ISAAC's KOMET and SOLOR

A Treatise on Symbolic Data Systems

ISAAC's KOMET and SOLOR: A Treatise on Symbolic Data Systems

My Design in this Book is not to explain the Properties of Light by Hypotheses, but to propose and prove them by Reason and Experiments.

—Isaac Newton

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Preface

Symbolic information uses symbols to represent perception, interpretation, communication, knowledge, facts, data, and planning. Symbolic information is specifically concerned with symbolic representation and interpretational infrastructure.[1]

An interpretational infrastructure establishes meaning, value, and usefulness for the symbols, and can generate and decode the symbols. Without consistent meaning of the symbols, there can be no stable knowledge, facts, or data. After the initial assignment or development of meaning, the interpretation of symbols must remain consistent if the symbols are to be used for perception, memory, communication, or planning.

Symbols have no meaning or usefulness without an interpretational infrastructure. Because the symbols and the interpretational infrastructure are both essential, they must develop or evolve together.

[1] http://science.jeksite.org/info1/pages/page2.htm

Part I. Motivation and foundation

Table 1. Current Motivation and Foundation Review

Section	Section Name	Description, Topics	Comments	Perspective	Readability	Intent/ usefulness	Suggestion
0.0	Preface	Definition of symbolic information, interpretation, infrastructure.	At a very high-level this is what SOLOR is	High-level	Good, not too technical	Useful for orienting people to one of the goals of SOLOR which is to provide a user-friendly way to navigate disparate content	
0.1	Motivation and foundation	Gaps in C-CDA citing whitepaper to call out gaps in adherence to standard terminologies. The architectural stack is introduced.	Percent breakdown of gaps in C-CDA by source terminology. I think a lot could be added to this section.	In the weeds, introduce SOLOR, define architectural stack	Okay, but if this is the first part people read we should set the stage and introduce basic concepts	Why should people care about the remaining 400 pages?	Each of the layers in the architetural stack should be defined at a high level. In defining SOLOR, we say it should be working hand in hand with the clinical statement model, but the clinical statement model is not yet defined. The current challenges that close the section are broad and not well defined
1.0	SOLOR	Essential challenge of informatics and why we should care about		Technical, very high level about health informatics	Jargon heavy	Explain why we should care about foundational pro blems with	Not clear what knowledge assets are. This section

Section	Section Name	Description, Topics	Comments	Perspective	Readability	Intent/ usefulness	Suggestion
		knowledge assets				application of codes and terms .	could be simplfied.
1.1	The Menagerie	Defines health informatics architecture and says that there are many disparate terminologies that are neither coordinated in their authoring nor in their update process.		Technical, very high level about health informatics			This section, as it is, should be named "Health Informatics Architecture". If we want it to be about the menagerie then we should define examples of disparate clinical terminologies in this section.
1.2	Semantic Interoperability Architecture	Defines semantic interoperability architecture, but then goes on to say that the purpose of this document is NOT to define semantic interoperability but to define foundational interoperability.	Explains how SOLOR uses SNOMED CT, LOINC, RxNORM to build coherent architecture	Technical	Convoluted	The numbered bullet points highlight how SOLOR aims to build its architecture at a high level	
1.3	Life Critical Systems (All)	SOLOR should support life-critical systems. This section goes on to define many facets of life-critical		Very high-level about life-critical systems and software	Flow could be better	Explain how SOLOR is useful in the grander scheme of things.	Give examples of how exactly SOLOR supports each of the sub-headers in this section.

Section	Section Name	Description, Topics	Comments	Perspective	Readability	Intent/ usefulness	Suggestion
		systems. This is at a higher level than the previous sections about health IT systems overall and not specifically about architecture.					
1.4	Architectural Challenges (All)	Challenges related to building architecture that supports terminology models. Again, these are back in the weeds related to architecture.	I like this section, but it should be later in Part 1	In the weeds about integrated terminology systems		This is useful in highlighting that there there are challenges to consider.	Move towards end of the section
1.5	SOLOR enabling milestones (All)	List of other efforts like UMLS, SNOMED CT etc. This is broader again describing various terminologies and coordination efforts.	These should be defined earlier in the Menagerie in my opinion	In the weeds about terminology			Move into Menagerie section and abbreviate it?
1.6	Data Elements Modeling	Clinical data elements, how these relate to statements and how SOLOR may help. This section on its own is a self-contained	Defines data elements and their common attributes, goes on to explain how SOLOR would assist.	Informatics-specific perspective	The section reads well but doesn't fit in with the other topics		This entire section seems out of place here

Section	Section Name	Description, Topics	Comments	Perspective	Readability	Intent/ usefulness	Suggestion
		white paper. This should be a separate section, out of place.					
2.0	ISAAC	Architecture: definitions of foundational, interaction architecture. The benefits of having layers in the architectural stack.	Good definitions, but should be grouped together with section 1.2 above.	Technical, in the weeds about SOLOR architecture	Jargon heavy but it's decent		
2.5.1, 2.5.2	Benefits of derivable layers, Binding between layers	Benefits of derivable layers should probably go with the introduction of the architectural diagram at the start of the section.	Architecture				
3.0	KOMET	This section is empty	Look at Frozen Compendium: 21, 9, Appendix A				

Overview of current SIA part 1 structure

"The Preface is about symbolic info and interpretational infrastructure. The motivation section sets the stage by describing CCDA's and lack of mapping to terminologies. Integrated terminology model is needed. The motivation section then mentions the architectural stack and 2 broad challenges related to the architecural stack.

The book starts with Chapter 1 called SOLOR with a description of the overall challenge of informatics and why we need improved systems for CDS, patient safety etc. Then the paper defines health informatics architecture, and points out the menagerie of various terminologies that are not coordinated in their processes. Next, the semantic interoperability architecture is introduced; however the scope of this document is to describe the foundational architecture NOT the semantic interoperability architecture.

The following section introduces life-critical systems and how a foundational architecture is needed to save lives.

Next, the text goes back into the details of architectural challenges related to terminology models. After this we get a description of various terminologies and coordination efforts that have enabled SOLOR.

Chapter 2 brings us back to informatics architecture again, providing definitions of foundational and interaction architecture and the needs for the architectural layers. Then we dive into the benefits of the layers.

Chapter 3 is reserved for KOMET which is blank. "

Recommended SIA part 1 structure

Table 2. Recommended Part 1 Structure

Section	Description
Preface	The goal of this book to describe informatics architecture. Define this at a high-level somehow.
Motivation and the Architectural Stack	Setting the stage, starting first with why informatics is of urgent importantance for CDS and patient safety. Then, define the essential challenges of informatics. Perhaps here mention that the scope of this book is to define and explore informatics architecture.
	Informatics Architecture: definitions of foundational, interaction architecture etc. The benefits of having layers in the architectural stack.
	Broadly introduce the architetectural stack and a overall defintion of each.
	Life-critical systems need this sort of architectural stack upon which they can save lives.
	Design principle
Foundation Intro	Definitions for building blocks : concepts, semantics etc
	Introducing health informatics arch. and disparate terminologies. Deep dive into SNOMED CT, LOINC, RxNorm, UMLS etc. and how these efforts are siloed.
	Introduce the notion of informatics architecture. Re-iterate the fact that this chapter focuses on the foundational level of the stack.
	Description of Foundational Layer: [this is a bit of a black box to me]
SOLOR back-end	SOLOR' Architecture will help provide an integrated model. Describe the transformation process, chornology process.
	Architectural Challenges we must address
SOLOR front-end	KOMET: Knowledge management enviornment is the user-interface to the front-end. Define user-interface principles, DevOps processes.

Recommended Part 1 (Opening) structure

PREFACE

States the goals to explore informatics architecture.

MOTIVATION

Begin by highlighting medical errors and how health IT can assist and save lives. Then, the essential challenge of informatics is defined and discussed which has limited our ability to truly be effective. In this book we will define and explore informatics architecture.

Definitions for informatics architecture: what is foundational architecture and interaction architecure. Introduce the architectural stack and overall defintiion of each layer. Discuss the benefits of a architectural stack composed of layers.

FOUNDATION

Define building blocks of foundational/semantic informatics: concepts, semantics, etc. Then introduce and describe health informatics architecture, including the landscape of disparate terminologies. Describe SNOMED CT, LOINC, RxNorm, and efforts like UMLS are siloed.

RE-introduce the notion of informatics architecture. Re-iterate that this chapter is about the foundational level of the stack. The description of the foundational layer will follow [this is a black box to me].

The section that follows will include SOLOR and how it helps the foundational layer. SOLOR's architecure and architectural challenges that remain to be solved will be dicussed. Finally, SOLOR's front-end knowledge management enivornment will be described, including important design elements that were incorporated. "

A recent whitepaper[2] cited that great strides have been made in healthcare data interoperability in the past decade… the vast majority of clinicians and patients have access to some portion of their health data in electronic format, thanks to the proliferation of electronic health record (EHR) systems installed in clinical care environments. The data in these EHRs usually follow HL7's Consolidated Clinical Document Architecture (C-CDA) as it has become the generally accepted primary data standard for structured clinical data exchange.

However, the whitepaper also found that significant gaps exist in the accurate encoding of the data contained in those C-CDA documents – in an analysis conducted of C-CDA documents produced by various EHR vendors and clinical organizations, the four most frequent problems identified as part of this analysis were that medications should be encoded in RxNorm (frequency of medication appearing in 13.7% of sampled test case documents), vital signs and results should use LOINC (9.2% of sampled documents), vital signs, and results should use unified code of units of measure (UCUM) for physical values (8.7% of sampled documents) and the inclusion of conflicting status information for medications (6.7% of sampled documents)[3].

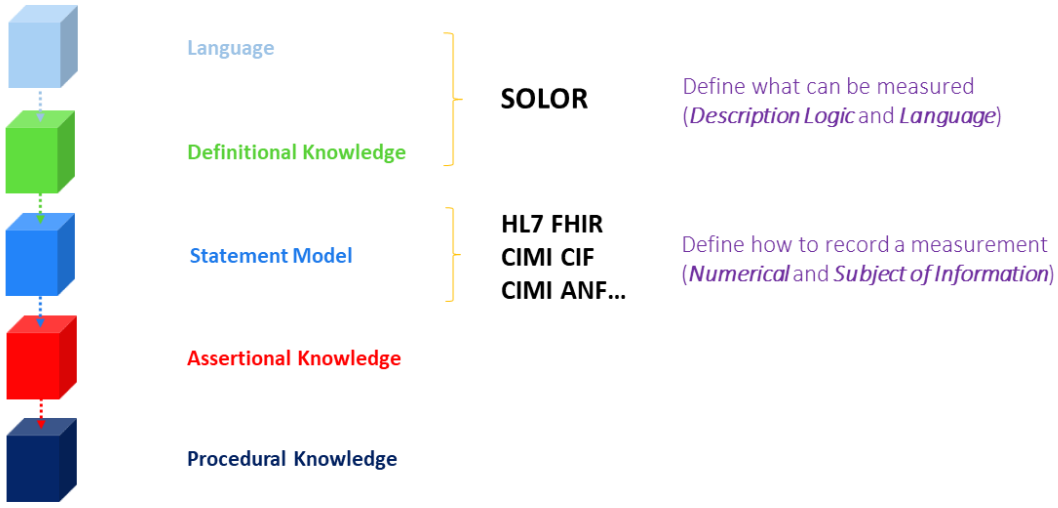
These issues can have a direct impact on patient safety and point to the need to be able to consistently represent and encode clinical data and observations. This is the next great challenge to conquer for health data interoperability to positively influence patient outcomes nationwide through clinical decision support.

SOLOR (System of Logical Representation) is an effort that is directly tackling these issues of representation. SOLOR is an integrated medical terminology system, based on the overlapping but distinct terminology systems of SNOMED, LOINC and RxNorm. SOLOR was designed to unambiguously define what can be measured (concepts). Working hand in hand with SOLOR, there needs to be a clinical statement model, of which there are quite a few (HL7 FHIR, CIMI, ANF) which defines how to record a measurement. Measurements may be quantitative or existential.

The following diagram shows how SOLOR and clinical statement models are interrelated in the architectural stack:

[2] John D. Amore, et. al; "Interoperability Progress and Remaining Data Quality Barriers of Certified Health Information Technologies", July 6, 2018
[3] Ibid, Page 6

Figure 1. Architectural Stack - proposed new graphics



Current challenges include the following:

1. Further tooling and guidance need to be developed to be able to show how concepts can be modeled in SOLOR and particular statement models applied

2. Gaps need to be addressed in the various statement models in terms of representing measurements consistently, especially with existential (non-quantitative) measurements

   ab

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1. SOLOR

> Let me try to explain to you, what to my taste is characteristic for all intelligent thinking. It is, that one is willing to study in depth an aspect of one's subject matter in isolation for the sake of its own consistency... ...It is what I sometimes have called "the separation of concerns", which, even if not perfectly possible, is yet the only available technique for effective ordering of one's thoughts, that I know of.
>
> A scientific discipline emerges with the—usually rather slow!—discovery of which aspects can be meaningfully "studied in isolation for the sake of their own consistency", in other words: with the discovery of useful and helpful concepts. Scientific thought comprises in addition the conscious search for the useful and helpful concepts.
>
> —Edsger W. Dijkstra

The essential challenge of informatics practice within the healthcare enterprise, is to quickly deliver a high-fidelity reasoned interpretation of principles and facts to the point of care—and then to quickly aggregate these point of care experiences for analytic analysis so that new principles and facts can be formulated and validated as part of a continuous optimization of healthcare knowledge and delivery. To effectively answer this challenge, we must focus on simplification and integration of knowledge assets, and on build, test, deploy, and release processes for delivering these assets to the points of care and analysis. This focus on perhaps mundane topics is not because we think that novelty has no place in our work; rather, that without a focus on aspects of our delivery challenge that are often treated as peripheral to the overall problem, we cannot achieve reliable, rapid, low-risk knowledge-asset development and delivery in an efficient manner.

1.1. The Menagerie

> All architecture is design but not all design is architecture. Architecture represents the significant design decisions that shape a system, where significant is measured by cost of change.
> —Grady Booch

Health Informatics Architecture is a clinical and technical discipline that is concerned with the representation of clinical knowledge, clinical organizational information and patient-specific clinical data within health information systems and with the technical methodologies used to process that data for patient care, quality assurance, and other secondary uses.

The importance of defining informatics architecture is in part illustrated by the current state of affairs surrounding informatics architecture. Today, a menagerie of inconsistent and overlapping terminology, information, and messaging models hinders Clinical Decision Support efforts that try to store and analyze encoded clinical data. The current complexity encountered when trying to integrate these models—and the lack of coherence between (and sometimes within) the models themselves—must be overcome to build a foundation for scalable and extensible clinical decision-support architecture.

We believe that defining—and validating—a coherent informatics architecture is a first step to enable implementation of meaningful clinical decision support that can be shared between organizations.

1.2. Semantic interoperability architecture

The semantic interoperability architecture is concerned with the export and import of knowledge and data from this architecture to another that does not share the same semantic foundation. This *semantic interoperability architecture* would not be necessary if all systems shared the same foundational architecture, but such homogeneity is unrealistic at this time. Defining the semantic interoperability architecture will be a follow-on activity after the basics of the foundational architecture are defined and validated. As such, the semantic interoperability architecture is not a focus of this document at this time.

While defining the particulars of the semantic interoperability architecture is not the current focus, we are concerned with builidng a foundation that will support semantic interoperability. We achieve this foundation in two ways:

1. Use of SNOMED CT, RxNorm, and LOINC as the primary building blocks for the foundational architecture.

2. Enablement of *semantic operability* within the foundational architecture through normalization of representation and achieving coherence within and among the primary building blocks of the architecture.

Semantic interoperability of systems that do not share a common foundation may be challenging or unattainable. Although we may seek interoperability, it may be far easier to obtain *semantic operability* through shared coherent architecture. The more common the foundations of systems that attempt to interoperate, the more likely successful interoperability may be achieved.

1.3. Life-critical systems

SOLOR must support many use cases, some of which are life-critical. The architecture must do its part to ensure timely and correct diagnosis, prevention, and/or treatment with correct dose to the correct patient. If the system supporting these use cases fails or malfunctions, death, serious injury, failure of timely diagnosis, or failure of disease prevention may result.

We must be equally concerned with circumstances where systems give incorrect information (such as advising a particular medication to treat a condition when the patient is known to be allergic to that medication), as well as circumstances where systems fail to give potentially life saving information (such as failing to identify potential fatal interactions between patient's known medical conditions and a proposed treatment plan).

The architecture must provide a framework within which life-critical systems support can be developed, but the responsibility of properly utilizing that framework lies with the implementation of the architectural components.

If the architecture provides for safety, then all systems that build upon that architecture can realize the safety benefits inherent in the architecture's design.

1.3.1. Provenance

Evidence-based medicine requires that all evidence represented in the environment have a known provenance—an accounting of the original source of the information, and any subsequent processing that information has gone through. This provenance is essential to provide justification of recommendations to the end user, and to properly curate the evidence used by the system to make recommendations.

1.3.2. Audit trail

The architecture must provide for an audit trail of documentary evidence of the sequence of activities that result in any changes to the declarative or procedural knowledge provided within the architecture.

1.3.3. Medical device suitability

A medical device is any item that treats, diagnoses, or monitors patients. Medical devices have come to increasingly rely on complex embedded software. This software needs to ensure patient safety and meet regulations set by agencies like the Food and Drug Administration (FDA). Coherent informatics

architecture is a foundation that medical devices should be able to depend upon. As such, the architecture must enable an application to meet requirements for embedded medical device software.

1.3.4. Quality assurance

Part of the quality assurance process for life-critical systems must include a hazard analysis, where the types of mistakes that could be present in a system are categorized by potential severity of an event caused by a defect and likelihood of encountering such a defect.

The severity levels are typically:

- Catastrophic: defect results in multiple fatalities
- Hazardous: defect results in serious or fatal injury
- Major: defect results in major injury or illness
- Minor: defect results in discomfort or minor illness
- No safety effect: defect results in no consequences

The likelihood of encountering a defect are typically represented as:

- Probable: Probability of occurrence per operational hour > 1 x 10-5
- Remote: Probability of occurrence per operational hour > 1 x 10-7
- Extremely remote: Probability of occurrence per operational hour > 1 x 10-9
- Extremely Improbable: Probability of occurrence per operational hour < 1 x 10-9

The quality assurance process must be able to ensure that the level of quality assurance applied to a component of the system must be proportional to its severity and likelihood, and should result in quantitative assessments of the risk of encountering defects of different types.

The quality assurance must also consider the probably of defects from interacting with data encoded with previous versions of the system. Ensuring the quality of operations over historical data is a relatively unique concern for a health-focused informatics architecture.

1.3.5. Encoded knowledge is software

Encoded knowledge elements—concepts, descriptions, logical definitions, clinical facts, and clinical rules—are software instructions executed by a computer. Just as java bytecodes are the form of instructions the Java virtual machine executes, encoded knowledge elements are the form of instructions executed by terminology servers, semantic query engines, and various forms of expert systems (rule based, or otherwise).

As encoded knowledge is software, we must provide for the same tight controls for encoded knowledge development as we would for any other software that was a component of a life-critical system.

Encoded knowledge cannot be an afterthought or a design element that is not architecturally significant. Applying encoded knowledge to clinical data is a fundamental purpose of clinical information systems.

As knowledge is software, we must recognize that:

- The vast majority of knowledge encoding problems is traceable to errors made during the design and development process.

- Typically, testing alone cannot fully verify that encoded knowledge is complete and correct. In addition to testing, other verification techniques and a structured and documented development process should be combined to ensure a comprehensive validation approach.
- Encoded knowledge may improve with age, as latent defects are discovered and removed. However, as knowledge is constantly updated and changed, such improvements are sometimes countered by new defects introduced during the change.
- Seemingly insignificant changes in encoded knowledge can create unexpected and very significant problems elsewhere. The development process should be sufficiently well planned, controlled, and documented to detect and correct unexpected results from encoded knowledge changes.

(Adapted from General Principles for Software Validation

The architecture must play its role in ensuring the quality of encoded knowledge. Principles of modularization, standardization, quality measurement, configuration management, and management of changing knowledge over time must be part of the architectural design.

1.3.6. FDA Principles of Software Validation

PARASOFT

1.3.6.1. Requirements

A documented software requirements specification provides a baseline for both validation and verification.

1.3.6.2. Defect Prevention

Software quality assurance needs to focus on preventing the introduction of defects into the software development process rather than trying to "test quality into" the software code after it is written.

1.3.6.3. Time and Effort

Preparation of software validation should begin early; i.e., during design and development planning and design input.

1.3.6.4. Software Life Cycle

Software validation takes place within the environment of an established software life cycle.

1.3.6.5. Plans

The software validation process is defined and controlled through the use of a plan. The software validation plan defines "what" is to be accomplished through the software validation effort.

1.3.6.6. Procedures

The software validation process is executed through the use of procedures. These procedures establish "how" to conduct the software validation effort.

1.3.6.7. Software Validation after a Change

Due to the complexity of software, a seemingly small local change may have a significant global system impact.

Whenever software is changed, a validation analysis should be conducted not just for validation of the individual change, but also to determine the extent and impact of that change on the entire software system.

1.3.6.8. Validation Coverage

Validation coverage should be based on the software's complexity and safety risk - not on firm size or resource constraints. The selection of validation activities, tasks, and work items should be commensurate with the complexity of the software design and the risk associated with the use of the software for the specified intended use.

1.3.6.9. Independence of Review

Self-validation is extremely difficult. When possible, an independent evaluation is always better, especially for higher risk applications.

1.3.6.10. Independence of Review

Self-validation is extremely difficult. When possible, an independent evaluation is always better, especially for higher risk applications.

1.3.6.11. Flexibility and Responsibility

Software is designed, developed, validated, and regulated in a wide spectrum of environments, and for a wide variety of devices with varying levels of risk.

1.3.6.12. Software Life Cycle Activities

Software is designed, developed, validated, and regulated in a wide spectrum of environments, and for a wide variety of devices with varying levels of risk.

- Quality Planning
- System Requirements Definition
- Detailed Software Requirements Specification
- Software Design Specification
- Construction or Coding
- Testing
- Installation
- Operation and Support
- Maintenance
- Retirement

1.3.6.13. Quality Planning

Design and development planning should culminate in a plan that identifies necessary tasks, procedures for anomaly reporting and resolution, necessary resources, and management review requirements, including formal design reviews.

1.3.6.14. Requirements

The software requirements specification document should contain a written definition of the software functions.

A software requirements traceability analysis should be conducted to trace software requirements to (and from) system requirements and to risk analysis results.

1.3.6.15. Design

In the design process, the software requirements specification is translated into a logical and physical representation of the software to be implemented. The software design specification is a description of what the software should do and how it should do it.

At the end of the software design activity, a Formal Design Review should be conducted to verify that the design is correct, consistent, complete, accurate, and testable, before moving to implement the design.

1.3.6.16. Construction or Coding

Source code should be evaluated to verify its compliance with specified coding guidelines. Such guidelines should include coding conventions regarding clarity, style, complexity management, and commenting.

1.3.6.17. Testing by the Software Developer

Test plans and test cases should be created as early in the software development process as feasible.

Once the prerequisite tasks (e.g., code inspection) have been successfully completed, software testing begins. It starts with unit level testing and concludes with system level testing.

Code-based testing is also known as structural testing or "white-box" testing. It identifies test cases based on knowledge obtained from the source code, detailed design specification, and other development documents. Structural testing can identify “dead” code that is never executed when the program is run.

The level of structural testing can be evaluated using metrics that are designed to show what percentage of the software structure has been evaluated during structural testing. These metrics are typically referred to as "coverage" and are a measure of completeness with respect to test selection criteria.

1.3.6.18. User Site Testing

User site testing should follow a pre-defined written plan with a formal summary of testing and a record of formal acceptance. Documented evidence of all testing procedures, test input data, and test results should be retained.

1.3.6.19. Maintenance and Software Changes

When changes are made to a software system, either during initial development or during post release maintenance, sufficient regression analysis and testing should be conducted to demonstrate that portions of the software not involved in the change were not adversely impacted. This is in addition to testing that evaluates the correctness of the implemented change(s).

1.4. Architectural Challenges

Defining guidelines for an evolutionary architecture for the next decade is not an easy task.[30]

How did we end up with a menagerie instead of a productive ecosystem? Before we embark on our next adventure, we should spend time to understand how we got where we are, and how we may avoid making the same mistakes. There are several antipatterns that are pervasive in health IT systems. These antipatterns include *accidental complexity*, *design by committee*, and *stovepipe*. These antipatterns are discussed in the following sections.

1.4.1. Accidental complexity

Accidental (or incidental) complexity is complexity that arises in computer programs or their development process that is non-essential to the problem to be solved. While essential complexity is inherent and unavoidable, accidental complexity is caused by the approach chosen to solve the problem.[49]

Some examples of accidental complexity as they relate to informatics are described in the following sections.

1.4.1.1. Semantic-laden identifiers

Solving a distributed identifier allocation problem by using namespaces that are assigned to organizations (or committees in the case of HL7), semantics are often introduced into the identifier, which some developers used to identify what organization created the components that where associated with those identifiers.

Exposing derivable semantics in the identifier can lead to complexity when users/developers demand that the semantics be maintained, which may result in unnecessary retirement as described in the next section.

Reliance on UUIDs rather than on identifiers with derivable semantics would eliminate this complexity.

1.4.1.2. Unnecessary retirement

An unintended side effect of using identified namespaces as part of distributed identifier assignment, is an increase in the complexity of transferring responsibility for a component from one organization to another. This complexity includes an elaborate sequence of marking a component for retirement in one release, actually retiring it in a subsequent release, and creating an essentially identical component with an identifier derived from the new organizations namespace, and the need for creation of mapping solutions to keep historical relationships between components retired for these reasons to the current concepts that replace them.

Again, reliance on UUIDs rather than on identifiers with derivable semantics would eliminate this complexity.

1.4.1.3. Post-coordination

Terminology models sometimes make it necessary to require post-coordination to provide domain coverage at the point of care, however, the information models we use in healthcare typically can’t handle post-coordination well. Reliance on the information model to represent post-coordination has introduced complexity that might be avoided if we used a dynamic means to assign unique identifiers to post-coordinated expressions.

1.4.1.4. Accidental complexity solutions

Accidental complexity must be minimized in any good architecture, design, and implementation. Working in short iterations with ongoing design reviews may help reduce accidental complexity.

We must also develop an example implementation in parallel with the architecture, so that complexity can be identified early, and evaluated critically with respect to the essential or accidental nature of that complexity.

1.4.2. Design by committee

1.4.2.1. No unifying vision

Design by committee is the result of having many contributors to a project, but no unifying vision.

A complex software design is the product of a committee process. The design has so many features and variations that it is infeasible for any group of developers to realize the specifications in a reasonable time frame.

1.4.2.2. Interoperability at the expense of operability

Interoperability provides an illusion of operability between disparate systems, and therefore there is no need to standardize.

1.4.2.3. Design by committee solutions

A solution to design by committee is to articulate a set of architectural principles to which architectural components will be evaluated against, and to have the committee be advisory to an architect that provides the unifying vision.

1.4.3. Stovepipe

The Stovepipe Enterprise antipattern is characterized by a lack of coordination and planning across a set of systems.[36]

If every subsystem has a unique interface, then the system is overly complex. Absence of common multisystem conventions is a key problem for systems. For example, currently, essentially no terminology systems are the same with regard to their representation and semantics, despite the requirement that they must work together.

1.4.3.1. Overlapping and unreconciled models

SNOMED CT and LOINC are classic examples of two terminologies that are proposed for common use in health IT, but that are not well coordinated, and have unreconciled content (content that is not made consistent or compatible).

As an example of unreconciled content, SNOMED CT and LOINC all have representations for Amoxicillin. In LOINC, Amoxicillin is a textual value in the has-component field of the concept:

```
AMOXICILLIN [MASS/VOLUME] IN SERUM OR PLASMA
  HAS-COMPONENT: AMOXICILLIN
```

While SNOMED CT has the concept:

```
AMOXICILLIN MEASUREMENT (PROCEDURE)
 COMPONENT: AMOXICILLIN (SUBSTANCE)
```

In SNOMED CT, Amoxicillin is also a concept, rather than just a text value.

From an end-users perspective, the artificial separation and uncoordinated development of these important systems has been a burden. RxNorm may help bridge the medication components of the overlap, but there are other overlapping domains (method, type of scale, system, time aspect, and non-pharmaceutical components) that RxNorm does not cover. The UMLS may help us formally reconcile some of these other domains, but if coordination and reconciliation can be part of the development processes for these sources, rather than a cleanup exercise for implementers, we can allocate resources to solving more compelling problems.

We hope that the newly announced cooperative agreement between IHTSDO (owners of SNOMED CT) and the Regenstrief Institute (owners of LOINC) will change the coordination of these two systems in a significantly helpful way.

Although SNOMED CT and LOINC are classic examples of overlapping and unreconciled models, there are many other examples. The UMLS Source Release Documentation identifies 169 sources, most of which are uncoordinated, and have independent models. These overlapping and unreconciled models create an unnecessary burden for the implementer.

1.4.3.2. Uncoordinated development

Today, related components from different organizations do not share their work prior to a release. The result of this lack of sharing is that dependent components are always out of date with the latest release of the underlying standard. For example, how can you keep a mapping of SNOMED CT to ICD-9-CM components up to date, when it takes 6 months after the release of SNOMED CT to update and quality assure the map? As an implementer, does that mean you should wait 6 months for the map to be updated before deploying the latest SNOMED CT release? What if the new SNOMED CT release contains new content that may improve the diagnosis, treatment, or prevention of disease? Is it really acceptable to delay implementation of the latest SNOMED CT release by 6 months while waiting for dependent system components to be updated after the fact?

1.4.3.3. Stovepipe solutions

The primary solution for the stovepipe systems we are working with is to break down the barriers that prevent collaborative development of content, tools, processes, and ultimately architecture.

Today, deployment delay is not a significant issue because clinical decision support is nascent, and pharmacy, laboratory, and clinical systems are poorly integrated. However, if we successfully create compelling decision support on an integrated platform, coordination of development and release cycles among clinical terminologies, logical representation, clinical facts, and clinical knowledge bases will become increasingly important. We must prepare for success and work to better coordinate development among dependent components.

In [new reference] Architectural opportunities we outlined many opportunities that are helping to break down those barriers. Here we propose leveraging those opportunities. Those opportunities include acquisition and development of open-source tooling. Improvements in open-source tooling will help break down collaborative barriers significantly. Such improvement is a fundamental focus of our architecture effort.

The solution to the stovepipe antipattern is effective collaboration without barriers of proprietary concern.

1.4.4. A collaborative path forward

The Health Information Technology Standards Committee (HITSC) is a federal advisory committee which provides recommendations on health IT standards. They have identified SNOMED CT, RxNorm, and LOINC as key clinical vocabularies for Meaningful Use and for HIPAA transactions.

We plan to collaborate closely with these systems—indeed we plan to found the entire architecture on top of them—rather than treat them as an architectural afterthought. As these systems are foundational, we plan to collaborate closely and directly contributie to SNOMED CT, RxNorm, and LOINC when possible.

1.5. SOLOR enabling milestones

While our current state of affairs is less than desired, there has been tremendous work and good progress over the last 25 years. Our challenge today is to leverage these works to form the coherent architecture we seek. In the following subsections, we describe the an incomplete inventory of systems that provide architectural opportunities we hope to leverage.

1.5.1. Unified Medical Language System

In 1986, the National Library of Medicine (NLM) began a long-term research and development project to build the Unified Medical Language System (UMLS®). The purpose of the UMLS is to aid the development of systems that help health professionals and researchers retrieve and integrate electronic biomedical information from a variety of sources. REF-UMLS FIX.

The UMLS efforts have been instrumental in focusing attention on issues surrounding clinical terminology, as well as providing means of interoperation between different terminology systems. We hope to leverage knowledge gained via the UMLS experience—as well as content developed and curated as part of UMLS efforts—to bootstrap our efforts.

1.5.2. SNOMED RT support for description logic

Kaiser Permanente developed SNOMED RT (Reference Terminology) and donated its work to the College of American Pathologists in the hope that a robust standard for encoding clinical data would evolve. SNOMED RT was first released in 2000.

SNOMED RT was the first clinical terminology outside of a research environment to use description-logic as its knowledge representation foundation. This effort made a distinction between reference uses of terminology (uses related to knowledge representation and retrieval) and interface uses of terminology (uses related to correctness and efficiency of user data input).

SNOMED RT was designed to complement the broad coverage of medical concepts in SNOMED RT with a set of enhanced features that significantly increases its value as a reference terminology for representing clinical data. SNOMED RT represented multiple hierarchies and incorporates description logic.

1.5.3. SNOMED CT support for user interface customization

SNOMED CT (Clinical Terms) was first released in 2002. A distributed team within the US and the United Kingdom integrated SNOMED RT and the UK's Clinical Terms Version 3 (formerly known as the Read Codes) into a single terminology. SNOMED CT has become the most comprehensive, multilingual clinical healthcare terminology in the world.

SNOMED CT introduced expanded dialect support that allows language customization to be represented as a core component of SNOMED CT. This integrated approach eliminates the expensive and error-prone approach of mapping interface terminologies to reference terminologies.

In addition to the expanded dialect support, SNOMED CT introduced reference extensions—a standard means to extend terminology content by referencing component identifiers. These reference extensions

provide means to specify alternative taxonomy navigation, ordering of items in taxonomy lists, and other essential features of interface terminology.

This new SNOMED CT framework created a means by which an integrated terminology system could provide for interface and reference needs of clinical systems.

1.5.4. Standard extension model

SNOMED CT does not cover all the concepts required for representation of clinical concepts in the informatics architecture. Therefore, we must have a standard model to extend resources, and to contribute the extensions to responsible organizations when appropriate.

The SNOMED CT extension model provides such a standard model for extension that we can build upon. Organizations are currently using this standard extension model with success.

1.5.4.1. Spanish extension

The Spanish extension of the International Release is updated each year in April and October. Although Spanish is the first language extension to SNOMED CT, it is not the only language extension. SNOMED CT is currently available in American English, British English, Spanish, Danish and Swedish, with other translations under way or nearly completed in French and Dutch.

1.5.4.2. United Kingdom SNOMED CT extension

The British National Health Service produces 2 extensions to SNOMED CT. The UK Clinical Extension, and the UK Drug Extension.

1.5.4.3. United States SNOMED CT extension

The US Extension to SNOMED CT® is a listing of the concepts, descriptions, relationships and their history for terminology content accepted by the NLM as a formal extension to the SNOMED CT International Release.

The main purposes of the US Extension to SNOMED CT are to:

1. Provide “rapid” access to concept IDs for use by implementers, pending action by IHTSDO on content submissions likely to be added to the SNOMED CT International Release.

2. Provide standard terminology needed for US clinical use cases, but not generally useful in other countries, e.g., regulatory or legislatively mandated terms specific to the US.

The US Extension includes both active and inactive content that is harmonized with the most recently published version of the SNOMED CT International Release. As the content of the extension grows and undergoes consistent review, realignment and harmonization with the International Release, users should expect changes to the US Extension related to all future releases of SNOMED CT.

The US Extension is being developed to facilitate the use of SNOMED CT as the primary coding terminology for clinical information in electronic health records, research data bases and clinical trials databases, except in the domains of medications and laboratory tests, which are covered by RxNorm and LOINC respectively. As local vocabularies often provide variable ways of representing commonly used concepts, the use of a common set of SNOMED CT concepts will maximize data interoperability among institutions. Users unable to find terms they think are appropriate should contact the NLM to request additional content to the US Extension. Content suitable for inclusion in the International Release may be submitted by NLM to the IHTSDO contemporaneously with its evaluation, modeling and ID assignment in the US Extension.

If accepted into the International Release, the corresponding US Extension entries will be linked to the International Release content and labeled as “retired” in the US Extension.

1.5.4.4. Australian SNOMED CT extension

SNOMED CT Australian Release (SNOMED CT-AU) is the Australian extension to SNOMED CT, providing local variations and customizations of terms relevant to the Australian healthcare community. It includes the international resources along with all Australian developed terminology and documentation for implementation in Australian clinical IT systems.

1.5.5. RxNorm

Pharmacy related matters are of massive importance in our health care system. For example, adverse drug events (ADEs) comprise the largest single category of adverse events experienced by hospitalized patients, accounting for about 19 percent of all injuries. Clinical information systems can play a critical role in preventing such injuries, and in ensuring proper prescribing practices.

RxNorm was created to provide a means of interoperability between one pharmacy information system and another. First released in 2005, RxNorm includes the VA’s NDF-RT, which codes clinical drug properties, including mechanism of action, physiologic effect, and therapeutic category.

RxNorm is the official HITSP standard for exchanging information on clinical drugs, using the combination ingredient + strength + dose form. RxNorm is freely available, and part of the UMLS, and can form a foundational component of an informatics architecture.

1.5.6. SNOMED CT transition to the IHTSDO

In 2007, the SNOMED CT intellectual property rights were transferred from the College of American Pathologists to the SNOMED SDO® in the formal creation of the International Health Terminology Standards Development Organization (IHTSDO). The IHTSDO is a not-for-profit association that is owned and governed by its national Members. In January 2012 eighteen countries were Members of IHTSDO, more countries are joining every year.

SNOMED CT is now owned, maintained and distributed by the IHTSDO. Historic commercial proprietary concerns surrounding SNOMED CT licensing have been eliminated, enabling SNOMED CT to serve as a foundation for open informatics architecture.

1.5.7. IHTSDO open-source tooling

In 2009, the IHTSDO made a software workbench open source. This open-source framework validated many architectural ideas, including change-set configuration management to support distributed development.

The IHTSDO workbench validated a temporal model of

- A time period datatype, including the ability to represent time periods with no end (infinity or forever)
- System-maintained transaction time
- Temporal queries at current time, time points in the past or future, or over durations
- Predicates for querying time periods

This open source environment includes a description-logic classifier, and distributed editing capabilities that can be leveraged in a architectural implementation that can be used to validate the architecture.

1.5.8. SNOMED CT Release Format 2

In January 2012, SNOMED CT's RF2 format officially replaced the RF1 format. The new format has better features for configuration management of and reference extensions to SNOMED CT's contents. This new format will accommodate evolving requirements without the need for further fundamental change in the foreseeable future.

1.5.9. IHTSDO and GMDNA

In 2012, the IHTSDO and the Global Medical Device Nomenclature Agency (GMDNA) responsible for the international naming system for medical devices (GMDN) signed a Cooperation Agreement with the IHTSDO, resulting in the use of GMDN as the medical device component in SNOMED CT.

1.5.10. SNOMED CT and LOINC agreement

In 2013, the IHTSDO and the Regenstrief Institute agreed that they would work together to link SNOMED CT and LOINC. This agreement means that LOINC can be integrated into SNOMED CT by means of SNOMED description logic statements that define LOINC codes, and that these description logic statements will be a part of future SNOMED CT releases.

1.5.11. VA interagency agreement with NLM

In September of 2013, the VA and the National Library of Medicine (NLM) entered into an interagency agreement (IAA) to accelerate the pace of clinical terminology standards development and integration in areas that support Veterans health care and benefits determination. The VA has a long history of successful use of health information technology to support its mission and of effective collaboration with other federal agencies to promote the development and use of health data standards. VA seeks to accelerate the enhancement of clinical terminology standards and related infrastructure for internal uses such as clinical decision support, quality improvement, research and business processes and for external data sharing with key partners including the Department of Defense and VA academic affiliates across the country.

Under the IAA, NLM will work with the VA to make specific enhancements to SNOMED CT, LOINC, and RxNorm in order to:

- Modify and add to SNOMED CT and/or the US Extension to SNOMED CT, to LOINC, and to RxNorm so they evolve more rapidly and effectively to support current and emerging priority use cases for the VA and its federal and private sector partners.
- Coordinate enhancements to the IHTSDO Workbench/Open Tooling Framework so that NLM and VA development efforts are mutually beneficial and support more rapid improvements to SNOMED CT and more effective integration of SNOMED CT with other relevant health IT standards.
- Expand the content and capabilities of the NLM Value Set Authority Center as needed to support more effective authoring, validation, maintenance, and use of vocabulary value sets for clinical decision support and other high priority VA use cases, as well as for clinical quality measures.
- Allow predicates for querying time periods

The initial set of high priority tasks to be addressed by the VA and NLM under the IAA include:

- Establish principled relationships between LOINC and SNOMED CT so that they form an interlocking set to support effective integrated use by the VA and other US health care providers.
- Finalize specific rules and parameters for relating and connecting LOINC and SNOMED CT content in the laboratory test domain.

- Initiate analysis for other domains of interest to the VA.
- Determine the magnitude and prioritize the changes that must be made to LOINC and SNOMED CT to instantiate these relationships and connections in light of the VHA's priority use cases.

1.5.12. SNOMED CT, RxNorm, and LOINC

Today, thanks to all the prior efforts of many individuals and organizations, we have an opportunity to leverage the combination of SNOMED CT, RxNorm, and LOINC as a coherent foundation for informatics architecture. There is still work to be done, as the integration of LOINC and SNOMED CT is only beginning, and how best to utilize RxNORM will require careful consideration. But the opportunity is compelling; we must take advantage of it.

1.6. "Data Element" Modeling and Its Relationship to Clinical Domain Models and SOLOR

Walter Sujansky

1.6.1. Introduction

Recently, there has been lively discussion regarding the appropriate role of "clinical data elements" and forms-based data collection as a data-representation system for EHRs. This section attempts to char- acterize the "data-element" model for representing clinical data, and assess its strengths and weaknesses relative to alternative models, particularly with regards to supporting data retrieval and analysis. This section also provides general recommendations for retaining the advantages of data elements for data collection, while mitigating their limitations for data analysis.

1.6.2. Data Elements

"Data element" is a longstanding concept used in information technology and data modeling[1]. Recently, the definition and use of data elements has been proposed as the basis for structured data capture within EHRs and other clinical applications.

1.6.2.1. Context for Recent Consideration of Data Elements: Structured Data Capture

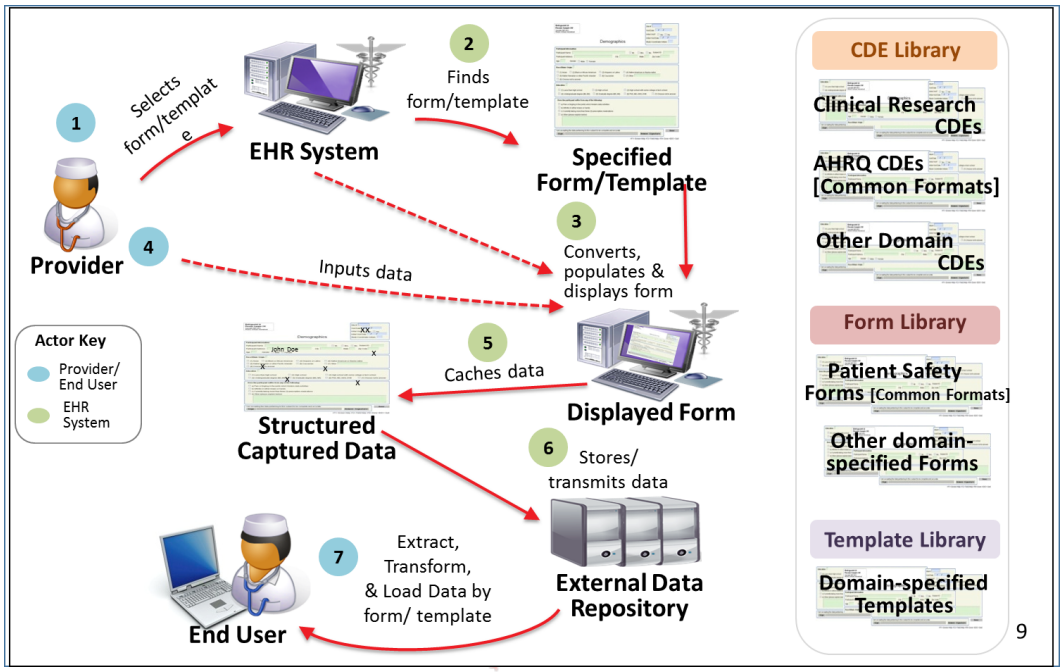
In 2013, the Office of the National Coordinator (ONC) Standards & Interoperability (S&I) Framework launched an initiative to develop "Structured Data Capture" standards for EHRs[2]. The purpose of structured data capture (SDC) in the context of this initiative was to enable the collection of structured data within EHRs *to supplement data collected for other purposes, including clinical research, adverse event reporting, and public health reporting*. In other words, SDC was not intended as a model for primary data entry into EHRs, but rather as a mechanism to collect data from EHRs and/or from the users of EHRs for secondary purposes, such as research and specific reporting needs.

Figure 1.1, "Envisioned model for structured data capture (SDC) using data elements." illustrates the envisioned model for such data collection. The model entails an EHR user selecting a "form" or "template" from a forms repository that is external to the EHR (steps 1 and 2). This form, which specifies the exact data elements needed for the intended research or reporting purpose, becomes the artifact used to collect the requisite structured data. The EHR "auto-populates" whichever of the form's data elements it can from

[1] https://en.wikipedia.org/wiki/Data_element.
[2] https://oncprojectracking.healthit.gov/wiki/display/TechLabSC/SDC+Home.

the EHR's own database - via mappings specified within the form – (step 3), and then prompts the user to enter manually values for the remaining data elements (step 4). The completed form is then locally saved (step 5), as well as transmitted to an external data repository (step 6), from which it can be accessed for its intended research, reporting, and analytical purposes (step 7).

Figure 1.1. Envisioned model for structured data capture (SDC) using data elements.



Within this model, "data elements" comprise the individual units of information that are collected when each "question/answer" pair in a form is populated. Examples range from simple concepts, such as a patient's height, to complex concepts, such as the severity of a medication adverse event. In all cases, the precise meaning, allowable values, and other attributes of the data elements are carefully defined.

"Common data elements" (CDEs) are data elements that are shared across a community of interest. The standardized and mutually agreed-upon definitions of CDEs enable their re-use in different contexts and aide in the exchange and repurposing of clinical data. The SDC model envisions the definition of many CDEs for use in various data-collection use cases.

1.6.2.2. The Attributes of Data Elements

The ONC S&I SDC initiative did not actually define common data elements that may be used in forms, but only standardize the set of *defining attributes* that may be used to specify such data elements (leaving it to others to actually define the elements). The standardized attributes defined by S&I number approximately 75, and the full set is available in a document from the ONC S&I web site[3].

The most important required attributes for each data element include:

- Data Element Unique Identifier
- Data Element Name

[3]See ("SDC Data Element Attributes" tab in https://oncprojectracking.healthit.gov/wiki/download/attachments/16123327/SDC%20SWG%20Data%20Element%20Mapping%20Templatev4%20%282%29.xlsx?version=1&modificationDate=1489605858000&api=v2

- Text definition
- Datatype of permitted values
- Set of permitted values when enumerated (including display text and code, if coded)

Notably, coded values from standard terminologies must be *pre-coordinated* (i.e., the SDC standard does not allow post-coordinated expressions as the values of data elements).

Other relevant attributes include the units of measure and high/low ranges for numerically-valued data elements, as well as mappings to corresponding data elements in standardized clinical data representations, such as C/CDA (to facilitate the automated population of data elements from EHR contents).

1.6.2.3. Data Element Examples

Although the ONC S&I SDC initiative did not define any specific data elements, other similar initiatives have produced libraries of defined data elements that serve as good examples of the concept. Notable among these libraries is the NIH Common Data Element (CDE) repository[4]. The repository contains data elements that have been recommended or required by NIH Institutes and Centers and other organizations, including the NCI, NLM, and AHRQ.

The repository also contains libraries of structured data collection forms in which the specified data elements appear. Together, the forms and the CDEs exemplify the envisioned role of data elements in capturing and representing clinical information. Among examples of defined data elements in the repository are the following (with their definitions and allowable values):

Data Element Name	Definition	Allowable Values
Person Birth Date	The month, day and year on which the person was born.	"DATE" Datatype
AJRR Colorectal Cancer Tumor T Stage	Extent of the primary colon and rectal cancer based on evidence obtained from clinical assessment parameters determined prior to treatment.	"T0" (C60840), "T1" (C60844), "T2" (C60845), "T3" (C89945), "T4a" (C89946), ...
Adverse event severity grade scale	The grading scale of the severity or intensity of the adverse event	"Grade 1" = Mild (no intervention needed), "Grade 2" = Moderate (local intervention needed), "Grade 3" = Severe (hospitalization needed), "Grade 4" = Life threatening (urgent intervention needed), "Grade 5" = Death due to adverse event
Tissue Donor Sex Behavior With Other Person Injectable Dosage Form Drug Abuse Personal Medical History Performed Indicator	An indication of whether the donor had sexual activity with others who have utilized drug injections (intravenous and/or intramuscular and/or subcutaneous) for non-medical use in the last 5 years as provided by the primary history source.	"Yes" (C49488), "No" (C49487), "Unknown" (C17998)

As evident from these examples, CDEs may represent simple, familiar clinical concepts, or complex esoteric concepts. Complexity can arise from either the definition of a CDE (as with the “Tissue Donor Sex Behavior” example), and/or from the definitions of its allowable values (as with the “Adverse Event Severity Grade” example). In either case, complex CDEs can pack a lot of clinical semantics into concise, atomic representations.

1.6.3. The Limitations of Data Elements

The model of forms and data elements prescribed by the S&I SDC initiative has certain advantages with respect to standardizing data collection for secondary purposes. If different parties within a community do, indeed, use the same forms containing the same common data elements when collecting data, those data will be more uniform and amenable to aggregation, exchange, and pooled analysis.

However, if a community creates and uses forms and data elements in a less-than-disciplined fashion, the resulting data sets will lack uniform semantics, preventing pooled analysis or (worse) generating incorrect

[4] https://cde.nlm.nih.gov/form/search.

analytical results. Given the inherent limitations of common data elements as a paradigm for modeling clinical semantics, there is a real danger of this occurring.

The primary limitation of common data elements is that they are defined and used independently of any information model representing the context in which they are populated or the relationship among their populated values. The context of and relationships among populated data elements are represented only by the structure of the forms in which they are populated. These forms, however, lack any formal model to, for example, denote the relationships among their constituent data elements. Further, the same data elements can appear in different forms, such that the context in which the data elements are populated (and, hence, the complete semantics of the collected data) can vary depending on the form in which they appear.

For example, a form may include the data element “Adverse event name,” followed by the data element “Adverse event severity”. The value of the latter is meaningless for purposes of data analysis unless associated with the value of the former (in particular, if multiple adverse events were present, with differing severities). Other than the sequence of the two data elements, however, forms have no way to formally represent this association. Also, “Adverse event severity” could appear in a different form, following the data element “Past adverse event name”. In this case, the semantics and implications of the value of “Adverse event severity” would be different than if it were associated with a currently experienced adverse event (for example, if it were “life threatening”). None of these contexts of and associations between data elements are formally represented, however. The result is that the values of data elements cannot be reliably aggregated or analyzed without access to the form(s) in which each the values was collected and a manual assessment of the semantics of the values when collected via each such form. Lastly, in the absence of a uniform information model, data analysts would have trouble determining the set of attributes that could have been populated to describe a particular clinical event, such as an adverse event, diagnosis, or treatment.

The independent creation of common data elements in the absence of an information model also increases the chances that duplicative or overlapping data elements may be created by a community if great care and coordination are not exercised, with no guaranteed means of subsequent reconciliation or mapping. For example, the following two data elements could be defined and used by different parties within the same community:

Data Element Name	Definition	Allowable Values
Adverse event severity	The severity or intensity of the adverse event	None, Mild, Moderate, Severe, Life-threatening, Death
Life-threatening adverse event	The presence of a life-threating adverse event	Present, Absent, Unknown

In this case, a data analyst searching a pooled data set for all instances of life-threatening adverse events would have to know that both of these data elements existed, and would have to query for instances of the first data element with a value of “Life-threatening” or “Death”, and instances of the second data element with a value of “Present”. Many other such situations could arise, because of the variable ways that the same or similar clinical concepts can be modeled as data elements.

1.6.4. Recommendations and Relationship to SOLOR

To enable the consistent analysis of populated data elements without requiring detailed knowledge of the myriad forms used to collect those values, it is important to specify a clinical data model that exists independently of the forms. This data model should consist of (1) an *information model* (a.k.a., “clinical

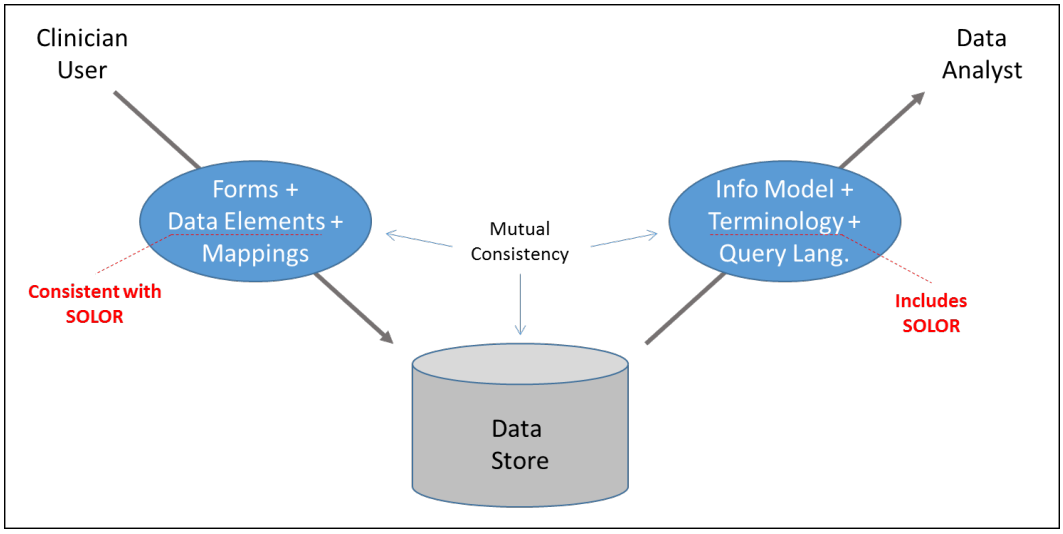
domain model") to represent the context of and relationships among individual data elements, akin to a relational or object-oriented schema, and (2) a *terminology model* to represent the discrete clinical concepts represented by individual data elements and their allowed values.

For example, the information model would specify *Adverse Event* as a clinical object type, which could be instantiated and further described by a set of explicitly related attributes, such as "AE Name", "AE Code", "AE Manifestation", "AE Severity", and "AE Start Date". Any enumerated value sets for these attributes would be specified by reference to the terminology model or to other objects of the information model. For example, the values of the "AE Manifestation" attribute could be constrained to any concept in the terminology that was an Observation or a Disease. Together, the information model and terminology model would specify a clinical data model that represented the scope, structure, and semantics of any collected data and that supported data aggregation and analysis regardless of the specific data-entry instruments (including forms) that were used for data collection.

Examples of information models consistent with this approach include OpenEHR[5,6] and CIMI[7,8]. Examples of applicable terminology models include SNOMED-CT[9] and SOLOR[10].

The specification of a clinical data model, as described above, still allows for the use of common data elements and standardized forms for data collection, as defined by the S&I SDC model. However, achieving the benefits of both forms-based data entry and model-based data analysis requires the *mapping* of data elements that appear in forms to semantically equivalent representations that are consist with the clinical data model. These mappings allow data collected via forms to be transformed to equivalent data that conform to the clinical data model, which can then serve as a single, uniform point of reference for querying and analyzing the data. In this manner, clinicians can use familiar forms and data elements to enter data (without requiring any knowledge of the more complex underlying data model), and analysts can use the clinical data model to query and analyze the collected data (without requiring any knowledge of the data-collection forms that were used to enter them). Figure 1.2, "Proposed model for the collection and analysis of structured data." illustrates this approach to collecting and analyzing clinical data.

Figure 1.2. Proposed model for the collection and analysis of structured data.



[5]Demski H, Garde S, Hildebrand C. Open data models for smart health interconnected applications: the example of openEHR. BMC Med Inform Decis Mak. 2016 Oct 22;16(1):137. (available at https://www.ncbi.nlm.nih.gov/pubmed/27770769).
[6]http://www.openehr.org/what_is_openehr.
[7]Goossen, W. Detailed Clinical Models: Representing Knowledge, Data and Semantics in Healthcare Information Technology. Healthc Inform Res. 2014 Jul; 20(3): 163–172.
[8]http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models.
[9]http://www.snomed.org/snomed-ct.
[10]http://www.solor.io/.

Importantly, the forms and data elements that will be used by clinicians must be created and maintained in coordination with the clinical data model that will be used by analysts. Such coordination is required to ensure that the former remains consistent with and can be reliably mapped to the latter as both evolve over time.

Also, transformation between the forms-based view of collected data and the clinical-model-based view can occur in real time, as the forms are completed and their data stored. Alternatively, the transformation could occur later, when data are moved from an initial (forms-based) data store to a secondary (model-based) data store. The appropriate strategy will depend on the intended uses of the collected data and how promptly data analysis will follow data collection.

Lastly, the SOLOR terminology plays an important role in both the forms-based model and the clinical data model. As mentioned, a terminology model, such as SOLOR, is needed as part of the clinical data model to rigorously represent the individual clinical concepts within the model. However, the definition of common data elements and data-collection forms in the forms-based model must also take into account the content of SOLOR, because the common data elements and their values will need to map to SOLOR concepts (to support the transformations described above). In practice, it is much better to consider such mappings at the time that the common data elements and forms are defined, rather than define them independently and hope that a mapping to SOLOR is possible at a later time.

2. ISAAC

The ISAAC (InformaticS [Agile|Analytic] ArChitecture) effort seeks a holistic approach to architecture that supports novelty within a rigorous—and vertically integrated—deployment pipeline that enables knowledge engineers, developers, testers, build managers, and operations personnel to work together effectively to deliver assets to the points of care and analysis. This pipeline must support integrated delivery of iterative revisions of specifications, services, and content which are today delivered by isolated silo organizations who place the implementation burden upon their consumers. This pipeline will be built from existing software-based best practices, and will embrace DevOps culture and practice by emphasizing collaboration and communication while automating the process of product delivery. ISAAC's KOMET (KnOwledge Management EnvironmenT) realizes ISAAC's architecture within a DevOps environment that integrates development, testing, publication, and delivery of specifications, content, and services into a vertically integrated environment that supports continuous delivery.

2.1. Informatics Self-describing Agile Architecture

An architecture is more than a thin veneer on top of a bunch of unstructured database tables.

The architecture provides a foundation. We need a principled foundation so we stop building the skyscraper from the third floor up.

ISAAC provides a robustly versioned and self-describing architecture for knowledge representation and execution.

2.2. Architectural Aspects

Informatics Architecture is a clinical and technical discipline that is concerned with the *representation* of clinical knowledge, organization-specific clinical information, and patient-specific clinical data. Successful representation concerns a) the foundation of the architecture, b) how the representation is presented to —and manipulated by—the user, and c) how the representation is made interoperable with other environments. To meets these needs, we describe three aspects of informatics architecture: *foundational architecture*, *interaction architecture* and *semantic interoperability architecture*, respectively.

Note that the role of the Informatics Architect differs from the role of other types of business and technical architects involved in the field of enterprise architecture (e.g., data architect, solution architect, enterprise architect, etc). More details are available here: Different types of architects (available from: https://blog.prabasiva.com/2008/08/21/different-types-of-architects/) [http://blog.prabasiva.com/2008/08/21/different-types-of-architects/]

2.3. Foundational architecture

The foundational informatics architecture is the primary focus of this document

The foundational architecture is concerned with the taxonomy, classification, and declarative and procedural search of an information pool. This architecture lives within the logical architecture of the enterprise, but does not try to define the overall systems architecture, or the physical architecture that supports the foundational architecture.

2.4. Interaction architecture

The interaction architecture is concerned with navigation, interface layout and functionality, and other aspects of the user's information access experience. This document will only address the interaction architecture aspects of the authoring environment. The interaction architecture for end user applications, such as patient record systems or other clinical applications, is beyond the scope of this document.

2.5. Derivable logical layers

The foundational informatics architecture must be a layered logical architecture that fits within the business logic layer (aka the domain logic layer) of the VA's health management platform.

Layering the architecture is important for keeping the architecture sufficiently simple at each layer so that it remains comprehensible to a single mind. As layers are ascended, whole systems at lower layers become simple components at the higher layers, and may disappear altogether at the highest layers.

Figure 2.1. Architectural layer overview

These architectural layers provide constraints on what type of components may be created in each layer. The padstone[1] layer of the architecture is the identifiable component layer. All higher layer components must be derived from (to come from a source or origin; to originate from) the padstone's identifiable component, thus providing a uniform means of identifying all components of the architecture.

The lowest layers are the most critical, as changes to those layers have greater impact, as the higher layers are dependent upon them. Also different candidate architectures may share common lower layers, while differentiating themselves at the higher layers (for example, one organization may require a different technology for it's clinical rules engine).

2.5.1. Benefits of derivable layers

The layers of the architecture must be derivable from the layers below. Derivable in the sense that a component of one layer must only reference components of the same layer, or components defined in layers below.

Derivable layers eliminate unreconciled overlap between layers, such as the terminology model, the assertion & request model, and the context model. This resolves a historic informatics architectural problem: how to manage the overlap between the terminology models and the information models.

In part, this historic problem is a side effect of a stovepipe design process, where information models where developed independent of the terminology systems meant to populate those models. Information model developers were frequently unaware of the terminology systems semantics, and how those semantics may interfere with those of the information model. A classic example would be to have a terminology that may pre-coordinate severity information (mild asthma, moderate asthma, and severe asthma), while the information model may provide a specific field for severity information. The information model may even provide a required and irreconcilable value sets for these overlapping fields (such as a 5 point severity scale then the terminology system uses a 3 point severity scale internally).

In this architecture, the components traditionally know as terminology models and information models are coherent parts of the same architecture. This integration enables simplification of implementation, and also enables a level of validation and testing that is not possible when information models are developed independent of the other components of the overall architecture.

2.5.2. Binding between layers

This architecture does not specify the means of binding between layers. Binding may potentially be implemented as native objects within a shared execution environment by some layers, by static or dynamic XML objects between other layers, or by URI specification between layers.

Although the means of the binding between layers is not specified, the means of identifying the components being bound is mandatory. All components will be identified by UUIDs assigned by the identifiable component layer.

2.5.3. Declarative knowledge layers

[insert figure here]

Declarative knowledge is defined as the factual information stored in memory and known to be static in nature. Other names, e.g. descriptive knowledge, propositional knowledge, etc. are also given. It is the part of knowledge that describes how things are. Things/events/processes, their attributes, and the relations between these things/events/processes and their attributes define the domain of declarative knowledge. [9]

2.5.4. Clinical data layers

[insert figure here]

2.5.5. Procedural knowledge layers

[insert figure here]

Procedural knowledge is the knowledge of how to perform, or how to operate. Names such as know-how are also given. It is said that one becomes more skilled in problem solving when he relies more on procedural knowledge than declarative knowledge. [9]

2.5.6. Documentation

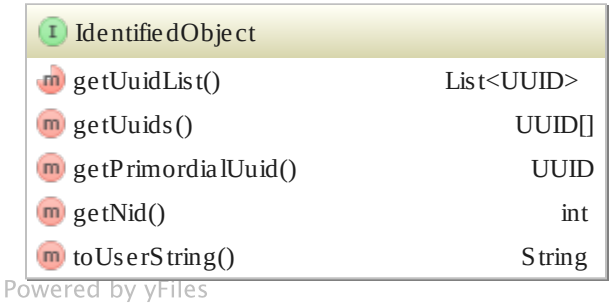
Documentation is a cross-cutting concern A well-documented system is inextricably linked to our ability to understand, maintain, and assure the quality of that system. Just as declarative knowledge layers derive from the ones below, the documentation must have the ability to derive selected content from the systems they document. For example, if a document references the definition of a particular concept, or lists the children of that concept in a table or diagram, that table or diagram should be derivable from the concept's source as part of an automated build process, assuring that the documentation remains up-to-date despite inevitable change within the documented system.

2.5.7. Separation from implementation architecture

There is no specific requirement to use a terminology server. The implementation architecture is free to layer the components differently as long as the architectural requirements are met.

2.6. Object identity

Figure 2.2. Identified Object



The identifiable component layer manages the reproducible assignment of Universally Unique Identifiers (UUIDs) to all imported components as well as the assignment of primordial UUIDs to all internally generated components. If imported components already provide UUIDs to identify components, those UUIDs will be used.

If the imported components do not have UUIDs, but have ISO Object Identifiers (OIDs) assigned by HL7,[1] or the component's provider, then the environment will generate Version 5 UUIDs for those components using the ISO OID namespace UUID of 6ba7b812-9dad-11d1-80b4-00c04fd430c8 defined in the Internet Engineering Taskforce RFC 4122.[2]

If the imported components do not have UUIDs or OIDs—but have internally unique and immutable identifiers—then a UUID namespace for that source will be assigned internally, and Version 5 UUIDs will be generated for the source on that basis.

If the imported components do not have internally unique and immutable identifiers, then a UUID namespace for that source will be assigned internally, and Version 5 UUIDs will be generated off of a unique hash of the component's data fields that are sufficient to assure uniqueness and immutability of the generated identifier.

The original identifiers for the imported sources will be stored as reference extensions to the component during the import process. The management and retrieval of these externally generated identifiers is not the responsibility of the identifiable component layer.

If imported components have both provided UUIDs as well as OIDs that would compute different UUIDs, then both the provided and computed UUIDs must be associated with the component, and any single UUID will be sufficient to uniquely identify and retrieve the component.

2.6.1. Multiple identifiers and component merging

The identifiable component layer must allow components to have more than one UUID identifier, and if previously independent components are given each other's identifiers as alternate identifiers, the identifiable component layer must dynamically merge the parts of these previously distinct components into a single integrated component.

This merging of components by merging identifiers is a simple means for managing duplicated content as it is identified. This duplicate management process does not require retirement of one component, with pointers to the other component, and the additional overhead that such retirement would entail.

2.6.2. Uniform resource identifiers

The architecture will integrate components from many sources, including at least SNOMED CT, RxNorm, and LOINC. Users of the architecture should not need to concern themselves with the source of the content—as a foundational goal of the environment is to provide integrated and coherent content that is a single seamless system to the end user. All components will have original or assigned UUIDs, therefore, all components will be identifiable by URIs of the form:

urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6

Since these URIs for SNOMED CT, RxNorm, and LOINC will be reproducibly assigned, users of the same architecture can use these identifiers to encode and share clinical knowledge.

In addition, if locally-developed content becomes incorporated into standards at some point in the future, the ability to support multiple UUIDs ensures that the encoded clinical knowledge based on those UUIDs can remain stable. Users and implementers of the architecture may choose to share locally developed content identified in this manner. The stable UUIDs provides a means of sharing before such work is integrated into a standard, as well as a smooth transition when the work is integrated into a standard.

2.6.3. Uniform resource identifier validation

Although the urn:uuid URI provides for unique identification, it is not safe in the sense that a typographical error in the URI could yield an incorrect result with little or no awareness on the part of the individual that constructed the URI. The architecture must allow for dynamic validation of URIs by some means, in specific contexts—such as when accepting generated input.

We are not recommending checksums, or other methods for ensuring the URI does not get corrupted in transport—the ISO 7 layer model for error free transmission across a network is robust. We are recommending that there be a method that URIs are associated with human readable text from the component the URI represents, so that the coupling between a meaningless identifier useful to the computer, and a text representation comprehensible to a human is provided.

2.6.4. Component query

The architecture must support queries over collections of components.

2.6.5. Component result set

A result set is composed of a set of component identifiers that match a set of criterion.

2.6.5.1. AND

Compute the intersection of the set results from given child clauses.

2.6.5.2. OR

Compute the union of the results of the child clauses.

2.6.5.3. NOT

Computes the relative complement of the result of the child clause with respect to the set of all components that are processed by the query.

2.6.5.4. XOR

Computes the exclusive disjunction between the result sets of each child clause. This operator enables the ability to determine differences between identical child clauses that have different view coordinates, to determine what changed between to versions of the system.

2.7. Module & chronicle

STAMP versioning

Figure 2.3. Stamped Version

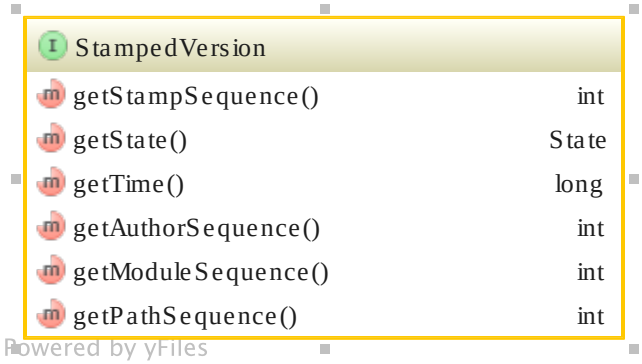


Figure 2.4. Latest Version

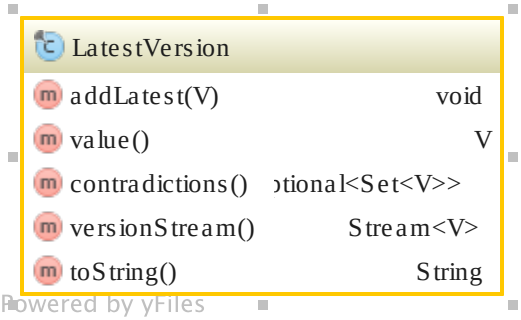
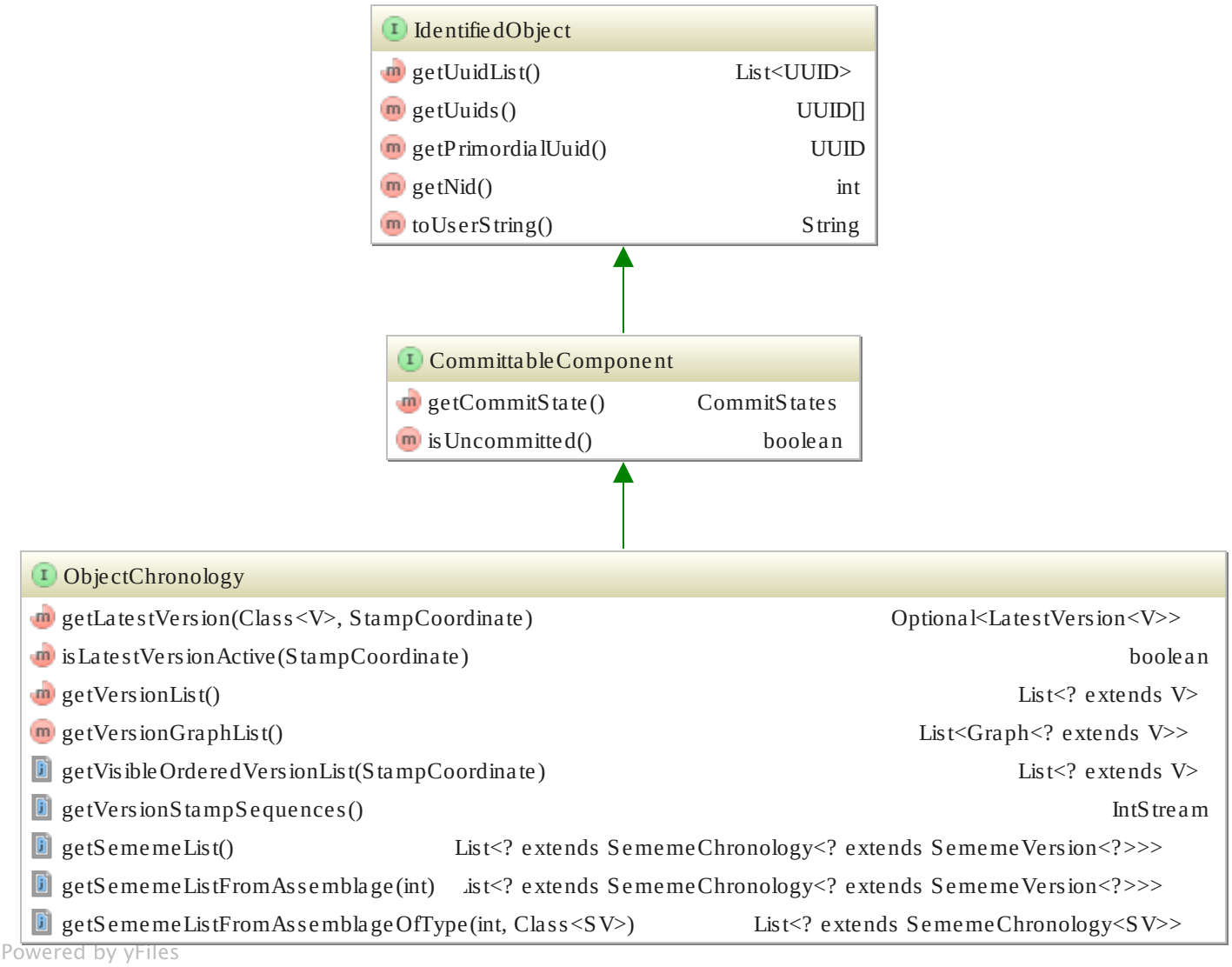


Figure 2.5. Object Chronology



The chronicle layer provides a means to generically represent the revisions to a component over time, and to index those revisions by status (active, inactive), effective time of change, author of change, module within which the change occurred (international edition, US extension, etc.), and the development path of the change (development, release candidate, etc.). Taken together, these fields can be referred to as a versions STAMP (status, time, author, module, and path).

The version STAMPS provides a foundation for version control and configuration management of all the components of the information architecture.

The STAMP will provide a means to modularize content so that modules can be turned on and off depending on specific use cases, and that modular content can be developed independently from unrelated modules. This modularity will enable simplified development and quality assurance processes for each module.

2.7.1. Distributed version control

Version control provides an audit trail for any changes to components of the informatics architecture, and the ability to roll back or forward to any version of any component as needed. The architecture must provide for standard distributed version control concepts of push, pull, paths, tags, commits, revisions, changesets, contradictions, branching, and merging for these components in the authoring environment.

The underlying data representation of the architectural components must be append-only so that a complete audit trail of all changes to all components is assured.

2.7.1.1. Path origins

Each path may have zero or more origins. An origin is a position (a point in time) on another path, and the downstream path will inherit all the changes that occurred on the upstream path prior to the origin position. Multiple origins enable a working path to be created from two or more systems that may have independent paths. For example, a path for development of a mapping between SNOMED CT and ICD-10 may have one origin on the SNOMED CT release path and another origin on the ICD-10 release path.

2.7.1.2. Commit record

Each commit to a chronicle must be accompanied by a commit record, which records what other STAMPS of that chronicle where visible to the author when the commit was made. This commit record will be used to determine if unsynchronized commits (commits that occurred before the author's commit, but that have not propagated through the distributed version control system) have been subsequently synchronized, generating an ERR event.

2.7.1.3. Version equality

Each version within the chronicle must have a standard means to test for content equality (versions with equivalent content, but whose author, commit time, or commit path may differ), and to test for absolute equality (versions with equivalent content and identical author, commit time and path). These different methods of equality will be used when managing ERRs, and when merging paths, and promoting content.

2.7.1.4. Path precedence ordering

Each version within the chronicle must be ordered first by the path upon which a commit is made, and secondarily must be ordered within the path by the time of commit.

2.7.1.5. Path promotion

The environment must provide the ability to promote selected content from one path to another as part of a controlled release process. This promotion process must be automatable, and repeatable. When path promotion occurs in the generation of release candidates, the process may be repeated many times, and therefore the process needs to be reproducible.

2.7.1.6. Event requiring review

During distributed development multiple authors may commit changes to the same components without being aware of concurrent changes made by other authors. These concurrent commits may be deliberate, for example in the case of duplicate editing for quality assurance or training, or may be inadvertent. The system must specify rules for determining if an Events Requiring Review (an ERR) is generated, and when concurrent commits may be managed in an automated way.

2.7.2. Concurrent coordinated development

Concurrent development is necessary to support coordinated content.

For example, if a pharmacy knowledge base is not current with the latest version of SNOMED, then drug-disease interactions may be missed. If a system is not using the latest version of SNOMED with the latest diagnoses, an enterprise may have to either fail to properly record a patient's diagnoses, or may have to create unnecessary local enhancements that will have to be later reconciled with the already released content in SNOMED.

The authoring environment for the architecture must support concurrent distributed development using a store and forward approach so that isolated development activities can be integrated despite lack or real-time network connectivity.

2.7.2.1. Change sets

Changes made by authors must be represented as changesets, and these changesets must be independent entities that can be applied to—or removed from—other configurations of the authoring environment.

2.7.2.2. Branching

<this section needs significant revision>

Branching, in revision control and software configuration management, is the duplication of an object under revision control (such as a source code file, or a directory tree) so that modifications can happen in parallel along both branches.

Branches are also known as trees, streams or codelines. The originating branch is sometimes called the parent branch, the upstream branch (or simply upstream, especially if the branches are maintained by different organizations or individuals), or the backing stream. Child branches are branches that have a parent; a branch without a parent is referred to as the trunk or the mainline.[1]

In some distributed revision control systems, such as Darcs, there is no distinction made between repositories and branches; in these systems, fetching a copy of a repository is equivalent to branching.

Branching also generally implies the ability to later merge or integrate changes back onto the parent branch. Often the changes are merged back to the trunk, even if this is not the parent branch. A branch not intended to be merged (e.g. because it has been relicensed under an incompatible license by a third party, or it attempts to serve a different purpose) is usually called a fork.

Branches allow for parts of software to be developed in parallel.[2] Large projects require many roles to be filled, including developers, build managers, and quality assurance [http://en.wikipedia.org/wiki/Software_quality_assurance] personnel. Further, multiple releases on different operating system platforms may have to be maintained. Branches allow contributors to isolate changes without destabilizing the codebase, for example, fixes [http://en.wikipedia.org/wiki/Patch_(computing)] for bugs, new features [http://en.wikipedia.org/wiki/Feature_(software_design)],[3] and versions [http://en.wikipedia.org/wiki/Software_versioning] integration [http://en.wikipedia.org/wiki/System_integration]. These changes may be later merged [http://en.wikipedia.org/wiki/Merge_(revision_control)] (resynchronized) after testing.

A development branch or development tree of a piece of software is a version that is under development [http://en.wikipedia.org/wiki/Software_development], and has not yet been officially released [http://en.wikipedia.org/wiki/Software_release]. In the open source [http://en.wikipedia.org/wiki/Open_source] community, the notion of release is typically metaphorical, since anyone can usually check out any desired

version, whether it be in the development branch or not. Often, the version that will eventually become the next major version is called the development branch. However, there is often more than one subsequent version of the software under development at a given time.

2.7.2.3. Merging

<this section needs significant revision, and an updated graphic>

Merging (also called integration) in revision control, is a fundamental operation that reconciles multiple changes made to a revision-controlled collection of files. Most often, it is necessary when a file is modified by two people on two different computers at the same time. When two branches are merged, the result is a single collection of files that contains both sets of changes.

adts [http://www.explain.com.au/oss/docbook/]

[1] http://www.hl7.org/oid/index.cfm

[2] http://tools.ietf.org/html/rfc4122#appendix-C

In some cases, the merge can be performed automatically, because there is sufficient history information to reconstruct the changes, and the changes do not conflict. In other cases, a person must decide exactly what the resulting files should contain. Many revision control software tools include merge capabilities.

There are two types of merges: automatic and manual.

Automatic merging is what revision control [http://en.wikipedia.org/wiki/Revision_control] software does when it reconciles changes that have happened simultaneously (in a logical sense). Also, other pieces of software deploy automatic merging if they allow for editing the same content simultaneously. For instance, Wikipedia allows two people to edit the same article at the same time; when the latter contributor saves, their changes are merged into the article instead of overwriting the previous set of changes.

Manual merging is what people have to resort to (possibly assisted by merging tools) when they have to reconcile files that differ. For instance, if two systems have slightly differing versions of a configuration file and a user wants to have the good stuff in both, this can usually be achieved by merging the configuration files by hand, picking the wanted changes from both sources (this is also called two-way merging). Manual merging is also required when automatic merging runs into a change conflict; for instance, very few automatic merge tools can merge two changes to the same line of code (say, one that changes a function name, and another that adds a comment). In these cases, revision control systems resort to the user to specify the intended merge result.

Merge algorithms are an area of active research, and consequently there are many different approaches to automatic merging, with subtle differences. The more notable merge algorithms include three-way merge, recursive three-way merge, fuzzy patch application, weave merge, and patch commutation.

2.7.3. Standardized release process

The architecture will provide a standard mechanism to release artifacts outside the immediate development team.

2.7.4. Configuration management

The architecture must allow organization of components into modules, identification of dependencies between modules, and specification of compatible versions of dependent modules.

Assembly of compatible components for testing and runtime.

2.7.5. Runtime time travel

The architecture must be able to cope simultaneously with historic data that was encoded using previous versions of the system, with current data that was encoded using current versions of the system. This historic and current data must in turn be processable by decision-support components of the system, in a manner appropriate for a life-critical system. Encoded knowledge must have STAMPs for all versions of its content. The overall system must be under configuration control such that all the valid STAMPs for any version of the system is retrievable for processing historic data, and encoded patient data must record the version of the system that it was encoded with.

Unlike other types of software which utilize a single version , all version of the encoded knowledge that has

2.7.6. Chronicle query

The architecture must provide for querying component chronicles.

2.7.6.1. View coordinate

The architecture must provide for a limited set of temporal query capabilities appropriate for identifying and managing change to encoded knowledge over time. These temporal queries must allow for temporal queries at current time, time points in the past or future, or over durations.

Each query must be given a view coordinate that specifies if the default temporal constraints for the query are at the current time, or a time point in the past of future. Individual clauses in the query may introduce additional view coordinates to enable durations

2.7.6.2. Status

Queries must allow the components status (active or inactive) to be part of the query criterion. For example, include only active components within the query criterion.

2.7.6.3. Author

Queries must allow the author of a change to be part of the query criterion. For example, only include changes that where not made by Chief Terminologist in the results of a query.

2.7.6.4. Changed from previous version

Computes the components that have been modified since during the time period specified by starting and ending view coordinates.

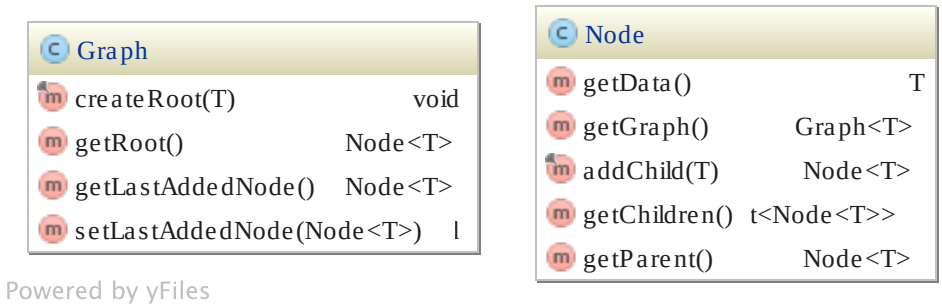
2.7.6.5. Module and/or path

Queries must allow the module within which—and the path upon which—a change is made to be part of the query criterion. For example, only consider changes that occurred in a language module on the release candidate path as part of a query.

2.8. Graph

Graph is a foundational structure.

Figure 2.6. Graph and Node



2.8.1. Logical Expression

Figure 2.7. Logical Expression

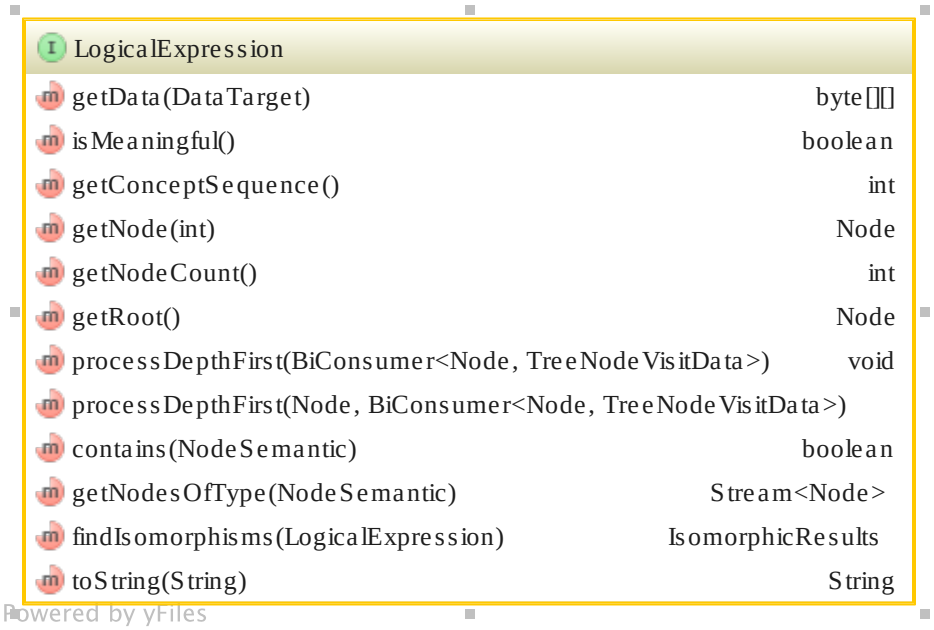


Figure 2.8. Logical Node

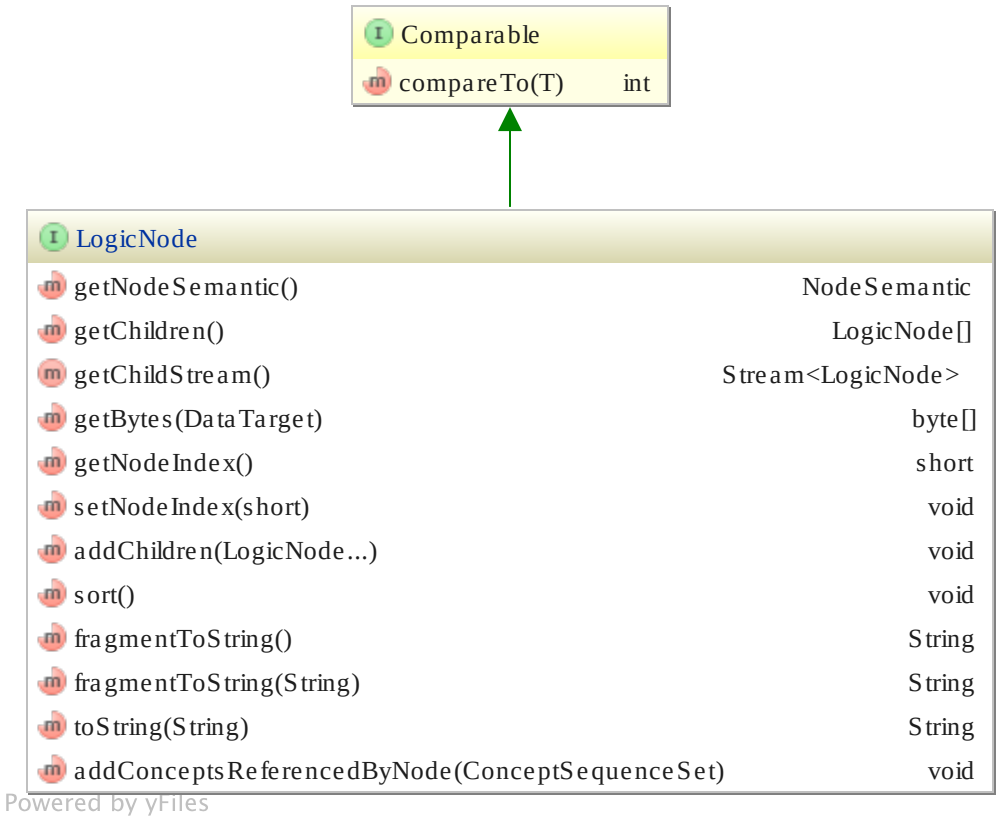
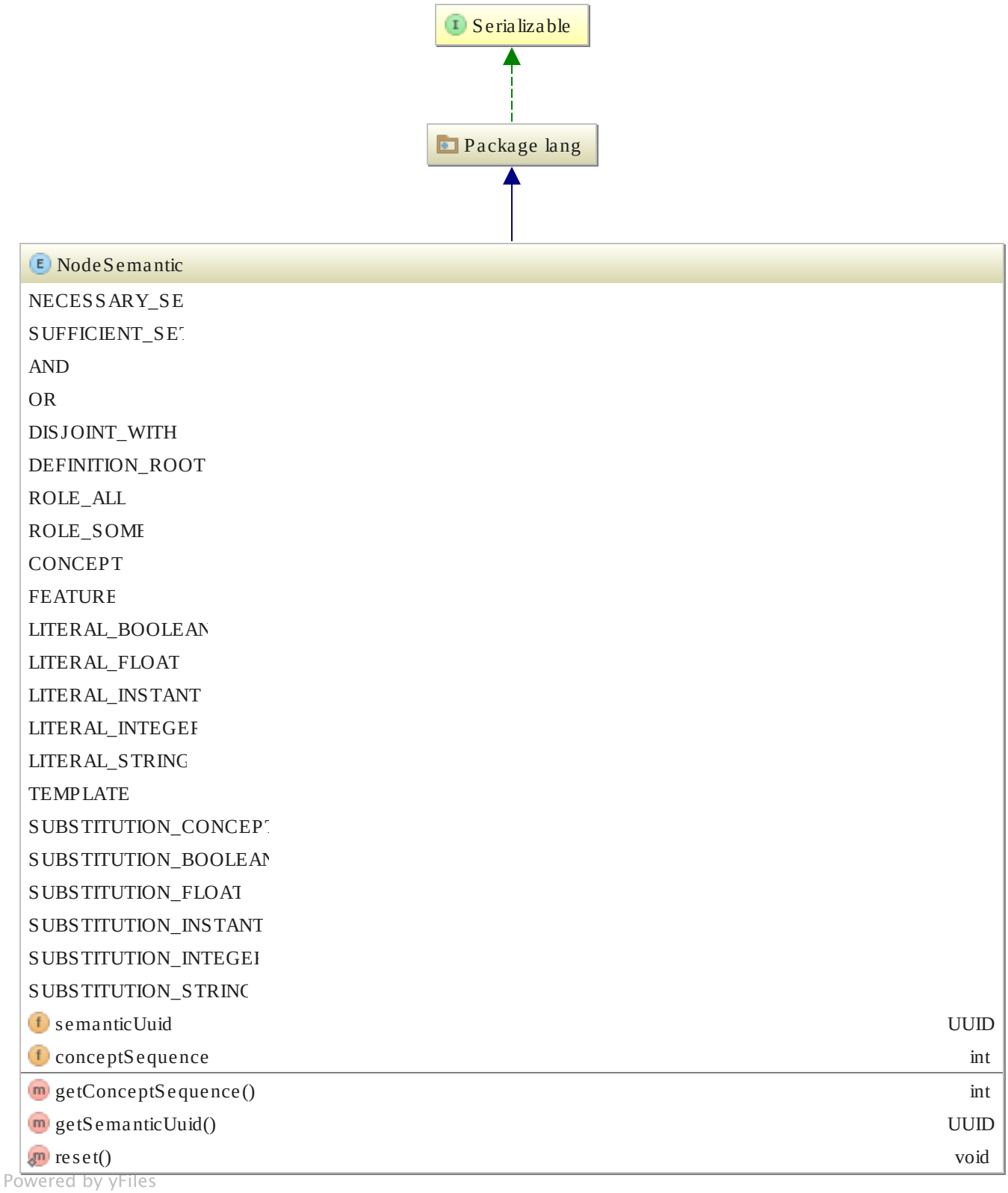


Figure 2.9. Node Semantic



2.9. Semantic

Text

Figure 2.10. Semantic object

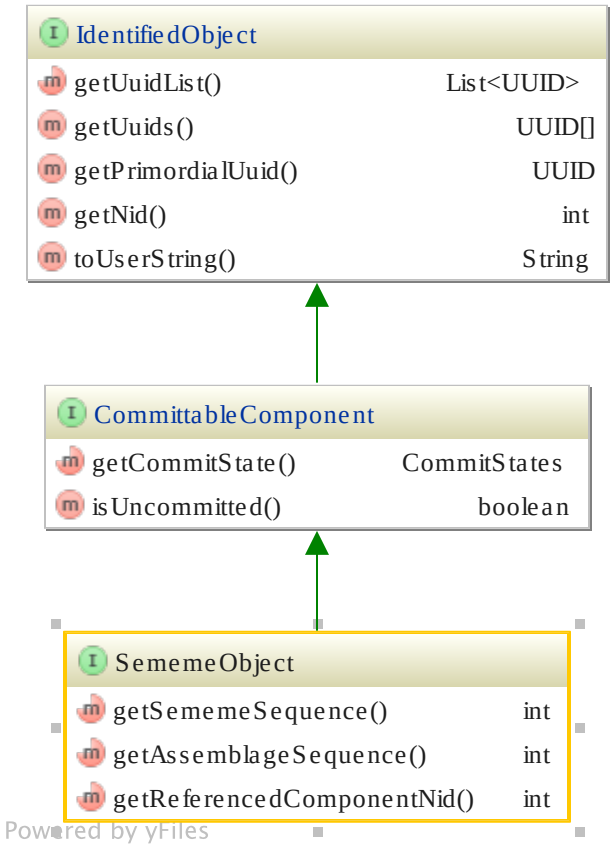
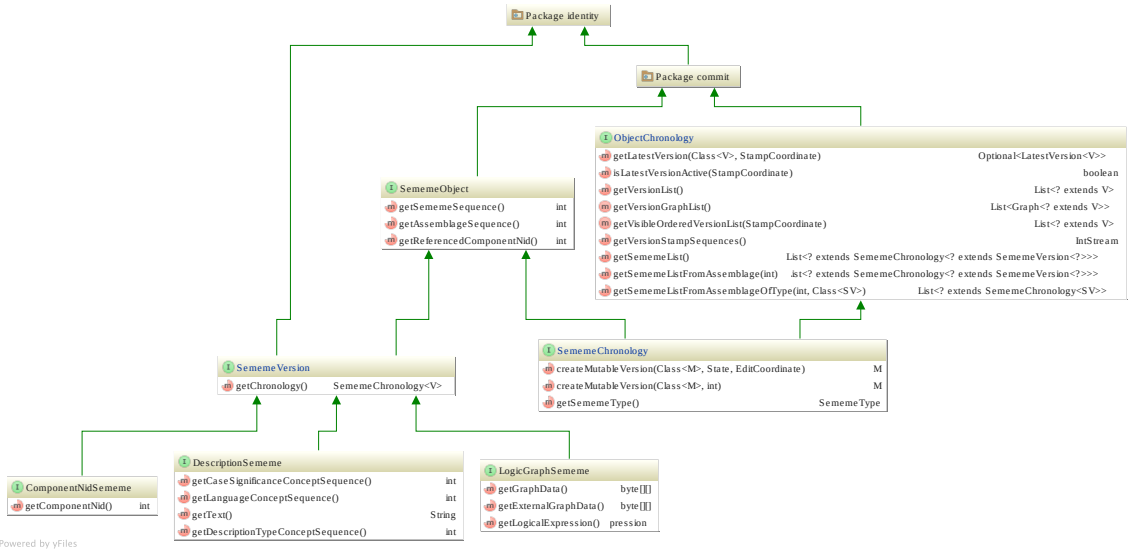


Figure 2.11. Semantic Chronology & Versions



Semantic[1] enables addition of semantic data (semantic meme == Semantic to the underlying concepts content, in a standardized way that provides for the same means of identifying, modularizing, and versioning content.

Clinical facts such as side effects or treatment effects of medications are just one of many examples of reference extensions. Laboratory reference ranges that represent standard normal, higher, and lower bounds of laboratory test values by age and ethnic group are another example.

2.9.1. Assemblage

An Assemblage is a collection of Semantic for a particular purpose.

The Assemblage consists of Semantic that reference an component, and provide additional data to that member for some purpose.

Or development experience has shown that the language surrounding naming of concepts related to Refexes has been challenging, with many similar sounding entities (Refex, Refset, Refex Collection, Refex ID, Refex Member ID, Referenced Component, Extended Component, Reference Extension, Component Reference, and more). In the requirements here, we hope to provide a more systematic and less confusing naming standard for Semantic concepts. Part of the reason for the choice of Assemblage as opposed to use of Refset Concept, is to provide more clarity, and to use terms that do not have baggage that prevents unambiguous interpretation of what is meant by the term.

2.9.1.1. Assemblage identity

Every reference extension Assemblage is identified by a concept created specifically for this purpose. The identifier of this concept is the identifier of the Assemblage. The Assemblage concept is annotated with metadata to enable proper display and processing of the members of the Assemblage.

[1] A Semantic (from Greek σημα#νω (s#maín#), meaning "mean, signify") is a semantic unit of meaning. A Semantic is a proposed unit of transmitted or intended meaning; it is atomic or indivisible. It can be thought of as the semantic counterpart to any of the following: a meme in a culture, a gene in a genetic make-up, or an atom (or, more specifically, an elementary particle) in a substance.--Wikipedia

2.9.1.2. Assemblage metadata

Every Assemblage will have metadata associated with it that indicates the purpose of the Refex in general terms (navigation, mapping, navigation, reference ranges, etc.). In addition, the metadata will define the semantics of each extension field, and will provide standard ordering for presentation of those fields, and standard naming information for those fields, so that Refex data can be presented to consumers in a sensible manner.

2.9.2. Description Semantic

2.9.2.1. Language

The language requirements enable direct support for user interface customization for different user groups. In the past, interface terminologies have been proposes as an alternative to supporting the language requirements within a single integrated system. Use of independent terminologies creates a mapping and maintenance burden that is unnecessary.

2.9.2.1.1. Typed descriptions

The architecture must allow all descriptions to be given a metadata type that indicates the way the typed description describes the concept of which it is a part. For example, description types may include: fully-specified-name, synonym, and definition.

2.9.2.1.2. Multilingual support

Each description specifies the language that it is from. Identical spelling may not have the same meaning in different languages, for example: pie in Spanish refers to foot#the lower extremity of the leg below the ankle, on which a person stands or walks. In English pie means a baked dish of fruit, or meat and vegetables, typically with a top and base of pastry.

Since concepts are organized by meaning, and since descriptions are associated with only one concept, having a particular description stand for two different concepts is not allowed. To prevent problems caused by false cognate and false friends between languages, all descriptions are assigned to a single language, within a concept that represents the meaning of that description within that language.

Descriptions are not required to be unique, and therefore a Spanish description of pie can be within the concept for the lower extremity of the leg below the ankle, on which a person stands or walks, and the English description of pie can be within the concept for a baked dish of fruit, or meat and vegetables, typically with a top and base of pastry.

2.9.2.1.3. Dialect support

The architecture must provide a standard means of identifying if a particular description is preferred or acceptable in a particular dialect. Dialect is to be interpreted broadly, not just to represent geographical variation in language, but it is also to represent variation in language caused by role or profession. For example, one dialect may support use of words or phrases that patients can readily understand (e.g. before bedtime) and another dialect may support words or phrases specific for caregivers (e.g. qhs).

2.9.2.1.4. Terminology query

The IA must provide flexible (able to support current use cases and adapt to new use cases), effective (high quality results), and efficient (fast response time and high throughput) search over textual components of the IA.

2.9.2.1.4.1. Language coordinate

Defines version, language, dialect, module, path, and version for retrieval.

2.9.2.1.4.2. Concept specification

Consists of a concept identifier as well as a current textual description of that concept. The use of Concept Specifications ensures validation of a computable key (the concept identifier) with human interpretable text. If the concept retrieved from the identifier does not contain the textual description, a validation error will be throws.

End users must not constrict by entering or copying and pasting concept identifiers. They must be provided a drag-and-drop interface uses concept specs so that the identifiers may be validated against the users understanding of the description of those components as part of the query process.

2.9.2.1.4.3. Regular expressions

Queries must support regular expression clauses over descriptions.

2.9.2.1.4.4. Indexed full-text search

Queries must support full-featured text search clauses over descriptions.

Text search features must include:

· Ranked searching -- best results returned first

· Phrase queries

· Wildcard queries

· Proximity queries

· Range queries

· Fielded searching (e.g. title, author, contents)

· Simultaneous update and searching

· Flexible faceting, highlighting, joins and result grouping

· Fast, memory-efficient and typo-tolerant suggestions

2.9.2.1.4.5. Concept for component substitution

Substitute the concept that encloses a component in the result set of the child clause. For example, return the concept for all members of a comment Refex that have an active status.

2.9.2.1.4.6. Fully specified description substitution

Substitute the fully specified description—in the specified preferred language and dialect—for all active concept members of the veterinary Refex.

2.9.2.1.4.7. Preferred description substitution

Substitute the preferred description —in the specified preferred language and dialect—for all active concept members of the veterinary Refex.

2.10. Concept

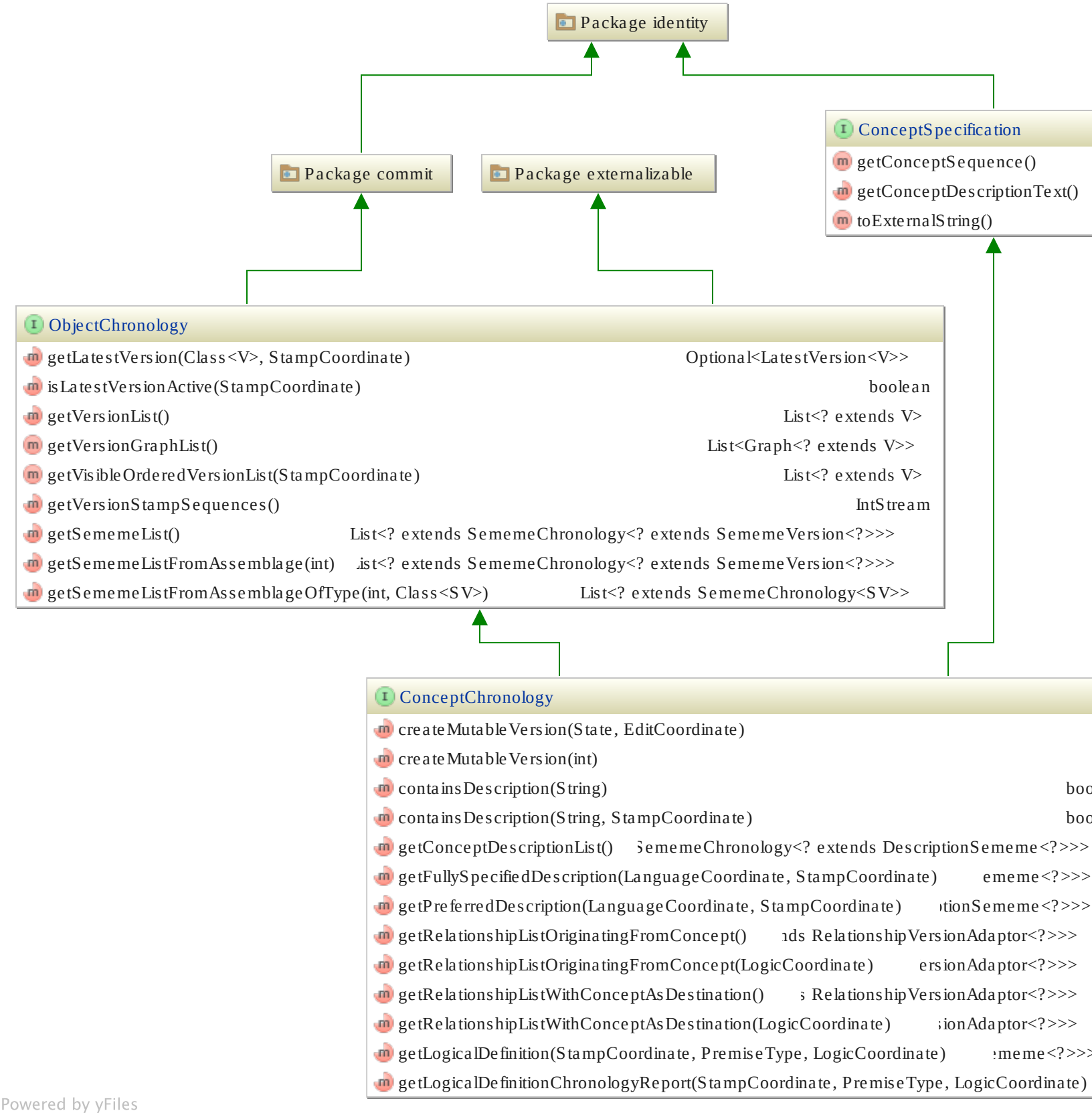
ConceptChronology extends ObjectChronology with specific methods to identify and describe concepts. All identifiable concepts used in higher layers must be present in this layer.

The architecture is concept oriented. Its entries are organized conceptually, rather than by term. Whereas a dictionary starts with the term in a given language and captures all its possible meanings, the terminology layer is based on the concept, that is, the conceptual content, to which the terms in various languages correspond. [10]

2.10.1. Homogenous semantics units

The concept-orientation principle will extend to all declarative semantics within the architecture. For example, units of measure will be represented as concepts (as SNOMED CT already provides), rather than as text fields (as UCUM would provide). Although the internal representation of the architecture will be concept-oriented, the ability to interoperate with text-based semantics may be provided through reference extensions (as described in Section 3.8 Reference extension layer) to the appropriate concept.

As with units of measures, language information will be encoded as concepts, rather than text fields. Text fields will not be used for machine processable semantics. Text fields will only be used for presenting language to the user for comprehension of the underlying concepts.

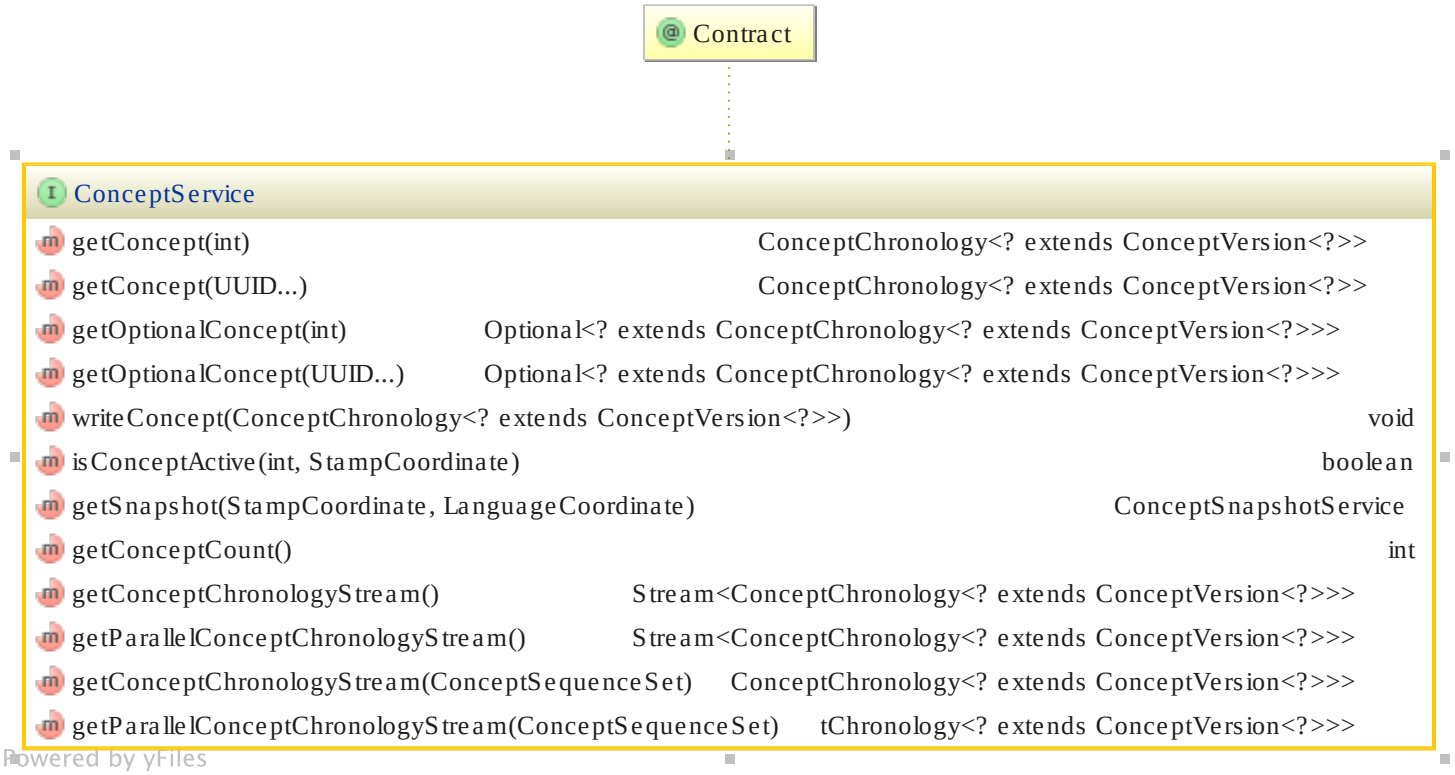


This constraint ensures that the traditional “information models” that are representable and can have well defined and consistent relationship with the concepts layer, and that those models can be specifically designed to work coherently with the underlying concepts.

2.10.1.1. Concept service

Text

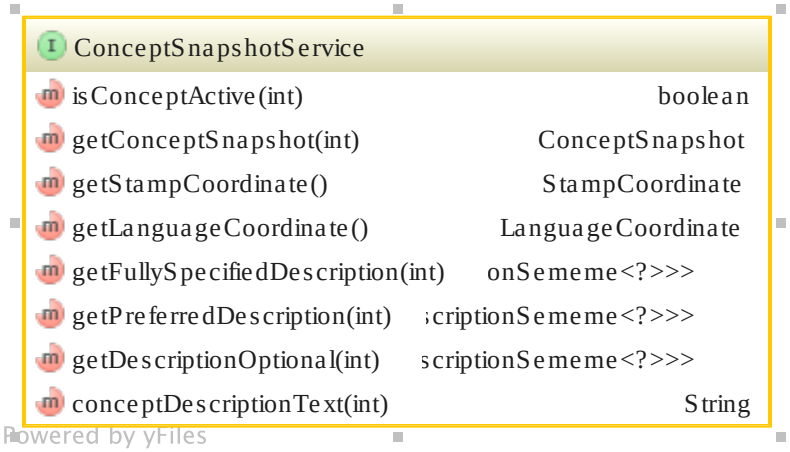
Figure 2.13. Concept service



2.10.1.2. Concept snapshot service

Text

Figure 2.14. Concept service



2.10.2. Language & dialect

Text

2.10.3. Versioned Graph

Text

2.10.4. Description logic

Text

2.10.5. Taxonomy

Text

2.10.6. Query

Text

2.10.7. Transformation

Text

2.10.7.1. Nesting transformation

Text

2.10.7.2. Flattening transformation

Text

2.10.7.3. Isosemantic transformation

Text

2.10.7.4. XSLT extensions

XSLT extensions provide for accessing computed values, values that can not be obtained simply from the structure of underling objects

2.10.7.4.1. kind-of

From the computed taxonomy relationships, based on the DL

2.10.7.4.2. member-of

Member of a assemblage based on query and STAMP version

2.10.7.4.3. description-of

Using language, dialect, and STAMP version.

2.10.8. Rule

Text

2.10.9. Domain

The domain layer hosts abstractions built from the underlying layers that describes selected aspects of a sphere of knowledge, influence, or activity. The domain model is a representation of meaningful real-world concepts pertinent to the domain that need to be modeled in software. The concepts include the data involved in the business and rules the business uses in relation to that data.

2.10.9.1. Semantic document markup

Specifically choosing names to avoid confusion between HL7 structured documentation such as clinical document architecture.

2.10.9.2. Terminology model

Defines a general-purpose representation of terminology systems able to represent SNOMED CT, LOINC, and RxNorm using description logics, languages, and dialects.

2.10.9.3. Semantic extension model

Defines a general-purpose representation of terminology systems able to represent SNOMED CT, LOINC, and RxNorm using description logics, languages, and dialects.

2.10.9.4. Observable model

SNOMED/LOINC observable model.

2.10.9.5. Observation result model

CIMI observation result model.

2.10.9.5.1. Presence, absence, and unknown

Dot blot hemorrhage absent vs zero Dot blot hemorrhages vs it is not known if the patient has dot blot hemorrhages. [0,0]; $(0,\infty)$; $[0,\infty)$.

2.10.9.5.2. Proximal provenance

The proximal provenance represents the last step in determining how the value of the observation result was obtained. For a blood pressure measurement, examples may be concepts such as "by provider measurement," "by patient report," or "from prior encounter document." In the case of a null value for an observation result, examples may be concepts such as "not asked", "not asked because question is not applicable", "not asked because patient is unconscious." The proximal provenance supports a superset of the semantics of the HL7 null flavors for null values, in addition to supporting provenance information regarding bona fide values.

2.10.9.5.3. Subject of information

This value is associated with the patients, partner, relative, etc. Needs to have the ability to represent the precision necessary for a genetic history.

2.10.9.6. Request model

abc

2.10.9.7. Encounter document model

Represents the assertions and requests that are associated with an encounter with either the patient, a specimen related to the patient, or data pertaining to the patient

2.10.9.8. Questionnaire model

A static representation of questions in machinable form, that when presented to—and completed by—a user from within a compliant application, results in a well-formed encounter document.

2.10.10. Script

Text

2.10.11. Workflow

Text

2.11. ISAAC layer concerns

- Start at the bottom layer
- Can the layer represent the necessary information?

- Will addressing the concern at this layer result in undesirable combinations/complications? (maybe each layer defines it's own rules?)

2.11.1. Identity

Every identified object is given a UUID.

2.11.2. Chronology

An identified object may participate in one or more modules over time, and that participation may be with a status of active or inactive within that module, may be on a development branch, or master branch of that module, and the participation within that branch is authored by an identified entity at a point in time.

2.11.3. Semantic extensibility

An identified chronology may extended another identified chronology by specifying the identifier of the object it is extending, and a second identifier for another identified chronology that defines the semantics of the relationship. The identifier of the extension chronology is the origin identifier, and the identifier of the extended chronology is the destination identifier. The identifier of the identified chronology that defines the semantics of the relationship provides a type identifier for the relationship, and the set of all extensions of a particular type are referred to as an assemblage[2], to easily differentiate this type of set from other types of sets via a naming convention.

2.11.4. Representational generality

The ability for chronologies to semantically extend (add meaning to) other chronologies results in an property-graph data structure, where the properties of a node are represented by the identifiers of it's semantic extensions. A bonus of the underlying chronology associated with each identified chronology is that the resulting property graph is versioned and modular, and thus can represent relationships between objects that may change over time.

The property graph is a generic mathematically-oriented graph that supports both labels and key/value properties. More formally, it is a directed, binary, attributed multi-graph.

The property-graph data structure can represent any parsable computing language, such as OWL EL, Java, Drools, and so forth. As such, it is a general representation that can confidently serve as a general foundation for symbolic data.

Interesting article on relating property graphs to RDF. [3]

2.11.5. Modularity

Modules have identity, branches, snapshot versions, and released versions.

ISAAC defines a modular system and a service platform for clinical knowledge management that implements a complete and dynamic component model. ISAAC provides an environment for the modularization of knowledge resources into artifacts. Artifacts are uniquely identified by a group id and an artifact ID which is unique within a group. Each artifact is a tightly coupled, dynamically loadable collection of language, definitional, assertional, statement, and procedural resources that explicitly declare their external dependencies (if any). http://www.mkbergman.com/489/ontology-best-practices-for-data-driven-applications-part-2

[2] A collection of things.
[3] https://neo4j.com/blog/rdf-triple-store-vs-labeled-property-graph-difference/

2.11.6. Configuration

Versioned dependencies between modules represent configurations of a system.

2.12. Crosscutting concerns

2.12.1. Understandability, reproducibility, and utility

2.12.2. Query

2.13. Coordinate-based separation of concerns

2.13.1. STAMP coordinate

2.13.2. Language coordinate

2.13.3. Logic coordinate

2.13.4. Manifold coordinate

Frequently, one coordinate in isolation is not sufficient. The manifold[4] coordinate provides a single coordinate that integrates the other three for

2.13.5. Snapshot services

[4] A whole composed of diverse elements.

3. ISAAC's KOMET

3.1. Introduction to Komet

Nothing

3.1.1. KOMET

The VA's Foundational Informatics Architecture – which we call ISAAC – is an integrative logical architecture, which deliberately builds each new layer upon selected, compatible elements of its underlying components to build a coherent system. The Foundational Informatics Architecture builds primarily upon SNOMED CT, RxNorm, and LOINC by integrating their content and semantics, and normalizing the means to identify and version components, lexically search, logically define, semantically retrieve, and collaboratively extend. Support for evolutionary change is a critical feature of the Foundational Informatics Architecture (DERIVIATE), given that support for changes in knowledge over time is a critical aspect of health informatics.

The primary goal of the Foundational Informatics Architecture (DERIVIATE) is semantic operability (vs. interoperability). Semantic operability is the meaningful (semantic) use of data within the various components and uses of a single health IT system (vertical integration). Semantic operability is achieved by using a coherent integration of SNOMED CT, RxNorm, and LOINC as the primary building blocks upon which the foundational architecture is based. DERIVIATES's strict separation of concerns enables terminology components, as well as higher order derived structures such as clinical rules, to undergo evolutionary change without requiring changes to the architecture that it resides within. This allows for an agile environment with a stable architecture.

The lowest 'pad stone' layer of the DERIVIATE architecture is the integrated suite of standard terminologies including SNOMED CT, RxNorm and LOINC. Two higher layers build upon this terminology 'pad stone'. A Clinical Data layer uses standardized terminology to describe facts about a patient e.g., "John Doe has PNEUMONIA." A Procedural Knowledge layer uses standardized terminology to express biomedical and organizational knowledge, independent of any specific patient. For example, "Hydrochlorothiazide treats Hypertension" or "Myocardial Infarction elevates Troponin T Levels." CDS rules, order sets and documentation templates are also expressed in the "Procedural Knowledge" layer.

