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3.4 Clinical Data Standards

CHAPTER OUTLINE

3.4.1 STANDARDS DEVELOPMENT HISTORY AND CURRENT PROCESS

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The history of standards development in healthcare is the history of consensus building through the use of the scientific method. It is the history of scientific invention, first-to-market, natural monopolies, snake oil salesmen, regulatory oversight, market consensus, and international treaties. And its modern history traces back over 400 years.

The longest running healthcare standard still currently in use is the International Classification of Diseases (ICD-10), which began in London by The Worshipful Company of Parish Clerks, who kept weekly mortality statistics from 1592 to 1595 and then continuously from 1603. These London Bills of Mortality were simple ledgers and tallies of all the ways people passed away… Plague, Spotted Fever, Consumption, Childbearing, and so forth.

As a city practice, London kept these ledgers out of public interest. But in so doing, the records allowed the different parishes to begin to standardize the language they used in describing disease. A person didn't simply die of fever. But they died of Yellow Fever or Scarlet Fever. And that *shared language* would eventually prove critical to the standardization of medical practice around the world.

Over the years, the London Bills of Mortality were extended by luminaries such as John Snow, William Farr, François Bossier de Lacroix (Sauvages), Carl Linnaeus, and William Cullen to include hierarchical classification, indexes, codesets and other *structured data* elements.

By the 1800s, the Scientific Revolution had spread to both the European Continent and to the Americas; and the field of medicine was being transformed from a practice of barber-surgeons, grocers, and apothecaries into the beginnings of the field of study we know today. Critical to this process was a rigorous survey of both the Body and Mind.

While Greek theories of the four humors continued to be widely taught through the 1700s, the work of William Harvey on the mechanisms of blood circulation began the systematic mapping of the Body, resulting in Henry Gray's seminal work

Anatomy of the Human Body. This work, in turn, laid the foundation for modern Pathology, as it provided a *reference model* for practitioners to use.

The College of American Pathologists would eventually take the ideas present in Gray's Anatomy, and develop the Systematized Nomenclature of Medicine, which includes anatomy, diseases, findings, procedures, microorganisms, and other substances. It includes structural representation of human and veterinary subjects, and provides a topographic axis to locate disease according to body organ.

Outside the field of medicine, the steam engine was transforming the world, and railroads tracks were being laid across nations. Rail gauge was a continual source of interoperability problems, preventing cars from one rail line from traveling on another, causing accidents, and costing the industry untold amounts of losses. The problems lasted for decades, eventually prompting Charles Dudley to form ASTM International, a standards group to test materials used in rails, and later influencing rail gauge agreements and the size of the standard boxcar and shipping container.

Also of note was the invention of electricity, which gave rise to the telegraph and standardized the way we communicate. The early Morse code alphabet eventually gave way over the years to the 5 bit Baudot code used in teleprinters (with support for lowercase characters!), the 6-bit TeleTypeSetter (TTS) code of early modems, the 7-bit ASCII code that has punctuation, and the 16 bit Unicode character sets with support for Cyrillic, Greek, Hebrew, and other alphabets.

Meanwhile, the clinicians working in sanitariums, asylums, and debtor's prisons were making their progress in surveying the Mind. Like the earlier parish clerks who kept records of weekly mortality statistics; the stewards of public incarceration systems began keeping statistics of the mental states of their wards. And like the efforts of the London Parish Clerks and the Surgeon Pathologists, they began creating a shared language for describing mental states.

Eventually, theorists such as Sigmund Freud, Carl Jung, and Magnus Hirschfeld began synthesizing their data into theories of cognition and thought. They also began developing judgements on what behavior is typical or normal, and what behavior is atypical. The American Psychiatric Association compiled these observations into the standard now known as The Diagnostic and Statistical Manual of Mental Disorders (DSM).

Ethical medical progress took a large step backwards during the World Wars, wherein the eugenics movement in Europe lead to widespread genocide and war crimes. The Nuremberg Code resulted, which was the first worldwide standard on how (not) to conduct medical research. Facing the fallout of the second world war—both literally and figuratively—the international community began devoting huge amounts of resources during post-war reconstruction to creating new processes for consensus building and governance.

Organizationally, these efforts resulted in the United Nations and International Organization for Standardization (ISO). And of particular note is the development of the international balloting process. Much attention was given to balloting and voting systems in the late 40s and 50s as part of academia's contribution to postwar reconstruction. Not only was there a need to incorporate countries into a new world order, but the consequences of mismanaged outcomes in light of nuclear warfare gave game theory an urgency it never had before.

Consequently, post-war reconstruction led to the modern standards balloting process that is still used today by the ISO, Institute of Electrical and Electronics Engineers (IEEE), ASTM, Health Level Seven (HL7), and other standards bodies.

As the world was settling into post-war reconstruction, a new era of commodity electronics began, which resulted in an explosion of development in audio/video devices. And while most people trace the history of the Digital Imaging and Communications in Medicine (DICOM) standard through the history of radiologic sciences; it was the work of the Institute of Electrical and Electronics Engineers that resulted in the laserdiscs and coaxial cables that eventually became the CD-ROM format and Ethernet cables that allow modern radiology equipment to be networked together; and it was the work of the Joint Photographic Experts Group which defined the digital formats that allowed images to be digitally stored and visualized on televisions, discs, and network cabling.

Meanwhile, the International Organization for Standardization (ISO) and the International Telegraph and Telephone Consultative Committee (CCITT) were both developing models for describing electronic switchboard and telecommunication routing infrastructure. In the late 70s they independently created network interconnection models; and in 1983 these documents were *merged* to form the standard called the Basic Reference Model for Open Systems Interconnection.

More commonly known as the ISO 7 Layer Network Model, the model includes the following layers: Physical, Data Link, Network, Transport, Session, Presentation, Application.

With the electronics and networking technology in place, the 1980s saw the first modern interoperability standard of electronic medical record systems. Begun as a project at the University of California at San Francisco Medical Center, the UCSF protocol eventually became the Health Level Seven (HL7) working group by 1987 and a full blown standards development organization by the early 90s.

Thirty years later, the HL7 organization is still going strong, developing modern interoperability standards such as the Continuity of Care Document (CCD) and the Fast Healthcare Interoperability Resources (FHIR) standard.

Once hospital systems began managing their clinical records and billing systems with computers, it was only a matter of time before people realized that everybody was duplicating effort and continuously reinventing the wheel. So organizations set about *harmonizing* these efforts, much like ASTM had done for the railroads. Like the railroads, standardization was a process that came about *after* the networking did.

Early efforts harmonizing clinical terms were conducted by the National Library of Medicine and the Regenstrief Institute in Indiana…. institutions whose missions are to catalog and improve the nation's health. While we tend to think of these institutions nowadays as being repositories and curators of genomics and pharmacogenomics research. However, prior to the personal computer revolution and the Human Genome Project, the challenging problems of the day were coordinating health measurements, observations, and documents commonly used in laboratories; and managing large inventories and catalogs of pharmaceuticals by hand.

So it was the early 1990s when the Regenstrief Institute published the Logical Observation Identifiers Names and Codes (LOINC) data dictionary. And a few years later, the National Library of Medicine used the Unified Medical Language System to publish the RxNorm dictionary, which incorporates data from First Databank, Gold Standard Drug Database, and Multum.

In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act kicked off health care reform in the U.S. Providing $25.9 billion to promote the adoption of health information technologies, it provided incentives for every hospital in the nation to adopt an electronic health record (EHR) system. However, while the Act encouraged hospitals to adopt EHR systems, in the interest of promoting free-market solutions, it didn't specify *which* EHR system. Accordingly, hospitals implemented many dozens of different solutions, setting the stage for a need for interoperability initiatives.

