HL7 Process and Governance

Introduction to Health Level Seven (HL7) Organization

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Our Team

Greetings!

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Agenda

• HL7 International
  – Vision and Mission
  – What is it
  – How is it Organized
  – Organizational Chart
  – Affiliates
  – Role in enabling interoperability
  – 30 Second “Intro to FHIR”
HL7 International’s Vision

A world in which everyone can securely access and use the right health data when and where they need it.
HL7 International’s Mission

HL7 empowers global health data interoperability by developing standards and enabling their adoption and implementation.
HL7 International is a Consensus Driven Standards Development Organization (SDO)
HL7 International

• HL7 International is a not-for-profit Standards Development Organization (SDO)
  – Headquartered in Ann Arbor, MI
  – Has an office in Brussels, Belgium

• HL7’s members (providers, vendors, payers, consultants, government groups and others who have an interest in the development and advancement of clinical and administrative standards for healthcare) develop HL7’s standards.
What is HL7 International?

• HL7 International is one of several American National Standards Institute (ANSI) accredited Standards Developing Organizations (SDOs) operating in the healthcare arena.

• Most of these SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claims processing) transactions.
History of HL7 (Through 2004)

- **Version 1.0** Published
- Implementation Support Guide published
- **Version 2.2** Published
- **Version 2.2 ANSI**
- **Version 2.3.1** Published and ANSI
- **PRA** (CDA 1.0)
- **Messages**
- **Organization**
- **ANSI**
- More Than Messages

- **1987** First Meeting Hospital University of PA..
- **1988** Version 2.0 Published
- **1989** Charter member of ANSI HISPP
- **1990** Version 2.1 Published
- **1996** 1997 1998 1999 2000 2001 02 03 2004
- **2000** Arden Syntax 2.0
- **2001** 2.4
- **2002** 2.5
- **Version 2.3 Published and ANSI**
- **Version 3.0 Published**
- **CCOW**

First work on SOA (Services) with HSSP

2005 06 07 08 09 10 11 12 13 14 15 16 17

CDA 2.0

Version 2.6 Published

Version 2.7 Published

Version 2.8 Published

Version 3 Normative Edition
HL7 INTERNATIONAL: WHAT IS IT? HOW IS IT ORGANIZED?
Steering Divisions

- **Clinical**
  - Anesthesia
  - Attachments
  - Biomedical Research Integrated
  - Clinical Decision Support (CDS)
  - Clinical Genomics
  - Clinical Interoperability Council (CIC)
  - Clinical Quality Information (CQI)
  - Clinical Statement
  - Community Based Care
  - Emergency Care
  - Health Care Devices
  - Learning Health Systems (LHS)
  - Patient Care (PC)
  - Public Health (PH)
  - Pharmacy

- **Infrastructure**
  - Arden Syntax
  - Conformance
  - FHIR Infrastructure (FHIR-i)
  - Implementable Technology Specifications (ITS)
  - Infrastructure and Messaging (InM)
  - Mobile Health
  - Modeling & Methodology (MnM)
  - Security
  - Service Oriented Architecture (SOA)
  - Structure Documents
  - Templates
  - Vocabulary

- **Administrative**
  - Attachments
  - Electronic Health Record (EHR)
  - Financial Management (FM)
  - Imaging Integration (II)
  - Orders and Observations (OO)
  - Patient Administration (PA)

- **Organizational Support**
  - Education
  - Electronic Services and Tools (EST)
  - Healthcare Standards Integration (HSI)
  - Process Improvement Committee (PIC)
  - Project Services
Technical Steering Committee (TSC): Mission

• Mission: To provide the technical direction to the HL7 organization to achieve the vision of creating the best and most widely used standards in healthcare.
  – The TSC oversees and coordinates the technical efforts contributed by the HL7 participants to ensure that the efforts of the Working Group (WG) are focused on the overall HL7 mission.
  – TSC will provide input and operationalize the strategic initiatives. The TSC also reviews and provides oversight to projects during the approval process.
    • This allows the TSC to identify gaps and overlaps between projects of the Working Group and the strategic initiatives.
What is an Affiliate?

• An Affiliate is an independent legal entity that:
  – Represents its country and country affiliate members at HL7 International meetings and within its country/territory on HL7 matters;
  – Participates in HL7 International’s standards development and governance processes;
  – Promotes the relevance and fitness of the HL7 Protocol Specifications, HL7 Educational Material and Other HL7 Material in its country/territory;
What is an Affiliate (Contd.)?

