

Division of Laboratory Systems



I'm a Frontline Facility – How can I safely test clinical specimens from a suspected Ebola patient?

Nancy Cornish, M.D., PhD
Vicki Herrera, MS

November 17, 2022



Agenda

- Introduction
 - *New and relevant OneLab™ Resources*
 - *Today's Presenters*
- I'm a Frontline Facility – How can I safely test clinical specimens from a suspected Ebola patient?
- Q&A
- Upcoming Events

Resources



Introduction to Laboratory Risk Management (LRM)

This [basic level eLearning course](#) provides details on applying risk management principles and briefly describes related practices to emphasize the importance of risk management in laboratory settings.

Fundamentals of Working Safely in a Biological Safety Cabinet

This [basic-level eLearning course](#) provides information on the safe use of Class II biological safety cabinets. Topics covered include major parts of a BSC, how a BSC works, how to work safely inside a BSC, and what to do if there is an emergency while working in a BSC.

Division of Laboratory Systems

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Moderator



Nancy Cornish, M.D., PhD

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Presenter



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Centers for Disease Control and Prevention



Welcome





**Vicki Herrera, MS
NETEC Laboratory Working Group Lead**



Objectives

-  **Discuss frontline facility's clinical testing options**
-  **Identify potential hazards in laboratory processes**
-  **Discuss risk mitigation strategies for laboratory testing**

Overview

-  **Current Sudan Ebolavirus Outbreak Overview**
-  **Risk Assessment**
-  **Mitigating the Risk**
-  **Other Considerations**

A person wearing a white protective suit and gloves is working in a laboratory biosafety cabinet. The person is leaning over a work surface, possibly handling a sample. The biosafety cabinet has a glass front and a perforated metal floor. There are various pieces of equipment and supplies on the work surface, including a white container and some papers. The background is slightly blurred, showing more of the laboratory environment.

Current Sudan Ebolavirus Outbreak Overview



Uganda Ebola Virus Disease Outbreak Update as of 11/15/2022

September 20, confirmed Ebola virus disease outbreak caused by the Sudan virus in the Mubende district, western Region of Uganda

