

Conception of a SNOMED CT and HL7 V3 standard:

Domain Analysis Model for Preoperative Anesthesia Assessment Project

Conception: --noun: origination; beginning, a design; plan, the act or power of forming notions, ideas, or concepts¹

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Thanks to my dog, Jack, for keeping my feet warm.

Abstract

Purpose: Standards development can take three or more years before adoption for use. The purpose of this paper is to describe the analysis portion in the development of an HL7 V3 standard. The International Health Terminology Standards Development Organisation (IHTSDO), which owns and maintains SNOMED CT, and the HL7 Anesthesia working groups along with a senior informaticist at Duke University have begun such an analysis by using a Domain Analysis Model (DAM). A DAM and its artifacts or deliverables are the products of the Domain Analysis Process as described in the HL7 Health Development Framework (HDF). The HDF is a framework of modeling and administrative processes, policies and deliverables used by HL7 to produce specifications for a proposed standard. The project's intent is the creation of a new standard for Preoperative Anesthesia Assessment Terminology with metadata for terms as appropriate in SNOMED CT and HL7 V3. The results of this project will be part of a subsequent project that will ultimately map the terms to the HL7 V3 Reference Information Model (RIM). Information on standards is difficult to assemble and synthesize. As such to the average healthcare professional, the subject of healthcare information standards can seem abstract, confusing and cluttered with acronyms. Therefore, in addition to describing the Domain Analysis Process, a secondary purpose is to provide an introductory overview, a primer, on 1: interoperability, 2: standards: what they are, what they mean, their development and their relevancy to key current US Government electronic health record initiatives, 3: HL7 V3, and 4: SNOMED CT. With the increase in adoption of electronic health record (EHR) systems, there will be an increasing requirement for professional experts from every clinical domain to assist in EHR systems development. The intended audience for this paper is that clinician who is interested in furthering the standards development process but has little knowledge surrounding that said process. The intent of the paper is to give that clinician a jump start into the subject of standards and interoperability.

The true benefit from electronic health record (EHR) adoption will come from interoperability. Simply, interoperability is the sharing of accurate health information within organizations, between organizations and between organizations and patients. In order to achieve interoperability between diverse systems, interoperability standards are employed to define vocabulary, protocols, presentation and other features of health information.

In addition to the known benefits of electronic information sharing, standards and interoperability has become even more urgent as it is one of the main foci of the American Recovery and Reinvestment Act of (ARRA) and the HITECH Act of 2009, which has authorized the Centers for Medicare and Medicaid Services (CMS) to provide reimbursement incentives for eligible professionals and hospitals who become successful ‘meaningful users’ of electronic record technology beginning in 2011. In addition to being two of the most successful and important standards used internationally for healthcare information systems, Health Level Seven Version 3 (HL7 V3) and the Systemized Nomenclature of Medicine-Clinical Terms (SNOMED CT) have been identified by the Office of the National Coordinator for Health Information Technology (ONC) as two of the standards future EHRs must incorporate in their design in order meet ‘meaningful use’ criteria.

About the author: Ellen S. Torres is in addition to an MBI student, is also a full time practicing Certified Registered Nurse Anesthetist (CRNA) with an interest in the advancement of interoperability of healthcare information particularly in relationship to the domains of and surrounding Anesthesia.

1. Introduction

For the purposes of this document, Electronic Health Record (EHR) will use the National Alliance for Health Information Technology (NAHIT) definition:

“An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization.”²

The electronic health record (EHR) in hospitals had its beginnings in 1971, when the El Camino Hospital in California implemented the first comprehensive EHR in the United States.³ Until recently, EHR adoption and implementation into hospitals has been slow. Slow EHR uptake has been due in part, to costs,⁴ implementation challenges and end user resistance.⁵

EHRs are composed of multiple specification frameworks which are intended to meet various use cases such as ordering lab tests, storing and archiving those tests, then making the stored results available to available to authorized persons. The sophisticated and comprehensive EHR should have the capabilities to allow every individual’s medical history to accumulate throughout their life and to permit any authorized person to easily access up to date information, to provide the best and most cost-effective health care possible. An additional benefit of EHR adoption and of semantic interoperability will include the ability of consumers having access to their own personal health records and allowing them to move easily between clinicians. For the purpose of this paper, the term ‘interoperability’ will imply semantic interoperability. Payers can benefit from economic efficiencies and clinicians would be able to exchange information not only within their organization but between organizations. The ability to share health information between organizations, between providers, and patients has been one of the promised rewards for adoption of electronic health records not only across the United States but also across nations.

Data sharing should increase safe care of patients and also aid in research capabilities. However, this sharing of electronic health data cannot happen without a standard way of communicating the precise meaning of data. For information or data to be interoperable, structured data that was created on one EHR vendor's product would be understandable and interpretable by another vendor's product. A diagnosis code of myocardial infarction will mean the same across vendors and when placed in the EHR database's own structure, be able to be associated with other codes for myocardial infarction and not for something else like, cancer. Therefore, interoperability requires standards to define vocabulary, protocols, presentation and other features of health information. Even more importantly, there needs to be an industry wide agreement about, and the adoption of these standards.

Since 2003, the United States has been increasingly committed toward the implementation of comprehensive EHR adoption. In 2004, \$139 Million was allocated by the US Department of Health and Human Services (HHS) to facilitate progress towards developing and implementing EHRs nationwide by 2014 with the goal of reducing healthcare costs, reducing medical errors, and facilitate research.⁶

Recently, there is increased pressure in the United States from the Obama Administration for EHR adoption and implementation. On February 17, 2009, President Obama signed in to law what is officially known as the American Recovery Reinvestment Act (ARRA)⁷ and Health Information Technology for Economic and Clinical Health Act (HITECH).⁸ The 'Stimulus Law' provides \$19.2 billion in spending on health IT. The goal of the HITECH Act is intended to encourage more effective and efficient healthcare through the use of technology, thereby reducing the cost of healthcare while enabling access to healthcare by all Americans.

Health information management technology is developing at a rapid pace, in many cases faster than standards can be developed. The need and urgency for standards is clear, however in order to

achieve the true benefit of EHR implementation, which is interoperability, there must be careful attention to the architecture and components. The systems that enable cost effective interoperable EHRs cannot be built before there are standards and their related tools.⁹ The rigorous process for standards development is necessary for them to be safe, reliable and reusable. Therefore standards development can take years. One difficulty or barrier in the standards development process is that standards are created primarily through a consensus process of volunteer experts in the specific domain. The need to expand scope, to address gaps, or to produce standards more efficiently may require an increase in paid staff. Another difficulty is the political processes: incentive payments, vendors, and competing standards. Even though there is a diversity of standards development initiatives, time frames may be mismatched with the ambitious accelerated push toward EHR implementations. However, until standards exist, they cannot be adopted.

In EHR systems, the capture of clinical information as structured data using a standard defined terminology (e.g. SNOMED CT)¹⁰ offer the advantages of processing data locally for use in patient care, sharing data, research and quality of care measurements.¹¹ There are many shared terms between clinical disciplines or domains, however, as with each domain; the domain of Anesthesia has terms which are unique to it. The advancement of technology in anesthesia and the adoption of interoperable Anesthesia Information Management Systems (AIMS) cannot occur without defined standardized terminology. However, terms as words in the dictionary have no real meaning without context. The Health Level 7 V3 (HL7 V3) defines the grammar of a language or terminology for healthcare.¹² The collaborative efforts of the Anesthesia working group of HL7 and the International Health Terminology Standards Development Organization (IHTSDO) Anesthesia Special Interest Group will provide a step toward interoperability and the exchange of preoperative anesthesia assessment information.

1.1 Background and Scope

The Anesthesia Patient Safety Foundation (APSF) mission is “to assure that no patient shall be harmed by the effects of anesthesia”¹³ Within the APSF, the International Organization for Terminology in Anesthesia (IOTA) was formed to create a standardized terminology for the anesthesia community worldwide. IOTA projects cover development of terminology, ontology and schema definition. IOTA has been formally adopted by IHTSDO-SNOMED as an official extension group that is creating the ‘Anesthesia Subset’ of terms for SNOMED CT.¹⁴ IOTA is lead by Dr. Terri Monk, Dr. Martin Hurrell, and Dr. Andrew Norton. These prominent members are also the lead members of the IHTSDO-SNOMED Anesthesia special interest group and the HL7 Anesthesia working group.

The IHTSDO-SNOMED CT Anesthesia special interest group (SIG) and HL7 Anesthesia working group (WG), have begun A Domain Analysis Model (DAM) for Preoperative Anesthesia Assessment. A DAM and its artifacts or deliverables are the products of the Domain Analysis Process as described in the HL7 Health Development Framework (HDF).¹⁵ The HDF is a framework of modeling and administrative processes, policies and deliverables used by HL7 to produce specifications for a proposed HL7 V3 standard. The project’s intent is the creation of a new standard for Preoperative Anesthesia Assessment Terminology with metadata for terms as appropriate in SNOMED CT and HL7 V3. The results of this project will be part of another that will ultimately map the terms to the HL7 V3 Reference Information Model (RIM). To guide the project group in this initial phase, they will develop Use Cases for anesthesia preoperative assessment and incorporate common anesthesia preoperative assessment concepts used in the US, UK and Netherlands in driving the development of SNOMED CT terms related to anesthesia which may not already be covered in SNOMED CT. Other deliverables for the project are a Unified Modeling Language (UML) activity model and class diagram. The project is in its

beginning stages and is projected to completion for 3rd quarter 2011. For the purposes of this paper, I will contain the scope to describing the initial phase.

The Domain Analysis Model: Preoperative Anesthesia Assessment Project is a HL7 and IHTSDO-SNOMED CT project; therefore this paper will also provide an overview of these two standards development organizations (SDO) specifically.

The standards domain is cluttered with confusing cryptic acronyms. Therefore, I have attempted to provide definitions throughout the text. In addition, a partial list of organizations and acronyms can be found in Appendix D and E.

The intended audience for this paper is that healthcare professional who is interested in furthering the standards development process but has little knowledge surrounding that said process. The intent of the paper is to give that healthcare professional a rudimentary overview, however including enough detail so that he/she may be able to begin to participate with some foundation.

In addition to an MBI student, I am also a full time practicing Certified Registered Nurse Anesthetist (CRNA) with an interest in the advancement of interoperability of healthcare information particularly in relationship to the domain of Anesthesia.

Disclaimer: The topic of standards and interoperability is vast, complicated and changing rapidly. It is currently one of the top subjects on the minds of every health IT professional. In four months of study, I have but scratched the surface.

1.3 Sources

A few of the sources for this paper are articles from informatics peer review journals. However, the most current information has been through pertinent organizations websites, their publications, news releases, meeting minutes and listservs. Industry expert's blogs and RSS feeds have also been excellent sources for up to date information on standards and interoperability. A partial list is included in Appendix F.

Experience is one of the best instructors. Through participating in the Domain Analysis Model Preoperative Anesthesia Assessment project, project leads Patricia Gunter, Terri Monk, and Andrew Norton have been excellent and patient sources for information.

Due to health IT changing and evolving at a rapid pace, the references in this paper will be limited to those prior to April 15, 2010.

2: Meaningful Use

On February 17, 2009, President Obama signed in to law what is officially known as the American Recovery Reinvestment Act (ARRA)⁷ and Health Information Technology for Economic and Clinical Health Act (HITECH).⁸ The ‘Stimulus Law’ provides \$19.2 billion in spending on health IT. The HITECH agenda is to 1: Increase access to care, 2: Improve quality of care, 3: Decrease the costs of care, and 4: Promote meaningful use of EHRs.

On December 30, 2009, the Centers for Medicare and Medicaid Services (CMS)¹⁶ published a Notice of Proposed Rule Making (NPRM) on the ‘meaningful use’ electronic health record (EHR) incentive program¹⁷. On the same day, the Office of the National Coordinator for Health Information Technology (ONC)¹⁸ published a companion interim final rule (IFR) describing the certification criterion for EHR’s that qualify for the ‘Meaningful Use’ program.¹⁹ The final rule is expected spring, 2010. Implementation an EHR will not be adequate. Organizations will be required to demonstrate ‘meaningful use’ of that EHR. The IFR established the initial set of standards, implementation specifications and certification criteria for EHR technology.

Together, these two documents make up the basis for the ARRA-HITECH incentive program in which healthcare providers move forward with their health IT initiatives in order to achieve the basic requirements of Medicare and Medicaid incentive payments starting in 2011. The incentive requirements are staged in three segments with penalties that will reduce reimbursements for unmet requirements starting in 2015. The specifications are many. Some of the specifications are the use of electronic ordering of medications, laboratory, and referrals and maintenance of an up to date problem list. Certification of EHR systems must conform to basic testing and certification to ensure it has the capabilities needed to improve quality, safety and efficiency in hospitals and offices. Meaningful Use has also stipulated that EHRs must use certain structured data standards. Health Level Seven Version 3(HL7 V3)²⁰ and the Systemized Nomenclature of Medicine-

Clinical Terms (SNOMED CT) which is owned and maintained by the International Health Terminology Standards Development Organisation (IHTSDO)¹⁰ have been identified as two of these standards future EHRs must incorporate in their design in order to meet Stage 1 meaningful use.¹⁷

3. Interoperability

Consider the simple telephone: it does not matter what company made the phone or whether the call is placed through a wireless or landline connection. From any phone you can call any other phone. When applied to healthcare, technical interoperability means to have that same ability of machines to communicate efficiently, regardless of the make or the institution where they are at. Semantic interoperability occurs when the messages interchanged are completely understood regardless of language.

3.1 Healthcare Interoperability Defined

The National Alliance for Health Information Technology (NAHIT) played a significant role in elevating healthcare IT. NAHIT accomplished its mission and ceased operations in September, 2009.²¹ Collaborating with ONC they developed key health IT consensus based definitions. These definitions have been adopted industry wide and used in proposed legislative language.²² Following is NAHIT's consensus defined four levels of interoperability:²³

A. Definition

In healthcare, *interoperability* is the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged.

B. Levels

Level 1: Non-electronic data. Examples include paper, mail, and phone call.

Level 2: Machine transportable data. Examples include fax, email, and unindexed documents.

Level 3: Machine organizable data (structured messages, unstructured content). Examples include HL7 messages and indexed (labeled) documents, images, and objects.

Level 4: Machine interpretable data (structured messages, standardized content). Examples include the automated transfer from an external lab of coded results into a provider's EHR.

Data can be transmitted (or accessed without transmission) by HIT systems without need for further semantic interpretation or translation.

Level 4: *Semantic Interoperability*, or just ‘*interoperability*’ as it is referred to for most situations today, is also defined as the ‘ability to automatically interpret the information exchanged meaningfully and accurately in order to produce useful results as defined by the end users of both systems. To achieve semantic interoperability, both sides must defer to a common information exchange reference model. The content of the information exchange requests are unambiguously defined: what is sent is the same as what is understood.’²⁴

Healthcare Information Management Systems Society (HIMSS) has added the following dimensions to the definition of Interoperability: ²⁵

- Uniform movement of healthcare data
- Uniform presentation of data
- Uniform user controls
- Uniform safeguarding of data security and integrity
- Uniform protection of patient confidentiality
- Uniform assurance of common degree of system service quality (e.g., reliability, performance, and dependability)

Healthcare is not alone in interoperability challenges. Businesses and banks have struggled with all manner of data communication. ²⁶ The disastrous effects of the lack of interoperable communication ability between police, fire and other first responder for 911 and Katrina are well known.²⁷

A report by the Commission on Systemic Interoperability (CSI), ‘Ending the Document Game’ ²⁸ identifies the challenges of widespread interoperable EHR use into three issues:

- Providers and consumers must adopt the tools necessary for health data sharing
- Providers and consumers must be connected so data can flow
- Data must be interoperable so that data can be meaningfully shared

Interoperability can be considered the ‘holy grail’ of healthcare information management (HIM). In order for this elusive goal to become reality, it requires the infrastructure, framework, and standards to define vocabulary, protocols, presentation and other features of HIM.

