The National Patient Safety Agency

We recognise that healthcare will always involve risks, but that these risks can be reduced by analysing and tackling the root causes of patient safety incidents. We are working with NHS staff and organisations to promote an open and fair culture, and to encourage staff to inform their local organisations and the NPSA when things have gone wrong. In this way, we can build a better picture of the patient safety issues that need to be addressed.

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National Patient Safety Agency

Bedrails – Reviewing the evidence

A systematic literature review

The National Patient Safety Agency

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1. Purpose

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This review of the literature on bedrails is intended as a resource for NHS organisations writing or reviewing local bedrail policies or guidelines used for adult patients in hospitals, or educating staff who use bedrails in hospitals.

It aims to collect what is known about bedrails and organise the information coherently, giving staff a better understanding of the evidence. An understanding of the evidence will help staff to give patients the information they need to make an informed decision on bedrails, or to decide whether using bedrails is in the best interests of a patient who does not have capacity.

It is good practice to consider falls and bedrails policies together to ensure synergy.

This review was written by Frances Healey, NPSA Patient Safety Manager, with particular thanks due for advice and support from Dr David Oliver and Dr Alisoun Milne.

2. Why is a literature review important?

Unless we adopt a systematic approach, we tend to seek out evidence which fits our beliefs or opinions. This may be a particular problem for bedrails, as many papers on bedrails are opinion pieces rather evidence based (Box 1). To avoid bias, this review used a systematic strategy to search the literature. The appendix describes how this was carried out, gives more detail on each bedrail study that is included, and where any study was not included gives reasons for this. This review uses any evidence from healthcare settings, including studies which took place in a mix of hospitals and nursing homes, and nursing home studies where these might be relevant to hospital settings.

This review includes some papers which would normally be excluded without comment because they are not scientific studies. Some are very small, and are descriptions of local changes in practice or local circumstances of falls. However, because there are very few scientific studies of bedrails, these papers have often been cited by others as evidence, and therefore their findings and limitations need to be explored. Many papers on bedrails come from outside the UK and some are based on data from more than twenty years ago, which means their relevance to current practice must be carefully examined.

2. Why is a literature review important?

Box one: Opinions on bedrails

Opinion is not the same thing as evidence. However, it is important to consider opinions expressed in the literature, because clinical decisions can be influenced by culture, beliefs, values and role models as well as by evidence. Many authors offer strong opinions on bedrails, for example:

'a seemingly innocuous bed feature...has turned into a killer' 1

'bedrails...deprive older patients of their dignity and autonomy' ²

'...evidence suggests their use is dangerous and possibly unethical' ³

'...inherent dangers as well as the humiliation for a patient' 4

'absurd' 'distasteful' and equated to 'the use of fetters in schizophrenia' ⁵

'not only unethical but...a type of physical abuse' 6

Many authors state they are challenging the accepted view, for example:

'Bedrails are viewed as a benevolent means of patient protection. This article challenges those beliefs...' 7

'Raising bedrails is often regarded as a benign, even essential, safety measure...these assumptions have been challenged for many years.' 8

This review located no papers which actually took the position that bedrails were benevolent, whilst articles challenging their use existed 46 years ago⁹ and many have been published in the last ten years. ¹⁰ It appears the challenge to the accepted view may have become the accepted view. Because the papers are establishing a challenge to the view that bedrails increase safety, there is inevitably an emphasis on harm. Doctors, rather than nurses, appear to be the most outspoken critics. ¹¹ ¹² ¹³

2. Why is a literature review important?

This review took care to exclude studies which referred to body restraint devices used outside the UK. These include '...wrist and ankle restraints (leather or cloth) full-sheet restraints, soft belts or vests, crotch/pelvic ties, suit/harnesses...'¹⁴ Their use in North America, ¹⁵ Australia, ¹⁶ and Europe¹⁷ appears fairly common, but these devices are not marketed in the UK, and UK hospital surveys have found no signs of their use. ¹⁸ Because these devices are in common use outside the UK, papers on restraint may not describe them, and UK readers may in error assume a paper about 'night-time restraint removal' refers to bedrails, when actually it refers to vest, belt and cuff devices used in bed.

Many papers on bedrails refer to the findings from these body restraint studies by applying the logic that bedrails are or can be a form of restraint, therefore the findings from these restraint studies also hold true for bedrails.^{20 21} However, there is no reason to think the experience or outcome of being tied to a bed or chair with a belt or vest with straps is equivalent to that of being nursed in a bed with bedrails.

Key points:Why is a literature review important?

- This review used a systematic approach to search the literature
- Because there are few scientific studies, descriptive studies are also included
- Many papers on bedrails are opinion pieces, rather than evidence based
- Papers on bedrails focus on their potential to cause harm
- Papers on body restraints used outside the UK cannot be applied to bedrails

3. What do we mean by bedrails?

Bedrails are also called side rails, cotsides, or safety rails. This review uses the word 'bedrails' as it is the clearest term and because patients prefer it.²² The term 'bedrails' is used here to describe rails on the sides of adult beds used in healthcare settings – not rails on trolleys, or rails on children's cots.

Bedrails can have very different sizes and designs, and bedrails used in the UK may be different from bedrails used in other countries. For example, a New Zealand study²³ describes full length bedrails more than double the UK standard height.²⁴

Bedrails are safety devices intended to reduce the risk of accidentally slipping, sliding, rolling or falling from bed. They may also be used as reassurance for patients who are anxious about falling from bed. Whilst some patients may use bedrails to assist themselves in changing their own position²⁵ or as a convenient hanging point for call bells or other equipment, they are not designed for this purpose.²⁶

Key points:What do we mean by bedrails?

- 'Bedrails' describes rails on the sides of adult beds in healthcare settings
- Patients prefer the word bedrails
- Bedrails are intended to reduce the risk of accidentally slipping, sliding, rolling or falling from bed.

4. Are bedrails a form of restraint?

4. Are bedrails a form of restraint?

Manufacturers of bedrails are clear that they are safety devices intended to reduce the risk of accidentally slipping, sliding, rolling or falling from bed.

Whilst a basic definition of restraint might be 'restricting movement' many medical interventions restrict unintended movement (for example, plaster casts to stop a patient displacing a fracture) or unintentionally restrict movement (for example, a patient dependant on oxygen who can only walk near the oxygen supply). Restraint is therefore defined as 'the intentional restriction of a person's voluntary movement or behaviour...' 27 Behaviour is planned or purposeful actions rather than unconscious, accidental or reflex actions.

Although non-UK studies tend to equate restraint with specific devices (usually vest, belt or cuff restraints) UK guidance is clear that physically holding a patient, sedating a patient, or controlling exits can also be forms of restraint depending on the circumstances. Staff may automatically link restraint with abusive or institutional practice, but there will be situations where restraint is not only ethically and legally justified but required under a duty of care, for example if a delirious patient is attempting to remove tubes and drips their survival is dependant on, or a depressed patient is attempting to commit suicide.

No device, action, or medication can be labelled in itself as restraint, as this will depend on the circumstances. Bedrails are not a form of restraint if used to protect patients from accidentally falling out of bed, or if used for immobile patients. Bedrails used to stop a patient who wanted to get out of bed would be a form of restraint. However, as most bedrails marketed in the UK have horizontal bars extending from 22cm to 27cm above the mattress, and do not completely surround the bed bedrails would be unlikely to keep a patient in bed against their wishes.

4. Are bedrails a form of restraint?

Key points:

- Restraint is defined as 'the intentional restriction of a person's voluntary movement or behaviour...'
- In some situations restraint can be a form of abuse, but in other situations restraint may be ethically and legally justified or required
- A bedrail used to stop a patient accidentally falling out of bed is not a form of restraint
- A bedrail used to stop a patient who wants to get out of bed would be a form of restraint, but is also likely to be ineffective

5. How often are bedrails used in the UK?

Published rates of bedrail use over whole hospitals in UK settings are fairly rare:

- In 1996 one acute hospital found 8% of beds had bedrails in use³⁰
- In 2003 five acute hospitals found 32% of beds had bedrails in use³¹
- In 2004 one acute hospital found 28% of adult beds had bedrails in place³²
- In 2006 seven acute hospitals found 35% of adult beds had bedrails in use (26% of beds had a full set of bedrails raised)³³

These published rates suggest a possible rise over time. This might be related to changing patient type, with lengths of stay reduced and therefore patients who are more dependant and more likely to need bedrails. It might also be related to increased availability of pressure relieving mattresses (some of which require bedrails for safe use) or to the greater use of profiling beds in UK hospitals, as around 80% of these are purchased with integral bedrails³⁴ replacing earlier designs of bed where separate bedrails could be added if required.

Key points: How often are bedrails used in the UK?

- Published rates of bedrail use in UK hospitals range from 8% to 35%
- A possible increase over the last decade could relate to changes in patients' needs or changes in hospital beds and mattresses

6. Do we know which patients are likely to fall out of bed?

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Most falls in hospital happen whilst the patient is mobilising but around a quarter of falls in hospital are falls from bed.³⁵ Although multiple risk factors for falls in general have been identified³⁶ only two falls risk assessment tools designed to predict falls in general have been validated outside their original test population.³⁷ No validated tools to predict falls from bed have been published, and it is not clear whether the risk factors for falls from bed are the same as risk factors for falls in general. Falls from bed, like falls in general, are likely to arise from a complex interaction between an individual patient's health issues, treatment, disabilities, mental state, behaviour, and environment.

