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REVIEW

# Electronic health records and cardiac implantable electronic devices: new paradigms and efficiencies

**David J. Slotwiner** [1,2]

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**Abstract** The anticipated advantages of electronic health records (EHRs)—improved efficiency and the ability to share information across the healthcare enterprise—have so far failed to materialize. There is growing recognition that interoperability holds the key to unlocking the greatest value of EHRs. Health information technology (HIT) systems including EHRs must be able to share data and be able to interpret the shared data. This requires a controlled vocabulary with explicit definitions (data elements) as well as protocols to communicate the context in which each data element is being used (syntactic structure). Cardiac implantable electronic devices (CIEDs) provide a clear example of the challenges faced by clinicians when data is not interoperable. The proprietary data formats created by each CIED manufacturer, as well as the multiple sources of data generated by CIEDs (hospital, office, remote monitoring, acute care setting), make it challenging to aggregate even a single patient's data into an EHR. The Heart Rhythm Society and CIED manufacturers have collaborated to develop and implement international standard-based specifications for interoperability that provide an end-to-end solution, enabling structured data to be communicated from CIED to a report generation system, EHR, research database, referring physician, registry, patient portal, and beyond. EHR and other health information technology vendors have been slow to implement these tools, in large part, because there have been no financial incentives for them to do so. It is incumbent upon us, as clinicians, to insist that the tools of interoperability be a prerequisite for the purchase of any and all health information technology systems.

**Keywords** Cardiac implantable electronic device · Pacemaker · Implantable defibrillator · Cardiac resynchronization therapy · Interoperability · Health information technology · Electronic health record · Integrating the Healthcare Enterprise · Data standards · Office of the National Coordinator for Health Information Technology · Meaningful use

**Abbreviations**

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| CIED | Cardiovascular implantable electronic device |
| DICOM | Digital Imaging and Communication in Medicine |
| EHR | Electronic health record |
| EPRC-IE | Electrophysiology Report Content for a CIED Implant or Explant procedure |
| HIT | Health information technology |
| HL7 | Health Level 7 |
| IDCO | Implantable Device Cardiac Observation profile |
| IEEE | Institute of Electrical and Electronics Engineers |
| IHE | Integrating the Healthcare Enterprise |
| ONC | The Office of the National Coordinator for Health Information Technology |
| RCS-EP | Registry Content Submission for Electrophysiology profile |

The anticipated advantages of HIT and specifically electronic health records (EHRs)—improved clinician efficiency, patient outcomes, and quality of patient care, enabled by the ability to share information among care

✉ David J. Slotwiner
djs2001@med.cornell.edu

[1] School of Health Policy and Research, Weill Cornell Medical College, New York City, NY, USA

[2] Division of Cardiology, Cardiac Electrophysiology Laboratory, New York Presbyterian Queens, 65-45 Main Street, Flushing, NY 11355, USA

providers—have largely failed to materialize [1, 2]. Perhaps the greatest disappointment from the perspective of clinicians is the lack of interoperability between EHRs and other HIT and between the countless systems that generate data upon which clinical decisions are based [3].

The Healthcare Information and Management Systems Society defines interoperability as the extent to which systems and devices can exchange data and interpret that shared data. No single stakeholder in the HIT arena has the ability to overcome the obstacles to achieving interoperability. Vendors have proprietary advantages and competitive markets to consider. Hospitals and healthcare systems—the purchasers of most HIT (including EHRs)—are at the mercy of the available HIT products. Since health systems are the primary customer for HIT vendors, enterprise systems are designed to enhancing revenue cycle management and compliance with meaningful use over clinical patient care. This results in EHRs that requires significant modification to enhance clinical usability and interoperability.

