Safeguarding public health

MHRA

Device Bulletin

Safe Use of Bed Rails

DB2006(06)
December 2006
website only

DH Department of Health

Contents

1 Executive summary

This document updates and replaces our previous guidance provided in DB 2001(04) 'Advice on the safe use of bed rails'.

This guidance:

- applies mainly to 'third party' bed rails, i.e. those that are not supplied by the bed manufacturer
- clarifies that bed rails used following an individual risk assessment can be very beneficial for some bed occupants
- draws attention to the need for a full risk assessment of the suitability of the bed rail, bed and bed base in combination for the bed occupant
- highlights the potential risks associated with the use of different types of bed rail
- provides general guidance for reducing the risk of entrapment
- provides information that can be used to develop a local policy to ensure the safe use of bed rails
- highlights the importance of regular maintenance
- provides information on how to report incidents to the MHRA
- identifies other literature which may be useful for background information or reference material.

1.1 Who this document is for

This document is aimed at all users, carers and staff with responsibility for the provision, prescription, use, maintenance and fitting of bed rails. This includes:

- MHRA liaison officers (for onward distribution)
- nurses in hospitals and the community
- occupational therapists
- care home managers and staff
- carers in the community and care-at-home staff
- community equipment stores (CES) and loan store managers
- those responsible for purchasing beds and bed rails
- maintenance staff
- health and safety managers
- risk managers.

2 Introduction

Bed rails are used extensively in care environments to prevent bed occupants falling out of bed and injuring themselves. They usually achieve this very successfully.

However, there have been serious incidents reported to MHRA. The majority of these involved third party bed rails used on domestic, divan and metal framed beds that have led to injury and death by asphyxiation after entrapment of the head or neck.

Most incidents occurred in community care environments, particularly in residential and private nursing homes.

Most of these deaths could have been prevented if adequate risk assessments and appropriate risk management had been carried out.

2.1 Scope

This bulletin identifies areas for safe practices, so that policies and procedures can be reviewed and put in place. This includes:

- risk management
- management responsibilities
- meeting legal requirements
- planned training
- planned maintenance.

It also identifies areas such as:

- ensuring that a bed rail is necessary
- the need for good communication between bed occupant and carers or staff
- compatibility of the bed rail and bed, mattress and occupant combination
- correct fitting and positioning of the bed rails initially and after each period of use
- re-assessing for changing needs of the bed occupant.
- the need for risk assessment before the provision and use of bed grab handles.

2.2 Clinical governance

Care organisations are required to make safety a priority when delivering patient care. This generally occurs within a framework of risk management and clinical governance. Assessments by healthcare professionals are increasingly being used as a method of identifying, quantifying and managing risks associated with the use of medical devices before a device is used. The MHRA recommends that organisations operate fully documented risk management procedures for all medical devices.

2.3 Bed rails

For the purpose of this document the term **bed rail** will be adopted, although other names are often used, such as: bed side rails, side rails, cotsides, and safety sides.

In general, manufacturers intend their bed rails to be used to prevent bed occupants from falling and sustaining injury. They are **not** designed or intended to limit the freedom of people by preventing them from intentionally leaving their beds; nor are they intended to restrain people whose condition disposes them to erratic, repetitive or violent movement.

Rigid bed rails can be classified into **two basic types:**

- **integral** types that are incorporated into the bed design and supplied with it, or are offered as an optional accessory by the bed manufacturer, to be fitted later

- **third party** types that are not specific to any particular bed model. They are intended to fit a wide range of domestic, divan or metal framed beds from a different supplier.

We know from our investigation that the integral type is involved in far fewer adverse incidents than the third party type. The majority of integral bed rails meet recognised product standards that include generally acceptable gaps and dimensions when fitted to the bed. They may also be CE marked as medical devices to the Medical Devices Regulations [1], in combination with, or as an accessory to the bed.

All types of bed rail should be used with care and only after a full, documented risk assessment has been carried out for each bed occupant. This will determine if their use is the most appropriate method of risk management for the bed occupant.

2.4 Bed grab handles

Bed rails should **not** be confused with **bed grab handles** (also known as bed levers or bed sticks) which are designed to aid mobility whilst transferring to and from a bed.

Bed grab handles are **not** designed to prevent patients falling from their bed.

Bed grab handles come in a variety of sizes and designs (Figures 1 and 2). They should not be used as, or instead of, bed rails, despite the larger models looking similar in both size and design.

