Clinical Document Architecture for Common Document Types

PEHRC
June 18, 2007
Liora Alschuler
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
Alschuler Associates, LLC

- Consultants in standards-based solutions for healthcare information working with vendors, providers, standards developers
- Clients
  - Military Health System
    - Enterprise-wide documents, files, images (DFIEA)
  - Centers for Disease Control and Prevention
    - Implementation Guide for infectious disease reporting (NHSN)
  - North American Association of Central Cancer Registries
    - Implementation Guide for cancer abstracts
  - Department of Health and Human Services
    - Subcontracts on Health IT Standards Panel (HITSP) and Health Information Standards for Privacy and Confidentiality (HISPC)
  - American Hospital Association
    - Use case development for healthcare IT standards initiative
  - CDA4CDT
    - Co-founder & Project Management
  - Private, commercial clients: Fortune 100 and startups

- [www.alschulerassociates.com](http://www.alschulerassociates.com)
• HL7
• CDA
  – what is it
  – where is it used
• CCD
• CDA4CDT
  – & the PEHRC
Health Level Seven

• 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 Steering Divisions

**Foundation & Technologies**
- Implementable Technology Specifications
- Implementation/Conformance
- Infrastructure & Messaging
- Java
- Modeling & Methodology
- Security
- Service Oriented Architecture
- Templates
- Vocabulary

**Structure & Semantic Design**
- Clinical Context Object Workgroup
- Clinical Decision Support
- Electronic Health Record
- Financial Management
- Genomics
- Orders & Observations
- Patient Administration
- Scheduling & Logistics
- Structured Documents

**Domain Experts**
- Anesthesiology
- Attachments
- Cardiology
- Clinical Guidelines
- Community Based Collaborative Care
- Emergency Care
- Government Projects
- Health Care Devices
- Imaging Integration
- Laboratory
- Patient Care
- Patient Safety
- Pediatrics Data Standards
- Public Health Emergency Response
- Pharmacy
- Regulated Clinical Research Information Management
CDA: A Document Exchange Specification

- This is a CDA
- and this
- and this
- and this
- and this
- and this
- and this
The CDA document 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 Design Principles

• priority is patient care, other applications facilitated
• minimize technical barriers to implementation
• promote longevity of clinical records
• scoped by exchange, independent of transfer or storage
• enable policy-makers to control information requirements
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 who presents with a history of asthma in his teens. He was hospitalized once and has been able to be weaned off steroids.

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

Header

- Readable: required
- Computable: optional
CDA Header: Metadata

• Identify
  – Patient
  – Provider
  – Document type...

• Sufficient for
  – Medical records management
  – Document management
  – Registry/repository
  – Record locator service
  – Store, query, retrieve

---

**Good Health Clinic Consultation Note**

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

**MRN:** 12345
**Sex:** Male
**Created On:** April 7, 2000
CDA Body: Human-readable report

- Any type of clinical document
  - H&P
  - Consult
  - Op note
  - Discharge Summary...

- Format: tif, PDF, HTML, XML:
  - Paragraph
  - List
  - Table
  - Caption
  - Link
  - Content
  - Presentation

Vital Signs

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

Skin Exam

Erythematous rash, palmar surface, left index finger.
CDA Body: Machine Processible

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

```
<title>Past Medical History</title>
- <text>
  - <list>
    - <item>
      <content ID="a1">Asthma</content>
    </item>
    + <item>
    + <item>
  </list>
</text>
- <entry>
  - <observation classCode="COND" moodCode="EVN"/>
```
CDA: Incremental Semantic Interoperability

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

```xml
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD02" />
<templateId root="2.16.840.1.113883.3.27.1776" />
```

**History of Present Illness**

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

**Past Medical History**

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

**Medical History**

- Family history
- Social history
- Review of systems
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
CDA for Information Exchange in the US

- Recommended by Health Information Technology Standards Panel (HITSP) work groups
- CMS Notice of Proposed Rule Making
  - Claims attachments using CDA + X12
  - First pilot concluded, others underway
- Widespread vendor adoption:
  - Integrating the Healthcare Enterprise
  - CDA4CDT
  - Other
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**
  - Kaiser, Trinity, Partners, Ochsner...
## CDA for Information Exchange

