



Briefing Note

Serial number 2024/048 Date 22/10/2024

Event Multi-region cluster of *Burkholderia stabilis* ST1565 suspected to be associated with non-sterile ultrasound gel – **Update, new Field Safety Notice and product recall for action**

Notified by

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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
- **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,



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intensive care, medical, surgical, maternity, paediatric, neonatal and radiology services.

- Royal College of Anaesthetics
- Royal College of Emergency Medicine
- Royal College of General Practitioners
- Faculty of Intensive Care Medicine
- Royal College of Obstetricians and Gynaecologists
- Royal College of Ophthalmologists
- Royal College of Paediatrics and Child Health
- Royal College of Pathologists
- Faculty of Pharmaceutical Medicine
- Royal College of Physicians
- Faculty of Public Health
- Royal College of Radiologists
- Faculty of Sexual and Reproductive Healthcare
- Faculty of Sport and Exercise Medicine
- Royal College of Surgeons of England
- Cystic Fibrosis Trust
- Cystic Fibrosis Medical Association
- British Thoracic Society
- Society of Radiographers

Summary:

This is an update to Briefing note 2024/045 (issued 17 October 2024).

Key Updates:

- There have been no new cases of *B. stabilis* ST 1565 since the previous Briefing Note 2024/045.
- Ultragel Medical Kft has issued an urgent [Field Safety Notice](#) (FSN) to recall lot 2024.04 of Ebrington Medical AquaUltra Clear ultrasound gel 260g
- NHS Supply Chain have updated the [Important Customer Notice](#) (ICN) to suspend distribution of specific products (published on 17 October 2024) to include the FSN.
- 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 this product lot
- MHRA continue to engage the manufacturer to obtain assurance on safety of other batches of products

UKHSA Key Recommendations:

1. The [FSN](#) advises product users to immediately stop using lot 2024.04 of Ebrington Medical AquaUltra Clear ultrasound gel 260g, and quarantine and dispose of this product lot
2. The [FSN](#) advises distributors and suppliers to immediately stop supplying lot 2024.04 of Ebrington Medical AquaUltra Clear ultrasound gel 260g, quarantine stock of this product lot, and suppliers should liaise with the distributor regarding disposal.
3. 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.



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4. 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 new cluster of *B. stabilis* ST 1565 potentially associated with a batch of non-sterile ultrasound gel. *B. stabilis* is a member of the *Burkholderia cepacia complex* (Bcc) group which is widespread in the environment and typically considered an opportunistic pathogen of low virulence. Bcc has frequently been implicated in the contamination of medicinal and hygiene products.

As of 22/10/2024, there are 6 confirmed and 2 probable cases in this cluster in the UK, all in England (one case amended from probable to confirmed since prior briefing note). Isolates have been recovered from sterile body sites for all cases. Bcc species are a particular risk to patients with cystic fibrosis (CF), severe lung disease, severe immunocompromise and intensive care patients. We are not aware of any cases with CF.

Targeted product sampling of a specific ultrasound gel product has recovered *Burkholderia* species (provisionally identified as *B. cepacia* group or *B. stabilis*). Confirmatory whole genome sequencing testing is awaited to confirm whether gel isolates are of the outbreak strain.

The manufacturer has issued a [FSN](#) to voluntarily recall of the implicated product lot. Pending further investigation, the manufacturer has temporarily suspended production, and the UK supplier has temporarily suspended distribution. NHS Supply Chain have published and have updated an [Important Customer Notice](#) to suspend distribution of specific products. MHRA continue to engage the manufacturer to obtain assurance on safety of other batches of products supplied by the manufacturer. UKHSA is working with partners to implement control measures and prepare risk communications, and ensure alternate products are available.

Implications & Recommendations for UKHSA Regions

UKHSA regional teams are asked to be aware of this incident and are requested to use their DIPC, microbiology and laboratory networks to share information in this briefing note for further cascade.

New cases thought to be linked to this cluster 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 (AMRHA) for identification and sequencing.

Implications & Recommendations for NHS

NHS and independent laboratories



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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 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 2024.04](#)
- [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](#)