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Applying Human Factors Methods to Inform the Implementation of a Novel Medical Device

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Abstract— **Usability testing was performed to identify usability problems with a medical device designed to detect respiratory depression. Personnel lacking formal human factors training developed and implemented the test plan. Quantitative usability test analysis involved measuring task completion time, success rate, and usability issue frequency. Qualitative data was collected via visual observations of the participants. Significant usability problems were identified with the following tasks: entering patient information, opening alarm settings, and adjusting alarms. The test results were used to improve the hospital's clinical training.**

Keywords— **Human Factors, Usability Testing.**

I. Introduction

In 2017 Island Health purchased a monitoring device to provide early warning of respiratory depression in some of their medical/surgical wards. As the first significant example of continuous monitoring for the majority of the clinical staff in these care areas, it was deemed important to trial and evaluate the equipment and associated procedures prior to implementation. In addition to a clinical trial (field study) expected to obtain feedback related to the utility of the clinical procedures drafted to direct practice, usability testing was conducted to provide a higher degree of objectivity and to identify usability problems. [1]

The organization had no Human Factors (HF) Specialist available to plan or implement usability testing; a co-op student enrolled in the fourth year of an undergraduate program in Biomedical Engineering was assigned the project. Knowing that a well-designed HF assessment can expose characteristics of a device that cause user errors or reduce effectiveness, efficiency, and user satisfaction [1], the objective was to obtain information to:

- Confirm that staff could effectively use the device with little or no model-specific training,
- Improve the script to be used during clinical training,
- Provide feedback to the device manufacturer.

II. Methods

A test plan was established using published resources [2, 1] and telephone consultation with an individual with prior experience in applying usability testing (Mr. Wrae Hill). Usability testing involves observing end-users while they complete simulation scenarios using the device in situations that would commonly be encountered if the device was implemented [1].

Documents supporting the usability tests were developed. These included a consent form, data collection spreadsheet, visual presentation (orienting the viewer to the device), moderator script, scenarios, the usability test plan, and post-test questionnaire.

The anticipated user group consisted of Registered Nurses (RNs) at the Royal Jubilee Hospital (RJH) from the Medical/Surgical Units. The goal was to recruit RNs for the testing who met these criteria:

- Full-time or part-time employment as an RN at RJH
- At least 1 year of experience as an RN
- Currently assigned to a medical/surgical unit

The usability test was designed to answer the following questions about the device:

- How easily did RNs learn to use the device?
- How quickly were RNs able to perform basic tasks on the device?
- What are the most prominent mistakes and the severity of the mistakes?
- What were the RNs overall experience with the device?
- Do RNs understand the purpose/value of the device?
- Are there any safety issues with the device?

The test procedure for each participant session followed these steps:

- The Moderator explained what the usability test was for and gave general guidelines (e.g. asked participant to speak out loud while using the device).
- The participant signed the consent form; Moderator started video/audio recording.

- Moderator provided orientation training for device. This training was designed to familiarize the participant with the device, but not provide specific knowledge regarding the device operation.
- The participant answered pre-test demographic questions.
- The participant read aloud the background information of the scenario and was given the list of tasks. The participant performed the tasks until completion or frustration. This process repeated until all scenarios were completed.
- The participant completed the post-test questionnaire.
- The moderator asked questions that arose while observing the participant and debriefed the participant.

The participants were asked to perform 13 tasks:

1. Turn on machine
2. Apply electrodes
3. Enter patient information
4. Start basic monitoring
5. Accept default alarms
6. Interpret status
7. Open alarm settings
8. Adjust alarms
9. Open settings
10. Adjust respiratory trace
11. Adjust alarm delay
12. Remove electrodes
13. Power down device

The test data included observer notes logged during the test sessions, questionnaires, and audio/video recording of each test session recorded from an "over-the-shoulder" view such that the user-screen interactions could be seen and the participant voice could be heard. This data provided the necessary quantitative data values for usability metrics outlined:

