Implementation Strategies for Success: Data Use & Reuse

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VITL/Blueprint

about me

- HL7
  - Co-editor, HL7 Clinical Document Architecture
  - Co-chair, Structured Documents TC
  - Director

- Alschuler Associates, LLC
  - XML-based solutions for providers, vendors (Spinosa)
    - Consulted on Care Data Santa Barbara architecture
  - CDA strategy for Military Health System (Tricare)
  - Principal in NLM/HL7 EHR project, Phase I, Interoperability Survey
  - Duke "Single Source" Proof of Concept (Kush, Bain)
  - PM for HIMSS demos 1999-2004 (Rishel, IHE)
  - Convened Mt. Washington Project for Brailer RFI response (Jordan, Spinosa, Klein, Gettinger, Boate, Blocker)

- Review of Systems
- Review of Standards
- Some conclusions about what is important

NLM/HL7 EHR Study

- Co-authors Ann Blocker; DeLeys Brandman, MD
- Supporting HL7's contract with NLM
  - Short timeframe
  - Identify potential areas for Phase II work
- Reviewed over 100 sites, selected 8
- Criteria
  - Active data exchange
  - Use of standards
  - Well-known sites, lower priority

Study sites

- Broad study:
  - Spokane, WA
  - Finland
  - Crete (Greek National infrastructure)
  - The Netherlands
- Focus study:
  - Germany: CDA Referrals
  - Bangor, ME: community MPI
  - Seattle, WA: provider network with local cache, RLS
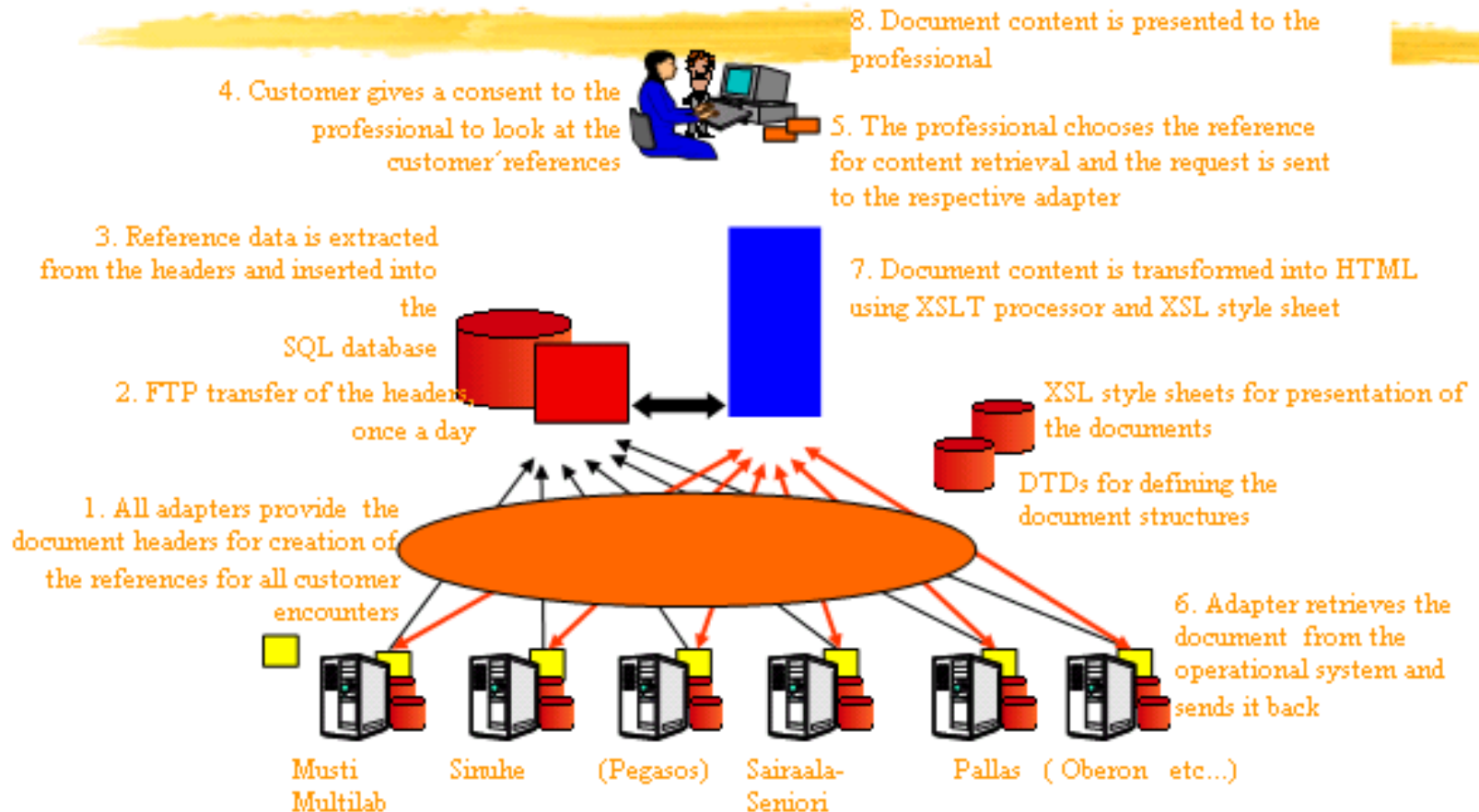 - Mendocino, CA: rural, open source

Finland

- Population: 5.3 million
- Wired
- Public, private healthcare financing
- Part of pan-EU PICNIC project (1997-2002)
- Satakunta Macropilot: regional exchange through a record locator service
- HIT environment
  - Strong penetration of EMR
  - Consistent use of "forms" for data entry
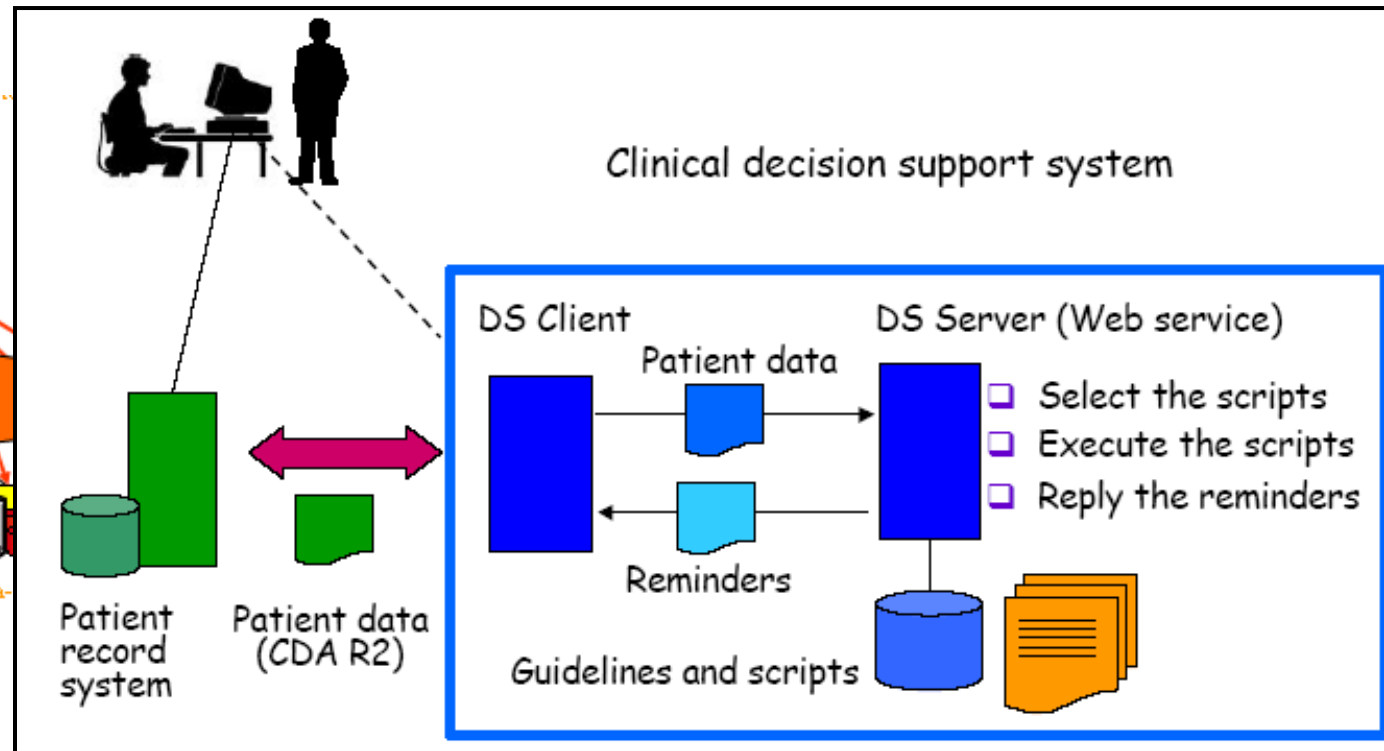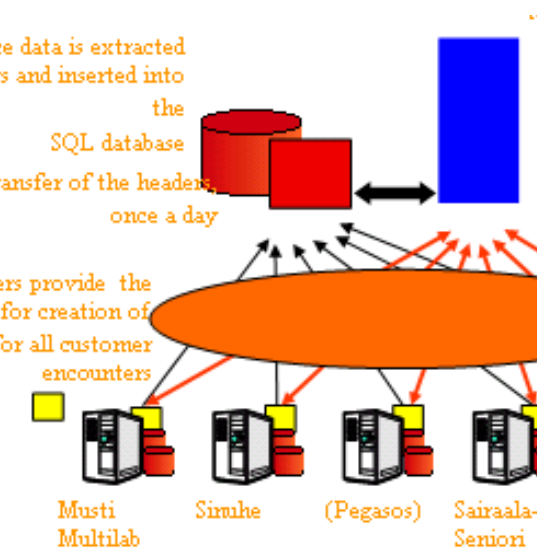
Aluetietojärjestelmä

40% of Finnish population covered including Helsinki

How XML and HL7 CDA are used

8. Document content is presented to the professional

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

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   Simhe   (Pegasos)   Sairaala-Seniori   Pallas   (Oberon etc...)

