New Standards Accelerate Device Integration

The evolution of medical application standards has resulted in a suite of interrelated XML-based standards that could ease the integration of Point of Care Devices with Departmental, Laboratory and Hospital Information Systems.
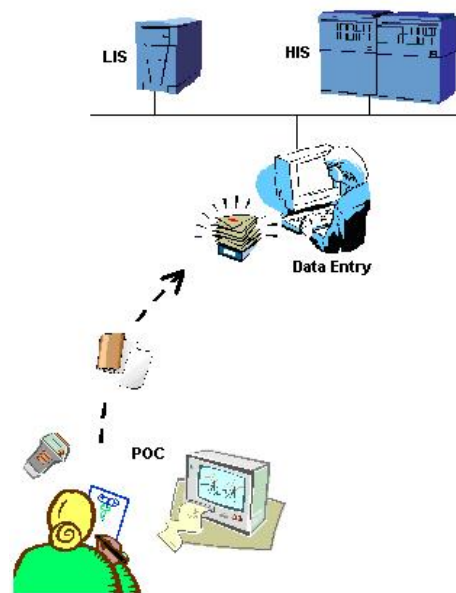
Brian D. Handspicker

Hospital Point of Care (POC) testing is projected to nearly triple over this decade, from $1 billion in 1998 to $3.2 billion in 2008 (EAC 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 the laboratory information systems (LIS) and hospital information systems (HIS) systems. To date, few POC test results are electronically uploaded into LIS and HIS systems. In fact, barely half of POC test results are ultimately transmitted or entered manually to maintain complete records.[1] Electronic integration of POC test information has been hampered by multiple, incompatible, proprietary approaches to connecting POC devices to networks and LIS systems. Yet, in the face of dramatically higher manual data entry requirements, something must be done to ease the POC testing data integration problem.

This article provides an overview of the relevant software application standards for integrating Point of Care devices with Laboratory Information Systems (LIS) and Hospital Information Systems (HIS).
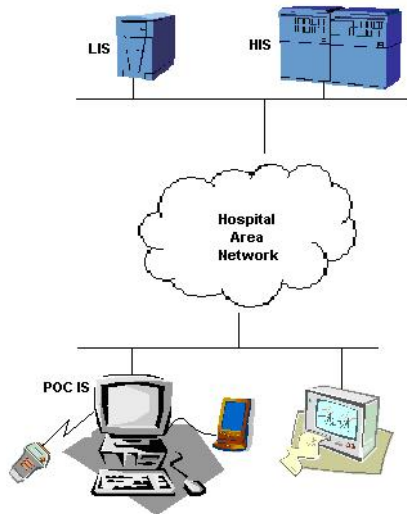
Integration of Point of Care Devices

In vitro diagnostics (IVD) and non-invasive testing devices have become ubiquitous at the point of care in every healthcare facility. Whether handheld, portable or cart-based, POC devices provide convenience administering tests and immediacy of in results. However, an EAC survey indicated that as of 1999, only 15% of the results of such tests are transmitted electronically to laboratory or hospital information systems (LIS/HIS). In 1999 another 15% of tests were manually re-entered into information systems.[2] Even in 2001 most results now are still either printed out or manually written on charts. They must then be re-entered into other information systems such as LIS and HIS. Few POC devices have been fully integrated with all possible commercial LIS and HIS systems. And of course, fewer still work with systems developed in-house. So healthcare professionals must still laboriously document test results in paper records and administrative staff must still re-enter the digitally generated data into the LIS/HIS if the electronic medical records are to be complete.

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[1] Stephans, Emery J., "Developing open standards for point-of-care connectivity", <u>IVD Technology Magazine</u>, September 1999.

[2] Ibid.

The goal of many healthcare providers has been full-connectivity of POC devices and departmental, laboratory and hospital information systems. In the past, lack of standards resulted in unreasonable costs of integrating each individual POC device with each and every proprietary LIS and HIS software system. POC device manufacturers have responded with departmental or POC information systems that can act as a proxy to upstream LIS/HIS systems. These departmental systems allow POC devices to connect via docking stations, infrared or wireless connections to upload test information. However, this intermediary still must communicate with the LIS/HIS system to implement a fully integrated system. The advent of POC connectivity standards driven by the CIC has completed the set of specifications required to full integration across the entire healthcare network – from Point of Care to Laboratory to Hospital Back Office.

