

HITRD RFI Responses, March 15, 2019

ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

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Thank you very much for the opportunity to comment on this very important issue.

I am an academic Anesthesiologist and Critical Care Physician actively engaged in research focusing on closed loop physiological systems and artificial intelligence using acute care data. I am the executive editor for the section on technology, monitoring and computing for Anesthesia & Analgesia, I am the founder of Sironis a start up company developing closed loop systems for anesthesia management (specifically hemodynamic management), I am the co-owner of 4 patents on closed loop hemodynamic systems, I have licensed these technologies to Edwards Lifesciences and some of them are commercially available in Europe and are undergoing FDA regulated study, I am receiving industry (Edwards Lifesciences and Masimo) as well as NIH (NHLBI) funding for research projects related to big data, machine learning approaches, and closed loop system development, and I am a paid consultant for Edwards Lifesciences and Masimo Corp.

(1) Interoperability is the first, essential, foundational step toward automation and intelligent systems. These systems are not here to replace physicians or healthcare providers but rather to help them a higher level of care by insuring compliance with protocol of care, physiological endpoint, decreased variability of care, and early, precise detection of disease and therapeutic interventions.

The lack of standard for interoperability and the lack of common architecture and vocabulary for electronic systems in healthcare is a major barrier to the development of these systems. The lack of common vocabulary and architecture in EHR systems and healthcare data is also a major barrier to data sharing and building of large, multi institutional data sets that would greatly help accelerate new discovery and creation of publicly accessible databases.

Creating standards for interoperability is thus a critical step forward. We need clear pathways to move from in silico research, to in vivo research and finally to translational research in the clinical setting for closed loop physiological systems and intelligent/machine learning algorithms. Today the most important barrier is the inability to run translate to clinical studies in the United States to explore applications of these systems.

In my experience one of the main barrier is also the business case between key players: automated systems need collaborations between monitoring companies (sensors) and drug infusion devices (actuator). These two industries have different regulatory environment and business models and it is extremely difficult for them to find incentives to work together to develop automated systems. Part of the difficulty is the regulatory pathway and the lack of clarity they are facing. On the other hand, AI systems need partnership with EHR companies: these companies are used to not be regulated and are concerned about the implementation of Machine learning CDS and the regulatory consequences. These challenges are made even more difficult in the absence of clear, well defined standards on interoperability.

(2) Academia, Industry (Monitoring, EHR and drug infusion devices), DOD, FDA, patient safety experts, patient representatives, payers (to discuss the financial benefits/risks of such standards), professional societies and physicians (IMPORTANT: not only professional societies because there is a risk they could impede the development of systems that could be beneficial to the public but perceived as a threat to their professions).

(3) I think the business case is one of the challenge. Some form of an egg/chicken issue. Lack of incentive regarding data sharing and standards and also the fact that even though lack of standards is perceived

as an issue for some of the development we are talking about, it also gives some freedom to operate to industry.

(4) Yes, it is very viable and much needed. In every industry autonomous systems and digital solutions are improving safety and efficiency. The health care system and our patients need the added safety such systems and applications could bring. Standards are needed to achieve this vision. The military applications are even more obvious. Autonomous and early warning systems would help move closer to a zero death on the battlefield by early identification of life threatening conditions and on-site resuscitation. Here again, standards for interoperability are the first foundational step toward scalable development and commercialization of these systems.

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