



Managing Ebola Virus Contaminated Medical Waste and Environmental Infection Control

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John Lowe Ph.D.

- No financial relationships to disclose

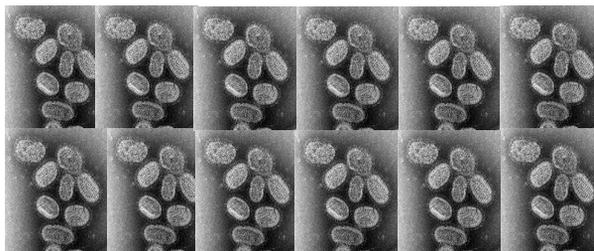


Presentation Outline

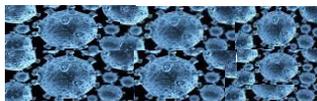
- Introduction
- Background
- Hierarchy of Controls
- Waste Management
- Decontamination
- Personal Protective Equipment
- Care of Deceased
- Transportation
- Laboratory
- Questions



Is Ebola virus highly infectious? Yes



Influenza
1,000



HIV
100

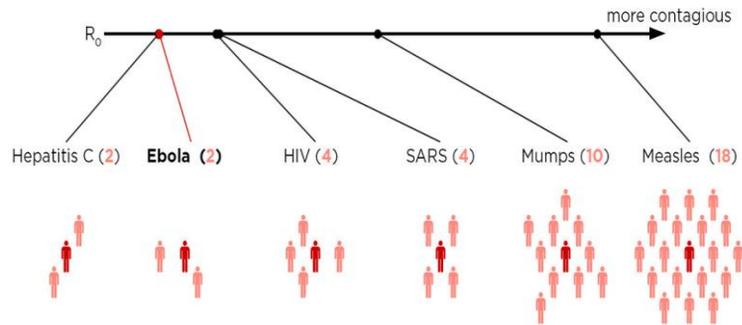


Ebola
1



How Contagious is Ebola?

The number of **people** that **one sick person** will infect (on average) is called R_0 . Here are the maximum R_0 values for a few viruses.



Source: NPR



Ebola Spread

- Ebola virus is spread through direct contact with blood or body fluids (including but not limited to feces, saliva, urine, vomit, and semen).
- The virus can penetrate through non-intact skin or mucous membranes.
- The virus also can be spread through contact with objects (like needles and syringes) that have been contaminated with the virus, or infected animals.





Major article

Planning and response to Ebola virus disease: An integrated approach



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Key Words:
Incident command
Biocontainment
Leadership

The care of patients with Ebola virus disease (EVD) requires the application of critical care medicine principles under conditions of stringent infection control precautions. The care of patients with EVD requires a number of elements in terms of physical layout, personal protective apparel, and other equipment. Provision of care is demanding in terms of depth of staff and training. The key to safely providing such care is a system that brings many valuable skills to the table, and allows communication between these individuals. We present our approach to leadership structure and function—a variation of incident command—in providing care to 3 patients with EVD.

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SCHOOL OF PUBLIC HEALTH-
BLOOMINGTON

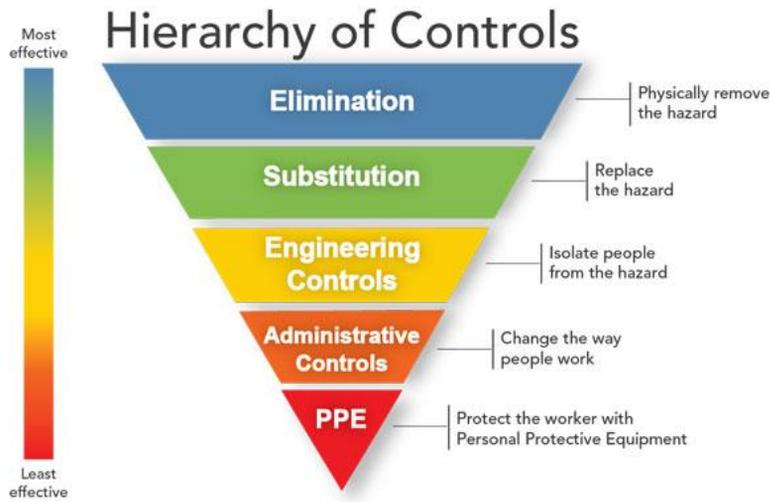
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Cases at Nebraska

- 3 U.S. citizens (2 survived, 1 deceased) infected with EBOV in Liberia, and 1 U.S. permanent resident infected in Sierra Leone.
- 72 hr..... notice of confirmed EBOV transport
- Transferred by air ambulance to Omaha, NE

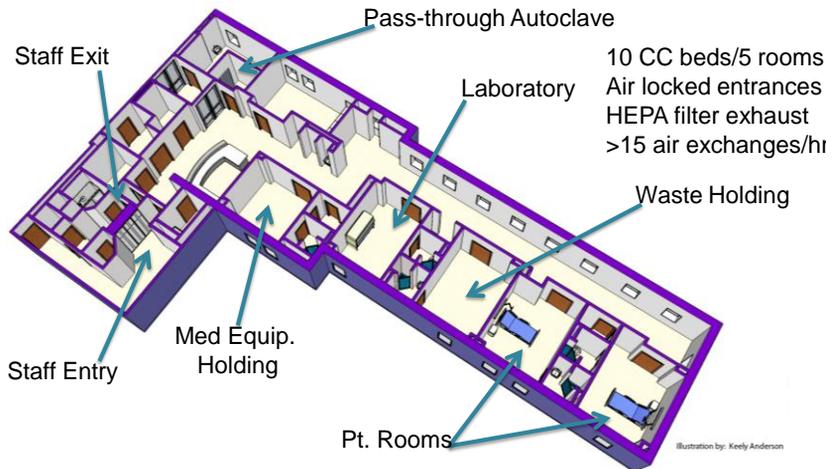




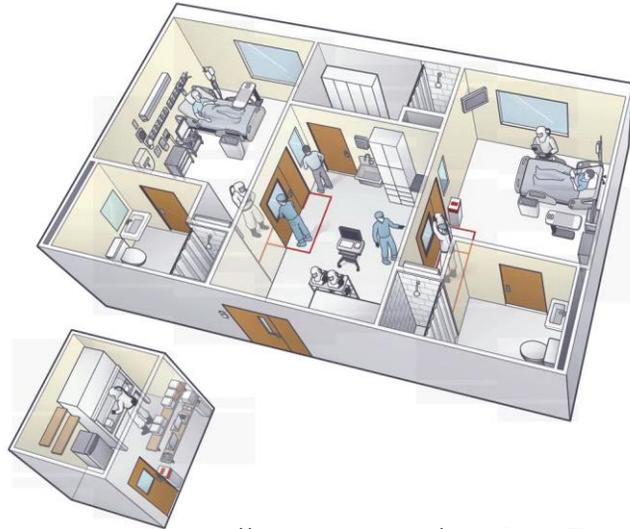
<http://www.cdc.gov/niosh/topics/hierarchy/>