The first such initiative was the BlueButton initiative. The Veterans Administration had been an early adopter of EHR systems; and at the time of the HITECH Act was arguably the largest electronic health network in the country. The BlueButton initiative helped veterans download their health records from VistA (the EHR of the VA). However, while it provided data in an easy-to-read format that veterans could understand, it was difficult to import into other systems.

As the HITECH Act was being implemented, the Medicare EHR Incentive Program (administered by the Centers for Medicare & Medicaid Services) selected the HL7 Continuity of Care Document (CCD) as the extract format for clinical care summaries. Effectively, the HL7 group took the data that the Veterans Administration was exporting in the BlueButton initiative, and used it as a starting point for a more structured file format that could be both exported and imported between EHR systems.

The HL7 Group had its eyes on a larger initiative though…. adoption of modern web standards and web services as the default transport and exchange format for EHR systems. Using the moniker Fast Healthcare Interoperability Resources (FHIR), the HL7 Group began marshaling the resources and industry support for adopting standard protocols such as HTTP, REST, OAuth, and OpenId for their next generation interoperability standard. The FHIR standard is expected to go normative in 2018.

As of this writing, future directions and trends in interoperability appear to be heading towards distributed ledger systems and blockchains, as well as swarm file systems such as Interplanetary File System (IPFS). These technologies are trying to address the underlying interoperability problem of unsynchronized data by creating distributed networks where data cannot be accessed unless it is already synchronized and distributed across the entire network.

Concisely, we can describe the standardization process as involving the formation of consensus around shared language, structured data, and reference models. Formation of consensus can be difficult though; and often requires the identification of pain points that incentivize stakeholders to engage in the merging and harmonization of competing standards.

Once stakeholders are on board to sponsor a standard, a more structured balloting process can be initiated. Such a process involves creating working groups, creating drafts of the standard, balloting and voting, subsequent revisions, finalizing and distributing the standard, and then maintaining the standard. These activities can involve hundreds or thousands of participants and take years to accomplish. Yet, they reliably produce standards that have wide consensus, support, and adoption.

And this is exactly what is happening in healthcare with the adoption of electronic medical records. We are currently developing consensus around which shared languages, which vocabularies and ontologies to use, which exchange formats to support, and which reference models to adopt as standard. The HL7 group is leading the effort to ballot these things and create official standards. It’s an exciting time to be involved in healthcare IT!

3.4.2 DATA STANDARDS AND DATA SHARING

Data standards are the methods, protocols, terminologies and specifications for the collection, exchange, storage and retrieval of information associated with healthcare applications.[1] Standards exist for nearly every type of medical data, such as: electronic health records (EHRs); clinical decision support instructions; pharmacy data; laboratory orders and results; radiological images and interpretations; billing, coding and reimbursement data; quality metrics; administrative processes; scheduling; medical devices and remote monitoring systems; and many others.

There are several key components of data standards which enable sharing[2]

1. Data definition—what data are collected and exchanged
2. Data interchange formats—the methods for encoding data into binary format so that it may be transmitted among disparate systems.
3. Terminologies—the medical terms that are used to describe the data as well as the relationships among terms and concepts.
4. Knowledge representation—the way that medical evidence (i.e. literature, guidelines, etc) are structured for clinical decision support systems.

Data Elements and Data Types

Data elements are individual pieces of information related to healthcare, such as a glucose measurement, systolic blood pressure, date of birth, etc. **Data types** define the form that such information takes. Simple data types include date, time, strings, integers, real

1 Aspden P, et al. eds. Health Care Data Standards. In: Patient Safety: Achieving a New Standard for Care. Washington, DC: National Academies Press; 2004.

2 AHIMA Work Group. Data Standards, Data Quality, and Interoperability (2013 update). Journal of AHIMA 84(11):64-69 [expanded web version].

numbers, etc. In addition to the form, data types should indicate the units of measurement. For example, glucose is measured as milligrams per deciliter[3] (mg/dL) and so on. To achieve **interoperability**, message formats must also include encoding specifications which define the relationships between data elements, architectures, and clinical templates. For example, in a fully interoperable system, a glucose measurement of 126 mg/dL in taken at 11:15 PM in New York would be automatically translated to 7.0 mmol/L at 16:15 in London.

OID

The first step in translating concepts from one terminology to another is identifying the terminology itself. The Object ID repository was jointly developed by the International Telecommunications Union—Telecommunication standardization sector (ITU-T) and the International Organization for Standards (ISO) for naming of objects in a permanent and unambiguous way. Nearly any item can be listed, but for our purposes, the OID is used for referencing standards, terminologies, algorithms, templates, rules, protocols, file formats and the like. For example, Logical Observation Identifiers Names and Codes (LOINC) is given the code 2.16.840.1.113883.6.1. The OID dot notation is hierarchical and specifies that this particular object is an external code system defined by HL7 in the USA.[4]

3.4.3 TRANSACTION STANDARDS

There are several transaction standards which are prevalent in healthcare. From a technical standpoint, there is not much difference between transactions and messages. For our purposes, transactions typically involve systems external to our facility (e.g. a retail pharmacy or insurer) while messages refer to communications within our facility (order entry, lab results, etc.)

National Council for Prescription Drug Programs (NCPDP)

The National Council for Prescription Drug Programs (NCPDP) is an American National Standards Institute (ANSI) accredited Standards Development Organization (SDO) which is responsible for outpatient pharmacy communications (inpatient pharmacy orders generally use HL7 V2—See Sect. 3.4.4). Some of the many standards the NCPDP has developed relate to: Benefit Integration; Billing Units; Formulary and Benefit; Manufacturer Rebates; Medicaid Subrogation; Medical Rebates Data Submission; Pharmacy ID Cards; Prescription File Transfer; Product Identifiers; Prior Authorization Transfer; and Universal Claim Forms.[5]

There are two important versions of NCPDP Script. Version 8.1 was required for HIPAA compliance, and version 10.6 is required for Meaningful Use. Figure 9-1 shows an example SCRIPT transaction.

```
UNA:+./*'
UIB+UNOA:0++1234567+++77777777:C:PASSWORDA+7701630:P+19971001:081322'
UIH+SCRIPT:008:001:NEWRX+110072+++19971001:081322'
PVD+P1+7701630:D3+++++MAIN STREET PHARMACY++6152205656:TE'
PVD+PC+6666666:0B+++JONES:MARK++++6152219800:TE'
PTT++19541225+SMITH:MARY+F+333445555:SY'
DRU+P:CALAN SR 240MG::::240:ME+EA:60:38+:1 TID+85:19971001:102*ZDS:30:804+0+R:1'
UIT+110072+6'
UIZ++1'
```

FIGURE 9-1

SCRIPT message in United Nations/Electronic Data Interchange for Administration, Commerce and Transport (UN/EDIFACT) format. This format is very similar to the HL7 V2 format discussed in Sect. 3.4.4. Some interesting things to note about this message: The first line starts with the characters UNA and specifies the delimiters that will be used for the rest of the message: component data element separator (: in this sample); data element separator (+ in this sample); decimal mark (. in this sample); escape character (/ in this sample); the asterisk is not used; segment terminator ('in this sample). In the UIH segment, we see that this is a SCRIPT message and it is creating a new prescription (NEWRX). Emphasis mine.

