NIOSH Extramural Award Final Report Summary

Title: * Invalid Patient Transfer-Transport-Lift-Weigh System
Investigator: Theodore Williamson, R.N.

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15 March 1997

Roy M. Fleming, Ph.D., Associate Director for Grants
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Dear Dr. Fleming:

In conformation with the U.S. Public Health Service Grants Policy Statement, this report on SBIR Phase I grant #1 R43 OH03380-01 is hereby submitted. Accompanying this Performance Report is a videotape so that the funding agency, the National Institute for Occupational Safety and Health, will have graphic, as well as written, evidence of the performance of the *Invalid Patient Transfer-transport-lift-weigh System,* which development was accomplished by Black Mountain MedCrafters, Charlotte, NC, the small business entity which received the grant.

The goal of the grant process was to develop a device which may be useful in decreasing the incidence of occupational injury in the American health care industry. Specifically, the goal was to develop a device which could accomplish transfer and transport of hospital and other patients without manual lifting by nursing personnel. Inherent in this goal was to develop a device which would be safe for patients and staff members, easily and conveniently used and stored, and cost effective.

Testing was designed and conducted by Professor Bernice Owen of the University of Wisconsin-Madison, who served as an Ergonomic Consultant before and during the grant process. She collaborated with Dr. Roger Jensen, Senior Ergonomist at UES, Inc. (Dayton, OH). Both of these Consultants have agreed to play similar roles in Phase II testing of 60 devices in 15 Veterans Administration hospitals. Dr. Jensen's primary role was that of Systems Safety Analyst. The following criteria were used to test the device in the College of Nursing and Health Professions nursing laboratory at the University of North Carolina (Charlotte, NC) with nine randomly-chosen student volunteers. Testing sequences yielded 6,252 data points.

Testing Criteria

1. Perceived exertion to the
   a) Neck
   b) Shoulders
   c) Middle Back
   d) Lower Back

2. Perceived Patient Comfort and Security

3. Time to perform
   a) Transfer from a hospital bed
   b) Transfer from the floor to a hospital bed
   c) Transport from one location to another along a narrowly-defined corridor

Results

Please refer to Professor Owen's report which is enclosed.

1. **Perceived Exertion** - The device outperformed all of the other devices tested. Although Professor Owen's report shows only slightly better scores in this category against the (estimated) $5000 Invacare lift, the videotape will suggest that the SCAT! feasibility model has the potential for significant improvement in terms of exertion by nursing personnel.

   Rationale for less-than-expected performance of the SCAT! against the Invacare lift in terms of perceived exertion:

   (a) The new device, the SCAT!, was overdesigned with schedules 10, 20 and 40 stainless steel pipe to insure absolute safety during testing of the device. This added an estimated 24.5 kilograms to the weight of the SCAT!;

   (b) Several features of the device were poorly designed (see Principal Investigator's *Critique of the Design* and Dr. Jensen's *Systems Safety Analysis* which follow at the end of this Performance Report). Two examples of poor design were the hoisting frame storage latches and the hammock-attachment carabiners. What seemed to work well in the shop proved extremely difficult for several of the student volunteers (see videotape).

2. **Patient Comfort and Security** - The scores for the new device were significantly better in this category against all of the other methods tested. Redesign will show further improvement in terms of patient comfort and security.

3. **Time to Perform** - The feasibility model bested the other devices tested, i.e., the stretcher and the lift in the respective (1) <u>transport</u> and (2) <u>lift from the floor</u> sequences. The planned redesign will significantly improve these scores. The redesigned device will never match the speed of manual methods for a transfer from a bed, but other benefits will be realized which may improve *overall* time for a transfer or transport (see Professor Owen's comments on page 17 of her report). The selected sequences on the videotape, however, for this maneuver and for lifting a patient from the floor, show a dramatic improvement over the average tested times in Professor Owen's report, further illustrating this new device's potential.

Systems Safety Analysis

Please refer to Dr. Roger Jensen's report which is enclosed. None of Dr. Jensen's safety and design analyses fell within the "Unacceptable" (irremediable) range.

Principal Investigator's Critique

Enclosed please find the Principal Investigator's critique of design flaws revealed during Phase I testing. Alternative ideas are presented. Southerland Associates, Inc., an engineering firm in Charlotte, NC, has contracted with Black Mountain MedCrafters to redesign the device. This prominent firm has a 32,000 square foot fabrication facility, and will build the production prototype and 60 models for field testing in Phase II. Dr. Jensen will participate in the Phase II design process.

Architectural Analysis

Patricia Kucker, MARCH, AIA (University of Virginia - Charlottesville, VA) performed an architectural analysis of the movement of this device versus a stretcher into a contemporary, smallish semi-private hospital room. This report was developed for the Phase II application, but is included with this report for your edification.

Videotape

A 17-minute videotape (enclosed) was prepared with selected sequences from the Phase I study.

Selling Price

This new device can be manufactured for a now-estimated $2500-$3000 and sold for about $6000. This is the current selling price for two good stretchers. Top-of-the-line lifts are currently selling in the $5000-$6000 range. Black Mountain MedCrafters is currently in meaningful communication with several of America's top medical device manufacturers. It is hoped that one of them will agree to a partnership in the Phase II proposal.

Offshoot Device

Using this innovation, i.e., surrounding a bed to effect a patient transfer, has caused the development of another, much smaller, device which can, without manual lifting, remove a recumbent patient from bed and transfer him/her to a commode, easy chair or wheelchair - *or serve as a wheelchair.*

Acknowledgements

The writer would like to thank the National Institute for Occupational Safety and Health for the tremendous financial and personal help, and for the awesome trust given to him. NIOSH will be given due credit for the development of this device, and for the development of the company which engendered it. Special thanks are due to Dr. James Collins of ALOSH in Morgantown, WV, whose willing and frank "down home" advice and counsel did much to insure a successful Phase I study.

Very special thanks are due to you, Dr. Fleming. It was you who inspired the opening and closing of this new device - what, in the final SBIR Phase I analysis, was the most dependable and least troublesome of all the engineering innovations embodied in this equipment. The new, in-line actuator technology, thanks in part to you, will make this new equipment appear to open as if by magic!

Respectfully and gratefully submitted,

T. Williamson

Theodore Anthony Williamson, RN
Principal Investigator

Enclosures: (5)

Principal Investigator's Critique of Design Flaws

This critique of SBIR grant #1 R43 OH03380-01 explores design flaws in the feasibility model of the "Invalid Patient Transfer-transport-lift-weigh System". The device will be redesigned accordingly, and will be UL-(or equivalent) approved before field trials.

1.	Problem: Solution:	The device was too tall. Decrease height of device.
2.	Problem: Solution:	The motor housing was too large. Decrease size of housing to appropriately fit components.
3.	Problem: Solution:	The gate housing protruded from end of device. Recess gate housing under patient. Use smaller transport oxygen bottle.
4.	Problem: Solution:	The patient hammock was poorly designed. Design hammock with appropriate width and length. Eliminate head and foot "rails".
5.	Problem: Solution:	Hoisting frames were too tall. Decrease height of hoisting frames.
6.	Problem: Solution:	Caster rollability was poor. Select casters with increased rollability.
7.	Problem: Solution:	Device was too heavy. Choose appropriate schedule of stainless steel pipe to support double the maximum patient load.
8.	Problem: Solution:	Hoisting frame carabiner pinched finger of one test subject. Select fastener of appropriate size and with remote latch control.
9.	Problem: Solution:	Hoisting frame carabiners too large. Select smaller fastener.
10.	Problem: Solution:	Hoisting frame carabiners eccentrically-shaped. Select fastener with uniform shape to avoid "hammock-settling".
11.	Problem: Solution:	Height of hoisting frame depends upon user's judgement. Use stepper motor to incrementally raise and lower hoisting frames to predetermined levels. Provide covered override switch for unforeseen adjustments.
12.	Problem: Solution:	Hoisting frame storage fasteners difficult for user. Select fasteners with remote latch control.
13.	Problem: Solution:	Hoisting frame may strike patient's head. See solution numbers 5 and 11 above.
14.	Problem: Solution:	Patient's feet may catch on pipe. Design stop for patient's feet. Lengthen hammock. Provide inservice education.

15. Problem: Hammock may sway side-to-side with patient movement, catching on pipe during ascent or descent.
Solution: Provide warnings and training to watch hammock (and patient) carefully during ascent and descent, guiding hoisting frame with hand if swaying occurs.

16. Problem: Patient may fall out of device from side.
Solution: Provide hoisting frame to hoisting frame side rails. Provide warning to use side rails and waist belt. Provide inservice education.

17. Problem: Confused and disoriented patient may clutch at pipe during ascent and descent.
Solution: Provide grommeted openings at side of hammock for application of soft restraints. Provide inservice education.

18. Problem: Hammock side supports uncomfortable to roll over when placing patient on hammock.
Solution: Provide flat, rather than round, hammock side supports with openings for the attachment of hoisting frame fasteners.

19. Problem: Waist belt buckle uncomfortable to roll over when placing patient on hammock.
Solution: Provide flat waist belt buckle.

20. Problem: Patient may strike cross bar of hoisting frame when sitting up.
Solution: Place head-end hoisting frame so that arc of patient's head (when sitting up) will miss hoisting frame components.

21. Problem: Device may tip over. This event is unlikely, but was considered by Dr. Jensen. Shop tests showed that the same radial force (applied at a 36" height) to this device and to a stretcher caused the stretcher to tip over first. Stretchers typically have recessed casters and consequently a narrow wheel base.
Solution: Design recessed battery and charger housing at foot-end of device to (1) decrease center of gravity further; and, (2) equalize weight distribution. (also see solution number 1 above).

22. Problem: Hammock must be oriented correctly before placing patient on it.
Solution: Color-code hammock ends to match with appropriate hoisting frame fasteners. Provide inservice education.

23. Problem: Patient may be fearful of being hoisted.
Solution: Provide reassurance. Design appropriate speed of lift. Provide hand grips on hoisting frames. Provide inservice education.

24. Problem: Wrong switch may be pressed.
Solution: Provide tactile and visual switch differentiation.

25. Problem: Tight fit around bed. Hospital beds typically 38-40" in width. Inside width of device (when open) was 43"
Solution: Device has design capability of up to 48" inside width (when open). Device has 29" outside width when closed.

26. Problem: Battery may fail during transport.
Solution: Provide emergency power supply. Provide low voltage indicator on instrument panel. Design motor and actuators with low amperage requirement. Design power supply to double expected daily usage. Provide battery charger for night shift replenishment of battery storage capacity. Provide inservice education.

27. Problem: Hammock clamps may catch on bed when surrounding bed for transfer/transport.
Solution: Hammock clamps were eliminated as unnecessary on the advice of Consultants, and they were not employed during the study. They were removed for the second day of the study (see videotape). It was thought that 4-point support provided stable platform for transport.

28. Problem: Fingers may be pinched when device closes.
Solution: Provide soft, durable plastic end caps. Provide warning label and inservice education.

29. Problem: Gate housing did not open completely.
Solution: Design hinges to allow complete opening of gate(s).

30. Problem: Shelf, when in place, inhibited opening of device.
Solution: Design shelf brackets on non-opening side of device.

31. Problem: Inconvenient to remove monitor shelf from storage.
Solution: Design shelf to fold up at foot of device when not in use.

32. Problem: Actuator motors create unsightly bulge in housing.
Solution: Use new in-line actuator motors with extender sleeves to mimic pipe.

33. Problem: Utility (lower) hammock found to be unnecessary and inconvenient.
Solution: Eliminate utility hammock from design.

34. Problem: Bed pan pocket on side rail interfaces with the patient.
Solution: Design storage for bed pan and toilet tissue in one of housings.

35. Problem: Hammock occasionally "jerks" during ascent or descent.
Solution: Design cable guide to prevent piling and then slipping of cables when winding on reels.

36. Problem: Foot-end of device stops at footboard of bed when surrounding bed.
Solution: Design to straddle bed completely.

37. Problem: Device may have problem maneuvering in small, semi-private patient room.
Solution: Width and length of device is the same or less than that of standard stretcher designs. See accompanying architectural drawings of technique for surrounding a bed for transfer/transport in a small, semi-private patient room.

38. Problem: Threat of running over patient's head or feet when picking up from floor.
Solution: Provide inservice education on proper (diagonal) technique for picking a patient up from the floor.

39. Problem: Single cable ferrule may fail.
Solution: Design double ferrules or safer method of attaching cable to reels or hoisting frames.

40. Problem: Personnel may exceed design limit of 500 pounds.
Solution: Provide warning label(s) and inservice education.

Submitted to Dr. Roy M. Fleming, Associate Director for Grants, NIOSH, 15 March 1997.

