

-CPSI Project Summary Report-

Assessing the Risk of Patient Entrapment in Hospital Beds within Vancouver Coastal Health Facilities

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Acknowledgments

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I would also like to thank the Canadian Patient Safety Institute for providing me with the necessary funding required to execute and successfully complete this patient safety initiated project.

Executive Summary

The objective of this project was to assess existing hospital beds¹ with side rails for the risk of patient entrapment.

In the last 26 years, there have been incidents of patient entrapment that have resulted in serious injury and/or death reported to FDA in the States and Health Canada. In December 2006, Health Canada released a document entitled “Hospital Beds: Patient Entrapment Hazards, Side Rail Latching Reliability, and Other Hazards.” The Hospital Bed Safety Workgroup (HBSW), initiated by the FDA in partnership with Health Canada, has developed the guidance and designed a cone and cylinder tool to test risk zones of patient beds. Realizing the threat to patient safety, VCH Regional Risk Management and Healthcare Technology Management discussed the issue of patient entrapment and decided to take a two-step approach to address it. Biomedical Engineering was charged with conducting the first step, Entrapment Risk Assessment. This project was completed during the period of May 1, 2007 to August 31, 2007 with 50% funding from Canadian Patient Safety Institute (CPSI).

During this four- month project, 63 health care facilities were visited and at each facility each type of bed and mattress combination was tested following the Health Canada guidance.

It was found that the majority of beds within VCH failed the test (failed one or more zones of the test) mainly for two reasons: the mattresses are not of the right size and structure; the beds frame and the rail do not comply with the 1999 FDA guidelines for bed manufacturing.

Four mitigation strategies are recommended.

Introduction

Health Canada has received, between 1980 and 2006, 51 reported incidents of hospital bed patient entrapments, 26 of which have led to death. In the USA, between 1985 and 2006, there were 739 reported incidents of patients being caught, trapped, entangled, or strangled in beds with rails that were reported to the Food and Drug Administration (FDA). Of these reports, 439 people died, 125 had a non-fatal injury, and 175 were not injured because staff intervened. Health Canada and the FDA feel these numbers are low, as they suspect that many healthcare providers fail to report these incidents. Entrapment occurs when part of the patient's body gets stuck in or under the rail, between the mattress and the rail, between split rails, or between the mattress and the head or footboard. Reported incidents show that the majority of the patients trapped were elderly, frail, or confused and reside in long-term care facilities.

In April 1999, 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), whose goal is 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." The guidance contains the potential areas of entrapment, the main body parts at risk, and the recommended dimensional limits for each zone.

The seven zones of patient entrapment are illustrated below in the following figure:

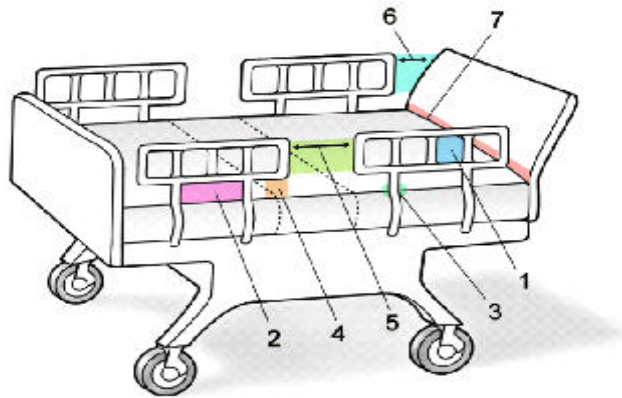


Figure 1: Seven Identified Zones where Patients could become caught, trapped, or entangled within the Hospital Bed System

(Source: Health Canada)

Based on a review of FDA reported patient entrapments, Zones 1, 2, 3, and 4 (See Appendix A for illustrations) account for 80 % of the accidents. Therefore, the HBSW has developed a dimensional limit for these four zones and a cone and cylinder tool to test these zones.

In 2006, Regional Risk Management and Healthcare Technology Management discussed the issue of patient entrapment and decided to take a two-step approach to address it. Biomedical Engineering was charged with conducting the first step, Entrapment Risk Assessment.