- Success rate of completion
- Time to complete the tasks
- Frequency of errors
- Types of errors
- User satisfaction

Data collected was managed and analyzed using a spreadsheet adapted from Rosemberg [3] to calculate the severity of each issue. Severity is a measure of how important it is to fix each usability issue, with high severity corresponding to high importance. Severity takes into account the importance of the task, the importance of the user interface (UI) screen, the frequency of the issue, and the impact of the issue. Severity is calculated with following formula:

$$Severity = (Task\ Importance) \cdot (UI\ Importance) \cdot (Frequency) \cdot (Impact)$$

Some subjectively is unavoidable in defining the importance to tasks and user interfaces, and the justifications / rationale for each decision were documented to support arguments for product improvements.

Five participants were recruited for the usability test including an RN with two years' experience, two RNs with 20 years' experience (one had a previous orientation to the device from the vendor's representative, the other had not), a certified Nurse Educator with 11 years' experience, and a Clinical Nurse leader with 30 years' experience.

III. Results

A comprehensive list of usability issues was created by viewing the simulation test videos. Each identified issue was assigned a unique identifying number, a scope (i.e. the screen where it happened), the task that it hindered, and an impact level. The videos were viewed again and the participants for which each issue occurred were logged. Lastly, the severity of each issue was calculated.

Table 1 lists the issues identified via this process.

Table 1: Quantitative Analysis of Usability Issues

Issue	Task	Issue description	Impact	Frequency	Severity
1	Turn on machine	Required 2+ button presses to turn on machine	Minor	80%	25.6
2	Apply electrodes	Did not attach patient cable to machine correctly	Major	20%	9.6
3	Enter patient info	Attempts to type patient data into disabled input field	Minor	80%	25.6
4	Enter patient info	Closes keyboard	Major	20%	9.6
5	Enter patient info	Attempts to select disabled input field 3+ times	Major	80%	38.4
6	Enter patient info	Attempts to move cursor with tab/return	Suggestion	40%	6.4
7	Enter patient info	Took longer than 120s to activate input fields (may require hint)	Blocker	20%	12.8
8	Accept default alarms	Confusion expressed about Minute Ventilation Marker	Suggestion	60%	7.2

Table 1 (Continued)

Issue	Task	Issue description	Impact	Frequency	Severity
9	Accept default alarms	Confusion expressed when restore defaults when already at default	Suggestion	20%	2.4
10	Open alarm settings	Opens settings menu to adjust alarms	Minor	100%	32.0
11	Open alarm settings	Hits "Pause Alarms" to adjust alarms	Minor	60%	19.2
12	Adjust alarms	Thought that alarms were adjusted when they were not	Blocker	80%	51.2
13	Adjust alarms	Changes display range metric instead of alarms	Major	80%	19.2
14	Adjust alarms	Took longer than 120s to find alarm menu (may require hint)	Blocker	60%	38.4
15	Adjust alarms	Attempted to move disabled sliders 3+ times	Major	60%	28.8
16	Adjust alarms	Attempted to enable sliders by click Off label above slider	Minor	60%	19.2
17	Adjust alarms	Fails to click on slider or toggle on/off button 3+ times	Major	60%	28.8
18	Adjust alarms	Overshoots slider end position 3+ times	Minor	80%	25.6
19	Adjust alarms	Failed to operate alarms setting screen without stylus	Blocker	40%	25.6
20	Adjust alarm delay	Tried to find alarm delay by pausing alarms	Minor	40%	6.4
21	Adjust alarm delay	Took longer than 120s to find alarm delay (may require hint)	Blocker	60%	9.6
22	Adjust respiratory trace	Took longer than 120s to find respiratory trace (may require hint)	Major	40%	2.4
23	Adjust alarm delay	Adjusts respiratory trace time interval and instead of alarm delay	Minor	60%	4.8
24	Misc.	Touches button outside of pop-up	Suggestion	40%	3.2

IV. Discussion

Four issues had a severity level greater than 30.0: #5, #10, #12 and #14. Issue #5 involved difficulty entering patient data into the device and issues #10, #12, and #14 involved confusion with adjusting alarms. The common intervention method for a poorly designed device is to implement a more comprehensive training protocol [4]. Not only is training expensive due to the time requirements of education staff and practitioners, it has mixed results for improving patient safety [5].

