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# Quality, Standards, and Exchange of Clinical Data

**Association For Pathology Informatics Annual Summit 2017**

**May 22nd, 2017**

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PATHOLOGY INFORMATICS SUMMIT 2017
May 22-25, 2017
Pittsburgh, PA
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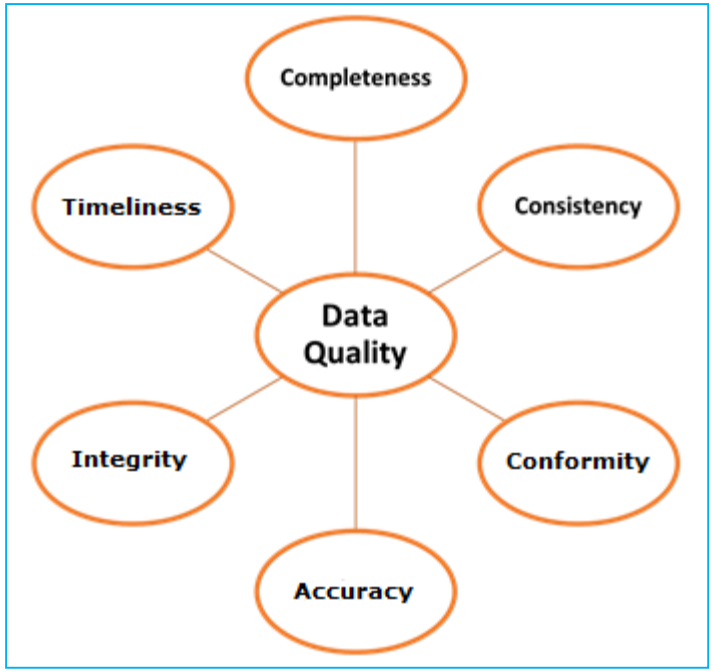
# Outline

- Data Quality
- Clinical Data Standards
- Terminology Standards
- Data Exchange Standards

# Data Quality

# Data Quality

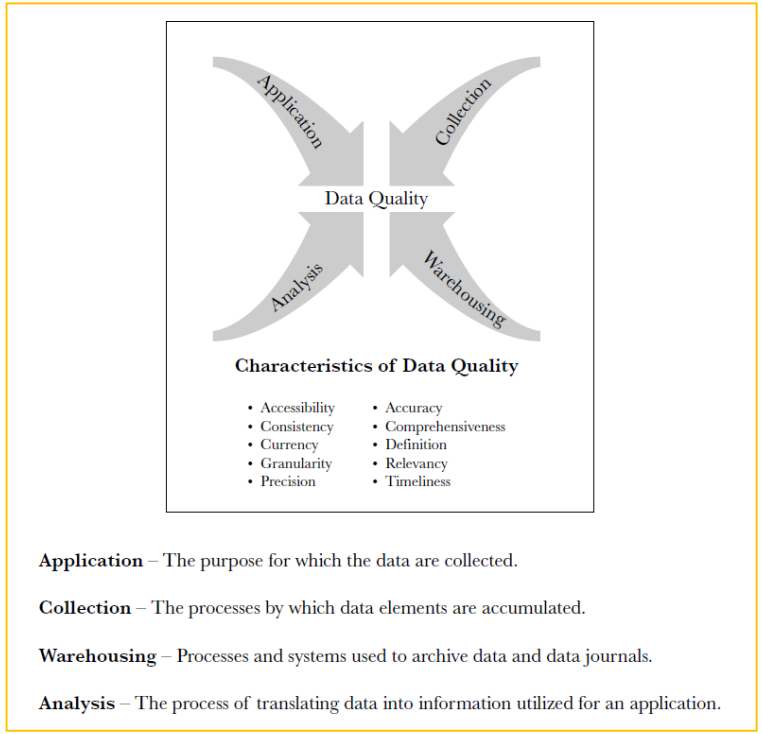
- More than just data accuracy
- Data quality cannot be assessed without data quality standards
- Dimensions of data quality
  - Method to measure data quality
  - Established for a variety of industries/businesses
- No universally recognized set of health care data quality standards
  - *Quality of data needed in any situation is driven by how data will be used*




Wager KA, et al. Managing Healthcare Information Systems (2005).

# Data Quality in Healthcare

- American Health Information Management Association (AHIMA): Data Quality Management Tool
  - Guidance to assist health care organizations in establishing data quality standards




*Defines characteristics of data quality that can be applied to application, collection, warehousing and analysis of data in healthcare*

Wager KA, et al. Managing Healthcare Information Systems (2005).

# Data Quality Characteristics

- **Data accuracy** = data are the correct values and are valid (ex. typographical error)
  - *Syntactic accuracy* – permissible value
  - *Semantic accuracy* – closeness to true value (correctness)
- **Data accessibility** = data items should be easily obtainable and legal to collect (can't access data it's of no use)
- **Data comprehensiveness** = all required data elements are included (data not useful if not complete)
- **Data consistency** = value of the data should be reliable and same across applications (ex. use of an abbreviation that has two different meanings)
- **Data currency** = data should be up-to-date (many data become obsolete after a period of time)

Wager KA, et al. Managing Healthcare Information Systems (2005).

# Data Quality Characteristics

- **Data definition** = clear definitions should be provided so that current and future data users will know what the data mean (ex. use of data dictionaries)
- **Data granularity/atomicity** = attributes and values of data should be defined at the correct level of detail (ex. patient name recorded as three data elements: last name, first name, middle name)
- **Data precision** = how close to an actual size , weight or other standard a particular measurement is
- **Data relevancy** = data are meaningful to the performance of the process or application for which they  are collected
- **Data timeliness** = defined by how data are being used and their context

Wager KA, et al. Managing Healthcare Information Systems (2005).

