COVER FEATURE

Testing the Nation's Healthcare Information Infrastructure: NIST Perspective

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The National Institute of Standards and Technology is enabling the development of an integrated healthcare information infrastructure by developing test tools and techniques that will facilitate seamless exchange of information across the healthcare enterprise.

According to the Centers for Medicare and Medicaid Services, the US spent nearly $2.6 trillion on healthcare in 2010, an amount estimated to nearly double by the end of this decade (www.cms.gov). This rate of spending was underscored by Athenahealth CEO Jonathan Bush: "The US spends an amount equal to 300 percent of India's GNP on healthcare, and India's population is three times ours" (*Fortune*, 16 Jan. 2012, p. 22). In an attempt to rein in healthcare costs, the Obama administration, like the preceding Bush administration, has initiated a major effort to move from paper-based medical record keeping to electronic health records (EHRs). These efforts established the Office of the National Coordinator for Health Information Technology (ONC) and formulated financial incentives for the nation's physicians to use EHRs, which will jointly lead to considerable automation in the healthcare industry.

To take advantage of such automation, information generated in the healthcare enterprise must be digitally encoded with the right semantics, archived for efficient storage and retrieval, and transported reliably, securely, and efficiently, without any information loss. Accordingly, the National Institute of Standards and Technology has been working closely with ONC; Integrating the Healthcare Enterprise (IHE; www.ihe.net), an initiative by healthcare professionals and industry to improve the way healthcare computer systems share information; and other organizations, such as IEEE, to accelerate the adoption of information technology by US healthcare enterprises.

NIST, specifically its Information Technology Laboratory, is involved in several healthcare automation activities focused on developing associated test methods, protocols, and specifications, for interoperability. These projects, which frequently involve coordination with related organizations such as IHE, have been devised according to healthcare information flows.

INFORMATION FLOW IN HEALTHCARE SERVICES

The healthcare services industry generates and processes large amounts of complex information relating to patient diagnosis, testing, monitoring, treatment, and health management; billing for healthcare services; and asset management of healthcare resources. Healthcare delivery is a collaborative process, with many physicians, specialists, nursing staff, and technicians from multiple organizations participating in patient treatment. In addition, many external organizations, including government agencies, insurance companies, employers, medical researchers, pharmacists, and even lawyers in malpractice suits use the resulting healthcare information.

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The healthcare industry creates and uses different classes of information, including the following five types:[1,2]

- detailed medical records of each patient for every episode of illness or type of healthcare delivered;
- workflow for patient referrals to specialists,[3] physician orders for diagnostic tests or procedures, and hospital admission and discharge;
- detailed administrative records for managing healthcare resources—for example, scheduling patient appointments, tracking hospital bed utilization, and inventory management of pharmaceutical supplies;
- billing for healthcare services, healthcare cost control procedures, and coordination of benefits; and
- research reports, clinical observations, results of new pharmaceutical clinical trials, and new guidelines.

One category of information flow occurs within the healthcare services industry and is characterized as follows:

- An administrator obtains patient medical history, employment and social data, and health insurance information and enters the data into the patient's chart.
- A nurse records the patient's vital signs, medications, and chief complaints for a particular visit.
- A physician conducts an examination and writes or dictates an "encounter note" for subsequent transcription and signoff for inclusion in the chart. An administrator submits billing information identifying services rendered and the diagnosis codes for use in insurance claims.
- Larger healthcare institutions might have internal advisory groups that recommend treatment guidelines (evidence-based medicine) to be followed by the healthcare staff to improve healthcare quality.

A second category of information flow involves information exchanged between healthcare facilities:

- The physician might prescribe an order for a laboratory or diagnostic imaging test or procedure, refer the patient to a specialist, or have the patient admitted to a hospital. In some cases, the physician would include the patient's relevant clinical history.
- The results of a laboratory test or the report and images of a diagnostic imaging would subsequently be sent to the physician.
- Upon the patient's discharge from the hospital, the discharge summary would be sent to the patient's physician.