Figure 1 shows the distribution of total issue severities per task. The top three tasks with the highest total severity were adjusting alarms, entering patient information, and opening alarm settings. The device design required patient information be entered before patient monitoring could begin, and appropriate alarm settings were critical to prevent alarm fatigue.

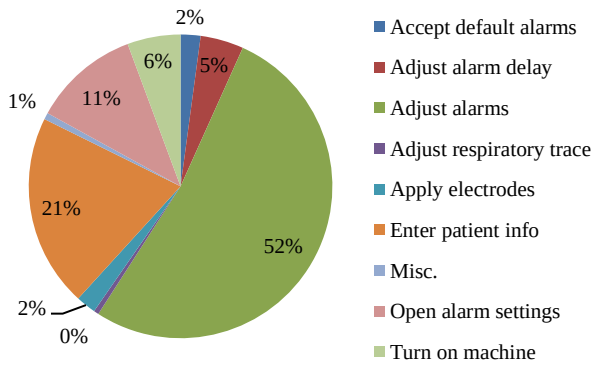

Fig. 1 Total Severity per Task

Based on the analysis of observed usability issues, the authors produced a narrated video compilation of usability errors; the video was an effective communication tool when presenting the findings to the manufacturer's representatives and to the clinical educators as they were preparing the training material. The video illustrated some of the qualitative data collected; the participants' frustration, confusion, and misinterpretations provided insight into the underlying causes of the poor quantitative results.

Table 2 shows the time each of the five participants required to complete the tasks – "INC" means they were unable to complete the task without assistance.

Table 2 Quantitative Analysis of Task Completion
INC indicates incomplete; unable to independently complete task

Task	Task	Time in seconds					Success rate
		1	2	3	4	5	
1	Turn on machine	21	13	10	17	12	100%
2	Apply electrodes	132	133	92	108	100	100%
3	Enter patient info	40	53	INC	56	83	80%
4	Start basic monitoring	4	18	4	12	5	100%
5	Accept default alarms	75	7	29	9	46	100%
6	Interpret status	10	15	10	18	13	100%
7	Open alarm settings	25	35	INC	INC	INC	40%
8	Adjust alarms	90	45	76	INC	INC	60%
9	Open settings	2	2	3	4	3	100%
10	Adjust respiratory trace	71	6	11	55	INC	80%
11	Adjust alarm delay	11	8	INC	144	INC	60%
12	Remove electrodes	15	13	17	30	25	100%
13	Power down device	15	4	4	31	10	100%

Tasks #7 and #8 were problematic and both involved the alarms. Only 40% of participants could find and open the alarm settings without assistance. Once the alarm settings were open, only 60% of users could properly adjust the alarms without assistance or a stylus to use with the touchscreen. One participant was unable to enter patient data into the machine (Task #3), a critical task as it is a prerequisite to starting the monitoring.

One of the goals of the usability testing was to confirm that staff could effectively use the device with little or no model-specific training; in fact the testing provided compelling evidence that an untrained individual was likely to make errors when adjusting alarms - if they were able to use the device at all. The results of the testing were used to improve the script used during clinical training. The manufacturer indicated their intention to make improvements to the user interface to address some of the design issues identified and documented.

V. Conclusions

The U.S. Food and Drug Administration (FDA) now requires that medical device manufacturers submit a Human Factors Engineering or Usability Engineering (HFE/UE) report which provides information about the device use safety and effectiveness [4]. The report which might have been submitted to the FDA for this particular device was not available to the hospital to inform the purchase and implementation. Significant design problems were identified that should have been identified and addressed prior to the device being released to the market. The hospital has adjusted their clinical training to mitigate the problems identified.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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