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
    - Author, *ABCD... SGML: A Manager's Guide to Structured Information,* 1995
    - 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

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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
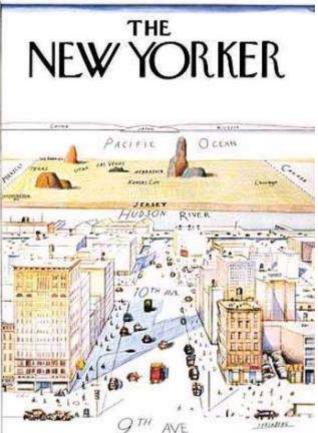
    - clinical trials.

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.
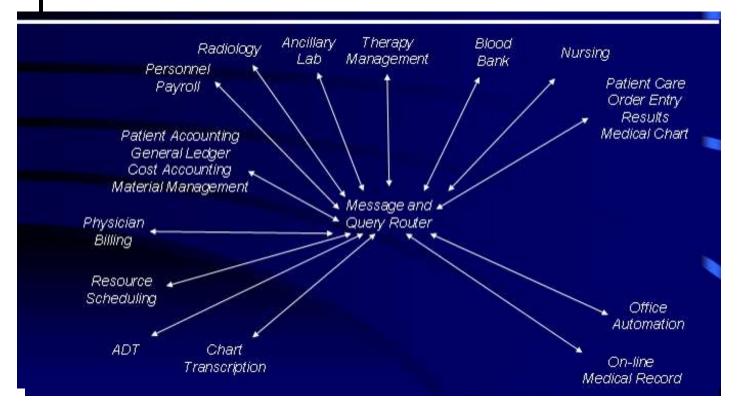
Saul Steinberg

- View of the World from 9th Avenue

- Tends to apply to healthcare IT

The Hospitalist

- Everything revolves around the interface engine

The Radiologist

- Everything revolves around the pictures

SPL

- Does everything revolve around the label?

in truth...everything revolves around my mother

- Healthcare IT *is* about the patient
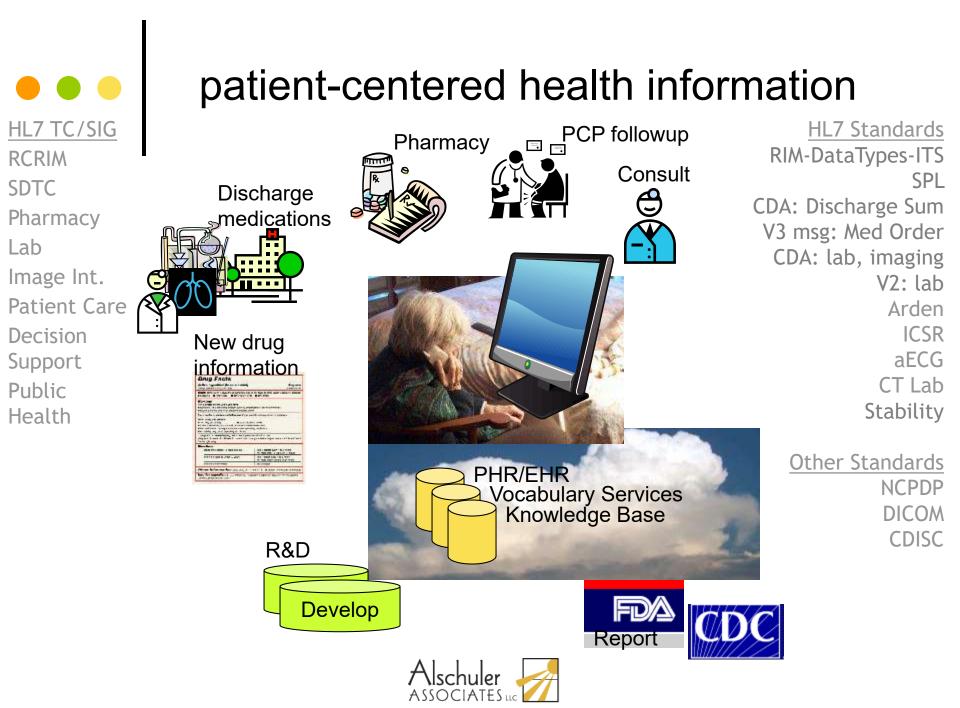
Healthcare IT
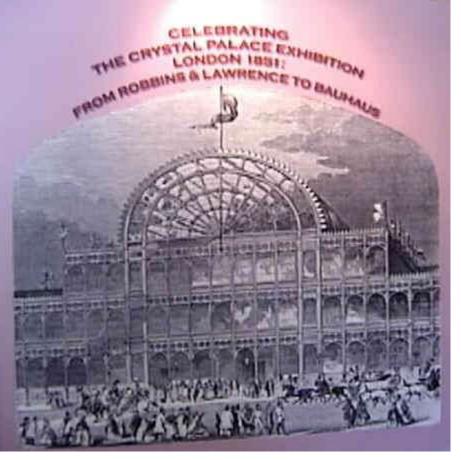
- IOM perspective
  - Institute of Medicine, To Err Is Human
  - 98,000 preventable deaths each year
- MOM perspective
  - Post discharge
  - What meds?
  - Followup visit: no value

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patient-centered health information

Discharge medications

Pharmacy

PCP followup

Consult

New drug information

PHR/EHR
Vocabulary Services
Knowledge Base

R&D

Develop

Report

FDA

CDC

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Information as interchangeable parts

American Precision Museum
Windsor, Vermont
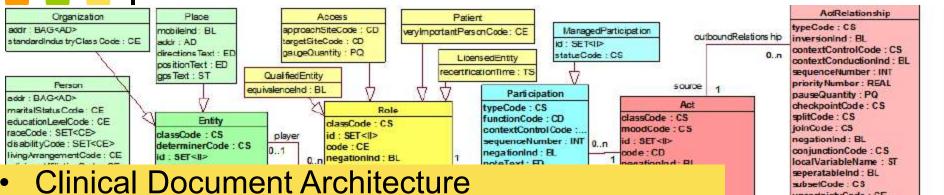
"Unlike Colt with an ornate exhibit patterned on the display of weapons in mediaeval castles, the Robbins & Lawrence exhibit was remarkable for its simplicity: six rifles only, which in turn were dismantled and reassembled to demonstrate interchangeability of parts to the amazement of those present."

