

Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

EBOLA: The Ebola virus is a lipid enveloped virus in the family Filoviridae. Members of this family also include Marburg, Lassa, and other viruses that cause hemorrhagic fever, a group of illnesses that damage the vascular system and in severe cases, lead to bleeding under the skin, in internal organs or from body orifices (e.g. mouth, eyes and ears)¹. Infection with the Ebola virus is now referred to as: Ebola virus disease (EVD)². There is a diagnostic test to determine if the patient has EVD. There is no current FDA approved effective medication or treatment for those who become infected with Ebola other than supportive hydration, electrolyte balancing and oxygen. The death rate of those infected is between 50-90%. There is no vaccine or preventative treatment.

TRANSMISSION

Person-to-person transmission occurs by very close personal contact with an infected individual or with their body fluids during the late stages of infection or after their death^{3,4}. During the care of an infected individual, spread of the virus can occur through contact with infected body fluids on the patient, on their clothes or bedding, on surfaces such as bedrails, side tables, the floor, or on reused unsterilized syringes, needles, thermometers or other virus-contaminated medical equipment. Transmission has occurred by handling the bodies of deceased humans in preparation for funerals^{5,6}. Bodies can remain contagious for up to 60 days. Infections may also occur when handling sick or dead non-human primates.

Virus containing body fluids from individuals infected with the Ebola virus:

- Blood
- Breast milk
- Organs and tissues
- Saliva
- Semen
- Stool
- Sweat
- Urine
- Vaginal secretions
- Vomit
- Amniotic fluid (possibly)

Note: Ebola virus has been isolated from semen 61 days after the initial symptoms of infection appear. Transmission through semen has occurred 7 weeks after clinical recovery^{3,4,7}.

Incubation period: It requires 2 to 21 days (more often 4-9 days) before symptoms of infection occur. The infected individual is not contagious until symptoms appear. Hemorrhage begins to present 4-5 days after general symptom onset^{8,9}.

Survival outside the body: The virus can survive and remain infective in liquid or dried organic matter at room temperature for a number of days¹⁰. A 2010 study recovered infective Ebola virus from an indoor environment six days after contamination (under optimal conditions for viral survival)¹¹. The Ebola virus can also survive for several days at 39°F (4°C), and is indefinitely stable at -70°C. Infectivity can be preserved by lyophilization (freeze-drying)^{5,29}.

How Ebola enters the body: Intact skin is a barrier, but scratches, cuts (large or tiny), rashes, and abrasions, ruin the barrier integrity and become routes for viral entry. Additionally, Ebola virus can enter the body through mucosal tissues after being deposited by contaminated fluids through physical contact, splashes, splatters,

Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

sprays, or possibly aerosols. Mucosal tissues include the eyes, mouth, throat, lungs inside of nose, vaginal tissues, intestines, and urinary tract^{3,4}.

Aerosols: Infections have occurred after handling sick or dead infected non-human primates and the bodies of deceased humans in preparation for funerals. It is possible transmission could have occurred through aerosol droplets^{3,4,5}. Small-particle aerosol exposure and transmission has been demonstrated in non-human primates in the laboratory^{2,4}.

Infectious dose: 1 – 10 aerosolized infective viruses are enough to cause an infection in humans¹².

Preventing the spread of Ebola virus requires preventing contact with the virus by:

- Immediate isolation for patients who are confirmed or suspected of being infected with the Ebola virus.
- Protecting all the routes of entry into the body with appropriate personal protective equipment (PPE) as described below.
- Disinfecting, sterilizing or in any other effective way, destroying the viruses that may be contaminating surfaces, medical instruments, linens, etc., before they can contaminate and infect anyone else.
- Properly containing the body of deceased victims in fluid proof body bag and appropriately cremating or burying them immediately.