Key points: Do we know which patients are likely to fall out of bed?

- At least a quarter of patient falls in hospitals are falls from bed
- It is unclear whether the risk factors for falls from bed are the same as for falls in general, but multiple risk factors will affect individual patients differently

7. Patient, relative, and staff attitudes towards bedrails

7. Patient, relative, and staff attitudes towards bedrails

Although there are many studies published on attitudes to body restraint devices outside UK settings, only three studies could be located on attitudes towards bedrails, whilst two bedrail reduction studies also give some information on patients' attitudes towards bedrail use.

One study published in 2001 interviewed 17 patients in a rehabilitation ward in Northern Ireland who had been nursed in reclining chairs, chairs with screw-on tabletops, had tagging systems attached, or had bedrails.³⁸ Whilst the overall results of the study do not separate out patients' opinions on bedrails, some individual quotes relating to bedrails can be extracted. Three comments about bedrails are positive, one patient is upset that the bedrails stopped him getting out of bed alone, and one objected to the design rather than the bedrail itself. Three patients commented that they had no problem getting round the bedrails if they wanted to, and one commented the bedrails were cold. The reasons the patients thought nurses used bedrails included standard practice, because the patient tossed and turned, for nurses' peace of mind, to avoid blame or litigation if the patient fell out of bed, and to stop bedclothes slipping to the floor.

A further study published in 2001 involved interviews with nine relatives of patients with bedrails in the same setting.³⁹ Only five of the relatives recalled that staff had explained the reasons for the bedrails to them, but all expressed an understanding that they were for safety, to prevent falls from bed. Two relatives said they were also useful to help the patient change their own position in bed. Three commented you expect bedrails on beds for older patients. One said they could make a barrier between them but that the nurses had shown her how to take the bedrails down

7. Patient, relative, and staff attitudes towards bedrails

when visiting, and one commented the patient didn't like them 'but it is for his own good, you know'.

On probing by the interviewers, the nine relatives between them succeeded in identifying the risk of climbing over bedrails, poorly attached bedrails that might fall off, leg entrapment or injury and 'there's a million to one chance somebody would try to get their head through the bedrails'. The relatives made suggestions for improved bedrail design including mesh covers, padding, narrower gaps between the rails, and plastic instead of metal.

In the context of a questionnaire on falls prevention^{40 41} carried out around 2003, 57 patients and 43 relatives in a general hospital in the south of England were asked their opinion on bedrails. The question was phrased to describe bedrails used as restraint 'using bedrails to make it more difficult to get out of bed'. Even phrased in this way 89% of patients and 90% of relatives thought bedrails were acceptable. Patients were slightly more positive about the use of bedrails than they were of putting a falls risk symbol on the head of the bed with the patient's consent, and thought bedrails considerably more acceptable than nursing patients on a mattress on the floor. In the same study 100 staff were asked their opinion on bedrails; 64% of staff thought bedrails were acceptable.

One study in a Canadian rehabilitation unit⁴² where bedrails had been routinely used in 2001 allowed new patients to choose between being in a group continuing to have bedrails and a group testing a new policy aimed at minimising bedrail use. Out of sixty patients, 24 choose to keep bedrails (40%). Patients choosing to keep bedrails were found to be less independent and more ill.

One study in three USA care homes in 1999 made extensive efforts to reduce bedrail use.⁴³ Patients were educated on the dangers of bedrails by researchers who were convinced bedrails were harmful, and their bedrails kept in the down position for increasing periods of time. Despite this some patients wanted to keep their bedrails.

7. Patient, relative, and staff attitudes towards bedrails

Key points: Patient, relative, and staff attitudes towards bedrails

- Patients with bedrails are mainly positive or neutral about their use, but some are upset by them
- Relatives think bedrails are acceptable but are aware of the potential for harm
- Patients think bedrails are more acceptable than most other falls prevention measures
- Some patients were reluctant to manage without bedrails

8. Evidence on deaths and injury caused by bedrails

Eleven studies where death or injury was caused by bedrails were located. Each study included reports from a variety of settings, although most of the cases included appear to be from nursing home settings. Eleven sets of advice issued by safety organisations in response to bedrail deaths or injuries were also located. More detail on these studies and a summary of the advice can be found in the appendix.

One study looked at 74 deaths reported to an accident investigation database in the USA over four years.⁴⁴ Four studies looked at some or all of 413 deaths and 292 injuries related to bedrails reported to a separate database in the USA.^{45 46 47 48} These reports were made over 21 years during which there were over 600 million hospital admissions⁴⁹ and an unknown number of patients were nursed with bedrails in nursing homes or their own home. The majority of reports came from nursing homes.⁵⁰ Six additional papers describe individual incidents of death from bedrails^{51 52} or local reports of bedrail injuries.^{53 54 55 56} Because most of the larger studies overlap, the findings which follow in Box 2 are drawn from all of them, but the percentages quoted are taken from the largest of the detailed studies.⁵⁷

The bedrail failure deaths described in these studies (where the bedrail broke or became detached and the patient fell to the floor) often involved poorly maintained or incorrectly attached bedrails.

The bedrail related entrapment deaths described in these studies often involved 'hybrid assembly'. Hybrid assembly means that beds, bedrails and mattresses which were not designed to go together were used together. Whilst each piece of equipment may have been safe when used alone, in combination they produced lethal entrapment gaps. Hybrid assembly is a particular problem in

care home or domestic settings where divan style beds are used. However, it is a potential problem in all healthcare settings where bed and mattresses were not checked for compatibility or are interchanged. Most beds remain in use for longer than mattresses, so replacement mattresses that do not fit the bed correctly might be purchased, mattresses are often changed in response to patients' pressure relief needs, and detachable bedrails can remain in use for decades whilst designs of beds change.

The bedrail related entrapment deaths described in these studies also included bedrails with unsafe designs, particularly gaps between the bars of the bedrail which were wider than current manufacturing standards allow.

Patients involved in deaths through bedrail entrapment tended to be very confused, restless, elderly, and frail. It was also noted that patients who died had sometimes previously been found and rescued from a similar position, or had had minor injuries from trapping their limbs in the bedrails. Any such entrapment should be seen as a warning that a more serious entrapment may occur unless changes are made to the patient's care.

Because postural asphyxiation can be a slow process, regular and frequent observation is believed to reduce the risk of death through any form of bedrail entrapment. However, an individual case study suggests a patient can move from the centre of the bed into a trapped position in less than 2 minutes and asphyxiate within 14 minutes.⁵⁸

Box Two: How bedrails can cause death and injury

Entrapment between or below bedrail bars

Some deaths occurred through head or chest entrapment in poorly designed bedrails, especially wide gaps between vertical bars in bedrails, wide gaps between the lowest horizontal bar in bedrails and the bedbase, and triangular gaps in a 'half' bedrail which is not available in the UK. In some cases the latch had failed during the patient's struggles and collapsed, compressing them further. Because some of these deaths occurred as long as 21 years ago, subsequent changes in bedrail design appear to have eliminated most of these risks. However, healthcare organisations need to ensure that any outdated bedrails which are not safely designed⁶⁰ have been removed. Bedrails with the correct gaps to avoid head, neck or chest entrapment will still present a risk of leg or arm entrapment, which can lead to minor or rarely severe injury but is unlikely to be fatal.

Entrapment between the top of the bedrail and the head of the bed

Some deaths occurred where the patient's neck was trapped in the gap between the top of the bedrail and the head of the bed. This risk can be avoided if this gap is kept smaller than the width of a patient's neck (6cm) or if this is not possible, wider than the width of their head (25cm).⁶¹ Beds purchased with integral rails in the UK in recent years will conform with these standards, but again healthcare organisations need to ensure that any outdated beds whose integral bedrails are not safely designed have been removed. Where detachable bedrails are used, staff need to be trained on placing these so the gap between the top of the bedrail and the headboard are within safe limits. Theoretically the same risk would apply at the foot of the bed with a patient who has been so restless they are 'upside down' in bed. Together these entrapments between or below bedrail bars or between the top of the bedrail and the head of the bed accounted for 38% of deaths and injuries, and an additional 14% of cases involved injury from limb entrapment between the rails.

Poorly attached or broken bedrails leading to falls from bed

22% of deaths and injuries occurred because bedrails fell off and the patient fell to the floor, either because the bedrail broke when the patient rolled against it, or because the bedrail was not properly attached. This risk can be reduced if bedrails are regularly checked and maintained, and staff are trained on the correct fitting of detachable bedrails.

Entrapment between the mattress and the bedrail 18% of deaths and injuries occurred when the patient became trapped between the side of the mattress and the bedrail; suffocation occurred because the patient's airways were blocked where their face was squashed against the mattress, or because their neck or chest was compressed. This risk can be reduced by the use of mattress retainers, and by checking that the mattress is the right size for the bed, without a gap between the mattress side and the bedrail that the patient's body or head could slip in to.62 Some of these incidents involved pressure relieving mattresses. 63 The expansion of the mattress behind the patient added to the pressure on the patient's chest, neck or face. Most of the mattresses appear to have been types which are rarely used in the UK, but one incident involved an alternating pressure overlay, and one 'egg crate' foam.

Entrapment through body restraints caught on bedrails Some deaths occurred through body restraints becoming caught on bedrails, leading to suffocation. These deaths are unlikely to be relevant in the UK where body restraints are not used.

Entrapment in the central gap between split bedrails Rarely (5% of cases) deaths or injuries occurred when patients slid either head or feet first through the gap between split bedrails, and became stuck halfway.

