

QAS515SP08

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Title: Two side rails (full length) option bed to reduce patient entrapments or falls and injuries related.

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Introduction and problem statement:

Bed rails are used very widely in hospitals and throughout the community to prevent patients falling out of their beds, help patients in turning and repositioning within the bed, and provide a hand-hold for getting into or out of the bed. However, there have been a number of adverse incidents involving bed rails used that have led to injury and in some cases death. Many Incidents occurs were patients strangulated and died or developed serious injuries when they fall down from bed and trapped between the side rails.

(Between January 1, 1985 and January 1, 2006, FDA received 691 incidents of patients caught, trapped, entangled, or strangled in hospital beds. The reports included 413 deaths, 120 nonfatal injuries, and 158 cases where staff needed to intervene to prevent injuries. Most patients were frail, elderly or confused) 1.

All available kinds of bed rails have the risk for entrapment both split and full length bed rails could cause related injuries or entrapment, to avoid these incidents and to protect the patients from bed entrapment we should avoid the poor side rails designs which have a very large spaces between the bars which could allow the patient to slip through, or the one have gaps between the end of the side rails and the head/footboard that may lead to cause entrapment.

"Health care organizations need to look at these devices like any restraint and evaluate the rationale for using them. Don't pull up the side rail and walk away. Both split and full rails have the potential to cause fall-related injuries as well as entrapment. Health care organizations need to look on bed rails as potentially restrictive devices, or restraints, and ask themselves what kind of surveillance needs to be in place to assure safety." said Elizabeth Capezuti, PhD, RN, FAAN, associate director for nursing science at the Center for Health in Aging at Emory University. (Capezuti, 2002)6

Other options could be considered instead of using bed rails, such as beds with adjustable height used in the lowest position, soft cushioning on the floor to avoid a patient's fall, pressure alarm systems to alert caregivers that a person has moved from their normal position, and many other methods, however still we need the bed rails in many cases due to the nature of the sickness or the disease in a special population, we can't avoid using the bed rails completely, for this reason here we will try to find a better bedrails design, as a full length two sides specifically to fit the bed without any gap or spaces, with a permanent vinyl cover easily wipes clean for easy care, and with a flexible frames.

We will implement the human factors engineering (HFE) countermeasures to safe lives; protect patients and any one else using the bed rails from entrapment. Prevent and avoid this major problem from occurrence by using full length rails bilateral, along the bed side, as one piece without any spaces or gaps, with extra options of a pressure alarm system and air bags, which will be activated as a response to the present of a continuous pressure on the bed rails.

Bed rails must be designed to safe patients not to kill them.

Background:

Bed rails are used extensively on patients bed to avoid falls, on stretchers or beds while transporting patients following surgery or when relocating a patient to a new room or unit; very helpful in turning and repositioning patients within the bed; may provide a feeling of comfort and security, or facilitate access to bed controls; and may be used as a physical barrier to limit the voluntary movement out of bed (physical restraint).

Bed rails are adjustable metal or rigid plastic bars that attach to the bed and are available in a variety of shapes and sizes from full to half, one-quarter, and one-eighth in lengths, serve a variety of purposes, some of which are in the best interest of the patient's health and safety.

The most popular bedrails in use are:

1. Full-Length Rail: A one-piece rail that extends along the side of the bed from the head to the foot section.
2. $\frac{3}{4}$ -Length Rail: A one-piece rail that extends along the side of the bed three-quarters of the way down from the head of the bed.
3. Half-Length Rail: A one-piece rail that extends along the side of the bed one-half the length of the bed from the head of the bed.
4. Quarter-Length Rail: A one-piece rail that extends along the side of the bed approximately $\frac{1}{4}$ the length of the bed from the head of the bed.
5. Split Rails: A pair of half rails. One set extends along the side of the bed from the head of the bed to the mid-section of the bed. The other set extends from the mid-section of the bed to the foot of the bed. Generally, there is a space between the two sets of rails.
6. Transfer Bar: A one-piece device, attached to the bed frame on one or both sides of the bed that is grasped to aid in bed entry and exit.

