Using IHE and HL7 Conformance to Specify Consistent PACS Interoperability for a Large Multi-Center Enterprise

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ABSTRACT

As part of its patient care mission, the U.S. Veterans Health Administration performs diagnostic imaging procedures at 141 medical centers and 850 outpatient clinics. VHA's VistA Imaging Package provides a full archival, display, and communications infrastructure and interfaces to radiology and other HIS modules as well as modalities and a worklist provider. In addition, various medical center entities within VHA have elected to install commercial picture archiving and communications systems to enable image organization and interpretation.

To evaluate interfaces between commercial PACS, the VistA hospital information system, and imaging modalities, VHA has built a fully constrained specification that is based on the Radiology Technical Framework (Rad-TF) Integrating the Healthcare Enterprise. The Health Level Seven normative conformance mechanism was applied to the IHE Rad-TF and agency requirements to arrive at a baseline set of message specifications. VHA provides a thorough implementation and testing process to promote the adoption of standards-based interoperability by all PACS vendors that want to interface with VistA Imaging.

KEYWORDS

- Conformance ▪ HL7 ▪ IHE ▪ Imaging ▪ Interface ▪ Interoperability ▪ Messaging ▪ PACS

Within its VistA open-source integrated information system, the U.S. Veterans Health Administration provides the ability to capture, store, display, and manage clinical and administrative images. Since the inception of the VistA Imaging module in 1990, nearly one billion images have been captured into local and regional VistA databases for association with patient records.

The integration of VistA Imaging into the nationwide cross-facility veterans' medical record has been discussed frequently in research. VistA Imaging assists the clinical care team in improving the quality of care[1] and implementing care plans,[2] and has been cited and demonstrated at professional meetings[3,4] as an example of the successful application of open standards-based systems across distributed networks.

VHA medical centers use a variety of modalities and architectures to fulfill the need for image acquisition, viewing, and storage. Images are usually acquired by means of a commercial device, such as a digital X-ray camera or a flatbed scanner. For image viewing and storage, some facilities use VistA capabilities virtually exclusively, while other facilities have acquired commercial picture archiving and communications systems to satisfy particular image management needs.

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To ensure smooth integration and mitigate patient safety risks, it is essential that commercial devices consistently exhibit a set of known, acceptable behaviors both when operating on a stand-alone basis and also when interfacing with other systems. This is true throughout the healthcare community, both within and outside of VHA. The need for interoperability among systems is the major impetus behind the development of industry standards such as Digital Imaging and Communications in Medicine (DICOM)[5] and Health Level Seven (HL7).[6]

Roles, Limitations of Standards

Standards such as DICOM and HL7 provide implementors with a common framework within which to specify data to be exchanged between systems and the expected communications behaviors of those systems. While the role of standards in providing consistently exchangeable data structures is important, there are inherent limits to what data exchange standards can accomplish by themselves.

Data exchange is intended to facilitate interoperability in two regards.[7] Interoperability is facilitated syntactically, so that all communicating parties may know what data to expect and where a particular piece of data, such as patient name, may be found; and semantically, so that all communicating parties may agree on the particular instance concepts to be discussed—for example, specific types of thoracic images.

The limitations of messaging standards arise from the fact that standards tend to serve as facilitators of communication more than as specifiers of metadata. While certain controlled vocabularies—for instance, those included in SNOMED CT—will be widely applicable across certain sectors of the healthcare industry, the use of some other codes and identifiers—for example, those used to denote room and bed—will vary widely by locale and institution size and may even be unique to a particular enterprise. As a result, it is impossible for standards-developing organizations to attempt to catalog every current workflow, to fully constrain metadata, and to foresee every future practice. Ideally, standards will provide frameworks for interoperability—semantic as well as syntactic—and for constraining specific types of communications according to the distinct needs of a variety of implementers.

It is possible to approach, or even to achieve, full syntactic interoperability through the application of standards. This can be achieved through compliance with structural definitions and processing rules that constitute the normative backbone of an information-exchange standard. For example, DICOM, with its rules for handshaking between application entities,[8] possibly may come as close as any major standard to facilitating plug-and-play syntactic interoperability. On the other hand, resolving issues associated with semantic interoperability require that standards be available to provide a framework for constraint and that vendors and implementers agree on enforcing the constraints. Both the provision and application of a constraint framework are important facets of the broad concept of conformance.

Conformance Efforts in Standards

There are significant efforts under way to achieve conformance in healthcare IT standards.

