

Tuberculosis Case Definitions

BACTERIOLOGICALLY VS. CLINICALLY CONFIRMED CASES OF TB



Bacteriologically-confirmed TB case:

A person from whom a biological specimen is positive by a WHO-recommended rapid diagnostic test, culture, or smear microscopy.



Clinically-diagnosed TB case:

A person who does not fulfill the criteria for bacteriological confirmation but has been diagnosed with TB disease by a medical practitioner who has decided to give the person a full course of TB treatment.

This definition includes pulmonary cases diagnosed based on X-ray abnormalities and extrapulmonary cases diagnosed based on suggestive histology.

Clinically diagnosed cases subsequently found to be bacteriologically positive (before or after starting treatment) should be reclassified as bacteriologically confirmed.

CLASSIFICATION BASED ON ANATOMICAL SITE OF THE DISEASE

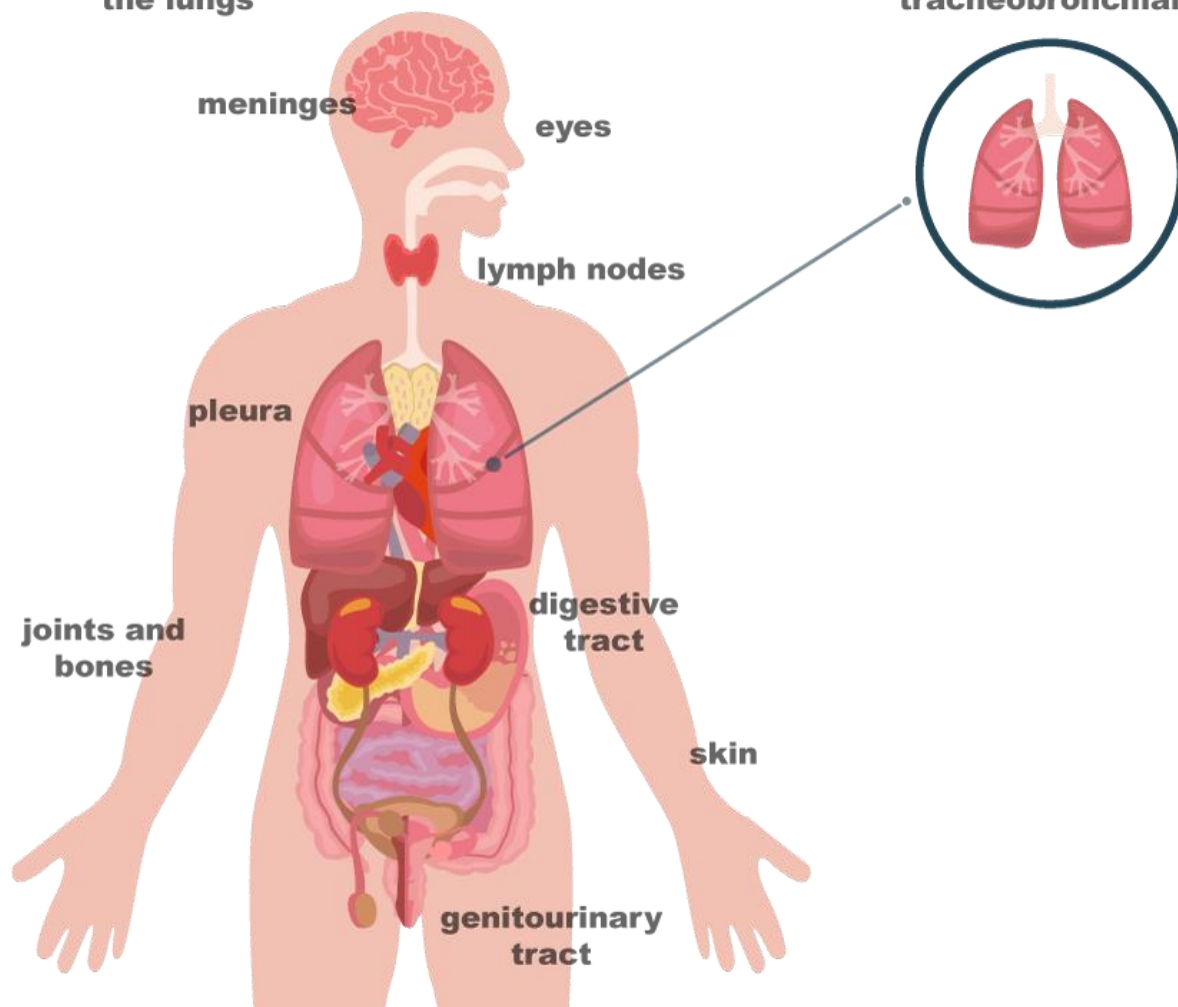
Pulmonary tuberculosis (PTB): A person with TB disease involving the lung parenchyma or the tracheobronchial tree.

Note: A case with both pulmonary and extrapulmonary TB should be recorded and counted as a pulmonary TB case for surveillance purposes. Miliary TB is classified as pulmonary TB.

Extrapulmonary tuberculosis (EPTB): A person with TB disease involving organs other than the lung parenchyma or tracheobronchial tree (e.g., pleura, lymph nodes, eyes, digestive tract, genitourinary tract, skin, joints and bones, meninges).

Extrapulmonary TB involves organs outside the lungs

Pulmonary TB affects the lungs- parenchyma or the tracheobronchial tree



CLASSIFICATION OF A PERSON WITH TB DISEASE BY HISTORY OF PREVIOUS TREATMENT FOR TB

New cases: A person with TB disease who has never been treated for TB or has only ever taken TB drugs for less than 1 month.

