

Interoperability of Medical Device Information and the Clinical Applications: An HL7 RMIM based on the ISO/IEEE 11073 DIM

Mustafa Yuksel and Asuman Dogac

Abstract—Medical devices are essential to the practice of modern healthcare services. Their benefits will increase if clinical software applications can seamlessly acquire the medical device data. The need to represent medical device observations in a format that can be consumable by clinical applications has already been recognized by the industry. Yet, the solutions proposed involve bilateral mappings from the ISO/IEEE 11073 Domain Information Model (DIM) to specific message or document standards. Considering that there are many different types of clinical applications such as the electronic health record and the personal health record systems, the clinical workflows, and the clinical decision support systems each conforming to different standard interfaces, detailing a mapping mechanism for every one of them introduces significant work and, thus, limits the potential health benefits of medical devices. In this paper, to facilitate the interoperability of clinical applications and the medical device data, we use the ISO/IEEE 11073 DIM to derive an HL7 v3 Refined Message Information Model (RMIM) of the medical device domain from the HL7 v3 Reference Information Mode (RIM). This makes it possible to trace the medical device data back to a standard common denominator, that is, HL7 v3 RIM from which all the other medical domains under HL7 v3 are derived. Hence, once the medical device data are obtained in the RMIM format, it can easily be transformed into HL7-based standard interfaces through XML transformations because these interfaces all have their building blocks from the same RIM. To demonstrate this, we provide the mappings from the developed RMIM to some of the widely used HL7 v3-based standard interfaces.

Index Terms—Clinical applications, ISO/IEEE 11073 Domain Information Model (DIM), HL7 Reference Information Model (RIM), medical devices, electronic health record (EHR) systems, personal health record (PHR) systems .

I. INTRODUCTION

A WIDE range of clinical applications such as clinical decision support systems, clinical workflows, electronic health

record (EHR), and personal health record (PHR) systems use data from the medical devices such as blood pressure (BP) monitors, glucose meters, pulse oximeters, ECG monitors, and cardiovascular implantable electronic devices.

To make device data in ISO/IEEE 11073 Domain Information Model (DIM) [1] consumable by clinical applications, Integrating the Healthcare Enterprise (IHE) [2] and the Continua Health Alliance [3] have developed profiles. IHE, within the scope of the “Device Enterprise Communication (DEC)” Profile [4], provided a mapping of the IEEE 11073 DIM to *HL7 version 2.5 Unsolicited Observation (ORU) Message* format. In the Continua Health Alliance work, the IEEE 11073 DIM is mapped to *HL7 Personal Health Monitoring Report (PHMR)* document format [5]. In other words, in each of these works, a bilateral mapping is defined from DIM to a message standard or to a document standard.

Although these mappings proved to be very useful, there are many different clinical applications, conforming to different standard interfaces that require automated acquisition of medical device observations. For example, the EHR/PHR systems, the clinical workflows, and the clinical decision support systems, each with a different interface, also need medical device data.

In this paper, we specialize the HL7 v3 Reference Information Model (RIM) [6] to the medical device domain using the IEEE 11073 DIM to obtain its Refined Message Information Model (RMIM). An RIM, like HL7 RIM, defines a generic structure to express the concepts in the eHealth domain. This generic RIM is then refined to subdomains such as laboratory, pharmacy, patient administration, and in our case to the medical device domain.

The novelty of this approach is that it provides a common denominator for different HL7 RIM-based interfaces of various clinical applications rather than using the bilateral mappings between the device models and different application standards. This facilitates interoperability because the concepts are derived from a common RIM through a well-defined refinement process and, hence, the building blocks of the interfaces are similar, and they can be traceable back to the RIM.

In the refinement process [7], to obtain RMIM from the RIM, first, the Domain Message Information Model (DMIM) is derived from the HL7 RIM where only the required classes, attributes, relationships for building the messages for a particular domain are included. The next step is to build the RMIM by specializing the necessary classes, attributes, and associations used in a set of messages for a particular subdomain.

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M. Yuksel is with the Software Research, Development and Consultancy Ltd., Ankara 06531, Turkey, and also with the Department of Computer Engineering, Middle East Technical University, Ankara 06531, Turkey (e-mail: mustafa@srcd.com.tr).

A. Dogac is with the Software Research, Development and Consultancy Ltd., Ankara 06531, Turkey (e-mail: asuman@srcd.com.tr).

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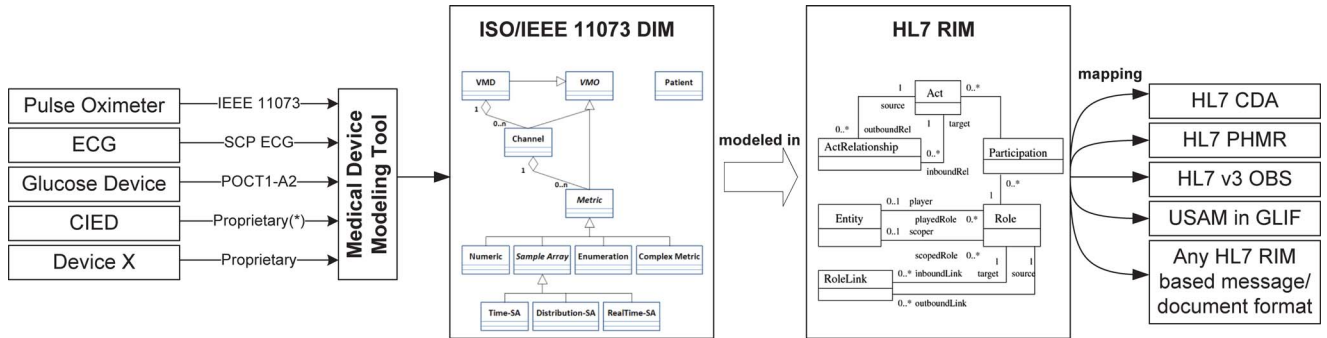


Fig. 1. Overall view of the proposed medical device interoperability framework.

