Integrating the Healthcare Enterprise White Paper

Implantable Cardiac Device Interrogation (ICDI) Integration Profile

This white paper provides information regarding the *Implantable Cardiac Device Interrogation Profile (ICDI)* of IHE Cardiology. Although this Profile is nearing completion of its technical specification, it is beyond the scope of Year 2 (2006) demonstrations.

In addition to the Profile described in this document, there are other IHE Cardiology Profiles specifically applicable to Electrophysiology: Urgent Implantable Rhythm Control Device Identification Profile (PDQ-IRCD) Profile and Profiles for the EP Lab. These Profiles are described in separate white papers.

Problem Statement: Cardiac electrophysiologists follow patients with implantable cardiac devices from multiple vendors. These devices include pacemakers, implantable cardioverter-defibrillators, and cardiac resynchronization therapy devices. These devices generate and store data about device identification, therapy settings, diagnostics, testing, and patient observations. As part of patient follow-up, an interrogation of the implanted

devices is performed (either in clinic or remotely from the patient's residence). Information is collected about the device, such as device identification, therapy settings, device diagnostics, and therapies delivered. These interrogations are performed by the vendor's proprietary interrogation equipment such as a device programmer or pacing system analyzer.

To improve workflow efficiencies, cardiology and electrophysiology practices require the access to, and management of, key summary implantable rhythm control device interrogation information via a central system such as an electronic health record (EHR), device clinic data management system, or Website. To address this need, the *Implantable Cardiac Device Interrogation Profile* defines a standards-based method for the translation and transfer of summary device interrogation information from the interrogation system to the information management system.

Use Cases: There are three primary use cases associated with this profile: In-clinic follow-up, implantation and remote follow-up.

In clinic follow-up: A patient presents at an electrophysiology follow-up clinic for his regularly scheduled appointment, where he is seen by a clinic nurse. The nurse interrogates the device using the programmer that is associated with the patient's implanted device, extracting the data (e.g., programmed settings, status, events) from the device, and reviews the data. Once the nurse completes the assessment, a physician reviews the findings, and makes the necessary adjustments to the implanted device's programmed parameters, the patient's pharmacologic regimen, etc. The changes are made and documented, and the patient is sent home.

Currently, there are several limitations regarding the way the data extracted from the implanted device are handled. First, the data (from the initial interrogation and in the "final" state) are often captured on paper, to facilitate review outside of the exam room (e.g., in the physician's office prior to seeing the patient in the examination room) and to document the information for the patient's chart. Second, if the clinic has an EHR, it is often necessary for someone to manually enter the key data or scan the printed reports into the system. Even in those cases where the clinic's system is capable of taking data from the programmer in electronic form, this data must be translated from the device manufacturer's proprietary format into the receiving system's proprietary format, which may not be compatible with other EHR systems that may need to store the same data, necessitating repetitive entry or translation efforts.

This IHE profile addresses the data transfer and storage problems outlined above by profiling a standard format for the transmission of device interrogation data

into and between information systems.

Implantation: A patient is admitted to the hospital and is transported to the cardiac catheterization laboratory for implantation of a pacemaker or ICD. Records may be generated by a pacing systems analyzer, a device programmer, and/or the implanted device. Getting the records of the implant testing and the device programming into the patient's paper or electronic healthcare record are subject to the same issues as described above. It is often also necessary to get this information to the various physicians and clinics involved in the post-implant follow-up of the patient. These physicians and clinics face similar problems getting this information into their own medical records. Finally, the implanting physician needs to dictate operative notes after the case, requiring a hard copy of the information.

This IHE profile addresses the data transfer and storage issues outlined above by profiling a standard format for transmission of the device interrogation and, where applicable, the pacing system analyzer data, into and between data management systems. This will permit viewing of the data from any hospital location with EHR access, facilitating the implanting physician's dictation of operative notes. Similarly, it facilitates the transmission of the implant data to the remote offices of those involved in the follow-up care of the patient.

Remote Follow-up: A physician supplements patients' office visits with remote follow-up using in-home device interrogation ("trans-telephonic"). The physician may follow devices from several different manufacturers, and hence, must retrieve the interrogated device data from multiple sources. This data may be in the form of paper-documented reports, electronic information viewable at a manufacturers' website, or a data feed to an in-office information system.

This scenario is currently problematic because the physician cannot manage and view all of the incoming data from the multiple vendors in a single place. There is no standard way to integrate the data into a central EHR or other information system.

This IHE profile addresses the jumble of all the incoming reports by using the same standard format for remote device interrogation data as for in-office data. This allows for the transfer of the data into an EHR system or other data management system, and for software applications to present data from different manufacturers' devices in a consistent manner. Such applications could produce various summary reports, e.g., for all current patients, or for a single patient over time.