Nebraska Biocontainment Unit



Emory SCDU



<https://www.youtube.com/watch?v=63cTXQxntbw>



NBU Research

- Decontamination using gaseous chlorine dioxide and vaporized hydrogen peroxide
- Mathematical Modeling of particle trajectory in the NBU
- Vaporized Hydrogen Peroxide decontamination of complex medical equipment and rooms
- Autoclave evaluation for decontamination of soiled items
- Evaluation of appropriate PPE usage by employees
- Evaluation of an Infrared thermal detection system (ITDS) for fever recognition



Infection Control Procedures

- Donning and Doffing PPE procedures
- Designated donning and doffing PPE areas
- Designated clean and dirty zones
- Designated zones in which staff performing their roles can enter
- Daily cleaning checklists with dedicated cleaning equipment for each zone
- Designated areas to keep 'clean' equipment vs equipment that has been in the patient care area i.e. x-ray machine
- Designated pathways for removing waste and used linen
- A method for transferring equipment, medications and other supplies from 'clean to dirty' and 'dirty to clean'
- A method for communication 'Provider to Provider' 'Provider to Patient' 'Patient to Family or SO'



Personal Protective Equipment

A method for evaluating health care workers' personal protective equipment technique

Elizabeth L. Beam, MSN, RN,^a Shawn G. Gibbs, PhD, CIH,^b Kathleen C. Boulter, BA, RN,^d Marcia E. Beckerdite, MSN, RN, CIC,^d and Philip W. Smith, MD^c
Omaha, Nebraska

Background: Given the potential for the transfer of infectious diseases among patients in isolation, health care workers (HCWs), and other patients in the hospital environment, the proper use of personal protective equipment (PPE) is paramount. The literature is limited regarding studies of HCWs' use of PPE in patient care tasks.

Methods: A pilot study was conducted to examine the feasibility of using a simulated health care environment to assess HCWs' technique when implementing standard airborne and contact isolation precautions. The participants (n = 10) were assigned patient care tasks based on their specific professional roles. The encounters were digitally recorded during donning and doffing of PPE, as well as during interactions with the simulated patient. Powdered fluorescent marker was used as a measure of contamination.

Results: The pilot data show various inconsistencies in the HCWs' PPE technique. Each of the 10 participants committed at least one breach of standard airborne and contact isolation precautions.

Conclusion: An expanded research study of HCW behaviors is needed to properly examine these contamination and exposure pathways. Training programs should be developed that emphasize the common errors in HCWs' PPE technique.

Key Words: infection control; patient care; contamination; simulation.

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Adaptation & Expansion of Materials



EBOV Waste Regulations

- Waste from confirmed EBOV patient is classified as Category A infectious substances.
- “medical equipment, sharps, linens, and used health care products (such as soiled absorbent pads or dressings, kidney-shaped emesis pans, portable toilets, used Personal Protection Equipment (gowns, masks, gloves, goggles, face shields, respirators, booties, etc.) or byproducts of cleaning) contaminated or suspected of being contaminated”
- Must meet Category A shipping standards

U.S. Department of Transportation Guidance for Transporting Ebola Contaminated Items, a Category A Infectious Substance Accessed September 15, 2014

U.S. Department of Transportation's Hazardous Materials Regulations (HMR; 49 C.F.R., Parts 171-180)



Category A Exemptions

- Corpses, remains, and anatomical parts transported for interment, cremation, or medical research at a college, hospital, or laboratory.
- Laundry or medical equipment complying with OSHA bloodborne pathogens standard intended for use, cleaning or refurbishment. Does not apply to medical equipment being transported for disposal.
- Material that has been treated to fully eliminate, neutralize, or inactivate the pathogen (e.g., **through autoclave or incineration**).
 - Requires validation of sterilization

U.S. Department of Transportation Guidance for Transporting Ebola Contaminated Items, a Category A Infectious Substance Accessed September 15, 2014

U.S. Department of Transportation's Hazardous Materials Regulations (HMR; 49 C.F.R., Parts 171-180)



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Commentary

Nebraska Biocontainment Unit perspective on disposal of Ebola medical waste

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Clinical practices surrounding the current Ebola epidemic have been center stage in discourse concerning research and practice of care. As the medical community becomes more sophisticated in understanding the many facets of treating and containing this virus, the Nebraska Biocontainment Unit has identified Ebola medical waste disposal as a key area of concern for U.S. hospitals. The requirements for processing Ebola medical waste stand to impact most U.S. hospitals currently preparing readiness plans to receive and treat patients with suspected or confirmed Ebola virus disease (EVD).

The U.S. Centers for Disease Control and Prevention (CDC) has issued recommendations to guide health care facilities in preparing to isolate potential or confirmed EVD patients, and hospitals have established plans to isolate and care for these patients.^{1,2} The CDC's guidance includes facility and provider EVD preparedness checklists to aid the U.S. health system in preparing to prevent the spread of the virus within the United States.³ Hospitals are undertaking multiple measures to minimize the risk of EVD, including estab-

Two high-level isolation facilities located at the University of Nebraska Medical Center and Emory University have treated EVD patients in the U.S. These units are ideally equipped for treating patients in high-level isolation because each unit is staffed with HCWs rigorously trained in donning and doffing PPE, and the facilities have been specifically engineered for high-level isolation with in-unit waste processing capability.⁴ The Nebraska Biocontainment Unit's strategy for waste management uses a pass-through autoclave to process all medical waste exiting the high-level isolation unit. Through discussions with health care entities planning for EVD patients, first-hand knowledge gained by treating EVD patients transported to the United States, and review of current guidance, we provide insight into key logistical and regulatory considerations for management of EVD medical waste in facilities without in-unit waste sterilization capabilities.

EBOLA MEDICAL WASTE

Lowe, J.J., Gibbs, S.G., Schwedhelm, S., Nguyen, J., Smith, P.W. 2014. Nebraska Biocontainment Unit Perspective on Disposal of Ebola Medical Waste. American Journal of Infection Control. 42:1256-1257. http://www.ajicjournal.org/pb/assets/raw/Health%20Advance/journals/ymic/YMIC_3269.pdf



Waste Streams

- Solid waste stream
- Liquid waste
- HCW linens
- Patient
Electronics



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Waste Handler PPE

- Biocontainment Unit staff handle all waste processing: Nurses, Medical Technicians, & Industrial hygienists

	Containers	Cubic Feet	Weight (lbs)
Event 1	101	464.4	1011.5
Event 2	88	387.2	1806.5
Event 3	34	156.4	880.2



Healthcare and Emergency Responder Organization Education Through Simulation. Personal Protective Equipment: Biological Level-C Doffing. Omaha: University of Nebraska Medical Center, 2010 Available at 2014.