# Systematic vs. Random Data Errors

- **Data error** = failures of data to meet established quality standards
  - *Have negative impact on one or more of the characteristics of data quality*

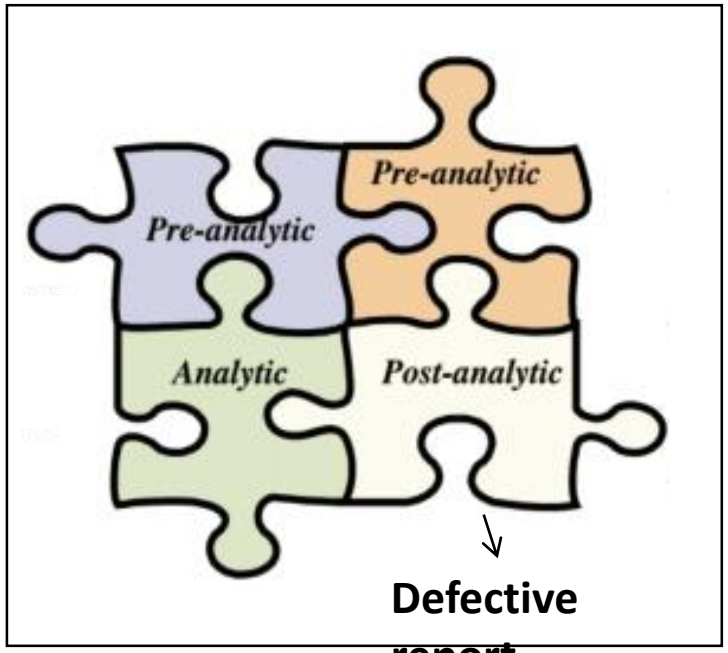
- **Systematic errors** = flaw or discrepancy in adherence to standard operating procedures or systems

- **Random errors** = due to carelessness rather than lack of training (ex. transcription error)

Wager KA, et al. Managing Healthcare Information Systems (2005).

# Data Quality in Pathology

- Errors can occur across all phases of the process of pathology*
  - *Preanalytic* = receiving and preparing specimen
  - *Analytic* = interpretation
  - *Postanalytic* = conveying results to clinician
- In surgical pathology, where data quality issues are generally more complex, quality is determined by
  - *Diagnostic accuracy*
  - *Report completeness*
  - *Timeliness*
  - *Clear and comprehensible pathology reports*




*For more on quality measures in anatomic pathology – archived presentations by Dr. Liron Pantanowitz

Zarbo RJ, et al. Arch Pathol Lab Med. 2005;129:1237-45.
Nakhleh RE. Arch Pathol Lab Med. 2011;135:1394-97.

# Reporting in Surgical Pathology

- Traditional pathology reports are written in **free text** narrative format
  - *Variability* in
    - Diagnostic terminology
    - Reporting styles
    - Report content
- Lack of emphasis on human readability of report or optimization of report formatting

**FINAL DIAGNOSIS**

A. BONE MARROW, LEFT ILIAC CREST, BIOPSY, TOUCH PREP, ASPIRATE, AND PERIPHERAL SMEAR:
Hypocellular erythroid-dominant marrow with markedly decreased megakaryocytes. (See note.)

Note: The bone marrow biopsy specimen is mildly hemorrhagic, but is adequate for evaluation. The marrow cellularity is overall approximately 20% (range 5 to 40%). The myeloid to erythroid ratio is reversed. Myeloid maturation appears shifted to the left. Erythroid maturation is complete. Megakaryocytes are markedly decreased with overall normal morphology. There are rare non-paratrabecular small aggregates of small lymphoid cells with irregular nuclei. The lymphoid cells account for 5% of the marrow cellularity and occupy 1% of the intertrabecular marrow space. Giemsa stain was examined as part of the histologic evaluation of this case. Immunohistochemical stains of the core biopsy reveal rare scattered megakaryocyte with overall normal morphology. A CMV stain and in-situ hybridization for Epstein-Barr virus encoded RNA (EBER) are negative.

The aspirate smear is adequate for evaluation, but hemodilute and paucicellular. The touch prep slide contains many cells with stripped cytoplasm and is inadequate for evaluation. A 200 cell count reveals: 21% neutrophils and precursors; 61% erythroid precursors; 5% lymphocytes; 8% monocytes; 3% eosinophils; 2% basophils; <1% promyelocytes; <1% blasts; and 0% plasma cells. Myeloid maturation is normal. Erythroid maturation is normal with occasional nuclear budding irregularities and basophilic cytoplasmic stippling. Megakaryocytes are not identified.

CBC results from 1/1/2014 are as follows: WBC 3.7; HGB 7.8; HCT 23.3%; MCV 100 fl; and PLT 4. Auto differential: 9.0% polys; 06.1% lymphs; 1.9% monos; 0.0% eos; 1.4% basos; and 1 nRDC/100WBC. Review of the peripheral smear from 1/2/2014 with similar CBC counts confirms pancytopenia and mild anisopoikilocytosis and polychromasia among red cells. Leukocytes have normal morphology.

Summary: The overall findings are of a hypocellular erythroid-dominant marrow with rare megakaryocytes with overall normal morphology. The differential diagnosis is broad and includes immune/engraftment, drug/immunosuppressive, and/or infectious causes. While CMV reactivation cannot be confirmed based on this biopsy, immunohistochemistry is much less sensitive than following CMV viral load. Correlation with other laboratory and clinical findings is recommended. See also results of flow cytometry below. Also see results of cytogenetics Also see results of molecular genetic studies for chimerism, which shows >96% donor marrow.

has acted as the primary sign out pathologist for this case but under the supervision of , who has reviewed all aspects of the case prior to reporting.

The findings were discussed with Dr. by review of slide on .

# Improving Data Quality in Pathology Reports

- Healthcare documentation has two parts
  - Data capture
  - Report generation

Both must be considered in order to have high quality data

- *Ways to improve quality in pathology reports*
  - *Use standardized terminology upfront when data is initially being captured*
    - *CAP cancer protocols and CAP electronic cancer checklists*
  - *Optimize report formatting for human readibility*

# Synoptic Reports

- Terminology: “guidelines, protocols, templates, practice parameters, checklists”
- Provides uniform standardized data elements in the form of checklists to ensure that pathologists make note of these findings in their reports
- Data is summarized as a list of previously defined data elements

- ***Synoptic standard for cancer reporting in anatomic pathology***
  - *CAP Cancer Protocols (CCP) and CAP electronic Cancer Checklists (eCC)*

KIDNEY (LEFT): ADENOCARCINOMA
MACROSCOPIC
SPECIMEN TYPE: Radical Nephrectomy
LATERALITY: Left
TUMOR SITE: Upper pole
FOCALITY: Unifocal
TUMOR SIZE: Greatest dimension is 7.2 cm
MACROSCOPIC EXTENT OF TUMOR: Tumor extends into major veins
MICROSCOPIC
HISTOLOGIC TYPE: Clear cell (conventional) renal carcinoma
HISTOLOGIC GRADE: (Furhman Nuclear Grade): 2
PATHOLOGIC STAGING (pTN)
PRIMARY TUMOR (pT): pT3
REGIONAL LYMPH NODES (pN): Nx
Number of lymph nodes examined: 0
Number of lymph nodes involved: 0
MARGINS: Renal vein margin positive
ADRENAL GLAND: Univolved
VENOUS (LARGE VESSEL) INVASION (V)(excluding renal vein and inferior vena cava): Negative
LYMPHATIC (SMALL VESSEL) INVASION (L): present
ADDITIONAL PATHOLOGIC FINDINGS: Chronic glomerulonephritis present in non-involved renal parenchyma.

# CAP Cancer Protocols

- Set of *standardized protocols* for the most commonly reported forms of cancer
- Goal: Improve quality and uniformity of information in pathology reports
- Developed by the CAP cancer committee
- Consist of data elements structured as a set of questions and prospective answers
- Staging is based on the AJCC Staging Manual
- Includes reference information and is updated periodically
- Available in doc and pdf versions
- Electronic cancer checklists (eCC) were released in early 2007 to advance use in computerized pathology reporting (developed and maintained by PERT Committee)

# Benefits of Using Synoptic Reports

- Significantly improves *completeness* of cancer reports across a broad range of tumor types Idowu MO, et al. Arch Pathol Lab Med. 2010;134:969-74.
- *Simplifies*, standardizes, and *prioritizes* the recording of information
- Ensures that pathologists are kept abreast of the *latest* minimum reporting standards for all tumors
- Secondary users, such as *cancer registries*, can more efficiently extract meaningful staging and prognostic data than from narrative reports
- Improved information to support clinical *decision* making, i.e. increased clinician *satisfaction* Lankshear S, et al. Arch Pathol Lab Med. 2013;137:1599-1602.c

Lankshear S, et al. Arch Pathol Lab Med. 2013;137:1599-1602.

# Synoptic Reports vs. Structured Data

- *Not all synoptic reports contain structured data*
- Many **synoptic reports** are simply word processing documents that appear structured to humans
  - They provide visibly structured blocks of free text which is embedded in the pathology report
- Truly **structured data** is entered in many smaller specific text fields rather than a few large ones
  - Every single data element has its own predefined place in the database
  - Every discrete data element is directly linked to its inherent context

***Synoptic reports clarify findings for clinicians while structured data clarifies findings for computers***

# Advantages of Structured Data Capture

- Beyond the benefits of synoptic reporting, truly *structured data* in the form of discrete data elements allows for
  - Advanced data-querying capabilities
  - Automated analysis
  - Decision support
  - Predefined comment generation or staging

- *Required for the future of pathology informatics and computational pathology*

Ellis DW. Pathology. 2011;43:404-9.

# Clinical Data Standards

# Importance of Clinical Data Standards

- Promote consistent naming of individuals, events, diagnoses, treatments, etc.
- Allow better use of data for patient care as well as secondary uses (quality assurance, research, public health, etc.)
- Enhance ability to transfer data among applications (better system integration)
- Facilitate interoperability among information systems and users

Hammond WE, et al. (2014) in Biomedical Informatics by E. Shortliffe and J. Cimino, 4th ed. 211-254.

# Methods for Standards Development

- **Ad hoc**
  - Groups agree to use common but informally developed specification
- **De facto**
  - Single vendor controls industry
- **Government mandate**
  - Government agency creates standard and mandates is use
- **Consensus**
  - Interested parties work in open process
  - Many of the key healthcare data standards are developed in this way

Hammond WE, et al. (2014) in Biomedical Informatics by E. Shortliffe and J. Cimino, 4th ed. 211-254.

# Selection and Adoption of Standards

- Six criteria for standards adoption
  - Maturity of specification
  - Maturity of underlying technology components
  - Market adoption
  - Ease of implementation and deployment
  - Ease of operations
  - Intellectual property
- Developed by HIT Standards Committee
  - Federal advisory committee that makes recommendations on standards to the National Coordinator for Health IT

Hammond WE, et al. (2014) in Biomedical Informatics by E. Shortliffe and J. Cimino, 4th ed. 211-254.

# Main Types of Clinical Data Standards

- Identifier Standards
- Transaction Standards
- Terminology Standards
- Data Exchange Standards

# Medical Terminology Standards

# Medical Terminology Standards

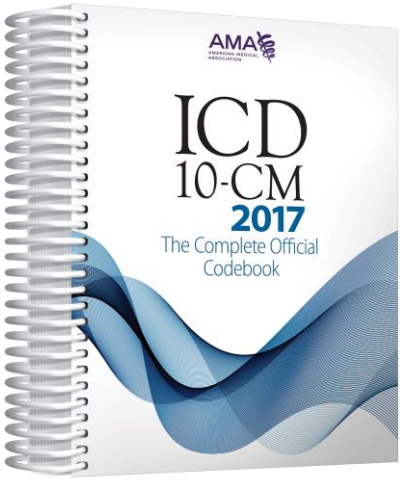
- **ICD** (International Classification of Diseases)
- **CPT** (Current Procedural Terminology)
- **LOINC** (Logical Observation Identifiers, Names and Codes)
- **SNOMED-CT** (Systematized Nomenclature of Medicine-Clinical Terms)
- Foundational Model of Anatomy
- Gene Ontology
- RxNorm
- MeSH (Medical Subject Headings)
- NCI Thesaurus (National Cancer Institute Thesaurus)
- UMLS (Unified Medical Language System)

# Definitions of Key Terms

- **Concept** = fundamental unit of meaning within a terminology or classification system (ex. ischemia)
- **Term** = word or phrase which names a particular concept
  - Multiple terms may convey the identical concept: ex. stroke and cerebrovascular accident
- **Classification** = system for organizing concepts in a particular area of knowledge into related groupings (ex. ICD-10-CM)
- **Terminology** or **nomenclature** = set of terms for concepts in a particular area of knowledge (ex. ICD-10-CM)
  - Definitions NOT required (unlike a vocabulary)
- **Ontology** = vocabulary that includes information about relationships among concepts (ex. SNOMED-CT)
- **Semantic relationships** = expressions of the connections between various concepts (ex. SNOMED-CT)

