National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

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

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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.

Additional information:

From 1 January 2018 to 31 December 2022, the MHRA received 18 reports of deaths related to medical beds, bed rails, trolleys, bariatric beds, lateral turning devices and bed grab handles, and 54 reports of serious injuries. The majority of these were due to entrapment or falls.

Investigations into incidents involving falls often found the likely cause to be worn or broken parts, which should have been replaced during regular maintenance and servicing, but which were either not carried out or were carried out improperly.

Incidents involving entrapment were found to involve factors including:

- A lack of any risk assessment.
- Risk assessment not being updated following a change of equipment or a change in a patient's condition.
- A lack of maintenance and servicing.
- Incompatibility issues - for example, accessories (bumpers), pressure relieving mattresses.
- Children and adults with atypical anatomy using inappropriate equipment. Young patients and adults with smaller body anatomy should be using beds or cots compliant with BS EN 50637:2017, which is based on the international standard for medical beds.

Action 2. Training for applicable staff should be relevant to their role and include, where appropriate, the risks and operation of these devices, the provision of training to carers/patients, reporting issues, servicing and maintenance and risk assessments.

Action 3. For more information on a medical device management system (inventory/database), see the MHRA's guidance on Managing Medical Devices. This should include as a minimum the manufacturer, make and model, lot number, location and date of last service of the device.

Action 5. Organisations which regularly require beds for children and for children and adults with atypical anatomy should plan to replace non-compliant beds as soon as possible.

The MHRA has updated the guidance on the management and safe use of bed rails to include learnings from incidents reported to us. The MHRA met with relevant organisations and stakeholders to ensure that the updated guidance is widely supported. The updates include:

- The need for risk assessments to be updated regularly. The frequency of reviewing the risk assessment will vary depending on the patient and their circumstances and should be recorded as part of the risk assessment, but will likely be more frequent for children.
- The entrapment risks that trolleys with side rails share with medical beds.
- Additional risks relating to bariatric beds and lateral turning devices.
- The differences between bed rails and bed grab handles and the risks if they are used incorrectly.
- Involving the patient and/or their family or carers in the decision to use bed rails.
- Ensuring that the most up-to-date version of the instructions for use are being used and are provided to the bed occupant and/or their family and carers.

Stakeholder engagement

We consulted with NHS England and representatives from Scottish and Welsh Governments and the Department of Health Northern Ireland; Royal College of Occupational Therapists; Care Quality Commission (CQC); MDSO Network Editorial Board; Hospice UK; National Association for Safety and Health in Care Services (NASHiCS). The Health and Safety Executive provided a limited amount of support to MHRA in producing this guidance.