DICOM. Recognition of the need for consistent frameworks to specify interoperability has historically preceded the development of mechanisms by which to constrain interoperability definitions. The DICOM standard for imaging had its beginnings in the early 1980s, but a detailed conformance structure was not specified until DICOM Version 3 was released in 1993. At that time, DICOM Part 2 provided a detailed mechanism by which implementers could specify the behavior of their systems for handshaking, data exchange, and exception processing. The assertion of adherence to a specified set of behaviors is referred to as a DICOM conformance statement, which "specifies the service classes, information objects, communications protocols, and media storage application profiles supported by the implementation."[9]

The intent of a DICOM conformance statement is to document implementation constraints and limitations. Well-written conformance statements bridge almost all interoperability gaps, although it is possible to incompletely specify exception behaviors, such as what should happen when a required element is empty or when an element is out of the range of enumerated values that are specified in the

DICOM standard.

In 2003 and 2004, DICOM conformance underwent a major revision.[10] While a DICOM conformance statement is the major communications tool for implementations, some vendors have historically provided more useful information than others. The revisions were designed to increase the amount of useful information exchanged, to ensure more rigorous adherence to the DCS template, to provide additional "real-world" examples and to improve conformance statement readability by including an executive summary. One notable example of the DCS revision is not only to list the DICOM attributes used, but also to describe exactly how they are being used.

Through education and marketing efforts, DICOM conformance has been embraced throughout the imaging industry. Medical enterprises, including those operated by the Veterans Health Administration, expect product vendors to make DICOM conformance statements available as specifications and assertions of standard behavior.

HL7. By contrast, the HL7 Version 2 standard took somewhat longer to develop a conformance structure. The Andover Working Group convened in the late 1990s to discuss issues of HL7 conformance and began close collaboration with HL7 in 1997 with the formation of the HL7 Conformance Special Interest Group. Since then, the HL7 Conformance SIG has been continually seeking to define and develop conformance mechanisms for all the standards administered by HL7, including the Version 2 and Version 3 standards.

A milestone was reached in 2003 with the publication of Version 2.5 of the HL7 standard, which includes a conformance framework in Section 2.12 of Chapter 2, entitled "Control." This conformance framework covers the specification of "dynamic" (functional) and "static" (data table) definitions in the context of a well-documented use case. HL7 provides for both the publication of a conformance profile and the assertion of a conformance claim. Version 2.6 of the HL7 standard will devote a separate chapter, 2B, to conformance, and will further document the structures and mechanisms to be employed to achieve normative conformance.

IHE. Before the development of HL7 conformance, however, many recognized the need to integrate HL7 interfaces both among themselves and with interfaces using other standards such as DICOM. Beginning in 1998, the Radiological Society of North America and the Healthcare Information and Management Systems Society began meeting jointly to document use cases in radiology that would necessitate interoperability. Their efforts culminated in 1999 with the publication of the original IHE technical framework, which provided reference models (profiles) for information exchanges in several contexts, including scheduled workflow, patient information reconciliation, and simple image and numeric reporting.

The IHE approach has proved to be useful and extensible. Other clinical information technology domains, including cardiology, laboratory, eye care, and infrastructure, have developed or are in the process of developing IHE technical framework documents. While the profiles published in the IHE technical frameworks are not fully constraining conformance mechanisms, they do provide baseline sets of definitions and functionality that vendors and implementers may support by issuing an IHE integration statement. Interoperating products that implement IHE profiles can rely on other actors providing critical information in a consistent manner, resulting in cost-effective partitioning of features across an entire system architecture.

> ***"...commercial PACS systems needed to connect to the rest of the VHA enterprise in a standard, well-documented fashion."***

In 2005, IHE provided a radiology users handbook. The handbook was designed to increase the usability of the IHE framework by showing how to use the framework to analyze current data sharing problems, how to purchase upgrades based on IHE, and how to reap the benefits of even partial implementations. Other domains are following the lead of radiology by producing similar handbooks.

IHE and HL7 convergence. While IHE profiles and HL7 conformance have both followed the general principle of documenting expected behaviors in the context of a use case, their approaches varied somewhat at the beginning. This was to be expected: the development and publication of the original IHE radiology technical framework predated that of HL7 Version 2.5, in which conformance was first documented, by several years, and IHE was intended to be used to profile other standards—particularly, in the beginning, DICOM—in addition to HL7.

A typical IHE radiology technical framework profile[11] contains two major components. There is the profile description, actors, and process flows, which appear in Volume I of the technical framework. There is also detail of individual transactions in support of these profiles, which, in the technical framework, appear in Volumes II and III, typically divided into sections covering scope, use case roles, referenced standards, interaction diagram, transaction detail (in the case of HL7, this includes trigger events, message semantic, and expected actions), and expected behaviors on the part of the transaction receiver.

