Ensuring Adequate Laboratory Biosafety

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GLI Strategic Priorities

• Establish GLI partnership projects
• Develop templates for country-specific roadmaps for laboratory strengthening
• Develop human resource strategies
• Develop appropriate laboratory biosafety standards
• Develop a TB lab accreditation system
• Move new diagnostics into countries
Why is Biosafety Needed in the Tuberculosis Laboratory?

- Risk of infection with *Mtb* is higher for TB lab workers than for other lab workers
  - 1.4-fold higher for TB microscopists
  - 21.5-fold higher for DST technicians
- Infection often results from unrecognized production of infectious aerosols
- Infection can also occur from needle sticks, through broken skin, etc.
Biosafety

The application of a combination of administrative controls, containment principles, laboratory practices and procedures, safety equipment, and laboratory facilities to enable laboratorians to work safely with potentially infectious microorganisms.
Administrative Controls

• Supervision by an experienced scientist
• All personnel are well trained, proficient, aware of hazards, follow rules
• Routine medical surveillance
• Biosafety and operations manuals
• Emergency plans for spills, accidents, etc.
• Appropriate facilities and safety equipment
Good Laboratory Practices

- Restrict or limit access when working
- Biohazard warning signs
- Prohibit eating, drinking and smoking
- Prohibit mouth pipetting
- Minimize splashes and aerosols
- Decontaminate work surfaces daily
- Decontaminate wastes
Containment

- **Primary Containment**: protect worker and immediate laboratory environment
  - good microbiologic techniques
  - safety equipment
  - facility design

- **Secondary Containment**: protect the environment outside the laboratory
  - facility design
  - waste management
Biosafety Level (BSL)

• Conditions under which an infectious agent can ordinarily be safely handled.
• Conditions are a combination of:
  • laboratory practices and techniques
  • safety equipment
  • laboratory facilities
• Usually agent and procedure specific
  • generic BSLs are available for many infectious agents
  • procedure-specific BSLs often missing
GLI Biosafety Projects

• Biosafety guidance for TB lab procedures
  • Technical consultation in Sept. 2008
  • Expert meeting in April 2009
  • WHO and CDC were the lead agencies

• Specifications for a ventilated work station suitable for direct AFB-smear microscopy
  • Expert consultation in Sept. 2009
  • CDC and APHL were the lead agencies
Biosafety Guidance

• Consensus recommendations for minimum biosafety requirements for
  • AFB-smear microscopy
  • Culture
  • Drug-susceptibility testing
  • Molecular testing

• Based on a risk assessment for each TB diagnostic procedure
  • generation of infectious aerosols
  • concentration of bacilli
Direct AFB-Smear Microscopy

Limited risk of generating infectious aerosols

• Work can be done on an open bench
  • separate bench for smear-preparation

• Facility: adequately ventilated enhanced BSL1 or basic BSL2 laboratory
  • natural or mechanical ventilation; 6–12 ACH
  • directional airflow

• Proper disposal of infectious material
Processing Sputum Specimens for Smear, Culture, Molecular Tests

Risk of generating infectious aerosols during centrifugation and specimen manipulation

- Work with specimens should be done in a biosafety cabinet (BSC)
  - BSC class I or II may be used
- Facility: adequately ventilated BSL2 lab
  - directional airflow; 6–12 ACH
- Use aerosol-containing rotors or buckets
- Proper disposal of infectious material
Processing Cultures for Smear, ID, Subculture, DST, Molecular Tests

High risk of generating infectious aerosols during manipulation of liquid suspensions

• Work with cultures should be done in a BSC
  • class I or II BSC may be used
  • certified at least annually

• Facility: adequately ventilated BSL3 or enhanced BSL2 laboratory
  • directional airflow; not recirculated

• Use aerosol-containing rotors or buckets

• Proper disposal of infectious material
BSL3 – Secondary Containment

BSL2 secondary containment plus:
• Controlled access to a separate area
• Double door entry
• Single-pass air; 6-12 air changes/hour
• Enclosures for aerosol generating equipment
• Room penetrations sealed
• Walls, floors and ceilings are water resistant for easy cleaning
If a facility does not have all required BSL3 features (e.g. sealed penetrations, solid ceiling), an acceptable level of safety for conducting routine procedures, including culture, may be achieved in a BSL2 facility providing:

- Directional inward airflow is maintained and exhaust air is discharged to the outside
- Access to the laboratory is restricted when work is being performed
- The recommendations for BSL3 practices, procedures, and safety equipment are rigorously followed
Next Steps for Work Group

- Finalize guidelines
- Distribute guidelines
GLI Biosafety Projects

- Biosafety guidance for TB lab procedures
  - Technical consultation in Sept. 2008
  - Expert meeting in April 2009
  - WHO and CDC were the lead agencies

- Specifications for a ventilated work station suitable for direct AFB-smear microscopy
  - CDC and APHL were the lead agencies
Why is a Ventilated Work Station Needed for Direct Microscopy?

- Risk of *Mtb* infection with is 1.4-fold higher for TB microscopists than non-TB workers
- Potential need for increasing BSL
  - Increased vulnerability of HIV-infected staff
  - Decreased treatment efficacy (M/XDR TB)
  - Increased exposure (unreliable airflow)
- Class I and II BSCs are expensive and require annual maintenance
What is Done in The Work Station

- Open sputum cup
- Smear (disposal sticks/loops, re-usable loops w/ flame/micro-incinerator)
- Air dry
- Close sputum cup
- Disposal of sticks
- heat fix?
- Stain?
A Simple, Inexpensive Biological Safety Cabinet For Use in Developing Nations

by

R. W. Smithwick and G. P. Kubica

Figure 3. A simple airflow gauge: A. Close-up drawing of construction.
B. Placement in BSC for airflow check (see text for details).
Objectives of Expert Consultation

- To assess the need for ventilated work stations in resource-limited settings
- To provide guidelines for design, materials, and construction of work stations
- To provide guidance on validating the recommendations to ensure the safety, reliability, and integrity of the work stations
Issues Addressed

• General requirements to reduce risk of infection with AFB smear microscopy
• Balance need for safety with unintended messages about AFB smear microscopy
• Appropriate vs. non-appropriate use
  • not intended for TB culture, TB DST
• A guideline is not a standard and certification will not be available
Recommendations made for Minimum Requirements

- Materials
- Ergonomics
- Electric Components
- Design
- Validation
- SOP Checklist
Next Steps for Work Group

• Prepare report of expert consultation
• Prepare guidelines in simple language suitable for an international audience detailing instructions how to construct a work station
• Prepare specifications for materials, ergonomics, electric components, design, validation, and SOPs
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