HITRD RFI Responses, March 15, 2019

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

DISCLAIMER: The RFI public responses received and posted do not represent the views and/or opinions of the U.S. Government, NSTC Subcommittee on Networking and Information Technology Research and Development (NITRD), NITRD National Coordination Office, and/or any other Federal agencies and/or government entities. We bear no responsibility for the accuracy, legality or content of all external links included in this document.

Request for Information Response: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

Submitted by:

Point of Contact:
Tracy Rausch, CCE

Steven Dain, MD
John Howse, MD
Major General (retired) Elder Granger MD, FACP, FACPE, CMQ,
Bobby Shah

DocBox
[redacted]
[redacted]
www.docboxmed.com
[redacted]

It is a privilege to respond to the request for information titled: “Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care” issued on behalf of the Networking and Information Technology Research Office, National Coordination Office, National Science Foundation.

DocBox is a small business founded in 2007. DocBox has developed an innovative medical IoT platform that serves as a point of integration for medical and non-medical devices, clinical and operational software applications, and hospital information systems based on the Integrated Clinical Environment standard (ICE) architecture. Since 2011, DocBox has been conducting research and advanced development of its medical IoT platform for the integration of equipment at the point of care. $13M of contract R&D funding was awarded to DocBox by the Department of Defense (USAMRMC), including active Joint Warfighter Funding of $5.3M. In addition, $30M in basic research funding has been awarded to DocBox collaborators by USAMRMC, NIH, NIST, NSF, FDA, and DHS since 2004. The principal mission of this R&D effort is to develop technology that safely and securely integrates and enables interoperability of medical devices. Furthermore, the platform enables the ability for innovation to occur rapidly in healthcare through a platform approach that not only shows value in patient safety and quality improvements but financial returns through greater efficiency through automation.

The DocBox team is made of clinical/biomedical engineers, software engineers and physicians. Members of our DocBox team have been working on medical device interoperability (MDI) since its inception in various forms. Our members have participated and chaired national and international standards committees, represented providers by writing standards, providing content to contract language or developing health delivery organization requirements around medical device interoperability. DocBox was founded by a clinical engineer and supported by physicians that were frustrated by the limitations imposed by the technology that was, and is still currently available, that didn’t meet their research, clinical and operational needs. Our mission is to improve the safety, quality and efficiency of patient care.

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

Healthcare data is complex. Not all relevant data is available when and where it is needed. Terminology is often diverse, ambiguous, ill-defined and synonyms have differing definitions. Current data models are dated and do not meet the needs of today’s healthcare landscape that requires multiple providers, with differing

qualifications and differing roles, caring for patients in diverse locations including the home. The volume of data that is required, used and stored to provide safe, quality care is unprecedented. The current or lack of adopted architectures for near-patient medical systems and data has led to inefficient operational and clinical practices; data is siloed, sometimes leading to adverse events due to incomplete, difficult, or impossible to access information when it's most needed.

There are numerous challenges and impediments to realizing MDI. The reasons for this are multiple:

(1) Health IT communication standards are dated and not sufficient to achieve medical device interoperability. The scope of current standards is insufficient to address the use cases needed to implement MDI.
(2) Current health IT architecture has challenges with the addition of medical devices into the infrastructure
(3) When integration is currently achieved, the solutions are overly complicated, cost prohibitive, and don't satisfy integration requirements or fulfil the *Future Vision* outlined in the RFI.

Unfortunately, the healthcare industry has made only minor advancements since 2004, due to the lack of usable standards and meaningful and scalable interoperability of medical devices. The data from these sources is the root of all other healthcare data which is currently siloed, that has prohibited meaningful innovation for decades.

Current approaches to achieve MDI only focus on data "in motion" between components. To achieve the ability to transport retrospective data from one system to another, current integration approaches are sufficient. Building a simple API between a device gateway to an EHR solves the integration of data into the EHR, but problems arise when this data is utilized, because the data lacks metadata, context and rigorous definitions for the data terminology.

Existing standards do not provide the means to adequately describe information, lacking a way to describe the context or metadata which is needed to accompany the data. When a clinician views a heart rate in the EHR, they won't know which of the 18 different potential sources of heart rate were used for the record, and yet the EHR usually has only one field for heart rate. Therefore, data going into the EHR loses specificity. IEEE 11073 has attempted to layout this granularity but unfortunately, the standard lacks definitions for many of the terms, and most EHRs do not have fields which support such metadata. Furthermore, each standard does not have a comprehensive set of nomenclature and data model required for near-patient care.

