



# PROMOTING INFECTION PREVENTION IN DIALYSIS FACILITIES (PIPDF)

## Ebola Gap Analysis – A Report to the Centers for Disease Control and Prevention

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In 2014 and 2015, a widespread epidemic of Ebola virus (EBOV) occurred in West Africa. As of June 10, 2016, the total of confirmed, probable and suspected cases of Ebola virus disease (EVD) in West Africa was 28,616, with 11,310 deaths.<sup>1</sup> Travel of several patients from West Africa to the United States raised concern regarding the level of preparedness of healthcare facilities to safely care for patients with EVD.

For example, in September 2014, a man who flew from Liberia to Dallas, Texas, became ill with EVD after his arrival and subsequently died in a Dallas hospital.<sup>2</sup> Two critical care nurses who cared for him subsequently developed EVD of moderate severity and were hospitalized and treated with investigational agents.<sup>3</sup> Another healthcare worker (HCW) who returned from West Africa was hospitalized in October 2014 in New York City where he was treated successfully. In addition to these four patients, seven individuals with Ebola symptoms, including six HCWs, were transported by charter aircraft from West Africa to U.S. hospitals; six of these patients recovered.<sup>2</sup> Seven of the 11 patients treated in the United States were treated in the Serious Communicable Disease Unit (SCDU) at Emory University Hospital and the Nebraska Biocontainment Unit (NBU) at the University of Nebraska Medical Center.<sup>4</sup>

Of 27 patients who received therapy in United States and Europe, five (19%) required renal replacement therapy (RRT).<sup>5</sup> Management of multiple cases of EVD requiring RRT illustrated a number of gaps in the level of preparedness of U.S. healthcare facilities, including hemodialysis units, to care safely and effectively for patients with suspected or confirmed EVD. Minimizing the risk to HCWs was of paramount importance, given the fact that 509 of 876 HCWs who developed EVD in West Africa had died.<sup>6</sup> However, experience at the SCDU, BCU and the Clinical Center at the National Institutes of Health demonstrated that with adequate training, preparation and adherence to infection control protocols, treatment of EVD, including RRT can be delivered safely.<sup>7-9</sup>

The degree to which hemodialysis units are prepared to safely care for patients with suspected or proven infection due to emerging pathogens that may be highly contagious and capable of causing

potentially fatal infections most likely differs between out-patient hemodialysis units and those located in tertiary inpatient facilities. Diseases of concern include Ebola virus disease (EVD), Middle East Respiratory Syndrome (MERS), Severe Adult Respiratory Syndrome (SARS), influenza caused by avian strains with increased virulence, or other emerging threats such as Zika virus infection.<sup>10</sup> The Centers for Disease Control and Prevention (CDC) established a 3-tier system—which included frontline healthcare facilities (Level I), Ebola Assessment Hospitals (Level II), and a total of 55 Ebola Treatment Centers (Level III)—for handling patients with suspected or proven EVD.<sup>2,11</sup>

Although CDC believes that it is unlikely that a person who may have EVD will present to ambulatory care settings such as an outpatient hemodialysis center, CDC nevertheless recommends that ambulatory care centers be prepared for such an event due to its potential threat to HCWs and the general public.<sup>12</sup> CDC's concern for such an occurrence is illustrated by an event that affected a large dialysis organization. During the early phases of the 2014-2015 EVD outbreak, an in-center hemodialysis patient reported being on an airline flight with a nurse who had cared for a patient with EVD. At the time, there was no specific guidance available for how to manage secondary contacts. Fresenius Medical Care treated the hemodialysis patient using staff-assisted home dialysis with Nxstage equipment and bagged fluids, administered by a nurse wearing personal protective equipment (PPE). Effluent was discharged to a commode in the patient's room and a continuous drip of chlorine bleach was concurrently run along with the waste.