In the third category of information flow, information is transmitted between a healthcare facility and external agencies:

- The office administrator submits claims to an insurance agency using the physician-supplied codes for claims processing, and sometimes seeks benefits authorization for specialized treatment for the patient.
- Health insurance agencies might seek additional justification for treatment provided to the patient or for a recommended course of tests or treatment.
- Health insurance agencies might provide a list of preferred medications (formularies) and other cost containment measures to healthcare facilities.
- Managed care organizations and other payer agencies might also provide treatment guidelines.
- Life insurance companies might seek a patient's medical record to evaluate the risk of a policy applicant or to identify fraud due to a known, but undisclosed, preexisting medical condition.

The foundation for healthcare information sharing is the electronic health record (or electronic medical record), as it contains all the relevant patient healthcare data in sharable form.

- Clinic nursing staff occasionally might need to report incidents of certain diseases to public health agencies and record pediatric immunizations with the appropriate state's vital statistics bureau.
- Medical researchers might seek medical records of patients with certain profiles for investigations; the clinic might provide the information (with patient consent) after removing patient-identifiable data.
- Malpractice lawsuits might require a healthcare facility to submit medical records of patients (with profiles similar to the litigant's) to determine adherence to standards of practice.

Finally, accrediting organizations in this information flow category might review patient records to review operational and quality standards.

ELECTRONIC HEALTH RECORDS

The EHR or electronic medical record (EMR) is the foundation for healthcare information sharing, as both contain all the relevant patient healthcare data in sharable form. In healthcare delivery, the EHR serves integrating functions similar to a manufacturing bill of materials. Although the terms EMR and EHR are used interchangeably, ONC makes a distinction between these two, as follows (see htttp://www.healthit.gov). EMRs represent digital versions of the paper charts in a doctor's office. An EMR contains the medical and treatment history of the patients in one practice, but the information in EMRs doesn't travel easily out

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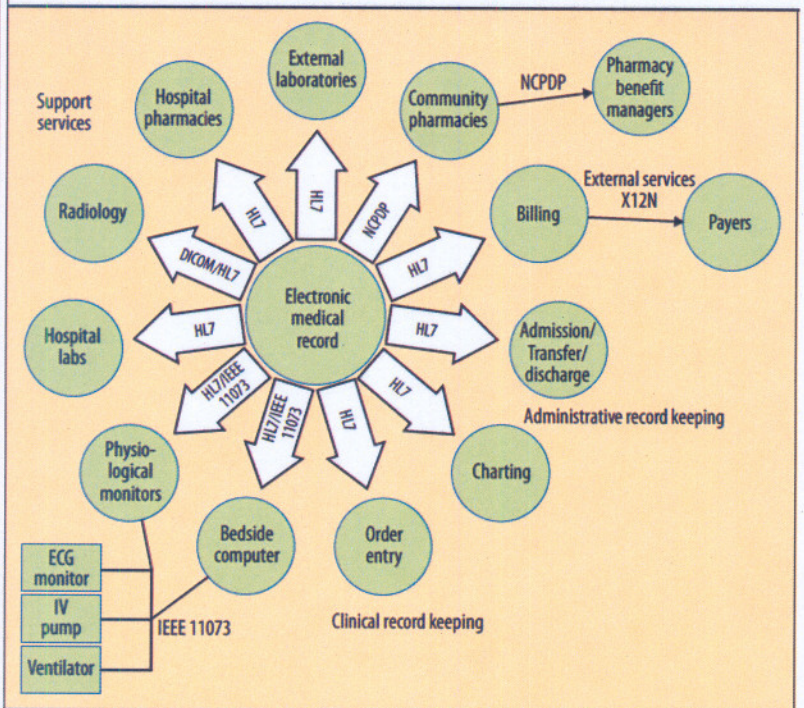

Figure 1. Standards that link to an electronic health record. (Source: US Congress, Office of Technology Assessment, *Bringing Healthcare Online: The Role of Information Technologies*, OTA-ITC-624, US Government Printing Office, Washington, D.C., 1995.)

of the practice. EHRs do all those things, and more. EHRs focus on the patient's total health, going beyond standard clinical data collected in the provider's office and include a broader view on a patient's care. EHRs are designed to reach out beyond the health organization that originally collects and compiles the information.