Aluetietojärjestelmä

- Preserves investment in legacy (e.g., "working") technology
- Self-paced migration
- Avoids central data store
- Model for US RHIO "record locator services"

- Upgrading to CDA R2
- Piloting decision support as network service

Aluetietojärjestelmä

- Not strongly federated
- Rogue region:
  - site to site query/response
  - Direct EMR integration
- Next generation
 - Will create central store of some data for performance
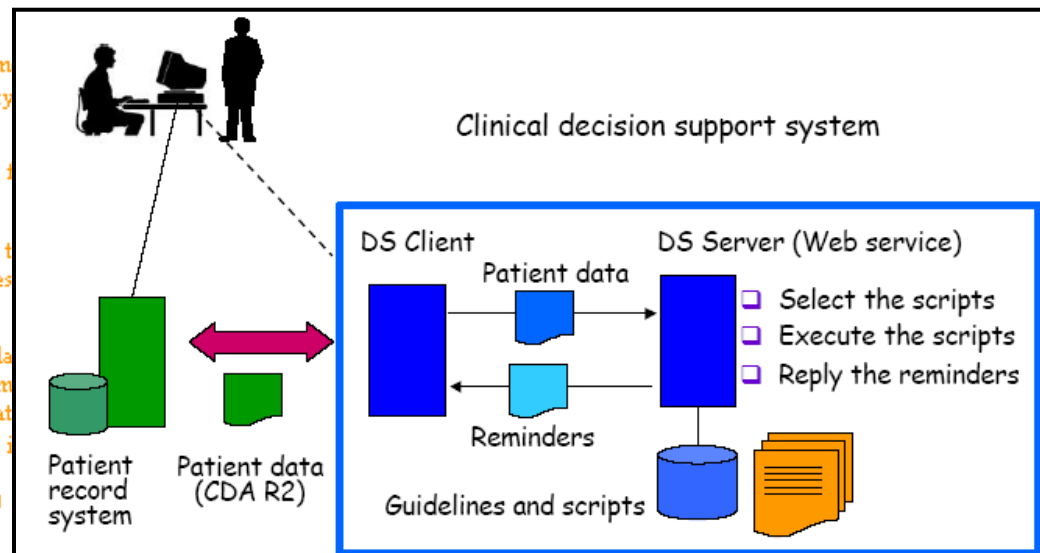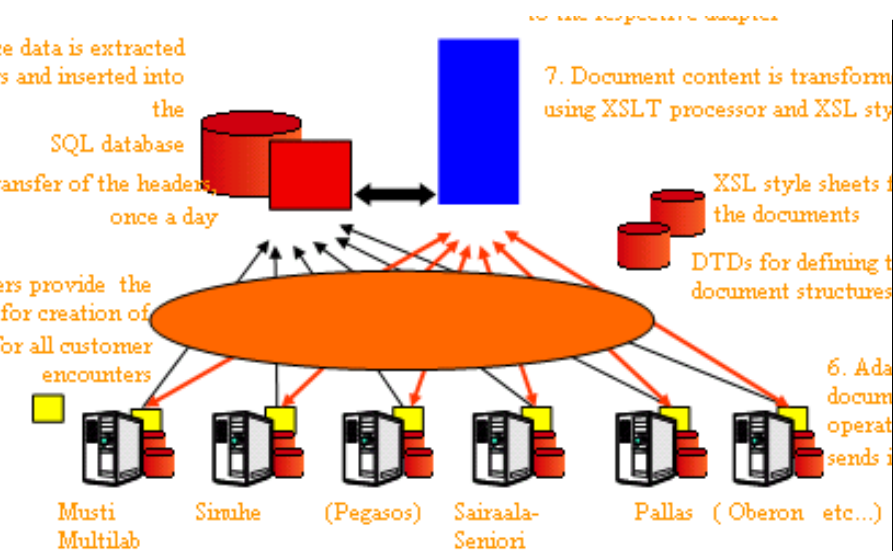
Crete

- Base population about size of Vermont, larger in summer
- Top Greek research institute: Foundation for Research and Technology (FORTH)
- Participated in PICNIC
- Public, private healthcare financing
- Innovation
- HIT environment: heterogeneous
  - 7 district hospitals
  - 3 of 1 primary care hospitals fully electronic
 - 250 remote practices

Crete: HygeiaNet
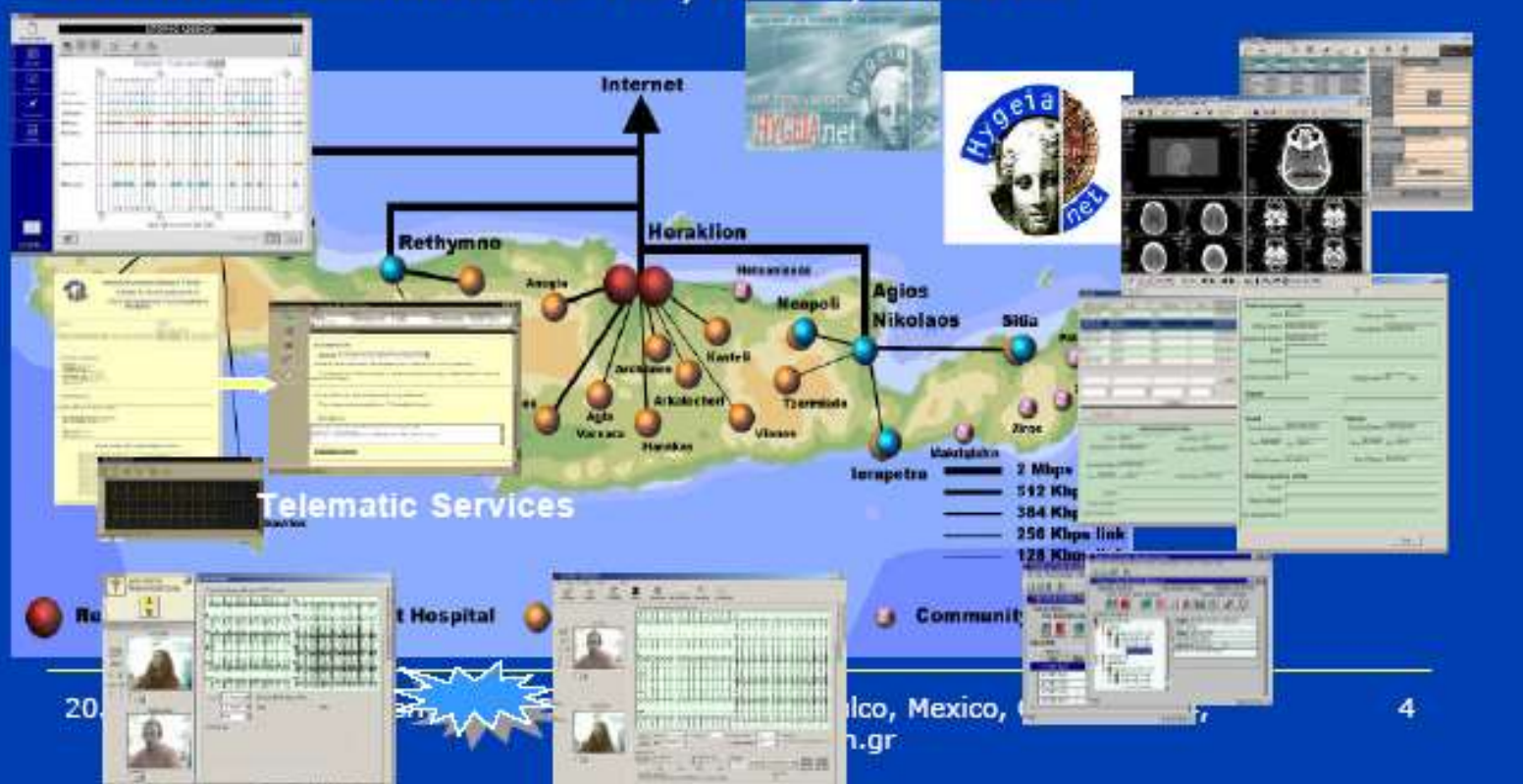
CDA for Mobile Health: Meeting the needs of Rural Communities in Twister
Chronaki, 2nd International Conference on the CDA, October, 2004
http://www.hl7.de/iamcda2004/fprogram.html

Crete

- eHealth plaform
  - Instant messaging backbone
  - Db of active shared folders (notification, awareness)
  - Medical device components on network
  - Standard protocols
  - Digital signature
  - Java Web interface, accessible in mobile devices
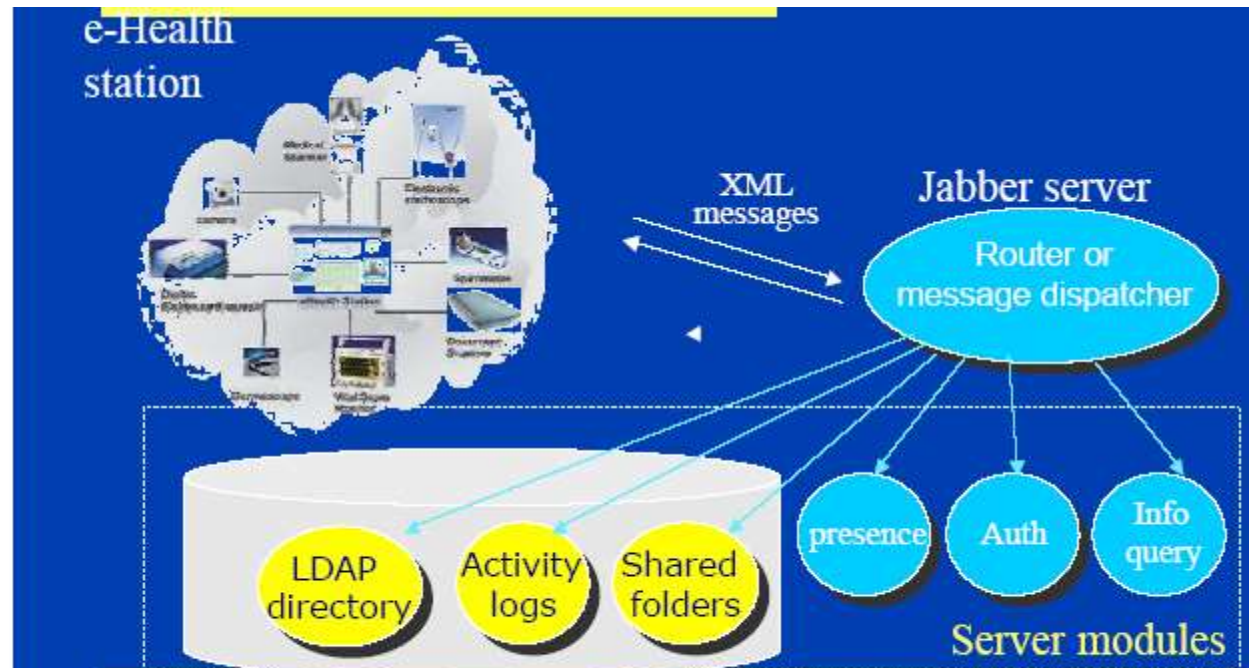
V-EMR, Crete, Athens

