

The Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care

**A summary of the February 2019 Request for Information
and July 2019 Listening Session**

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Introduction

In February 2019 the Networking and Information Technology Research and Development (NITRD) Program's Health Information Technology Research and Development Interagency Working Group (HITRD IWG) issued a Request for Information (RFI) ¹ to collect input from industry, academia, and nongovernmental organizations on new approaches to solve the interoperability issues between medical devices, data, and platforms. On July 17, 2019, the group followed up with an in-person Listening Session² that included 76 representatives from the device, standards, academic, and medical communities, and the government.

Both the RFI and the Listening Session were focused on the interoperability of medical and consumer health devices, applications, and platforms, including the ability to submit data to the electronic health record (EHR). The challenge is that devices, applications, and platforms can deliver more real-time data than the current EHR environment can technically support. This is an important issue because patient-centric device interoperability is necessary to enable a new generation of applications, safety interlocks, closed loop device control, and other innovative patient-care solutions.

To guide the participants, the RFI provided a vision of seamless interoperability, both within hospitals and communities, along with the following questions:

- 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?
- Identify the relevant parties and their contributions to your interoperability solution.
- Identify the challenges and impediments to making interoperability happen. How might these issues be addressed and by whom?
- 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 you have.

As a follow-on, and based on the RFI responses, Listening Session participants were asked to provide additional detail and address the following issues:

- Governance: Who should be involved? What mechanisms/policy can be used? Would certification be required? If so, what infrastructure would industries use for self-regulation and self-monitoring?
- What is the catalyst for interoperability? Define it to raise attention regarding potential benefits in safety and costs?
- What are the incentives from each stakeholder's perspective?
- What is the biggest step we can take in the next year, next three years, and next five years?

¹ <https://www.federalregister.gov/documents/2019/02/15/2019-02519/request-for-information-action-on-interoperability-of-medical-devices-data-and-platforms-to-enhance>

² <https://www.nitrd.gov/nitrdgroups/index.php?title=Medical-Device-Interoperability-2019>

Summary of Inputs

The information gathered from both the RFI and the Listening Session was integrated, summarized, and grouped by the following themes:

- Vision
- Stakeholders
- Leadership and governance
- Exchange and semantics of data and metadata
- Access to control of devices
- Incentives
- Management and modernization of standards
- Infrastructure, tools, testbeds, and use cases
- Catalysts for Interoperability
- Action plan for the next five years

Vision

Most participants supported the overall vision of seamless interoperability; where they differed was in scope and feasibility. For example, some participants focused only on enhancing interoperability within the hospital or a specific department setting (e.g., the Intensive Care Unit), while others saw the vision extending into rehabilitation and care for aging populations in the community.

Stakeholders

National and international stakeholders are understood to include device manufacturers (of both traditional medical devices and nontraditional devices), standards bodies, regulatory agencies (especially the Food and Drug Administration [FDA] and the Office of the National Coordinator of Health Information Technology), EHR vendors, insurers, healthcare agencies, healthcare providers and health delivery organizations, patients and caregivers, governmental funding agencies, and foundations that have supported important research implementations.

Leadership and Governance

Advances in communication and information technologies provide optimism for the future of healthcare, but there are many gaps that still need to be addressed. Participants expressed that any leadership and governance plan should include:

- An interoperability governing model that:
 - Is a nonprofit public-private partnership.
 - Includes members of the medical device, consumer device, and EHR industry; groups that coordinate healthcare purchasing (i.e., buying groups); healthcare delivery, academia, and government. FDA was considered a required partner.
 - Represents various stakeholder perspectives, including healthcare agencies, device manufacturers, businesses, standards organizations, buying groups, insurers, providers, and consumers.
 - Provides new guidelines for vendor intellectual property.
 - Collects relevant data to measure avoided and avoidable patient harm associated with interoperability.

