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a publication for the medical community

ENTRAPMENT: A PREVENTABLE INJURY

The issue of entrapment in the healthcare setting receives very little attention unless a patient is harmed. Manufacturers and facilities strive to reduce the number of entrapment incidents every year. While incidents do occur, they happen less frequently than medication errors or life-threatening infections.

According to the US Food and Drug Administration (FDA), entrapment is defined as "an occurrence involving a patient who is caught, trapped, or entangled in the hospital bed system."[1] The hospital bed system includes the bed frame, bed rails, and mattress, as well as the spaces in or around those parts. The patient's head, neck, and chest are most at risk for severe entrapment injury in the bed rails or frame.[1]

INCIDENCE

The latest data on entrapment reveals that between 1985 and 2008, 803 incidents were reported to the FDA of patients caught, trapped, entangled, or strangled in beds with side rails. Of these reports, 480 people died, 138 had a nonfatal injury, and 185 were not injured due to nursing staff intervention. The highest demographic of those injured were patients who were frail, elderly, or confused.[2]

Based on these incidents, a working group called the Hospital Bed Safety Group (HBSG) was formed in 1999 to address the problem.[1] Participants consisted of the FDA, the Veteran's Administration, and other federal agencies, as well as Health Canada and representatives from the hospital bed industry manufacturers. The goal of HBSG was to improve the safety of hospital beds for all patients in all healthcare settings—especially those who are particularly vulnerable to entrapment, such as the older adult.[3]

EQUIPMENT: BED RAILS

Beds with rails are widely used not only in hospitals, ambulatory care facilities, and other clinical settings, but also in nursing homes and increasingly in non-clinical settings such as assisted living facilities and patient homes. Bed rails are usually metal, plastic, or a combination of both. They are adjustable and are available in multiple sizes and lengths, including full, half, and quarter lengths. Commonly used synonyms for the term "bed rails" are side rails, bed side rails, grab bars, and safety rails. They are used in a variety of clinical situations, including:

- Use with stretchers and beds for safe transport in moving a patient between hospital areas
- Aid in turning and repositioning a patient or helping a patient in and out of bed
- Providing comfort and a sense of security, especially if the bed is in its highest position

Continued

DO'S AND DON'TS

✓ ***DO*** **CREATE A SAFE BED ENVIRONMENT**

✗ ***DON'T*** **FORGET REGULARLY SCHEDULED MAINTENANCE**

✓ ***DO*** **INSTRUCT THE PATIENT AND FAMILY ABOUT BED RAIL SAFETY**

✓ ***DO*** **MAKE SURE THE SUPPORT SURFACE AND FRAME ARE COMPATIBLE**

✗ ***DON'T*** **UTILIZE THE AUTOMATIC USE OF BED RAILS**

✓ ***DO*** **RESTRICT THE USE OF PHYSICAL RESTRAINTS AS MUCH AS POSSIBLE**

- Improving patient functionality, such as with electronics and buttons in the bed rail
- Serving as a barrier to define the edge of the mattress or as a physical restraint

Bed rails may pose an added risk to the patient. In 1997 the FDA issued a safety alert titled "Entrapment Hazards with Hospital Bed Side Rails" and issued a report that identified risk factors and entrapment locations on a hospital bed.[4]

(See Figure 1: Bed Entrapment Zones.)

RISK FACTORS

There are a number of reasons patients become entrapped in the bed rail. When patients attempt to exit their beds, they are at the highest risk of entrapment—especially the elderly and the confused. Confused patients may attempt to go over the bed rail, try to get out between two raised rails, or go around the bottom of a rail; the patient may become entangled or entrapped in the attempt. The risk of injury from a fall is proportional to the height of the fall, which means that patients falling from a greater height because the bed rail is raised are at a greater risk of severe injury or death.[5]

The following medical conditions raise the risk of entrapment for patients:

- Frailty or old age
- Experiencing agitation, delirium, or confusion
- Having pain, uncontrolled movements, or hypoxia
- Urinary retention or fecal impaction

The absence of aid in toileting and repositioning can increase risk as the patient tries to get out of bed to use the bathroom or attempt to get comfortable.[6]

EQUIPMENT: BED FRAMES

Bed frames are designed with safety as the priority. Medical bed manufacturers adhere to international standards to develop and test bed frames for entrapment. The current standard is International Electrotechnical Commission (IEC) 60601-2-52; manufacturers follow this standard to decrease entrapment incidents.[7] Beds built prior to this standard are grandfathered in until their retirement from the fleet.

IEC 60601-2-52 defines the minimum and maximum length and height of the bed rail in proportion to the bed frame itself, including the amount of space between the bed rail and the headboard and footboard. By also taking into account human factors and ergonomics, IEC 60601-

2-52 promotes better engineering and the design of products that are safe for humans to use. Human factors include patient height, weight, and other physical dimensions.