Once the RMIM is obtained this way, XML transformations are enough to generate various different HL7-based interfaces such as the HL7 PHMR standard used by the EHR/PHR systems; the HL7 v3 Observation message used in clinical workflows and the Unified Service Action Model (USAM) standard used in the Guideline Interchange Format (GLIF) for clinical decision support because all these standard interfaces are generated from HL7 RIM. Fig. 1 gives an overview of the proposed medical device interoperability framework.

We further note that not all the devices conform to the ISO/IEEE 11073 DIM. To be able to get data from proprietary devices in 11073 format, there is a need for a “medical device modeling tool” that enables translation of medical device data instances in a proprietary message format, or in any other standard sensor representation format to the ISO/IEEE 11073 format. However, this work is not within the scope of this paper but is addressed in the IHE “Rosetta” project mentioned later.

The paper is organized as follows. Section II introduces the previous work in this area. Section III briefly summarizes the involved standards, namely ISO/IEEE 11073 DIM and HL7 RIM. Section IV gives details of how to specialize HL7 RIM to the medical device domain model as represented in 11073 DIM and derives its RMIM, which we call 11073 RMIM. In Section V, we describe how to generate different HL7-based standard application interfaces from 11073 RMIM. In Section VI, we provide a discussion of our paper and explain its long-term sustainability. Finally, Section VII concludes this paper and presents the future work.

II. PREVIOUS WORK

The interoperability of healthcare information systems and medical devices has been an active research and development area. Galarraga *et al.* [8] reported two barriers to expansion of telemonitoring services, both related with interoperability: 1) heterogeneity of devices and systems and 2) difficulty of integration with healthcare information systems used routinely by healthcare professionals. They presented an ISO/IEEE 11073-based architecture as a middleware for integrating medical device data with healthcare information systems and discussed the importance of collaboration among 11073, HL7, and IHE.

Yao *et al.* [9] used IEEE 1073 Medical Information Bus (former name of 11073 standards) and Bluetooth-based sen-

sor units for achieving plug-and-play system for home care. A pulse oximeter and a three lead ECG are connected to a base station that uses a specific software for displaying user demographic information, device status, and physiologic data. Lebak *et al.* [10] further extended that implementation with HL7 messaging capability to remotely store patient data.

In 2008, Martinez *et al.* [11] described a proof-of-concept design of a patient monitoring solution for intensive care unit using ISO/IEEE 11073 (X73) in the bedside environment and CEN/ISO EN 13606 to communicate the information to an electronic healthcare record (EHR) server. At the bedside end, the system is a plug-and-play sensor network communicating with a gateway that collects medical information and sends the data to a monitoring server. The monitoring server transforms this information into an EN 13606 extract to be stored on the EHR server.

Similarly, Fioravanti *et al.* [12] presented a middleware platform that is able to run in different mobile devices and manage data coming from a variety of medical devices. The platform provides a data storage unit that conforms to the nomenclature of IEEE 11073 and includes application services, mapping data into an ontology-based dictionary to be able to combine data from multiple heterogeneous sources.

The implementation conformance statements (ICSs) can 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. In [13], National Institute of Standards and Technology (NIST) has developed an XML schema and ICS generation tool providing device manufacturers a systematic approach to define device specialization in collaboration with the IEEE 11073 committee.

Tran *et al.* [14] described a middleware developed for the mCare 300 vital signs monitoring device with the capability of receiving data from this device and converting them to the HL7 ORU Message that can be consumed by healthcare information systems conforming to this standard.

Strahle *et al.* [15] described the integration of the anesthesia cockpit into a service-oriented architecture with a Web application server. This server physically connects to the data ports of the anesthesia unit and transforms ventilation and hemodynamic data into Web services. The implemented Web services for hemodynamic and respiration data are using an XML

vocabulary that is predominantly taken from the ISO/IEEE 11073-10201 standard.

Related with standardization efforts, IHE has defined “IHE Patient Care Device Profiles” among which the ‘DEC Profile’ [4] is for transmitting information from medical devices at the point of care to the enterprise applications. For this purpose, ISO/IEEE 11073 DIM is mapped to HL7 v2.5 Observation Report and the IEEE 11073 Data Types are mapped to HL7 v2.5 Data Types. For the semantic interoperability layer, IHE has developed the “Rosetta Terminology Mapping Profile” [16] to provide the mapping between the proprietary device parameters to IEEE 11073 nomenclature. Each row of the Rosetta table, which is under development, gives the vendors’ displayed name and units of measure together with the equivalent IEEE 11073 identifier and the UCUM units of measure [17].

A more specialized version of this profile is IHE “Implantable Device Cardiac Observation Profile” [18] for transferring information from an interrogated implantable cardiac device to the healthcare enterprise information management systems.

The Continua Health Alliance addresses the integration of medical device data into EHR/PHR and has developed the EHR/PHR Network (xHRN) interface [19] based on the HL7 PHMR document format constraining HL7 CDA Release 2.

There are the following additional related standardization efforts. A work group has been established under HL7, called HL7 Health Care Devices [20], and in the HL7 Therapeutic Devices Domain, the Implantable Cardiac Device DMIM [21] is defined. Furthermore, in [22], as a major device connectivity gap, the Healthcare Information Technology Standards Panel (HITSP) states that to represent abstract device semantics that have been specified using ISO/IEEE 11073 standards in an HL7 CDA document, a normative mapping is needed between ISO/IEEE 11073 constructs and HL7 version 3 RIM elements, for which currently there is no active work. In this paper, we also intend to fill in this gap.

III. BACKGROUND

In this section, we present a brief introduction to the standards and frameworks used in this paper, namely, ISO/IEEE 11073 DIM and the HL7 v3 RIM. Both IEEE and HL7 are ANSI [23] accredited standards developing organizations.