Clinicians and patients—the two groups with arguably the most at stake—are largely voiceless in the decision-making and purchasing equation as most EHRs are purchased by large healthcare organizations. The US Health and Human Services Office of the National Coordinator for Health Information Technology (ONC), the US governmental agency tasked with oversight and certification of EHRs, has, to date, focused on meaningful use as its primary tool to increase adoption of EHRs. The objectives of the first and second stages of the meaningful use program have been to ensure that practitioners replace paper charting with EHRs, to encourage clinicians to switch to electronic order entry and prescribing, to engage patients through the implementation of health portals, and to set the groundwork for interoperability by recording clinical information as structured data which can be stored in and accessed from EHRs and other HIT systems [4]. Up to this point, interoperability has not been a priority.

However, calls for interoperability are growing, and regulatory agencies as well as HIT vendors are taking notice. In an October 2014 press conference, US Health and Human Services Secretary Sylvia Burwell acknowledged interoperability to be the key to unlocking the real value of healthcare information systems for practicing physicians and all healthcare consumers [5]. Several of the largest HIT vendors have joined together to form the CommonWell Health Alliance, an organization with the stated objective of creating a vendor-neutral platform for HIT interoperability based upon common data standards and policies [6]. Most recently, in October 2015, ONC released its final version of the Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap version 1.0 [7]. The document describes ONC's vision of interoperability as necessary for a "learning health system," in which health information flows seamlessly and is available to the right people, at the right place, at the right time, and specifies a sequence of technological and health policy steps to achieve this vision by 2024.

Managing data from cardiovascular implantable electronic devices (CIEDs) provides a clear example of the clinical challenges that arise when data is not interoperable. Each implantable device communicates exclusively with a proprietary programmer and remote monitoring transceiver. The data generated by these communications may then be stored by either printing to paper and then scanning the image into an HIT system or exporting the data in the manufacturer's proprietary format. There are significant limitations associated with both of these options. Scanning a printed file into an electronic health record renders the data in an image file that is readable by humans but stripped of information that can be interpreted by computers. This leaves the data locked in an image file format, requiring human transcription of the data if it is to be used for any subsequent analysis such as generating graphical trends of CIED function over time or creating a database of a practices' CIEDs and their associated model and serial numbers in the event of a recall or device performance advisory.

Alternatively, if the data is exported in the manufacturer's proprietary file format, it can only be read by the manufacturer's software or by third-party vendors who have made arrangements with the CIED manufacturer to obtain the proprietary code. Several vendors have developed software products and/or services to assist clinicians in the management and tracking of data from multiple CIED manufacturers. These niche electronic medical record products alleviate some of the challenges associated with aggregating and managing data from multiple manufacturers producing data from many different sites (e.g., office, hospital, remote monitoring), but ultimately, the data ends up locked in another proprietary format, leaving a clinical practice at the mercy of a proprietary vendor. If an alternative vendor develops a superior product, or if there is a need to use the data for purposes other than those provided by the device HIT vendor, an expensive and labor-intensive custom software interface would need to be created to export the data in yet another proprietary format.

Interoperability requires that information (data) be organized in a predictable format and that it is communicated using standardized content and definition. This concept, known as structured reporting, is fundamental to the goal of entering data once into HIT and then being able to use it for many purposes [8, 9]. Within the cardiovascular arena, significant groundwork has been laid over the past 10 years under the leadership of the Heart Rhythm Society, the American College of Cardiology, and the Society for Coronary Angiography and Intervention and others in partnership with industry and regulatory agencies to develop the infrastructure necessary to achieve interoperability (Fig. 1) [10, 11]. As a result of this

