EVALUATION OF A NOVEL MEDICAL DEVICE BY

SIMULATING STRANGULATION HAZARDS

Judy Findlay,M.A.Sc.P.Eng[1], Kim Shearer,RN,Ph.Dc[2], Thom Bellaire,Dipl.T[1], Christine Flegal,M.A.,[1], Angie Wong,B.Sc.[1], Pia DeZorzi,RN,B.ScN,CPON [2]

1. BC Institute of Technology 2. BC Children's Hospital

INTRODUCTION

The potential for infant or child strangulation and/or asphyxia in the home environment is well documented in the health care literature.[1] Strangulation by entanglement is the sixth leading cause of infant mechanical suffocation in the United States[1], while in Canada, 19/100,000 deaths were attributed to suffocation in the 0 to 4 years age group [3]

Children in hospitals are also at risk for strangulation or asphyxia. The risk is directly associated with the tubing and lines used for the delivery of intravenous fluids, oxygen therapy, cardio-respiratory monitoring, and other treatments and diagnostic techniques.[2] The percentage of hospitalized pediatric patients who receive intravenous (IV) therapy is estimated to be 90% by the authors from BC Children's Hospital (BCCH).

The length of IV tubing is considered a risk factor as it can vary in length between 2.1 and 2.7 meters to accommodate the distance from the patient in the bed/crib to the infusion pump, a device used to maintain an even rate of fluid administration. Depending on fluid requirements and drug therapy, an infant or child may have several IV lines leading to multiple pumps, as well as oxygen or other monitoring or therapeutic tubes or lines, thereby increasing their risk of entanglement. Anecdotally, nurses often recount finding patients entangled in tubing; however, unless harm to the patient is identified, a report is not formally documented or necessarily even charted. Entanglements not associated with death are not required to be reported in Canada[4].

A significant risk factor for entanglement is age and cognitive development. The population at greatest risk has been identified as infants from the age of 3 to 36 months and children who are cognitively or developmentally impaired.[2] Constant observation is difficult to achieve with nurse/patient ratios in most pediatric settings ranging from 1:3 to 1:4 and with parents/caregivers not necessarily available 24 hours per day. As a result, there are times (particularly during sleeping periods) when infants or children are unobserved or unattended.

There have been reported incidents of asphyxiation, strangulation, and death or near death of children in hospitals in Canada and the United States.[2,3] Following the IV tubing strangulation death of an 11 month old infant in Edmonton, AB in 2001, a Health Canada Advisory (2002) directed health care organizations to continuously observe or monitor children who are known to be at risk of entanglement when there is no other option for treatment. Further to this, the Canadian government sponsored a national patient safety workshop in 2003 which explored the issue of strangulation. Guidelines for improving tubing and line safety resulted from this workshop with recommendations including: the adoption of technology to ensure properly separated, labeled and secured line connections, and human factors engineering concepts to reduce the risk of tubing-related adverse events.[5]

As a result, an interdisciplinary, interagency team was formed in 2004 to develop prototype devices that would prevent tubing entanglement for at-risk patients. Three prototypes were designed and fabricated under contract by British Columbia Institute of Technology (BCIT) for BCCH. These prototypes were tested by nurses using models of infants and children (dolls) of various sizes in the BCCH Nursing Education Laboratory. One prototype was selected for further development: a vest with an attached channel made of fabric to collect tubing together and direct it away from the child.

INNOVATIVE SOLUTION

In July 2007, the author institutions partnered, sharing the costs and benefits to develop the Vest device. The Health Technology Research Group (HTRG) at BCIT works under a Quality System certified to ISO 13485 for development of medical devices. Consequently, the development of the prototype followed a rigorous process including: development and review of a complete set of design requirements, risk management, detailed design, prototype fabrication, and design verification. Direct care providers (nurses) were engaged during the

design review process to ensure the user requirements were incorporated into the design from the early stages.

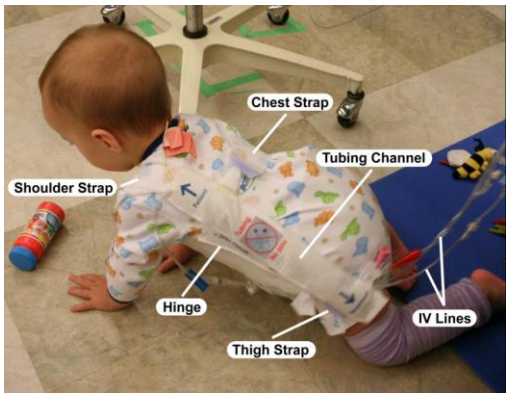

Figure 1 The Hug™ installed on a baby

The resulting set of design requirements focused on addressing the safety and effectiveness of the Vest. This list included safety, ergonomic, functional and performance requirements. The prototype product is a soft flexible garment that consists of a vest with one shoulder strap, one thigh strap, and a long channel that retains the various tubings. The Vest is fitted to the patient with hook and loop material, and a hinged channel that holds the tubings can be oriented on the front or back of the patient. The new prototype is aptly called The Hug™. Designed as a single-patient device that could be worn for several days, the Vest is easily removed and replaced for diaper changes or bathing. Because of the expected range of sizes of patients, the design is scalable. The prototype was developed in two sizes that could be fitted to the expected range of sizes of patients aged 6-18 months and 18-36 months. After bench-testing and improvements, the Vest was produced in sufficient numbers for evaluation in an environment that allowed for the simulation of strangulation hazards.