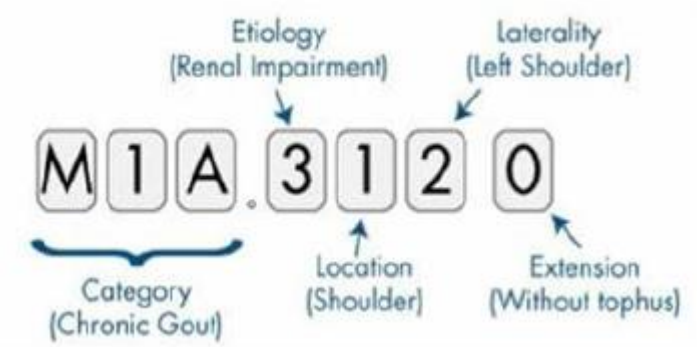
# ICD

- **I**nternational **C**lassification of **D**iseases
- One of the first medical coding systems in widespread use
- Changes and modifications are overseen by the National Center for Health Statistics (NCHS) and the Centers for Medicare and Medicaid Services (CMS)
- Tabular list of diseases and injuries
  - Organized by cause or anatomic location
  - Highest degree of specificity should always be used
- Important for billing in the U.S.
- Family of Codes
  - Specialized version for oncology: ICD-0
  - U.S. used/s ICD-9-CM/ICD-10-CM: clinical modifications (CM) with more variants
- ICD-9-CM was used for over 20 years in the U.S. until October 1, 2015 when we switched over to ICD-10-CM



# ICD-9 vs ICD-10

- Major limitation of ICD-9-CM was small number of available codes with no more room for additional codes
- ICD-10-CM structure is similar to ICD-9-CM
- Number of diagnosis codes expanded from 14,000 to over 90,000
- ICD-10 codes are alphanumeric instead of just numeric
- Codes vary from 3 to 7 characters
  - Three characters to the left of the decimal = category
  - Characters to the right of the decimal = various levels of detail (etiology, laterality, etc)



# ICD Organized by Cause or Anatomic Location

**2017 ICD-10-CM Codes**

- A00-B99 Certain infectious and parasitic diseases
- C00-D49 Neoplasms
- D50-D89 Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism
- E00-E89 Endocrine, nutritional and metabolic diseases
- F01-F99 Mental, Behavioral and Neurodevelopmental disorders
- G00-G99 Diseases of the nervous system
- H00-H59 Diseases of the eye and adnexa
- H60-H95 Diseases of the ear and mastoid process
- I00-I99 Diseases of the circulatory system
- J00-J99 Diseases of the respiratory system
- K00-K95 Diseases of the digestive system
- L00-L99 Diseases of the skin and subcutaneous tissue
- M00-M99 Diseases of the musculoskeletal system and connective tissue
- N00-N99 Diseases of the genitourinary system
- O00-O9A Pregnancy, childbirth and the puerperium
- P00-P96 Certain conditions originating in the perinatal period
- Q00-Q99 Congenital malformations, deformations and chromosomal abnormalities
- R00-R99 Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified
- S00-T88 Injury, poisoning and certain other consequences of external causes
- V00-Y99 External causes of morbidity
- Z00-Z99 Factors influencing health status and contact with health services

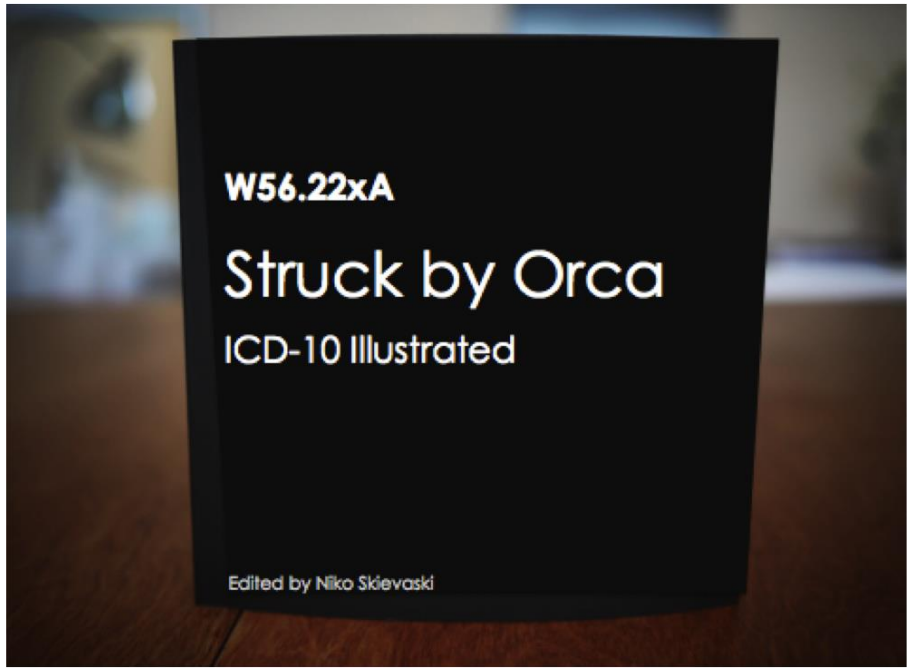
# ICD-10-CM Examples

- Highly granular, almost too granular in some cases…
- 50% of all codes are related to musculoskeletal system
- 25% of all codes are related to fractures
- 36% of all codes distinguish laterality
- Mostly affects orthopedics and Ob/Gyn

- C50 Malignant neoplasm of breast
  - C50.0 Malignant neoplasm of nipple and areola
    - C50.01 Malignant neoplasm of nipple and areola, female
      - C50.011 Malignant neoplasm of nipple and areola, right female breast
      - C50.012 Malignant neoplasm of nipple and areola, left female breast
      - C50.019 Malignant neoplasm of nipple and areola, unspecified female breast
    - C50.02 Malignant neoplasm of nipple and areola, male
      - C50.021 Malignant neoplasm of nipple and areola, right male breast
      - C50.022 Malignant neoplasm of nipple and areola, left male breast
      - C50.029 Malignant neoplasm of nipple and areola, unspecified male breast
  - C50.1 Malignant neoplasm of central portion of breast
    - C50.11 Malignant neoplasm of central portion of breast, female
      - C50.111 Malignant neoplasm of central portion of right female breast
      - C50.112 Malignant neoplasm of central portion of left female breast
      - C50.119 Malignant neoplasm of central portion of unspecified female breast
    - C50.12 Malignant neoplasm of central portion of breast, male
      - C50.121 Malignant neoplasm of central portion of right male breast
      - C50.122 Malignant neoplasm of central portion of left male breast
      - C50.129 Malignant neoplasm of central portion of unspecified male breast
  - C50.2 Malignant neoplasm of upper-inner quadrant of breast
    - C50.21 Malignant neoplasm of upper-inner quadrant of breast, female
      - C50.211 Malignant neoplasm of upper-inner quadrant of right female breast
      - C50.212 Malignant neoplasm of upper-inner quadrant of left female breast
      - C50.219 Malignant neoplasm of upper-inner quadrant of unspecified female breast
    - C50.22 Malignant neoplasm of upper-inner quadrant of breast, male
      - C50.221 Malignant neoplasm of upper-inner quadrant of right male breast
      - C50.222 Malignant neoplasm of upper-inner quadrant of left male breast
      - C50.229 Malignant neoplasm of upper-inner quadrant of unspecified male breast
  - C50.3 Malignant neoplasm of lower-inner quadrant of breast
    - C50.31 Malignant neoplasm of lower-inner quadrant of breast, female
      - C50.311 Malignant neoplasm of lower-inner quadrant of right female breast