<http://app1.unmc.edu/nursing/heroes/mpv.cfm?updateindex=53&src=yt> Accessed October 29, 2014

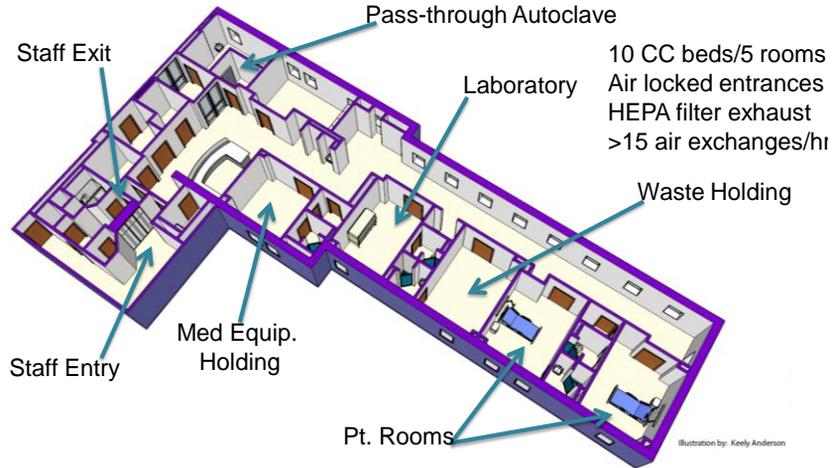


Liquid Waste

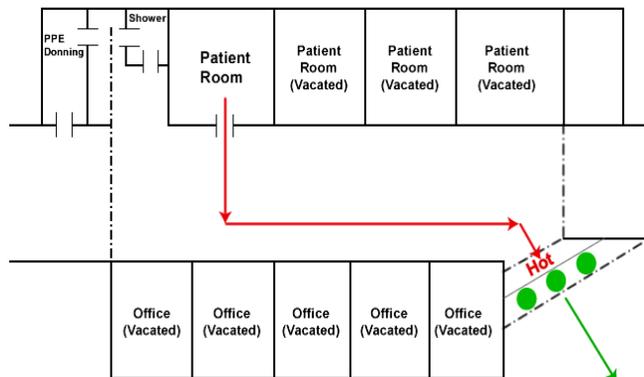
- All EBOV liquid waste (exceptions for items that would be difficult to open, such as suction canisters) is placed into the toilet with the appropriate concentration of an USEPA approved hospital disinfectant.
- This is limited to the patients room.
- It is held for at least twice the manufacturer recommended contact time.
- Either the lid is closed or a rigid, nonporous closure is placed over the toilet before it is flushed.



Nebraska Biocontainment Unit



Packaging and removal of waste





Waste Transport

- Transported as Category B,
 - Labeled and tracked similar to Category A
 - Incinerated and ashes taken to landfill
- ONE CATEGORY A INCITERATOR in the U.S.
- ONE LANDFILL receiving ashes from INCITNERATED CATEGORY A WASTE
- Significant costs associated with Category A disposal 



Considerations

- Alternative on-site sterilization methods/validation for Category A exemption
- Waste processing training, designation of staff, holding site
- Validation of virus inactivation
- Landscape of waste disposal sites and regulations – incineration facilities and landfills 



Commentary

Nebraska Biocontainment Unit patient discharge and environmental decontamination after Ebola care



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The Nebraska Biocontainment Unit (NBU), which operates through collaboration of Nebraska Medicine, the University of

DISCHARGE PROCESS FOR A PATIENT SUCCESSFULLY TREATED FOR EVD

27



Commentary

Environmental infection control considerations for Ebola



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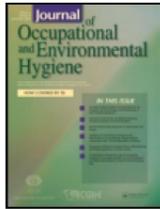
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28





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A Case Study on Decontamination of a Biosafety Level-3 Laboratory and Associated Ductwork Within an Operational Building Using Gaseous Chlorine Dioxide

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29



Strategies formed by Years of Research--- UVGI, ClO_2 , VHP, O_3



30



Daily Cleaning

- Bleach wipes are used constantly throughout the day.
- In the evening the following is done
 - Floors Mopped with Bleach (3 separate mop buckets for patient room, other dirty areas, and clean area)
 - Mop heads are autoclaved
 - All surfaces bleach wiped.



NBU Daily Environmental Cleaning Checklist for Non-Patient Care Areas
 Clean surfaces of gross contamination before you disinfect
 Friction is the key to removing biohazard.
 Use one disinfectant wipe per checklist item.

Date: / / 2014	✓ when complete	Agent Used
High-touch Surfaces Undressing Area		
Staff entry door handles (both sides)		Bleach Wipes
12" square area around door handle (both sides)		
Undressing area locker faces (special attention to handles/ knobs)		
Undressing area locker faces (special attention to handles/ knobs)		
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Staff Bathroom		1:10 Bleach Solution Or 1:14 if concentrated bleach is used (Single Dip Method)
Bathroom door knob / plate (inner/outer)		
12" square area above/below door handle (both sides)		
Bathroom light switch		
Bathroom handrails by toilet		
Bathroom sink		
Toilet seat/chin		
Toilet flush handle		
Sink/faucet/handles		
Mirror		
Paper towel holder		Unless otherwise specified
Toilet paper holder		
Empty Trash/re-bag trash can		
Staff Shower		
Shower room door knob/ plate (inner/outer)		
Shower room light switch		
Shower room sink		
Shower stall (remove any hair from drain)		
Toilet seat/chin		
Toilet flush handle		
Sink/faucet/handles		
Mirror		
Paper towel holder		
Toilet paper holder		
Empty Trash/re-bag trash can		
Change green laundry bag per protocol		
High-touch Surfaces Redressing Area		
Redressing area locker faces (special attention to handles/ knobs)		
Walls, door, door frames in walk through shower area		
Follow Chlorine Shoe Dip protocol		
Change green laundry bag per protocol		
Empty Trash/re-bag trash can as needed		

NBU Cleaning Check lists

- Separate checklists for each zone
- Involve hospital infection control in creating the checklists
- Wear appropriate PPE for the zone being cleaned



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Case Study

Surrogate Testing Suggests That Chlorine Dioxide Gas Exposure Would Not Inactivate Ebola Virus Contained in Environmental Blood Contamination

The ability to decontaminate a room potentially containing the Ebola virus is important to healthcare facilities in the United States. The Ebola virus remains viable in body fluids, a room that has housed a patient with Ebola virus disease must have all surfaces manually wiped with an approved disinfectant, which increases occupational exposure risk. This study evaluated the efficacy of gaseous chlorine dioxide inactivation of bacterial organisms in blood as the Ebola virus surrogates and as the organisms used by the Nebraska Biocontainment Unit to provide the margin of safety for decontamination. Bacillus anthracis, Escherichia coli, Enterococcus faecalis, and Mycobacterium smegmatis blood suspensions that were exposed to ClO₂ gas concentrations and exposure limits. The log reduction in Colony Forming Units (CFU) was determined for each bacterial blood suspension. Exposure parameters approximating industry practices for ClO₂ environmental decontamination (360 ppm concentration to 780 ppm-hr exposure, 65% relative humidity) as well as parameters exceeding current practice (1116 ppm concentration to 1400 ppm-hr exposure; 1342 ppm concentration to 1487 ppm-hr exposure) were evaluated. Complete inactivation was not achieved for any of the bacterial blood suspensions tested. Reductions were observed in concentrations of B. anthracis spores (1.3–3.76 log) and E. faecalis vegetative cells (1.3 log) whereas significant reductions in vegetative cell concentrations for E. coli and M. smegmatis blood suspensions were not achieved. Our results showed that bacteria in the presence of blood were not inactivated using gaseous ClO₂ decontamination. ClO₂ decontam-

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Terminal Cleaning

- 48 hour stand down
- Team of HCW comes in and bleach wipes and mops entire Unit
- Unit is exposed to 100-1000 mJ/cm²
 - Other options VHP, ClO₂
- Another 48 hour stand down



Decontamination

- Personnel
- Location
- Medical Devices
- Out of service time



Decontamination





37

Personal Protective Equipment

Masks
Respirators
Gowns
Coveralls
Gloves
Disposable Boots
Head Covers
Eye Protection



CDC Recommended PPE for the Dry Patient



Single Use (Disposable) Face Shield

Single Use (Disposable) Surgical Mask

Single use (disposable) fluid-resistant gown that extends to at least mid-calf or coverall without integrated hood

Single use (disposable) gloves with extended cuffs. Two pairs of gloves should be worn.