A normative HL7 conformance profile contains three pieces. There is the use case model. Then, there is a dynamic definition, which includes an interaction profile, usually a UML activity diagram (however, simpler UML interaction models were also used in conformance prototypes), and acknowledgement conditions. Finally, the conformance profile contains static definitions, including a message-level static definition, a segment-level static definition, and a field-level static definition.

After HL7 Version 2.5 published the above-outlined conformance structure in Section 2.12 of Chapter 2, IHE domains such as laboratory[12] began to apply it for use in the HL7 transactions that they documented.

VHA PACS Interface Requirements

The Department of Veterans Affairs has been a highly visible supporter and participant in standards development efforts, both in healthcare and elsewhere. VA is a benefactor of HL7 and is one of the nation's largest deployers of DICOM interfaces. Consistent with this level of involvement, VA expects that interfaces deployed in VHA medical enterprises will not only use industry standards but will adhere to the guidelines of the IHE technical frameworks where such guidelines apply.

During 2004, it was recognized that commercial PACS systems needed to connect to the rest of the VHA enterprise in a standard, well-documented fashion. This was necessary not only to accelerate the achievement of interoperability but to ensure quality patient care as well. In particular, use of standard interfaces would mitigate the risk of associating acquired images with the wrong patient or study, a critical issue in achieving patient safety.

In October 2004, the VistA Imaging and Radiology development teams began developing a profile document that would completely specify both the content of HL7 messages to be exchanged between VistA modules and commercial PACS, and the behaviors of systems using those messages. Work and preliminary testing on this document continued throughout 2005. The final Version 1.0 of the HL7 interface specification was published on the Web in December 2005.[13] A complementary document for DICOM interfaces was being developed in early 2006.[14]

The remainder of this paper will discuss the content of the HL7 profile document and how it uses HL7 and IHE structures and constraints as well as behavioral specifications to achieve the objectives of interface standardization and patient safety risk mitigation.

HL7 Messages in IHE and the VistA Profile

The scheduled workflow profile of the IHE Radiology technical framework provides for using several HL7 messages to communicate patient registration and order information. Registration information is communicated by means of a number of trigger events associated with the admission-discharge-transfer message type, of which VistA uses the following:

- A01 (admit/visit notification)
- A02 (transfer a patient)
- A03 (discharge/end visit)
- A04 (register a patient)
- A08 (update patient information)
- A11 (cancel admit/visit notification)
- A12 (cancel transfer)
- A13 (cancel discharge)
- A40 (merge patient—patient identifier list)
- A47 (change patient identifier list)

In addition, VistA uses the ORM (general order message) message type with trigger event O01 to communicate order information using the following order control codes:

- NW (new order/service)
- CA (cancel order/service request)
- XO (change order/service request—used by VistA to indicate the examination is complete)

Finally, VistA uses the ORU (observation result unsolicited) message type with trigger event R01 to transmit report information.

Expected Behavior by the Commercial PACS System

Commercial PACS systems are expected to adhere to the following general guidelines:

- Storage of radiology orders sent using the ORM message, including the study instance UID.
- Updating demographic and visit information when received for patients for whom orders are on file.
- Storage of at least the most recently approved report.
- Alerting the sending system (VistA) of exceptions by using the standard ACK (acknowledgement) message, including a fully populated ERR segment.

In addition, there are specific requirements for handling particular field information.

Some of these requirements affirm IHE specifications for processing HL7 elements, while others are implementations of patient safety or data validation requirements that are directed by VHA but are not specifically addressed in the IHE Radiology technical framework. Both types of requirements are discussed within the VistA profile document. This is accomplished by broadening the document to incorporate both interface behavior (as directed by IHE and HL7) and application behavior (as required by VHA).

Documenting Interface Behavior

As specified by Version 2.5 of the HL7 Standard, interface behavior is documented by stating and illustrating the use case, discussing messaging flow, and providing details of the elements of the messages, the message segments, and the individual fields.

The use case portion of the profile contains an illustration of the transaction and participating actors using UML constructs, as well as a narrative overview of the purpose of the transaction and the responsibilities of the individual

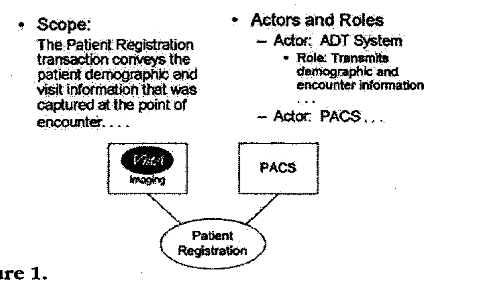

Figure 1.