- **IHE choice for Medical Summaries: 2006**

<table>
<thead>
<tr>
<th>Company</th>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>MediNotes</td>
<td>MediNotes e</td>
</tr>
<tr>
<td>NextGen Healthcare Information Systems</td>
<td>NextGen EMR</td>
</tr>
<tr>
<td>AllScripts</td>
<td>Touchworks EHR</td>
</tr>
<tr>
<td>GE Healthcare</td>
<td>Centricity® Enterprise Solution (formerly Carecast)</td>
</tr>
<tr>
<td>Philips Medical Systems</td>
<td>Xtenity</td>
</tr>
<tr>
<td>McKesson</td>
<td>Horizon Ambulatory Care</td>
</tr>
<tr>
<td>CapMed/IBM</td>
<td>Personal HealthKey</td>
</tr>
<tr>
<td>Eclipsys</td>
<td>Sunrise</td>
</tr>
<tr>
<td>Medical Informatics Engineering</td>
<td>Webchart</td>
</tr>
<tr>
<td>Dictaphone</td>
<td>Enterprise Workstation</td>
</tr>
<tr>
<td>Epic Systems</td>
<td>EpicCare</td>
</tr>
<tr>
<td>GE Healthcare</td>
<td>Centricity® Physician Office</td>
</tr>
<tr>
<td>Misys Healthcare Systems</td>
<td>Misys Connect</td>
</tr>
<tr>
<td>Siemens</td>
<td>Soarian</td>
</tr>
</tbody>
</table>
Patient: MCKNIGHT, LAWRENCE
Birthdate: May 20, 1966
Consultant: Timothy Weaver

Reason for Visit
- visit for: follow-up exam

Chief Complaint
- back pain

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

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

Final Diagnosis:
- Atypical Chest Pain
- CAD, s/p 3VCABG
- Hypertension
- Bipolar Disease
- Hx Stroke
- Hx Nephrolithiasis
- Hx Appendectomy

Allergies:
- NSAID
CDA for Information Exchange

- IHE choice for profiles: 2007

<table>
<thead>
<tr>
<th>XPHR</th>
<th>XDMS - Referral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capmed</td>
<td>Allscripts</td>
</tr>
<tr>
<td>GHNIHE</td>
<td>Bell/XWave</td>
</tr>
<tr>
<td>Nextgen</td>
<td>Epic</td>
</tr>
<tr>
<td>Blueware</td>
<td>GE</td>
</tr>
<tr>
<td>Capmed</td>
<td>Medinotes</td>
</tr>
<tr>
<td>CGI</td>
<td>MIE</td>
</tr>
<tr>
<td>CPSI</td>
<td>Misys</td>
</tr>
<tr>
<td>GE</td>
<td>Nextgen</td>
</tr>
<tr>
<td>IBM</td>
<td>Bell/XWave</td>
</tr>
<tr>
<td>Infinit</td>
<td>Eclipsys</td>
</tr>
<tr>
<td>MIE</td>
<td>Epic</td>
</tr>
<tr>
<td>Misys</td>
<td>GE</td>
</tr>
<tr>
<td>NoMoreClipboard</td>
<td>Medinotes</td>
</tr>
<tr>
<td>Quovadx</td>
<td>Medquist</td>
</tr>
<tr>
<td>SMS</td>
<td>MIE</td>
</tr>
<tr>
<td>Softmedical</td>
<td>Misys</td>
</tr>
<tr>
<td>Nextgen</td>
<td>Tiani Spirit</td>
</tr>
</tbody>
</table>

CDA & CCD

• IHE Profiles 2005-2007 based on the Care Record Summary (CRS)
  – first standard implementation guide for CDA
  – restricted to “level 2” to avoid competition w/CCR
  – covered a wider number of use cases
• IHE 2007-2008 will move to conform with CCD
• New CDA implementation guides also conform with CCD
The primary use case for the ASTM CCR is to provide a snapshot in time containing a summary of the pertinent clinical, demographic, and administrative data for a specific patient.

From its inception, CDA has supported the ability to represent professional society recommendations, national clinical practice guidelines, standardized data sets, etc.

From the perspective of CDA, the ASTM CCR is a standardized data set that can be used to constrain CDA specifically for summary documents.

The resulting specification is known as the Continuity of Care Document (CCD).
CCD maps the CCR elements into a CDA representation.

<table>
<thead>
<tr>
<th>CCR data element</th>
<th>CDA R2 correspondence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>Section</td>
</tr>
<tr>
<td>Result</td>
<td>Observation</td>
</tr>
<tr>
<td>DateTime</td>
<td>Observation / effectiveTime</td>
</tr>
<tr>
<td>IDs</td>
<td>Observation / id</td>
</tr>
<tr>
<td>Description</td>
<td>Observation / code</td>
</tr>
<tr>
<td>Status</td>
<td>Observation / statusCode</td>
</tr>
</tbody>
</table>
<Results>
  <Result>
    <CCRDataObjectID>2.16.840.1.113883.19.1</CCRDataObjectID>
    <DateTime>
      <Type>
        <Text>Assessment Time</Text>
      </Type>
      <ExactDateTime>200004071430</ExactDateTime>
    </DateTime>
    <Type>
      <Text>Hematology</Text>
    </Type>
    <Description>
      <Text>CBC WO DIFFERENTIAL</Text>
    </Description>
    <Code>
      <Value>43789009</Value>
      <CodingSystem>SNOMED CT</CodingSystem>
    </Code>
    <Status><Text>Final Results</Text></Status>
  </Result>
</Results>

