Usability Study of Two Common Defibrillators Reveals Hazards

Rollin J. Fairbanks, MD, MS
Stanley H. Caplan, MS
Paul A. Bishop, MPA, EMT-P
Aaron M. Marks, BA, EMT-P
Manish N. Shah, MD, MPH

From the Departments of Emergency Medicine (Fairbanks, Shah), and Community and Preventative Medicine (Shah), University of Rochester School of Medicine, Rochester, NY; Usability Associates, Rochester, NY (Caplan); Monroe Community College, Rochester, NY (Bishop); and Monroe Ambulance, Rochester, NY (Marks).

Mr. Marks is now with Bridgeborn Government Solutions, Arlington, VA.

Study objective: This usability study evaluates the user interface of 2 common monitor-defibrillators, the Lifepak10 and Lifepak12, to identify use-related hazards.

Methods: Fourteen paramedics familiar with both devices completed 4 EMS simulator scenarios using each device. The scenarios involved "quick look" and monitoring, defibrillation, synchronized cardioversion, and replacing paper. Qualitative and quantitative data were collected, including both participant self-evaluation (scored 1 to 9) and expert observer evaluation (scored 0 to 4).

Results: Participant ratings demonstrated that for performing a quick look, the Lifepak10 was easier to use (mean 8.0 versus 7.1), and for synchronized cardioversion the Lifepak12 was easier (mean 6.7 versus 5.3). Participants performed better on the Lifepak12 than the Lifepak10 for synchronized cardioversion (mean 3.1 versus 1.6) and replacing paper (mean 3.0 versus 2.1). One participant did not complete the final questionnaire. Of the remaining 13, 11 (85%) participants preferred the Lifepak12 for use on a regular basis. Eight (62%) paramedics thought that the Lifepak12 would be more effective in an emergency; 9 (69%) believed that the Lifepak10 is quicker to learn. Paramedics reported difficulty using the devices with gloves and confusion in "sync" mode. Of note, 50% of participants inadvertently delivered an unsynchronized countershock for supraventricular tachycardia.

Conclusion: Although the Lifepak10 is easier to learn, the Lifepak12 is perceived as easier to use and more effective in emergencies. The high failure rate in synchronized cardioversion indicates a need to reevaluate the user interface design for this function. Limitations of this study include the use of simulation. [Ann Emerg Med. 2007;50:424-432.]

0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2007.03.029

SEE EDITORIALS, P. 384 and 433.

INTRODUCTION

Background

Medical providers often depend on medical devices such as monitor-defibrillators in critical and time-dependent situations. It is important that these devices be designed with an emphasis on reducing the potential for adverse events.[1] Although the traditional response to adverse events and near misses in medicine has been to blame the provider, experts in patient safety have demonstrated that there is often a deficiency in a system component, such as the user-interface design of a medical device, that is the actual root cause.[2-10]

Medical providers interact with medical devices through the user interface, which typically consists of visual and auditory displays (to communicate information to the user) and controls (to communicate instructions to the device). A good user-interface design follows human-factors engineering design standards and takes into consideration the capabilities and limitations of the user, as well as any limitations imposed by the environment(s) in which the device is intended to be used.

The user interface has a surprisingly powerful ability to facilitate and avert hazards.[6,11,12] The evaluation of user-interface design is a well-established component of safety engineering in other complex industries, but its role in the medical industry is underrecognized.[1,13,14]

Usability testing is a method used by human factors engineers to evaluate a device's user interface and its effect on user performance and safety.[14-19] Few usability studies are found in the medical literature, and we are aware of none that examine manual monitor-defibrillator devices.[20-22]

Editor's Capsule Summary

What is already known on this topic

Studies of device usability have been highly beneficial in other high hazard industries but are relatively uncommon in health care.

What question this study addressed

What user-interface design problems are present in 2 commonly used monitor-defibrillators that might contribute to hazards in use?

What this study adds to our knowledge

Observation of 14 paramedics using these devices revealed serious usability problems. Both devices permitted unsynchronized defibrillation when synchronized countershock was intended; most users did not recognize this problem. It also displayed an artifact similar to ventricular fibrillation when "quick look" paddles were used without manually selecting "paddle mode."

How this might change clinical practice

Wider use of usability testing would identify hazards and ultimately contribute to safer design of medical devices.

Importance

Emergency medical services (EMS) providers are concerned about adverse events.[23] Monitor-defibrillators are complex medical devices, and their use has been shown to save lives in the out-of-hospital environment, but they also have potential for harm.[9,24] Identification of use-related hazards and subsequent optimization of user-interface design are essential for safe operation of these devices.

Goals of This Investigation

The objectives of this study were to evaluate and compare the usability of 2 commonly used manual monitor-defibrillators and to identify user-interface-related hazards that may lead to adverse events.