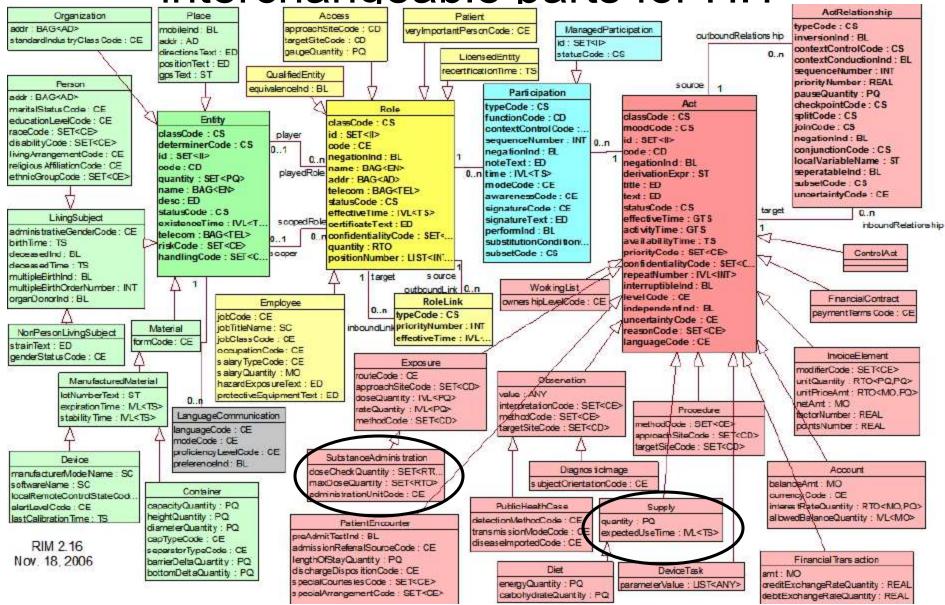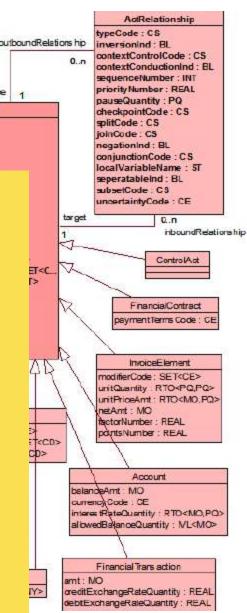# HL7 Reference Information Model: interchangeable parts for HIT

RIM 2.16
Nov. 18, 2006

HL7's RIM-based specifications

- Clinical Document Architecture
  - clinical document exchange
  - based on RIM, vocabulary, XML
  - 1st 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...

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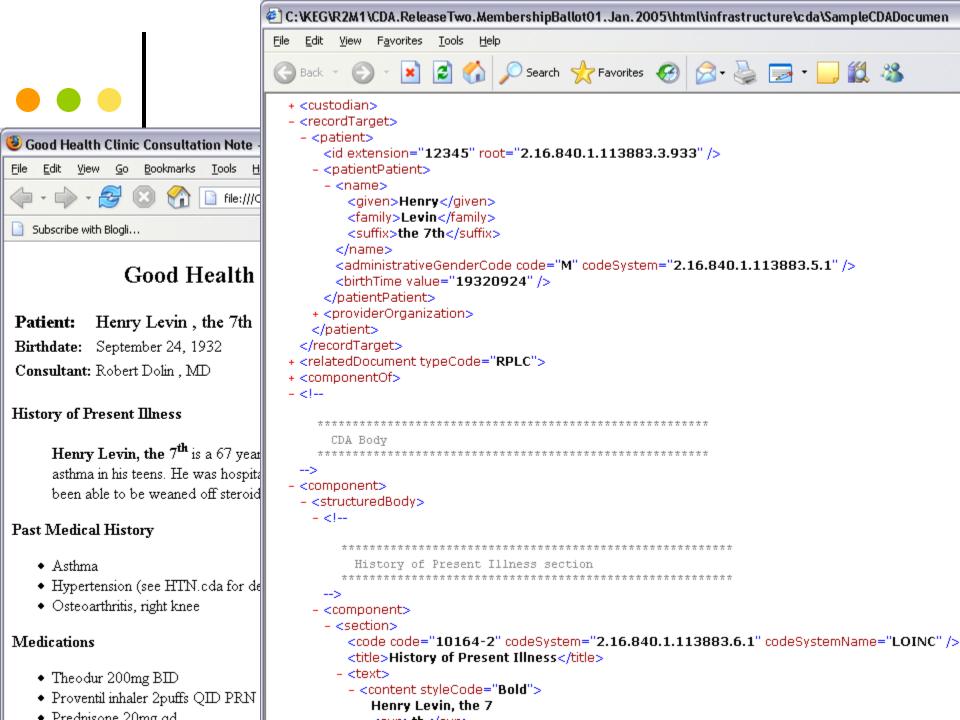
what is XML?