3 At least in the United States.
4 For much more information on OID's see http://oid-info.com/
5 For much more information, see https://www.ncpdp.org/Standards/Standards-Info

FIGURE 9-2

Example of an X12N 276 message—a request for claim status. Segments begin with 2–3 letter descriptors and end with an exclamation point. Line breaks are added for readability, but would not exist in an actual message. ST and SE signify the begin and end of a transaction, respectively. The reference number 0046 is repeated on the first and last line to indicate a closed loop. Modern X12 messages can also be transmitted in eXtensible Markup Language (XML) format, which uses open and close elements for the same purpose. (i.e. <transaction> </transaction>)

```
ST*276*0046!
BHT*0010*13**20030109!
HL*1**20*1!
NM1*PR*2*PAYER NAME*****21*9012345918341!
PER*IC*PROVIDER CONTACT INFO*TE*6145551212!
HL*2*1*21*1!
NM1*41*2******46*111222333!
HL*3*2*19*1!
NM1*1P*2*PROVIDER NAME*****FI*FEDERAL TAX ID!
NM1*1P*2*PROVIDER NAME*****XX*NPI NUMBER!
NM1*1P*2*PROVIDER NAME*****SV*PROVIDER NUMBER!
HL*4*3*22*0!
DMG*D8*19191029*M!
NM1*QC*1*DOE*JOHN****MI*R11056841!
TRN*1*500!
REF*1K*940922!
REF*BLT*131!
AMT*T3*28.00!
DTP*232*RD8*20020501-20020501!
SE*18*0046!
```

ASC X12

The Accredited Standards Committee X12[6] (also known as ASC X12) is an SDO chartered by ANSI. It produces the X12 Electronic data interchange (EDI) standards that facilitate electronic interchange of all sorts of business transactions, such as order placement and processing, shipping and receiving information, invoicing, payment and cash application data.

The X12N subcommittee is responsible for developing standards related to insurance. Of those, the following transaction types are of interest to healthcare:

- 837: Medical claims with subtypes for Professional, Institutional, and Dental varieties.
- 820: Payroll Deducted and Other Group Premium Payment for Insurance Products
- 834: Benefits enrollment and maintenance
- 835: Electronic remittances
- 270/271: Eligibility inquiry and response
- 276/277: Claim status inquiry and response
- 278: Health Services Review request and reply

Figure 9-2 shows an example of an X12 transaction.

3.4.4 MESSAGING STANDARDS

Health Level Seven International (HL7)

Health Level Seven International is a standards developing organization (SDO) which is accredited by the American National Standards Institute (ANSI) and International Organization for Standards (ISO) which creates and maintains interchange formats for healthcare information. Its eponymous protocol, HL7 version 2 (V2) is the primary clinical messaging standard in the US, and is used in over 90% of hospitals. When people say "HL7 message", they generally mean V2. There are four basic types of HL7 Messages:

1. ADT: Admit, Discharge, Transfer—for tracking when patients enter, leave or move within a facility
2. ORM: ORder Management—placing or cancelling orders

6 Incidentally, the 12 in X12 doesn't mean anything. It was assigned sequentially by ANSI when ASC was accredited.

```
MSH|^~\&|CE|001|RD|001|201704080113||ORM^O01|212358388404784272|P|2.2|||AL|AL
PID|||000587355||DOE^John^A||19491104|M||B|300 CENTRAL AVE^FL 2^EAST ORANGE^NJ^07018||(973)266-
3307|(973)266-3307|EN|S|CA|3251075|580485125||||VI
PV1||I|5I^523^1^EOGH||||7111^WELBY^MARCUS^W|7111^WELBY^MARCUS||MED||||||7111^WELBY^MARCUS^W|||
|||||||||||||||||||||201703272145
ORC|NW|39084339||9483357^ICC-
EO|NW||001^^^201704080113^^S||201704080113|E300454^NIGHTENGALE^FLORENCE^^RN||7111^WELBY^MARCUS^
W~7111^WELBY^MARCUS^W|5I||201704080113||||^NIGHTENGALE^FLORENCE^^RN||||||||||^^^^^^^^V
OBR||39084339||4367104^CHEST X-RAY--PORTABLE ONCE
S^^^^PHDICT|||||||||||7111^WELBY^MARCUS^W|||||||CR|||1^^^201704080113^^S||||chest tubes
placement.|||||201704080113|||||||^^^^CHEST X-RAY--PORTABLE^ILW-
XSERVC||PERFORM_IMMEDIATE_FLG^Y^LEOEXT~GE_FIRST_SERVICE_DTTM^2017-04-
08:01:13:00^LEOEXT~REASON_FOR_EXAM^chest tubes placement.^LEOEXT
NTE||P
```

FIGURE 9-3

Example of an HL7 V2 message sent when Dr. Welby ordered a portable chest x-ray for his patient John Doe. Emphasis mine. See text for explanation

3. ORU: Observation Result—lab results, radiology results, vital signs
4. DFT: Detail Financial Transaction—financial transactions that are sent to a billing system

The V2 standard was the first commonly used messaging standard and has been embraced and extended by many developers. As a result, the standard often differs somewhat between implementations and offers limited interoperability. V2 messages are separated by vertical bars and carets (i.e. |'s and ^'s), commonly called pipes and hats.[7] Figure 9-3 is a message which was sent when a doctor ordered a portable chest x-ray after placing a chest tube.

The message is composed of several **segments**. In this message, the segments are MSH (Message Header), PID (Patient IDentification), PV1 (Patient Visit), ORC (ORder Common), OBR (OBservation Request) and NTE (Note). Each segment has a number of **fields** (also called **composites**) which are separated by vertical bars. The order of these fields is determined by specification (although implementations vary somewhat). Consider the PID segment:

```
PID|||000587355||DOE^John^A||19491104|M||B|300 CENTRAL AVE^FL 2^EAST ORANGE^
NJ^07018||(973)266-3307|(973)266-3307|EN|S|CA|3251075|580485125||||VI
```

To parse this, we have to review the HL7 specification. Table 9-1 shows the first few fields for the PID segment.

Each of the field data types is also explicitly defined, and can be further separated into **components** by the caret delimiter. For example, Extended Patient Name (XPN) in field 5 has 14 components. The first few are shown in Table 9-2.

DICOM

Digital Imaging and Communications in Medicine (DICOM) is an ANSI accredited SDO which is responsible for handling, storing, printing, and transmitting medical images. DICOM is actually a collection of standards which has evolved over many years, and includes file formats, network communications protocols and even definitions of grayscale necessary for printing and screen display.

7 Actually, the first five characters following the letters MSH in the beginning of the message will serve as delimiters for the remainder of the message. They are: Field Separator (normally |); Component Separator (normally ^); Subcomponent Separator (normally &); Field Repeat Separator (normally ~); Escape Character (normally \).

TABLE 9-1

EXAMPLE OF HL7 PID SEGMENT DEFINITION

SEQ	CONTENTS	DATA TYPE	REQUIRED	LENGTH
1	Set ID	SI	O	4
2	Patient ID	CX	B	20
3	Patient identifier list	CX	R	250
4	Alternate patient ID	CX	B	20
5	Patient name	XPN	R	250
6	Mother's maiden name	XPN	O	250
7	Date/time of birth	TS	O	26
8	Administrative sex	IS	R	1

Explanation of data types: *SI* Set Identifier, *CX* Extended composite ID, *XPN* Extended Person Name, *TS* Time Stamp. *IS* coded value from a table. For field #8, this is a one-character code for sex: *M* Male, *F* Female, *O* other, *U* Unknown. The *required* column has three choices: *O* Optional, *R* Required, *B* only present for backwards compatibility. In our example, we can see that fields 1, 2, 4 and 6 are blank, which is consistent with the specification. Field 3 tells us that the patient identifier is 000587355. From field 5, we learn that his name is John A. Doe (more on this below). Field 7 gives his date of birth as November 4, 1949. Field 8 tells us he is male. Thus, although some of the HL7 message can be interpreted from context, its full explanation requires reviewing the implementation standard

TABLE 9-2

EXAMPLE OF HL7 XPN COMPOSITE FIELD DEFINITION

SEQ	CONTENTS	DATA TYPE	REQUIRED	LENGTH
1	Family name	FN	O	194
2	Given name	ST	O	30
3	Second and further given names or initials thereof	ST	O	30
4	Suffix (e.g., Jr. or III)	ST	O	20
5	Prefix (e.g., Dr)	ST	O	20
6	Degree (e.g., MD)	IS	B	6

Explanation of Data Types: *FN* Family Name, *ST* String data, *IS and ID* coded values from a table, *TS* Time Stamp. Continuing our example, we see that field 5 of PID is DOE^John^A. According to the message header (MSH), components are separated by the caret character. The first component is Family Name (DOE); the second component is Given Name (John); and so on

A DICOM message is a stream of **elements** which are composed of an **element tag**, optional **value representation**, **value length** and **value**.

