Medical Device Interoperability and the Integrating the Healthcare Enterprise (IHE) Initiative

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Clinical engineers (CEs) and hospital information technology (IT) professionals are well aware that "plug and play" for medical device data is, in practical terms, still mostly a dream. When there is a need for device data to flow from a device to another vendor's automated system, it is a custom engineering problem often requiring special interfacing software and extra processors, adding expense and potentially reducing overall system reliability. Significant labor is also required for configuration and testing.[1] Solving the problem for one pair of systems is little help with the next pair.

Yet, a variety of parameters—vital signs; settings; infusion rates; alarm events, settings and configuration; and other data obtained from and sent to medical devices—are a critical part of tracking the patient's state and planning and evaluating treatment in all clinical contexts, ranging from the home to the hospital operating rooms and care areas. This lack of data flow is a serious problem, potentially preventing clinicians from having timely access, or possibly any access at all, to observational data that would help them give the safest and most effective patient care.

Various government, standards and vendor alliance organizations are at work on general, vendor-neutral solutions to different aspects of the medical device communications problem. There is hope that these efforts are gathering momentum and beginning to link up with one another in a way suggesting a sustainable "critical mass."

This article looks at one such effort, the patient care devices domain of the Integrating the Healthcare Enterprise (IHE) initiative. It presents the work this group is engaged in now and describes how it is reaching out to other organizations with similar goals to further energize progress toward the barrier-free flow of device data.

The IHE Organization

The "Integrating the Healthcare Enterprise" organization is an international voluntary collaboration of vendors, healthcare providers, regulatory agencies, and independent experts working on improving medical data interoperability in a number of subject areas (domains),

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such as radiology, within healthcare. IHE was started in 1997 with the goal of improving the integration of imaging data into the hospital IT infrastructure. Since then, its scope has expanded into numerous other "domains" including laboratory, pathology, cardiology, eyecare, and IT infrastructure. (The IT infrastructure domain addresses common issues such as security or document exchange.)

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IHE Terms: A Glossary

IHE domain—A functional subdivision of IHE covering a particular subject area, such as IT infrastructure, radiology, or patient care devices. Each domain has a planning committee charged with gathering and prioritizing goals as well as general management of the effort, and a technical committee charged with filling in the technical details in profile documents, the technical framework, and technical white papers.

Integration Profile—A specification created by the IHE development process showing in detail how to apply existing standards such as HL7 or DICOM to a particular clinical information management use case. It gives vendors a tested, uniform guide for implementation of the responsibilities of the use case, and it gives healthcare providers a specific identifier to use in purchasing specifications.

Actor—A party to a clinical data exchange, which in the general case may be either person or an automated system but in IHE cases is most often an automated system, collaborating with other actors to accomplish a particular use case.

Transaction—A complete unit of information exchange between actors.

Brief Proposal—Statement from a stakeholder such as a healthcare provider or association of the clinical information management problem that a stakeholder believes that IHE should work on.

Detailed Proposal—After a brief proposal is submitted, it is "worked up" with further detail, a discussion of the technical means by which it may be accomplished, and a rough estimate at the amount of work to make it real.

Technical Framework—The technical document collecting the profiles for an IHE domain and details for each the transactions and actors.

Supplement—A document of a profile that is in development and will be, but is not yet ready to be, added to a technical framework.

IHE Integration Statement—A vendor's detailed statement of what IHE profiles and actors are supported by a particular version of a particular product.

Connectathon—An annual testing event where vendors bring products with IHE profile implementations and independent monitors check interoperability.

Showcases—Demonstrations where vendors show interoperability of products implementing IHE profiles.

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The IHE domain concerned with electronic medical devices, the patient care devices domain (IHE PCD Domain), is freely open to any organization that wants to help achieve the goals of medical device interoperability and is able to work on the issues and contribute to progress by participating in telephone conferences, ballots, document preparation and editing, and face-to-face meetings.

In the case of the PCD Domain, participants are drawn from manufacturers of (for example) patient monitors, ventilators, anesthesia machines and infusion pumps; representatives of healthcare providers and provider organizations; government agencies such as, in the U.S., the National Institute of Standards and Technology (NIST) and the Food and Drug Administration (FDA); and individual technical experts, clinical engineers, physicians, pharmacists, nurses, respiratory therapists, and other clinical specialists. IHE domains are typically sponsored by professional societies in the subject area of the domain. The IHE PCD Domain is sponsored by the Healthcare Information and Management Systems Society (HIMSS) and the American College of Clinical Engineering (ACCE).

