

Project Title: Value of New Drug Labeling Knowledge for e-Prescribing
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Organization: Regenstrief Institute
Mechanism: RFA: HS04-012: Demonstrating the Value of Health Information Technology (THQIT)
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Summary Status as of: August 2008, Conclusion of Grant

Strategic Goal: Develop and disseminate health IT evidence and evidence-based tools to improve the quality and safety of medication management via the integration and utilization of medication management systems and technologies.

Business Goal: Knowledge Creation

Summary: The objectives of this project were to: 1) create new knowledge and evidence regarding the benefits of uniform standards for health information for the dissemination of computer-actionable knowledge that can improve patient safety and quality of care, and 2) to develop and implement health information technology (IT) in diverse health care settings. The Food and Drug Administration (FDA) has been working for several years on a new format to disseminate prescribing information—the “package insert”—with improved usability for providers. The next release of the electronic Structured Product Label (SPL) is intended to include computer-interpretable prescribing information in an HL7-standard data structure. This project assessed the value that the upcoming FDA-mandated electronic drug labeling standard will bring to existing and emerging computerized provider order entry (CPOE) systems and e-prescribing tools on the Regenstrief Medical Gopher CPOE system and on a newly-developed, complete HL7 standards-based, open-source prescribing tool.

All published SPL labels were loaded into our standards-based data and knowledge systems. Algorithms were developed to extract the vendor-independent clinical drug descriptions from the vendor and product-centric labels; while SPL labels still cover only 23 percent of RxNorm clinical drugs, they were found to describe 77 percent of actual community pharmacy dispensing records. This foundation was supplemented by the Regenstrief Gopher knowledge base, exported into an XML format and into a relational database for mapping to standard terminologies.

SPL knowledge was evaluated using a large set of drug-intolerance, ordering, and dispensing records covering more than 50,000 patients over 30 years. Here it was found that the more systematic nature of the public knowledge sources improved the sensitivity of the system to detect adverse situations such as drug-allergy conflicts and possible drug-drug-interaction events by a factor of between two and four. The medication order entry application, which was created based on these standards, includes an allergy list, a problem list, and a list of both historical and current medications. It promotes tracking indications with drug orders by allowing drag-and-drop relation between problems and prescriptions being written.

As planned, the system operates solely from standard public knowledge sources without any manual maintenance of order catalogs or decision support knowledge, so it suggests that one of the very costly steps of deploying EHR applications, the local creation of data dictionaries, may indeed be overcome using available format and content standards.

Specific Aims

- Investigate how SPL can help in knowledge management of existing CPOE systems such as the Regenstrief Medical Gopher system. **(Achieved)**
- Develop a standards-based e-prescribing system which would use SPL, the underlying HL7 standards and terminologies as a foundation. **(Achieved)**

2008 Activities: Focus group end-user testing events were undertaken, and they found that some of the project's further-reaching goals, particularly the linking of medications to managed problem lists, were of lesser interest to prospective adopters. On the other hand, it was found that some significant basic administrative data management functions were necessary to make the system more practical for everyday use. Fragmentation of the environments in which this system was to be deployed made its actual deployment challenging. For example, one site had a proprietary electronic medical record system in which doctors would maintain allergies and problems; the e-prescribing function would have been required to either interface with a non-interoperable system or force the user to enter the same data twice. In both of the test adopter sites, competing implementations of other software were occurring prior to when this project's application was ready. Thus, the initial plan to deploy the system remotely on stand-alone server computers was not completed.

Preliminary Impact and Findings: The standards-based data and knowledge tools have been made publicly available and were significantly improved through this project. This work has shown that standard data formats and terminology are both valuable for integrating health care data and knowledge for clinical decision support with minimal manual efforts, and that the role of terminology is specifically for the purpose of mapping and providing detailed knowledge content. The software piloted a certain "late binding" approach to terminology, whereby terminology is a useful tool for data linkage, but is not a precondition for storing, querying, and operating with the data. This is shown best by the ability to use the SPL labels and their descriptions of drugs directly for medication data entry without requiring any "clinical drug" terminology: the user simply types the names of ingredients or brands into a simple entry box and auto-completion ensures that orders are for items that are available on the market. Thus various drug databases could easily be used at different times, including Multum, SPL, and RxNorm, simply by loading this knowledge content into the system. Overall this project found that the specific need for application terminology management was minimal using the standards-based approach. It was found that mapping local terminology to standard terminology and SPL was possible, and that such mappings could provide value to improve legacy application dictionaries. For example, the project demonstrated how RxNorm, NDFRT, and SNOMED-CT can be used to make inferences about the Problem List of a single patient record using the Medications List. While the sensitivity was much less than desirable, the specificity was reasonable, particularly in the context of term frequency. Furthermore, challenges and opportunities for these standards and their utility as a knowledge base for clinical decision support have been identified. The Regenstrief Institute, which hosted this grant, is currently undertaking a CPOE system redesign project, revising an existing in-house CPOE system. Because of the progress made during this grant, particularly in developing a standards-based approach to CPOE system architecture, this project will play an integral role in the development of a new Regenstrief system. It is hoped that the new system will receive wide distribution and provide value to the broader community.

Selected Outputs

Schadow G. Structured product labeling improves detection of drug-intolerance issues. *J Am Med Inform Assoc* 2009;16:211-219.

Burton MM, Schadow G, Simonaitis L. Medication and indication linkage: a practical therapy for the problem list? *AMIA Annu Symp Proc* November 2008; 6:86-90.

Schadow G. Structured product labeling improves detection of drug-intolerance issues. AMIA Annu Symp Proc November 2008; 6:646.

Dolin RH, Giannone G, Schadow G. Enabling joint commission medication reconciliation objectives with the HL7 / ASTM Continuity of Care Document standard. AMIA Annu Symp Proc October 2007; 186-90.

Mantena S, Schadow G. Evaluation of the VA/KP problem list subset of SNOMED as a clinical terminology for electronic prescription clinical decision support. AMIA Annu Symp Proc October 2007; 498-502.

Schadow G. Assessing the impact of HL7/FDA Structured Product Label (SPL) content for medication knowledge management. AMIA Annu Symp Proc October 2007; 646-50.

Available at: Regenstrief Institute, Inc. HL7 Java SIG. Implementation of HL7 v3 (RIM based application architecture). <http://aurora.regenstrief.org/javasig>. Accessed May 2009.

Available at: Regenstrief Institute, Inc. Biomedical Workbench Framework and Order Entry Application. <http://aurora.regenstrief.org/mw>. Accessed May 2009.

Grantee's Most Recent Self-Reported Quarterly Status: The project has been completed. Although implementation did not take place in as many sites as had been hoped due to conflicts with other ongoing technology projects, development and knowledge transfer offered significant insight into how to streamline CPOE software for maximum utility using open-source information.

Milestones: Progress is on track in some respects but not others.

Budget: Spending is roughly on target.