MDSO Network Bed Rails FAQ

The Medical Device Safety Officer (MDSO) Network has produced this Frequently Asked Questions (FAQ) resource in consultation with the Medicines and Healthcare products Regulatory Agency (MHRA) and NHS England (NHSE), to help answer questions received from members of the MDSO Network regarding the Bed Rails National Patient Safety Alert (NatPSA). This resource is intended to supplement the official MHRA NatPSA and guidance by providing additional clarification around points contained within the original alert. To be clear, none of the information within this document places new actions or requirements on organisations. This resource has been made available for wider sharing and you are welcome to download and circulate to colleagues.

The MDSO network represents NHS Trusts and private organisations who provide healthcare in England. The MDSO role is designed to support patient safety within organisations by providing specialist advice on medical device safety notices, including implementing and sharing learning from medical device incidents.

Please note that there may be references to the "MDSO Network MS Teams channel" throughout the document. This is a closed forum and therefore if you are not an MDSO but would like access to any of the resources hosted on the MDSO Network MS Teams channel, please contact your organisations MDSO who will be able to share those with you.

Document history:

Version Control (VX.X)	Date (Format DD/MM/YY)	Summary of formatting changes
V1.4	06/12/2023	• First version released
V1.5	28/03/2024	• Added introductory paragraph to explain document purpose • New questions (2f and 8c), and 2a expanded

Key links:

- Guidance: Bed rails management and safe use
- NatPSA/2023/010/MHRA
- Guidance: Managing medical devices
- Further information about the MDSO network

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) trolleys?
   A: There are no specific standards for patient trolleys, and they do not fall under the scope of the medical bed standards, BS EN 60601-2-52:2010+A1:2015 and BS EN 50637:2017. Therefore, you are not required to replace non-compliant trolleys 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. If side rails are used with trolleys there is a risk of entrapment, particularly if the occupant is left unattended. Incidents of entrapment and falls resulting in severe harm and fatality have been recorded. Additionally, patient flow issues can result in patients remaining on trollies for longer periods of time which can mean they effectively operate as a bed. In these cases, a risk assessment is still required.

   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.

f. Q: Are insufficient funding or inability to source compliant beds appropriate reasons for using non-compliant beds?
A: Action 5 of the Alert states that non-compliant beds can be used if there is a reason to do so. An inability to source appropriate compliant beds or insufficient funding to procure compliant beds are both suitable reasons for using non-compliant beds. In order to complete Action 5, there would still need to be measures in place to ensure that this is noted in the risk assessment and measures are taken to reduce entrapment risks as far as possible. If this is in place, then Action 5 can be considered to be completed.

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.

c. Q: Is the deadline being extended? What should an organisation do if they are unable to complete all actions by the deadline?
A: The MHRA is not planning to extend the deadline due to the severity of the risk. The MHRA have consulted with key stakeholders about whether the deadline should be extended and it was agreed that the deadline should not be extended. If an organisation is unable to complete an action, it should be added to their risk register with a clear action plan for completing the action as soon as possible. Adding this to the risk register does not count as completing the action.