UK Health Security Agency

Briefing Note

Serial number **2024/050** **Date** **11/11/2024**

Event Multi-region cluster of *Burkholderia stabilis* ST1565 associated with non-sterile ultrasound gel – **Update, new Field Safety Notice to recall additional products**

Notified by
Sarah Milligan, Consultant in Public Health, HCAI, Fungal, AMR, AMU & Sepsis Division

Authorised by
Colin Brown, Deputy Director, HCAI, Fungal, AMR, AMU & Sepsis Division
Yimmy Chow, Regional Deputy Director Lead
Susan Hopkins, Strategic Response Director
Emma O'Brien, Communications

Contact HCAIAMR.IOIG@ukhsa.gov.uk

IRP Level Routine

Incident Leads Sarah Milligan, Consultant in Public Health and James Elston, Consultant Epidemiologist

Instructions for Cascade

- UKHSA Private Office Groups who cascade within Groups
- UKHSA Regions Directorate
    - UKHSA Field Services
    - UKHSA Health Protection Teams including UKHSA Regional Deputy Directors. UKHSA regional teams are asked to cascade to their DIPC, microbiology and laboratory networks.
    - Deputy Directors in Regions Directorate
- UKHSA Lab Management Teams
- UKHSA Regional Communications
- Generic inbox for each of the devolved administrations
- DHSC CMO (excluding internal UKHSA briefing notes)
- National NHSE EPRR
- **NHS National Operations Centre** to cascade to GP practices, NHS Trusts in particular to emergency, intensive care, medical, surgical, maternity, paediatric, neonatal and radiology services, and microbiology departments
- **Devolved Administrations** to cascade to Medical Directors and other DA teams as appropriate to their local arrangements
- **Regional Deputy Directors** to cascade to Directors of Public Health
- **UKHSA microbiologists** to cascade to non-UKHSA labs (NHS labs and private)
- **UKHSA microbiologists** to cascade to NHS Trust infection leads
- **NHS labs/NHS infection leads/NHS microbiologist/NHS infectious disease specialists** to cascade to clinical teams and managers of services which use ultrasound gel in their practice. This may include but is not limited to emergency, intensive care, medical, surgical, maternity, paediatric, neonatal and radiology services.

UK Health Security Agency

- Royal College of Anaesthetics - president@rcoa.ac.uk
- Royal College of Emergency Medicine - president@rcem.ac.uk
- Royal College of General Practitioners - Chair-RCGP@rcgp.org.uk
- Faculty of Intensive Care Medicine - contact@ficm.ac.uk
- Royal College of Obstetricians and Gynaecologists - president@rcog.org.uk
- Royal College of Ophthalmologists - president@rcophth.ac.uk
- Royal College of Paediatrics and Child Health - s.w.turner@abdn.ac.uk
- Royal College of Pathologists - president@rcpath.org
- Faculty of Pharmaceutical Medicine - president@fpm.org.uk
- Royal College of Physicians - mumtaz.patel@rcp.ac.uk
- Faculty of Public Health - president@fph.org.uk
- Royal College of Radiologists - president@rcr.ac.uk
- Faculty of Sexual and Reproductive Healthcare - president@fsrh.org
- Faculty of Sport and Exercise Medicine - president@fsem.ac.uk
- Royal College of Surgeons of England - president@rcseng.ac.uk
- Cystic Fibrosis Trust – Clare.Corbett@cysticfibrosis.org.uk
- Cystic Fibrosis Medical Association - kwsouth@liverpool.ac.uk
- British Thoracic Society – bts@brit-thoracic.org.uk
- Society of Radiographers – GillH@sor.org
- Infection Prevention Society - gina.groom@ips.uk.net; lynne.duncan@ips.uk.net
- Royal College of Nursing - president@rcn.org.uk
- Royal College of Midwives - president@rcm.org.uk

Summary:
This is an update to Briefing notes 2024/045 (issued 17 October 2024) and 2024/048 (issued 22 October 2024) following update to Field Safety Notice (FSN) recalling additional products.

Key Updates:

- There has been no change in total number of *Burkholderia (B.) stabilis* ST1565 cases (6 confirmed and 2 probable).
- Targeted product testing and whole genome sequencing of isolates obtained from cases and gel supports the hypothesis of non-sterile ultrasound gel as the source linked to this outbreak.
- The manufacturer previously issued a FSN to recall a specific product lot of ultrasound gel. However, following investigation by the manufacturer and further evidence of contamination, this recall has now been expanded and the FSN updated to include an additional product lot.
- Distributors, healthcare professionals and other customers are advised to immediately stop using and selling products listed in the FSN and to quarantine and dispose of the product.
- MHRA continue to engage the manufacturer to obtain assurance on safety of other batches of products.

