

**HOSPITAL BEDS AND THE VULNERABLE PATIENT**  
**Minutes from the Hospital Bed Safety Workgroup Meeting (HBSW)**  
**March 28-30, 2001**  
(final sent 6-26-01)

**Day 1**

The morning session began with the issues groups working in small group sessions. The groups were Issue Groups 2 and 7 and Issue Groups 3/4/5 and 6.

**Issue Groups 2 and 7 ---- Clinical Guidelines**

- Janet Myder, leader of Issue Group 2, announced that the Clinical Guidelines are essentially completed. They will now be sent to the Legal Team being formed by Julie Braun. After the legal review, they will be sent to the Health Care Financing Administration (HCFA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The two government agencies will be asked to review the Guidelines to see if it is in conflict with their existing policies. Following this, reviewed and concurrence by Hospital Bed Safety Workgroup (HBSW) will be sought.
- Vera Mayer asked if we could add more home care information into the Guidelines. Janet said that she would send the Guidelines to the National Association for Home Care and ask if they can provide additional home care information.
- The question came up if the Clinical Guidelines should be focus tested. The idea was rejected.
- The idea to develop a “Pocket Card” (a quick reference pocket guide) to supplement the Guidelines was suggested and accepted. The card will be developed later since the group hopes to send the Guidelines out as soon as possible.
- The group suggested that an evaluation form be designed for the Clinical Guidelines and the Brochure. This will be followed-up by the IG 7 Outreach group.

**Issue Groups 2 and 7 ---- Hospital Bed Safety Brochure**

- The first 50, 000 brochures have been printed and sent out. FDA funded an additional 50,000. When this supply is exhausted, new sources for brochure funding will need to be found.
- Denis Roy has translated the brochure in French for those who are interested.

- The question of when to update the brochure was brought up. At a minimum, we would seek feedback from our users and base revision plans on the need to change/update the information.

### **Issue Groups 2 and 7 ----Outreach -- Chaired by Beryl Goldman and Liz Capezuti**

- Beryl has received hundreds of requests for the brochure. The comments she has received are excellent.
- One manufacturer wished to print thousands of the brochure, A Guide to Bed Safety and place their company name. The Work Group agreed that an addition such as “compliments of...” or “distributed by ...” would be acceptable but that changes may not be made to the brochure. The legal team will also serve as a source of advisement for the work products of the HBSW.
- **ACTION ITEM:** Each organization on the Hospital Bed Safety Work Group that was sent a large quantity of brochures is asked to send the following information to Beryl Goldman:
  - ◆ How many brochures have they sent out and to whom? (general groups)
  - ◆ Did they publicize the brochure in journals and newsletters?
  - ◆ Have they placed information about the brochure on their Web site?
  - ◆ Please send copies of their articles or press releases which promote bed safety to Beryl.
- The Issue Groups suggested the names of many organizations that should be contacted to serve as multiplier groups for the Clinical Guidelines and the other products produced by the HBSW.
- **ACTION ITEM:** All HBSW members send the name, address and contact person (if known) for any potential multiplier organizations to Beryl Goldman. These multiplier organizations will be asked to write journal and newsletter articles and put the HBSW information on their Web Site.

Note: When information is placed on a Web Site, it is important that all links be connected to the original site so that if a change is made in the Brochure or Clinical Guidance, the links can be changed. This site is: [www.fda.gov/cdrh/beds/](http://www.fda.gov/cdrh/beds/)

### **Issue Groups 3/4/ 5 and 6**

Issue Group 3/4/5 and Issue Group 6 convened and heard presentations from many of its members in preparation for its update to the full workgroup. More details follow.

## **Individual Issue Group Presentations**

Each Issue Group gave status reports based on the discussion held in the morning sessions.

### **Issue 1. Working with Regulatory Agencies**

FDA is planning to send a letter to HCFA asking the agency to consider signing the Memorandum of Agreement.

Note: Since the meeting, this letter has been sent to HCFA. FDA recently had a meeting with the Consumer Product Safety Commission (CPSC) to discuss the regulatory authority over portable side rails. CPSC has the authority to regulate portable side rails for use by toddlers (ages 2-5). FDA is checking with Counsel to see if we have jurisdiction for portable rails intended for adult use.

