
NETEC
EMORY MEDICINE
UNMC Nebraska Medicine
NYC HEALTH+ HOSPITALS
Bellevue
www.netec.org

NETEC

Laboratory Considerations for Ebola Virus and Other Special Pathogens

Elizabeth Beam, Crystal Evans,
Vicki Herrera, Peter Iwen, & Karen Stiles

EMORY MEDICINE
UNMC Nebraska Medicine
NYC HEALTH+ HOSPITALS | Bellevue

Objectives

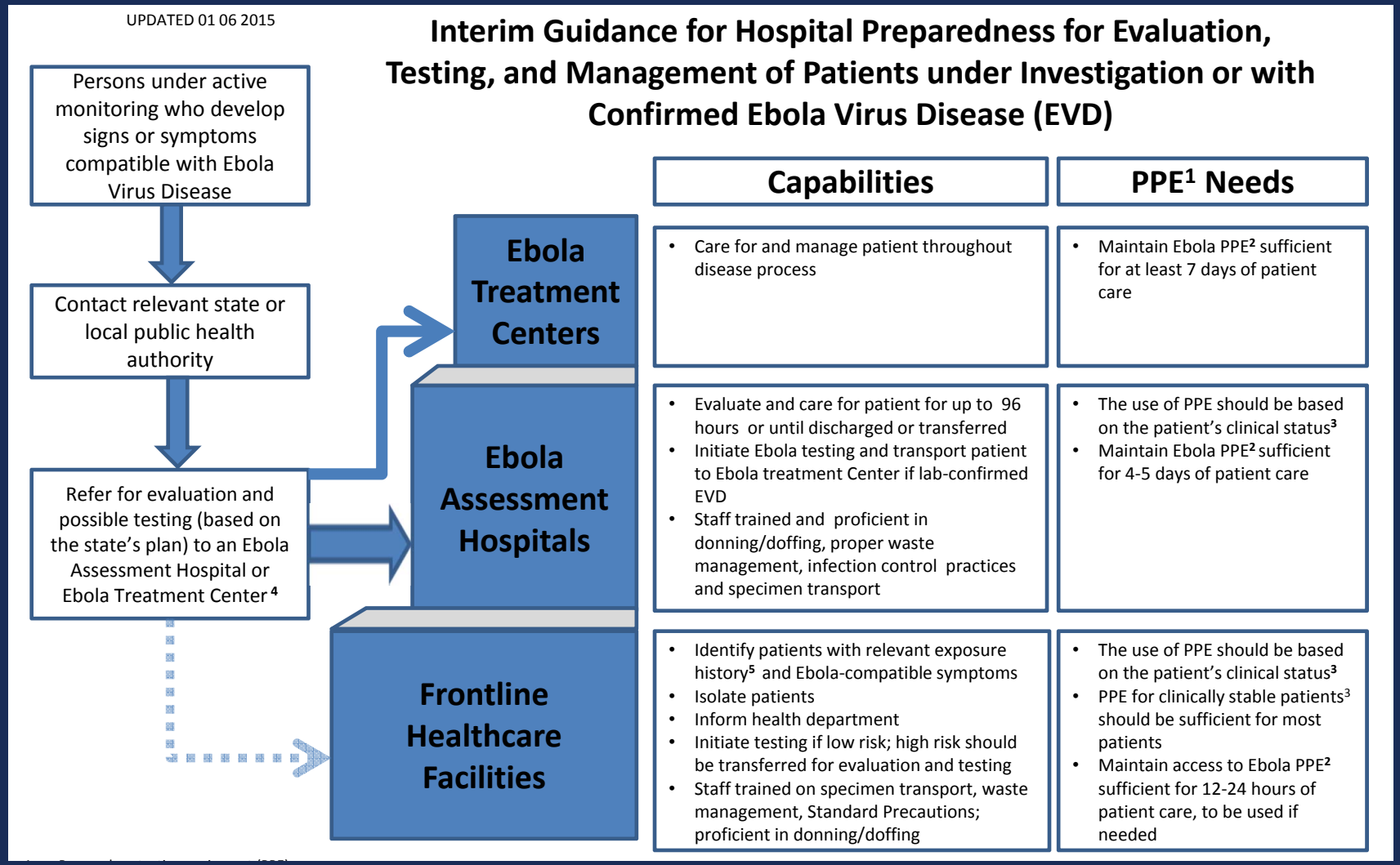
NETEC

Pertaining to the care of a PUI or patient infected with a high risk pathogen

1. Describe components of a biological risk assessment
2. Identify critical elements to collect, package, and ship a diagnostic specimen
3. List elements of a response plan to provide clinical laboratory services
4. Discover lessons learned to identify and correct potential gaps in clinical laboratory practices

Poll Everywhere Slide Placeholder

Tiered Approach



Tiered Approach

Be prepared to promptly:

- Identify – Determine low vs high risk
- Isolate – Activate High Consequence Pathogen Plan
- Inform – Infection control & local public health agency

- Ensure there is no delay in patient care
  - Prepare to test, manage, and treat alternative etiologies of febrile illness (e.g., malaria in travelers) as clinically indicated.

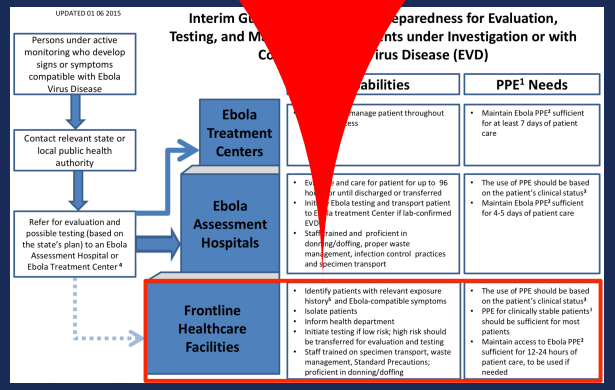
Tiered Approach

Frontline Healthcare Facilities

Note:

1. Frontline Facilities
   - Protocols in place to test a critically ill patient if needed.
2. Clear open communication
   - Between leadership and testing staff.
   - Leadership needs to understand risk, testing staff be involved with planning.
3. Exercise, Exercise, Exercise!!

• Identify patients with relevant exposure history[5] and Ebola-compatible symptoms • Isolate patients • Inform health department • Initiate testing if low risk; high risk should be transferred for evaluation and testing • Staff trained on specimen transport, waste management, Standard Precautions; proficient in donning/doffing	• The use of PPE should be based on the patient's clinical status[3] • PPE for clinically stable patients[3] should be sufficient for most patients • Maintain access to Ebola PPE[2] sufficient for 12-24 hours of patient care, to be used if needed



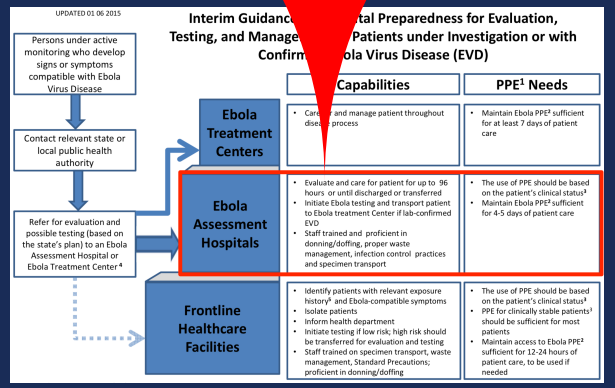
Tiered Approach

Ebola Assessment Hospitals

Note:

1. Provide patient care up to 96 hrs
2. Prolonged care for critically ill patient
3. Transport specimens to PHL (Public Health Lab)

• Evaluate and care for patient for up to 96 hours or until discharged or transferred • Initiate Ebola testing and transport patient to Ebola treatment Center if lab-confirmed EVD • Staff trained and proficient in donning/doffing, proper waste management, infection control practices and specimen transport	• The use of PPE should be based on the patient's clinical status[3] • Maintain Ebola PPE[2] sufficient for 4-5 days of patient care



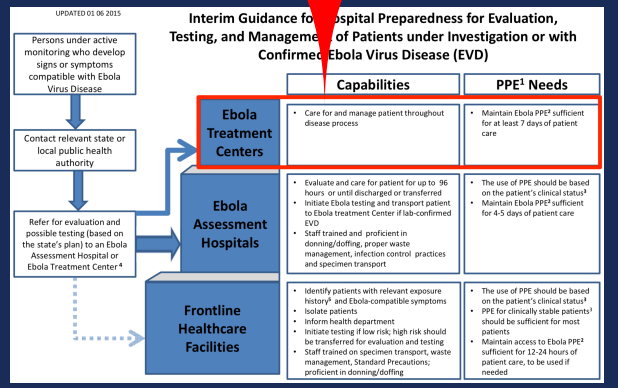
Tiered Approach

Ebola Treatment Centers

Note:

1. Provide care for duration of illness
2. Consultation with PHL and CDC

• Care for and manage patient throughout disease process	• Maintain Ebola PPE[2] sufficient for at least 7 days of patient care



Focus

Tiered approach intended to include EV as well as other special pathogens

Lassa fever virus	Marburg virus
Monkey pox virus	Smallpox virus
MERS coronavirus	SARS coronavirus
Highly pathogenic influenza viruses	
Andromeda: Unknown pathogen which appear highly hazardous	

- Pathogens may vary but transmission modes remain limited to contact, droplet and airborne
  - Plans modified based upon a risk assessment and pathogen characteristics

Laboratory Flow

NETEC

Pre-analytic

- Activation of lab
- Specimen collection
- Specimen transport (within vs outside facility)
- Specimen processing

Analytic

- Local vs distant
  - Public health vs clinical
- Testing of the specimen

Post-analytic

- Reporting results
- Specimen storage
- Reflex testing
- Waste management
- Environmental decontamination
- Occupational health plan for employees

Objective #1

Pertaining to the care of a PUI or patient infected with a high risk pathogen

1. Describe components of a biological risk assessment
2. Identify critical elements to collect, package, and ship a diagnostic specimen
3. List elements of a response plan to provide clinical laboratory services
4. Discover lessons learned to identify and correct potential gaps in clinical laboratory practices

Risk Assessment

What does a laboratory safety risk assessment look like for special pathogens?

- Identify hazards
  - Activities performed
  - Likelihood of exposure
  - Consequences of personnel exposure
- Goal of risk assessment
  - Determine exposure risks and develop the means to mitigate these risks
- Ongoing risk assessment process

Risk Assessment Components

- ✓ Identify potential hazards
- ✓ Define personnel at risk
- ✓ Take action for mitigation
- ✓ Maintain a record of findings and mitigation
- ✓ Develop an ongoing risk assessment process

Risk Assessment Template

Procedure

- Packaging receipt and transfer

Potential hazard(s)

- Leaking package
- Unexpected delivery
- Breakage of specimen container

Mitigation

- Place into plastic bag and transfer to BSC
- Wear appropriate PPE
- Contact RO/ARO/Safety Officer
- Make arrangements to deliver to appropriate area
- Decontaminate exposed area
- Contain and autoclave contaminated materials

https://www.aphl.org/programs/preparedness/documents/aphl-template.pdf

Identify Potential Hazards

- Specimen collection
- Specimen transport
- Specimen processing
  - Working within a BSC
  - Vortex/centrifugation
- Test specimen
  - Closed system
  - POC instrumentation
- Inactivation
- Waste handling
  - Decontamination
  - Storage of excess specimen

Identify Potential Hazards

Defining your personnel at risk

Who is collecting the specimens?

Who is running the tests?

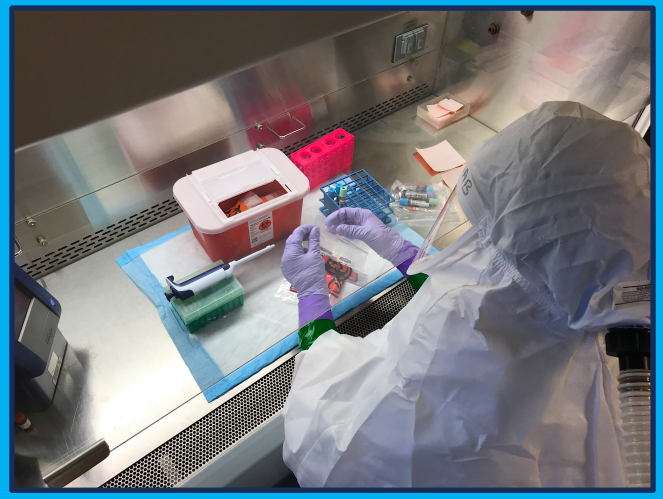
Who else may be handling specimens?

Who is packaging and transporting the specimens?

Mitigate the Risks

Engineering controls

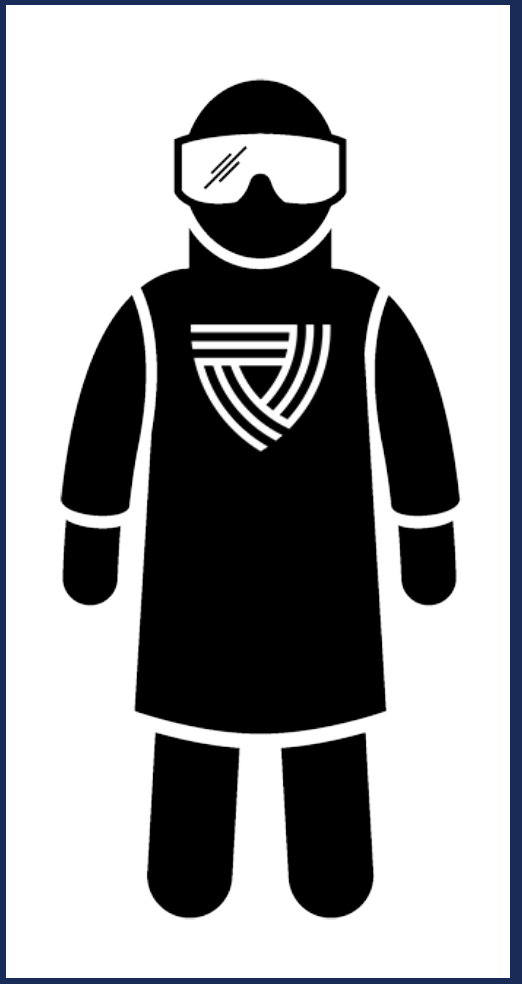
- Biosafety cabinet
- Sharps containers
- Sealed centrifuge rotors or safety cups
- Facility Characteristics:
  - Laboratory ventilation
  - Anteroom



Biological Risk Assessment

Mitigating the risk

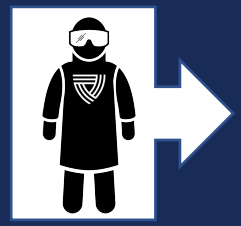
- PPE Utilization
  - Staff aware of requirements
  - Annual competency assessments
  - PPE care, storage, and routine inspection
  - PPE selection
    - Face shields, splash guards
    - Disposable lab coats, surgical gowns, or suits
    - Over sleeves, booties, bonnet
    - Nitrile gloves
    - Respiratory protection selection
      - Users enrolled in Respiratory Protection Program
  - Closed toe shoes that cover entire foot worn in laboratory



PPE in the Clinical Laboratory

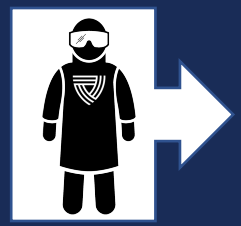
Resources

- Develop a personalized PPE plan for the work in your laboratory, or institution based upon your risk assessment.



- Clinically Stable PUIs:

https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance-clinically-stable-puis.html

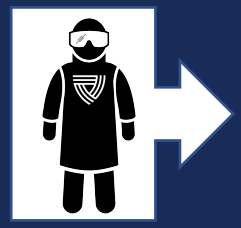


- Patients with confirmed EVD or Clinically Unstable PUIs:

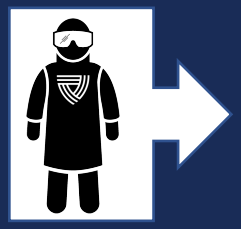
https://www.cdc.gov/vhf/ebola/healthcare-us/ppe/guidance.html

Site-Specific PPE

PPE



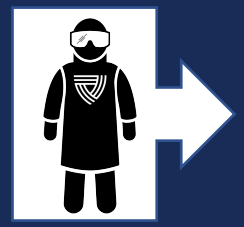
- Frontline issues:
  - Develop a PPE kit with resources easily available at your facility.
  - Periodic checks of expiration dates and training.



- Assessment & Treatment:
  - Develop PPE donning and doffing protocols
    - Vary based upon tests performed, composition of your team members, and suspected pathogen.
  - Each laboratory setting may use slightly different processes
    - Based on CDC Guidance
    - Input from team for comfort and tolerance.

Pathogen-Specific PPE

Bloodborne Versus Respiratory



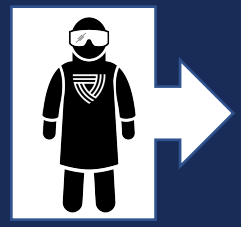
	Bloodborne	Respiratory	Spores
Gloves	X	X	X
Double gloving	X	Optional	X
N95 mask – fit tested	X	X	
PAPR	X	X	X
Goggles/ faceshield	X	X	X
Head and neck covers	X	X	X
Impermeable gown	X	X	X
Impermeable, fluid resistant body coverings	X	X	X

Important: Cover mucous membranes

Utilization of a PAPR

NETEC

PPE



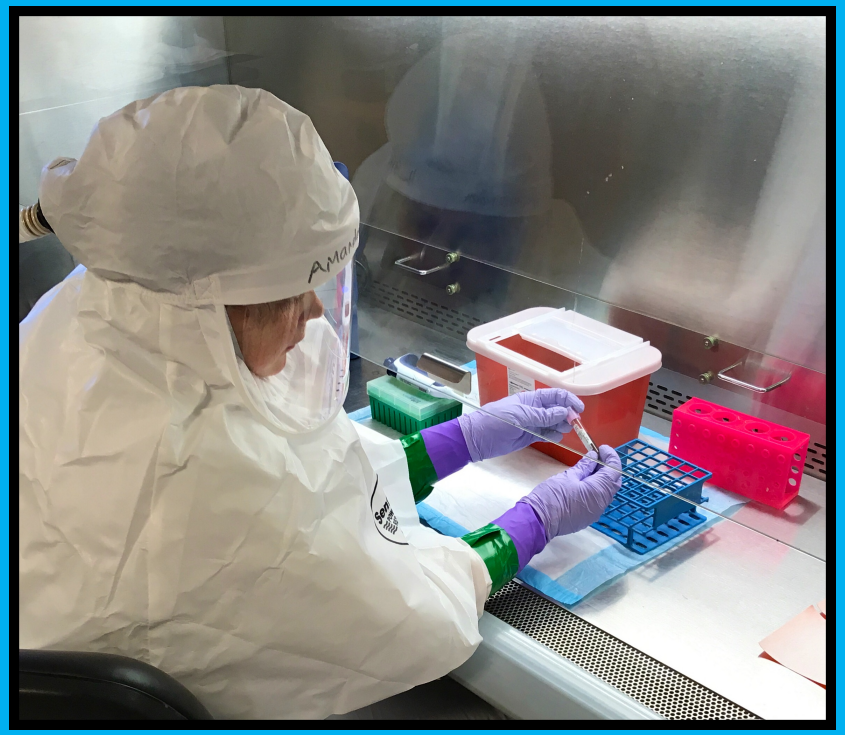
When should a Powered Air Purifying Respirator (PAPR) be considered?

- Does your risk assessment include spores?
- Other issues:
  - Latex allergy
  - Fit testing issues
  - Health issues
- Considerations
  - Training on equipment use
  - Battery maintenance
  - Decontamination between uses

Biological Risk Assessment

Engineering controls

- Some laboratory equipment may not be appropriate
  - Generation of aerosols
  - Recommended disinfectants
    - May affect instrument's performance
    - Void manufacturer's warranty
- CDC and FDA working with manufacturers to assess and resolve safety issues of laboratory equipment



Biological Risk Assessment

Mitigation findings

Provide written records that risk assessments were:

Performed

and

Addressed

Biological Risk Assessment

Administrative controls

- SOPs
- Staff aware of occupational injury procedures
- Right-to-know training
- Unit-specific training
- Safety and Health plans

Biological Risk Assessment

Ongoing process

- Continued evaluation of procedures
  - Make sure appropriate
  - Staff trained and follow procedures as written

- Assess new practices, test kits, and equipment as they appear.

Chemical Risk Assessment

- Proper labeling
- Fire Department Permit
- Chemical Inventory
- Safety Data Sheets accessible to staff
- Incompatible chemicals segregated
- Flammable liquids stored
- Rated chemical cabinets, refrigerators, or freezers
- Excessive chemicals
- Compressed gas cylinders
- Chemicals at eye level, acids, bases
- Chemical fume hoods

Objective #1: Think, Pair and Share

Q1: Describe the five major components of a biological risk assessment program.

(as related to Ebola or other Special Pathogens of Concern, ie. High Consequence Pathogens)

Objective #1: Think, Pair and Share

Q2: Describe the laboratory expectations for:

- Frontline Hospital
- Assessment Hospital
- Treatment Center

Objective #2

Pertaining to the care of a PUI or patient infected with a high risk pathogen

1. Describe components of a biological risk assessment
2. **Identify critical elements to collect, package, and ship a diagnostic specimen**
3. List elements of a response plan to provide clinical laboratory services
4. Discover lessons learned to identify and correct potential gaps in clinical laboratory practices

EMTALA

NETEC

Emergency Medical Treatment & Labor Act

Ensure there is no delay in the care of these patients by being prepared to test, manage, and treat alternative etiologies of febrile illness (e.g., malaria in travelers) as clinically indicated.