The level of preparedness needed in outpatient dialysis units, where performing hemodialysis on patients with EVD is not recommended, is substantially different than at Level III facilities, where hemodialysis is most likely to take place. The analysis below is intended to identify gaps in the preparedness of hemodialysis units to deal with EBOV, and lists recommended preventive measures. Many of the recommendations might also assist hemodialysis units with their ability to care for patients with other highly virulent emerging pathogens.

## Gap Analysis of Outpatient Hemodialysis Units

A description of possible gaps in EVD preparedness in outpatient hemodialysis centers has been submitted for publication in Clinical Journal of the American Society of Nephrology.<sup>13</sup> Its content is included here for the purpose of providing CDC with a complete gap analysis.

No patients with EVD were cared for in outpatient hemodialysis units in the U.S during the 2014-2015. However, the experience when an EVD patient was admitted to the hospital in Dallas revealed several issues that could well affect outpatient hemodialysis centers. The non-specific signs and symptoms of EVD, suboptimal triage practices, poor communication between healthcare personnel, and lack of adequate types or use personal protective equipment contributed to nosocomial transmission to healthcare personnel.<sup>3</sup>

**Onsite written emergency preparedness plan.** Many outpatient hemodialysis units lack policies for dealing with patients with possible EBOV or other highly contagious or highly virulent pathogens such as those mentioned above. The Centers for Medicare and Medicaid Services (CMS) requires that healthcare facilities, including end-stage renal disease facilities, have an emergency preparedness plan that can be used to deal with various infectious diseases and other conditions.<sup>14</sup>

**A written communication plan.** Facilities need a written process and list of relevant telephone numbers for alerting key dialysis center personnel such as the Medical Director and Clinical Manager, an affiliated infection preventionist, and local and state public health authorities about the presence of a patient being evaluated for possible EVD.

**A staff member to monitor news about the occurrence of EBOV transmission.** Hemodialysis units should designate an individual, such as the Nurse Manager or Chief Technician, who will be responsible for monitoring news reports, public health alerts or relevant websites (e.g., [www.cdc.gov/vhf/ebola/](http://www.cdc.gov/vhf/ebola/)) regarding news of ongoing transmission of EBOV or other emerging pathogens capable of causing severe disease. During the 2014-2015 outbreak, one large dialysis organization (Fresenius Medical Care) activated a multidisciplinary “disaster team” and utilized daily teleconference calls to monitor the situation. In addition, educational material was made available to personnel, and dialysis centers were provided with recommendations regarding triage strategies and protocols.

**Triage policies and procedures for emerging pathogens.** However, anecdotal evidence suggests that many dialysis units lack a policy and adequate resources for appropriate triage of patients, which would include questions about potentially important exposures that might put patients at risk during periods when emerging pathogen transmission is occurring. This gap is particularly problematic in outpatient dialysis units, where patients frequently enter the unit and proceed directly to their assigned chair without contact with an “in-take” person or receptionist. Some units do not have written policies on managing staff who have returned from an area where EBOV transmission is occurring. Triage policies and procedures should be in place to identify patients with suspected EVD.

**Personnel with specialized training on donning and doffing PPE.** When EBOV transmission has been reported in the world, a limited number of personnel, including nurses and patient care technicians, should be trained on how to identify EVD patients, and the specific measures for donning and doffing PPE when evaluating a patient with possible EVD or infection due to other emerging pathogens. The competency of trained individuals should be documented. Maintaining a cadre of appropriately trained staff is

complicated by the high rate of staff turnover encountered in many out-patient dialysis facilities, and frequent use of traveling dialysis staff.

**Designated space for evaluating patients with possible EVD.** It is likely that numerous facilities have not designated a location in the dialysis center in which to immediately place a patient who is being evaluated for possible Ebola virus infection. Some units may lack the necessary space required. A private room, ideally with access to a sink and toilet, is preferred, but may not be present in all outpatient facilities. The room need not be equipped for hemodialysis, as proceeding with hemodialysis is not recommended in out-patient dialysis centers except under extraordinary circumstances.

