members and why it is needed
- Regular follow up after TPT initiation
- Motivation for treatment completion
- Check for drug side effects like
  - Tingling, numbness and weakness of hands and feet
  - Inform the health facility immediately in case of drug side efects

Operational tips for successful TPT

- When you bring the newly detected PwTB to the health facilities for their treatment initiation, bring their household contacts to the facilities on the same day for TB screening and TPT initiation to take part in the same round of treatment education and counselling as the index PwTB.
- The same community Community Treatment Supporter of the index PwTB should also supervise the TPT of their household contacts.

Management of TB and its co-morbidities

What are the co-morbidities of TB?

There are strong associations between active TB disease and other Communicable diseases or Non-Communicable Diseases (as listed below), and they can affect the patient together, thus making the case management more challenging. We call it TB co-morbidities.

- Communicable diseases
  - HIV and AIDS
  - Hepatitis B and C
  - Covid19
- Non-Communicable Diseases (NCDs)
  - Diabetes mellitus
  - Smoking
  - Alcohol use disorders, drug addiction
  - Chronic lung diseases, like asthma, bronchitis, occupational lung diseases
  - Cancer
  - Depression and other mental illnesses
- In a community where the TB burden is high, many people have LTBI, but they don't suffer from active TB disease, as their immunity is strong.

Brief descriptions of the diseases commonly observed as co-morbidities of TB HIV and AIDS

HIV (human immunodeficiency virus) is a virus that attacks the body's immune system. If HIV is not treated, it can lead to AIDS (acquired immunodeficiency syndrome).

Once people get HIV, they have it for life. An HIV-infected person can remain symptom-free for many years (chronic HIV infection). However, if his/her blood is tested, the diagnosis of HIV is confirmed. During this phase the person can transmit the virus to others.

AIDS is the final stage of HIV infection characterized by multiple infections in the body due to severe damage of the immune system. If not treated, the person suffering from AIDS survives for a short time only.

How HIV can be prevented

1) Abstinence from sex
2) Being faithful to the spouse (having one sexual partner only)
3) Protected penetrative sexual acts, by current and consistent use of condoms
4) Compulsory screening of blood before transfusion
5) Complete prohibition of sharing of needles and syringes
6) HIV counselling and testing during pregnancies
7) Periodic HIV counselling and testing of high-risk groups, like sex workers, people who inject drugs, MSM (Men who have sex with men), transgender persons, migratory and mobile people

Treatment of HIV

With proper medical care, HIV can be controlled. People with HIV who get effective HIV treatment can live long, healthy lives and protect their partners. We call it Anti-Retroviral treatment or ART. ART is provided to the patients with multiple anti-retroviral drugs. ART can't kill the HIV but stops its multiplication in the body and makes it inactive. So, HIV can't damage the immune system anymore, and the body remains healthy even in the presence of HIV. The person should take ART lifelong. Adherence to ART can also make the HIV-infected person less infectious to others. ART is regarded as an effective tool to minimize the transmission of HIV in the community. To expand the coverage, ART should be initiated soon after the person is detected as HIV-positive.

How TB and HIV are co-related

HIV enhances activation of TB infection and development of active TB disease. TB enhances progression to the phase of AIDS from chronic HIV infection. The presence of both diseases makes case management difficult.

All newly diagnosed PwTB should be counselled and tested for HIV, if found to be positive they should be initiated on ART along with the TB drugs.

According to the latest Annual Report of Central TB division, Ministry of Health, at least 3% of the newly diagnosed PwTB are found to be infected with HIV with geographic variations.

Diabetes

We should eat the right quantity of different kinds of food with the right balance of carbohydrates, protein, fat, vitamins, and minerals to remain healthy, especially women during pregnancy.

What happens to those foods after we eat them? The food we eat breaks down into its simpler forms by the action of special chemical agents inside our digestive system known as 'enzymes'. The simpler form of food then enters the blood stream from the digestive system and is carried to the tissues of the body for nourishment and energy production.

Please remember that food rich with carbohydrates is essential to produce energy in our body so that we can do all our day-to-day work efficiently with that energy.

How do carbohydrates produce energy? Carbohydrates are broken down to its simplest form in our digestive system and that form is known as glucose. Glucose then enters the blood stream from the digestive system and is carried to the tissues of the body. The tissues utilize the glucose to produce energy.