• An Affiliate is an independent legal entity that:
  – Distributes, translates and localizes the HL7 Protocol Specifications as appropriate;
  – Administers HL7 Certification tests within its Territory when suitable and authorized to do so; and
  – Promote HL7 standards, educates, informs and supports current and potential users within the Territory to promote consistent and widespread usage of the standards.
HL7 INTERNATIONAL PROCESS: MEETINGS AND BALLOTS
HL7 International Meetings

- Working Group Meetings occur three times a year (Typically January, May and September).
- September meeting is designated a “plenary” meeting.
  - Monday AM is a special program dedicated to business and reporting state of the organization.
- Most (if not all) HL7 International work groups have face-to-face meetings during a working group meeting.
HL7 International Meetings

• Agenda usually progress work with time allocated to:
  – Version 2
  – Version 3
  – CDA
  – FHIR
  – Joint meetings with related work groups

• Current ballots normally take priority
HL7 International Meetings

• Work Groups (WG) have defined decision making processes that specify how they run meetings, debate and vote on issues discussed in a meetings.
  – Working Group Meeting (WGM) agendas are posted by WGs before the meeting and are available in the WGs pages on HL7.org, HL7 WiKi and HL7 Confluence (see WG page under other resources for the location of agendas).
  – Conference calls are also scheduled and distributed via List Server for the WG and listed on the WG page.
HL7 International Meetings

• Work Groups can customize their decision making processes. However:
  – Process Improvement Committee (PIC) guidelines constrains the framework
    • PIC has default and generic templates for decision making practices
  – By-Laws and Governance and Operations Manual (GOM) take precedence
  – Default conduct is Robert’s Rules of Order.
HL7 Products and Projects

• Project Lifecycle relies on the concept of HL7 International Products.

• Examples:
  – Product Brand
    • Messaging, Arden Syntax, CDA, XML, FHIR….
  – Version
    • V2, V3, R1, R2, R3, …
  – Multiple projects may be required to create viable ‘product’
30 second “Intro to FHIR”

• Pronounced “FIRE”
• Arose from the “Fresh Look Task Force” in 2012
• As significant as the leap from v2 to v3;
  – Still leverage v3 infrastructure & knowledge
  – But focus more on ease of implementation
• RESTful enabled and based on resources but also supports document, messaging & services paradigms;
30 Second “Intro to FHIR”

• All data is contained in a set of 100 resource definitions (for all of healthcare)
• Employs the 80-20 rule: Resources contain the elements 80% of systems will actually use;
• Everything else is handled by controlled extensions.
• There was strong support from the US ONC’s Standards Advisory Panel for FHIR.
30 Second “Intro to FHIR”

• ONC commissioned the creation of the JASON report (suggested reading).
  – Jason Report (Final)

• Recent HHS and ONC announcements encourage use of FHIR API for EHRs.
Questions
Thank you and enjoy the WGM!
APPENDIX: SLIDES THAT PROVIDE ADDITIONAL INFORMATION, BUT NOT PART OF THE PRESENTATION
Key URLs

- HL7 landing page: http://www.hl7.org/
- HL7 FHIR: http://hl7.org/fhir/
- HL7 gForge: https://gforge.hl7.org/gf/
- HL7 Confluence: https://confluence.hl7.org/
- Working Group Meetings: http://www.hl7.org/events/workgroupmeetings.cfm?ref=nav
Key URLs

• HL7 Standards:  
  http://www.hl7.org/implement/standards/product_matrix.cfm?ref=nav

• HL7 Work Groups:  
  http://www.hl7.org/Special/committees/index.cfm?ref=nav
Ballots

• The end product of a ballot process is a document.
• The document could stand on its own, however, most balloted documents are a part of a published Standards Document (e.g., HL7 2.6, HL7 3.0, FHIR, Implementation Guide (IG) based on a specific HL7 standard etc.)
HL7 Project Criteria

- Be consistent with HL7 strategic direction
- Include appropriate project documentation - project charter, scope, resources, timelines, assumptions, constraints, planned deliverables, etc. per PMO methodology
- Be aligned with market demand
- Be sponsored by stakeholders intending to implement the product produced by the project
HL7 Project Criteria (contd.)

• Define a reasonable balloting strategy to meet market demand and implementation timelines
• Define how the project will engage with other impacted work groups
• Follow project approval protocols to ensure appropriate project socialization and sign-off has taken place
HL7 International Version 2.x

• First widely used version 2.1 published in 1991
• Used in 90%+ provider organizations in the US and widely supported by vendors.
• Generally requires bi-lateral negotiations between communicating parties.
• Backwards-fitted (imperfectly to HL7 International Reference Information Model (RIM))
HL7 International Version 2.x

• Not well normalized.
  – Segments & Data Elements moved to a single location (Chapter 2) only in 2.5 in 2003.
• Makes no formal attempt to define process
• Most implementations are a mix of versions ranging from 2.1 to 2.3 (even though current version is 2.9)
HL7 International Version 3
First approved for publication and promotion to ANSI as an HL7 Standard in September, 2004.
Current Version: 2015
Normative Edition