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Healthcare Interoperability and HL7 CDA

November 7, 2013

Objectives

- Define healthcare interoperability
- Communicate the purpose of interoperability
- Review regulatory governance
- Explain role of standards development organizations
- Discuss challenges to HIT interoperability
- Review incremental semantic interoperability approach
- Introduce HL7, CDA R2, and related concepts

Healthcare Interoperability

What is HIT interoperability?

- A complex healthcare system requires a diverse information technology infrastructure. One size does not fit all.
- Electronic health record (EHR) products must be able to share information seamlessly to realize their full potential. An interoperable HIT environment makes this possible.

(www.HealthIT.gov)

Healthcare Interoperability

Three “levels” of interoperability:

1) Technical or Functional: Data flow from one application to another with a defined physical format.
[Concerned with Syntax and Structure]

2) Semantic: HIT systems communicate information in a form that will be understood in exactly the same way by both sender and receiver.
[Concerned with Model and Vocabulary]

3) Process: Systems are successfully implemented into actual work settings.
[Making It Work: Processes and People]

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Healthcare Interoperability

Why HIT interoperability?

- HIT interoperability enables better workflows and reduced ambiguity, and allows data transfer among EHR systems and healthcare stakeholders.
- Ultimately, an interoperable environment improves the delivery of healthcare by making the right data available at the right time to the right people.

(www.HealthIT.gov)

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Why healthcare interoperability?

Main driver: Improve patient safety and service quality

- Ensure precision of clinical information
- Reduce incidence of medical errors
- Save costs by avoiding fraud and duplication of service
- Save time for practitioners and patients
- Create a longitudinal, unique, shared, life-long EHR

Usually a combination of these goals drives the need for interoperability in a given setting.

HIT Interoperability

Standards are particularly critical to four key areas of EHR technology in creating an interoperable HIT environment:

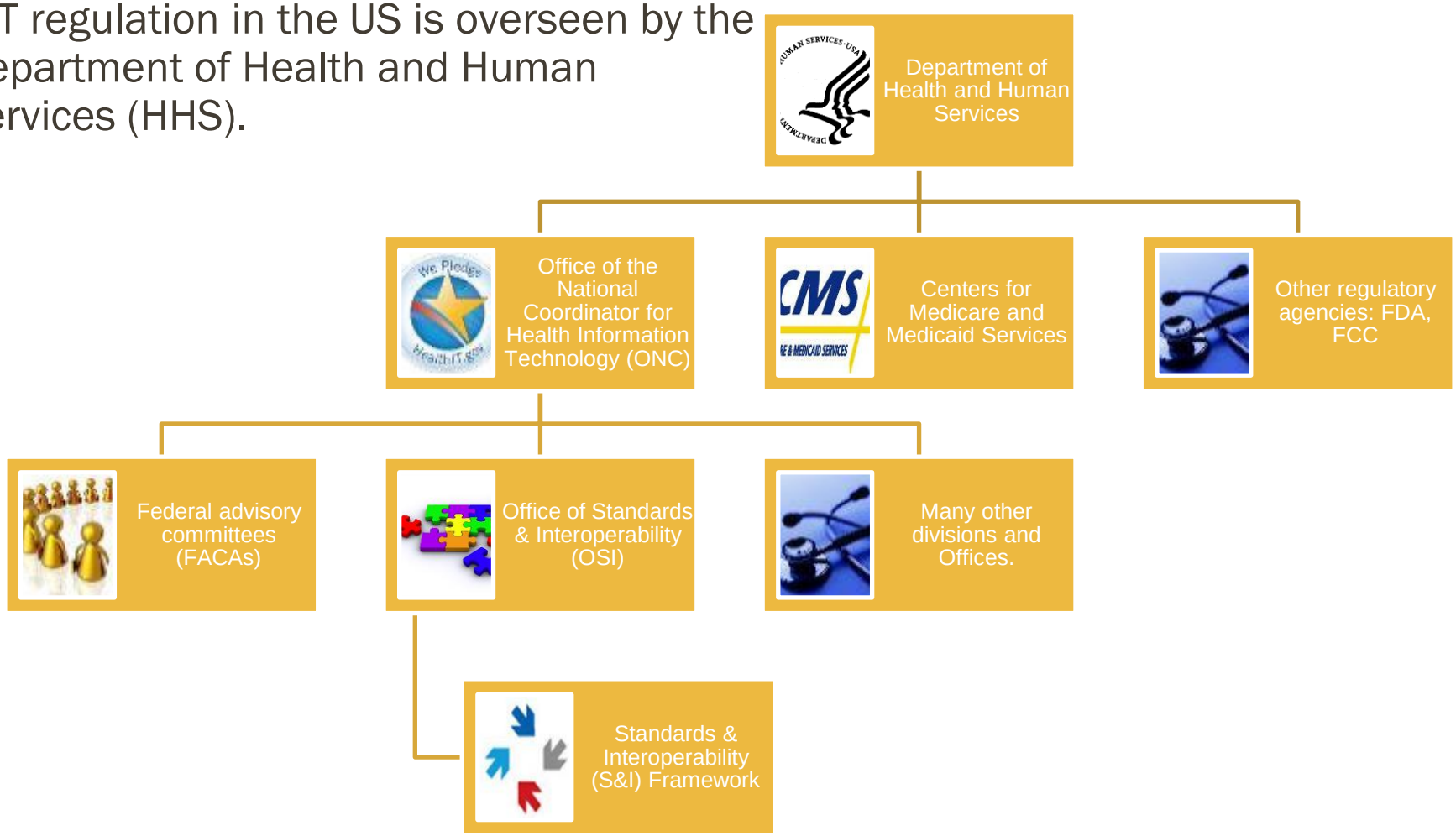
- How applications interact with users (e.g., e-prescribing)
- How systems communicate with each other (e.g., messaging standards)
- How information is processed and managed (e.g., health information exchange)
- How consumer devices integrate with other systems and applications (e.g., tablet PCs, etc.)

