Bed Safety: A Wake-up Call

Bedrails and devices that offer assistance getting into and out of bed are not uncommon in assisted living (AL) environments. Yet safety at night and while getting into and out of bed is an issue for residents who may have problems with mobility, memory, sleep disturbance, or incontinence. Safety is a problem even for those who can get out of bed and walk unassisted. Incidences of entrapment, entanglement, and falls have led the Food & Drug Administration (FDA) to issue guidance designed to reduce the occurrence of bedrail entrapments.

In March 2006 the FDA's *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment* highlighted 7 zones of entrapment and explained how to measure those zones. An innovative "Bed System Measurement Device" was developed to comply with this guidance. The guidance identifies specific issues associated with hospital bed systems and provides design recommendations for manufacturers of these systems.

The 7 areas or zones that present a potential for entrapment follow:

Zone 1: Within the rail. Openings at any space along the perimeter of the rail should be small enough to prevent the head from entering.

Zone 2: Under the rail, between the rail supports, or next to a single rail support. This space is the gap under the rail between a mattress compressed by the weight of a patient's head and the bottom edge of the rail at a location between the rail supports or next to a single rail support. The FDA recommends that this space be less than 120 mm (4-3/4 inches) to prevent head entrapment.

Zone 3: Between the rail and the mattress. The space between the inside surface of the rail and the mattress compressed by the weight of a patient's head should be small enough to prevent head entrapment when taking into account the mattress compressibility, any lateral shift of the mattress or rail, and the degree of play from loosened rails.

Zone 4: Under the rail, at the ends of the rail. This is the gap that forms between the mattress compressed by the patient and the lowermost portion of the rail at the end of the rail. Factors that may increase the gap size are mattress compressibility, lateral shift of the mattress or rail, and degree of play from loosened rails. The space poses a risk for entrapment of a patient's neck. It may change with different rail height positions and as the head or foot sections of the bed are raised and lowered. The space may increase, decrease, become less accessible, or disappear entirely. Thus, in some positions, the potential for entrapment in this zone may still exist when the deck is articulated.

Zone 5: Between split bedrails.

Zone 6: Between the end of the rail and the side edge of the head or foot board.

Zone 7: Between the head or foot board and the mattress end.

Although 7 potential zones of entrapment have been identified, the FDA is recommending dimensional limits for zones 1 to 4 because these zones were most frequently reported as having entrapments.

The time and place to incorporate a bed system measurement program to prevent entrapment for each AL resident is during the individualized service plan (ISP) meeting. The ISP meeting is designed to meet the individual needs and preferences of each resident. Complete resident assessments before the resident moves into the community, and reassess every 6 months thereafter or when there is any significant change in condition. Negotiated risk agreements regarding bed entrapment provide an excellent formal mechanism to allow residents and their families to make informed decisions about their care and to document that the parties have had an open and frank discussion concerning bed entrapment.

Until recently the AL resident in need of some type of bed mobility or assistance in and out of bed could purchase a variety of commercially designed side rails or assistive devices. However, since the FDA's Hospital Bed Safety Workgroup (HBSW) report, some state agencies have made it extremely clear that any near-miss or entrapment death would be unacceptable for AL residents.

In the long-term care industry, an increase in entrapment near-misses and deaths in nursing homes over the last 4 years resulted in mandatory removal of all side rails. Examination of bed systems now takes place during each annual survey visit.

The *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment* is available online at: www.fda.gov/cdrh/beds/guidance/1537.pdf. ALC