Postural asphyxiation through collapsing with neck or chest over bedrails

Very rarely deaths occurred when the patient's upper body was 'draped' across the top of the bedrail, compressing their chest or neck. The patients who died in this way appear to have been extremely weak or paralysed. This risk would remain even with correctly maintained and fitted bedrails.

No papers on bedrail related deaths in UK settings have been published but the Medicines and Health Care Products Regulatory Agency (MHRA) have had reports of 21 bedrail related deaths over the seven years 2000 – 2006.⁶⁴ These relate to bedrail entrapment or bedrail failure, mainly in nursing or residential homes or the patient's own home. Of these deaths, three were deaths from bedrail entrapment in a hospital setting. During this period over 60 million patients were admitted to hospitals in England and Wales.

The MHRA found similar circumstances behind fatal bedrail entrapment as the non-UK studies, including hybrid assemblies of incompatible equipment (referred to by the MHRA as 'third party bedrails') or unsafe designs of bedrails not meeting current standards, or poorly maintained bedrails, or incorrectly fitted bedrails. Additionally, the MHRA identified a hazard when standard bedrails were used for patients whose bodies were outside the range of normal adult body sizes, for example child-sized adults, very emaciated adults, and those with microcephaly or hydrocephaly.

Three studies of non-fatal bedrail injury in UK hospital settings were found. One study in a UK acute teaching hospital during 1994⁶⁶ found eight direct injuries from bedrails were reported over 15 months. A 1999 study in a UK community hospital setting⁶⁷ stated that after introducing clinical guidelines on bedrail use there was a '90% reduction' in 'incidents surrounding the use of bedrails' but no numbers or details are given. A study based on the NPSA's National Reporting and Learning System (NRLS) estimated 1,250 reports of injuries from striking or trapping limbs in bedrails are made every twelve months from hospitals and mental health units in England and Wales, usually involving minor injuries to the lower leg, and notes that the Health and Safety Executive (HSE) had six reports of serious injuries (including two fractures and one dislocation) from bedrail entrapment in hospital settings over a three year period.⁶⁸

Key points: Evidence on deaths and injuries caused by bedrails

- Bedrail failure occurs when poorly fitted or poorly maintained bedrails break or become detached, and patients fall from bed
- Bedrail entrapment occurs when patients' necks, chests or limbs are trapped within the bedrail or between the bedrail and the bed or mattress
- In the USA, an average of around 20 deaths a year have occurred through bedrail entrapment or bedrail failure, mainly in nursing home settings
- In the UK, an average of around three deaths a year have occurred through bedrail entrapment or bedrail failure in care homes and patients' own homes
- Bedrail entrapment deaths in UK hospital settings are very rare, with three reports in seven years located by the MHRA
- Improvements in bedrail design have eliminated some fatal entrapment risks
- Fatal entrapment risk can be further reduced through putting systems in place to correctly fit and maintain bedrails and ensure beds, mattresses and bedrails are compatible with each other
- Standard adult bedrails may not be suitable for patients with unusual body sizes
- Death from entrapment may be less likely to occur if patients are frequently observed
- Minor injuries, and more rarely serious injuries, can occur through arm or leg entrapment in bedrails
- Frequent observation may reduce entrapment risk, but entrapment can occur between regular and frequent checks

9. Evidence from hospitals on bedrails' impact on falls, and injury from falls

One before-and-after study, one randomised controlled trial, and 13 other studies were located. More detail on these studies can be found in the appendix.

One large scientific before-and-after study in a New Zealand rehabilitation hospital during 1994⁶⁹ examined falls rates in bed areas before and after the introduction of a policy and education aimed at reducing bedrail use. The proportion of beds with bedrails attached fell from around 30% to around 11%. Falls in bed areas rose significantly from 186 in the six months before the study to 232 in the six months after the study. Overall injuries were 76 pre-policy and 78 post-policy. Hip fracture, hip pain and serious lacerations increased from 6 to 7.* The increases in injury were not statistically significant.[†]

One cluster randomised controlled trial of multi-faceted falls prevention in a UK acute hospital included a prompt for staff to review bedrail risk or benefit for individual patients. Falls rates reduced significantly and injury rates showed a non-significant increase. No information was collected on whether there were any actual changes in levels of bedrail use. Because this was a multi-faceted study, it is not possible to separate out the impact of bedrails from that of other interventions in the study such as medication review and improved footwear.

One study in a Canadian rehabilitation hospital⁷¹ aimed to randomise patients between care teams where bedrail use was routine on admission and care teams where bedrail use was restricted, but allowed some patients to choose which group they

^{*} The results given here are based on independent tests for statistical significance carried out as part of a published meta-analysis, and clarification of some findings on injury in the original paper where text and tables are not consistent with each other. See table 4 in the appendix

joined. This resulted in patients with less independence and more co-morbidity being more likely to be allocated to the routine bedrails group. The patients in the routine bedrails group fell on two occasions, whilst the patients where bedrail use was restricted fell 10 times. The effect of bedrail use could not be separated from the differences between the two groups.

Other studies looked back at bedrail use in relation to local reports of falls. All these studies relied on staff reports of falls, and could be affected by under-reporting or missing information. These studies had very different findings on the proportion of falls from bed which occurred with bedrails raised:

- 6% in a UK acute hospital during 1994 72
- 7% in English/Welsh acute hospitals during 2005 73
- 8% in English/Welsh hospitals and mental health units in 2006 74
- 35% in an Australian specialist hospital during 1993-2000 75
- 40% in older people's speciality in a UK acute hospital in 1999 76
- 41% in an acute hospital in the USA during 1981⁷⁷
- 90% in an acute hospital in the USA during 1987-1991⁷⁸
- 100% of 'falls from bed whilst sleeping' in a US acute hospital during1980/81 79

Unfortunately, most of these studies do not state what percentage of beds had raised bedrails, and without that information they cannot be used to estimate the likelihood of falling with or without bedrails. The high rates reported from US hospitals in the 1980s have to be considered in the context that bedrail use in that setting was at the time standard practice for all patients aged over 65.80

Two studies did include the percentage of bedrails in use. The study from wards within an older people's speciality in a UK acute hospital in 1999⁸¹ found that 40% of patients had bedrails in use. This study found 45% of falls from bed occurred whilst bedrails were in place. The study based on reports to the NRLS in 2006 from hospitals in England and Wales⁸² found that bedrails were recorded as raised in 8% of reports of falls from bed. A survey taken from a random sample of hospitals reporting to the NRLS in

[†] As only a minority of patients fall from bed, and even fewer are injured in falls, very large numbers of patients may be needed to detect changes in the numbers of injuries from falls. Because most injuries from falls are minor, studies taking place in single hospitals are unlikely to be powered to detect changes in serious injury

the same year indicated 35% of patients had bedrails in use, with 26% having bedrails raised on both sides of the bed.⁸³

One cohort study in an acute academic hospital in the USA published in 2005 compared 98 patients who fell with 318 controls matched for length of stay.⁸⁴ Having one or more bedrails raised was associated with a statistically significant reduced risk of falling. Injury rates were not analysed.

However, interpreting these studies is difficult because the patients given bedrails are likely to be different to the patients who were not given bedrails. The finding that the proportion of falls from beds with bedrails was similar to or lower than the proportion of beds with bedrails in use could be interpreted as showing bedrails reduce falls from bed, but could also be explained by bedrails being given to patients who were less likely to fall (although nurses generally give bedrails to patients they consider more likely to fall.)⁸⁵ With retrospective studies like these, there is no way of knowing which explanation applies.

Even when studies do not give information on levels of bedrail use, they can provide information on the likelihood of injury once patients have fallen from beds with or without bedrails. Four of the studies above included information on injury rates:

- In a UK hospital in 1994, falls from beds with bedrails accounted for 6% of falls from bed, and 4% of injuries.
- In an older people's speciality in a UK acute hospital in 1999, falls from beds with bedrails accounted for 45% of falls from bed, and 43% of injuries.
- In a small Australian specialist hospital during 1993-2000 the proportion of injuries was lower in falls from beds with bedrails than it was in falls from bed without bedrails, but not statistically significant. One death occurred in a fall from bed with bedrails.
- In English/Welsh hospitals in 2005, harm occurred in 14% of falls from bed with bedrails, and 31% of falls from bed without bedrails. 89 No significant differences in moderate, severe or fatal injuries were found, but minor injuries were significantly more likely to occur in falls from bed without bedrails, and minor head injuries occurred seven times more often in the falls from bed without bedrails (highly statistically significant). 90

The reason for head injuries occurring much more often in falls from bed without bedrails is not clear, but samples of descriptions attached to the reports from English/Welsh hospitals in 2005 suggest that if patients fall from beds with bedrails, they usually do so feet first towards the foot of the bed, whilst falls from beds without bedrails are usually slips or rolls from a lying down position, where the patient's head may strike the floor or bedside equipment.

A review of legal claims in England initiated in 2000-2005 identified 154 claims relating to death or injury from falls from bed. 91 Bedrails were raised in only four cases (3% of the total). Legal cases are unlikely to be a representative sample, as litigation is usually considered only when there is a belief appropriate care has not been given, so this study cannot be used to estimate the likelihood of falls with or without bedrails.

One study in an Australian acute hospital in 1989 compared single fallers with multiple fallers, and found those patients who fell from bed were likely to remain single fallers.⁹² This finding has been cited by others as evidence that bedrails are unnecessary even if a patient falls from bed⁹³ but the study collected no information on bedrail use and it is possible clinical staff added bedrails after the first fall from bed.

