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LOG OF MEETING

SUBJECT: The Hospital Bed Safety Work Group

DATE OF MEETING: October 24-25, 2000

DATE OF LOG ENTRY: December 20, 2000

PERSON SUBMITTING LOG: Scott Heh - ESME

LOCATION: DePaul University Law Center, Chicago, IL

CPSC ATTENDEES: Scott Heh – ESME

NON-CPSC ATTENDEE(S): Representatives from manufacturers of hospital beds, healthcare organizations, medical research institutions, patient advocacy groups, and government agencies. An attendance list was not available at the time of this report.

SUMMARY OF MEETING:

See attached meeting minutes provided by staff at the Food and Drug Administration (FDA).

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The Hospital Bed Safety Work Group
Chicago Bed Meeting – October 2000
Hospital Beds and the Vulnerable Patient
Final (sent 12-19-00)

On October 24 and 25, 2000, The Hospital Bed Safety Work Group (HBSW) met to continue its work of reducing the hazards associated with patient entrapment in hospital beds. The Hospital Bed Safety Work Group is made up of representatives of the federal government, national health care organizations, manufacturers of hospital beds and medical researchers. The DePaul University College of Law hosted the meeting in Chicago.

Patient entrapment with hospital bed side rails can occur in hospitals, nursing homes and at home. The FDA continues to receive reports of death and injury when patients become entangled or trapped between the mattress and bed rail or in the bed rail openings. The patients most at risk for entrapment are frail, elderly or confused.

To date the work group has primarily focused on raising awareness of the entrapment hazard and educating caregivers and family members on the problems associated with bed rail use. The work group recently issued an educational brochure, *"A Guide to Bed Safety"* that highlights the benefits and risks of bed rails, ways to meet a patient's need for safety, and patient or family concerns about bed rail use. This brochure is available on the FDA web site for bed safety at: http://www.fda.gov/cdrh/beds/

Day 1: October 24, 2000

The meeting opened with a welcome from Dr. Larry Kessler and Dr. Lireka Joseph. Larry had several introductory remarks that helped set the tone for the meeting.

- He said it was important for us to work together and to be open. This is our opportunity to communicate.
- We do not have to agree all the time, but we should strive to figure out what we can do to make "things" work.
- We need to work on formalizing our group and
- We are now in a transition period---we are moving from ideas to actual products.

The first presentation of the morning was from the Consumer Product Safety Commission followed by each issue group's presentation.

Mr. Scott Heh, U.S. Consumer Product Safety Commission

The Consumer Product Safety Commission (CPSC) represented by Scott Heh, Mechanical Engineer and Project Manager, presented remarks on CPSC's mandatory safety standard to reduce the risk of death and injury associated with entrapment in bunk beds. This safety standard states, in part, that a child may become entrapped in a bunk bed when he or she becomes wedged between the bed and the wall or when the child slips his torso through an opening in the bed that is too small for his head to pass through. Mr. Heh discussed CPSC's work in developing a voluntary standard to address entrapment hazards associated with portable bed rails. Portable bed rails are devices intended to be installed on an adult bed to prevent children from falling out of bed. These portable bed rails can pose a risk of fatality, typically when they shift away from the mattress and the child becomes entrapped between the mattress and portable rail.

Issue Leader Presentations:

Issue 1: Encourage Consistency among Regulatory Bodies

Formal closure to the work of Issue Group 1 was presented by Jeannie Miller (HCFA). A joint letter signed by HCFA and FDA was sent by HCFA to all State Survey and Certification agencies in August 2000. The letter defined each agency's definition of physical restraints and their position on bed rails as a restraint. HCFA has received positive feedback from the state agencies on this letter.