IMMEDIATE ISOLATION OF SUSPECTED OR CONFIRMED EVD PATIENT:

- Immediately place patient in a private room with personal toilet facilities and implement strict Standard, Contact, and Droplet precautions.
- The mattress and pillow must be fluid resistant.
- All devices used must be disposable or dedicated. If dedicated but to be used after patient discharge, a thorough disinfection must be completed. A week of post-disinfection quarantine if possible is an added safety measure as no reports of Ebola virus survival longer than 6 days have ever been reported.
- Avoid aerosol generating procedures if at all possible. If aerosol generating procedures are anticipated, place patient in an airborne isolation room initially to avoid patient transport, and wear a fluid resistant N95 respirator or greater when performing these procedures.

PERSONAL PROTECTION

- Make certain scratches, cuts, rashes, abrasions, etc., are covered with waterproof dressings.
- Remove jewelry
- The United States Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) recommend masks for protection from Ebola as part of Standard, Contact, and Droplet protection. Though not stated in the guidelines, **it is critical that masks are fluid resistant** to prevent splashes, sprays and cough-propelled droplets of virus-contaminated blood, saliva or other body fluid from penetrating the mask.
 - Because of the life-threatening nature of this disease, if a mask is worn, it should have an **ASTM F2100 Level 3 designation: the highest fluid penetration and filtration efficiency level**. The Level will be listed on the box label^{13,14,15}. ASTM Levels 1 or 2 could be used outside the Ebola isolation area.
 - To qualify for each ASTM designation, the mask material must also pass a particle filtration test with a challenge of 0.1 micron particles. However, this challenge size represents airborne particles that can float on air currents and be sucked through the gaps between the mask and the face when the wearer inhales. Although any mask with an ASTM Level Designation has

Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

passed this 0.1 micron challenge, the test is not included in chart below for fear it will give the wearer or purchaser a false sense of security that a medical mask will protect against very small droplets. If anticipating exposure to small infectious aerosols, a fluid resistant respirator of N95 or greater designation must be worn.

Mask: ASTM F2100 Spray, Splatter, Droplet Protection Level Designation (Level 3 highest)		
Level	Test Description	Must Pass
3	ASTM F1862 Pressure spray synthetic blood: simulates high blood pressure ASTM 2101 Bacterial Filtration Efficiency (droplet)	160mm Hg ≥ 98
2	ASTM F1862 Pressure spray synthetic blood: simulates normal blood pressure ASTM 2101 Bacterial Filtration Efficiency (droplet)	120mm Hg ≥ 98
1	ASTM F1862 Pressure spray synthetic blood: simulates systolic blood pressure ASTM 2101 Bacterial Filtration Efficiency (droplet)	80mm Hg ≥ 95

- **Note:** When an Ebola virus infected patient is in the late stages of EVD, blood pressure will drop, but other sources of propelled fluids, including diarrhea and vomit, contain the infective virus and can be delivered with force. Fluid resistance is still essential.
- **Respirators.** CDC is recommending face masks; avoiding aerosol generating procedures, and; wearing a respirator if aerosol generating cannot be avoided. As noted, there have been studies and observations demonstrating a potential small droplet dispersal component of Ebola virus transmission^{2,3,4,5}. The highest probability of generating small droplets presenting the highest risk would occur during aerosol generating procedures, but should also be considered a risk during care of late stage EVD patients. Because disposable respirators are designed to prevent gaps in the respirator-to-face seal, small infectious droplets cannot be drawn into the mucosa-lined respiratory zone through mask-face skin gaps (area of least resistance) when the wearer inhales. A mask does not provide that seal and thus pulls a portion of inhaled air in through the gaps. The virus may land on the inside surface of the mask, the facial skin, or oropharyngeal mucosa. Respirators must be fit tested to the wearer, ensuring the size and model fit snugly¹⁶. **Every time a disposable respirator is donned, the wearer must immediately perform a seal check¹⁷. This critical verification takes only seconds. As with masks, respirators must also be fluid resistant for the same reason (wick-through; strike-through).**
 - **Avoid aerosol generating procedures.** Avoid aerosol-generating procedures if at all possible. If they must be performed, PPE must include an N95 respirator or higher level respiratory protection). Procedure should be performed in an airborne infection isolation room¹⁸.
 - **Note:** Some respirators possess staples in the filtration portion of the respirator. After the stress of use, holes can develop where the staples penetrate the fabric. This will not necessarily be detected during fit tests as the respirator has not yet been in actual use, subjected to the continual pull of the elastic attached to the staples.
- **Eye protection or face shield is essential.** If eye contamination suspected, rinse eyes immediately & excessively with saline or water. *Face shields do not take the place of face masks or respirators.*
- **Gowns or coveralls.** CDC recommends wearing a fluid resistant (front and back) gown or coverall with snug-fitting cuffs. ANSI/AAMI PB70:2012¹⁹ sets requirements for different performance levels. Level 4 is

Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

the most protective and would be appropriate for working with Ebola patients, especially in the late stages of the disease. The lower fluid resistant levels are appropriate for Standard, Contact and Droplet precautions dealing with less lethal pathogens. For high exposure risk, a full body suit with Level 4 verified testing and adequate coverage would be appropriate.

ANSI/AAMI PB70:2012 The Most protective is Level 4			
Level	Test ID and description	Required	What's better
4	ASTM F1670:Penetration by forced spray synthetic blood	Pass	Pass
	ASTM F1671:Bloodborne pathogen penetration: bacteriophage virus in fluid pressed through	Pass	Pass
3	AATCC 42:Spray impact – amount penetrated after fluid drop impact	< 1.0g	Lower
	AATCC 127:Hydrostatic pressure – pressure needed to force water through	≥ 50cm	Higher
2	AATCC 42:Spray impact – amount penetrated after fluid drop impact	≤ 1.0g	Lower
	AATCC 127:Hydrostatic pressure – pressure needed to force water through	≥ 20cm	Higher
1	AATCC 42:Spray impact – amount penetrated after fluid drop impact	< 4.5g	Lower

- **Severe exposure:** For situations in the field or other similar conditions dealing with high levels of viral contamination and fluids, a full body fluid-resistant certified biohazard suit should be worn.
- **Head covers.** During later stage EVD, virus-contaminated droplets can fall onto exposed hair. When contaminated hair is touched, the hand can become contaminated and transport the virus to other places on the individual or to other animate and inanimate surfaces in the environment. Although not specified in many guidelines, wearing a fluid-resistant head cover while insuring the maximum amount of head, neck, and face coverage is achieved would be best practice within the Ebola isolation unit during late stage EVD.
 - **Note:** If coverage is not complete, wash exposed areas of the face and neck with soap and water to remove any contamination after tasks are completed or if contamination has occurred. Consider 70% alcohol wipe thereafter.
- **Foot/leg covers.** For additional protection during the late EVD stage, fluid resistant foot/leg covers can protect footwear and legs from contamination and prevent transporting the virus to others when the patient is in the late stages of EVD (bleeding, diarrhea, vomiting) when likelihood of fluid contamination is high, during patient fluid cleanup, etc.
- **Gloves.** Examination or surgical gloves as appropriate:
 - All gloves must be powder-free. Virus can readily contaminate powder particles and be dispersed throughout the vicinity as do glove powder particles.
 - Neither vinyl nor polyethylene gloves are appropriate for barrier protection when performing tasks with potentially infectious materials.

Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

- Good barrier powder-free gloves include nitrile, natural rubber latex, polyisoprene, and neoprene. In some situations, a medical glove beneath a thick orthopedic type surgical glove may be appropriate for procedures on a patient, or new thick utility glove as for cleaning.
- Double glove, making certain one glove is under the gown cuff and the other glove is over the cuff. It may be prudent to tape the glove to the cuff with duct tape to prevent cuff slip or roll down.
- **Be extremely careful not to disperse viral contaminants during PPE removal.** Assume outward facing surface of all PPE are contaminated with infectious Ebola. It is preferred that assistance in PPE removal is given by a designated individual who is scrupulously appareled and trained in appropriate PPE removal techniques, biohazard bag processing, disinfection of the area, etc. A written procedure should be clearly posted.
- **Hand hygiene.** Wash hands with soap and water immediately after removing PPE. Soap and water are recommended due to the amount of organic contamination (blood, vomit, etc.) present that can interfere with the efficacy of alcohol hand sanitizers. Soap helps organics and the virus slip off, and water rinses them into the sewage system where they are effectively destroyed by standard sewage treatment procedures.
 - **Note:** If caring for patients in an area without sewage treatment, wash with soap and water into a basin. After finishing, add 1 part household bleach to 10 parts of the water (10% v/v) in the basin to destroy any remaining infective virus. Hold for 10 minutes before assuming disinfection is complete.
- **70-90% ethyl alcohol (ethanol) based hand sanitizers** will destroy lipid enveloped viruses like Ebola very effectively if the organic soiling is not present. This higher concentration than normally recommended is appropriate for disinfecting non-enveloped viruses including Norovirus, thus providing an added safety factor for the more easily disinfected enveloped Ebola virus. (See further rationale for this non-enveloped virus safety factor in the Surface Disinfection section.) The alcohol based hand sanitizer can also be used after a soap and water wash first to remove organic matter (soiling), if present.

SURFACE DISINFECTION IS CRITICAL TO PREVENTING THE SPREAD OF EBOLA

The Ebola virus can stay infective for up to 6 days on surfaces in ideal conditions^{10,11}. Attention to rigorous disinfection practices is essential. Fortunately, the virus is destroyed by most standard disinfectants used in healthcare^{5,28,29,30,31}. However, because of the severe morbidity and high mortality risk posed by the virus, the high number of infective viruses in the blood during the late stages of the disease, the extremely low number of Ebola virus required to cause an infection, and the probable high level of organics presence in body fluid spills and splatters, higher disinfectant concentrations than normally used in standard healthcare environmental cleaning are appropriate.

In the United States, healthcare facilities are to use Environmental Protection Agency (EPA)-registered hospital disinfectants with a label claim for a non-enveloped (a.k.a hydrophilic) virus (e.g., norovirus, rotavirus, adenovirus, poliovirus) to disinfect surfaces in rooms of patients with suspected or confirmed Ebola virus infection. There are no specific label claims against Ebola. However, because it is much harder to destroy non-enveloped viruses than it is enveloped viruses (a.k.a hydrophobic) like Ebola, the use of disinfectants with a label

Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

claim of being effective against non-enveloped viruses will be effective against the Ebola virus while providing an added safety margin.

In situations or countries where EPA approved disinfectants against non-enveloped viruses (viruses much harder to destroy than enveloped viruses including Ebola) are not available, select disinfectants proven to be effective against non-enveloped viruses by recognized agencies.

If such approved disinfectants for non-enveloped viruses are not available, household bleach (hypochlorite at 5.25% to 6.25%) can be diluted to a working concentration appropriate for Ebola virus disinfection.

Important: *The effectiveness of many disinfectants, including hypochlorite, are weakened or inactivated by the presence of organic contamination of the surface to be disinfected^{20,21}.* Organic substances in this context include blood, vomit, feces, pus and sputum. Normally, cleaning with a detergent first to remove the organic contamination would be recommended. However, to reduce the risk of staff infection during clean-up procedures, a higher concentration of the disinfectant can reduce the viral load despite inactivation of a percentage of the disinfecting free chlorine. For example, hypochlorite is usually used at a working concentration of 100-500ppm chlorine for routine hospital disinfection, after cleaning with a detergent to remove organic matter. However, if heavily soiled with organic matter potentially containing Ebola (high lethality; high viral concentration in blood; very few viruses necessary for infection), a 1:10 solution of hypochlorite (household bleach) is appropriate (1 part bleach to 10 parts water v/v). This is equivalent to 5,000ppm chlorine. Another way to make this concentration is to add 1½ cups household bleach to one gallon of water. Because the effectiveness of diluted hypochlorite decays over time, working solutions should be prepared fresh every 24 hours^{22,23}.