1. Data Element Tag: a 4-byte number identifying the type of data. In the past, this was separated into separate group and element codes, but today that distinction is only historical. The tag is usually expressed in hexadecimal notation. For example, (0010,0010) corresponds to Patient Name. The canonical list of data types can be found in the data dictionary.
2. Value Representation (VR): an optional 2-character string identifying the format of the data. (e.g. PN is Person Name, DA is date, and so on)
3. Value Length (VL): the length of the value in bytes
4. Value Field: the actual data. Some fields are unrestricted, and contain nearly anything, while others are constrained to a restricted vocabulary. For example, patient sex is constrained to be one of Male, Female or Other.

DICOM files are stored as binary streams, without any human-readable punctuation, although some implementations use XML internally to make it more editable. Figure 9-4 is an example of the first few bytes of a DICOM file for a chest X-Ray.

Element	Binary	Meaning
1	08 00 00 00	Data Element: (0008,0000) - Group Length
	04 00 00 00	Value Length: 4 bytes
	1E 01 00 00	Value: 286
2	08 00 08 00	Data Element: (0008,0008) - Image Type
	10 00 00 00	Value Length: 16 bytes
	4F 52 49 47 49 4E 41 4C 20 50 52 49 4D 41 52 59	Value: ORIGINAL PRIMARY
3	08 00 12 00	Data Element: (0008,0012) - Creation Date
	0A 00 00 00	Value Length: 10 bytes
	31 39 39 35 2E 30 37 2E 32 30	Value: 1995.07.20
4	08 00 13 00	Data Element: (0008,0013) - Creation Time
	08 00 00 00	Value Length: 8 bytes
	31 31 3A 32 32 3A 30 37	Value: 11:22:07

FIGURE 9-4

DICOM image format with explanations. DICOM files are machine readable, but not human readable. This fragment of a chest x-ray shows that the file was created on July 20, 1995 at 11:22:07 and has a total of 286 elements. Only the first four are shown here

3.4.5 NOMENCLATURES, VOCABULARIES, AND TERMINOLOGIES

Terminologies

A **terminology** is a controlled, limited **vocabulary** used to express all the **terms** or **concepts** in a domain. For example, in HL7 V2, the gender of a person is limited to one of Male, Female, Unknown or Other. According to the designers of V2, all persons may be assigned to one of these values, and there is no person that can claim to be more than one of these. This type of vocabulary is often encountered in surveys where the subject is allowed to select an item from a menu of choices.

A **code** is a short, usually alphanumerical representation applied to a term so that it can be more easily processed (e.g. M for male). In a **nomenclature**, concepts can be combined according to specific rules to form more complex concepts, such as in the Systematized *Nomenclature* of Medicine (SNOMED, which is an ontology—see Sect. 3.4.6).[8] A **thesaurus** is a network of terms that relate to each other in more or less complex ways.

ICD-10

ICD-10 is the tenth revision of the International Statistical Classification of Diseases and Related Health Problems, a vocabulary created by the World Health Organization (WHO). It contains codes for diseases, symptoms, physical findings, external causes of injury and social problems.

In 2016, ICD-10 Clinical Modification (ICD-10-CM) replaced the 9th revision as the standard method for encoding diagnoses in the US. Some of the differences between ICD-9 and ICD-10 are shown in Table 9-3.

8 de Lusignan S. Codes, classifications, terminologies and nomenclatures: definition, development and application in practice. Inform Prim Care. 2005;13(1):65–70.

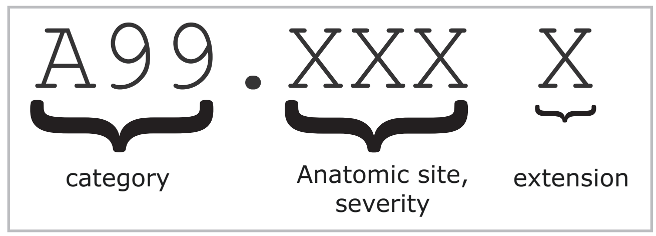
TABLE 9-3

DIFFERENCES BETWEEN THE NINTH AND TENTH REVISIONS OF THE INTERNATIONAL CLASSIFICATION OF DISEASES

	ICD-9	ICD-10
Number of codes	13,000	68,000
Length of code (chars)	3–5	5–7
Specificity	Somewhat detailed	Very detailed
Laterality (i.e. right or left)	Not specified	Specified
Visit type (i.e. initial, repeat)	Not specified	Specified
Max codes reported	4	12

FIGURE 9-5

Anatomy of an ICD-10 code. Key: A, letter; 9, number; X, alphanumeric character



ICD-10 is arranged in a hierarchical format by organ system and etiology. There is no multi-hierarchy, meaning that a code can only exist in only one branch of the hierarchy. In general, the longer the code, the more specific is the meaning. Payors often demand the most specific code possible for billing purposes. The code is 5–7 characters in length. The first character, a letter, specifies the major class (usually organ system involved). The next two characters, which are numbers, complete the category. A decimal point separates the next few characters which, if present, provide additional information. Figure 9-5 shows the anatomy of an ICD-10 code, and the list of major categories is shown in Tables 9-4 and 9-5.

Some examples:

C50.212, Malignant neoplasm of upper-inner quadrant of left female breast.
I80.01, Phlebitis and thrombophlebitis of superficial vessels of right lower extremity.

One of the key features of ICD-10 codes is that they provide justification for hospitalization, procedures and other services. For example, a patient with diagnosis code H66.001 (Acute suppurative otitis media without spontaneous rupture of eardrum, right ear) may justify the performance of Myringotomy with insertion of ventilating tubes (Current Procedures and Terminology code 69436). Without this diagnosis (or another qualifying diagnosis), an insurer may question the necessity of the procedure and may refuse to pay.

Diagnosis Related Group

Originally developed at Yale in the 1970s, this list of 745 principal diagnoses are meant to describe hospital inpatient episodes of care, in terms of the amount of resources required and the intensity of services provided. They are used by the Center for Medicare and Medicaid Services (CMS) to determine reimbursement under the inpatient prospective payment system (IPPS). Computer programs called **groupers** are used to classify discharges into one of the DRG codes. The current set of DRGs is known as the Medicare Severity Diagnosis Related Groups (MS-DRGs). DRGs are grouped into 25 body systems, known as Major Diagnostic Categories (MDCs). Severity of diagnosis is specified as having Major Comorbid Conditions (MCC) or Comorbid Conditions (CC) or without comorbid conditions. Since patients with comorbidities require more resources, they typically stay in the hospital longer (greater length of stay, LOS). As a result, the reimbursement weights are higher. In general, the LOS is reported as a geometric mean instead of an arithmetic mean because the geometric mean better accounts for outliers.