Data context, for example, reporting the source, averaging time, body site, and concomitant technical alarms, becomes mandatory when fulfilling the requirements necessary for automation. To achieve the desired state of automation through machine learning and artificial intelligence, decision support algorithms must be able to evaluate the data type, source and quality of data obtained electronically from different devices, as automatically obtained data has not been human-validated like the data entered by healthcare providers in the EHR.

Metadata that describes measurement context, for example, the signal averaging time, body site, patient position, environmental conditions, and concomitant technical alarms, is essential to enable advanced algorithms to interpret patient monitoring data at a level typically achieved by a co-located expert clinician.

Data required to satisfy the scenarios, as described in the Integrated Clinical Environment (ICE) standard ASTM F2761-09 and IEEE 60601-1-10 for physiological closed-loop control, require not only real-time data but retrospective data, for example the last measured patient weight and the last time the patient was administered a certain drug. Through our government funded research, DocBox has prototyped several of these scenarios and found that it is necessary to combine the relevant parts of six different standards and then fill in the gaps where no standard existed to create a comprehensive patient model to meet the necessary data requirements for such an app.

No currently available standard considers the ramifications of multiple medical device components simultaneously attached to a single patient or the need to get information from other sources distant to the patient. Data must operate in multiple many-to-many communication patterns, as multiple devices and applications may use the same data simultaneously. An example is a flow sheet application for documentation requires ventilator, infusion pump, and multiparameter monitor data to automate the documentation process. Simultaneously a smart alarm application may also need data from the monitor and infusion pump. A sepsis algorithm may need data from the microbiology lab, hematology lab and patient temperature, heart rate and blood pressure from a multiparameter monitor. Currently, this is impossible to accomplish as data is siloed in multiple gateways and the EHR, data has poor or no context, or the time reported by a device may be highly inaccurate. As a result, novel decision support algorithms cannot be deployed because the data is unavailable.

Existing standards are based around a clinician encounter-based approach to clinical care. As we move to real-time systems across the continuum of care, the system needs to operate outside the normal scope of a clinician encounter. The functional requirements for data to achieve MDI should be architected in a patient-centric approach, rather than a device-centric (IEEE 11073) or encounter centric (HL-7) approach.

Existing standards continue to be based on outdated legacy standards or attempt to develop industry-specific communication protocols rather than leveraging existing standards from other markets and industries. This approach originated when there were very few and immature standards, yet they continue to promulgate in healthcare standards. Patient safety and cybersecurity are missing in any of the existing health IT or informatics standards, partially due to the age and scope of the requirements in existing informatics standards.

Healthcare continues to develop informatics standards in conference rooms, then hope for industry adoption. Clinical implementations and systems research must be done to complete these efforts. There is no federal entity that has a mandate to complete healthcare systems research. The Institute of Medicine has called for the adoption of systems engineering in healthcare, and the implementation of an approach for a learning healthcare system. Both ideas are fundamentally correct, yet there is no pathway to define these concepts, implement them or determine the requirements. It is essential to research the systems of healthcare like we do disease, to ensure that the correct requirements are derived. Resulting in that technologies are implemented to solve the pressing problems of healthcare.

Further complicating matters is that over the past decade there has been the development of numerous overlapping, competing “standards” and multiple versions, most lead by industry collaborative efforts with little in the way of coordination between them. These “standards” activities preserve the leaders in the market’s position of existing technologies for siloed proprietary solutions that do not meet the needs of modern healthcare. Other industry derived solutions only further silo the data (IHE patient care devices) by segmenting out parts of the market in arbitrary ways and make data unavailable for reliable, safe, secure, real-time use.

These standards are myopic in scope and requirements and have not considered the healthcare system. Their approach of avoiding discussion of “difficult scenarios,” for example, closed-loop, remote or autonomous command and control, and full disclosure of the medical device communications protocols, under the auspices of “getting something done” has failed. It is also contrary to good systems engineering practices.

