Hazards With Medical Devices: The Role of Design

Rollin J. Fairbanks, MD, MS
Robert L. Wears, MD, MS

From the Department of Emergency Medicine, University of Rochester, Rochester, NY (Fairbanks); and the Department of Emergency Medicine, University of Florida Jacksonville, FL, and the Clinical Safety Research Unit, Imperial College, London, UK (Wears).

0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2008.07.008

SEE RELATED ARTICLES, P. 512 AND 515.

[Ann Emerg Med. 2008;52:519-521.]

There is a growing body of literature highlighting the role of medical device design in preventing (or facilitating) adverse events.[1-9] However, adverse event investigations in medicine often overlook subtle, latent hazards in design.[6] These inquiries often end (prematurely) with recommendations for remediation, new policies, and "soporific injunctions about better training."[10] However, these are the weakest and least sustainable options for improving human performance or system safety[11] and reflect an impoverishment of ideas about what it is possible to do. In contrast, identification and subsequent modification of the nonhuman contributors to the event can have a lasting influence because they will outlast institutional or individual memory, the effect of training, or knowledge of policies.

In this issue of *Annals*, 2 articles describe untoward events involving monitor/defibrillators. Stewart[12] reports a significant delay in defibrillation caused by leads-off artifact which mimicked asystole, and Hoyer et al[13] report an incidental finding during a simulation study involving the inadvertent powering down of a defibrillator when defibrillation was intended.

Stewart[12] describes a code team working on a cardiac arrest patient for 13 minutes while the monitor/defibrillator was inadvertently set to "paddles" mode, creating an artifact that led them to treat the patient for what they thought was pulseless electrical activity and asystole. In reality, the providers were responding to artifact and likely missed an opportunity to provide early defibrillation to a patient in ventricular fibrillation. Once shocks were delivered, the patient regained a pulse but had sustained profound neurologic injury. Although initial reactions to this event might be to provide retraining or reminders, these are known to be short-lived and ineffective interventions. Better solutions, as the author points out, might be to replace the paddles with multifunction pads (which allow monitoring), change the default lead selection, or eliminate older monitor/defibrillators that do not automatically detect wrong lead selection. Although these interventions need to be carefully evaluated and may require investment, they at least offer the prospect for real and sustained change, whereas adding training or posting reminders gives only the appearance of activity.

In the second article, Hoyer et al[13] described an unexpected finding during a simulation study, in which they observed 5 occurrences of physicians inadvertently powering down a defibrillator when they intended to deliver a shock. This misstep was probably facilitated by the design of the controls and the lack of a forcing function that would not allow a fully charged monitor/defibrillator to be powered off without confirmation. The authors point out that common devices (eg, multimedia projectors) require confirmation before powering down and ask why defibrillators would be designed without this protection.

Technologies often fail to deliver their promised benefits when they are not designed in a way that matches the needs, cognitive processes, and environments of the intended users.[14-18] In addition, purchasers (eg, hospital supply officials) and end users seem naive about the role that device design can play in enhancing or degrading safe and effective performance.[19,20]

Even worse, manufacturers have publicly taken the stand that it is up to the end user to use the device correctly, as long as there is an instruction manual that describes "correct operation."[21] In fact, in a recent litigation involving inadvertent delivery of an unsynchronized shock (triggering ventricular fibrillation) when synchronized cardioversion was intended, a vendor's representative has testified under oath that a physician should have taken time to ask emergency department (ED) staff for an operator's manual for the monitor/defibrillator and read it after he arrived in the ED to perform a cardioversion.[21] Although simulation studies have shown that this kind of mishap is relatively common,[8] these attitudes suggest a complete loss of touch with the actual environment in which medical devices are used. It would be hard to find a physician or nurse who has even seen or would know where to find, much less read, an operator's manual for any of the devices they use in their daily practice. No other hazardous industry would deploy technology in this manner, putting the burden of proof on the user to prove that a device is hazardous, rather than on the vendor to prove that it is not.[22]

If one takes a systems approach to designing a medical device in a user-centered manner, then the device would match the way practitioners think, the way they operate in their daily

practice, and the limitations of their environment and working conditions.[23] Such an approach adds expense to development (although it may save overall resources from the societal point of view), so there is currently a negative incentive for developers to attend to the problems of usability. In addition, a recent Supreme Court ruling has limited the liability of medical device manufacturers,[24] decreasing the threat of litigation. Although the Food and Drug Administration (FDA) requires a human factors analysis during the approval process for new medical devices,[25] these analyses are neither independent nor publicly available; their adequacy is clearly questioned by the fact that both the devices in these cases were FDA approved. Other potential actors such as The Joint Commission, state departments of health, professional organizations, and payers have paid even less attention to medical device design. The factor of public dread that has motivated public and regulatory safety efforts in the nuclear power, aviation, chemical, and oil industries is not salient because adverse events and near misses in health care are small in their destructive potential. In addition, when compared to these industries, incident investigations in health care tend to be superficial, lacking in resources and technical sophistication, and are not independent of stakeholder interests, all of which are factors that limit the potential for learning. This unfortunately leaves pressure from consumers as the sole motivating factor for improvement, but the primary consumers, hospital supply officials, are not focused on patient safety and seem unaware of design issues.

