Ebola Virus Disease 2.0 Contact Hours

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(Updated 10/21/2014)

Course Objectives:

1. Define the Ebola virus disease (EVD).

2. Explore the signs and symptoms of Ebola virus.

3. Learn about case terminology for the exposure risk levels for Ebola virus.

4. Understand how to diagnose Ebola virus.

5. Explore ways Ebola virus can be transmitted.

6. Explore ways Ebola virus is treated.

7. Understand the details regarding the most recent experimental drugs for Ebola virus.

8. Identify the status of vaccines for Ebola virus.

9. Discuss current travel protocols and advisories.

10. Learn about the most recent events leading up to Ebola infection within the United States including patient status and the U.S. government response.

11. Discuss the handling of patients suspected with EVD in U.S. hospitals using the latest tightened CDC infection control protocols, including the Three Principles for Infection Control for Healthcare Workers and the Five Pillars of Safety.

12. Explore the National Nurses United (NNU) response to the events surrounding the healthcare personnel infections in the U.S.

Introduction

Ebola virus disease (EVD), or Ebola hemorrhagic fever is a severe disease that is often, but not always, fatal in humans. Up until recently it was only experienced in Africa, with a 90% fatality rate in that region. The Ebola virus disease causes a viral hemorrhagic fever disease (VHF). Symptoms of Ebola include fever and additional symptoms like severe headache, muscle pain, vomiting, diarrhea, stomach pain, or unexplained bleeding or bruising.

Ebola viruses have been present in several African countries. It was in 1976, near the Ebola River, that the first Ebola virus was discovered in what is now known as the Democratic Republic of the Congo. Since then, outbreaks of Ebola among humans have appeared sporadically in Africa. The most current outbreak is taking place in West Africa.

The virus is spread through ***direct contact*** of broken skin or unprotected mucous membranes in the eyes, nose, or mouth, or with the blood or body fluids (e.g., urine, feces, saliva, semen, sweat, breast milk and other secretions) of a person who is sick with Ebola, or with objects like needles and syringes that have been contaminated with the virus, or infected wild animals.

Ebola is ***not*** spread through the air or by water, or in most cases, by food. It has been shown in Africa that Ebola can

possibly be spread by hunting, processing, and consuming infected animals (e.g., bushmeat). The natural hosts of the Ebola virus are the fruit bats of the *Pteropodidae* family.

A person infected with Ebola virus is not contagious until symptoms appear. One cannot catch Ebola from someone who is infected but does not have symptoms. Severely ill patients require intensive supportive care. Early detection and treatment is critical for a patient's survival and the safety of healthcare personnel, as well as infection control in the general public who may come in contact with an infected and symptomatic patient.

There is currently no specific licensed treatment or vaccine that is available for either people or animals infected with the disease. Since 2006, the Food and Drug Administration (FDA) has issued Ebola Virus Emergency Use Authorizations as per the Department of Homeland Security (DHS) because the Ebola virus has been deemed to display "a material threat against the United States population sufficient to affect national security." As the disease has progressed into the United States borders, there have been experimental drugs authorized for use in treating patients in emergency cases.

Health care providers should be vigilant of and evaluate any patients who potentially have Ebola virus using the strict safety protocols in effect as per the CDC and their facilities where they work.

Past Ebola outbreaks have occurred in Democratic Republic of the Congo (DRC), Gabon, South Sudan, Ivory Coast, Uganda, Republic of the Congo (ROC), South Africa (imported). The current (2014) Ebola outbreak is occurring in the West African countries of Guinea, Liberia, Sierra Leone, and Nigeria and is the largest Ebola epidemic in history according to the Centers for Disease Control and Prevention (CDC).

Signs & Symptoms

A Person Under Investigation (PUI) is a person who has both consistent symptoms and risk factors as described below.

Symptoms of Ebola typically include:

- Fever (greater than 38.6°C or 101.5°F)
- Severe headache
- Muscle pain
- Weakness
- Diarrhea
- Vomiting
- Abdominal (stomach) pain
- Lack of appetite
- Unexplained bleeding or bruising

Epidemiologic risk factors within the past 21 days before the onset of symptoms include:

- Contact with blood or other body fluids or human remains of a patient known to have or suspected to have EVD
- Residence in, or travel to, an area where EVD transmission is active
- Direct handling of bats, rodents, or non-human primates from disease-endemic areas.