The VA must have tools to help knowledge workers create and maintain standards-based clinical decision support artifacts at enterprise scal. Tools must be able to produce CDS content that is standards compliant when such standards exist (e.g. HL7 CDS Artifact Specificaiton DSTU 1.3). Tools must also build CDS artifacts that contribute to an ecosystem of semantic operability. This necessarily means means building artifacts using standards-based "pad stone" building blocks of SNOMED CT, RxNorm and LOINC. CDS knowledge engineering content development tools must create artifacts in the layered approach desribed in DERIVIATE (i.e., tools must build more complex standards-based artifacts by reusing less complex standards-based artifacts as components whenever possible). Tools supporting a highly collaborative, integrated and layered knowledge management environment must be carefully designed to be highly reusable within a common framework and use experience.

In the following sections we will first describe the common features required of all components in the integrated standards-based knowledge management tool suite and then document tool-specific requirements necessary for each artifact type.

3.1.1.1. Heuristic principles

To develop an optimal user interface (UI) for all of the editors that will be used to create and update clinical decision support artifacts, the Contractor shall execute an agile, User-Centered Design (UCD) and implementation process that addresses the stages shown in the figure below. Note that each stage is meant to be iterative and repeated as often as needed for each editor before moving to the next editor.

Part of user-centered design includes measuring usability.

Measuring usability starts with the five attributes of usability commonly referenced in the literature, shown below.

- Easy to learn (and re-learn)
- Efficient to use (performance)
- Effective to use (completion)
- Prevents errors (not cause harm)
- Satisfying to use (subjective impression

To accomplish this, the usability testing strategy consists of two main components:

- 1) Formative Testing: Evaluating the usability of early designs of the user interface for the CDS editors and Governance Tool prior to and/or during software development.
- 2) Summative Testing: Measuring and testing system usability of the coded software that is stable and releasable in a test account with valid test data.

CDS and other knowledge artifacts share many similarities. Certain similarities are manifest in their basic components and structure. All CDS and knowledge artifacts should refer to standard terminologies (i.e., the lower layers of DERIVIATE) for the clinical entities and clinical actions comprising the higher order artifact. For example, a CDS rule that evaluates if a specific medication is being taken by a patient as a condition for execution should refer to RxNorm medications. DERIVIATE layers more complex artifacts on top of the terminology pad stone and on top of each other. In general, more complex layers each specify an artifact-specific syntax to orchestrate terminological and other less complex components into the desired higher level artifact. This means that more complex CDS artifacts may be composed of CDS artifacts of lesser complexity.

CDS artifacts of different levels of complexity may be developed by the same knowledge engineers. This has important implications for design and functionality of the user interface. The user interface must be consistent and provide an integrated view of knowledge artifacts at all levels of complexity. CDS artifacts must be searchable in clinically relevant ways, regardless of their final composition. An obvious example is finding artifacts containing identical or similar terminological concepts. Another is that basic editing functions must be consistent, easily learned and similar to typical editing conventions (e.g., copy, paste)

Knowledge engineers must collaborate to develop CDS artifacts in several ways. First, knowledge engineers may request review and critique of their work products by others, both informally during the build process and formally prior to release. Some CDS artifacts will be complex due their sheer size or because they are composed of collections of sub-artifacts. For example, a complex artifact for ordering clinical subspecialty consults may contain sub-artifacts of ECA rules, order sets and documentation templates. Knowledge engineers may take responsibility for portions of a complex knowledge artifact, divided by section or by sub-artifact type. Knowledge engineers must be able to request the development of sub-artifacts by other knowledge engineers and to track fulfillment. Tools must be able to support collaboration amongst knowledge engineers.

CDS artifacts share common metadata because they are formally dependent on each other (i.e., expression of asset to asset linkages). Artifacts must share common metadata regarding time stamps, editing, versioning and tracking. Other types of metadata are common because of overlapping requirements for linking the assets to the deploying organization, to the literature and to clinical work processes.

The fact that there are numerous similarities among CDS and other knowledge artifacts has important implications for the knowledge engineering tools used to create them. In short, CDS knowledge engineering tools share many common features and capabilities that will be described in the sections below. We acknowledge the work done by Zhou and colleagues regarding rule authoring environments requirements and reuse certain of their best practice requirements in this document.

3.1.1.2. Look and feel

3.1.1.3. Document template editor

The HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU (Draft Standard for Trial Use) Release 1.3, page 38, presents the following definition of documentation template from the HeD (Health eDecisions) Artifact Sharing Use Case:

"… a documentation template is a structured form for recording information on a patient into a set of predefined data slots. These templates are used to guide structured data entry within an EHR or other clinical information system."

The types of clinical documents that can be represented using documentation template artifacts include, but are not limited to, patient visit (encounter) summaries, procedure notes, consultation reports, patient-reported outcomes, and flowsheets.

A Documentation Template editor should be able to create documentation template artifacts representing a variety of clinical document types for use at both the VA local (facility) and enterprise level.

The HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3 includes Documentation Templates as a primary artifact type and Figure 4 on page 39 of the specification, provides a conceptual overview diagram of required and optional components.

The purpose of the Documentation Template editor tool is to support the creation of standardized Documentation Template knowledge artifacts. The Government requires a model-based Documentation Template editor that will allow the user to create documentation template knowledge artifacts that are based on SME-defined content that can be implemented within the VA's electronic health record (EHR) at the point of care and within the clinical workflow, and that conforms to the specifications in the HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3 (or later HL7 version or final standard if one is released).

The VA requires a Documentation Template Editor that can be used by the VA and non-VA end users to generate Documentation Templates of various types as may be needed in the full spectrum of medical practice. The Documentation Template Editor shall generate documentation templates that ultimately will be used by VA clinicians to manage patient care in a production environment.

The Documentation Template Editor shall be able to be used to create any type of documentation template as a structured collection of documentation concepts (also referred to as "form elements" or "observation items"). Per the HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3, "Each documentation concept … also can be thought of as a question to the user entering the data". Elements within the documentation concept serve a purpose to guide and constrain the user's responses -- for example, a list from which to choose an answer; whether an answer is a number, a date, or some other type; and the cardinality of the answer. (HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3, pages 38 and 39.)

Documentation concepts are contained in an action of type CollectInformationAction, enabling these concepts to be presented to the user conditionally (e.g., to ask questions appropriate to a patient's gender or to ask questions based on other responses), to compute responses for a concept based on previous responses or data from an EHR score (e.g., a risk score), and to bind the responses into expressions that can drive logic elsewhere in the documentation template (e.g., ask questions conditionally as described above). Thus, resulting documentation templates are capable of branching logic, and the forms created must be able to specify all the actions (such as action of type CollectInformationAction) within the HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3.

The documentation concepts in a template typically are organized hierarchically, into sections and subsections with the concepts themselves at the very bottom of the structure. In HeD Knowledge Artifact schema, these "sections" are called actionGroups - which in documentation templates may have behavior indicators associated with each actionGroup, e.g., whether a documentation concept must have a response.

3.1.1.4. Event condition action rule editor

The HL7 Version 3 Standard: CDS Knowledge Artifact Specification, Release 1.3, page 31, presents this definition of an event condition action (ECA) rule from the HeD (Health eDecisions) Artifact Sharing Use Case:

… an event condition action rule is an artifact with the general syntax "on event, if condition is true, then do action." The event triggers the invocation of the rule. The condition is a logical test that, if satisfied or evaluates "true," causes an action. The action part consists of a set of operations to execute. These actions may in turn cause further events to occur, which may in turn cause other ECA rules to fire…The action groups are the containers and organizers of the actions in an ECA rule. A rule typically has a single action group (top level section), but may have more. Conceptually, a set of actions in a rule could be considered a "mini order set" which is presented to a clinician at certain times and under certain conditions. As such, the actions may be structured hierarchically using action groups and behaviors to specify how the orders should be a shown to a provider, and to place restrictions on how a provider chooses from the available set of orders. It should be noted that this is just a conceptual example, and that not all actions are necessarily orders. For example, an action can be a creation of a new event that triggers another rule, a future encounter, or the creation of a state description of the patient.

"Efficient rule authoring tools are critical to allow clinical Knowledge Engineers (KEs), Software Engineers (SEs), and Subject Matter Experts (SMEs) to convert medical knowledge into machine executable clinical decision support rules."

An ECA Rules editor should be able to facilitate the user's ability to generate both local (i.e., for a single facility), VISN (i.e, for a group of facilities), and enterprise-level ECA rules that are standardized, sharable, interoperable, and extensible.

The VA requires a model-based ECA Rules editor that will allow the user to generate ECA Rule knowledge artifacts based on SME-defined content that can be implemented within VA's electronic health record (EHR) at the point of care and within the clinical workflow. The ECA Rules editor shall generate CDS knowledge artifacts with the general syntax "on event, if condition is true, then do action."

The VA requires an ECA Rules editor that will be used by government and non-government end users to generate ECA rules applicable to the full spectrum of medical practice, including generation of ECA rules that support the application of clinical practice guidelines and protocols in patient care as well as the dynamic management of these guidelines and protocols. The ECA Rules editor shall generate ECA rules that ultimately will be used by VA clinicians to manage patient care in a production environment.

The CDS knowledge artifacts generated by the ECA Rules editor shall conform to specifications defined in the HL7 Version 3 Standard: CDS Knowledge Artifact Specification, Release 1.3 (or later version or final standard if one is released).

3.1.1.5. Condition editor

3.1.1.6. Expression editor

3.1.1.7. Action editor

3.1.1.8. Order set editor

Clinical orders are used to initiate the majority of healthcare delivery activities in the US and thus are a major driver of cost, quality and safety. Orders are used in virtually all healthcare settings including (but clearly not limited to) medication prescribing, laboratory tests, imaging, procedures, consultations, encounters and hospital admissions. In the VA, for example, well over 1.2 million orders are entered every day and VistA contains billions of orders in aggregate.

Clinical orders' ubiquity and impact on healthcare delivery has made ordering a central focus of quality improvement efforts. Health Information Technology (HIT) was used to improve the ordering process when paper was the only available medium. Computerized provider order entry has taken clinical quality, safety and efficiency improvement initiatives to another level. Order related interventions are manifold and include allergy and interaction checking among medications and foods, appropriateness checks amongst all combinations of disease, drugs and labs; the establishment and enforcement of ordering prerequisites; and limitation of authority to place orders.

Order sets are an important category of order related interventions that enjoy widespread use because they have been shown to improve quality while enhancing the efficiency of the ordering provider (a rarity).

The HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3, includes order sets as a primary artifact and on page 34, presents this definition of an order set from the HeD (Health eDecisions) Artifact Sharing Use Case:

…an order set is a pre-defined and approved group of orders related to a particular clinical condition (e.g., hypertension treatment and monitoring) or stage of care (e.g., hospital admission to Coronary Care Unit). An order set is used as a checklist for the clinician when managing a patient with a specific condition. It is a structured collection of orders (or actions in the HeD schema) relevant to that condition and presented to the clinician in a computerized provider order entry system (CPOE).

Ordering providers use order sets as check lists, menus, and order construction shortcuts. Order sets are often embellished with clinical rational and guidance about their proper use and literature references for the ordering provider.

The HL7 CDS specification provides a conceptual overview diagram of required and optional components.

An order/order set editor is needed that will be used to create knowledge artifacts for individual orders and order sets applicable to the full spectrum of medical practice and which conform to specifications defined in the HL7 version 3 Standard: CDS Knowledge Artifact Specification, Release 1.3 (or later version or final standard if one is released).

3.1.1.9. Aggregate artifact editor

The VA intends to use HL7 KNART artifacts for a variety of purposes in addition to documentation. In particular, we will include document templates as a core component for the ordering of specialty consults in combination with orders and order sets. We refer the class of artifacts that are composed of multiple KNART artifacts as "composite artifacts". We anticipate that there will be need for multiple types of composite artifacts in addition to specialty consultations.

The majority of the effort of creating specialty consults and other composite artifacts above and beyond construction of the subcomponents will be devoted to subcomponent integration into the desired consult. Other requirements can be met using editing environments for the individual subcomponents.

3.1.1.10. Presentation layer editor

The HL7 CDS Artifact specification is designed as an interchange format for CDS artifacts. This approach promotes the exchange of clinical decision support content because poorly shareable platform-specific implementation details are not included in the exchanged artifacts. While platform-specific implementation details are absolutely needed in order to execute the artifact in a given live HIT system, they might impede efforts to implement the clinical components of CDS artifact in some other environment. The separation of CDS artifact interchange format from implementation format is an important step towards creating an ecosystem of shareable standards-based CDS on shareable standards-based data. As a result of these beneficial tradeoffs, HL7 CDS Artifacts must be transformed from an interchange format to an implementation format in order to be executed.

The purpose of presentation layer tools is to support the conversion of standardized interchange artifacts into implementable CDS artifacts. The scope included in this section includes any type of tool needed for CDS exchange artifact conversion. The initial tool to be constructed will support the conversion of HL7 CDS Documentation Templates with CQL into HTML5 templates with Drools DRL.

3.1.1.11. Governance workflow management

Achieving standards-based shared clinical decision support at the enterprise scale is a complex undertaking with many technical and organizational steps that require careful orchestration. Knowledge management tools supporting organizational processes are as important as technical tools for achieving wide-spread support, implementation and adoption of knowledge products such as clinical decision support rules, order sets and documentation templates. Numerous organizational challenges must be met at different phases of the CDS lifecycle, including problem identification, solution analysis, knowledge development, organizational vetting, impact assessment and periodic assessment (fig x in introduction).

CDS enterprise governance tools are designed to support organizational vetting and periodic review of enterprise knowledge artifacts. The desired end results are high quality knowledge artifacts that have been reviewed and approved for implementation by appropriate and authoritative bodies. Organizational vetting and periodic review involves various subject matter experts and governing bodies to perform the following functions:

- Critically assess and evaluate the proposed CDS artifact
- Document potential issues
- Decide to pursue or ignore identified issues
- Develop potential resolutions to those issues
- Approve of one or more resolutions and re-evaluate the proposed remediated artifact.

To complicate matters, different groups may be involved in vetting and periodic review of the same artifacts. Methods to integrate and harmonize or version and track different CDS artifacts are an essential feature of governance tools. Business requirements supporting these essential steps are described below.

3.1.1.12. Metrics and refactoring support

We need to think through the types of metrics and refactoring. Look at some of Fowler's books on these topics, and then come up with analogies for our domain.

3.1.1.12.1. Linguistic knowledge refactoring

Linguistic knowledge codifies the relationship between our words, and the shared concepts we hope they adequately represent. In ISAAC, we depend on several aspects of linguistics to make abstract concepts, initially defined with only a set of identifiers, sufficiently concrete to prove a shared understanding of the thoughts those concepts represent. For ISAAC, relevant aspects of linguistics include morphology (the structure of words), syntax (the structure of sentences), semantics (meaning), pragmatics (language in context), language variation (i.e., dialects), and language change over time.

3.1.1.12.2. Definitional knowledge refactoring

T-Box semantics

3.1.1.12.3. Declarative knowledge refactoring

A-Box semantics

3.1.1.12.4. Imperative knowledge refactoring

4. Design approach

4.1. Requirements driven

Capturing requirements is difficult. Capturing architecturally significant requirements is PARTICULARLY difficult.
—[7]

The goal is to provide an architecture that defines reference and interface aspects in a way that provides robust solutions to the inherit complexity of the domain, but that does not introduce accidental complexity via its implementation decisions, or unnecessary complexity secondary to design-by-committee solutions or unnecessary complexity from failure to refactor stovepipe efforts.

A few caveats:

- Requirements will likely differ according to a terminology content developer's intention (e.g., a developer creating content for the core of a standardized terminology vs. a developer creating a refset or value set). Depending on their use case, the elements listed below may seem superfluous or excessive to one content developer while the same element may be considered necessary or essential to another content developer.
- The comments below reflect thoughts on what would be useful for a SNOMED CT editing application, but the general principles also apply to other terminologies (i.e., LOINC and RxNorm) that would also be integrated in the editing environment.
- These comments reflect experiences using the IHTSDO Workbench and two of the Apelon terminology editing applications: the Terminology Development Environment (TDE) and the Distributed Terminology System (DTS). Each of these applications is unique and has highly beneficial components. The list below reflects a brief composite of features found most useful about these applications as well as a notes about elements that would have been additionally helpful/useful.

4.1.1. User Interface

Elements that have been helpful:

- In general, the application is "simple" in design, making it easy to view and use for long periods of time
- Easy log-in and launch process
- Configurable "panels" or "areas" with clearly defined editing purposes (e.g., terminology editing panels, taxonomy browser, search panel) o
    - The user can choose which panels they want to see and can configure the editing window for their preference and need depending on the editing activity they are attempting to perform (i.e., terminology editing vs. refset development)
    - Information necessary to create or edit content is visible in one window/location (i.e., reduced toggling between windows)

- A variety of panels to perform editing tasks and view the terminology:
  - Concept viewing/editing panel to see the full view of the concept (including stated and classified/inferred views; it is also helpful to be able to have at least 2 panels open simultaneously)
  - Taxonomy browser (for SNOMED CT editing, this includes being able to choose the stated vs. inferred view as well as the ability to see the primitive vs. fully defined status of the concept)
  - Concept history (to view previous versions of a concept)
  - Immediate access to “recent” concepts viewed or edited
  - Separate search panel
  - Batch editing panel
- Appearance:
  - Color contrast exists between text and background and there is ample white or negative space
  - Text that is easy to read (perhaps even configurable by the user)
  - If there are multiple windows/panels, consistent labeling (titles) for each window for easier navigation
  - Clearly delineated controls (“buttons”) (for saving, canceling, drop-down menus, etc.) and tooltips to explain what buttons are for if not immediately apparent
  - Controls are consistent in labeling and functionality throughout the application
  - Components of the concept are easy to read, color-coded (i.e., concept descriptions are one color, its definition status another color, and its defining relationships another color, etc.), and consistent for each concept
  - Consistency of appearance (text, background, controls) across multiple panels and windows
  - Alerts and error messages are obvious and explain what needs to be addressed
  - Limited scrolling is required

Additional components that would be useful:

- For SNOMED CT specifically, the content is so vast that it is difficult to view the taxonomy in its entirety in a single panel. The ability to view a “focused taxonomy browser” (a view limited to one concept and only its immediate subtypes and supertypes) would be especially helpful.
- It would be beneficial if the most often used functions/tasks had their own highly visible control/button in immediate view. (For example, in the case of SNOMED CT, this might mean having the new concept automation or the classifier function visible as controls/buttons in the arena window.) If multiple terminologies are edited in one application, this may not be feasible since the editing requirements will likely differ.

4.1.2. Editing functionality

Each terminology will have specific editing functionality requirements; however, there are certain elements which will likely be relevant to all terminologies and the application as a whole.

Elements that have been helpful:

- In general, the application is easy to use, efficient (minimizes the number of actions needed to perform tasks), and attempts to reduce user error
- Drag/drop and copy/paste functionality for ease, efficiency, and accuracy (as opposed to typing, which is time-consuming and can increase errors)
  - Right-click drop-down menus can also serve this function well (e.g., for adding descriptions or components (attribute-value pairs))
- Automations are helpful for certain processes such as creating and retiring content. They also make these processes more efficient and reduce user error.
  - o Example: New concept automation in the Workbench automatically creates the preferred term (including Great Britain preferred term if appropriate), removes erroneous spaces from fully specified names, allows easy assignment of parent concept and additional relationships, assignment of primitive/fully defined status, etc.
- Use of context-sensitive editing functionality increases efficiency by guiding the user to available next options
- QA (quality assurance) rule implementation: As in the Workbench, multiple levels of QA implementation including “real-time QA” (with specific error alerts if a QA rule is violated to give the user immediate feedback and opportunity for error correction) and separate “batch QA” functionality to review any violations of all editorial rules
- Classifier functionality (with error alerts (equivalency, cycle, etc.)) and identification of concepts in errors (Note: while this functionality may seem specific to SNOMED CT, due to mapping and content development efforts in progress by the IHTSDO and the Regenstrief Institute, this functionality may eventually apply to LOINC as well.)
- Easy workflow integration
- The ability to have a “test environment” to test content changes, especially those changes expected to have large-scale results (the UAT version of the Workbench was extremely helpful for this purpose)

Additional components that would be useful:

- Ability to add a “note” to the concept with information which would allow authors to add an internal (unpublished) comment which might communicate additional information about the concept such as why it was created, why it was modeled in a certain way, etc.
- Ability to add a “tag” or “flag” to a concept to note that it is a member of an extension (or possibly even a mapping or value set)
- Ability to use some functions found in common computer applications would be very helpful (e.g., undo, redo, copy/paste from word processing or spreadsheet documents, keyboard shortcuts)
- For each standardized terminology that will be implemented in the editing environment, there will be unique editing and QA functionality requirements. It will be helpful to delineate and make clear to the user, which functions/buttons/actions pertain to each terminology. The same will likely be true for delineating which QA rules apply to each terminology as well.

4.1.3. Search and Query Functionality

The ability to search using multiple parameters simultaneously would be of immense value for terminology content developers as well as implementers. In addition to finding specific concepts, further reasons for the value of a robust search component include the following:

- QA of the terminology, for example:
  - Finding concepts/content that are incorrectly or inadequately defined and further edit them such that they aggregate where one would normally expect
  - Finding duplicate content that needs to be addressed
- Finding concepts appropriate for a refset, value set, or even mapping (the ability to use multiple search parameters will be helpful)
- Finding post-coordinated expressions, if they are created

Some search parameters which would be very helpful include:

- Ability to search for terms (fully specified names and synonyms) by:
  - Word fragments
    - Example: Searching for *scop* will retrieve all instances of “scop” within a word (endoscope / endoscopy, fluoroscope / fluoroscopy, etc.) as well as anywhere within a term (“Endoscopic biopsy of esophagus” and “Gastric endoscopy”)
  - Terms/fragments in any order
    - Example: Searching for *aort*stenos* would return “aortic valve stenosis” as well as “stenosis of fetal aortic valve”
  - Fully specified name only vs. all descriptions/terms/synonyms (including option to only see a certain description type – FSN, preferred term – displayed)
  - Numeric identifiers
- Ability to search for groups of concepts by:
  - Specific content:
    - IHTSDO SNOMED CT International Edition vs. NLM US Extension vs. VA (or other) Extension
    - Refset (e.g., Non-human refset, Allergy refset, etc.)
    - Tag or flag (noted above)
  - Parameters specific to the terminology such as:
    - Attribute (role) relationships (e.g., all concepts with “finding site of X”)
    - Hierarchy / group (e.g., all <disorder> concepts with an “associated morphology of X”)
    - Fully defined vs. primitive status
    - Stated vs. inferred concept definition
    - Active vs. inactive status (as well as both)
- Ability to search for concepts using combinations of above parameters

- Number returned (count)
- Numeric identifier
- Fully specified name of concept
- Active vs. Inactive status
- Ability to export the search results to a spreadsheet and other formats

Examples of queries for content editing (SNOMED CT-specific) where the ability to query using the above parameters would be useful:

Example 1:Search for or exclude specific content

The Office of National Coordinator has created a Clinical Quality Measure (CQM) tracker that allows CQM implementers to submit questions and raise issues. One issue noted by an implementer is that some CQM value sets contain non-human/veterinary concepts from SNOMED CT. It might be helpful for authors of CQMs to exclude this content when creating their value set content. See: http://jira.oncprojectracking.org/browse/CQM-793

Example 2: Search for concepts using word fragments in any order

The ability to search for concepts using word fragments and in any order would by highly beneficial. This allows the user to find concepts with variations in words. This can be useful for finding concepts that may have been named inconsistently (e.g., “fluoroscopic guidance” vs. “fluoroscopy guided”) but should be modeled consistently so that they aggregate appropriately together in the terminology.

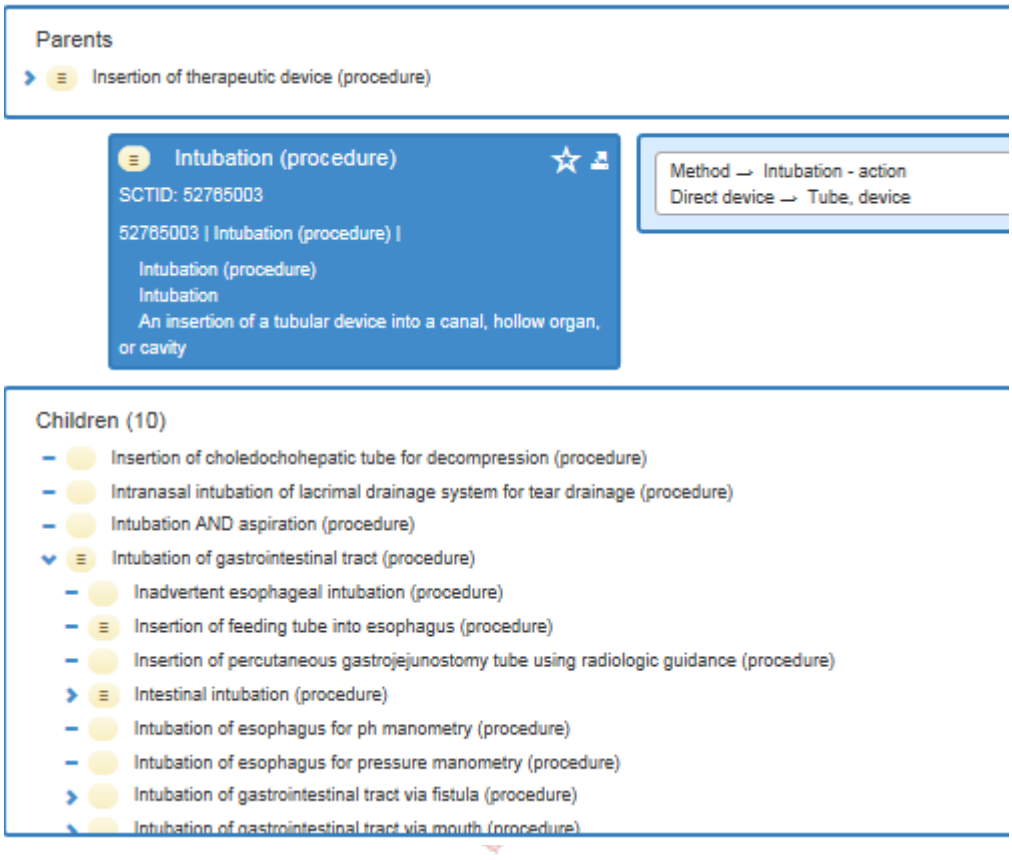
Example 3: Search for concepts using attribute relationships and multiple simultaneous parameters

The terms “intubation” and “insertion of tube” are used somewhat inconsistently with respect to procedure concepts within SNOMED CT, and likewise, this subset of concepts has also been modeled inconsistently. For example, some concepts have the term “intubation” in the FSN, however, they are modeled with an attribute relationship specifying a value of “Insertion – action (qualifier value).” The reverse is also true: concepts with the term “insertion” in the FSN are modeled with the value “Intubation – action (qualifier value).” The following images illustrate this issue and are taken from the CliniClue SNOMED CT browser using the January 2014 SNOMED CT International Release.

The descendants of **Intubation (procedure)** are modeled with the Method attribute value “Intubation – action (qualifier value)” and a Direct Device attribute value “Tube, device (physical object)” (or one of its descendants).

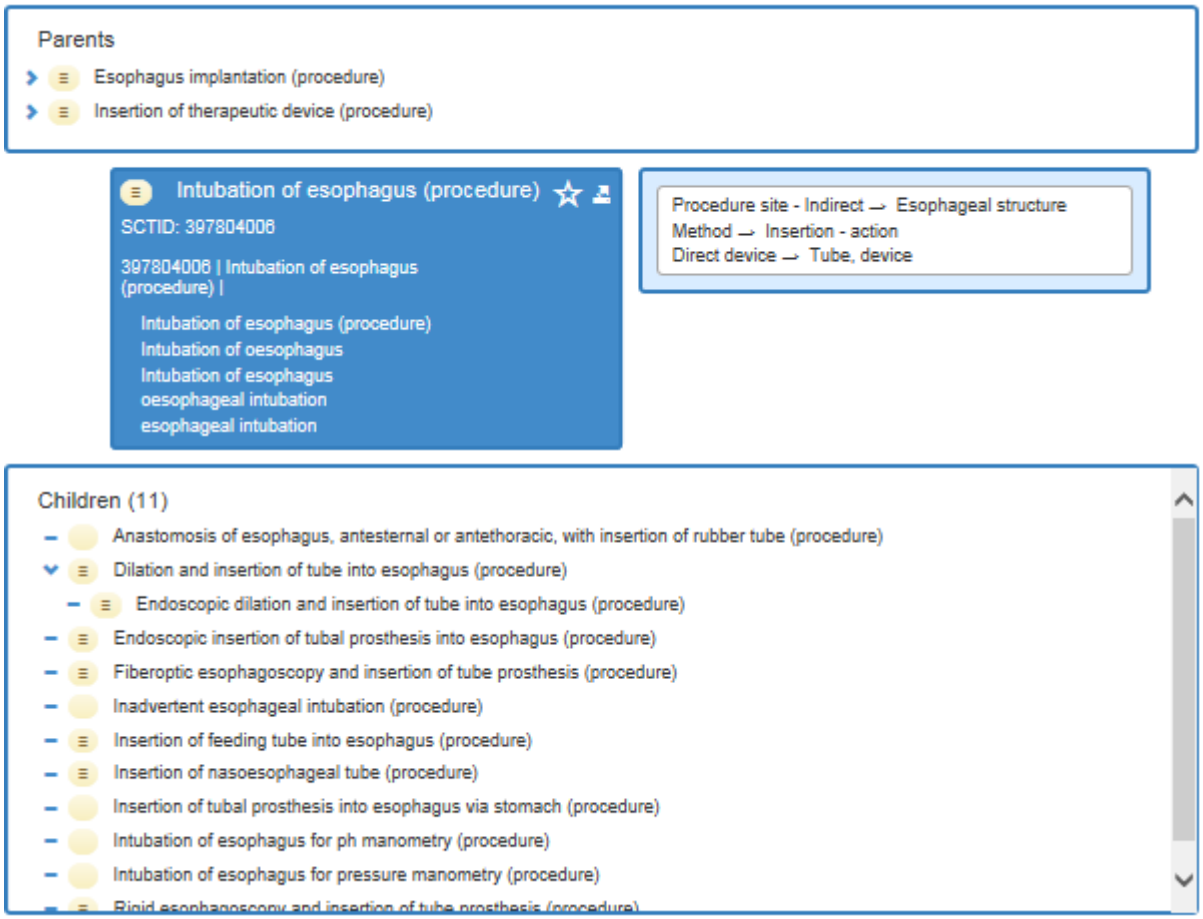
- The descendants of Intubation (procedure) include **Intubation of gastrointestinal tract (procedure)** and **Inadvertent esophageal intubation (procedure)**.
- Also note that there are concepts containing variations of the phrase “insertion of tube” in this subhierarchy and that they are modeled with the Method attribute value Intubation – action (qualifier value).

Figure 4.1. Descendants of Intubation



However, there is a separate sub-hierarchy, **Intubation of esophagus (procedure)** and its descendants, due to the top-level concept having been modeled with a Method attribute value of “Insertion – action (qualifier value).” It is likely that an implementer of SNOMED CT would expect this sub-hierarchy to be integrated with the Intubation (procedure) hierarchy – and that **Inadvertent esophageal intubation (procedure)** would be a subtype.

Figure 4.2. Intubation of Esophagus



In order to determine whether and how this content could/should be harmonized within SNOMED CT, it would be ideal to have the ability to search by:

- FSN only as well as word fragments
  - Number of concepts with FSNs containing variations of “intubation”
  - Number of concepts with FSNs containing variations of the phrase “insertion of tube”
- Attribute relationships as well as stated and inferred concept definitions
  - Number of concepts modeled with a Method attribute value of “Intubation – action (qualifier value)”
  - Number of concepts modeled with a Method attribute value of “Insertion – action (qualifier value)”

4.1.4. Summary

This document attempted to outline some of the elements which would be especially helpful for a terminology editing application. The list of elements is not comprehensive, and there are many areas that could be described in greater detail, particularly with respect to SNOMED CT content development and editing (e.g., a list of required editing functionality and all QA rules). For a terminology editing application involving multiple terminologies, each section of the list will expand significantly.

4.1.5. Integrated development and operations

Challenges still remain around how demand for application functionality and updates are managed within the business, and how this new development work is deployed into production.

When paired with end-to-end (requirements-to-release) application release automation, DevOps can increase the release flow and deliver killer apps to the business.

Improving communications and integrating processes between these long-divided groups is a goal the entire IT industry should be working toward. This is particularly urgent because the delivery speed software requires is always increasing and, at the same time, the tolerance for application errors is decreasing.

4.1.5.1. Bridge gap between development and operations

While many businesses have invested in automating their development, few have the ability to smoothly connect the critical components of the application lifecycle in order to bridge the gap between application development and IT operations. Delivering applications successfully requires organizations to marry the creation of better apps with improved processes to put them into the hands of users.

As teams grow and face larger volumes of software, siloed paper-based practices for the management of each stage of development and operations are evolving into more automated and interconnected processes. This orchestrated approach to application development does not mean throwing out all of the existing tools and solutions; instead companies should integrate what they already have.

4.1.5.2. Release management

Release management is a prime example: Instead of automating the process and release tasks so that each lovingly crafted application is deployed properly, companies too often rely on manual deployments or scripts that are manually updated each time, or both. In any case, time and effort are wasted in the release process, and increased potential for errors and botched deployments results. Application lifecycle-management processes and best practices in release management must be considered as integral to the entire process. Working together, release management and service management can further help DevOps.

The paradigm shift of DevOps results from the rapidly increasing number of application releases being developed. Business demands more revenue growth through online applications, and development is working hard to deliver the changes that facilitate this shift. In distributed systems and mainframe environments, IT operations departments aren’t equipped to handle this increase, resulting in a backlog of applications to release. Organizations are adopting DevOps to respond to the need to release more often and more apps each time.

4.1.6. Terminology layer

The terminology layer will be populated with normalized SNOMEDCT, RxNorm, and LOINC content, where normalized means that all overlapping content has been reconciled, and that these three terminology systems function as a single coherent terminology for the purposes of higher layers in the architecture.

4.1.6.1. Concept orientation

4.1.6.1.1. Standard metadata

The terminology layer will provide standard metadata for it’s own use as well as for use by the layers above. The standard metadata will be represented as Concepts within the terminology layer, and those Concepts will be appropriately organized taxonomically.

4.1.6.2. Content extension layer

The content extension layer enables organizations to add additional concepts and descriptions to meet their local needs. These extensions will be made available to the organization whose terminology they extend (SNOMED, RxNorm, and/or LOINC) in an automated way so that they can be considered for addition to the standard.

The terminology with content extensions will appear as a single coherent terminology for the purposes of higher layers in the architecture.

Content extensions allows:

- A national or organizational definition of a concept, which is more rigorous or specific than existing concept;
- Extension descriptions may be colloquial synonyms for concept or descriptions for an extension Concept.

4.1.6.3. Reference extension layer

4.1.6.3.1. Refex member

The Refex member extends a component chronicle with a mandatory Assemblage id, and referenced component id fields, as well as optional extension fields.

4.1.6.3.1.1. Member id

Consistent with the requirement for every component to have a unique identifier, every refex member will have a unique identifier, referred to as the member id.

4.1.6.3.1.2. Assemblage field

Every Refex member must specify the Assemblage that it is a component of. Typically, this specification is accomplished by referencing the identifier of the Assemblage concept, although use of object pointers may be acceptable in some implementations.

4.1.6.3.1.3. Extended component field

Each Refex member must specify the component it extends. Typically, this specification is accomplished by referencing the identifier of the component it extends, although use of object pointers may be acceptable in some implementations.

Our development experience indicates that this is one of the fields that can be confusing to communicate properly. In this case, the order terms is important and “extended component” is reserved specifically for identifying the component that the Refex member extends, and should not be confused with a “component extension” which is an extension field, and discussed next. Historically “referenced component” has been used, but extension fields also have “referenced components” by nature of having an id for component in their data fields. This overlap of meaning has led to past confusion and difficulty in communicating Refex concepts.

4.1.6.3.1.4. Extension cardinality

Refex members may have a one-to-one, or many-to-one relationship to the component they extend. The cardinality relationship between the extended component and the refex members must be defined as part of the Assemblage metadata.

4.1.6.3.1.5. Extension Polymorphism

Refex members of an Assemblage may have polymorphic fields. Each allowed polymorphic pattern must be specified as part of the Assemblage metadata, including the semantics of each field, presentation order of the fields, and information for labeling presentation of each field in an individual or tabular arrangement.

4.1.6.3.1.6. Dynamic member definition

The cardinality, and polymorphic data patterns must be definable at Assemblage author time, and certain aspects must be mutable (addition of a new pattern, updating a display name, or changing the order of presentation), other aspects must be immutable (cardanility, and semantics of an existing pattern cannot be modified, nor can the fields of the pattern change in size or data type)

4.1.6.3.1.7. Component extension fields

The Refex member may contain extension fields that reference another component: another concept, description, relationship, or another Refex member. For example, an extension field with unit of measure semantics in a reference range Refex may reference the concept milligrams per deciliter. Typically, this specification of an extension field's value is accomplished by referencing the identifier of the component, although use of object pointers may be acceptable in some implementations.

These extension fields are referred to as component extensions fields, not to be confused with the member's extended component field. The order of term reference is significant, and must be used consistently.

4.1.6.3.1.8. Scalar extension fields

The Refex member may contain extension fields that contain scalar information: integers or floating point numbers. For example, an extension field with substance-concentration semantics in a reference range Refex may contain a value of 0.625.

These extension fields are referred to as scalar extensions fields.

4.1.6.3.1.9. String extension fields

The Refex member may contain extension fields that contain text information. For example, an extension field with patient-instructions semantics in a laboratory test Refex may have the text "You must be fasting for 12 hours prior to this test".

These extension fields are referred to as string extensions fields.

4.1.6.3.2. Refex query requirements

4.1.6.3.2.1. Component is member of an Assemblage

Queries must enable a components membership in an Assemblage be part of the query criterion. For example, to determine if a dispensable medication concept is a member of a formulary Refex.

4.1.6.3.2.2. Component field of Refex member matches criterion

Refexes may include component fields where any valid component identifier (for a concept, description, or other Refex member) may be used. The match criterion may include any of the semantic query clauses (component is, component is kind-of, etc). For example, find all the medications who are members of the of the formulary Refex, and that are also members of the common side effects Refex, and the side effect type field of the Refex is a kind of kidney disease.

4.1.6.3.2.3. Scalar field of Refex member matches criterion

Refexes may include scalar fields such as integer, float, and long. Queries must enable scalar comparisons (<, ≤, =, ≥, >) of appropriate Refex fields as part of the query criterion. For example, find all diagnosis concepts where a diagnostic criterion Refex member's "value" field is ≥ 13 and the "units of measure field" references the concept value for "109/L".

4.1.6.3.2.4. Text field of Refex member matches criterion

Refexes may include text fields. Queries must enable regular expression and full-featured text search clauses on these Refex fields. The necessary text search features are previously described in: 3.6.5 .

4.1.6.4. Logic layer

The logic layer provides axiomatic definition of underlying concepts using references extensions associated with each concept. These logical reference extensions can be modularized, and can support the representation of the stated and inferred form of different description logics concurrently. The logical representation must be able to support OWL Full semantics.

Logic is required to support semantic retrieval.

The logic requirements enable the reference-terminology characteristics of the architecture.

4.1.6.4.1. Sufficient sets

The architecture must allow for distinguishing between defining axioms that are necessary, and those that are part of a set that are both necessary and sufficient.

The following example illustrates the reason we must distinguish between necessary and sufficient conditions. [The graphic notation used in these examples is described in Appendix B: SNOMEDCT Diagramming Standards .]

[insert Definition of tuberculous-arthritis figure here]

[insert Definition of bacterial-arthritis figure here]

The current SNOMEDCT model does not distinguish between relationships that are necessary conditions and those that are part of a set of necessary and sufficient conditions. For any fully defined concepts the set of defining relationships are regarded as necessary and sufficient.

As a result, some currently released fully defined concept definitions may include conditions that are necessarily true but are not required as part of the set of sufficient conditions.

Consider the examples shown in Figure 6 Definition of tuberculous-arthritis and Figure 7 Definition of bacterial-arthritis

The definition of tuberculous-arthritis differs from that of bacterial-arthritis in two respects. The first difference, the causative-agent of mycobacterium-tuberculosis-complex is sufficient to define the concept . However, the nature of the inflammation that results is, necessarily, granulomatous.

Thus an expression that specifies bacterial-arthritis with causative-agent mycobacterium-tuberculosis-complex is clinically equivalent to the concept tuberculous-arthritis even though it does not explicitly refine the nature of the inflammation.

In contrast the current SNOMEDCT model computes bacterial-arthritis with causative-agent mycobacterium-tuberculosis-complex as supertype of tuberculous-arthritis, rather than equivalent to tuberculous-arthritis. This computation occurs because the expression bacterial-arthritis with causative-agent mycobacterium-tuberculosis-complex does not specify of the nature of the inflammation.

This inability to represent multiple sufficient sets, and to distinguish between necessary and sufficient conditions leads to errors in retrieval, which in turn can lead to errors in decision support. Figure 8 shows how necessary and sufficient sets to represent tuberculous-arthritis using multiple sets that separate necessary and sufficient conditions.

[insert Definition of tuberculous-arthritis using necessary and sufficient criterion figure here]

The padstone is a type of simple foundation that consists of a single stone that both spreads the weight on the ground and raises the timber off of the ground.

Support for sufficient sets that distinguish between necessary and sufficient conditions is readily available in open-source classifiers, with acceptable scalability, and therefore, support for such distinctions is required.

4.1.6.4.2. Role hierarchies

Role hierarchies allow for the definition of inheritance relationships among roles.

4.1.6.4.3. General concept inclusions

General concept inclusion axioms are axioms that allow any Concept, primitive or defined, to be asserted to be a subclass of any other Concept. This ability leads to a unified classification hierarchy in which all Concept that include the presence of another given Concept occur together.

4.1.6.4.4. Concrete domains

Allow for values and relations between them

Mostly useful for full modeling of medications (strength, quantity), but also can be used for age groups, pressure ulcer size, and other similar clinical needs.

4.1.6.4.5. Incremental classification

This architecture assumes an incremental classification capability such than new concept definitions can be classified without needing to re-classify the rest of terminology content. Incremental classification supports sub-second classification time—subject to minimum hardware requirements.[1]

4.1.6.4.6. Single codes for post-coordinated expressions

Incorporating incremental classification as part of the Informatics Architecture enables real-time classification of post-coordinated expressions, enabling generation of single codes for complex expressions. Having single codes for post-coordinated expressions enables simplification of the information model, and corresponding database representations that support that information model.

4.1.6.4.7. Negation

Negation is currently only supported in the context model. Negation may be admitted to the logic and expression model if scalable solutions can be identified and proven reliable for an operational environment.

4.1.6.4.8. Semantic query requirements

The architecture must provide the ability to query by semantics—the ability to query based on the meaning of the Concepts—in addition to being able to query by regular expressions and text as provided by the terminology layer. Examples are given below.

4.1.6.4.8.1. Semantic coordinate

Semantic queries require specification of the description logic family against which the query will be performed (EL++, SH), and if the query will be against the stated concept axioms, or inferred concept axioms.

4.1.6.4.8.2. Concept is

Matches a concept from Concept Specification.

4.1.6.4.8.3. Concept is child of

Computes the set of concepts that are a child of the input concept. The set of children of a given concept is the set of all concepts that lie one step below the input concept in the terminology hierarchy. This Clause has an optional parameter for a previous ViewCoordinate which allows for queries of previous versions.

4.1.6.4.8.4. Concept is descendent of

Computes the set of concepts that are descendants of the specified concept spec. The set of descendants of a given concept is the set of concepts that lie beneath the input concept in the terminology hierarchy. This Clause has an optional parameter for a previous ViewCoordinate which allows for queries of previous versions.

4.1.6.4.8.5. Concept is kind of

Calculates the set of concepts that are a kind of the specified concept. The calculated set is the union of the input concept and all concepts that lie beneath the input concept in the terminology hierarchy. This Clause has an optional parameter for a previous ViewCoordinate which allows for queries of previous versions.

4.1.6.4.8.6. Concept contains relationship of type

Compute the set of concepts that have relationships of a particular type. The relationship type is qualified by is, is-kind-of, is-child-of, or is-descendent-of. For example, find all concepts that contain relationships that have a type that is a kind-of procedure-site.

4.1.6.4.8.7. Concept contains relationship restriction

Compute the set of concepts that have relationships with a restriction of a particular type. The relationship restriction is qualified by is, is-kind-of, is-child-of, or is-descendent-of. For example, find all concepts that contain relationships that have a restriction that is a kind-of eye structure. This clause can be combined with the relationships of type clause to find all concepts that contain relationships that have a type that is a kind-of procedure-site and have a restriction of kind-of eye structure.

4.1.6.4.8.8. Concrete domains

Concrete domains extend description logics by integrating numerical domains in a schematic way. For example, being able to represent and reason over scalars with predicates of $\leq$, $<$, $=$, $>$, and $\geq$. The ability to reason over such numerical domains is a requirement for decision support applications.

4.1.6.5. Expression layer

The expression layer supports the representation of post-coordinated expressions, the incremental classification of those expressions with regard to the underlying description logic definitions of the terminology. Each post-coordinated expression will be given a unique identifier that can be persistently stored, and can be used to retrieve the expression, as well as the indexing information generated from its classification.

4.1.6.6. Clinical fact layer

Clinical facts are declarative bits of knowledge that extend concepts in the underlying terminology. For example, a “may treat” reference extension may codify that aspirin (from RxNorm) may treat headaches (from SNOMED). Higher layers may use these clinical facts to provide decision support. The clinical facts layer provides no independent means to provide decision support. It merely enables clinical facts to be represented as identifiable components with the same versioning and modularity capabilities as all the other components of the architecture.

4.1.6.7. Declarative knowledge artifacts

Declarative knowledge will be imported into—and exported from—the environment as a maven-compatible artifact. This artifact will be a zip file that contains the data of the artifact, and will have a fully qualified group identifier (e.g. org.ihtsdo), artifact identifier (e.g. sct-concept-full-international-rf2), and a version (e.g. 201307310000). All the data associated with a module will be contained within the artifact’s zip file. A Project Object Model (pom) file will describe the dependencies of the artifact, and will also includes additional information such as artifact license terms and information about the organization that produced the artifact.

These artifacts, with associated pom files and checksum information, will be published to—and primarily accessed from—an artifact repository than enables automated transitive dependency resolution.

These sources of these artifacts must be under version control (subversion, git, or otherwise), and must be released using a standard maven release process that ensures an automated, comprehensive, verified, and reproducible release process with a complete audit trail.

4.1.6.8. Assertion & request layer

The assertion and request model defines how expressions populate assertion and request objects.

This layer is not for tracking of pending and/or rejected requests such as laboratory tests or pharmacy requests that have been requested but not collected or processed. Such tracking is part of workflow management systems outside the scope of this architecture. The assertion and request layer is to represent the reconciled requests such as a patient’s medication list, as well as assertions made about a patient such as laboratory assertions, and history and physical examination assertions.

4.1.6.8.1. Negation

The assertion model provides the architectures support for negation. Clinical knowledge bases will depend on the assertion and request model to process clinical data.

4.1.6.9. Context layer

The context model determines how subject of information, subject of record, source of information, time of encounter, encounter providers, and other related contextual information are represented.

4.1.6.10. Clinical knowledge base layer

Clinical knowledge bases integrate the contextual model, the assertion and request model, and clinical facts to provide

4.1.6.11. Clinical rules layer

The clinical rules layer provides a control structure for sending selected patient data to the clinical knowledge base for analysis, and returns the results of that analysis to the calling application.

4.1.6.12. Clinical classifications layer

Clinical classifications, such as ICD-10-CM are laden with context, and determining if a patient meets one or more criterion within the classification requires clinical rules that can process the assertion & request and context models.

The Situation with Explicit Context taxonomy of SNOMED CT will also be part of the clinical classifications layer.

4.1.6.13. Documentation

Documentation must have the ability to derive selected content from the systems they document. If a document references the definition of a particular concept, or lists the children of that concept in a table or diagram, that table or diagram should be derivable from the concept's source as part of an automated build process, assuring that the documentation remains up-to-date despite inevitable change within the documented system.

The architecture must support the ability to generate documents with a static linear narrative in a book-like output medium as well as support for topic-based authoring.[2] Documentation sources must be under configuration management, and must be part of a standard release process that is tightly coupled to the release process of the components, implementations or other artifacts they describe. Documentation sources must be managed in a way that supports distributed development of documentation sources.

4.1.6.13.1. Modular authoring[3]

The architecture must include a standard means for documenting its components, implementations, and other artifacts using XML based open standards. Documents sources must be presentation neutral—and non-proprietary—and they must capture the logical structure of the content. Document sources must be able to include all or part of content from compatible external source files using XIncludes and XPointer as a means to specify what parts of which external source files to include.

4.1.6.13.1.1. Reusable

The ability to use reuse topics, illustrations, and other documentation written by others saves time when creating new works. The architecture must support such reuse without impediment.

4.1.6.13.1.2. Contextually variable

The ability to add variations to an existing topic and other documentation makes it possible to reuse existing documentation objects with minimal change--and without fear of creating dual-source documents whose contents will tend diverge over time.

The output rendering must allow for displaying or hiding URIs of components, for providing hyperlinks to a designated server from these URIs; for display or suppression of text associated with the components;

for choosing the type of term(s) to display within the document (preferred, fully specified, other) and the language and dialect of terms(s) to display; and must allow for generation of graphics where appropriate.

4.1.6.13.2. Modular delivery

Documentation must be generated as part of a continuous integration process, where documentation artifacts are automatically published when changes to source documentation is committed. Dependencies between documents from different modules must be resolved via an automated—and non-proprietary—dependency management system during the continuous integration process.

4.1.6.13.2.1. Readable

Modular documentation components must allow the material to be presented without distractions, once the user navigates to the page they need, whether by navigating, searching, or following a link.

4.1.6.13.2.2. Regular

When documentation artifacts stem from shared information templates and go through common production procedures, the delivered topics tend to be more regular in appearance and structure. That regularity helps a user anticipate where information will be found, and helps them skim for information more easily.

4.1.6.13.2.3. Findable

Users must be able to easily find the information they need, searching based on text search, topic type, indexes, table of contents, or metadata that applies to the information they need.

4.1.6.13.2.4. Dynamically deliverable

The document generation process must support a variety of publication formats, including HTML, XHTML, and PDF. Documentation must be able to include identified components from within the architecture using URIs—with document-generation time validation—and with output rendering options appropriate to the type of knowledge.

Documents must be built from reusable components, and the components must have the ability for contextual variations. It must be possible to construct built-to-order documents "on the fly", in response to user demands, rather than having to pre-create static versions of all possible variations.

Once such a system is in place, it becomes possible for users to further customize the results by modifying the list of selected topics, rearranging their order, or even by adding new topics.

4.1.6.14. Execution qualities

Other execution qualities such as security are outside the scope of the Informatics Architecture, and will be defined by the Systems Architecture.

4.1.6.15. Evolution qualities

The architecture must evolve gracefully to meet requirement and environmental changes. As architecture provides a fundamental structure of a software system, its evolution and maintenance would necessarily impact its fundamental structure. As such, architecture evolution is concerned with adding new functionality as well as maintaining existing functionality and system behavior.

4.1.6.15.1. Testability

Testability is the degree to which a software artifact (i.e. a software system, software module, requirements- or design document) supports testing in a given test context.

Testability is not an intrinsic property of a software artifact and cannot be measured directly (such as software size). Instead testability is an extrinsic property that results from interdependency of the software to be tested and the test goals, test methods used, and test resources (i.e., the test context).

A lower degree of testability results in increased test effort. In extreme cases a lack of testability may hinder testing parts of the software or software requirements at all.

4.1.6.15.2. Maintainability

Maintenance is the modification of a software product after delivery to correct faults, to improve performance or other attributes

Maintenance is a very broad activity that includes error correction, enhancements of capabilities, deletion of obsolete capabilities, and optimization. Because change is inevitable, mechanisms must be developed for evaluation, controlling and making modifications

4.1.6.15.3. Extensibility

Extensibility (not to be confused with forward compatibility [http://en.wikipedia.org/wiki/Forward_compatibility]) is a system design [http://en.wikipedia.org/wiki/System_design] principle where the implementation takes future growth into consideration. It is a systemic measure of the ability to extend a system [http://en.wikipedia.org/wiki/System] and the level of effort required to implement the extension. Extensions can be through the addition of new functionality or through modification of existing functionality. The central theme is to provide for change – typically enhancements – while minimizing impact to existing system functions.

Extensibility means the system is designed to include hooks and mechanisms for expanding/enhancing the system with anticipated capabilities without having to make major changes to the system infrastructure. A good architecture provides the design principles to ensure this—a roadmap for that portion of the road yet to be built. Note that this usually means that capabilities and mechanisms must be built into the final delivery which will not be used in that delivery and, indeed, may never be used. These excess capabilities are not frills, but are necessary for maintainability [http://en.wikipedia.org/wiki/Maintainability][1] and for avoiding early obsolescence [http://en.wikipedia.org/wiki/Obsolescence].

Extensibility can also mean that a software system's behavior is modifiable at run time [http://en.wikipedia.org/wiki/Run_time_(program_lifecycle_phase)], without recompiling or changing the original source code. For example, a software system may have a public Application Programming Interface [http://en.wikipedia.org/wiki/Application_Programming_Interface] that allows its behavior to be extended or modified by people who don't have access to the original source code. The extra functionality can be provided through either internally or externally coded extensions.

4.1.6.15.4. Scalability

Scalability can be measured in various dimensions, such as:

- Administrative scalability: The ability for an increasing number of organizations or users to easily share a single distributed system.
- Functional scalability: The ability to enhance the system by adding new functionality at minimal effort.
- Geographic scalability: The ability to maintain performance, usefulness, or usability regardless of expansion from concentration in a local area to a more distributed geographic pattern.
- Load scalability: The ability for a distributed system [http://en.wikipedia.org/wiki/Distributed_system] to easily expand and contract its resource pool to accommodate heavier or lighter loads or number of

inputs. Alternatively, the ease with which a system or component can be modified, added, or removed, to accommodate changing load.

4.1.6.16. Use cases

Given the architecture, we can pursue an architecture centric, use case driven, iterative, and incremental approach. Relevant internal and external efforts are described below.

4.1.6.16.1. VA core research priorities for 2013

VA core research priorities in 2013 will include Mental Health, Gulf War Veterans' Illnesses and Exposures, Prosthetics, Traumatic Brain Injury, Spinal Cord Injury, Women Veterans, and a special initiative on Researching Pain. [11]

4.1.6.16.2. Electronic quality measures

Electronic measures (eMeasures) are standardized performance measures in an electronic format. eMeasures can promote greater consistency in measure development and in measuring and comparing performance results. They also can provide more exact requirements about where information should be collected, and drive greater standardization across the measures and greater confidence in comparing outcomes and provider performance.

Under the Department of Health and Human Services (HHS) direction, the National Qualify Forum (NQF) was tasked with retooling 113 endorsed quality measures from a paper-based format to an eMeasure format. The architecture must allow for versioned representation of these 113 quality measures, and must support the ability to query patient data to determine if these quality measures have been met. Sample eMeasures are provided on the ONC HIT website eCQI Resource Center (https://ecqi.healthit.gov/ecqms).

4.1.6.16.3. Comparative effectiveness research

The 100 initial priority topics for comparative effectiveness research provides a rich source for use cases. [12] This entire list of priority topics is provided in Appendix A .

4.1.6.16.4. Clinical Element Models

Clinical Element Models are Intermountain Healthcare’s strategy for representing detailed clinical models – granular, computable models defining the logical structure of data elements used in healthcare. [13] The architecture must allow for versioned representations of Clinical Element Models to the extent those models are defined using terminology systems that are part of the informatics architecture.

4.1.6.16.5. Value sets

The Value Set Authority Center (VSAC) is provided by the National Library of Medicine (NLM), in collaboration with the Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services.

The VSAC provides downloadable access to all official versions of vocabulary value sets contained in current Clinical Quality Measures (CQMs). The value sets in the VSAC describe the specific populations included and excluded in order to properly calculate each CQM. Each value set consists of the numerical values and human-readable names, drawn from standard vocabularies such as SNOMED CT® and ICD-10-CM, which are used to define clinical concepts used in clinical quality measures (e.g., patients with diabetes, clinical visit).

The architecture must allow for versioned specifications and versioned value sets to the extent those models are defined using terminology systems that are part of the informatics architecture.

The architecture must allow for automated import and export of all value set artifacts into an authoring environment provided by VSAC for the terminologies that the architecture supports, and allow those value set artifacts to be transformed into an architecture-specific representation and published into the run-time environment.

4.1.6.16.6. Open Infobutton

Open Infobutton is a part of the Veterans Health Administration (VHA) Open Source Electronic Health Record Agent (OSEHRA [http://www.osehra.org/]). Infobuttons are context-sensitive links embedded in electronic health record (EHR) systems. They use context such as patient demographics, user role, or clinical setting to help anticipate the information needs of the clinician. Open Infobutton is a Web service that enables Infobutton capabilities to be embedded in EHR systems.

http://www.openinfobutton.org

4.1.6.17. Architectural boundaries

The architecture addressed by this document is not about messaging between external systems, nor is it about messages or data that do not relate specifically to encoding patient data, and processing that encoded data. For example, we do not address:

- pharmacy order messages, laboratory order messages, Admission/Discharge/Transfer (ADT) messages
- results reporting messages
- order tracking
- data interchange between incoherent systems

In the future, a messaging architecture and data interchange architecture may build upon the foundational informatics architecture defined here—if this architecture meets their needs. We are happy to consider requirements concerning messaging and data interchange architecture for inclusion in this architecture so we may better support these needs. However, we are maintaining a singular focus for the foundational informatics architecture which will be built on top of a coherent set of ONC approved standards and will focus on encoding and retrieving clinical data from this set of standards, and on reasoning over the retrieved clinical data for clinical decision support.

4.1.6.18. Candidate architectures

Some promote the HL7 Reference Information Model (RIM) as an appropriate foundation for application architecture. [14] However, the HL7 RIM has also been described as an “incoherent standard” with “obstacles [that] are insurmountable” and that “the time has come to abandon an unworkable paradigm.” [15] This later sentiment is consistent with our own experience.

Here is an extract from the UML specification:

A Classifier defines a type. Type conformance between generalizable Classifiers is defined so that a Classifier conforms to itself and to all of its ancestors in the generalization hierarchy. Class is a kind of classifier whose features are attributes and operations. Attributes of a class are represented by instances of Property that are owned by the class. Some of these attributes may represent the navigable ends of binary associations.

Type is therefore defined by the Classifier and its generalization relationships not by Class Properties. However if for complexity of the model all the instances of say Medication have the same attributes and

behavior (operations) then an attribute can be used to identify a medication using terminology. All the rules for structure and behavior are contained in the Medication type class.

This mechanism is also in XML with Complex and Simple Types and in Classes in Java.

The HL7 organization is well aware of the problems and criticisms of the RIM, and in April 2011, the HL7 Board authorized a “fresh look” task force to focus on how interoperability could be better achieved. This task force resulted in the Clinical Information Modeling Initiative (CIMI), an effort that is currently focusing on detailed clinical models rather than defining integrative architecture. [16] The ability to represent CIMI developed models may provide validation use cases for informatics architecture, but CIMI does not have a candidate architecture to build upon at this time.

HL7 is primarily concerned with defining standards surrounding interoperability and is less concerned with defining architecture for encoded knowledge. Therefore, the HL7 RIM is not suitable as a candidate architecture.

The closest existing architectural foundation is SNOMEDCT’s architecture. Although a good starting point, the SNOMEDCT architecture cannot meet our requirements without minor modification and modest extension. We propose such modifications and extensions—manifest as the DERIVIATE architecture—next. If successfully validated, concepts from the DERIVIATE architecture may influence future refinement of SNOMEDCT’s architecture.

[1] A modern 64 bit laptop with 8 GB of RAM (<$1800 USD) is sufficient to enable sub-second incremental classification performance.

[2] http://norman.walsh.name/2007/02/05/painting

[3] https://blogs.oracle.com/coolstuff/entry/modular_docs_part_1_why

4.2. Architecture centric

4.2.1. Derivable logical layers

The foundational informatics architecture must be a layered logical architecture that fits within the business logic layer (aka the domain logic layer) of the VA’s health management platform.

Layering the architecture is important for keeping the architecture sufficiently simple at each layer so that it remains comprehensible to a single mind. As layers are ascended, whole systems at lower layers become simple components at the higher layers, and may disappear altogether at the highest layers.

Figure 4.3. Architectural layer overview

These architectural layers provide constraints on what type of components may be created in each layer. The padstone[1] layer of the architecture is the identifiable component layer. All higher layer components must be derived from (to come from a source or origin; to originate from) the padstone’s identifiable component, thus providing a uniform means of identifying all components of the architecture.

The lowest layers are the most critical, as changes to those layers have greater impact, as the higher layers are dependent upon them. Also different candidate architectures may share common lower layers, while differentiating themselves at the higher layers (for example, one organization may require a different technology for it’s clinical rules engine).

4.2.1.1. Benefits of derivable layers

The layers of the architecture must be derivable from the layers below. Derivable in the sense that a component of one layer must only reference components of the same layer, or components defined in layers below.

Derivable layers eliminate unreconciled overlap between layers, such as the terminology model, the assertion & request model, and the context model. This resolves a historic informatics architectural problem: how to manage the overlap between the terminology models and the information models.

In part, this historic problem is a side effect of a stovepipe design process, where information models where developed independent of the terminology systems meant to populate those models. Information model developers were frequently unaware of the terminology systems semantics, and how those semantics may interfere with those of the information model. A classic example would be to have a terminology that may pre-coordinate severity information (mild asthma, moderate asthma, and severe asthma), while the information model may provide a specific field for severity information. The information model may even provide a required and irreconcilable value sets for these overlapping fields (such as a 5 point severity scale then the terminology system uses a 3 point severity scale internally).

In this architecture, the components traditionally know as terminology models and information models are coherent parts of the same architecture. This integration enables simplification of implementation, and also enables a level of validation and testing that is not possible when information models are developed independent of the other components of the overall architecture.

4.2.1.2. Binding between layers

This architecture does not specify the means of binding between layers. Binding may potentially be implemented as native objects within a shared execution environment by some layers, by static or dynamic XML objects between other layers, or by URI specification between layers.

Although the means of the binding between layers is not specified, the means of identifying the components being bound is mandatory. All components will be identified by UUIDs assigned by the identifiable component layer.

4.2.1.3. Declarative knowledge layers

[insert figure here]

Declarative knowledge is defined as the factual information stored in memory and known to be static in nature. Other names, e.g. descriptive knowledge, propositional knowledge, etc. are also given. It is the part of knowledge that describes how things are. Things/events/processes, their attributes, and the relations between these things/events/processes and their attributes define the domain of declarative knowledge. [9]

4.2.1.4. Clinical data layers

[insert figure here]

4.2.1.5. Procedural knowledge layers

[insert figure here]

Procedural knowledge is the knowledge of how to perform, or how to operate. Names such as know-how are also given. It is said that one becomes more skilled in problem solving when he relies more on procedural knowledge than declarative knowledge. [9]

4.2.1.6. Documentation

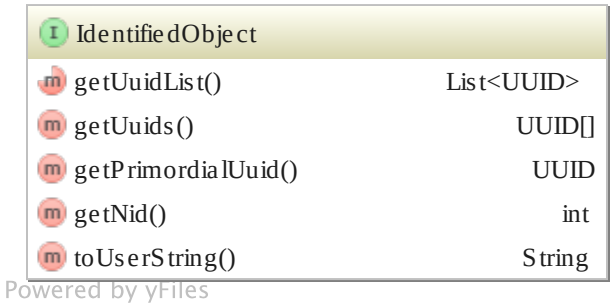
Documentation is a cross-cutting concern A well-documented system is inextricably linked to our ability to understand, maintain, and assure the quality of that system. Just as declarative knowledge layers derive from the ones below, the documentation must have the ability to derive selected content from the systems they document. For example, if a document references the definition of a particular concept, or lists the children of that concept in a table or diagram, that table or diagram should be derivable from the concept's source as part of an automated build process, assuring that the documentation remains up-to-date despite inevitable change within the documented system.

4.2.1.7. Separation from implementation architecture

There is no specific requirement to use a terminology server. The implementation architecture is free to layer the components differently as long as the architectural requirements are met.

4.2.2. Object identity

Figure 4.4. Identified Object



The identifiable component layer manages the reproducible assignment of Universally Unique Identifiers (UUIDs) to all imported components as well as the assignment of primordial UUIDs to all internally generated components. If imported components already provide UUIDs to identify components, those UUIDs will be used.

If the imported components do not have UUIDs, but have ISO Object Identifiers (OIDs) assigned by HL7,[1] or the component's provider, then the environment will generate Version 5 UUIDs for those components using the ISO OID namespace UUID of 6ba7b812-9dad-11d1-80b4-00c04fd430c8 defined in the Internet Engineering Taskforce RFC 4122.[2]

If the imported components do not have UUIDs or OIDs—but have internally unique and immutable identifiers—then a UUID namespace for that source will be assigned internally, and Version 5 UUIDs will be generated for the source on that basis.

If the imported components do not have internally unique and immutable identifiers, then a UUID namespace for that source will be assigned internally, and Version 5 UUIDs will be generated off of a unique hash of the component's data fields that are sufficient to assure uniqueness and immutability of the generated identifier.

The original identifiers for the imported sources will be stored as reference extensions to the component during the import process. The management and retrieval of these externally generated identifiers is not the responsibility of the identifiable component layer.

If imported components have both provided UUIDs as well as OIDs that would compute different UUIDs, then both the provided and computed UUIDs must be associated with the component, and any single UUID will be sufficient to uniquely identify and retrieve the component.

4.2.2.1. Multiple identifiers and component merging

The identifiable component layer must allow components to have more than one UUID identifier, and if previously independent components are given each other's identifiers as alternate identifiers, the identifiable component layer must dynamically merge the parts of these previously distinct components into a single integrated component.

This merging of components by merging identifiers is a simple means for managing duplicated content as it is identified. This duplicate management process does not require retirement of one component, with pointers to the other component, and the additional overhead that such retirement would entail.

4.2.2.2. Uniform resource identifiers

The architecture will integrate components from many sources, including at least SNOMED CT, RxNorm, and LOINC. Users of the architecture should not need to concern themselves with the source of the content—as a foundational goal of the environment is to provide integrated and coherent content that is a single seamless system to the end user. All components will have original or assigned UUIDs, therefore, all components will be identifiable by URIs of the form:

urn:uuid:f81d4fae-7dec-11d0-a765-00a0c91e6bf6

Since these URIs for SNOMED CT, RxNorm, and LOINC will be reproducibly assigned, users of the same architecture can use these identifiers to encode and share clinical knowledge.

In addition, if locally-developed content becomes incorporated into standards at some point in the future, the ability to support multiple UUIDs ensures that the encoded clinical knowledge based on those UUIDs can remain stable. Users and implementers of the architecture may choose to share locally developed content identified in this manner. The stable UUIDs provides a means of sharing before such work is integrated into a standard, as well as a smooth transition when the work is integrated into a standard.

4.2.2.3. Uniform resource identifier validation

Although the urn:uuid URI provides for unique identification, it is not safe in the sense that a typographical error in the URI could yield an incorrect result with little or no awareness on the part of the individual that constructed the URI. The architecture must allow for dynamic validation of URIs by some means, in specific contexts—such as when accepting generated input.

We are not recommending checksums, or other methods for ensuring the URI does not get corrupted in transport—the ISO 7 layer model for error free transmission across a network is robust. We are recommending that there be a method that URIs are associated with human readable text from the component the URI represents, so that the coupling between a meaningless identifier useful to the computer, and a text representation comprehensible to a human is provided.

4.2.2.4. Component query

The architecture must support queries over collections of components.

4.2.2.5. Component result set

A result set is composed of a set of component identifiers that match a set of criterion.

4.2.2.5.1. AND

Compute the intersection of the set results from given child clauses.

4.2.2.5.2. OR

Compute the union of the results of the child clauses.

4.2.2.5.3. NOT

Computes the relative complement of the result of the child clause with respect to the set of all components that are processed by the query.

4.2.2.5.4. XOR

Computes the exclusive disjunction between the result sets of each child clause. This operator enables the ability to determine differences between identical child clauses that have different view coordinates, to determine what changed between to versions of the system.

4.2.3. Module & chronicle

STAMP versioning

Figure 4.5. Stamped Version

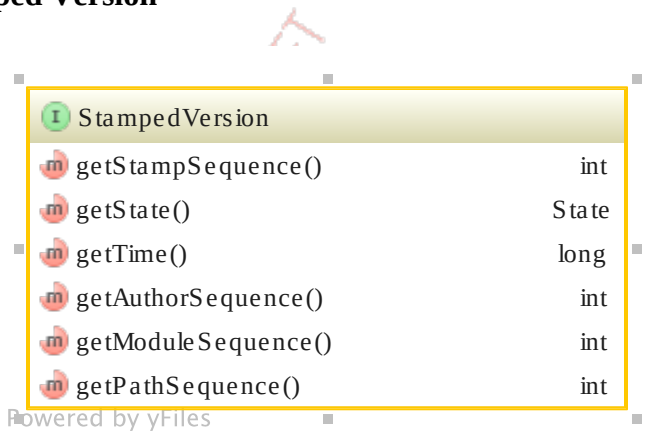


Figure 4.6. Latest Version

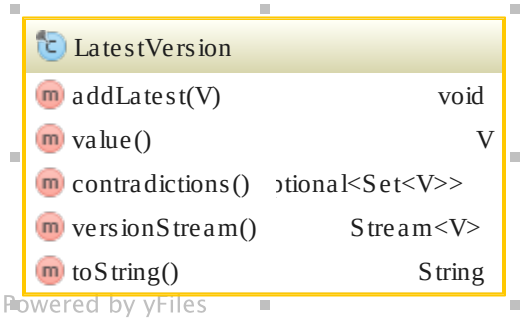
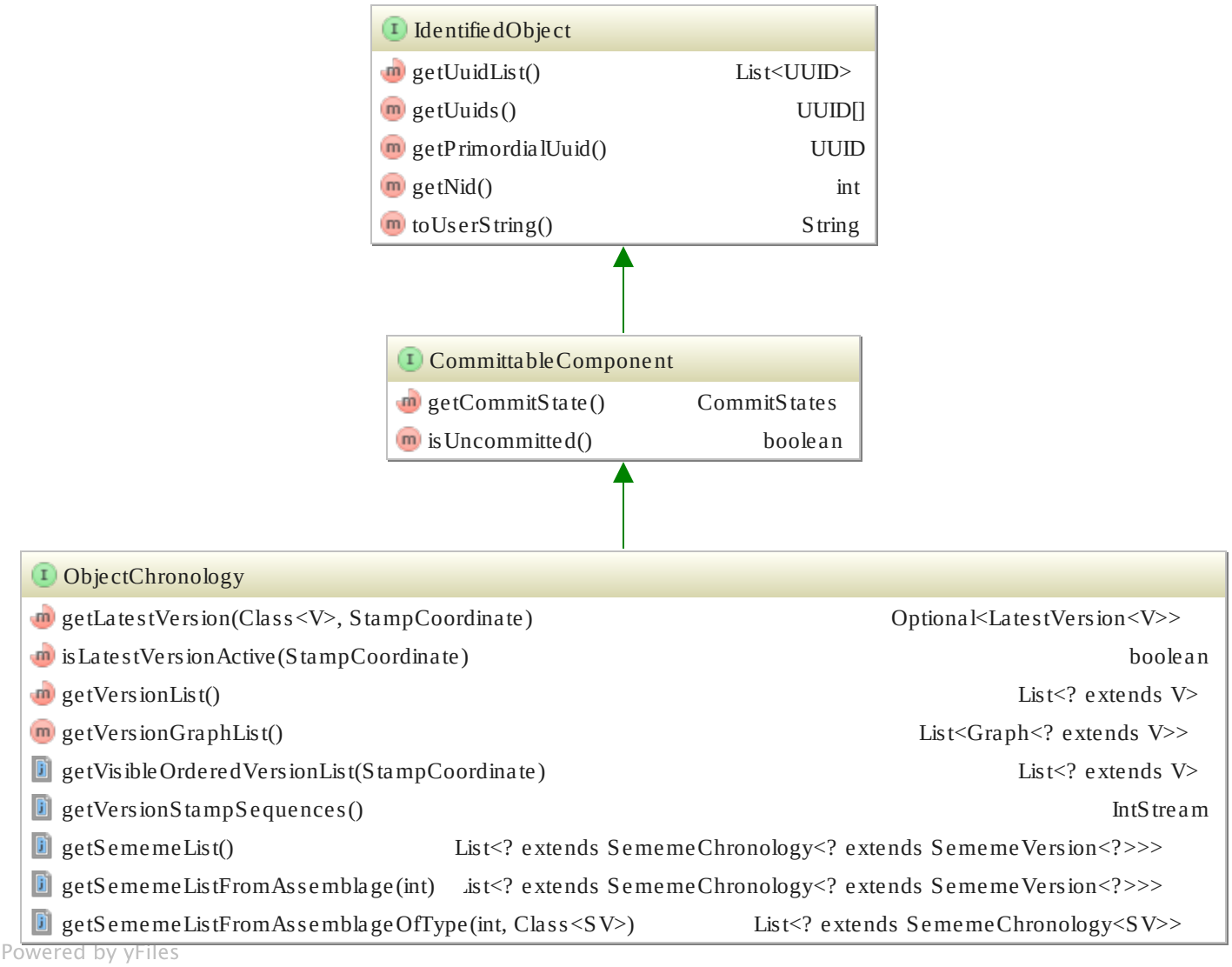


Figure 4.7. Object Chronology



The chronicle layer provides a means to generically represent the revisions to a component over time, and to index those revisions by status (active, inactive), effective time of change, author of change, module within which the change occurred (international edition, US extension, etc.), and the development path of the change (development, release candidate, etc.). Taken together, these fields can be referred to as a versions STAMP (status, time, author, module, and path).

The version STAMPS provides a foundation for version control and configuration management of all the components of the information architecture.

The STAMP will provide a means to modularize content so that modules can be turned on and off depending on specific use cases, and that modular content can be developed independently from unrelated modules. This modularity will enable simplified development and quality assurance processes for each module.

4.2.3.1. Distributed version control

Version control provides an audit trail for any changes to components of the informatics architecture, and the ability to roll back or forward to any version of any component as needed. The architecture must provide for standard distributed version control concepts of push, pull, paths, tags, commits, revisions, changesets, contradictions, branching, and merging for these components in the authoring environment.

The underlying data representation of the architectural components must be append-only so that a complete audit trail of all changes to all components is assured.

4.2.3.1.1. Path origins

Each path may have zero or more origins. An origin is a position (a point in time) on another path, and the downstream path will inherit all the changes that occurred on the upstream path prior to the origin position. Multiple origins enable a working path to be created from two or more systems that may have independent paths. For example, a path for development of a mapping between SNOMED CT and ICD-10 may have one origin on the SNOMED CT release path and another origin on the ICD-10 release path.

4.2.3.1.2. Commit record

Each commit to a chronicle must be accompanied by a commit record, which records what other STAMPS of that chronicle where visible to the author when the commit was made. This commit record will be used to determine if unsynchronized commits (commits that occurred before the author's commit, but that have not propagated through the distributed version control system) have been subsequently synchronized, generating an ERR event.

4.2.3.1.3. Version equality

Each version within the chronicle must have a standard means to test for content equality (versions with equivalent content, but whose author, commit time, or commit path may differ), and to test for absolute equality (versions with equivalent content and identical author, commit time and path). These different methods of equality will be used when managing ERRs, and when merging paths, and promoting content.

4.2.3.1.4. Path precedence ordering

Each version within the chronicle must be ordered first by the path upon which a commit is made, and secondarily must be ordered within the path by the time of commit.

4.2.3.1.5. Path promotion

The environment must provide the ability to promote selected content from one path to another as part of a controlled release process. This promotion process must be automatable, and repeatable. When path promotion occurs in the generation of release candidates, the process may be repeated many times, and therefore the process needs to be reproducible.

4.2.3.1.6. Event requiring review

During distributed development multiple authors may commit changes to the same components without being aware of concurrent changes made by other authors. These concurrent commits may be deliberate, for example in the case of duplicate editing for quality assurance or training, or may be inadvertent. The system must specify rules for determining if an Events Requiring Review (an ERR) is generated, and when concurrent commits may be managed in an automated way.

4.2.3.2. Concurrent coordinated development

Concurrent development is necessary to support coordinated content.

For example, if a pharmacy knowledge base is not current with the latest version of SNOMED, then drug-disease interactions may be missed. If a system is not using the latest version of SNOMED with the latest diagnoses, an enterprise may have to either fail to properly record a patient's diagnoses, or may have to create unnecessary local enhancements that will have to be later reconciled with the already released content in SNOMED.

The authoring environment for the architecture must support concurrent distributed development using a store and forward approach so that isolated development activities can be integrated despite lack or real-time network connectivity.

4.2.3.2.1. Change sets

Changes made by authors must be represented as changesets, and these changesets must be independent entities that can be applied to—or removed from—other configurations of the authoring environment.

4.2.3.2.2. Branching

<this section needs significant revision>

Branching, in revision control and software configuration management, is the duplication of an object under revision control (such as a source code file, or a directory tree) so that modifications can happen in parallel along both branches.

Branches are also known as trees, streams or codelines. The originating branch is sometimes called the parent branch, the upstream branch (or simply upstream, especially if the branches are maintained by different organizations or individuals), or the backing stream. Child branches are branches that have a parent; a branch without a parent is referred to as the trunk or the mainline.[1]

In some distributed revision control systems, such as Darcs, there is no distinction made between repositories and branches; in these systems, fetching a copy of a repository is equivalent to branching.

Branching also generally implies the ability to later merge or integrate changes back onto the parent branch. Often the changes are merged back to the trunk, even if this is not the parent branch. A branch not intended to be merged (e.g. because it has been relicensed under an incompatible license by a third party, or it attempts to serve a different purpose) is usually called a fork.

Branches allow for parts of software to be developed in parallel.[2] Large projects require many roles to be filled, including developers, build managers, and quality assurance [http://en.wikipedia.org/wiki/Software_quality_assurance] personnel. Further, multiple releases on different operating system platforms may have to be maintained. Branches allow contributors to isolate changes without destabilizing the codebase, for example, fixes [http://en.wikipedia.org/wiki/Patch_(computing)] for bugs, new features [http://en.wikipedia.org/wiki/Feature_(software_design)],[3] and versions [http://en.wikipedia.org/wiki/Software_versioning] integration [http://en.wikipedia.org/wiki/System_integration]. These changes may be later merged [http://en.wikipedia.org/wiki/Merge_(revision_control)] (resynchronized) after testing.

A development branch or development tree of a piece of software is a version that is under development [http://en.wikipedia.org/wiki/Software_development], and has not yet been officially released [http://en.wikipedia.org/wiki/Software_release]. In the open source [http://en.wikipedia.org/wiki/Open_source] community, the notion of release is typically metaphorical, since anyone can usually check out any desired version, whether it be in the development branch or not. Often, the version that will eventually become the next major version is called the development branch. However, there is often more than one subsequent version of the software under development at a given time.

4.2.3.2.3. Merging

<this section needs significant revision, and an updated graphic>

Merging (also called integration) in revision control, is a fundamental operation that reconciles multiple changes made to a revision-controlled collection of files. Most often, it is necessary when a file is modified by two people on two different computers at the same time. When two branches are merged, the result is a single collection of files that contains both sets of changes.

adts [http://www.explain.com.au/oss/docbook/]

[1] http://www.hl7.org/oid/index.cfm

[2] http://tools.ietf.org/html/rfc4122#appendix-C

In some cases, the merge can be performed automatically, because there is sufficient history information to reconstruct the changes, and the changes do not conflict. In other cases, a person must decide exactly what the resulting files should contain. Many revision control software tools include merge capabilities.

There are two types of merges: automatic and manual.

Automatic merging is what revision control [http://en.wikipedia.org/wiki/Revision_control] software does when it reconciles changes that have happened simultaneously (in a logical sense). Also, other pieces of software deploy automatic merging if they allow for editing the same content simultaneously. For instance, Wikipedia allows two people to edit the same article at the same time; when the latter contributor saves, their changes are merged into the article instead of overwriting the previous set of changes.

Manual merging is what people have to resort to (possibly assisted by merging tools) when they have to reconcile files that differ. For instance, if two systems have slightly differing versions of a configuration file and a user wants to have the good stuff in both, this can usually be achieved by merging the configuration files by hand, picking the wanted changes from both sources (this is also called two-way merging). Manual merging is also required when automatic merging runs into a change conflict; for instance, very few automatic merge tools can merge two changes to the same line of code (say, one that changes a function name, and another that adds a comment). In these cases, revision control systems resort to the user to specify the intended merge result.

Merge algorithms are an area of active research, and consequently there are many different approaches to automatic merging, with subtle differences. The more notable merge algorithms include three-way merge, recursive three-way merge, fuzzy patch application, weave merge, and patch commutation.

4.2.3.3. Standardized release process

The architecture will provide a standard mechanism to release artifacts outside the immediate development team.

4.2.3.4. Configuration management

The architecture must allow organization of components into modules, identification of dependencies between modules, and specification of compatible versions of dependent modules.

Assembly of compatible components for testing and runtime.

4.2.3.5. Runtime time travel

The architecture must be able to cope simultaneously with historic data that was encoded using previous versions of the system, with current data that was encoded using current versions of the system. This historic and current data must in turn be processable by decision-support components of the system, in a manner appropriate for a life-critical system. Encoded knowledge must have STAMPs for all versions of its content. The overall system must be under configuration control such that all the valid STAMPs for

any version of the system is retrievable for processing historic data, and encoded patient data must record the version of the system that it was encoded with.

Unlike other types of software which utilize a single version , all version of the encoded knowledge that has

4.2.3.6. Chronicle query

The architecture must provide for querying component chronicles.

4.2.3.6.1. View coordinate

The architecture must provide for a limited set of temporal query capabilities appropriate for identifying and managing change to encoded knowledge over time. These temporal queries must allow for temporal queries at current time, time points in the past or future, or over durations.

Each query must be given a view coordinate that specifies if the default temporal constraints for the query are at the current time, or a time point in the past of future. Individual clauses in the query may introduce additional view coordinates to enable durations

4.2.3.6.2. Status

Queries must allow the components status (active or inactive) to be part of the query criterion. For example, include only active components within the query criterion.

4.2.3.6.3. Author

Queries must allow the author of a change to be part of the query criterion. For example, only include changes that where not made by Chief Terminologist in the results of a query.

4.2.3.6.4. Changed from previous version

Computes the components that have been modified since during the time period specified by starting and ending view coordinates.

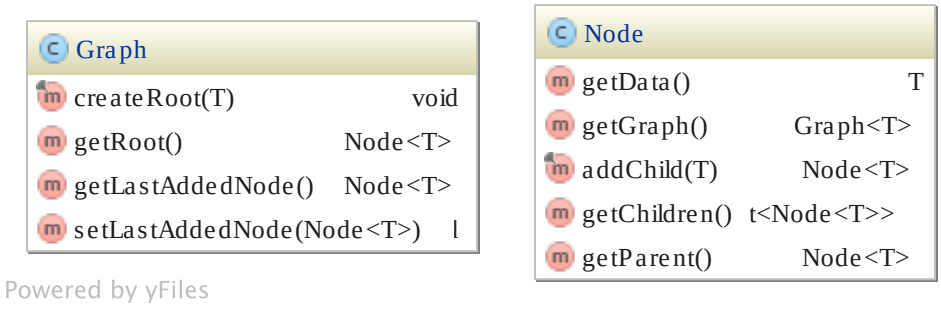
4.2.3.6.5. Module and/or path

Queries must allow the module within which—and the path upon which—a change is made to be part of the query criterion. For example, only consider changes that occurred in a language module on the release candidate path as part of a query.

4.2.4. Graph

Graph is a foundational structure.

Figure 4.8. Graph and Node



4.2.4.1. Logical Expression

Figure 4.9. Logical Expression

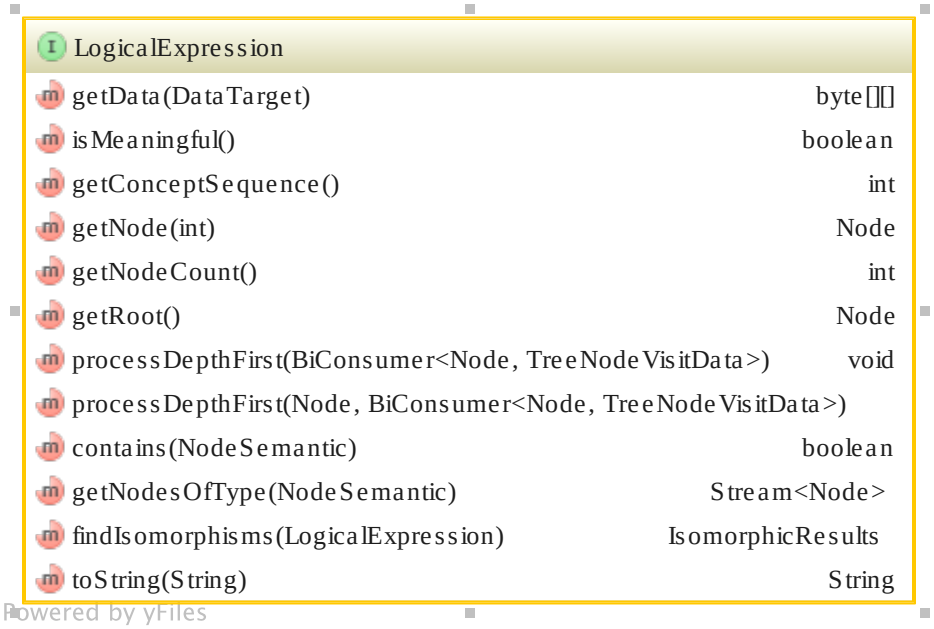


Figure 4.10. Logical Node

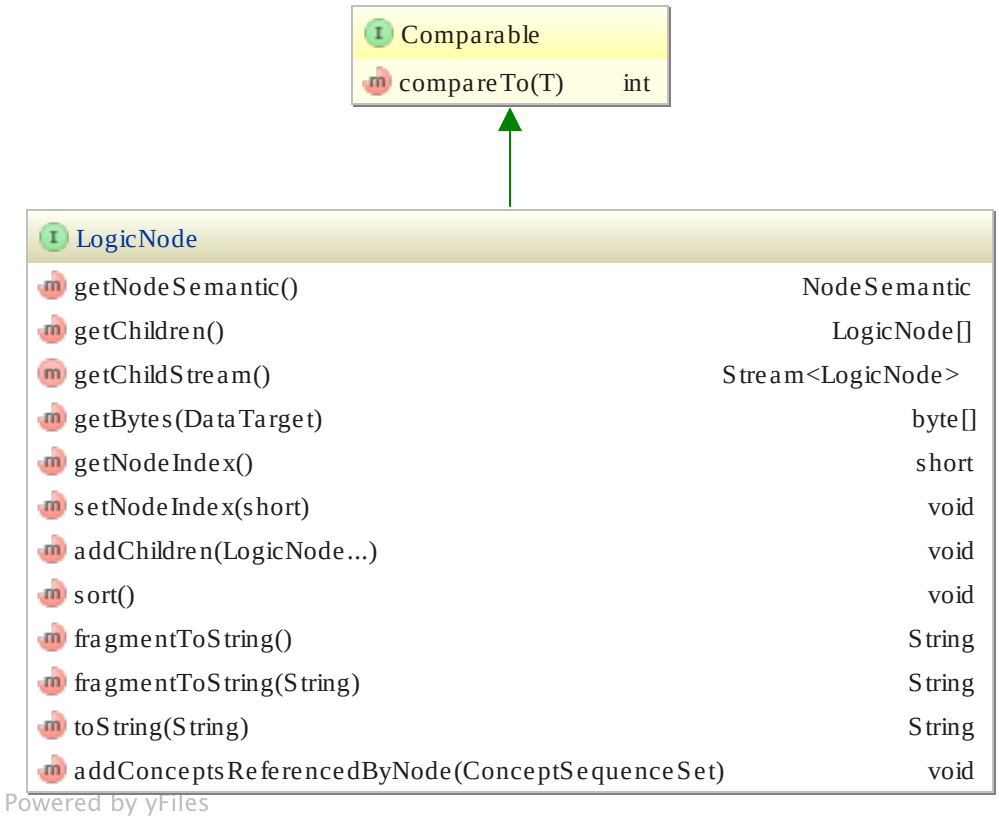
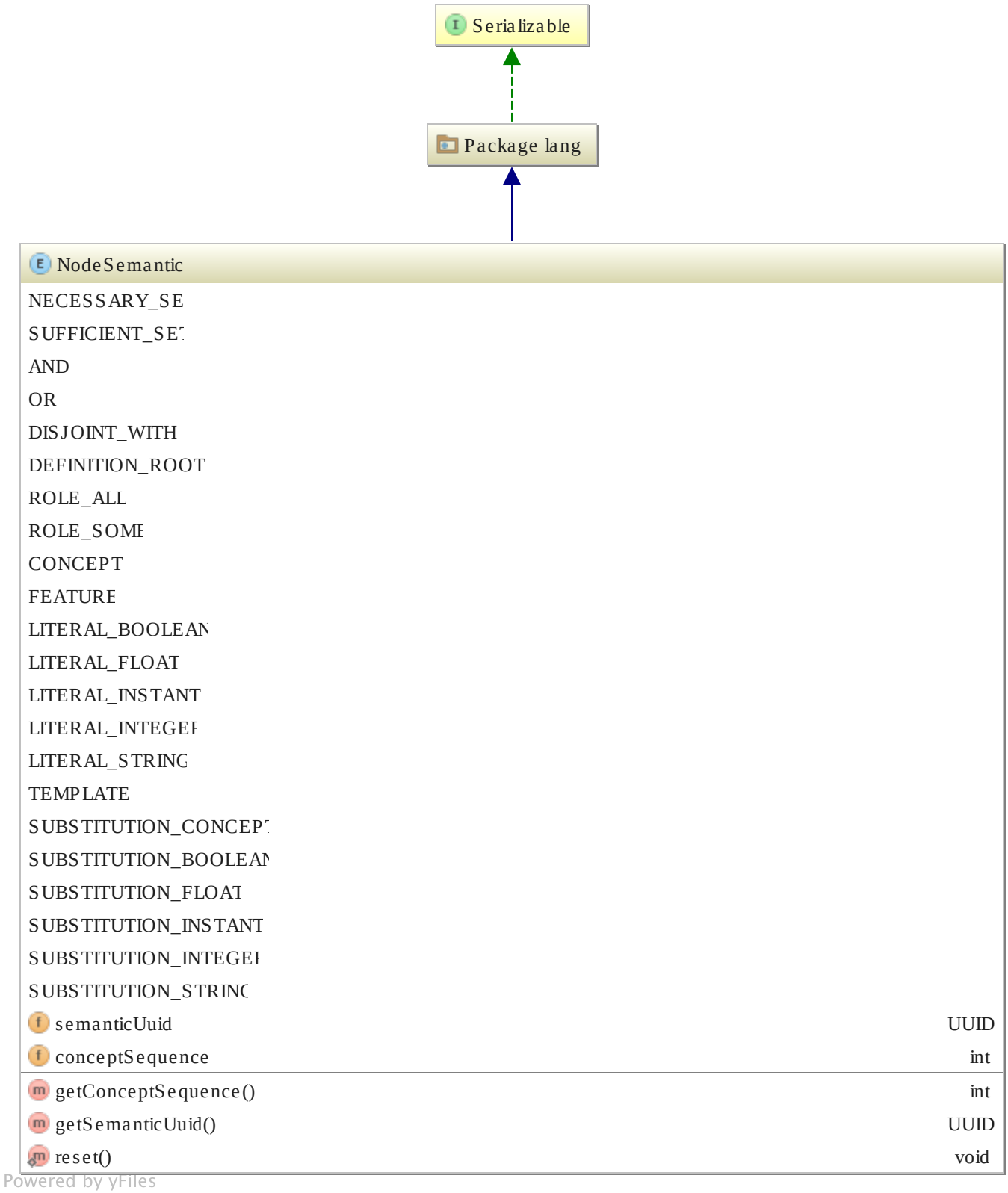


Figure 4.11. Node Semantic



4.2.5. Semantic

Text

Figure 4.12. Semantic object

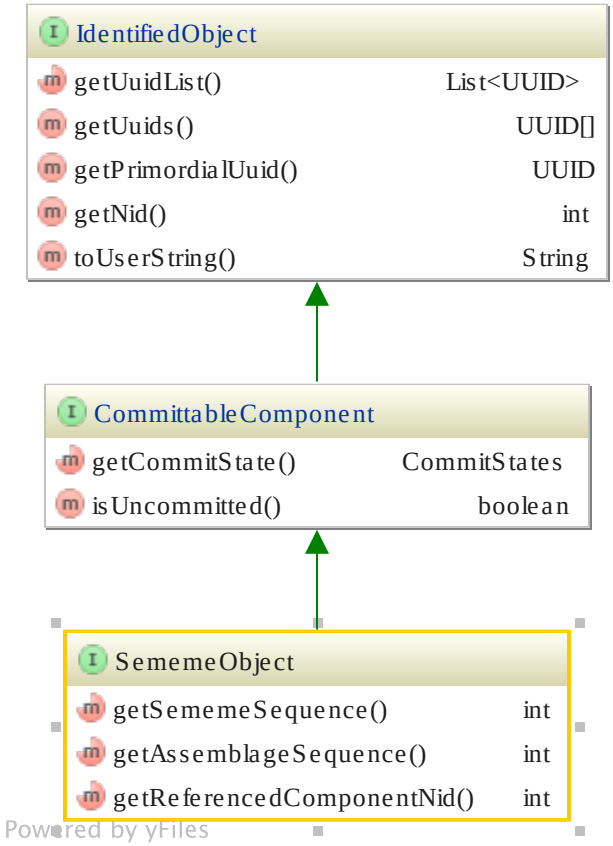
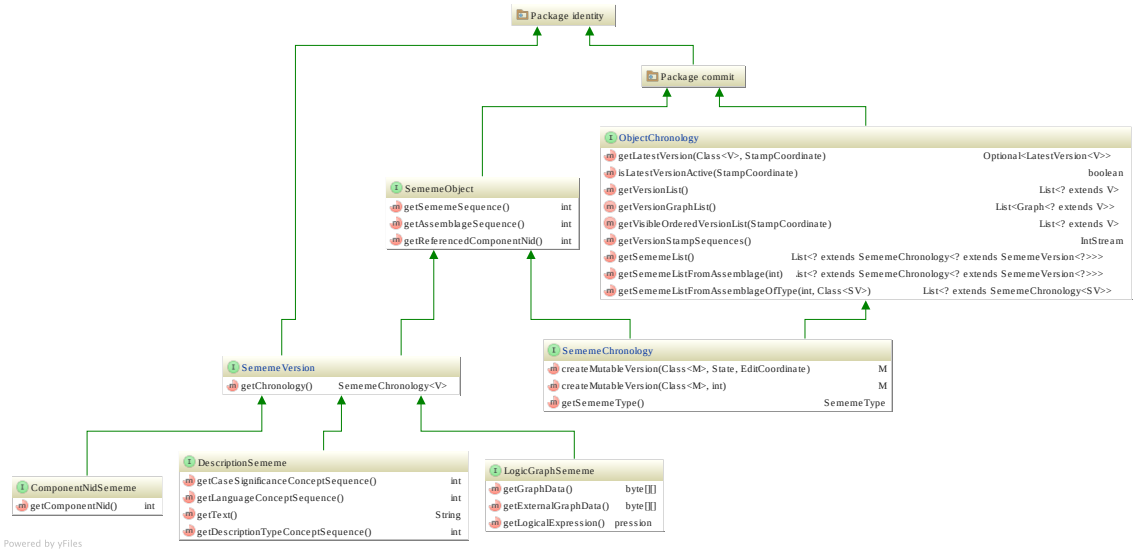


Figure 4.13. Semantic Chronology & Versions



Semantic[1] enables addition of semantic data (semantic meme == Semantic to the underlying concepts content, in a standardized way that provides for the same means of identifying, modularizing, and versioning content.

Clinical facts such as side effects or treatment effects of medications are just one of many examples of reference extensions. Laboratory reference ranges that represent standard normal, higher, and lower bounds of laboratory test values by age and ethnic group are another example.

4.2.5.1. Assemblage

An Assemblage is a collection of Semantic for a particular purpose.

The Assemblage consists of Semantic that reference an component, and provide additional data to that member for some purpose.

Or development experience has shown that the language surrounding naming of concepts related to Refexes has been challenging, with many similar sounding entities (Refex, Refset, Refex Collection, Refex ID, Refex Member ID, Referenced Component, Extended Component, Reference Extension, Component Reference, and more). In the requirements here, we hope to provide a more systematic and less confusing naming standard for Semantic concepts. Part of the reason for the choice of Assemblage as opposed to use of Refset Concept, is to provide more clarity, and to use terms that do not have baggage that prevents unambiguous interpretation of what is meant by the term.

4.2.5.1.1. Assemblage identity

Every reference extension Assemblage is identified by a concept created specifically for this purpose. The identifier of this concept is the identifier of the Assemblage. The Assemblage concept is annotated with metadata to enable proper display and processing of the members of the Assemblage.

[1] A Semantic (from Greek σημα#νω (s#maín#), meaning "mean, signify") is a semantic unit of meaning. A Semantic is a proposed unit of transmitted or intended meaning; it is atomic or indivisible. It can be thought of as the semantic counterpart to any of the following: a meme in a culture, a gene in a genetic make-up, or an atom (or, more specifically, an elementary particle) in a substance.--Wikipedia

4.2.5.1.2. Assemblage metadata

Every Assemblage will have metadata associated with it that indicates the purpose of the Refex in general terms (navigation, mapping, navigation, reference ranges, etc.). In addition, the metadata will define the semantics of each extension field, and will provide standard ordering for presentation of those fields, and standard naming information for those fields, so that Refex data can be presented to consumers in a sensible manner.

4.2.5.2. Description Semantic

4.2.5.2.1. Language

The language requirements enable direct support for user interface customization for different user groups. In the past, interface terminologies have been proposes as an alternative to supporting the language requirements within a single integrated system. Use of independent terminologies creates a mapping and maintenance burden that is unnecessary.

4.2.5.2.1.1. Typed descriptions

The architecture must allow all descriptions to be given a metadata type that indicates the way the typed description describes the concept of which it is a part. For example, description types may include: fully-specified-name, synonym, and definition.

4.2.5.2.1.2. Multilingual support

Each description specifies the language that it is from. Identical spelling may not have the same meaning in different languages, for example: pie in Spanish refers to foot#the lower extremity of the leg below the ankle, on which a person stands or walks. In English pie means a baked dish of fruit, or meat and vegetables, typically with a top and base of pastry.

Since concepts are organized by meaning, and since descriptions are associated with only one concept, having a particular description stand for two different concepts is not allowed. To prevent problems caused by false cognate and false friends between languages, all descriptions are assigned to a single language, within a concept that represents the meaning of that description within that language.

Descriptions are not required to be unique, and therefore a Spanish description of pie can be within the concept for the lower extremity of the leg below the ankle, on which a person stands or walks, and the English description of pie can be within the concept for a baked dish of fruit, or meat and vegetables, typically with a top and base of pastry.

4.2.5.2.1.3. Dialect support

The architecture must provide a standard means of identifying if a particular description is preferred or acceptable in a particular dialect. Dialect is to be interpreted broadly, not just to represent geographical variation in language, but it is also to represent variation in language caused by role or profession. For example, one dialect may support use of words or phrases that patients can readily understand (e.g. before bedtime) and another dialect may support words or phrases specific for caregivers (e.g. qhs).

4.2.5.2.1.4. Terminology query

The IA must provide flexible (able to support current use cases and adapt to new use cases), effective (high quality results), and efficient (fast response time and high throughput) search over textual components of the IA.

4.2.5.2.1.4.1. Language coordinate

Defines version, language, dialect, module, path, and version for retrieval.

4.2.5.2.1.4.2. Concept specification

Consists of a concept identifier as well as a current textual description of that concept. The use of Concept Specifications ensures validation of a computable key (the concept identifier) with human interpretable text. If the concept retrieved from the identifier does not contain the textual description, a validation error will be throws.

End users must not constrict by entering or copying and pasting concept identifiers. They must be provided a drag-and-drop interface uses concept specs so that the identifiers may be validated against the users understanding of the description of those components as part of the query process.

4.2.5.2.1.4.3. Regular expressions

Queries must support regular expression clauses over descriptions.

4.2.5.2.1.4.4. Indexed full-text search

Queries must support full-featured text search clauses over descriptions.

Text search features must include:

· Ranked searching -- best results returned first

· Phrase queries

· Wildcard queries

· Proximity queries

· Range queries

· Fielded searching (e.g. title, author, contents)

· Simultaneous update and searching

· Flexible faceting, highlighting, joins and result grouping

· Fast, memory-efficient and typo-tolerant suggestions

4.2.5.2.1.4.5. Concept for component substitution

Substitute the concept that encloses a component in the result set of the child clause. For example, return the concept for all members of a comment Refex that have an active status.

4.2.5.2.1.4.6. Fully specified description substitution

Substitute the fully specified description—in the specified preferred language and dialect—for all active concept members of the veterinary Refex.

4.2.5.2.1.4.7. Preferred description substitution

Substitute the preferred description —in the specified preferred language and dialect—for all active concept members of the veterinary Refex.

4.2.6. Concept

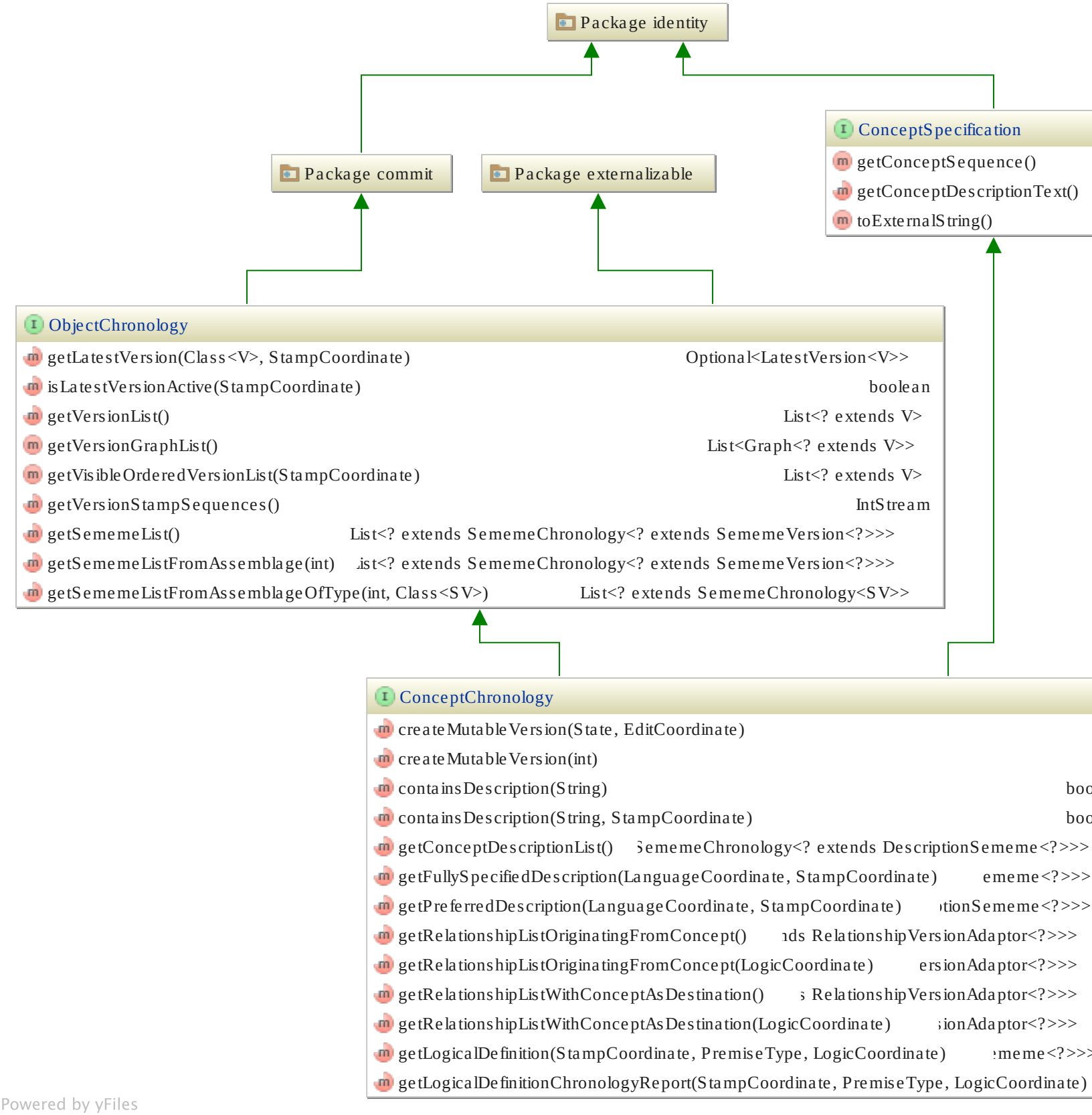
ConceptChronology extends ObjectChronology with specific methods to identify and describe concepts. All identifiable concepts used in higher layers must be present in this layer.

The architecture is concept oriented. Its entries are organized conceptually, rather than by term. Whereas a dictionary starts with the term in a given language and captures all its possible meanings, the terminology layer is based on the concept, that is, the conceptual content, to which the terms in various languages correspond. [10]

4.2.6.1. Homogenous semantics units

The concept-orientation principle will extend to all declarative semantics within the architecture. For example, units of measure will be represented as concepts (as SNOMED CT already provides), rather than as text fields (as UCUM would provide). Although the internal representation of the architecture will be concept-oriented, the ability to interoperate with text-based semantics may be provided through reference extensions (as described in Section 3.8 Reference extension layer) to the appropriate concept.

As with units of measures, language information will be encoded as concepts, rather than text fields. Text fields will not be used for machine processable semantics. Text fields will only be used for presenting language to the user for comprehension of the underlying concepts.

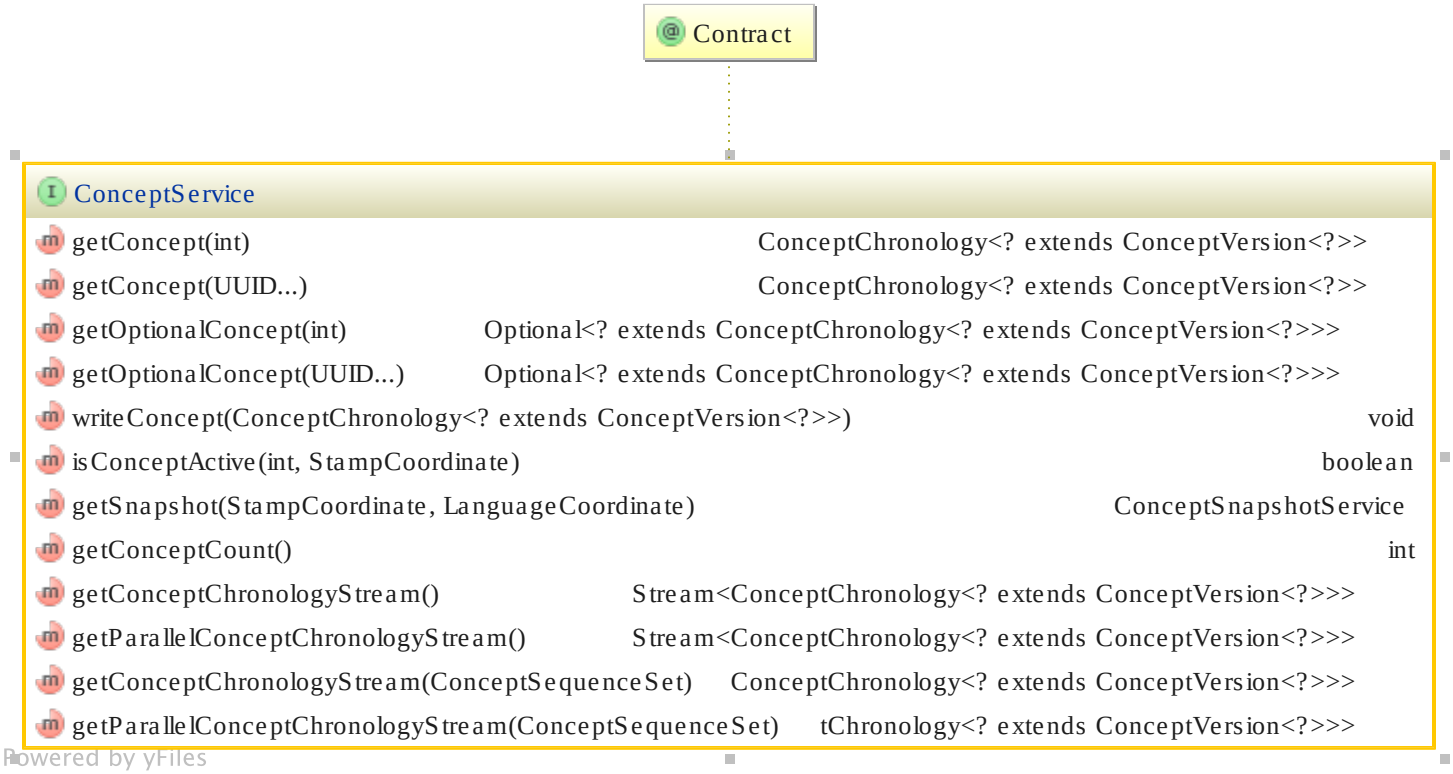


This constraint ensures that the traditional “information models” that are representable and can have well defined and consistent relationship with the concepts layer, and that those models can be specifically designed to work coherently with the underlying concepts.

4.2.6.1.1. Concept service

Text

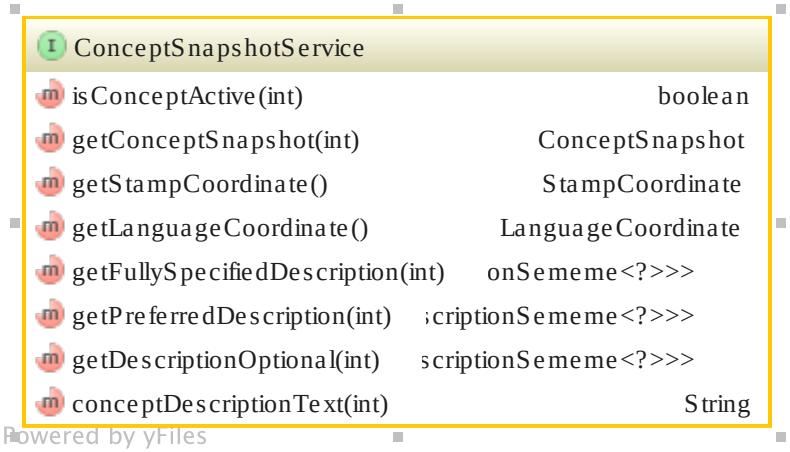
Figure 4.15. Concept service



4.2.6.1.2. Concept snapshot service

Text

Figure 4.16. Concept service



4.2.6.2. Language & dialect

Text

4.2.6.3. Versioned Graph

Text

4.2.6.4. Description logic

Text

4.2.6.5. Taxonomy

Text

4.2.6.6. Query

Text

4.2.6.7. Transformation

Text

4.2.6.7.1. Nesting transformation

Text

4.2.6.7.2. Flattening transformation

Text

4.2.6.7.3. Isosemantic transformation

Text

4.2.6.7.4. XSLT extensions

XSLT extensions provide for accessing computed values, values that can not be obtained simply from the structure of underling objects

4.2.6.7.4.1. kind-of

From the computed taxonomy relationships, based on the DL

4.2.6.7.4.2. member-of

Member of a assemblage based on query and STAMP version

4.2.6.7.4.3. description-of

Using language, dialect, and STAMP version.

4.2.6.8. Rule

Text

4.2.6.9. Domain

The domain layer hosts abstractions built from the underlying layers that describes selected aspects of a sphere of knowledge, influence, or activity. The domain model is a representation of meaningful real-world concepts pertinent to the domain that need to be modeled in software. The concepts include the data involved in the business and rules the business uses in relation to that data.

4.2.6.9.1. Semantic document markup

Specifically choosing names to avoid confusion between HL7 structured documentation such as clinical document architecture.

4.2.6.9.2. Terminology model

Defines a general-purpose representation of terminology systems able to represent SNOMED CT, LOINC, and RxNorm using description logics, languages, and dialects.

4.2.6.9.3. Semantic extension model

Defines a general-purpose representation of terminology systems able to represent SNOMED CT, LOINC, and RxNorm using description logics, languages, and dialects.

4.2.6.9.4. Observable model

SNOMED/LOINC observable model.

4.2.6.9.5. Observation result model

CIMI observation result model.

4.2.6.9.5.1. Presence, absence, and unknown

Dot blot hemorrhage absent vs zero Dot blot hemorrhages vs it is not known if the patient has dot blot hemorrhages. [0,0]; $_{(0,\infty)}$; [0,∞).

4.2.6.9.5.2. Proximal provenance

The proximal provenance represents the last step in determining how the value of the observation result was obtained. For a blood pressure measurement, examples may be concepts such as "by provider measurement," "by patient report," or "from prior encounter document." In the case of a null value for an observation result, examples may be concepts such as "not asked", "not asked because question is not applicable", "not asked because patient is unconscious." The proximal provenance supports a superset of the semantics of the HL7 null flavors for null values, in addition to supporting provenance information regarding bona fide values.

4.2.6.9.5.3. Subject of information

This value is associated with the patients, partner, relative, etc. Needs to have the ability to represent the precision necessary for a genetic history.

4.2.6.9.6. Request model

abc

4.2.6.9.7. Encounter document model

Represents the assertions and requests that are associated with an encounter with either the patient, a specimen related to the patient, or data pertaining to the patient

4.2.6.9.8. Questionnaire model

A static representation of questions in machinable form, that when presented to—and completed by—a user from within a compliant application, results in a well-formed encounter document.

4.2.6.10. Script

Text

4.2.6.11. Workflow

Text

4.3. Iterative and incremental

4.3.1. Continuous delivery

Text

4.3.2. Quality management

Text

Part II. Language representation

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5. Language

Language is used to describe identified components.

5.1. Language Layer Concerns

5.1.1. Language

5.1.2. Dialect

5.2. Cross Cutting Concerns

5.2.1. Understandability, Reproducibility, and Utility

5.2.2. Query

5.3. Concordance

The language used to describe a component must be concordant with the underlying semantics of the object being identified.

5.4. KOMET support for Language

6. SOLOR language representation

7. KOMET support for language

Part III. Definitional representation

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8. Definitional

8.1. Definitional Layer Concerns

8.1.1. EL++ definitions of concepts

8.2. Definitional Layer Exclusions

8.2.1. Logical negation

8.2.2. Measurement

8.3. Crosscutting Concerns

8.3.1. Understandability, Reproducibility, and Utility

8.3.2. Query

8.4. Definitional Operators

is one of the few description logics for which standard reasoning problems such as consistency, and concept subsumption are decidable in polynomial time. To gain this tractability, commonly-used constructors such as universal value restrictions, inverse roles, and functional roles have been sacrificed.[1]

8.4.1. Conjunction

8.4.2. Disjointness

8.4.3. Reflexive roles

8.4.4. Role inclusions

role inclusions allow expression of role hierarchies, transitive roles and right identities.

[1]Comparison of Reasoners for large Ontologies in the OWL 2 EL Profile. Kathrin Dentler, Ronald Cornet, Annette ten Teije, and Nicolette de Keizer http://www.semantic-web-journal.net/sites/default/files/swj120_2.pdf

8.4.5. Necessary axioms

8.4.6. Sufficient axioms

8.4.7. Defining relationships

Role relationship are represented as existential restrictions

8.4.8. Quantities

Concrete domains are a construct that can define new classes by specifying restrictions on attributes that have literal values (as opposed to relationships to other concepts). The binary operators, equal to, greater than, greater than or equal to, less than, and less than or equal to, can be used in concrete domain expressions, and literal values can be integers, floating point numbers, string literals, and dates. [2]

Concrete domains are used to model quantities in the definition of concepts, such as defining how much ibuprofen may be in a medication tablet.

8.4.9.

8.5. Principles

This section identifies the fundamental principles that will be applied when creating the models for Clinical Decision Support (CDS) Knowledge Artifacts ("KNARTs").

8.5.1. Principle 1: Separation of Concerns

Definition: Separation of Concerns[3]

The use of Immutable Objects is a technique that fulfills the Separation of Concerns principle.

Attributes that describe specific semantic concepts should be grouped together into a single class and not be spread across a number of classes. Doing the latter leads to tight coupling between classes. Doing the former leads to better decomposition of a potentially complex domain.

Example: Attributes for a Role (e.g., Practitioner) should not be mixed with attributes for an Entity (e.g., Person). This allows a person to assume a number of roles over their lifetime or to function in more than one role.

[2] SNOROCKET 2.0 Concurrent Domains and Concurrent Classification

[3] wikipedia: In computer science [https://en.wikipedia.org/wiki/Computer_science], separation of concerns (SoC) is a design principle for separating a computer program [https://en.wikipedia.org/wiki/Computer_program] into distinct sections, such that each section addresses a separate concern [https://en.wikipedia.org/wiki/Concern_(computer_science)]. A concern is a set of information that affects the code of a computer program. A concern can be as general as the details of the hardware the code is being optimized for, or as specific as the name of a class to instantiate. A program that embodies SoC well is called a modular [https://en.wikipedia.org/wiki/Modular_programming] program. Modularity, and hence separation of concerns, is achieved by encapsulating [https://en.wikipedia.org/wiki/Encapsulation_(computer_programming)] information inside a section of code that has a well-defined interface. Encapsulation is a means of information hiding [https://en.wikipedia.org/wiki/Information_hiding]. Layered designs in information systems are another embodiment of separation of concerns (e.g., presentation layer, business logic layer, data access layer, persistence layer. The value of separation of separation of concerns is simplifying development and maintenance of computer programs. When concerns are well-separated, individual sections can be reused, as well as developed and updated independently. Of special value is the ability to later improve or modify one section of code without having to know the details of the other sections, and without having to make corresponding changes to those sections.