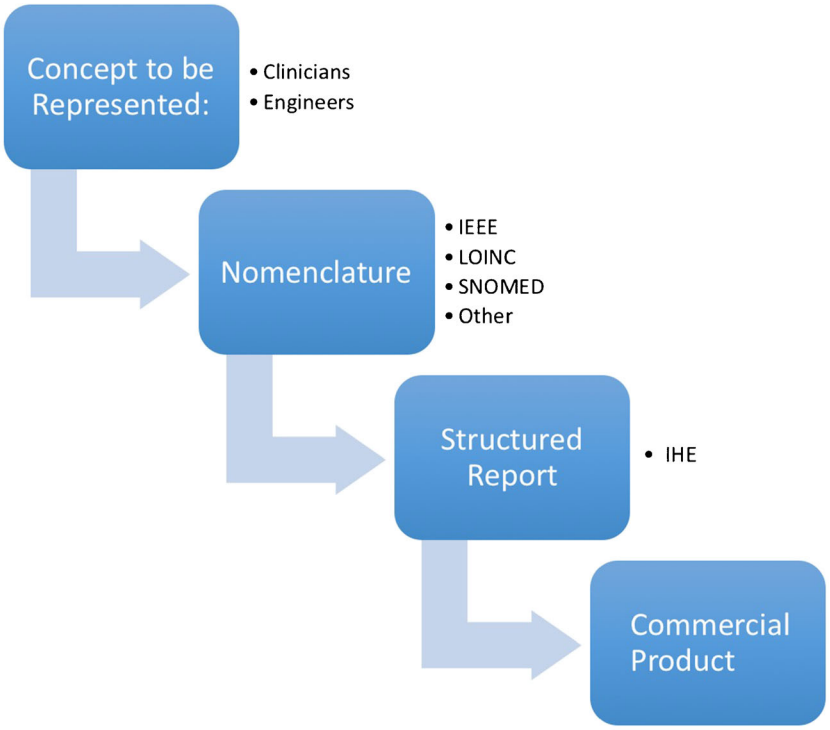


**Fig. 1** Developing health information technology standards for interoperability first requires clinicians and engineers to define the concepts to be represented. Next, a standard nomenclature is identified, which addresses these concepts. The codes from that nomenclature are selected and are packaged as a value set. Depending upon the type of data, the nomenclature could utilize the Systematized Nomenclature of Medicine (SNOMED) codes, a systematic, computer-processable collection of medical terms and definitions, which cover anatomy, diseases, findings, procedures, and more, or Logical Observation Identifiers Names and Codes (LOINC), which is a database and universal standard for identifying medical laboratory observations, or the Institute of Electrical and Electronics Engineers (IEEE) as in the case of CIEDs. Next, interoperability requires that data be structured in a coherent and predictable format. Structured reporting utilizes standardized data element and adds an additional layer of instructions to communicate the context in which the data element is being used. Integrating the Healthcare Enterprise (IHE) promotes the coordinated use of established standards such as IEEE, LOINC, and SNOMED to address specific clinical needs in support of optimal patient care. The interoperability of the clinical concepts is achieved when by both sending and receiving health information technology systems support the nomenclature and interoperability profile. *HIT* health information technology, *CIED* cardiac implantable electronic device

work, the cardiovascular arena is poised to see truly interoperable HIT systems. However, vendors will only adopt these standards and communication protocols if there are financial drivers. Clinicians can exert powerful influence by requiring vendors to demonstrate compliance with data standards and interoperability protocols in the request for proposal bidding process when new HIT is to be purchased. Ultimately, regulatory agencies, clinicians, and patient advocacy groups will likely all play important roles in focusing the financial drivers that will spur HIT vendors to adopt the tools required for meaningful interoperability.

CIEDs are at the forefront of this revolution because nomenclature and communication protocols have been defined, and the CIED vendor community has recognized the value and supported the development of these data standards and communication protocols for interoperability [12, 13]. The interoperability specifications described below enable HIT systems to communicate CIED data without the need for custom interfaces or continuous revisions (Fig. 2).

## 1 Components of interoperable HIT systems

The fundamental building block upon which interoperability depends is a controlled vocabulary (Fig. 3). There must be a selected list of concepts—data elements—that have explicit definitions. Standard development organizations serve the critically important role of bringing stakeholders together to develop, coordinate, and promulgate technical data standards intended to address the needs of users. To achieve interoperability (exchange of these standardized data elements) across the healthcare enterprise, there must be an accepted protocol that specifies the organization (syntactic structure) of the data elements. The single data element alone is not sufficient to communicate between HIT systems. Semantic interoperability includes not just packaging of the data (syntax) but also the simultaneous transmission of the meaning with the data (semantics). To achieve semantic interoperability, the data element requires an additional layer of information to communicate the context in which the data element is being used. One