Although 8-10 days is the most common incubation period where symptoms may appear, that can surface anywhere from 2-21 days after exposure to the Ebola virus.

Recovery *is* a possibility for some who become sick with Ebola. The reason for this is not yet fully understood but early detection and treatment are known to be crucial elements for a successful recovery.

Source: CDC, 2014.

Case Terminology

A "Probable Case" is a PUI whose epidemiologic risk factors include high or low risk exposure.

A "Confirmed Case" is acase with laboratory-confirmed diagnostic evidence of Ebola virus infection.

Exposure Risk Levels

Levels of exposure risk are defined as follows:

High risk exposures

A *high risk exposure* includes any of the following:

- Percutaneous (e.g., needle stick) or mucous membrane exposure to blood or body fluids of EVD patient
- Direct skin contact with or exposure to blood or body fluids of an EVD patient without appropriate personal protective equipment (PPE)
- Processing blood or body fluids of a confirmed EVD patient without appropriate PPE or standard biosafety precautions
- Direct contact with a dead body without appropriate PPE in a country where an EVD outbreak is occurring

Low risk exposures

A *low risk exposure* includes any of the following:

- Household contact with an EVD patient

- Other close contact with EVD patients in health care facilities or community settings. Close contact is defined as:

1. Being within approximately 3 feet (1 meter) of an EVD patient or within the patient's room or care area for a prolonged period of time (e.g., health care personnel, household members) while not wearing recommended personal protective equipment (i.e., standard, droplet, and contact precautions).
2. Having direct brief contact (e.g., shaking hands) with an EVD patient while not wearing recommended personal protective equipment.

- Brief interactions, such as walking by a person or moving through a hospital, do not constitute close contact

No known exposure

Having been in a country in which an EVD outbreak occurred within the past 21 days and having had no high or low risk exposures is classified as *no known exposure*.

Source: CDC, 2014.

Diagnosis

Diagnosing Ebola in a person who has been infected for only a few days is difficult because the early symptoms, such as red eyes and a skin rash, are not necessarily limited to Ebola virus infection and can be identified often in patients with more commonly occurring diseases.

However, if a person has the early symptoms of Ebola and there is reason to believe that an Ebola diagnosis should be considered, the patient should be isolated and public health

professionals notified immediately. Samples from the patient can then be collected and tested to confirm infection.

Laboratory tests used in diagnosis include:

Timeline of Infection	Diagnostic tests available
Within a few days after symptoms begin	o Antigen-capture enzyme-linked immunosorbend assay (ELISA) testingo IgM ELISAo Polymerase chain reaction (PCR)

o Virus isolationLater in disease course or after recoveryo IgM and IgG antibodiesRetrospectively in deceased patiento Immunohistochemistry testingo PCRo Virus isolation

Source: CDC, 2014.

Also included in the initial testing should be *malaria* analysis due to the fact that it is the most common cause of febrile illness in people who have traveled to the impacted countries.

Testing Period for Patients with Suspected EVD in U.S. Hospitals

CDC recommends testing for all persons with onset of fever within 21 days of having a high-risk exposure such aspercutaneous or mucous membrane exposure or direct skin contact with body fluids of a person with a confirmed or suspected case of EVD without appropriate personal protective

equipment (PPE). In addition, testing is recommended if laboratory processing of body fluids of suspected or confirmed EVD cases without appropriate PPE or standard biosafety precautions, or participation in funeral rites or other direct exposure to human remains in the geographic area where the outbreak is occurring without appropriate PPE.

For people with a high-risk exposure but without a fever, testing is recommended only if there are other compatible clinical symptoms present and blood work findings are abnormal (i.e., thrombocytopenia <150,000 cells/µL and/or elevated transaminases).

Ebola Sample Collection Procedure

On August 5, 2014, an Emergency Use Authorization (EUA) was issued by the FDA to authorize the emergency use of the EZ1 (Ebola Zaire virus, detected in the West Africa outbreak in 2014) Real-time reverse transcription RT-PCR Assay of the Department of Defense (DoD), in order to achieve the possible detection of Ebola Zaire virus.