4. Standards

Standards are in use everywhere in our everyday lives, most of which we take for granted.

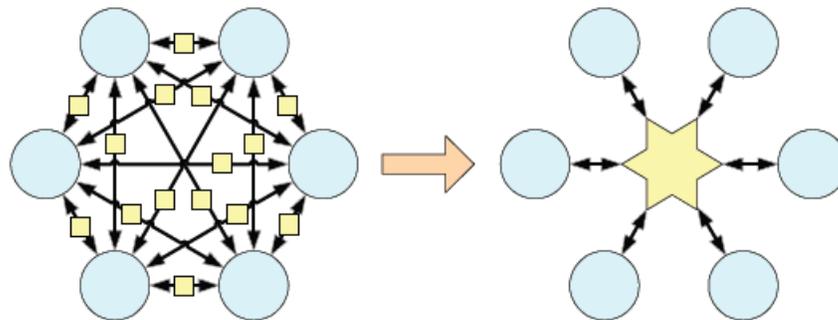
Standards allow for quality, reliability, efficiency and interchangeability. Take the typical three pronged plug which fits into the corresponding duplex outlet standard in all of North America.²⁹

Adapters will be required if you take your shaver or cell phone charger with you to Europe, since the European standard is different and may even vary from country to country within Europe.

Now, it would not be convenient if the same charging interface was used for of your mobile devices: cell phones, blue tooth headsets, GPS, laptops, and others?

The benefits of standards are illustrated very well in Figure 1 from the book: Principles of Health Interoperability HL7 and SNOMED, by Tim Benson:

Figure 1:³⁰



The figure on the left illustrates the need for fifteen specifications for linking six domains. The figure on the right illustrates if only one where used. As Dr. Benson describes, linking 2 nodes only needs a single specification, if 6 nodes requires 15, using the formula $(N^2-N)/2$, linking 100 nodes requires 4,950.³⁰

4.1 What are Standards?

Standards are models, principles, policies, or rules that provide an agreed-upon framework for doing and understanding things. As described by the International Standards Office (ISO) a standard is a “document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context”³¹ The ISO also stipulates that a standard should be aimed at promoting the optimum benefits of the community and be based on the efforts and results of science, technology and experience. An international standard is one that is adopted by an international standardizing standards organization and is made available to the public such as the ISO or International Electrotechnical Commission (IEC)³²

4.2 Standards Development Process

As described by Dr. Marshall in ‘The Standards Value Chain’,³³ standards go through typically three stages prior to implementation: development, profiling, and testing, with each stage in the process taking three years or more.

4.2. A Development

The work of developing standards or updating existing ones is done by Standards Developing Organizations (SDOs). SDOs can be regional (e.g. ANSI)³⁴ or international (e.g. ISO).³⁵ Standards, like laws, many are formed through a consensus process. However, unlike laws, they are created primarily by the input of groups of volunteers with a special interest in a specific area or domain. A non consensus SDO is the National Library of Medicine which produces the standard, RxNorm.³⁶ Of the consensus SDOs, many consist of volunteer professionals who maintain jobs in the domain of interest. Most standards development organizations (SDO) only meet face-to-face once a year, with the bulk of the volunteer effort being done through email and

teleconferencing. In addition to work in their main domain of interest, many volunteer in their domain of interest for other standards developing organizations (SDO), since one domain will have interests or projects which overlap with another. For example, the same core group for the anesthesia domain is represented at both the IHTSDO SIG (and SNOMED) and the HL7 working group (WG). Also, members of the anesthesia domain collaborate with other special interest groups such as the IHTSDO Implementation SIG, and the ISO/IEEE 11073.³⁷ The goal of this collaborative effort between the IHTSDO anesthesia SIG and ISO/IEEE 11073 WG will result in harmonization of the two standards for device integration.

Collaboration and harmonization of standards can occur at the level of the working groups from SDOs, as described above or between the SDOs themselves. One example of the collaborative effort is the relationship between HL7 and the Clinical Data Interchange Standards Consortium (CDISC),³⁸ which are working together to develop global, open, consensus based medical research data standards.³⁹ There are however, some barriers to collaboration such as the possible limited view of the broader impact by the volunteer group. And the political impact of the SDO's stakeholders: the government, customers, or the monetary impact of competing SDOs. Benefits of collaborative efforts are consolidation and conservation of the limited resources, faster time deployment, which in turn means a more rapid time to implement in the market place.⁴⁰ Section 8 describes one of the first steps, the analysis, of the development of a standard.

The resulting documents produced from the SDO working groups are generally first published as drafts, are then opened for comments from a wider audience and revised. This process may occur several times before there is the final standards document. Many SDOs also require one or more trial or reference implementations prior to release. (e.g. HL7, OASIS)⁴¹ This rigorous attention is necessary for safe, effective, efficient, reusable standards. Each SDO determines how its products are made available; some are available free to the public, however, since the standards

development process cost a great deal of money, time and resources, virtually all but a few standards are distributed on a commercial basis.

Types of standards related to health information management:

The ability to capture and share healthcare data is a science in its infancy. As are the standards being developed to allow that information to be shared.

Terminology or data standards: Health related terminologies are sets of terms which represent a system of concepts within a specific field or domain of healthcare. The focus of terminology standards is on making information understandable and useful to humans.

Terminology standards include classifications and vocabularies.

- Terminology classifications standards use a hierarchical index. In ICD-9,⁴² high blood pressure: Disease of the circulatory system>hypertensive disease>essential hypertension, which then is a code of 401. SNOMED CT¹⁰ uses descriptive logic in a IS-A hierarchy where high blood pressure IS-A systemic arterial finding. (SNOMED CT is described in section 6).
- Controlled vocabularies use a subject indexing schemes for retrieval, such as cars would be listed in the phone book under ‘Automobiles’ instead of ‘Dealerships’. The MeSH database of the US National Library of Medicine is organized in this way.⁴³

Technology standards: Many of these standards are not only applicable to healthcare but to other areas that require exchange of electronic data and security. Examples are HTTPS⁴⁴ and XML⁴⁵ amongst others. The most recognized messaging standard for health information management is the HL7 Messaging standard,²⁰ which enables the exchange, or technical interoperability of information. (HL7 V3 is described in section 5).

4.2. B. Standards profiling

It is often difficult to determine which standard is right for an application. Since standards are the result of an analysis and design process, they indicate what the application needs to do but not how to design the application itself. Profiling is a mechanism for extending existing standards for use in different ways. Standards profiling organizations create products in which multiple applicable standards are selected and combined for specific use case scenarios. Examples of standards profiling organizations are:

- Integrating the Healthcare Enterprise (IHE) ⁴⁶ which develops integration profiles or systems using coordinated established standards for communicating patient information.
- openEHR⁴⁷ which creates specifications, open source software and tools. OpenEHR uses archetype profile⁴⁸ of reusable models of content and process along with interfaces to terminology.
- Healthcare Information Technology Standards Panel (HITSP) ⁴⁹ The HITSP was operated under contract to the US Department of Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC), but was administered by the American National Standards Institute (ANSI).³⁴ HITSP's contract ended on April 30, 2010. HITSP was formed as a public-private partnership to integrate and harmonize relevant healthcare standards to enable and support interoperability of healthcare applications. The standards work of HITSP has been incorporated into the Interim Final Rule (IFR), which defines the standards and certifying criteria for defining and demonstrating meaningful use of certified EHRs. The HITSP specifications are also intended to support healthcare software applications of the Nationwide Health Information over the Internet (NHIN).⁵⁰

4.2. C. Standards Testing

Healthcare IT systems must be tested and inspected to determine how well they conform to the specifications of the standards. Examples of testing organizations are:

- Integrating the Healthcare Enterprise (IHE)⁴⁶ provides a detailed implementation and testing process to promote the adoption of standards based interoperability applications. The IHE Connectathon is a multinational, multivendor large scale interoperability testing event which validates health IT systems for interoperability and compliance with IHE profiles.
- Certification Commission for Health Information Technology (CCHIT)⁵¹ is a private not for profit organization, which until early 2010, has been the only officially recognized program for certifying EHR systems. Systems meeting criteria are said to be CCHIT Certified.
- National Institute of Standards and Technology (NIST)⁵² is not a certifying organization nor does it create standards. NIST provides the necessary conformance tests, and tools to advance healthcare IT standards that are complete and testable. In addition, NIST in collaboration with the Health IT Standards Committee, which reports to ONC, will provide the methods and tools necessary to test for compliance with existing standards as established by HSS/ONC in the IFR to meet meaningful use criteria.¹⁹ ONC has also stated its intention to use NIST's National Voluntary Laboratory Accreditation Program (NVLAP)⁵³ to perform the accreditation of ONC authorized EHR testing and certification organizations. The accredited organizations would then be authorized to perform the testing and certification of complete EHRs and EHR systems. These EHRs and EHR systems would then be HHS (US Department of Health and Human Services) certified and thereby qualifying them for access to 'meaningful use' stimulus funds.

4.3 Electronic Health Record Standards Categories

Creating an effective and complete EHR requires numerous standards. There are a few SDOs that have developed frameworks and guidelines to address the mission of providing standards for entire EHR domain. SDOs can fall into three categories: those who are working toward enabling complete EHRs, those who address subsets, and those who provide stand alone standards.

Following is a partial list of examples.

4.3. a. Work toward complete EHRs:

- Health Level 7 (HL7)²⁰ is an ANSI accredited SDO that produces standards in the domain of clinical and administrative data. Formed originally to address the need for messaging standards for insurance processing, today it provides interoperability standards that improve care delivery, optimize workflow, and health information among healthcare providers. HL7's vision is to 'create the best and most widely used standards in healthcare.' (HL7 is described in section 5).
- Integrating Healthcare Enterprise (IHE)⁴⁶ facilitates regional deployment of interoperable products. Products which must meet compliance with IHE integration profiles.

4.3. b. SDOs addressing subsets

- openEHR⁴⁷ focuses on creating and sharing EHRs using open source software through consumers and clinicians instead of vendors. Their mission is to make the interoperable, life-long EHR a reality and to improve health care in the information society.
- Digital Imaging and Communications in Medicine (DICOM)⁵⁴ is a standard that permits the interoperable handling, storing, printing, and transmitting of medical imaging information. It combines a file format definition with a network communications protocol.

- Clinical Data Interchange Standards Consortium (CDISC)³⁸ is a global, open, multidisciplinary, non-profit organization that has established standards to support the acquisition, exchange, submission and archive of clinical research data and metadata. The CDISC mission is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

4.3. c. Stand alone SDOs

The standards created by these SDOs are generic but which are essential elements of EHR frameworks. Listed below are only a two of the many.

- International Health Terminology Standards Development Organisation (IHTSDO)¹⁰ maintains and promotes the usage of SNOMED CT, a multilingual health information exchange standard. (SNOMED CT is described in section 6).
- Logical Observation Identifiers Names and Codes (LOINC)⁵⁵ are a universal standard and database to identify laboratory and other clinical observations with the purpose of assisting in the electronic exchange and gathering of clinical results for outcomes management, clinical care and research. LOINC is maintained by the Regenstrief Institute, Inc.⁵⁶

4.4 Administrative Standards

- Health Insurance Portability and Accountability Act (HIPAA)⁵⁷ set national standards for the protection of individually identifiable health information. It also gives patients an array of rights with respect to their information. However, it also permits the disclosure of health information if needed for patient care and other important purposes.

4.5 Standards and ‘Meaningful Use’¹⁷

On December 30, 2009, the Department of Health and Human Services released the Notice of Proposed Rule Making (NPRM) establishing the Electronic Health Record (EHR) Incentive Program, commonly referred to as the Meaningful Use of an EHR, and the Interim Final Rule (IFR)¹⁹ establishing the initial set of standards, implementation specifications and certification criteria for EHR. Refer to Appendix A for a table of the content and vocabulary standards selected which includes Adopted Standard(s) to Support Meaningful Use Stage 1 (2011) and Candidate Standard(s) to Support Meaningful Use Stage 2 (2013). In addition to incorporation of the designated standards, to qualify for incentives, EHRs also will be required to be US Department of Human Health and Services (HHS) certified.⁵⁸ In the past, the sole certification path for EHRs was through Certified Commission for Health Information Technology (CCHIT).⁵¹ It is HHS certification that will determine access to incentive monies, not CCHIT certification.

5. Health Level 7 (HL7)²⁰

Each healthcare setting is radically different from another in terms of business relationships, payment structures, politics, data collected, and software systems. This means hospitals, clinics, imaging centers and so on, each have their own unique requirements. Today, the need for applications to share clinical data is critical. The explosion in the number of clinical applications and the national push for a centralized electronic health record are only two factors driving the requirement for a common language between applications.

HL7, the standard developing **organization**, is a non-profit ANSI accredited Standards Development Organization (SDO), established in 1987 that produces standards for the domain of clinical and administrative data. It has over 3000 members and affiliates in over 55 countries. It is a collaborative volunteer organization with its members consisting of vendors, providers, consultants and others who have an interest in the advancement of clinical and administrative standards for healthcare information management. HL7's vision is 'to create the best and most widely used standards in healthcare'.²⁰ The name HL7 is derived from 'Healthcare' and 'Level 7' refers to the seventh level of the Open Systems Interconnection (OSI),⁵⁹ the application level.

Consisting mostly of subject matter experts, HL7 standards are developed by HL7 domain specific working groups. HL7 is most widely known for its messaging standard, HL7 Versions 2 and 3. However, HL7 has produced other internationally recognized standards. They are:

- Version 2.x Messaging standard (Interoperability specifications for computer systems)
- Version 3 Messaging standard
- Arden Syntax (Formalism for expressing medical logic rules)
- GELLO (An Object-Oriented Query and Expression Language for CDSS)
- Visual / Context Integration (CCOW)
- Version 2.x XML (XML encoding of HL7 messages)
- Clinical Document Architecture (CDA)
- Electronic Health Record System (EHR) Functional Model
- Personal Health Record System (PHRS) Functional Model
- Services (i.e., Services as related to a Services Oriented Architecture)

For the purposes of this paper, only HL7 version 3 will be discussed. Descriptions of all HL7 standards can be found on the HL7 website.

5.1 HL7 Version 3.0

HL7, the **standard**, has the “aim to support any and all healthcare workflows”⁶⁰ HL7 V3 is not a software application. A few of the challenges with Version 2 are the lack of consistent data model, which causes inconsistencies, and the lack of precision in the standard. The HL7 V3 standard corrects these issues and incorporates more trigger events and message formats than previous versions. It is a number of flexible standards, guidelines, and methodologies by which healthcare data in the form of messages can be transmitted among computer systems, where a ‘message’ is a collection of data that sends information about an event in the healthcare setting. It uses a Reference Information Model (RIM) as a common source for information content of specifications. The RIM is a high level generic information model that represents all of healthcare. The RIM is an essential part of HL7 V3 as it provides a precise representation of the semantic and lexical connections that exist between the information carried in the fields of HL7 messages. As part of HL7 V3, methods were developed that allows HL7 specifications to draw on codes and vocabularies from different sources. The use of standardized vocabulary (e.g. SNOMED CT) ensures unambiguous interpretation of the code sources and code values across healthcare information systems. The HL7 RIM, the HL7 Abstract Data Types Model, the HL7 Vocabulary model, and the model driven processes of the Health Development Framework (HDF) combine to provide a methodology for the development of consensus based standards for healthcare information system interoperability.