It is essential to carry out a risk assessment based on the bed occupant's requirements and the manufacturer's instructions for use to ensure that use of the bed grab handle does not introduce unacceptable risks for the bed occupant.

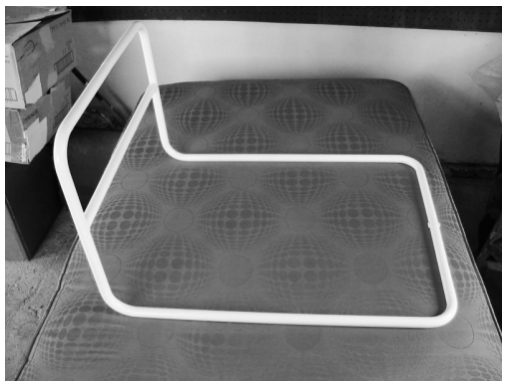

Figure 1

Figure 2

3 Risk management and assessment

3.1 Risk management

When bed rails and bed safety equipment are prescribed, issued or used, it is essential that any risks are balanced against the anticipated benefits to the user. Where manufacturers cannot remove risks during the design process, subsequent warnings of any risk should be clearly displayed in the user instructions and product markings. Any such warnings or limitations to use, including the necessary maintenance schedules throughout its intended life, should be passed on to all users of the equipment and complied with.

Users, carers and prescribers need to carefully consider the content of the manufacturer's instructions for use and any warnings about risks.

The equipment should only be used and maintained in line with the manufacturer's instructions for use. If the manufacturer's instructions do not fully cover these points then please report this to the MHRA (see section 9).

3.2 Risk assessment

There are many bed rails on the market, having a variety of fitting and operation methods. There is also a wide range of beds: divans, wooden and metal bedsteads, hospital type beds, adjustable beds etc.

The possible combinations of bed rails, beds and mattresses, together with the uniqueness of each bed occupant, means that a careful and thorough assessment is necessary if serious incidents are to be avoided.

It is unlikely that one type of bed and bed rail will be suitable for a wide range of users with different physical sizes and needs.

The points to consider during a risk assessment include:

- is the person likely to fall from their bed?
- if so, are bed rails an appropriate solution?
- if not an appropriate solution, can an alternative method of bed management be used?
- could the use of a bed rail increase risk – for example, if an active but disorientated bed occupant tries to climb over it?

- could the risk of falling from bed be reduced by means other than bed rails?
- could the bed occupant's physical or clinical condition increase the risk of entrapment?

Our adverse incident investigations have shown that the physical or clinical condition of bed occupants means that some are at greater risk of entrapment in bed rails. Those at greater risk include older people and adults or children with:

- communication problems or confusion
- dementia
- cerebral palsy
- very small or very large heads
- repetitive or involuntary movements
- impaired or restricted mobility.

Risk assessments should be carried out before use and then reviewed and recorded after each significant change in the bed occupant's condition, replacement of any part of the equipment combination and regularly during its period of use.

3.3 Risk assessment checklist example

We provide an example of a risk assessment checklist, as a result of feedback from users of bed rails and the findings of adverse incident investigations.

Please note that it should not be adopted or used without adequate consideration of a specific bed occupant's needs and local policies. The checklist should be used in conjunction with the guidance in this document, together with the judgement of the nurse, therapist, user and carer involved.

Risk assessment checklist example

Is the bed rail to be used with a typically sized adult bed occupant? (for a child or a small adult, see section 5.2)	☐ Yes ☐ No
Does the manufacturer/supplier provide any information on special considerations or contra-indications?	☐ Yes ☐ No
Do you have enough information from the supplier to be able to select and fit the bed rail appropriately?	☐ Yes ☐ No
Is the bed rail suitable for the intended bed, according to the supplier's instructions?	☐ Yes ☐ No
Do the fittings or mattress allow the bed rail to be fitted to the bed securely, so that there is no excessive movement?	☐ Yes ☐ No
Does the benefit of any special or extra mattress outweigh any increased entrapment risk created by extra compression at the mattress edge?	☐ Yes ☐ No
Are the bed rails high enough to take into account any increased mattress thickness or additional overlay?	☐ Yes ☐ No
Are gaps avoided that could present an entrapment risk to the bed occupant? Is their head or body large enough not to pass: • between the bars of the bed rails? • through any gap between the bed rail and side of the mattress? • through the gap between the lower bed rail bar and the mattress, allowing for compression of the mattress at its edge?	 ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
Are gaps between bars / rails less than 120 mm?	☐ Yes ☐ No
Are the headboard / footboard to bed rail end gaps less than 60 mm or greater than 250 mm?	☐ Yes ☐ No
Has the bed rail been inspected and maintained regularly, if previously used?	☐ Yes ☐ No

'Yes' boxes indicate the desired outcome. If any 'No' box has been ticked, there may be a serious risk of entrapment with the proposed combination. Review immediately.

