INFORMATICS PROFESSIONALS. LEADING THE WAY.

1G-1 – Clinical Data Standards

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Clinical Informatics
Board Review Course

Clinical Informatics Subspecialty Delineation of Practice (CIS DoP)

Domain 1: Fundamental Knowledge and Skills (no Tasks are associated with this Domain which is focused on fundamental knowledge and skills)

Clinical Informatics

K001. The discipline of informatics (e.g., definitions, history, careers, professional organizations)
K002. Fundamental informatics concepts, models, and theories
K003. Core clinical informatics literature (e.g., foundational literature, principle journals, critical analysis of literature, use of evidence to inform practice)
K004. Descriptive and inferential statistics
K005. Health Information Technology (HIT) principles and science
K006. Computer programming fundamentals and computational thinking
K007. Basic systems and network architectures
K008. Basic database structure, data retrieval and analytics techniques and tools
K009. Development and use of interoperability/exchange standards (e.g., Fast Health Interoperability Resources [FHIR], Digital Imaging and Communications in Medicine [DICOM])
K010. Development and use of transaction standards (e.g., American National Standards Institute X12)
K011. Development and use of messaging standards (e.g., Health Level Seven [HL7] v2)
K012. Development and use of ancillary data standards (e.g., imaging and Laboratory Information System[LIS])
K013. Development and use of data model standards
K014. Vocabularies, terminologies, and nomenclatures (e.g., Logical Observation Identifiers Names and Codes [LOINC], Systematized Nomenclature of Medicine --Clinical Terms [SNOMED-CT], RxNorm, International Classification Of Diseases[ICD], Current Procedural Terminology [CPT])
K015. Data taxonomies and ontologies
K016. Security, privacy, and confidentiality requirements and practices
K017. Legal and regulatory issues related to clinical data and information sharing
K018. Technical and non-technical approaches and barriers to interoperability
K019. Ethics and professionalism

The Health System

K020. Primary domains of health, organizational structures, cultures, and processes (e.g., health care delivery, public health, personal health, population health, education of health professionals, clinical research)
K021. Determinants of individual and population health
K022. Forces shaping health care delivery and considerations regarding health care access
K023. Health economics and financing
K024. Policy and regulatory frameworks related to the healthcare system
K025. The flow of data, information, and knowledge within the health system

Domain 2: Improving Care Delivery and Outcomes

K026. Decision science (e.g., Bayes theorem, decision analysis, probability theory, utility and preference assessment, test characteristics)
K027. Clinical decision support standards and processes for development, implementation, evaluation, and maintenance
K028. Five Rights of clinical decision support (i.e., information, person, intervention formats, channel, and point/time in workflow)
K029. Legal, regulatory, and ethical issues regarding clinical decision support
K030. Methods of workflow analysis
K031. Principles of workflow re-engineering
K032. Quality improvement principles and practices (e.g., Six Sigma, Lean, Plan-Do-Study-Act [PDSA] cycle, root cause analysis)
K033. User-centered design principles (e.g., iterative design process)
K034. Usability testing
K035. Definitions of measures (e.g., quality performance, regulatory, pay for performance, public health surveillance)
K036. Measure development and evaluation processes and criteria
K037. Key performance indicators (KPIs)
K038. Claims analytics and benchmarks
K039. Predictive analytic techniques, indications, and limitations
K040. Clinical and financial benchmarking sources (e.g., Gartner, Healthcare Information and Management Systems Society [HIMSS] Analytics, Centers for Medicare and Medicaid Services [CMS], Leapfrog)
K041. Quality standards and measures promulgated by quality organizations (e.g., National Quality Forum [NQF], Centers for Medicare and Medicaid Services [CMS], National Committee for Quality Assurance [NCQA])
K042. Facility accreditation quality and safety standards (e.g., The Joint Commission, Clinical Laboratory Improvement Amendments [CLIA])
K043. Clinical quality standards (e.g., Physician Quality Reporting System [PQRS], Agency for Healthcare Research and Quality [AHRQ], National Surgical Quality Improvement Program [NSQIP], Quality Reporting Document Architecture [QRDA], Health Quality Measure Format [HQMF], Council on Quality and Leadership [CQL], Fast Health Interoperability Resources [FHIR] Clinical Reasoning)
K044. Reporting requirements
K045. Methods to measure and report organizational performance
K046. Adoption metrics (e.g., Electronic Medical Records Adoption Model [EMRAM], Adoption Model for Analytics Maturity [AMAM])
K047. Social determinants of health
K048. Use of patient-generated data
K049. Prediction models
K050. Risk stratification and adjustment
K051. Concepts and tools for care coordination
K052. Care delivery and payment models

Domain 3: Enterprise Information Systems

K053. Health information technology landscape (e.g., innovation strategies, emerging technologies)
K054. Institutional governance of clinical information systems
K055. Information system maintenance requirements
K056. Information needs analysis and information system selection
K057. Information system implementation procedures
K058. Information system evaluation techniques and methods
K059. Information system and integration testing techniques and methodologies
K060. Enterprise architecture (databases, storage, application, interface engine)
K061. Methods of communication between various software components
K062. Network communications infrastructure and protocols between information systems (e.g., Transmission Control Protocol/Internet Protocol [TCP/IP], switches, routers)
K063. Types of settings (e.g., labs, ambulatory, radiology, home) where various systems are used
K064. Clinical system functional requirements
K065. Models and theories of human-computer (machine) interaction (HCI)
K066. HCI evaluation, usability engineering and testing, study design and methods
K067. HCI design standards and design principles
K068. Functionalities of clinical information systems (e.g., Electronic Health Records [EHR], Laboratory Information System [LIS], Picture Archiving and Communication System [PACS], Radiology Information System [RIS] vendor-neutral archive, pharmacy, revenue cycle)
K069. Consumer-facing health informatics applications (e.g., patient portals, mobile health apps and devices, disease management, patient education, behavior modification)
K070. User types and roles, institutional policy and access control
K071. Clinical communication channels and best practices for use (e.g., secure messaging, closed loop communication)
K072. Security threat assessment methods and mitigation strategies
K073. Security standards and safeguards
K074. Clinical impact of scheduled and unscheduled system downtimes
K075. Information system failure modes and downtime mitigation strategies (e.g., replicated data centers, log shipping)
K076. Approaches to knowledge repositories and their implementation and maintenance
K077. Data storage options and their implications
K078. Clinical registries
K079. Health information exchanges
K080. Patient matching strategies
K081. Master patient index
K082. Data reconciliation
K083. Regulated medical devices (e.g., pumps, telemetry monitors) that may be integrated into information systems
K084. Non-regulated medical devices (e.g., consumer devices)
K085. Telehealth workflows and resources (e.g., software, hardware, staff)