(www.HealthIT.gov)

In the US, a regulatory framework guides and governs the HIT industry.

Regulatory Framework

HIT regulation in the US is overseen by the Department of Health and Human Services (HHS).



Regulatory Framework

- Office of the National Coordinator (ONC)

The principal federal entity charged with coordination of nationwide HIT efforts. The position of National Coordinator was created in 2004, through an Executive Order, and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009.

- Centers for Medicare & Medicaid Services (CMS)

Works with ONC to coordinate the Meaningful Use (MU) incentive program. MU is a multistage set of standards defined by CMS that governs the use of electronic health records and allows eligible providers and hospitals to earn incentive payments by meeting specific criteria.

Regulatory Framework

- The Federal Advisory Committee Act (FACA) created the Health IT Policy Committee and the Health IT Standards Committee within the ONC to make recommendations on national HIT policy and standards for the use and exchange of health information.
- OSI oversees the Standards and Interoperability (S&I) Framework, a collaborative community of participants from the public and private sectors who are focused on providing the tools, services, and guidance to facilitate the functional exchange of health information.
- The end product of this regulatory process is made into law, e.g., the MU final rule cited in the Federal Register.

Standards Development

Standards development organizations (SDOs)

- An organization whose primary activities are developing, coordinating, and revising technical standards that address the needs of a wide base of adopters.
- Most SDOs parcel out their standardization work to committees or subcommittees that focus on particular standards in a particular area. Those committees develop draft documents, which are then subject to review and approval, either by a formal balloting process or some other specified means of reaching consensus.
- Examples of SDOs include HL7, ANSI, W3C, NCPDP, and many others.

