Interim case definitions

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Workshop for Early Implementers

Implementation and roll-out of the Xpert MTB/RIF system

for rapid diagnosis of tuberculosis and multidrug-resistance

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THE STOP TB DEPARTMENT

World Health Organization

Outline

- Why need for (new) case definitions
- Determinants of case definitions
- *Interim* case definitions
- Next steps

Why need for case definitions (1)

- Proper patient registration and case notification
- Selecting appropriate standard treatment regimens
- Cohort analysis of treatment outcome

- Standardizing the process of data collection for TB control
- Accurate monitoring of trends in TB case detection (notification) and evaluation of the effectiveness of TB programmes

- Evaluating the proportion of cases according to site, treatment history and bacteriology

Why need for *interim* case definitions (2)

- Proper patient registration and case notification
- Selecting appropriate standard treatment regimens
- Cohort analysis of treatment outcome

- Standardizing the process of data collection for TB control
- Accurate monitoring of trends in TB case detection (notification) and evaluation of the effectiveness of TB programmes

- Evaluating the proportion of cases according to site and treatment history

Determinants of "current" definitions:

- Site of TB disease
  - Pulmonary or Extrapulmonary
- Severity of TB disease
  - Severe and less severe (mild)
- History of previous treatment
  - New (never treated or less than 1 month of treatment)
  - Previously treated (relapse, failure, default)
  - Transfer-in
  - Other (unknown history of previous treatment or unknown result of previous treatment,)
- Bacteriology
  - Smear positive or negative or not done
  - Culture positive or negative or not done
- HIV status – critical for treatment decisions

Determinants of "*interim*" definitions:

- Site of TB disease
  - Pulmonary or Extrapulmonary
- Severity of TB disease
  - Severe and less severe (mild)
- History of previous treatment
  - New (never treated or less than 1 month of treatment)
  - Previously treated (relapse, failure, default)
  - Transfer-in
  - Other (unknown history of previous treatment or unknown result of previous treatment,)
- HIV status – critical for treatment decisions

Interim case definitions

- **TB case**
  - Patient with *M. tuberculosis complex* identified from a clinical specimen, by conventional culture or **by a newer method recommended by WHO (Xpert MTB/Rif)**
  - Patient in whom health worker (clinician or other practitioner) has diagnosed TB and decided to treat the patient with the whole course of anti-TB treatment
  - Pulmonary case with 1 or more initial sputum smear examinations positive for acid-fast bacilli (AFB) - in countries lacking lab. capacity to routinely identify *M. tuberculosis complex* and with functional EQA system.

Interim case definitions (2)

- **TB case**
  - Patient diagnosed **positive on Xpert MTB/RIF**
  - No need for any other test (smear microscopy, culture, DST)
    - if no resistance to rifampicin detected
- Monitoring of treatment response with smear microscopy (2 months, 5 months and end of treatment)
- Outcomes "cured" and "failed" apply (even if smear microscopy or culture were not done at start of treatment)

Interim case definitions (3)

- **TB (R-resistant)**
  - Patient diagnosed **positive on Xpert MTB/RIF and R-resistant**
- Monitoring of treatment response with smear microscopy and culture (in line with the PMDT guideline)
- Same treatment outcomes as for MDR-TB

Next steps

- Expert consultation on 12-13 May 2011 to discuss case definitions, treatment monitoring and outcome definitions
- Presentation to STAG for endorsement (20-22 June 2011)
- Dissemination to all implementers (WHO website) and collection of data throughout the year
- Global consultation (December 2011 – tentative – to evaluate the roll-out of the tool, analyze the data and revisit *interim* definitions)