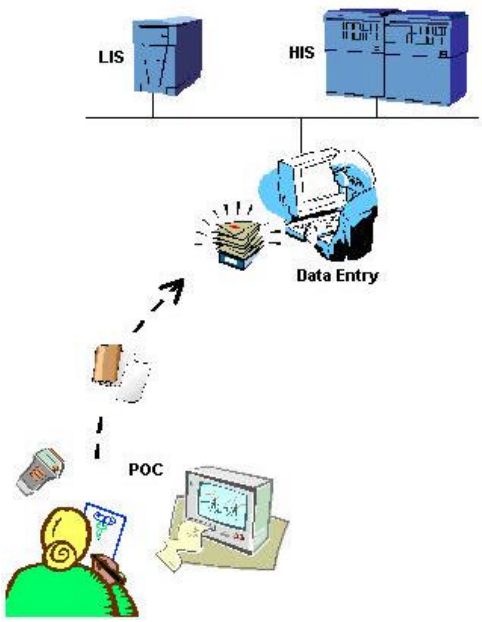
Next Generation Point of Care Information Systems

A vision for delivering healthcare departmental information systems, using the latest point-of-care integration standards, clinical information standards and web services technologies.

The Problem Today

In Vitro Diagnostics (IVD) and non-invasive testing devices have become ubiquitous at the point of care (POC) in every healthcare facility. Whether handheld, portable or cart-based, POC devices provide for convenient administering of tests and immediacy of results. However, most results are still either printed out or manually transcribed. They must then be re-entered into other information systems, such as Laboratory Information Systems (LIS) and Hospital Information Systems (HIS). This results in opportunities for errors. Few POC devices have been integrated with LIS and HIS systems. Simple POC devices cannot be expected to be able to send complex EDI Test Report Transaction Sets to the LIS/HIS systems. And, the LIS/HIS systems may not have the resources for real-time POC test data correlation.



POC device manufacturers responded with departmental or POC Information Systems (POCIS) that 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 POCIS must communicate with the LIS/HIS system to implement a fully integrated system. Most of these departmental systems have only been integrated with commercial LIS/HIS products on an “as needed” basis. The lack of standards has limited the availability of ubiquitous end-to-end POC integration. In addition, a perpetual challenge facing developers has been how to find and use the network services and LIS/HIS services that allow the resulting distributed system to communicate. The de facto way of solving this is through hard-coded location of proprietary connections and services. This forces the POCIS developer to build custom integration modules for every different healthcare information system used by their customers. With the wide variety of commercial and homegrown healthcare information systems, implementing proxy point of care information systems is still very challenging.

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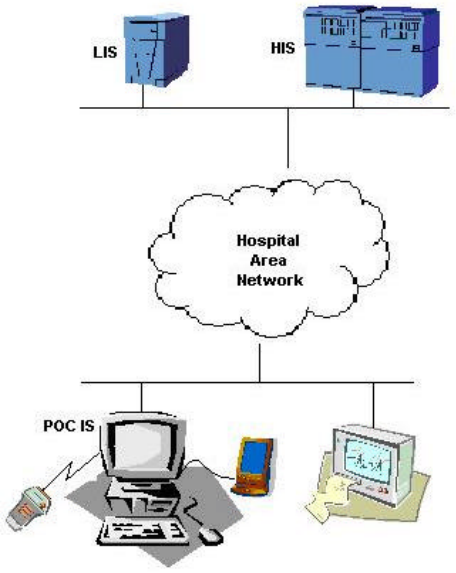
The Opportunity

The goal of many healthcare providers has been full-connectivity of POC devices and departmental, laboratory and hospital information systems. Electronic integration of POC test information has been hampered by multiple, incompatible, proprietary approaches to connecting POC devices to networks and information systems. This lack of standards has resulted in unreasonable costs of integrating each individual POC device with each and every proprietary LIS and HIS software system.



