PROVIDER HEALTH ADVISORY

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CDC: Reports of Paraburkholderia fungorum Associated with Non-sterile Ultrasound Gel

The Centers for Disease Control and Prevention (CDC) has issued an alert regarding reports of Paraburkholderia fungorum (an environmental bacterium) associated with the use of ultrasound gel in multiple states from 2024-2025. The bacterium was found in product testing of non-sterile ultrasound gel products. The CDC is recommending that healthcare providers 1) use only single-use ultrasound gel products labeled as "sterile" for ultrasounds before procedures that involve puncturing the skin, 2) be trained in the proper use of ultrasound gel products, and 3) consider any ultrasound gel labeled "bacteriostatic" or "preservative" as non-sterile for clinical purposes.

To **report** any adverse events related to quality problems associated with the use of any ultrasound gel products use the FDA's MedWatch Adverse Event Reporting Program.

Please see the attached alert for more information.

Alert: Use Only Sterile Ultrasound Gel for Percutaneous Procedures

For Everyone

MAY 13, 2025

WHAT TO KNOW

- CDC has received reports of *Paraburkholderia fungorum* (an environmental bacterium) associated with the use of ultrasound gel from multiple states from 2024–2025.
- Use of non-sterile ultrasound gel for percutaneous procedures (procedures that involve puncturing the skin) risks patient safety.
- CDC is assisting with an ongoing multistate investigation.

Summary

- Product testing identified an environmental bacterium, *Paraburkholderia fungorum* (formerly *Burkholderia fungorum)*, from two non-sterile ultrasound gel products.
- Genetically similar isolates of *P. fungorum* were also detected primarily from patient blood cultures; some of these patients were known to have undergone ultrasound-guided percutaneous procedures prior to culture collection.
- CDC is assisting with an ongoing multistate investigation involving use of non-sterile ultrasound gel for ultrasound-guided percutaneous procedures.

Recommendations for healthcare providers

Safety alert

1. 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).

2. Healthcare providers who perform ultrasounds and/or ultrasound-associated procedures should be trained in the appropriate use of ultrasound gel products.

3. 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.

Background

Multiple prior healthcare outbreaks have been reported associated with the use of contaminated, non-sterile ultrasound gel for ultrasound-guided percutaneous procedures, including outbreaks associated with bacteria in the *Burkholderia cepacia* complex.[1] [2] Percutaneous procedures involve skin or tissue puncture, including but not limited to the placement of central and peripheral intravenous catheters, amniocentesis, paracentesis, tissue biopsy, and surgical procedures.

Use of non-sterile ultrasound gel for percutaneous procedures can result in patient harm. Microorganisms that may be present in non-sterile ultrasound gel can spread to sterile body sites (like the bloodstream) through procedures involving skin or tissue puncture, which can cause serious infections. Even for microorganisms that do not cause infection, they could also contaminate test (culture) specimens during collection,

which could lead to unnecessary antimicrobial treatment and diversion of healthcare and laboratory resources. Either of these risks are not limited to scenarios where there is known product contamination, since microorganisms may be present in non-sterile products.

Current outbreak summary

In September 2024, CDC was notified by Minnesota Department of Health about a cluster of *Paraburkholderia fungorum* — a bacterium rarely associated with human illness [3] — detected in blood cultures collected from patients at multiple healthcare facilities. The bacterial isolates recovered from these patients were found to be closely related through whole-genome sequencing (WGS). [4] Most patients did not appear to have clinical infection with this organism.

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. 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 [Branchburg, NJ]); these product isolates are also genetically related to the *P. fungorum* patient isolates. Further investigation by healthcare facilities confirmed that some of these patients had undergone ultrasound-guided percutaneous procedures prior to culture collection.

CDC, along with state and local jurisdictions, continues to investigate in coordination with the U.S. Food and Drug Administration (FDA).

Additional resources

Considerations related to the use of ultrasound gel in healthcare facilities can be found in this CDC MMWR article. [1] [5]

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.

SOURCES

CONTENT SOURCE:
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

REFERENCES

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5. 5. AIUM Official Statement: Guidelines for Cleaning and Preparing External- and Internal-Use Ultrasound Transducers and Equipment Between Patients as Well as Safe Handling and Use of Ultrasound Coupling Gel. J Ultrasound Med Off J Am Inst Ultrasound Med. 2023;42(7):E13-E22. Accessed April 14, 2025.