

A Summary of the February 2019 Request for Information: Action on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

For Discussion Purposes Only

Prepared by the HITRD IWG Organizing Committee

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Background

In February 2019 the Networking and Information Technology Research and Development Program's (NITRD) Health Information Technology Research and Development Interagency Working Group (HITRD IWG) issued a Request for Information (RFI) ([Document Number: 2019-02519](#)) to collect input on new approaches from industry, academia, and non-governmental organizations, to solve the interoperability issues between medical devices, data, and platforms.

The RFI provided a vision of seamless interoperability between medical devices, data, and platforms in both hospitals and the healthcare community. The IWG requested that respondents answer the following four questions:

- 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?
- 2) Identify the relevant parties and their contributions to your interoperability solution.
- 3) Identify the challenges and impediments to making interoperability happen. How might these issues be addressed and by whom?
- 4) Is the federal vision for interoperability outlined in this RFI viable? Please explain why you have reached that conclusion.

The following summarizes the 37 submitted responses to the RFI.

Summary of Responses

A. Vision

Most respondents supported the vision of seamless interoperability described in the RFI. Differences mainly involved scope and feasibility. Some focused only on enhancing interoperability within the hospital or specific department (e.g., the Intensive Care Unit), while others saw the vision extending to rehabilitation and other community services for an aging population. Feasibility is addressed in detail in Section C (Themes).

B. Relevant Parties

The RFI respondents identified national and international stakeholders that are relevant to interoperability, including: device manufacturers (both traditional medical devices and non-traditional devices), standards bodies, regulatory agencies, electronic health record vendors, insurers, healthcare agencies, health care providers, patients, and caregivers.

C. Themes

The RFI responses have been grouped by topic as follows:

1. Data and metadata
2. Access to control of devices
3. Leadership and governance
4. Incentives
5. Management and modernization of standards
6. Infrastructure, tools, and use cases

1. Data and Metadata

To enable the reliable and usable exchange of data and metadata, information sharing networks require the consistent use of standards, semantics, and a common set of “rules of the road” for exchange. Responses to the RFI emphasized the following points:

- Current terminologies are diverse, ambiguous, ill-defined, and lacking an ontological framework.
- Semantic standardization is needed to allow stakeholders and data users to have a universal understanding of the data represented (e.g., is the blood glucose value taken when fasting or at various times during the day?).
- Stakeholders need a community forum around the concept of “interoperability” to define use cases, models, verification activities, and means for sharing adverse information to enable improvements.

- Metadata that describes measurement context (for example, the signal averaging time, body site, patient position, environmental conditions, concomitant technical alarms, and how often data are transmitted from the device) is essential to create and implement advanced analytics to interpret patient monitoring data at a level typically achieved by a co-located expert clinician. Interaction between medical devices in real-time and with the EHRs data are severely limited by the absence of device metadata.
- All devices should be required to share data that are traditionally available to a medical device operator through a standardized device interface.
- Interoperability should not only happen between devices in a clinical setting, but also between remote monitoring products, outpatient and emergency-care devices, and electronic health records (EHRs).

2. Access to Control of Devices

There is value in seeking interoperability and the automation of healthcare processes to enhance patient care and safety. However, respondents emphasized the need for:

- Functional medical device interoperability to realize the advantages of closed loop systems (i.e., where machines interact and control functions in an automated system) and medical devices that exchange information to enhance care or stabilize a patient without human intervention. Currently, this level of closed loop control does not exist.
- A focus on post-launch maintenance of interoperability, and identification and management of emergent behaviors.
- Policy and protocols, like those used in other industries, to support safety investigations.
- Addressing issues in access and control both pre- and post-marketing.
- A legal construct for information sharing to support safety, security, and reliability. For example, if a patient is injured while a set of interoperable devices is being used to support their care, robust systems will be needed to perform root-cause analysis. There is lack of clarity on the distribution of responsibilities when groups of interoperable medical devices are incorporated into systems – some of which may include interoperable devices that are not medical devices.

3. Leadership and Governance

Advances in communication technology provides optimism for the future of healthcare, but many gaps still need to be addressed. Respondents expressed that any leadership and governance plan should include the following:

- An understanding and reconciliation of the many different stakeholder perspectives including: healthcare agencies, device manufacturers, small, medium, and large businesses, standards organizations, standards bodies, insurers, providers, and healthcare consumers.

