



Photo: Riccardo Venturi



WHO recommendations for biosafety in tuberculosis laboratories

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Content overview

- Risk assessment and the classification of TB laboratories
- Essential biosafety measures for TB laboratories
- Low-risk TB laboratories
- Moderate-risk TB laboratories
- High-risk TB laboratories (TB-containment laboratories)

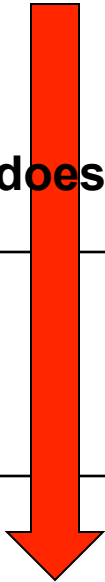
What is Biosafety?

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

Risk Group Classifications and which Biosafety Level (BSL)

RISK GROUP CLASSIFICATION	WORLD HEALTH ORGANIZATION LABORATORY BIOSAFETY MANUAL 3RD EDITION 2004*
Risk Group 1	(No or low individual and community risk) A microorganism that is unlikely to cause human or animal disease. BSL 1
Risk Group 2	(Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited. ?BSL 2
Risk Group 3	(High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available. ? BSL 3
Risk Group 4	(High individual and community risk) A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available. ? BSL 4

Where does TB fit?



Determining minimum biosafety measures

- AFB Microscopy remains the primary diagnostic tool for the diagnosis of TB
- More than 37,000 microscopy laboratories in the 22 high-burden limited-resource settings
- Rapid molecular tests (e.g. Xpert MTB/RIF) are being scaled-up in laboratories with minimal biosafety precaution
- Other more sophisticated tests are performed at regional or central laboratories

*Need for practical guidance to countries to ensure at least the minimal precautions can be implemented in TB laboratories depending on which procedure is being performed using **a risk assessment based approach***

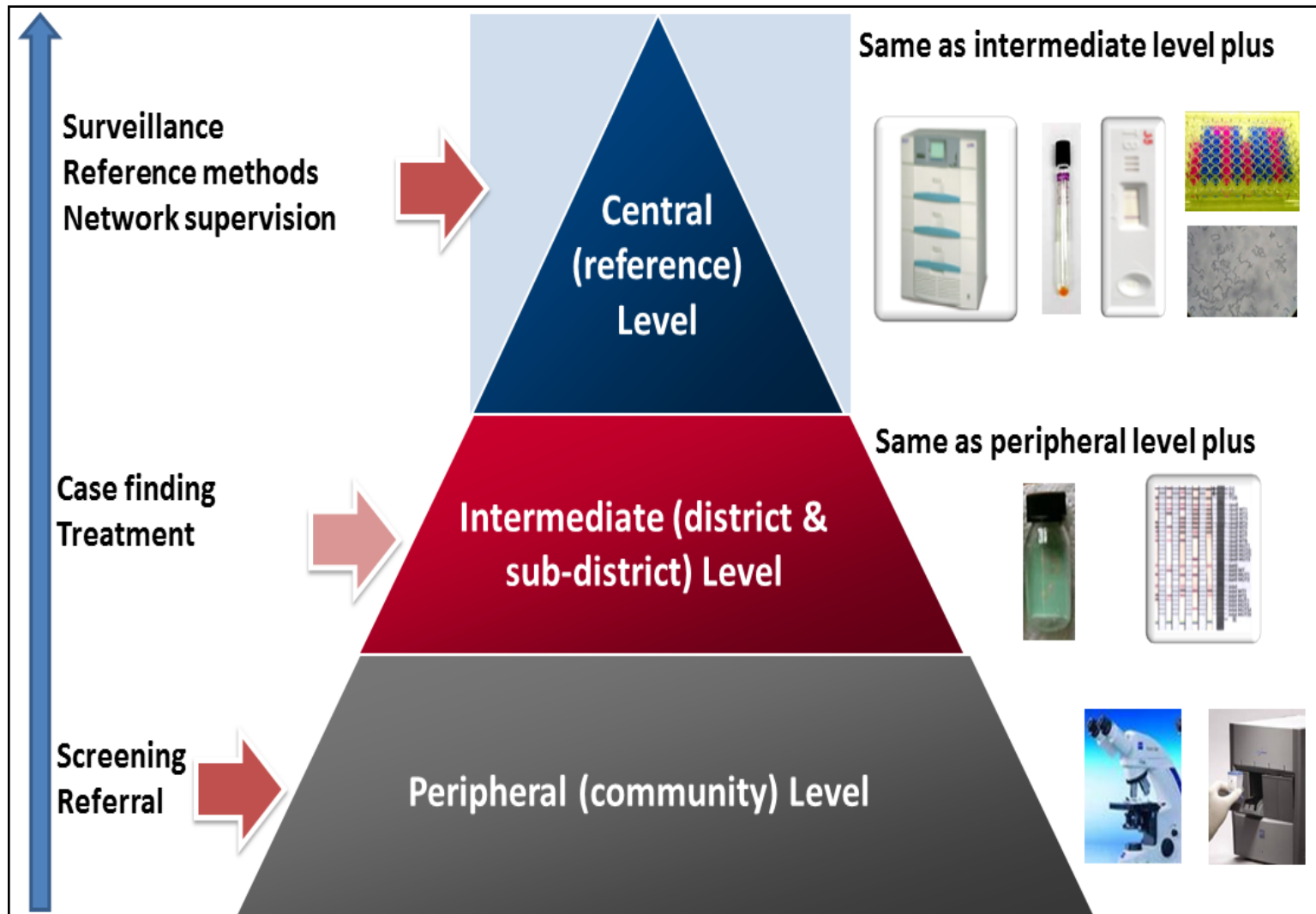
Current approaches are based on Bio-Risk Assessment