HL7 V3’s primary goal is ‘to offer a standard that is definite, deterministic, testable, and enables certification for conformance of HL7 implementations.’¹⁵

Benefits of HL7 V3:

- Provides an efficient and viable means of sharing information between disparate health care systems by establishing uniform and consistent communication rules.
- Defines the packaging and transmission of healthcare information between organizations and/or systems.
- Allows for efficient and seamless systems integration by setting the language, structure, data types and supporting vocabularies and terminologies.
- Enables delivery and sharing of a longitudinal view of patient health information.

5.2 Health Development Framework (HDF) ¹⁵

The HDF is a framework of modeling and administrative processes, policies and deliverables used by HL7 committees to produce specifications for a proposed standard. The HDF applies a model driven process to HL7 technical specifications, not just messages. The HDF uses a Project Life Cycle for Product Development (PLCPD) that identifies five major stages: (See Appendix C)

- Project Initiation Process
- Domain Analysis Process
- Specification Design Process
- Standard Profiling Process
- Technology Specification Process

The second stage: Domain Analysis Process will be described in Section 8.

5.3 HL7 Reference Information Model (RIM)

An ANSI and ISO standard, the RIM is a critical component of the HL7 V3 development process. Communications between entities usually takes the form of a message composed of message elements, triggered by some event. There is a sender and a receiver. Interoperability requires consistency in the message format and content. The RIM and the vocabulary domains are the bases for the semantic specification of message elements. The goal of RIM is to reduce the implementation costs of HL7 enabled solutions and further standardize the HL7 communication specifications between healthcare systems. The object model created as part of the standards development process, the RIM, is a static pictorial representation of clinical data (domains) and

identifies the life cycle of events that a message or groups of related messages will carry. The HL7 V3 RIM is a shared model between all domains. Up until 2009, the RIM was maintained through a harmonizing process as the primary method for adopting RIM and Vocabulary content changes. Beginning in 2009, HL7 adopted the ‘ANSI Continuous Maintenance Process’.⁶¹ The HL7 V3 normalized RIM is shown in Appendix B.

On the technical level the RIM is modeled using the Unified Modeling Language (UML) syntax.⁶² UML is a graphical language, used to visualize, specify, modify, construct and document the artifacts of an object oriented software intensive system. The class diagram is the main building block of object oriented modeling and provides a static view of a particular domain. There are five components of an UML class diagram:

- Package—A collection of related classes
- Class—Something about which information is maintained
- Attribute—An element of information pertaining to a class
- Data Type—A specification of the structure and value constraint for an attribute
- Relationship—An association between classes

The RIM is a UML model class diagram based several classes; however there are six core classes that make up the backbone of the RIM. Rules and restrictions on allowable attributes for each class make up the RIM and how they relate to each other. Cardinality and optionality constraints also exist on relationships between classes and on attributes.

The six core classes of the RIM are: ⁶³

- **Act:** A record of something that is being done, has been done, can be done or is intended or requesting to be done. Acts are the pivot of the RIM: domain information and process record are represented primarily in Acts.
 - In the business domain of HL7, an Act is considered an ‘intentional action.’
 - In the clinical domain, an Act is linked to medical knowledge, such as guidelines
 - A record of an intentional action is considered an ‘act instance’
 - A single Act may have multiple participating Roles (see Roles below)

- **Entity:** A physical thing, group of physical things or an organization capable of participating in Acts in healthcare.
 - It may include a living subject, organism, material, device, organization, or group of physical things capable of participating in an Act.
 - It does not include events/actions/acts, the definition of things, or the roles that things can play (e.g. patient, provider)

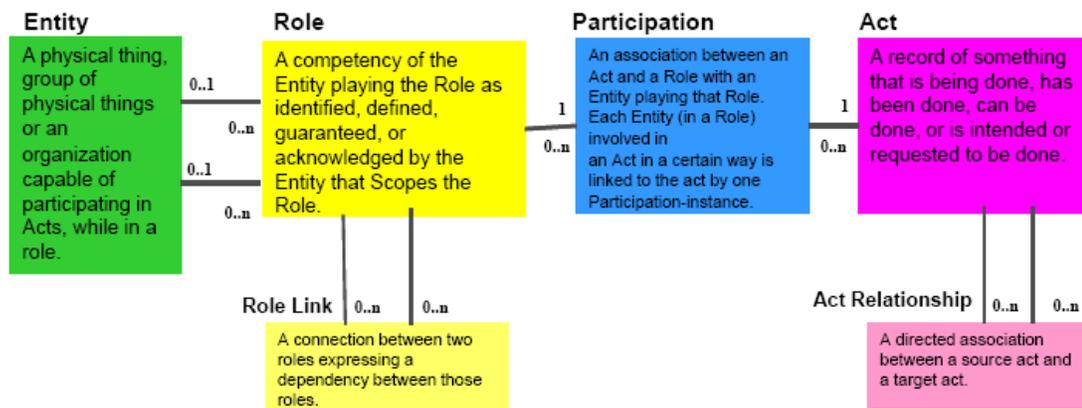
- **Role:** Describes the task that Entities play or provide as they participate in healthcare Acts.
 - For a particular Role, an Entity can participate in an Act
 - Each role is played by one Entity
 - A particular Entity in a particular Role can participate in an Act in many ways
 - e.g.: A person in the Role of a practitioner can participate in a patient encounter as the consultant physician or as an attending physician.
 - A single Role may participate in multiple Acts

- **Participation:** An association between an Act and a Role.
 - The Entity playing the Role is the actor.
 - Each Entity involved in an Act is linked to the Act by one Participation instance.

- **ActRelationship:** A directed association between a source Act and a target Act.
 - Represents the connection of one Act to another:
 - e.g.: the relationship between an order for a blood test and results of the blood test
 - It includes Act to Act associations such as collector/component, predecessor/successor, and cause/outcome.
 - Every ActRelationship instance is like an arrow with a point (headed to the target) and a butt (coming from the source).

- **RoleLink:** A connection between two roles expressing a dependency between those roles

Figure 2: RIM Classes



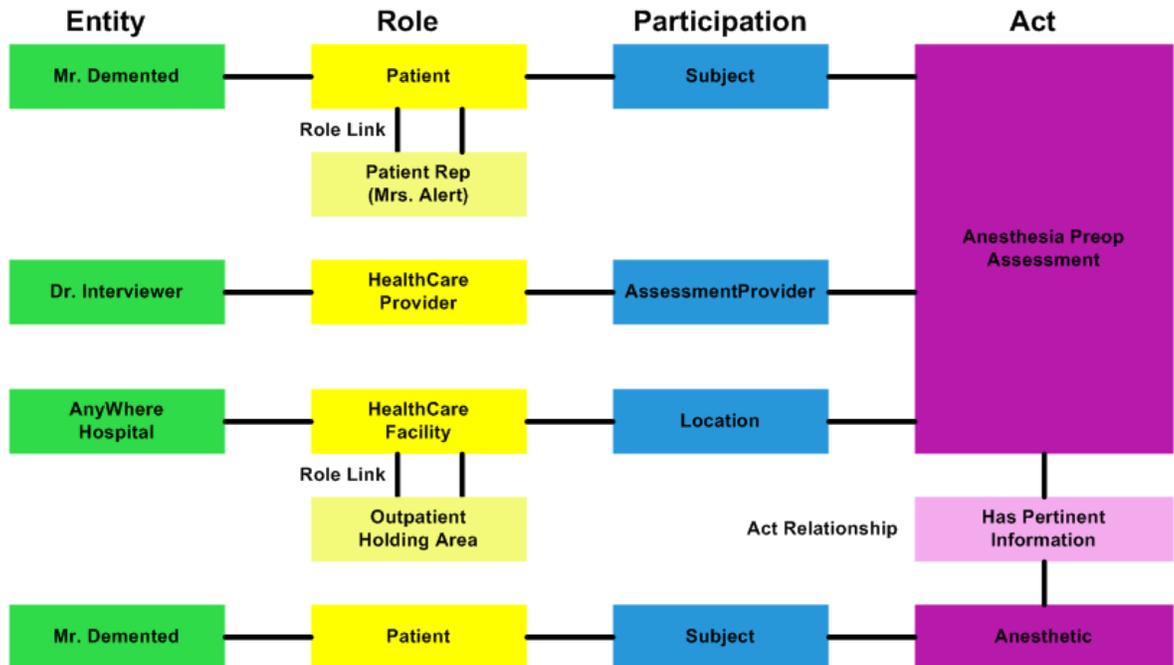
Acts connect to Entities in their Roles through Participations, but can also connect to other Acts through Act Relationships.

Classes are color coded with Green = Entity, Yellow = Role, Blue = Participation, Red/Pink = Act

RIM classes in illustration:

Mr. Demented arrives has arrived at the surgical outpatient holding area for preparation of inguinal hernia operation. Dr. Interviewer, a healthcare provider performs a preoperative anesthesia assessment. Mrs. Alert, Mr. Demented’s wife answers Dr. Interviewer’s questions as Mr. Demented cannot appropriately. Later, Mr. Demented has an anesthetic tailored to his needs from the information obtain in this preoperative assessment.

Figure 3: Instance of an Act: Anesthesia Preoperative Assessment in a high level RIM with a second Act instance of Anesthetic linked by an Act Relationship.



Structural Attributes in RIM

The meaning of each class when used in an HL7 message is determined by one or more structural attributes. For example, every Act has a class code and a mood code. The class code states what sort of Act this is, such as an observation, an encounter, or the administration of a drug. Mood is analogous to the tense of a verb. Mood codes indicate whether an Act has happened: as in an event, or is a request or order for something to happen, or intent, or a criterion for an event.

For Example:

- “weight = 100kg” is an observation event
- “measure weight daily” is a request-order
- “reduce weight to 80kg” is an intent
- “if weight is greater than 80kg” is a event criterion

When the RIM is put to use, a particular context or domain is defined in a UML use case model.

The RIM defines a set attributes and associations for each class, which are the only ones allowed in HL7 messages. Each attribute has a specified Data Type. Attributes and Data Types then become the tags in HL7 XML messages. The class model that is based on the RIM provides a static view of the information needs of an HL7 V3 standard. The class model created and RIM accompanied by models for use cases, data and technical specifications, and other supporting documents, will provide a complete view of the requirements and design of an HL7 standard. The complete HL7 V3 standards development is a long process as depicted in Appendix C which can take three years or more. However, such rigor is vital for a standard to be applicable, reliable, and reusable.

6. SNOMED CT^{10,30,64}

The **S**ystematized **N**omenclature of **M**edicine (SNOMED) is a hierarchical multidimensional classification system. SNOMED was designed as a comprehensive nomenclature of clinical medicine for the purpose of accurately storing and/or retrieving records of clinical care in human and veterinary medicine.

SNOMED CT (**S**ystematized **N**omenclature of **M**edicine-**C**linical **T**erms) standard is a controlled medical terminology licensed and maintained by the International Health Terminology Standards development Organisation (IHTSDO). It is a comprehensive, multilingual clinical terminology that allows a consistent way to index, store, retrieve and aggregate clinical data across domains for documentation and reporting. SNOMED CT is a coding scheme that identifies concepts and terms, and a multidimensional classification which can only be used in computer systems. SNOMED CT is more than terms. It contains terms, plus codes, plus the ability to put them together.

SNOMED CT is made up of concepts and their attributes, which consists of relationships to other concepts. As such, relationships are modeled as a triple: concept-attribute-concept. For example, kidney disease IS-A disorder of kidney. Each SNOMED CT concept has a numeric code assigned: the SNOMED CT identifier-SCTID. Permanence is an important principle of SNOMED CT. Once a concept is created, it is never deleted. It may be given an ‘inactive’ status and a reason why it is inactive. This principle is what allows SNOMED CT to be backwards compatible and future proof. The concepts are organized in hierarchies with multiple levels of granularity. It has a vertical structure with a parent child relationship, where concepts may have multiple parents. It also has horizontal relationships, where using attribute concepts may be linked to each other. Currently, SNOMED CT has eighteen top level concepts which descend from the single Root concept: the “SNOMED CT Concept”, which has the SCTID code: 138875005. Under this root, the top level concepts are:

Clinical finding/disorder

- Represents the results of a clinical observation, assessment or judgment, an includes both normal and abnormal clinical states
- Includes the sub-hierarchy of 'Disease'

Procedure/intervention

- Represent intentional activities performed in the healthcare

Observable entity

- Represents a question or procedure which can produce an answer or result. e.g.:
What is systolic blood pressure?

Body structure

- Includes normal as well as abnormal anatomical structures.

Organism

- Includes organisms in human and animal medicine, including organisms in the causes of diseases.
- Includes sub-hierarchies: Animal, Microorganism, and Plant.

Substance

- Includes concepts that can be used for recording active chemical constituents of drug projects, food and chemical allergens, adverse reactions, toxicity or poisoning information, and physicians and nursing orders.
- Includes sub-hierarchies: Body substance, Dietary substance, Diagnostic substance.

Pharmaceutical/biologic product

- This is separate from the Substance hierarchy. This is a top level hierarchy to clearly distinguish drug products from their chemical constituents, which are defined in Substance.

Specimen

- Includes concepts representing items that are obtained for examination or analysis
- Includes attributes which specify the body structure, the procedure used to collect the specimen, the source of the collected specimen, and the substance of the specimen.

Special concept

- Includes sub-hierarchy of Inactive Concept

Physical object

- Includes natural and manmade objects, such as devices: ventilator or artificial kidney.

Physical force

- Include concepts representing physical forces that can play a role as mechanism of injury, such as spontaneous combustion.

Event

- Includes concepts that represent occurrences, such as floods or a bioterrorist attack.

Environment or geographical location

- Includes types of environments and named locations such as countries or states.

Social context

- Includes social conditions and circumstances significant to healthcare, such as ethnicity, life style, or occupation
- Includes sub-hierarchies ethnic group, occupation, person, religion /philosophy.

Staging and scales

- Includes sub-hierarchies of assessment scales and tumor staging systems, such as Glasgow coma scale and Duke's Staging System.

Linkage Concept

- Includes sub-hierarchies of link assertion and attribute.
- Enables uses of SNOMED CT concepts in HL7 V3 statements.

Qualifier Value

- Contains concepts such as laterality.

Record Artifact

- Refers to an electronic record and its parts.

An example: Fracture of femur (concept Id: 71620000) clinical finding

Has a description of:

Fracture of femur (disorder) is the fully specified name

Fracture of femur is a preferred term

Fracture of upper leg as synonym

Fracture of thigh as synonym

Is fully defined as:

Is a Fracture of lower limb

Is an injury of thigh

Has a finding sight of bone structure of femur

7. SNOMED CT and HL7 V3 Working Together

Even though the IHTSDO and HL7 had been working informally together for many years, in 2009, the two SDOs formally agreed to work collaboratively on standards development processes. This will promote interoperability by coordinating standards strategies and plans using mutually agreed upon processes.¹⁰

People often have different ways of saying the same thing. By linking synonyms to a single concept, SNOMED CT allows computer systems to recognize the common meaning of synonymous terms. In this way, a healthcare provider can use terms they are accustomed to using, but through synonyms, terms will map back to the same concept. SNOMED CT contains over 310,000 unique concepts and more than 1.3 million links or relationships between them that ensure information is captured consistently, accurately, and reliably. A SNOMED CT expression is a collection of references to one or more concepts to express a clinical idea. A pre-coordinated expression uses a single code, while post-coordinated expressions use two or more codes are usually presented using compositional grammar.¹⁰ For example, post-coordination by qualification makes the meaning of ‘Appendectomy’ qualified by ‘Priority = Emergency’.