Signature..Principal Investigator
SBIR grant #1 R43 OH03380-01

EVALUATION OF VARIOUS ASSISTIVE DEVICES
USED FOR
TRANSFERRING AND TRANSPORTING "PATIENTS"

(Various Devices VS SCAT)

Study Conducted by and
Report Submitted by
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for Ted Williamson,
Project Director of
SBIR Phase I,
1 R43 OH03380-01
October 31, 1996

PURPOSE OF STUDY

The purpose of this study was to demonstrate the efficacy of various assistive devices in reducing neck/shoulder/back stress to nursing students while carrying out the patient handling tasks of: transfer from the bed, transfer from floor to bed, and transporting a patient from one location to another. The purpose also included the "patient's" reaction in relation to feelings of comfort and security while being transferred and transported.

The assistive devices used in transferring from the bed were a draw sheet, two friction reducing assistive devices, and the SCAT; a modern, battery operated mechanical lift and SCAT were used for transferring from the floor to the bed; and a stretcher and SCAT were used for transporting.

METHODOLOGY

Setting: The study took place in the nursing laboratory at the College of Nursing , University of North Carolina- Charlotte (UNCC) from August 5 to 6, 1996 and September 28 to 29, 1996.

Subjects: Nine senior level nursing students in the generic nursing program from UNCC volunteered to be in the study. Two groups of four students each were formed by the following method: each student drew a card; the cards were numbered from 1 to 8. Those with numbers from 1 to 4 formed Group 1; those with numbers from 5 to 8 formed Group 2. All subjects were involved as transferrers, transporters, and "patients". (Eight students were planned for the study, but one student was not able to be involved for the full study so the ninth student fulfilled her work for Day 4 of the study).

The range in age for the group was 21 to 35 years of age with a mean of 25.3 years (sd=5.4). Height ranged from 64 to 75 inches ($\bar{x}$=67.2, sd=3.6); and weight from 98 to 249 pounds ($\bar{x}$=154, sd=47.4). There were no statistically significant differences between the groups in relation to age, height, or weight.

All the subjects indicated they had experience lifting and transferring patients; seven of the eight had experience in health care setting as an employee in addition to experience as a student nurse. All indicated they experienced no neck/shoulder/back pain related to this work.

Instruments: Demographic data sheets were used to ascertain age, height, weight, history of lifting/transferring patients, and back pain history (Appendix A). A rating of perceived exertion likert scale was used (0=no exertion, 10=extremely hard exertion) to determine the exertion felt to the neck, shoulder, mid back and low back while carrying out each task (Appendix B). Patient comfort and patient feeling of security scales were used to determine reactions from "patient" subjects (0=very comfortable, 7=extremely uncomfortable; 0=very secure, 7=extremely insecure) (Appendix C). The above data sheets also had a general comment section at the bottom of the form. A case situation was used to determine rank preferences for use of devices, rationale for ranking, and number of people needed to carry out each task with each device (Appendix D).

Subjective ratings were deemed adequate for this study because Owen, Garg and Jensen (1992) found no significant difference in findings using the Borg scale and the more complicated, time consuming, and labor intensive biomechanical model methods.

Tasks Performed:

1. Transfer from bed to stretcher via use of draw sheet. A draw sheet typically is under "patient"; so for this task, the draw sheet was already under the "patient" while in the bed. The stretcher was brought parallel to the bed and brakes locked. One subject was on pushing side (bed side), two subjects were on pulling side (they knelt up on stretcher). All subjects rolled the draw sheet close to the "patient" and grasped it for transfer. On the count of 3, two subjects pulled and one pushed so the "patient" was transferred to the edge of the bed. The two subjects that were pulling then stood on the floor while the pushing subject knelt on the bed. With the second push-pull the "patient" was transferred to the middle of the stretcher.

2. Transfer from bed to stretcher via use of Friction ReducerI. The "patient" was turned to the side away from the stretcher. The draw sheet, which was already under the "patient", was lifted up and the Friction ReducerI placed to touch the shoulder and buttock of the "patient"; the draw sheet was pulled over the Friction ReducerI, the "patient" was then turned back to a supine position (with the Friction ReducerI and draw sheet under her). The stretcher was then placed parallel to the bed and brakes locked. The subjects then positioned themselves for the transfer as in the above task and transferred the "patient" to the edge of the stretcher and then to the middle of the stretcher.(Therefore, they pulled the "patient" over to the stretcher via the draw sheet with the friction reducing device under the draw sheet).

3. Transfer from bed to stretcher via use of Friction ReducerII. Same as task 2 except used Friction ReducerII instead of Friction ReducerI.

4. Transfer from floor to bed via battery operated mechanical lift. "Patient" was on floor with sheet under her. "Patient was turned to her side and sling fanfolded and placed half way under "patient". "Patient" was then turned to her other side and sling pulled through. The "legs" of the mechanical lift were spread to

wide position and the mechanical lift was brought to the "patient". Legs of "patient" were lifted so the base of the mechanical lift could go under the legs of the "patient". The Lift was then lowered so loops of sling could be attached to hooks on the lift. With one subject by the "patient", the other subject pushed the buttons so the lift could go to a higher position and then they moved the lift to the bed. Both subjects positioned the "patient" into the bed. The lift was lowered, sling released from lift, "patient" turned from side to side to remove sling.

5. Transport "patient" via stretcher for 35 feet "Patient" was already on the stretcher. Side rails were pulled up. One subject was positioned at the head of stretcher and requested to push. The other subject was at the side of the stretcher, guiding the stretcher and pushing an IV stand. The stretcher was pushed about 10 feet and then maneuvered around a 90 degree angle corner and pushed another 25 feet where the pathway was only 46 inches wide.

6. Transfer "patient" from bed to SCAT One subject brought the hammock to the bed. The "patient" was turned to one side and the hammock placed under the "patient". The "patient" was then turned to the other side and hammock pulled through. "Patient" was then turned back to be in supine position with hammock under her. One subject brought SCAT to bottom of bed, pressed OPEN SCAT, and pushed SCAT over bed. Each subject removed the hoisting frame from her side, hooked the carabiners to the hammock, and fastened the safety belt on the "patient". One subject pressed the UP button until the "patient's" body could clear the foot of the bed and the SCAT was pulled away from the bed.

7. Transfer from floor to bed via SCAT "Patient" was on the floor with a sheet under her. "Patient" was turned to her side and hammock placed under her; she was then turned to other side so hammock could be pulled through and "patient" rest in supine position on the hammock. One subject brought the SCAT to the area and pushed OPEN SCAT button; with SCAT fully extended, the SCAT was rolled around the "patient". The SCAT hoisting frames were removed from the hooks and lowered to the "patient". The frames were hooked via the carabiners to the hammock and the safety belt fastened. One subject pressed the UP button so the "patient's" body could clear the bed and both subjects pushed the SCAT over the bed. The DOWN button was pressed until the "patient" was lying on the bed. The carabinders were unhooked, the hoisting frame elevated to position via the UP button, the hoisting frame was hooked into place, and the SCAT removed from the bed. The "patient" was then turned so the hammock could be removed.

8. Transport "patient" via SCAT for 35 feet "Patient" was already on the SCAT. One subject was positioned at the head of SCAT and requested to push. The other subject was at the side

or foot end of the SCAT to guide. The SCAT was pushed about 10 feet and then maneuvered around a 90 degree angle corner and pushed another 25 feet where the pathway was only 46 inches wide.

Equipment/Devices Used In The study: The stretcher delivered to the laboratory for the study was a Hausted SimCare by Simmons. It was 35 inches high and not adjustable for height; it was also 35 inches wide (including the side rails which did not recess); the brakes were "under" the stretcher (22 inches in from the bottom end of the stretcher, and 8 inches in from the side of the stretcher) and the brakes did not hold. There was also some type of a rail at the top and bottom of the stretcher but it pulled out if used for pushing or pulling. This stretcher was used for Tasks 1,2, and 3 for Group 1.

The following stretcher was used for tasks 1,2,3, and 5 for Group 2, and for Task 5 for Group 1. It was a Simmons stretcher which was 29 inches wide, was adjustable for height, the side rails recessed, the brakes were functional and were within easy reach for use, and there were no rails at the top and bottom of the stretcher.

The mechanical lift used was a modern battery operated model. The universal sling was used; this sling does not have a head rest.

The draw sheet was the typical draw sheet used in health care settings.

The Friction ReducerI is a friction-reducing device placed under the draw sheet. It has two layers of Gortex-type material and between the layers is silicone lubricant which permits the layers to slide over each other very easily.

The Friction ReducerII is a cylindrical mat; the inner side of the cylinder is covered with a specially processed slippery material. For use, the device is laid down flat with the upper and lower inner sides facing each other hence providing friction reducing properties.

Some of the design of the SCAT was changed inbetween the August and September study dates. The September design was used in this study and the description of that will be described by Ted Williamson.

Procedure: The original design for the study was a counter balanced panel design consisting of:

Day 1

Group 1 - carry out the tasks using the assistive devices of draw sheet, Friction ReducerI, Friction ReducerII, battery operated mechanical device using the Universal sling, and to transport the "patient" via a regular stretcher.

Day 2

Group 2 -carry out all the tasks using the SCAT device starting with bed to SCAT, then floor to bed, and finally transport.

Day 3

Group 1 - carry out all the tasks using the SCAT device but in reverse order from Group 2.

Day 4

Group 2 - carry out the tasks using the same assistive devices in Day 1 but carry out tasks in reverse order from Group 1.

Day 5

Groups 1 and 2 - Ranking of devices preferred based on a case situation and rationale stated for the ranking. General discussion relating to preferences, ease of using, ease of understanding, etc.

Day 1 was carried out as planned (except the mechanical lift and transporting the "patient" were not completed because time ran out due to completing the demographic data sheets, instructions on how the subjects would be paid, etc.).

On day 2 the plan for Day 4 was carried out because the SCAT was not ready for use; however, the tasks were performed in a different order because a newer stretcher was requested and did not arrive first thing in the morning. Transferring "patient" from floor to bed was done first; then the order was bed to stretcher using the Friction ReducerII, Friction ReducerI, and draw sheet. This group transported last.

On Day 3 Group 1 completed the tasks of lifting from the floor and transporting the "patient" and were then dismissed.

Days 4 and 5 -there was no study activity because the SCAT was not ready for use.

Days 2 and 3 of the original design were carried out approximately 8 weeks later.

The general procedure for carrying out each task was as follows:

1. Each subject followed a grid which displayed when each was to be the "patient" and when each was to be in which position for the transfer (eg on the pulling side for the "patient's" hip position, on the pulling side for the "patient's" shoulder and torso position, or on the pushing side); each subject experienced each position with each "patient".

2. The subjects got into their positions and were taught how to carry out the task.

3. The subjects practiced the task once (on two occasions the group asked to practice the task twice) and stated they were comfortable in knowing how to carry out the task.

4. The subjects carried out the task.

5. The subjects filled out the data sheets.

6. The carrying out of all tasks were timed with a stop watch.

RESULTS

In all, the participants completed 521 reports of transfers with 4 ratings of perceived exertion and 2 ratings of patient comfort and security, yielding 6,252 data points. Although the perceived exertion scale went from 0 (nothing at all) to 10 (extremely hard), most ratings were near the lower end of the scale. Over all, perceived exertion to the low back while transferring from the bed using a draw sheet had the highest average rating of 3.3, while perceived exertion to the neck while transporting a patient with a stretcher or the SCAT had the lowest average ratings (0.22 and 0.25).

Total Perceived Exertion, Patient Comfort/Security, and Time
(Table 1, page 7)

Two totals, one for perceived exertion and the other for the patient, were computed from the separate ratings. Ratings of perceived exertion to the neck, shoulder, middle back, and lower back were added together to get the perceived exertion total, and the ratings for comfort and security were added together for the patient total. The averages for each device are presented in Table 1. For each task, total ratings of perceived exertion were lower with the SCAT compared to the other devices, and the differences were statistically significant for transfer from bed ($F = 32.90$, $p < .001$) and patient transport ($F = 8.47$, $p < .001$). Patients reported significantly less discomfort and insecurity with the SCAT than with the comparison devices for all tasks.

Analyses of the total time taken to move the patient with each device found that transfers from the bed took longer with the SCAT than with the comparison devices, patient transport took less time, and transfers from floor to bed took about the same number of seconds.

Overall effect sizes are relatively large, with many effects as large as or larger than half a standard deviation.

Perceived Exertion Total and the Patient Total are illustrated in Figures 1 and 2 (pages 8 and 9).

Table 1. Total Perceived Exertion Ratings, "Patient" Ratings, and Time While Transferring and Transporting; Each Device vs SCAT.

