Bed rails, once thought of as a contributor to patient safety, now have proven to be a significant threat to the elderly and confused. Incidences of entrapment, entanglement, and falls (from atop a raised rail) have led to new guidelines for compliance. The problem is that no existing side rail products are compliant with these new standards, except for one product currently in limited distribution. For assisted living facilities and other care facilities, the dangers extend beyond simple fines to resident injury and loss of life directly related to faulty equipment. How a facility makes use of existing equipment until compliant rails are installed may mean the difference between resident life, death, and the resulting culpability.

BEST INTENTIONS, DEADLY CONSEQUENCES

No one really knows how many deaths and injuries actually have been caused by bed rails or other restraints. However, anyone who works in a hospital or long-term care facility such as an assisted living facility sees the risk every day. Elderly residents with limited mobility, who try to get up themselves, get caught under or through the very rails designed to keep them safe. Limbs are caught between rails. Bodies fall through split rails. Residents fall to the floor trying to climb over high rail sides. Or, heads are caught between old compressed mattresses and the bottom of the rail.

Most incidences of injury relating specifically to product design go unreported, or are simply dismissed as falls. But the numbers that were reported were disturbing enough for the FDA, in partnership with the U.S. Department of Veteran Affairs, representatives of health care organizations and patient advocacy groups to form a working committee to study the problem and create improved product and usage guidelines. In 2004 this committee, the Hospital Bed Safety Workgroup (HBSW), outlined specific risks associated with entrapment due to product failure. (A list of HBSW participating organizations is found at the end of this article.)

Since then, manufacturers have been slow to innovate, and care facilities have been inconsistent in their efforts to reduce potential risks. Most commonly, facilities simply eliminate bed rails altogether. As a compliant solution is now available, facilities would do well to upgrade equipment in the best interest of safety and resident comfort.

In addition to the outlined zones, it is common for residents with some mobility to attempt to climb over the rails, especially traditional split bed rails. The attempt to climb over a fail often results in a fall from a significantly higher height than a mere hospital bed.

Mattress Compression is a leading culprit in why beds become entrapment-prone. Old mattresses do not comply with dimension specifications assumed by most existing bedrail designs. These existing designs do not account for changes in mattress depth through use. Nor do existing designs adapt to variances in mattress length and width.

The FDA recognizes that beds have complex geometries that make applying the criteria difficult. Articulation of the bed, or raising/lowering, for instance, affects some standards, as does the type of mattress. Exclusions include air fluidized therapy beds, bariatric beds, stretchers and mechanical lifting devices. Partial exclusions include kinetic treatment tables and rotation beds. Regardless, standards are in place for most beds and will be enforced with increasing regularity.

CLINICAL NEEDS ASSESSMENTS

Each State defines its own standards of compliance, presumably based on HBSW guidelines. It is important to note that the decisions to use or to discontinue the use of a bed rail should be made in the context of an individualized resident assessment using an interdisciplinary team.
with input from the resident, the residents’ family and or/ the residents’ legal guardian. The resident’s right to participate in care planning should be balanced with the caregivers’ responsibility to provide care according to professional standards and any applicable state and federal laws.

SAFE DEVICES

Unfortunately there is only a limited number of institutionally designed bed mobility devices that will comply with the HBSW strict and specific standards relating to the dimensional tolerance in all zones.

One such device is the Halo Safety Ring (Figure 1) which takes into account the varying tolerances of mattresses, including both shifting and mattress compression. The transfer bar itself is ergonomically designed, is easy to use for resident support, and in no way will entrap or entangle, regardless of the size of the patient. Because of an adjustable base that is form-fit and customizable to any institutional bed, mattress size, and bed frame, the system does not “gap.” It also does not loosen over time, requiring tightening. The Halo Safety Ring locks into place to enable the residents to use the device as a quad-like cane attached to the side of the bed, allowing residents to better assist themselves, while ultimately preventing back injuries and workman’s compensation claims by staff members at long-term care facilities.

The Halo Safety Ring articulates with the rising of the head portion of the bed, maintaining compliance with the alternative dimensional guidelines, while enabling the resident to maneuver in the bed while in an inclined position.

The design of the Halo Safety Ring, which utilizes a 3 lateral mattress stay on the opposite end of the transfer bar, eliminates compressibility factors by permanently pushing the upper portion of the mattress up against the Halo Safety Ring, maintaining compliance with the 2 1/3 inch guidelines in zones 2, 3, 4 and 5, if zone 5 is now defined as the space between the headboard and the beginning of the Halo Safety Ring. The positioning of the Halo Safety Ring 12 ½ inches of more from the head of the bed allows for compliance with the HBSW guidelines while creating a viable exit point for residents.

If the complete removal of all rails in the long-term care industry is the only answer to entrapment, we as caregivers are missing an opportunity that will allow residents the safety, comfort and simple ability to continue with their independence for as long as they are capable. Devices such as the Halo Safety Ring must become part of an interdisciplinary approach which encourages resident to maintain their independence and quality of life for as long as possible, while minimizing the institutional risks and cost associated with high-risk, high-care bed-ridden residents. ALC

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STANDARDS PER ZONE

- **Zone 1: Within the rail**
  Non-Compliance includes any open space within the perimeter of the rail. Infractions are caused by loosened bars or rails that would increase the size of the space.

  **What you can do?** Tighten all bars. Consider mattress replacement if it can close the possible entrapment space.

- **Zone 2: Between the top of the compressed mattress and the bottom of the rail, between rail supports**
  Mattress compressibility and lateral shift of the mattress have significant effects on likelihood of entrapment. Restless residents may enlarge this zone by compressing the mattress beyond the specified dimensional limits. Mattress compressibility, lateral shift of the mattress and degree of play from loosened rails have significant effects on likelihood of entrapment. With articulation, this zone may increase.

  **What you can do?** Consider Mattress replacement.

- **Zone 3: Between the rail and the mattress**
  What you can do? Consider mattress replacement.

- **Zone 4: Between the top of the compressed mattress and the bottom of the rail, at the end of the rail**
  This is the most dangerous of all zones, as it is responsible for the most reported deaths. Factors affecting entrapment include mattress compressibility, lateral mattress shift, rail shift and degree of play from loosened rails.

  **What you can do?** Tighten all bars. Consider mattress replacement if it can close the possible entrapment space.

- **Zone 5: Between the split bed rails**
  Split bed rails are no longer typically used in long-term care facilities or institutions where residents are mobile.

  **What you can do?** Immediately discontinue use of split bed rails for potentially mobile residents.

- **Zone 6: Between the end of the rail and the side edge of the head or foot board**
  Residents are at risk for both neck and chest entrapment.

  **What you can do?** Tighten all bars. Make sure that space at its narrowest point is small enough to prevent neck entrapment (less than 2 1/2 inches) and large enough to prevent chest entrapment (more than 12 1/2 inches).

- **Zone 7: Between the head of footboard and the mattress end**
  This zone is extremely affected by mattress compressibility, shifting and degree of play from loosened head and footboards.

  **What you can do?** Tighten all bars. Consider mattress replacement.

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**Fig. 1 Halo Safety Ring**

This image illustrates the Halo Safety Ring, a device designed to prevent entrapment of residents in beds. It highlights the various zones where entrapment can occur and outlines the standards and actions that can be taken to ensure a safe environment. The diagram is useful for understanding the dimensional requirements and the potential hazards in different parts of the bed, especially at the head and foot areas. The text accompanying the diagram provides detailed explanations of how to prevent entrapment and the necessary actions to take in case of non-compliance with safety standards.