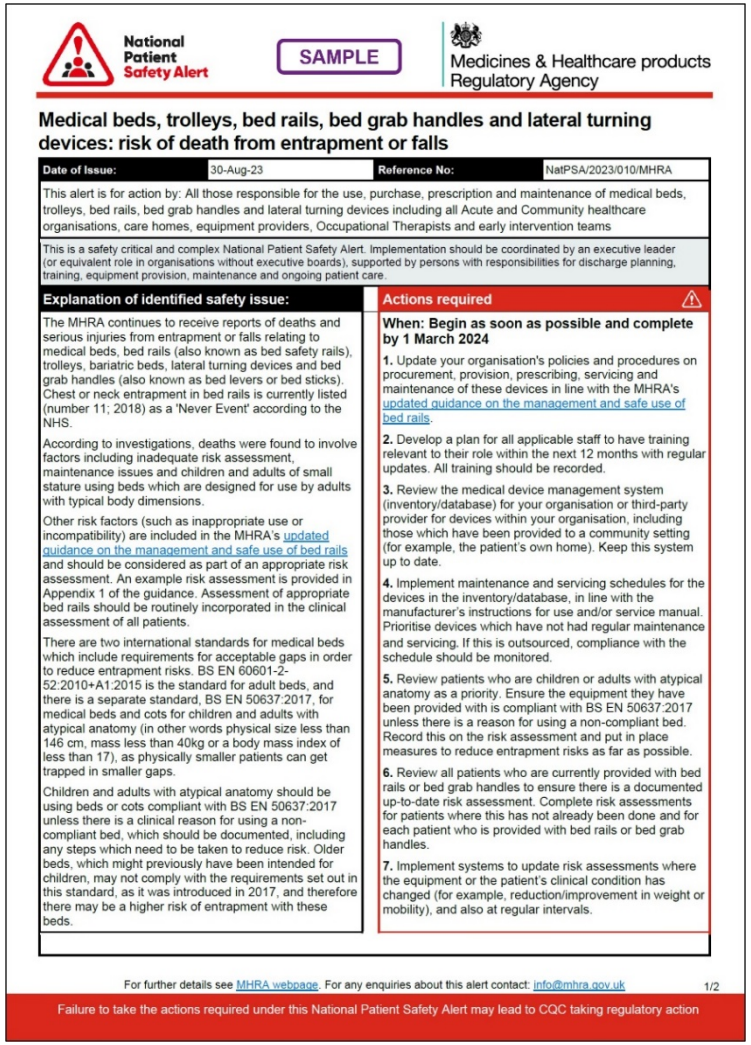
NatPSA safety alerts formats

MHRA



National Patient Safety Alert

SAMPLE

Medicines & Healthcare products Regulatory Agency

Medical beds, trolleys, bed rails, bed grab handles and lateral turning devices: risk of death from entrapment or falls

Date of Issue:	30-Aug-23	Reference No:	NatPSA/2023/010/MHRA

This alert is for action by: All those responsible for the use, purchase, prescription and maintenance of medical beds, trolleys, bed rails, bed grab handles and lateral turning devices including all Acute and Community healthcare organisations, care homes, equipment providers, Occupational Therapists and early intervention teams

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards), supported by persons with responsibilities for discharge planning, training, equipment provision, maintenance and ongoing patient care.

Explanation of identified safety issue:

The MHRA continues to receive reports of deaths and serious injuries from entrapment or falls relating to medical beds, bed rails (also known as bed safety rails), trolleys, bariatric beds, lateral turning devices and bed grab handles (also known as bed levers or bed sticks). Chest or neck entrapment in bed rails is currently listed (number 11; 2018) as a 'Never Event' according to the NHS.

According to investigations, deaths were found to involve factors including inadequate risk assessment, maintenance issues and children and adults of small stature using beds which are designed for use by adults with typical body dimensions.

Other risk factors (such as inappropriate use or incompatibility) are included in the MHRA's updated guidance on the management and safe use of bed rails and should be considered as part of an appropriate risk assessment. An example risk assessment is provided in Appendix 1 of the guidance. Assessment of appropriate bed rails should be routinely incorporated in the clinical assessment of all patients.

There are two international standards for medical beds which include requirements for acceptable gaps in order to reduce entrapment risks. BS EN 60601-2-52:2010+A1:2015 is the standard for adult beds, and there is a separate standard, BS EN 50637:2017, for medical beds and cots for children and adults with atypical anatomy (in other words physical size less than 146 cm, mass less than 40kg or a body mass index of less than 17), as physically smaller patients can get trapped in smaller gaps.

Children and adults with atypical anatomy should be using beds or cots compliant with BS EN 50637:2017 unless there is a clinical reason for using a non-compliant bed, which should be documented, including any steps which need to be taken to reduce risk. Older beds, which might previously have been intended for children, may not comply with the requirements set out in this standard, as it was introduced in 2017, and therefore there may be a higher risk of entrapment with these beds.