Specimen Collection

Determine safest method of specimen collection on a patient under investigation for a high consequence pathogen.

Establish a plan for collection, add to emergency protocol

Who collects specimens in isolation room? Designate in plan

- Nursing staff have prior experience collecting blood or NP swab?
- If laboratory collects, are they trained in advance PPE?

What blood collection method is optimal:

- Best Practice: Vacutainer System
- Needle and Syringe – Avoid for safety reasons unless patient dehydrated, need transfer device
- IV Line (used in most EDs) – One time use?
- Port Line –Complicated
- Butterfly – Least Safe

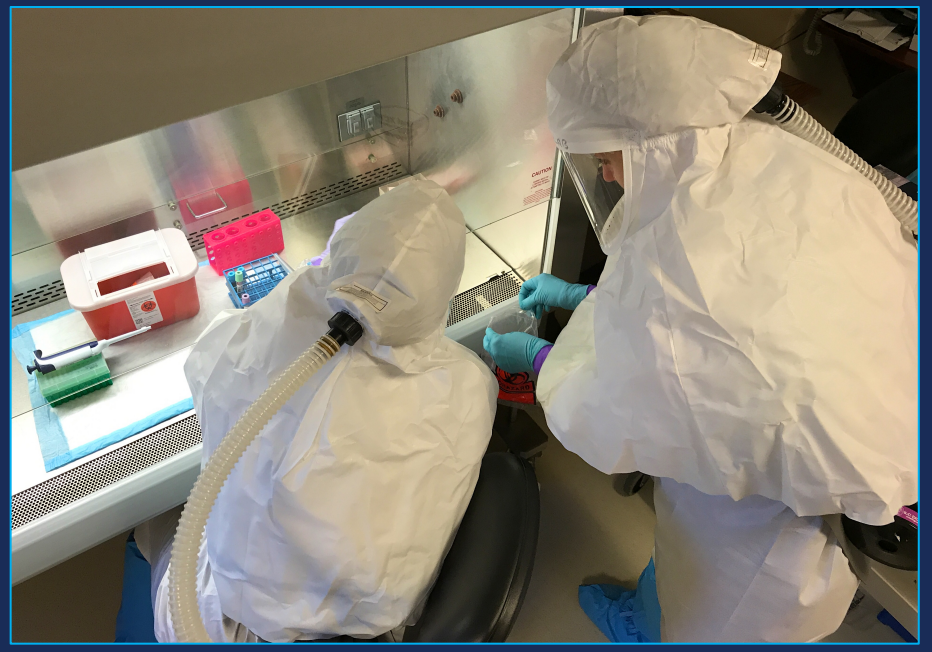
Specimen Collection

Why is a partner needed for collection in Frontline facility?

- Designed like partner donning/doffing - staff's safety in mind
  - Partner/Trained Observer who reads step-by-step checklist, assists
  - Partner who does actual collection task
- Observe for breach, not normally noticed by person collecting specimen
- Eliminate stress
- In case an emergency arises

Important Reminders:

- Staff with previous collection experience
- Practice, don't wait until real event!! Exercise annually!
- Incorporate into current hospital Ebola plan



Specimen Collection

High Risk Specimen Collection Considerations:

- Facility PPE protocol – What can Frontline do with the PPE they have?
  - Work slowly and methodically, be cognizant of each movement..
  - If breach is observed, STOP and critically think through the situation.
  - Determine best method of collection
  - Determine burden of contamination
  - Multiple glove changes
  - Double bag
  - How to package specimens to consider them sterile for clean side?

Specimen Collection

NETEC

Best practices in Collection

Apply tourniquet **<**1 min

DON'T Anchoring vein from above - risk of needle stick

DON'T use "winged" collection for coag tests

Use **no larger** than 21 gauge needle

Vein is punctured **bevel up**

Proper angle of Insertion **<** 30°

Proper order of draw, proper order is:

- **Blood culture tube or bottle**
- **Blue**
- **Red, red speckled, or gold**
- **Dark or light green, green speckled**
- **Lavender, pearl, pink**
- **Gray**

Adequate mixing of tubes

Specimen Collection

Correct method: Inserting the Needle

- Anchor the vein
  - Grasp arm with your non-dominant hand
  - Use thumb to pull skin taut
- Smoothly and confidently insert the needle bevel up
  - 15-30° angle

Specimen Collection

Mini Exercise

- List collection supplies needed for collection, to be organized prior to entering the hot zone

- Using infection control practices and considering "burden of contamination", design step-by-step plan to:
  1. collect blood from PUI in isolation
  2. collect nasopharyngeal swab

- Design protocol to complete Chain-of-Custody

Specimen Collection

Mini-Exercises Discussion
High Consequence Specimen Collection

Laboratory Skills participants to share lessons learned

- Collection supply list
- Create checklist of actions
- Partner tasks
- Documentation/Chain of Custody

Specimen Collection

Mini- Exercises Discussion
High Consequence Specimen Collection

- Supply list
  - Gather ahead of time
  - Lay out in organized manner
  - Position relative to patient
  - Keep safety in mind

CHECK & ORGANIZE YOUR SUPPLIES!

Gather supplies to take into PUI isolation area (hot zone):

- ☐ Appropriate specimen container(s) as advised by the public health laboratory
- ☐ Appropriate collection supplies such as appropriate
  - ❖ vacutainer adapter system or needle & syringe with transfer device
  - ❖ alcohol pads, iodine preps, etc.
  - ❖ tourniquet
  - ❖ other specimen collection devices for respiratory, such as nasopharyngeal swab
- ☐ Disinfectant wipes
- ☐ Large adsorbent pads
- ☐ Medical waste container
- ☐ Multiple sizes of gloves
- ☐ Printed patient labels with 2 identifiers
- ☐ Permanent Blue or Black Ink Pen (NO Sharpie)
- ☐ Small bio-hazard bags with ABSORBENT MATERIAL (included in kit)
- ☐ Large bio-hazard bags (included in kit)
- ☐ Trained observer/Partner checklist (included in kit)
- ☐ **DO NOT TAKE TRANSPORT KIT INTO HOT ZONE**

Specimen Collection

Mini- Exercises Discussion
High Consequence Specimen Collection

- Create checklist of actions
- Partner tasks

Tasks performed in isolation area (hot zone):

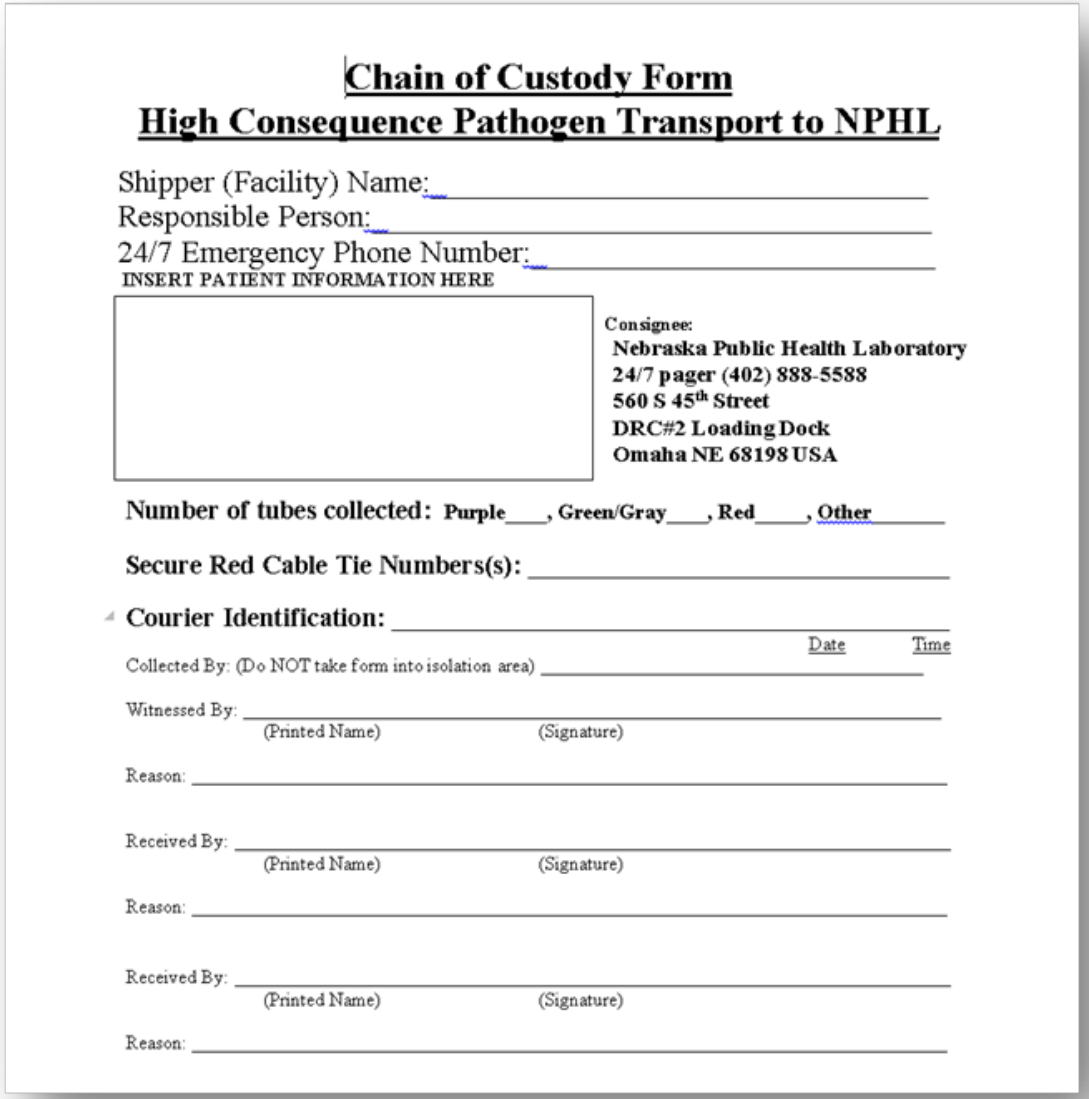
Trained observer/Partner #2 read out-loud step-by-step checklist – Work slowly, methodically, be aware of possible contamination. If a breach is observed, STOP critically think through the situation.