Risk assessments should be carried out before use and then reviewed and recorded after each significant change in the bed occupant's condition, replacement of any part of the equipment combination and regularly during its period of use.

4 Purchase, selection, safe fitting and use of bed rails

4.1 Purchase

Adjustable or profiling beds usually have compatible integral type bed rails available from the manufacturer; these are preferable to other systems that may not fit as well.

Third party bed rails require careful selection, see 4.2 below.

If bed rails are being purchased for stock, general factors can be considered at the purchase stage:

- is the spacing between the bars less than 120 mm? A larger spacing can cause entrapment for an adult
- the types of bed they are likely to be used on; specific models or a range
- whether they meet any recognised product standards regarding dimensions, such as BS EN 60601-2-38 [2] or BS EN 1970 [3]
- whether they are suitable for children or small adults.

4.2 Selection

In community care environments it is common for beds and bed rails to have been acquired from different sources.

Bed rails for divan beds (domestic) are nearly always a third party type, not tailored for one specific bed or mattress length and width, or a specific mattress density.

In all cases it is essential that the selection process follows a risk assessment considering the needs of the bed occupant (see section 3.2).

Questions to consider when selecting a bed rail:

- are the instructions for use (IFU) available? If the manufacturer does not provide them, do not select the bed rail and report this to the MHRA (see section 9)
- does the manufacturer provide advice on any contra-indications for its use (i.e. times not to use), and can they be followed?
- is the bed rail suitable for the bed to which it will be fitted?
- is it to be used with a person of small build (e.g. a child)?

- are there spaces between the bed rail bars that are an obvious entrapment hazard?
- is maintenance information available?

4.3 Safe fitting and use

It is essential that all bed rails can be fitted correctly to an appropriate bed base allowing safe use. This will include points such as:

- can the bed rail be fitted to the bed correctly?
- do staff understand how to fit it properly?
- are mounting clamps, if present, used in the correct orientation?
- is there a gap between the lower bar of the bed rail and the top of the mattress which could cause entrapment?
- does the mattress compress easily at its edge, creating an entrapment hazard?
- will the gap between the end of the bed rail and the headboard or wall allow entrapment?
- is there a gap between the bed rail and the side of the mattress that could trap the bed occupant's head or body?
- is the bed rail secure and robust – could it move away from the side of bed and mattress in use, creating an entrapment hazard?
- do the dimensions and overall height of the mattress(es) compromise the effectiveness of the bed rail – are extra height bed rails needed?

4.4 What to avoid

As a result of a number of investigations, the MHRA has identified a number of issues largely associated with third party bed rails that, if avoided during the selection process, will reduce the likelihood of adverse incidents. For example avoid:

- poor bed rail designs with bar spacing of more than 120 mm, which could allow an occupant to slip between them
- gaps between 60 mm and 250 mm at the end of the bed rail and the headboard / footboard which could be sufficient to cause neck entrapment
- using bed rails designed for a divan bed on a wooden or metal bedstead; this can create gaps which may entrap the occupant

- using insecure fittings or designs which permit the bed rail to move away from the side of the bed or mattress, creating an entrapment hazard
- using only one side of a pair of third party bed rails when the other side is against a wall – the single rail may be insecure and move
- mattress combinations whose additional height lessens the effectiveness of the bed rail and may permit the occupant to roll over the top. Extra height bed rails are available if mattress overlays are to be used
- mattress and bed rail combinations where the mattress edge easily compresses, introducing a gap between the mattress and the bed rail.

5 Special considerations

5.1 Adjustable or profiling beds

Most profiling beds feature integral bed rails that are incorporated into the bed design or are offered as an optional accessory by the bed manufacturer. We have found they are involved in far fewer adverse incidents than the third party type.

They may also be CE marked to the Medical Devices Regulations in combination with, or as an accessory to, the bed.

Some beds have a single-piece bed rail along each side of the bed; these require care in use because when the bed profile is adjusted entrapment hazards can be created, which are not present when the bed is in the horizontal position.

