The Interoperability Journey*

NETTAB Workshop on Clinical Bioinformatics
14 October 2011, Pavia

Amnon Shabo (Shvo), PhD
Co-Chair, Medical Informatics Community, IBM Research
IBM Haifa Research Lab (HRL)

* The presentation is based on key slides from my NETTAB Special Session talk on interoperability.
Challenges

- Interoperability Foundations

- Key Standards
  - Clinical Genomics
  - CDA
  - Family History

- The EHR

- IHRB
Universal Exchange Language? The New Generation of Standards!

![Diagram](image)

Observation O₁ (consisting of Observations O₁₁ and O₁₂ and related to Subject S₁), is the reason for Procedure P₁ (performed by Clinician C₁) which is the cause of Observation O₂…

**Grammar**

Insert into basic health objects

**Clinical Statement**

**Observation Object**

**Procedure Object**

**Participant Object**

**Medication Object**

**Lab**

**Pharma**

**Docs**

**Others**
To Achieve Semantic Computation & Interoperability...

...all standards need to derive from a Central Health RIM:

Central Health RIM (e.g., an extended HL7 V3 Reference Information Model): Bio & medical-informatics standard specs are derived from the same RIM
The core classes:
An Entity plays a Role which Participates in an Act
Challenges

- Interoperability Foundations

- Key Standards
  - Clinical Genomics
  - CDA
  - Family History

- The EHR

- IHRB
HL7 Clinical Genomics Data Standards: Encapsulate & Bubble-up

- **Genomic Data Sources**
- **Clinical Practices**
- **EHR System**
- **Knowledge** (KBs, Ontologies, registries, reference DBs, Papers, etc.)
- Decision Support Applications
  - Bubble up the most clinically-significant raw genomic data into specialized HL7 objects and link them with clinical data from the patient EHR

---

**the challenge...**

- Encapsulation by predefined & constrained bioinformatics schemas
- Bubbling-up is done continuously by specialized CDS applications
HL7 Clinical Genomics v3 Static Models

- Family History
- Genetic Loci
- Genetic Variation
- Gene Expression
- Phenotype (utilizing the HL7 Clinical Statement)

Utilize

- CDA IG
- RCRIM
- LAB

Constrained

Domain Information Model: Genome

Normative

*DSTU* = Draft Standard for Trial Use
CDA Overview

- **CDA** – a generic specification

- Could be used to represent various types of documents:
  - Consultation note
  - Visit / progress note
  - Referral letter
  - Discharge summary
  - Operative note
  - …

- A document type is also called ‘template’ or ‘implementation guide’
An abstract Clinical Genomic Statement (CGS) template that
- Has at its core a genomic observation (e.g., a DNA sequence variation)
- If it’s a reportable finding, then it should be associated with indications and interpretations, specimen and genomic source class
- The major finding can be associated with associated observation (e.g., amino acid change)
- Optionally, performers may be specified (overriding header performers)

The CGS abstract template is instantiated by specialized CGS’s, e.g., for genetic variations or cytogenetics.
Family History: PHR-EHR-GEN Convergence

Enable
Decision Support
e.g., risk analysis algorithms

EHR

PHR

Genomics

Enable Decision Support e.g., risk analysis algorithms
There’s currently a tension between the two goals:
The more expressive it is -
the less interoperable it is

Expressive structures lead to optionality
- Possible solution: Constraints
  - Archetypes with EHR 13606 (European/ISO Standard)
  - HL7 Templates (no formalism has been agreed upon)
    - OCL is examined
    - GELLO (OCL-based) for clinical decision support
- Public registries of templates
  - Need dedicated IT to provide registry services!
Template-based Information Model for HyperGenes

CDA Template
- Header
  - subject id
- Body
  - reference1 to GV
  - reference2 to GV
  - reference2 to PD
  - clinical & environmental observations

GV Template
- subject id
- Genomic Observations
- Phenotypes

Pedigree Template
- subject id

Raw Genomic Data
- subject id
- HapMap / BSML / MAGE Relational schemas
  - optimized for persistency
  - Encapsulation or referencing

