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Submitted electronically at [HITRD-RFI@nitrd.gov](mailto:HITRD-RFI@nitrd.gov)

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

The Heart Rhythm Society (HRS) appreciates the opportunity to provide preliminary comments, through the Request for Information (RFI), on Interoperability of Medical Devices, Data, and Platforms to Enhance Patient Care.

HRS is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients as well as the primary information resource on heart rhythm disorders. Founded in 1979, HRS represents more than 6,400 specialists in cardiac pacing and electrophysiology, including physicians, allied professionals, scientists and their support personnel. Cardiac electrophysiology is a distinct sub-specialty of cardiology. Most electrophysiologists are eligible for board certification in clinical cardiac electrophysiology and cardiology through the American Board of Internal Medicine. Cardiac electrophysiologists implant and manage patients with pacemakers and defibrillators (cardiac implantable electronic devices or CIEDs), perform electrophysiology studies to determine the mechanisms of rhythm disorders, and perform curative catheter ablations to treat and prevent a variety of cardiac arrhythmias. The discipline of electrophysiology has undergone significant change in recent years, creating significant advances in the diagnosis and treatment of some of cardiology's most challenging diseases such as sudden cardiac death, atrial fibrillation and heart failure. As these enhancements occur, HRS remains committed to improving the quality, safety, and efficiency of patient care.

The letter will address the four 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?*
- *Who are the relevant parties and their contributions to your interoperability solution?*
- *What are 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 that you have.*

**Background**

Wireless home monitoring is now standard of care for patients with implantable pacemakers and defibrillators. These devices generate tremendous quantities of data which must be organized, interpreted and stored. Each manufacturer has developed proprietary software and terminology, which makes it very labor intensive and inefficient for practices to achieve these requirements. It also impacts clinical care and makes it difficult for patients to access their data to obtain basic information such as battery status.

Since 2005, HRS has partnered with clinicians and engineers from the four major manufacturers of implantable pacemakers and defibrillators as well as other medical societies under the guidance of Integrating the

Healthcare Enterprise (IHE) to develop a common nomenclature that encompasses the key concepts required to manage patients with these devices, regardless of manufacturer. On August 27, 2012, the Institute for Electrical and Electronics Engineering (IEEE) approved the controlled vocabulary for CIEDs. Subsequently, it was approved as an international standard by the International Standards Organization (ISO) and recognized by the U.S. Food and Drug Administration and became known as ISO/IEEE 11073-10103:2014 (Health informatics -- Point-of-care medical device communication -- Part 10103: Nomenclature -- Implantable device, cardiac).

Unfortunately, the device manufacturers have not fully implemented the data standard in commercial products. Therefore, the data for patients with implanted pacemakers and defibrillators remains locked in proprietary formats, available primarily in display formats such as PDF, with data not directly abstracted, primarily suited for scanning into electronic records. HRS and its clinical partners continue to develop the nomenclature and advocate for its implementation by the vendor community. However, vendors have seen no financial or other compelling incentive to implement it.

Work is currently underway by the HRS Interoperability Working Group to revise the existing IEEE 11073-10103 nomenclature to further decrease the ambiguity in the data structure and to enhance its utility by adding additional terms needed made necessary by advancing technology.

We are thankful that the National Coordination Office for Networking and Information Technology Research and Development recognizes the need to solve the interoperability issues between medical devices, data and platforms and we are delighted to share our experience and recommendations. Since HRS is a medical professional society, our recommendations will focus on the role of health care providers and clinical societies in developing interoperability solutions. We believe that, given the breadth of data generated by the practice of clinical medicine and the nuances of language, achieving interoperability requires a coalition of clinicians, informaticians, industry, process engineers and EHR/HIT vendors with a participation from relevant federal agencies.

*(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?*

#### **1. Development of a controlled vocabulary - Clinicians**

Clinicians must first develop controlled vocabulary or standardized set of words and phrases that define and describe the concepts required to manage the particular device or disease. This step is necessary to organize the information for subsequent retrieval and overcome the ambiguities of natural language as well as differences in definition imposed by each CIED vendor.

#### **2. Specification of data elements – Industry Engineers**

Each concept of the controlled vocabulary and its associated metadata must be clearly defined as data elements and developed in an existing information model such as Logical Observation Identifiers Names and Codes [LOINC] or Systematized Nomenclature of Medicine-Clinical Terms [SNOMED-CT]).

#### **3. Agreement on data management framework – Industry Engineers**

Capture, transmission, and use of structured data necessitates technical data models (the framework for management of the data itself in database systems) as well as specification of data transmission handshake standards or digital container formats for communication between systems

#### **4. Structured Reporting – Clinicians & Industry Engineers**

Finally, the process for data capture and validation must be integrated into consistent clinical workflows. These best practice processes must be tuned to the specific context (e.g., pacemaker or defibrillator

implantation or removal, in-person clinic follow-up, remote monitoring, heart failure management). The general principles of structured reporting include the acquisition of information as data (rather than prose) by the individual closest to the data along with the use of the data for multiple purposes (e.g., procedure reporting, quality assessment, registry reporting).