Split bed rails (one pair at the head end and one pair at the foot end) also require care in use because the space between the head and foot end rails may vary according to the bed profile adjustment. Therefore, on some designs, entrapment hazards may be created when the bed is adjusted to profiles other than flat.

Care should be taken to use the rails as instructed by the bed manufacturer.

5.2 Using bed rails with children

Most bed rails are designed to be used only with adults and adolescents. A risk assessment (see section 3) should always be carried out on the suitability of the bed rail for the individual child or small adult, as bar spacing and other gaps (e.g. between the bed base/mattress/rails) will need to be reduced.

There are no published standards on bed rails for children. Other standards addressing entrapment risks suggest element spacing should fall within the range 45 mm to 78 mm.

When purchasing or making assessments of bed rails for children, seek guidance on suitable rails from the manufacturers and assess their compatibility with the size of the individual child and the specific circumstances of use.

5.3 Mattress overlays for pressure ulcer prevention or reduction

Before and during use of mattress overlays with bed rails, consider:

- the reduction in the effective height of the bed rail relative to the top of the mattress may allow the occupant to roll over the top of it; extra height bed rails may be required (see Figure 17 in section 7)

- the hazard of entrapment between the side of the mattress and the bed rail may be exacerbated due to the soft, easily compressible nature of the overlay and/or mattress edge (see Figures 15 and 16 in section 7)

- if the standard mattress is replaced with an air mattress or lightweight foam mattress, third party bed rail assemblies (including the mattress and bed occupant) can tip off the bed when the bed occupant rolls against the bed rail. This is because many third party bed rails rely on the weight of a standard mattress to hold the assembly in place.

5.4 Inflatable bed sides

Inflatable bed sides are not generally adjustable and may need to be used with a mattress of particular dimensions. When carrying out an assessment on the risk of entrapment, the elasticity (compression and extension) of the material should be taken into account, as the inflatable rails may change shape when the bed occupant leans against them.

Some inflatable bed sides house the mattress in its own ‘pocket’ or compartment, a feature which greatly reduces entrapment risks between the mattress and the side walls.

Inflatable bed sides need to be fully inflated to be effective. They may deflate over time so regular checks should be made to ensure this has not happened.

Care should be taken to use the inflatable bed sides as instructed by the manufacturer.

5.5 Footboards and headboards

If bed rails are required, a headboard or footboard may also be needed. Bed rails must be fitted correctly to avoid creating an entrapment gap (see Figures 11 and 12 in section 7).

Boards with ornamental posts can allow clothing to become caught and should not be used for bed occupants who may not be in control of their movement. They may also have inappropriate gaps that could be an entrapment hazard (see Figure 3).

Figure 3

5.6 Non-metallic materials

Some beds are supplied with wooden or plastic bed rails. If these are poorly designed they can be too flexible and may deform under force, creating an entrapment hazard between the rail and the side of the mattress.

5.7 Bed rail bumpers

Bed rail bumpers, padded accessories or enveloping covers are primarily used to prevent impact injuries but they can also reduce the potential for limb entrapment when securely affixed to the bed or rail. However, bumpers that can move or compress may themselves introduce entrapment risks.

Some covers are not air-permeable and may present a suffocation risk; establish that they are air permeable from the manufacturer or supplier before purchasing.

5.8 Mattress dimensions

The length, width and height of the mattress should be checked to ensure that these dimensions are within the limits specified by the bed manufacturer and do not provide gaps that could increase the risk of entrapment. If the mattress is not the right size, the bed rails may not fit properly and create entrapment gaps.

5.9 Alternatives

Alternatives to bed rails may be considered, such as:

- beds with variable height used in the lowered position
- ‘netting’ or mesh bed sides
- specially made ‘low height’ beds
- alarm systems to alert carers that a person has moved from their normal position or wants to get out of bed.

6 Maintenance

MHRA adverse incident investigations have revealed that some incidents with bed rails have been caused or exaggerated by a lack of maintenance. Bed rails should be included in planned preventative maintenance (PPM) schemes.

Bed rails should be maintained in accordance with the manufacturer's recommendations. For more information on managing medical devices refer to DB 2006(05) [4].

Adjusters, clamps and fixings can wear, work loose, deform or be missing completely, giving rise to unwanted free play which can increase important gaps. Telescopic components can also become loose or jammed, discouraging correct adjustment. Bed clothes, sheets and valances may need to be removed for good access to check these areas properly.

It is also possible that material fatigue can occur. Plastic components also need particular attention as they can degrade due to age, exposure to light and some cleaning chemicals.