Important: *Paper and cotton are cellulose based materials. Cellulose reduces the effectiveness of hypochlorite and hydrogen peroxide.* Higher concentrations of the disinfectant can compensate. Do not leave paper towels or cotton cloths in open cleaning bucket containing diluted hypochlorite, for example, as the effective concentration of chlorine will diminish significantly^{24,25}. The use of polypropylene wipes or wipes that contain coated cellulose specifically treated to prevent disinfectant inactivation and absorption exist but must be confirmed with official data from the manufacturer.

Important: Do not mix hypochlorite (bleach) with other cleaning agents (e.g. ammonia) as toxic fumes can be produced injuring healthcare staff and patients^{26,27}.

A written policy and procedure should be in place to address removal and cleaning of large spills or otherwise deposited, fluid-contaminated areas as well as for biohazard bag processing. The following example will discuss the use of hypochlorite, but other regulated disinfectants proven effective against non-enveloped viruses (as detailed above) are appropriate when available. For example, such an EPA approved disinfectant is required for healthcare facilities in the U.S.

1. Don appropriate PPE as described above, including fluid resistant foot and leg covers.
2. Use forceps to pick up any syringes, needles or other instruments from the spill prior to disinfection and place in impenetrable container to prevent accidental injury during cleanup.
3. Gently place paper towels over the contaminated fluid to avoid splatter and absorb contaminated fluid.
4. Carefully apply a 1:10 final dilution of household bleach (5,000ppm to overcome the cellulose and organic matter) starting at the perimeter and working towards the center^{20,21, 22}.

Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

5. Allow sufficient contact time which depends on the disinfectant, its concentration, and the amount and nature of the spill. For a 1:10 dilution of hypochlorite, with minimal fluid dilution from the contaminated surface, 10 minutes is sufficient⁴⁰.
6. After the label-required contact time, remove the saturated towels carefully and place into biohazard bags. Absorb any remaining fluid with additional paper towel and dispose into the biohazard bag. Assume the paper towels are still contaminated (extra precaution for the high-lethality and low infectious dose of this pathogen). Assuming the exterior of the biohazard bag to be contaminated and place in a rigid container to prevent re-contamination of the area and for later transport.
7. Now disinfect the area again, freed of the organic load and cellulose absorbing cover paper towels. This time the lower working concentration of 1:100 (500ppm free chlorine) would be effective, but the same 1:10 working solution (5,000ppm free chlorine) provides an added safety factor. The working hypochlorite solution may be poured onto the surface or spread with a polypropylene wipe or other approved wiper demonstrated to not absorb or inactivate the biocidal free chlorine. Wait for the required contact time. Place used wipes in biohazard bags as noted above.
8. Rinse disinfected surface with water after disinfection is completed to reduce damage to surfaces and remove the strong chlorine odor that can adversely affect already nauseated patients^{22,9}.
9. Steam sterilize (autoclave), incinerate biohazardous waste, or present for disposal by specialized biohazard team. Follow state or local regulations for handling biohazard waste disposal.

Note: The Ebola virus is destroyed by both steam sterilization and incineration. There will be no infectious viruses in the exhaust steam or incineration smoke.

Physical destruction: Ebola virus are also inactivated by:

- Heating for 30 to 60 minutes at 140°F (60°C)
- Boiling for 5 minutes
- Gamma irradiation (1.2 x10⁶ rads to 1.27 x10⁶ rads)
- UV radiation^{5,28,29,30,31} However, it is important to note, Ebola viruses incorporated within organic matter can survive UV radiation³².