Cross mappings are used to reference other terminologies and classifications. Currently, SNOMED CT cross map to ICD-9 CM,⁶⁵ ICD-10,⁶⁶ CPT,⁶⁷ LOINC,⁵⁵ and OPCS.⁶⁸ It supports ANSI, DICOM,⁵⁴ HL7,²⁰ and ISO³⁵ standards.

SNOMED CT was designed to be syntax neutral and HL7 V3 set out to be terminology neutral, each standards developing in parallel. It is now recognized the need for the process of terminology binding,⁶⁹ which binds what is said to how it is said. Terminology binding refers to the association between a data point or a node of an information or data model and the set of terms that can be used to populate that data point's value.

To ensure that H7 V 3 standards achieve interoperability when using concepts from SNOMED CT, HL7 and SNOMED CT committees collaborated on the HL7 Terminfo project in 2006.⁷⁰

The Terminfo project addresses the issue of how best to incorporate SNOMED CT into HL7 V3 message structures, where there is more than one way to do the same task. The Terminfo project has produced a guide for using SNOMED CT concepts in HL7 V3 communication standards.

Because there are multiple ways to express the same meaning and because there is some overlap or conflict between the two standards, the Terminfo guide recommends:

Terminology to be used for:

- Specific concepts and value sets
- Subsets/refsets including navigation hierarchies
- Simple semantic relationships, such as laterality
- Inclusion and exclusion constraints based on the SNOMED CT concept model
- Post coordinated expressions

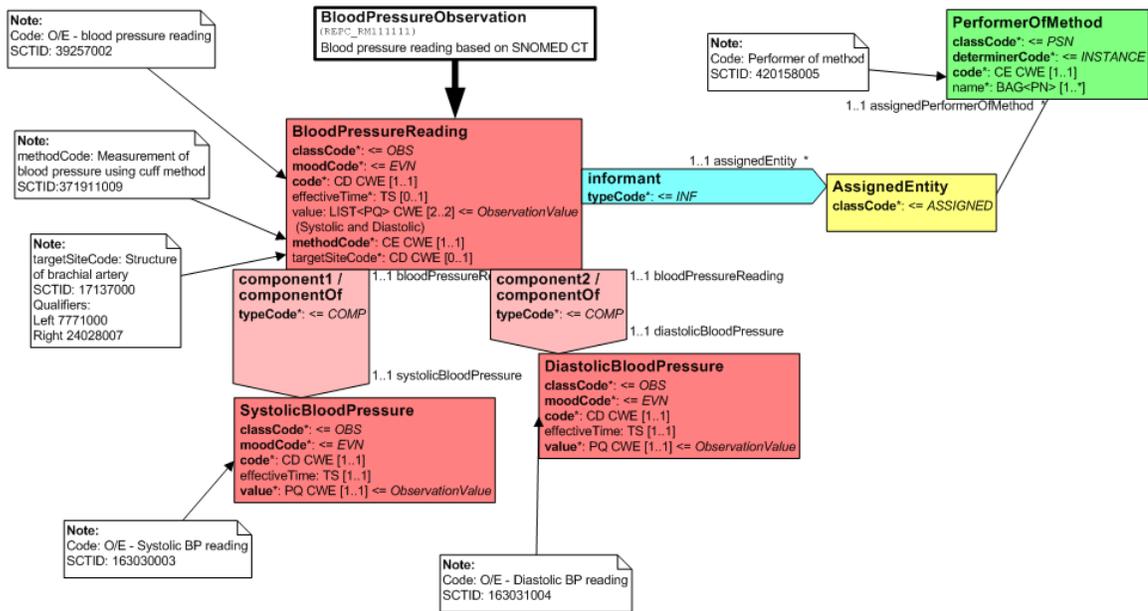
Information model be used for:

- Instance information and meta data for any clinical statement such as dates and times, people and places, numbers and quantities
- Grouping and organization of the record framework
- Differences due to the work processes for a specific use case

Example 1: Adapted from Ryan, A. “Towards Semantic Interoperability in Healthcare: Ontology Mapping from SNOMED CT to HL7 version 3.”⁷¹

Illustrates the technical aspects of mapping a SNOMED CT Concept: Blood Pressure reading and its attributes mapped to HL7 V 3 Reference Information Model where Blood Pressure Reading concept is as an Observation.

Blood Pressure Concept and its attributes from SNOMED-CT represented in HL7

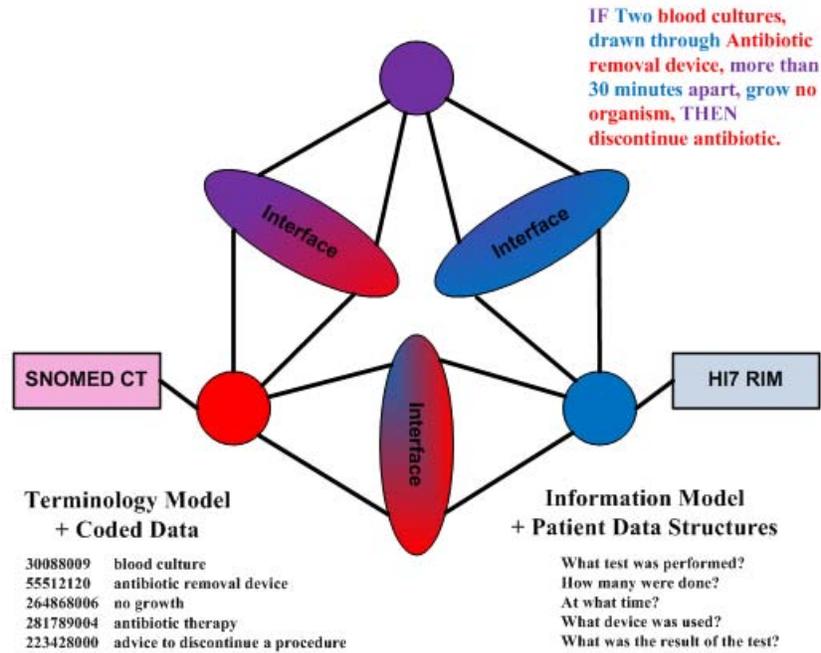


Mapping from SNOMED-CT to HL7 V3

SNOMED-CT		HL7	
Concept	Attribute	Class	Attribute
O/E - blood pressure reading	n/a	Observation	code
Structure of brachial artery	Finding Site	Observation	targetSiteCode
Left	Finding Site - Laterality	Observation	targetSiteCode
Right	Finding Site - Laterality	Observation	targetSiteCode
Measurement of blood pressure using cuff method	Finding method	Observation	methodCode
Performer of method	Finding Informer	Informant	Person::code
O/E - Systolic BP reading	Is a	ComponentOf	Observation::code
O/E - Diastolic BP reading	Is a	ComponentOf	Observation::code

Example 2:

Illustrates SNOMED CT and HL7 V3 messages working together in a Clinical Decision Support Model: Adapted from the International HL7 Interoperability Conference proceedings, 2006.⁷²



8. Domain Analysis Model: Preoperative Anesthesia Assessment

The Project

The IHTSDO: SNOMED CT Anesthesia special interest group (SIG) and HL7 Anesthesia working group (WG), have begun A Domain Analysis Model (DAM) for Preoperative Anesthesia Assessment. A DAM and its artifacts or deliverables are the products of the Domain Analysis Process (DAP) as described in the HL7 Health Development Framework (HDF) ¹ and following.

8.1. Domain Analysis Process (DAP): Analysis and Requirements

“The Health Development Framework (HDF) documents the processes, tools, actors, rules, and artifacts relevant to development of all HL7 standard specifications, not only messaging.” ⁽¹⁾ The Project Life Cycle for Product Development (PLCPD) is a cyclical process flow and presents the HL7 strategy for product or project lifecycle process. The HL 7 standard development starts after a project is approved. The next step consists of analyzing the project requirements indentified in the Domain Analysis Process (DAP). DAP is the analysis step of the Project Life Cycle for Product Development as depicted in Annex 1. Domain Analysis Model (DAM) and its artifacts or deliverables are the products of the Domain Analysis Process and are the basis for HL7 V3 standards specification design. The process is performed by a specific domain work group which can consist of domain experts and business analysts who understand their systems interoperability needs. Both the DAM and the resulting standard rely on UML models and diagrams to manage the contents and to provide views of the information and interactions between systems. The process encourages project teams to focus on the underlying information and process requirements before designing a standard. “A DAM defines what needs to be done, not how to do

it.” (1)The DAM is used to create standard specifications by harmonizing it with HL7 references including the RIM, structural vocabulary, and application roles.

The following will be a high level overview of the Domain Analysis **Process** and artifacts as it relates to the conception of an SNOMED CT and HL7 V3 standard for Preoperative Anesthesia Assessment.

Disclaimer: The project is in its beginning stages and is projected for completion for 3rd quarter 2011. The artifacts or documents specifically relating to the Anesthesia Preoperative Assessment have been provided by project lead: Patricia Gunter. Such artifacts are work in progress and not the finalized documents that will be submitted. I have taken the liberty to include additional images and documents to further explain the DAP. The narrative portion is my own unless otherwise noted.

8.2. Domain Analysis Model for Preoperative Anesthesia Assessment

8.2.1 Introduction

Anesthesia Information Management Systems (AIMS) are electronic records of the analysis of anesthesia care related activities that can include preoperative assessment, intra-op events, and post operative assessments. AIMS can also provide the administrative benefits of billing and anesthesia related charges. A recent study shows an increasing number of AIMS being instituted at US academic anesthesia departments since 2007.² The ability to share electronic health information requires many standard terminologies and standards for communicating the data. As with the usage of clinical terms from other domains, recognized standard preoperative anesthesia assessment terms will promote use and ease of electronic health information exchange between organizations and within organizations. The use of internationally developed consensus standards

will ultimately also have a positive effect on patient safety, support clinical decisions, support quality improvement and provide research data.

In 3rd quarter, 2009, the DAM Preoperative Anesthesia Assessment project scope statement was submitted and approved. The scope statement defines the DAM Preoperative Anesthesia Assessment project, which sets out to develop clinical content standards to enable the seamless interchange of data within and between healthcare information systems. Standard preoperative anesthesia assessment terms will provide secondary data uses like quality improvement, support clinical decisions, and clinical research.

8.2.2 Project Members/Roles:

Project Lead and Modeling Facilitator: Patricia Gunter, Senior Informatist, Duke University

From the IHSTDO Anesthesia SIG and HL7 Anesthesia WG: Volunteer Anesthesia clinician subject matter experts:

Terri Monk, VA Duke University, US
Andrew Norton, UK
Martin Hurrell, UK
Ronald Cornet, Netherlands
Craig Weldon, Duke University, US
Guy Dear, Duke University, US
Heather Fredrick, Duke University, US
Irina Gasanovoa, Southwestern University, US
Stephanie Byerly, Southwestern University, US
Ellen Torres, Kaiser Permanente, US

Collaborating Groups:

Anesthesia Patient Safety Foundation (APSF)
International Organization for Terminology in Anesthesia (IOTA)
Society for Technology in Anesthesia (STA)
International Health Terminology Standards Organization (IHTSDO)
Society for Computing and Technology in Anesthesia (SCATA)
Association for Paediatric Anaesthetists (APA)

8.2.3 Project Work Process

Work meetings are accomplished through an on-line web conferencing tool, usually in 2 hour blocks. Due to the inherent difficulties in anesthesia clinicians' schedules, there is no set meeting schedule. Meeting times are worked out to fit the schedule of the majority. Consistent with HL7 and SNOMED standards development, decisions are by consensus.

8.2.4 Scope: (from HL7 Project Scope Statement)

The goal of the DAM Preoperative Anesthesia Assessment Project is to support the exchange and understanding of anesthesiology data by establishing standard definitions and values for common anesthesiology data elements. In addition to clinicians, this standardization will also be beneficial to groups and organizations devoted to quality, research, health insurance, standards development, and electronic medical records. Much work has been done in the area of anesthesiology terminology classification, and this project will seek to build upon and further enhance that work.

The first release of the DAM Preoperative Anesthesia Assessment Project will focus on the clinical content that is common to all preoperative evaluations, both pediatric and adult. With substantial input from anesthesiologists, the team will create use cases and an activity diagram to identify the data that are routinely collected during the preoperative evaluation process. It will document those data elements, define them, and define the sets of permissible values, where appropriate. Finally, the team will create the UML class model to show how those data are tied together. The class model will not tie back to the RIM at this point in time. Later releases of the DAM Preoperative Anesthesia Assessment Project will address those areas that are specific to pediatrics and specific to adult perioperative anesthesia care.

8.3. Domain Analysis Modeling (DAM) artifacts:

- *In HL7, artifacts are documents that are results of analysis.*

--Note: Artifact descriptions are from the HL7 HDF unless otherwise noted.

8.3.1 Storyboard

- *A storyboard is narrative description of a series of steps involving the exchange of information between participants to achieve the objectives of the healthcare process.*

8.3.2 Use Cases

- *Use case analysis identifies communication interactions and integration scenarios the project is intended to support. Use cases illustrated in the storyboards identifies the actors participating in the use case, pre-conditions, flow of events, post conditions, and the events or interactions.*

Anesthesia Preoperative Assessment Use Case Overview

(Project artifact: Patricia Gunter, author)

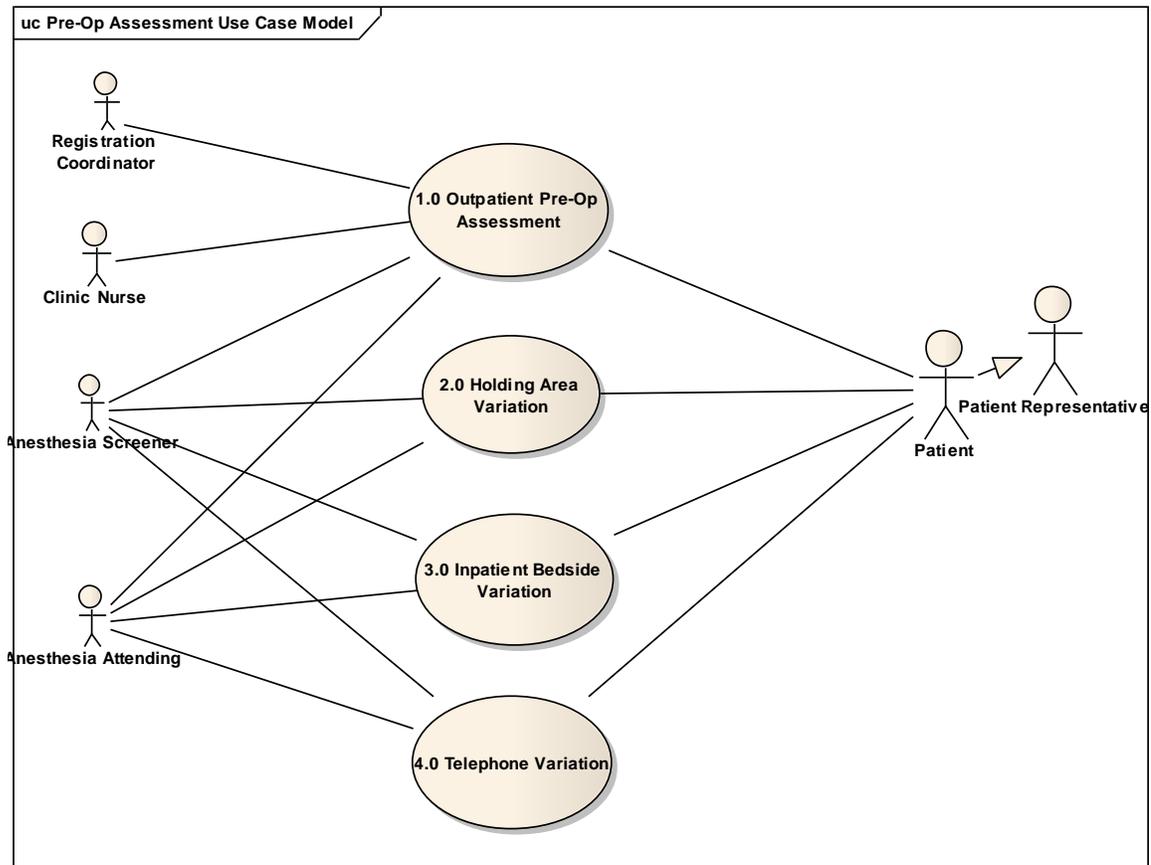
There are four basic use cases that describe the different processes for conducting a pre-operative anesthesia assessment. They are very similar, and are based primarily upon the physical location of the patient and the timeframe of the assessment. The actual location and sequence of events is not significant, but rather the information that is being collected. The use cases are a tool to help assure that all data that is relevant is accounted for.