Task	Device	Total Perceived Exertion	Total "Patient"	Total time
		X̄(SD)	X̄(SD)	X̄(SD)
Transfer from the bed	Draw Sheet	10.37* (6.78)	4.66* (3.30)	26.37* (7.05)
	Friction ReducerI	8.67* (5.26)	3.50 (2.62)	44.83* (9.51)
	Friction ReducerII	9.32* (5.20)	4.71* (2.62)	42.79* (10.76)
	SCAT	2.27 (2.28)	2.90 (1.72)	159.12 (50.59)
Transfer from the floor	Mech Lift	5.06 (4.03)	5.06* (3.02)	445.69 (85.63)
	SCAT	4.66 (2.87)	3.78 (1.68)	440.00 (66.08)
Transport 35 feet	Stretcher	3.03* (2.83)	2.03 (1.78)	26.53* (4.44)
	SCAT	1.64 (0.80)	1.37 (1.48)	16.75 (1.63)

* ($p<.01$)

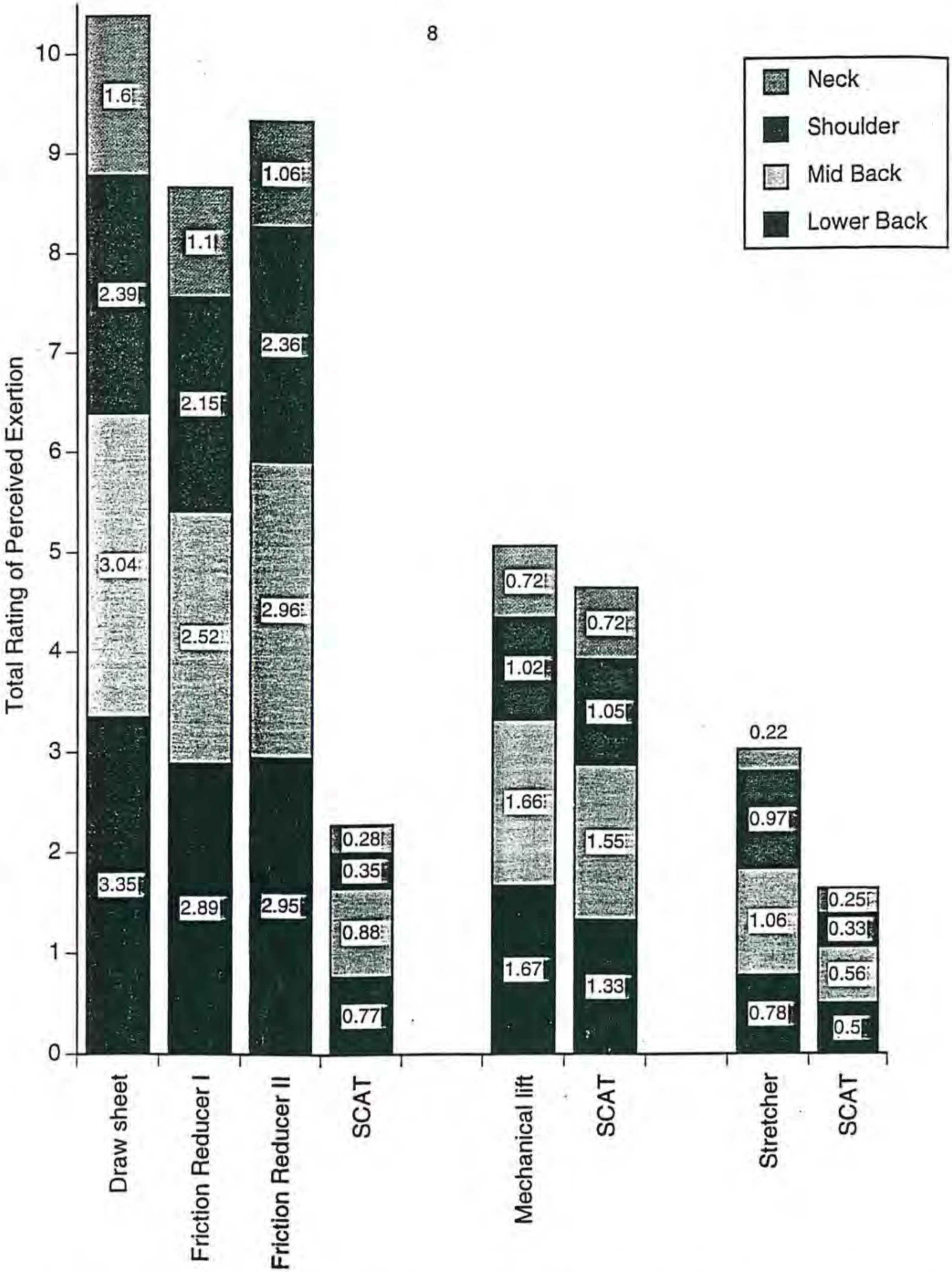

Figure 1. Total perceived exertion as the sum of the average ratings for neck, shoulder, mid back, and lower back.

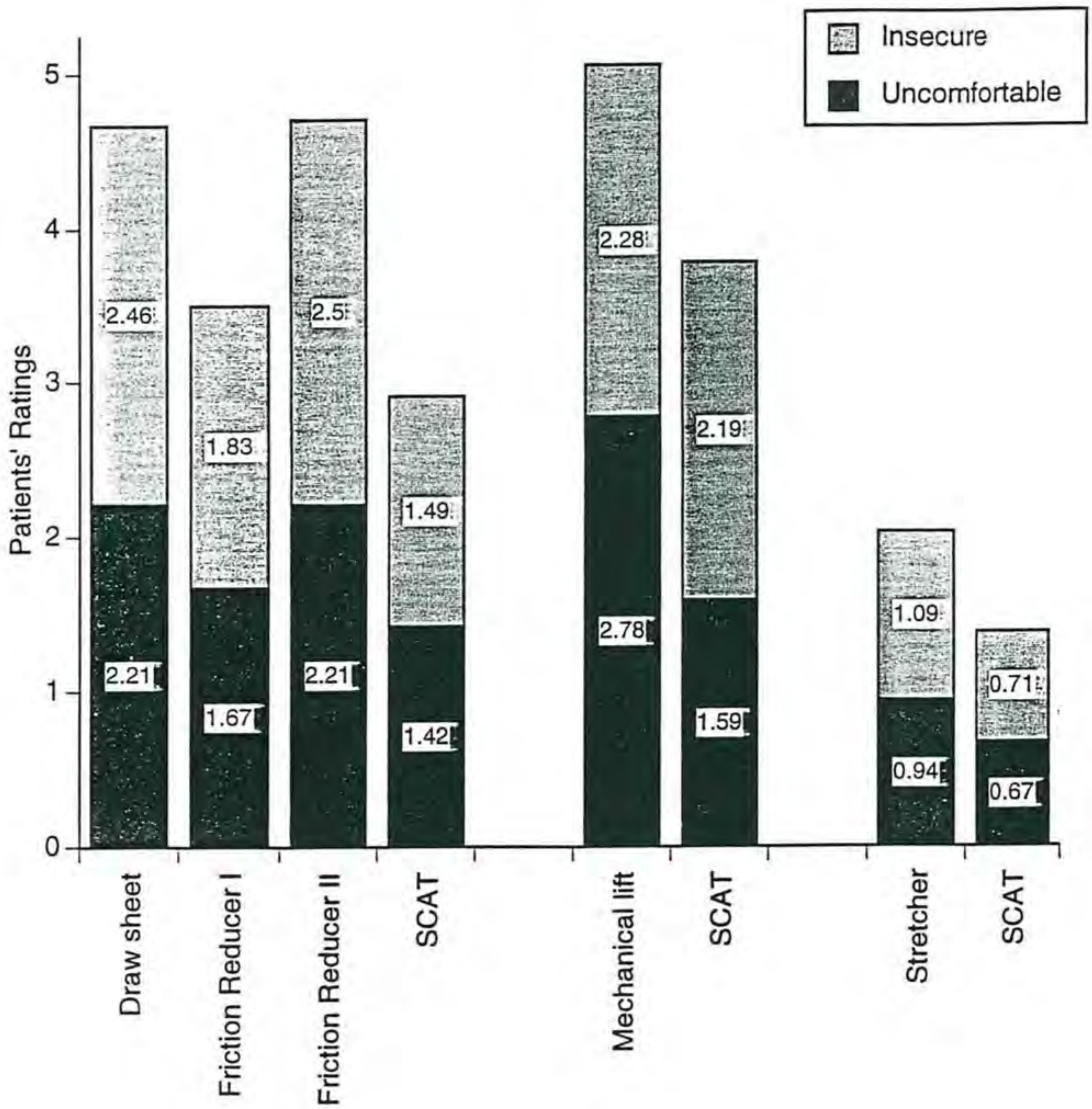

Figure 2. Total patient rating as the sum of the average ratings for comfort and security.

Average Scores for Perceived Exertion and Patient Comfort and Security (Tables 2 and 3, pages 11 and 12)

Comparisons of these average scores are presented in Tables 2 and 3.

From the Bed. Ratings of perceived exertion with the SCAT were significantly lower for each of the four locations: neck, shoulder, middle back and low back. This was true for all of the three comparison devices: draw sheet, Friction Reducer I and II. According to the patient ratings, patients were more comfortable and secure with the SCAT compared to the draw sheet and Friction Reducer II, but there was no significant difference for Friction Reducer I.

From the Floor. When perceived exertion to the neck, shoulder, mid back and lower back are looked at separately, there are no significant differences between the SCAT and the mechanical lift. Patients are significantly more comfortable with the SCAT, and there is no significant difference in patient security.

Patient Transport. For this task, the only significant difference in perceived exertion was to the shoulder, where the SCAT was rated lower than the stretcher. Although patient ratings favor the SCAT, the differences are not significant.

Preference of Device For Transfer/Transport (Table 4, page 13)

From the Bed. Four of the 7 subjects selected SCAT for their first choice for this transfer. Rationale given was that there is less exertion to those making the transfer when using the SCAT. No one ranked the SCAT lower than second choice (out of four choices). Two subjects selected Friction Reducer I as first choice with rationale that this device is easy, fast to use, and takes less time. One respondent selected Friction Reducer II for first choice because it is small and easy to slide the "patient"; one subject ranked this device last because she felt 3 people were needed to make the transfer with this device. Six of the 7 respondents ranked the draw sheet last and all gave rationale that it takes too much effort and exertion when using this device.

From the Floor. All subjects ranked the SCAT as the device of choice for this transfer. Rationale given were that it allows the "patient" to lie flat, and the "patient" is well supported.

Transport the "Patient". All subjects ranked the SCAT first and the reasons for this ranking were that the "patient" and equipment were secure and there was no need to transport the IV pole as well as push the device.

Table 2. Ratings of Perceived Exertion for Transferring and Transporting "Patients"; Each Device VS SCAT.

Task	Device	Rating Perceived Exertion			
		Neck $\overline{X}$(SD)	shoulder $\overline{X}$(SD)	MidBack $\overline{X}$(SD)	Low $\overline{X}$(SD)
Transfer from the bed	Draw Sheet	1.60* (1.77)	2.39* (2.00)	3.04* (1.90)	3.35* (2.66)
	Friction ReducerI	1.10* (1.20)	2.15* (1.77)	2.52* (1.73)	2.89* (2.02)
	Friction ReducerII	1.06* (1.07)	2.36* (1.74)	2.96* (1.68)	2.95* (2.05)
	SCAT	0.28 (0.48)	0.35 (0.48)	0.88 (0.99)	0.77 (1.00)
Transfer from the floor	Mech Lift	0.72 (0.93)	1.02 (1.48)	1.66 (1.46)	1.67 (1.58)
	SCAT	0.72 (0.83)	1.05 (0.86)	1.55 (1.01)	1.34 (1.17)
Transport 35 feet	Stretcher	0.22 (0.45)	0.97* (0.96)	1.06 (1.08)	0.78 (0.83)
	SCAT	0.25 (0.53)	0.33 (0.56)	0.56 (0.85)	0.50 (0.80)

Rating of Perceived Exertion (0=no exertion, 10=extremely heavy, hard exertion)

* (p<.001)

Table 3. Ratings of "Patient" Comfort and Security. Each Device VS SCAT.