Two descriptions of the impact of a change in bedrail policy have been published, but these are not scientific studies and contain very little detail. A 1999 study in a UK community hospital setting⁹⁴ stated that after reissuing clinical guidelines aimed at reducing bedrail use there was 'no increase in falls'. A 1990 study on a UK ward caring for older people⁹⁵ stated that requesting compliance with a guideline reduced bedrail use from 100% of beds to 25% of beds. Falls occurring before the change in practice are not stated but only three falls are said to have occurred in the year following this change.

Key points: Evidence from hospitals on bedrails' impact on falls and injury from falls

- One scientific study of bedrail reduction in a hospital setting resulted in a statistically significant increase in falls and non-significant increases in injury and serious injury
- One scientific cohort study found having bedrails raised was associated with a statistically significant reduction in the risk of falls
- Studies looking back at reports of falls from bed need to be interpreted with care, as patients who are given bedrails are likely to be different from patients who are not given bedrails
- The four studies including injury rates all showed falls from beds with bedrails were associated with lower rates of injury, but this was statistically significant in only one study
- No significant differences in moderate, severe or fatal injuries was found between falls from bed with bedrails and falls from bed without bedrails

10. Evidence from nursing homes on bedrails' impact on falls, and injury from falls

10. Evidence from nursing homes on bedrails' impact on falls, and injury from falls

Although this literature review is intended to inform policy and practice in hospitals, studies in nursing homes may have some relevance. Outside the UK, nursing homes may be used for short term rehabilitation and serve a similar patient group to UK community hospitals. The environment in nursing homes may be very different to acute hospitals – for example, nursing homes will have more single rooms and carpeted floors – but may be similar to small NHS units used for longer term care or rehabilitation of clients with mental health needs or learning disabilities.

Five studies were located. Because all five took place in nursing homes in the USA, body restraints may have been in use at the same time as bedrails for some patients, which is likely to affect the findings.

One small before-and-after study in the rehabilitation wing of a nursing home during 1994/95% compared falls in bedrooms before and after a bedrail reduction programme, which involved policy, education, and introducing bed alarms. No new patients were permitted bedrails until after a week's assessment, and existing patients' split bedrails were taken down one section at a time. Bedrails were reintroduced only if patients fell from bed more than three times, or were injured in a fall from bed, or for exceptional patients (e.g. with unstable epilepsy). Bedrail use reduced dramatically from almost all patients to around 13% of patients. Falls rose from 19 before to 31 after (an increase of

10. Evidence from nursing homes on bedrails' impact on falls, and injury from falls

61%). There were two minor injuries before, and one minor injury and one serious head injury after. The study was too small to produce statistically significant results.

A small before-and-after study in a nursing home⁹⁷ followed 93 residents during a bedrail reduction programme. Actual rates of bedrail use are not noted, but 16 residents fell in the bed area before the bedrails reduction programme, and 35 fell in the bed area after the bedrails reduction programme (a statistically significant increase of 118%). Falls increased particularly in patients with visual impairment. Injury rates are not stated, but the study implies most falls resulted in no more than minor harm, and the study was too small to expect to detect significant changes in injury.

One before-and-after study in three nursing homes in 1999 included seeking alternatives to bedrail use such as body pillows and crash mats. 98 The efforts made to reduce bedrail use appear extensive, including early morning management inspections to check compliance. Bilateral bedrail use reduced from 31% of beds to 18% of beds. Falls from bed decreased slightly from 142 to 126, patients injured decreased slightly from 42 to 35, and hip fractures increased from one to two, but none of these changes was statistically significant and occupied bed days had also reduced between the before and after periods of the study.

One very small study looked at 16 reports of falls from bed in a nursing home in 1982. 99 Fourteen of these falls occurred from beds with bedrails raised. Like the hospital studies from this period discussed above, this study has to be considered in the context of bedrail use approaching 100% for older patients at that time in the USA.

One study in three nursing homes¹⁰⁰ looked back at 318 reports of falls from bed collected in 1990/91 during a study aimed at reducing the use of body restraints. Bilateral bedrail use averaged 64%. Three patients had serious injuries in falls from beds with bilateral bedrails, and two had serious injuries from falls from beds with partial or no bedrails. The actual number of falls with or without bedrails is not given, but patients with bilateral bedrails were found to have been no more likely to fall once corrections were made for differences in dependency and confusion between patients. The paper includes detailed statistical analysis, but may be limited because only a very small number of

10. Evidence from nursing homes on bedrails' impact on falls, and injury from falls

patients in either group did not fall, and a high proportion were restrained by body restraint devices.

Key points: Evidence from nursing homes on bedrails' impact on falls, and injury from falls

- Studies from US nursing homes may have only limited relevance to UK hospital settings
- Most nursing home studies were too small to produce statistically significant results
- Although one bedrail reduction study found no significant change in falls and injured patients, two other bedrail reduction studies saw falls increase by 60% and 118%
- Patients with visual impairment may be particularly likely to fall if their bedrails are removed

11. Additional evidence

References in the literature are made to three aspects of risks relating to bedrails which have not been established by trials but have a scientific foundation or can be locally tested.

Papers state bedrails can increase the likelihood or severity of injury because if the patient climbs over them and falls from a greater height, the effect of gravity will make injury more likely or more severe. 101 102 This has a clear scientific foundation but the findings described earlier in this literature review - that falls from beds with bedrails appear to result in lower proportions of injury - would suggest staff are avoiding their use for patients likely to climb over them. A study in seven UK hospitals 103 suggested staff were very aware of the need to avoid bedrail use if the patient might climb over their bedrails, and those patients who were considered both mobile enough and confused enough to be at risk of climbing over their bedrails made up a very small proportion of hospital patients (ten patients out of 1,092 patients surveyed, or slightly less than 1%).

One paper suggests alternating pressure mattresses may 'propel' patients out of bed¹⁰⁴ as by giving under the weight of a patient they will create a downwards slope to push the patient towards the edge of the bed. Patients who need alternating pressure mattresses are likely to have poor mobility and would be unable to save themselves from falling off the edge of the bed without bedrails. Alternating pressure mattresses vary in design, but this 'propelling' effect can be locally tested by staff members lying in non-central positions on alternating pressure mattresses (at floor level for safety). Staff should also refer to the manufacturers' guidance on safe use.

Papers often state that there is no evidence that bedrails prevent falls from bed¹⁰⁵ loe because no randomised controlled trials have been carried out. In a systemic review of the effectiveness of parachutes¹⁰⁷ the authors used humour to make a serious point

that the effect of some inventions can be proven without the need for randomised controlled trials. Bedrails, like parachutes, can be tested pragmatically. Their effect on preventing slipping, sliding or rolling out of bed (the only types of falls they are designed to prevent) can be locally tested by a staff member lying on a bed with bedrails, closing their eyes, and rolling or sliding from side to side. Repeating the experiment without bedrails is not advised.

Key points: Additional evidence on bedrails

- The risk of injury for a patient climbing over bedrails is theoretically higher, but staff appear aware of the need to avoid bedrails for these patients
- Some alternating pressure mattresses may create a risk of falls from bed if used without bedrails
- Bedrails can be demonstrated to prevent slipping, rolling or sliding from bed

12. Conclusions

12. Conclusions

Papers including evidence on bedrails are few. Most are not scientific studies, and many are too small to produce statistically significant results. A pure approach to evidence would mean this literature review was only one sentence long - there are no specific randomised controlled trials, therefore we have no robust evidence. This review has instead aimed to take an approach known as critical realism¹⁰⁸ acknowledging the complexity of the evidence and the difficulty in interpreting it, and highlighting the more scientific studies as well as describing a range of information on bedrails from reliable sources.

This review found strongly negative opinions were often expressed about bedrails in papers. However, patients with bedrails were mainly positive or neutral about their use, and some patients were reluctant to manage without bedrails.

All healthcare involves risks as well as benefits. The evidence confirms that the risk of death and injury from bedrails is real, but not random. Papers on bedrails often warn that bedrails can kill, but miss the opportunity to help staff understand the importance of correctly fitting and maintaining bedrails of the appropriate size for the bed, mattress and patient to reduce this risk. Each and every death is an individual tragedy for the patient, their family and friends, and the staff caring for them, but the risk of fatal entrapment in hospitals appears lower than one in ten million admissions to hospitals in England and Wales, and can be further reduced by following advice issued by the MHRA.¹⁰⁹

Falling from bed also presents a risk to patients. Around one in 200 hospital patients fall from bed, and 90 fractured neck of femurs and eleven deaths caused in falls from bed were reported in England and Wales during 2006.¹¹⁰ This review did not locate evidence for the views often expressed in the literature that bedrails increase falls and injury overall. Of the retrospective reviews of accident forms or patient records that included statistical analysis¹¹¹ ¹¹² ¹¹³ ¹¹⁴ none found that falls, injury or serious injury was significantly less likely without bedrails, whilst one study found that falls were significantly more likely to occur in

patients without bedrails¹¹⁵ and one study found that injury was significantly more likely to occur in falls without bedrails.¹¹⁶ Of the before and after trials that included statistical analysis¹¹⁷ ¹¹⁸ ¹¹⁹ none found that falls, injury, or serious injury were significantly less likely when bedrail use was reduced, and two studies found that falls increased significantly.¹²⁰ ¹²¹ Despite the actual findings, some papers stated that the risks of bedrails always outweigh the benefits¹²² or that they should no longer be used.¹²³

It is notable that the studies of bedrail reduction¹²⁴ ¹²⁵ ¹²⁶ were aimed at reducing or eliminating bedrail use for all patients, rather than considering patients as individuals. Whilst the evidence does not support this approach, neither does it support an approach of routine bedrail use. There are undoubtedly patients for whom the risks outweigh the benefits, just as there are patients for whom the benefits will outweigh the risks. Hospital patients are each unique individuals, and decision making needs to be based on an individual assessment of risks and benefits.

