MDSO Network Bed Rails FAQ

Document history:

Version Control (VX.X)	Date (Format DD/MM/YY)	Summary of formatting changes
V1.4	06/12/2023	First version released

Key links:

- Guidance: Bed rails management and safe use
- NatPSA/2023/010/MHRA
- Guidance: Managing medical devices

Questions:

1. **Scope**
   a. Q: Does the NatPSA apply to patients on active caseloads as well as previous patients who have been discharged / individuals in the community?
   A: Yes, this alert applies to all patients provided with equipment and does not differentiate between patients who have been discharged from an active caseload. Whoever has commissioned the service to provide equipment in the community has a responsibility to ensure the actions within this alert are followed. This alert is intended to address the known issue of patients being discharged home with equipment and then subsequently receive no further follow-up or periodic risk assessment.

   b. Q: Examination Couches: do these fall outside the scope of this alert? Although they are not patient trolleys, some of these do have 'side rails' but not 'bed rails'?
   A: Examination couches may present a risk if patients are left unattended and in this situation the principles of this alert should be considered. However, no incidents have been reported so far for this type of medical device and therefore they are not currently included within the scope of this alert.

   c. Q: Are cots included in this alert?
   A: Yes, the alert applies to cots and cribs.

2. **Standards**
   a. Q: What standards apply to patient / Emergency Department (ED) trollies?
   A: There are no specific standards for patient / ED trollies, however, they are still required to comply with the UK Medical Device Regulations 2002 (as amended), which includes ensuring

that risks are reduced as far as possible. Side rail entrapment and falls from patient / ED trollies resulting in severe harm and fatality have been recorded. Additionally, patient flow issues can also result in patients remaining on trollies for longer periods of time which can mean they effectively operate as a bed, so in these cases the same risk assessments should apply.

b. Q: Do all adult beds in-use have to meet either BS EN 60601-2-52:2010+A1:2015 or BS EN 50637:2017?
A: Beds are only required to meet the applicable standards in-place at the time of purchase. This alert recognises newer standards are in-place that offer additional safety benefits when compared to earlier standards. The alert and guidance requests that beds made to older standards are phased out as soon as reasonably practicable.

c. Q: Do you have any advice for the continued use of older legacy equipment which may not be compliant with the recent standard for medical beds / cots for children and adults with atypical anatomy?
A: See page 11 of MHRA guidance on managing and using bed rails safely. Although legacy beds can continue to be used, they may not have been assessed to the current standards by the manufacturer. Therefore, you will need to assess if they are still suitable for your requirements. If continuing to use this legacy equipment is thought to pose an increased risk to patients, then a risk would need to be raised on your risk register to monitor / record this and appropriate mitigation strategies. It is good practice to have a replacement plan for equipment, and any identified risks can then be discussed with the replacement plan budget holder.

d. Q: Is the alert asking for all beds to be compliant with both standards or is it dependent on the patient? For example, if Older Peoples services have beds that are all compliant with BS EN 60601-2-52:2010+A1:2015 then we are okay to continue using them providing they are not an atypically sized adult?
A: It is unlikely that any beds meet both standards and this is not a requirement of the alert. The bed needs to be compliant for the patient that is using it, and the alert advises on which standard is relevant depending on the size and anatomy of the patient.

e. Q: Please can a list be provided that shows which make/models are confirmed as compliant with either or both standards?
A: This is not currently available, however if you contact your procurement / purchasing department they can send out a request for information and / or tender asking for BS EN 50637 compliant beds.

3. Training

a. Q: What kind of training is required e.g. user training on all beds / trolleys, risk assessments? How often should training be completed? Is this intended to be 'user training' on all beds/trolleys and if so, how often is sufficient?
A: See page 14 of MHRA guidance on managing and using bed rails safely. The training refresher period will be influenced by complexity of device and clinical environment it is used in. In some cases, one-off training may be suitable whereas in high-risk areas such as critical care (e.g. patient with unstable spines and / or more complicated beds), periodic refresher

training may be more appropriate. You may also want to seek additional guidance from the manufacturer.

b. Q: Are there any training resources available or being developed e.g. a national eLearning module?
A: Currently there aren't any generic training modules available. A bank of shared resources is being developed on the MDSO Network MS Teams channel. If you have any training resources that you have found helpful, then please share these with the MDSO Network and these can be added to the MDSO MS Teams channel for others to access. Discussions are underway to explore the possibility of further training materials.

c. Q: How are people in community services completing retrospective risk assessments as this would require a review of patients which were not funded for?
A: Currently unable to provide an answer to this question, however we will update in the future if this information becomes available.

4. Maintenance

a. Q: How often do other Trusts service their trolleys and beds?
A: Beds and trollies should be serviced in-line with manufacturer recommendations. Any extension of the service period should only be done as part of a documented risk assessment. See MHRA guidance on managing medical devices for further information.

5. Purchasing

a. Q: Have any Trusts been able to purchase beds using capital money?
A: This depends on local interpretation of capital rules as to whether a number of beds can be grouped together into a single capital purchase. If you are unsure of the requirements within your organisation, discuss this with your Capital Finance Manager.

6. Risk Assessments

a. Q: Is there a resource sharing page for risk assessments and other useful tools?
A: A subchannel has been set up in the MDSO Network MS Teams channel.

b. Q: What would be considered an appropriate risk assessment for a hospital setting.
A: An example of a risk assessment checklist is provided in Appendix 1 of the MHRA guidance on managing and using bed rails safely.

c. Q: How should action 6 be interpreted for a hospital setting?
A: Action 6 refers to both bed rails and bed grab handles, so if any organisation uses either of these then Action 6 would apply.

d. Q: What would be considered a regular interval for updating risk assessments for patients in an acute setting?

A: This depends on the patient but should be detailed in the organisations policy as well as a dynamic risk assessment process that accommodates and responds to the changing risk of each patient during their stay.

e. Q: Does the alert require a bed rail assessment specifically or is it for any bed equipment prescribed for an individual patient?
A: Any assessment should consider all factors including bed rails and other bed equipment that may present a risk to the patient. Bed rail assessments are usually to be found associated or aligned to the Trust Falls Prevention Policy for patients in a hospital setting (Action 7).

f. Q: When a bed is issued to a patient from an acute Trust to facilitate discharge, who is responsible for ongoing risk assessments in the following years?
A: There needs to be clear lines of accountability between organisations to agree who this responsibility lies with. However, if this is not clear please contact your ICS / ICB to discuss further.

7. Incidents

a. Q: Please can you give examples of incidents that have caused patient harm as this will help provide further context.
A: Examples are provided in the updated MHRA guidance on managing and using bed rails safely which was published alongside the alert.

8. Miscellaneous

a. Q: It would be helpful to see hear an acute vs community perspective?
A: A dedicated forum has been created on the MDSO Network MS Teams channel for resources to be shared.

b. Q: Please provide examples of lateral turning devices that are referred to in the alert.
A: A lateral turning device is typically a mattress that can inflate on one side to facilitate turning of a patient. The MHRA alert applies to all models of turning device as they are used on patients who are unable to move themselves and therefore would be unable to remove themselves from harm if they were left unattended.