Mycobacteriology Service Implementation

Module 1
Version 2019

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INTRODUCTION

- Why are we doing this?

Tuberculosis Overview

- https://www.cdc.gov/tb/topic/basics/howtbspreads.htm
- Latent versus Active Infection
- Infective dose = 1 – 10 organisms

2017 TB Facts – Worldwide

- One of the top 10 leading causes of death
- 10 million infections with 1.6 million deaths
- 1 million pediatric infections with 230,000 deaths
- Infectious triad– HIV/STDs/Tuberculosis
- TB is #1 killer of HIV positive people
- Resistance problematic
  - Multidrug resistant (MDR) – Isoniazid and Rifampin
  - Extensively resistant (XDR) – Isoniazid, Rifampin, fluoroquinolones, and at least 1 of the following 2nd line injectable antibiotics: Amikacin, Capreomycin, Kanamycin
  - Pan-resistant (PDR) – Resistant to all known antibiotic treatments

Primary Route of TB Transmission

Aerosols – cough, sneeze, sing, talk, spit….

https://www.youtube.com/watch?v=9qqHOKUXY5U

40,000 droplet nuclei

In the TB Laboratory we work with…

- Patient specimens of unknown infectivity
- Patient specimens of varying volume and organism concentration
- Concentrated cultures of organisms of known infectivity
- Processes that generate aerosols:
  - Opening/disinfecting specimen containers
  - Decontamination/Digestion/Concentration of specimens
  - Grinding of tissues
  - Pipetting/Pouring (into or out of a container)
  - Preparation of direct specimen and culture smears
  - Centrifugation
  - Media/Test inoculation
  - Staining of smears
  - Spills, sprays, leaks and breaks

Where do I begin?

SAFETY FIRST!!!

- **Risk Groups and Biosafety Levels**
- Personal Protective Equipment
- Cleaning procedures and Disinfectants
- Minimizing Aerosols
- Managing Spills
- Managing Biohazardous Waste

Qualifying the Organism

Risk Groups are classifications that describe the relative hazard posed by infectious agents or toxins in the laboratory.

A biosafety level is a specific combination of work practices, equipment and facility design to minimize possible exposure to dangerous biological agents and toxins

Risk Groups

Biosafety Level

Understanding Risk Groups

RISK GROUP	National Institutes of Health (United States)	World Health Organization
1	Agents that are not associated with disease in healthy adult humans. This group includes a list of animal viral etiologic agents in common use. These agents represent no or little risk to an individual and no or little risk to the community.	(**No or low individual and community risk**) – A microorganism that is unlikely to cause human disease or animal disease.
2	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. These agents represent a moderate risk to an individual but a low risk to the community.	(**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 preventative measures are available and the risk of spread of infection is limited.
3	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. These agents represent a high risk to an individual but a low risk to the community.	(**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.
4	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. These agents represent a high risk to the individual and a high risk to the community.	(**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.

Biosafety Level 1

Recommended for work with organisms not known to cause disease in healthy adults *(e.g. Bacillus subtilis)*

- Restrict access to authorized personnel.
- Make sinks for hand washing readily accessible.
- Make eyewash stations readily
- accessible.
- Make appropriate PPE available and ensure their use.
- Ensure that laboratory benchtops are impervious to liquids and resistant to chemicals.
- Ensure that laboratory surfaces and equipment are easily cleaned and disinfected and that cleaning procedures are done on a regular basis and whenever the surfaces or equipment are contaminated.
- Decontaminate solid waste within the laboratory (e.g. autoclaving) or package the waste to be transported off site.

Type of Organism

Work Practices

Biosafety Level 2

Recommended for work with organisms associated with human disease but not transmitted by aerosols

(e.g. Salmonella species)

Follow BSL 1 practices PLUS:

- Display universal biohazard signs outside of the laboratory.
- Perform specimen processing in a biological safety cabinet (BSC).
- Use centrifuge safety cups to perform centrifugation of mycobacteriology specimens.
- Ensure that an autoclave or other decontamination equipment/method is available and use for the treatment of infectious waste.
- Ensure the availability and use of the appropriate personal protective equipment (PPE).
- Carefully place all sharps in conveniently located, puncture resistant containers.
- Train personnel to observe good microbiological practices and techniques

Type of Organism

Work Practices

Biosafety Level 3

Recommended for work with hazardous organisms primarily transmitted by aerosols *(e.g. Mycobacterium tuberculosis)*

Follow BSL 1 and 2 practices PLUS:

- Control access to the laboratory
- Perform all manipulations of cultures and clinical specimens in a Class II biological safety cabinet.
- Maintain negative-pressure airflow in the laboratory.
- Include double doors and an anteroom in the laboratory design.
- Discharge HEPA-filtered exhaust air from the BSC outside the facility
- Use all appropriate PPE (i.e. closed-front gowns) and containment devices.
- Use fit-tested HEPA-filtered respirators or masks when aerosols may be generated.
- Collect baseline serum samples from all personnel for serological determination of immune status

