HL7 Standards and their Application

May 17, 2007

Indexing Structured Product Labeling: Clinical and Practical Approaches Using Data Elements in SPL

Washington, DC
Alschuler Associates, LLC

- Consultants in standards-based solutions for healthcare
  - Specialize in XML, CDA document-based applications
- Working with
  - Vendors
  - Providers and RHIOs
  - Standards developers
- Clients
  - Department of Health and Human Services
    - Subcontracts on Health IT Standards Panel (HITSP) and Health Information Standards for Privacy and Confidentiality (HISPC)
  - Centers for Disease Control and Prevention
    - Implementation Guides for infectious disease reporting and cancer abstracts
  - Military Health System
    - Partner with Apptis, Inc. for development of enterprise-wide documents, files, images (DFIEA)
  - American Hospital Association
    - Use case development for healthcare IT standards initiative
  - Private, commercial clients: Fortune 100 and startups
- www.alschulerassociates.com
• Liora Alschuler
  – Consultant in healthcare IT 1997-present
    • Background in electronic text, industry analyst with Seybold Publications, xml.com
    • Founded consulting firm in 2005
  – Volunteer standards work
    • Health Level Seven Board of Directors (2005-2008)
    • Co-chair Structured Documents Technical Committee
    • Co-editor Clinical Document Architecture (CDA)
  – liora@alschulerassociates.com
SPL in HL7 Context

- Key specification for interoperable health records
- Supports cross-enterprise decision support and patient safety.
  - SPL in perspective with related efforts from HL7
  - Demonstrates how SPL complements the move to interoperable health records and electronic documents for:
    - delivery of care,
    - public health reporting, and
    - clinical trials.
HL7 Mission

HL7 is an international community of healthcare subject matter experts and information scientists collaborating to create standards for the exchange, management and integration of electronic healthcare information.

HL7 promotes the use of such standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery for the benefit of all.
Saul Steinberg

- View of the World from 9th Avenue

- Tends to apply to healthcare IT
The Hospitalist

- Everything revolves around the interface engine
• Everything revolves around the pictures
• Does everything revolve around the label?
in truth...everything revolves around my mother

• Healthcare IT is about the patient
Healthcare IT

• IOM perspective
  – Institute of Medicine, To Err Is Human
  – 98,000 preventable deaths each year

• MOM perspective
  – Post discharge
  – What meds?
  – Followup visit: no value
patient-centered health information

New drug information

Pharmacy

Consult

PCP followup

Discharge medications

PHR/EHR Vocabulary Services Knowledge Base

FDA Report

CDA: Discharge Sum
V3 msg: Med Order
CDA: lab, imaging
V2: lab
Arden
ICSR
aECG
CT Lab
Stability

Other Standards
NCPDP
DICOM
CDISC

HL7 Standards
RIM-DataTypes-ITS
SPL

HL7 TC/SIG
RCRIM
SDTC
Pharmacy
Lab
Image Int.
Patient Care
Decision
Support
Public
Health

R&D
Develop

Study
Develop

Alschuler ASSOCIATES LLC
“Unlike Colt with an ornate exhibit patterned on the display of weapons in mediaeval castles, the Robbins & Lawrence exhibit was remarkable for its simplicity: six rifles only, which in turn were dismantled and reassembled to demonstrate interchangeability of parts to the amazement of those present.”
HL7 Reference Information Model:
interchangeable parts for HIT
HL7’s RIM-based specifications

- **Clinical Document Architecture**
  - clinical document exchange
  - based on RIM, vocabulary, XML
  - 1<sup>st</sup> cousin of SPL

- **Regulated Clinical Research Information Management**: in addition to SPL
  - Annotated ECG
  - CT lab
  - Stability
  - Generic Incident Notification
  - Protocol representation
  - Regulated product submission
  - BRIDG: CDISC/HL7 modeling
why can’t we just use XML?

• let’s take a look...
what is XML?

- XML is Extensible Markup Language (www.w3c.org)
- In XML, structure & format are conveyed by *markup* which is embedded into the information

```xml
- <section>
  <code code="11348-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="HISTORY OF PAST ILLNESS" />
  <title>Antécédents médicaux</title>
  <text>
    - <table border="1">
      - <tbody>
        - <tr>
          - <th>Pathologie</th>
        </tr>
      </tbody>
    </table>
  </text>
</section>
```
Good Health Clinic Consultation Note

Patient: Henry Levin, the 7th
Birthdate: September 24, 1932
Consultant: Robert Dolin, MD

History of Present Illness

Henry Levin, the 7th is a 67 year old male with a history of asthma in his teens. He was hospitalized in his 30s for severe exacerbation of asthma and was able to be weaned off steroid therapy with the use of inhaled steroids and montelukast.