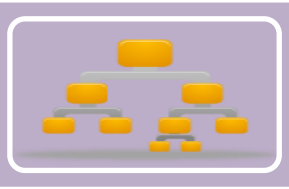
Standards Development

Document Standards

HL7 (Clinical Document Architecture - CDA)

Messaging Standards

HL7 (V2 and V3), NCPDP, X12, DICOM

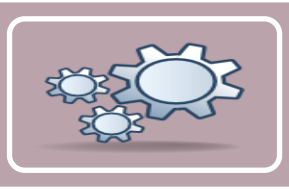


Vocabulary

Regenstrief (LOINC), IHTSDO (SNOMED CT®), NLM

Transport Standards

W3C (HTTP), SMTP



Integration Standards

IHE

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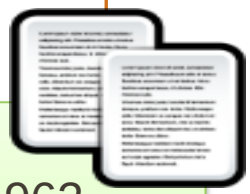
Standards Development

Messaging Standard (HL7 V2 Messaging)

MSH|^~\&|GHH LAB|ELAB-3|GHH
OE|BLDG4|200202150930||ORU^R01|CNTRL-3456|P|2.4
PID|||555-44-4444||**EVERYWOMAN^EVE**^E^^^^L|JONES|**19620320**|**F**|||153
FERNWOOD DR.^ ^STATESVILLE^OH^35292||(206)3345232|(206)752-
121||||AC555444444||67-A4335^OH^20030520
OBR|1|845439^GHH OE|1045813^GHH
LAB|15545^**GLUCOSE**|||200202150730|||||||| 555-55-
5555^PRIMARY^PATRICIA P^^^^MD^^|||||||||F||||||444-44-
4444^**HIPPOCRATES^HOWARD** H^^^^MD
OBX|1|SN|1554-5^GLUCOSE^POST 12H
CFST:MCNC:PT:SER/PLAS:QN||^**182|mg/dl**|
70_105|H|||F



Eve Everywoman
Female, born 03/20/1962
Test: Serum glucose
Result: 182 mg/dl (High)
By: Howard Hippocrates, MD

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Standards Development

Document Standard (HL7 CDA Document)