This test was meant for use in *Trizol*-inactivated whole blood or Trizol-inactivated plasma specimens from individuals in affected areas with signs and symptoms of Ebola virus infection, or who are at risk for exposure or may have been exposed to the 2014 Ebola Zaire virus, in concurrence with epidemiological risk factors.

Trizol-inactivated samples are whole blood and plasma that have been treated with Trizol, a chemical solution used in RNA/DNA/protein extraction from the Ambion part of Life Technologies. Blood and plasma samples potentially infected with all species and strains of Ebola virus can be rendered non-infectious by adding 3 parts Trizol with 1 part whole blood or plasma by *trained and authorized healthcare professionals* by following specific methods explained below:

1. Add 0.75mL of Trizol LS to a microcentrifuge tube.
2. Within a BSC, and using appropriate personal protective equipment, add 0.25mL of whole blood or plasma sample to the microcentrifuge tube containing Trizol LS.
3. Vortex the tube for at least 5 seconds and incubate at ambient temperature for 5 minutes +/-30 seconds.
4. Once the procedure is complete, samples can be handled following appropriate safety precautions defined by the testing laboratory.

Specimens should be collected using appropriate infection control precautions for Ebola or other hemorrhagic fever viruses in addition to following the directives provided by the manufacturer of the specimen collection device.

Shipping the specimens needs to be performed strictly according to the policies of the shipping performer, customs regulations, and the requirements of the laboratory meant to receive the specimens.

While treatment with Trizol has been shown to be an effective method to disrupt viruses and to stabilize the target nucleic acid, specimens should still be handled as if they were infectious and present a potential safety hazard. This authorization is limited to the use of the authorized EZ1 rRT-PCR Assay on specified instruments by laboratories designated by DoD.

On October 10, 2014, the FDA responded to the DoD's request to amend this EUA by reissuing the August 2014 EUA with DoD-requested amendments integrated within. The amendments authorize the use of the DoD EZ1 rRT-PCR Assay in whole blood or plasma specimens, in addition to Trizol-inactivated whole blood or Trizol-inactivated plasma specimens, from individuals with signs and symptoms of Ebola virus infection or who are at risk for exposure or may have been exposed to the Ebola Zaire virus in conjunction with epidemiological risk factors, in affected areas, by laboratories designated by DoD. The

amendments also include revisions to the Instructions for Use, product insert, and Fact Sheets for Health Care Providers and Patients to address the addition of whole blood and plasma specimens.

In addition, on October 10, 2014, the FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of the Centers for Disease Control and Prevention (CDC) Ebola Virus NP Real-time RT-PCR and VP40 Assay, for the in vitro qualitative detection of Ebola Zaire virus in whole blood, serum, and plasma specimens from individuals in affected areas with signs and symptoms of Ebola virus infection and/or epidemiological risk factors. These also be used with urine specimens when tested in conjunction with a patient-matched whole blood, serum, or plasma specimen. This authorization is limited to the use of the authorized CDC Ebola Virus NP Real-time RT-PCR Assay on the Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument by qualified laboratories designated by CDC.

As of this course's latest revision, other tests being submitted to the FDA and the World Health Organization (WHO) to be considered for Emergency Use Authorization include Roche Holding AG's Ebola virus test which runs on the Basel-based drug company's LightCycler 480, which up until now has only been used for research purposes, and another Roche analyzer, the cobas z 48 system.

Transmission

According to the CDC, due to the fact that "the natural reservoir of ebolaviruses has not yet been proven," the method by which the virus first appears in humans at the onset of an outbreak remains unexplained. However, researchers speculate that the first patient was infected through contact with an

infected animal.

When an infection does occur in humans, the virus can be spread to others in several ways. The virus is spread through direct contact (through broken skin or mucous membranes) with:

- An infected person's blood or body fluids (urine, saliva, feces, vomit, sweat, and semen)
- Objects (such as needles) that have been contaminated with infected body fluids
- Infected animals

The family, friends and healthcare workers in close contact with Ebola patients are at the highest risk of getting sick because they may come in contact with infected blood or body fluids.

During outbreaks of Ebola, the disease can spread quickly within healthcare settings if proper precautions are not taken. Exposure to EVD can occur in healthcare settings where hospital staff are not wearing appropriate protective equipment.