Past Medical History

- Asthma
- Hypertension (see HTN.cda for details)
- Osteoarthritis, right knee

Medications

- Theodur 200mg BID
- Proventil inhaler 2 puffs QID PRN
- Prednisone 20mg ad

CDA Body

---

<custodian>
- <recordTarget>
  - <patient>
    <id extension="12345" root="2.16.840.1.113883.3.933" />
    - <patientPatient>
      - <name>
        <given>Henry</given>
        <family>Levin</family>
        <suffix>the 7th</suffix>
      </name>
      - <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1" />
      - <birthTime value="19320924" />
    </patientPatient>
    + <providerOrganization>
    </patient>
  </recordTarget>
  + <relatedDocument typeCode="RPLC">
  + <componentOf>
    - <!--
      CDA Body
      -->
    - <component>
      - <structuredBody>
      - <!--
        History of Present Illness section
        -->
      - <section>
        <code code="10164-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" />
        <title>History of Present Illness</title>
        <text>
          <content styleCode="Bold">
            Henry Levin, the 7
          </content>
        </text>
      </section>
    </component>
  </componentOf>
</relatedDocument>
</recordTarget>
</custodian>
why XML alone isn’t enough

• With a few simple tags, and controlled vocabulary, XML can describe anything

• but...

• the tags need to be defined:
  
  `<orderNum> : HL7: order placed`

  `<orderNum> : CDISC: visit sequence`

• CDA tags are defined by the HL7 Reference Information Model (RIM) and use standard controlled vocabulary
Dr. Dolin asserts that Henry Levin manifests hives as a previously-diagnosed allergic reaction to penicillin.

Why isn’t XML + SNOMED enough?
Allergies & Adverse Reactions

- Penicillin - Hives
- Aspirin - Wheezing
- Codeine - Itching and nausea
Next: series of coded “clinical statements”

Observation: RIM-defined
History: SNOMED
Hives: SNOMED

Observation: RIM-defined
History: SNOMED
Allergy to penicillin: SNOMED

Relationship: RIM-defined
RIM-defined CDA structures + vocabulary =
Hives manifests an allergic reaction to penicillin
Then: supply context

CDA Header

---

Who is the subject?

Target: RIM-defined
Id: local

```xml
<id extension="c266" root="2.16.840.1.113883.3.933" />
<code code="11488-4" codeSystem="2.16.840.1.113883.6.1" displayName="Consultation note" />
<title>Good Health Clinic Consultation Note</title>
<effectiveTime value="20000407" />
<confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25" />
<setId extension="BB35" root="2.16.840.1.113883.3.933" />
<versionNumber value="2"/>
+<legalAuthenticator>
+<author>
+<custodian>
  <recordTarget>
    <patient>
      <id extension="12345" root="2.16.840.1.113883.3.933" />
      <patientPatient>
        <name>
          <given>Henry</given>
          <family>Levin</family>
          <suffix>the 7th</suffix>
        </name>
        <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1" />
        <birthTime value="19320924"/>
      </patientPatient>
    </providerOrganization>
  </recordTarget>
</author>
</custodian>
</recordTarget>
```
Investing in Information

• “Single Source”
  – Create once
  – Use many
  – Reuse clinical data in clinical trials

• Duke Clinical Research Institute
  – Proof of Concept
  – Principals:
    • Landen Bain, Rebecca Kush, Liora Alschuler
    • Microsoft, primary technology partner
The Challenge: Integrate Patient Care and Clinical Research Data
Single Source vs. Previous Solutions

- **eSource & electronic data capture**
  - redundant with creation of clinic note
  - require information reside in EMR/EHR
  - proprietary data formats

- **CDA & CDISC in “single-source”**
  - capture trial data, merge it into clinic note (re-use)
  - work with current technology, workflow
  - open, non-proprietary data formats
Fully coded, proprietary

EDC without data standards, courtesy Charles Jaffe, MD, Astra-Zeneca (now CEO of HL7)
CDA in Starbrite Trial

Manual creation and re-entry of CRF

HIS

LIS

lab, ADT, meds, source documents

display

CLINIC

CRO

Current processes (dual source)

Redundant creation of chart note
CDA in Starbrite Trial

Proposed processes (single source)
One CDA, many applications: clinical trials

Source CDA (principal investigator, author’s view)

Clinic note inserted into patient chart

Archival CDA XML

Case report form submission to research database

Report on “Single Source” project to be published by JAMIA: Journal of the American Medical Informatics Association
Where do we start?