- An interoperability management model that:
 - Is a shared model that includes the development of infrastructure and tools for demonstrating and validating interoperability for both clinical care and clinical research (e.g., clinical trial recruitment and data capture).
 - Uses an architecture that enables innovation and rapid deployment of emerging technologies in a safe and effective environment.
 - Supports thoughtful procurement of interoperable devices (i.e., through a staged approach like that of the Federal Risk and Authorization Management Program).
 - Provides device interoperability, scalability, safety, and security testing and validation that includes real-world settings and interoperability sandboxes.
 - Supports documentation of device actions for forensic purposes (e.g., black box recorders in aviation).
 - Uses third-party certification to create trust in safety-critical settings
- An interoperability leadership team that:
 - Studies past efforts (both successful and unsuccessful), identifies key performance indicators, and implements a pilot or demonstration project to build support.
 - Establishes a “start date” for interoperability in recognition of the fact that full interoperability cannot be achieved immediately but must be phased in as legacy systems and software are phased out and data is moved.
 - Defines and encourages a culture of excellence with approaches that ensure implementation of consensus standards and requirements.
 - Considers in advance how to measure patient benefit.

Exchange and Semantics of Data and Metadata

To enable the reliable and usable exchange of data and metadata, information-sharing networks require the consistent use of standards (e.g., for semantics) and a common set of rules for exchange. Participants emphasized the following needs:

- An ontological framework to allow for all relevant data to be interoperable or at least for users to understand safety implications. Current terminologies are diverse, ambiguous, ill defined, and lacking such a framework.
- A common understanding of the data represented for stakeholders and data users. Semantic standardization is necessary but often lacks the necessary detail (e.g., is the blood glucose value taken when fasting or at various times during the day?).
- Metadata that describes measurement context and patient variables (e.g., the signal averaging time, body site, patient position, environmental conditions, concomitant technical alarms, and how often data are transmitted from the device) to create and implement advanced analytics typically achieved by a co-located expert clinician. Interaction between medical devices in real time and with EHR data is severely limited by the absence of device metadata.
- A standardized device interface for all devices that are deemed interoperable. Data that is traditionally displayed to a medical device operator should go through a standardized device interface so as not to disrupt intellectual property. Such a system will require versatility and integration of nonmedical device data. Alternatively, the community could consider other approaches (e.g., the DataStream model) to provide prespecified, interoperable data necessary for use in new systems, without giving users additional access to all the device or system data being generated.

- Interoperability that occurs across the entire data lifecycle both in and across different settings such as: within a clinic or hospital, between remote monitoring products, outpatient and emergency-care devices, and medical equipment management and maintenance.
- Clear definitions of who owns the data (e.g., device manufacturer, healthcare provider, patient,) vs. who can access the data for purposes of interoperability.
- Methods to support the middleware required for interoperability. This could include licensing and subscriptions if a clear commercial benefit does not otherwise exist.
- A community forum for stakeholders to define use cases, models, and verification activities, and to enable improvements through problem sharing.
- Benchmarks should be developed to establish ground truth for interoperability.

Access to Control of Devices

There is value in the automation of healthcare processes to enhance patient care and safety. The advantages of closed-loop systems (i.e., where machines interact and control functions in an automated system) and medical devices that exchange information (e.g., to stabilize a patient without human intervention) require functional medical device interoperability. Currently, this level of closed-loop control is only available as a vertically integrated solution from a single manufacturer. Participants emphasized the need for:

- A clearance pipeline for interoperable devices like the FDA 510K certification.³ This pipeline could have separate streams for hardware, software, and updates.
- Post-launch maintenance of interoperability, and identification and management of emergent behaviors are needed to identify undesirable consequences and establish mechanisms to provide feedback.
- Policy and protocols to support safety investigations (as in other industries) that span regulatory agencies.
- Access and control of both pre- and post-market data to protect manufacturers' intellectual property but also to ensure data are not reverse engineered by competitors to identify proprietary information.
- 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 a lack of clarity on the distribution of responsibilities when groups of interoperable devices are incorporated into broader IT systems.
- Platforms to provide supporting functionality to enable application development without recreating the sensor/actuator infrastructure. This can promote innovation by enabling the evaluation of new technologies and decreasing time to market.

