National Patient Safety Alert

UK Health Security Agency

The safe use of ultrasound gel to reduce infection risk

Date of issue:	11/11/2021	Reference no:	NatPSA/2021/010/UKHSA

This alert is for action by: healthcare providers (NHS and independent) of facilities providing ultrasound services; clinicians and practitioners using ultrasound gel in their practice

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders, heads of departments using ultrasound gel and heads of procurement.

Explanation of identified safety issue:

Ultrasound gel is available in both sterile and non-sterile preparations. Non-sterile ultrasound gel has been associated with contamination and outbreaks of infection in various settings worldwide.

UKHSA (formerly Public Health England) has identified that a long-standing outbreak of *Burkholderia cepacia* is linked to a non-sterile ultrasound gel product used in hospitals in the UK and Ireland. *B. cepacia* is widespread in the environment and typically considered to be an organism of low virulence and an opportunistic pathogen, though has been associated with contaminated medicinal and hygiene products.

Cases spanned a wide age range and were predominantly hospitalised patients in England including individuals cared for in critical care settings. Most isolates (*B. cepacia* isolated from patient samples) were from sterile sites (i.e. blood, body fluids) or were otherwise considered to be invasive (e.g. retrieved from the lower respiratory tract). The nature of samples and available information indicated that there were a range of clinical presentations including some cases with serious illness. Although we are not aware of deaths attributed to *B. cepacia* infection in this outbreak, it is possible that it may have been a contributory factor for some patients.

B. cepacia was recovered from multiple samples of a single brand of ultrasound gel from Trusts from across the UK. Pulsed-field gel electrophoresis and whole genome sequencing indicated that gel and case isolates were closely related, consistent with a common source outbreak. The investigation highlighted issues in clinical practice and a lack of guidance on the safe use of ultrasound gels to mitigate risks associated with these products.

NHS Supply Chain have previously issued an important customer notice. Interim guidance on the safe use of ultrasound gel was issued by Public Health England in February 2021 and updated guidance was issued by UKHSA in November 2021.

Actions required

Actions to be completed by 31/01/22

1. Review and amend policies, protocols, training and awareness-raising materials to ensure they are aligned to UKHSA guidance for safe use of ultrasound gel, including that:

a. **Sterile** ultrasound gel in single use containers is always used:

i. for invasive procedures
ii. if an invasive procedure is likely to be undertaken in the following 24 hours
iii. in labour where there is high likelihood of C-section or use of invasive instrumentation during delivery
iv. where there is contact with or near to non-intact skin
v. where the ultrasound examination is near to an indwelling invasive device
vi. where there is contact with mucous membranes (sterile gel to be used inside and outside of probe covers),
vii. for severely immunocompromised patients
viii. for all procedures in high-dependency/intensive-care settings including neonatal intensive care units

b. For **non-sterile** ultrasound gel used outside of the indications above, ensure only pre-filled disposable (i.e. non-refillable) bottles or single-use sachets are used

2. Cease using large containers of ultrasound gel intended for decanting:
   a. dispose of any containers in use, as well as the bottles decanted into
   b. remove any such bottles or containers from storage and clinical areas
   c. amend purchasing systems so that these products cannot be purchased

For further detail, resources and supporting materials see: UKHSA guidance for safe use of ultrasound gel

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Organisational implementation of this alert is aligned to the guidance recommendations outlined in the full version of the UKHSA guidance for the safe use of ultrasound gel.

General principles for the safe use of ultrasound gel:
For both sterile and non-sterile gel:

- ensure healthcare workers carry out hand hygiene before and after use of ultrasound gel
- ensure gel is stored according to manufacturer's instructions in an area that is dry and away from potential sources of contamination
- dispose of a gel container if it appears soiled, is damaged or is out of date

For sterile ultrasound gel:

- ensure that only unopened sachets and containers that are labelled as 'sterile' are used
- do not reuse the container or sachet once opened, either with other patients or stored and reused with the same patient, as sterile gels are for single use only

For non-sterile ultrasound gel:

- do not decant gel from a larger container into other bottles
- use single use sachets or pre-filled, multi-patient disposable bottles; ensure pre-filled disposable bottles are not re-filled
- once opened, date the bottle and dispose of it when either empty, after one month or on expiry date, whichever comes first
- clean the whole bottle, including the tip, with a disinfectant wipe between uses
- ensure the tip/nozzle of the bottle does not come into contact with anything; if it does, clean immediately with a disinfectant wipe
- after the procedure remove all residual gel from the patient's skin and advise patients to wash area when feasible
- if an invasive procedure is subsequently undertaken within 24 hours of the use of non-sterile gel at or near to the site, then ensure all residual gel is removed, and the skin is thoroughly cleaned using antiseptic skin preparation in line with local policy for the procedure (Note: use of sterile ultrasound gel is required in advance of invasive procedures)

The warming of gel is not recommended unless there is a clinical benefit that outweighs applying gel at room temperature. Where warming of gel is performed:

- use dry heat warmers instead of warm water
- ensure gel bottles are kept upright in warmers and not inverted
- clean warmers regularly according to the manufacturer's instructions, where these exist, or clean according to local guidance

Stakeholder engagement
UKHSA have consulted with the following organisations and societies to develop this National Patient Safety Alert: The Medicines and Healthcare Products Regulatory Agency, the Department for Health and Social Care, NHS England and NHS Improvement, Public Health Wales, NHS National Services Scotland, Public Health Agency Northern Ireland, NHS Supply Chain and patient and public representatives.

Advice for Central Alerting System (CAS) officers and risk managers
This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts.