



Introduction to Health Level Seven (HL7) International Organization & Process Orientation

January 2018

HL7 Working Group Meeting

New Orleans, LA January 2018

Calvin Beebe

Agenda

■ HL7 International

- What is it
- How is it Organized
- Vision and Mission
- Organizational Chart
- Affiliates
- Role in enabling interoperability
- What's in a name?

Agenda

- How do we work?
 - Consensus Driven
 - Work Groups
 - Technical Steering Committee
 - Steering Divisions
- HL7 International Processes
 - Meetings
 - Projects
 - Ballots
- HL7 Products
- Appendices

HL7 INTERNATIONAL

WHAT IS IT & HOW IT IS ORGANIZED?

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.

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

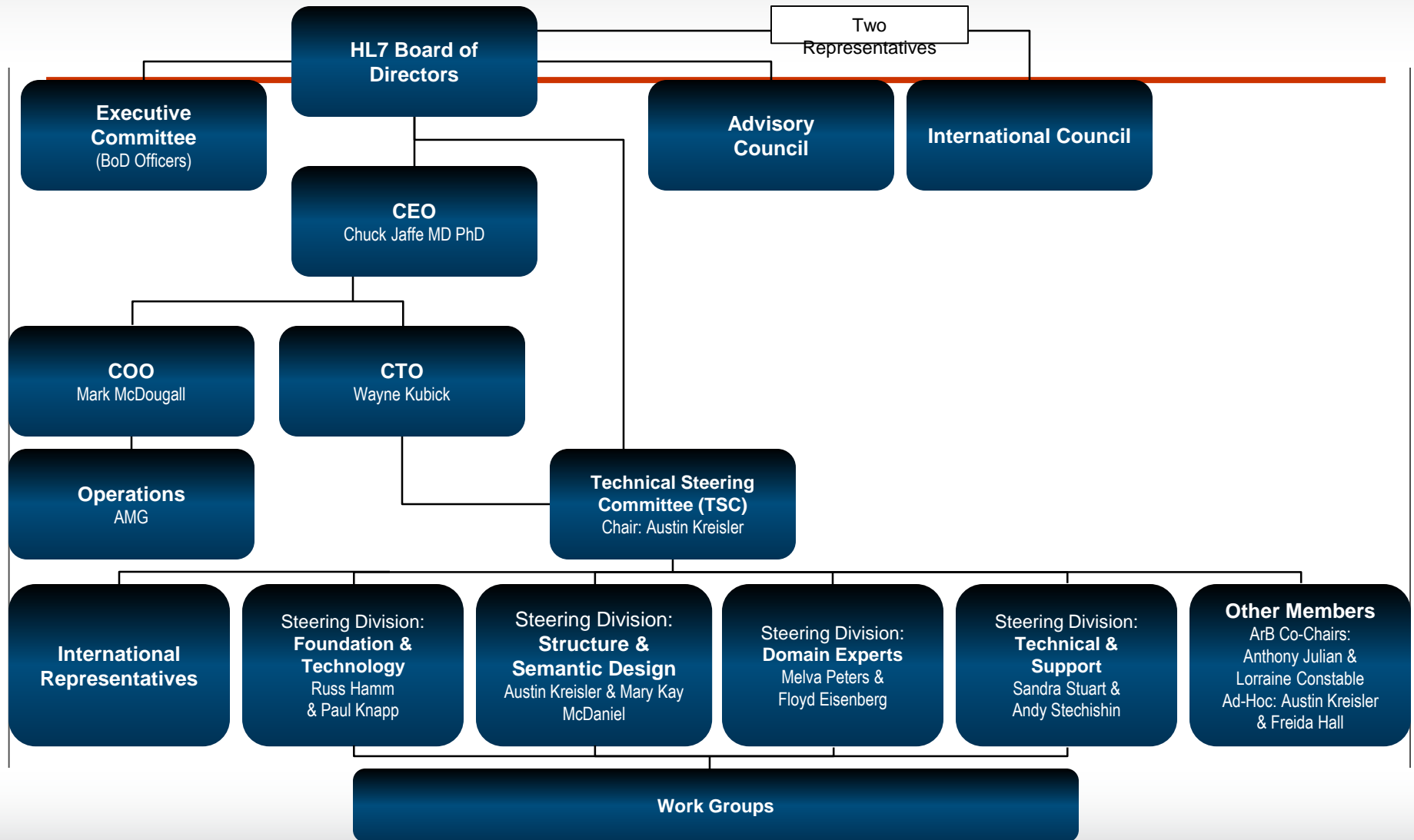
- HL7 International is a not-for-profit Standards Development Organization (SDO)
 - Headquartered in Ann Arbor, MI
 - Has an office in Brussels, Belgium
- HL7's members (providers, vendors, payers, consultants, government groups and others who have an interest in the development and advancement of clinical and administrative standards for healthcare) develop HL7's standards.

HL7 International's Mission

HL7 empowers global health data interoperability by developing standards and enabling their adoption and implementation.



7 Organizational Chart



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;
 - Distributes, translates and localizes the HL7 Protocol Specifications as appropriate;
 - Administers and proctors HL7 Certification tests within its Territory when suitable and authorized to do so as provided below; and
 - Promote HL7 standards, educates, informs and supports current and potential users within the Territory to promote consistent and widespread usage of the standards.

35 HL7 International Affiliates / Countries



Argentina



Russia



Romania



Philippines



Serbia



Norway

New Zealand



Australia



Austria



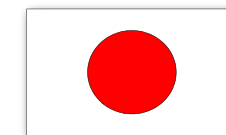
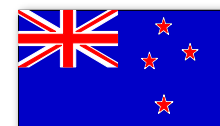
Singapore

And growing

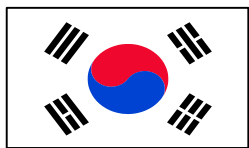


Uruguay

United Kingdom



Japan



South Korea



Bosnia and Herzegovina



Singapore

Italy



India



Hong Kong



Spain



Switzerland

The Netherlands



Slovenia



Taiwan



Sweden



Croatia



Czech Republic



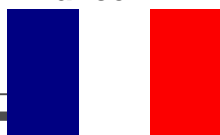
Denmark



Finland



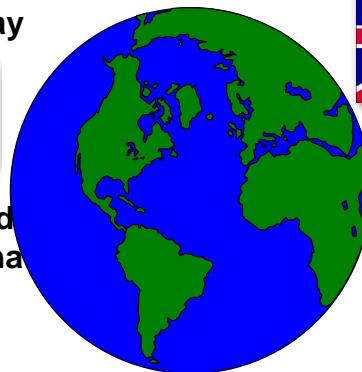
France



Germany



Greece



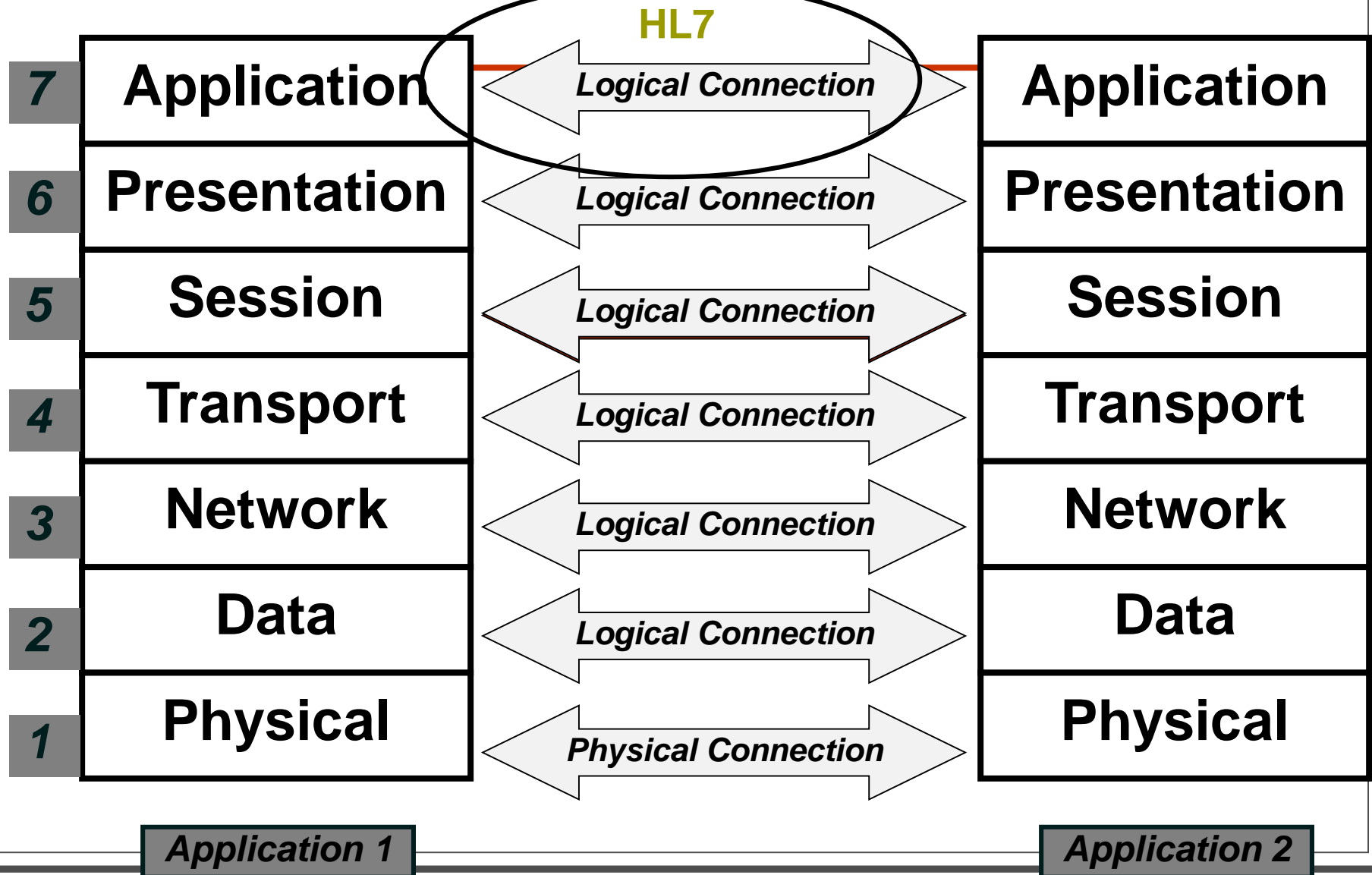
Health Level Seven (HL7)

"Level Seven" refers to the seventh level of the International Organization for Standardization (ISO) seven-layer communications model for Open Systems Interconnection (OSI) - the application level.

The application level interfaces directly to and performs common application services for the application processes.

Although other protocols have largely superseded it, the OSI model remains valuable as a place to begin the study of network architecture.

The OSI Model



HL7 INTERNATIONAL

HOW DO WE WORK?

HL7 International is a Consensus Driven Standards Development Organization (SDO)

Consensus Driven Standards

■ Are:

- Volunteer-driven
- Not a full-time commitment by most
- Marked by uneven levels of participation
- Participant developers have unequal levels of understanding
- Balloted with required resolution of negative ballots
- ***Consensus standards are intended to meet the needs of the many and thus are prone to compromise.***

What is HL7 International?

- Like all ANSI-accredited SDOs, HL7 International adheres to a strict and well-defined set of operating procedures that ensures consensus, openness and balance of interest.
- A frequent misconception about HL7 International (and presumably about the other SDOs) is that it develops software.
 - While some small amount of software is developed (e.g., tools), what we actually develop are standards specifications.
 - Our most widely used standards specifications enable disparate healthcare IT applications to exchange key sets of clinical and administrative data.

What is HL7 International?

- Members of HL7 International are known collectively as the “Working Group”, which is organized into individual work groups.
- The work groups are directly responsible for the content of the our products.
- Work groups can also serve as a source for exploring new areas that need to be covered by HL7 International’s published standards.

HL7 International's Work Groups

- Affiliate Due Diligence
- Anatomic Pathology
- Anesthesia
- Application Implementation and Design
- Architecture Review Board
- Arden Syntax
- Attachments
- BRIDG
- Child Health
- Clinical Decision Support
- Clinical Genomics
- Clinical Information Modeling Initiative
- Clinical Interoperability Council
- Clinical Quality Information
- Clinical Statement
- Community Based Collaborative Care
- Conformance & Guidance for Implementation/Testing
- Education
- Electronic Health Records
- Electronic Services & Tooling
- Emergency Care

- FHIR Infrastructure
- Financial Management
- Governance and Operations
- Health Care Devices
- Healthcare Standards Integration
- Imaging Integration
- Implementable Technology Specifications
- Infrastructure and Messaging
- International Council
- International Mentoring
- Learning Health Systems
- Marketing
- Mobile Health
- Modeling and Methodology
- Orders and Observations
- Organizational Relations
- Patient Administration
- Patient Care
- Pharmacy

- Policy Advisory
- Process Improvement
- Project Services
- Public Health and Emergency Response
- Publishing
- Regulated Clinical Research Information Management (RCRIM)
- Security
- Services Oriented Architecture
- Structured Documents
- Technical Steering Committee
- Templates
- Vocabulary

Technical Steering Committee (TSC) - Mission

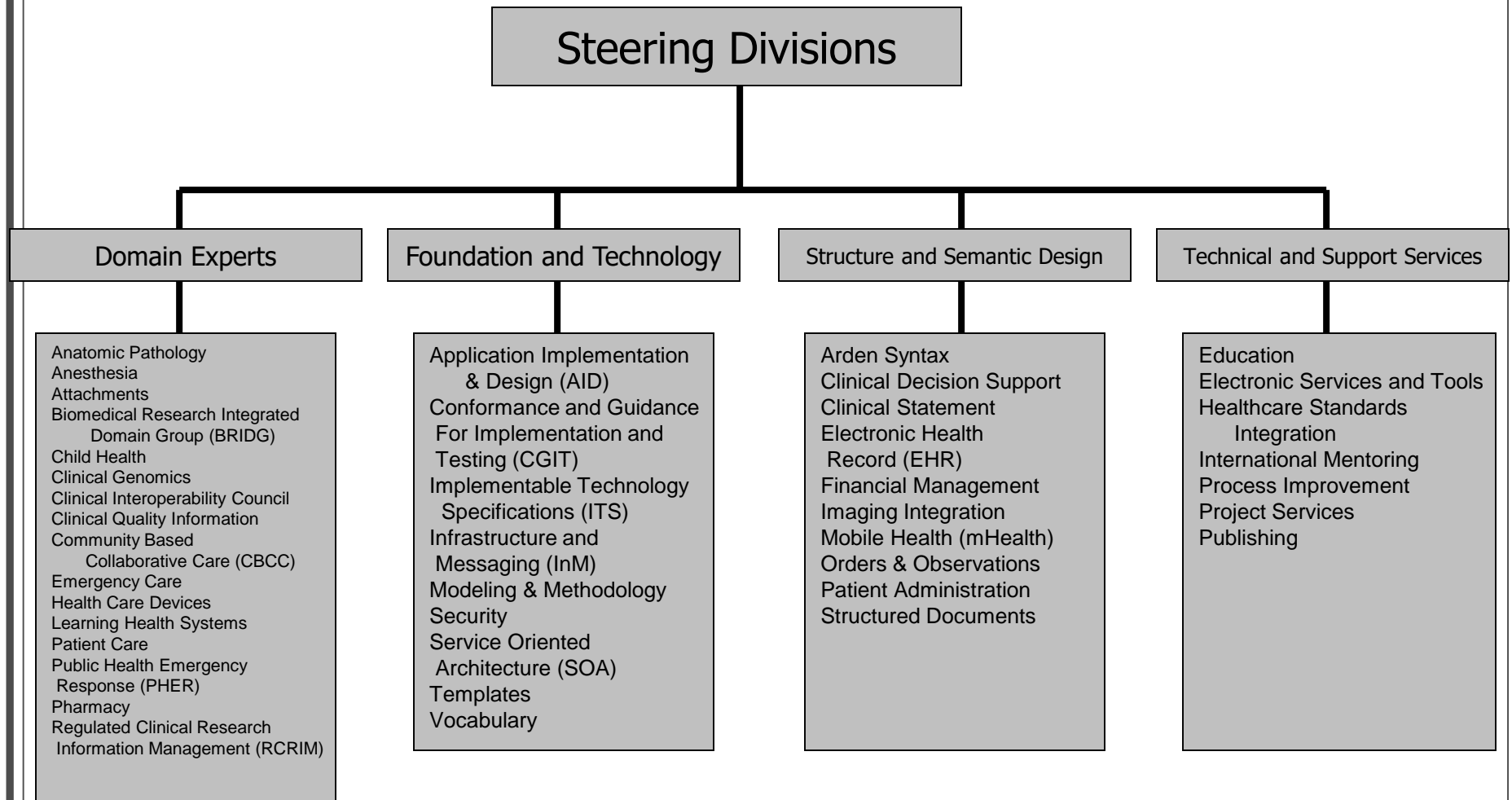
- Mission: To provide the technical direction to the HL7 organization to achieve the vision of creating the best and most widely used standards in healthcare.
 - The TSC oversees and coordinates the technical efforts contributed by the HL7 participants to ensure that the efforts of the Working Group (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.

Technical Steering Committee - Structure

■ Technical Steering Committee -

- 6 elected voting representatives, 4 appointed voting members
- TSC-elects their Chair; CTO is ex-officio co-chair
- Foundation & Technologies Steering Division
 - 2 Elected SD Co-Chairs plus Co-Chairs of workgroups in SD
- Structure & Semantic Design Steering Division
 - 2 Elected SD Co-Chairs plus Co-Chairs of workgroups in SD
- Domain Experts Steering Division
 - 2 Elected SD Co-Chairs plus Co-Chairs of workgroups in SD
- Technical & Support Services Steering Division
 - 2 Elected SD Co-Chairs plus Co-Chairs of workgroups in SD

HL7 Steering Divisions



HL7 INTERNATIONAL PROCESS

MEETINGS AND BALLOTS

HL7 International Meetings

- Working Group Meetings occur three times a year.
- 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 have defined decision making processes that specify how they run meetings, debate and vote on issues discussed in a meetings.

HL7 International Meetings

- Work Groups can customize their decision making processes. However:
 - PIC guidelines constrains the framework
 - HL7 International Process Improvement Committee (PIC) has default and generic templates for decision making practices
 - HL7 International's By-Laws and Policy and Procedures 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'

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
- 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

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 etc.)

Ballots

■ Documents can be:

➤ Informative

- An Informative Document is the product of a Work Group that is not currently deemed normative, but nonetheless is intended for general publication. It explains or supports the structure of the HL7 Protocol Specifications, or provides detailed information regarding the interpretation or implementation of an HL7 Protocol Specification. The TSC shall approve the issuance of an informative document ballot.

➤ Draft Document for Comment Only

- A Work Group, with the concurrence of the TSC, may submit proposed content or requirements documents, such as a Domain Analysis Model (DAM), to comment-only review. The intent is to gather input from members outside of the Work Group on the viability and clarity of the proposed content or requirements document. The review of proposed content or requirements documents does not seek a vote, per se, but will capture all comments.

Ballots

■ Standards for Trial Use (STU)

- Content is balloted by the general membership as the draft of a future standard which will, following a pre-specified period of evaluation and comment (usually 2 years), be expeditiously incorporated into normative standard.
- STU's require at least two verified implementations that demonstrate the standard's use.
- Prior to 2016, these were referred to as "Draft" (DSTU's).

■ Normative Standard

- Content is balloted by the general membership and is considered a structural component of the HL7 Standard.
- Negative ballots must be resolved.
- Normative Standards are typically registered with ANSI.

Ballots

- Ballots normally progress through two or more cycles of ballots.
 - Ballot pool is limited to declared interested members;
 - Negative votes must be accompanied with a specific reason justifying the negative vote;
 - Affirmative w/edit change; Abstention with comment.

ALL HL7 Balloted Standards are introduced first as a STU and must show some successful implementations before being advanced as a Normative Standard.

Ballots

- Work Groups must resolve negative votes:
 - Accept the voters comment and recommended solution.
 - Negotiate with the voter and get them to agree to withdraw their negative.
 - Declare the vote non-persuasive.
 - Voters may appeal to the TSC and Board. They can also re-vote their same negative vote on the next round of balloting.
 - Substantive changes to a ballot (either to fix a negative or add new material) merit another round of balloting.

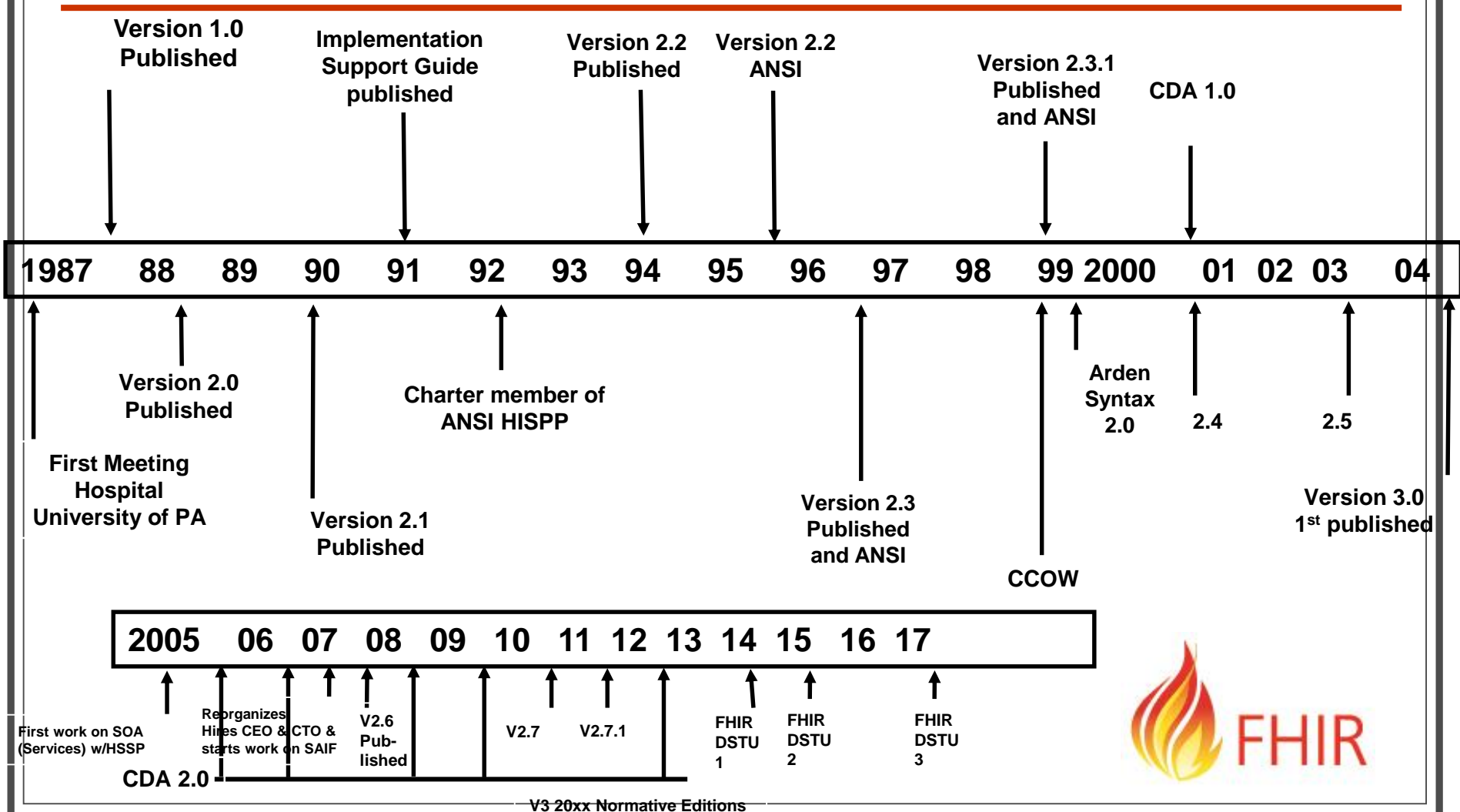
Ballots

- When 75% (for *normative documents*) of the responses are registered as affirmatives...and hopefully all negatives withdrawn, a document is ready for publication as an HL7 International Standard.

HL7 PRODUCTS

History of HL7

(Through 2012)



V3 20xx Normative Editions

HL7 International Products

- HL7 International has a number of major product lines:
 - Version 2.x
 - Version 3 Reference Information Based Products
 - Version 3 Messaging
 - Version 3 Clinical Document Architecture (CDA)
 - CDA Implementation Specifications or IGs (e.g., CCD)
 - Version 3 Services
 - Gello
 - Attachments
 - Structured Product Labeling
 - EHR-S & PHR-S Set of Standards
 - **FHIR (Fast Health Interoperability Resources)**
 - Arden Syntax

A project to create Product-Line Management and coordinate common elements and better define “backward-break” issues is now being formulated in the Technical Steering Committee.

HL7 International Diversifies

- HL7 International started with and is traditionally thought of as “messaging”. For most of its life, however, HL7 International has also produced more than messaging standards.
 - Electronic Data Exchange in Healthcare Environments (*i.e. “messaging”*)
 - Version 2 & Version 3
 - Arden Syntax
 - GELLO
 - Visual / Context Integration (CCOW)
 - Version 2.x XML (*XML encoding of HL7 International messages*)
 - Clinical Document Architecture (CDA)
 - *Clinical Context Document Implementation Guide (CCD)*
 - Electronic Health Record System (EHR-S) Functional Model
 - Personal Health Record System (PHR-S) Functional Model
 - Services (*i.e., Services as related to a Services Oriented Architecture*)

HL7 Subject Domains

- ADT
- Order entry
- Result reporting
- Clinical Guidelines
- Clinical Observations
- Scheduling
- Patient care
- Immunizations
- Discharge summaries
- Mobile Computing
- Adverse event reporting
- Automated waveforms
- Medical transcriptions
- Referrals
- Consultations
- Clinical trials
- Nursing care plans
- Data Warehousing

... And Growing ...

HL7 Subject Domains

- XML
- Terminology/Vocabulary/Ontology
- Certification
- Conformance
- Security transactions
- Claims attachment
- Accountability, Quality, Assurance
- Blood Bank
- Personnel Management
- Arden Syntax
- Component Based Messaging (i.e., Java)
- Visual/Context Integration
- Government Projects
- Master Patient Index
- SOA
- Image Management

HL7 INTERNATIONAL VERSION 2.X

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))
- 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 2.7)



ANSI/HL7 V2.8.1-2014
August 27, 2014

HL7®

HL7 MESSAGING STANDARD VERSION 2.8.1
An Application Protocol for Electronic Data Exchange
in Healthcare Environments

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An ANSI Approved American National Standard
Use of this standard is covered under HL7's Intellectual Property Compliance Guidelines.

Version 2.7 Chapters*

- | | |
|--|---|
| 1. Introduction | 12. Patient Care |
| 2. Control / Data Types /
Conformance & Code Tables | 13. Clinical Laboratory Automation |
| 3. Patient Administration | 14. Application Management |
| 4. Orders | 15. Personnel Management |
| 5. Queries | 16. Non-US eClaims (<i>new to 2.6</i>) |
| 6. Financial Management | 17. Materials Mgmt. (<i>new to 2.6</i>) |
| 7. Observations | |
| 8. Master Files | <i>Appendices:</i> |
| 9. Medical Records / Information Mgmt | A. <i>Data Definition Tables</i> |
| 10. Scheduling | B. <i>Lower Layer Protocol</i> |
| 11. Patient Referral | C. <i>BNF Definitions</i> |
| | D. <i>Glossary</i> |
| | E. <i>Index</i> |

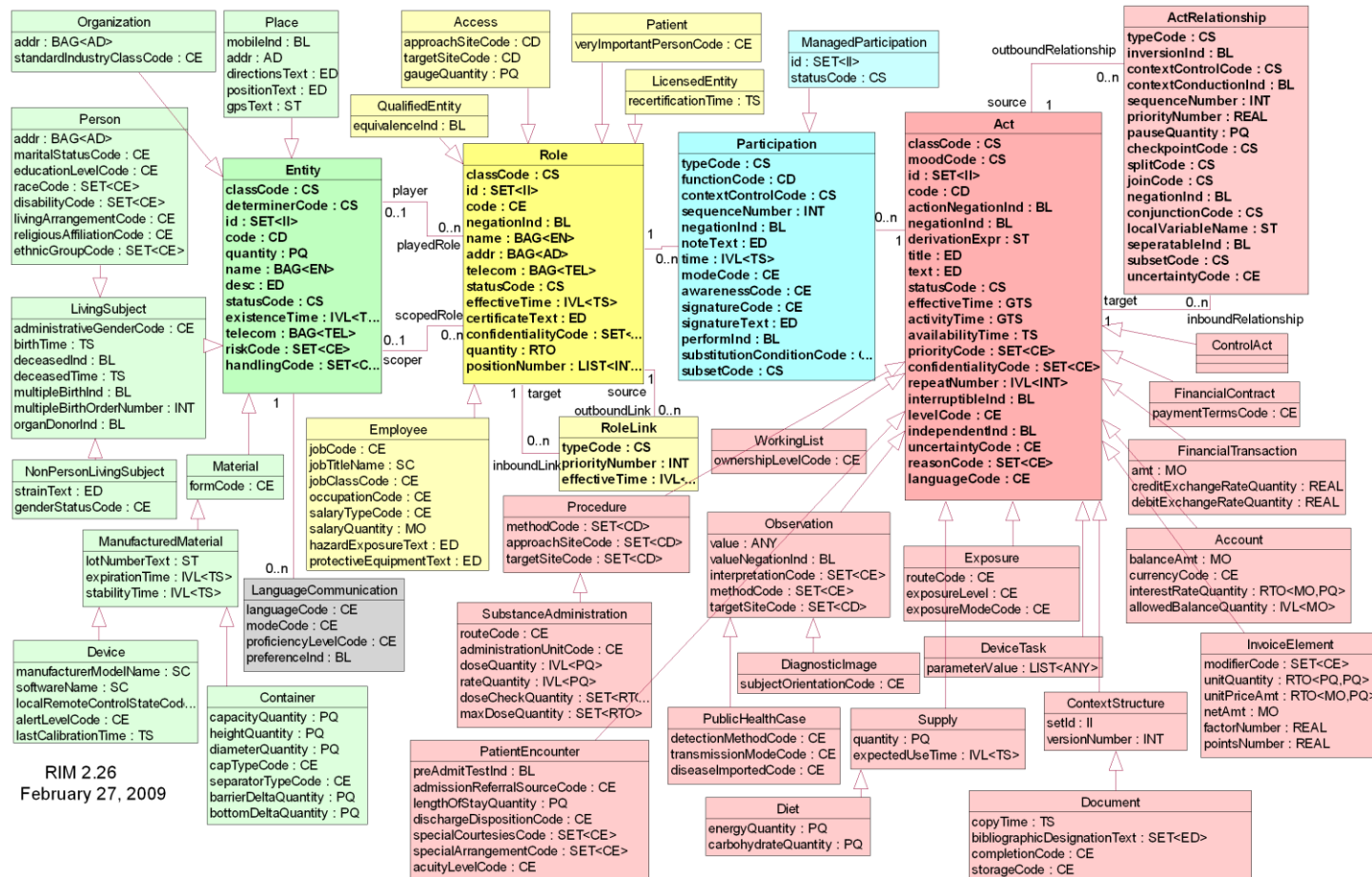
2.7 is available on the HL7 "Standards" section of the HL7 web site. CDs are also available.

HL7 INTERNATIONAL VERSION 3

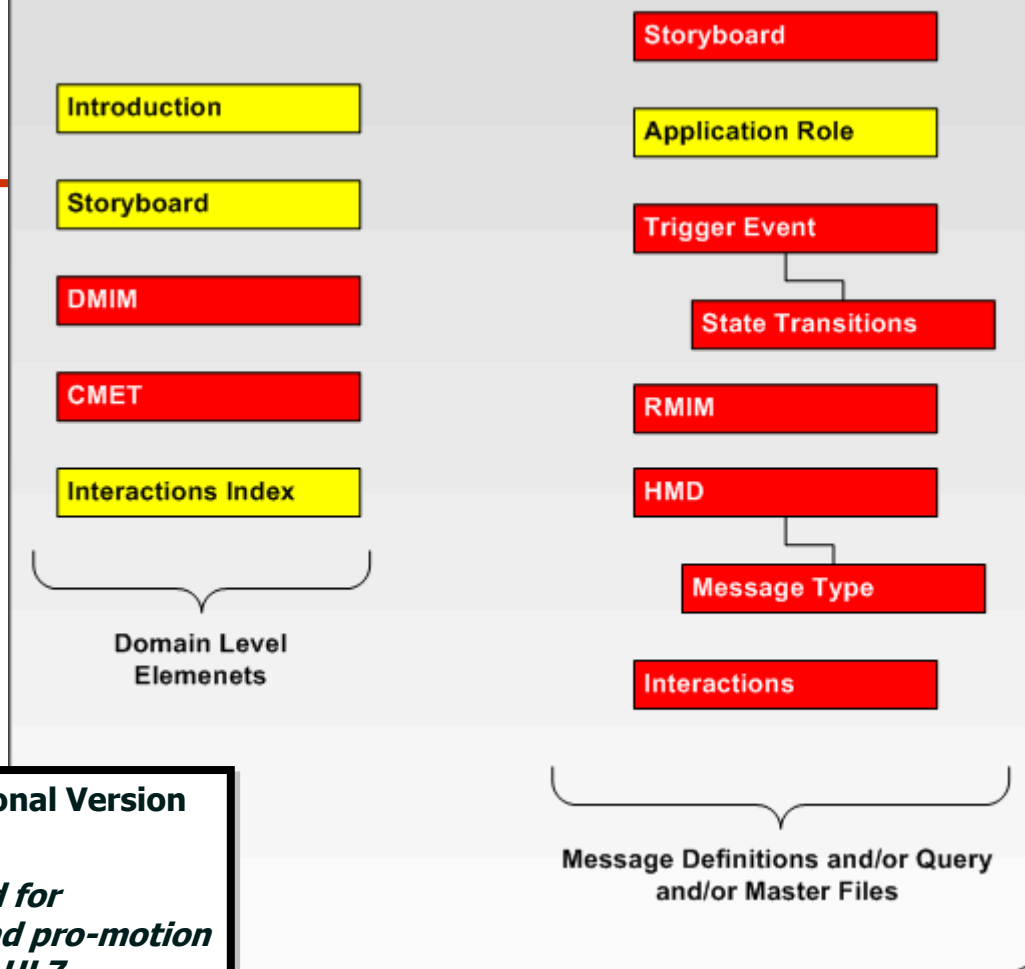
HL7 Version 3

- A suite of specifications based on HL7's Reference Information Model (RIM)
- Represented a new approach to clinical information exchange based on a model driven methodology

V3 RIM



Domain Document Elements



Legend

Reference: Content is harmonized during HL7 meetings or approved by the HL7 Board. It is not subject to ballot acceptance

Informative: Content is balloted by general membership; however, it is not considered to be a structural part of the standard, only supporting information.

Normative: Content is balloted by general membership and is considered structural component of HL7 standard. Negative ballots MUST be resolved.

Draft Standard for Trial Use: Content is balloted by general membership as the draft of a standard which will, following a suitable period for evaluation and comment, be expeditiously incorporated into a fully balloted and accredited version of the standard.

Note: Some Foundation Document groupings (for example ITS XML or Transport Protocols) may be balloted during a cycle as Normative at Committee or Member while other documents contained in that same grouping might be DSTU or Informative.

HL7 International Version 3

First approved for publication and pro-motion to ANSI as an HL7 Standard in September, 2004.

Current Version: 2015 Normative Edition

Message Definitions and/or Query and/or Master Files

Clinical Document Architecture

HL7's CDA vs. C-CDA

■ C-CDA **defines a set of CDA documents!**

The HL7 Consolidated CDA is an implementation guide which specifies a library of templates and proscribes their use for a set of specific document types.

■ CDA **the schema for those documents!**

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange.

Consolidated CDA (C-CDA 2.1)

Continuity of Care Document

History and Physical

ONC - CEHRT

Discharge Summary

HITSP - C32, C80, C83

Consultation Notes

IHE – PCC

Diagnostic Imaging Rpt

HL7 – CCD

Procedure Note

HL7 – CDA

Operative Note

Progress Note

Unstructured Documents

C-CDA

- ☐ Care Plan
- ☐ Referral Note
- ☐ Transfer Summary

Fast Healthcare Interoperability Resources (FHIR)

What the Market Wants

- Faster implementations
- Conformance & Conformability testing
- Computable Semantic Interoperability
- Better Quality, Methodology & Tools
- Confidentiality/Security
- Harmonization with other standards
- Support of the latest communication technologies

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;
- 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.