November 15, Outbreak has spread to nine districts

Confirmed cases

140

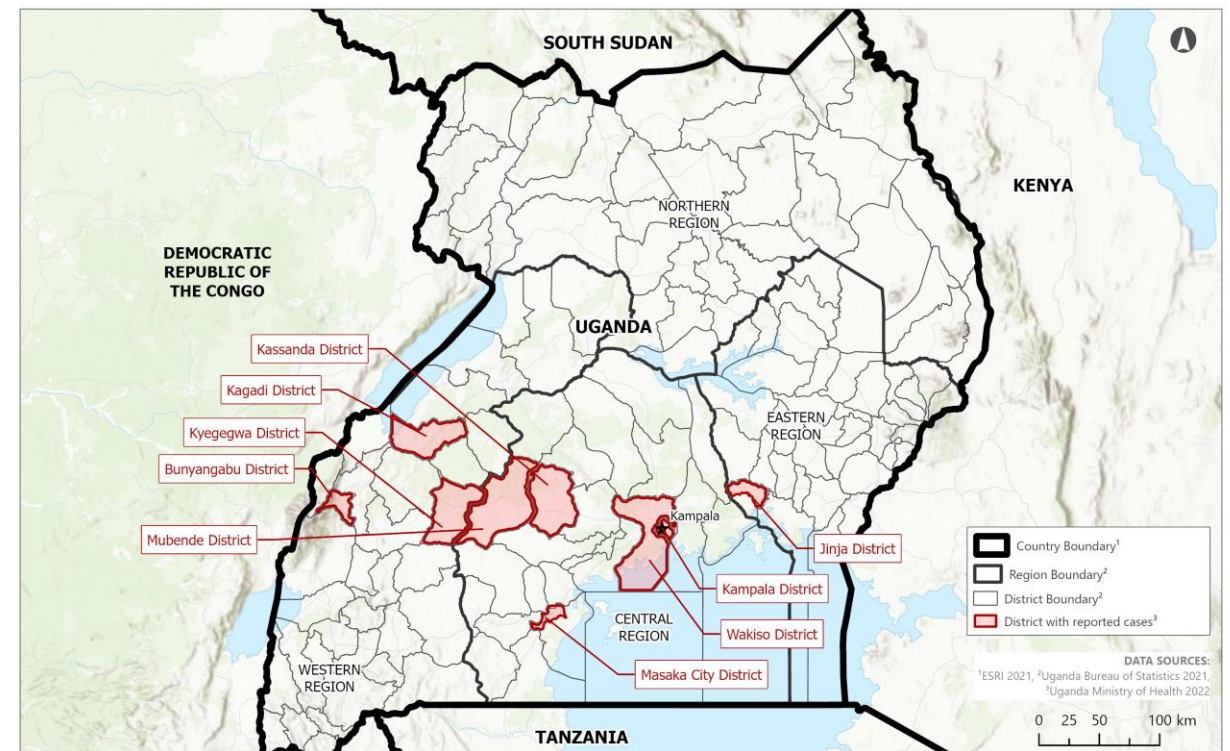
Deaths among confirmed cases

55

Health Care Workers

- 18 infected
- 7 deaths

Uganda: Ebola Virus Disease Outbreak 2022



ATSDR

Centers for Disease Control and Prevention
Agency for Toxic Substances
and Disease Registry

GRASP

Geospatial Research, Analysis, and
Services Program

Travel and Spread

➔ **CDC has issued a level 2 travel alert for the area**

International spread is currently low

U.S. health care workers should remain vigilant and screen patients with compatible symptoms, exposures, and recent travel history

Health care facilities should implement identify, isolate, and inform process for early and rapid patient identification

Health care facilities should review their special pathogens preparedness plans

A person wearing a white lab coat and gloves is working in a biosafety cabinet. The cabinet has a glass front and a perforated metal floor. There are various pieces of equipment and supplies inside, including a white container and a small box. The background is a plain wall.

Risk Assessment



Frontline Facility

What does that mean?



Frontline Facilities

Who are the Frontline Facilities?

- **Everyone!**
- **Size varies greatly – 2 bed – 1000+ bed.**

What are my expectations as a Frontline?

- **Clinical laboratories should be prepared to provide a timely and minimum menu of testing to ensure that medical evaluation is not delayed for any patient.**
- **Frontline healthcare facilities are not expected to provide prolonged care (>12–24 hours) for a severely ill patient.**

<https://www.cdc.gov/vhf/ebola/laboratory-personnel/safe-specimen-management.html>

Is that a reasonable expectation?

- **It depends!**
- **What if?**

Test Menu Considerations



Testing Menu Considerations

Recommended tests for patient care & management. Can your facility perform these?

- CBC, including differential, and platelet count
- Sodium, potassium, bicarbonate, blood urea nitrogen, creatinine, and glucose concentrations
- Liver function tests
- Coagulation testing, specifically prothrombin time (PT), expressed as an international normalized ratio (INR)
- Urinalysis (dipstick)
- Blood culture for bacterial pathogens
- Malaria testing (smear or rapid testing or PCR)*
- Influenza virus testing during periods when influenza prevalence is high**

Testing Menu Considerations

Questions to ask

What testing does your facility currently offer?

Do you have any Point of Care (POC) devices?

Do you have an automated system?

Have you discussed with the care team what tests are expected?

What are the must haves and the what are the wish list items?

Communication is key!

What are Some Considerations in Routine Testing?

Routine laboratory testing can and has been done successfully and safely on patients with special pathogens.

Risk Management Process



Process Steps

Step 1:

Identify the hazards and risks.

Step 2:

Evaluate the risks.

Steps 3-4:

Implement a risk mitigation plan, as needed.

Step 5:

Evaluate effectiveness of controls.

Risk Assessment: Identify Hazards and Risks

Important

Evaluate the process from beginning to end for every test and laboratory process



What are some of the risks in a laboratory?

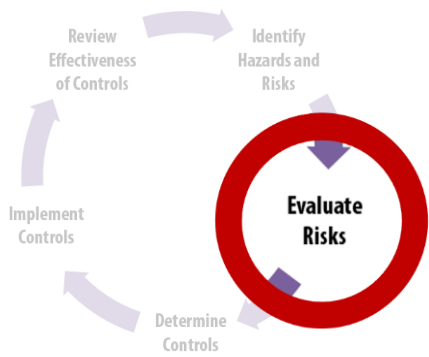
- **Open tubes**
- **Centrifugation**
- **Sharps**
- **Leaky specimens**
- **Performing smears**
- **Spills**
- **Fixing slides**
- **Slide agglutination**
- **No BSC**
- **Working alone**
- **Allergy to latex**