Task	Device	"Patient" Ratings: Comfort $\overline{X}$(SD)	Security $\overline{X}$(SD)
Transfer from the bed	Draw Sheet	2.21* (1.77)	2.46* (1.70)
	Friction ReducerI	1.67 (1.29)	1.83 (1.50)
	Friction ReducerII	2.21* (1.20)	2.50* (1.59)
	SCAT	1.42 (1.00)	1.49 (1.00)
Transfer from the floor	Mech Lift	2.78* (1.70)	2.28 (1.54)
	SCAT	1.59 (0.79)	2.19 (1.05)
Transport 35 feet	Stretcher	0.94 (1.10)	1.09 (0.89)
	SCAT	0.67 (0.75)	0.71 (0.80)

Patient Comfort (0=extremely comfortable, 7=extremely uncomfortable)
Patient Security (0=extremely secure, 7=extremely insecure)
* ($p<.005$)

Table 4. Rankings of Preference For Use of Devices and Number of Personnel Needed for Transfer/Transport

Task	Device	Rank of Preference			Number of Personnel Needed
		$\bar{X}$	SD	Range	$\bar{X}$
Transfer from the Bed	SCAT	1.4	.53	1-2	1.8
	Friction ReducerI	2.0	.81	1-3	2.0
	Friction ReducerII	2.7	.95	1-4	2.7
	Draw Sheet	3.8	.37	3-4	3.0
Transfer from the Floor	SCAT	1.0			2.0
	Mech lift	2.0			2.0
Transport 35 feet	SCAT	1.0			2.0
	Stretcher	2.0			2.4

Number of Personnel Needed To Transfer/Transport the "Patient."

From the Bed. Six of the 7 subjects stated 2 people were needed to make the transfer with the SCAT and cited it was easier to have One person on each side of the SCAT. One subject stated one person could make the transfer because she felt no body strain and the patient was not in danger of falling.

All subjects indicated 2 people were needed to transfer using Friction ReducerI; rationale given was that one person was needed on each side of the bed for safety of the patient.

Six of the 7 stated 3 people were needed for transferring with Friction ReducerII because one was needed for each side of the bed and the third was needed to support the head or feet during transfer.

Six of the 7 indicated a need for 3 people to transfer by use of the draw sheet; one subject stated 4 people were needed. They indicated the 3 or 4 were needed because of the amount of exertion needed to push and pull with nothing to reduce the friction.

From the Floor. All subjects stated 2 people were needed to carry out this task with the mechanical lift and the SCAT. One is needed on each side of the patient to position the patient, maneuver the device, and watch the patient.

Transport the Patient. All of the subjects indicated 2 were needed for this task using the SCAT. Four of the 7 stated 2 people were needed for transporting with the stretcher; the other 3 subjects indicated 3 were needed for transporting with the stretcher so one could maneuver the IV pole and the other 2 could maneuver the stretcher.

Differences Between Groups and Raters

Differences between the two groups of subjects were examined with a t-test. Many significant differences were found. Results for each task are reported in Appendix E. For totals of perceived exertion, the groups were not significantly different on four devices: Friction ReducerII, SCAT for transfer from the bed, stretcher and SCAT for transport. With the draw sheet, Friction ReducerI, the mechanical lift, and the SCAT for transfer from the floor, Group 2 reported higher perceived exertion than Group 1.

On the patient total, the two test groups were significantly different with all devices except for the mechanical lift. Usually, Group 1 scored lower than Group 2 (draw sheet, Friction Reducers I and II, SCAT for transfers from the bed and the floor, and Scat for transport); with stretcher for transport, Group 2 scored lower.

Individual differences between raters within each group were also examined, and consistent differences between raters were found. These results are also in Appendix E.

The significant differences between the two subject groups and the participants in each group do not threaten the validity of the findings because each group and each subject completed all the tasks. However, the finding has implications for future studies. Because the ratings of the subjects within each group are not independent, an appropriate design will include as many different groups as possible.

DISCUSSION

In this study the subjects ranked the SCAT as the preferred device to use when transferring "patients" from the bed, transferring "patients" from the floor, and transporting "patients".

When transferring from the bed, they indicated lower ratings of perceived exertion to the neck, shoulder, midback, and low back when using the SCAT than when using the draw sheet or either of the friction reducers. There were no differences in the subjects' rating of perceived exertion to any of the body parts when transferring the "patient" from the floor to the bed using the SCAT or the mechanical lift. When comparing the SCAT to the stretcher for transporting "patients", the subjects indicated more stress to the shoulder when using the stretcher; there were no differences in ratings to the other body parts.

There were no differences in the ratings of comfort and security by "Patients" when transferred from the bed by use of the SCAT and friction reducerI; however, the SCAT received higher ratings of comfort and security when compared to draw sheet or friction reducerII. "Patients" were more comfortable being lifted from the floor with the SCAT but felt equally as secure while being lifted from the floor with the SCAT or the mechanical lift. There were no differences in "patient" feelings of comfort and security while being transported in the SCAT or stretcher.

It took subjects about 2 and 1/2 minutes to transfer the "patient" from the bed with the SCAT; it took less than a minute to make the transfer with the draw sheet or the friction reducers. It took about 7 minutes to transfer the "patients" from the floor with both the SCAT and the mechanical lift. Transporting the "patients" with the stretcher took longer time than when transporting with the SCAT.

Rating of Perceived Exertion.

While the scale ranged from 0 to 10; the highest average rating for any body part using any assistive device was 3.3; therefore, subjects tended to rate their exertion at the lower end of the scale. This is comparable to findings of other studies where most respondents used the lower half of the scale (Garg and Owen, 1992; Owen et al, 1995).

When transferring the "patient" from the bed, the subjects rated the SCAT the lowest for perceived exertion to the neck, shoulder, midback, and low back. The subjects indicated in their preference rankings that these low ratings were the major reason why they preferred to use the SCAT over the other devices when making this type of a transfer.

The most common method used in clinical practice for transferring a patient from bed to stretcher is to pull the patient over using the draw sheet; this method was rated the highest for perceived exertion to all body parts. These findings coincide with the literature which cites transfer from bed to stretcher by use of a draw sheet as a stressful task (Owen et al, 1995).

The neck was the body part that consistently received the ratings of least perceived exertion. The mid back and lower back received the higher ratings. According to the literature (Jensen, 1990), the low back is the body part most often cited for overexertion injuries.

Friction Reducer II received higher exertion ratings than Friction Reducer I. Possible reasons for this are the shape and size differences between the two devices. Friction Reducer I covers the full length and width of the bed so when the "patient" is transferred, the head and feet of the "patient" are supported whereas Friction Reducer II does not cover the whole bed and supports the "patient" from shoulder to thigh only.

"Patient" Comfort and Security.

"Patients" reported feeling most comfortable and secure while being transferred and transported with the SCAT. When compared to the SCAT, the draw sheet and Friction ReducerII were least comfortable and secure. Both the draw sheet and the Friction Reducer II provide support to the "patient" only between the shoulders and thighs so lack of support to the head and feet may account for these ratings.

When being transferred from the floor, the "patients" indicated they were less comfortable in the mechanical lift than the SCAT. The "patients" indicated in their comments that they were less comfortable because the sling used with the mechanical lift did not have a head support; therefore, they had to support their own heads until they were lifted from the supine position on the floor into the recumbent sitting position for the transfer. They did, however, feel as secure in the mechanical lift transfer as they did in the SCAT.

The "patients" felt as comfortable and as secure in the stretcher as compared to the SCAT for transporting from one location to another location.

Time (in seconds) to make the transfer/transport

Time obviously is an important factor to consider when carrying out patient care activities. When transferring from the bed, the SCAT took significantly more time than the other three devices. However, this can be somewhat misleading when one considers that the subjects indicated they needed an average of 3 people to transfer with the draw sheet but only needed and average of 1.8 people to transfer with the SCAT. The extra time needed to find and use 3 persons for the draw sheet transfer may actually take more time than transferring with the SCAT.

Also, the extra time needed for the SCAT may not so important when one considers the subjects indicated less exertion when comparing the SCAT with the draw sheet or the friction reducers. Also "patients" are more comfortable and feel more secure when the SCAT is used versus use of the draw sheet and friction reducers which take less time.

Additional Factors

The task of weighing the "patient" was not studied in this project. However, weighing can be done at the same time as when transferring the "patient" when using the SCAT. Therefore, an additional transfer to a weighing device can be eliminated through use of the SCAT.

The SCAT is versatile in that it can be used for all the tasks studied in this project. This is not true for the other assistive devices studied.

CONCLUSION

The SCAT was an effective device to use for transferring "patients" from the bed, lifting them from the floor, and transporting them from one location to another. For many of the transfers it does take more time but time can be offset by: the lesser amount of exertion perceived to various body parts by the individuals doing the transfers, the greater feelings of comfort and security expressed by the "patients", and the fewer number of people needed to carry out these transfers.

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Owen, B.D., Garg, A., & Jensen, R. (1992). Four methods for identification of most back-stressing tasks performed by nursing assistants in nursing homes. International Journal of Industrial Ergonomics, 9, 213-220.

Owen, B.D., Keene, K., Olson, S., & Garg, A. (1995). An ergonomic approach to reducing back stress while carrying out patient handling tasks with a hospitalized patient. In Hagberg, Hofmann, Stobel & Westlander, Occupational Health for Health Care Workers, Landsberg, Germany: ECOMED, 298-301.

Code Number _____

Group 1 ___ 2 ___

Age _____

Weight _____lbs

Height ______inches

Yr in Nursing Program Generic: 1st ___ 2nd ___ 3rd ___ 4th ___
RN: 1st ___ 2nd ___ 3rd ___ 4th ___

Estimate the number of patient lifts/transfers you have done in your student program ______

Have you experienced back, shoulder, or neck pain due to this?
Yes ___ No ___

Have you had experience in lifting/transferring patients/residents outside your nursing program: Yes ___ No ___

If Yes, in what setting:
Hospital ___ Length of time employed, ____Months

Nursing Home ___ Length of time employed, ____Months

Home Care ____ Length of time employed, ____Months

Other- Specify
___________ Length of time employed, ____Months

If yes, did you experience back/neck pain on the job? Yes___ No___

If yes, number of lost work days due to this back pain ____

Location of the back pain: Neck Yes ___ No ___

Shoulder Yes ___ No ___

Upper/Mid Back Yes ___ No ___

Low Back Yes ___ No ___

APPENDIX B -1

Code Number _____

Group 1 ___ 2___

Patient Number ___

TASK: Transfer from bed to stretcher

Position 1___ 2___ 3___

Device: Draw sheet ___ Slipp ___ Nordic slide ___

Positions

RATING of PERCEIVED EXERTION
(Please rate the amount of exertion you felt for the following body parts when you performed the above task or activity)

_____neck

_____Shoulder

_____Upper/Middle Back

_____Lower Back

Scale for Rating of Perceived Exertion

0	Nothing at all
1	Very light, just noticeable
2	
3	Fairly light
4	
5	Somewhat hard
6	
7	Hard
8	
9	Very hard
10	Extremely hard

COMMENTS:

Code Number _____

Group 1 ___ 2___

Patient Number ___

TASK: Floor to bed with patient lifter

Position 1___ 2___

Position 1: apply sling
maneuver lift

Position 2: apply sling
Help maneuver

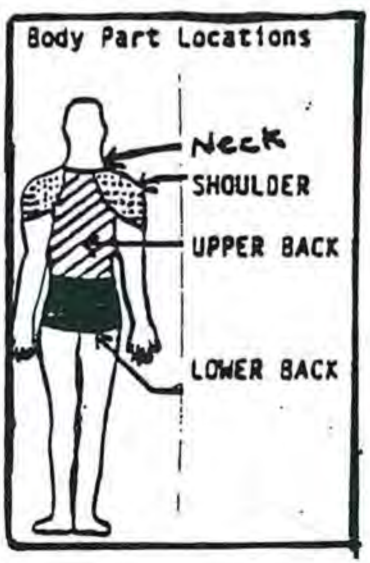
RATING of PERCEIVED EXERTION
(Please rate the amount of exertion you felt for the following body parts when you performed the above task or activity)

_____neck

_____Shoulder

_____Upper/Middle Back

_____Lower Back

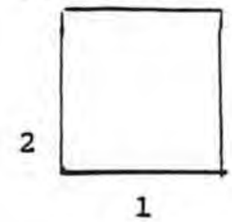


Scale for Rating of Perceived Exert

0	Nothing at all
1	Very light, just noticeab.
2	
3	Fairly light
4	
5	Somewhat hard
6	
7	Hard
8	
9	Very hard
10	Extremely hard

COMMENTS:

Positions



Code Number _____

Group 1 ___ 2___

Patient Number ___

TASK: Push bed 20 feet

Position 1___ 2___

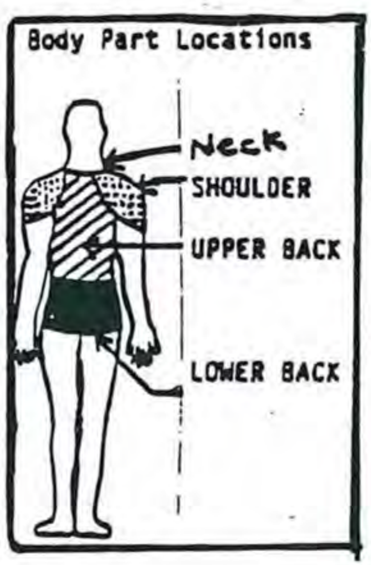
RATING of PERCEIVED EXERTION
(Please rate the amount of exertion you felt for the following body parts when you performed the above task or activity)