Type of Organism

Work Practices

Biosafety Level 4

Recommended for work with organisms causing life threatening or untreatable diseases by aerosols or Unknown transmission (e.g. Ebola virus)

**viral cultures*

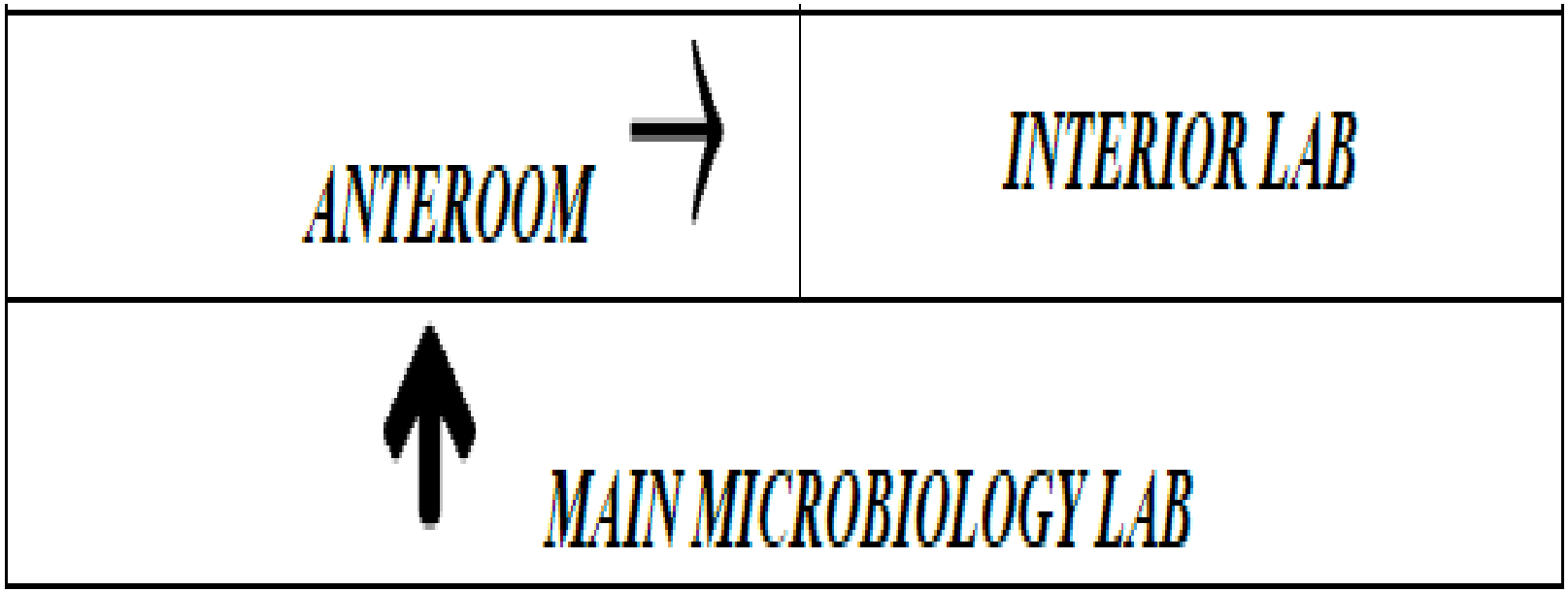
Follow BSL 3 practices PLUS:

- Control access to the laboratory
- Perform all manipulations of cultures and clinical specimens in a Class II biological safety cabinet.
- Maintain negative-pressure airflow in the laboratory.
- Include double doors and an anteroom in the laboratory design.
- Discharge HEPA-filtered exhaust air from the BSC outside the facility
- Use all appropriate PPE (i.e. closed-front gowns) and containment devices.
- Use fit-tested HEPA-filtered respirators or masks when aerosols may be generated.
- Collect baseline serum samples from all personnel for serological determination of immune status

Type of Organism

Work Practices

Laboratory Design



SAFETY FIRST!!!

