

Health Advisory

Update: Increase in Cases of Non-respiratory *Burkholderia cepacia* complex in Pennsylvania August 6, 2021

SUMMARY POINTS

- The Pennsylvania Department of Health (DOH) and Philadelphia Department of Public Health (PDPH) continue to work with the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), and other state and local health departments to investigate *Burkholderia cepacia* complex (Bcc) infections.
- To date, a total of 61 positive Bcc cultures have been identified including the following sources: blood (52), sputum (4), abdominal fluid/drainage (2), wound (1), amniotic fluid (1) and bile (1).
- Investigation has determined that patients developed Bcc infections, including bloodstream infections, after having undergone ultrasound-guided procedures in which ultrasound gel produced by Eco-Med Pharmaceuticals Inc. was used.
- Eco-Med Pharmaceuticals Inc. issued a voluntary recall of certain lots of its Eco-Gel 200/MediChoice® M500812 ultrasound gel due to bacterial contamination.
- CDC advises that healthcare facilities should always use single-use, sterile ultrasound gel packets for ultrasonography used in preparation for or during transcutaneous procedures
- DOH and PDPH request that healthcare facilities notify their local health department or the Bureau of Epidemiology immediately about clusters (2 cases or more in the same facility) of non-respiratory Bcc occurring on or after 6/1/2021.

The Pennsylvania Department of Health and PDPH continue to work with CDC, FDA, and other state and local health departments to investigate multiple clusters of Bcc infections associated with ultrasound gel produced by Eco-Med Pharmaceuticals Inc.

To date, a total of 61 positive Bcc cultures from 13 facilities located in Philadelphia (6), Montgomery (2), Dauphin (2), Allegheny (1), Bucks (1), and Chester (1) counties have been identified. The positive Bcc cultures were obtained from the following sources: blood (52), sputum (4), abdominal fluid/drainage (2), wound (1), amniotic fluid (1) and bile (1). No patients in these heterogenous clusters are known to have cystic fibrosis.

On August 4, 2021, Eco-Med Pharmaceuticals Inc. issued a [press release](#) and [voluntary recall](#) of certain lots of its Eco-Gel 200/MediChoice® M500812 ultrasound gel due to bacterial contamination. Please review the recall closely as the ultrasound gel products are sold under different brand names and include a variety of products. Healthcare facilities should identify the affected products listed in the recall and destroy/return or stop use/quarantine products as indicated in the recall instructions.

Infection Prevention and Control Recommendations Related to Ultrasonography:

CDC advises that healthcare facilities should always use single-use, sterile ultrasound gel packets for ultrasonography used in preparation for or during transcutaneous procedures, such as placement of central and peripheral intravenous lines, amniocentesis, and paracentesis. This includes avoiding use of bottles of nonsterile ultrasound gel for visualization prior to such procedures (e.g., vein marking, visualizing ascites). Healthcare facilities should also review facility practices related to ultrasound probe reprocessing to ensure they are aligned with manufacturer's instructions for use and appropriate professional society guidelines.

The primary infection control measures for prevention of ultrasonography related Bcc infections in healthcare settings are:

- Thorough cleaning and disinfection of ultrasound devices and other equipment (ex. transducers, warmers) and surfaces that may come in contact with the ultrasound gel product. EPA registered healthcare disinfectants including products from EPA list B (tuberculocidal products) are appropriate disinfectants for this purpose.
- Cleaning and disinfection of high-touch surfaces in areas where ultrasonography is performed with appropriate disinfectants.
- Use of single-use packets of sterile ultrasound gel for all vascular access procedures (i.e central and peripheral access) and other sterile or aseptic procedures that require ultrasonography. Do not use ultrasound gel from multi-use bottles for these types of procedures.
- Use only sterile gel beneath sterile probe covers and between the probe cover and skin.
- Use single-use packets of sterile ultrasound gel when there is the potential for it to come in contact with a healing post-operative incision or wound.
- If non-sterile ultrasound gel has been used prior to a sterile or aseptic procedure (for the same or different procedure), perform thorough skin prep prior to the sterile or aseptic procedure.
- Do not refill bottles of ultrasound gel. A multi-use bottle should be discarded when empty.
- Adherence to hand hygiene. Alcohol-based hand rub (ABHR) is effective against *B. cepacia* and is the preferred method for routine hand hygiene.
- Adherence to proper personal protective equipment for sterile procedures.

PA DOH recommends the following:

Clusters of non-respiratory *B. cepacia* complex positive cultures since June 1, 2021, should be immediately reported to DOH at 1-877-PA-HEALTH or to the local health department. Philadelphia cases should be reported to 215-685-6748. Additionally, available non-respiratory *B. cepacia* complex isolates should be saved at the clinical laboratory of origin until further notice.

Healthcare facilities should report any patient infections related to the use of potentially contaminated medical products to [FDA's MedWatch Adverse Event Reporting program](#).

B. cepacia, typically associated with respiratory infections in individuals with cystic fibrosis and other respiratory diseases, can also be transmitted by contaminated medications and devices. *B. cepacia* is frequently resistant to many common antibiotics and decisions on the treatment should be made by using antibiotic susceptibility testing.

Any questions or concerns regarding these recommendations should be directed to the PADOH at 1-877-PA-HEALTH or your local health department.

More information about *B. cepacia* can be found at the Centers for Disease Control and Prevention webpage: <http://www.cdc.gov/HAI/organisms/bCepacia.html>

We ask that hospitals, EMS councils, FQHCs, long-term care facilities, and local health jurisdictions please share this information with all medical, infection control, nursing, and laboratory staff and other key personnel within their respective facilities and networks as appropriate.