I’m Stuck and I Can’t Get Out! Hospital Bed Entrapment

Healthcare facilities have submitted to PA-PSRS over 100 reports of hospital bed rail entrapment since June 2004. In the past, healthcare workers considered bed rails a useful device to prevent patient falls from bed. While bed rails have their benefits, their use or misuse may also place patients at significant risk, resulting in death or serious injury.

Definitions
Entrapment is an occurrence involving a patient who is caught, trapped, or entangled in the hospital bed system, which includes the spaces in or around the bed rail, hospital bed mattress, or hospital bed frame. Bed rails are adjustable plastic or metal bars that attach to the bed frame. They are available in several shapes and sizes, ranging from full to half, one-quarter, and one-eighth lengths. Entrapped body parts associated with risk for severe injury include the head, neck, and chest.

Incidence
From 1985 through 2005, the U.S. Food and Drug Administration (FDA) received 691 reports of hospital bed entrapment including 413 deaths, 120 nonfatal injuries, and 158 occurrences of staff intervention which prevented injuries.

In response to reports of entrapment, FDA partnered with the Veteran’s Administration, Health Canada, other federal agencies, national healthcare organizations, representatives from the hospital bed industry, and patient advocacy groups to form the Hospital Bed Safety Workgroup (HBSW). Its goal was “to improve safety of hospital beds for patients in all healthcare settings who are most vulnerable to the risk of entrapment, particularly that of older adults.” The FDA and the HBSW have produced guidance documents that healthcare facilities and manufacturers can use as references to reduce entrapment risks. (See the section below on Entrapment Prevention Resources.)

Entrapment Zones
In an effort to standardize/clarify the bed entrapment discussion, FDA and HBSW defined seven areas of the hospital bed system in which patient entrapment is most likely to occur.

PA-PSRS Reports of Entrapment Harm
About 4% of the entrapment reports were classified as Serious Events, and about 50% of the Incidents indicated some type of injury. The remaining reports indicated either that no injury occurred or no injury was specified. The majority of entrapments resulted in either no harm or minor injuries (i.e., abrasions, skin tears, lacerations, bruises/redness, indentations, pain/discomfort); however, all reports indicated that healthcare workers needed to extricate the patient to prevent greater harm.

The most severe injury reported had a Harm Score of F (i.e., an event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization). In this case, the patient required an extended hospital stay to treat a significant methicillin resistant Staphylococcus aureus (MRSA) infection of a skin tear on a leg that had been caught in a side rail.

Age
Sixty-eight percent of the entrapped patients were 70 years of age or older. However, the ages of entrapped patients reported ranged from 10 months to 99 years old. Therefore, all ages may be at risk of entrapment, particularly if other risk factors are present.

Body Part Entrapped
Thirty-nine percent of the PA-PSRS entrapment reports did not specify the body part entrapped. Entrapment of the head and chest (associated with potential for serious injury) occurred in 9% of the reports. The most common entrapped body parts were lower extremities (25%) and upper extremities (11%). Nine percent of reports involved entrapment of more than one body part, while another 3.5%...
involved the hip/pelvis. The remaining 3.5% indicated that the body/torso was entrapped.

**Entrapment Zone**
Eighty-seven percent of the entrapments reported to PA-PSRS occurred in three zones: Zone 5 (39%), Zone 1 (26%), and Zone 3 (22%). (See Table 1 for additional statistics on PA-PSRS entrapment reports.) This pattern varies from the FDA’s data in which the majority of reported entrapments occurred in Zones 1 through 4. The Joint Commission on Accreditation of Healthcare Organizations has received sentinel event reports of entrapment that involved Zones 1, 3, 5, and 6. These variations may be the result of FDA’s and Joint Commission’s databases containing a greater proportion of deaths and serious injuries, while the PA-PSRS reports are predominantly near misses.

**Benefits of Bed Rails**
In certain circumstances, bed rails can be beneficial. They can remind a patient not to get out of bed, if there is medical equipment attached or if it is medically contraindicated. A patient can use them while repositioning or turning while in bed. They can be used as hand-holds to assist the patient while getting in or out of bed. Bed rails also define the sides of an unfamiliar bed and may also provide the patient with a sense of security and comfort. They can prevent rolling out of bed and reduce the risk of falling from a bed or litter during transport. Bed rails may also provide convenient access to bed controls, the nursing call bell, and television and radio. However, these collective benefits must be weighed against the risks of using bed rails.