MATERIALS AND METHODS

Study Design

This is a prospective crossover study of paramedic use of manual monitor-defibrillator devices in a simulated EMS environment. In contrast to traditional research methods, in usability testing the object of the research is the device; the goal is not to assess users' performance but rather to identify design characteristics that could lead to hazards in use. The study was approved by the University of Rochester Research Subjects Review Board.

Setting

Usability testing was conducted at the Monroe County Public Safety Training Facility's Crime Scene Simulator, a 4-room apartment with an observation deck separated by 1-way mirrors.

Figure 1. Usability test setup with SimMan and defibrillator. Note 1-way mirror in background.

Tasks were performed using a Laerdal SimMan (Wappingers Falls, NY) patient simulator (Figure 1). Two monitor-defibrillators were selected for this study, the Physiocontrol Lifepak10 and the Medtronic Physio-Control Lifepak12 (Redmond, WA). Selection was based on prescreening questionnaires, which revealed that participants were most familiar with these 2 devices. The Lifepak12 is a newer-generation device, and Figures 2 and 3 show that these models have quite different user interfaces, although the core functions are similar: rhythm monitoring, defibrillation, cardioversion, and external pacing. The Lifepak12 device was equipped with hands-free defibrillator patches, and the Lifepak10 was equipped with paddles, consistent with practice in the local area. Factory default settings were used on both devices.

Selection of Participants

Fourteen EMS provider participants with experience using both devices were recruited from the local EMS community.[25]

Methods of Measurement and Data Collection and Processing

A detailed description of study procedures has been previously reported, and is summarized in Figure 4.[26]

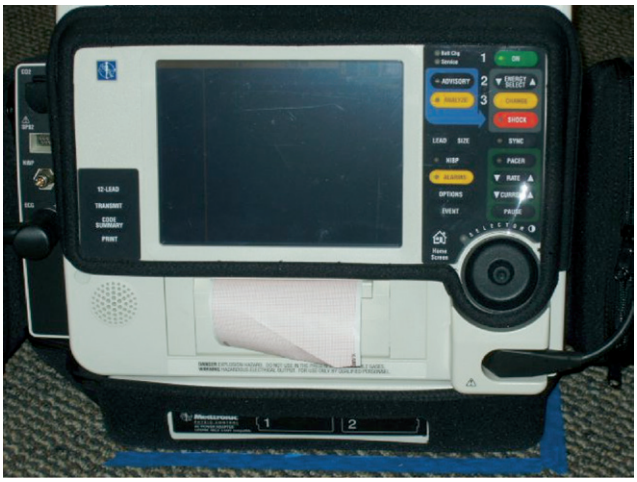

Figure 2. Medtronic Physio-Control Lifepak12.

Figure 3. Physio-Control Lifepak10. Figures 1-3 reproduced with permission from *Proceedings of the Human Factors and Ergonomics Society 48th Annual Meeting,* Santa Monica, CA: Human Factors and Ergonomics Society, 2004.

Participants were familiarized with the simulator and defibrillator devices and instructed to follow the local treatment protocols and to wear gloves.

Participants were presented with 4 scenarios typical for out-of-hospital care: ECG monitoring using a "quick look" technique (through paddles or pads), defibrillation, synchronized cardioversion, and replacing the paper. Quick look is a technique used in EMS to allow a rapid initial assessment of the ECG rhythm, accomplished by placing the paddles or pads on the patient's chest. Defibrillation is the delivery of a shock that occurs immediately, in contrast to synchronized cardioversion, which delivers a shock at a specific time in the cardiac cycle.

Participants completed all of the following tasks with 1 device and then repeated all tasks on the other. The model used first was randomly assigned.

Task 1: Quick Look and Routine Monitoring: Perform a quick look on an unresponsive patient with a pulse and then monitor the ECG using the chest leads.

Task 2: Defibrillation: Perform a quick look, confirm the presence of ventricular fibrillation, and then deliver 2 defibrillations.

Task 3: Synchronized Cardioversion: Perform 2 sequential synchronized cardioversions on a patient with unstable tachycardia. During the first attempt, the monitor is set to display an exceedingly low R-wave amplitude.

Task 4: Paper Change: Print a 10-second rhythm strip (device is preset to be out of paper).

During the scenarios, participants were asked to "think aloud," a technique to help observers gain insight into the thought process of participants.

Outcome Measures

Immediately after each task, participants assigned a numeric rating (1 to 9) in response to the question, How would you rate the ease or difficulty of doing this task? (in which 1 is "very difficult" and 9 is "very easy"). Participants were then asked why they chose this rating, and responses were recorded and transcribed. Once all 4 tasks had been completed on 1 device, a postdevice questionnaire was completed before tasks on the next device were begun. This questionnaire collected qualitative data with open-ended questions such as what the participant specifically liked and disliked about using the device, quantitative data assessing the participants' level of confidence in their ability to effectively use the device for the tasks in the simulation, and an overall device use rating. At the end of the entire session, a final questionnaire was administered to assess perceptions of comparison between devices.