- Enter the data once, then reuse

Diagram:
- Documenting care
  - Link to Diagnostic imaging
  - Link to Pathway, guidelines
  - Share care
  - Orders
  - Quality improvement
  - Decision support
  - Public health
  - Reimbursement
  - Clinical trials

Create data
It’s the data

• Problems with data today:
  – Paper
  – If electronic, then narrative
  – If data, not coded
  – If coded, proprietary
  – If standard, still too loose
It’s the data

• Major cost of a new implementation
  – Not the hardware
  – Not the software
  – Not even the consultant…
  – It’s the data
It’s the data

• Mayo Clinic: data is their key capital asset
  – Not the buildings
  – Not the equipment
  – Not the staff
  – It’s the data
It’s the data

- Steve Ruberg, Eli Lilly/CDISC, *Applied Clinical Trials*, February, 2002:

  “The essential kernel of the whole clinical development process is the data… Thus, without a data-centric approach to developing any e-clinical solution, we are unlikely to be fully successful. The data is the foundation on which we build our entire effort.”
CDA from dictation

- Dictaphone (Nuance)
CDA from Dictation

• narrative documents can be enhanced through natural language processing and use of templates with no disruption to the existing workflow
CDA from an EMR

Yoshida, Kim

Visit Navigator (Encounter Date: 01/26/2002, Office Visit) - Viewing

Allergies: "Verified on 1/3/2002" POTASSIUM GLUCONATE, CYSTEINE
Vitals: BP: 126/90, P: 76, T: 97.9 °F (36.6 °C), T Srv: , Resp: 12, W: 121 lbs, H: 5'4" BMI: 20.77 kg/m², BSA: 1.57 m², LMP: , SS: Never

Progress Notes
Subjective:
34 y.o. female w/lump in breast for physical exam. Reports that it is not painful to touch.

Objective:
1.5 cm lump palpated.

Assessment:
Possibly problematic.

Plan:
Lab and pathology work ordered.

SmartSets - Encounter Matches
1. EMERGENCY DEPARTMENT - STANDARD ORDERS

Diagnoses (View Only)
Go to Diagnosis Entry

<table>
<thead>
<tr>
<th>P</th>
<th>Diagnosis</th>
<th>Code</th>
<th>Comment</th>
<th>Qualifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>P</td>
<td>LUMP OR MASS IN BREAST</td>
<td>611.72</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Orders (View Only)
Go to Order Entry
Data standards development: Data elements and Clinical Document Architecture CDA

Jari Porrasmaa
University of Kuopio, HIS R&D, SerAPI project
Association of Finnish Local and Regional Authorities, Core dataset project HL7 Finland, technical committee member
HL7 Service Oriented Architecture SIG co-chair (HL7-OMG HSSP)
Seamless Care and CDA, Finland
Aluetietojärjestelmä

~60% of Finnish population covered including Helsinki

How XML and HL7 CDA are used

1. All adapters provide the document headers for creation of the references for all customer encounters
2. FTP transfer of the headers once a day
3. Reference data is extracted from the headers and inserted into the SQL database
4. Customer gives a consent to the professional to look at the customer’s references
5. The professional chooses the reference for content retrieval and the request is sent to the respective adapter
6. Adapter retrieves the document from the operational system and sends it back
7. Document content is transformed into HTML using XSLT processor and XSL style sheet
8. Document content is presented to the professional

XSL style sheets for presentation of the documents
DTDs for defining the document structures
Crete: HygeiaNet

7 hospitals, 15 primary health care centers: ICT, EHR, medical devices commitment standards i.e. HL7, DICOM, education

CDA for Mobile Health: Meeting the needs of Rural Communities in Twister Chronaki, 2nd International Conference on the CDA, October, 2004
http://www.hl7.de/iamcda2004/fprogram.html
Patient: Jeanne PETIT
Birthdate: January 5, 1948
Consultant: Christophe CHARI

Antécédents personnels

Antécédents médicaux

Pathologie  Date de survenue
Méninigite bact.  1979
Asthme lors de l'enfance 1950-1955

Antécédents chirurgicaux

Procédure  Date de réalisation
Amygdalotomie par dissection 1973
HISTORY OF SYMPTOMS and DISEASES

<observation classCode="OBS" moodCode="EVN">
<code code="29547-7">
  codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC"
  displayName="HISTORY OF SYMPTOMS and DISEASES">
<translation code="1">
  codeSystem="2.16.840.1.113883.2.1.1.1.1.1"
  codeSystemName="Ill" displayName="Anamnesi radiologica">
</translation>
</code>
</observation>

