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 decides 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)**: resistancetomore 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 Fluor quinolone 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 retreatment.
 - 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: 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 Fluoroquionolone 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 cured and treatment completed

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.

CATEGORY IV REGISTER

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Serial No.	Registration No.	Date of Registration	Name in full (Three names)	Sex (M/F)	Age - Tear(s)/Month(s) Weight at Begietration	Height at Registration	BMI/Z score/BMI for age	Address Tel/Mobile (Patient & Treatment supporter)	Occupation (specify)	Type of TB P/EP	ng ag	Bacteriologically confirmed	Date GeneXpert sample collected	Date GeneXpert results made at the lab	Gene Expert results	Registration group	Resistance Pattern	R I	н	Z	∃ Kr	m An	n Cm	Fq	Pto/Eto	PAS Oth	ner	Date sample taken for DST	Date DST results are read in the lab	Have second line drugs ever been taken before? Yes/No	Regimen and Date started	Modified Intensive Phase Regimen (in drug initials) Date started	Initials Continuation Phase Regimen (in drug initials) Date started	Modified Continuation Phase Regimen (in drug initials) Date started	s	С	S	С	S	S S	С
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Registration Group

Relapse

Loss to follow-up
After failure of first treatment with first line drugs After failure of treatment with first line drugs FRT

TI Treatment in

0 Other

Resistance pattern

MDR Multi drug resistant TB

XDR Extensively resistant TB Poly drug resistant TB PDR

Mono drug resistant TB (except RR) MR Rifampicin monoresistant TB

GeneXpert results

MTB detected, rifampicin resistance not detected;

MTB detected, rifampicin resistance detected;

MTB detected, rifampicin resistance indeterminate;

MTB not detected;

Invalid/no result/error

Nutrition support

NC Nutrition Couseling

FS Food support

MN Micronutrient support

ND Not Done

Z score/BMI for age/BMI

Severely Malnourished <15.9 Moderately Malnourished 16 - 18.4 MM Normal 18.5-24.9 N Overweight 25-29.9 ow Obese >30

Smear (S) and Culture(C) results during treatment

Mont	n 4	Month 5	Mont	th 6	Month 7	Mor	nth 8	Month	9 Mc	onth 10	Мог	nth 11	Mont	h 12	Month	n 13	Month 1	4 Mc	onth 15	Mon	th 16	Mont	h 17	Mont	h 18	Month	19	Month :	20	Month 21	Мог	nth 22	Mon	th 23	Month	n 24			TB/	HIV act	ivitie	es			
s	С	s c	s	С	s c	S	С	S (C s	S C	s	С	s	С	S	С	s c	s	С	s	С	s	С	s	С	S	С	s	С	s c	s	С	S	C	S	С	RBS	Nutrition support	HIV Pos / Neg / Not Done Date	ART Y/N,N/A	Start date	Start date	Treatment Outcome	Date of Treatment Outcome	Comments
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Notation method for recording smears

No AFB seen Scan 1 - 9 AFB per 100 HPF 10 - 99 AFB per 100 HPF 1- 10 AFB per HPF +++ > 10 AFB per HPF

Notation method for recording cultures

No growth reported Repo Fewer than 10 colonies 10 - 1000 colonies More than 100 colonies

Innumerable or confluent growth

Drug abreviations

Th - Thioacetazone

Bdq - Bedaquiline Cfz - Clofazimine H -Isoniazid R - Rifampicin E - Ethambutol Z - Pyrizinamide S - Streptomycin

Lzd- Linezolid Amx/clv- Amoxicillin clavulin Dlm- Delaminid Rf - Rifabutin

Am - Amikacin Km - Kanamycin Cm - Capreomycin Cfx - Ciprofloxacin Ofx - Ofloxacin Lfx - Levofloxacin

Mfx - Moxifloxacin

Pto - prothionamide Eto - Ethionamide Cs- Cycloserine PAS - P- aminosallilic acid Imp Imipinem HDI -High dose Isoniazid

Gfx - Gatifloxacin

Outcome of treatment

C Cured (Smear negative)

TC Treatment complete (No smear results)

F Treatment Failure

D Dead

LTFU Lost **NE** Not Evaluated