- XML is Extensible Markup Language (www.w3c.org)

- In XML, structure & format are conveyed by *markup* which is embedded into the information

```
- <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>
```

File   Edit   View   Favorites   Tools   Help

Back   Search   Favorites

```
  + <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
          ********************************************************
        -->
      - <component>
        - <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
```

Good Health Clinic Consultation Note

File   Edit   View   Go   Bookmarks   Tools

Subscribe with Blogli…

Good Health

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... asthma in his teens. He was hospit... been able to be weaned off steroid...

Past Medical History

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

Medications

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

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

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|Why isn't XML + SNOMED enough?

Good Health Clinic Consultation note

Consultant:	Robert Dolin, MD
Date:	April 7, 2000
Patient:	Henry Levin, the 7th MRN: 12345 Sex: Male
Birthdate:	September 24, 1932

History of Present Illness
Henry Levin, the 7th is a 67 year old male referred for further asthma management. Onset of asthma in his ~~twenties~~ teens. He was hospitalized twice last year, and already twice this year. He has not been able to be weaned off steroids for the past several months.

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

Medications
- Theodur 200mg BID
- Albuterol inhaler 2puffs QID PRN
- Prednisone 20mg qd
- HCTZ 25mg qd

Allergies & Adverse Reactions
- Penicillin
- Aspirin – Wheezing
- Codeine – Itching and nausea

Family History
- Father had fatal MI in his early 50's.

"hives": SNOMED CT **247472004**

"Dr. Dolin asserts that Henry Levin manifests hives as a previously-diagnosed allergic reaction to penicillin"

First: human readable

Allergies & Adverse Reactions
- Penicillin - Hives
- Aspirin - Wheezing
- Codeine – Itching and nausea

```xml
<!--

*********************************************************
  Allergies & Adverse Reactions section
*********************************************************
-->
<component>
    <section>
        <code code="10155-0" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" />
        <title>Allergies and Adverse Reactions</title>
        <text>
            <list>
                <item>Penicillin - Hives</item>
                <item>Aspirin - Wheezing</item>
                <item>Codeine - Itching and nausea</item>
            </list>
        </text>
</component>
```

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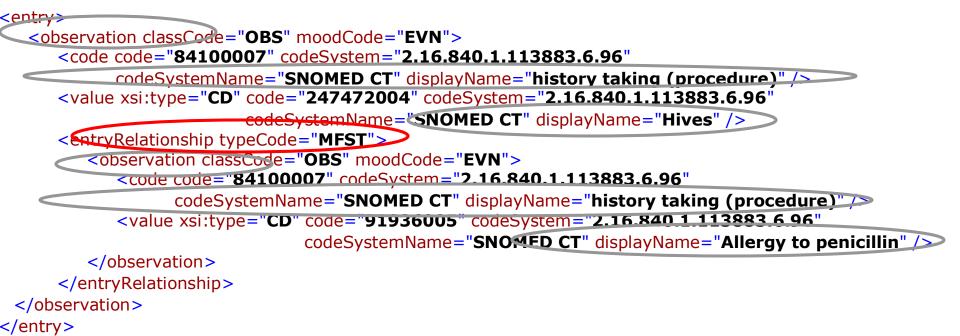# Next: series of coded "clinical statements"

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

```xml
<entry>
    <observation classCode="OBS" moodCode="EVN">
        <code code="84100007" codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED CT" displayName="history taking (procedure)" />
        <value xsi:type="CD" code="247472004" codeSystem="2.16.840.1.113883.6.96"
                    codeSystemName="SNOMED CT" displayName="Hives" />
        <entryRelationship typeCode="MFST">
            <observation classCode="OBS" moodCode="EVN">
                <code code="84100007" codeSystem="2.16.840.1.113883.6.96"
                    codeSystemName="SNOMED CT" displayName="history taking (procedure)" />
                <value xsi:type="CD" code="91936005" codeSystem="2.16.840.1.113883.6.96"
                    codeSystemName="SNOMED CT" displayName="Allergy to penicillin" />
            </observation>
        </entryRelationship>
    </observation>
</entry>
```

