MEDICAL DEVICE & DIAGNOSTIC INDUSTRY

New Standards Accelerate Point-of-Care Device Integration

The industry's goal of full connectivity between point-of-care devices and information systems seems within reach.

BRIAN D. HANDSPICKER

HOSPITAL POINT-OF-CARE (POC) testing is projected to nearly triple within a decade, rising from $1 billion in 1998 to $3.2 billion in 2008 (Enterprise Analysis Corp., 1999, Stamford, CT). With laboratory testing increasing only slightly over the same period, there will be a dramatically higher percentage of POC testing information that must be integrated into laboratory and hospital information systems.

To date, few POC test results are uploaded electronically into those information systems. In fact, barely half of POC test results are ultimately transmitted or entered manually to maintain complete records, according to an EAC point-of-care testing survey. The electronic integration of POC test information has been hampered by multiple incompatible proprietary approaches to connecting POC devices to networks and laboratory information systems. Yet, in the face of dramatically higher manual data-entry requirements, something must be done to ease the POC testing data integration problem.

Illustration by EYEWIRE

POC DEVICE INTEGRATION

IVD and noninvasive testing devices have become ubiquitous at the point of care in every healthcare facility. Whether handheld, portable, or cart-based, POC devices provide both convenience in administering tests and immediate availability of results. Even so, an EAC survey indicated that as of 1999, only 15% of the results of such tests were transmitted electronically to laboratory or hospital information systems. In 1999, another 15% of tests were manually entered into information systems. Even in 2001, most results still were either printed out or manually written on patient charts. The information must then be entered separately into other electronic medical records systems such as

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laboratory or hospital information systems.

Few POC devices have been fully integrated with all possible commercial systems. Fewer still work with systems developed in-house. As a result, healthcare professionals must laboriously document test results in paper records, and clerks must then enter the digitally generated data into the laboratory or hospital information systems if the electronic medical records are to be complete.

The goal of the POC device manufacturers has been the full connectivity of POC devices with departmental, laboratory, and hospital information systems. In the past, the lack of standards resulted in unreasonable costs because each individual POC device had to be integrated with each and every proprietary information system.

POC device manufacturers have responded with departmental or POC information systems that can act as a proxy to upstream laboratory and hospital information systems. These departmental systems allow POC devices to connect via docking stations or infrared wireless connections to upload test information. This intermediary still must communicate with the laboratory or hospital information systems, however, to implement a fully integrated system. Toward that end, IVD manufacturers have come together to create the POC connectivity standards needed for full integration across the entire healthcare network—from point of care to laboratory to hospital back office.

STANDARDS DEVELOPMENT ORGANIZATIONS

A number of chartered and de facto standards organizations and consortia help to define the standards for the medical and healthcare industries. In addition, many of the standards developed by these groups are passed along to national and international chartered standards development organizations for broader consensus approval, which increases the appeal and value of the standards. These latter organizations include:

- ANSI—American National Standards Institute.
- ASC X12—Accredited Standards Committee X12 (EDI).
- IEC—International Electrotechnical Commission.
- IEEE—Institute of Electrical and Electronics Engineers.
- ISO—International Organization for Standardization.
- UN/EDFACT—United Nations Electronic Data Interchange for Administration, Commerce and Transport.

THE CONNECTIVITY INDUSTRY CONSORTIUM

POC manufacturers have also come together to create the connectivity standards needed for full integration across the entire healthcare network—from point of care to laboratory to hospital back office. Members of the POC industry formed the Connectivity Industry Consortium (CIC) with the mission to "expeditiously develop, pilot, and transfer the foundation for a set of seamless plug-and-play POC communication standards."

The consortium's goal was to develop standards that would "enable a seamless information exchange between point-of-care devices, electronic medical records, and laboratory information systems." By building on top of existing and evolving medical application and medical data communication standards, the CIC working groups produced three specifications that satisfy the requirements of bidirectionality, device-connection commonality, commercial software interoperability, security, and QC/regulatory compliance: the device access point (lower-layer) proposal, the device upper-layer proposal, and the electronic data interchange (EDI) interface proposal.