**Dedicated supply of appropriate PPE.** Outpatient hemodialysis units should have a dedicated supply of the types of PPE recommended for evaluating patients with suspected EVD who are awaiting transfer to an EVD Assessment Hospital or Ebola Treatment Center. PPE recommended by CDC for caring for stable patients with suspected EVD includes:<sup>15</sup>

- Single-use (disposable) fluid-resistant gown that extends to at least mid-calf, or single-use (disposable) fluid-resistant coveralls without integrated hood.
- Single-use (disposable) full face shield.
- Single-use (disposable) facemask.
- Single-use (disposable) gloves with extended cuffs. Two pairs of gloves should be worn. At a minimum, outer gloves should have extended cuffs.

**Lack of awareness of basic measures for managing suspected EVD patients.** Critical dialysis unit personnel should be familiar with a preparedness plan that includes 3 basic measures to be implemented when EBOV transmission is occurring in the world: Identify, Isolate and Inform

*Identify patients with travel and direct exposure history:*

- At every entrance to the dialysis center, place signs that include the following: epidemiological clues to possible disease exposure (i.e., countries with active Ebola transmission), signs and symptoms of infection, and who to notify if the patient or visitor has both exposure and appropriate signs or symptoms.
- Include messages about the signs and symptoms of Ebola virus disease in all telephone contacts with the patient (e.g., reminders about appointments) and who to contact prior to arrival at the dialysis center.
- Screen all patients immediately at the time of arrival at the dialysis unit, and ask if the patient has traveled to a country with widespread Ebola virus transmission, or had contact with an individual with confirmed EVD within the previous 21 days.
- If patient has positive exposure history, determine if the patient has signs and symptoms, including fever (subjective or greater than 100.4°F or 38°C) or any Ebola-compatible symptoms: fatigue, headache, weakness, muscle pain, vomiting, diarrhea, abdominal pain, or bleeding.
- If patient does not have signs or symptoms of possible Ebola, advise patient to monitor for fever and symptoms for 21 days after last exposure in consultation with the health department.
- For asymptomatic patients with a positive exposure history, consideration may be given to staff-assisted hemodialysis at the patient's home, or dialyzing the patient in a dialysis center at the end of the day, followed by careful disinfection of equipment and surfaces.
- For patients who have a positive exposure history and Ebola-compatible signs or symptoms, isolate patient.



*Isolate patient immediately; avoid unnecessary direct contact:*

- Place patient in private room or area, preferably enclosed with a private bathroom or covered commode.
- If direct contact is necessary, appropriate PPE and dedicated equipment must be used to minimize transmission risk.
- Only essential personnel with training and competency in donning and doffing PPE correctly should evaluate the patient. This step may be challenging given the limited number of medical staff (e.g., registered nurses) that are present at any given time in an outpatient facility, and the fact that physician and mid-level providers are not present most of the time and have offices that are often not located adjacent to the facility.
- If patient has obvious bleeding, vomiting or copious diarrhea, then do not re-enter room until EMS personnel trained to transport the patient arrive.
- Do not perform phlebotomy or any other procedures unless urgently required for patient care or stabilization.
- Consult with a health department before cleaning up blood or body fluids. Any reusable equipment should not be reused until it has been appropriately cleaned and disinfected with an EPA-registered disinfectant which has activity against non-enveloped viruses (e.g., Norovirus, rotavirus, adenovirus).

*Inform Health Department and prepare for safe transport:*

- Contact the relevant health department immediately.
- Prepare for transfer to a hospital identified by the health department for evaluation of patients with possible Ebola.
- Coordinate with health department regarding:

- Who will notify the receiving emergency department or hospital about the transfer, and
- Arrangements for safe transport to accepting facility designated by public health officials.
- Do not transfer patient without first notifying the health department.

### **Gap Analysis for Inpatient Hemodialysis Centers**

During the 2014-2015 outbreak, the SCDU, NBU, Clinical Center at the National Institutes of Health and CDC identified a number of gaps in EBOV preparedness and developed a variety of solutions.<sup>7,9,16,17</sup> Gaps in the preparedness of in-patient dialysis units may include the following.