- ☐ Pre-position supplies on tray/table, adjacent to patient
- ☐ Lay out supplies; work from clean to dirty side with medical waste container nearby.
- ☐ Set out at least 20 disinfectant wipes for easy access.
- ☐ Prep patient according to specimen type required, (blood, respiratory, etc.)
- ☐ Lead Partner #1 collects appropriate specimen(s), in specific order: Clear, Blue, Red, Gold, Green, Purple Grey top. Mix well, place on clean disinfectant wipe.
- ☐ **Change outer gloves using good glove-in-glove technique**, hand sanitize with new wipe and discard, put on new outer gloves.
- ☐ With new wipe, pick up top of tube.
- ☐ Pick up 2nd wipe, and clean bottom of tube with good friction
- ☐ Holding the bottom of tube with the wipe, use the other hand to wipe the TOP of vacutainer lid (thoroughly remove blood droplets from indent of rubber stopper).
- ☐ Lay specimen container down on new disinfectant wipe to dry, discard used wipes.
- ☐ Repeat disinfection step with each tube or device collected, using new wipes,

Specimen Collection

Mini-Exercises Discussion
High Consequence Specimen Collection

- Initiated outside of collection site (hot zone)
- Each individual handling the transport kit must complete
- Keep copy in laboratory for 2 years
- Final signature is done at the public health laboratory



Chain of Custody Form
High Consequence Pathogen Transport to NPHL

Shipper (Facility) Name: _____
Responsible Person: _____
24/7 Emergency Phone Number: _____
INSERT PATIENT INFORMATION HERE

Consignee:
Nebraska Public Health Laboratory
24/7 pager (402) 888-5588
560 S 45th Street
DRC#2 Loading Dock
Omaha NE 68198 USA

Number of tubes collected: Purple___, Green/Gray___, Red___, Other_____

Secure Red Cable Tie Numbers(s): _____

Courier Identification: _____

Date Time

Collected By: (Do NOT take form into isolation area) _____

Witnessed By: _____
(Printed Name) (Signature)

Reason: _____

Received By: _____
(Printed Name) (Signature)

Reason: _____

Received By: _____
(Printed Name) (Signature)

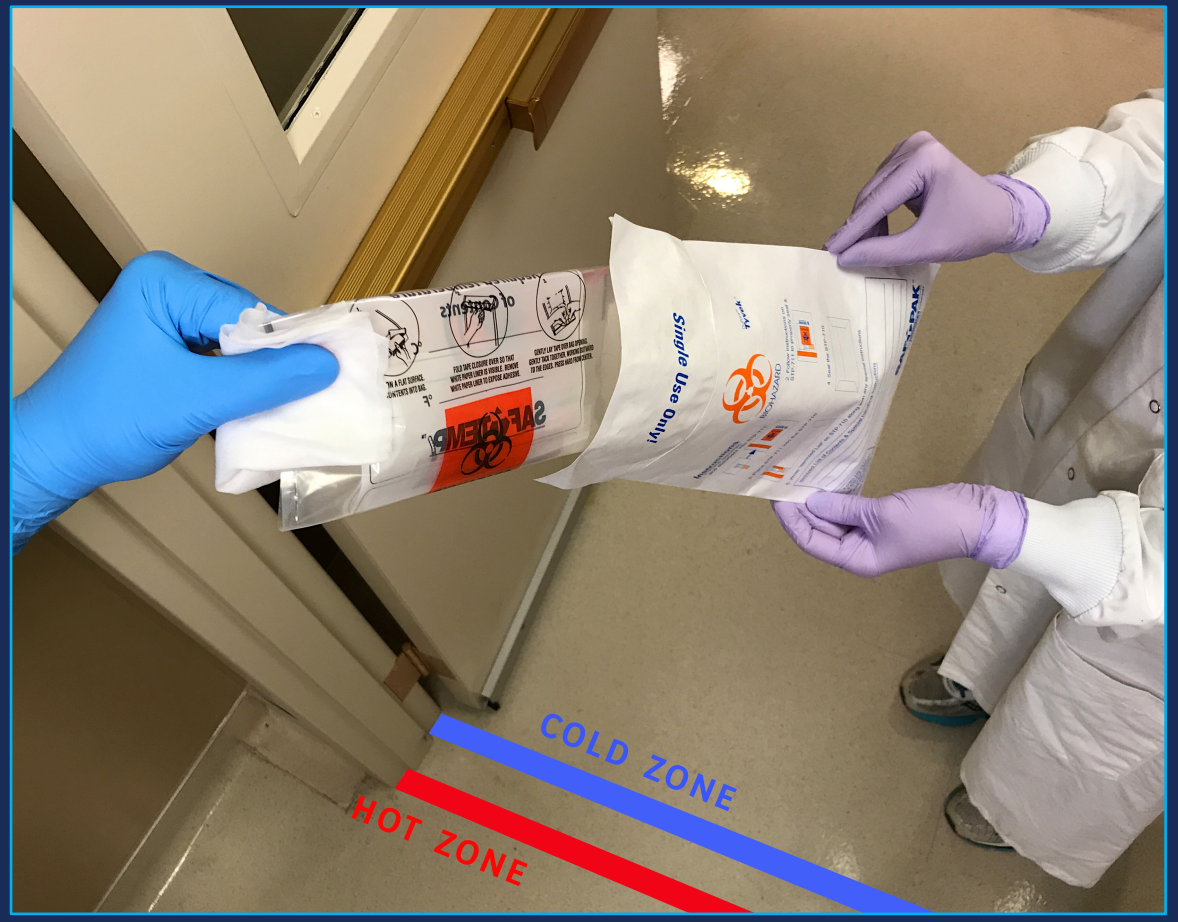
Reason: _____

Specimen Packaging

Packaging on clean side dependent on:

1. Pathogen Suspected

2. Courier and Destination



Specimen Shipping

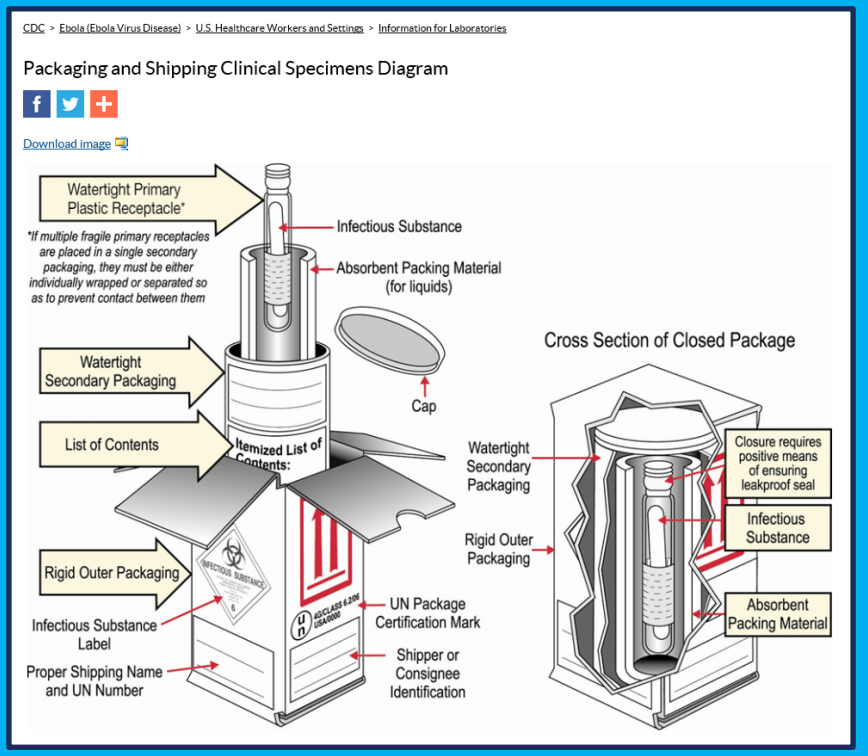
Courier/Destination

- Once shipping category determined, packaging material is dependent on courier and destination:
  - Frontline hospital to on-site laboratory
  - Frontline hospital to commercial reference lab – Prohibited!
  - Frontline hospital to PHL
  - PHL to CDC

Specimen Transport

On-site laboratory

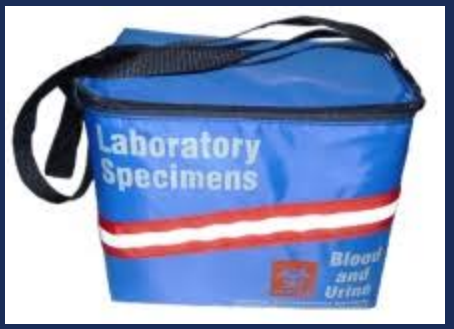
- Lab directly across from isolation room?
- Lab route requires walking thru units or public area?
- TRIPLE PACKAGE



Specimen Transport

On-site laboratory

- Ongoing risk assessment:
  - Triple Package if transported through public areas
  - **DO NOT** use pneumatic tube system
  - Use rigid leak-proof container
  - Consider using a buddy system
  - Chain-of-Custody needed?



- Upon arrival to Laboratory
  - Unpack in BSC with PPE
  - Test in BSL-2 using BSL-3 precautions

Specimen Shipping

Transport Frontline to PHL

Commercial courier vs Government courier?

Commercial Courier:

- Package and transport in accordance with DOT Hazardous Materials Regulations and IATA Dangerous Goods Regulations
- Individuals packaging and shipping infectious substances must be trained and certified
  - DOT requires every three years
  - IATA requires every two years
- Requires specific UN-certified packaging, labels, marking, and specific documentation
  - Shippers Declaration
  - Guide 158 Spill Instructions

Specimen Shipping

Transport to PHL

- Most commercial ground couriers do NOT accept even specimens from PUI:
  - Documented proof of major liability insurance
  - Required training in Security Awareness, Blood Borne Pathogens, Task Specific Responsibilities
  - Need better vetting of couriers
    - Usually not properly trained on appropriate paperwork, or recognize difference between Category A and B

- FedEx will accept specimens from PUI:
  - Shipper MUST be Certified DOT Div 6.2
  - Use certified shipping systems (boxes)
  - Tedious Paperwork – Shippers Declaration
  - Should Frontline hospitals that don’t routinely ship category A be required to?

Specimen Shipping

Government Couriers

Shipping Exceptions to DOT Regulations

* DURING PUBLIC HEALTH EMERGENCIES, LAW ENFORCEMENT AGENTS OR OTHER DESIGNATED STATE OFFICIALS WITH IDENTIFICATION MAY DELIVER SPECIMENS APPROVED BY THE DHHS AS FOUND IN THE 49CFR CODE 171.1 d(5-6)
  * Transportation of a hazardous material by a Federal, state, or local government employee solely for noncommercial Federal, state, or local government purposes
  * Under these circumstances, hospitals may be exempt from using the “official” shipping regulations, including training. Permission for exemption must be granted by state officials.