8.5.2. Principle 2: Immutability

Definition: Immutable Object[4]Although building immutable objects ... requires a bit more up-front complexity, the downstream simplification forced by this abstraction easily offsets the effort. One of the benefits of switching to a functional mindset is the realization that tests exist to check that changes occur succesfully in code. In other words, testing's real purpose is to validate mutation - and the more mutation you have, the more testing is required to make sure you get it right. If you isolate the places where changes occur by severely restricting mutation, you create a much smaller space for errors to occur and have fewer places to test.

Finally, one of the best features of immutable classes is how well they fit into the *composition* abstraction.

https://www.ibm.com/developerworks/library/j-ft4/index.html

8.5.3. Principle 3: Phenomenon

Definition: Observation of Phenomenon[5]Observation is the active acquisition of information from a primary source. In living beings, observation employs the senses. In science, observation can also involve the recording of data via the use of instruments. The term may also refer to any data collected during the scientific activity. The human mind, and modern scientific instruments can extensively process "observations" before they are consciously surfaced to the observer. This unconscious or automated pre-processing of data makes answering the question as to where in the data processing chain "observing" ends and "drawing conclusions" begins difficult. For our purposes, we do not try to draw a line between "observing" and "drawing conclusions" because for our analysis purposes, the distinction is immaterial.

https://www.revolvy.com/main/index.php?s=Qualitative%20property&item_type=topic

8.5.4. Principle 4: Measurement

Definition: Standard…

Definition: Measurement consists of using observation to compare the phenomenon being observed to a standard [not a normal range]. Measurement asserts something. These standards can be qualitative, that is, only the absence or presence of a property is noted, or quantitative if a numerical value is attached to the observed phenomenon by counting or measuring. The standard of comparison can be an artifact, process, or definition which can be duplicated or shared by all observers, if not by direct measurement then by counting the number of aspects or properties of the object that are comparable to the standard. Measurement reduces an observation to a number which can be recorded, and two observations which result in the same number are equal within the resolution of the process.

Units of measure: Units of measure can include relative measures... Relative to effective time, Relative to Unix Epoch, Relative to freezing point of water, relative to absolute zero. Others have a concern that there should be no units of measure for Ratio... It is dimensionless. What is wrong with saying that the units are dimensionless? What use cases cannot be met? We can call it something other than units of measure if that is the underlying problem... Level of measurement or scale of measure [https://en.wikipedia.org/wiki/Level_of_measurement#Nominal_scale] may provide a basis for what we are looking for.

[4]wikipedia: Used in object-oriented and functional programming, an immutable object is something that cannot be changed after it is created, in contrast to mutable objects that can be changed after they are created. There are multiple reasons for using immutable objects, including improved readability and runtime efficiency and higher security.

[5]wikipedia: In scientific usage, a phenomenon is any event that is observable, however common it might be, even if it requires the use of instrumentation to observe, record, or compile data concerning it. For example, in physics [https://en.wikipedia.org/wiki/Physics], a phenomenon may be described by a system of information [https://en.wikipedia.org/wiki/Information] related to matter [https://en.wikipedia.org/wiki/Matter], energy [https://en.wikipedia.org/wiki/Energy], or spacetime [https://en.wikipedia.org/wiki/Spacetime], such as Isaac Newton [https://en.wikipedia.org/wiki/Isaac_Newton]'s observations of the moon [https://en.wikipedia.org/wiki/Moon]'s orbit and of gravity [https://en.wikipedia.org/wiki/Universal_gravitation], or Galileo Galilei [https://en.wikipedia.org/wiki/Galileo_Galilei]'s observations of the motion of a pendulum [https://en.wikipedia.org/wiki/Pendulum].

Level of measurement or **scale of measure** is a classification that describes the nature of information within the values assigned to variables [https://en.wikipedia.org/wiki/Dependent_and_independent_variables].

8.5.5. Principle 5: Composition Over Inheritance

Definition: TBD

Composition over inheritance (or composite reuse principle) in object-oriented programming is the principle that classes should achieve polymorphic behavior and code reuse by their composition (by containing those instances of other classes that implement the desired functionality) rather than inheritance from a base or parent class.

To favor composition over inheritance is a design principle that gives the design higher flexibility. It is more natural to build business-domain classes out of various components than trying to find commonality between them and creating a family tree.

Initial design is simplified by identifying system object behaviors in separate interfaces instead of creating a hierarchical relationship to distribute behaviors among business- domain classes via inheritance. This approach more easily accommodates future requirements changes that would otherwise require a complete restructuring of business-domain classes in the inheritance model.

https://en.wikipedia.org/wiki/Composition_over_inheritance

Item for Consideration: Should we say that we only allow inheritance for a single concern, i.e., we can subtype measurement but not subtype a combination of phenomenon type and measurement type?

8.5.6. Principle 6: Analysis Normal Form Clinical Statements Represent the Minimum Disjoint Set

Analysis Normal Form (ANF) clinical statements represent the minimum disjoint set of statement topic and circumstances and may not be further specified.

Current examples of naming these top-level clinical statement types are shown in the table below. HOwever, it is possible that a few more will need to be added. The proof would be if we find a use case that does not fit into any of the top-level statements shown below.

Table 8.1. Current Top-Level Clinical Statements

	Clinical Statement	
Top-Level Clinical Statement Type	**Topic**	**Circumstance**
Phenomena Measurement	Phenomena	Measurement
Phenomena Measurement Goal	Phenomena	Goal
Action Request	Action	Request
Action Performance	Action	Performance

8.5.7. Principle 7: Analysis Normal Form Classes Cleanly Separate Concerns

Analysis Normal Form (ANF) classes must cleanly separate the concerns of concept definition and the concerns of domain models.

- Need to define thoroughly the domain models here. The strawman description is that domain model use concept definitions as a building block to define non-defining relationships or associations between concepts. The domain model represent cardinality, optionality, and other constraints.
  - Example: Laterality should be a concern of either the concept definition or the domain model, but not both. We can relax this principle for the Clinical Input Form but for ANF, we need a clean and invariant separation of concerns.
- Need to determine better names for "concept definition" and "domain models."

8.5.8. Principle 8: Unique Concerns are Part of the ANF Topic

Concerns unique to a discipline are included as part of the topic in Analysis Normal Form.

Example: Route of administration specification within a request is unique to a discipline (pharmacological therapeutics), but not part of requests from other disciplines (e.g., homework requests from school) and would be represented in the topic, not in the circumstance.

8.5.9. Principle 9: Universal Concerns are Part of the ANF Circumstance

Concerns that are universal to all disciplines are included as part of the circumstance in Analysis Normal Form.

Example: All requests have a requestor; therefore, the requestor would be part of the circumstance in Analysis Normal Form.

8.5.10. Principle 10: Clinical Statement Model Stability

Stability is different from immutability. Stable means that the model can still meet unanticipated requirements without having to change. It is not acceptable to change the model every time a new way to administer a drug or to treat a condition is identified. By representing these types of potentially dynamic concerns in the terminology expressions, as opposed to static fields in a class structure, we do not have to change the model every time something new is discovered. As Terry Winograd said, anticipating breakdowns, and providing a space for action when they occur, is a design imperative.

In some regards, in this context "stable" means "not brittle." A model easily broken by changes that someone could anticipate is one possible definition of brittle. A stable model is critical in the phase of a known changing landscape. We do that by isolating areas of anticipated change into a dynamic data structure. That dynamic data structure may also be immutable in an object that represents a clinical statement.

8.5.11. Principle 11: Overall Model Simplicity

In cases where different principles collide, we shall favor the enhancement of simplicity of the entire system over simplicity in one area of the system.

8.5.12. Principle 12: Cohesion

Related classes should reside in the same module or construction. The placement of a class in a module should reduce the dependencies between modules.

8.5.13. Principle 13:Reusability

Architectural patterns should encourage class reusability where possible. Reusability may further refine encapsulation when composition is considered.

8.5.14. Principle 14: Assumption-free

Implied semantics must be surfaced explicitly in the model.

Example: Implicit in the statement "I order a book from Amazon" are: paying for the book, delivery of the book to some location, and the transfer of ownership of the book from the vendor to the client.

8.5.15. Principle 15: Design by Class Specialization and/or Composition

The capture of additional model expressivity must be captured by composition and/or by class specialization. The modeling approach should avoid the use of design by constraint (except for terminology binding and attribute type constraints) as it violates proper decoupling and encapsulation. An example of design by constraint is to create a single procedure class containing all attributes for all known procedures and constraining out irrelevant attributes in a more specialized model. This approach is very difficult to implement and violates numerous object-oriented best practices

8.5.16. Principle 16: No False Dichotomies

Dichotomies that are not completely disjoint (mutually exclusive) lead to arbitrary classification rules and result in ambiguity based on different assumptions about the domain. These must be avoided.

8.5.17. Principle 17: Model Should Avoid Semantic Overloading

Semantic overloading occurs when a model attribute's meaning changes entirely, depending on context. While the refinement of the semantics of an attribute in a subclass is acceptable, a change of meaning is problematic. For instance, in FHIR, the Composition class defines an attribute called Subject. In some subclasses, the attribute may be the entity that this composition refers to (e.g., the patient in a medical record). In other cases, it is the topic being discussed by the composition (e.g., a medication orderable catalog).

8.5.18. Principle 18: Convention over Configuration

Convention over configuration (also known as coding by convention) is a software design paradigm used by software frameworks that attempt to decrease the number of decisions that a developer using the framework is required to make without necessarily losing flexibility.

8.5.19. Principle 19: Model Consistency

Patterns should allow the consistent representation of information that is commonly shared across models. For instance, attribution and participation information should be captured consistently. Failure to do so forces implementers to develop heuristics to capture and normalize attribution information that is represented or extended differently in different classes (e.g., FHIR).

8.5.20. Principle 20: Model Symmetry

There should be symmetry in the models wherever we can have it.

8.6. Concerns

This section identifies concerns related to the application of the fundamental principles that will be applied when creating the models for Clinical Decision Support (CDS) Knowledge Artifacts ("KNARTs").

8.6.1. Concern 1: Phenomenon Measurement

We need a simple, and universally applicable way to represent phenomenon measurement.

8.6.1.1. Technique 1.1: A quantitative approach

As we've discussed:

[0,0] absent

[0,3] possibly present, but no more than 3

[0,∞] unknown

[1,∞] present

[4-6] 4-6

8.6.2. Concern 2: Identification of Equivalent Observation Results

Identification of equivalence is imperative to enable data analytics, decision support, and other secondary uses of data.

8.6.2.1. Technique 2.1 Inverse Concepts

Inverse concepts are concepts which are considered opposites of another. Loosely based on the idea of a multiplicative inverse. Cooperative = 1/Uncooperative. Define Cooperative as the LEft Inverse Form (LEIF), and Uncooperative as the Right Inverse Form (RIF). We create editorial guidelines as to what constitutes a LEIF vs a RIF concept. We start out with a straw man rule that "Concepts that assert the positive are LEIF concepts, Concepts that are the inverse of a LEIF concept are RIF concepts." By generically stating right and left hand sides of the inverse function Cooperative inverse Uncooperative -> LEIF inverse RIF, we have a semantically unburdened categorization, so RIF concepts are not required to negate something… And we are not bound specifically to our first straw-man rule of "asserting the positive" if we find better discriminators.

We then work to move RIF concepts to a set of RIF extensions. RIF concepts will be excluded from the normalized form, and must be converted to LEIF concepts as part of the normalization process.

The Inverse function will apply specifically to an Observation Result. We won't try to apply it to an expression for the purposes of using that expression in classification.

8.6.2.2. Technique 2.2 OWL EL Profile Definitions and Classification of Normalized Form

OWL EL profile with concrete domains supports multiple sufficient sets, and necessary conditions, and an ability to include concrete domains, such as ingredient strength, Concepts which have provably equivalent definitions by an appropriate classifier are considered equivalent.

8.6.2.3. Technique 2.3 Equivalence by Generalization and Subsumption

Often, equivalence is most appropriately considered with regard to a generalization. For example, all patients with presence or absence of diabetes mellitus. The equivalence to diabetes mellitus is determined though the use of an is-a taxonomy computed as part of Technique 2.2.

8.6.2.4. Technique 2.4 Equivalence Among Post-coordinated and Pre-coordinated Expressions

All post-coordinated expressions are converted to concepts with a single identifiers, and the equivalence of the post-coordinated and pre-coordinated expressions is determined through the classifier's computation of logical equality, and through use of the is-a taxonomy the classifier computes

8.6.2.5. Technique 2.5: Multiple Sufficient Sets, Independent of the Necessary Sets

Need to insert description here.

8.6.2.6. Technique 2.6: Concrete Domains

Need to insert description here.

8.6.3. Concern 3: Identification of Logical Inconsistencies

Need description for this concern.

8.6.3.1. Technique 3.1 Disjoint Concepts

Identifying concepts as disjoint can be used to identify logical inconsistencies, at data entry time, or during other

8.7. "Not Elsewhere Classified" Revisited

Each concept used as a [interpretation, qualifier, ?], within a value set, must be accompanied by sufficient information to reconstruct the value set, and the value set must provide a partial order such that the concept's "range" of meaning can be determined.

For example, a concept representing a color selected from the value set {Red, Green, Blue} will have a different range than a color selected from the value set {Red, Orange, Green, Yellow, Blue (get a better example of a granular color set ordered properly by em spectrum)}.

Create a set of "intrepretative concepts," or a similar construct, that is the intrepretation of that concept when constrainted by a value set...

Same preferred name, fully specified name incorporates the identify of the refset that constrained the concept.

8.7.1. Values from Constraints

If a concept is used as an intrepretation, the values from which they were selected must accompany somehow so that the value can be determined against a partial ordering.

Interpretation concepts can have children just like the can have units of measure?

9. SOLOR definitional knowledge

9.1. Top Level Categories

9.1.1. Phenomenon

9.1.2. Action

Procedure + event?

9.1.3. Organism

9.1.4. Substance

Food?

9.1.5. Physical object

Pharmaceutical / biologic product

9.1.6. Specimen

9.2. Accepted relationship types

9.2.1. Is a

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.2.2. Morphology

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.2.3. Causative agent

The term disease causative agent usually refers to the biological pathogen that causes a disease, such as a virus, parasite, fungus, or bacterium, or can refer to a toxin or toxic chemical that causes illness. Welding fume as a causative agent.[1]? Where would it be represented?[2]

9.2.4. Episodicity

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.2.5. Topography

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.2.6. Process

Pathologic processes are not always pathologic?

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.2.7. Severity

Definition. Insert definition here.

[1] Welding of stainless steel is a well recognised cause of occupational asthma, the chrome in the fume has been shown to be the cause in some challenge tests. Non-stainless steel welding is more problematic as specific causative agents have not been demonstrated, but nevertheless occupational asthma occurs. Probably the best evidence comes from longitudinal studies of apprentice welders.

[2] https://en.wikipedia.org/wiki/Disease_causative_agent

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.3. Undetermined relationship types

9.3.1. After

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.3.2. Before

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.3.3. Clinical course

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.3.4. Due to

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.3.5. During

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.3.6. Occurrence

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.3.7. Temporally related to

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.4. Excluded relationship types

9.4.1. Associated with

In some cases, you may wish to make association with things that are absent. So if you exclude logical negation, you can't make these associations within the definitional layer, you must make these associations within the statement layer.

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.4.2. Finding informer

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.4.3. Finding method

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.4.4. Has interpretation

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.4.5. Interprets

Definition. Insert definition here.

Utility. Describe why the role is useful here.

Example of correct use. Give an example of correct use here.

Example of incorrect use. Give an example of incorrect use here.

9.5. Concept Analysis: Identify SOLOR Content that Requires Special Handling

9.5.1. Purpose

The creation of RefSets containing SNOMED CT concepts that require special handling supports the maintenance of this content over time without the necessity of re-reviewing the entire content.

Concepts may require special handling for a number of reasons:

- Hierarchies may be incorrect and could affect retrieval

- Concepts may require retirement or movement to the “Situation” hierarchy
- Use of concepts may have to be limited

The concepts identified in this task as either meeting inclusion or exclusion criteria belong to the following categories:

- Concept includes negation
- Concept is not related to the subject of record
- Concept is a compound observations concept
- Concept is ambiguous within a RefSet

This document outlines the agreed upon rules, the reasoning for applying those rules and provides practical examples of how they are applied. Also, included are the inter-rater reliability metrics for the concepts evaluated and specificity and sensitivity metrics for the keywords used to find relevant concepts.

9.5.2. General Approach

The initial task was to evaluate 50,000 concepts and determine their potential membership in one or more of the RefSets.

For each of the RefSets for inclusion, word patterns that explicitly or implicitly identify a concept as a member of the RefSet were developed. As a first automated step, queries using string matching of those patterns or keywords were applied to the following SNOMED CT hierarchies:

1. Clinical Findings
2. Procedures
3. Body Structures

Based on the keywords, terminologists developed a set of rules for each inclusion/exclusion to be applied to each RefSet.

The sets of concepts that resulted from the initial automated query were then assigned to at least two independent reviewers to confirm or deny RefSet membership for each concept based on the rule sets. Disagreements between the reviewers were extracted and analyzed to determine if the rules needed to be adjusted in order to achieve maximum reproducibility. Adjustments included clarifying rules, adding rules or in some cases eliminating ambiguous rules.

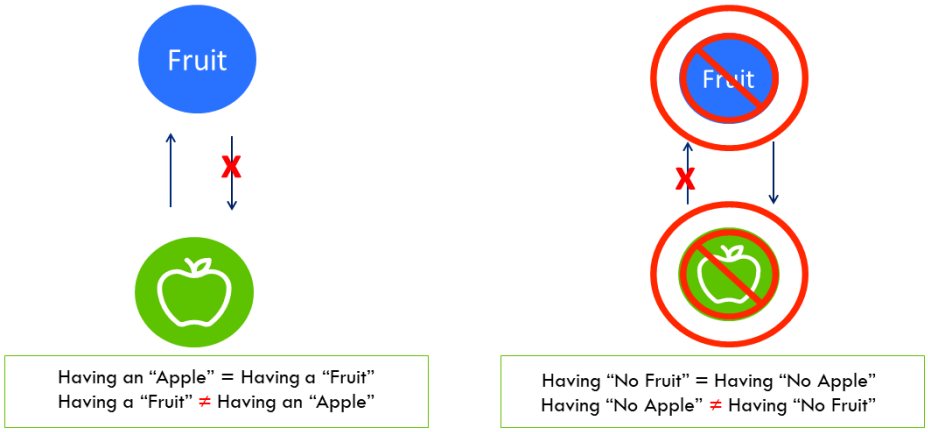
Certain concepts such as “Dental referral - child (procedure)” or “Fetal distress affecting management of mother (disorder)”, which were identified as ambiguous to an extent, where inclusion or exclusion from RefSet membership could not be determined were extracted and added to a separate RefSet.

9.5.3. Concepts Including Negation

Negation, where in the strictest sense within the description logic realm, is "NOT" and it means "everything but". If one were to express "not diabetes", it equates to "everything but diabetes".

This is further complicated within SNOMED by the parent-child relationship "isA". Take the following figure as an example:

Figure 9.1. Effect of isA on Negation



In a hierarchical structure, isA is a one-way pointer. If B is achild, and A is a parent, that means B isA A. However, one cannot flip that relationship. For example, one can express that one is "having an apple", and by the definition of isA, one can assume that one is "having a fruit" (apple is a fuit). However, this directionality cannot be flipped because "having a fruit" does not necessarily mean that one is "having an apple".

In a separate example, what if "No apple" is a child of "No fruit"? If one were having "no apple", it doesn't necessarily mean that one is having "no fruit" (one could very well have other fruits). However, in this scenario, if one were to express having "no fruit", one could deduce that one is also having "no apple". Note the directionality of the isA in this scenario, which is opposite of the previous example.

Not shown in the figure, but what if "No apple" is a child of "Fruit"?

Although simplistic, this example shows how negated concept in a hierarchical structure significantly complicates any calculations. Without a way to properly identify if a concept is a 'negated' concept, computational methods could not be applied because the directionality as shown with the apple/fruit example would complicate any calculations.Therefore, it was deemed necessary that such "negated" concepts within SNOMED required identification such that they can be segragated for further special handling.

“Negation” vs. “Affirmation” are two polar opposite paradigms within the SNOMED CT Concept Model. Where “Affirmation” represents a statement that e.g. a finding or a disorder is present, negation states their absence.

However, in SNOMED, the expression of "no diabetes" is a positive assertion that something is not present. This is different than "everything but diabetes". As a result, these two potentially different semantics could lead to confusion and delay if one were to apply computational methods - does "No diabetes" mean "everything but diabetes" or "diabetes is not present"?

Example:

65124004 |Swelling (finding)| vs. 300890009 |Swelling absent (situation)|

"Negation" concepts are generally located in the "situation with explicit context" hierarchy, where the Context terminological model is consistently applied. Concepts including or implying negation, which are located outside this hierarchy pose challenges for the logical semantic hierarchies they reside in. For the purpose of this project we focused only on identifying concepts that are currently not located within the "situation with explicit context" hierarchy. Some of these identified concepts may need to be relocated to the situation hierarchy as a result of this project.

Currently the logical hierarchy for negation concepts remains "upside-down".

Example:

162298006 |No headache (situation)| is a subtype of 81765008 |No pain (situation)|, but "no headache" does not mean, the patient has no pain.

9.5.3.1. Rule Set Considerations

Besides clearly *stated* negation in the SNOMED CT (SCT) Fully Specified Names (FSN), implied negation had to be considered in a number of contexts.

Example: Symptom not changed (finding) vs. Late syphilis with clinical manifestations other than neurosyphilis (disorder)

The first concept clearly states the negation ("NOT changed"), the words "other than" in the second concept implies it.

9.5.3.2. Rules Defined For Inclusion in "Negation" RefSet

- FSN states that something about the Subject of Record is "absent".

  Example: Ankle movement **absent** in *"No ankle movement (finding)"*

- FSN states that something about a procedure is "absent" (Assumption: Procedures are documented, when they are carried out on a Subject of Record).

  Example: Use of contrast media **absent** in *"Magnetic resonance imaging without contrast (procedure)"*

- FSN negates everything "**other**" than what it describes.

  Example: Perception of anything **other** than light in *"Perceives light only (finding)"*

9.5.3.3. Queries to Identify Candidate Concepts for Negation RefSet

Identify content that would need to be evaluated for negated concepts:

- All Situations with a Finding Context = Known Absent
- All Situations with a Procedure Context assigned
- Any concept in Clinical Findings, Procedures, Situation with Explicit Context*, and Body Structures hierarchies with strings matching:
  - lower(term) like '% no %'
  - or lower(term) like 'no %'
  - or lower(term) like '% not %'
  - or lower(term) like 'not %'

- or lower(term) like '%unilateral%'
- or lower(term) like '%none %'
- or lower(term) like '%without%'
- or lower(term) like '% only %'
- or lower(term) like '%unable%'
- or lower(term) like '%inability%'

The query results were reviewed and either accepted or denied based on the development of a set of rules as described above.

9.5.3.4. Examples for Inclusion/Exclusion in Negation RefSet

Keyword: “NO”

SCT ID	FSN	INCLUSION	COMMENT
276038000	No help available (finding)	✓	Something about the subject
304327001	No ankle movement (finding)	✓	
164899008	Electrocardiogram: no heart block (finding)	✓	
405491001	Adverse incident resulting in no harmful effect (finding)	✓	
226238008	No beef diet (finding)	⊗	“No beef” is not about the su

Keyword: “NOT”

SCT ID	FSN	INCLUSION	COMMENT
288887001	Does not eat (finding)	✓	Something about the subject
401169009	Not yet walking (finding)	✓	
248256006	Not getting enough sleep (disorder)	✓	
303863001	Reduction of dislocated joint, not prosthetic (procedure)	✓	Something about the proced
183052003	Recommendation not to eat (procedure)	⊗	“Not” does not apply to the p

Keyword: “WITHOUT”

SCT ID	FSN	INCLUSION	COMMENT
41119002	Akinetic seizure without atonia (finding)	✔	Something **about the subject**
448521006	Incontinence without sensory awareness (finding)	✔	
400081000	Blister without infection (disorder)	✔	
90084008	Magnetic resonance imaging without contrast (procedure)	✔	Something **about the proced**

Keyword: “NONT” or "NON-X"

SCT ID	FSN	INCLUSION	COMMENT
398278002	Sensory nerve conduction block - none (finding)	✔	Something **about the subject**
369984009	Immature white blood cells - none present (finding)	✔	
50874004	Nonerosive nonspecific gastritis (disorder)	✔	
34390007	Nonexcisional debridement of burn (procedure)	✔	Something **about the proced**
445303008	Compression of lymphedema using nonelastic compression device (procedure)	⊗	“**Nonelastic**” does **not** apply

Keyword: “ONLY”

SCT ID	FSN	INCLUSION	COMMENT
260296003	Perceives light only (finding)	✔	Everything **other** than what t
170745003	Diabetic on diet only (finding)	✔	
267728009	Blind or low vision - one eye only (disorder)	✔	
173209004	Mediastinoscopy - inspection only (procedure)	✔	
169471006	Progestogen-only pill failure (finding)	⊗	“Progestogen-only” is about t

Keyword: “UNABLE”

SCT ID	FSN	INCLUSION	COMMENT
282475008	Unable to run (finding)	✓	Something about the subject
288885009	Unable to eat (finding)	✓	

Keyword: "INABILITY"

SCT ID	FSN	INCLUSION	COMMENT
47695004	Inability to cope (finding)	✓	Something about the subject
249881006	Inability to imitate tongue movements (finding)	✓	

Keyword: "REJECTED"

SCT ID	FSN	INCLUSION	COMMENT
135839007	Sample rejected (finding)	✓	Something about the subject Assumption: "Sample/Specir
373880007	Specimen rejected / not processed (finding)	✓	record.
284348003	Excision of rejected transplanted kidney (procedure)	⊗	"rejected" is not about the p

9.5.4. Concepts Where Patient Is Not Subject of Record

The default context of SNOMED CT concepts as stated in the SNOMED CT Editorial Guide means that, unless stated otherwise within the description or the definition of the concept, clinical findings are occurring to the subject of record (the patient) and procedures are performed on the subject of record (the patient).

The only exceptions are concepts whose description actually contains a specific context (e.g. father smokes), and these are all grouped in the "situation with explicit context" hierarchy. Concepts, where the patient is not the subject of record outside this hierarchy do not adhere to the guidelines. For the purposes of this project we are not focusing on the concepts within the "situation with explicit context" hierarchy as they have their context already identified using the context attributes.

9.5.4.1. Rule Set Considerations

Definition for Inclusion: The SNOMED CT concept is about something / someone other than the patient.

Although it can be assumed that all SNOMED CT concepts, which are included in this RefSet are ultimately used to document something in a patient's record, this particular concept for documentation is **NOT** about the patient.

Rule for Inclusion in "Patient Not Subject of Record" RefSet:

The concept is about patient's family, family members, friends or other social contacts, even if it is the patient's family members, friends or other social contacts.

Examples:

- Findings of relatives surviving (finding)
- Family tension (finding)

9.5.4.2. Queries to Identify Candidate Concepts for Patient Not Subject of Record RefSet

Identify content where the subject of record in NOT the patient:

- Subject Relationship Context < > Subject of Record
- Any concept in Clinical Findings, Procedures, Situation with Explicit Context*, and Body Structures hierarchies with strings matching:
  - lower(term) like '%father%'
  - or lower(term) like '%mother%'
  - or lower(term) like '%family%'
  - or lower(term) like '%caregiver%'
  - or lower(term) like '%paternal%'
  - or lower(term) like '%maternal%'
  - or lower(term) like '%child%'
  - or lower(term) like '%wife%'
  - or lower(term) like '%husband%'
  - or lower(term) like '%partner%'
  - or lower(term) like '%spouse%'

The query results were reviewed and either accepted or denied based on the development of a set of rules as described above.

9.5.4.3. Examples for Inclusion/Exclusion in "Patient Not Subject of Record" RefSet

Examples: "Family", "Family Members", "Friends" or Other "Social Contacts"

SCT ID	FSN	INCLUSION	COMMENT
169944002	Mother has a social worker (finding)	✓	Although it is the patient's "Moth about the "*Mother*", "*Father*" or "
185412005	Father made appointment (finding)	✓	
224334009	Friend arrested (finding)	✓	
224139006	Lives with mother (finding)	⊗	Concept is about the **patient**, who
307101004	Deserted by father (finding)	⊗	Concept is about the **patient**, who **father**
228302005	Drinks with friends (finding)	⊗	Concept is about the **patient**, who

9.5.5. Concepts Including Compound Observation

Compound Observations are the set of concepts within SNOMED CT that involve the combination of more than one observation. While these concepts do not necessarily have issues with them, the fact that they combine multiple concepts into one can cause modeling issues that affect retrieval.

9.5.5.1. Rule Set Considerations

Definition for Inclusion: The SNOMED CT concept describes more than one observation or procedure

Rules for Inclusion in "Compound Observation" RefSet:

- Concept is about X ***and*** Y, e.g., *Malaise and fatigue (finding)*
- Concept is about X ***or*** Y, e.g., *Mass in head or neck (finding)*
- Concept is about X ***with*** Y, e.g., *Cough with fever (finding)*
- Concept is about X ***without*** Y, e.g., *Bee sting without reaction (disorder)*
- Concept is about X ***not*** Y, e.g., *Radiographic image not correlated with tumor pathology finding (finding)*
- Concept is about X ***due to*** Y, e.g., *Malnutrition due to child maltreatment (disorder)*
- Concept is about X ***associated with*** Y, e.g., *Limited duction associated with other condition of eye (disorder)*
- Concept is about X ***after to*** Y, e.g., *Seizure after head injury (finding)*

9.5.5.2. Queries to Identify Candidate Concepts for Compound Observation RefSet

Identify content that are compound observation concepts:

- Any concept in Clinical Findings, Procedures, Situation with Explicit Context*, and Body Structures hierarchies with strings matching:
  - lower(term) like '% and %'
  - or lower(term) like '% with %'
  - or lower(term) like '% without %'
  - or lower(term) like '% w/o %'
  - or lower(term) like '% due to %'
  - or lower(term) like '% and/or %'
  - or lower(term) like '% after %'
  - or lower(term) like '%resulting%'
  - or lower(term) like '% caused by %'
  - or lower(term) like '% causing %'
  - or lower(term) like '% prior %'

The query results were reviewed and either accepted or denied based on the development of a set of rules as described above.

Examples "X and Y"

SCT ID	FSN	INCLUSION	COMMENT
417850002	Respiratory tract congestion and cough (disorder)	✓	
247805009	Anxiety and fear (finding)	✓	Concepts describe more than
16932000	Nausea and vomiting (disorder)	✓	

Examples "X or Y"

SCT ID	FSN	INCLUSION	COMMENT
211506004	Contusion wrist or hand (disorder)	✓	
248477007	Swelling or edema (finding)	✓	Concepts describe more than
287613009	Middle ear syringing or suction (procedure)	✓	

Examples "X with Y"

SCT ID	FSN	INCLUSION	COMMENT
271503005	Pleural empyema with fistula (disorder)	✓	Concepts describe more than
120608000	Blister with infection (disorder)	✓	
29532006	Proctoscopy with biopsy (procedure)	✓	
408821002	Lives with partner (finding)	⊗	In these examples, the use of the description of more than
223455001	Assisting with procedure (procedure)	⊗	

Examples "X without Y"

SCT ID	FSN	INCLUSION	COMMENT
448521006	Incontinence without sensory awareness (finding)	✓	Concepts describe more than
41119002	Akinetic seizure without atonia (finding)	✓	
140921000119102	Ischemic stroke without coma (disorder)	✓	
609242005	Lives in apartment without elevator access (finding)	⊗	In these examples, the use of constitute an observation abo
262312009	Without floor of mouth depressed (finding)	⊗	

9.5.6. Task 5.10 Identify SOLOR Content that Requires Special Handling White Paper

9.5.6.1. Purpose

The original Reference Set of 50,000 SNOMED concepts completed in the first iteration, and described in Section 2 below, was evaluated to determine if they meet the following criteria:

1. Concept includes laterality
2. Concept is an inverse of a concept
3. Concept is a primitive concept versus those that should be fully defined

This review resulted in eight additional RefSets that identify the concepts that meet and those that do not meet the criteria above.

- Laterality Correct: Clinical Findings, Observable Entities, Specimens and Procedures where the Finding and Procedure Site attributes use the correct body structure concept that involves laterality.
- Laterality Incorrect: Clinical Findings, Observable Entities, Specimens and Procedures where the Finding and Procedure Site attributes do not use the correct body structure concept that involves laterality.
- Doesn't Include Laterality: Clinical Findings, Observable Entities, Specimens and Procedures where the Fully Specified Name (FSN) doesn't involve laterality.
- Ambiguous: Any of the 50,000 concepts where the FSN was ambiguous as to whether it contained laterality.
- Is Inverse: Concepts that currently have or could have an inverse or opposite concept in SNOMED CT.
- Is Not Inverse: Concepts that were not considered as inverse or opposite concepts.
- Can Be Fully Defined: Concepts that can be fully defined now but are not being fully modeled and/or specified as fully defined.
- Cannot Be Fully Defined: Concepts that will always remain primitive or would require major changes to the concept model to be fully defined.

9.5.6.2. Approach to Identify Content for 50,000 SNOMED Concepts RefSet

The below approach was used to identify the first RefSet, which included 50,000 SNOMED concepts:

1. To identify content that would need to be evaluated for laterality concepts:
    - Set 1: Find all concepts with "right", "left", or "bilateral" in an active term. This identifies all concepts that could potentially represent a lateralized concept based on a term.
    - Find all concepts where Set 1 is used as a destinationId for a defining relationship in the Relationship table. This identifies concepts that use the concepts from Set 1 as a value for a defining relationship, which would include both children of concepts in Set 1 and those that use them for other defining relationships.
    - Set 2: Find all concepts with a laterality defining attribute. This would identify all Body Structures that use a Laterality Attribute.
    - Find all concepts where Set 2 is used as a destinationId for a defining relationship in the Relationship table. This query would identify those concepts that do not have a term with "right", "left", or "bilateral" but do use a Body Structure as a value for a defining relationship.
    - Remove from all sets any concepts from the Body Structure hierarchy.
2. To identify content where there is an inverse concept:
    - Any concept with strings matching a set of keywords that would indicate the inverse of another concept
        - Able to vs Unable to
        - Normal vs Abnormal
        - Present vs Absent

- Decrease vs Increase
- Acquired vs Congenital
- Localized vs Generalized
- Does vs Does not
- Benign vs Malignant
- Complete vs Incomplete
- Accidental vs Intentional
- Active vs Inactive
- Acute vs Chronic
- Adequate vs Inadequate
- Open vs Closed
- Attends vs Does not attend
- Can vs Cannot
- (Stable or Stability) vs (Unstable or Instability)
- Primary vs Secondary
- Positive vs Negative
- Major vs Minor
- Increased vs Decreased
- Direct vs Indirect
- Early vs Late
- Internal vs External
- Extrinsic vs Intrinsic
- High vs Low
- Legal vs Illegal
- Appropriate vs Inappropriate
- Increasing vs Decreasing
- Effective vs Ineffective
- Insufficient vs Sufficient
- Irregular vs Regular

- Loosening vs Tightening
- Success vs (Unsuccess or not success)
- Known vs unknown
- Narrow vs Wide
- Always vs Never
- Dependent vs Nondependent
- Hodgkin vs nonhodgkin
- Smoker vs nonsmoker
- Traum vs nontraum
- Urgent vs nonurgent
- Venomous vs nonvenomous
- Old vs new
- Satisfact vs (unsatisfactory or not satisfac)
- Use vs does not use
- Lengthening vs Shortening
- Near vs Far
- Infect vs noninfect
- Inflammatory vs noninflammatory
- Obstruct vs unobstruct
- (Loss or Lost) vs Gain
- Fit vs (unfit or not fit)

- Additional keywords were identified during our review process that should be added to future review efforts:
  - Anteversion vs Retroversion
  - Soft vs Firm
  - Recessive vs Dominant
  - Mature vs Immature
  - Functional vs Non-functional

3. To identify content that are currently primitive concepts, but may be able to be fully defined:

- Select all concepts that are intermediate primitives, meaning they have both ancestors and descendants that are fully defined but they are primitive
- Select all concepts that are primitive leaf nodes but they have fully defined ancestors

9.5.6.3. Rules for Evaluating Membership in RefSets

The following rules were used to evaluate membership in one or more of the eight RefSets:

- Inverse vs Not Inverse
- Laterality Correct vs Laterality Incorrect vs Doesn't Include Laterality vs Ambiguous
- Primitive but should be fully defined vs. Always Primitive

Scope and boundaries for RefSet membership have to be defined as clearly as possible to support reproducibility of concept inclusion.

9.5.6.3.1. Inverse

The purpose of the Inverse RefSets is to identify concepts that should have an opposing concept due to a description indicating an opposite or inverse concept, regardless of whether that opposing concept currently exists in SNOMED CT. It is not the purpose to identify and pair opposing concepts. In many cases, the opposing concept does not exist in SNOMED CT and the next iteration (not a part of this PWS) of this RefSet should be to link the two inverse concepts together to identify missing content.

Rules for Inclusion in "Inverse" RefSet:

1. Concepts were only considered inverse if a valid opposing concept should exist in SNOMED CT. For example, 56313000|Abnormal placenta affecting management of mother (disorder)| was not considered to be inverse since the opposing concept would be "Normal placenta affecting management of mother" which would not be a valid concept.
2. Anatomical positions and relative locations such as lateral, medial, distal, proximal, etc., were not considered to be inverse.
3. If there is an Open procedure and the only "closed" concept that would ever need to be created would be one that uses only one specific device, we would consider these two concepts as inverse. For example, 179820004 |Open excision of implanted ligament (procedure)| is inverse of 179891009 |Arthroscopic excision of implanted ligament (procedure)| and 265071006 |Open bilateral clipping of fallopian tubes (procedure)| is inverse of 176979002 |Endoscopic bilateral clipping of fallopian tubes (procedure)|.
4. Male and Female were not considered to be inverse.

9.5.6.3.2. Laterality

The purpose of the Laterality RefSets is to identify concepts that are not currently modelled with the correct body structure that utilizes laterality. This only pertains to laterality as currently represented in SNOMED CT, which is used to designate one or both of paired bilaterally symmetrical (or near symmetrical) body structures. It therefore does not apply to sidedness of specific body structures. For example 364006 |Acute left-sided heart failure (disorder)| is not a lateralized disorder since the heart is not a bilaterally symmetrical body structure. For more information on laterality vs sidedness, please see *Choosing Sides. Assigning*

Laterality as an Attribute in SNOMED® CT [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2244155/?page=1].

Rules for Inclusion in "Laterality" RefSet:

1. If the concept being evaluated includes laterality in its FSN and it is not modelled using a Finding Site or Procedure Site, even in cases where there is no current SCT body structure concept with the correct laterality, it will be marked as incorrect. For example, 16730001000004104 |Thrombosis of left peroneal vein (disorder)| should be defined with Structure of left peroneal vein, which does not currently exist in SNOMED CT.

2. All bilateral concepts were evaluated against the current SNOMED CT modelling guidance, which requires the use of two separate role groups with one representing the right body structure and one representing the left body structure. If the concept is modelled using the bilateral body structure (e.g. 40638003 |Structure of both eyes (body structure)|), it was added to the Laterality Incorrectly Modeled RefSet. For example, 12239101000119100 |Bilateral degeneration of macula (disorder)| should have two different role groups, one with 721947001 |Structure of macula lutea of left eye (body structure)| and the other with 721945009 |Structure of macula lutea of right eye (body structure)|.

3. If the concept being evaluated included a plural form of a potentially lateralizable body structure in the FSN, we considered this concept to represent bilaterality and evaluated it as such. For example, 248422003 |Warm hands (finding)| does not specify right, left, or bilateral in the FSN but since it uses the term "hands," we considered it to be bilateral and evaluated against the current SNOMED CT modelling guidance as stated above.

4. If the concept being evaluated represented sidedness of a non-bilaterally symmetrical body structure, it was added to the Does Not Include Laterality RefSet. For example, 111283005 |Chronic left-sided heart failure (disorder)| represents heart failure on the left side of the heart.

5. If the concept being evaluated was ambiguous as to whether it represented one side vs both sides, it was placed in the Ambiguous Laterality RefSet. For example, "lacrimal canaliculi" concepts were considered to be ambiguous since their FSNs did not specify if it was the lacrimal canaliculi of both eyes or the right or left eye.

9.5.6.3.3. Primitive

The purpose of the Primitive RefSets is to identify concepts that could be easily fully defined under the current concept model of SNOMED CT. From the SNOMED CT Technical Implementation Guide, a fully defined concept is defined as:

"A Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept] is considered to be fully defined [https://confluence.ihtsdotools.org/display/DOCGLOSS/fully+defined] if its defining characteristics [https://confluence.ihtsdotools.org/display/DOCGLOSS/defining+characteristic] are sufficient to define it relative to its immediate supertype(s). A Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept] which is not fully defined [https://confluence.ihtsdotools.org/display/DOCGLOSS/fully+defined] is Primitive [https://confluence.ihtsdotools.org/display/DOCGLOSS/Primitive] and this is indicated by the value of the definitionStatusId [https://confluence.ihtsdotools.org/display/DOCGLOSS/definitionStatusId] field.

1. 233604007 |Pneumonia| [http://snomed.info/id/233604007] is a lung disease but unless defining characteristics [https://confluence.ihtsdotools.org/display/DOCGLOSS/defining+characteristic] are speci-

fied that effectively distinguish 233604007 |pneumonia| [http://snomed.info/id/233604007] from other lung diseases then it is regarded as a primitive [https://confluence.ihtsdotools.org/display/DOCGLOSS/primitive]Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept].

If a Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept] is primitive [https://confluence.ihtsdotools.org/display/DOCGLOSS/primitive] then the defining characteristics [https://confluence.ihtsdotools.org/display/DOCGLOSS/defining+characteristic] for that Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept] are incomplete. It is not possible to automatically compute that a Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept] represented as a postcoordinated [https://confluence.ihtsdotools.org/display/DOCGLOSS/postcoordinated] combination of several Concepts [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept] is or is not a subtype [https://confluence.ihtsdotools.org/display/DOCGLOSS/subtype] of a particular primitive [https://confluence.ihtsdotools.org/display/DOCGLOSS/primitive]Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept].

2. The Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept] "lung disease" qualified by 246075003 |causative agent| [http://snomed.info/id/246075003] = 41146007 |bacteria| [http://snomed.info/id/41146007] may be 233604007 |pneumonia| [http://snomed.info/id/233604007] but could also be "bronchitis."

   In contrast if a Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept] is fully defined [https://confluence.ihtsdotools.org/display/DOCGLOSS/fully+defined] it is possible to state that any Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept] represented as a combination of the same defining characteristics [https://confluence.ihtsdotools.org/display/DOCGLOSS/defining+characteristic] is equivalent to or a subtype [https://confluence.ihtsdotools.org/display/DOCGLOSS/subtype] of that Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept].

3. **Example:** Assume that the Concept [https://confluence.ihtsdotools.org/display/DOCGLOSS/Concept]53084003 |bacterial pneumonia| [http://snomed.info/id/53084003] is fully defined [https://confluence.ihtsdotools.org/display/DOCGLOSS/fully+defined] as 312342009 |infective pneumonia| [http://snomed.info/id/312342009] with 246075003 |causative agent| [http://snomed.info/id/246075003] = 41146007 |bacteria| [http://snomed.info/id/41146007] and that 9861002 |pneumococcus| [http://snomed.info/id/9861002] is a 41146007 |bacteria| [http://snomed.info/id/41146007]. It then follows that the post coordinated representation of 233607000 |pneumococcal pneumonia| [http://snomed.info/id/233607000] as 312342009 |infective pneumonia| [http://snomed.info/id/312342009] with 246075003 |causative agent| [http://snomed.info/id/246075003] = 9861002 |pneumococcus| [http://snomed.info/id/9861002] is computably a subtype [https://confluence.ihtsdotools.org/display/DOCGLOSS/subtype] of |bacterial pneumonia.| [http://snomed.org/fictid]”

Rules for Inclusion in “Primitive” RefSet

1. If the evaluated concept can be fully defined within the current SNOMED CT concept model and no changes are required, then it will be placed in the Can Be Fully Defined RefSet. For example, 201558003 |Reactive arthropathy of shoulder (disorder)| can be changed to fully defined today as there is nothing missing from its definition.

2. If a concept could be fully defined by the addition of a new concept to represent a single parent or by adding a single concept that could be used as a value for a current concept model attribute, the concept will be placed in the Can Be Fully Defined RefSet. For example, 207959006 |Closed fracture lumbar vertebra, wedge (disorder)| currently cannot be considered as fully defined because an Associated Morphology concept doesn’t currently exist to represent a Wedge Fracture. By adding that single concept, the concept will then be able to be fully defined.

3. If the evaluated concept requires a change to the Concept Model, for example, adding a new attribute or changing the range of values an existing Concept Model attribute takes, then it will be placed in the Can Not Be Fully Defined RefSet. For example, 427252003 |Pain radiating to right side of chest (finding)| cannot be fully defined because there is no concept model attribute to represent that the pain radiated to the right side of the chest. Currently, it only indicates radiating pain and doesn't specify the body structure of chest or that it is on the right side.

9.5.6.4. Reliability of Rule Sets

In order to determine reliability of the identified keywords and rule sets for each RefSet, metrics of agreement/disagreement for the initial review were used.

Two Terminologists reviewed the SNOMED CT concepts individually, applying the initial set of rules for each RefSet. After this first review, disagreements between the two Terminologists were extracted from the concept files and re-assigned for discussion and reconciliation.

Metrics for Inter-Rater Reliability

In the course of the reconciliation discussion, the initial rules were re-evaluated and either confirmed, adjusted, clarified or eliminated to achieve a set of rules that is sufficiently expressive and reproducible.

The RefSet membership status of all reconciled concepts was updated in the RefSets.

The following metrics for agreement/disagreement percentages between the first two reviewers were calculated:

- Laterality RefSets Agreement = 84.12%
- Inverse RefSets Agreement = 98.81%
- Fully Defined RefSets Agreement = 82.84%

9.5.6.5. Sensitivity and Specificity

Using the defined set of keywords, the sensitivity and specificity of the initial automated queries was tested against the final RefSets. After running the queries and evaluating the concepts for inclusion in their appropriate RefSet, we further categorized the results as either a True Positive, True Negative, False Positive, or False Negative. Running the queries against the original 50,000 concepts the following metrics were applied to the results:

- Sensitivity = number of True Positives/number of True Positives + number of False Negatives
- Specificity = number of True Negatives/ number of True Negatives + number of False Positives

9.5.6.5.1. Sensitivity and Specificity of Search Criteria for "Laterality"

Table 9.1. Table 1. Sensitivity and Specificity of Laterality Search Criteria.

Laterality Results	Query Total	Doesn't Include Laterality	Incorrect Laterality	Correct Laterality	Ambiguous
No Term, Attribute =side	9317	9225	81	0	11

Laterality Results	Query Total	Doesn't Include Laterality	Incorrect Laterality	Correct Laterality	Ambiguous
No Term, Attribute = RLB	94	9	11	74	0
Term, Attribute = RLB	3899	11	661	3227	0
Term, No Attribute	2545	1530	960	55	0
Totals	15855	10775	1713	3356	11

Table 9.2.

True Positive

True Negative

False Positive

False Negative

Before creating assignments we categorized the concepts as either those that have a term that included right, left, or bilateral and those that have an attribute that uses a concept with a laterality of right, left or bilateral. If the concept had a term with right, left or bilateral and no attribute or if the attribute had a laterality where the value was the parent (side) of right and left we considered those concepts to be within the set that probably did not include laterality. If the concept was associated with a laterality attribute that was either right or left we considered it to probably include laterality whether it was correctly modelled or not.

Sensitivity of 78.38% and Specificity of 99.81%

9.5.6.5.2. Sensitivity and Specificity of Keywords for “Inverse”

Table 9.3. Table 2. Sensitivity and Specificity of keywords for "Inverse".

Inverse Results	Query Total	Is Inverse	Is Not Inverse
Removed Keywords	5875	1773	4102
Original Keywords	18416	12155	6261
Totals	24291	13928	10363

Table 9.4.

True Positive

True Negative

False Positive

False Negative

After conducting a pilot certain keywords were identified a less likely to be inverse. We separated these concepts into separate assignments. After further review, 30% of these concepts contained other keywords that made them inverse.

Sensitivity of 82.27% and Specificity of 39.58%

9.5.6.6.5.3. Sensitivity and Specificity of Search Criteria for “Can Be Fully Defined”

Primitive Results	Query Total	Can Be Fully Defined	Cannot Be Fully Defined
Leaf Nodes	28394	7458	20936
Intermediate Primitives	2133	677	1456
Other	2154	573	1581
Totals	32681	8708	23973

Table 9.5. Table 3. Sensitivity and Specificity of Search Criteria for "Can Be Fully Defined".

Primitive Results	Query Total	Can Be Fully Defined	Cannot Be Fully Defined
Leaf Nodes	28394	7458	20936
Intermediate Primitives	2133	677	1456
Other	2154	573	1581
Totals	32681	8708	23973

Table 9.6.

True Positive
True Negative
False Positive
False Negative

Leaf Nodes and Intermediate Primitives were concepts that we would more likely see as concepts that should be Fully Defined. However, in many cases that really depended upon whether new Concept Model attributes could be added to SNOMED CT. The other Primitive concepts we reviewed were concepts that were not Leaf Nodes and Intermediate Primitive concepts that we reviewed and we did not expect to find many of them that could be fully defined.

Sensitivity of 26.65% and Specificity of 73.40%

9.5.6.6. Conclusion

The Inverse RefSets had good inter-rater agreement but the Fully Defined and Laterality RefSets had lower inter-rater agreement rates. The Fully Defined and Laterality RefSets both required the evaluation of the modeling of the defining relationships and judging their correctness. The experience of the clinical reviewing team with the SNOMED CT Concept Model is critical to getting a high inter-rater agreement rate when creating RefSets that depend on reviewing modelling. As the SNOMED CT Concept Model increases in complexity, the education and experience with modelling of SNOMED CT concepts will become even more critical in reviewing and maintaining these RefSets.

For the 5,069 concepts that were identified as having laterality, 33.79% were deemed to be incorrectly modeled. While this is a rather large number, SNOMED International is currently modeling a large number of laterality concepts and this number should be decreasing with each release.

The sensitivity for the Primitive RefSets is relatively low because reviewers needed to decide if the addition of some qualifier value or a new parent concept would make these concepts definable. In many cases there

needed to be the addition of new concept model attribute to fully define concepts. The queries used to identify these concepts for review were not able to tell which primitive concepts could be fully defined with and without Concept Model changes. Overall, the exercise of reviewing primitives is very useful to identify more concepts that could be fully defined.

Overall, this approach to identify SNOMED CT concepts that require special handling shows that automated queries can be very useful as a first "screening" step, but manual review and reconciliation still has to be performed to arrive at evaluated RefSets that adhere to reliable inclusion/exclusion criteria. Creating RefSets that identify modeling issues can present problems when the review of concepts spans multiple release dates and the tooling used to do the review is updated while the review is still taking place. This requires additional work at the end of the project to ensure that the review of the concepts for errors does not identify concepts that were correctly placed when they were initially reviewed, but are now incorrectly placed due to corrections or changes made to the latest release.

9.5.7. Reliability of Rule Sets

In order to determine reliability of the identified keywords and rule sets for each RefSet, metrics of agreement/disagreement for the initial review were used.

After the first two Terminologists reviewed the 50,000 SNOMED CT concepts individually, applying the initial set of rules for each RefSet. After this first review, disagreements between the two Terminologists were extracted from the concept files and re-assigned for discussion and reconciliation.

9.5.7.1. Initial Metrics for Inter-Rater Reliability

In the course of the reconciliation discussion, the initial rules were re-evaluated and either confirmed, adjusted, clarified or eliminated to achieve a set of rules that is sufficiently expressive and reproducible.

The RefSet membership status of all reconciled concepts was updated in the RefSets.

The following metrics for agreement/disagreement percentages between the first two reviewers were calculated:

Concepts	**Agreement (%)**
Negated	95.89
Ambigous	99.72
Compound Observation	94.75
Patient is not Subject of Record	99.13

9.5.7.2. Second Review for Inter-Rater Reliability

After producing the "baseline" RefSets on which the two Terminologists agreed, another team of two reviewers reviewed a random 10% of the concepts in the baseline RefSets, applying the rules for Inclusion/Exclusion. Inter-rater reliability was calculated again between the two new reviewers.

	Compound	Negation	Patient
Review Count	4321	1273	71
# of disagree	251	140	17
% agreement	94%	89%	76%

The results of this exercise show that the rules for the "Compound Observation" RefSet appear to be the most reproducible. The numbers for "Negation" and "Patient not subject of information" are lower.

However, considering that the second team of reviewers have not been part of the previous discussions around the inclusion/exclusion criteria and were only given the rule sets to follow, we perceive the results as positive.

The results of these metrics informed the final decision on the Inclusion/Exclusion criteria for each final RefSet.

9.5.8. Final Set of Keywords and Rules

Based on the metrics and findings above, the set of keywords for **automatic queries** remained unchanged for all RefSets. The rules for manual reviews was adjusted. This final set represents the criteria with the highest reproducibility.

9.5.8.1. Final Keywords and Rules for “Negation”

A number of keywords, which had initially been used to manually identify “Negation” concepts were excluded after reconciliation of disagreements between the first team of reviewers. Those pertained mostly to implied negation.

Examples for excluded keywords during manual review:

- Rejected
- Unchanged
- Declined
- Diminished
- Unsatisfactory
- Impairment

Examining the actual concepts containing these keywords in appeared that, although there seems to be a “flavor” of something “negative”, they do not satisfy the rule of “something absent about the patient (or the procedure)”.

9.5.8.2. Final Keywords and Rules for “Patient not Subject of Information”

During the initial discussion and reviews of candidate concepts for this RefSet, the following rules had been stated:

- Concept is about samples, even if the "sample" originates from the patient, e.g.

  Sample contaminated (finding)

- Concept is about objects or devices, e.g.

  Dialysis catheter in situ usable (finding)

- Concept is about patient’s family, family members, friends or other social contacts, even if it is the patient’s family members, friends or other social contacts, e.g.

Finding of relatives surviving (finding)

Discussions about the kinds of concepts in 1 and 2 (above) resulted in excluding them. A concept pertaining to a “sample” was agreed as still being about the patient, because the sample is sourced from the patient. The same reasoning was applied to the pattern of concepts about objects or devices because, e.g. the “catheter” is seen in the patient’s body.

This reasoning lead to leaving a single rule for inclusion in this RefSet: ***Concept is about patient’s family, family members, friends or other social contacts, even if it is the patient’s family members, friends or other social contacts.***

9.5.8.3. Final Keywords and Rules for “Compound Observation”

A number of keywords, which had initially been used to manually identify “Compound” concepts were excluded after reconciliation of disagreements between the first team of reviewers.

Examples for excluded keywords during manual review (excerpt):

- Finding related to X, e.g. “Finding related to provision of home help (finding)”
    - Closer examination of this concept pattern revealed that these concepts appear to be navigational in their intent
- Procedure X using Y, e.g. “External fixation using unilateral bar (procedure)”
    - The “using” pattern simply specifies the way the procedure is performed, rather than constituting a separate procedure
- Procedure X by technique Y, e.g. “Microbial identification by nucleic acid probe, with amplification (polymerase chain reaction) (procedure)”
    - The “technique” patterns, too, simply specifies the way the procedure is performed, rather than constituting a separate procedure

9.5.9. Sensitivity and Specificity

Using the defined set of keywords the sensitivity and specificity of the initial automated queries was tested against the final RefSets. By running the queries against the original 50,000 concepts the following metrics were applied to the results:

- Percentage of concepts from the final RefSets returned by the query (Sensitivity)
- Percentage of concepts returned by the query that were false positives/false negatives (Specificity)

9.5.9.1. Sensitivity and Specificity of Keywords for “Negation”

Sensitivity of 73% and Specificity of 95%

9.5.9.2. Sensitivity and Specificity of Keywords for “Patient not Subject of Information”

Sensitivity of 75% and Specificity of 99%

9.5.9.3. Sensitivity and Specificity of Keywords for “Compound Observation”

Sensitivity of 93% and Specificity of 94%

9.5.10. Conclusion

For all three categories of RefSets, the set of keywords for automated queries returned results with a high rate of Specificity. The Sensitivity for the “Compound Observation” RefSet was also high. However, the Sensitivity of the queries for “Negation” and “Patient not Subject of Information” was lower. Identifying additional keywords may be useful to elevate the Sensitivity in those categories.

The reproducibility of the rules stated and applied during the two manual review cycles was perceived positive.

Overall, this approach to identify SNOMED CT concepts that require special handling shows that automated queries can be very useful as a first “screening” step, but manual review and reconciliation still has to be performed to arrive at evaluated RefSets that adhere to reliable inclusion/exclusion criteria.

9.6. Concrete Domains

9.6.1. Introduction

Concrete domains can be used in SNOMED CT to represent and reason over values like integers in Description Logic. Our initial work focused on medications and evaluating the use of concrete domains to represent not only the product strength, but also the unit of use size. To fully test the feasibility of concrete domains, additional attributes were also added, in order to fully represent all information regarding medications, which will then allow concepts to be fully defined. Thus, this will enable testing the equivalence and subsumption of concepts by the Description Logic classifiers within the tooling.

At the beginning of the project there was no ability to represent numeric attributes of concepts in SNOMED CT, which made machine readability of numeric attributes difficult, prone to error, and left a large portion of Products as primitive concepts. Without the ability to fully represent the numeric properties, equivalence checking and subsumption using the Description Logic classifier is not possible. With the introduction of the new Drug Concept Model in the July 2017 International Release the representation of product strength and units will begin to be modelled over the next few releases. However, this new Drug Concept Model does not utilize concrete domains but instead creates the strength numbers as concepts themselves to be used as values for the product strength attributes.

9.6.2. Approach

By using a lexical search for string containing integers and textual representation of integers, 10,114 potential Pharmaceutical / Biologic Product concepts were identified, which were modeled with the proposed attributes including one attribute to represent product strength. To properly represent the numeric information contained in these products, the Australian Medicines Terminology Approach that applied to its Australian extension content and not to the International SNOMED CT content was utilized.

To speed up the modeling process, already available data around strength and units from NDF-RT through RxNorm RXNSAT relationships that was linked to the SNOMED CT concepts through the RXCUI was used. Technical validation was performed on these values and any incorrect strength or units we identified were corrected before using these values to populate the relationships. After loading the new relationships

into the terminology editor, further manual review was conducted to verify the relationships and add any missing information.

Using the findings from the drug modeling, the team evaluated other hierarchies that were identified as having potential for modeling concrete domains.

9.6.3. Attributes for Representing Medications

Below are attributes that have been added to the medications model to represent concrete domains:

- **Has Basis of Strength Substance (BoSS)** – The substance(s) that correspond to the strength. If strength is not stated then this attribute is not used. The Has Active Ingredient attribute is still used and grouped together with this attribute
  - Range: << Substance (substance)
- **Has Product Strength** – The strength of the Has Basis of Strength Substance and is always grouped together
  - Range: Float 0 to 1000000000
- **Units** – Unit of Measure is always associated with the Strength
  - Range: <<Unit (qualifier value)
- **Has Unit of Use** – Describes a discrete unit that a product presents in, for example a vial, bag, etc.
  - Range: (<<)Type of drug preparation (qualifier value) and (<<) Unit of drug administration (qualifier value)
- **Unit of Use Size** – Represents the size of the unit of use
  - Range: Float 0 to 1000000000
- **Unit of Use Quantity** – Represents the pack quantity
  - Range: Float 0 to 1000000000

9.6.4. Findings

Under the new SNOMED CT International Drug Concept Model, existing concepts will be updated to meet the new modelling guidelines and terming updated to conform to the terming guidelines in the editorial guide. One of the most frequent issues we found while modelling the medication attributes was that the Fully Specified Names (FSN) were not completely fully specified or that the values needed to fully define a concept were not available. For example, the common issues we saw around FSN's were due to the salt or dose form not present or not fully defined in the FSN, but modelled with the more specific value in the current Has active ingredient and Has dose form attributes. With the SNOMED CT International review and application of the new modelling guidelines these FSN's should be corrected and fix the issues we found with FSN's.

- *Example:*

  (FSN does not explicitly state that it is an Oral suspension):

  370762006 |Azithromycin 1g/packet oral (product)|

  <<< 392327001 |Oral form azithromycin (product)| :

127489000 |Has active ingredient (attribute)| = 391805000 |Azithromycin dihydrate (substance)|, 411116001 |Has dose form (attribute)| = 385024007 |Oral suspension (qualifier value)|

Another common issue with fully defining concepts using our proposed model was associated with sugar free, gluten free, preservative free, etc. dose forms. This issue is currently out of scope for the new SNOMED CT International Drug Concept Model and will prevent the concepts that currently exist in SNOMED CT from being fully defined. A potential solution for representing these dose forms and fully defining the drug concepts would be to create concepts in the qualifier value hierarchy for sugar free dose form, gluten free dose form, etc and use a nested relationship to combine it with the other appropriate dose form. This would eliminate the need to create all the possible combinations of dose forms required to support the Drug Concept Model.

- *Example:*

  320108004 |Salbutamol 2mg/5mL sugar free syrup (product)|

  <<< 135639005 |Oral form albuterol (product)| :

  127489000 |Has active ingredient (attribute)| = 48474002 |Albuterol sulfate (substance)|, 411116001 |Has dose form (attribute)| = (385032004 |Syrup (qualifier value)| + XXXXXX|Sugar free dose form(qualifier value)|)

The sections of the SNOMED CT International Drug Concept Model dealing with Grouper, Virtual Medicinal Product (VMP), and Virtual Medicinal Product Form (VMPF) concepts in the Pharmaceutical / biological product hierarchy did not affect our concrete domain work as these concepts do not include product strength as a part of their FSN. However, correcting issues with these concepts will have downstream effects on the modelling of the concepts we made modified.

The section that was most relevant to the concrete domain work was the Virtual Clinical Drug model. The main differences between our approaches are:

- Strength is not represented as a number in the SNOMED CT International model, but as a conceptid that is a representation of that number.
- The SNOMED CT International model currently has no way to represent ranges of strength (for example radiopharmaceuticals).
- The SNOMED CT International model separates out numerator and denominator for both strength and units whereas we chose to normalize the strength.

After the testing of concrete domains using the pharmacy model we reviewed concepts in findings, procedures and observables to determine the feasibility of applying concrete domains to concepts in those hierarchies as well. We identified 3668 concepts that may potentially benefit from the use of concrete domains in these hierarchies.

These concepts mainly fall into 4 categories:

- **Grades/Stages/Scales**

  This category of concepts is least likely to benefit from concrete domains as some grades/stages/scales are alpha-numeric and would more likely fall into a similar model as the SNOMED International Drug Concept Model.

  - *Examples:*

    109970006 |Follicular lymphoma, grade 1|

112110007 |Glasgow coma scale, 4|

112241002 |Lymphoma stage III 1|

- **Measurements/Percentiles**

  This category of concepts mirrors the requirements of the Drug Concept Model most closely and would be very similar in that it would require both an attribute for recording the numeric value and another attribute to record the unit. This would also require the ability to capture less than, greater than and equal to which is not currently something supported in the SNOMED CT International Drug Concept Model. Therefore using concrete domains would be a much more suitable solution as it allows for that capture of that information but would require a change to the SNOMED CT Release Format to accommodate these relationships.

  - *Examples:*

    314643009 |Child head circumference < 0.4th centile|

    385303005 |pT3: Tumor more than 5 cm in greatest dimension (anal canal)|

- **Timing/Frequency**

  While these concepts contain numeric values, they may not lend themselves to being captured by concrete domains due to the fact that there are some expressions like “every 12 months”, “once a week”, “five times a week”, etc.

  - *Examples:*

    34259007 |Measurement of glucose 5 hours after glucose challenge for glucose tolerance test|

    416755008 |Cervical smear every 12 months for life|

- **Dosing Number/Episode**

  This would be a small subset of concepts that would be affected but would be a good target for a set of relationships to use for post-coordination instead of adding pre-coordinated concepts to the standard. Making these relationships strictly available through post-coordination and using concrete domains would not require a change to the release format. It would however require existing concepts (less than 100) to be retired in order for all concepts to be aggregated appropriately.

  - *Examples:*

    170425007 |Typhoid and Paratyphoid first dose|

    231499006 |Endogenous depression first episode|

9.7. Disjoint Content

9.7.1. Introduction

Classes are disjoint if they cannot have common instances. In an ontology, all classes are assumed to have potential overlapping instances unless they are explicitly stated to not have them. The current modeling of SNOMED CT does not contain any such statements, therefore all concepts are considered to have the potential to allow overlapping concepts. For example, there is no formal statement that would prohibit the clinical findings and body structure hierarchies from containing concepts that have parents from both

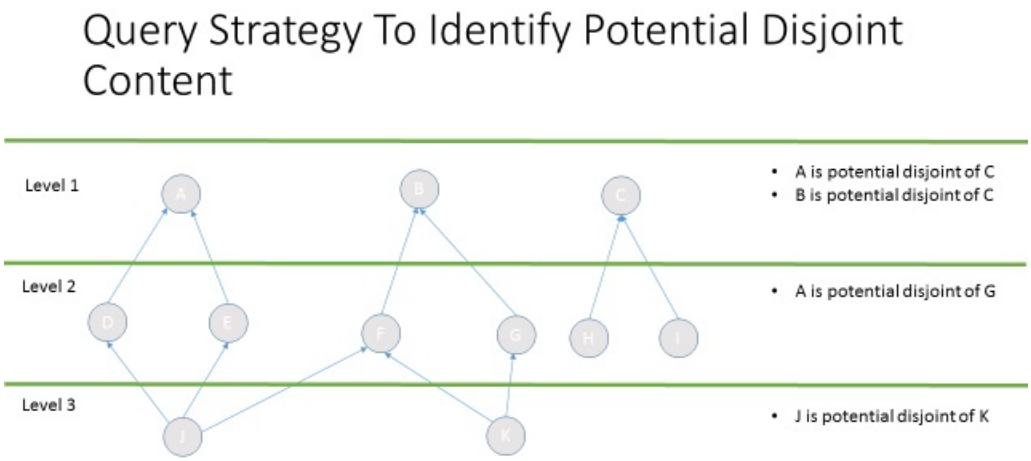
hierarchies even though this should never be the case. With the exception of the physical object and products that currently overlap, the top level primitive hierarchies like clinical findings and body structures should be disjoint.

9.7.2. Problem

Explicitly stating disjoint content would assist not only in detecting potential modeling errors, but also potentially aid in creating correct post-coordinated expressions. With more extensions to SNOMED CT being created at the National Release Center level and at the local implementations, more rich features are needed to ensure the correct creation of local content. SNOMED CT contains many concepts with similar Fully Specified Names across upper level primitive hierarches that can easily be assigned as a parent to a concept in another upper level primitive hierarchy. For example, “Hematoma” exists in both the disorder and morphologic abnormality hierarchies. If you are modeling a subtype of hematoma in the disorder hierarchy the morphologic abnormality could easily be chosen by a less experienced modeler if the tools used to model do not appropriately specify the hierarchy the parent comes from. Without the disjoint statements explicitly stated, the classifier would not be able to detect this error and a separate Quality Assurance (QA) statement derived from documentation would be needed to prevent this error. Likewise, having explicit disjoint statements can assist in the creation of post-coordinated expressions as they can be queried and used to restrict the allowable parents assigned when using multiple focus concepts.

9.7.3. Solution

All top level primitive concepts should be stated as disjoint with the exception of 260787004 |Physical object (physical object)|and 373873005 |Pharmaceutical / biologic product (product)|. A particular focus was placed on primitive hierarchies of substance and body Structure. For each hierarchy, we focused on identifying all concepts that are currently disjoint from each other beginning at the top of the hierarchy and traversing downward. This method will identify potential disjoint statements, which were reviewed by clinicians to confirm that they are correct.



9.7.4. Results

We utilized the US Extension to SNOMED CT to perform our initial assessment for disjoint statements. While calculating the disjoint statements for the upper level hierarchies we noticed that 243796009 |Situation with explicit context (situation)| and 123037004 |Body structure (body structure)| were not being

calculated as potentially disjoint. The single concept that was causing them not to be stated as disjoint was 119741000119108 |History of amputation of right lower limb (situation)| due to the fact that it was modeled in the US Extension as having parents in both hierarchies. This issue was reported to the National Library of Medicine and has been corrected in the March 2017 US Extension.

We added 169 disjoint statements to the upper level primitive hierarchies to test the feasibility of running a reasoner over them successfully and within a reasonable amount of time using disjoint statements using the minimum number of statements needed.

We utilized the tls2_StatedRelationshipsToOwlKRSS_Script_INT.pl from the SNOMED International GitHub registry to create an OWL file from the March 2017 US Edition release. Utilizing this file within the Protégé 5.2.0 editor and the included HermiT reasoner, we reasoned over the OWL file without disjoint statements in 3,015,366 milliseconds. We then added the 169 disjoint statements to the upper level primitive concepts and were able to reason over this version in 2,494,176 milliseconds.

We then performed the same test using the Snorocket reasoner plugin and achieved the results of 122,438 milliseconds and 54,498 milliseconds respectively. Therefore adding disjoint statements does not increase the time to reason over the OWL version of SNOMED, but actually significantly decreased the amount of time using both reasoners we tested.

We tested an additional 133 concepts for potential disjointness within the substance, body structure, and situation with explicit context hierarchies as these hierarchies are most likely to benefit from the addition of disjoint statements. We were able to add 13 substance statements, 1193 body structure statements, and 12 situation with explicit context statements. These disjoint statements only cover the immediate children for the all the hierarchies listed above except for body structures, where we went down three levels to identify potential disjoint content.

However, adding disjoint statements to these concepts will provide limited benefit for error checking. The body structure and substance hierarchies will have limited use cases for extension and post-coordination once the redesign is complete. The situation with explicit context hierarchy is one where heavy post-coordination and/or extension will take place, however most of this work will involve assigning a single parent that is a direct subtype of the upper level primitive. A more productive use of resources would be to focus on addressing any modeling issues in these hierarchies and introducing a mechanism for blocking the editing of these concepts without editorial approval. Focusing only on the first level below the upper level primitives in each of these hierarchies would be the best use of resources in the short term until the redesign of the concept model for body structure and substances is complete.

9.7.5. Conclusion

Without statements to detect disjoint content, there is a potential for modeling errors, such as modeling incorrect parents for SNOMED CT concepts. This will affects both equivalence detection and content retrieval via the SNOMED CT hierarchies. Adding disjoint content statements to the SNOMED CT definitions will assist both SNOMED CT International and extension content creators by providing built in QA to prevent errors in assigning parents. The creation of these statements should focus on the upper level primitive hierarchies and their direct descendants. Assigning further statements may become more useful once the redesign of the concept model for the various hierarchies is complete.

9.8. Meronomy / Partonomy

9.8.1. Introduction

Partonomy/Meronomy is a type of hierarchy that deals with part-whole relationships. *Part-of* Relationships are:

- Transitive – a part of a part is also a part of the whole, example below:
  - Atrioventricular junction: Part of = Entire Heart
  - Entire Heart: Part of = Entire heart and pericardium
  - Entire heart and pericardium: Part of = Entire middle mediastinum, Part of = Entire cardiovascular system

    Therefore, Atrioventricular junction is a part of the Entire heart and pericardium, Entire middle mediastinum, and the entire cardiovascular system.
- Reflexive – a part is a part of itself
- Antisymmetric – nothing is a part of its parts
  - The Entire Heart is not a part of the Atrioventricular junction

For this task we will be evaluating the representation of *Part-of* relationships in the Body Structure, Pharmaceutical/Biologic Product, and Laboratory Procedure (LOINC) hierarchies, and developing and testing a proposed model where appropriate.

9.8.2. Tooling

To evaluate the proposed model for the three hierarchies, we will continue to use the termMed's termSpace authoring tool. termSpace currently supports Object Properties with reflexive and transitive properties. For the Pharmaceutical/Biological Product hierarchy, we will use Nested Expressions to represent the powders used for injection solutions, as they do not currently exist as pre-coordinated concepts. termSpace can represent LOINC concepts to support the partonomy modeling of laboratory concepts; however, these concepts will need to be transformed into a SNOMED RF2 format in order to load them into termSpace. Due to the complexities of adding LOINC to termSpace we were not able to test the LOINC model at this time. We will continue to work with termMed to represent LOINC in termSpace to potentially test the model in future iterations.

9.8.3. Body Structure Concepts

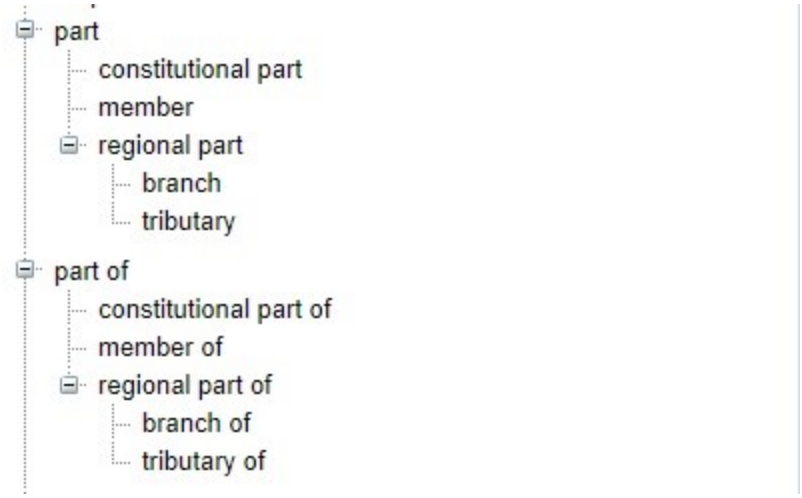
There are currently 42,596 *Part-of* Relationships assigned to Body Structure concepts remaining from the 2003 decision to transform them to non-defining.

SNOMED International is currently in discussions with Foundational Model of Anatomy (FMA) to collaborate on an anatomy model in SNOMED CT. SNOMED International is currently modeling *Part-of* relationships in a Protégé version of the Body Structure hierarchy; however, they are only exporting the resulting *IS-A* relationships. As a part of the *IS-A* and *Part-of* Modeling Subproject at SNOMED International, they plan to perform Quality Assurance (QA) to the *Part-of* relationships and assign sub-attributes of *Part-of*:

- Regional part of
- Constitutional part of
- Systemic part of

SNOMED International is currently in the process of documenting the updated Anatomy Model at: https://confluence.ihtsdotools.org/display/IAP/Revision+of+IS-A+relationships+for+anatomy

FMA also includes a role hierarchy for *Part-of* relationships as seen below:



9.8.3.1. Proposed Body Structure Model

With the forthcoming update to the SNOMED CT Anatomy concept model, we do not recommend exploring this area for concept model work, but instead focus on the Pharmaceutical/Substance and Laboratory hierarchies, where no current implementation of partonomy is planned.

9.8.4. Pharmaceutical / Substance Concepts

At this time, SNOMED project groups have not held a discussion around partonomy for Pharmaceutical/Substances. The most promising area where partonomy would apply within the Pharmaceutical Product hierarchy are products that are made up of two or more products, for example a package that contains two separate tablets. For example, Clarithromycin 500mg tablet and lansoprazole 30mg capsule would be considered parts of a concept like 317329000 |Clarithromycin 500mg tablet and lansoprazole 30mg capsule and amoxycillin 500mg capsule pack (product)|. Concepts like this are different from a single product that contains two or more active ingredients. These packages can be made of products that have different active ingredients or can be products that have the same active ingredient, but different strengths for each product in the package.

9.8.4.1. Proposed Pharmaceutical / Substance Model

We propose to add a new attribute |Has packaging component (attribute)| that will take as a value another concept from the product hierarchy. This will be a *Part-of* attribute and will need to be transitive and reflexive. These concepts will need to have a new hierarchy to live under as they are not really subtypes of the product that make up the packages but are packages that contain them. We suggest creating a new hierarchy named “Package” containing multiple products (product) and as needed create sub-hierarchies to ease navigation.

Below are examples of the products that potentially require the addition of new product concepts in order for the new attribute to be modeled or require the use of nested expressions to represent the missing content. For our pilot work we represented these concepts using nested expressions, however if the model were implemented in the International Release of SNOMED CT it may require creating pre-coordinated concepts.

- Disodium etidronate 400mg tablet and calcium carbonate 1.25g effervescent tablet pack (product) – Disodium etidronate 400mg tablet and calcium carbonate 1.25g effervescent tablet exist and will be used to fully define this concept. We need to determine the purpose of the parent concept, 346404007 |Disodium etidronate+calcium carbonate (product)|.

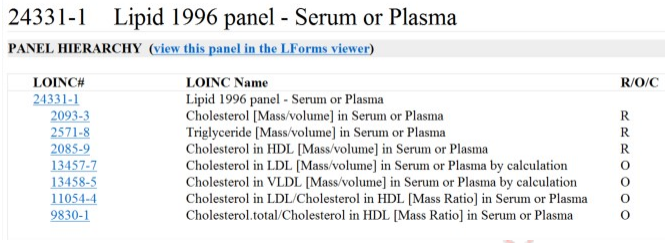
- Lutropin alfa 75iu injection (pdr for recon)+solvent (product) – solvent is packaged separate from the powder. Being able to model the solvent part + the powder part will allow for a fully defined concept.

There are some drugs, mainly multi-tablet packages that do have the individual clinical drugs represented as pre-coordinated concepts and will not require the use of a nested expression.

- 324934004 |Proguanil hydrochloride 100mg tablet and chloroquine phosphate 250mg tablet pack (product)| - Proguanil hydrochloride 100mg tablet and chloroquine phosphate 250mg tablet both exist as separate pre-coordinated concepts and could be used to fully define this concept.
- Quetiapine 25mg+100mg+150mg tablet starter pack (product) – This concept is a representation of three separate tablets contained within a pack. All three tablets exist as separate pre-coordinated concepts and we could easily fully define this concepts with three separate “Has packaging” components.

9.8.5. Laboratory Concepts

Part-of Relationships will be useful in the definition of LOINC concepts that represent Panels. These panel concepts contain both individual laboratory tests and other panel concepts. Panels may also require multiple sufficient sets to represent tests that are not always a part of the panel but optional.



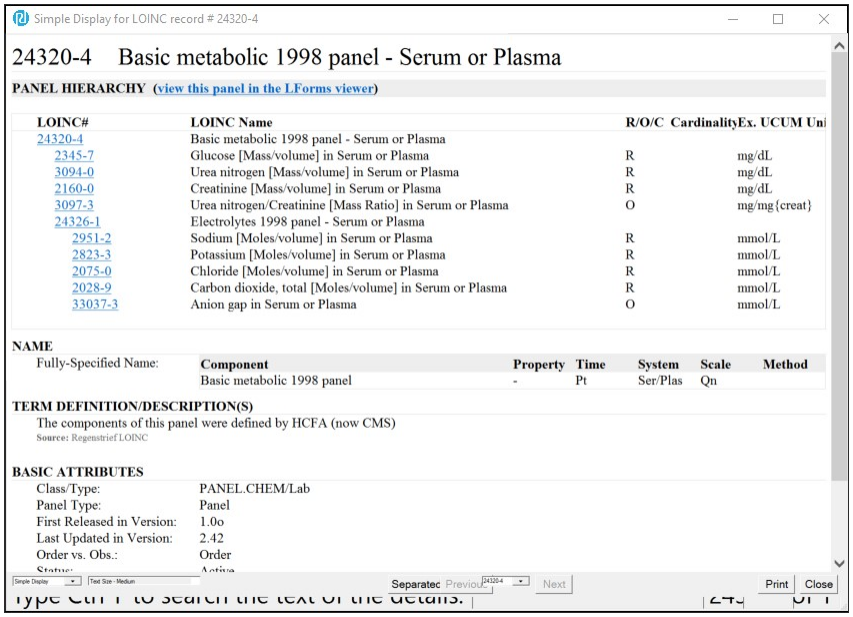
24331-1 Lipid 1996 panel - Serum or Plasma

PANEL HIERARCHY (view this panel in the LForms viewer)

LOINC#	LOINC Name	R/O/C
24331-1	Lipid 1996 panel - Serum or Plasma	
2093-3	Cholesterol [Mass/volume] in Serum or Plasma	R
2571-8	Triglyceride [Mass/volume] in Serum or Plasma	R
2085-9	Cholesterol in HDL [Mass/volume] in Serum or Plasma	R
13457-7	Cholesterol in LDL [Mass/volume] in Serum or Plasma by calculation	O
13458-5	Cholesterol in VLDL [Mass/volume] in Serum or Plasma by calculation	O
11054-4	Cholesterol in LDL/Cholesterol in HDL [Mass Ratio] in Serum or Plasma	O
9830-1	Cholesterol.total/Cholesterol in HDL [Mass Ratio] in Serum or Plasma	O

9.8.5.1. Proposed Laboratory Model

We propose to add a new attribute that applies to concepts in the Observable Entity hierarchy named Contains lab test (attribute). This attribute will take other Observable Entity concepts as values and will be transitive and reflexive.



Simple Display for LOINC record # 24320-4

24320-4 Basic metabolic 1998 panel - Serum or Plasma

PANEL HIERARCHY (view this panel in the LForms viewer)

LOINC#	LOINC Name	R/O/C	CardinalityEx.	UCUM Uni
24320-4	Basic metabolic 1998 panel - Serum or Plasma			
2345-7	Glucose [Mass/volume] in Serum or Plasma	R		mg/dL
3094-0	Urea nitrogen [Mass/volume] in Serum or Plasma	R		mg/dL
2160-0	Creatinine [Mass/volume] in Serum or Plasma	R		mg/dL
3097-3	Urea nitrogen/Creatinine [Mass Ratio] in Serum or Plasma	O		mg/mg{creat}
24326-1	Electrolytes 1998 panel - Serum or Plasma			
2951-2	Sodium [Moles/volume] in Serum or Plasma	R		mmol/L
2823-3	Potassium [Moles/volume] in Serum or Plasma	R		mmol/L
2075-0	Chloride [Moles/volume] in Serum or Plasma	R		mmol/L
2028-9	Carbon dioxide, total [Moles/volume] in Serum or Plasma	R		mmol/L
33037-3	Anion gap in Serum or Plasma	O		mmol/L

NAME

Fully-Specified Name:

Component	Property	Time	System	Scale	Method
Basic metabolic 1998 panel	-	Pt	Ser/Plas	Qn	

TERM DEFINITION/DESCRIPTION(S)

The components of this panel were defined by HCFA (now CMS)

Source: Regenstrief LOINC

BASIC ATTRIBUTES

Class/Type:	PANEL.CHEM/Lab
Panel Type:	Panel
First Released in Version:	1.0o
Last Updated in Version:	2.42
Order vs. Obs.:	Order
Status:	Active

Separatec Previous 24320-4 Next Print Close

To fully represent the information contained within the LOINC Panel spreadsheet an Ordered RefSet would have to be created because the tests contained in the panel are ordered in the spreadsheet.

In order to represent the optional tests that are sometimes part of a Panel there are several options. These optional tests and panels could be represented in an Association Reference Set, but a better representation may be using multiple sufficient sets.

9.9. Task 5.5.2 Logical Nesting Whitepaper

9.9.1. Introduction

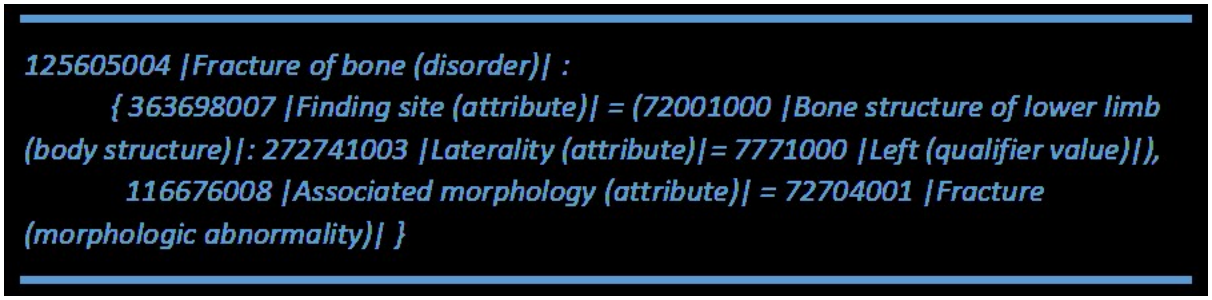


Figure 1: Example of Compositional Grammar with a nested laterality

A Nested Expression is an expression that is defined within another expression, the enclosing expression. Due to simple recursive scope [https://en.wikipedia.org/wiki/Scope_(programming)] rules, a Nested Expression is itself invisible outside of its immediately enclosing expression. The nesting is theoretically possible to any ideas of depth, although only a few levels are normally used in practice. Nested Expressions have been a part of SNOMED CT post-coordinated expressions for years and are able to be represented as a part of the compositional grammar.

However, SNOMED International is not currently permitting the use of nesting outside of post-coordinated expressions. The rational as stated in the SNOMED CT Logic Profile Enhancements document [https://docs.google.com/document/d/1tqNEA6S4fEF4fgj15OPabYA2E0VTz8epxvRRwczKizQ/edit#heading=h.yijdvy700v01] is due to two main reasons currently limiting the use of nested expression:

1. Lack of support in RF2

2. Potential for arbitrary levels of nesting

The ability to have Nested Expressions applied to pre-coordinated concepts in SNOMED CT would be beneficial to fully define concepts where the values for attributes are currently not represented as pre-coordinated concepts, for example lateralized body structures. Since creating pre-coordinated concepts to cover every aspect of medicine would lead to combinatorial explosion, Nested Expressions allow for the creation of a wide variety of concepts to supplement content that is currently missing from the international release. However, since nested expressions can be recursive, there need to be some limitations on the amount of expressivity allowed to keep content creation using nested expressions understandable and reproducible and to keep quality checks simple. Although Nested Expressions are easily represented in the compositional grammar syntax and OWL, they would require major changes to the SNOMED CT RF2 structure.

The purpose of this task is to identify a sample of expressions that are not nested and do not require nesting (see file named “der2_Refset_SimpleSnapshot_VA1000161_20180531_No Nesting_readable”) and a sample of expressions that should be nested and where we have proposed a model for nesting (see file named “der2_Refset_SimpleSnapshot_VA1000161_20180531_Nesting_readable”).

9.9.2. Tooling

To evaluate the proposed model for nesting we used the termMed termSpace authoring tool, which allowed us to add alternate definitions to SNOMED CT concepts and test the effects. Although termSpace currently supports nesting, this feature will be removed with the September 2018 US Release due to the Model Advisory Group's decision not to support nesting. One concern not to support nesting is the notion that it would cause a Description Logic classifier to take longer to complete classification. However, we have not yet seen any significant decrease in classification time with using nested expressions at a single level.

9.9.3. Pharmaceutical / Biological Concepts

During our work on partonomy, we identified the need to use Nested Expressions to fully define products in two instances. The first instance involved concepts that did not have a precoordinated concept available to fully define drugs that were representing packages that contain multiple drugs. The second set of concepts represented a powder that is packaged separately from the solution used to mix prior to use. The model below represents the pharmacy model we tested in the Base Year and has not been updated to the new drug model SNOMED International released in January 2018.

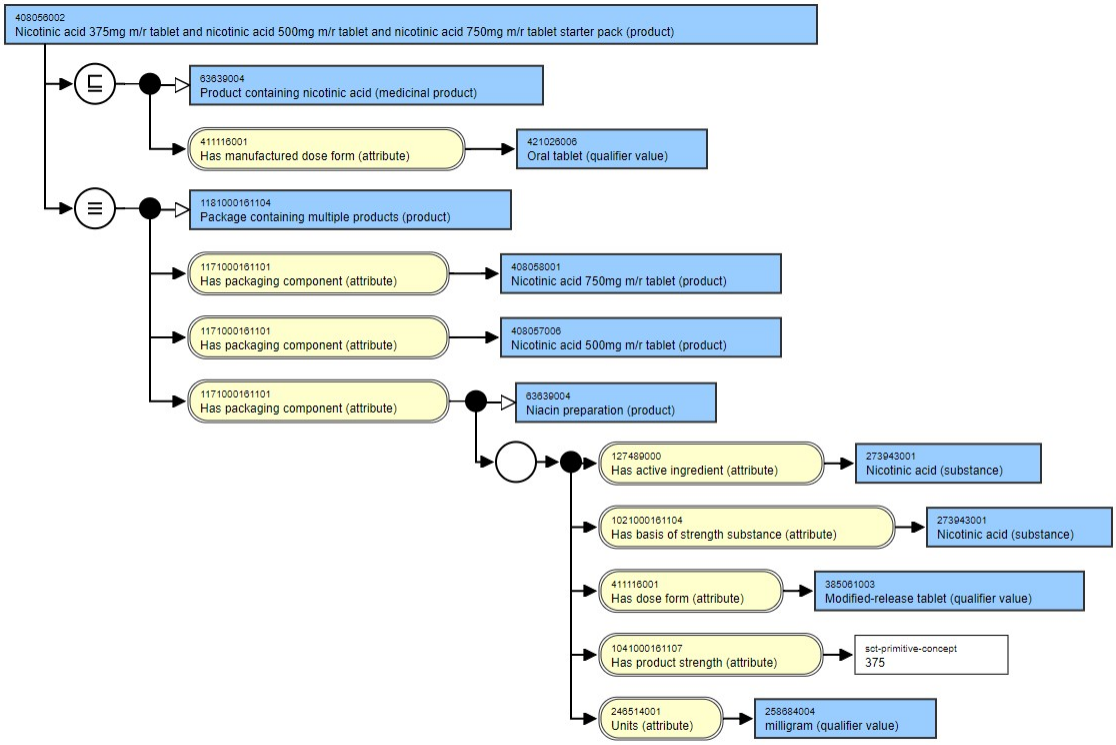


Figure 2: Example of starter pack that contains multiple tablets. Diagram contains the current SCT definition (top) and the updated definition (bottom) using partonomy with a nested expression.

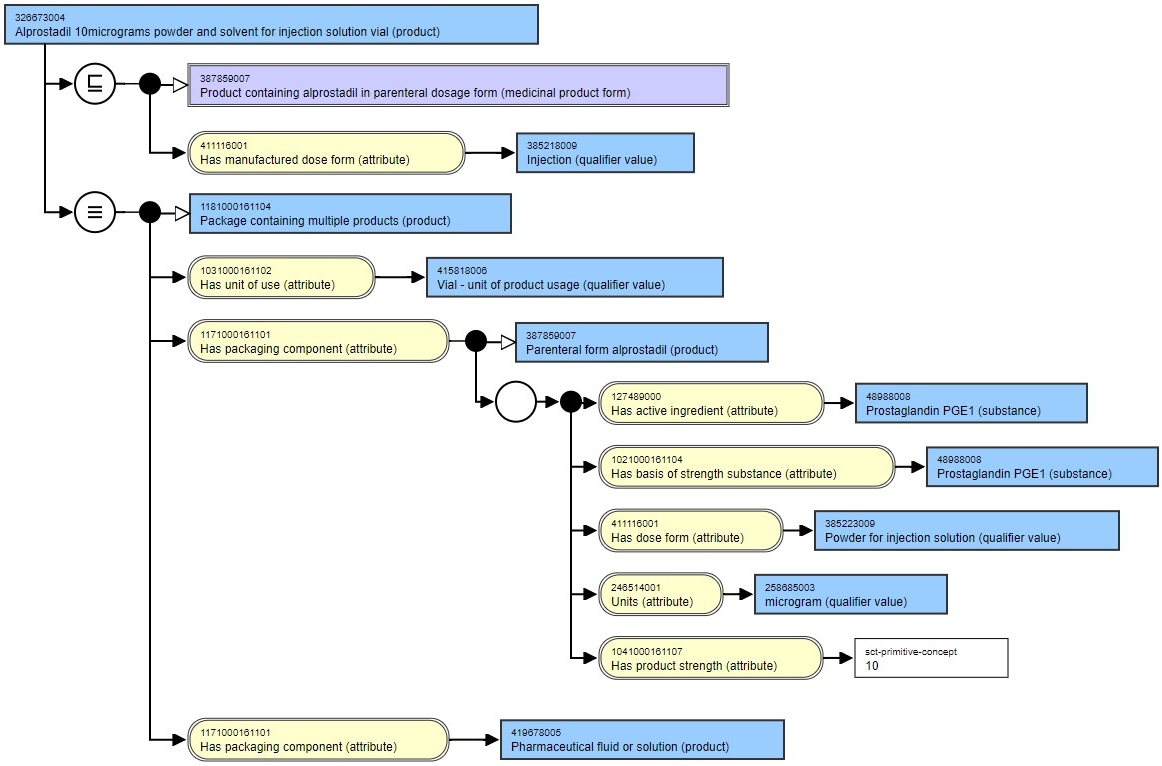


Figure 3: Example of an injection powder that is packaged separate from the solvent. Diagram contains the current SCT definition (top) and the updated definition (bottom) using partonomy with a nested expression.

9.9.4. Findings and Procedures Involving Laterality

Our work on identifying Findings and Procedures that incorrectly use laterality has identified a set of concepts that are not currently modeled correctly due to a lateralized body structure not existing as a precoordinated concept. Rather than add these concepts to an extension or submit them for addition they could easily use nested expressions to represent the missing body structure concepts that have a laterality attribute assigned to them.

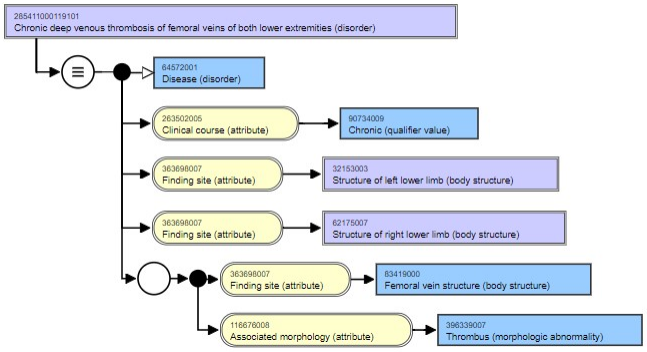


Figure 4: Current definition of Chronic deep venous thrombosis of femoral veins of both lower extremities (disorder) where laterality is not correctly defined.

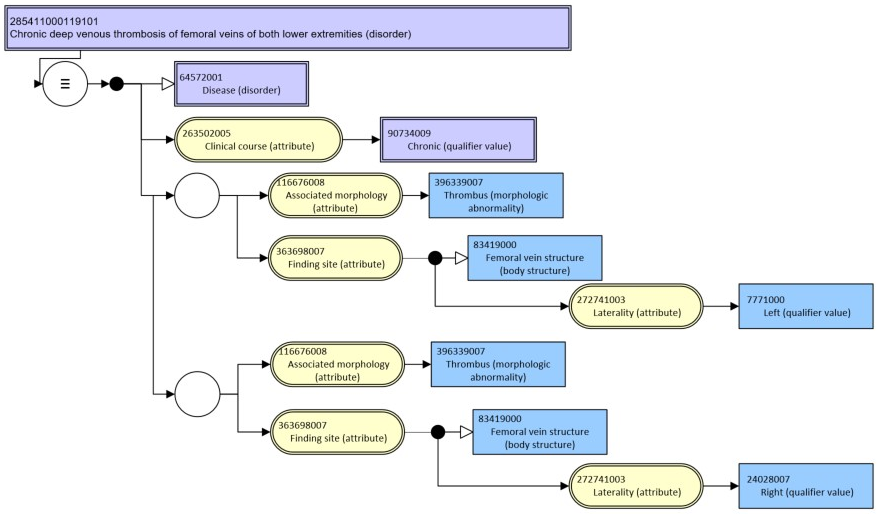


Figure 5: Updated definition of Chronic deep venous thrombosis of femoral veins of both lower extremities (disorder) where laterality is represented as a nested expression.

9.9.5. Recommendations

Support for Nested Expressions in the international and national releases would require major changes to the RF2 specification and are not a part of the recommended Logic Profile Enhancements. In addition, there must be constraints on the ability to model Nested Expressions to ensure errors are not introduced due to the ability to infinitely Nest Expressions. While Nested Expressions are not supported at the international and national level due to distribution issues, there is a definite benefit for including them in local extensions.

Using Nested Expressions to represent missing lateralized anatomy concepts will cut down the need to request new body structure concepts or temporarily creating new concepts in local extensions that will have to be reconciled with each international/national release. We chose to represent the package concepts using Nested Expressions rather than creating new concepts in an extension. However, these concepts would be much better suited as a pre-coordinated concept in the international or national release as they have the potential to be used for data recording or retrieval. Any further uses of nesting outside of laterality would need to be evaluated and constrained to ensure that modeling can be easily checked for completeness and consistency. Outside of the two use cases we tested for Nested Expressions, one could make modifications to findings and procedures that are used as values for defining relationships. However, in most cases these concepts would probably be better suited as pre-coordinated concepts.

9.9.6. Deliverables

We have created two Reference Sets as a part of PWS Task 5.5.2 to represent (1) those reviewed concepts where nesting could be used to represent both the product and laterality nesting and (2) those reviewed concepts that would not need nesting.

9.9.7. Additional Issues

When modeling the Pharmaceutical/Biological Product hierarchy, we used the model developed in the Base Year to test concrete domains. SNOMED International has since started utilizing the new drug model in the January 2018 international release. The work we did in the Base Year will become obsolete as the new model is implemented. The new SNOMED CT drug model will allow for the addition of more fully defined content including the addition of more values to represent concepts that include units of

presentation like cartridges, which do not exist in the model we evaluated in the Base Year. We have begun to remove the definitions that were added to the Pharmaceutical/Biological Product hierarchy in the Base Year that are included in the review of concepts for Nested Expressions but were included in the No Nesting RefSet as they do not require a nested expression. In some cases, these concepts were partially modeled in the Base Year by an automated update. For example:

- 318166002 |Bendrofluazide+potassium 2.5mg/7.7Mmol m/r tablet (product)|
- 318171009 |Bendrofluazide+potassium 2.5mg/8.4Mmol m/r tablet (product)|
- 134499006 |Budesonide + formoterol fumarate 100/6mcg breath-actuated dry powder inhaler (product)|
- 134498003 |Budesonide+eformoterol fumarate 200/6mcg breath-actuated dry powder inhaler (product)|
- 318165003 |Bumetanide+potassium 500mcg/7.7Mmol m/r tablet (product)|
- 447089002 |Amlodipine 5mg + hydrochlorothiazide 25mg + olmesartan medoxomil 40mg tablet (product)|

In the Pharmaceutical/Biological Product hierarchy we identified allergy kits that are represented as separate concepts should potentially be considered duplicates:

- 358640003 Silver birch allergy initial kit (product)
- 358641004 Silver birch allergy maintenance kit (product)
- 346734001 Timothy grass allergy initial kit (product)
- 346754000 Timothy grass allergy maintenance kit (product)
- 346735000 Treemix allergy initial kit (product)
- 346755004 Treemix allergy maintenance kit (product)

10. Requirements to Represent Absence in Interoperability Standards

Note to readers: This document is not intended to constrain or complicate efforts to design useful specifications, but rather to provide a forum for consensus about what works, and, ideally, reduce the need to recapitulate the problem in future discussions. If there are important facets missing, we would like to include them. We call special attention to the maps in "Appendices, Maps".

10.1. Introduction to "Representation of Absence"

Standards provide value by establishing consistent conventions for communication. When different communities of stakeholders establish these conventions for the same or for overlapping domains, the divergence in standards compromises their value. This divergence presents a fundamental challenge to any effort to broaden interoperability standards beyond the communities that define them. The problem affects even the most easily harmonized elements: two standards families may define specifications that are both structurally and semantically identical for, e.g., allergy criticality, but use different data types, names, and terminology systems to express these specifications.

Different elements may differ in how deeply they suffer from this issue. Allergy criticality specifications differ, but their structural similarity suggests a simple path for harmonization, so simple that ad hoc operational transformation may seem like an easier way to handle the difference rather than trying to coordinate consensus around harmonizing the standards themselves.

Negation is different: it has been represented in forms so diverse that it is not always obvious how to transform or harmonize them, or even when such transformation might be necessary. Negation is often modeled as a property of a business class, but logically and semantically, it's not really a predicate so much as a quantification: it doesn't refine our understanding of a concept; rather, it tells us how many of them there are. As a result, its presentation as a property causes a variety of problems:

1. Negative answers to questions can be modeled as binary forms; records of absence of notionally present business objects require different forms, and these forms tend to be inconsistent.

2. The scope of what parts of the model are negated must be carefully specified; e.g., to assert that a rash was absent at a point in time does not negate other properties of the record, e.g., the identity of the person making the assertion.

3. Negation can be implied by positive assertions, and the scope of what parts of reality are negated can depend on fluid colloquial assumptions of open and closed world boundaries. E.g., "left hemiplegia" seems to imply an absence of "right hemiplegia" but not of "headache."

4. The indeterminacy of the boundaries of implication mean that negation is logically intractable. Attempts to use computable logical tools such as description logic fail when faced with content that contains logical negation.

This document was conceived of to encourage consensus on how to support common understanding of this peculiarly difficult data element.

10.2. Objective

In order to properly represent absence consistently in standards specification and provide guidance on dealing with the variety of specifications that already exist, this document will:

1. Identify best practices for incorporating negative semantics into standards design, and

2. Specify explicit transformations between the most prevalent standards (CDA and FHIR).

10.3. Methods

10.3.1. Scope

The problem is abstract, and it requires some care to define.

First, "negation" as a term of logic has a long history of difficult implications[1]. It is defined as the logical operation of asserting the falsehood of a proposition, or as a proposition that is the negative of some other proposition. Efforts to apply description logics (DL) to clinical decision support have successfully demonstrated the ability to infer general facts from specific ones, e.g., a cerebral hemorrhage from a subdural hemorrhage: positive statements can be "classified"' with DL, making the application of rules that apply to large numbers of concepts simpler. But introducing negation causes logical propositions to become computably intractable. In addition, identifying where negation occurs is not always simple, because one positive assertion may entail another negative one; e.g., asserting that a patient has a blood type of A implies that the patient does not have a blood type of B. For these reasons, most efforts to implement description logics begin by excluding negative semantics from scope.

Efforts to use logically negative semantics in information modeling, too, have encountered difficulties of unanticipated depth. A prominent example is the HL7 Version 3 Reference Information Model (RIM). The RIM goes to some length to define precise semantics for a negation indicator and its effect on each attribute of the classes in which it is used, but when it was implemented in CDA by knowledgeable architects, it was found that the intuitively obvious meaning assigned in CDA was contrary to its definition in the RIM.

We avoid the issues caused by the abstractness of the concept of negation, and of its implications for computability, by focusing instead on more concrete requirements. In none of the cases we examine do patients or providers use the terms "negation," "true," or "false." We use the term "negation" only as a convenient label for the problems we discuss in this document. No actual information artifact or specification should use the term, for to do so is to introduce an intractable problem into the design. Where the concept seems applicable, it can always be specified more concretely and in better alignment with domain business practices: e.g., as a status of "refuted" or "resolved" for a condition, as a status of "not done" for a procedure," or as a clearly defined test result value.

Second, the boundary between negation and ignorance is complex and murky. Where possible, we differentiate the two. An assertion that no information is available is simply an assertion of ignorance; it does not tell us anything about the presence or absence of a phenomenon. We do not find many cases where the issues overlap: a value of "not applicable" for "last menstrual cycle" or of "no information" for "family history" complicates the data type for the response, but it does not mix the semantics of the answer and the metadata.

The case of "no known allergies" does complicate things. Logically, the semantics of this phrase are complex, describing a clinical history in which no allergies have been detected, but with respect to the actual presence of allergies it can be considered to be null. However, we may observe that this is true

[1] A full bibliography would be a project in itself, but for a survey, see Laurence Horn, A Natural History of Negation (Chicago: University of Chicago Press, 1989); for a cogent summary for informatics, see Alan Rector, "What's in a code?" Kuhn KA, Warren JR, Leong T-Y, (eds) Medinfo 2007. IOS Press; 2007. pp 730-734.

for any negative assessment. A statement that the patient has “no bleeding disorders,” recorded before administration of a blood thinner, in practice means “no known bleeding disorders.” Functionally, the bleeding disorder statement and the allergy statement are equivalent: both intend a prima facie assertion of absence, and both are subject to uncertainty. Clinicians may want to know whether such a denial has been recorded, but they will also always ask again before undertaking a procedure. The epistemological uncertainty of the record means that logical inference is always defeasible – always subject to revision in the light of new evidence – and this state means that automated decision support can never control care decisions, but only inform decision makers.

Similarly, the question of *certainty* overlaps explicitly with assertions of absence. It seems, in a logical framework, that a 90% level of confidence in an assertion is equivalent with a 10% level of confidence in the assertion’s negation, and that any level under 100% would therefore imply a simultaneous negative assertion. But this is not the case. The assertions in question are not value-neutral; they are records of clinical concern. A 10% likelihood of cancer is an indubitable concern, and any negative semantics that might be implied may affect the urgency, but not the tenor, of the concern.

Data *quality* is closely related to certainty, and it follows the same pattern. Irrespective of the confidence we place in the source, if a concern is asserted, concern is present.

10.3.2. Approach

Our approach is twofold.

For the objective of identifying best practices for standards specifications, we collect and catalog cases where negative semantics are used in health records. We consider three facets for these cases: the content (what cases are recorded for something being absent, not done, or otherwise “negated”), the use (when and how are these cases employed), and the form (the patterns that specifications have adopted for representing this information). For these cases, we identify characteristic problems and attempt to articulate best practices for designing standards that avoid the problems.

We collected examples from the following sources:

- Veterans Administration use cases
- Patient Care workgroup meetings, listserv threads, and project conference calls
- Clinical Quality workgroup meetings, listserv threads, and project conference calls
- NegEx Lexicon
- Individual participant contributions
- Physician Quality Reporting System (PQRS) measures
- Veterans Administration Informatics Architecture project team
- HL7 CDA Example task force examples
- FHIR examples

For the objective of providing guidance to implementers of existing standards, we collect the currently published examples of negation and propose transformation mappings.

10.4. Results

Relevant information came in many forms. In the examples, we identify kinds of content (prohibitions, absent pathologies, etc.) and kinds of use (orders, decision support, condition life cycle, etc.). We also identify different information structures.

The full list of examples is in "Appendices, Use Cases".

10.4.1. Content cases

We found six general classes of content.

A. Normal phenomenon absent

a. Blindness, amenorrhea, asplenia

b. No next of kin

B. Pathological phenomenon absent

a. Patient has not had chicken pox

b. No evidence of cancer

c. Resolved problems; e.g., Healed fracture

C. Risk factor absent

a. My uncle does not have hemophilia

b. No allergy to latex

D. Procedure not done

a. Test not performed because patient in incubator

b. Patient did not keep appointment

E. Procedure contraindicated

a. Do not turn patient

b. Consent not given

F. Patient engagement

a. Patient does not have goal

10.4.2. Use cases

We find ten general cases of use, with associated content patterns.

Note that content pattern A, normal phenomenon absent, does not appear in the list of usage cases. We find these cases consistently identified as positive assertions of concern rather than as absent phenomena; e.g., “blind,” not “vision absent.”

It’s not clear whether patient disengagement (content case F) should be considered a contraindication.

1. Change in circumstances. A phenomenon is asserted to have some probability of presence which is later retracted because a condition was resolved.

   a. Content cases: B (Pathological phenomenon absent)

   b. Examples

i. The patient had [communicable disease] but it has been cured.

ii. No evidence of cancer

2. Change in knowledge. A phenomenon is asserted to have some probability of presence which is later retracted because a condition was misdiagnosed and later refuted, entered in error, or because it was a possible or differential diagnosis that was later refuted.

   a. Content cases: B (Pathological phenomenon absent)

   b. Examples

      i. The patient was suspected of having Lyme disease but it has been refuted.

3. Diagnostic protocol. A clinician asks about phenomena associated with a suspected condition in order to refine clinical understanding.

   a. Content cases: B (Pathological phenomenon absent), C (Risk factor absent)

   b. Examples

      i. A clinician asks a patient with scleritis whether the patient has any autoimmune diseases.

      ii. A test for presence of streptococcus is returned negative.

      iii. PTSD screening negative.

4. Order criterion. Direction is given while or until a phenomenon is absent.

   a. Content cases: B (Pathological phenomenon absent)

   b. Examples

      i. Nothing to eat or drink until respiratory distress dissipates.

5. Quality criterion. A measure defines a population in whom a phenomenon is absent

   a. Content cases: B (Pathological phenomenon absent)

   b. Examples

      i. “Percentage of patients . . . who do not experience a major complication . . .”

6. Clinical Decision criterion. A rule makes operation dependent on the absence of a phenomenon.

   a. Content cases: B (Pathological phenomenon absent)

   b. Examples

      i. Recommend aspirin to ED patients presenting with chest pain with no bleeding disorders.

7. Specific safety protocol. A clinician asks about contraindications before conducting a procedure.

   a. Content cases: C (Risk factor absent)

   b. Examples

      i. The clinician asks about allergies before administering an antibiotic.

ii. The clinician asks about adverse effects of a medication.

iii. Patient is not NPO.

8. General safety protocol. A clinician asks about general risk factors.
   a. Content cases: C (Risk factor absent)
   b. Examples
      i. A patient reports no tobacco use.
      ii. Not pregnant.
9. Quality criterion. A measure identifies procedures not done.
   a. Content cases: D (Procedure not done)
   b. Examples
      i. “Percentage of children . . . not dispensed an antibiotic prescription”
10. Prohibition
   a. Content cases: E (Procedure contraindicated)
   b. Examples
      i. “do not flush central line”

10.4.3. Specification Patterns

We find 4 modeling patterns, with examples spanning specification families.

Table 10.1. Modeling Pattern

Category		Example
Absent Class		CIMI Clinical Statement with Absence Context
Coded property	focal	FHIR Allergy code, including "no known allergies"
	modifier	FHIR Condition status, including "refuted"
Boolean presence indicator		RIM Observation value negation indicator FHIR Procedure not done indicator
Quantification		Observation result value of 0 ANF value of 0..0

The broadest pattern is the use of distinct classes for distinct kinds of assertion. CIMI provides a “present assertion” class for identifying problems and other instances and an “absence assertion” for communicating

the absence of such problems. This seems appealing in that the details of a problem's attributes are specific to the presence assertions, and these details may be irrelevant to an assertion of absence. One issue with this assumption is that a negation may be intended to apply to a more specific case; e.g., it may be necessary to assert that a patient has no stage 4 pressure ulcers, though lower-stage ulcers may be present. Other properties generally considered proper to presence assertions may, in some cases, be needed for absence assertions. Actual cases have not been identified for this requirement, so it may not be needed.

A more common pattern is the use of coded properties to assert **absence**. Allergy records may be the most common domain where the documentation of absence is necessary, and the FHIR AllergyIntolerance resource uses this pattern. The "code" property (formerly "substance") supports values identifying a variety of substances, but it also supports "no known allergies," as well as a small set of more specific absences. Once concern with this approach is that the meanings of the values imply different semantics for their association with the model: "latex" is the subject of "what substance causes the problem"; "no allergy to latex" re-wires the predicate to "full statement of presence or absence of sensitivity to substance." For close-to-user forms, this divergence does not present problems. For secondary uses, it may be acceptable: if the use is to check a proposed substance administration against allergies, and the routine finds no match between the proposed dose of penicillin and the record object "no known allergies," the semantic mismatch doesn't cause a problem. But there is a mismatch, and it could cause unanticipated problems.

A special case of the **coded property** pattern is where a property that usually only qualifies the class includes a value that modifies it. The Condition resource has a status property that includes "resolved" and "refuted" values, each of which denotes the absence of the subject condition.

The **Boolean presence indicator pattern** hews closest to the logical semantics of negation, and it brings most of the resulting issues into the information modeling world. The range of a Boolean property is "true" and "false." These values presume the existence of a proposition with a truth value. Software classes don't typically meet this requirement: even when they are presumed to be assertions of the existence of the business objects they represent, the properties of the class are properties of the represented object, not of the assertion. The HL7 RIM addresses this difficulty by distinguishing between properties that represent the clinical phenomenon and those that annotate the representation: "descriptive" properties, which describe the referent phenomenon (and whose semantics may change according to negation and mood), and "inert" properties, which describe the assertion itself (and whose semantics don't change with mood and negation). This distinction is, as we have observed, subtle enough to confuse the very experienced.

An additional wrinkle for these properties is that they tend to be envisioned as special cases, so they are named for the edge cases they support. As a result, the semantics of the value is inversely related to the semantics of the modified class. A negation indicator of "true" means that the notional observation is not present; "false" means that it is present.

A final pattern leverages the fact that negation is a quantification by recording presence and absence as **quantities**. The Analysis Normal Form assertion contains a quantity property that can be used both for quantitative measurements and for quantities of presence. In order to do so, it defines an interval data type that supports open and closed boundaries. A value of absent has closed upper and lower bounds of zero (i.e., "[0..0]"); a value of present has an open lower bound of zero (i.e., "(0..#)"). An allergy specification would record not only a substance (or class of substances) but its presence or absence as an interval quantity. Negative semantics don't complicate the computation, and the meaning of the substance code field remains stable. (A minor semantic wrinkle is that $_{\infty}$ isn't a number, so that value will have to be handled prior to calculation.)

The goal of this design is to represent clinical facts as consistently as possible to support automated inference. The ability to use such a record as a reliable indicator of absence still relies on the effective application of quantification to open-world semantics: the assertion that an allergy assertion has a count of zero does not necessarily rule out the possibility that some other allergy assertion might not. And any assertion of absence is, as noted above, defeasible.

10.5. Discussion

10.5.1. Content

Most cases fit in well-defined categories. Category boundaries depend on judgment, and it's possible to define categories at higher or lower levels of granularity. Our goal is to differentiate categories only when they require different processing logic. Absence of sight and amenorrhea are both typically represented as positive assertions of concerns, so we classify them together and expect both to surface in clinical records as concerns; absence of a bleeding disorder is a record of a safety check, and we do not expect to see it as a concern.

Most cases were classified as absences of pathologies. This may be partly an artifact of the data collection process, but it is true that absence is typically relevant to care provision as the result of checking for some kind of notional concern, whether actually suspected or as a safety protocol.

A significant number of items might be expected to be inferred from broad normal findings, using the "chart by exception" pattern. A radiology image, for instance, may be annotated by the radiologist as showing "no mediastinal widening," but for a given modality and angle, absence of certain pathologies may be inferred. A normal chest x-ray implies "no mediastinal widening" whether it is annotated or not. The confidence with which such conclusions may be asserted may vary with the uniformity of the protocol, but whether the absence is stated or inferred, its representation is that of absent pathology.

Assertions that procedures were not done were exclusively the province of quality measures. There were also cases of patients not showing up for appointments—the procedure did not occur, and the reason is provided, just as for a quality measure. Clinical uses for procedure all involve prohibition and contraindication.

The most difficult cases were those that most closely aligned with actual negation semantics, being where a patient denies holding a goal or denies consent for a treatment. The latter case is a contraindication; the former context to help providers understand compliance issues.

We did not find cases that exercise the limits of negative semantics, such as double negatives or inference of negation given some logically contradictory situation. The few line items in the sample that venture near this territory were judged "not relevant" due to being contrived, not based on actual requirements.

10.5.2. Uses

The ten categories of use align broadly as: updates to durable concern records, negative answers to protocol questions, use of these facts as criteria, and prohibitions.

When providers record changes in circumstances or knowledge (a resolved or refuted condition), the knowledge typically involves a durable concern. These phenomena may be recorded as problems, and they may have a significant body of supporting evidence, goals, related procedures, and other information associated with them.

Negative answers to protocol questions, on the other hand, are typically transient forms of little utility beyond the immediate clinical context. Safety protocol negatives ("not pregnant") demonstrate this most clearly. Whether it holds for "chart by exception" inferences on diagnostic procedures, such as "no mediastinal widening" based on a normal chest x-ray, may depend on the degree of interest on concern regarding the phenomenon.

Facts that serve as criteria may fall into either category. Criteria for future acts tend to be recorded as needed; e.g., direction to take a medication until a symptom abates can be supported by periodic assessment of the symptom. Criteria for measures tend to be existing records, and absence is usually inferred from

a lack of documentation. As we observed earlier, criteria for clinical use, including decision support, are confirmed at the point of care, and prior records cannot be relied on.

A more critical category of negation is prohibition. Assertions that procedures are not to be done must be persisted for human review and for order checks, so a key dimension is the timeframe over which the prohibition is in effect. Whether classification is necessary may depend on the complexity of the prohibition. An order to avoid turning a patient is unlikely to cause logical confusion; an order to avoid specific classes of medication is a bit more complex but can be supported with affirmative classification logic.

10.5.3. Patterns

It's critical to be able to distinguish records of presence from records of absence in a predictable way. It is less clear what design patterns are best suited to this need. The pattern of using **distinct classes** for present and absent phenomena makes the distinction clear. It also makes it difficult to aggregate statements about presence, absence, and degrees of uncertainty or state change. The convention doesn't provide obvious direction on how to handle phenomena that were present at one time and have ceased to be present. There may be uses for which this pattern is well suited, but we haven't identified them.

The **coded element** pattern is more common, partly because it is a convenient extension of the presence pattern. The primary difficulty is that there are two distinct patterns of extension—by status and by protocol: both patterns are common. Extension by status includes state changes that denote absence, whether clinical progression (i.e., resolution) or epistemological progression (i.e., refutation or "entered-in-error"). Extension by protocol encompasses cases where a question is asked by protocol and refuted, and the refutation is captured in the same property as the classification of the affirmation—viz., "no known allergies" in the allergy field.

The **negation indicator** seems to be an inappropriately aggressive abstraction of domain information. Boolean properties in general are more abstract than the concrete requirements of the domain; this might be acceptable where such generalization provides a way to aggregate diverse colloquialisms, but where no such value is identified, it only obfuscates the clinical semantics. The result is an inaccurate promise of logical tractability at the cost of human comprehensibility. The problem can be ameliorated by giving a Boolean property a more specific name, e.g., "not done indicator," but such a property usually overlaps semantically with status values (refuted, cancelled). This may not be the case with ProcedureRequest.doNotPerform, but a coded property would still provide flexibility for use cases not yet recognized.