Connecting to SDOs

While many standards exist that are relevant to healthcare data and communications, often the practical implementer is left with no clear detailed template of how the standard can best be applied to a particular situation. IHE does not exist to create standards, but rather "integration profiles," which show how to apply existing standards from internationally recognized standards development organizations (SDOs) to particular medical information exchange needs. Revelant SDOs include such groups as AAMI, Health Level 7 (HL7), Digital Imaging and Communications in Medicine (DICOM), ISO/IEEE 11073 (Health Informatics, Point-of-care Medical Device Communication) and CEN/TC 251 and ISO/TC 215 (Health Informatics).

When IHE work reveals a problem or gap in a standard, the IHE committee involved communicates this to the SDO as a request for clarification, extension, or enhancement to the standard. The SDO processes these requests according to its normal procedures. In many cases, communication is aided by overlap of membership between IHE committees and related standards committees. IHE has Memoranda of Understanding in effect for PCD Domain activities with HL7, IEEE 11073 and ISO/TC 215 to facilitate collaborative work.

Table 1. IHE PCD Domain Challenges

Area	Example of Use	Partners
Patient care and safety	Support interoperable device data in • "Current awareness" displays such as operating room dashboard displays • Clinical charting systems • Long-term medical record • Clinical decision support	Health Level 7, ISO/IEEE 11073 committees
Electronic health record integration and "meaningful use"	Including vital signs and trends in standardized health records	U.S. Healthcare Information Technology Standards Panel (HITSP)
Seamless availability of device data in the "continuum of care"	Maximize consistency between data interchange methods in the range between home care and high-acuity hospital—collaborating with Continua Alliance	Continua Alliance
Quality and efficiency	Enabling the use of device data in retrospective outcome and quality studies	
Heterogeneous infrastructure	Problems posed for hospitals by integrating systems in a multivendor environment with mixed networking (e.g. wired and wireless)	
Point-of-care integration	In addition to the communication of device data to enterprise systems, some use cases require communication among multiple devices in a multivendor point-of-care environment	ISO/IEEE 11073 committees, Medical Device "Plug and Play" Interoperability Program, ASTM F29 Integrated Clinical Environment (ICE)
Impartial conformance testing		National Institute of Standards and Technology

The IHE also has an important collaboration in the United States with the Healthcare Information Technology Standards Panel (HITSP), which selects standards and profiles for uses in the United States particularly related to government institutions and activities. Like IHE, they are not a standards development organization, and are chartered not to create standards but to select them and facilitate their use. In a great many cases, they adopt IHE profiles for this purpose. As in the case of SDOs, there is close cooperation between HITSP committees and IHE committees, helped by overlap in membership.

IHE PCD Domain Goals

The IHE PCD Domain aims to promote safe and effective clinical care where regulated medical devices are used, with barrier-free communication of measurements, settings, event, and control data between devices and between devices and other clinical and enterprise systems.

While the PCD Domain has had an in-hospital focus, it is increasingly clear that in-home medical devices present similar challenges, and that collaboration with manufacturers of home-focused, sometimes unregulated, devices is necessary.

Table 1 lists the areas that the IHE PCD Domain aims to address, along with examples of use and partner organizations.

How the IHE Process Works

There are many descriptions of the IHE process available in journal articles and on the web—see the IHE website (www.ihe.net) and in particular the IHE wiki (http://wiki.ihe.net) for full details, reference documents, and meeting schedules and minutes. Following is a quick and informal summary of the process to illuminate the points that are being made about IHE PCD Domain work.

Gathering Proposals

The PCD Domain Planning Committee seeks valid use cases of device information exchange that meet significant healthcare provider needs. The process begins with a proposal of a particular interoperability problem to solve. This can come from anyone in the field; you need not be an IHE participant or IHE member to make a proposal. At the beginning of the process of making each year's work plan, a Call for Proposals is widely publicized anywhere the group thinks it is likely to attract interest, chiefly the professional societies and trade magazines.