A. ISO/IEEE 11073 DIM

IEEE 11073 standards are based on an object-oriented domain information model called the “DIM” [1]. The DIM is comprised of eight packages for organizing the device domain. The medical and the patient packages shown in Fig. 2(a), concentrate on the representation of the medical devices and their observations, and the patient data, respectively. The other packages deal with device to device interoperability issues such as device configuration and synchronization.

The medical package consists of four main classes “Virtual Medical Object (VMO),” “Virtual Medical Device (VMD),” “Channel,” and “Metric.” VMO is the base class for all classes in the package and is used for consistent naming and identification of the objects. VMD is an abstraction of a medical device.

Channels are used to relate each Metric object in a hierarchical structure to the VMD. Metric is the base class for representing both qualitative and quantitative medical device observations. The device observation can be a simple numerical value such as BP, which can be represented with a “Numeric” object or it can be a complex waveform which can be represented in a “Real Time Sample Array” object.

It is possible to represent a medical device with objects using the DIM. However, in order to define interoperable medical devices, the attributes of these objects must consist of codes that are specified in a data dictionary. “ISO/IEEE 11073-10101: Nomenclature” [24] standard is a data dictionary of vital signs domain, which is used to represent the DIM objects with common codes.

B. HL7 Version 3 RIM

The primary goal of HL7 [25] is to provide standards for the exchange of data among healthcare computer applications. Unlike HL7 version 2, HL7 version 3 (HL7 v3) is based on an object-oriented data model, which is called the “RIM” [6]. The RIM contains all the classes and their attributes that cover the medical domain and is comprised of six “back-bone” classes: Act, Participation, Role, Entity, RoleLink, and ActRelationship.

In HL7 v3 RIM, every happening documented in the healthcare domain is represented by the Act class. The Participation class defines the context for an Act by defining the relationship between Act and Role classes. Physical things and beings that take part in healthcare are represented by the Entity class. The Role class establishes the roles that entities play as they participate in healthcare acts. The ActRelationship class defines the relationship between two instances of the Act class. Similarly, the RoleLink defines the relationship between two instances of the Role class.

IV. SPECIALIZING HL7 RIM TO THE IEEE 11073 DIM

When specializing the HL7 RIM to a specific domain model, first, the appropriate subset of the RIM classes as well as a subset of their attributes is selected and the corresponding DMIM is created.

The domain model in our case is given by the 11073 DIM. However, from the eight packages of the 11073 DIM, it suffices to model the Medical and the Patient packages because these two packages contain the information to represent medical devices, their channels, measurements, data types, and the related patient information.

In specializing the HL7 RIM to represent the 11073 DIM, we first note some apparent correspondences among their classes.

- 1) *Virtual Medical Device*: In the DIM, a medical device is represented by a VMD class and in the HL7 RIM, there is a class named Device (a subclass of Entity class) that is used for the same purpose.
- 2) *Channel*: In the DIM, the Channel class is used to group related Metric objects; in the HL7 RIM, the Act class with classCode “CLUSTER” can be used for grouping the related information.

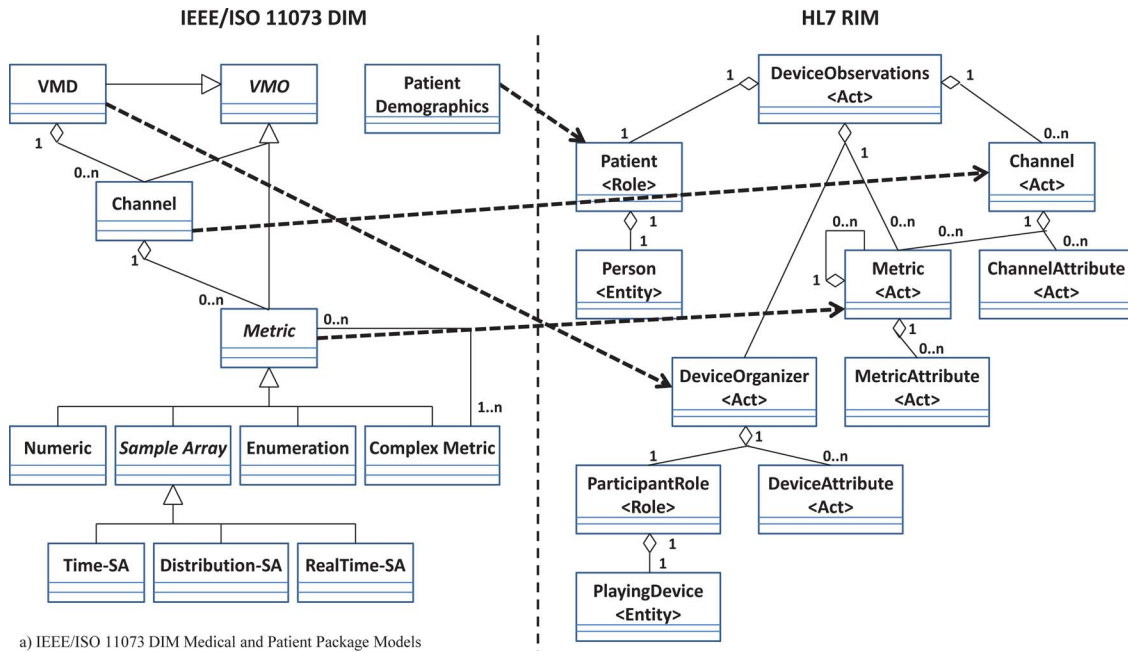


Fig. 2. Refining the HL7 v3 RIM to the medical device domain as specified by the ISO/IEEE 11073 DIM.

