Moving Toward Semantic Interoperability of Medical Devices

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Abstract

NIST researchers are collaborating with medical device experts to facilitate the development and adoption of standards for medical device communications throughout the healthcare enterprise as well as integrating it into the electronic health record. NIST researchers have developed a tool and corresponding electronic representation of an international standard's information model that provides several important capabilities leading toward device semantic interoperability. We describe our XML schema and tool developed which is built upon the medical device communication standard ISO/IEEE 11073. Central to this approach is a capability of the tool to develop and produce implementation conformance statements (ICSs). Users execute the tool to produce statements disclosing details of a specific implementation and specifying features provided by a particular medical device. Device ICSs can subsequently be compared and utilized across device interfaces to help overcome the semantic interoperability problem that is so prevalent today and has prevented proliferation of plug-and-play interoperable solutions.

1. Introduction

In a recent survey conducted by Healthcare Information and Management Systems Society (HIMSS)[1], the respondents identified "cross enterprise sharing of patient care device data" as one of their highest priorities. Goals established to meet this priority include shortening decision time, increasing productivity, minimizing transcription errors, and investing in and developing ways to correctly define and interpret the data exchanged. To meet such goals intercommunication among medical devices and clinical information systems is necessary as point-of-care devices are often the primary source (or destination) of patient care information and data. Conformance and interoperability testing of medical device data communication is essential leading to long term value propositions which include:

- Integrity of data – automatic population of all information systems – reducing medical errors,
- Automating systems to capture clinical data into Electronic Health Records (EHRs) thus saving time for clinicians,
- Improving agility of enterprises to meet varied patient loads,
- Improving life-cycle cost of ownership,
- Access to patient data across devices and systems so custom communication interfaces can be eliminated thus allowing for best of breed and even plug-and-play devices.

This paper describes a *standards-based* schema and test tool developed by NIST researchers to assist medical device domain experts. Central to this approach is a standard information model that represents medical devices and Implementation Conformance Statements (ICS) used to capture device implementation details by specifying exactly which features are implemented. Conformance statements, produced by device manufactures and implementers, provide an effective way to increase the likelihood of communicating data correctly. Data must be consistently represented syntactically and semantically for the successful interpretation of medical devices over varying makes and models.

2. Background

The Information Technology Laboratory (ITL) within the Department of Commerce's National Institute of Standards and Technology (NIST) is collaborating with the International Organization for Standardization/Institute of Electrical and Electronics Engineers, Inc. (ISO/IEEE) 11073 Medical Device Communications and the Integrated Health Enterprise - Patient Care Devices (IHE-PCD) domain working groups. NIST/ITL is engaged with the medical device industry and is developing conceptual information-based frameworks and test tools to ensure device implementations are conformant to medical device standards. This effort ultimately contributes to high priority needs to reduce medical errors, promote patient

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safety and provide accurate information into electronic medical and health record systems.

2.1 ISO/IEEE 11073 Standard

A single communication standard is desirable to address the medical device plug-and-play interoperability problem. The reality, however, is that several standards were developed for specific applications to address the layers or levels needed to allow communication between medical devices and medical systems. Furthermore, the main medical device manufacturers have developed proprietary solutions.

Over the past several years the primary international standards development organizations (i.e., ISO, IEEE, and the European Committee for Standardization (CEN)) have harmonized to avoid competition and work together on a single set of standards. The international standard *ISO/IEEE 11073 Health informatics – Point of care medical device communication* (here after referred to as '*x73*') is intended to enable communication among medical devices and healthcare information systems. The x73 family of standards, while parts are still in draft form, have been developed with a high level of international participation. The standard is targeted at acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc. x73 is comprised of a family of standards that can be layered together to provide optimal connectivity for the specific devices being interfaced. x73 is based on the International Organization for Standardization's Open Systems Interconnection (ISO-OSI) seven layer communications model[2].

The x73 family of standards is complex and allows for a high degree of flexibility in its application. The standard defines the information model for specific devices including device attributes, value ranges, and access. Data (e.g., measurement and state) is modeled using the Unified Modeling Language[3] (UML) in the form of information objects that can be accessed and manipulated via an object access service protocol.