- Pathogenicity of the infectious agent
- Route of transmission
- Agent stability and infectious dose
- Concentration of agent
- Type of laboratory procedures to be done
- Availability of effective prophylaxis or therapy
- Skill level and vulnerability of at-risk personnel (e.g. HIV infection)
- Epidemiology of TB

How to conduct risk assessment for TB laboratory

- Identify the inherent hazards
- Decide who might be harmed and how
- Evaluate the risks and decide on precautions
- Record your findings and implement them
- Review your assessment and update it if necessary

WHO recommended diagnostics for use at different levels of laboratory sophistication



*Available at: <http://www.who.int/tb/dots/laboratory/policy/en>

Biosafety (risk) Levels for TB Laboratories

High-risk TB laboratory (TB-containment laboratory)

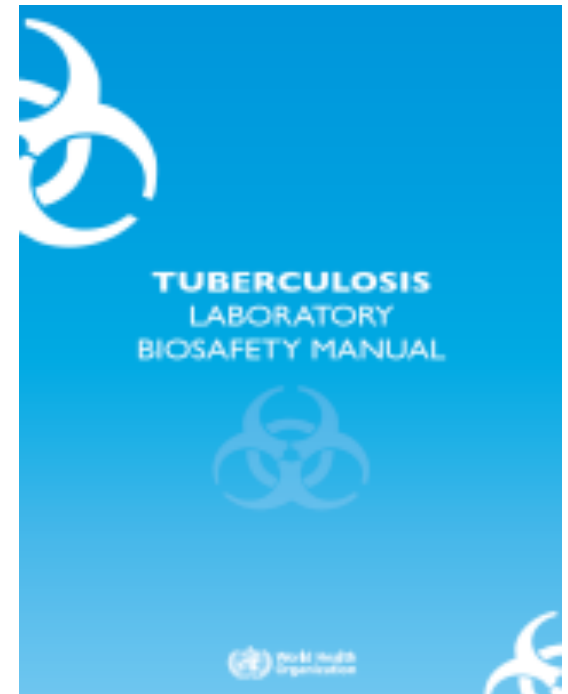
- Culture, DST, LPA (cultures)

Moderate-risk TB laboratory

- liquifying (processing) samples

Low-risk TB laboratory

- Microscopy, Xpert



Biosafety Guidance AFB Microscopy

Limited risk of generating infectious aerosols

- Work can be done on an open bench
 - restricted access to the laboratory
 - separate bench for smear-preparation
- Adequately ventilated laboratory
 - 6-12 ACH, directional airflow
 - Natural or mechanical ventilation
- Proper disposal of infectious material

Biosafety Guidance:

Processing sputum specimens for culture
inoculation and/or direct molecular tests (1)

Moderate risk of generating infectious aerosols during centrifugation and specimen manipulation

- Laboratories must have restricted access and be separated from public areas
- Impermeable surfaces for easy cleaning
- Air flows into lab without re-circulation to non-lab areas (directional airflow)
 - 6-12 ACH, passive or mechanical ventilation
 - closed windows
 - All work MUST be performed within a certified BSC
- Proper disposal of infectious material

Biosafety Guidance:

Processing sputum specimens for culture inoculation and/or direct molecular tests (2)

Moderate risk of generating infectious aerosols during centrifugation and specimen manipulation

- Class I or II Biosafety Cabinet used for all open manipulation of agents
 - **BSCs must be properly installed and certified at least annually**
 - **BSC exhaust may be**
 - ducted to outside using a hard duct or thimble fitting
 - recirculated into the room if assured that the BSC is functioning properly
- Use aerosol-containment centrifuge rotors

Biosafety Guidance:

Manipulating cultures for smear preparation,
identification tests, DST, or molecular tests

*High risk of generating infectious aerosols during
manipulation of liquid suspensions*

**Work done in a TB-containment lab which has restricted
access and a double door entry**

- Impermeable surfaces for easy cleaning
—sealing room for fumigation is not required
- Air flows into lab without re-circulation to non-lab areas (directional airflow)
—6-12 ACH, mechanical ventilation, sealed windows
- Autoclave available on site

High-risk TB Laboratory

TB containment laboratory

- Double door airlock
- Separate air inlet
- Venting of BSC via thimble
- Aerosol containment
- Negative pressure monitoring
- Uni-directional airflow
- PPE
- Autoclave for waste disposal



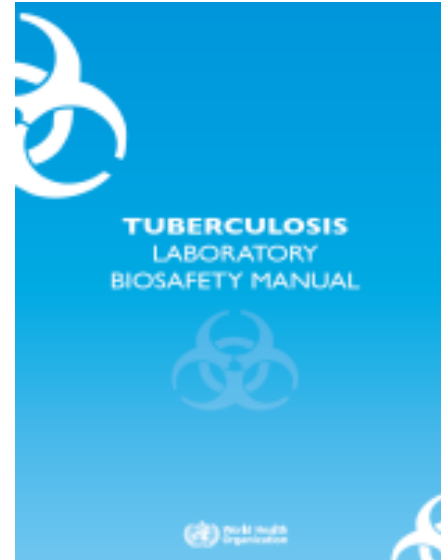
- Necessary for performing culture and DST

Determining which precautions to use

- When non-standard procedures need to be performed it is the responsibility of laboratory director assesses potential risks for the work by performing a risk assessment and to determine what additional precautions may be needed.
- Lab directors may specify more or less stringent practices when information is available to suggest altered risk
 - e.g., increased precautions can be implemented for XDR TB cultures or staff at greater risk

Questions?

The TB containment laboratory



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