HL7 Structured Product Labeling – Electronic Prescribing Information for Provider Order Entry Decision Support

Gunther Schadow MD PhD

Regenstrief Institute and Indiana University School of Informatics, Indianapolis, IN

Prescribing errors are an important cause of adverse events, and lack of knowledge of the drug is a root cause for prescribing errors. The FDA is issuing new regulations that will make the drug labels much more useful not only to physicians, but also to computerized order entry systems that support physicians to practice safe prescribing. For this purpose, FDA works with HL7 to create the Structured Product Label (SPL) standard that includes a document format as well as a drug knowledge representation, this poster introduces the basic concepts of SPL.

Introduction

In outpatient practice, the most common type of adverse events are drug events. Foster, Bates et al.[1] found 66% of all adverse events 3 weeks post hospitalization were adverse drug events, and a total of 4%-9% of patients had preventable adverse events. Lindley et al.[2] found that of elderly patients admitted to a hospital 27% of the patients had adverse drug events of which 47% was due to contra-indicated or unnecessary drugs. Leape, Bates et al. found that about half of the errors leading to actual preventable adverse drug events occur during in ordering. Leading root causes are lack of knowledge of the drug (36%) and lack of information about the patient (31%) at the time of prescribing.

The U.S. Food and Drug Administration is addressing the problem of lack of knowledge of the drugs with new regulations to both reorganize the content of labeling to better meet the prescribing practitioners needs (Physicians' Labeling Rule, PLR[3]) and create drug information in electronic form using the HL7 standard Structured Product Labeling (SPL). In its second release, SPL will be used not only for the distribution of human readable text, but also for encoding strategically important data elements that can drive decision-support functions in computerized provider order entry (CPOE) systems. The author of this poster is principle designer of the SPL specification.

Methods

Prescribing Information Highlights

The approach of the PLR and SPL is to structure the text of the label in logical sections and sub-sections, each addressing a specific topic (e.g., each indication is discussed in its own sub-section.) Each sub-section contains an excerpt that consists of both a short fragment of text and a structured representation of the critical knowledge conveyed by that sub-section. The text fragment is mounted into a "Highlights" section that summarizes the prescribing information on a half page at the top of the displayed label document, so a prescribing provider can cross-check quickly for the most critical safety issues. The structured representation of the knowledge can drive a CPOE system to assist the physician in creating prescriptions more efficiently and safely, including validating proper indication, checking for dosage errors, contraindications and interactions.

Knowledge Representation

The philosophy behind the SPL knowledge representation is that encoding of drug knowledge should be comparable to electronic drug prescriptions, both in structure of the information and in the use of vocabulary. This is achieved by using the HL7 Reference Information Model (RIM) and by keeping SPL modeling in close alignment with the HL7 pharmacy order domain model. The HL7 RIM allows to use the same data structures for capturing either electronic prescriptions or general normative drug knowledge by changing just one attribute (*Act moodCode*)[4]. Thus, in the center of SPL clinical drug knowledge is the *SubstanceAdministration* class as a definition of a safe and effective use of the drug, considering indication, dosage, and issues requiring special caution.

References

[1] Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. The incidence and severity of adverse events affecting patients after discharge from the hospital. Ann Intern Med. 2003 Feb 4;138(3):161-7.

[2] Lindley CM, Tully MP, Paramsothy V, Tallis RC. Inappropriate medication is a major cause of adverse drug reactions in elderly patients. Age Ageing. 1992 Jul;21(4):294-300.

[3] Food and Drug Administration. Requirements for submission of labeling for human prescription drugs and biologics in electronic format [21 CFR Parts 314 and 601.] Federal Register 68(238). 2003 Dec 11. 69009-20.

[4] Schadow G, Russler DC, McDonald CJ. Conceptual Alignment of Electronic Health Record Data with Guidelines and Workflow Knowledge. Int J Med Inf. 2001 Dec;64(2-3):259-74.