Under what conditions can't glucose in the blood enter the tissues of the body and thus fails to give them the necessary energy? The entry of glucose from the blood to the tissues depends on the presence of a hormone named 'insulin'. Insulin is produced in a special gland of our body called the pancreas. The pancreas is located behind the upper portion of our digestive tract.

Entry of glucose from blood to the tissues of the body can be hampered in two ways:

- If production of insulin by the pancreas is much less than what is needed, glucose can't enter the body tissues.
- Secondly, the insulin is produced by the pancreas in sufficient amount but due to some reason or other the insulin is not effective to push the glucose from the blood to the tissues.

In both cases, tissues have less glucose than needed to produce energy. This is because most of the glucose remains in the blood and our body tissues can't utilize it, either due to insufficient insulin or ineffective insulin. Glucose gives us energy to do our day-to-day work. When our body tissues have less glucose, they do not get enough energy to do daily work. Therefore, you will feel tired and weak even after doing little work.

This condition is actually a disease, and we call it Diabetes Mellitus or simply diabetes.

What are the risk factors of Diabetes?

- High blood pressure
- High fat level in the blood
- Age over 45
- Overweight
- Family history of Type 2 diabetes
- Prolonged alcohol intake
- Lack of exercise and physical inactivity
- Sustained stress and anxiety
- Diabetes during pregnancy[7]

Please remember the normal blood glucose level is as follows:

- Fasting: 90 - 120
- 2 hours after food intake: below 180
- Random (any time after food intake): Less than 140

Symptoms of diabetes

- Many a time diabetes has no symptom, and the person is found to be diabetic after a blood test only Diabetes can also produce the following symptoms:
- Being very thirsty
- Being very hungry
- Weight loss despite continuous eating
- Frequent passing of urine
- Blurring of vision
- Tingling or numbness in hands or feet
- Frequent infections in the skin, external genitalia, urinary tract, gum
- Wounds that don't heal easily
- Extreme unexplained fatigue accompanied by nausea, vomiting and persistent headaches
- Sexual impotence

How to prevent diabetes

- Reduce body weight if you are obese
- Reduce high blood pressure
- Avoid irregular intake of food
- Do regular exercise – brisk walking, cycling and swimming are best to prevent diabetes
- Avoid a stressful life – go for meditation and yoga
- Check your blood sugar regularly, at least every 6 months

How TB and diabetes are corelated

Diabetes delays the cure from TB even after treatment initiation. Tuberculosis can accentuate diabetic conditions.

All PwTB should be screened for diabetes in the NTEP. Around 14% of the newly diagnosed patients are found to be diabetic.

[7] Sometimes, blood sugar level abnormally rises due to imbalance of hormones in the body during pregnancy.
The blood sugar level generally becomes normal after the pregnancy. owever, diabetes during pregnancy may continue or relapse after the pregnancy in some women. The children who are born of the pregnant mothers may also become diabetic.

Mental illnesses:

Depression is a common co-morbidity of tuberculosis (TB) and is associated with poor adherence to treatment. Clinical depression, if co-morbid with TB, is also associated with increased morbidity, mortality, community TB transmission, and drug resistance. Depression may increase risk of TB reactivation, contribute to disease progression, and/or inhibit the physiological response to anti-tuberculosis treatment. Tuberculous infection and/or disease reactivation may precipitate depression. Clinical depression may also be triggered by TB-related stigma, exacerbating other underlying social vulnerabilities, and/or may be attributed to the side effects of anti-tuberculosis treatment. Depression may negatively impact health behaviors such as diet, healthcare seeking, medication adherence, and/or treatment completion. As several of the core symptoms of TB and depression overlap, depression often goes unrecognized in individuals with active TB, or is dismissed as a normative reaction to situational stress. The World Health Organization's Global End TB Strategy calls for integrated patient-centered care and prevention linked to social protection and innovative research. It will require multidisciplinary approaches that consider conditions such as TB and depression together, rather than as separate problems and diseases, to end the global TB epidemic.

Covid-19

Coronavirus disease 2019 (COVID-19) coinfection with other respiratory pathogens poses a serious concern that can complicate diagnosis, treatment, and prognosis. Since Covid-19 and tuberculosis are both severe respiratory infections, their symptoms may overlap and even increase mortality in case of coinfection.

