Bed Safety Evaluation in Hospitals and Nursing Homes

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Background

- About 2.5 million hospital and nursing home beds are in use in the United States.
- Between 1985 and 1999, 371 incidents of patients caught, trapped, entangled, or strangled in beds with rails were reported to FDA.
Background, continued

- Of these 371 incidents,
  - 228 people died,
  - 87 had a nonfatal injury, and
  - 56 were not injured because staff intervened.
- Most patients were frail, elderly, or confused.
- Generally, it is assumed that many injuries and “close calls” are not reported.
Development of Hospital Bed Safety Work Group (HBSW)

- Established in April 1999
- Food and Drug Administration leadership
- *Shared Goal*: to reduce the risk of entrapment and injuries related to hospital beds, focusing on bed rails
HBSW: A National Partnership

- **Government**
  
  FDA, VHA, HCFA, CDC, Health Canada

- **Professional/Regulatory**
  
  JCAHO, American Nurses Association, National Association for Home Care, American Medical Directors’ Association, Bureau of Program Certification, American Society for Healthcare Engineering, American Association of Homes & Services for the Aging, American Health Care Association, American Society for Healthcare Risk Management

- **Health Care**
  
  Highland Chateau Health Care Center, RN+ Systems, Jewish Home and Hospital, Kendall Corporation, Martin Memorial Health Systems, Beverly Enterprises, Good Samaritan Society, Iona House
National Partnership

- Advocacy
  Untie the Elderly, AARP, National Citizens’ Coalition for Nursing Home Reform, Consumer Product Safety Commission, National Citizens’ Coalition or Nursing Home Reform

- Industry
  Hill-Rom, Sunrise Medical, Hard Manufacturing, Basic American Medical Products, ECRI, Invacare Corporation, Basic American Medical Products, Stryker Medical, Carroll Healthcare, Hilenbrand Industries

- Individual members
  Attorneys, Researchers
Issues Groups

1. *Regulation*: Reconciliation of regulatory definitions and requirements related to bed safety


   - Development and evaluation of design guidance for safer bed systems;
   - Creation of suitable options for continued use of older equipment
4. **Research**: Enhancement of scientific knowledge on the bed environment (A. Nelson)

5. **Education**: Outreach efforts to improve patient safety regarding bed systems (G. Powell-Cope)

6. Legal affairs
Accomplishments

- *Regulatory.* A joint letter signed by HCFA and FDA was sent by HCFA to all State Survey and Certification agencies in August 2000.

- *Regulatory.* Letter defined each agency’s definition of physical restraints and their position on bed rails as a restraint.
Accomplishments, continued

- **Clinical Guidance**: Universal Clinical Guidance for the Assessment for Use and Implementation of Hospital Bed Siderails in Hospitals, Long Term Care Facilities and Home Health Settings (DRAFT)

- **Outreach**: Resident/family brochure on risks of side rails and alternatives to their use, press releases, publications (www.fda.gov/cdrh/beds)
**Dimensional Criteria:** Criteria proposed for measurements at entrapment zones
- Based on 1st, 5th percentiles for head, neck, chest measurements (15 anthropometric data sources, international representation)
- Validated using FDA entrapment data
- Consistent with international standards under development

**Corrective Action Document:** Guidelines for action on beds that do not meet standards including mitigation strategies and bed replacement (DRAFT)
Entrapment Zones

Entrapment Zone 1 (H)  Entrapment Zone 2 (I)
Entrapment Zones

Entrapment Zone 3 (A)  

Entrapment Zone 4 (D)
Entrapment Zones

Entrapment Zone 5 (E)  Entrapment Zone 6 (F)
Entrapment Zones

Entrapment Zone 7 (J)

Full-Length Rail

Headboard
Purposes of Current Study

(1) Evaluate a facility-based approach for bed safety assessment
(2) Determine evidence-based recommendations for intervention
(3) Determine relative risk and cost benefit comparison of interventions.
Seven Objectives

O1: Determine the variability of bed systems (frame, mattress, bed rails) by make, model and unit location at six VA health care systems

O2: Evaluate each bed according to proposed safety criteria in seven critical “bed-safety zones”
Seven Objectives

O3: Empirically refine the process for measuring beds according to the proposed dimensional criteria

O4: Estimate the incidence and etiology of bed-related adverse events (close calls, injuries, falls from bed, and deaths)
Seven Objectives

O5: Evaluate the attributable risk of each bed system and its sub-components for each outcome using an analytic model.

O6: Design a system for prioritizing interventions to improve bed safety based on risks, benefits and cost of interventions

O7: Develop a strategic plan to mitigate the bed-related patient risks identified in VISN 8
Goals for Site Visit

- To measure all bed systems in long term care and medical/surgical areas
  - Standardized procedure using a “cone/cylinder” made to simulate head, neck and chest dimensions
  - Electronic data entry at bedside
  - Approximately 15 minutes per bed
  - Beds are measured unoccupied
  - Infection control procedures approved by Infection Control at Tampa VAMC
Goals for Site Visit

- Sticker placed next to bar code will indicate \( NP \) (not pass) or \( P \) (pass)
- Collect incident report data on bed-related falls and entrapment for one year (2/00 – 2/01)
Post Site Visit Work

- Data will be compiled in Tampa
- Expert panel will develop replacement/mitigation plan for each facility based on measurements, risks, benefits and costs
- VISN and VAMC level reports will be generated and distributed
HBSW will submit dimensional criteria to FDA for consideration as a “guidance document” (public record, 2-year process)

- Data Collection through mid July
- Final report by September 1
- Report submitted to VAMCs and VISN Sept. 15
- March 7-8, 2002 conference by HBSW (following annual falls conference)

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