HBSW/FDA Frequently Asked Questions (FAQ) on Entrapment Issues

The Hospital Bed Safety Workgroup (HBSW) was formed to develop solutions to reduce the incidence of patient entrapment in hospital beds. The HBSW Advisory Committee, a subgroup of the HBSW, provides guidance and advice based on its members' consensus opinion about the products and documents developed by the HBSW. The committee's mission is to answer the public's questions about HBSW documents and the entrapment assessment kit and to assist National Safety Technologies, the kit supplier, in answering technical questions regarding the bed assessment. In addition, the Advisory Committee will determine if the entire HBSW should reconvene to address issues that are raised or to review the progress and impact of the guidance information and tools in reducing the incidence of entrapment in hospital bed systems.

This collection of frequently asked questions and answers will be revised, as needed, to provide information to healthcare providers in order to help prevent patient entrapment in hospital bed systems.

Question 1: What are the HBSW documents and for how should they be used?

Answer: The HBSW published several documents over the past decade. They include:

- The HBSW brochure, *A Guide to Bed Safety; Bed Rails in Hospitals, Nursing Homes and Home Health Care: The Fact*, which defines the problem of bed system entrapment.
- The HBSW mitigation document, *A Guide for Modifying Bed Systems and Using Accessories to Reduce the Risk of Entrapment*, which can help healthcare providers determine an approach for assessing existing beds, mitigating risks, and deciding who should be involved in these tasks.
- The U. S. Food and Drug Administration (FDA) dimensional guidance document (which HBSW helped create), *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff*, which manufacturers may use in designing new bed systems and accessories and healthcare providers may use to identify entrapment risks in legacy bed systems.
- The HBSW guide entitled *Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings*; which healthcare providers and other clinical staff can use to assess patients for entrapment risks and to mitigate those risks.
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These documents are available at http://www.fda.gov/cdrh/beds/ or from the assessment kit supplier, National Safety Technologies at http://www.nst-usa.com/Pages/frameset.html?MainFrame.

Question 2: Are healthcare providers required to comply with the HBSW documents?

Answer: As stated in the FDA *Hospital Bed System Dimensional Guidance and Assessment Guidance to Reduce Entrapment*, "The FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited." Similarly, the other HBSW documents are guidances not requirements. However, some states and authorities having jurisdiction (e.g., state Departments of Health) have adopted or might chose to adopt the HBSW documents into their requirements for healthcare providers, and thus the documents may be required to be followed in certain localities.

Question 3: As a healthcare provider, what are my responsibilities related to bed safety?

Answer: Healthcare providers should provide a safe sleeping environment for patients. In regard to entrapment, the HBSW information can help providers determine and mitigate bed system entrapment risks for patients.

As published in the FDA *Hospital Bed System Dimensional Guidance and Assessment Guidance to Reduce Entrapment*, "Not all patients are at risk for an entrapment, and not all hospital beds pose a risk of entrapment. We suggest that facilities … determine the level of risk for entrapment and take steps to mitigate the risk. Evaluating the dimensional limits of the gaps in hospital beds is one component of an overall assessment and mitigation strategy to reduce entrapment. As a result, healthcare facilities may use this guidance as part of a bed safety program to help identify entrapment risks that may exist with current hospital bed systems."

HBSW publications are available at the FDA Center for Devices and Radiological Health Web site, http://www.fda.gov/cdrh/beds.

Question 4: How can surveyors cite facilities for an unsafe bed when there are no regulations that define dimensions related to entrapment?

Answer: While authorities having jurisdiction (e.g., state Departments of Health) might chose use the FDA and HBSW documents to regulate bed use in healthcare facilities, the documents should not be interpreted as regulatory mandates (see also answer to Question 2). Because there are no national regulations that must be followed, the FDA dimensional guidance and HBSW documents might be viewed by some regulatory authorities or accrediting agencies as representing a "best practice" because they were developed by the long-term work of the HBSW. (The HBSW is a partnership among the FDA, the medical bed industry, national healthcare organizations, patient advocacy groups, and other federal agencies [Centers for Medicare & Medicaid Services, Consumer Product Safety Commission, and the Department of Veterans Affairs]. Its goal is to reduce the risk of hospital bed system entrapment.) Best practices for safe and quality care are considered important by regulators regardless of the origin of the practice.

Question 5: Who is responsible for measuring beds, and who will be responsible for remedies?