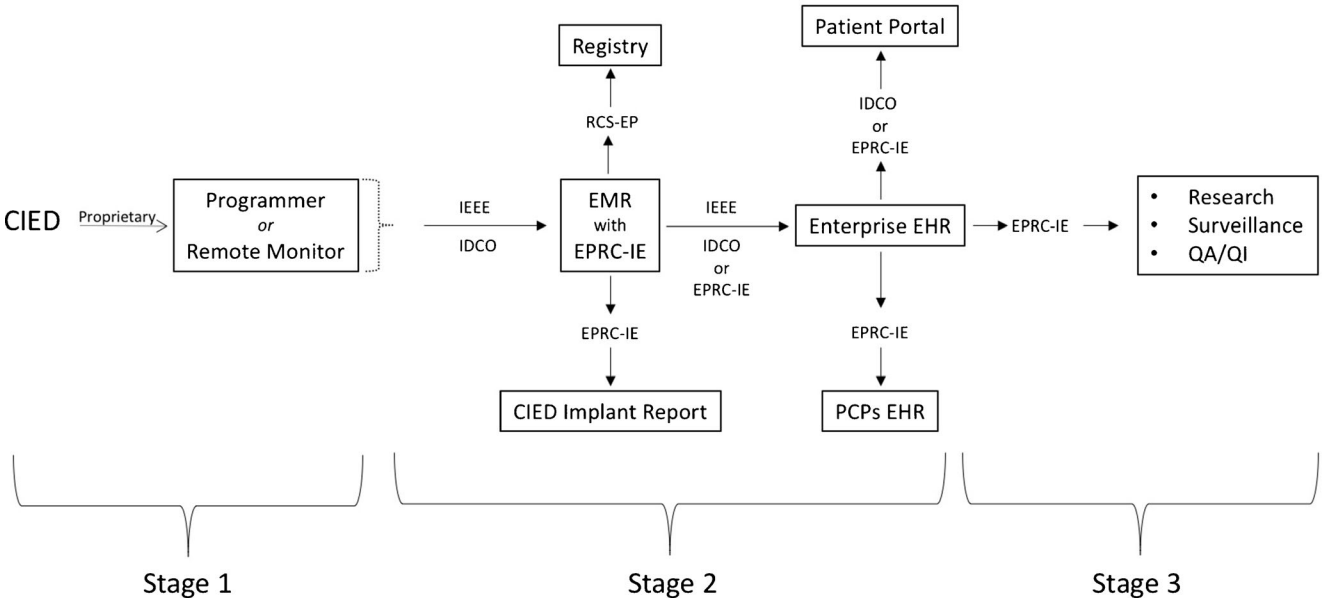


**Fig. 2** Example of data communication possible when systems implement controlled vocabulary (such as IEEE standard) and communication protocols (such as the IHE IDCO, EPRC-IE, or RCS-EP profiles). Stage 1, proprietary communication protocol is still required between CIED and programmer or remote monitoring servers. Stage 2, data may be exported from the programmer or remote monitoring server in an interoperable format consisting of IEEE nomenclature packaged in IDCO profile for interoperable communication with any EHR that supports the IDCO profile. Pictured above is a sequence of data flowing to an EMR used to create a CIED implant report using the EPRC-IE profile. The data may then be sent to the enterprise EHR and then to the patient portal and the PCP EHR. The data may also be communicated to a registry through the RCS-EP profile. Stage 3, data may be utilized for additional analysis (via EPRC-IE) such as research, device surveillance, and QA/QI activities. *CIED* cardiac implantable electronic device; *IEEE* Institute of Electrical and Electronics Engineers; *IDCO* Implantable Device Cardiac Observation profile; *EHR* electronic health record; *EPRC-IE* Electrophysiology Report Content for CIED Implant, Explant, and Revision Procedure Reports; *PCP* primary care physician; *QA/QI* quality assessment/quality improvement

of the largest and internationally well-recognized such organizations is Integrating the Healthcare Enterprise (IHE) [14].