With the fund from Canadian Patient Safety Institute and matching fund from VCH, regional Biomedical Engineering hired a second year engineering co-op student from the Simon Fraser University to conduct the project under supervision of 2 biomedical engineers.

Site test and data collection have been completed successfully over the project term, May 1, 2007 to August 31, 2007.

Test Methodology

An on-site test of each bed model and mattress combination was performed at all directly funded VCH facilities and contracted facilities. Of the 63 facilities visited, 35 are privately contracted long term care residential homes, 14 are directly funded extended care and long term care facilities, 10 are directly funded acute care facilities, and 4 are privately contracted hospices. At each facility, one sample bed of each model was tested using the cone and cylinder tool according to Health Canada/FDA guidelines and result documented using a systematic approach. Due to the limited amount of time for this project, Providence Health Care and Assisted Living facilities were excluded indefinitely.

The specialized cone and cylinder tool was developed by the HBSW to test hospital bed systems for the potential of patient entrapment. This tool measures the spaces within the hospital bed system to accurately determine if the dimensions within the perimeter of the rail and areas between the rail and mattress meet HBSW's guidelines. The cone represents the size and weight of a small adult human head and the cylinder represents the size and weight of a small adult human neck. The following is a photograph of the tool that was used for the testing procedure:

The recommended dimensional limits developed by the HBSW are based on anthropometric data of the head and neck. These dimensions are for head breadth and neck diameter, 120 mm and 60 mm, respectively. A dimension of 120 mm encompasses the 5th percentile of female head breadth in all data sources used to develop this recommendation. In other words, this is the smallest measured head breadth for a female adult and is at least 20 mm below the average female head breadth. A dimension of 79 mm encompasses the 1st percentile of female neck diameter although several factors, such as neck compressibility, loss of muscle mass in the neck when people age, and the asymmetrical shape of the neck, support a reduced measurement. Therefore, as determined by the HBSW, the neck can compress up to 25% of its normal diameter and, taking this approximation into account, yields a recommended dimensional limit of 60 mm.

We tested 1-2 beds in each model in a facility for 4 Zones using the cylinder tool. They were tested with the mattresses that were most commonly used on them. The bed passes ONLY

when it passes ALL 4 Zones. Other wise they are defined as either Fail Due to Mattress (marked as Fm in the result sheet) or Fail Regardless of Mattress (marked as F).

If the sample beds pass, the model passes, and vice versus. We consider all beds of that model pass when the sample beds from that model pass.

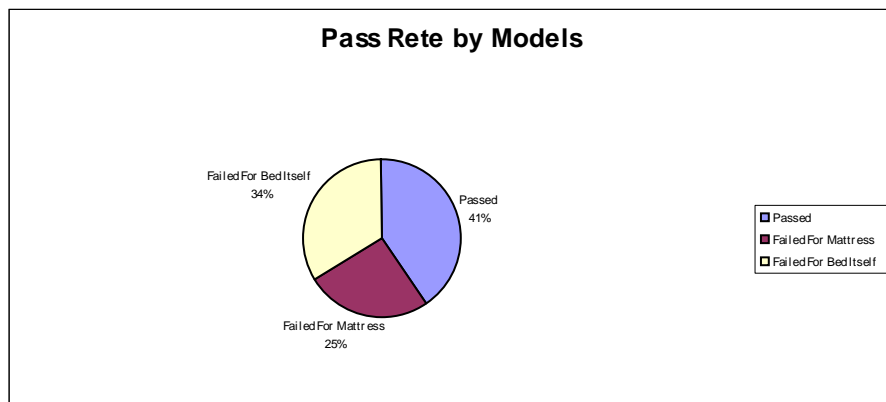
We were only able to determine the number of beds that fail/pass the test for the sites that have an accurate inventory, not for those without.

Findings and Discussion

A total of 322 beds were tested for 106 models in this project. Only 43 models passed, representing approximately 2,000 beds (26% of the total 7,600 beds covered by this project). The other 63 models failed, 27 models due to mattress and 36 models due to the bed itself, representing 3,600 (48%) beds and 2,000 beds (26%) respectively. Simply put, 5,600 out 7600 beds within VCH are not compliant² with HBSW guidelines.