The Institute of Electrical and Electronic Engineers (IEEE) assumed development responsibility for the lower-level data communications standards. Health Level 7 assumed development responsibility for the XML and EDI interfaces between device managers and laboratory information systems, and the National Committee for Clinical Laboratory Standards (NCCLS) took primary publication responsibility for the complete set of CIC specifications. These organizations committed to a timeline that would produce an approval-level connectivity standard for publication by July 2001. The result will be known as the Universal Connectivity Standard for Point of Care (UCSPOC) devices. The specifications were handed over to chartered standards development organizations for publication and further development.

APPLICATION STANDARDS FOR POC DEVICES

The UCSPOC standard was developed using the foundations of the Health Level 7 (HL7) standard, an all XML-based laboratory and hospital information system integration standard, which was itself derived from the broadly implemented HL7/ANSI standards of the past. The HL7 group planned to release HL7 version 3 for balloting in December 2001. Under the

Standard Name	Standards Development Bodies	Date Approved
UCSPOC	CIC/NCCLS/IEEE/HL7	May 2001 (CIC)
Clinical Context Object V1.3-2001	ANSI/HL7	June 2001 (ANSI)
Arden Syntax V2.0-1999	ANSI/HL7	July 1999 (ANSI)
Clinical Document Architecture	ANSI/HL7	November 2000 (ANSI)
HL7 Version 3	ANSI/HL7	January 2002 (projected, HL7)
Medical Information Bus 1073.3.2	IEEE/ANSI/ISO	June 2000 (ANSI)

Table I. Relevant medical software application standards.

HL7 consortium umbrella, standards for an XML-based clinical document architecture, clinical context object, and the Arden syntax have been developed and standardized. Taken together, these standards form a comprehensive framework for standards-based integration between POC devices and laboratory information systems, as well as between laboratory and hospital information systems.

In addition, the IEEE Medical Information Bus standards (IEEE 1073) define the low-level data communication protocols for use with infrared wireless devices (IrDA) as well as docked and hard-wired devices.

THE XML EVOLUTION

Over the past 20 years, many successful industry solution standards have been built around EDI standards defined by the Accredited Standards Committee (ASC X12) in the United States and by the United Nations Electronic Data Interchange for Administration, Commerce, and Transport (UN/EDIFACT). The EDI-based standards supported a broad range of industry-specific business processes.

This very flexibility slowed adoption, however, and made it expensive to implement and deploy solutions based on the standards. There were just too many options and too many deployment-specific configurations. The result was standardized chaos—no consistency in how data was modeled, limited ability to relate data (e.g., a patient diagnostic test result to a patient hospital information system record), and too many variations in how the data were exchanged between systems. Previous versions of HL7 were based on EDI standards and inherited both the strengths of adaptability and the weakness of poor integration across multiple deployments.

In the past five years, the World Wide Web Consortium (W3C) has been defining new standards for the description of data in what is known as the extensible markup language (XML). Approved as a W3C recommendation in 1998, XML has become the basis for a wide range of data models, protocols, and document objects. The extensible nature of XML makes it flexible and adaptable—potentially leading to some of the same problems with which the EDI community struggled. The W3C approval of an XML schema in May 2001, however, provided a standard means for constraining and focusing XML-based specifications.

Each of the software application integration standards currently being developed for medical POC devices and for laboratory and hospital information system communities is either based on XML or has been adapted to exploit it.

AN INTRODUCTION TO XML

XML. The extensible markup language (XML) is the universal format for structured documents and data on the Web. Like HTML, it uses human-readable tags to indicate the purpose of information in the document. Unlike HTML, however, the tags are definable by document designers. For more information on each, check the following Web sites:

- XML in 10 points (http://www.w3.org/XML/1999/XML-in-10-points).
- XML 1.0 (http://www.w3.org/XML/#9802X110).
- XML Namespaces (http://www.w3.org/XML/#9901names).

XML Schema. The ability of XML to allow definable tags raises a problem. Without some means of specifying what tags are allowed in a document, users could find themselves back in the EDI situation—too much flexibility and too many options. The XML schema provides a means for defining the structure, content, and semantics of XML documents. It is like a recipe for how an XML document should be built—what kind of data goes where in the document.