Then: supply context

```
<!--
****************************************************
  CDA Header
****************************************************
-->
<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>
                <id extension="M345" root="2.16.840.1.113883.3.933" />
            </providerOrganization>
        </patient>
    </recordTarget>
```
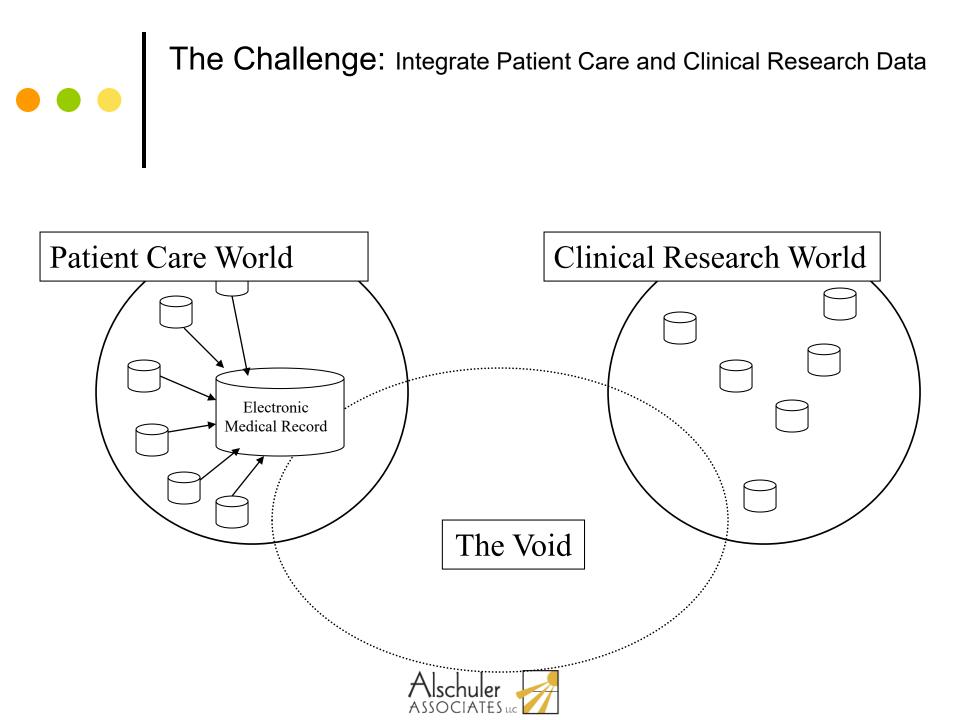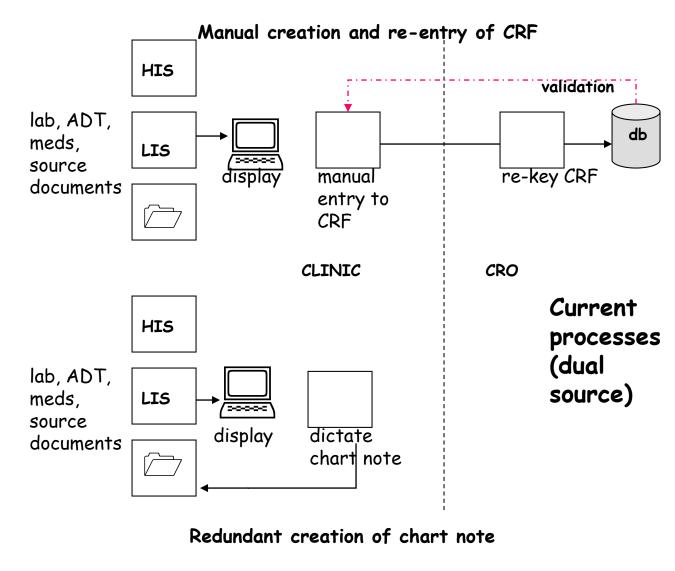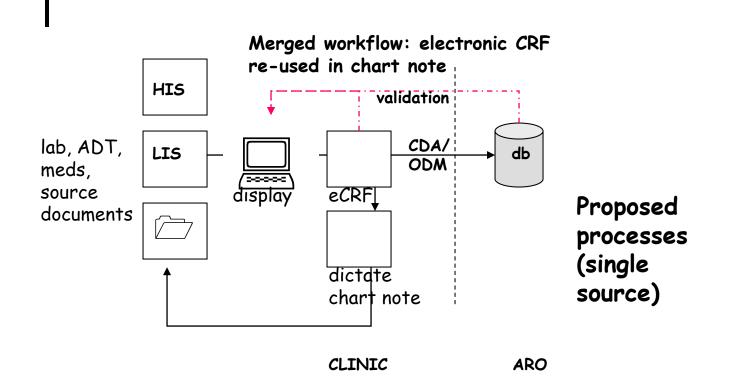
Who is the subject?

Target: RIM-defined

Id: local

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

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The Challenge: Integrate Patient Care and Clinical Research Data

Patient Care World

Clinical Research World

Electronic
Medical Record

The Void

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)

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CDA in Starbrite Trial

Manual creation and re-entry of CRF

HIS	

lab, ADT, meds, source documents

LIS → display → manual entry to CRF ——— re-key CRF → db

validation

CLINIC   CRO

Current processes (dual source)

HIS

lab, ADT, meds, source documents

LIS → display   dictate chart note

Redundant creation of chart note

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CDA in Starbrite Trial

Merged workflow: electronic CRF re-used in chart note

HIS

LIS

lab, ADT, meds, source documents

display

validation

eCRF

CDA/ODM

db

dictate chart note

CLINIC

ARO

Proposed processes (single source)

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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

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Where do we start?

- Enter the data once, then reuse

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

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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

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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)

Dictaphone PROGRESS NOTE - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address: http://nlpr03:8080/nlpr/RID/IHERetrieveDocument?requestType=DOCUMENT&preferredContentType=application/hl7-cda-level-

Dictaphone PROGRESS NOTE

PRF:
Date: February 21, 2002
Patient: Chris Preza   MRN: 4010049   Sex:

PROGRESS NOTE

- CHIEF COMPLAINT: ::

  Palpitations and ringing in the ears.

- SUBJECTIVE: ::

  This otherwise healthy 43-year-old female, whom I generally see once or twice yearly, presents today with complaints of palpitations for 2 to 3 weeks and most recently, mild intermittent ringing in both ears. She suspects this may be related to an OTC preparation she started taking 3 months ago for nocturnal leg cramps. The preparation name on the bottle she brought in indicates it is Quinine sulfateUSP 300 mg tablets. Although she started on 1 tablet h.s., she had no relief one week and started on 2 tabs h.s. with subsequent relief of the leg cramps. Her symptoms started about 4 weeks after commencing the drug. She initially made no connection and tolerated the palpitations.

  About 2 weeks ago she started taking Tagamet 200 mg OTC for heartburn. Last week she began to notice mild intermittent tinnitus. She denies breathlessness, headaches, visual changes, nausea, rashes and dizziness. Her skipped beats not sustained, disappear with sleep and generally don't interrupt activity or work significantly, but she is definitely bothered by them. She also consumes 2 cups of caffeinated coffee each morning and has noted that she feels a little anxious at the end of the morning. She also since the palpitations are slightly more frequent at noon. She is pleased that her leg cramps disappeared and sleeps much better. The heartburn was also helped by the Tagamet. She is ambivalent about stopping the quinine, though concerned that the palpitations may get worse. She denies any recent illnesses, exposure to chemicals or major change in lifestyle.