This is not an all-inclusive list

Risk Assessment: Evaluate Risks

Important

Evaluate the process from beginning to end for every test and laboratory process



Risk Assessment Matrix

Risk assessment matrix		Injury severity				
		Insignificant	Minor	Moderate	Major	Critical
Hazard likelihood	Highly likely	Medium	High	High	Extreme	Extreme
	Likely	Low	Medium	High	Extreme	Extreme
	Possible	Low	Low	Medium	High	High
	Unlikely	Rare	Rare	Low	Medium	High
	Rare	Rare	Rare	Low	Low	Medium

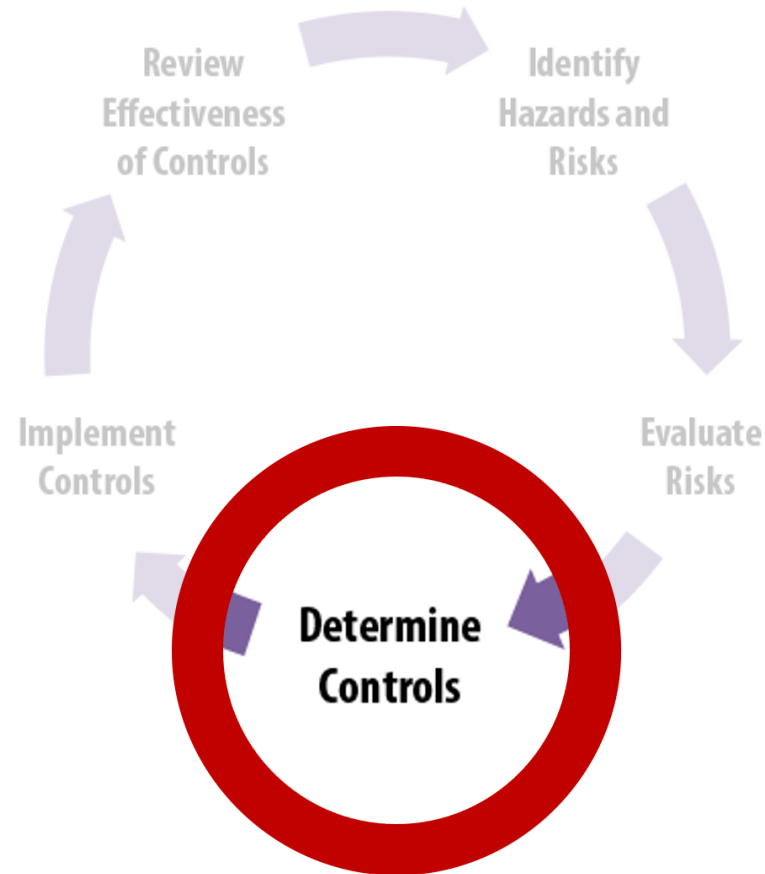


Mitigating the Risk



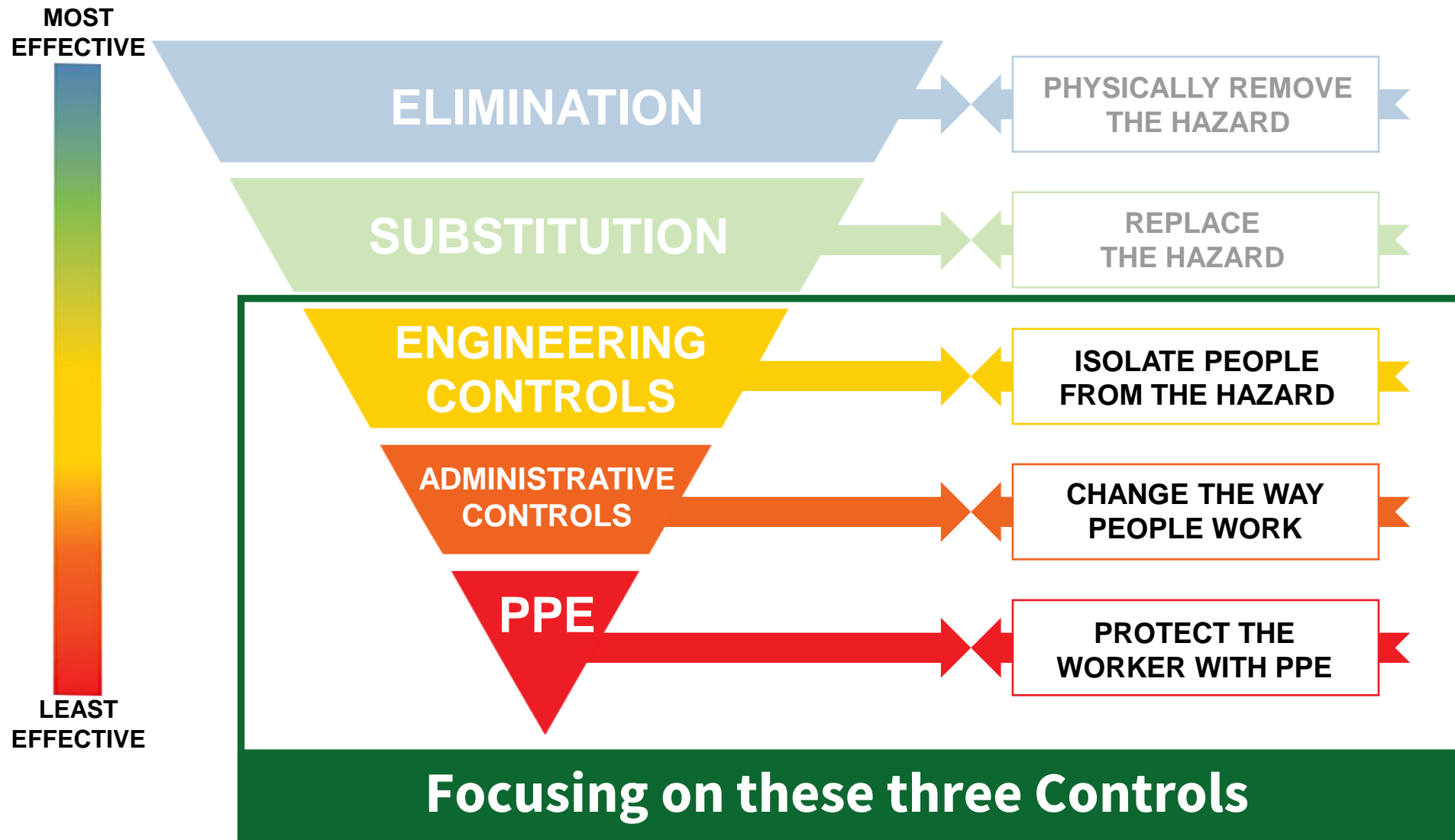
Risk Mitigation

You have identified the risk, now how do you ‘control’ the risk?



YOUR SAFETY IS JUST AS IMPORTANT AS THE PATIENT'S!

Risk Mitigation





Personal Protective Equipment



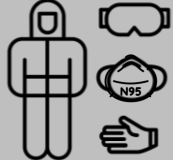

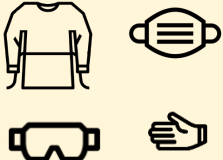

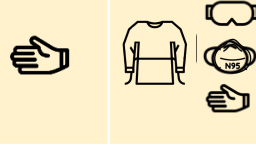



Virus Family	Illness Caused	Common Geography	Vector or Source	Person-to-person spread	Precautions	PPE	Comments
Filoviridae	Ebola Virus Disease	Central, sub-Saharan Africa	Presumed bat	YES	Contact, Droplet/Airborne, Eye		Full body coverage for acute (wet) phase