The medical device industry itself has come to the aid of developers of POCIS with the completion of a number of new standards for the integration of POC devices with POCIS and new standards for the integration of POCIS with LIS/HIS systems. These standards specify how a POCIS can act as an "Access Point" to consolidate POC data from multiple POC devices and act as a "Data Manager" to store, process and forward POC data to LIS/HIS systems.

POC Device to POCIS Standards. The Universal Connectivity Standard for Point of Care (POCCIC) by the Connectivity Industry Consortium[1] specifies the protocols required to integrate POC devices with POC Information Systems. The first two POCCIC standards define the low-level network protocols for connecting POC devices to POC Access Points and the high-level protocol for the messages to be exchanged between POC Device and POC Data Manager. The third standard defines the POC Test Results XML/EDI documents to be exchanged between POC Data Manager and HL7-based LIS/HIS systems.

POCIS to LIS/HIS Standards. Health Level 7[2] (HL7) is preparing to release HL7 Version 3 – 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 XML-based Clinical Information documents have been developed and standardized. This forms a foundation for the exchange of clinical information, including POC test results, between POC Device Managers and LIS/HIS systems via HL7 protocols.

Web Services Standards. Finally, Internet standards such as SOAP, WSDL and UDDI have come to fruition providing comprehensive support for registering web

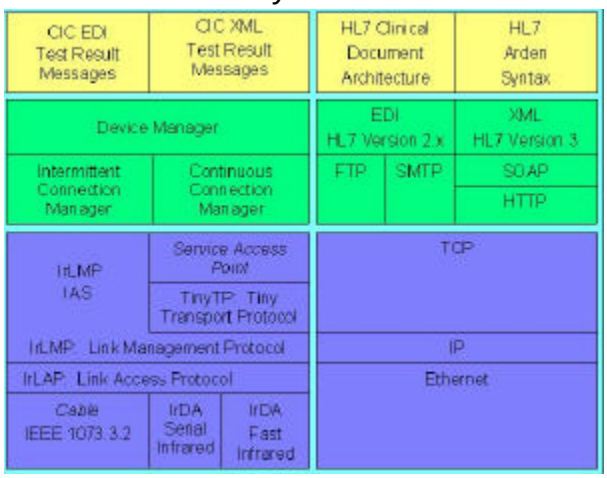
[1] www.poccic.org
[2] www.hl7.org

services, identifying messages and protocols supported by a web service and transporting messages and service requests between web services. This allows POC Information Systems to access network services and LIS/HIS services using Internet standards rather than vendor-specific proprietary mechanisms.

Taken together these POC, LIS/HIS and Internet standards form a comprehensive framework for web services-based integration between POC device, POCIS and LIS systems, as well as between LIS and HIS systems.

Introduction to POC Information System Standards

POC Information Systems act as intermediaries or proxies between often very simple POC testing devices and often very sophisticated Laboratory and Hospital Information Systems. POC Information Systems need to be able to integrate the results from many different types of POC devices, correlate and manage the resulting POC information, and, repackage POC information into formal test results as XML documents, or EDI transaction sets for the LIS/HIS systems. A number of standards have been defined by the healthcare industry to ease the development of these information systems.



HL7 Clinical Document Architecture. The Clinical Document Architecture (CDA) defines how clinical documents (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."[3]

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.

[3] HL7 CDA Website, www.hl7.org/

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:

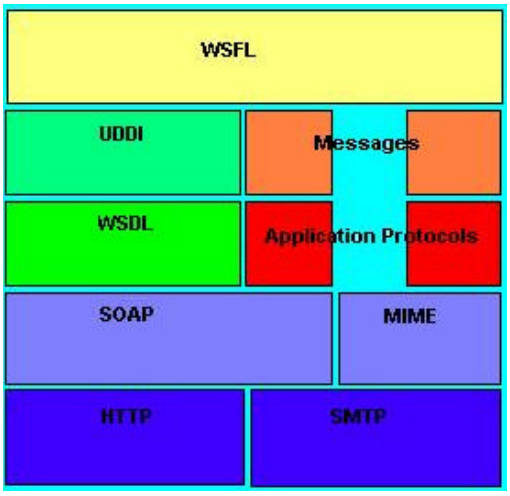
- Device Access Point (Lower-Layer) Proposal
- Device Upper-Layer Proposal
- EDI Interface Proposal