Although large healthcare institutions have significant investments in EHR-based computer systems, it is estimated that only a small percentage of US small practices use an EHR system in their daily practice (www.aafp.org).[4] In most healthcare settings—especially small clinics—paper-based records and fax-based communications are still the norm. Recent incentive programs issued by the Centers for Medicare and Medicaid Services, however, are accelerating EHR adoption by both small and large practices (www.cms.gov/ehrincentiveprograms).

The adoption of standards for information interchange will help to integrate disparate healthcare systems. However, rather than being geared simply to support human readability of medical reports, healthcare data integration implementations should incorporate the formalism and details necessary for proper computer interpretability of such information. The formalism and details contained within NIST's Health Level Seven International's (HL7's) Clinical Document Architecture (CDA) standard (http://hl7book.net/index.php?title=CDA) are exemplary in this regard.

HL7, briefly, is the global authority on interoperability standards for health IT (www.hl7.org).[5] Such measures would prevent the loss of information during data interchange that could otherwise occur due to differences in terms, codes, and related semantics in various healthcare vocabularies. By using IT that adheres to HL7, healthcare institutions could deal transparently with information obtained from external agencies as well as with information generated by in-house healthcare information systems. Their applications could perform data mining of patient medical records for healthcare quality metrics, identify patients across populations for timely medical interventions, and check for compliance with preventive-service protocols.

A variety of messaging and information exchange standards permits an enterprise to integrate the various health information systems and archive the data as an EHR or EMR (www.nist.gov/healthcare/index.cfm). In addition to HL7, such standards include Digital Imaging and Communications in Medicine (DICOM), IEEE 11073 Healthcare Devices and Personal Health Devices, and others listed by the Healthcare Information and Management Systems Society's Integrating the Healthcare Enterprise initiative and ANSI's Healthcare Information Technology Standards Panel.

Figure 1 illustrates the classes of clinical information and some of the standards that link these classes to a full EHR. Specifically, HL7 messaging standards allow disparate healthcare information systems to communicate with each other. Version 2.x, although the most common implementation, is likely to be superseded by version 3.0, which uses an object-oriented approach. Independent healthcare institutions can submit orders and referrals via HL7 for healthcare services for their patients. DICOM standards enable the interchange of information between imaging systems and facilitate remote access for physicians at their clinic.

With standards-based integration of information systems and authenticated remote access to reports and images, physicians can review radiologists' reports and diagnostic images for use in patient counseling. One concern with the current standards, however, is that they deal only with syntactic issues. Thus, due to the disparate

nature of the medical terminology in various EHRs (it is common for different EHRs to use different terminology to represent the same concept), it is increasingly important to develop tools and techniques for semantic interoperability.

HEALTH IT TESTING AT NIST

NIST's Information Technology Laboratory (for brevity, we use "NIST" to denote this laboratory from here on) is collaborating with industry, healthcare informatics-related standards organizations, consortia, and government agencies to build tools and prototypes to advance the adoption of IT within healthcare systems. NIST researchers are carrying on several activities in particular:

- Collaborating with HL7 to help ensure that HL7 messaging and EHR systems' conformance can be defined and measured at an appropriate level.
- Providing technical leadership on IHE projects, specifically for cross-enterprise document sharing and patient care devices.
- Providing technical leadership to build a common Web-based tool set that integrates testing tools and activities of various standards development organizations, consortia, and other organizations; also, providing technical leadership on the development, selection, and implementation of security specifications for securely communicating health information.
- Collaborating with ONC to achieve a Nationwide Health Information Network (NwHIN) and developing several test procedures for "meaningful use." According to ONC, "meaningful use is the set of standards defined by the Centers for Medicare and Medicaid Services (CMS) Incentive Programs that governs the use of electronic health records and allows eligible providers and hospitals to earn incentive payments by meeting specific criteria."
- Collaborating with the Centers for Medicare and Medicaid Services to provide guidance on the Health Insurance Portability and Accountability Act Security Rule.
- Participating in the ONC Federal Advisory Committee on Health Information Technology Standards Committee and associated working groups to pursue these efforts. Working groups include HL7, IEEE 11073, the National Council for Prescription Drug Programs, and the American Telemedicine Association.