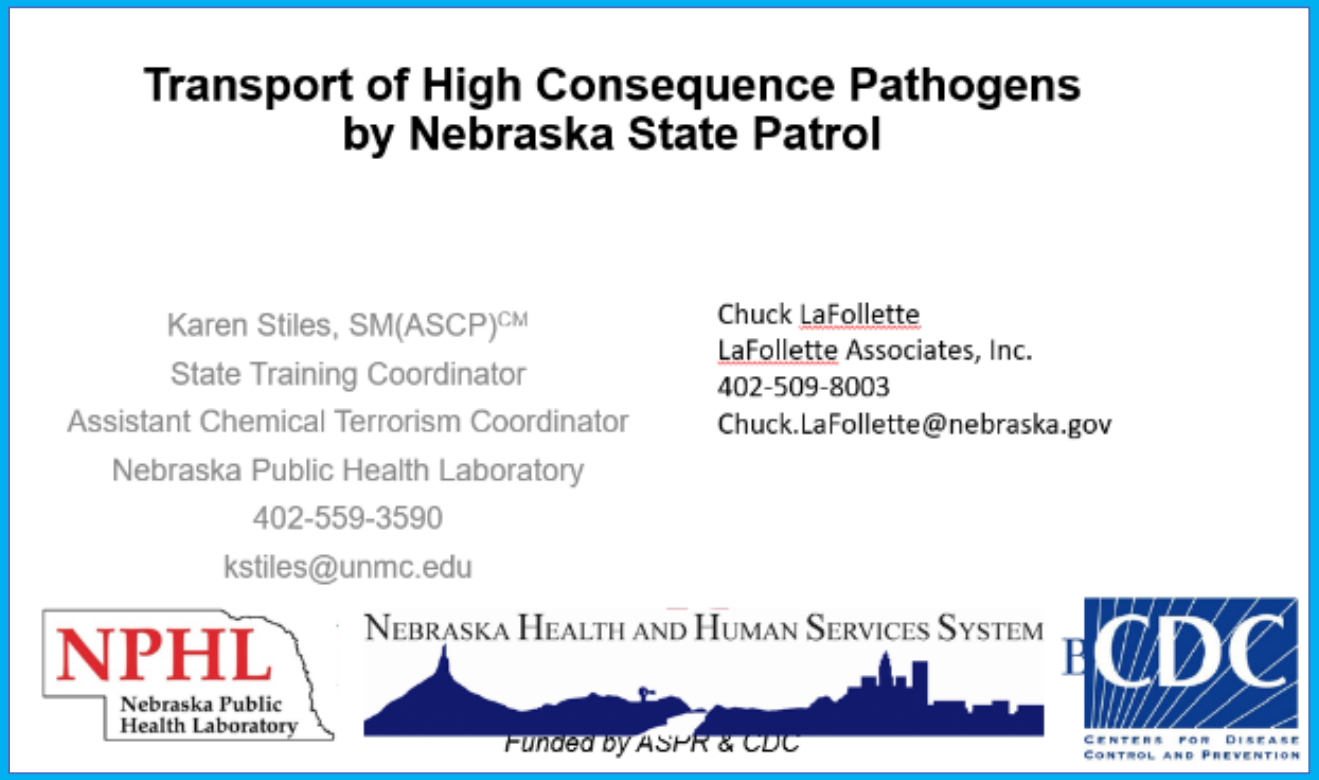
* Triple package required for safety reasons

Specimen Shipping

NETEC

Government Couriers – Nebraska Example

- Set up relationships with your state
- Create a MOA before the event occurs
- Just-in-Time training



Specimen Packaging

Packaging is dependent on pathogen suspected

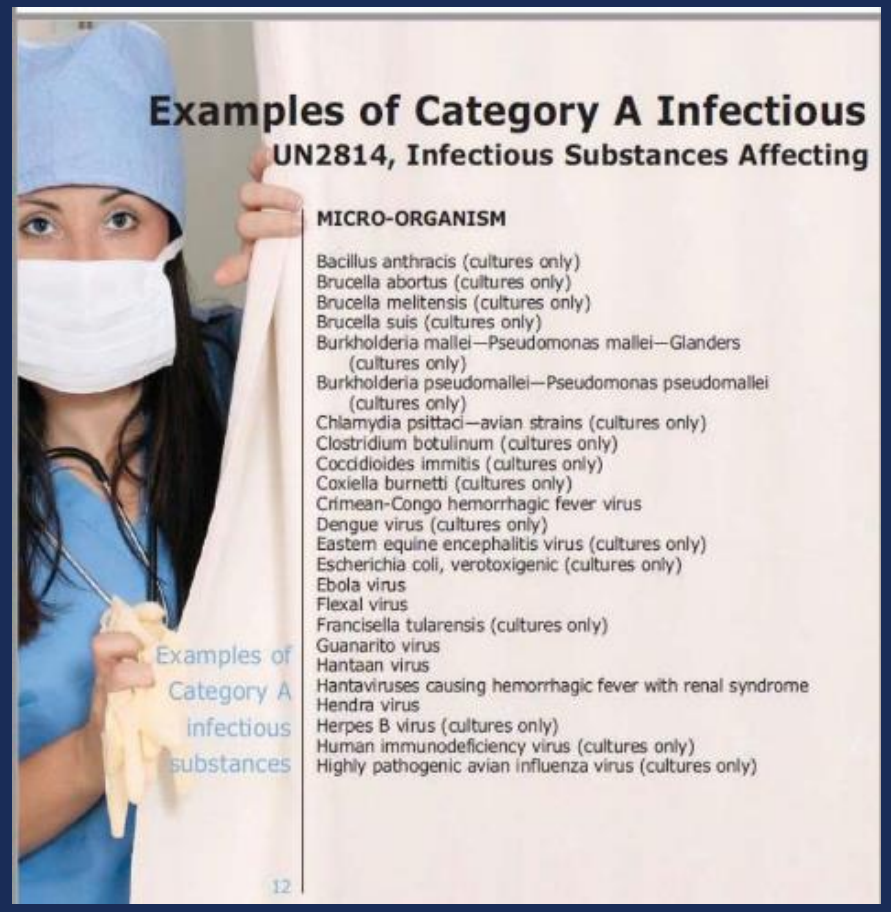
Contact Public Health Laboratory to confirm proper shipping methods

Public Health Lab will determine if:

- Category A
- Category B

Specimen Packaging

Packaging when pathogen is suspected: Category A



Substances:
Humans

Japanese Encephalitis virus (cultures only)
Junin virus
Kyasanur forest disease virus
Lassa virus
Machupo virus
Marburg virus
Monkeypox virus
Mycobacterium tuberculosis (cultures only)
Nipah virus
Omsk hemorrhagic fever virus
Poliovirus (cultures only)
Rabies and other lyssaviruses (cultures only)
Rickettsia prowazekii (cultures only)
Rickettsia rickettsia (cultures only)
Rift Valley fever virus (cultures only)
Russian spring-summer encephalitis virus (cultures only)
Sabia virus
Shigella dysenteriae type I (cultures only)
Tick-borne encephalitis virus (cultures only)
Variola virus
Venezuelan equine encephalitis virus (cultures only)
Vesicular stomatitis virus (cultures only)
West Nile virus (cultures only)
Yellow fever virus (cultures only)
Yersinia pestis (cultures only)

KS – Hide for Presentation version

List provided as guidance only! NOT all inclusive

Specimen Packaging

Packaging when pathogen is suspected: Category B

Examples of Category B

- MERS specimens
- Influenza specimens - Seasonal
- Carbapenem Resistant Enteric isolates
- TB specimens

Exceptions

- WHO changes level
- H1N1 2009

KS – Hide for Presentation version

Contact Public Health Laboratory to confirm proper shipping metho

Specimen Shipping

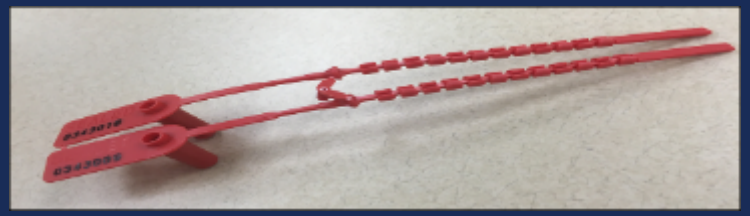
Building a Transport Kit

Nebraska Example: No Product that Expires!

- Contents:
  - Category A system
  - Biohazard bag/absorbent
  - Cold packs (Instruct to freeze)
  - Secure cable ties
- Folder:
  - Procedure
  - Contact information
  - Map/directions
  - Chain-of-custody forms
  - DOT Emergency Response Information

Specimen Shipping

Building a Transport Kit: What's in the box…

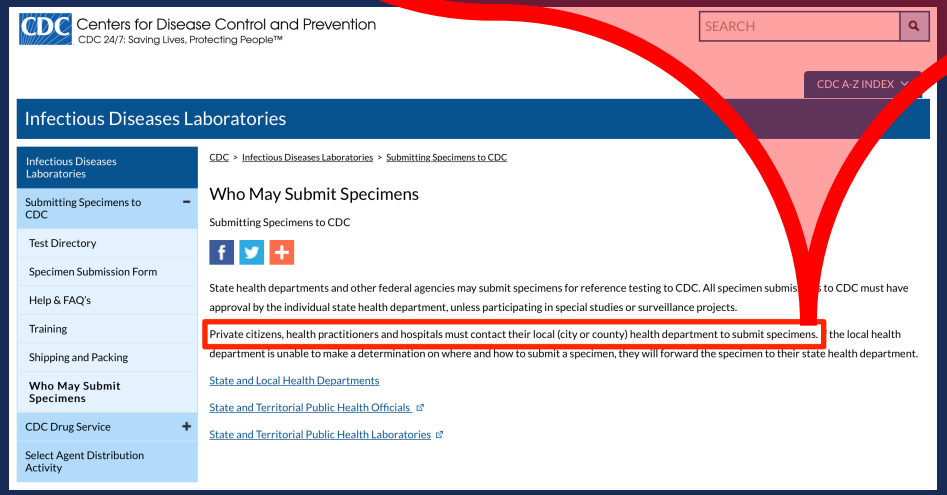


Specimen Shipping

Transport to CDC

PHLs should be primary shipper to CDC

Private citizens, health practitioners and hospitals must contact their local (city or county) health department to submit specimens.



Specimen Shipping

Transport to CDC

- Public Health Laboratories SHOULD be primary shipper to CDC
  - Appropriate packaging
  - CDC "DASH" Form 50.34 (Data and Specimen Handling form)
  - Courier arrangements
  - PHL provides storage of excess clinical specimen (in some cases)
  - Result reporting
  - Quarantine & Contact Tracing (Epidemiology)

- In Emergency – Frontline Hospital may be asked to ship to CDC
  - Is it necessary to have Frontline facility ship directly?
  - Communicate with the jurisdictional PHL
  - MUST be certified in DOT Division 6.2
  - Required to complete CDC DASH forms
  - Stressful for facility who has never shipped category A

KS – Hide for Presentation version

Specimen Shipping

Specimen collection and transport resources

- Collecting, Transporting, and Submitting of specimens for Ebola Virus Testing:
  - https://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/specimens.html
- Packaging Diagram (close up):
  - https://www.cdc.gov/vhf/ebola/healthcare-us/laboratories/shipping-specimens.html
- Certification, Dangerous Goods
  - http://www.iata.org/publications/dgr/Pages/index.aspx
- Submission of specimens to CDC
  - https://www.cdc.gov/laboratory/specimen-submission/who-may-submit-specimens.html

Objective #2: Round Table Discussion

NETEC

Round Table Discussion

Objective #2: Round Table Discussion

NETEC

Risk Assessment on Specimen Collection:

- How do you plan for dehydrated patient that may be hard to stick?
- How would specimen collection occur for a combative/acutely psychotic patient?
- How do you collect for nasopharyngeal, urine or stool?