The **quantified presence** pattern may be a workable answer for secondary uses. It seems too far from an intuitive representation of clinical processes to be generally useful for close-to-user forms. But, unlike the Boolean pattern, it does provide a consistent, unambiguous, and logically tractable way to represent the presence of concerns consistently, whether captured as unary "symptoms" or "concerns" or as binary questions with answers.

10.6. Conclusions

Recorded assertions of absence are defeasible; they can never be used for clinical decisions. They might be used to support decision-support recommendations, subject to effective and safe usability engineering. It may not be advisable to spend much effort trying to make such computations accurate, as no matter how sophisticated the analysis of prior assertions, the underlying data will always be stale.

Patterns for capture of such statements may use any of the identified modeling patterns, with some caveats.

The **distinct class** pattern offers limited benefits for significant overhead. In quality measure systems, distinct classes may be useful, but the negative flavors are often inferred from empty queries, so it's not clear that a corresponding structure on the clinical capture side make sense.

The **negation indicator** pattern offers the promise of logical inference, but the promise is false. Negation is logically intractable, and the abstraction of the Boolean structure obfuscates the actual domain information of interest. At least one case was identified where a concrete question seems defensibly supported by a Boolean value, but it could be equally well supported by terminology without preventing support of unforeseen use cases.

The **coded element** solution works, though it also presents challenges, including model impedance. As long as the challenges are recognized and handled appropriately, they may be the least problematic cost of the domain. Specifications need to address absence and other negative semantics and provide explicit and concrete guidance to implementers on how to manage impedance and other sources of model ambiguity.

The **quantified presence** solution offers unparalleled consistency in recording facts. Its counter-intuitive representation makes it difficult to promote in domain information models, but it may provide an excellent pattern for analytical transformations.

For standards design, we propose four best practices:

1. Model negative semantics concretely, in ways that are fit for purpose (e.g., “refuted,” “contraindicated”). Avoid generalizing to more abstract forms without specific near-term use cases for doing so.
2. Support consistency within models by providing implementers with one way to say things.
3. Support consistency across clinical models by using similar patterns and providing concret guidance on managing impedance issues.
4. Provide explicit instructions for how negated statements in your specification should be transformed from and to other widely adopted specifications.

With respect to the tactical issue of transformation, we provide transformations from C-CDA to FHIR in "Appendices, Maps". Note that the alignment issues here are global: the CDA allergy, for instance, is explicitly represented within a concern act, which is not present in FHIR. This context issue means that the mappings provided will either be asserted to be incorrect or they will document agreed but implicit semantics in one or both formalisms.

10.7. Appendices

10.7.1. Glossary

Table 10.2. Glossary

Term	Definition
Defeasible	Capable of being annulled or made void (Webster)
Finding	A fact asserted about a patient Stedman's: "A clinically significant observation, usually used in relation to one found on physical examination or laboratory test."
Modifier	A concept that changes the meaning of another concept. E.g, to say that a patient has a "family history of" diabetes does not state that the patient has diabetes. Compare Qualifier. SKMT: string which, when added to a term, changes the meaning of the term in the clinical sense (ISO)

Term	Definition
Negation	the logical operation of asserting the falsehood of a proposition, or a proposition that is the negative of some other proposition. SKMT: indicator specifying that the Act statement is a negation of the Act as described by the descriptive (HL7)
Observable	A property that may be assessed and characterized in terms of a result value; a question. SKMT: Hierarchy in SNOMED CT which represents a question about something which may be observed or measured. (SCT)
Post-coordinated	The quality of being composed of separate concept identifiers. Post-coordination can be achieved either in expression syntaxes defined by code systems for the creation of valid post-coordinated concepts or in model elements with model bindings that articulate how the respective element values are related. SKMT: Representation of a clinical meaning using a combination of two or more concept identifiers (SCT; Candidate)
Pre-coordinated	The quality of being composed of a single concept identifier, as defined in a code system. SKMT: compositional concept representation (2.4.1) within a formal system (2.5.1), with an equivalent single unique identifier (ISO)
Qualifier	A concept that refines another concept within its semantic scope. E.g, a "left" arm is still an arm. Compare Modifier. SKMT: string which, when added to a term, changes the meaning of the term in a temporal or administrative sense (ISO)

10.7.2. Sources

Cheatham, Edward. SNOMED CT Post-Coordination rules, Draft guidance document. NHS NPFIT, document NPFIT-FNT-TO-DPM-0311.01

- Guidance suggests storing "close-to-user" forms is a more conservative approach, and that canonical forms can be derived for data operations.

Ceusters, Werner, Peter Elkin and Barry Smith. “Negative Findings in Electronic Health Records and Biomedical Ontologies: A Realist Approach”, International Journal of Medical Informatics 2007; 76: 326-333. PMC2211452.

- "We introduced a new family of ‘lacks’ relations into the OBO Relation Ontology. . . . By expanding the OBO Relation Ontology, we were able to accommodate nearly all occurrences of negative findings in the sample studied."

Ceusters, Werner, Peter Elkin and Barry Smith. “Referent Tracking: The Problem of Negative Findings” (MIE 2006), Studies in Health Technology and Informatics, vol. 124, 741–6. (This issue also published as Ubiquity: Technologies for Better Health in Aging Societies. Proceedings of MIE2006, edited by Arie Hasman, Reinhold Haux, Johan van der Lei, Etienne De Clercq, Francis Roger-France, Amsterdam: IOS Press, 2006.)

- "Referent tracking" assigns IDs to things to avoid confusion, e.g., when two people assert that a patient has a fracture and it cannot be determied whether they are the same fracture. To the extent that particulars have identifiers, this is in line with Restful (or OWLish) URIs. But they are also required to be unique. Another constraint is the identifiers are only given "real world phenomena," so the question is how to handle something negated. The authors propose a new "lacks" relationship for describing particulars that don't exhibit identified universals.

HL7. HL7 Version 3 Reference Information Model

- Observation.valueNegationInd 6.36.2 "This attribute should only be used when the terminology used for Observation.value is not itself capable of expressing negated findings. (E.g. ICD9)."

- Act.actionNegationInd 6.5.5 "The actionNegationInd works as a negative existence quantifier on the actual, intended or described Act event. In Event mood, it indicates the defined act did not occur. In Intent mood, it indicates the defined act is not intended/desired to occur. In Criterion mood, it indicates that the condition is based on the non-occurrence of the event. It is nonsensical to have a negationInd of true for acts with a mood of definition. The actionNegationInd negates the Act as described by the descriptive properties (including Act.code, Act.effectiveTime, Observation.value, Act.doseQty, etc.) and any of its components."

Horn, Laurence. A Natural History of Negation (Chicago: University of Chicago Press, 1989).

- Thorough.

Rector, Alan. What's in a Code?

- On separation of ontology from terminology & use of "situation" construct to harmonize positive & negative assertions

Rector, Alan. Negation & Null Values (rough notes)

- On preference for "absent" to "negation," at least at first

Rhodes, Bryn. Negation in QDM. https://github.com/esacinc/cql-formatting-and-usage-wiki/wiki/negation-in-qdm

- Analysis of decisions for quality language expressions.

SNOMED International. SNOMED CT Technical Implementation Guide: 7.8.2.4.7 Retrieving absent findings

- This section discusses how negation changes the rules for subsumption testing. The solution is to reverse the candidate/predicate relation for Situation with Explicit Context findings using "known absent" or a descendant. Note that this approach assumes a pattern of Procedure with explicit context. The pattern of an Observable with value "absent" is not addressed. This approach can probably be generalized. Note: TiG in revision. This information can be reviewed in a prior version, but it is subject to change and is not a current SI publication.

Wagner, Gerd. Web Rules Need Two Kinds of Negation. http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.331.2050

- Seems to address case of inferred vs explcit negation, but examples cloud the issue. Suggests that because the richness of domain information does not fit neatly into Boolean categories, Boole needs more values (as opposed to not using a Boolean operator).

10.7.3. Use Cases

Table 10.3. Use Cases

ID	Item	Content category	Use category	Source
1	m. CXR: Normal. No mediastinal widening, valve disease, or CHF i.e., no CHF	Pathological phenomenon absent	Diagnostic protocol	VA Use Case Angina 1 - EDCare 2.20.15
2	b. Confirms allergies: No known drug allergy	Pathological phenomenon absent	General safety protocol	VA Use Case Angina 1 - EDCare 2.20.15
3	d. Smoking history: No tobacco use	Pathological phenomenon absent	General safety protocol	VA Use Case Angina 1 - EDCare 2.20.15
4	b. CV: Chest pressure 5 out of 10 after 3 SL-NTG tablets, S1S2, No murmurs or gallop Exam: No murmur	Pathological phenomenon absent	Diagnostic protocol	VA Use Case Angina 1 - EDCare 2.20.15
5	e. GU: Verbalizes no problems with voiding	Pathological phenomenon absent	Diagnostic protocol	VA Use Case Angina 1 - EDCare 2.20.15
6	b. Since chest pain started 45 minutes ago, it is too early to see any elevation in cardiac enzymes (Troponin, CK-MB)	Not relevant: Null		VA Use Case Angina 1 - EDCare 2.20.15
7	a. History of Tobacco use: No	Pathological phenomenon absent	General safety protocol	VA Use Case Angina 2 TelemetryCare 2.20.15
8	a. Notes cardiac rhythm: Sinus rhythm without ectopy, HR 84 i.e., No ectopy	Pathological phenomenon absent	Diagnostic protocol	VA Use Case Angina 2 TelemetryCare 2.20.15
9	Cardiologist evaluates the reading and enters	Pathological phenomenon absent	Diagnostic protocol	VA Use Case Angina 2

ID	Item	Content category	Use category	Source
	the interpreted result in the EHR. Result: Normal echocardiogram. No cardiomegaly or effusion. Good valve function. Ejection Fraction: 58% i.e., No cardiomegaly			TelemetryCare 2.20.15
10	Reviews ECG reading and enters the interpreted result in the EHR. Result: SR 76. No ectopy. No hypertrophy. i.e., No hypertrophy	Pathological phenomenon absent	Diagnostic protocol	VA Use Case Angina 2 TelemetryCare 2.20.15
11	a. Begin light exercise (walking on a level surface for 5 minutes, 3 times a day). Add 1 minute to each session, each day until able to complete 10-15 minutes in each session without cardiac symptoms. cardiac symptoms absent	Pathological phenomenon absent	Clinical decision criterion	VA Use Case Angina 2 TelemetryCare 2.20.15
12	Allergies: No known drug allergy	Pathological phenomenon absent	General safety protocol	VA Use Case CHF - ED 20150305
13	o Cardiac rhythm (ECG): Sinus tachycardia (ST) without ectopy i.e., No ectopy	Pathological phenomenon absent	Diagnostic protocol	VA Use Case CHF - ED 20150305
14	1. Sinus tachycardia (ST) Q waves in the inferior leads, inferolateral ST- and T-wave changes (This is unchanged from the previous	not relevant: Comparison		VA Use Case CHF - ED 20150305

ID	Item	Content category	Use category	Source
	admission-3 months ago).			
15	i. If the patient does not produce 250ml urine in first 30 minutes, furosemide 40mg IV x1 should be administered	not relevant: Threshold		VA Use Case CHF - ED 20150305
16	a. Confirms allergies: No known drug allergy	Pathological phenomenon absent	General safety protocol	VA Use Case CHF - ED 20150305
17	a. Smoking history: No tobacco use	Pathological phenomenon absent	General safety protocol	VA Use Case CHF - ED 20150305
18	1. Nothing to eat or drink until respiratory distress dissipates	Contraindication	Clinical decision criterion	VA Use Case CHF - ED 20150305
19	1. History of Tobacco use: No	Pathological phenomenon absent	General safety protocol	VA Use Case CHF - IMC 20150305
20	a. AUDIT-C - Score: 0 (No symptoms of abuse)	Pathological phenomenon absent	Specific safety protocol	VA Use Case Depression - Outpatient Follow-up 2.26.15
21	Head/Neuro: WNL Heart: S1S2, BP normal	not relevant: Normal		VA Use Case Depression - Outpatient Follow-up 2.26.15
22	Abdomen: Soft, benign. No GI/GU issues. i.e., No GI/GU issues	Pathological phenomenon absent	Diagnostic protocol	VA Use Case Depression - Outpatient Follow-up 2.26.15
23	Extremities: No swelling, pedal pulses strong. i.e., No swelling	Pathological phenomenon absent	Diagnostic protocol	VA Use Case Depression - Outpatient Follow-up 2.26.15
24	b. Adverse effects from the medication a. None noted	Pathological phenomenon absent	Diagnostic protocol	VA Use Case Depression - Outpatient Follow-up 2.26.15
25	i. Provider notices that the patient did not tolerate Prazosin in the past (which was	Normal phenomenon absent	Specific safety protocol	VA Use Case Depression - Outpatient Follow-up 2.26.15

ID	Item	Content category	Use category	Source
	started to address difficulty sleeping)			
26	*[Wellbutrin]* . . . was discontinued due to irregular heartbeats and hyperventilation	Procedure not done	Procedure assessment	VA Use Case Depression - Outpatient Follow-up 2.26.15
27	*[Prozac]* discontinued due to irregular heartbeats and restlessness	Procedure not done	Procedure assessment	VA Use Case Depression - Outpatient Follow-up 2.26.15
28	Patient still refuses cessation treatment despite motivational interventions	Procedure not done	Procedure assessment	VA Use Case Depression - Outpatient Follow-up 2.26.15
29	a. Smoker: No	Pathological phenomenon absent	General safety protocol	VA Use Case DM 1 Diagnosis of Diabetes 2.20.15
30	a. Substance Use: No	Pathological phenomenon absent	General safety protocol	VA Use Case DM 1 Diagnosis of Diabetes 2.20.15
31	Patient completes PTSD screening k. Results: Negative	Pathological phenomenon absent	Specific safety protocol	VA Use Case DM 1 Diagnosis of Diabetes 2.20.15
32	Patient completes alcohol use screening l. Result: 2 (Negative)	Pathological phenomenon absent	General safety protocol	VA Use Case DM 1 Diagnosis of Diabetes 2.20.15
33	Extremities: No swelling, bilateral pedal pulses +2, i.e., No swelling	Pathological phenomenon absent	Diagnostic protocol	VA Use Case DM 2 Follow Up Outpatient Visit 2.20.15
34	Head/Neuro: WNL	not relevant: Normal		VA Use Case DM 2 Follow Up Outpatient Visit 2.20.15
35	a. Smoker: No	Pathological phenomenon absent	General safety protocol	VA Use Case DM 3 - Referral for Annual Podiatry Screening 2.20.15
36	b. Alcohol Use: No	Pathological phenomenon absent	General safety protocol	VA Use Case DM 3 - Referral for Annual Podiatry Screening 2.20.15
37	5. Wound assessment: Medial portion of right	Pathological phenomenon absent	Diagnostic protocol	VA Use Case DM 3 - Referral for

ID	Item	Content category	Use category	Source
	big toe (approx. 5 mm x 5mm) at top of toenail is slightly red. No breakdown. No sign of infection. i.e., No breakdown			Annual Podiatry Screening 2.20.15
38	Provider removes ingrown toenail without complications. No infection noted. Skin intact, with slight inflammation. i.e., No infection noted	Pathological phenomenon absent	Diagnostic protocol	VA Use Case DM 3 - Referral for Annual Podiatry Screening 2.20.15
39	a. Patient notes that work has been busy, and that no time has been available to make the appointment	Patient alignment	Procedure assessment	VA Use Case DM 4 Care Coordinator Telephone Follow Up 2.20.15
40	do not know whether uncle has/ had colon cancer	not relevant: Null		HL7 PC Orlando 1/12/16
41	my uncle does not have hemophilia	Risk factor absent	Specific safety protocol	HL7 PC Orlando 1/12/16
42	Congenital absence of coronary artery	Normal phenomenon absent		HL7 PC Orlando 1/12/16
43	Left kidney resected (absent)	Normal phenomenon absent		HL7 PC Orlando 1/12/16
44	Left leg amputated (not present)	Normal phenomenon absent		HL7 PC Orlando 1/12/16
45	No vision in right eye	Normal phenomenon absent		HL7 PC Orlando 1/12/16
46	no menses	Normal phenomenon absent		HL7 PC Orlando 1/12/16
47	no spleen	Normal phenomenon absent		HL7 PC Orlando 1/12/16
48	definiteExistence e.g., obvious	not relevant: Certainty		NegEx Lexicon

ID	Item	Content category	Use category	Source
49	definiteNegated-Existence e.g., patient was not	not relevant: Certainty		NegEx Lexicon
50	experiencer e.g., sister's	not relevant: Other subject		NegEx Lexicon
51	future e.g., at risk for, concern for	not relevant: Risk		NegEx Lexicon
52	historical e.g., changing, previous	not relevant: Past		NegEx Lexicon
53	indication e.g., rule out	not relevant: Rule out		NegEx Lexicon
54	probableExistence e.g., evidence for, appears	not relevant: Certainty		NegEx Lexicon
55	probableNegated-Existence e.g., fails to reveal	not relevant: Null		NegEx Lexicon
56	pseudoExperiencer e.g., by her husband	not relevant: Other subject		NegEx Lexicon
57	pseudoHistorical e.g., history and examination	not relevant: Past		NegEx Lexicon
58	pseudoNegation e.g., no change	not relevant: Comparison		NegEx Lexicon
59	uncertain e.g., either	not relevant: Certainty		NegEx Lexicon
60	Radiology negative findings - get example list for chart by exception	Pathological phenomenon absent	Diagnostic protocol	RadLex (Richard Esmond)
61	Assertion of intention not to breast feed	Patient alignment	Procedure assessment	CIMI CQI project
62	Absence of assertion of intent to breast feed	not relevant: Null		CIMI CQI project
63	1. It is the case (that I do know) that the Patient has problem X,	not relevant: Abstract	affirmative, not negation	PC thread 2/25
64	2. It is not the case (that I do know) that the Patient has problem X,	not relevant: Abstract	null value	PC thread 2/25/16

ID	Item	Content category	Use category	Source
65	3. It is the case that I don't know if the Patient has problem X,	not relevant: Abstract	null value	PC thread 2/25
66	4. It is the case that I don't know if the Patient has any problems (ie any).	not relevant: Abstract	null value	PC thread 2/25
67	5. It is the case (that I do know) that the Patient has no problems (ie none).	not relevant: Abstract		PC thread 2/25/16
68	patientAssertedStatus - unconfirmed/ excluded - scope of "I'm allergic to penicillin"	not relevant: Abstract	How to interpret the focal concept (drug, product, class) is orthogonal to negation	PC thread 2/29/16
69	clinicianAssertedStatus - confirmed/ refuted - "Patient is/isn't allergic to penicillin"	Pathological phenomenon absent		PC thread 2/29/16
70	no allergy to latex	Pathological phenomenon absent	Specific safety protocol	PC thread 3/1/16
71	closed head injury without loss of consciousness i.e., no loss of consciousness	Pathological phenomenon absent	Two observations. Conjunction introduces de Morgan's law if negated.	Kcampbelll
72	mother not present	Normal phenomenon absent		Unknown
73	not allergic to clindamycin (from MU test data - allergy list) - provenance is important to consider	Pathological phenomenon absent	Specific safety protocol	20160323 call
74	does not have diabetes (from MU test data - problem list) - provenance is important to consider i.e., no diabetes	Pathological phenomenon absent		20160323 call

ID	Item	Content category	Use category	Source
75	Preference that an action not be done: [Margaret]	Patient alignment	Preference	Negation call 3/23
76	Goal was not met	not relevant: Status	status of tracked goal	Negation call 3/23
77	won't admin flu vaccine due to egg allergy	Contraindication		Negation call 3/30/16
78	reason for discontinuing medication	Procedure not done		Negation call 3/30/16
79	Quitting smoking is not my goal	Patient alignment		Negation call 3/30/16
80	5-year survival is not my goal	Patient alignment		Negation call 3/30/16
81	follow up not needed	Contraindication		Negation call 3/30/16
82	patient did not show up	Patient alignment	May record as appointment status	Negation call 3/30/16
83	procedure not done because patient ate	Procedure not done		Negation call 3/30/16
84	did not use antithrombotic device on legs (supply)	Procedure not done	Measure or protocol exception	Negation call 3/30/16
85	did not supply electric wheelchair	Procedure not done		Negation call 3/30/16
86	did not provide vaccine because out of stock	Procedure not done		Negation call 3/30/16
87	did not do a variety of things for reason X	Procedure not done		FHIM call 4/1/16
89	No bleeding disorders	Pathological phenomenon absent	Safety process; not on problem list	NEMSIS
90	Not on anticoagulants or thinners	Risk factor absent		NEMSIS
91	Refute the absence of a condition	not relevant: Abstract	No concrete example found	
92	patient not pregnant	Risk factor absent		Negation call 4/13
93	“No Known Medicine Allergies,	Pathological phenomenon absent		MM mail 4/5

ID	Item	Content category	Use category	Source
	mom sts food Allergies”			
94	“no known med allergies but has food other allergies”	Pathological phenomenon absent		MM mail 4/5
95	“Father states pt has no known allergies, but states close family members have had severe reactions to: PCN, succinylcholine chloride, anectine, and quelizine”	Pathological phenomenon absent		MM mail 4/5
96	“no known allergies but has problems with ingesting some meds”	Pathological phenomenon absent		MM mail 4/5
97	“NO KNOWN. CODEINE CAUSES NAUSEA”	Pathological phenomenon absent	Question of whether codeine should be recorded with low criticality	MM mail 4/5
98	“Allergic to antibiotics but no known which class”	not relevant: Null		MM mail 4/5
99	hearing screening not done - needed for quality measure	Procedure not done		Negation call 4/20
100	Hand lost in accident	Normal phenomenon absent		invented 5/5/16
101	[condition in remission]	not relevant: Status	This is a problem clinical status	WGM 5/10/16
102	[condition refuted]	not relevant: Status	This is a problem verification status	WGM 5/10/16
103	Ted: nested negation See fhir dstu questionnaire	not relevant: Abstract	no concrete example found	WGM 5/10/16
104	[assert that a batch of stuff is absent]	not relevant: Abstract		WGM 5/10/16
105	[handle context conduction]	not relevant: Abstract	no concrete example found	WGM 5/10/16

ID	Item	Content category	Use category	Source
106	no family; no home; transportation; POA i.e., no family	Normal phenomenon absent	These are concerns	WGM 5/10/16
107	No next of kin	Normal phenomenon absent	These are concerns	decomposition of other requirements 6/21
108	no evidence of cancer (path)	Pathological phenomenon absent	Note that this assertion is qualified	decomposition of other requirements 6/21
155	no MRSA found (lab)	Pathological phenomenon absent		decomposition of other requirements 6/21
109	no family; no home; transportation; POA i.e., no home	Normal phenomenon absent	These are concerns	decomposition of other requirements 6/21
110	no family; no home; transportation; POA i.e., no transportation	Normal phenomenon absent	These are concerns	decomposition of other requirements 6/21
111	no family; no home; transportation; POA i.e., no POA	Normal phenomenon absent		decomposition of other requirements 6/21
112	No abnormality detected (BL) [openEHR-EHR-CLUSTER.exam-.v0]	Pathological phenomenon absent	Measure or protcol exception	openEHR exam pattern
113	Represent inference of "absence" from empty query - specific use not yet determined, but, e.g., CDS logging	not relevant: Abstract		CQI call 8/5
114	Reason for [absence or] delay in fibrinolytic therapy	Procedure not done	Measure of protocol exception	CQI - The Joint Commission Measure AMI-7a
115	Reason for discontinuation of parenteral anticoagulation therapy	Procedure not done		CQI - The Joint Commission Measure VTE-3

ID	Item	Content category	Use category	Source
116	Reason for delay in initiation of IV thrombolytic	Procedure not done		CQI - The Joint Commission Measure STK-4
117	Reason for not providing overlap medication (IV or subcutaneous anticoagulation therapy and warfarin on the same day)	Procedure not done	Measure or protocol exception	CQI - The Joint Commission Measure VTE-3
118	Reason for not providing tobacco cessation medication at discharege	Procedure not done		CQI - The Joint Commission Measure TOB-2, TOB-3
119	Reason for not providing Venous thromboembolism therapy or prophylaxis (medication or antithrombotic device use	Procedure not done	Measure or protocol exception	CQI - The Joint Commission Measures STK-1, VTE-1, VTE-6
120	Reason for not providing statin medication at discharge	Procedure not done		CQI - The Joint Commission Measure STK-6
121	Reason for not initiating antenatal steroids	Procedure not done		CQI - The Joint Commission Measure PC-03
122	rule out	not relevant: Status	ambiguous: use "provisional," "differential" or "refuted"	Negation call 8/10
123	to exclude a search result for specific code system	not relevant: query		FHIR list, 8/23
124	do not turn patient	Contraindication		FHIR Gforge comment
125	do not give blood or blood products	Contraindication		FHIR Gforge comment
126	do not flush central line	Contraindication		FHIR Gforge comment
127	do not take blood pressure on left arm	Contraindication		FHIR Gforge comment

ID	Item	Content category	Use category	Source
128	"patient says that they have never had chicken pox"	Pathological phenomenon absent		FHIR Zulip 9/5
129	not currently taking	Risk factor absent	Typically not represented as a provider intervention but as a fact about the patient.	FHIR Zulip 9/5
130	Patient does not consent to surgery	Patient alignment		PC 9/20/16
131	healed fracture (no fracture)	not relevant: Status	This is a concern status	PC 9/20/16
132	Patient is not NPO	Doesn't fit	Specific safety protocol	PC 9/20/16
133	1. Nothing to eat or drink until respiratory distress dissipates [respiratory distress absent]	Pathological phenomenon absent		VA Use Case CHF - ED 20150305
156	1. Nothing to eat or drink until respiratory distress dissipates [NPO]	Contraindication		VA Use Case CHF - ED 20150305
134	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	Patient alignment	Closed world	PQRS 47
135	Percentage of children 3 months through 18 years of age who were	Procedure not done	Closed world	PQRS 65

ID	Item	Content category	Use category	Source
	diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode			
136	Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period [condition not in remission]	not relevant: Status	this is a problem status	PQRS 69
137	Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy	Procedure not done	Closed world	PQRS 93
138	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since	Procedure not done	Closed world	PQRS 102

ID	Item	Content category	Use category	Source
	diagnosis of prostate cancer			
139	Percentage of adults 18 through 64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or 3 days after the episode	Procedure not done	Closed world	PQRS 116
140	Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period	Procedure not done	Closed world	PQRS 121
141	Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care	Procedure not done	Closed world	PQRS 122
142	Percentage of patients, regardless of age, with a current diagnosis of melanoma	Procedure not done	Closed world	PQRS 137

ID	Item	Content category	Use category	Source
	or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment			
143	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within 12 months	not relevant: Threshold	threshold, not negation	PQRS 141
144	Final reports for procedures using fluoroscopy that document radiation	not relevant: Comparison	2 conditional queries	PQRS 145

ID	Item	Content category	Use category	Source
	exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available)			
145	Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours	not relevant: Status	Clinical status of disorder	PQRS 166
146	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/ secondary	Procedure not done	Closed world	PQRS 243

ID	Item	Content category	Use category	Source
	prevention (CR) program for the qualifying event/ diagnosis who were referred to a CR program			
147	Percent of patients undergoing open repair of small or moderate sized non-ruptured abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7) i.e., who do not experience a major complication	not relevant: Threshold	Discharge threshold	PQRS 258
148	Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2)	not relevant: Threshold	Discharge threshold	PQRS 259
149	Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis.	Procedure not done	Closed world	PQRS 312
150	Patients aged 18 years and older who had surgery for primary rhegmatogenous	Procedure not done	Closed world	PQRS 384

ID	Item	Content category	Use category	Source
	retinal detachment who did not require a return to the operating room within 90 days of surgery.			
151	Percentage of patients with a diagnosis of primary headache disorder for whom advanced brain imaging was not ordered.	Procedure not done	Closed world	PQRS 419
152	Left hemiplegia	Normal phenomenon absent	implies right hemiplegia absent	team call 3/8/17
153	Closed head injury		implies no open head wound	team call 3/8/17
154	Do you have a spleen? Order check question for live vaccine	Normal phenomenon absent		team call 3/8/17
157	Patient has zero pressure ulcers	Pathological phenomenon absent	count question synonymous with "absent"	VA IA project
158	Head CT without Contrast	Procedure not done	Modality kind	IA group call 17/10/20
159	Are you experiencing chest pain now?	Pathological phenomenon absent		IA group
160	Have you experienced chest pain in the past?	Pathological phenomenon absent		IA group
161	When you experience chest pain does it radiate?	Pathological phenomenon absent		IA group
162	wound has no odor	Pathological phenomenon absent		IA group
163	What concerns are active?	Pathological phenomenon absent		

10.7.4. Maps

Table 10.4.

C-CDA key elements	FHIR key elements	Notes
<act classCode="ACT" moodCode="EVN"> <code code="CONC" codeSystem="2.16.840.1.113883.5.6"/> <statusCode code="active"/> <entryRelationship typeCode="SUBJ">	Concern not covered in FHIR example	This could be membership in a FHIR concern list; no examples exist
<observation classCode="OBS" moodCode="EVN" negationInd="true">	"resourceType": "AllergyIntolerance"	CDA observation is generic; FHIR implies allergy object
<code code="ASSERTION" codeSystem="2.16.840.1.113883.5.4"/>		C-CDA pattern follows TermInfo
Not covered in example subentry for problem status?	"clinicalStatus": "active", "verificationStatus": "confirmed",	FHIR statuses might be seen to narrow the scope of the negation; they are also optional. Would recommend removal. CDA status describes the record object; also supports a problem status (deprecated) but it's not specified in Allergy or used in example
<effectiveTime> <low nullFlavor="NA"/> </effectiveTime>		time required by C-CDA template
<value xsi:type="CD" code="419199007" displayName="Allergy to substance (disorder)" codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT"/>	"coding": "system": "http://snomed.info/sct", "code": "716186003", "display": "No Known Allergy (situation)"	Semantic mapping engages here 716186003 has 'allergic disposition' as its associated finding, the parent of 'allergy to substance'

Table 10.5.

CCDA to FHIR	FHIR to CCDA
When observation.code is Assertion & observation.value is a descendant of [allergic condition?], create a FHIR AllergyIntolerance resource	When valueCode is a descendant of [allergic condition?], create an observation with code of Assertion and value of the condition
If negationInd is null or false, use the allergic condition value	When valueCode is a Situation, with a findingContext of "known absent," put the associatedFinding value into the observation.value, and set the negationInd to True
If negationInd is True, use the situation with explicit context that asserts the the condition identified is known absent	Set required fields: statusCode to "completed" and effectiveTime to NA
If no such situation code exists, provide an expression	
clinicalStatus and verificationStatus are optional: do not populate unless the CDA instance includes a status	

C-CDA example:

http://hl7-c-cda-examples.herokuapp.com/examples/view/0ff4ddb1f9ccae6fd6aa9b5db98ae4d9f22290af

FHIR example: http://build.fhir.org/allergyintolerance-nka.json.html

11. KOMET support for description logic

11.1. Graphical representation

Part IV. Statement representation

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12. Representing Statements

> My Design in this Book is not to explain the Properties of Light by Hypotheses, but to propose and prove them by Reason and Experiments.
>
> —Isaac Newton

The purpose of this document is:

1. To define a *statement* for the purpose of data representation.

2. To define the types of *statements* and their *attributes*.

3. To provide a set of guidelines to model *statements*.

A statement is an expression of facts or plans. We will use two common—and misleadingly simple—statement topics: *Pulse Rate* and *Blood Pressure* as expository statements. If a patient told a clinician that their pulse rate was 120 and their BP was 160/95, or a clinician told a patient that they should keep their resting *pulse rate* below 70, and their *Blood Pressure* below 120/70, they would be mutually understood. The ability for the creator of the statement and the interpretor of the statement to each believe that they *understand* the statement is the first requirement.

12.1. Clinical Observation Modeling

Supporting Domain Semantics, Flexibility, and Interoperability
Walter Sujansky

12.1.1. Introduction

This white paper emerged from discussions among informaticists, computer scientists, and medical doctors about the appropriate modeling of clinical observations in information systems. The participants included representatives of the VHA-DoD, CIMI, HL7-FHIR, FHIM, SNOMED-CT, and OpenEHR initiatives[1]. The paper does not necessarily represent a consensus among the discussants or the viewpoint of any particular discussant. Its purpose is to provide background on the topic, to summarize a number of the viewpoints expressed, and to provide preliminary recommendations for further consideration. The contents are subject to further modification as the discussion evolves.

12.1.2. Statement Models

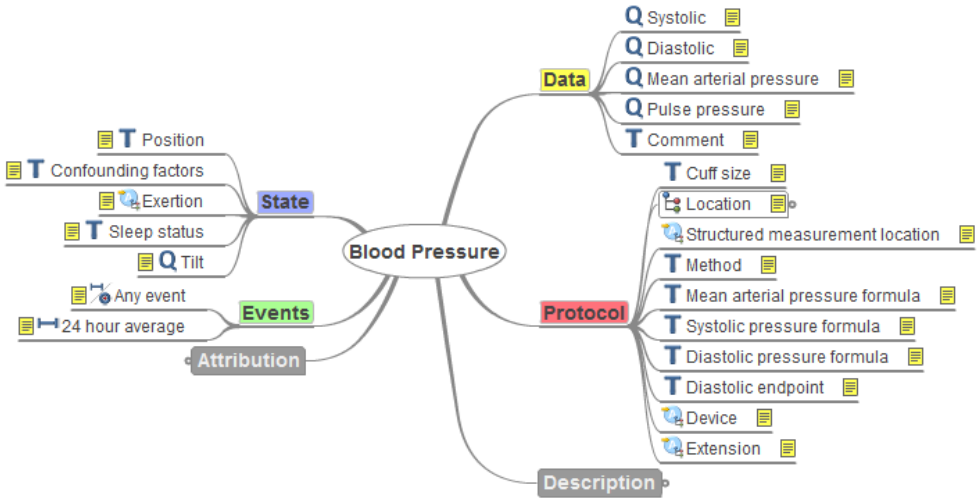
Statement models ([2]) are conceptual-level data models of the discrete statements about patients that can be stored in, processed by, and retrieved from a clinical information system. statement models are defined for discrete types of clinical statements such as blood pressure measurements, lab test results, physical exam findings, patient-reported symptoms, clinical diagnoses, and other observations.

statement models define the structure and semantics of discrete clinical observations as formal “types” that are later instantiated to represent specific recorded observations that apply to particular patients. Like object types in programming languages, these type definitions include enumerations of the specific data elements that may make up the observation, the datatypes used to populate those elements, and which

[1]VHA = Veterans Health Administration; CIMI = Clinical Information Modeling Initiative; HL7-FHIR = HL7 Fast Healthcare Interoperability Resources working group; FHIM = Federal Health Information Modeling.
[2]Statement models are also referred to as “Clinical Observation Models,” “Archetypes,” “Clinical Event Models,” and “Clinical Models” in the informatics literature and vernacular.

elements must be populated in every instantiated object versus optionally populated. Figure 12.1 shows the graphical depiction of an example statement model for a blood pressure measurement.

Figure 12.1. Example clinical object model for a blood pressure measurement



12.1.2.1. The Role of Clinical Observation Models

In general, clinical observation models serve at least two purposes.

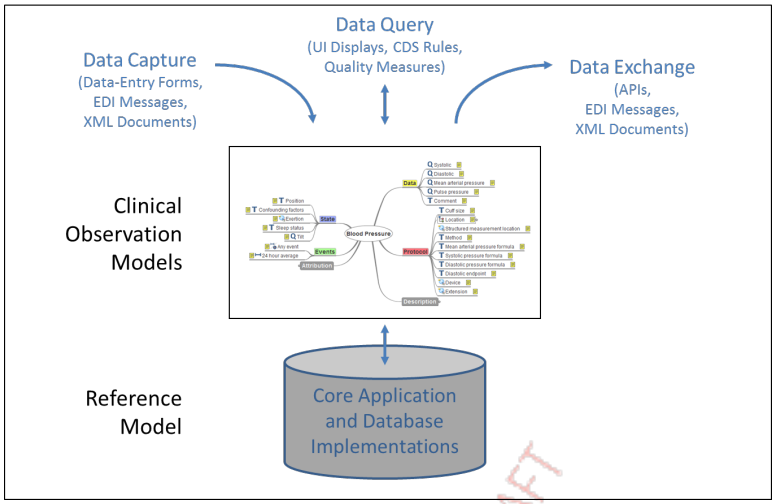
1. statement models *standardize* the capture, retrieval, and exchange of clinical observations within and between information systems. As seen in Figure 12.1, even relatively basic observations can comprise numerous sub-components. Different implementers of clinical information systems may model these sub-components and their relationships in arbitrarily different ways, which can prevent different software modules from managing and processing the same observations consistently and correctly. Formal and agreed-upon statement models provide a shared model of each type of observation that enables software modules created by different implementers to handle the same observations uniformly. Note that such software modules may comprise different parts of the same information system (such as the user interface and the rules engine of a single EHR) or entirely different information systems (such as distinct EHRs from different commercial vendors).

2. Statement models *de-couple* the creation and maintenance of domain-specific objects in clinical medicine (such as observations) from their technical implementation in software code and database structures. The types of clinical observations that may be recorded in software systems are numerous, diverse, and subject to relatively frequent modification over time, as well as customizations across clinical sub-domains. Meanwhile, the technical implementation of software applications and clinical databases is an arduous process that requires the careful design, detailed writing, and extensive testing of software code. Whenever changes are required to an application or database, a time-consuming and costly implementation process must be applied. Clinical applications and databases, however, that are implemented at a more abstract level can process *any* statement models that conform to a certain high-level reference model. Such implementations may not need to change as statement models are added or updated. statement models can therefore serve as conceptual-level objects that represent domain-specific data and drive domain-specific functionality without being tightly coupled, at least in theory, to the underling implementation of the information system.

Figure 12.2 shows how statement models serve both of these purposes in an information system. Note how the set of clinical information models serves as a “view” or “interface” to all clinical data that may be

stored by and retrieved from the information system. The design of the statement models is flexible and must conform only to a “reference model” of basic data structures. These basic structures are, in fact, the only objects tightly coupled with the underlying application and database implementations. In this manner, the statement models provide a standard conceptual model against which all data-input, data-query, and data-exchange functions operate, and that can be readily extended without (again, in theory) costly modifications to the underlying application and database. The approach for creating and maintaining information systems in this way is called *Model Driven Development*.

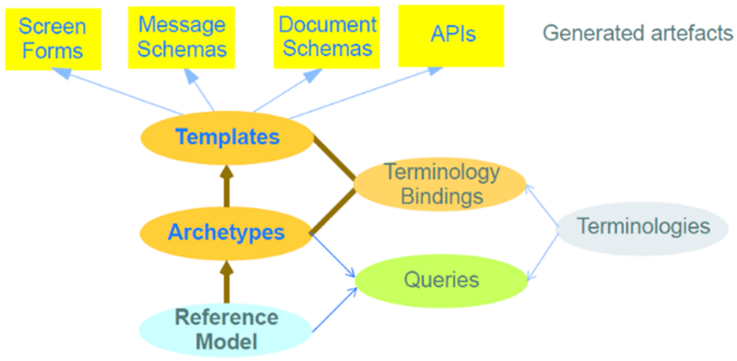
Figure 12.2. The role of clinical observation models in electronic health record systems



12.1.3. OpenEHR: An Example Framework for Clinical Observation Modeling

In considering the appropriate design of statement models, it’s useful to review how such models will be used in practice within a Model Driven Development architecture. OpenEHR[3,4] offers one such architecture that is relatively complete and mature, so it serves as a good example. Figure 12.3 illustrates the components of the OpenEHR architecture, which are further described below.

Figure 12.3. OpenEHR architecture

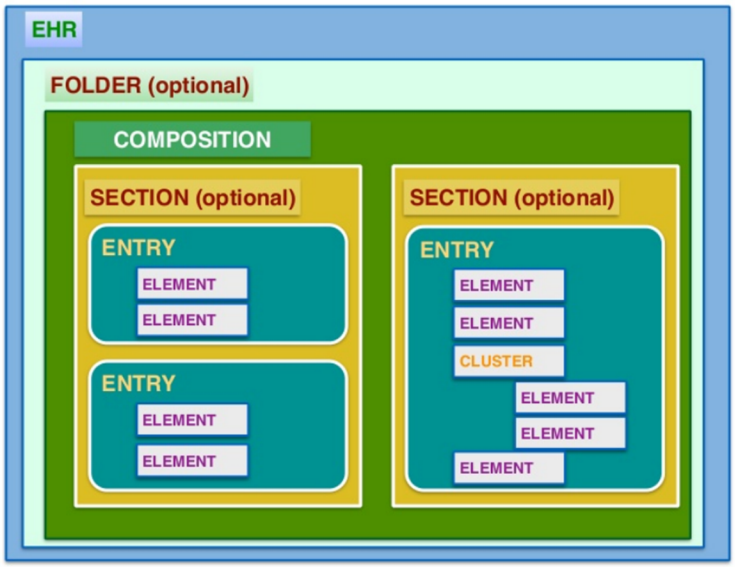


[3]Demski H, Garde S, Hildebrand C. Open data models for smart health interconnected applications: the example of openEHR. BMC Med Inform Decis Mak. 2016 Oct 22;16(1):137. (available at https://www.ncbi.nlm.nih.gov/pubmed/27770769).
[4]http://www.openehr.org/what_is_openehr.

12.1.3.1. OpenEHR Reference Model

The foundation of the OpenEHR architecture is a reference model that contains only the most generic set of objects and data types needed to define the contents of an EHR. These objects include organizing structures such as “Folders”, “Compositions”, and “Sections”, as well as generic clinical data objects such as “Entries”, “Clusters” of entries, and “Elements” that comprise the entries. The reference model also includes several dozen data types that may be used to populate the values of Elements, such as “Quantity”, “Text”, and “Timed Event”. Collectively, these constructs define the general building blocks available to construct more detailed models for representing clinical observations, actions, and other data in EHRs. Figure 12.4 shows the constructs of the OpenEHR reference model and how they are hierarchically organized to create the “scaffolding” for patient records.

Figure 12.4. OpenEHR Reference Model



Within the reference model, the “Observation” class is a specific sub-type of the “Entry” object, and it is used to record information from a direct observation or measurement on a patient or to record the perspective of the patient, such as in history taking. The Observation class includes only a small number of data elements that are inherited by all clinical observation models, such as “Subject” (the person to whom the observation applies) and “Information Provider” (the person or agent who generated the observation). Otherwise, all Entries and Elements used to record actual observations are specified within sub-types of the Observation class, which OpenEHR calls “Archetypes.”

12.1.3.2. OpenEHR Archetypes

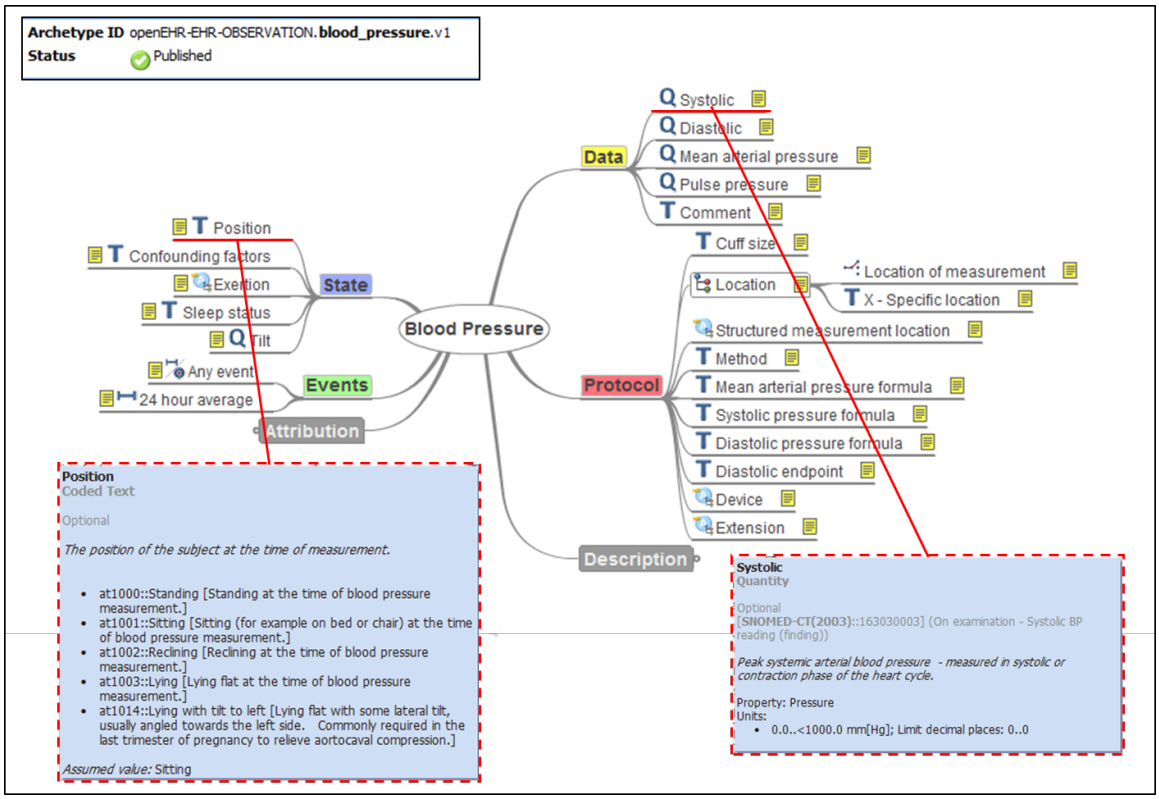
Archetypes are clinical object models that specify:

1. the set of Elements that may be used to represent various kinds of observations
2. the datatypes used to populate those Elements
3. which Elements must be populated versus being optional, and
4. whether Elements can have only one or may have multiple values.

The values of Elements, themselves, may be collections of other Elements (“Clusters”) or instances of other Archetypes (effectively, nested Archetypes). Figure 12.5 shows the graphical representation of an OpenEHR archetype.

For primitive Elements, the Archetype may define further constraints that define how the Element may be populated, as shown in the callouts of Figure 12.5. For example, the value of the “Systolic” Element in the Blood Pressure Artifact is specified to be a “Quantity” datatype, to represent the property of “Pressure”, and to be recorded using the units of measure “mm[Hg]”. Similarly, the “Position” Element is specified to be a “Coded Text” datatype and to be populated by one of several enumerated code values, with the code for “Sitting” being the default if no other value is specified.

Figure 12.5. Example of an OpenEHR Archetype



OpenEHR Archetypes must be defined using only the constructs of the underlying Reference Model, as shown in Figure 12.3. This constraint ensures that the Archetypes may be stored and processed by the underlying database and application implementations, which are otherwise loosely bound to the specific structures of the Archetypes themselves.

The OpenEHR framework uses a specific structured language to define Archetypes, the Archetype Definition Language (ADL). Figure 12.5 shows the graphical rendering of an Archetype, although the actual definition is specified using a text-based ADL expression (not shown). Other Model-Driven Development frameworks, of course, may use different languages for defining statement models and different graphical rendering methods.

Like structured data types and object classes in programming languages, Archetypes specify and constrain in detail how instances of actual data (clinical observations, in this case) may be represented within the information system. These specifications govern how software modules must create instances of those observations (i.e., modules such as graphical user interfaces or EDI interface engines) and how software modules may retrieve and process instances of those observations (i.e., modules such as user displays or decision-support rule engines). Using conceptual-level Archetypes rather than low-level data structures for these purposes allows domain experts to formally specify Archetypes, and (in theory, at least) de-couples Archetype specifications from low-level implementation dependencies.

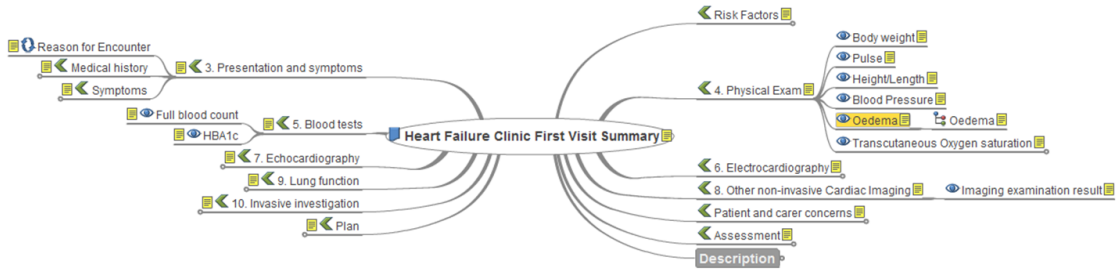
OpenEHR currently includes several hundred Archetypes[5], including many for clinical observations. The framework, however, remains very much a work in progress, and many Archetypes remain in draft form.

12.1.3.3. OpenEHR Templates

To support specific use cases and system functions, OpenEHR allows Archetypes to be combined and/or further constrained to create purpose-specific data structures called “Templates”. Templates may then drive the automated generation of computing artifacts used to collect, retrieve, or export clinical observations (see Figure 12.3).

Figure 12.6 shows an example OpenEHR Template that represents the information captured during an initial visit to a heart failure clinic. Note that the template combines a number of Archetypes, such as Blood Pressure, Pulse, and Full Blood Count, as well as adds navigational and organizational nodes such as “Physical Exam.” The latter nodes are also Archetypes, specifically sub-classes of the Section object specified in the Reference Model.

Figure 12.6. Example of an OpenEHR Template



Although not shown in Figure 12.6, Templates may also include additional constraints applied to their constituent Archetypes. Such constraints may entail the inclusion of only a subset of the Archetype’s Elements, the allowance of only a subset of the coded values specified for an Element, the designation of default values for Elements, etc. The purpose of these constraints is to customize an Archetypes for use in a specific context, while ensuring that any data collected or retrieved using Templates that contain the Archetype conform to the Archetype’s underlying constraints.

For example, Figure 12.7 shows a graphical user interface (“Screen Form”) for data entry generated from the heart-failure Template in Figure 12.6. Because the Template design constrained the Blood Pressure Archetype to include only the “Systolic” and “Diastolic” Elements (as opposed to the full set of Elements shown in Figure 12.5), the Screen Form displays only those two Elements. Note that the display includes the units of measure and allowed value ranges specified for the “Systolic” and “Diastolic” Elements, as derived from the complete Archetype. In this manner, all data collected via Screen Forms generated from the Template in Figure 12.6 will conform to the constraints specified within the Archetypes that the Template includes. This aspect of Model Driven Development allows the observation modeling features and constraints that are formally specified in Archetypes to be uniformly and automatically applied across various uses of the Archetypes (through Templates) within and across information systems.

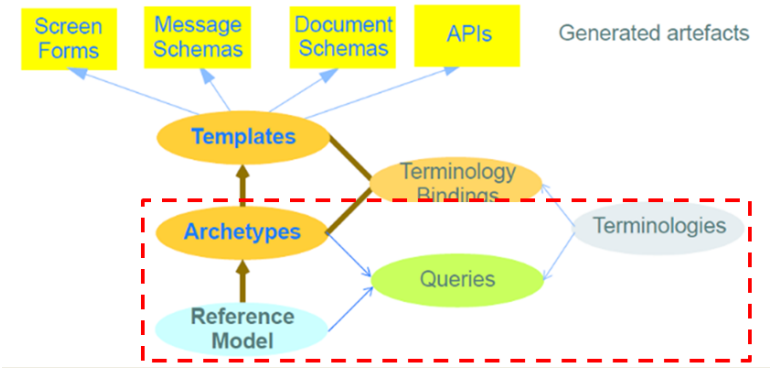
[5]See http://www.openehr.org/ckm/ for an online listing.

Figure 12.7. Example of a Screen Form generated from an OpenEHR Template

12.1.3.4. Querying OpenEHR Data

Although OpenEHR Templates may combine and further constraint Archetypes to enable purpose-specific data collection and data processing, the querying of OpenEHR data need not consider the structure of any individual Templates that were used to instantiate clinical observations. Rather, querying requires knowledge of only the Archetypes, the underlying Reference Model, and any controlled terminologies used in the definition of Archetypes (See Figure 12.8 for a graphical representation of these dependencies).

Figure 12.8. Architectural components used in querying of OpenEHR data.



As discussed above, all persisted observation data must conform to the constraints of the Archetypes used to collect them (even if those Archetypes are combined and further constrained in Templates). Further, none of the navigational elements of Templates (such as the grouping of Archetypes into a “Physical Exam” category, as shown in Figure 12.6) influence the semantics of the Archetype data collected via Templates. Specifically, the semantics of a clinical observation represented by an Archetype should exist independently of any encompassing navigational or organizational category in which that Archetype may appear within a Template (Archetypes must be carefully designed to confer this property).

At the same time, queries may reference sub-parts of an OpenEHR medical record in which the Archetype instances were recorded. These named sub-parts of a record, such as “Problem List” and “Medication Order List,” are also Archetypes defined to specialize the “Section” class of the Reference Model (see Section 12.1.3.1).

Finally, queries may also reference the terminology model from which specific codes were drawn when defining clinical observation Archetypes. For example, a query could seek to retrieve any patient with a diagnosis subsumed by the coded concept “Cardiovascular Disease,” although no Archetype specifically references that very general disease concept. Such a query would rely upon the hierarchical subsumption relationships represented in the terminology model to associate the general “Cardiovascular Disease” con-

cept with the specific disease concepts (such as “Atherosclerosis”) that are actually referenced in defined Archetypes.

12.1.4. Patterns for Clinical Observation Modeling

Model-Driven Development provides a useful framework to build EHR systems that include standardized representations of medical data and that are flexible and extensible. However, the ultimate effectiveness of these EHR systems depends to a great extent on the specific design of the clinical observation models they include. As discussed, the same types of observations may be modeled in many different ways, and the design choices made influence the ease and consistency with which the clinical observation models can be used. This section discusses some of those choices and the design criteria that should govern them.

12.1.4.1. Clinical Observations in the Abstract

It’s useful to consider what clinical observations essentially are. In the abstract, they are discrete patient descriptors that document information gathering, diagnostic testing, and decision making about patients. Such descriptors may include, for example, a diagnosis, an LDL cholesterol level, a systolic blood pressure measurement, an Apgar score, a patient-reported symptom, or a family history.

Each clinical observation pertaining to a patient consists in the abstract of two general components:

- The Aspect of the patient that is being described, either implicitly or explicitly. For example, the observation “The patient’s systolic BP is 130 mmHg” explicitly describes the Aspect “Systolic Blood Pressure,” whereas the observation “The patient has asthma” implicitly describes the aspect “Diagnosis”. If the general form of a patient descriptor is “The patient has X of Y”, the aspect denotes “X”.

- The Value or Magnitude of the descriptor. For example, the observation “The patient’s systolic BP is 130 mmHg” specifies the magnitude “130” whereas the observation “The patient has asthma” specifies the value “Asthma”. If the general form of a patient descriptor is “The patient has X of Y”, the value or magnitude denotes “Y”.

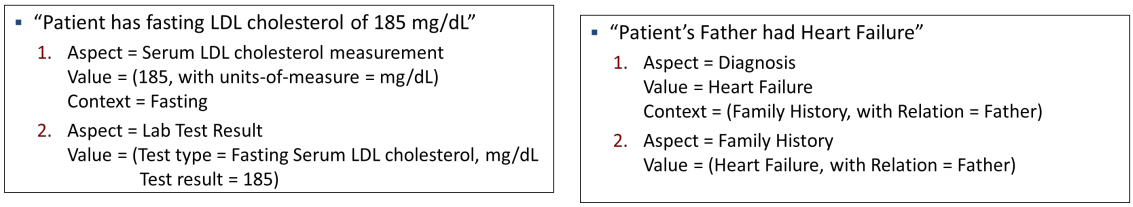
The aspect and the value/magnitude of an observation may, themselves, be further modified or qualified to denote the complete semantics of the observation. For example, the aspect “Systolic Blood Pressure” in the example above could be further qualified by the date/time that the measurement was taken or the position of the patient at the time it was taken. Likewise, the magnitude “130” in the example above could be further qualified to specify that the units of measure that apply are “mmHg”.

Sometimes, a third component of a clinical observation is specified:

- The Context in which the clinical observation occurred or was recorded. This component typically denotes information that is important to record but does not directly modify the Aspect or the Value/Magnitude. Examples may include who specifically reported the observation (e.g., the patient versus the patient’s mother) or what instrument or technique was used to collect the observation (e.g., by rhythm strip versus 12-lead EKG). Notably, there is sometimes a fuzzy distinction between information that modifies the Aspect of a clinical observation and information that denotes its Context. For example, the fasting state of a patient at the time a serum LDL cholesterol measurement was taken could be considered to denote the Context of the measurement (with the Aspect being simply “Serum LDL Cholesterol”) or the fasting state could denote a qualifier of the Aspect (with the Aspect being “Serum LDL Cholesterol, with FastingState = True”).

Based on these abstract components of a clinical observation, the same observation can be modeled in different ways. The examples in Figure 12.9 show reasonable variations in the use of aspect, value, and context to represent the same observation semantics.

Figure 12.9. Example variations in modeling of clinical observations



12.1.4.2. General Design Patterns for Clinical Observations

At least three general structural patterns may be considered for the design of clinical observation models, Assertion, Evaluation, and Belief:

- Assertion pattern. No Aspect is explicitly specified; a Value, with possible qualifiers is always specified; a Context is optionally specified. Example:
  - Aspect = NULL
  - Value = (Asthma, with type = intrinsic, with severity = mild, with status = active)

  This pattern assumes that, for every Value, the Aspect of the patient that is being described is implicit and unambiguous, and therefore need not be explicitly specified. The pattern is most naturally suited for symptoms, exam findings, past medical history findings, and diagnoses, where the assumption usually holds. However, exceptions exist. For example, the Assertion pattern cannot distinguish between a patient-reported symptom of "arm weakness," and a physical exam finding of "arm weakness" (unless "patient-reported" or "physical-exam" are denoted as Contexts). .

- Evaluation pattern. An Aspect is always specified; a Value, with possible qualifiers is always specified; a Context is optionally specified. Example:
  - Aspect = Serum LDL Cholesterol
  - Value = (185, with units-of-measure = mmHg)
  - Context = Fasting

  This pattern explicitly specifies the Aspect and considers it the "question" that the observation is addressing. The Value constitutes the "answer" to the question. The pattern is most naturally suited to observations represented as "attribute/value" pairs, such as simple testing results (blood glucose, FEV1), scoring instruments (Apgar, Braden scores), and patient characteristics with quantitative or ordinal values (pulse, pain intensity).

- Belief pattern. An Aspect, with possible qualifiers, is always specified; a Value, with possible qualifiers is always specified; a Context is optionally(but rarely) specified. Examples:
  - Aspect = Diagnosis
  - Value = (Asthma, with type = intrinsic, with severity = mild, with status = active)
  - Aspect = Serum LDL Cholesterol, with Fasting-State = True
  - Value = (185, with units-of-measure = mg/dL)

  This pattern is the most general and can be applied equally to symptoms, findings, diagnoses, test results, scoring instruments, and quantitative characteristics. It does require, however, that an Aspect is explicitly specified in all cases as part of the observation model (although this constraint does not necessarily require that the Aspect be specified by users at the time the observation is instantiated, since user-interface functionality may populate the Aspect automatically and "behind the scenes" for observations where it is implied and unambiguous).

[6]Walker D. GP Vocabulary Project—Stage 2 Report: SNOMED Clinical Terms (SNOMED CT); November, 2004. Available from: https://www.semanticscholar.org/paper/Gp-Vocabulary-Project-Stage-2-Snomed-Clinical-Walker/4353b85e1afbeb93b81b38398f94882c6d5119cd.

12.1.4.3. Desiderata for Clinical Observation Model Design Patterns

Given that multiple design patterns exist for clinical observations, it's useful to consider design criteria that can guide modeling choice. Among the best known criteria for designing clinical concepts are the properties of Understandability, Reproducibility, and Usability[6], defined as follows:

- Understandability: Concept definitions should be understandable by average clinicians and others who use the definitions (such as data analysts), given brief explanations.
- Reproducibility: The retrieval and representation of the same concept should not vary according to the nature of the interface, user preferences, or the time of entry.
- Usability: One should not model concepts, concept properties, or distinction among concepts for which there is no current use in healthcare.

Among these criteria, reproducibility is arguably the most important in selecting optimal design pattern for clinical observations, because the property of reproducibility most influences the value of clinical observations as *standardized* representations of clinical information that can be shared by different software modules and information systems. As illustrated in Figure 12.2, multiple software modules may use the same clinical observation models to implement distinct functions. To ensure that the creation, use, and exchange of clinical data is done uniformly, the clinical object models must not vary according to the contexts in which they are created or processed, i.e., they must be reproducible.

To help ensure reproducibility, modelers should follow at least two guidelines when creating clinical observation models: Avoid arbitrary variation and explicitly represent clinically relevant distinctions. Figure 12.10 illustrates relevant examples and counterexamples of these guidelines. Note that the first example shows three different modeling patterns for the same type of observation. In this case, it would be preferable to model all observations of this type using only one of the patterns (applying any one of the patterns to all three observations is left as an exercise for the reader). The second example shows an observation for which the complete clinical meaning of the finding ("Weakness in Right Arm") depends on whether it was objectively discerned by the physician through examination, or just subjectively reported by the patient.

Figure 12.10. Guidelines for designing clinical observation models

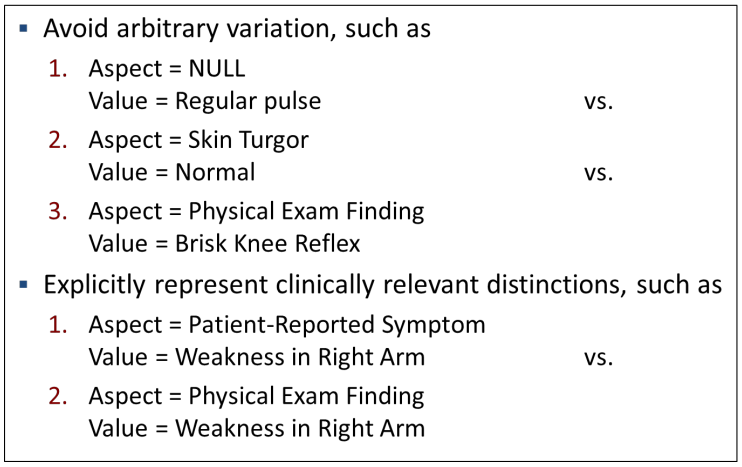
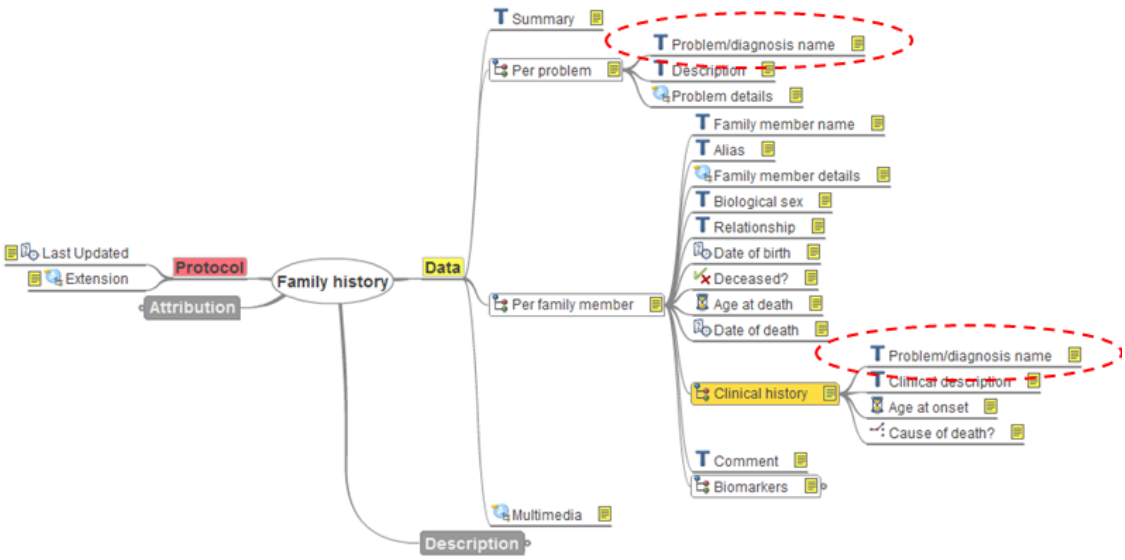


Figure 12.11 shows a poorly designed clinical observation model that violates the reproducibility criterion. Using this model, the family history of a particular problem or diagnosis could be represented in two different ways, depending on the user's preference. Such variation in the representation of the same observation entered by one user or another will necessarily complicate subsequent data querying and analysis. For

example, a data analyst seeking all patients with a family history of coronary artery disease would have to search both the “Per problem” and the “Per family member” paths of each “Family History” observation stored in the EHR.

Figure 12.11. A poorly designed clinical observation model



12.1.4.4. Recommendations

Given the Model-Driven Development approach and the design considerations described above, two general options exist for specifying clinical observation models:

1. Standardize on a single design pattern for all clinical observation models (i.e., either the Assertion, Evaluation, or Belief pattern described in Section 12.1.4.2). This approach may facilitate the tasks of data analysts and software developers, who will need to learn many clinical observation models to use them effectively in application development, CDS rule design, clinical measure specifications, etc.

   With this option, the “Belief” pattern is likely preferred, as it is the most generic and supports all manner of clinical observations, as described in Section 12.1.4.2.

2. Allow multiple design patterns, specific to individual types of observations models (e.g., all lab results, all symptoms, all physical exam findings), or even to specific observation models (e.g., distinct models for skin turgor versus knee reflex). This approach offers maximum flexibility in modeling specific clinical observations in the most natural manner. Because individual clinical observation models will often be quite complex and extensive in any case (as seen from the examples in this report), the basic pattern they follow (i.e., Assertion vs. Evaluation vs. Belief) may be the least of the variations among them that data analysts and software developers will need to be concerned with. Hence, it may not practically matter whether clinical observation models conform to a single pattern or to multiple patterns, as long as the models are clearly documented.

In net, option 2 may be the preferred approach. Modelers should allow for multiple design patterns, as needed, but strive for maximum standardization for any specific type of observation (i.e., lab result versus symptom versus diagnosis, etc.). Such an approach will enable maximum flexibility for modeling different observations in an optimal fashion, while minimizing arbitrary variations among clinical observation model designs.

12.2. Needs title

A *statement* represents an entry in a record that documents in a structured/computable manner information about a subject of information, such as a patient or a relative of the patient, and that is asserted by a particular source, recorded, and potentially verified.

Clinicians author clinical statements and enter them into their organization's electronic health record (EHR). Clinicians typically input the information via a manner that we call here the *clinical input form (CIF)*. However, the CIF is not a literal form that clinicians select and enter data in. Rather, it refers to the manner in which information is presented to the clinicians and how they input the data, such as by constraining the information to allow only certain values to be entered, such as through a drop-down list or radio button, or breaking up large chunks of related information into smaller parts. For example, when a clinician orders a medication, rather than selecting this information all at once with a single item, they will choose the various parts of the medication order, such as:

- Kind of drug and strength (e.g., Acetaminophen 150 mg)
- Amount and how often the patient should take the medication (e.g., 1 tablet twice daily)
- Duration (2 days)
- Any constraints (e.g., do not exceed a total daily dosage of 600 mg)

Ideally, the way the information is presented to clinicians is in a manner that is most efficient for the clinicians to use. However, what is an efficient way for clinicians to select and input data may not be the most efficient way for data analysts to use when they are querying data once it has been normalized and stored in a database, such as when creating a new CDS rule or compiling prevalence statistics. For this, the data is normalized using the *analysis normal form (ANF)* and stored in a database. Again, the ANF is not necessarily a physical structure, but is how a data analyst might see the data when they are looking at it in a database, and not as clinicians would see it in the user interface (i.e., CIF).

- Clinician collects data à Clinical Input Form
- Data is normalized à Transformation process from CIF to ANF à Representable/storable in multiple types of databases, which could include VistA but a separate process would need to be performed to make that happen.
- Data analyst who is using or querying the data (e.g., creating a CDS rule or working on prevalence statistics) à ANF (it is how the data is represented or stored in the database; must know enough about the data to know what is stored in the topic vs. what is stored as a result or detail)

Table 12.1. General Statement Model

Statement
Narrative:
Topic:
Subject of information:
Statement time:
Act:

Editorial Rule 12.1. Topic

The *topic* is the center of interest or activity represented by the statement. A few examples of topics include [Insulin dependent diabetes mellitus type 1A] , [Pulse rate] , [Administration of medication] . For each of these topics, the information that must be described is quite different, so CIMI describes topic types that contain the appropriate properties to describe the required information for the given topic. The number of topic types will change as CIMI progresses, but currently the allowable topic types are EvaluationResult, Assertion, and Procedure.

Editorial Rule 12.2. Subject of information

The *Subject of Information* represents who or what the statement refers to. In most cases, the *Subject of Information* refers to who or what the record within which this statement is embedded is about. In such cases, the *Subject of Information* may be referred to as the *Subject of Record*. In other cases, the *Subject of Information* may refer to a relative of the *Subject of Record* (mother, father, uncle...), and would be recorded appropriately in such circumstance.

Editorial Rule 12.3. Statement time

The Statement time is the time the statement is made. The statement time is independent of the period of time that a statement refers to, which may be past, present, or future, and is represented separately as part of the act.

Editorial Rule 12.4. Act

The Act is information that details the act related to the topic, either a request act, or a performance act.

12.2.1. Statement Layer Concerns

The statement layer is primarily concerned with representation of instance data.

12.2.1.1. Measurement

12.2.1.2. Reporter

12.2.1.3. Performer

12.2.1.4. Subject of information

12.2.2. Crosscutting Concerns

12.2.2.1. Query

12.2.3. Understandable, Reproducible, and Useful

Given a narrative, fill out the form

Example 12.1. Pulse observed to be 110

A patient tells their health-care provider that they had a [# Pulse rate] on Monday, April 23rd at 9:15 am Pacific Standard Time.

Example 12.2. Resting pulse requested to be less than 70

A health-care provider tells a patient that they would like their resting pulse to be less than 70.

In the case of a human interpretor, they can often believe that they understand a statement, even when there is a great deal of information missing from the statement. In the above example, it was probably assumed that the units used to measure the blood pressure was mm/Hg, that the patient was at rest and seated, and that the pressure was measured from a brachial artery, either the brachial artery in the right arm, or the brachial artery in the left arm.

In a face-to-face interaction, statements can often be clarified to confirm assumed content, and to ensure effective communication of information from the creator to the interpretor. When recording statements for future interpretation, such verification of assumed content cannot be performed. This inability to clarify statements after the fact requires that statements sufficiently record the circumstances necessary to reproducibly interpret the statement.

Editorial Rule 12.5. Understandable

Editorial rules must be understandable to an editor or user simply by reading the definition or rule. A statement must be understandable to the creator and the interpreter.

Editorial Rule 12.6. Reproducible

Independent observers encountering a topic and equivalent circumstances will record equivalent statements

Editorial Rule 12.7. Useful

The representation must be useful for the purposes that the modeling is intended to support.

12.2.4. Structured Statement

Narrative: Pulse observed to be 100 bpm on Monday, April 23rd at 9:15 am Pacific Standard Time

Action Topic: Pulse

Circumstance: facts or conditions relevant to an action; Two types of action: request, performance

Table 12.2. Patient pulse representation of narrative with Structured Statement

Performance Statement	
Narrative:	Pulse observed to be 100 bpm on Monday, April 23rd at 9:15 am Pacific Standard Time
Topic:	Pulse

Performance Statement		
Subject of information:	Patient of Record	
Statement time:	Monday, April 23rd 2018 at 9:15 am Pacific Standard Time	
Act:	Circumstance:	Timing:
	Result:	120 beats per minute

12.2.4.1. Modeling Principles

The modeling guidelines were developed in accordance with the principles shown below.

- **Separation of Concerns:** As defined by Wikipedia[7]: Separation of Concerns (SoC) is a design principle for separating a computer program into distinct sections, such that each section addresses a separate concern. A concern is a set of information that affects the code of a computer program. A concern can be as general as the details of the hardware the code is being optimized for, or as specific as the name of a class to instantiate. A program that embodies SoC well is called a modular program. Modularity, and hence separation of concerns, is achieved by encapsulating information inside a section of code that has a well-defined interface. Encapsulation is a means of information hiding. Layered designs in information systems are another embodiment of separation of concerns (e.g., presentation layer, business logic layer, data access layer, persistence layer). The value of separation of concerns is simplifying development and maintenance of computer programs. When concerns are well-separated, individual sections can be reused, as well as developed and updated independently. Of special value is the ability to later improve or modify one section of code without having to know the details of the other sections, and without having to make corresponding changes to those sections.

  The use of immutable objects (see principle B Immutability below) is a technique that fulfills the Separation of Concerns principle.

  Attributes that describe specific semantic concepts should be grouped together into a single class and not be spread across a number of classes. Doing the latter leads to tight coupling between classes. Doing the former leads to better decomposition of a potentially complex domain.

- **Example:** Attributes for a Role (e.g., Practitioner) should not be mixed with attributes for an Entity (e.g., Person). This allows a person to assume a number of roles over their lifetime or to function in more than one role.

- **Immutability:** An Immutable Object as defined by Wikipedia[8]: Used in object-oriented and functional programming, an immutable object is something that cannot be changed after it is created, in contrast to mutable objects that can be changed after they are created. There are multiple reasons for using immutable objects, including improved readability and runtime efficiency and higher security.

  Although building immutable objects…requires a bit more up-front complexity, the downstream simplification forced by this abstraction easily offsets the effort. One of the benefits of switching to a functional mindset is the realization that tests exist to check that changes occur successfully in code. In other words, testing's real purpose is to validate mutation – and the more mutation you have, the more testing is required to make sure you get it right. If you isolate the places where changes occur by severely restricting mutation, you create a much smaller space for errors to occur and have few plates to test.

  Finally, one of the best features of immutable classes is how well they fit into the composition abstraction.

[7] https://en.wikipedia.org/wiki/Separation_of_concerns
[8] https://en.wikipedia.org/wiki/immutable_object

- **Composition Over Inheritance:** Composition over inheritance (or composite reuse principle) in object-oriented programming is the principle that classes should achieve polymorphic behavior and code reuse by their composition (by containing those instances of other classes that implement the desired functionality) rather than inheritance from a base or parent class.

  To favor composition over inheritance is a design principle that gives the design higher flexibility. It is more natural to build business-domain classes out of various components than trying to find commonality between them and creating a family tree.

  Initial design is simplified by identifying system object behaviors in separate interfaces instead of creating a hierarchical relationship to distribute behaviors among business-domain classes via inheritance. This approach more easily accommodates future requirements changes that would otherwise require a complete restructuring of business-domain classes in the inheritance model.

  Item for Consideration: *Should we say that we only allow inheritance for a single concern, i.e., we can subtype measurement but not subtype a combination of phenomenon type and measurement type?*

- **Statement Model Stability:** Stability is different from immutability. Stable means that the model can still meet unanticipated requirements without having to change. It is not acceptable to change the model every time a new way to administer a drug or to treat a condition is identified. By representing these types of potentially dynamic concerns in the terminology expressions, as opposed to static fields in a class structure, we do not have to change the model every time something new is discovered. As Terry Winograd said, anticipating breakdowns, and providing a space for action when they occur, is a design imperative.

  In some regards, in this context “stable” means “not brittle.” A model easily broken by changes that someone could anticipate is one possible definition of brittle. A stable model is critical in the phase of a known changing landscape. We do that by isolating areas of anticipated change into a dynamic data structure. That dynamic data structure may also be immutable in an object that represents a clinical statement.

- **Overall Model Simplicity:** In cases where different principles collide, we shall favor the enhancement of simplicity of the entire system over simplicity in one area of the system.

- **Cohesion:** Related classes should reside in the same module or construction. The placement of a class in a module should reduce the dependencies between modules.

- **Reusability:** Architectural patterns should encourage class reusability where possible. Reusability may further refine encapsulation when composition is considered.

- **Assumption-free:** Implied semantics must be surfaced explicitly in the model.

  - **Example:** Implicit in the statement, “I order a book from Amazon” are: paying for the book, delivery of the book to some location, and the transfer of ownership of the book from the vendor to the client.

- **Design by Composition and/or Class Specialization:** The capture of additional model expressivity must be captured by composition and/or by class specialization. The modeling approach should avoid the use of design by constraint (except for terminology binding and attribute type constraints) as it violates proper decoupling and encapsulation. An example of design by constraint is to create a single procedure class containing all attributes for all known procedures and constraining out irrelevant attributes in a more specialized model. This approach is very difficult to implement and violates numerous object-oriented best practices.

- **No False Dichotomies:** Dichotomies that are not completely disjoint (mutually exclusive) lead to arbitrary classification rules and result in ambiguity based on different assumptions about the domain. These must be avoided.

- **Model Should Avoid Semantic Overloading (semantic precision):** Semantic overloading occurs when a model attribute's meaning changes entirely, depending on context. While the refinement of the semantics of an attribute in a subclass is acceptable, a change of meaning is problematic. For instance, in FHIR, the Composition class defines an attribute called Subject. In some subclasses, the attribute may be the entity that this composition refers to (e.g., the patient in a medical record). In other cases, it is the topic being discussed by the composition (e.g., a medication orderable catalog).

- **Convention Over Configuration:** Convention over configuration (also known as coding by convention) is a software design paradigm used by software frameworks that attempt to decrease the number of decisions that a developer using the framework is required to make without necessarily losing flexibility.

- **Model Consistency:** Patterns should allow the consistent representation of information that is commonly shared across models. For instance, attribution and participation information should be captured consistently. Failure to do so forces implementers to develop heuristics to capture and normalize attribution information that is represented or extended differently in different classes (e.g., FHIR).

- **Model Symmetry:** There should be symmetry in the models wherever we can have it.

- Iterative development and validation using use cases

Table 12.3. Pulse Measurement Statement

Performance Statement		
Narrative:		
Topic:		
Subject of information:		
Statement time:		
Performance Act:	Circumstance:	Timing:
	Result:	120 beats per minute

Table 12.4. Pulse Request Statement

Request Statement		
Narrative:		
Topic:		
Subject of information:		
Statement time:		
Request Act:	Circumstance:	Timing:
		Repetition:
	Requested result:	< 70 beats per minute

12.2.4.2. Measurement

Editorial Rule 12.8. Measurement

Define measurement

Editorial Rule 12.9. Lower bound

The lower bound is the smallest reported value of the measurement. If only one value is reported, then the lower bound is the same as the upper bound.

Editorial Rule 12.10. Upper bound

The upper bound is the largest reported value of the measurement. If only one value is reported, then the upper bound is the same as the lower bound.

Editorial Rule 12.11. Include lower bound

Indicate if the lower bound is within the interval represented by this measurement, or outside the interval represented by this measurement.

Editorial Rule 12.12. Include upper bound

Indicate if the upper bound is within the interval represented by this measurement, or outside the interval represented by this measurement.

Editorial Rule 12.13. Resolution

An optional numeric representation of the resolution of this measurement, using the same semantics as the measurement itself.

Editorial Rule 12.14. Measure semantic

A concept that defines the semantic interpretation of the upper and lower bounds of this measurement.

12.2.5. Statement Types

The types of clinical statements are listed and described below. The rationale for selecting these types is: Clinicians basically do two categories of things with a patient that need to be documented as clinical statements:

1. **Performance of action**: Actions may include passive observation of a phenomenon related to patients and their health status or family history, and may also include active interventions, such as providing education or administering medications or documenting that a patient is participating in exercise to improve their overall health status.

2. **Request for action**: Requests for future actions may include defining goals, consultation with other providers, or active interventions.

NOTE: Given that this work is not finalized yet, it is possible that additional clinical statement types may need to be added in the event during creation of the KNARTs there are clinical terminology artifacts identified that do not fit into any of the types listed above.

Any statement that states or implies an “if/then” clause should be expressed and captured as an ECA rule

Example:

- “Free-text reminder: Consider [ordering X procedure] for patients with suspected pericarditis, myocarditis, hypertrophic cardiomyopathy, or pulmonary hypertension.”

- Implied “if/then” clause: **IF** pericarditis, myocarditis, hypertrophic cardiomyopathy, or pulmonary hypertension is suspected – **THEN** consider ordering X procedure.

- Rather than capturing the above statement as a free text reminder, building an appropriate ECA rule should be considered.

12.2.5.1. Performance Statements

An action statement describes an action that has previously been performed, and – if applicable - the results of that action. As shown in the examples below, this can range from documenting that a subject of record:

- Was observed to have the presence or absence of a clinical phenomenon
- Underwent a specific test/screening or procedure, and its resultant value, if any
- Was administered a medication or other substance
- Was provided educational materials
- Has any other state or specific characteristic that is clinically relevant

If the action statement:

- Regards a measurement that was taken, all information about that measurement will be included as part of the clinical statement, such as its value and unit of measure and any details about how the measurement was taken.
- Results in an order(s) placed during the same encounter that was made to learn more about the phenomenon or to monitor it, then a link will be made to the order(s).

Examples of Action clinical statements:

1. Systolic blood pressure of 120 mmHg taken from right brachial artery while seated and no more than 30 minutes from when the patient last urinated
2. Diabetes mellitus is present
3. Diabetes mellitus is not present
4. Three dot blot hemorrhages
5. Dot blot hemorrhage is present
6. Patient taking one Acetaminophen 100 mg tablet by mouth daily as needed for pain
7. Positive screen for fall risk
8. Negative screen for PTSD and depression
9. Family history of colon cancer
10. Patient provided educational materials on pre-diabetes diagnosis
11. Patient counseled on the health risks of continuing smoking

12.2.5.2. Request Statements

A Request clinical statement describes a request for an action made by a clinician. Most of the times, but not always, the object of the request (e.g., lab test, medication order) will be fulfilled by someone other than the clinician (e.g., lab technician, pharmacist) making the request. All information about the request will be documented in this clinical statement, including information about details relating to the request, such as patient must fast for 12 hours before having a lipids blood test.

Examples of Request clinical statements:

1. Lipids panel for patient Jane Doe. Patient must fast for 12 hours prior to the blood test.
2. Head CT with contrast for patient John Doe.
3. Cardiology referral for patient Mary Smith.
4. Penicillin medication for patient Michael Smith to be taken twice a day by mouth with food for 10 days.
5. Advised to participate in group tobacco cessation counseling once a week.
6. Advised to lose 15 pounds within 3 months.
7. Advised to exercise at least 3 times a week for 30 minutes per day for 3 months.
8. Advised to decrease the number of packs smoked per day from 3 to 2 within 6 months by using a nicotine patch.

12.2.6. Statement Building Blocks

The following components are used in multiple places within clinical statements.

12.2.6.1. Stamp Coordinate

The stamp coordinate represents the versions of the integrated terminology and statement model used to represent a clinical statement.

12.2.6.2. Phenomena and Interval Values

In many representation models, such as SNOMED-CT and CIMI, a somewhat arbitrary distinction exists between the modeling of “Findings” and “Observable Entities.” The former typically document the presence or absence of some phenomenon in the patient (such as whether the patient has a pressure ulcer), whereas the latter characterize some feature of the patient or the patient’s condition (such as the number of pressure ulcers a patient has). Table 12.5, “An undesirable redundancy in representing clinical observations.” shows an example of the different representations for these two similar observations when modeled as Findings versus Observable Entity.

Table 12.5. An undesirable redundancy in representing clinical observations.

Pressure Ulcer as Finding	Pressure Ulcer as Observable Entity
[Pressure Ulcer(s)]#(value)#[Present]	[Pressure Ulcer(s)]#(value)#5
[Pressure Ulcer(s)]#(value)#[Absent]	[Pressure Ulcer(s)]#(value)#0

Because the observation of pressure ulcers in a patient could be correctly modeled as either a Finding or Observable Entity, any subsequent query to determine whether a patient had a pressure ulcer would need to test for the observation in two different ways:

Because the observation of pressure ulcers[# Tetralogy of Fallot] in a patient could be correctly modeled as either a Finding or Observable Entity Text before. [# Overriding structures] Text after.

any subsequent query to determine whether a patient had a pressure ulcer would need to test for the observation in two different ways

IF EXISTS object WHERE object.conceptId = "3456_PressureUlcers" AND (object.value = "Present" OR object.value > 0)

This duality of representation complicates data querying and significantly increases the possibility that data analysts will not be aware of and account for all the ways that an observation may be represented, resulting in false-negative query results.

To resolve the arbitrary distinction between "Findings" and "Observable Entities," one must consolidate these redundant concepts types into the single concept type "Phenomenon." Further, one must introduce a new data type to represent the values of Phenomena, one that can express both the "presence" (present/absent/indeterminate) and numeric (integer, real) values that Findings and Observable Entities can currently represent, respectively. This new data type is an "interval value"

12.2.6.2.1. The Interval Value Data Type

An interval value data type (or "interval value") formally represents a numeric interval between two non-negative real numbers. The interval can be open or closed. Examples of interval values are:

[5,5], [0,10), $_{(0,\infty]}$, [0,0]

The formal syntax of interval values is represented by the following grammar:

Interval :: ['[' | '('] N1 ',' N2 [']' | ')']

N1 :: Non-Negative Real Number

N2 :: [Non-Negative Real Number | $_{\infty}$]

The semantics of this grammar are as follows:

'[' and ']' : Inclusive boundary (i.e. >= and <=)

'(' and ')' : Exclusive boundary (i.e., > and <)

$_{\infty}$: infinity, is > every Non-Negative Real Number

N1 <= N2

The interval value data type provides a single way to represent both "presence" values and numeric values for a phenomenon. In general, the interval value represents the numeric range within which the observed value of a phenomenon occurs. Note that this formalism allows both exact values and ranges of values to be expressed.

In the special case that the beginning and end point of an interval are the same number, *n*, the meaning is that the value of the phenomenon is *exactly n*.

[5,5] : exactly 5 ; [0,0] : exactly 0

In the special case that the beginning of the interval is a number, *n*, and the end point is $_{\infty}$, the meaning is that the value of the phenomenon is > *n* or >=*n*, depending on whether the interval is open or closed.

$_{(0,\infty]}$: > 0 ; $_{[10,\infty]}$: >= 10

The interval value also represents whether a phenomenon is "present", "absent", or "indeterminate". Specifically, any interval value that includes *only* numbers that are > 0 also denotes the value "present".

Any interval value that includes only the number 0, itself, denotes the value “absent”. Any interval value that includes *both* the number 0 and at least one number > 0 denotes the value “indeterminate”. Lastly, there are two interval values that explicitly denote “present” and “absent,” respectively. These value may be assigned to phenomena that would not otherwise take on a numeric value (such as “nausea”):

Nausea value = $_{(0,\infty]}$: present

Nausea value = [0,0] : absent

Figure 12.12, “The semantics of interval values assigned to phenomena, as shown through examples.” lists a number of phenomena and how their current values (as “Findings” or “Observable Entities”) would be represented instead as interval values under the model proposed here.

Figure 12.12. The semantics of interval values assigned to phenomena, as shown through examples.

12.2.6.2.2. Comparing Interval Values using IsWithin()

Phenomena that represent clinical observations must be assigned interval values, so the querying of such phenomena for purposes of data retrieval and data analysis requires the comparison of interval values. Specifically, one must be able to test whether one interval value *is within* (i.e., encompassed by) another interval value. For example, if one wanted to retrieve only those patients who had between 1 and 5 pressure ulcers, one would test whether a patient had the phenomenon “pressure ulcer” recorded with a value interval that was within the interval [1,5]. Note that this test would retrieve patients who had pressure-ulcer interval values, for example, of [1,1], [4,4], and [3,5], but not those who had [0,0] or [1,10].

Formally, the comparison of two interval values is done using the predicate *IsWithin(i_1, i_2)*, where i_1, i_2 are interval values. The values of the IsWithin() predicate may be TRUE, FALSE, or UNKNOWN, determined as follows:

TRUE => if a number is in i_1, then it is definitely in i_2 (i_2 “subsumes” i_1)

FALSE => if a number is in i_1, then it is definitely NOT in i_2 (i_2 “$i_1$is disjoint with” i_1)

UNKNOWN => if a value is in, it may or may not be in i_2 (i_2 “overlaps” i_1)

Examples of interval-value comparisons:

IsWithin([5,5], [0,10]) => TRUE (interval i_2 “subsumes” interval i_1)

IsWithin([15,20], [0,10]) => FALSE (interval i_2 “is disjoint with” interval i_1)

IsWithin([5,15], [0,10]) => UNKNOWN (interval i_2 “overlaps” interval i_1)

Other useful examples:

IsWithin([2,2], (0,∞]) => TRUE

IsWithin([0,2], (0,∞]) => UNKNOWN

IsWithin((0,2], (0,∞]) => TRUE

IsWithin([0,0], (0,∞]) => FALSE

IsWithin([0,0], [0,0]) => TRUE

12.2.6.3. Querying Phenomena Using Interval Values

Based on the definition of the IsWithin() predicate, patient records may be queried for the presence or the numeric value of clinical observations using a single formalism.

12.2.6.3.1. UUID

The UUID is the means by which all clinical statement items that require unique identifiers are identified.

12.2.6.3.2. Logical Expression

12.2.6.3.3. Stamp Coordinate

12.2.6.4. Compound Statements

12.2.6.4.1. Use case: Systolic BP while seated with feet on the floor for 5 minutes

Principles

- **Proposed Principle 1:** Clinical statements have separable and inseparable components; clinical statements with separable components are considered *compound* clinical statements
- **Proposed Principle 2:** Separable components are statements, which require a value.
  - The values can be
    - numerical
    - pseudo-numerical, e.g. low/medium/high
    - Present/absent
- **Proposed Principle 3:** Clinical statements with values can stand alone
- **Proposed Principle 4:** Clinical statements with present/absent values can be components that play a role in the focus of the statement
- **Proposed Principle 4:** Inseparable components of clinical statements do not require values

Compound clinical statements with separable components should be represented as “panels”, with each separable clinical statement as a “stand alone” statement, which can be referenced by multiple “panels”.

Examples:

Table 12.6. Separable/Inseparable Statements - Blood Pressure Measurement Use Case

USE CASE	SEPARABLE STATEMENTS	INSEPARABLE COMPONENTS
BP of 120/80 mmHg on right brachial artery, patient in sitting position for at least 5 min., using adult BP cuff, urinary bladder voided within 30 min. before measurement	Systolic BP = 120 mmHg	Using adult BP cuff
	Diastolic BP = 80 mmHg	Right brachial artery
	Time since last urination = 30 min. or less	Sitting position

	Time in sitting position = 5 min. or more	

The “panel” above would consist of the following statements:

1. Blood pressure on right brachial artery, using adult cuff, with patient in sitting position
2. Systolic BP = 120 mmHg
3. Diastolic BP = 80 mmHg
4. Time since last urination = 30 min. or less
5. Time in sitting position = 5 min. or more

Table 12.7. Separable/Inseparable Statements - Administration of Nitroglycerin Use Case

USE CASE	SEPARABLE STATEMENTS	INSEPARABLE COMPONENTS
Administration of nitroglycerin 0.4 mg tablet sub-lingual every 5 minutes as needed for chest pain; maximum 3 tablets (routine)	Strength = 0.4 mg	Administration
	Frequency = every 5 minutes	Nitroglycerin
	Maximum dosage = 3 tablets	Tablet
		As needed
		Sublingual
		For chest pain
		Routine

The “panel” above would consist of the following statements:

- Administration of nitroglycerin tablets as needed, sublingual, for chest pain, routine priority
- Medication strength = 0.4 mg
- Frequency = every 5 minutes
- Maximum dosage = 3 tablets

Pseudo-numerical values are qualitative scales, e.g.

- Low/medium/high
- Mild/moderate/severe
- Tumor staging and grading
- + pos./++ pos./+++ pos.

Statements with absent/present values are considered **inseparable** components, if they are **part of** the focus of the statement.

Example statement: Patient has warm skin and blue eyes.

Warm skin and blue eyes are the focus of this statement; both components have a value of “present” and they are **part of** the focus of the statement and are therefore considered inseparable:

- Blue eyes = present
- Warm skin = present

Other components, such as *right brachial artery* or *adult BP cuff* in the BP measurement use case are considered separable, although they may appear to be able to stand alone and have values of present/absent.

Example action statement: Systolic BP 120 mmHg taken on right brachial artery, using adult BP cuff

The right brachial artery and the adult BP have (implied) values of "present", but they are **not part of the focus** of the statement (Blood pressure). Therefore, they are considered separable.

- Right brachial artery = present
- Adult BP cuff = present

The right brachial artery **plays a role** as the site of the blood pressure. Similarly, the adult BP cuff **plays a role** as the device used to perform the measurement.

Example request statement: BP measurement to take on right brachial artery, using adult BP cuff

The right brachial artery and the adult BP have (implied) values of "present", but they are **not part of the focus** of the statement (blood pressure). Therefore, they are considered separable.

- Right brachial artery = present
- Adult BP cuff = present

The right brachial artery **plays a role** as the site of the blood pressure measurement. Similarly, the adult BP cuff **plays a role** as the device used to perform the measurement.

The two examples above show, that the focus of the statements does not change. It is in both cases the blood pressure. The roles of the right brachial artery and the adult BP cuff consequently do not change, either.

The separable components of a clinical statements are also variables. BP measurement can be performed at a different body site (e.g. left brachial artery) or using a different device (e.g. digital BP machine). However, the focus of the statement remains the same.

Other examples:

- Head CT with contrast: Contrast media plays a role as an imaging substance used
- Dobutamine stress echocardiogram: Dobutamine plays a role as a substance to induce cardiac stress
- BP measurement taken at doctor's office: The office plays a role as an environment
- Body temperature reported by nurse: The nurse plays a role as the finding informer

12.2.6.4.1.1. Details

- **Proposed Principle 1:** Details refine or further qualify the topic. Topic type and topic focus together with the details sufficiently define instance requests.
- **Proposed Principle 2:** Not every action or request requires details to be sufficiently defined.
- **Proposed Principle 3:** A detail has a key and a value, where the value can be a concept or a numeric range with unit.

- **Proposed Principle 4:** A detail can be a separable or inseparable part of a complex clinical statement.

The criteria for identifying the focus and details that are not part of the focus, but play a role in a clinical statement suggest that "details" are all components, which play a role and are therefore separable components.

Examples:

Table 12.8. Separable/Inseparable Statements – Details

Detail	Description	Has (Pseudo-) Numeric Value	Has Present/ Absent Value	Part of Focus of Statement	Plays Role	Separable/ Inseparable
Actor	Person making the request or documenting/reporting the action	no	yes	no	yes	separable
Approach/ Access Route	Passage used to reach the procedure site or take a measurement	no	yes	no	yes	separable
Body position	Position of the body during a procedure/test	no	yes	no	yes	separable
Priority	Priority of the request, e.g. Stat or Routine	yes	yes	no	yes	separable
Indication	Reason that a request was made or an action taken	no	yes	no	yes	separable
Duration	A length of time, such as for 7 days, within 24 hours, or as needed	yes	yes	no	yes	separable
Frequency	How often something must be done, such as daily, twice per day	yes	yes	no	yes	separable
Detail	**Description**	**Has (Pseudo-) Numeric Value**	**Has Present/ Absent Value**	**Part of Focus of Statement**	**Plays Role**	**Separable/ Inseparable**
Route of Administration	Way in which something, such as a medication, is given to a patient, such as by mouth/oral, intravenously, sublingual	no	yes	no	yes	separable
Strength	Strength of a unit of the medication/drug itself, such as 25 mg	yes	yes	no	yes	separable
Amount	Amount of the medication/ drug that is to be taken at a given time, such as 2 tablets	yes	yes	no	yes	separable
Dosage	Equals strength multiplied by amount, e.g. 2 tablets of 25mg equals 50mg	yes	yes	no	yes	separable

Projection	The path taken by an x-ray beam or ultrasonographical wave as it passes through the body	no	yes	no	yes	separable
Substance used	Substance such as contrast media for imaging or catecholamine for stress induction	no	yes	no	yes	separable
Device used	Device used to perform something, such as using a BP cuff to measure blood pressure	no	yes	no	yes	separable
Device setting	Specific settings for a device used to perform a procedure, such as O2 Flow Rate 5 to 12 L/min	yes	no	no	no	separable
Informer	Person who reports a test result or gives information about the patient	no	yes	no	yes	separable
Detail	**Description**	**Has (Pseudo-) Numeric Value**	**Has Present/ Absent Value**	**Part of Focus of Statement**	**Plays Role**	**Separable/ Inseparable**
Performer	Person who performs an action	no	yes	no	yes	separable
Assessment Scale	Reference scale use for scoring	no	yes	no	yes	separable

12.2.6.4.1.1.1. Details/Roles in the Context of Use Cases

- **Role: Approach/Access Route**
  - Passage used to reach the procedure site or take a measurement.
    - Excision of rib by *cervical approach*
    - Administration of enema via *rectal route*
- **Role: Body Position**
  - The position of the body during a procedure/test.
    - Colonoscopy in *right lateral position*
    - Blood pressure measurement in *seated position*
    - ECG in *lying position*
- **Role: Body Site**
  - The body site of a finding or a procedure
    - Blood pressure measurement on *right brachial artery*

    - Removal of tattoo from *left upper arm*

- **Role: Priority**
    - The priority of the request, such as Stat or Routine.
        - Blood sugar measurement 3 times/day, *routine*
- **Role: Indication**
    - The reason for a request made or an action taken.
        - ECG to evaluate *chest pain*
        - X-ray of hands to evaluate *rheumatoid arthritis*
        - Patient placed in observation status due to *suicidal thoughts*
- **Role: Duration**
    - A length of time, such as for 7 days, within 24 hours
        - Physical therapy for *3 weeks*
        - Administration of Aspirin 200mg oral tablets for pain as needed for *2 days*
- **Role: Frequency**
    - How often something must be done, such as daily, twice per day or once in a 24-hour period.
        - Chest x-ray *once daily* to evaluate pneumonia
        - Psychiatric evaluation *bi-weekly* for PTSD
- **Role: Route of Administration**
    - The way in which something, such as a medication, is given to a patient.
        - Patient taking two Acetaminophen 100mg tablets *by mouth*
- **Role: Strength**
    - The strength of the medication/drug
        - Patient taking two Acetaminophen *100mg* tablets by mouth
- **Role: Amount**
    - The amount of the medication/drug that is to be taken at a given time, such as 2 tablets.
        - Patient taking *two* Acetaminophen 100mg tablets by mouth
- **Role: Dose Form**
    - The form of preparation of a medication
        - Patient taking *two* Acetaminophen *100mg tablets by mouth*

- **Role: Dosage**
  - Equals strength multiplied by amount.
    - Patient taking two tablets of Acetaminophen 100mg each = *amount of 200mg*.
- **Role: Projection**
  - The path taken by an x-ray beam or ultrasonographical wave as it passes through the body
    - MRI of brain *sagittal and transversal*
    - *Transthoracic* echocardiogram
- **Role: Substance Used**
  - Substance such as contrast media for imaging or catecholamine for stress induction
    - Head CT with *contrast*
    - *Radioisotope* study of musculoskeletal system
    - *Dye* test of fallopian tube
- **Role: Device Used**
  - A device used to perform an action, such as using a sphygmomanometer to measure blood pressure or a ventilator to help a patient breath.
    - Lithotripsy using *laser*
    - Biopsy using *Watson capsule*

- **Role: Device Setting**
  - Specific settings for a device used to perform a procedure, such as
    - Oxygen therapy, *O2 Flow Rate 5 to 12 L/min.*
    - Electrode setting for electro-surgery *12 watts*
- **Role: Family Member**
  - Blood relative of the patient, such as mother, maternal grandfather. This information is used to identify which family member(s) have a history of certain phenomena.
    - *Maternal* pyrexia
    - Drug misuse by *father*
- **Role: Informer**
  - Person reporting/documenting an action result or giving information about the patient.
    - Patient medical history reported by *spouse*
    - Bedside blood sugar measurement reported by nurse
- **Role: Performer**

- Person performing an action
  - Blood pressure measurement taken by *physician*
  - Diabetes education given by *dietician*

12.2.6.5. Encoded Statements

12.2.6.5.1. Procedures

12.2.6.5.2. Finding, Observation, and Phenomenon

12.2.6.6. Statement Models

Analysis normal form and clinical input form

12.2.7. Validation

1. To provide a validation framework for inter-modeler reliability when applied in the field.

2. To provide information on how clinical statements will be modeled for the KBS Clinical Decision Support (CDS) Knowledge Artifact (KNART) project. Once the models are approved, model slots bound to terminologies will be identified for subsequent terminology binding definitions proposed by the VA Terminology Team. Modeling of clinical statements outside of the CDS KNART project is currently beyond the scope of this effort.

   These modeling guidelines were derived from several documented use cases. The main goal of this effort is to provide a reproducible and a principled approach to the formal capture of clinical knowledge within Information Models and their references to underlying Terminology Models. Currently, the proposal and examples are independent of any specific terminology.

   These guidelines will be distributed to a variety of participants to contribute to a modeling exercise. After having read the guidelines, participants will be asked to access a survey where they will view a number of clinical statements and indicate how they would model them. ***When attempting the modeling exercise, it will be important to model per the guidelines specified in this document regardless of how existing terminologies, such as SNOMED-CT, may model these concepts***. In the future, an exercise to reconcile approaches may be conducted but is out-of-scope at this time.

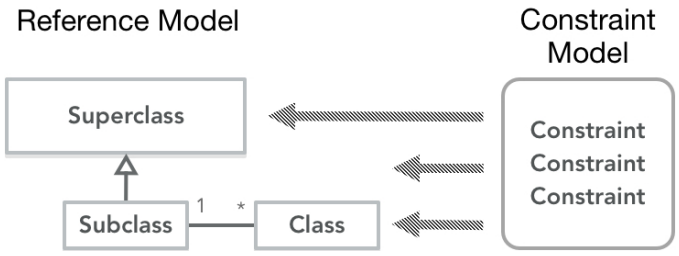
13. CEM to CIMI Conversion White Paper

13.1. Introduction

This paper will describe an approach to the transformation of detailed clinical models from the Clinical Element Model (CEM) standard to the Clinical Information Modeling Initiative (CIMI) version 2 standard. CIMI is currently a working group within Health Level Seven (HL7). The CEM models used as the source for the translation will be provided by Intermountain Healthcare.

In detailed clinical modeling there is a general approach shown in Figure 13.1, "Reference Model Constraint Paradigm", that most standards have taken where there is a reference model which is then constrained with constraint models. In Figure 13.2, "Detailed Clinical Modeling Standards", the reference model and constraint model of various standards are shown. Additional information shown is the syntax used to describe the reference or constraint model, and if the standard is shaded grey, this symbolizes that clinical content is modeled in this part of the standard.

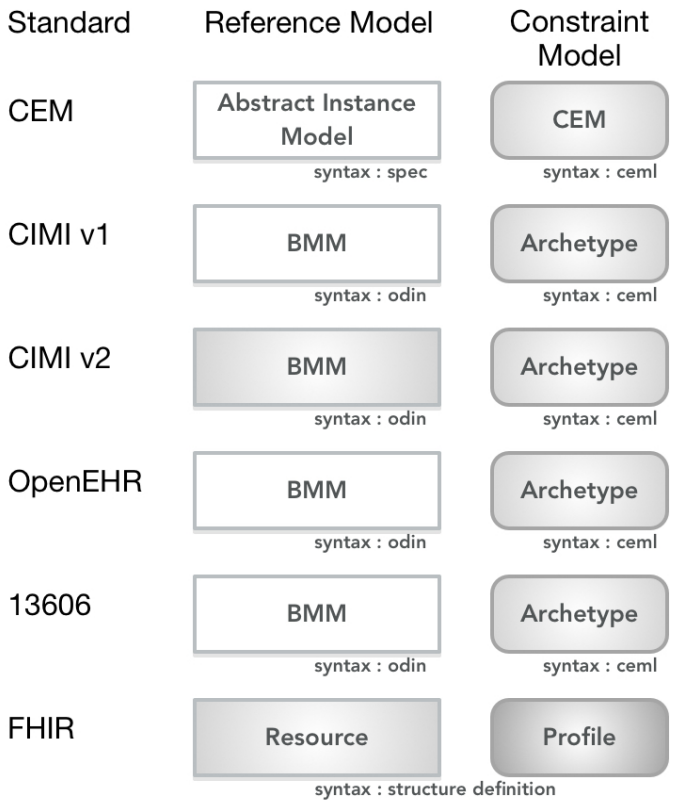
Figure 13.1. Reference Model Constraint Paradigm



The reference model for the CEM standard is called the Abstract Instance Model. It is not formally defined with a syntax, but instead is defined in a specification which can then be implemented in various implementations such as java or xml. This reference model is very small and has no defined clinical content. Instead, clinical content is defined only in the constraint models of the CEM standard which are written in Clinical Element Modeling Language (CEML).

The reference model for the CIMI v2 standard describes clinical content in both the reference and constraint models using the Archetype formalism developed by OpenEHR. The reference model is described in the Basic Meta-Model (BMM) using Object Data Instance Notation (ODIN) and the constraint models are described as Archetypes with Archetype Definition Language (ADL).

Figure 13.2. Detailed Clinical Modeling Standards



13.2. Clinical Element Model

The Clinical Element reference model, as seen in Figure 13.3, “Clinical Element Abstract Instance Model”, is a recursive model. In the figure, the stacks of grey disks within 'items', 'mods', and 'quals' are meant to represent a collection of referenced Clinical Elements. These Clinical Elements could then reference other Clinical Elements, and so on, leading to a recursive tree with infinite variety.

An instance of a Clinical Element could look like Figure 13.4, “Clinical Element Instance”. In reality, one could put any data into these slots in the reference model, and the reference model has no inherent mechanism to validate whether this is good data or nonsense. This is where the Clinical Element Constraint Model comes into play. These constraint models are called CEMs and are written in CEML. A possible CEML example for the previous instance is shown in Example 13.1, “CEML for Systolic Blood Pressure”. If we compare the instance to the CEML, we can see the instance contains a field called type with a value of 'SystolicBloodPressure'. This value is the name of the CEM that will be used to validate the instance, which is the CEML example given. The CEML then states the instances must contain a key with a code of 'SystolicBloodPressure_CODE', must have a datatype of type 'Quantity', and has a constraint that states the Quantity must have a unit of 'MillimetersOfMercury_CODE'. Also stated in the CEML is that an allowable qualifier can reference the 'BodyPosition' CEM, but that the valueset within 'BodyPosition' has been constrained to 'SBP_BodyPosition_VALUESET_CODE'.

Figure 13.3. Clinical Element Abstract Instance Model

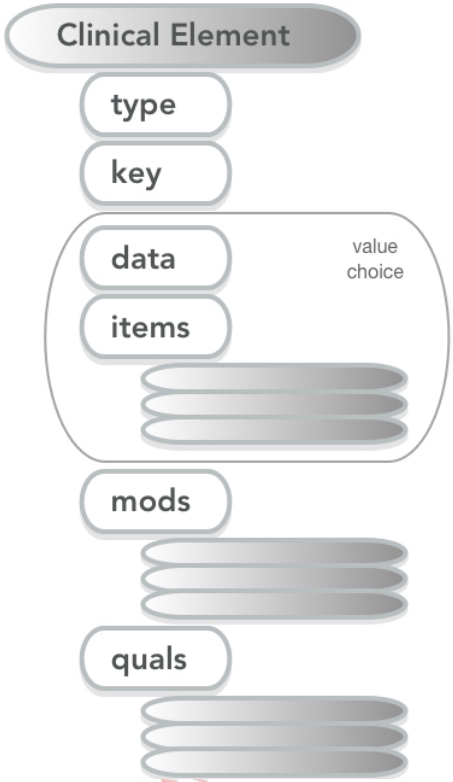
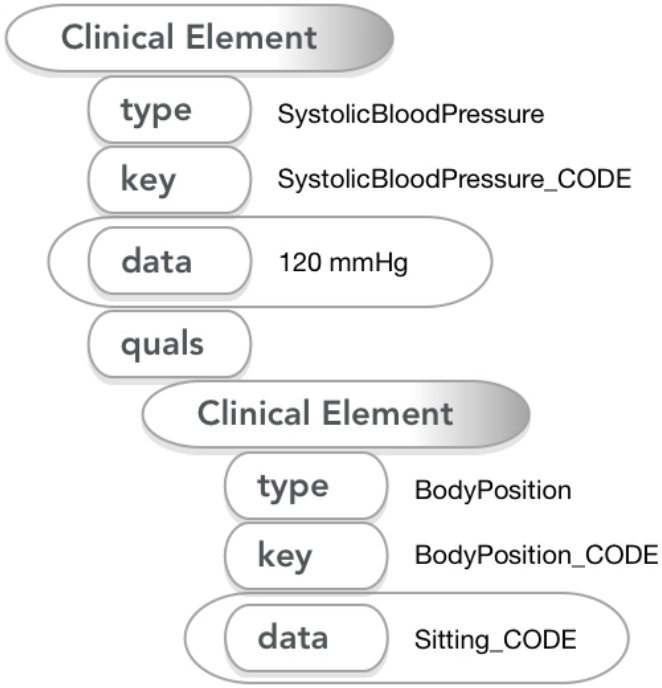


Figure 13.4. Clinical Element Instance



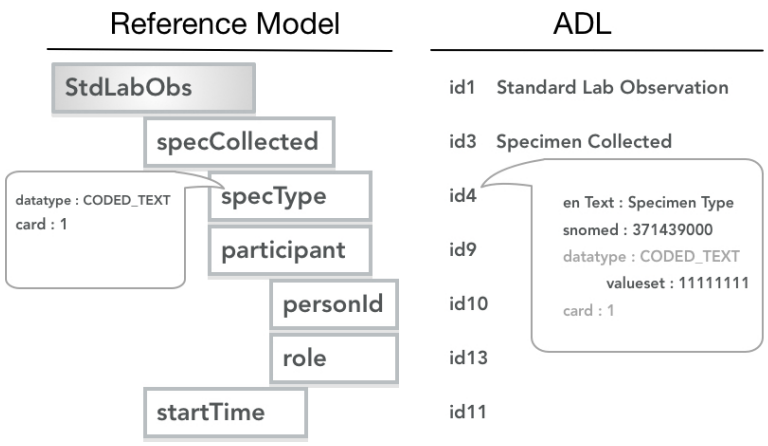
Example 13.1. CEML for Systolic Blood Pressure

```
cem SystolicBloodPressure
    key     SystolicBloodPressure_CODE
    data    Quantity
    qual    BodyPosition
       id   bodyPosition
       card 0-1
    constraint data.quantity.unit_code
       value   MillimetersOfMercury_CODE
    constraint bodyPosition.data.codeableConcept.valueset
       value   SBP_BodyPosition_VALUESET_CODE
```

13.3. CIMI Model

The CIMI Reference Model, as seen in Figure 13.5, “CIMI model with Archetype Constraint”, contains clinical content and is very similar to a UML model, but is declared in a BMM. In fact, CIMI modelers are currently modeling in UML and then generating the BMM from the UML model. On the left hand side of the figure, is an example of a possible standard lab observation model described with the BMM. In the BMM, models are declared along with their named properties. The properties can either reference other models or some declared datatype, and a cardinality can be assigned.

Figure 13.5. CIMI model with Archetype Constraint

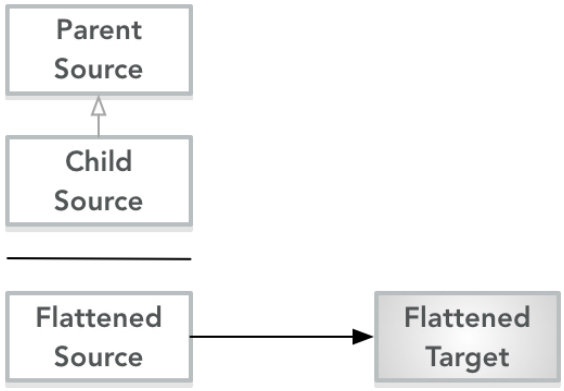


The CIMI BMM is then constrained using Archetypes defined in ADL to bind standard terminology such as 'about' codes and allowable valuesets for coded fields. Also bound can be descriptive text in various languages. And finally, the cardinality can be further specified. In the figure, an example of an Archetype is given on the right which constrains the example BMM model on the left. The 'specType' node from the reference model is bound to an id of 'id4' and then various constraints are bound to 'id4'.

13.4. Transformation

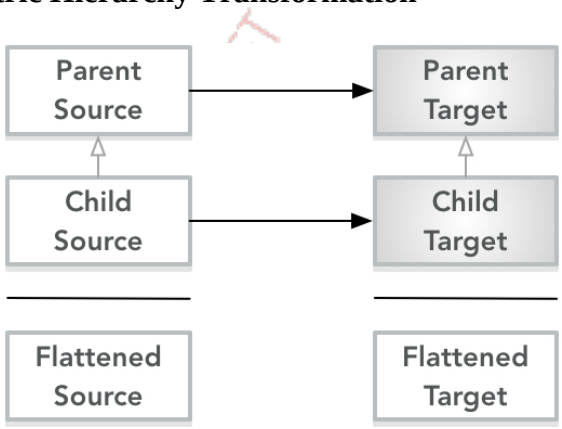
The transformation from CEMs to CIMI models with respect to inheritance hierarchy could take one of two approaches. The first approach, as seen in Figure 13.6, “Asymmetric Hierarchy Transformation”, would be to compile and collapse the inheritance hierarchy of the CEMs and then transform the resulting collapsed model. In this approach, the original inheritance hierarchy is lost in the resulting target CIMI models.

Figure 13.6. Asymmetric Hierarchy Transformation



In the second approach, as seen in Figure 13.7, “Symmetric Hierarchy Transformation”, each model in the hierarchy is transformed to a parallel model in the target hierarchy, which results in a preservation of the original inheritance hierarchy. This second approach is the approach we are taking in the transformation of CEMs to CIMI models for two reasons. First, it allows us the possibility to reverse the transformation process for parts of the transformation where needed. Second, it will allow the generated CIMI models to fit within the hierarchy as if CIMI had modeled them rather than simply creating large CIMI compliant models that stand alone.

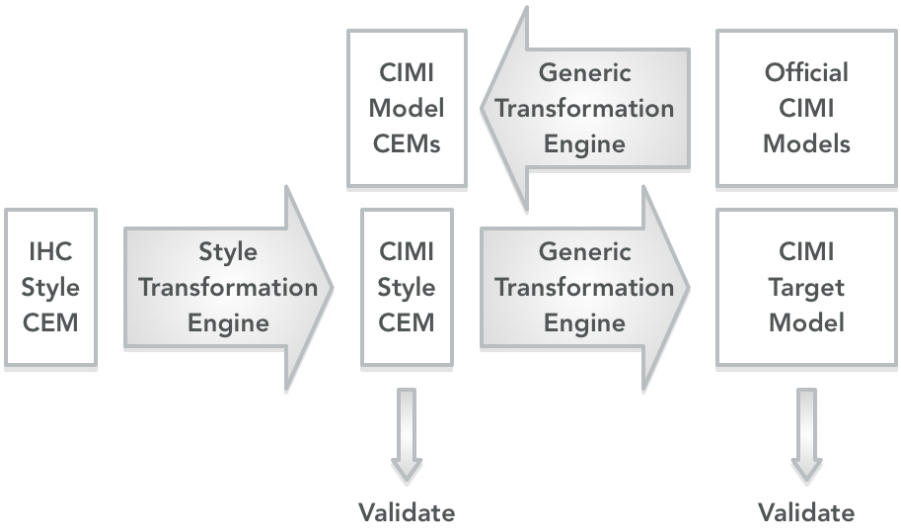
Figure 13.7. Symmetric Hierarchy Transformation



13.4.1. Transformation Strategy

The overall strategy for transformation of Intermountain CEMs to CIMI models is shown in Figure 13.8, “Transformation Strategy”. The first step starts in the upper right hand corner of the diagram with the existing official CIMI models. These models will be back transformed with a generic transformation engine to CIMI Model CEMs so that we will have a collection of the CIMI base models in a CEM form. We call this step a generic transformation because it is simply a syntactic transformation of BMM/ADL to the identical semantic representation but in CEML. No modeler knowledge is required as input to this process, and any CIMI model can act as input and the resulting CEM will be generated.

Figure 13.8. Transformation Strategy

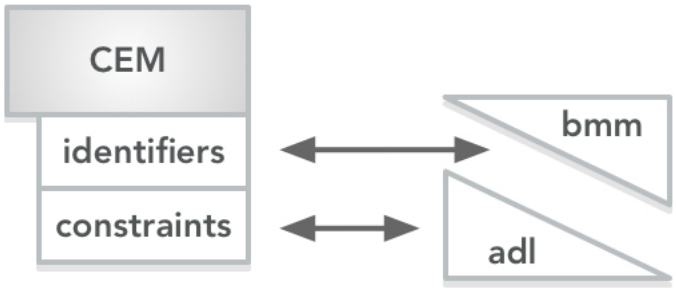


The next step in the transformation starts on the left hand side of the diagram, where Intermountain Healthcare style CEMs are transformed to CIMI style CEMs. This part of the transformation is modeler dependent, as a modeler will be required to write the individual transform rules. These rules are transforming differences in legitimate styles of modeling between Intermountain and CIMI. For example, a modeler at Intermountain may have chosen to use a pre-coordinated coded field for body location, but CIMI may prefer this field to be post-coordinated. For this style transformation, the modeler would write the rule that splits the single field into two named fields and the appropriate valuesets are assigned.

At this point, the stack of transformed CIMI CEMs can be compiled and validated. If the transformed CEMs are all valid, the transformation can continue with a generic syntax transformation to CIMI BMM and Archetypes. With the final target completed, the entire stack of CIMI models can be compiled and validated.

Despite the different paradigm between CIMI and CEM, where CIMI describes clinical content in both the reference and constraint model, and CEM uses only the constraint model, there is actually a close parallel between the two. Figure 13.9, “CEML to BMM/ADL Transformation”, shows that the identifier declarations within CEML map closely to the CIMI BMM reference model. And the constraints within CEML map closely to the CIMI Archetype ADL constraints. This parallelism will allow us to build the generic transformation between these two formalisms.

Figure 13.9. CEML to BMM/ADL Transformation



13.4.2. Datatype Issues

Even with the similarities, there still remains a few problems for the generic transformation engine. First, CIMI and CEM use a different set of datatypes. Some of these align quite nicely, such as CIMI's CODED_TEXT and CEM's CodeableConcept which are both used to represent coded fields. Others such as CIMI's YESNO and Boolean datatypes have only a partial alignment to CEM's Boolean datatype. A second problem is that the CIMI BMM allows properties to be named datatypes. In other words, the property specimenType could be a coded field in the BMM. This is not allowed in a CEM, where the property specimenType must point to another CEM model and NOT directly to a datatype.