Jeane Nitsch, HCFA, presented some highlights of the new legislation, H.R. 4365-95, signed by President Clinton on Oct 17th that may exclude bed rails from being considered a restraint. HCFA will be preparing guidance regarding this new legislation. It was noted that this bill would not supercede any stricter regulation. As of December, we have no new information on this issue. For more information visit the HCFA web site at: www.hcfa.gov/medicaid/scindex.htm

Dr. Larry Kessler raised the issue of a labeling regulation. This issue was raised at the February 2000 meeting in Stuart, Florida. He introduced Dr. Joseph.

Dr. Lireka Joseph described the differences between developing a federal "Regulation" versus a federal "Guidance". Dr. Joseph cited the multiple stages required for developing a federal regulation, e.g. specifications, preamble, public review, draft regulation, public review, final regulation, public review plus assessment of documents for paperwork burden, economic costs, impact on small entities, and impact on States jurisdiction. Guidance, on the other hand, simply defines the FDA's interpretation of an issue, is not binding upon constituents, and may be revised more easily. Lastly, she defined the difference between Level 1 and Level 2 Guidance. Level 1 Guidance deals with significant controversial issues while Level 2 Guidance deal with more routine, less controversial issues.

The work group agreed that a labeling regulation would not be pursued. However, Dr. Joseph indicated that the FDA would welcome the development of draft guidance by non-federal organizations of the HBSW.

Issue 2: Clinical Guidelines (formerly Universal Standard of Care.)

Ms. Janet Myder, American Health Care Association, began her talk by distributing the product of Issue 2's work, Clinical Guidance For the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings. Ms. Myder's Issue Group was charged with the task of preparing a uniform set of recommendations for caregivers in hospitals, long tem care facilities and home care settings to use when assessing their patients' need for and possible use of bed rails. The components of the guidelines are not now intended to serve as clinical standards or requirements for care nor are they intended now to be interpreted as the best or only options for care.

In her report, Ms. Myder cited several reasons for developing the Clinical Guidance. These were in part, the variation among settings, the increasing awareness of the risk of using side rails, and the need for a uniform approach to the question of whether to use side rails.

Issue 3/4/5: Evidence-Based Equipment Design

Lance Lockwood lead a group of presenters describing the work of Issue Group 3/4/5. This issue group focused on evidence-based design, design guidance and assessment of legacy equipment.

Denis Roy discussed the group's work that involved identifying key entrapment zones in and around the bed system and the development of dimensional criteria based upon anthropometric data. Additionally, he described the completion of a review of past FDA adverse event data and comparison of bed dimensions for the events to validate the proposed dimensional criteria. The validation study confirmed that the proposed dimensions are appropriate and had they been in place, would have effectively mitigated the hazards in a vast majority of the reported events.

Kendra Doyle next presented a prototype of a bed system assessment tool that provides facilities the means to physically measure components of the hospital bed system and then compare existing equipment to the recommended dimensional criteria. She demonstrated the use of this tool for each entrapment zone on a bed mockup brought to the meeting by Issue Group 3/4/5. The Workgroup felt that the demo was very instructive. Discussion ensued about the demo being videotaped for future educational use by healthcare facilities.

Mike Chellson, next presented a decision tree algorithm entitled "Legacy Equipment Evaluation Guidance" which is intended to aid facilities to perform an analysis once a patient assessment has been completed. Considerable discussion ensued concerning one aspect of the algorithm dealing with non-conforming equipment and whether that equipment should continue to be used or not. Prevailing sentiment seemed to be that this non-conforming equipment should not continue to be used. Issue Group 3/4/5 will reassess this portion of the algorithm.

Mark Bruley summarized the results of a bed survey completed by ECRI in April 2000 to identify the types of beds that are in use in hospitals and nursing homes. Although the response rate was very low, the survey provided some interesting insight such as:

-40percent of the beds in facilities were purchased prior to 1990
-Hundreds of bed models are in-use in facilities
-Half-length and full-length rails are the most common types of rails used.

Lastly, Susan Meadows described a "Quick Reference Tool for Providers and Facilities." This work incorporated the ECRI survey data and the proposed issue group dimensions. Charts were developed to enable facilities to make a quick identification of bed component combinations of highest risk requiring immediate attention. These charts will continue to be refined as new data is received by Issue Group 3/4/5.