Objective observer ratings were obtained by an EMS physician investigator with human factors engineering training (R.J.F.), who assigned a numeric rating for the success level of each task, 0 (failed) to 4 (excellent). Qualitative data were collected through direct observation, think-aloud comments during the tasks, and follow-up questions during interviews.

Primary Data Analysis

Standard qualitative and usability testing analysis techniques were used.[27,28] Recorded interviews, questionnaire data, and observer comments were transcribed, thematically coded, and sorted into groups of similar issues. An inductive content analysis was conducted by a committee of 4 investigators (R.J.F., S.H.C., A.M.M., M.N.S.) and emerging themes were identified. Mean ratings were calculated for the participant rating scales and the observer scales for each task and device model, and confidence intervals around the differences of these means were calculated.

RESULTS

The 14 participants were 21% women and had an average of 9 years' experience as advanced life support EMS providers (range 1 to 24).

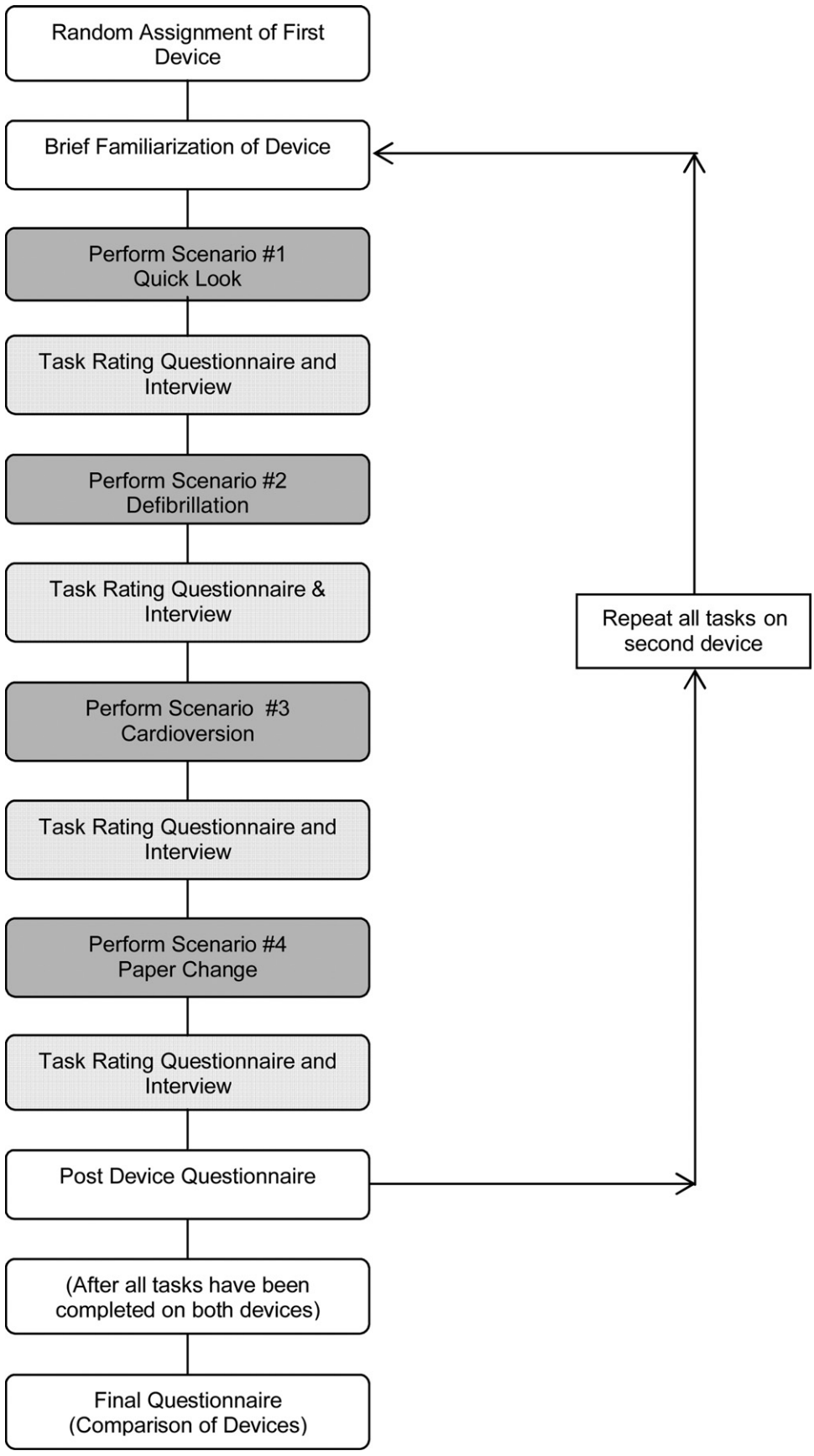

Figure 4. Study procedure.