At a minimum, outer gloves should have extended cuffs and must completely cover the gown cuff.

<http://www.cdc.gov/vhf/ebola/healthcare-us/ppe/>



Recommended PPE for the Wet Patient



Single use face shield, surgical hood extending to shoulders, and N95 Respirator **OR** PAPR with a full face shield, helmet, shroud (not shown)

Single use fluid-resistant or impermeable gown that extends to at least mid-calf **OR** coverall without integrated hood (not shown)

Two pairs of single use, disposable gloves. At a minimum, outer gloves should have extended cuffs.

Single use fluid-resistant **OR** impermeable apron that covers the torso to the level of the mid-calf

Single use fluid-resistant or impermeable boot covers that extend to at least mid-calf **OR** single-use fluid-resistant or impermeable shoe covers, which are acceptable only if used with a coverall with integrated socks (not shown)

<http://www.cdc.gov/vhf/ebola/healthcare-us/ppe/>



PPE



NETEC



NETEC



NETEC



DISCHARGE PROCESS FOR A PATIENT SUCCESSFULLY TREATED FOR EVD

- **Must maintain infection control and proper PPE throughout process**
- HCWs remain in (PPE)
- Prior to patient discharge, all surfaces disinfected
- Patient in a clean disposable gown to a clean adjacent hospital room to shower for 10 minutes with CHG.
- Mop path the patient walked to enter
- Patient dons a clean disposable gown with shoe covers
- Led out of the room where the patient is met by a HCW in standard contact PPE
- Patient is escorted to the NBU's exit corridor where the patient takes a second 10-minute CHG shower
- Dresses in clean street clothing, and exits the NBU.



Deceased Patient Management

- **Know your state and local regulations**
- **Ebola virus can be transmitted in postmortem care settings through unsafe handling of remains**
- **Only personnel trained in handling infected human remains and wearing recommended PPE should touch or move any remains**
- **Do not:**
 - wash or clean the body
 - embalm the body
 - perform an autopsy
 - remove any inserted medical equipment from the body, such as:
 - intravenous (IV) lines
 - endotracheal or other tubing
 - implanted electronic medical devices
- **Cremate the body when possible**

• <http://www.cdc.gov/vhf/ebola/healthcare-us/hospitals/handling-human-remains.html>

Deceased Patient Management

- **Procedures for removal of patient remains need to be predetermined with:**
 - State and Local Health Department
 - Hospital
 - Funeral Home
 - Other stakeholders
- **Procedures should be developed to:**
 - Enable family observation
 - Protect HCWs
 - Eliminate potential for patient remains to transfer contamination outside the isolation unit

• Jelden KC, Gibbs SG, Smith PW, et al. Nebraska Biocontainment Unit Patient Discharge and Environmental Decontamination after Ebola Care. American Journal of Infection Control. 43 (2015) 203-5.



Deceased Patient Management

- Visitation of patient remains can be facilitated through a video link
- Do not allow direct access to remains
- Make counseling services available to family
- Complete all necessary documentation prior to removal of patient remains to comply with hospital and state and local health department regulations
- Have pre-existing MOU with a crematory and funeral director for cremation services after receipt of permission from family and the local health department

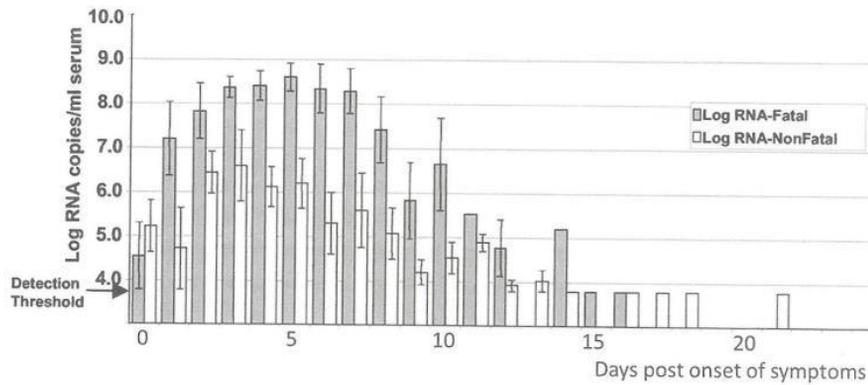
•Jelden KC, Gibbs SG, Smith PW, et al. Nebraska Biocontainment Unit Patient Discharge and Environmental Decontamination after Ebola Care. American Journal of Infection Control. 43 (2015) 203-5.

Guidance for Safe Handling of Human Remains of Ebola Patients in U. S. Hospitals and Mortuaries

- **Equipment list**
- **Step-by-step guidelines for**
 - Postmortem preparation
 - Transportation of remains
- **Mortuary care and disposition of remains**
- **Resources for more information**

•<http://www.cdc.gov/vhf/ebola/healthcare-us/hospitals/handling-human-remains.html>

Figure 1. Ebola virus RNA copy levels in sera over time from 45 Ebola Virus Disease (EVD) patients (27 fatal, 18 non-fatal)¹⁴



Slide from Pete Iwen, PhD

CDC document, Review of Human-to-Human Transmission of Ebola Virus



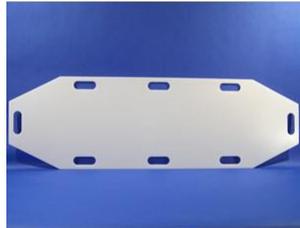
Coordination

- Family
- Funeral Home
- Nebraska State Patrol
- Omaha Police Department
- Nebraska Division of Public Health
- County Public Health
- County Emergency Management
- Nebraska Medical Center Security
- Medical Examiner





http://www.callawayjones.com/wp-content/uploads/render_product-7.php_2.png



<http://www.medicus-health.com/ProductImages/medicus/2004M3.jpg>



Bioseal system used for containment of highly infectious remains



Body Sealer Basics

Learning Center: Biological / Chemical / Hosp. Decon. / Shelter Training / Radiological / START Triage / Emergency Response

Body Sealer Basics

UNLOCK THIS BADGE
25 Points
Login to Take the Quiz

Tweet G+ Like

Introduction to the use of Body Sealer equipment used in the containment of bio-hazardous remains.

This video was produced in collaboration with the Nebraska Biocontainment Unit at The Nebraska Medical Center (nebraskamed.com) and describes procedures used within that facility. You may need to change your use of the Body Sealer depending on the needs of your organization.

