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காச நோய்த் தடுப்பும் மார்பு நோய்களுக்குமான தேசிய செயற்திட்டம்  
NATIONAL PROGRAMME FOR TUBERCULOSIS CONTROL & CHEST DISEASES  
Public Health Complex, 555/ 5, Elvitigala Mawatha, Narahenpita, Colombo-05, Sri Lanka

All Consultant Respiratory Physicians,  
Consultant Microbiologist - NTRL  
All District Tuberculosis Control Officers  
MDRTB Coordinator  
Chief Pharmacist- CDS

**Tuberculosis Case Definitions – Revision 2013**


The World Health Organization has revised previous standard case definitions for TB, Drug Resistant TB, the categories used to define outcomes and the standing reporting frame work for TB in 2013. This revision is made mainly due to following reasons:

- Introduction of WHO approved rapid diagnostics (WRD) such as Xpert MTB/Rif into practice in many countries.
- The definitions need to use less judgemental language, so the terms “defaulter” and “TB suspect” have been replaced by “lost to follow-up” and “presumptive TB”, respectively.
- The definition of a bacteriologically confirmed case needs to be more flexible to allow the incorporation of results from WRD.
- The current treatment outcome definitions of “cured” and “treatment failed” in multidrug-resistant TB (MDR-TB) cohorts need simplification to allow their wider application to patients still on treatment.

As data on TB need to be comparable within the National Tuberculosis Programme in a country as well as between countries, standard case definitions and uniform system of data reporting need to be adopted.

Therefore, NPTCCD has decided to adhere to the revised definitions in the annexure with effect from 01 January 2014.

Please bring this into notice of all the staff attached to your institutions.

  
Dr K. N. Gamini Seneviratne  
Director

cc- DGHS  
DDG (PHS) I

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## A. Revised Definitions

**Presumptive TB** A patient who presents with symptoms or signs suggestive of TB (previously known as a TB suspect).

### A 1 Case Definitions

**Case of a "Bacteriologically confirmed TB"** A patient whose biological specimen is positive by smear microscopy, culture or WRD (such as Xpert MTB/RIF).

**Case of a "clinically diagnosed TB"** One who does not fulfil the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician who has decided to give the patient a full course of TB treatment.

*This definition includes cases diagnosed on the basis of X-ray abnormalities or suggestive histology and extrapulmonary cases without laboratory confirmation.*

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

Bacteriologically confirmed or clinically diagnosed cases of TB are also classified according to:

- anatomical site of disease;
- history of previous treatment;
- drug resistance;
- HIV status.

#### A.1.1 Classification based on anatomical site of disease

**Pulmonary tuberculosis (PTB)** Any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree.

Miliary TB is classified as PTB because there are lesions in the lungs.

*Tuberculous intra-thoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitutes a case of extrapulmonary TB.*

A patient with both pulmonary and extrapulmonary TB should be classified as a case of PTB.

**Extrapulmonary tuberculosis (EPTB)** Any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges.

#### A.1.2 Classification based on history of previous TB treatment (patient registration group)

**New patients** Patients who have never been treated for TB or have taken anti-TB drugs for less than 1 month.

**Previously treated patients** Patients who have received 1 month or more of anti-TB drugs in the past.

*They are further classified by the outcome of their most recent course of treatment*

- **Relapse patients**

Patients who have previously been treated for TB, were declared *cured* or *treatment completed* at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection).

▪ **Treatment after failure patients**

Patients who have previously been treated for TB and whose *treatment failed* at the end of their most recent course of treatment.

▪ **Treatment after loss to follow-up patients**

Patients who have previously been treated for TB and were declared *lost to follow-up* at the end of their most recent course of treatment.

(These were previously known as *treatment after default patients*.)

▪ **Other previously treated patients**

Patients who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

**Patients with unknown previous TB treatment history**

Patients who do not fit into any of the categories listed above.

New and relapse cases of TB are **incident** TB cases.

**A.1.3 Classification based on HIV status**

**HIV-positive TB patient**

Any bacteriologically confirmed or clinically diagnosed case of TB who has a positive result from HIV testing conducted at the time of TB diagnosis or other documented evidence of enrolment in HIV care, such as enrolment in the pre-ART register or in the ART register once ART has been started.

**HIV-negative TB patient**

Any bacteriologically confirmed or clinically diagnosed case of TB who has a negative result from HIV testing conducted at the time of TB diagnosis.

Any HIV-negative TB patient subsequently found to be HIV-positive should be reclassified accordingly.

**HIV status unknown TB patient**

Any bacteriologically confirmed or clinically diagnosed case of TB who has no result of HIV testing and no other documented evidence of enrolment in HIV care.