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.4"/>
  <!-- Problem Observation template -->
  <id root="d11275e7-67ae-11db-bd13-0800200c9a66"/>
  <code code="404684003"
        codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT"
        displayName="Finding"/>
  <text>
    ...
  </text>
  <statusCode code="completed"/>
  <effectiveTime>
    <low value="1990"/>
  </effectiveTime>
  <value xsi:type="CD" code="73211009"
          codeSystem="2.16.840.1.113883.6.96"
          codeSystemName="SNOMED CT"
          displayName="Diabetes Mellitus (disorder)"/>
</observation>
```

Patient's problem: Diagnosed with diabetes in 1990.

Standards Development

Vocabularies/terminology "standards":

- These are not strictly considered standards and their caretaker organizations may not be SDOs.
- **Regenstrief Institute** maintains LOINC (Logical Observation Identifiers Names and Codes), a database of medical terminology related to EHRs. For example, LOINC specifies codes for laboratory tests and clinical report types.
- **International Health Terminology Standards Development Organization (IHTSDO)** maintains SNOMED CT ® (Systematized Nomenclature of Medicine Clinical Terms), a computer-processable hierarchy of medical terms providing codes for diseases, findings, procedures, microorganisms, substances, etc.

Standards Development

Vocabularies/terminology “standards” (continued)

- National Library of Medicine (NLM) maintains RxNorm, which provides normalized names for clinical drugs and links these names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software.
- There are many other terminologies used in HIT systems.

Collaboration Among SDOs

HL7, ONC, Health Story Project, and IHE collaborated to consolidate CDA document templates to support MU Stage 2 (MU2).

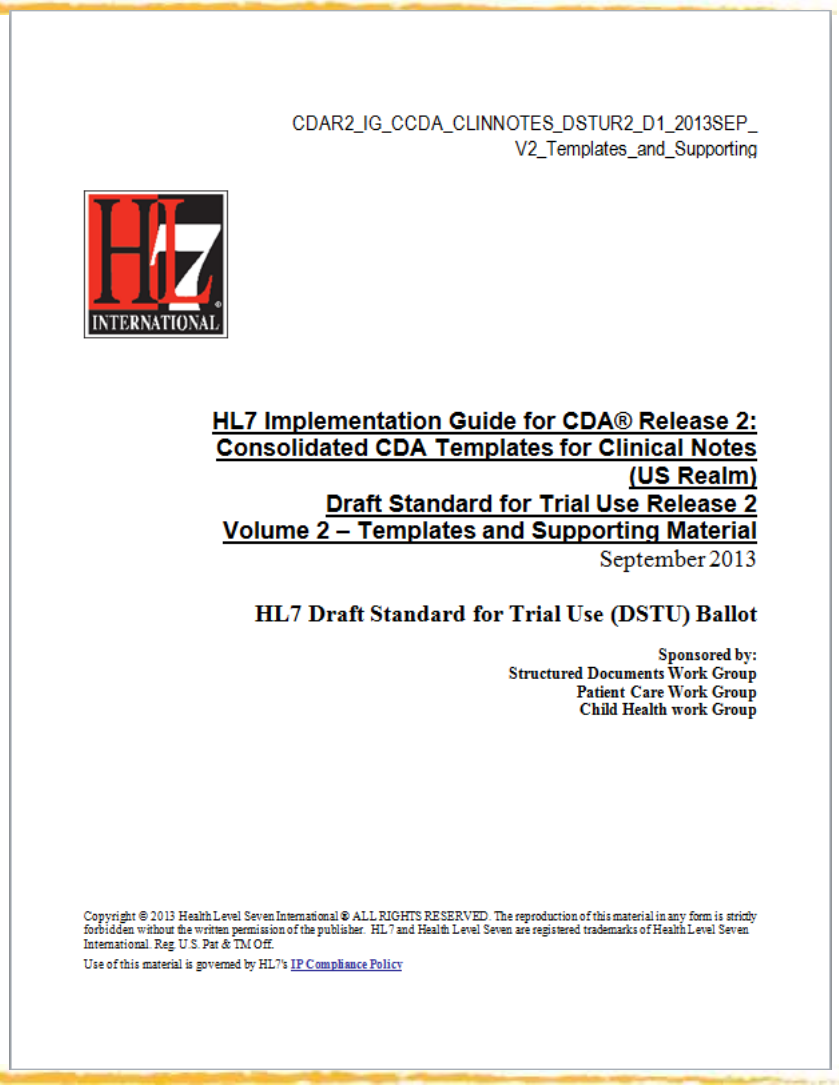
The result of this collaboration is Consolidated CDA (C-CDA), which was then referenced in the Final Rule for MU2 as the format for the exchange of clinical summary data.

Over 140 volunteers participated in weekly calls and offline work.

Collaboration Among SDOs

C-CDA is a library of reusable templates and defined document types such as:

- Continuity of Care Document (CCD)
- Consultation Note
- Discharge Summary
- History and Physical Note (H&P)
- Procedure Note
- Progress Note
- Unstructured Document



CDAR2_IG_CCDA_CLINNOTES_DSTUR2_D1_2013SEP_
V2_Templates_and_Supporting

HL7 INTERNATIONAL

HL7 Implementation Guide for CDA® Release 2:
Consolidated CDA Templates for Clinical Notes
(US Realm)
Draft Standard for Trial Use Release 2
Volume 2 – Templates and Supporting Material
September 2013

HL7 Draft Standard for Trial Use (DSTU) Ballot

Sponsored by:
Structured Documents Work Group
Patient Care Work Group
Child Health work Group

Collaboration Among SDOs

The templates developed as part of the C-CDA project are used across document types and are reusable as conceptual representations of specific clinical content.

For example:

- Problem Observation template – represents a patient's complaint/problem/finding/diagnosis, e.g., fever.
- Vital Signs Observation template – represents a discrete recording of a vital sign, e.g., a patient's temperature.