Incentives

The current business models of medical device manufacturers and EHR vendors lack enough incentives to drive interoperable or semi-interoperable solutions. In fact, many stakeholders see open communication between devices as a threat to their market share. The use of government incentive programs such as the 2009 Health Information Technology for Economic and Clinical Health Act were mentioned. Participants felt that an incentive strategy should consider:

- Learning from business models and standards adopted by other industries that have achieved interoperability. For example, before cell phone service became interoperable, network providers had to move between service zones.

³ <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510k-clearances>

- Educating stakeholders about the benefits of data interoperability to improve care for patients and reduce costs for insurers and purchasers of insurance.
- Adopting a flexible approach that encourages the adoption of data field and format standards, such as Fast Healthcare Interoperability Resources, while avoiding strict mandates that fail to keep pace with innovation.
- Adding value to industry stakeholders, such as a reduced timeframe for premarket approval and clearance.
- Highlighting examples and opportunities for different approaches by creating platforms, such as Challenge.gov (www.challenge.gov).
- Supporting innovative business models such as tying adoption of interoperability standards to reimbursement and/or linking interoperable equipment to value-based care.
- Increasing innovation in small businesses by reducing perceived regulatory burden for clearance and supporting nontraditional funding approaches (Small Business Innovation Research, collaboration with another similar system).
- Coordinating standards across government agencies, including those who deliver healthcare.
- Leveraging “patent pools”⁴ like those the communications and information technology industries used to achieve interoperability.

Management and Modernization of Standards

There was 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. Participants considered how to develop interoperable system standards that manufacturers will readily adopt. Points discussed included:

- Establishing a common core of standards that allow proprietary improvements and are enforceable.
- Solving questions of coverage, coordination and harmonization.
- Ensuring the privacy and security of patient information shared over devices complies with Health Insurance Portability and Accountability Act of 1996 regulations and other laws (Federal, state, and local).
- Developing usable guidance and tools to support interoperability standards.
- Disclosing standards to drive business including incentives for those who participate in standards development.
- Setting new standards for control loop algorithms.
- Creating an accelerator for adoption of standards (e.g., the DaVinci Project) to drive interoperability.
- Establishing standards for compliant interface and data formats, communication, metadata common core, and for safety with a focus on error reduction.
- Considering payment for those who participate in developing the standards.
- Ensuring standards are readily updatable and are acceptable across relevant sectors.
- Eliminating interference between medical devices and consumer devices.
- Making clear standards and certifications available to buyers at each phase.

⁴ Patent pools can be defined as agreements between two or more patent owners to license one or more of their patents to one another or to third parties. Often, patent pools are associated with complex technologies that require complementary patents in order to provide efficient technical solutions.

Infrastructure, Tools, Platforms, Testbeds, and Use Cases

Improved infrastructure and tools will enhance the development of interoperability of medical devices and their governance. These include reference architectures and open platforms, use cases, test beds, test procedures, and implementation guides. Implementation guides are essential for users to understand system requirements and identify hazardous situations, and they should be complemented by robust test capabilities and procedures. For example, the provider-payer interoperability industry uses implementation guides to connect EHRs and billing management systems. Once created, implementation guides can greatly reduce the time and effort of implementing individual interoperability activities. However, creating these guides is a time-consuming process; they must be developed, tested, and then formalized by a respected governance and standards body.

Real-life, end-to-end use cases are also necessary to allow the interoperability ecosystem to identify gaps prior to full implementation, evaluate the developed processes and standards, and pilot new areas. Standards developers and promoters must start with, and continually work from, compelling, real-life use cases that reflect the needs, concerns, and constraints of potential standards adopters and allow stakeholders to get a clear sense of the direct benefits (e.g., for clinical care, business, or clinical research).

Catalyst for Interoperability

Even though medical device interoperability has been a focus of government and industry for the past decade, it seems that little progress has been made. RFI and Listening Session participants noted that catalysts are needed to drive the advancement and adoption of interoperable systems. These catalysts must highlight the safety and cost benefits of better measurements, avoidable errors, and enhanced security and privacy. Potential catalysts include:

- Leveraging current healthcare system concerns such as clinician burnout, efforts to contain healthcare costs, consumer health technology used outside the healthcare system, low productivity, and high capital and operating costs.
- Engaging patient safety organizations to support interoperability standards.
- Teaming with Medicare and top healthcare providers (e.g., both government and for-profit providers) to be early adopters.
- Presenting interoperability as the path forward for data privacy in the 21st century.
- Educating the public (including lawmakers) on the socioeconomic benefits of medical device interoperability.