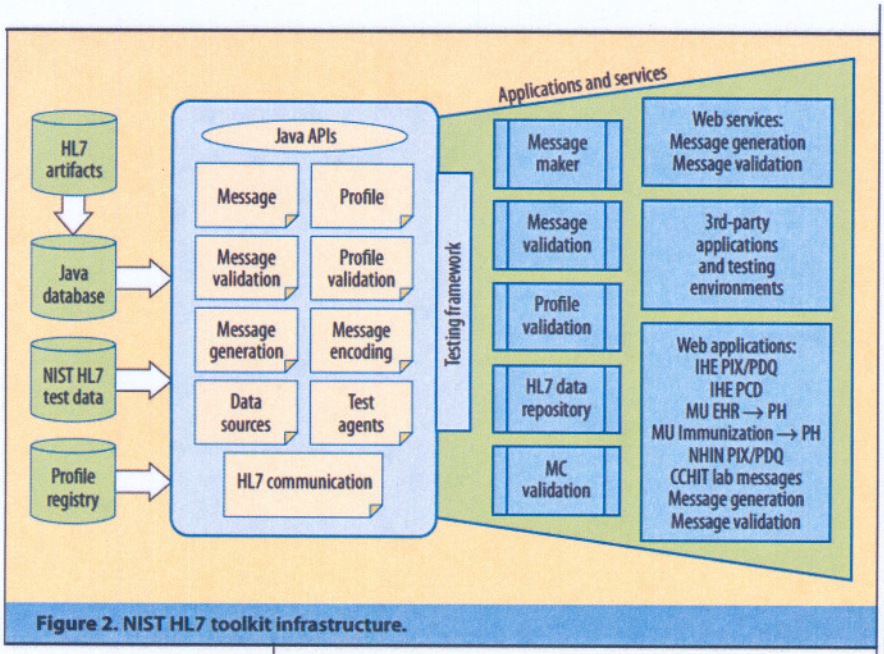

Figure 2. NIST HL7 toolkit infrastructure.

Following are several NIST projects, at various stages of completion, that have resulted from these activities.

HL7 testing toolkit

As Figure 2 shows, NIST is building a toolkit for testing HL7 message interfaces based on message profiles. The toolkit's foundation is a set of Java APIs and a testing framework that supports activities such as automated message generation, message validation, and use case testing. Developers can use the toolkit to build tools or Web services, or they can incorporate it into third-party applications and testing environments.

NIST has applied the toolkit to develop numerous tools for creating messages, cross-referencing patient identity, and formulating EHR queries. The toolkit's main focus is on HL7 version 2, although developers have recently added capabilities to the toolkit to support version 3 validation. Tools are delivered as stand-alone applications, Web services, and Web applications.

The HL7 (version 2) standard, around which we have based the toolkit, is a specification for moving clinical and administrative information between healthcare applications. In the US, 90 percent of hospitals use the HL7 standard. Its adoption in other care settings such as outpatient and long-term care facilities or telemedicine is necessary to ensure that organizations can reap the benefits of widespread electronic communication. However,

the cost-restrictive nature of managing an HL7 system to achieve interoperability is a concern for widespread adoption in these other settings.

When originally developed, the HL7 standard was designed to accommodate the many diverse processes within the healthcare industry. Although a universal design was necessary to gain broad industry support, the initial design resulted in a standard that could not be sufficiently constrained to provide a single and consistent interpretation, which prohibited plug-and-play installations. Consequently, systems were difficult to implement and debug, resulting in undue costs.

To help alleviate this shortcoming, HL7 introduced the concept of message profiles. A message profile is a subset of the HL7 messaging standard that constricts message definition so that it specifically states a message's optional constructs and processing rules. However, if EHR vendors do not follow the profile rules, interoperability problems will persist. Conformance testing is essential. NIST is developing testing tools to ensure that vendors apply message profiles as intended to fulfill the promise of interoperable healthcare systems.

Legislation calls for the voluntary certification of health information technology to encourage more widespread adoption of interoperable health IT.

Clinical Document Architecture validation

The HL7 version 3 Clinical Document Architecture (CDA) is an XML-based markup standard intended to specify the encoding, structure, and semantics of clinical documents for exchange, and is not itself a document type. CDA was developed using the HL7 development framework, which is based on the HL7 Reference Information Model. NIST—in collaboration with IHE's Patient Care Coordination (PCC) domain, the Quality, Research and Public Health domain, and HL7—is working on a series of testing tools for promoting CDA's adoption by vendors and users of healthcare information systems.