If the patient's HIV status is subsequently determined, he or she should be reclassified accordingly.

**A.1.4 Classification based on drug resistance**

Cases are classified in categories based on drug susceptibility testing (DST) of clinical isolates confirmed to be *M. tuberculosis*

- **Monoresistance:** Resistance to one first-line anti-TB drug only.
- **Polydrug resistance** Resistance to more than one first-line anti-TB drug (other than both isoniazid and rifampicin)
- **Multidrug resistance (MDR)** Resistance to at least both isoniazid and rifampicin.
- **Extensive drug resistance (XDR)** Resistance to any fluoroquinolone and to at least one of three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance.
- **Rifampicin resistance (RR)** Resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs.  
It includes any resistance to rifampicin, whether monoresistance, multidrug resistance, polydrug resistance or extensive drug resistance.

## A.2 Treatment outcome definitions

The new treatment outcome definitions make a clear distinction between two types of patients:

- Patients treated for drug-susceptible TB;
- Patients treated for drug-resistant TB using second-line treatment (defined as combination chemotherapy for drug-resistant tuberculosis which includes drugs other than those in Group 1).

*The two groups are mutually exclusive. Any patient found to have drug-resistant TB and placed on second-line treatment is removed from the drug-susceptible TB outcome cohort. This means that management of the standard TB register and of the second-line TB treatment register needs to be coordinated to ensure proper accounting of the outcomes of treatment.*

### A.2.1 Treatment outcomes for TB patients (excluding patients treated for RR-TB or MDR-TB)

All bacteriologically confirmed and clinically diagnosed TB cases should be assigned an outcome from this list **except** those with RR-TB or MDR-TB, who are placed on a second-line drug regimen

Outcome	Definition
<b>Cured</b>	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.
<b>Treatment completed</b>	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.
<b>Treatment failed</b>	A TB patient whose sputum smear or culture is positive at month 5 or later during treatment.
<b>Died</b>	A TB patient who dies for any reason before starting or during the course of treatment.
<b>Lost to follow-up</b>	A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.
<b>Not evaluated</b>	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.
<b>Treatment success</b>	The sum of <i>cured</i> and <i>treatment completed</i> .

Patients found to have an RR-TB or MDR-TB strain at any point in time should be started on an adequate second-line drug regimen. These cases are **excluded** from the main TB cohort when calculating treatment outcomes and included only in the second-line TB treatment cohort analysis (section A.2.2). If treatment with a second-line drug regimen is not possible, the patient is kept in the main TB cohort and assigned an outcome from among those in table in section A.2.1 above.

### A.2.2 Outcomes for RR-TB/MDR-TB/XDR-TB patients treated using second-line treatment

Outcome	Definition
<b>Cured</b>	Treatment completed as recommended by the national policy without evidence of failure AND three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.

Treatment completed	Treatment completed as recommended by the national policy without evidence of failure BUT no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.
Treatment failed	Treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of: <ul style="list-style-type: none"> <li>▪ lack of conversion by the end of the intensive phase</li> <li>▪ bacteriological reversion in the continuation phase after conversion to negative, <i>or</i></li> <li>▪ evidence of additional acquired resistance to fluoroquinolones, <i>or</i></li> <li>▪ second-line injectable drugs, <i>or</i></li> <li>▪ adverse drug reactions (ADRs)</li> </ul>
Died	A patient who dies for any reason during the course of treatment.
Lost to follow-up	A patient whose treatment was interrupted for 2 consecutive months or more.
Not evaluated	A patient for whom no treatment outcome is assigned. (This includes cases "transferred out" to another treatment unit and whose treatment outcome is unknown)
Treatment success	The sum of <i>cured</i> and <i>treatment completed</i>

*For Treatment failed, lack of conversion by the end of the intensive phase implies that the patient does not convert within the maximum duration of intensive phase applied by the programme, i.e., 8 months.*

*If a particular patient is on a regimen without a clear distinction between intensive and continuation phases, a cut-off 8 months after the start of treatment should be considered to determine when the criteria for Cured, Treatment completed and Treatment failed start to apply.*

*The terms "conversion" and "reversion" of culture as used here are defined as follows:*

**Conversion (to negative):** *culture is considered to have converted to negative when two consecutive cultures, taken at least 30 days apart, are found to be negative. In such a case, the specimen collection date of the first negative culture is used as the date of conversion.*

**Reversion (to positive):** *culture is considered to have reverted to positive when, after an initial conversion, two consecutive cultures, taken at least 30 days apart, are found to be positive. For the purpose of defining Treatment failed, reversion is considered only when it occurs in the continuation phase.*