THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Training on EQA and National TB Laboratory Network

Module 2: Background and Principles of Rechecking

Date

Uganda Supranational Reference Laboratory

Content Outline

- Background of rechecking
- Principles of rechecking

Background Of Rechecking (1)

- Purpose of rechecking
  - Screening for possible problems of AFB microscopy in sample of smears examined in routine work
- Aim of rechecking
  - Improving quality of AFB microscopy
  - Not correction of diagnoses
  - Not substitute for internal quality control
  - Not substitute for regular supervision

High Quality AFB Microscopy

- Essential for proper patient management
  - Missed diagnosis of AFB-pos. patient (false negative=FN) or delayed diagnosis: death or advanced, disabling, disease
  - Incorrect diagnosis as AFB-pos. (false positive=FP): drug side effects, social and economic consequences

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Critical Resources for EQA Implementation / Expansion

Blinded rechecking

- Adequate number of rechecking laboratories
- Sufficient number of staff
  - 1st and 2nd controllers capable of comfortably absorbing additional workload on slides' rechecking
  - to perform problem-solving supervisory visits
- Functional microscopes, in sufficient quantity, at all levels:
  - microscopes for controllers

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Rechecking Merits and Demerits

Merits

- It shows what happens in practice
- Can be highly motivating if done correctly

Demerits

- Workload, especially for intermediate and central levels
- Impossible in highly decentralized microscopy service or very low TB prevalence

Principles Of Rechecking (1)

- Random, representative, sample of slides from each laboratory is rechecked
- Rechecking is blind: rechecker (=first controller) does not know results of the laboratory
- Discordant slides (pos. at laboratory and neg. by rechecker, or the reverse) are rechecked by second controller (gold standard)
- Errors assigned to laboratory or first controller

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Principles Of Rechecking (2)

- Analysis to identify centers that may perform below standard
- This needs to be confirmed by further checks and on-site visits
- Identification of possible sources of errors and need for remedial action

Prerequisites For Rechecking

- A well functional TB programme
  - Regular supervision
  - Highly functional TB laboratory network, particularly at intermediate level
  - Possibility for corrective actions
  - (Additional) resources: personnel, materials, funds

Inputs For Rechecking (1)

- Personnel
  - Supervisors for sample collection and feedback
  - Rechecking coordinators at intermediate levels
  - National level coordinator
  - First level controllers
    - Sufficient time
    - Motivated
    - Seniority not required
  - Second level controllers
    - Experienced, dedicated
    - Sufficient time
    - High level qualifications/position not required

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Inputs For Rechecking (2)

- Materials and funds
  - Microscopy centre
    - Slide boxes, pencils/diamond markers
  - Supervisors collecting the slides
    - Slide boxes, sampling forms, transport
  - Controllers
    - TIME, staining facilities/equipment, transport
  - TB coordinators
    - Forms, tools for analysis (computer), transport

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Sample Size Concepts (1)

- Random, representative selection of any slide, irrespective of result and type (diagnostic, follow-up)
- Fixed number of slides per laboratory per year
- Sample size based on statistical system called Lot Quality Assurance Sampling (LQAS)
- LQAS allows selection of the smallest possible sample for assurance of the quality of laboratories
- Sample size is usually between 40 and 90 slides annually per lab

Sample Size Concepts (2)

- Number of false negative (FN) allowed in the sample is set at 0 (= no FN allowed)
  - If no FN: quality of the centre is acceptable
  - If >0 FN: not sure that quality of the centre is acceptable, further investigation needed
- Clear-cut false positive (FP, i.e. 1+, 2+, 3+) are also not allowed

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Comparison of Sample Sizes: New and Old Method

- Compared with old rechecking method- all positives and 10% of negatives- the sample size of LQAS method is much smaller

Annual volume of slides	Positive slides	Negative slides	Old rechecking method	New rechecking method
520	74	456	120	62
2556	182	2374	459	135
6822	355	6467	1001	208

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Sample Collection

- Usually quarterly
- May be more or less frequent
- Division of annual sample by interval period
- Ensure that total sample has been selected

Assessment

- What are the prerequisites for an effective rechecking program?
- What is the advantage of using the LQAS system for determining sample size compared to the earlier recommended method of rechecking all positives and 10% of negatives?
- What does "blinded" rechecking mean?

SUMMARY

- The purpose of rechecking is to screen for possible problems in AFB microscopy based on a sample of smears examined in routine work
- Clear errors found may still be due to chance, but may also indicate problems; further investigations are needed for those laboratories

SUMMARY

- The sample of routine slides should be as small as possible, representative and random
- Rechecking requires a substantial investment of financial, material and human resources

Acknowledgments