_____neck

_____Shoulder

_____Upper/Middle Back

_____Lower Back



Scale for Rating of Perceived Exert

0	Nothing at all
1	Very light, just noticeab
2	
3	Fairly light
4	
5	Somewhat hard
6	
7	Hard
8	
9	Very hard
10	Extremely hard

COMMENTS:

Code Number _____

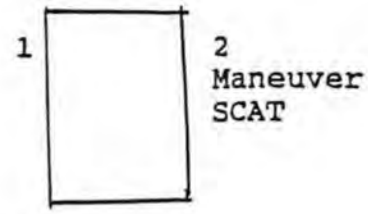
Group 1 ___ 2___

Patient Number ___

TASK: Transfer from bed to SCAT

Position 1___ 2___

Positions:



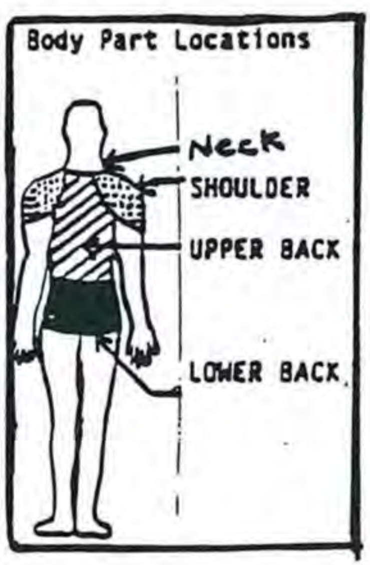
RATING of PERCEIVED EXERTION
(Please rate the amount of exertion you felt for the following body parts when you performed the above task or activity)

_____neck

_____Shoulder

_____Upper/Middle Back

_____Lower Back



Scale for Rating of Perceived Exert

0	Nothing at all
1	Very light, just noticeab
2	
3	Fairly light
4	
5	Somewhat hard
6	
7	Hard
8	
9	Very hard
10	Extremely hard

COMMENTS:

Code Number _____

Group 1 ___ 2___

Patient Number ___

TASK: Floor to bed with SCAT

Position 1___ 2___

Position 1: apply sling
maneuver SCAT

Position 2: apply sling
Help maneuver

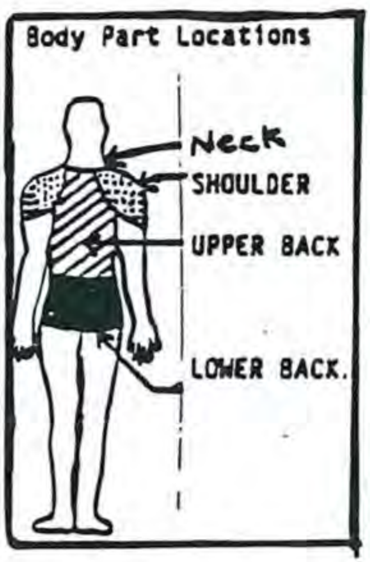
RATING of PERCEIVED EXERTION
(Please rate the amount of exertion you felt for the following body parts when you performed the above task or activity)

_____neck

_____Shoulder

_____Upper/Middle Back

_____Lower Back



Scale for Rating of Perceived Exer

0	Nothing at all
1	Very light, just noticeab
2	
3	Fairly light
4	
5	Somewhat hard
6	
7	Hard
8	
9	Very hard
10	Extremely hard

COMMENTS:

Code Number _____

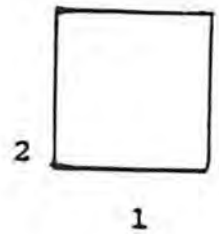
Group 1 ___ 2___

Patient Number ___

TASK: Push SCAT 20 feet

Position 1___ 2___

Positions



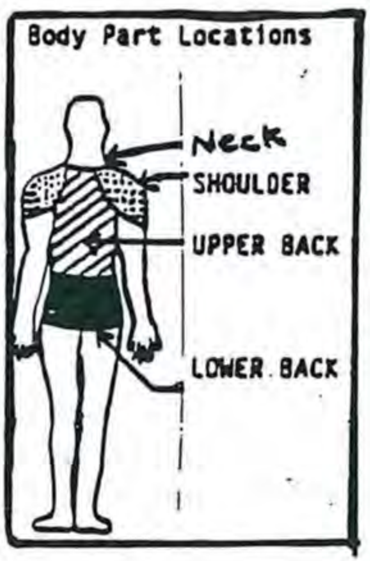
RATING of PERCEIVED EXERTION
(Please rate the amount of exertion you felt for the following body parts when you performed the above task or activity)

_____neck

_____Shoulder

_____Upper/Middle Back

_____Lower Back



Scale for Rating of Perceived Exert

0	Nothing at all
1	Very light, just noticeab.
2	
3	Fairly light
4	
5	Somewhat hard
6	
7	Hard
8	
9	Very hard
10	Extremely hard

COMMENTS:

Comfort and Security Ratings for "Patient"

Code Number ____

Group 1 ___ 2 ___

Task ______________________________

1. Please rate how comfortable you felt when the nursing students performed the above task on you:

0	1	2	3	4	5	6	7
Extremely Comfortable							Extremely Uncomfortable

2 Please indicate how secure you felt when the nursing students performed the above task on you:

0	1	2	3	4	5	6	7
Extremely Secure							Extremely Insecure

COMMENTS:

You are Mrs. Higgins. You need to be transferred from the bed. The staff give you a choice of one of the following assistive devices for use in the move; draw sheet, Slipp, Nordic Slide or SCAT. All of these assistive devices are in your room so they are easily accessible to the staff. The appropriate number of personnel are available to help with the transfer. Rank which assistive device you would choose first, second, third and fourth (last); give the rationale for your rankings.

Group Number ____ Code Number ____

RANK (first=1, second=2, etc,)

From the bed

RANK	DEVICE	RATIONALE
1		
2		
3		
4		

Indicate **number of personnel needed** to make this transfer safely and give rationale (include yourself in the total).

RANK	DEVICE	NUMBER	RATIONALE
1			
2			
3			
4			

You are Mrs. Higgins. You have fallen on the floor. The nurse examines you and finds no injury so you can be lifted and put into bed. The staff give you a choice of one of the following lift devices for use in this lift from the floor: mechanical lift or SCAT. Both of these lift devices are in your room so they are easily accessible to the staff. The appropriate number of personnel are available to help with the lift from floor to bed. Rank which assistive device you would choose first and second and give the rationale for your rankings.

Group Number ____ Code Number ____

From the floor

RANK	DEVICE	RATIONALE
1		
2		

Indicate **number of personnel needed** to make this transfer safely and give rationale (include yourself in the total).

RANK	DEVICE	NUMBER	RATIONALE
1			
2			

You are Mrs. Higgins. You need to be transported to the ER. You have an IV going. The staff give you a choice of one of the following transport devices for use in the move: stretcher or SCAT. All of these assistive devices are in your room so they are easily accessible to the staff. The appropriate number of personnel are available to help with the transfer. Rank which assistive device you would choose first and second and give the rationale for your rankings.

Group Number ____ Code Number ____ APPENDIX D -3

Transport to ER

RANK	DEVICE	RATIONALE
1		
2		

Indicate **number of personnel needed** to make this transport safely and give rationale (include yourself in the total).

RANK	DEVICE	NUMBER	RATIONALE
1			
2			

Appendix E

Differences between groups on total perceived exertion and total patient ratings for each device.

	Group 1			Group 2			t
	n	X	SD	n	X	SD	
Total Perceived Exertion							
Transfer from the bed							
Draw sheet	36	6.25	4.87	36	14.50	5.89	6.48*
Friction Reducer I	36	6.06	3.11	36	11.27	5.71	4.82*
Friction Reducer II	36	8.78	5.05	36	9.86	5.37	0.88
SCAT	31	2.81	3.07	34	1.79	1.41	1.68
Transfer from the floor							
Mechanical lift	32	3.81	4.18	32	6.31	3.50	2.59*
SCAT	32	3.56	3.30	32	5.75	1.82	3.28*
Transport 35 feet							
Stretcher	32	3.31	3.75	32	2.75	1.44	-0.79
SCAT	32	1.43	2.33	16	2.06	1.91	0.99
Total Patient Ratings							
Transfer from the bed							
Draw sheet	36	2.42	2.09	36	6.92	2.70	7.91*
Friction Reducer I	36	1.92	2.25	36	5.08	1.92	6.43*
Friction Reducer II	36	3.50	2.79	36	5.92	1.78	4.38*
SCAT	31	1.77	1.17	34	3.94	1.48	6.58*
Transfer from the floor							
Mechanical lift	32	4.37	3.52	32	5.75	2.29	1.85
SCAT	32	3.06	1.22	32	4.50	1.72	3.86*
Transport 35 feet							
Stretcher	32	2.68	2.09	32	1.37	1.07	-3.17*
SCAT	32	0.50	0.80	16	3.12	0.81	10.65*

*$p < .05$

Each Participant's Average Total of Perceived Exertion Rating
(Neck + Shoulder + Mid back+ Lower Back)

		Transfer from bed				Transfer from floor		Transport 35 feet	
ID	Weight	Draw Sheet	FR I	FR II	SCAT	Mech Lift	SCAT	Stretcher	SCAT
1	135	5.67	9.11	13.56	**6.75**	9.38	**8.12**	8.25	**4.50**
2	247	3.33	6.22	8.00	**2.00**	0.00	**1.62**	1.12	**0.00**
3	125	6.56	3.56	6.33	**2.12**	1.12	**0.75**	0.12	**0.75**
4	98	9.44	5.33	7.22	**0.25**	4.75	**3.75**	3.75	**0.50**
5	138	18.78	12.00	12.78	**2.25**	10.25	**6.00**	4.12	**2.00**
6	202	16.67	18.33	14.56	**3.43**	7.00	**7.25**	2.62	**4.00**
7	155	11.44	7.78	6.22	**0.67**	5.25	**4.70**	2.25	**0.75**
8	139	11.11	7.00	5.89	**1.22**	2.75	**5.17**	2.00	**0.00**

Each Participant's Average Total for Patient Comfort and Security

		Transfer from bed				Transfer from floor		Transport 35 feet	
ID	Weight	Draw Sheet	FR I	FR II	SCAT	Mech Lift	SCAT	Stretcher	SCAT
1	135	2.56	1.67	3.22	**1.12**	2.75	**3.12**	1.12	**0.88**
2	247	1.56	1.11	2.22	**1.87**	3.12	**2.75**	2.75	**0.38**
3	125	3.22	2.56	4.67	**2.00**	6.00	**3.37**	3.88	**0.50**
4	98	2.33	2.33	3.89	**2.00**	5.62	**3.00**	3.00	**0.25**
5	138	7.44	5.22	6.00	**4.50**	4.12	**5.37**	1.25	**3.40**
6	202	6.11	5.56	6.00	**3.71**	6.25	**3.50**	1.62	**2.60**
7	155	6.11	4.89	5.78	**4.33**	7.12	**4.30**	1.62	**3.50**
8	139	8.00	4.67	5.89	**3.56**	5.50	**5.00**	1.00	**3.00**

January 13, 1997

Mr. Ted Williamson
Black Mountain MedCrafters
648 Ideal Way
Charlotte, NC 28203

Dear Ted:

Enclosed is my report for the Phase I grant. I believe the report demonstrates the feasibility of applying systems safety methods to identify product risks prior to design of the production model. Most of the hazards can be controlled by designing appropriately. Some hazards will need to be addressed by including procedures in the training package that will accompany each SCAT! All hazards that might be encountered during regular operation of the SCAT! will need to be addressed in an operations manual. I envision the operations manual being kept in a storage pocket somewhere on each device.

I think the SCAT! will fill a need. Any hospital administrator concerned about preventing back injuries among nursing staff should recognize the value of having at least one SCAT!. Hospitals that serve major college football teams should be particularly interested because of the need to handle 300 pound linemen. The patient handling equipment currently on the market cannot do all the things the SCAT! can.

Ted, working on this project has been one of the most interesting undertakings in my professional career of 26 years. Thanks for including me.

Sincerely,

Roger C. Jensen, Ph.D.