Bed rail assemblies must be traceable, for example by labelling with an in-house number. This enables them to be inspected on a regular basis to ensure that they are maintained in a satisfactory condition. Traceability also allows them to be recalled should a safety issue arise, such as a manufacturing fault. Records should be kept of inspections, repairs and maintenance and suppliers of the bed rails should be contacted for advice and replacement parts.

Bed rails found to be unsuitable or in poor condition should be withdrawn from use and scrapped, by physically destroying them. If they are kept or stored (Figure 4), they can easily find their way back into use with potentially disastrous consequences.

Figure 4

Aspects to check during planned maintenance include:

- presence of rust – this can affect the ease of adjustability of telescopic tubes
- welded joints are sound, not showing signs of cracking or failure
- cracking of paint or coating – can point to deeper structural failure
- flaking chrome plating – can cause lacerations
- missing locking handles and fixing clamps (Figure 5)
- loose fixings – these affect the rigidity of the assembly. Nuts should be of the self-locking type (Figure 6)
- free play in joints – this can point towards loose, worn or incompatible components (Figure 7)
- stripped threads on bed frame clamps – does not allow them to be tightened securely
- bent or distorted components (Figure 8).

Any of the above conditions are a good reason to stop using the bed rails.

Figure 5

Figure 6

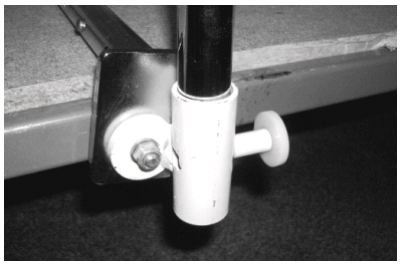

Figure 7

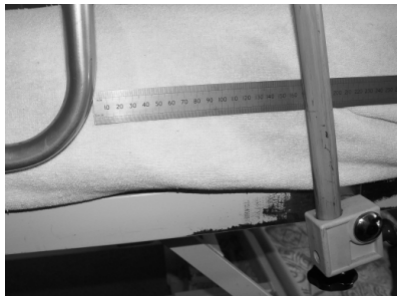

Figure 8

7 Illustrated examples

In this section we provide pictures of common problems that arise with third party bed rails and give some examples of the adverse incidents that have been reported to us.

7.1 Incorrect or omitted risk assessment and consideration of the physical size of the bed occupant

A bed rail was supplied to the parents of a disabled child being cared for in the community. No assessment of the child's physical size was carried out to determine if an entrapment hazard existed. The gap between the horizontal bedrail bars was too large. The child slipped through the gap and was asphyxiated as a result of head entrapment between the bed rail bars. See Figure 9 below.

In another case, a bed rail with a bar spacing of 170 mm was being used for an older person being cared for in a nursing home. No risk assessment was carried out to determine if the device was suitable for use, considering the space between the bars and the bed occupant's size. The person asphyxiated as a result of head and neck entrapment when their body slipped between the bars.

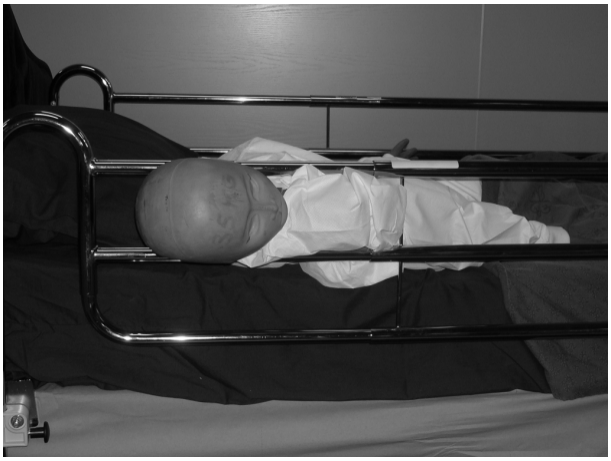

Figure 9

7.2 Incompatibility or unsuitability of a bed rail for the bed

A bed rail intended for use on a divan bed (i.e. having a flat base, the common domestic type of bed) was used on a hospital type bed. This produced a large gap between the bottom of the bed rail and the bed. A disabled child slipped feet first between the bed rail and the bed. The gap was not large enough for the child to pass completely through and the child was trapped at chest level and died from postural asphyxiation (i.e. compression of the chest). See Figure 10 below.