	Marburg virus		Fruit bat				
Arenaviridae	Lassa fever	West Africa	Rodents	YES	Contact, Droplet/Airborne, Eye		Full body coverage for acute (wet) phase
	Junín Machupo (Bolivian HF) Guanarito (Venezuelan HF) Sabia (Brazilian HF)	South America					
Bunyaviridae	CCHF – Crimean Congo Hemorrhagic Fever	Europe, Mediterranean, Middle East, Africa, India, China	Tick, infected livestock	YES	Contact, Droplet*, Eye		*Add respiratory protection (N95 or ↑) for centrifugation 
	Hantaviruses (HPS/HFRS*) (Sin Nombre, Andes virus)	Worldwide	Rodent	Possible	Standard Precautions unless Andes virus suspected		Contact, Droplet/Airborne, Eye for potential Andes virus or contact/clean-up of rodent droppings
	Rift Valley Fever	All of sub-Saharan Africa	Mosquito	No	Standard Precautions		
Flaviviridae	Yellow Fever	Tropics	Mosquito	Blood*	Standard Precautions		*Potential risk of Yellow Fever transmission in blood transfusion, immediately post vaccination 
	Dengue	Tropics	Mosquito	No			
	Kyasanur	India	Tick	No			
	Omsk	Siberia					

Table Illustration

What is Different about VHF PPE and Why?