Issue 6: Enhance Our Scientific Knowledge to Improve Clinical Effectiveness and Safety of Bed Systems

Georgene Saliba and the Issue Group 6 members have been looking at ways to increase the understanding of the nature of patient entrapment in hospital beds. A draft questionnaire to be used by the FDA when it receives an entrapment adverse event report was presented. The questionnaire was designed to obtain detailed information on the events, circumstances and types of equipment in place when an entrapment event takes place. A profile of the information could be put together and sent to hospitals and nursing homes.

The group felt that to properly answer the questionnaire, the reporter of the entrapment adverse event would need to have the questionnaire at the time the entrapment is investigated. Otherwise, the likelihood of the reporter having specific details and recall of the adverse event would be slim.

The issues of confidentiality over the information in the questionnaire were important concerns to healthcare facilities. The workgroup questioned what would be done with the information once it is collected and how would the reporter get the questionnaire. For now the proposal, to refine the questionnaire and delivery strategies, was postponed. The workgroup will await the information from the closed insurance claims studies by Julie Braun and Dr. Liz Capezuti.

Questions raised for future research:
How to determine the magnitude of the problem—entrapment and falls at the bedside?
How to determine the effectiveness of mitigating strategies?
Dr. Audrey Nelson and her team at the VA will look into these research questions.

Georgene Saliba has passed the leadership of Issue Group 6 to Dr. Audrey Nelson of the VA. Georgene has been a strong leader for Issue Group 6 over the past 2 years and will remain an active participant in the work group. We thank her for her leadership.

Issue 7----Create Uniform Educational Outreach

Rita Gallagher's report addressed the following topics:

1. Distribution of the Bed Safety Brochure
   Now that the brochure has been completed, there must be a concerted effort to get it into the hands of as many appropriate groups as possible.
   - The initial printing order was for 50,000 copies. FDA will distribute these copies among the Working Group members.
   - Each member will take the responsibility for getting the brochures to their organization members. This is a multi- tiered process.
     - They should put the brochure on their organization's web page if there is one available.
     - They should put an article in their newsletter/journal advertising the brochure. It was agreed upon at the Chicago meeting that a generic article about the brochure would be prepared. This generic article could then be adapted to meet the needs of each organization.
     - Any organization having a professional meeting may wish to include the brochure as exhibit material.
   - A small sub group could be formed to identify other organizations (not included in the working group) that may help to serve as multiplier groups to disseminate the brochure.
2. When the Clinical Guidance has been completed, a similar distribution plan will be adopted.
3. Several suggestions were made for further educational endeavors.
   - Create a module on bedrail safety for use by nursing schools.
   - Create a display for professional meetings
   - Produce an educational teleconference

Likewise, Rita Gallagher has passed the leadership of Issue Group 7 to Liz Capezuti. Issue Groups 7 and 2 have merged into a single group. This combined group will be co-chaired by Janet Myder and Liz.

Next, a presentation of the Memorandum of Agreement was given to the workgroup. This document will formalize the work group now that the group has moved from the idea phase to producing work products.

Memorandum of Agreement:

Jay Rachlin distributed a draft of a Memorandum of Agreement (MOA) to the Workgroup. The purpose of the MOA is to identify the mutually shared goal of each participant to reduce the

continuing public health concern of entrapment of patients in hospital beds. The MOA is intended to serve as a broad, over-arching document to establish goals for the Hospital Bed Safety Workgroup and to foster cooperation, coordination and communication between all members of the Workgroup. There was general consensus among the group to support the MOA. A couple of questions were raised and a small group consisting of Jim Carpenter (Hill-Rom), Jeannie Miller (HCFA) and Jay Rachlin (FDA) was formed to address the remaining questions and redistribute the MOA to the Workgroup for comment and consensus agreement. The threesome will plan to complete this work by mid-December.