*Remember you **cannot** contract Ebola though the air, through water, or through food.*

Proper cleaning and disposal of instruments, such as needles and syringes, is also critical. FOLLOW ALL OF YOUR FACILITY'S GUIDLEINES FOR EFFECTIVE ENVIRONMENTAL CLEANING. If instruments are not disposable, be sure to sterilize them before using them again. Without sufficient sterilization of the instruments, virus transmission can extend and intensify an outbreak.

Treatment

As of this course's latest revision, no specific vaccine or medicine (e.g., antiviral drug) has been validated to be effective against Ebola.

Symptoms of Ebola are dealt with as they surface. When used early, the following basic interventions can help avoid fatality.

- Providing intravenous fluids and balancing electrolytes (body salts) to maintain hydration
- Maintaining oxygen status and blood pressure
- Treating other infections if they occur

Early symptoms, such as headache and fever, are nonspecific to ebolaviruses, and so cases of EVD may be misdiagnosed at first. This is why the disease is difficult to diagnose clinically in the early stages of infection. Even though timely treatment of Ebola virus is crucial, it is still challenging due to these reasons.

Patients who face death from the disease have shown they have not developed a critical immune response to the virus at the time of death. There was a patient successfully treated at Emory Hospital in Atlanta, Florida who is thought to have plasma that contains the antibodies necessary to fight the virus. His plasma has been transfused to three other patients whose blood type is compatible with the original patient in question. It is unknown the extent to which this treatment is effective because it is being used in conjunction with other forms of treatment.

Still, if a person has the early symptoms of Ebola and there is reason to believe that Ebola should be considered as a diagnosis, the patient need to be isolated and public health professionals notified. Supportive therapy can continue with proper protective clothing until samples from the patient are tested to confirm infection.

Drugs

There are experimental treatments that have been tested and shown to be effective in animal subjects. One such drug is *brincidofovir*, made by the Bioparma company Chimerix, Inc.. This was used on Mr. Duncan but his condition was said to be of such an advanced stage by the tme he received the drug that it was of no use. On October 17, 2014, Chimerix was given dispensation by the FDA to begin a trial of brincidofovir. There two other experimental antiviral drugs that have already been used to attempt to treat the virus.

These include Mapp Biopharmaceutical Inc.’s ZMapp and Tekmira Pharmaceuticals’ TKM-Ebola injection. U.S. health officials have asked three advanced biology laboratories to submit plans from producing ZMapp. Supply of the drug ran out in August 2014, after it was deployed to medical workers who contracted the disease in West Africa. The product is a combination of three different monoclonal antibodies that bind to the protein of the Ebola virus.

ZMapp is being established as a therapeutic product for treatment of people infected with Ebola virus, but not to prevent infection in the same manner as a vaccine. The best way to prevent infection currently is with strict infection control measures.

Tekmira Pharmaceuticals is a Canadian company. The TKM-Ebola injection works by blocking genes that help the Ebola virus reproduce and spread. It is in limited supply and has been used on at leasy one patient so far.

Vaccines

Currently there are no FDA approved vaccines for Ebola. The

NIH's National Institute of Allergy and Infectious Diseases is working on developing an Ebola vaccine. NIH recently declared that they are accelerating their work, and intending to launch phase 1 clinical trials of an Ebola vaccine in the fall of 2014. NIH is also supporting private enterprises such as the Crucell biopharmaceutical company, BioCryst, Profectus Biosciences in their development and testing of vaccines that could be applied to Ebola prevention. The NIH and the Thomas Jefferson University are also collaborating to generate an Ebola vaccine based on the established rabies vaccine. BioCryst is expected to begin Phase 1 testing in late 2014.

The Department of Defense's Defense Threat Reduction Agency is funding two other companies, Tekmira and Biocryst Pharmaceuticals, and working with a company called Newlink to develop therapeutic candidates for Ebola in early development and an Ebola vaccine candidate.

Current Travel Protocols and Advisories

The CDC is helping with exit screening and communication efforts in the affected areas of West Africa to avoid sick travelers from exiting the country via air travel. In addition, airports in Guinea, Liberia, and Sierra Leone are screening outbound travelers for Ebola symptoms, including fever, and passengers are required to respond to a health questionnaire. CDC is also swelling support in the area by extending their staff to assist in building capacity on the ground. As of the time of the latest revision of this course, the state of Texas is seeking to ban travel from the countries where the outbreak is contained to the state of Texas.

