ebXML Case Study: A Clinical Guideline Registry for the SAGE Project

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Abstract:

The SAGE project seeks to create a standards-based technology infrastructure for computable (machine executable) clinical guidelines that can be shared and readily deployed within different clinical information system platforms. To help realize that vision, Apelon is developing clinical guideline registry software based on an ebXML Registry. We are using our expertise in medical terminologies and associated server technology to facilitate indexing and retrieval of registered guidelines.

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1 Executive Overview

Clinical guidelines capture best practices for providing medical care. For example, a hypertension guideline might assist doctors and nurses by offering consensus recommendations for managing the treatment of a patient with high blood pressure.

The SAGE project seeks to create a standards-based technology infrastructure for computable (machine executable) clinical guidelines that can be shared and readily deployed within different clinical information system platforms. To help realize that vision, Apelon is developing clinical guideline registry software based on an ebXML Registry. We are using our expertise in medical terminologies and associated server technology to facilitate indexing and retrieval of registered guidelines.

1.1 Business Need

Quality healthcare at affordable cost is a crucial imperative for all elements of society. Improved outcomes and reduced expenses can be achieved through consistent application of accepted best practices as reflected in clinical guidelines. Maximal sharing and reuse of guidelines requires that they be expressed in a standard format using standard terminology. It also requires that such guidelines be readily available; thus a state of the art, Internet-accessible guideline registry promises enormous benefits.

1.2 Project Description

The SAGE project focuses on enabling healthcare organizations to

1. Author and encode clinical practice guidelines in a standard computable format, and
2. Deploy those guidelines easily within any standards-conforming clinical information system.

Those goals will be realized by delivering

1. An interoperable *guideline model* for expressing guidelines,
2. An interoperable *guideline workbench* for authoring, editing, encoding and maintaining guidelines according to the model,
3. A web-based *guideline registry* for registering, managing and accessing shared guidelines, and
4. A *guideline deployment system* for integrating guidelines within a clinical information system and supporting their execution at runtime.

Thus, guidelines expressed in a standard format using standard terminology can be created, registered, managed, updated and retrieved – also based on standard terminology, then integrated into different clinical systems where they communicate according to standard data access and service interfaces. In the SAGE prototype, the guideline workbench is based on Stanford's Protégé-2000 system with Apelon's Distributed Terminology System (DTS) Server plugged-in, the guideline registry uses an ebXML registry with Apelon components as described in this document, and the guideline deployment system is the IDX Carecast™ system.

We believe that using standard terminology within guidelines makes them easier to author, explain, understand, share, localize and execute. Similarly, the use of standard terminology in guideline metadata makes guidelines easier to index and retrieve.

2 Participants

2.1 Industry

The SAGE project is conducted by an industrial and academic consortium led by IDX. Other participants are Apelon, Intermountain Healthcare, Mayo Clinic, University of Nebraska Medical Center, and Stanford Medical Informatics.

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2.2 Users

During the current development phase, use is limited to SAGE participants. Wider use is envisioned upon successful completion of the project.

2.3 Other

This work is funded in part by the U.S. Department of Commerce, National Institute of Standards and Technology, Advanced Technology Program, Cooperative Agreement Number 70NANB1H3049.

3 ebXML Specifications Used

We are using the latest OASIS ebXML Registry specifications:

- Registry Information Model v2.1
- Registry Services Specification v2.1

3.1 Other Standards Used (where applicable)

Several standard medical terminologies are being used for guideline indexing and retrieval on a prototype basis, including:

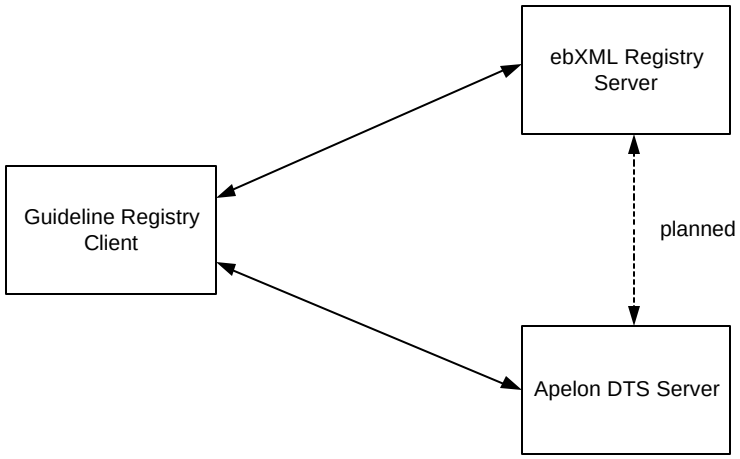
- Medical Subject Headings (MeSH) 2003, from the National Library of Medicine.
- The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) from the World Health Organization.
- SNOMED Clinical Terms (SNOMED CT), from SNOMED International, a division of the College of American Pathologists (CAP).

4 Technical Description

As illustrated below, our distributed guideline registry system uses a pair of servers:

- A generic ebXML Registry server, and
- An Apelon DTS server.

Apelon has also developed a guideline-specific client that interacts with both servers. The section on Future Plans (below) discusses direct synergy between the servers.



The ebXML Registry Server supports registration, management, update and retrieval of guideline packages along with their metadata in the form of attributes, slots, context sensitive classifications according to both internal and external classification schemes, auditable events and associated registry objects. The packages themselves may include both machine-readable guideline specifications and related human-readable documents. We are using the ebxmlrr-server software from SourceForge (http://sourceforge.net/projects/ebxmlrr/) deployed with an Apache Tomcat servlet engine, together with a PostgreSQL 7.3 relational database system supported by the Cygwin UNIX emulation environment, all running on Windows 2000.