Other use cases showing slight variations could have been defined. There may be additional venues for conducting assessments, and the sequence of events may differ slightly. Use case 2 described in Annex 2, for example, includes the scenario in which the patient is unable to sign the consent. It is not included in the other use cases, but that could certainly occur. Another example is the use of an interpreter. An interpreter may be involved in any of the assessment scenarios,

but creating separate use cases or alternate flows would not add value since the only data that is collected is the interpreter's name. The fact that the interpreter has been identified as a potential actor is sufficient.

The uses cases here represent the "usual" clinical scenarios. The important point is that the list of data elements identified is comprehensive enough to cover the less routine scenarios.

Figure 8.3.2.a: High Level Use Case Diagram



USE CASE 1 OUTPATIENT CLINIC PRE-OPERATIVE ASSESSMENT (project artifact: Patricia Gunter, author)

1. Use Case Name: Outpatient Clinic Pre-operative Assessment

1.1. Goals

- 1.1.1. Perform pre-operative history and physical
- 1.1.2. Perform necessary pre-operative labs, studies, and consults
- 1.1.3. Provide pre-operative teaching
- 1.1.4. Discuss anesthesia techniques
- 1.1.5. Obtain signed consent

1.2. Textual Description (Storyboard)

This use case describes a pre-operative anesthesia assessment that is done in an outpatient clinic setting; specifically, the clinic is staffed by providers with experience in pre-anesthesia assessment who have the experience to discuss anesthesia techniques and obtain anesthesia consent. The attending in this setting is an anesthesiologist or other doctor familiar with the issues of pre-anesthesia assessment.

This scenario begins when the patient is scheduled for surgery or a procedure that requires anesthesia, and the surgeon/proceduralist has requested a pre-operative anesthesia assessment prior to the surgery.

The patient arrives for the pre-operative anesthesia assessment, possibly accompanied by a surrogate (family member, friend, co-worker, etc) or a legal representative (parent, guardian, power of attorney, or healthcare proxy). The surrogate and legal representative may or may not be the same person. The surrogate may provide information in the event that the patient is unable to do so, but is not legally able to give consent. A legal representative may do both.

The patient registers at the front desk and receives a copy of the pre-op questionnaire to complete. If he/she is unable to complete the form, the surrogate or legal representative may complete the form. A staff person may also assist in the completion of the form, and/or a registered interpreter may be asked to assist throughout the process. The completed form goes into the patient's medical record. A clinic nurse calls the patient back and takes vital signs. A pre-op screener (usually a PNP or PA) sees the patient next to complete a history and physical. The screener will provide educational information to the patient and/or the surrogate/legal representative, and if the patient's medical condition warrants, will refer the patient for a specialty consult (e.g. cardiology). The screener also may order pre-op labs and tests or request additional records. The screener enters the information into the pre-op assessment system either via a paper or electronic form.

The screener will also discuss anesthesia options with the patient and/or surrogate/legal representative, and consent is signed. If the patient is unable to sign the consent, and a legal representative is not available, the screener attempts to contact the legal representative over the phone to obtain phone consent. If the legal representative is found, and verbal consent is given, the consent is signed by the physician and a witness. If the legal representative is not found, and the surgery is not urgent, the surgery will be postponed until consent can be obtained.

If needed, the screener reviews the assessment with the anesthesia attending. The attending may request additional information, labs, tests, or services. The attending then approves and signs the pre-op assessment. In the event that the record cannot be signed by the pre-op clinic attending, the assessment will be signed on the day of surgery by the anesthesiologist taking care of the patient.

1.3. Actors

1.3.1.Primary:

- 1.3.1.1. Patient
- 1.3.1.2. Clinic Nurse
- 1.3.1.3. Screener (Prescribing-Level Pre-op Provider PNP/PA)

1.3.2.Secondary:

- 1.3.2.1. Registration Coordinator
- 1.3.2.2. Attending

1.3.3.Optional:

- 1.3.3.1. Patient surrogate
- 1.3.3.2. Patient legal representative
- 1.3.3.3. Technician (lab, EKG, X-ray, etc.)
- 1.3.3.4. Specialist (including Blood Conservationist and
- 1.3.3.5. External Healthcare Entity
- 1.3.3.6. Interpreter
- 1.3.3.7. Consent Witness

2. Basic Flow

2.1. Register the Patient

2.1.1. Actors

- 2.1.1.1. Patient
- 2.1.1.2. Registration Coordinator

2.1.2.Steps

The patient arrives at the clinic

- 2.1.2.1. The patient is given a paper pre-op questionnaire to complete

2.2. Obtain Vitals

2.2.1. Actors

- 2.2.1.1. Clinic Nurse
- 2.2.1.2. Patient

2.2.2.Steps

- 2.2.2.1. The patient is called back by the clinic nurse
- 2.2.2.2. The clinic nurse takes vital signs and records the results in the pre-op assessment

2.3. Complete the pre-operative H & P

2.3.1. Actors

2.3.1.1. Screener

2.3.1.2. Patient

2.3.2. Steps

2.3.2.1. The screener receives information from the patient about the current health status of the patient, as well as the patient's medical history and the patient's family medical history

2.3.2.2. The screener records the information in the electronic pre-op record

2.3.2.3. The screener provides pre-operative education to the patient

2.4. Obtain consent

2.4.1. Actors

2.4.1.1. Screener

2.4.1.2. Patient

2.4.2. Steps

2.4.2.1. The screener discusses the various anesthesia techniques and options with the patient

2.4.2.2. The patient signs the anesthesia consent form

2.5. Review the pre-op assessment

2.5.1. Actors

2.5.1.1. Screener

2.5.1.2. Anesthesia Attending

2.5.2. Steps

2.5.2.1. The screener reviews the pre-op assessment with the attending

2.5.2.2. The attending signs the pre-op assessment

3. Alternate Flows

3.1. Order labs and studies

3.1.1. Actors

3.1.1.1. Screener or attending

3.1.1.2. Technician

3.1.1.3. Patient

3.1.2. Steps

3.1.2.1. The screener or attending decide that there is a need for additional tests or studies

3.1.2.2. The technician performs the tests and the results become part of the pre-op assessment

3.2. Refer patient to a specialist for a consult

3.2.1. Actors

3.2.1.1. Screener

3.2.1.2. Specialist

3.2.1.3. Patient

3.2.2.Steps

- 3.2.2.1. The screener decides to refer the patient to a specialist
- 3.2.2.2. The specialist sees the patient and provides a report
- 3.2.2.3. The specialist report becomes part of the patient's medical record and/or pre-op assessment

3.3. Request for Additional Records

3.3.1. Actors

- 3.3.1.1. Clinic Nurse or Screener
- 3.3.1.2. Patient
- 3.3.1.3. External Healthcare Entity

3.3.2. Steps

- 3.3.2.1. The screener or attending decide that additional information is needed from external records

- 3.3.2.2. The clinic nurse or screener obtain written consent from the Patient to obtain the records

- 3.3.2.3. Information from the external records are received from the external healthcare entity, and become part of the patient's medical record and/or assessment

3.4. Patient surrogate acts on behalf of the patient

3.4.1. Register the patient

3.4.1.1. Actors

- 3.4.1.1.1. Patient surrogate
- 3.4.1.1.2. Registration Coordinator

3.4.2. Complete the pre-operative H & P

3.4.3. Steps

- The patient arrives at the clinic, accompanied by a surrogate

- 3.4.3.1. The surrogate is given a paper pre-op questionnaire to complete

3.5. Patient legal representative (including the parent of a minor child) acts on behalf of the patient

3.5.1. Register the patient

3.5.1.1. Actors

- 3.5.1.1.1. Patient legal representative
- 3.5.1.1.2. Registration Coordinator

3.5.2. Complete the pre-operative H & P

3.5.2.1. Steps

- 3.5.2.1.1. The patient arrives at the clinic, accompanied by a legal representative

- 3.5.2.1.2. The legal representative is given a paper pre-op questionnaire to complete

3.5.3. Obtain written consent from legal representative

3.5.3.1. Actors

- 3.5.3.1.1. Screener
- 3.5.3.1.2. Patient legal representative

3.5.3.2. Steps

3.5.3.2.1. The screener discusses the various anesthesia techniques and options with the patient legal representative

3.5.3.2.2. The patient legal representative signs the anesthesia consent form

3.5.4. Obtain phone consent

3.5.4.1. Actors

3.5.4.1.1. Screener

3.5.4.1.2. Patient legal representative

3.5.4.1.3. Anesthesia Attending

3.5.4.1.4. Consent witness

3.5.4.2. Steps

3.5.4.2.1. The screener discusses the various anesthesia techniques and options with the patient legal representative over the phone

3.5.4.2.2. The patient legal representative gives verbal consent for the anesthesia

3.5.4.2.3. the witness sign the consent form

3.5.5. Request for Additional Records with legal representative consent

3.5.5.1. Actors

3.5.5.1.1. Clinic Nurse or Screener

3.5.5.1.2. Legal Representative

3.5.5.1.3. External Healthcare Entity

3.5.5.2. Steps

3.5.5.2.1. The screener or attending decides that additional information is needed from external records

3.5.5.2.2. The clinic nurse or screener obtains written consent from the legal representative to obtain the records

3.5.5.2.3. Information from the external records are received from the external healthcare entity, and become part of the patient's medical record and/or assessment

4. Special Requirements

No special requirements have been specified for this use case.

5. Preconditions

5.1. Surgeon schedules patient for surgery

5.2. Surgeon refers patient to outpatient screening clinic

5.3. The patient has a valid MRN

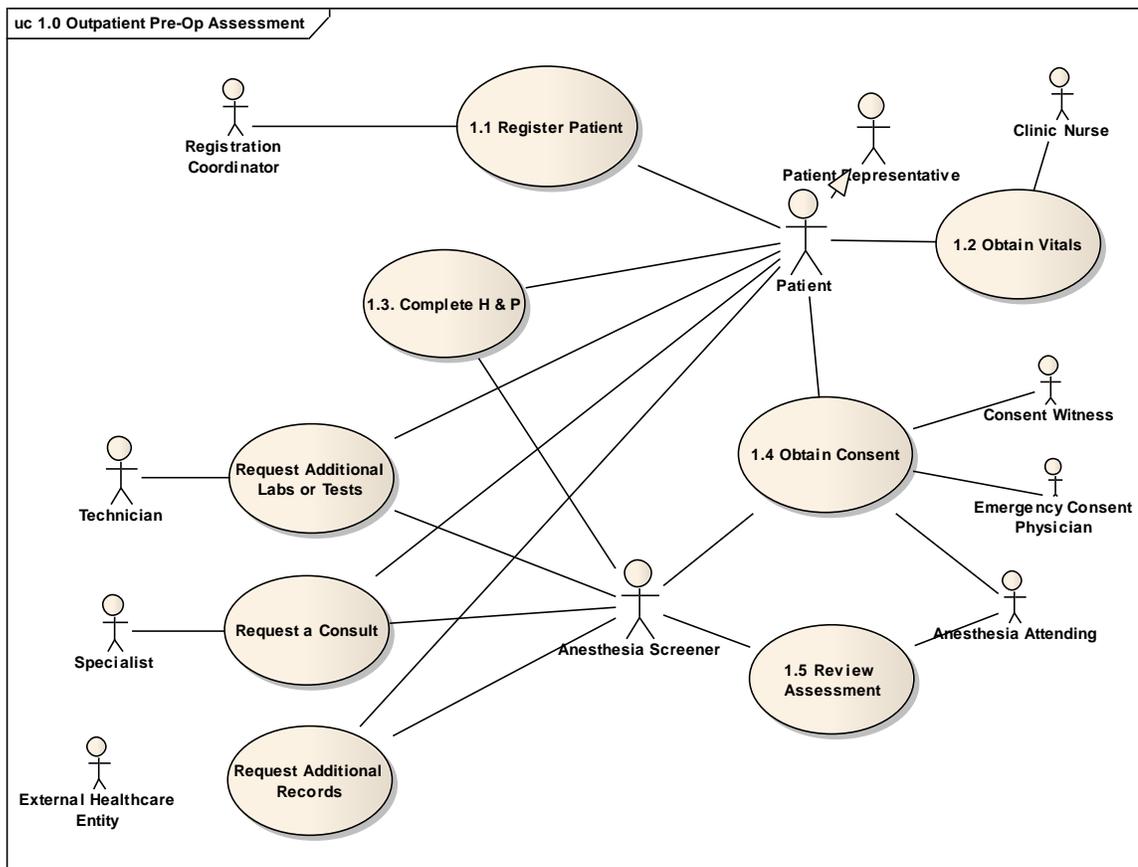
6. Postconditions

- 6.1. Pre-operative history and physical is complete
- 6.2. Pre-operative labs, studies, and consults have been obtained if needed
- 6.3. Pre-operative teaching has been provided to patient and parent/guardian
- 6.4. Anesthesia techniques have been discussed with patient and/or legal representative
- 6.5. Signed consent has been obtained