- Medication Activity template – represents the administration of medication to a patient, e.g., "Tylenol was given to the patient."

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Challenges to HIT Interoperability

Why is interoperability so hard to achieve in healthcare?

(I draw money from my bank account from any ATM in the world and …

you can bet that my bank will figure out where, when, and how much.

Other industries have got it right!)

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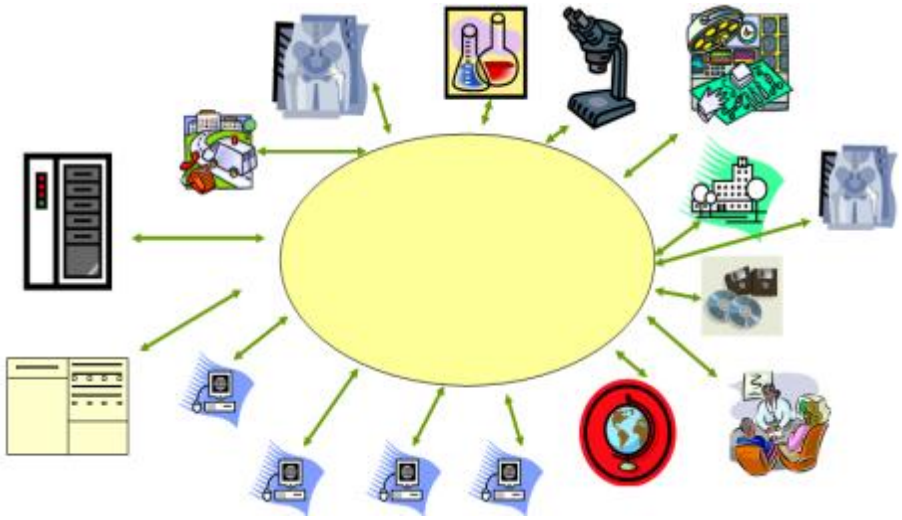
Challenge #1: Variability of applications

In healthcare, there are hundreds (or even thousands) of actors with their own applications:



- Individual practitioners
- Primary care centers
- Clinical laboratories
- Blood banks
- Hospitals/clinics
- Pharmacies
- Payers (insurance companies, government, others)
- Public healthcare authorities

The list goes on and on …

Now, add the patient (PHR)!

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Challenge #2 : NIH syndrome

NIH: "Not invented here"

- Common disease among developers, engineers, investigators, academics; some traces found in clinicians.
- Those afflicted with NIH declare everything not designed personally by them – or by some part of their team – to be useless, annoying, depressing, cumbersome, stupid, outrageous, careless, inappropriate, incomprehensible, and too complicated.

"Who can possibly know more about my own business than I do?"

Challenge #3: Distinct document types

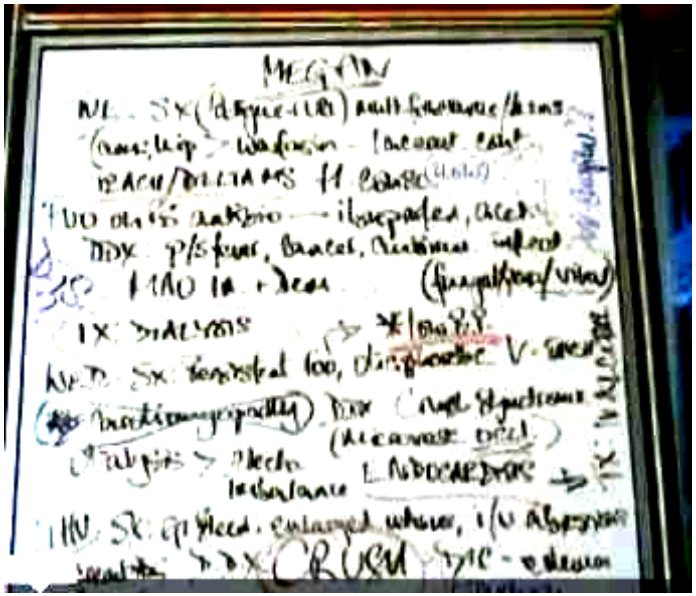
Clinical document types (and associated structure) for documenting each process are defined by each organization (they are not standardized):

- Evaluation note
- History and Physical (H&P) note
- Surgical notes
- Observation reports
- Referrals
- Discharge reports
- Immunization reports
- …

Challenge #4: Semantics and vocabulary

Our domain's semantics are difficult to represent in a precise way.

There is no single controlled vocabulary today covering ALL coded concepts.



(Patient chart borrowed from the "Megan" episode of *House*)

Think about the representation of this chart!

In this episode, they acted – wrongly – based on evidence taken from ANOTHER patient's PAPER chart!

Challenge #5: Purpose of records

Medical records serve at least four different purposes:

- Primary care
- Payment
- Legal defense
- Secondary use (disease surveillance, public health, research)
- … got more?

Challenge #6: Confidentiality

Sometimes we are not allowed to share what we need to share (security measures).

Everyone wants "encryption" (not helpful for interoperability).

- Role-based access to information
- Nonrepudiation/verification of senders and receivers
- Digital certificates/electronic signatures
- "De-identification" of patients for secondary uses (and sometimes for primary use!)

All these make interoperability that much more difficult…

Challenge #7: Tension (push/pull)

Clinicians *push* natural language **vs.** **Programmers and researchers *pull* computable data**

When you are saving someone's life, are you thinking about pushing the proper RxNorm or SNOMED code into the medical record?