Published: 07/24/2012
Running Time: 06:47

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Body Sealer Basics

0:28 / 6:47

0 Comments Sort by Top

<https://app1.unmc.edu/nursing/heroes/mpv.cfm?updateindex=86&src=yt>

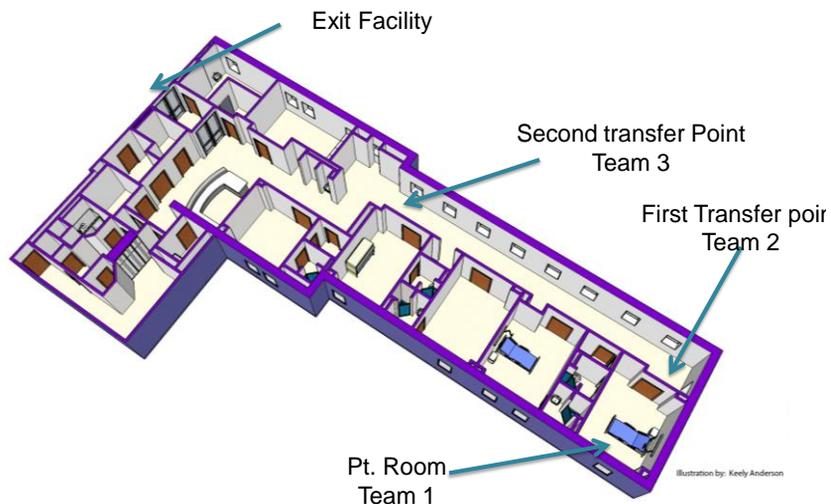


REMOVAL OF REMAINS FOR A PATIENT WITH EVD

- **Must maintain infection control and proper PPE throughout process**
- The remains are contained in the 3 isolation layers: (1) heat-sealed biosafety level 4 containment bag, (2) 18-mL-thick leak-proof laminated vinyl bag, and (3) a second 18-mL-thick leak-proof laminated vinyl bag.
- Once outside the NBU, no PPE is necessary (gloves used)
- Remains are moved to a funeral home
- NBU staff accompany until cremation is complete; cremated remains and certificates are returned to the family.



Biocontainment Unit



Facility Transport

- Modesty Cover
- Transport team
- Site and route of entry into facility
- Security
- Chain of Custody
- Emergency Kit
- Environmental disinfection



Vehicles



<https://s3.amazonaws.com/CFSV2/galleries/cpm/5594036d544f5-3664-3309-1511305611IMG4612.JPG>



<http://www.ketv.com/image/view/-/18418526/medRes/1/-/maxh/358/maxw/538/-/vngs38z/-/cruisers1-JPG.jpg>



Transport and Management of Patients With Confirmed or Suspected Ebola Virus Disease

Alexander Isakov, MD, MPH*; Wade Miles, NRP; Shawn Gibbs, PhD, MBA; John Lowe, PhD; Aaron Jamison, NRP; Raymond Swansinger, PA-C, MPAS

*Corresponding Author. E-mail: aisakov@emory.edu.

The foundation of safe care for patients with confirmed or suspected Ebola virus disease is effective infection control practice, which requires implementation of appropriate administrative policies, work practices, and environmental controls, accompanied by focused education, training, and supervision. In 2002, Emory University partnered with the Centers for Disease Control and Prevention to develop a capability for the evaluation and management of individuals with serious communicable disease. In 2005, the University of Nebraska developed a similar isolation capability. In each case, the hospitals partnered with emergency medical services (EMS) professionals to ensure safe out-of-hospital transport and management of their patients. The objectives of these hospital and out-of-hospital collaborations were to close education, training, and practice gaps to best facilitate the care for patients with serious communicable disease while ensuring the safety of the medics and the general public through meticulous implementation of infection control practices as recommended by Centers for Disease Control and Prevention. The description of practices implemented by EMS teams in these communities for the transport of patients with confirmed Ebola virus disease is shared so that others might more readily implement these practices, policies, and procedures as applicable to their mission requirements and system design. Transport of patients with relevant travel history and development of illness (persons under investigation) is also included. [Ann Emerg Med. 2015;66:297-305.]

Isakov, A., Miles, W., Gibbs, S.G., Lowe, J.J., Jamison, A., Swansinger, R. 2015. Transport and Management of Patients with Confirmed Ebola Virus Disease. *Annals of Emergency Medicine*. 66(3): 297-305.



55

CONSIDERATIONS FOR SAFE EMS TRANSPORT OF PATIENTS INFECTED WITH EBOLA VIRUS

John J. Lowe, PhD, Katelyn C. Jelden, BS, Paul J. Schenarts, MD, Lloyd E. Rupp, Jr., EMT-P, Kingdon J. Hawes, NREMT-P, Benjamin M. Tysor, NREMT-P, Raymond G. Swansinger, PA-C, MPAS, Shelly S. Schwedhelm, RN, MSN, Philip W. Smith, MD, Shawn G. Gibbs, PhD, CIH

ABSTRACT

The Nebraska Biocontainment Unit through the Nebraska Medical Center in Omaha, Nebraska, recently received patients with confirmed Ebola virus from West Africa. The Nebraska Biocontainment Unit and Omaha Fire Department's emergency medical services (EMS) coordinated patient transportation from airport to the high-level isolation unit. Transportation of these highly infectious patients capitalized on over 8 years of meticulous planning and rigorous infection control training to ensure the safety of transport personnel as well as the community during transport. Although these transports occurred with advanced notice and after confirmed Ebola virus disease (EVD) diagnosis, approaches and key lessons acquired through this effort will advance the ability of any EMS provider to safely transport a confirmed or suspected patient with EVD. Three critical areas have been identified from our experience: ambulance preparation, appropriate selection and use of personal protective equipment, and environmental decontamination. **Key words:** Ebola; EMS; transport

PREHOSPITAL EMERGENCY CARE 2014;Early Online:1-5

Lowe, J.J., +Jelden, K.C., Schenarts, P.J., Rupp, L.E., Hawes, K.J., Tysor, B.M., Swansinger, R.G., Schwedhelm, S.S., Smith, P.W., Gibbs, S.G. 2015. Considerations for Safe EMS Transport of Patients Infected with Ebola Virus. *Prehospital Emergency Care*. 19(2):179-183. <http://dx.doi.org/10.3109/10903127.2014.983661>



Coordination

- EMS
- U.S. Department of State
- Nebraska State Patrol
- Omaha Police Department
- U.S. Federal Bureau of Investigation
- Nebraska Division of Public Health
- County Emergency Management
- Nebraska Medical Center Security
- Omaha Airport Authority/Offutt Air Force Base



