

REPUBLIC OF KENYA



MINISTRY OF HEALTH

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



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MOH/REG/DNTLDP/05

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** 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:MDR TB** with resistance to either Fluoroquinolone or a second-line injectable drugs (Capreomycin, Kanamycin and Amikacin)
6. **Extensively drug resistance (XDR TB): MDR TB** with resistance to both Fluoroquinolone and to at least one of three second-line injectable drugs (Capreomycin, Kanamycin and Amikacin).

Outcomes	Definition
Treatment Completed (TC)	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.
Cured (C)	DRTB patient who completes treatment with three or more consecutive negative cultures taken at least 30 days apart after the intensive phase.
Death (D)	A patient who dies from any cause while on DR-TB treatment.
Loss to Follow Ups (LTFU)	A patient who interrupts DR-TB treatment for two or more consecutive Months.
Treatment failure (F)	Treatment terminated or need for permanent regimen change of at Least two anti-TB drugs because of: <ul style="list-style-type: none"> • Lack of conversion by the end of the intensive phase; or • Bacteriological reversion in the continuation phase after conversion to negative • Evidence of additional acquired resistance to fluoroquinolones or Second-line injectable drugs; or • Adverse drug reactions
Not evaluated (NE)	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	
New (N)	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).
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
After failure of First Line Treatment (FFT)	Patients who return after having failed the first treatment i.e smear positive at earliest, month 5
After failure of Retreatment (FRT).	Patients who return after having failed the re-treatment regimen.
Transfer in (TI)	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					Comments									
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			

Notation method for recording smears	
Report	Interpretation
o	No AAFB seen
Scanty	1-9 AFB per 100HPF
+	>10-99 AFB per 100HPF
++	>1-10 AFB in 50HPF
+++	>10 AFB in 20HPF

Notation method for recording cultures	
Growth	G
No Growth	NG
Non tuberculous mycobacteria isolated but no growth of MTB	NG (NTM)
Contaminated	C

Drug Abbreviations			
H	Isoniazid	Km	Kanamycin
R	Rifampicin	Lfx	Levofloxacin
E	Ethambutol	Mfx	Moxifloxacin
Z	Pyrazinamide	Pto	Prothionamide
S	Streptomycin	Eto	Ethionamide
Bdq	Bedaquiline	Cs	Cycloserine
Cfz	Clofazimine	PAS	P-aminosallic Acid
Amx/clv	Amoxicillin Clavulin	Imp	Imipinem
Dlm	Delamind	HDI	High doze Isoniazid
Am	Amicacin	Lzd	linezolid

Outcome Treatment	
C	Cured
TC	Treatment Complete
D	Dead
LTFU	Lost to follow up
F	Treatment failure
NE	Not Evaluated



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