Putting the Proposals in Order

The proposals are studied by the PCD Domain Planning Committee, whose job is choosing, from the universe of possible medical device data interconnectivity opportunities, the next ones to work on. The committee prioritizes

Table 2. Overview of Current PCD Domain Activities

Activity	Description	Status
Device Enterprise Communication (DEC)	Sending device data to an enterprise system using HL7 v.2.6 (PCD-01 transactions), specifying subset of device data to subscribe to (PCD-02).	Part of current Technical Framework
Rosetta Terminology Management (RTM)	Specifying uniform terms and codes for clinical and technical observations from devices, to reduce risk of mistaken or lost measurement identity, and also permissible valid units of measure for observations. Conformance to RTM is required in all other PCD Domain profiles to which it is applicable.	Supplement to Technical Framework, spread-sheets, data files
Point-of-Care Infusion Verification (PIV)	Sending an infusion order to an infusion pump using HL7 v.2.6 for verification by a clinician before initiation, to reduce risk of medication errors.	Supplement, to be included in update to Technical Framework
Alarm Communications Manage-ment (ACM)	Sending details of a physiological or technical alarm from a patient care device to an alarm management system and from there typically to a phone or other hand-held device for notification of the event to appropriate persons.	Supplement, to be included in update to Technical Framework
Implantable Device—Cardiac—Observations (IDCO)	Profile for an intermediary system to send device data from an implantable device to an enterprise system in HL7 v.2.6 messages.	Supplement
Medical Equipment Management (MEM)	For assisting hospital clinical engineering and IT departments with locating, troubleshooting, and maintaining patient care devices with a uniform communications interface for device technical data.	White paper
Waveform Communication Management (WCM)	Extending the DEC Profile to support the encoding of patient care device waveform data (ECG, ventilator waveforms, etc.) in HL7 v.2.6 messages.	Supplement in development
Device Point-of-Care Integration (DPI)	Analyzing requirements for patient-safe, reliable, low-latency communications between patient care devices at the point of care, beyond simple export of observational data to enter-prise systems. Examples would be dynamic device discovery and association with an intermediary system, safety interlocks involving multiple heterogeneous devices, communication from a measurement device to a therapeutic device.	White paper

them according to clinical impact and also takes into account technical feasibility, what resources are required (mainly the time of IHE volunteers), what is feasible in a one-year development cycle, and what moves the effort toward its longer-term goals.

Making the Proposals Implementable
The PCD Domain Technical Committee then generally charters a subcommittee to develop the technical details of the profile, building a consensus view of the detailed technical requirements, the interfaces and the most appropriate applicable standards

The subcommittee then designs and documents an Integration Profile, with full details on standards options chosen and explicit directions and examples for implementers.

Note that the medical device market is an international one, and profile development is planned to meet international needs. If a particular national chapter sees the need for a profile to be further specialized for its

needs, it may create and document a version of the profile with additional constraints applied for its particular environment.

Supporting Implementers
It is an important ongoing responsibility of the PCD Domain members to give direct assistance to implementers of the program to help them succeed in completing their implementation and passing the verification tests. These interactions may result in clarification and correction of the profile specifications.

Supporting Testing
Integration profiles are not of much use unless you can verify whether an implementation really conforms to them. Here the individual IHE domains such as the PCD Domain design and document test plans, and also get major assistance from IHE Testing and Tools Committee with tools for preliminary test result recording. These tools can be used for product qualification before

Connectathon testing events and for official test recording during the events.

Testing support is evolving toward increasing automation, with IHE collaborating with a more general effort in NIST towards an open infrastructure for healthcare IT interoperability testing.[2]

NIST researchers have also been active collaborators with the IHE Patient Care Devices domain in terminology management and medical device communications conformance testing (see "Developing Semantic Interoperability," below).

Connectathon

The implementation activities lead up to the main annual test event, known as a "Connectathon." To the extent possible, implementations are tested "virtually" over the Internet during a Virtual Connectathon. This is followed by the physical Connectathon, where a large number of vendors meet face to face, interconnect their implementations, and set out to prove to a group of independent monitors—medical device professionals who are not connected with vendors—that they have achieved interoperability in accordance with standardized test procedures. If the vendor's product passes the required tests, it is eligible to be demonstrated in an IHE Interoperability Showcase. Connectathons and interoperability demonstrations are held in North America, Europe, and the Asia/Pacific region. Preparation is in progress for a showcase including the PCD Domain in Korea in late 2010.