The evaluation project was conducted at BCIT's Living Laboratory – a full scale simulation lab that can be configured to resemble any environment. The lab is equipped with video, audio and recording equipment for recording data. The Lab also contains a viewing theatre with one-way glass which allows observers to unobtrusively monitor evaluation activities.

To test the effectiveness and safety of the device, human factors testing and observation in a simulated hospital environment took place with a representative sample of infant children and caregivers.

Study Objectives

The key objectives of this study were to:

1. Demonstrate in a simulated laboratory environment the effectiveness of the Vest as an anti-entanglement protection device in children ages 6 to 36 months who have one or more medical lines or tubings attached as in a typical clinical scenario.

2. Demonstrate that the Vest does not put infants or toddlers who have single or multiple tubings or lines at increased risk of harm.

3. Evaluate the Vest against key design requirements.

4. Determine whether the Vest was ready for validation testing in hospital settings.

EVALUATION

After institutional ethical review, fourteen subject pairs (infant and caregiver) were recruited. Several recruited caregivers were also nurses.

A hospital room was simulated with the use of equipment, a hospital crib, and an intravenous and feeding pump from BCCH. A play area was created adjacent to the crib area and included a padded rubber mat, toys and a couch. A camera was positioned to capture the participants' actions. Non-invasive tubing (a peripheral IV line, a central line, a nasogastric (NG) tube, and an oxygen line) were connected to a garment worn by the infant to simulate tubings installed on the patient. The other end of the tubing was attached to an IV pole or pump.


Figure 2 BCIT Living Laboratory

A crossover design (subjects served as their own controls) was used in which subjects were observed wearing the Vest, and the garment with tubings, for a pre-specified period in three settings: in the crib, in the caregiver's arms, and in the play area. This was followed by a period without the Vest, but with the

tubings still attached. Data was collected using standardized recording forms, video recording, and by user survey.

During each study period, two observers watched for occurrences of selected events related to safety and ergonomics, and captured the data on standardized forms. One observer managed the trial from beside the subjects. The second observer was behind a one-way mirror. Child and parent activities were captured on video. Measurements included: time taken to install and remove the Vest, the number and lengths of medical tubing, the slippage of tubing in the channels, and anatomical dimensions of the child subjects. Vests were inspected for damage following each trial. A new Vest was used for each subject.

Subjects (infants and caregiver) were observed for a portion of the time without interference from researchers and then instructed or encouraged to perform various sleep time behaviours such as placing their bodies in different positions, moving around, rolling over, etc. The goal was to create possible scenarios where tubing entanglement may occur.

All movements, behaviours, incidents of entanglement (with or without the device), and the factors surrounding the entanglement were captured and documented via video recording and researchers' observations. Researchers and the caregiver were positioned near the bed so that if risky entanglement should occur, they could release them immediately.

DATA COLLECTION AND ANALYSIS

Review of User Questionnaires

Adult subjects (the caregivers) filled out a questionnaire after the observation period. The numerical scale responses to eleven questions were binned and are summarized. The answers to subjective questions in the caregiver questionnaire were collected together, grouped where appropriate and summarized.

Review of written data

During the trials, observations were made by a main observer in the room with the subjects, and a second observer behind the one-way glass. Data from the main and secondary recorders were included. All data recorded on the study tools were entered into spreadsheets and analyzed. For situations where the number of observed events was recorded, the larger of the two recorded counts was used.

Review of Video Tapes

For analyzing the entanglement results all the video data was reviewed, and a detailed incident log was created, identifying each incidence of entanglement. This log was used to identify the number of times entanglement occurred at four different locations: legs and feet; torso below arms; torso above arm(s); or neck. The log also indicated partial (180 – 360 degree loop around a part of the body) or full entanglement (greater than 360 degree loop around a part of the body). In the analysis reported here, partial and full entanglements were both counted as entanglement. The entanglement log was analyzed in spreadsheet format, and the results reported. Table 1 gives the comparative results for the highest risk entanglement, i.e. situations in which any tubing tangles around the neck, or around the torso above the arms. Either scenario could lead directly to strangulation if unchecked. The table shows the reduction in the incidence for various scenarios.