Objective #2: Round Table Discussion

Has your facility planned a route for transport of a specimen from the point-of-entry to the testing site internally?

- What are the important characteristics of an appropriate transport container?
- Are appropriate transport containers available and are staff trained in packaging and transport?

Objective #2: Round Table Discussion

Has your facility planned transport of a specimen to an external facility?

- Are appropriate Category A shipping materials readily available?
- How are transport and testing processes communicated with the PHL?
- Has proposed commercial courier been vetted and properly trained to accept a Category A package containing a high consequence pathogen for shipment?

Objective #3

NETEC

Pertaining to the care of a PUI or patient infected with a high risk pathogen

1. Describe components of a biological risk assessment
2. Identify critical elements to collect, package, and ship a diagnostic specimen
3. **List elements of a response plan to provide clinical laboratory services**
4. Discover lessons learned to identify and correct potential gaps in clinical laboratory practices

Objective #3

3 List elements of a response plan to provide clinical laboratory services

- Test Menu
- Staffing Model
- General Lab Safety/How to mitigate risks
- Cleaning, Disinfection & Specimen Disposal

Test Menu

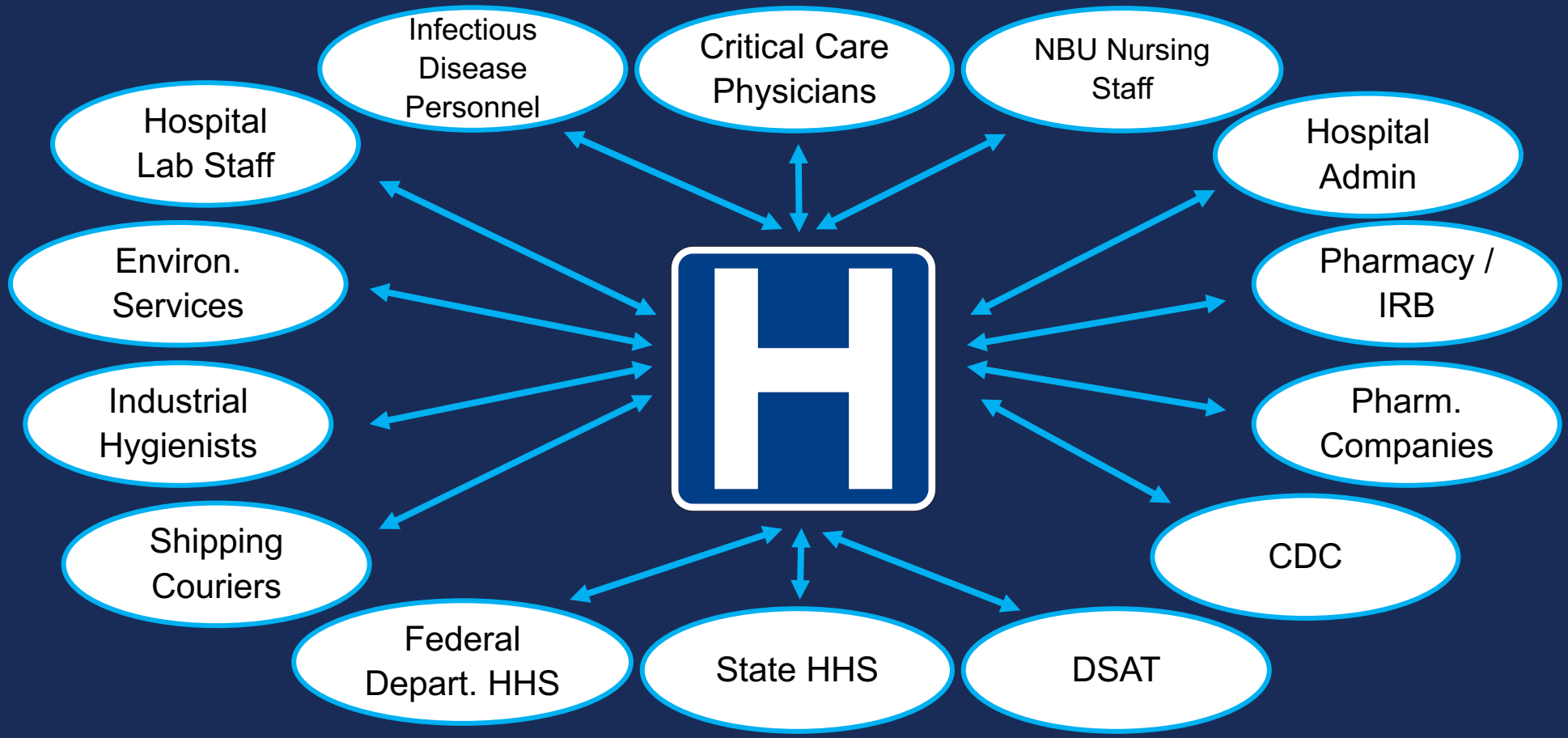
How do you decide what testing to provide & which instruments to use?

- Communication
  - Which test are a “necessity” to care for a patient?
  - Which tests are on the “Wish List”?
- Risk Assessments
  - Test specific

Test Menu

NETEC

! Communication is key !



Test Menu

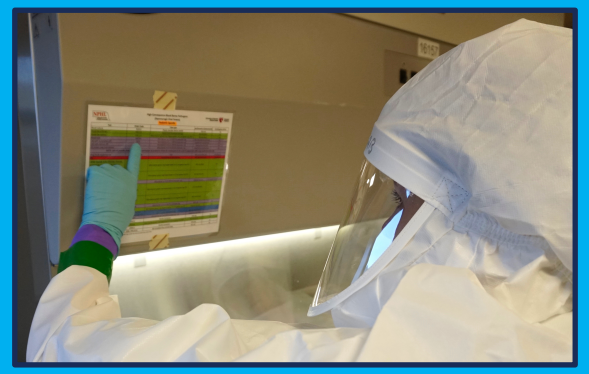
- Where are you performing the testing?
  - POC at the bedside
  - In a Main Laboratory
  - BSC vs. open bench
- Open vs. Closed systems
  - How are you mitigating risk from start to finish?
  - What are you doing with waste?
- Selecting Point-Of-Care equipment
  - Review risk v. benefit of different options.
  - QC & Proficiency – who will be trained?

Test Menu

- Who is performing the testing?
  - Medical personnel (Nurses, Resp Therapist, Clinician, etc.) at the bed side?
    - Do they know how to pipette? If not, risks related to syringe or disposable pipette…more splash.
  - Laboratorians?
- Blood bank
  - Agglutination, limited to typing Rh Factor
  - If not, give O negative.

Test Menu

- Quick Reference
  - Color Coded
  - Laminated for clinical areas



NPHL Nebraska Public Health Laboratory

High-Consequence Blood Borne Pathogens (Viral hemorrhagic Fevers)

University of Nebraska Medical Center — Nebraska Medicine

Test	Order Code	Tube type	performed at (Instrument)	Centrifugation (NPHL)
Blood culture	BLDCU	Plastic Aerobic Bactec bottle	NPHL lab	No
Blood Gas arterial	POC113	Heparnized blood gas syringe	BCU lab (iStat)	No
Blood Gas venous	POC114	4.5 ml green top PST	BCU lab (iStat)	No
Blood type	ABORH	3 ml (EDTA) lavender top	BCU Lab (slide forward type)	No
CBC with automated diff	CBCP	3 ml lavender top	Hospital Core Lab (Sysmex)	No
CBC with manual diff	CBCM	3 ml lavender top	Hospital Core lab	No
DIC screen (see note below)		3 ml lavender top	Hospital Core Lab (Sysmex)	No
NOTE: Lab will provide platelet count and examination of peripheral smear for schistocytes to be used in conjunction with coag results from BCU lab				
Drug Study experimental	**No test code**	5ml lavendar top (Qty 1) OR 3ml lavendar top (Qty 2)	BCU Lab or NPHL Lab	Yes (Plasma)
HIV	SUD	4ml red top	BCU Lab or NPHL Lab	Yes (Serum)
i-STAT Chem8: BUN, Chloride, Glucose, Ionized Calcium, Potassium, Sodium, TCO2, Hematocrit and estimated Hemoglobin	POC136	4.5 ml green top PST	BCU lab (iStat)	No
Liver Panel Plus: Albumin, Alkaline Phosphate, ALT, Amylase, AST, Total Bilirubin, GGT, and Total Protein	LIVERP	4.5 ml green top PST	BCU lab (Piccolo)	No
Malaria	MALP	3 ml lavender top	Hospital Core lab	BCU lab will prepare smears
MetLac12: Albumin,BUN, Calcium, Chloride, Creatinine, Glucose, Lactate, Magnesium, Phosphorus, Potassium, Sodium, Total CO2	METLAC	4.5 ml green top PST	BCU lab (Piccolo)	No
MetLyte Plus CRP: BUN, CRP, Chloride, CK, Creatinine, Glucose, Potassium, Sodium, Total CO2	METLYT	4.5 ml green top PST	BCU lab (Piccolo)	No
Molecular Assay	SPPRB	3 ml or 5ml lavender top	NPHL lab	No
Prealbumin	PAB	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core Lab	Yes
PT/PTT	Coagulation Panel (For Biocontainment Unit Use Only)	1.8 ml or 2.7 ml citrate tube (blue top)	BCU lab (Hemochron)	No
Reticulocyte Count	RETCT	3 ml lavender	Hospital Core lab	No
Sputum Culture	SPUCU	Sterile Container	NPHL lab	No
Troponin	POC24	4.5 ml green top PST	BCU lab (iStat)	No
Urine Culture	URNCU	Sterile Container	NPHL lab	No
Urine electrolytes	UNA, UKS,UCLS	BD Urinalysis Plus conical tube	BCU Lab	No
SST Gold Top, Serum Separator Tube; Green PST Top, Lithium heparin Plasma Separator Tube; Lavender Top, EDTA anticoagulant; Blue, sodium citrate				updated 9/2016

Test Menu

NETEC

NPHL Nebraska Public Health Laboratory

High-Consequence Respiratory Pathogens (Adults and Pediatrics)

University of Nebraska Medical Center | Nebraska Medicine

Test	Order Code	Tube type	performed at (Instrument)	Centrifugation (NPHL)
Molecular Assay - MERS-CoV	MERSC	Nasalpharyngeal swab	NPHL lab	No
Sputum Culture	SPUCU	Sterile Container	NPHL lab	No
Respiratory Viral Pathogen Panel	*Reflux only - test will be run if MERSC is negative*		Micro Lab	No

* All Respiratory Specimens will go to NPHL
* All Non-Respiratory Specimens will go to CORE lab for routine testin

updated 9/2016

- Simplification for respiratory pathogens
- Core lab testing can be done safely.