TB CO-MORBIDITY MANAGEMENT

What are the overall impacts of co-morbidities of TB?

- Makes treatment of TB difficult/delayed due to the presence of other conditions
- Makes treatment of other co-morbid conditions difficult due to the presence of TB
- The patient must take more pills and may face more side effects of the drugs
- More risk and incidences of lost-to-follow-up among PwTB due to increasing side effects of drugs of TB and other illnesses
- More risk and incidences of treatment failure and relapse of TB
- More risk and incidences of death in PwTB

What we should do to manage TB and co-morbidities

- Bi-directional screening
- Dual treatment of the co-morbid conditions

What is Bi-directional screening?

- Objective of bi-directional screening - Early detection of TB and co-morbidities
- How to conduct bidirectional screening
  - Screen routinely the newly diagnosed PwTB for the presence of critical co - morbidities
    - Communicable diseases – HIV and AIDS, Covid-19, Hepatitis B and C (not yet mandatory)
    - Non-Communicable disease - Diabetes and others
  - Screen routinely the people infected by HIV or Covid-19 or those suffering from diabetes or other NCDs for the presence of active TB disease.
    - Symptomatic screening
    - X-ray screening

- Rapid molecular test of presumptive TB cases

Dual treatment

- Objective: Treat TB and co-morbidities together to reduce incidences of death
  - TB-HIV co-infection
    - Start ATT first
    - Start ART after 2-3 weeks of ATT initiation.
    - Continue ART after completion of ATT.
  - TB-Diabetes co-association
    - Start ATT
    - Treat diabetes according to severity of blood sugar level
    - Diet
    - Anti-diabetic drugs
    - Insulin
  - TB-Covid-19 co-infection
    - Screen and test all PwTB for C19 by RT -PCR test
    - Ensure full protective measures like mask, sanitizers, and social distancing.
    - Vaccinate PwTB for C19: 3 doses (2 essential and 1 booster)
    - Special respiratory care for complicated cases
    - Similarly, all C19 cases to be screened for TB by CXR and CBNAAT
  - TB-Hepatitis B and C
    - Hepatitis B and C, which are viral infections of the liver, tend to damage the liver considerably if not diagnosed and treated on time. The drugs used to treat TB are also, to a certain extent, hepatotoxic (damaging to the liver). So, a PwTB with chronic Hepatitis B and C might have poor treatment outcomes due to these factors. However, Hepatitis B screening of newly diagnosed PwTB is not mandatory like HIV despite strong recommendations given by certain TB-Hepatitis co-infection prevalence study reports.

Please remember

In the TB projects of HPPI, we must ensure HIV testing and diabetes testing of ALL PwTB who are detected through the screening efforts in the projects.

CHAPTER TWO
THE END-TB STRATEGY

Global situation of TB – A brief from the Global TB Report 2022

- TB is present in all countries and age groups.
- TB is curable and preventable.
- Ending the TB epidemic by 2030 is among the health targets of the United Nations Sustainable Development Goals (SDGs).
- An estimated global total of 10.6 million people fell ill with TB in 2021, equivalent to 134 cases per 100 000 people, globally.
- This is an increase of 4.5% from 10.1 million TB cases in 2020.
- Among the TB cases, around 60% were male, 30% female and 10% children (below 14 years).

- Geographically, most TB cases in 2021 were in the WHO regions of South-East Asia (45%), Africa (23%) and the Western Pacific (18%), with smaller shares in the Eastern Mediterranean (8.1%), the Americas (2.9%) and Europe (2.2%).
- 30 high-TB-burden countries accounted for 87% of new TB cases. Eight countries account for two thirds of the total, with India leading the count, followed by Indonesia, China, the Philippines, Pakistan, Nigeria, Bangladesh and South Africa.
- Among all TB cases, 6.7% were among people living with HIV.
- Worldwide, TB is one of the top 10 causes of death and the leading cause from a single infectious agent (above HIV/AIDS).
- In 2021, there were an estimated 1.4 million deaths among HIV-negative people, and 187 000 among HIV-positive people, for a combined total of 1.6 million, more than in 2019 (1.4m) and 2020 (1.5m)
- The Covid-19 pandemic worsened the TB epidemic in the countries by hampering TB case detection and treatment.
- Multidrug-resistant TB (MDR-TB) remains a public health crisis and a health security threat.
- Globally, there were an estimated 450,000 incident cases of MDR/RR-TB in 2021, up 3.1% from 437 000 in 2020. This is mostly due to the Covid-19 pandemic.
- In 2019, 206 030 people with multidrug- or rifampicin-resistant TB (MDR/RR-TB) were detected and notified, a 10% increase from 186 883 in 2018.
- Globally, the TB incidence is falling at about 2% per year and between 2015 and 2019 the cumulative reduction was 9%. This was less than halfway to the End-TB Strategy milestone of 20% reduction between 2015 and 2020