These healthcare standards define the protocols for exchange of data between very different types of systems. However, they do not specify: how a POCIS finds LIS/HIS systems, how to identify what services, messages and protocols they support, or how to reliably extend the services offered beyond the POC standards. For these requirements we must look to technologies developed by the Internet community for "Web Services."

Introduction to Web Services Standards

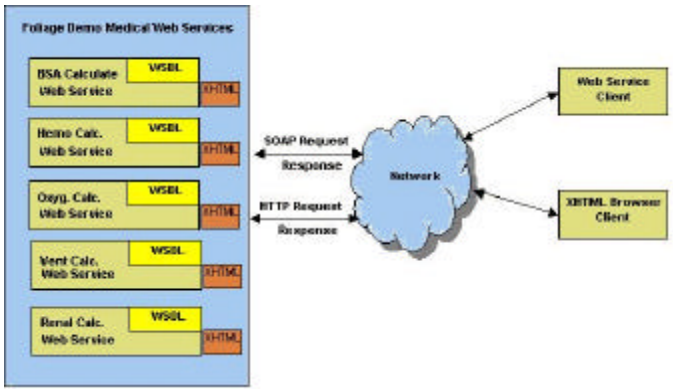
A web service is a collection of objects and operations that are accessible through standard Internet protocols and services. These web services can be invoked on demand to provide services as simple as a small calculation or as complex as an entire business process. The protocols and services that enable web services include:

- XML – eXtensible Markup Language
- WSFL – Web Service Flow Language
- UDDI – Universal Description, Discover and Integration Service
- WSDL – Web Service Description Language
- SOAP – Simple Object Access Protocol
- MIME – Multipurpose Internet Mail Extensions
- HTTP – Hypertext Transport Protocol
- SMTP – Simple Mail Transport Protocol



These technologies provide a language for expressing objects, a language for defining workflow across web services, a language for finding business partners and services, a language for specifying the programmatic interfaces of services and protocols for binding with and invoking the operations supported by the web services.

To demonstrate the flexibility and power of web services, Foliage Software Systems has developed a basic medical calculation web service using Microsoft .NET technology that performs the following calculations:



- Body surface area calculation
- Hemodynamic calculations
- Oxygenation calculations
- Ventilation calculations
- Renal calculations

These simple medical calculation web services describe their implementation and interface in WSDL files. Clients can be either remote web service clients, that communicate with the web services using SOAP requests and SOAP responses, or browser-based clients, that communicate with the web services via HTTP through XHTML pages that encapsulate the service. Refer to http://www.foliage.com/medical for information on accessing this web service.

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 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.

Web Services Flow Language (WSFL). WSFL is an XML-based specification for representing the business workflow across and between web services required to implement a specific business process.

Universal Description, Discovery and Integration (UDDI). UDDI is a specification for registering potential network accessible business partners offering web services (i.e. white pages), the web services offered (i.e. yellow pages), and the technologies supported by the web services (e.g., which specific protocols, document types, transaction sets are supported).

Web Services Description Language (WSDL). WSDL is an XML-based specification for representing the programmatic details of a web service. WSDL allows a service provider to specify the abstract Service Interface (including messages and operations supported). In addition WSDL allows a service provider to specify the concrete Service Implementation (including data formatting, network protocol, network address and port) of a specific installed web service.

