The bed is a ubiquitous device in most health care settings, and it can be seen as a centerpiece for medicine—almost all residential and inpatient care revolves around the patient in the bed. Ensuring adequate maintenance and safety of hospital bed systems—defined by the Food and Drug Administration (FDA) Hospital Bed Safety Workgroup (HBSW) as “a bed frame, mattress, bed rails, as well as other accessories that are compatible with each other”—is an important part of patient care and requires careful planning. Although this article frequently refers to “hospital” beds and “patients,” the issues and recommendations described are applicable to the long-term care (LTC) setting. “Hospital bed” is an industry term and is not limited to the setting in which the bed is situated or the individual using it.

Entrapment Risks

The FDA defines entrapment as “an event in which a patient is caught, trapped, or entangled in the space in or about the bed rail, mattress or hospital bed frame.” While entrapment is a rare event for the general patient population, it cannot be ignored. Between January 1, 1985, and January 1, 2013, the FDA received more than 900 reports of patients becoming caught, trapped, entangled, or stranded in their hospital beds; 531 of these patients died, 151 patients sustained nonfatal injuries, and staff intervention was necessary to prevent injury in 220 cases. The agency believes that entrapments are likely underreported.

It is important to remember that not all individuals are at high risk of entrapment and not all beds pose a risk of entrapment. Those who are most vulnerable to entrapment in beds are typically older or have cognitive impairment, functional dependency, or a small body. Additional risk factors include weakness, difficulty communicating, spasticity, and traumatic brain injury. Generally, entrapment risk increases with the number of patient risk factors.

Entrapment Zones

According to HBSW, seven “zones” within bed systems pose a risk of entrapment for patients. Figure 1 provides an illustration and descriptions of these seven zones. Note that six of the seven zones are related to bed siderails. Although bed siderails may be considered a form of restraint by federal or state regulators, they may also be used as positioning aids in a manner that does not meet those definitions. Caregivers should be aware that the siderails present an entrapment risk, regardless of the intended use or regulatory definitions, and should stay alert to these risks whenever siderails are used.

The FDA noticed that zones 1 through 4 accounted for the majority of entrapments reported to the MAUDE database; in fact, as of 2005, these zones accounted for approximately 80% of reported entrapments. HBSW has issued specific dimensional recommendations for those zones. The agency’s “Guidance for Industry and FDA Staff: Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment” outlines HBSW’s dimensional test methods, with diagrams, for bed systems.

The head, neck, and chest are the three key body parts to watch for in preventing entrapment. To prevent a pa-
E CRI Strategies

To prevent head entrapment <120 mm (4.75 in)
To prevent neck entrapment <60 mm (<2.375 in); any V-shaped openings should be >60°
To prevent chest entrapment <318 mm (<12.5 in)

Table 1. HBSW-Recommended Dimensions for Bed System Openings

a patient’s head to fit underneath the rail, between the rail supports, or next to a single support.
• For zone 3, the goal is to see whether it is possible for a patient’s head to fit in the horizontal space between the rail and mattress.
• For zone 4, the goal is to determine whether the patient’s neck can slide or become wedged under the end of the rail.

The FDA and HBSW do not have dimensional guidance or test methods for entrapment zones 5, 6, or 7, but they both suggest that if these zones are a concern for a facility, staff may wish to consult HBSW’s general mitigation strategies.1

Health care facilities should have a policy regarding who is responsible for bed testing, what training is required, and at what intervals the testers should inspect the beds. Some facilities have assigned this responsibility to representatives from facilities management, nursing, or clinical engineering. Implementation and scheduling of testing, including funding for mitigation remedies, should be determined by a facility committee consisting of representatives from the following departments: risk management, clinical engineering, purchasing, materials management, and the safety committee.4

The FDA and HBSW do not believe that beds need to be tested “all at once, all at one time, or only once.” The organization should gauge the risk of entrapment at the facility and take steps to minimize this risk with a bed safety program. Reassessing a bed may be necessary under certain common circumstances, such as the following4:
• When there is reason to believe that components (eg, rails, surfaces) have become worn
• When accessories (eg, surface overlays, positioning poles) are added or removed
• When components of the bed system (eg, rails, surfaces) are changed or replaced

HBSW studied the amount of time it takes for a person to test a bed for entrapment risk and found that it can range from a few minutes to over an hour; understandably, testers with more experience generally evaluated the beds faster. HBSW estimates that bed assessment will take approximately 15 minutes per bed when using the test methods described in Appendix F of FDA’s “Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment.”3

To protect workers who inspect and test beds from musculoskeletal injury, HBSW recommends that testers be limited to eight beds per day. Additional provisions to limit injuries can include the following: use a height-adjustable table to transport the 15-lb testing tool suggested in HBSW’s recommendations; transport the measurement tool in a case on wheels with a handle long enough for comfortable

Testing for Entrapment
While the FDA guidance has specific recommendations for testing, it may also be helpful to understand the goals of testing the four major entrapment zones, listed below3:
• For zone 1, the goal is to see whether it is possible for a patient’s head to fit through the opening of the rail, thus becoming trapped.
• For zone 2, the goal is to see whether it is possible for

Figure 1. Seven bed entrapment zones

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. Between the rail, at the ends of the rail
5. Between split bedrails
6. Between the end of the rail and the side edge of the headboard or footboard
7. Between the headboard or footboard and the end of the mattress
use; and ensure that the height of the bed is elevated while the tester is measuring the bed. ³

Another problem that facilities must address during bed safety testing is interrater reliability. Different testers may get different results for the same bed, but even the same tester can obtain different results when repeating a test. Vari-

Use of testing tools differently.

