

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 for 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
2. *Clinical*: Development of a standard of care for use of bed rails (S. Hoffman)
3. *Bed Equipment Evaluation and Design*: (A. Nelson, G. Powell-Cope)
 - Development and evaluation of design guidance for safer bed systems;
 - Creation of suitable options for continued use of older equipment

Issues Group

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

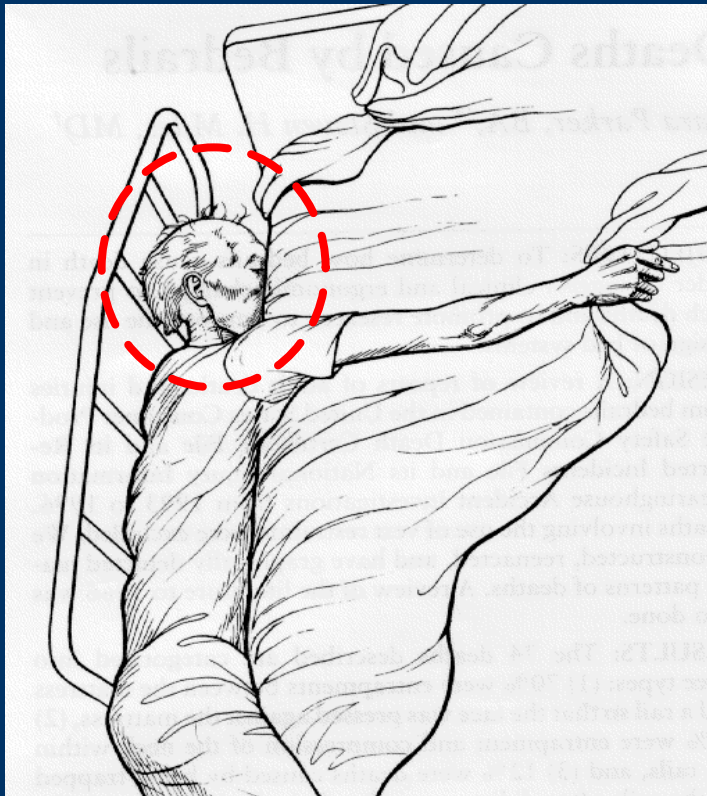
- ◆ *Clinical Guidance*: Universal Clinical Guidance for the Assessment for Use and Implementation of Hospital Bed Siderails in Hospitals, Long Term Care Facilities and Home Health Settings (DRAFT)
- ◆ *Outreach*: Resident/family brochure on risks of side rails and alternatives to their use, press releases, publications (www.fda.gov/cdrh/beds)

Bed Legacy Equipment, Evaluation, New Design

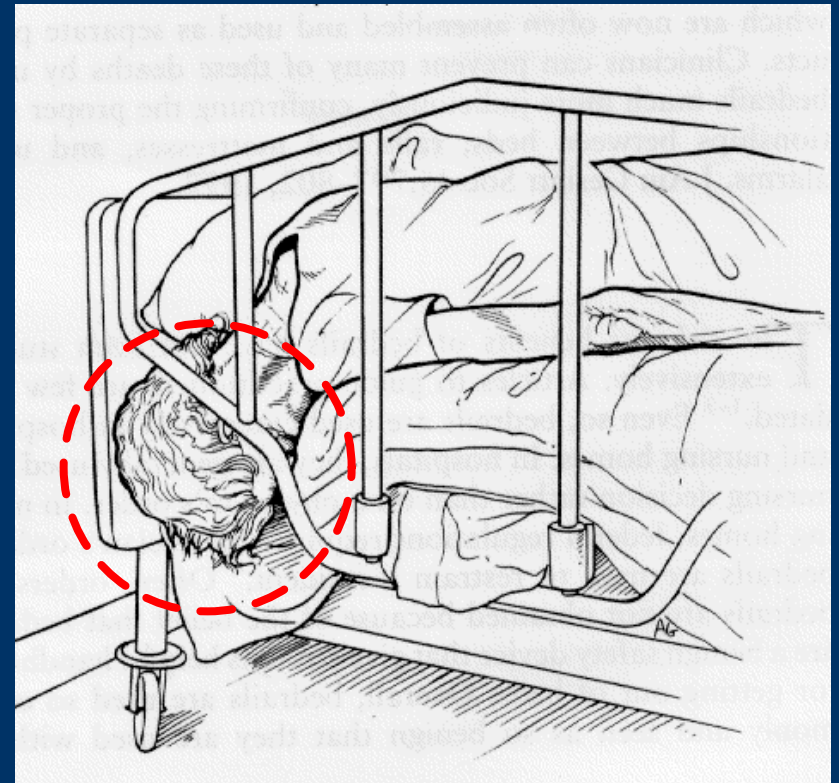
- ◆ *Dimensional Criteria*: Criteria proposed for measurements at entrapment zones
 - Based on 1st, 5th percentiles for head, neck, chest measurements (15 anthropometric data sources, international representation)
 - Validated using FDA entrapment data
 - Consistent with international standards under 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)