# ICD-10-CM Examples

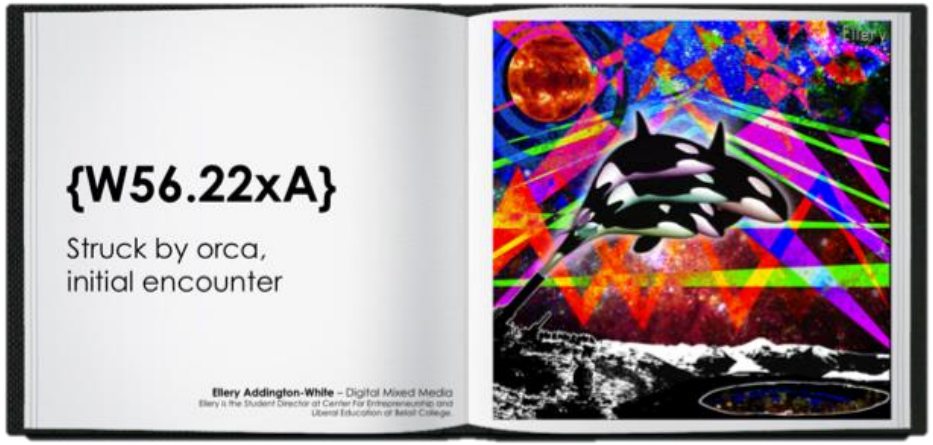
- Unnecessary granularity?



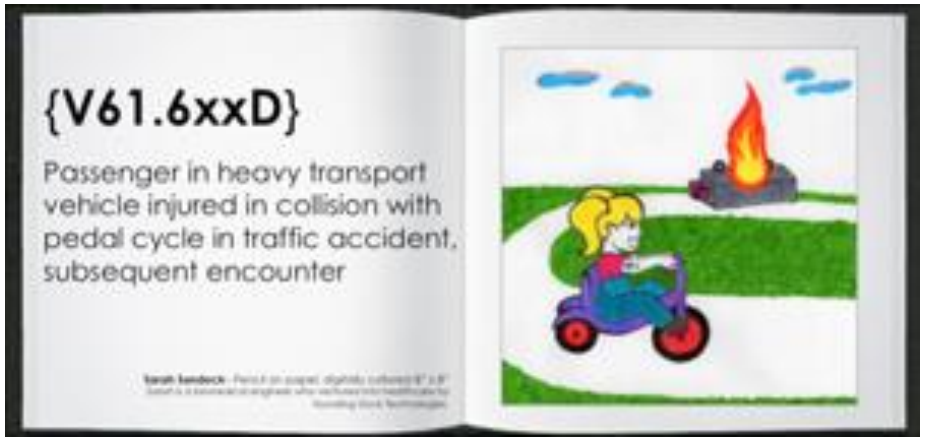

**Contact with crocodile or alligator** W58- >

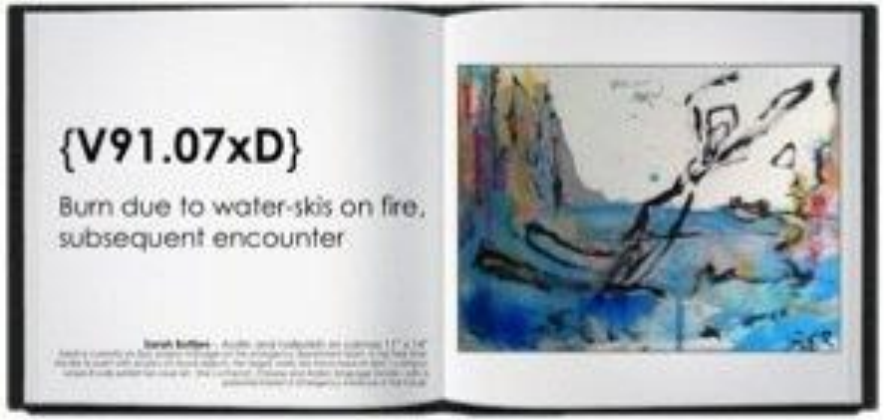
- W58 Contact with crocodile or alligator
  - W58.0 Contact with alligator
    - W58.01 Bitten by alligator
      - W58.01XA ..... initial encounter
      - W58.01XD ..... subsequent encounter
      - W58.01XS ..... sequela
    - W58.02 Struck by alligator
      - W58.02XA ..... initial encounter
      - W58.02XD ..... subsequent encounter
      - W58.02XS ..... sequela
    - W58.03 Crushed by alligator
      - W58.03XA ..... initial encounter
      - W58.03XD ..... subsequent encounter
      - W58.03XS ..... sequela
    - W58.09 Other contact with alligator
      - W58.09XA ..... initial encounter
      - W58.09XD ..... subsequent encounter
      - W58.09XS ..... sequela
  - W58.1 Contact with crocodile
    - W58.11 Bitten by crocodile
      - W58.11XA ..... initial encounter
      - W58.11XD ..... subsequent encounter
      - W58.11XS ..... sequela
    - W58.12 Struck by crocodile
      - W58.12XA ..... initial encounter