Answer: It is up to the healthcare facility to determine who should measure beds and mitigate identified risks. Some facilities have assigned the bed assessment task to physical plant, nursing, or clinical/biomedical engineering staff. The implementation, scheduling, and funding of mitigating remedies may be jointly addressed by a committee with representatives of risk management, engineering, purchasing, materials management, and the safety committee.

Question 6: Will the HBSW review or endorse educational programs on prevention of bed entrapments?

Answer: The HBSW does not review, approve, endorse, or recommend language for bed entrapment prevention educational programs developed by other parties. As with any published material, FDA- and HBSW-published documents may be used for educational purposes and may be cited as bibliographic references.

Question 7: Whom can I contact for answers to other questions about HBSW information?

Answer: The HBSW Advisory Committee will address questions on HBSW documents. Send questions via e-mail to the Committee by contacting National Safety Technologies via their Web site www.nst-usa.com or send questions to the Committee via e-mail to bedsafety@ecri.org. Put "Attn: HBSW Advisory Committee" in the subject line or header of any communications. The Committee will discuss each question and update the FAQ accordingly.

Question 8: Why did the FDA produce the dimensional guidance document?

Answer: The FDA guidance was developed to improve the safety of hospital beds by identifying guidelines to reduce the risk of the most serious hazards—patient death or injury from entrapment in the openings and gaps in hospital bed systems. The guidance will help ensure that all new hospital beds are designed to reduce the potential for entrapment and that risks with existing (legacy) bed systems are identified.

In 1995, FDA noticed a pattern of deaths and injuries in hospital beds that investigation indicated may have been largely preventable. Our August 23, 1995, Safety Alert (Available at: www.fda.gov/cdrh/beds/.) generated considerable interest from the healthcare community. In fact, reports of this type of incident increased following the alert, which suggested we had tapped into an important health issue.

FDA held a meeting with many stakeholders including representatives of the hospital bed system industry, patient care advocacy groups, healthcare providers, and organizations that investigate this type of incident. As a result of the discussions, FDA realized that the problem was multidimensional and that a single regulatory solution would not be effective in addressing the many facets of entrapment. A voluntary consortium of national bed system experts, known as the Hospital Bed Safety Workgroup, was formed to address the complex problem. The HBSW's expertise assisted FDA in producing its guidance entitled *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff*, which was published on March 10, 2006.

Question 9: What is Health Canada's position on the HBSW materials?

Answer: Health Canada, through the Medical Devices Bureau of the Therapeutic Products Directorate, has participated in the development of the HBSW documents. As an active partner in the development of the documents, Health Canada will now be reviewing the final version to determine its suitability for incorporation into its own guidance documents. Please see the Health Canada Web site at http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/index_e.html for updates on this issue. In the meantime, manufacturers that sell beds in Canada and Canadian user facilities are encouraged to consult the HBSW documents and take note of their recommendations.

Question 10: If a bed has full-length rails, does it need to be tested? Such rails are not shown on the instructional video.

Answer: Any type of rail attached to a bed should be assessed for entrapment risks. Full-length rails should be tested in the same manner as any other type of rail. Note that some full-length rails can present an entrapment risk when the bed is articulated (e.g., head elevated, knees raised), thus testing full-length rails in articulated bed positions is particularly important. The video provides a general guide to bed assessment, and the dimensional test method provided detailed instruction on bed assessment. See APPENDIX F: Hospital Bed Safety Workgroup Dimensional Test Methods for Bed Systems in *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff* for additional testing instructions.

Question 11: When the measuring instructions say to push the mattress until it stops, what should be done about mattress stops?

Answer: Mattress retainers or stops are designed to hold a mattress in a particular position in the mattress support platform. If a tester can easily override the mattress stop by pushing the mattress, then it is possible that this movement could occur during normal use by a patient. Thus the bed system should be tested with the mattress pushed as far

away from the rail being measured as possible (e.g., against the opposite rail). However, the tester should not force the mattress past the stops. Similarly, if moveable stops are used, then the stops should be positioned so that they do not inhibit mattress position during testing, because the moveable stops could possibly be out of position at some time. The rationale for this thinking is that if the mattress can be in an adverse position, the testing should reveal this possibility. Thus, if mattress stops can mitigate the adverse mattress position, they should be deployed to do so.