IHE is a not-for-profit organization led by healthcare professionals and industry to develop protocols, called interoperability profiles, which facilitate sharing of clinical data among HIT systems. HIT systems developed in accordance with IHE data exchange profiles are able to communicate with one another without the need to develop custom interfaces. It is important to note that IHE does not create data standards. Interoperability profiles document how data standards (such as those developed by the Institute of Electrical and Electronics Engineers (IEEE), Health Level 7 (HL7), and Digital Imaging and Communication in Medicine (DICOM)) will be used by the sending and receiving system to achieve interoperability.

There are two types of IHE profiles, content and workflow profiles. Content profiles define the structure and the value sets needed to represent clinical concepts and are used in conjunction with workflow profiles which focus on the exchange of the content and sharing of common clinical concepts, including patient identifiers, demographic data, order, and clinical and procedural data, across all of the participating HIT systems. For example, the IHE Electrophysiology Implant/Explant Report Content profile specifies the content structure for a clinical report of a pacemaker, implantable defibrillator, or cardiac resynchronization therapy device implant and explant surgical procedure. Similar to other content profiles, it includes indications, description of the procedure(s) performed, medications, complications, and findings. The IHE Cardiac Catheterization Workflow profile integrates the ordering, scheduling, imaging acquisition, storage, and viewing of cardiac catheterization procedures.

The semantic definitions of CIED data elements as well as the syntactical organization required for interoperability are described below.

## 2 CIED nomenclature

The Institute for Electrical and Electronic Engineering is the standard development organization recognized internationally as the governing body of the controlled vocabulary for information obtained during interrogation (in person or remote) of a pacemaker, implantable defibrillator, or cardiac resynchronization therapy device. This nomenclature was developed under the guidance of the Heart Rhythm Society with full engagement and support from all CIED manufacturers. Working together, this group reached consensus on the approximately 250 data elements necessary to clinically manage a pacemaker, implantable defibrillator, or resynchronization