This literature review was undertaken to inform the NPSA Safer practice notice *Using bedrails safely and effectively*.¹²⁷ This safer practice notice aims to improve the safety of patients in hospitals through informing patients and staff about the relative risks of falls and injury with and without bedrails, and what steps they can take to reduce the risks. It aims to ensure that bedrails are used when appropriate to reduce the risk of patients accidentally slipping, sliding, falling or rolling out of bed, and that bedrails are not used inappropriately as restraints. The safer practice notice was released together with the third report of the NPSA's Patient Safety Observatory *Slips, trips and falls in hospital*¹²⁸ to ensure prevention of falls can be considered in a much wider context than bedrails alone.

12. Conclusions

Key points: Conclusion

- The evidence on bedrails is limited
- Patients were mainly positive or neutral about the use of bedrails
- The risk of fatal bedrail entrapment is real, although extremely rare in hospitals
- The risk of fatal bedrail entrapment is not random, and can be reduced further by following advice on using bedrails safely
- Bedrail reduction programmes may result in increases in falls
- Patients with bedrails appear less likely to fall, and less likely to be injured if they fall
- Neither elimination of bedrails, nor routine bedrail use, is appropriate. Decision making on bedrails needs to be based on an assessment of risks and benefits as they apply to individual patients

13. Appendix

This review used existing systematic academic literature reviews and a systematic literature search which included bedrails within their wider topics of falls prevention or restraint. Because these reviews did not always search for all the alternative words used for bedrails a supplementary search of the main clinical databases was made (see Table 1 below).

Through these searches 543 articles were located.

Articles were included if they were original studies of:

- direct consequences of the use of bedrails (e.g. injury or death caused by bedrails)
- indirect consequences of the use of bedrails (e.g. falls or changes in mobility)
- staff', patients' or relatives' views on bedrails
- prevalence/incidence of bedrails in UK settings

Single case studies specific to bedrails or anecdotal accounts of changes in bedrail use even if of poor quality were not excluded, but their limitations are explored in the main text. Paediatric studies were not included. Articles where the full text was not available in English were not included. Articles published before 1980 were not included.

Of the 543 articles identified, 499 were excluded because they related to body restraints, or were papers discussing previously published evidence, or covered cots for children, or were prevalence of bedrails in specialities, or outside the UK. Whilst examples of attitudes to bedrails were drawn from excluded articles, this was opportunistic rather than systematic. Thirty two papers were included in this literature review. Twelve additional papers did not fit the criteria, but had some mention of original facts on bedrails, and are included in the appendix Table nine.

An additional search was made for directives on bedrails produced by agencies involved in collecting reports of injuries from falls and bedrails (HSE, MHRA, and NPSA in the UK and the US Food 13. Appendix

and Drug administration and Joint Commission on Accreditation of Healthcare Organisations in the USA). Eleven directives were located and included in the appendix Table three.

TABLE 1 – Systematic review and literature search sources

Reference	Keywords	Context
Oliver D Gosney M Victor C et al. (2005) Prevention of falls and injuries in hospitals and care homes: systematic review, meta-analysis and economic evaluation Department of Health accidental injury prevention programme	bedrail, cotside, 'restraint-physical' and 'protective devices'	Systematic review of prevention of falls in hospitals and care homes
Evans D Wood J Lambert L Patient injury and physical restraint devices: a systematic review Journal of Advanced Nursing 2003 41 3 274-282	restrain, bedrail, siderail, cotside	Systematic review of patient injury and physical restraint devices. Twelve studies were located but all relate to use of body restraints and only two studies record concurrent use of bedrails
Gallinagh R Slevin E McCormack B Side rails as physical restraints in the care of older people: a management issue Journal of Nursing Management 2002 10 299-306	side rails, cot sides, restraints, beds, equipment	Systematic literature search of side rails as physical restraint
Additional search for this literature review	restraint, bedrail, side rail, cotside, safety rail	Allied & Complementary Medicine - 1985 to date (AMED) British Nursing Index - 1994 to date (BNID) CINAHL (R) - 1982 to date (NAHL) DH-DATA - 1983 to date (DHSS) EMBASE - 1974 to date (EMZZ) EMBASE - 1996 to date (EMED) King's Fund - 1979 to date (KFND) MEDLINE - 1950 to date (MEZZ) MEDLINE - 1996 to date (MEDL) PsycINFO - 1806 to date (PSYC)

TABLE 2 – Evidence on deaths and injury from bedrails

Reference	Identified cases	Source	Location	Study type	Findings
Everitt 1997 ¹³²	8 injuries	Locally reported incidents	UK large acute teaching hospi- tal 1994/1995	Review of locally reported incidents involving direct injury from bedrails as part of a wider study of falls from bed	8 direct injuries from bedrails in 15 months, mainly lacerations, grazes, bruising
FDA 2006 ¹³³	413 deaths 120 injuries 158 near misses (subset of Highert 2005 but with entrapment deaths 2003-2005 added)	US Food and Drug Administration	USA all settings 1985 – 1/1/2006	Death/injury related to bedrail entrapment	413 deaths 120 injuries 158 near misses Seven zones of entrapment are identified: 1. within the rail (between bars) 2. between the lowest rail and bed base 3. between bedrail and mattress 4. under the rail at bed ends 5. between split rails 6. between end of rail and side of head or foot board 7. herween head of foot hoard and mattress end
Gray 1990 ¹³⁴	1 injury	Locally reported incident	Hospital	Case study	Single instance of bruising from bedrails in down position
Hignett 2005 ¹³⁵	396 deaths 292 injuries 53 near misses 53 unclear 794 total	US Food and Drug Adminis- tration	USA all settings 1985 - 2002	Death/injury related to bedrails aimed primarily at establishing involvement of split rails but providing a comprehensive summary of all bedrail incidents located	Between rails/gaps 287/794 Collapsed rail + fall to floor 164/794 Rail/mattress gap 138/794 Limb between rails 106/794 Between split sides 34/794 453 rail type other/unknown 'Half' rails (USA inverted triangle design) more likely to be associated with death, full rails with injury, split rails with near misses (perhaps due to their location in acute settings)
Miles 1996 ¹³⁶	1 death	Coroner's case	USA prior to 1996	One case study where the patient's position was photographed (rather than reconstructed) after death	The patient's upper body was compressed between mattress and rail.

132 Everitt V, Bridel-Nixon J the use of bedrails: principles of patient assessment *Nursing Stand-* 134 ard 1997 12(6)44-47

136 Miles S A case of *death* by physical restraint: new lessons from a photograph *Journal of the American Geriatrics Society,* 1996 Mar, vol. 44, no. 3, p. 291-2,

¹³³ USA Food and Drug Administration Hospital Bed System Dimensional and Assessment Guidance to reduce Entrapment http://www.fda.gow/cdrh/beds/guidance/1537.html accessed on 2977/06

¹³⁴ Gray CS Gaskell D Cot sides: a continuing hazard for the elderly *Geriatric Medicine* 1990 20 21-22

¹³⁵ Hignett S, Griffiths P Do Split-side rails present an increased risk to patient safety? *Quality and Safety in Health Care* 2005;14;113-116

TABLE 2 – Evidence on deaths and injury from bedrails (continued)

Reference	Identified cases	Source	Location	Study type	Findings
Miles 1998 ¹³⁷	2 deaths	Coroner's cases	USA prior to 1998	One case study where position at death had been taped by monitoring camera One case study where the patient's position was photographed (rather than reconstructed) after death	One patient slid between split bedrails until his chest was compressed; took only two minutes to get into this position and was found asphyxiated 14 minutes after becoming trapped. The second patient's upper body was compressed between mattress and rail.
Miles 2002 ¹³⁸	35 deaths (subset of num- bers above in Hignett 2005)	US Food and Drug Adminis- tration	USA all settings 1994 - 2001	Deaths related to bedrails and pressure relieving air or foam mattresses.	13 built in air particulate mattresses 19 large air-cushion mattresses† 1 eggcrate foam overlay 1 alternating pressure overlay Inappropriate gaps in bedrails also implicated.
O'Connor 2003 ¹³⁹	1 injury	Locally reported incident	Hospital	Case study	Single instance of bedrail injury being misinterpreted as a symptom of illness, leading to misdiagnosis
Parker 1997 ¹⁴⁰	74 deaths	US Consumer Products Safety Commission	USA all settings 1993 to 1996	Deaths related to bedrails	52 entrapment between mattress and rail 8 neck entrapment within rails 5 draped over bedrail 9 partial slide out of bed with chest or neck compression 51 female 21 male 51 aged 70+ 26 aged 81+

In the UK these mattresses are usually hired for use in specialist units such as burns units. Most pressure relieving mattresses used in the UK are alternating pressure mattresses or overlays, foam These have multiple air pillows usually twice as high as a normal mattress, all of which are constantly leaking air and having it pumped back in, providing a drying cushion of air for the patient. The study describes 'built in air particulate mattresses' which are known in the UK as air fluidised beds and 'large air-cushion mattresses' which are known in the UK as high air loss mattresses. mattresses or overlays, or fibre overlays.