This question is also addressed in "Testing Tips and Frequent Questions" in Appendix F-HBSW Dimensional Test Methods for Bed Systems of FDA's *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff*. It states:

> Some test instructions ask you to push the mattress "until it stops." Usually that means pushing it until either:
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> - the mattress retention system (such as mattress stops, straps, Velcro) engages and keeps you from pushing the mattress any further, or
> - the mattress stops against the opposite side rail(s).
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> Always make sure you push the mattress straight across; it should not be crooked on the bed.

Question 12: We see that Zones 5, 6, and 7 do not have test methods. Should these be tested, and, if so, how?

Answer: Although seven potential zones of entrapment have been identified by FDA and HBSW, no dimensional guidance or test methods have yet been developed for Zones 5, 6, and 7. FDA recommends dimensional limits and testing for zones 1 through 4, because these zones were most frequently reported as the sites of entrapments. FDA will continue to monitor entrapments in all the zones and collaborate with HBSW on possible assessment and remedial action.

In the meantime, if these zones are of concern (e.g., for a particular patient, for a particular bed system), mitigation strategies such as those described in *A Guide for Modifying Bed Systems and Using Accessories to Reduce the Risk of Entrapment* should be used.

Question 13: Is there an accepted recommended minimum requirement for the height of the bed rails above the top of the mattress when the rails are in the "up" position?

Answer: Because the height of the rail above the mattress is not related to entrapment, the FDA guidance document does not specify a side rail height recommendation.

As a point of information, recommendations vary among standards organizations regarding the minimum height of the top of the rail above the mattress. For hospital beds specifically, the international hospital bed standard, IEC 60601-2-38, amended in 1999, recommends 8.7 inches (220 mm). However, the U.S. Consumer Products Safety Commission in 16 CFR Parts 1213 and 1513, *Consumer Product Safety Standard for Bunk Beds* recommends 5 inches (127 mm) as the minimum height, as does the American Society for Testing and Materials (ASTM) in ASTM F1427-96.

Question 14: During a recent conference, a presenter made the following comment: "As resident injuries are 'high risk' for litigation, all residents should have a physician's order for side rails, whether up or down, whether restrictive or not." Is this true?

Answer: Any decision about bed rail use should be made based on an individual patient assessment as discussed in *Clinical Guidance For The Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities, and Home Care Settings.*

Question 15: During a recent conference, a presenter suggested that the use of a "net enclosed bed" is an alternative to bedrails. Is that appropriate?

Answer: HBSW did not address or comment on the use of net enclosed beds as an alternative to bed rails.

Question 16: How long will it take to measure a bed?

Answer: Based on the several studies conducted by HBSW as part of the development of the dimensional guidance, measuring a bed took from a few minutes to more than an hour. Also, as the testers gained experience with measuring beds, the testing time grew shorter. We estimate it will take 15 minutes to test a bed according to the test method described in APPENDIX F: Hospital Bed Safety Workgroup Dimensional Test Methods for Bed Systems in *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff.*

Question 17: Do we need to measure every bed in our facility?

Answer: No, not all at once, all at one time, or only once. Evaluating the dimensional limits of the gaps in hospital beds is one component of an overall and ongoing assessment and mitigation strategy to reduce entrapment. Not all patients are at risk for an entrapment, and not all hospital beds pose a risk of entrapment. We suggest that healthcare facilities determine the level of risk for entrapment and take steps to mitigate the risk through a bed safety program.

Question 18: How often should beds be tested?

Answer: Bed safety programs should include plans for the reassessment of hospital bed systems. Reassessment may be appropriate when (1) there is reason to believe that some components are worn (e.g., rails wobble, rails have been damaged, mattresses are softer) and could cause increased spaces within the bed system, (2) when accessories such as mattress overlays or positioning poles are added or removed, or (3) when components of the bed system (e.g., new bed rails or mattresses) are changed or replaced.

Question 19: Are the HBSW/FDA documents applicable to children in hospital beds?

Answer: No. The documents and the tools used to measure gaps were produced considering an adult population's size and for use with beds designed for care of the adult patient. The dimensions are not appropriate to children in most cases. Check with the bed supplier to determine if the bed was designed to care for a child.

Question 20: What should be considered when placing children in adult beds?

Answer: HBSW has not addressed the issue of children in adult beds. There are many beds designed for care of the pediatric patient, and it is appropriate to provide a pediatric bed for a child patient, in most cases. Check with the bed supplier to determine if the bed was designed to care for a child. Also, while the dimensional guidance is not appropriate for children in most cases, the HBSW Clinical Guidance document can serve as an outline to assessing the child patient and the bed system for entrapment risks.