Actions required

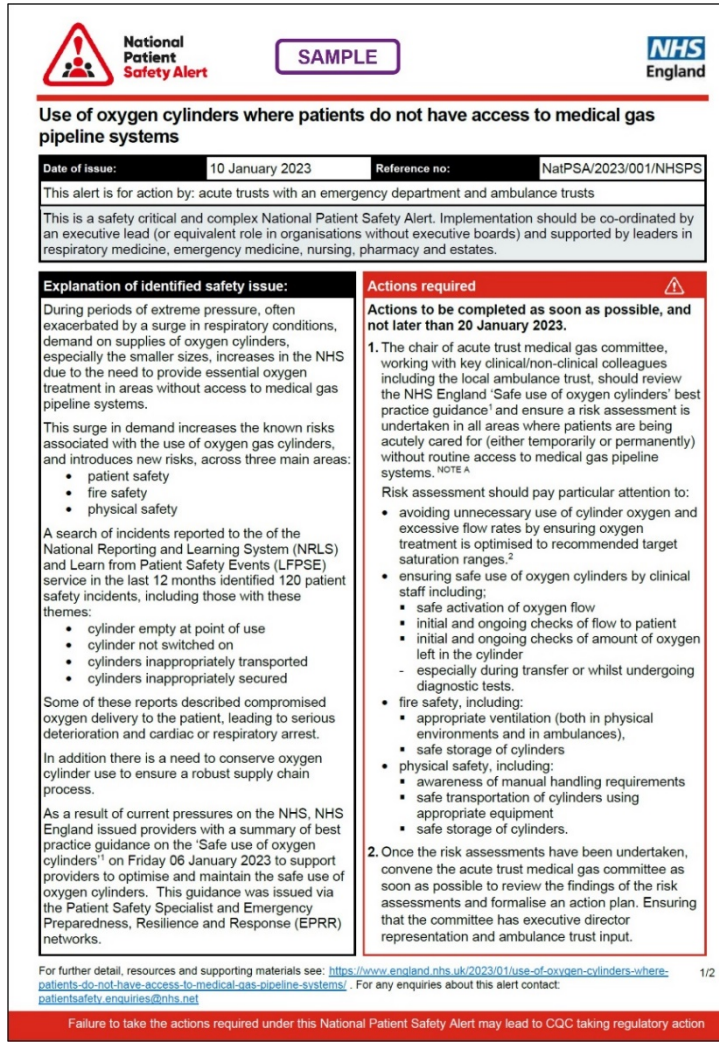
When: Begin as soon as possible and complete by 1 March 2024

1. Update your organisation's policies and procedures on procurement, provision, prescribing, servicing and maintenance of these devices in line with the MHRA's updated guidance on the management and safe use of bed rails.
2. Develop a plan for all applicable staff to have training relevant to their role within the next 12 months with regular updates. All training should be recorded.
3. Review the medical device management system (inventory/database) for your organisation or third-party provider for devices within your organisation, including those which have been provided to a community setting (for example, the patient's own home). Keep this system up to date.
4. Implement maintenance and servicing schedules for the devices in the inventory/database, in line with the manufacturer's instructions for use and/or service manual. Prioritise devices which have not had regular maintenance and servicing. If this is outsourced, compliance with the schedule should be monitored.
5. Review patients who are children or adults with atypical anatomy as a priority. Ensure the equipment they have been provided with is compliant with BS EN 50637:2017 unless there is a reason for using a non-compliant bed. Record this on the risk assessment and put in place measures to reduce entrapment risks as far as possible.
6. Review all patients who are currently provided with bed rails or bed grab handles to ensure there is a documented up-to-date risk assessment. Complete risk assessments for patients where this has not already been done and for each patient who is provided with bed rails or bed grab handles.
7. Implement systems to update risk assessments where the equipment or the patient's clinical condition has changed (for example, reduction/improvement in weight or mobility), and also at regular intervals.

For further details see MHRA webpage. For any enquiries about this alert contact: info@mhra.gov.uk 1/2

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

NHS England



National Patient Safety Alert

SAMPLE

NHS England

Use of oxygen cylinders where patients do not have access to medical gas pipeline systems

Date of issue:	10 January 2023	Reference no:	NatPSA/2023/001/NHSPS

This alert is for action by: acute trusts with an emergency department and ambulance trusts

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 leaders in respiratory medicine, emergency medicine, nursing, pharmacy and estates.

Explanation of identified safety issue:

During periods of extreme pressure, often exacerbated by a surge in respiratory conditions, demand on supplies of oxygen cylinders, especially the smaller sizes, increases in the NHS due to the need to provide essential oxygen treatment in areas without access to medical gas pipeline systems.

This surge in demand increases the known risks associated with the use of oxygen gas cylinders, and introduces new risks, across three main areas:

- patient safety
- fire safety
- physical safety

A search of incidents reported to the of the National Reporting and Learning System (NRLS) and Learn from Patient Safety Events (LFPSE) service in the last 12 months identified 120 patient safety incidents, including those with these themes:

- cylinder empty at point of use
- cylinder not switched on
- cylinders inappropriately transported
- cylinders inappropriately secured

Some of these reports described compromised oxygen delivery to the patient, leading to serious deterioration and cardiac or respiratory arrest.

