HL7 Version 3 – Standards with Increased Specificity

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HL7’s mission - 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. Specifically, to create flexible, cost effective standards, guidelines, and methodologies to enable healthcare information system interoperability and sharing of electronic health records.” (Source: HL7 Mission statement, revised 2001)
Interoperability

- Main Entry: **interoperability**
  - Function: *noun*
  - Date: 1977
  - : ability of a system ... to use the parts or equipment of another system
  - Source: Merriam-Webster web site

- **interoperability**
  - : ability of two or more systems or components to exchange information and to use the information that has been exchanged.
Phrased another way -
Complete semantic understanding of a data exchange can only be achieved if the sender and receiver *share a common model* of the data that represents the domain of communication *and* if the sender and receiver *use common sets of terms* (codes) drawn from terminologies that are fully defined and comprehensively represent the concepts in the domain of communication.
• Functional interoperability requires a robust scheme for formatting the data so that they can be assembled into messages and disassembled (parsed) reliably and efficiently, and

• Systems that will reliably and rapidly transport the data from one computing application to another
Functional & Semantic Interoperability

- Defined process for sharing
- Reference Information Model
- Common Data Types
- Common Terminologies
- Common content specification at complex levels – a.k.a. clinical templates
- Clinical document architectures
- Conformance requirements
- Document standards
- Trigger Events

From: W. E. Hammond, Ph.D., 2002
Why Version 3?

- Even as the first Version 2 standards were being accepted and implemented, HL7 began to seek a *better* way to develop standards
- Version 2 used a quick-design approach to meet immediate needs in the health care IT community
- But it is an *ad hoc* method that is difficult to coordinate and control
- Hence, Version 3
The “essence” of Version 3

- Apply the ‘best practices’ of software development to developing standards – a model-based methodology
- Predicate all designs on two semantic foundations – a reference information model and a complete, carefully-selected set of terminology domains
- Require all Version 3 standards to draw from these two common resources
- Use software-engineering style tools to support the process.
Normative RIM Class Diagram

- 4 Primary Subject Areas
- 35 Classes
- 181 Attributes
- 9 Associations
- 28 Generalizations

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Core concepts of RIM

- Every happening is an **Act**
  - Procedures, observations, medications, supply, registration, etc.
- Acts are related through an **ActRelationship**
  - composition, preconditions, revisions, support, etc.
- **Participation** defines the context for an Act
  - author, performer, subject, location, etc.
- The participants are **Roles**
  - patient, provider, practitioner, specimen, specimen, etc.
- Roles are played by **Entities**
  - persons, organizations, material, places, devices, etc.
HL7 innovation - devices

- HL7 Model Repository – data base holding the core of HL7 semantic specifications
  - RIM - Storyboards
  - Vocabulary domains - Interaction models
  - Message designs - Message constraints
- Tool sets designed against the repository to
  - Permit management of repository content
  - Review and browsing of semantic specifications
  - Design of abstract information structures based on the RIM for use in messages, templates, documents, etc.
  - Publish HL7 specifications and standards
  - Support implementation of HL7 standards
Demo Example – POLB_RM992100

Laboratory Observation Order
(POLB_RM992100)
Common entry point for laboratory order communication.

ObservationOrder
- classCode*: <= OBS
- moodCode*: <= ORD
- id*: II [1..1]
- code: CE CWE <= ObservationType (e.g. LOINC code)
- text
- statusCode*: CS CWE <= StatusType "active"
- effectiveTime*: "phys time, start time" aimed for
- activityTime: IVL<TI>
- priorityCode: CE CWE <= PriorityCode "R"
- confidentialityCode*: [1..*] <= Confidentiality "N"
- methodCode: <= ObservationMethod
- targetSiteCode: <= ActSite