CDC has updated the protocols from when the outbreak began in August 2014 to when it has appeared in the United States in September-October 2014, to protect against further spread of disease for when a sick person arrives in the U.S. These

include a request that airline crews inquire of sick travelers if they have been in Guinea, Liberia, or Sierra Leone in the last 21 days. If they have AND they show any Ebola symptoms, the CDC must be immediately contacted. If sick travelers have not been in the previously listed countries then routine procedures should be followed. These include advising the CDC of sick travelers on a plane before arrival, assessment of sick travelers, and if necessary, isolation and transport to a medical facility. CDC, along with Customs & Border Patrol, have also provided guidance to airlines for managing sick passengers and crew and for disinfecting aircraft. CDC has circulated a Health Alert Notice reminding U.S. healthcare workers of the importance of taking steps to prevent the spread of this virus, how to test and isolate suspected patients, and how they can protect themselves from infection.

The protocols put in place by the CDC to ensure the safe transport and care of patients with infectious diseases back to the United States. The methods provide for the entire process from patients leaving their bedside in a foreign country, to their transport to an airport and boarding a non-commercial airplane equipped with a special transport isolation unit, to their arrival at a medical facility in the United States that is appropriately equipped and staffed to handle such cases. It is the responsibility of the CDC to ensure that travel and hospitalization is done in such a way as to minimize the risk of spreading infection and to secure the safety of the American public. Patients were evacuated in similar ways during SARS.

CDC has suggested that U.S. residents avoid nonessential travel to Guinea, Liberia, and Sierra Leone. If they must travel, such as for humanitarian aide work in response to the outbreak, they recommend protection by following CDC’s advice for avoiding contact with the blood and body fluids of people who are infected with Ebola.

The Situation in the United States

As of the time this course's latest revision, on October 17, 2014, there have been eight confirmed cases of patients have contracted the disease in the U.S. and have been or are being treated for Ebola.

One U.S. citizen has died while abroad, a government official in Liberia who was a naturalized U.S. citizen, caring for his sister who was suffering from Ebola in Liberia.

Of the eight confirmed cases, as of the last revision of this course, three have been discharged after receiving treatment. Of these, two were treated and discharged from at Emory University Hospital in Atlanta, Florida in late August and one was discharged from Nebraska Medical Center in September but was again admitted to a Massachusetts hospital on October 4. He was released the following day.

The remaining four patients are all undergoing treatment for Ebola. These include a journalist diagnosed while reporting from Liberia, now being treated at Nebraska Medical Center, an unknown patient receiving treatment at Emory University Hospital (details on the patient's occupation, source of infection, etc. are currently not officially determined), and notably, two nurses who cared for Thomas Eric Duncan, the Liberian resident who became the first Ebola patient to be diagnosed in the U.S.

Mr. Duncan passed away from the disease on October 8, 2014 in Dallas, Texas. The details of how effectively protocols were set up and followed have been investigated to determine why and how some of the healthcare professionals caring for him have become infected. The circumstances are still under investigation but updated warnings and protocols have been released by the CDC and transmitted via the states' departments of health nationwide in light of these infections.

The nurses have each been transported for treatment from

Dallas to Emory University Hospital and a National Institutes for Health (NIH) hospital Maryland.

At the time of the latest revision of this course, there are four U.S. hospitals that are specially equipped with biocontainment facilities and are said to have the combined capacity to treat fewer than a dozen Ebola patients at a time. These are Emory University Hospital; the NIH in Bethesda, Maryland; Nebraska Medical Center in Omaha; and St. Patrick Hospital in Missoula, Montana. According to U.S. health officials, many large U.S. hospitals around the country following protocols can be set up to receive and treat Ebola patients. Still, the most recently diagnosed patients have been carefully transported to one of these facilities.

76 other health care workers who may have come into contact with Mr. Duncan after he was hospitalized are being monitored for Ebola symptoms, according to the CDC. In addition, these workers have been prohibited from traveling by air to any destinations, as one of the nurses was able to travel before she became symptomatic and thus contagious and able to be diagnosed. There are almost 50 other people in the Dallas community who may have had contact with Mr. Duncan who are being monitored from possible exposure. As of the time of this course's last revision, all being monitored were asymptomatic.

