Process Without Progress: Emergency Medicine, Patient Safety, and the Need for Science

Christopher Nemeth, PhD

From Applied Research Associates, Evanston, IL.

0196-0644/$-see front matter

doi:10.1016/j.annemergmed.2011.08.016

SEE RELATED ARTICLE, P. ■■■.

[Ann Emerg Med. 2011;■■:■■.]

> The first principle is that you must not fool yourself, and you are the easiest person to fool.[1]
>
> —*Richard Feynman*

Often paraphrased as "science is a way of trying not to fool yourself," the above quote comes from Nobel Prize–winning physicist Richard Feynman's 1974 address[1] to California Institute of Technology graduates. In this issue of *Annals*, DeLuca et al[2] presents a review of automated external defibrillator misadventures that have been reported to the Food and Drug Administration (FDA) through the Manufacturer and User Facility Device Experience (MAUDE) database. This article discusses patient safety research in emergency medicine and how to avoid fooling yourself.

Databases such as MAUDE appear to inspire confidence. They're repositories for data, and data suggest science is at work. Programs seem to put faith in databases as a solution. For example, patient safety organizations are encouraged to funnel their reports to a national database.[3] The Office of the National Coordinator for Health Information Technology recently proposed creation of an information technology problems database as the solution to the risks of health care information technology.[4] Data aggregations seem to account for events such as misadventures. But the context that formed the event and gave it meaning is missing. How can we trust our view of what happened without understanding context?

Context is also an issue in the DeLuca effort. The FDA cautions that "MAUDE data [are] not intended to be used either to evaluate rates of adverse events or to compare adverse event rates across devices."[5] This is for good reason. Submitting a report to the MAUDE database may be voluntary. We can't know the true number of events that really did occur. And MAUDE reports are not verified, so we have no way to know whether the reports are actually true. The essay uses MAUDE report data to account for events in which automated external defibrillators were reported to malfunction. It notes that the FDA mandates reporting when using a device results in a fatality. But being mandatory does not guarantee compliance. Did the device cause a fatality, or did the patient die because of some other reason? It isn't necessarily clear.

The author describes these as limitations. These aren't limitations, though. They're flaws. Publication in a journal requires proving the point an author tries to make. Even if the analysis is good, starting with data that can't be verified makes us vulnerable to fooling ourselves.

MAUDE data are not the only ones that may be available yet misleading. For example, the FDA's substantial equivalence procedure is based on the legacy of previous ("predicate") equivalent products. But legacy devices were not necessarily subject to rigorous science when they were initially approved.[6]

Being well informed about issues related to patient safety starts with having good data—valid observations of actual phenomena. This includes understanding equipment, such as automated external defibrillators. Without data on human cognitive performance in health care and how technology affects it, we have no valid information on what the real world of health care is like. Without these kinds of valid, reliable data, any efforts to improve patient safety are just a collective guess.[7]

Could the MAUDE data be used in some way? Yes, they could, if only to note that something's up. The reports suggest where to look for data that *are* valid. Not an ending for research, but a starting point. And that needs a guide. I have found these resources to be a great help in this kind of work.

- Barley and Orr's *Between Craft and Science*[8] describes the ethnographic study of technical work.
- *Workplace Studies* by Luff et al[9] and Heath and Luff's *Technology in Action*[10] describe approaches to the study of complex systems, particularly those that feature advanced technology.
- Bordens and Abbott's *Research Design and Methods*[11] clearly describes data collection and analysis.
- *The Craft of Research* by Booth et al[12] demonstrates how to turn a topic into a research problem and then build a warrant for claims based on the research.

DISCUSSION

Efforts by the emergency medicine community to improve safety for practitioners and patients are not only desirable but also necessary. Effort alone, though, is insufficient to make progress. Progress relies on methodical inquiry—honest,

organized, deep looks at the real world—to ensure that what we do is free from presumption and bias that can otherwise afflict human reasoning. It also takes time to understand what we have learned and share it with others in a way that helps. Understanding what to look for in the real world, appreciating it, and making sense of it rely on an open mind, tools of inquiry, and patience. I've recommended taking a methodical approach. That leads to the topic of science. And the next question is, what *is* science? Feynman[13] reflected, "I learned then what science was about: it was patience. If you looked, and you watched, and you paid attention, you got a great reward from it—although possibly not every time." Science, then, is patiently observing the real world.

The pressure to publish and accommodate demanding clinical schedules pushes the emergency department (ED) community into a difficult position. Resources and time are limited, which makes it all the more important to use research time and funds effectively.

This is not a call for "evidence-based medicine." It's a call to do original research. Develop insightful research that gets at the actual nature of emergency medicine and its safety issues. Then build on the work that others have done on that theme.

The most direct way to combine medicine and scientific inquiry into patient safety is collaboration between qualified MDs and PhDs. In these ventures, MDs contribute expertise in medicine. PhDs in human factors or other safety sciences have expertise in the design and execution of research on human performance and contribute theories and tools to make it instructive. Peer-reviewed articles by collaborating MDs and PhDs[14-21] have reported on such work for years.