- CDA R2 from local systems
- ICD-10, SNOMED for vocabulary
- Local (hospital) XML databases
- Web services for retrieval
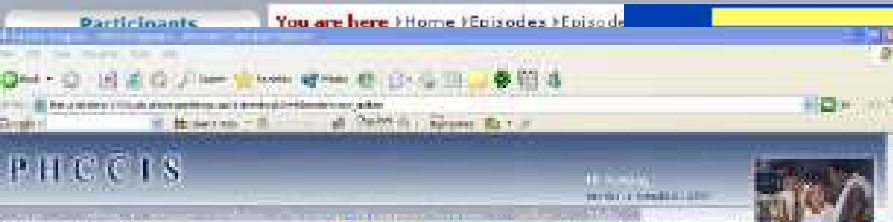
TWISTER

- – Terrestrial wireless infrastructure integrated with satellite communication (2004-2007)
- – Broadband rural access
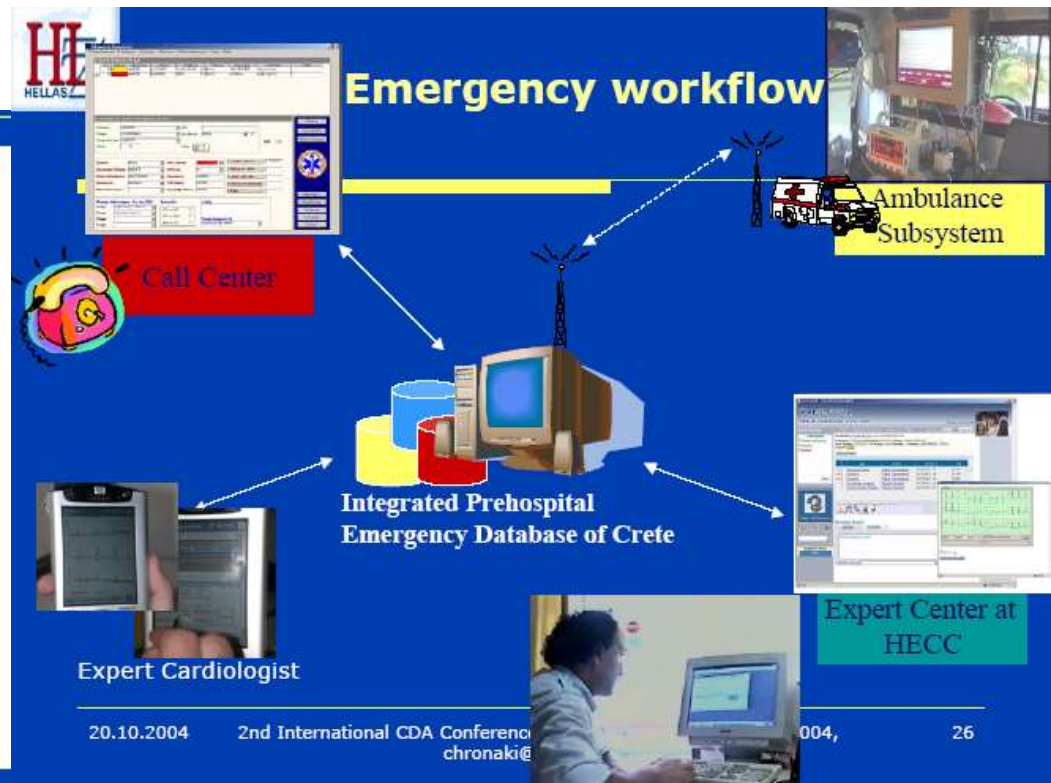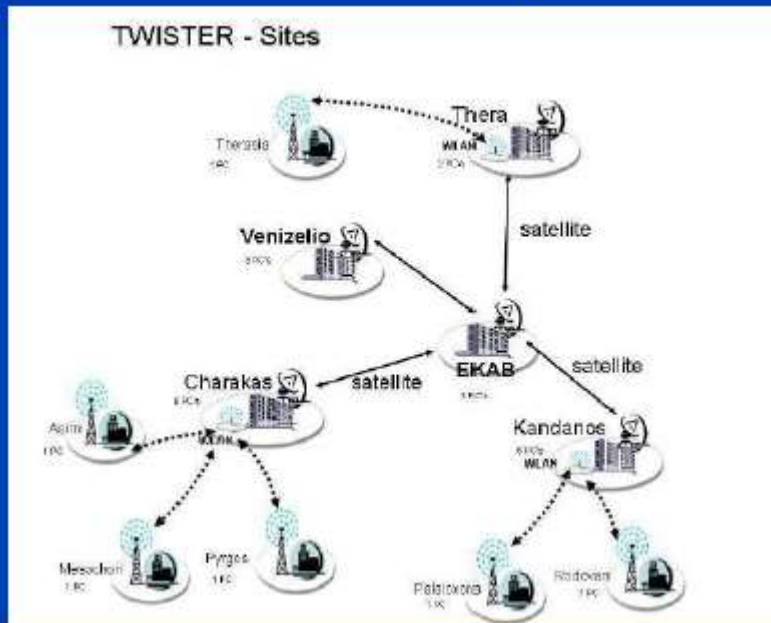
Crete

- ## V-EMR
  - Light weight local applications, devices, shared services
  - Net became the EMR
  - Distribute through RLS (OMG), publish/subscribe, push, cache
- ## National picture
  - Santorini, other regions
  - National RFP, 3 year implementation
  - "Propagating?" "No, disintegrating"

Finland & Crete

- Comparable investment
- Different architecture, different infrastructure
- Focus on data, adjust network
- Standards-enabled

Finland & Crete Lessons: EMR

- ## Not a precondition
  - ### Don't ignore lack of EMR (GR)
    - Network services as V-EMR
    - Incremental steps to participate

- ## Not an accessory
  - ### Don't ignore local EMR (FI)
    - Get everything out of it that you can
    - Provide integration back into local EMR

Review of Standards

- HL7
- Clinical Document Architecture

Interoperability: How do I get it?

- ## HL7:
  - doesn't just mean **MSH|^~\&|SMARTCLINIC_1|DRSGROUP|OPENLINK_1|DRSGROUP|20040130095828-0500||ADT^A04|20040130095828!7|T|2.3.1EVN||**

- ## Parse:
  - An organization
  - A syntax
  - A set of specifications

HL7 the organization

- Member-supported
  - Approximately 2000
  - 500 corporate
  - Provider, vendor, academic, consultant
- US-based, close to 30 international affiliates
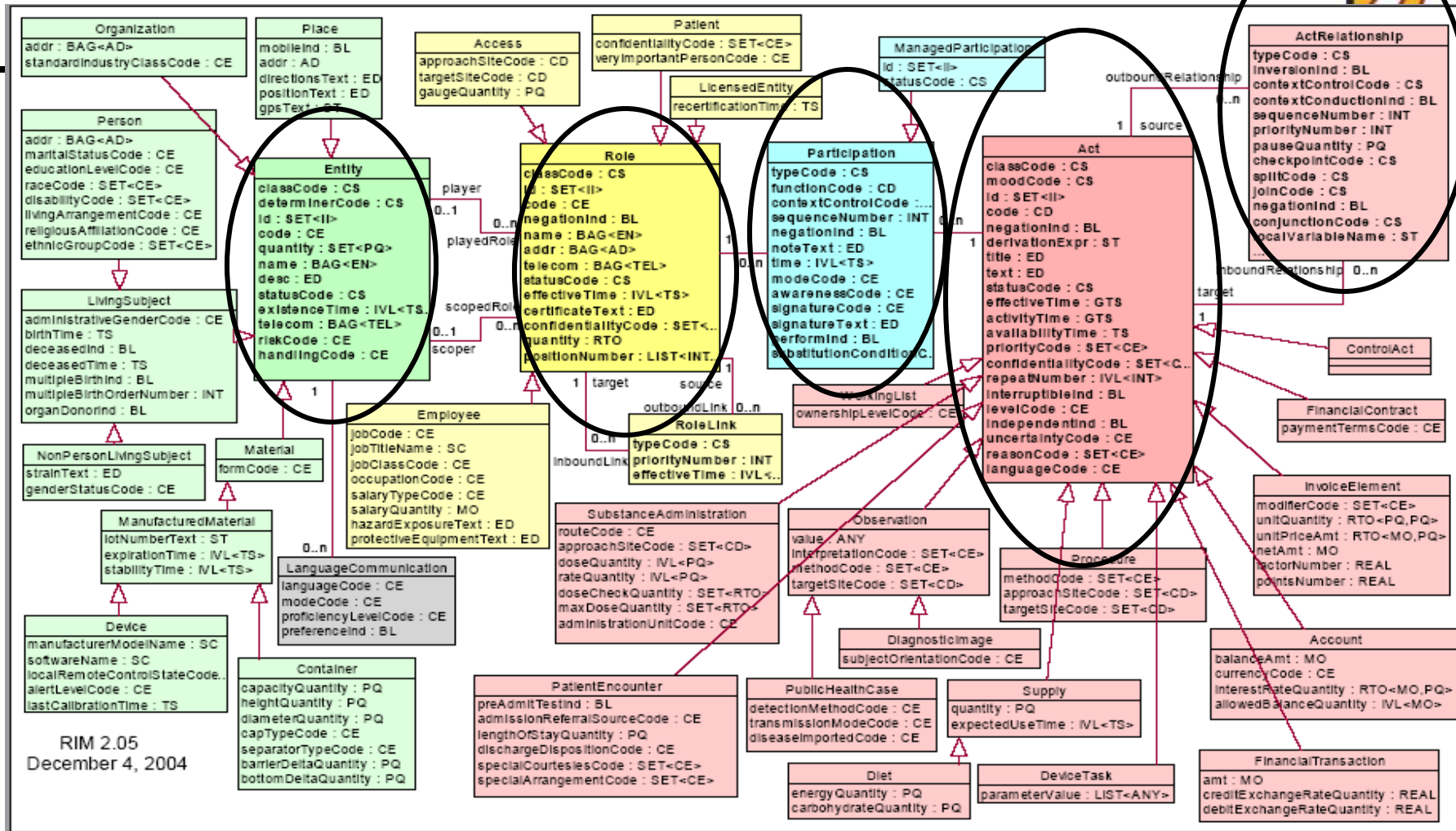- 20 years old
- 90% penetration of US hospital market