**Risks of Bed Rails**
While bed rails are commonly thought to prevent falls, patients who fall while climbing over raised bed rails are at greater risk of serious injuries, including head trauma, lacerations, fractures, and dislocations. Raised bed rails may increase patient agitation. Bed rails enhance feelings of isolation and restriction/imprisonment, thereby negatively affecting self esteem. Moreover, the confinement of bed rails may prevent patients who are able to get out of bed from conducting routine activities, such as retrieving an object or going to the bathroom. (In instances where bed rails prevent patients from going to the bathroom, patient incontinence may be likely to occur.) Lastly, bed rails are associated with severe bodily injury, suffocation, strangulation, and death.

**Risk Factors for Entrapment**
Risk factors for entrapment may be patient-related, care-related, or equipment-related.

**Patient-Related**
Bed rail entrapments commonly occur in frail, elderly patient populations. Mentally or behaviorally impaired persons may be at risk, including those with agitation, delirium, hypoxia, confusion, dementia, and memory problems. Those with uncontrolled body movements may find themselves in an entrapment situation from which they cannot independently...
extricate themselves. Patients at fall risk or with serious sleeping problems may get entrapped in the bed system while attempting to get out of bed unassisted. Incontinent patients and those with acute urinary retention or fecal impaction are at risk for entrapment when they attempt to go to the bathroom by getting out of bed with the bed rails raised. Those with limited mobility in bed (such as hemiparesis) or a physical deformity may be at risk because they may be physically unable to extract themselves from the bed system. Patients taking sedative or psychoactive drugs may not be aware of entrapment as it occurs.

### Care-Related

Entrapment is more likely when the following care is not provided on a timely basis: toileting, position changes, pain management, or other interventions to promote patient comfort.

### Root causes involved with Joint Commission’s entrapment sentinel event reports revealed the following contributing factors:

- Breakdown in communication—among staff, with/between physicians, or with administration
- Equipment factors—problems with configuration of the bed, mattress, or bed rail (e.g., bed rail protector was not used or mattress or rail not compatible with bed frame)
- Problems with patient assessment—adequacy, scope/timing, patient observation
- Staffing and supervision—lack of leadership, use of agency nurses, staff orientation

### Equipment-Related

In older bed systems, the original design may not have accounted for the risk of patient entrapment. More commonly, however, entrapment risk may increase after aging bed system components are replaced. For example, replacement mattresses may be undersized and not fit as snugly as the initial mattresses.

Use of air pressure mattresses may further increase the entrapment risk. When a patient moves to one side of some types of air mattresses, that side compresses while the center of the mattress raises. The resulting “slide” allows the patient to move from the mattress to the bed rail. Such compression can also result in a wider space between the rail and the mattress, thus increasing entrapment risk.

If side rails no longer lock into the raised position, patient movement may cause a partially raised rail to fall onto a patient’s neck or extremity. Additional equipment-related entrapment risks include: bed rails with winged lower edges, improper match of bed frame with bedrails, loose bed rails, improper installation of the bed system, wide spaces between the bars in the rails, holders/supports that remain when the bed rail is removed.

FDA reports and Joint Commission sentinel event reports implicated no particular rail configuration at higher risk for entrapment: both full and half length rails were associated with entrapment.

### Risk Reduction Strategies

There are several “A’s” involved in reducing the risk of entrapment: Approach, Assessment, Awareness, and Actions.

#### Approach Strategies

While healthcare workers have used bed rails as a patient safety mechanism (e.g., for fall prevention), their use may pose an unwarranted hazard. Rather than automatically applying bed rails, it is prudent for healthcare workers to conduct a risk-benefit analysis; that is, to make bed rail decisions on a case-by-case basis, founded upon individualized patient assessment using input from the interdisciplinary healthcare team and the patient, family, and/or patient’s legal guardian.