When you are writing clinical software, are you thinking about pulling free text into a natural language processing (NLP) or an artificial intelligence (AI) engine?

Challenge #7: Tension (push/pull) … continued

Natural language	vs.	Computable data
Henry Levin is a 67-year-old male who **manifests** ***wheezing*** as an **allergic reaction** to ***codeine***.		MFST 56018004|2.16.840.1.113883.6.96 420134006|2.16.840.1.113883.6.96 2670|2.16.840.1.113883.6.88

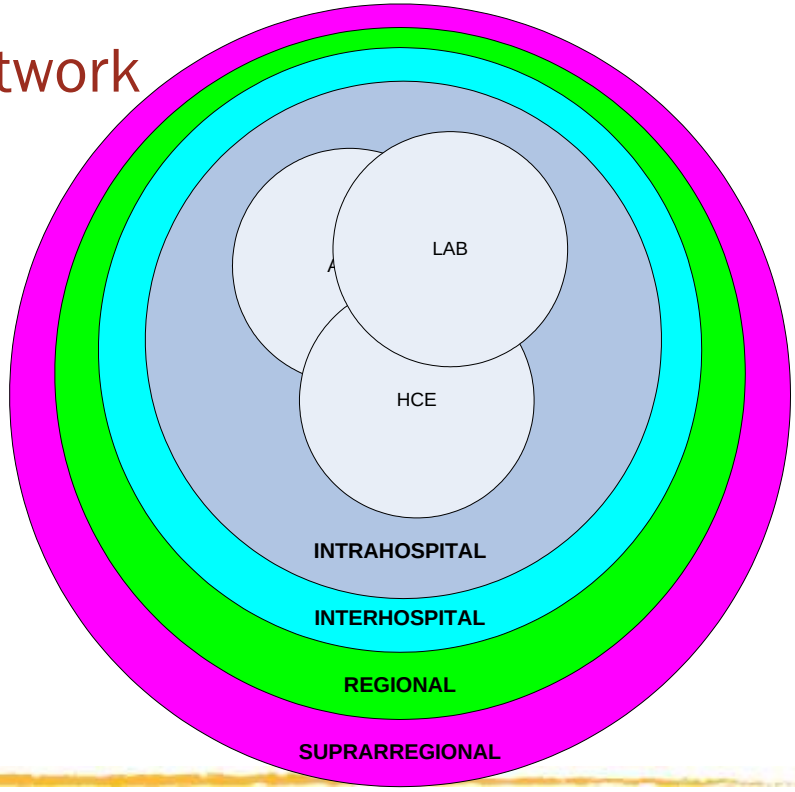
Most clinical documents contain a mix of free text and "fielded" data:

- Most data can be fielded and almost all fielded data can be turned into narrative (but you may not want to read it).
- Clinicians report that the 2 to 5% that is free text is the most essential.

How do we end this …?

The problem is worse as we go forward:

- We have achieved interoperability within a hospital and need to integrate with another hospital across the street.
- We integrate within a healthcare network but then need to integrate with the rest of the city.
- The city is integrated but is not in communication with the rest of the region.
- We integrate the region but …well, you get the point.



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… and do we have a clear strategy?

Should all hospitals, practitioners, etc., store the information in a specific place or in a specific format?

Should everyone replace all their applications? (Achieving this can take years.)

Should we do everything at once or is there any evolutionary strategy?

Yes, there is!

Incremental Semantic Interoperability

Semantic Interoperability

Sharing information between heterogeneous systems and processes; using it automatically.

Incremental Semantic Interoperability

Don’t try to boil the ocean all at once; start small, grow large.

HL7 Mission Statement

Clinical Interoperability

"To provide a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services."

In other words, create flexible, cost-effective standards, implementation guides (IGs), and methodologies to allow interoperability between HIT systems and exchange of EHRs.

Note: HL7 standards are created and balloted by consensus among users/providers, industry, government agencies, and other standards development organizations (SDOs), e.g., ISO, American National Standards Institute (ANSI), Clinical Data Interchange Standards Consortium (CDISC), European Committee for Standardization (CEN). Detailed discussions occur on a variety of interoperability scenarios.

HL7 Tools

HL7 Standards for Healthcare Information Exchange (HIE)

V3 Messaging

CDA

V2.X Messaging

Services and Other Standards

(RLUS, Arden syntax, JELLO, etc.)

HL7 Tools: CDA R2

Latest version: CDA Release 2 (CDA R2)

- Normative Edition since 2005 (R3 being discussed now)
- ANSI standard since 2005
- HL7 CDA R2 is an ISO standard
- Available only with XML syntax

Strengths: Regional implementations of shared document repository; shares the RIM with V3; unique identifiers; vocabulary control and further constraint with other V3 sub-products; widely used worldwide; easier to implement.

Weakness: Wanting to use it as if it were the entire Swiss army knife.

