

The Safety of Medical Devices

Perspective

by Christopher Nemeth, PhD

Edward Tenner is right. Technology does have reverberations, including unintended consequences, or "revenge effects."⁽¹⁾ While such drawbacks are inherent in technology, our poor understanding of technology in health care is a much larger problem. We don't know enough about products or systems that people use to know what can happen. Compared with ignorance, the revenge effects that are inherent in technology are minor.

When we talk about the safety of medical devices, "safe" implies an expectation that a device will keep us free from harm. How safe are medical devices? Eleven years after the Institute of Medicine report *To Err is Human* (2), there is ample evidence to indicate that issues with device safety remain substantial and widespread. Here are just a few examples.

- Device recalls are the most valid current measure of device failure. I reviewed 1,573 medical device recalls for the U.S. Food and Drug Administration (USFDA) Center for Devices and Radiologic Health (CDRH) that occurred during January 2006–May 2008. Eight hundred ten (51.5%) had human factors (3) at issue and failed in one or more aspects of reliability, efficiency, or safety. For example, software malfunction prevented a defibrillator from delivering shocks when needed. The back of a patient chair on a tomography system bent and broke off, allowing a patient to fall. A ventricular assist device (VAD) permitted implantation of the wrong size nut, causing a poor connection with the inflow cannula that resulted in patient death (Nemeth C, unpublished data).
- Even when the threat from a medical device is known, its solution can still be elusive. In April 2006, members of the surgical team placed an anesthetized patient onto a modular table during preparations for a spinal procedure. While the team adjusted the table, it swung loose and the patient fell to the floor but sustained no injury. The surgical department was aware of the table's flaws, but was willing to trade off the table's safety issues with the unit's features that they felt made it desirable to continue its use. Warranty and USFDA approval concerns precluded the hospital from modifying the equipment. The hospital developed a report of the event for the manufacturer. It also produced a brief improvement plan that included training surgical care team members and hanging a warning sign from the lever on the side of the table's head end control housing. The sign was not used. The table and its inherent safety problems remained in use.⁽⁴⁾
- A recent article on the danger presented by interchangeable intravenous and feeding tubes (5) generated a series of simple, presumptive solutions (6) pointing in directions that could almost be predicted, from clinicians (label the tubes; don't replace trained practitioners with others who are less qualified), to a government agency (we're on it), and a trade organization (have the government mandate bar codes).

While notions about solutions are simple, the problem and its context are complex. In all of the above examples, the "device" does not stand alone, but is instead part of a larger system that influences its use and effects on patient care and outcomes. The [Figure](#) illustrates how an infusion "device," the most widely used information technology (IT) in health care, is actually an interdependent network of relationships. It's a socio-technical system that spans all who develop, supply, and use the result, from the level of the care provider or manufacturer organization, to associations and regulators, to government. This requires a different approach to safety: at the systems, not the device, level.

Complex systems have properties of operation and failure that require study.⁽⁷⁾ Health care is a complex sector, with complex phenomena that make it more difficult to generate reliable evidence.⁽⁸⁾ Health care continues to resist study for a number of reasons. Departments are separated and teams resist scrutiny. Organizations are pressured to maximize revenue by operating at, or near, saturation. Devices increase in complexity and new versions replace them frequently. Even if we did understand today's version of hardware or software, tomorrow's version will soon come along to replace it. The training that care providers receive about devices is protracted and designed to show what to do when things go right, and omits what to do when they go wrong. Reporting systems abound but lack data collection standards and robust evaluation processes that might make them useful. Too few clinicians question the effect a new technology may have on the patient. Too few manufacturers invest in understanding human performance and how to accommodate operator needs and abilities. Oversight by government agencies is impeded because they are obliged to respect what they are and are not authorized to do, such as oversee devices that are already in the market.

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