There are two major reasons: the mattresses are not of the right size (too short or too narrow) and right structure (too soft on the edge); the beds frame and the rail do not comply with the 1999 FDA guidelines for bed manufacturing because either the beds were manufactured before 1999 or the manufacturers didn't follow the guidelines.

The following graph shows the result by model and by number of beds:



² This approximation was concluded based on analyzing the bed inventory gathered during inspection and some uncertainty does exist.

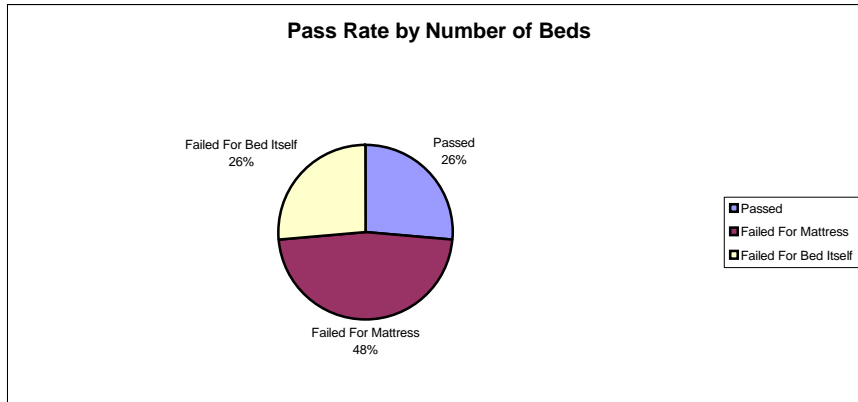


Figure 2: Pass Rate by Models and by Number of Beds

In general, the beds manufactured before 1999 typically failed 3 to 4 zones, depending on the mattress. Beds manufactured during 1999-2002, when HBSW was still developing the recommended dimensional limits of these four zones, passed Zones 1 to 3, but usually not 4. Lastly, beds manufactured after 2002 most likely pass all 4 zones. These generalizations are only valid given that the correct size mattress with a firm perimeter is placed on the hospital bed frame.

The majority of patient beds within VCH are from the following 4 manufacturers: Carroll Healthcare, Hill-Rom, MC Healthcare, and Stryker Bertec. Acute care beds from mostly Stryker and Hill-Rom, while long-term care beds from Carroll Healthcare, MC Healthcare and occasionally Stryker Bertec.

There are approximately 1000 Hill-Rom Century and Centra model beds within VCH that are significantly outdated according to the HBSW guidelines. These beds did the worst in the test. In fact, there was a patient entrapment around early February 2007. (Zone 1 entrapment. See Appendix A for illustration). This occurred when the patient was articulated upwards in the bed and the pillows slipped out from underneath his head while sleeping, causing his head to slide over and into the rail. There was also recently a Zone 5 entrapment in a Stryker Go Bed FL17E in August 2007 and another case in the Go Bed where nursing staff intervened on a large, obese

man who was trapped between the split rails around the waist and hip area. The occurrence of these entrapments could have been avoided if the patients had been in beds with split rails that were farther apart.³ These Go Beds, as well as the Stryker FL13E78 and FL13E80 models, all have the same rail configuration and pose a risk of a Zone 5 entrapment. In addition, the Zone 5 area changes on these models when the bed is articulated. The photograph below illustrates why this model could be a risk:

There were also two other cases of patient entrapment that happened in California, as seen below in the following links.

<http://www.applications.dhs.ca.gov/pressreleases/store/PressReleases/04-81.html>

<http://www.applications.dhs.ca.gov/pressreleases/store/PressReleases/03-53.html>

The highest risk exists where patient monitoring is limited, when the majority of the population is elderly with a physical or mental disorder such as dementia, and when patients and/or residents are partly or entirely staff dependent. Therefore, long-term and extended care facilities should be fully aware of the risk of entrapment. One strategy that could be implemented is to place all the highest risk patients closer to areas that are optimally observed by staff and/or place newer beds⁴ in areas where high risk patients are less likely to be monitored. Based on observation, these strategies are already being implemented by staff in some facilities.