<section>
  <code code="30954-2"
    codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"/>
  <title>Laboratory results</title>
  <text>
    CBC (04/07/2000): HGB 13.2; WBC 6.7; PLT 123
  </text>
  <entry>
    <observation classCode="OBS" moodCode="EVN">
      <id root="2.16.840.1.113883.19" extension="1"/>
      <code code="43789009"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT"
        displayName="CBC WO DIFFERENTIAL"/>
      <statusCode code="completed"/>
      <effectiveTime value="200004071430"/>
    </observation>
  </entry>
</section>
CDA Business Case

- **Gentle on-ramp to information exchange** - CDA is straight-forward to implement, and provides a mechanism for incremental semantic interoperability.

- **Improved patient care** - CDA provides a mechanism for inserting best practices and evidence-based medicine directly into the process of care (via the same “template” mechanism used to build CCD), thereby making it easier to do the right thing.

- **Lower costs** – CDA provides necessary information to coordinate care, reducing redundant testing and optimizing care delivery for quality and cost.

- **CDA hits the “sweet spot”** – CDA encompasses all of clinical documents. A single standard for the entire EHR is too broad. Multiple standards and/or messages for each EHR function may be difficult to implement. CDA is “just right”.

<((CDA4CDT!!))>
CDA beyond CCD

• Not everything we want to exchange is a summary
• Let’s look at what’s happening with development of other document types...
Other CDA content profile development

– Within HL7:
  • Clinical domains: anatomic pathology, imaging, lab, anesthesiology, pediatrics, long term care, others?
  • ASIG: HIPAA Attachments – adding dental

– Outside HL7: Public health & MDS
  • NAACCR Cancer abstracts (no HL7 ballot)
  • CDC Infectious Disease Reports (will be HL7 ballot)
  • MDS: soon, from HHS

– IHE
  • 2006: 1 content type built on HL7 CRS
  • 2007: 7 content types, some constrain CRS, others new
  • Current cycle:
    – updating all to be consistent with CCD
    – adding Discharge Summary

– CDA4CDT
CDA for Common Document Types

• Project initiated in January, 2007
  – M*Modal
  – AHDI (was AAMT)/MTIA
  – AHIMA

• Strong support from dictation / transcription and document management industries

• Cooperation/coordination with HL7, IHE, EHR vendors and providers
CDA4CDT Mission

• Develop CDA Implementation Guides (IGs) for common types of electronic healthcare documents
• Bring them through the HL7 ballot process
• Promote their use and adoption by healthcare organizations and health information exchange networks
Rationale

- Enlarge and enrich the flow of data into the electronic health record
- Speed the development of interoperable clinical document repositories
- Bridge the gap between narrative documents produced through dictation and the structured, computable records within an EHR
Why would physicians promoting the EHR have an interest in documents?

• Assumptions:
  – EMR/EHR is the solution
  – Documents are the problem

• Questions:
  – Are they mutually exclusive or complementary?
  – Can eDocuments bridge the gap?
Problems with Documents

- Can’t compute
- Can’t automate decision support
- Can’t validate conformance to content requirements
- And why are they still prevalent?
  - Nuanced & precise
  - Support human decision making
  - Retain current workflow
  - eDocuments support narrative & codes
    - multiple indices optimized for reimbursement, decision support, quality metrics, research
- Document management completes the EMR
Why encourage continued use of documents?

• Worst case:
  – no computable clinical data
  – no reuse
  – + information at the point of care

• Best case:
  – fully computable data to populate EHR

• Likely case:
  – section-level reuse (i.e. HPI pre-populates Discharge Summary) – we can do this now
  – gradual rise in semantic interoperability
Why not keep pushing for fully interoperable records?

- **Semantic interoperability** is hard
  - over 250,000 concepts in SNOMED CT
  - we can’t give up, we need safe computability
- Need information at the point of care
- Networks need data: self-sustaining networks have Big Data
  - Initial ROI will spur further investment
  - MTIA members process 300M documents/year
- Complex systems are built from simple systems
- CDA: *no loss of computability*
CDA4CDT: bridging the gap between EHRs and eDocuments

- CDA4CDT will:
  - Establish consensus on content using CDA eDocument format
  - Propagate support for CDA within the dictation/transcription industry
  - Create consistent electronic documents for importation into EMR, document repositories and health information exchanges
  - Increase EMR adoption

- Highest potential:
  - Massively increase amount of data in fledgling exchange networks because minimally disruptive to current workflow

