

## HITRD RFI Responses, March 15, 2019

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

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# JOHNS HOPKINS

## **RESPONSE TO NITRD REQUEST FOR INFORMATION: ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE**

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# Medical Device Interoperability

## I. Summary

Under the leadership and direction of the Dean of the Medical Faculty and CEO of Johns Hopkins Medicine, Dr. Paul B. Rothman, Johns Hopkins launched a precision medicine initiative branded as Hopkins *inHealth*. When this program launched in 2016, Dr. Rothman noted, “At Johns Hopkins Medicine, our patients are at the center of everything we do.” Dr. Rothman went on to note that “Johns Hopkins pioneered the idea of tailoring treatment to the individual” and one of our founding physicians, Dr. William Osler, “believed medicine should begin and end with careful observation of the patient.” (Rothman, September 6, 2016).

Johns Hopkins’ *inHealth* precision medicine initiative is comprehensive and seeks to use carefully curated information about the patient to inform and empower clinical decision making at the bedside as well as power the bench-to-bedside program within Johns Hopkins to speed delivery of innovative and effective treatment of the patient condition. Effective use of medical devices and analysis and implementation of the data those devices provide is a key component of the overall precision medicine ecosystem we are building to achieve Dr. Rothman’s vision of providing state-of-the-art care tailored to the individual patient.

In response to the NITRD request for information on new approaches to solve the interoperability issues that hinder achievement of the vision outlined in this RFI, Johns Hopkins suggests a public/private partnership model where governmental guidance and efforts to improve medical device interoperability are informed by not only governmental subject matter experts convened in conference rooms but by iterative and interactive partnerships with clinical, operational, and information technology leaders in the private clinical community. In particular, recommendations and regulations that seek to solve a particular challenge may sound good on paper but may need adjustments to avoid real-world unintended consequences that could result in unintended cost increases or impractical real-world solutions. Johns Hopkins would be interested in participating in such a partnership pending Johns Hopkins executive approval.

## II. Johns Hopkins Respondents

### A. Executives

1. **Dr. Peter Greene, Chief Medical Information Officer, CMIO**
2. **Stephanie Poe, Chief Nursing Information Officer, CNIO**
3. **Darren Lacey, Chief Information Security Officer, CISO**
4. **Alan Coltri, Chief Systems Architect**

### B. Information Technology Leadership

1. **David Li, Director, Clinical Information Systems**
2. **Ed Grogan, Sr. IT Director, Sibley Memorial Hospital**
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## III. RFI Questions

### A. Summary

Johns Hopkins agrees with NITRD's assertion that there are issues that make medical device interoperability across the continuum of care challenging. The challenges are multifactorial and span the continuum of care including emergency department, acute care inpatient settings, ambulatory clinical settings, and with the patient's home. Our responses below highlight our shared concern and we would welcome the opportunity to participate more fully in future discussions on this important topic.

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### 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?

Ideally, the medical device interoperability pathway would require as few systems and as few connections as possible. In its simplest form we would want the path to look something like this:

**Medical device → Middleware → Target System (EMR or precision medicine DB or both).**

Today's middleware solutions must solve a multitude of issues including transforming vendor-specific proprietary data feeds into standardized output data formats like HL7 or XML. In addition, they serve to provide Electronic Medical Records (EMRs) with a single interface source thus allowing the EMR to interface with a single platform instead of dozens of heterogeneous interfaces from various makes and models of medical devices. Today's middleware platforms provide a useful and necessary function given the diversity of medical device interface formats. If all medical device manufacturers and EMR vendors conformed to a universal interface standard, middleware solutions and other target systems could focus on providing features and functions that add more value than simply translating one data format to another.

Our vision is to create a robust and sustainable architecture across Johns Hopkins Medicine that achieves the following goals:

- a. Easy and accurate association of each medical device and the data it transmits with the correct patient. Clinical provider interactions with devices should be intuitive and follow the lean sigma principle of minimizing the opportunities for error.
- b. Medical devices should be capable of transmitting ALL pertinent data including device ID (important for infection control tracking), machine settings, and ALL physiologic measurements
- c. Medical device manufacturers should not limit full dataset availability to outside vendors while requiring purchase of additional Original Equipment Manufacturer (OEM) software or products in order to access the full dataset as an OEM marketing strategy. While this is understandable from the vendor perspective as a way to establish a comparative advantage, it artificially increases the cost of medical device interoperability in large healthcare settings where vendor variability across medical devices is significant.
- d. Ideally, devices will natively provide, several communication modalities (wired Ethernet, serial, WiFi wireless, Bluetooth wireless, etc.)

