

## Frequently Asked Questions Related to Ebola

### 1. **What level of personal protective equipment (PPE) should be used when providing care to patients suspected of or confirmed with an Ebola infection?**

Guidance around PPE has evolved rapidly in the days after the first cases of Ebola in the U.S. Provider organizations with clinical staff experienced in caring for Ebola patients believed the level of PPE initially recommended by the Centers for Disease Control and Prevention (CDC) provided inadequate protection. The CDC subsequently revised its guidance to more closely match guidelines from Médecins Sans Frontières (Doctors Without Borders). ECRI Institute's guidance on PPE follows below. Hospitals should be familiar with the PPE recommendations from the following organizations, determine for themselves the appropriate level of PPE based on an individualized risk assessment, and check for updates to these recommendations regularly:

- Guidance on Personal Protective Equipment To Be Used by Healthcare Workers During Management of Patients with Ebola Virus Disease in U.S. Hospitals, Including Procedures for Putting On (Donning) and Removing (Doffing), *Centers for Disease Control and Prevention*, 10/20/2014 ([view](#))
- Filovirus Haemorrhagic Fever Guideline, *Doctors Without Borders*, 2008 ([view](#))
- Interim Infection Prevention and Control Guidance for Care of Patients in Healthcare Settings, with Focus on Ebola, *World Health Organization*, 9/2014 ([view](#))

### 2. **What is ECRI Institute's guidance on PPE?**

While the PPE Level, as compared to those National Institute for Occupational Safety and Health (NIOSH)/Environmental Protection Agency (EPA) levels defined in terms of the OSHA HAZWOPER standard 29 CFR 1910.120, is comparable to a **Level C ensemble**, the selection of PPE components of the ensemble for exposure to the Ebola virus are not driven by either harmful chemical or airborne particulate exposure or because Ebola transmission is via the airborne route, as one would expect when respiratory protection is being recommended. Instead, the level of PPE recommended by CDC, which stresses the necessity for “no exposed skin” and the use of either a N95 or powered air purifying respirator (PAPR) is due to the nature of the potential exposures to healthcare workers in treating a patient infected with the Ebola virus and the severity of the virus in general.

Because Ebola patients tend to emit copious amount of vomitus and diarrhea, and because touching those fluids is key to inadvertent transmission, PPE ensembles should be such that a fluid resistant or impermeable seal is made over the healthcare worker's entire body. Protective garments, eye/face protection, foot protection, respiratory gear, and particularly gloves contaminated with the virus can all become potential reservoirs from which the virus is spread to other parts of a healthcare worker's own body, the body of other workers or patients, as well as stationary and mobile surfaces in the healthcare environment. While this is the case with any infectious agent that spreads by direct contact, the high morbidity and mortality rate associated with Ebola and the copious bodily fluids are the primary driving forces behind the selection and use of PPE for Ebola cases.

PPE is a system (an ensemble) and to best ensure the safety of our healthcare workers, we must treat it as a system within a number of other systems including, but not limited to, our infection prevention and employee health systems. Therefore, while there is no one-size-fits-all recommendation for the individual components for a PPE ensemble to interface with Ebola patients, there are some aspects of the PPE and its selection that must be adhered to:

- I. All PPE selection and use must be in accordance with applicable OSHA regulations, including the General Industry PPE standard 29 CFR 1910.132, the Respiratory Protection standard 29 CFR 1910.134, and the Bloodborne Pathogens (BBP) standard 29 CFR 1901.1030. This includes performing a thorough hazard assessment and developing an exposure control plan that complies with all of the standards, including offering the correctly sized PPE that collectively creates an effective

ensemble against Ebola exposure as recommended by CDC and others.

To comply with the applicable standards, a hospital must also provide appropriate training on the correct uses and limitations of all PPE provided. This includes how to correctly put on (don), take off (doff) and fit-check (in the case of respirators) each respective piece of PPE, as well as what is required after using the PPE in terms of disposal (as in the case of one-time use items) or proper cleaning, disinfection and storage in the case of those items that are reusable. The latest CDC guidance on PPE for Ebola exposure recommends that a “dedicated trained observer” read aloud each step in the donning and doffing procedures for those healthcare workers using the PPE ensemble as well as **visually confirm and document that the steps were followed correctly**. While dedicated trained observers are not required by OSHA, they are being recommended by CDC to help ensure that the components of the PPE ensemble are donned and doffed in the correct manner and order so as to minimize inadvertent self-contamination.