RESULTS

Table 1: Reduction of Neck and Above Arm entanglements with the Vest

Scenario	Reduction in Entanglement using Vest
All scenarios	71%
In crib (N=13)	85%
Small Vest	20%
Large Vest	75%
Back Channel	63%
Front Channel	79%

DISCUSSION

Evaluating the design

The primary design objective was to develop a product that reduces the risk of strangulation. The study showed that the frequency of all entanglement around all parts of the body was reduced by 66% when the Vest was used. The frequency of neck and above-arm entanglement (which leads to risk of strangulation) was reduced by 71% when the Vest was used. In the crib setting, the frequency of neck and above arm entanglement was reduced by 85% when the Vest was used. It is not known whether similar results would be obtained in the clinical setting.

27 of 29 Design Requirements were substantially met

A key study objective was to verify that the Vest met the design requirements. Twenty of 29 design requirements were completely satisfied. Many of these were safety requirements that needed to be verified prior to testing the Vest in the hospital setting. Minor gaps were identified between design requirements and the prototype performance for 7 of

29 requirements. Issues identified included the fit around the patients' thigh, material bonding issues, some de-lamination of the stretchy fabric, design limits for the sizing of the vests, some slippage of tubing in the channel, size of the channel, and some isolated incidents of mistakes in installing and using the Vest.

For two of the 29 design requirements, there were more significant gaps between design requirements and Vest performance:

Safety Requirement: Eliminate slack tubing in the vicinity of the neck of the patient

The Vest did not 'eliminate' all slack tubing in the vicinity of the neck. While the device was 100% effective in eliminating slack tubing at the top end of the channel, the tubing exiting the bottom of the channel was found to entangle around the neck or above the arms some of the time in 8 of 14 subjects. The frequency of entanglement was significantly reduced when the Vest was used (71%), but tubing emerging from the bottom end of the channel was still available for entanglement. Determining whether to improve the design to further reduce the risk of entanglement, to change the design requirement, or both are critical tasks for the project team to complete prior to hospital use. Important factors to consider are the extent to which caregivers would rely on a device that claims to reduce the risk of entanglement, and the level of performance that warrants this reliance.

Ergonomic Requirement: Time to apply the Vest should be less than 60 seconds

The average time to apply the Vest on a live subject was 5 minutes. This value can be expected to decrease with experience by nurse caregivers and with less active patients. In fact, when two caregivers performed a second install, the time for installation was reduced by approximately 2 minutes. Users indicated they were satisfied with the time required to install the Vest. The design requirement should be revisited and possibly changed given the large number of factors that influence actual installation times. The time to apply the Vest should also be tested in a hospital setting.

User Feedback

In analyzing the user surveys, it was found the reaction of all caregivers to the Vest was overall positive by the 15 questions in the research tool. Generally users judged the Vest to have an appealing appearance, to be intuitive, easy to use, requiring low time requirement for placement on the child, comfortable to the patient, and lowering or eliminating entanglement risks. Users liked the ease of access to patient handling, judged the Vest to be safe, and expected it to be easy to incorporate into the acute care setting.

All users indicated they would use the Vest. The main reasons given were that it helped manage the medical lines and tubing, lowered risk of entanglement, increased sense of security, and was very comfortable. Users also offered useful comments about the design and labeling of the Vest.

CONCLUSION

The design of the Vest as a solution to reduce the probability of entanglement has been shown to be fairly successful. However, it is recommended that the product development team successfully complete the following steps prior to evaluating the device in hospital settings**:**

1. Examine the causes of entanglement, explore possible design changes to further mitigate the risk, and modify the design requirement related to eliminating slack.
2. Investigate issues that need further consideration and possibly design improvements e.g. the slipping of tubing, the size of the channel, and the sizing of the vests.
3. Address minor documented issues of designed fit and fabrication.
4. Conduct a detailed hazard analysis including a review of safety-related issues identified in this report.
5. Complete the design verification tasks (including durability testing), and conduct a design review prior to fabricating vests for hospital evaluation.

ACKNOWLEDGEMENTS

The development of the first baby vest is attributed to inventors Resi Fladl and Thom Bellaire.

REFERENCES

[1] Drago, D. A., & Dannenberg, A.L. "Infant mechanical suffocation deaths in the United States, 1980-1997." *Pediatrics, 103*(5), e59. 1999.

[2] Garros, D., King, W. J., Brady-Fryer, B., & Klassen, T. P. "Strangulation with intravenous tubing: a previously undescribed adverse advent in children." *Pediatrics*, 111, e732-734, 2003

[3] Beaulne, G. (Ed.). Choking and suffocation. In *For the Safety of Canadian Children and Youth*. Ottawa: Public Health Agency of Canada. 1997.

[4] Philip Neufeld, Health Canada, personal communication 2003.

[5] Memo, Health Canada & Canadian Association of Paediatric Health Centres, 2003.