Because the infectious dose for Ebola and some other Viral Hemorrhagic Fevers is very small and the amount of virus present in many body fluids is very large, Full Body Coverage PPE is recommended.

- PPE selection should consider tasks to be performed, how close or prolonged contact will be, potential exposures to blood or any body fluids, and contaminated items and surfaces.
- Patient condition may change rapidly and the sudden presence of body fluid risk should be anticipated.
- Patients may present at any point of illness. Screening for symptoms and travel at all points of entry, including EMS, can reduce HCW exposure.
- The use of a Trained Observer should be considered. Tasks include verifying correct donning, observation of staff during patient care, specimen collection, waste handling procedures, and close observation and verification of safe doffing.
- Donning complex ensembles takes time
- Once appropriately donned, take care to avoid contamination of PPE and the patient care environment.
- Not all PPE is amenable to being cleaned while in use.
- Contamination of PPE, skin, or clothing may not be visible. Trained observers should monitor for inadvertent contamination during use and doffing of PPE.
- Regardless of task, consider PPE contaminated and doff with care.

What PPE Should be Used for Ebola?

PPE when there is the potential for body fluid exposure



Minimum PPE for a stable PUI, or those without vomiting, bleeding, or diarrhea



Fluid resistant sleeved aprons can provide added protection to less-protective isolation gowns

Staff should be aware of the protective qualities and limitations of their PPE.



Full body coverage:

- Coverall or Gown
- Shoe or boot covers
- Head cover, hood, or shroud

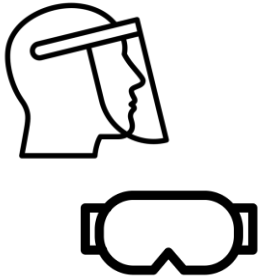
Blood and viral penetration resistance:
Gown = ANSI/AAMI PB70 Level 4
Coverall = ASTM F1671 or EN14126



Isolation gown:

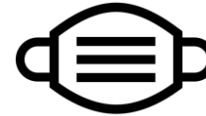
- Choose level of gown based on risk.

AAMI PB70 Level 1-3 have increasing levels of resistance to fluids, Level 4 tested for viral transfer



Eye protection:

- Full face shield or goggles with circumferential protection



Medical or surgical mask:

- For droplet or source protection only. Does not provide respiratory protection.



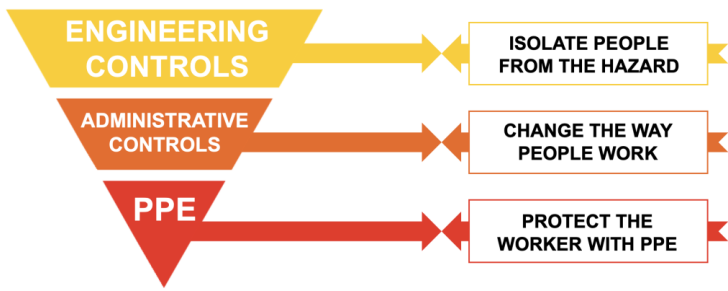
Respiratory protection:

- N95 or higher filtering face piece respirator (FFR) or Powered Air Purifying Respirator (PAPR)



Gloves:

- Non-sterile medical exam gloves. Double gloving and the use of extended cuff gloves may be advised.