- XML Schema Part 0: Primer (http://www.w3.org/TR/XM/schema-0/).
- XML Schema Part 1: Structures (http://www.w3.org/TR/XM/schema-1/).
- XML Schema Part 2: Datatypes (http://www.w3.org/TR/XM/schema-2/).

XML Protocol (SOAP). The XML protocol allows two or more systems to communicate using XM. The XML protocol provides a framework for XML-based messaging systems, which include specifying a message envelope format and a method for data serialization.

- SOAP Version 1.2, working draft published July 9, 2001.
- XML Protocol Abstract Model, working draft published July 9, 2001.

HEALTH LEVEL 7 STANDARDS

The Health Level 7 group has been the center for hospital information system standards for the healthcare community for more than a decade. The standard bearer for the organization has been the suite of EDI-based standards colloquially referred to as HL7. In recent years, however, the work done by HL7 subcommittees and by third-party efforts adopted by the HL7 consortium has broadened the scope of the organization to include standards in support of laboratory information systems, human factors, and POC devices.

HL7 CCOW. The Clinical Context Object Workgroup (CCOW) specifications define standards for the visual integration of healthcare applications. According to the HL7 CCOW mission statement, "Applications are visually integrated when they work together in ways that the user can see in order to enhance the user's ability to incorporate information technology as part of the care delivery process." The current standards define COM/ActiveX messages and HTTP-based messages. However, CCOW 1.5, which is projected for 2002, will define a mapping to the simple object access protocol (SOAP) that supports XML-based object-oriented messaging over HTTP to and from the context manager. The CCOW mission statement can be found at http://www.hl7.org/special/committees/visual/visual.cfm#mission.

The HL7 standard context management specifications

documents include the following:

- CCOW overview document.
- CCOW overview slides.
- Technology- and Subject-Independent Component Architecture, version CM-1.2.
- Component Technology Mapping: ActiveX, version CM-1.2.
- Data Definition: Patient Subject, version CM-1.2.
- Data Definition: User Subject, version CM-1.2.
- User Interface: Microsoft Windows OS, version CM-1.2.
- Technology Mapping: Web, version CM-1.2.
- User Interface Icon Files: Microsoft Windows OS, version CM-1.2.

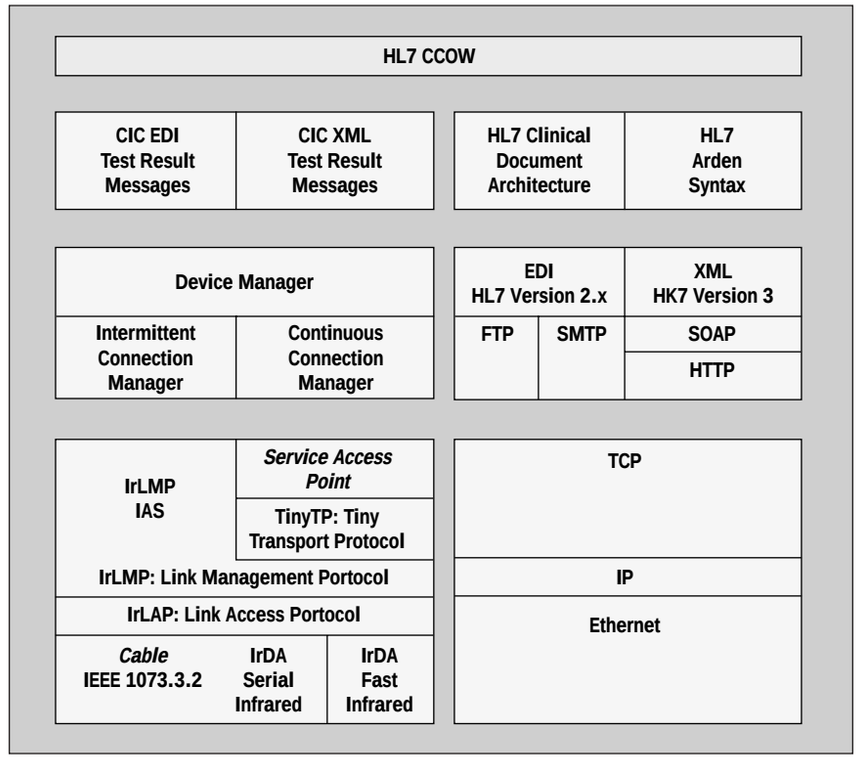

Figure 1. The Clinical Context Object Workgroup specifications define standards for the visial integration of heathcare applications.