The End-TB Strategy:

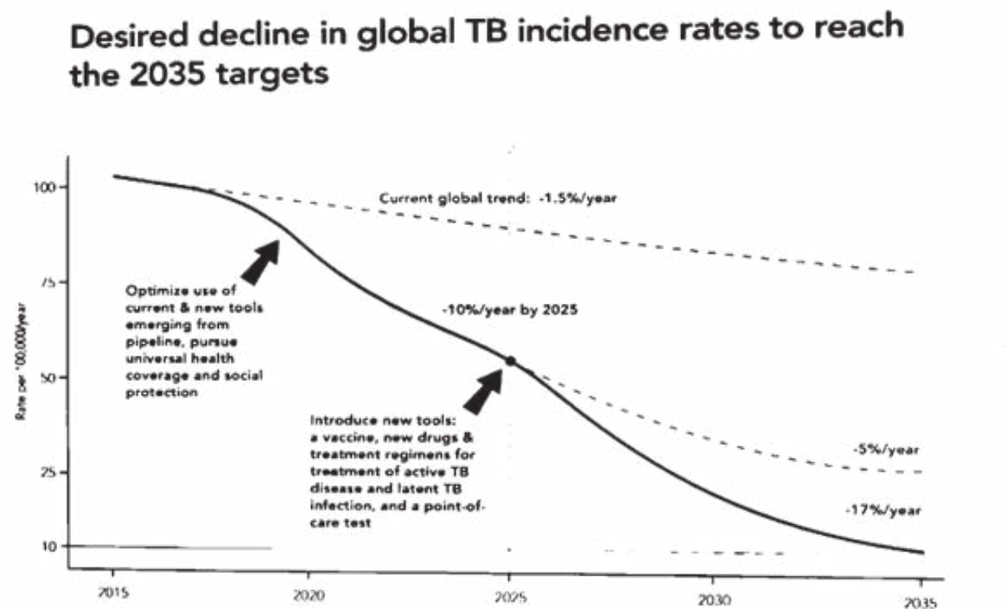
WHO introduced the End-TB Strategy in 2015 with the

- Vision: A world free of TB. Zero deaths, disease and suffering due to TB.
- Goal: End the global tuberculosis epidemic by 2035.

Targets – END TB (source: WHO)

	Milestone		SDGs	END TB
	2020	2025	2030	2035
Reduction in number of TB Deaths compared with 2015 (%)	35	75	90	95
Reduction in TB incidence (new cases) rate compared with 2015 (%)				
Tb-affected families facing catastrophic costs due to TB (%)				

Desired level of reduction of TB incidence: The TB incidence indicates newly diagnosed TB cases in the community and is expressed in per 100,000 people. Currently, the TB incidence rate, globally, is declining at the rate of 1.5%, which is far below the expected level to reach the phase of TB elimination, and the desired decline rate should be 10% by 2025 and 17% by 2035.



Definition of TB Elimination: Elimination as defined by the World Health Organization (WHO), means that there should be less than 1 case of TB for a population of a million people. (1 million = 10 lacs).

Priority indicators for TB elimination

Global priority indicators and targets for monitoring the implementation of the End-TB Strategy - All countries should aim to reach these targets at the latest by 2025.

Treatment coverage
Number of people that developed TB, and were notified and treated, out of the total estimated number of incident cases in the same year (%).
≥ 90%

TB treatment success rate
Number of TB patients who were successfully treated out of all notified TB cases (%).
≥ 90%

Preventive treatment coverage
Number of people living with HIV and children who are contacts of cases who were started on preventive treatment for latent TB infection, out of all those eligible (%).
≥ 90%

TB affected households facing catastrophic costs
Number of TB patients and their households that experienced catastrophic costs due to TB, out of all TB patients (%)
0%

Uptake of new diagnostics and new drugs
Number of TB patients who were diagnosed using WHO-recommended rapid tests, out of all TB patients (%).