Good market penetration in the US, selected by Summary Documents exchange under Meaningful Use (MU)

Domains: Any domain that generates clinical documents

Incremental semantic interoperability

Let's see how …

CDA = Header + Body

CDA Header:

Patient, provider, and encounter information

CDA Body:

- Clinical report
  - Discharge summary
  - Care record summary
  - Progress note
  - H&P
  - Public health report
- Contains the report information in both narrative (free-text) form and coded (computable) form.

CDA Levels

What levels of interoperability exist?

What level do we need?

What level can we support (pay for/develop/deploy/ imagine) today?

Is there any way to begin with some level of interoperability and increment it in the future?

CDA Levels

CDA Incremental Semantic Interoperability:

Level 1: Non-XML Body or narrative-only CDA document. No coded content outside the Header.

Level 2: Structured Body with Section coding (LOINC section codes).

Level 3: Same as Level 2 but with coded entries as well.

What is CDA R2?

A specification for exchange of clinical documents, defining their structure and semantics

An ANSI standard developed by HL7's Structured Documents Working Group (SDWG)

An ISO standard

Relies on:

- XML
- HL7 RIM
- HL7 development methodology
- HL7 Release 1 (R1) data types
- Controlled vocabularies (SNOMED, LOINC, ICD-9, HL7, etc.)

What is a CDA R2 document?

Anything can be a document: reflects the historical form of a medical record, mixing free text and discrete data items.

But a clinical document compliant with CDA R2 has:

- Persistence (legal retention period)
- Stewardship (is administered by an organization)
- Potential for authentication
- Context (who, when, where, etc.)
- Completeness (the entire document is authenticated)
- Human-readability

CDA documents are not:

- Data fragments
- Longitudinal health records
- **Messages** (explained on next slide)

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Messages vs. Documents (I)

Feature	Documents	Messages
Life cycle	Persistent	Temporal
Communication	Between people	Between applications
Intended to be human-readable	Generally yes	Generally no
Have recognized legal status	Generally yes	Generally no
Definition	Best practice	Ad hoc
Context	Usually described within the document	Not usually described within the message
Completeness	Is a complete communication	Is a piece of a larger story

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Messages vs. Documents (II)

Other considerations:

- Messages are appropriate for transient information, e.g., what is the current state of an object.
- Documents are appropriate for recording the final state/result of an object/action.
- The relationship between the systems (inter-hospital/ intra-hospital, etc.) is a factor in determining whether to use a document or a message.
- Temporal axis: Does the receiver need the information online (use a message) or can he/she wait until the end of the episode/act (use a document)?
- Privacy/security: Generally documents are more secure as they could include digital signatures.

CDA R2 Goals

- Keep patient care as the priority (Challenge #5: Purpose of records); facilitate post-exchange secondary applications as needed.