Elizabeth Capezuti, Ph.D., R.N., APRN-BC, FAAN, Associate Professor and Co-Director of the John A. Hartford Foundation Institute for Geriatric Nursing,
I’m Stuck, and I Can’t Get Out! Hospital Bed Entrapment (Continued)

New York University College of Nursing, an expert on restraints and bed rail safety, states the following about bed rails:

Healthcare organizations need to look at these devices like any restraint and evaluate a 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. Healthcare organizations need to look at bed rails as potentially restrictive devices, or restraints, and ask themselves what kind of surveillance needs to be in place to assure safety.8

The Centers for Medicare & Medicaid Services (CMS)9 and Joint Commission1 define bed rails as restraints when they are used to prevent a patient from voluntarily getting out of bed. Therefore, the use of bed rails must be considered by balancing patient rights with the caregiver’s responsibility to provide care based upon individualized assessment, applicable laws and regulations, and professional standards of care.

Assessment Strategies

Conducting individualized and ongoing patient assessment is another method to reduce entrapment risk.3 Effective patient assessment involves the interdisciplinary healthcare team, the patient, and his or her family. Obtaining the following information will identify the patient at risk for entrapment and falls and will indicate whether the patient could benefit from restraint use.3,8

- Medical diagnoses, symptoms, and the patient’s medical stability
- Surgical interventions the patient requires
- Underlying conditions that might place the patient at risk for entrapment, including the following:
  - cognitive/mental status changes
  - incontinence
  - pain level and extent of pain control
  - lack of muscle control
  - physical deformities
  - ability to adequately communicate needs or problems
- Sleeping habits and bedtime routines, as well as customary sleeping environment
- Familiarity/comfortableness/accessibility of surroundings
- Distance from the bed to the toilet
- Level of patient independence (e.g., ability to safely toilet, get in and out of bed)
- Patients who meet fall risk criteria
- Appropriateness of the bed for patient needs
- Level of caregiver support that the patient requires
- Presence of medications, sedation, or prepping agents that might increase the risk of entrapment

Similar to patient assessment, regular and ongoing equipment assessment (i.e., of the bed system entrapment zones) provides a foundation upon which to reduce the risk of entrapment.3,8 FDA recently produced a “Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment.” They guidance describes a test tool developed by the HBSW for use by healthcare facilities to measure bed systems. This cone and cylinder tool is designed to simulate the 95th percentile for the size and weight of a small adult female head and a compressed neck. The tool includes a force gauge — a scale to measure less than or equal to 12 pounds of force during certain test conditions. While the tool is designed to measure all entrapment zones, FDA currently gives no dimensional recommendations for Zones 5, 6, and 7. The tool comes with a training and instructional video10 that explains how to use the tool and perform the bed measurements. The tool is used on a made bed and can measure gaps/spaces when the bed is placed in the flat position, as well as in other bed surface configurations. The tool is available online at http://www.nst-usa.com.10

The testing process may be more efficient if one person performs the measurements, while another records the findings.11 Debate exists concerning whether all beds with identical bed system components should be measured individually.11 One school of thought contends it may not be necessary to measure each of these beds if one bed in the category passes. The exception is when a particular bed system passes marginally; in such an instance,
I'm Stuck, and I Can't Get Out! Hospital Bed Entrapment (Continued)

all beds with identical bed system components should be individually measured. Another perspective is that every bed should be measured because identical bed systems are subjected to different wear and tear and some bed systems may pass the test while others may not.

FDA, with recommendations from the HBSW, has published nonbinding guidance with dimensional recommendations for hospital beds for Entrapment Zones 1 through 4. The dimensional guidance pertains to full-size hospital beds that are the subject of the FDA and HBSW studies. These dimensional limits are summarized in Table 2. The majority of FDA reports of serious injury have occurred in these four zones. In the future, FDA hopes to publish dimensional recommendations for the other zones, as well as for beds in different configurations/positions. Or, the FDA may consider adopting international standards to address dimensional recommendations.

Assessment of bed systems includes the following:

- Ensuring that the bars within bed rails are closely spaced to prevent a patient’s head from passing through
- Determining whether the space between the bed rail and the mattress prevents a patient from falling in the gap
- Checking for conditions that over time might increase the gap between the bed rails and mattress; for example, damage to bed rails, age, and the use of cleaning agents on the mattress may cause shrinkage or compression
- Because mattresses are not all alike, checking the gap between the mattress and bed rails when replacing a mattress in the bed system

Reassessment of hospital bed systems is appropriate when:

- Changing bed system components (e.g., new mattresses)
- Adding or removing accessories (e.g., positioning poles or mattress overlays)
- Components appear to be wearing (e.g., wobbly side rails or soft/uneven mattress surfaces)

Action Strategies
The assessment becomes the foundation for developing actions, including ongoing care plans and treatment programs designed, among other things, to reduce entrapment risk.