3. Scope

The context of a medical device for the work defined in this paper is derived from the x73 standard: *A device, apparatus, or system used for patient monitoring, treatment, or therapy, which does not normally enter metabolic pathways*[4]. The scope of medical devices in this context is further limited to patient-connected medical devices that provide support for electronic communications. Examples of data captured and exchanged by devices include communication of physiologic waveform data, time critical alerts, and open/closed loop control. A key requirement is that the semantics of the data which is communicated is not a function of the communication method.

The problem domain spans two primary levels of data communication: device and enterprise. The *device* level relates to data captured and emitted via periodic reports often many times per minute and aperiodic reports for event type information; and the *enterprise* level which is typically synopsis or filtered reports derived at the device data level and communicated via observations within electronic health records.

Our objectives include addressing device-level conformance leading to interoperability across devices and at the enterprise level (to meet IHE-PCD goals). Our work attempts to contribute to achieving primary objectives of the standard of providing plug-and-play interoperability for patient-connected medical devices; and facilitating the efficient exchange of vital signs and medical device data, acquired at the point-of-care, in all health environments. Scope is limited to the identification of upper layer (i.e., application) functionality of patient care devices and not in describing the syntax and semantics of the communicated data stream emitted and received between devices. Device functionality regarding time-based exchange of data (i.e., asynchronous [non real-time] versus isosynchronous [near-time] versus synchronous [real-time]) is also outside the scope of work.

The term "*implementer*" represents a device manufacturer or vendor while the term "*user*" represents the individual(s) executing the tool described in the following sections.

4. Problem Description

Schrenker and Cooper[5] present the typical scenario of *"… the plethora of medical devices surrounding the patients in a hospital intensive care unit (ICU). A patient connected to one or more vital-signs monitors may also be receiving drugs or other fluids under the control of an infusion pump. More-acutely-ill patients may have some of their physiological processes supported by devices such as ventilators – in addition to the monitors and pumps just mentioned. And other devices are brought to the bedside to address chronic or acute conditions; these would include hemodialysis machines and defibrillators. Finally, voluminous data records are being created for each patient from the output of all these machines. Vital-signs measurements, along with any changes in the therapeutic regimen, need to be captured in the patient record and often communicated elsewhere, such as the pharmacy."*

They state for two or more interfacing devices to communicate that "*the devices must be able to understand the format and content of the messages they communicate*

to each other; that is, they must speak the same language, both grammatically and semantically."[5] This leads to what IHE PCD Technical Framework describes as the core of the so-called plug-and-play interoperability problem: *"In order to achieve semantic interoperability each class of device must use the same terminology and data organization or modeling for common information."*[6]

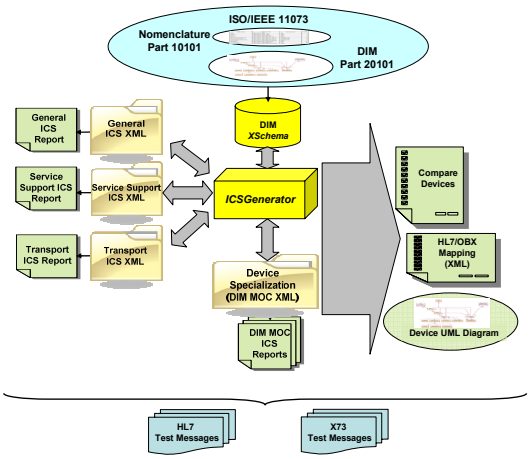

Figure 1. High level system model

Standards are vital to the deployment of information technologies for interoperable healthcare systems and information exchange. However, standards are not enough to ensure interoperability. In fact standards are only meaningful if implemented in a consistent and correct way. To help ensure that implementations adhere to the standard(s), requirements must be identified and a determination made that the implementation conforms. To support interoperability of medical devices, specific details about the way definitions of the x73 standard are applied to an implementation must be captured. Thus, to increase the likelihood of medical device interoperability implementers are required to provide specific details about their device by declaring statements of conformance.