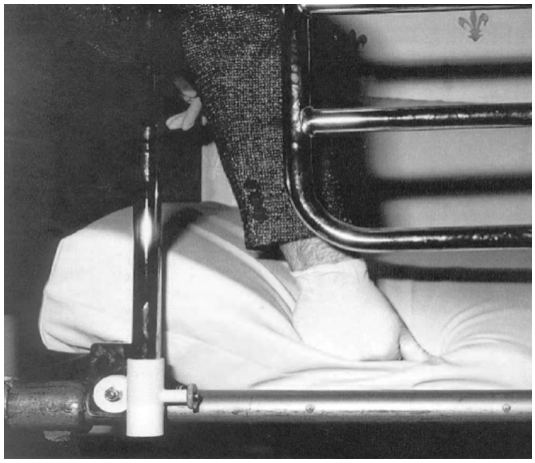

Figure 10

7.3 Entrapment in inappropriate gaps

Entrapment can happen between the end of the bed rail and the headboard if the gap is inappropriate. Avoid gaps between 60 mm and 250 mm which could be sufficient to cause neck entrapment, as shown in Figures 11 and 12 below.

Figure 11

Figure 12

Entrapment can also occur in the space between a poorly fitting mattress and side of the bed rail or bed rail that does not fit the bed base snugly enough. See Figure 13.

Figure 14 shows how the compressible nature of the edge of most mattresses can contribute towards the entrapment potential of existing gaps. This is further illustrated by the bed occupant's weight compressing the mattress in both Figures 15 and 16.

Figure 13

Figure 14

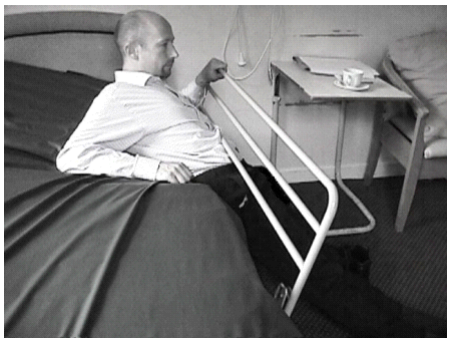

Figure 15

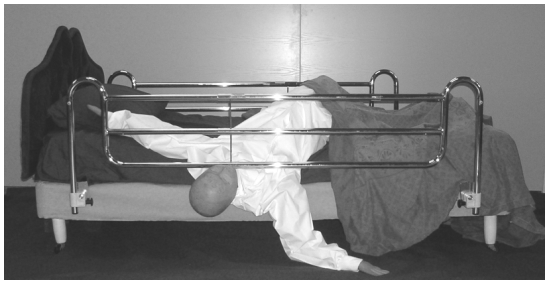

Figure 16

7.4 Bed occupants falling over the top of the bed rails

This can occur if the bed rails are not high enough or are compromised by too high a mattress or mattress combination. For example, a pressure ulcer reduction overlay system was added to a bed that already had a bed rail fitted to it. The additional height of the overlay mattress was not taken into consideration and this compromised the effectiveness of the bed rail (Figure 17). The bed occupant fell from the bed over the rail, sustaining a head injury (Figure 18).

Figure 17

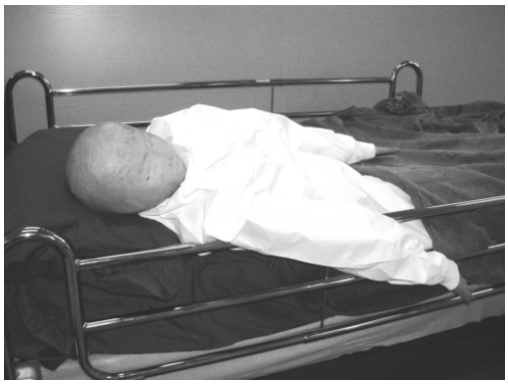

Figure 18

7.5 Bed rails in poor condition from lack of maintenance

A care home had fitted bed rails to a resident's divan bed. One of the side rail pair moved away from the side of the bed, creating a gap in which the resident became trapped and died as a result. On inspection, the locking mechanism to secure the bed rails against the sides of the bed (under the mattress) was missing. The incident could have been prevented if regular maintenance checks had been in place. Figure 19 shows the overall bed rail assembly and its poor fit on the divan bed base. Figure 20 shows a close-up of the foot end cross bar; the set screw, essential to lock the cross bar to the correct width for the divan base, is missing. Figure 21 shows the large entrapment gap that can result.