HL7 the specs

- First success: V2
  - So loose, everyone could implement it
  - So loose, everyone could implement it
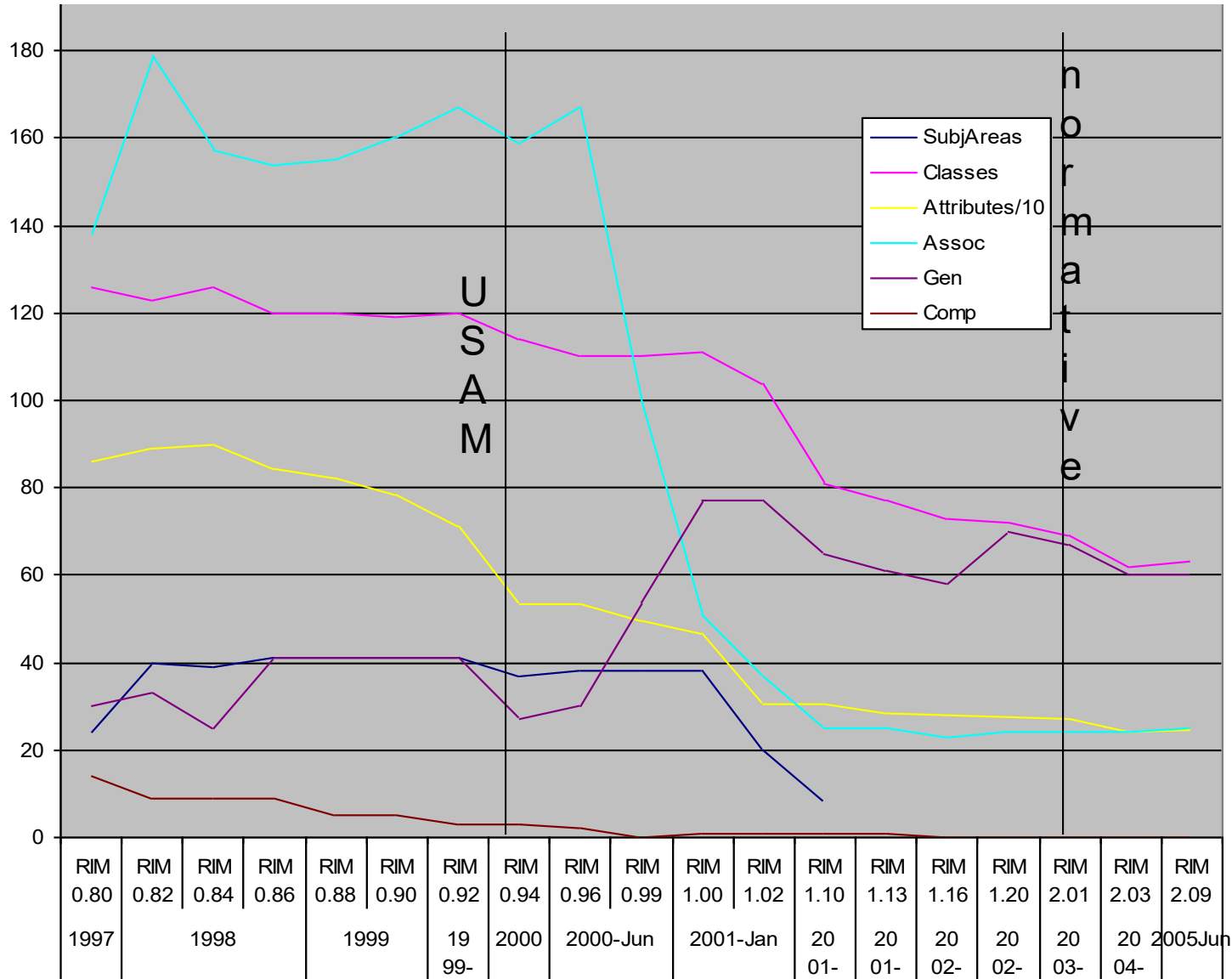- Let's look at V3

HL7 V3

- Model-based architecture
- Specialize and constrain the model
- Define implementation specifications based on those constraints
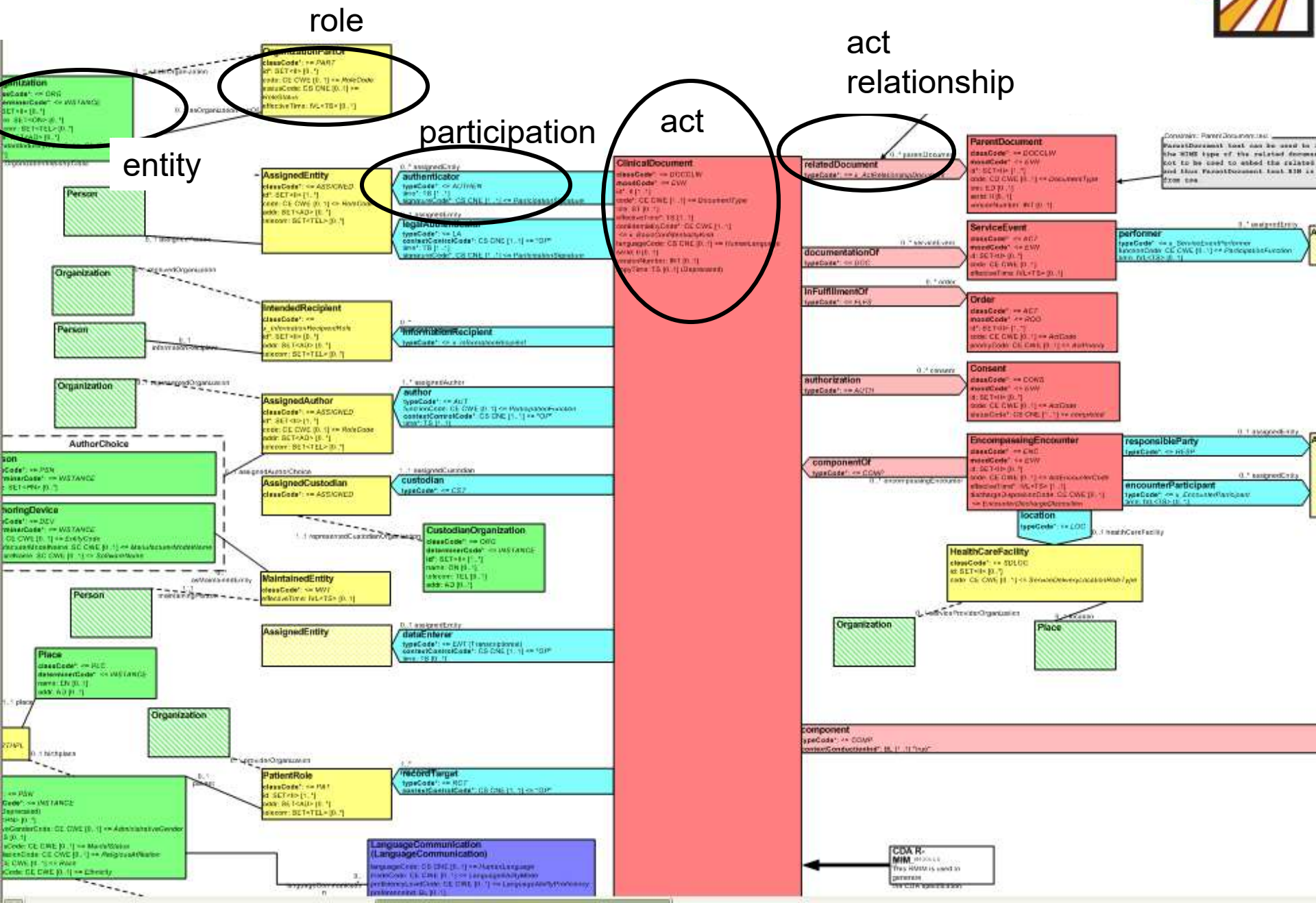
HL7 V3: model-based architecture

HL7 Reference Information Model (RIM)

Rise & fall & rise of the RIM

"refined" model: class clones

role

act relationship

act

participation

entity

CDA "hierarchical descriptor"

No	Element Name	Ca	Mar	Co	Rim Source	of Message Element Type	S	Domain
	CDA (POCD_HD000040) Hierarchical Description							
16	**patientRole**	1..1			Participation	PatientRole	N	
17	classCode	1..1	M	R	Role	CS	D	PAT
18	id	1..*			Role	SET<II>	D	
19	addr	0..*			Role	SET<AD>	D	
20	telecom	0..*			Role	SET<TEL>	D	
21	**providerOrganization**	0..1			Role	Organization	N	
22	classCode	1..1	M	R	Entity	CS	D	ORG
23	determinerCode	1..1	M	R	Entity	CS	D	INSTANCE
24	id	0..*			Entity	SET<II>	D	
25	name	0..*			Entity	SET<ON>	D	
26	telecom	0..*			Entity	SET<TEL>	D	
27	addr	0..*			Organization	SET<AD>	D	
28	standardIndustryClassCode	0..1			Organization	CE	D	OrganizationIn
29	**asOrganizationPartOf**	0..1			Entity	OrganizationPartOf	N	
30	classCode	1..1	M	R	Role	CS	D	PART
31	id	0..*		R	Role	SET<II>	D	
32	code	0..1			Role	CE	D	RoleCode
33	statusCode	0..1			Role	CS	D	RoleStatus
34	effectiveTime	0..1			Role	IVL<TS>	D	
35	*wholeOrganization*	0..1			Role	Organization	R	
36	**patient**	0..1			Role	Patient	N	
37	classCode	1..1	M	R	Entity	CS	D	PSN
38	determinerCode	1..1	M	R	Entity	CS	D	INSTANCE
39	id	0..1			Entity	II	D	
40	name	0..*			Entity	SET<PN>	D	
41	administrativeGenderCode	0..1			LivingSubject	CE	D	Administrative
42	birthTime	0..1			LivingSubject	TS	D	
43	maritalStatusCode	0..1			Person	CE	D	MaritalStatus
44	religiousAffiliationCode	0..1			Person	CE	D	ReligiousAffilia
45	raceCode	0..1			Person	CE	D	Race