- 3) *Metric*: In the 11073 DIM, Metric abstract class through its actual classes such as Numeric, Time Sample Array, and Complex Metric are used to report the measurements of the device, whereas in the HL7 RIM any kind of measurement or observation is represented with the Observation class (a subclass of Act class).
- 4) *Patient Demographics*: Patient Demographics class in the Patient Package of the 11073 DIM is used to keep very basic patient demographics information since medical devices have limited capacity; in the HL7 RIM, the Patient class (a subclass of the Role class) together with the Person class (a subclass of Entity class) is used for the same purpose.

However, in these class correspondences, some of the attributes of the 11073 DIM classes do not match with the attributes of the respective HL7 RIM classes. Consider for example, the two attributes of the Numeric class: Absolute-Time-Stamp and Nu-Measure-Resolution. The former is used to store the time of observation while the latter is used to report the resolution of measurement, i.e., the minimum difference between two observed values. Although Absolute-Time-Stamp matches with the effectiveTime attribute of the Observation class in RIM, there is no matching attribute in the Observation class for the Nu-Measure-Resolution attribute.

Our challenge, therefore, is to refine the HL7 RIM such that the information given in the 11073 DIM medical device and the patient packages can be fully represented. We start the refinement process, whose result is shown in Fig. 2, by noting that every happening documented in the healthcare domain is represented by the Act class in the RIM and, therefore, create a copy of Act class with classCode “CONTAINER” and rename it as the DeviceObservations class. This class contains a required

DeviceOrganizer class and zero or more Channel and Metric classes and a Patient class. In this way, the DeviceObservations class becomes the entry point for a group of measurements obtained from a medical device.

The DeviceOrganizer class, which is a copy of the Act class in the HL7 RIM with the classCode “CLUSTER,” is associated with the PlayingDevice class through a ParticipantRole participation. The PlayingDevice class is a copy of Device class in HL7 RIM and is used to describe the medical device realizing the observations.

After this step, the DMIM is refined by setting the cardinality of the attributes and relations and renaming the class names. As a result, the RMIM is created by complying with the “HL7 Refinement, Constraint, and Localization” guidelines [7]. To be able to specify nonmatching attributes of the 11073 DIM, a DeviceAttribute class, which is a copy of Observation class in the HL7 RIM is defined and the nonmatching attributes are specified within this class through the “component” ActRelationship links. Names of these nonmatching attributes are specified with the “code” attribute of the DeviceAttribute class in their original nomenclature given in 11073, i.e., 11073-10101.

Additionally, a copy of Observation class in the HL7 RIM is renamed as Metric corresponding to the Metric class in the 11073 DIM. Similar to the DeviceAttribute class, a MetricAttribute class is also defined to be able to specify nonmatching attributes of the 11073 DIM Metric class. Also, a recursive relationship from the Metric class to itself is specified in order to model the 11073 DIM Complex Metric class.

The Channel object, which is not mandatory in the DIM model, can contain one or more Metric objects when used. A copy of the Act class with the classCode “CLUSTER” in RIM is specialized to represent the Channel object in

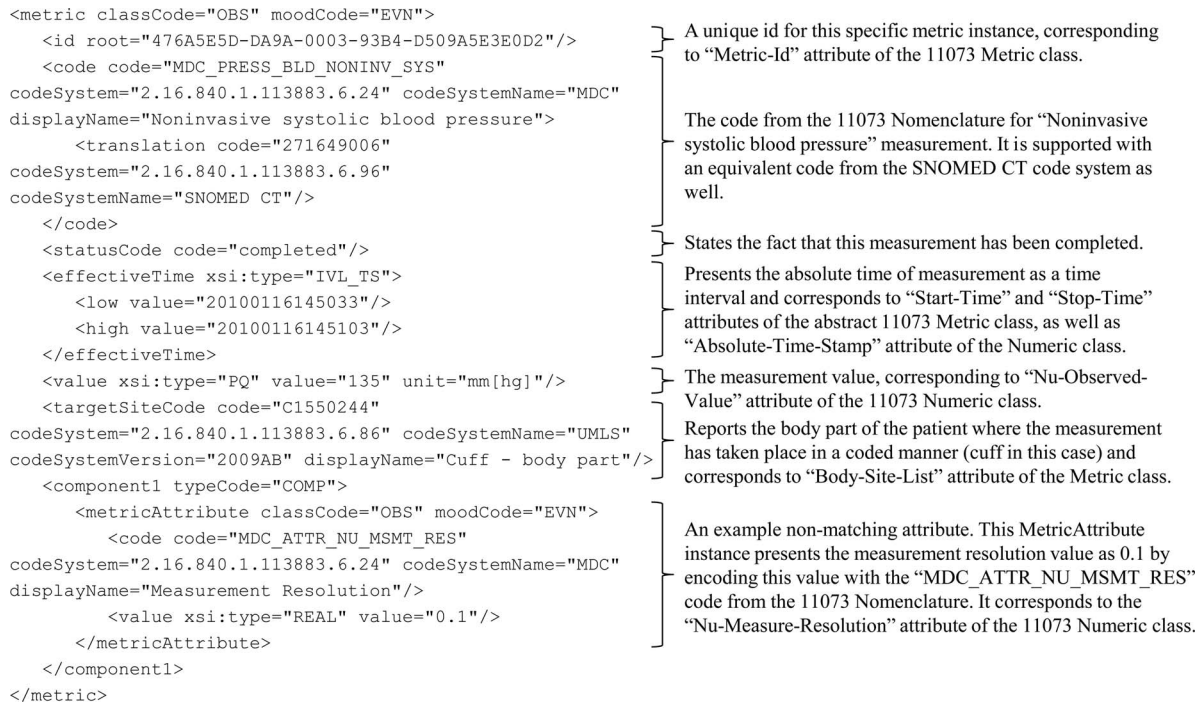


Fig. 3. Example Metric Object in our HL7 RMIM reporting noninvasive systolic BP measurement from a BP cuff device.