Figure 19

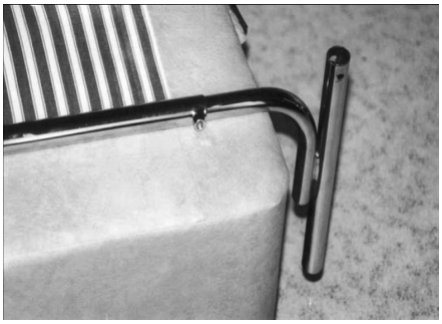

Figure 20

Figure 21

7.6 Use of a mattress that was too light to keep the bed rail assembly in position

Some designs rely on the weight of the divan or standard mattress to keep the bed rails in position. A lighter mattress can allow the rails to move away from the side of the bed, creating an entrapment gap, or the rails may fall off the bed completely. See Figure 22 below.

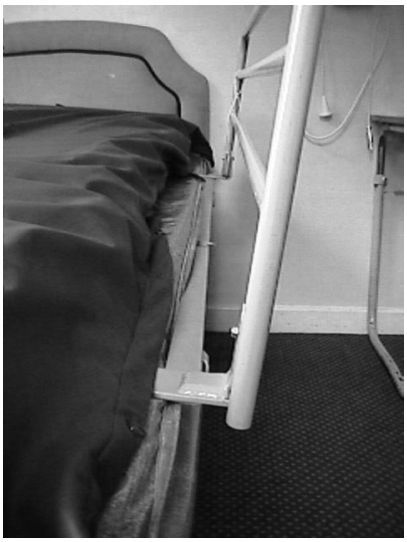

Figure 22

8 Legislation

8.1 Health and Safety at Work Act

People responsible for making decisions on the provision of bed rails and the care of people for whom they have been provided need to be aware of their duties under relevant health and safety legislation.

The Health and Safety at Work etc. Act [5] places duties on:

Employers and self-employed persons – to avoid exposing those not in their employment (e.g. members of the public and patients) to health and safety risks.

Employees – to take reasonable care for the health and safety of themselves and others affected by their acts, and to co-operate with their employer on health and safety obligations.

8.2 The Management of Health and Safety at Work Regulations

The Management of Health and Safety at Work Regulations [6] require that employers and the self-employed should make a suitable and sufficient assessment of the risks to the health and safety of persons not in their employment which arise out of or in connection with their undertaking. Advice on the issues that need to be taken into account, when assessing the risks from bed rails, is contained in section 3.

Employers also need to ensure that all employees who are responsible for selecting, fitting, maintaining and checking bed rails have received appropriate training.

9 Reporting adverse incidents

9.1 What is an adverse incident?

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons.

Adverse incidents may arise due to:

- shortcomings in the design or manufacture of the device itself
- inadequate instructions for use
- inadequate servicing and maintenance
- locally initiated modifications or adjustments
- inappropriate user practices (which may in turn result from inadequate training)
- inappropriate management procedures
- the environment in which a device is used or stored
- selection of the incorrect device for the purpose
- conditions of use may also give rise to adverse incidents.

9.2 What should be reported?

Any adverse incident involving a device should be reported to the MHRA, especially if the incident has led to, or were it to occur again, could lead to:

- death, life-threatening illness or injury or the potential for death or injury in the future
- deterioration in health or permanent impairment of body structure or function
- the necessity for medical or surgical intervention
- hospitalisation or prolongation of existing hospitalisation.

You should also inform us of:

- any other device-related adverse incidents
- any minor faults and discrepancies

These may take on a greater significance when aggregated with other similar events – they may help demonstrate trends or may indicate inadequate design, manufacture or quality assurance on the part of the manufacturer or supplier.

Reports of adverse incidents that appear to be caused by human error are also helpful as:

- the error may be partly (or wholly) due to deficiencies in the design of the device or instructions for use
- they will help prevent repetition of mistakes possibly by promulgation of advice or through improvements to the design of future devices.

Please remember that the MHRA is concerned with preventing the occurrence of adverse incidents, not with assigning blame or liability.

9.3 When should an incident report be made?

All incidents should be reported as soon as possible. Serious cases should be reported to the MHRA by the fastest means available, preferably online via our website (www.mhra.gov.uk). Fax or e-mail reports should be followed up by a confirmatory telephone call. Telephone reports should be followed up as soon as possible by a written report.

The initial report of an incident should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information.

9.4 How to report an incident

We strongly recommend that, where possible, you report to us online via the MHRA website (www.mhra.gov.uk) or via our site on the NHSnet (nww.mhra.nhs.uk). Successful use of this route will provide the reporter with immediate confirmation of receipt and a unique incident reference number.