<text> 1978: Exeresi nodulo benigno della mammella destra.
  2/1/2006: Diagnosi eco mammografica di nodulo sospetto QSE della
  mammella sinistra di 15 mm circa.
  11/01/2006: Biopsia escisionale QSE della mammella sinistra:
</text>
</observation>
診療情報提供書（患者紹介）

1999年11月17日

医療機関
浜松市病院

内科

担当医
松永 充治

所在地
〒789-6789 浜松市6丁目3番
TEL 053-435-1111

患者氏名
患者女

生年月日
1939年3月3日

疾患名
肺癌（小細胞癌）Stage IV

紹介目的
御依頼いただきました放射線治療ならびに化学療法の終了

既往歴
特になし

家族歴
特になし

症状経過
平成11年5月16日当科入院、胸壁部C T、頭部MRI、骨シンチ検査を実施しました。入院翌日より放射線治療を開始しております。

治療経過
右側肺門を含めたmain tumorに対し63Gy/35f、両側鎖上部に45025fの照射を施しました。特に副反応はみられず、7月3日よりCBDCA 450mg＋VP-16 100mg×3の化学療法を3コース施行しました。転移脳腫瘍の消失を認めるが、現在は落ち着いております。

Main tumorは現在径12mmほどに縮小、頸頭リンパ節は転移を認めず消退しております。マーカーは添付資料のように変化せず境界域のままですが、左上葉の含気も十分であり、咳嗽も下記内服薬程度でコントロールできています。

ご本人の希望もあり、今後の経過観察につきよろしく御診察の程、御協力お願い申し上げます。
Health Level Seven

• Potential to leverage large amounts of clinical data
• It’s not really all about the data...
HL7 Products & Services

- V2 Messages
  - V2M Infrastructure
  - V2M Administrative
  - V2M Departmental
  - V2M Clinical
- CCOW
- Arden
- V3 Foundation
  - V3F Reference Information Model
  - V3F Vocabulary Domains/Value Sets
- V3 Messages
  - V3M Infrastructure
  - V3M Administrative
  - V3M Departmental
  - V3M Clinical
- V3 Documents
  - V3D Administrative (SPL)
  - V3D Knowledge
  - V3D Clinical (CDA)
- V3 Services
  - V3S Java Services (Java SIG)
  - V3S Web Services (OMG)
- V3 Rules
  - V3R GELLO
- Community Networking in Healthcare IT
EHR vs. EHR-S

- **Electronic Health Record (EHR)**
  - The underlying single, logical patient record
  - The data elements comprising the record
  - Needs to serve as the legal record

- **Electronic Health Record System (EHR-S)**
  - Software that provides functionality to:
    - Create and maintain the record
    - Accomplish the various clinical, research, and business purposes of the record
  - Monolithic system or a system of systems
Is Not...
- A messaging specification
- An EHR specification
- An implementation specification (not the “how”)
  - Does not prescribe technology
  - Does not dictate how functions must be implemented (e.g., via the user interface, database design)

Is...
- A system specification
- An EHR system specification
- A reference list of functions that may be present in an EHR-S (the “what”)
  - Enables consistent expression of functionality
  - Provides flexibility for innovation and product differentiation
  - Gold standard, sensitive to what can practically be done by a system, future system development
EHR-S Functional Model at a Glance

Approximately 130 functions over 3 sections

Functions describe the behavior of a system in user-oriented language so that key features within functions are recognizable to the stakeholders of an EHR system
Key Distinctions in the Model

- **System vs. user action**
  - What a system can do in an automated fashion
  - Providing the ability for a user to perform an action