7. Extension Points

There are no extension points associated with this use case

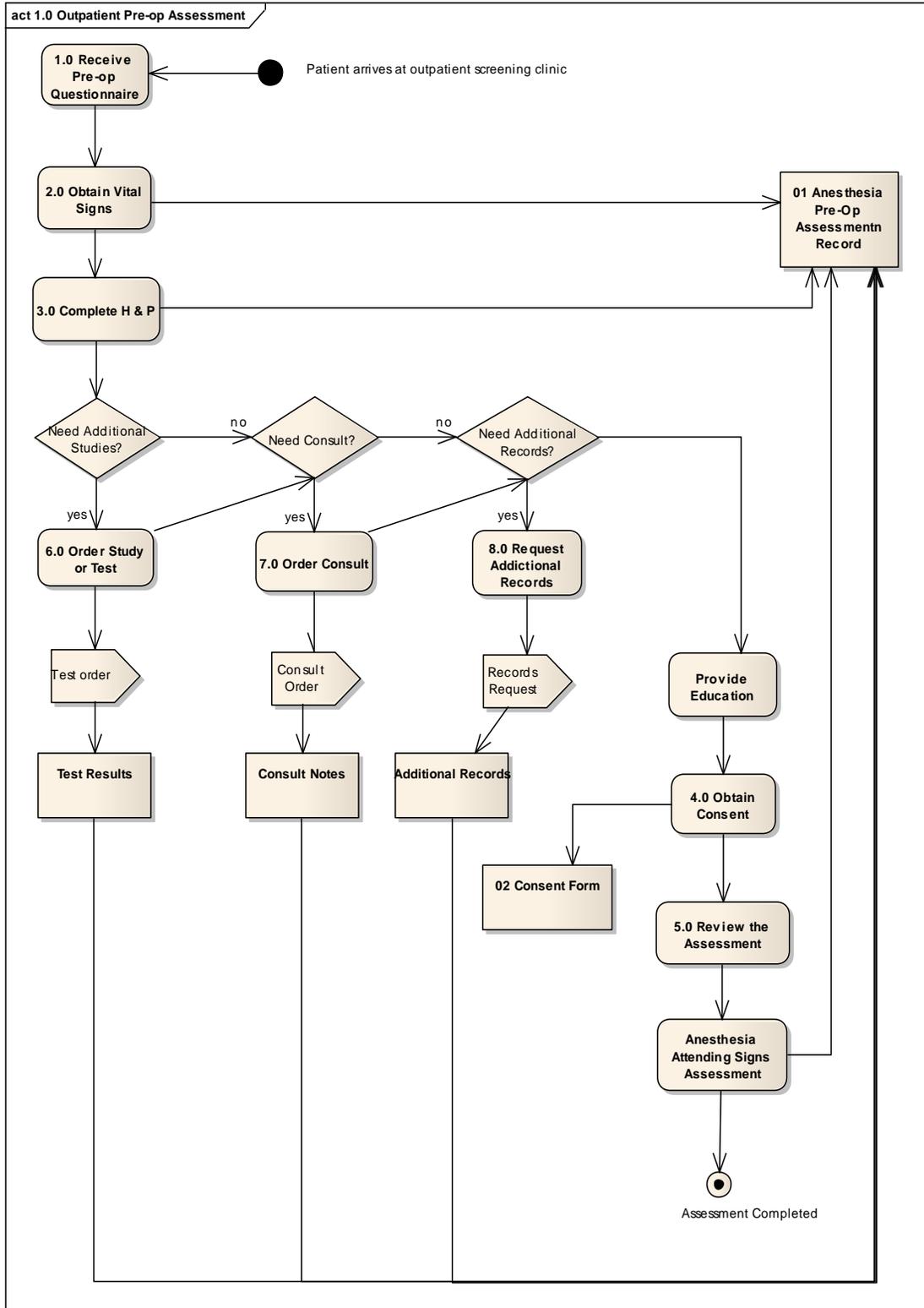
Figure 8.3.2.b: Detailed Use Case Diagram



8.3.3 Process Flow

- *While the Class diagram depicts the static view of the domain, the process flow represents a dynamic aspect of the domain in an Activity Diagram. It depicts the clinical process included in the domain. An activity diagram can identify the step by step sequence of information that is passed from one actor to another and can be depicted in a “Swim-Lane Diagram.” The exact sequence is inconsequential in an anesthesia preoperative assessment.*

Figure 8.3.3: Outpatient Preoperative Anesthesia Assessment Activity Diagram



8.3.4 Data Elements

- *Data elements are a unit a data that has precise meaning. It has a data element name, definition, representative terms, and can have code attached.*

Because it is important to start with what already existed, each member was asked to submit from their organization: anesthesia preoperative questionnaires that patients filled out that were either electronic or paper and anesthesia preoperative evaluation guidelines that were either electronic or paper. The domain is thought to be well represented with submissions from the Netherlands, United Kingdom, Duke University, Veterans' Administration Hospital, and from Kaiser Permanente Anesthesia National Build. From the submissions a master set of data elements that are currently being evaluated for scope and relevancy by the group. The resulting list will be categorized and the group will define by consensus the clinical definitions and permissible values for those data elements.

8.3.5 Glossary of Terms

- *Glossary for the DAM focuses on concepts of the domain analysis and their attributes. Some of the concepts in the glossary may also appear as classes or attributes in the information model.*

e.g.:

A. Substitute Decision Maker:

A person who is authorized under legislation to consent on behalf of the client to the collection, use or disclosure of protected information about the client/patient.

B. Patient:

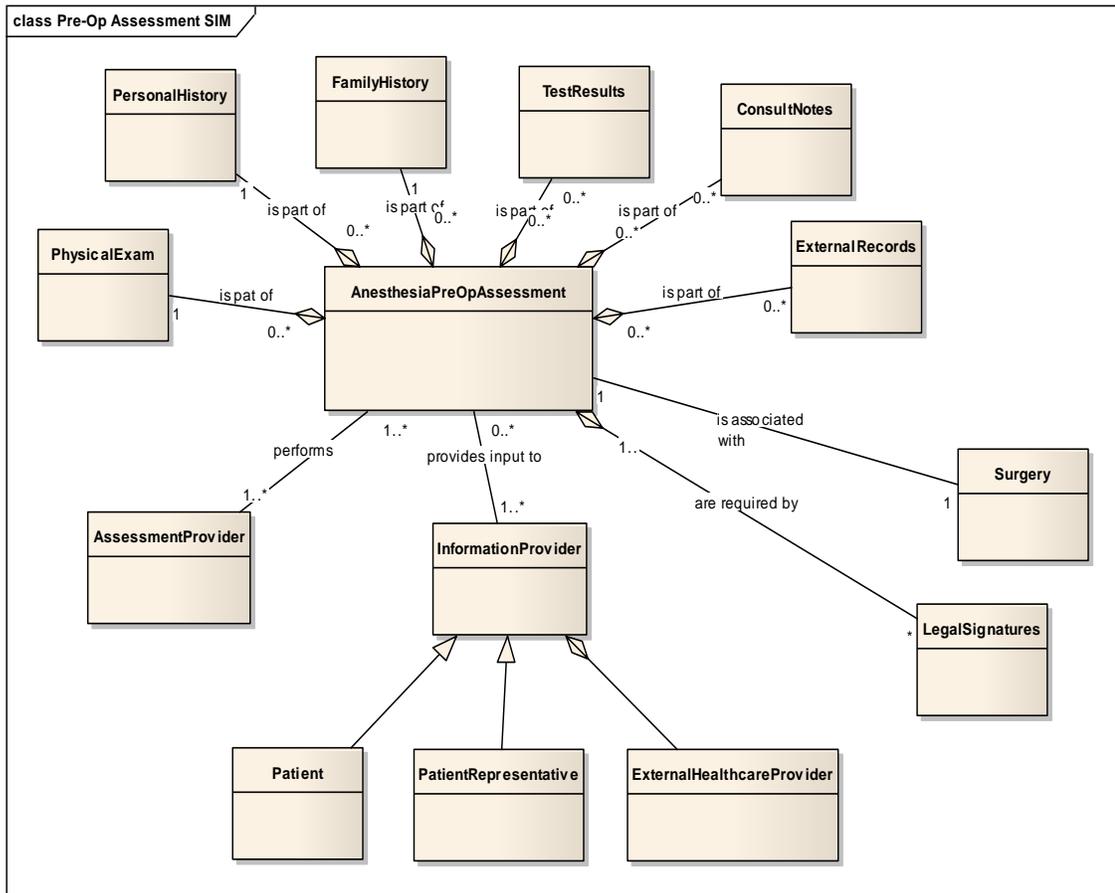
A role played by a living subject as a recipient or potential recipient of healthcare services from a healthcare provider Organization.

Attribute	Notes
firstname String Public	A non-unique textual identifier or moniker of a person. This is usually the given name for a person.
lastname String Public	A non-unique textual identifier or moniker of a person. This is usually the family name for a person.
midinitials String Public	The first letters of the person's middle name.
affiliation String Public	Organizational affiliation for a person. Examples: Hospitals Sponsor companies

8.3.6 Class Diagram

- The class diagram is the main building block of object orient modeling. It is a static model of the domain, in this case, Anesthesia Preoperative Assessment, by showing the classes, attributes, and relationships between the classes. Class models can be created at different levels of detail. A high level class model would describe the categories of data in a domain. However, class models for automated code generation and for communicating computable metadata are modeled at a granular level. A completed class diagram is itself a RIM for that class.*

Figure 8.3.6: A high level Anesthesia Preoperative Assessment Class diagram. All classes required have not yet been identified. Each data element will be placed in the appropriate class. Additional classes may be identified.



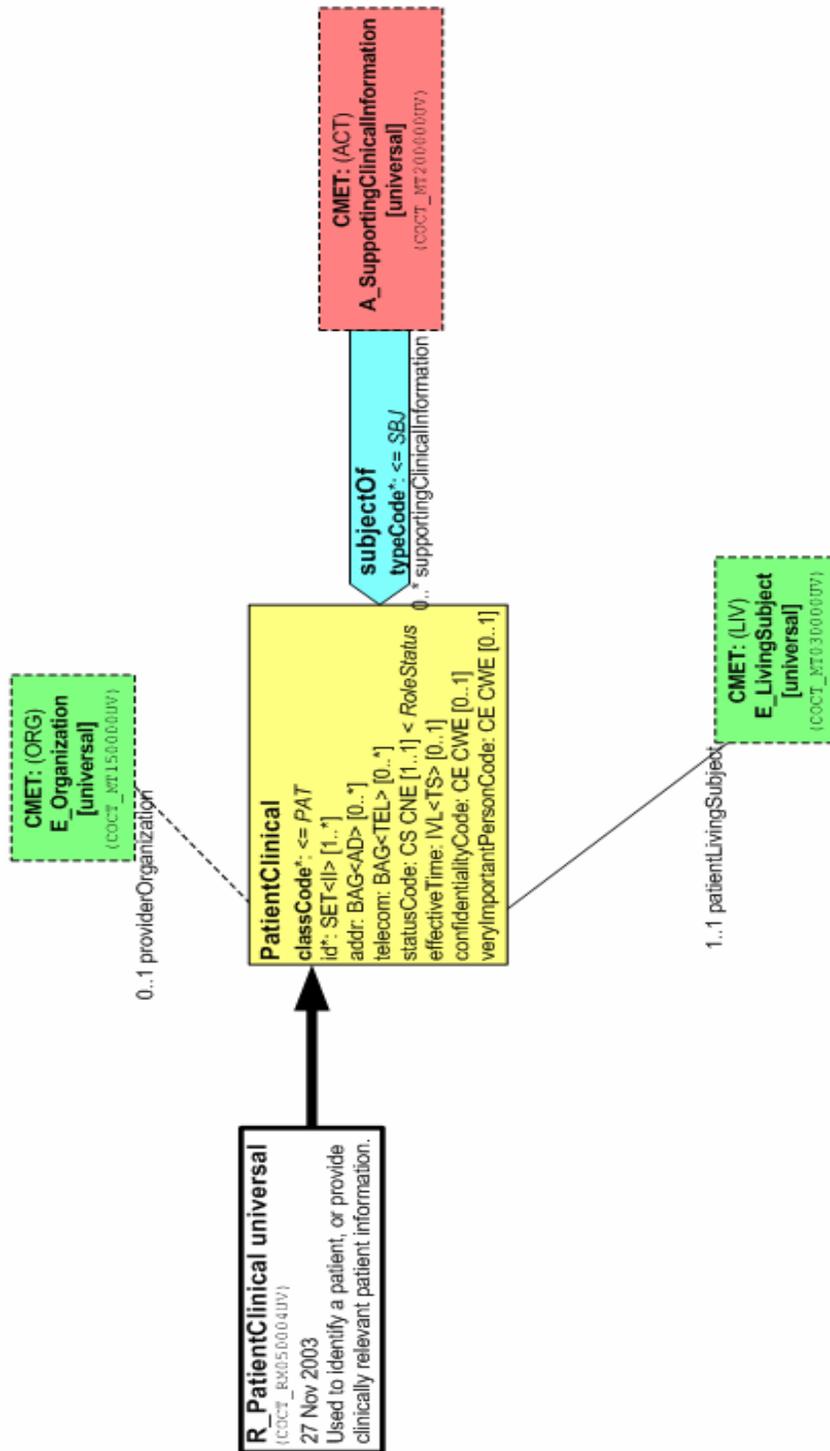
8.3.4 Common Message Element Types (CMET) ³

--Note: I have added this description and images to alert the reader of CMETs potential usage.

- *CMETs are pre-defined components or classes that are reused for several RIMs and/or messages. Each CMET has its own corresponding RIM diagram with the color of the box being determined by the color of their base class (pink for Acts, yellow for Roles, green for Entities). Most CMETs are standards. In HL7 V3, there is the domain of 'Shared Messages.' Shared Messages include CMETs or common data elements shared by all the clinical domains. CMETs can be used for any class in which the CMET attributes fulfill the attributes for the class you are defining, in this way providing for consistency for common classes. For example, for the patient class in the domain Anesthesia Preoperative Assessment above, we may use the CMET: R_PatientClinical universal (COCT_RM050004UV01) which is similar to R_Patient Universal, except that it adds a participation to allow for supporting clinical information. There are also other CMET associations to allow for other supporting information, such as E_LivingSubject universal.*

Figure 8.3.4 R_PatientClinical universal (COCT_RM050004UV01)

---Corresponding hierarchical message description and XML message can be found in Anesthesia Preoperative Assessment Project Annex 3 and 4



8.4. Future Work

Future work consists of:

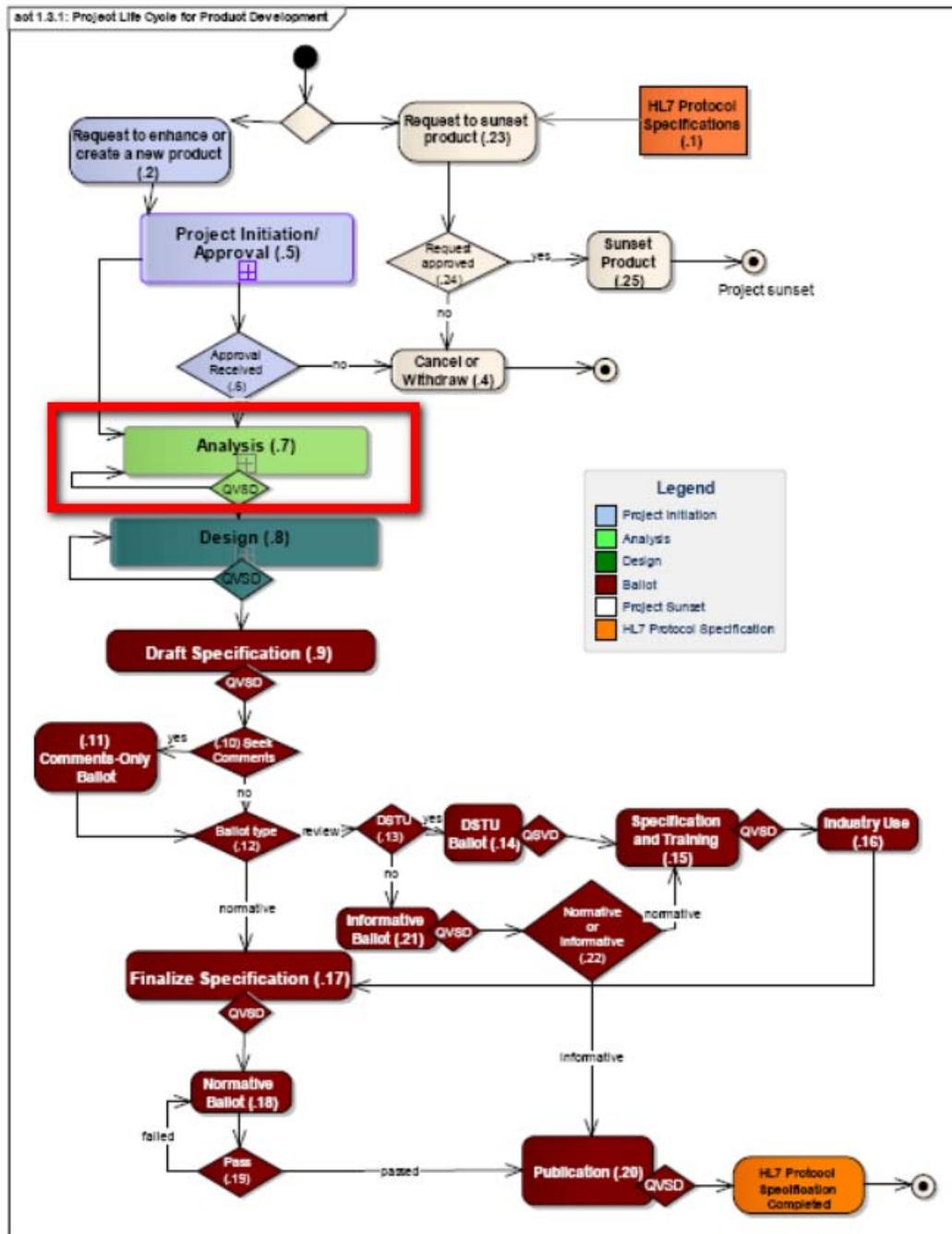
- Continued evaluation of the list of data elements for scope and relevancy.
- Defining data elements which require definitions with assignment of permissible values.
- Mapping of the data elements to SNOMED CT and International Organization for Terminology in Anesthesia (IOTA).