- Defining success:
  - At least 25% of RFPs for transcription, EMRs, integration and information exchange cite compliance as a requirement
CDA4CDT

• **Scope**
  – Develop implementation guide for use across the industry
  – Rapid development, leverage framework, precedents
  – Establish section-level content, reuse section templates

• **H&P Timeline**
  – Initial draft *in 7 weeks*
  – Balloted as HL7 Draft Standard for Trial Use
    • March 26 ballot open, April 24 close
    • Ballot reconciliation approximately 5 weeks
    • Revised draft to ballot in August

• **Consult Note Timeline**
  – Target August 2007 initial ballot

• **Discharge Summary: Coordinating with IHE on publication**
  – Target publication fall 2007
Technical working group

- A focused group of working volunteers
  - prior knowledge of CDA
  - experience implementing CDA
  - familiarity with the current set of CDA implementation guides
- Participation is open at all stages of the ballot and ballot review process
- CDA4CDT retains no copyright of balloted material
H&P Method

Review precedents:
- ASTM's Standard Specifications for Healthcare Document Formats (E2184.02) (Headings and subheadings used in the healthcare industry and associated with specific report types)
- HL7/ASTM Continuity of Care Document (CCD)
- Clinical LOINC document and section codes
- HL7 ASIG CDA R2 Attachment for Clinical Notes
- HL7 Care Record Summary (CRS)
- IHE profiles, including the content profiles within Patient Care Coordination
- MHS/DoD-VA-IM-IT Demo Project Discharge Summary and SOAP HL7 CDA R2 Implementation Guides

- Review samples/templates:
  - Sample CDA documents developed for local provider institutions (Mayo Clinic, University of Pittsburgh Medical Center, New York Presbyterian, and others)
  - Non-CDA sample documents supplied by participating providers and vendors
  - H&P templates from AHIMA, vendors, providers

- Statistical analysis: over 15,000 dictated H&Ps by M*Modal
- Test design against samples
Ballot results

• 78 comments received
  – ACP, Trinity Health, Kaiser Permanente, VHA, Regenstrief
  – Epic, GE, Medqufst, Northrop

• All comments addressed
  – All negatives will be withdrawn
  – Draft in revision
  – Will re-ballot in August/September

• If passed, will be “Draft Standard for Trial Use” (DSTU)
  – stable platform for implementation
  – within 2 years either normative or revised
Ballot issues

• Most difficult
  – balance diversity of current practice against desire for consistency
  – where can you lead the industry, where must you follow?

• Clarify intended content
  – Past Medical History vs. Surgical History

• Physical exam: diversity of practice
  – Define full set of sub-headings
  – Allow narrative &/or sub-sections
Consult Note

- Same method as H&P
  - consistent with precedents
  - large scale analysis of dictated notes
  - reuse section-level content
  - review E&M guidelines

- Examine required metadata

- Examine report contents
  - Require “reason for referral”
  - Relationship with “reason for visit”, “chief complaint”

- Seeking pre-ballot review
Future work

• Horizontal: additional document types
  – Op note
  – Specialize the History & Physical
• Vertical: supporting implementation
  – Quick Start Guides for implementers
  – Training for implementers
• Promotion: Among providers
  – Education on utility, strategic value
  – End-user training for compliance
• Whatever it takes to support and promote widespread adoption
How can PEHRC, PEHRC members get involved?

• Participate in design review
  – through CDA4CDT
  – through HL7 Structured Documents TC
  – through HL7 Board of Directors

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

• Encourage implementation
  – within professional society
  – within practice group
CDA for Common Document Types

• Founders:
  - M*Modal
  - AHDI
  - MTIA
  - AHIMA

• Benefactors:
  - Spheras
  - MedQuist
  - InterFix
  - 3M
  - Precyse Solutions
  - Webmedx
  - mdivouch

• Participants:
  - Acusis, Kaiser Permanente, Mayo Clinic, Military Health System,
    University of Pittsburgh Medical Center, GE Healthcare

• Management:
HL7: patient-centered health information

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

**New drug information**

**Discharge medications**

**Consult**

**PCP followup**

**Pharmacy**

**R&D**

**Develop**

**PHR/EHR Vocabulary Services Knowledge Base**

**FDA Report**

**CDC**

**HL7 Standards**
RIM-DataTypes-ITS
SPL
CDA: Discharge Sum
V3 msg: Med Order
CDA: lab, imaging
V2: lab
Arden
ICSR
aECG
CT Lab
Stability

**MOUs**
X12, ADA
ASTM, CEN
CDISC, DICOM, eHI
IEEE, IHE,
OASIS, OMG,
NCPDP, CAP, WEDI

**Develop R&D Study**
CDA from Dictation

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