PROMOTING A CULTURE OF SAFETY

Ongoing individualized assessment is required to reduce a patient's risk of entrapment. Information is obtained by observing the patient and interviewing family regarding sleep habits and bedtime routines. The assessment may also include distance to the toilet and level of patient independence—more specifically, the patient's ability to be mobile, use the toilet safely, and get in and out of bed with or without assistance. Also essential is the review of any medications that may cause sedation, confusion, or low blood pressure. The bed frame must also be assessed for proper function through regular maintenance and service.

CONCLUSION

Entrapment is preventable with a thorough assessment of both the patient and his/her environment and with equipment usage that is in accordance with IEC 60601-2-52. Assessment of risk for entrapment should include focus on both individual patient risk factors and the bed system in all care settings.

FDA FYI

The Food and Drug Administration (FDA) is an agency within the US Department of Health and Human Services. It consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods and Veterinary Medicine, Global Regulatory Operations and Policy, and Operations.

The FDA publishes the report "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment". This guidance provides recommendations relating to hospital beds and hospital bed accessories, and is intended to reduce life-threatening entrapments associated with hospital bed systems. It characterizes the body parts at risk for entrapment, identifies the locations of hospital bed openings that are potential entrapment areas, and recommends dimensional criteria for these devices. For the full guidance document, visit the FDA website section on Medical Devices.

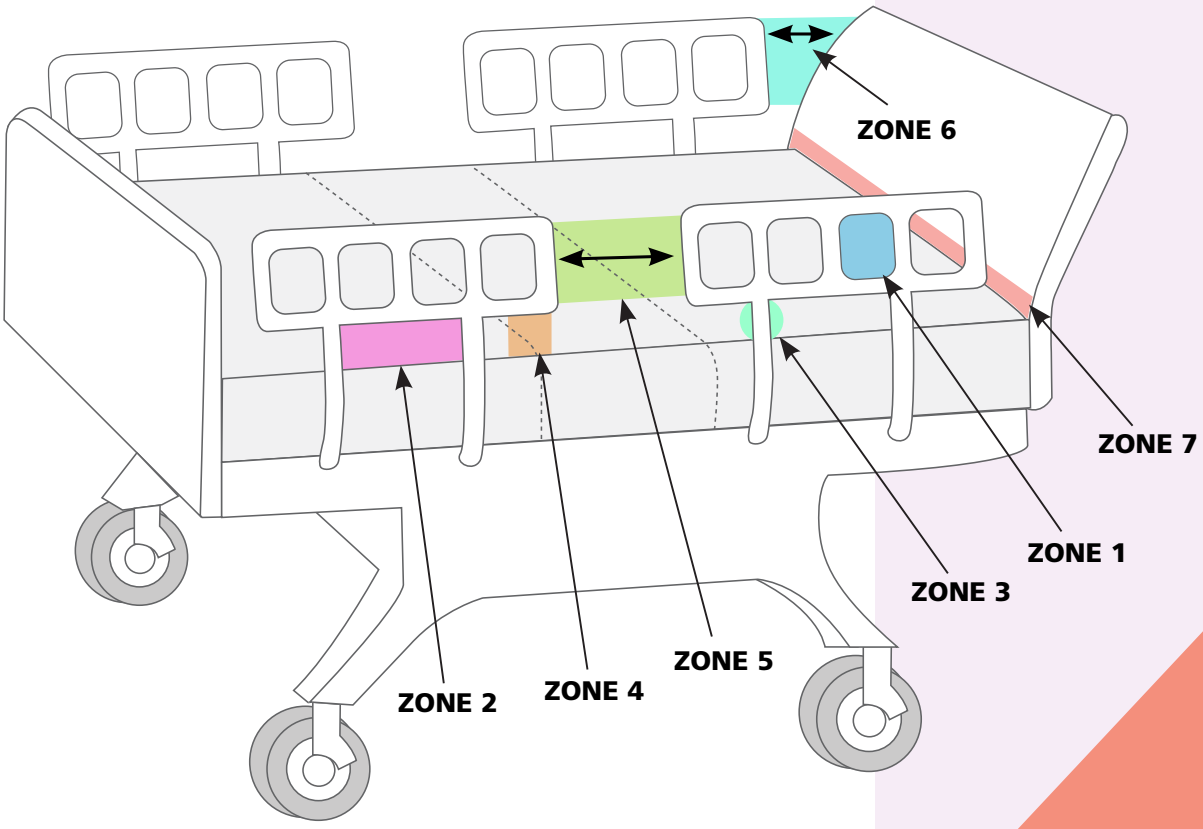

FIGURE 1: BED ENTRAPMENT ZONES

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