Accurately and clearly defined conformance requirements together with implementation statements of conformance will aid the state of device communication standardization, which to date, has not matched the proliferation of the telecommunications industry mainly because such IT standards *"are inadequate to fully address the needs of the clinical IT domain, particularly at the patient bedside."*[5]

5. NIST's Approach: Conformance Leading Toward Interoperability

Information models and test tools are being developed at NIST to help device manufactures make the determination that requirements are implemented according to the standard. Conformance testing is a way to determine directly or indirectly that relevant requirements are fulfilled. Systems which conform to the same standard increase the likely-hood that those systems or components are interoperable and thus exchange, interpret, and apply information correctly and consistently. Defining device implementation features based on a recognized standard's information model and naming conventions are a critical step to obtaining conformance; moving toward syntactic and semantic interoperability within the point of care medical device communication arena.

5.1 Implementation conformance statements

Implementers provide specific details about a device by issuing an Implementation Conformance Statement (ICS). The ICS is a form of data sheet that discloses details of a specific implementation and specifies which features are provided. The ICS provides a consistent means to describe device features spanning manufactures or various makes and models. ICSs can effectively narrow the scope of device interfaces by defining supported features thus leading to a reduction (and ultimately elimination) of the need to have unique interfaces for each connecting or communicating device. Through collaboration with the x73 committee, NIST has developed an XML schema and ICS generation tool providing device manufacturers a systematic approach to define device specialization. The result of this approach are ICSs (in the form of tables as required by the standard) based on the x73 standard's domain information model and terminology convention known as nomenclature.

While ICSs provide understanding of the details of an implementation, they are not sufficient to promote interoperability of devices or applications. In addition to, or as replacement of the ICS, detailed application or functional communication profiles (e.g., medical device interoperability profiles) providing more specific conformance requirements are needed. Such additional specifications or standards are necessary to fully enable an implementation or a system using the x73 standard.

5.2 High level system model

NIST has developed an XML schema (hereafter referred to as ***XSchema***) and a corresponding ***ICSGenerator*** tool (Figure 1). The ***XSchema*** is essentially an electronic representation of the x73 standard's medical device information model implemented in the ***ICSGenerator*** tool. ICSs may be created to specialize scope of implemented features supported by a device as intended by the manufacturer and defined by, and in, a standard representation. ICSs therefore define device functionality in an unambiguous manner such that other devices (or

device manufactures) can clearly interpret the feature definitions leading to increased likelihood of device interoperability.

5.3 NIST XML Schema

The x73 family of standards contains parts based on an object-oriented systems management paradigm (objects and their interactions) used to describe objects shared between devices through a communication link. ***Part 10101: Nomenclature*** defines the set of attributes used to name and term information objects and ***Part 10201: Domain Information Model*** (DIM) of x73 defines the overall set of information objects as well as the attributes, methods, and access functions which are abstractions of real-world entities in the domain of medical devices and device communication. This information model is the prerequisite for interoperability of medical devices and device systems.

Taking advantage of the object-oriented modeling method, an XML schema was developed as a meta-grammar for electronically defining the syntactic structure and partial semantics of the x73 DIM. The ***XSchema*** addresses the requirements of the standard's detailed specification. The ***XSchema*** provides information modeling capabilities and maintains the integrity of the structure and vocabulary set by the standard. The ***XSchema*** was augmented to represent the complete UML model used by the x73 DIM, including:

- Object definition,
- Containment relationship (class instance),
- Attribute definition,
- Attribute groups,
- Behavior definition,
- Notification definition, and
- Inheritance among object types.

Features implemented in the ***XSchema*** to satisfy the requirements identified in the x73 standard include capabilities to:

- Represent common data types,
- Ensure DIM object definition (attributes, behaviors and notifications),
- Ensure containment association,
- Represent attributes/notification/behavior inheritance,
- Represent the service model for communicating systems,
- Ensure object cardinality,
- Ensure term codes (Managed Objects, attributes, behaviors and notifications), and
- Allow for future extensions of the model.

NIST developed a tool, called ***ICSGenerator*** that is based on the x73 DIM. ***ICSGenerator*** utilizes the ***XSchema*** to provide the parsing capabilities necessary to assure that manufacturers are defining the information required by the x73 standard. Furthermore, manufacturers may adopt this public domain XML schema to contribute to their own implementation development goals. Adoption of the schema into a manufacturer implementation information model maintains integrity of the structure and vocabulary as defined by the x73 standard.

