

## 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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Response to the HITRD IWG Request for Information (RFI), Federal Register Notice: 84 FR 4544:  
Action on Interoperability of Medical Devices, Data and Platforms to Enhance Patient Care

March 17, 2019

Dear HITRD,

The Association for the Advancement of Medical Instrumentation® (AAMI) is a nonprofit organization founded in 1967. It is a diverse community of approximately 7,000 professionals united by one important mission—the development, management, and use of safe and effective health technology.

AAMI is the primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals. AAMI helps members:

- Contain costs
- Stay on top of new technology and policy developments
- Add value in healthcare organizations
- Improve professional skills
- Enhance patient care

The AAMI standards program consists of over 100 technical committees and working groups that produce Standards, Recommended Practices, and Technical Information Reports for medical devices. The AAMI Interoperability Working Group is the consensus body that develops American national Standards and Technical Information Reports that focus on the safety and efficacy of the interoperability of medical devices.

Our vision of interoperability encompasses a means to enable the rapid development of new applications for patient safety and improved health based on platform solutions that provide for “plug and play” sensors, actuators, displays and other interoperable components. A key objective is to re-use existing infrastructure, technology, and standards wherever possible.

The deployment of multivendor interoperable systems requires technical, policy, and legal constructs for data interchange to support claims of safety, clinical effectiveness, security, and acceptable quality of service. This is, in large part, due to the technical necessity to integrate both FDA regulated and non-regulated technologies when implementing clinical end-to-end solutions. It is the integration of these diverse technologies within one or more “system of systems” by equally diverse stakeholders that drives the need for transparency in the technical, policy, and legal framework.

Recently published and in-progress standards (in particular AAMI standards and those published jointly with UL) address technical aspects of the framework and provide a starting point for potential regulatory or legal aspects. The main focus of these standards is to assure the following: 1) interoperable devices should be designed to transmit interoperable data in a manner that does not degrade the performance of the core medical device functions, and 2) the design enables the instantiation of emergent system properties while maintaining system safety.

We recommend the following:

- (1) Support the safe and secure deployment of systems comprised of interoperable components through formulation of an interoperability framework. The framework could parallel the NIST cyber security framework (CSF). Such a framework would concisely provide key concepts and terminology that illustrates the path to application of these technologies to improve patient safety.

- (2) Establish a small set of core interoperability-related concepts, with standardized terminology that can be embraced by all stakeholders. These concepts would relate to data exchange capability, clinical function, performance, risk disclosure, and detecting and sharing safety related emergent conditions.
- (3) Support the development of and industry adoption of standards used within the medical device industry, including the ASTM F2761-09/ AAMI 2700-1:2019 (standard for the Integrated Clinical Environment) and AAMI/UL 2800, Standard for Safety for Medical Device Interoperability, is a family of standards related to interoperability of medical devices. Additional relevant AAMI standards under development:
  - a. AAMI SW92/Ed. 1, Integrated Clinical System: Patient Controlled Analgesia (PCA)
  - b. AAMI SW95/Ed. 1, Requirements for the forensic (black box) data logger for an integrated clinical environment (ICE) for Medical devices and medical systems —Basic safety and essential performance of the patient-centric ICE for medical devices
  - c. AAMI TIR75/Ed. 1, Factors to Consider When Multi-Vendor Devices Interact Via an Electronic Interface
- (4) Continue to engage working groups that focus on interoperability of medical devices, specifically the devices used at the point of care (by professional and lay users).
  - a. Members in these working groups are involved in development or application of the ISO/IEEE 11073-series of consensus standards that define a nomenclature for communication of information from various point-of-care medical device types. These same standards are incorporated into the Continua Design Guidelines (CDGs), a freely available and open implementation framework for end-to-end interoperability of personal connected health devices and systems.
  - b. The vision is to enable a series of complimentary standards or best-practice guidelines intended to address or be applied to each part of the total product lifecycle (TPLC). Consistent application of these standards could support a predictable interaction amongst interoperable devices and validity of information generated from the interactions. The information could be clinical in nature, for use with a patient, as example, or specific to the networked component and app interactions themselves, such as a “black-box recorder”.
  - c. At present, it seems that (1) the available set of standards are either incomplete in their coverage of the TPLC concept or (2) are not complimentary, meaning they address similar aspects, but are not harmonized in the approach. Without solving both the coverage and the harmonization, adoption of these standards by manufacturers will lag and will not lead to safe interoperable systems. Additionally, buyers may want interoperable devices, but not until they can have both end-to-end and TPLC aspects of interoperable devices addressed. Without a pull from buyers, manufacturers will be reluctant to spend the resources designing, developing and supporting interoperable devices. This needs to account for the current state that medical device manufacturers are not yet effectively delivering open communication interfaces to HDO's. It is also important to promote the inclusion of clinical scenarios in consensus standards to provide clarity on the intended applications and proposed benefits of the standards. One example is Annex B of ASTM F2761, which includes seven clinical scenarios that demonstrate the current state (without interoperability), the proposed state (with interoperability), as well as the benefits and potential risks of the proposed solutions. (See [http://www.mdnp.org/uploads/ASTM\\_F2761-09\\_ICE\\_Annex\\_B\\_Clinical\\_Scenarios.pdf](http://www.mdnp.org/uploads/ASTM_F2761-09_ICE_Annex_B_Clinical_Scenarios.pdf))
  - d. Many of the design-stage challenges are currently being addressed through various standards and groups like PCH Alliance. In fact, successful interoperability often requires an alliance to facilitate conformance to one or more standards and implementation criteria. The PCH Alliance serves as an excellent example of a healthcare interoperability

alliance. Note, however that PCH standards have not in the past addressed non personal-health devices, real-time data delivery including waveforms, and alarms, which are needed for many patient-safety related solutions in high-acuity care settings. In addition, comparably little focus has been given to post-launch maintenance of interoperability and identification and management of emergent behaviors. When groups of interoperable medical devices are incorporated into systems – some of which may include interoperable devices that are not medical devices – there is a lack of clarity on the distribution of responsibilities. For example, if a patient is injured while a set of interoperable devices is being used to support their care, it is unclear who will perform root-cause analysis. If the event is reportable to FDA, it is again unclear which entity would do that. Similarly, in the event of a cybersecurity breach, it is unclear who will respond or coordinate the response. A “black box recorder” could help provide data for these analyses.

- (5) Investigate the need for a legal construct for technical information sharing to support safety, security, and reliability. This is in large part due to the need to use FDA regulated and non-regulated technologies for clinical end-to-end solutions. We recommend gathering further information on the viability of supporting legal constructs.
  - a. Such a construct could include a framework (Medical Device Interoperability Framework) similar to the NIST Cybersecurity Framework. The framework could aid in laying groundwork for regulators and manufacturers to operate from when considering systems comprised of interoperable devices.
  - b. The solution will also likely require independent third parties that can support monitoring and investigation (e.g., root-cause analysis) given that systems will likely be comprised of devices from competitors.
  - c. Such a framework should address what information should be communicated between devices and what supporting information is necessary such that device can be used safely. (See, for example, government funded research on “Medical Device Interface Data Sheets (MDIDS) and other MGH MD PnP program research results that are being applied to inform AAMI standard development.)
  - d. Such a framework would enable industry consortia to develop platforms for specific clinical applications, such that specific instances can be readily deployed.

Please let us know if we can provide additional information.

Thank you,

*/\*signed\*/*

Julian M. Goldman, MD

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