IHE Integration Statements

For vendors and potential purchasers of products, the critical end result of the process is the vendor's Integration Statement, saying what IHE Profiles and options a particular version of a particular product supports.

Current IHE PCD Domain Activities

While space does not permit a substantial summary of each of the PCD Domain activities now in progress, Table 2 and the following paragraphs summarize a sampling of them.

First Project: Device Enterprise Communication Profile

The IHE PCD Domain identified and acted on its highest-priority integration project first: making a unified, vendor-neutral HL7 profile for communicating observations from common patient care devices (such as physiological monitors, ventilators, and infusion pumps) to clinical information systems (such as charting systems) and to general electronic medical record systems, so that it would not be necessary to create "one-off" integrations for each device and vendor. These data are chiefly patient physiological measurements or device settings, but may also include other data items, such as device alarm state and technical data from the device such as its battery charge status, if applicable. This first project became known as the Device Enterprise Communications profile.

The effort involved determining what information was required by the receiving systems, how it should most usefully be put in an HL7 observation report, and in particular how to identify all the measurements and other information items using uniform, standards-based identifiers in place of the vendor-specific identifiers previously used. This project was accomplished with the participation of engineers representing numerous manufacturers. It was also tested by those manufacturers, along with the participating information system vendors.

Vendors are now beginning to release products that are accompanied by an Integration Statement identifying the product as conforming to the profile, which will help buyers procure interoperable systems.

As an example of IHE PCD Domain outreach efforts, aspects of the DEC profile (as well as the Rosetta Terminology Management project described below) will be used by the Continua Health Alliance for Wide Area Network communication of home personal health data to electronic health record (EHR) systems. In all likelihood this profile will also be adopted as part of a U.S. national requirement by HITSP.

Developing Semantic Interoperability: The Rosetta Terminology Management (RTM) Project

The backbone of Device Enterprise Communication, and of all PCD Domain profiles, is the uniform semantic representation of measurements and units of measure.

IHE PCD Domain members have recognized that the biggest single barrier to meaningful and safe exchange of patient care device data between systems is that systems do not use a uniform set of terms to identify data items. Each vendor uses a home-grown proprietary identifier for, say femoral artery diastolic pressure. Other systems from the same vendor will understand the meaning of the identifier, but in the real world it is essential that clinical observations retain their correct identity when passed be-

tween systems from different vendors: say, from a patient monitoring gateway system to a clinical charting system or an electronic health record system.

Traditionally, such a medical device data interface between systems from two different vendors required the development of a complete mapping of the sending system's terminology to the receiving system's terminology. This is not just a simple clerical task—mapping requires expertise with medical measurements and frequently required consulting with experts from both vendors to resolve subtle but medically important differences between definitions.

To work toward a durable solution to this key problem, the Rosetta Terminology Management (RTM) team, led by GE's Paul Schluter, PhD, first collected many hundreds of terms currently in use by vendors and correlated them with the terms from the ISO/IEEE 11073 standard nomenclature (ISO/IEEE 11073-10101)[3]. This terminology was found to be the best fit to medical device data from among available standards. Among the alternatives considered were SNOMED (Systematized Nomenclature of Medicine) and LOINC (Logical Observation Identifiers Names and Codes), which have many desirable features and include a good proportion of the required terms and concepts, but unlike ISO/IEEE 11073 were not developed specifically for medical device data and consequently do not cover many needed terms.

Though MDC is the most complete set of appropriate terms, there are areas needing further development, for example terms for ventilator and anesthesia machine measurements and settings. Subgroups of members with appropriate expertise including physicians from the rel-

evant specialties have made much progress developing new uniform terms and codes. These will be communicated to the ISO/IEEE 11073 committees for review and, if accepted, standardization.

Another area of irregular semantic variation in device data interchange has been in units of measure associated with particular measurements. An important part of the RTM effort has been, in addition to regularizing measurement terms using MDC nomenclature and the Unified Code for Units of Measure (UCUM),[4] to divide up the units of measure in actual use into the scientifically valid and the invalid, and to identify the latter as unacceptable in PCD Domain profiles.