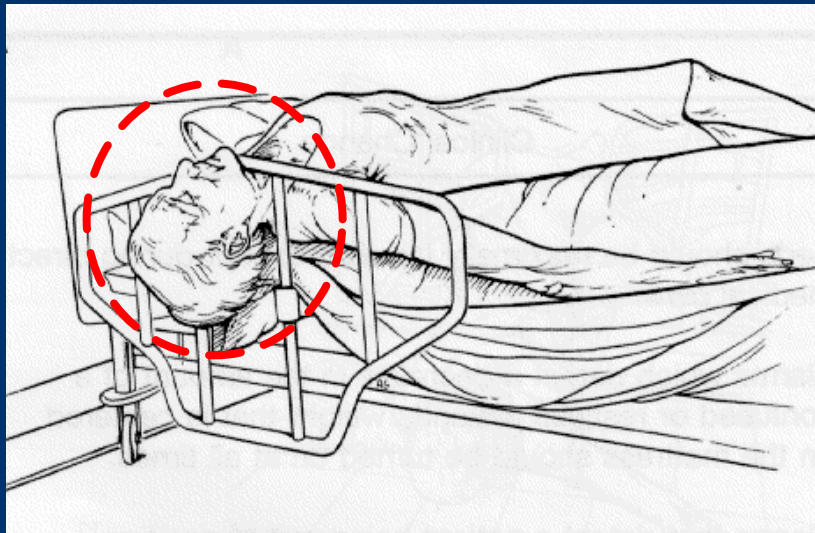


Entrapment Zone 2 (I)

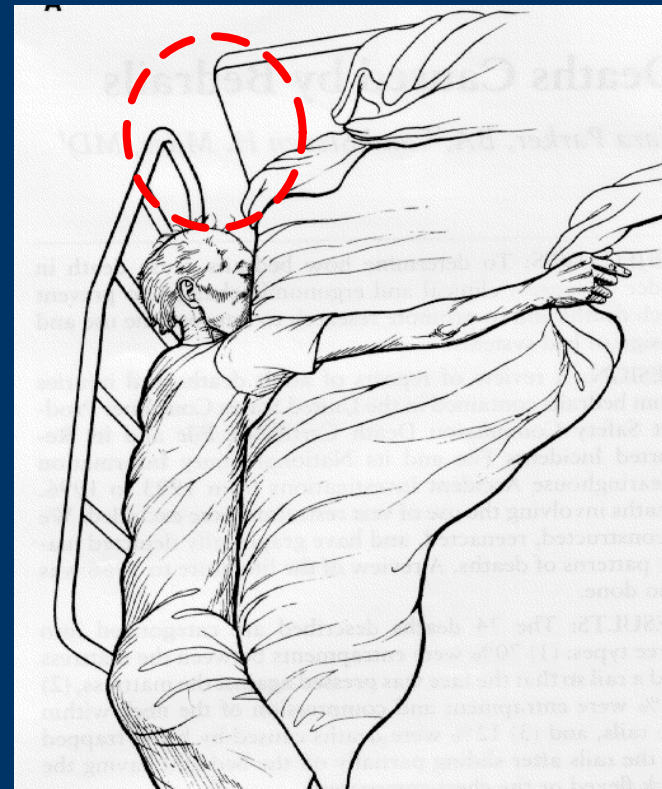


Entrapment Zones

Entrapment Zone 3 (A)

