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Safe and Scalable Device Design: A Call for Open Standards

To the Editor:

We commend Pronovost *et al.*¹ for their recent comments regarding the paucity of automated and interconnected medical devices to improve patient safety. Although they identify that a big step forward occurred a year ago when technology companies agreed to share patient data with clinicians at the Patient, Safety Science, and Technology Summit, they did not emphasize that a key, although missing, piece preventing the interoperability of devices was a lack of a common digital code or language across all devices.

The history and political economic trajectory of the World Wide Web development from the 1990s provide our industry with a good roadmap to promote interoperability of our medical devices. Many of us would agree that one of the benefits and the power of the World Wide Web lies in that we can access information from different locations, different computers, and different operating systems including Apple, Windows, Linux, and Android *etc.* The strength and utility of the World Wide Web derives from the fact that the network is so vast because of the interoperability of all the different devices into common coding protocols. The fact that all of our Web browsers use the same address prefix (<http://www>) is not an accident—but a common coding agreement. Let us not forget that in the early 1990s, when Jim Clark and Marc Andreessen were developing the Mosaic Web browser (funded by the National Science Foundation), they emphasized a set of open protocols for the Internet, which was promoted by other computer scientists including Tim Berners-Lee, Vint Cerf, and Bob Kahn, to ensure that every system could “talk to each other.” These protocols still exist as some of the universal Internet acronyms such as FTP, HTTP, HTML, SSL, SMTP, POP, and TCP/IP. The private companies followed this trend when Microsoft, International Business Machines (IBM), and other technology companies developed XML (extensible markup language) and SOAP (simple object access protocol)—which, in the words of *New York Times* author Thomas Friedman, flattened the world of Internet technology so that individual companies would stop competing over market dominance of the Internet alone with proprietary code but rather focus on the quality of the products that the consumers used on the Internet itself.²

The medical industry needs a similar story to ultimately reach the same level of interoperability and automation of its

devices. However, this needs to be done *via* a joint effort of public policy and private industry. It is not enough for the medical device companies to merely share patient data with clinicians. We need the Food and Drug Administration (FDA) to promote an agreed-upon coding language and a set of “open protocols” for medical devices and electronic medical records before it grants FDA clearance. Once a common coding language or standard emerges, medical devices and records will truly be able to speak to each other. We will then be able to experience realistic “plug-in-play” capabilities within our wards, our operating rooms, and our intensive care units and realize the possibilities of patient safety design that Pronovost *et al.* have kindled in our minds. Such a common standard will also lower the coding barriers for entry into this product market thus allowing entrepreneurial clinicians and researchers to create decision support and data management systems that can be widely integrated in less expensive ways into care across the country. As clinicians, we need to promote this movement by voting with our hospital dollars when we make device purchases and we need to lobby the FDA to promote interoperability with sound public policy regulations to help advocate for the ultimate safety of our patients.

Competing Interests

The authors declare no competing interests.

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In Reply:

We thank Drs. Saluja and Kamdar for their comments on our recent editorial view entitled, “From Heroism to Safe Design: Leveraging Technology” which appeared in the March 2014 issue of *ANESTHESIOLOGY*.¹ We agree that technology has been proposed as a healthcare solution and is also viewed as an impediment to clinical care by many. This dichotomy is typical of an under-engineered system in which technical capabilities exceed the cultural and workflow processes that use the technology. We are not suggesting that technical solutions should or even can replace clinical decision making and acumen. However, the example of narcotics overdose is often used to highlight failures of our current system. The responses of patients to narcotics are highly

variable, and our reliance on clinical acumen to prescribe the correct dosage results in the unnecessary deaths of hospitalized patients every year. Technical systems already exist to prevent or dramatically reduce these deaths. However, as suggested by Drs. Saluja and Singh, these solutions may not be acceptable to hospitals because they are perceived as simply increasing the complexity and noise in the care system. This is precisely why we believe that the engineered approach needs to integrate technologies not only with other technologies (such as the electronic health record) but also with the needs of patients and the practice of clinicians.

We also agree that healthcare technology development is largely driven by well-intentioned innovators and market forces. Manufacturers work hard to create technologies that they believe will help patients. However, our current incentives are not aligned with promoting integration and efficiency. It is our responsibility as healthcare providers to promote and work toward integrated and efficient systems. In other industries, the productivity gains achieved through systems design and engineering have driven the relative costs of technology down—and this is particularly true as the costs of manpower increase.

The development of the World Wide Web and the open standards that it employs is a highly instructive model. Indeed, it is not enough for device companies to share data—but we do believe that this is a starting point for the kind of initiative described by Drs. Kamdar and Hofer. Although the development of the World Wide Web is instructive, there are some crucial differences between the development of Web standards and the requirements for such standards in medicine. Most importantly, the World Wide Web was initially developed entirely through government contracts by academics. Only when the power of the Internet was demonstrated, did it begin its march toward commercialization and wider development. Another example is the development of modern military aviation systems. In this case, the U.S. government recognized that the lack of systems integration in military aircraft was both a safety and financial liability. Working with engineering partners at government-sponsored laboratories, the government specified open integration standards for the aviation industry. The key to the

adoption of these standards was that industry recognized that the only path to purchase was by adopting the standards—because the U.S. government was the sole purchaser.

The current healthcare landscape is incentivized very differently. The U.S. Food and Drug Administration (FDA) exists largely to assure the safety of devices and not to create standards. Healthcare purchasing organizations are often blind to standards and are much more attuned to cost of ownership. Finally, there is no sole purchaser and in the case of health care the federal government can only use indirect measures, such as meaningful use, to affect adoption of standards and purchasing of technology.

Ultimately, federal and state governments, the FDA, industry, healthcare organizations, and academic centers will need to work together to develop these standards. As with the agreement to open data sources to clinicians and patients, newly developed standards will threaten some existing business and clinical care models, but they will open us to a world of development and improvement that other industries have enjoyed.

Finally, we do have a “long way to go” until we can move beyond heroism and adopt a culture, technology, and system of safety. Although the path is likely to be difficult, we believe that it is a path worth taking and the only one that will allow us to achieve the best for our patients and society.

Competing Interests

The authors declare no competing interests.

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