# ICD-10-CM Examples



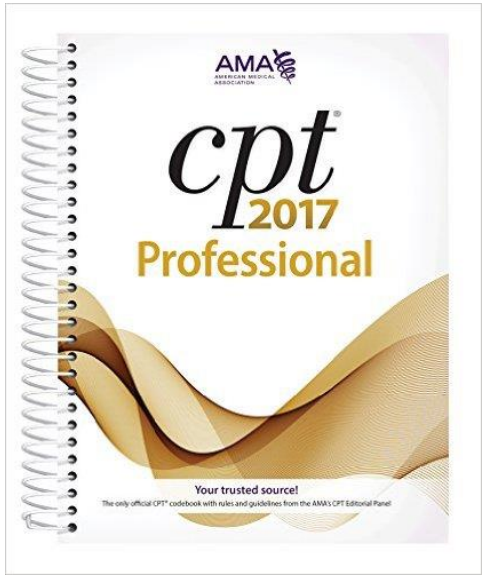




# CPT

- **C**urrent **P**rocedural **T**erminology
- Used to report medical services performed by physicians
- Important for billing and claims information
- Published by the American Medical Association
- First published in 1966 and is regularly updated
  - Obtaining or modifying a code may take a long time (use generic code until then)
- Pathology and laboratory codes fall into the range of 80000 to 89999
  - Hundreds of codes for clinical laboratory tests
  - Only a few dozen codes for surgical pathology → divided into levels based on amount of effort required (ex. Incidental appendix = level II (88302); colectomy for tumor = level VI (88309)



# LOINC

- **L**ogical **O**bservation **I**dentifiers and **C**odes (LOINC)
- Universal standard for representing lab tests and other clinical observations
- Developed by Regenstrief institute (Indiana University)
- First released in 1995
- Widely supported by most LIS vendors
- More than 70,000 codes

LOINC®
from Regenstrief

# LOINC

- For each lab test/observation, specify 6 major parts (axes)
  - Component or analyte name (e.g. glucose)
  - Property measured (e.g. concentration)
  - Timing of a measurement (e.g. point in time)
  - System or sample (e.g. serum/plasma)
  - Scale of measurement (e.g. quantitative)
  - Method used (optional) (e.g. glucometer)
- LOINC code for a specific lab test contains up to five numeric digits followed by a hyphen and a check number (ex. 50873-9)
  - Each unique combination of properties can potentially be assigned a LOINC code
  - If a different combination of properties is needed, user can request a new code to be created
- Complicated: More than 600 codes for glucose alone
  - Complex to use and sometimes difficult to choose correct code

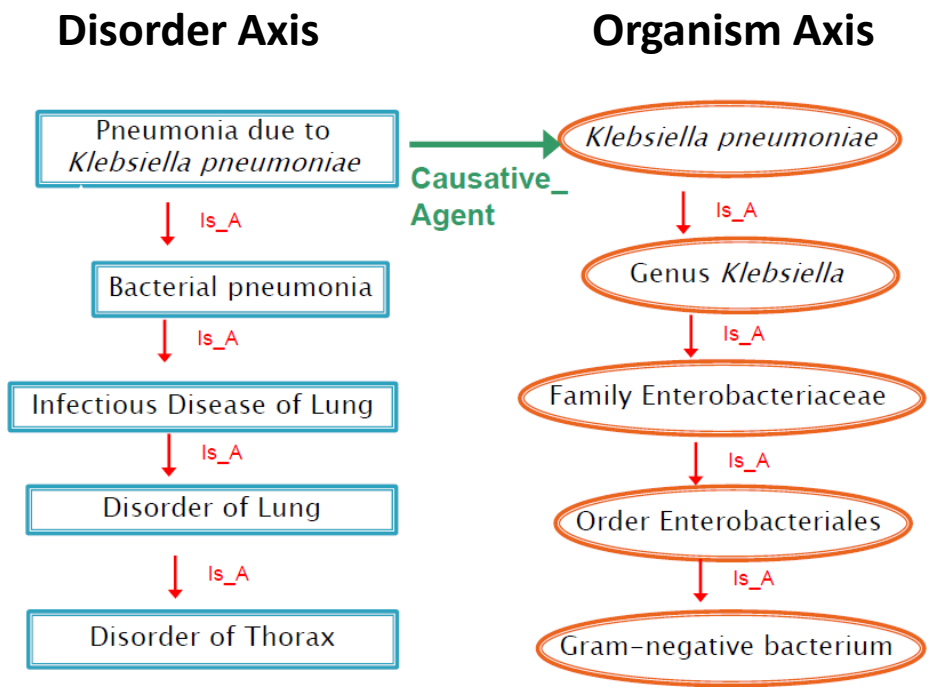
# SNOMED CT History

- **S**ystematized **N**omenclature of **M**edicine **C**linical **T**erms
- One of the most complete vocabularies for describing clinical observations and findings
- Based on SNOP (Systematized Nomenclature of Pathology) developed by CAP in the 1960s
  - In 2007 ownership passed onto IHTSDO (International Health Terminology Standards Development Organization)

IHTSDO delivering
SNOMED CT®
the global clinical terminology

# SNOMED CT

- Hierarchical organization
  - 12 main hierarchies (axes) (Ex. Specimen, body structure, disorder, organism, etc.)
- Detailed and extensive, containing
  - > 300,000 concepts (fundamental unit of meaning)
  - > 1 million English language descriptions (including synonyms)
  - > 1 million relationships between concepts
- Ontology
- Key features
  - Relationships between hierarchies allows for flexible coding
  - Terms can be combined to create more complicated concepts (e.g., lung + inflammation)  (pre/post coordination)
  - Some mapping exists to other coding systems