Table. Participant rating of "task ease of use" and observer rating of "task success" for each device, and the 95% confidence interval (CI) around the difference between them.

	Task 1: Monitoring			Task 2: Defibrillation			Task 3: Cardioversion			Task 4: Paper Change		
Device	**Lifepak10**	**Lifepak12**	**Difference (95% CI)**	**Lifepak10**	**Lifepak12**	**Difference (95% CI)**	**Lifepak10**	**Lifepak12**	**Difference (95% CI)**	**Lifepak10**	**Lifepak12**	**Difference (95% CI)**
Participant rating "How would you rate the ease or difficulty of doing this task?" 1 (very difficult) to 9 (very easy)												
Rating (mean)	8.0	7.1	0.9 (0.04-1.7)	6.9	6.9	0.0 (−1.2-1.1)	5.3	6.7	1.4 (0.3-2.6)	6.4	6.9	0.4 (−1.4-0.6)
Observer rating of task success: 0 (failed) to 4 (excellent)												
Rating (mean)	3.4	3.1	0.3 (−0.4-1.0)	3.2	3.2	0.0 (−0.8-0.8)	1.6	3.1	1.5 (0.5-2.5)	2.1	3.0	0.9 (0.1-1.7)

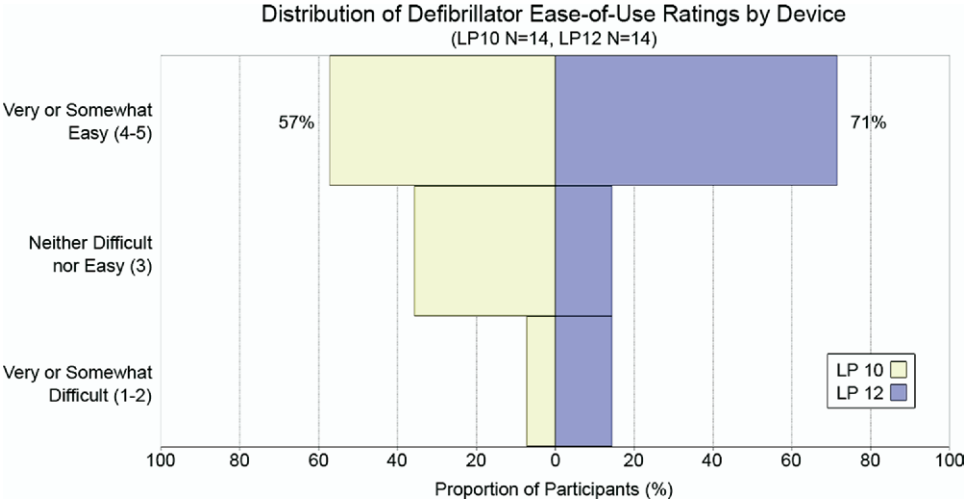

Figure 5. Participant ratings on "using the overall defibrillator" acquired after all 4 tasks were performed on each device model.

Participants' ease of use ratings are summarized in the Table. There were similar ratings between devices for tasks 2 and 4. The newer Lifepak12 was deemed less easy to use for the routine monitoring task yet easier to use for the more complex synchronized cardioversion task. Observer ratings, also shown in the Table, revealed similar success between devices for the routine monitoring and defibrillation tasks but better success on the newer Lifepak12 for the synchronized cardioversion and the paper-change tasks. The overall ease of use ratings for each device are shown in Figure 5. Eight participants (57%) rated the Lifepak10 and 10 (71%) rated the Lifepak12 somewhat or very easy to use.

The postdevice questionnaires revealed several findings. For both defibrillator models, the synchronized cardioversion and paper-change tasks were rated as the more difficult tasks. Three participants thought that defibrillation was the most difficult task on the Lifepak12, in contrast to none for the Lifepak10. Visibility of information on the display and replacing paper ease of use were both rated higher for the Lifepak12 than for the Lifepak10. Understanding the status information of the display received a favorable rating 3 times for the Lifepak10 compared with 8 times for the Lifepak12, though the means were similar (3.9 and 4.3, respectively).

One participant did not complete the final questionnaire. Analysis of the remaining 13 revealed that 11 (85%) participants preferred the Lifepak12 for use on a regular basis. And although 8 (62%) said the Lifepak12 would be more effective in an emergency, 9 (69%) believed the Lifepak10 is easier to learn.

Several themes emerged from the qualitative data and are presented below, organized by topic.