¹³⁷ Miles S Parker K Pictures of fatal bedrail entrapment A*merican Family Physician* 1998 58 8 1755-1756

¹³⁸ Miles SH Deaths between bedrails and air pressure mattresses Journal of the American Geriatric Society 2002 50 1124-1125

¹³⁹ O'Connor B Moore A Watts M Hess' sign produced by bedrail injury Irish Medical Journal 2003 96 10 313

¹⁴⁰ Parker K Miles SH Deaths caused by bedrails Journal of the American Geriatric Society 1997 44 797-802

TABLE 2 – Evidence on deaths and injury from bedrails (continued)

Reference	Identified cases	Source	Location	Study type	Findings
					64 entrapment between mattress and rail
					25 neck entrapment within rails
	72 deaths				18 between split rails
	75 injuries				17 body restraint in place too
Todd	13 near misses	US Food and	USA all settings	Deaths and Injury related to bedrails but represent	57 female
1997141	(subset of pum-	Urug Adminis- tration	1985 - 1995	the first part of Hignett	23 male
	bers above in			מטטאי	51 aged 75+
	Hignett 2005)				36 aged 85+
					80% below 11 stone in weight
					58% nursing homes
Jehan,	Injuries, num-	Locally reported	UK Community	Anecdotal description of	No numbers given but states '90% reduction in reported incidents surrounding the use of bedside rails'. Numbers
_	bers not stated	incidents	hospital	the Impact of a change in bedrails policy	were likely to have been small given the setting and time period.

141 Todd JF Ruhl CE Gross TP Injury and death associated with hospital bed side-rails: reports to the US Food and Drug Administration from 1985 to 1995 American Journal of Public Health 1997 87 12 2052

142 Jehan W Restraint or protection? The use of bedside rails Nursing Management 1999 6 2 9-13

13. Appendix

TABLE 3 - Directives issued on bedrail safety

- 143 Department of Health January 1994 Safety action Bulletin Use of Hospital Bed safety Sides and Side Rails
- 144 USA Food and Drugs Administration Safety alert entrapment hazards with Hospital Bed Side Rails 23/8/95
- 145 Medical Devices Agency (now Medicines and Healthcare products Regulatory Agency) Hazard Notice 1997/11 Bed Side Rails (Cot sides) – Risk of entrapment London: MHRA
- 146 Joint Commission on Accreditation of Healthcare Organizations 2002 Sentinel Event Alert: bed rail-related entrapment deaths accessed at www.jointcommission.org/Sentinel EventAlert/sea_27.htm on 29/7/06
- 147 MHRA 2002 Bed safety equipment; an evaluation London: Medicine and Healthcare products Regulatory Agency access at www.mhra.gov.uk
- 148 Medicines and Healthcare products
 Regulatory Agency MDA/2004/007
 13 February 2004 Bed rails: twin bar designs entrapment and asphyxiation
- 149 Medicines and Healthcare products Regulatory Agency MDA/2004/014 replacement mattresses for hospital beds used in hospitals and the community
- 150 USA Food and Drug Administration Hospital Bed System Dimensional and Assessment Guidance to reduce Entrapment http://www.fda.gov/cdrh/ beds/guidance/1537.html accessed on 29/7/06
- 151 MHRA Device Bulletin 2006(06) the safe use of bedrails London: Medicine and Healthcare products Regulatory Agency access at www.mhra.gov.uk
- 152 MHRA Device Alert 2007/009 Beds Rails and Grab Handles London: MHRA www.mhra.gov.uk
- 153 NPSA *Safe and effective use of bedrails* London: NPSA www.npsa.nhs.uk

Reference	Country	Key content
		Raise awareness of risk of entrapment between rail bars or between rails and mattresses
DH 1994 ¹⁴³	UK	Consider padding, pillows or different bar spacing
		Be aware most entrapped patients were confused and restless
		Regularly inspect for any gaps wide enough to entrap head or body, including gaps between rail and mattress
		Check new purchases of bedrails and mattresses for compatibility with bed
FDA 1995 ¹⁴⁴	USA	Install bedrails at correct distance between head and foot of bed
		Consider protective barriers to close off gaps
		Bed rails should not be used as a substitute for body restraints
		Be aware of entrapment risk when purchasing, selecting, fitting and adjusting bedrails
MDA 1997 ¹⁴⁵	UK	Check gaps between rail and mattress, rail and bed, and between bed bars for hazards
		Increase vigilance when using bedrails
		Train staff in awareness of entrapment risk
		Assess patients for risk of entrapment
JCAHO 2002 ¹⁴⁶	USA	Inspect beds for potential entrapment gaps
JC/ 1110 2002	03/1	Use nets/padding to reduce entrapment risk
		Observe patients at risk of entrapment more closely
		Educate patients/relatives about entrapment risks
MDA 2002 ¹⁴⁷	UK	A review of the characteristics of bedrails marketed as medical devices in the UK in relation to bedrail entrapment dimensions and bedrail failure risks
MHRA 2004a ¹⁴⁸	UK	Remove any two bar bedrails where the gap between rails is greater than 12cm
MHRA 2004b ¹⁴⁹	UK	Check mattress compatibility
FDA 2006 ¹⁵⁰	USA	Non-binding recommendations on dimensions of various aspects of bedrails in relation to beds and mattresses, and techniques for testing these, intended for the assessment of existing equipment and the design of new equipment
MHRA 2006 ¹⁵¹	UK	Comprehensive advice on purchasing, maintaining, risk assessing and fitting of bedrails
MHRA 2007 ¹⁵²	UK	Requirement to check compatibility of beds, mattresses and bedrails and grab handles
NPSA 2007 ¹⁵³	UK	Requirement to review policy in hospitals to ensure appropriate bedrail use, patient decision making, and safe equipment systems

TABLE 4 – Bedrail studies in hospital settings

Reference	Study type	Setting	Study size	Bedrail use before	Bedrail type	Intervention	Bedrail use after	Results	Statistical significance
Hanger, 1999 ¹⁵⁴	Scientific before and after study of bedrail reduction	NZ Stroke hospital rehabilitation	135 beds six months before/six months after	29.6% of beds had bedrails attached (whether bedrails were raised or lowered not measured, whether beds occupied or wacant not measured)	One piece full length extending 50cm above top of mattress, lever to raise/lower but spanner needed to remove from beds	Policy and education to reduce bedrail use, better treatment of delirium, use of toileting programmes and mattresses on floor	11.5% of beds had be- drails attached (whether bedrails were raised or low- ered not meas- ured, whether beds occupied or vacant not measured)	Overall falls 361 before/43.1 after Falls in the bed area 186 before/23.2 after Total injuries 76 before/78 after Serious lacerations, hip fractures and hip pain 6 before/7 after Neuro obs 27 before/11 after	Increase in bed area falls broken into sub-periods and stated not significant in original publication but was significant on re-analysis (Oliver, 2006) Stated significant decrease in serious injury but actually decrease in occasions neuro obs were recorded
Healey, 2004 ¹⁵⁵	Cluster RCT of multifaceted falls prevention including bedrail prompt	UK acute and community hospital wards	193 beds six months before/six months after in control and intervention	Not measured	Not stated	Multi-faceted risk factor reduction including prompt to review risk/ benefit of bedrails	Not measured	Unable to separate impact of bedrail prompt as multi-faceted intervention. Intervention group falls 300 before/240 after 45 injuries before/49 after	Unable to separate impact of bedrail prompt as multifaceted intervention, but decrease in falls statistically significant
Jehan, 1999 ¹⁵⁶ fnote same study also cited in Table two]	Description of local initiative to reduce bedrail use,	UK Community trust	Not stated but nine months before/three months after implied	Not stated	Not stated	Introduction of clinical guidelines	Not stated	'a fall connected to bedside rails every three days on average' before 'noincrease in falls' after	No falls figures provided before or after; no statistical analysis

The authors state that serious injury declined significantly from 33 injuries to 18 injuries. However, if the text of the paper is read the apparent change in serious injury occurred in an extra category not included in the results tables but defined within the text as head injuries where neurological observations were taken. These decreased from 27 to 11. It appears minor bruises and lacerations to the head were counted as minor injuries unless neurological observations were taken, in which case they were counted as serious injuries. However, taking neurological observations does not in itself indicate serious injury any more than checking blood pressure indicates serious hypertension, and therefore this appears to be a measure of nursing beliefs and practice than actual seriousness of injury.

154 Hanger HC, Ball MC, Wood LA. An analysis of falls in hospital. Can we do without bedrails? Journal of the American Geriatric Society 1999;47: 529-31

155 Healey F, Monro A. Cockram A, Adams V, Heseltine D. Using targeted risk factor reduction to prevent falls in older hospital inpatients. A randomised controlled trial. Age Ageing 2004;33: 390-5.

