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MINISTRY OF HEALTH

UGANDA Supranational® Reference Laboratory

Timely Accurate Diagonostics for a TB-Free Africa

Training on EQA and National TB Laboratory Network

Module 10: Problem Oriented Supervision and Problem Solving

Date

Uganda Supranational Reference Laboratory

Content Outline

- Scope of problem-oriented supervision
- Problem-oriented supervision as the aim of the EQA program
- Problem identification and solving
  - Many (or almost all) HFP as well as HFN
  - False positives
  - False negatives
  - Quantification errors
- Laboratory indicators

Scope of Problem-Oriented Supervision

- Checking each and every item and procedure is very time consuming:
  - the need to observe the routine work for most of a day
- Alternative: screening for a few important points based on earlier findings
- Opposite to screening the whole process
  - only specific areas of the laboratory work are targeted for checks
- Effective time management
- Most of it can be done by general TB supervisors

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Laboratory Register Checks

- The register should be complete and up to date, results look plausible
- Check on the last pages if all sputa arrived have been entered
- Check if results of the day before were registered
- Check with the recent past results if, according to the WHO revised policies:
  - most (but not all) suspects had two smears examined
  - detected cases had at least one positive result

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Laboratory Register Checks (cont.)

- Cross-check the TB lab register against the TB patient register:
  - All cases recently detected should be registered for treatment
  - Promote writing a note in the lab register:
    - the patient register number
    - where the detected case was sent for treatment
- Cross-check the TB patient register against the TB lab register:
  - assess delay between a positive result and start of treatment
- Make counts
  - Estimate total workload
  - Calculate indicators

Looking at Smears

- Macroscopic inspection with the naked eye:
  - -detect poor smearing and identify deficiencies
  - -assess quality of staining, i.e. decolorization and counterstaining
  - -check identification / labeling of
    - sputum containers
    - freshly smears or stained smears awaiting examination

Looking at Smears (cont.)

- Microscopic observation of a few recent positives:
  - assess quality of staining - if the red colour of AFB is deep and even
  - inspect how the microscope functions

Note: smears should be strong positives and definitely recent ones to avoid a wrong impression because of possible fading

Blinded Rechecking Efficiency and Reliability

- The collection of slides kept should be inspected
  - for probable completeness
  - conditions of storage (out of sunlight, properly arranged by number)
- Slides should NOT
  - be separated as positives and negatives
  - have the result written on them

Blinded Rechecking Efficiency and Reliability (cont.)

- Inquire about
  - regularity of sampling and how this is done
- Check feedback preferably by requesting reports received
  - If reports are present:
    - check reports for plausibility and results
  - In case serious errors were detected in rechecking
    - inquire about actions taken and their effectiveness ("evolution of errors")

Important Issues

- Blinded rechecking system and on-site supervision
  - are complementary to each other
  - will function less effectively without each other
- Analysis of laboratory indicators and EQA data will guide supervisors to focus on those elements which can be possible sources of errors
- Development and observance of algorithms while investigating of errors will help supervisors to
  - find deficiencies
  - correct deficiencies
  - prevent appearance of errors in future

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Problem Identification and Solving: Investigation of Rechecking Errors

Investigation of Errors

- Consider:
  - types and number of errors detected
  - the controllers' qualitative remarks

- **false positive, false negative or both?**
- **false positives:**
  - only low, or also high?
  - in which numbers?
- **false negatives**:
  - low, high, or both?
  - in which numbers?
- **quantification errors?**
  - when interpreting consider if restaining was used or not

Many (or almost all) HFP as well as HFN

- Indicate a serious problem:
  - total lack of training
  - or unusable microscope
  - or smears were not examined

- Investigation:
  - examine a 3+ smear with that microscope, to see if it works properly
  - request the microscopist to examine a clear-cut positive and a negative smear with a good microscope, to see if he/she knows what is AFB
  - if both are OK: conclude at total neglect, not examined

False Positives

- Just one HFP:
  - administrative error
    - poor slide numbering
    - transcription error
  - failure of the controllers to detect AFB
- Only LFP
  - limitation of the controls
    - poor reproducibility in this range,
    - damaged smears...
  - hazy microscope
  - confusion regarding recognition of AFB

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False Positives (cont.)