It came to my attention during the assessment process that the discontinued use of bed rails and the transition to low beds, with adjacent mats on the floor, is slowly gaining popularity amongst the healthcare community. In the USA, there are states⁵ that have already banned the use of bed rails in hospital beds due to incidents of side rail entrapment which have led to patient death. It is important to reconsider the relationship between the care giver and patient when

³ Health Canada has recommended a dimension of no less than 318 mm between split rails.

⁴ The major manufacturing companies in VCH are participating members of the Hospital Bed Safety Workgroup and now design their beds according to these new guidelines for reducing entrapment.

⁵ Three examples are Washington, Arizona, and California.

delivering care with these low beds. For example, the care giver should be placing the bed at a comfortable height when working on the patient to avoid any unnecessary back strain which could lead to injury. Bed manufacturing companies are now making beds that go from the highest position to the lowest position at very quick speeds. This transition to low beds is becoming widely accepted throughout the health care community considering that many facilities do not use bed rails due to a ‘no-restraint’ policy.

Recommendations

Bed Replacement

In VCH, there are approximately 3500 directly funded beds and 4200 privately contracted beds excluding those of the Providence Healthcare. The majority of beds within VCH fail one or more zones. For beds in long-term care facilities that are 15 years old or older, failed ALL four zones regardless of mattress, replacement seems the best option. The ***Hill-Rom Century and Centra models*** are of the most concern. Other old beds from companies such as ***Dominion Metal Ware Industries, MC Healthcare (used to be Metal Craft Healthcare), and Carroll Healthcare DLX Series*** are also of concern.

As mentioned above, new beds from major bed manufacturers are in compliance with the Guidance. Manufacturing companies are also designing beds where the bed frame can go as low as 7 inches to the ground. With a 6 inch mattress on the bed frame, this would put the patient at a total elevation of 13 inches from the ground. In the unfortunate event of a patient/resident rolling out of bed, this low bed would minimize the height at which a patient falls, thus eliminating the need for bed rails altogether. This new design is discussed in an HBSW document titled, “*A Guide for Modifying Bed Systems and Using Accessories to Reduce the Risk of Entrapment.*”

Retrofitting

Some manufacturers provide retrofitting kits for older beds in order to comply with HBSW’s guidelines. Obviously this is a viable option for failed beds with remaining useful life. Hill-Rom can supply retrofitting kits for their old beds. MC Healthcare can provide rail

replacement on most of their older beds. Carroll Healthcare can also provide rail replacement. But Stryker Bertec does not provide any kind of rail replacement.

It is recommended that a trial test be done on these retrofit kits to ensure compliance.

Mattress Replacement

The most cost-effective corrective action that can be taken to reduce the risk of patient entrapment is to use mattresses of the right size for the beds. Usually the manufacturers specify mattress dimensions on the bedpan. If not, length, width, and depth⁶ measurements should be taken from bed manufacturer to ensure a correct fit. It is also important to ensure that mattresses are centered on the frame of the bed to avoid increasing gap.

In addition, the firm perimeter of the mattress decreases the gaps between the rail and mattress because the edge of the mattress will not compress under the weight of the patient. The firm perimeter also helps keep the patient in the centre of the mattress and in turn the centre of the bed, away from the edges where a patient is at risk of rolling out of bed or becoming entrapped. While doing inspections at facilities throughout VCH, it was observed that many mattresses were not fitting bed frames properly and were not firm around the edge, thus causing many hospital bed systems to fail the test. For example, the ***MIP Integriderm 9000 V/SR*** and the ***MIP Integriderm 9000 V/BR*** was routinely not the proper size mattress for many hospital bed frames and they do not have a firm perimeter. There are many of these mattresses within VCH.

