Which Ways of Reducing Risk are Best?

A process that requires ongoing patient evaluation and monitoring will result in optimizing bed safety. Many patients go through a period of adjustment to become comfortable with new options. Patients and their families should talk to their health care planning team to find out which options are best for them.

Patient or Family Concerns About Bed Rail Use

If patients or family ask about using bed rails, health care providers should:

- Encourage patients or family to talk to their health care planning team to determine whether or not bed rails are indicated.
- Reassure patients and their families that in many cases the patient can sleep safely without bed rails.
- Reassess the need for using bed rails on a frequent, regular basis.

To report an adverse event or medical device problem, please call FDA's MedWatch Reporting Program at 1-800-FDA-1088.

For additional copies of this brochure, see the FDA's website at http://www.fda.gov/cdrh/beds/

For more information about this brochure, contact Beryl Goldman at 610-335-1280 or by e-mail at bgoldman@kendaloutreach.org. She has volunteered to answer questions.

For information regarding a specific hospital bed, contact the bed manufacturer directly.

Developed by the Hospital Bed Safety Workgroup

Participating Organizations:
- AARP
- ABA Tort and Insurance Practice Section
- American Association of Homes and Services for the Aging
- American Health Care Association
- American Medical Directors Association
- American Nurses Association
- American Society for Healthcare Engineering of the American Hospital Association
- American Society for Healthcare Risk Management
- Basic American Metal Products
- Beverly Enterprises, Inc.
- Care Providers of Minnesota
- Carroll Healthcare
- DePaul College of Law
- ECRI
- Evangelical Lutheran Good Samaritan Society
- Hill-Rom Co., Inc.
- Joerns Healthcare, Inc.
- Joint Commission on Accreditation of Healthcare Organizations
- Medical Devices Bureau, Health Canada
- National Association for Home Care
- National Citizens’ Coalition for Nursing Home Reform
- National Patient Safety Foundation
- RN+ Systems
- Stryker Medical
- The Jewish Home and Hospital
- Untie the Elderly, The Kendal Corporation
- U.S. Food and Drug Administration

October 2000

Brochure Revised January 2008
Today there are about 2.5 million hospital and nursing home beds in use in the United States. Between 1985 and 2008, 772 incidents of patients* caught, trapped, entangled, or strangled in beds with rails were reported to the U.S. Food and Drug Administration. Of these reports, 460 people died, 136 had a nonfatal injury, and 176 were not injured because staff intervened. Most patients were frail, elderly or confused.

**Patient Safety**

Patients who have problems with memory, sleeping, incontinence, pain, uncontrolled body movement, or who get out of bed and walk unsafely without assistance, must be carefully assessed for the best ways to keep them from harm, such as falling. Assessment by the patient’s healthcare team will help to determine how best to keep the patient safe.

Historically, physical restraints (such as vests, ankle or wrist restraints) were used to try to keep patients safe in health care facilities. In recent years, the health care community has recognized that physically restraining patients can be dangerous. Although not indicated for this use, bed rails are sometimes used as restraints. Regulatory agencies, health care organizations, product manufacturers and advocacy groups encourage hospitals, nursing homes and home care providers to assess patients’ needs and to provide safe care without restraints.

**The Benefits and Risks of Bed Rails**

Potential benefits of bed rails include:
- Aiding in turning and repositioning within the bed.
- Providing a hand-hold for getting into or out of bed.
- Providing a feeling of comfort and security.
- Reducing the risk of patients falling out of bed when being transported.
- Providing easy access to bed controls and personal care items.

Potential risks of bed rails may include:
- Strangling, suffocating, bodily injury or death when patients or part of their body are caught between rails or between the bed rails and mattress.
- More serious injuries from falls when patients climb over rails.
- Skin bruising, cuts, and scrapes.
- Inducing agitated behavior when bed rails are used as a restraint.
- Feeling isolated or unnecessarily restricted.
- Preventing patients, who are able to get out of bed, from performing routine activities such as going to the bathroom or retrieving something from a closet.

*In this brochure, the term patient refers to a resident of a nursing home, any individual receiving services in a home care setting, or patients in hospitals.

Most patients can be in bed safely without bed rails. Consider the following:
- Use beds that can be raised and lowered close to the floor to accommodate both patient and health care worker needs.
- Keep the bed in the lowest position with wheels locked.
- When the patient is at risk of falling out of bed, place mats next to the bed, as long as this does not create a greater risk of accident.
- Use transfer or mobility aids.
- Monitor patients frequently.
- Anticipate the reasons patients get out of bed such as hunger, thirst, going to the bathroom, restlessness and pain; meet these needs by offering food and fluids, scheduling ample toileting, and providing calming interventions and pain relief.

When bed rails are used, perform an on-going assessment of the patient’s physical and mental status; closely monitor high-risk patients. Consider the following:
- Lower one or more sections of the bed rail, such as the foot rail.
- Use a proper size mattress or mattress with raised foam edges to prevent patients from being trapped between the mattress and rail.
- Reduce the gaps between the mattress and side rails.