Apelon's high performance DTS Server provides uniform access to multiple standard medical terminologies. In this application, it expedites selection of appropriate guideline metadata from medical terminologies via hierarchical browsing and by searching based on code lookup, text matching, attribute queries, etc. For example, the disease or condition that is diagnosed, treated or prevented by a particular guideline can be selected from the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). DTS is written in Java and runs on Windows 2000 and XP, along with certain UNIX platforms.

Apelon's Guideline Registry client connects with both of the servers and provides end users with a custom GUI for submitting and managing guidelines through their life cycle in the registry, as well as for finding and retrieving guidelines of interest, all by means of standard terms. The client is a prototype implemented in Java. It builds on the JAXR client API implemented by the ebxmlrr-client software from SourceForge, along with the DTS client API implemented by Apelon. It also leverages Apelon's rich set of graphical terminology interface components.

5 Benefits and Challenges

5.1 Business

A standards-based approach is central to the mission of the SAGE Project. Today, no standard technology compares with the ebXML registry in meeting our needs for a highly functional web-based guideline registry. As the specifications continue to be enhanced over time, we expect to benefit accordingly.

5.2 Technical

We have found the ebXML Registry specifications to be very sound and reasonably complete. As part of this project, we are identifying suitable metadata items for guidelines and mapping them to the Registry Information Model (RIM). During that process, we have found several opportunities for usefully extending the ebXML registry specifications; we look forward to interacting with the OASIS ebXML Registry Technical Committee towards that end.

The SourceForge ebXML Registry implementation was in alpha status when we began and just recently progressed to beta status, which naturally presented certain operational challenges. We are also anticipating implementation of several important registry features such as full life-cycle management that will be crucial for ongoing maintenance of registered guidelines. Meanwhile, the SourceForge team is to be congratulated for their professionalism and readiness to engage in dialogue and collaboration.

5.3 Lessons Learned

While we are not yet far enough along in this project to draw conclusive historical lessons, we are quite pleased so far with our adoption of an ebXML registry.

6 Future Plans

Over the remainder of the SAGE project's three year term, we will continue to enhance and extend our guideline registry software and take advantage of new features provided by future versions of the ebXML specifications.

We are particularly interested in the idea of defining a standard terminology service interface for the ebXML registry server and prototyping its implementation. By "plugging in" such a service, a registry server could exploit large external classification schemes in the form of standard terminologies (served by DTS, for example) to define constraints on metadata types and to validate metadata instances associated with specific guidelines – or any other sort of artifact for that matter. Furthermore, a registry server could support powerful new types of queries based on taxonomic and other relationships modeled within external terminologies. Such facilities could be based on the content of registry entries as well as their metadata.

We intend to validate scenarios for guideline registry usage such as the following hypothetical example:

1. A joint NSF / medical specialty society team uses the guideline workbench to author a clinical guideline, say for routine diabetes care, building on standard terms and relationships selected via the workbench's DTS plug-in connected to a local or Internet-accessible DTS server.
2. Using the guideline registry client, the resulting guideline is submitted to a public guideline registry on the Internet along with descriptive metadata, including terms drawn from a DTS server. For example, the guideline's subject might be chosen from MeSH and the disease or condition that is prevented, diagnosed, or treated by the guideline might be selected from ICD-9-CM. The registry server independently interacts with a DTS server to validate the metadata, e.g., that the subject is indeed a valid MeSH entry.
3. After peer review and revision, the registered guideline is advanced to *approved* status.

4. A clinician at a hospital, Dr. Jones, browses or searches the public registry for a guideline of interest and determines that it may be appropriate for local adoption. She selects and retrieves the guideline, then it imports into her own installation of the guideline workbench. She may also enter a subscription with the public registry for notification of any changes to the public guideline.
5. In consultation with colleagues, Dr. Jones customizes the selected guideline for local use. The DTS plug-in enables her to review mappings from standard terms to local terms and tailor the guideline with local terms as appropriate. Other adjustments based on local clinical and information system resources may also be made.
6. The localized guideline is registered in the hospital's local guideline registry, where it can be versioned and managed locally. After further review and testing, the appropriate hospital committee accepts the guideline for production use. Staff physicians and nurses are briefed throughout.
7. Using guideline deployment software that comes with the hospital's CareCast (or other) clinical information system software, the guideline is integrated into regular production use. At appropriate points in the care process, the guideline facilitates best practices by prompting for data needed in the electronic patient record, offering options, presenting advice, issuing alerts, scheduling follow-up visits, etc. Of course the caregiver remains able to appropriately exercise independent medical judgment.

In time, we hope to make a guideline registration service based on our software more widely available.

Appendix A. Acknowledgments (where applicable)

The following individuals were instrumental in the success or progress of this effort:

- Nick Beard of IDX is Principal Investigator of the SAGE project. Bob Abarbanel of IDX is the project's Senior Director.
- At Apelon, Derrick Butler provides SAGE software development, John Carter, Ron Nath, and David Sperzel provide medical informatics expertise, Eric Mays provides executive direction, and Tony Weida provides project leadership.
- Mark Musen, Ravi Shankar, and Samson Tu of Stanford University's Medical Informatics Department are working with us on defining suitable metadata for SAGE guidelines.

Appendix B. Revision History

Rev	Date	By Whom	What
SAGE-01	05-Jan-2003	Tony Weida	Initial version.
SAGE-02	10-Mar-2003	Tony Weida	Added usage scenario and made assorted revisions for publication.
SAGE-03	01-Apr-2003	Tony Weida	Further editorial improvements.
SAGE-04	17-May-2003	Tony Weida	Revised notices (Publish date to www.ebxml.org).

Appendix C. Notices

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