DIM as in the case of DeviceOrganizer. Again, it can have any number of ChannelAttribute classes in order to represent the nonmatching attributes of the 11073 DIM Channel class.

A. Representing the Metric Object With HL7 Datatypes

The Metric in the 11073 DIM is the base class for a number of classes, namely *Numeric*, *SampleArray*, *Enumeration*, and *Complex Metric* classes. The *SampleArray* class also has three subclasses: the *RealTime SampleArray*, the *Time SampleArray*, and the *Distribution SampleArray* classes. These classes are used whenever an observation value is to be represented in the DIM. There are no specific RIM classes to correspond to these classes. Yet, HL7 has a very complex abstract data types specification that can even represent a histogram. Hence, in our modeling, we specify just one Metric class which is an Observation class for all these classes. By using different data types in the “value” attribute of this Observation class, it becomes possible to express any of these classes.

For example, the Numeric class of the 11073 DIM, depending on whether it is simple or compound, contains one or more NumericObservationValue (NuObsValue) objects, which are the actual measurement values. The attributes of the Numeric class describe the measurement conditions such as the measurement resolution and the accuracy deviation, whereas NuObsValue object specifies the particular observation type, the actual observed value and its unit. This type of information is represented with the Physical Quantity (PQ) data type in HL7. Therefore, the data type of “value” attribute of the Metric class is set as “PQ” and then the measurement value and its unit are given within

this attribute (see Fig. 3). The data type of the “value” attribute can be set to collection types such as list, set or bag so that compound values and arrays can be represented as well. In the case of Complex Metric instances, the “value” attribute of the root Metric class is not suitable since a Complex Metric can contain any number of Numeric, Sample Array, and Enumeration objects. In this case, for each instance of noncomplex Metric classes, a new Metric instance is created in RIM and attached to the root Metric class. The root Metric class does not directly hold any values, but groups together related values as a complex class.

In order to clarify the specialization of the attributes of our RMIM to the 11073 DIM, we provide an example Metric object complying with the XML Schema derived from 11073 RMIM, which reports the noninvasive systolic BP measurement of a BP cuff device as shown in Fig. 3.

We first explain the correspondences between the standard attributes of the HL7 Observation class and the associated attributes in the original 11073 DIM Metric and Numeric classes. As already mentioned, the “code” element (i.e., attribute) is obtained from the 11073 Nomenclature, which is “MDC_PRESS_BLD_NONINV_SYS” code for noninvasive systolic BP. It is also supported with a code from SNOMED CT within the “translation” element. The “value” element of metric element in the example gives the actual value of the measurement. According to the 11073 DIM, systolic BP measurement is a numeric value. In HL7, the PQ data type is used to present the measurement value together with its unit. The descriptions and correspondences to the 11073 DIM attributes of the remaining XML elements in this Metric object are already provided in Fig. 3.