Relevant Application Standards for Point of Care Devices

The medical device industry itself has come to the aid of the healthcare industry with the completion of the Universal Connectivity Standard for Point of Care (UCSPOC) by the Connectivity Industry Consortium (CIC). The members of the POC industry formed the CIC with the mission to "expeditiously develop, pilot, and transfer the foundation for a set of seamless 'plug and play' POC communication standards". By building on top of existing and evolving medical application (HL7) and medical data communication (IEEE) standards, the CIC was able to deliver specifications that satisfied their mission in slightly under a year.

Relevant Medical Software Application Standards		
Standard Name	Standards 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)

Health Level 7 (HL7) is preparing to release HL3 Version 3 for balloting in December 2001. HL7 is an all XML-based LIS/HIS integration standard derived from the broadly implemented HL7/ANSI standards of the past. In addition, under the 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 comprehension framework for standards based integration between POC devices and LIS systems, as well as between LIS and HIS systems.

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

Standards Development Organizations

A number of chartered and de factor standards organizations and consortia help to define the standards for the medical and healthcare industries. These include:

AAMI - Association for the Advancement of Medical Instrumentation
NCCLS - National Committee for Clinical Laboratory Standards
CIC - Connectivity Industry Consortium
HL7 - Health Level 7
AACC - American Association of Clinical Chemistry
AdvaMed - Advanced Medical Technologies Association
        (formerly Health Industry Manufacturers Association)
MDMA - Medical Device Manufacturers Association
NEMA - National Electrical Manufacturers Association

In addition, many of the standards developed by these organizations are progressed to national and international chartered standards development organizations for broader consensus approval to increase the appeal and value of the standard. These 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 XML Evolution of Software Integration Standards

Over the past twenty years many very successful industry solution standards have been built around Electronic Data Interchange standards defined by ASC X12 (US) and UN/EDIFACT. EDI-based standards supported a broad range of industry-specific business processes. However, this very flexibility slowed adoption and resulted in expensive implementation and deployment of solutions based on the standards. There were just too many options and too many deployment-specific configurations. The result was a bit of standardized chaos – no consistency in how data was modeled, limited ability to related data (e.g. a patient diagnostic test result to a patient HIS record) and too many variations in how the data was exchanged between systems. Previous versions of HL7 were based on EDI 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 has been defining new standards for the description of data called 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 very flexible and adaptable – potentially leading to some of the same problems with which the EDI community struggled. However, the W3C approval of XML Schema in May 2001 provided a standard means for constraining and focusing XML-based specifications.

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. However, unlike HTML, the tags are definable by document designers.

- XML in 10 points
- XML 1.0

- [XML Namespaces](#)

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, we could find ourselves back in the EDI situation – too much flexibility and too many options. XML Schemas provide a means for defining the structure, content and semantics of XML documents. They are 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](#)
- [XML Schema Part 1: Structures](#)
- [XML Schema Part 2: Datatypes](#)

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 includes specifying a message envelope format and a method for data serialization

- *[SOAP Version 1.2 Working Draft](#)* published, 9 July 2001
- *[XML Protocol Abstract Model Working Draft](#)* published, 9 July 2001

Each of the software application integration standards currently being developed for the medical POC device, LIS and HIS communities is either based on XML or has been adapted to exploit XML.

Health Level 7

Health Level 7 has been the center for hospital information system standards for the healthcare community for over a decade. The "standard-bearer" for the organization has been the suite of EDI-based standards colloquially referred to as "HL7". However, in recent years the work done by HL7 subcommittees and by third party efforts "adopted" by the HL7 consortium have broadened the scope of the organization to include standards in support of Laboratory Information Systems, Human Factors and Point of Care Devices.

HL7 CCOW.   CCOW specifications define standards for the visual integration of healthcare applications. "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."[3] The current standards define COM/ActiveX messages and HTTP-based messages. However, CCOW 1.5 (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.