HL7 Arden Syntax. The Arden Syntax for medical logic systems, an ANSI standard, enables the sharing of computerized health knowledge between personnel and laboratory or hospital information systems. It supports knowledge bases that can be represented as a set of discrete modules.

The Arden Web site (http://www.hl7. org/Special/committees/Arden/arden.htm) explains it this way:

> Each module, referred to as a medical logic module (MLM), contains sufficient knowledge to make a single decision. Contraindication alerts, management suggestions, data interpretations, treatment protocols, and diagnosis scores are examples of the health knowledge that can be represented using MLMs. Each MLM also contains management information to help maintain a knowledge base of MLMs and links to other sources of knowledge. Health personnel can create MLMs directly using this format, and the resulting MLMs can be used directly by an information system that conforms to this specification.

HL7 Clinical Document Architecture. The clinical document architecture (CDA) standard defines how clinical documents (e.g., discharge summaries or patient records) are exchanged between information systems. As HL7's CDA Web site explains, "by leveraging the use of XML, the HL7 reference information model (RIM), and the coded vocabularies, the CDA makes documents both machine-readable, so they are easily parsed and processed electronically, and human-readable, so they can be easily retrieved and used by the people who need them."

HL7 Version 3. The HL7 suite of messaging standards defines how clinical information is exchanged between POC devices and laboratory and hospital information systems. Previous ANSI-approved versions of the suite exploit EDI for the definition of message formats. But those previous versions suffered from the weaknesses that come along with EDI's inherent flexibility.

In version 3, the XML schema is used to define a rigorous messaging standard with strictly defined message formats. With this version, HL7 will have defined a suite of standards that are testable and therefore certifiable. While still highly flexible, there is very little optionality in version 3, thus allowing certification labs to certify vendors' conformance. The following specifications are still in the ballot and revision process: Version 3 Abstract Data Types, Version 3 XML Implementation Technology Specification, and Version 3 Messages XML Implementation Specification.

In the meantime, some insight into the direction of version 3 can be gained by looking at the following works in progress:

- The reference information model (RIM; http://www.hl7.org/about/hl7about.htm#RIM).
- The metamodel, methodology, and modeling (http://www.hl7.org/Special/committees/mnm/mnm.htm)
- Message type language.
- Version 3 message building.

IEEE MEDICAL INFORMATION BUS

The Institute of Electrical and Electronics Engineers has defined standards for data communications for medical devices. The CIC specifications reference 1073.3.2 for IrDA (infrared) networking for POC devices. Other medical information bus standards may be applicable for other types of POC device connectivity.

- 1073.4.1-2000—*IEEE Standard for Medical Device Communications—Physical Layer Interface—Cable Connected—Amendment 1: Corrections and Clarifications.*

• 1073.3.2-2000—*Medical Device Communications—Transport Profile—IrDA Based—Cable Connected.*

• 1073.3.1-1994—*IEEE Standard for Medical Device Communications—Transport Profile—Connection Mode.*

• 1073-1996—*IEEE Standard for Medical Device Communications—Overview and Framework.*

NCCLS STANDARDS

The National Committee for Clinical Laboratory Standards has responsibility for defining standards for laboratory information systems, laboratory automation systems, and laboratory procedures and protocols (in the medical sense as well as the IT sense of the term). These standards include the following two medical software application standards relevant to POC device manufacturers:

• *AUTO3-A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard.* This is a messaging standard that facilitates accurate and timely electronic exchange of data and information between the automated laboratory elements. AUTO3 has adapted and incorporated HL7 triggers, messages, and segments, with permission.

• *AUTO6-P Point-of-Care Connectivity; Proposed Standard.* This provides a framework for engineers to design devices, workstations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bidirectionally with access points, data concentrators, and laboratory information systems from a variety of vendors.

CONCLUSION

With a comprehensive set of XML-based medical information standards on the near horizon, the full integration of POC testing devices and laboratory and hospital information systems will soon follow. Full integration holds the promise of reduced clinical overhead costs, improved patient care, and new sales opportunities for device manufacturers—both delivering new standards-based solutions and providing the opportunity to get a foot in the door in accounts that were once captive to other vendors' proprietary solutions.