# Data Exchange Standards

# Data Exchange Standards

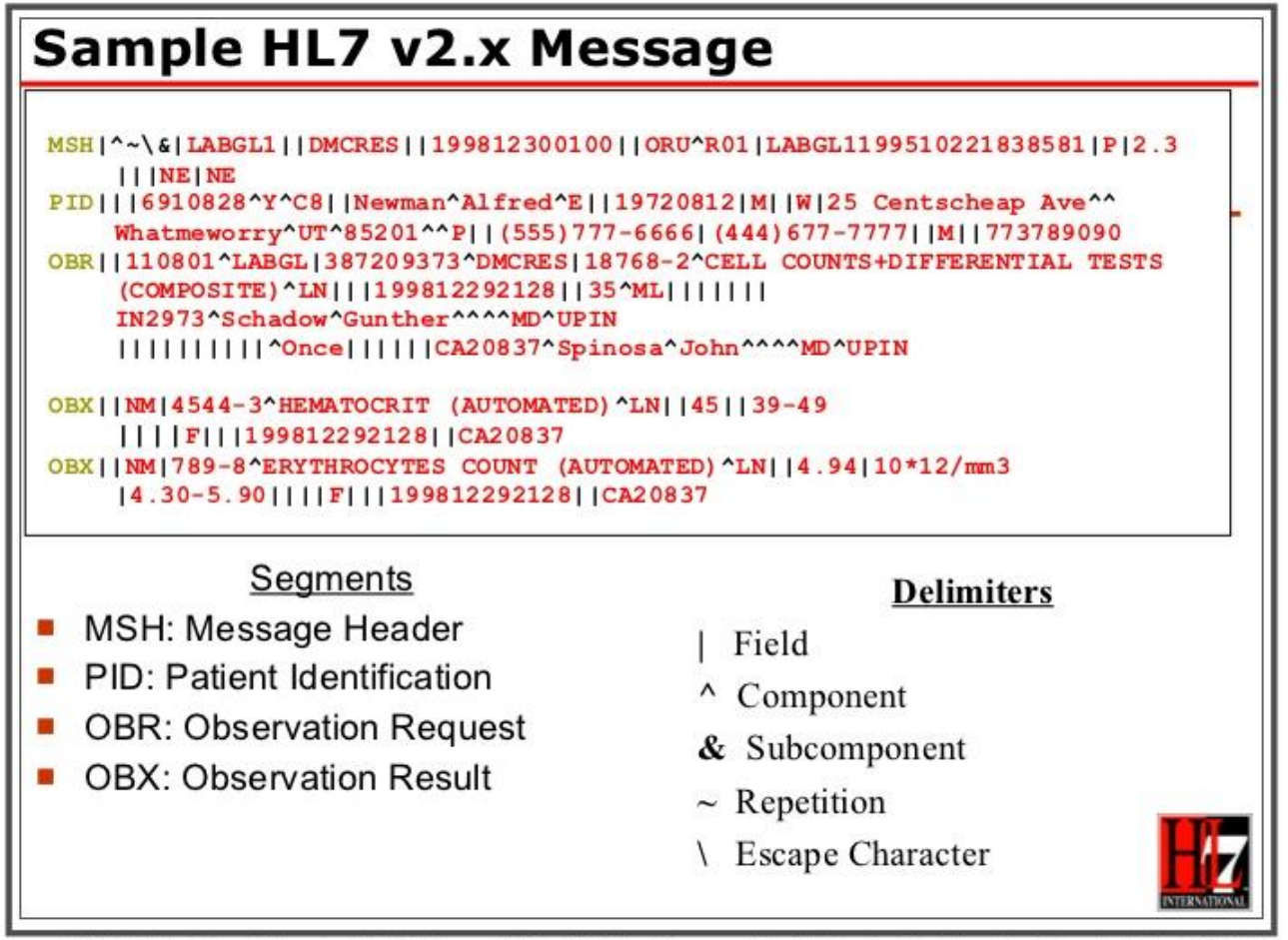
- **HL7** (Health Level 7)
- **CDA / CCD / CCR**
- **DICOM** (Digital Imaging and Communications)
- IEEE 1073 / ISO 11073
- SCRIPT
- ELINCS
- SMART (Substitutable Medical Apps, Reusable Technologies)

# Health Level 7 (HL7)

- Most important standard for the electronic exchange of data in healthcare environments
- Founded in 1987
- Standards are developed in a collaborative effort involving many volunteer groups
- Name is based on the OSI seven-layer model of network communications (seventh level = application level)
- Represents a “common syntax” which software from different vendors can use to communicate with each other
- Based on the theory that although each healthcare system stores data in different ways, the data elements stored and the concepts they represent are essentially the same
- Two substantially different versions (v2 and v3)

# HL7 version 2

- Current version (2.x)
- Supported by most vendors
- Defines the structure (syntax, format) of the message but NOT the specific content
- Sender and receiver must understand meaning of messages
- Message constructs are specific for a particular task
  - Contain those data elements specific for a certain type of data exchange
- Message consists of predefined sequence of mandatory and optional bar/character delimited segments and fields
- Segments defined by three-character identifier

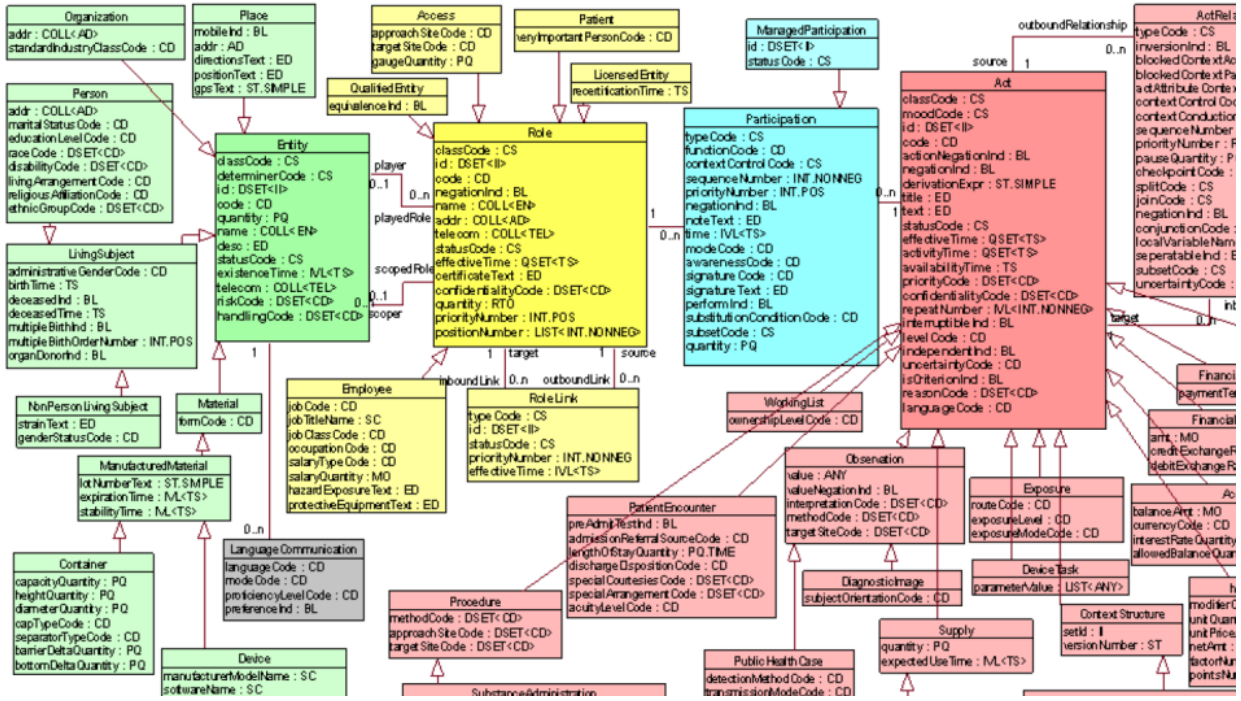


# HL7 version 2

- Helps but does not eliminate interfacing issues between different systems
  - Vendors develop HL7 interface specifications for their own systems → usually do not match those of other vendors
  - Institutions can also define custom, site-specific segments
  - Lab test name codes definitions differ between different systems → translation tables are necessary
  - Interfacing requires cooperation among vendors, lab, IT support