Evidence indicates that half-rails have a risk of entrapment and full rails have a risk of entrapment as well as falls that occur when patients climb over the rails or footboards when the rails are in use. Recognizing this risk, the U.S. Food and Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS), have taken action to reduce the injuries related to bed rails.

The FDA MedWatch Reporting Program receives reports of entrapment hazards. In 1995 the FDA issued a Safety Alert entitled, "Entrapment Hazards with Hospital Bed Side Rails."⁵

In 1997, the FDA wrote an article, based on the reported hospital bed adverse events that identified potential risk factors and entrapment locations about the hospital bed.

CMS issued guidance in June 2000 for surveyors to determine hospitals compliance with these regulations. 3

One section of the guidance states:” It is important to note that side rails present an inherent safety risk, particularly when the patient is elderly or disoriented. Even when a side rail is not intentionally used as a restraint, patients may become trapped between the mattress or bed frame and the side rail. Disoriented patients may view a raised side rail as a barrier to climb over, may slide between raised, segmented side rails, or may scoot to the end of the bed to get around a raised side rail. When attempting to exit the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if he/she had fallen from the height of a lowered bed without raised side rails”.3

The FDA guidelines identifies specific parts of the body at risk for entrapment, describes potential entrapment areas, recommends maximum and minimum dimensional limits of gaps or openings in hospital bed systems, at the same time provides a scientific basis for the dimensional limits derived from a review of international anthropometric data, a review of historical entrapment data, and a retrospective study to verify the proposed dimensional limits.

Here we attached the summary of the FDA bed dimensions and the body parts dimensions.

Summary of FDA Hospital Bed Dimensional Limit Recommendations

| Zone | Dimensional Limit Recommendations |
|---|-----------------------------------|
| | |
| 1 Within the rail | <120 mm (< 4 3/4 ") |
| 2 Under the rail, between rail supports or next to a single rail support | < 120 mm (< 4 3/4 ") |
| 3 Between rail and mattress | <120 mm (< 4 3/4 ") |

| | |
|---|---|
| <p>4</p> <p>Under the rail, at the ends of the rail</p> | <p><60 mm (< 2 3/8 ")</p> <p>AND</p> <p>>60° angle</p> |
|---|---|

*(1)

Key Body Part Dimensions

| Key Body Part | Dimension |
|---------------|---|
| Head | 120 mm (4 3/4 inches) |
| Neck | 60 mm (2 3/8 inches) and an angle > 60 degree |
| Chest | 318 mm (12 1/2 inches) |

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Joint Commission recommendations:

In the Sentinel Event Alert from the Joint Commission, Bed Rail-Related Entrapment Deaths, JCAHO recommends to assess the patient/resident for risk of entrapment, and then evaluate the bed for entrapment potential. These recommendations are consistent with other strategies to manage the patient risk through proper equipment selection such as assessing the potential risk of pressure ulcers and then determining the proper equipment to meet clinical needs, such as an air fluidized bed. In the alert, in their alert, JCAHO notes that gap measurement is at the discretion of the individual health care organization.⁶

To help prevent entrapment deaths associated with bed rails, Joint Commission recommends that health care organizations take these precautions:

1. Provide proper education to staff about entrapment dangers with bed rails.
2. Assess patients for risk of entrapment, including physical, mental, behavioral or medication impairment.
3. Re-evaluate beds for entrapment potential, including "gap" measurement and appropriate sizing of mattresses for bed frames.
4. For individual patients at risk for entrapment, implement appropriate changes to beds (for example, the use of retrofit kits, bed rail netting, clear padding, Velcro or anti-skid mats) to reduce the risk of entrapment.
5. When possible, keep patients with risk factors for entrapment under more frequent close observation.
6. Educate the patient and family about the purpose and potential dangers of bed rails.