Patient Registration Message

Segment	ADT Message	Usage	Cardinality	HL7 Chapter
MSH	Message Header	R	[1..1]	2
EVN	Event Type	R	[1..1]	3
PID	Patient Identification	R	[1..1]	3
[PD1]	Additional Demographics	X	[0..0]	3
[{ NK1 }]	Next of Kin / Associated Parties	X	[0..0]	3
PV1	Patient Visit	R	[1..1]	3
[PV2]	Patient Visit – Additional Info.	X	[0..0]	3
[{ ROL }]	Role	RE	[0..2]	12
[{ DB1 }]	Disability Information	X	[0..0]	3
[{ OBX }]	Observation / Result	R	[2..2]	7
[{ AL1 }]	Allergy Information	RE	[0..99]	3
[{ DG1 }]	Diagnosis Information	RE	[0..1]	6
[DRG]	Diagnosis Related Group	X	[0..0]	6

Figure 2.

actors, as shown in Figure 1.

Dynamic profile: interaction model. Each part of the profile is supported by an illustration and discussion of interface flows between systems, as distinguished from the contents of particular messages. The illustration of interface flow, including acknowledgments, is in the form of a UML activity diagram.

Dynamic profile: acknowledgments. Following the activity diagram in each portion of the profile is a discussion of the behaviors of the receiving system. HL7 conformance mandates the listing of acknowledgment responsibilities; for example, in the VistA profile document, if PACS accepts ADT registration messages, it shall return an original mode ACK application acknowledgment, as defined in the HL7 Standard and prescribed by the IHE radiology technical framework. The trigger event of the acknowledgment message shall be equal to the trigger event of the message that was received.

Static profile: message level. The HL7 standard publishes an abstract syntax listing for all messages defined by the standard. This abstract message syntax shows all segments that may be used for a particular trigger event, including segment order, repeatability, and optionality. In most messages, including the patient registration messages, the standard definition allows most segments to be optional.

An implementable message profile as specified by HL7 conformance must fully constrain the repeatability and optionality of all segments used in a message. Where the standard message uses curly braces { } to indicate repeatability and square brackets [ ] to indicate optionality, the message-level static profile augments the syntax to show explicit cardinality and usage, as shown in Figure 2.

Note that the message-level static definition contains no optionality. All segments are either required (R), required if known (RE), not supported (X), or conditional (C or CE). If a segment may repeat, its upper limit of cardinality is constrained, although this is not required by HL7 conformance.

Static profile: segment level. Each HL7 segment is defined in the standard by listing its fields in tabular form in the order in which they appear in a segment instance. Most fields are optional within a segment; however, when the HL7 default encoding is in use, the field delimiters must be included in a segment instance if later fields are populated within the segment.

Like the message-level static definition, the segment-level static definition contains no optionality. Usage and cardinality are fully constrained.

Static profile: field level. HL7 conformance states that field content must be fully specified for those fields that are populated by elements from code sets. The VistA profile augments this requirement by adding a brief narrative field definition, including a fully constrained attribute listing for those elements that have complex data types.

Documentation of Application Behavior

Application behavior is outside the scope of the HL7 standard and the IHE technical framework. The documentation of both interface and application behavior distinguishes the profile document from a minimal HL7 conformance profile, leveraging the profile document to state specific expectations of how the application is expected to act on the data it receives from VistA. The following paragraphs

Basic Order Data Set

The following are the elements of the Basic Order Data Set. All mapped DICOM elements, if they were provided and listed below, must be preserved either in the PACS generated DICOM Modality Worklist (C-FIND) SOP class and/or in all C-STORE storage SOP classes that are used to store and forward instances by PACS. Superscript ^{MWL} is used if only the Modality Worklist SOP class applies.

