



Medicines & Healthcare products Regulatory Agency

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[REDACTED]

18th December 2023

Dear [REDACTED]

FOI 23/946 – queries from NPSA

Thank you for your Freedom of Information request dated 20th November 2023, where you asked: *In regard to the National Patient Safety Alert dated 30-Aug-2023 reference NatPSA/2023/010/MHRA please could you provide more information on the following issues:*

- 1. What is meant by the term “regular” for updates or reviews of risk assessments? Please provide your definition of it.*
- 2. Regarding the 18 deaths please can you breakdown which pieces of equipment each of the deaths related to*
- 3. Regarding the 54 serious injuries please can you breakdown which separate pieces of equipment caused the injuries as currently beds, trolleys, bed rails, lateral turning devices and bed grab handles are grouped together*
- 4. Regarding the date of March 2024 which actions are expected to be completed by then?*
- 5. Is it correct that in the past Bed Grab Handles were risk assessed due to the alert from 2007 only involving medical beds, but the new alert from 2023 is including risk assessments for third party bed levers and bed sticks on divan beds as well?*

This is significant for us because over 12,000 bed levers have been issued. Bed rails previously known as cot sides have an established Risk Assessment form. Do you have a form in mind as a risk assessment for bed levers on divan beds?

Further to you request please see a response to each of your questions:

1. The frequency of risk assessment reviews will be highly dependent on the bed occupant. Part of the initial risk assessment should include determining how regularly the assessment should be reviewed. This will be more frequently for bed occupants whose condition is changing rapidly, whether this is a positive or negative change, as their needs and the risks of using these devices may change. It is therefore not possible to give a specific timeframe for regular reviews, but that this will be at a frequency to ensure the risk assessment is continuing to be appropriate to the bed occupant in view of their continued safety.
2. Regarding the 18 deaths stated please see the breakdown below:

Table 1: Displays the number of reports received for each piece of equipment.

Equipment	Number of reports
Bed	5
Bed grab handles	5
Rails	8

Please note, the inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. Additionally, the figures provided above are not the same as complication rates.

- Regarding the 54 serious injuries stated, please see the breakdown below:

Table 2: Displays the number of reports received for each piece of equipment.

Equipment	Number of reports
Bed	30
Bed grab handle	4
Rails	18
Other	6

Please note, the inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. Additionally, the figures provided above are not the same as complication rates.

- All actions are expected to be completed by the deadline of 1 March 2024. Action 2 requires that there is a plan in place for training staff by this deadline of 1 March 2024. Training of all staff should be completed within 12 months of this date.
- The alert from 2007 applied to all bed rails and bed grab handles, not only to bed grab handles used with medical beds. Along with this, the previous version of the Guidance document (current version linked to in the National Patient Safety Alert), had stated that bed grab handles (including bed sticks and bed levers) carried many of the same risks as bed rails and should therefore be risk assessed. Again, there was no mention of this only applying to those used with medical beds. The MHRA therefore considers that the requirement to carry out risk assessments for all bed grab handles, bed levers or bed sticks is not new and has been in place for several years.

The MHRA does not have a specific risk assessment for bed grab handles, however, given that they share many of the same risks as bed rails, it is likely that a modified version of the bed rails risk assessment would be appropriate.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team
 Safety and Surveillance
 Medicines and Healthcare products Regulatory Agency

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