CONCLUSION

The 1974 Cal Tech address by Feynman was titled "Cargo Cult Science." In it, he compared those who perform science without insight to South Sea Island cargo cults in the 1940s. These were indigenous peoples who had seen aircraft land with supplies during World War II Pacific Island campaigns. Without understanding what airlifts were, they mimicked superficial aspects of landing strips and flight in the hope that the planes would return. Of course, the planes didn't land. Those who mimic the process of science without understanding it are in the same boat.

Time, resources, and the faith of patients who rely on the ED community, are precious. Mimicking science wastes all three. Science will not necessarily produce the right answer right away. But the ED community is obliged to get on with understanding the real world through genuine inquiry that is open minded, methodical, and patient.

The author acknowledges Robert Wears, MD, MS, and Jay Crowley, MS, of the Food and Drug Administration for insightful comments during the preparation of this editorial.

Supervising editor: Judd E. Hollander, 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 as per ICMJE conflict of interest guidelines (see www.icmje.org). The author has stated that no such relationships exist.

Address for correspondence: Christopher Nemeth, PhD, Email cnemeth@ara.com.

REFERENCES

1. Feynman R. Cargo cult science. *Engineer Sci*. 1974;June:10-13.
2. DeLuca LA Jr, Simpson A, Beskind D, et al. Analysis of automated external defibrillator device failures reported to the Food and Drug Administration. *Ann Emerg Med*. 2011;XX.XX.
3. Agency for Healthcare Research and Quality, Department of Health and Human Services. About the PSOPPC. Available at: https://www.psoppc.org/web/patientsafety/gettingstarted. Accessed August 22, 2011.
4. Egerman P, Probst M. Memorandum to David Blumenthal: Adoption-Certification Workgroup HIT safety recommendations. Available at: http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_911847_0_0_18/AdoptionCertificationLetterHITSafetyFINAL508.pdf. Accessed August 22, 2011.
5. Food and Drug Administration. MAUDE=Manufacturer and User Facility Device Experience. 2011. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm. Accessed August 14, 2011.
6. Institute of Medicine. *Medical Devices and the Public's Health: The FDS 510(k) Clearance Process at 35 Years. Committee on the Public Health Effectiveness of the FDA 510(k) Clearance Process*. Washington, DC: National Academies Press; 2011.
7. Nemeth C. *Perspective: The Safety of Medical Devices. Web M&M: Morbidity and Mortality Rounds on the Web*. Washington, DC: Agency for Healthcare Research and Quality; 2011.
8. Barley SR, Orr JE, eds. *Between Craft and Science: Technical Work in US Settings*. Ithaca, NY: Cornell University Press; 1977.
9. Luff P, Hindmarsh J, Heath C, eds. *Workplace Studies: Recovering Work Practice and Informing System Design*. New York, NY: Cambridge University Press; 2000.
10. Heath C, Luff P. *Technology in Action*. New York, NY: Cambridge University Press; 2000.
11. Bordens KS, Abbott BB. *Research Design and Methods: A Process Approach*. 7th ed. San Francisco, CA: McGraw-Hill; 2009.
12. Booth WC, Colomb GG, Williams JM. *The Craft of Research*. 3rd ed. Chicago, IL: University of Chicago Press; 2008.
13. Feynman R. What is science? 1966. Presented at the fifteenth annual meeting of the National Science Teachers Association, 1966 in New York City. Reprinted from *The Physics Teacher* Vol. 7, issue 6, 1969, pp 313-320 by permission of the editor and the author. Available at: http://www.feynmanomline.com. Accessed August 14, 2011.
14. Xiao Y, Fairbanks RJ. Speaking systems engineering: bilingualism in health care delivery organizations. *Mayo Clin Proc*. 2011;86:719-720.
15. Fairbanks RJ, Bisantz AM. Understanding better how clinicians work. *Ann Emerg Med*. 2011;58:123-125.
16. Pennathur PR, Cao D, Sui Z, et al. Development of a simulation environment to study emergency department information technology. *Simul Healthc*. 2010;5:103-111.
17. Wears R, Nemeth C. Replacing hindsight with insight: toward a better understanding of diagnostic failures. *Ann Emerg Med*. 2007;49:206-209.

18. Patterson ES, Woods DD, Cook RI, et al. Collaborative cross-checking to enhance resilience. *Cogn Technol Work*. 2007;9:155-162.
19. Patterson ES, Woods DD, Roth EM, et al. Three key levers for achieving resilience in medication delivery with information technology. *J Patient Saf*. 2006;2:33-38.
20. Nemeth CP, Wears RL, Woods DD, et al. Minding the gaps: creating resilience in healthcare. In: Henriksen K, Battles JB, Keyes MA, et al, eds. *Advances in Patient Safety: New Directions and Alternative Approaches. Vol. 3. Performance and Tools*. Rockville, MD: AHRQ; 2008:(9.29 MB). AHRQ Publication No. 08-0034-3.
21. Nemeth CP, O'Connor MF, Klock PA, et al. Discovering healthcare cognition: the use of cognitive artifacts to reveal cognitive work. *Organization Studies*. 2006;27:1011-1035.