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- e. Medical devices can be readily and easily replaced or moved with a mechanism to quickly and accurately ensure that patient context is maintained and vital sign association with the wrong patient is minimized.
- f. The number of applications involved in medical device integration and interoperability is kept to a minimum. Today, the number of systems required to connect medical devices AND satisfy all of the use case scenarios is too large. Medical device manufacturers are increasingly requiring that you buy their middleware software packages to access data on medical devices while maintaining their FDA approval status. This results in healthcare providers having to purchase multiple software packages from multiple vendors. In addition, many application vendors require or strongly encourage a particular middleware solution to front-end the application to minimize the types of interfaces they need to support.
- g. Medical device data transmission should meet established cybersecurity standards to ensure that PHI data is kept secure both at rest and in transit.
- h. The medical device data formats would adhere to at least one universal standard or multiple commonly accepted standards (HL7 IHE, XML, JSOC, etc.).
- i. Medical devices should be capable of temporarily storing vital signs data if network connectivity is lost and then transmitting the backlog when network connectivity is restored.

This plan would address the following key pain points and use cases:

- a. Association of vital signs with the wrong patient if a device is replaced or moved and the appropriate patient or room/bed identifiers are not updated.
- b. Vital sign data collected during transport (e.g., inpatient trip to radiology) is often not available for automated vital signs capture as there is no mechanism to store/forward vital signs data when network connections are lost.
- c. The number of disparate systems needed to connect various devices is growing due to OEM requirements for associated software and/or vendor requirements for middleware from business partners. Sometimes the need for additional software is not due to vendor mandate but due to unique functions available in some systems but not others.

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

The key relevant parties for Johns Hopkins' interoperability solutions are as follows:

Internal Stakeholders/parties:

- Patients
  - Our patients are at the center of everything we do.
  - Our medical device interoperability solutions need to support safe, efficient, quality care
  - Medical device interoperability solutions need to improve, not compromise, patient safety (e.g., electrical isolation, avoid fall risks, etc.)
- Clinical Providers (physicians, nurses, technicians, respiratory therapists, others)
  - Our providers need to be able to interact with medical device interoperability solutions in a way that doesn't distract them from their primary focus, the patient.
  - User interfaces by clinical providers need to be intuitive and minimize confusion and cognitive load to operate.
  - It should be easy to associate the device with the patient, easy to initiate normal functions, obvious when it is not working, and easy to remediate common problems.
- Administrators
  - Our administrators are key to helping us procure necessary resources (financial, technical, and human) to install, support, enhance medical device interoperability (MDI).
  - Administrators are instrumental in making sure that our MDI efforts are in line with departmental and enterprise-wide strategic priorities.
- Central Information Technology professionals (project managers, analysts)
  - Medical Device Interoperability is coordinate on an enterprise level by central IT at Johns Hopkins.
  - There are lots of pockets of subject matter experts within the clinical community, clinical engineering, researchers, IT, and professors.
  - We are still working to fully integrate/coordinate these efforts into one large cohesive community.

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- We have made some small strides by standing up a Johns Hopkins Medicine, enterprise medical device integration workgroup. This workgroup is co-chaired by a provider, a nursing informatics professional, and an information technology director.
- Cybersecurity is a major priority for Johns Hopkins and the dual missions of protecting our devices from cyber threats and protecting the organization from threats exploited through medical device vulnerabilities are a major concern and focus of our efforts in this space.
- Biomedical/clinical engineers
  - Our clinical/biomedical engineers are key to device acquisition, device safety checks, installation/deployment, support and maintenance.
  - They partner with IT to manage the deployment, replacement, expansion of medical devices across the enterprise.
  - The lines are blurring between medical devices and IT devices and the line of demarcation for support is becoming VERY blurry and is an ongoing concern.
- Helpdesk
  - Our HelpDesk plays an important role in logging problem calls, routing those calls to the right stakeholders for remediation, and escalating problems as necessary.

### External Stakeholders/parties:

- Vendors
  - Our vendor partnerships are also key to our MDI strategy.
  - Johns Hopkins has enjoyed generally positive relationships with our vendor partners, GE Healthcare, Philips, CapsuleTech, Medical Informatics Corporation, Connexall, and others.
  - We seeing a trend in the industry of OEM vendors (GE, Philips) to push customers to buy more and more of their software solutions including blocking of selected information to competitor software products to maintain a competitive advantage and further monetize their product offerings.
  - Customers are being forced to buy software solutions that are duplicative in order to gain access to the full complement of information available from the native medical device.
- Government/Regulatory Agencies/Standards Organizations:

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- Federal, State, Local agencies
- FDA
- Joint Commission
- Health Level Seven International
- Others
- The above named agencies all play a role in helping and in some case hindering interoperability. To the extent that they move the needle toward universal adoption of data collection, data transmission, and data security these efforts are helpful. To the extent that they hamper innovation and solutions that solve unique problems they can sometimes hinder interoperability.

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

The major challenges and impediments for interoperability are as follows:

#### 1. Cost:

The capital and ongoing operating costs of purchasing, installing, and maintaining these systems is becoming a major challenge as financial pressures to reduce the cost of healthcare increases as vendors are seeking new and creative ways to monetize their product offerings. In particular, we're seeing a major trend towards vendor recognizing the financial value of patient/hospital data and seeking rights to use this data for the benefit of the vendor's financial bottom line.

In addition, the need for more human resources to architect, install, and maintain these solutions is growing even as our healthcare organizations are under pressure to reduce human resources within the organization to keep costs contained.