### **Issue Group 2**

Janet Myder discussed the Clinical Guidelines.

- The Guidelines are a broad effort so that they may be adapted to several environments (hospital, long-term care facility and home care). The guidelines are not Standards.
- A strong attempt was made to remove all prescriptive language.
- It is hoped that the Guidelines will be ready for distribution sometime during the summer.

#### **ACTION ITEM:** Issue 2.

The Issue Group will develop a clinical decision tree designed for caregivers. The Issue 2 decision tree will be merged with the Issue 6 Corrective Action Guide.

### **Issue Group 3/4/5**

Lance Lockwood and work group members continue their multi-faceted work. The following topics were discussed at length. Their current status is outlined below.

#### **Dimension Recommendations**

- Complete Dimension recommendations in Good Guidance Practice Format and plan to submit to FDA
- Align the Dimensional and Assessment tool documents.
- Include IG3 position statement on patient falls
- Invite members of the international standards group, IEC 60601/SC62D/WG 10, to next meeting

### **Legacy Equipment/Accessories to mitigate**

- Recommendations of equipment that needs to be removed from the field
- Develop a Bed frame and Mattress matching system.
- Include accessory list into the Corrective Action document  
IG3 will seek input from all members of HBSW as accessories cross IG2, IG3.

### **Instructional Video Content**

- Work continues on the development of this video. The work is 50% complete.
- FDA has the lead.

### **Equipment Assessment (cones, educational materials, videos, etc.) and Educational Outreach Kits**

- Provide complete package for relevant user. ECRI will take the lead.  
(At the June 1<sup>st</sup> Issue Group 3,4,5 meeting, the details of the kits were discussed and are provided in **Attachment C**)
- Develop an introduction or overarching document for all tools and guidance.

### **Issue 6 Group**

Audrey Nelson and workgroup members will continue work on the Corrective Action Guide to include:

- Create flowchart for Corrective Action document and Issue Group 3/4/5 Decision tree
- Review and finalize the Corrective action document and comments on patient falls.
- The Decision Tree of Issue Group 2 and Corrective Action must be harmonized.

### **Issue 7 Group**

- Continue to send out the Brochures and get the Clinical Guidelines out as soon as possible. Beryl asked the group to think about sources of funding for the next reprinting of the Brochure and for the Clinical Guidelines.
- Publicize as discussed in morning session.
- Prepare Evaluation Form, Clinical Decision Tree and “Pocket Card”.

## **Day 2**

### **Discussion**

A number of issues were discussed. They included:

#### **When will our work be completed?**

The morning session began with a general discussion regarding how long it will be before the group completes its work. The point was made that whenever we meet, many more projects seem to be generated.

Most feel that much of the work is close to completion. It was noted that while our working group is progressing at a national level, some of the states are working independently to produce their own recommendations regarding hospital bed safety. If we do not work quickly and send out our recommendations, the country will be peppered with various state recommendations.

#### **What products should be sent out and in which order?**

It was recommended the HBSW's products be released as quickly as possible in the following order:

- Clinical Guidance
- Dimensional guidance
- Assessment Tool
- Corrective Action Guidance

#### **What is our end goal?**

The questions of the scope of our Workgroup was raised in light of the fact that patient falls is a much more common problem. We acknowledged this and it was suggested that another work group be formed at a later date to address falls.

#### **When is final – final?**

This issue was discussed again. The recommendation was that clear progression stages should accompany any document. This is similar to the stages used in Standards development. Thus, it is important that at least a preliminary review by key people within each organization occurs **early** in the concept/development stage of the document. We agreed that we must avoid situations where key people in organizations review documents, for the first time, long after the workgroup is past the stage for editorial and conceptual review. The following flowchart outlines a typical development/review process.