156 Jehan W Restraint or protection? The use of bedside rails Nursing Management 1999 6 2 9-13

TABLE 4 – Bedrail studies in hospital settings (continued)

Reference	Study type	Setting	Study size	Bedrail use before	Bedrail type	Intervention	Bedrail use after	Results	Statistical significance
Ralphs- Thibodeau	Part- randomised study of bedrail reduction	Canadian rehabilitation hospital	Four care team areas within one unit, 60 patients over three months	Not stated but routine on admission, reducing as stay progressed	Not stated	New policy requiring bedrail use only in emergencies or after MDT assessment	Not stated	2 falls in bedrails-up group, 10 falls in bedrails-down group (includes all falls, falls from bed not stated)	Results confounded by allowing 20 patients to self select, bedrails-up group therefore more dependent and more comorbidity.
Watson, 1990 ¹⁵⁸	Description of local initiative to reduce bedrail use	UK Elderly care	One ward, duration and patient numbers not stated	100%	Not stated	Compliance with RCN 1992 guidance	25%	no figures for falls before 'only three falls from bed in a year' after	No falls figures provided before; no statistical analysis

157 Ralphs-Thibodeu S, Knoefel F, Benjamin K et al. Patient choice; an influencing factor on policy-related research to decrease bedrail use as physical restraint Worldwiews on evidence based nursing 2006 3 1 31-9

158 Watson R Brunton M Restrain yourself Nursing the Elderly 1990 2 5 20-21

TABLE 5 – Accident form reviews in hospital settings

Reference	Study type	Study location	Period of study	Level of bedrail use	Findings on falls	Findings on injury
Catchen, 1983 ¹⁵⁹	A review of 343 falls 'associated with beds' in patients aged 65+	US urban acute hospital	12 months in 1980/81	Not stated but bedrail use said to be standard in US hospitals in this era for all patients aged 65+	No numbers given. States only a minority of the falls were falls from bed whilst sleeping, but that all falls from bed whilst sleeping occurred with the bedrails up.	No numbers given. States that falls from bed whilst sleeping were more likely to result in injury.
Bates, 1995 ¹⁶⁰	A review of 62 patients who fell and sustained serious injury compared with 62 controls	US urban acute hospital	4 years + three months in 1987- 1991	Not stated	10 falls were falls from bed, of these nine occurred with the bedrails raised	N/A
Everitt 1997 ¹⁶¹ Inote also included in Table two]	A review of 281 falls from bed	UK teaching hospital	15 months in 1994/1995	Not stated	16/283 fell with bedrails 32/283 fell without bedrails 225/283 bedrails not mentioned	8 direct injuries from bedrails 5/16 injured in falls from bed with bedrails 8/32 injured in falls from bed without bedrails 118/225 injured in falls from bed where bedrails not mentioned (including one #NOF)
Gaebler 1993 ¹⁶²	50 multiple fallers compared with 50 single fallers	Australian acute hospital	6 months in 1989	Not stated	19 single fallers (38%) fell from bed. Multiple fallers were significantly less likely to fall from bed	Similar injury rates between groups 60%/58% but injury rates not broken down to falls from bed
Govier 2000 ¹⁶³	A review of 126 falls from bed	UK general hospital (eight selected 'high risk' wards)	6 months in 1999	83/206 (40%)	57/126 fell with bedrails 69/126 fell from bed without bedrails	21/57 injured in falls from bed with bedrails 28/69 injured in falls from bed without bedrails

159 Catchen H Repeaters: Inpatient accidents among the hospitalised elderly *The Gerontologist* 1983 23 3 273-276

¹⁶⁰ Bates DW Prues K Souney P et al. Serious falls in hospital patients: correlates and resource utilization American Journal of Medicine 1995 99 137-143

¹⁶¹ Everitt V, Bridel-Nixon J the use of bedrails: principles of patient assessment Nursing Standard 1997 12(6)44-47 162 Gaebler S Predicting which patient will fall again....and again Journal of Advance Nursing 1993 18 1895-1902

¹⁶³ Govier I Kingdom A The rise and fall of cot sides Nursing Standard 2000 14 31 40-41

TABLE 5 – Accident form reviews in hospital settings (continued)

Reference	Study type	Study location	Period of study	Level of bedrail use	Findings on falls	Findings on injury
NPSA 2007 ¹⁶⁴	A review of 346 random reports of falls to national database and 200 falls from bed selected from reports providing bedrail status, with additional sample for severe injury	English/Welsh acute hospitals	Random samples from larger collection of reports made during 2005	Not known	28% falls overall from bed 7% of falls from bed with bedrails 36% of falls from bed without bedrails	14/100 injured with bedrails 31/100 injured without bedrails Difference in overall injury significant No significant difference in moderate or severe injury rates Minor head injuries 21 without bedrails, 3 with bedrails (highly significant)
Innes 1983 ¹⁶⁵	A review of 270 falls included an unstated number of falls from bed	US acute hospital	11 months in 1981	Not stated	41% of falls from bed with both sides raised	Not stated
Krauss 2005 ¹⁶⁶	A review of 98 patients who fell from bed compared with 318 controls matched for length of stay	US academic hospital	Not stated	Not stated	'having one or more bedrails raised was associated with a statistically significant reduced risk of falling'	Not stated
Oliver 2006 ¹⁶⁷	A review of 154 legal daims made for injury from falls from bed	NHS hospitals in England	5 years 2000- 2005	Not known	Bedrails were raised in 4/154 cases (3%)	As these were litigation cases, all involved injury
Van Leeu- wen 2001 ¹⁶⁸	A review of 136 falls from bed	Australian small specialist hospital (ophthalmology and drug/alcohol detoxification)	7 years April 1993 to March 2000	Not stated	55/136 fell with bedrails 38/136 fell without bedrails 43/136 bedrails not mentioned	21/55 injured in falls from bed with bedrails including one death and twenty minor or moderate injury. Number of injuries in falls from bed without bedrails not stated but text states the proportion of minor and moderate injury was lower in falls with bedrails than in falls without bedrails but did not reach statistical significance

¹⁶⁴ NPSA Slips, trips and falls in hospital 2007 London: NPSA Access at www.npsa.nhs.uk

¹⁶⁵ Innes EM Turman W Evaluation of patient falls Quality Review Bulletin 1983 9 30-35

Krauss MJ Evanoff B Hitcho E et al A case-control study of patient, medication and care-related risk factors for inpatient falls Journal of General Internal Medicine 2005 50 2 116-122

Healey F Oliver D Preventing falls and injury in hospitals: where are efforts best directed? Health Care Risk Report 2006 12 7 15-17 167

Van Leeuwen M Bennett L West S et al Patient falls from bed and the role of bedrails in the acute care setting Australian Journal of Advanced Nursing 2001 19 2 8-13

TABLE 6 – Bedrail studies in nursing/care home settings

Reference	Study type	Setting	Study size	Bedrail use before	Bedrail type	Intervention	Bedrail use after	Results	Statistical significance
Brown, 1997 ¹⁶⁹	Before and after study of bedrail reduction	USA nursing home with very dependent residents	93 residents six months before/six months after	Not stated	Not stated	Education of staff and bedrail reduction programme	Not stated	16 falls in the bedroom before, 35 after Before 4% of visually impaired subjects fell, after 40% fell. Injury numbers not stated but implies most falls were no-harm.	Increase in falls significant, increase in falls in visually impaired subjects highly statistically significant
Hoffman, 2003 ¹⁷⁰	Before and after study of bedrail reduction	USA three long term care units	180 beds over one year before/ one year after 1999/ 2000	Bilateral 31.3% Single side 44.3%	Not stated but recording pro-forma suggests mix of split and traditional bedrails	Removal of bedrails, addition of crash mats, hip protectors, body pillows, position alarms, moving bed next to wall	Bilateral 18.3% Single side 30% †	Falls from bed 142 in total 2.28 per 1,000 bed days before/126 in total 2.13 per 1,000 bed days after Patients injured 43 before (30% of 142) 35 after (28% of 126) Minor injury (counting multiple injuries in same fall) 69 before/49 after* Hip # 1 before/ 2 after	Not statistically significant
Si, 1999 ¹⁷¹	Before and after study of bedrail reduction	USA rehabilitation unit within nursing home	25 beds over one year before/ one year after	Not stated but 'almost all' implied	Split bedrails integral to bed	Progressive removal of split side bedrails for existing residents. No bedrails for new residents until after one week's assessment.	Implies but does not specify 17 out of 130 admissions had bedrails in use	Falls in the bed area 19 before/31 after Total injuries 2 be- fore2 after Minor injury 2 before 1 after Serious injury 0 before/1 after	Not powered to detect significance

the bed, rather than in situations where free access was left to one side of the bed. Also implies bed rail use increased in periods when the researchers were not inspecting the unit 'the use of rails was somewhat The project encouraged placing beds against the wall, so some of the reduction in bilateral bedrail use occurred where one side of the bed was against the wall and one bedrail was in use on the other side of variable....rail use tended to decrease...immediately after intense feedback and monitoring

170 Hoffman SB, Powell-Cope G, MacClellan L, Bero K. BedSAFE - A Bed Safety Project for Frail Older Adults. Journal of Gerontological Nursing 2003 29(11): 34-42

171 Si M Neufeld RN Dunbar J Removal of bedrails on a short-term nursing home rehabilitation unit The Gerontologist 1999 39 5 611-614

^{**} Most studies count only the most serious injury rather than multiple injuries, as two small bruises are not necessarily worse from the patients' perspective than one large bruise. 169 Brown EL A study of a side rail reduction program in a long-term care facility: implications for a professional nursing staff. Columbia University Teacher's College PhD p 1-129

