HITRD RFI Responses, March 15, 2019

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

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MDii™

Medical Device Integration & Informatics

Date: March 15, 2019

Name of Organization filing comment:

MDii, LLC
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MDii Mission Statement:

We are dedicated to improving patient care with the integration of medical devices and electronic health records, while enabling clinical innovation and reducing overall total cost of ownership.

In response to:

Federal Register Notice: 82 FR 4544
https://www.nitrd.gov/news/RFI-action-on-interoperability-of-medical-devices-data-and-platforms.aspx
Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO), National Science Foundation.
Notice of request for information

Subject line: RFI Response: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

Executive Summary:

We envision medical device interoperability as seamless, functional, and user-friendly as today's mobile device functional expectations. Implementing our vision starts with predicate work, then fills gaps as needed to deliver future interoperability.

A future, one where we tell our kids there was a day (not that long ago) when medical devices did not seamlessly interact with one another or computers as they do now (e.g. 2025). Our future leaders are utterly bewildered, "What do you mean? How did medical devices work where you couldn't simply connect them… ? Wait, but how were they used to take care of patients without talking to one another?" That future is inevitable. Hard to imagine anything else.

At a recent social gathering, after explaining that our company helps improve patient care by connecting medical devices to computing infrastructure and is working to enable the capability of measured physiologic values altering the medications delivered by an infusion pump or settings on a ventilator… the head of their ICU said - "Wow, that's fantastic. We need that. I'd love to be a part of it. So cool someone is working on it. It's so hard for "regular" clinicians to see past today. Past the patients right in front of us, let alone keeping the place running. I hope you're wildly successful. Happy to hear someone is thinking about what the future of patient care will look like."

Open, seamlessly interoperable medical devices and communications infrastructure is the way there. Interoperability needs to be a core function of the device and built into its operating system, rather than an afterthought or ancillary function to be configured at implementation. To reduce the financial risk and time commitment, manufacturers will need a shared set of design standards and possibly incentives to comply.

In the near-term, we envision real-world experience and knowledge sharing concentrating on how to achieve interoperability from current state-of-the-art and standards. Today, healthcare delivery organizations bear a disproportionate share of the time and cost burden of integrating medical devices with other systems. To mitigate patient risks healthcare delivery organizations must complete extensive discovery (on technology they do not manufacture), systems analysis, trial and error testing and incurring related implementation costs.

As the cost of healthcare in the US has skyrocketed, it is wholly inefficient to have hospitals repeat extensive discovery and testing already completed by another organization implementing the same combination of medical devices and other systems. Sharing knowledge of successful regular maintenance (e.g. application or medical device updates, patches, upgrades…) offers similar efficiencies.

Further, we envision a new public-private medical device industry alliance that offers certification in the interoperability standards, modeled after commercially successful interoperable technologies such as USB, WiFi and Bluetooth. Although out of our domain expertise, the NHTSA and its regulation and/or requirements for vehicle safety and innovation (e.g. automated vehicles, vehicle-to-vehicle communications, vehicle cybersecurity, vehicle data privacy…) may be a good analogy and/or precedent framework.

To accelerate adoption of standards and certification to reach 'critical mass' we envision incentivizing the medical device manufacturers, electronic health records software companies and integration software companies to demonstrate compliance (as the Affordable Care Act incentivized hospitals to demonstrate Meaningful Use of EHR systems).

We have developed the foundation of an implementation methodology with centralized testing, based on today's industry standards, that is extensible across organizations. We would welcome vetting our processes with others to see if it's a workable national model that could be the early groundwork for our recommended alliance and certification.

Text below in *italics* are supplemental excerpts from original RFI included for clarity.

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

Vision for addressing interoperability:
Vet and articulate a national medical device interoperability agenda and vision, develop a framework of applicable standards, identify and fill gaps, and possibly most important – require certification.

Having the benefit of 20+ years of experience, connecting over 5,000 medical devices, and participating in numerous Standards efforts – we envision a set of interoperability definitions, design and communications standards, for adoption and compliance by medical device manufacturers, electronic health records software companies and integration software ('middleware') companies. So that, compliant medical devices, EHR systems, and integration software seamlessly work together without any manual initial configuration (i.e., "plug 'n play"), or minimal configuration, as in today's mobile devices.

Leverage and build on current medical device communication standards and successful interoperability models to establish a new public-private medical device industry alliance requiring certification. It is conceptually modeled after commercially successful interoperable technologies like USB, WiFi and Bluetooth.