- **Practice vs. what a system can reasonably or practically perform**

- **Granularity and careful expression of conformance**
  - Health information management
  - Maintaining a legal business record
<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Statement</th>
<th>Description</th>
<th>Conformance Criteria</th>
</tr>
</thead>
</table>
| DC.1.1. 1| Identify and maintain a patient record    | Identify and maintain a single patient record for each patient. | A single record is needed for legal purposes, as well as to organize it unambiguously for the provider. Health information is captured and linked to the patient record. Static data elements as well as data elements that will change over time are maintained. The patient is uniquely identified after which the record is tied to that patient. Combining information on the same patient, or separating information where it was inadvertently captured for the wrong patient, helps maintain health information for a single patient. | 1. The system SHALL create a single logical patient record.  
2. The system SHALL provide the ability to uniquely identify a patient and tie the record to a single patient.  
3. The system SHALL provide the ability to merge or link patient information in a controlled method upon an authorized user recognizing the identity of the patient.  
4. When health information has been mistakenly associated with a patient, the system SHALL leave, but mark as such, the health information in the record of the patient in which it was mistakenly associated.  
5. When health information has been mistakenly associated with a patient, the system SHALL provide the ability to associate it with the correct patient. |
<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Statement</th>
<th>Description</th>
<th>Conformance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>DC.1.9.3</td>
<td>Manage order sets</td>
<td>Provide order sets based on provider input or system prompt.</td>
<td>Order sets, which may include medication orders, allow a care provider to choose common orders for a particular circumstance or disease state according to standards or other criteria. Recommended order sets may be presented based on patient data or other contexts.</td>
<td>1. The system SHALL support presentation of order set(s))&lt;br&gt;2. The system SHALL support modification of order sets at the patient level&lt;br&gt;3. The system SHALL record each component of an order set that is ordered.&lt;br&gt;4. The system SHOULD provide an alert where orders may conflict&lt;br&gt;5. The system SHALL store and manage health information (I.2.5.1 and I.2.5.2)</td>
</tr>
</tbody>
</table>
Organization: simple view

Board of Directors
Business affairs
Elected

Technical Steering Committee
Technical affairs
Appointed officers plus chairs of the committees & SIGs

The Working Group
The working HL7
Any member can register for any committee or SIG

Technical Committees
Create normative specifications or chapters in the standard

The Membership
Members get discounts at meetings and have no-charge access to the Standards

Special Interest Groups
Collaborate in area of interest to contribute to the work of the TCs

Non-Member Participation
Non-members can register and participate in most activities, including some ballots
Committees & Special Interest Groups

- Anatomic Pathology
- Anesthesia
- Architecture Review Board**
- Arden Syntax
- Attachments
- Cardiology
- Common Message Element Types***
- CCOW*
- Clinical Decision Support*
- Clinical Genomics
- Clinical Guidelines
- Community Based Health Services
- Conformance
- Infrastructure & Messaging*
- Education**
- Electronic Health Records*
- Electronic Services**
- Emergency Dept.
- Financial Management*
- Government Projects (US)
- Imaging Integration
- Implementation**
- International Affiliates**
- Java
- Laboratory
- Health Care Devices
- Marketing**
- Medical Records/
  Information Management*
- Modeling & Methodology*
- Orders & Observations*
- Organization Review**
- Outreach for Clinical Research*
- Patient Administration*
- Patient Care*
- Patient Safety
- Pediatric Data Standards
- Personnel Management*
- Pharmacy
- Process Improvement**
- Public Health & Emergency Response
- Publishing**
- Regulated Clinical Research Information Management (RCRIM)*
  (formerly Clinical Trials)
- Scheduling & Logistics*
- Security*
- Service Oriented Arch.
- Structured Documents*
- Technical Steering Committee**
- Templates
- Tooling**
- Vocabulary*
- XML

* Technical Committees, ** Board Committees, ***Task Force  

As of 06/06
Organization

- Foundation & Technology
Organization

- Structure & Semantic design patterns
Organization

• Domains (1 of 2)
Organization

• Domains

(2 of 2)
Agreements/MOUs

* Accredited Standards Committee X12 — ASC-X12
* American Dental Association — ADA
  o ADA Joint Project Statement
* American Society for Testing Materials — ASTM
* CEN/TC 251
* Clinical Data Interchange Standards Consortium — CDISC
* Digital Imaging and Communication In Medicine — DICOM
* eHealth Initiative – eHI
* Institute for Electrical and Electronic Engineers — IEEE
* Integrating the Healthcare Enterprise — IHE
* Medbiquitous
* National Council for Prescription Drug Program — NCPDP
* OASIS
* Object Management Group — OMG
* University of Nevada Las Vegas — UNLV
* College of American Pathologists - SNOMED International Division — SNOMED
Patient Safety
virtual tour

HL7-IHE Demonstration
HIMSS 2004
FDA, Pharma revise SPL
Patient safety officer alerts FDA; FDA alerts Pharma.
FDA publishes alert; ACP publishes alert; MLM updates
PCP queries ED system for patient data
Atrial Fibrillation

Select a section to view guidance statement information on Atrial Fibrillation.

- Prevention
- Screening
- Diagnosis
- Consultation for Diagnosis
- Hospitalization
- Non-drug Therapy
- Drug Therapy
- Patient Education
- Consultation for Management
- Follow-up

FDA publishes alert; ACP revises PIER Guidelines
Thank you!
Questions?
Liora@alschulerassociates.com