Coordination



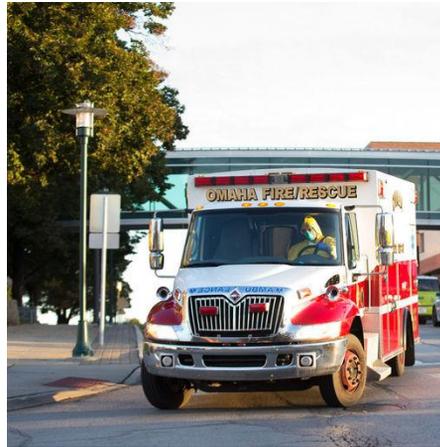
CDC undated



EMS Personnel PPE



UNMC 2014



Ray Soderlin / The World-Herald



Patient Isolation



Follow vehicle





Considerations

- Screening
 - 9-1-1 call centers, clinics, referral centers, EMS point of care
- Multi-agency coordination/logistics
 - EMS, 911, law enforcement, emergency management, isolation hospital
- Personnel PPE/patient isolation methods
 - Deployable Ebola squads, tiered PPE approach for PUI, confirmed, acuity
- Provision of care in transit
- Decontamination, waste processing and disposal





Facility Transport

- Transport team
 - Hospital, EMS, blended team
- Site and route of entry into facility
- Security
- Environmental disinfection



Laboratory

- NPHL was designated as the lab to test specimens for the BCU
 - BSL-3 lab
 - Contact with CDC
 - Part of LRN
- Tests initially provided
 - iSTAT, electrolytes
 - Malaria smears
 - Transport of specimens to the CDC



Prior to 1st Patient

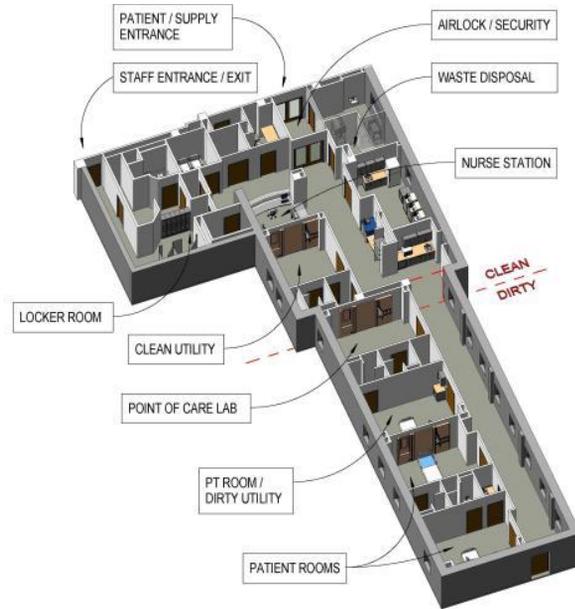
- Lab test menu needed to expand
 - Additional POC tests
 - Liver function
 - Coagulation
 - Define where testing could safely be performed
- Identify commercial carrier to transport specimens off-site
- Molecular testing capabilities
 - Monitor known positive patient
- Work force training
 - Not all laboratorians can work in BSL-3



During 1st Patient

- Defined essential test list
- On-site laboratory developed
 - Decreased TAT
 - Decreased specimen handling
 - Provided interaction with care team
- Laboratory became operational upon receipt of 2nd patient





3D Illustration

Bio Containment Unit

LEO A DALY



Biosafety Cabinet in BCU



Mobile laboratory unit



BCU Laboratory Equipment



Minimum Laboratory Requirements

- **Facilities**
 - Negative (or neutral) pressurization
 - Isolated room with closed door
 - Sink for hand washing
 - Counter-top space
- **Equipment**
 - Biological safety cabinet
 - Class II A2
 - Desk top centrifuge
 - Sealed rotor
 - Safety cups
 - Point of care devices
 - Computer/fax
- **Laboratory supplies**
 - Pipettors
 - PPE
 - Waste disposal containers

Consider making the laboratory mobile



Testing Meets Performance Specifications

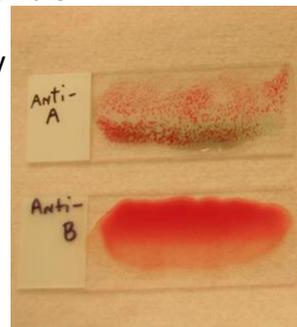
Non-Waived FDA-Approved/Cleared

- Adhere to CLIA requirements
 - Clinical Laboratory Improvement Amendments
 - Centers for Medicare/Medicaid Services regulates all lab testing on humans
- Verification
 - Accuracy
 - Compare results to an established method
 - Precision
 - Show repetition of testing at various concentrations
 - Reportable ranges
 - Determine range of values that can be measured



Major Learning Lessons

- On-site laboratory optimized specimen testing
- Laboratory test menu needed to be flexible
- Not all tests could be performed safely
- Communication was essential
 - Physicians
 - Critical care
 - Infectious diseases
 - Other medical staff
 - Laboratorians
- Laboratory policies/procedures needed to be fluid
- Expanded pool of trained laboratory personnel required

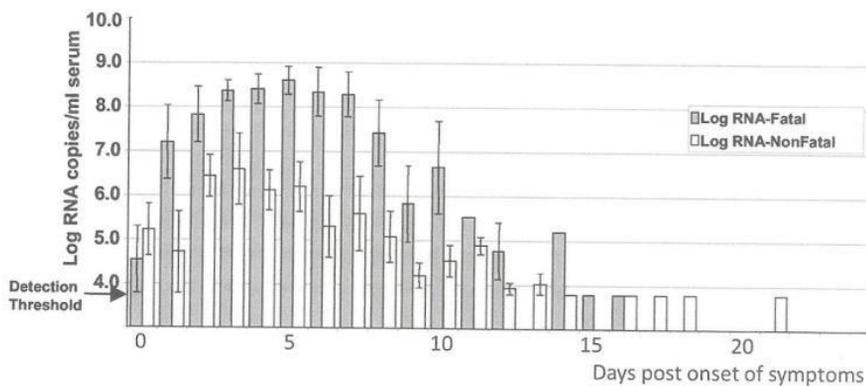


Risk of Handling EV-Infected Specimens

- High viral loads in symptomatic patient
 - >100,000,000 pfu/ml
- Infectious dose
 - <10 viable viral particles
- Micro-droplets of blood could easily contain enough virus to cause infection
- Additional thoughts
 - EVD difficult to treat and high mortality
 - High degree of anxiety by both the public and medical personnel to exposure



Figure 1. Ebola virus RNA copy levels in sera over time from 45 Ebola Virus Disease (EVD) patients (27 fatal, 18 non-fatal)¹⁴



CDC document, Review of Human-to-Human Transmission of Ebola Virus

Safety Considerations

- CDC Recommendations

“....specimens from (a) PUI for EVD (can safely be handled) by following blood borne and body fluid precautions.”

“Perform a risk assessment to determine the potential for sprays, splashes, or aerosols generated from lab procedures.”

29CFR Part 1910 No. 1030, OSHA Bloodborne pathogens



AJCP / EDITORIAL

Safety Considerations in the Laboratory Testing of Specimens Suspected or Known to Contain Ebola Virus

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From the ¹Department of Pathology and Microbiology, College of Medicine, University of Nebraska Medical Center, Omaha; ²Nebraska Public Health Laboratory, Omaha; ³Department of Internal Medicine, Division of Infectious Diseases, University of Nebraska Medical Center, Omaha; ⁴Department of Psychiatry, College of Medicine, University of Nebraska Medical Center, Omaha; ⁵Department of Anesthesiology, Division of Critical Care, University of Nebraska Medical Center, Omaha; and ⁶Department of Environmental, Agricultural, and Occupational Health, College of Public Health, University of Nebraska Medical Center, Omaha.