Seven of 14 (50%) participants performed at least 1 unsynchronized defibrillation when they intended to perform a synchronized cardioversion on the patient with SVT. Five of the 7 events occurred on the model that the participant prospectively stated they used most often in their practice. This event occurred only with the Lifepak10 for 4 participants, only on the Lifepak12 for 1 participant, and on both machines for 2 participants, and it occurred most often (but not always) during the second shock. In 5 of the 7 cases, the provider never recognized the mistake. Both units passively reset out of synchronized mode after a synchronized shock is delivered.

Several instances of delayed cardioversion were observed with the Lifepak10 when the participant was not aware that the signal gain was too low to facilitate "marking" of the ECG R wave. Observers noted related problems with the synchronized cardioversion mode feedback. After the participant pushed the "sync" button, the Lifepak10 displayed the word "SYNC" in steady state (eg, not flashing), which seemed to indicate that the machine was in synchronized mode. In fact, a constant display of the word "sync" indicates that the device is in synchronized mode but not ready to deliver a shock, whereas a flashing

display indicates a state of readiness, which caused confusion among some participants, one of whom even attempted to deliver a shock before the device was ready, thus learning by trial that the device was not ready.

Participants made multiple comments about the buttons, suggesting that they sometimes lead to confusion. Comments included reports of difficulty finding the right button and that they look too similar, particularly on the Lifepak12. One participant stated, "It is a busy display, and you have to look around at a lot of buttons to figure out which one you want to push." Another commented that the controls for the ECG amplitude and the QRS beep volume were easy to confuse.

Participants noted another difficulty with the button configuration: "With the gloves on, it is hard to hit the button in the right place because they are fairly flat and close together." This was sometimes noted to cause a hazard, such as inadvertent increase of the defibrillator energy level: "One time my thumb slipped and I hit the energy button instead of the charge button."

During the paper-change task on the Lifepak10, some participants pressed the "record" button repeatedly when the strip did not print. The Lifepak10 has no formal feedback mechanism to notify the user when it is out of paper, so the user must figure this out by trial and error. Also, the button is soft and gives no tactile, auditory, or visual feedback to the user to acknowledge that the input has been received (though paper printing is feedback in normal use). But the Lifepak12 avoided this problem because when the device was out of paper and the user pressed the "print" button, the device emitted a beep and displayed the words "check printer." An observer noted the following when watching a participant try to figure out why the Lifepak10 was not printing: "He presses the button repeatedly, stares at the screen, and says 'I'm trying to record here.'" In contrast, the effectiveness of the feedback provided by the Lifepak12 is demonstrated by this think-aloud comment, overheard as the participant was attempting to print a strip: "It's telling me to check printer . . . . Oh, the paper is out."

Participants had difficulty changing paper on both devices, particularly with gloves on. There were multiple occurrences of participants placing the paper with incorrect orientation (eg, putting it in backwards). Participants noted that the instructional diagram was not helpful, that the device accepted the paper even when it was oriented in the wrong direction, and that once paper was incorrectly placed, recognizing the problem took trial and error. When trying to correct the problem, participants had difficulty removing the incorrectly placed paper, especially with gloves on. Participants said, "It's difficult for me to get the paper out of there," and "You have to look down inside to see which way the paper goes, and it's not real visible," and "I couldn't get my fingers in to grasp the paper." Most participants had to take their gloves off to finish the paper-change task.

Participants found that several functions were difficult with gloves on. In addition to difficulty retrieving a wrongly placed roll (as discussed above), few participants were able to remove the wrapper from the new paper roll with their gloves on. When describing her problems changing paper, one participant said, "The difficulty increased because I had to take my gloves off to get to the paper and open it." Participants also had difficulty grasping the zipper tabs on the paper storage compartment when they had gloves on. Some of the participants' gloves actually became entangled in the zipper mechanism. In addition, participants reported that it was difficult to operate the defibrillator paddle controls when wearing gloves.

Participants commented on the difference between the devices in the selection of energy levels. The Lifepak10 easily progressed through each adult dose, but with the Lifepak12, participants had to toggle through several pediatric doses, resulting in the need for several inputs to go from one level to next during the defibrillation and cardioversion tasks. One participant expressed a typical concern: "I really disliked having to step through energy levels . . . so there is a lot of pushing buttons needlessly."

Observers noted that the Lifepak10 does not go automatically into paddles mode when the paddles are removed from the case. When the device is powered on, it is programmed to default to lead II (a programmable selection that makes sense for EMS because the majority of use is for simple monitoring). In some cases, the participants did not initially select the paddles mode when they attempted to perform a quick look. Because artifact produced when the device is set to lead II but not attached to the patient can mimic asystole or ventricular fibrillation, the potential for identification of the wrong rhythm exists. This problem is avoided in the Lifepak12 model, which recognizes when the leads are not connected to the patient and displays a message.