- Risk Groups and Biosafety Levels
- Personal Protective Equipment
- Cleaning procedures and Disinfectants
- Minimizing Aerosols
- Managing Spills
- Managing Biohazardous Waste

Personal Protective Equipment

- Gloves
- Gowns
- Goggles/Face shields
- Fit-Tested N95 Respirator or Powered Air Purifying Respiratory (PAPR)

Personal Protective Equipment

- Choose properly sized gloves that do not impair the circulation or make it difficult to securely grasp and hold items
- Gloves should be long enough to overlap gown sleeves
- Perform hand hygiene before donning and after removal of gloves
- Change gloves when soiled, torn or the integrity is in question

GLOVES

- Disposable, solid front gown with snug (knit) cuffs, made of impermeable material
- Secured at the neck and back, or with overlap in the rear and secured at the side

GOWNS

Personal Protective Equipment

- EYEGLASSES DO NOT PROVIDE PROTECTION
- Goggles protect the eyes only
- Face shields designed to protect the eyes, face and mucous membranes
- Both must be properly sized and secured or can be ineffective

- Fit test must be performed:
- Before first use
- At least annually
- Whenever there is a change in facial structure (i.e. weight gain or loss)
- Whenever there is a change in the amount or type of facial hair
- Whenever there is a change in the make or model of the respirator

GOGGLES/FACE SHIELD

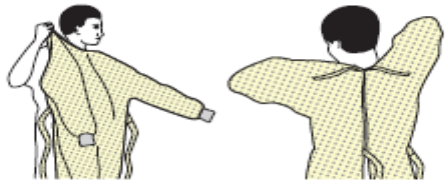
FIT-TESTED RESPIRATOR

SEQUENCE FOR PUTTING ON PERSONAL PROTECTIVE EQUIPMENT (PPE)

The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet or airborne infection isolation precautions. The procedure for putting on and removing PPE should be tailored to the specific type of PPE.

1. GOWN

- Fully cover torso from neck to knees, arms to end of wrists, and wrap around the back
- Fasten in back of neck and waist



2. MASK OR RESPIRATOR

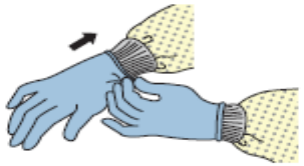
- Secure ties or elastic bands at middle of head and neck
- Fit flexible band to nose bridge
- Fit snug to face and below chin
- Fit-check respirator

3. GOGGLES OR FACE SHIELD

- Place over face and eyes and adjust to fit

4. GLOVES

- Extend to cover wrist of isolation gown



USE SAFE WORK PRACTICES TO PROTECT YOURSELF AND LIMIT THE SPREAD OF CONTAMINATION

- Keep hands away from face
- Limit surfaces touched
- Change gloves when torn or heavily contaminated
- Perform hand hygiene

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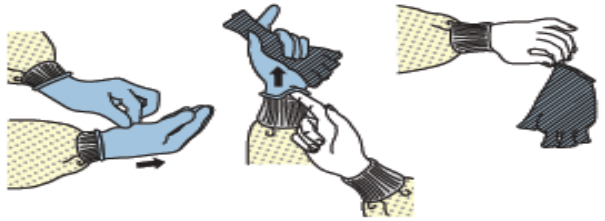
HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE)
EXAMPLE 1

There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. Here is one example. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator **after** leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GLOVES

- Outside of gloves are contaminated!
- If your hands get contaminated during glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Using a gloved hand, grasp the palm area of the other gloved hand and peel off first glove
- Hold removed glove in gloved hand
- Slide fingers of ungloved hand under remaining glove at wrist and peel off second glove over first glove
- Discard gloves in a waste container



2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band or ear pieces
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

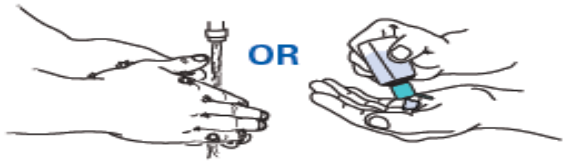
3. GOWN

- Gown front and sleeves are contaminated!
- If your hands get contaminated during gown removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Unfasten gown ties, taking care that sleeves don't contact your body when reaching for ties
- Pull gown away from neck and shoulders, touching inside of gown only
- Turn gown inside out
- Fold or roll into a bundle and discard in a waste container

4. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container

5. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



PERFORM HAND HYGIENE BETWEEN STEPS IF HANDS BECOME CONTAMINATED AND IMMEDIATELY AFTER REMOVING ALL PPE

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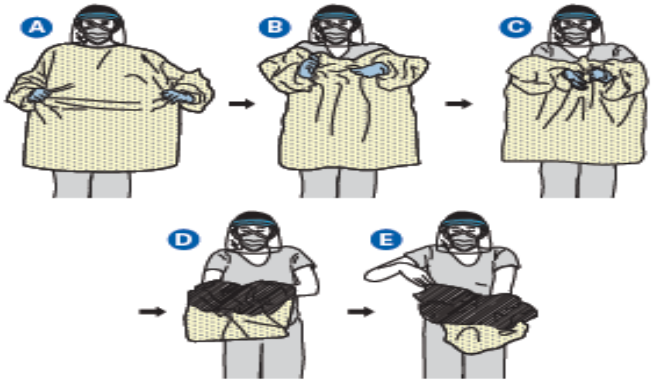
HOW TO SAFELY REMOVE PERSONAL PROTECTIVE EQUIPMENT (PPE) EXAMPLE 2