Domain 4: Data Governance and Data Analytics

K086. Stewardship of data
K087. Regulations, organizations, and best practice related to data access and sharing agreements, data use, privacy, security, and portability
K088. Metadata and data dictionaries
K089. Data life cycle
K090. Transactional and reporting/research databases
K091. Techniques for the storage of disparate data types
K092. Techniques to extract, transform, and load data
K093. Data associated with workflow processes and clinical context
K094. Data management and validation techniques
K095. Standards related to storage and retrieval from specialized and emerging data sources
K096. Types and uses of specialized and emerging data sources (e.g., imaging, bioinformatics, internet of things (IoT), patient-generated, social determinants)
K097. Issues related to integrating emerging data sources into business and clinical decision making
K098. Information architecture
K099. Query tools and techniques
K100. Flat files, relational and non-relational/NoSQL database structures, distributed file systems
K101. Definitions and appropriate use of descriptive, diagnostic, predictive, and prescriptive analytics
K102. Analytic tools and techniques (e.g., Boolean, Bayesian, statistical/mathematical modeling)
K103. Advanced modeling and algorithms
K104. Artificial intelligence
K105. Machine learning (e.g., neural networks, support vector machines, Bayesian network)
K106. Data visualization (e.g., graphical, geospatial, 3D modeling, dashboards, heat maps)
K107. Natural language processing
K108. Precision medicine (customized treatment plans based on patient-specific data)
K109. Knowledge management and archiving science
K110. Methods for knowledge persistence and sharing
K111. Methods and standards for data sharing across systems (e.g., health information exchanges, public health reporting)

Domain 5: Leadership and Professionalism

K112. Environmental scanning and assessment methods and techniques
K113. Consensus building, collaboration, and conflict management
K114. Business plan development for informatics projects and activities (e.g., return on investment, business case analysis, pro forma projections)
K115. Basic revenue cycle
K116. Basic managerial/cost accounting principles and concepts
K117. Capital and operating budgeting
K118. Strategy formulation and evaluation
K119. Approaches to establishing Health Information Technology (HIT) mission and objectives
K120. Communication strategies, including one-on-one, presentation to groups, and asynchronous communication
K121. Effective communication programs to support and sustain systems implementation
K122. Writing effectively for various audiences and goals
K123. Negotiation strategies, methods, and techniques
K124. Conflict management strategies, methods, and techniques
K125. Change management principles, models, and methods
K126. Assessment of organizational culture and behavior change theories
K127. Theory and methods for promoting the adoption and effective use of clinical information systems
K128. Motivational strategies, methods, and techniques
K129. Basic principles and practices of project management
K130. Project management tools and techniques
K131. Leadership principles, models, and methods
K132. Intergenerational communication techniques
K133. Coaching, mentoring, championing and cheerleading methods
K134. Adult learning theories, methods, and techniques
K135. Teaching modalities for individuals and groups
K136. Methods to assess the effectiveness of training and competency development
K137. Principles, models, and methods for building and managing effective interdisciplinary teams
K138. Team productivity and effectiveness (e.g., articulating team goals, defining rules of operation, clarifying individual roles, team management, identifying and addressing challenges)
K139. Group management processes (e.g., nominal group, consensus mapping, Delphi method)

Knowledge Statements from the DoP

K009. Development and use of interoperability/exchange standards (e.g., Fast Health Interoperability Resources [FHIR], Digital Imaging and Communications in Medicine [DICOM])

K010. Development and use of transaction standards (e.g., American National Standards Institute X12)

K011. Development and use of messaging standards (e.g., Health Level Seven [HL7] v2)

K012. Development and use of ancillary data standards (e.g., imaging and Laboratory Information System[LIS])

K013. Development and use of data model standards

K080. Patient matching strategies

K081. Master patient index

1G1: Clinical Data Standards

1G1

- Standards and Interoperability: Basic Concepts
- Identifier Standards
- Transaction Standards
- Message Exchange Standards

1G2

- Terminology Standards

Why are standards important in clinical informatics?

Promote consistent naming of individuals, events, diagnoses, treatments, etc.

Allow better use of data for patient care as well as secondary uses, such as quality assurance, research, public health, etc.

Enhance ability to transfer data among applications, allowing better system integration

Facilitate interoperability among information systems and users

What is a standard?

There's a standard for that!

From ISO, 2004 (cited by Benson, 2016)

- A standard document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the optimum degree of order in a given context

Standards facilitate interoperability

IEEE original definition, widely cited (1991)

- "The ability of two or more systems or components to exchange information and to use the information that has been exchanged."

More recent IEEE definition

- https://www.standardsuniversity.org/article/standards-glossary/
- "Ability of a system or a product to work with other systems or products without special effort on the part of the customer. Interoperability is made possible by the implementation of standards"

New definition from 21st Century Cures Act

- https://www.healthit.gov/curesrule/
- Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user
- Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law
- Does not constitute information blocking

Levels of interoperability for healthcare (Walker, 2005)

No interoperability

- e.g., mail, fax, phone, etc.

Machine-transportable (structural)

- Information cannot be manipulated
- e.g., scanned document, image, PDF

Machine-organizable (syntactic)

- Sender and receiver must understand vocabulary
- e.g., email, files in proprietary format

Machine-interpretable (semantic)

- Structured messages with standardized and coded data
- e.g., coded results from structured notes, lab, problem list, etc.

Value of standards throughout history

Roman chariots

Railroad tracks

Telephones

ASCII text in computers

Wi-Fi to connect computers, smartphones, tablets, etc., wirelessly to the Internet

Global financial transactions

Other examples?

Benefits and limitations of standards

Benefits

- Interoperability
- May allow innovation based on common foundation

Limitations

- Dominance by one segment of industry
- May stifle innovation

May be a mixed bag

- Microsoft “standards,” e.g., Windows, Office, etc.
- Ever hear of Esperanto? Why did English prevail? (Patterson, 1999)
- “The nice thing about standards is that there are so many of them to choose from.” (Tanenbaum, 2010 – disputed)

Integrating the Health Enterprise (IHE, https://www.ihe.net/)

Non-federal effort that identifies and demonstrates solutions to real-world interoperability problems

- Organizes interoperability showcases to demonstrate solutions
  - https://www.himss.org/what-we-do-initiatives/himss-interoperability-showcase

Organized across various clinical and operational domains

- Each domain produces own set of Technical Framework documents in coordination with other domains
- Committees in each domain review and republish these documents annually, often expanding with supplements that expand existing or define new profiles
- Profiles eventually republished for trial implementation; if criteria for successful testing achieved, profile is published in final form
  - https://www.ihe.net/resources/profiles/

No discussion of standards is complete without mentioning HIPAA

Health information standards were a key focus of the Health Insurance Portability and Accountability Act of 1996 (HIPAA; aka, the Kassebau- Kennedy Act)

Main focus of legislation, however, was health insurance issues

- Reducing denial based on pre-existing conditions
- Improving portability across jobs

But now HIPAA is best known for its addressing of

- Standards for financial transactions and code sets
- Unique identifiers for patients, healthcare providers, and employers
- Development of privacy and security standards for transmission of electronic health data

HIPAA privacy and security regulations expanded in HITECH

Clinical informatics standards

Identifiers

Transactions

Message exchange

Terminology

Identifiers

Various approaches exist (or have been proposed) for

- Patients
- Providers
- Employers
- Health Plans

Patient identifiers

Benefits

- Easy linkage of records
- Facilitate health information exchange
- Reduce errors and costs arising from duplicate records

Risks

- Easy linkage of records
- Potentially compromise privacy and confidentiality

Government-issued patient identifiers in the US

HIPAA mandated creation of patient identifiers but public pressure forced prohibition

Could/should we use the social security number as a national health identifier?

- Technical problems: many duplicates, no check digit for checksum validation (Winkler, 2009)
- Other problems: used for too many other purposes, including re-identification from public data sources (Acquisti, 2009)

Recent repeal of HIPAA ban on national health identifier (Grannis, 2019)

Alternatives to a national identifier

Use of probabilistic matching algorithms to link patient records based on various attributes, e.g., name, address, date of birth, phone, etc.