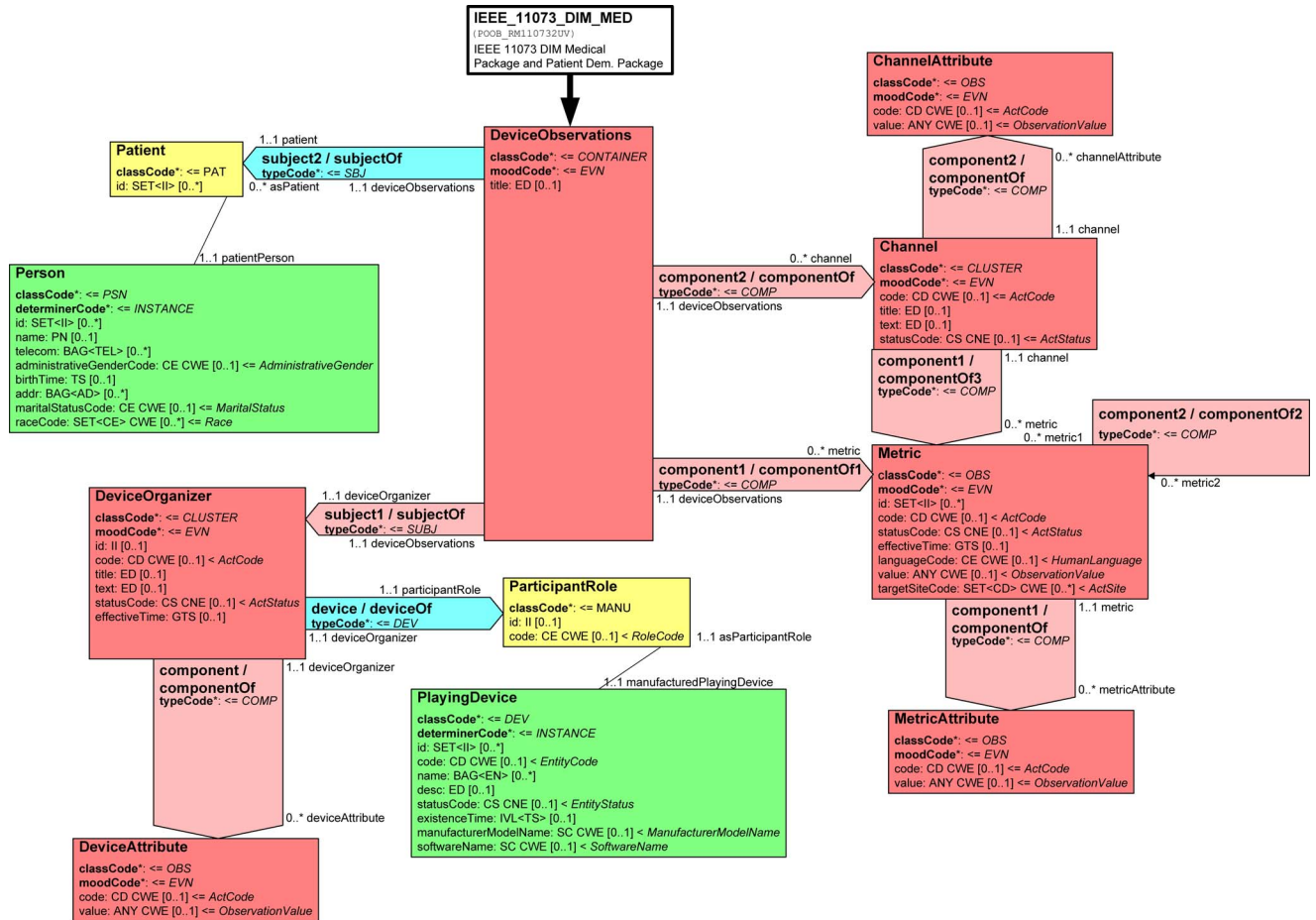


Fig. 4. HL7 RMIM for the 11073 DIM.

The data for nonmatching attributes, on the other hand, are represented using the extension mechanism we have developed by introducing MetricAttribute class. In the example, the measurement resolution (i.e., the minimum difference between two observed values) of the BP cuff device for systolic BP measurement is given, which corresponds to the “Nu–Measure–Resolution” attribute of the 11073 Numeric class.

B. HL7 v3 Design Process of Our Modeling

The RMIM for the ISO/IEEE 11073 DIM medical and patient packages is shown in Fig. 4. The RMIM is designed using RMIM Designer version 4.5.11 [26]. In this phase, the Data Types Abstract Specification, Release 1 [27] is used as seen in the RMIM diagram. However, during schema generation phase, both XML Implementation Technology Specification—Data Types R1 [28] and XML ITS—Data Types R2 (i.e., ISO-Harmonized Data Types, Release 1) [29] compliant XML Schemas have been generated. After finalizing the RMIM, it is stored into a local copy of RIM Repository version 2.30.3 and then opened with RoseTree version 4.2.43 [30] in order to create the hierarchical message definition (HMD) of the model. After getting the HMD, which is still Data Types R1 compliant, we have generated the XML Schema definition (XSD) [31] of our model twice, one compliant with the older but widely used XML ITS Data Types

R1 and the other one compliant with the latest ISO-Harmonized Data Types by using HL7 v3 Generator [32] versions 3.1.8 and 3.3.1, respectively.

The ISO-Harmonized Data Types is important because 11073 is a standard by IEEE and ISO and the harmonized data types is a joint effort by CEN, IEEE and HL7. By complying with this latest initiative, it becomes possible to increase the interoperability support of the 11073 RMIM.

The resources created during this process, that is, RMIM, HMD, XSD, and sample XMLs are available from [33].

V. MAPPING THE 11073 RMIM TO HL7-BASED STANDARD INTERFACES

The 11073 RMIM created as described can easily be mapped to the other HL7-based message or document standards. To demonstrate this, in this section, we provide three example mappings: to the HL7 PHMR draft standard [5]; to the HL7 v3 Common Observation message and to the USAM standard used in the GLIF [34].

A. Mapping the 11073 RMIM to the HL7 PHMR

The PHMR is a document that carries personal healthcare monitoring information including the representation of the measurements captured by devices, notes, summaries, and graphs.

TABLE I
MAPPING THE 11073 RMIM TO THE HL7 CDA-BASED PHMR

11073 RMIM	PHMR (CDA) XPath	Comments
Patient	/ClinicalDocument/recordTarget/patientRole	
Person	/ClinicalDocument/recordTarget/patientRole/patient	
Channel	//section[templateId/@root="2.16.840.1.113883.10.20.1.16"]/entry/organizer OR //section[templateId/@root="2.16.840.1.113883.10.20.1.14"]/entry/organizer	Can be within "Vital Signs" or "Results" section
ChannelAttribute	//organizer/component/observation	The root organizer maps to a Channel
Metric	//organizer/component/observation	
MetricAttribute	//organizer/component/observation/entryRelationship/observation	
DeviceOrganizer	//section[templateId/@root="2.16.840.1.113883.10.20.1.7"]/entry/organizer	The root organizer maps to a DeviceOrganizer
DeviceAttribute	//organizer/component/observation	
ParticipantRole	//organizer/participant/participantRole	
PlayingDevice	//organizer/participant/participantRole/playingDevice	

In order to represent such varying data, a Clinical Document Architecture (CDA) [35] based format has been chosen by HL7, and wherever possible, templates that are defined by HL7 Continuity of Care Document (CCD) [36] are reused. Since the CDA and the developed 11073 RMIM are both derived from the HL7 v3 RIM, mapping between these two formats is easy in contrast to the effort of directly mapping the 11073 DIM to CDA.

In CDA, the body of the document is composed of sections that can be nested as much as needed, and these sections contain entry classes such as observation, procedure, and substanceAdministration for formal representation of clinical statements. In the PHMR case, the top level sections can only be "Vital Signs," "Results," "Medical Equipment," "Purpose," or "Medications." The content of all these sections are constrained by HL7 CCD specifications. The medical device data can be given within either the "Vital Signs" or the "Results" section; their structure is the same but some specific measurements such as blood pressure, temperature, oxygen saturation, respiratory rate, and pulse are presented in the "Vital Signs" section while the rest are given in the "Results" section. In each of these sections, there is an organizer class that is used for reporting a group of measurements. The Channel class in the 11073 RMIM directly maps to this organizer class. Both the organizer class and the Channel class are copies of the Act class with classCode CLUSTER in the RIM; hence, all their attributes are identical. Similarly, Metric class in our 11073 RMIM is a copy of Observation class in the RIM and, hence, matches with the observation class included by the organizer class and used for reporting the actual measurements. The extension mechanism that we have developed for nonmatching attributes of Metric class is also inherent in the CDA structure. In our model, the main observation class (i.e., Metric) establishes component relationships with MetricAttribute classes which are also instances of observation class for representing nonmatching attributes. In the PHMR, an observation class establishes entryRelationships with other observation classes in the same way. This structure can be used to represent Complex Metric classes as well.