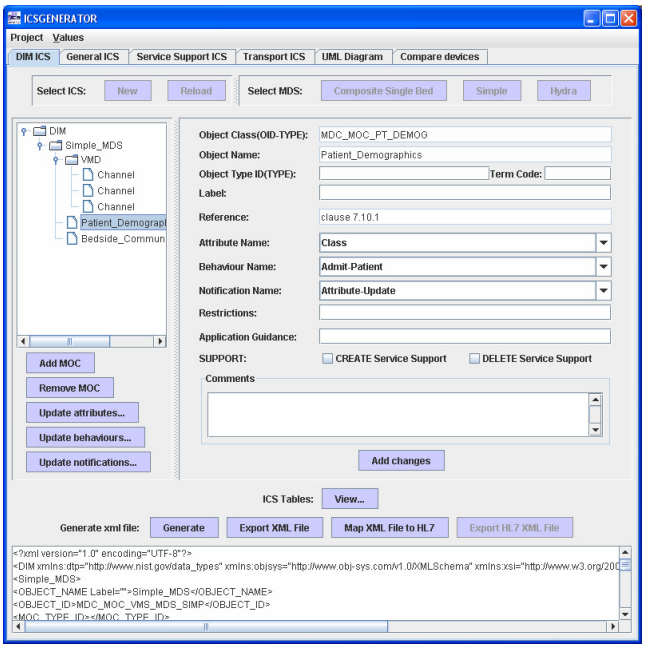

Figure 2. *ICSGenerator* tool screen shot

5.4 ICSGenerator

The ***ICSGenerator***[7] tool enables users to define a specific medical device implementation and specify which features are provided. ***ICSGenerator*** characterizes a device by the x73 DIM objects it implements.

5.4.1 Device specialization (DIM XML)

ICSGenerator processes an XML instance file based on the x73 DIM. The XML instance file is validated against the ***XSchema*** which contains all the managed objects, object relationships and associated information. Using the ***ICSGenerator*** tool's interface, a user specifies a medical device to produce a graphical containment tree representation of the device (Figure 2: middle left panel showing DIM, Simple_MDS, VMD, Channel, etc.). Each object is identified using nomenclature from the standard by name, type ID, label, and a reference to the clause in the standard where the object is defined. Additional

information such as restrictions, application guidance, attribute access, and value ranges may also be entered (Figure 2: upper center panel). Mandatory attributes are automatically populated as users dynamically create their device containment.

Capabilities of the tool include adding, removing, and updating managed objects, including associated attributes, behaviors, and notifications. The tool meets requirements established by the x73 DIM by allowing creation of XML instance files which are compliant to the x73 standard, as validated against the ***XSchema***. Validation against the ***XSchema*** includes checking constraints such as containment relationship, cardinality, object ID, and attribution. Post processing the resultant saved XML instance files provides users with the capability to produce ICS and device comparison reports, generate device object UML diagrams, and to map the x73 device defined information to HL7 observation message segments (see Figure 1).

Users may describe private and external extensions using the tool, however such extensions are denoted (via a color code) as outside the standard's information model (and therefore not validated against the ***XSchema***). As device capabilities change over time the saved XML instance file may be reloaded into ***ICSGenerator*** and subsequently modified to reflect those changes.

5.4.2 ICS Reports

ICSGenerator addresses a key requirement of the x73 DIM conformance model by producing ICS reports. The resultant conformance statements are in the form of tables mirroring the standard's identified templates. Generally, the column headers of an ICS table contain the following information:

- *Index*, which is an identifier (e.g., a number) of a specific feature,
- *Feature*, which briefly describes the characteristic for which a conformance statement must be made,
- *Reference*, which is a reference to the definition of the feature (may be empty),
- *Status*, which specifies the conformance requirement (i.e., the requirements for a conforming implementation regarding the feature). In some cases, the standard does not specify conformance requirements, but a definition of the status of a particular feature is still required,
- *Support*, which is filled out by the implementer and specifies the characteristics of the feature in the implementation, and
- *Comment*, which contains additional information provided by the implementer.