If a facility has multiple models of bed frames and mattresses, it is recommended that some kind of colour-coding system be developed so that beds and mattresses can be matched easily for compatibility. It was observed during the inspection process that matching the appropriate size mattress to bed frame was more chaotic in larger facilities with large variety of beds and mattresses.

⁶ The International Hospital Bed Standard recommends 8.7 inches as the minimum height from the top of the rail to the top of the mattress.

If purchasing is unsure of whether a certain model of mattress fits the beds, Biomedical Engineering is happy to provide the test tool with manual to sample test the new bed-mattress system/combination prior to purchase.

Modification

Zone 1 Modification

We can place pads, pillows, netting etc. draping over the rail to prevent a patient's body part from entering the rail openings. These may have to be specially designed for each type of rail configuration or some companies can provide them.⁷

Zone 2 and 3 Modifications

Having a mattress with the correct width, depth and with a firm perimeter will reduce patient entrapment at these zones because this will decrease open spaces or gaps between the rails and mattress. As a temporary solution, if the mattress is too narrow or small, we could place pads or wedges to act as 'stuffers' for filling up any spaces between the rail and mattress. Loose/shaky rails may cause larger gaps and need to be fixed. It is most ideal that facilities undertake bed preventative maintenance programs to keep their beds in good physical condition and most importantly, safe for their patients.

Many new types of beds have mattress stoppers at corners of the bedpan. If the mattress has a tendency to slide around and there are no mattress stoppers, Velcro or anti-skid mats could be used to prevent the mattress from sliding off centre.

Zone 4 Modifications

⁷ We noticed that some Stryker Bertec models already had pads in place.

To prevent Zone 4 entrapments, it is recommended to try 1) putting a thicker mattress on the bed frame,⁸ 2) replacing the existing rails with newer ones from the manufacturing company, or 3) putting a wedge on the bottom ends of the rails to prevent wedging of the neck⁹.

Some beds have rails with more than one working positions and failed Zone 4 (or Zone 2) when in certain position. Fixing (locking) the rails in a position safe for Zone 4 and Zone 2 helps. Beds with rails that are rounded or V-shaped at the edges are more of a potential risk for neck entrapment.

This rounded or V-shaped edge can cause what is known as a ‘wedging effect’ of the neck and occurs when a patient’s neck becomes ‘wedged’ underneath the rail, at the end of the rail. Health Canada has recommended a limit of greater than 60 degrees, measured from the horizontal, for the edges of rails. The following photograph is an example of when Zone 4 does not comply with HBSW guidelines:

Managerial Actions

Beside the technical recommendations above, bringing entrapment issue into attention of management and caregivers is also very helpful if not more.

- Closer monitoring of patient effectively minimizes the chance of entrapment.
- Reducing the mismatches of bed and mattress by reducing bed and mattress models through regular capital planning. There are over 100 bed models and at least 50 models (estimated) of mattress in use across VCH. We could upgrade bed systems to fewer models free of entrapment issue and make sure only compatible mattresses on them.

⁸Be careful that the mattress is not too thick in order to comply with the International Hospital Bed Standard for minimum height from the top of the rail to the top of the mattress.

⁹ Carroll Healthcare is a provider of this kind of retrofit kit on their square edged side rails only. Otherwise, this recommendation could be designed within the health authority.

- Whenever we plan to purchase mattress, make sure entrapment issue is taken into consideration of capital planners and buyers.

Conclusion

The majority of patient beds within VCH do not comply with the HBSW guidelines for entrapment according to our test results. Certain models, usually old ones, are of serious concern: the *Hill-Rom Century and Centra models and old Dominion Metal Ware Industries models* fail most Zones and should be the first to take care of. *Carroll Healthcare DLX Series* are also of concern.

We also found out that mattress of right size and with a firm perimeter cannot be more critical to patient bed system. The *MIP Integriderm 9000 V/SR* and the *MIP Integriderm 9000 V/BR* was routinely not the proper size mattress for many hospital bed frames and they do not have a firm perimeter. These two models should be avoided when purchasing.

Positioning the mattress on the bed is important as well.

We have made technical recommendations to address basically short- term concerns. In the long run, the entrapment prevention should be integrated into regional strategies for capital planning, purchasing and on-going monitoring/inspection program for both bed and mattress.