TABLE 9-4

MAJOR CATEGORIES FOR ICD-10 CODES

A00-B99	Certain infectious and parasitic diseases
C00-D49	Neoplasms
D50-D89	Diseases of the blood and blood-forming organs
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 and chromosomal abnormalities
R00-R99	Symptoms, signs and abnormal clinical and laboratory findings
S00-T88	Injury, poisoning and other consequences of external causes
V00-Y99	External causes of morbidity
Z00-Z99	Factors influencing health status and contact with health services

Don't memorize these

TABLE 9-5

EXAMPLE ICD-10 CODES SHOWING INCREASING SPECIFICITY

CODE	EXPLANATION
H66	Suppurative and unspecified otitis media
H66.0	Acute suppurative otitis media
H66.00	Acute suppurative otitis media without spontaneous rupture of eardrum
H66.001	Acute suppurative otitis media without spontaneous rupture of eardrum, right ear

The letter H specifies diseases of the eye, ear and mastoid process. H65-H75 are disease of the middle ear and mastoid process

There are four guiding principles for creation of DRGs[9]

1. The data used to calculate the DRG should be routinely available
2. The overall number of DRGs is relatively small
3. Each DRG contains patients with similar resource requirements
4. Patients within a DRG should be clinically similar

9 These are the academic reasons for creation of DRGs. The practical reason was actually financial. Prior to the introduction of DRGs, hospitals were paid on a per diem basis for inpatient care, which created an incentive for long hospital stays and increasing the intensity of inpatient services. When payors shifted to the prospective payment model with DRGs, they were paid a flat rate based on the DRG code, which is why hospitals are now incentivized to discharge patients as soon as possible.

TABLE 9-6

EXAMPLES OF SEVERAL MEDICARE SEVERITY DIAGNOSIS RELATED GROUPS (MS-DRG)

MS-DRG	MDC	TYPE	TITLE	WEIGHT	GMLOS	AMLOS
280	05	MED	Acute myocardial infarction, discharged alive w/MCC	1.7289	4.7	6.0
281	05	MED	Acute myocardial infarction, discharged alive w/CC	1.0247	3.0	3.7
282	05	MED	Acute myocardial infarction, discharged alive w/o CC/MCC	0.7562	2.0	2.4

Abbreviations: *MDC* Major Diagnostic Category, *GMLOS* Geometric Mean Length Of Stay, *AMLOS* Arithmetic Mean Length Of Stay, *MCC* Major Comorbid Condition, *CC* Comorbid condition. Major Diagnostic Category 05 refers to diseases of the circulatory system

TABLE 9-7

SELECTED EMERGENCY DEPARTMENT PROCEDURES WITH CURRENT PROCEDURAL TERMINOLOGY CODES AND RELATIVE VALUE UNIT WEIGHTS

SERVICE	CPT CODE	RVU
EKG rhythm interpretation	93042	0.22
Application of finger splint	29130	0.83
Single laceration up to 2.5 cm (scalp, neck, axillae, external genitalia, trunk-including hands and feet)	12001	1.27
Level III ED exam	99283	1.75
Single laceration repair 2.6–7.5 cm (scalp, neck, axillae, external genitalia, trunk-including hands and feet)	12002	2.08
Endotracheal intubation	31500	3.24
Critical care (30–74 min)	99291	6.31
Treatment of shoulder dislocation	23650	8.18

Examples[10] (Table 9-6):

Current Procedural Technology®

Current Procedural Technology® (CPT) is a set of codes maintained by the American Medical Association (AMA) for the purposes of describing procedures and services for billing and analytic use. Although the AMA maintains an exclusive copyright, these codes are used by nearly every insurer, including the Centers for Medicare and Medicaid services (CMS), which means that most users of these codes must pay yearly licensing fees to the AMA.

Each code has an associated Relative Value Unit (RVU) weight associated with it which roughly correlates to the degree of skill, risk and/or time required for the procedure. The total RVU for a procedure can be broken down into separate measurements for the work, the practice expense and the professional liability insurance cost (PLI). Table 9-7 shows some common Emergency Department procedures with RVU. Some codes are **bundled** and can not be billed together. For example, when a physician bills for critical care (99291), he can not separately bill for a regular ED exam (99283) because it is assumed that a regular exam is part of critical care services.[11] There are many complex rules about what codes can be included on the same bill. These rules vary from payor to payor.

10 CMS. Table 5.—List of medicare severity diagnosis-related groups (MS-DRGs), relative weighting factors, and geometric and arithmetic mean length of stay—FY 2015 final rule, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2015-FR-Table-5.zip accessed 4/20/17.

11 Critical care subsumes many other ED activities. The following is a list of items that can not be billed separately when critical care is included: Interpretation of cardiac output measurements (93561, 93562). Pulse oximetry (94760, 94761, 94762); Chest X-ray interpretation (71010, 71015, 71020); Blood gases (99090); Gastric intubation (43752, 91105); Transcutaneous pacing (92953); Ventilator management (94002-94004, 94660, 94662); Vascular access procedures (36000, 36410, 36415, 36591, 36600).

RVUs are used by insurers to determine reimbursement. They are also used to compute the relative contribution of physicians to a group practice, and are frequently used as the basis for determining raises, bonuses and other accolades.

Other Terminologies

There are many other noteworthy terminologies and many being created each day. The following terminologies are somewhat less common.

Universal Medical Device Nomenclature System

The Universal Medical Device Nomenclature System (UMDNS) is a hierarchical terminology for medical devices including both device types and specific make/model records.

Examples

CODE	SHORT NAME	DESCRIPTION
16652	Defibrillators, implantable	Defibrillators that are permanently inserted (implanted) abdominally, pectorally, or subcutaneously. Pectoral and abdominally implanted defibrillators are connected to the patient's heart through a set of epicardial or transvenous leads. These defibrillators consist of a hermetically sealed container, including a lightweight battery, electronic circuitry to sense cardiac activity and produce the electrical pulses (shocks), and electrode leads that conduct the myocardial signals to the defibrillator and the electrical defibrillating pulses to the patient, when needed. Implantable defibrillators are used to sense ventricular fibrillation and initiate defibrillation by applying an electric shock to the heart to depolarize the myocardium. Some of these stimulators have memory modules for storage and retrieval of the cardiac electrical activity, and some have programmable capabilities. Subcutaneous implanted defibrillators that are connected to leads and electrodes anchored under the skin above but not touching the heart are also available. Implantable defibrillators are used as life saving devices mainly for tachycardia, ventricular fibrillation, and cardiac arrest
17428	Dressings, nonimpregnated, synthetic, film	Synthetic dressings made of synthetic polymers (typically polyurethane). These dressings are usually transparent films coated with an adhesive that is permeable to water vapor and oxygen but impermeable to liquids and bacteria. Synthetic film dressings do not absorb usually wound exudates; they are used mainly in wound management

National Drug Code

The National Drug Code (NDC) is a unique identifier for the approximately 10,000 labelled drugs approved by the Food and Drug Administration. Barcodes that appear on drug vials are typically the NDC. The NDC is a 10-digit number broken into three segments. The first four digits identify the labeler (manufacturer, packager or distributor). The next four digits are the product code which specify the strength, formulation and dosage form. The last two digits are the package code which describes the size and contents of the package. The first four digits (labeler code) are assigned by the FDA, while the product and package codes are assigned by the labeler.

Example

CODE	MEANING
0777-3105-02	0777 is the labeler code for Dista Pharmaceuticals 3105 is the product code for Prozac (fluoxetine) 20 mg tablet 02 specifies a bottle of 100 pills

Health Care Financing Administration Common Procedure Coding System

The Health Care Financing Administration Common Procedure Coding System (HCPCS) provides codes for products and services not mentioned in CPT.