The toolkit can validate documents from legacy Health Information Technology Standards Panel (www.hitsp.org) work, the IHE PCC domain documents, and HL7 documents. The toolkit also includes sample documents of syntactically correct XML files for most document types. The NwHIN testing team also uses this toolkit at IHE Connectathons (multivendor testing events held worldwide) to check for meaningful use (MU) and for patient identity to validate documents being exchanged. Users access the tool via a webpage form where they upload their XML file or through a SOAP-based Web service to automatically load and validate from external applications. NIST has future plans to expand the toolkit to support the Quality Reporting Document Architecture's Quality Reporting and e-Measures format.

Meaningful-use Stage 1 test method

The US Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the 2009 American Recovery and Reinvestment Act, emphasizes the need for the US to begin using EHRs. To encourage more widespread adoption of interoperable health IT, the legislation calls for ONC, in consultation with NIST, to establish a program for the voluntary certification of health IT as being in compliance with applicable criteria to meet defined MU requirements. MU will be implemented in three stages: Stage 1 in 2011, Stage 2 in 2013, and Stage 3 in 2015. Further details of these stages can be obtained at www.healthit.gov. Physicians will receive federal financial incentives depending on how well they conform to criteria described in rules associated with each stage.

Under the health IT certification program, ONC-authorized testing organizations use the NIST test method and conformance tools to evaluate EHR software and systems so that doctors' offices, hospitals, and other healthcare providers can have confidence in the systems they purchase. In collaboration with ONC, NIST has developed the necessary functional and conformance testing requirements, test cases, and test tools in support of Stage 1 of the MU health IT certification program and is currently working on the other two stages.

In August 2010, NIST published an ONC-approved test method (encompassing test procedures, data, and tools) for testing EHR systems to meet MU Stage 1 certification criteria and standards. During the test method's development, NIST collaborated with ONC to ensure that the relevant standards and certification criteria were consistent and effectively represented within the test procedures. The approved NIST-developed test method evaluates EHR system components such as electronic prescribing of patient prescriptions to pharmacies, submission of laboratory results to the Centers for Disease Control and Prevention (CDC), how pediatric doctors plot and display growth charts of patients, and how vendors control access so that only authorized users can retrieve information.

The following tools for MU Stage 1 testing are complete and available from NIST (we are working on Stage 2 tools, which should be available in a few months):

- Stage 1 Test Method (http://healthcare.nist.gov/use_testing/effective_requirements.html). This method defines the approved version 1.1 test procedures that Authorized Testing and Certification Bodies (ATCBs) use in the health IT certification program.

- Reportable Lab Results and Immunizations (http://healthcare.nist.gov:8080/HL7V2MuValidation2011). With this HL7 v2 test tool, ATCBs can assess the certification criteria for doctors to use in submitting immunizations and reporting lab results to the CDC.
- Clinical Document Architecture (CDA) Validation (http://hit-testing.nist.gov/cda-validation/mu.html). NIST provides an HL7 Continuity of Care Document (CCD) validation tool designed specifically to support MU Stage 1 testing.

According to ONC, more than 2,500 EHR products for ambulatory care and more than 800 products for in-patient care are currently certified for MU Stage 1 (http://oncchpl.force.com/ehrcert/CHPLHome; a product is not necessarily a complete EHR—see ONC's website for definition of a product). All products can be traced back to NIST-developed test procedures and tools.