TABLE 7 – Accident form reviews in nursing home settings

Reference	Study type	Study location	Period of study	Level of bedrail use	Findings on falls and injury	Other findings
Capezuti 2002 ¹⁷²	A review of falls from bed analysed in relation to data collected on 319 patients during a body restraint reduction programme. 131 patients with bilateral bedrails were compared with 188 patients with no siderails or one	3 US Nursing homes	Between 1990 and 1992	46% to 71% bilateral rails (varied over time and be- tween homes and averaged 64%) Concurrent use of body restraints	Numbers of falls not given but the note that 5 falls resulting in serious injury amounted to 1.57% of all falls in the study implies 318 falls in total. However, since only 9.4% (30 falls) were recurrent falls this would mean 288 patients fell and only 31 patients fell and only small number of non-fallers might limit the validity of the analysis related to falls.	Patients given bilateral bedrails significantly less independent and more cognitively impaired. Patients who fell were significantly less independent and more cognitively impaired. Demographic details and 'behavioural symptoms score' not significantly different. When adjustments were made for the differences between groups, no statistically significant difference in the likelihood of falling could be found
Rubenstein 1983 ¹⁷³	A review of 16 falls from bed	US nursing home	Around 1982	Not stated but routine use for patients aged over 65 implied	14/16 fell with bedrails Injuries not stated	

These two situations are not separated in the results. It is unknown if the use of single side rails occurred in situations where the other side of the bed was against the wall (which would be expected to have the same impact on falls as bilateral bedrails)

173 Rubenstein HS, Miller FH Postel S et al. Standards of medical care based on consensus rather than evidence; the case of routine bedrail use for the elderly Law Medicine and Health Care 1983 11 271-276

¹⁷² Capezuti E, Maislin G, Strumpf N, Evans LK Side rail use and bed-related fall outcomes among nursing home residents Journal of the American Geriatric Society 2002 50(1):90-96

TABLE 8 – Patients', relatives' or staff views on bedrails

Reference	Study type	Setting	Findings
Gallinagh 2001	Includes patients' views of bedrails within study of patients' views on chair/bed restraint	Northern Ireland older person's rehabilitation ward within acute hospital	Whilst the overall results of the study do not separate out patients' opinions on bedrails, some individual quotes relating to bedrails can be extracted. 3 comments on bedrails were positive, 1 patient was upset that the bedrails stopped him getting out of bed alone 1 patient objected to the design rather than the bedrail itself 2 patients commented that they had no problem getting round the bedrails if they wanted to 1 commented the bedrails were cold The reasons the patients thought nurses used bedrails included standard practice, because the patient tossed and turned, for nurses' peace of mind, to avoid blame or litigation if the patient fell out of bed, and to stop bedclothes slipping to the floor.
Gallinagh 2001 ¹⁷⁵	Interviews with nine relatives of patients who had bedrails in use	Northern Ireland older person's rehabilitation ward within acute hospital	5 recalled that staff had explained the reasons for the bedrails to them 9 expressed an understanding that they were for safety, to prevent falls from bed. 2 said they help the patient change their own position in bed. 3 commented you expect bedrails on beds for older patients. 1 said they could make a barrier between them but that the nurses had shown her how to take the bedrails down when visiting. 1 commented the patient didn't like them 'but it is for his own good, you know'. On probing by the interviewers, the nine relatives between them succeeded in identifying the risk of climbing over bedrails, poorly attached bedrails that might fall off, leg entrapment or injury and 'there's a million to one chance somebody would try to get their head through the bedrails'. The relatives made suggestions for improved bedrail design including mesh covers, padding, narrower gaps between the rails, and plastic instead of metal.
Vassallo 2004 176 177	Questionnaire on falls prevention which referred to bedrails completed by 57 patients, 43 relatives, 49 doctors, 40 nurses and 11 therapists	General hospital in Southern England	89% of patients thought bedrails were acceptable 90% of relatives thought bedrails were acceptable 64% of staff thought bedrails were acceptable For context: 7% of patients thought being nursed on a mattress on the floor to prevent falls was acceptable 84% of patients thought a notice at the bed head, with patient consent, to highlight risk of falls was acceptable

174 Gallinagh R, Nevin R, McAleese L, Campbell L Perceptions of older people who have experienced physical restraint British Journal of Nursing 2001 10,13,852-859

¹⁷⁵ Gallinagh R Nevin R Campbell L et al Relatives' perception of side rail use on the older person in hospital British Journal of Nursing 2001 10 6 391-398

¹⁷⁶ Vassallo M, Stockdalle R, Wilkinson C et al. Acceptability of falls prevention measures for hospital inpatients Age and Ageing 2004 33;4;400

¹⁷⁷ Vassollo M, Wilkinson C, Stockdale R et al. Attitudes to restraint for the prevention of falls in hospital Gerontology 2005 51;1; 66-70

TABLE 8 – Patients', relatives' or staff views on bedrails (continued)

Reference	Study type	Setting	Findings
Ralphs- Thibodeau ¹⁷⁸ [note also included in Table 4]	Part-randomised study of bedrail reduction	Canadian rehabilitation hospital	In an attempt to carry out a cluster controlled trail between routine bedrails/no bedrails, they found some patients insisted on choosing which group they were allocated to. 7/30 patients moved to the routine bedrails group, and 17/30 residents agreed to stay in the routine bedrails group (24/60 = 40%). 13/30 patients moved to the no bedrails group, and 23/30 agreed to stay in it (36/60 =60%) Patients who choose bedrails were less mobile and more dependent
Hoffman, 2003 ¹⁷⁹ Inote also included in Table 6]	Before and after study of bedrail reduction	USA three long term care units	Describes very intensive steps taken to get bedrails removed from residents who wanted to keep them, including taking the bedrails down for increasing periods. Staff who advocated that the patients' wishes should be respected were seen as a barrier to the successful implementation of the bedrail reduction programme: 'one nurse told us "advocating for the patient is never wrong"this view becomes particularly problematic'

178 Ralphs-Thibodeu S, Knoefel F, Benjamin K et al. Patient choice; an influencing factor on policy-related research to decrease bedrail use as physical restraint Worldviews on evidence based nursing

179 Hoffman SB, Powell-Cope G, MacClellan L, Bero K. BedSAFE - A Bed Safety Project for Frail Older Adults. Journal of Gerontological Nursing 2003 29(11): 34-42

TABLE 9 - STUDIES WITH PERIPHERAL REFERENCE TO BEDRAILS

Keterence	Content
Ball MC Hanger HC Thwaites JH Bed rails: a barrier to independence? Clinical rehabilitation 1997 11 347-349	Time taken by patients to stand from beds with no bedrails, compared to beds with bedrails attached but down. The latter was on average two seconds slower, but confounded by an order effect
Brandeis GH Baumann MM Hossain M et al. The prevalence of potentially remediable urinary incontinence in frail older people: a study using the minimum data set Journal of the American Geriatric Society 1998 45 2 179-184	USA correlation study of bedrails and incontinence. Correlation likely to be due to other confounding factors such as mobility problems and cognitive impairment.
Capezuti E, Strumpf N, Evans L, Maislin G Outcomes of nighttime physical restraint removal for severely impaired nursing home residents <i>American Journal of Alzheimer's disease</i> 1999 14 3 157-164	Study focussed on body restraints. Side rail use levels noted as 96.7% for this group of severely impaired residents
Gallinagh R Nevin R McIlroy D et al The use of physical restraints as a safety measure in the care of older people in four rehabilitation wards: findings from an exploratory study International <i>Journal of Nursing studies</i> 2002 39 147-156	Study of restraint use and nurses' rationale; bedrail main form of restraint but bedrail data not separated from chair restraint data
Hignett S Masud T Jansen S (2005) Review of in-patient falls associated with hospital bed rails In Bust P and McCabe PT (eds) Contemporary Ergonomics London: Taylor and Francis 475-479	Bedrail prevalence study within medical directorate. Bedrails used on 46% of beds at night and 18% by day. Risk assessment documentation available for 71%. Avoiding falls most common reason for use (42%) followed by patient/relative request (22%)
Levine JM Hammond M Marchello V et al. Changes in bedrail prevalence during a bedrails-reduction initiative 2000 1 1 34-36	USA bedrail reduction study but no outcome measures. Overall bedrail use increased from 50% to 56% of beds during a bedrail reduction programme, but fewer beds had all four split rails raised.
Miller P Safe in a cocoon <i>Nursing times</i> 1989 85 41 38-40	Article with anecdotal descriptions of harm from bedrails but in context of promoting the use of cocoons (sheet restraints)
Mollassiotis A Newwell R Nurses' awareness of restraint use with elderly people in Greece and the UK: a cross-cultural pilot study <i>International Journal of Nursing Studies</i> 33 2 201-211	Nurse attitudes to restraint UK/Greece – unclear whether or not restraint defined as including bedrails
Rollins MO Safety issues surrounding the use of bedrails Nursing Older People 2006 17 10 20-21	A vignette of a patient with bedrails used to discuss previously published evidence
Ross JER, Mass ML et al. Evaluation of two interventions to reduce falls and fall injuries. The challenge of hip pads and individualized elimination rounds. In Funk SG et al, eds. <i>Key aspects of elder care: managing falls, incontinence and cognitive impairment.</i> Springer 1992;	Hip protector/toileting study with anecdotal mention of bedrails
Rubin BS Dube AH Mitchell EK Asphyxial deaths due to physical restraint a case series <i>Archives of Family Medicin</i> e 1993 2 4 405-408	Deaths related to body restraints. 13 deaths also involved bedrails. Included infants.
Tinetti ME Lui WL Ginter SF Mechanical restraint and fall-related injuries among residents of skilled nursing facilities <i>Annals of Interim Medicine</i> 1992 116 369-374	Study focussed on body restraints. Side rail use levels noted as 62%

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