Errors or oversights can occur during testing.

Some testers may be more inclined to pass or fail a bed when test results are on the border between passing and failing.

A long period might have elapsed between tests, which may affect the bed components (eg, surface, rails, rail supports).

Standardizing the training of technicians who will be responsible for the testing of beds can help decrease the variability in test results. If a bed is close to failing, FDA recommends repeating the test (double-checking that all steps were performed correctly) or obtaining a second opinion. These options should be addressed in facility policy regarding testing.³

HBSW and FDA believe that health care providers are instrumental in ensuring that their patients have safe sleeping environments. While the HBSW and FDA entrapment mitigation and bed safety documents mentioned in this article are provided as guidance only, these groups have recognized that some states and authorities with jurisdiction over health care facilities have adopted or may choose to adopt the suggested guidance as requirements for their health care providers. Additionally, although the FDA and HBSW guidance documents are not regulatory mandates, they may be viewed by regulatory authorities and accrediting agencies as best practice.⁴ It is prudent, then, to review local guidance regarding bed inspection and safety to ensure that the facility is in compliance with all applicable regulations and accreditation standards.

Creating or Reviewing a Bed Safety Program

Step 1. Establish an interdisciplinary group that will take responsibility for measuring existing bed systems and newly purchased bed systems and take corrective actions when necessary. Consider including representatives from clinical engineering, nursing (including frontline staff), medicine, physical or occupational therapy, housekeeping, and quality management. HBSW suggests that these responsibilities could also be a function of the quality improvement or patient safety committee.

Step 2. Identify clinical areas that are high entrapment risks to help direct priorities for bed replacement and corrective actions. High-risk units can be identified through patient, environmental, and monitoring characteristics (Table 2). Typically, long-term care resident units have the highest level of risk, followed by the medical-surgical unit.

Step 3. Take an updated inventory of the bed systems at the facility to assess the types of beds being used. Maintaining an inventory of beds used by unit, including the manufacturer and model, can help identify replacement and corrective action needs.

Step 4. Evaluate beds in accordance with FDA’s “A Guide for Modifying Bed Systems and Using Accessories to Reduce the Risk of Entrapment.”¹

Step 5. Initiate corrective actions as needed, based on the following:

• The recommended dimensional criteria for the four major entrapment zones

• Risk analysis by entrapment zone

• Use of bed accessories for each zone

Corrective actions and mitigation strategies can be obtained from the bed manufacturer; however, HBSW has also offered guidance.¹ Any modification of the bed to prevent entrapment should not increase the risk of other injuries to the patient or health care worker.

Step 6. Ensure that an integrated approach is used when purchasing beds: consider the inventory of existing beds,

Table 2. Bed Safety: Risk Factors for Entrapment¹

<table>
<thead>
<tr>
<th>Patient Factors</th>
<th>Environmental Factors</th>
<th>Patient Monitoring Factors</th>
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<tbody>
<tr>
<td>• Older age</td>
<td>• Configurations that make it difficult to see residents (eg, private rooms, large wards with long hallways)</td>
<td>• Low staffing levels</td>
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<tr>
<td>• Cognitive impairment</td>
<td></td>
<td>• Fewer staff at night</td>
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<tr>
<td>• Functional dependency</td>
<td></td>
<td>• Care delivery processes that do not appropriately account for basic patient needs (eg, toileting, feeding, pain management)</td>
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<tr>
<td>• Small body frame</td>
<td></td>
<td>• Staff with limited familiarity with patients</td>
</tr>
<tr>
<td>• Weakness</td>
<td>• Bed systems with unsafe gaps or openings</td>
<td>• Limited use of technology (eg, cameras, bed-exit alarms)</td>
</tr>
<tr>
<td>• Communication impairment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Spasticity</td>
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<tr>
<td>• Traumatic brain injury</td>
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options for corrective actions, and quality monitors that can assist in bed safety planning. Representatives from purchasing, clinical engineering, and management, as well as other staff, should be involved in balancing the patient and environmental risk factors, along with patient and staff preferences and cost. Priority for bed replacement should focus on the areas that will reap the most benefits—those with the highest risk.

**Step 7.** Implement a quality monitoring initiative to catch near misses and entrapment events to ensure that corrective actions are appropriately implemented. Additionally, mitigation strategies for entrapment reduction may affect falls, which are often monitored through quality improvement.

It is important to be aware that the HBSW recommendations are not designed for all hospital beds. Most relevant for aging services providers, exclusions include the following air-fluidized therapy beds, for which FDA recommends that facilities ensure that the therapeutic benefits outweigh the entrapment risk of these beds. Bariatric beds are also not included, because the data used to derive the dimensional limits did not include these patients.

For some bed types, the dimensional guidance may be used, but only under certain circumstances. Beds that are used for specific populations of patients or under certain circumstances may come with additional hazards or requirements for maintenance (Box 1).

**Conclusion**

Understanding the issues that place some patients at risk from beds can help health care workers identify solutions to help prevent adverse events, such as entrapment, from occurring.

**References**