Definition
- typeCode*: <= AN
- concept*: <= ObservationDefinition

Ordered Test

Author

Physician

Performer

Laboratory

Subject

Specimen

Record target

Patient
Demo Example – POLB_RM992100

Order

Author
- Physician
- Performer
- Laboratory

Subject
- Specimen
- Record target
- Patient

Definition
- Ordered test
Our example schema

```xml
<xs:complexType name="POLB_MT992100.ObservationOrder">
  <xs:restriction base="Observation">
    <xs:sequence>
      <xs:element name="id" type="ID"/>
      <xs:element name="code" type="Act.code" minOccurs="0"/>
      <xs:element name="text" type="ED" minOccurs="0"/>
      <xs:element name="statusCode" type="Act.statusCode"/>
      <xs:element name="effectiveTime" type="GTS" minOccurs="0"/>
      <xs:element name="activityTime" type="TVL_TS" minOccurs="0"/>
      <xs:element name="priorityCode" type="Act.priorityCode" minOccurs="0"/>
      <xs:element name="confidentialityCode" type="Act.confidentialityCode" maxOccurs="unbounded"/>
      <xs:element name="methodCode" type="Observation.methodCode" minOccurs="0" maxOccurs="unbounded"/>
      <xs:element name="targetSiteCode" type="Observation.targetSiteCode" minOccurs="0" maxOccurs="unbounded"/>
      <xs:element name="author" type="POLB_MT992100.Author" nillable="true" minOccurs="0"/>
      <xs:element name="performer" type="POLB_MT992100 Performer1" nillable="true" minOccurs="0" maxOccurs="unbounded"/>
      <xs:element name="recordTarget" type="POLB_MT992100.RecordTarget" nillable="true" minOccurs="0" maxOccurs="unbounded"/>
      <xs:element name="subject" type="POLB_MT992100 Subject2" nillable="true" minOccurs="0" maxOccurs="unbounded"/>
      <xs:element name="definition" type="POLB_MT992100 Definition" nillable="true" minOccurs="0"/>
    </xs:sequence>
    <xs:attribute name="type" type="Classes" default="Observation"/>
    <xs:attribute name="classCode" type="ActClass" default="OBS"/>
    <xs:attribute name="moodCode" type="ActMood" default="ORD"/>
  </xs:restriction>
</xs:complexType>

<xs:complexType name="POLB_MT992100.Author">
  <xs:restriction base="Participation">
    <xs:sequence>
      <xs:element name="signatureCode" type="Participation.signatureCode"/>
      <xs:element name="signatureText" type="ED" minOccurs="0"/>
      <xs:group ref="COCT_MT080000P"/>  <!-- CMET reference -->
    </xs:sequence>
    <xs:attribute name="type" type="Classes" default="Participation"/>
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    <xs:attribute name="contextControlCode" type="ContextControlPropagating"/>
  </xs:restriction>
</xs:complexType>

<xs:complexType name="POLB_MT992100.Performer1">
  <xs:restriction base="Participation">
    <xs:sequence>
    </xs:restriction>
</xs:complexType>
```

Bringing it together

- One Reference Model, one set of tools, one process produce
  - The mundane – a Common element for patient
  - The complex – a specification to communicate annotated ECGs for clinical trials
  - Large, rich sets – electronic claims, clinical trial data
  - The esoteric – clinical genomics
  - The basics – message control (headers)

- All taken from RIM to schemas, and published with a single set of effective tools
1996  Introduced concepts to Technical Leadership
1997  Presented methodology and draft RIM to WG
       Created Vocabulary Technical Committee
1998 - 1999 Refined the RIM and methodology
2000  Approved CDA Level 1 – the first RIM-based
       HL7 standard
2001  Published first “non-draft” RIM, version 1.0
2001 - 2002 Started ballot cycles on V3 Message content
2003  RIM approved as standard
       Principles of extensibility & localization approved
       as Standard
       Annotated ECG approved as Informative Specification
Lessons from the time-table

- Formal processes have a long gestation period for learning and adapting.
- Development of common model is not a “free” process.
- Reaching agreement on a single model is both exciting and – very difficult.
- Once the pieces are in place, actual standards design is amazingly quick.
- The formal methodology CAN be readily adapted as we learn new requirements for the standard and its publication.
### V3 Ballot History - Overall

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**Advance to final approval**

Approved HL7 standards or informative documents

Expanding scope
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<td>CCCCC</td>
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<td>Patient Care</td>
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Critical next steps

- Complete balloting on the core foundation specifications – implementation specifications for XML, common message elements, etc.
- Mine the experience of the early adopters to build Implementation Guides and tools for implementation
- Establish registries to track the implementation experience of adopters in order to feed-back into the standards
- Expand the cadre of “V3-capable” implementers by simplification, tooling, training
- Find the right balance between specifications that are “rigorously complete” and specifications that are readily implemented to solve extant problems
- Learn to deal with the demands of “continuous development” of our standards without draining the energies of our volunteers.
- Figure out what it means to be “done” with the first set of V3 messaging standards (so that we can celebrate, even as we continue developing).