A device conformance statement is composed of general information, the services supported, the managed medical objects (not base classes) used by the implementation referred to as the *managed object class* (MOC), and MOC attributes, behavior and notifications. The ***ICSGenerator*** tool allows a user to create seven different ICS reports: *General*, *Service Support*, *Transport*, *DIM MOC*, *MOC Attribute*, *MOC Behavior*, and *MOC Notification.*

- The *General ICS* contains information specifying what versions/revisions are supported by the device and also some high-level system behavior definitions. Features captured by the General ICS include Conformance Deviation, Object Containment Tree, Private and External Objects, and Private Nomenclature Extensions.
- The *Service Support ICS* describes what services are implemented in the service model. Only communicating devices should supply a Service Support ICS. Features captured by Service Support ICS include services supported by the device such as the "GET", "SET", "EVENT REPORT", "ACTION", "CREATE", and "DELETE" services.
- The *Transport ICS* captures the transport profile used by the device. To date, the tool allows conformance statements about Infrared Data Association (IrDA) cable connected devices to be identified by users. Device features supported can be obtained for the *IrDA link access*, *IrDA link management,* and the *tiny transport* protocols.
- A *DIM MOC ICS* contains object information as well as specific restrictions about the object implementation.
- The *MOC Attribute ICS* defines attributes used and/or supported as well as corresponding attribute value ranges, restrictions for attribute access, attribute availability, and information.
- The *MOC Behavior ICS* contains all implemented object methods that can be invoked by the "ACTION" service.
- The *MOC Notification ICS* specifies all implemented notifications (typically in form of the "EVENT" and "REPORT" services) that are emitted by the supported objects.

5.4.3 Comparing Devices

ICSGenerator provides a methodology to quickly select and compare two or more device representations based on derived source XML instance files validated against the ***XSchema***. Object, attribute, behavior, and notification reports are produced documenting common characteristics. Refer to the ***ICSGenerator*** User's Guide[7] for criteria used to determine what constitutes common objects, attributes, behaviors and notifications between devices.

Resultant comparison reports can be viewed from an object characteristic level, including object attributes, behavior, and notifications. Comparison reports include

highlighted commonalities and differences of selected device representations. Reports produced using ***ICSGenerator*** are derived from the standard as implemented in the ***XSchema***. The reports serve an important step toward semantic interoperability by providing implementers a way of determining exactly what features are supported across devices thus focusing attention on specific functionality and intention. Therefore, the desired meaning of the data communicated will likely persist between devices and/or be correctly integrated into electronic health records.

5.4.4 Producing Device UML Diagrams

The ***ICSGenerator*** provides the capability of automatically producing a UML class diagram describing the device data model based on the DIM XML. Thus, each device may be specified in a commonly adopted representation for modeling software artifacts[3]. This capability benefits manufacturers by enabling an easy mechanism to create electronic descriptions of a device which may be used as an aid in interoperability testing.

5.4.5 Mapping IEEE x73 information objects to HL7 observations

Functionality has been included in ***ICSGenerator*** to apply device specific information into the Health Level 7 (HL7) messaging standard used throughout the healthcare enterprise. It is anticipated that transformations into orders and observations can occur by providing the capability of specializing medical devices. Defining device containment, information objects, associated attributes, and data based on information entered about point of care medical devices is necessary to achieve this functionality.

ICSGenerator is used to produce an XML instance file. Post-processing is applied to this file to map particular device attributes to observation segments in HL7 messaging formats. HL7[8] (Version 2.5, chapter 7) Observation Reporting (specifically "OBX" segments) defines the syntax and coding requirements used for patient care device data communications in the IHE-PCD Technical Framework.

HL7 segments produced from the tool may subsequently be used to derive HL7 profiles, messages, and test suites, further leading to device interoperability and integration into healthcare systems. This functionality also contributes to the workflow of orders being filled by medical devices with resultant data captured in the electronic health record, which is a primary goal of the IHE-PCD.