Prescriber actions may include the following:

- Minimizing mental status-altering medications
- Being mindful of medications to avoid in the elderly, such as those on the Beers list. (See: Pennsylvania Patient Safety Reporting System. The Beers Criteria: screening for potentially inappropriate medications in the elderly. PA-PSRS Patient Saf Adv 2005 Dec;2(4):11-15. Available from Internet: http://www.psa.state.pa.us.)
- Ordering alternative interventions for sleeping medications
- Timing diuretics so that they are given before the late afternoon or evening
- Treating pain/prescribing analgesia

<table>
<thead>
<tr>
<th>Zone</th>
<th>Dimensional Limit</th>
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<tbody>
<tr>
<td>1</td>
<td>No less than 120mm (4 ¾”)</td>
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<tr>
<td>2</td>
<td>No less than 120mm (4 ¾”)</td>
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<tr>
<td>3</td>
<td>No less than 120mm (4 ¾”)</td>
</tr>
<tr>
<td>4</td>
<td>No less than 60mm (2 3/8”) AND Greater than 60° angle</td>
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</tbody>
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Table 2. Entrapment Zone Dimensional Limits

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I’m Stuck, and I Can’t Get Out! Hospital Bed Entrapment (Continued)

- Assessing, ruling out, and treating reversible causes of hypoxia and delirium
- Ordering physical therapy to promote safe standing, ambulation, and mobility

Reducing entrapment involves many patient care interventions, such as the following, that fall under the general categories of fulfilling patient needs by anticipating and accommodating them and providing alternatives:2-4,13

- Anticipating and providing pain relief and calming interventions on a timely basis
- Providing distractions (e.g., television, music, food/fluids) to reduce agitation/restlessness, especially for patients who do not sleep throughout the night
- Planning physical activities during the day to encourage restful sleep and diversional activities at any time to reduce wandering/agitation
- When possible, accommodating and incorporating patient’s preferred bedtime habits/routines into evening care
- If medically indicated, using padded bed rails for patients with active movement or seizure disorders
- Restricting the use of physical restraints on patients while in bed
- Positioning patients for comfort and developing a timely schedule for turning and positioning
- If bed rails must be used, performing ongoing assessments of the patient’s mental and physical status so that bed rails are used only when medically necessary
- Keeping those at risk for entrapment under more frequent observation
- Lowering one or more bed rail sections
- Elevating the head of beds of those patients with chronic obstructive pulmonary disease, reflux, congestive heart failure, and while infusing enteral fluids
- Promptly cleaning urine and/or feces from incontinent patients
- Adhering to a toileting schedule that is customized to patient needs
- Reassessing and revising the patient’s care plan whenever entrapment or near-miss entrapment occurs
- Obtaining input from the patient and family about how to individualize interventions
- Anticipating patient’s hunger and thirst by offering food and fluids

Reducing or eliminating bed rail use can be accomplished progressively using a systematic approach.3 Using the following alternatives to bed rails may enhance patient safety:3,4,8,14

- Using high/low beds and keeping beds in the lowest position with wheels locked when clinical care is not being provided
- Placing mats next to the bed, for patients at risk of falling out of bed
- Using transfer, positioning bars, hand-holds, overbed trapeze or mobility aids for patient use instead of bed rails to increase patient’s mobility in bed and to assist patients getting in/out of bed
- Providing diversions to reduce agitation
- Placing the patient’s call bell and personal items within reach and providing visual and verbal reminders to use the call bell when assistance is needed
- Using bed alarms to alert healthcare workers when patients are attempting to get out of bed
- Posting coded signs to notify the healthcare team that a patient is an entrapment risk
- Using border-defining mechanisms such as body pillows or cushions to assist the
I’m Stuck, and I Can’t Get Out! Hospital Bed Entrapment (Continued)

