INTRODUCTION

Cases of patient entrapment in hospital beds have been reported to both Health Canada\(^1\) and the Food and Drug Administration (FDA)\(^2\) in the United States. In over half the reported cases, the patient has died. Entrapment occurs when part of the patient’s body becomes trapped in or under the rail, between the mattress and the rail, between split rails, or between the mattress and the head or footboard. These reported incidents show that the majority of the patients trapped were elderly, frail, or confused and resided in long-term care facilities.

In response to these incidents, the FDA, in partnership with Health Canada, the hospital bed industry, national healthcare organizations, patient advocacy groups, and other federal agencies, formed the Hospital Bed Safety Workgroup (HBSW) in April 1999, with the goal to improve the safety of hospital beds for patients most vulnerable to the risk of entrapment in all healthcare settings.

On March 10, 2006, the FDA published a guidance entitled, "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment." Subsequently, on December 20, 2006, Health Canada released a similar draft document entitled, “Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards.” These documents describe the potential areas (zones) of entrapment and recommend dimensional limits for each zone.

Based on a retrospective study of the patient entrapments reported to the FDA, four zones were identified that account for 80% of the entrapments. These zones involve the entrapment of the head and neck. The HBSW subsequently developed a “cone and cylinder tool” to test these zones. This tool measures the spaces within the hospital bed system (the bed and the mattress) to determine if the dimensions fall within the recommended limits of the guidelines of the HBSW. The cone on the tool represents the size of a small adult head and the cylinder represents the size of a small adult neck.

The four zones are as follows:

- **Zone 1** is any open space within the perimeter of the rail.

- **Zone 2** is the gap under the rail between a mattress compressed by the weight of a patient’s head and the bottom edge of the rail at a location between the rail supports, or next to a single rail support.

- **Zone 3** is the space between the inside surface of the rail and the mattress compressed by the weight of a patient’s head.

- **Zone 4** is the gap that forms between the mattress compressed by the patient, and the lowermost portion of the rail, at the end of the rail.
THE STUDY

With support from the Canadian Patient Safety Institute, the Healthcare Technology Management Department (HTM) within the Vancouver Coastal Health Authority (VCHA) followed the recommendation from Health Canada and undertook a study to assess the risk of entrapment in hospital beds within VCHA. The scope of the study was to take an inventory of hospital beds and determine their compliance with the HBSW guidelines. Sixty-three sites were visited, comprising 35 privately contracted long term care residential homes, 14 directly funded extended care and long term care facilities, 10 directly funded acute care facilities, and 4 privately contracted hospices. Nine of these sites had to be excluded from the study because an inventory of the hospital beds at these sites was not available. At the remaining 54 sites, there are 7046 hospital beds.

At each site, one or two samples of each model of hospital bed system were tested using the cone and cylinder tool according to Health Canada/FDA guidelines.

RESULTS AND DISCUSSION

In all, a total of 322 beds were tested representing 112 models. Only 38 models passed, accounting for 2032 beds (29% of the total 7046 beds). The other 74 models failed, 41 due to an incompatible mattress (Zones 2, 3, and 4) and 33 due to excessively large gaps in the rail (Zone 1). These accounted for 2823 (40%) beds and 2191 beds (31%) respectively. Approximately 71% of hospital beds within VCH are not compliant with HBSW guidelines. The majority of hospital beds within VCH are from the following 4 manufacturers: Carroll Healthcare, Hill-Rom, MC Healthcare, and Stryker Bertec. Acute care beds are mostly from Stryker and Hill-Rom, while long-term care beds are mostly from Carroll Healthcare, MC Healthcare and occasionally Stryker Bertec.

The majority of the hospital beds that were not compliant with the guidelines were in the extended care and long term care facilities that have the patient population that is most at risk of entrapment.

Beds manufactured before 1999 typically failed three or four zones, depending on the mattress. Beds manufactured during 1999-2002 when the guidelines were under development by the HBSW typically passed Zones 1 to 3, but not 4. Beds manufactured after 2002 when the guidelines were published typically passed all 4 zones.

Of note, during the 3 month period of the study, four cases of patient entrapment within VCHA were brought to the attention of HTM.

THE NEXT STEPS

The next step of the study is to determine the options and cost to bring the noncompliant beds into compliance. Upgrading the hospital beds is one means of mitigating the entrapment risk, along with other means such as staff education, redistribution of beds, changes in clinical practice, changes in purchasing practice, and establishing preventative maintenance for the hospital beds. Guidance for mitigating the risk of entrapment is given in FDA publications.

The only option to upgrade being considered for hospital beds no longer supported by the manufacturer is replacement. Mattress replacement will likely resolve the noncompliance of hospital beds that failed zones 2, 3, and 4.

For hospital beds that are not compliant in zone 1, a number of options exist. These include retrofit kits from the manufacturer, replacing the bed rails, and generic covers for the rails.

ACKNOWLEDGEMENTS

I would like to acknowledge the Canadian Patient Safety Institute for their help with funding this study.

REFERENCES