Number of TB patients who were treated with regimens including new TB drugs, out of those eligible for treatment with such drugs (%).
≥ 90%

Country support for ending TB:

To roll out the End-TB strategy, countries will need to

- Advocate for political commitment, multisectoral collaboration and a high-level national mechanism to implement the End-TB strategy
- Assess the TB situation, health system response and capacities, and policies
- Collaborate with
  - Other health programs and departments
  - Primary healthcare
  - Other Ministries and line-departments
  - CSOs, affected communities
  - The private sectors, CSRs (Corporate Social Responsibility departments)
  - International partners and donors

CHAPTER THREE

ORGANIZATION OF NTEP (NATIONAL TB ELIMINATION PROGRAMME) OF INDIA

Summary of India's TB Prevalence Survey 2019 – 21

- India undertook one of the largest national TB prevalence surveys for near accurate estimation of the burden at National level and in 20 State groups from 2019 to 2021, to know the actual disease burden of TB at a national level.
- The survey estimated the point prevalence of microbiologically confirmed pulmonary TB (PTB) among persons ≥15 years in age in India at the national level and for 20 individual states / state groups.
- The survey also explored health seeking behavior and estimated the prevalence of TB infection
- The estimated point prevalence of microbiologically confirmed Pulmonary TB among persons aged more than 15 years at National level was 316 per lakh population.

- The prevalence of all forms of TB was estimated to be 312 per lakh population.
- Delhi tops the country in prevalence of tuberculosis with 534 cases per 1 lakh population, the TB prevalence survey reveals. Rajasthan, with 484 cases per 1 lakh population, had the second highest TB prevalence, followed by Uttar Pradesh (481), Haryana (465) and Chhattisgarh (454). Kerala had the lowest prevalence (115).

The Covid-19 pandemic worsened the situation of the TB epidemic globally and in India and the bad situation, though improved, still continues.

India's strategy of TB elimination by 2025

India has made great progress towards TB prevention and control with the adoption of the National Strategic Plan 2020-2025 with significantly greater allocated resources and high-level political commitment. Aligning with the global End-TB Strategy, India has announced the target of ending TB by 2025, five years ahead of the rest of the world. The End-TB strategy is comprised of a multi-pronged approach incorporating patient-centered care and prevention, bold policies and supportive systems, and intensified research and innovation. In the past decade, India has made great strides towards ending TB, but the challenges, especially in a high burden setting, are great, and achieving our ambitious targets and goals will require partnering with all stakeholders including civil society and the community.

Moving towards TB elimination

Moving towards TB elimination in India means that, in a similar way to the NSP 2017 - 2025, the actions required for the NSP 2020 - 2025 have been arranged in four strategic areas, or "Pillars" of Build, Prevent, Detect & Treat. The 2020-25 NSP continues to emphasize the early diagnosis of all PwTB , together with reducing transmission and treating those at first engagement with the right drugs and regimens together with suitable patient support systems.

Reducing the TB Incidence

A commitment has been made to achieve the 2030 SDG targets by 2025. This requires aggressive actions to reduce the TB incidence by 80% and TB mortality by 90% in 2025 compared to 2015.

What actions are needed to achieve the required reduction in incidence?

To understand the implications of different actions for NSP strategies and interventions, a "modelling" exercise was undertaken to define the TB burden (incidence and mortality) under different scenarios of scaling-up existing and potential new interventions.

Key interventions which are focused on reducing the TB incidence are:

- Population screening for TB through outreach.
- Use of molecular tests for TB diagnosis.
- High standard of care in the private sector through comprehensive engagement.
- Achieving a high rate of treatment success.
- Introducing preventative therapy of adult and adolescent contacts.

These interventions will have a considerable impact on the TB disease burden, but it is said that they will not on their own have sufficient impact. Additional bold measures to prevent incidence at the population level are said to be urgently required.

Key Indicators and Targets

Across the NSP there are a total of 37 indicators which have been set. This will allow the success of the NSP to be monitored annually over the next five years.