- The size of the gap in which the body part was entrapped
- Position of bed rails (lowered, fully raised, intermediate level)
- Zone of entrapment
- Number of side rails raised at the time of the occurrence and type of rails
- Sections of the frame that were raised and approximate elevation for each section
- Information on the size of the gap that contributed to the entrapment
- Mattress height and height of bed rail from the top of the mattress
- Make, model, manufacturer of hospital bed system
- Condition of the patient before and after entrapment

Reports containing the following information will promote comprehensive analysis and effective corrective actions:7,14

- The entrapped body part and its size (e.g., head breadth, chest depth, neck diameter)
I’m Stuck, and I Can’t Get Out! Hospital Bed Entrapment (Continued)

• Body part injured

• Modifications/changes made to the bed system before and after the entrapment

An entrapment risk reduction program goes beyond the consistent, comprehensive reporting of entrapment occurrences. Reducing the risk of entrapment also includes maintaining, reviewing, and taking corrective actions based on report review and the following documentation:14

• Individualized patient care plans

• Bed system maintenance records

• Policies and procedures that specify risk factors and interventions to prevent entrapment

• Safety checklists for patients at high risk for entrapment

• Failure mode and effects analyses, root cause analyses, and the relevant improvement measures in response to actual or potential bed entrapment occurrences

For an example of maintaining, reviewing, and taking corrective actions, see the sidebar “Steps to Modify Openings in Existing Hospital Bed Systems.”

Steps to Modify Openings in Existing Hospital Bed Systems14

1. Assign responsibility
2. Determine high risk clinical units, if appropriate
3. Inventory bed systems
4. Evaluate bed systems for conformance to FDA’s bed system entrapment dimensional guidance
5. Initiate corrective action
6. Bed replacement plan — determine new purchases
7. Implement quality monitoring program

with healthcare workers concerning whether bed rails are indicated1,4,8

• Providing a brochure to patients/families concerning the dangers of bed rail use and promoting a safer environment2,15, such as the FDA/HBSW “A Guide to Bed Safety” at http://www.fda.gov/cdrh/beds/bed_brochure.html

• Using patient care rounds as an opportunity to discuss entrapment and identify risks

Awareness Strategies

While education and training about appropriate bed rail use promotes a safer and more comfortable patient environment, awareness must be heightened across the healthcare continuum. Individuals that awareness efforts should reach include staff, patients, families, physicians/prescribers, as well as materials managers, healthcare engineering professionals, long term care ombudsmen, and representatives of legislative and regulatory agencies.2 Examples of strategies to raise awareness include the followingː2

• Providing orientation and training concerning the risks of entrapment and interventions to reduce such risk.8

• Encouraging patients and families to learn about bed safety and the purpose and potential dangers of bed rails, and to talk

Notes
I’m Stuck, and I Can’t Get Out! Hospital Bed Entrapment (Continued)


The PA-PSRS Patient Safety Advisory is issued quarterly, with periodic supplements. Previous issues are available on the Patient Safety Authority Web site at www.psa.state.pa.us. Click on “Advisories” in the left-hand menu bar.

Selected articles in previous issues include:

- Anesthesia Awareness (Sept. 2005)
- Expecting the Unexpected: Ambulatory Surgical Facilities and Unanticipated Care (Sept. 2005)
- Forgotten But Not Gone: Tourniquets Left on Patients (June 2005)
- Hidden Sources of Latex in Healthcare Products (June 2004)
- Medication Errors Linked to Drug Name Confusion (Dec. 2004)
- Mismatching Medical Devices and Accessories (Mar. 2005)
- Overdoses Caused by Confusion Between Insulin and Tuberculin Syringes (Oct. 2004)
- Risk of Fire from Alcohol-Based Solutions (June 2005)
- Risk of Overdose from Multiple Transdermal Patches (Sept. 2004)
- The Role of Empowerment in Patient Safety (Dec. 2004)
The Patient Safety Authority is an independent state agency created by Act 13 of 2002, the Medical Care Availability and Reduction of Error (“Mcare”) Act. Consistent with Act 13, ECRI, as contractor for the PA-PSRS program, is issuing this newsletter to advise medical facilities of immediate changes that can be instituted to reduce serious events and incidents. For more information about the PA-PSRS program or the Patient Safety Authority, see the Authority’s website at www.psa.state.pa.us.

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