POCD_HD000040

CDA schema
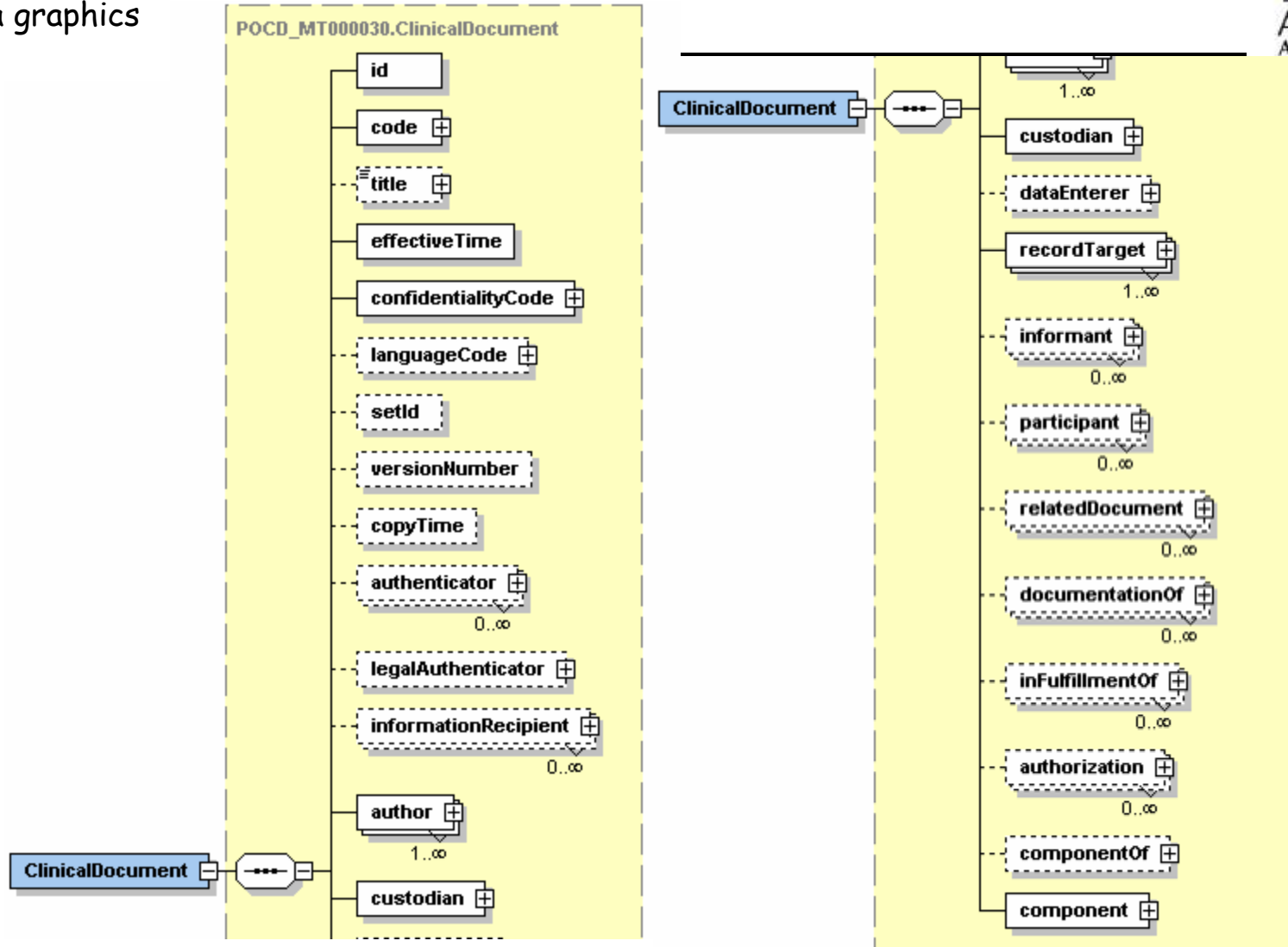
HL7's Development Framework

Reference Information Model

RMIM

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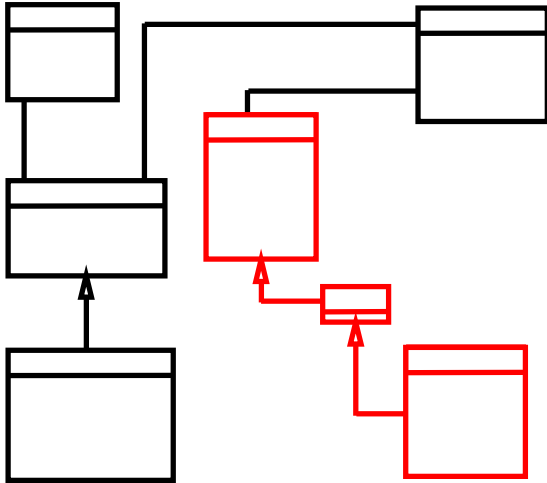
- subset of RIM
- tighten constraints
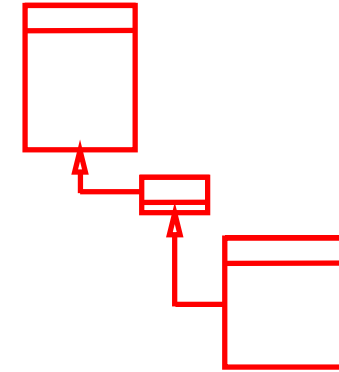
- linearization
- additional constraints

- algorithm

XML Schema

```
<xs:element name="ClinicalDocument"
type="CDA_MT000017.ClinicalDocument" />
    - <xs:group name="CDA_MT000017">
        - <xs:sequence>
<xs:element name="ClinicalDocument"
type="CDA_MT000017.ClinicalDocument" />
```
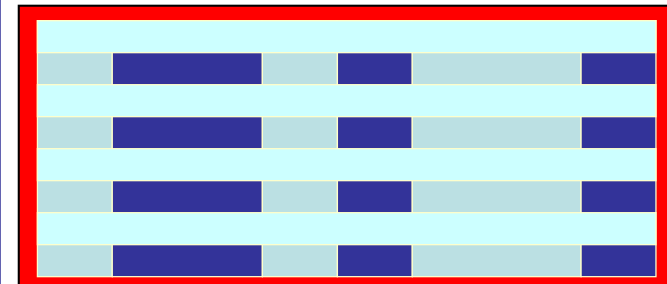
Hierarchical Description

Interoperability: How do I get it? CDA

- Isn't this a bit much?
- Couldn't we just stick *SNOMED codes* into X-HTML?
  - *(after all, we paid $14,000,000 to use them)*

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

CDA Body: 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"

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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>
```

Next: series of related statements