Additional environment of care/equipment recommendations cited in the literature include the following:

1. Act on federal and private equipment alerts.
2. Ensure that all bed leases have a provision stating that the owner will immediately forward safety alerts and install new safety modifications.
3. Inspect all bed frames, bed rails, and mattresses as part of a regular maintenance program to identify areas of possible entrapment.
4. When bed rails and mattresses are purchased separately from the bed frame, check with the manufacturers to make sure they are compatible.
5. Be alert to replacement mattresses and bed rails with dimensions different from the original equipment supplied or specified by the bed frame manufacturer. Not all bed rails, mattresses, and bed frames are interchangeable.
6. Use the manufacturer's instructions to ensure the proper installation of bed rails.

7. When installing protective barriers to close off open spaces, follow organization procedures and/or the manufacturer's installation specifications.
8. Consider placing Velcro or other antiskid material between the mattress and the mattress deck to reduce mattress slippage to one side or toward the foot of the bed.
9. Use padded bed rail covers to reduce trauma and to obscure bar spaces for any agitated patient or when the patient's head can pass between head rail bars.

Analysis:

Available statistical data related to beds entrapments:

"There are about 2.5 million hospital and nursing home beds in use in the United States. Between 1985 and 2008, 772 incidents of patients caught, trapped, entangled, or strangled in beds with rails were reported to the U.S. Food and Drug Administration, of these reports, 460 people died, 136 had a nonfatal injury, and 176 were not injured because staff intervened. Most patients were frail, elderly or confused".⁴

This is a huge lost on lives due to a preventable reason, a proper designing of the bedrails is only one option, but what I believe the continuous assessment and close observation to those are at risk for bed entrapment more beneficial to save lives.

Healthcare organizations should use the FDA Clinical Guidance to consider the patient population that is served and their risk for bed rail entrapment, and then, if appropriate, focus on the bed rail dimensions.

Assessing the needs of the patient and, if indicated, re-evaluating the bed for entrapment potential, is a realistic way to manage this risk. With the multi types of beds, and bed/mattress combinations, each healthcare facility, must test their beds by conducting a periodic review to verify that they are in good repair and the mattresses properly fit the bed is a good starting point toward assuring that the hospital beds perform their designed patient care function. In addition, to the risk analysis to identify the proper equipment is available for patients identified as "at risk" for bed rail entrapment.

When bed rails are used, it is important to perform on going assessments of the patient's status and closely monitor high-risk patients, such as those who are confused, restless, very frail, or are unable to move in bed independently.

Patient's population and the potential entrapment areas:

The populations at risk for entrapment are patients who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, and acute urinary retention that cause them to move about the bed or try to exit from the bed.

There are multiple factors increase the risk of entrapment such as the absence of timely toileting, position change, and nursing care. The risk may also increase due to technical issues such as the size of mattresses, bed rails with winged edges, loose bed rails, or design elements such as wide spaces between vertical bars in the rails themselves.

Most of the individuals involved in these incidents can be classified as elderly, frail, and confused. 85% of the entrapments are of those who are over 65 years of age. These individuals constitute a large of the resident population of long term care facilities, with 89.8% of the residents being over age 65, and 63% being disoriented or memory impaired.¹¹

Based on FDA safety alert regarding the use of bedrails the potential areas of Entrapment are:

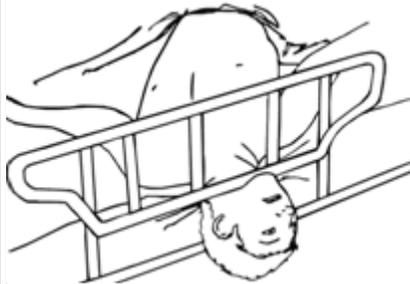
1. Within the Rail
2. Under the Rail, Between the Rail Supports or Next to a Single Rail Support
3. Between the Rail and the Mattress
4. Under the Rail, at the Ends of the Rail
5. Between Split Bed Rails
6. Between the End of the Rail and the Side Edge of the Head or Foot Board
7. Between the Head or Foot Board and the Mattress End
8. The first four zones constitute 87% of the entrapment incidents based on the available statistics.¹¹

Drawings of Potential Entrapment in Hospital Beds

Zone 1 - Entrapment within the rail



Zone 2 - Entrapment under the rail, between the rail supports or next to a single rail support