A simple solution that solves both of these problems is to create CEMs for every CIMI datatype. In this way, when CEM's are being generated from CIMI models as the source, these constructed datatype CEMs are used in place of the original CIMI datatypes. When going the other direction, these constructed datatype CEMs will be replaced with actual CIMI datatypes. Two examples of these constructed datatypes can be seen in Example 13.2, “Datatype Wrapping”

Example 13.2. Datatype Wrapping

```
cem YESNO_DT
    key     YesNoDatatype_KEY_CODE
    data    Boolean

cem Boolean_DT
    key     BooleanDatatype_KEY_CODE
    data    Boolean
```


13.4.3. BMM Packaging

Another issue regarding the generic transformation involves the packaging of CIMI models within a BMM. CIMI currently has three BMM files called 'Core', 'Foundation', and 'Clinical' and within each of these, there are multiple packages, and then a random order to the models within these packages. CEM models, on the other hand, each exist in their own file. Thus, in the generic transformation, going from CIMI to CEM and back to CIMI and retaining the original packaging would be impossible without externally recording the packaging location in some way.

13.4.4. Recursion Issues

Another problem with the generic transformation is that CIMI models within the BMM allow recursion. For example, a Substance model could reference an Ingredient model which could then reference the original Substance model creating an infinite recursive tree from Substance on down. Although the CEM Abstract Instance Model is recursive with respect to the generic Clinical Element, CEML currently does not allow recursive constraint models. The simplest solution here is to modify the CEM compiler to allow recursion. It should be noted that the CEM compiler did allow recursion in the past, but the decision was made to disallow it at some point along the evolution of CEML.

13.4.5. ADL and CEML Constraint Consistencies

ADL and CEML Constraints used to bind terminology to the model, such as simple binding of about codes and valuesets have high consistency and should pose no problems in the transformation. Also, cardinality constraints within the two should pose no problems.

13.4.6. ADL and CEML Constraint Inconsistencies

One major difference that exists between CEML and ADL is the ability of one constraint model to peek into another constraint model and further constrain that model. This is called an 'inner constraint', as the outer model is constraining the inner model. This can be seen in Example 13.1, “CEML for Systolic Blood Pressure”, where the SystolicBloodPressure model constrains the valueset of the inner BodyPosition model. ADL does not have a mechanism to step into another ADL model and further constrain that inner model. But ADL does have the ability to walk a deep path in the BMM to apply a constraint, so in many cases it won't be a problem. In the CEML example above, this problem could be solved by creating a SystolicBloodPressureBodyPosition model thus constraining with a new model rather than an inner constraint.

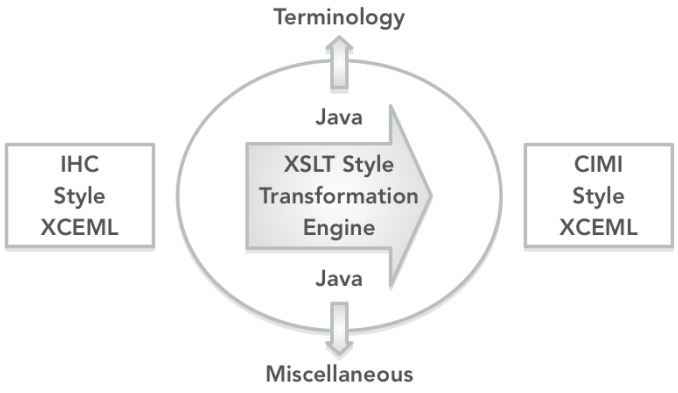
Another problem is the random assignment of id's in ADL such as 'id2', 'id5', and 'id34'. A round trip of the generic transformation engine could possible end up with different id's and still be consistent and valid. In this case, storing id information to an external file could be used to keep id's consistent.

13.4.7. Style Transformation

The Style Transformation, as seen in Figure 13.10, “Style Transformation”, will use existing Intermountain Healthcare CEMs as the source of the transformation. These CEMs currently exist both in CEML and in XCEML with the latter being an XML representation of the CEML syntax. It is the XCEML form that will be used as input to the style transformation engine which will use XSLT for the transformation, and generate CIMI style CEMs in XCEML syntax. The XSLT engine will provide XSLT functions to simplify writing transformation rules for the modeler. Functions will also be provided to call external java functions for terminology lookups or complexities that arise such as CEML path parsing.

It should be noted that although Intermountain Healthcare has finished most of the models we require, they have not finished the terminology mapping of these models. Coordination with Intermountain will be required to finish this work.

Figure 13.10. Style Transformation



13.5. Conclusion

Despite the semantic and syntactic differences that exist between CIMI and Intermountain CEMs, there are also many consistencies. Although it is probable we will encounter issues not discussed in this white paper, it is equally probable we will also find a workable solution for those problems. Using the transformation methodology presented will give us a high probability for success in the transformation from Intermountain CEMs to CIMI models.

14. Analysis Normal Form Statements

The goals of Analysis Normal Form (ANF) are to enable analysts to understand the data and how it is stored in lieu of having to teach them about the thousands of ways data can be entered (i.e., CIF), and to ensure the data we need expressed can be expressed in an operable, scalable way. The more normalized the data, the simpler it is to analyze reducing the likelihood of analysis errors. The probability of patient safety risks increases greatly without the ANF. Examples of problems that can occur are:

- An inability to determine that two clinical statements are equivalent
    - Taking two 250 mg acetaminophen tablets is the same as taking one 500 mg tablet but the analyst only queries for one of the statements, not both.
    - Presence of dot blot hemorrhage and 2 dot blot hemorrhages observed are equal in regard to presence and absence but the analyst queries only for presence vs. a quantitative finding of dot blot hemorrhages.
- An inability to express something that is clinically significant
    - We may not be able to express chest pain on inspiration, which can be a sign of pleurisy. The ability to differentiate cardiac chest pain from other types of chest pain is clinically important. An example of something that needs to be represented is chest pain that worsens when you breathe, cough, or sneeze.
- An error is made in recording or in querying a repository for clinical statements
    - On October 1, 2016, a provider enters a medication order for acetaminophen 250 mg for a patient to take 1 tablet twice daily for 2 days starting October 1, 2016
        - CIF: Provider enters the medication order
        - ANF: Analyst creates a CDS rule to identify all patients ordered acetaminophen during the period September 1 – December 31, 2016. However, while the analyst creates a query to search for a clinical statement (i.e., Request) where acetaminophen was the direct substance and was ordered during the period September 1 – December 31, 2016, the analyst did not include a Request topic of “Administration of drug or medication PO BID for pain.” Thus, the medication order would not be included in the query results.

A. **ANF Clinical Statements Represent the Minimum Disjoint Set:** ANF clinical statements represent the minimum disjoint set of statement topic, result, and details and may not be further specified.

B. **ANF Classes Cleanly Separate Concerns:** ANF classes must cleanly separate the concerns of concept definition and the concerns of domain models.

- **NOTE:** Need to define the domain models thoroughly here. The strawman description is that domain models use concept definitions as a building block to define non-defining relationships or associations between concepts. The domain model represents cardinality, optionality, and other constraints.
    - **Example:** Laterality should be a concern of either the concept definition or the domain model, but not both. We can relax this principle for the Clinical Input Form (CIF) but for ANF we need a clean and invariant separation of concerns.
- **NOTE:** Need to determine better names for “concept definition” and “domain models.”

14.1. Clinical Statements

A clinical statement represents an entry in the patient record that documents clinical information:

- about a subject of information, such as a patient or a relative of the patient
- that is asserted and recorded by a particular source, such as a clinician
- in a structured/computable manner

Clinicians typically enter information into an EHR in a certain manner: the clinical input form (CIF) The CIF is not a literal “form”. It refers to the manner in which information is presented to the clinicians and how they enter the data, e.g.

- by constraining the information to allow only certain values to be entered, such as through a drop-down list or radio button
- breaking up large chunks of related information into smaller parts like in medication orders

14.1.1. Principles

- **Proposed Principle 1:** There are two types of clinical statements:
  - **Performance of action**, which include passive observation of a phenomenon related to patients and their health status or family history, and active interventions, such as providing education or administering medications.
  - **Request for action**, which may include passive observation of a phenomenon related to patients and their health status or family history, and active interventions, such as providing education or administering medications.
- **Proposed Principle 2:** Both types of clinical statements consist of topics and circumstances
- **Proposed Principle 3:** Each clinical statement can have only one topic and multiple circumstances

14.2. Clinical Statement Decision Tree

14.3. Clinical Statement Components

Table 14.1. Example Clinical Statement Model

Clinical Statement	
Narrative:	Ibuprofen 400 mg tablet oral every 6 hours as needed for back pain; may increase dose frequency to one tablet every 4 hours
Statement type:	*[Request]*
Subject of info:	*[410604004 |Subject of record]*
Mode:	*[Template]*
Authors:	*[223366009|Healthcare professional]*
Action topic:	*[Procedure]-* *#(260686004|Method)#[129445006|Administration - action]* *#(363701004|Direct substance)#[197805|Ibuprofen 400 MG Oral Tablet]* *#(410675002|Route of administration)#[260548002|Oral]*
Circumstance:	Request Circumstance Timing: `[2007-04-05T14:30Z, 2007-04-05T15:00Z]±P5M` *[ISO 8601]* Purposes: *[161891005 |Backache (finding)]* Triggers: Ø associate statement backache present Participants: *[410604004 |Subject of record]* Priority: *[50811001 |Routine (qualifier value)]* Repetitions: Repetition Start: Anytime, as needed Duration: 24 hours Frequency: 4-6 hours Maximum: Ø Duration: Ø Result: 4
Associations:	Ø
Statement time:	`[2007-04-05T14:30Z, 2007-04-05T15:00Z]±P5M` *[ISO 8601]*
Stamp coordinate:	*[SOLOR Module]*, *[Release Path]*, 2007-04-05T14:30Z
Statement id:	a3b46565-f8cd-4354-b4b6-3dff42d33496
Subject of record ID:	Ø

14.3.1. Statement Identifier

The UUID is the means by which all clinical statements requiring unique identifiers are identified.

14.3.2. Mode

Needs clarification

14.3.3. STAMP coordinate

[SOLOR Module], [Release Path], [Date/Time in ISO 8601 Standard Format]

14.3.4. Narrative

The clinical statement as a whole, e.g. “Ibuprofen 400 mg tablet oral every 6 hours as needed for back pain; may increase dose frequency to one tablet every 4 hours”

14.3.5. Statement time

Time when the statement was documented in ISO 8601 Date/Time Standard Format

14.3.6. Subject of Record Identifier

UUID identifier for the subject of record.

14.3.7. Statement Authors

Figure 14.1. Participant

Optional list of participants, e.g. “Healthcare professional”, “Nurse”

14.3.8. Participant Role

Optional role for participants, e.g. “Requester”.

14.3.9. Participant Identifier

Optional. UUID Identifier for the participant.

14.3.10. Subject of Information

Subject of Information is used to express **WHO** the clinical statement is about, e.g. the patient or a family member.

14.3.11. Statement Type

Statement Type distinguishes between a performance (“performed”) and a request (“requested”). Performances may be observational performances, e.g. the observation of a clinical finding or disorder being present or absent. They can also be statements of a procedure or intervention, which has been performed on the subject of record in the past, e.g. “12-lead electrocardiogram”. Performances can – but do not have to – include quantitative or qualitative results, e.g. “3 dot blot hemorrhages” or “Hepatitis A antibody positive”.

14.3.12. Topic

The topic is the expression of **WHAT** is being requested or what was performed. For both clinical statement types (request or performance) a pre-coordinated or post-coordinated SOLOR “procedure” concept as a logical expression is required to sufficiently capture the action, which is either requested or performed.

Requests for actions are always procedures or interventions:

- Stress echocardiogram
- Administration of Aspirin 81 mg oral tablet
- Systolic blood pressure measurement

Performances of actions can be performed procedures like the examples above. They can also be observational procedures, describing the absence or presence of clinical findings or disorders. In these cases, the observation action of the clinical findings and disorders is performed:

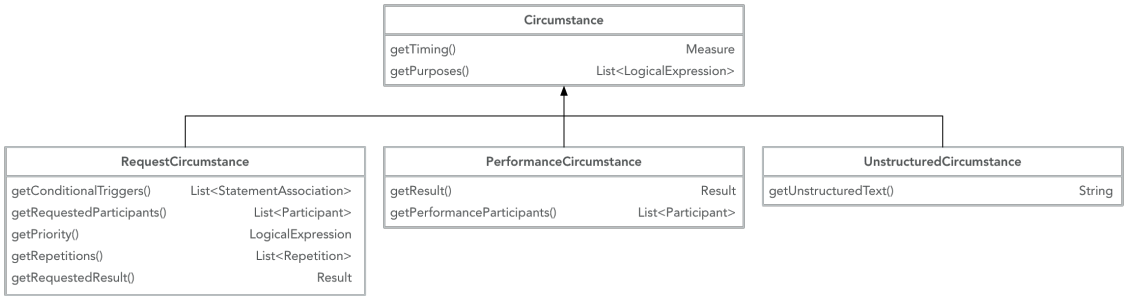
- Observation of congestive heart failure
- Observation of history of malignant neoplasm of bone
- Observation of numbness of left arm
- Observation of history of cognitive behavioral therapy

The topic is the central component of clinical statements.

- The topic defines the action being performed or requested.
- The topic has to be able to exist on its own yet still retain original intent and clarity of meaning.
- The topic includes what is being requested, measured or observed.

14.3.13. Circumstance

Figure 14.2. Circumstance, including request, performance, and unstructured subtypes

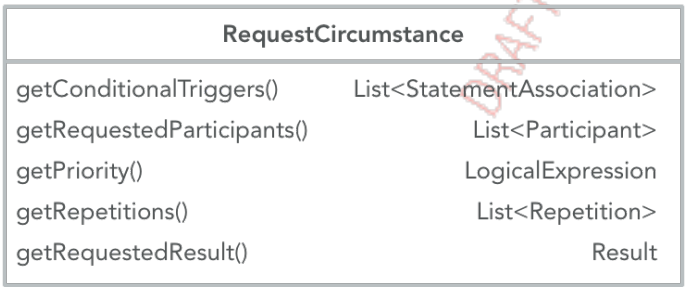


Circumstances can describe **HOW**, **WHY** and **WHEN** a requested or performed action will be or was carried out. Requests and performances have some shared circumstances:

- Timing: **WHEN** a requested action should be performed or **WHEN** an observed finding or disorder was present or absent.
  - Examples:
    - Cardiology Consult in 2 weeks
    - Breast cancer screening 3 months ago
- Purpose: **WHY** an action was requested or performed
  - Examples:
    - Echocardiogram to evaluate arrhythmia
    - Education about allergens for anaphylaxis management Other circumstances are specific to requests or performances.

14.3.13.1. Request Circumstance

Figure 14.3. Request circumstance



Request circumstance further specify **HOW** a requested action is to be performed, e.g. how often, how long or with which category of priority.

14.3.13.1.1. Conditional Triggers

Needs clarification

14.3.13.1.2. Requested Participants

Requested participants can be either specific persons or roles who perform an action, assist in performing an action or are targets of an action. **Examples:**

- Cardiology consultation with Chief Cardiologist
- Smoking cessation education with patient and patient’s spouse

14.3.13.1.3. Priority

Expresses the priority with which a requested action has to be carried out, e.g. “routine” or “stat”.

14.3.13.1.4. Repetitions

Figure 14.4. Repetition

If an action is requested for more than a single occurrence, the repetition allows to specify:

- When the repeated action should begin (PeriodStart), e.g. NOW
- How long the repetitions should persist (PeriodDuration), e.g. for 3 weeks
- How often the action should occur (EventFrequency), e.g. 3 times per week
- Maximal number of occurrences (EventMaximum), e.g. 10 times
- How long every occurrence should last (EventDuration), e.g. for 5 minutes

14.3.13.1.5. Requested Result

A patient goal to be achieved or a request for action further specified or quantified.

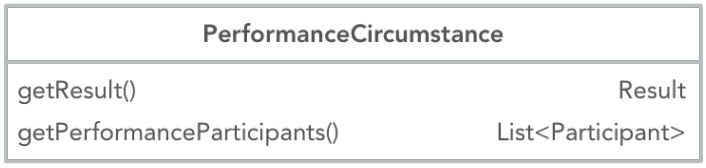
Examples:

Narrative: Administration of Metoprolol tartrate 50 mg oral daily 2 times to lower systolic blood pressure to <130 mmHg

Narrative: Diltiazem 30 mg, one tablet oral daily 4 times

14.3.13.2. Performance Circumstance

Figure 14.5. Performance



14.3.13.2.1. Result

Result of diagnostic or observational procedures

Examples:

Narrative: Systolic blood pressure 120 mmHg

Narrative: Body weight 165 pounds

14.3.13.2.2. Performance Participants

Participants in performing the action, e.g. technician, nurse

14.3.13.3. Unstructured Circumstance

14.3.13.3.1. Unstructured Text

14.3.14. Statement Associations

Figure 14.6. Statement Association

14.3.14.1. Association Semantic

14.3.14.2. Associated Statement ID

14.4. ANF Modeling Guidelines

14.4.1. Introduction

The purpose of this section is to describe editorial guidelines for modeling terminology artifacts used to express the content of Knowledge Artifacts (KNARTs), e.g. Documentation Templates, Consultation Requests and Order Sets, in a computer readable form. This section will attempt to outline background information related to terminology models for KNARTs as well as provide modeling guidelines necessary for encoding clinical statements. This is a working draft document and subject to change.

14.4.2. Background

Knowledge Artifacts are computable representations of Clinical Decision Support (CDS) knowledge. They consist of clinical statements and orders within a framework of structured clinical documentation. Terminology artifacts in this context are developed to represent the clinical assertions and their values and are composed of standard clinical terminologies. The prioritized terminologies for the representation are SOLOR terminologies (SNOMED CT, LOINC and RxNorm) in alignment with the recommendations and requirements by the Office of the National Coordinator for Health Information Technology (ONC) and the VA – Department of Defense (DoD) Interagency Program Office (IPO). This section will describe each of the terminology artifact components and provide guidelines for modeling the values of these components. These guidelines are under development and remain subject to change as a result of the need to develop a consistent terminology model and coding strategy.

14.4.3. KNART Types and Structure

Four types of KNARTs have been developed for the VA KNART Project:

- Documentation Template

- Order Set
- Consultation Request
- Event Condition Action (ECA) Rule

The clinical content of each KNART is specific to clinical domains and prioritized areas of focus within the domains.

Example:

- Domain: Cardiology includes
  - Chest Pain/Coronary Artery Disease
  - Atrial Fibrillation
  - VTE Prophylaxis

The “Composite KNART” for each of the clinical focus areas above is comprised of at least the documentation template, the order set and the consultation request. Many, but not all Composite KNARTs also have ECA rules.

14.4.4. Documentation Templates

Documentation templates are created to document clinical information about patients, such as History and Physical, and treatment provided in the past as well as past results from lab tests, imaging procedures and other diagnostic studies. In many cases, the clinical information captured here is associated with either a defined timeframe, e.g. diagnostic studies within the past year, or a more undefined timeframe, e.g. history of prior cardiac evaluations.

14.4.5. Order Sets

Order sets are used to document requests for diagnostic or therapeutic procedures for the patient. As such, these requested procedures will occur at a future time.

Common categories for the ordered procedures include:

- Administration/Prescription/Dispensing of medications
- Imaging procedures
- Electrophysiology procedures
- Therapies
- Laboratory procedures
- Education procedures

The requested procedures may also include additional information, e.g.

- Timing, e.g. when the action should be performed
- Specific instructions for the procedures
- Priorities

- Frequencies

14.4.6. Consultation Request

Consult Requests are often relatively short KNARTs, which include

- Reason for Consult, e.g. chest pain
- Consult Specialty, e.g. cardiology
- Priority, e.g. Routine
- Referring Physician
- Referring Physician Contact Information

14.4.7. ECA Rule

ECA Rules are used in Clinical Decision Support to trigger a defined action after a distinct event occurred. Example: Notify clinician if laboratory test result with “abnormal” flag has been received.

14.5. Terminology Service Request (TSR)

The clinical statements within a KNART, which have to be captured by standard terminologies using a number of codes from e.g., SNOMED CT, RxNorm or LOINC are represented in Terminology Service Requests (TSRs). One TSR contains a variable number of Instance Requests (IRs), each of which represents a single clinical statement. The format used to assemble and encode a TSR is a MS Excel spreadsheet template.

The example below shows orders as they potentially appear in a KNART:

Figure 14.7. Order Example (Cardiology Order Set)

[Section Selection Behavior: More than one may be selected. Optional]

- ☐ resting 12-lead electrocardiogram to evaluate chest pain (routine)
- ☐x-ray chest to evaluate chest pain(routine)

The order from the KNART above appears in the TSR as an Instance Request:

Figure 14.8. Order Set Instance Request in TSR Template

	A	B	D
1	**Instance Request**	Textual Representation	resting 12-lead electrocardiogram to evaluate chest pain (routine)

14.6. Terminology Modeling Guidelines

The request and performance clinical statement types as described in the ANF Model and Guidelines section of this document have a number of shared components. Other components are specific to the statement type. The following sections will define the terminology modeling principles for each component in detail. The choice of logical expressions to use for each component is not always straightforward, and the terms in the SOLOR terminologies are not always unambiguous in their semantic meaning. In situations

where there may be more than one choice or more than one way to code a clinical statement or one of its components, it is important to ensure consistency of modeling approaches across clinical domains and clinical statements.

The following chapters describe the terminology modeling guidelines based on the current ANF model and the current TSR template fields. The TSR template has two tabs for Instance Requests (IRs). One tab “request” contains IRs for requested actions, one tab “performance” contains IRs for performed actions. Both tabs have a number of fields in common. Some fields are different and unique to the specific type of IR.

14.6.1. Instance Request (Request and Performance)

Represents the clinical statement to be modeled.

14.6.2. statementID (Request and Performance)

Not for modeling. ID will be assigned by KNART developers.

14.6.3. statementType (Request and Performance)

Format: Logical Expression

Terminology: SNOMED CT

Coding: Either “385644000 |Requested (qualifier value)|” for request IRs or “398166005 |Performed (qualifier value)|” for performance IRs

14.6.4. METADATA: model fit (Request and Performance)

Currently not in use.

14.6.5. METADATA: model fit comments (Request and Performance)

Currently not in use.

14.6.6. subjectOfInformation (Request and Performance)

Format: Logical Expression

Terminology: SNOMED CT

Subject of information is in most cases the patient: 410604004 |Subject of record (person)|. However, if the information is about, e.g. the patient’s mother or another family member, it is not the patient.

Examples: 72705000 |Mother (person)|, 303071001 |Person in the family (person)|

14.6.7. topic (Request and Performance)

The topic field represents what is being requested or has been performed. Although both request and performance IRs share this field, the handling is different to a certain extent.

Format: Logical Expression

Terminology: SOLOR

The actual coding of the topic depends on the procedure requested or performed. Generally, pre-coordinated or post-coordinated expressions are used. Post-coordinated expressions can be “hybrids” and include terms from different terminology standards (See Medication example below).

The pre-coordinated or post-coordinated expressions in the topic field are ALWAYS procedures.

14.6.8. Medication (Request and Performance)

Currently, medications are interpreted as the administration of a medication, not the prescription. The administration can be either requested or documented as being done. Therefore, all medications are post-coordinated based on the SCT “416118004 |Administration (procedure)” concept. To capture the drug itself, RxNorm codes are used. The specific RxNorm codes depend on the specificity of the IR. Attribute/value pairs needed to fully post-coordinate the expression are SCT concepts.

Example Instance Request:

Naproxen sodium 550 mg tablet oral every 12 hours as needed for back pain 100 tablets 2 refills

Post-coordinated expression with *conceptual graph* [1] syntax:

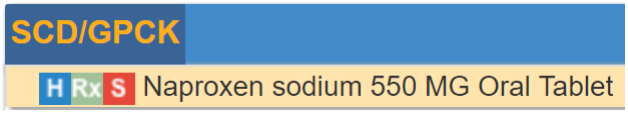
```
[416118004 |Administration (procedure)]
      ->(260686004 |Method (attribute))->[129445006 |Administration - action (qualifier value)]
      ->(363701004 |Direct substance (attribute))->[Rx;849431 Naproxen sodium 550 MG Oral Tablet]
      ->(410675002 |Route of administration (attribute))->[260548002 |Oral (qualifier value)]
```

Coding guidelines for dosage, frequency, total number of tablets and refills etc. will be discussed in later sections. This detailed information is typically only included in medication requests, while performances typically only document that the medication has been taken as a “History of….” Statement.

Notes:

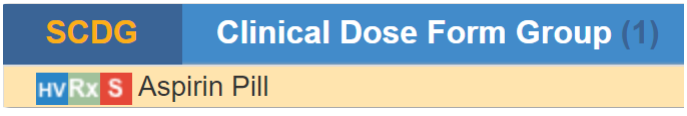
1. The IR is specific enough regarding strength and dose form. Therefore, the RxNorm SCD code can be applied

Figure 14.9. RxNorm SCD Code



2. Other medication requests or performances are less specific. The IR might only state “Aspirin tablet”. In these cases, the RxNorm SCDG codes are used:

Figure 14.10. RxNorm SCDG Code



3. If the IR states a class of drugs, e.g. “Glucocorticoids”, the coding approach is cascaded:

[1] https://en.wikipedia.org/wiki/Conceptual_graph#Graph-based_knowledge_representation_and_reasoning_model

→ First choice: SNOMED CT concept from the “product” hierarchy

→ Second choice: NDF-RT code

4. “Route of administration - oral” is included in the post-coordinated expression. Although the RxNorm code includes “oral tablet” it does not sufficiently capture that this tablet is administered orally.

5. The “Rx;” prefix for the RxNorm code in the post-coordinated expression indicated the terminology standard. Current modeling guideline: All concepts are SNOMED CT concepts, unless otherwise stated.

6. The IR example states: Naproxen sodium 550 mg tablet oral every 12 hours as needed for back pain 100 tablets 2 refills. Although it is not explicitly stated, the currently agreed upon policy is to interpret this as: 1 tablet at a time.

14.6.9. Non-Medication Procedures (Request and Performance)

Other procedures in the “topic” field, e.g. diagnostic procedures, therapeutic procedures, consults or observational procedures are coded as pre-coordinated or post-coordinated expressions using SNOMED CT concepts.

For IRs (either request or performance) a “simple” procedure, e.g. “Echocardiogram”, entering the procedure code “40701008 |Echocardiography (procedure)|” in the topic field sufficiently captures the IR.

For more complex IRs, particularly where body sites or lateralities are included, some principles to ensure consistency in the modeling must be applied.

1. Always post-coordinate when “laterality” is involved

   - There are many pre-coordinated SCT concepts, which include body site and laterality, e.g. “1451000087102 |Computed tomography of right lower limb (procedure)|”, but not all body sites in SCT are lateralized.

     - To achieve consistency in the modeling approach, instead of using the pre-coordinated concept above, post-coordinate the body structure and the laterality as shown below:

       [241570001 |Computed tomography of lower limb (procedure)]-

       ->(363704007 |Procedure site (attribute))

       ->[61685007 |Lower limb structure (body structure)]- ->(272741003 |Laterality (attribute))->[24028007 |Right (qualifier value)];

2. For IRs without involving laterality, the choice for coding the topic is cascaded:

   a. 1st choice: existing pre-coordinated concept

   b. 2nd choice: post-coordinated expression, using existing concepts within the constraints of the concept model

   c. 3rd choice: post-coordinated expression, using existing concepts outside the constraints of the concept model, after discussion and approval

   d. 4th choice: new SCT HSPC SOLOR extension precoordinated concept, after discussion and approval; use generated UUID until the concept is created

14.6.10. Observational Procedures (Performance)

In the “performance” tab of TSRs, many of the IRs pertain to the documentation of findings or disorders. These are “observational” procedures, often documented within “history and physical” sections of documentation templaWeaktes, which describe the presence or absence of a finding or disorder.

This category of IRs is always captured as a post-coordinated expression in the topic field.

Example IR: Weakness of neck

Post-coordination:

```
[a997cc03-3e99-40eb-833a-6374c7750a3a |Observation procedure (procedure)]
        ->(363702006 |Has focus (attribute))->[249931001 |Weakness of neck (finding)]
```

Example IR: Right arm pain

Post-coordination:

```
[a997cc03-3e99-40eb-833a-6374c7750a3a |Observation procedure (procedure)]-
        ->(363702006 |Has focus (attribute))->[22253000 |Pain (finding)]-
                ->(363698007 |Finding site (attribute))->[53120007 |Upper limb structure (body structure)]-
                        ->(272741003 |Laterality (attribute))->[24028007 |Right (qualifier value)];
```

14.6.11. Unstructured (Request and Performance)

Format: Plain text

Currently used to capture textual information for which there is no model at this time.

14.6.12. statementAssociation.semantic (Request and Performance)

Format: Logical Expression

Terminology: TBD Currently not in use

14.6.13. statementAssociation.statementId (Request and Performance)

For use by KNART developers.

14.6.14. Timing (Request and Performance)

The “timing” circumstance has six components:

1. timing.lowerBound

   Format: Number (“float”)

2. timing.upperBound

Format: Number (“float”)

3. timing.includeLowerBound

   Format: TRUE or FALSE (“Boolean”)

4. timing.includeUpperBound

   Format: TRUE or FALSE (“Boolean”)

5. timing.resolution (optional)

   Format: Number (“float”)

6. timing.measureSemantic

   Format: ISO 8601 Date/Time Format

Timing is used to capture a time or time range for

- Requests for action at a future time
- Performance of action, which has taken place in the past (including “History of X….)

The timing is always expressed as a time or time range relative to the statement time, using the ISO 8601 Date/Time Standard format[2].

If the actual time or time range is not specified in the IR, the following expressions are used:

- ISO 8601 prior to statement time
- ISO 8601 following statement time

If the time or time range is specified in the IR, the expression also follows the ISO 8601 Standard, using the appropriate prefixes for periods of time:

- P for period
- M for months
- W for weeks
- Y for years

Using additional fields in the timing circumstance, depends upon the degree of specificity within the IR.

Example (unspecific): History of breast cancer

Table 14.2. Timing - unspecific

timing.lowerBound	1
timing.upperBound	inf
timing.includeLowerBound	TRUE

[2] https://en.wikipedia.org/wiki/ISO_8601

timing.includeUpperBound	FALSE
timing.resolution	
timing.measureSemantic	ISO 8601 prior to statement time

The IR implies:

- Breast cancer was present in the patient's history = timing.lowerBound = 1
- No time range specified = timing.upperBound = inf (infinite)
- There was at least 1 instance = timing.includeLowerBound = TRUE
- "upper bound" is infinite = timing.includeUpperBound = FALSE ("inf" is never included!)
- IR does not specify units of time, e.g. years, months = timing.resolution = blank

Note: The expression of "present" could also be correctly indicated using

timing.lowerBound = 0

timing.includeLowerBound = FALSE

Not including "0" also expresses that there has to be at least "1". However, it is the current agreed policy to use the "1/TRUE" option.

Example (specific range): Anticonvulsant therapy greater than 2 years

Table 14.3. Timing - specific range

timing.lowerBound	24M
timing.upperBound	inf
timing.includeLowerBound	FALSE
timing.includeUpperBound	FALSE
timing.resolution	1M
timing.measureSemantic	ISO 8601 prior to statement time

The IR expresses:

- Anticonvulsant therapy for more than 2 years (24 months) was present in the patient's history = timing.lowerBound = 24M
- No upper time limit specified = timing.upperBound = inf (infinite)
- There was anticonvulsant therapy for more than 24 months = timing.includeUpperBound = FALSE
- Timing.measureSemantic = ISO 8601 prior to statement time
- timing.resolution field:
  - This field is optional, but if a time or time range is specified, the resolution has to be specified.
  - The use depends on the desired granularity of the time increments

- Some of the reasoning about how to use these fields depends on the clinical relevance.

Example (specific date): Completed Appointed on March 12 2018 with Cardiology

Table 14.4. Timing - specific date

timing.lowerBound	2018-03-19T12:01
timing.upperBound	2018-03-19T23:59
timing.includeLowerBound	TRUE
timing.includeUpperBound	TRUE
timing.resolution	
timing.measureSemantic	ISO 8601

Note: ISO 8601 uses the 24 hour standard for time of day.

14.6.15. Purpose (Request and Performance)

Format: Logical Expression

Terminology: SNOMED CT

The “purpose” field is used to capture WHY a procedure was requested or performed in a post-coordinated expression, based on two possible procedures:

Evaluation procedure: 386053000 |Evaluation procedure (procedure)|

Therapeutic procedure: 277132007 |Therapeutic procedure (procedure)|

The procedure is refined by post-coordinating with a “363702006 |Has focus (attribute) |” attribute and identifying a finding/disorder or procedure concept as the value for the attribute.

Example IR: Resting 12-lead electrocardiogram to evaluate for arrhythmia

```
[386053000 |Evaluation procedure (procedure)]
->(363702006 |Has focus (attribute))->[ 698247007 |Cardiac arrhythmia (disorder)]
```

Example IR: Naproxen sodium 550 mg tablet oral every 12 hours as needed for back pain 100 tablets 2 refills

```
[277132007 |Therapeutic procedure (procedure)]
->(363702006 |Has focus (attribute))->[161891005 |Backache (finding)]
```

IRs can have more than one purpose.

14.6.16. requestedResult (Request and Performance)

The “requestedResult” circumstance has eight components:

1. requestedResult.lowerBound

Format: Number (“float”)

2. requestedResult.upperBound

   Format: Number (“float”)

3. requestedResult.includeLowerBound

   Format: TRUE or FALSE (“Boolean”)

4. requestedResult.includeUpperBound

   Format: TRUE or FALSE (“Boolean”)

5. requestedResult.resolution (optional)

   Format: Number (“float”)

6. requestedResult.measureSemantic

   Format: Logical Expression

7. requestedResult.healthRisk

   Format: Logical Expression

8. requestedResult.status

   Format: Logical Expression

The “requestedResult” fields 1 – 6 above are used to capture IRs, which

- enumerate what is being requested, e.g. Administration of a medication **1 tablet at a time**
- specify the intended outcome of an action, e.g. Administration of Metoprolol to **achieve systolic BP < 130 mmHg**

Example IR: Metoprolol tartrate 50 mg tablet oral daily 2 times

Table 14.5. requestedResult -Example 1

requestedResult.lowerBound	1
requestedResult.upperBound	1
requestedResult.includeLowerBound	TRUE
requestedResult.includeUpperBound	TRUE
requestedResult.resolution	
requestedResult.measureSemantic	421026006 |Oral tablet (qualifier value)|

Note: This should not be confused with “frequency”. Although not stated explicitly, it is understood that the IR states: ONE tablet, twice a day.

Example IR: Acetaminophen 325 mg tablet oral two tablets every 6 hours

Table 14.6. requestedResult -Example 2

requestedResult.lowerBound	2
requestedResult.upperBound	2
requestedResult.includeLowerBound	TRUE
requestedResult.includeUpperBound	TRUE
requestedResult.resolution	
requestedResult.measureSemantic	421026006 |Oral tablet (qualifier value)|

14.6.17. conditionalTrigger (Request)

Format: Logical Expression

Terminology: TBD

Currently not in use.

14.6.18. conditionalTrigger.statementId (Request)

UUID as identifier for the conditionalTrigger statement.

14.6.19. Priority (Request)

Format: Logical

Expression Terminology: SNOMED CT

The priority field captures the standard priorities associated with a request for action, e.g. stat, routine

14.6.20. repetition.period (Request)

The “repetition.period” has twelve components. Six components for the repetition period start and six components for the repetition period duration. The fields are used to capture WHEN a repeated action should start and HOW LONG the requested action should be repeated.

1. repetition.periodStart.lowerBound

   Format: Number (“float”)

2. repetition.periodStart.upperBound

   Format: Number (“float”)

3. repetition.periodStart.includeLowerBound

   Format: TRUE or FALSE (“Boolean”)

4. repetition.periodStart.includeUpperBound

   Format: TRUE or FALSE (“Boolean”)

5. repetition.periodStart.resolution (optional)

Format: Number (“float”)

6. repetition.periodStart.measureSemantic

   Format: Logical Expression

14.6.21. repetition.period components

Example IR: Naproxen sodium 550 mg tablet oral every 12 hours as needed for back pain

Table 14.7. repetition.period Example

repetition.periodStart.lowerBound	[NOW,NOW] relative to statement time
repetition.periodStart.upperBound	
repetition.periodStart.includeLowerBound	
repetition.periodStart.includeUpperBound	
repetition.periodStart.resolution	
repetition.periodStart.measureSemantic	
repetition.periodDuration.lowerBound	1
repetition.periodDuration.upperBound	inf
repetition.periodDuration.includeLowerBound	TRUE
repetition.periodDuration.includeUpperBound	FALSE
repetition.periodDuration.resolution	1
repetition.periodDuration.measureSemantic	258703001 |day (qualifier value)|

If the IR does not explicitly state a period start time, the default entry in this field is “[NOW,NOW] relative to statement time”.

Note: “[NOW,NOW]” is not to be confused with priority “stat”. The “NOW” is simply used where there is not a specified time, e.g. 1 week from now.

If a repetition period start/stop time is specified, the “upper/lower bound” components and the measure-Semantic are used as in all other timing related circumstances.

14.6.22. repetition.periodDuration components

Every repetition has a duration, even if it is not explicitly stated in the IR. In the example above, the IR states a frequency (every 12 hours), but not a duration. In these cases it is understood that the duration is “infinite”. The same understanding is true for IR statements described as “daily”. The “upper/lower bound” components and the “measure.semantic” are used in the same way as in all other timing related circumstances.

Note: The “repetition.periodDuration” fields are currently also used to capture numbers of tablets (or other units) and number of refills, if these are stated in the IR. The tablets/refills are used to calculate how long the administration period can be.

Example IR: Aspirin 81 mg oral tablet daily as needed, 30 tablets, 3 refills

30 tablets + 3 refills = 120 tablets

1 tablet/day = 120 days

Table 14.8.

repetition.periodDuration.lowerBound	1
repetition.periodDuration.upperBound	120
repetition.periodDuration.includeLowerBound	TRUE
repetition.periodDuration.includeUpperBound	TRUE
repetition.periodDuration.resolution	1
repetition.periodDuration.measureSemantic	258703001 |day (qualifier value)|

14.6.23. repetition.eventFrequency (Request)

This circumstance is used to capture the requested frequency of any repeated action, e.g. 3 times/day, once/week.

The “repetition.eventFrequency” circumstance has six components.

1. repetition.eventFrequency.lowerBound

   Format: Number (“float”)

2. repetition.eventFrequency.upperBound

   Format: Number (“float”)

3. repetition.eventFrequency.includeLowerBound

   Format: TRUE or FALSE (“Boolean”)

4. repetition.eventFrequency.includeUpperBound

   Format: TRUE or FALSE (“Boolean”)

5. repetition.eventFrequency.resolution (optional)

   Format: Number (“float”)

6. repetition.eventFrequency.measureSemantic

   Format: Logical Expression

Example IR: Naproxen 550mg tablet oral every 12 hours

Table 14.9. repetition.eventFrequency - Example 1

repetition.eventFrequency.lowerBound	12
repetition.eventFrequency.upperBound	12
repetition.eventFrequency.includeLowerBound	TRUE
repetition.eventFrequency.includeUpperBound	TRUE
repetition.eventFrequency.resolution	
repetition.eventFrequency.measureSemantic	258702006 |hour (qualifier value)|

Example IR: Ibuprofen 400 mg tablet oral every 6 hours; may increase dose frequency to one tablet every 4 hours

Table 14.10. repetition.eventFrequency - Example 2

repetition.eventFrequency.lowerBound	4
repetition.eventFrequency.upperBound	6
repetition.eventFrequency.includeLowerBound	TRUE
repetition.eventFrequency.includeUpperBound	TRUE
repetition.eventFrequency.resolution	
repetition.eventFrequency.measureSemantic	258702006 |hour (qualifier value)|

The “upper/lower bound” components and the measureSemantic are used as in all other timing related circumstances.

14.6.24. repetition.eventSeparation (Request)

Currently not in use.

14.6.25. repetition.eventDuration (Request)

This circumstance will be used to capture, HOW LONG each requested event should last, e.g. “Physical therapy 3 times per week for 1 hour.

Currently not in use.

15. Clinical Input Form Statements

A clinical statement represents an entry in the patient record that documents in a structured/computable manner clinical information about a subject of information, such as a patient or a relative of the patient, and that is asserted by a particular source, recorded, and potentially verified.

Clinicians author clinical statements and enter them into their organization's electronic health record (EHR). Clinicians typically enter the information via a manner that we call here the clinical input form (CIF). However, the CIF is not a literal form that clinicians select and enter data in. Rather, it refers to the manner in which information is presented to the clinicians and how they enter the data, such as by constraining the information to allow only certain values to be entered, such as through a drop-down list or radio button, or breaking up large chunks of related information into smaller parts. For example, when a clinician orders a medication, rather than selecting this information all at once with a single item, they will choose the various parts of the medication order, such as:

- Kind of drug and strength (e.g., Acetaminophen 150 mg)
- Amount and how often the patient should take the medication (e.g., 1 tablet twice daily)
- Duration (2 days)
- Any constraints (e.g., do not exceed a total daily dosage of 600 mg)

Ideally, the way the information is presented to clinicians is in a manner that is most efficient for the clinicians to use. However, what is an efficient way for clinicians to select and enter data may not be the most efficient way for data analysts to use when they are querying data once it has been normalized and stored in a database, such as when creating a new CDS rule or compiling prevalence statistics. For this, the data is normalized using the analysis normal form (ANF) and stored in a database. Again, the ANF is not necessarily a physical structure, but is how a data analyst might see the data when they are looking at it in a database, and not as clinicians would see it in the user interface (i.e., CIF).

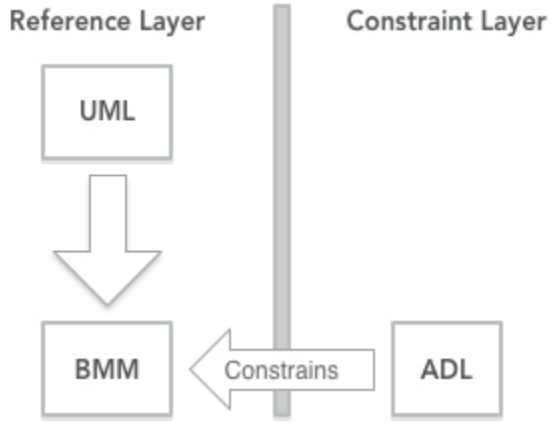
As a forward to this discussion it is necessary to provide some historical background about the Clinical Information Modeling Initiative(CIMI) model. The CIMI working group created a reference model with no working knowledge of a division between analysis normal form and clinical input form. The model they created was developed along standard lines of informatics thinking and thus ended up being a CIF model because CIF models are the norm in informatics. Thus, CIMI simply called this model the CIMI model. But now to distinquish it from the ANF model being proposed to CIMI, we will call the current CIMI model, the CIMI CIF model.

15.2. Basics of the CIMI Clinical Input Form

The CIMI CIF Model consists of two layers as shown in Figure 15.1, "CIMI CIF Model Layers". A reference model layer that defines the structural classes and named attributes, and a constraint layer which constrains these structural attributes by value, subtype, cardinality, and terminology. The basic modeling rule that CIMI CIF follows is: new named attributes are added in the Reference Layer and the constraining of existing attributes occurs in the Constraint Layer.

The CIMI CIF Reference Model layer is authored using Unified Modeling Language (UML). These class definitions may be viewed at http://models.opencimi.org/cimi_doc/.

Figure 15.1. CIMI CIF Model Layers



The constraint layer is described using Archetype Definition Language (ADL). ADL is a formal language with a textual syntax for describing constraints on the classes described in the reference layer. A re-usable formal constraint model defined in ADL is called an Archetype. The full collection of CIMI CIF Archetypes may be viewed at http://models.opencimi.org.

One complexity that needs to be addressed here is that ADL can only be used to constrain reference classes defined in a lightweight proprietary UML like specification called Basic Meta-Model (BMM). For this reason, CIMI has developed tooling that transforms the CIMI UML models into the BMM specification. Although this complexity does exist, to ease understanding, the reader can simply imagine that ADL is directly constraining the UML classes.

The UML/BMM classes are more abstract and the archetypes are where specific semantics such as 'blood glucose' or 'diabetes present; are asserted.

15.2.1. Structures

The CIMI UML/BMM model has three concentric layers: a Core that defines datatypes and a root class, a Foundation that describes compositional patterns similar to ISO 13606, and a Clinical model layer constructed on top of the Foundation.

Most clinical specifications will be based on the Clinical Statement pattern defined in the Clinical model layer. But this pattern does employ structures built out of Foundation and Core classes, so familiarity with these layers will be helpful. For more information consult the CIMI Architecture Guide.

15.3. Clinical Statement Pattern

The central focus of the CIMI Reference Model is the Clinical Statement. A Clinical Statement represents structured electronic communication made about a patient typically documented as an 'entry' in the patient record. For example, Clinical Statement can be used to represent the following statements made about a patient.

- Patient has diagnosis of congestive heart failure.
- Patient has a family history of breast cancer.
- Patient has a goal of smoking cessation.
- Patient has an order for Physical Therapy.
- Patient has a lab result of Serum Sodium equals 130 mEq/L with delta flag.

- Patient had an appendectomy.

Clinical Statement, shown in Figure 15.2, “Clinical Statement”, has a ‘key’, ‘topic’, ‘context’, and ‘meta’. The ‘key’ is the terminology meaning binding for the entire Clinical Statement. The ‘topic’ is the clinical entity being described. The ‘context’ describes the circumstances that form the setting in which the ‘topic’ should be evaluated. Finally, ‘meta’ is the collection of metadata that is associated with the clinical statement: the who, where, why and when information.

Figure 15.2. Clinical Statement

Topic The ‘topic’ is the clinical entity described by the Clinical Statement. A few examples of topic include clinical assertions, evaluation results, and procedures. For each of these topics the information described is quite different. Therefore, CIMI describes topic types that contain the appropriate attributes to describe the required information for the given topic. The number of topic types will change as CIMI progresses. Currently the allowable topic types are EventTopic, ProcedureTopic and FindingTopic which has suptypes of EvaluationResultTopic and AssertionTopic.

Context The ‘context’ describes the circumstances that form the setting in which the ‘topic’ should be evaluated. CIMI describes context types that contain the appropriate attributes to describe the required information for the given context. The number of context types will change as CIMI progresses. Currently the allowable context types are EventContext, ActionContext, and FindingContext. ActionContext has subtypes with examples including RequestContext, OrderContext and PerformanceContext. FindingContext has subtypes with examples such as PresenceContext, AbsenceContext, and GoalContext.

Metadata ‘metadata’ is not actually an attribute of ClinicalStatement, but is intended here to represent the various attributes in clinical statement that represent metadata about the clinical statement. This includes attribution information relating to the statement itself such as who authored, verified, recorded, or signed the statement or more informally, the who, where, why, and when information. Other attributes of this nature are recordStatus and encounter.

15.3.1. Examples Using Topic and Context

Earlier, descriptive examples of Clinical Statements were given. Here we will represent a few of these examples using the Clinical Statement ‘topic - context’ paradigm. In Figure 15.3, “Patient has diagnosis of congestive heart failure.”, the example for “Patient has diagnosis of congestive heart failure” is illustrated. The topic has been declared to be of type AssertionTopic stating “assertion of congestive heart failure”, and the context has been declared to be of type PresenceAbsenceContext stating “Known Present”. What may not be apparent in the figure is that when the topic is declared to be of type AssertionTopic then all the attributes of AssertionTopic are available for use. However, in the figure only the attribute named ‘result’ is shown for clarity.

In Figure 15.4, “Patient has an order for Physical Therapy.”, the example for “Patient has an order for Physical Therapy.” is shown. The topic has been declared to be of type ProcedureTopic stating “procedure of type physical therapy”, and the context has been declared to be of type OrderContext. Again, the majority of attributes for ProcedureTopic and OrderContext are not shown for clarity.

Figure 15.3. Patient has diagnosis of congestive heart failure.

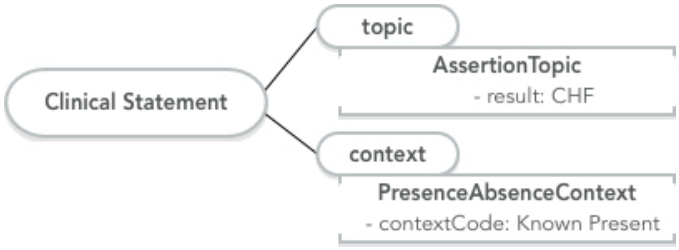
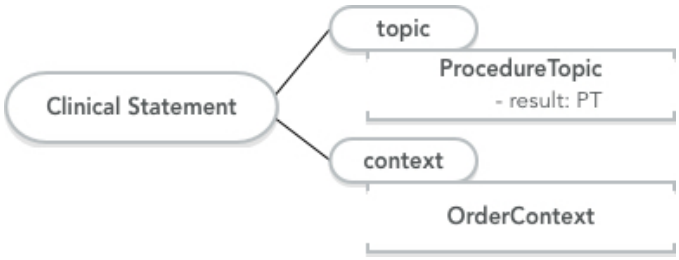


Figure 15.4. Patient has an order for Physical Therapy.



StatementTopic and StatementContext are both collections of attributes and have the following characteristics:

1. They are reusable components that can be assembled to form clinical statements. For instance, one can coordinate the ProcedureTopic with the ProposalContext to represent a ProcedureProposal statement. Alternatively, ProcedureTopic may be paired with OrderContext to create a ProcedureOrder statement.

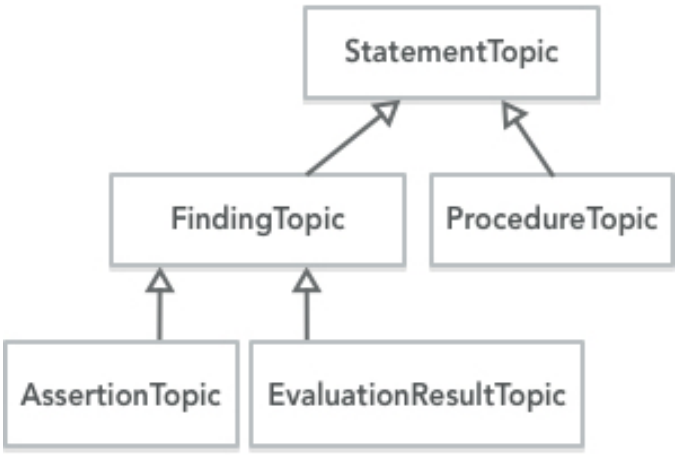
2. They represent groupings of attributes aligned with the SNOMED Clinical Terms (SNOMED CT) Concept Model. For instance, ProcedureTopic is aligned with the SNOMED CT Procedure Concept Model. PerformanceContext aligns with the Situation with Explicit Context Concept (SWEC) Concept Model.

3. They provide for a mechanism to state presence or absence of a finding as well as performance or non-performance of an action. For instance, the pairing of ProcedureTopic with NonPerformanceContext allows for the expression of a procedure that was not performed.

15.4. Topic Patterns

Topic Patterns include all the attributes required to fully describe a clinical entity. The topic patterns CIMI has developed to date include FindingTopic, ProcedureTopic, and EventTopic, wheith FindingTopic having children of AssertionTopic and EvaluationResultTopic. They are shown in Figure 15.5, “Topic Hierarchy” and are described in the following sections. Each of these topic subtypes contain a collection of attributes that describe the given pattern. These patterns provide the foundational structure for detailed clinical model (DCM) archetype instances that can be visualized at http://models.opencimi.org

Figure 15.5. Topic Hierarchy



15.4.1. AssertionTopic

The first topic type described here is the AssertionTopic pattern with its included attributes, as shown in Figure 15.6, “AssertionTopic”. ConditionTopic, shown in Figure 15.7, “ConditionTopic” is a child of AssertionTopic which is used to represent a clinical finding such as the presence (or absence) of a condition in a patient. For example:

- ChestPainAssertion asserts the presence of chest pain.
- ChestPainAbsenceAssertion asserts the absence of chest pain.
- EdemaAssertion asserts the presence of edema.

Figure 15.6. AssertionTopic

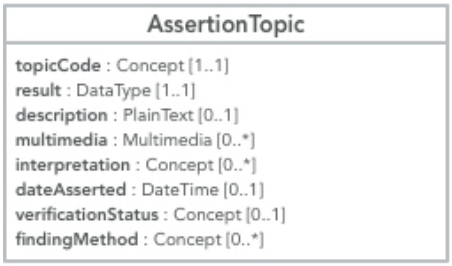


Figure 15.7. ConditionTopic

The assertion pattern for a clinical statement is as follows:

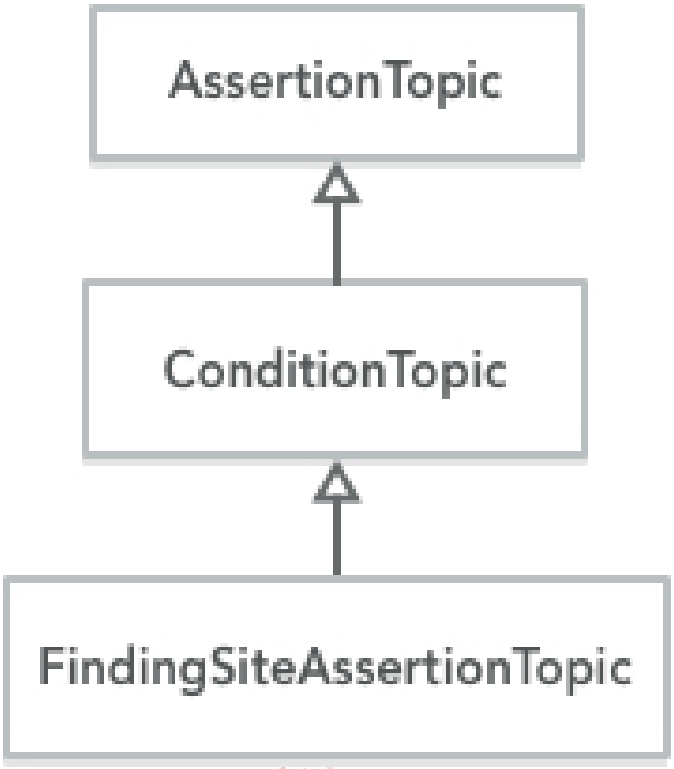
- topic.topicCode = a code meaning “assertion”.
- topic.result = a code representing what is being asserted (i.e., “rash”, “auto accident”, “hypertrophy”, etc.).

15.4.1.1. Assertion Hierarchy

The full hierarchy for AssertionTopic is shown in Figure 15.8, “Assertion Hierarchy”. AssertionTopic serves two important purposes: (1) it provides the core set of assertion attributes that are relevant in assertion of presence and absence; and (2) it is the parent type for the more specific assertions such as ConditionTopic and FindingSiteAssertionTopic. If additional attributes are identified as needed to properly model assertions they would either be added to one of the existing assertion types or a new type could be created with these attributes. This modeling decision would be based on whether adding these attributes make sense for existing assertions types or whether they should be used to create a new subset of assertions. Typically an attribute is added to the parent class if that attribute is relevant in all the subclasses derived from the parent class. If an attribute is only relevant in some of the subclasses then the attribute is introduced in these subclasses. This ensures that a class does not have an attribute that is incongruent and thus requires that attribute to be occasionally constrained out. For instance, it is viewed as bad practice to create an Animal class that contains arms, legs, and wings and then create a subclass of dog that constrains out wings since dogs do not have wings.

Note there are two ways to introduce an attribute that is not always used. A UML class specialization specifies a new class that has all of the attributes of its parent and may then specify additional attributes. An archetype may choose to use whichever class, parent or child, is appropriate. Or, the additional attribute may be added to the original class and the archetype may then use the attribute or "constrain it out" by setting its cardinality to zero. As previously state, CIMI modelers prefer the first approach, extension through UML class specialization, that avoids the need to constrain elements out of archetypes.

Figure 15.8. Assertion Hierarchy



15.4.1.2. Assertions

Assertions affirm or deny the existence of clinical conditions, diseases, symptoms, etc., in the patient. As just described, different varieties of assertion may extend an existing AssertionTopic class with any additional attributes necessary to fully represent this new group of assertions. Table 1 shows examples of clinical statements using the AssertionTopic class for the topic, and Table 2 shows examples of clinical statement using FindingSiteAssertionTopic for the topic. These examples show the 'topic.topicCode', 'topic.result', and 'context.contextCode' for each, with the addition of any extra attributes from the chosen topic needed to describe the clinical statement. Context will be discussed in depth later in this document. For now, be aware the chosen context is a full class with many attributes but here we are only showing the context code attribute that is common to all context types.

Example 15.1. The patient has diabetes mellitus type 1 which was diagnosed at age 24

```
DiabetesMellitusAssert
    topic.topicCode: Assertion
    topic.result: Diabetes mellitus type 1 (disorder)
    topic.ageAtOnset: 24 years
    context.contextCode: Confirmed present (qualifier value)
```

Example 15.2. The patient does not have diabetes mellitus type 1

```
DiabetesMellitusAbsentAssert
```

```
    topic.topicCode: Assertion
    topic.result: Diabetes mellitus type 1 (disorder)
    context.contextCode: Known absent (qualifier value)
```

Note, in the CIMI alignment with the SNOMED CT concept model, the AssertionTopic pattern corresponds to the Finding hierarchy as inflected by the Situation hierarchy.

Note AssertionStatement.topic.topicCode is not part of this construction. It is modeled with the fixed term "assertion" and is as semantically inert as we can manage.

Other attributes may also inflect the semantics; e.g., an AssertionStatment.topic.findingMethod that would align with the concept model's Finding.findingMethod.

15.4.1.3. Finding Site Assertions

A FindingSiteAssertionTopic is an assertion about a finding found on the body. This assertion is a "design by extension" assertion because it contains the additional attribute findingSite that is used to capture the body site affected by the condition. The FindingSiteAssertionTopic encourages post-coordination as shown in examples 3 and 4, and intentionally aligns with the SNOMED CT Clinical Findings concept model.

Example 15.3. The patient has a femur fracture in the right leg

```
FractureAssert
    topic.topicCode: Assertion
    topic.result: Fracture of bone (disorder)
    topic.findingSite.code: Bone structure of femur
    topic.findingSite.laterality: Right (qualifier value)
    context.contextCode: Confirmed present (qualifier value)
```


Example 15.4. The patient has a stage two pressure injury on the right ischial tuberosity

```
WoundAssert
    topic.topicCode: Assertion
    topic.result: Pressure ulcer stage 2 (disorder)
    topic.findingSite.code: Skin structure of ischial tuberosity
    topic.findingSite.laterality: Right (qualifier value)
    context.contextCode: Confirmed present (qualifier value)
```

15.4.2. Evaluation Result

The second topic pattern we will discuss is EvaluationResultTopic which is used to document a characteristic of a patient or a clinical value being observed. An EvaluationResultTopic may hold the name of a test in the 'topicCode' attribute (e.g., "heart rate evaluation", "serum glucose lab test", etc.) and the resulting value of the test in the 'result' attribute. Viewed another way, the EvaluationResultTopic topicCode holds a question (e.g., "what is the heart rate?", "what is the serum glucose?") and the 'result' holds the answer. Any clinical statement such as a laboratory test, a vital sign, or a questionnaire question that fits this pattern of a question and a resulting value is modeled with the EvaluationResultTopic pattern.

The evaluation result pattern for a clinical statement is as follows:

- topic.topicCode = what's being evaluated ("heart rate", "serum glucose", "breath sound", etc.).
- topic.result = the result of the evaluation ("72 bpm", "100 mg/dL", "rales")

The following is an isosemantic comparison of the evaluation result pattern to the previously described assertion pattern. In the previous section, we illustrated assertion models using rash, auto accident, and hypertrophy. Below we show what these assertion examples would look like if we hypothetically modeled them using the Evaluation Result pattern. Note, CIMI avoids creating models where the 'result' specifies "presence/absence" or "yes/no", so this is a clear indicator that the assertion pattern is preferred in these cases.

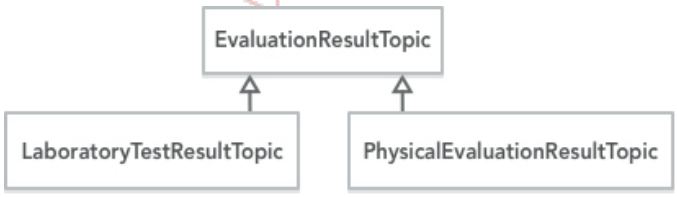
Assertion	• topic.topicCode = a code meaning "assertion" • topic.result = a code representing what's being asserted ("rash", "auto accident", "hypertrophy", etc.)
EvaluationResult (This is hypothetical)	• topic.topicCode = what's being evaluated ("rash", "auto accident", "hypertrophy", etc.) • topic.result = "present" or "yes"

Like Assertion, Evaluation Result corresponds to the SNOMED CT concept model. The EvaluationResultStatement.topic.topicCode attribute corresponds to the observation being evaluated.

15.4.2.1. Evaluation Result Hierarchy

EvaluationResultTopic currently has two subtypes; LaboratoryTestResultTopic (that includes additional attributes necessary to describe laboratory tests) and PhysicalEvaluationResultTopic.

Figure 15.9. Evaluation Result Hierarchy



15.4.2.2. Modeling in the Constraint Layer

This section will use LaboratoryTestResultTopic, which exists in the Reference Model Layer, to further describe modeling in the Constraint Layer. There are different categories of laboratory tests that differ in their resulting data type, such as quantitative labs and nominal labs, where the former would have a QUANTITY result and the latter would have a CODED_TEXT result. For the different lab categories there is not a need for new named attributes only a need to constrain the result to the appropriate datatype. The modeler has a choice to make in this situation as the datatype could be constrained in a new class subtype in the reference layer or as an archetype in the constraint layer. Since a new named attribute is not required the style CIMI has adopted as the constraint would occur in the constraint layer and an ADL Archetype would be created for both QuantitativeLaboratoryTestResult and NominalLaboratoryTestResult.

15.4.2.3. Evaluation Result Subtypes

LaboratoryTestResultTopic	LaboratoryTestResultTopic contains attributes specific to the lab evaluation process. These include information about the physical process (e.g., specimen) plus process management information (e.g., status).

PhysicalEvaluationResultTopic PhysicalEvaluationResultTopic contains attributes specific to the clinical evaluation process. These include information about the physical examination process (e.g., patient position, body site).

Example 15.5. The patient's skin turgor is friable

```
SkinTurgorEval
    topic.topicCode: Skin turgor (observable entity)
    topic.result: Fragile skin (finding)
    topic.evaluationProcedure: Inspection (procedure)
    context.contextCode: Confirmed present (qualifier value)
```

Example 15.6. The patient's systolic blood pressure is 120 mmHg

```
SystolicBloodPressureEval
    topic.topicCode: Systolic arterial pressure (observable entity)
    topic.result: 120
        unitsOfMeasure: Millimeter of mercury (qualifier value)
    topic.evaluationProcedure: Auscultation (procedure)
    context.contextCode: Confirmed present (qualifier value)
```

15.4.2.4. Guideline: Assertion versus Evaluation

In most cases the decision between using the evaluation result pattern and the assertion pattern is intuitive and straightforward. "Urine color", for example, is clearly best modeled as an evaluation result because the attribute being evaluated is the color of the patient's urine and the result of the evaluation is the set of codes representing the colors that may be observed. To model urine color as an assertion would require the creation of a large number of pre-coordinated concepts. The key would be "assertion" and result would be populated with a code from a set of codes such as "amber urine" (meaning "the patient has amber urine"), "clear urine", etc.

However, this highlights any evaluation model may be transformed into an assertion model. (Conversely, any assertion model may be transformed into an evaluation model.) In the case of urine color, the decision is intuitive. In other cases the decision is less clear.

For example, "heart rhythms" (bradycardic, tachycardic, etc.) may be modeled as multiple assertion models (bradycardia, tachycardia, etc.) or as a "heart rhythms" evaluation model whose data is constrained to a value set (containing "bradycardic", "tachycardic", etc.).

The general guideline is if it is natural to think of the concept as a noun, as a condition or state that exists in the patient, model as an assertion or set of assertions. If the statement about the patient is thought of as a name/value pair (i.e., a noun representing the attribute and an adjective representing the value), such as "hair color" = ("black", "brown", "blonde"), then model it as an evaluation. However, it is important to note both styles are allowed and the true determinant of their use is whether a result for a given criteria other than true/false or present/absent is specified.

This discussion highlights the importance of isosemantic models. Even if one model or set of models can be agreed upon as the preferred storage model (e.g., assertion models for "bradycardia" and "tachycardia" instead of an evaluation model with "bradycardic" and "tachycardic" as values), inevitably there will be use cases (e.g., data entry, messaging, reporting, etc.) for the other model and a need to identify use cases where

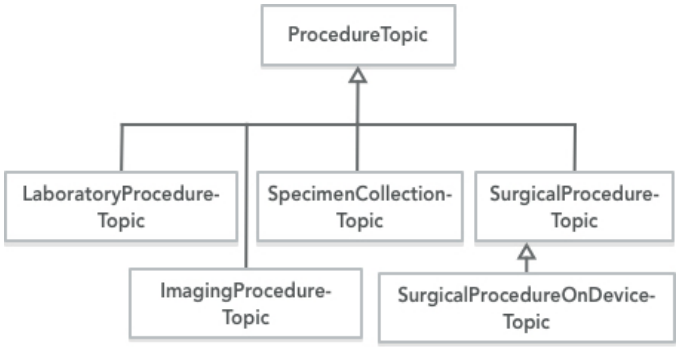
different modeling patterns describe semantically identical phenomena. These patterns are isosemantic. An essential (as of now unfulfilled) requirement is for a mechanism of identifying isosemantic models, managing isosemantic groups, and transforming between them. We expect a great deal of this work to be facilitated by the semantic underpinnings of the models supporting the ability to classify the content of two models and determine their logical relations (equivalent, subsumed, disjoint).

It should be noted the Assertion vs. Evaluation topic is solely concerned with the structure and schema pattern used to capture clinical information. Choosing Assertion vs. Evaluation patterns has nothing to do with whether the information being captured is subjective vs. objective.

15.4.3. ProcedureTopic

Procedure models are used to represent actions taken related to the care of a patient such as a cholecystectomy, peripheral IV placement, delivery of a warm blanket, dressing change, ambulation, patient education, etc. The CIMI ProcedureTopic, as shown in Figure 15.10, “Procedure Hierarchy”, is a base class for a number of specializations such as surgical, imaging, and laboratory procedures. The CIMI Procedure Model is aligned with the SNOMED CT Procedure Concept Model when such an alignment exists.

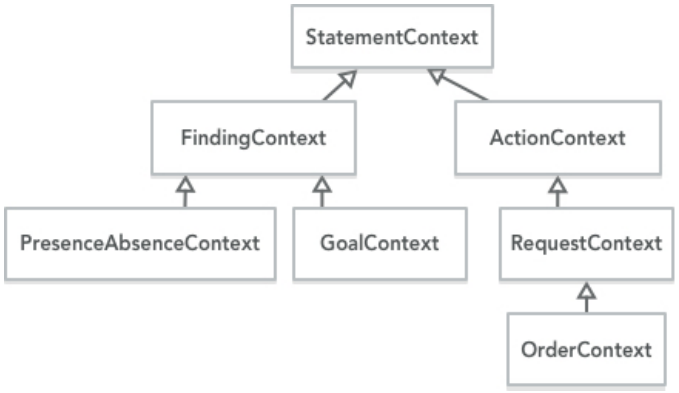
Figure 15.10. Procedure Hierarchy



15.5. Context Patterns

When a Clinical Statement is defined it will be modeled as a combination of a topic and a context. The ‘context’ describes the circumstances that form the setting in which the ‘topic’ should be evaluated. Specializations within the context hierarchy, shown in Figure 15.11, “Procedure Hierarchy”, add important attribution information for the situation being described.

Figure 15.11. Procedure Hierarchy



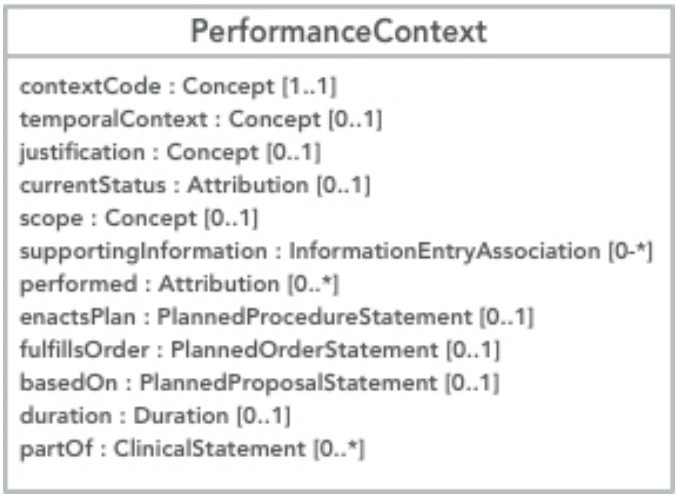
The StatementContext abstract class has the following three specializations:

FindingContext The FindingContext class aligns with the SNOMED Situation with Explicit Context for findings and provides the context for either the EvaluationResultTopic or AssertionTopic of a clinical statement. For instance, a context about a finding may state that the finding was present or absent.

ActionContext The ActionContext class aligns with the SNOMED Situation with Explicit Context for procedures and provides the context for the Act topic of a clinical statement. For instance, a statement about a procedure may specify the procedure has been proposed, ordered, planned, performed, or not performed. Each action context, in turn, has its own lifecycle. An example of the PerformanceContext class is shown in Figure 15.12, “PerformanceContext”.

EventContext Not shown in the above diagram, EventContext is a child of StatementContext. At this time specializations of EventContext have not been defined. It is anticipated that EventOccurrence and EventNonOccurrence specializations will be introduced.

Figure 15.12. PerformanceContext



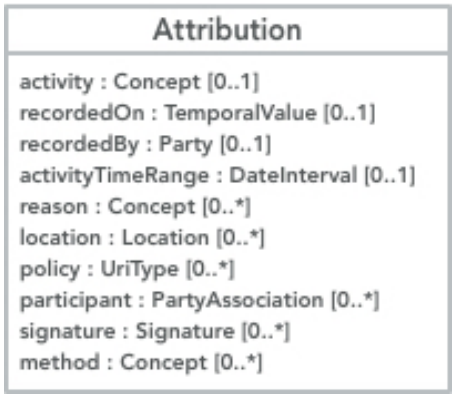
15.6. Metadata

The final division of the Clinical Statement pattern is the metadata which is a collection of attribution/provenance information regarding the topic/context being described by the clinical statement.

15.6.1. The CIMI Attribution/Provenance patterns

In the CIMI model, provenance information is represented by the Attribution class shown in Figure 15.13, “Attribution Class”. The Attribution class provides a pattern for the capture of provenance information such as the what, who, when, where, why, and how associated with a particular activity – e.g., provenance attributes about the verification of a clinical statement (e.g. the provider performing the surgery in O.R. suite 6).

Figure 15.13. Attribution Class



CIMI currently includes two attribution patterns:

1. Attribution information as a part of the clinical statement – In this pattern, the ClinicalStatement pattern contains a number of attributes of type Attribution (e.g., ClinicalStatement.authored and ClinicalStatement.verified). This pattern provides a consistent way to capture attribution information that extends beyond simply the agent of an activity (e.g., the author). When attribution is part of the ClinicalStatement model, any change to the attribution for an activity will result in a version change.

2. Attribution information external to the clinical statement - CIMI allows the capture of provenance information external to the clinical statement through the Provenance class. The provenance class contains the Attribution class and provides pointers to one or more clinical statements (e.g., the Provenance.target attribute). This pattern allows the addition and modification of provenance information associated with a clinical statement without impacting its version.

15.7. Differences between ANF and CIF

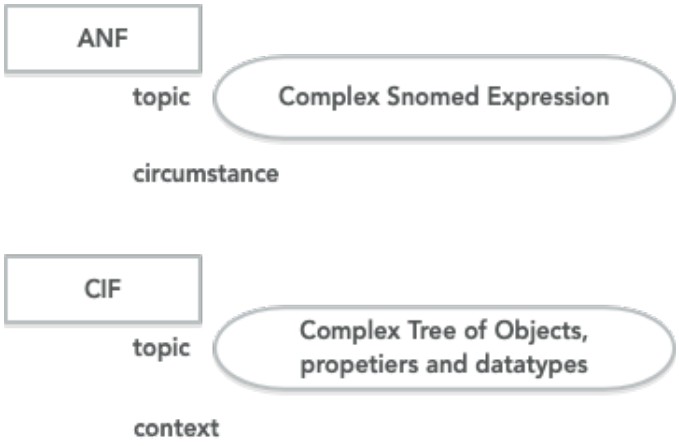
There are two fundamental differences between ANF and CIF. The first is the representation of topic, and the second is the representation of results.

1. The representation of topic.
2. The represenation of results.

15.7.1. The Representation of Topic

In the ANF model, the topic is represented by a single field containing a simple to complex snomed expression whereas in the CIF model, all the pieces of information that make up the topic are broken out and structured as needed into multiple properties with propery names and appropriate datatypes.

Figure 15.14. Topic Comparison



One implication of this is that the ANF is using two formalisms to represent the detailed clinical model. First it uses the formalism that represents the ANF reference model and constraints such as HL7's StructureDefinition syntax or OpenEHR's BMM/ADL syntax. Second, it uses Snomed's syntax for post-coordinated Snomed expressions. Tools for authoring and analysis would be required to parse and process both syntaxes.

The CIF model, on the otherhand, would be fully represented using the formalism that represents the CIF reference model and contraints such as HL7's StructureDefinition syntax or OpenEHR's BMM/ADL syntax.

15.7.2. The Representation of Results

In the CIMI CIF model, EvaluationResult and Assertion models are used to represent results. EvaluationResult has a topic representing what is being observed, and a result represented by a choice of datatypes. An Assertion on the otherhand, has simply a topic with a value of 'assertion', and a result stated what is being asserted.

In the ANF moded, the topic represents what is being observed and the result may only be a range of either a count or quantity. No coded results are allowed.

In the CIF model, when creating a model with a numeric result, the choice is quite clear and the choice will be an EvaluationResult, such as a topic of 'SerumSodium' and result with a numeric quantity. In this case, the CIF and ANF model or very aligned, except for the fact that the ANF model will use a range of that quantity.

But when a CIF model has a potential coded result, the choice between EvaluationResult and Assertion becomes muddied. For example, a model for Breath Sound could be an EvaluationResult with a topic of 'breath sound' and a coded rusult with the following valueset. Thus any of the breath sounds within the valueset can act as a result for this model. The other option, is that each of the breath sounds in the valueset is modeled as an Assertion with a topic of 'assertion', and a result of each particular code. To decided which model is better, usually we ponder how the clinician thinks about the data, or how it will be collected, or how it will be queried.

The ANF model can not do an EvaluationResult style model as it doesn't allow code results. Thus ANF is forced to make one and only choice, which is an assertion style where the particular breath sound is the topic, and the result will be numeric count indicating presence or absence.

- Absent

- Audible
- Clear
- Coarse Breath Sounds
- Coarse Crackles
- Crackles
- Diminished
- Expiratory wheezing
- Faint
- Fine Crackles
- Forced
- Inspiratory wheezing
- Left Ventricular Assist Device Noise
- Markedly Decreased
- Moderately Decreased
- Pleural Rub
- Pleural Rub
- Prolonged Expiration
- Rhonchi
- Slightly Decreased
- Stridor
- Tubular Breath Sounds
- Upper Airway Congestion
- Wheeze

When querying instance data, the Assertion or ANF style is much more difficult for things like breath sounds. To query any breath sound instances, you have knowledge of all possible breath sound topics and query for each. With the EvaluationResult style, querying is simpler as you simply query for a topic of 'breath sound', and the code result tells you what type of breath sound it is. Thus you do not have to know all the members of the valueset apriori to form the query.

15.8. Appendix A - Glossary

Table 15.1. Glossary

Term	Acronym	Definition
Archetype		A re-usable, formal model of a concept expressed as a computable constraint model defined in ADL
Archetype Definition Language	ADL	ADL is a formal language for expressing archetypes. It provides a formal, textual syntax for describing constraints on any domain entity whose data is described by an information model
Attribute		A field in any class
Clinical Information Modelling Initiative	CIMI	An initiative established to improve the interoperability of healthcare information systems through shared implementable clinical information models
Clinical Statement		Structured electronic communication made about a patient typically documented as an 'entry' in the patient record
Complex Clinical Statement		A statement that is composed of parts where each part can only be fully understood in the context of its parent

Term	Acronym	Definition
Compound Clinical Statement		A clinical statement composed of one or more clinical statements that may exist outside of the containing parent statement
Constraint Model		A formal specification used for describing constraints on an Underlying Reference Model. The Constraint Model is used to express clinical information models (i.e. archetypes)
Context		The circumstances that form the setting in which the 'topic' should be evaluated
Detailed Clinical Model	DCM	A relatively small, standalone information model designed to express a precise clinical concept in a standardized and reusable manner
Governance		The use of a set of processes, customs, policies, laws and institutions to direct the way people administer
Isosemantic Models		A model that, while different in structure, represents the same semantic content as a second model
Key		The main concept of interest in a clinical statement, about which the other attributes and relationships provide additional information
Meta		Attribution information relating to the statement itself such as who authored, verified, recorded, or signed the statement. Meta includes the who, where, why and when information
Terminology Binding		The assertion of a relationship between the information model and the terminology
Topic		The clinical entity described by the Clinical Statement e.g. clinical assertions, evaluations results, and procedures
Topic Pattern		Attributes required to fully describe a clinical entity

16. Isosemantic Transformation

Isosemantic models refer to models that may share a different structure but which are semantically equivalent. In order for two models to be isosemantic the models must support bidirectional transformations without any information loss. Isosemantic models allow models whose representations better address clinical requirements while retaining formal and detailed semantics. For instance, while a more post-coordinated information model may facilitate integration with existing systems, an interface model may favor greater terminology pre-coordination and a simpler structure that aligns better with the needs of an input form presented to a clinician. Typically, isosemantic models range between two poles - a highly detailed information model that makes little use of terminology pre-coordination and post-coordinated expressions and a highly simplified information model where most of the model representation resides in a fully post-coordinated terminology expression based on an underlying concept model. Many isosemantic models reside within this continuum.[1]

16.1. Transformation Languages for Converting CIMI DCM Instances to SOLOR DL Expressions

Walter Sujansky

16.1.1. Introduction

This whitepaper addresses processes for transforming clinical data that were collected using an object-oriented data model (CIMI) into semantically equivalent data structures represented using a description-logic model (SOLOR). The paper discusses the motivation for performing such transformations and evaluates several candidate languages for specifying and executing the transformations. Specific recommendations are made regarding the next steps in selecting the best language for CIMI-to-SOLOR transformations of clinical data.

16.1.2. Motivation for CIMI to SOLOR Transformations

CIMI detailed clinical models (DCMs)[2,3] are object-oriented templates for capturing, representing, and sharing clinical observation data. They define and constrain, at a conceptual-modeling level, the structure and the coding used to represent certain types of observations. For example, Figure 16.1, “CIMI DCM. ” shows a simplified DCM for representing pain symptoms[4].

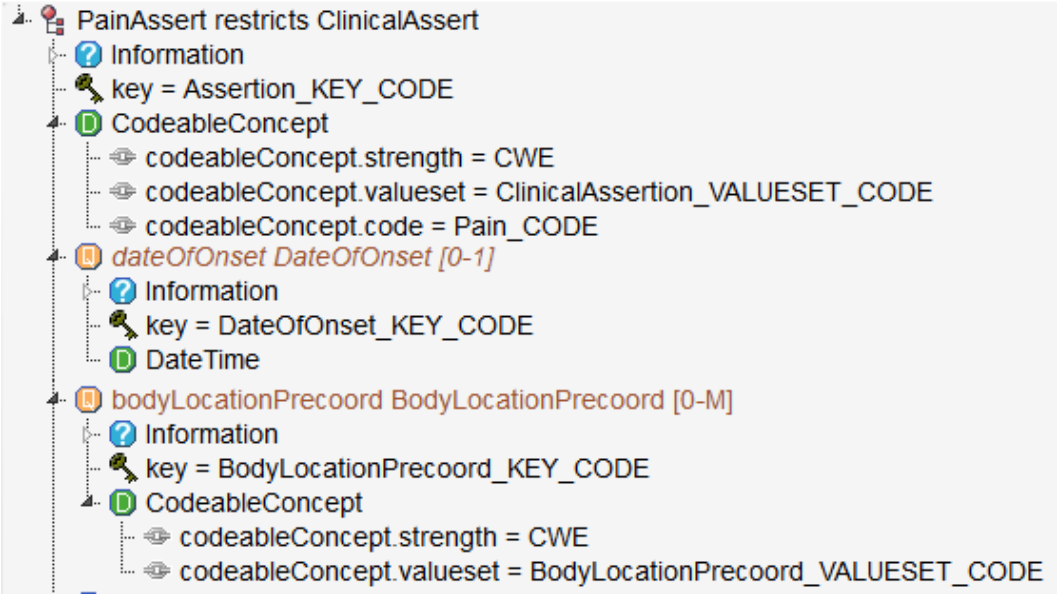
[1] http://models.opencimi.org/cimi_doc/CIMIArchitectureGuide/CIMIArchitectureGuide.html

[2] Goossen, W. Detailed Clinical Models: Representing Knowledge, Data and Semantics in Healthcare Information Technology. Healthc Inform Res. 2014 Jul; 20(3): 163–172.

[3] http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models (Accessed 9/30/2017).

[4] The actual syntax shown is from the Clinical Event Model, a representation model closely related to CIMI, but which provides a larger compendium of relevant examples at this time (CIMI models are still in the process of being defined).

Figure 16.1. CIMI DCM.



Note that the DCM is a template that can be used to represent instances of pain symptoms in many different anatomical locations at different times, but always conforming to a single, predictable pattern. For example, Figure 16.2, “CIMI instance, rendered as XML. ” shows a particular instance of the Pain DCM which documents a patient’s symptom of pain in the right lower quadrant of the abdomen on a particular date. Note that, in this case, the pain instance is represented in XML, although DCMs, themselves, do not specify any particular rendering format.

Figure 16.2. CIMI instance, rendered as XML.

```
<?xml version="1.0" encoding="UTF-8"?>
<PainAssert>
   <Archetype archetypeId="4784894573"/>
   <CodeableConcept>
      <Code codingSystem="SCT" code="22253000" text="Pain"/>
   </CodeableConcept>
   <DateOfOnset dateTime="2017-04-21 00:00:00"/>
   <BodyLocationPrecoord>
      <CodeableConcept>
         <Code codingSystem="SCT" code="48544008" text="Right lower quadrant of abdomen"/>
      </CodeableConcept>
   </BodyLocationPrecoord>
```

Although DCMs are very useful for standardizing the representation of clinical data to facilitate portability and interoperability, these models confer minimal computable semantics to the data represented. With the exception of supertype/subtype relationships (e.g. “PainAssert” is a subtype of “ClinicalAssert”, as shown in the first line of Figure 16.1, “CIMI DCM. ”), DCMs do not support logical inferencing with respect to patient-data instances.

Logical inferencing allows computer systems to draw new, logically sound conclusions based on patient data. Such inferencing, which includes equivalence testing, subsumption testing, and attribute inferral, can be very useful in the retrieval and processing of clinical data for decision support, research, quality measurement, etc.

16.1.2.1. Benefitting from Description Logic Semantics

Description logics (DLs) are ontological representation systems based on a subset of first order logic. A prominent example of a DL system in healthcare is SNOMED-CT, and its derivative system SOLOR. SOLOR defines a formal model for the representation of ontological knowledge and includes an inference engine ("reasoner") for deriving new, latent information based on the represented knowledge and the rules of logic.

For example, SOLOR can automatically infer that "Appendicitis" is a "Gastrointestinal Disease" and involves the process of "Inflammation", based solely on the rules of logic and provided ontological definitions of "Gastrointestinal Disease", "Gastrointestinal System", "Appendicitis", and "Appendix". Such inferences can be useful, for example, in finding all patients who have a gastrointestinal disease for purposes of research, or determining why a specific patient may have a fever for purposes of decision support.

Although SOLOR is based on a different formalism that CIMI DCMs, SOLOR representations of medical concepts share a number of features with CIMI DCMs. Specifically, both modeling systems use of an object-oriented framework that organizes concepts into hierarchies and specifies the features of concepts using attributes, which themselves can take other defined concepts as values. Hence, there exists the opportunity to map between CIMI DCMs and SOLOR expressions, and to transform CIMI data instances into SOLOR concept expressions based on these mappings. The sound execution of such transformations allows clinical information systems to capture and share data using the CIMI formalism, but then retrieve and analyze the data using the SOLOR formalism and the additional inferencing power it provides.

16.1.2.2. Example

Returning to the example of Figure 16.1, "CIMI DCM. " and Figure 16.2, "CIMI instance, rendered as XML. ", imagine one wished to query a patient database to retrieve all patients who had experienced abdominal pain, i.e. pain located somewhere in the abdomen. If patient data were represented only as instances of CIMI DCMs, one would do this by searching for all patients who had an instance of the "PainAssert" DCM with the code for "Abdomen" as the value of its "BodyLocationPrecoord" attribute:

SELECT PatientID FROM Findings WHERE Findings.CodeableConcept.Code.code = "22253000 (Pain)" AND Findings.BodyLocationPrecoord.CodeableConcept.Code.code = "7584978 (Abdomen)"

However, this query would retrieve only those patients with documented pain located generally in the "Abdomen," and would miss any patients with pain documented in sub-parts of the abdomen, such as the "Lower abdomen", the "Right lower quadrant of the abdomen", the "Epigastrium", etc. To retrieve all patients with pain anywhere in the abdomen, the query would have to include all possible sub-parts of the abdomen, as well as the general abdomen itself:

SELECT PatientID

FROM Findings

WHERE Findings.CodeableConcept.Code.code = "22253000 (Pain)" AND

(Findings.BodyLocationPrecoord.CodeableConcept.Code.code = "7584978 (Abdomen)" OR

Findings.BodyLocationPrecoord.CodeableConcept.Code.code = "6487587 (Lower Abd.)" OR

Findings.BodyLocationPrecoord.CodeableConcept.Code.code = "6487588 (RLQ of Abd.)" OR

Findings.BodyLocationPrecoord.CodeableConcept.Code.code = "7584978 (Epigastrium)" OR

…etc.)

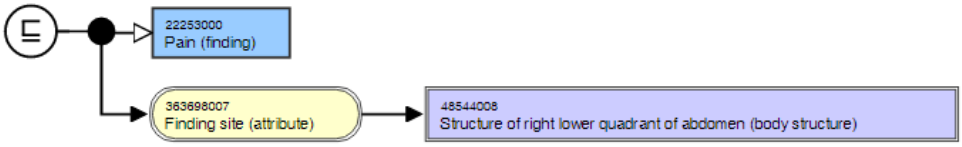
The exhaustive inclusion of all such abdominal sub-parts and sub-sub-parts in every query that needs to specify the abdominal area would be onerous, as well as subject to error as the coded terminology representing these sub-parts changes over time. Further, formulation of queries with respect to CIMI DCM instances requires a detailed knowledge of the nested DCM data structure and the specific combinations of attributes that represent certain semantic concepts.

However, there is a better alternative if one could first transform the CIMI DCM representations of all recorded observations into SOLOR DL representations. Such transformations would allow the same query to be formulated and executed more easily using DL inference.

For example, the expression in Figure 16.3, “Description-logic representation of the CIMI DCM instance shown in Figure 16.2, “CIMI instance, rendered as XML. ”. ” shows the DL formulation of the same[5] “Pain in right lower quadrant” observation represented in Figure 16.2, “CIMI instance, rendered as XML. ”. Figure 16.3, “Description-logic representation of the CIMI DCM instance shown in Figure 16.2, “CIMI instance, rendered as XML. ”. ” shows both the textual and the equivalent graphical rendition of the DL expression.

Figure 16.3. Description-logic representation of the CIMI DCM instance shown in Figure 16.2, “CIMI instance, rendered as XML. ”.

```
SubClassOf:
Pain and
  ( Finding site some Structure of right lower quadrant of abdomen)
```

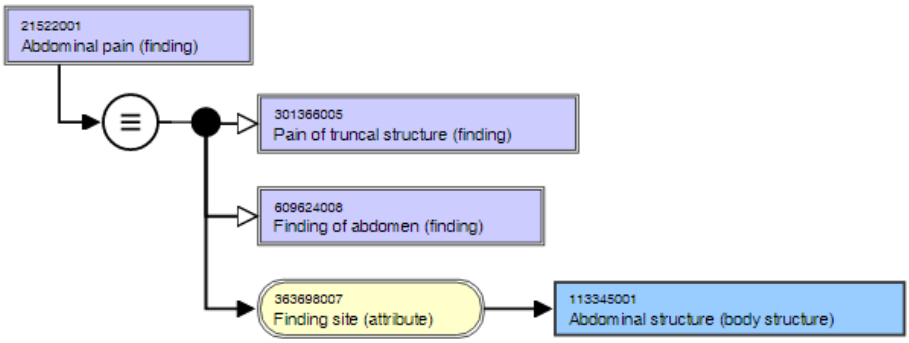


Initially, the DL expression in Figure 16.3, “Description-logic representation of the CIMI DCM instance shown in Figure 16.2, “CIMI instance, rendered as XML. ”. ” is subsumed within the SOLOR concept hierarchy only by the concept “Pain,” because the expression explicitly specifies only that the expression is a sub-class of Pain. This hierarchical classification would not help a query to recognize that the patient with this finding, in fact, has an instance of “Abdominal pain.” However, the SOLOR ontology also includes the DL definition of the more specific concept “Abdominal Pain,” specified as follows:

[5]Note that this representation lacks the temporal “DateOfOnset” attribute, because that attribute falls outside of the SOLOR concept model (as further discussed in Section Section 16.1.3.3, “Outputs”).

Figure 16.4. Description-logic definition of “Abdominal Pain.”

```
EquivalentTo:
Pain of truncal structure and
Finding of abdomen and
  ( Finding site some Abdominal structure)
```

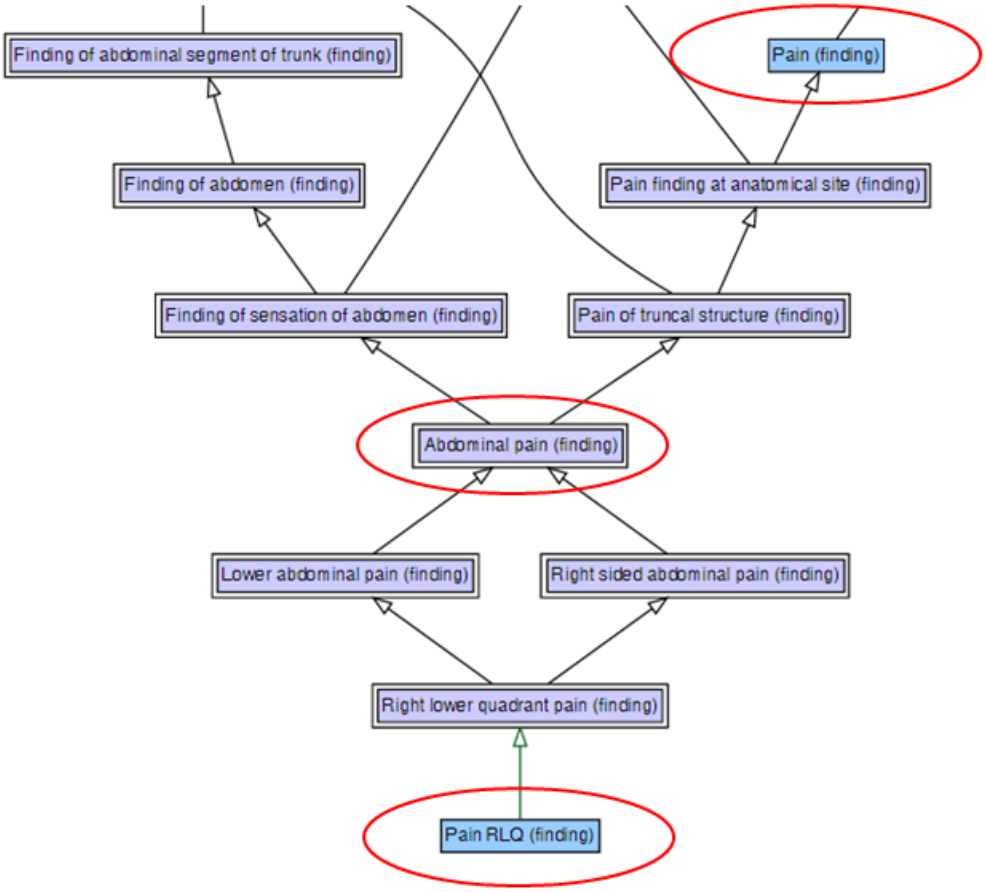


Based on this logical definition of “Abdominal Pain,” on the DL definitions of several other clinical concepts, and on formal rules of logic, a SOLOR reasoner can infer that the DL expression for “Pain in right lower quadrant” is subsumed by “Abdominal Pain.” In fact, the reasoner can correctly classify the expression into the subsumption hierarchy of Figure 16.5, “Inferred subsumption hierarchy. ”. Using these inferred subsumption relationships, the previous query to retrieve all patients who had experienced abdominal pain may now be reformulated as follows:

SELECT PatientID FROM Findings WHERE SOLOR-Expression(Findings) Is-A SOLOR-Code(“Abdominal Pain”)

where “SOLOR-Expression” is a function that converts the CIMI DCM instance into an equivalent DL expression, and SOLOR-Code(“Abdominal Pain”) is a function that resolves to the existing coded concept for abdominal pain in the SOLOR terminology. Note that “Is-A” represents a predicate that tests for subsumption between the two. In this manner, the power of DL semantics can greatly simplify query formulation against a large compendium of complex patient data collected using CIMI DCMs.

Figure 16.5. Inferred subsumption hierarchy.



16.1.3. Mechanics of the Transformation Process

The process to transform CIMI DCM instances to DL expressions involves certain inputs and outputs, and entails a certain architectural framework. These attributes create certain requirements for the transformation language and execution engine to be used for this task, and are discussed in this section.

16.1.3.1. Overview

Figure 16.6, “Architectural framework for transforming CIMI DCM instances to DL expressions. ” summarizes the transformation process to convert CIMI DCM data instances to SOLOR post-coordinated DL expressions[6]. At the instance (“Data”) level, the task must automatically and faithfully transforms data represented in the CIMI object-oriented formalism to data represented in the SOLOR DL formalism, which consists of the EL profile of the OWL 2 description-logic language[7]. A transformation engine performs the transformation process on any CIMI DCM data instance by applying a set of mapping specifications written in a transformation language.

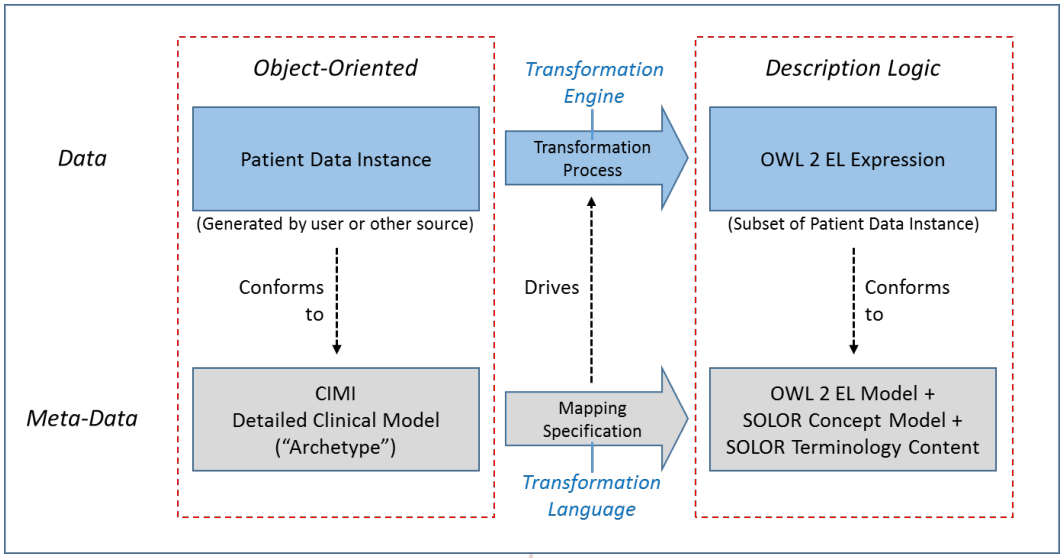
The mapping specifications are defined at the model (“Meta-Data”) level. Specifically, they are based on the structure and contents of a particular CIMI DCM, and can only transform data instances conforming

[6] SOLOR post-coordinated expressions are a derivative of, and very similar to, SNOMED-CT post-coordinated expressions, which are formally defined in the following document: http://doc.ihtsdo.org/download/doc_CompositionalGrammarSpecificationAndGuide_Current-en-US_INT_20150522.pdf (Accessed 9/30/2017).

[7] https://www.w3.org/TR/owl2-profiles/#OWL_2_EL (Accessed 9/30/2017).

to that DCM. Each distinct DCM, therefore, requires its own mapping specifications. The mapping specifications are also specific to the SOLOR DL model and terminology contents, because the model and contents define the allowed outputs of the transformation process.

Figure 16.6. Architectural framework for transforming CIMI DCM instances to DL expressions.



16.1.3.2. Inputs

The inputs to the transformation process are instances of CIMI DCMs rendered in some structured, parseable language. For purposes of this analysis, we will assume that the inputs are rendered in XML, as this is a common syntax for representing clinical data (e.g., XML is also used by other standards for modeling patient data, such as FHIR and C/CDA).

Further, the inputs conform to some defined CIMI DCM. Figure 16.2, "CIMI instance, rendered as XML. " showed a simple example of such an XML-rendered data instance that conforms to a CIMI DCM, specifically the DCM shown in Figure 16.1, "CIMI DCM. ".

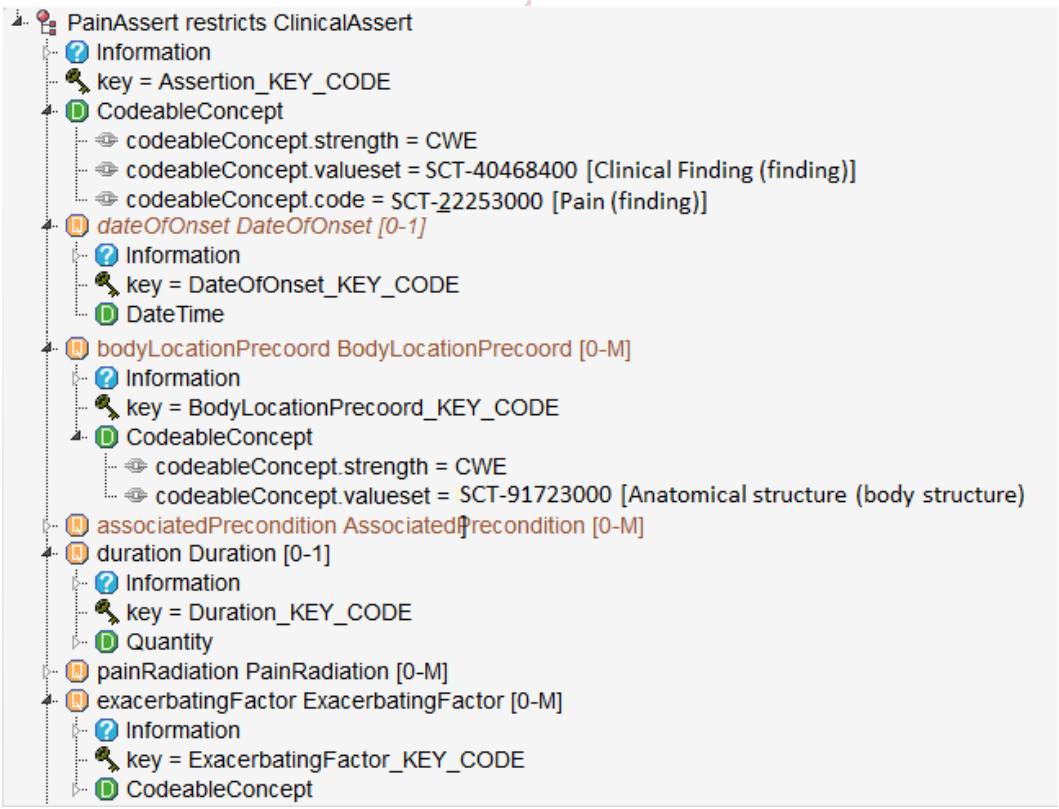
Figure 16.7, "An alternative CIMI DCM instance of a pain observation. " shows another, more complex example of a pain observation represented as an XML document. This observation is an instance of the more complex CIMI DCM for pain shown in Figure 16.8, "An alternative CIMI DCM for pain observations. ", which is similar to that in Figure 16.1, "CIMI DCM. ", but contains numerous additional attributes, such as "duration," "painRadiation," and "exacerbatingFactor." Note that certain of the attributes of the DCM are optional (having [0-1] or [0 – M] cardinality) and therefore not populated in the DCM instance shown in Figure 16.7, "An alternative CIMI DCM instance of a pain observation. ".

The DCM instance in Figure 16.7, "An alternative CIMI DCM instance of a pain observation. " is another example of an input to the CIMI-to-SOLOR transformation process. It is the example used in the next section to describe the outputs of the transformation process.

Figure 16.7. An alternative CIMI DCM instance of a pain observation.

```
<?xml version="1.0" encoding="UTF-8"?>
<PainAssert>
   <Archetype archetypeId="4784894573"/>
   <CodeableConcept>
      <Code codingSystem="SCT" code="22253000" text="Pain"/>
   </CodeableConcept>
   <DateOfOnset dateTime="2017-04-21 00:00:00"/>
   <BodyLocationPrecoord>
      <CodeableConcept>
         <Code codingSystem="SCT" code="48544008" text="Right lower quadrant of abdomen"/>
      </CodeableConcept>
   </BodyLocationPrecoord>
   <Duration>
      <Quantity value="2" units="days"/>
   </Duration>
   <ExacerbatingFactor>
      <CodeableConcept>
         <Code codingSystem="LN" code="83184-2 " text="Eating"/>
      </CodeableConcept>
   </ExacerbatingFactor>
</PainAssert>
```

Figure 16.8. An alternative CIMI DCM for pain observations.



16.1.3.3. Outputs

The outputs to the transformation process are SOLOR post-coordinated DL expressions that are semantically consistent with the input data instances. These expressions must conform to three aspects of the SOLOR terminology model

1. OWL 2 EL Description Logic. SOLOR (like SNOMED-CT) uses just a subset of complete first-order logic to define medical concepts and represent post-coordinated expressions. The OWL 2 EL subset of first-order logic was chosen to ensure polynomial-time inference operations, in particular classification of the large SOLOR terminology corpus. OWL 2 EL definitions and expressions can be represented using a number of equivalent syntaxes, including the SNOMED Expression Grammar, Manchester Syntax, OWL Functional Syntax, OWL/XML syntax, and OWL/RDF syntax. Most examples in this paper use the Manchester Syntax, for clarity and brevity (e.g., see Figure 16.3, “Description-logic representation of the CIMI DCM instance shown in Figure 16.2, “CIMI instance, rendered as XML. ”. ”). In practice, the output of CIMI-to-SOLOR transformations may best be rendered in OWL Functional Syntax, which is still relatively concise and supported as an input format by most OWL reasoners. Figure 16.13, “Output of the XSLT script in Figure 16.12, “Sample XSLT Transformation Script.” run against the CIMI DCM instance in Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”.” shows an example of this syntax.

2. SOLOR Content Model. SOLOR (like SNOMED-CT) constrains the attributes that can be used to describe each type of medical concept, as well as the allowed values for those attributes. The specification of the allowed attributes and values is called the SOLOR Content Model. Figure 16.9, “Excerpt of the SOLOR Concept Model for Clinical Findings”, for example, shows an excerpt of the SOLOR Concept Model for observations of the type “Clinical Finding”.

Figure 16.9. Excerpt of the SOLOR Concept Model for Clinical Findings

Defining Attribute	Subsumed Attribute	Allowable Values
| FINDING SITE |		| Anatomical or acquired body structure | 442083009 (<<)
| ASSOCIATED MORPHOLOGY |		| Morphologically abnormal structure | 49755003 (<<)
| ASSOCIATED WITH |		| Clinical Finding | 404684003 (<<) | Procedure | 71388002 (<<) | Event | 272379006 (<<) | Organism | 410607006 (<<)
| SEVERITY |		| Severities | 272141005 (<=)(< Q)
| CLINICAL COURSE |		| Courses | 288524001 (<=)(< Q)
| EPISODICITY |		| Episodicities | 288526004 (<=)(< Q)
| HAS DEFINITIONAL MANIFESTATION |		| Clinical finding | 404684003 (<<)
| OCCURRENCE |		| Periods of life | 282032007 (<)
| FINDING METHOD |		| Procedure | 71388002 (<=)
| FINDING INFORMER |		| Performer of method | 420158005 (<<) | Subject of record or other provider of history | 419358007 (<<)

Meaning of Allowable Values (*Range*) notations:

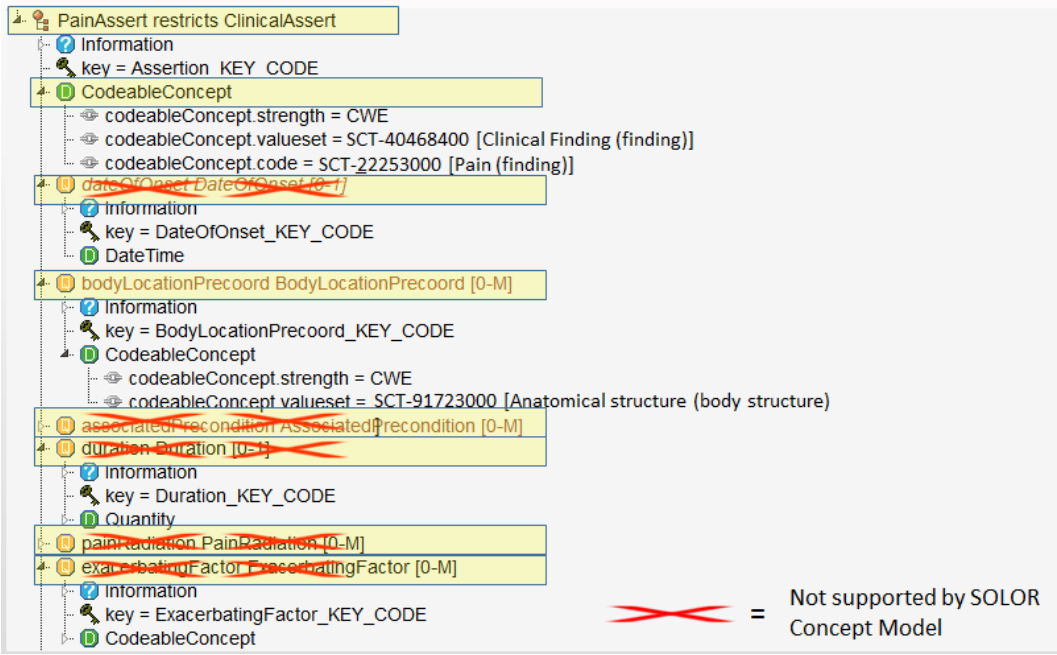
(<<) this code and *descendants*,
(<) *descendants* only,
(<=) *descendants* only (stated) except for supercategory groupers,
(==) this code only,
(< Q) *descendants* only when in a qualifying *Relationship*,
(< Q only) *descendants* only, and only allowed in a qualifying *Relationship*.

Note that “Clinical Finding” is the concept type for all pain observations, and therefore the SOLOR Concept Model shown in Figure 16.9, “Excerpt of the SOLOR Concept Model for Clinical Findings” specifies the set of attributes that can be assigned in the DLs transformation of the CIMI DCM instance shown in Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”. In particular, a number of the attributes allowed by the DCM are not allowed by the SOLOR Concept Model (e.g., “DateOfOnset”, “Duration”, and “ExacerbatingFactor”), which results in their necessary exclusion from the transformation result. The mapping specification for the DCM must include only the allowed attributes and values to produce valid SOLOR DL output results. Figure 16.10, “Excluded attributes of the CIMI DCM for Pain findings.” illustrates the attributes of the DCM originally shown in Figure 16.8, “An alternative CIMI

DCM for pain observations. ” that must be excluded. Note that the DCM attribute “BodyLocationPrecoord” is not excluded, because it maps to the semantically equivalent attribute “Finding Site” in the SOLOR Concept Model.

3. SOLOR Terminology Content. Lastly, the transformed CIMI DCM instance can only include references to codes and concepts that already exist within the SOLOR Terminology Model. For example, the value of the “BodyLocationPrecoord” attribute (“Right lower quadrant of abdomen” in the example of Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”) can only be transformed to an existing SOLOR concept, or to a nested post-coordinated expression consisting of existing SOLOR concepts and attributes. In this case, the specified value does map to an existing SOLOR concept, “Structure of right lower quadrant of abdomen,” so an accurate translation of that attribute/value pair is possible.

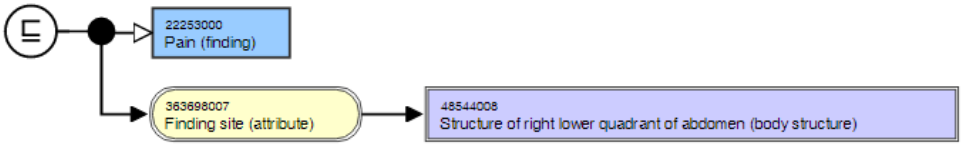
Figure 16.10. Excluded attributes of the CIMI DCM for Pain findings.



When this set of constraints on the output of DCM-to-CIMI transformations is applied, the output of transforming the DCM instance shown in Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ” is the DL expression shown in Figure 16.11, “Description-logic expression that is output of transforming the CIMI DCM instance Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”.”.

Figure 16.11. Description-logic expression that is output of transforming the CIMI DCM instance Figure 16.7, "An alternative CIMI DCM instance of a pain observation. ".

```
SubClassOf:
Pain and
  ( Finding site some Structure of right lower quadrant of abdomen)
```



16.1.4. Choice of Transformation Languages

A number of options exist for expressing the transformation logic for CIMI-to-SOLOR translations and for executing the transformation on specific instances of CIMI DCMs. This section discusses several of the options and the trade-offs among them.

16.1.4.1. XSLT

XSLT is a W3C-standard language for the transformation of structured data[8]. XSLT transformation scripts take as input any valid XML document and produce as output an ASCII-formatted document (including XML, HTML, other formatting languages, free text, etc.). The XSLT language specifies transformations through declarative, rule-based commands (see below).

XSLT is widely used in modern information processing, including in health care applications. Numerous XLST transformation engines exist, including commercial and open-source versions. These implementations are mature, stable, and high-performance, and are available as runtime libraries or embedded in XLST authoring/editing applications. Excellent documentation and training are available for XSLT.

16.1.4.1.1. Overview of Language and Data Model

XSLT scripts operate over source "trees" containing the structured contents of parsed XML documents. These trees contain as their nodes the various constructs of specific XML documents, i.e., the named elements, attributes, and text values that appear in the documents. Figure 16.7, "An alternative CIMI DCM instance of a pain observation. " in the preceding section shows a sample XML document that, upon parsing, becomes a source tree for XSLT transformations. This tree will include the elements "PainAssert", "Archetype", and "DateOfOnset", the attributes "archetypeId" and "dateTime", and the text values "4784894573" and "2017-04-21 00:00:000".

XSLT uses the sub-language "XPath"[9] to reference portions of the XML source tree for purposes of navigating the tree and selecting specific parts of it to translate. XPath is essentially a query language for identifying and retrieving XML sub-trees that match specified criteria. For example, the XPath query

/PainAssert//Code[@codingSystem != 'SCT']/@text

will return the value of the "text" attribute for every "Code" element that appears within a "PainAssert" element and does not have a "codingSystem" attribute value equal to "SCT". When executed against the

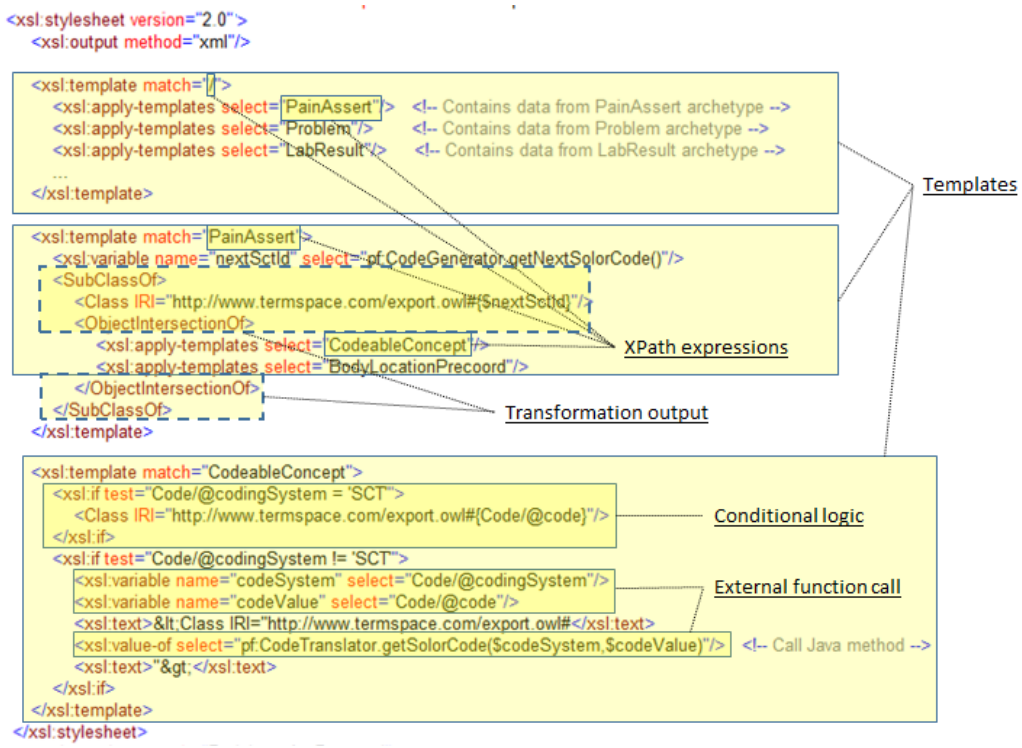
[8] https://en.wikipedia.org/wiki/XSLT (Accessed 9/30/2017).
[9] https://en.wikipedia.org/wiki/XPath (Accessed 9/30/2017).

XML document of Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”, for example, this query would return the text value “Eating”.

The actual transformation logic in XLST scripts is specified as a series of “templates”. Each template matches to a specified sub-part of the source tree and specifies what output will be generated for that sub-part. Template are generally called from within other templates via a declarative template-matching process, and a recursive traversal and transformation of the input tree occurs through this template-invocation model. The transformation logic within templates may include various conditional, branching, and formatting constructs, as well as calls to external functions written in various programming languages (such as Java).

Figure 16.12, “Sample XSLT Transformation Script.” shows an excerpt from an XSLT transformation script used to transform the CIMI DCM instance in Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”. Note that the transformation output is specified as any text (including XML elements) that is not preceded by the XML namespace prefix “xsl:”. In this case, the output includes the XML element “SubClassOf”, which is an element name in the OWL/XML syntax used to render the SOLOR DL output of a CIMI-to-SOLOR transformation (see Figure 16.13, “Output of the XSLT script in Figure 16.12, “Sample XSLT Transformation Script.” run against the CIMI DCM instance in Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”.” for the complete OWL/XML output of the transformation).

Figure 16.12. Sample XSLT Transformation Script.



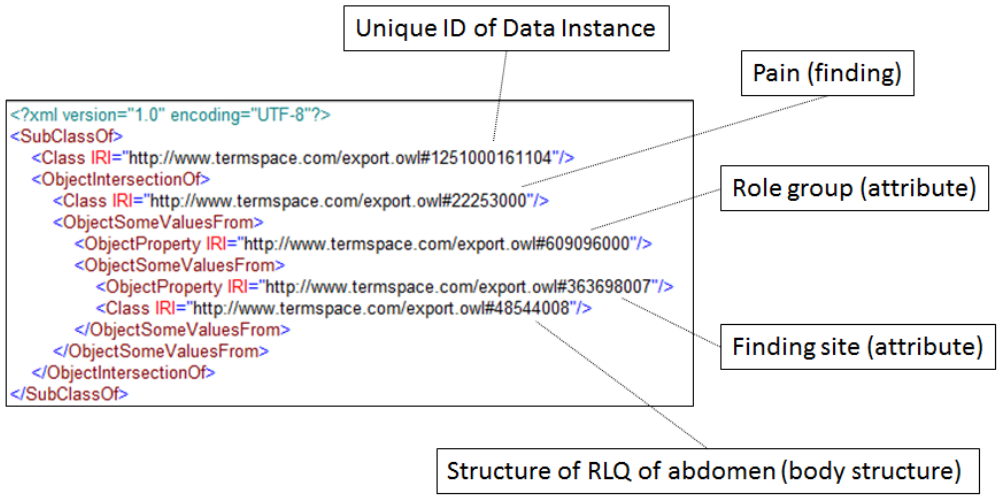
16.1.4.1.2. Example Transformation

The XSLT excerpt shown in Figure 16.12, “Sample XSLT Transformation Script.” is part of a larger XSLT script that can translate any instance of the CIMI DCM specific in Figure 16.8, “An alternative CIMI DCM for pain observations. ” into an appropriate SOLOR DL expression. In the case of this script, the output is rendered using the OWL/XML Syntax, although (as discussed in Section Section 16.1.3.3, “Outputs”) any number of equivalent syntaxes could be used to render the OWL 2 EL output of the translation.