Participants and observers noted a predominant problem with tangled leads on both devices, including frustration due to perceived time delays.

Defibrillation is normally accomplished one of 2 ways, by manually applying paddles to the patient's skin or through hands-free multipurpose patches, which are also capable of monitoring and pacing. Many of the paramedics stated that the ability to control the defibrillator from the paddles is a beneficial tool. However, participants had trouble using the energy select feature, especially with gloves. This problem was exacerbated because the control is found on the left side, which is nondominant for most providers. The hands-free mechanism was praised by participants for allowing the operator to be located remotely from the patient when performing countershocks, likely to decrease the chance of an accidental shock.

LIMITATIONS

Several limitations to our study must be recognized. First, the devices are capable of performing more functions than were tested in our scenarios. However, we chose routine and emergency tasks that are typical of those performed by paramedics and some that incorporate multiple functions. We

did not control for previous experience with the individual devices in our analyses. But all participants reported familiarity (and field experience) with both models, and the need to use both models is a valid reflection on actual practice in our region, where paramedics frequently work for more than 1 agency and share equipment during multiple agency responses.

One of the key requirements of usability testing is to observe the device being used in true environmental conditions. Although we realistically simulated typical EMS scenarios, we were not able to conduct the test in all possible environments, such as inside a helicopter or ambulance or outside in the sun. For example, the displays were not tested in a high-ambient-light environment. Using context-appropriate stress levels in usability testing is also important. Although this study could not reproduce the stress involved with a true patient care situation, the more stressful real environment is likely to reveal even more hazards than we found.

Because it was important to select device models that participants would be familiar with and because almost all EMS agencies in our local region use Medtronic/Physio-control products, we did not test products from other manufacturers. However, it is likely that interface design issues are present in other brands of devices, and it was not our intent to compare usability between manufacturers.

Finally, the usability test scenarios did not involve simulated pediatric patients. Therefore, our results may not have identified issues that arise when tasks are performed on children.

DISCUSSION

Traditionally in medicine when an adverse event occurs the natural reaction is to assign fault to a person. The systems approach to reducing adverse events emphasizes that latent factors exist that either facilitate hazards or fail to protect patients from the effects of hazards. Failures in medical device user-interface design serve as an example of latent errors that can lead to adverse events.

Although usability testing has been recognized as an important component of medical device development, some experts in medical device usability assert that medical product manufacturers do not always conduct usability testing early enough in the development process and instead often identify usability problems after the final product has been produced, when design changes are prohibitively expensive.[16,29]

Published standards for the design of medical devices now specify a need for usability testing before US Food and Drug Administration approval, but there is no requirement to make results available to the consumer.[14,30,31] A higher level of awareness of the existence of usability testing might cause medical device consumers to request usability testing results when considering a new product.[32] This might in turn drive change in the industry, which presently has no motivation from the consumer to produce usability testing results.

One of the key principles in user-interface design is consideration for the actual conditions under which the device is intended to be used. Several issues identified by this study show room for improvement in designing devices for the EMS environment. For example, EMS providers are usually wearing gloves during patient care, and tasks such as changing paper and selecting defibrillation energy levels were found to be difficult with gloves on, which is significant because the need for new paper often arises during high-task times, which use larger amounts of paper, such as during resuscitations.

The most significant and potentially harmful use-related hazard noted by observers was the inadvertent failure to perform synchronized countershocks. This failure occurred most often during the second shock in the sequence, which suggests that the devices' passive reset out of synchronized mode was a contributing factor (eg, the only indication of mode change is the silent disappearance of the word "sync" on the display). Our data demonstrate that the device changes modes (from synchronized to unsynchronized) without effectively communicating this change to the user. A solution to this might be an audible alert or a message on the display that must be acknowledged by the user before proceeding. This hazard is not insignificant because unsynchronized countershock has the potential to cause ventricular fibrillation.[33]

A related user-interface design factor that confused several participants was that a constant display of the word "sync" on the Lifepak10 (and the indicator light on the Lifepak12) indicated that the device was in synchronized mode but not ready (eg, a problem state) while flashing indicated a state of readiness. This display is in conflict with population stereotypes in our culture, in which a flashing display indicates a problem condition.[34]

The monitor-defibrillator devices used in this study are also commonly found in the emergency medicine setting, where it is likely that similar problems occur. In contrast to EMS providers who use the monitor-defibrillator devices for daily ECG monitoring, most emergency departments (EDs) use installed bedside telemetry devices for this function and so use the portable devices only in emergencies. A low frequency of use can lead to decreased familiarity, so it is possible that some of the issues identified by this study are magnified in the ED setting.

