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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