- II. Any/all employees that will be issued a respirator must have a medical evaluation by a licensed healthcare professional per Appendix C of 29 CFR 19010.134, prior to wearing the respirator.
- III. Any/all respirators that are issued must be NIOSH-certified, including but not limited to filtering facepieces like an N95, full or half-face elastomeric air-purifying respirators, and/or powered air purifying respirators. All tight-fitting respirators must be fit-tested in accordance with 29 CFR 1910.134 Appendix A, recognizing that there are physical, ethnic and/or religious reasons why a healthcare worker may not be able to wear a tight-fitting respirator.
- IV. The more reusable PPE that is used in the overall ensemble, the more equipment there is to clean and disinfect after interfacing with an Ebola patient. This factor should be considered in light of the hospital’s PPE, respirator, BBP and infection prevention programs. Therefore, PPE selection must be made both in terms of maximizing worker protection and in limiting the risk of spreading the virus resulting from inadvertent contamination due to the reuse of protective equipment that was not properly cleaned and disinfected.
- V. Recognize that the use of tight-fitting respirators and fluid-resistant or impermeable outer garments are likely to increase worker discomfort. Make sure that your PPE program accounts for the fact that, depending on the nature of the tasks at hand, workers may not be able to work as efficiently and effectively in such equipment, and therefore the hospital is likely to have to provide additional time and resources per shift for donning, doffing, and monitoring PPE, work breaks and rehydration. Workers should be trained on the signs and symptoms of heat stress, as well as certain cardio-pulmonary abnormalities that can result from wearing (especially tight-fitting) respirators.
- VI. Each type of PPE carries with it pros and cons in terms of uses. A healthcare facility must evaluate PPE in conjunction with the activities associated with typical patient interaction to determine whether one type of PPE better meets the human factors needs (e.g., equipment interface and/or communication issues with respirators) of the specific tasks involved. For example, if a clinician needs to use a stethoscope, your program should have a PPE ensemble designated for such activities, recognizing that the specific components of the worker’s overall ensemble are also likely to change when a patient’s condition is worsening. As the virus progresses and symptoms increase, so does the likelihood of contact with vomitus and diarrhea, dictating some of the components of the overall PPE ensemble to change.

With this in mind ECRI Institute provides the following guidance on the general types of PPE ensemble to be used when treating an Ebola patient.

A Level C ensemble is typically comprised of:

- I. **Headgear:** A NIOSH-approved respirator such as a filtering facepiece N95 or loose-fitting powered air-purifying respirator (PAPR). Keeping in mind that PPE is a system within the hospital’s other systems, if the N95 (or similar tight-fitting respirator) is to be worn, each healthcare worker must be fit-tested prior to wearing the respirator in accordance with OSHA’s General Industry Respirator Protection standard 29 CFR 1910.134. Fit-testing requires significant time and expense, and should be a factor in the hospital’s selection of the type of respirator. By their very nature tight-fitting (non-powered) air-purifying respirators such as N95 tend to promote a greater degree of worker discomfort compared to PAPRs and

air-supplying respirators. If a filtering facepiece is used, the ensemble must include at a minimum fluid-resistant or impermeable garments that cover the head and neck, as well as goggles and/or face shield. As a result, when an N95 or similar filtering piece is used, it is imperative that the hospital's ensemble include all these other components to cover the head and neck. While transmission of the Ebola virus is not airborne (but possibly droplet), the assigned protection factor (APF) of a filtering facepiece like an N95 is 10, which means that one out ten particles will get into the worker's breathing zone, bypassing the seal the respirator makes against the wearer's face.

Rather than use a tight-fitting filtering facepiece, a healthcare facility is equally able to use a PAPR, especially a loose-fitting PAPR. Loose-fitting PAPRs do not require fit testing. While there are several basic models of PAPRs, they are all motorized units that use a battery to power a fan that draws ambient air from the worker's environment through a set of combination or high-efficiency particulate air (HEPA) filters, and delivers 6 cubic feet of air per minute (CFM) to the breathing zone of the wearer. Some PAPRs have a plastic visor/face shield that extends down from a head bonnet to protect the majority of the eye and face area, while others have a full shroud that covers not only the head and neck, but also the shoulders to some extent.

A hospital choosing to use PAPR need not use the cartridges that are designated by NIOSH for chemical, biological, radiological and nuclear exposures, which are the ones used as part of the PPE ensembles for patient decontamination and emergency management programs. Instead, cartridges that are rated as HEPA and are typically a magenta color are proper for Ebola exposure scenarios. In keeping with CDC's requirement that body coverings be single-use (disposable) fluid-resistant or impermeable, hospitals should make sure that the material from which the bonnet and hood of the PAPR is constructed is resistant or impermeable to human blood and bodily fluids. It should be noted that by using a hooded PAPR that covers the head and neck, it negates the need to purchase separate single-use (disposable) fluid-resistant or impermeable bonnets, neck covers, goggles and/or face shields. Remember, PPE is a system, so if supplies of any necessary component become depleted, the entire system's overall effectiveness is compromised, resulting in increased exposure risk to the workers.