Recurrent case (formerly known as relapse case): A person with TB disease who has previously been treated for TB, was declared cured or treatment completed at the end of their most recent course of TB treatment and is now diagnosed with a new episode of TB.

Re-registered case (also known as a retreatment case): A person with TB disease who has been notified previously as a TB case, who has not been declared cured or treatment completed, and is now being started on a new course of TB treatment.

Note: Examples of re-registered cases include:

- ✓ a person who was declared treatment failed during or at the end of their most recent course of TB treatment and who is starting a new course of TB treatment (normally using a different drug regimen)
- ✓ a person who was declared lost to follow-up before, during or at the end of their most recent course of TB treatment and who has returned to start a new course of TB treatment
- ✓ a person whose outcome after their most recent course of TB treatment is undocumented and who has returned to start a new course of TB treatment.

Unknown previous treatment history: A person with TB disease who has no documented history of TB treatment

New episode: A person with TB disease who has either a new, recurrent or unknown previous TB treatment history (i.e., any case apart from a re-registered case)



CLASSIFICATION OF A PERSON WITH TB DISEASE BY HIV STATUS

HIV-positive: A person with TB disease who has a documented positive result from HIV testing before, at the time of TB diagnosis or during the TB episode.

HIV-negative: A person with TB disease who has a negative result from HIV testing conducted at the time of TB diagnosis.

Note: If the person is subsequently found to be HIV-positive during their TB treatment, they should be reclassified as an HIV-positive TB case.

HIV status unknown: A person with TB disease who has no result from HIV testing and no documented evidence of receiving treatment for HIV.

Note: If the person's HIV status is subsequently determined, they should be reclassified as an HIV-positive TB case or an HIV-negative TB case, as appropriate.



TREATMENT TYPES, TREATMENT COVERAGE AND TREATMENT INITIATION

First-line TB medicine (or drug): An agent used to treat a person with DS-TB disease.

E.g., Isoniazid, rifampicin, ethambutol, pyrazinamide

Second-line TB medicine (or drug): An agent used to treat a person with DR-TB disease.

E.g., Fluoroquinolones - Ofloxacin (OFX), levofloxacin (LEV), moxifloxacin (MOX) and ciprofloxacin (CIP); Injectable antituberculosis drugs- Kanamycin (KAN), amikacin (AMK) and capreomycin (CAP).

Treatment initiation:

The initiation of an appropriate treatment regimen for a person with TB disease.

Note: It is recommended to monitor this step in the pathway of care because diagnosis of TB disease does not necessarily mean that a person will be offered or accept to take treatment.



CLASSIFICATION OF A PERSON WITH TB DISEASE BY SUSCEPTIBILITY OR RESISTANCE TO TB MEDICINES (NOT MUTUALLY EXCLUSIVE)

Drug susceptibility testing (DST): In vitro testing of a strain of *M. TB* complex using either: 1) molecular, genotypic techniques to detect resistance-conferring mutations; or 2) phenotypic methods to determine susceptibility to a medicine.

Drug-resistant TB (DR-TB): A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to any TB medicines tested. When available, DST results for individual drugs should be recorded.

Drug-susceptible TB (DS-TB): A person with TB disease for whom there is no evidence of infection with a strain of *M. tuberculosis* complex that is resistant to rifampicin or isoniazid. This includes people for whom DST was not done or for whom DST shows a strain of *M. tuberculosis* complex that is susceptible to both rifampicin and isoniazid.

This definition should only be used for the purposes of initiation of treatment for DS-TB and the recording of treatment outcomes. Wherever available, DST results for individual drugs should be recorded and used to define a person's drug susceptibility status. When DST results are not available for individual drugs, their absence should also be recorded.

Isoniazid-resistant, rifampicin-susceptible TB (Hr-TB): A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to isoniazid but susceptible to rifampicin.

Rifampicin-resistant TB (RR-TB): A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to rifampicin.

Note: These strains may be either susceptible or resistant to isoniazid (i.e., MDR-TB) or resistant to other first-line or second-line TB medicines.

Multidrug-resistant TB (MDR-TB): A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to both rifampicin and isoniazid.

MDR/RR-TB: MDR-TB is a subset of RR-TB, and the two are often grouped together using the term MDR/RR-TB.

Pre-extensively drug-resistant TB (pre-XDR-TB): A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to rifampicin (and which may also be resistant to isoniazid), and which is also resistant to at least one fluoroquinolone (either levofloxacin or moxifloxacin).

Extensively drug-resistant TB (XDR-TB): A person with TB disease who is infected with a strain of *M. tuberculosis* complex that is resistant to rifampicin (and which may also be resistant to isoniazid), and which is also resistant to at least one fluoroquinolone (levofloxacin or moxifloxacin) and to at least one other “Group A” drug (bedaquiline or linezolid).



OUTCOMES OF TB TREATMENT FOR BOTH DS- AND DR-TB

Cured: A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who completed treatment as recommended by the national policy with evidence of bacteriological response and no evidence of failure.

Treatment completed: A person with TB disease who completed treatment as recommended by the national policy whose outcome does not meet the definition for cure or treatment failure.

Treatment failed: A person with TB disease whose treatment regimen needed to be terminated or permanently changed to a new regimen option or treatment strategy.

Died: A person with TB disease who died for any reason before starting, or during the course of, treatment.

Lost to follow-up: A person with TB disease who did not start treatment or whose treatment was interrupted for two consecutive months or more.

Not evaluated: A person with TB disease to whom no treatment outcome was assigned, excluding those lost to follow up.

Treatment success: A person with TB disease who is either cured or completes their treatment.