- More HFP, with or without LFP

  - sloppy administrative procedures
  - confusion regarding recognition of AFB
  - no restaining in situations with fading of staining, not even of discordants
  - not examining all smears but copying positive results to the second and/or third smear of a series
  - rarely contaminated carbolfuchsin stain

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Investigation of False Positives

- Not needed for LFP occurring at low frequency, similar to other labs and the first controller
- Not urgent for a single high false positive

- Check the listed result on the rechecking form with that in the laboratory register:
  - same number and result?
    - if not: correct all records
    - if result/identification is uncertain: exclude the rechecking result from analysis

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Investigation of False Positives (cont.)

- Ask the technician to show the AFB in the false positive slide with his / her microscope:
  - clearly visible?
    - if NO: faulty microscope - adjust or repair or replace microscope
  - true AFB?
    - if NO AFB but artefacts: educate the technician
    - if YES: report controller error to the rechecking coordinator
      - rechecking process needs improving?
      - recheckers to be replaced?
  - if no AFB are seen: restain and re-examine HFP again
    - If AFB appeared: fading; need to restain more?
    - If NO: damaged smear?

Investigation of False Positives (cont.)

- Look for signs of sloppy administration / identification:
  - is laboratory register up-to-date?
  - are sputum examination forms used?
  - is labeling on sputum pots done consistently?
  - do results on forms/lists correspond to those in the register?
  - are isolated positive/scanty results in case series not so rare?

- Many LFP:
  - check if quantification scale is understood
  - if too many LFP:
    - check as many recent LFP as possible on the spot, without restaining;
    - ask the technician to show what he/she considers to be AFB

False Negatives

- Single LFN
  - NO investigation
  - Monitor evolution

- Single HFN
  - an administrative error; or copying results from other smears
  - some smears are not examined: days of overload

False Negatives (cont.)

- Several HFN, and/or LFN

  - very thick smears
  - bad stain or poor staining / poor staining technique
  - poorly lighted or hazy microscope (due to dirt, fungus or oil inside, other problems)
  - contaminated methylene blue or rinsing water
  - superficial or no examination
  - very rarely: technician doesn't know AFB; colour blindness

Investigation of False Negatives

- Look at a full box of smears:
  - if many too thick, AFB hard to see: poor smearing / less light
  - if many too red background: destaining faulty
  - if many too dark blue: smearing / counterstaining faulty
- Look at carbolfuchsin stain poured on a new slide on the staining bridge:
  - can you see the bridge easily? is colour too light?
    - If YES: bad carbolfuchsin staining solution, replace

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Investigation of False Negatives (cont.)

- Examine positive smears with their microscope
  - is light in the microscope less bright?

    If YES:
    - check correct position of a condenser and diaphragm
    - remove filters (if used)
    - if mirror is used: find better place for examination
    - check for heavy fungus growth

Investigation of False Negatives (cont.)

- Examine positive smears with their microscope (cont.)
  - hazy view, or complete blur? If YES:
    - try to clean eyepieces, condenser, light source and objectives and check again; replace obviously damaged parts
  - check red staining of AFB in a few recent non-restained strongly positive smear:
    - strong or weak red?
    - solidly stained or thin or granular AFB?

Investigation of False Negatives (cont.)

- Exclude contamination of methylene blue (only if rechecked smears were restained)
  - repeatedly stain known negative smears, check if (atypical) AFB appear
  - make ZN smears from taps and containers / glassware used for preparation of solution and staining: AFB found?
    - If contamination is confirmed, exclude the laboratory's sample from evaluation
- Check the register for daily workload:
  - less than 25 smears on average per technician involved in ZN microscopy?

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Investigation of False Negatives (cont.)

- No reason found after all previous checks:
  - assume superficial reading to be the cause if false negatives not so rare and more are LFN
  - suspect administrative mistake if exceptional (more chance to be HFN)

Quantification Errors

- May be caused by:
  - lack of quantification skills or motivation
  - poor microscope
  - poor staining solutions or staining procedure

- When interpreting, consider:
  - whether the rechecking procedure was used with or without restaining?

Investigation of Quantification Errors

- Lack of quantification skills:
  - use a panel for confirmation

- Smears for rechecking were *restained*, and quantifications consistently higher for recheckers (and possibly accompanied by false negatives)
  - check staining solutions (and staining procedure if solutions are good)
  - check the microscope (light, sharpness)

  (check positive smears without restaining to differentiate)

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Investigation of Quantification Errors (cont.)