There are dozens of other people who are currently being monitored or are in an official quarantine of some sort. These include those who came in contact with the nurse who was able to travel, both over the course of her travel, and in the region where she visited, in northeast Ohio. At this juncture, the 21-day quarantine is not required of them.

U.S. Government Response (outside the CDC)

In addition to the CDC working with U.S. hospitals to establish and monitor protocols, the Federal government has

named Ron Klain as “Ebola Czar” whose “responsibility it will be to make sure that all the government agencies who are responsible for aspects of this response, that their efforts are carefully integrated. He will also be playing a role in making sure the decisions get made,” according to the White House Press Secretary speaking on October 17, 2014.

On October 20, 2014, the Pentagon announced that the Defense Secretary has ordered the Northern Command Commander to organize a team of 30 healthcare professionals who will spend a week in specialized training for infection control and personal protective equipment (PPE). The training will be provided by the U.S. Army Medical Research Institute of Infectious Diseases. The team members will include 20 critical care nurses, five doctors who specialize in infectious diseases and five trainers in infectious disease protocols. Once training is completed, the team will exist in a “prepare to deploy” status for 30 days. The team is meant for use in situations within the U.S. and will not be dispatched overseas. Their goal is to identify, train, and prepare forces in advance of potential requests to ensure quick response. They are prepared to go into action as other Department of Defense (DoD) personnel would in advance of other types of civil support mission like hurricane disaster relief and wildfire firefighting.

U.S. Hospital Protocols

Infection Prevention and Control Recommendations for Suspected and Confirmed Ebola virus Cases

The CDC has tightened previous infection control protocols for healthcare workers caring for patients with Ebola in light of the infection contracted by the nurses caring Mr. Duncan in Dallas. The CDC wishes that with these new guidelines that the

ambiguity that has been criticized by most notably, the National Nurses United (NNU) nurses' union, will be cleared up. The guidance focuses on specific personal protective equipment (PPE) health care workers should use and offers detailed instructions for how to put the equipment on and take it off safely.

Recent experience from safely treating patients with Ebola at Emory University Hospital, Nebraska Medical Center and National Institutes of Health Clinical Center are reflected in the guidance.

The enhanced guidance is centered on three principles:

- All healthcare workers undergo rigorous training and are practiced and competent with PPE, including taking it on and off in a systemic manner
- No skin exposure when PPE is worn
- All workers are supervised by a trained monitor who watches each worker taking PPE on and off.

All patients treated at Emory University Hospital, Nebraska Medical Center and the NIH Clinical Center have followed the three principles. None of the workers at these facilities have contracted the illness.

Recommendations for personal protective equipment (PPE) and environmental infection control measures are applicable to any healthcare environment. Healthcare personnel (HCP) refers to all those working in healthcare environment, both paid and volunteer, who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or aerosols generated during certain medical procedures.

HCP include, but are not limited to, physicians, nurses,

nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual personnel, home healthcare personnel, and persons not directly involved in patient care (e.g., clerical, dietary, house-keeping, laundry, security, maintenance, billing, chaplains, and volunteers) but possibly exposed to infectious agents that can be transmitted to and from HCP and patients.

The guidance provided by the CDC's most recent guideline for isolation precautions is not intended to apply to persons outside of healthcare environments.

CDC's Three Principles for Infection Control for Healthcare Workers

Principle #1: Rigorous and repeated training

Focusing only on PPE gives a false sense of security of safe care and worker safety. Training is a critical aspect of ensuring infection control. Facilities need to ensure all healthcare providers practice numerous times to make sure they understand how to appropriately use the equipment, especially in the step by step donning and doffing of PPE. The CDC and its partners will increase training offerings for healthcare personnel across the country to reiterate all the aspects of safe care recommendations.

Principle #2: No skin exposure when PPE is worn

Given the intensive and invasive care that US hospitals provide for Ebola patients, the tightened guidelines are more directive in recommending no skin exposure when PPE is worn.

CDC is recommending all of the same PPE included in the August 1, 2014 guidance, with the addition of coveralls and single-use, disposable hoods.