References

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Exclusions

Below are those products for which some, or all, of the recommended dimensional criteria are not valid. Please note that the products listed below are not free from risk of entrapment. Users should regularly and consistently identify and address areas of potential entrapment for each patient or resident through a comprehensive bed safety program.

Total exclusion from the scope of this project:

- Air fluidized therapy beds are excluded because the nature of the therapy does not allow the patient to exit the bed easily. When these products are used, Health Canada recommends that steps be taken to ensure that the therapeutic benefit outweighs the risk of patient entrapment.
- Bariatric (obesity) beds, pediatric beds and infant cribs are excluded because Health Canada did not use anthropometric data for these groups in determining the recommended dimensional limits of the entrapment zones.
- Stretchers not used for extended-stay, examination tables, operating room tables, radiology tables; proning tables, exercise and range of motion tables, bathing units, and mechanical lifting

devices are excluded from the scope of this project because they are not ordinarily used as hospital beds. It was noted that Zone 1 would be the only area that the majority of stretchers within VCH would apply to and would fail this zone indefinitely.

- Universal side rails or assist bars are excluded because these products are purchased from an outside source and installed on the bed after purchase. It was observed that these rails or assist bars may pose a risk of entrapment due to the wide open space that exists within its perimeter. When these products are used, Health Canada recommends that steps be taken to ensure that the clinical benefit outweighs the risk of patient entrapment.

Partial Exclusion from the scope of this project:

- Kinetic treatment tables and rotation beds are excluded from the dimensional limits except for those spaces within the perimeter of the rail due to the special design requirements of these beds (see Zone 1 in Appendix A). When these products are used, Health Canada recommends that steps be taken to ensure that the therapeutic benefit outweighs the risk of entrapment.

- Labor, delivery, recovery, and postpartum (LDRP) specialty beds are excluded from the dimensional limits for the area under the rail at the end of the rail due to the special design requirements for obstetric care (see Zone 4 description in Appendix A).

- Pressure Reduction Therapeutic Products Framed flotation therapy beds (specialty air beds built into a hospital bed frame), powered air mattress replacements, and similar pressure reduction products that have therapeutic benefits such as reducing pressure on skin are easily compressed by the weight of a patient and may pose an additional risk of entrapment when used with conventional hospital bed systems. When these types of mattresses compress, the space between the mattress and the bed rail may increase and pose an additional risk of entrapment. While entrapments have occurred with the use of framed flotation therapy beds and air mattress replacements, these products are excluded from the dimensional limit recommendations, except for those spaces within the perimeter of the rail (see Zone 1 description in Appendix A). This partial exemption is due to the highly compressible nature of these mattresses, which poses technical difficulties with measuring certain dimensional gaps in these types of products.

Additional caution should be taken when using these products to ensure a tight fit of the mattress to the bed system. If a powered air mattress is replacing a mattress on a bed system that meets HBSW recommendations with the original mattress, the resulting bed system with the new air mattress may still pose a risk of entrapment. When these products are used, Health Canada recommends that steps be taken to ensure that the therapeutic benefit outweighs the risk of entrapment.

NOTE: Health Canada recommends the dimensional limits in this guidance for bed systems using mattress overlays. It is recommended that steps be taken to assess the therapeutic benefit to the patient when applying a mattress overlay to a bed system that does not meet the recommended dimensional limits. The clinical benefit should outweigh the risk of entrapment presented by the use of such a system.

Glossary

Hospital Bed System: defined as the bed frame, mattress, bed rails, as well as other accessories that are compatible with each other.

Patient Entrapment: refers to an event in which a patient is caught, trapped, or entangled in the spaces or gaps in or about the bed rail, mattress, or hospital bed frame.

Bed Rails: Commonly used synonymous terms are side rails, bed side rails, grab bars and safety rails. Bed rails are rigid bars that are attached to the bed and are available in a variety of sizes and configurations from full length to half, one-quarter, and one-eighth length and are used as restraints, reminders, or as assistive devices.