The HL7 Clinical Document Architecture

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Liora Alschuler

- Consultant in healthcare IT 1997–present
  - Founded consulting firm in 2005
  - Background in electronic text, industry analyst with Seybold Publications, xml.com

- Volunteer standards work
  - Health Level Seven Board of Directors (2005–2008)
  - Co–chair Structured Documents Technical Committee
  - Co–editor Clinical Document Architecture (CDA)
  - Co–editor, Continuity of Care Document (CCD), H&P, Consult, Op Note

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- Standards–based solutions for vendors, providers, standards developers
- CDA Implementations:
  - Military Health System
    - Enterprise–wide documents, files, images (DFIEA)
  - Centers for Disease Control and Prevention
    - Implementation Guide for Healthcare Associated infection Reports for the National Healthcare Safety Network
  - North American Association of Central Cancer Registries
    - Implementation Guide for cancer abstracts
  - Department of Health and Human Services
    - Supporting the Health IT Standards Panel (HITSP); Health Information Standards for Privacy and Confidentiality (HISPC); Assistant Secretary for Planning and Evaluation, prototype of the Minimum Data Set (MDS)
  - CDA4CDT
    - Co–founder & Project Management
  - Private, commercial clients: Fortune 100 and startups
Health Level Seven (HL7)

- Non-profit ANSI Standards Development Organization
- 20 years old
- 2000+ members
  - individual, corporate
- 30 affiliates
  - US affiliate in near future
- “A model community”: building standards to a single information model
HL7 Standards

• Version 2.x
• Version 3
  – Messages
  – CDA: Clinical Document Architecture
• Others
  – EHR Functional Model
  – CCOW: Clinical Context Object Working Group (= Desktop Integration)
  – Arden Syntax (Decision Support)
  – ...
HL7 V2 message

• Series of message definitions
• Syntax proprietary to HL7 (EDI–like)
• Following same patterns
• 2.6 most recent: continual evolution
• Widespread use for enterprise integration
HL7 Version 3

• Single Reference Information Model
CDA: Clinical Document Architecture

- An HL7 Version 3 specification
  - ANSI/HL7 CDA R1.0–2000
  - ANSI/HL7 CDA R2.0–2005
- Created & maintained by HL7 Structured Documents Technical Committee (SDTC)
- A specification for document exchange using
  - Extensible Markup Language (XML)
  - the HL7 Reference Information Model (RIM)
  - Version 3 methodology
  - and vocabulary (SNOMED, ICD, local,...)
The CDA Defined

CDA Release 2, section 2.1:

A clinical document ... has the following characteristics:

- Persistence
- Stewardship
- Potential for authentication
- Context
- Wholeness
- Human readability

- therefore, CDA documents are *not*:
  - data fragments, unless signed
  - birth–to–death aggregate records
  - electronic health records
CDA: A Document Exchange Specification

• This is a CDA
• and this
• and this
• and this
• and this
• and this
How the CDA is developed: *just enough* HL7 Development Framework

Reference Information Model

RMIM

- subset of RIM
- copy, rename
- constrain

XML Schema

Hierarchical Description

- linearization
- additional constraints

- algorithm
CDA = Header + Body

- **CDA Header**
  - Metadata required for document discovery, management, retrieval

- **CDA Body**
  - Clinical report
    - Discharge Summary
    - Care Record Summary
    - Progress Note
    - H&P
    - Public health report
  - … any content that carries a signature
CDA Header

- The header describes:
  - The document itself (unique ID, document type classification, version)
  - Participants (providers, authors, patients...)
  - Document relationships (to orders, other documents...)

- Metadata sufficient for document management
  - Medical records management
  - Document management
  - Registry/repository
  - Record locator service
  - Store, query, retrieve
• Any type of clinical document
  • Discharge Summary
  • Care Record Summary
  • Progress Note
  • H&P
• Public health report
  – … potential for signature
• Format: non-XML...tif, PDF, HTML,
• Format: XML
  – Paragraph
  – List
  – Table
  – Caption
  – Link
  – Content
  – Presentation

Vital Signs

Date / Time | April 7, 2000 14:30 | April 7, 2000 15:30
Height | 177 cm (69.7 in)
Weight | 194.0 lbs (88.0 kg)
BMI | 28.1 kg/m²
BSA | 2.05 m²
Temperature | 36.9 °C (98.5 °F) | 36.9 °C (98.5 °F)
Pulse | 86 / minute | 84 / minute
Rhythm | Regular | Regular
Respirations | 16 / minute, unlabored | 14 / minute
Systolic | 132 mmHg | 135 mmHg
Diastolic | 88 mmHg | 88 mmHg
Position / Cuff | Left Arm | Left Arm