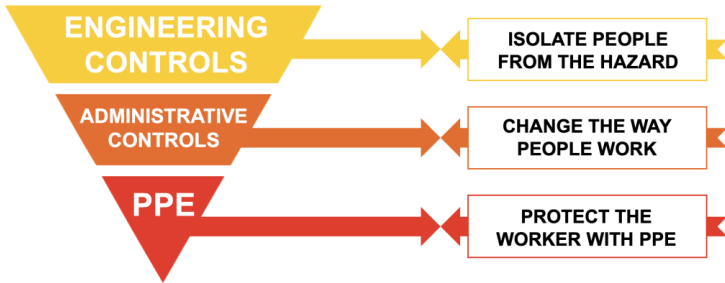


Engineering Controls

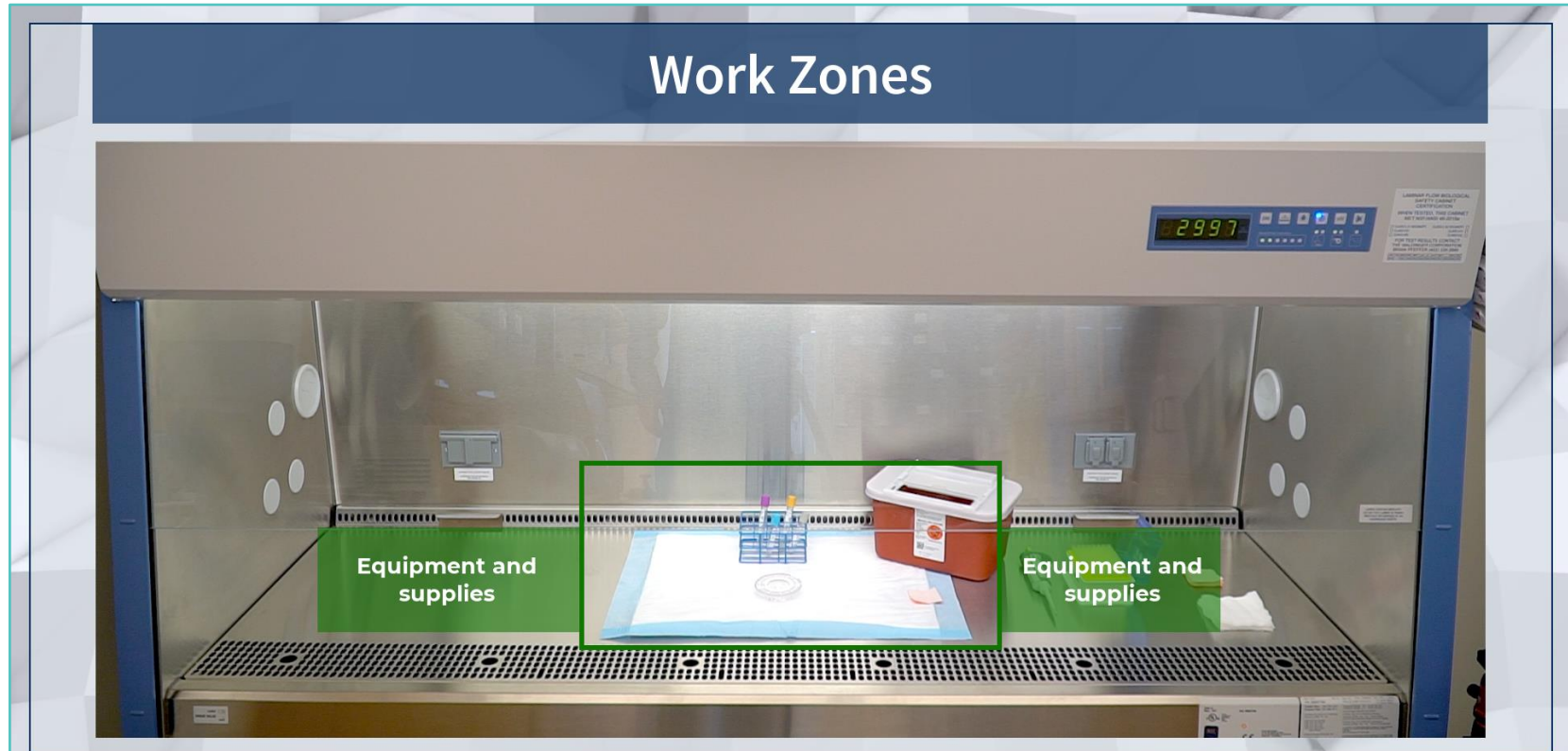


Risk Mitigation: Biosafety Cabinet

Engineering Controls



Do not block the front or rear air flow grates

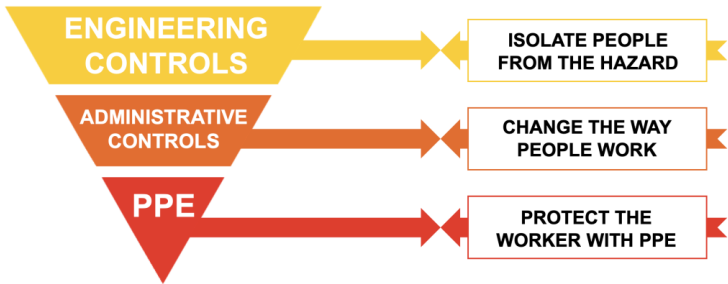


BSC Basics



Risk Mitigation: Specimen Collection

Engineering Controls



Risk = Specimen Collection

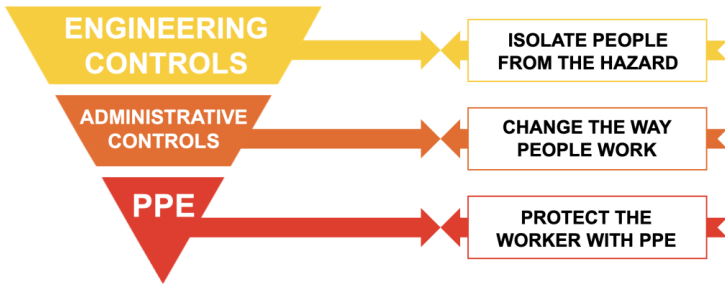
Mitigation:

- Hand placement when drawing blood sample
- PPE
- Absorbent pads
- Sharps container
- Safety devices



Risk Mitigation: Opening a Tube

Engineering Controls



Risk = Opening a Tube

Mitigation:

- PPE
- BSC
- absorbent pads
- POC instrument vs. automated

This is not an all-inclusive list

Tips for Risk Mitigation



BSC Practices



Tips for Risk Mitigation



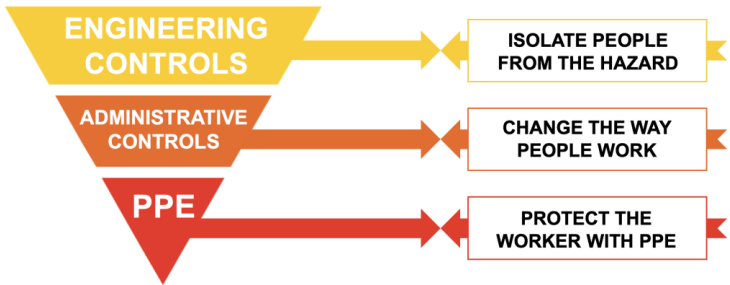
Absorbent pads make it easier to see any potential contamination

BSC Practices