Examples

CODE	MEANING
PL001007	Progressive addition lenses
Q6001007	Service furnished by a locum tenens physician
UE001007	Used durable medical equipment
A0998001003	Ambulance response and treatment, no transport
A4267001003	Contraceptive supply, condom, male, each

3.4.6 ONTOLOGIES AND TAXONOMIES

A **classification** is an arrangement of concepts into groups according to established criteria, such as the International *Classification* of Disease. The term **taxonomy** is also used this way to mean a rigidly hierarchical structure where each child concept inherits characteristics from a parent concept. For example, tuberculosis is a kind of pneumonia which is a kind of infectious disease. An **ontology** is an extension of a taxonomy where concepts can be related in multiple different ways in addition to simple parent-child relationships.[12] For example, a taxonomy may assert that tuberculosis (is a kind of) pneumonia. An ontology defines its concepts by relationships to other concepts, and would add that tuberculosis (is caused by) *Mycobacterium tuberculosis;* tuberculosis (has symptom) cough; tuberculosis (has symptom) hemoptysis, etc. One way to think of the difference between a taxonomy and an ontology is that a taxonomy is a family tree, while an ontology is Facebook.[13]

Ideal ontologies have several characteristics[14]

1. Concept orientation—elements of the terminology are coded concepts with hierarchical relationships to other coded concepts. Redundant, ambiguous and vague concepts are excluded
2. Concept permanence—coded concepts remain in the dictionary forever. Codes are never deleted or reused
3. Nonambiguity—coded concepts have only one meaning.
4. Explicit versioning—each version of the dictionary is given a version number
5. Meaningless identifiers—the codes themselves are unrelated to the hierarchy or relationship among concepts. (i.e. codes themselves are non-semantic)
6. Multihierarchy (or polyhierarchy)—concepts may be reached through multiple different paths. (e.g. viral meningitis could be found under the classification of infectious disease or neurological disease or related to the presenting symptom of headache)
7. Formal definitions—concepts are defined in a formal way so as to make detection of duplicates easier
8. Multiple granularities—concepts have varying degrees of specificity for different users. (e.g. a family practitioner may be satisfied with code for "coronary artery disease" while a cardiologist may benefit from a more specific code, such as "history of acute anterolateral myocardial infarction with posterior extension")
9. No residual categories—concepts are defined with as much specificity as possible, so that containers such as "not otherwise specified" are not needed.
10. Nonredundancy—coded concepts must be unique so that even if multiple terms refer to the same entity, only one code is found in the dictionary. Alternatively, when redundant codes do exist, they are easily recognized as aliases or synonyms.

12 A nice review of some common ontologies can be found in Cimino JJ, Zhu X. The practical impact of ontologies on biomedical informatics. Yearb Med Inform. 2006:124–35.

13 Academically speaking, taxonomy and ontogeny are different terms. Practically speaking, the distinction is blurred in modern literature.

14 One of the seminal papers in this area is Cimino JJ. Desiderata for Controlled Medical Vocabularies in the Twenty-First Century. Methods Inf Med. 1998 Nov; 37(4–5): 394–403.

TABLE 9-8

TERM TYPES FOR RXNORM, PUBLIC DOMAIN BY NATIONAL LIBRARY OF MEDICINE

TTY	NAME	DESCRIPTION	EXAMPLE
IN	Ingredient	A compound or moiety that gives the drug its distinctive clinical properties. Ingredients generally use the United States Adopted Name (USAN)	Fluoxetine
PIN	Precise ingredient	A specified form of the ingredient that may or may not be clinically active. Most precise ingredients are salt or isomer forms	Fluoxetine hydrochloride
DF	Dose form	How the drug is used	Oral solution
SCDC	Semantic clinical drug component	Ingredient + strength	Fluoxetine 4 MG/ML
SCDF	Semantic clinical drug form	Ingredient + dose form	Fluoxetine oral solution
SCD	Semantic clinical drug	Ingredient + strength + dose form	Fluoxetine 4 MG/ML oral solution
BN	Brand name	A proprietary name for a family of products containing a specific active ingredient	Prozac
SBDC	Semantic branded drug component	Ingredient + strength + brand name	Fluoxetine 4 MG/ML [Prozac]
SBDF	Semantic branded drug form	Ingredient + dose form + brand name	Fluoxetine oral solution [Prozac]
SBD	Semantic branded drug	Ingredient + strength + dose form + brand name	Fluoxetine 4 MG/ML oral solution [Prozac]

RxNorm[15]

RxNorm is a project of the National Library of medicine to normalize the format of clinical drugs. It is based on what type of drugs a clinician might order and what form those drugs take when administered to a patient (as opposed to the form produced by the manufacturer).[16] It relies on a combination of 14 commercial and noncommercial sources of drug information, such as the Food and Drug Administration product labels, Medical Subject Headings (MeSH), Micromedex®, First Databank® and others. In order to remove redundant entries, drug components are placed into a semantic normal form (SNF) which expresses the active ingredient(s), strength, dosage and unit of measurement. Each component is assigned a Concept Unique Identifier (CUI).

From here, the concept is expanded into many different term types (TTY) which include varying types and amounts of information, some of which are shown in Table 9-8.

In RxNorm, concepts are linked to each other using several bidirectional relationships. For example Zyrtec is a tradename of Cetrizine, and Cetrizine has a tradename of Zyrtec. Figure 9-6 shows some of the relationships among the CUI's associated with this medication.

There are approximately 80,000 items in the RxNorm database.

SNOMED CT[17]

Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) is a comprehensive, hierarchical medical vocabulary that was initially developed by the College of American Pathologists and England's National Health Service. Since 2007, it has been distributed by the International Health Terminology Standards Development Organization (IHTSDO).

15 See http://www.nlm.nih.gov/research/umls/rxnorm/overview.html for more information.
16 For example, amoxicillin is produced as a powder which is reconstituted by a pharmacist to create a suspension. Prescribers will request a certain dosage of amoxicillin suspension to treat a child with acute otitis media. It is of no interest to the prescriber how that suspension came into being. Thus, when producing a list of prescribable drugs, it would not make sense to include amoxicillin powder, but it would make sense to include amoxicillin suspension.
17 For much, much more information, see http://www.snomed.org/. Also, visit the IHTSDO SNOMED browser, at http://browser.ihtsdotools.org/