Paper forms for reporting incidents may be downloaded from the MHRA website (www.mhra.gov.uk) and then either completed electronically and e-mailed or printed and sent by mail or fax.

Copies of forms are also available from:

MHRA
Adverse Incident Centre
Market Towers
1 Nine Elms Lane
London SW8 5NQ

E-mail: aic@mhra.gsi.gov.uk
Tel: 020 7084 3080
Fax: 020 7084 3109

Important: Full details (name, contact address and telephone numbers etc.) should always be included on your forms and in any telephone messages. This will allow us to contact you to acknowledge receipt of your report or message and to request any further information that may be needed. Further details are given in the first Medical Device Alert of each year (for example MDA/2006/001 [7]).

10 References and bibliography

10.1 References

1 The Medical Devices Regulations 2002. Statutory Instrument 2002 No. 618. ISBN 0110423178.
http://www.opsi.gov.uk/SI/si2002/20020618.htm

2 BS EN 60601-2-38: 1997, Revision 1, 'Medical Electrical Equipment – Part 2. Particular requirements for the safety of electrically operated hospital beds'. *Note: contains a similar clause on the requirements and dimensions for bed rails as published in BS EN 1970:2000.*
http://www.bsonline.bsi-global.com/server/index.jsp

3 BS EN 1970:2000 'Adjustable Beds for Disabled Persons'. Contains a clause that specifies requirements and dimensions for bed rails. *Note: this standard covers beds that are intended for use by adults and adolescents (i.e. people over 12 years old).*
http://www.bsonline.bsi-global.com/server/index.jsp

4 Device Bulletin DB 2006(05). Managing Medical Devices. MHRA 2006. http://www.mhra.gov.uk

5 Health and Safety at Work etc. Act 1974. London: HMSO, 1974. ISBN 0105437743. *See sections 2 and 3.*

6 Management of Health and Safety at Work Regulations 1999. Statutory Instrument 1999 No. 3242. ISBN 0 11 085625 2.
http://www.opsi.gov.uk/SI/si1999/19993242.htm

7 Medical Device Alert MDA/2006/001 'Reporting adverse incidents and disseminating Medical Device Alerts'. MHRA 2006.
http://www.mhra.gov.uk

10.2 Bibliography

MHRA publications

Medical Device Alert MDA/2004/014 – Replacement mattresses for hospital beds used in hospitals and the community.

Medical Device Alert MDA/2004/007 – Bed rails: twin bar designs.

Equipped to Care – the safe use of medical devices in the 21st centuty. ISBN 1 84182 1405.
http://www.mhra.gov.uk

NHS PASA publications
Bed Safety Equipment EL8. March 2002.

Equipment for daily living Bed Grab Handles – EL9/MDA02127. January 2003.
http://www.pasa.nhs.uk/evaluation/details.asp?id=1277

Moving and Handling: Electrically powered profiling beds - MH4/MHRA 03038. Part 1, Hospital beds. July 2003.
http://www.pasa.nhs.uk/evaluation/details.asp?id=44

For more information visit www.pasa.nhs.uk/evaluation
E-mail: cep@pasa.nhs.uk

Legislation
Provision and Use of Work Equipment Regulations 1998. Statutory Instrument 1998 No. 2306. ISBN 0 11 079599 7.
http://www.opsi.gov.uk/SI/si1998/19982306.htm

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995. SI 1995 No. 3163. London: HMSO, 1995. ISBN 0110537513.
http://www.opsi.gov.uk/SI/si1995/Uksi_19953163_en_1.htm

Distribution

This Device Bulletin should be brought to the attention of:

- MHRA liaison officers (for onward distribution)
- nurses in hospitals and the community
- occupational therapists
- care home managers and staff
- carers in the community and care-at-home staff
- community equipment stores (CES) and loan store managers
- those responsible for purchasing beds and bed rails
- maintenance staff
- health and safety managers
- risk managers.

Technical enquiries

Enquiries concerning the content of this Device Bulletin should be addressed to:

Andy Marsden
MHRA
Market Towers
1 Nine Elms Lane
London
SW8 5NQ E-mail: andy.marsden@mhra.gsi.gov.uk

Medicines and Healthcare products Regulatory Agency

An executive agency of the Department of Health

We enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe.

Medicines and Healthcare products Regulatory Agency
ISBN 1-90-073159-2