Staffing Model

How many staff members do you need?

How long is each shift?

Volunteer vs. Mandatory?

Staffing Model

How many staff members do you need?

- Buddy System
- Sick personnel
- Pregnant Personnel
- Other Health concerns
- Family Obligations
- Health Monitoring

Staffing Model

NETEC

Shifts

? How long can staff safely stay in PPE?

? 12 hr shifts? or 8 hr shifts?

? 24/7 Coverage?

Staffing Model

Volunteer vs. Mandatory

How do you get your staff's buy in?

- Transparency
- Drills
- Leadership involvement

Laboratory Testing

Mitigating the risks

- Situational awareness:
  - Where is your lab testing taking place?
    - Patient Room
    - Main Laboratory
    - Alternate Room
  - How many people will be working in that area?
  - Hot/Warm zones?

Laboratory Testing

Mitigating the risks

- Situational awareness:
  - What is the route to the laboratory?
    - How are you packaging the specimen?
    - Who is transporting the specimen?
    - How many people/Security needed?

Laboratory Testing

Mitigating the risks

- Administrative controls
  - Do you have a BSC?
  - Do you have a centrifuge with sealed rotors?

If not, what can you use to mitigate splash, spray and/or aerosol risk?

Laboratory Testing

Mitigating the risks

- What does your work flow look like?

- How are you setting up your supplies?
- Are you working with everything within reach?
- Minimize your movements
- Do you have a spill procedure in place & do staff know how to use them? Have you done any spill exercises?

Laboratory Testing

Mitigating the risks

How does the laboratory processing and testing differ among pathogens; Ebola vs. Respiratory Illness (i.e.. MERS, SARS, Avian Influenza)?

- PPE
- Staffing
- Testing Menu

Is this information shared with the laboratory?

Group Activity: The MacGyver Exercise

NETEC

Directions:

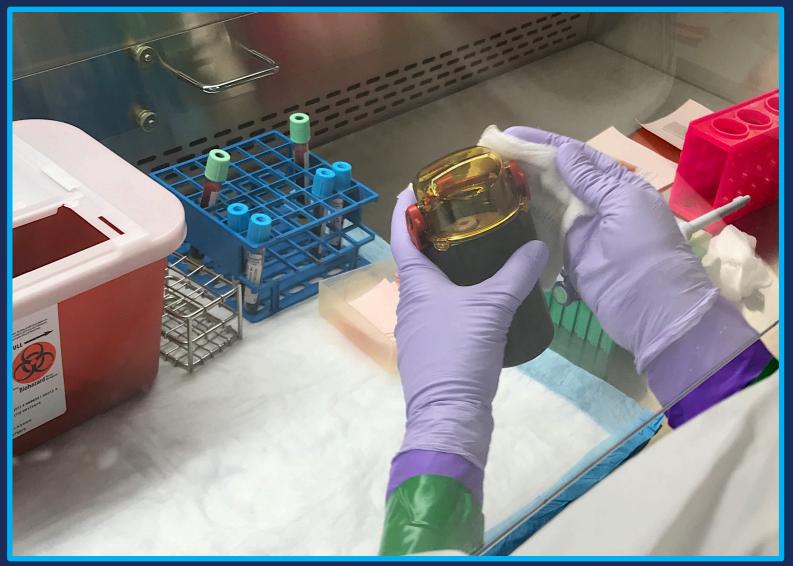
Set up a safe work space for handling specimens with available supplies

Share: Risk mitigation strategies with available resources

Laboratory Testing

Cleaning & disinfection

- Clean from outside in
- If using a BSC – recommend using a rigid container (i.e. sharps container) to discard all waste before removing from BSC
- Appropriated disinfectants
  - Bleach v. Other
- Instrument decontamination
- Whole area decontamination
- Do you have a procedure in place?



Laboratory Testing

Cleaning & disinfection

When to clean/disinfect:

- RESET: Room and BSC cleaned after each testing event…surfaces, instruments, removing all waste.

- Full disinfection of space after activation similar to clinical care area process.

Laboratory Testing

Waste

Manage waste as you go

Use small sharps containers

- Fit well in your BSC.
- Put all waste in sharps container
- Close sharps container and bleach wipe exterior, hand to buddy for waste container, and then manage as room is cleaned.

Laboratory Testing

Waste

- Absorbent pad used as “work space” in the BSC
  - Wrapped up for removal inside sharps container.

- De-gloving required to move hands away from BSC area.
  - Clean gloves to go back in to perform disinfection.

Laboratory Testing

Specimen storage

Have you considered what to do with your specimens after testing is done?

- Should you have a tracking and specimen management system?
- Should these specimen be discarded immediately after testing? How long can you store them?
- Should you document destruction?

Staffing Model: Round Table Discussion

NETEC

Scenario:

A patient with a high risk exposure to EV has just been admitted to your ED, and is symptomatic. Your laboratory staff has received word that laboratory testing will be necessary while waiting for EV confirmation results. Your laboratory staff consists of 10 people – 2 have called in sick, 1 is pregnant, 1 is nursing, 1 is on vacation and 1 is taking immunosuppressing drugs for an illness.

Describe a staffing model in this situation

*Include: Who will do the testing?
What will your staff schedule will be?
Any other considerations?

Staffing Model: Round Table Discussion

NETEC

Scenario:

Your laboratorian is centrifuging a specimen from a suspected patient with EVD when the tube breaks. The centrifuge being used does NOT have sealed rotors.

Q: How would you mitigate the risk of opening and cleaning out that centrifuge?

Staffing Model: Round Table Discussion

Scenario:

A PUI arrives at your hospital complaining of fever, headache, fatigue and stomach pain. This patient has had a high risk EV exposure. In addition to an EV screening test, the physician on call orders blood cultures.

(*Assume blood cultures are done using glass bottles on an automated system)

Q: After doing a risk assessment of the blood culture process, is this a test your facility would offer?

If the answer is Yes, how would you mitigate the risks of a blood culture test?

Objective #4

NETEC

Pertaining to the care of a PUI or patient infected with a high risk pathogen

1. Describe components of a biological risk assessment
2. Identify critical elements to collect, package, and ship a diagnostic specimen
3. List elements of a response plan to provide clinical laboratory services
4. Discover lessons learned to identify and correct potential gaps in clinical laboratory practices

Poll Everywhere Slide Placeholder

First Hand Experiences

Texas Presbyterian Experience

Emory Experience

Denver Health Experience

Texas Presbyterian Experience

NETEC

Facility specifics

- Successfully cared for 3 patients in 3 weeks with EVD.
- New laboratory area (2010) with a special room for isolation (TB) that could be used to run closed POC testing with a BSL-2 cabinet.
- Closed robotic chemistry line
- Self contained hematology
- CoAgs were not closed…but used iStat in spite of FDA approval only for Coumadin patients.
- Had a small portable autoclave in their department.

Notes from an August 2017 call with Nancy Cornish (CDC), Beverly Dickson (Texas Presbyterian), Laura Knoll (Texas Presbyterian), and Connie Sellers (Texas Presbyterian).

Texas Presbyterian Experience

Key lessons learned

- Close communication between physicians (ordering), nurses (drawing), and laboratorians (processing).
- Strict time frames for running labs.
- Buddy system.
- Good to have team members with MacGyver skills for Apollo 13-like problems.

Texas Presbyterian Experience

NETEC

Continuing education

- Systematic training twice per year
  – Educational Module

- Drill:
  - Shipping, blood malaria test
  - Roles: Buddy, Tester, Runner

Texas Presbyterian Experience

- Training Site: https://www.cdc.gov/ophss/csels/dls/index.html
- BSC Course: https://www.cdc.gov/labtraining/training-courses/biological-safety-cabinets.html

Emory Experience

Key lessons learned

- Flexibility
- Communication
- Back to basics
- Fatigue/Backfill
- Safety first culture
  - PPE/Full PAPR
  - Psychological impact
- Dedicated laboratory
- Preplanning-what tests & when

Denver Health Experience

Lessons learned

- Asking for help
- Difficulty in shutting down parts of micro lab
- No packaging certification
- Phone tree
- Purchasing decisions
- Preplanning with physicians
- Staffing issues

Other Lessons Learned

NETEC

Laboratory scalability

Laboratory sustainability

Common challenges

Other Lessons Learned

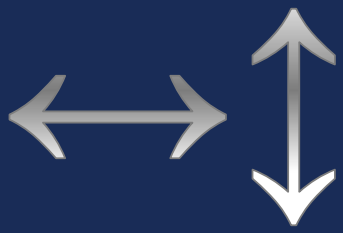
Laboratory Scalability

PUI
(Patient's Under Investigation)