LABORATORY SAFETY

Biosafety level: Ebola is a Group 4 pathogen with an infectious dose of 1 to 10 inhaled viruses. There can be no shortcuts to protection.

Laboratory-acquired infections: There are many opportunities for accidents to occur in the laboratory. One reported near-fatal Ebola case followed a minute finger prick in an English laboratory³³. A Swiss zoologist contracted Ebola virus after performing an autopsy on a chimpanzee in 1994^{4,34}. In 2004, a similar case was reported in the United States³⁵, and a fatal case in Russia³⁶. The Marburg virus is morphologically indistinguishable from the Ebola virus. In 1967, 31 workers at a laboratory in Marburg, Germany suffered from fever, diarrhea, vomiting, and massive bleeding from a variety of internal organs due to infection from the Marburg virus. Seven of the workers would eventually succumb to their infection³⁷.

Primary hazards in the laboratory: Accidental inoculation, inhalation of infectious aerosols and droplets, and/or direct contact of specimen, homogenates, dilutions, etc., with broken skin, rashes or mucous membranes including eyes, nares, mouth, and lungs. Use a certified Class II Biosafety cabinet or Plexiglas splash guard with PPE to protect skin and mucous membranes as noted in the PPE above when working with the specimen of

Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

suspected or confirmed EVD patients. All manufacturer-installed safety features for laboratory instruments should be used.

Important: Experimental work with Ebola virus is not addressed in this document. Experimental work often utilizes increased viral concentrations and extensive manipulations requiring a Containment Level 4 facility^{3,4,38,39}.

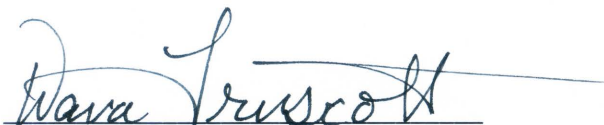
Protective clothing: Personnel entering a laboratory actively working with suspected Ebola specimen should remove jewelry and street clothing to change into dedicated laboratory clothing and shoes, or don full coverage protective apparel (i.e., completely covering all street clothing). Additional protection may be worn over laboratory clothing when infectious materials are directly handled. This protection includes items such as solid-front, and fluid resistant gowns with tight fitting wrists, gloves, and fluid resistant respiratory protection. A fluid-resistant respirator, N95 or greater, is necessary for any task that could generate aerosols. AVOID aerosol generation procedures if at all possible. Eye protection must be used where there is a known or potential risk of exposure to splashes or sprays⁴⁰. Shoe and legging covers should be worn if there are spills to be disinfected or risk of splatter or spray.

Sources/specimens: Sources of the virus include blood, serum, urine, respiratory and throat secretions, semen, organs and tissues or their homogenates from human or animal hosts^{3,4,39}.

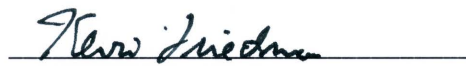
Transporting specimens within the hospital or institution: Per CDC, and in compliance with 29 CFR 1910.1030, specimens should be placed in a durable, leak-proof secondary container for transport within a facility. To reduce the risk of breakage or leaks, do not use any pneumatic tube system for transporting suspected EVD specimens. If necessary to hold specimen, they should be refrigerated at 2°-4°C, with all containment requirements in place.

Preparing specimen for transport: CDC has an Ebola specific laboratory specimen handling, packing and shipping instruction alert to which laboratories must comply. The CDC Guideline: Case Definition for Ebola Virus Disease (EVD), can be accessed at: <http://www.cdc.gov/vhf/ebola/hcp/interim-guidance-specimen-collection-submission-patients-suspected-infection-ebola.html>. No specimen will be accepted by the FDA without prior consultation. For consultation call the CDC's Emergency Operations Center (EOC) at 770-488-7100.

For more information and updates, please refer to subject matter expert websites that include those found in the Resources section of this document.



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Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

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Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

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Kimberly-Clark Ebola Virus Disease (EVD) Precautions Brief: September 19, 2014

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