Many methods show relatively high level of accuracy (Grannis, 2003; Tromp, 2011; Sayers, 2016)

- Methods use widely in health information exchange (Kho, 2015; McFarlane, 2016)

Research still required for problems with non-standardized ("dirty") data (Randall, 2013) and missing data (Ong, 2014)

Provider identifiers

Universal Physician Identifier Number (UPIN) was maintained by the US government for physicians who treated Medicare patients

National Provider Identifier (NPI) now assigned to all US physicians

- Issued by the National Provider System (NPS), overseen by the Department of HHS
- 10-digit number with last digit serving as check digit
- CMS no longer processes claims without NPI

Transactions

ASC X12N standards designed to encourage electronic commerce for health claims, simplifying previous situation of 400+ different formats

- HIPAA mandated use of these standards for healthcare business electronic data exchange
  - “Administrative simplification”
- Original version of HIPAA ASC X12 standards was called version 4010 and was superseded by Version 5010, which had deadline for compliance of January 1, 2012
  - https://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/Version_5010.html
  - https://www.ama-assn.org/practice-management/hipaa-administrative-simplification

ASC X12N transactions – Version 5010

Health claims and equivalent encounter information (837)

Enrollment and disenrollment in a health plan (834)

Eligibility for a health plan (request 270/response 271)

Health care payment and remittance advice (835)

Health plan premium payments (820)

Health claim status (request 276/response 277)

Referral certification and authorization (278)

Coordination of benefits (837)

Message exchange standards

Health Level 7 (HL7)

Fast Healthcare Interoperability Resources (FHIR)

Images: Digital Imaging and Communications (DICOM)

Devices: IEEE 1073 / ISO 11073 and others

ePrescribing: NCPDP and SCRIPT

Laboratory: ELINCS

Patient summaries: CCR, CCD, and ABBI

Platforms: Substitutable Medical Apps, reusable technologies (SMArt)

Health Level 7 International (HL7)

https://www.hl7.org/index.cfm

Major messaging standards for healthcare as well as the standards development organization that supports the standard

Name based on OSI seven-layer model of network communications

Substantially different versions

- Version 2 widely used and syntactic-oriented
- Version 3 never widely adopted, aims for semantic interoperability, superseded by Fast Healthcare Interoperability Resources (FHIR)

Documentation less than ideal but

- Standards documents on Web site with voluminous detail
- Overview book (Benson, 2016)

HL7, version 2

(Henderson, 2007; Benson, 2016)

Current versions (2.X) supported by most vendors for interchange of data

Is mostly a syntax, where sender and receiver must understand meaning of messages, but subsequent versions adding more semantics (meaning)

Implemented by bar-delimited ASCII files

Each message has segments consisting of three-character identifier and values, e.g.,

- MSH – message header
- EVN – event type
- PID – patient identifier
- OBR – results header
- OBX – result details

HL7 version 2.5 example (Benson, 2016)

MSH|^~\&||^123457^Labs|||200808141530||ORU^R01|123456789|P|2.4

PID|||123456^^^SMH^PI||MOUSE^MICKEY||19620114|M|||14 Disney Rd^Disneyland^^^MM1 9DLPV1|||5N|||||G123456^DR SMITH

OBR|||54321|666777^CULTURE^LN|||20080802|||||||SW^^^FO

OT^RT|C987654

OBX||CE|0^ORG|01|STAU||||||F

OBX||CE|500152^AMP|01||||R|||F

OBX||CE|500155^SXT|01||||S|||F

OBX||CE|500162^CIP|01||||S|||F

Report from Lab123457, 15:30 14-Aug-2008, Ref 123456789

Patient: MICKEY MOUSE, DoB: 14-Jan-1962, M

Address: 14 Disney Rd, Disneyland, MM1 9DL

Specimen: Swab, FOOT, Right, Requested By: C987654,

Location: 5N

Patients GP: Dr Smith (G123456)

Organism: STAU

Susceptibility:

AMP R

SXT S

CIP S

HL7 version 3 (Hinchley, 2007)

Attempts to introduce semantics (meaning, also termed computable semantic interoperability) beyond syntax of version 2

- Differences demonstrated in (Spronk, 2007)

Based on Reference Information Model (RIM), an object model of entities that pass messages (Mead, 2006)

- Implemented in eXtensible Mark-Up Language (XML)

Thought by many to be complicated, by some overly so

- Some aspects have been called “incoherent” (Smith, 2006)

Fast Healthcare Interoperability Resources (FHIR)

https://www.hl7.org/fhir/

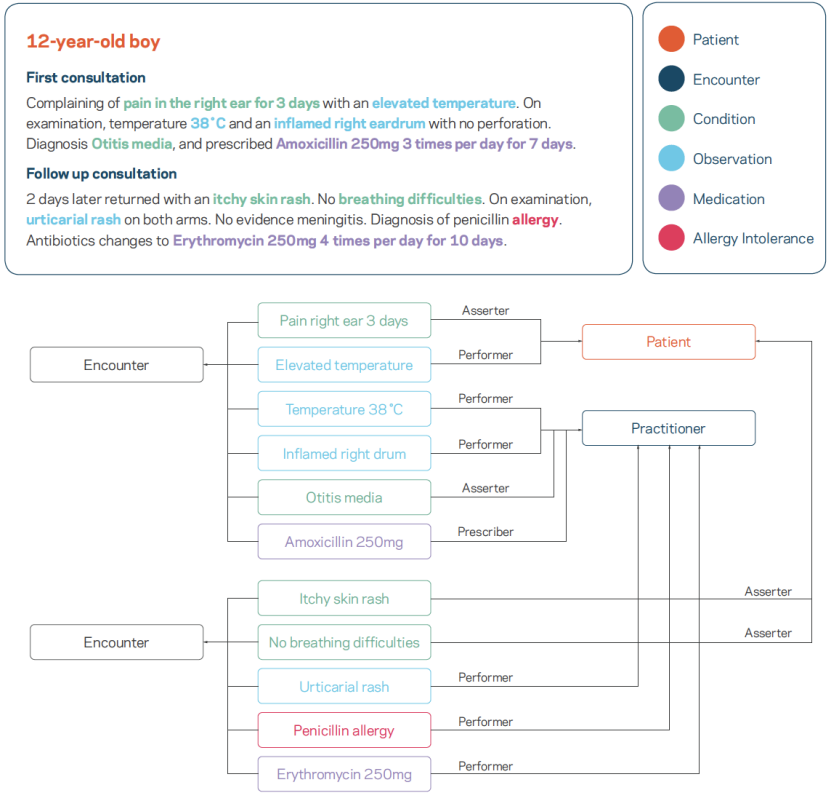
Response to complexity of HL7 V3, but maintaining compatibility with other HL7 standards

Uses “modern” application programming interface (API) approach but less detailed semantics than HL7 V3

Key component is Resource, which defines and represents data elements, building them from data types that define common reusable patterns of elements

- Allows specification of controlled terminologies for naming of data elements

From patient story to FHIR Resources (Hay, 2017)



Growing development of Resources

Clinical

General:
- AllergyIntolerance
- Condition (Problem)
- Procedure
- ClinicalImpression
- FamilyMemberHistory
- RiskAssessment
- DetectedIssue

