

REPUBLIC OF KENYA



MINISTRY OF HEALTH

# NATIONAL TUBERCULOSIS, LEPROSY & LUNG DISEASE PROGRAM CATEGORY IV DR TB - 03 FACILITY REGISTER



February 2023  
MOH/REG/DNTLDP/05

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## Revised case Definitions

A **bacteriologically confirmed TB case**-has a positive specimen by smear microscopy, cculture, Xpert MTB/RIF,Truenat,LF Lam or Lamp.

A **clinically diagnosed** TB Case is one who does not fulfill 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. 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. **Rifampicin resistance (RR TB):** resistance to Rifampicin detected using phenotypic or genotypic methods.
3. **Polydrug resistance (PDR TB):** resistance to more than one first-line anti-TB drug (other than both Isoniazid and Rifampicin).
4. **Multidrug resistance (MDR TB):** resistance to both Isoniazid and Rifampicin with or without resistance to other first-line drugs.
5. **Pre-XDR TB:** fulfills the definition of multidrug resistant and rifampicin-resistant TB (MDR/RRTB) and which are also resistant to any fluoroquinolone
6. **Extensively drug resistance (XDR TB):** fulfills the definition of MDR/RR TB and also resistant to any Fluoroquinolone and at least one additional group A drugs ( Bedaquiline,and Linezolid)

Outcomes	Definition
<b>Treatment Completed (TC)</b>	DRTB patient who has completed Treatment as recommended 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.
<b>Cured (C)</b>	DRTB patient who completes treatment with three or more consecutive negative cultures taken at least 30 days apart after the intensive phase.
<b>Loss to Follow Ups (LTFU)</b>	A patient who interrupts DR-TB treatment for two or more consecutive Months.
<b>Treatment failure (F)</b>	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; or</li> <li>• Bacteriological reversion in the continuation phase after conversion to negative</li> <li>• Evidence of additional acquired resistance to fluoroquinolones or Second-line injectable drugs; or</li> <li>• Adverse drug reactions</li> </ul>
<b>Dead (D)</b>	A patient who dies from any cause while on DR-TB treatment.
<b>Not evaluated (NE)</b>	A patient for whom no treatment outcome assigned. (This includes cases "transferred out" to another treatment unit and whose treatment outcome is unknown).

Classification of Category IV TB Patients	
<b>New (N)</b>	Patients who have never received anti-tuberculosis treatment, or who have received anti-tuberculosis treatment for less than one month. (Note: patients who had DST at the start or within one month of a WHO regimen and are then switched to a second line regimen because of resistance are placed in this group, even if they received more than one month of Category I treatment).
<b>Relapse (R)</b>	Patients previously treated for tuberculosis that has been declared cured or treatment completed, and then diagnosed with MDR-TB.
<b>Return after loss to follow up</b>	Patients who return to treatment with confirmed MDR-TB after interruption of treatment for two months or more
<b>After failure of First Line Treatment (FFT)</b>	Patients who return after having failed the first treatment i.e smear positive at earliest, month 5
<b>After failure of Retreatment (FRT).</b>	Patients who return after having failed the re-treatment regimen.
<b>Transfer in (TI)</b>	Patients who have been transferred from another register for treatment of drug-resistant TB to second line 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.



# Smear (S) and Culture (c) results during treatment

Month 4		Month 5		Month 6		Month 7		Month 8		Month 9		Month 10		Month 11		Month 12		Month 13		Month 14		Month 15		Month 16		Month 17		Month 18		Month 19		Month 20		Month 21		Month 22		Month 23		Month 24		HIV Information												
Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Smear	Culture	Is the Patient Diabetic? Y/N	Other Comorbidities	HIV Pos/Neg/Not Done / Declined Date	CPT Y/N, Date	ART Y/N, N/A Date	Nutrition Support	Treatment Outcome	Date of Treatment Outcome	Comments				

W	
o	No AAFB seen
Scanty	1-9 AFB per 100HPF
+	>10-99 AFB per 100HPF
++	>1-10 AFB in 50HPF
+++	>10 AFB in 20HPF

Key 7 - Cultures	
<b>Growth</b>	G
<b>No Growth</b>	NG
<b>Non tuberculous mycobacteria isolated but no growth of MTB</b>	NG (NTM)
<b>Contaminated</b>	C

Key 8 - Drug Abbreviations			
<b>GROUP A</b>		<b>GROUP B</b>	
Lfx	Levofloxacin	Cfz	Clofazimine
Mfx	Moxifloxacin	Cs	Cycloserine
Bdq	Bedaquiline	Trd	Terizidone
Lzd	Linezolid	<b>GROUP C</b>	
		Dlm	Delaminid
		Pto	Prothionamide
		Eto	Ethionamide
		PAS	P- aminosallic Acid
		Imp	Imipinem
		Am	Amicacin
		Km	Kanamycin
		E	Ethambutol
		Z	Pyrazinamide

Key 9 - Outcome Treatment	
<b>C</b>	Cured
<b>TC</b>	Treatment Complete
<b>D</b>	Dead
<b>LTFU</b>	Lost to follow up
<b>F</b>	Treatment failure
<b>NE</b>	Not Evaluated



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