MLS Laboratory Update: CDC Issues Alert Regarding Multi-State Cluster of *Paraburkholderia fungorum*

MAY 20, 2025

Purpose of this Message:

To update healthcare providers and laboratorians on the multi-state cluster of *Paraburkholderia fungorum* involving the use of non-sterile ultrasound gel for ultrasound-guided percutaneous procedures and to provide the link for the CDC Alert issued May 13, 2025. This message is also being received by Infection Preventionists in Minnesota and other healthcare providers.

Action Item:

Please see the May 13, 2025 Alert from the Centers for Disease Control and Prevention (CDC) regarding multiple cases of *Paraburkholderia fungorum* isolated from blood cultures and related to the use of non-sterile ultrasound gel: CDC Alert: Use Only Sterile Ultrasound Gel for Percutaneous Procedures (https://www.cdc.gov/healthcare-associated-infections/bulletins/outbreak-ultrasound-gel.html)

Background:

The Minnesota Department of Health (MDH) has been investigating a cluster of *Paraburkholderia fungorum* and *Paraburkholderia* species, which are primarily environmental and plant microorganisms and have rarely been identified as a human pathogen. In August 2024, the MDH Public Health Laboratory (MDH-PHL) noted an increase in blood culture isolates submitted from clinical laboratories subsequently identified as either *Paraburkholderia fungorum* or *Paraburkholderia* species using 16S ribosomal DNA sequencing by MDH-PHL. Further investigation resulted in the CDC Alert: *Use Only Sterile Ultrasound Gel for Percutaneous Procedures* released May 13, 2025.

Summary of CDC Alert

- In September 2024, CDC was notified by the Minnesota Department of Health about a cluster of *Paraburkholderia fungorum* — a bacterium rarely associated with human illness — detected in blood cultures collected from patients at multiple healthcare facilities.

- As of May 8, 2025, CDC is aware of **40 isolates** of *P. fungorum* primarily isolated from patient blood cultures. These isolates are linked by WGS and are from patients in four U.S states and two other countries.
- Some of these patients were known to have undergone ultrasound-guided percutaneous procedures prior to culture collection.
- Product testing across these jurisdictions has isolated *P. fungorum* from at least two non-sterile ultrasound gel products (**MediChoice® [lots: 240302; 240306] and ClearImage® [lots: 230221, 230256, 240227, 240230], both manufactured by NEXT Medical Products Company.**
    - These product isolates are also genetically related to the *P. fungorum* patient isolates.
- CDC is assisting with an ongoing multistate investigation involving use of non-sterile ultrasound gel for ultrasound-guided percutaneous procedures.

CDC Safety alert

CDC recommends the following for healthcare providers:

- Use only single-use ultrasound gel products labeled as "sterile" for ultrasonography in preparation for or during percutaneous procedures (e.g., placement of central and peripheral intravenous lines, amniocentesis, paracentesis, tissue biopsy, and surgical procedures).
- Healthcare providers who perform ultrasounds and/or ultrasound-associated procedures should be trained in the appropriate use of ultrasound gel products.
- An ultrasound gel product label's claim of "bacteriostatic" or "preservative" without a specific indication of sterility should be considered non-sterile for clinical purposes.

Action Item Details:

Isolate Submission:

- Please submit isolates to the MDH-PHL as part of this investigation.
    - Contact Paula Snippes Vagnone at Paula.Snippes@state.mn.us.
- Please include: Patient Name, DOB, Specimen Collection Date, Specimen Source, Facility Name, Contact Name, Contact Phone/Email

Case Reporting:

Please report if *Paraburkholderia fungorum* or *Paraburkholderia* species is identified in a culture from any body site. Reporting of these cases is per MN Rules 4605.7000 to 4605.7900 including “Unusual or increased case incidence of any suspect infectious illness”.

- Notify MDH of culture result: Laura Tourdot, laura.tourdot@state.mn.us
- Please include: Patient Name, DOB, Specimen Collection Date, Specimen Source, Facility Name, Contact Name, Contact Phone/Email

- Conduct additional review to determine if ultrasound gel procedure was used for percutaneous collection of blood or body fluid.

Additional Information:

- Previous MLS messages regarding *Paraburkholderia fungorum*:
    - MLS Laboratory Update: October 1, 2024
      MDH Investigating Paraburkholderia fungorum (https://www.health.state.mn.us/diseases/idlab/mls/labalerts/241001pfungorum.pdf)
    - MLS Laboratory Update: January 10, 2025
      MDH Investigating Multi-state Cluster of Paraburkholderia fungorum (https://www.health.state.mn.us/diseases/idlab/mls/labalerts/250110pfungoruminvest.pdf)
- Considerations related to the use of ultrasound gel in healthcare facilities can be found in this CDC MMWR article (https://www.cdc.gov/mmwr/volumes/71/wr/mm7148a3.htm#B1_down).
- Facilities should report any adverse events or quality problems experienced with the use of any ultrasound gel products to the product manufacturer and FDA's MedWatch Adverse Event Reporting program (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda)

Thank You:

Thanks to those laboratories who have submitted isolates and case information thus far. We appreciate your partnership as we continue to investigate this concerning cluster.

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To obtain this information in a different format, call: 651-201-5200.