Am J Clin Pathol January 2015;143:4-6

DOI: 10.1309/AJCP26MIFUIETBPL

Reference to the Ebola virus causes concern among all individuals, whether from the public or within the medical community. Realization that patients with Ebola virus disease (EVD) have now been recognized in the United States in response to the major outbreak occurring in West Africa has heightened this fear. Recently, the World Health Organization declared the Ebola epidemic to be a Public Health Emergency of International Concern to provide containment of this major international health threat. In response to this threat to public health, the United States has stepped up efforts to

patients.³ In our risk assessment, we determined that the core laboratories where chemistry and hematologic testing takes place do not have facilities that can safely handle specimens suspected of containing or known to contain Ebola virus. For example, the processing of open tubes without the availability of a biosafety cabinet and the centrifugation of specimens without safety cups or sealed rotors are common practices within the core laboratory. In addition, clinical laboratories that do have the facilities to perform biosafety level 3 (BSL-3) practices (to include



Performing a Risk Assessment

- Is there a potential for aerosol generation?
 - Vortexing
 - Pipetting
 - Centrifugation
 - Opening and closing tubes
- Are sharps used?
- Are appropriate PPE available?
 - Face shields, gowns, gloves, respiratory protection, booties, bonnet
- Are staff trained in the utilization of the PPE?
 - Doffing and donning
- Is a protocol for waste disposal available?



Results of Our Risk Assessment

- Chemistry automated analyzer
 - Initial centrifugation did not use sealed rotors
- Coagulation automated analyzer
 - Required open tube testing
- Blood Bank
 - Cross matching required open tube centrifugation
- Biosafety cabinets were not universally available

Comment: Not all laboratory sections were able to safely handle specimens from a patient with the potential to have Ebola virus.



Special Report

An Integrated Approach to Laboratory Testing for Patients with Ebola Virus Disease

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Karen Stiles, MT(ASCP)SM^{CM},³ James L. Wisecarver, MD, PhD,^{1,4}
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Lab Med Fall 2014;45:e146-151

DOI: 10.1309/LMTULFM62W3RKMYI

Beginning in 2003, the Nebraska Medical Center in Omaha developed a laboratory capability plan in conjunction with the creation of a biocontainment unit (BCU) for treatment of patients harboring emerging infectious organisms. The laboratory response planning involved experts at the Nebraska Public Health Laboratory (NPHL), University of Nebraska Medical Center (UNMC), the Nebraska Department of Health and Human Services (DHHS), and the Centers for Disease Control and Prevention (CDC). Special emphasis was placed on diagnostic testing for highly contagious and

pathogenic organisms, including *Francisella tularensis* and high consequence viruses causing avian influenza and hemorrhagic fevers such as Ebola.

Due to the recognition that certain organisms and conditions would need to be ruled out, preparations also included the capability to test specimens for other diseases, including malaria and tuberculosis. Originally, a limited number of point of care (POC) hematology and chemistry tests were planned, to monitor patients who harbored a high consequence pathogen. This testing was to be performed in the biosafety level 3 (BSL-3) laboratory within the NPHL at UNMC, which is within 1 city block from

Abbreviations

Where will the laboratory be located?

- Patient care area
- Core laboratory facility
- Separate BSL-3 laboratory suite
- Integrated approach

Iwen, PC, et al. An integrated approach to laboratory testing for patients with Ebola virus disease (Special Report). Lab Medicine. 45: e146-151.

Core Laboratory Automated Chemistry Analyzer



Table 11
Essential and Supplemental Tests Used for the Support of a Patient Infected With Ebola Virus^a

Test	Laboratory Location ^b	Centrifugation Required ^c
Essential		
CBC count with automated differential	Core	No
Basic metabolic panel	Core	Yes ^d
Magnesium	Core	Yes
Comprehensive metabolic panel	Core	Yes ^d
Ionized calcium ^g	BCU	No
Standard calcium	Core	Yes ^d
Phosphorous	Core	Yes
Cortisol	Core	Yes
Troponin	Core	Yes
Blood gases ^e	BCU	No
Lactate	Core	Yes ^d
Protime ^g	BCU	No
Partial thromboplastin time ^g	BCU	No
Platelet count	Core	No
Blood typing ^{f,g}	BCU	No
Culture procedures ^h	NPHL ⁱ	No
Molecular assay ^j	NPHL ⁱ	No
Supplemental		
Manual differential	Core	No
Lipase	Core	Yes
Amylase	Core	Yes
Creatine kinase total	Core	Yes
Malaria smear ^k	Core	No
HIV screen	Core	No

Be flexible!

Iwen, PC, et al. 2015. Safety considerations in the laboratory testing of specimens suspected or known to contain Ebola virus (editorial). Amer J Clin Path, 143: 4-5



Who will operate the laboratory?

- Requires staff with specialized training in BSL-3 containment
- Staff required to be trained to operate POC testing devices
- Buddy system coverage 24/7
- Our set-up
 - NPHL personnel coordinate the testing of all specimens from a PUI or infected with EVD



How will results of testing be communicated?

- Hard copy
 - PHL
- Electronic
 - Laboratory information system
 - Hospital information system
- Direct download
 - POC instrument
 - Automated chemistry and hematology analyzers



Cannot have enough data ports!



How will specimens be transported on-site?

- Follow Category A shipping practices
 - Double bag
 - Hard-walled container
 - Biohazard symbol
- Potential Ebola virus positive specimens
 - Consider using plastic specimen collection devices
 - Try not to use containers that have the potential to leak
 - Urine cups
 - Bleach wipe containers and the outside of each bag
- Utilize a buddy system for transport



How will specimens be transported off-site?

- Transportation requirement to the PHL for screening
- Specimens with the potential to have Ebola virus
 - DOT classified as Category A infectious substances
- Shipper must be trained and certified to be a Category A shipper
- Courier must meet certain certification requirements to ship Category A specimens
 - Most private shippers are not



NPHL Provides Shippers

Category B – UN3373 Category A – UN2814

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Complexity of shipping specimens known to contain Ebola virus



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SHIPPER	CONSIGNEE	DESCRIPTION	TOTAL
UNIVERSITY OF NEBRASKA ATTN: ELLEN DEYSEK 586805 NEBRASKA MEDICAL CTR OMAHA, NEBRASKA 68198	[REDACTED]	ACCOUNT # 11519 INVOICE AMT 1,900.00 BALANCE DUE: 1,900.00 PAGE 1	
09/22/14 NHD#: 101186591 Caller: Karee Stiles	Nebraska Public Heal / Centers for Disease Karee Stiles/Peter I / ATTN STAT LAB: USP 540 South 45th Street / 1600 Clifton Road DRC #2 Loading dock	PCS 1 NET 24.0	BASE RATE 240.00 ORIG- CHICAGO 1,334.00 DANGEROUS GOODS, BYD 75.00 AIRLINE SECURITY/ FUEL 251.00
Ref: 3353013476	OMAHA NE / ATLANTA GA United States / United States Signed: Latayna Green		USD 1,900.00



Select Agent Issue

Monday, September 08, 2014

CDC Guidance: Compliance with Select Agent Regulations For Labs Handling Specimens Containing Ebola Virus



9052

'Select agents' are those pathogens that have been deemed to pose a significant biological hazard, and among those, **Tier 1 select agents are considered** "biological agents and toxins present the greatest risk of deliberate misuse with significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence, and pose a severe threat to public health and safety."