There have been tens of thousands of hours of time, effort and resources spent in meetings and demonstrations promulgating different solutions. Billions of dollars have been spent on health IT solutions that are difficult to support, learn and use which cause provider burnout and create just as many errors. Most of these demonstrated solutions do not solve the real day to day problems that healthcare providers face. They just merely solve issues that are technically feasible with the equipment and standards that

are currently available. They do not satisfy current healthcare provider and IT needs, let alone the vision of automation and intelligent systems. There is little or no proof they add value to patient healthcare through improvements in safety, quality or efficiency. They are just adding complexity to a paper process which was made digital. The effort to achieve MDI has been ongoing for almost 3 decades, yet the current flawed approach has not changed. One of the key challenges moving forward with this effort is the need to balance the pathway for the adoption, with the rigors of getting the requirements correct that allow for future innovation.

The oft-repeated vendor statement that HDO's have not been repeatedly requesting MDI for the past decade plus is inaccurate. The HDO's have repeatedly been asking for solutions to improve patient safety, implement automation and provide them with solutions that provide value. These requests were laid out in HITSP TN905 (2010) and various peer-reviewed literature. Since 2004 there has been meetings, government research funding, and providers requesting these requirements mostly to deaf ears. The technology providers have repeatedly fallen short with solutions to meet these requirements. HDO's and healthcare can no longer afford to invest in solutions that do not meet the needs of the system, and this failure of technology vendors has continued to put patients' lives at risk and stifled research and innovation across healthcare.

Solutions for these issues should be resolved by appropriate joint engineer and clinician-led leadership, a national initiative to solve this problem based on requirements derived from real- life clinical and operational scenarios to create simple viable solutions. There has been a decade worth of funded research in this area, which the researchers are prepared to share with the industry but moving to the next level requires national and international participation and leadership.

Although healthcare informatics professionals should have a place at the table for these discussions, they should not be leading the effort. The concepts of command and control, automation and real-time decision support is well outside the scope of their knowledge base. Requirements are created from a multidisciplinary team of healthcare and systems engineers. Again, this effort needs to be a clinician lead activity to get the requirements necessary to fully realize the tremendous capabilities of automation and decision-making algorithms.

Most importantly this is a different sector of healthcare and should be treated as such. The research for algorithms, automation, and visualization has been occurring for decades in medicine, but understanding how to scale and understand the safety and security requirements to implement these solutions is what has been lacking. The infrastructure is not about a new algorithm or AI/ML but, the infrastructure necessary

to innovate, deploy and advance the industry using these emerging technologies in a safe and effective solution.

The collision of health information technology, medical devices, and medicine bring together three verticals in the same industry who speak different languages, started from different places and involve a set of professionals who are challenged to communicate due to their diverse education and backgrounds. Autonomous medical care has the potential to revolutionize medicine as computers did in the 1980s when existing monitoring technologies were adopted.

What is your vision for addressing interoperability issues between medical devices, data, and platforms? How would this plan to create interoperable systems address your crucial use cases and pain points?

DocBox has spent the last decade conducting MDI research, and has developed a platform and infrastructure for the collection and utilization of near patient data to support and facilitate research and innovation with the goal of improving patient care. We believe our platform can be a pathway forward for MDI and have made the technical and business commitment to support it.

Our vision is that MDI is the foundation of a distributed architecture which enables intelligent systems and automation for improvements in safety, effectiveness, and efficiency.

Our first assumption is that the types and numbers of medical devices, currently thought of as standalone electromechanical systems, are going to expand. Medical Devices implemented as software have already entered into the market. However, with advancements in machine learning (ML) and AI, the number of medical devices as software is going to grow. Novel ways to visualize data, automated systems, and real-time decision support are all going to fall into this category. Consequently, the platform and MDI strategies must account for new types of medical devices, while supporting existing legacy devices and health IT systems. Our research team and collaborators refer to software as a medical device as a “medical device app” or more simply an “app”.