Disease Model

EHR

*Template (or profile) is a set of constraints specific to a project/solution*
The HyperGenes IT Landscape

New knowledge & Information:
- HL7 RIM-based XML Database
- Mass Data
  - Non-XML format, e.g., genomic; images; sensors

Health Semantic Warehouse

Data Marts

Analysis

Data

Provenance & Export

Promote & Export

HL7 RIM-based XML Database

EHR

Patient data

Sources of Proprietary or Standard

Sources of Proprietary or Standard

Exploration

XQUERY

Analysis

RESEARCH

HEALTHCARE

RDF

HL7 v3

Promote & Export

Exploration

XQUERY

Analysis

RESEARCH

HEALTHCARE

15
IHE Cross-Enterprise Document Sharing (XDS)
epSOS – European Patients Smart Open Services

Country B
- POC (Pharmacy)
- POC (Hospital)
- POC (General Practitioner)

Country A
- POC (Pharmacy)
- POC (Hospital)
- POC (General Practitioner)

epSOS Circle of Trust

IHE & CDA are key standards!

Source: epSOS project documentation
USA National Health Information Network

*Based on IHE XDS*

**Source:** NHIN specifications

---

*IHE XDS = Integrating the Healthcare Enterprise – Cross Enterprise Document Sharing*
Challenges

- Interoperability Foundations

- Key Standards
  - Clinical Genomics
  - CDA
  - Family History

- The EHR

- IHRB
From Medical Records to EHR

Medical record
Every authenticated recording of medical care (e.g., clinical documents, patient chart, lab results, medical imaging, personal genetics, etc.)

Cross-institutional

From medicine to health...

Longitudinal (possibly lifetime)
EHR
A single computerized entity that continuously aggregates and summarizes the medical and health records of individuals throughout their lifetime

Health record
Any data items related to the individual’s health (including data such as genetic, self-documentation, preferences, occupational, environmental, lifestyle, nutrition, exercise, risk assessment data, physiologic and biochemical parameter tracking, etc.)
EHR – Layers of Temporal and Summative Data

Temporal Data

Summative Info

Evidence

Topical data

Non-redundant data

Ongoing extraction and summarization

Medical records: charts, documents, lab results, imaging, etc.
A collaboration of CEN and HL7 experts to express the EHR model using the HL7 Reference Information Model (RIM)
Rise of the EHR…

1. Extend IHE XDS* to handle any source data while transforming to RIM-based representation
2. Persist incoming data in a RIM-based repository that also plays an XDS Repository
3. Represent the CEN EHR 13606 spec over the RIM
4. Ongoing update of the patient-centric EHR and summarization of temporal data
Challenges

- Interoperability Foundations
- Key Standards
  - Clinical Genomics
  - CDA
  - Family History
- The EHR
- IHRB
From the PCAST report:
“The approach that we describe requires that there be a common infrastructure for locating and assembling individual elements of a patient’s records, via secure “data element access services” (DEAS). Importantly, this approach does not require any national database of healthcare records; the records themselves can remain in their original locations. Distinct DEAS could be operated by care delivery networks, by states or voluntary grouping of states, with possibly a national DEAS for use by Medicare providers. All DEAS will be interoperable and intercommunicating, so that a single authorized query can locate a patient’s records, across multiple DEAS.”

Is it really an axiom?!
Patient-centric EHR Challenges

- Longitudinal EHRs should not be virtual / federated
  - **Rationale**: sources might not be available or be semantically different; true summarization cannot be done “on the fly”

- Given the need for aggregated EHR, the challenge is –
  - EHR sustainability!