Here is another way to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. **Remove all PPE before exiting the patient room** except a respirator, if worn. Remove the respirator after leaving the patient room and closing the door. Remove PPE in the following sequence:

1. GOWN AND GLOVES

- Gown front and sleeves and the outside of gloves are contaminated!
- If your hands get contaminated during gown or glove removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp the gown in the front and pull away from your body so that the ties break, touching outside of gown only with gloved hands
- While removing the gown, fold or roll the gown inside-out into a bundle
- As you are removing the gown, peel off your gloves at the same time, only touching the inside of the gloves and gown with your bare hands. Place the gown and gloves into a waste container



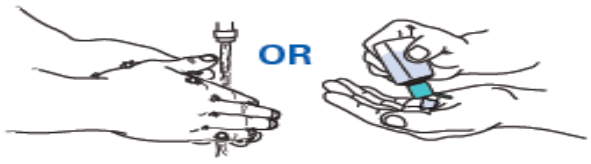
2. GOGGLES OR FACE SHIELD

- Outside of goggles or face shield are contaminated!
- If your hands get contaminated during goggle or face shield removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Remove goggles or face shield from the back by lifting head band and without touching the front of the goggles or face shield
- If the item is reusable, place in designated receptacle for reprocessing. Otherwise, discard in a waste container

3. MASK OR RESPIRATOR

- Front of mask/respirator is contaminated — DO NOT TOUCH!
- If your hands get contaminated during mask/respirator removal, immediately wash your hands or use an alcohol-based hand sanitizer
- Grasp bottom ties or elastics of the mask/respirator, then the ones at the top, and remove without touching the front
- Discard in a waste container

4. WASH HANDS OR USE AN ALCOHOL-BASED HAND SANITIZER IMMEDIATELY AFTER REMOVING ALL PPE



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Cleaning Procedures and Disinfectants

- Must use tuberculocidal disinfectants approved for use by the Infection Control department (i.e. Bleach)
- Disinfectants must be used according to manufacturer directions/laboratory guidelines to ensure effectiveness
- Disinfection should occur in a Class II biological safety cabinet (BSC)

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Minimizing Aerosols

- All manipulations of specimens/cultures should be performed in a BSC or using methods to contain aerosols
- Absorbent toweling should be placed on the workbench to catch and contain droplets and spills
- Containers for specimens that have been sonicated, ground, centrifuged, etc. should never be opened outside of the BSC.

SAFETY FIRST!!!

- Risk Groups and Biosafety Levels
- Personal Protective Equipment
- Cleaning procedures and Disinfectants
- Minimizing Aerosols
- **Managing Spills**
- Managing Biohazardous Waste

Managing Spills

- Spills may occur at any point in the process, from receipt and storage of supplies to the transporting of biohazard waste
- Cleanup is determined by the amount/size of the spill, the materials contained in the spill, and the location of the spill

Minor Spills

Spills less than 20 cc volume or active culture broken/spilled in the BSC

1. Use forceps to remove any broken sharps or small materials.
2. Place absorbent toweling over the spill.
3. Slowly pour disinfectant on the absorbent towels starting at the periphery of the spill and working towards the center.
4. All the spill to sit undisturbed for 15 -20 minutes.
5. Place all used absorbent toweling and contaminated non-sharps materials in an autoclave bag
6. Wipe down BSC work surface with 10% household bleach solution and allow to dry.
7. Once dry, wipe down the BSC work surface with 70% ethanol to prevent corrosion of the stainless steel surface.
8. Autoclave discarded biohazard materials as per laboratory procedure.

Major Spills

- Live, actively growing cultures of mycobacteria, select agents or other agents classified as greater than biosafety level 2
  - Specimens from a known AFB positive patient.
  - Contaminated fluids or tissues as referenced in item 1 or from patients listed in item 2
  - Major contamination of room surfaces (walls, ceiling).
- **DO NOT IMMEDIATELY LEAVE THE ROOM.**
- **If the event involved a failure of the exhaust system for the biological safety cabinet,** immediately turn on the portable HEPA exhaust filtration system

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- **Managing Biohazardous Waste**

Managing Biohazardous Waste

- All waste from the TB area is autoclaved immediately upon completion of work in the area.
- Waste must be autoclaved before removal from the department.
- Biological Indicators should be included in each run.
- Solid waste (i.e. solid agar cultures media) should be autoclaved for at least 30 minutes on a Gravity cycle
- Liquid waste (i.e. discarded digestant) should be autoclaved for at least 30 minutes on a Liquid cycle.


to be continued