Another factor that comes into play with PAPRs is that the air blowing into the head piece not only reduces potential heat stress but also reduces cardio-pulmonary strain on the workers. This may enable them to work more comfortably for longer periods. When fully charged, a PAPR battery will typically give 8-10 hours of use. Loose-fitting PAPRs are also the viable option for staff with facial hair. Lastly, while the route of exposure to the Ebola virus is not truly airborne (which would necessitate more emphasis on the effectiveness of the respirator), the assigned protection factor (APF) of a typical loose fitting PAPR is 25 or can be as high as 1000. This means that only one out 25 or one out of 1000 particles (like a droplet containing the Ebola virus) would get into the wearer's breathing zone. This is compared to the APF of 10 discussed earlier that is characteristic of N95 and other filtering facepieces.

- II. **Other garments:** Different garments can act as components of a hospital's overall Ebola exposure PPE ensembles, but the overarching requirement is that all the garments (including head, neck, and boot/shoe covers) and gloves should be single-use, fluid-resistant, or impermeable. The gowns or coveralls should not have an integrated hood and should extend down at least to the worker's mid-calf. Coveralls can have integrated foot covers or socks. One subtle but effective feature, thumb hooks, have been shown to help the wearer keep the sleeve of the gown or coverall over the inner glove when in use. While taping the sleeve of the gown or coverall to the wrist of the inner glove is also an option, this additional step is likely to make the process of removing the PPE more difficult and cumbersome. When fluid-resistant boot covers are used, they must extend at least to the mid-calf. Single-use shoe covers are only acceptable when they are used with a single-use fluid-resistant coverall that has integrated socks.

When a patient exhibits copious amounts of vomitus and or diarrhea, hospital workers should increase their layers of fluid-resistant or impermeable bodily protection by using a fluid-resistant or impermeable apron. Two pairs of nitrile examination gloves should be worn, making sure they are appropriately sized for each healthcare worker using them. Those potentially exposed should wear two pairs of gloves, one over the other. The inner nitrile glove is tucked under the cuff of the gown or coverall, while the outer nitrile glove, which has an extended cuff (also called gauntlet-style), is pulled over the cuff of the gown or

overall. The boot/shoe covers should also be single-use and extend up the leg at least to the mid-calf. When there are workers using boot covers, hospitals should select covers that have walking surfaces that minimize the risk of slipping.

3. **What clinical protocols are available for patients suspected of, or confirmed with, Ebola infection?**

The selection of clinical protocols for your organization should be based on your organization's individualized risk assessment and your decisions about what your goals are should a patient present with suspected/confirmed infection. For most community hospitals, the primary goals will be to recognize, isolate, provide interim care, and transport the patient to designated regional Ebola treatment centers currently being determined by CDC.

Emory Healthcare has posted its Ebola Preparedness Protocols [here](#). Emory Healthcare and Nebraska Medical Center also participated in a webinar hosted by CDC in which they discussed their preparations. The recorded webinar and slides are [available here](#). These materials contain guidance that your institution can adapt to your local setting and circumstances.

4. **What new technologies are available or are on the horizon for rapid screening and assessment or treatment?**

ECRI Institute is developing Product Briefs on the following emerging technologies, which will be posted on the ECRI Ebola Resources page as they become available:

- I. The Aethlon Hemopurifier® by Aethlon Medical for purifying blood infected with hemorrhagic viruses
- II. ZMAPP: experimental drug for treatment of Ebola infection
- III. AVI 6002 and AVI-7537 in development by Sarepta Therapeutics: Safety and Pharmacokinetic Profiles of Phosphorodiamidate Morpholino Oligomers (PMOs) with Activity against Ebola Virus and Marburg Virus: Results of Two Single-Ascending-Dose Studies
- IV. TKM-Ebola for treatment of Ebola infection in development (Tekmira Pharmaceuticals Corporation, Burnaby, British Columbia, Canada)
- V. Rapid point of care tests for diagnosing Ebola
- VI. Technologies for decontaminating Ebola/hemorrhagic virus patient rooms
- VII. Technologies for decontaminating Ebola patient equipment

5. **How should medical devices and equipment used in caring for patients with suspected/confirmed infections be cleaned, decontaminated, or disposed of?**

ECRI Institute has developed guidance for healthcare providers on how to handle medical equipment used in the care of these patients. This guidance is posted on ECRI Institute's Ebola Resource Center under "Technology Management."