DEFIBRILLATOR USABILITY STUDY AMONG PARAMEDICS

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ABSTRACT

A usability test was conducted of two different manual defibrillators regularly used in the prehospital setting by emergency medical personnel. The purpose of the study was to demonstrate that design attention is needed to make manual defibrillators more error resistant and less hazardous to patient safety. Fourteen paramedics performed four tasks in a "laboratory" environment that included a computerized Laerdal SimMan™ patient simulator. Even without environmental factors and the urgency of actual life-saving situations, more than twenty user interaction problems were found. Ten of the more prominent or consistent problems found are discussed here, and a design solution is proposed for each problem.

INTRODUCTION

User interface design and evaluation is a well-established component of safety engineering in fields such as the aviation, automotive, and nuclear industries. It has not yet been fully recognized as a significant issue in medicine, specifically as a component of patient safety. Usability testing, a common methodology used by human factors engineers, is an important tool for the evaluation of medical devices, and is recommended by the FDA (Kaye and Crowley, 2000). A search of the medical literature yields few reports of medical device usability testing, likely because medical device manufacturers do not normally publish the results of usability tests they conduct.

Multi-functional, manual monitor/defibrillators/ pacemaker devices, generally referred to as "defibrillators" in the health care industry (and in this paper for simplicity), should be distinguished from simpler, less capable automated external defibrillators (AEDs) that are intended for use by the lay rescuer. Health care providers, including emergency medical services (EMS) providers such as paramedics, use defibrillators for three main functions: to observe heart rhythms (the monitor function), to apply electrical shock to patients to convert abnormal heart rhythms (the defibrillator and cardioversion functions), and to apply a pattern of electric impulses to regulate the speed and rhythm of the heart (the temporary pacemaker function). In contrast to the hospital setting, paramedics use these devices in unique settings--roadways, living rooms, the back of ambulances, in poorly lighted conditions, or in vehicles in motion. Most medical devices are marketed for both the in-hospital and prehospital use. It is clear that the EMS industry has unique user requirements for these devices, yet few are designed specifically for EMS.

The American National Standards Institute (ANSI) and the Association for the Advancement of Medical Instrumentation (AAMI) groups have published standards for the design of medical devices in general as well as for cardiac monitors and defibrillators specifically. (ANSI/AAMI 1993, 1996) ECRI has published extensive technical evaluations of different defibrillator models, but with minimal attention to user interface issues (ECRI, 1998). Although there are published usability studies looking at the AEDs (for example Eames, Larsen, & Galletly, 2003), we could find none that look at fully manual devices.

PURPOSE

This study was done to (1) identify user interface design problems with currently popular defibrillators used in the EMS environment and (2) suggest design recommendations that can be used in future defibrillator designs to make them more usable and error resistant. The results are intended to be used as design guidance by medical product developers and as evaluation guidance by medical providers who purchase defibrillators.

METHODS

Participants

Fourteen EMTs (12 experienced paramedics and 2 paramedic students) were recruited from the local EMS community. Institutional review board (IRB) approval was obtained from the University of Rochester Medical Center and each participant was given informed consent prior to the initiation of data collection. Participants were each paid for their participation.

Apparatus and Facilities

The Monroe County Public Safety Training Facility's Crime Scene Simulator was used as the platform for the usability testing. This facility contains a 3-room "apartment" with an observation deck separated by one-way mirrors, which allows for unobtrusive observation and videotaping of the session. Each task was performed on a Laerdal SimMan patient simulator (see Figure 1) and the LP12 and LP10 defibrillator units (see Figures 2 and 3) were used for each task. These models were selected after screening forms completed by potential participants revealed that they were more familiar with these two units than any other. As seen in the figures, these models have quite different user interfaces. An audio recorder was used to record the participant feedback, and these were transcribed for the database.

Procedure

Four scenarios typical to EMS patient care were selected, and were programmed on the patient simulator. The investigators provided verbal (scripted) instructions to the participant prior to each task and collected observational data while the participants performed the tasks. The participants were told in advance what they would be expected to do. They were presented with all of the following tasks using one defibrillator, and then repeated all tasks on the other defibrillator. The defibrillator model used first was alternated between participants.

Figure 1. Usability test setup with SimMan™ and defibrillator.

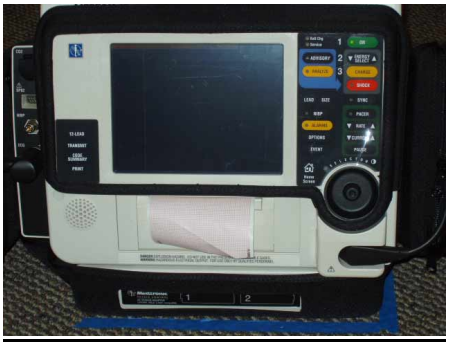

Figure 2. Medtronic Physio Control Lifepak® 12

Figure 3. Physio Control Lifepak® 10

Task 1: "no shocks." Apply the defibrillator to an adult patient who has collapsed and is unresponsive, perform a "quick look," and then use the monitor to perform continuous monitoring of the heart rhythm in lead II. (Note, "lead II refers to a particular view of the electrical activity of the heart, and the term "quick look" refers to the ability to monitor the electrocardiogram (ECG) tracing by putting the defibrillator paddles or patches on the patient's chest.)