- Allow a cost-effective implementation using standards and promoting flexibility.
- Support document exchange between users with different technological abilities; minimize implementation barriers (incremental interoperability); complexity of CDA can vary depending on current needs and goals.
- Do not tie exchange to the transfer or storage mechanism.
- Prepare the design reasonably fast without extending the specification (but instead constraining or "templating" it).

Major CDA Implementations in the US

Mayo Clinic:

- Initiated in 1999. About 50,000 documents each week
- Clinical documents are the “most important capital asset”

New York Presbyterian Hospital:

- “CDA Philosophy”: mix of fielded data and narrative
- Best format for information mining and aggregation across applications
- Clinical notes contain critical information in narrative
- One-third of all discharge summaries are in CDA format

Military Health System (MHS):

- Healthcare Artifacts & Images Management System (HAIMS)

  Enterprise-wide document management integrated with the EHR
  web services gateway to Veterans Health Administration (VHA), civilian providers

- MHS/VHA Bidirectional Health Information Exchange (BHIE)

Major CDA Implementations in the US

University of Pittsburgh Medical Center:

- Narrative notes using speech recognition, NLP
- Linking of radiology reports with picture archiving and communication system (PACS)-rendered images

Others:

- Beth Israel Deaconess
- Duke
- Kaiser
- Trinity
- Partners
- Ochsner
- University of Alabama
- National Health Safety Network (NHSN)
- …

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CDA Around the World

CDA is fundamental to national/regional exchange

Germany		SCIPHOX
Finland		Aluetietojärjestelmä
Greece		HYGEIAnet/WebOnColl
Japan		MERIT-9 (MML)
Canada		Infoway
France		Dossier Médical Personnel
Italy		TeleMed Escape
US		Center for Healthcare Innovation (CHI), IHE
Argentina		Hospital Italiano de Buenos Aires
England		National Program for HIT
Turkey		National Health Information System (NHIS)

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Primary Usage: Collaborative Care

- Document persistence and management, independent of transport
- Supported by heterogeneous tools (selected by user)
- Integration of diverse distributed applications generating XML and non-XML data: standardized metadata
- Mixing of narrative (free text) and discrete data
- Document searches by metadata: patient, provider, place, date, etc.
- Integration of transcription systems to EHR systems
- Full document context, continuation of paper world

Secondary usage: Information reuse for summary reports, decision support, healthcare

Advantage of having all documents in the same format

Possible Exchange Scenarios

Provider to Payer:

- Claims attachment
- Longitudinal EHR

Provider to Provider:

- Referral
- Diagnostic report

Provider/Payer to Public Healthcare:

- Universal EHR
- Selected patients' EHR (reportable diseases, chronic diseases, etc.)
- Population summary reporting

Public Healthcare to Provider/Payer:

- Access to universal EHR information

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(Questions ?)

Thank you !