Simple Object Access Protocol (SOAP). SOAP, also known as the XML Protocol (XMLP), allows two or more systems to communicate using XML. SOAP provides a framework for XML-based messaging systems, which includes specifying a message envelope format and a method for data serialization. SOAP can use HTTP, SMTP and many other application protocols for message transport.

Hypertext Transport Protocol (HTTP). HTTP is the standard Internet protocol for transferring information between web servers and web browsers. It is the protocol most often used to transport SOAP messages.

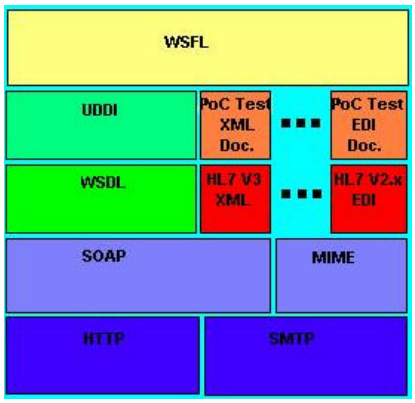
Simple Mail Transport Protocol (SMTP). SMTP is the standard Internet protocol for transferring electronic mail messages between mail servers and mail browsers. It can be used to transfer SOAP messages as well as MIME-encoded EDI messages.

Multipurpose Internet Mail Extensions (MIME). MIME is the multipart envelope standard for Internet mail messages (e.g., those transferred using SMTP). It includes support for multiple types of content (e.g., images, audio, video) and multiple content objects. SOAP messages can be encapsulated in MIME envelopes. In addition, EDI transaction sets can be encapsulated in MIME envelopes.

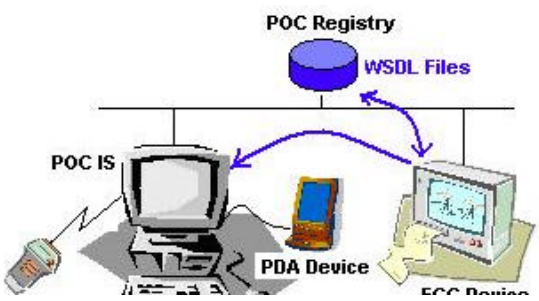
Using these workflow, discovery, binding and invocation services, the service requester and service provider are able to integrate without any knowledge about the implementation details of the other. The message-based integration supported by web services ensures that the participant need only know about the format and content of the messages exchanged. By hiding the details of implementation of web services, this loose-coupling model helps healthcare information systems overcome integration challenges between POC devices, POCIS, LIS and HIS systems.

Implementing Standards-based POC Information Systems

The POC, LIS/HIS and Internet standards discussed in this brief form a comprehension framework for web services-based integration between POC devices, POCIS and LIS systems, as well as between LIS and HIS systems. Web services technologies, such as UDDI, WSDL, SOAP, MIME, SMTP and HTTP, provide standard mechanisms to POCIS for finding out what services are supported on a healthcare-wide network and for exchanging documents and messages with those web services. LIS/HIS standards, such as HL7 Version 2.5 (EDI) and HL7 Version 3 (XML), provide standard protocols to POCIS for exchanging documents with LIS/HIS systems using web services technologies. And, POC connectivity standards provide mechanisms for POC devices to communicate with POC Information Systems. For example, consider the following use-case:



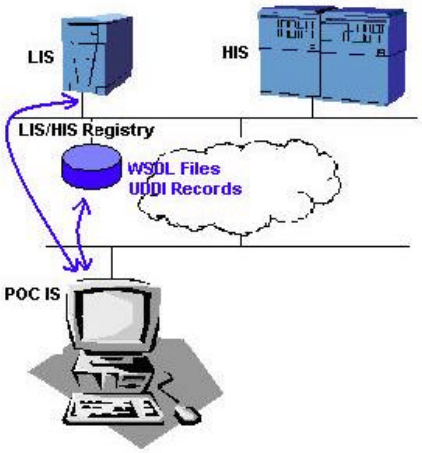
POC to POCIS Integration. To communicate with a local POC Information Systems, POC devices must first be able to find an appropriate local POCIS. Web Services Description Language files can be used to