In our 11073 RMIM, the DeviceOrganizer class holds device related data, while in PHMR there is a dedicated "Medical Equipment" section that holds an organizer class for keeping device data. Again, these two organizer classes are derived from the same class in HL7 RIM. The relationships and subclasses of these two classes can be mapped very easily as well, because the same classes from RIM are retrieved, this time by applying

almost the same renaming. They both have ParticipantRole and PlayingDevice classes as the Entity and Role classes for the device. For representing nonmatching attributes of the device, in PHMR, observation classes are attached to the organizer class through component relationships, which are identical to the DeviceAttribute classes attached to the DeviceOrganizer class in our 11073 RMIM.

As in CDA, patient demographics information is presented within "recordTarget" Participation class in PHMR. The Role class of this Participation class is a copy of the Patient class (renamed as "patientRole") and its Entity class is a copy of the Person class (renamed as "patient") in the HL7 RIM. Hence, "subject2" Participation class, "Patient" Role class, and "Person" Entity class in our 11073 RMIM directly correspond to "recordTarget," "patientRole," and "patient" classes in the PHMR, respectively. Since they are copies of the same classes in the RIM, all their attributes are identical.

As a summary, the mapping from the developed 11073 RMIM to HL7 PHMR is straightforward because there are exact matches to all 11073 RMIM classes. The differences, when they occur, are dissimilar paths of matching classes in the complete schema and certain renamings that are easily handled by using XML transformations. The complete mapping is given in Table I. Being copies of same HL7 RIM classes, the corresponding classes and all their attributes are identical, that is, they have identical classCodes and typeCodes.

To further demonstrate the similarities between the 11073 RMIM and the HL7 PHMR, the example given in Fig. 5 provides the PHMR representation of the Metric object of Fig. 3. It can be easily noticed that the XML instances are almost identical. For compliance with the original CDA schema, the XML element names of the root Metric object ("metric") and the nonmatching measurement resolution attribute ("metricAttribute") are renamed as "observation" in the PHMR representation. The identifiers of the relevant CCD templates are added at the beginning of the root observation corresponding to our metric instance; 2.16.840.1.113883.10.20.1.31 and 2.16.840.1.113883.10.20.9.8 are the identifiers of the CCD Result Observation and Numeric Observation templates, respectively. The final difference between the two XML representations is that in the PHMR instance the medical device that provides the measurement value is identified with its unique id within the "participant" relationship, because a PHMR document can aggregate several measurements from several devices. Complying with the 11073 DIM, the details of the single