The results of this study highlight several successes of the Lifepak12 user-interface design. The Lifepak12 is the newer-generation replacement for the Lifepak10, and because monitoring technology has advanced considerably, the Lifepak12 includes more monitoring functions than the Lifepak10. As a result, the user interface is necessarily much more involved, and without careful human factors engineering, this could lead to a higher incidence of use-related hazards. The most significant hazard we observed, inadvertent unsynchronized defibrillation, occurred much less often on the Lifepak12. Although participants perceived that the Lifepak10 was easier to learn, they thought the Lifepak12 had better visibility of information, better communicated status, and an easier paper-change mechanism. The majority of participants said they

would prefer to use the Lifepak12 on a regular basis, and most believed it was more effective in an emergency. Thus, the Lifepak12 user-interface design not only eliminated several problems encountered on the older Lifepak10 but also was the preferred device by participants, despite its increased complexity. Although proprietary companies do not generally publish the results of their own usability studies in the medical literature, it is evident that the manufacturer has given attention to the user-interface design of the Lifepak12.

Finally, our data highlight the need for further study of hazards in EMS, beyond that of event reporting, one traditional method of evaluating hazards in an environment. Five of the episodes of inadvertent defibrillation were completely unrecognized by the participants. To learn about adverse events that occur during actual patient care, it will be necessary to use simulation or real-time data collection methods such as videotaping and analysis of event and vital sign data stored by the monitor-defibrillator devices.

In conclusion, the Lifepak10 seems easier to learn, but the Lifepak12 is perceived as easier to use continually and more effective in emergencies. Several use-related hazards were identified, suggesting a need for further focus on user-interface design of medical devices used in the emergency medicine setting. Additional training of medical personnel to compensate for user-interface design problems is not, by itself, the answer to avoiding adverse events in medicine.

The authors wish to thank Jennifer Williams, Sarah Campbell, MS, Peter Bonadonna, EMT-P, and the paramedic participants for their assistance with this study, as well as the Monroe Community College and the Monroe County Public Safety Training Facility for the use of equipment and facilities.

Supervising editor: Robert L. Wears, MD, MS

Author contributions: RJF and SHC conceived the study, designed the study, and obtained research funding. RJF, SHC, and MNS supervised the conduct of the trial and data collection. RJF, PAB, AMM, and MNS undertook recruitment of participating paramedics. RJF, SHC, and MNS managed the data. All investigators participated in the qualitative analysis. MNS provided statistical advice and RJF, SHC, and MNS analyzed the data. RJF and SHC drafted the article, and all authors contributed substantially to its revision. RJF takes responsibility for the paper as a whole.

Funding and support: By *Annals* policy, all authors are required to disclose any and all commercial, financial, and other relationships in any way related to the subject of this article, that may create any potential conflict of interest. See the Manuscript Submission Agreement in this issue for examples of specific conflicts covered by this statement. This research was supported by the University of Rochester Department of Emergency Medicine research seed funding. At the time of the study, Drs. Fairbanks and Shah were supported by funding from the National Institutes of Health (1R41NR009592) and Agency for Healthcare Research and Quality (1U18HS015818), and Dr. Shah, by funding from Health Resources and Services Administration.

Publication dates: Received for publication June 2, 2006. Revisions received January 3, 2007, and March 22, 2007. Accepted for publication March 27, 2007. Available online May 11, 2007.

Presented in part at the Human Factors and Ergonomics Society 48th annual meeting, September 2004, New Orleans, LA; and the National Association of EMS Physicians meeting, January 2006, Tucson, AZ.

Reprints not available from the authors.

Address for correspondence: Rollin J. (Terry) Fairbanks, MD, MS, NREMTP, Department of Emergency Medicine, University of Rochester Medical Center, 601 Elmwood Avenue, Box 655, Rochester, NY 14642; 585-273-3849, fax 585-275-2092; E-mail Terry.Fairbanks@Rochester.edu.