- Smears for rechecking were *not restained* and quantifications consistently higher for recheckers (and possibly accompanied by false negatives)
  - check the microscope (light, sharpness)

- No problem detected: lack of efforts

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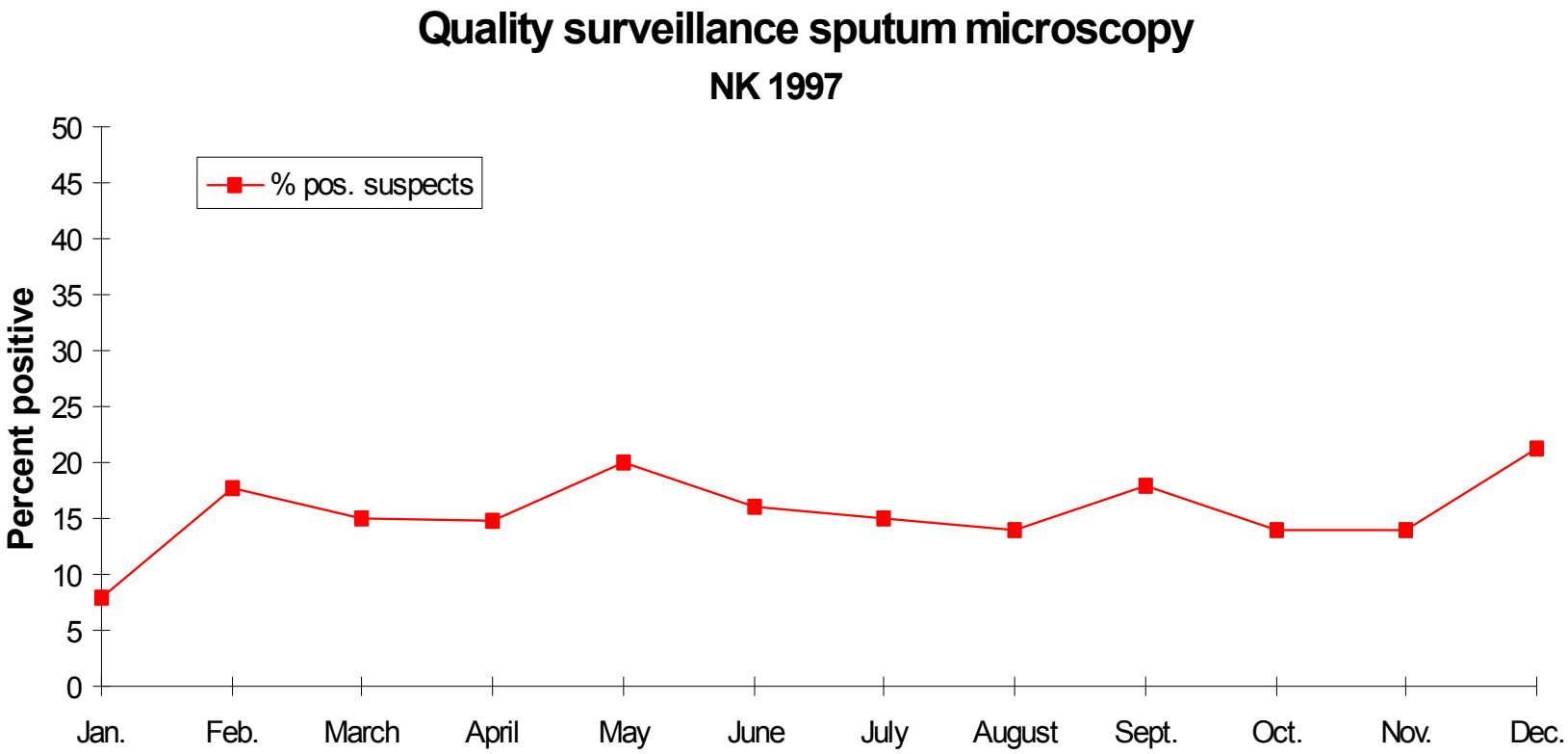
Laboratory Indicators

Positives Prevalence of Suspects Smears

- Indicates lab quality, but also
  - accessibility (financial, geographical)
  - selection of suspects
- Normal prevalence: 10% ?
  - varies ~ NTP: accessibility, other diseases (HIV !)
  - varies ~ level of service
  - seasonal variations ...
- Extract lab quality ?
  - compare units at same level
  - only gross lab deficiencies may show

Monitoring Percent of Positive Suspects Smears (I)



