



Briefing Note

Serial number 2024/045 **Date** 17/10/2024

Event Multi-region cluster of *Burkholderia stabilis* ST1565 suspected to be associated with non-sterile ultrasound gel

Notified by

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Contact HCAIAMR.IOIG@ukhsa.gov.uk

NIRP 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
 - 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 as appropriate 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

Summary:

UKHSA are investigating a cluster of *Burkholderia (B.) stabilis* sequence type (ST) 1565 suspected to be associated with a non-sterile ultrasound gel product used in clinical settings in England. Isolates have been recovered from sterile sites for all cases. We are collaborating with system partners to investigate and implement control measures.

Whilst investigation is being undertaken, supply of a specific non-sterile ultrasound products has been suspended by NHS Supply Chain.

Burkholderia cepacia complex (Bcc) has frequently been implicated in the contamination of numerous medicinal and hygiene products. Laboratories are reminded to refer all new Bcc isolates to the Antimicrobial Resistance and Healthcare Associated Infection Reference Unit for identification and sequencing.

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 are investigating a new cluster of *B. stabilis* ST 1565 with cases in multiple regions in England potentially associated with a batch of non-sterile ultrasound gel product. *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 17/10/2024, there are 5 confirmed and 3 probable cases in this cluster in England, with no known cases in Scotland, Wales or Northern Ireland. Cases are predominantly older adults (range 11-79, median 67.5 years). 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 has recovered *Burkholderia* species (provisionally identified as *B. cepacia* group or *B. stabilis*) from multiple non-sterile ultrasound gel products supplied by healthcare providers and settings linked to confirmed and probable cases. Confirmatory whole genome sequencing testing is awaited to confirm whether gel isolates are of the outbreak strain.

UKHSA has established a national incident with a multi-stakeholder incident management team including MHRA and NHS supply chain. The manufacturer of the potentially associated product has temporarily suspended production, and the UK supplier has temporarily suspended distribution, pending further investigation. MHRA are working closely with the manufacturer and communication from the manufacturer will follow. NHS Supply Chain have published an [Important Customer Notice](#) to suspend distribution of specific products and will update as more information becomes available. 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 regions are asked to be aware of this incident and to share information to ensure Directors of Infection Prevention and Control, and IPC and Microbiology Leads in NHS Trusts and Independent care providers are aware of and adhere to the UKHSA [guidance for safe use of ultrasound gel](#) which outlines the safe use of non-sterile ultrasound gel and when to use sterile ultrasound gel and the previously issued [National Patient Safety Alert](#). 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

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

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

IPC teams

IPC teams are asked to share [guidance for safe use of ultrasound gel](#) with service providers and managers of facilities providing ultrasound services, and ultrasound guided procedures, ensuring adherence to the previous issued [National Patient Safety Alert](#). This includes but is not limited to emergency, intensive care, medical, surgical, maternity, paediatric, neonatal and radiology services. The guidance should be cascaded to clinicians/practitioners as appropriate.



Registered healthcare providers are reminded of their obligations to comply with the Health and Social Care Act 2008: code of practice on the prevention and control of infections (or equivalent), of relevance criterion 1, 6 and 9. This includes the education, training and proficiency demonstration of staff before undertaking procedures independently and includes where relevant the safe use of ultra-sound gel products and aseptic technique.

Front-line clinicians and practitioners

Healthcare providers, clinicians and practitioners using ultrasound gel 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

- [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](#)