# HL7 version 3

- Attempts to introduce semantics or meaning beyond just syntax of version 2
- Based on a human readable Reference Information Model (RIM)
- Implemented in eXtensible Markup Language (XML)
- Not widely adopted as it is thought to be too complicated



# FHIR

- **F**ast **H**ealth **I**nteroperable **R**esources
- New and much hyped messaging standard that seems to be a big deal
- Fast to learn, develop and implement
- Messaging Standard developed in response to complexity of HL7 version 3 (compatible with other HL7 standards)
- Merges good components of HL7 v2 and v3 with a focus on implementation
- Almost all vendors have embraced and adopted (Epic, Cerner)
- Proliferating significantly even though it's still a draft standard
- First non-draft standard was released in March
- Potential to unify and integrate pieces of data from multiple systems

# FHIR


- Basic building block = (reusable) resource
  - Smallest unit of transaction (defined behavior, meaning, identity and location) (folders in a filing cabinet) (e.g., patient, medication, procedure, family history, etc.)
  - Common way to define and represent data elements
- Easier to implement than previous message standards because it uses modern web technologies
- Content is freely available with focus on common scenarios
- Supports specifications for privacy and security
- Supports development of mobile applications (makes it easier for third party developers to provide medical applications which can be easily integrated in existing systems)

# CDA / CCD / CCR

- CDA (Clinical Document Architecture)
  - Standard for specifying structure and semantics of clinical documents for exchange
  - Part of the HL7 version 3 suite
  - Semantic content is derived from RIM and is implemented in XML
  - Specifies that the content of the document consists of a mandatory textual part (human readable) and optional structured parts (for software processing) that rely on coding systems (SNOMED and LOINC) to represent concepts
  - Examples of document types include Discharge Summary, Imaging Report, History & Physical, and Pathology Report
- CCD (Clinical Continuity Document)
  - Specific use case of CDA to support continuity of patient care
  - Included in Stage 1 and 2 of meaningful use

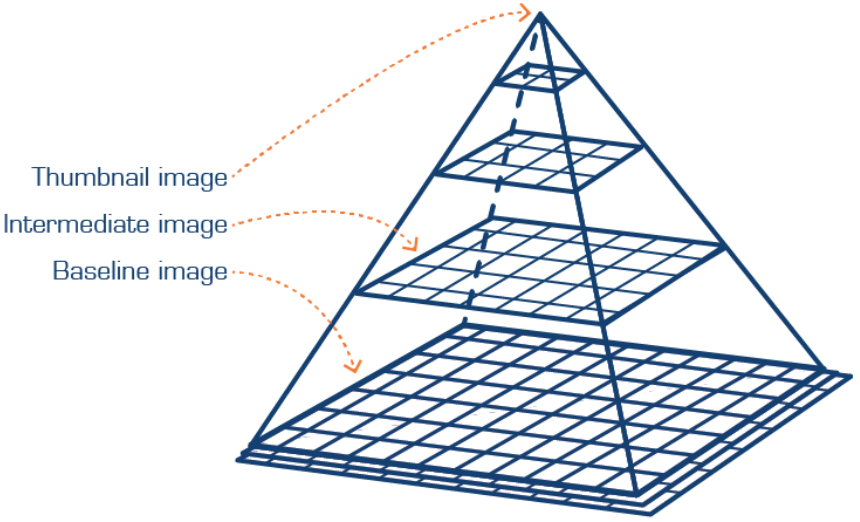
- CCR (Continuity of Care Record)
  - Patient health summary standard
  - Developed by health care practitioners to improve continuity of patient care
  - Implemented in XML
  - Report Consists of core elements contained in 6 sections
  - Can be converted into CCD (Note: Some CCD features are not supported in CCR (cannot convert CCD to CCR)

# DICOM

- **D**igital **I**maging and **CO**mmunications in **M**edicine
- International standard for handling, storing, printing, and transmitting medical images
- Allows integration of medical imaging devices from multiple vendors
- First published in 1993
- Maintained by NEMA (National Electrical Manufacturers Association)
- Widely adopted in radiology
- Includes a file format definition and a network communication protocol

# DICOM for Pathology

- **Workgroup-26**
  - Deals with pathology
  - Representatives from most major pathology imaging vendors, pathologists, consultants and researchers
- **Supplement 122**
  - Introduced mechanism for pathology specimen identification/description at the level of the image
  - Approved 2008
- **Supplement 145**
  - Specifies how to incorporate WSI images into DICOM
    - Large image sizes, need for rapid panning, focus, zoom in quickly to higher magnification, higher resolution
  - Solved by tiling and multiframe encoding (represented by image pyramid diagram)
  - Approved 2010



# Obstacles to DICOM Adoption in Pathology

- Storage costs (large file sizes)
- Network speeds
- Pathology LIS needs to become more image centric (ex. image level specimen information)
- Intellectual property/licensing issues around supplement 145 → seems to have been recently resolved with plans for a DICOM connectathon in the fall

# Future Trends in Medical Data Standards

- Expansion of standards outside typical hospital and primary care setting (research, healthcare devices, directly from patients)
- Growth in use of the HL7 FHIR standard
- Terminology standards will need to expand their content coverage (molecular)
- Expansion of real-time digital data transfer and analytics for care improvement

# Summary

- Data quality cannot be measured without defining a set of standards. The dimensions of data quality used in other industries can be applied to healthcare.
- In anatomic pathology, initially capturing data in a structured and standardized synoptic format is an effective method for improving data quality, but report formatting is also important as it relates to communication of data.
- Clinical data standards are important for ensuring consistent naming, facilitates secondary uses of data, improves interoperability of data.
- We reviewed examples of medical terminology standards (ICD, CPT, LOINC, SNOMED) and data exchange standards (HL7 v2 and v3, FHIR, CDA/CCD/CCR, DICOM) relevant to pathology.

# Thank you!