Done   Local intranet

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CDA from Dictation

- narrative documents can be enhanced through natural language processing and use of templates with no disruption to the existing workflow

M*Modal view of "validation display"

Tagged content	Transcript of physician's words
Tobacco use None	Negative for tobacco use, but likes to have a glass wine on occasion.
Alcohol use Occasional	
Penicillin 250 mg. 1/day	On admission he was on penicillin 250mg a day and hydroxyurea 500mg twice a day.
Hydroxyurea 500 mg. 2/day	

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CDA from an EMR

Allscripts Touchworks

IHE

Eclipsys Remote Access - Microsoft Internet Explorer

File   Edit   View   Favorites   Tools   Help

Back ▾ ⚫ ▾ 🗷 🗎 🏠 | 🔍 Search ☆ Favorites ⚫ | 🖉 ▾ 🖫 🖃 ▾ ⚫

Address 🗎 http://localhost/RAS/DesktopDefault.aspx?&tabloc=1&tabindex=7&tabid=123   ▾ ➡ Go Links

Patient: LAWR

Birthdate: N   🗔 Viewer

Consultant: T   CI   🔲 Show VTB
                    Home ▾   Summaries   Problems

Care Record Summary - Microsoft Internet Explorer

File   Edit   View   Favorites   Tools   Help

Creation Date: February 16, 2006

Reas

Chie   http://66.78.214.22:8080 - Siemens XDS Viewer : TouchWorks Care Record Summary - Microsoft Internet Explorer

MCKNIGHT, LAWRENCE
Male PT #145831 MR #145831

Siemens Soarian (XML)

                http://66.78.214.22:8080 - Siemens XDS Viewer : Discharge Summary 2/15/2006 1:33:42 PM - Microsoft Internet Explorer

MCKNIGHT, LAWRENCE
Male PT #145831 MR #145831

Viewing document: Discharge Summary 2/15/2006 1:33:42 PM

Reas   Patient: LAWRENCE MCKNIGH   Siemens Soarian (PDF)   Adobe Rea
              Birthdate: May 20, 1966
Dr. S   Consultant: Timothy Weaver   al - Discharge Summary
imagi
              Reason for Visit   Patient Name: MCKNIGHT   , LAWRENCE   Admit Date: 02/13/2006 14:20
Hist
                 • visit for: follow-up exam   MRN: 145831   Discharge Date:
  •
              Chief Complaint   Birthdate: 05/20/1966   Dictated By: R Remote
Con
                 • back pain   Gender: Male   Attending MD:
  •
  •   Reason for Referral
              Dr. Saibabu: This appears to be muscular strain,   Final Diagnosis:
Aller
                                                                    Atypical Chest Pain
              History of Present Illness   CAD, s/p 3V CABG
                                                                   Hypertension
                 • lower back pain radiating to the right toes   Bipolar Disease
Export   Hx Stroke
                                                                   Hx Nephrolithiasis
                                                                   Hx Appendectomy

                                                                 Allergies:

HL7 Affiliates

Argentina

Spain

Switzerland

Australia

New Zealand

Taiwan

Canada

Brazil

Mexico

The Netherlands

China

Korea

Croatia

Japan

Czech Republic

Italy

Turkey

Denmark

Ireland

Finland

India

United Kingdom

France

Greece

Germany

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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

4. Customer gives a consent to the professional to look at the customer´references

8. Document content is presented to the professional

5. The professional chooses the reference for content retrieval and the request is sent to the respective adapter

3. Reference data is extracted from the headers and inserted into the SQL database

7. Document content is transformed into HTML using XSLT processor and XSL style sheet

2. FTP transfer of the headers once a day

XSL style sheets for presentation of the documents

DTDs for defining the document structures

1. All adapters provide the document headers for creation of the references for all customer encounters

6. Adapter retrieves the document from the operational system and sends it back

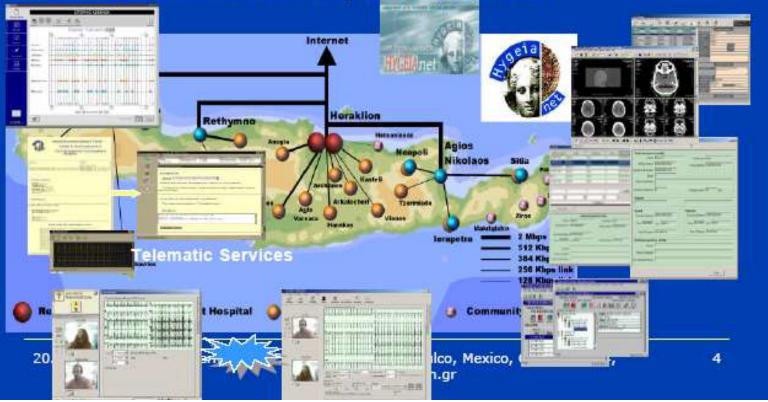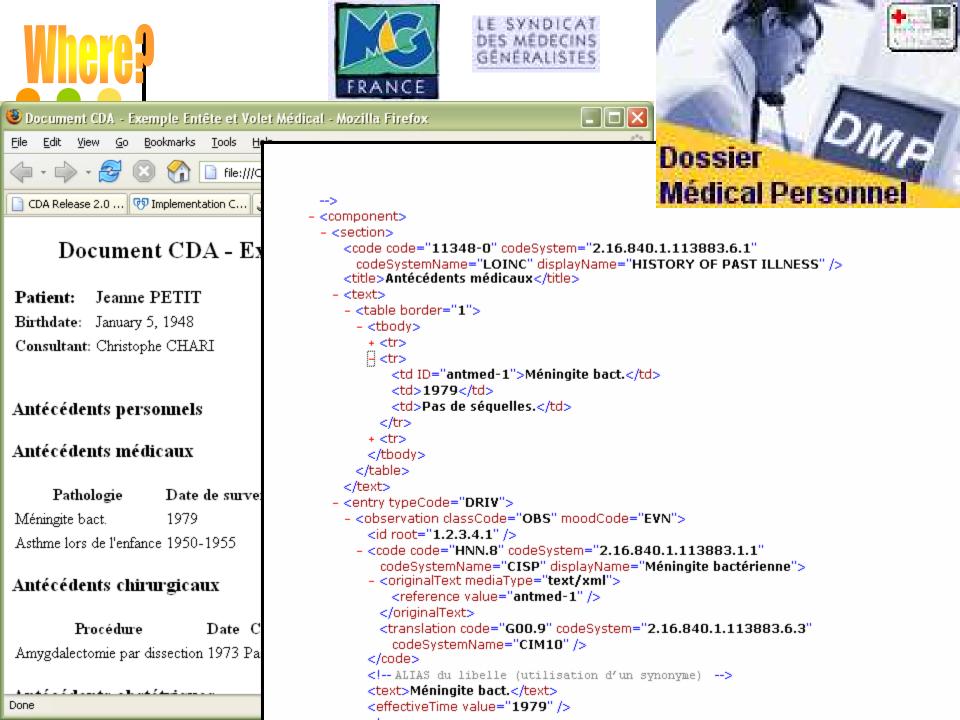Musti Multilab   Simuhe   (Pegasos)   Sairaala-Seniori   Pallas   (Oberon etc...)