India's goal of TB elimination

Government of India has decided to eliminate TB by 2025

Organization of the NTEP of India

Goal: TB-free India by 2025

Key Strategies

- Reach the difficult-to-reach Key and Vulnerable Populations (KVP)
- Reduce TB incidence in KVP

Overall approaches

- Improve identification, reach, screening, and TB case detection in the KVP (all types)
- Enhance treatment initiation and successful treatment completion in the TB patient by minimizing pre-treatment and on-treatment lost-to-follow-up (all types)
- Facilitate early diagnosis and treatment initiation of TB co-morbidities.
- Ensure TB preventive treatment and its completion in the targeted groups, like household contacts and PLHIV.
- Follow up after treatment completion to detect recurrence of TB and disability due to TB.
- Promote community engagement, address stigma and discrimination, use rights -based approaches, gender -responsive services, protection of human rights, multi -sectoral accountability and coordination, and stakeholders' active participation in the TB elimination drives in the KVP.
- Assist MoH in policy revision and adoption of new policies.
- Carry out operational and implementation research, and adopt innovative ideas and interventions for the KVP.

Organization of NTEP

Central-level: Central TB Division, modal agency of TB Elimination in MoH, supported by National training and Research Institutes, National TB Expert committees

State-level: State health ministry, State TB Cell

District level: District TB Office

Please remember, the Health and Wellness Centres (HWCs) will be the key service delivery centers for TB at the primary healthcare level.

Organization of the NTEP at state-level

State NTEP Organization

State TB office - State tuberculosis officer
State TB training and demonstration centre - Director
District TB centre - District tuberculosis officer
Tuberculosis unit - 1 per 5 Lakh population

Medical officer - TB control/MOTC
Senior treatment supervisor/STS
Senior TB lab supervisor/STLS
Microscopy centre/DMC with LT-1 per Lakh population
Treatment centres /Health and Wellness Centres/PHI
DOTS providers.

Laboratory Network of NTEP

- National Reference Labs: 6
- State-level labs
- Liquid culture DST: 50
- LPA: 64
- Private/corporate labs (NTEP accredited): 19
- District-level CBNAAT (Genexpert): 1180
- DMCs: 20356

Source: India TB Report 2021

NIKSHAY online TB notification system (Ni=End, KSHAY = TB)

- The Nikshay serves as a National PwTB Information management tool for all sectors and for all types of patients.
- Presents live online data of TB notifications.
- Acts as a surveillance tool under the National TB Elimination Programme: The entire TB care cascade referral for testing and notification, outcome declaration and all drop-out events, are tracked and monitored.
- Helps in Digital Adherence monitoring. ICT based self-adherence reporting can be monitored through the system.
- Performs Direct Benefit Transfers/DBT. For the provision of Government benefits to the patients, according to eligibility, various schemes get transferred to relevant beneficiaries through integration with the Public Financial Management System (PFMS)
- Helps in the management of staff, health facilities and reporting hierarchy.
- Is like an MIS Reporting tool. Based on various monitoring parameters, Nikshay supports the attainment of various milestones in the patient lifecycle (e.g. Universal Drug Susceptibility offered is counted when a molecular resistance test for the Rif is added to a patient) and shows various reports to the programme managers at TU, District, State and National level.

- Nikshay provides a National Data repository of TB information for advanced analytics: Since the Nikshay Dashboard contains a wealth of data concerning each PwTB, it provides an unlimited potential for analysis of data and generating insights into TB epidemiology and programme functioning.

Data entered into NIKSHAY platform

Program staff manages information of each patient throughout the patient lifecycle related to

- Testing (diagnosis including co-morbidity testing and follow-up)
- Treatment initiation
- Public health action (contact tracing, co-morbidities)
- Adherence monitoring
- Treatment outcomes
- Transfer and referral for testing
- DBT

Nikshay Mitra

- The initiative was launched by the President of India in 2022.
- The initiative aims to ensure additional diagnostic, nutritional, and vocational support to those on TB treatment and encourages elected representatives, corporates and NGOs to come forward as donors to help the patients towards recovery.
- More than 47,000 Nikshay Mitra and 8.8 lakh PwTB have been connected through the Nikshay 2.0 portal
- The initiative ensures three-pronged support that includes nutritional, additional diagnostic, and vocational support.
- Nikshay Mitra (Donor) for this programme includes co-operative societies, corporates, elected representatives, individuals, institutions, non-governmental organizations, political parties and partners who can support by adopting the health facilities (for individual donor), blocks/urban wards/districts/States for accelerating the response against TB to complement the government efforts.
- For effective engagement of the community in the path towards ending TB in India, MoHFW is implementing the “Community Support to PwTB ” through Pradhan Mantri TB Mukt Bharat Abhiyaan.
- The campaign of TB-Mukt Bharat (TB-free India) through a mass movement against TB (Jan Andolan) is a critical initiative of Government of India to enhance TB awareness and promote TB elimination.