6. Related Work: Validating Medical Device PDUs

NIST is collaborating with the x73 Medical Device Communications working group in developing a test tool which validates basic syntax and structure of medical device message protocol data units (PDUs) being exchanged. Information is initially defined in an abstract syntax such as Abstract Syntax Notation One (ASN.1) (ISO/IEC 8824) or medical device data language. Typically for efficiency in the form of integers, the information is then mapped to and interchanged through a transfer syntax, e.g., basic encoding rules (BER) or medical device encoding rules (MDER). However, abstract syntax languages are generally unsuitable for high-precision human understanding, especially of medical terms. Objects described in ASN.1, as defined in the x73 standard, have been converted into XML schema definitions. The XML schema definitions will be used to validate XML wrapped messages derived from PDUs exchanged between medical devices. The NIST prototype ***ValidatePDU*** tool[7] will flag incorrect syntax and data type errors. Future functionality is to include performing semantic checking in addition to syntactic checking to help ensure that communicating entities can correctly exchange and interpret medical device data. Validation of data entered by the user into the ***ICSGenerator*** interface is based in part on the common ASN.1 data types defined in the x73 DIM and as used by ***ValidatePDU***.

7. Summary

The need for a widely adopted medical device message communication standard is essential to the process of medical device and system integration. However, use of standards alone does not ensure system interoperability. Creation of an XML schema and ***ICSGenerator*** tool provides several important capabilities leading toward semantic interoperability of medical devices and the information exchanged between those devices. At the core of the NIST developed ***ICSGenerator*** tool is an information model based on an instantiation of the ISO/IEEE 11073 domain information model (DIM). The tool processes the electronic instance of the DIM described in XML and validated against the NIST ***XSchema*** to graphically represent the DIM containment relationship. The tool provides users an easy to use interface to manipulate the standard's information model by adding and/or removing objects; including the object's attributes, behavior, and notifications. The abstract representation of a device is created by a user, validated by the tool against the ***XSchema***, and saved in XML format. The resultant XML files therefore define a device which are x73 DIM compliant described using the x73 standard's nomenclature.

The ***XSchema*** and ***ICSGenerator*** tool promote semantic interoperability in several ways. The ability to produce ICSs which define in a report format a device's general, service support, transport, and managed medical object information is an important contribution helping clinical engineers, device manufacturers, and vendors. Device

conformance statements identifying specific implemented features are useful when comparing such devices across multiple makes and models. Furthermore, reports showing device objects graphically represented in a common modeling language (i.e., UML) lead to consistent and precise device descriptions more readily available without underlying object content information. Together, these capabilities enable manufacturer's to define device interfaces in such a way that increase the likelihood of interoperating with other device models or manufacturers.
NIST is working directly with the *IEEE Health Informatics - Point of care medical device - Domain information model - XML schema format working group* under sponsorship of the IEEE Engineering in Medicine and Biology Society 11073 Committee (EMB/11073). The proposed NIST DIM ***XSchema*** project plan was submitted and is under consideration for approval by the IEEE **N**ew **S**tandards **Com**mittee (*NESCOM*). NIST will continue to participate with the IEEE working group to move the DIM ***XSchema*** forward as a normative part of the x73 standard (specifically *P11073-10202 - Standard for Health informatics - Point-of-care medical device communication - Domain information model (DIM) - XML schema format*).

NIST also continues to actively participate with the on-going work of the IHE-PCD working group to map x73-based device information into HL7 observation messaging formats. Post-processing the ***ICSGenerator*** produced XML files will directly support testing efforts of manufacturers planning to participate in the second year IHE-PCD interoperability demonstrations known as the "Connectathon" and at the 2008 Health Information and Management Systems Society[1] (HIMSS) Conference. These demonstrations are a realization of manufacturers coming together to exchange medical device data based on real-life scenario use cases. This work contributes to development of IHE-PCD *Integration Profiles* and *Transactions* in year two and beyond. This work, in conjunction with profile builder tools, facilitates the creation of IHE-PCD Integration Profiles from a device specialization perspective. In the future, enhancements may potentially eliminate the need to use more complicated general profile builder tools which work nicely across all IHE and HL7 message domains. However, unlike the profile building tools, ***XSchema*** and ***ICSGenerator*** are focused on the complex device information model to produce device-derived physiologic information observations.

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