Skin Exam

Erythematous rash, palmar surface, left index finger

required
- Clinical statement: Model-based computable semantics
  - Observation
  - Procedure
  - Organizer
  - Supply
  - Encounter
  - Substance Administration
  - Observation Media
  - Region Of Interest
  - Act

```xml
<title>Past Medical History</title>
- <text>
  - <list>
    - <item>
      <content ID="a1">Asthma</content>
    </item>
  </list>
- <entry>
  - <observation classCode="COND" moodCode="EVN">
    <code code="39154008"
      codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT" display="clinical diagnosis"/>
    <effectiveTime value="1950"/>
    - <value xsi:type="CD" code="195967001"
      codeSystem="2.16.840.1.113883.6.96"
      codeSystemName="SNOMED CT" display="Asthma">
      - <originalText>
        <reference value="#a1"/>
    </value>
  </entry>
```

Optional
CDA: Incremental Semantic Interoperability

- Standard HL7 metadata
- Simple XML for point of care human readability
- RIM semantics for reusable computability ("semantic interoperability")
Investing in Information

• CDA can be simple
• CDA can be complex
• Simple encoding relatively inexpensive
• Complex encoding costs more
• You get what you pay for:
  – like charging a battery,
  – the more detailed the encoding
  – the greater the potential for reuse
CDA from Dictation

- narrative documents can be enhanced through natural language processing and use of templates with no disruption to the existing workflow
eForms: Microsoft InfoPath
CDA from an EMR
Primary Use Cases

• access/portability/exchange
  – query/locate by patient, provider, practitioner, setting, encounter, date
  – access distributed information through common metadata
  – document management

• integration
  – transcription systems
  – EHR records

• re-use/derivative data
  – summaries, reports
  – decision support
Past Medical History

- Asthma
- Hypertension
- Osteoarthritis

Prior dx #a3: Osteoarthritis
Target Site: Knee joint, right

Level 1: Human readable
Level 2: Machine processible
Level 3: Machine processible
Example

Diagnosis of contact dermatitis on finger.

<observation classCode="COND" moodCode="EVN">
  <code code="14657009"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED CT"
    displayName="Established diagnosis"/>
  <effectiveTime value="200004071530"/>
  <value xsi:type="CD" code="40275004"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED CT"
    displayName="Contact dermatitis">
    <translation code="692.9"
      codeSystem="2.16.840.1.113883.6.2"
      codeSystemName="ICD9CM"
      displayName="Contact Dermatitis, NOS"/>
  </value>
  <targetSiteCode code="56213003"
    codeSystem="2.16.840.1.113883.6.96"
    codeSystemName="SNOMED CT"
    displayName="Skin of finger"/>
</observation>
- Hives as an allergic reaction to penicillin
CDA Level 3

<observation classCode="OBS" moodCode="EVN">
<templateId root="2.16.840.1.113883.10.20.1.18" />
<!-- Alert observation template -->
{id root="4adc1020-7b14-11db-9fe1-0800200c9a66" />
<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
<statusCode code="completed" />
<value xsi:type="CD" code="282100009" codeSystem="2.16.840.1.113883.6.96" display="Adverse reaction to substance" />
<participant typeCode="CSM">
<participantRole classCode="MANU">
<playingEntity classCode="MMAT">
<code code="70618" codeSystem="2.16.840.1.113883.6.88" display="Penicillin" />
</playingEntity>
</participantRole>
</participant>
<entryRelationship typeCode="MFST" inversionInd="true">
<observation classCode="OBS" moodCode="EVN">
<templateId root="2.16.840.1.113883.10.20.1.54" />
<!-- Reaction observation template -->
<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4" />
<statusCode code="completed" />
<value xsi:type="CD" code="247472004" codeSystem="2.16.840.1.113883.6.96" display="Hives" />
</observation>
</entryRelationship>... </observation>
Siemens Soarian (XML)

Siemens Soarian (PDF)