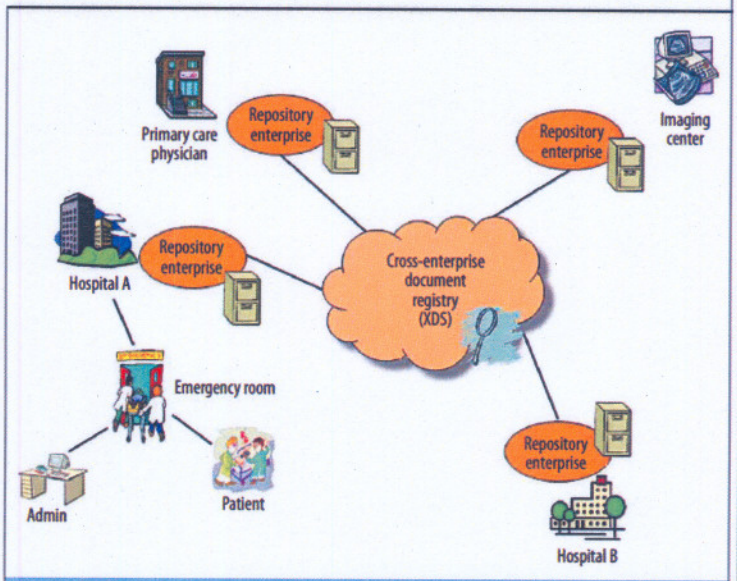

Figure 3. Cross-enterprise document sharing (XDS). Healthcare professionals within a community can use XDS to access a patient's clinical information regardless of where it is located.

Cross-enterprise document sharing

NIST is working with industry to develop a standards-based registry infrastructure that will allow healthcare professionals to find and access all pertinent patient clinical information regardless of the healthcare organization that creates and manages the documents. Additionally, NIST is collaborating on the IHE project on Cross-Enterprise Document Sharing (XDS). Specifically, NIST is a primary author of the XDS standards-based specification. As Figure 3 shows, healthcare professionals can use XDS to manage document sharing between any healthcare enterprise, from a private physician's office to an acute care in-patient facility and personal health record systems.

Sharing is managed through document repositories and a document registry to create a longitudinal patient information record within a given clinical domain. These are distinct entities with separate responsibilities. A document repository stores documents in a transparent, secure, reliable, and persistent manner and can respond to document retrieval requests. A document registry stores information about those documents so that the documents of interest for a patient's care can be easily found, selected, and retrieved irrespective of the repository where they are actually stored.

Using document registries to share clinical information intraorganizationally presents unique challenges: data interoperability and interchange, for example, requires standardized metadata, interfaces, and formats; moreover, the technology must support strict adherence to security and privacy policies related to healthcare information.

NIST has developed a reference implementation for the XDS specification and a Web-based test suite, allowing vendors to determine conformance to the XDS profile. Vendors also use the test suite as an early stage tool for interoperability testing. The reference implementation is available as IHE open source, an open source project hosted on Source Forge (http://iheos.sourceforge.net). The NIST test suite is available at http://ihexds.nist.gov.

Medical device communication testing

In a typical intensive care unit, a patient might be connected to one or more vital-sign monitors, receive fluids through multiple infusion pumps, and be supported by a ventilator. Each of these medical devices can capture volumes of data, which is available multiple times per second, on a per-patient basis. Today, these devices do not communicate and have little or no plug-and-play interoperability.

Medical device interoperability raises several issues:

- Manually captured data is labor intensive, recorded infrequently, and prone to human error.
- Expensive custom connectivity equipment might be used only for patients with acute needs.
- Detection of patient problems such as adverse drug events is hindered due to the inability to collect real-time data from multiple devices.
- Vendors intending to communicate data between devices must develop specialized interfaces for each device.

The ISO/IEEE 11073 (x73) Healthcare Devices and Personal Health Devices Working Groups are defining a set of standards to enable medical devices to interoperate and electronically capture and process data. These working groups are collaborating with the IHE Patient Care Device Domain to develop a framework for integrating medical device data into an EHR.

NIST is actively developing medical device communication test methodologies and tools to enable consistent and correct communication between medical devices and device-gateways across the healthcare enterprise. This work is intended to provide standards-based, rigorous validation of medical device communication through conformance leading to interoperability. Rigorous testing is essential to achieve multivendor and enterprise-wide interoperability, and it must be predicated on sufficiently specified medical device and enterprise-communication standards. The NIST software test tools aim to meet the X73-defined requirements as well as the enterprise/electronic health record level defined in the HL7 messaging standard.

Electronic health information exchange that follows patients across providers regardless of geographical boundaries greatly improves the clinical decision-making process.