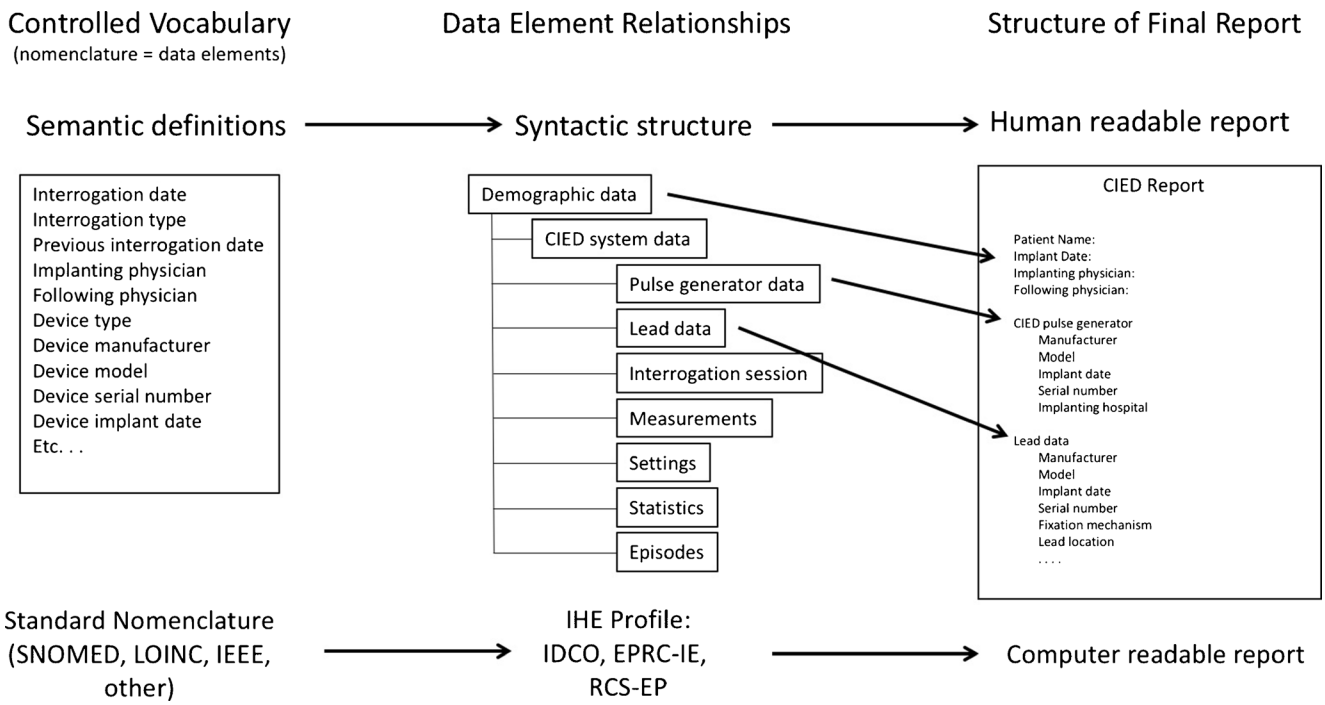


**Fig. 3** Controlled vocabularies are the fundamental building blocks upon which interoperability depends. The definition of each data element (semantic meaning) is specified by the standard development organization governing body. Data elements specific to CIEDs are under the purview of IEEE, but other elements of the report are specified by SNOMED such as the diagnosis code or LOINC such as laboratory values. In order to communicate the semantic meaning of data across health IT systems, the organization of the data elements (syntactic structure) must also be communicated. For CIED data, the syntactic structure is specified by the IHE IDCO and/or EPRC-IE profiles. Finally, these data elements may be organized into a human or machine (computer) readable report as specified by the IHE EPRC. *CIED* cardiac implantable electronic device, *IEEE* Institute for Electrical and Electronic Engineering, *SNOMED* Systematized Nomenclature of Medicine, *LOINC* Logical Observation Identifiers Names and Codes, *IT* information technology, *IHE* Integrating the Healthcare Enterprise, *IDCO* Implantable Device Cardiac Observations, *EPRC* Electrophysiology Report Content

therapy device. Engineers from each CIED vendor reached consensus on the definitions of each data element including, for example, pacing modes, refractory periods, episode counters, mode switch definitions, and tachyarrhythmia detection zone terms. Allowances were made to ensure that vendor-specific features with proprietary competitive market advantages could be accounted for and supported by the final nomenclature. The first iteration of the nomenclature was distributed for comment by IEEE members and subsequently approved as an IEEE standard. It is now available for use and is presently being implemented by all CIED manufacturers but only a limited number of HIT vendors. Work to extend this nomenclature is ongoing based on industry needs, real-world experience, and usage in the clinical environment.

## 3 CIED data interoperability

To facilitate exchange IEEE nomenclature between HIT systems and convey not only the meaning of the data elements but also the organization of the data elements, the following three IHE profiles have been created:

- Implantable Device Cardiac Observations (IDCO) profile [15]
- Electrophysiology Report Content for Implant and Explant (EPRC-IE) profile [16]
- Registry Content Submission for Electrophysiology (RCS-EP) profile for the National Cardiovascular Data Registry [17]

These profiles have gone through harmonization efforts to ensure that they can all communicate with each other in a meaningful way. The IDCO profile specifies how to transfer CIED device-related data represented using IEEE nomenclature from any CIED to any HIT system such as an EHR. The EPRC-IE profile specifies how the CIED data elements and surgical procedure note variables are to be included in a pacemaker, implantable defibrillator, cardiac resynchronization therapy, or implantable loop recorder implant or explant report, represented using IEEE nomenclature and structured using HL7 Clinical Document Architecture. The RCS-EP profile specifies the content structure and value sets for reporting the data collected on defibrillator implant and explant procedures that are reported to the National Cardiovascular Data Registry Implantable Defibrillator Registry.