```
<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>
```
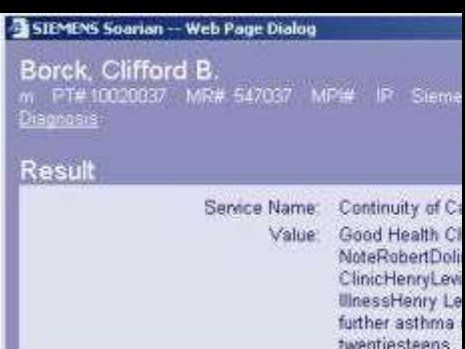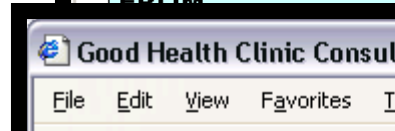
CDA Header

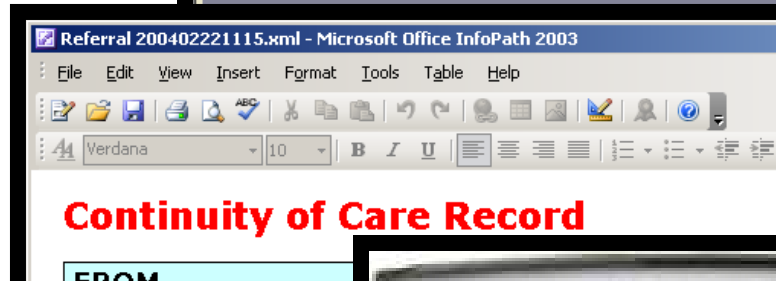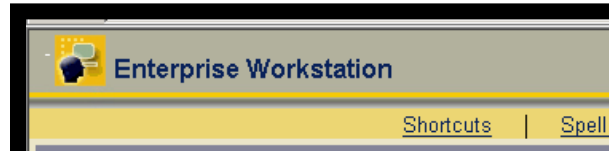Patient, provider, document type, organization…

Interoperability: How do I get it?

- One example of V3:
- Clinical Document Architecture
  – ANSI/HL7 CDA R2-2005 (R1-2000)
- First balloted V3 specification and most widely implemented

CDA: A Document Exchange Specification

- This is a CDA
- and this
- and this
- and this
- and this
- and this

CDA Impleme...

SCIPHOX - Communication between Physician Offices and Hospitals AkteOnline or health record on-line

CMS/WEDI/Empire Claims Attac...
Mayo Clinic - Rochester Notes I...

Cardiology Reports and Structured Data Communication

E-MS Electronic Medical Summary

Clinical Information Sharing based o...

Health...CDA Boundary Infos...

Vancouver Island Authority

CEMOL (On-Line Medical Certifications)

Acquire - CDA V2 Project from A...

CDA for JAVA (CDA4j)

The Netherlands

Germany

United Kingdom

Finland

Lithuania

Canada

Denmark

Czech R

China

Ireland

Switzerland

Israel

South Korea

United States

Italy

India

Japan

Spain

Taiwan

Greece

Turkey

Mexico

GMS PICNIC: Denmark

Argentina

Discharge Summary and Referral in the ...d Lakes District Health Boards

GMS PICNIC: Crete

Southern Africa

Brazil

Australia

General Practice Computing Group (project 16) - eForms, CDA

New Zealand
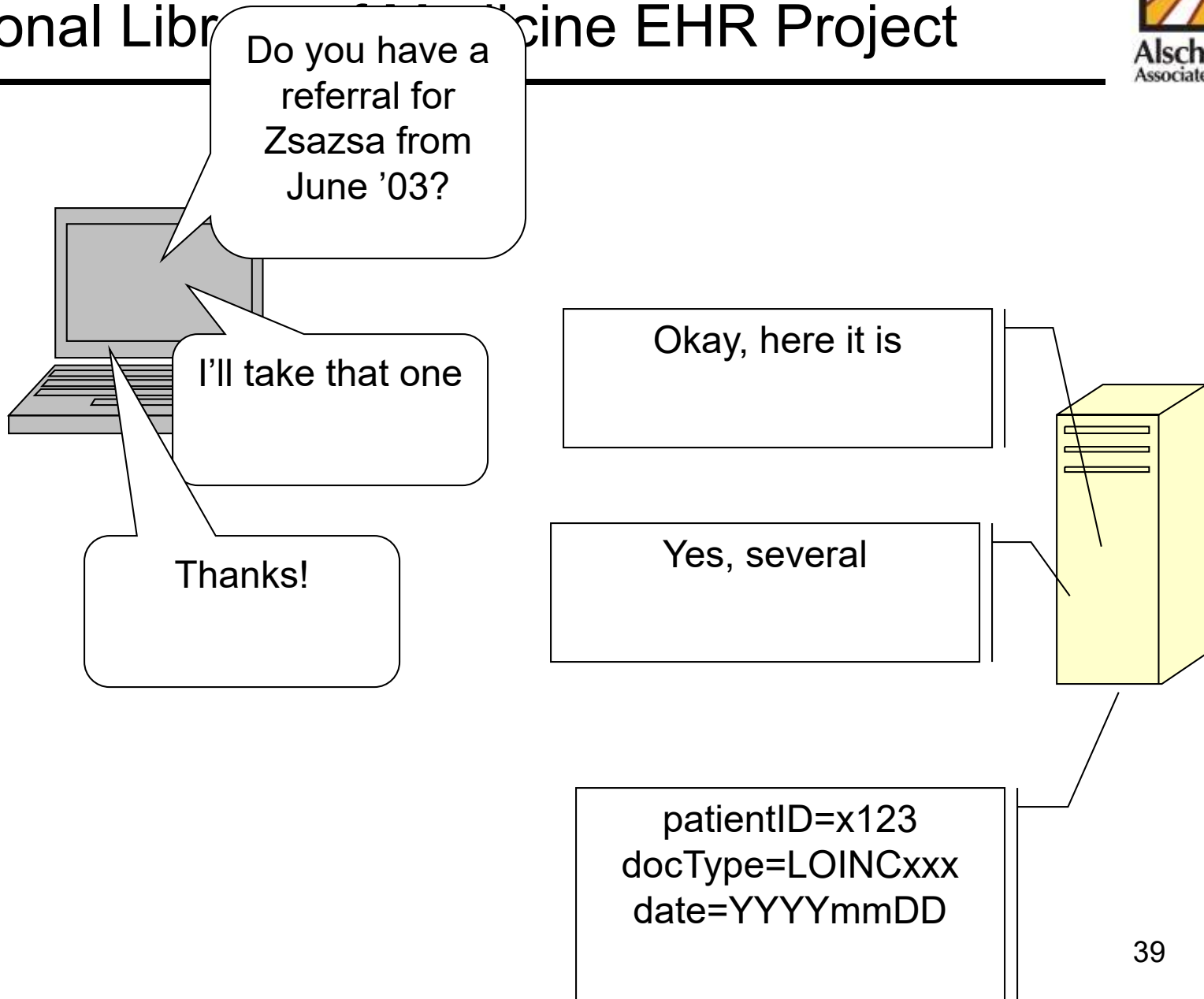
Please send any corrections or additions to cbeebe@mayo.edu
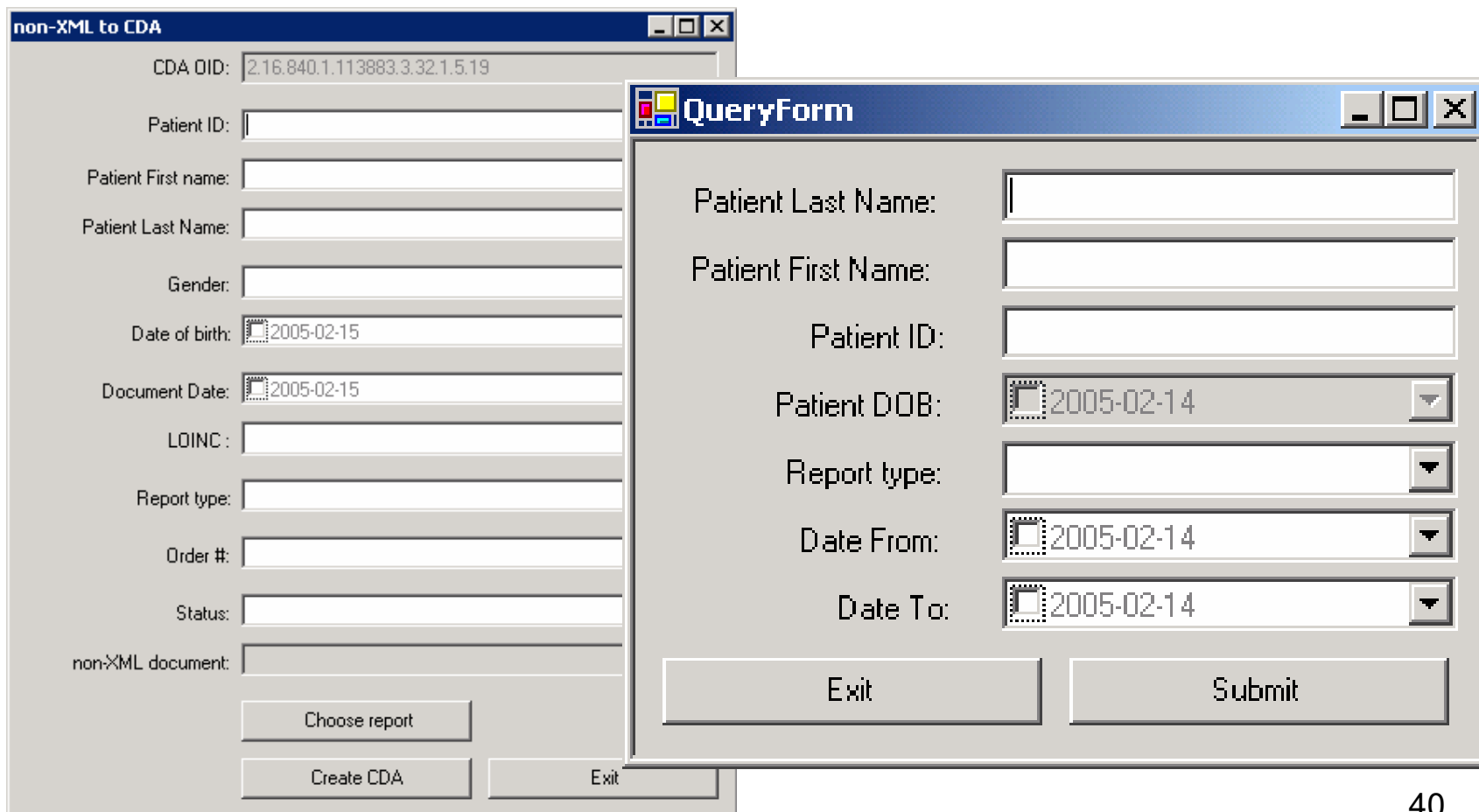
Investing in Information

- Simple documents
  - retrieval, display
  - metadata registry
- Two examples of higher-level investment:
  - HIMSS 2004, Dr. John Madden, Duke University Medical Center, created a CDA pathology note that doubles as a tumor board report
  - Also at Duke, the Starbrite "Single Source" Proof of Concept for clinical trials

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- ## Create & request a document

A single
data REPRESENTATION standard

facilitates multiple
document PRESENTATION standards !

Clinical history
Hemoptysis
Smoking
RUL mass

Gross description
|Specimen 1|
A 210 gram, 7 x 5 x 4 cm right upper lobectomy. There is a firm, palpable mass in the apex. The overlying pleura is intact. Sectioning discloses a solitary 3.5 x 2.5 x 2 cm stellate, scirrhous mass in the apical periphery, 2 cm remote from the hilum. There is no apparent invasion of the pleura. The hilar lymph nodes are of normal size and consistency. 1-1 = bronchovascular margin; 1-2 = frozen section control; 1-2 to 1-6 = representative tumor; 1-7 = hilar lymph nodes.

CPT Codes
1. 88309/FR

Intraoperative consultation
|Specimen 1|
Non-small cell carcinoma

Microscopic description
|Specimen 1|
Microscopic description is performed.

Images

Tum

Typ

Mag

Stai

○ Click here to insert immunohistochemical findings...
○ Click here to insert molecular diagnostic findings...
○ Click here to insert electron microscopic findings...

Diagnosis

☑ Right upper lobe ☐ Left upper lobe

☐ Right middle lobe ☐ Lingula

CARCINOMA OF LUNG, ☐ Right lower lobe ☐ Left lower lobe , (| Lobectomy ▼ |)
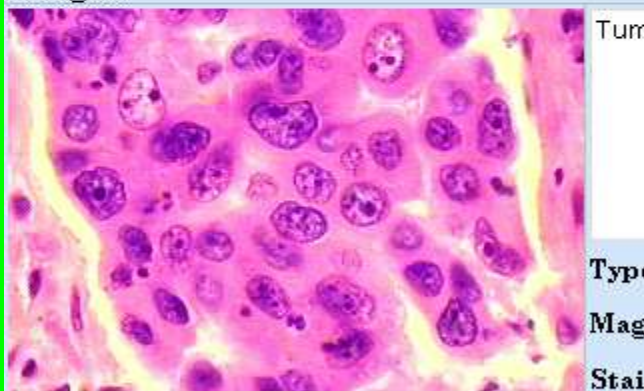
Pathologist view: CAP/ACoS standards compliant, template-driven data entry

Clinical history
Hemoptysis
Smoking
RUL ma

Gross desc
|Specimen 1|
A 210 gram,
overlying ple
the apical pe
hilar lymph n
section cont

CPT Codes
1. 88309/

Intraopera
|Specimen 1|
Non-small ce

Microscop
|Specimen 1|
Microscopic

Images

Click here to
Click here to
Click here to

Diagnosis

CARCINOMA

Alschuler
Associates, LLC