## **Flow Chart:**

### **Concept development**



Action: HSBW Legal team conceptual review



### **HBSW Issue Group develops working draft**



Action: All relevant stakeholders must be involved  
First Draft review occurs



### **HBSW comments (This usually involves multiple drafts and reviews)**



Action: Initiate path to endorsement by member organizations  
Review by HBSW legal team  
Review by organizations (This is the final time to debate ideas/concepts/language)



### **Issue Group develops final draft**



Action: HSBW Legal team review



### **HBSW Concurrence**



Action: Member Organization sign-off (Should be a quick turnaround time as member organizations should be familiar with the document)

## **Speaker from the State of Michigan**

Tom Martin, representing the State of Michigan Department of Health, discussed the new guidelines for the use of bed rails to be followed by long-term care facilities in Michigan. He also mentioned that several other states are in the process of preparing guidelines for bed rail use. He urges that the HBSW get their recommendations finalized so that they can be adopted by Michigan and other states. Mr. Martin distributed the Interim Guidelines for Bed Rail Use and the legislative State House Bill No. 5689, which approved it.

## **Memorandum of Agreement**

Jay Rachlin provided an update on the status of the Memorandum of Agreement (MOA). Twenty organizations had signed on as signatories. It was requested that those organizations that have not submitted their concurrence form do so within the next few weeks.

Note: Since the meeting, 7 additional organizations have signed on bringing the total number of signatories to 27. This is nearly 100 percent of our partners. See **Attachment A** for a list of MOA signatories.

### **Day 3**

Day 3 was devoted to developing a timeline to track our projects. This timeline is provided as **Attachment B** to these minutes.

### **Next Meeting**

Health Care Financing Administration (HCFA) will host the next meeting of the Hospital Bed Safety Work Group scheduled for November 1-2, 2001 in Baltimore.

## **Attachment A**

### **Members of the Hospital Bed Safety Workgroup**

#### Signatories to the HBSW Memorandum of Agreement

- AARP
- American Association of Homes and Services for the Aging
- American Health Care Association
- American Medical Directors Association
- American Nurses Association
- American Society for Healthcare Risk Management/American Hospital Association
- Basic American Metal Products
- Beverly Enterprises, Inc.
- Care Providers of Minnesota
- Carroll Healthcare
- ECRI
- Exceptional Parent Foundation For Education
- Evangelical Lutheran Good Samaritan Society
- Hard Manufacturing Co., Inc.
- Hill Rom
- Iona Senior Services
- Law Offices of Julie A. Braun
- Medical Devices Bureau, Health Canada
- National Association for Home Care
- National Citizens Coalition for Nursing Home Reform
- National Patient Safety Foundation/American Medical Association
- RN+ Systems
- Stryker Medical
- Sunrise Medical, Inc.
- Untie the Elderly, The Kendal Corporation
- U.S. Department of Veterans Affairs
- U.S. Food and Drug Administration

#### Consultants to the Hospital Bed Safety Workgroup

- Joint Commission on Accreditation of Healthcare Organizations
- U.S. Consumer Product Safety Commission
- U.S. Centers for Medicare & Medicaid Services (formerly Health Care Financing Administration)



Task	Staffing	2001												2002											
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
<b>Dimensional Guidance</b>																									
• Buy in from HBSW	IG3																								
• Submit to FDA Dockets	IG3																								
• Draft GGP Document and submit for public review	FDA																								
• Public review completed	FDA																								
• Final document completed	FDA																								

<b>IEC/HBSW Equipment Spacing Dimensions</b>																									
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
• IEC WG10 and IG3 alignment	IG3																								
• Promote HBSW recommendations in WG10/IEC	D. Roy, J. Todd																								

<b>Corrective Action Guide</b>																									
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
• Complete Methods document	IG3																								
• Accessory definitions	IG3																								
• Define acceptability criteria	IG3																								
• Corrective Action Guide	IG3 Corrective Action Subteam																								
• Corrective Action Guide Conference Call	IG3																								

<b>Open Issues</b>																									
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
• Items to be removed from the market	IG3/M. Bruley																								
• Labeling (New product development warnings, color coding (if possible) and legacy warnings)	IG3																								