The IHE IDCO profile has been adopted by the four leading CIED manufacturers, Biotronik, Boston Scientific, Medtronic, and St. Jude. Remote monitoring services from all manufacturers provide the option to download CIED data as specified in the IHE IDCO profile. Physical programmers, some of which would require additional hardware, have limited adherence to these standards, although some manufacturers do provide the option to export data as specified in the IHE IDCO profile. While CIED manufacturers have embraced the IEEE nomenclature and IHE IDCO profile, HIT systems, including CIED procedure reporting systems, EMRs, and EHRs, have been slower to adopt it (although some have).

Data obtained in accordance with the IHE IDCO profile from either a remote monitor or a physical programmer may be shared across the spectrum of compatible HIT systems without the need for custom interfaces (Fig. 2). The data can be imported once into an EHR or HIT system and used for multiple purposes including creating reports; communicating with other care providers; providing access for patients via health portals; submitting data to clinical registries; and utilizing the data for research, quality assessment, and improvement.

## 4 Future work

The IDCO profile is being implemented with some variations across CIED vendors. This means that some customization is still required. Continued curation of IDCO data standards, including outlining appropriate implementation and use of the standard, is ongoing, with release of version 2.0 to include additional data elements and the ability to communicate alerts to downstream HIT actors such as an EHR. There is also need to develop a standard for digital waveforms specific to CIED to facilitate electronic transfer of waveform data with structured data, although this will be a significant undertaking.

The EPRC-IE profile addresses operative reports but not yet the office and follow-up remote reports. These are planned for the next iteration of the profile.

## 5 Discussion

Health information technology vendors have been slow to respond to the interoperability needs of clinicians and patients, even when the interoperability specifications have been created as is the case for CIEDs. In their defense, they have been forced to direct resources to meet the meaningful use criteria set by the Office of the National Coordinator. With finite resources, they must prioritize work according to customer requests. Given the financial penalties associated with failure to comply with meaningful use, now incorporated into the Medicare Access and the Children's Health Insurance Program Reauthorization Act (MACRA), the priority is clear. Unfortunately, there is still no financial incentive for HIT vendors to focus on interoperability. The Heart Rhythm Society and the American College of Cardiology are actively engaged with the HIT vendor community to promote the IHE IDCO and related IHE profiles. There will be a financial incentive beginning in 2017 when the National Cardiovascular Data Registry will start requiring data to be submitted using the HL7 Clinical Document Architecture and RCS-EP profile specification.

A common refrain from the HIT vendors is that customers are not requesting interoperability. This argument fails to recognize that customers, as defined by the HIT vendors, are usually hospital executives who are far removed from the workflow and information needs of clinicians. Also, while clinicians understand the problems encountered by the lack of interoperability, they are not aware of the technological solutions. Therefore, they are not in a position to request the tools needed for true interoperability. The complexity of the equation demonstrates the challenges of achieving interoperability—even once the nomenclature and interoperability profile have been created and agreed upon by the primary stakeholders. ONC may ultimately be in the best position to encourage or require HIT manufactures to adopt interoperability standards as a prerequisite for certifying HIT as eligible for the meaningful use program.

## 6 Conclusions

The groundwork for the true interoperability of CIED data has been created. The standard-based interoperability specifications now exist to aggregate CIED data into a single vendor-neutral repository, without developing custom interfaces for each CIED and HIT system. While some gaps remain and additional features will be desirable for the next iterations of the standard specifications, the fact remains that these specifications (industry-standardized nomenclature and the IHE IDCO, EPRC-IE, and RCS-EP profiles) provide an end-to-end solution enabling structured data to be communicated from CIED to reporting systems, to clinical repositories, to clinical applications, to registries, to referring physicians, to patient portals, and beyond, all with standard-based interoperable solutions. By structuring the data according to internationally accepted specifications, data may be entered once and used for multiple purposes, avoiding repetitive data entry and the associated inefficiencies and inherent risks of errors and inaccuracies. It is incumbent that the Office of the National Coordinator of Health Information Technology and we as healthcare providers insist that the tools of interoperability, such as IHE interoperability profiles and the IDCO profile, become a prerequisite for vendor certification under the meaningful use and future HIT certification programs.

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