Health Level-Seven Standard Context Management Specifications include:

- **[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

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[3] HL7 CCOW Mission Statement

HL7 Arden Syntax for Medical Logic Systems (ANSI Standard). The Arden Syntax enables the sharing of computerized health knowledge between personnel, laboratory information systems and hospital information systems. It supports knowledge bases that can be represented as a set of discrete modules. "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."[4]

HL7 Clinical Document Architecture.   The Clinical Document Architecture (CDA) defines how clinical document (e.g. discharge summaries, patient records, etc.) are to be exchanged between information systems. "By leveraging the use of XML, the HL7 Reference Information Model (RIM) and 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."[5]

HL7 Version 3. The HL7 suite of messaging standards defines how clinical information is exchanged between POC devices, Laboratory Information Systems and Hospital Information Systems. Previous ANSI-approved versions of the suite, exploit EDI for the definition of message formats. However, those previous versions suffered from the weaknesses that come along with EDI's inherent flexibility. In Version 3, XML Schema is used to define a rigorous messaging standard with strictly defined message formats. With Version 3, 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 due out in December 2001 and are expected to be balloted in January 2002:

- Version 3 Abstract Data Types
- Version 3 XML Implementation Technology Specification
- V3 Messages XML Implementation Specification

In the mean time, some insight into the direction of Version 3 can be gained by looking at the following "work in progress":

- **Reference Information Model (RIM)**
- **Meta-Model (Methodology and Modeling)**
- **Message Type Language**
- **Version 3 Message Building**

CIC - The Universal Connectivity Standard for Point of Care

Members of the medical device industry formed the Connectivity Industry Consortium in 1999 to develop standards that would "enable a seamless information exchange between point-of-care devices, electronic medical records and laboratory information systems." The CIC working groups produced three specifications that satisfy the requirements of bi-directionality, device connection commonality, commercial software interoperability, security, and QC / regulatory compliance:

- Device Access Point (Lower-Layer) Proposal
- Device Upper-Layer Proposal
- EDI Interface Proposal

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[4] HL7 Arden Syntax Website
[5] HL7 CDA Website

The members of CIC ratified these specifications early in 2001. With the CIC specifications ratified, they are now being handed over to relevant chartered ("de jure") standards development organizations for publication and future development. IEEE will have development responsibility for the lower level data communications standards. HL7 will have development responsibility for the XML and EDI interfaces between device managers and LIS. NCCLS will have primary publication responsibility for the complete set of CIC specifications. These SDOs (NCCLS, HL7, and IEEE) have committed to a timeline that will produce an 'Approval Level' connectivity standard for publication by July 2001."

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 (infra-red) 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--Amendment1: 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

National Committee for Clinical Laboratory Standards (NCCLS)

The National Committee for Clinical Laboratory Standards has responsibility for defining standards for Laboratory Information Systems, Laboratory Automation Systems as well as Laboratory Procedures and Protocols (in the medical sense as well as the IT sense of the term). These standards include the following 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*
"Messaging standards that facilitate 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, from Health Level Seven (HL7)*"[6]

AUTO6-P *Point-of-Care Connectivity; Proposed Standard*
"A framework for engineers to design devices, work stations, and interfaces that allow multiple types and brands of point-of-care devices to communicate bi-directionally with access points, data concentrators, and laboratory information systems from a variety of vendors."[7]

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[6] NCCLS Standards Description
[7] Ibid

HL7 CCOW

| CIC EDI Test Result Messages | CIC XML Test Result Messages | HL7 Clinical Document Architecture | HL7 Arden Syntax |

| Device Manager | | EDI HL7 Version 2.x | XML HL7 Version 3 |
| Intermittent Connection Manager | Continuous Connection Manager | FTP | SMTP | SOAP HTTP |

IrLMP IAS	Service Access Point / TinyTP Tiny Transport Protocol	TCP
IrLMP: Link Management Protocol	IP
IrLAP: Link Access Protocol	Ethernet
Cable IEEE 1073.3.2	IrDA Serial Infrared	IrDA Fast Infrared	

Conclusion

With a comprehensive set of XML-based medical information standards on the near horizon, the ideal of full integration of Point of Care Testing Devices and LIS/HIS systems will soon follow. Foliage clients have found that 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 as well 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 designing for these new standards. Foliage has been actively participating in leading edge XML-based standards. As we break new ground for our clients, effective use of appropriate standards can help resulting POC device software to progress through the regulatory processes on a timely basis. Hospital IT staff should start planning for the future of these integrated devices. And, Hospital Administrators should start asking vendors about their product plans for future procurement planning.

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