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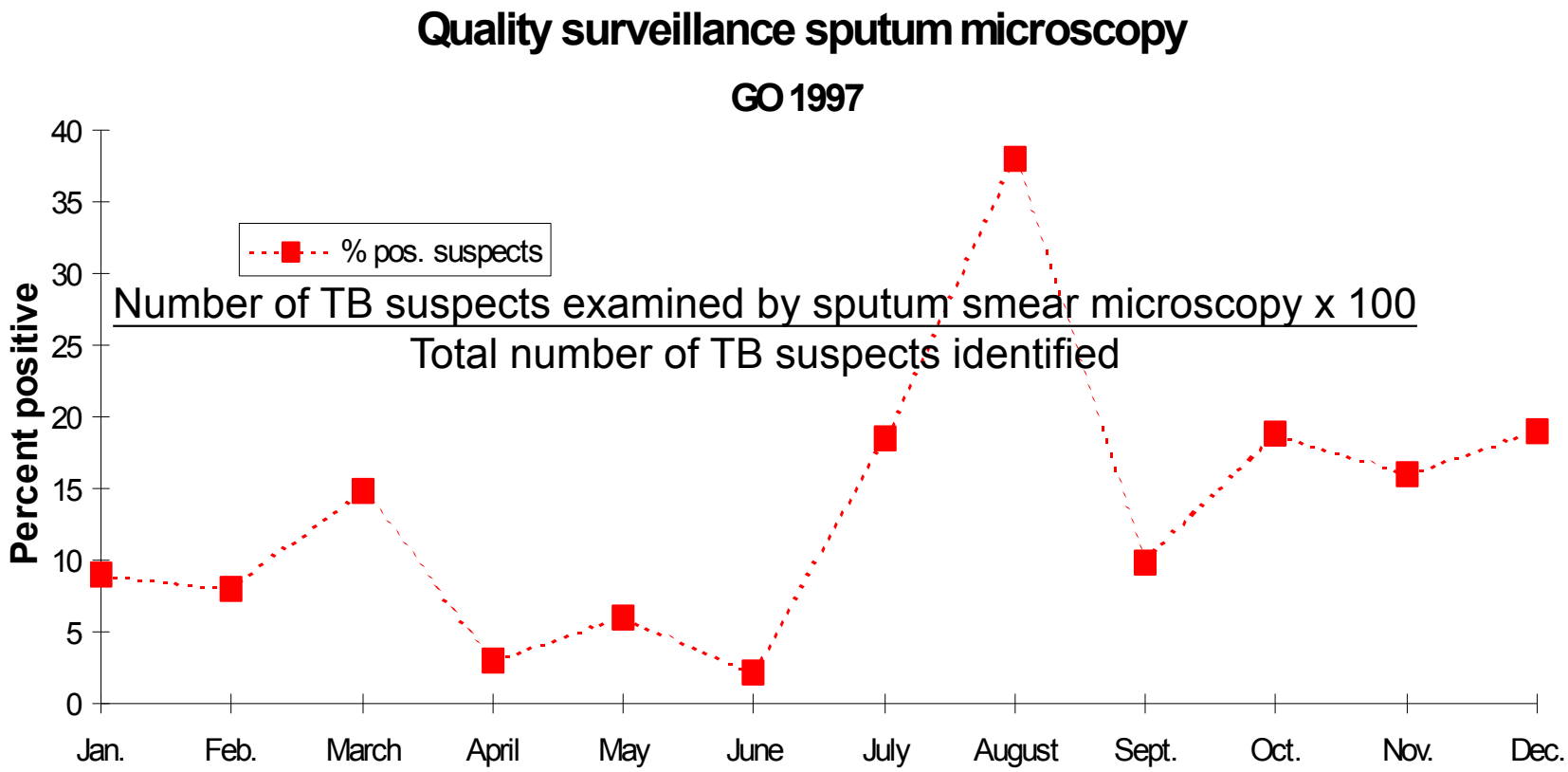
Monitoring Percent of Positive Suspects Smears (II)