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Use case:
Augmenting interactions between four basic system actors –
At its essence, healthcare involves a patient and a clinician. The clinician must process a great deal of information from disparate data sources, to see patterns or trends to inform diagnoses.

From a medical device and/or systems perspective, a common combination of the basic involved actors exists: a patient, and one or more of: clinician(s), diagnostic device(s), and therapeutic device(s).

Today, communication or interaction between these four actors is a strictly human (i.e. interpreting data and taking physical action). Including a recently added fifth actor, an

electronic health record to the mix, clinicians are still required to analyze the data and take action manually with the medical device(s) themselves.

Today's state-of-the-art is to send unidirectional data to the EHR. Interactions to- or between-medical devices (particularly when different manufacturers are involved) is virtually non-existent.

Medical device interoperability can augment the necessary data analysis and save clinicians time previously spent on mundane or repetitive tasks. It could also provide additional data processing capabilities such as patient monitoring continuity when a clinician is not at the patient's bedside.

Pain points:

- Persistently difficult – It is difficult even for the well-informed to enable results-based communications between medical devices and computers, these communications are limited (missing alarms, waveforms, settings, signal quality) and are fraught with timestamp, patient context and software revision challenges.
- Variables – We've made tremendous effort, but variable terminology inconsistencies or confusion on the underlying principle persists.
- Cabling – Custom or unique device-level cabling, there are far too many specialized cables or adapters required to connect medical devices.
- Inadequate native network communication – Network communications often nonexistent or rely on converting serial communications to Ethernet often using 40 year old technology (i.e. generic or proprietary terminal servers).
- Unmet expectations – Today's state-of-the-art leaves a great deal of unmet expectations for medical device interoperability innovators and early adopters.
- Software revision management – Figuring out what testing is needed when there is a software update to a component (e.g. medical device, communication driver, consuming application, sending application, operating system, anti-malware, middleware, hardware…) can be unnerving
- Forward and backward compatibility – Balancing hardware capability with application requirements. It is impractical to ask hospitals to replace large portions of their medical device inventory to get incremental functions.
- Remote control – It is exceedingly difficult, pragmatically impossible, to establish input and/or settings-based communications with therapeutic devices.
- Decentralized testing – Today's default implementation processes requires detailed configuration and testing when connecting medical devices to communications infrastructure. These costs are incurred by hospitals, possibly unnecessarily redundant, across the US and possibly internationally.

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

Parties and contributions:

- Proposed new alliance – Develop overarching standards framework, identify gaps, develop testing and certification criteria.
- Federal agency(ies) – Regulatory oversight and identification of authorized certification bodies.
- Standards Development Organizations – Leverage and adapt existing standards, develop explanatory text to help clarify which standards apply under overarching framework.
- Medical device manufacturers – Adopt new standards and processes, build medical device and systems with interoperability and an open communication platform as a core function of their product.
- Middleware vendors - Rapidly changing layer of the necessary technology stack which enables today's functionality by bridging legacy systems with current data demands. As new medical devices with native network communication capabilities are available, middleware vendors will likely need to evolve.
- Electronic health records – Product and core functions will continue to evolve and make incremental improvements.
- Healthcare delivery organizations – Making an existing inventory of medical devices seamlessly interoperable is likely impractical. Healthcare delivery organizations will need to plan how to fund, procure and transition-in new capabilities.
- End users - The vast majority of clinical users are pre-occupied with patient care (busy with their day jobs) and keeping up with the rate of change their obligated to maintain. They will require awareness and need to be heard to better understand the needs of the everyday clinician. Innovators and early adopters will play a key role.

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

Challenges and impediments:

- Existing inventories – The biggest immediate impediment are existing inventories of medical devices.
    - Medical devices are too expensive to replace any sooner than the period they are typically amortized, frequently 7-10 years sometimes longer. Many of the medical devices in use today were not designed with external communications as a core function.
    - The most common approach discussed among domain experts is: ignore them. Draw a line. Simply state anything before XYZ release or date was not built for this kind of functionality and level of interoperability.
- Product development lifecycle – A second contributing complication is the development life-cycle of a new medical device, which easily reaches 4-7 years.
    - Any technology that a medical device manufacturer builds into their system needs to be relatively stable for a number of years, preferably more than ten. That is a long time when compared to the timeframe many computing systems or consumer electronics are considered old or approach becoming obsolete at three years.
    - Domain experts have cited that inherent latencies in meeting regulatory clearance often binds you to older technology even though new and/or better capabilities emerged since their initial submission for the fear of making changes and incurring additional costs.
    - Not have a great deal of experience with the regulatory processes involved, but possibly the proposed alliance and certification could work on how to expedite or facilitate demonstrating forward/backward compatibility and substantially equivalent functions when new technologies are available (USB 1.0 vs 2.0…).
- Manufacturer incentives – Manufacturers have little incentive to uniformly adopt an open communications standard.
    - Many see open communications as a threat to their existing or potential market share (e.g. Why would we open our communication channels, when we have a solution to integrate other's devices into our platform?)
    - We are under the impression than building to open standards has in reality brought down the cost of interoperability with computing systems. If history holds true, there is ample opportunity for innovative companies to build revenues in emerging markets and capabilities.
- Ongoing costs – Off the shelf software and planned or unplanned system changes.
    - A chronic pain point that will require clarification even further than the good work recently completed is how to manage medical device software revision changes, operating system and/or anti-malware updates.
    - Secure, interoperable systems require regularly scheduled patching and updates.

    - Develop and publish standard processes. End-users and/or healthcare delivery organizations cannot be left guessing how to test, what to look for after an update and how to mitigate risks an update may present to patients.
- Risks involved – USB took a while to be stable and for the most part error-free.
    - The margin of error is far smaller when working with medical devices. Fortunately, the industry as a whole is generally technologically behind when compared to others, so there is a better foundation to build on.
    - Tread carefully, be careful what you wish for, and due diligence. The good news, is it's likely more complicated to fly planes and that industry is pretty good at it.
- Strong suppliers - Due to steep market entry barriers the medical device industry is generally led by large, powerful manufacturers often entrenched in the status quo.
    - Is is challenging for small, nimble and/or innovative medical device manufacturers to penetrate market as compared to consumer electronics. As a result among other reason, the industry is slow or resistant to adopt the open communication and interoperability standards that competition has directly and indirectly forced on consumer electronics market.
    - It will not be simple to establish an achievable interoperability standard for device makers and software vendors; they must be on-board.
    - Nor will it be easy to obtain commitment from device manufacturer and software vendors to design and implement an interoperability standard.
- Cost of inactivity - A potential insidious challenge is the cost of inactivity.
    - Today's state-of-the-art requires no certification. There is no centralized or independent testing to help assure that the various assembled components work as expected. Each and every installation is left on their own devices to discover and document expected outcomes, test plans, test cases, execute testing, identify and mitigate residual risks… When you consider the cost incurred by each healthcare organization to complete this work – the cost nationally could be staggering. These costs are repeatedly absorbed by healthcare delivery organizations and passed on as part of their overhead to payors.

How might these issues be addressed and by whom?

- Under the jurisdiction of an applicable Federal agency (e.g. FDA, ONC, CISA) form an industry allegiance – Document a roadmap with dates for compliance to improve interoperability and overall safety akin to what the NHTSA did for vehicular safety (e.g. seatbelts, third brake light, airbags, antilock brakes…)
- Define the standard – With input and agreement from device makers and software vendors. Set a future date by when device makers and software vendors' new products must comply.
- Incentives – Incentivize device makers and software vendors to comply with the interoperability standard (federal government if needed).
- Where are the gaps – Identify where holes with todays' various standards exist and what needs to be developed to fill potential medical device specific needs (e.g. resolving communication hierarchy between sophisticated medical devices each with their own

operating system, including the possibility of life-support systems such as anesthesia machines, ventilators, infusion pumps…)

- Develop – Leverage framework where established interoperability best practices, standards and certification such as:
    - USB, Bluetooth, and WiFi wherever possible
    - Use broadly adopted standards like Ethernet like and certification (cooper cable certification using TIA/ISO for the latter)
- Frame – What low-level capabilities medical devices need to be incorporated to support interoperability (driver, software version, device function, time synchronization, patient and/or user context, inbound data requirements, signal quality…).

(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 federal vision for a medical device, data, and platform interoperability end state outlined in this RFI is viable. We conclude this because we have extensive experience integrating medical devices of many types (e.g., physiological monitors, anesthesia machines, fetal monitors, heart-lung machines, ventilators) of many makes and models with electronic health records systems. We have seen the technical and organizational challenges firsthand and can inform future processes with lessons learned on how to overcome the challenges. As the Affordable Care Act incentivized hospitals to achieve meaningful use of electronic health records systems, so too can a federally-sponsored incentive program incentives medical device makers and software vendors to comply with an achievable interoperability standard to which they have contributed insight and input.