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
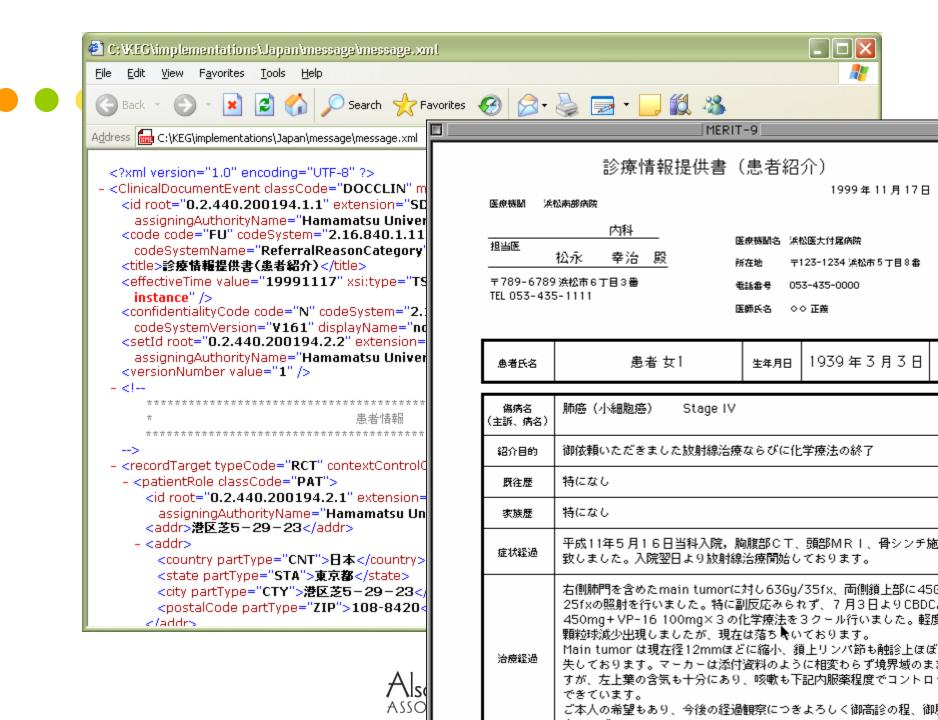http://www.hl7.de/iamcda2004/fprogram.html

Where?

MG FRANCE — LE SYNDICAT DES MÉDECINS GÉNÉRALISTES

Dossier Médical Personnel — DMP

Document CDA - Exemple Entête et Volet Médical - Mozilla Firefox

File Edit View Go Bookmarks Tools Hel

file:///C

CDA Release 2.0 ...   Implementation C...

Document CDA – Ex

Patient: Jeanne PETIT
Birthdate: January 5, 1948
Consultant: Christophe CHARI

Antécédents personnels

Antécédents médicaux

Pathologie	Date de surve
Méningite bact.	1979
Asthme lors de l'enfance	1950-1955

Antécédents chirurgicaux

Procédure	Date	C
Amygdalectomie par dissection	1973	Pa

Done

```xml
-->
- <component>
  - <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>
          - <tr>
              <td ID="antmed-1">Méningite bact.</td>
              <td>1979</td>
              <td>Pas de séquelles.</td>
            </tr>
          + <tr>
          </tbody>
        </table>
      </text>
    - <entry typeCode="DRIV">
      - <observation classCode="OBS" moodCode="EVN">
          <id root="1.2.3.4.1" />
        - <code code="HNN.8" codeSystem="2.16.840.1.113883.1.1"
            codeSystemName="CISP" displayName="Méningite bactérienne">
          - <originalText mediaType="text/xml">
              <reference value="antmed-1" />
            </originalText>
            <translation code="G00.9" codeSystem="2.16.840.1.113883.6.3"
              codeSystemName="CIM10" />
          </code>
          <!-- ALIAS du libelle (utilisation d'un synonyme) -->
          <text>Méningite bact.</text>
          <effectiveTime value="1979" />
```

CDA Italian Style

Where?