<b>Research and Data Collection</b>																									
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
• Legal case studies	Julie Braun/Liz Capezuti/IG6																								
• VA Pilot study – VA facilities	Gail and Audrey																								
• VA Pilot study – non-VA facilities	Gail and Audrey																								

Task	Staffing	2001												2002											
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
<b>Outreach</b>																									
• Develop outreach plan	IGs 2 & 7																								
• Implement distribution and outreach plans	IGs 2 & 7																								
• Develop plan for feedback/updating	IGs 2 & 7																								
• Communication to "other" associations not represented	IG7 - Beryl																								
• Develop and post list of speakers categorized by specialty & geographic area	IG7																								
• Write press release	Rita																								
• Develop cross linking among products	Subteam: Sarah, Fred, Liz & Lance																								
• Develop preamble to all future products																									
• Develop references list																									
• Develop generic PowerPoint speaker kit																									
• Dissemination of HBSW Products																									
• Develop plan for future distribution of products	IGs 2 & 7																								
• Reevaluation of brochure (web-based evaluation forms)	IG7 - Beryl																								
• Distributing clinical guidance	IGs 2 & 7 - Janet, Liz , Beryl																								
• Clinical decision tree																									
• Develop	IG2 - Janet																								
• Distribute	IG 7 - Beryl, Liz																								
• Pocket card for clinical assessment																									
• Develop	IG2 - Janet																								
• Distribute	IG 7 - Beryl, Liz																								
• Continue to disseminate information re HBSW in professional presentations																									
• Fall Prevention Workshop VISN 12	Audrey Nelson																								
• University of Louisiana	Beryl																								
• AAHSA Annual Meeting, San Diego, CA	Beryl																								
• Prevention Conference - Tampa, FL	Audrey Nelson																								
• Bed Safety Conference	Audrey Nelson																								

Task	Staffing	2001												2002											
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
<ul style="list-style-type: none"> <li>Disseminate information re HBSW in publications</li> </ul>	Liz																								
<ul style="list-style-type: none"> <li> <ul style="list-style-type: none"> <li>Continue to publish HBSW-related items, e.g., brochures in professional journals and books</li> </ul> </li> </ul>	Liz																								
<ul style="list-style-type: none"> <li>Publish scientific basis of dimensional guidance</li> </ul>	Denis Roy																								
<ul style="list-style-type: none"> <li>Publish guidelines in peer reviewed <b>clinical</b> journal (e.g., AJN)</li> </ul>	IG7 - Liz																								
<ul style="list-style-type: none"> <li>Begin submitting articles to consumer journals, e.g., AARP</li> </ul>	IG7																								
<ul style="list-style-type: none"> <li>Federal Register publication of draft guidance</li> </ul>	FDA																								
<ul style="list-style-type: none"> <li>Curriculum development project</li> </ul>	Rita, Liz, Beryl and Larry																								
<ul style="list-style-type: none"> <li>Develop Educational Aides for non-clinical/consumer audiences</li> </ul>																									
<ul style="list-style-type: none"> <li>Develop video for risk managers</li> </ul>	Subteam: Georgene, Audrey, Julie, Jeff, Doni																								
<ul style="list-style-type: none"> <li>Develop Video for Administrators</li> </ul>	Subteram: Janet, Evie, Lance and Doni																								
<ul style="list-style-type: none"> <li>Obtain funding sources to produce materials</li> </ul>	Rick, FDA, Rita, Liz																								

## Attachment C

### Bed System Entrapment Assessment Kit

Hospital Beds Safety Workgroup  
May 31 – June 1, 2001 Meeting  
Tampa, FL  
Issues Group 3, 4, 5

Notes from presentation by Mark Bruley of ECRI and the group's discussion on May 31, 2001 related to the **Bed System Entrapment Assessment Kit**.