Goggles are no longer recommended as they may not provide complete skin coverage in comparison to a single use disposable full face shield.

Additionally, goggles are not disposable, may fog after extended use, and healthcare workers may be tempted to manipulate them with contaminated gloved hands. PPE recommended for U.S. healthcare workers caring for patients with Ebola includes:

- Double gloves
- Boot covers that are waterproof and go to at least mid-calf or leg covers
- Single use fluid resistant or impermeable gown that extends to at least mid-calf ***or*** coverall without intergraded hood.
- Respirators, including either N95 respirators or powered air purifying respirator (PAPR)
- Single-use, full-face shield that is disposable
- Surgical hoods to ensure complete coverage of the head and neck
- Apron that is waterproof and covers the torso to the level of the mid-calf should be used if Ebola patients have vomiting or diarrhea

The CDC describes different options for combining PPE to allow a facility to select PPE for their protocols based on availability, healthcare personnel familiarity, comfort and preference while continuing to provide a standardized, high level of protection for healthcare personnel.
This includes having:

- **Two specific, recommended PPE options** for facilities to choose from. Both options provide equivalent protection if worn, donned and doffed correctly.
- **Designated areas for putting on and taking off PPE.** Facilities should ensure that space and lay-out allows for clear separation between clean and

potentially contaminated areas

- **Trained observer to monitor PPE** use and safe removal
- **Step-by-step PPE removal instructions** that include:

o Disinfecting visibly contaminated PPE using an EPA-registered disinfectant wipe prior to taking off equipment

- **Disinfection of gloved hands** using either an EPA-registered disinfectant wipe or alcohol-based hand rub between steps of taking off PPE.

Principle #3: Trained monitor

CDC is recommending a trained monitor actively observe and supervise each worker taking PPE on and off. This is to ensure each worker follows the detailed processes, especially to disinfect visibly contaminated PPE. The trained monitor can spot any missteps in real-time and immediately address.

PPE is Only One Aspect of Infection Control

It is critical to focus on other prevention activities to halt the spread of Ebola in healthcare settings, including:

- Prompt screening and triage of potential patients
- Designated site managers to ensure proper implementation of precautions
- Limiting personnel in the isolation room
- Effective environmental cleaning

"Think Ebola"* and *"Care Carefully"

The CDC reminds health care workers to "Think Ebola" and to "Care Carefully." Health care workers should take a detailed travel and exposure history with patients who exhibit fever, severe headache, muscle pain, weakness, diarrhea, vomiting,

stomach pain, unexplained hemorrhage. If the patient is under investigation for Ebola, health care workers should activate the hospital preparedness plan for Ebola, isolate the patient in a separate room with a private bathroom, and to ensure standardized protocols are in place for PPE use and disposal. Health care workers should not have physical contact with the patient without putting on appropriate PPE.

The CDC's guidance for U.S. healthcare settings is similar to MSF's (Doctors Without Borders) guidance. Both CDC's and MSF's guidance focuses on:

- **Protecting skin and mucous membranes** from all exposures to blood and body fluids during patient care
- **Meticulous, systematic strategy for putting on and taking off PPE** to avoid contamination and to ensure correct usage of PPE
- **Use of oversight and observers** to ensure processes are followed
- **Disinfection of PPE prior to taking off:** CDC recommends disinfecting visibly contaminated PPE using an EPA-registered disinfectant wipe prior to taking off equipment. Additionally, CDC recommends disinfection of gloved hands using either an EPA-registered disinfectant wipe or alcohol-based hand rub between steps of taking off PPE. Due to differences in the U.S. healthcare system and West African healthcare settings, MSF's guidance recommends spraying as a method for PPE disinfection rather than disinfectant wipes.

The CDC's Five Pillars of Safety

CDC reminds all employers and healthcare workers that PPE is only one aspect of infection control and providing safe care to patients with Ebola. Other aspects include five pillars of

safety:

- **Facility leadership has responsibility** to provide resources and support for implementation of effective prevention precautions. Management should maintain a culture of worker safety in which appropriate PPE is available and correctly maintained, and workers are provided with appropriate training.
- **Designated on-site Ebola site manager** responsible for oversight of implementing precautions for healthcare personnel and patient safety in the healthcare facility.
- **Clear, standardized procedures** where facilities choose one of two options and have a back-up plan in case supplies are not available.
- **Trained healthcare personnel**: facilities need to ensure all healthcare providers practice numerous times to make sure they understand how to appropriately use the equipment.
- **Oversight of practices** are critical to ensuring that implementation protocols are done accurately, and any error in putting on or taking off PPE is identified in real-time, corrected and addressed, in case potential exposure occurred.