UKHSA Key Recommendations:

1. The FSN advises to immediately stop distribution and use of listed products, and to quarantine and dispose of products.

UK Health Security Agency

2. Laboratories are reminded to refer all new *Burkholderia cepacia complex* (Bcc) isolates to the Antimicrobial Resistance and Healthcare Associated Infection Reference Unit for identification and sequencing.
3. Healthcare providers, clinicians and practitioners using ultrasound gel are reminded that there are published recommendations from UKHSA on guidance for safe use of ultrasound gel which outlines measures to reduce risk to patients associated with the use of non-sterile ultrasound gel and when to use sterile gel. UKHSA previously issued a National Patient Safety Alert to ensure alignment to this guidance and contents of this alert remain valid.

Background and Interpretation:
UKHSA is investigating a cluster of *B. stabilis* ST 1565, described previously in Briefing Notes 2024/045 and 2024/048. As of 11/11/2024, there are 6 confirmed and 2 probable cases in the UK, all in England. Since the previous Briefing Note 2024/048, one previously reported probable case has now been excluded from the cluster, and one further probable case has since been identified.

Targeted product sampling of opened and unopened bottles of Ebrington AquaUltra Clear 260g ultrasound gel (lot 2024.04) recovered *Burkholderia* species (provisionally identified as *B. cepacia* group or *B. stabilis)*. Further testing has now confirmed the same sequence type as case isolates (*B. stabilis* ST1565). Whole genome sequencing has also indicated close relatedness between case and gel isolates.

Investigation by the manufacturer has found evidence of contamination during the manufacturing process. Additionally, product sampling of unopened bottles of another product lot (lot 2024.06) has also revealed evidence of contamination with *Burkholderia* species.

As a result, the manufacturer has published an updated FSN on 8 November 2024 to recall this additional product lot. UKHSA is working with partners to implement control measures and prepare communications, and ensure alternate products are available.

Implications & Recommendations for UKHSA Regions
UKHSA regional teams are asked to be aware of this incident and to use their DIPC, microbiology and laboratory networks to share information in this briefing note for further cascade. New cases potentially linked to this outbreak should be notified to HCAIAMR.IOIG@ukhsa.gov.uk

---

Implications & Recommendations for UKHSA sites and services
UKHSA microbiologists are asked to support cascade to NHS and other non-UKHSA labs, as well as NHS Trust infection control leads. Clinical laboratories are requested to refer all new isolates of *Burkholderia cepacia complex* (Bcc) to the Antimicrobial Resistance and Healthcare Associated Infection Reference Unit (AMRHAI) for identification and sequencing.

Implications & Recommendations for NHS
NHS and independent laboratories

NHS and Independent laboratories are requested to submit any new isolates of Bcc to the AMRHAI reference laboratory.

IPC teams
IPC teams are asked to share the FSN with service providers and managers of facilities providing ultrasound services and ultrasound guided procedures. Providers and managers are asked to follow information in the FSN to quarantine and return or dispose of products. If you have concerns about incidents in relation to use of this product, please report via the MHRA Yellow Card Scheme.

IPC teams are asked to share guidance for safe use of ultrasound gel with the same providers and managers to ensure adherence to the previous issued National Patient Safety Alert.

Front-line clinicians and practitioners
Healthcare providers, clinicians and practitioners using ultrasound gel should stop using the product listed in the FSN. Clinicians are reminded to follow recommendations in the UKHSA guidance for safe use of ultrasound which outlines measures to reduce risk to patients associated with the use of non-sterile ultrasound. UKHSA previously issued a National Patient Safety Alert to ensure alignment to this guidance and contents of the alert remain valid.

Implications and recommendations for Local Authorities
None

References/ Sources of information

- Field Safety Notice AquaUltra Clear ultrasound transmission gel (lot 2024.06 and lot 2024.04)
- Good infection prevention practice: using ultrasound gel - GOV.UK (www.gov.uk)
- National Patient Safety Alert: The safe use of ultrasound gel to reduce infection risk
- NHS England » National infection prevention and control manual (NIPCM) for England
- Health and Social Care Act 2008: code of practice on the prevention and control of infections - GOV.UK (www.gov.uk)
- NHS Supply Chain: Important Customer Notice