Tier 1 Select Agents and Toxins		
PHS Agents and Toxins	Overlap Agents	USDA Agents
Botulinum neurotoxins	Bacillus anthracis	Foot And Mouth Disease virus
Botulinum neurotoxin-producing species of Clostridium	Burkholderia mallei	Chikungunya virus
Ebola virus	Burkholderia pseudomallei	Rinderpest virus
Francisella tularensis		
Marburg virus		
Variola major virus (Smallpox virus)		
Variola minor virus (Alastrim)		
Yersinia pestis		

As you might have already guessed, the various species of Ebolavirus are Tier 1 select agents, which makes everything contaminated (by blood, sweat, feces, urine, etc.) by an Ebola infected patient potentially a select agent – and subject to rigorous safety regulations – as well.

Are specimens collected from a patient suspected to have Ebola infection covered by the select agent regulations?

No, specimens would not be subject to the Federal select agent regulation until identified as containing Ebola virus by viral isolation.

How do select agent regulations apply to specimens that have tested positive by molecular methods?

The select agent regulations would not apply until the specimen that has tested presumptively positive using molecular methods has been proven to contain live-infectious Ebola virus by virus isolation.

Any specimens that are confirmed by virus isolation to contain live-infectious Ebola virus must be reported to DSAT immediately by telephone (404-718-2000), Email (Irsat@cdc.gov), or FAX (404-718-2096) and be followed up with APHIS/CDC Form 4 within seven days of the initial report.



How will specimens be disposed?

- On-site disposal
 - Decontamination (treat as Medical Waste)
 - Autoclaving
 - Monitoring essential
 - Chemical disinfection
 - Archiving
 - Experimental drug study requirement
 - Future research opportunities
- Off-site disposal
 - Known Ebola virus positive specimens
 - Classified as Category A infectious substances
 - Not all waste management companies will accept



Specimen Collection Guidance

Test	Order Code	Tube type	performed at (Instrument)	Centrifugation (NPHL)
Amylase	AMY	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXI)	Yes
B12 level	VB12	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXI)	Yes
Blood culture	BLDCU	Plastic Aerobic Bactec bottle	NPHL lab	No
Blood Gas arterial	POC113	Heparinized blood gas syringe	BCU lab (Stat)	No
Blood Gas venous	POC114	4.5 ml green top PST	BCU lab (Stat)	No
Blood type	ABORH	3 ml lavender top	BCU Lab (slide forward type)	No
Basic metabolic panel	BMET	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXC)	Yes
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 (DXI)	No
Comp metabolic panel	CMET	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXC)	Yes
Cortisol	CORTS	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXI)	Yes
Creatine Kinase Total	CK	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXI)	Yes
C-Reactive protein	CRP	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core Lab	Yes
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 lavender (Qty 1) top OR 3ml lavender top (Qty 2)	BCU Lab or NPHL Lab	Yes
Fe/Ferritin/TIBC	TIBC	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXI)	Yes
Folate level	VFOL	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core Lab	Yes
Sputum Culture	HPT	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXI)	Yes
HIV	SUD	5 ml red top		No
Ionized Ca(STAT CHEM8+)		4.5 ml green top PST	BCU lab (Stat)	No
Lactic Acid	LA	5 ml grey top	Hospital Core lab (DXC)	Yes
Lipase	LIPA	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXI)	Yes
Magnesium	MG	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXC)	Yes
Malaria	MALP	3 ml lavender top	Hospital Core lab	BCU lab will prepare smears
Phosphorus	PO4	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXC)	Yes
Prealbumin	PAB	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core Lab	Yes
PT/PTT	Coagulation Panel	1.8 ml or 2.7 ml blue top	BCU lab (Hemochron)	No
Reticulocyte Count	RETCT	3 ml lavender	Hospital Core lab (DXI)	No
Sputum Culture	SPUCU	Not applicable	NPHL lab	No
Standard Ca++	CA	5 ml gold top SST tube, or 4.5 ml green top PST	Hospital Core lab (DXC)	Yes
Troponin	TROP	6 ml green top PST	Hospital Core Lab (DXI)	Yes
Urine Culture	URNCU	Not applicable	NPHL lab	No
Urine electrolytes	UNA, UKS,UCLS	BD Urinalysis Plus conical tube	NPHL lab	No

SST Gold Top, Serum Separator Tube, Green PST Top, BiliUm heparin Plasma Separator Tube, Lavender Top, EDTA anticoagulant, Grey Top, Fluoride oxalate, Blue, sodium citrate

updated 11-14-14

What level of risk are you willing to accept?

- Do not underestimate the anxiety level of your medical staff
- UNMC/NM
 - Knew that specimens containing Ebola virus would be tested
 - Our “line in the sand”
 - No open-tubed processing or centrifugation would occur outside BSL-3 containment.
 - BCU laboratory
 - Centrifugation
 - POC testing
 - NPHL BSL-3 laboratory
 - Molecular assay
 - Microbiology testing e.g. blood cultures
 - Archive specimens



Final Comments

- Steps facilities should consider:
 - Define an essential list of tests,
 - Perform risk assessments to determine which tests can be done safely,
 - Determine alternatives for tests that cannot be done safely,
 - Identify where laboratory testing will be done,
 - Weigh safety and the optimal management of the patient, and
 - Provide for open lines of communication!

Disclaimer: This presentation provides a template that can be used as facilities develop their own unique programs for the laboratory assessment of specimens from a patient with a high risk pathogen.



Minimum Level of Containment

- Appropriate PPE
 - Gloves
 - Water resistant gown
 - Full face shield or goggles
 - Respirator
 - Booties
 - Hair bonnet
- Equipment
 - Certified biosafety cabinet or Plexiglass splash shield
 - Centrifuge with sealed rotor or safety cups
 - May require coordination with TB lab
- Protocols
 - Doffing and donning
 - Specimen collection
 - Transportation
 - Decontamination and waste disposal
 - Training in BSL-3 practices



Nebraska Biocontainment Unit Leadership Team

Phillip Smith MD Director, Angela Hewlett MD,
Shelly Schwedhelm RN, Elizabeth Beam RN, Kate Boulter RN,
Shawn Gibbs PhD CIH, John Lowe PhD

Nebraska Biocontainment Unit Staff

23 RN, 6 RT, 4 CT, 11+ MD, 2 PhD

Supporting Departments

Infection Control, Clinical Technology, Nebraska Public
Health Laboratory, Core Clinical Laboratory, Public Affairs,
Environmental Services, University & Hospital Facilities,
Facilities Planning, and many more

External Partners

U.S. Department of State, Stericycle, Omaha Fire EMS,
State & County Public Health, Cardinal Health, Apple, Offutt
AFB, Eppley Airport and many many more



On behalf of the Nebraska Biocontainment Unit

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