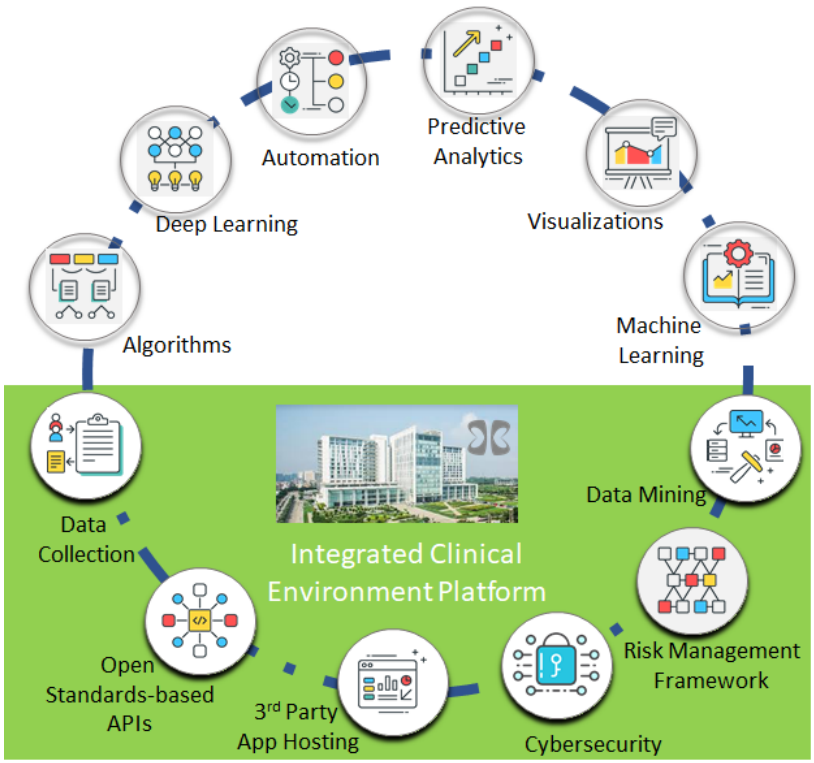

Figure 1: A platform with the foundation of meaningful MDI would enable advances that medicine needs to improve healthcare both clinically and operationally.

The vision for the DocBox platform is derived from the requirements that satisfy the exemplar scenarios provided by Annex B of ASTM F2761 Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model. Although our complete vision for our platform has not been realized, the initial products of this project have been commercialized and are in clinical use. We have clinically demonstrated the initial framework that can achieve medical device interoperability. The remainder of this section discusses our future vision of what a platform for MDI should include and the desired outcomes of such a system.

The platform, which is the enabling infrastructure part of this ecosystem should:

1) *be open and standards-based*. Existing standards are not complete enough to achieve the scenarios laid out in HITSP TN905 or ASTM F2761 Annex B. Expanded or new standards need to be written to satisfy these requirements. Currently, areas where there are known gaps include, but are not limited to, quality of service, cybersecurity, standard vocabularies, mature secure communications protocols, information model components which provide safety.

2) *have the ability to safely and securely connect to legacy devices*. Health Delivery Organizations cannot afford to discard their legacy devices that don't currently meet the requirements for communications, safety, security or information model requirements natively available on their medical device interface.

3) *have a cybersecurity and risk management framework* allowing for multiple vendors' devices and apps to safely send and receive data. The platform should provide isolation for the safe performance of life support and other safety critical functions. These frameworks simplify the requirements for each device or app connected to the platform, so each device or app doesn't have to bear the burden of protection alone but can leverage the platform to achieve the desired cybersecurity goals. The framework also simplifies technical and use policies which will enable rapid development and adoption of these systems.

4) *support multiple communications protocols* and be flexible enough to adopt future protocols over time. Technology moves much faster than healthcare, yet we must bridge the gap. Therefore, the ability to integrate fully functional protocol adapters is essential. Leveraging field proven communications protocols from other industries enables more rapid adoption and reduces cost, as software development tooling is often readily available. Protocols supported by the Industrial Internet Consortium such as DDS, or consumer IoT protocols such as MQTT are examples that can be leveraged.

The ability to send, receive and store different types of data, with its appropriate metadata is essential to the success of any platform that enables MDI. Healthcare providers hate to wait for patient data to appear at the bedside! We need to evaluate and use more modern database technologies to optimize this healthcare ecosystem.

The healthcare industry should look to other industries-aerospace, banking, hospitality services and logistics and not develop new protocols or standards unless it is absolutely necessary. Policy efforts around the protection and sharing of this data need to be considered alongside the technical requirements.

The comprehensive patient-focused information that is envisioned borrows the best from existing standards and fills in the gaps. New standards will need to address the requirements for use cases required to bring ML/AI and automation to healthcare through MDI into fruition.