NOTES

CHAPTER FOUR

GENERAL CONCEPT OF CONTINUUM OF TB CARE IN KEY AND VULNERABLE POPULATIONS

Background:

Tuberculosis (TB) is one of the leading causes of death and the second leading infectious disease after Covid-19 (above HIV/AIDS) worldwide. Multi-drug resistant TB and co-morbid conditions of TB with HIV, diabetes, and Covid-19 increase the challenges of the country-level TB programmes multifold.

Humana People to People India is one of the active partners of the Government of India to raise and complement its country-wide ‘mass-awareness movement on TB’ (Jan Andolan). We work with highly vulnerable homeless people in large metropolitan cities to protect them from the menace of TB. Our TB projects for homeless people in Delhi elicited that the estimated burden of TB ranges from 1400 to 1700 per 100,000 population. There is an urgent need to address TB-related issues in urban- based homeless populations through a concerted and comprehensive approach.

(Field interaction with a PwTB . Source: HPPI)

Humana People to People India's goal, key strategies and overall approaches to support the TB elimination drive in India align with the country's vision, goal and strategic plan of TB elimination by 2025.

Goal: TB-free India by 2025

Key Strategies

- Reach the difficult-to-reach Key and Vulnerable Populations (KVP)
- Reduce TB incidence in KVP

Overall approaches

- Improve identification, reach, screening, and TB case detection in the KVP (all types)
- Enhance treatment initiation and successful treatment completion in the PwTB by minimizing pre-treatment and on-treatment lost-to-follow-up (all types)
- Facilitate early diagnosis and treatment initiation of TB co-morbidities.
- Ensure TB preventive treatment and its completion in the targeted groups, like household contacts and PLHIV.
- Follow up after treatment completion to detect recurrence of TB and disability due to TB.
- Promote community engagement, address stigma and discrimination, use rights-based approaches, gender-responsive services, protection of human rights, multi-sectoral accountability and coordination, and stakeholders' active participation in the TB

elimination drives in the KVP.

- Assist MoH in policy revision and adoption of new policies.
- Carry out operational and implementation research, and adopt innovative ideas and interventions for the KVP.

Guiding principles of HPPI's TB Projects

1. **Addressing Key and Vulnerable Populations (KVP)**
2. **Continuum of Care (CoC)**

1. Addressing Key and Vulnerable Populations

1a.Categorization of Key and Vulnerable Populations

Key and vulnerable (KVP) populations are certain population groups in whom the TB disease and infection burden, and mortality/death due to TB, is much higher than in the general population. We categorize the KVP as shown in the slide below:

KVP (Key and Vulnerable Population): Higher TB burden

Biological: Compromised health situation

- HIV & AIDS, Diabetes, malnutrition, substance abuse, alcoholism, smoking , occupational lung diseases, chronic lung diseases, mental illnesses

Social: Poor living conditions and socio-economic status

- Migratory population, mobile population, mining population, homeless, slums, refugees, internally displaced population, vagabonds, conflict zones, those staying in orphanage and shelter homes, prisoners, those living in mental asylums, sex workers, transgender

Geographical: difficult - to - reach areas where access to health - facilities is highly challenging

- Islanders, those living in mountains and forests, any other marginalized popultation.

HPPI's key approaches in all its TB projects will aim to reduce TB buren in the KVP

