

HITRD RFI Responses, March 15, 2019

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

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To Whom it May Concern:

(1) What is your vision for addressing interoperability issues between medical devices, data, and platforms?

Our vision for addressing interoperability issues is to develop/refine communications and nomenclature standards and develop tools that map existing protocols to the standards via software or hardware adapters. Each manufacturer would provide software (or a hardware adapter) to convert its data to a standard protocol that would permit plug-and-play interoperability. The technology, however, must be accompanied by incentives to adopt it.

How would this plan to create interoperable systems address your key use cases and pain points?

Our product aggregates data (in high resolution) from 30+ medical devices to address data management issues in neurocritical care. At present, each device has its own communications protocol. In addition, each device exhibits a varying degree of compliance to its own protocol, some have overt errors, and some have significant safety issues. It has been a challenging and slow process to interface the devices in a way that captures their full bandwidth of data (not just an hourly measurement for a medical record). An interoperability standard would ease our job of device interfaces, hopefully, to the point of plug-and-play. The focus could then shift to creating value in the integrated data that these devices provide (e.g. safety features, individualized care, etc.).

(2) Who are the relevant parties and their contributions to your interoperability solution?

Continued work from standards organizations such as IEEE, IHE, NIST and DICOM will likely play a significant role.

There needs to be an incentive to adoption of the standards. Ideally this would be in the form of realizing the value interoperability creates rather than enforcing the use of the standards...or perhaps both.

(3) What are the challenges and impediments to making interoperability happen? How might these issues be addressed and by whom?

Writing software to connect devices in a reliable way is tedious and developing standards is painfully slow. The standards efforts could be accelerated (a continual effort rather than committees meeting monthly). The implementation job could be shifted to the device manufacturers once a standard is agreed upon.

Regulatory barriers also exist. Small and medium sized medical device manufacturers are burdened by an out-of-control regulatory system (especially for the CE Mark) that seems to be more interested in their profits than in assuring the safety and quality of medical devices. The system consists of rules that change frequently resulting in excessive and costly audits. This system actually impedes changes that could permit interoperability due to the amount of time and paperwork involved.

(4) Is the federal vision for a medical device, data, and platform interoperability end state outlined in this RFI viable? Please explain why you have reached the conclusion that you have.

The vision is valuable but its viability has been challenging as noted by the many attempts to realize the vision. These attempts include projects from Johns Hopkins (Dr. Peter Pronovost, funded by the Moore Foundation), MGH (Dr. Julian Goldman, MD PnP, funded by NIH and DOD), West Health (internally funded), Center for Medical Interoperability, NantHealth, [OR.NET](#) (Europe), and others, including our efforts (Moberg Research, funded by DOD).

Several of these attempts are notable in that they attempted to develop communication standards and/or medical device adapters. To our knowledge none of these attempts have been widely adopted.

We have seen projects fail from academia because they do not have the industry experience and fail from industry because they do not see the return on their investment. We have participated in both. Our own DOD-funded efforts developed a medical device adapter...but it was cheaper for the customer to just purchase a cable and for us to embed the protocol software in our data aggregator. However, the collection of data from multiple devices has allowed us to demonstrate and commercialize clinical use cases that are now driving the need for connected devices.

The HITECH Act of 2009 provided incentives to connect devices to the medical record but these incentives were put in place before there was much thought put into the technology (e.g. standards) to do such. This resulted in the growth of several non-compatible industry offerings (e.g. Capsule, Nuvon, NantHealth, etc.) which just propagated the non-interoperability.

Thanks for the opportunity to comment.

Regards,

Dick Moberg

Dick Moberg
President

