

# Definitions (Chapter 4) and Recording and reporting (Chapter 18)

2.DOTS-Plus consultants' course

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# Content

- How to use the definitions of patient groups and treatment outcome categories.
- How to fill in and use the different forms for Category IV
- How to analyse the data by calculating and assessing main indicators
- How to establish and implement the Category IV Recording and reporting system in an area

# Scope

- Based upon and an extension of the basic DOTS information system
- Contains minimum variables and forms.
- Quarterly routine collection versus annual collection or ad hoc studies
- Can be modified as necessary to suit the local context.

# Definitions - Chapter 4

## Categories, definitions, and procedures facilitate:

- Standardized patient registration and case notification – to allow comparison between countries and programs and over time;
- Assignment of patients to appropriate regimens;
- Case evaluation according to site, bacteriology, and treatment history;
- Cohort analysis of registered Category IV patients and Category IV treatment outcomes.

# Categories

- Category I: new cases,
- Category II: previously treated cases,
- Category III is under revision. It used to indicate smear negative and extrapulmonary cases where only 3 drugs were used in the intensive phase, but many countries now include these cases in Category I.
- Category IV: drug resistant TB
- Paediatric cases is another category.

# What is a "chronic" TB case?

- IUATLD/WHO strict definition: a patient who failed (still smear pos) a full retreatment (Cat II)
- Practical definition: a patient who has been treated several times and who the health services has given up as incurable
- Better not use the concept chronic?

# Definition of category IV patients?

Patients who meet WHO Category IV diagnostic criteria and are entered in Category IV register:

- proven MDR-TB: confirmed by DST
- suspected MDR-TB - meet the diagnostic criteria for Cat IV regimens

# Definitions of resistance

- **Mono-resistance:** *M. tuberculosis* resistant to one first-line antituberculosis drug.
- **Poly-resistance:** resistant to more than one first-line antituberculosis drug, other than both isoniazid and rifampicin.
- **Multidrug-resistance:** resistant in vitro to at least isoniazid and rifampicin
- **Extreme drug-resistance:** MDR strains resistant in vitro also to quinolones and one of the injectibles (kanamycin, amikacin or capreomycin)(?)

# Sputum conversion

- Two sets of consecutive negative smears and cultures taken 30 days apart.
- Used to monitor program performance:
  - proportion of patients who are smear- and culture-negative at one point in time (6 months after the start of treatment), or:
  - frequency and timing of conversion.

# Delays in DST results

- Sputum collected, result of positive smear microscopy, entered in District TB register and started on Cat I treatment
- Delay for 1.line DST result:
  - LJ culture ca 2 months, additional 1 month for DST at least
  - Liquid media culture and DST, total 4 weeks?
  - Liquid media culture, rapid test for Rifampicin – total 2-3 weeks?
  - Additional time for 2.line DST unless included at start

# Leaving District TB register

- When DST shows MDR-TB, the patient is given treatment outcome: "failure/switched to Cat IV because of MDRTB"

# Enter in Cat IV register:

- Date of Cat IV registration:
  - Date of entry in Cat IV register?
  - Date of MDR-TB DST result?
  - Date of medical commission meeting?
  - NOT: Date of treatment start

# Category of patient

- Category when the sputum was taken that showed MDRTB, - although the patient may have taken Cat I or Cat II treatment for weeks/months afterwards

# Cat IV case registration (I)

**New:** never received antituberculosis treatment, or who have received antituberculosis treatment for less than one month.

**Previously treated only with first-line drugs** for one month or more.

**Previously treated with one or more second-line drugs** for one month or more with or without first-line drugs.

# Cat IV case registration (II)

- **New**
- **Relapse** – A patient previously treated for TB, declared cured or treatment completed, and who is diagnosed with TB.
- **Treatment after failure** – A patient who is started on TB treatment after having failed previous treatment.
  - After failure of Cat I treatment
  - After failure of retreatment

# Case registration (II cont)

- **Treatment after default:** returns to treatment, following interruption of treatment for 2 or more consecutive months.
- **Transfer in:** transferred from another register for treatment of drug-resistant TB to continue Category IV treatment.
- **Other:** do not fit the above definitions. This group includes Category IV patients who were treated outside DOTS programmes.

# Treatment outcome:

- **Cured:** completed treatment and has at least five consecutive negative cultures from samples collected at least 30 days apart in the final 12 months of treatment.
- **Treatment completed:** completed treatment but does not meet the definition for cure because of lack of bacteriological results (i.e. fewer than five cultures were performed in the final 12 months of treatment).
- **Died:** died for any reason during the course of MDR-TB treatment.

# Treatment outcome (cont.)

- **Failed:** two or more of the five cultures recorded in the final 12 months of therapy are positive, or any one of the final three cultures is positive. (in addition clinical definition)
- **Defaulted:** treatment interrupted for two or more consecutive months for any reason.
- **Transferred out:** transferred to another reporting and recording unit and for whom the treatment outcome is unknown.

# Cohort analysis - by dates

Three dates should be recorded

1. Date of initial registration as a TB case  
(from the District Tuberculosis Register):
2. Date of registration in Category IV (from  
Cat IV register)
3. Date of starting Category IV treatment  
(from Cat IV register)

# Cohort analysis (II)

- Interim treatment status at 6 months after the start of treatment, preliminary at 24 months, final at 36 months
- All patients should be assigned the first outcome they experience.
- Programmes may wish in addition to record subsequent outcomes among patients followed systematically.