References

1. Singureanu I. Health Level 7. [Online]. 2010 [cited 2010 April 12]. Available from: <http://gforge.hl7.org/gf/project/hdf/frs/>.
2. Egger Halbies C. Adoption of anesthesia information management systems by academic departments in the United States. *Anes Anal.* 2008;107(4).
3. Health Level Seven International. [Online]. 2010 [cited 2010 April 10]. Available from: <http://www.hl7.org/index.cfm>.

Annex 1

Project Life Cycle for Product Development (1): Analysis process highlighted



Annex 2

USE CASE 2 HOLDING AREA PRE-OPERATIVE ANESTHESIA ASSESSMENT

(Project artifact: Patricia Gunter, author)

1. Use Case Name: Holding Area Pre-operative Anesthesia Assessment

1.1. Goals

- 1.1.1. Review patient history and perform pre-operative physical examination
- 1.1.2. Obtain necessary pre-operative labs, studies, and consults
- 1.1.3. Provide pre-operative teaching
- 1.1.4. Discuss anesthesia techniques
- 1.1.5. Obtain signed consent

1.2. Textual Description (Storyboard)

This use case describes a pre-operative anesthesia assessment that is done for a patient just prior to surgery in the pre-op holding area. There are three scenarios in which this type of assessment may occur. 1) The patient is checking in for scheduled surgery and did not have an assessment done ahead of time, 2) the patient is coming from the emergency department or directly from the surgeon's office, and is having unscheduled surgery, or 3) the patient is an inpatient who has not had a bedside anesthesia assessment done.

The patient arrives in the pre-operative holding area. If the patient is unable to participate fully in the assessment, a surrogate (family member, friend, co-worker, etc.) or legal representative (parent, guardian, power of attorney, or healthcare proxy) may also be present to provide information. The surrogate and legal representative may or may not be the same person. The surrogate may provide information in the event that the patient is unable to do so, but is not legally able to give consent.

The pre-op holding nurse checks the patient in and obtains a set of vital signs. The pre-op screener (usually a resident or CRNA) obtains an abbreviated medical history from the patient, and obtains a signature from the patient consenting to the anesthesia. The screener provides educational information to the patient, and if needed, orders additional labs and tests. Rarely in this scenario the screener may order specialty consults or request additional records. The screener discusses anesthesia techniques with the patient and obtains a signed consent. If the patient or legal representative are both unable to sign the consent and the surgery is urgent, the attending and a second physician may sign the consent.

Finally, the screener enters the information into the pre-op assessment either via the paper or electronic form.

1.3. Actors

1.3.1.Primary:

- 1.3.1.1. Patient
- 1.3.1.2. Pre-op Holding Nurse
- 1.3.1.3. Screener (i.e. anesthesia resident or CRNA)

1.3.2.Optional

- 1.3.2.1. Patient surrogate
- 1.3.2.2. Patient legal representative
- 1.3.2.3. Specialists
- 1.3.2.4. Technician (lab, EKG, X-ray, etc.)

2. Basic Flow

2.1. Check the Patient into the Pre-Op Holding area

2.1.1. Actors

- 2.1.1.1. Pre-op holding nurse
- 2.1.1.2. Patient

2.1.2. Steps

- 2.1.2.1. The patient arrives in the pre-op holding area
- 2.1.2.2. The pre-op nurse checks the patient in
- 2.1.2.3. The pre-op holding nurse obtains vitals signs from the patient

2.2. Collect History on the Patient

2.2.1. Actors

- 2.2.1.1. Screener
- 2.2.1.2. Patient

2.2.2. Steps

- 2.2.2.1. The screener receives information from the patient about the current health status of the patient, as well as the patient's medical history and the patient's

family medical history

- 2.2.2.2. The screener records the information in the pre-op assessment system
- 2.2.2.3. The screener provides pre-operative education to the patient

2.3. Obtain consent

2.3.1. Actors

- 2.3.1.1. Screener
- 2.3.1.2. Patient

2.3.2. Steps

- 2.3.2.1. The screener discusses the various anesthesia techniques and options with the patient

- 2.3.2.2. The patient signs the anesthesia consent form

3. Alternate Flows

3.1. Order labs and studies

3.1.1. Actors

- 3.1.1.1. Screener or Attending
- 3.1.1.2. Technician

- 3.1.1.3. Patient
- 3.1.2.Steps
 - 3.1.2.1. The screener or attending decide that there is a need for additional tests or studies
 - 3.1.2.2. The technician performs the tests and the results become part of the pre-op record
- 3.2. Refer patient to a specialist for a consult
 - 3.2.1. Actors
 - 3.2.1.1. Screener
 - 3.2.1.2. Specialist
 - 3.2.1.3. Patient
 - 3.2.2.Steps
 - 3.2.2.1. The screener decides to refer the patient to a specialist
 - 3.2.2.2. The specialist sees the patient and provides a report
 - 3.2.2.3. The specialist report becomes part of the pre-op record
- 3.3. Request for Additional Records
 - 3.3.1. Actors
 - 3.3.1.1. Screener
 - 3.3.1.2. Patient
 - 3.3.2. Steps
 - 3.3.2.1. The screener or attending decide that additional information is needed from external records
 - 3.3.2.2. The screener obtain written consent from the patient to obtain the records
 - 3.3.2.3. Information from the external records become part of the pre-op record
 - 3.3.3. Emergency consent
 - 3.3.3.1. Actors
 - 3.3.3.1.1. Screener
 - 3.3.3.1.2. Anesthesia Attending
 - 3.3.3.1.3. Emergency 2nd Physician
 - 3.3.3.2. Steps
 - 3.3.3.2.1. The screener is unable to contact a legal representative for the patient
 - 3.3.3.2.2. The attending and the emergency 2nd physician sign the consent form
- 3.4. Surrogate acts on behalf of the patient
 - 3.4.1. Collect History on the Patient
 - 3.4.1.1. Actors
 - 3.4.1.1.1. Pre-op holding nurse
 - 3.4.1.1.2. Patient surrogate
 - 3.4.1.2. Steps
 - 3.4.1.2.1. The screener receives information from the patient surrogate about the current health status of the patient, as well as the patient's medical history and the patient's family medical history

- 3.4.1.2.2. The screener records the information in the pre-op assessment system
- 3.4.1.2.3. The screener provides pre-operative education to the patient surrogate
- 3.5. Patient legal representative acts on behalf of the patient
 - 3.5.1. Collect History on the Patient
 - 3.5.1.1. Actors
 - 3.5.1.1.1. Pre-op holding nurse
 - 3.5.1.1.2. Patient legal representative
 - 3.5.1.2. Steps
 - 3.5.1.2.1. The screener receives information from the legal representative about the current health status of the patient, as well as the patient's medical history and the patient's family medical history
 - 3.5.1.2.2. The screener records the information in the pre-op assessment system
 - 3.5.1.2.3. The screener provides pre-operative education to the legal representative
 - 3.5.2. Obtain consent
 - 3.5.2.1. Actors
 - 3.5.2.1.1. Screener
 - 3.5.2.1.2. Patient legal representative
 - 3.5.2.2. Steps
 - 3.5.2.2.1. The screener discusses the various anesthesia techniques and options with the
 - 3.5.2.2.1.1.1.1.1. legal representative
 - 3.5.2.2.2. The legal representative signs the anesthesia consent form
 - 3.5.3. Request for Additional Records with legal representative consent
 - 3.5.3.1. Actors
 - 3.5.3.1.1. Screener
 - 3.5.3.1.2. Patient's legal representative
 - 3.5.3.2. Steps
 - 3.5.3.2.1. The screener or attending decide that additional information is needed from external
 - 3.5.3.2.1.1.1.1.1. records
 - 3.5.3.2.2. The screener obtain written consent from the legal representative to obtain the
 - 3.5.3.2.2.1.1.1.1.1. records
 - 3.5.3.2.3. Information from the external records become part of the pre-op record

4. Special Requirements

No special requirements have been specified for this use case.

5. Preconditions

- 5.1. Surgeon schedules patient for surgery
- 5.2. No outpatient or bedside per-op assessment has been done
- 5.3. The patient has a valid MRN

6. Postconditions

- 6.1. Pre-operative history is complete
- 6.2. Pre-operative labs, studies, and consults have been obtained if needed
- 6.3. Pre-operative teaching has been provided to patient, surrogate, or legal representative
- 6.4. Anesthesia techniques have been discussed with patient, surrogate, or legal representative
- 6.5. Signed consent has been obtained

7. Extension Points

There are no extension points associated with this use case

Annex 3

Base hierarchical message description for R_PatientClinical universal (COCT_RM050004UV01)

COCT_HD050004UV01 R_PatientClinical universal	(Link to Excel View) Derived from RMIM: COCT_RM050004UV01
PatientClinical	
classCode [1..1] (M) Patient (CS) {CNE:V: RoleClassPatient , root="PAT"}	
id [1..*] Patient (SET<II>)	
addr [0..*] Patient (BAG<AD>)	
telecom [0..*] Patient (BAG<TEL>)	
statusCode [1..1] Patient (CS) {CNE:D: RoleStatus }	
effectiveTime [0..1] Patient (IVL<TS>)	
confidentialityCode [0..1] Patient (CE) {CWE:D: Confidentiality }	
veryImportantPersonCode [0..1] Patient (CE) {CWE:D: PatientImportance }	
<i>patientEntityChoiceSubject</i> [1..1] (E_LivingSubjectUniversal)	
<i>providerOrganization</i> [0..1] (E_OrganizationUniversal)	
<i>subjectOf</i> [0..*] (Subject)	
Subject	
typeCode [1..1] (M) Participation (CS) {CNE:V: ParticipationTargetSubject , root="SBJ"}	
<i>actChoice</i> [1..1] (A_SupportingClinicalInformationUniversal)	

Annex 4

5.2 Corresponding XML message for R_PatientClinical universal (COCT_RM050004UV01)

```
<xs:annotation>
  <xs:documentation>Generated using schema builder version 3.3.2b. Stylesheets:
  StaticMifToXsd.xsl version 2.0</xs:documentation>
</xs:annotation>
<xs:include schemaLocation="../coreschemas/infrastructureRoot.xsd"/>
<xs:include schemaLocation="COCT_MT030000UV08.xsd"/>
<xs:include schemaLocation="COCT_MT150000UV02.xsd"/>
<xs:include schemaLocation="COCT_MT200000UV01.xsd"/>
<xs:include schemaLocation="COCT_MT120300UV.xsd"/>
<xs:include schemaLocation="COCT_MT120100UV.xsd"/>
<xs:include schemaLocation="COCT_MT120500UV.xsd"/>
<xs:complexType name="COCT_MT050004UV01.PatientClinical">
  <xs:sequence>
    <xs:group ref="InfrastructureRootElements"/>
    <xs:element name="id" type="II" minOccurs="1" maxOccurs="unbounded"/>
    <xs:element name="addr" type="AD" minOccurs="0" maxOccurs="unbounded"/>
    <xs:element name="telecom" type="TEL" minOccurs="0" maxOccurs="unbounded"/>
    <xs:element name="statusCode" type="CS" minOccurs="1" maxOccurs="1"/>
    <xs:element name="effectiveTime" type="IVL_TS" minOccurs="0" maxOccurs="1"/>
    <xs:element name="confidentialityCode" type="CE" minOccurs="0" maxOccurs="1"/>
    <xs:element name="veryImportantPersonCode" type="CE" minOccurs="0"
maxOccurs="1"/>
    <xs:choice>
      <xs:element name="patientPerson" type="COCT_MT030000UV08.Person"
nillable="true" minOccurs="1" maxOccurs="1"/>
      <xs:element name="patientNonPersonLivingSubject"
type="COCT_MT030000UV08.NonPersonLivingSubject" nillable="true" minOccurs="1"
maxOccurs="1"/>
    </xs:choice>
    <xs:element name="providerOrganization" type="COCT_MT150000UV02.Organization"
nillable="true" minOccurs="0" maxOccurs="1"/>
    <xs:element name="subjectOf" type="COCT_MT050004UV01.Subject" nillable="true"
minOccurs="0" maxOccurs="unbounded"/>
  </xs:sequence>
  <xs:attributeGroup ref="InfrastructureRootAttributes"/>
  <xs:attribute name="classCode" type="RoleClassPatient" use="required"/>
</xs:complexType>
<xs:complexType name="COCT_MT050004UV01.Subject">
  <xs:sequence>
    <xs:group ref="InfrastructureRootElements"/>
    <xs:choice>
```

```

    <xs:element name="substanceAdministration"
type="COCT_MT200000UV01.SubstanceAdministration" nillable="true" minOccurs="1"
maxOccurs="1"/>
    <xs:element name="observationIntolerance"
type="COCT_MT120300UV.ObservationIntolerance" nillable="true" minOccurs="1"
maxOccurs="1"/>
    <xs:element name="procedure" type="COCT_MT200000UV01.Procedure"
nillable="true" minOccurs="1" maxOccurs="1"/>
    <xs:element name="observationDx" type="COCT_MT120100UV.ObservationDx"
nillable="true" minOccurs="1" maxOccurs="1"/>
    <xs:element name="observationGeneral"
type="COCT_MT120500UV.ObservationGeneral" nillable="true" minOccurs="1"
maxOccurs="1"/>
  </xs:choice>
</xs:sequence>
<xs:attributeGroup ref="InfrastructureRootAttributes"/>
<xs:attribute name="nullFlavor" type="NullFlavor" use="optional"/>
<xs:attribute name="typeCode" type="ParticipationTargetSubject" use="required"/>
</xs:complexType>
</xs:schema>

```

Conclusion

The work of anesthesia terminology standards is accomplished by the International Organization for Terminology in Anesthesia (IOTA). IOTA consists of enthusiastic individuals who are dedicated toward the advancement of anesthesia patient safety and anesthesia patient quality initiatives through the standardization of terminology relating to anesthesia for electronic health record systems. Members of IOTA are involved in HL7 and IHTSDO standards development organizations with members also collaborating with working groups from other SDOs. The HL7/IHTSDO: Domain Analysis Model Preoperative Anesthesia Assessment is but one of their current projects. HL7 uses the Health Development Framework (HDF) for product and messaging projects which incorporates the use of UML tools in a structured process to provide the specifications for a proposed standard. The DAM is the analysis portion of the process. A project such as the DAM Preoperative Anesthesia Assessment as with most standards development is a long process that can take at least three or more years before a standard is ready for publishing. This is due in part to the voluntary consensus structure standards development organizations such as IHTSDO and HL7 use. The voluntary nature can present many logistical problems associated with the coordination of schedules over multiple and international time zones. However, the benefit of incorporating the consensus of global and diverse interests provides for a transparency in the processes and increases the robustness and quality of the standard once it is published.