Single Patient

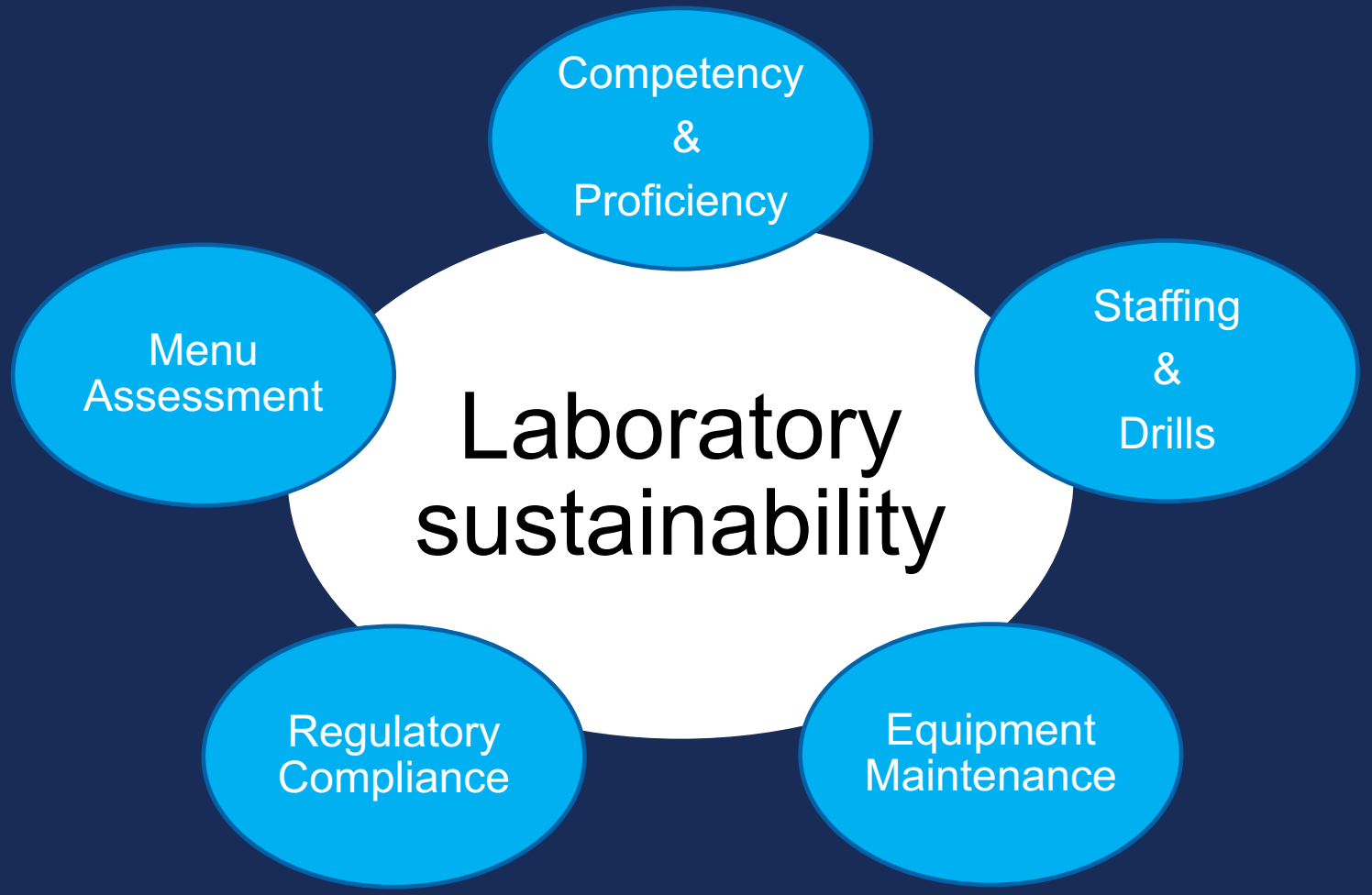
Multiple Patients

- Historically Treatment Hospitals had no more than 2 EVD patients at any time
- How would your facility deal with a significant outbreak/epidemic of a high consequence pathogen?
  - Room, Unit, Ward, Facility
- How soon can the laboratory be activated and at what scale?
  - Specimen collection devices
  - Reagents
  - Test Menu – Never say never
- Just-in-time training for lab staff?
  - Competency issue



Other Lessons Learned

Laboratory sustainability



Other Lessons Learned

Common challenges

- Managing 24/7 patient care…especially in critical care scenarios.
  - Voluntary vs. mandatory teams
  - Shifts, frequent draws
  - Ethical issues related to managing this type of response such as characteristics of the team (pregnancy, illness, chronic illness, addressing fears)
  - Post-event temperature monitoring
  - Technologist selection and training

- Communications
  - Plan for manual entry of results, calling critical results.
  - Active participant patient care team. What is needed? What is possible?
  - Media coverage, community concerns, co-worker scrutiny

Other Lessons Learned

Common challenges

- What are the challenges (safe space):
  - In your laboratory.
  - In your institution (Frontline, Assessment, Treatment Center).
  - In your state public health laboratory.
- Practice, practice, practice
  - Use it or lose it.
  - How do we engage staff in exercising these advanced laboratory skills?
  - Mystery patient drill toolkit
    - https://netec.org/exercises/
    - Under ‘General materials’
- How to manage the lack of a sealed rotor centrifuge
- How to manage the lack of a BSC…

Other Lessons Learned

Common challenges

- Worst-Case Scenario
  - Does your risk assessment include a situation where the patient is not recognized as a positive case until routine laboratory is drawn and tested?
  - How would you identify who was involved with the laboratory testing?
  - How would you sequester the samples and waste?

Summary

Be prepared to provide care for patients awaiting results for high consequence pathogen testing.

Laboratory services must be provided with the highest quality results in a safe testing environment.

Summary

Labs must adhere to local, state, and federal regulations while helping care for patients.

Lab safety can be assured through administrative controls, engineering controls, and personal protective equipment.

Consideration should be given to lab scalability and sustainability.

Resources

Disinfection resources

- Environmental Infection Control in Hospitals for Ebola Virus Disease:
  - https://www.cdc.gov/vhf/ebola/healthcare-us/cleaning/hospitals.html
- Disinfectants for Use Against the Ebola Virus:
  - https://www.epa.gov/pesticide-registration/list-l-epas-registered-antimicrobial-products-meet-cdc-criteria-use-against
  - https://www.epa.gov/sites/production/files/2017-06/documents/20172006.listl_.pdf

Waste resources

- Waste Management Guidance for Ebola Virus Disease:
  - https://www.cdc.gov/vhf/ebola/healthcare-us/cleaning/waste-management.html

Resources

Contact Information

- Pete Iwen (piwen@unmc.edu)
- Karen Stiles (kstiles@unmc.edu)
- Vicki Herrera (vlherrera@unmc.edu)
- Crystal Evans (crystal.evans@emoryhealthcare.org)
- Elizabeth Beam (ebeam@unmc.edu)

Acknowledgements

- Special thanks to Reynolds Salerno, Luis Lowe, Elizabeth Weirich, Danielle Daniely, Aufra Araujo, and Nancy Cornish at the Centers for Disease Control for their guidance in developing this course for laboratorians.

- Special thanks to Beverly Dickson, Laura Knoll, and Connie Sellers at Texas Presbyterian in Dallas, Texas for sharing their powerful story.

Take Home Message

Successfully providing care for patients (and co-workers) infected with EVD or other special pathogens is possible with risk assessment and preparedness measures.

Glossary of Acronyms

- **ASPR**: Office of the Assistant Secretary for Preparedness and Response
  - Within the US DHHS
- **BSC**: Biosafety Cabinet
  - AKA: Biological Safety Cabinet, Microbiological Safety Cabinet
- **BSL-**: Biosafety Level
  - BSL-1, -2, -3, -4
- **CDC**: Centers for Disease Control and Prevention
- **DASH Form**: CDC's Data and Specimen Handling form
  - Also seen as CDC DASH
- **DHHS**: Department of Health and Human Services
  - Also seen as HHS
- **DOT**: Department of Transportation
- **DSAT**: Division of Select Agents and Toxins
  - Within the Office of Public Health Preparedness and Response (PHPR)

Glossary of Acronyms

- **ED**: Emergency Department
- **EMTALA**: Emergency Medical Treatment and Labor Act
- **EPA**: Environmental Protection Agency
- **EVD**: Ebola Virus Disease
  - Also seen as EV: Ebola Virus
- **FDA**: United States Food and Drug Administration
- **HPAI**: Highly Pathogenic Avian Influenza
  - Also seen as HPI: Highly Pathogenic Influenza
- **IATA**: International Air Transport Association
- **IRB**: Institutional Review Board
- **IV Line**: Intravenous line
- **MERS**: Middle East Respiratory Syndrome
  - Also seen as MERS-CoV: Middle East Respiratory Syndrome Coronovirus

Glossary of Acronyms

- **MOA**: Memorandum of Agreement
  - Also seen as MOU: Memorandum of Understanding
- **NBU**: Nebraska Biocontainment Unit
  - Nebraska Medicine, University of Nebraska Medical Center (UNMC)
- **NP swab**: Nasopharyngeal swab
- **PAPR**: Powered Air Purifying Respirator
- **PHL**: Public Health Lab
- **PHPR**: The Office of Public Health Preparedness and Response
- **POC instrumentation**: Point of Care instrumentation
  - AKA: Point of Contact
  - In contrast with Central Laboratory Instrumentation
- **PPE**: Personal Protective Equipment
- **PUI**: Person Under Investigation
  - Presenting with clinical features and epidemiological risk for a special pathogen

Glossary of Acronyms

- **QC**: Quality Control
- **RO**: Responsible Official
  - **ARO**: Alternate Responsible Official
- **SARS**: Severe Acute Respiratory Syndrome
  - Also seen as SARS-CoV: SARS-associated Coronovirus
- **SOPs**: Standard Operating Procedures
- **TB**: Tuberculosis
- **TO**: Trained Observer
- **TRACIE**: Technical Resources Assistance Center, and Information Exchange
  - Within ASPR
  - Usually seen as ASPR TRACIE
- **UN-certified**: Regulations set by the United Nations Expert Committee of Hazardous Good for transportation of hazardous materials
- **WHO**: World Health Organization

Exercise

Scenario-based Tabletop

(In this course, or for use in your own institution)

Exercise

NETEC

Scenario:

- Global news reports large outbreak of Marburg Virus in Democratic Republic of Congo, Uganda, and Kenya. https://www.cdc.gov/vhf/marburg/pdf/factsheet.pdf
- Multiple cases reported in New Jersey, traveled through Newark Airport
- Patient arrives in your Emergency Room with fever, cough, shortness of breath

Q: What does your ED staff do next?

Include:

- What PPE is the patient given upon arrive to protect the ED staff?
- When do you ask travel questions, at registration or after patient taken in for triage?
- What if patient was in waiting room for awhile?

Exercise

NETEC

Scenario:

- Patient later reluctantly reports traveling through Newark Airport same timeframe as initial cases

Q: What does your Emergency room staff do next?

Include:

- Who makes the decision to isolate?
- Who do you call? Within hospital? Outside hospital?
- Would your facility activate some type of Incident Command?
- What type of high-level PPE does your ED have in place?
- Does your ED have advance PPE & collection protocols in place?
- Has your ED recently exercised advance PPE & collection protocols?
- What other elements go into decisions of what PPE to use?

Exercise

Scenario:

- Physician determines in-house laboratory testing is necessary:

Include:

- Does your facility have normal fever testing protocol and what laboratory testing does it include?
- Who in the ED is designated to collect the specimens? Have they been trained/exercised in high-level PPE?
- Does your ED have protocol in place to notify laboratory of incoming high-risk specimens?
- How would you transport to your laboratory?
- What laboratory protocol will be changed if notification was received?

Exercise

Scenario:

- Physician determines in-house laboratory testing is necessary (continued):

Include:

- What PPE protocol would be changed in the laboratory?
- Has your facility's laboratory completed Risk Assessments for High Consequence Pathogens to determine testing capabilities?
- If the risk assessment determines that a certain laboratory instrument is too risky to use, what alternative plans have been made?
- How do you destroy specimens after testing?

Exercise

Scenario:

- Your hospital has been asked to collect specimens to be tested at the local Public Health Laboratory in your jurisdiction for Marburg Testing:

Include:

- Who would do the shipping? Would it be shipped from the isolation room or do you have to transport to the laboratory first?
- Does your state have protocol to transport to PHL?
- Is your facility certified to ship Category A?
- Does your facility have the proper shipping supplies?


NETEC
EMORY MEDICINE
UNMC Nebraska Medicine
NYC HEALTH+ HOSPITALS
Bellevue
www.netec.org