VistA Data Description	HL7	DICOM
Order set	ORC-8-Parent	No DICOM mapping as this field merely holds together multiple VistA Cases (Imaging Service Requests) for the same Patient
Location/Institution (Contains institution and location where imaging is performed)	OBR-20-Filler Field 1	(0040,0011)^{MWL} Scheduled Procedure Step Location (0008,0080) Institution Name (0008,0082) Institution Code – SQ
Ordering Provider	OBR-16-Ordering Provider	(0032,1032) Requesting Physician
Callback Phone Number	OBR-17-Order Callback Phone Number	(0040,2010)^{MWL} Order Callback Phone Number
Full Accession Number (exam date concatenated with the Case Number: "MMDDYY-nnnn")	OBR-19-Placer Field 2	Full Accession Number: (0008,0050) Accession Number Case Number only (nnnn): (0020,0010) Study ID (0040,0100)^{MWL} Sch.Proc.Step (0040,1001)^{MWL} Requested Procedure ID

Figure 3.

discuss the extensions that the VistA interface document applies to the conformance profile.

Basic data sets. The VistA profile publishes a list of data sets that are expected to be stored by PACS to facilitate interoperability with modalities that use DICOM messaging. HL7 fields and components are mapped to DICOM structures for guidance to the PACS implementor, as shown in Figure 3.

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The mappings in the basic data sets are consistent with the IHE HL7 order mapping to DICOM modality worklist.[16] IHE defines the mapping of the HL7 ADT and ORM messages to the DICOM modality worklist attributes. HL7 messages contain information regarding the order, not scheduling or resource management information. Scheduling and resource management are internal to the actor referred to by IHE as the department system scheduler—often the radiology information system—and is outside the scope of interoperability and conformance.

Extensions to application behavior. To protect patient safety and fulfill agency requirements, applications are expected to perform specific validation on certain data elements. For example, order updates must be validated not only on the patient identifier in PID-3 but also on name, sex, date of birth, and social security number.

As an example, the dynamic profile of the order message contains a discussion of expected application behavior with respect to the study instance UID that is transmitted in the ZDS segment. When PACS receives an order message containing order control code NW or XO and there is no previous case assigned this study instance UID, it shall assign the study instance UID from the ZDS segment to the case that it files on its system. The study instance UID shall be placed in the DICOM header of all images acquired for this study. It shall be available for queries. If there is a previous case already in PACS for which this study instance UID is assigned, then PACS will notify the sending system of the anomalies via an HL7 application acknowledgment and will not update the order. PACS is responsible for notifying support staff and users of anomalies as needed.

Transmission of exception information. Exception processing is rigorously specified in the dynamic profile. For example, if the value received in MSH-9.1-message type, MSH-9.2-trigger event, MSH-11-processing code, or MSH-12-version ID is invalid, the value AR (application reject) shall be returned in MSA-1-acknowledgment code, and the appropriate value from HL7 Table 0357 shall be returned in ERR-1-error code and location.

Or, if the value received in MSH-5-receiving application or MSH-6-receiving facility is invalid, the value AE (application error) shall be returned in MSH-1-acknowledgment code, and the value 103 (table value not found) shall be returned in ERR-1-error code and location.

Review and Testing

In addition to a link to the VistA profile document, vendors are provided with a summary[15] of requirements to be tested. A detailed testing suite has been developed by the VistA imaging team and is periodically validated and reviewed by a panel of VHA informaticists and clinicians.

Testing is performed by executing options within a testing engine that is isolated outside the VA firewall. Options cover both expected normal interface behavior (non-exception flows) and behavior in the event of irregularities (exception flows).

Vendors contact the VistA imaging team to schedule validation of their HL7 interfaces against VistA requirements. This validation typically takes place over a period of three or four days, with about two hours of testing per day. The entire course of validation covers 30 to 40 specific tests. Results of testing then are transmitted to the vendor.

Variances from expected behavior are classified as Category 1 (required for validation), Category 2 (retesting required) and Category 3 (not required for validation). Interfaces are not validated until all Category 1 and 2 variances have been resolved. While no vendor has yet resolved all Category 1 and 2 variances, it is anticipated that vendors will begin to release interfaces in 2007 that conform to the essential requirements in the VistA profile.

Lessons Learned

Profiles based on the conformance vocabularies provided by HL7, DICOM, and IHE are the primary tool for communicating interface specifications between VA developers, IT staff, and vendors. The VA continues to evolve to an IHE-based integration strategy as a long-term goal. Having an IHE-based integration strategy enables the VA to leverage the cooperative work of the entire industry.

The HL7 conformance structure enables the full, testable, and verifiable specification of an interface between an internal hospital information system and a commercial product as outlined in the IHE technical framework. In addition, the conformance structure may be extended to document specific behaviors needed to assist in implementation interoperability, to mitigate patient safety risks, and to satisfy enterprise error reporting requirements. Processes developed for an HL7 requirements document and testing methodology can be reproduced to test other portions of an overall interface architecture using standards other than HL7.

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