Care Provision:
- CarePlan
- Goal
- ReferralRequest
- ProcedureRequest
- NutritionOrder
- VisionPrescription

Medication & Immunization:
- Medication
- MedicationOrder
- MedicationAdministration
- MedicationDispense
- MedicationStatement
- Immunization
- ImmunizationRecommendation

Diagnostics:
- Observation
- DiagnosticReport
- DiagnosticOrder
- Specimen
- BodySite
- ImagingStudy
- ImagingObjectSelection

Identification

Individuals:
- Patient
- Practitioner
- RelatedPerson

Groups:
- Organization
- HealthcareService
- Group

Entities:
- Location
- Substance
- Person
- Contract

Devices:
- Device
- DeviceComponent
- DeviceMetric

Workflow

Patient Management:
- Encounter
- EpisodeOfCare
- Communication
- Flag

Scheduling:
- Appointment
- AppointmentResponse
- Schedule
- Slot

Workflow #1:
- Order
- OrderResponse
- CommunicationRequest
- DeviceUseRequest
- DeviceUseStatement

Workflow #2:
- ProcessRequest
- ProcessResponse
- SupplyRequest
- SupplyDelivery

Infrastructure

Information Tracking:
- Questionnaire
- QuestionnaireResponse
- Provenance
- AuditEvent

Documents & Lists:
- Composition
- DocumentManifest
- DocumentReference
- List

Structure:
- Media
- Binary
- Bundle
- Basic

Exchange:
- MessageHeader
- OperationOutcome
- Parameters
- Subscription

Conformance

Terminology:
- ValueSet
- ConceptMap
- NamingSystem

Content:
- StructureDefinition
- DataElement

Operations Control:
- Conformance
- OperationDefinition
- SearchParameter

Misc:
- ImplementationGuide
- TestScript

Financial

Support:
- Coverage
- EligibilityRequest
- EligibilityResponse
- EnrollmentRequest
- EnrollmentResponse

Billing:
- Claim
- ClaimResponse

Payment:
- PaymentNotice
- PaymentReconciliation

Other:
- ExplanationOfBenefit

Toward the future

21st Century Cures Act mandated development of interoperability rule

- https://www.healthit.gov/curesrule/

FHIR to be messaging standard for all healthcare data exchange

US Core Data for Interoperability specifies Resources that must support basic data exchange

- https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi

Clinical Document Architecture (CDA; Boone, 2011)

Much healthcare information is in “documents” required for human reading, but still want computable structure

CDA defines XML-based standard structure and metadata for clinical documents

- Templates are reusable, computable components of CDA documents
- “Unstructured” documents can be “wrapped” in CDA framework
- Current release is version 2 (Boone, 2011)

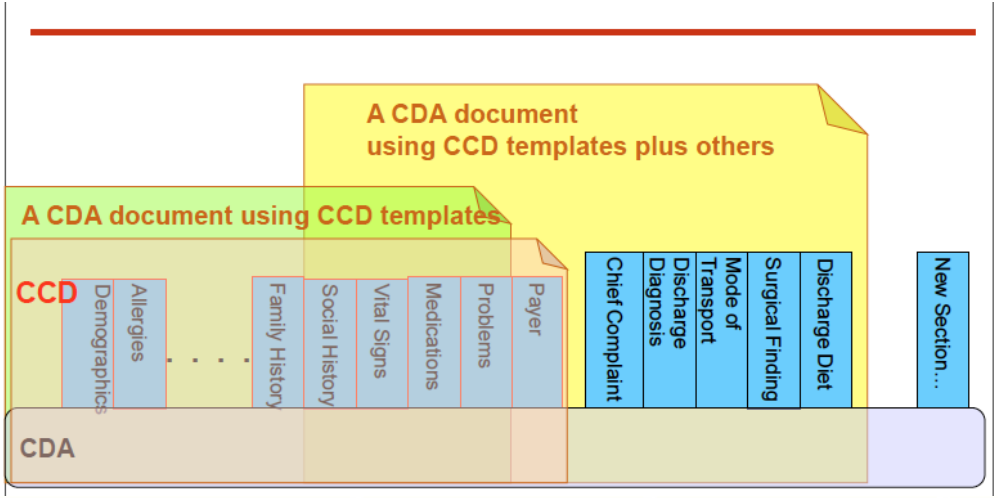
Three “levels” of CDA

- Level 1 – general document specification
- Level 2 – adds document types with allowable structures
- Level 3 – adds mark-up expressible in RIM

Toward Consolidated CDA

A series of “reusable templates” consisting of

- Document templates – from Health Story Project, guides for specific types of common clinical notes, which are based on
- Section templates – describe basic elements of notes, which are based on
- Entry templates – contain the actual data



Digital Imaging and Communications (DICOM)

(Pianykh, 2010)

Developed by American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA)

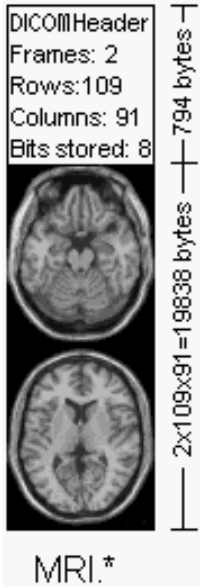
- https://www.dicomstandard.org/

Defines how images and associated data are moved between electronic devices, including information systems

Used in most radiology picture and archiving systems (PACS)

DICOM format files (https://people.cas.sc.edu/rorden/dicom/index.html)

Overall



Header

First 128 bytes: unused by DICOM format
Followed by the characters 'D','I','C','M'
This preamble is followed by extra information e.g.:

0002,0000,File Meta Elements Group Len: 132
0002,0001,File Meta Info Version: 256
0002,0010,Transfer Syntax UID: 1.2.840.10008.1.2.1.
0008,0000,Identifying Group Length: 152
0008,0060,Modality: MR
0008,0070,Manufacturer: MRIcro
0018,0000,Acquisition Group Length: 28
0018,0050,Slice Thickness: 2.00
0018,1020,Software Version: 46\64\37
0028,0000,Image Presentation Group Length: 148
0028,0002,Samples Per Pixel: 1
0028,0004,Photometric Interpretation: MONOCHROME2.
0028,0008,Number of Frames: 2
0028,0010,Rows: 109
0028,0011,Columns: 91
0028,0030,Pixel Spacing: 2.00\2.00
0028,0100,Bits Allocated: 8
0028,0101,Bits Stored: 8
0028,0102,High Bit: 7
0028,0103,Pixel Representation: 0
0028,1052,Rescale Intercept: 0.00
0028,1053,Rescale Slope: 0.00392157
7FE0,0000,Pixel Data Group Length: 19850
7FE0,0010,Pixel Data: 19838

Transfer Syntax UID reports structure and compression of image, e.g., JPEG and amount of compression

NCPDP and SCRIPT

National Council for Prescription Drug Programs (NCPDP, https://www.ncpdp.org/) has developed family of standards for pharmacy claims benefits

SCRIPT is NCPDP standard for electronic communications between prescriber and pharmacy

HITECH meaningful use criteria require NCPDP and SCRIPT standards for e-prescribing