```xml
<entry>
  <entryChoice>
    <Observation>
      <code code="37149302" codeSystem="2.16.840.1.113883.6.96">
        <originalText>Venous (large vessel) invasion</originalText>
      </code>
      <value xsi:type="CD" code="4022308" codeSystem="2.16.840.1.113883.6.96">
        <originalText>Negative</originalText>
      </value>
    </Observation>
  </entryChoice>
</entry>
<entry>
  <entryChoice>
    <Observation>
      <code code="39571509" codeSystem="2.16.840.1.113883.6.96">
        <originalText>Lymphatic (small vessel) invasion</originalText>
      </code>
      <value xsi:type=
        <originalText>
      </value>
    </Observation>
  </entryChoice>
</entry>
<entry>
  <entryChoice>
    <Observation>
      <code code="371
        <originalText>
      </code>
      <entryRelationship>
        <entryChoice>
          <Observation>
            <code code="363661006" codeSystem="2.16.840.1.113883.6.96">
              <originalText>Regional lymph node status</originalText>
```
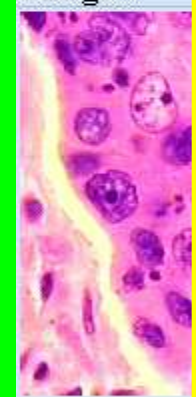
Repository view:
HL7-CDA standard XML with XQuery-ready, context-linked SNOMED encodings

Clinical history
Hemoptysis
Smoking
RUL ma...

Gross desc...
|Specimen 1|
A 210 gram,
overlying ple...
the apical pe...
hilar lymph n...
section cont...

CPT Codes
1. 88309/...

Intraopera...
|Specimen 1|
Non-small ce...

Microscop...
|Specimen 1|
Microscopic ...

Images

Click here to
Click here to
Click here to

Diagnosis

CARCINOMA

South Hospital

Patient: Smith , John
MRN: 13279
DOB: 1/1/1950
Sex: M

Accession # 123.456.789

Date: 1/31/2004

Surgical Pathology Report

Clinical History
- Hemoptysis
- Smoking
- RUL mass

Gross Examination

Specimen 1	A 210 gr... The over... scirrhou... invasion... bronchovascular margin, F-2 = frozen section control, F-2 to F-8 = representative tumor, F-9 = hilar lymph nodes.

Microscopic Examination

Specimen 1	Microscopic description is performed.

Diagnosis

Clinician view: Traditional format, print/electronic delivery

Clinical history
Hemoptysis
Smoking
RUL ma...

Gross desc...
|Specimen 1|
A 210 gram,
overlying ple...
the apical pe...
hilar lymph n...
section cont...

CPT Codes
1. 88309/...

Intraopera...
|Specimen 1|
Non-small ce...

Microscop...
|Specimen 1|
Microscopic ...

Images

```
<entry>
  <entryCh...
    <Obser...
      <cod...
        <o...
      </co...
      <val...
        <o...
      </va...
      <o...
    </Obse...
  </entryC...
</entry>
<entry>
  <entryCh...
    <Obser...
      <cod...
        <o...
      </co...
      <val...
        <o...
      </va...
    </Obse...
```

South c...
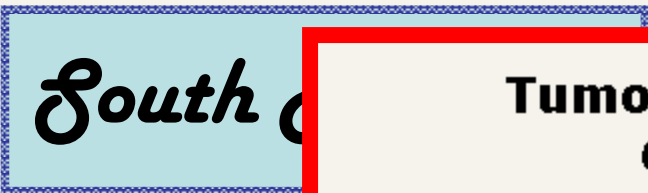
Accession # 1...

Date: 1/31/2004

Clinical History
- Hemoptysis
- Smoking
- RUL mass

Gross Examination

Patient: Smith | John

Tumor Registry Coding Form
Carcinoma of Lung

PATIENT

Given Name: John
Family Name: Smith
DOB: 1/1/1950
Surgery: 1/31/2004

Predicted stage classification

| pT2 | pN0 | pM see elsewhere |

Site	RightUpperLobe
...mor type	Adenocarcinoma
Size	3.5
Grade	Grade 3
...al pleura	Negative
...hest wall	Negative
...iastinum	Negative
...s ≥2 cm ...m carina	Negative
...s <2 cm ...m carina	Indeterminate
...r nodules	Negative

Tumor registrar view: Irrelevant items filtered, stage computed automatically