A related tool is the ICSGenerator (http://hit-testing.nist.gov/medicaldevices/index.html), which facilitates creation of vendor conformance statements that would be applicable to testing a particular X73 device. With the ICSGenerator, users can easily develop and produce implementation conformance statements. Users such as medical device vendors, manufacturers, and clinical engineers can execute the tool to produce statements that disclose details of a specific implementation and specify the features provided by a particular medical device—that is, a device profile. Medical device vendors can compare device implementation conformance statements based on, and required by, the x73 standards and use them across device interfaces to help overcome the semantic interoperability problem.

Conformance test tools can use device profiles in conjunction with messages to and from devices to determine standards conformance and validity. The ValidatePDU tool can determine not only the correctness of the x73 message, but also the message's compliance to a user-defined profile (derived via the ICSGenerator tool). ValidatePDU provides basic syntax, structure, and low-level semantic checking for one or more captured messages. Both ValidatePDU and ICSGenerator use the electronic representation of the x73 standards information model that NIST researchers implemented in an XML schema. These tools (and information model) are publicly available (http://hit-testing.nist.gov/medicaldevices/index.html). Medical device test message generation is also possible to facilitate future manager/agent conformance test scenarios.

IHE CONNECTATHONS

Each year, the IHE sponsors Connectathons in North America, Europe, and Asia to promote interoperability among IHE profile implementations (www.ihe.net/connectathon). The Connectathons are cross-vendor structured testing events where developers of health information systems can compare their implementations with those of other vendors. The goal is to promote the adoption of standards-based interoperability solutions defined by IHE in commercially available healthcare IT systems.

The 2012 North American Connectathon held in Chicago, Illinois, featured more than 160 systems from 117 participating organizations, which performed and verified more than 3,500 successful tests of IHE integration profiles. Ninety percent of the applications demonstrated at the Connectathon used the NIST test tools. Participants and monitors use NIST tooling in cross-enterprise document sharing, patient identity and queries, patient care devices, and CDA validation to compare them against the IHE profiles.

Interest in the Connectathons and NIST tooling to support them has been growing; at the 2012 event, IHE Korea and IHE Japan began using NIST tooling with IHE Australia to learn how to use the technology for their respective Connectathons.

NWHIN TESTING

NwHIN is a set of standards, services, and policies that enable secure health information exchange over the Internet. NwHIN is not a physical network but rather is a foundation for the communication of health information across diverse entities and communities around the country. Electronic health information exchange that follows patients across providers regardless of geographical boundaries greatly improves the clinical-decision-making process by providing clinicians with updated, relevant, and accessible patient data (http://nwhin.siframework.org/NwHIN+Basics.)

These standards, services, and policies enhance patient care quality and evolve care coordination by helping move current paper-based medical records to an electronic process for securely storing and sharing EHRs. NIST has been involved in the testing process for "on-boarding," the process by which an organization joins the Nationwide Health Information Network Exchange, which verifies that it complies with NwHIN-supported specifications. On-boarding includes verifying an organization's eligibility for participation (must be a federal agency or ONC contractor), that its

gateway complies with the NwHIN specifications, and that it can exchange information.

NwHIN uses an existing set of NIST tools with modifications based on the NwHIN specifications (http://hit-testing.nist.gov:12080/xdstools2nwhin). The tools include XDS, Cross-Community Patient Discovery Query and Retrieve (XCPD), Patient Identity Cross Reference, Patient Discovery Query, and a CDA validator. These tools help to automate the on-boarding process and allow potential participants to completely test their gateways at the NIST website before they start on-boarding. The NwHIN network might play a larger role in meaningful use testing in Stage 2.

The creation of an integrated healthcare information infrastructure depends on all parties involved—consumers, healthcare professionals, researchers, and insurers—having systems, tools, and information that are complete, correct, secure, and interoperable. Until we achieve a full-scale interoperability of software systems in the healthcare enterprise, we will not realize the full benefits of using information technology in healthcare. Achieving true interoperability would require that three tightly integrated activities must succeed: standards development, implementation support (including implementation guidance and precertification testing), and comprehensive conformance and interoperability testing. Thus, true interoperability testing cannot be achieved without having the right standards, implemented in the right way, and tested—both for syntax and semantics—to the right requirements. NIST will continue the research and development activities required to support and test a fully integrated and interoperable healthcare enterprise.

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