However, simply shifting the blame to device manufacturers, who are also working under severe constraints, will not solve the problem. We rather wish to foster a greater sense of shared responsibility and an understanding among hospital supply officers and root cause analysis teams that the design of medical devices can have an enormous influence on patient safety and thus warrants more attention. In linguistics, there is an aphorism that a native speaker of a language can never make a grammatical error (because, after all, the language is that which native speakers speak). A similar attitude should inform adverse event investigations related to devices; if a reasonable user appears to have made an error with a device, we should start by presuming a design problem rather than a user problem and work from that starting point to find avenues for improvement.

There is an ethical component to patient safety[26]; we have an ethical responsibility to respond to adverse events and near misses by improving the system in ways that will protect future patients. Especially once we know what can happen, we cannot be satisfied with weak solutions that provide the illusion of action but will accomplish little or nothing, such as new policy, exhortation, and training. Caregivers, supply officers, health care leaders, regulators, manufacturers, and users of medical devices must take into account the role device design can play in improving safety. This will require both will and resources, but to do nothing condemns both patients and clinicians to future tragedies.

Supervising editor: Michael L. Callaham, MD

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 might create any potential conflict of interest. See the Manuscript Submission Agreement in this issue for examples of specific conflicts covered by this statement. Rollin J. Fairbanks serves as an expert witness for an ongoing medical device liability case (Johnson v. Medtronic), which alleges that defibrillator design contributed to an adverse event. However, remuneration is not based on outcome of the case, and parties involved with the case had no association with or involvement with the development of this editorial. Dr. Fairbanks is supported by a research training grant from the Emergency Medicine Patient Safety Foundation through the Society for Academic Emergency Medicine.

Publication date: Available online August 22, 2008.

Address for reprints: Rollin J (Terry) Fairbanks, MD, MS, Department of Emergency Medicine, University of Rochester Medical Center, 601 Elmwood Avenue, Box 655, Rochester, NY 14642; 585-463-2920, fax 585-463-2966; E-mail Terry.Fairbanks@Rochester.edu.

REFERENCES

1. 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(9 suppl):S406-413.
2. 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.
3. Macdonald RD, Swanson JM, Mottley JL, et al. Performance and error analysis of automated external defibrillator use in the out-of-hospital setting. *Ann Emerg Med*. 2001;38:262-267.
4. Monsieurs KG, Vogels C, Bossaert LL, et al. A study comparing the usability of fully automatic versus semi-automatic defibrillation by untrained nursing students. *Resuscitation*. 2005;64:41-47.
5. Drews FA, Picciano P, Agutter J, et al. Development and evaluation of a just-in-time support system. *Hum Factors*. 2007; 49:543-551.
6. 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; September 26-30, 2005.
7. Gosbee J, 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, England: BMJ Press; 2001:301-317, chapter 316.
8. Fairbanks RJ, Caplan SH, Bishop PA, et al. Usability study of two common defibrillators reveals hazards. *Ann Emerg Med*. 2007;50: 424-432.
9. Karsh BT, Scanlon M. When is a defibrillator not a defibrillator? when it's like a clock radio. The challenge of usability and patient safety in the real world. *Ann Emerg Med*. 2007;50:433-435.
10. Perrow C. *Complex Organizations: A Critical Essay*. 3rd ed. New York, NY: Random House; 1986.
11. Wickens CD, Gorden SE, Liu Y. *An Introduction to Human Factors Engineering*. New York, NY: Longman; 1998.

12. Stewart JA. Delayed defibrillation caused by unexpected ECG artifact. *Ann Emerg Med*. 2008;52:515-518.
13. Hoyer CS, Christensen EF, Eika B. Adverse design of defibrillators: turning off the machine when trying to shock. *Ann Emerg Med*. 2008;52:512-514.
14. Koppel R, Metlay JP, Cohen A, et al. Role of computerized physician order entry systems in facilitating medication errors. *JAMA*. 2005;293:1197-1203.
15. Tenner E. *Why Things Bite Back: Technology and the Revenge of Unintended Consequences*. New York, NY: Vintage Books; 1997.
16. Rochlin GI. *Trapped in the Net: The Unanticipated Consequences of Computerization*. Princeton, NJ: Princeton University Press; 1997.
17. Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. *J Am Med Informat Assoc*. 2004;11:104-112.
18. Cook RI, Woods DD. Adapting to new technology in the operating room. *Hum Factors*. 1996;38:593-613.
19. Johnson TR, Tang X, Graham MJ, et al. Attitudes toward medical device use errors and the prevention of adverse events. *Jt Comm J Qual Patient Saf*. 2007;33:689-694.
20. Johnson CW. Why did that happen? exploring the proliferation of barely usable software in healthcare systems. *Qual Saf Health Care*. 2006;15(suppl 1):i76-81.
21. Deposition of David Hahn, MD, p 108-110, Case No. 07 CY CV 02477 in the Circuit Court of Clay County, MO (Oct 18, 2007).
22. Jackson D, Thomas M, Millett LI. Executive summary. In: Jackson D, Thomas M, Millett LI, eds. *Software for Dependable Systems: Sufficient Evidence?* Washington, DC: National Academy Press; 2007:1-15.
23. Klein G, Woods DD, Bradshaw JM, et al. Ten challenges for making automation a "team player" in joint human-agent activity. *IEEE Intelligent Syst*. 2004;19:91-95.
24. Riegel v. Medtronic, Inc., case number WL 440744, Supreme Court, 2008.
25. Burlington DB. Human factors and the FDA's goals: improved medical device design. *Biomed Instrum Technol*. 1996;30:107-109.
26. Patankar MS, Brown JP, Treadwell MD. *Safety Ethics: Cases From Aviation, Healthcare, and Occupational and Environmental Health*. Aldershot, UK: Ashgate; 2005.