**On-site written emergency preparedness plan.** In-patient units where patients with suspected or proven EVD are cared for should have policies for dealing specifically with admission, subsequent care and discharge of one or more patients suspected or proven to have an infection due EBOV and other viruses of special concern listed above.

**A written communication plan.** Dialysis unit nurse managers need to be educated on need for prompt communication with the Medical Director and infection preventionist regarding pending admission of a patient with suspected or proven EVD who requires RRT.

**Infrastructure required for managing patients with suspected or proven EVD.** Dialysis should only be performed in an isolation room in which intensive care can be delivered.<sup>7,18</sup> Some hospitals lack optimal locations in which to treat patients with suspected EVD patients, such as having two adjacent isolation rooms that are equipped for performing hemodialysis and for donning and doffing PPE, with a restricted ante-area that can be used to access both rooms.<sup>11,16,19</sup> A space for handling potentially

contaminated waste is also needed. Some facilities do not have separate entrances and exits for treatment units, which consensus guidelines recommend.<sup>20</sup>

To minimize the number of healthcare personnel who enter the rooms of patients with suspected or proven EVD, special systems that permit remote video monitoring and communication between personnel in the patient's room and others in adjacent areas are desirable, but are not currently present in all Ebola Treatment Centers.<sup>7</sup> Such capability could be especially valuable in facilitating communication between pediatric patients and their parents.<sup>21</sup>

Ebola Treatment Centers that might be called upon to treat patients with suspected or proven infection due to highly virulent pathogens that are transmitted via the airborne route (e.g., MERS-CoV, SARS-CoV) would benefit from having treatment rooms that are under negative pressure, and have air that is HEPA filtered and 100% exhausted to the outside at sites away from hospital air intake locations.<sup>4</sup> However, only not all Ebola Treatment Centers had treatment rooms with negative-pressure rooms and HEPA filtration of exhausted air.<sup>20</sup>

**Adequately trained personnel.** A recent survey revealed that a substantial proportion of hospitals that might have needed to care for an EVD patient in 2014-2015 had trained only 30% of frontline providers on appropriate use of PPE.<sup>19</sup> Providing an adequate number of trained staff to care for critically ill patients with EVD initially represented a problem in several Ebola Treatment Centers.<sup>20,22</sup>

- Dialysis unit personnel, who might be called upon to either administer RRT, or observe and assist intensive care unit personnel caring for a patient with suspected or proven EVD, require adequate training of modes of transmission of EBOV and the specific isolation precautions and protocols needed for care of EVD patients.<sup>11</sup> Because donning, and especially doffing, of PPE are complicated and difficult to perform correctly,<sup>23-25</sup> these procedures should be observed by an assistant. Laboratory-based studies suggest that PPE training using fluorescent lotion with

immediate feedback and MS2 bacteriophage markers can illustrate potential errors and improve doffing technique.<sup>23-25</sup> Detailed recommendations on the types of PPE that minimize the risk of exposure and techniques for donning and doffing by those caring for patients with suspected or confirmed EVD, and for trained observers and doffing assistants have been published by CDC.<sup>15,26</sup>

- Ebola Treatment Centers need to have an adequate number of intensive care unit nurses with sufficient expertise in administering RRT via continuous RRT (CRRT) as well as all other aspects of ICU care, and who have been previously been trained and validated for proficiency in donning and doffing PPE required during care of patients with suspected or proven EVD.<sup>27</sup> To limit the number of potentially-exposed personnel, having bedside nurses perform daily and terminal cleaning is also recommended.
- CRRT trainers who can be on-call 24/7 to assist ICU or other nurses who may have questions when providing CRRT to a patient with EVD may be needed.
- Train in advance a group of physicians (infectious diseases specialists, intensivists) and technicians (e.g., radiology and laboratory staff) who will be involved in the care of EVD patients regarding the special protocols for donning and doffing PPE required during care of patients with suspected or proven EVD who require CRRT, and document their proficiency. This training needs to be done periodically in inter-epidemic periods. The optimal frequency with which re-training is conducted has not been established.
- Limit the number of healthcare personnel who provide patient care and perform procedures.<sup>18</sup>

**Potential CRRT-related risks.** Exposure of personnel to blood during initiation and performance of CRRT is of major concern, and can be reduced using several strategies.