UES, Inc. • 4401 Dayton-Xenia Rd. • Dayton, Ohio 45432-1894 • Phone: 513/426-6900 • Fax: 513/429-5413

Evaluation of Prototype Patient Lifting and Transporting Device for Safety and Usability

by

Roger C. Jensen, Ph.D.[1]

Safety Analyst

Background

This report describes the systems safety evaluation of a prototype device for lifting and moving patients within healthcare facilities. Black Mountain MedCrafters—the developer—named the device "SCAT!™".[2]

Goals of the systems safety evaluation were to:

1. identify any hazards to patients
2. identify any hazards to care providers
3. identify human usability problems
4. demonstrate use of a Fault Tree Analysis (FTA)
5. demonstrate use of a Failure Mode and Effects Analysis (FMEA)
6. develop a Preliminary Hazard List (PHL) for the prototype device
7. provide recommendations for designers of the production model

The Food and Drug Administration (FDA) regulates medical device, including patient handling equipment. Therefore, relevant guidelines developed by FDA were consulted. Two FDA documents, circulated for public comment during 1996, were directly relevant to the analyses reported here:

- FDA. *Design Control Guidance for Medical Device Manufacturers*, draft March 1, 1996.
- FDA. *Do It By Design: An Introduction to Human Factors in Medical Devices*, draft March 1, 1996.

Table 1 provides a concise description of systems safety methods recognized in the FDA documents.

Table 1. Systems safety methods

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[1] Dr. Jensen is a Senior Ergonomist with UES, Inc. Credentials relevant to this project are: Certified Safety Professional--Systems Safety Aspects; Certified Professional Ergonomist; Registered Professional Engineer

[2] Self-Contained All-Purpose Transport system

Table 1. Systems safety methods

Method	Description
Fault Tree Analysis FTA	FTA is a method for analysis that starts with an identified undesirable event. The analyst then identifies the combinations of events that are necessary in order for the undesired event to occur. The results is a chart with the undesired event at the top. FTA is a useful method for identifying ways to prevent an undesired event from occurring.
Failure Mode and Effects Analysis FMEA	FMEA is a systematic, tabular method for evaluating and documenting the causes and effects of known types of component failures. It is useful for understanding how critical it is for individual components to be reliable.
Hazard Analysis HA	HA is a two part process. The first part produces a Preliminary Hazard List. This involves taking each intended function of the product, listing steps involved, and identifying any hazards that might be encountered during each step. The Preliminary Hazard List is a first cut at listing the hazards that might be encountered while the device is being used for an intended function. It is called *preliminary* because it is developed while the product is still in the design and prototype stage, and is expected to undergo numerous changes prior to marketing. The analysis may need further revisions as production problems are encountered and resolved, and as users provide feedback. The second part of a HA involves assigning each hazard ratings for probability and for severity. Based on the probability and severity of each hazard, an index of risk is determined using a method such as that of the U.S. armed services.
Hazard Control Precedence Sequence HCPS	HCPS is an ordered set of options intended to help an analyst look for ways to deal with hazards. Safety professionals generally agree on the philosophy underlying the precedence of controls for hazards. A precedence list from the FDA illustrates the preferred order of hazard controls: Design to eliminate or minimize hazard; Provide safety mechanisms; Provide warning mechanisms; Control with labeling and training; Accept remaining hazards.

According to the Phase I grant application, the system safety evaluation will demonstrate the feasibility of applying systems safety methods to identify, and design out, significant product risks before production and marketing. Success will be indicated if the recommendations either: document acceptability of the design as is, or recommend a specific alternative design that corrects identified design problems.

Methods

Systems safety methods used for this project were those identified in Table 1: FTA, FMEA, HA, and HCPS. The following text describes the use of each method.

Fault Tree Analysis

The undesired event selected for analysis was a patient being dropped. An event box was drawn for this event and placed at the top of a fault tree diagram. The safety analyst, Dr. Jensen, then identified the combinations of events required for the undesired event to occur. These events were placed on the fault tree diagram, below the top event. Gate symbols were placed beneath event boxes, on lines connected to lower event boxes. An "OR" gate was used if the upper event will occur when any one of the lower events occurs. None of the events had an "AND" gate (applicable if the upper event will occur only when all of the events just below it occur together).

Failure Modes and Effects Analysis

An FMEA table was constructed by the safety analyst. In the left column, components were listed. For this Phase I project, the analysis was limited to components that hold up the hammock. Columns to the right were used for describing the what would happen if the component fails. Three columns on the right side of the table were used for recording safety ratings. The safety ratings in these three columns were based on the U.S. Military Standard 882B.

For each component failure, the safety analyst assigned ratings for both probability of occurrence and hazard severity. Figure 1 shows the rating categories for both probability (rows) and severity (columns). Numbers in the middle of the Figure1 indicate the Hazard Risk Index.

	Hazard Severity Ratings			
Probability of Occurrence During Lifetime of Product	Catastrophic	Critical	Marginal	Negligible
Frequent	1	3	7	13
Probable	2	5	9	16
Occasional	4	6	11	18
Remote	8	10	14	19
Improbable	12	15	17	20

Hazard Risk Index	**Decision Guidelines**
1 - 5	Unacceptable
6 - 9	Undesirable
10 - 17	Acceptable with review
18 - 20	Acceptable without review

Figure 1. Hazard Risk Index values, based on severity and probability categories (adapted from MIL-STD-882B)

Criteria used for probability of occurrence categories, based on MIL-STD-882B, were:

Frequent:	likely to occur frequently
Probable:	will occur several times in the life of an item
Occasional:	likely to occur some time in life of an item
Remote:	unlikely but possible to occur in life of item
Improbable:	so unlikely that it can be assumed occurrence may not be experienced

Criteria used for hazard severity categories, based on MIL-STD-882B, were:

Catastrophic:	death or system loss
Critical:	severe injury, severe occupational illness, or major system damage
Marginal:	minor injury, minor occupational illness, or minor system damage
Negligible:	less than minor injury, occupational illness, or system damage

The Hazard Risk Index number for each component failure was found in Figure 1. These values were recorded in the right-most column of the FMEA table.

Hazard Analysis

The safety analyst observed nine nursing students perform a set of tasks using the device. The tasks performed were:

- Lift a patient from the floor using the device and move the patient onto a bed.
- Transfer a patient from bed to device.
- Transport a patient via the device a distance of 35 feet.

The purpose of the observations was to identify situations that might present a risk of injury to the patient or to the nursing students while performing the above tasks. The safety analyst also looked for and listened for indications that the tasks were mentally or physically difficulty for the nursing students.

After a group of nursing students completed the tasks, they participated in a group discussion with the safety analyst. These discussions were structured to address one task at a time. The various steps involved in performing each task were discussed in order. For each step, the nursing students express their thoughts on any hazards that might pose a risk to the nurses or their patient. They also commented on any operational difficulties they encountered while performing the step. Their comments were recorded by the safety analyst.

The safety analyst developed a Preliminary Hazard List. It included the hazards identified from the observations and comments of the nursing students. It also included hazards identified in the FMEA.

Hazard Control Precedence Sequence

For each hazard on the Preliminary Hazard List, options for control were considered. Also, for each component failure in the FMEA, options for control were considered. The options considered were those listed by the the FDA.[3] In order of most preferred to least preferred these options were:

1. Design to eliminate or minimize hazard
2. Provide safety mechanisms
3. Provide warning mechanisms
4. Control with labeling and training
5. Accept remaining hazards

Findings

Findings from the four systems safety analyses are reported in the following four sub-sections.

Fault Tree Analysis

The fault tree in Figure 2 applies to the undesired event of a patient, supported in the hammock of SCAT!™, being dropped. Below the top event is an "OR" gate, indicating that the patient will be dropped if either of two events occur. The two events are represented as a left branch and a right branch on the fault tree.

The event on the left branch is for the entire hammock falling. Three ways this could happen are depicted in the lower event boxes on the left branch. These are:

1. motor releases hammock by failing to maintain torque on the motor shaft
2. entire SCAT!™ tips over
3. connection between the motor and the hammock fails

The event on the right branch is the patient falling off the hammock. Four ways this could happen are depicted in the lower event boxes on the right branch. Below three of the four events in the right branch of the fault tree are additional event boxes.

[3] FDA. *Do It By Design: An Introduction to Human Factors in Medical Devices*, draft March 1, 1996.

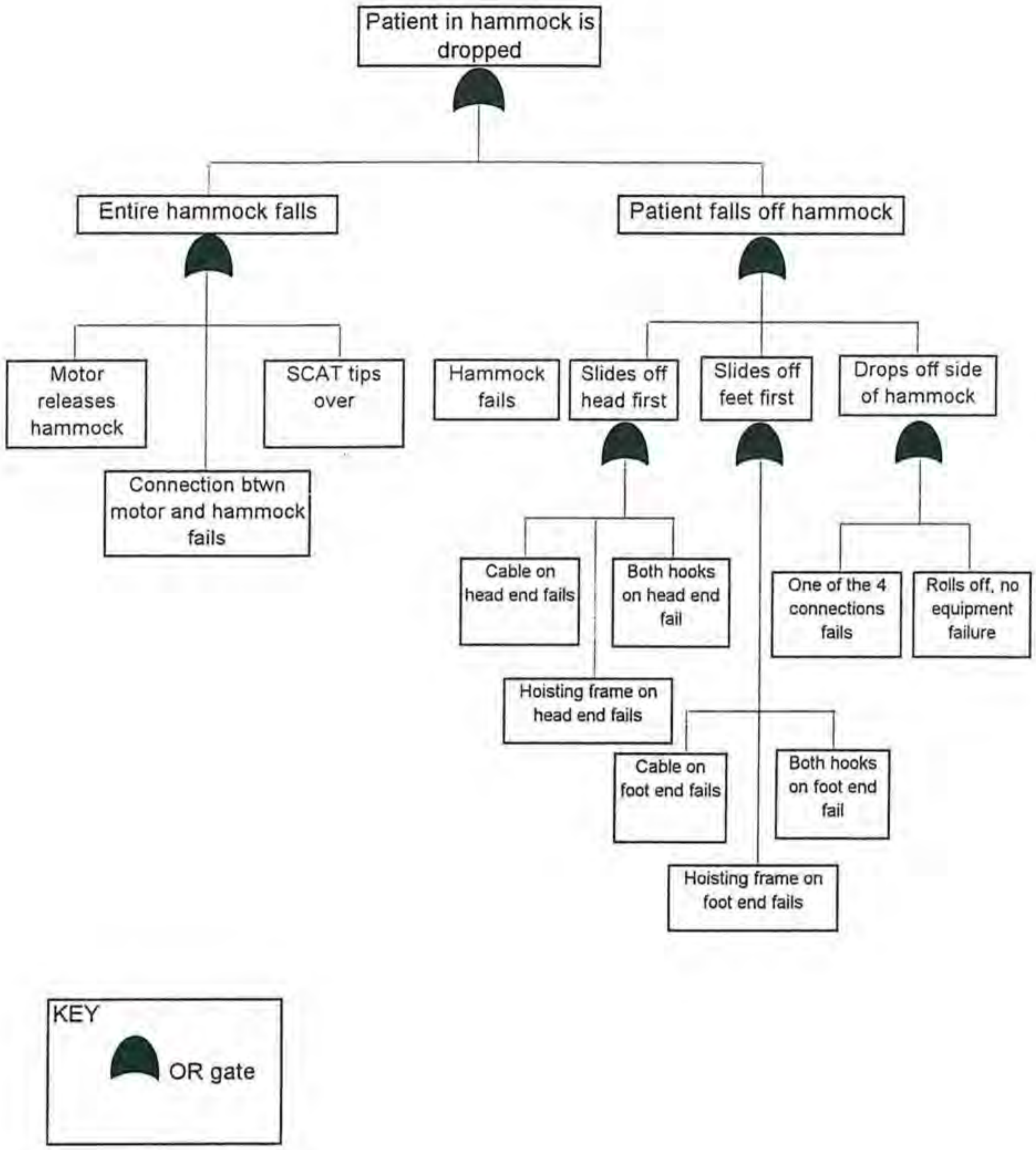

Figure 2 Fault Tree Diagram for the event of dropping a patient

The following outline presents the same concept as the right side of the fault tree diagram

- Patient falls off hammock one of four ways:
  - Patient falls through hammock due to failure of hammock material, frame, or eye-hooks.
  - Patient slides off the hammock head first
    - when one or both hooks on head end of hammock fail,
    - when hoisting frame on head end fails, or
    - when the cable on the head end fails.
  - Patient slides off the hammock feet first
    - when one or both hooks on foot end of hammock fail,
    - when hoisting frame on foot end fails, or
    - when the cable on the foot end fails.
  - Patient drops off one side of the hammock
    - when hammock support on one side fails, or
    - by patient rolling off one side while hammock remains suspended.