ICDI Profile Benefits: This IHE profile provides benefits to clinicians and administrative staff focusing on improving patient care and reducing inefficiencies, specifically by:

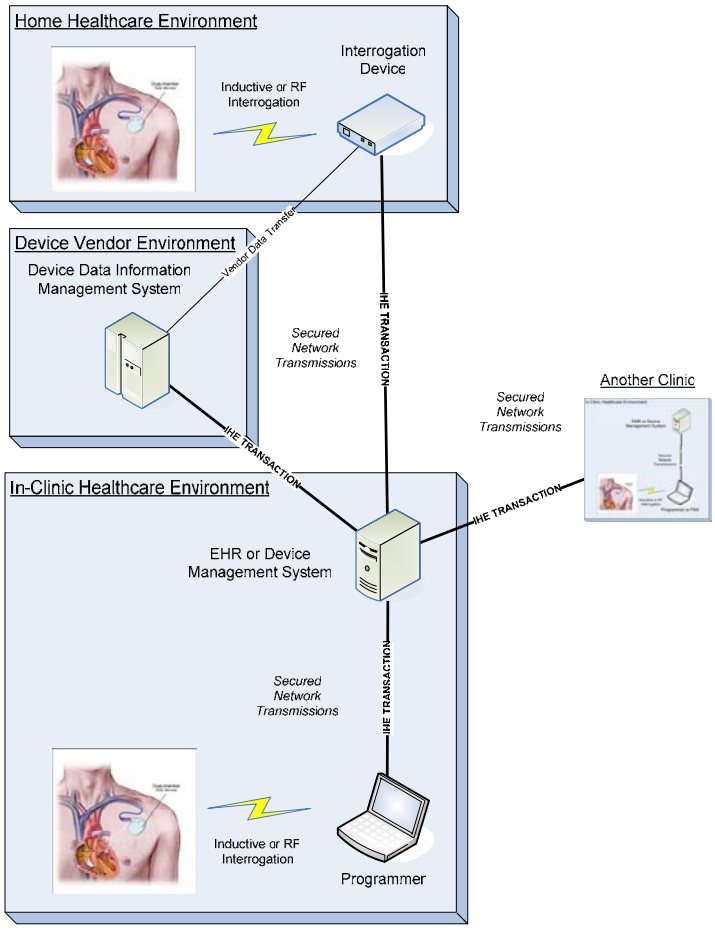
- Providing a standards-based format for the transmission of data from programmers, pacing system analyzers, and remote follow-up systems
- Facilitating the transfer of data from multiple manufacturers' equipment or remote follow-up systems into an EHR or other information system
- Allowing a single information system to manage and display the data retrieved from multiple manufacturers' equipment and remote follow-up systems
- Facilitating the transfer of data between EHRs/information systems

How the ICDI Identification Profile actually works: IHE defines "Actors" that are responsible for performing certain roles. Examples of actors in the Implantable Cardiac Device Interrogation Profile include the Observation Creator (programmers and remote follow-up systems), the HL7 Router (integration engines) and the Observation Repository (EHR station or website). Transactions" between actors are defined by the profile, allowing multiple actors to be integrated in a standardized fashion.

For more technical details regarding the IHE Actors and Transactions, please refer to the IHE Cardiology Technical Framework and Supplements documents.

In an example of a real-world application of this profile, an EHR or data management system would be able to receive discrete data and complete reports from implantable cardiac devices manufactured by different vendors via the manufacturers' programmers and remote follow-up systems, or from other third party follow-up services, in a standardized format. The EHR system would then be able to process and store the data, prepare reports, and provide a single point at which the physician can access and view newly acquired or historical data.

The following figure is a graphic representation of potential uses for the IHE ICDI profile.



Importance of the IHE Process: IHE provides a collaborative forum in which the clinical professionals of the Heart Rhythm Society meet with all of the implantable device manufacturers, as well as vendors of clinical information systems, to agree on a standards-based approach to solving a significant patient management and data management issue, and to improve the efficiency of care delivery. Moreover, IHE provides testing programs, "Connectathons", through which implementations adhering to the Profile can be independently evaluated, thus speeding the deployment of the Profile's capabilities to market.

Purchasing Using IHE: One of the key concepts of IHE is the ability to definitively describe interfaces with a single sentence. Using the statements below mitigates the need for thousands of pages of technical documentation, interface engines, and on-site testing. For example, the following statements should be included in any request for proposal (RFP) for various equipment purchases:

*"The **Implantable Cardiac Device** system shall support the IHE Implantable Cardiac Device Interrogation (ICDI) Profile as the Observation Creator Actor."*

*"The **Cardiology Information System** or **Electronic Healthcare Record System** shall support the IHE Implantable Cardiac Device Interrogation (ICDI) Profile as the Observation Repository Actor."*

*"The **Cardiology Information System** or **Integration Engine System** shall support the IHE Implantable Cardiac Device Interrogation (ICDI) Profile as the HL7 Router Actor."*

Summary: IHE Integration Profiles improve patient care and access to information in the clinical environment. It is worth your time to learn more about IHE. See www.ihe.net or www.acc.org/ihe.htm .

Consider joining the "IHE Cardiology Users' Group" which holds web seminars, teleconferences, and other educational opportunities on an informal basis. For more information, send an email to ihe@acc.org.