#### 2. Technical Challenges:

- a. Cybersecurity: The need to apply security patches in a timely manner on standard operating systems embedded in medical devices and not invalidating FDA approvals is an ongoing challenge.
- b. As organizations like Johns Hopkins is committed to ensuring the latest, most secure network connectivity (wireless connectivity in particular), equipment vendors are

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struggling to keep up with embedding wireless cybersecurity compatibility in their product offerings (e.g., EAP/TLS SHA2 certificate security).

- c. Some computers are now FDA class-2 medical devices. Some medical devices now have many of the same operating systems as traditional computing devices and are more likely to be network connected.
  - d. Clinical engineers, in general, are now being required to be fully trained and committed to learning the technical nuances of IT support (networking, cybersecurity, operating system patching, etc.) Our IT folks generally are not trained as certified clinical engineers and may need to be.
  - e. Reliability of WiFi connections is also a major challenge in large academic medical center environments given the technical challenges involving electromagnetic interference, access point coverage, bandwidth saturation, and dead zone mitigation.
3. Political/Organizational challenges:
- a. Although we enjoy a generally good partnership with clinical engineering, we do not have enterprise-level governance of this group and the level of cooperation is largely driven by informal influence without the benefit of a formal governance structure. As a result, we sometimes struggle with local vs. enterprise decision-making, system procurement, and fleet replacements. We are making progress but still have many opportunities for improvement.
  - b. In many cases, the lines of responsibility for IT vs. clinical engineering exist in silos vs. being under one single organizational structure. This historical setup is slowly changing but many academic medical centers still have separate/distinct leadership structures. Gartner recently shared with Johns Hopkins that they are receiving a lot of calls about this trend and they are contemplating a possible research project to address the blurring lines of governance between IT and clinical engineering.
4. Solving disparate clinical/operational needs:
- a. Various stakeholders and projects have different goals and requirements. Researchers want access to as much data as possible to support a wide variety of hypotheses to achieve results that are statistically significant.
  - b. Compliance and security administrators want to place strong governance controls in place to restrict data access to only the data the researcher is entitled to access

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based on their Institutional Review Board (IRB) approvals and regulatory and legal requirements.

- c. Clinical providers want access to medical device data in real-time to make timely, important clinical decisions.
- d. Clinical providers also want actionable, pertinent alarms sent to their clinical communication device that signal a need for clinical intervention in near-real-time with little to no latency. They also want software solutions that assess and manage alarms to reduce alarm fatigue by filtering nuisance alarms and forwarding life-critical alarms.
- e. Researchers in general do not require real-time medical device data with minimal latency in data transmission. There are, of course, some researchers who may want near-real-time data depending on their research protocol.
- f. Some devices only provide a single data feed for alarms, tabular vital sign data (e.g., 1-minute vitals), and high-speed, waveform data (Hz level). Few software solutions can collect, process, and forward these disparate datasets from a single device to disparate target systems to serve the need of different stakeholders.
- g. Johns Hopkins has a number of active and planned initiatives that rely on strong medical device interoperability. Like most organizations, we've successfully implemented automated vital signs collection for physiologic monitors, anesthesia machines, and a few other devices to facilitate improved clinical documentation. We are struggling to expand the numbers and types of devices we connect to the EMR due to cost and resource constraints. We have several initiatives exploring telemedicine options and working to find ways to provide improved clinical surveillance with a higher provider to patient ratio. We are also working on creating an enterprise-level architecture for the collection, transmission, and organization of comprehensive patient data (including medical device data) to support our individualize medicine program branded as our *inHealth* Precision Medicine program.

### **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.**

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The short answer from our perspective at the moment is that the vision as outlined in this RFI is not currently viable. The vision is well-stated in terms of an idealized state but few if any solutions available today can seamlessly serve all of the requirements of making that vision a reality. There are technical limitations within most systems. There are usability challenges and considerations that are hard to overcome. There are financial challenges including not only the initial price of deployment but the pace of technological change and equipment/software obsolescence. Our organization is on a good path to break down the barriers between clinical care, research, and teaching to improve the role of medical device interoperability in furthering the mission of bench-to-bedside care improvements but they are not completely dissolved.

In answer to the question about how each of the issues outlined above can be addressed and by whom, we would offer the following answer: The solution to achieving the vision for true medical device interoperability will require a thoughtful, iterative process that addresses BOTH the clinical and usability goals outlined in NITRD's vision AND aligns the incentives to achieving those goals so that ALL stakeholders (including those who need to profit from their contributions) are able to contribute to the common vision while still remaining true to their individual missions.

Johns Hopkins is extremely grateful for the opportunity to contribute to this RFI on medical device interoperability and would love to be a partner in moving the needle forward for our organization, for the healthcare industry, and for the country. Thank you for the opportunity and for your leadership in sparking the public/private partnerships needed to make a difference.

## IV. References

### A. Books

None

### B. Web Sites

Rothman, Paul B., M.D. (2016, September 6). One Size Doesn't Fit All. Retrieved March 5, 2019 at <https://www.hopkinsmedicine.org/news/articles/one-size-doesnt-fit-all>