Risk Mitigation: No Biosafety Cabinet

Engineering Controls



Risk = No Biosafety Cabinet

Mitigation:

- Shield
- Separate room for testing
- Glove box
- Can you eliminate traffic in the area?



Risk Mitigation: Aerosolization

Engineering Controls



Risk = Aerosolization

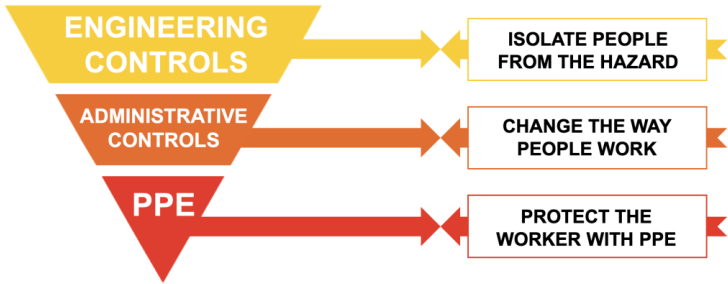
Mitigation:

- BSC
- PPE
- Shield
- closed rotor centrifuge



Risk Mitigation: Leaky Sample

Engineering Controls



Risk = Leaky Sample

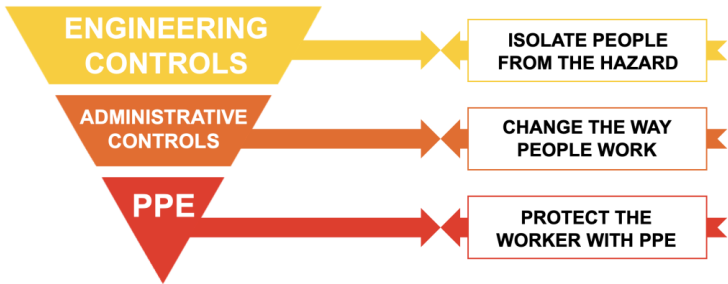
Mitigation:

- BSC
- PPE
- Shield
- EPA-Approved Wipes



Risk Mitigation: Transportation

Engineering Controls



Risk = Transportation

Mitigation:

- Triple packaging
- Rigid container
- Absorbent material
- Pneumatic tube system not recommended



Laboratory Cleaning, Disinfection, and Waste Management

➤ **Cleaning and disinfection with an EPA-registered hospital grade disinfectant**