Action Plan: One to Five Years

Year	Action Plan
1-3 years	<ul style="list-style-type: none"> • Identify a governance organization. • Engage all stakeholders and consider their viewpoints. • Develop public-private partnerships and consortiums. • Design an interoperability roadmap with lessons learned. • Establish use cases and create interoperability ontologies • Build on current test environments to allow iteration and attention to issues. • Create pilots or proof-of-concept testbeds (clinical and preclinical). • Work with FDA guidance on content of premarket submissions. • Identify standards gaps and issues and modify or create standards for interoperability. • Create a vendor data validation plan.
3-5 years	<ul style="list-style-type: none"> • Assess pilots and demonstration projects. • Identify Federal funding for interoperability. • Hold a Challenge.gov competition for interoperability adoption. • Extend outreach and engage trade associations. • Integrate interoperability in value-based care definitions and leverage those in telehealth regulations.

Conclusion: A Way Forward

The response to the 2019 HITRD RFI and Listening Session indicate that now is the time to actively promote and support the interoperability of medical devices, data, and platforms. Inaction incurs costs to patients, healthcare providers, device manufacturers, and the Nation. One participant described this eloquently: “Today’s state of the art requires no certification. Currently, there is no centralized or independent testing to help assure that the various assembled components work as expected. Each installation is left to their own devices to discover and document expected outcomes, test plans, test cases, execute testing, and identify and mitigate residual risks. If you consider the cost incurred by each healthcare organization to complete this work, the cost nationally would be staggering.”

Participants also cited the need for innovative platform-based systems to support rapid and efficient development of applications and safety systems, where sensors, actuators, and applications provide “plug and play” capabilities. Participants emphasized the need to standardize nomenclature for data and metadata (possibly centered around the patient instead of the device) and for describing clinical procedures. Several cited the need to develop an overall framework that uses communities of interest to establish use cases, guidelines, verification methods, governance and regulatory structures, and independent safety assessment boards that could cut across regulatory agencies, since not all components in the system would be under a single regulatory authority. Business cases, incentives, and roadmaps are needed to enable safe, market-based solutions. Healthcare providers need a means to speak with one consistent voice so that manufacturers can deliver cost-effective interoperable products that meet their needs.

Finally, future medical devices, data, and platforms, which include standards for interoperability, cybersecurity, and control, will support semiautonomous and fully autonomous medical care systems that improve patient safety and quality of care. To realize this vision of device interoperability requires an open, extensible architecture as a conceptual framework for innovation, supported by implementation guides, data and metadata standards, and test suites for conformance and compliance testing.

About the Authors

The NITRD Program is the Nation's primary source of federally funded work on pioneering information technologies (IT) in computing, networking, and software. The NITRD Subcommittee of the National Science and Technology Council's Committee on Science and Technology Enterprise guides the multiagency NITRD Program in its work to provide the R&D foundations for ensuring continued U.S. technological leadership and meeting the needs of the Nation for advanced IT. The National Coordination Office (NCO) supports the NITRD Subcommittee and the Interagency Working Groups (IWGs) and Teams that report to it. The NITRD Subcommittee's Co-Chairs are Kamie Roberts, NCO Director, and, Margaret Martonosi, Assistant Director of the National Science Foundation Directorate for Computer and Information Science and Engineering. More information about NITRD is available online at <http://www.nitrd.gov>.

NITRD's Health IT (HITRD) IWG focuses on more efficient and effective healthcare through IT-related technologies that support effective health monitoring; individualized screening, diagnosis, and treatment; improved disease prevention and disaster and emergency response; and broad access to health and healthcare information and resources. HITRD activities also contribute to building and sustaining a vibrant community of professional health IT researchers and practitioners. More information is available online at <https://www.nitrd.gov/nitrdgroups/index.php?title=HITRD>.

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