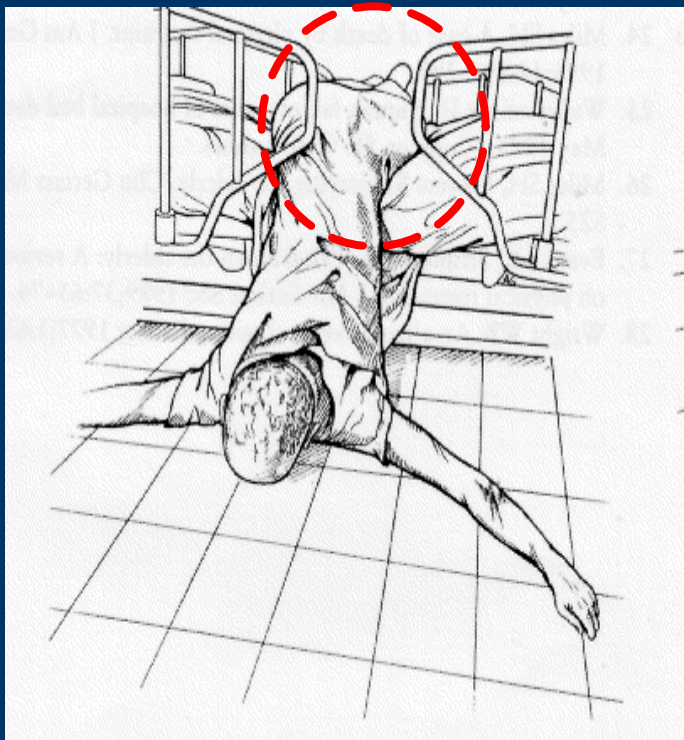


Entrapment Zone 4 (D)



Entrapment Zones

Entrapment Zone 5 (E)

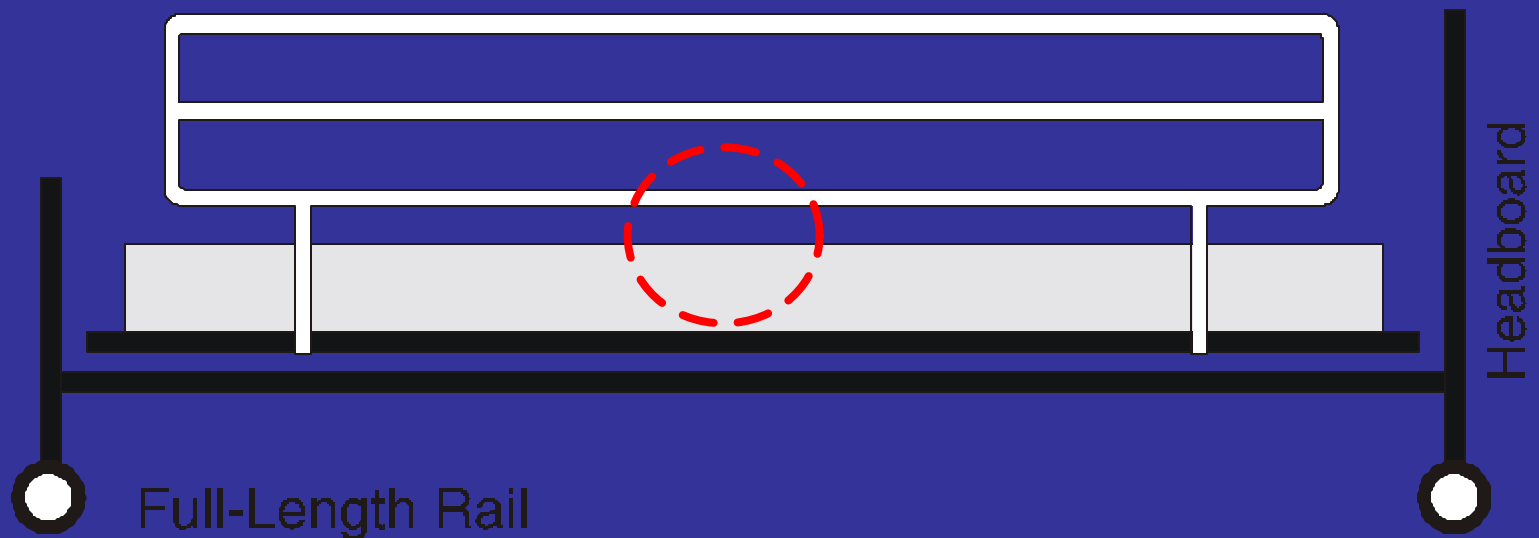


Entrapment Zone 6 (F)



Entrapment Zones

Entrapment Zone 7 (J)



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

Time Table

- ◆ 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)
- www.patientsafetycenter.com