

Update #1 on Ebola Virus Disease (EVD)

Friday August 8, 2014

Target audience: Clinical laboratories

Background

Since March 2014, the largest outbreak of EVD ever documented and the first recorded in West Africa has elicited an international response. As of August 6, 2014, a total of 1,711 cases and 932 deaths (case fatality 55-60%) have been reported across the affected countries of Guinea, Sierra Leone, Liberia and Nigeria.

EVD is characterized by sudden onset of fever and malaise, accompanied by other nonspecific signs and symptoms, such as myalgia, headache, vomiting, and diarrhea. Patients with severe forms of the disease may develop hemorrhagic symptoms and multi-organ dysfunction, including hepatic damage, renal failure, and central nervous system involvement, leading to shock and death.

Person-to-person transmission occurs through direct contact with bodily fluids such as, but not limited to, blood, urine, sweat, semen, and breast milk, as well as exposure to contaminated objects. The incubation period is usually 8–10 days (ranges from 2–21 days). Patients can transmit the virus while febrile through later stages of disease, as well as postmortem, when persons touch the body during funeral preparations.

Patient Evaluation Criteria

Further details of clinical symptoms, patient evaluation, and diagnostic testing criteria are available on the MDCH website for emerging diseases at: www.michigan.gov/emergingdiseases.

EVD case definition is available at: <http://www.cdc.gov/vhf/ebola/hcp/case-definition.html>

Laboratory Testing for Ebola Virus Disease

Authorization for testing is required DO NOT SEND SPECIMENS DIRECTLY TO CDC

If testing for EVD is warranted based on the Patient Evaluation and Diagnostic Testing Criteria referenced above, please contact MDCH Communicable Disease Division to obtain testing authorization at:

517-335-8165 during normal business hours

517-335-9030 after normal business hours

Laboratory Safety

The CDC has announced that US hospitals can safely manage a patient with EVD by following recommended isolation and infection control procedures (<http://www.cdc.gov/vhf/ebola/hcp/infection-prevention-and-control-recommendations.html>). Standard, contact and droplet precautions are recommended for management of hospitalized patients with known or suspected EVD. Ebola virus is inactivated by EPA-approved hospital disinfectants.

It is expected all laboratorians collecting or handling specimens follow established protocols compliant with the OSHA bloodborne pathogens standard which encompasses blood and other potentially infectious materials. This includes wearing appropriate personal protective equipment (PPE) and adhering to engineered safeguards, for all specimens regardless of whether they are identified as being infectious.

Recommendations for specimen collection: full face shield or goggles, masks to cover all of nose and mouth, gloves, and impermeable gowns. Additional PPE may be required in certain situations. Don and remove PPE according to hospital infection control guidelines.

Recommendations for laboratory testing: full face shield or goggles, masks to cover all of nose and mouth, gloves, impermeable gowns AND use of a certified class II Biosafety cabinet or plexiglass splash guard, sealed centrifuge cups as well as manufacturer-installed safety features for instruments.

Routine Laboratory Testing (not for Ebola Diagnosis)

Routine laboratory testing includes traditional chemistry, hematology, and other laboratory testing used to support and treat patients. Precautions as described above offer appropriate protection for healthcare personnel performing laboratory testing on specimens from patients with suspected infection with Ebola virus. Testing should be limited to avoid aerosol production and skin or mucous membrane exposure. Open specimen tubes in a biological safety cabinet or utilizing a splash shield.

NOTE: Malaria diagnostics should be a part of initial testing because it is a common cause of febrile illness in persons with a travel history to the affected countries.

Diagnostic Testing for Ebola Available at CDC

Acute infections will be confirmed using a real-time RT-PCR assay (CDC test directory code CDC -10309 Ebola Identification). Virus isolation may also be attempted. Serologic testing for IgM and IgG antibodies will be completed for certain specimens and to monitor the immune response in confirmed EVD patients (#CDC-10310 Ebola Serology).

Lassa fever is also endemic in certain areas of West Africa and may show symptoms similar to early EVD. Diagnostic tests including but not limited to RT-PCR, antigen detection, and IgM serology may be utilized to rule out Lassa fever in EVD-negative patients.

When Specimens Should Be Collected for Ebola Testing

Ebola virus is detected in blood only after onset of symptoms, most notably fever. It may take up to 3 days post-onset of symptoms for the virus to reach detectable levels. Virus is generally detectable by real-time RT-PCR from 3-10 days post-onset of symptoms, but has been detected for several months in certain secretions. Specimens ideally should be taken when a symptomatic patient reports to a healthcare facility and is suspected of having an EVD exposure; however, if the onset of symptoms is <3 days post-onset of symptoms, a subsequent specimen will be required to completely rule-out EVD.

Preferred Specimens for Ebola Testing

A minimum volume of 4mL whole blood preserved with EDTA, clot activator, sodium polyanethol sulfonate (SPS), or citrate in **plastic** collection tubes can be submitted for EVD testing. Do not submit specimens in glass containers. Do not submit specimens preserved in heparin tubes. Specimens should be stored at 4°C. Specimens other than blood may be submitted upon consult. Standard labeling should be applied for each specimen.

Laboratory Specimen Collection Guidance

Early recognition and identification of suspect EVD patients is critical. Additional patient care considerations include:

- Limit the use of needles and other sharps as much as possible
- Phlebotomy, procedures, and laboratory testing should be limited to the minimum necessary for essential diagnostic evaluation and medical care
- All needles and sharps should be handled with extreme care and disposed in puncture-proof, sealed containers
- Do not use a pneumatic tube system for transporting suspected EVD specimens.

Packaging and Shipping Clinical Specimens to MDCH BOL

Please complete both the MDCH Specimen and CDC Submission Forms.

All specimens should be packaged and shipped to MDCH BOL on ice packs as Category A Infectious Substance in accordance with federal and international shipping regulations.

Link to MDCH Specimen Submission Form:

http://www.michigan.gov/documents/DCH-0583TEST_REQUEST_7587_7.pdf

(Be sure to write or type the test requested, i.e. "Ebola virus serology" and/or "Ebola virus PCR" into the blank space found under "Hepatitis" at the bottom right side of page 1.)

Link to CDC Specimen Submission Form:

http://www.michigan.gov/documents/mdch/HUMAN_form-50-34_410210_7.pdf

Steps for laboratories to take now

No action is required at this time, other than to monitor the situation and be aware of current guidance, including the interim infection prevention and control recommendations for hospitalized patients with EVD.

Further Information

This is a rapidly evolving situation. This document is based on currently available information. This guidance document will be updated as additional information becomes available.

More information is available on the CDC EVD website at: <http://www.cdc.gov/vhf/ebola/index.html>

Questions

For laboratory related questions, please contact

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