HISTORY OF SYMPTOMS and DISEASES

```xml
<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="III" displayName="Anamnesi radiologica ">
</translation>
</code>
<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>
```

Ing. Paolo Marcheschi

HL7 Italia Technical Ch

co-chair HL7-CDA, HL

IHE Cardiology Projec

Ir

File Edit View Favorites Tools Help

Back Search Favorites

Address C:\KEG\implementations\Japan\message\message.xml

```xml
<?xml version="1.0" encoding="UTF-8" ?>
- <ClinicalDocumentEvent classCode="DOCCLIN" m
    <id root="0.2.440.200194.1.1" extension="SD
      assigningAuthorityName="Hamamatsu Univer
    <code code="FU" codeSystem="2.16.840.1.11
      codeSystemName="ReferralReasonCategory"
    <title>診療情報提供書（患者紹介）</title>
    <effectiveTime value="19991117" xsi:type="TS
      instance" />
    <confidentialityCode code="N" codeSystem="2.
      codeSystemVersion="V161" displayName="no
    <setId root="0.2.440.200194.2.2" extension=
      assigningAuthorityName="Hamamatsu Univer
    <versionNumber value="1" />
- <!--
        *******************************************
        *                             患者情報
        *******************************************
  -->
- <recordTarget typeCode="RCT" contextControlC
  - <patientRole classCode="PAT">
      <id root="0.2.440.200194.2.1" extension=
        assigningAuthorityName="Hamamatsu Un
      <addr>港区芝5-29-23</addr>
    - <addr>
        <country partType="CNT">日本</country>
        <state partType="STA">東京都</state>
        <city partType="CTY">港区芝5-29-23</
        <postalCode partType="ZIP">108-8420<
      </addr>
```

MERIT-9

診療情報提供書（患者紹介）

1999年11月17日

医療機関　浜松南部病院

内科

担当医　松永　幸治　殿

〒789-6789 浜松市6丁目3番
TEL 053-435-1111

医療機関名　浜松医大付属病院

所在地　〒123-1234 浜松市5丁目8番

電話番号　053-435-0000

医師氏名　○○ 正義

患者氏名	患者 女1	生年月日	1939年3月3日

傷病名（主訴、病名）	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，胸腹部CT、頭部MRI、骨シンチ施致しました。入院翌日より放射線治療開始しております。
治療経過	右側肺門を含めたmain tumorに対し63Gy/35fx、両側鎖上部に450 25fxの照射を行いました。特に副反応みられず、7月3日よりCBDC 450mg+VP-16 100mg×3の化学療法を3クール行いました。軽度 顆粒球減少出現しましたが、現在は落ちいております。 Main tumor は現在径12mmほどに縮小、鎖上リンパ節も触診上ほぼ 失しております。マーカーは添付資料のように相変わらず境界域のま すが、左上葉の含気も十分にあり、咳嗽も下記内服薬程度でコントロ 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高診の程、御

Health Level Seven

- Potential to leverage large amounts of clinical data
- It's not really *all* about the data...

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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

EHR slides by:
Donald T. Mon, PhD
Vice President, Practice Leadership
American Health Information
Management Association

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The Functional Model

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

Direct Care		
	C1.0	Care Management
	C2.0	Clinical Decision Support
	C3.0	Operations Management and Communication
Supportive	S1.0	Clinical Support
	S2.0	Measurement, Analysis, Research, Reporting
	S3.0	Administrative and Financial
Information Infrastructure	I 1.0	EHR Security
	I 2.0	EHR Information and Records Management
	I 3.0	Unique identity, registry, and directory services
	I 4.0	Support for Health Informatics & Terminology Standards
	I 5.0	Interoperability
	I 6.0	Manage business rules
	I 7.0	Workflow

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

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Key Distinctions in the Model

- System vs. user action
  - What a system can do in an automated fashion
  - <u>Providing the ability</u> 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

Structure & Key Distinctions Identified

ID	Name	Statement	Description	Conformance Criteria
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

Key Distinctions (cont.)

ID	Name	Statement	Description	Conformance Criteria
DC.1.9.3	**Manage order sets**	**Provide order sets based on provider input or system prompt.**	**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.**	1. **The system** SHALL **support presentation of order set(s))** 2. **The system** SHALL **support modification of order sets at the patient level** 3. **The system** SHALL **record each component of an order set that is ordered.** 4. **The system** SHOULD **provide an alert where orders may conflict** 5. **The system** SHALL **store and manage health information (I.2.5.1 and I.2.5.2)**

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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

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

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

Non-Member Participation
Non-members can register and
participate in most activities,
including some ballots