In addition there is a need to conserve oxygen cylinder use to ensure a robust supply chain process.

As a result of current pressures on the NHS, NHS England issued providers with a summary of best practice guidance on the 'Safe use of oxygen cylinders'[1] on Friday 06 January 2023 to support providers to optimise and maintain the safe use of oxygen cylinders. This guidance was issued via the Patient Safety Specialist and Emergency Preparedness, Resilience and Response (EPRR) networks.

Actions required

Actions to be completed as soon as possible, and not later than 20 January 2023.

1. The chair of acute trust medical gas committee, working with key clinical/non-clinical colleagues including the local ambulance trust, should review the NHS England 'Safe use of oxygen cylinders' best practice guidance[1] and ensure a risk assessment is undertaken in all areas where patients are being acutely cared for (either temporarily or permanently) without routine access to medical gas pipeline systems. NOTE A

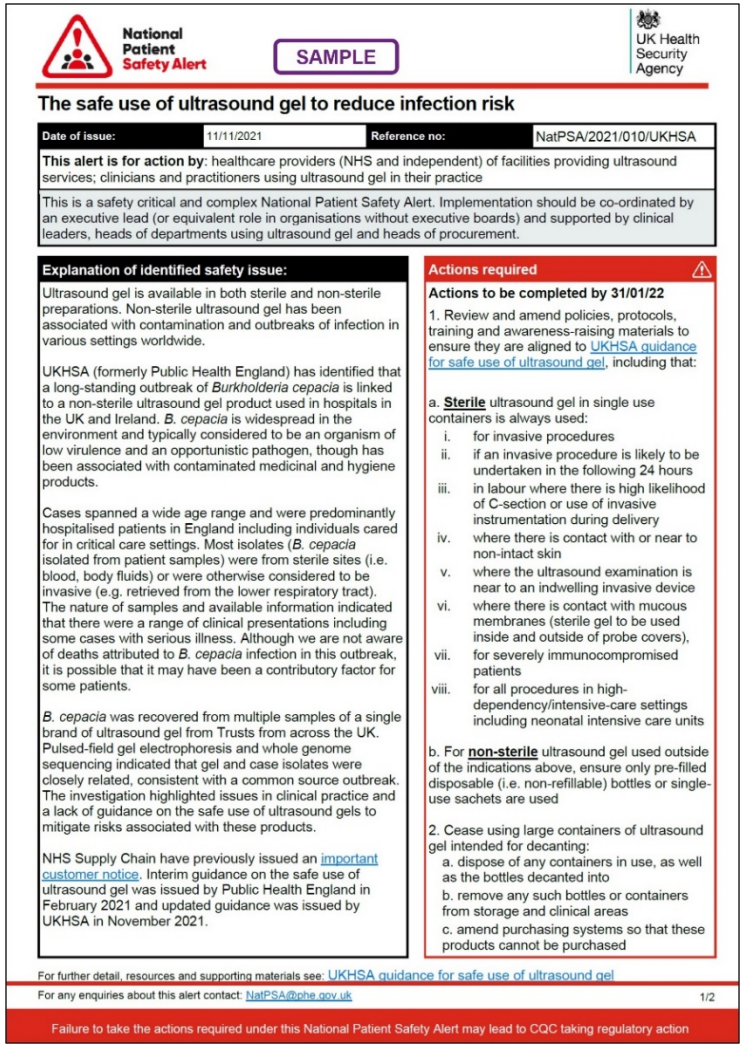
   Risk assessment should pay particular attention to:

   - avoiding unnecessary use of cylinder oxygen and excessive flow rates by ensuring oxygen treatment is optimised to recommended target saturation ranges.[2]
   - ensuring safe use of oxygen cylinders by clinical staff including;
     - safe activation of oxygen flow
     - initial and ongoing checks of flow to patient
     - initial and ongoing checks of amount of oxygen left in the cylinder
     - especially during transfer or whilst undergoing diagnostic tests.
   - fire safety, including:
     - appropriate ventilation (both in physical environments and in ambulances),
     - safe storage of cylinders
   - physical safety, including:
     - awareness of manual handling requirements
     - safe transportation of cylinders using appropriate equipment
     - safe storage of cylinders.
2. Once the risk assessments have been undertaken, convene the acute trust medical gas committee as soon as possible to review the findings of the risk assessments and formalise an action plan. Ensuring that the committee has executive director representation and ambulance trust input.

For further detail, resources and supporting materials see: https://www.england.nhs.uk/2023/01/use-of-oxygen-cylinders-where-patients-do-not-have-access-to-medical-gas-pipeline-systems/ . For any enquiries about this alert contact: patientsafety.enquiries@nhs.net 1/2

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

UK Health Security Agency



National Patient Safety Alert

SAMPLE

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

For any enquiries about this alert contact: NatPSA@phe.gov.uk 1/2

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