- Designate a highly competent individual, who has also been trained to follow CDC guidelines for proper PPE procedures to perform catheter insertion.<sup>18</sup>

- The preferred site for central catheter placement for hemodialysis of EVD patients is the right internal jugular.<sup>7</sup> If this placement is not possible, the next choice should be femoral sites, with the left internal jugular being the last option. The subclavian site should be avoided whenever possible. During line placement, consider draping additional nearby surfaces (beyond the standard full-barrier precautions used for central line insertion) to decrease potential blood transfer to these surfaces.<sup>27</sup>
- Whenever possible, perform hemodialysis using CRRT. CRRT is preferred because it requires fewer circuit changes and generates less solid and liquid waste than intermittent hemodialysis.<sup>18,27</sup>
- Identify in advance potentially high-risk maintenance procedures (e.g., changing circuits and filters, etc.) that may be required during a course of CRRT, and create a checklist for how these procedures should be performed to minimize exposure to body fluids.
- If clinically appropriate, consider regional citrate anticoagulation during CRRT to extend filter life and minimize the number of times that nurses are required to exchange the CRRT circuits.<sup>7,27</sup>

**Shortages of specialized PPE.** Obtaining an adequate supply of PPE appropriate for caring for patients with suspected or proven EVD was a major problem for hospitals during the 2014-2015 outbreak period.<sup>11,19</sup> Contributing factors included the large number of PPE required for care of EVD patients and for training personnel on correct donning and doffing technique, the different types of PPE needed, and supply chain problems.<sup>17,28</sup> Improvements in predicting the type and number of PPE necessary during future outbreaks of highly virulent emerging diseases could reduce supply chain problems.

**Insufficient point-of-care testing equipment.** Due to concerns over transport and safe handling of potentially contaminated specimens in automated clinical laboratories, it is recommended laboratory tests be conducted whenever possible using point-of-care equipment, which is ideally located adjacent to the patient treatment area. Initially, at least one Ebola Treatment Center facility reported not having point-of-

care equipment in the unit, a deficiency that was later rectified.<sup>16</sup> Other facilities may not have enough devices to dedicate to caring for an EVD patient for the duration of their stay.<sup>11</sup>

- In conjunction with hospital administration, clinical engineering, and laboratory directors, assure that adequate laboratory equipment for point-of-care testing will be dedicated for use in treating a patient with EVD throughout the course of his/her treatment. The lack of easily accessible diagnostic assays to detect EBOV early in the 2014 outbreak suggests the need to develop point-of-care assays for other emerging highly virulent pathogens.
- If necessary, laboratory tests cannot be performed using point-of-care equipment, there should be defined plans for how specimens will be handled when they leave the patient care area.<sup>16</sup>
- Point-of-care imaging equipment for radiography and ultrasonography should be available adjacent to treatment units, and nurses and radiology personnel should receive training on the specific procedures for handling equipment when imaging EVD patients.<sup>29</sup>

**Waste management issues.** Inadequate plans for how to safely store and dispose of large volumes of waste generated during care of EVD patients represented a significant problem for Ebola Treatment Centers.<sup>7,9,11</sup> Care of EVD patients results in large amounts of solid waste (PPE, dialysis filters and tubing) and liquid waste (CRRT effluent, urine, feces).<sup>7,9</sup> Inadequate autoclave volume to disinfect solid wastes prior to transport, shipping issues, terminal disposal problems and refusals to handle liquid or solid waste occurred in the United States during the 2014-2015 outbreak.<sup>9</sup>

Some facilities that cared for patients with suspected or confirmed EVD did not have the capability to sterilize infectious waste on site,<sup>20</sup> and those that did used a variety of methods to render EBOV-contaminated materials non-infectious.<sup>7,9,30</sup> Based on subsequent studies that have raised questions regarding optimal techniques for disinfection/sterilization of EBOV-contaminated solid wastes,<sup>31</sup> additional research on best practices for disinfection of such materials may be warranted.

Although there is currently a lack of epidemiological evidence of EBOV transmission from sewage, how to dispose of liquid waste from the care of EVD patients has been a matter of some debate.<sup>32-34</sup> Due to local and state regulations, the SCU, NBU and Clinical Center at NIH mixed potentially-contaminated liquid waste with a disinfectant prior to disposal in a sanitary sewer.<sup>4,9</sup>

- Ebola Treatment Centers need to establish in advance and have a written policy for how to safely store, disinfect and dispose of solid waste. Disposal of liquid waste, including CRRT effluent, must be done in a manner that is compliant with local and state public health regulations.<sup>7,8</sup>
- Define special procedures to minimize splashing during disposal of CRRT effluent or other liquid waste and document competency of responsible personnel.<sup>4,7</sup> A plan should be in place even if the presence of viable Ebola virus in effluent is unlikely.<sup>7</sup>

**Terminal disinfection of equipment and patient care areas.** Preferably, initial terminal room cleaning/disinfection using a disinfectant effective against non-enveloped viruses should be performed by nurses who have cared for the patient. Although there is insufficient evidence to know if it was necessary, additional consideration should be given to performing final decontamination of the entire isolation unit using hydrogen peroxide vapor or mobile ultraviolet (UV) light technology.<sup>7-9</sup>

**Lack of administrative support and financial resources.** Some hospitals preparing to handle patients with suspected EVD reported a lack of sufficient administrative support and commitment, and a few reported lack of reimbursement for setup expenses incurred.<sup>35</sup> The issue could also be a problem if future outbreaks of other highly virulent transmissible pathogens occur.

## DISCUSSION

Based on the efforts of CDC, SCDU, BCU, NIH Clinical Center and others, much has been learned regarding how to safely and effectively perform hemodialysis on patients with EVD. Timely publication by CDC of recommendations dealing with all aspects of the diagnosis and management of patients with suspected or proven EVD aided the multitude of healthcare facilities that dealt with such patients and contributed immeasurably preventing transmission of EBOV to healthcare personnel and the community.

CDC's recommendations and development of the three-tier system for managing patients with suspected or confirmed EVD provided an infrastructure designed to minimize potential and real gaps in care that existed in the United States during the 2014-2015 outbreak. Many of the general strategies developed for management of patients with EVD should also be applicable, with appropriate modifications, for handling patients with other severe transmissible diseases that may emerge in the future.<sup>10</sup>

During the course of the 2014-2015 EBOV outbreak, multiple potential and actual gaps in EBOV preparedness were identified in the United States. Issues relating to PPE (optimum types of equipment, donning and doffing procedures and supply chain problems) and disposal of solid and liquid waste posed the greatest problems. Lack of optimal physical infrastructure, an inadequate number of appropriately trained personnel, and the absence of standardized policies and procedures were also identified as gaps in preparedness.

Concerns have been raised regarding the sustainability of high-level isolation units (HLIUs) such as Ebola Treatment Centers in the absence of an ongoing or immediate threat of transmission of highly-virulent pathogens.<sup>35,36</sup> Uncertainty exists regarding the level of funding that will be appropriated to support and improve HLIUs as governmental agencies' priorities change. Formation of the network of 10 National Ebola Training and Education Centers, also referred to as Regional Ebola and Other Special Pathogens Treatment Centers (RESPTC), by the Department of Health and Human Services and CDC



should improve the capacity of the healthcare system to deal with moderate to large-scale outbreaks that might occur in the United States in the future.<sup>37</sup>

CDC has identified a number of areas that require further research and evaluation, including improvements in infrastructure, processes for detection, triage and isolation of individuals with EVD, the design of PPE, new technologies for environmental cleaning and disinfection, and best infection control practices.<sup>38</sup> Securing continued funding for such activities is likely to represent an ongoing challenge.

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