Figure 16.13, “Output of the XSLT script in Figure 16.12, “Sample XSLT Transformation Script.” run against the CIMI DCM instance in Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”.” shows the actual result of executing the XSLT script on the CIMI DCM instance shown in Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”. The resulting DL expression can be directly loaded into a SOLOR terminology reasoner and classified with respect to all of the other concepts in the terminology. The result of this classification would be the subsumption hierarchy shown in Figure 16.5, “Inferred subsumption hierarchy. ”, which can be used subsequently to infer that the original CIMI DCM instance matches the query condition for patients with abdominal pain:

WHERE SOLOR-Expression(Findings) Is-A SOLOR-Code(“Abdominal Pain”)

Figure 16.13. Output of the XSLT script in Figure 16.12, “Sample XSLT Transformation Script.” run against the CIMI DCM instance in Figure 16.7, “An alternative CIMI DCM instance of a pain observation. ”.



16.1.4.1.3. Advantages and Limitations

XSLT is effective in representing and executing the transformation logic needed for CIMI-to-SOLOR translations, at least in a limited set of test cases explored. In general, XSLT provides various advantages, as well as limitations, for this task.

Advantages

- A powerful language
- Declarative – automated matching of templates to data
- Extensible via extension functions and external function calls
- Many mature implementations
- Good tooling (e.g., Eclipse plugin, XMLSpy)
- Good documentation

Limitations

- Transformation specifications are verbose and hard to read/understand/debug/maintain
- Transformation are entirely syntactic
- Limited to XML input – CIMI DCM instances rendered in other formats cannot be translated

16.1.4.2. FHIR Mapping Language

The FHIR mapping language (FML)[10] is a relatively new, bespoke transformation language specifically designed to transform HL7 FHIR[11] resources to alternative representations, including different FHIR resources, C/CDE documents, etc. The mapping language was created by Graham Grieve as a specification of the QVT framework for model-transformation languages (see Section Section 16.1.4.3, “QVT”).

16.1.4.2.1. Overview of Language and Data Model

Conceptually, FML is similar to XSLT in that it (a) consists of declarative rules that are automatically matched to input data, (b) includes a sub-language (“FHIRPath”) to reference parts of source parse trees, and (c) has the ability to reference external functions written in different languages. There are also notable differences between FML and XSLT. FHIR inputs are not constrained to XML documents, but may include any object models and rendering syntaxes conformant with OMG’s Meta Object Facility (MOF) language[12]. MOF is a general formalism for representing object models as directed acyclic graphs (DAGs), and MOF-compliant models can use various syntactic constructs to represent the classes, attributes, and attribute values of such graphs.

Hence, in FML, there is no built-in notion of source trees containing XML “elements”, “attributes”, “comments”, “namespaces”, etc. In fact, FML transformation rules do not specify any target syntax for inputs or outputs, just the general concepts of named classes, class members, and member values. This flexibility would allow CIMI-to-SOLOR transformation inputs to be represented in different formats than XML, were that to be deemed preferable. For example, instances rendered using JSON, ODIN[13], or ASN1 syntax could be the inputs of FML transformations.

16.1.4.2.2. Example Transformation

Figure 16.14, “Sample FHIR Mapping Language script.” shows an excerpt from a transformation script written in the FHIR mapping language. This particular script translates prostate cancer reports formatted in a non- standard HL7 FHIR format[14] to equivalent reports formatted as standard FHIR Diagnostic Report resources. Note that the script references classes in the input and output data models, such as “Prostate” and “DiagnosticReport”, respectively. The script may do this because the MOF-compliant models for the input and output instances are specified in the first line of the script, and these models include the “Prostate” and “DiagnosticReport” classes, respectively. Note also how the script iteratively traverses the input instance, first addressing and translating the top-level node (“Prostate”), then addressing its child nodes (“Prostate.subject” and “Prostate.performer”).

[10] https://www.hl7.org/fhir/mapping-language.html (Accessed 9/30/2017).
[11] https://www.hl7.org/fhir/index.html (Accessed 9/30/2017).
[12] http://www.omg.org/mof/ (Accessed 9/30/2017).
[13] http://www.openehr.org/releases/BASE/latest/docs/odin/odin.html (Accessed 9/30/2017).
[14] In this case, the Royal College of Pathologists of Australasia (RCPA) standard structured report for prostate cancer (see http://fhir.hl7.org.au/fhir/rcpa/prostate.html).

Figure 16.14. Sample FHIR Mapping Language script.

```
map "http://fhir.hl7.org.au/fhir/rcpa/StructureMap/ProstateMap" = "Prostate Ca Report --> FHIR DiagnosticReport"

uses "http://fhir.hl7.org.au/fhir/rcpa/StructureDefinition/ProstateCaReport" as source

group for types ProstateCaReport
  input source : ProstateCaReport as source

  Prostate : for source
             make create("DiagnosticReport") as cdr,  cdr.status = "final",
                                                      cdr.code = cc("http://snomed.info/sct", "7923847102") then {

      Prostate.subject : for source.subject : Reference 1..1 as v
                         make cdr.subject = v
      Prostate.performer : for source.performer : Reference 0..1 as v
                           make cdr.performer as pr,  pr.actor = v

      }

endgroup
```

The output of an FML transformation is not a text-rendered document (unlike XSLT), but an internally stored DAG consistent with the specified output model (in the case above, the logical model of the FHIR DiagnosticReport resource). Subsequently, the DAG may be rendered in any number of syntaxes, including XML, JSON, or the tables and fields of a relational database. For example, Figure 16.15, “Output of the sample FHIR Mapping Language script, rendered as XML.” and Figure 16.16, “Output of the sample FHIR Mapping Language script, rendered as JSON.” show the outputs of the FML transformation script shown in Figure 16.14, “Sample FHIR Mapping Language script.” rendered as XML and JSON, respectively.

Figure 16.15. Output of the sample FHIR Mapping Language script, rendered as XML.

```
<Bundle xmlns="http://hl7.org/fhir">
   <id value="Prostate-genexample-1-map"/>
   <type value="collection"/>
   <entry>
      <fullUrl value="http://fhir.hl7.org.au/fhir/rcpa/DiagnosticReport/1"/>
      <resource>
         <DiagnosticReport>
            <id value="1"/>
            <status value="final"/>
            <code>
               <coding>
                  <system value="http://snomed.info/sct"/>
                  <code value="7923847102"/>
               </coding>
            </code>
            <subject>
               <reference value="Patient/8003608166687160"/>
            </subject>
            <performer>
               <actor>
                  <reference value="Organization/8003623233350148"/>
               </actor>
            </performer>
            <request>
               <reference value="ProcedureRequest/1"/>
            </request>
         </DiagnosticReport>
      </resource>
   </entry>
</Bundle>
```

Figure 16.16. Output of the sample FHIR Mapping Language script, rendered as JSON.


```
{ "resourceType" : "Bundle",
  "id" : "Prostate-genexample-1",
  "type" : "collection",
  "entry" : [
    {
      "fullUrl" : "http://fhir.hl7.org.au/fhir/rcpa/DiagnosticReport/1",
      "resource" : {
        "resourceType" : "DiagnosticReport",
        "id" : "1",
        "status" : "final",
        "code" : {
          "coding" : [
            { "system" : "http://snomed.info/sct",
              "code" : "7923847102" }
          ]
        },
        "subject" : {"reference" : "Patient/8003608166687160" },
        "performer" : [
          { "actor" : { "reference" : "Organization/8003623233350148" } }
        ],
        "request" : [
          { "reference" : "ProcedureRequest/1" }
        ]
      }
    }
  ]
}
```


16.1.4.2.3. Advantages and Limitations

The FHIR Mapping Language may also be effective in representing and executing the transformation logic needed for CIMI-to-SOLOR translations. As with XSLT, however, there exist certain trade-offs in its use.

Advantages

- Support for input formats other than XML
- Transformation logic produces semantic DAGs, which can be subsequently rendered in a variety of syntaxes.
- The mapping specifications are more concise and easy to read/understand than XLST

Limitations

- Inputs/outputs other than FHIR logical models currently require additional custom programming
- Only XML and JSON are currently supported as output syntaxes without custom programming
- Only one implementation to date (as a library)
- Limited tools for authoring/editing transformation scripts

- Limited sources of documentation
- Few knowledgeable programmers

16.1.4.3. QVT

A third alternative is to develop a new transformation language customized to support the requirements of CIMI-to-SOLOR translations, based on the QVT language used to develop the FHIR Mapping Language.

16.1.4.3.1. Overview

QVT[15] is a general model-transformation framework and language developed by the Object Management Group . It includes both an imperative ("QVT-O") and a declarative ("QVT-R") version, and offers considerable flexibility in defining the constructs of purpose-specific transformation languages. Although QVT is intended for the transformation of data *models* rather than data instances, the FHIR Mapping Language shows that it can be applied to the latter task as well.

A number of implementations of QVT exist as open-source and commercial software offerings. These include:

- ATL (open source). Probably the most widely used and maintained of the available implementations. Includes a library of existing QVT transformations, to serve as examples and templates.
- Eclipse M2M Project (open source). An Eclipse project that includes authoring tools for QVT transformations, as well as various transformation engines (including the one from ATL).
- ModelMorf (proprietary)
- Others (see https://en.wikipedia.org/wiki/QVT)

16.1.4.3.2. Advantages and Limitations

The strength of QVT is that it is very abstract, which confers great flexibility and configurability to create custom transformation languages. However, the abstractness also makes QVT quite difficult to understand and learn, and there are limited resources to assist in the learning process. For example, a search on Amazon Books for references on the QVT framework yielded only 8 relevant results, most of which were not in English. In contrast, a similar search for XSLT references returned 270 results.

16.1.4.4. Recommendations

Given the requirements of the CIMI-to-SOLOR transformation task and the features of available transformation languages, the following two-pronged approach is recommended at this time:

1. Perform further sample CIMI-to-SOLOR transformations using XSLT. This pilot activity will shed further light on the feasibility of XSLT for the task, the effective use of external functions, and the readability/maintainability of the resulting transformation scripts.
2. In parallel, explore the customization and use of a QVT-based transformation language for CIMI-to-SOLOR transformations. This approach will allow for the rendering of CIMI DCM instances in formats other than XML. Pilot use of QVT will enable comparison with XSLT in terms of (a) feasibility, conciseness, and maintainability of transformation scripts, (b) utility of the available tooling and documentation for QVT, and (3) the required customization effort to create a production CIMI-to-SOLOR transformation capability based on QVT.

[15] http://www.omg.org/spec/QVT/1.2/PDF/ (Accessed 9/30/2017).

16.1.5. Conclusion

A semantically correct and efficient model for translating CIMI DCM instances to SOLOR DL expressions could confer the benefits of both the object-oriented and description-logic models to clinical data management. Reconciliation and translation between the two models, however, is in an early phase of exploration. Considerable further work, as outlined in this whitepaper, is needed to demonstrate the feasibility of such translations and the utility of the resulting DL expressions for data analysis, decision support, and quality improvement.

17. KNART statement supports

KNARTS support the creation of statements through standardized questionnaires and order sets.

18. KOMET support for statements

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25. Data Registries

Data registries are organised systems with a 'predetermined scientific, clinical or public health purpose.' Data registries are used to prospectively collect, analyse and disseminate data related to a population with specific characteristics in common, for example people with a particular condition, having a certain treatment or using a health-related service. They are cohort studies that are developed with a predetermined health-related aim.

Registry limitations:[1]

- • **Quality of data and methods**: patient registries are only as good as the underlying data collection and methods. It is critical that the research design is robust and the relevant outcomes are defined appropriately.
- **Incorrect or missing data**: problems with remembering information or recalling information correctly can be an issue with patient-reported data.
- **Confounding and bias**: there may be issues such as channeling bias to newer treatments for sicker patients, information bias and selection bias.
- **Heavy investment in time and resources**: commitment and engagement are needed from participating patients. It can be difficult to recruit patients and it can take time to accumulate data, resulting in delays between data collection and reporting (sometimes years). Such data can become out of date in fast-changing disease areas.
- **Lack of standards and uniformity**: lack of standardised data collection across hospitals, regions and countries prevents the pooling of data across registries.
- **Lack of comparator**: in product-specific registries having no comparator prevents assessment of relative effectiveness.

[1] https://rwe-navigator.eu/use-real-world-evidence/sources-of-real-world-data/patient-registries/

26. Instance persistence

Walter Sujansky

26.1. Introduction

This document is a technical white paper that describes various options for representing post-coordinated expressions encoded in SNOMED CT (SCT) and for supporting query processing against such expressions.

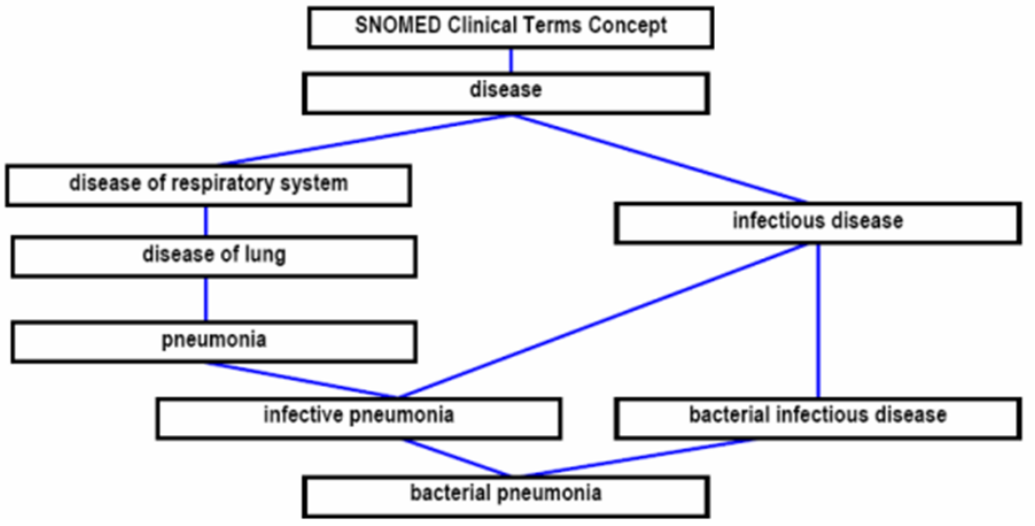
This document first provides a brief background on post-coordination in SCT and describes the scope of our analysis. The report next describes the requirements for managing clinical observations that were used to inform the analysis. The following section presents a set of relevant design dimensions and specific design options for each dimension. Lastly, the report presents a set of recommendations with respect to each design dimension, as well as an example observation instance encoded per these recommendations.

26.2. Background and Scope

Healthcare organizations are striving to capture and store clinical observations in an electronic format. The goal of this project is to standardize the storage of observations in order to enable the sharing of observation data among clinical applications (such as inpatient and outpatient EHRs) and the centralization of services that automatically process observation data (such as reporting and decision support services).

The standardization of clinical observations in a manner that supports automated processing requires a formal terminology model. The most important requirements of such a terminology model are that (1) it can represent any clinician-specified observation accurately and precisely and (2) it can support automated query and retrieval operations correctly and efficiently. Many healthcare organizations have selected SNOMED CT (SCT) for its clinical observation terminology model.

SCT consists of a large set of pre-defined medical concepts (currently > 350,000 concepts) that are hierarchically organized and inter-related. The size of SCT helps the terminology meet the first requirement noted above, i.e. adequate coverage of the observations that clinicians need to document. The hierarchical and other relationships within SCT help it meet the second requirement, i.e., support for relevant query and retrieval operations. To illustrate the contents and structure of the SCT terminology, the following graphic shows a subset of the pre-defined concepts that might be used to populate a medical record:



Using SCT, a clinician can document that a patient has bacterial pneumonia by specifying in the patient's record the unique SCT identifier for that concept, i.e., the clinician would add the following entry:

Bacterial Pneumonia (ConceptID = 53084003)

Additionally, a reporting program would use the SCT hierarchy to automatically retrieve the same patient's record in response to the query "retrieve all patients with any infectious disease (Infectious Disease : ConceptID = 40733004) on their problem list". The program could automatically determine whether bacterial pneumonia (Bacterial Pneumonia : ConceptID = 53084003) is an infectious disease (Infectious Disease : ConceptID = 40733004) by using a process called *subsumption testing*.

Importantly, SCT also supports the ability to express new medical concepts by combining pre-existing ones. This process, called *post-coordination*, enables clinicians who use SCT to express observations that do not appear as pre-defined concepts in the terminology, thereby vastly increasing SCT's expressive power. For example, a clinician could document that a patient has "bacterial pneumonia caused by methicillin-resistant Staph. Aureus" by combining the pre-existing concept "bacterial pneumonia" with the pre-existing concept "Methicillin Resistant Staph. Aureus" and specifying that the latter is the "causative agent" of the former. The patient's medical record would then contain an entry consisting of the following expression:

Bacterial Pneumonia (ConceptID = 53084003) : Causative Agent (ConceptID=246075003) = Methicillin Resistant Staph. Aureus (ConceptID=115329001)

If specified correctly, post-coordinated expressions also support subsumption testing. Hence, the patient whose record contains the expression above would also be identified by the query "find all patients with a diagnosis of any infectious disease (Infectious Disease : ConceptID = 40733004) in their record."

For additional background information on the SNOMED terms and concepts used in this report, please see the glossary in Appendix A.

Although very useful, post-coordination creates a number of practical challenges for information systems that support this capability. The foremost challenge, and the one that has been most studied, is the design of user interfaces that enable clinicians to create post-coordinated expressions efficiently, intuitively, and in a manner that is consistent with the SCT terminology model. However, another important set of challenges pertain to the management of post-coordinated expressions *after* they have been specified by clinicians. These management tasks include the appropriate persistence of post-coordinated observations in a patient database and efficient subsumption testing against records that include post-coordinated observations. This report addresses those data-management challenges, which include:

- Determining the *degree of transformation and normalization* to apply to post-coordinated expressions when they are persisted in a database. What transformations and normalizations appropriately balance the needs of storage efficiency, retrieval performance, terminology evolution, and medicolegal requirements?

- Determining the specific *structure and syntax* for representing post-coordinated expressions when they are persisted in a database. What structure and syntax appropriately balance the needs of storage efficiency, retrieval performance, interoperability, and software evolution?

- Determining the appropriate way to represent the *contextual modifiers* for observations within post-coordinated expressions. For example, representing modifiers that indicate whether an observation is a current diagnosis for the patient, a past medical problem of the patient, or a disorder in the patient's family history.

- Determining appropriate strategies for *optimizing the performance of subsumption testing* against post-coordinated expressions (a critical but inherently costly operation). Potential strategies include main-

taining a transitive closure of the SCT hierarchy and incorporating post-coordinated concepts into the SCT terminology model ("just-in-time pre-coordination").

The report first summarizes requirements for managing clinical observations that pertain to the persistence and processing of post-coordinated SCT expressions. The report then describes various options for addressing the challenges listed above, including advantages and disadvantages, and concludes with specific technical recommendations.

The sections below use the following terms, as defined by the SCT terminology model. For readers not familiar with these terms, a glossary appears in Appendix A.

concept Concept Attribute Relationship Concept Definition Pre-coordinated concept Expression Post-coordinated Expression Refinement Focus Concept Subsumption Testing Equivalence Testing Predicate Expression Candidate Expression

26.3. Requirements and Assumptions

The recommendations in this report are based on requirements and assumptions related to the electronic capture, storage, and analysis of clinical observations. Although the requirements for managing observations cover many areas, such as terminology maintenance, data entry, and validation, the items below include only those requirements most relevant to the *persistence* and *subsumption testing* of *post-coordinated observation expressions*. These requirements fall into several categories.

26.3.1. Expressivity Requirements

The representation of observation expressions must fully and unambiguously capture the meaning intended by the documenting clinician. The representations of captured observations must support review by clinical care givers with no loss of information or change in meaning. This is critical for safe and effective clinical care. The representations must also support automated processing with a minimum of information loss or distortion (although 100% fidelity may not be possible or needed).

One of the purposes of using SCT for electronic health records is to support the expressivity needs of both human users and computer processes. Free text provides expressivity for human users at the cost of reliable automated analysis. Traditional coding systems, such as ICD-9-CM, support automated analysis at the cost (sometimes) of rich and accurate clinical expressivity. The following alternative representations of an observation show some of the trade-offs.

Free Text: "Fx L femur 2^{-0} to MVA"

This is the form that a clinician might document in a medical record, if unconstrained by a coding system or terminology model. It is concise and understandable to clinicians, but would require sophisticated natural language processing to support automated analysis.

ICD-9-CM: 821.00 (Fracture of unspecified part of femur closed)

This is the code that a clinician might select if constrained to the list of ICD-9-CM codes. It supports certain automated analyses (such as classification), but does not fully express the clinical observation. For example, although there do exist additional "E" codes that specify the cause of injuries, E codes are optional for billing purposes and unlikely to be assigned by clinicians. Also, ICD-9-CM does not specify the laterality of limb fractures.

SCT Post-coordinated expression: Fracture of Femur : Finding Site = Structure of Femur : Laterality = Left,

This is the post-coordinated expression that is consistent with the SCT terminology model. It consists of a formal representation this is amenable to classification as a "fracture" or an "injury of left lower

extremity" via subsumption testing. Although SCT does contain a concept for "motor vehicle accident," the terminology model does not currently allow ("sanction") that this concept be designated as the cause of an injury. Specifying the cause would require adding a free-text annotation to the expression (for example, the text "due to MVA"). Such an annotation would fall outside the SCT terminology model. By allowing such annotations, the complete clinical information may be captured, although only the structured SCT expression is amenable to automated analysis. Specifically, subsumption testing could not automatically classify the observation as an "injury due to a motor vehicle accident"

Text rendition of SCT post-coordinated expression: "Fracture of femur, left, due to MVA"

This is the text rendition of the post-coordinated expression, intended for human review. The full expression has been condensed to remove redundant information, and the free-text annotation has been appended. Like the free-text expression, it is concise and complete. Unlike the free-text expression, it corresponds to a structured representation that supports (some) automated processing based on a formal terminology model.

26.3.2. Retrieval and Analysis Requirements

The post-coordinated SCT expressions stored in the medical record must support a number of different tasks (use cases):

1. **Human review** of an individual patient's medical record in the course of providing or reviewing that patient's clinical care. Examples include display of the medical record to a primary care physician, referred specialist, emergency-room physician, disease-management nurse, insurance claims reviewer or medical malpractice attorney.

2. Application of **automated decision-support** logic to an individual patient's medical record to improve the provision, review, or billing of that patient's clinical care. Examples include guideline software that suggest needed interventions during a clinical encounter or coding software that suggests the optimal billing codes for a clinical encounter.

3. **Search** of a large patient database for patients that match a certain clinical profile based on inclusion and exclusion criteria. Examples include searches for patients eligible for a prospective clinical trial, searches for patients whose data applies to a case-control study, or searches for patients with chronic diseases who have not received needed interventions.

4. Analysis of a large patient database to create **statistical abstractions** that are useful for clinical, operational, research and business purposes. Examples include the calculation of clinical quality measures to identify variations across the enterprise, the determination of case mix to help operational planning or insurance contracting, and the statistical analysis of electronic medical records to test research hypotheses.

These use cases suggest a number of specific requirements for the persistence and subsumption testing of post-coordinated observation expressions:

- The persisted representation(s) must support complete, accurate, and familiar display of recorded observations to human users. The typical user is a busy professional whose time is valuable and who needs to review a medical record quickly.

- Automated decision support in the context of a specific patient's medical record often must occur in real time, but it does not entail a large volume of data. Given the limited data volume, the performance requirements for each subsumption test are not as great as when search or analysis over an entire patient database are involved (See Section Section 26.3.3, "Performance Requirements"). However, the observation expressions must support complete and correct inferences, because direct patient care is often affected.

- Search and statistical abstraction over large databases create special performance requirements that may need to be addressed through the transformations of operational data structures to (redundant) analytical data structures and through hardware and/or software optimizations.

26.3.3. Performance Requirements

A reasonable performance criterion for a pair-wise subsumption test is 10-20 ns.

To consider the performance requirements related to subsumption testing of post-coordinated expressions, it is useful to consider the operations involved and the steps required to perform each operation.

Automated decision support, search, and statistical abstraction all entail the following prototypical operation in a patient medical record: Evaluation of a Boolean predicate (P) against the set of observations in the medical record (R). The evaluation may be as simple as

P = Does R contain “myocardial infarction”?

or as complex as

P = Does L contain “history of myocardial infarction” or “myocardial infarction” and “status post CABG” but NOT “family history of coronary artery disease”?

The evaluation of these expressions entails pair-wise subsumption testing between the concepts in the predicate and the concepts in the medical record. Subsumption testing is required (rather than testing of exact concept equivalence) because observations are recorded to varying degrees of detail. For example, one clinician may document “myocardial infarction”, another “acute myocardial infarction”, and a third “acute non-Q wave myocardial infarction.” Nevertheless, in all cases the patient has a type of “myocardial infarction,” and subsumption testing must correctly infer this.

For a predicate containing N concepts and a medical record containing M concepts, as many as N x M subsumption tests are required to evaluate the predicate against the record (although in practice, certain logical optimizations can reduce the actual number of subsumption tests performed, depending on the formulation of the predicate and the contents of the record). In the typical case, one can presume that 3 – 6 subsumption tests will be required to evaluate a predicate against each problem list in a medical record, although this may vary and should be further evaluated based on empirical data.

Prior to each pair-wise-subsumption test, the persisted observation expression must “pre-processed” as follows:

1. The observation must be retrieved from the database (requiring one or more disk reads and certain database manipulations, such as joins)

2. The observation must be loaded into program memory (which may require parsing or data-type conversion)

3. The observation must be in a representation suitable for subsumption testing (which may require normalization)

The specific form in which post-coordinated observation expressions are persisted will affect the time required to pre-process the expressions. For example, storing the normalized form of an expression will eliminate the need for step 3 and storing a binary representation of the expression will reduce the time required for steps 1 and 2.

Lastly, the pair-wise subsumption test is performed by the appropriate algorithm. For pre-coordinated concepts, the test may be as simple as a tree traversal or table lookup. For post-coordinated concepts, however,

the test entails a logical analysis of the structure of each concept in the context of the entire terminology. Depending on the complexity of the expressions being tested and the size of the terminology, subsumption testing of post-coordinated expressions may be an expensive operation. Depending on the performance achieved by the vendor's terminology engine, certain optimizations may be considered (See Sections Section 26.4.4, "Computation of Transitive Closure" - Section 26.4.6, "Partial Subsumption Testing of Post-Coordinated Expressions").

26.3.4. Medicolegal Requirements

Legal requirements governing medical records vary by state. However, most states require the attestation of patient care entries by the responsible author (typically via signature). Attestation confirms that the author is the source of the entries and is taking responsibility for the accuracy of the content. Additionally, state law typically prohibits the subsequent modification of a patient care entry without further attestation of the change in such a way that the original entry is preserved.

Given these requirements, it is important that any system for documenting observations capture and retain not only a structured internal representation of the observations (no matter how useful these may be for computer-based processing), but also the specific textual rendition that the user entered, viewed, and attested to. Features or operations that change or delete this textual rendition without the knowledge and further attestation of the user present potential medicolegal risks. For example, a change to the text rendition of an observation caused by an update to the SCT terminology (such as the designation of a different preferred term) could potentially create medicolegal problems. At the same time, features and operations that transform, normalize, or abbreviate the structured *internal* representation of a patient care entry for purposes of technical optimization are presumably acceptable, provided that they do not alter the representation's meaning such that it no longer corresponds to the textual rendition that the user attested to.

26.3.5. Terminology-Versioning Requirements

The SCT terminology is regularly updated, through both local additions and periodic maintenance releases from the SNOMED authority. Such updates may occur as frequently as several times per year, and each update may entail a significant number of content additions and changes. Whatever design decisions are made with respect to the representation of post-coordinated observation expressions and the performance of subsumption testing, the following conditions must be met:

- Terminology updates may require no *manual* review or editing of patient-specific data (i.e., individual patient observations).
- Terminology updates may require no *manual* review or editing of application code, including queries used in decision-support logic or reporting.

Note that these conditions do not preclude the *automated* review and editing of patient data and/or application code, provided that such operations can be performed efficiently and reliably. For example, a terminology update may necessitate certain formatting changes to data in patient records, provided that such changes can be performed automatically and without risk of corrupting clinical data.

26.4. Options for Persistence and Management of Post-Coordinated Observations

This section addresses a variety of design decisions that must be made to implement persistence and subsumption testing for post-coordinated SCT expressions. Each sub-section describes a design dimension, presents a set of relevant options, and lists the advantages and disadvantages of each option. Specific recommendations regarding each design decision are presented in Section Section 26.5, "Recommendations".

The selection of options and the evaluation of their pros and cons was developed in the context of the requirements and assumptions, as well as available literature on post-coordinated expressions and subsumption testing using SNOMED-CT.

26.4.1. Abstract Models and Normalization

The logical underpinnings of the SCT terminology model allow SCT expressions (including single concepts) to be represented in a number of different but semantically equivalent forms (also known as “abstract models” in the SNOMED parlance). For example, the following two expressions of an observation are semantically equivalent:

Close-to-User Form: Fracture of Femur

Long Normal Form: Disease : Associated Morphology = Fracture Finding Site = Bone Structure of Femur

The question arises as to which form or forms of an observation should be persisted in the patient record. Different forms of an expression are best suited for different purposes and operations. For example, the *Close-to-User Form* represents the expression as it was initially created by the user. This form is typically concise and documents the exact expression that the clinician specified. The *Long Normal Form* represents a transformation of the close-to-user form to a normalized form needed for subsumption testing.

Transformations among semantically equivalent forms are made possible by the logical definitions of concepts and the hierarchical relationships among concepts in the SCT terminology. Importantly, the transformation of an expression from one form to another can yield different results after the contents of the SCT terminology change. For example, if a relationship is added to the definition of a concept or a new concept is added to the SCT hierarchy, the normalized form of an expression may change.

26.4.1.1. Definitions

Close-to-User Form: The SCT expression as specified by the user or as encoded by a clinical application to represent the semantics of a single clinical observation.

The close-to-user form of an expression is the most faithful and unchanging representation of the information entered. Some experts believe that, for clinical safety and accountability purposes, this should be regarded as the primary stored and communicated form of clinical information encoded using SCT.

Example: Allergic Asthma : Course = Chronic

Short Normal Form: The normalized form of the SCT expression that is most efficient when the expression appears as the *Predicate* in a subsumption test. In practice, this is the form that would typically appear in database queries seeking patients with specific kinds of observations or combinations of observations. Technically, the Short Normal Forms contains only non-redundant relationships that appear in the definition or refinement of the expression.

Example: Asthma : Due To = Allergic Reaction, Course = Chronic

Long Normal Form: The normalized form of the SCT expression that is most efficient when the expression appears as the *Candidate* in a subsumption test. In practice, this is the form that would typically appear in the patient’s record. Technically, the Long Normal Forms contains all relationships that appear in the definition or refinement of the expression, whether redundant or not.

Example: Asthma : Due To = Allergic Reaction, Associated Morphology = Obstruction, Finding Site = Bronchial Structure, Course = Chronic

Canonical Form: (short or long): The normalized form that is needed when an expression is used in an equivalence test. The Canonical form is the same as the Short or Long normalized form, except that the

exact syntactic representation and sequence of relationships are standardized so that text representation of two equivalent expressions will be lexicographically identical. The process for testing equivalence between two expressions entails transforming both to their canonical normalized forms and testing whether the resulting strings are identical.

Example: 195967001 | asthma | : 116676008 | associated morphology | = 26036001 | obstruction | ,260908002 | course | = 191268006 | chronic ,42752001 | due to | = 419076005 | allergic reaction | ,363698007 | finding site | = 955009 | bronchial structure |

(Note that all descriptions have been normalized to lower-case text, and the sequence of relationships has been normalized to alphabetical)

Text-Rendered Form: The text string that appears in the patient record to represent the Close-to-User form of an SCT expression. This form is relevant when a clinical application renders post-coordinated expressions differently than they appear in the SCT syntax. Such rendering may be needed to display an intuitive, human-readable form of the expression. Note: This form is not part of the SNOMED model.

Example: Allergic Asthma, Chronic

(Text rendering of the Close-to-user form “Allergic Asthma : Course = Chronic”)

26.4.1.2. Options

The following table summarizes which forms are persisted in each of the options described:

Option	Close-to-User	Short-Normal	Long-Normal	Canonical	Text-Rendered
1	XXX				
2	XXX		XXX		
3	XXX		XXX		XXX
4	XXX	XXX	XXX	XXX	XXX

Option 1. Store the Close-to-User form only. This form must be stored at a minimum, because it is required to derive all other forms. Also, this form should be stored because it represents the concept that the clinician directly specified as the observation. When displaying observations, dynamically transform the Close-to-User form to the Text-Rendered Form (may either be done in the terminology server, or by the client application). When performing subsumption testing against observations, dynamically transform all expressions to their Long Normalized Forms prior to executing the test. When performing equivalence testing involving observations, dynamically transform all expressions to the Canonical Forms. When performing subsumption testing with observations as the Predicate Expressions, dynamically transform them to the Short Normal Forms.

PROS:

- Most disk-space efficient
- No need to recompute Long Normal Forms across entire database when the SCT terminology is versioned
- Ability for client applications or terminology services to change the text-rendering behavior without needing to recompute Text-Rendered Form across entire database
- Equivalence testing (which requires the Canonical Form) is infrequently performed on patient data -- subsumption testing is the more common operation.

- Use of patient data as the Predicate Expression (which benefits from the Short Normal Form) is uncommon – patient data is more commonly used as the candidate expression.

CONS:

- Expressions must be transformed to their Long Normal Forms each time a subsumption test is performed on them, which may slow subsumption testing significantly. Subsumption testing against patient observations will be a frequent operation.
- The Text-Rendered form displayed to the clinician who entered the observation and subsequently to all clinicians who view the medical record is not statically persisted. If the text-rendering behavior of software is changed, the contents of the patient record, as seen by clinicians, may effectively change.

Option 2. Store the Close-to-User form and the Long Normal Form only. Dynamically generate the other forms when needed.

PROS:

- Relatively disk-space efficient
- Long Normal Form of each expression is immediately available as a candidate expression, improving performance of subsumption testing
- The terminology server can immediately test whether a Close-to-User form may be unambiguously transformed to a Long Normal Form, and prompt the calling application for more information if an unambiguous transformation does not exist.
- Ability for client applications or terminology services to change the text-rendering behavior without needing to recompute Text-Rendered Form across entire database
- Equivalence testing (which requires the Canonical Form) and use of observations as Predicate expressions in subsumption tests are infrequent, so not persisting these forms is acceptable.

CONS:

- Need to compute Long Normal Form at the time observations are stored, which will impact the documentation of observations in a synchronous system.
- Need to recompute Long Normal Forms across entire database when the SCT terminology is versioned.
- Volatility of Text-Rendered Form displayed to users if/when the text-rendering algorithms change.

Option 3. Store the Close-to-User form, the Text-Rendered Form, and the Long Normal Form. Dynamically generate the Short Normal Form and Canonical Forms when needed.

PROS:

- A persistent Text-Rendered form is more consistent with medicolegal standards for the patient record. Improved performance for the display of the Text-Rendered Form of observations, because it does not need to be generated dynamically for each display. No performance impact on entry of new observations, because the Text-Rendered form must be computed synchronously anyway.
- Long Normal Form of each expression is immediately available as candidate expression, and the ability to convert to Long Normal Form can be verified in real time.
- Equivalence testing (which requires the Canonical Form) and use of observations as the Predicate expression in subsumption tests are infrequent.

CONS:

- Need to recompute Long Normal Forms across entire database when the SCT terminology is versioned.
- Possibly need to recompute Text-Rendered Form across entire database if/when the text-rendering algorithms change (although these forms may remain unchanged for medicolegal purposes).

Option 4. Store all forms. Generate and store all forms immediately. Recompute relevant forms across the entire database when the SCT terminology or text-rendering algorithms are updated.

PROS:

- A persistent Text-Rendered form is more consistent with medicolegal standards for the patient record, with no detriment to performance.
- Forms for subsumption testing and equivalence testing are immediately available, maximizing performance of these operations.

CONS:

- Least disk-space efficient. Redundant storage of forms that are semantically equivalent and can be derived from a single representation.
- Need to recompute Text-Rendered Form across the entire database if/when the text-rendering algorithms change.
- Need to recompute Long Normal Form, Short Normal Form, and Canonical Form across entire database when the SCT terminology is versioned.

26.4.2. Structure and Syntax for Persistence

It is possible to store any given abstract model of a post-coordinated expression in a number of structural and syntactical ways within a database. These alternative representations are known as “representational forms” in the SNOMED parlance. For example, one could represent a post-coordinated expression (Close-to-User form) such as

Fracture of Femur : Finding Site = Structure of Head of Femur :

Laterality = Left,

Morphology = Spiral Fracture,

Severity = Severe

in a single relational database field as a text string with delimiters:

Problem_Instance_Expressions : Table

InstanceID	ProblemExpression
1	7162000|Fracture of Femur|:{363698007|Finding Site|=2812003|Structure of Head of Femur|:2727410003|Laterality|=7771000|Left|},116676008|Morphology|= 73737008|Fracture, Spiral|,246112005|Severity|=24484000|Severe

Alternatively, one could represent the same expression (Close-to-User form) as a set of associated rows in a relational database table:

Problem_Instance_Expressions : Table

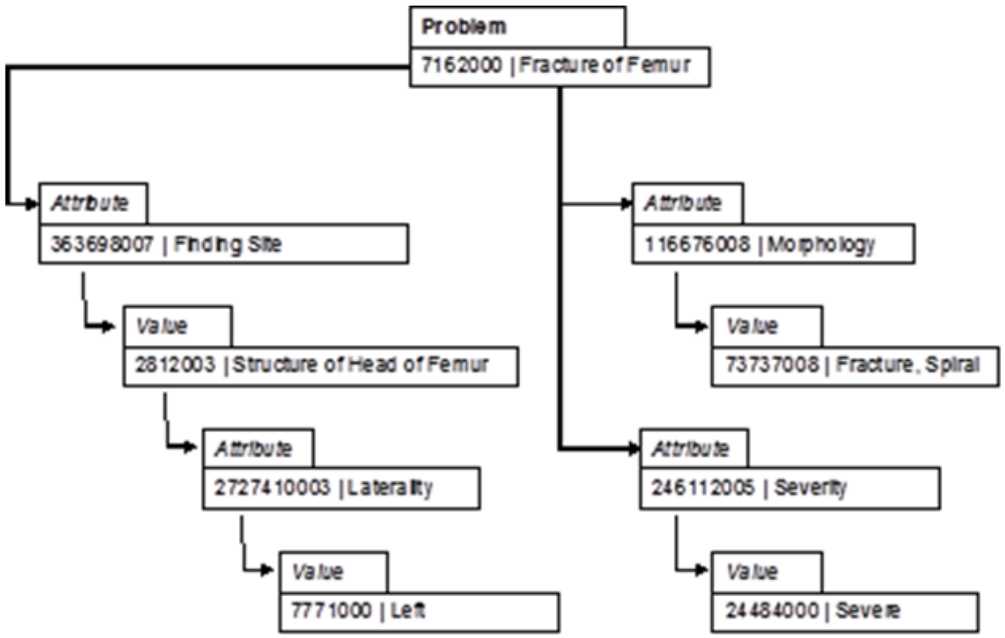
InstanceID	ParentInstanceID	SCT_AttributeID	SCT_AttributeDesc	SCT_ValueID	SCT_ValueDesc
1				7162000	Fracture of Femur
2	1	363698007	Finding Site	2812003	Structure of Head of Femur
3	2	2727410003	Laterality	7771000	Left
4	1	116676008	Morphology	73737008	Fracture, Spiral
5	1	246112005	Severity	24484000	Severe

If a Caché hierarchical database is used, the same expression could be stored as a single text data value:

Problem

7162000|Fracture of Femur|:{363698007|Finding Site|=2812003|Structure of Head of Femur|:2727410003|Laterality|=7771000|Left|},116676008|Morphology|= 73737008|Fracture, Spiral|,246112005|Severity|=24484000|Severe

Alternatively, the expression could be stored as a set of data elements in a structured hierarchical tree:



An application could retrieve and correctly process any of these representations. The selection of representational forms for post-coordinated observation expressions impacts the following properties of an information system:

- Storage and retrieval performance
- Processing performance (i.e., subsumption testing)
- Interoperability

- Development and maintenance costs

This section analyzes options regarding representational forms for the medical record system in the context of the functional requirements in Section Section 26.3, “Requirements and Assumptions” The discussion first addresses representation in a relational database, and then covers representation in an object-oriented database (such as Caché).

26.4.2.1. SNOMED Compositional Grammar

The SNOMED compositional grammar is a BNF grammar developed by the SNOMED authority to represent SCT expressions as single, parse-able text strings[1]. An example observation expression represented in the compositional grammar is:

```
7162000|Fracture of Femur|:{363698007|Finding Site|=2812003|Structure
of Head of Femur|:2727410003|Laterality|=7771000|Left|},116676008|Mor-
phology|= 73737008|Fracture, Spiral|,246112005|Severity|=24484000|Se-
vere
```

The grammar specifies that each SCT concept and attribute within an expression is represented by its concept ID and (optionally) a text description. The relationships among concepts are specified by the appropriate positioning of reserved-character delimiters (specifically, the set “ : = , { } ( ) | ”).

PROS:

- Concise (especially if text descriptions are omitted)
- Efficient retrieval - allows an entire concept to be retrieved with a read operation on a single field of a single relational table (if a relational database is used); requires no relational joins to retrieve an entire concept, regardless of its size or complexity
- Efficient storage – allows an entire concept to be persisted with a write operation to a single field of a single relational table or to a single array cell in a hierarchical database.

CONS:

- No logical operations are possible on observation expressions as they appear in the database. Specifically, SQL-based or ObjectScript-based searches of the database for specific SCT observations or observation attributes are not possible. All such searching must be done outside of the database within middleware that is capable of parsing and processing SCT expressions. Such additional middleware will have to be purchased or developed (Note: Given the need for subsumption testing, an operation not supported by any commercial relational database engine, such additional middleware will need to be procured regardless of the representational form in which observations are persisted.).
- No logical operations are possible on observation expressions until a processing engine parses the expressions and constructs corresponding in-memory data structures. The performance of queries against large data sets (e.g., for quality reporting or clinical research) will be negatively impacted by this requirement, and even real-time queries against smaller data sets (e.g., for decision support rules) may be prohibitively slowed. An alternative approach would be to store the *binary images* (“BLOBs”) of observation expressions (as defined by the proprietary software systems that will process those expressions). This approach would obviate the need to parse the expressions and algorithmically build corresponding data structures. The value of such an approach depends on the processing time required to construct in-memory data structures from the SNOMED compositional grammar relative to the time required to perform subsumption testing subsequent to the construction of the data structures. If the time

[1]The complete BNF grammar is specified in http://www.snomed.org/snomedct/documents/abstract_models_and_representational_forms.pdf

required for subsumption testing dwarfs the time required to construct the data structures, the storage of binary images may not be worthwhile (given the potential maintenance costs – see discussion of binary images below).

- The syntax of the compositional grammar is not an industry standard (unlike XML – see below), so that few if any commercial tools exist for parsing compositional grammar expressions and building/processing the in-memory data structures that such parsing generates.

- The expressions offer minimal human readability (especially if text descriptions are omitted). Although expressions rendered in the compositional grammar will never be displayed to clinician users, programmers and analysts may wish to review them for debugging purposes.

Note: The SNOMED compositional grammar is relatively new and currently used for demonstration purposes only. Specifically, it is not an industry standard that is supported by commercial tools and it may be subject to change as experience with it increases. Therefore, if PHS chooses to use a compositional grammar to represent observation expressions, it could modify the SNOMED compositional grammar to better meet its needs. For example, the PHS compositional grammar could require concepts to be represented using HLE GUIDs in addition to or instead of SNOMED Concept IDs. Also, any errors or omissions in the grammar that PHS uncovers could be addressed without the need to maintain consistency with the "official" SNOMED compositional grammar.

26.4.2.2. HL7 CD Data type (XML)

The HL7 Concept Descriptor (CD) data type is a model developed within HL7 version 3.0 for representing concept expressions. Instances of the CD data type are rendered as XML expressions consistent with a defined XML schema. The XML schema for the HL7 CD data type is very similar to the SNOMED concept grammar, with the following exceptions: (1) The HL7 CD data type specifies that concept expressions are rendered as standard XML elements, and (2) the HL7 CD data type does not allow multiple SCT concepts to be combined as the top-level focus concept of a concept expression (e.g., "Fracture of Tibia" + "Fracture of Fibula").

For example, the same post-coordinated expression shown in Section Section 26.4.2.1, "SNOMED Compositional Grammar" is rendered in the HL7 CD data type as follows:

```
<code codeSystem="2.16.840.1.113883.6.96" code="7162000" displayName="
Fracture of Femur">

<qualifier>

<name code="363698007" displayName="Finding Site"/>

<value code="2812003" displayName="Structure of Head of Femur">

<qualifier>

<name code="2727410003" displayName="Laterality"/>

<value code="7771000" displayName="Left"/>

</qualifier>

</qualifier>

<qualifier>

<name code="116676008" displayName="Morphology"/>
```

```
<value code="73737008" displayName="Fracture, Spiral">

</qualifier>

<qualifier>

<name code="246112005" displayName="Severity"/>

<value code="24484000" displayName="Severe"/>

</qualifier>

</code>
```

Whether a relational or hierarchical database is used, the HL7 CD datatype could represent post-coordinated expressions as an alternative to the SNOMED compositional grammar.

PROS:

- HL7 CD renderings of SCT expressions are also single, discrete text strings. Hence, the same benefits exists with regards to retrieval and storage performance as do in using the SNOMED compositional grammar.

- Relative to the SNOMED compositional grammar, certain logical operations on observation expressions may be possible within the database management system. Specifically, a number of commercial DBMSs now include facilities to query within data elements that are XML-typed. For example, an SQL query could retrieve all observations that are severe by including the selection criterion "…WHERE observation.code.qualifier.name.displayName= "Severity" and observation.code.qualifier.value.displayName= "Severe"). (Although I do not believe that Caché currently supports such operations.)

- Use of standard XML allows application developers to leverage many open-source and commercially available resources for generating, parsing, validating, and processing XML data. The task of developing and maintaining interfaces between patient databases and the decision-support and analytical tools that process patient data would be somewhat reduced if a representation based on XML were used.

- A representational form based on HL7 is the most likely to emerge as an industry standard. If SCT, itself, is widely adopted, then a thriving market of tools might appear for processing patient data encoded in the HL7 CD data type, which would give PHS more product choices for querying, analyzing, and displaying the medical record data already persisted in its patient databases. Additionally, the HL7 CD data type is consistent with the HL7 v3.0 messaging model. If and when v3.0 messaging is widely supported, the representation of observations as CD data types would allow PHS to exchange medical record data seamlessly among its own applications and applications at other institutions. **Note**: Adoption of v3.0 is probably a long way off in the United States, however.

CONS:

- XML is significantly more verbose and less disk-space efficient than the SNOMED compositional grammar. The post-coordinated "Fracture of Femur" expression required 200 characters to encode in the SNOMED compositional grammar, but 590 characters in the HL7 CD data type. Even a simple expression consisting of a single SCT concept (such as "Pneumonia") requires 85 characters in the HL7 CD rendition, while only 22 in the SNOMED compositional grammar.

- Although ostensibly a standard, the XML schema for the HL7 CD data type may need to change in response to extensions to the SCT terminology model. For example, the incorporation of Facets into

the SCT model would require the addition of a new XML tag to the CD data type to fully represent the facets of SCT expressions. Coordination between HL7 and SNOMED would then be required to allow SCT users to leverage extensions to the SCT model within their HL7-compliant applications.

26.4.2.3. Proprietary Binary Representation

A third way of representing SCT expressions as single, discrete data elements entails storing *binary images* of the concept expressions. The binary images are serialized renditions of in-memory data structures, as defined by a specific application or a set of applications that share a specific data type (for example, the LE middleware). Most modern relational DBMSs as well as Caché can store binary images in BLOB-typed fields. Applications can retrieve the values of BLOB-typed fields and immediately convert the data into appropriate internal data structures by de-serializing it (i.e., without the need to parse any text expressions). This mode of writing and reading binary observation expressions via serialization and de-serialization (respectively) is typically much more efficient than generating and parsing structured text strings.

PROS:

- Significantly improved performance in moving SCT concept expressions between the applications that create and process them and the databases that persist and share them. The performance will be superior even to representational forms that persist concept expressions as text-encoded strings in individual database fields (such as XML or SNOMED compositional grammar). If the parsing of XML or compositional-grammar expressions is prohibitively expensive for certain types of queries (such as searches across an entire database), this approach may be required.

- Somewhat reduced disk-space requirements for storing observation expressions.

CONS:

- Significantly increased maintenance burden because any changes to the definitions of data structures used by applications to internally represent SCT observation expressions (including very minor changes with no semantic significance) will necessitate a conversion of all persisted observation expressions across the entire database.

- No ability whatsoever to perform logical operations on observation expressions as they appear in the database. The binary images of these expressions are wholly opaque to SQL or Caché ObjectScript, and any processing first requires retrieval and de-serialization by an application that has implemented the appropriate data type.

26.4.2.4. Relational Decomposition

If a relational database is used, an alternative general approach for persisting an observation expression entails decomposing the expression into a set of relational fields and/or relational rows (as opposed to storing the expressions within a single relational field, as proposed in Sections Section 26.4.2.1, “SNOMED Compositional Grammar” - Section 26.4.2.3, “Proprietary Binary Representation”).

Relational decomposition offers the advantage of exposing SCT observation expressions to database processing, i.e., to selective retrieval and analysis using SQL commands. For example, storing the focus concept of an observation expression in a designated field (distinct from any refinements, which are stored in other fields) allows one to retrieve only the focus concept and compare it to a target SCT concept via subsumption testing. This operation is less costly than general-purpose subsumption testing, because both the focus concept and the target concept are pre-coordinated concepts. Where the target concept is very general (such as “respiratory disease”) and the focus concept is derived from the close-to-user form (which is typically a relatively specific concept), comparison against the focus concept alone will yield accurate results in most cases. Consideration of the refinements is not needed. Note: The focus concept in the *Close-*

to-User form must be used for such comparisons, because the focus concept in the Long Normal Form may frequently be very general – e.g., “disease”.

The decomposition of observation expressions into relational fields may be done in two general ways – Unrestricted and Restricted decomposition.

26.4.2.4.1. Unrestricted Decomposition

Unrestricted relational decomposition is the most flexible approach, allowing a concept refinement to contain any combination of attributes and values to any potential depth. The following table shows the “Fracture of Femur” example represented in an unrestricted way using an “object-attribute-value” table:

Problem_Instance_Expressions : Table

InstanceID	ParentInstanceID	SCT_AttributeID	SCT_AttributeDesc	SCT_ValueID	SCT_ValueDesc
1				7162000	Fracture of Femur
2	1	363698007	Finding Site	2812003	Structure of Head of Femur
3	2	2727410003	Laterality	7771000	Left
4	1	116676008	Morphology	73737008	Fracture, Spiral
5	1	246112005	Severity	24484000	Severe

Note that the field names are entirely generic, and the semantics of the expression is entirely conveyed by field values and by the structure imparted through the foreign key “ParentInstanceID”.

PROS:

- Expressivity – any SCT expression can be represented in this format, regardless of the number or depth of its refining attributes.

- Generality – The unrestricted format is relatively resilient to changes in the SNOMED terminology content. For example, if additional attributes are added, the database schema need not be changed. The SCT_AttributeID and SCT_AttributeDesc fields are already capable of storing any SNOMED attribute. If multiple values for certain attributes become allowed, the database schema already supports that as well. (Note: For simplicity, the table structure cannot represent Relationship Groups, but this construct could be supported with the addition of a single field).

- Referential integrity – The highly granular decomposition allows concept that may appear within multiple observation expressions to be represented as single instances (with multiple references). A unique instance of a concept guarantees that only one version exists in the database. Conversely, if a concept is duplicated across a database within each observation expression in which it appears, the potential is created that instances of the concept may become inconsistent if any changes are made to some but not all of them. In practice, however, this is not a concern for concepts that appear within SCT observation expressions. This is because the pre-coordinated concepts that appear in such expressions already have referential integrity, because they exist solely within the SCT terminology model (only references to these concepts, consisting of concept identifiers and perhaps text descriptions, appear within the post-coordinated observation expressions). The complex, structured concepts that appear in SCT observation expressions (i.e., sub-expressions, such as “Structure of head of Femur: Laterality = Left”) need not have referential integrity, because such concepts are all individual instances of observations and may be different in each observation expression in which they appear. Therefore, referential integrity is, in fact, not an advantage of persisting SCT observation expressions in an unrestricted relational form.

CONS:

- Poor retrieval performance – the retrieval of a single post-coordinated expression might require a large number of relational joins, depending on the depth to which the attributes extend. In the example above, two joins would be required to retrieve the attributes of “Fracture of Femur”, and then the “Laterality” attribute for “Structure of Head of Femur.”

- Poor storage performance – complex expressions need to be decomposed into individual attribute/value pairs, which are separately inserted in the database field (along with the appropriate foreign key references). Indexes on the “InstanceID” and “ParentInstanceID” must be updated for each row entered.

- Need for non-SQL support – Because post-coordinated expressions may be defined to an arbitrary depth of attributes, an arbitrary number of relational joins may be required to retrieve such expressions. Hence, SQL alone cannot be used to specify the queries required to retrieve such expressions. Either database stored procedures or programs external to the database are required to retrieve post-coordinated expressions stored in an unrestricted relational form (both of which offer poorer performance than SQL queries alone, which can be better optimized). Although in practice, most clinical observations specified as post-coordinated expressions will not extend beyond two or three levels, the normalized forms of these expressions may nest more deeply.

26.4.2.4.2. Restricted Decomposition

Restricted relational decompositions entail table structures in which the values of attributes are represented in specific, dedicated fields. The model is “restricted” in the sense that the full set of attributes that are supported are pre-defined in the relational schema, and other attributes or arbitrary nesting of attributes are not supported. The following table shows the “Fracture of Femur” example encoded in a restricted relational schema.

Problem_Instance_Expressions : Table

InstanceID	ProblemDesc	FindingSiteValueDesc	SiteLaterality ValueDesc	MorphologyValueDesc	SeverityValueDesc	OnsetValueDesc	AccessValueDesc	PriorityValueDesc
1	Fracture of Femur	Structure of Head of Femur	Left	Fracture, Spiral	Severe			
2	Cholecystectomy						Open Approach	Emergency

Note that the focus concept appears in the second field (“Problem Desc”), and the values of various refinements appear in the following fields. Due to space constraints, only the description of each concept is shown, although the ConceptID would also be represented in a realistic example.

PROS:

- Retrieval performance – Entire post-coordinated expressions can be retrieved without any relational joins, regardless of the number of attributes or the depth of nesting (although not all of the attributes or nesting specified by the user may be represented).

- Post-coordinated expressions can be retrieved using SQL queries alone, without the need for stored procedures or programming external to the database.

CONS:

- Complexity – Given the number of different SCT concepts that may appear as focus concepts in post-coordinated expressions, the set of potential attributes that refine these concepts is large. The SCT terminology model contains 50 different attributes, so up to 50 fields may be required in a restricted relational model to represent the possible refinements that could appear in post-coordinated observation expressions.

- Brittleness – the relational schema must be changed each time an attribute of interest is added to the SCT terminology model.

- Sparseness – Given the variety of attributes that may be refined for different types of observation concepts (findings, procedures, observable entities, etc.), only a small subset of attributes will have non-null values in any given post-coordinated expression (e.g., see the example table above). Most attributes will not be populated because the user has not specified a value or because the attributes are not relevant to

the kind of observation specified (e.g., the “Morphology” of a “Cholecystectomy”). The sparseness will create inefficiencies when observation expressions are retrieved and processed by applications, because each potential field in each retrieved data row will have to be tested iteratively for a non-null value (although the vast majority of the values will, in fact, be null).

- Relatively poor storage performance – complex expressions must be decomposed into their constituent attribute/value pairs; the attributes must be correctly mapped to the corresponding field names in the table schema, and a correct SQL expression constructed.

26.4.3. Representation of Context

The observations in patients’ medical records frequently include *context qualifiers*. These qualifiers add clinically important information about the meaning of a symptom, finding, test result, diagnosis, or procedure in the context of the patient’s medical treatment. The information that context qualifiers typically add includes:

If? Is this item definitely present, possibly present, or definitely absent? Should it be ruled out?

Who? Does this item pertain to the patient herself, or to a family member of the patient?

When? Is this item present now, was it present long ago or recently, will it be present in the future?

As with the medical concepts that form the core of observation expressions, it is also important to represent context qualifiers in a formal and consistent way that is amenable to automated analysis. For example, a query may selectively seek patients who have active hepatitis rather than a past history of hepatitis, or patients who definitely have diabetes rather than suspected diabetes. There are a number of options for representing context based on the use of SCT and the existing PHS methodologies.

26.4.3.1. SNOMED Context Model

The SNOMED context model provides a formal model for representing the context of Findings and Procedures (including Findings and Procedures that appear as focus concepts of post-coordinated expressions). The model is fully consistent with the SCT terminology model and supports subsumption testing. The context model in the current release of SCT can represent three context dimensions for Findings and Procedures:

Findings *Finding context* [is the finding present, absent, possibly present?] *Temporal context* [is the finding present now, was it present in the past, both?] *Subject relationship context* [does the finding pertain to the patient, to the patient’s family member?]

Procedures *Action context* [was the procedure already performed, is it under consideration, is it planned?] *Temporal context* [was the procedure performed in the past, is it being performed now?] *Subject relationship context* [does the procedure pertain to the patient, to the patient’s father, brother?]

Context is added to findings and procedures by creating a *context wrapper* for the finding or procedure. The context wrapper is a concept expression, itself, with a focus concept of “Context Dependent Finding” or “Context Dependent Procedure”. These expressions include a set of refinements that specify the relevant finding or procedure, as well as its context values. For example, the following concept expression denotes that the patient has a confirmed mild tear of the right ACL ligament:

Context-Dependent Finding :

Finding Context = Definitely Present

Temporal Context = Current

Subject-Relationship Context = Subject of Record

Associated Finding = Tear of Anterior Cruciate Ligament :

Severity = Mild,

Finding Site = Anterior Cruciate Ligament :

Laterality = Right

Representing context in this way in patients' medical records supports subsumption testing over the associated finding as well as the context attributes. For example, the following predicate expression subsumes any observation describing a definite or probable ACL tear in the patient at any point, past or present:

Context-Dependent Finding : Finding Context = Known Present Temporal Context = Current or Past Subject-Relationship Context = Subject of Record Associated Finding = Tear of Anterior Cruciate Ligament

This predicate expression above subsumes the post-coordinated observation expression shown earlier because the concept "Known Present" subsumes "Definitely Present" and the concept "Current or Past" subsumes "Current" in the SCT terminology. The predicate expression would not, however, subsume a context-dependent finding with a Finding Context of "Known Absent" or a Subject-Relationship Context of "Person in the Family."

Default Context: A feature of the SNOMED Context model is that each context attribute is assigned a default value if no value is explicitly specified. Therefore, a user need not specify a value for each concept expression and the database need not store a value for each concept expression if the intended values match the defaults. The default values for Findings and Procedures are:

Context-Dependent Findings *Finding context* = Known Present *Temporal context* = Current *Subject relationship context* = Subject of Record

Context-Dependent Procedures *Procedure context* = Done [actually, I'm unsure of this] *Temporal context* = Current *Subject relationship context* = Subject of Record

By applying these defaults, the following context-dependent finding (as specified by a user) would be subsumed by the predicate expression above:

Context-Dependent Finding : Associated Finding = Tear of Anterior Cruciate Ligament : Severity = Mild, Finding Site = Anterior Cruciate Ligament : Laterality = Right

Note that, without explicitly adding the default values for the unspecified context attributes at the time that subsumption testing is performed, the finding would not be subsumed by the predicate because the predicate would be more specific.

Use of the SNOMED context model entails the following advantages and disadvantages:

PROS:

- Supports subsumption testing that involves context without need to introduce any new subsumption-testing capabilities or content subsets. For example, the standard subsumption-testing algorithms and existing SCT concept hierarchy can already infer that the candidate expression "Myocardial infarction, brother" is subsumed by the predicate expression "Myocardial infarction, first-degree blood relative."

- The independent representation of the Finding context, Temporal context, and Subject-Relationship context allows new post-coordinated expressions to denote many combinations of context values with-

out the need to enumerate all possible combinations *a priori*. For example, the current PHS context model would require the addition of a new qualifier to represent the context “No history of”, whereas the SNOMED context model could represent this context with the combination of existing qualifiers: Finding Context = “Known Absent” and Temporal Context = “Past.”

CONS:

- The current SNOMED content may not represent all of the context qualifiers that PHS requires. Specifically, the addition of a local concept may be required to represent the “rule out” context.

- The SNOMED context model is significantly more complex than the existing PHS model, and users will not be able to understand and apply it without a simplifying application layer. For example, user interfaces should still allow clinicians to select and to view context qualifiers such as “No family history,” with translation “behind the scenes” to the appropriate SNOMED context representation (in this case, Finding Context = “Known Absent” and Subject Relationship Context = “Person in the Family”).

26.4.3.2. Alternative SNOMED-based Context Model

An alternative to the context model described above is a model that extends the existing set of non-defining attributes for all Findings and all Procedures in the SCT terminology model so that context can be represented simply as the value of a new qualifier. This extension would entail the following changes to the SCT terminology:

New Attribute: “Observation Qualifier”

New Concept sub-hierarchy:

SNOMED CT Concept* Qualifier Value* Observation Qualifier Value Family History of No Family History of Past History of Possibility of Rule Out Status Post

New Relationships (non-defining, refinable):

Procedure*: Observation Qualifier = Observation Qualifier Value Clinical Finding*: Observation Qualifier = Observation Qualifier Value Observable Entity*: Observation Qualifier = Observation Qualifier Value

(*Existing SCT concepts)

Using this model, for example, “s/p emergency cholecystectomy” would be represented as:

```
Cholecystectomy: Priority = Emergency, Observation Qualifier = Status
Post
```

PROS:

- A relatively simple model for querying observation expressions, because queries would require evaluating a single straightforward parameter rather than (possibly) a set of more obscure parameters. For example, it is simpler to look for observations and procedures in a patient’s past medical history by testing for observation expressions with an Observation Qualifier = “Family History” than discerning which specific value of the Temporal Context attribute applies (“Past”? “Past Specified”? “Past Unspecified”? “Recent”?).

- Supports some limited subsumption testing, specifically predicate expressions that search for observations in a single concept category with a single Observation Qualifier value. For example, the following

predicate expression, which matches any emergency procedure, would logically subsume the representation of “s/p emergency cholecystectomy” shown above:

```
Procedure: Priority = Emergency
```

However, predicate expressions cannot combine concepts using disjunctions (“OR”) or negations (“NOT”). Therefore, this context model would not support a predicate expression to search for any Clinical Finding, Observable Entity, or Procedure that occurred in the present *or* the past. Retrieving all such observations would require several subsumption tests. The SNOMED Context model, in contrast, does support such a predicate expression because a Temporal Context value of “current or past” exists:

Context-Dependent Finding :

Finding Context = Known Present

Temporal Context = Current or Past

Subject-Relationship Context = Subject of Record

CONS:

- Because a single Observation Qualifier must represent all three dimensions of context (current/past, present/absent, patient/family), all of the relevant combinations must be enumerated as possible values of Observation Qualifier. For example, the documentation that a patient has “no history of” a disorder would necessitate the addition of a new Observation Qualifier Value (“No History of”), whereas the SNOMED context model could represent this context with a novel combination of existing context values (i.e., Finding Context = Known Absent and Temporal Context = Past).

- The addition of the relationship “Observation Qualifier = Observation Qualifier Value” to all Procedure, Observable Entity, and Clinical Finding concepts in the SCT terminology may create semantically nonsensical expressions when such concepts are used outside the documentation context of the patient medical record. For example, a Procedure concept specified as an ordered procedure could be assigned a “Observation Qualifier Value” of “Status Post” (which wouldn’t make sense in that documentation context). Because certain of the context qualifiers apply only when a concept is used in the documentation context of a medical record, the “Observation Qualifier” attribute probably should not be assigned to all Procedure, Observable Entities, and Clinical Findings concepts in the SCT model. The SNOMED context model avoids this problem by assigning context attributes only to the special wrapper concepts of Context Dependent Finding and Context Dependent Procedure.

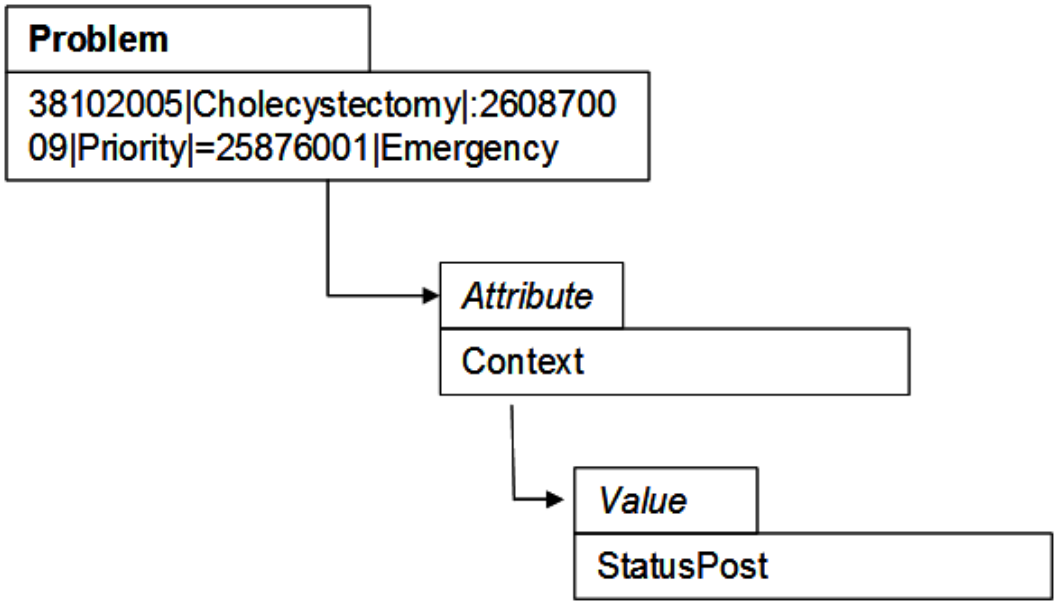
26.4.3.3. Relational Context Model

A third alternative is to introduce the notion of an Observation Qualifier attribute with the same set of potential values, but not explicitly add this attribute to the SCT terminology model. Rather, the attribute and its values would be represented only as an additional field in the relational table or an additional attribute in the Caché tree structure (i.e., similar to a partial Restricted Relational Decomposition, except the Observation Qualifier attribute would not be part of the SCT terminology model). For example, under this model, the “s/p emergency cholecystectomy” observation would be represented in the relational database as:

Problem_Instance_Expressions : Table

	InstanceID	ProblemExpression	ContextCode
	1	38102005|Cholecystectomy|:260870009|Priority|=25876001|Emergency	StatusPost
▶			

and in a Caché tree structure as:



PROS:

- Also a relatively simple model.
- Avoids the problem of adding the Observation Qualifier attribute to all Procedure, Observable Entity, and Clinical Finding concepts in the SCT terminology and creating potentially nonsensical concept expressions in certain documentation contexts.
- Provides richer testing against logical combinations of contexts than afforded by the SNOMED expression language. Specifically, SQL queries may explicitly search for Boolean combinations of ContextCode values, such as “WHERE ContextCode = ‘HistoryOf’ OR ContextCode = ‘StatusPost’ “, without requiring multiple subsumption tests.

CONS:

- Supports no logical subsumption testing involving context values (e.g., to infer that “past” is subsumed by “past or current”).
- Involves the same combinatorics to represent new combinations of “present/absent”, “current/past”, and “patient/family” context designations.

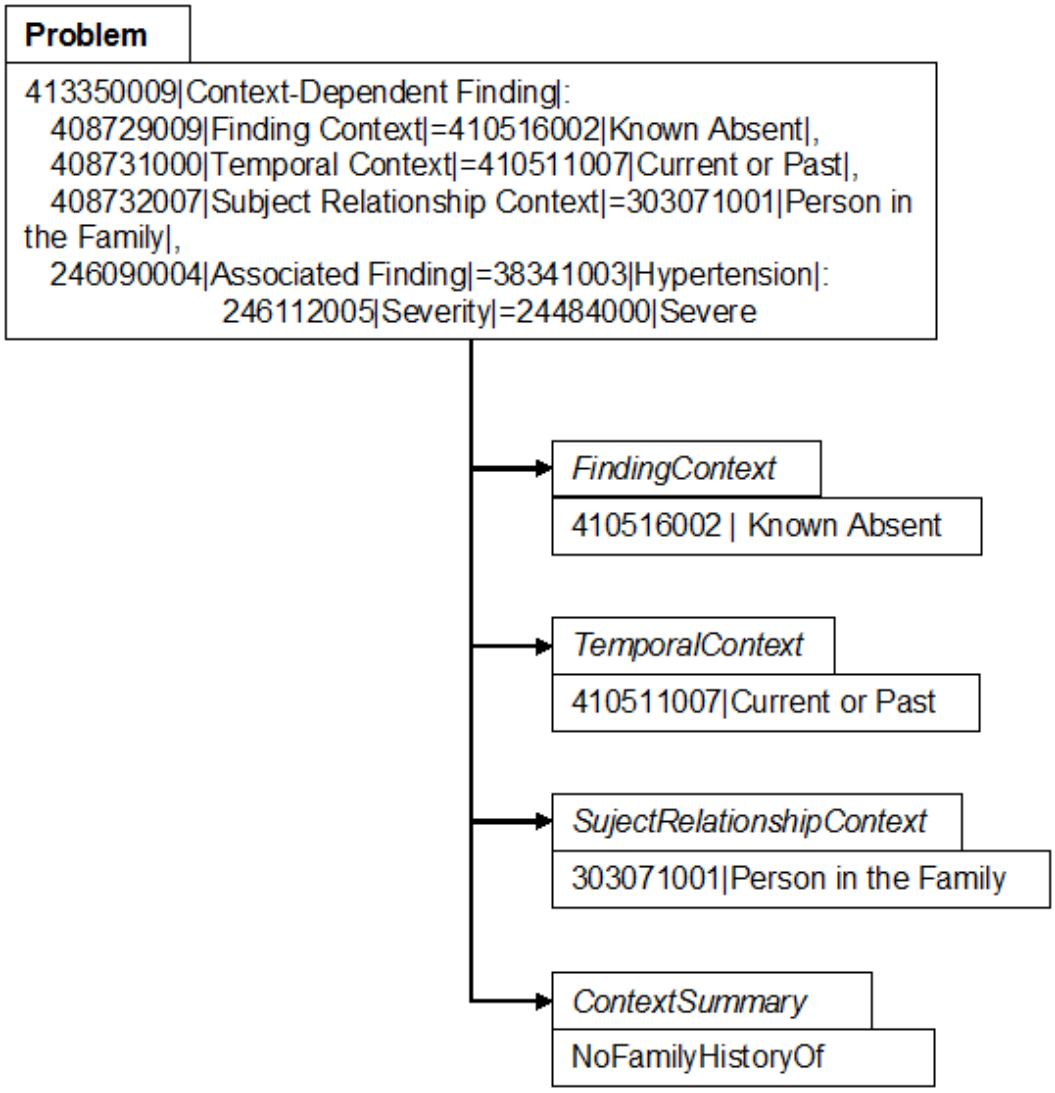
26.4.3.4. Combination of Approaches

Lastly, a fourth approach entails combining elements of the approaches above. For example, one could use the SNOMED context model, but redundantly represent the values of the context qualifiers in their own relational fields, as well as represent a new “summary qualifier” field whose value stores a more intuitive representation of the context (which would be derived from the combination of SNOMED context values). Under this model, the documentation of “no family history of severe hypertension” would be represented in a relational table as:

Problem_Instance_Expressions : Table

InstanceID	ProblemExpression	FindingContext	TemporalContext	SubjectRelationshipContext	ContextSummar
1	413350009|Context-Dependent Finding|: 408729009|Finding Context|=410516002|Known Absent|, 408731000|Temporal Context|=410511007|Current or Past|, 408732007|Subject Relationship Context|=303071001|Person in the Family|, 246090004|Associated Finding|=38341003|Hypertension|: 246112005|Severity|=24484000|Severe	Known Absent	Current or Past	Member of Family	NoFamilyHistoryOf

and in a Caché tree structure as:



PROS:

- Supports full subsumption testing of observations with context, when needed
- Avoids the problem of adding the Observation Qualifier attribute to all Procedure, Observable Entity, and Clinical Finding concepts in the SCT terminology, which could lead to nonsensical concept expressions in certain documentation contexts.
- Provides a derived summary context that approximates the current observation qualifiers and provides a convenient search key for certain analyses.
- Supports testing against logical combinations of SCT context specifiers using SQL expressions, such as “WHERE SubjectRelationshipContext = ‘Mother’ OR SubjectRelationshipContext = ‘Sister’ “. In the absence of storing the SCT context specifiers in separate fields, multiple subsumption tests would be required to apply such logic.

CONS:

- Some redundant representation of data, which entails decreased storage performance and increased risk of inconsistencies.

26.4.4. Computation of Transitive Closure

Subsumption testing against patient observations is an important but computationally intensive operation. Testing subsumption between two pre-coordinated concepts entails determining whether the concepts (i.e., their GUIDs) have an ancestor-descendant relationship in the SCT concept hierarchy. Unless certain optimizations are applied (as discussed below), this determination entails a tree traversal of the hierarchy, which has exponential combinatorics. In large terminologies, such as SCT, exponential tree traversals may be prohibitively slow for queries that must execute in real time or queries that must evaluate many observations.

Subsumption testing of post-coordinated expressions is even more complex. It requires an algorithmic comparison of the predicate and candidate expressions (in their normalized forms), which itself requires several steps that involve subsumption testing:

1. Determine whether the predicate's focus concept subsume the candidate's focus concept. Note: Both focus concepts will be primitive SCT concepts following normalization.

2. Determine whether all of the relationship attributes of the predicate's focus concept subsume at least some of the relationship attributes of the candidate's focus concept.

3. For each subsumed relationship attribute, determine whether its value in the predicate expression subsume the value in the candidate expression. If the value of an attribute is a concept that, itself, has attributes, apply steps 1, 2, and 3 recursively.

Note: In practice, the post-coordinated observation expressions specified by clinicians will typically have a small number of relationship attributes. However, when a candidate expression is converted to its Long Normal Form (as required for subsumption testing), the number of attributes may increase significantly (e.g., see Section Section 26.4.1.1, " Definitions"). This increase, in turn, increases the number of subsumption tests required.

A recognized strategy to improve the performance of subsumption testing is to compute and store the *transitive closure* of the pre-coordinated concepts in the SCT concept hierarchy. The transitive closure is the set of all ancestor-descendant pairs in the hierarchy. For example, the small hierarchy shown in Sec. Section 26.2, "Background and Scope" would generate the following ancestor-descendant pairs:

disease => infectious disease disease => infective pneumonia disease => bacterial pneumonia infectious disease => infective pneumonia infectious disease => bacterial pneumonia infective pneumonia => bacterial pneumonia etc…

The storage of a transitive closure significantly improves the performance of subsumption testing. Each pair-wise subsumption test becomes a lookup in an indexed list of ancestor-descendant pairs (typically an O(n log n) operation with n = number of levels in the hierarchy), rather than a recursive tree traversal (an $O(k^n)$ operation). However, this approach requires storing the transitive closure, which may be very large, and updating the transitive closure whenever the structure of the concept hierarchy changes. The addition of a single concept, for example, may generate many new ancestor-descendant pairs.

The options with respect to precomputing transitive closures include the following:

26.4.4.1. Compute no transitive closure

PROS:

- The default approach, which requires the least amount of disk storage and is simplest to implement and maintain.

CONS:

- Potential for prohibitively slow performance for subsumption testing against observations.

26.4.4.2. Compute the full transitive closure of the relevant SCT concept hierarchy

PROS:

- A significant performance improvement for subsumption testing of pre-coordinated observation concepts. Such subsumption tests may be performed as single lookups in the indexed table.
- A significant performance improvement for subsumption testing of post-coordinated observation expressions. Each of the subsumption tests needed for this operation (i.e., tests between primitive SCT concepts) may be performed as single lookups in the indexed table.

CONS:

- An increase in required storage. Depending on the depth and interconnectedness of the SCT concept hierarchy (which is a multi-hierarchy), the transitive closure table might contain millions of entries. For example, the NCBI ontology, which consists of 230,000 concepts, generates a transitive closure containing 3.5 million concept pairs. A transitive closure for the SCT hierarchy will likely be comparable. In practice, however, each entry will require modest storage space, as it will contain only two GUIDs (each requiring 8 to 16 bytes).
- An increase in complexity and risk of error when the SCT terminology content changes (as a result of PHS edits or SNOMED releases). Any content updates will require appropriate updates to the transitive closure table. A mechanism will need to exist to perform these updates reliably and efficiently. If the transitive closure tables are cached by client applications (to enable local computation of decision-support queries, for example), updates will also require a mechanism to refresh the local caches in an appropriate, timely, and coordinated manner.

26.4.4.3. Compute the transitive closure for primitive concepts only

PROS:

- Relative to computation and maintenance of the full transitive closure, this approach may require significantly less storage space. Although primitive concepts constitute the majority of the SCT concept hierarchy, they appear typically at higher levels of the hierarchy (where less branching exists). The result may be many fewer ancestor-descendant pairs in which both concepts are primitive, although one would want to confirm this empirically.
- A significant performance improvement for subsumption testing of post-coordinated observation expressions (which entails pair-wise subsumption testing of primitive concepts only).
- Somewhat less complexity and risk when the SCT terminology content changes, because only additions, deletions, or modifications of primitive concepts generates changes to the transitive closure tables.

CONS:

- No performance improvement for subsumption testing of pre-coordinated concepts unless (1) both are primitive concepts or (2) both are first normalized. Depending on the frequency with which pre-coordinated concepts appear in medical records and query expressions, this may be acceptable.
- Some additional complexity in maintaining the transitive closure because the primitive/defined state of concepts will have to be considered in determining their effect on the transitive closure.

26.4.5. Just-in-Time Pre-coordination

Just-in-time (JIT) pre-coordination is a further optimization for subsumption testing that involves post-coordinated expressions. The method assumes that a transitive closure table for the SCT hierarchy exists (see Section Section 26.4.4, “Computation of Transitive Closure”). For each post-coordinated expression that is created by a user, a new local concept definition and local concept identifier are created (“just-in-time”), stored in a reference table, classified with respect to the SCT hierarchy, and added to the transitive closure table. The identifier for the post-coordinated expression is stored in the patient’s medical record (instead of the expression itself), and the expression is referenced for any subsumption test that involves that patient’s medical record. Because the identifier has already been classified with respect to the entire SCT hierarchy in the course of adding it to the transitive closure, subsumption testing against the post-co-ordinated expression requires only an index lookup, rather than application of the full algorithm described in Section Section 26.4.4, “Computation of Transitive Closure”.

Note that before a new post-coordinated expression is added to the transitive closure table, the system first searches the set of existing expressions in the reference table (using equivalence testing) to check whether the new expression already appears there. If the expression does appear, its existing identifier is simply placed in the patient’s medical record, and no other operations are required.

26.4.5.1. Implementation of Just-in-Time Pre-Coordination

PROS:

- Reduces subsumption testing to a single lookup in the transitive-closure table in all cases, whether the subsumption test involves pre-coordinated concepts or post-coordinated expressions.

CONS:

- Significantly increases the overhead for adding post-coordinated observations to patient’s medical record. At a minimum, for each post-coordinated observation that a user specifies, the system must search the table of existing local concepts to check whether that observation expression was previously pre-coordinated. If it was not, the system must create a new pre-coordinated concept corresponding to the observation expression, classify that concept with respect to the existing SCT hierarchy, and update the transitive closure table with all of the new entries generated by the addition of the local concept. Although this process could be deferred, to prevent disrupting the user workflow, the benefits of JIT pre-coordination cannot be realized until this indexing process completes.

26.4.5.2. No Implementation of Just-in-Time Pre-Coordination

PROS and CONS: The opposite of those described in the section above.

26.4.6. Partial Subsumption Testing of Post-Coordinated Expressions

Finally, another potential optimization for subsumption testing of post-coordinated expressions entails testing only the *focus concepts* within such expressions, rather than the focus concepts and their full sets of attributes and values. Because the focus concept is always a pre-coordinated concept, a single “standard” subsumption test is sufficient, without need to apply the algorithm in Section Section 26.4.4, “Computation of Transitive Closure”.

For example, partial subsumption testing would reduce the following pair-wise subsumption test

Predicate expression: Pneumonia (ID = 233604007)

Candidate expression: Bacterial Pneumonia (ID = 53084003) : Causative Agent (ID=246075003) = Methicillin Resistant Staph. Aureus (ID=115329001)

To the simpler subsumption test:

Predicate query expression: `Pneumonia (ID = 233604007)`

Candidate observation expression: Bacterial Pneumonia (ID = 53084003)

PROS:

- The post-coordinated expression need not be normalized prior to subsumption testing
- A single pair-wise subsumption test can determine whether a candidate post-coordinated expression is subsumed by the predicate expression, rather than the potentially several pair-wise tests required by the algorithm in Section Section 26.4.4, “Computation of Transitive Closure” (depending on the structure of the predicate and candidate expressions).
- The pair-wise subsumption test involves pre-coordinated concepts only, which is a simpler operation. If a transitive closure table for the SCT terminology is available, the test can be performed with a single lookup in this table.
- Subsumption testing of post-coordinated concepts may take longer to implement than that for pre-coordinated concepts. By allowing partial subsumption testing, the PHS system could capture, store, and process post-coordinated expressions during the interim period before full functionality is available. When full subsumption testing becomes available, the data would already exist to support it and the transition to the full mode of processing would be relatively straightforward.

CONS:

- In a minority of cases, partial subsumption testing will produce incorrect results. This occurs when a post-coordinated candidate expression is logically subsumed by a predicate expression, but an attribute of the focus concept in the candidate expression is required to correctly infer subsumption. This can be seen in the following example: *Predicate query expression*: `Chronic Rhinitis (ID = 86094006)` *Candidate observation expression*: `Rhinitis (ID = 70076002) Course (ID = 260908002) Chronic (ID = 90734009) Severity (ID = 246112005) Mild (ID = 255604002)` The partial subsumption test would conclude that the focus concept “Rhinitis” is NOT subsumed by “Chronic Rhinitis,” although the complete post-coordinated expression would be subsumed by “Chronic Rhinitis” (given the refining attributes of “Rhinitis” and the definition of “Chronic Rhinitis” in the SCT terminology).
- This approach will not work if the SNOMED context model is used, because the focus concept in all observation expressions of this model is either “Context Dependent Finding” or “Context Dependent Procedure” (see Section Section 26.4.3.1, “SNOMED Context Model”). The finding or procedure, itself, is a *value* of the attribute Associated Finding or Associated Procedure, and these values will not be considered by a partial subsumption test unless they are first extracted from the expression by a pre-processing step.

26.5. Recommendations

26.5.1. Abstract Model

We recommend persisting the following forms for each post-coordinated observation expression (Option 3):

1. Close-to-user form (i.e., the SNOMED expression that the user actually specified). This form will allow the system to later re-derive the other normalized forms when necessary.

2. Text-rendered form (i.e., the original text display of the expression that the user specified). This form is important for medicolegal purposes to provide a record of the information that the user viewed and attested when updating the patient record (including any text annotations that may not be captured in the formal SNOMED representation). This form is also important for clinical care, to ensure that subsequent users see the same and complete clinical expression that the author intended.

3. Long-normal form (i.e., the normalized form that may be used in subsumption testing without further transformation). The caching of this form is important for reasonable performance when subsumption testing is performed against post-coordinated expressions. This form may need to be updated when changes to the SCT terminology content occur (either due to local extensions or periodic SNOMED releases). A process will need to exist to scan the entire medical record and update relevant post-coordinated expressions following content revisions.

The Short-normal form and Canonical form need not be persisted because they will rarely be used and can be derived from the Close-to-user form when needed.

Note: The question arises as to whether the long-normal form of *pre-coordinated* concepts (i.e., those with single GUIDs) should also be derived and persisted in the medical record. The proper approach is YES, *if post-coordinated expressions may appear as predicates in queries*. In these cases, subsumption testing will require that the candidate expression be in its normalized form even if it is a pre-coordinated concept. If post-coordinated expressions will not appear as predicates in queries, then the normalized form of pre-coordinated concepts need not be persisted (because testing subsumption between two pre-coordinated concepts does not require it).

The derivation, storage, and maintenance of the long-normal form for observation expressions will certainly create additional overhead for electronic health record systems. If organizations plan to maintain a separate analytical data store (data warehouse) for performing complex queries across many patient records, they may wish to persist and maintain the long normal form in the analytical data store only. If queries and subsumption tests against the operational data store involve the records of individual patients only (such as the queries typically executed for real-time decision support), it may be feasible to derive the long normal forms of post-coordinated observations at the time the patient's record is retrieved. Such "just-in-time" normalization would not be practical in the analytical data store, however, where queries that search large data sets must perform efficiently.

26.5.2. Structure and Syntax

If a relational database will be used, I recommend persisting post-coordinated expressions using the SNOMED compositional grammar, or some local variation thereof (e.g., including GUIDs rather than SNOMED concept IDs). This approach will enable complete post-coordinated expressions to be written to and retrieved from the database efficiently.

Because subsumption-testing and other logical operations on post-coordinated expressions will require specialized middleware (i.e., the Health Language Engine), there is little advantage to exposing the structure of such expressions to SQL and related programming tools. The performance disadvantages of exposing the structure through various relational decompositions could be significant.

The SNOMED compositional grammar is preferred to the HL7 CD data type and to a binary representation primarily because the latter approaches will require greater maintenance effort. A binary representation may need to change each time the middleware that defines it is updated. HL7 may maintain the CD data type on a different schedule or based on different requirements than those of PHS, creating undue constraints.

If the Cache hierarchical database will be used, I am not sufficiently familiar with the technology to make a recommendation regarding structure and syntax. If a single data element will be used to store post-coordinated expressions, however, I again recommend using the SNOMED compositional grammar rather than the HL7 CD data type or a binary representation (for the same reasons as above). However, it may be

preferable to store the components of post-coordinated expressions as discrete data elements in a structured hierarchical tree (see Section Section 26.4.2, “Structure and Syntax for Persistence”), depending on the technical capabilities of Caché.

26.5.3. Representation of Context

I recommend the hybrid approach described in Section Section 26.4.3.4, “Combination of Approaches”. This approach provides a variety of mechanisms to query the context associated with an observation (whether post-coordinated or pre-coordinated), depending on the needs of the analysis and the skills of the analyst. The only disadvantage of the approach is the storage of redundant data elements. However, unlike the storage of the long normalized form (which also represents redundant information), these data elements do not need to be updated with each extension or revision of the SNOMED terminology because they are derived from the close-to-user form, rather than the normalized form.

26.5.4. Computation of Transitive Closure

Although I am not familiar with HLI’s specific plans for implementing subsumption testing, I believe that the computation and maintenance of a transitive closure table will be essential to make such a feature computationally feasible. The question remains whether the transitive closure should be computed and maintained within the Terminology Server (i.e., as a feature of the terminology middleware), or within EHR’s own computing environment (i.e., as a feature of the medical record system). The former approach makes much more sense, since it allows maintenance of the terminology and the transitive closure to be centrally managed and coordinated. Also, it is likely that any other user of the terminology server that use the planned subsumption-testing feature will require a transitive closure table (particularly if they use the SNOMED terminology), so providing the table and the mechanisms to maintain it will be a practical requirement for the terminology server.

To enable efficient subsumption testing of pre-coordinated or post-coordinated observation expressions, I recommend computing the full transitive closure table for the relevant SCT hierarchy (rather than a table of primitive concepts only). If the creation or maintenance of the full table proves too difficult, costly, or error-prone, HLI can later scale back the table to include primitive concepts only.

26.5.5. Just-in-Time Pre-coordination

I do not recommend the approach of just-in-time pre-coordination at this time. The additional complexity and overhead involved in potentially updating the terminology and the transitive-closure table each time a post-coordinated observation expression is created is unlikely to be justified by whatever performance gains are achieved. If a transitive closure table exists for all pre-coordinated concepts, execution of the algorithm in Section Section 26.4.4, “Computation of Transitive Closure” is likely to be sufficiently fast, even in the absence of JIT pre-coordination.

However, given the additional demands on analytical queries against large data sets, PHS may wish to consider implementing JIT pre-coordination in any data warehouse that contains post-coordinated observation expressions. For this application, the batch processes required to find and classify all unique post-coordinated expressions may be more feasible (given the greater down time available for non-operational databases) and more valuable (given the greater performance requirements of each subsumption test when thousands may be required by a single query).

26.5.6. Partial Subsumption Testing

Partial subsumption testing of post-coordinated expressions, as described in Section Section 26.4.6, “Partial Subsumption Testing of Post-Coordinated Expressions”, is a viable short-term strategy that will allow post-coordinated expressions to be created by users and leveraged in queries even before the algorithms to support full subsumption testing aren implemented in LE. It is likely that the vast majority of subsumption

tests executed using this method will return correct results, given the types of observation expressions and queries that are likely to exist. However, PHS must bear in mind the potential for incorrect subsumption-testing results until a correct algorithm is implemented. Specifically, PHS may wish to refrain from relying on subsumption testing in “mission-critical“ operations.

To facilitate the use of this technique, we recommend separately persisting the focus concept of the relevant clinical observation for each observation expression. For example, if the post-coordinated expression is:

Context-Dependent Finding : Finding Context = Definitely Present Temporal Context = Current Subject-Relationship Context = Subject of Record Associated Finding = Tear of Anterior Cruciate Ligament : Severity = Mild, Finding Site = Anterior Cruciate Ligament : Laterality = Right

the persisted record would contain a separate and discrete representation of:

Tear of Anterior Cruciate Ligament

26.5.7. Summary of Recommendations: An Example

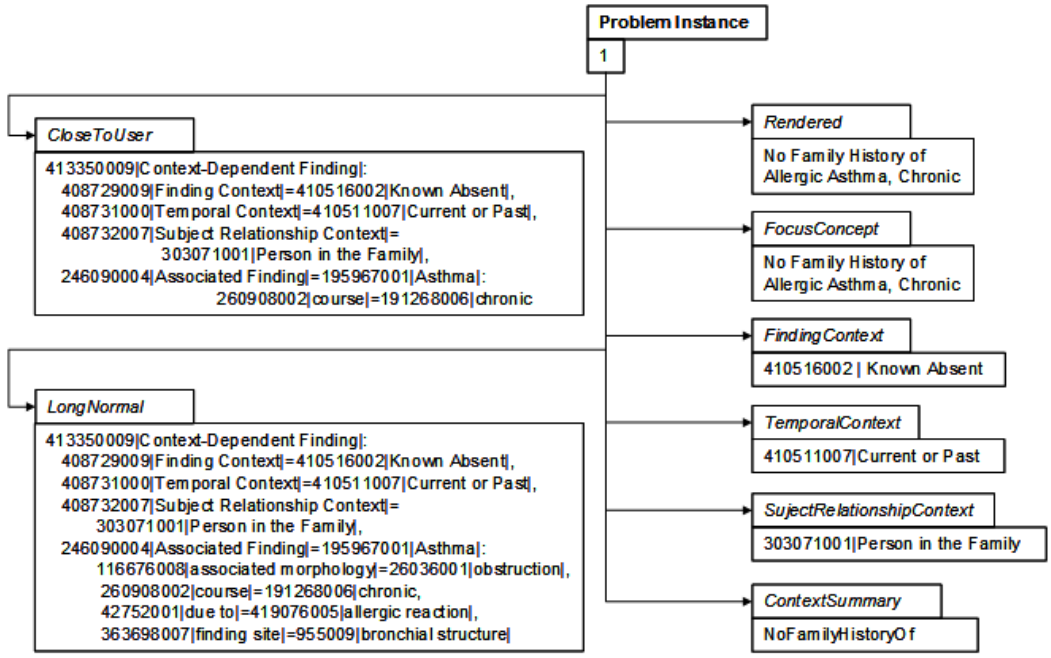
Based on each of the preceding recommendations, this section presents the representation of a single post-coordinated expression in the recommended persisted form. The expression represents the entered observation:

“No family history of chronic allergic asthma”

Relational Representation:

InstanceID	Problem_Rendered	Focus_Concept	Problem_CloseToUser	Problem_LongNormal	FindingContext	TemporalContext	SubjectRelationshipConte	ContextSummary
3875903	No Family History of Allergic Asthma, Chronic	389145006| Allergic asthma	413350009|Context-Dependent Finding|: 408729009|Finding Context|= 410516002|Known Absent|, 408731000|Temporal Context|= 410511007|Current or Past|, 408732007|Subject Relationship Context|= 303071001|Person in the Family|, 246090004|Associated Finding|= 389145006|Allergic asthma|: 260908002|course|=191268006|chronic	413350009|Context-Dependent Finding|: 408729009|Finding Context|= 410516002|Known Absent|, 408731000|Temporal Context|= 410511007|Current or Past|, 408732007|Subject Relationship Context|= 303071001|Person in the Family|, 246090004|Associated Finding|= 389145006|Allergic asthma|: 116676008|associated morphology|= 26036001|obstruction|, 260908002|course|= 191268006|chronic, 42752001|due to|= 419076005|allergic reaction|, 363698007|finding site|= 955009|bronchial structure|	410516002| Known Absent	410511007| Current or Past	303071001| Person in the Family	NoFamilyHistoryOf

Caché Hierarchical Representation:



Part VIII. Appendices

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Informatics Architecture Use Cases

VHA Knowledge-Based Systems

Informatics Architecture Use Cases

1. Unstable Angina with ST-Elevation Myocardial Infarction

Angina 1

1.1. Introduction

1. This use case was created to evaluate the ontology created by the VistA Evolution GUI Research project. It includes common assessments, observations, interventions, and cognitive goals that arise while caring for a patient in this scenario to ensure that the ontology can accommodate these concepts.

2. All clinical data in this use case is synthetic. Data was created to support the flow of this use case and provide examples of clinical observations that are documented throughout the interaction.

3. Clinical decision making in this use case is based, primarily, on VA/DoD Clinical Practice Guidelines for the Management of Ischemic Heart Disease, available at: http://www.healthquality.va.gov/guidelines/CD/ihd/

4. Additional clinical resources are listed below in the Reference section.

5. The intent of this use case is to capture actions that commonly occur when a patient presents with unstable angina. Many of the steps in this use case occur concurrently in an emergent case. In similar scenarios, the same actions may occur in slightly different order.

6. Cognitive goals are included in some 'Actions' to provide insight on the Provider or healthcare professional's mental process at that point of the encounter.

7. Hyperlinks present in the Appendix column are included to provide examples of the data fields and values that may be entered by the EHR user during this step of the use case.

Hyperlinks present in the Standards column suggest standardized terminologies that may be used to capture data in this step of the use case.

1.2. Actors

Patient: a person receiving or registered to receive medical treatment

Provider: Physician, physician assistant (PA), or nurse practitioner (NP). All are skilled health-care professionals trained and licensed to diagnose and treat patients within their defined scope of practice.

Registration Clerk (Reg. Clerk): a hospital employee that collects demographic, insurance and "reason for visit" information from a new patient and enters this information in to the Admission/Discharge/Transfer (ADT) system and/or the electronic health record (EHR).

Triage Nurse (Triage RN): A licensed nurse that assesses symptoms, health-related complaints, and vital signs to determine the degree of urgency for care.

Unit Clerk (UC): a hospital employee that performs administrative duties to facilitate workflow and patient care in the emergency department (ED) or a nursing unit.

Emergency Department Technician (ED Tech): a hospital employee that is trained to provide basic tasks such as vital signs and laboratory draws under the supervision of an RN or Provider.

Registered Nurse (RN): a licensed healthcare professional that is trained to provide nursing care to patients in inpatient and outpatient settings, within their defined scope of practice.

Licensed Social Worker (LSW): a licensed healthcare professional that assists patients to improve their quality of life and social needs, and facilitates care after discharge.

Interventional Cardiologist: A board-certified cardiologist that is credentialed to perform percutaneous coronary interventions via cardiac catheterization.

Nurse's Aide/Assistant (NA): a trained healthcare worker that provides assistance with patient care, under the supervision of an RN.

Clinical Pharmacist – a licensed healthcare professional that often collaborates with physicians and other healthcare professionals to coordinate pharmaceutical interventions and promote health and disease prevention within their scope of practice.

Dispensing Pharmacist – a licensed healthcare professional that dispenses medications, monitors medication parameters and potential drug interactions, and provides information about medications, within their scope of practice.

Radiology Technician (Rad Tech) – a licensed radiography professional that performs diagnostic imaging exams on patients to help physicians assess illness and injury.

Radiologist - a licensed physician that specializes in diagnosing and treating diseases and injuries by using medical imaging.

EKG Technician (EKG Tech) – a cardiology technologist that administers basic electrocardiogram tests to patients. The results are then read by a cardiologist or other licensed physician.

Respiratory Therapist (RT) – a licensed healthcare practitioner that provides care and treatment to patients requiring breathing and oxygenation support.

Charge RN – a registered nurse that is responsible for the efficient management of a nursing unit or department, including admissions, discharges, and the oversight of all nursing and support staff.

1.3. Description

53-year-old white male presents to the ED with chest pain and is diagnosed as having a ST-elevation myocardial infarction (STEMI)

1.4. Trigger

1. Patient is brought to the ED by their family member
2. Patient is experiencing crushing chest pain (radiating to their jaw and neck), shortness of breath (dyspnea), nausea, and sweating (diaphoresis) after attempting to shovel their front walkway.

1.5. Preconditions

1. Patient has a history of stable angina that is usually relieved by rest, however the above symptoms worsened with rest.

2. Patient has taken one sublingual (SL) nitroglycerin (NTG) tablet, without relief.

1.6. Postconditions

Minimal guarantees:

1. Data fields required to support this clinical workflow will be present in the EHR.
2. Data entered will be stored utilizing the appropriate clinical vocabulary.

Success guarantees:

1. EHR supports patient-centered care, guided by goals set by the patient.
2. Patient receives evidence-based care based on the health concerns that are noted during the outpatient visit.
3. Patient will achieve improved outcomes and satisfaction as a result of care facilitated by EHR functionality.

1.7. Assumptions

1. Emergency Department (ED) can provide assessment and initial treatment of life-threatening conditions.
2. ED utilizes a trained healthcare professional to triage (prioritize the care of patients based on clinical need) patients presenting to the ER.
3. ED utilizes the following triage levels:
   a. Resuscitation – immediate threat to life (i.e. cardiac or respiratory arrest, major trauma, shock, etc.)
   b. Emergent – potential threat to life (i.e. chest pain with cardiac suspicion, severe respiratory distress, decreased level of consciousness (LOC), etc.)
   c. Urgent – condition with significant distress (i.e. mild to moderate respiratory distress, head injury without decrease in LOC but with vomiting, etc.)
   d. Less urgent – conditions with mild to moderate discomfort (i.e. head injury –alert without vomiting, depression without suicidal attempt)
   e. Non-urgent – conditions are minor and treatment can be delayed (i.e. skin lacerations, sore throat, etc.)
4. All RNs, PAs, NPs, and physicians are certified in Advance Cardiac Life Support (ACLS).
5. Hospital is a Level 1 trauma center that is equipped to handle patients who present with any and all levels of medical severity.
6. Hospital has a full service Cardiac Catheterization Laboratory that has an Accreditation for Cardiovascular Excellence (ACE) and is credentialed to provide percutaneous cardiac interventions (PCI), including the placement of cardiac stents.
7. Hospital has an Interventional Cardiologist on call, who is present in the hospital and available to do an emergent PCI.
8. The Cardiac Catheterization unit has a room and staff available to support an emergent PCI case.

9. EHR is able to send notifications to healthcare providers when a task has been added to their work list (i.e. Radiology Technician receives notification when an X-ray has been added to his/her work list).

10. EHR is integrated with Picture Archiving Communication System (PACS).

11. EHR has computerized physician order entry (CPOE) functionality.

12. Medications ordered via CPOE system automatically populate the electronic Medication Administration Record (eMAR).

    a. Status of medication administration is documented on the eMAR (i.e. 'G' for Given, 'R' for Refused by Patient, etc.), along with the healthcare professional's electronic signature and any pertinent information (i.e. heart rate when administering a beta-blocker, or the reason for patient refusal when entering 'R' for Refused by Patient)

13. Facility uses Bar Code Medication Administration (BCMA) system to validate administration of medication to all ED and inpatients.

14. BCMA system is integrated with the EHR.

15. EHR can manage the transition from Triage to Provider (e.g., move from one work list to another), ED to inpatient, etc.

16. EHR can generate referral request as entered by Provider.

17. Standard vocabularies utilized by the organization include: ICD10 for diagnosis, RxNorm for medications, SNOMED-CT for clinical assessments, care that is provided and lab results, and LOINC for laboratory tests.

1.8. Normal Flow

Step	Component	Narrative
1.	**Action**	Patient's family member (wife) pulls up to ED entrance, runs in to waiting area and calls for help
	Actors	Patient's family member Patient Triage RN ED Tech
	Action breakdown	ED Tech and Triage RN run to the car (bringing a stretcher), assist patient on to stretcher and wheel the patient in to the Triage area.
2.	Action:	Triage RN completes a brief assessment to determine the patient's condition and the urgency of required care.
	Cognitive Goal:	*Rapid assessment of patient condition.*
	Actors	Patient Triage RN ED Tech Family member
	Action breakdown	Chief Complaint: Crushing chest pain (8 out of 10), unrelieved by rest and 1 sub-lingual nitroglycerin (SL-NTG) tablet.

Step	Component	Narrative
		PMH: Stable angina, dyslipidemia, hypertension (HTN) Allergies: NKDA Current medications: a. SL-NTG as needed. One taken 10 minutes ago. b. Lovastatin 40 mg once daily – taken last night c. HCTZ 12.5 mg daily – taken this morning d. Lisinopril 10 mg daily – taken this morning e. High level assessment: f. LOC: Alert and fully oriented g. Temp: 99 F h. BP: 169/98 i. HR: 106 and slightly irregular j. Cardiac rhythm by ECG monitor: Sinus tachycardia (ST) with rare premature ventricular contractions (PVCs) k. Resp: 24 and shallow l. Pulse Oximetry: 94% on room air Skin: pale and diaphoretic
	Technology	EHR Data Entry
	Applicable Standards	SNOMED, LOINC
	Appendix	Sample Triage Assessment Form
3	Action	Triage RN determines that patient has a severity index of '2' requiring immediate emergency nursing care. *Note: Steps 2 and 3 often occur concurrently.*
	Cognitive Goal	*Assessment of severity of condition. Is the patient's condition life threatening?*
	Actors	Triage RN Patient ED Charge RN ED Physician ED RN
	Action breakdown	Triage RN does the following: a. Moves the patient via stretcher to the 'Emergent' section of the ED

Step	Component	Narrative
		b. Notifies the ED charge nurse and ED attending physician of the new ED patient and their condition. c. Flags the patient as requiring Emergent care by an RN in the HER d. Provides transition of care report to the ED RN that will be caring for the patient
	Technology	EHR a. Status entry b. Data visualization for report
	Appendix	Refer to Emergency Severity Index Triage Tool for EDs [http://www.ahrq.gov/professionals/systems/hospital/esi/esi1.html] Sidebar B Initial Evaluation of Ischemic Heart Disease/ VHA Clinical Guidelines [http://www.healthquality.va.gov/guidelines/CD/ihd/ihd_poc_combined.pdf]
4	Action	ED RN initiates standing orders for emergency interventions that are indicated in the management of ischemic heart disease.
	Cognitive Goal:	*Rapid assessment of patient condition.*
	Actors	ED RN ED Tech Patient
	Action Breakdown	ED RN does the following (unless noted as being delegated to the ED Tech): a. Places the patient on a cardiac monitor (patient is still in ST with rare PVCs) b. Obtains updated set of vital signs (BP: 158/90, HR: 102, RR: 22) c. Places the patient on 2L of oxygen via nasal cannula (NC) d. Evaluates chest pain (still 8 out of 10, crushing, radiating to jaw) e. Obtains 12 lead electrocardiogram (ECG) a. ST-elevation is noted on the ECG b. ECG interpretation **(by machine):** Anterior wall MI i. ED Provider is notified f. Starts a peripheral intravenous (IV) line – *performed by EDT* g. Sends blood sample for Chem 7, CBC, cardiac enzymes (troponin, CK, and CK-MB), Lipid profile, PT/PTT – *orders for labs entered by RN, blood drawn and sent by EDT* h. Administers medications

Step	Component	Narrative
		a. 325 mg chewable aspirin i. Highlights the medication in the eMAR, scans the medication, next scans the patient, then administers the medication after receiving BCMA verification of appropriate administration b. 2 mg Morphine Sulfate IV i. Follows process noted above for aspirin administration. Enters pain level of 8 out of 10 when prompted by BCMA system since administration of a pain medication requires documentation of the patient's pain level. c. 1 tablet of .4 mg SL-NTG (Note: this is the second dose that the patient has received) i. Follows process noted above for aspirin administration. Enters BP: 158/90, when prompted by BCMA system since administration of a SL-NTG should be held if SBP < 100. i. Orders Chest X-ray (CXR)- PA and Lateral views *Note: Each of these interventions is 'ordered' by activating the "Standard ED Order Set for Chest Pain." The ED RN enters the orders as verbal orders, which are then "signed off" by the Provider.* *Note: RN specifies 'Nurse draw' when entering order for lab work. EHR integrates with department printer, which prints labels for blood tubes. If the RN had specified 'Lab draw' the blood draw would have been added to a Laboratory Technician's work list.*
	Technology	EHR a. Biomedical device integration to record VS and pulse oximetry b. Data entry of care performed c. Activation of standing order set for chest pain via CPOE by RN d. Documents medications that were administered in the Medication Administration Record (MAR)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Refer to Standard ED Order Set for Chest Pain [http://www.methodistmd.org/dotAsset/5f69e994-056b-445f-8eda-df8b529cbfb8.pdf] MAR Sample [http://pharmacyprime.ie/PDF/MARS_CHART_EXAMPLE.PDF]

Step	Component	Narrative
		VA Clinical Practice Guidelines for the Management of Ischemic Heart Disease [http://www.healthquality.va.gov/guidelines/CD/ihd/ihd_sum_combined.pdf]
5	Action	Provider receives notification that a verbal order has been placed in his/her name
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	Provider opens notification and views the task listed in their work queue a. Provider opens patient record in EHR and views data entered to date b. Provider enters ED room to assess patient (assessment results are documented in Step 13)
	Technology	EHR a. Notification system b. Data visualization
	Standard	
	Appendix	
6	Action	Registration clerk enters insurance and demographic information in to the EHR system via tablet as verified by the patient's wife.
	Cognitive Goal:	
	Actor(s)	Registration Clerk Family member
	Action Breakdown	Registration Clerk enters the following information in to the system: a. Demographic information b. Primary and Secondary Insurance information: Tricare, member #: xxx-xx, etc. c. Next of Kin contact information d. Religious preference
	Technology	EHR Registration System a. Data entry
	Standard	a. Address [http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf] b. Sex [http://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.1038] c. Ethnicity [http://www.whitehouse.gov/omb/fedreg_1997standards] d. Race [http://www.cdc.gov/minorityhealth/populations/REMP/definitions.html]

Step	Component	Narrative
	Appendix	Hospital Registration Form [http://www.saintpetershcs.com/uploadedFiles/preadmission%202010.pdf]
7	Action	ED RN evaluates status of chest pain and vital signs
	Cognitive Goal:	*Evaluate effectiveness of interventions and need for escalation of therapy*
	Actor(s)	ED RN Patient
	Action Breakdown	a. Patient reports pain is a 5 out of 10 b. VS: BP 150/90, HR 95, RR 20, Pulse Ox: 98% on 2LNC c. ED RN administers 1 tablet of .4 mg SL-NTG *(Note: this is the third dose that the patient has received. Standing orders cover up to 3 administrations of SL-NTG. BCMA is used to record this administration.)*
	Technology	EHR a. Biomedical device integration to record VS and pulse oximetry b. Data entry of care performedDocuments medications that were administered in the electronic Medication Administration Record (eMAR)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
8	Action	Radiology Technician (Rad Tech) receives notification that a diagnostic X-ray for an Emergent ED patient has been added to his/her work list
	Cognitive Goal:	*Management of work queue. Ensure the proper diagnostic test is performed on the proper patient*
	Actor(s)	Rad Tech Patient
	Action Breakdown	Rad Tech receives notification that a task has been added to his/her work list for an Emergent ED patient. a. Rad Tech checks work list in EHR, completes the procedure as ordered and documents completion. b. Rad Tech flags the CXR as ‘ready for interpretation’ by Radiologist
	Technology	EHR a. Integration with Notification system b. Data entry c. Status entry
	Standard	LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	

Step	Component	Narrative
9	Action	Radiologist receives notification that a CXR is ready for interpretation for an Emergent ED patient
	Cognitive Goal:	*Accurate evaluation of CXR (taking reason for CXR and old films in to consideration)*
	Actor(s)	Radiologist
	Action Breakdown	Radiologist receives notification that a chest film is ready for interpretation. a. Radiologist checks work list in EHR, views the indicated CXR and enters the CXR results and interpretation. b. Radiologist flags the CXR as 'Resulted'
	Technology	EHR integration with PACS and Notification system a. Image visualization b. Data entry c. Status entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	CXR Result Format [http://radreport.org/template/0000102]
10	Action	Provider receives notification that the CXR results are available
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	Provider receives notification that a CXR ordered in their name has been 'resulted'. a. Provider pulls up results via hospital issued cellphone. b. Provider utilizes EHR to view chest film to compare against previous images (if available).
	Technology	EHR integration with PACS and Notification system a. Image visualization b. Data visualization
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	CXR Result Format [http://radreport.org/template/0000102]
11	Action	Registration clerk (Reg. Clerk) obtains Advance Directive and Authorization for Disclosure of Personal Health Information (PHI) from patient
	Cognitive Goal:	
	Actor(s)	Reg. Clerk Patient

Step	Component	Narrative
	Action Breakdown	Reg. Clerk provides tablet with Advance Directive and Authorization for Disclosure of PHI information of forms. a. Patient completes Advance Directive form b. Patient waives Authorization for Disclosure of PHI at this time.
	Technology	EHR (integration with hand held tablets)
	Standard	
	Appendix	Advance Directives Form [http://www.saintpetershcs.com/uploadedFiles/Advancedirective.pdf] Authorization for Disclosure of Protected Health Information [http://www.saintpetershcs.com/uploadedFiles/Policy%20768-7%20-%20Attachment%20-%20Authorization%20-%20For%20Release%20of%20Health%20Information%20REVISED%2003-25-10.pdf]
12	Action	ED RN receives notification that diagnostic results have been returned for this patient
	Cognitive Goal:	*Ensure results are not life threatening or will affect indicated treatment. Evaluate initial of cardiac enzymes for ischemic indications.*
	Actor(s)	ED RN
	Action Breakdown	ED RN receives alert that lab and CXR results have been returned. He/she accesses lab results in the EHR. Relevant lab values include: a. Troponin: 0.1 mcg/ml b. CK: 150 ng/ml c. CK-MB: 3 ng/ml d. K+: 4.1 e. Hgb: 15 g/dl f. Hct: 45% g. PT: 12 seconds h. PTT: 63 seconds i. Cholesterol, total: 180 j. HDL: 50 mg/dl k. LDL: 170 l. Triglycerides: 190 m. CXR: Normal. No mediastinal widening, valve disease, or CHF
	Technology	EHR (Visualization of lab and diagnostic reports)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]

Step	Component	Narrative
		b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	
13	Action	Provider assesses patient
	Cognitive Goal:	*Expedite History and Physical. Formulate differential diagnosis (i.e. Acute Coronary Syndrome vs. STEMI). Determine if patient is a candidate for emergency reperfusion.*
	Actor(s)	Provider Patient
	Action Breakdown	a. Confirms past medical history (PMH) and enters active conditions to the Problem List (Stable Angina, HTN, Dyslipidemia) b. Confirms allergies: NKDA c. Confirms current medications: a. Lovastatin 40 mg once daily – taken last night b. HCTZ 12.5 mg daily – taken this morning c. Lisinopril 10 mg daily – taken this morning d. Smoking history: No tobacco use e. Completes physical assessment a. Neuro: Alert and fully oriented b. CV: Chest pressure 5 out of 10 after 3 SL-NTG tablets, S1S2, No murmurs or gallop c. Resp: 20 and slightly shallow. Lungs clear d. GI: Abdomen soft, flat with bowel sounds in all quadrants. e. GU: Verbalizes no problems with voiding f. Skin: Slightly pale. Diaphoretic. Warm and intact. g. Psych: Calm and cooperative with wife present
	Technology	EHR a. Data entry to Problem List, Allergies and Current Medication b. Visualization of lab and diagnostic reports c. Data entry of assessment
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/] c. LOINC [http://search.loinc.org/search.zul?query=BMI]

Step	Component	Narrative
		d. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Adult Health History [http://georgetownmedical.com/util/documents/hx-physical-form.pdf] Head to Toe Physical Assessment Components [http://www.bing.com/images/search?q=physical+assessment +form&id=93FC06872326E1C4EFD077EA45F90F9AD366E450&FORM=IQFRBA#view=de
14	Action	Provider discusses clinical findings and treatment options with patient
	Cognitive Goal:	*Engage and educate patient. Assess patient understanding to facilitate informed decisions.*
	Actor(s)	Provider Patient
	Action Breakdown	a. New diagnosis confirmed by ECG: Anterior Wall Myocardial Infarction a. This diagnosis is added to the Problem List b. Since chest pain started 45 minutes ago, it is too early to see any elevation in cardiac enzymes (Troponin, CK-MB) c. Recommend emergent revascularization of coronary artery with cardiac catheterization and possible balloon inflation and/or stent placement based on clinical studies showing the best outcomes for this scenario. A referral to an Interventional Cardiologist can be placed immediately. a. Alternative treatment is intravenous thrombolytic therapy b. Pros and cons of each treatment discussed with patient c. Provider can access Clinical Care Guidelines, American Cardiology Recommendations, and Risk Evaluation Following a MI resources via hyperlink or Infobutton, as needed d. Continued chest pain after administration of 3 SL-NTG tablets and elevated blood pressure indicate need for intravenous nitroglycerin (IV NTG) e. Beta-blocker medication is indicated for ischemic heart disease
	Technology	EHR (Data entry to Problem List)
	Standard	
	Appendix	
15	Action	Patient conveys their Goal, in relation to their new diagnosis
	Cognitive Goal:	
	Actor(s)	Patient Provider
	Action Breakdown	Patient states that they, “Want to do whatever is necessary to maintain optimal heart function so that they can live a full life. That includes having a catheter placed in my heart.”
	Technology	EHR (Data entry of Patient Goal)

Step	Component	Narrative
	Standard	
	Appendix	
16	Action	Patient conveys their treatment preference and agrees to a plan of care
	Cognitive Goal:	
	Actor(s)	Provider Patient
	Action Breakdown	Care Plan Activities / Targeted Completion: a. Signs verbal order that ED RN entered to activate ED standing orders for patients presenting with chest pain / Immediately b. Emergency consultation with Interventional Cardiologist – *initiated by Provider*/ Within 1 hour c. Probable emergent cardiac catheterization (if confirmed by Interventional Cardiologist) a. Nothing to eat or drink in preparation for procedure / Immediately d. Start IV NTG to manage chest pain / Immediately e. Start Beta-blocker (Metoprolol) / Immediately
	Technology	EHR a. Data entry of Care Plan
	Standard	
	Appendix	
17	Action	Provider utilizes CPOE to enter orders for agreed upon care
	Cognitive Goal:	*Determine appropriate orders for this patient with continued chest pain and a potential pending PCI.*
	Actor(s)	Provider
	Action Breakdown	Provider enters the following orders: a. Interventional Cardiology Consult STAT a. Reason: Acute Anterior Wall MI. Evaluate for Percutaneous Coronary Intervention (PCI) b. NPO (Nothing by mouth) for possible cardiac catheterization with PCI c. IV NTG. Start at 10 mcg/min – increase by 10 mcg/min every 5 minutes until pain free or SBP < 100. Maximum dose 200 mcg/min. d. Metoprolol 5 mg IV x 3 doses, at 2 minute intervals if HR >50 and SBP > 100. e. Give Metoprolol 50 mg p.o. 15 minutes after last dose of IV Metroprolol
	Technology	EHR

Step	Component	Narrative
		a. CPOE
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
18	Action	Provider pages Interventional Cardiologist (IC)
	Cognitive Goal:	
	Actor(s)	Provider Int. Cardiologist
	Action Breakdown	Provider pages Interventional Cardiologist on call to notify of STAT consult for John Doe, PatientID 233433. Int. Cardiologist accepts consult and will come to the ED to evaluate the patient immediately.
	Technology	N/A
	Standard	
	Appendix	
19	Action	ED RN receives notification of new order for PatientID 233433.
	Cognitive Goal:	
	Actor(s)	ED RN
	Action Breakdown	ED RN receives notification that the provider has ordered IV NTG for the patient. a. Metoprolol 5 mg IV and IV NTG bag is obtained from the medication Pyxis. IV tubing obtained from the supply cart.
	Technology	EHR integration with Notification system
	Standard	
	Appendix	
20	Action	ED RN administers cardiac medications, as ordered
	Cognitive Goal:	*Evaluate chest pain and how BP has been affected by NTG. Safe administration of additional meds to reduce cardiac ischemia.*
	Actor(s)	ED RN Patient
	Action Breakdown	a. ED RN evaluates vital signs and chest pain b. BP: VS: BP 150/88, HR 90, RR 20, Pulse Ox: 98% on 2LNC c. Patient reports chest pain 4 out of 10, in chest only d. ED RN opens eMAR for the patient and views the IV NTG order e. Scans IV NTG bag and then patient's wristband f. Enters BP 150/88 when prompted to evaluate patient's BP. g. Enters 'I' for Infusing in eMAR and rate of 10 mcg/min

Step	Component	Narrative
		h. Primes IV tubing, sets IV pump to infuse 10 mcg/min, and starts infusion i. ED RN views Metoprolol 5 mg IV (x 3 doses) order in eMAR j. Scans Metoprolol 5 mg IV ampule (ED RN receives pop up notification to check heart rate prior to administration of Metoprolol. If HR < 50 the medication should be held) k. Scans patient's wristband l. Enters 'G' for Given in BCMA and HR 90 m. (Note: ED RN would go on to administer remaining IV and PO doses of Metoprolol as ordered, if well tolerated by patient)
	Technology	EHR a. Biomedical device integration to record VS and pulse oximetry b. Data entry of care performed c. Integration with BCMA System
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
21	Action	Interventional Cardiologist arrives in ED and enters PatientID in to EHR
	Cognitive Goal:	*Form differential diagnosis from information gathered. Identify additional questions or clarifications that need to be answered.*
	Actor(s)	Int. Cardiologist
	Action Breakdown	Interventional Cardiologist views PMH, current medication list, allergies, chief complaint, diagnosis, provider and nursing notes, and diagnostic results (including labs, ECG, and CXR)
	Technology	EHR a. Query b. Data visualization
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/] c. LOINC [http://search.loinc.org/search.zul?query=BMI] d. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
22	Action	Interventional Cardiologist enters patient room to evaluate for emergent catheterization

Step	Component	Narrative
	Cognitive Goal:	*Diagnose patient. Determine eligibility for reperfusion therapy. Assess patient understanding of the recommended intervention to obtain informed consent.*
	Actor(s)	Int. Cardiologist Patient
	Action Breakdown	Interventional Cardiologist: a. Assesses patient, reviews health history and new diagnosis of acute myocardial infarction. b. Evaluates for contraindications of reperfusion therapy c. Confirms recommendation of immediate cardiac catheterization with possible intervention d. Confirms that the patient has only had a small glass of water earlier that morning to take meds. Last solid food was the evening before. e. Explains the procedure, along with risks and benefits.
	Technology	
	Standard	
	Appendix	
23	Action	Patient provides consent for procedure recommended by the Int. Cardiologist
	Cognitive Goal:	
	Actor(s)	Patient Int. Cardiologist
	Action Breakdown	Patient signs informed consent for Percutaneous Angiogram, Diagnostic Cardiac Catheterization, and possible Percutaneous Coronary Intervention with possible balloon angioplasty and possible stent placement.
	Technology	
	Standard	
	Appendix	
24	Action	Interventional Cardiologist enters pre-catheterization orders
	Cognitive Goal:	*Determine indicated pre-cath orders for this patient.*
	Actor(s)	Int. Cardiologist
	Action Breakdown	Examples of entered orders: a. Admit to Cardiac Outpatient Surgery b. Diagnosis: Acute Anterior Wall Myocardial Infarction c. Code status: Full d. Ensure consent for procedure is on chart e. Prep bilateral femoral sites

Step	Component	Narrative
		f. Start new IV line in left arm a. Infuse 0.9% Sodium Chloride at 100 cc/hr g. Pre-op medications: a. Diphenhydramine 50 mg IV ON CALL b. Valium 5 mg PO ON CALL
	Technology	EHR a. CPOE
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Refer to: Pre-Cardiac Catheterization Orders [http://apps.umchealthsystem.com/forphysicians/medicalorders/Pre-Op%20Cardiac%20Cath.pdf]
25	Action	ED RN provides transition of care report to the Cath Lab RN that will be caring for the patient
	Cognitive Goal:	
	Actor(s)	ED RN Cath Lab RN
	Action Breakdown	Report is completed verbally, over the phone. Cath Lab RN enters PatientID in computer, views all documentation entered in ED, along with Pre-Catheterization orders.
	Technology	EHR a. Query b. Data visualization
26	Action	Patient is transferred to ‘Holding’ area of Cath Lab via stretcher
	Cognitive Goal:	
	Actor(s)	ED RN Patient Cath Lab RN
	Action Breakdown	Cath Lab RN assumes care of the patient and will complete Pre-Catheterization orders while procedure room is being prepped.