Task 2: "stacked shocks." Apply the monitor to an adult patient, do a quick look and observe a fatal heart rhythm (ventricular fibrillation), deliver three consecutive defibrillation shocks, observe conversion to a normal heart rhythm, and then connect the device for continuous monitoring of the heart rhythm in lead II.

Task 3: "synchronized cardioversions." Connect the device to monitor lead II, note a rapid heartbeat and perform synchronized cardioversion. Note no change in the rhythm, repeat synchronized cardioversion, and then note conversion to a normal rhythm. (In this task, the system is programmed to give a "low voltage" tracing, a situation not uncommon but which has the ability to confound some devices.)

Task 4: "record rhythm strip." Turn on the monitor and print a rhythm strip. (In this task, the monitor is out of paper. The participant must recognize this problem and replace the paper to successfully complete the task.)

DATA COLLECTION AND ANALYSIS

Both quantitative and qualitative data were collected from the participants and observers. After each task, the participants used a 1-10 scale to rate their perceived ease/difficulty of performing the task. After all 4 tasks were completed on each defibrillator model, the participant completed a post-defibrillator questionnaire. After both defibrillator model sessions were completed, a final questionnaire was administered that asked them to compare the two models. In addition, the investigators assigned a numerical rating (1-4) that described the participant's level of success in completing each task. Qualitative information about specific operator errors and inefficiencies was collected through administrator's observation, think aloud during the tasks and follow up probing about questionnaire responses. The recorded interviews, observer ratings and comments, and questionnaire data were transcribed and thematically coded, sorted, and manually assessed for trends using standard qualitative analysis techniques. (Pope, Ziebland, & Mays, 2000)

RESULTS AND RECOMMENDATIONS

Although a comparative evaluation of the two defibrillators was not the purpose of the study, a comparison of participants' questionnaire responses was done to gain insight into problems we observed. For use on a regular basis, eleven participants preferred the LP12 while only one preferred the LP10 (others preferred them "about the same"). This reflected the feeling that the LP12 (8 participants) would be more effective in an emergency situation than would the LP10 (3 participants). "Quicker to learn" was an apparently less important factor because it was perceived as characteristic of the LP10 more often (9 participants) than was the LP12 (3 participants). Almost the same number of participants, 7 and 5 respectively, said the LP12 and the LP10 were "easier to use". These variations in preferences are consistent with the findings from analysis of our observations and from participant comments that identified specific problems on each of the defibrillators and their accessories. Ten of the more prominent or consistent problems found are discussed here, and a design solution is proposed for each problem (bulleted).

1. Too many buttons in too small an area (LP12). The LP12 was the object of observed problems and participant complaints about the density of buttons and their close proximity. The resultant confusion and difficulty finding the right button was typified by a participant who commented "a busy display and you've got to look around at a lot of buttons to figure out which ones you want to push to get the thing to do what you want it to do." Several inadvertent actuations were noted by the observers, and participants reported these problems as well. For example, "one time my thumb slipped and I hit the energy button instead of the charge button and [the energy setting] went up." Another participant stated "with the gloves on it is kind of hard to hit the button because they are fairly flat and close together."

- *Recommendation:* Arrange related controls into groups and make a distinct delineation between them. Use a combination of spacing, form factors, color, and graphical demarcations to distinguish adjacent groups. When using spacing, keep it to a "just noticeable distance" to avoid adding to the

overall size of the device. When using colors, make sure high contrast is maintained between text and background. Identify each group with a label.

2. Unnecessary scrolling to accomplish setting. During the energy selection process prior to delivery of a shock, both models require the user to toggle through several rarely used energy levels to get to the desired setting. One participant expressed frustration by commenting "I really disliked having to step through energy levels that I would never ever give."

- *Recommendation:* Allow quickest access to most frequently used setting. Most patients are adults and need the higher settings.

3. Synchronized mode feedback is confusing. As required by the published standards (ANSI/AAMI HE74), the LP 10 displays the word "SYNC" to indicate it is in synchronized mode. But when the ECG waveform amplitude is too small the machine is unable to deliver a synchronized shock, despite the fact that the word "SYNC" is displayed. Participants discovered (by trial and error) that the mode is only fully engaged when the word "SYNC" is flashing. This is in conflict with recognized patterns, as a constant display usually means "operational," while flashing means there is a problem. For example, one human factors textbook states that "visual displays that blink or are very bright imply urgency and excitement." (Eastman Kodak, 2004)

- *Recommendation:* The LP12 has solved this problem as there does not appear to be an amplitude too low to allow SYNC mode to operate. In the absence of this technology, give direct feedback to the user if the amplitude is too low for cardioversion.