In addition, transparency is critical to understand what components of the data standard individual vendors have implemented.

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

Collaboration between clinical societies, the medical device manufacturers and the electronic health record manufacturers is essential. Together, we must work through the appropriate standards development organizations to create non-proprietary solutions. Participation by Regulatory Agencies such as FDA and ONC is helpful.

To date, our work has included the following groups:

- Heart Rhythm Society physicians and staff
- American College of Cardiology physicians and staff
- Cardiac rhythm management companies, including Abbott Laboratories, Boston Scientific Corporation, Biotronik, Medtronic, Inc.,
- Electronic health record companies: EPIC Systems Corporation, GE Healthcare, Cerner
- Remote monitoring companies: Geneva Health Solutions, Heartbeat, Implicity, Lille Group, LindaCare, Murj
- Practice and cardiac device management system companies: Nextgen, Lumedx, Scottcare
- Institute of Electrical and Electronics Engineers (IEEE)
- Integrating the Healthcare Enterprise (IHE) Patient Care Device (PCD) Domain
- Food and Drug Administration (FDA)

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

### **Challenges:**

The greatest single challenge is the absence of a clear incentive for industry to develop and implement interoperability solutions, and/or the absence of punitive consequences for failing to do so. Additional challenges include:

- Health care providers desperately want interoperability solutions, but they are far removed from most purchasing decisions. They also do not know how to ask for interoperability because it is complex.
- Health care systems recognize the need for interoperability but since solutions do not exist, they cannot add the requirement to RFP's.
- Industry (both device manufacturers and electronic health record developers) must prioritize resources. To date, they have not had a financial or regulatory incentive to implement interoperability solutions.

### **Potential Solutions:**

Improve and promote standards:

- Incentivize participation of physicians, nurses and industry in standardization work.
- Promote the advantages of standard implementations and maybe trademark standards (example: IEEE 802.11 = "WiFi", IEEE 11073-10103 = ?)

Incentivize industry:

- A transparent and neutral resource such as the Office of the National Coordinator for Health Information Technology could develop resources that would make it possible for manufacturers to indicate their level of support for interoperability solutions.

Regulatory:

- Requirements for supporting interoperability solutions.
- Support of the work on electrophysiology lab certification by the Intersocietal Accreditation Commission (IAC) that currently requires structured reporting within each institution and ongoing quality improvement both of which are dependent on a structured and consistent nomenclature.

### *Collaboration with Federal Agencies*

HRS believes that collaboration with federal agencies will be necessary to realize the full potential of meaningful interoperability of data acquired from CIEDs. As such, we would like to extend an invitation for you to participate in HRS's efforts. In addition, we would be delighted to attend the June/July 2019 conference and provide additional information about our initiatives.

### *Other HRS Initiative*

The Implantable Device Cardiac Observation (IDCO) profile<sup>1</sup> specifies the creation, transmission, and processing of discrete data elements and report attachments associated with implantable pacemaker, implantable defibrillators (ICDs), and cardiac resynchronization therapy device (CRT) interrogations (observations) or messages. This profile has been developed by HRS in partnership with cardiac rhythm management (CRM) industry (all vendors represented), tested, validated and certified by the IHE's rigorous standards development process. It uses the IEEE 11073 nomenclature as proposed by HRS clinicians to evaluate and monitor the function of all cardiac monitors, pacemakers, ICDs and CRT devices regardless of vendor. In addition, it provides a framework for data acquisition and transmission as discussed above.

The IDCO interoperability profile is available for implementation and clinical use. However as with many initial introductions of new standards, and although the IDCO profile was developed in partnership with industry, we have been unsuccessful in convincing industry to implement the full IDCO profile in their market release products. As a result, only a limited set of data can be transmitted in the IDCO profile. In turn, this situation has limited our ability to seek adoption and implementation by the electronic health record (EHR) industry and personal health record vendors. It also has limited our ability to encourage utilization of the interoperability profile for data registries, quality monitoring, and post-market approval U.S. Food and Drug Administration (FDA) surveillance studies.

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HRS appreciates the opportunity to provide NCO with this input and looks forward to working with you to further implement interoperability of Medical Devices, Data, and Platforms. If you have questions regarding HRS's comments or would like to discuss our initiatives, please contact Isabelle LeBlanc, the HRS Director, Health Policy [ileblanc@hrsonline.org](mailto:ileblanc@hrsonline.org).

Sincerely,



Gerald A. Serwer, MD, FHRS  
Chair, HRS Interoperability Workgroup



G. Stuart Mendenhall, MD, FHRS  
Vice-Chair, HRS Interoperability Workgroup

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<sup>1</sup> PCD Implantable Device Cardiac Observation. IHE Website.  
[https://wiki.ihe.net/index.php/PCD\\_Implantable\\_Device\\_Cardiac\\_Observation](https://wiki.ihe.net/index.php/PCD_Implantable_Device_Cardiac_Observation)