The lists of terms and units are maintained in computable (XML) formats, and the RTM effort has included a close collaboration with NIST researchers John Garguilo, Sandra Martinez and Maria Cherkaoui in design of RTM verification tooling.[5]

A Next Step: Point-of-Care Integration

Communications from patient care devices to enterprise systems are highly valuable, but they do not exhaust the ultimate promise of fully integrated medical device systems. Many potential clinical scenarios involve interactions between multiple patient care devices at the point of care and need not involve enterprise systems at all. Additionally, dynamic discovery and association of newly connected devices over the network, standardization of the generally proprietary "first hop" communications link from device to an intermediary or gateway system, symmetric communication between devices, efferent control to a device, and more, involve technical requirements far beyond the HL7 v.2-based observation reporting that the first IHE PCD Domain profiles centered on. Here again there is a strong link to IEEE 11073 committees investigating the technical requirements in relation to existing and planned standards. The NIST team has made a strong contribution to future conformance testing of these capabilities.

These requirements bear a close relation to scenarios envisioned in the Integrated Clinical Environment (ICE) emerging series of standards from ASTM subcommittee F29.21 (Part I to be published as ASTM F2761:2009) pioneered by Julian Goldman, MD, and colleagues of the Medical Device "Plug and Play" Interoperability Program (MDPnP) hosted at the Center for the Integration of Medicine & Innovative Technology, Cambridge, MA (see http://mdpnp.org/ICE.html). An IHE PCD Device

A simulated operating room from the 2009 HIMSS Interoperability Showcase. Photo courtesy of John Rhoads.

tem, which could then be checked and approved by an appropriate clinician without the need for manual keying of all the numbers of the order. The PCD Domain planning committee agreed that this would be a valuable and feasible project, so the infusion pump group collaborated with HL7 experts from the technical committee in designing and documenting the PIV communications profile. It was successfully verified by several manufacturers of infusion management systems and information systems at the 2009 Connectathon, and is now available for commercial implementation.

The astute reader will have noticed that a guiding consideration in the IHE process is the allocation of scarce volunteer labor. This leads to the obvious way you can influence every aspect of the process: readers who are interested in the goals of the group will always be welcomed if they want to participate. This participation can take many forms, of which intense technical work is not necessarily always the most important—a familiarity with real-world uses of clinical care devices, such as clinicians and clinical engineers and technicians have, and a willingness to provide "reality checks" is always highly valued. A simple email can get you started; contact Manny Furst at efurst@ieee.org to inquire. ■

Point-of-Care Integration subgroup, the ICE-PCD Analysis Committee, with the collaboration of Tracy Rausch and other ICE/MDPnP associates, has been analyzing ICE clinical scenarios to identify technical needs to support standards-based solutions to the technical requirements implicit in the scenarios.

How You Can Influence the Process

Everyone involved in medical device data handling or the clinical use of device data is invited to make their ideas known concerning what real-world problems need to be matched with an interoperability specification. This can be in the form of a new profile proposal, or simply emailing one of the PCD Domain planning committee cochairs with your ideas about what is important (and not important) in the realm of medical device data interchange.

As an example of how this process works, take the recent development of the Point-of-Care Infusion Verification (PIV) profile. It is well-known that manual entry of infusion pump settings by clinicians is a time-consuming and error-prone part of a process that is critical to the safe and effective treatment of many acute-care patients. A group of infusion pump experts submitted a proposal for the development of a communications profile so that a hospital information system could communicate an infusion order to a pump or infusion management sys-

References

1. **Zaleski, J.** Integrating Device Data into the Electronic Medical Record. Weinheim, Germany: Wiley-VCH, 2009.
2. **Snelick RD, Gebase LE, Skall MW.** Conformance Testing and Interoperability: A Case Study in Healthcare Data Exchange. International Conference on Software Engineering Research and Practice, SERP'08, Las Vegas, NV, July 2008. CSREA Press, 2008.
3. ISO/IEEE 11073-10101 Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature, First edition, 2004-12-15. ISO and IEEE, 2004.
4. **Schadow G, McDonald CJ.** The Unified Code for Units of Measure (UCUM). Indianapolis, IN: Regenstreif Institute. Available at: http://aurora.regenstrief.org/UCUM.
5. **Garguilo JJ, Martinez SI, Cherkaoui M.** Medical Device Communication: A Standards-based Conformance Testing Approach, 9th International HL7 Interoperability Conference 2008 proceedings, Crete, Greece, October 2008. Available at: http://xw2k.nist.gov/medicaldevices/ICSGenerator/docs/IHIC08_Med_Device_Communication_Testing.pdf.