It is essential to consider the lessons learned from current EHR implementations when writing new standards. This new system, requirements, and architecture must provide for easy usability; from easy to use and understand, unambiguous standards, through to

the entire product life-cycle. These newly interoperable systems will provide ample opportunity for usability research and development to improve ease of use. This will produce systems that people like to use resulting in improved patient safety and quality of care. Finally, improvements in usability is essential to decrease the complexity of clinicians' lives, reducing stress and contributing to a better work environment.

The platform should enable multiple communication protocols, which transmit a patient-focused data model allowing for multiple applications from multiple vendors to utilize the data simultaneously.

Risk management, good manufacturing practice and product life-cycle considerations must be addressed by standards, platform, medical device and software developers. The systems we are envisioning have components that need to meet safety-critical requirements, and therefore we must engineer the entire technology and systems to meet those needs. Therefore, technical and policy requirements around risk management should be part of this infrastructure.

When creating this new exciting sector of the healthcare industry, developing the correct standards, technology and policies is essential, with MDI as one of the foundational pieces of the puzzle. These platforms will enable the rapid, safe, and effective innovation that healthcare has been demanding for decades.

In summary, to meet these requirements, we must:

(1) implement a standard patient-centric data model leveraging multiple standards.
(2) implement standardized vocabularies of terms.
(3) leverage a set of mature data communication protocol(s) that already exist and are deployed in other industries that meet the requirements for the vast diversity of use cases in healthcare
(4) adopt an architecture that meets the requirements in the comprehensive set of exemplar clinical scenarios;
(5) facilitate easy usability of standards and product throughout their respective life-cycles
(6) Use sound risk management principles throughout the standards, R&D, and product life-cycle processes
(7) critically evaluate existing standards and help develop new standards to fill the gaps
(8) have funding for reference implementations and architectures.

Not all the existing standards work needs to be discarded. Some of it can be leveraged and enhanced to meet those requirements, although it requires expert leadership to

meet the task to achieve interoperability. Policy changes will be required to promote the adoption of these new technology solutions. It would be helpful to industry experts charged with using the current alphabet soup of existing "standards" that guidelines are created to aid in deciding which "standard" to apply in which situation and task standards' committees to develop the missing pieces to fill the gaps.

Solutions and standards must evolve through demonstration and outcomes, not just meetings. This effort is a separate activity from existing EHR integration as the requirements for that effort is a small subset of the requirements necessary to achieve meaningful medical device interoperability. It should also include the prototyping and reference implementations of solutions not only in simulated clinical environments but in live clinical environments.

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

The DocBox vision and commercial product development is based on concepts from the MDPnP program at Harvard University and Massachusetts General Hospital that was established in 2004, requirements and clinical and operational input from Medanta the Medicity in Gurgaon India, and from work with or by the following: AAMI, Underwriters Laboratories, ISO Technical committees 121 and 215, IEEE 11073, Food and Drug Administration, University of Waterloo Electrical and Computer Engineering.

Requirements were derived by studying the user and technical needs by exploring clinical and operational scenarios, security and documentation of use cases to help write the requirements necessary for easy to use, safe, secure medical device interoperability. This research has been primarily funded by the Department of Defense USAMRMC with additional funding by NIH, DOD, NSF, NIST and private funds. Several multidisciplinary workshops, with attendees from academia, the US FDA, medical device industry, computer scientists have been held. Members of the DocBox team have attended and presented at many of these events.

The concept of MDI has been endorsed by the American Society of Anesthesiologists, the American Medical Association, Society of Technology in Anesthesia. The ICE standard is a recognized consensus standard by the US FDA.

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 federal vision outlined in the RFI is congruent with our vision of a vendor agnostic patient-centric, data-centric medical device interoperability platform. DocBox has demonstrated the technical feasibility of this federal *future vision*. DocBox has built the first generation of such a system that meets many of the requirements above. The platform is currently being used daily in clinical care.

The DocBox team stands ready to support this effort to promote medical device interoperability. We have supported, participated in the development of standards and prototyping demos in the name of promoting MDI from before the inception of DocBox to the present, and stand by the commitment to make our platform open and interoperable. DocBox would like to have the opportunity to brief the committee in person about our work and progress to date which has been funded by prime contract from R&D USAMRMC (W81XWH-17C-0013). We wish to thank you again for this opportunity, and also look forward to participating in your conference in June/July 2019.