

CDA and SPL – HL7 Standards for Healthcare Documents

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What Are We Talking About?

- Documents
- Problems in healthcare and solutions provided by XML - a nice fit
 - Need to exchange information (documents)
 - Need to aggregate and re-use information
 - Need to extract data from clinical documents
 - Varying levels of technical expertise or access to technology
 - Multiple constituencies
 - Longevity of information

For example . .

- Approved Product Information document
 - aka Product labeling
 - aka Prescribing information
 - aka Package insert
 - aka Structured Product Characteristics (SPC)
- vs Label

The Problem


- Authoring, updating and storage at manufacturer, regulatory agency
- Dissemination
- Re-use of labeling content; data analysis

The Problem - Authoring, Updating and Storage

- Tend to have standard format - see Regulations, sample PIs
 - Document sections
 - Coded elements
 - Standard elements and figures within narrative text
- Variability in format and content across multiple regulatory domains - dependence on legislation
- Interoperability - national, international
- Modular updating and storage
- Metadata and document management


The Problem - Dissemination

- Timeliness of information
- Logistics of exchange
- Documents in different formats



The Problem - Re-use

- Data buried in narrative
- Taking advantage of redundant or “canned” information
- Research
- Data analysis
- Clinical decision support



In Other Words . .


- Need both **human readability** and **machine processability**



A Solution

SPL (Structured Product Labeling)

- standardized XML markup of product information documents
- an HL7 RIM-based standard
- a CDA-based standard




What is SPL?

- SPL is an extensible document specification that defines the semantics and structural constraints necessary for the representation of product labeling documents
- SPL is based on the HL7 Clinical Document Architecture (CDA)
- SPL is intended to be used as the basis for regulatory guidance documents and tooling applications for exchange of product labeling documents




The Best Things About SPL

- SPL markup maintains human readability while providing machine processability
- SPL allows scalable implementation of document markup
- SPL is flexible - e.g., doesn't impose naming or nesting of sections
- SPL markup facilitates exchange of product labeling documents
 - Local tag names can be mapped to SPL
 - “One transformation away from exchange”
- SPL facilitates modular handling of document sections




Scope of SPL

- The standard will be applicable to multiple types of product labeling:
 - Human prescription drug
 - Human over-the-counter drug
 - Devices
 - Blood products
 - Biologicals
 - Veterinary products
 in multiple international domains
- The granularity of markup will evolve




Design of SPL

- Deliberately flat structure
- Flexible
 - Permits varying granularity of markup
 - Does not force or enforce names or organization of sections or data elements
- Extensible - Facilitates localisation for standard codes and vocabularies
- Scalable - increasing granularity of markup
- Uses HL7 Version 3 information model and data types
- Can be constrained (guidances, templates)




Why XML?

- Application independent
- Preserves human readability of documents
- Semantic markup of documents facilitates machine processability, e.g.:
 - Extraction
 - Storage in a database
 - Re-use (including combination from multiple sources)
 - Interchange
 - Automation
 - Re-ordering




XML in Healthcare

- Clinical practice guidelines
- Clinical documentation
 - Electronic Patient Record
 - Clinical Documents
 - Data aggregation and analysis ("doers, viewers, chewers")
 - Remote Data Entry
- Communication, message exchange
- Security (digital signatures etc.)
- Consumer and physician portals
- Controlled vocabulary




Why CDA?

- Document markup standard for clinical documents
- Exchange standard ("one transformation away from exchange")
- Permits migration to more granular markup as needed and as technology and expertise permits
- Supports patient care
- Ensures both human readability and machine processability
- Facilitates integration with other healthcare documents
- Extensive international acceptance



What is CDA?

- Clinical Document Architecture
- ANSI/HL7 CDA R1.0-2000
- First XML specification for healthcare
- First balloted standard using HL7 Version 3 and RIM
- Create/maintained by HL7 Structured Documents Technical Committee
- Editors - Liora Alschuler, Calvin Beebe, Sandy Boyer, Bob Dolin, Fred Behlen



CDA Fundamentals

- A clinical document is defined as having:
 - Persistence
 - Stewardship
 - Potential for authentication
 - Context
 - Wholeness
 - Human readability
- "A clinical document is a defined and complete information object that can include text, images, sounds, and other multimedia content."
- May be original markup or may be result of mapping or transformation from original markup

CDA Goals

- Give priority to **delivery of patient care**.
- Allow **cost effective implementation** across as wide a spectrum of systems as possible.
- Support **exchange of human-readable documents** between users, including those with **different levels of technical sophistication**.
- Promote **longevity** of all information encoded according to this architecture.
- Enable a wide range of **post-exchange processing applications**.
- Be compatible with a wide range of **document creation applications**.
- Promote **exchange that is independent of the underlying transfer or storage mechanism**.
- Enable **policy-makers to control their own information requirements** without extension to this specification

Key CDA Design Principles

- **Technical barriers to the use of the architecture should be minimized.**
- **Document specifications based on this architecture should accommodate such constraints and requirements as supplied by appropriate professional, commercial, and regulatory agencies.**
- **CDA documents must be human readable using widely-available and commonly-deployed XML-aware browsers and print drivers and a generic CDA style sheet written in a standard style sheet language.**
- **Use open standards.**

Role of HL7 Version 3

- Use of Reference Information Model (RIM) permits **semantic interoperability**
- **Abstract model**
 - Act, Participation, Role, Entity
- Use of V3 data types
- V3 methodology and tooling
- **Vocabulary**
- **"HL7 speak"**
 - clones, players and scopes, shadows, RMIM, HMD

CDA and Other Structured Documents


The structure is flexible

The human-readable document is preserved


The semantics of markup come from the RIM

Modeling a concept using the RIM

Current CDA RMIM




- Using CDA or SPL allows us to bite off what we can chew
- Start simple and build on that




SPL Components

- Same as CDA components:
 - Header (fully RIM-derived)
 - Context
 - XML Body (may be largely unstructured up to fully encoded)
 - Sections, with:
 - Narrative text
 - Coded observations
 - RIM-derived data structures
 - Observation media
 - Links to other documents




CDA vs SPL

- SPL is not a “clinical document”
- Which Header attributes apply
- Use of set ID and version ID
- ‘Patient’ is required in CDA; also, encounter, provider, authentication
- CDA/MedRec RMIM only considers medical record business rules (e.g., no revised docs)
- Need for coded elements within narrative text for both
- No ability to version sections in CDA
- How to require specific Observations - use Templates? Archetypes?




How SPL Was Built

- **Document analysis**
 - A task whereby the semantic content of a document is organized into an information model.
- Process:
 - Identify document **components** and **relationships**
 - Requires both **content** and **technical experts**
 - Look at **sample documents**
 - Involves aspects of **use case analysis**
 - Need understanding of **business rules** and intended applications
- HL7 Development Framework – standard methodology



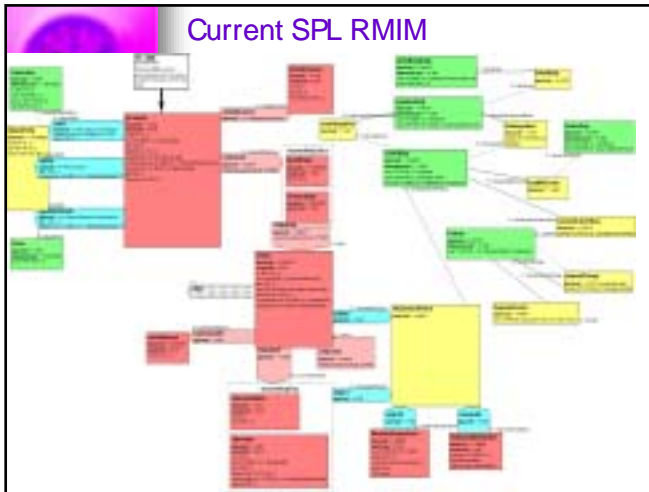
SPL Requirements

- Metadata
- Sections, e.g.:
 - Boxed warning
 - Indications and Usage
 - Dosage and Administration
 - How Supplied
 - Contraindications
 - Warnings
 - Precautions
 - Drug Interactions
 - Laboratory Tests
 - Pregnancy
 - Nursing Mothers
 - Pediatrics
 - Geriatrics
 - Adverse Reactions
 - Overdosage
 - Clinical Pharmacology
 - Carcinogenesis, Mutagenesis, Impairment of Fertility
- Coded data elements
 - Descriptive information about ingredients, dosage form and packaging



SPL and Vocabulary

- Vocabulary
 - constrains RIM to produce RMIM
 - Vocabulary domains = value sets for coded SPL components
 - May be HL7 or external
- Referencing to regulatory vocabularies
- Referencing to other external vocabularies (e.g., LOINC)
- International issues
- Some RIM harmonization required - e.g., additions, changes in definitions



Status and Plans for SPL

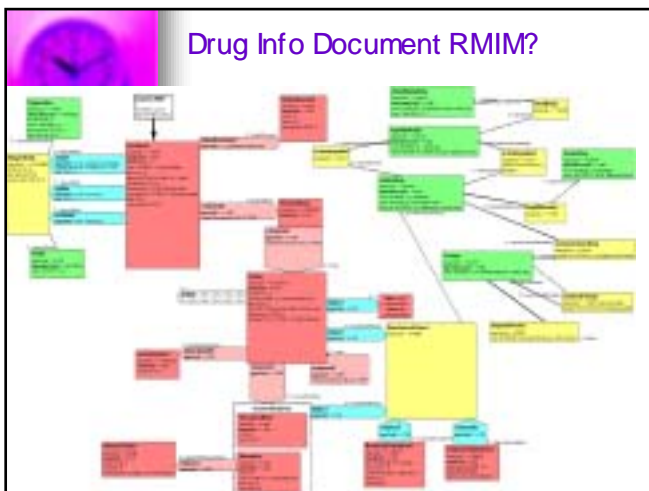
- SPL has passed two committee level HL7 ballots
- Current ballot cycle just opening – put out as DSTU (draft standard for trial use)
- Will go to full membership ballot in next few months

Status and Plans for CDA

- 2nd committee level ballot for CDA Release Two (including full Level Three encoding and schema) just went to ballot (December 2003)
- Looking at requirements for other non-clinical CDA-based documents, e.g.:
 - consents
 - referrals
 - practice guidelines
 - privacy/access
 - registry records

Structured Documents

- As a result of issues raised by use of CDA for SPL and potential use for other non-“clinical” documents, a decision was made to look into the design of generic “structured documents” as an overall umbrella for CDA, SPL, etc.
- Common characteristics
 - Sections, text, structured data
 - Flexibility of structure
 - Mapping from local tags (e.g., AusDI)
- Exercise - create a model?



For More Details

- Latest working draft of CDA; minutes of meetings; other documents
 - Structured Documents Technical Committee page on HL7 website (www.hl7.org)
- SPL and CDA ballots and other HL7 V3 ballots
 - www.hl7.org



An Invitation

- How to get involved:
 - CDA:
 - HL7 Structured Documents Technical Committee listserv
 - Contact any of the Structured Documents TC co-chairs
 - SPL:
 - Contact editor (Sandy Boyer)
 - HL7 RCRIM Technical Committee listserv
 - CDA teleconfer ences
 - HL7 meetings (see www.hl7.org for schedule)



<?Q & amp; A?>

. . . thank you for your interest