GROUP DISCUSSION

The last part of Day 1 was spent in a group discussion. Dr. Kessler moderated the discussion as each issue leader presented current and new work items. This gave the entire working group a clearer idea of the scope of work facing them and the need to begin the task of prioritizing and obtaining help from other issue groups.

Day 2: October 25, 2000

The second day of the meeting opened with a presentation of a study to review closed insurance claims. It is anticipated that this study may help change the view that caregivers are always negligent if care is provided without siderail use.

Julie A. Braun, J.D. LL.M. Closed Claim Study

Julie Braun presented an early overview of her closed claim study on siderail and legal liability. As part of her study, she intends to review federal and state appellate cases that involve bed siderails. In these cases, she plans to extract information related to types of defendants, and the cause and outcomes of the cases. As part of her data analysis, Ms. Braun will look at the history of the suits and awards and determine if any patterns can be identified. This project is expected to be completed and presented to the group by May 2001.

A follow-up study is being considered to review open claims. This could give the Workgroup a clue as to what is in the pipeline regarding future claims.

Following the presentation, the work group members spent the rest of the morning session and through the lunch hour working in their specific issue groups. The afternoon session began with the issue groups' reports to the entire workgroup on their current activities. Dr. Lireka Joseph moderated the session and the conclusion "wrap-up" session.

Issue Group Reports Presented to the Full Workgroup

Issue 1: Encourage Consistency among Regulatory Bodies

A new work item for this issue group is that the Consumer Product Safety Commission (CPSC) and the Food and Drug Administration (FDA) will maintain communication on the issue of portable bed siderails. Although these rails are intended for use with toddlers, these rails are sometimes used for adults. CPSC will keep FDA informed regarding their work on the development of standards for portable bed side rails.

Issue 2: Clinical Guidelines

Issue 2 members will continue to review and refine the Clinical Guidance. Issue Group 2 will receive a list of the critical comments consolidated from the members of Issue Group 3/4/5. Issue Group 2 will also obtain review from other key organizations, e.g. Health Care Financing Administration, Joint Commission on Accreditation of Healthcare Organizations, Occupational Health and Safety Administration, National Association of Home Care, American Hospital Association and the Veterans Administration, to determine if any parts of the guidance are in conflict with any organization's policies. Upon completion of this review, Issue Group 2 will obtain review from the full Workgroup.

Once the guidance is finalized, Issue Group 2 will work with Issue Group 7 to disseminate the Guidance.

Issue 3/4/5: Evidence-Based Equipment Design

Issue Group 3/4/5 is finishing several activities to address the risk of entrapment. These activities include: 1) the completion of dimensional criteria for the bed system configuration developed from over 15 anthropometric data sources, 2) The completion of a retrospective validation of the dimensional criteria based on a survey of past hospital events, 3) The design of a bed system assessment tool that provides facilities the means to physically measure and then compare existing equipment to the recommended dimensional criteria, and 4) A decision tree to aid facilities in an analysis of bed options once a patient assessment has been completed.

Issue 6: Enhance Our Scientific Knowledge to Improve Clinical Effectiveness and Safety of Bed Systems

Issue Group 6 will develop a pilot study to evaluate the entrapment assessment tool in 3,000 patient beds in Florida's Veterans Administration Medical Centers. In addition, the group will develop an assessment tool training video to assist caregivers in the proper use of the tool. The time line for this effort is:

- December 2000 - develop study proposal
- January 2001 - review and finalize proposal
- February 2001- train staff for data collection
- March/April 2001 -collect data
- June 2001 – complete final report

Issue 7----Create Uniform Educational Outreach

Issue Group 7 will continue its work of disseminating the Bed Safety Brochure as outlined in the Issue 7 status report. Plans are being developed for preparing articles for journals, newsletters and other less formal publications.
Eventually all work products will be channeled through Issue 7 group for outreach.

The next Hospital Bed Safety Meeting is planned for March 28-30, 2001