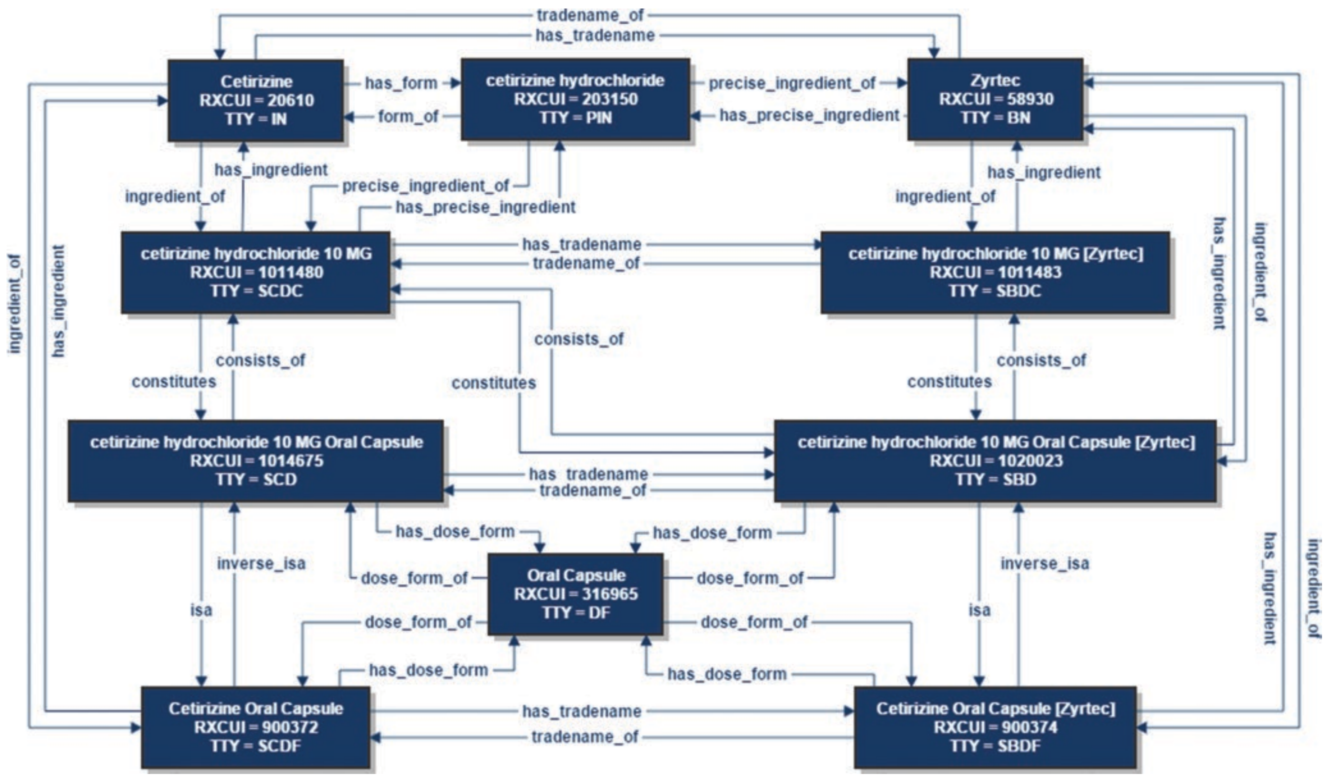


FIGURE 9-6

Semantic map of cetrizine, public domain by National Library of Medicine. Abbreviations: RXCUI, prescription Concept Unique Identifier; For explanations of TTY, see Table 9-8

TABLE 9-9

CORRELATION BETWEEN A CLINICAL NOTE AND SNOMED CONCEPTS

44 year old man complains of moderate, constant pain in the bilateral lower back for the past 3 weeks	Age more than 40 years (699716008); Male (248153007); Constant pain (426206001); Lower back (37822005); Moderate Severity (6736007); 3 weeks (4831000175101)
Past medical history: pulmonary embolism	History of pulmonary embolus (161512007)
Medications: Xanax 1 mg bid	Administration of substance via oral route (434589000); Alprazolam 1 mg tablet (371281008); Twice a day(229799001)
Lab results: Hgb 15 mg/dL	Hemoglobin normal (165399006)
CT scan of head: negative	Computerized axial tomography of brain without radiopaque contrast (396205005); Has interpretation (363713009); Negative (260385009)
Plan: follow up with Dr. Hinds 1 week	Referral to doctor (306253008); Private doctor (310174000); 1 week (4791000175109)

SNOMED includes concepts and the relationships between concepts. There are 19 top-level hierarchies, including body part, clinical finding, procedure, substance, event and others. The most common concepts are assigned by **pre-coordination**, where each concept is assigned a number (SCTID). For example, the SCTID for headache is 25064002. Newer or more complicated concepts are identified by **post-coordination**, where terms are defined by a combination of two or more basic codes. (e.g. Head = 69536005, Ache = 410711009).

Table 9-9 is the author's attempt to extract SNOMED concepts from a brief clinical note.

Each SNOMED concept is related to one or more other concepts. The most common relationship is the parent-child relationship (called **is_a** in SNOMED). For example,

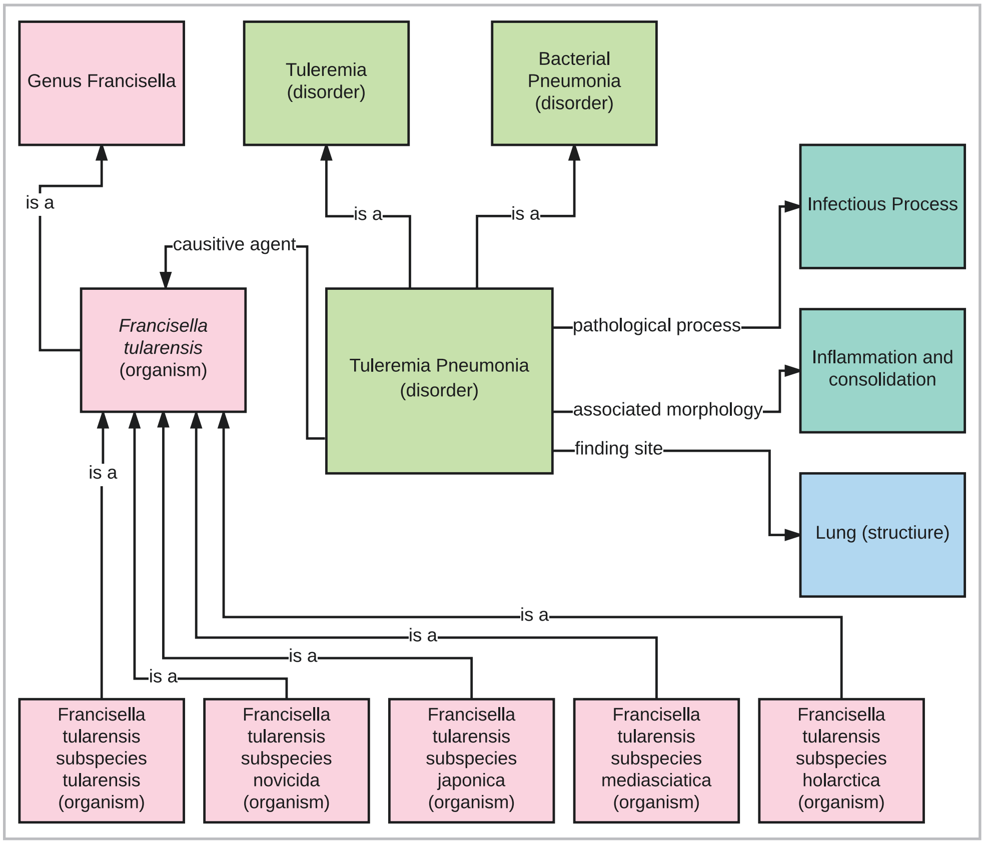


FIGURE 9-7

Diagram of ontological relationships in SNOMED, with Tularemia in the center

Glioblastoma multiforme (393563007) is a Primary malignant neoplasm (372087000), which in turn is a Malignant neoplastic disease (363346000), which is a Neoplastic disease (55342001) which is a Neoplasm and/or hamartoma (399981008) which is a Disease (64572001) which is a Clinical Finding (404684003) which is a SNOMED Top Concept (138875005). SNOMED is also multi-hierarchical, which means that a concept can inherit from multiple parents. Glioblastoma multiforme (393563007) also is a Glioma (393564001) which is a Neoplastic disease (55342001), and so on.

SNOMED concepts can also be linked by non-hierarchical terms. Consider, Pulmonary Tularemia (45556008) which is linked to *Francisella tularensis* (51526001) as *causitive_agent*. It is also linked to Lung (39607008) as a *finding_site*. Some of these links are depicted in Fig. 9-7.

In total, the there are 311,000 concepts, 800,000 descriptions, and almost a million relationships in the latest release of SNOMED CT.

LOINC

Logical Observation Identifiers, Names, and Codes (LOINC) includes 80,000 defined entries for laboratory and clinical observations.[18] LOINC is maintained and distributed by the Regenstrief institute, and is free for all users. The current code set includes laboratory terminology, vital signs, hemodynamics intake/output, EKG, obstetric ultrasound, cardiac echo, urologic, imaging, endoscopic procedures, ventilator management, and selected survey instruments.