1.9. Data fields required

See appendix references as examples/guides

Example 1. Chrushing chest pain

Eternal ID Chief Complaint: Crushing chest pain (8 out of 10), unrelieved by rest and 1 sub-lingual nitroglycerin (SL-NTG) tablet.

1.10. Notes and Issues

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2. Patient with STEMI, S/P stent placement is admitted to Telemetry Unit

Angina 2

2.1. Introduction

1. This use case was created to evaluate the ontology created by the VistA Evolution GUI Research project. It includes common assessments, observations, interventions, and cognitive goals that arise while caring for a patient in this scenario to ensure that the ontology can accommodate these concepts.

2. All clinical data in this use case is synthetic. Data was created to support the flow of this use case and provide examples of clinical observations that are documented throughout the interaction.

3. Clinical decision making in this use case is based, primarily, on VA/DoD Clinical Practice Guidelines for the Management of Ischemic Heart Disease, available at: http://www.healthquality.va.gov/guidelines/CD/ihd/

4. Additional clinical resources are listed below in the Reference section.

5. This use case demonstrates actions that commonly occur over the course of a patient's post-revascularization stay in a Telemetry unit. It is not intended to include every action over the course of their stay. In similar scenarios, the sequence of events/actions may be slightly different.

6. Cognitive goals are included in some 'Actions' to provide insight on the Provider or healthcare professional's mental process at that point of the encounter.

7. Hyperlinks present in the Appendix column are included to provide examples of the data fields and values that may be entered by the EHR user during this step of the use case.

8. Hyperlinks present in the Standards column suggest standardized terminologies that may be used to capture data in this step of the use case.

2.2. Actors

Patient: a person receiving or registered to receive medical treatment

Interventional Cardiologist: A board-certified cardiologist that is credentialed to perform percutaneous coronary interventions via cardiac catheterization.

Provider: Physician, physician assistant (PA), or nurse practitioner (NP). All are skilled health-care professionals trained and licensed to diagnose and treat patients within their defined scope of practice.

Unit Clerk (UC): a hospital employee that performs administrative duties to facilitate workflow and patient care in the emergency department (ED) or a nursing unit.

Registered Nurse (RN): a licensed healthcare professional that is trained to provide nursing care to patients in inpatient and outpatient settings, within their defined scope of practice.

Licensed Social Worker (LSW): a licensed healthcare professional that assists patients to improve their quality of life and social needs, and facilitates care after discharge.

Nurse's Aide/Assistant (NA): a trained healthcare worker that provides assistance with patient care, under the supervision of an RN.

Sonographer – a skilled technologist that is trained to operate special imaging equipment utilized in diagnostic tests (i.e. ultrasound machine for echocardiograms)

Patient Transporter – a hospital employee that assists with the transfer of patients to and from procedures, and throughout the hospital as requested

Clinical Pharmacist – a licensed healthcare professional that often collaborates with physicians and other healthcare professionals to coordinate pharmaceutical interventions and promote health and disease prevention within their scope of practice.

Dispensing Pharmacist – a licensed healthcare professional that dispenses medications, monitors medication parameters and potential drug interactions, and provides information about medications, within their scope of practice.

EKG Technician (EKG Tech) – a cardiology technologist that administers basic electrocardiogram tests to patients. The results are then read by a cardiologist or other licensed physician.

Charge RN – a registered nurse that is responsible for the efficient management of a nursing unit or department, including admissions, discharges, and the oversight of all nursing and support staff

2.3. Description

A 53 year old white male status post stent placement via cardiac catheterization for Acute Myocardial Infarction (AMI) is admitted to a Telemetry unit for monitoring

2.4. Trigger

Patient has been cleared to leave the post-interventional cardiology recovery room (ICRR) and be admitted to the facility's Telemetry Unit for monitoring.

2.5. Preconditions

1. Patient presented to the ED with unstable angina, was diagnosed with an Anterior Wall Myocardial Infarction, and underwent percutaneous coronary intervention (PCI) and stent placement within 60 minutes of presentation and 85 min of chest pain onset

2. PCI was successful and the blocked artery is fully patent after the procedure

3. Patient is pain-free after the procedure and there is no further evidence of active MI on post-catheterization ECG

4. Patient received post-catheterization care in the post-interventional cardiology recovery room (ICRR), is over the acute recovery of the procedure, and has been cleared for transfer to the Telemetry Unit by the Interventional Cardiologist.

5. Right femoral site was used for catheterization access

    a. Sheath was pulled in the Cath Lab and femoral site is benign

2.6. Postconditions

Minimal guarantees:

1. Data fields required to support this clinical workflow will be present in the EHR.

2. Data entered will be stored utilizing the appropriate clinical vocabulary.

Success guarantees:

1. EHR supports patient-centered care, guided by goals set by the patient.

    b. Patient receives evidence-based care based on the health concerns that are noted during the outpatient visit.

    c. Patient will achieve improved outcomes and satisfaction as a result of care facilitated by EHR functionality.

2.7. Assumptions

1. EHR is able to send notifications to healthcare providers when a task has been added to their work list (i.e. Radiology Technician receives notification when an X-ray has been added to his/her work queue).

    b. EHR is integrated with Picture Archiving Communication System (PACS).

    c. EHR is integrated with information systems in the following departments: Pharmacy, Laboratory, Radiology, Cardiology, Dietary, Rehabilitation

    d. EHR has computerized physician order entry (CPOE) functionality

    e. Orders entered via CPOE are automatically implemented and assigned to the appropriate work queue (i.e. CBC in a.m. is automatically assigned to the Laboratory work queue)

    f. Medications ordered via CPOE system automatically populate the electronic Medication Administration Record (eMAR).

    g. EHR system allows the Provider to select existing active medication to pre-populate discharge medication orders. Provider can then de-select any carried over medication, if desired.

    h. Orders for discharge medications entered via CPOE are sent directly to the outpatient pharmacy that is designated by the patient.

    i. Facility uses Bar Code Medication Administration (BCMA) system to document administration of medication to all ED and inpatients.

    j. BCMA system is integrated with the EHR.

    k. EHR A/D/T system allows user to tentatively hold a bed, pending formal orders from Provider (e.g. ICU or Telemetry bed post-PCI while patient is recovering from the procedure)

    l. EHR can manage the transition of tasks (e.g., move tasks from one work queue to another)

    m. PatientID is a unique ID assigned to a specific patient for each unique hospital stay

n. Standard vocabularies utilized by the organization include: ICD10 for Diagnosis, RxNorm for medications, SNOMED-CT for clinical assessments, care that is provided and lab results, and LOINC for laboratory tests.

2.8. Normal Flow

Step	Component	Narrative
1	Action	Interventional Cardiologist admits patient to Telemetry Unit for monitoring
	Cognitive Goal:	*Determine indicated care and orders for this unique patient post-PCI.*
	Actor(s)	Int. Cardiologist
	Action Breakdown	Utilizes Standard Cardiology Admission Order Set via CPOE and adds additional orders, as needed. For example: a. Admit to Telemetry Unit b. Dx: Anterior Wall Myocardial Infarction. S/P PCI and stent placement c. Allergies: NKDA d. History of Tobacco use: No e. Condition: Stable f. Code Status: Full code g. VS: Per unit protocol h. Diet: Low fat, Low cholesterol, Low salt i. Heparin Lock IV. j. Activity: BR x 4 hours, then advance as tolerated k. Labs: CPK, CK-MB, Troponin q 6 hrs x 3 l. CBC/diff, BMP, PT/PTT in a.m. m. EKG and Echocardiogram in a.m. n. Cardiac education o. Medications: a. HCTZ 12.5 mg po daily – start in a.m. b. Lisinopril 10 mg po daily – start in a.m. c. Metoprolol 100 mg po twice daily – start this p.m. d. ASA 325 mg po daily – start in a.m. e. Lovastatin 40 mg once daily – start this p.m. f. Clopidogrel 75 mg po daily – start in a.m.

Step	Component	Narrative
		g. Flush Heparin Lock with 1 cc 0.9% Normal Saline solution every 8 hours.
	Technology	EHR a. CPOE
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	Refer to Cardiac Admission Orders [http://www.rwjf.org/content/dam/farm/toolkits/toolkits/2008/rwjf27120]
2	Action	Interventional Cardiology Recovery Room (ICRR) Unit Clerk enters formal bed request in Admission/Discharge /Transfer (ADT) System
	Cognitive Goal:	*Implement physician order for appropriate bed assignment (based on severity of illness driving the intensity of service).*
	Actor(s)	ICRR Unit Clerk
	Action Breakdown	ICRR Unit Clerk views available Telemetry beds and selects appropriate bed for patient, as ordered by physician
	Technology	EHR a. Integration with ADT system
	Standard	
	Appendix	
3	Action	Telemetry Charge RN receives notification that a new patient is being admitted to the Telemetry unit
	Cognitive Goal:	*Evaluate and determine patient acuity so proper nursing assignment is made.*
	Actor(s)	Telemetry Charge RN Telemetry RN
	Action Breakdown	Telemetry Unit Charge RN receives notification that an admission has been given a bed assignment on his/her unit. a. Charge RN queries EHR to view ED information, Catheterization Report, ICRR Nursing Notes, and admission orders to assess acuity of patient b. Charge RN assigns an RN to care for the patient, based on current workload and patient acuity and provides the PatientID so that the Telemetry RN can view relevant information in the patient's record. c. Charge RN 'approves' admission and flags the bed as 'available to accept transfer'
	Technology	EHR

Step	Component	Narrative
		a. Query by PatientID b. Bed assignment within EHR c. Data visualization d. Integration with ADT system
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	
4	Action	ICRR RN calls Telemetry RN assigned to care for 'John Doe' and provides verbal report, then transfers patient to Telemetry bed
	Cognitive Goal:	*Formulate and ask appropriate questions during report to gather information required to properly care for patient*
	Actor(s)	ICRR RN Telemetry RN
	Action Breakdown	ICRR RN provides transition of care report. a. Telemetry RN acknowledges patient admission on EHR bed tracker, validates patient with PatientID, and assigns him/herself as the primary care nurse a. Views Catheterization Report, ICRR Nursing notes, and Telemetry Admission Orders in patient record b. ICRR RN transfers patient to Telemetry Unit after report is completed
	Technology	EHR a. Manage patient assignment through EHR bed tracker b. Query by PatientID c. Data visualization
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	Refer to Critical Care Nursing Assessment and Flow Sheet [http://www.cantonmercy.org/uploads/File/pdf/6334_24Hr_Critical_Care.pdf]
5	Action	Telemetry RN assumes care of patient

Step	Component	Narrative
	Cognitive Goal:	*Evaluate baseline assessment. Determine areas of concern and/or observations requiring additional interventions.*
	Actor(s)	Telemetry RN
	Action Breakdown	Telemetry RN: a. Attaches telemetry box to patient and ensures monitoring is effective a. Notes cardiac rhythm: Sinus rhythm without ectopy, HR 84 b. Checks vital signs a. BP 124/78, HR 84, RR 18, Pulse Oximetry on room air: 98% c. Checks right femoral catheterization site and pedal pulses: a. Femoral site clean and dry with band-aid b. Bilateral femoral, popliteal, dorsalis pedis, posterior tibialis pulses +2, feet warm with good color d. Performs head to toe assessment. Results documented on Telemetry Nursing Flow Sheet
	Technology	EHR a. Integration with biomedical devices b. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	Refer to: Telemetry Nursing Flow Sheet [http://www.cantonmercy.org/uploads/File/pdf/6395_Step_Down_Telemetry.pdf]
6	Action	Cardiac Nurse Practitioner assumes care of patient. Documents formal History of Present Illness (HPI) and performs assessment
	Cognitive Goal:	*Perform assessment. Validate existing orders and ensure no additional orders are indicated. Determine relevant information to be included in HPI.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider: a. Queries EHR on PatientID and reviews all documentation and diagnostic results from ED and Cath Lab b. Interviews patient about Chief Complaint, PMH, etc. c. Performs head to toe assessment. d. Creates HPI documentation

Step	Component	Narrative
		e. Enters SOAP note f. Ensures Cardiac Admission Orders address all indicated care (no additional orders are indicated)
	Technology	EHR a. Data visualization b. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	Refer to: History of Present Illness Documentation [http://r.search.yahoo.com/_ylt=A0LEViP7.KtUJ74AbQAPxQt.;_ylu=X3oDMTByNW1iMWN2BHNlYwNzcgRwb3MDMRV=2/RE=1420585339/RO=10/RU=http%3a%2f%2fwww2.sunysuffolk.edu%2fmccabes%2fH%26P%2520guide%2520for%2520pdarev.doc/RK=0/RS=Z7BjPbb7uLomK15w4NcJV6eKkBc-] Head to Toe Physical Assessment Components [http://www.bing.com/images/search?q=physical+assessment+form&id=93FC06872326E1C4EFD077EA45F90F9AD366E450&FORM=IQFRBA#view=de SOAP Note Explanation and Example [http://nurseone.ca/~/media/nurseone/page-content/pdf-en/soap_documentation_e.pdf]
7	Action	Cardiac Nurse Practitioner discusses patient's condition and the indicated plan of care for the coming days
	Cognitive Goal:	*Determine recommended plan of care. Engage and educate patient. Assess patient understanding to facilitate informed decision making.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider discusses the following with the patient: a. Admitting diagnosis: Anterior Wall Myocardial Infarction b. Procedure performed: PCI with stent placement and resultant clear blood flow in the left anterior descending coronary artery (LAD) c. Indicated care post myocardial infarction a. Aspirin and Clopidigrel for blood thinning b. Beta-blocker and ACE inhibitor to support cardiac function c. Lipid lowering medication due to PMH and cardiac risk

Step	Component	Narrative
		d. Echocardiogram to evaluate Left Ventricular Function e. Serial cardiac enzymes to monitor cardiac markers f. ECG in a.m. to evaluate current cardiac rhythm g. Advance activity as tolerated, cardiac rehabilitation after discharge h. Follow low fat, low cholesterol, low sodium diet i. Cardiac education
	Technology	
	Standard	
	Appendix	Refer to: VA/DoD Clinical Practice Guidelines for Management of Ischemic Heart Disease [http://www.healthquality.va.gov/guidelines/CD/ihd/ihd_poc_combined.pdf]
8	Action	Patient verbalizes care preferences and goals
	Cognitive Goal:	
	Actor(s)	Patient Provider
	Action Breakdown	Patient verbalizes that they are “grateful for the excellent care that has been provided and are willing to do anything and everything that is recommended to make a full recovery and reduce future risks.”
	Technology	
	Standard	
	Appendix	
9	Action	Together, the Nurse Practitioner and Patient agree upon a plan of care after discussion of recommended plan of care.
	Cognitive Goal:	
	Actor(s)	Provider Patient
	Action Breakdown	Care Plan Activities/Targeted Initation: a. Anti-platelet medications, as ordered/ In morning b. Cardiac medications, as ordered/ In morning c. Lipid lowering medication, as ordered/ This evening d. Serial cardiac enzymes/ Immediately e. ECG and Echocardiogram/ In morning f. Activity as tolerated/ Immediately

Step	Component	Narrative
		g. Cardiac diet/ Immediately h. Cardiac education/ Immediately, reinforce prior to discharge
	Technology	EHR a. Data entry of Care Plan
	Standard	
	Appendix	
10	Action	Dispensing Pharmacist receives notification of new medication orders and dispenses ordered medications
	Cognitive Goal:	*Ensure patient safety by evaluating for drug-drug interactions and allergy concerns.*
	Actor(s)	Disp. Pharmacist
	Action Breakdown	Dispensing Pharmacist: a. Receives notification that new medication orders have been placed and added to their work queue b. Pharmacist clicks on the notification link and views medication orders, admitting diagnosis, and allergies c. Ensures that there are no drug-drug interactions or medications ordered that conflict with patient allergies (*this is done via decision support of the pharmacy system)* d. 'Dispenses' medication via Pyxis system for nursing access and administration
	Technology	EHR a. Pharmacy Information System Suite b. Visualization of data c. Visualization of eMAR
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] c. ICD10 [http://www.icd10data.com/]
	Appendix	
11	Action	Telemetry RN performs q 4 hour assessment and enters SOAP note at the end of his/her shift
	Cognitive Goal:	*Evaluate patient condition for procedure complications, clinical improvement, and observations that indicate a change in the plan of care.*
	Actor(s)	Telemetry RN Patient
	Action Breakdown	Telemetry RN:

Step	Component	Narrative
		a. Evaluates and records cardiac rhythm a. Sinus rhythm without ectopy, HR 78 b. Checks and records vital signs a. BP 120/74, HR 78, RR 18, Pulse Oximetry on room air: 99% c. Checks right femoral catheterization site and pedal pulses: a. Femoral site clean and dry with band-aid b. Bilateral femoral, popliteal, dorsalis pedis, posterior tibialis pulses +3, feet warm with good color d. Performs head to toe assessment. Results documented on Telemetry Nursing Flow Sheet e. Documents input and output f. Administers Lovastatin 40 mg p.o. by using BCMA system g. Enters SOAP note at end of shift
	Technology	EHR a. Integration with biomedical devices b. Data entry c. eMAR
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Refer to: Telemetry Nursing Flow Sheet [http://www.cantonmercy.org/uploads/File/pdf/6395_Step_Down_Telemetry.pdf] SOAP Note Explanation and Example [http://nurseone.ca/~/media/nurseone/page-content/pdf-en/soap_documentation_e.pdf]
12	Action	**Fast forward to the next morning.** Sonographer reviews work queue for the day and completes ordered diagnostic tests.
	Cognitive Goal:	*Prioritize and manage work queue. Ensure the proper diagnostic test is performed on the proper patient.*
	Actor(s)	Sonographer
	Action Breakdown	Sonographer checks work queue in EHR and finds that an Echocardiogram is ordered for inpatient “John Doe” PatientID: 323343. a. Sonographer uses work queue (validating patient via PatientID) and reviews diagnostic order and patient history

Step	Component	Narrative
		b. Sonographer adds task to Patient Transport work queue to bring patient "John Doe" to Ultrasound via wheelchair.
	Technology	EHR a. Query by PatientID b. Data visualization c. Integration with Patient Transport System
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
13	Action	Patient Transporter receives notification of patient transfer and completes the request
	Cognitive Goal:	
	Actor(s)	Patient Transporter Patient
	Action Breakdown	Patient Transporter receives notification of transfer task added to their work queue. a. Transporter opens notification, completes the transfer as requested, and flags the transfer as complete
	Technology	EHR a. Integration with Patient Transport System
	Standard	
	Appendix	
14	Action	Sonographer completes echocardiogram for patient "John Doe"
	Cognitive Goal:	*Prioritize and manage work queue. Ensure the proper diagnostic test is performed on the proper patient.*
	Actor(s)	Sonographer
	Action Breakdown	Sonographer checks work queue in EHR and finds that an Echocardiogram is ordered for inpatient "John Doe" PatientID: 323343. a. Sonographer uses work queue (validating patient via PatientID) and reviews diagnostic order and patient history b. Sonographer adds task to Patient Transport work queue to bring patient "John Doe" to Ultrasound via wheelchair.
	Technology	EHR a. Query by PatientID b. Data visualization

Step	Component	Narrative
		c. Integration with Patient Transport System
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
15	Action	Cardiologist receives notification of inpatient diagnostic test added to his/her work queue for interpretation
	Cognitive Goal:	*Accurate evaluation of Echocardiogram (taking reason for exam and patient history, if needed, in to consideration)*
	Actor(s)	Cardiologist
	Action Breakdown	Cardiologist clicks on link in work queue notification to open inpatient echocardiogram reading for "John Doe" a. Cardiologist evaluates the reading and enters the interpreted result in the EHR. Result: Normal echocardiogram. No cardiomegaly or effusion. Good valve function. Ejection Fraction: 58%
	Technology	EHR a. PACs system b. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	
16	Action	Echocardiogram (ECG) Technician views work queue and completes ECGs as ordered
	Cognitive Goal:	*Task completion. Flag result for interpretation by Cardiologist.*
	Actor(s)	ECG Tech
	Action Breakdown	ECG Technician completes ECG, downloads reading, and flags the test as "ready for interpretation" by Cardiologist
	Technology	
	Standard	
	Appendix	
17	Action	Cardiologist receives notification of diagnostic test added to his/her work queue for interpretation
	Cognitive Goal:	*Accurate evaluation of ECG (taking reason for exam and patient history, if necessary, in to consideration)*
	Actor(s)	Cardiologist
	Action Breakdown	Cardiologist clicks on link in work queue notification to open ECG reading for patient "John Doe" a. Reviews ECG reading and enters the interpreted result in the EHR. Result: SR 76. No ectopy. No hypertrophy.

Step	Component	Narrative
	Technology	EHR a. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	
18	Action	Cardiac Nurse Practitioner receives notification that diagnostic results are available for her patient, “John Doe”
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	Provider opens link in notification and views ECG and Echocardiogram results.
	Technology	EHR a. Data visualization
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	
19	Action	**Fast forward to the next morning.** Healthcare team discusses patient condition and plan of care during interdisciplinary patient rounds.
	Cognitive Goal:	*Evaluation of patient condition and indicated care after discharge. Informed, collaborative decision-making related to the care indicated for this unique patient. This includes patient education and engagement.*
	Actor(s)	Provider Telemetry RN Charge RN Social Worker/ Case Manager Clinical Pharmacist Patient
	Action Breakdown	Healthcare team a. Reviews HPI, PMH, course of treatment, and care plan b. Reviews most recent physical assessment c. Utilizes Infobutton, Clinical Care Guidelines and other resources to evaluate indicated discharge care options d. Formulates a recommended discharge plan that they will discuss with the patient.

Step	Component	Narrative
		Healthcare team enters patient's room to evaluate condition a. Determines that the patient's condition warrants discharge that afternoon a. Discuss discharge plans and instructions with the patient b. Clinical Pharmacist (and Provider) review medications indicated for discharge (including drug safety, side effects, dosage titration and interactions), and confirm that the patient should remain on the following medications as ordered (HCTZ, Lisinopril, Metoprolol, ASA, Lovastatin, and Clopidogrel) c. Discuss need for psychosocial support at home. Patient and healthcare team agree that no additional support is needed d. Ensure that patient receives all indicated education related to heart disease, heart attack recovery, and post-catheterization recovery e. Discuss the importance of exercise and cardiac rehabilitation f. Discuss patient-specific risks a. Counsel patient on their increased long term mortality risk and the importance of compliance to care regimen g. Follow up with Cardiologist on a regular basis
	Technology	EHR a. Data visualization of Problem List, Care Plan, eMAR, Patient Goals
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	
20	Action	Patient verbalizes goal related health condition and discharge
	Cognitive Goal:	
	Actor(s)	Patient Provider Healthcare Team
	Action Breakdown	Patient verbalizes that they are eager to change their lifestyle, make healthier food choices, get in better shape to manage their heart health, and do whatever else is recommended.
	Technology	EHR a. Data entry as Patient Goal
	Standard	

Step	Component	Narrative
	Appendix	
21	Action	Patient agrees to the discharge plan that was presented by their healthcare team
	Cognitive Goal:	*Evaluate patient understanding of their discharge plan of care and responsibilities, along with their commitment to execute the plan.*
	Actor(s)	Patient Provider Healthcare Team
	Action Breakdown	Care Plan Activities / Targeted Initiation a. Continue HCTZ, Lisinopril, Metoprolol, ASA, Lovastatin, and Clopidogrel as ordered, after discharge / Immediately b. Follow up with Cardiologist in 3 days / Make appt. immediately c. Cardiac education (encourage patient to view 'Optimizing your Heart Health' program on Channel 2 of inpatient TV system shown daily at 10 a.m. and 2 p.m., nurse will review/discuss cardiac education packet with patient, provide information about 'Living with Heart Disease' free classes offered by the hospital system) / Immediately d. Begin light exercise (walking on a level surface for 5 minutes, 3 times a day). Add 1 minute to each session, each day until able to complete 10-15 minutes in each session without cardiac symptoms. / Tomorrow e. Cardiac rehabilitation / Schedule evaluation for 2 weeks after discharge
	Technology	EHR a. Data entry in Care Plan
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Refer to: Exercise and Activity after a Heart Attack [http://www.uwhealth.org/healthfacts/cardiology/6090.html]
22	Action	Provider enters discharge orders in EHR
	Cognitive Goal:	*Determine if any additional considerations need to be addressed for patient discharge*
	Actor(s)	Provider
	Action Breakdown	Provider utilizes CPOE to enter the following orders a. Discharge to home today b. Follow up with Cardiologist in 3 days c. Discharge medication: a. HCTZ 12.5 mg po daily – start in a.m.

Step	Component	Narrative
		b. Lisinopril 10 mg po daily – start in a.m. c. Metoprolol 100 mg po twice daily – start this p.m. d. ***ASA 325 mg po daily – start in a.m. e. ***Lovastatin 40 mg once daily – start this p.m. f. ***Clopidogrel 75 mg po daily – start in a.m. d. Cardiac education a. Nurse to review cardiac education packet with patient b. Encourage patient to view 'Optimizing your Heart Health' on inpatient TV channel 2 c. Provide information about 'Living with Heart Disease' free classes e. Begin light exercise, as tolerated and discussed by healthcare team f. Cardiac rehabilitation a. Schedule evaluation for 2 weeks after discharge g. Provide post Heart Attack and post Cardiac Catheterization discharge instructions
	Technology	EHR a. CPOE
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
23	Action	Telemetry RN receives notification of new orders in his/her work queue
	Cognitive Goal:	*Determine level of patient understanding of their condition, plan of care, lifestyle changes, and follow up care after discharge.*
	Actor(s)	Telemetry RN
	Action Breakdown	Telemetry RN reviews and implements the above orders as displayed in his/her work queue. a. After cardiac education is completed, the RN reviews discharge instructions and ensures patient understands all instructions and the plan of care b. Provides the patient with copies of all discharge instructions c. Teaches the patient how to utilize the Patient Portal to view his/her medical record after discharge d. Completes final SOAP note that encompasses all patient education and discharge teaching that has been reviewed

Step	Component	Narrative
	Technology	EHR a. Data visualization b. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Refer to: Discharge Instructions post Heart Attack [http://www.ebscohost.com/images-nursing/assets/PERC%20-%20Discharge%20Instructions%20Handout.pdf] Discharge Education and Instructions post Heart Attack (NLM) [http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000090.htm] Discharge Instructions post Cardiac Catheterization [http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000091.htm]
24	Action	Discharge protocol completion
	Cognitive Goal:	*What are the relevant facts to communicate about this patient's encounter in the Discharge Summary?*
	Actor(s)	Respective clinician
	Action Breakdown	After reviewing discharge instructions with the patient (with return demonstration, if appropriate): a. The discharge provider's medication orders are sent via e-RX to the outpatient pharmacy in the lobby. b. The discharge provider's referrals are automatically sent to the referring provider (if applicable) c. The discharge summary is automatically sent to the primary care provider's office—patient care coordinator
	Technology	CPOE interoperability with external Pharmacy Suite System
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Refer to: Hospital Discharge Summary [http://clerkship.medicine.ufl.edu/portfolio/interpersonal-and-communicative-skills/discharge-summarytransfer-noteoff-service-note-instructions/]
25	Action	Patient is discharged to home from hospital
	Cognitive Goal:	
	Actor(s)	Telemetry RN Patient
	Action Breakdown	Telemetry RN discharges patient to home via wheelchair.
	Technology	

Step	Component	Narrative
	Standard	
	Appendix	

2.9. Data fields required

See appendix references as examples/guides.

2.10. Notes and Issues

1. Entries that include *** indicate compliance with a Meaningful Use clinical quality measure
   a. CMS 100 – Aspirin Prescribed at Discharge
   b. CMS 30 – Statin Prescribed at Discharge

2.11. References for Clinical Management of Ischemic Heart Disease

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3. Congestive Heart Failure: Previously Diagnosed, Acute Exacerbation - Emergency Care

CHF

3.1. Introduction

15. This use case was created to evaluate the ontology created by the VistA Evolution GUI Research project. It includes common assessments, observations, interventions, and cognitive goals that arise while caring for a patient in this scenario to ensure that the ontology can accommodate these concepts.

16. All clinical data in this use case is synthetic. Data was created to support the flow of this use case and provide examples of clinical observations that are documented throughout the interaction.

17. Clinical decision making in this use case is based, primarily, on VA/DoD Clinical Practice Guidelines for the Management of Chronic Heart Failure, available at: http://www.healthquality.va.gov/guidelines/cd/chf/index.asp

18. Additional clinical resources are listed below in the Reference section.

19. The intent of this use case is to capture actions that may occur when a patient presents to the hospital with a CHF acute exacerbation. Many of the steps in this use case occur concurrently in an emergent case. In similar scenarios, the same actions may occur in slightly different order.

20. Cognitive goals are included in some 'Actions' to provide insight on the Provider or healthcare professional's mental process at that point of the encounter.

21. Hyperlinks present in the Appendix column are included to provide examples of the data fields and values that may be entered by the EHR user during this step of the use case.

22. Hyperlinks present in the Standards column suggest standardized terminologies that may be used to capture data in this step of the use case.

3.2. Actors

Patient: a person receiving or registered to receive medical treatment

Provider: Physician, physician assistant (PA), or nurse practitioner (NP). All are skilled health-care professionals trained and licensed to diagnose and treat patients within their defined scope of practice.

Registration Clerk (Reg. Clerk): a hospital employee that collects demographic, insurance and "reason for visit" information from a new patient and enters this information in to the Admission/Discharge/Transfer (ADT) system and/or the electronic health record (EHR).

Triage Nurse (Triage RN): A licensed nurse that assesses symptoms, health-related complaints, and vital signs to determine the degree of urgency for care.

Unit Clerk (UC): a hospital employee that performs administrative duties to facilitate workflow and patient care in the emergency department (ED) or a nursing unit.

Emergency Department Technician (ED Tech): a hospital employee that is trained to provide basic tasks such as vital signs and laboratory draws under the supervision of an RN or Provider.

Registered Nurse (RN): a licensed healthcare professional that is trained to provide nursing care to patients in inpatient and outpatient settings, within their defined scope of practice.

Licensed Social Worker (LSW): a licensed healthcare professional that assists patients to improve their quality of life and social needs, and facilitates care after discharge.

Nurse's Aide/Assistant (NA): a trained healthcare worker that provides assistance with patient care, under the supervision of an RN.

Clinical Pharmacist – a licensed healthcare professional that often collaborates with physicians and other healthcare professionals to coordinate pharmaceutical interventions and promote health and disease prevention within their scope of practice.

Dispensing Pharmacist – a licensed healthcare professional that dispenses medications, monitors medication parameters and potential drug interactions, and provides information about medications, within their scope of practice.

Radiology Technician (Rad Tech) – a licensed radiography professional that performs diagnostic imaging exams on patients to help physicians assess illness and injury.

Radiologist - a licensed physician that specializes in diagnosing and treating diseases and injuries by using medical imaging.

EKG Technician (EKG Tech) – a cardiology technologist that administers basic electrocardiogram tests to patients. The results are then read by a cardiologist or other licensed physician.

Respiratory Therapist (RT) – a licensed healthcare practitioner that provides care and treatment to patients requiring breathing and oxygenation support.

Charge RN – a registered nurse that is responsible for the efficient management of a nursing unit or department, including admissions, discharges, and the oversight of all nursing and support staff.

Medical Sonographer (Ultrasound Technician) – trained healthcare professionals that operate special imaging equipment to create/capture images helping providers assess and diagnose medical conditions.

House Supervisor – registered nurse who coordinates bed management and staff mix in the hospital to assure that effective nursing services are provided, and quality standards are met.

Hospitalist – A physician whose primary focus is the general medical care of hospitalized patients.

3.3. Description

A 72-year-old white female presents to the emergency department (ED), with her adult daughter, in moderate respiratory distress (using accessory muscles) with the ability to say three to four words in between respirations. The patient indicates the problem has progressively gotten worse within the past 24 hours. The patient complains of a persistent cough (especially at night). Note that patient reports that she has not taken any of her medications for her “sugar and heart” in about one week (because she ran out and could not get her medications refilled). Patient appears pale, sweaty, and dusky nailbeds noticed. Through the daughter and with acknowledgement from the patient, the triage nurse identifies the patient. Respiratory distress is potentially life threatening (Emergency Severity Index Triage Tool for EDs); therefore, the medical team urgently treats the patient.

3.4. Trigger

1. Patient’s adult daughter brings the patient to the ED.
2. Patient is in respiratory distress (use of accessory muscles).

3.5. Preconditions

1. Obesity (adult onset)
2. Diabetes Type 2 (15 years ago)
3. Hypertension (15 years ago)
4. Heart failure (1 year ago)
5. Myocardial Infarction ((MI) 2 years ago)
6. Dsylipidemia (2 years ago)

Note: The health system’s electronic health record (EHR) shows that the patient has been seen at the hospital previously. And, most recently treated (slightly over three months ago) for an acute heart failure episode with a hospital stay of two days. The patient’s past medical history and medications are present in the EHR.

3.6. Postconditions

Minimal guarantees:

1. Data fields required to support this clinical workflow will be present in the EHR.
2. Data entered will be stored utilizing the appropriate clinical vocabulary.

Success guarantees:

1. EHR supports patient-centered care, guided by goals set by the patient.
2. Patient receives evidence-based care based on the health concerns that are noted during the outpatient visit.
3. Patient will achieve improved outcomes and satisfaction as a result of care facilitated by EHR functionality.

3.7. Assumptions

1. Emergency Department (ED) is capable of providing assessment and initial treatment of life-threatening conditions.

2. ED utilizes a trained healthcare professional to triage (prioritize the care of patients based on clinical need) patients presenting to the ER.

3. ED utilizes the following triage levels:

    a. Resuscitation – immediate threat to life (i.e. cardiac or respiratory arrest, major trauma, shock, etc.)

    b. Emergent – potential threat to life (i.e. chest pain with cardiac suspicion, severe respiratory distress, decreased level of consciousness (LOC), etc.)

    c. Urgent – condition with significant distress (i.e. mild to moderate respiratory distress, head injury without decrease in LOC but with vomiting, etc.)

    d. Less urgent – conditions with mild to moderate discomfort (i.e. head injury –alert without vomiting, depression without suicidal attempt)

    e. Non-urgent – conditions are minor and treatment can be delayed (i.e. skin lacerations, sore throat, etc.)

4. All RNs, PAs, NPs, and physicians are certified in Advance Cardiac Life Support (ACLS).

5. Hospital is a Level 1 trauma center that is equipped to handle patients who present with any and all levels of medical severity.

6. Hospital has a full service Cardiac Catheterization Laboratory that has an Accreditation for Cardiovascular Excellence (ACE) and is credentialed to provide percutaneous cardiac interventions (PCI), including the placement of cardiac stents.

7. Hospital has an Interventional Cardiologist on call, who is present in the hospital and available to do an emergent PCI.

8. The Cardiac Catheterization unit has a room and staff available to support an emergent PCI case.

9. EHR is able to send notifications to healthcare providers when a task has been added to their work list (i.e. Radiology Technician receives notification when an X-ray has been added to his/her work list).

10. EHR is integrated with Picture Archiving Communication System (PACS).

11. EHR has computerized physician order entry (CPOE) functionality.

12. Medications ordered via CPOE system automatically populate the electronic Medication Administration Record (eMAR).

    a. Status of medication administration is documented on the eMAR (i.e. ‘G’ for Given, ‘R’ for Refused by Patient, etc.), along with the healthcare professional’s electronic signature and any pertinent information (i.e. heart rate when administering a beta-blocker, or the reason for patient refusal when entering ‘R’ for Refused by Patient)

13. Facility uses Bar Code Medication Administration (BCMA) system to validate administration of medication to all ED and inpatients.

14. BCMA system is integrated with the EHR.

15. EHR can manage the transition from Triage to Provider (e.g., move from one work list to another), ED to inpatient, etc.

16. EHR is able to generate referral request as entered by Provider.

17. Standard vocabularies utilized by the organization include: ICD10 for diagnosis, RxNorm for medications, SNOMED-CT for clinical assessments, care that is provided and lab results, and LOINC for laboratory tests.

3.8. Normal Flow

Step	Component	Narrative
1	Action	Patient's family member (daughter) pulls up to ED entrance, and with assistance, pushes her mother into the ED
	Cognitive Goal:	
	Actor(s)	Patient's family member Patient Triage RN ED Tech
	Action Breakdown	ED Tech assists patient from car to wheel chair, and wheels to the Triage area.
	Technology	
	Standard	
	Appendix	
2	Action	Triage RN completes a brief assessment to determine the patient's condition and the urgency of required care.
	Cognitive Goal:	*Rapid assessment of patient condition.* ***Patient Goal:*** *"I am having a real hard time breathing. Please don't let me die."*
	Actor(s)	Patient Triage RN ED Tech Family member
	Action Breakdown	Chief Complaint: "I am having a real hard time breathing. Especially when I try to walk and at night. My breathing has gotten worse since I have not been able to take my sugar and heart medications for over a week." Allergies: NKDA Current medications: a. Carvedilol 25mg PO BID b. Captopril 12.5mg PO TID c. Furosemide 20mg PO QD

Step	Component	Narrative
		d. Digoxin 0.125mcg PO QD e. Lipitor 40mg PO QD f. Lantus [http://www.lantus.com/hcp/dosing-titration/dosing-calculator] (Insulin Gargine) 16U SC QD g. High level assessment: • LOC: Alert and fully oriented (x3) • Temp: 99 F • BP: 190/92 mmHg • HR: 118 bpm • Cardiac rhythm (ECG): Sinus tachycardia (ST) without ectopy • Resp: 26/min and shallow • Pulse Oximetry: 90% on room air • Skin: pale and diaphoretic • Weight: 190lbs (with ~5lb weight gain in the past week)
	Technology	EHR a. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	Sample Triage Assessment Form [http://img.docstoccdn.com/thumb/orig/70160047.png]
3	Action	Triage RN determines that patient has a severity index of '2' requiring immediate emergency nursing care. **Note**: Steps 2 and 3 often occur concurrently.
	Cognitive Goal:	*Assessment of severity of condition. Is the patient's condition life threatening?*
	Actor(s)	Triage RN Patient ED Charge RN ED Physician ED RN
	Action Breakdown	Triage RN does the following: a. Patient placed on stretcher (with triage nurse and ED tech). Moves the patient via stretcher to the 'Emergent' section of the ED

Step	Component	Narrative
		b. Notifies the ED charge nurse and ED attending physician of the new ED patient and their condition c. Flags the patient as requiring Emergent care by an RN in the EHR d. Provides transition of care report to the ED RN that will be caring for the patient
	Technology	EHR a. Status entry b. Data visualization for report
	Standard	
	Appendix	Emergency Severity Index Triage Tool for EDs [http://www.ahrq.gov/professionals/systems/hospital/esi/esi1.html] Treatment Algorithm [http://www.healthquality.va.gov/guidelines/CD/chf/chf_full_text.pdf] (p. 7)
4	Action	ED RN initiates standing orders for emergency interventions that are indicated in the management of heart failure.
	Cognitive Goal:	*Select and implement appropriate emergency interventions to hypertension and respiratory distress.*
	Actor(s)	ED RN ED Tech Patient
	Action Breakdown	ED RN does the following (unless noted as being delegated to the ED Tech): a. Places the patient on a cardiac monitor (patient is still in ST) b. Obtains updated set of vital signs (BP: 186/90, HR: 115, RR: 26) c. Places the patient on 6L of oxygen (O2) via non-rebreather face mask d. Completes 12 lead electrocardiogram (ECG) a. Sinus tachycardia (ST) Q waves in the inferior leads, inferolateral ST- and T-wave changes (This is unchanged from the previous admission-3 months ago). b. ED Provider is notified e. Starts a peripheral intravenous (IV) line – *performed by EDT* f. Sends blood sample for BNP, CMP, Magnesium, Phosphorus, CBC, CPK-MB, Troponin, PT/PTT – *orders for labs entered by RN, blood drawn and sent by EDT* g. Performs POC blood glucose: 200 mg/dL – performed by EDT when labs were drawn (in f)

Step	Component	Narrative
		h. Administers medications (medications available in ED Pyxis) a. Nitroglycerin IV, 5mcg/minute titrating rapidly by 20mcg/min until systolic BP is 120<150 mmHg i. Highlights the medication in the eMAR, scans the medication, next scans the patient, then administers the medication after receiving BCMA verification of appropriate administration b. Insulin Sliding Scale protocol i. Follows process noted above for nitroglycerin IV administration c. Furosemide 20mg IV administration one dose i. Follows process noted above for nitroglycerin ii. If the patient does not produce 250ml urine in first 30 minutes, furosemide 40mg IV x1 should be administered i. Orders Chest X-ray (CXR)- PA and Lateral views j. Echocardiogram not indicated because previously done three months ago. ***Note**: Each of these interventions is 'ordered' by activating the "Standard ED Order Set for Chest Pain." The ED RN enters the orders as verbal orders, which are then "signed" by the Provider in the EHR.* ***Note**: RN specifies 'Nurse draw' when entering order for lab work. EHR integrates with department printer, which prints labels for blood tubes. If the RN had specified 'Lab draw' the blood draw would have been added to a Laboratory Technician's work list.*
	Technology	EHR a. Biomedical device integration to record VS and pulse oximetry b. Data entry of care performed c. Activation of standing order set for chest pain via CPOE by RN Documents medications that were administered in the Medication Administration Record (MAR)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Heart Failure Emergency Department Orders [http://www.scpcp.org/webdocs/hf-shared-practices/KE%202/FRH%20ED%20Order%20Set.pdf] MAR Sample [http://pharmacyprime.ie/PDF/MARS_CHART_EXAMPLE.PDF]

Step	Component	Narrative
		VA Clinical Practice Guidelines for the Management of Chronic Heart Failure [http://www.healthquality.va.gov/guidelines/CD/chf/chf_full_text.pdf] Standing Sliding Scale Insulin Orders [http://www.pharmacypracticenews.com/download/insulinslidingscale.pdf]
5	Action	Provider receives notification that standing orders (function as verbal orders requiring signature) has been placed in his/her name
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	Provider opens notification and views the task listed in their work queue a. Provider opens patient record in EHR and views data entered to date b. Provider enters ED room to assess patient *(assessment results are documented in Step 13)*
	Technology	EHR a. Notification system b. Data visualization
	Standard	
	Appendix	
6	Action	Registration clerk enters insurance and demographic information in to the EHR system via tablet as verified by the patient's wife.
	Cognitive Goal:	
	Actor(s)	Registration Clerk Family member
	Action Breakdown	Registration Clerk enters/validates/updates the following information in to the system: a. Demographic information b. Primary and Secondary Insurance information: Medicare, member #: xxx-xx, etc. c. Next of Kin contact information d. Religious preference
	Technology	EHR Registration System a. Data entry
	Standard	a. Address [http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf] b. Sex [http://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.1038] c. Ethnicity [http://www.whitehouse.gov/omb/fedreg_1997standards]

Step	Component	Narrative
		d. Race [http://www.cdc.gov/minorityhealth/populations/REMP/definitions.html]
	Appendix	Hospital Registration Form [http://www.saintpetershcs.com/uploadedFiles/preadmission%202010.pdf]
7	Action	ED RN evaluates respiratory effort and function, along with vital signs
	Cognitive Goal:	*Evaluate effectiveness of interventions and need for escalation of therapy.*
	Actor(s)	ED RN Patient
	Action Breakdown	a. Patient is reporting slight to moderate ease with breathing difficulty b. VS: BP 150/80, HR 96, RR 20, Pulse Ox: 95% on 6L non-rebreather c. Nitroglycerin IV at 45 mcg/min with SBP=120<150 mmHg
	Technology	EHR a. Biomedical device integration to record VS and pulse oximetry b. Data entry of care performed c. Documents medications that were administered in the electronic Medication Administration Record (eMAR)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
8	Action	Radiology Technician (Rad Tech) receives notification that a diagnostic X-ray for an Emergent ED patient has been added to his/her work list
	Cognitive Goal:	*Management of work queue. Ensure the proper diagnostic test is performed on the proper patient.*
	Actor(s)	Rad Tech Patient
	Action Breakdown	Rad Tech receives notification that a task has been added to his/her work list for an Emergent ED patient. a. Rad Tech checks work list in EHR, completes the procedure as ordered and documents completion. b. Rad Tech flags the CXR as ‘ready for interpretation’ by Radiologist
	Technology	EHR a. Integration with Notification system b. Data entry c. Status entry

Step	Component	Narrative
	Standard	a. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	
9	Action	Radiologist receives notification that a CXR is ready for interpretation for an Emergent ED patient
	Cognitive Goal:	*Accurate evaluation of CXR (taking reason for CXR and old films in to consideration)*
	Actor(s)	Radiologist
	Action Breakdown	Radiologist receives notification that a chest film is ready for interpretation. a. Radiologist checks work list in EHR, views the indicated CXR and enters the CXR results and interpretation. b. Radiologist flags the CXR as 'Resulted'
	Technology	EHR integration with PACS and Notification system a. Image visualization b. Data entry c. Status entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	CXR Result Format [http://radreport.org/template/0000102]
10	Action	Provider receives notification that the CXR results are available
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	Provider receives notification that a CXR ordered in their name has been 'resulted." a. Provider pulls up results via hospital issued smart phone. b. Provider utilizes EHR to view chest film to compare against previous images (if available).
	Technology	EHR integration with PACS and Notification system a. Image visualization b. Data visualization
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	CXR Result Format [http://radreport.org/template/0000102]
11	Action	Registration clerk (Reg. Clerk) obtains Advance Directive and Authorization for Disclosure of Personal Health Information (PHI) from patient
	Cognitive Goal:	
	Actor(s)	Reg. Clerk

Step	Component	Narrative
		Patient
	Action Breakdown	Reg. Clerk provides tablet with Advance Directive and Authorization for Disclosure of PHI information of forms. a. Patient completes Advance Directive form b. Patient waives Authorization for Disclosure of PHI at this time.
	Technology	EHR integration with hand held tablets
	Standard	
	Appendix	Advance Directives Form [http://www.saintpetershcs.com/uploadedFiles/Advancedirective.pdf] Authorization for Disclosure of Protected Health Information [http://www.saintpetershcs.com/uploadedFiles/Policy%20768-7%20-%20Attachment%20-%20Authorization%20-%20For%20Release%20of%20Health%20Information%20REVISED%2003-25-10.pdf]
12	Action	ED RN receives notification that diagnostic results have been returned for this patient
	Cognitive Goal:	*Ensure results are not life threatening or will affect indicated treatment.*
	Actor(s)	ED RN
	Action Breakdown	ED RN receives alert that lab and CXR results have been returned. He/she accesses lab results in the EHR. Relevant lab values include: Cardiac Values Troponin: <0.1 mcg/ml CK: 150 ng/ml CK-MB: 3 ng/ml BNP 620 mg/mL (H) CBC RBC=4.03 trillion cells/L WBC=6.4 billion cells/L Hgb=13.2 g/dL Hct=37.5% Plt=300 billion/L CMP Albumin=4.2 g/dL Alkaline phosphate=95 IU/L ALT=20 IU/L

Step	Component	Narrative
		AST=21 IU/L BUN=14 mg/dL Calcium=9.0 mg/dL Chloride=100 mmol/L CO2=28 mmol/L Creatinine=1.9 mg/dL (H) Glucose=200 mg/dL Potassium=4.5 mEq/L Sodium=140 mEq/L Total bilirubin=1.1 mg/dL Total protein=7.0 g/dL Magnesium=2.8 mEq/L Phosphorus=2.1 mEq/L ABG Ph=7.44 PaCO2=35 PaO2=68.2 (L) SaO2=90% (L) HCO3=23 BE=-0.75 Note=Room Air Coags PT: 12 seconds PTT: 63 seconds CXR Mildly enlarged cardiac silhouette and pulmonary venous congestion Note: pulmonary venous congestion is new when compared to previously hospital admission's discharge CXR Echo (from previous hospital admission, three months ago)

Step	Component	Narrative
		mildly dilated left ventricle with slightly increased wall thickness, inferobasilar akinesis, and an ejection fraction (EF) estimated at 35% to 40%
	Technology	EHR a. Visualization of lab and diagnostic reports
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	
13	Action	Provider assesses patient
	Cognitive Goal:	*Expedite History and Physical. Formulate differential diagnosis (e.g., Exacerbation of CHF vs Pulmonary Embolism).*
	Actor(s)	Provider Patient
	Action Breakdown	a. Confirms past medical history (PMH) and enters active conditions to the Problem List (CHF, Obesity, DM Type 2, HTN, MI 2 years ago) b. Confirms allergies: NKDA c. Confirms current medications listed in step 2. d. Smoking history: No tobacco use e. Completes physical assessment a. Neuro: Alert and fully oriented b. CV: No Chest pain, S1S2, S3 (common with volume overload) c. Resp: 20 and slightly shallow. Lungs rales lower lobes bilaterally with wheezing d. GI: Abdomen soft, flat with bowel sounds in all quadrants. e. GU: Verbalizes no problems with voiding f. Skin: Slightly pale. Diaphoretic. Warm and intact. +1 pedal edema bilateral g. Psych: Calm and cooperative with wife present
	Technology	EHR a. Data entry to Problem List, Allergies and Current Medication b. Visualization of lab and diagnostic reports c. Data entry of assessment
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]

Step	Component	Narrative
		c. LOINC [http://search.loinc.org/search.zul?query=BMI] d. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Adult Health History [http://georgetownmedical.com/util/documents/hx-physical-form.pdf] Head to Toe Physical Assessment Components [http://www.bing.com/images/search?q=physical+assessment +form&id=93FC06872326E1C4EFD077EA45F90F9AD366E450&FORM=IQFRBA#view=de
14	Action	Provider discusses clinical findings and treatment options with patient
	Cognitive Goal:	*Engage and educate patient. Assess patient understanding to facilitate informed decisions.* ***Patient Goal:*** *"I am starting to feel a little better. I just want to be back to my normal. I know I need to take my meds."*
	Actor(s)	Provider Patient
	Action Breakdown	a. Diagnosis confirmed by previous medical history, lab results, CXR, previous echo, and physical assessment: Acute exacerbation, congestive heart failure (respiratory distress, DM type 2, hypertension) a. Problem list reviewed and updated b. Recommendation: i. Admission to IMC i. Reintroduce outpatient medication regimen controlling heart failure, hypertension, and DM type 2 ii. Start anticoagulation therapy (clinical guidelines/protocol) ii. Start education with patient and help identify barriers to self-care (including medication management adherence) **Note**: full education is not appropriate during emergent medical management; this task will be carried out through the inpatient and discharge process iii. Provider can access Clinical Care Guidelines, American Cardiology, American Heart Association, and American Diabetes Association resources via hyperlink or Infobutton, as needed
	Technology	EHR a. Data entry to Problem List
	Standard	
	Appendix	
15	Action	Patient conveys agreement to the treatment plan of care
	Cognitive Goal:	
	Actor(s)	Provider

Step	Component	Narrative
		Patient
	Action Breakdown	Care Plan Activities / Targeted Completion a. Signs verbal order that ED RN entered to activate ED standing orders for patients presenting with heart failure / Immediately b. Admission to IMC / Once bed is available i. Nothing to eat or drink until respiratory distress dissipates c. Wean nitroglycerine IV once PO medications have been dispensed by pharmacy / Immediately
	Technology	EHR a. Data entry of Care Plan
	Standard	
	Appendix	
16	Action	Provider utilizes CPOE to enter orders for agreed upon care
	Cognitive Goal:	*Determine appropriate orders for this patient.*
	Actor(s)	Provider
	Action Breakdown	Provider enters the following orders: 1. Admit to IMC, transfer order, with recommended orders for Hospitalist (provider) 2. Move patient to O2 NC, starting at 6L as tolerated keeping SaO2 >95%, Notify MD and perform ABG if SaO2 <95% 3. CHF Admission Order Set 4. Lovenox 40mg SC QD 5. Carvedilol 25 mg PO BID 6. Captopril 12.5 mg PO TID 7. Furosemide 20 mg PO QD 8. Digoxin 0.125 mcg PO QD 9. Lantus [http://www.lantus.com/hcp/dosing-titration/dosing-calculator] (Insulin Gargine) 16U SC QD (starting with normal cardiac diet, tomorrow) 10. Titrate nitroglycerine by half within first 30 minutes of administration of PO medications; turn off nitroglycerine 1 hour after administration of PO medications Note: notify MD if systolic BP >150mmHg
	Technology	EHR a. CPOE

Step	Component	Narrative
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Heart Failure Admission Order Set [https://www.heart.org/idc/groups/heart-public/@wcm/@hcm/@gwtg/documents/downloadable/ucm_308978.pdf]
17	Action	Nurse pages house supervisor for bed management/admission
	Cognitive Goal:	
	Actor(s)	ED RN House Supervisor
	Action Breakdown	ED RN pages house supervisor relaying new admission to hospital. Admission order also triggers on house supervisor's work queue (within the EHR)
	Technology	EHR a. Work queue
	Standard	
	Appendix	Heart Failure Admission Order Set [https://www.heart.org/idc/groups/heart-public/@wcm/@hcm/@gwtg/documents/downloadable/ucm_308978.pdf]
18	Action	ED RN receives notification of new order for PatientID ########.
	Cognitive Goal:	
	Actor(s)	ED RN
	Action Breakdown	ED RN receives notification that the provider has placed admission orders to IMC
	Technology	EHR integration with Notification system
	Standard	
	Appendix	ED Flow Sheet [http://www.azdhs.gov/bems/documents/trauma/EmergencyServicesTraumaFlowSheet.pdf]
19	Action	ED RN administers cardiac medications, as ordered
	Cognitive Goal:	*Evaluate how respiratory status, BP, and urinary output has been affected by medication therapy.*
	Actor(s)	ED RN Patient
	Action Breakdown	a. ED RN evaluates vital signs, I/O, and respiratory status b. BP: VS: BP 148/88, HR 90, RR 20, Pulse Ox: 98% on 6LNC, U/O=600 ml/last hour c. Enters BP 148/88 when prompted to evaluate patient's BP with nitroglycerine drip continuing d. Enters 'I' for Infusing in eMAR and rate of 45 mcg/min Scans patient's wristband e. Note: elevated blood glucoses will be managed once transferred to IMC

Step	Component	Narrative
	Technology	EHR a. Biomedical device integration to record VS and pulse oximetry b. Data entry of care performed
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
20	Action	House supervisor has found bed placement in IMC
	Cognitive Goal:	
	Actor(s)	House Supervisor ED Nurse
	Action Breakdown	a. House supervisor calls ED nurse and provides information on IMC admission bed b. House supervisor changes patient bed to a transfer status to IMC bed (indicating patient remains in ED until transfer is complete)
	Technology	EHR a. Work queue b. Bed management
	Standard	
	Appendix	
21	Action	ED RN provides transition of care report to the IMC RN that will be caring for the patient
	Cognitive Goal:	
	Actor(s)	ED RN IMC RN
	Action Breakdown	Report is completed verbally, over the phone. IMC RN enters PatientID in computer, views all documentation entered in ED, and accepts patient as an assignment.
	Technology	EHR a. Query b. Data visualization c. Bed management
	Standard	
	Appendix	
22	Action	Patient is transferred to IMC via stretcher

Step	Component	Narrative
	Cognitive Goal:	
	Actor(s)	ED RN Patient IMC RN
	Action Breakdown	IMC RN assumes care of the patient, will review and acknowledge heart failure admission orders while patient is being transported from ED to IMC. **Note**: Patient is transported by ED RN and ED Tech (because of patient acuity to cardiac care).
	Technology	
	Standard	
	Appendix	

3.9. Data fields required

See appendix references as examples/guides

3.10. Notes and Issues

References for Clinical Management of Ischemic Heart Disease

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4. Congestive Heart Failure: Previously Diagnosed, Acute Exacerbation – Admitted to Intermediate Care Unit

CHF 2

4.1. Introduction

1. This use case was created to evaluate the ontology created by the VistA Evolution GUI Research project. It includes common assessments, observations, interventions, and cognitive goals that arise while caring for a patient in this scenario to ensure that the ontology can accommodate these concepts.

2. All clinical data in this use case is synthetic. Data was created to support the flow of this use case and provide examples of clinical observations that are documented throughout the interaction.

3. Clinical decision making in this use case is based, primarily, on VA/DoD Clinical Practice Guidelines for the Management of Chronic Heart Failure, available at: http://www.healthquality.va.gov/guidelines/cd/chf/index.asp

4. Additional clinical resources are listed below in the Reference section.

5. The intent of this use case is to capture actions that may occur when a patient presents to the hospital with a CHF acute exacerbation. Many of the steps in this use case occur concurrently in an emergent case. In similar scenarios, the same actions may occur in slightly different order.

6. Cognitive goals are included in some 'Actions' to provide insight on the Provider or healthcare professional's mental process at that point of the encounter.

7. Hyperlinks present in the Appendix column are included to provide examples of the data fields and values that may be entered by the EHR user during this step of the use case.

8. Hyperlinks present in the Standards column suggest standardized terminologies that may be used to capture data in this step of the use case.

4.2. Actors

Patient: a person receiving or registered to receive medical treatment

Provider: Physician, physician assistant (PA), or nurse practitioner (NP). All are skilled health-care professionals trained and licensed to diagnose and treat patients within their defined scope of practice.

Registration Clerk (Reg. Clerk): a hospital employee that collects demographic, insurance and "reason for visit" information from a new patient and enters this information in to the Admission/Discharge/Transfer (ADT) system and/or the electronic health record (EHR).

Triage Nurse (Triage RN): A licensed nurse that assesses symptoms, health-related complaints, and vital signs to determine the degree of urgency for care.

Unit Clerk (UC): a hospital employee that performs administrative duties to facilitate workflow and patient care in the emergency department (ED) or a nursing unit.

Emergency Department Technician (ED Tech): a hospital employee that is trained to provide basic tasks such as vital signs and laboratory draws under the supervision of an RN or Provider.

Registered Nurse (RN): a licensed healthcare professional that is trained to provide nursing care to patients in inpatient and outpatient settings, within their defined scope of practice.

Licensed Social Worker (LSW): a licensed healthcare professional that assists patients to improve their quality of life and social needs, and facilitates care after discharge.

Nurse's Aide/Assistant (NA): a trained healthcare worker that provides assistance with patient care, under the supervision of an RN.

Clinical Pharmacist – a licensed healthcare professional that often collaborates with physicians and other healthcare professionals to coordinate pharmaceutical interventions and promote health and disease prevention within their scope of practice.

Dispensing Pharmacist – a licensed healthcare professional that dispenses medications, monitors medication parameters and potential drug interactions, and provides information about medications, within their scope of practice.

Radiology Technician (Rad Tech) – a licensed radiography professional that performs diagnostic imaging exams on patients to help physicians assess illness and injury.

Radiologist - a licensed physician that specializes in diagnosing and treating diseases and injuries by using medical imaging.

EKG Technician (EKG Tech) – a cardiology technologist that administers basic electrocardiogram tests to patients. The results are then read by a cardiologist or other licensed physician.

Respiratory Therapist (RT) – a licensed healthcare practitioner that provides care and treatment to patients requiring breathing and oxygenation support.

Charge RN – a registered nurse that is responsible for the efficient management of a nursing unit or department, including admissions, discharges, and the oversight of all nursing and support staff.

Medical Sonographer (Ultrasound Technician) – trained healthcare professionals that operate special imaging equipment to create/capture images helping providers assess and diagnose medical conditions.

House Supervisor – registered nurse who coordinates bed management and staff mix in the hospital to assure that effective nursing services are provided, and quality standards are met.

Hospitalist – A physician whose primary focus is the general medical care of hospitalized patients.

4.3. Description

A 72-year-old white female with respiratory distress (acute exacerbation, congestive heart failure) is stabilized and transferred to IMC.

4.4. Trigger

Patient has been stabilized in the ED with admission orders to IMC.

4.5. Preconditions

1. Obesity (adult onset)
2. Diabetes Type 2 (15 years ago)
3. Hypertension (15 years ago)
4. Heart failure (1 year ago)
5. Myocardial Infarction ((MI) 2 years ago)
6. Dyslipidemia (2 years ago)

Note: The health system's electronic health record (EHR) shows that the patient has been seen at the hospital previously. And, most recently treated (slightly over three months ago) for an acute heart failure episode with a hospital stay of two days. The patient's past medical history and medications are present in the EHR

4.6. Postconditions

Minimal guarantees:

1. Data fields required to support this clinical workflow will be present in the EHR.
2. Data entered will be stored utilizing the appropriate clinical vocabulary.

Success guarantees:

3. EHR supports patient-centered care, guided by goals set by the patient.
4. Patient receives evidence-based care based on the health concerns that are noted during the outpatient visit.
5. Patient will achieve improved outcomes and satisfaction as a result of care facilitated by EHR functionality.

4.7. Assumptions

1. EHR is able to send notifications to healthcare providers when a task has been added to their work list (i.e. Radiology Technician receives notification when an X-ray has been added to his/her work queue).

   b. EHR is integrated with Picture Archiving Communication System (PACS).

   c. EHR is integrated with information systems in the following departments: Pharmacy, Laboratory, Radiology, Cardiology, Dietary, Rehabilitation

   d. EHR has computerized physician order entry (CPOE) functionality.

   e. Orders entered via CPOE are automatically implemented and assigned to the appropriate work queue (e.g., CBC in a.m. is automatically assigned to the Laboratory work queue)

   f. Medications ordered via CPOE system automatically populate the electronic Medication Administration Record (eMAR).

   g. EHR system allows the Provider to select existing active medication to pre-populate discharge medication orders. Provider can then de-select any carried over medication, if desired.

   h. Orders for discharge medications entered via CPOE are sent directly to the outpatient pharmacy that is designated by the patient.

   i. Facility utilizes Hospitalists to provide and manage care of hospitalized patients.

   j. Facility uses Bar Code Medication Administration (BCMA) system to document administration of medication to all ED and inpatients.

   k. BCMA system is integrated with the EHR.

   l. EHR A/D/T system allows user to tentatively hold a bed, pending formal orders from Provider (e.g. ICU, IMC, or Telemetry bed post-PCI while patient is recovering from the procedure)

   m. EHR can manage the transition of tasks (e.g., move tasks from one work queue to another)

   n. PatientID is a unique ID assigned to a specific patient for each unique hospital stay

   o. Standard vocabularies utilized by the organization include: ICD10 for Diagnosis, RxNorm for medications, SNOMED-CT for clinical assessments, care that is provided and lab results, and LOINC for laboratory tests.

4.8. Normal Flow

Step	Component	Narrative
1	Action	Hospitalist (provider) admits patient to IMC (after receiving report from the ED Provider) **Day 1**
	Cognitive Goal:	*Determine indicated care and orders for this unique patient admitted from ED with congestive heart failure.*
	Actor(s)	ED Provider Hospitalist (provider)

Step	Component	Narrative
	Action Breakdown	Receives telephone report from ED physician, and utilizes Heart Failure Admission Order Set [https://www.heart.org/idc/groups/heart-public/@wcm/@hcm/@gwtg/documents/downloadable/ucm_308978.pdf] via CPOE and adds additional orders, as needed. For example: 1. Admit to IMC 2. Dx: Congestive Heart Failure (428.0), Respiratory Distress (J80) Secondary: DM type 2, hypertension, obesity, dyslipidemia 3. Allergies: NKDA 4. History of Tobacco use: No 5. Condition: Stable 6. Code Status: Full code 7. VS: Per unit protocol, daily weights 8. Diet: Low fat, Low cholesterol, Low salt (cardiac diet), Strict I/O 9. Heparin Lock IV. 10.Activity: Advance as tolerated, starting in AM 11.Labs: CBC/diff, BMP, fasting Lipid profile, PT/PTT in AM 12.Move patient to O2 NC, starting at 6L as tolerated keeping SaO2 >95%, Notify MD and perform ABG if SaO2 <95% 13.Medications: a. ***Lovenox 40mg SC QD b. Carvedilol 25 mg PO BID c. Captopril 12.5 mg PO TID d. Furosemide 20 mg PO QD e. Digoxin 0.125 mcg PO QD f. Lipitor 40mg PO QD g. Lantus [http://www.lantus.com/hcp/dosing-titration/dosing-calculator] (Insulin Gargine) 16U SC QD h. Titrate nitroglycerine by half within first 30 minutes of administration of PO medications; turn off nitroglycerine 1 hour after administration of PO medications i. Note: notify MD if systolic BP >150mmHg j. Administer Influenza vaccination, if patient has not be vaccinated this season

Step	Component	Narrative
		k. Administer Pheumococcal immunization if not previously vaccinated, or if vaccination was > 5 years ago.
	Technology	EHR CPOE
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	Heart Failure Admission Order Set [https://www.heart.org/idc/groups/heart-public/@wcm/@hcm/@gwtg/documents/downloadable/ucm_308978.pdf]. (pages 1-3)
2	Action	IMC Unit Clerk confirms formal bed transition from ED to IMC in Admission/ Discharge /Transfer (ADT) System
	Cognitive Goal:	*Implement physician order for appropriate bed assignment (based on severity of illness driving the intensity of service).*
	Actor(s)	IMC Unit Clerk
	Action Breakdown	IMC Unit Clerk views available IMC beds and, in collaboration with the IMC Charge RN, selects appropriate bed for patient, as ordered by physician
	Technology	EHR a. Integration with ADT system
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	ED Flow Sheet [http://www.azdhs.gov/bems/documents/trauma/EmergencyServicesTraumaFlowSheet.pdf]
3	Action	ED RN provides transition of care report to the IMC RN that will be caring for the patient
	Cognitive Goal:	*Formulate and ask appropriate questions during report to gather information required to properly care for patient.*
	Actor(s)	ED RN IMC RN
	Action Breakdown	ED RN provides transition of care report verbally over telephone to the IMC RN a. IMC RN acknowledges patient admission on EHR bed tracker, validates patient with PatientID, and assigns him/herself as the primary care nurse

Step	Component	Narrative
		a. Views ED encounter notes, and Heart Failure Admission Orders [https://www.heart.org/idc/groups/heart-public/@wcm/@hcm/@gwtg/documents/downloadable/ucm_308978.pdf] in patient record b. ED RN and ED Tech transfers patient to IMC after report is completed
	Technology	EHR a. Manage patient assignment through EHR bed tracker b. Query by PatientID c. Data visualization
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	ED Flow Sheet [http://www.azdhs.gov/bems/documents/trauma/EmergencyServicesTraumaFlowSheet.pdf]
4	Action	IMC RN assumes care of patient
	Cognitive Goal:	*Evaluate baseline assessment. Determine areas of concern and/or observations requiring additional interventions*
	Actor(s)	IMC RN
	Action Breakdown	IMC RN: a. Attaches cardiac leads to patient and ensures monitoring is effective a. Notes cardiac rhythm: Sinus rhythm without ectopy, HR 84 b. VS a. BP 146/80, HR 84, RR 20, Pulse Oximetry on 4L O2 NC: 96% c. I/O d. Performs head to toe assessment. Results documented on Nursing Flow Sheet
	Technology	EHR a. Biomedical device integration b. Data entry
	Standard	EHR a. SNOMED-CT b. LOINC

Step	Component	Narrative
	Appendix	Stepdown Nursing Flow Sheet [http://www.cantonmercy.org/uploads/File/pdf/6395_Step_Down_Telemetry.pdf]
5	Action	Hospitalist (Provider) assumes care of patient. Documents formal History of Present Illness (HPI) and performs assessment
	Cognitive Goal:	*Perform assessment. Validate existing orders and ensure no additional orders are indicated. Determine relevant information to be included in HPI.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider: a. Queries EHR on PatientID and reviews all documentation and diagnostic results from ED b. Interviews patient about Chief Complaint, PMH, etc. c. Performs head to toe assessment. d. Creates HPI documentation e. Enters SOAP note f. Ensures Heart Failure Admission Orders [https://www.heart.org/idc/groups/heart-public/@wcm/@hcm/@gwtg/documents/downloadable/ucm_308978.pdf] address all indicated care (no additional orders are indicated)
	Technology	a. Data visualization b. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	History of Present Illness Documentation [http://r.search.yahoo.com/_ylt=A0LEViP7.KtUJ74AbQAPxQt.;_ylu=X3oDMTByNW1iMWN2BHNlYwNzcgRwb3MD RV=2/RE=1420585339/RO=10/RU=http%3a%2f%2fwww2.sunysuffolk.edu%2fmccabes%2fH%26P%2520guide%2520for%2520pdarev.doc/RK=0/RS=Z7BjPbb7uLomK15w4NcJV6eKkBc-] Head to Toe Physical Assessment Components [http://www.bing.com/images/search?q=physical+assessment+form&id=93FC06872326E1C4EFD077EA45F90F9AD366E450&FORM=IQFRBA#view=de SOAP Note Explanation and Example [http://nurseone.ca/~/media/nurseone/page-content/pdf-en/soap_documentation_e.pdf]
6	Action	Hospitalist (Provider) discusses patient's condition and the indicated plan of care for the coming days

Step	Component	Narrative
	Cognitive Goal:	*Determine recommended plan of care. Engage and educate patient. Assess patient understanding to facilitate informed decision-making.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider discusses the following with the patient: a. Admitting diagnosis: Congestive Heart Failure (428.0), Respiratory Distress (J80) Secondary: DM type 2, hypertension, obesity b. Indicated care and education for managing chronic heart failure [http://www.rwjf.org/content/dam/supplementary-assets/2008/06/Heart-Failure-Patient-Teaching-Guide-2011.pdf] a. Beta-blocker and ACE inhibitor to support cardiac function (related to heart failure) and hypertension b. Diuretic to manage hypertension and heart failure c. Digoxin (in combination with diuretic) to manage heart failure d. DM type 2 management (with Lantus) e. Monitoring body weight daily f. Chest x-ray in AM to assess pulmonary congestion (resolution) g. Lab work in AM to evaluate cardiac, renal, liver and thyroid factors h. EKG in AM to evaluate cardiac electrical activity i. Echocardiogram to evaluate cardiac function j. Advance activity as tolerated (to patient's baseline) k. Follow low fat, low cholesterol, low sodium diet (cardiac diet) l. Cardiac education related to heart failure m. Referral to outpatient case management (related to medication compliance and mitigation of barriers to care access) c. Provider accesses Coronary Risk Assessment tool (i.e. Framingham) and/or Functional Status Assessment tools (i.e. Minnesota Living with Heart Failure Questionnaire [MLHFQ]), as needed via hyperlinks in EHR to facilitate additional assessment or provide context for discussion and patient education
	Technology	EHR a. Data visualization b. Visualization of clinical resources via hyperlinks
	Standard	

Step	Component	Narrative
	Appendix	VA/DoD Clinical Practice Guidelines for Management of Ischemic Heart Disease [http://www.healthquality.va.gov/guidelines/CD/ihd/ihd_poc_combined.pdf]
7	Action	Patient verbalizes care preferences and goals
	Cognitive Goal:	
	Actor(s)	Patient Provider
	Action Breakdown	Patient verbalizes that they are "thankful for not letting me die and I am willing to do anything in my reach to make sure I don't get any worse. I don't like hospitals, but I am glad I am receiving great care."
	Technology	EHR a. Data entry of Care Plan
	Standard	
	Appendix	
8	Action	Together, the Hospitalist (provider) and Patient agree upon a plan of care after discussion of recommended plan of care.
	Cognitive Goal:	
	Actor(s)	Provider Patient
	Action Breakdown	Care Plan Activities / Targeted Initiation a. Anticoagulation (Lovenox), as ordered / In morning b. Cardiac medications, as ordered / Immediately c. Heart failure medications, as ordered / Immediately d. DM type 2 management / With cardiac diet e. Chest x-ray, lab work, and EKG / In morning f. Activity as tolerated (patient baseline) / Immediately g. Cardiac diet / Immediately h. Heart failure education [http://www.rwjf.org/content/dam/supplementary-assets/2008/06/Heart-Failure-Patient-Teaching-Guide-2011.pdf] / Immediately and reinforce prior to discharge
	Technology	EHR a. Data entry of Care Plan
	Standard	
	Appendix	
9	Action	Dispensing Pharmacist receives notification of new medication orders and dispenses ordered medications

Step	Component	Narrative
	Cognitive Goal:	*Ensure patient safety by evaluating for drug-drug interactions and allergy concerns.*
	Actor(s)	Disp. Pharmacist
	Action Breakdown	Dispensing Pharmacist: a. Receives notification that new medication orders have been placed and added to their work queue b. Pharmacist clicks on the notification link and views medication orders, admitting diagnosis, and allergies c. Ensures that there are no drug-drug interactions or medications ordered that conflict with patient allergies (*this is done via decision support of the pharmacy system)* d. 'Dispenses' medication via Pyxis system for nursing access and administration
	Technology	EHR a. Pharmacy Information System Suite b. Visualization of data c. Visualization of eMAR
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] c. ICD10 [http://www.icd10data.com/]
	Appendix	
10	Action	IMC RN performs q 4 hour assessment and enters SOAP note at the end of his/her shift
	Cognitive Goal:	*Evaluate patient condition for procedure complications, clinical improvement, and observations that indicate a change in the plan of care.*
	Actor(s)	IMC RN Patient
	Action Breakdown	IMC RN: a. Evaluates and records cardiac rhythm i. Sinus rhythm without ectopy, HR 80 b. Checks and records vital signs i. BP 140/80, HR 80, RR 18, Pulse 2L O2 NC, 98% ii. Records I/O c. Performs head to toe assessment. Results documented on Nursing Flow Sheet

Step	Component	Narrative
		a. Notable: Lung sounds improving (mild rales right lower lobe) d. Documents input and output e. Administers medications as ordered (BCMA) i. Carvedilol 25 mg PO ii. Captopril 12.5 mg PO iii. Furosemide 20 mg PO iv. Digoxin 0.125 mcg PO v. Lipitor 40mg PO f. Enters SOAP note at end of shift g. Decreased nitroglycerine by half (30 minutes after PO medication administration) h. Discontinued nitroglycerine (60 minutes after PO medication administration)
	Technology	EHR a. Integration with biomedical devices b. Data entry c. eMAR
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Stepdown Nursing Flow Sheet [http://www.cantonmercy.org/uploads/File/pdf/6395_Step_Down_Telemetry.pdf] SOAP Note Explanation and Example [http://nurseone.ca/~/media/nurseone/page-content/pdf-en/soap_documentation_e.pdf]
11	Action	**Fast forward to the next morning.** Radiology Technician (Rad Tech) receives notification that a diagnostic X-ray for an IMC patient has been added to his/her work list **Day 2**
	Cognitive Goal:	*Prioritize and manage work queue. Ensure the proper diagnostic test is performed on the proper patient.*
	Actor(s)	Rad. Tech
	Action Breakdown	Rad Tech receives notification that a task has been added to his/her work list for an IMC patient.

Step	Component	Narrative
		a. Rad Tech checks work list in EHR, completes the procedure as ordered and documents completion. b. Rad Tech flags the CXR as 'ready for interpretation' by Radiologist
	Technology	EHR a. Query by PatientID b. Data visualization c. Integration with Patient Transport System
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
12	Action	Radiologist receives notification that a CXR is ready for interpretation for an IMC patient
	Cognitive Goal:	*Accurate evaluation of CXR (taking reason for CXR and old films in to consideration)*
	Actor(s)	Radiologist
	Action Breakdown	Radiologist receives notification that a chest film is ready for interpretation. a. Radiologist checks work list in EHR, views the indicated CXR and enters the CXR results and interpretation. b. Radiologist flags the CXR as 'Resulted'
	Technology	EHR integration with PACS and Notification system a. Image visualization b. Data entry Status entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	CXR Result Format [http://radreport.org/template/0000102]
13	Action	Hospitalist (provider) receives notification that the CXR results are available
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	Provider receives notification that a CXR ordered in their name has been "resulted." a. Provider pulls up results via hospital issued smart phone. b. Provider utilizes EHR to view chest film to compare against previous images (if available).
	Technology	EHR integration with PACS and Notification system

Step	Component	Narrative
		a. Image visualization b. Data visualization
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	CXR Result Format [http://radreport.org/template/0000102]
14	Action	IMC RN performs q 4 hour assessment and enters SOAP note at the end of his/her shift
	Cognitive Goal:	
	Actor(s)	IMC RN Patient
	Action Breakdown	IMC RN continues to follow prescribed care, heart failure admission orders (noted in step 1) with notable care including a. Advance cardiac diet b. Continue medication administration as prescribed c. Wean O2 to room air as tolerated (maintaining SaO2 >95%) d. Strict I/O e. VS i. BP 130/80, HR 80, RR 18, Pulse Oximetry on 2L O2 NC, 98% (Lung sounds clear)
	Technology	EHR a. Data visualization b. Data entry c. Biomedical device integration
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	Stepdown Nursing Flow Sheet [http://www.cantonmercy.org/uploads/File/pdf/6395_Step_Down_Telemetry.pdf]
15	Action	**Fast forward to the next morning.** Healthcare team discusses patient condition and plan of care during interdisciplinary patient rounds. **Day 3**
	Cognitive Goal:	*Evaluation of patient condition and the indicated acuity of care after diuresis and medication management.*
	Actor(s)	Provider

Step	Component	Narrative
		IMC RN Charge RN Social Worker/Case Manager Clinical Pharmacist Patient
	Action Breakdown	Healthcare team a. Reviews HPI, PMH, course of treatment, and care plan b. Reviews most recent physical assessment c. Utilizes Infobutton, Clinical Care Guidelines and other resources to evaluate indicated care options d. Formulates a recommended plan that they will discuss with the patient. i. Potential transfer to a medical unit if physical assessment is improved and patient's condition is stable Healthcare team enters patient's room to evaluate condition a. Determines that the patient's clinical condition warrants transfer to a medical unit this morning i. Discuss transfer plans with the patient b. Clinical Pharmacist (and Provider) review medications indicated for transfer (including drug safety, side effects, dosage titration and interactions), and confirm that the patient should remain on their current meds. c. Provider enters transfer orders to Medical unit *Note: Transfer of care to the Medical unit would occur as outlined above in Steps 1-4*
	Technology	
	Standard	
	Appendix	
16	Action	**Fast forward to the next morning.** Healthcare team discusses patient condition and plan of care during interdisciplinary patient rounds.
	Cognitive Goal:	*Evaluation of patient condition and indicated care after discharge. Informed, collaborative decision-making related to the care indicated for this unique patient. This includes patient education and engagement.*
	Actor(s)	Provider IMC RN

Step	Component	Narrative
		Charge RN Social Worker/Case Manager Clinical Pharmacist Patient
	Action Breakdown	Healthcare team a. Reviews HPI, PMH, course of treatment, and care plan b. Reviews most recent physical assessment c. Utilizes Infobutton, Clinical Care Guidelines and other resources to evaluate indicated discharge care options d. Formulates a recommended discharge plan that they will discuss with the patient. 4. Healthcare team enters patient's room to evaluate condition a. Determines that the patient's condition warrants discharge that afternoon a. Discuss discharge plans and instructions with the patient b. Clinical Pharmacist (and Provider) review medications indicated for discharge (including drug safety, side effects, dosage titration and interactions), and confirm that the patient should remain on the following medications as ordered a. Carvedilol 25 mg PO BID b. Captopril 12.5 mg PO TID c. Furosemide 20 mg PO QD d. Digoxin 0.125 mcg PO QD e. Lipitor 40 mg PO QD f. Lantus [http://www.lantus.com/hcp/dosing-titration/dosing-calculator] (Insulin Gargine) 16U SC QD c. Discuss need for psychosocial support at home related to medication compliance/barrier mitigation to plan-of-care d. Patient and healthcare team agree that no additional support is needed e. Patient will have pharmacy-to-door (mail order [http://www.washingtonpost.com/sf/brand-connect/wp/2014/03/17/consumer-benefits-of-receiving-medication-through-the-mail/]) prescription service setup f. Ensure that patient receives all indicated education related to heart failure

Step	Component	Narrative
		g. Discuss the importance of medication compliance and heart failure plan-of-care/education [http://www.rwjf.org/content/dam/supplementary-assets/2008/06/Heart-Failure-Patient-Teaching-Guide-2011.pdf] h. Discuss patient-specific risks a. Counsel patient on their increased long term mortality risk and the importance of compliance to care regimen i. Follow up primary care provider on a regular basis
	Technology	EHR a. Data visualization of Problem List, Care Plan, eMAR, Patient Goals
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD10 [http://www.icd10data.com/]
	Appendix	
17	Action	Patient verbalizes goal related health condition and discharge
	Cognitive Goal:	
	Actor(s)	Patient Provider Healthcare Team
	Action Breakdown	Patient verbalizes that they are eager to be more regular about taking their medications, and excited to have her prescriptions delivered directly to her house. The patient is also in agreement to monitor diet (cardiac), activity, and daily weights.
	Technology	EHR a. Data entry as Patient Goal
	Standard	
	Appendix	
18	Action	Patient agrees to the discharge plan that was presented by their healthcare team
	Cognitive Goal:	*Evaluate patient understanding of their discharge plan of care and responsibilities, along with their commitment to execute the plan.*
	Actor(s)	Patient Provider Healthcare Team
	Action Breakdown	Care Plan Activities/ Targeted Initiation a. Continue medications listed in step 16 / Immediately

Step	Component	Narrative
		b. Follow up with primary care provider within 3 days / Make apt immediately c. Heart failure education [http://www.rwjf.org/content/dam/supplementary-assets/2008/06/Heart-Failure-Patient-Teaching-Guide-2011.pdf] (i.e. notify healthcare provider if you gain 2 pound in one day or if you have trouble breathing (shortness of breath) / Immediately
	Technology	EHR a. Data entry in Care Plan
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
19	Action	Provider enters discharge orders in EHR
	Cognitive Goal:	*Determine if any additional considerations need to be addressed for patient discharge*
	Actor(s)	Provider
	Action Breakdown	Provider utilizes CPOE to enter the following orders a. Discharge to home today b. Follow up with primary care provider within 3 days c. Discharge medication: i. Carvedilol 25 mg PO BID ii. Captopril 12.5 mg PO TID iii. Furosemide 20 mg PO QD iv. Digoxin 0.125 mcg PO QD v. Lipitor 40 mg PO QD vi. Lantus [http://www.lantus.com/hcp/dosing-titration/dosing-calculator] (Insulin Gargine) 16U SC QD d. Heart failure education [http://www.rwjf.org/content/dam/supplementary-assets/2008/06/Heart-Failure-Patient-Teaching-Guide-2011.pdf] to be completed by IMC RN e. Activity as tolerated (to patient baseline)
	Technology	EHR a. CPOE
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	

Step	Component	Narrative
20	Action	IMC RN receives notification of new orders in his/her work queue
	Cognitive Goal:	*Determine level of patient understanding of their condition, plan of care, medication compliance, and follow up care after discharge.*
	Actor(s)	IMC RN
	Action Breakdown	IMC RN reviews and implements the above orders as displayed in his/her work queue a. After heart failure education is completed, the RN reviews discharge instructions and ensures patient understands all instructions and the plan of care b. Provides the patient with copies of all discharge instructions c. Teaches the patient how to utilize the Patient Portal to view his/her medical record after discharge d. Completes final SOAP note that encompasses all patient education and discharge teaching that has been reviewed
	Technology	EHR a. Data visualization b. Data entry c. EHR Patient Portal d. Data visualization
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Heart Failure Education [http://www.rwjf.org/content/dam/supplementary-assets/2008/06/Heart-Failure-Patient-Teaching-Guide-2011.pdf] Heart Failure Discharge Instructions [http://www.nlm.nih.gov/medlineplus/ency/patientinstructions/000114.htm]
21	Action	Discharge protocol completion
	Cognitive Goal:	*What are the relevant facts to communicate about this patient's encounter in the Discharge Summary?*
	Actor(s)	Respective clinician
	Action Breakdown	After reviewing discharge instructions with the patient (with return demonstration, if appropriate): a. The discharge provider's medication orders are sent via e-RX to the mail order pharmacy b. The discharge provider's referrals are automatically sent to the referring provider (if applicable) c. The discharge summary is automatically sent to the primary care provider's office—patient care coordinator
	Technology	CPOE interoperability with external Pharmacy Suite System

Step	Component	Narrative
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RXNORM [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Hospital Discharge Summary [http://clerkship.medicine.ufl.edu/portfolio/interpersonal-and-communicative-skills/discharge-summarytransfer-noteoff-service-note-instructions/]
22	Action	Patient is discharged to home from hospital **LOS: 3 days**
	Cognitive Goal:	
	Actor(s)	IMC RN Patient
	Action Breakdown	IMC RN discharges patient to home (with adult daughter) via wheelchair
	Technology	
	Standard	
	Appendix	

4.9. Data fields required

See appendix references as examples/guides

4.10. Notes and Issues

***Indicates an aspect of clinical care that falls within a Meaningful Use (MU) clinical quality measure (CQM)

A. CMS 190 – Intensive Care Unit Venous Thromboembolism Prophylaxis

4.11. References for Clinical Management of Ischemic Heart Disease

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5. Depression: Follow-up Outpatient Visit Use Case

Depression

5.1. Introduction

1. This use case was created to evaluate the ontology created by the VistA Evolution GUI Research project. It includes common assessments, observations, interventions, and cognitive goals that arise while caring for a patient in this scenario to ensure that the ontology can accommodate these concepts.

2. All clinical data in this use case is synthetic. Data was created to support the flow of this use case and provide examples of clinical observations that are documented throughout the interaction.

3. Clinical decision making in this use case is based, primarily, on VA/DoD Clinical Practice Guidelines for the Management of Major Depression and Post Traumatic Stress Disorder, available at: VA/DoD Clinical Guideline for Management of Depression [http://www.healthquality.va.gov/guidelines/MH/mdd/] and VA/DoD Clinical Guidelines for Management of PTSD [http://www.healthquality.va.gov/guidelines/MH/ptsd/]

    a. Additional clinical resources are listed below in the Reference section.

4. Cognitive goals are included in some Actions to provide insight on the Provider or healthcare professional's mental process at that point of the encounter.

5. Hyperlinks present in the Appendix column are included to provide examples of the data fields and values that may be entered by the EHR user during this step of the use case.

6. Hyperlinks present in the Standards column suggest standardized terminologies that may be used to capture data during this step of the use case.

5.2. Actors

Patient: a person receiving or registered to receive medical treatment

Provider: a skilled healthcare professional specializing in mental health that is licensed to practice medicine (within restrictions of their licensure). This can be a physician (MD or DO, i.e. Psychiatrist), nurse practitioner (NP), or physician assistant (PA).

Medical Office Assistant (MOA) also known as a Medical Assistant or Medication Technician: a healthcare care team member performing administrative and/or clinical tasks to support the work of physicians or other health professionals

5.3. Description

Routine follow-up visit for an existing diagnosis of depression and PTSD

5.4. Trigger

Patient arrives at a psychiatrist's office for a follow-up check on their depression (and PTSD)

5.5. Preconditions

This is a 32 year old male with a 6 month treatment history of major depression on Zoloft and receiving group psychotherapy. Risk assessment scores from the last visit 1 month ago: PHQ-9 (15), PCL (16), AUDIT-C (0), ASSIST (10) for Tobacco only. No suicidal ideations or risk of violence towards others.

PMH: Depression, PTSD, ETOH Abuse (Recovering), Right Above the Knee Amputation (AKA) 6 months ago – has prosthesis. Denies substance abuse of medications. Smokes 2 ppd. Patient does not have a Traumatic Brain Injury (TBI).

Psychosocial: Patient is S/P 2 deployments to Afghanistan, is estranged from family, has no close friends, lives alone and is unemployed. His best friend died during their last deployment together, when the patient was injured. He attends AA meetings daily, is undergoing vocational rehabilitation and has been seen by a community social service agency.

Depression Risk Factors:

- Family History of Depressive Disorder
- Age of Onset < 40
- Estranged from family and friends
- Stressful life events (2 deployments, and best friend in platoon died during last deployment)
- ETOH Abuse (Recovering)
- Right AKA 6 months ago (unable to drive at this time). Has prosthesis.
- Unemployed

Current Treatment regimen (prior to this follow up appointment):

- Zoloft 150 mg p.o. daily
- Weekly group psychotherapy
- Attending AA meetings regularly

Assumptions leading in to this use case:

- Patient was diagnosed with PTSD and MDD 6 months ago with screening and diagnostic tools utilized by the VHA.
- Patient has been receiving regular outpatient care for these conditions, during which time treatment (medication and psychotherapy) has been adjusted as indicated.
  - EHR is able to display a history of all implemented treatments, along with start and stop dates and reason for discontinuation
- Patient is compliant with care regimen that is agreed upon at each encounter with their provider.
- Patient has formed a trusting relationship with their Provider and is engaged in their care.
- Patient has signed a contract, agreeing to contact a health care provider if he is suicidal.
- Patient has refused Tobacco Cessation treatment.

5.6. Postconditions

Minimal guarantees:

1. Data fields required to support this clinical workflow will be present in the EHR.
2. Data entered will be stored utilizing the appropriate clinical vocabulary.

Success guarantees:

1. EHR supports patient-centered care, guided by goals set by the patient.
2. Patient receives evidence-based care based on the health concerns that are noted during the outpatient visit.

3. Patient will achieve improved outcomes and satisfaction as a result of care facilitated by EHR functionality.

5.7. Assumptions

1. EHR can manage the transition of MOA to Provider (e.g., move from one work list to another)
2. For this use case, the psychiatrist may also be substituted with another diagnostician—nurse practitioner or physician assistant.
3. Cognitive decision making throughout this office visit is based on VA/DoD Clinical Guideline for Management of Depression [http://www.healthquality.va.gov/guidelines/MH/mdd/] and VA/DoD Clinical Guidelines for Management of PTSD [http://www.healthquality.va.gov/guidelines/MH/ptsd/]
4. This use case focuses on management of depression (and PTSD). Detailed psychotherapy techniques and modalities would be outlined in the psychotherapist's encounter notes, as opposed to the PCP or psychiatrist's notes.
5. Management of depression (and PTSD), in this use case, is being overseen by a psychiatrist since the patient has comorbidities and the diagnoses have persisted beyond 3 months. Although, many patients with major depression disorder can be treated in primary care settings, indications for referral to a mental health specialist is indicated in some cases. These indications are outlined on page 37 of VA/DoD Clinical Guideline for Management of Depression [http://www.healthquality.va.gov/guidelines/MH/mdd/]
6. Standard vocabularies utilized by the organization include: ICD 10 for Diagnosis, RxNorm for medications, SNOMED-CT for clinical assessments, care that is provided and lab results, and LOINC for laboratory tests.

5.8. Normal Flow

Step	Component	Narrative
1	Action	Patient checks-in at front desk of medical office
	Cognitive Goal:	
	Actor(s)	MOA Patient
	Action Breakdown	a. MOA validates current patient demographics and billing information (i.e. current address and phone number, current insurance) b. MOA provides patient with tablet loaded with self-administered assessments for Depression (PHQ-9), PTSD (PCL), ETOH abuse (AUDIT-C), and Substance abuse (ASSIST)
	Technology	EHR (Registration System) a. Data visualization b. Data entry
	Standard	a. Address [http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf] b. Sex [http://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.1038] c. Ethnicity [http://www.whitehouse.gov/omb/fedreg_1997standards]

Step	Component	Narrative
		d. Race [http://www.cdc.gov/minorityhealth/populations/REMP/definitions.html]
	Appendix	Psychiatric Intake Form [http://cairncenter.com/forms/Psychiatric%20Intake%20Form.pdf]
2	Action	Patient accepts tablet, completes risk assessments, and returns tablet to MOA.
	Cognitive Goal:	
	Actor(s)	Patient MOA
	Action Breakdown	a. Patient answers all questions, resulting in the following scores (which will be evaluated by the Provider): a. PHQ-9 – Score: 17 b. PCL – Score: 15 c. AUDIT-C - Score: 0 (No symptoms of abuse) d. ASSIST – Score: 10 (Moderate risk for tobacco products)
	Technology	EHR a. Data entry
	Standard	
	Appendix	PHQ-9 (Depression Screening Tool) [https://www.myhealthevet.va.gov/mhv-portal-web/anonymous.portal?_nfpb=true&_pageLabel=mentalHealth&contentPage=mh_screening_tools/PHQ_SCREENING.HTML&WT.ac=mentalHealth_PHQScreen] PCL (PTSD Screening Tool) [https://www.myhealthevet.va.gov/mhv-portal-web/anonymous.portal?_nfpb=true&_pageLabel=mentalHealth&contentPage=mh_screening_tools/PTSD_SCREENING.HTML&WT.ac=mentalHealth_PTSDScreen] AUDIT-C (ETOH Screening Tool) [https://www.myhealthevet.va.gov/mhv-portal-web/anonymous.portal?_nfpb=true&_pageLabel=mentalHealth&contentPage=mh_screening_tools/ALCOHOL_SCREENING.HTML&WT.ac=mentalHealth_AlcoholScreen] ASSIST (Substance Abuse Screening Tool) [https://www.myhealthevet.va.gov/mhv-portal-web/anonymous.portal?_nfpb=true&_pageLabel=mentalHealth&contentPage=mh_screening_tools/ASSIST.HTML&WT.ac=mentalHealth_AssistScreen]
3	Action	MOA syncs tablet to EHR
	Cognitive Goal:	
	Actor(s)	MOA
	Action Breakdown	a. Risk assessment responses are uploaded to EHR and ready for Provider review b. Registration to EHR: flagged ‘ready to be roomed’

Step	Component	Narrative
	Technology	
	Standard	
	Appendix	
4	Action	Patient is roomed
	Cognitive Goal:	
	Actor(s)	MOA
	Action Breakdown	Patient is placed in room (in EHR)
	Technology	EHR a. Status entry in Registration System
	Standard	
	Appendix	
5	Action	MOA asks patient for their chief complaint (CC) and any updates on their psychosocial and medical history
	Cognitive Goal:	*Determine areas where existing history has changed.*
	Actor(s)	MOA Patient
	Action Breakdown	a. Reviews and validates reason for visit—routine outpatient visit for depression and PTSD management b. Reviews and updates psychosocial history (no changes)
	Technology	EHR a. Data entry b. Visualization of Psychosocial History
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]
	Appendix	Psychiatric Intake Form [http://cairncenter.com/forms/Psychiatric%20Intake%20Form.pdf] VA/DoD Clinical Guideline for Management of Depression [http://www.healthquality.va.gov/guidelines/MH/mdd/] VA/DoD Clinical Guidelines for Management of PTSD [http://www.healthquality.va.gov/guidelines/MH/ptsd/]
6	Action	MOA asks patient to list the medications that they are currently taking
	Cognitive Goal:	*Ensure understanding of what the patient is reporting. Determine clarifying questions if there are any concerns.*
	Actor(s)	MOA Patient

Step	Component	Narrative
	Action Breakdown	a. MOA initiates ***Medication reconciliation [http://www.healthit.gov/providers-professionals/achieve-meaningful-use/menu-measures/medication-reconciliation] by documenting a list of current medications that the patient reports taking. *(Medication reconciliation is not finalized until the Provider reviews the list of medication ordered, compares this to the list reported by the patient, and makes clinical decisions based on the comparison.)* a. Zoloft 150 mg p.o. daily
	Technology	EHR a. Visualization of Interventions (Current Medications) b. Data entry
	Standard	a. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	VA Medication Reconciliation [http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2390]
7	Action	Vital signs (VS) are taken by the MOA and entered in to the EHR
	Cognitive Goal:	
	Actor(s)	MOA Patient
	Action Breakdown	height=72” weight=176 lbs ***BMI=23.9 heart rate= 80 bpm respirations= 18 /min blood pressure= 124/74 mmHg temperature=98.2F
	Technology	EHR a. Data entry
	Standard	a. LOINC [http://search.loinc.org/] b. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	
8	Action	Patient ready for provider
	Cognitive Goal:	
	Actor(s)	MOA
	Action Breakdown	‘Ready for provider’ flag initiated in EHR
	Technology	EHR

Step	Component	Narrative
		a. Status entry in Registration System
	Standard	
	Appendix	
9	Action	Provider reviews patient record prior to entering patient room
	Cognitive Goal:	*Determine meaning of responses from the screening administered on patient arrival. Evaluate effectiveness of treatment based on information gathered to date. Plan areas of focus for the patient encounter (i.e. worsening PHQ-9 score -- what has prompted this?)*
	Actor(s)	Provider
	Action Breakdown	a. Reviews past medical history (PMH), current medications and dosages, current treatment regimen, and recent reports from specialist referrals (if indicated) b. Reviews information entered by MOA (including VS) and patient responses to the health risk screening tools. Evaluates scores for trends and/or concerns.
	Technology	EHR a. Query and visualization of Problem List, Patient History, Interventions and Observations
	Standard	a. LOINC [http://search.loinc.org/] b. SNOMED-CT [http://browser.ihtsdotools.org/] c. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD-10 [http://www.icd10data.com/]
	Appendix	
10	Action	Provider enters patient room and greets patient
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	
	Technology	
	Standard	
	Appendix	
11	Action	Provider discusses and documents the patient's expression of how they are feeling, along with their concerns.
	Cognitive Goal:	*Determine clear understanding of patient's feelings. Formulate clarifying questions, as needed.*
	Actor(s)	Provider Patient
	Action Breakdown	Patient: "I'm not very good. I'm so tired all the time. I'm not sleeping well and I have trouble concentrating. I go to my AA meetings, but that is about it."

Step	Component	Narrative
		After discussion with the patient, the Provider discovers that patient is concerned about long term living accommodations. The patient is running through his/her savings and will not be able to afford rent beyond the next 4 months.
	Technology	EHR a. Data entry
	Standard	
	Appendix	
12	Action	Provider completes psychiatric evaluation
	Cognitive Goal:	*Evaluate verbal and non-verbal clues to inform psychiatric assessment.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider assesses the patient's mental status, i.e.: a. Appearance: poorly groomed, patient slouching b. Behavior: subdued c. State of consciousness: alert and oriented x 3 d. Attention: slow to respond, shrugs shoulders in response to some questions e. Speech: soft, coherent
	Technology	EHR a. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Mental Status Exam portion of Psychiatric Evaluation [http://web.utah.edu/umed/courses/year3/psychiatry/psychaid.html]
13	Action	Provider completes and validates ***Medication Reconciliation
	Cognitive Goal:	*Evaluate for discrepancies. Educate and rectify, as needed.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider discusses the meds that the patient states they are currently taking against the medication that has been prescribed. a. Provider creates an updated list of current medications, documents the list in the system, and provides the patient with a copy at the end of the visit. *(Note: This information is included in the After Visit Summary)* a. Zoloft 150 mg p.o. daily
	Technology	EHR a. Data visualization

Step	Component	Narrative
		b. Data entry
	Standard	a. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	VA Medication Reconciliation [http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2390]
14	Action	Provider completes a head to toe assessment and documents results
	Cognitive Goal:	*Evaluate health to assess for medication side effects or physical manifestations of depression*
	Actor(s)	Provider Patient
	Action Breakdown	Head/Neuro: WNL Heart: S1S2, BP normal Lungs: Clear Abdomen: Soft, benign. No GI/GU issues. Extremities: No swelling, pedal pulses strong.
	Technology	EHR a. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Physical Exam (p 2) [https://www.uthsc.edu/gim/documents/ward-H&P.pdf]
15	Action	Provider evaluates current therapy
	Cognitive Goal:	*Determine areas of concern and begin to formulate a new plan of care*
	Actor(s)	Provider Patient
	Action Breakdown	Provider assesses: a. Effectiveness of current therapy a. PHQ-9 indicates worsening depression and patient doesn't feel well. Additional support is indicated. b. Adverse effects from the medication a. None noted c. Medical problems influencing recovery a. Patient smokes 2 packs/day, but refuses cessation therapy d. Psychosocial barrier to therapy a. Patient has financial concerns. They are not impacting therapy at present, but may in time e. Accuracy of diagnoses

Step	Component	Narrative
		a. Worsening moderate depression and PTSD are accurate diagnoses
	Technology	EHR a. Visualization of past Interventions and Observations
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/] c. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
16	Action	Provider discusses the possible next steps for the provision of care
	Cognitive Goal:	*Evaluate patient engagement and level of commitment. Formulate a plan of care that will work for the patient and achieve patient buy-in.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider discusses his/her concern about worsening depression and the need to adjust treatment to better manage the patient's condition a. Discuss medication management a. Provider views Intervention history (i.e. medications and treatments). This includes start and stop dates and the reason for discontinuation. i. Provider notices that the patient did not tolerate Prazosin in the past (which was started to address difficulty sleeping) ii. Provider also notes: Wellbutrin was prescribed from date *xx/xx/xxxx – xx/xx/xxxx* and was discontinued due to irregular heartbeats and hyperventilation, Prozac was prescribed from date *xx/xx/xxxx – xx/xx/xxxx* and was discontinued due to irregular heartbeats and restlessness, *etc.* iii. Zoloft was started at 50 mg/day on *xx/xx/xxxx*, increased to 100 mg on *xx/xx/xxxx*, and increased to 150 mg on *xx/xx/xxxx* b. Decide whether to increase dosage of Zoloft vs. adding a second medication (SSRI vs. SNRI vs. others) vs. switching to a different medication b. Discuss therapy options a. Provider visualizes psychotherapy history (i.e. started group therapy on date *xx/xx/xxxx* b. Decide whether to increase frequency of current psychotherapy vs. change type of psychotherapy (i.e. IPT vs. CBT) vs. add additional type of psychotherapy to current regimen c. Discuss psychosocial concerns

Step	Component	Narrative
		a. Visualize psychosocial support that has been provided (i.e. community based social service agency referral on *xx/xx/xxxx*, started vocational rehabilitation on *xx/xx/xxxx*, receiving telephone care coordination support) b. How can financial concerns be addressed? i. Initiate referral to Supported Housing Services ii. Discuss status of vocational rehabilitation and training d. Discuss smoking cessation. a. Patient still refuses cessation treatment despite motivational interventions.
	Technology	EHR a. Visualization of past Interventions and Observations
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/] c. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
17	Action	Patient articulates their care preferences, along with their goal
	Cognitive Goal:	*Accurate documentation of agreed up next steps.*
	Actor(s)	Provider Patient
	Action Breakdown	"I would prefer to stay on Zoloft since I am not having any side effects from it. I am okay with starting a second medication, if that is what it takes. I will start on individual therapy. I want to feel better. If you can get me help to figure out my money problems, I will take it."
	Technology	EHR a. Data entry of Patient Goal
	Standard	
	Appendix	
18	Action	Provider and patient agree upon the following changes to the care regimen, which are documented in the Care Plan.
	Cognitive Goal:	*Accurate documentation of agreed up next steps.*
	Actor(s)	
	Action Breakdown	Care Plan Activities / Targeted Completion a. Continue Zoloft 150 mg p.o. daily / Immediately b. Start Venlafaxine 37.5 mg daily x 4 days, then increase to 37.5 mg twice daily / Immediately

Step	Component	Narrative
		c. Referral for weekly individual psychotherapy – *by Provider* / Now d. Make appointment for weekly individual psychotherapy – *by Patient* / Immediately e. Continue weekly group psychotherapy / Ongoing f. Referral to Supported Housing Services provided. Patient to follow up / Immediately g. Continue Vocational Rehabilitation Training / Ongoing h. Follow up in 2 weeks to evaluate for medication side effects. - *Provider adds task for MOA to schedule appointment when patient checks out.* / 2 Weeks Note: Graphic User Interface (GUI) would allow user to populate a target date for each activity (i.e. 1 week = 1.17.15), along with a Completed date when the activity is completed/closed. Note: Patient understands that they are responsible for making appointments for all referrals and follow up appointments.
	Technology	EHR a. Data entry of Care Plan
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/] c. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
19	Action	Provider utilizes CPOE to implement orders and referrals.
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	Provider utilizes CPOE to order the following: a. Venlafaxine 37.5 mg daily x 4 days, then increase to 37.5 mg twice daily. Disp: 24 b. Referral for individual psychotherapy. 20 sessions. Diagnosis: Depression, PTSD. Reason: Worsening depression (PHQ-9 15 ->17 on Zoloft 150 mg daily and weekly group psychotherapy) c. Referral for Supported Housing Services
	Technology	EHR a. CPOE
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]

Step	Component	Narrative
		c. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
20	Action	Provider closes the visit by having the patient do a "return demonstration" of their next steps in the management of their health. This includes time frames for completion of each event. An after visit summary [http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/13_Clinical_Summaries.pdf] (AVS) is provided.
	Cognitive Goal:	*Evaluation of patient understanding.*
	Actor(s)	Provider Patient
	Action Breakdown	Patient states, "I am going to: a. Keep taking my Zoloft and start taking Venlafaxine (once a day for 4 days and then twice a day after that) b. Keep going to my group psychotherapy and make an appointment for weekly individual psychotherapy with the person that you recommended c. Contact Supported Housing Services and finish my Vocational Rehabilitation Training d. Make an appointment to see you in 2 weeks and let you know sooner if I am having side effects from the new medication.
	Technology	
	Standard	
	Appendix	After Visit Summary (AVS) [http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/743-notes.pdf]
21	Action	Patient 'checks out' with MOA
	Cognitive Goal:	
	Actor(s)	Patient MOA
	Action Breakdown	MOA view task list and sees that patient needs a follow up appointment in 2 weeks. a. OC schedules follow up appointment in 2 weeks b. OC marks the encounter as 'completed'
	Technology	Scheduling system a. Visualization of work list and Provider schedule b. Data entry
	Standard	
	Appendix	

Step	Component	Narrative
22	Action	Provider signs off on the encounter
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	a. Provider reviews and validates note and data entered during the encounter b. Provider signs off on the encounter
	Technology	EHR a. Visualization of data b. Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/] c. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	

5.9. Data fields required

See appendix references as examples/guides

5.10. Notes and Issues

1. Entries that include *** indicate compliance with a Meaningful Use clinical quality measure
   a. CMS 68 – Documentation of Current Medications in the Medical Record
   b. CMS 138 – Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention
   c. CMS 69 – Preventative Care and Screening: BMI Screening and Follow up Plan

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6. New patient profile and initial diagnosis of DM Type 2

DM 1

6.1. Introduction

1. This use case was created to evaluate the ontology created by the VistA Evolution GUI Research project. It includes common assessments, observations, interventions, and cognitive goals that arise while caring for a patient in this scenario to ensure that the ontology can accommodate these concepts.
2. All clinical data in this use case is synthetic. Data was created to support the flow of this use case and provide examples of clinical observations that are documented throughout the interaction.
3. Clinical decision making in this use case is based, primarily, on VA/DoD Clinical Practice Guidelines for the Management of Diabetes Mellitus in Primary Care, available at: http://www.healthquality.va.gov/guidelines/CD/diabetes/
4. Additional clinical resources are listed below in the Reference section.
5. Cognitive goals are included in some 'Actions' to provide insight on the Provider or healthcare professional's mental process at that point of the encounter.
6. Hyperlinks present in the Appendix column are included to provide examples of the data fields and values that may be entered by the EHR user during this step of the use case.
7. Hyperlinks present in the Standards column suggest standardized terminologies that may be used to capture data in this step of the use case.

6.2. Actors

Patient: a person receiving or registered to receive medical treatment

Provider: Physician, physician assistant (PA), or nurse practitioner (NP). All are skilled health-care professionals trained and licensed to diagnose and treat patients within their defined scope of practice.

Office Clerk (OC): an administrative assistant that manages appointment schedules for the physicians in the practice and handles insurance coverage intake and receipt of co-pays for office visits.

6.3. Description

New patient (35 year old white male) presents to primary care practice for a physical and is diagnosed with DM Type 2

6.4. Trigger

1. Patient arrives to primary care practice office for a scheduled physical that is required as a pre-employment requirement
2. Minimum demographic data was collected from patient over-the-phone for pre-arrival insurance/eligibility verification

6.5. Preconditions

1. The patient brings a copy of their most recent lab work drawn one year ago:
    a. Fasting—chem7 (blood):
        i. sodium (NA)=138 mEq/L
        ii. potassium (K)=3.9 mEq/L

iii. blood urea nitrogen (BUN)=12 mg/dL

iv. creatinine (Cr)=0.8 mg/dL

v. **glucose=135 (H**)

b. Fasting—**glycated hemoglobin (HbA1c)=6.4 (H)**

c. Fasting—lipid panel:

i. total cholesterol=185 mg/dL

ii. triglycerides=150 mg/dL

iii. high-density lipoproteins (HDL)=60 mg/dL

iv. low-density lipoproteins (LDL)=125 mg/dL

d. CBC

i. WBC = 6.6

ii. RBC = 4.7

iii. Hemoglobin = 14.5 grams/dL

iv. Hematocrit = 40.2 %

v. Platelet count = 235 billion/L

6.6. Postconditions

Minimal guarantees:

1. Data fields required to support this clinical workflow will be present in the EHR.
2. Data entered will be stored utilizing the appropriate clinical vocabulary.

Success guarantees:

1. EHR supports patient-centered care, guided by goals set by the patient.
2. Patient receives evidence-based care based on the health concerns that are noted during the outpatient visit.
3. Patient will achieve improved outcomes and satisfaction as a result of care facilitated by EHR functionality.

6.7. Assumptions

1. The patient was provided the option of entering their demographic and past medical history information via an online patient portal, however they did not have time to utilize this option. In this scenario, a patient portal tablet is provided to the patient when they present to the office to enter the required information.

   a. Patients who do not utilize the online patient portal prior to their appointment are asked to arrive for their appointment 15 minutes early to provide time for this required data collection.

2. The practice utilizes patient portal tablets in their office to capture patient demographic, past medical history (PMH), “reason for visit” information, etc.
   a. The patient portal can sync with the EHR and populate required fields in the EHR
   b. The patient portal enforces mandatory fields to ensure that all required data is captured
   c. The patient is oriented to the patient portal and enters all relevant and required information
3. Patient is able to select any Provider to complete the pre-employment physical
4. Patient has not had anything to eat or drink since the night before.
5. EHR can manage the transition of OC to Provider (e.g., move from one work list to another)
6. EHR has computerized physician order entry (CPOE) functionality
7. EHR is able to generate referral request as entered by Provider
8. Diabetics on oral hypoglycemic medications are managed by their primary care physician.
9. Standard vocabularies utilized by the organization include: ICD10 for Diagnosis, RxNorm for medications, SNOMED-CT for clinical assessments, care that is provided and lab results, and LOINC for laboratory tests.

6.8. Normal Flow

Step	Component	Narrative
1	Action	Patient checks in at front desk of medical office
	Cognitive Goal:	
	Actor(s)	OC Patient
	Action Breakdown	OC marks the patient as present in the scheduling system
	Technology	Scheduling system (data entry)
	Standard	
	Appendix	
2	Action	OC provides the patient with an electronic tablet to finish new patient information (e.g. demographic info, PMH, etc.)
	Cognitive Goal:	
	Actor(s)	OC Patient
	Action Breakdown	Patient enters the following information in to the system: a. Validates demographic information b. Validates insurance: Tricare, member #: xxx-xx, etc. c. PMH: melanoma on nose 2007, appendectomy 1990 d. Allergies: Penicillin (hives)

Step	Component	Narrative
		e. Current medications: none f. Smoker: No g. Alcohol Use: Social h. Substance Use: No i. Reason for visit: Pre-employment physical Patient completes depression screening (PHQ-2) j. Result: 0 (Negative) Patient completes PTSD screening k. Results: Negative Patient completes alcohol use screening l. Result: 2 (Negative) Patient completes substance use screening m. Result: Alcohol '5' (Low Risk)
	Technology	EHR Patient Portal (Data entry)
	Standard	
	Appendix	New Patient Sheet [https://www.freeprintablemedicalforms.com/download.php?file=TmV3X1BhdGllbnRfU2hlZXQucGRmLDE0OTY3MDMxNDUsZmNlNGZkZjgzYTY5Y%3D] Adult Health History [http://georgetownmedical.com/util/documents/hx-physical-form.pdf] VA/DoD Clinical Guidelines for Depression [http://www.healthquality.va.gov/guidelines/MH/mdd/CPGMDDClinicalGuidelinesPocketCard053013.pdf] PCL (PTSD Screening Tool) [https://www.myhealthevet.va.gov/mhv-portal-web/anonymous.portal?_nfpb=true&_pageLabel=mentalHealth&contentPage=mh_screening_tools/PTSD_SCREENING.HTML&WT.ac=mentalHealth_PTSDScreen] Alcohol Use Screening Tool [https://www.myhealthevet.va.gov/mhv-portal-web/anonymous.portal?_nfpb=true&_pageLabel=mentalHealth&contentPage=mh_screening_tools/ALCOHOL_SCREENING.HTML&WT.ac=mentalHealth_AlcoholScreen#noJavascript] Substance Abuse Screening Tool [https://www.myhealthevet.va.gov/mhv-portal-web/anonymous.portal?_nfpb=true&_pageLabel=mentalHealth&contentPage=mh_screening_tools/ASSIST.HTML&WT.ac=mentalHealth_AssistScreen#noJavascript]

Step	Component	Narrative
3	Action	OC accepts tablet back from patient, syncs it with the EHR, and completes registration process
	Cognitive Goal:	
	Actor(s)	OC
	Action Breakdown	a. Validates that all required fields are populated and house relevant data b. Enters demographic information in to EHR using standard vocabulary c. Registration to EHR: flagged 'ready for provider'
	Technology	Registration system (data transfer and validation) EHR (status entry)
	Standard	a. Address [http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf] b. Sex [http://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.1038] c. Ethnicity [http://www.whitehouse.gov/omb/fedreg_1997standards] d. Race [http://www.cdc.gov/minorityhealth/populations/REMP/definitions.html]
	Appendix	
4	Action	PA/NP views task list to review the day's list of scheduled appointments.
	Cognitive Goal:	*Plan the day ahead. Review charts (if time allows) and alert self to potential problems or areas for close review.*
	Actor(s)	Provider
	Action Breakdown	Views task list to review list of scheduled appointments for the day and the location of patients who have checked in with the front desk already
	Technology	Scheduling system (visualization)
	Standard	
	Appendix	
5	Action	PA/NP reviews information provided by the patient via the portal, lab results presented to the OC, and then searches the EHR system for other health care occurrences.
	Cognitive Goal:	*Create a patient "profile" with the gathered information, along with a list of indicated interventions based on age, demographics, and other data viewed. (i.e. will need flu shot if it is flu season).* ***Note: This cognitive function is supplemented by decision support reminders and notifications.*** *Form questions about gaps in information.*
	Actor(s)	Provider
	Action Breakdown	a. Provider queries the system by patient name, social security number, and Patient ID number. No results returned.
	Technology	EHR (Query and visualization)
	Standard	
	Appendix	

Step	Component	Narrative
6	Action	PA/NP calls patient in to examination room
	Cognitive Goal:	
	Actor(s)	Provider Patient
	Action Breakdown	Patient reports that they are “feeling fine and the only reason they made the appointment was for a pre-employment physical” a. Reviews and validates reason for visit—pre-employment physical b. Reviews and updates medical history c. Enters relevant existing history to the Active Problem List
	Technology	EHR (Visualization of Health History and Data entry)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]
	Appendix	
7	Action	PA/NP discusses lab results brought by the patient that were drawn one year ago
	Cognitive Goal:	*Create a differential diagnosis (i.e. Type 1 DM vs. Type 2 DM vs. Metabolic Syndrome, etc.) Select a ‘working’ diagnosis (DM Type 2). Begin to formulate a mental plan for additional diagnostic tests to confirm suspected diagnosis.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider discusses concern about elevated glucose and HbA1c. Patient states, “The other doctor explained that my blood sugar was a little high and I should watch what I eat. I feel fine though. I haven’t had any problems.”
	Technology	
	Standard	
	Appendix	
8	Action	PA/NP provides the patient a gown and allows time for the patient to change
	Cognitive Goal:	
	Actor(s)	Provider Patient
	Action Breakdown	
	Technology	
	Standard	
	Appendix	
9	Action	PA/NP returns to the exam room. Vital signs (VS) are taken and entered in to the EHR.