4. One model stays in "sync" mode after cardioversion, the other reverts to defibrillator mode. There were several cases in which a participant defibrillated when they intended to cardiovert. In one case, the participant defibrillated twice when cardioversion was indicated, and they were never aware of the errors. Defibrillating a patient who requires cardioversion can cause injury to the patient.

- *Recommendation:* Implement industry standardization for mode state after cardioversion. In order to achieve industry standardization, it is recommended that the ANSI standard consider addressing this issue in the future.

5. New paper rolls were installed in wrong orientation. Multiple participants placed the paper roll incorrectly in the paper well and some complained of unclear or concealed instructions. They made comments such as "You have to look down inside to see which way the paper goes, it's not very visible."

- *Recommendation:* Make instructions for paper loading visible from the paramedic's functional position and depict the paper orientation from that point of view when using an illustration. (Caplan 2004) Also, create a physical design barrier against wrong-way installation.

6. Full paper roll difficult to remove from paper well. The participants who were observed placing the paper roll in the wrong orientation had difficulty recovering because they were unable to fit their fingers in to grasp the roll.

- *Recommendation:* Allow for easy removal of a full paper roll from the paper well. One solution is to incorporate adequate finger clearance to grasp the roll with a gloved hand. A simpler approach is to add an aid for removing the roll. For example, battery compartments often have a small fabric strap under the batteries. Pulling on it lifts the batteries out of their spring-loaded compartment. (Caplan 2004)

7. No out-of-paper indication (LP10). Unlike the LP12, there is no feedback on LP10 to alert the user that it is out of paper. As a result, when faced with a printer that was out of paper, users invariably went through a trial and error process after pressing the "record" button before they diagnosed the problem. The button is soft and gives no tactile, auditory, or visual feedback to let the user know the input has been received. In normal use the initiation of paper printing serves as feedback, but in the absence of paper absolutely no feedback exists. With the exception of one, every participant pushed the record button repeatedly and took extra time and diagnostic steps before realizing something was wrong.

- *Recommendation:* As in the LP 12, display a message to the user when the printer is out of the paper. Incorporate tactile or auditory feedback into the "record" button.

8. Delay was experienced in removing needed accessories. Difficulties finding the right compartment and then in opening it to access the spare roll of paper were noted by the observer and were commented on by the participants. For example comments included: "The two-sided zippers on case is hard to open (since) you don't know where zipper is," and "The old hands can't find the zipper."

- *Recommendation:* Configure enclosure to allow rapid access to contents of case. Zipper design should be single sided (rather than double) and

include a large, easily visible dangling tab on the zipper end so it is easy to find and easy to grasp (even with gloved fingers). Additional participant concerns included the zipper damaging personal protective equipment by violating the integrity of nitrile gloves. This could be prevented by placing a shroud on the zipper to prevent catching the glove. Make compartments transparent, or with a transparent window, so the contents can be viewed without opening it.

9. Buttons are small, undifferentiated, and hard to use with gloves. The energy select controls can be difficult to use on the paddles, especially with gloves. Also, they are on the left side, which is non-dominant for most users. Several participants were observed having trouble with this and many had to take the paddle off the patient's chest to execute the control input. This situation occurred only on the LP10 since the LP12 did not use paddles.

- *Recommendation:* Use redundancy and low dexterity controls on paddles. Put important controls on both paddles so all can use dominant hand. Use control types that don't require fine motor movements.

10. Leads often become tangled. Participants were observed taking excessive time untangling leads and some expressed their frustration in the comments.

- *Recommendation:* Store leads so they can be applied without delay. Use a cable-management device that keeps leads untangled and does not exert tension on them when they are applied to the patient to avoid pulling leads off inadvertently. Technological solutions to this problem should be explored.

DISCUSSION

This study identified many problems with the interface design of two popular monitor/defibrillator/pacemaker units in the EMS setting. These problems were discovered by usability testing in a simulated situation with no environmental, physiological or time pressures applied to the participants. Field usability studies that incorporate these factors could yield even more usability issues and opportunities to improve the delivery of health care. Many of the usability issues already identified have the potential to cause (or fail to prevent) medical errors. These errors may cause a detrimental affect on patients. It is clear that medical device manufacturers and, ultimately, patients would benefit from more emphasis on usability design. Usability assessment needs to be done early and purchasers need to add usability to their selection criteria. This study also demonstrates the value of collaboration between medical and human factors professionals.

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