- A shared model that includes infrastructure and tools for demonstrating and validating interoperability. Interoperability for clinical care cannot be separated from interoperability for clinical research (e.g., clinical trial recruitment, data capture).
- Approaches that insure the implementation of consensus standards and requirements.
- A “start date” for expected interoperability in recognition of the fact that full interoperability cannot be achieved immediately but must be phased in as legacy systems are phased out.
- Improved testing and real-world validation of device interoperability, scalability, safety, and security. For example, it was noted that medical simulation has improved significantly in the last decade, but still lacks the real-world validation necessary for robust closed-loop control in medical treatment.
- A platform-based approach to infrastructure that enables innovation and rapid deployment of emerging technologies in a safe and effective healthcare environment.

4. Incentives

The current business models of medical device manufacturers and EHR vendors provide no incentive to implement interoperable or semi-interoperable solutions, in fact many see open communications as a threat to their market share. Clear incentives are necessary for industry to develop and implement these solutions. The use of examples such as the 2009 Health Information Technology for Economic and Clinical Health Act (HITECH Act) were noted. Respondents expressed that any plan for incentives should consider the following:

- An appropriate business model and set of standards that achieve true interoperability.
- Increased awareness and education of all stakeholders, including patients, about the benefits of clinical data interoperability and how it can improve care.
- Incentives that encourage the adoption of data field and format standards, such as FHIR, while avoiding strict mandates that fail to keep pace with innovation.
- Incentives that add value to the stakeholders, such as a reduced period for premarket approval and clearance for industry.

5. Management and Modernization of Standards

There is general agreement that data must be available where and when it is needed, in a reusable format that supports accurate identification of the device and patient. Current standards are either incomplete in their coverage of the total product lifecycle or they conflict with each other. Respondents stated that developing interoperable system standards, that manufacturers will readily adopt, requires:

- Solving questions of coverage, coordination and harmonization.
- Ensuring that the privacy and security of the patient’s information shared over devices complies with HIPAA regulations and other laws (Federal, state, and local).
- Usable guidance for developers new to this area.

6. Infrastructure, tools, and use cases

The proper infrastructure and tools will support and enhance the development and adoption of interoperability. Respondents discussed tools that include: reference architecture, use cases, test procedures, and implementation guides. Implementation guides, although time consuming to create, can reduce the time and effort to get an individual system fully functioning. They are used to understand the requirements, identify potential hazards, and are complimented by robust test capabilities and procedures. For example, the provider-payer interoperability industry uses implementation guides to connect EHRs and billing management systems. Implementation guides must be developed, tested, and formalized within a respected governance and standards body.

Use cases provide stakeholders with a clear sense of the direct benefit they will derive (e.g., for clinical care, business, or clinical research). Standards developers and promoters must be sure to begin with and continually work from compelling, real-life use cases that reflect the needs, concerns, and constraints of potential interoperability adopters.

D. Conclusion – A Federal Vision of Interoperability

The responses to the RFI indicate that now is the time to promote and support the interoperability of medical devices, data, and platforms; inaction incurs costs to patients, healthcare providers, and device manufacturers. While the vision is shared, respondents cited the need to develop platform-based systems to support rapid and efficient development of new applications where sensors, actuators and apps provide “plug and play” capabilities. Almost all pointed towards the need to standardize nomenclature for data and metadata (possibly centered around the patient instead of the device), and for describing clinical procedures. Several respondents pointed to the need to develop an overall framework that included communities of interest to establish specific use cases, guidelines, and verification methods; governance and regulatory structures; and independent interagency safety assessment boards (since not all system components would be under a single regulatory authority). Business cases, incentives, and roadmaps are needed to enable safe market-based solutions. When healthcare providers can present a unified voice, manufacturers can deliver a product that meets the needs and reduces costs for all stakeholders.

Finally, new medical devices, data and platforms must support future semi-autonomous and fully autonomous medical care systems. To achieve this vision requires an open, extensible architecture for interconnection as a conceptual framework. Implementation guides, data and metadata standards, and test suites for conformance and compliance testing will be the tools, but the stakeholders will drive the progress.