Failure Mode and Effects Analysis

The FMEA was limited to the components that hold the hammock up. A diagram of the components is provided in Figure 3. When the battery powered motor at the top of the diagram is on, it rotates the worm gear shaft. The rotational energy is transmitted through the gears to another shaft containing four reels. Each reel has one cable connected to it. Of the four cables, two lead to the hoist frame at the head end of the hammock, while the other two cables lead to the hoist frame at the foot end of the hammock. The path of each cable is controlled by two pulleys. The pulleys serve two purposes. One is to steer the cables from the horizontal direction within the overhead canopy to the vertical direction for raising and lowering the hammock. The other purpose is the connect to load cells that make it possible to weigh the patient in the hammock.

The four cables hang down from the canopy. Two cable connect to a hoist frame on the head end of the hammock. The other two cables connect to a hoist frame on the foot end of the hammock. For the prototype device these connection had each cable loop through an inverted U-loop welded to the top of each hoist frame. The loop formed by the cable was closed with a ferrule.

At the bottom of each hoist frame were two metal shafts, like legs. An eye-bolt was screwed into each leg. Thus, each leg had a circular foot. In order to attach the legs of the hoist frames to the hammock, four inverted U-loops were welded to the hammock frame. A caribiner was used to connect the U-loops of the hammock to corresponding eye-loops of the hoist frame.

Motor
‖
Worm gear shaft
‖
foot end===========Worm gear wheel and shaft===========head end

2 reels | | cables 2 reels | |

1st pulley 1st pulley

2nd pulley 2nd pulley

| | cables | |

∩ ∩ inverted U-loops atop hoist frame ∩ ∩

Hoist frame Hoist frame

O O eye-bolt loops bottom of hoist frame O O

ɋ ɋ carabiners ɋ ɋ

∩ ∩ inverted U-loops on hammock frame ∩ ∩

Hammock Hammock

Figure 3. Diagram of the components and linkages that support the hammock.

The FMEA examined the consequences of any of the components in Figure 3 failing. Table 2 contains results of the FMEA.

Hazard Analysis

Tables 3 through 5 summarize the findings from the observations of and discussions with the nursing students. Each table applies to one of the three tasks performed by the nursing students. The steps in each task are listed in each table. For each step the human use issues and injury possibilities are described. Table 3 is for the task of lifting a patient from the floor.

Table 2. Failure Mode and Effects Analysis

Component Identification	Function of Component	Failure Modes	Probable Cause	Symptoms of Failure	Existing Compensatory Provisions	Effects on Next Component	Effect on Entire System	Probability Rating	Severity Rating	Hazard Index
1. Battery	Provide elec. power to motor	Not enough power to run motor	Used too long	Motor stops	None	Motor stops	Hammock will not move	Frequent	Negligible	13
2. Battery cables	Transmit elec. power	Open circuit	Severed cable	Motor will not run	None	Motor idle	Hammock will not move	Improbable	Negligible	20
"	"	"	Bad connection at either end	"	"	"	"	Occasional	Negligible	18
3. Motor	Rotate shaft	Off	Auto shut off due to overheating	Hot and stops	Worm gear does not rotate backward	Worm gear stationary	Hammock stationary	Occasional	Negligible	18
"	"	"	Internal part fails	Stops	"	"	"	Occasional	Negligible	18
4. Worm gear shaft	Transmit motor's energy to worm wheel	Breaks	Fatigue	Not yet determined	None	Worm wheel unwinds	Hammock drops to floor	Improbable	Critical	15
	"	Stripped gears	Mismatched with worm wheel gear	Grinding noise	"	"	"	Remote	Critical	10
5. Cables btwn worm gear reels and hoist frame -- head end	Raise and lower hammock	Breaks chain of support for hammock	Tensile force exceeds cable capacity	Sudden drop of hoist frame -- head end	None	Head end of hoist frame drops	Patient falls head first	Remote	Catastrophic	8
"	"	"	Wear and tear thru usage	"	"	"	"	Remote	Catastrophic	8
"	"	"	Connection at either end of link fails	"	"	"	"	Remote	Catastrophic	8

continued

6. Cables btwn worm gear reels and hoist frame -- foot end	Raise and lower hammock	Breaks chain of support for hammock	Tensile force exceeds cable capacity	Sudden drop of hoist frame -- foot end	None	Foot end of hoist frame drops	Patient falls feet first	Remote	Critical	10
"	"	"	Wear and tear thru usage	"	"	"	"	Remote	Critical	10
"	"	"	Connection at either end of link fails	"	"	"	"	Remote	Critical	10
7. First pulley	Change cable direction horizontally 90 degrees	Breaks	Fatigue of center pin or attachment pin	Sudden drop of one corner of hammock	None	Cable comes off 2nd pulley and runs straight from reel to hole	Corner of hammock drops several inches	Remote	Critical	10
8. Second pulley	Change cable direction from horizontal to downward	Breaks	Attachment to frame overstressed	Sudden drop of one corner of hammock	None	Cable will run straight from 1st pulley down thru hole	Corner of hammock drops 2-4 inches	Remote	Marginal	14
9. Hoist frame for head end of hammock	Links lower end of cable to head-end of hammock	Breaks chain of support for hammock	One U-loop at top of hoist frame breaks off	Sudden drop of one corner of hammock	None	Corner of hammock descends	Patient may roll off side of hammock	Remote	Critical	10
"	"	"	Both U-loops at top of hoist frame break off	Sudden drop of head-end of hammock	None	Head-end hoist frame and hammock fall	Patient falls head first	Improbable	Catastrophic	12
"	"	"	One eye-bolt at bottom of hoist frame fails	Sudden drop of one corner of hammock	None	Corner of hammock descends	Patient may roll of side of hammock	Remote	Critical	10
"	"	"	Both eye-bolts at bottom end of hoist frame fail	Sudden drop of head-end of hammock	None	Head-end of hammock drops	Patient falls head first	Improbable	Catastrophic	12

continued

"	"	"	Failure of hoist frame -- head end	Sudden drop of head-end of hammock	None	Head-end of hammock drops	Patient falls head first	Improbable	Catastrophic	12
10. Hoist frame for foot end of hammock	Lower link in chain of support for foot end of hammock	Breaks chain of support for hammock	One U-loop at top of hoist frame breaks off	Sudden drop of one corner of hammock	None	Corner of hammock descends	Patient may roll off side of hammock	Remote	Critical	10
"	"	"	Both U-loops at top of hoist frame break off	Sudden drop of head-end of hammock	None	Foot-end hoist frame and hammock fall	Patient falls feet first	Improbable	Critical	15
"	"	"	One eye-bolt at bottom of hoist frame fails	Sudden drop of one corner of hammock	None	Corner of hammock descends	Patient may roll of side of hammock	Remote	Critical	10
"	"	"	Both eye-bolts at bottom end of hoist frame fail	Sudden drop of foot-end of hammock	None	Foot-end of hammock falls	Patient falls feet first	Improbable	Critical	15
"	"	"	Failure of hoist frame -- foot end	Sudden drop of foot-end of hammock	None	Foot-end of hammock drops	Patient falls feet first	Improbable	Critical	15
11. Hammock	Supports patient	One U-loop breaks	Fatigue of weld	Sudden drop of one corner of hammock	Siderail may be grabbed by patient	Patient starts to slide out of hammock	Patient falls out of hammock	Remote	Critical	10
"	"	Multiple U-loops break	Very heavy patient	Sudden drop of multiple corners of hammock	None	Patient starts to slide out of hammock	Patient falls out of hammock	Remote	Catastrophic	8
"	"	Material rips apart	Cut or worn	Visible tear or wear in material	Rely on nurses	No next component	Part (or all) of patient moves below hammock	Remote	Critical	10
"	"	Side support bends	Strength exceeded	Sudden bending	None	No next component	Patient may fall to floor	Remote	Critical	10

Table 3. Hazards and usability issues when raising a patient from floor and moving onto bed.

Step	Use Issues	Injury Possibilities
1. Positioning patient onto hammock	Uncomfortable to role over bar of hammock (both groups agree). Group 1 noted the seat belt also lumpy to role over if not tucked under rolled material. Knees on floor. Some were confused as to which end of hammock is for the head.	Patients with certain conditions may be made worst if hammock is not sufficiently rigid. One nurse caught finger in carabiner causing mild pain but no injury.
2. Move SCAT over patient	Tight fit reported by Group 1; they always moved over patient from the side with SCAT parallel to patient. Group 2 learned to move SCAT diagonally over patient and had no problem with tight fit. SCAT seemed too short.	Combative patient could bang head on SCAT. Could catch feet according to Group 1, but unclear why this was said.
3. Unhook hoist frame and lower to hammock	Hook under canopy was too small for the carabiners. As a result, this step took excessive time for some nurses.	Hoist frame could hit patient if not stabilized by the nurses.
4. Hook hoist frame to blue eyes on hammock support poles and raise patient	The blue U-loops on the hammock rails sometimes flip over and make attachment difficult. Swinging was disturbing for Group 1. Group 2 thought swinging was reduced when raised high and they preferred to be high during transport. Jerking was scarry for patient. See Footnote 2	Feet and head need watching while raising patient. Ankle flexion required by some subjects to avoid catching feet between hammock and horizontal rail 36" above floor. Also see Footnote 3.
5. Push SCAT to foot of bed	Swinging was disturbing to some patients. Group 2 preferred riding high.	Group 1 identified no injury possibilities. Two nurses in Group 2 mentioned feeling the upper back muscles being stressed.
6. Move patient over bed	Pushing can be difficult; wheels start out oriented sideways and need straightening. Footnote 3	
7. Lower, detach carabiners, and attach hoist frame to hooks in ceiling	Hook under canopy was too small for the carabiners. As a result, this step took excessive time for some nurses.	If hoist not secured well to ceiling it might fall and hit patient or a nurse possibly. Footnote 4.
8. Get hammock out from under patient	Uncomfortable for patient but not as uncomfortabble as when on floor. Task of nurses would be more difficult with a dead weight patient than with cooperative nursing students.	Potential to roll off bed; more potential if patient is big in circumference.
9. Pull/push SCAT away from bed	Manuevering was not easy; similar to pushing a guerney.	Patient might sit up and bump head on cross-bar of SCAT.

1. The possibility of a patient being dropped wasn't mentioned by either group. This eventuality is the subject of the fault tree analysis.

2. Occasionally a nurse will press a wrong button. Should design the four button controls to use coding by position and shape. One subject suggested a remote controller for up/down controls.

3. Bed must be horizontal for using SCAT to transfer onto it.

4. New method to attach hoist frame to ceiling should provide a clear indication that the attachment is complete and secure.

Table 4 shows the usability and hazards for the task of transferring a patient from a bed onto the device. Table 5 presents the same information for the task of transporting a patient 35 feet via the device.

Table 4. Hazards and usability issues when raising a patient from bed onto device

Step	Use Issues	Injury Possibilities?
1. Position hammock under patient	Being rolled over hammock bars was uncomfortable, but not as much as when on floor.	None identified.
2. Open SCAT, and move SCAT to surround bed	Manuevering was difficult (due to wheel being turned sideways before starting to push over bed).	None identified.
3. Detach and lower hoist, frame, hook carabiners to hammock frame	Easy.	Frame could bump patient if nurse fails to hold frame while lowering it.
4. Raise patient	Patient feels like forehead is going to contact cross bar.	If patient raises head it could hit cross bar.
Other comments	Occasionally a nurse will press a wrong button. Should design the four button controls to use coding by position and shape.	None identified.

Table 5 Hazards and usability issues when transporting a patient via the device

Step	Use Issues	Injury Possibilities?
1. Assume positions: one nurse behind to push, a second nurse on side to guide	No usability issues	None identified
2. Push and guide device	Some swinging of patient noted by Group 2. They suggested firming up the hammock.	None identified
3. Stop movement of device	No usability issues	None identified

Hazards identified during the trials are listed in Table 6. On the list are all hazards identified by the nursing students and the safety analyst. Hazards are included without regard to probability of causing an injury, and without consideration of the severity of possible injury. The list is limited to hazards that might be encountered while the device is being used for one of the tasks performed by the nursing students.