**Patient:** MCKNIGHT, LAWRENCE
**MRN:** 145831
**Admit Date:** 02/13/2006 14:20
**Discharge Date:**

**Chief Complaint:**
- back pain

**Reason for Visit:**
- visit for follow-up exam

**Reason for Referral:**
Dr. Saababu: This appears to be muscular strain.

**History of Present Illness:**
- lower back pain radiating to the right toes

**Allergies:**
- Atrial fibrillation
- Hypertension
- Bipolar Disease
- Stroke
- Hemiplegia

**Final Diagnosis:**
- Atrial fibrillation
- Hypertension
- Bipolar Disease
- Stroke
- Hemiplegia

**Gender:** Male

**Birthdate:** 05/20/1966

**History:**
- Hypertension
- Bipolar Disease
- Stroke
- Hemiplegia
- Appendectomy
Current Implementation: US

- Mayo Clinic
  - Initiated in 1999
  - About 50,000 documents each week
  - Clinical documents: Most important capital asset
- New York Presbyterian
  - “CDA Philosophy”: mix of fielded data and narrative
  - Best format for information mining and aggregation across applications
  - Clinical notes contain critical information in narrative
  - 1/3 of all discharges summaries
- Military Health System
  - Documents, Files, Images Enhanced AHLTA (DFIEA)
    - Enterprise-wide document management
    - Web-services gateway to VA, civilian providers
  - MHS/VHA Bi-direction Health Information Exchange
  - Enterprise Wide Referrals and Authorizations
- University of Pittsburgh Medical Center
  - Narrative notes using speech recognition, NLP
  - Linking radiology reports with PACS-rendered image
- Other
  - Duke, Kaiser, VA, Trinity, Partners, Vanderbilt, Geisinger, Ochsner...
In the world?

CDA: fundamental to national/regional exchange

- Germany  
  SCIPHOX
- Finland  
  Aluetietojärjestelmä
- Greece  
  HYGEIAnet/WebOnColl
- Japan  
  MERIT–9 (MML)
- Canada  
  e–MS
- France  
  Dossier Médical Personnel
- Italy  
  TeleMed Escape
- US  
  CHI, HITSP, IHE
- Argentina  
  Hosp. Italiano de Buenos Aires
- England  
  National Health Service
- Netherlands  
  NICTIZ
In the world?

Major pilots, experimental work
- Korea
- Mexico
- Israel
- New Zealand
- Australia
- Estonia
- Wales
- Spain
CDA: How to Create

- Creating CDA documents
  - scan or text file
  - transcription
  - eForms
  - desktop applications
  - EHR
  - DICOM Structured Report transform
CDA: How to Manage

- Clinical Data Repository?
- Custom Database?
- Good old file system?
- Document management system?
- Personal health record?
CDA: How to Distribute

- There are many ways to distribute CDA documents.
  - Fax
  - Sneaker-net
  - Email
  - X12
  - HL7 messaging
  - Custom Web Services (SOAP, XML-RPC, REST)
  - XDS
CDA: for the full patient record

HL7–balloted Implementation Guides:

- Continuity of Care Document (CCD) ASTM complete
- History & Physical (H&P) CDA4CDT complete*
- Consult Note CDA4CDT complete*
- Healthcare Associated Infection CDC/NHSN complete*
- Operative Note CDA4CDT May ’08**
- Diagnostic Imaging Reports DICOM May ’08**
- Personal Health Monitor Report Continua May ’08**
- PHR2PHR Summary AHIP/BCBSA May ’08**
- Quality Reporting Document Arch QRDA Sept ’08**
- others in development:
  - anesthesiology, anatomic pathology, lab, long term care, pediatrics

- * = will be published shortly
- ** = first ballot
CDA: for the full patient record

US Dept. of Health & Human Services:
- Health Information Technology Standards Panel (HITSP) Summary, Meds, Lab 2007– Quality, ED 2008
- HIPAA Claims Attachments HL7/X12 NPRM/complete
- Minimum Data Set (MDS) HHS proof of concept 08

Pilots/Prototypes:
- North American Association of Central Cancer Registries (NAACCR) NAACCR summer ’08
- Quality Reporting Document Architecture (QRDA) summer ‘08
  - Alliance for Pediatric Quality, Children's Hospital Corporation of America, HL7 Pediatric Data Standards SIG
- DICOM SR 2 CDA Transformation Guide DICOM summer ’08
- Integrating the Healthcare Enterprise IHE HIMSS 08
  - 7 Patient Care Coordination profiles using CCD
Summary of CDA Use Cases

- standardized metadata
- document persistence
- document independent of transport
- supported by heterogeneous tool set, users retain choice of tools
- integrates diverse, distributed applications
- integrate XML and non-XML sources with common metadata
- mixing of data and narrative (choice of usage)
- access across distributed systems
- low point of entry, ability to scale up
- supports shared care
- knowledge integration: links to other documents
- outcomes research
- retains full document context
- continuity with paper world
How can you get involved?

• Participate in design review
  – through HL7 Structured Documents TC
  – weekly calls: Thursday, 10am ET
  – f2f 3x/year

• Participate in the ballot
  – as HL7 member or non-member

• Encourage implementation
  – within professional society
  – within practice group
More Information

- at HIMSS: Tuesday, 4pm, HERE: Continuity of Care Document
- Wednesday, 3:15, HERE: What’s New with CDA?
- Wednesday, 5:30, HERE: The CCD in National and International Activities

- JAMIA
- XML http://www.w3.org/TR/xml
- Schematron http://www.schematron.com/

- www.AlschulerAssociates.com
  - these slides will be posted by ... 3/7/08
  - Quick Start Guides
  - CDA Validator
  - CDA Gallery
  - liora@alschulerassociates.com
Thank you!

Questions?