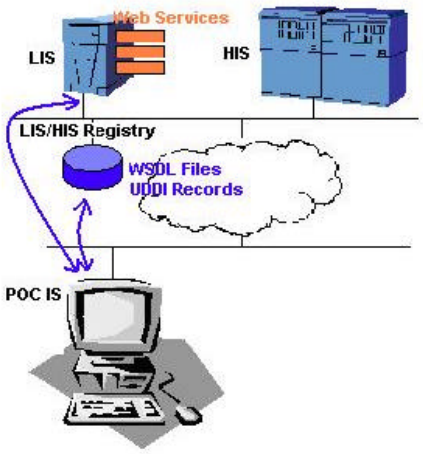
specify network addresses for local POCIS systems and identify which protocols and message types are supported by each POCIS. This allows the POC device to identify a POCIS that can act as a local POC Access Point to which POC data can be sent.

The POC device then communicates with the chosen Access Point (POCIS) via POCCIC lower-level network protocol (e.g., TinyTP over IrDA), exchanging test messages defined in the POCIC upper-layer access protocol.

The POCIS, acting as Access Point, also plays the role of Data Manager by collecting and storing these results. This information may include study data or other POC clinical information collected from other POC devices (e.g., records collected on PDA).



POCIS to LIS/HIS Integration. The POCIS can now use UDDI to find those LIS/HIS services that can accept the POC information. The UDDI registry allows various LIS and HIS system to register specific services, which can be as explicit as a service that accepts certain types of patient clinical information. The POCIS can identify which message formats and protocols are supported by the LIS/HIS systems (e.g., as defined in WSDL for each service). The POCIS can then forward data using a format and protocol appropriate to the target service (e.g., formatting test data as an EDI Test Transaction Set for an HL7 Version 2.5 based LIS, while formatting the same data as an XML Test Results Document for the HL7 Version 3 based HIS).



POCIS/LIS/HIS Value-added Web Services. The POCIS can also use UDDI and WSDL to find and use local and remote web services to analyze, process and consolidate POC data (e.g., accessing remote specialized ECG analysis software, finding database services, etc.) In addition, if the POCIS registers support for remote viewing services, LIS/HIS systems can use UDDI and appropriate protocols to access an ultrasound study or angiogram thumbnails from the POCIS system.

Conclusion

This vision of the next generation of Point of Care Information Systems has significant implications for device manufacturers, LIS/HIS system vendors and members of the medical community. With a comprehensive set of XML-based web services and medical information standards, the ideal of full integration of Point of Care testing devices and LIS/HIS systems will soon follow:

- Healthcare providers will have unprecedented access to complete medical information from anywhere in a healthcare network.
- POC device manufacturers and POCIS vendors will be able to deliver significantly more sophisticated features by exploiting web services.
- LIS/HIS vendors will be able to more easily integrate information and services from POC systems.

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. Device manufacturers and information system vendors should be participating in the development, planning and designing these new standards. Foliage has been actively supporting and 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. The advent of ubiquitous web services and definition of POC connectivity standards has completed the framework required to fully integrate the entire healthcare network – from Point of Care to Laboratory to Hospital Back Office.

About Foliage Software Systems

Foliage Software Systems delivers custom software and systems integration services. Since being founded in 1991, Foliage has completed more than 150 projects for clients in financial services, healthcare, semiconductors, wireless services, avionics, and e-business. More than 75% of Foliage's 100 software engineers have ten or more years of experience. A 95% employee retention rate facilitates teamwork and continuity from project to project. Foliage has been consistently profitable, is self-funded, and has annual revenue of more than $25 million. Foliage is headquartered in Burlington, Massachusetts, and has a development and sales center in Campbell, California. Learn more about Foliage's track record by selecting from more than 90 case studies at www.foliage.com/medical.

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