Table 6. Hazard identified during trials of the prototype SCAT!™ evaluated in 1996

Task†	Step	Hazard to	Hazard
1	1. Positioning patient onto hammock	Patient	Using the device for inappropriate patients may make their condition worse. An examples is a woman in nursing home who has fallen and broken her hip.
1	2. Move SCAT! over patient	Nurse	Catch finger in clamp of carabiner.
1	2. Move SCAT! over patient	Patient	Combative patient could bang head on SCAT! frame or wheel.
1	2. Move SCAT! over patient	Patient	Patient could catch feet according to Group 1, but unclear why this was said.
1	3. Unhook hoist frame and lower to hammock	Patient	Hoist frame could hit patient when it is lowered if nurse fails to guide it.
1	4. Hook hoist frame to blue loops on hammock support poles and raise patient	Patient	Patients' feet or head may get caught between hammock and frame of SCAT! while raising. Catching feet is far more likely than catching head.‡
1	5. Push SCAT! to foot of bed	Nurse	Stressing of upper back muscles may result in sprain or strain.
1	7. Lower, detach carabiners, and attach hoist frame to hooks in ceiling	Patient or Nurse	Hoist frame may, if not secured well to ceiling, fall and hit patient or nurse's arm/hand.
1	8. Get hammock out from under patient	Patient	Potential to roll off bed; more potential if patient is big in circumference.
1	9. Pull/push SCAT! away from bed	Patient	Patient might sit up and bump head on cross-bar of SCAT!.
2	3. Detach hoist, lower hoist and hook carabiners to hammock frame	Patient	Frame could bump patient if nurse fails to hold frame while lowering it.
2	4. Raise patient	Patient	If patient raises head, cross bar of frame could be bumped by forehead, nose, or other part of head.

† Task number in table refer to the following tasks:

1. Lift a patient from the floor using the device and move the patient onto a bed.
2. Transfer a patient from bed to device.
3. Transport a patient via the device a distance of 35 feet.

‡ Ankle flexion required by some subjects to avoid catching feet between hammock and horizontal rail (36" above floor).

Table 7 is the Preliminary Hazard List. It indicates which analysis led to identification of the hazard in the first column (*Trials* refers to the trials by nursing students). A hazard identification number is in the second column. The third column contains a description of the hazard.

Hazard Control Precedence Sequence

Each hazard listed in Table 7 appears to be controllable. Table 8 lists the hazards and indicates the method of control using code numbers as follows:

1. Design to eliminate or minimize hazard
2. Provide safety mechanisms
3. Provide warning mechanisms
4. Control with labeling and training
5. Accept remaining hazards

Comments are included in the right column of Table 8. For those hazards with a 1 code for control method, comments are intended for the designers of the production model. Some of these comments are quite general, others are more specific. All comments assume the designers are qualified engineers capable of appreciating the engineering concerns and finding appropriate solutions.

For the components that support the hammock and patient, specific design loads are not included in Table 8. These can be determined during Phase II. This will involve considerations of the heaviest patient to design for, and the cost of components. Two points can be made at this time. One is that each link in the chain of support (e.g., cable, cable connections, U-loops and eye-bolts of hoist frame, caribiner, and U-loops of hammock) is equally critical. There is no sense having the cable and caribiner rated for 1000 lb-force if the cable connection to the hoist frame is only good to 400 lb. The weakest link is the critical link. The second point is that approximately 2/3 of a patient's weight will be on the head end of the hammock. This is due to the distribution of body weight being concentrated in the torso. Thus, designers may want to consider using stronger components for the head end than for the foot end.

Several hazards in Table 8 have a 4 code for control method. These will be important during Phase II, when the training programs for nurses will be developed, and when an operating manual will be prepared.

The list of hazards is intended to be comprehensive for the risk of dropping a patient. Not considered during this Phase I analysis are: maintenance operations, routine battery changing and charging operations, and uses of the device for any tasks other than the three performed by the nursing students. The Fault Tree Analysis indicated that one possible way a patient could be dropped would be if the entire SCAT!™ tipped over. This was not considered in Phase I.

Table 7. Preliminary Hazard List for the prototype SCAT!™ evaluated in 1996

Process used to identify	Hazard ID Number	Description of Hazard
Trials	1	Use device for inappropriate patient
Trials	2	Pinch point in clamp of caribiner
Trials	3	When using device to pick up patient from floor, patient could suddenly move head and hit wheel guard or leg of device
Trials	4	When moving device over patient on floor, nurses could hit patient with wheel guard or leg of device
Trials	5	With patient on floor, when nurses lower hoist frame they could fail to guide it, and allow hoist frame to bumb patient
Trials	6	When raising patient from floor, patient's head or feet could get caught between hammock and horizontal width-extendor beam
Trials	7	When starting to push device, with patient in it, the upper back muscles of nurses are stressed, possibly resulting in a sprain or strain if abnormal resistance is encountered
Trials	8	When attaching hoist frame to under-side of canopy, nurse could fail to attach it securely; hoist frame may fall and hit patient or nurse's arm/hand
Trials	9	When getting hammock out from under patient, while on bed, the patient could roll off bed, particularly if patient is big in circumference
Trials	10	When pushing device away from bed, the patient might suddenly raise head, and have head bumped by cross-bar of device
Trials	11	While preparing to raise patient from bed, when nurses lower hoist frame they could fail to guide it, and allow hoist frame to bumb patient
Trials	12	While raising patient from bed with device, patient could raise head and bump face againt cross bar of hoist frame
FMEA	13	Failure of power supply to motor
FMEA	14	Failure of motor
FMEA	15	Failure of worm gear shaft
FMEA	16	Failure of cables between worm gear reels and hoist frame -- head end
FMEA	17	Failure of cables between worm gear reels and hoist frame -- foot end
FMEA	18	Failure of first pulley
FMEA	19	Failure of second pulley
FMEA	20	Failure of hoist frame -- head end
FMEA	21	Failure of hoist frame -- foot end
FMEA	22	Failure of hammock to support patient

Table 8. Hazard controls for the production model of SCAT!™ to be designed during Phase II

Hazard ID Number	Description of Hazard	Hazard Control Precedence	Comments
1	Use device for inappropriate patient	4	Emphasize in training of nurses. Include guidance in operations manual.
2	Pinch point in clamp of caribiner	5	Negligible injury potential, but consider when choosing caribiner for production model.
3	When using device to pick up patient from floor, patient could suddenly move head and hit wheel guard or leg of device	1	Wheel guards and lower part of device legs should not have any sharp edges that could hurt patient if bumped.
4	When moving device over patient on floor, nurses could hit patient with wheel guard or leg of device	1 & 4	Same advice as for Hazard 3 above. Include in training the technique of moving device over patient diagonally rather than laterally.
5	With patient on floor, when nurses lower hoist frame they could fail to guide it, and allow hoist frame to bumb patient	1 & 4	Legs of hoist frame should not have any sharp edges. The circular eye-bolt used for the prototype was OK. Training should include instruction on proper technique.
6	When raising patient from floor, patient's head or feet could get caught between hammock and horizontal width-extendor beam	1 & 4	Consider adding length to device to make room for taller patients. Teach nurses to have on nurse watch patient's feet while the second nurse watches patient's head.
7	When starting to push device, with patient in it, the upper back muscles of nurses are stressed, possibly resulting in a sprain or strain if abnormal resistance is encountered	1 & 4	Choose large wheels with low rotational friction for production model. Those used for prototype were OK. Instruct nurses that pushing the device with a patient is a task for two nurses, not one.
8	When attaching hoist frame to under-side of canopy, nurse could fail to attach it securely; hoist frame may fall and hit patient or nurse's arm/hand	1	Attachment mechanism in canopy should provide feedback (visual and/or auditory) to notify nurse when frame is securely attached to the canopy. Inadequate attachment should also be easily detectable.
9	When getting hammock out from under patient, while on bed, the patient could roll off bed, particularly if patient is big in circumference	4	Explain this hazard during training and instruct on technique to avoid it.
10	When pushing device away from bed, the patient might suddenly raise head, and have head bumped by cross-bar of device	4	The device would be moving very slowely when the head is bumped, so any injury would be negligible. But to avoid a head bump, teach nurses to instruct patients to keep head on pillow while device is moved away.

11	While preparing to raise patient from bed, when nurses lower hoist frame they could fail to guide it, and allow hoist frame to bumb patient	1 & 4	As noted for Hazard 5 above, legs of hoist frame should not have any sharp edges. The circular eye-bolt used for the prototype was OK. Training should include instruction on proper technique.
12	While raising patient from bed with device, patient could raise head and bump face againt cross bar of hoist frame	1 or 2	Put padding around middle of cross bar; or redesign hoist frame to not have a cross bar near the patient's face.
13	Failure of power supply to motor	1	By using a worm gear, this event will not injure anyone.
14	Failure of motor	1	By using a worm gear, this event will not injure anyone.
15	Failure of worm gear shaft	1	Make sure the manufacturer of the worm gear shaft makes quality shafts. Design gear interfaces so misalignment will never occur.
16	Failure of cables between worm gear reels and hoist frame – head end	1	Select cable rated for well over the greatest expected load. Method used to create the loop at low end of cable needs careful consideration to be sure it will hold. The simple once-through loop with a ferrule attachment may not be enough.
17	Failure of cables between worm gear reels and hoist frame – foot end	1	Select cable rated for well over the greatest expected load. Method used to create the loop at low end of cable needs careful consideration to be sure it will hold. The simple once-through loop with a ferrule attachment may not be enough.
18	Failure of first pulley	1	Design pulley attachment to canopy with plenty of strength, and flexibility to avoid bending that could fatigue metal.
19	Failure of second pulley	1	Design pulley attachment to canopy with plenty of strength, and flexibility to avoid bending that could fatigue metal.
20	Failure of hoist frame – head end	1	Design frame so it will be sturdy and capable of easily supporting 2/3 of the weight of the heaviest patient anticipated.
21	Failure of hoist frame -- foot end	1	Design frame so it will be sturdy and capable of easily supporting 1/3 of the weight of the heaviest patient anticipated.
22	Failure of hammock to support patient	1	The sides of the hammock frame must not bend much when supporting a heavy patient, e.g., 400 lb. Material between frame must be durable and strong. A forseeable site of failure are the stitched areas.

Summary and Conclusions

The systems safety analyses reported here were performed during a Phase I grant from NIOSH. The Phase I grant applications stated that the system safety evaluation will demonstrate the feasibility of applying systems safety methods to identify, and design out, significant product risks before production and marketing. Four systems safety methods were used.

The Fault Tree Analysis demonstrated a systems safety method for identifying events that could cause an identified undesirable event. For this demonstration, the undesired event was a patient being dropped from the hammock.

Hazards due to component failures were identified using Failure Mode and Effects Analysis. Like the Fault Tree Analysis, this analysis was limited to the components that hold the hammock and keep the patient from falling. The plan is to extend this analysis to other components during Phase II.

Hazards that may be encountered while using the SCAT!™ were identified by using Hazard Analysis. This analysis made use of observations of nursing students using the device to perform three patient handling tasks. Discussion with the nursing students also provided valuable information.

Methods to address hazards made use of the Hazard Control Precedence Sequence. This method helped identify several hazards that are adequately controlled with the design of the prototype device. Other hazards were identified that need to be addressed during design of the production model. Several hazards were found that will need to be included in the operating manual and in the training program for nurses.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date: April 2, 2001

From: Roy M. Fleming, Sc.D., Director, Research Grants Program RMF
Office of Extramural Programs, NIOSH, D30

Subject: Final Report Submitted for Entry into NTIS for Grant 1 R43 OH003380-01.

To: William D. Bennett
Data Systems Team, Information Resources Branch, EID, NIOSH, P03/C18

The attached final report has been received from the principal investigator on the subject NIOSH grant. If this document is forwarded to the National Technical Information Service, please let us know when a document number is known so that we can inform anyone who inquires about this final report.

Any publications that are included with this report are highlighted on the list below.

Attachment
cc: Sherri Diana, EID, P03/C13

List of Publications

No publications

Title: * Invalid Patient Transfer-Transport-Lift-Weigh System
Investigator: Theodore Williamson, R.N.
Affiliation: Black Mountain MedCrafters
City & State: Charlotte, NC
Telephone: (704) 373-9069
Award Number: 1 R43 OH003380-01
Start & End Date: 12/1/1995–10/15/1996
Total Project Cost: $100,000
Program Area: Control Technology
Key Words:

Abstract:
The goal of the grant process was to develop a device which may be useful in decreasing the incidence of occupational injury in the American health care industry. Specifically, the goal was to develop a device which could accomplish transfer and transport of hosiptal and other patients without manual lifting by nursing personnel. Inherent in this goal was to develop a device which would be safe for patients and staff members, easily and conveniently used and stored, and cost effective.

The developed device was evaluated to identify product risks prior to design of the production model. In comparison with other lifting devices, the SCAT was found to be an effective device to use for transferring patients from the bed, lifting them from the floor, and transporting them from one location to another. For many of the transfers, it does take more time, but time can be offset by: the lesser amount of exertion perceived to various body parts by the individuals doing the transfers, the greater feelings of comfort and security expressed by the patients, and the fewer number of people needed to carry out these transfers.

Publications
No publications to date.