```
                              ┌──────────────────────────┐
                              │ Display or print         │
                              │ (referring physician's   │
                              │ view                     │
                              └──────────────────────────┘
                             ↗
┌─────────────────┐                    ┌──────────────────┐
│ Source CDA      │ ─────────────────→ │ Archival CDA     │
│                 │                    │ XML              │
│ (pathologist,   │ ↘                  └──────────────────┘
│ author's view)  │
└─────────────────┘      ┌──────────────────────────┐
                         │ Tumor Board,             │
                         │ synopsis, meets          │
                         │ CAP reporting            │
                         │ guidelines               │
                         └──────────────────────────┘
```
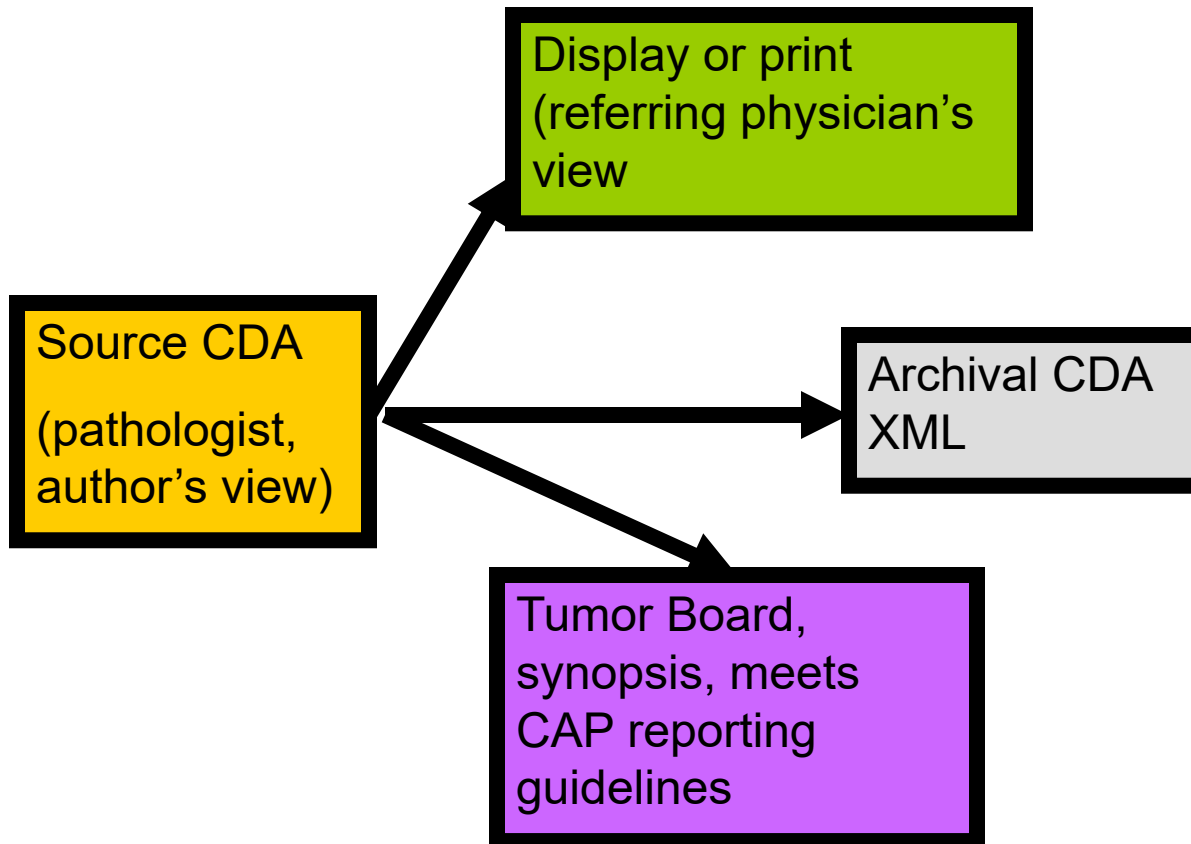
Investing in Information

- "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
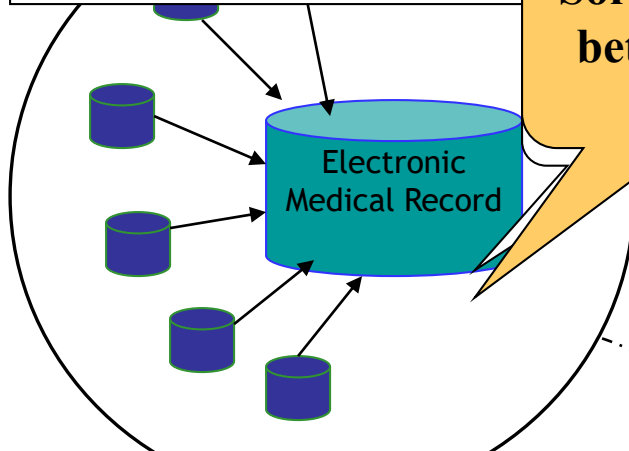   - Microsoft, primary technology partner

Different World Views

Patient Care World
- Multiple data sources and data types
- HL7 V2.x a pervasive standard
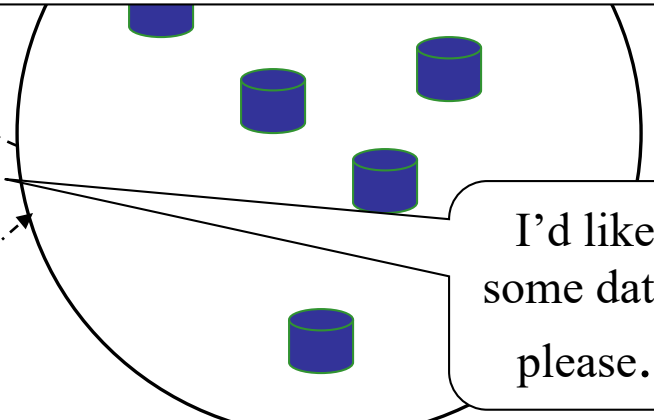- Electronic medical records assembled from mult...

Clinical Research World
- Carefully controlled data
- Each trial's data independent
- CDISC the emerging standard
- Data flows from sites to CROs to sponsors to FDA

Electronic Medical Record

Sorry, I've got better things to do

I'd like some data, please.

Patient Care World
- Clinicians want to see everything they can get
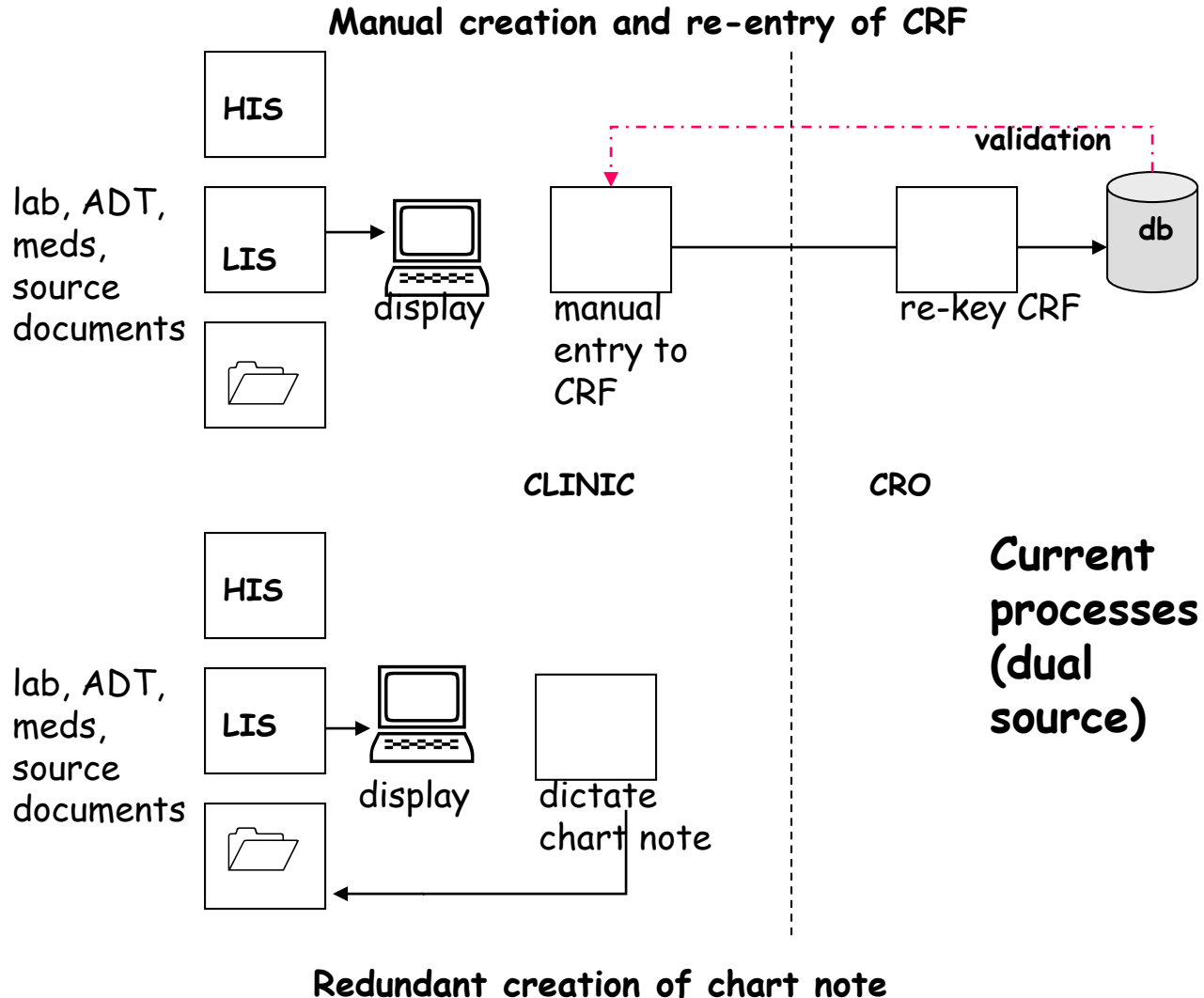- Data is organized around the patient

Clinical Research World
- Bio-statisticians tightly control what is gathered
- Data is organized around a trial

48

And the Result is…

EDC without data standards, courtesy Charles Jaffe, MD, Astra-Zeneca

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

validation

db

CLINIC

CRO

Current processes (dual source)

HIS

lab, ADT, meds, source documents

LIS

display

dictate chart note

Redundant creation of chart note

50

**Merged workflow: electronic CRF
re-used in chart note**

validation

HIS

lab, ADT,
meds,
source
documents

LIS

display

eCRF

CDA/
ODM

db

dictate
chart note

**Proposed
processes
(single
source)**

CLINIC

ARO

Some Conclusions

- What creates a healthy information environment?
  - Data
  - Business
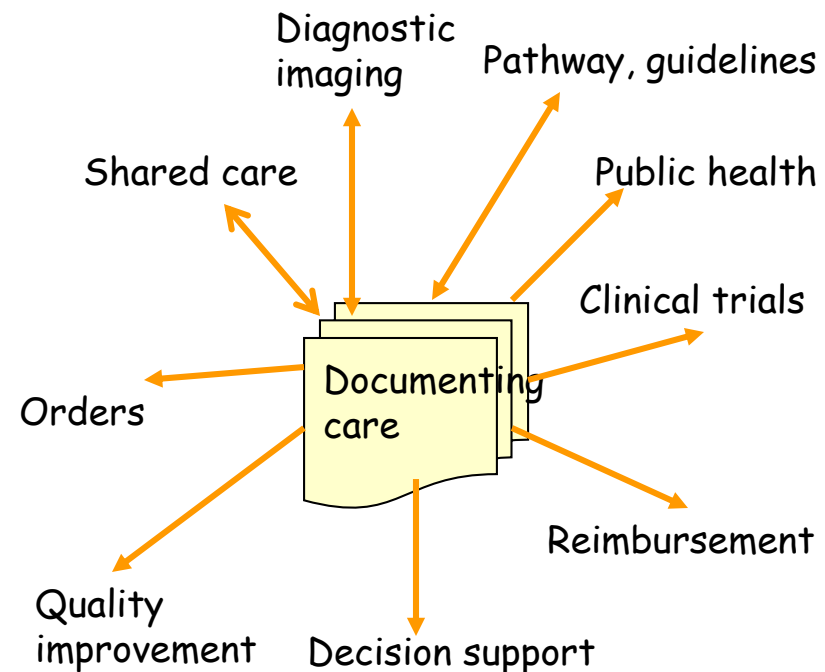 - Technology

Capture once, use many

– What can data standards accomplish in healthcare?
– dream scenario: patient visit
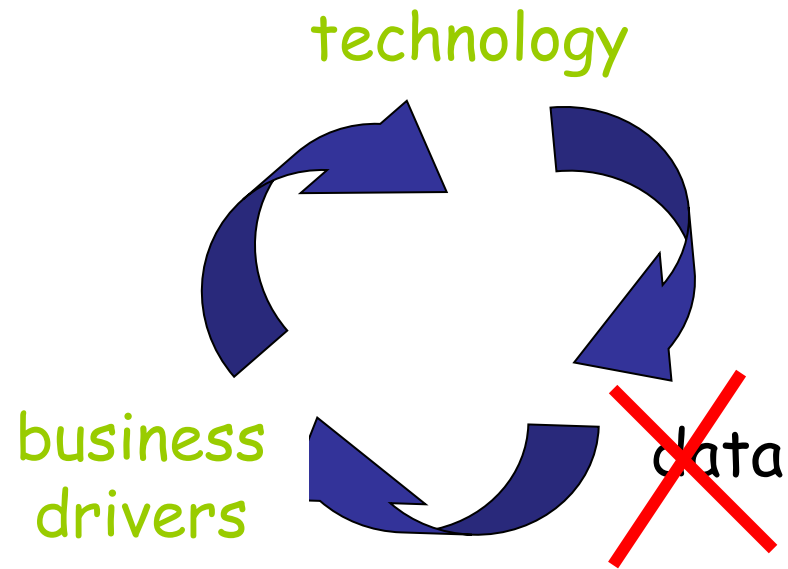
use:
  – clinician to clinician,
  – patient safety,
  – decision support,
- **reuse**:
  – drug safety;
  – public health;
  – quality monitoring;
  – clinical trials;
  – practice management;
  – reimbursement

Diagnostic imaging

Pathway, guidelines

Shared care

Public health

Clinical trials

Orders

Documenting care

Reimbursement

Quality improvement

Decision support

Information Ecology

technology

business
drivers

~~data~~

- Problems with data:
  - Paper
  - If electronic, then narrative
  - If data, not coded
  - If coded, proprietary
  - If standard, still too loose

It's the data

- Major cost of a new implementation
  - Not the hardware
  - Not the software
  - Not even the consultant…
  - It's the data

It's the data

Network a function of the number of nodes

- Number of nodes drives adoption
  - Internet, Web, fax…

It's the data

- Mayo Clinic: data is their key capital asset
  - Not the buildings
  - Not the equipment
  - Not the staff
  - It's the data

It's the data

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

  "The essential kernal of the whole clinical development processs 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.**"

"Critical mass"

- Few of the regional information sharing networks have achieved critical mass
  - Network a function of # of nodes

Who's minding the store?

- Business drivers
  - No precedent
  - Who owns this data? Perfunctory discussion
  - Patients rights: to a non-reusable printout?
  - Value: we know it's there, but
    - who does it belong to? Producers or resellers?
- Answers may emerge over time
  - Need to start the discussion
  - Factor in designing architecture

Information Ecology

technology

business
drivers
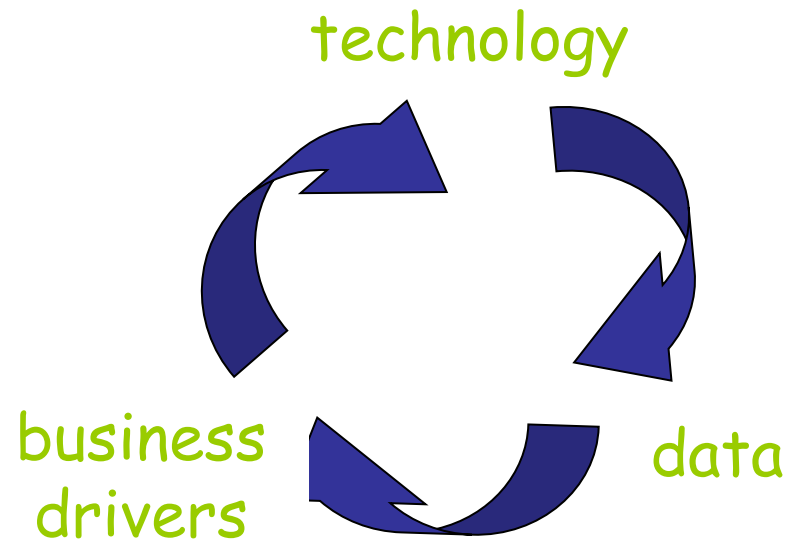
data

Networks

- How do you move data?
- Big database: precluded for security, privacy, business reasons
- Weaned on distributed, RLS
  - Eric Andersen
  - Santa Barbara
  - Finland
  - IHE XDS
- Now, need to look at alternate models

conclusions

- Focus on the data
  - Provider participation
  - Bring benefit to full spectrum of practices
- Don't get (too far) ahead of revenue stream
  - It's the US: business matters
- The technology is the easy part

Thank you!

Questions?