

REPUBLIC OF KENYA



MINISTRY OF HEALTH

**NATIONAL TUBERCULOSIS, LEPROSY &
LUNG DISEASE PROGRAM**

**CATEGORY IV DR TB - 03
FACILITY REGISTER**

VERSION 2016

Revised case Definitions

A bacteriologically confirmed TB case-has a positive specimen by smear microscopy, culture or Xpert MTB/RIF).

A clinically diagnosed TB case - has no bacteriologically confirmation but has been diagnosed with active TB by a HCW who has decided to give the patient a full course of TB treatment. Clinically diagnosed cases found to be bacteriologically positive (before or after starting treatment) should be reclassified as bacteriologically confirmed.

Definitions

1. **Monoresistance (MR)** resistance to one first-line anti-TB drug only.
2. **Polydrug resistance (PDR TB)**: resistance to more than one first-line anti-TB drug (other than both isoniazid and Rifampicin).
3. **Multidrug resistance (MDR TB)**: resistance to at least both isoniazid and Rifampicin.
4. **Extensive drug resistance (XDR TB)**: resistance to any Fluoroquinolone and to at least one of three second-line injectable drugs (Capreomycin, Kanamycin and Amikacin), in addition to multidrug resistance.
5. **Rifampicin resistance (RR TB)**: resistance to Rifampicin detected using phenotypic or genotypic methods.

Classification of category IV TB patients

Before enrolling a patient, for treatment determine whether s/he has previously received anti-tuberculosis treatment and if so, record the dates of treatment and the treatment outcome. Also record whether the patient ever previously received second-line drugs.

- **New (N)**. Patients who have never received anti-tuberculosis treatment, or who have received anti-tuberculosis treatment for less than one month. (Note: patient who had DST at the start or within one month of a WHO Category I regimen and are then switched to a Category IV regimen because of resistance are placed in this group, even if they received more than one month of Category I treatment).
- **Relapse (R)**. Patients previously treated for tuberculosis that has been declared cured or treatment completed, and then diagnosed with MDR-TB.
- **Return after loss to follow up**. Patients who return to treatment with confirmed MDR-TB after interruption of treatment for two months or more. (previously called return after default –RAD)
- **After failure of Category I treatment (FFT)**. Patients who return after having failed the first treatment.
- **After failure of Category I treatment (FFT)**. Patients who return after having failed the first treatment.
- **After failure of Category II treatment (FRT)**. Patient who return after having failed the re-treatment.
 - **Transfer in (TI)**. Patients who have been transferred from another register from treatment of drug-resistant TB to continue Category IV treatment. Their outcomes should be reported to the transferring unit so that it can report their outcomes in the cohort in which they originally started MDR-TB treatment.
 - **New extra pulmonary**. Patients who have never received anti-tuberculosis treatment for less than one month with tuberculosis of organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges.

Outcomes for RR-TB/MDR-TB/XDR-TB patients treated using second-line treatment

Outcome	Definition
Cured	Treatment completed with three or more consecutive negative culture taken at least 30 days apart after the intensive phase
Treatment Completed	Treatment completed 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 the permanent regimen change of at least two anti-TB drugs because of: <ul style="list-style-type: none"> • Lack of conversion by end of the intensive phase, or • Bacterial reversion in the continuation phase after conversion to negative, or • Evidence of additional acquired resistance to Fluoroquinolone or second-line injectable drugs, or • Adverse drug reaction (ADRs)
Died	A patient who dies for any reason during the course of treatment.
Loss to follow up	A patient whose treatment was interrupted for 2 consecutive months or more.
Transferred out (TO)	A patient who initiated treatment in one facility and is transferred to another to continue treatment for whom treatment outcome is unknown
Not Evaluated	A patient for whom no treatment outcome is assigned and “still on treatment”
Treatment success	The sum of <i>cured</i> and <i>treatment completed</i>

Note:

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 of 8 months.



Printed with support from USAID through the Tuberculosis Accelerated Response and Care (TB ARC) Activity