Zone 3 - Entrapment between the rail and the mattress



Zone 4 - Entrapment under the rail, at end of rail



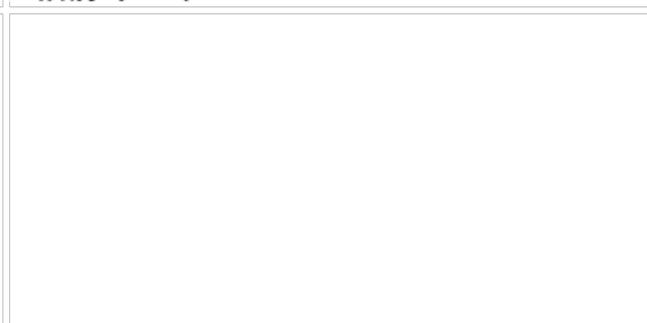
Zone 5 - Entrapment between split bed rails



Zone 6 - Entrapment between the end of the rail and the side edge of the head or foot board



Zone 7 - Entrapment between head or foot board and the mattress end





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HFE Countermeasure:

If it is determined that bed rails are required and that other environmental or treatment considerations may not meet the individual patient's assessed needs, or have been tried and were unsuccessful in meeting the patient's assessed needs, then close attention must be given to the design of the rail and the relationship between rails and other parts of the bed.

The suggested bed rail safety Guidelines from all responsible parties are as follows:

1. The bars within the bed rails should be closely spaced to prevent a patient's head from passing through the openings and becoming entrapped.
2. The mattress to bed rail interface should prevent an individual from falling between the mattress and bed rails and possibly smothering.
3. Care should be taken that the mattress does not shrink over time or after cleaning. Such shrinkage increases the potential space between the rails and the mattress.
4. Check for compression of the mattresses outside perimeter. Easily compressed perimeters can increase the gaps between the mattress and the bed rail.
5. Ensure that the mattress is appropriately sized for the selected bed frame, as not all beds and mattresses are interchangeable.
6. The space between the bed rails and the mattress and the headboard and the mattress should be filled either by an added firm inlay or a mattress that creates an interface with the beds rail that prevents an individual from falling between the mattress and bed rails.

7. Latches securing bed rails should be stable so that the bed rails will not fall when shaken.

8. Older bed rail designs that have tapered or winged ends are not appropriate for use with patients assessed to be at risk for entrapment.

9. Maintenance and monitoring of the bed, mattress, and accessories such as patient / caregiver assist items should be ongoing.”

I believe using full length rails bilateral, extended along the bed side, as one piece, without any spaces or gaps, with extra options of a pressure alarm system and air bags, which will be activated as a response to the pressures on the bed rails is the best way to control entrapment problem and minimizing related bed rails injuries.

Full length bedrails made of vinyl material and flexible frames with the ability to be articulated whenever the head or the foot of the bed articulated will avoid the entrapment at the articulation area, powering this system by pressure alarm and air bags to be activated in the occurrence of continuous high pressure at the bedrails.

Absolutely This bedrail without any spaces or gaps, attached to the bed as apart not as an accessory, the alarm system will allowed a quick response from the caregivers to respond immediately and give the proper help, while the airbags option will work the same goal as in the vehicles, it will protect the patient from falling down or out of the bed in case he tried to climb or jump over the bedrails, and the flexible frame will allow the users to reshape the bed rails based on the position of the bed especially when articulation is needed.

Conclusion:

If all other considerations such as patient family education, lowering the height of the bed providing a sitter to watch the confused patients or any other group of the special populations who are in need for bed rails not possible, I believe the full length bedrails made of vinyl material and flexible frames with the ability to be articulated whenever the head or the foot of the bed articulated to avoid the entrapment at the articulation area, powered by pressure alarm system and air bags which will be activated in the occurrence of continuous pressure at the bedrails is the best way to avoid entrapment incidents.

Absolutely This bedrail without any spaces or gaps, attached to the bed as a part not as an accessory, the alarm system will allowed a rapid response from the caregiver to respond immediately and give the proper help necessary whenever the patient move aggressively within the bed, while the airbags option will work the same goal as in the vehicles, it will protect the patient from falling down out of the bed in case he tried to climb or jump over the bedrails.

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