- **Main assertion**: None of the existing players in the healthcare arena can, or should, sustain lifetime EHRs
  - **Rationale**: Involves intensive IT computing tasks (archiving / preservation in particular) which are not the main focus nor expertise of existing players
  - If an existing player sustains EHRs, it might lead to ethical conflicts

* These assertions and the IHRB vision are not necessarily the view of the IBM corporate; they are research hypotheses.
EHR Sustainability Constellations

- **Government Centric**: e.g., UK, Denmark
  - Big brother

- **Provider Centric**: e.g., Canada
  - Partial data

- **Regional Centric**: e.g., USA, Finland
  - Limited

- **Consumer Centric**: e.g., Google Health
  - Non-reliable Data

- **Non-Centric**: Independent EHR Banks (IHRBs)
  - E.g., Canada
  - E.g., USA, Finland
  - E.g., Canada
  - E.g., Google Health
Main principles of the IHRB legislation

- The medico-legal copy of a medical record resides solely in an IHRB
- An IHRB must be independent of healthcare providers, health insurers, government agencies, or any entity that may present a conflict of interests
  - An IHRB must function as an objective entity, serving all stakeholders
  - An IHRB is the custodian of its customers’ EHRs, thus avoiding the need for the sensitive definition of EHR ownership
- Allow for multiple independent IHRBs, regulated by national (or international) regulators
- A consumer’s EHR is identified by its IHRB account number, so there is no need for unique IDs at any level (regional, national or international)
- Authorized access to all parties; only ethical committees can limit patient access
- A consumer can move from one IHRB to another
- Holding multiple accounts is not recommended, however
  - any attested medical record must reside in only one IHRB account
The Conceptual Transition

Current constellation: 
- Provider
  - Operational IT Systems
  - Archive-Medical Records

New constellation: 
- Provider
  - Standard-based Communications
  - Independent Health Records Bank

New Legislation

Healthcare
Consumer

Standard-based Communications
The EHR Main “Production Cycle”

1. Healthcare Provider receives the current EHR from the patient’s IHRB

2. Provides care to the patient

3. Sends medical records back to the patient’s IHRB

4. EHR is updated
The EHR “Production Cycle” with Pharma

1. Clinical Trials Sponsor receives the current EHR from the patient’s IHRB
2. Select, enroll & engage patient in a clinical trial
3. Sends trial records back to the patient’s IHRB account
4. EHR is updated
IHRB Main Benefits

- Healthcare providers cut costs of long-term archiving for medical records
- Healthcare providers have a complete medical history of any patient requesting care
- Healthcare providers have EHR summative information that facilitates the intake of new patients
- The EHR might also include moderated self documentation and other sources of health data
- Multiple competing IHRBs will provide better services to all parties
- No need for unique IDs that might harm individual privacy
- Privacy is better protected as it is in the core of the IHRB activity; mitigates the unavoidable tension of privacy versus availability
- Based on proper patient consent, truly anonymized data could be made available to public health agencies, clinical research institutes, and the pharma
IHRB Bills were introduced in the US!

Brownback (R-KS): Independent Health Record Bank Act of 2006:

- IHRB goals are to save money and lives in the health care system
- Only non-profit entities are permitted to establish IHRBs
- IHRBs function as cooperative entities that operate for the benefit and interests of the membership of the bank as a whole
- Revenue:
  - IHRB’s may generate revenue by
    - charging health care entities account holders account fees for use of the bank
    - the sale of non-identifiable and partially identifiable health information contained in the bank for research purposes
  - Revenue will be shared with account holders and may be shared with providers and payers as an incentive to contribute data
  - Revenue generated by an IHRB and received by an account holder, healthcare entity or health care payer will not be considered taxable income
More details can be found in my papers published in the Journal “Methods of Information in Medicine”

Comments: shabo@il.ibm.com

IHRB History:
1998: Amnon Shabo raises the idea and founds the Bankomed initiative, set out to establish a first experimental IHRB
1999: IHRB is the core of the Bankomed business plan, submitted to major venture capitalists in Israel
2003: IHRB is the core of the mEHR proposal made to the EC FP6 by 19 European partners (including IBM Research Lab in Haifa)
2004: HRB (Health Records Banks) is a core part of IBM Research Strategy in Healthcare
2005: IHRB is published in IP.com
2006: IHRB Bills were introduced in the US
The End

- Thanks for your attention!
- Questions?
- Comments: shabo@il.ibm.com

Unlocking the Power of Health Information.