Device manufacturers should be participating in the development of, planning for, and implementation of these new standards. The effective use of appropriate standards can help resulting POC device software progress through the FDA premarket aproval process in a timely manner. ■

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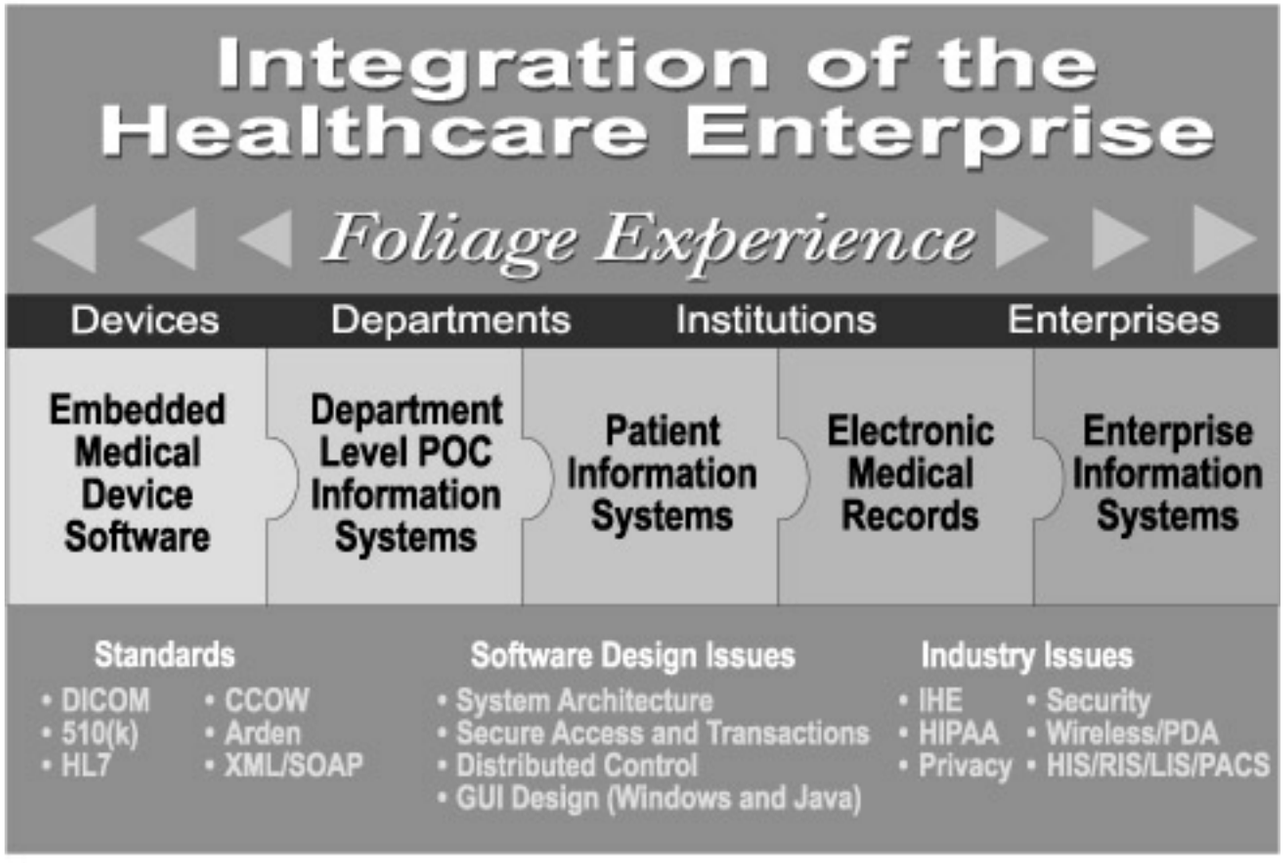

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Medical industry clients outsource their custom software development to Foliage to get the experience and technologies they need to get to market before their competition. Working with Foliage, clients create high performing life-critical medical devices and information management systems.

Medical Industry Standards and FDA 510 (k) Compliance

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