Some of the most common LOINC codes are shown in Table 9-10. By convention, LOINC codes are six digits long, with a hyphen between the fifth and sixth digit.

18 As of LOINC version 2.59, released 2/21/17, there are 83,377 terms.

TABLE 9-10

SEVERAL OF THE MOST COMMONLY USED CODES IN LOINC (LOGICAL OBSERVATION IDENTIFIERS, NAME AND CODES)

ID	NAME	CLASS
02160-0	Creatinine [mass/volume] in serum or plasma	CHEM
00718-7	Hemoglobin [mass/volume] in blood	Hem/BC
02823-3	Potassium [moles/volume] in serum or plasma	CHEM
02345-7	Glucose [mass/volume] in serum or plasma	CHEM
02951-2	Sodium [moles/volume] in serum or plasma	CHEM
03094-0	Urea nitrogen [mass/volume] in serum or plasma	CHEM
02028-9	Carbon dioxide, total [moles/volume] in serum or plasma	CHEM
02075-0	Chloride [moles/volume] in serum or plasma	CHEM
00789-8	Erythrocytes [#/volume] in blood by automated count	HEM/BC
00786-4	Erythrocyte mean corpuscular hemoglobin concentration [mass/volume] by automated count	HEM/BC

3.4.7 INTEROPERABILITY STANDARDS

In order for computers to communicate effectively, system designers must ensure that the terminologies and vocabularies used in each system can be directly and unambiguously mapped from one to another.

HL7 V3 and RIM

Health Level Seven Version 3 (HL7 V3) bears little resemblance to V2. V3 is encoded as eXtensible Markup Language (XML) and is not backward-compatible to V2. The major thrust in developing V3 was to create **semantic interoperability,** or the ability to exchange data with unambiguous shared meaning. The foundation for semantic interoperability in V3 is the **Reference Information Model** (RIM), which is composed of four base classes: entities (people, places, things), roles, participations and acts. As an example, suppose that Dr. Welby performs a cholecystectomy on Mr. Doe in Operating Room 6. Mr. Doe, Dr. Welby and OR-6 would be entities. Mr. Doe would have the role of patient and Dr. Welby the role of surgeon. The act would be a cholecystectomy, and participation would link all of the above. By extending these four classes, and combining them with standardized vocabularies and data types, nearly any kind of health information can be encoded and transmitted.

Different kinds of healthcare communications have different requirements. For example, a lab report must have a patient identifier and at least one result. An order for a chest x-ray must have a patient identifier, an ordering doctor, a reason for exam, etc. The set of rules defined for a particular type of communication is known as a **constraint.** By rigorously defining what can, should and can't be in a communication, the system of constraints can be used to ensure that the receiver will be able to interpret and use the message.

As of 2017, V3 has not been widely adopted as a messaging standard, nor has it supplanted V2 as expected. One notable exception is the **Clinical Document Architecture (CDA)**, a hierarchical text-based format for medical record interchange. One example of the CDA is the **Continuity of Care Document (CCD)**, which became immensely popular when it became a requirement for Meaningful Use in 2010.

```
<observation classCode="OBS" moodCode="EVN">
  <templateId root="2.16.840.1.113883.10.20.22.4.27"/>
  <id root="c6f88321-67ad-11db-bd13-0800200c9a66"/>
  <code code="3141-9" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Patient Body Weight - Measured"/>
  <statusCode code="completed"/>
  <effectiveTime value="20170514"/>
  <value xsi:type="PQ" value="86" unit="kg"/>
  <interpretationCode code="N" codeSystem="2.16.840.1.113883.5.83"/>
</observation>
```


FIGURE 9-8

A section of a Continuity of Care Document (CCD), which is a constraint on the Health Level 7 (HL7) Reference Information Model (RIM). The template and encoding are specified using numeric identifiers (e.g. 2.16.840.1.113883.6.1) as well as textual names (e.g. LOINC) which makes the document both human-readable as well as unambiguous enough for semantic interoperability. This observation shows that the patient's weight is 86 kg


```
<observation classCode="OBS" moodCode="EVN">
  <code code="50373000" codeSystem="2.16.840.1.113883.6.96"
        codeSystemName="SNOMED CT" displayName="Body height measure"/>
  <statusCode code="completed"/>
  <effectiveTime value="20170514"/>
  <value xsi:type="PQ" value="1.77" unit="m"/>
</observation>
```


FIGURE 9-9

Another section from the same CCD. This document uses a SNOMED CT term instead of LOINC to describe the finding. In this case, the patient's height is 1.77 m, and was recorded on May 14, 2017

Figures 9-8 and 9-9 show a small part of a CCD, specifically the height and weight of a patient. Observations are a child class of the act class. There are a few important things to note in this fragment. The first is that these messages follow a particular template. In this case, the template ID is 2.16.840.1.113883.10.20.22.4.27, which is an OID object corresponding to vital sign measurement. The specific measurement is *Patient Body Weight—Measured*, which corresponds to code 3141-9 in the LOINC vocabulary (The LOINC vocabulary, in turn is coded as OID 2.16.840.1.113883.6.1). The actual weight is 86 kg, which has interpretationCode of N. If you look up code system 2.16.840.1.113883.5.83, you will see that the code N means Normal.

FHIR

Fast Healthcare Interoperability Resources (FHIR, pronounced "fire") is a relatively new standard for transfer of medical information. It relies on well-established web technologies, such as Hypertext Transport Protocol (HTTP) with representational state transfer (REST) endpoints for transport; Hypertext Markup Language (HTML) and Cascading Style Sheets (CSS) for presentation; Javascript Object Notation (JSON) and extensible markup language (XML) for data representation; and Atom for publication and syndication.

FHIR supports transmission of documents, messages and services using RESTful endpoints. While many other standards support these paradigms, FHIR was designed to use identical content for all message types, meaning that there is no need to build a separate interface when transferring information from a message into a document. The fundamental building block of FHIR is a **resource**. Resources are atoms of information that have standard elements and consistent meaning across all contributors. This is accomplished through using reusable data types and common metadata. In addition, all resources also contain a human-readable component.

As of this writing (December 2017), FHIR v3.0.1 is classified as a Standard for Trial Use (STU) which means that the standard is likely to change before it becomes final (Fig. 9-10).

FIGURE 9-10

Example of a FHIR resource expressed in Javascript Object Notation (JSON), public domain by Health Level 7 International. Note that there is a human readable component with Hypertext Markup Language (HTML) markup in the text section


```
{
  "resourceType": "Patient",
  "id": "genetics-example1",
  "meta": {
    "lastUpdated": "2012-05-29T23:45:32Z"
  },
  "text": {
    "status": "generated",
    "div": "<div xmlns=\"http://www.w3.org/1999/xhtml\">Everywoman, Eve. SSN:\n
444222222</div>"
  },
  "identifier": [
    {
      "type": {
        "coding": [
          {
            "system": "http://hl7.org/fhir/v2/0203",
            "code": "SS"
          }
        ]
      },
      "system": "http://hl7.org/fhir/sid/us-ssn",
      "value": "444222222"
    }
  ],
  "active": true,
  "name": [
    {
      "use": "official",
      "family": "Everywoman",
      "given": [
        "Eve"
      ]
    }
  ],
  "telecom": [
    {
      "system": "phone",
      "value": "555-555-2003",
      "use": "work"
    }
  ],
  "gender": "female",
  "birthDate": "1973-05-31",
  "address": [
    {
      "use": "home",
      "line": [
        "2222 Home Street"
      ]
    }
  ],
  "managingOrganization": {
    "reference": "Organization/hl7"
  }
}
```

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