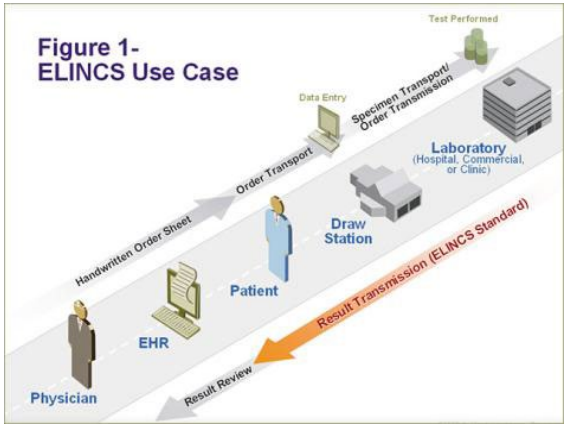
EHR-Laboratory Interoperability and Connectivity Standard (ELINCS)

https://www.chcf.org/project/elincs-the-national-lab-data-standard-for-electronic-health-records/

Goal to standardize laboratory ordering from and reporting to EHRs

Constrains ORU field of HL7 version 2 to defined set of allowable elements

Maintained by HL7



Continuity of Care Record and of Document (CCR, CCD)

CCR was a “set of basic patient information consisting of the most relevant and timely facts about a patient’s condition”

Goal was for use when patient was referred, transferred, or discharged among healthcare providers and/or facilities, containing basic information for providing continuity of care

Original CCR was not compatible with existing standards, so HL7 and vendors created CCD, which was based on HL7 V3 and CDA (EHRVA, 2007)

CCD has resulted in more standard use (D’Amore, 2011) but errors and allowable variation from standard has limited semantic interoperability (D’Amore, 2014)

CDA templates in CCD

Header
Purpose
Problems
Procedures
Family history
Social history
Payers
Advance directives
Alerts

Medications
Immunizations
Medical equipment
Vital signs
Functional status
Results
Encounters
Plan of care

Blue Button Initiative

"Public-private partnership to empower consumers with easy and secure access to their health records from a variety of sources in a format they can use"

- https://bluebutton.cms.gov/

Started as VA initiative to allow patients to download a care summary

Updated Version 2.0 added functionality specific to Medicare beneficiaries, including access to claims data

Adopts FHIR, OAuth2, and other recent standards

CMS has established process for developers to develop and receive approval for beneficiary-facing applications

Platforms

Much criticism that current EHRs are monolithic systems (“traps”) and not platforms (Mandl, 2012)

Substitutable Medical Apps, reusable technologies (SMART, https://smarthealthit.org/)

- Based on platform for “app” development accessing store of information (Mandl, 2012)
- SMART on FHIR uses FHIR as API (Mandel, 2016) – https://smarthealthit.org/smart-on-fhir/
- Has been implemented for genomics (Alterovitz, 2015) and precision medicine applications (Warner, 2016)
- Implementing SMART on FHIR in an EHR (Bloomfield, 2017)
- SMART on FHIR part of interoperability rule emanating from 21st Century Cures Act

Key Readings

Benson, T., Grieve, G., 2016. *Principles of Health Interoperability: SNOMED CT, HL7 and FHIR, 3rd ed. 2016 edition*. Springer, New York, NY.

Braunstein, M.L., 2018. *Health Informatics on FHIR: How HL7's New API is Transforming Healthcare, 1st ed*. 2018 edition. Springer.

Appendix

Examples and additional information

Suggested additional readings

Key reference

- Hammond, WE, Jaffe, C, et al. (2014). *Standards in Biomedical Informatics*. In *Biomedical Informatics: Computer Applications in Health Care and Biomedicine, Fourth Edition*. E. Shortliffe and J. Cimino. London, England, Springer: 211-254

General references

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- Braunstein, M. (2018). *Health Informatics on FHIR: How HL7's New API is Transforming Healthcare*. New York, NY: Springer.

Standards development

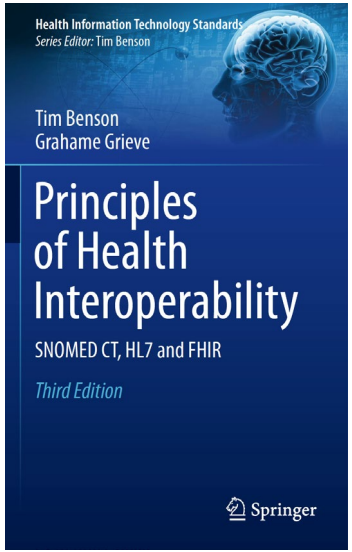
Comprehensive overview (Benson, 2016)

Health IT Standards 101 – another overview (Boone)

- http://motorcycleguy.blogspot.com/2012/04/healthit-standards-101.html

Stages of development (Hammond, 2014)

- Identification
- Conceptualization
- Discussion
- Specification
- Early implementation
- Conformance
- Certification



(Benson, 2016)

The standards development process – four approaches (Hammond, 2014)

Ad hoc – groups agree to informal specifications

De facto – single vendor controls industry

Government mandate – government agency creates standard and mandates its use

Consensus – interested parties work in open process

Some US standards bodies (private, non-profit)

American National Standards Institute (ANSI, https://www.ansi.org/) that accredits standards development organizations (SDOs), including in healthcare

- Accredited Standards Committee (ASC) X12
- Health Level 7 (HL7)
- American Society for Testing and Materials (ASTM, https://www.astm.org/), which has a Committee E31 on Healthcare Informatics

International standards bodies

International Organization for Standardization (ISO, www.iso.org)

- Technical Committee 215 (TC 215) focuses on health informatics standards
- https://www.iso.org/committee/54960/x/catalogue/

European Committee for Standardization (CEN, www.cen.eu)

- CEN/TC 251 is health informatics standards body for Europe

International Telecommunication Union (ITU, www.itu.int) - UN agency focused on telecommunications standards (general, not medical)

US government health information standards leadership efforts

A number of approaches over the years

- Consolidated Health Informatics (CHI) initiative – effort to adopt ready standards by health-related US government agencies
- Healthcare Information Technology Standards Panel (HITSP) of the Office of the National Coordinator for Health IT (ONC) – effort to identify ready standards and gaps needing to be filled
- ONC Health IT Standards Committee – formed to implement HITECH Act
- All standards activities now oversee by ONC Health IT Advisory Committee - https://www.healthit.gov/hitac/

Help from other federal agencies

- National Institute for Standards and Technology (NIST) – focused on efforts supporting ONC (https://www.nist.gov/itl/ssd/systems-interoperability-group/healthcare-standards-testing)
- National Library of Medicine (NLM) – efforts mostly around insuring terminology standards support messaging standards efforts (e.g., HL7)

Recent ONC standards activities

JASON report calls for move to more “modern” API-based approaches to interoperability (MITRE, 2014)

ONC establishes JASON Task Force to respond to recommendations and develops evolving plans and documents

Argonaut Project (2014) – implementing details

Interoperability Vision (2014) – vision and framework

Interoperability Roadmap (2015) – how to get there

Standards Advisory (2018) – standards ready for use, updated annually

Example IHE profiles from domain: Patient Care Coordination

https://wiki.ihe.net/index.php/Patient_Care_Coordination

[MS] Medical Summaries describes the content and format of Discharge Summaries and Referral Notes

[XPHR] Exchange of Personal Health Record describes the content and format of summary information extracted from a PHR system for import into an EHR system, and visa versa

[FSA] Functional Status Assessments describes the content and format of Functional Status Assessments that appear within summary documents

[QED] Query for Existing Data queries data repositories for clinical information on vital signs, problems, medications, immunizations, and diagnostic results

[IC] Immunization Content exchanges immunization data

[CM] Care Management exchanges information between HIT systems and applications used to manage care for specific conditions

[PPOC] Patient Plan of Care exchanges data related to creating and managing individualized patient care between and among HIT systems

[RCG] Request for Clinical Guidance obtains decision support when ordering medications, determining appropriate immunizations, diagnostic tests, etc.