Unambiguous comprehensive information on standards for health IT is difficult to assemble and synthesize. For the uninitiated, making sense of the technical jargon, acronyms, and the responsibilities of various organizations is a daunting task. Websites are full of jargon and are unintuitive. Industry blogs, and newsletters can be difficult to read. Information can be difficult to obtain within the industry also. For example, each working group within a SDO posts meeting

minutes on their respective websites. However, it appears to be difficult or impossible for the working groups to know whether the scope of their projects overlap with another domain's working group's project without active involvement by the working groups themselves. The same problem applies for projects across SDOs. In both cases, there could be a collaboration of efforts if one knew about the projects of the other.

US government HITECH initiatives toward the meaningful use of EHR systems add another dimension to the complicated and confusing domain of standards and health IT. As a result of the initiatives, there are new committees being formed. For example, the recent formation of the Federal Advisory Committee: Health IT Standards Committee. There are new collaborative efforts and new websites, such as the standards testing initiatives between ONC and NIST and the resulting new website: healthcare.nist.gov. There are organizations that have had important influence in healthcare IT that no longer exist. Such as the National Alliance for Health Information Technology (NAHIT) who defined key health IT terms, two of which are used in this paper: 'EHR' and 'Interoperability', ceased to exist as of September 2009. The Healthcare Information Technology Standards Panel (HITSP) who provided standards guidance to ONC and has done significant work in standards harmonization, ceased to exist as of April 30, 2010. There are changes in health information management requirements. For example, EHR systems will be required to be HHS certified and not CCHIT certified to meet incentive requirements. And finally, there is constant change of the key people involved. There are people leaving organizations, people joining, and the same people on multiple or overlapping committees.

Health information management technology is developing at a rapid pace. In addition, there will be an increase in the adoption of EHRs as healthcare organizations hurry to meet the HITECH and meaningful use criteria starting in 2011. With the advanced time table for EHR implementations, it should follow that significant attention is paid to the infrastructure and frameworks of EHR systems. Monies in the United States are being targeted for the increase

adoption of health IT. However, monies for standards development seem to be shorter supply. There appears to be a mismatch of the ambitious time frame of meaningful use implementation criteria and the standards required. Health IT standards are relatively new and since standards development is such a protracted process involving significant voluntary efforts. Politics and bureaucracy aside, it may be argued that monies spent toward standards development may influence the time for standards development since standards are required in order to achieve interoperability and interoperability is required in order to achieve 'meaningful use'.

APPENDIX A:

Interim Final Rule Content and Vocabulary Standards¹⁹

Adopted Content Exchange and Vocabulary Standards, ONC Proposed Rule (pp. 79-81)

Purpose	Adopted Standard(s) to Support Meaningful Use Stage 1	Candidate Standard(s) to Support Meaningful Use Stage 2
<i>Patient Summary Record</i>	HL7 CDA R2 CCD Level 2 or ASTM CCR	Alternatives expected to be narrowed based on HIT Standards Committee recommendations
Problem List	Applicable HIPAA code set required by law (i.e., ICD-9-CM); or SNOMED CT®	Applicable HIPAA code set required by law (e.g., ICD-10-CM) or SNOMED CT®
Medication List	Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm+	RxNorm
Medication Allergy List	No standard adopted at this time.	UNII
Procedures	Applicable HIPAA code sets required by law (i.e., ICD-9-CM or CPT-4®)	Applicable HIPAA code sets required by law (i.e., ICD-10-PCS or CPT-4®)
Vital Signs	No standard adopted at this time.	CDA template
Units of Measure	No standard adopted at this time.	UCUM
Lab Orders and Results	LOINC® when LOINC® codes have been received from a laboratory	LOINC®
<i>Drug Formulary Check</i>	Applicable Part D standard required by law (i.e., NCPDP Formulary & Benefits Standard 1.0)	Applicable Part D standard required by law
<i>Electronic Prescribing</i>	Applicable Part D standard required by law (e.g., NCPDP SCRIPT 8.1) or NCPDP SCRIPT 8.1 and NCPDP SCRIPT 10.6 Any code set by an RxNorm drug data source provider that is identified by the United States National Library of Medicine as being a complete data set integrated within RxNorm+	NCPDP SCRIPT 10.6 RxNorm

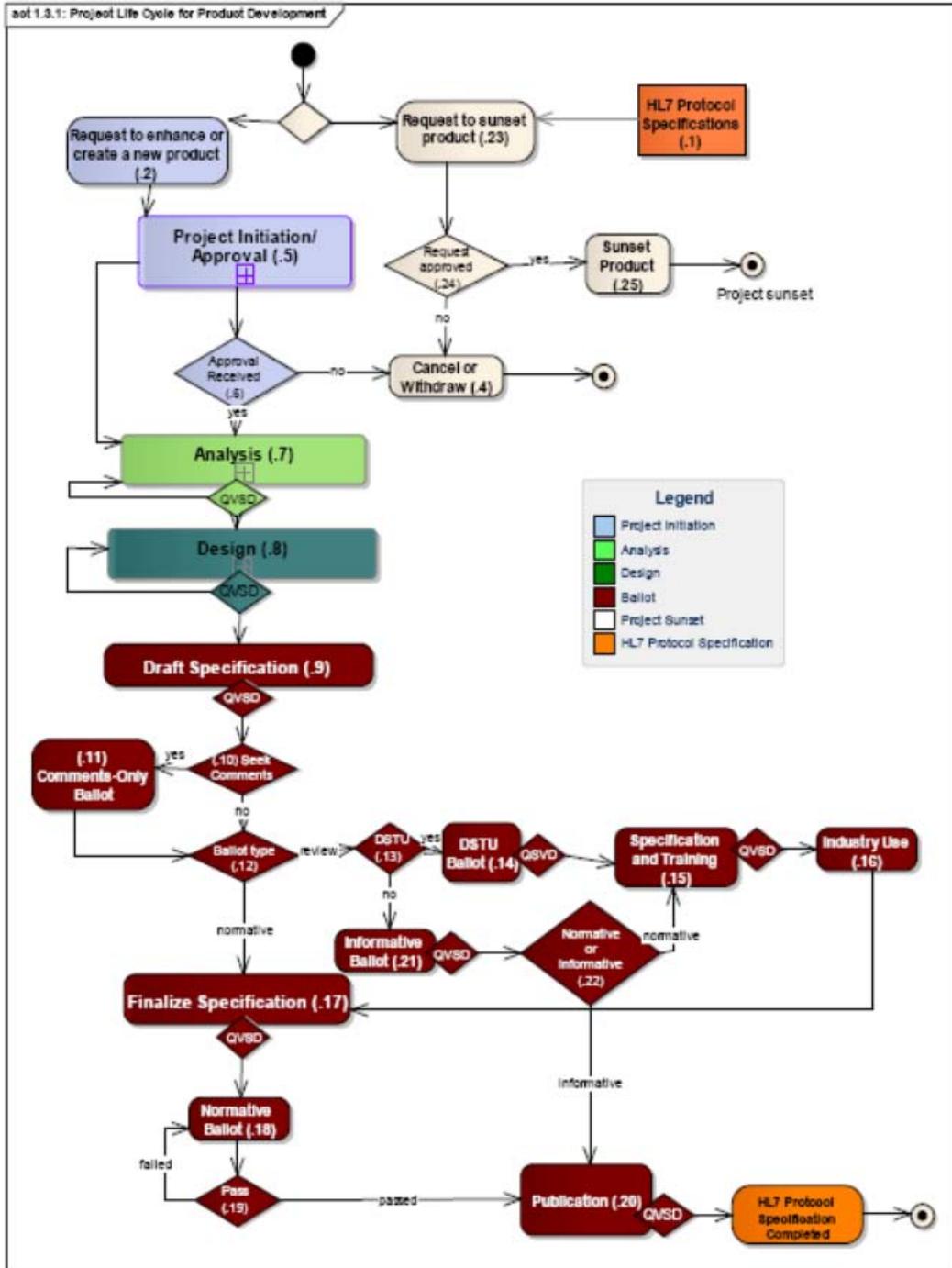
<i>Administrative Transactions</i>	Applicable HIPAA transaction standards required by law	Applicable HIPAA transaction standards required by law
<i>Quality Reporting</i>	CMS PQRI 2008 Registry XML Specification#,+	Potentially newer version(s) or standards based on HIT Standards Committee Input
Purpose	Adopted Standard(s) to Support Meaningful Use Stage 1	Candidate Standard(s) to Support Meaningful Use Stage 2
<i>Submission of Lab Results to Public Health Agencies</i>	HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Recommendations
	LOINC® when LOINC® codes have been received from a laboratory	LOINC®, UCUM, and SNOMED CT® or Applicable Public Health Agency Requirements
<i>Submission to Public Health Agencies for Surveillance or Reporting (excluding adverse event reporting)</i>	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Input
	According to Applicable Public Health Agency Requirements	GIPSE or According to Applicable Public Health Agency Requirements
<i>Submission to Immunization Registries</i>	HL7 2.3.1 or HL7 2.5.1	Potentially newer version(s) or standards based on HIT Standards Committee Recommendations
	CVX*,+	CVX

Adopted Privacy and Security Standards from ONC Proposed Rule (p. 85)

Purpose	Adopted Standard
<i>General Encryption and Decryption of Electronic Health Information</i>	A symmetric 128 bit fixed-block cipher algorithm capable of using a 128, 192, or 256 bit encryption key must be used (e.g., FIPS 197 Advanced Encryption Standard, (AES), Nov 2001).+
<i>Encryption and Decryption of Electronic Health Information for Exchange</i>	An encrypted and integrity protected link must be implemented (e.g., TLS, IPv6, IPv4 with IPsec). +
<i>Record Actions Related to Electronic Health Information (i.e., audit log)</i>	The date, time, patient identification (name or number), and user identification (name or number) must be recorded when electronic health information is created, modified, deleted, or printed. An indication of which action(s) occurred must also be recorded (e.g., modification).+
<i>Verification that Electronic Health Information has not been Altered in Transit</i>	A secure hashing algorithm must be used to verify that electronic health information has not been altered in transit. The secure hash algorithm used must be SHA1 or higher (e.g., Federal Information Processing Standards (FIPS) Publication (PUB) Secure Hash Standard (SHS) FIPS PUB 180-3).+
<i>Cross-Enterprise Authentication</i>	Use of a cross-enterprise secure transaction that contains sufficient identity information such that the receiver can make access control decisions and produce detailed and accurate security audit trails (e.g., IHE Cross Enterprise User Assertion (XUA) with SAML identity assertions).+
<i>Record Treatment, Payment, and Health Care Operations Disclosures</i>	The date, time, patient identification (name or number), user identification (name or number), and a description of the disclosure must be recorded.+

APPENDIX C:

HL7 PROJECT LIFE CYCLE FOR HL7 MESSAGE DEVELOPMENT AND ENHANCEMENTS¹⁴



Appendix D:

Organizations (not all inclusive)

AHIC	American Health Information Community
AHIMA	American Health Information Management Association
AHRQ	Agency for Healthcare Research and Quality
AMIA	American Medical Informatics Association
ANSI	American National Standards Institute
APSF	Anesthesia Patient Safety Foundation
CCHIT	Certification Commission for Healthcare Information Technology
CDISC	Clinical Data Interchange Standards Consortium
CMS	Centers for Medicare and Medicaid Services
CSI	Commission on Systemic Interoperability
DICOM	Digital Imaging and Communications in Medicine
HHS	Department of Health & Human Services
HIMSS	Healthcare Information Management Systems Society
HITSC	Health Information Technology Standards Committee
HITSP	Health Information Technology Standards Panel
HL7	Health Level 7
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IHE	Integrating Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organisation
IOM	Institute of Medicine
ISO	International Standards Office
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
LOINC	Logical Observation Identifiers Names and Codes
NAHIT	National Alliance for Health Information Technology; "The Alliance"
NHIE	NHIN Health Information Exchange
NHIN	Nationwide Health Information Network
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology
NLM	National Library of Medicine
OASIS	Organization for the Advancement of Structured Information Standards
OHITA	Office of Health Information Technology Adoption
OIS	Office of Interoperability & Standards
OMG	Object Management Group
ONC	Office of the National Coordinator (preferred abbreviation for ONCHIT)
ONCHIT	Office of the National Coordinator for Health Information Technology

Appendix E:

Acronyms (not all inclusive)

AIMS	Anesthesia Information Management System
ARRA	American Recovery and Reinvestment Act
CCD	Continuity of Care Document (CCR + CDA became CCD)
CDA	Clinical Document Architecture
DAM	Domain Analysis Model
DAP	Domain Analysis Process
DICOM	Digital Imaging and Communications in Medicine
HDF	Health Development Framework
HIE	Health Information Exchanges
HIM	Health Information Management
HIO	Health Information Organization
HIPAA	Health Insurance Portability and Accountability Act
HIS	Health Information System
HIT	Health Information Technology
HITSC	Health Information Technology Standards Committee
HITECH	Health Information Technology for Economic and Clinical Health Act
HTTPS	Hypertext Transfer Protocol Secure
ICD	International Classification of Diseases
IFR	Interim Final Rule
IT	Information Technology
LOINC	Logical Observations Identifiers, Names, Codes
MU	Meaningful Use
NPRM	Notice of Proposed Rule Making
RIM	Reference Information Model
RSS	Really Simple Syndication
SDO	Standards Development Organization
SIG	Special Interest Group
SNOMED CT	Systemized Nomenclature of Medicine-Clinical Terms
UML	Unified Modeling Language
UMLS	Unified Medical Language System
WG	Working Group
XML	Extensible Markup Language

Annex F:

Electronic Sources (not all inclusive)

NEWS

EHRWatch.com	http://ehrwatch.com
Government HealthIT	http://www.govhealthit.com/index.aspx
GovHealthIT(HSS)	http://healthit.hhs.gov/portal/server.pt?open=512&objID=1263&mode=2
Health Level 7	http://www.hl7.org/
HealthcareIT News	http://www.healthcareitnews.com/
HealthIT	http://www.healthit.com/
HIMSS	http://www.himss.org/ASP/index.asp
IHTSDO	http://www.ihtsdo.org/
Kaiser Health News	http://www.kaiserhealthnews.org/

BLOGS

Health IT Buzz	http://healthit.hhs.gov/blog/onc/
Healthcare Standards	http://motorcycleguy.blogspot.com/2010/04/visicalc-moment.html
HISTalk	http://histalk2.com/
HITSphere	http://www.hitsphere.com/
Kaiser Blog Watch	http://blog.kaiserhealthnews.org/
Life as a Healthcare CIO	http://geekdoctor.blogspot.com/2010/04/my-thanks-to-hitsp.html
Wes Rischel	http://blogs.gartner.com/wes_rishel/

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