30 Second “Intro to FHIR”

- There was strong support from the US
ONC’s Standards Advisory Panel for FHIR.
 - Led by Dr. John Halamka
- 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.

Project Argonaut

- This is not a HL7 project – though HL7 has supported it and it is tightly connected to the FHIR community.
- The approximately 70 Argonaut participants have pooled resources with the intent to focus on verifying FHIR solutions and producing FHIR implementation guides.
- Arose from the JASON Task Force, to enable API-based access to data via patient/provider portals and data exchange.

THE MOST HELPFUL SINGLE PIECE OF INFORMATION?

<http://www.hl7.org>

Other Useful Links

- [HL7 Glossary](#)
- [HL7 Work Groups](#)
- [HL7 Governance and Operations Manual](#)

QUESTIONS?

THANK YOU

ADDITIONAL SLIDES

What is HL7 International?

- HL7 International's domain is clinical and administrative data.
- Many of our Standards are also ISO TC-215 Standards.
- ISO TC-215 both adopts specific HL7 International Standards and also works with HL7 International to jointly develop standards.
- HL7 also collaborates with many other SDOs, such as through the Joint Initiative Council.

Enabling Interoperability

- Interoperability beyond a single point to point interface requires:
 - A profile that includes all of the related Standards Development Organizations (SDOs') elements (e.g., terminologies), and other directed references within the primary SDO product (e.g., state names & abbreviations).
 - A resolution of all pre-coordinated decisions to remove all optionality;
 - Full specification from Layers 1-7 (e.g., FHIR) (not just Level 7)
 - The publication of an implementation guide that is used by all communicating parties.
 - A published governance and update process that supports needed fixes and related updates.

Examples of Influencers & Drivers

- Governments (US ONC, Canada Health Infoway, Australia's NEHTA, UK's NHS CfH, ...)
- American National Standards Institute (ANSI—and other complementary national bodies)
- Vendors
- HL7 International Affiliates
- Clinical users & Consultants
- Healthcare Ontology/Terminology SDOs (e.g., IHTSDO (SNOMED), Regenstrief (LOINC), WHO, (ICD), etc.)
- Other International Standards Organization (ISO, DICOM, GS/1, CEN TC 251, etc.)
- Other US Healthcare related SDOs (e.g., X12N, NCPDP, etc.)

U.S. Health Messaging Standards Development Efforts

HL7 International

(Health Level 7)

ACR/NEMA (DICOM)

*(American College of Radiologists / National
Electrical Manufacturers Association)
(Digital Image Communications)*

X12 (X12N)

ASTM (E31)

*ASTM International
(was American Society of Testing Materials)*

IEEE

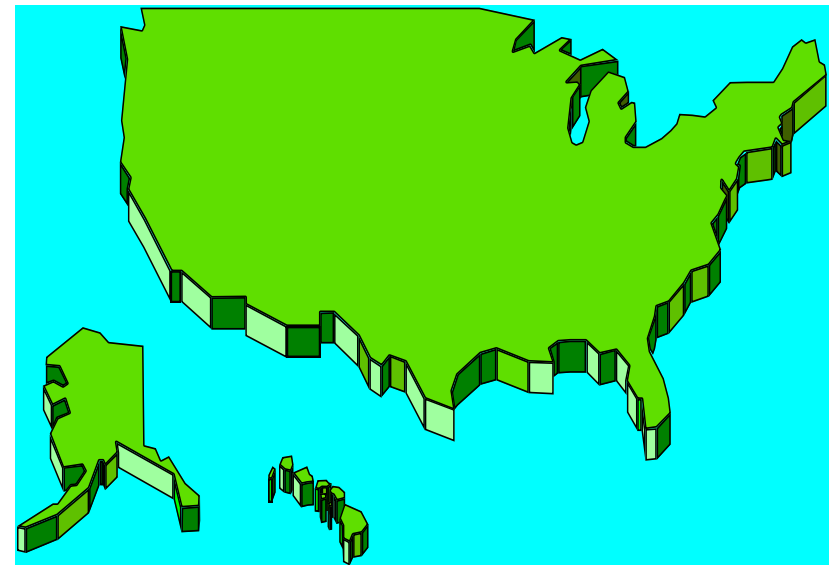
(Institute of Electrical and Electronic Engineers)

NCPDP

*(National Council of Prescription Drug
Producers)*

ADA

(American Dental Association)



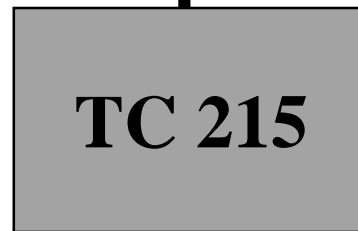
HL7—Country and International Standards



ORGANISATION
INTERNATIONALE DE
NORMALISATION



INTERNATIONAL
ORGANIZATION FOR
STANDARDIZATION



TC 251



What is the Origination of the name HL7?

The application level addresses definition of the data to be exchanged, the timing of the interchange, and the communication of certain errors to the application. The seventh level supports such functions as security checks, participant identification, availability checks, exchange mechanism negotiations and, most importantly, data exchange structuring.