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Committees & Special Interest Groups
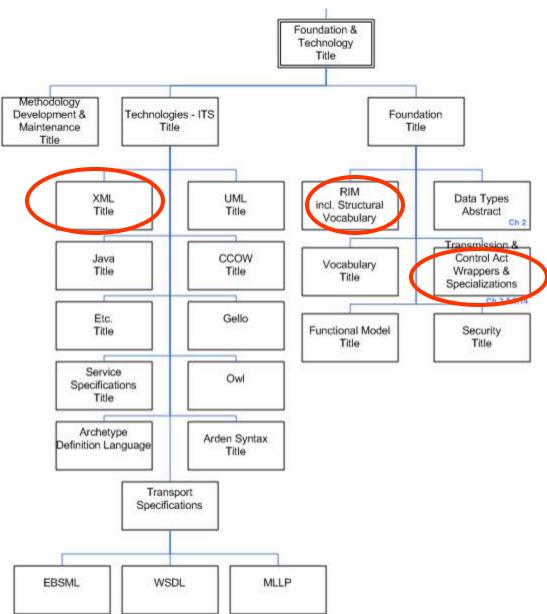
- Anatomic Pathology
- Anesthesia
- Architecture Review Board**
- Arden Syntax
- Attachments
- Cardiology
- Common Message Element Types***
- CCOW*
- Clinical Decision Support*
- Clinical Genomics
- Clinical Guidelines
- Community Based Health Services
- Conformance
- Infrastructure & Messaging*
- Education**
- 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
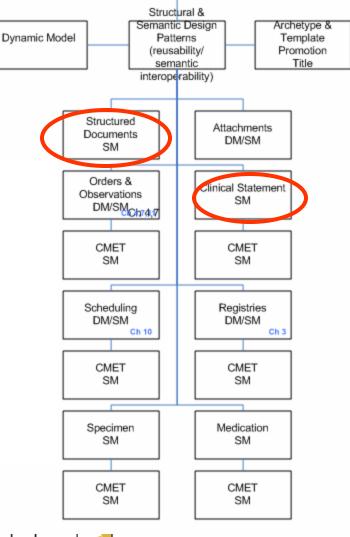
- Pediatric Data Standards
- Personnel Management*
- Pharmacy
- Process Improvement**
- Public Health & Emergency Response
- Publishing**
- Regulated Clinical Research Information Management (RCRIM)* (formerly Clinical Trials)
- Scheduling & Logistics*
- Security*
- Service Oriented Arch.
- Structured Documents*
- Technical Steering Committee**
- Templates
- Tooling**
- Vocabulary*
- XML

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

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As of 06/06

Organization: Strategic view

HL7 Membership

Board of Directors

CEO

Affiliate Relations

External Partnerships SDO's, Government, etc

Operations
COO

Technical Directorate
CTO, Technical Advisory Committee, technical staff

Sales (Revenue Production)

Marketing (Sales Support)

Production (Document Publication, Web Publication, Technical Editors, Tooling, etc.)

Project Management (Owns the delivery of the projects—tracks and coordinates deliverables from product management to publishing)

Product Management (Product Planning, Revenue Planning, Business Cases, Harmonization, Authoring, Content Editing)

Public Relations

Product Marketing

Membership

Meetings

Tutorials

Documents

Grants

Donations

Tooling Rollout (Educational/Support Training)

V2 Message Product Manager

V3 Message Product Manager

V3 Documents Product Manager

Other Product Managers

Foundation & Technologies Chairs

Structure & Semantic Design Chairs

Domain Expert Chairs

Organization

• Foundation
& Technology

Organization

- Structure & Semantic design patterns

Dynamic Model	Structural & Semantic Design Patterns (reusability/ semantic interoperability)	Archetype & Template Promotion Title

Structured Documents SM

Attachments DM/SM

Orders & Observations DM/SM Ch 4,7

Clinical Statement SM

CMET SM

CMET SM

Scheduling DM/SM Ch 10

Registries DM/SM Ch 3

CMET SM

CMET SM

Specimen SM

Medication SM

CMET SM

CMET SM

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Organization

- Domains (1 of 2)

Domain Interests (problem space) requirements

<<RIM Str Voc>> Archetypes

<<RIM Str Voc>> Templates

Laboratory

Pharmacy Title

Genomics Title

General Decision Support Title

Image Management Title

EHR Title

Consent Title

Government (Global)

Medical Records Title — Ch 9

Financial Management Title — Ch 6

Materials Management Title

Patient Administration Title — Ch 3

Personel Management Title — Ch 15

Emergency Response

Public Health

Clinical Research Title

RCRIM Title

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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

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Patient Safety virtual tour

HL7-IHE Demonstration

HIMSS 2004

Patient Safety

FDA, Pharma revise SPL

Patient Safety

Decision Support, Drug Interactions

Adobe
Berdy Medical
Carefx
CommerceNet
DCRI
Dictaphone
Digital Infuzion
Eclipsys
Epic
GE Medical Systems
Heartlab
IBM
INFINITT
Kodak
Kryptiq
Microsoft
Misys
Mortara
NIST
Philips Medical Systems
Raining Data
Sentillion
Siemens
SNOMED
XIMIS

Lab

Broker

PCP

FDA

ICU

Hospital

Pharma

ED

HL7 Standards
aECG
Arden
CCOW
CDA
ODM
RIM
SDM
SPL
V2
V3
IHE Profiles
CT
EUA
PIX
PSA
RID
SWF

Patient safety officer alerts FDA; FDA alerts Pharma.

Patient Safety
Decision Support, Drug Interactions

Adobe
Berdy Medical
Carefx
CommerceNet
DCRI
Dictaphone
Digital Infuzion
Eclipsys
Epic
GE Medical Systems
Heartlab
IBM
INFINITT
Kodak
Kryptiq
Microsoft
Misys
Mortara
NIST
Philips Medical System
Raining Data
Sentillion
Siemens
SNOMED
XIMIS

Lab

PCP

ACP

FDA

Hospital

Hospital

Pharma

HL7 Standards
aECG
Arden
CCOW
CDA
ODM
RIM
SDM
SPL
V2
V3
IHE Profiles
CT
EUA
PIX
PSA
RID
SWF

FDA publishes alert; ACP publishes alert;
MLM updates

Patient Safety

Decision Support, Drug Interactions

PCP queries ED system for patient data

Patient Safety
Decision Support - Drug Interactions

FDA publishes alert; ACP revises PIER Guidelines

Patient Safety
Decision Support, Drug Interactions

- Atrial Fibrillation
- Chronic Urticaria
- Congenital Heart Disease in Pregnancy
- Coronary Artery Disease in Women
- Deep Venous Thrombosis
- Drug Prescribing in Pregnancy

d test MLM

Thank you!
Questions?
Liora@alschulerassociates.com