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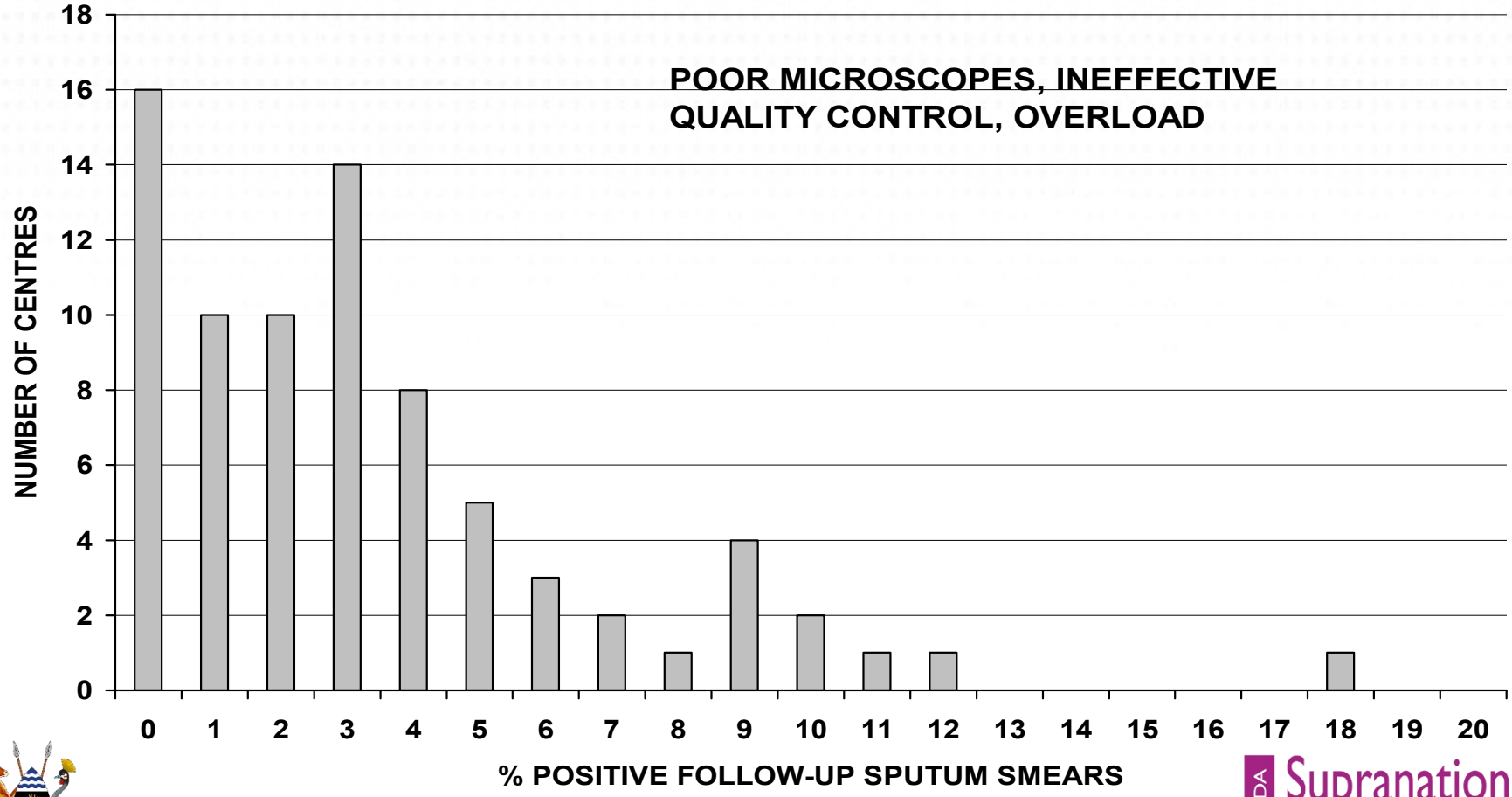
Positives Prevalence of Follow-up Smears

- Sensitive indicator of lab quality
- Normal prevalence may be around 10%
  - ~ population: early treatment? MDR-TB? HIV?
  - ~ guidelines: no. of smears first 2-3 months?
  - ~ correct registration: targets!!
- Interpretation of very low prevalence
  - superficial reading or bad microscope
  - and/or poor staining