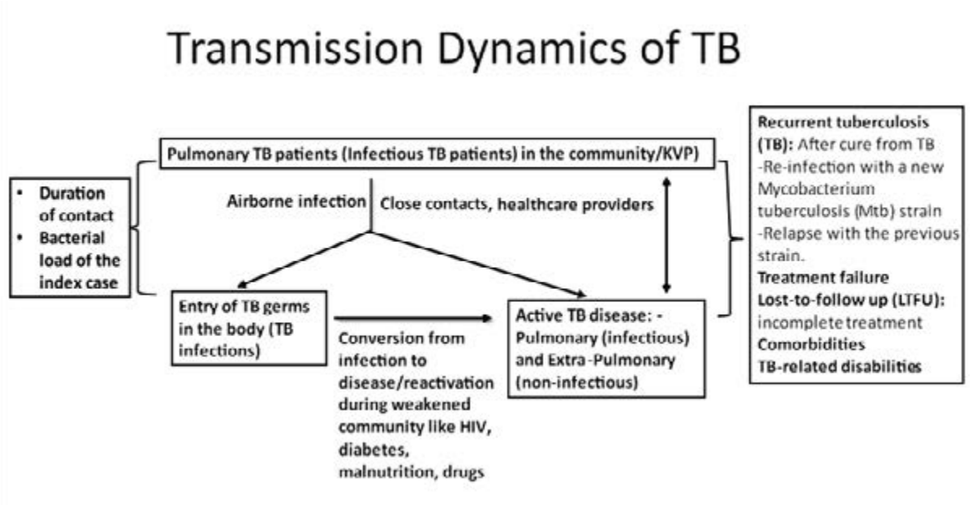
1b.Why the TB burden and mortality is high in KVP:

The key reasons are

- **Poor general health** – malnutrition, chronic alcoholism and drug addiction
- **Poor general living conditions** – overcrowding, poor/no ventilation, no sunlight, poor sanitation
- **Poor TB awareness and access to health services -** This causes late diagnosis, long exposure to PwTB, and late treatment initiation which leads to prolong ed infectiousness of the PwTB and spread of infection (the patient becomes non -infectious within 2-3 weeks of treatment initiation)
- **Poor treatment outcome of TB**
  - LTFU
  - Recurrence – re-infection, relapse
  - DRTB (MDR, XDR, TDR),
  - Co-morbidities (HIV, Hepatitis B and C, substance abuse, diabetes, chronic lung diseases, mental illnesses)
  - Death
- **No treatment of TB infections:** This can lead to reactivation to active TB disease in low immunity conditions.
- **Cross-cutting issues:** Migration, homelessness, stigma, gender inequity, violation of human rights, conflict situations, pandemics like Covid-19, poverty.

1c.TB transmission dynamics in the KVP

Early TB acquisition and transmission to close contacts, delay in diagnosis and treatment due to poor access to health services, incomplete treatment, recurrence of TB, co-morbidity and poor disease prevention and infection control establish the TB dynamics and chain of transmission in the KVP with a continuing high disease burden. This is described in the slide below.



2. Continuum of Care (CoC)

2a.What is Continuum of Care?

In patients with a disease/TB, this covers a step-by-step approach of patient-centric care in all phases of the illness, from diagnosis to cure and prevention.

Continuum of Care in the TB programmes for the KVP, as adopted by HPPI

- Design, planning and implementation of activities in line with Continuum of Care (CoC)
- CoC ranges from TB case detection to cure of TB, and treatment of TB infections
- Additionally, reduction of stigma and discrimination, addressing gender inequity, a rights- based approach, and empowerment of TB patients and poor and underprivileged communities
- Alignment of the TB programme with CoC
- A CoC-based approach should finally aim to
  - Cut the chain of transmission of TB
  - Subsequently, reduce the TB burden and mortality

2b.Critical CoC activities

The following table lists critical activities of the TB intervention linking to CoC.

Continuum of Care

S. No.	Key strategies to cut transmission of TB in the KVP communities	Continum of Care (CoC) - critical activites
1.	Early diagnosis and treatment initiation of TB including DRTB	• TB awareness • Active case finding • Facilitate TB diagnosis by SCT and accompained referrals • Facilitate treatment initiation
2.	Successful completion of TB and DRTB treatment	• Treatment education • Directly observed Treatment • Facilitate follow-up • Counselling • Retrieval of LTFU • Short treatment courses
3.	Early detection and successful management of co-morbid situations	• Facilitate comorbidity diagnosis and treatment
4.	Treatment of TB-infections and its completion	Facilitate treatment of TB-infections of healthy contacts of the index TB patients and PLHIV, treatment completion, shortt treatment courses
5.	Follow-up after treatment completion to detect recurrence due to re-infection and /or relapse	Follow-up of the TB patients after completion of their treatment at least for 6 months to maximum 2 years
6.	Social and structural interventions to address cross-cutting issues	• Psycho-social support, CRG • Stakeholder engagement, multisectoral collaboration • Policy, research

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