Presentation by Mark Bruley:

1. At the March 27-29, 2001, HBSW meeting it was recognized that the healthcare community needs a focal point for obtaining the full work product from the HBSW when completed. [Discussion by IG 3, 4, 5 concluded that an appropriate title for the product would be the **Bed System Entrapment Assessment Kit**.] At that time, lacking other viable options for provision of the work product to the healthcare community, Mr. Bruley offered to explore whether ECRI would undertake to be the agency responsible for printing, copying, assembling the various work product components (see below), and fulfilling orders for this product. The HBSW attendees encouraged Mr. Bruley to pursue this.
2. ECRI has now agreed to pursue being the agency from which the healthcare community could purchase the kit. ECRI has infrastructure, staff, engineering experience, and logistical support for distribution of educational materials and specialized testing devices to large numbers of healthcare facilities (in-house printing, IS support, shipping dept., stock storage, etc.)
3. **Main Components of the Kit**
  - 3-ring binder (with section dividers) for documents
  - Documents
  - Videos
  - Test Tools (cone/cylinder and fish scale)

#### 4. **Detailed List of Kit Components** 3-ring binder (with section dividers) for documents

##### ■ **Documents**

- Introductory Overview (not drafted)
- Clinical guidance
- Clinical assessment checklist for evaluating patients (not drafted), part of Guidance.
- Flow chart for clinical assessment
- Bed System Dimensional Guidance
- Bed System Assessment Guidance
- Corrective Action Guide
- Accessories list for remediation (drafted?)
- Consumer Brochure (not drafted)
- Laminated pocket reference cards with clinical guidance for licensed healthcare professionals (not drafted) (keep?)
- Laminated pocket reference cards guidance for unlicensed licensed healthcare providers (not drafted) (keep?)
- Assessment tool use checklist (not drafted)
- Instruction sheet for assessment tool assembly
- Assessment tool use checklist (not drafted)

##### ■ **Two Videos or DVDs**

- Videotape or DVD demonstrating the clinical application of the Bed System Assessment Guidance (i.e., how to use the assessment tool and apply the criteria)
- Videotape or DVD for administrators and risk managers explaining the importance of assessing bed entrapment risks (covered, in part, in Introductory Overview document?)

##### ■ **Test Tools**

- Assessment tool
- Fish scale

#### 5. **Target Facilities Statistics (USA)**

- 5,800 acute care hospitals
- 3,200 free standing surgical centers
- 17,000 long term care facilities
- Total – 26,000 facilities
- Significant investment in printing, test tool mass production, video reproduction, etc.
- Get statistics on the number of Canadian facilities

## **6. Supplier Logistics / Issues**

- Clinical staff reference cards lamination
- Videotape/DVD copying, labeling, storage
- Assessment Test Tool
  - Mass production subcontractor
  - Non-scratch surface
  - Design and materials
  - Cleanable
  - Labeling on tool: “Medical Bed System Entrapment Assessment Tool” (English French and Spanish) and “www.fda.gov/cdrh/beds/”
  - Storage of stock
  - Clinical staff safety during use of tool
- Promotion of Kit
- Cost of production/assembly/shipment
- Sales of the full kit (binder/video bundle and assessment tool/scale) is intended for primary sales: sales of only binder/videos (as a bundle) and of the assessment tool/scale to be available also.
- Sales price not yet established (rough estimate \$100-\$300 for full kit)
- Intellectual property
- Legal liabilities of supplier
  - Put disclaimers in guidance document

## **7. Discussion Notes and Next Steps**

- Assessment Tool
  - Design/materials review for manufacturing stage to be done by Sunrise Medical engineers via Tom Whelan
  - Quick disconnect needed between cylinder and cone
  - Safety strap to be attached to rail being tested for prevention of cone falling to floor during pull test; strap doubles as a carrying strap
  - Finalize design and materials
  - Cone should be 12 lbs.
  - Cylinder is 60 mm dia. by 120 mm long, no end protrusions
  - Interior inclusive angle of taper on cone is 30 deg. (see diagram)
  - Labeling should be recessed on bottom of cone
  - Put disclaimers (not drafted) re assessment tool use in the Clinical Guidance, Introductory Overview document, and/or Bed System Assessment Guidance
  - Seek production sub-contractor
- Videos – in production
- Documents completion
- HBSW Logos should appear on all documents and video labels
- Kit sales
- Get statistics on the number of Canadian facilities
- Documents finalization

# Drawing of Assessment Tool