Positives Prevalence of Follow-Up Smears : Example of Data Analysis



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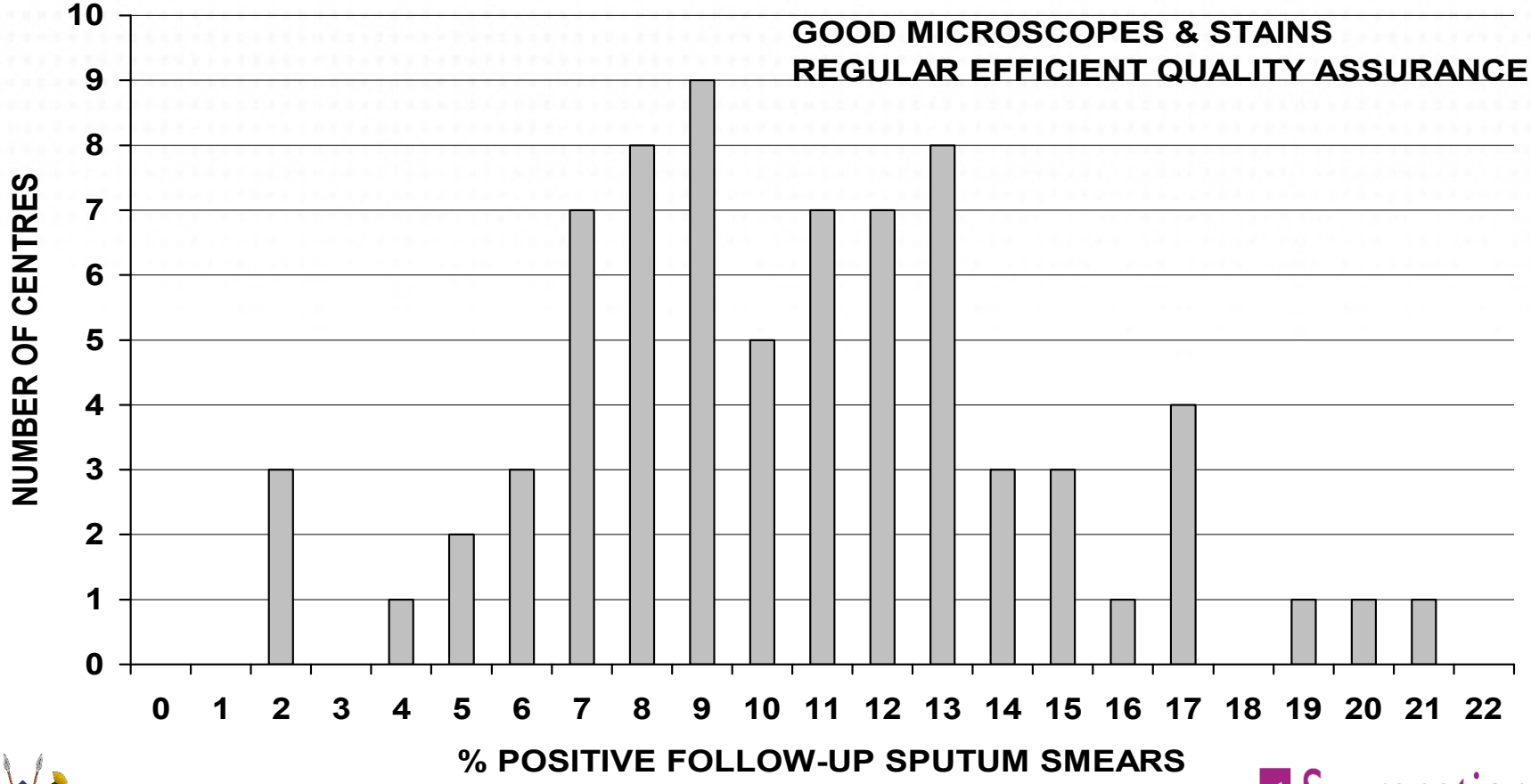
Positives Prevalence of Follow-Up Smears: Example of Data Analysis (cont.)



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How to Use These Indicators?

- Internal monitoring, charting
  - problem: fluctuations++
    - --> only larger units & selected indicators ?
- During supervision visits
  - can be used by TB supervisors as well
  - one value, i.e. full quarter or year
  - problem: time constraint in big units
    - selected indicators only, i.e. low positives
    - scan rather than count
- Calculate from lab reports
  - ideal: analysis by computer
  - problem: few NTPs have lab reports!

SUMMARY

- Problem-oriented supervision focuses on solutions or strategies for managing particular problems that were identified based on earlier findings

- To ensure high quality, besides observations also analysis of laboratory indicators, routine performance reports and data obtained from other EQA activities, especially blinded rechecking, should be used.

Assessment

- What is the scope of problem oriented support supervison?
- What do you consider during investigation of errors?

References

- WHO Laboratory Quality Management System Handbook
- WHO/GLI Tools.
- John, R. (1999). External Quality Assessment for AFB Smear Microscopy. *Public Health Practice Program Office Centers for Disease Control and Prevention, Rosemary Humes. Association of Public Health Laboratories, 17.*
- GLI Training package on EQA overview & Planning

Acknowledgments


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