[EDR] Emergency Department Referral communicates medical summary data from an EHR System to an EDIS System

Challenges of duplicate and overlaid records

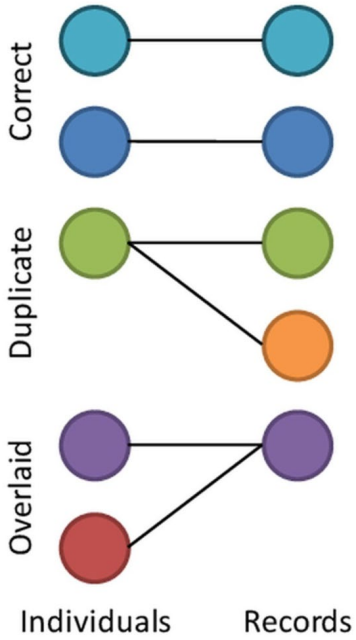
Identifier errors compromise quality of care and can be costly (Fernandes, 2001)

- $4,500 to correct duplicate patient records in operating room
- 325 minutes of work to correct duplicate records in hospital
- Cost increases with length of time error not identified

Duplicate records more likely to be associated with missed abnormal test results (Joffe, 2009)

Study of five large academic centers found (McCoy, 2013)

- Occurrence of matching first and last name was 16.5-40.7%, reduced to 0.2-15.5% when date of birth added
- Highly variable policies for preventing, detecting, and removing duplicate records, and for mitigating errors



Patient identifiers – key attributes (Connecting for Health, 2005)

Unique – only one person has a particular identifier

Non-disclosing – discloses no personal information

Permanent – will never be re-used

Ubiquitous – everyone has one

Canonical – each person has only one

Invariable – will not change over time

One solution is government-issued patient identifiers

Most industrialized countries have them, e.g.,

- New Zealand National Health Index (NHI, https://www.health.govt.nz/our-work/health-identity/national-health-index)
- Iceland Health Sector Database (Arnason, 2002)
  - Have also created national genetic database (Gulcher, 2000)
- Singapore issues National Registration Identity Card (NRIC) to all citizens and Foreign Identification Number (FIN) to all long-term visitors, which are used as identifiers in healthcare
- Most Western European countries also use them without controversy

Others argue it is unnecessary and politically infeasible in US

Connecting for Health, 2005

- "Not worth the fight" (Ferris, 2005; Ferris, 2005)
- Probably politically impossible to deploy in US
- There may be other ways to achieve goals for national identifiers
- Expenses up front; benefits accrue later

Counterpoint: Unique patient identifier would reduce errors and improve system interoperability in US (Hillestad, 2008; Detmer, 2010; Aranow, 2013)

- Costs would be substantial ($3.9-9.2 billion) but be offset by other improvements in healthcare system
- Would not significantly increase risk for security breaches over other options

Current state of patient record-matching (Morris, 2014)

From recently commissioned report by ONC

Imperative as a patient safety, care coordination, and data quality issue (among others)

Current state-of-art works well, but would benefit from standardizing patient-identifying attributes in record, such as

- First/given, middle/second given, and last/family names
- Suffix – e.g., Jr./Sr., II/III/etc., MD/RN/PhD, Esq., etc.
- Date of birth – YYYYMMDD, with HHMMSS if available
- Current and historical addresses – in some international format
- Phone number – all known
- Gender – from HL7 value set; M, F, UN

Also need process for handling changes across healthcare system

Advocates further research to evaluate algorithms and additional attributes as well as dissemination of best practices

Employer and health plan identifier standards

Employers – National Standard Employer Identifier (EIN)

- https://www.hhs.gov/hipaa/for-professionals/other-administration-simplification-rules/index.html

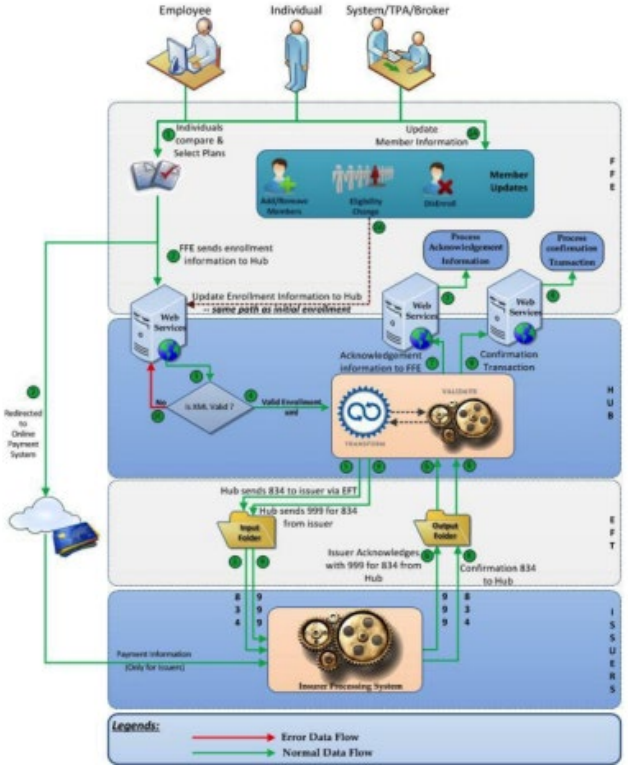
Health plans – new Health Plan Identifier (HPID) and Other Entity Identifier (OEID) mandated in Affordable Care Act (ACA)

- https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Unique-Identifier/HPID.html

You don’t believe these are important?

Part of the reason for the early failure of the Healthcare.gov (www.healthcare.gov) Web site was due to health plans not properly having implemented the 834 standard for enrollment and disenrollment in health plans

- News media: “Obamacare’s most important number: 834” (Kliff, 2013)
- More technical description (Laszewski, 2013)
- Many other informatics lessons learned as well (Blumenthal, 2013)



Another HL7 version 2.5 example (Hammond, 2014)

MSH|^~&\|DHIS|OR|TMR|SICU|199212071425|password|ADT|16603529|P|2.1<c>

EVN|A02|199212071425||<cr>

PID|||Z99999^5^M11||GUNCH^MODINE^SUE|RILEY|19430704 |F||C|RT. 1, BOX 97^ZIRCONIA^NC^27401 |HEND|(704)982-1234|(704)983-1822||S|C||245-33-9999<cr>

PV1|1|I|N22^2204|||OR^03|0940^DOCTOR^HOSPITAL^A|||SUR|||||A3<cr>

OBR|7|||93000^EKG REPORT|R|199401111000|199401111330|||RMT||||1994011111330|?|P030|||||199401120930|||||88-126666|A111|VIRANYI^ANDREW<cr>

OBX|1|ST|93000.1^VENTRICULAR RATE(EKG)||91|/MIN|60-100<cr>

OBX|2|ST|93000.2^ATRIAL RATE(EKG)||150|/MIN|60-100<cr>

...

OBX|8|ST|93000&IMP^EKG DIAGNOSIS|1|^ATRIAL FIBRILATION<cr>

Releases of HL7 V2
http://www.hl7argentina.org.ar/

V2.1 (1990): First implemented version - very basic, but still used

V2.2 (1994): Basic enhancements

V2.3 (1997): Scheduling and Finance messages added

V2.3.1 (1999): Pathology, Allergies, Referral as Scheduling

V2.4 (2000): Clinical Focus - Referrals and Discharge Summaries

V2.5 (2003): Data field lengths standardized

V2.5.1 (2007): Four data items added due to US regulatory requirements

V2.6 (2007): Data type changes

Coded Element (CE) → Coded With (No) Exceptions (CNE/CWE)

Time Stamp (TS) → Date/Time (DTM)

V2.7 (2011): Collaborative Care Message

V2.7.1 (2012): Lab Orders/Results features added for US “Meaningful Use”

V2.8 (2014): Authorization and Ordering information added

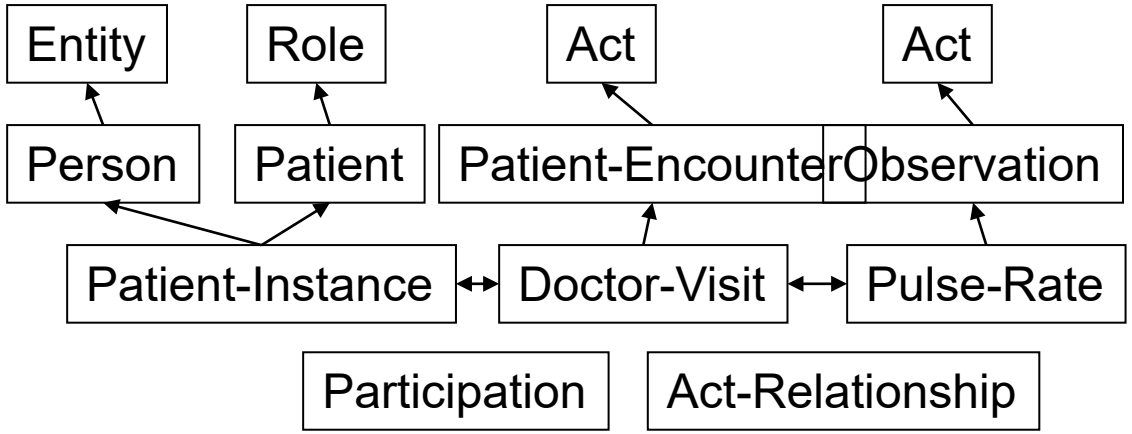
Overview of the RIM (Mead, 2005; Benson, 2016)

RIM uses object-oriented approach to define healthcare interactions based on five abstract classes

- Entity – things in world, e.g., people, organizations, other living subjects, drugs, devices
- Role – capability or capacity, e.g., patient, practitioner
- Participation – role in context of an act, e.g., performer, target
- Act – clinical or administrative definitions, e.g., observation, diagnosis, procedure
- Act relationship – links between acts, e.g., diagnosis act

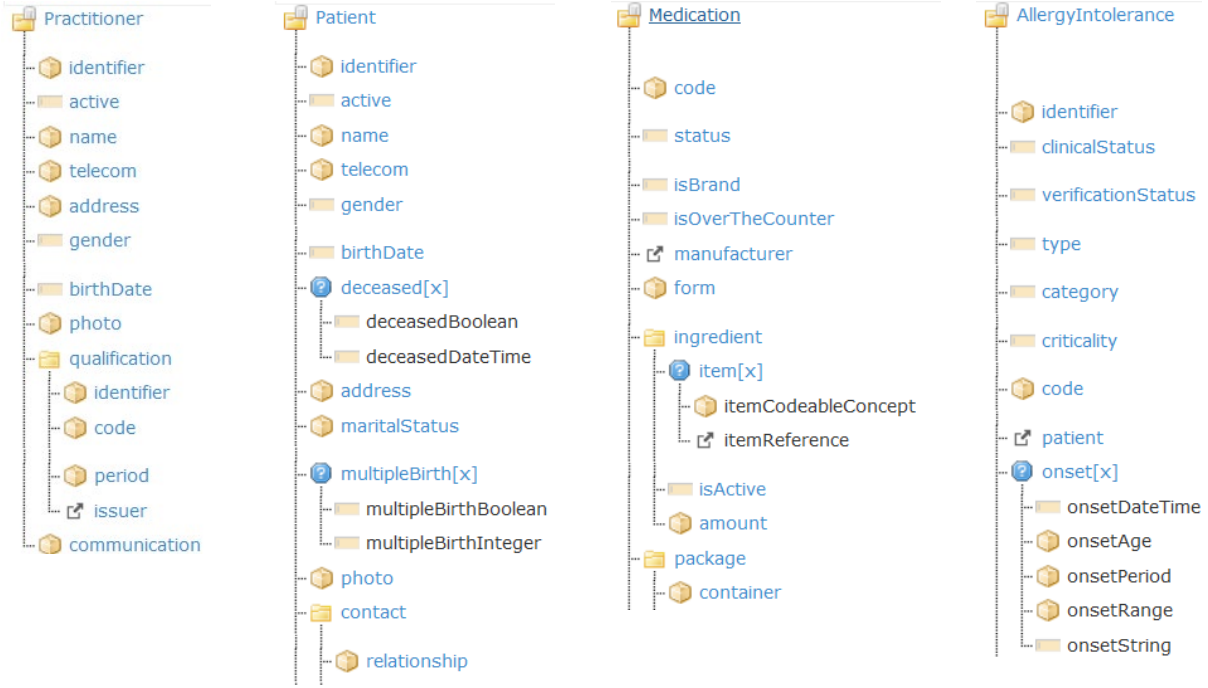
All clinical, administrative, financial, etc. activities of healthcare can be expressed in “constraints” to model

HL7 version 3 instance of pulse measured at physician office visit



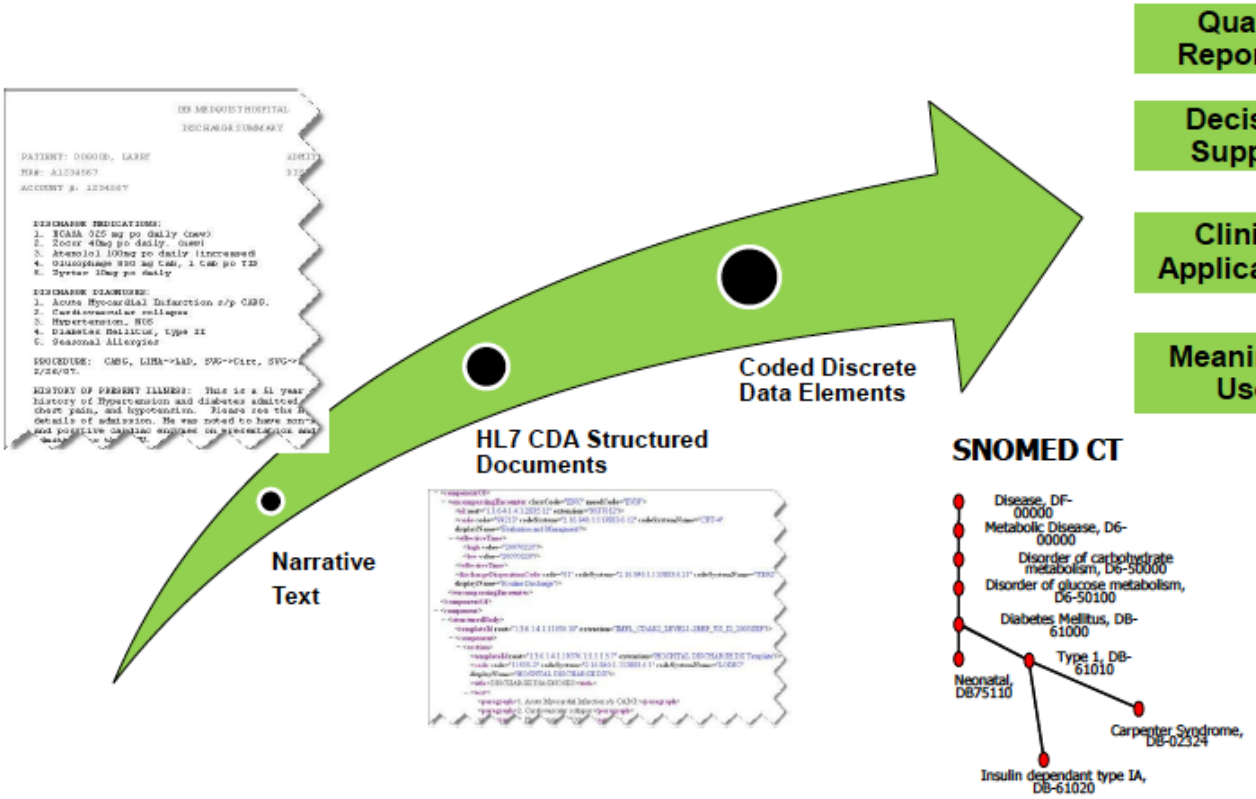
Observations modeled as Entity-Attribute-Value (EAV)
and ideally are based on standard terminology, e.g., pulse (palpated at wrist) – rate 50 beats/minute

Examples of FHIR Resources



Health Story – structuring CDA where cost-effective

(https://www.himss.org/himss-health-story-project)



CCDA document and section templates (ONC, 2012)

HL7 Implementation Guide for CDA®
Release 2: IHE Health Story Consolidation,
Release 1.1 - US Realm

Document Templates: 9

- Continuity of Care Document (CCD)
- Consultation Note
- Diagnostic Imaging Report (DIR)
- Discharge Summary
- History and Physical (H&P)
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

Section Templates: 60

Entry Templates: 82

Document Template	Section Template(s)		
Continuity 0f Care Document (CCD)	Allergies Medications Problem List Procedures Results Advance Directives Encounters	Family History Functional Status Immunizations Medical Equipment Payers Plan of Care	
History & Physical (H&P)	Allergies Medications Problem List Procedures Results Family History Immunizations Assessments	Assessment and Plan Plan of Care Social History Vital Signs History of Present Illness History of Present Illness	Chief Complaint Reason for Visit Review of Systems Physical Exam General Status

Section templates in YELLOW demonstrate CDA's interoperability and reusability.

Medical device standards (HIMSS Analytics, 2010; Day, 2011)

What is a medical device? From US Food, Drug, and Cosmetic Act, section 201(h)

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory that is:
  - Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes

Medical information bus (MIB)

Kennelly, 1997; Kennelly, 1998

Aims to develop standards for control and linkage of information from medical devices

Most implementations just transfer data, but there is capability to issue commands, e.g., change settings of an intravenous fluid (IV) pump

Emerged as IEEE 1073 and now ISO 11073, but never widely adopted

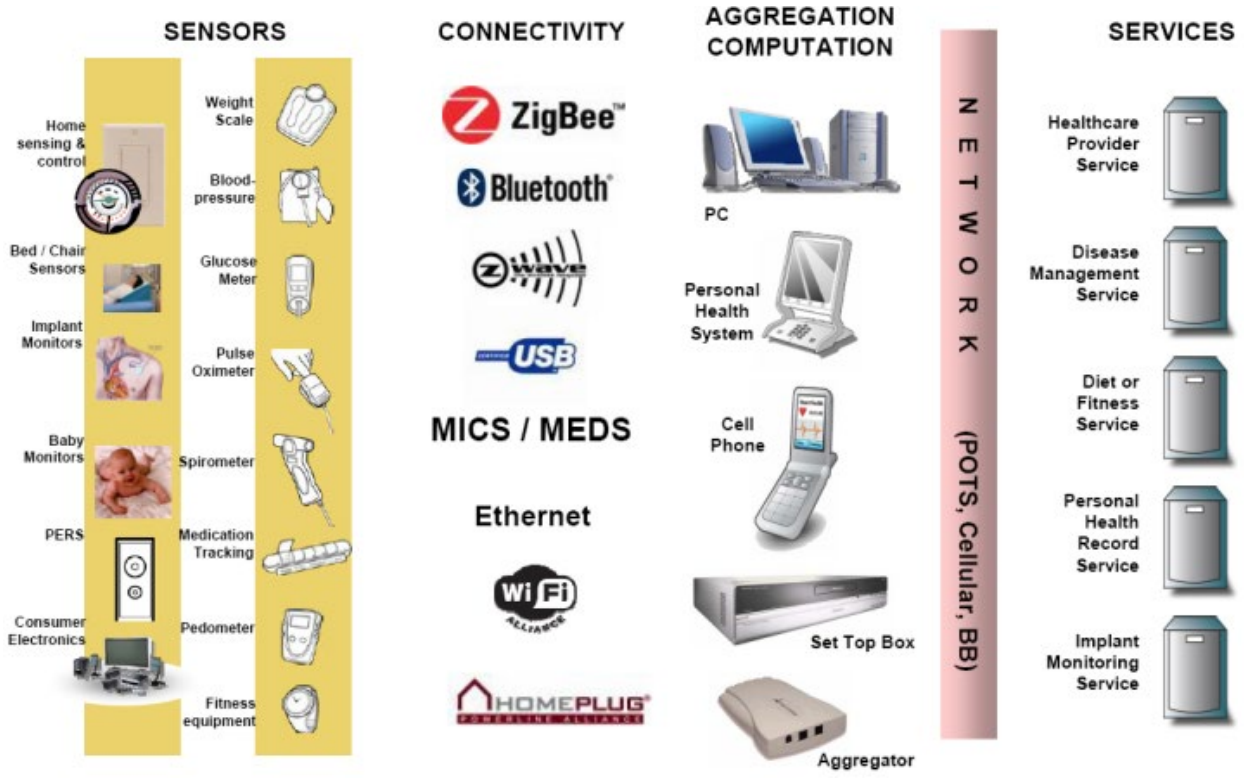
Related medical device standards

Open-Source Integrated Clinical Environment (OpenICE, www.openice.info) – prototype clinical ecosystem connecting medical devices and clinical applications

- Includes Medical Device "Plug-and-Play" Interoperability Program (www.mdpnp.org) – focus on interoperability of network-based medical devices (Whitehead, 2008; CIMIT, 2012)

Continua Health Alliance (www.continuaalliance.org) – consortium of companies and organizations devoted to interoperability of personal telehealth devices (Cnossen, 2010)

Continua “personal health eco-system”



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