REFERENCES

1. Fairbanks RJ, Caplan S. Poor interface design and lack of usability testing facilitate medical error. *Jt Comm J Qual Saf.* 2004;30:579-584.
2. Weinger MB, Pantiskas C, Wiklund ME, et al. Incorporating human factors into the design of medical devices [letter]. *JAMA.* 1998; 280:1484.
3. Crowley JJ, Kaye RD. Identifying and understanding medical device use errors. *J Clin Aging.* 2002;summer:188-193.
4. Welch DL. Human factors in the health care facility. *Biomed Instrument Tech.* 1998;32:311-316.
5. Gosbee JW, Lin L. The role of human factors engineering in medical device and medical system errors. In: Vincent C, ed. *Clinical Risk Management: Enhancing Patient Safety.* London: BMJ Press; 2001:301-317.
6. Perry SJ. An overlooked alliance: using human factors engineering to reduce patient harm. *Jt Comm J Qual Saf.* 2004;30:455-459.
7. Israelski EW, Muto WH. Human factors risk management as a way to improve medical device safety: a case study of the Therac 25 radiation therapy system. *Jt Comm J Qual Saf.* 2004;30:689-695.
8. Bogner MS. There is more to error in healthcare than the care provider. Proceedings of the Human Factors and Ergonomics Society 49th annual meeting, Orlando, FL. 2005:952-954.
9. Gosbee JW. Who left the defibrillator on? *Jt Comm J Qual Saf.* 2004;30:282-285.
10. Lum TE, Fairbanks RJ, Pennington EC, et al. Misplaced femoral line guidewire and multiple failures to detect foreign body on chest x-ray. *Acad Emerg Med.* 2005;12:658-662.
11. Wiklund ME. Eleven keys to designing error-resistant medical devices. *MDDI.* 2002;24:86-102.
12. Kushniruk AW, Triola MM, Stein B, et al. The relationship of usability to medical error: an evaluation of errors associated with usability problems in the use of a handheld application for prescribing medications. *Medinfo.* 2004:1073-1076.
13. American National Standards Institute, Association for the Advancement of Medical Instrumentation. HE 74: *2001—Human Factors Design Process for Medical Devices*. American National Standards Institute, Association for the Advancement of Medical Instrumentation; 2001.
14. CDRH. *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management. Guidance for Industry and FDA Premarket and Design Control Reviewers*. 2000:2-33.

15. Wichansky AM. Usability testing in 2000 and beyond. *Ergonomics.* 2000;43:998-1006.
16. Welch DL. Human factors analysis and design support in medical device development. *Biomed Instrument Tech.* 1998;32:77-82.
17. Gosbee JW, Klancher J, Arnecke B, et al. The role of usability testing in healthcare organizations. Paper presented at: Proceedings of the Human Factors and Ergonomics Society 45th annual meeting, Minneapolis, MN. 2001.
18. Kushniruk AW, Triola MM, Borycki EM, et al. Technology induced error and usability: the relationship between usability problems and prescription errors when using a handheld application. *Int J Med Inform.* 2005;74:519-526.
19. Caplan S. Test the ergonomics. *Machine Design.* 2004;76:108-109.
20. Obradovich JH, Woods DD. Users as designers: how people cope with poor HCI design in computer-based medical devices. *Hum Factors.* 1996;38:574-592.
21. Callejas S, Barry A, Demertsidis E, et al. Human factors impact successful lay person automated external defibrillator use during simulated cardiac arrest. *Crit Care Med.* 2004;32:S406-S413.
22. Eames P, Larsen PD, Galletly DC. Comparison of ease of use of three automated external defibrillators by untrained lay people. *Resuscitation.* 2003;58:25-30.
23. Fairbanks RJ, Crittenden CN, O'Gara KG, et al. The nature of adult and pediatric adverse events and near misses in EMS [abstract]. *Prehosp Emerg Care.* 2005;9:102-103.
24. Stiell IG, Wells GA, Field BJ, et al. Improved out-of-hospital cardiac arrest survival through the inexpensive optimization of an existing defibrillation program: OPALS Study Phase II. Ontario Prehospital Advanced Life Support. *JAMA.* 1999;281:1175-1181.
25. Faulkner L. Beyond the five-user assumption: benefits of increased sample sizes in usability testing. *Behav Res Methods Instrum Comput.* 2003;35:379-383.
26. Fairbanks RJ, Caplan S, Shah MN, et al. Defibrillator usability study among paramedics. Proceedings of the Human Factors and Ergonomics Society 48th annual meeting; September 24, 2004; New Orleans, LA.
27. Pope C, Ziebland S, Mays N. Qualitative research in health care. Analysing qualitative data. *BMJ.* 2000;320:114-116.
28. Jordan PW. *An Introduction to Usability*. Bristol, PA: Taylor & Francis; 1998.
29. Wiklund ME. Usability tests of medical products as prelude to the clinical trial. *Med Device Diagnostic Industry.* 1991:13:46-52.
30. ANSI/AAMI. HE 48: *1993—Human Factors Engineering Guidelines and Preferred Practices for Design of Medical Devices*. 1993.
31. Sawyer D. Do it by design. The FDA Center for Devices and Radiological Health (CDRH). Available at: http://www.fda.gov/cdrh/humfac/doit.html. Accessed August 15, 2006.
32. Keselman A, Tang X, Patel VL, et al. Institutional decision-making for medical device purchasing: evaluating patient safety. *Medinfo.* 2004:11(part 2):1357-1361.
33. Ebrahimi P, Rubin SA. Electrical cardioversion resulting in death from synchronization failure. *Am J Cardiol.* 1994;74:100-102.
34. Department of Defense. Design criteria standard for human engineering. MIL-STD 1472F, August 1999, Paragraph 5.2.2.3.3.