Source: CDC, October 20, 2014.

Further Protocols

Your facility may require further action of you should someone presenting Ebola symptoms who has traveled from one of the affected areas come to your facility. These include but are not limited to:

- **Triage precautions:** At entrance to all triage and acute care areas, posters should be in place asking patients to immediately inform staff if they are ill and have recently traveled to the affected region. Place surgical mask on patient immediately.
- **Restrict visitors**: Avoid entry of visitors into the patient's room. Exceptions may be considered on a case by case basis for those who are essential for the patient's wellbeing. A logbook should be kept to document all persons entering the patient's room. See CDC's infection control guidance on procedures for monitoring, managing, and training of visitors.
- **Avoid aerosol-generating procedures**: Avoid aerosol-generating procedures. If performing these procedures, PPE should include respiratory protection (N95 or higher filtering face piece respirator) and the procedure should be performed in an airborne infection isolation room.
- **Implement environmental infection control measures**: Diligent environmental cleaning and disinfection and safe handling of potentially contaminated materials is of paramount importance, as blood, sweat, vomit, feces, urine and other body secretions represent potentially infectious materials should be done following hospital protocols.

A Learning Process

After Mr. Duncan's death, the National Nurses United (NNU) took issue with the hospital's handling of that case. This included disputed claims as to why he was not diagnosed and isolated the first time he came to the emergency room, for how long and in what type of physical place (exposed, not in isolation) he was kept waiting, that the nurses' protective gear left their necks exposed and how they were advised by hospital personnel to handle said exposure (using medical tape four or five times around their neck, leaving questions of how

that tape should be removed), that hazardous waste has been left to pile up at some point, and that the nurses had received no “hands on” training and felt “unsupported” when authorities appeared to blame breaches of protocol on the nurse who got sick, for getting sick.

The hospital responded officially that they followed all updated CDC recommendations and in some cases went “above and beyond” them, with regard to isolation suit protocol, waste disposal, and training mandates. The hospital has replied that, “When the CDC recommended that nurses wear isolation suits, the nurses raised questions and concern about the fact that the skin on their neck was exposed. The CDC recommended that they pinch and tape the necks of the gown. Because our nurses continued to be concerned, particularly about removing the tape, we ordered hoods.”

In light of what occurred in Dallas, the NNU has called for all hospitals to have in place the highest standard of optimal protections, including Hazmat suits and hands-on training, such as intensive practice putting the Hazmat suits on and off, to protect all registered nurses and other hospital personal when facing Ebola. The newest CDC guidance described above has sought to address these concerns.

The NNU did a survey of 2,300 RNs at more than 780 healthcare facilities in 46 states and the District of Columbia regarding Ebola preparation. The results found that:

· 85% say their hospital has not yet provided education on Ebola that allowed for the nurses to ask questions and learn interactively. These numbers were unchanged at the time of the latest revision of this course.

· 40% said that their hospital has insufficient supplies for daily use on their units with 38% stating they have insufficient supplies of fluid resistant/impermeable gowns in their hospital. These numbers

were increasing at the time of the latest revision of this course.

- 41% reported that their hospital did not have plans to equip isolation rooms with plastic covered mattresses and pillows and to discard linens after use. Only 8% were aware that their hospital had such a plan in place.

The NNU is requesting that U.S. hospitals immediately implement a full emergency preparedness plan for Ebola and other infectious disease outbreaks. These include the following:

- Full training of hospital personnel, along with proper protocols and training materials and experiences (the ability for nurses to interact during training and ask questions) in order to best respond to outbreaks.
- Adequate Hazmat suit and other PPE supplies.
- Equip isolation rooms properly in order to assure safety for patients, visitors, and staff.
- Proper procedures for disposal of medical waste and linens after usage.

Source: NNU, 2014.

If all CDC and individual hospital protocols are followed, it is possible to contain the Ebola virus within the United States.

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