➤ **Category A waste is highly regulated**

- Hazardous Materials Regulations (HMR, 49 C.F.R., Parts 171-180)
- Best practice may be to sequester waste until results are received
- May want to create a log of specimens



Post-Testing HCW Medical Surveillance



Observe personnel for signs and symptoms of disease for one incubation cycle or until the disease of concern is ruled out

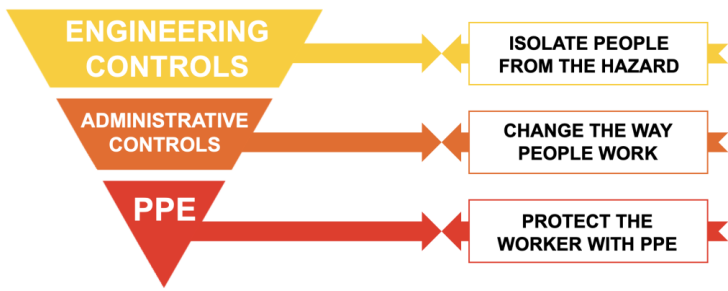


Coordinate with public health



Asymptomatic people are not contagious



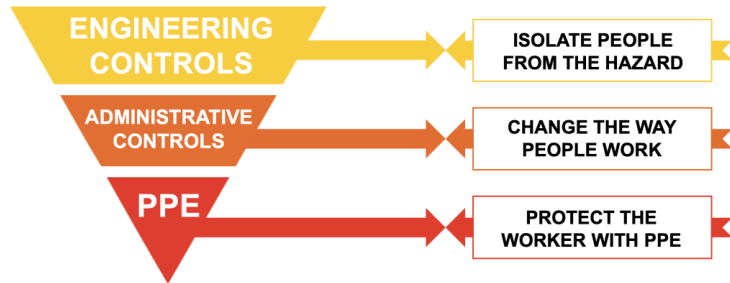


Administrative Controls












Risk Mitigation

Administrative Controls



Risk = Transportation

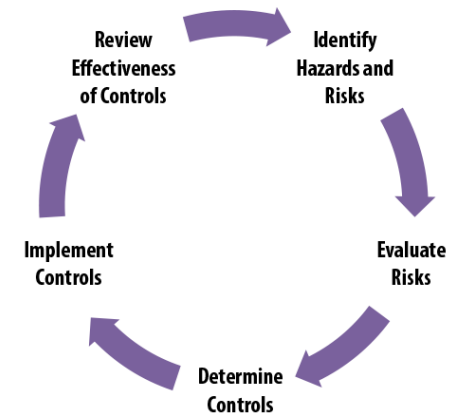
Mitigation:

-  **Training**
-  **Checklist**
-  **Contact list**
-  **Protocols**
-  **Testing**
-  **Activation**
-  **Cleaning and disinfection**
-  **Spill clean up**
-  **Etc.**

What Routine testing can you do?

Risk assessment

- Identify the risk
- Evaluate the risk
- Determine controls



Communication



Contact your local Public Health Department



Resources



Resources for PPE



Centers for Disease Control and Prevention

CDC 24/7: Saving Lives, Protecting People™

<https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html>

<https://www.cdc.gov/labtraining/training-courses/biological-safety-cabinets.html>



<https://dashtool.org/>

Personal Protective Equipment Module

Estimates minimum personal protective equipment (PPE) needed by hospital personnel managing patients suspected or known to be infected with a special pathogen.



PPE Guidance for Viral Hemorrhagic Fevers - <https://repository.netecweb.org/items/show/1693>

Space Recommendations for PPE Donning/Doffing - <https://repository.netecweb.org/items/show/1708>

Biosafety Level 3 Laboratories Biosafety Cabinet Practices- https://youtu.be/5isVPg_Sx5w

NETEC is Here to Help

NETEC will continue to build resources, develop online education, and deliver technical training to meet the needs of our partners

Ask for help!

- ➔ Send questions to info@netec.org - they will be answered by NETEC SMEs
- ➔ Submit a Technical Assistance request at [NETEC.org](https://www.netec.org)

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(On all major podcast players)

NETEC Skill videos

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Questions

Discussion





Upcoming OneLab Network Events



Build Your Laboratory Onboarding Template

December 16, 2022, 1-2PM ET

Register Now!

https://cdc.zoomgov.com/webinar/register/WN_5a0W5896TNmn5q3UzRS0MQ