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<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.1.31" />
  <templateId root="2.16.840.1.113883.10.20.9.8" />
  <id root="476A5E5D-DA9A-0003-93B4-D509A5E3E0D2" />
  <code code="271649006" codeSystem="2.16.840.1.113883.6.96"
codeSystemName="SNOMED CT"
displayName="Systolic blood pressure">
  <translation code="MDC_PRESS_BLD_NONINV_SYS"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC" />
  </code>
  <statusCode code="completed" />
  <effectiveTime>
    <low value="20100116145033" />
    <high value="20100116145103" />
  </effectiveTime>
  <value xsi:type="PQ" value="135" unit="mm[hg]" />
  <targetSiteCode code="C1550244"
codeSystem="2.16.840.1.113883.6.86" codeSystemName="UMLS"
codeSystemVersion="2009AB" displayName="Cuff - body part" />
  <participant typeCode="DEV">
    <participantRole>
      <id root="1.2.840.10004.1.1.1.0.0.1.0.0.1.2680"
assigningAuthorityName="EUI-64"
extension="1F-7C-46-92-9A-12-DE-3D" />
    </participantRole>
  </participant>
  <entryRelationship typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
      <code code="MDC_ATTR_NU_MSMT_RES"
codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"
displayName="Measurement Resolution" />
      <value xsi:type="REAL" value="0.1" />
    </observation>
  </entryRelationship>
</observation>

```

Fig. 5. Metric Object Representation in the HL7 PHMR.

medical device are presented in the DeviceOrganizer cluster in our 11073 RMIM.

B. Mapping to HL7 v3 Common Observation Message

The device observations are also needed in the clinical workflows and although HL7 v2.x is the most widely used message format, there is increasing use of HL7 v3 messages. The most suitable message for reporting medical device measurements in the list of HL7 v3 domains is the Common Observation message (RMIM artifact name: POOB_RM410000UV). Its RMIM can be found in [37].

In Common Observation message, the entry point is an EventChoice which can be either a ResultGroup (copy of Act) or CommonObservationEvent (copy of Observation). CommonObservationEvent expresses a single point-in-time observation made about a subject, but when there is a need for grouping multiple observations in a message, ResultGroup is used. Therefore, semantically, in our 11073 RMIM the Metric class maps to CommonObservationEvent and the Channel class maps to ResultGroup. Since these corresponding classes are derived from the same classes in the HL7 RIM, their attributes are exactly the same. The EventChoice has a recursive “component” relationship to itself so that both ResultGroup and CommonObservationEvent can contain themselves or each other. This recursive relationship makes it possible: 1) to represent the subcomponent association between a Channel and Metric(s); 2) to represent Complex Metric objects with one root and several child CommonObservationEvent instances; and 3) to accommodate nonmatching attributes with CommonObservationEvent instances attached to ResultGroup or CommonOb-

servationEvent instances as it is done with MetricAttribute and ChannelAttribute classes in our 11073 RMIM.

The subject of the Common Observation message is given in R_Subject Common Message Element Type (CMET) through “subject” participation to EventChoice. Within this CMET, patient (child of Role) and patientPerson (child of Entity) classes directly correspond to Patient and Person classes in our 11073 RMIM; they are used for the same purpose and are copies of exactly the same classes in the HL7 RIM. In the Common Observation message, the most appropriate participation for presenting device data is the “performer” participation to EventChoice, which is used for actual performer of the reported act/observation in the message. “performer” participation is bound to R_AssignedEntity CMET, in which assignedEntity (child of Role) and assignedDevice (child of Entity) classes exactly match with ParticipantRole and PlayingDevice classes in our 11073 RMIM. The only issue in the entire mapping process is finding a suitable place for nonmatching attributes of the VMD class in the 11073 DIM. In our 11073 RMIM, we designed a DeviceAttribute class for this purpose but such an additional class does not exist in the R_AssignedEntity CMET. Our solution is to create a dedicated ResultGroup for nonmatching device attributes and copy each DeviceAttribute instance as a CommonObservationEvent instance within this group.

Using this mapping it is possible to create, directly, HL7 v3 Common Observation messages from medical device data complying with our 11073 RMIM.

C. Mapping to USAM Used in GLIF

For representing medical data items, the GLIF supports the use of HL7 RIM version 1, which is also known as the USAM [38]. Service_Action class of HL7 RIM version 1 is used for representing generic patient data, which is renamed as Act class in the current versions of the RIM. Three subclasses of Service_Action class, namely Medication, Observation, and Procedure are used for representing detailed patient data. In GLIF, only the concrete data elements or measurements such as systolic BP are modeled using the USAM Observation class. Therefore, in the mapping from 11073 RMIM to USAM used in GLIF, just the Metric class is of interest. Furthermore, there is no container class in GLIF corresponding to the Channel class. Hence, the solution is to individually map all metric instances of a Channel object to USAM’s Observation class. In our 11073 RMIM, Metric is a copy of the HL7 RIM Observation class, which almost identically exists in USAM; hence, the metrics can be moved to GLIF instances as they are.

VI. DISCUSSION

There is not a unique, or yet IEEE/HL7 approved, way of modeling the 11073 DIM in the HL7 RIM. For example, we have introduced an aggregator class named “DeviceObservations” as the root and entry class of 11073 RMIM; though, another option can be to discard this class and use the “DeviceOrganizer” as the entry point and bind the other classes directly to it. However, it is not possible to generate very different RMIM representations of the 11073 DIM either. The alternatives may vary on minor

issues like different renaming of the selected HL7 RIM classes or changing the hierarchical arrangement of classes. Note that because the relationships among the classes are already fixed in the 11073 DIM, the number of possible alternatives for the latter case is very limited. Our objective is to be able to fully represent the medical and patient packages of the 11073 DIM in an HL7 RMIM, and this goal is achieved in a standard conformant manner.

Our work has already influenced the work of researchers at the University of Luebeck, Institute of Medical Informatics; currently, the 11073 RMIM is used for representing a part of intensive care data that are used by the Dräger Medical within their “Intensive Care Manager” system [39]. Among the other benefits, the researchers state that the adaptation of a standardized model improves the quality and decreases the waste of effort when integrating the devices with SmartCare Decision Support System [40] for automated weaning. When such a common model is not in place, SmartCare is adapted for every customer according to their specific data structures and device terminology.

We have been also in communication with experts from the relevant standardization organizations such as the HL7 Health Care Devices Work Group (HL7 DEV WG) [20] and Continua Health Alliance [3].

VII. CONCLUSION

There are indicators that interoperability between medical devices and healthcare systems can reduce integration costs by 30%, support staff charting time by 50%, practitioner charting time by 20% and increase the accuracy of data in EHR, as shown in a recent study [41].

As already mentioned, several profiles have been developed providing bilateral mappings from the ISO/IEEE 11073 DIM to a specific message or document standard. The need for a mapping between 11073 DIM and HL7 v3 RIM has also been identified by HITSP [22] to facilitate the mapping to all HL7 RIM-based document and message models.

In this paper, we address this gap by developing an HL7 RMIM representation of the 11073 DIM to enable different clinical applications to extract device data from a common standard model rather than using the bilateral mappings. We have shown that, once the medical device data are obtained in the RMIM format, it can easily be transformed into HL7-based standard interfaces through XML transformations because these interfaces all have building blocks from the same RIM.

The mappings from the developed RMIM to some of the most used HL7 v3-based standard interfaces such as the HL7 CDA-based PHMR standard used by the EHR/PHR systems; the HL7 v3 Common Observation message used in clinical workflows and the USAM standard used in the GLIF for clinical decision support are provided to support our argument.

In future work, we will use these mappings to automate the clinical follow up of patients with cardiac implants within the scope of the iCARDEA Project [42]. This project has set out to semiautomate the patient follow up processes through personalized care plans by correlating the data coming from medical

devices with the context of the patient obtained from his EHRs and PHRs and, hence, its first requirement was to achieve the interoperability of all this information.

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Mustafa Yuksel received the M.S. degree in the Department of Computer Engineering, Middle East Technical University, Ankara, Turkey, in 2008, where he is currently working toward the Ph.D. degree in the same department.

He is a full-time Senior Researcher at Software Research Development and Consultancy Ltd., Ankara. He has been providing consultancy services on the management of National Health Information System to the Turkish Ministry of Health as a part of SRDC consultancy team. His research interests include

healthcare informatics, semantic interoperability, e-business, and service-oriented architectures.



Asuman Dogac received the Ph.D. degree in the Department of Computer Engineering, Middle East Technical University, Ankara, Turkey, in 1981.

She is the Founding President of Software Research Development and Consultancy Ltd, Ankara. She has published more than 100 papers in refereed international conferences and journals. Her research interests include healthcare informatics, semantic interoperability, Internet computing, e-business, and service-oriented architectures.

Dr. Dogac is the recipient of several international and national awards, including the IBM (USA) Faculty Award in 2004 and Mustafa Parlar Science Award in 2000.