Step	Component	Narrative
	Cognitive Goal:	
	Actor(s)	Provider Patient
	Action Breakdown	
	Technology	
	Standard	
	Appendix	
10	Action	PA/NP returns to the exam room. Vital signs (VS) are taken and entered in to the EHR.
	Cognitive Goal:	*Assess health status. Determine observations outside of normal limits. Identify risk factors for DM (i.e. elevated BMI)*
	Actor(s)	Provider Patient
	Action Breakdown	height=72” weight=235 lbs ***BMI=31 heart rate= 82 bpm respirations= 18 /min blood pressure= 128/78 mmHg temperature=97.9F Eye exam = Right 20/20, Left 20/20 without glasses Pupils: Equal
	Technology	EHR (Data entry)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	Pre-employment Physical Exam form (page 2) [http://healthcareexpress.us/downloads/physical_evaluation_form.pdf]
11	Action	PA/NP performs a head to toe assessment, documents findings in EHR, and completes pre-employment physical form.
	Cognitive Goal:	*Assess health status. Determine observations outside of normal limits. Identify areas of concern if DM is confirmed (i.e. ingrown toenail)*
	Actor(s)	Provider Patient
	Action Breakdown	Eyes/Ears/Nose/Throat: Within normal limits (WNL)

Step	Component	Narrative
		Heart: S1S2, regular Pulses: + 2 throughout Lungs: clear bilaterally Abdomen: soft, benign, waist circumference = 42 inches Skin: intact. Visual inspection of feet: Ingrown toenail
	Technology	EHR (Data entry)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Pre-employment Physical Exam form (page 2) [http://healthcareexpress.us/downloads/physical_evaluation_form.pdf]
12	Action	Point-of-care (POC) analysis—fasting glucose performed due to elevated results in the past. Results entered in to EHR.
	Cognitive Goal:	*Evaluate fasting glucose to determine validity of differential diagnosis. If elevated, this is the second incidence of an elevated fasting blood glucose, therefore the patient will be diagnosed with DM Type 2.*
	Actor(s)	Provider Patient
	Action Breakdown	POC fasting glucose=145mg/dL
	Technology	EHR (Data entry)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	
13	Action	PA/NP utilizes hyperlinks to clinical guidelines and decision support resources to confirm diagnosis
	Cognitive Goal:	*Validate working diagnoses of Obesity and DM Type 2 by utilizing scientific resources.*
	Actor(s)	Provider Patient
	Action Breakdown	a. Provider views clinical guidelines for obesity and DM Type 2 that are available via an InfoButton and validates: a. Patient is obese based on BMI i. Obesity is added to the Problem List b. Fasting glucose is elevated. Since this is the second occurrence of fasting glucose >=126, the patient is now diagnosed as having DM Type 2 i. DM Type 2 is added to the Problem List

Step	Component	Narrative
	Technology	EHR (Links to Clinical Resources and Data entry on Problem List)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Standards of Medical Care in Diabetes [http://care.diabetesjournals.org/content/36/Supplement_1/S11.full] VA Clinical Practice Guidelines for Management of DM [http://www.healthquality.va.gov/guidelines/CD/diabetes/DM2010_FUL-v4e.pdf]
14	Action	PA/NP discusses findings and health concerns noted during the examination
	Cognitive Goal:	*Evaluate patient understanding and engagement following discussion of diagnoses' and indications for care.*
	Actor(s)	Provider Patient
	Action Breakdown	a. Patient is Obese based on elevated BMI b. Patient has Type 2 Diabetes Mellitus based on evidence of elevated fasting blood glucose levels >= 126 on 2 different occasions c. Provider discusses the clinical significance of these diseases, their impact on the body, and recommended treatment regimens a. Provider recommends detailed follow up for DM to properly manage the disease, along with a weight loss program (since DM may be caused by the obesity). b. Discuss the need for lifestyle changes and the possibility of starting on an oral hypoglycemic medication d. Patient is cleared for employment
	Technology	
	Standard	
	Appendix	
15	Action	Patient and PA/NP discuss the patient's goals based on these physical findings and recommendations
	Cognitive Goal:	*Understand patient perspective and goals. Begin to formulate a personalized plan of care for the patient.*
	Actor(s)	Provider Patient
	Action Breakdown	a. Patient states that they want to lose weight, since that will reduce insurance premiums and help with the diabetes b. They prefer group exercise classes, otherwise they tend to skip work out sessions. c. They also want to learn about as much as possible about DM, because they do not know anything about it.

Step	Component	Narrative
		d. They prefer to try lifestyle modification (diet and exercise) to manage their blood sugar before starting on a medication
	Technology	EHR (Data entry of Patient Goals and priorities)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Shared Decision Making Resource [http://www.healthquality.va.gov/guidelines/CD/diabetes/cpgSDMDMPOCKETFinalPRESS022513.pdf]
16	Action	Provider develops a care plan with the patient, based on their stated goals
	Cognitive Goal:	*Appropriate selection of interventions based on the patient's condition and preferences.*
	Actor(s)	Provider Patient
	Action Breakdown	a. Order: Chem 7, CBC, ***Fasting Lipid Profile, urine for microalbuminuria, and HbA1c **to be drawn during this appointment**. a. Add task for OC to print out lab orders b. Follow up in one month to evaluate blood sugar and weight with lifestyle modifications a. Add task for OC to schedule a follow up appointment in 1 month c. ***Refer to weight loss program for diet, exercise and behavior modification – *Make first appointment within next week. • *Weight loss goal – 5 pounds within next month d. Provide brochures on free exercise classes at local community center • *Attend 1 hour exercise class 3 times a week and walk 2 miles 4 times a week e. Refer to diabetic educator for disease specific education related to symptoms and management • *Make first appointment within next week f. Refer to support group education sessions for newly diagnosed diabetics. • *Attend one meeting/month g. ***Refer to Podiatrist • *Make appointment within next month • Provider adds task to review outcome of referral in 6 weeks h. ***Refer to Ophthalmologist • *Make appointment within next month. • Provider adds task to review outcome of referral in 6 weeks

Step	Component	Narrative
		i. Encourage patient to utilize patient portal Provide access information to patient portal so that patient can view records at any time j. Establish personalized goals: • *Maintain HbA1c < 7% • *Fasting blood sugar <125 • *BP < 140/80 • *LDL < 125 mg/dL
	Technology	EHR (Data entry of Care Plan)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	Physician Referral Form [http://www.mayo.edu/pmts/mc0600-mc0699/mc0688-04.pdf] VA Clinical Guidelines for Obesity [http://www.healthquality.va.gov/guidelines/CD/obesity/VADoDOBECPGPocketCardFINAL070314.pdf] DM Teaching Checklist [http://www.healthquality.va.gov/guidelines/CD/diabetes/DiabetesTeachingChecklist.pdf] Teaching Points for Patients with DM [http://www.healthquality.va.gov/guidelines/CD/diabetes/DiabetesTeachingFlipChart.pdf]
17	Action	Provider creates a care plan with the patient (based on their stated goals), then closes the OV by having the patient do a “return demonstration” of their next steps in the management of their health. This includes time frames for completion of each event. An after visit summary [http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/13_Clinical_Summaries.pdf] (AVS) is provided.
	Cognitive Goal:	*Evaluate patient understanding of the plan of care, along with their level of commitment. Determine if the patient would benefit from additional support mechanisms.*
	Actor(s)	Provider Patient
	Action Breakdown	Care Plan Activities / Targeted Completion a. Fasting lab work at the end of this visit. / Now b. Follow up appt. / 1 Month c. Make appt. w/ weight loss program and diabetic educator within next week / 1 week d. Lose 10 lbs within next 3 months (patient will monitor progress weekly) / 3 months

Step	Component	Narrative
		e. Attend exercise class 3 x's/week and walk 4 x's/week / weekly f. Attend 1 DM group therapy session per month / 1 month g. Make appointments. with Podiatrist and Ophthalmologist and be seen by these specialists within the next month / 1 month h. Work to achieve my personal goals / Ongoing *Note: Graphic User Interface (GUI) would allow user to populate a target date for each activity (i.e. 1 day = 1.10.15), along with a Completed date when the activity is completed/closed. GUI will also allow provider to view progress towards toward Activity Completion, if the activity spans a period of time (i.e. lose 10 lbs within the next 3 months).*
	Technology	EHR (Visualization of care plan)
	Standard	
	Appendix	AVS [http://www.healthit.gov/sites/default/files/avs-tech-guide.pdf]
18	Action	Patient 'checks out' with OC
	Cognitive Goal:	
	Actor(s)	Patient OC
	Action Breakdown	a. OC schedules follow up appointment in one week b. OC prints lab orders, labels blood vials and sends blood samples to lab c. OC marks the encounter as 'completed'
	Technology	Scheduling system (Data entry and visualization) CPOE (Visualization of lab orders for printing)
	Standard	
	Appendix	
19	Action	Provider signs off on the encounter
	Cognitive Goal:	
	Actor(s)	Provider
	Action Breakdown	a. Provider reviews and validates note and data entered during the encounter b. Provider signs off on the encounter
	Technology	EHR (Data entry and visualization)
	Standard	
	Appendix	
Alternative Flows:		
20	Action	Lab results are returned
	Cognitive Goal:	

Step	Component	Narrative
	Actor(s)	Patient
	Action Breakdown	a. Patient receives email notification that lab results are available on the patient portal i. Patient logs in to the patient portal to view results A. Patient clicks on information buttons for each result to view explanation of the lab test, result ranges, and links to additional information ii. Since Provider has set notification alert thresholds to only notify for abnormal results or lack of results, the lab results are added to the Provider's task list for viewing and the Provider only receives notification about elevated HbA1c and glucose levels
	Technology	
	Standard	
	Appendix	
21	Action	Patient has question about a specific lab result
	Cognitive Goal:	
	Actor(s)	Patient Provider
	Action Breakdown	a. Patient clicks on secure email icon within the patient portal, enters their question for the Provider, and hits the Send button b. Provider receives email notification that a secure message is waiting from a patient c. Provider enters secure email application, sends a response to the patient, and encourages the patient to email or call the office with any additional questions or concerns.
	Technology	
	Standard	
	Appendix	

6.9. Data fields required

See appendix references as examples/guides

6.10. Notes and Issues

1. Entries that include *** indicate compliance with a Meaningful Use clinical quality measure
    a. CMS 2 - Preventative Care and Screening: Screening for Clinical Depression and Follow-Up Plan

6.11. References for Clinical Management of Diabetes

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6.12. Additional References

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7. Follow-up Outpatient Visit for Established Diabetic Patient

DM 2

7.1. Introduction

1. This use case was created to evaluate the ontology created by the VistA Evolution GUI Research project. It includes common assessments, observations, interventions, and cognitive goals that arise while caring for a patient in this scenario to ensure that the ontology can accommodate these concepts.

2. All clinical data in this use case is synthetic. Data was created to support the flow of this use case and provide examples of clinical observations that are documented throughout the interaction.

3. Clinical decision making in this use case is based, primarily, on VA/DoD Clinical Practice Guidelines for the Management of Diabetes Mellitus in Primary Care, available at: http://www.healthquality.va.gov/guidelines/CD/diabetes/

4. Additional clinical resources are listed below in the Reference section.

5. Cognitive goals are included in some 'Actions' to provide insight on the Provider or healthcare professional's mental process at that point of the encounter.

6. Hyperlinks present in the Appendix column are included to provide examples of the data fields and values that may be entered by the EHR user during this step of the use case.

7. Hyperlinks present in the Standards column suggest standardized terminologies that may be used to capture data in this step of the use case.

7.2. Actors

Patient: a person receiving or registered to receive medical treatment.

Provider: a skilled health-care professional that is trained and licensed to practice medicine. This includes: Physician (MD or DO), nurse practitioner (NP) or physician assistant (PA).

Medical Office Assistant (MOA) also known as a Medical Assistant or Medical Technician: a health-care care team member that performs administrative and/or clinical tasks to support the work of Providers or other health professionals.

7.3. Description

Routine follow-up visit for previous diagnosis of patient with Diabetes Mellitus Type 2 (DM2)

7.4. Trigger

Patient arrives to physician office for their DM2 routine follow-up

7.5. Preconditions

1. Patient has already been diagnosed with DM2
2. Patient has an established relationship with this primary care provider.
3. Patient had laboratory tests completed one week prior to office visit.

a. Fasting—Chem7 (blood):

vi. sodium (NA)=140 mEq/L

vii. potassium (K)=4.5 mEq/L

vi- blood urea nitrogen (BUN)=13 mg/dL
ii.

ix. creatinine (Cr)=0.9 mg/dL

x. glucose=**120 (H)**

b. Fasting—glycated hemoglobin (HbA1c)=**7.5 (H)**

c. ***Fasting—lipid panel:

i. total cholesterol=185 mg/dL

ii. triglycerides=150 mg/dL

iii. high-density lipoproteins (HDL)=60 mg/dL

iv. low-density lipoproteins (LDL)=125 mg/dL

d. ***Micro-albumin (urine)=22 mg

7.6. Postconditions

Minimal guarantees:

1. Data fields required to support this clinical workflow will be present in the EHR.
2. Data entered will be stored utilizing the appropriate clinical vocabulary.

Success guarantees:

1. EHR supports patient-centered care, guided by goals set by the patient.
2. Patient receives evidence-based care based on the health concerns that are noted during the outpatient visit.
3. Patient will achieve improved outcomes and satisfaction as a result of care facilitated by EHR functionality.

7.7. Assumptions

1. EHR can manage the transition of MOA to Provider (e.g., move from one work list to another)
2. For this use case, the physician may also be substituted with another diagnostician—nurse practitioner (NP) or physician assistant (PA).
3. Cognitive decision making throughout this office visit is based on VA Clinical Practice Guidelines for Management of DM [http://www.healthquality.va.gov/guidelines/CD/diabetes/DM2010_FUL-v4e.pdf]
4. Standard vocabularies utilized by the organization include: ICD 10 for Diagnosis, RxNorm for medications, SNOMED-CT for clinical assessments, care that is provided and lab results, and LOINC for laboratory tests.
5. Diabetic patients on oral hypoglycemic medications are managed by their primary care provider.

7.8. Normal Flow

Step	Component	Narrative
1	Action	Patient checks-in at front desk of medical office
	Cognitive Goal:	
	Actor(s)	MA Patient
	Action Breakdown	a. Validates current patient demographics and billing information b. Registration to EHR: flagged 'ready to be roomed'
	Technology	Registration System (Data entry)
	Standard	a. Address [http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf] b. Sex [http://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.1038] c. Ethnicity [http://www.whitehouse.gov/omb/fedreg_1997standards] d. Race [http://www.cdc.gov/minorityhealth/populations/REMP/definitions.html]
	Appendix	New Patient Sheet [https://www.freeprintablemedicalforms.com/download.php?file=TmV3X1BhdGllbnRfU2hlZXQucGRmLDE0OTY3MDMxNDUsZmNlNGZkZjgzYTY5Y%3D]
2	Action	Patient is seated in waiting room
	Cognitive Goal:	
	Actor(s)	Patient
	Action Breakdown	
	Technology	

Step	Component	Narrative
	Standard	
	Appendix	
3	Action	Patient is escorted in to an exam room
	Cognitive Goal:	
	Actor(s)	
	Action Breakdown	MOA
	Technology	Patient is placed in room (in EHR)
	Standard	
	Appendix	
4	Action	Patient reports chief complaint (CC), and provides updates on psycho-social and medical history
	Cognitive Goal:	*Determine the reason for the patient's visit and relevant updates to their medical history.*
	Actor(s)	MOA Patient
	Action Breakdown	a. Reviews and validates reason for visit—routine OV for DM2 management b. Reviews and updates psychosocial history
	Technology	EHR (Visualization of Health History and Data entry
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]
	Appendix	Adult Health History [http://georgetownmedical.com/util/documents/hx-physical-form.pdf] Health Risk Assessment VA Clinical Practice Guidelines for Management of DM [http://www.healthquality.va.gov/guidelines/CD/diabetes/DM2010_FUL-v4e.pdf]
5	Action	MOA asks patient to provide an update on current medications
	Cognitive Goal:	*Thorough understanding and documentation of reported meds.*
	Actor(s)	MOA Patient
	Action Breakdown	MOA initiates ***Medication reconciliation [http://www.healthit.gov/providers-professionals/achieve-meaningful-use/menu-measures/medication-reconciliation] by documenting a list of current medications that the patient reports taking. *(Medication reconciliation is not finalized until the provider reviews ordered medications, compares the two lists and makes clinical decisions based on the comparison.)*
	Technology	EHR (Visualization of Interventions and Data entry)

Step	Component	Narrative
	Standard	a. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	VA Medication Reconciliation [http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2390]
6	Action	Patient provides MOA 90-day history of glucose readings from patient (if available).
	Cognitive Goal:	
	Actor(s)	MOA
	Action Breakdown	a. Patient reviews 90-day glucose history and places in temporary paper chart.
	Technology	EHR (Data entry)
	Standard	
	Appendix	Blood Sugar Tracker
7	Action	Vital signs (VS) are taken and entered in to the EHR
	Cognitive Goal:	
	Actor(s)	MOA Patient
	Action Breakdown	height=72” weight=265 lbs ***BMI=35.9 heart rate= 80 bpm respirations= 18 /min blood pressure= 124/78 mmHg temperature=98.4F
	Technology	EHR (Data entry)
	Standard	a. LOINC [http://search.loinc.org/] b. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Diabetes Provider Visit Form [http://www.diabetesinitiative.org/resources/tools/documents/45-PROV-ProviderSOAPform_web.pdf] (Section ‘O’) Diabetic Clinical Form and Problem List [http://www.diabetesinitiative.org/resources/tools/documents/3-MAIC-Clinicalform_resources_web.pdf]
8	Action	Point-of-care (POC) analysis—glucose performed and results entered in to EHR
	Cognitive Goal:	
	Actor(s)	MOA Patient

Step	Component	Narrative
	Action Breakdown	POC glucose=154mg/dL
	Technology	EHR (Data entry)
	Standard	a. LOINC [http://search.loinc.org/] b. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Diabetes Provider Visit Form [http://www.diabetesinitiative.org/resources/tools/documents/45-PROV-ProviderSOAPform_web.pdf] (Section 'O')
9	Action	Patient ready for provider
	Cognitive Goal:	
	Actor(s)	MOA
	Action Breakdown	'Ready for provider' flag initiated in EHR
	Technology	EHR (Status entry)
	Standard	
	Appendix	
10	Action	Provider reviews patient chart prior to entering patient room
	Cognitive Goal:	*Formulate priorities for this encounter (i.e. evaluation of current therapy). Determine if there are gaps in information or areas of concern to address. Evaluate gathered observations for trends or concerns.*
	Actor(s)	Provider
	Action Breakdown	a. Reviews past medical history (PMH), current medications and dosages, recent lab results and lab trends, recent diagnostic procedure results (if applicable), recent reports from specialist referrals b. Reviews information entered by MOA (including VS and Health Risk Assessment form) and evaluates for trends or concerns c. Evaluates patient's 90 day glucose history
	Technology	EHR (Visualization of Problem List, Patient History, Interventions and Observations)
	Standard	a. LOINC [http://search.loinc.org/] b. SNOMED-CT [http://browser.ihtsdotools.org/] c. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/] d. ICD-10 [http://www.icd10data.com/]
	Appendix	Diabetes Provider Visit Form [http://www.diabetesinitiative.org/resources/tools/documents/45-PROV-ProviderSOAPform_web.pdf] (completes chart and lab review section) Diabetic Clinical Form and Problem List [http://www.diabetesinitiative.org/resources/tools/documents/3-MAIC-Clinicalform_resources_web.pdf]
11	Action	Provider enters patient room and greets patient
	Cognitive Goal:	

Step	Component	Narrative
	Actor(s)	
	Action Breakdown	
	Technology	
	Standard	
	Appendix	Diabetes Provider Visit Form [http://www.diabetesinitiative.org/resources/tools/documents/45-PROV-ProviderSOAPform_web.pdf] (Section 'S')
12	Action	Provider discusses the patient's concerns and complaints and documents them
	Cognitive Goal:	*Establish patient's perspective on their health and disease management. Formulate discussion points or interventions to address patient's concerns*
	Actor(s)	Provider Patient
	Action Breakdown	"Sometimes I forget to take my medications in the morning because I am rushing out the door. I don't have time to pack my lunch, so I eat out nearly every day."
	Technology	EHR (Data entry)
	Standard	
	Appendix	Diabetes Provider Visit Form [http://www.diabetesinitiative.org/resources/tools/documents/45-PROV-ProviderSOAPform_web.pdf] (Section 'S')
13	Action	Provider completes and validates ***Medication Reconciliation
	Cognitive Goal:	*Determine if there are discrepancies between what meds the patient is taking and what they were ordered. Clarify expectations and medication orders to ensure proper provision of care and compliance.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider discusses what the patient states that they are currently taking against the medication that has been prescribed. a. Provider creates an updated list of current medications, documents the list in the system, and provides the patient with a copy at the end of the visit. *(Note: This information is included in the After Visit Summary)*
	Technology	EHR (Data entry)
	Standard	a. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	VA Medication Reconciliation [http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2390]
14	Action	Provider completes a head to toe assessment and documents results
	Cognitive Goal:	*Determine assessments that require discussion and/or follow-up. Evaluate for complications of DM.*
	Actor(s)	Provider Patient

Step	Component	Narrative
	Action Breakdown	Head/Neuro: WNL Heart: S1S2, BP normal Lungs: Clear Abdomen: Soft, benign Extremities: No swelling, bilateral pedal pulses +2, Foot exam: skin intact. ***Referral provided for annual evaluations (podiatrist, ophthalmologist)
	Technology	EHR (Data entry)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	Physical Exam (p 2) [https://www.uthsc.edu/gim/documents/ward-H&P.pdf] Physician Referral Form [http://www.mayo.edu/pmts/mc0600-mc0699/mc0688-04.pdf] (additionally allow the attachment of most recent OV, lab values, or other diagnostics)
15	Action	Provider discusses blood sugar control
	Cognitive Goal:	*Evaluate effectiveness of current care regimen. Refine the list of potential interventions to address noted concerns.*
	Actor(s)	Provider Patient
	Action Breakdown	a. Reviews 90-day history of home glucose readings (Average fasting glucose = 120) b. Reviews HbA1c result (HbA1c = 7.5) and trend. Shows patient data visualization. c. Reviews current diabetes medications 500mg Metformin BID (preferably AM meal and PM meal)
	Technology	EHR (Visualization of Interventions and Observations)
	Standard	a. LOINC [http://search.loinc.org/] b. SNOMED-CT [http://browser.ihtsdotools.org/] c. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	
16	Action	Patient discusses his/her goal related to diabetes management
	Cognitive Goal:	*Adjust potential interventions based on the patient's goals and preferences.*
	Actor(s)	Patient Provider
	Action Breakdown	“I really want to remain on a pill to control my blood sugar. I don’t want to have to start insulin injections”

Step	Component	Narrative
		a. ***Provider initiates dietary counsel referral for nutrition coaching (eating healthy with a busy lifestyle, tips/tricks) b. Improve Rx compliance by providing tips/tricks (place morning medication in briefcase or lunch bag) c. Provide referral to community wellness center (that provides group time management classes)
	Technology	EHR (Visualization of Goals, Order entry for referrals)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]
	Appendix	
17	Action	Provider assesses tobacco use
	Cognitive Goal:	*Address DM risk factors to improve ability to manage the disease. Select indicated cessation therapy if patient agrees to tobacco cessation.*
	Actor(s)	Provider Patient
	Action Breakdown	a. Pt. states that they smoke ½ pack of cigarettes a day and are open to quitting. b. Diagnosis of Tobacco User added to Problem List c. ***Tobacco Cessation protocol initiated VA Clinical Guideline for Treating Tobacco Use [http://www.healthquality.va.gov/guidelines/CD/mtu/phs_2008_quickguide.pdf] d. Prescription written for tapering dose of Nicotine patch: 21mg every day for 4 weeks, followed by 14 mg every day for 4 weeks, followed by 7mg patch every day for 4 weeks e. Start group counseling for cessation therapy f. Provide telephone counseling resource and printed materials on smoking cessation
	Technology	EHR
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. RxNorm [http://www.nlm.nih.gov/research/umls/rxnorm/] c. ICD-10 [http://www.icd10data.com/]
	Appendix	*Note: Provider navigates to medication order screen*
18	Action	*Provider closes outpatient visit by having the patient do a "return demonstration" of their next steps in the management of their health. This includes time frames for completion of each event. An after visit summary [http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/13_Clinical_Summaries.pdf] (AVS) is provided

Step	Component	Narrative
	Cognitive Goal:	*Evaluate patient understanding of the plan of care, along with their level of commitment. Determine if the patient would benefit from additional support mechanisms.*
	Actor(s)	Provider Patient
	Action Breakdown	Care Plan Activities / Targeted Completion a. Referral to Podiatrist by physician / Immediately b. Patient seen by a Podiatrist / 4 weeks c. Referral to Ophthalmologist by physician / Immediately d. Patient seen by an Ophthalmologist / 4 weeks e. Referral to Nutritionist by physician / Immediately f. Patient seen by a Nutritionist / 4 weeks g. Referral to community wellness center by physician / Immediately h. Medication management reinforcement by physician / Immediately i. Smoking cessation teaching with prescription aid / 1 week j. Repeat Chem7 and HbA1c one week prior to next visit. Lab slips provided to patient / 11 weeks k. Complete Nicotine patch tapering dose regimen as ordered / Immediately l. Provide referral for tobacco cessation group therapy, cessation literature, and telephone ‘quit line’ number / Immediately m. Follow-up visit scheduled in 3 months / 12 weeks *Note: Graphic User Interface (GUI) would allow user to populate a target date for each activity (i.e. 1 week = 1.17.15), along with a Completed date when the activity is completed/closed.* *Note: Patient understands that they are responsible for making appointments for all referrals, follow up visits, and lab work.*
	Technology	EHR (Data Entry, Registration/Scheduling)
	Standard	
	Appendix	AVS [http://www.healthit.gov/sites/default/files/avs-tech-guide.pdf]

7.9. Data fields required

See appendix references as examples/guides

7.10. Exceptions

1. Patient does not bring historic glucose readings to the appointment, therefore it cannot be entered
2. Patient refuses one or more evaluations of VS, therefore results cannot be entered in EHR

7.11. Notes and Issues

1. Entries that include *** indicate compliance with a Meaningful Use clinical quality measure
   a. CMS 123 – Diabetes: Foot Exam
   b. CMS 131 – Diabetes: Eye Exam
   c. CMS 134 – Diabetes: Urine Protein Screening
   d. CMS 64 – Diabetes: LDL Management
   e. CMS 88 – Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy
   f. CMS 68 – Documentation of Current Medications in the Medical Record
   g. CMS 138 – Preventative Care and Screening: Tobacco Use: Screening and Cessation Intervention
   h. CMS 69 – Preventative Care and Screening: BMI Screening and Follow up Plan

7.12. References for Clinical Management of Ischemic Heart Disease

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8. Referral to Podiatry for newly diagnosed patient with diabetes mellitus type 2

This patient is also new to the podiatry practice. DM 3

8.1. Introduction

1. This use case was created to evaluate the ontology created by the VistA Evolution GUI Research project. It includes common assessments, observations, interventions, and cognitive goals that arise while caring for a patient in this scenario to ensure that the ontology can accommodate these concepts.

2. All clinical data in this use case is synthetic. Data was created to support the flow of this use case and provide examples of clinical observations that are documented throughout the interaction.

3. Clinical decision making in this use case is based, primarily, on VA/DoD Clinical Practice Guidelines for the Management of Diabetes Mellitus in Primary Care, available at: http://www.healthquality.va.gov/guidelines/CD/diabetes/

4. Additional clinical resources are listed below in the Reference section.

5. Cognitive goals are included in some 'Actions' to provide insight on the Provider or healthcare professional's mental process at that point of the encounter.

6. Hyperlinks present in the Appendix column are included to provide examples of the data fields and values that may be entered by the EHR user during this step of the use case.

7. Hyperlinks present in the Standards column suggest standardized terminologies that may be used to capture data in this step of the use case.

8.2. Actors

Patient: a person receiving or registered to receive medical treatment

Provider: Physician, physician assistant (PA), or nurse practitioner (NP). These skilled health-care professionals are trained and licensed to diagnose and treat patients within their defined scope of practice.

Office Clerk (OC): an administrative assistant that manages appointment schedules for the physicians in the practice and handles insurance coverage intake and receipt of co-pays for office visits.

8.3. Description

New patient presents to podiatry practice for an initial diabetic foot exam (patient is newly diagnosed with DM type 2, with a mild ingrown toenail)

Note: This referral results from the DM1 use case.

8.4. Trigger

1. Patient arrives to podiatry practice office for a scheduled diabetic foot exam

2. Minimum demographic data was collected from patient over-the-phone for pre-arrival insurance/eligibility verification

3. Referral was received from primary care provider (for diabetic foot care, podiatrist)

8.5. Preconditions

1. The patient brings a copy of their most recent lab work drawn from primary care outpatient visit:

   a. Fasting—chem7 (blood):

      i. sodium (NA)=137 mEq/L

      ii. potassium (K)=3.7 mEq/L

iii. blood urea nitrogen (BUN)=12 mg/dL

iv. creatinine (Cr)=0.7 mg/dL

v. glucose=**134**

b. Fasting—glycated hemoglobin (HbA1c)=6.6

c. Lipids

d. Fasting—glycated hemoglobin (HbA1c)=**7.5**

e. Fasting—lipid panel:

i. total cholesterol=185 mg/dL

ii. triglycerides=150 mg/dL

iii. high-density lipoproteins (HDL)=60 mg/dL

iv. low-density lipoproteins (LDL)=125 mg/dL

f. micro-albumin (urine)=22 mg

8.6. Postconditions

Minimal guarantees:

1. Data fields required to support this clinical workflow will be present in the EHR
2. Data entered will be stored utilizing the appropriate clinical vocabulary

Success guarantees:

1. EHR supports patient-centered care, guided by goals set by the patient.
2. Patient receives evidence-based care based on the health concerns that are noted during the outpatient visit
3. Patient will achieve improved outcomes and satisfaction as a result of care facilitated by EHR functionality

8.7. Assumptions

1. The practice utilizes patient portal tablets in their office to capture patient demographic, PMH, CC info, etc.
   a. The patient portal can sync with the EHR and populate required fields in the EHR
   b. The patient portal enforces mandatory fields to ensure that all required data is captured
   c. The patient enters all relevant and required information
2. EHR can manage the transition of OC to provider (e.g., move from one work list to another)
3. EHR has computerized physician order entry functionality

4. EHR is able to receive referral request as entered by provider

5. Standard vocabularies utilized by the organization include: ICD10 for Diagnosis, RxNorm for medications, SNOMED-CT for clinical assessments, care that is provided and lab results, and LOINC for laboratory tests.

8.8. Normal Flow

Step	Component	Narrative
1	Action	Patient checks in at front desk of medical office
	Cognitive Goal:	
	Actor(s)	OC Patient
	Action Breakdown	OC marks the patient as present in the scheduling system
	Technology	Scheduling system (data entry)
	Standard	
	Appendix	
2	Action	OC provides the patient with an electronic tablet to finish new patient information (e.g. demographic info, PMH, etc.)
	Cognitive Goal:	
	Actor(s)	OC Patient
	Action Breakdown	Patient enters the following information in to the system: a. Validates demographic information b. Validates insurance: Tricare, member #: xxx-xx, etc. c. PMH: melanoma on nose 2007, appendectomy 1990 d. Allergies: Penicillin (hives) e. Current medications: none f. Smoker: No g. Alcohol Use: No h. Reason for visit: Initial diabetic foot exam (ingrown toenail noted by primary care physician)
	Technology	EHR Patient Portal (Data entry)
	Standard	
	Appendix	New Patient Sheet [https://www.freeprintablemedicalforms.com/download.php?file=TmV3X1BhdGllbnRfU2hlZXQucGRmLDE0OTY3MDMxNDUsZmNlNGZkZjgzYTY5Y%3D]

Step	Component	Narrative
		Adult Health History [http://georgetownmedical.com/util/documents/hx-physical-form.pdf]
3	Action	OC accepts tablet back from patient, syncs it with the EHR, and completes registration process
	Cognitive Goal:	
	Actor(s)	OC
	Action Breakdown	a. Validates that all required fields are populated and house relevant data b. Enters demographic information in to EHR using standard vocabulary c. Registration to EHR: flagged 'ready for provider'
	Technology	Registration system (data transfer and validation)
	Standard	a. Address [http://pe.usps.gov/cpim/ftp/pubs/Pub28/pub28.pdf] b. Sex [http://phinvads.cdc.gov/vads/ViewValueSet.action?oid=2.16.840.1.114222.4.11.1038] c. Ethnicity [http://www.whitehouse.gov/omb/fedreg_1997standards] d. Race [http://www.cdc.gov/minorityhealth/populations/REMP/definitions.html]
	Appendix	
4	Action	Podiatrist reviews information provided by the patient via the portal, lab results presented to the OC and in the system, the referral sent by the primary care physician, and then searches the EHR system for other health care occurrences
	Cognitive Goal:	*Formulate priorities for this encounter (i.e. document thorough baseline assessment and educate patient on indicated foot care regimen for diabetic patients). Determine if there are gaps in information or areas of concern to address. Evaluate severity of ingrown toenail noted in primary care notes.*
	Actor(s)	Provider
	Action Breakdown	a. Provider queries the system by patient name and is able to view data entered during the patient's recent Primary Care visit. b. Provider is also able to view lab results from recent blood draw.
	Technology	EHR (Query and visualization)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI] c. ICD-10 [http://www.icd10data.com/]
	Appendix	
5	Action	OC calls patient in to examination room
	Cognitive Goal:	
	Actor(s)	OC

Step	Component	Narrative
		Patient
	Action Breakdown	Patient is placed in room (in EHR)
	Technology	EHR (Data entry)
	Standard	
	Appendix	
6	Action	OC enters room with patient and takes Vital signs (VS) and enters VS in to the EHR
	Cognitive Goal:	
	Actor(s)	OC Patient
	Action Breakdown	height=72” weight=235 lbs ***BMI=31 heart rate= 82 bpm respirations= 18 /min blood pressure= 128/78 mmHg temperature=97.9F
	Technology	EHR (Data entry)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	
7	Action	Podiatrist enters exam room and discusses the reason for the patient’s visit/ chief complaint (CC) and updates the medical history
	Cognitive Goal:	*Clarify reason for visit and capture accurate PMH*
	Actor(s)	Provider Patient
	Action Breakdown	Patient reports that they are “there to have a foot exam because of the new diabetes diagnosis.” a. Reviews and validates reason for visit—diabetic foot exam b. Reviews and updates medical history c. Enters relevant existing history to the Active Problem List
	Technology	EHR (Visualization of Health History and Data entry)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]

Step	Component	Narrative
	Appendix	
8	Action	Podiatrist discusses lab results brought by the patient that were drawn by primary care provider (all results are within normal limits except fasting glucose = 110, HbA1c = 7.2%)
	Cognitive Goal:	*Evaluate severity of condition and patient's perspective on their disease.*
	Actor(s)	Provider Patient
	Action Breakdown	Patient states, “The other doctor explained that my blood sugar was high on more than two occurrences, and I have been diagnosed with diabetes. He said that my feet and eyes are at higher risk for issues, so I decided to take the referral and come see you. I feel fine though. I haven’t had any problems with my feet, except for this toenail that is a little ingrown.”
	Technology	EHR (Visualization of lab results)
	Standard	a. LOINC [http://search.loinc.org/search.zul?query=BMI]
	Appendix	
9	Action	Podiatrist asks patient to remove socks and shoes
	Cognitive Goal:	
	Actor(s)	Provider Patient
	Action Breakdown	
	Technology	
	Standard	
	Appendix	
10	Action	Podiatrist performs a comprehensive foot exam and documents findings in EHR
	Cognitive Goal:	*Assess condition of patient's feet. Determine observations outside of normal limits. Identify areas of concern (i.e. ingrown toenail), and begin for formulate potential interventions.*
	Actor(s)	Provider Patient
	Action Breakdown	Provider performs foot risk assessment, wound assessment, and physical exam of both feet, then documents the results. 1. Skin: integrity intact (skin warm, good turgor, skin dry, color normal (except for skin on right medial big toe along toenail, which is slightly red) 2. Nails: normal color, thickness, and intact 3. Pedal pulses + (posterior tibial, dorsalis pedis, right/left) 4. Monofilament test: + on five areas, right/left)

Step	Component	Narrative
		5. Wound assessment: Medial portion of right big toe (approx. 5 mm x 5mm) at top of toenail is slightly red. No breakdown. No sign of infection. 6. Foot risk assessment (low risk) ****NOTE: Visual, sensory and pulse exams meet care measured in CMS 123 (a Meaningful Use diabetes foot care measure)*
	Technology	EHR (Data entry)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]
	Appendix	Annual Comprehensive Diabetes Foot Exam Form VA Clinical Practice Guidelines for Management of DM [http://www.healthquality.va.gov/guidelines/CD/diabetes/DM2010_FUL-v4e.pdf], Algorithm F (Foot Screening)
11	Action	Podiatrist discusses findings and health concerns noted during the examination
	Cognitive Goal:	*Evaluate patient understanding and engagement following discussion of clinical findings.*
	Actor(s)	Provider Patient
	Action Breakdown	a. Patient is obese based on BMI. Increased BMI contributes to diagnosis of diabetes. b. Diabetic foot exam yielded the following results: feet in good health, except for mild ingrown toenail on right great toe. Ingrown toenail can be removed during this visit.
	Technology	EHR (Data entry on Problem List)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]
	Appendix	Standards of Medical Care in Diabetes [http://care.diabetesjournals.org/content/36/Supplement_1/S11.full]
12	Action	Patient and podiatrist discuss the patient's goals based on these physical findings and recommendations
	Cognitive Goal:	*Understand patient perspective and goals. Begin to formulate a personalized plan of care for the patient.*
	Actor(s)	Provider Patient
	Action Breakdown	a. Patient states that he wants to lose weight, since that will reduce insurance premiums and help with the diabetes b. Patient indicates that he wants to take care of his feet so he does not have any issues and agrees to removal of ingrown toenail.

Step	Component	Narrative
		c. Provider and patient discuss recommended foot care for diabetic patients
	Technology	EHR (Data entry of Patient Goals and priorities)
	Standard	
	Appendix	Shared Decision Making Resource [http://www.healthquality.va.gov/guidelines/CD/diabetes/cpgSDMDMPOCKETFinalPRESS022513.pdf]
13	Action	Provider removes ingrown toenail
	Cognitive Goal:	
	Actor(s)	Provider Patient
	Action Breakdown	Provider removes ingrown toenail without complications. No infection noted. Skin intact, with slight inflammation.
	Technology	EHR (Data entry of procedure and assessment)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]
	Appendix	
14	Action	Provider educates patient on diabetic foot care and care for ingrown toenail
	Cognitive Goal:	*Evaluate patient understanding and level of commitment following discussion of agreed upon interventions.*
	Actor(s)	Provider Patient
	Action Breakdown	Patient education: a. Keep feet clean and moisturized (do not place lotion in between toes) b. Keep feet covered with cotton or wool socks c. Wear enclosed shoes that fit properly (while awake)—no bare feet d. Referred to local shoe cobbler that specializes in diabetic feet e. Inspect feet daily (recommended prior to bed when moisturizing) f. Monitor right great toe for signs and symptoms of infection [http://www.aafp.org/afp/2009/0215/p303.html]. Notify MD immediately if any signs are present. g. Notify MD if redness of right great toe worsens or does not improve over the next 3 days.
	Technology	EHR (Data entry of Education)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	VA Clinical Guidelines for Obesity [http://www.healthquality.va.gov/guidelines/CD/obesity/VADoDOBECPGPocketCardFINAL070314.pdf]

Step	Component	Narrative
		DM Teaching Checklist [http://www.healthquality.va.gov/guidelines/CD/diabetes/DiabetesTeachingChecklist.pdf]
15	Action	Provider develops a care plan with the patient (based on their stated goals), then closes the OV by having the patient do a "return demonstration" of their next steps in the management of their health. This includes time frames for completion of each event. An after visit summary [http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/13_Clinical_Summaries.pdf] (AVS) is provided
	Cognitive Goal:	*Evaluate patient understanding of the plan of care, along with their level of commitment. Determine if the patient would benefit from additional support mechanisms.*
	Actor(s)	Provider Patient
	Action Breakdown	Care Plan Activities / Targeted Completion a. Place into action learnings from provider/patient education (#12) / Immediately b. Maintain follow-up appointment with primary care provider / 3 months c. Annual podiatry OV (diabetic foot exam) / 1 year d. Referral: shoe cobbler (specializing in diabetic feet) for appropriate shoe size and types of shoes by physician / Immediately e. Make appointment with shoe cobbler / 2 weeks f. Maintain weight loss goals as outlined by primary care physician (10 lbs over the next 3 months) / 3 months g. Attend exercise class 3x/week and walk 4x/week / Immediately h. Monitor right great toe inflammation and for signs and symptoms of infection. Call MD with any concerns / Immediately and daily for next 2 weeks i. Provider will send consult note outlining findings and the plan of care to the referring Provider / Within 24 hours *Note: Graphic User Interface (GUI) would allow user to populate a target date for each activity (i.e. Immediately = 1.10.15), along with a 'Completed' date when the activity is completed/closed. GUI will also allow provider to view progress towards Activity completion, if the activity spans a period of time.* *Note: Patient understands that they are responsible for making appointments for all referrals, follow up visits, and lab work.*
	Technology	
	Standard	

Step	Component	Narrative
	Appendix	

8.9. Data fields required

See appendix references as examples/guides

8.10. Notes and Issues

Entries that include *** indicate compliance with a Meaningful Use clinical quality measure

8.11. References for Clinical Management of Diabetes

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9. Diabetes Care Coordinator Telephone Follow-Up

DM 4

9.1. Introduction

1. This use case was created to evaluate the ontology created by the VistA Evolution GUI Research project. It includes common assessments, observations, interventions, and cognitive goals that arise while caring for a patient in this scenario to ensure that the ontology can accommodate these concepts.
2. All clinical data in this use case is synthetic. Data was created to support the flow of this use case and provide examples of clinical observations that are documented throughout the interaction.
3. Clinical decision making in this use case is based, primarily, on VA/DoD Clinical Practice Guidelines for the Management of Diabetes Mellitus in Primary Care, available at: http://www.healthquality.va.gov/guidelines/CD/diabetes/
4. Additional clinical resources are listed below in the Reference section.
5. Cognitive goals are included in some 'Actions' to provide insight on the Provider or healthcare professional's mental process at that point of the encounter.
6. Hyperlinks present in the Appendix column are included to provide examples of the data fields and values that may be entered by the EHR user during this step of the use case.
7. Hyperlinks present in the Standards column suggest standardized terminologies that may be used to capture data in this step of the use case.

9.2. Actors

Patient: a person receiving or registered to receive medical treatment

Patient Care Coordinator (PCC): a professional (usually registered nurse or social worker) within the medical care team that works with patients and medical professionals to remove barriers and reach health care goals.

9.3. Description

A 30-day follow-up telephone call from the care coordinator to review the status of each of the care plan action items (managing treatment for diabetes mellitus type 2) identified/discussed during the previous primary care provider (PCP) office visit (OV).

9.4. Trigger

1. Patient had a previous primary care office visit for treatment of diabetes mellitus (T-30 days)

2. Minimum identification reviewed on the phone call to ensure protection of PHI.

9.5. Preconditions

PCP Care Plan Activities (previous office visit) / Targeted Completion

a. Fasting lab work in a.m. / 1 day

b. Make appt. w/ weight loss program and diabetic educator within next week / 1 week

c. Lose 10 lbs. within next 3 months / 90 days

d. Attend exercise class 3 x/week and walk 4 x/week / Immediately

e. Attend 1 DM group therapy session per month / Immediately

f. Make appts. with Podiatrist and Ophthalmologist within next month / 1 month

g. Keep follow-up appt. with primary care provider / 3 months

h. Work to achieve my personal goals / Ongoing

9.6. Postconditions

Minimal guarantees:

1. Data fields required to support this clinical workflow will be present in the EHR.
2. Data entered will be stored utilizing the appropriate clinical vocabulary.

Success guarantees:

1. EHR supports patient-centered care, guided by goals set by the patient.
2. Patient receives evidence-based care based on the health concerns that are noted during the associated provider visits.
3. Patient will achieve improved outcomes and satisfaction as a result of care facilitated by EHR functionality.

9.7. Assumptions

1. Patient Care Coordinator that is assigned to assist this patient with the management of their condition will have an ongoing relationship that spans the continuum of care. The relationship is built on trust, mutual respect, and a shared vision.
2. EHR can manage the documentation Provider to PCC (e.g., move from one work list to another)
3. EHR has capability for telephonic office visit (non-prescribing/non-diagnosing provider)
4. EHR has compatible patient portal (to facilitate information sharing)
5. Diabetics on oral hypoglycemic medications are managed by their primary care providers
6. Standard vocabularies utilized by the organization include: ICD10 for Diagnosis, RxNorm for medications, SNOMED-CT for clinical assessments, care that is provided and lab results, and LOINC for laboratory tests
7. The patient portal has capability to send email reminders

9.8. Normal Flow

Step	Component	Narrative
1	Action	Patient receives a telephone call from the PCC
	Cognitive Goal:	
	Actor(s)	PCC Patient
	Action Breakdown	PCC appropriately identifies patient (protecting PHI) and asks the patient if now is still a good time for a 20-minute follow-up call (related to the last primary care visit)
	Technology	EHR (telephone visit encounter)
	Standard	
	Appendix	
2	Action	PCC level sets on previously identified patient goals identified in the outpatient visit notes/care plan Noted in “Preconditions”
	Cognitive Goal:	*Verify patient goals, along with their understanding of the care plan*
	Actor(s)	PCC Patient
	Action Breakdown	PCC level sets with patient about reason for the call—review current status of action items identified/mutually agreed upon goals from the previous primary care office visit (30 days ago) as related to managing diabetes. The action items are available via a. The after visit summary (AVS) provided at the end of the previous primary care office visit b. The patient portal (where pertinent medical information is available to the patient)
	Technology	EHR (Patient Portal)
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/] c. LOINC
	Appendix	AVS [http://www.healthit.gov/sites/default/files/avs-tech-guide.pdf]
3	Action	PCC confirms that the patient did have labs drawn and reviews labs with patient
	Cognitive Goal:	*Determine patient compliance and identify opportunities to reinforce importance of lab work*
	Actor(s)	PCC Patient

Step	Component	Narrative
	Action Breakdown	Relevant labs (glucose and HgA1c) are reviewed (EHR and patient portal). PCC provides education on lab results, where gaps are identified.
	Technology	EHR (Patient Portal)
	Standard	a. LOINC b. SNOMED-CT [http://browser.ihtsdotools.org/]
	Appendix	
4	Action	PCC asks patient about the status of making an appt. with the diabetes educator
	Cognitive Goal:	*Determine patient compliance and identify ways to facilitate completion of task.*
	Actor(s)	PCC Patient
	Action Breakdown	a. Provider queries the system within the patient record and does not see a referring report from the diabetes educator (which would indicate an education OV). b. Patient notes that work has been busy, and that no time has been available to make the appointment c. To prevent ongoing procrastination, the PCC offers to make the appointment for the patient since the diabetes educator is part of the medical practice (using the same scheduling system and EHR). i. The appointment is sent to the patient portal
	Technology	EHR (Query and visualization) EHR provider directory Scheduling System Patient Portal
	Standard	a. SNOMED-CT [http://browser.ihtsdotools.org/] b. ICD-10 [http://www.icd10data.com/]
	Appendix	
5	Action	PCC asks patient about the status of going to a weight loss group
	Cognitive Goal:	*Determine patient compliance and identify alternative interventions that may work better for the patient.*
	Actor(s)	PCC Patient
	Action Breakdown	The PCC asks the patient about going to one of the group weight loss sessions (e.g., Weight Watchers). The patient indicates a lack of will and readiness. The PCC explores the option of seeing a therapist specializing in weight management and food relationships. The patient agrees to see a therapist. The PCC submits a referral request to the primary care doctor (since referrals must be from diagnosing clinicians). In the meantime, the PCC sets up the

Step	Component	Narrative
		therapist appointment, since the therapist is employed by the same health system using the EHR and central scheduling system. 1. The therapist referral (with associated notes from PCC follow-up phone call) is awaiting provider signature. Once signed, the referral will be available to the therapist's office (via the EHR). 2. The therapy appointment is sent to the patient portal.
	Technology	EHR (Data entry) EHR provider directory EHR queue management Scheduling System Patient Portal
	Standard	
	Appendix	
6	Action	PCC asks patient about exercise
	Cognitive Goal:	*Determine patient compliance*
	Actor(s)	PCC Patient
	Action Breakdown	Prior to asking, the patient quickly indicated that they have been taking evening walks around the block (a little over 1 mile) every night. The PCC uses positive reinforcement and encourages the patient to slowly increase activity as tolerated, and reiterates the need to "switch-up" exercise routines. The PCC asks the patient if he would like a referral to an exercise physiologist. The patient indicated that he enjoys walking and maybe later he will go see the "exercise guru."
	Technology	EHR EHR provider directory
	Standard	
	Appendix	
7	Action	PCC asks about scheduled podiatrist and ophthalmologist visits
	Cognitive Goal:	*Determine patient compliance*
	Actor(s)	PCC Patient
	Action Breakdown	Patient confirmed that visits have been scheduled with podiatrist and ophthalmologist
	Technology	EHR (manual data entry since ophthalmologist and podiatrist are outside of health system EHR)
	Standard	
	Appendix	

Step	Component	Narrative
8	Action	PCC reviews with patient next steps
	Cognitive Goal:	*Evaluate patient understanding, engagement, and buy-in to their plan of care.*
	Actor(s)	PCC Patient
	Action Breakdown	Patient and PCC agree to complete another follow-up call in 2 weeks to review: 1. Therapist session (not details, but that the event occurred) 2. Diabetes educator (not details, but that the event occurred) 3. Determine if referral to exercise physiologist is necessary 4. Podiatry appointment outcome 5. Ophthalmology appointment outcome 6. PCC reviews contact information and asks if there are any unanswered questions 7. Patient thanks the PCC for the follow-up phone call
	Technology	
	Standard	
	Appendix	

9.9. Data fields required

See appendix references as examples/guides

9.10. Notes and Issues

References for Clinical Management of Diabetes

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A. Statement Use Cases

A.1. USE CASE 1: DEPRESSION: FOLLOW-UP OUTPATIENT VISIT

ACTORS

- Patient
- Medical Office Assistant
- Provider

PRECONDITIONS

This is a 32-year old male with a 6-month history of major depression on Zoloft and receiving group psychotherapy. Risk assessment scores from the last visit 1 month ago: PHQ-9 (15), PCL (16), AUDIT-C (0), ASSIST (10) for tobacco only. No suicidal ideation or risk of violence towards others.

- **PMH:** Patient had right above the knee amputation (AKA) 6 months ago and has prosthesis. Denies substance use of medications. Smokes 2 ppd. Patient does not have a traumatic brain injury (TBI).
- **Psychosocial:** Patient is S/P 2 deployments to Afghanistan, is estranged from family, has no close friends, lives alone, and is unemployed. His best friend died during their last deployment together, when the patient was injured. He attends AA meetings daily, is undergoing vocational rehabilitation and has been seen by a community social service agency.

WORKFLOW

- After patient arrives to the clinic and is checked in, he uses a VA tablet to complete risk assessments and the tablet is synced to the EHR. Patient's scores are:
  - PHQ-9: 17
  - PCL: 15
  - AUDIT-C: 0
  - ASSIST: 10 for tobacco only
- Patient is taken to a room and the MOA asks patient for their chief complaint (CC) and any updates to their psychosocial and medical history. MOA reviews and validates the reason for visit is a routine outpatient visit for depression and PTSD management. Patient has no updates to psychosocial history.
- MOA validates patient's medication history has not changed. Patient is taking 1 Zoloft 150 mg p.o. daily.
- MOA takes patient's vital signs:
  - Height = 72"
  - Weight = 176 lbs
  - BMI = 23.9

- Heart rate = 80 bpm
- Respirations = 18 / min
- Blood Pressure = 124/74 mmHg
- Temperature = 98.2F

- Provider reviews the patient record prior to entering the room, including seeing that the PHQ score has increased from 15 from a month ago, to 17 today.
- Provider asks the patient how he is feeling, along with his concerns. Patient: “I’m not very good. I’m so tired all the time. I’m not sleeping well and I have trouble concentrating. I go to my AA meetings, but that is about it.” After discussion with the patient, the provider also learns the patient is concerned about long term living accommodations and won’t be able to afford rent beyond the next 4 months.
- Provider completes a psychiatric evaluation. Patient’s mental status is assessed as:
  - Appearance: Poorly groomed, patient slouching
  - Behavior: Subdued
  - State of Consciousness: Alert and oriented x 3
  - Attention: Slow to respond, shrugs shoulders in response to some questions
  - Speech: Soft, coherent
- Provider performs medication reconciliation and validates that patient is taking Zoloft 150 mg p.o. daily.
- Provider completes a head to toe assessment:
  - Head/Neuro: WNL
  - Heart: S1S2, BP normal
  - Lungs: Clear
  - Abdomen: Soft, benign. No GI/GU issues.
  - Extremities: No swelling, pedal pulses strong.
- After discussion about the patient’s worsening depression and the need to adjust treatment to better manage the patient’s condition, Provider and patient agree upon the following changes to the care regimen, which are documented in the Care Plan:
  - Continue Zoloft 150 mg p.o. daily / Immediately
  - Start Venlafaxine 37.5 mg daily x 4 days, then increase to 37.5 mg twice daily / Immediately
  - Referral for weekly individual psychotherapy (provider responsibility; 20 sessions; diagnosis=depression, PTSD; reason=worsening depression) / Now
  - Make appointment for weekly individual psychotherapy (patient responsibility) / Immediately
  - Continue weekly group psychotherapy / Ongoing
  - Referral to Supported Housing Services provided. Patient to follow-up / Immediately

- Continue Vocational Rehabilitation Training / Ongoing
- Follow-up in 2 weeks to evaluate for medication side effects

- Provider discusses with patient the patient's goals to manage his health. The patient states he would like to complete the Vocational Rehabilitation Training. He feels that he can complete it within 6 months, if his housing situation is resolved and he won't be homeless.

BREAKDOWN OF ENCOUNTER INTO CLINICAL STATEMENTS

- Requests

1. **Medication:** 1 Venlafaxine 37.5 mg tablet daily x 4 days, then increase to 37.5 mg twice daily
   - **Topic:** Venlafaxine
   - Details:
     - Category/Type: Medication
     - Strength: 37.5 mg
     - **Dosage:** 1 tablet
     - Frequency: Daily
     - Duration: 4 days
     - **Instructions:** After 4 days, increase to 37.5 mg twice daily
2. **Referral:** Weekly individual psychotherapy, 20 sessions, diagnosis = depression, PTSD, reason=worsening depression
   - **Topic:** Individual Psychotherapy
   - Details:
     - Category/Type: Referral
     - Value: 20
     - **UOM:** Sessions
     - **Indication:** Worsening depression, PTSD
3. **Referral:** Supported Housing Services
   - **Topic:** Supported Housing Services
   - Detail:
     - Category/Type: Referral

- Action *(These need to be split out by topic, result, and details)*

1. Height: value = 72; UOM = inches
2. Weight: value = 176; UOM = pounds

3. BMI: value = 23.9; UOM = ???
4. Heart rate: value = 80; UOM = bpm
5. Respirations = value = 18; UOM = minute (is this correct for representing it?)
6. Systolic BP: value = 124; UOM = mmHg
    - *Where to put details*, such as position (e.g., seated, lying down), laterality, preconditions (e.g., patient urinated at least 30 minutes before BP taken), etc.?
7. Diastolic BP: value = 74; UOM = mmHg
8. Temperature: value = 98.2; UOM = F
9. Appearance: result (coded) = poorly groomed, patient slouching
10. Behavior: result (coded) = subdued
11. State of consciousness: result (coded) = Alert and oriented x 3
12. Attention: result (coded) = Slow to respond, shrugs shoulders in response to some questions
13. Speech: result (coded) = Soft, coherent
14. Head/Neuro exam: result (coded) = WNL
15. Heart exam: values = S1S2, BP normal
16. Lungs exam: value = Clear
17. Abdomen exam: value = Soft, benign. No GI/GU issues.
18. Extremities exam: No swelling, pedal pulses strong.
19. Patient attending weekly group psychotherapy
20. Patient enrolled in Vocational Rehabilitation Training
21. Goal = Complete Vocational Rehabilitation Training within 6 months, provided his housing situation is resolved and he won't be left homeless

B. Example Statements

B.1. Action Statement Examples

Table B.1. Example

Performance Statement	
Narrative:	Systolic blood pressure of 120 mm Hg taken from right brachial artery while seated and no more than 30 minutes from when the patient last urinated
Topic:	Measurement-of Systolic blood pressure **Approach/Access Route:** Right brachial artery (technique) **Body Position:** Seated (technique)
Subject of information:	Subject of record
Statement time:	
Act:	Circumstance: Timing: Result: 120 mm Hg

Action Clinical Statement Examples	**Topic**	**Result**	**Details**
1. Systolic blood pressure of 120 mmHg taken from right brachial artery while seated and no more than 30 minutes from when the patient last urinated	measurement-of Systolic blood pressure	**Value:** 120 **Unit:** mmHG **Precision:** (integer)	**Approach/Access Route:** Right brachial artery (technique) **Body Position:** Seated (technique) **Activity**: Rested for at least 10 minutes (technique) **Prerequisite**: Urinated within 30 minutes of BP being taken
2. Patient has systolic blood pressure of 122 mmHg while patient is seated, right brachial artery	measurement-of Systolic blood pressure	**Value:** 122 **Unit:** mmHG **Precision:** (integer)	**Approach/Access Route:** Right brachial artery (technique) **Body Position:** Seated (technique)
3. Patient has systolic blood pressure of 130 mmHg, while patient is seated, adult cuff, automated cuff, 30 minutes or less after emptying bladder,	measurement-of Systolic blood pressure	**Value:** 130 **Unit:** mmHG **Precision:** (integer)	**Device Used:** Adult cuff (technique) **Device Used:** Automated cuff (technique) **Body Position:** Seated (technique)

Action Clinical Statement Examples	Topic	Result	Details
at patient's home, taken by patient			**Prerequisite:** 30 minutes or less after emptying bladder (Not a detail: At patient's home Taken by patient – not a detail, but instead attribution information)
4. Patient has systolic blood pressure of 125 mmHg, while patient is seated, adult cuff, 30 minutes or less after emptying bladder, at doctor's office	measurement-of Systolic blood pressure	**Value:** 125 **Unit:** mmHG **Precision:** (integer)	**Device Used:** Adult cuff (technique) **Body Position:** Seated (technique) **Prerequisite:** 30 minutes or less after emptying bladder (Not a detail: At doctor's office – not a detail, but instead attribution information)
5. Patient has thromboembolism history	observation-of thromboembolism	**Value:** [0, inf) **Unit:** count **Precision:** (integer)	
6. Diabetes Mellitus present	diagnosis-of Diabetes Mellitus	**Value:** [1, inf) **Unit:** count **Precision:** (integer)	
7. Diabetes Mellitus not present	diagnosis-of Diabetes Mellitus	**Value:** [0,0] **Unit:** count **Precision:** (integer)	
8. Three dot blot hemorrhages	observation-of Dot blot hemorrhage	**Value: [**3,3] **Unit:** count **Precision:** (integer)	
9. Dot blot hemorrhage present	observation-of Dot blot hemorrhage	**Value:** [1, inf) **Unit:** count **Precision:** (integer)	
10. Patient taking one Acetaminophen 100 mg tablet by mouth daily as needed for pain	administration-of Acetaminophen	**Value:** [1, inf) **Unit:** count **Precision:** (integer)	***Strength:*** *100 mg* (technique) ***Amount:*** *1 tablet* (technique) **Route of Administration:** Oral (technique)

Action Clinical Statement Examples	Topic	Result	Details
			Frequency: Daily **Indication:** Pain
11.Positive screen for fall risk	observation-of fall risk	**Value:** [1,1] **Unit:** count **Precision:** (integer)	
12.Family history (mother) of colon cancer	observation-of colon cancer	**Value:** [0, 1] **Unit:** count **Precision:** (integer)	(Not a detail: Subject of Information is Mother)

B.2. Request Statement Examples

Orders Clinical Statement Examples	Topic	Result	Details
1. Request for x-ray chest to evaluate chest pain (routine)	performance-of Chest x-ray		**Indication**: Evaluate chest pain **Priority**: Routine
2. Request for administration of nitroglycerin 0.4 mg tablet sub-lingual every 5 minutes as needed for chest pain; maximum 3 tablets (routine)	administration-of nitroglycerin		**Strength**: 0.4 mg tablet (technique) **Dosage**: 1 (technique) **Frequency**: Every 5 minutes (technique) **Duration**: As needed (technique) **Route** of Administration: Sub-lingual (technique) **Indication**: Chest pain **Priority**: Routine **Constraint**: Maximum 3 tablets
3. Request for prescription of Synthroid 50mcg, QD, 1 hour before meals	prescribing-of Synthroid		**Strength**: 50mcg (technique) **Frequency**: QD (technique)

Orders Clinical Statement Examples	Topic	Result	Details
			Instruction: 1 hour before meals

C. Statement Queries

C.1. Normalized Querying of Phenomena

This section introduces a model for normalizing the querying of clinical observations represented as phenomena so that the semantics of various query formulations are more explicit and intuitive, especially when queries include explicit negation.

C.1.1. A Tri-Valued State of Knowledge: Present, Absent, and Indeterminate

The initial step involves abstracting the possible states of a clinical phenomenon as reflected in the medical record to three mutually exclusive and exhaustive values: Present, Absent, and Indeterminate. The informal definitions of these states are as follows:

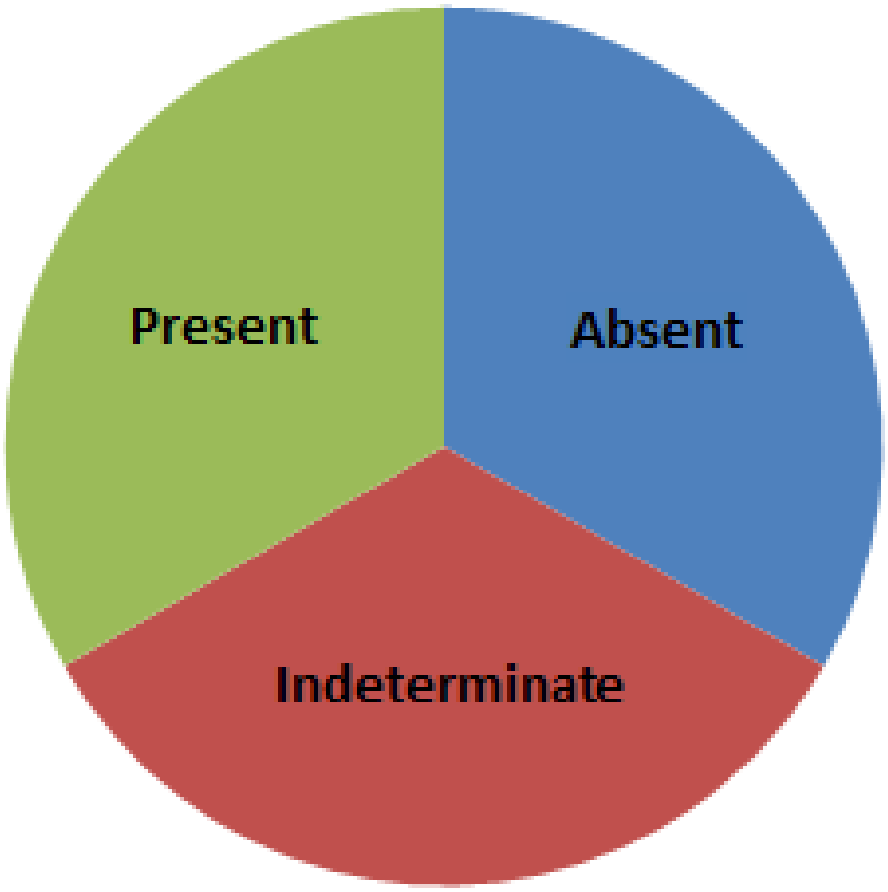
Present": The phenomenon is explicitly documented as present or can be logically inferred to be present

"Absent": The phenomenon is explicitly documented as absent or can be logically inferred to be absent

"Indeterminate": The phenomenon is neither "Present" nor "Absent"

Figure C.1, "The space of value assignments in a tri-valued approach to representing states of knowledge" illustrates this set of possible states and their relationships to each other.

Figure C.1. The space of value assignments in a tri-valued approach to representing states of knowledge



The implications of this conceptualization include the following logical statements, some of which may seem counter-intuitive (note that the symbol "#" connotes logical equivalence, i.e. "if and only if"):

Absent ##NOT Present AND NOT Indeterminate (Note: Absent implies NOT Present)

NOT Present # Absent OR Indeterminate (Note: NOT Present does not necessarily imply Absent)

Indeterminate # NOT Present AND NOT Absent (Note: It does not imply "Present OR Absent")

It's important to note that, in this conceptualization, Present, Absent, and Indeterminate reflect the possible states of *knowledge* about the clinical phenomenon in a particular patient, not the states of the phenomenon itself. For example, Absent does not indicate that the patient is necessarily free of the phenomenon, but only that the medical record indicates that the patient does not have it. Similarly, Indeterminate does not indicate that the patient is in some intermediate state between having and not having the phenomenon or that it is impossible to determine whether the patient has the phenomenon, but rather that, based on the information in the medical record, it cannot be known whether the patient does or does not have the phenomenon.

AXIOMS:

Based on this conceptualization, the three states of knowledge with respect to any phenomenon, ph, are formally defined via the following axioms, which use the prior definitions of "interval value" and the "IsWithin()" predicate:

Present(*ph*) ### *ph* where IsWithin(*ph*.value, $_{(0,\infty]}$) = TRUE

Absent(*ph*) ### *ph* where IsWithin(*ph*.value, [0,0]) = TRUE

Indeterminate(*ph*) # NOT Present(*ph*) and NOT Absent(*ph*)

Present(*ph*) OR Absent(*ph*) OR Indeterminate(*ph*)

NOT (Present(*ph*) AND Absent(*ph*))

NOT (Present(*ph*) AND Indeterminate(*ph*))

NOT (Absent(*ph*) AND Indeterminate(*ph*))

Figure 12.12, "The semantics of interval values assigned to phenomena, as shown through examples." shows several examples of how these axioms generate the appropriate value of Present, Absent, or Indeterminate for certain phenomena based on how those phenomena are documented in the patient record. Note that each row in the table represents a distinct state of the patient's medical record (i.e., they are not present in the record at the same time). In fact, the presence of certain of the rows in the record at the same time would be inconsistent with the logical model defined above.

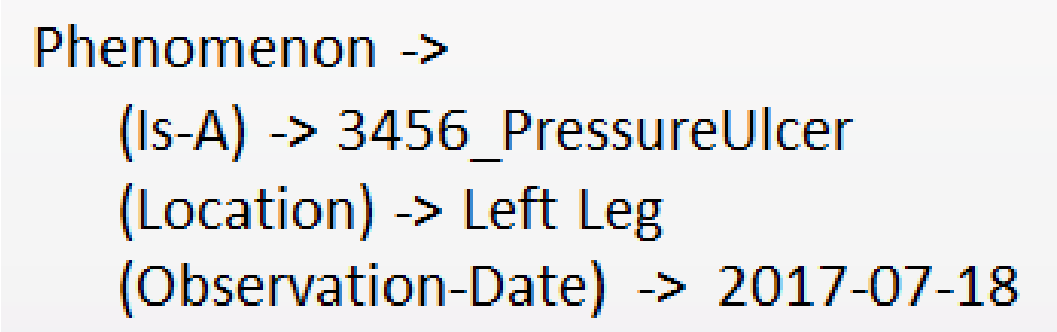
Figure C.2. Example assignments of present, absent, and indeterminate based on various interval values

Phenomenon *ph*	*ph*.value	Present/Absent/Indeterminate
Pressure Ulcer(s)	[5, 5]	Present
Pressure Ulcer(s)	(0, ∞]	Present
Pressure Ulcer(s)	[0, 0]	Absent
Pressure Ulcer(s)	[0, 3]	Indeterminate
Nausea	(0, ∞]	Present
Nausea	[0, 0]	Absent
Nausea	<no instances>	Indeterminate

C.1.2. Assigning Values to Phenomena That Include Refining Attributes

In contemporary models for representing clinical observations, such as SNOMED-CT, OpenEHR, and CIMI, observation instances can consist of post-coordinated concept expressions, i.e., a general concept that is further described and refined by a set of associated attribute/value pairs. Collectively, the concept and its refining attribute/value pairs characterize the distinct phenomenon that was observed. For example, Figure C.3, "A sample post-coordinated phenomenon. " shows such a post-coordinated expression comprising an observed phenomenon.

Figure C.3. A sample post-coordinated phenomenon.



When such a phenomenon is documented in the medical record and assigned an interval value, per the model specified in Section Section 12.2.6.2, "Phenomena and Interval Values", it is essential that the interval value corresponds to the conceptual entirety of the phenomenon. If interval values are not clearly assigned to the entirety of documented phenomena at the time the phenomena are captured and stored, then inconsistent and incorrect interpretations of the data may result.

Figure C.4, "The correct assignment of interval values to post-coordinated phenomena. " illustrates the correct assignment of interval values to two phenomena, the first of which documents that two pressure ulcers were present in the patient's left leg on a specific date, and the second of which documents that pressure ulcers were absent in the patient's right leg on the same date. The presence of both of these phenomena in the patient record at the same time is intuitively possible, and is consistent with the axioms of the model in Section Section C.1.1, "A Tri-Valued State of Knowledge: Present, Absent, and Indeterminate".

Figure C.4. The correct assignment of interval values to post-coordinated phenomena.

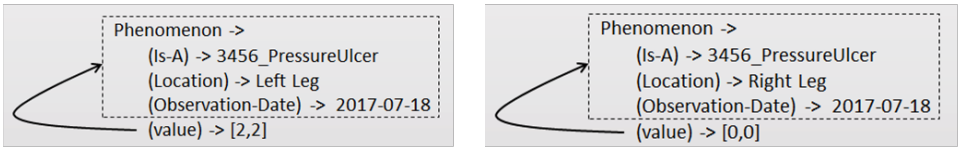
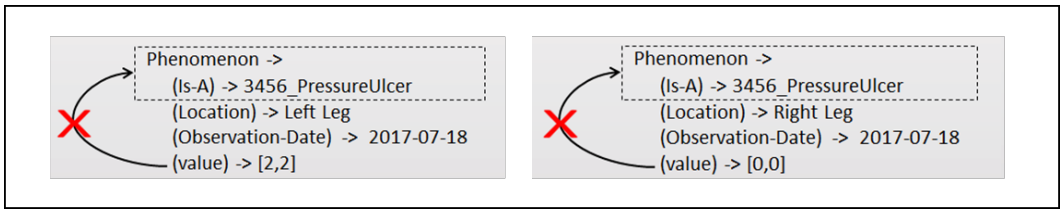


Figure C.5, "The incorrect assignment of interval values to post-coordinated phenomena. " illustrates the problems that may occur when interval values are erroneously assigned to just a subset of the post-coordinated expressions used to document phenomena. In this case, the interval values are assigned just to the general concept of a pressure ulcer, omitting the refining attributes from the scope of the assignment. This results in the representation that the patient both had and did not have pressure ulcers at the same time. Because the full set of refining attributes were not included in the scope of the interval-value assignment, an incorrect representation is created that is intuitively non-sensical and violates the axioms of Section Section C.1.1, "A Tri-Valued State of Knowledge: Present, Absent, and Indeterminate". Such representations can lead to incorrect data-retrieval, data-analysis, and inferencing results if used by automated processes later. This is underscored in the discussion of subsumption testing involving phenomena in Section Section C.2, "Normalized Querying using Subsumption Relationships Among Phenomena".

Figure C.5. The incorrect assignment of interval values to post-coordinated phenomena.



C.2. Normalized Querying using Subsumption Relationships Among Phenomena

As mentioned in Section Section E.1, “Confusion About Negation: “Absent” and “Not Present””, ontology-based representation models may produce incorrect results when performing subsumption testing over negated concepts. The root cause of these errors is that negation changes the basic rules of logical subsumption testing and must be explicitly handled as a special case. This section presents a formal model for handling subsumption over negated concepts when such concepts are represented as phenomena with assigned interval values.

C.2.1. Theoretical Foundation

The semantics of logical subsumption are based on set membership. The definitions of concepts (or phenomena) describe the characteristics of certain sets or types of instances in the real world. We say that phenomenon A *subsumes* phenomenon B if and only if any instance of phenomenon B is *necessarily* an instance of phenomenon A. In other words, if set A subsumes set B, the instances of set B are a subset of the instances of set A. Equivalently, membership in set B *implies* membership in set A for any instance, *I*, which can be represented by the logical statement

1. IF Member-Set-B(*i*) THEN Member-Set-A(*i*)

These relationships can be seen graphically in Figure C.6, “Set-theoretic view of the subsumption relationship. ”. Note that subsumption does not necessarily imply that Set B is a proper subset of Set A – Set A and Set B could be the same.

Figure C.6. Set-theoretic view of the subsumption relationship.

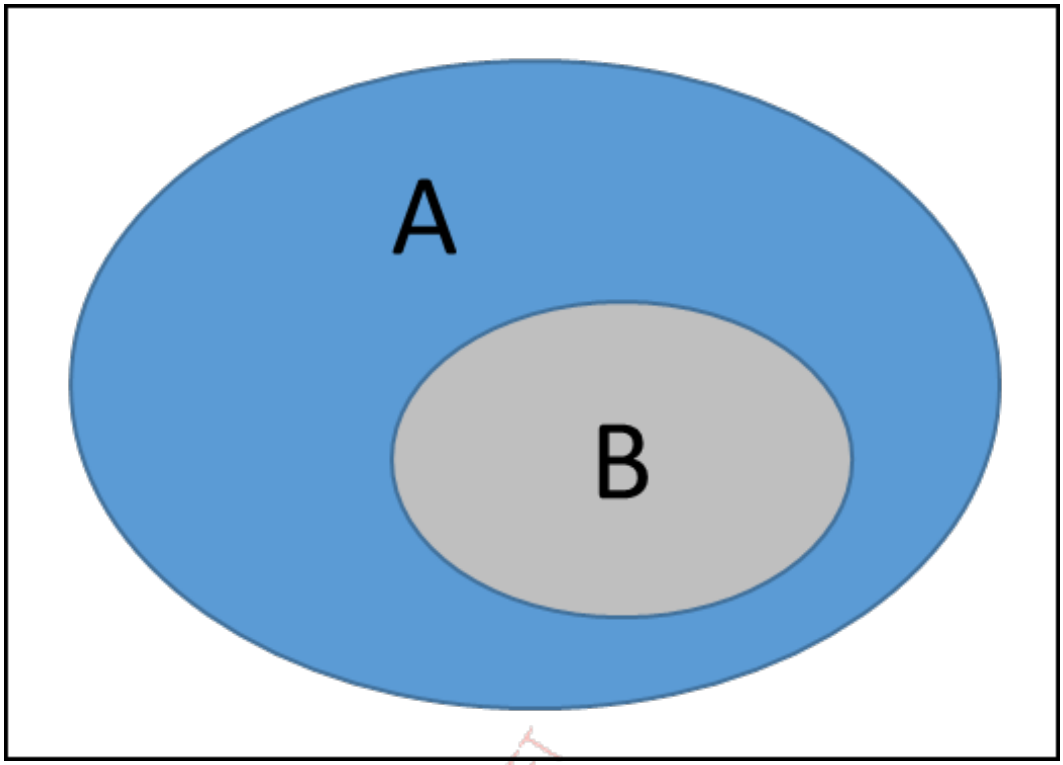
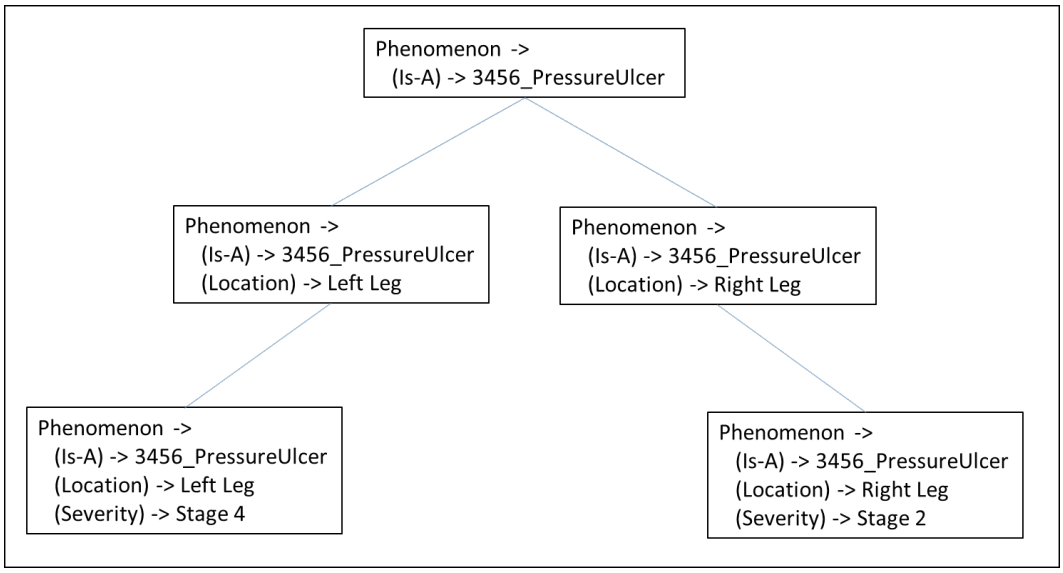


Figure C.7, “An example subsumption hierarchy for post-coordinated phenomena in the clinical domain. ” shows how subsumption relationships can apply to clinical observations. Specifically, the figure shows a subsumption hierarchy involving various types of pressure ulcer phenomena in which each parent phenomenon subsumes its child phenomena, given their respective definitions. In set-theoretic terms, any clinical observation that is an instance of (member-of) a child phenomenon is necessarily an instance of its parent phenomenon (and, indeed, any ancestors of that parent). For example, we would say that, if a patient has a stage-4 pressure ulcer in the left leg, then it’s necessarily true that the patient has a pressure ulcer (of some kind) in the left leg and also that the patient has a pressure ulcer (somewhere on her body).

Figure C.7. An example subsumption hierarchy for post-coordinated phenomena in the clinical domain.



Per classical logic, statement (1) also implies the contra-positive:

2. IF NOT Member-Set-A(*i*) THEN NOT Member-Set-B(*i*)

which makes intuitive sense if one considers that an instance cannot be a member of any subset of set A if it is not a member of set A to begin with. In the medical context, it's clear that a patient who does not have a pressure ulcer on the right leg cannot have a stage-2 pressure ulcer on the right leg.

Lastly, one should note that statement (1) does NOT imply the following statements:

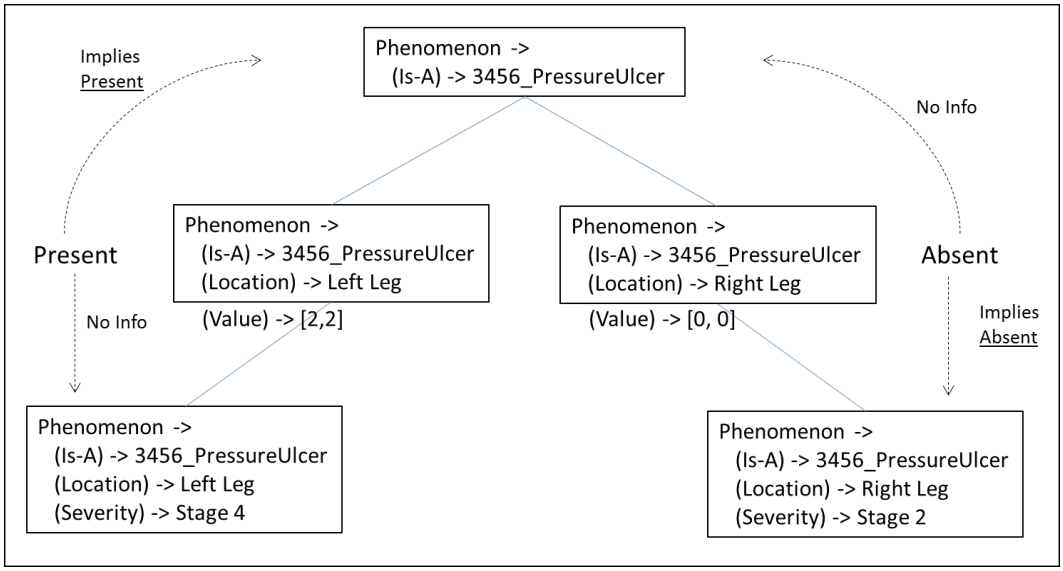
3. IF Member-Set-A(i) THEN Member-Set-B(i)

4. IF NOT Member-Set-B(i) THEN NOT Member-Set-A(i)

This can be seen clearly by inspection of Figure C.6, "Set-theoretic view of the subsumption relationship. ". Note specifically that membership in Set A does not *preclude* membership in Set B. It just does not necessarily imply it, i.e., it simply provides no definitive information either way. Similarly, lack of membership in Set B provides no definitive information as to lack of membership in Set A.

Extending this reasoning to the clinical domain, one can stipulate the inferences shown in Figure C.8, "Examples of correct subsumption inferences with respect to post-coordinated phenomena." when interval values are assigned to certain of the phenomena in the subsumption hierarchy. Specifically, the documented presence of a pressure ulcer in the left leg necessarily implies the presence of a pressure ulcer somewhere, but it does not provide definitive information about the presence of a stage-4 pressure ulcer in the left leg (e.g., it could be stage 3). Similarly, the absence of a pressure ulcer in the right leg necessarily implies the absence of a stage-2 pressure ulcer in the right leg, but it provides no definitive information about the absence of a pressure ulcer in general (e.g., there could be one in the left leg).

Figure C.8. Examples of correct subsumption inferences with respect to post-coordinated phenomena.



C.2.2. A Formal Model of Negation with Subsumption Relationships

Using these precepts of classical logic, one can generalize the set of axioms introduced in Section C.1.1, "A Tri-Valued State of Knowledge: Present, Absent, and Indeterminate" to incorporate subsumption inference into the determination of whether a specified phenomenon is Present, Absent, or Indeterminate, based on the state of a patient's medical record. The axioms below should replace those introduced earlier.

Present(*ph*) ### *ph'* where Is-A(*ph'*, *ph*) AND IsWithin(*ph'*.value, $_{(0,\infty]}$) = TRUE

Absent(*ph*) ### ph' where Is-A(*ph'*, ph') AND IsWithin(*ph'*.value, [0,0]) = TRUE

Indeterminate(ph) ## NOT Present(ph) AND NOT Absent(ph)

Is-A(*ph*, *ph'*) # IF an instance satisfies all properties of *ph*, then it necessarily satisfies all properties of *ph'*, i.e. *ph'* subsumes *ph*

Present(*ph*) OR Absent(*ph*) OR Indeterminate(*ph*)

NOT (Present(*ph*) AND Absent(*ph*))

NOT (Present(*ph*) AND Indeterminate(*ph*)

NOT (Absent(*ph*) AND Indeterminate(*ph*))

Again, for these axioms to hold and be mutually consistent, the scope of any interval value assigned to a phenomenon must include all of its refining attributes, as described in Section Section C.1.2, "Assigning Values to Phenomena That Include Refining Attributes".

Applying standard logical operators, the axioms above also imply the following logical statements:

NOT Present(*ph*) ##NOT (# ph' where Is-A(ph', *ph*) AND IsWithin(ph'.value, $_{(0,\infty]}$) = TRUE)

NOT Absent(*ph*) ##NOT (# ph' where Is-A(*ph*, ph') AND IsWithin(ph'.value, [0,0]) = TRUE)

Is-A(*ph*, *ph*) (allows degenerate case when present/absent are explicitly documented for a phenomenon)

NOT Present(*ph*) # Absent(*ph*) OR Indeterminate(*ph*)

(Note: NOT Present(*ph*) does not necessarily imply Absent(*ph*))

Absent(*ph*) ##NOT Present(*ph*) AND NOT Indeterminate(*ph*)

(Note: Absent(*ph*) does imply NOT Present(*ph*))

Returning to the original example of negation given in Section Section C.2.5, “Querying with Negation”, one can now explicitly specify the closed-world assumption or the open-world assumption in the manner that the query predicate is formulated based on the logical definitions of “Present” and “Absent”. Specifically, the query may be formulated as

IF EXISTS Phenomenon ph WHERE ph.patient_Id = 9876 AND ph.conceptCode = “3456_PressureUlcers” AND <*predicate*>

where <*predicate*> is either “NOT Present(ph)” (closed-world assumption) or “Absent(ph)” (open-world assumption). The ability to formulate the predicate using the higher-level abstractions “Present”, “NOT Present”, “Absent”, or “NOT Absent” allows data analysts to abstract away from the detailed, technical use of the IsWithin() predicate in the queries of Section Section C.2.5, “Querying with Negation”. It also obviates data analysts from understanding and correctly applying the logic of subsumption when negated phenomenon appear in the medical record. The complete truth table for the query above based on a number of potential values in the patient record are shown in Figure C.9, “Complete truth table for querying using interval values and the tri-valued model of knowledge”.

Figure C.9. Complete truth table for querying using interval values and the tri-valued model of knowledge

Pressure Ulcer Value	NOT Present(*ph*)	Absent(*ph*)	Present(*ph*)	NOT Absent(*ph*)
[3,3]	FALSE	FALSE	TRUE	TRUE
(0,∞]	FALSE	FALSE	TRUE	TRUE
[0,0]	TRUE	TRUE	FALSE	FALSE
[0,5]	TRUE	FALSE	FALSE	TRUE
<no records>	TRUE	FALSE	FALSE	TRUE

C.2.3. Practical examples

Two practical examples help to illustrate the applicability and utility of the models presented above. They represent differing clinical contexts in which the closed-world assumption or the open-world assumption are appropriate, and can be explicitly made in the formulation of data queries.

Example 1: Medication prescription.

A decision support rule concludes that a patient meets the clinical criteria to be on an antihypertensive, but must determine whether the patient is already taking such a medication before recommending its prescription. The logic is best formulated as

IF NOT Present(prescription for antihypertensive) THEN recommend prescribing an antihypertensive

In this case, the closed-world assumption is appropriate in formulating the query because (a) medication prescriptions are likely to be documented in the medical record and (b) the explicit absence of a medication

prescription is not likely to be explicitly document (otherwise, all of the medications that a patient were not taking would need to be documented).

Note also that, were a prescription for a specific antihypertensive agent, such as “Captopril” explicitly documented in the patient record, the axioms presented in Section Section C.2.2, “A Formal Model of Negation with Subsumption Relationships” would correctly infer that the predicate “NOT Present(prescription for antihypertensive)” was false, because Is-A(prescription for Captopril, prescription for antihypertensive).

Example 2: Drug allergy.

A different decision support rule concludes that a patient meets the clinical criteria to be prescribed penicillin, but must determine whether the patient is allergic to that drug before recommending such a prescription. Here, the logic is best formulated as

IF Absent(allergy to penicillin) THEN recommend prescribing a penicillin

In this case, the open-world assumption is more appropriate because (a) it’s important to be certain that no allergy exists, and (b) the presence of allergies is likely to be explicitly documented in the medical record. Note also the following implications of formulating the query in this way:

- The explicit assignment of the interval value “[0,0]” to the phenomenon “Allergy to a drug” (i.e., the documentation of “NKDA”) in the medical record will result in the predicate “Absent(allergy to penicillin)” evaluating to true per the axioms presented in Section Section C.2.2, “A Formal Model of Negation with Subsumption Relationships” (because Is-A(penicillin,drug)). This is the desired behavior.

- The explicit assignment of the interval value “(0,#]” to the phenomenon “Allergy to Amoxicillin” (i.e., the documentation of an allergy to Amoxicillin) in the medical record will result in the predicate “Absent(allergy to penicillin)” evaluating to false per the axioms presented in Section Section C.2.2, “A Formal Model of Negation with Subsumption Relationships” (because Is-A(Amoxicillin, penicillin)). Again, this is the desired behavior.

- If no phenomena related to drug allergies are documented in the medical record at all, the phenomenon “allergy to penicillin” will be indeterminate per the axioms presented in Section Section C.2.2, “A Formal Model of Negation with Subsumption Relationships”, which will imply that the predicate “Absent(allergy to penicillin)” is false, again per the axioms. This is also the desired behavior.

These examples show that the model specified in this paper for querying with negation works in a manner that is clinically appropriate in at least these two important cases.

C.2.4. Basic Querying

The example query in Section ??? seeking to determine whether a patient has a pressure ulcer may now be formulated more simply and consistently (using pseudo-SQL to represent the logic):

IF EXISTS Phenomenon ph WHERE ph.patient_Id = 9876 AND ph.conceptCode = “3456_PressureUlcers” AND IsWithin(ph.value, $_{(0,\infty])}$ = TRUE

Note that, with pressure ulcers represented as Phenomena, the single predicate “IsWithin(ph.value, $_{(0,\infty])}$ = TRUE” replaces the two expressions previously required when pressure ulcers could be represented as either Findings or Observable Entities (“object.value = “Present” OR object.value > 0”). The user formulating the query can reliably test for pressure ulcers in the patient’s record without concern for how that clinical observation is represented or what types of values it may have.

Similarly, to determine whether a patient has any test results within a specific numeric range, a similar formulation may be used, simply substituting the desired numeric reference interval in the IsWithin() predicate:

IF EXISTS Phenomenon ph WHERE ph.patient_Id = 9876 AND ph.conceptCode = “2468_SerumPotassium” AND IsWithin(ph.value, [0, 3.7)) = TRUE

The query above will evaluate to true if the patient 9876 has any serum potassium values < 3.7.

C.2.5. Querying with Negation

Querying for the absence of a clinical phenomenon for a specific patient introduces certain complications because of variations in the way that the phenomenon may or may not be represented in the medical record. For example, if a data-retrieval or data-analysis function needed to determine whether a patient did NOT have any pressure ulcers, the query could be formulated in at least two ways.

1. Under the *closed-world assumption* (CWA), which implies that all information about the state of the patient is included in the medical record. In this case, the absence of any information in the medical record supporting the presence of a pressure ulcer would be sufficient evidence that the patient had no pressure ulcers. The specific formulation of the query under this assumption would be: IF NOT (EXISTS Phenomenon ph WHERE ph.patient_Id = 9876 AND ph.conceptCode = “3456_PressureUlcers” AND IsWithin(ph.value, $_{(0,\infty])}$ = TRUE) (Note that the reference value in the IsWithin() predicate is “(0,#]” in this case.)

2. Under the *open-world assumption* (OWA). This assumption implies that not all information about the patient’s state is included in the medical record, so that the non-existence of some patient state cannot be assumed based solely on a lack of data asserting the presence of that state. In this case, the absence of some phenomenon can only be inferred if the patient record explicitly asserts such absence, or at least uncertainty about its presence. A specific formulation of the query under this assumption would be: IF EXISTS Phenomenon ph WHERE ph.patient_Id = 9876 AND ph.conceptCode = “3456_PressureUlcers” AND IsWithin(ph.value, $_{(0,\infty])}$ < > TRUE An alternative OWA formulation of the query with slightly different semantics would be: IF EXISTS Phenomenon ph WHERE ph.patient_Id = 9876 AND ph.conceptCode = “3456_PressureUlcers” AND IsWithin(ph.value, [0,0]) = TRUE (Note the different formulations of the IsWithin() predicates in these queries.)

The semantic distinctions among these query formulations are significant, in that they will generate different query responses for the same patient data in certain cases. Figure 12.12, “The semantics of interval values assigned to phenomena, as shown through examples.” shows the Boolean value for each query given different patient data instances in the medical record. Notably, the query values are different in the last two cases. Note that in Figure 12.12, “The semantics of interval values assigned to phenomena, as shown through examples.”, a Boolean value of TRUE indicates that the patient does NOT have pressure ulcers, whereas a Boolean value of FALSE indicates that the patient DOES have pressure ulcers (since the queries are testing for the absence of that phenomenon).

Figure C.10. Example truth table of negated querying under closed-world and open-world assumptions.

Pressure Ulcer Value	CWA Query	OWA Query 1	OWA Query 2
[3,3]	FALSE	FALSE	FALSE
(0,∞]	FALSE	FALSE	FALSE
[0,0]	TRUE	TRUE	TRUE
[0,5]	TRUE	TRUE	FALSE
<no records>	TRUE	FALSE	FALSE

The potential variance in query responses depending on how a negation query is formulated and how the absence of a phenomenon is represented in the medical record is a problem for health-care applications that depend on clear and consistent analysis of patient data. If data analysis of clinical observations is subject to misinterpretation, then medical applications may reach incorrect conclusions and/or provide incorrect advice, with adverse patient-safety consequences.

To avoid ambiguity in the representation and analysis of clinical observation data, a better formalized and more intuitive model for querying is required.

D. SOLOR Concept Glossary

Insulin dependent diabetes mellitus type 1A

Descriptions:

Insulin dependent diabetes mellitus type IA (disorder)

Insulin dependent diabetes mellitus type 1A

Insulin dependent diabetes mellitus type IA

Codes:

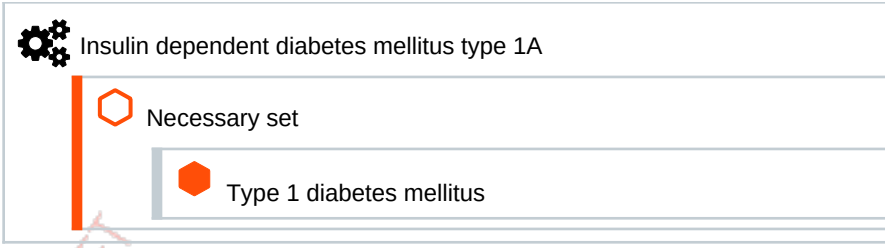
UUID: cc0759c3-623e-3417-badb-8dbad681e0f5

SCTID: 23045005

Text definition:

Ø

Axioms:



Pulse rate

Descriptions:

Heart rate measured at systemic artery (observable entity)

Pulse rate

Heart rate measured at systemic artery

PR - Pulse rate

Codes:

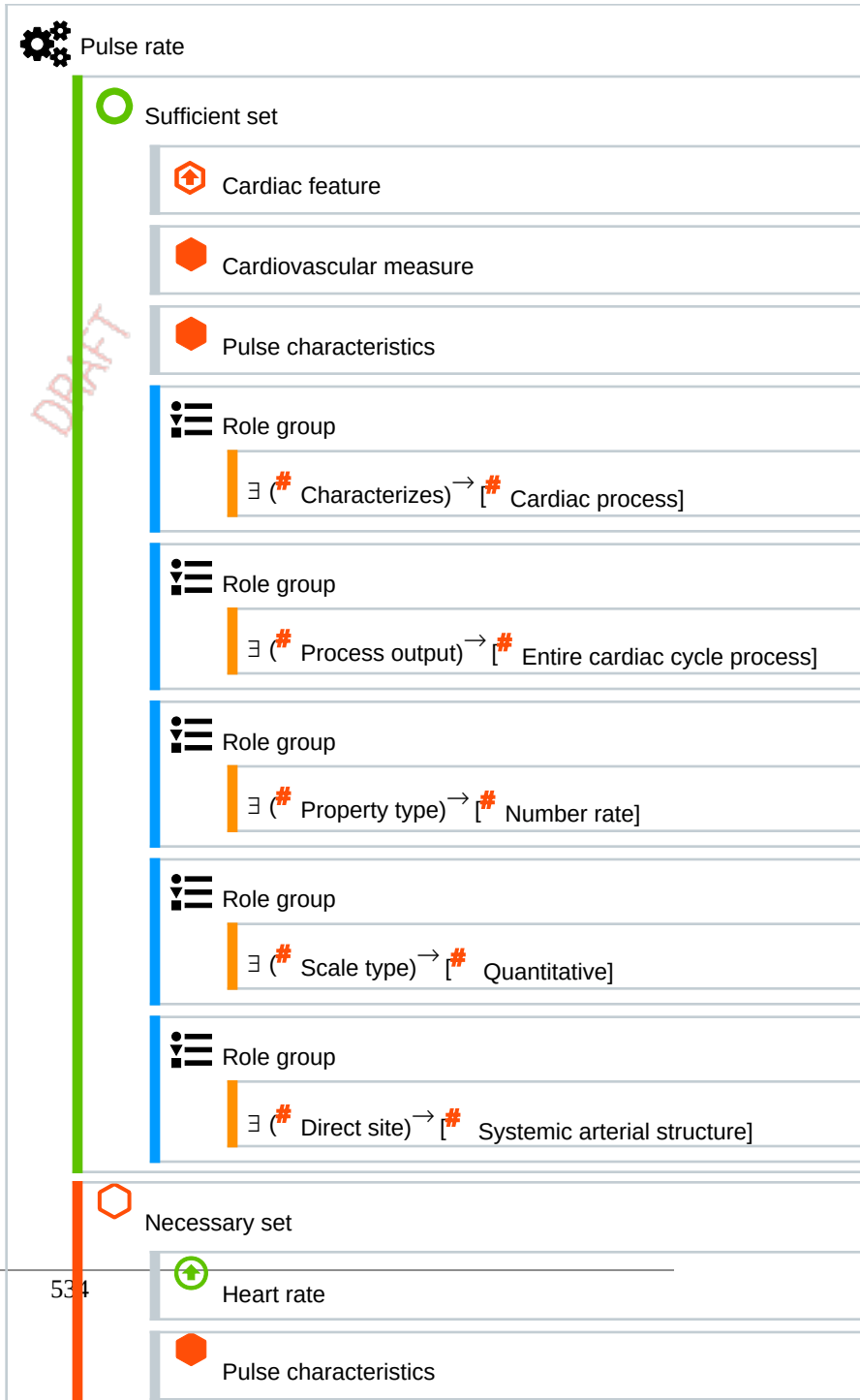
UUID: 1f621ed0-b2b9-37bf-ba99-cdcdc1a6e24a

SCTID: 78564009

Text definition:

Ø

Axioms:



Administration of medication

Descriptions:

- Administration of drug or medicament (procedure)
- Administration of medication
- Medication administration
- Medication treatment
- Medication administration treatments and procedures
- Administration of drug or medicament
- Giving medication

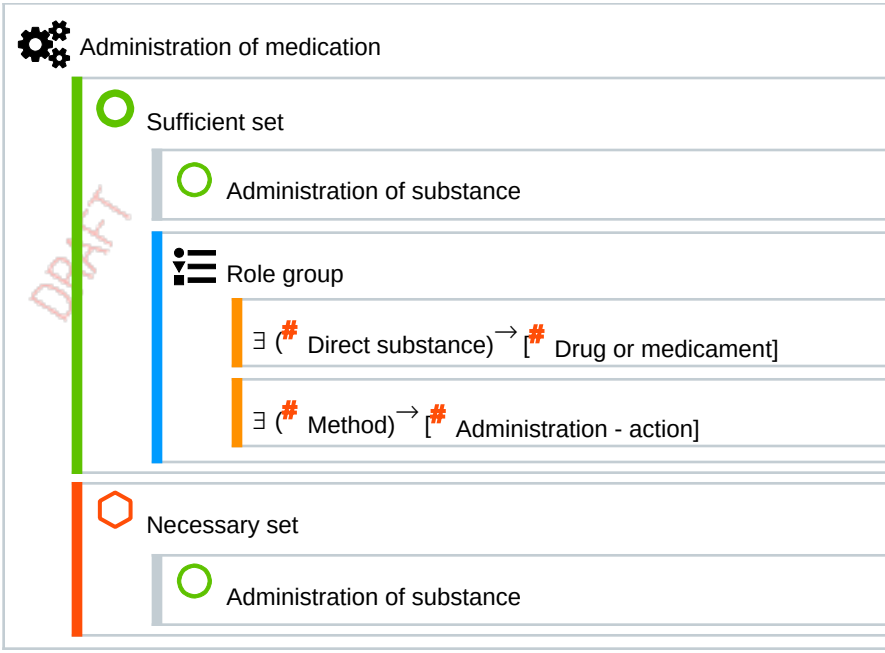
Codes:

- UUID: 8a39a4e6-97c8-3ab1-b589-71edfe1f32ce
- SCTID: 18629005

Text definition:

- Ø

Axioms:



Peripheral pulse taking

Descriptions:

Peripheral pulse taking (procedure)

Peripheral pulse taking

Peripheral pulse rate taking

Codes:

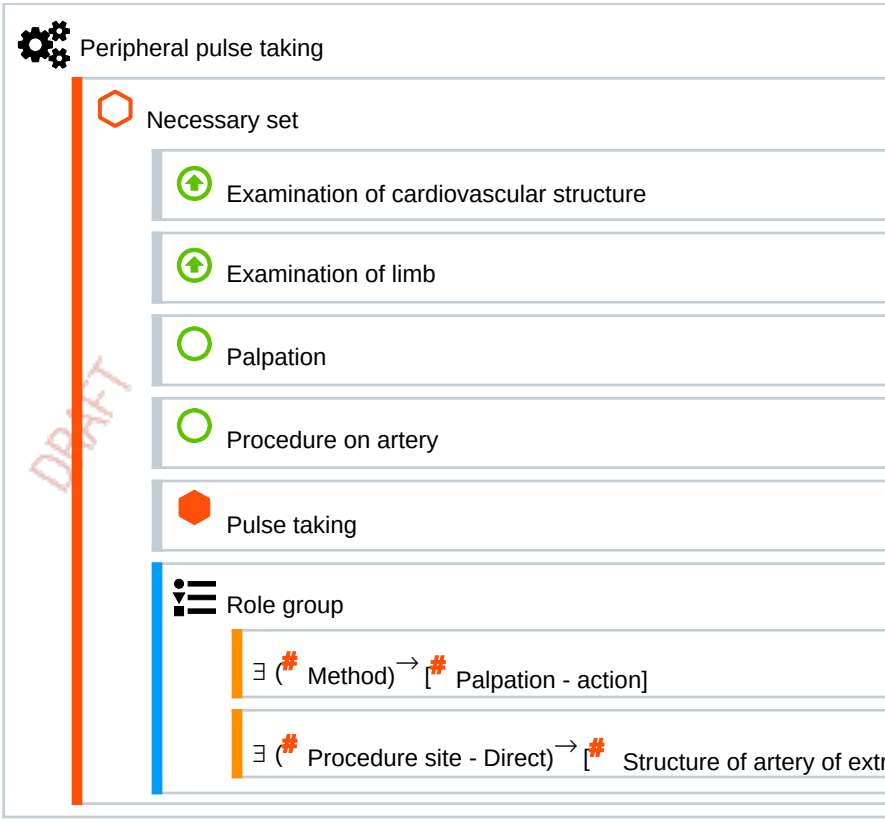
UUID: 8a07a847-abb7-3cae-997a-649205922577

SCTID: 424411004

Text definition:

Ø

Axioms:



Measurement of blood pressure at anterior tibial pulse using doppler

Descriptions:

Measurement of blood pressure at anterior tibial pulse using doppler (procedure)

Measurement of blood pressure at anterior tibial pulse using doppler

Anterior tibial doppler pressure

Codes:

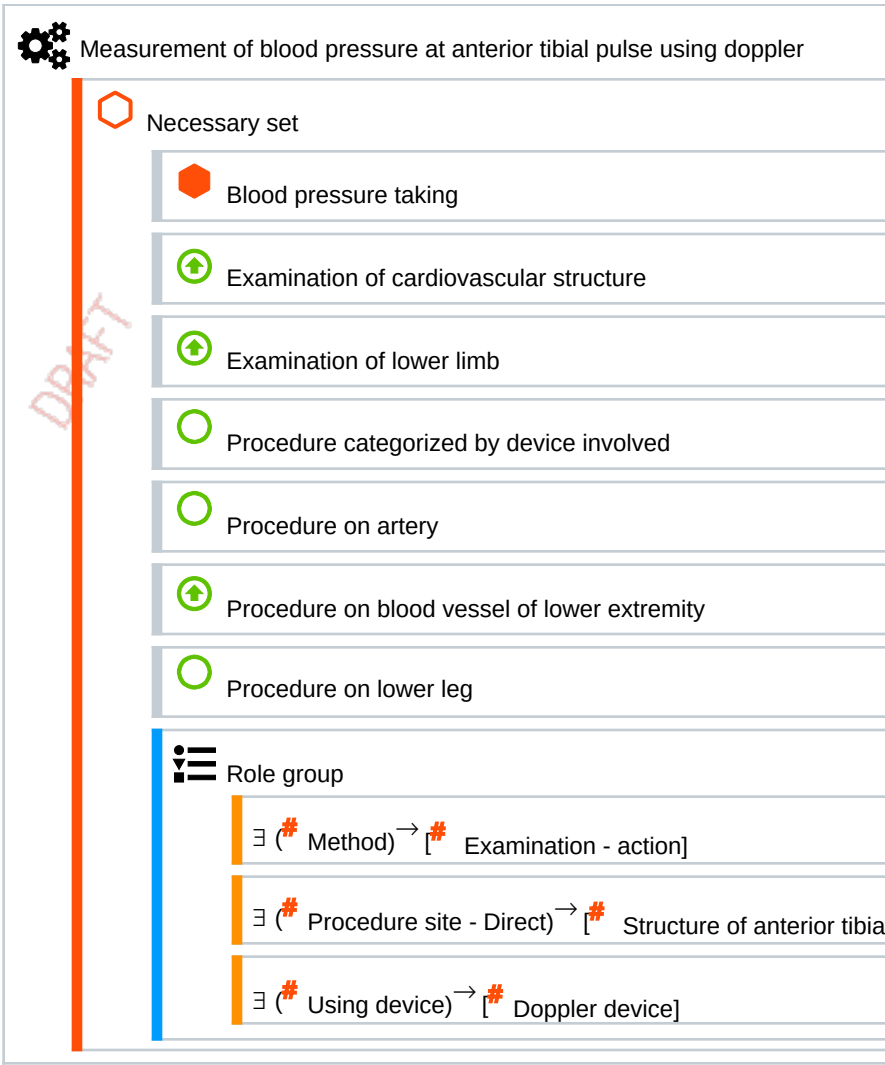
UUID: 697518a2-7d28-3bc3-8213-e5e7b3b86b99

SCTID: 446695008

Text definition:

Ø

Axioms:



O/E - pulse rate

Descriptions:

On examination - pulse rate (finding)

O/E - pulse rate

On examination - pulse rate

Codes:

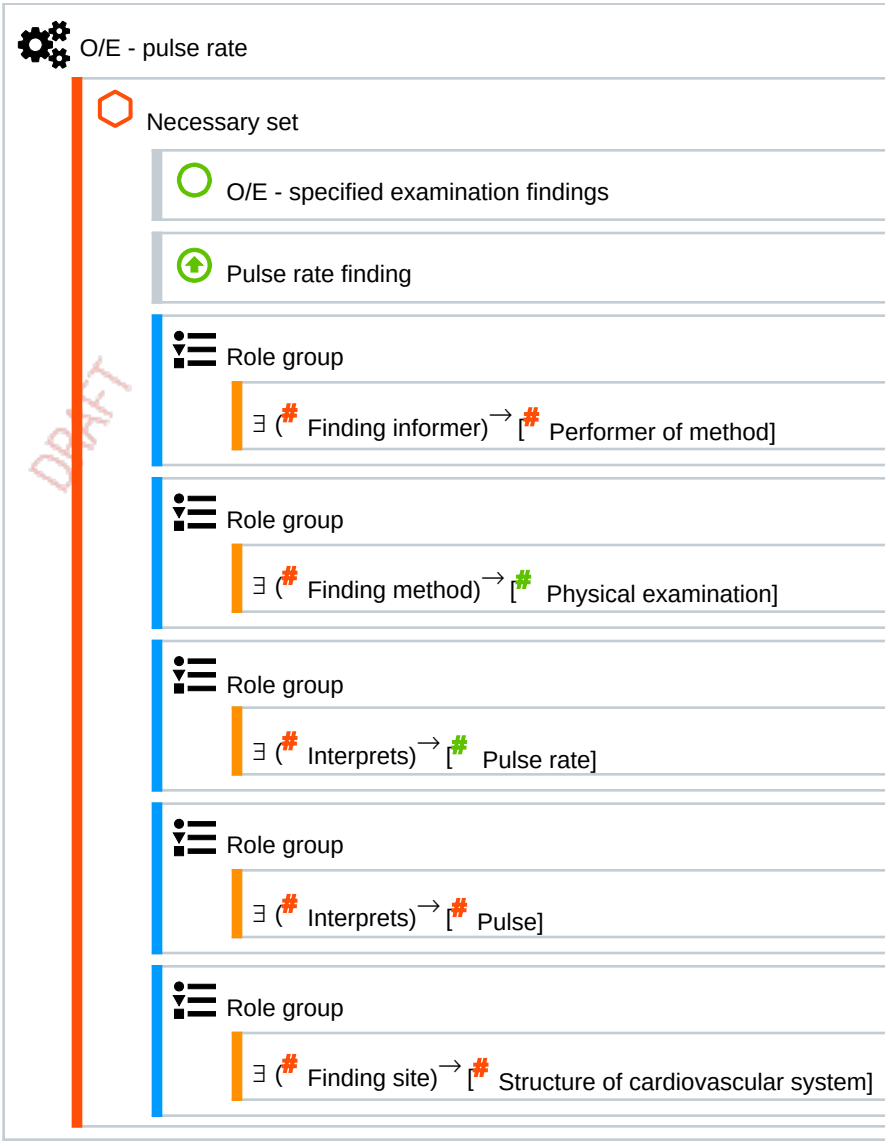
UUID: 5aa42d0d-682d-35ad-be48-2ad2542db16e

SCTID: 162986007

Text definition:

Ø

Axioms:



Measurement of blood pressure using cuff method

Descriptions:

Measurement of blood pressure using cuff method (procedure)

Measurement of blood pressure using cuff method

Codes:

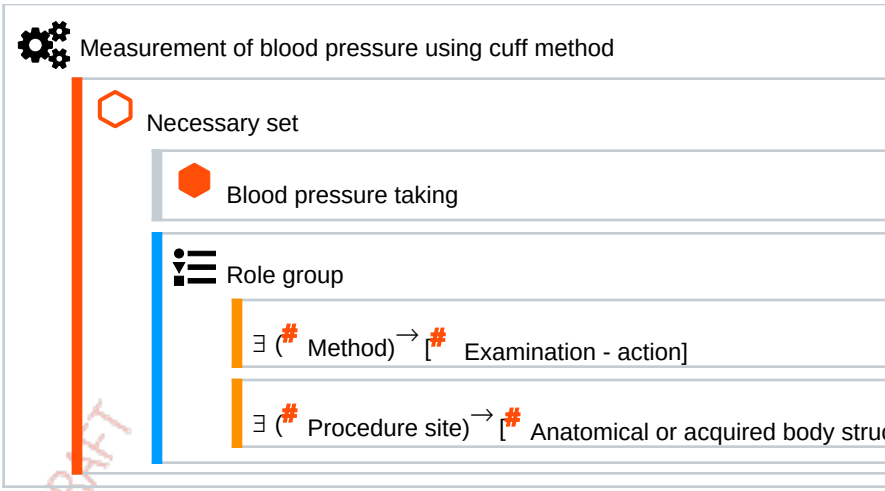
UUID: 74374092-8c3a-328c-9370-ba1ecba7a0d0

SCTID: 371911009

Text definition:

Ø

Axioms:



Blood pressure taking

Descriptions:

Blood pressure taking (procedure)

Blood pressure taking

Codes:

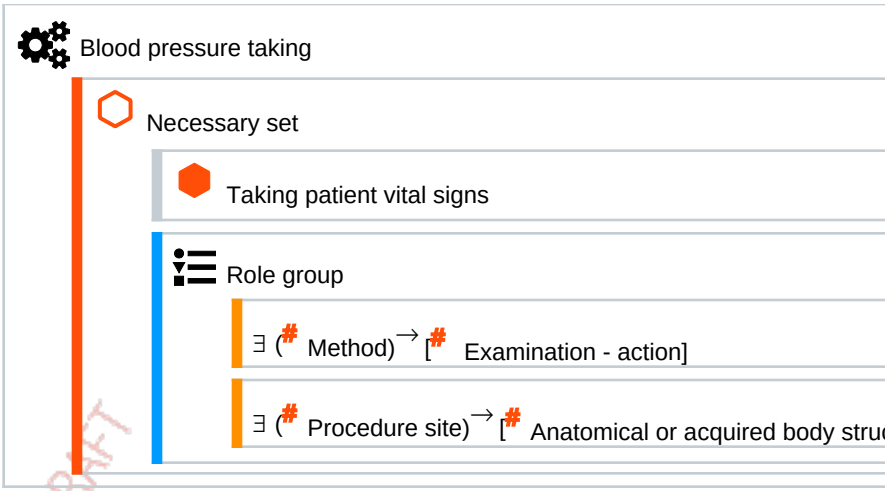
UUID: 215fd598-e21d-3e27-a0a2-8e23b1b36dfc

SCTID: 46973005

Text definition:

Ø

Axioms:



Terms Glossary

concept	A clinical idea The concept of a broken femur bone
Concept	A clinical idea to which a unique SNOMED ConceptId has been assigned Fracture of Femur (SNOMED ConceptID = 71620000)
Relationship	An association between two Concepts Fracture of Femur : Finding Site = Bone Structure of Femur
Concept Definition	A collection of Relationships that logically defines the meaning of a Concept in SNOMED Fracture of Femur : IS-A = Injury of Thigh, Finding Site = Bone Structure of Femur, Morphology = Fracture
Pre-coordinated concept	A concept that is pre-defined as a Concept in SNOMED Fracture of Femur (SNOMED ConceptID = 71620000) : IS-A = Injury of Thigh, Finding Site = Bone Structure of Femur, Morphology = Fracture
Expression	A collection of references to one or more Concepts used to express an instance of a clinical idea (i.e., in a particular patient) An expression may consist of a single ConceptID or a large collection of related Concepts Fracture of Femur OR Fracture of Femur : Finding Site = Structure of Head of Femur : Laterality = Left, Morphology = Spiral Fracture
Post-coordinated Expression	An expression created to represent an instance of a clinical idea that does not exist as a pre-defined Concept in SNOMED Fracture of Femur : Finding Site = Structure of Head of Femur : Laterality = Left, Morphology = Spiral Fracture
Refinement	The further specification or addition of Relationships to a predefined Concept to express a more specific concept Pre-defined Concept Fracture of Femur : IS-A = Injury of Thigh, Finding Site = Bone Structure of Femur, Morphology = Fracture Refinement Fracture of Femur : Finding Site = Structure of Head of Femur : Laterality = Left, Morphology = Spiral Fracture, Severity = Severe
Focus Concept	The core concept that is refined in a post-coordinated expression Fracture of Femur (SNOMED ConceptID = 71620000)

	IN Fracture of Femur : Finding Site = Structure of Head of Femur : Laterality = Left, Morphology = Spiral Fracture, Severity = Severe
Subsumption Testing	The logical determination of whether a concept (as represented by an Expression) is more specific than another concept (also represented by an Expression). If so, the more specific concept *is subsumed by* the more general concept, and the more general concept *subsumes* the more specific concept. Fracture of Femur (see Concept Definition above) SUBSUMES Fracture : Finding Site = Structure of Head of Femur : Laterality = Left, Morphology = Spiral Fracture (the head of the femur is a part of the femur, and a spiral fracture is a kind of fracture) Fracture of Femur (see Concept Definition above) DOES NOT SUBSUME Fracture : Finding Site = Bone Structure of Shaft of Fibula Morphology = Transverse Fracture (the shaft of the fibula is not a part of the femur)
Equivalence Testing	The logical determination of whether a concept (as represented by an Expression) is exactly the same as another concept (also represented by an Expression). If so, the two concepts are *equivalent.* Fracture of Femur (see Concept Definition above) IS EQUIVALENT TO Traumatic Injury : Finding Site = Bone Structure of Femur Morphology = Fracture Fracture of Femur (see Concept Definition above) IS NOT EQUIVALENT TO Traumatic Injury : Finding Site = Structure of Head of Femur : Laterality = Left, Morphology = Spiral Fracture (the second concept is more specific than “Fracture of Femur”; although it is subsumed by it, it is not equivalent to it)
Predicate Expression	The Expression that is being tested as the *more general* concept in a subsumption test. This is typically the expression that appears in a query. Fracture of Femur in the subsumption tests above.
Candidate Expression	The Expression that is being tested as the *more specific* concept in a subsumption test. This is typically the expression that appears in the patient record. The Post-coordinated Expressions in the subsumption tests above

Informatics [Agile|Analytic] Architecture	The underlying architecture - which we call ISAAC - is a logical architecture, not an implementation. It describes the logical informatics architecture that will be reflected in the systems architecture of VHA clinical systems. In addition, it is an integrative architecture, which deliberately builds upon selected, compatible elements of its underlying components to build a coherent system. It builds primarily upon SNOMED CT, RxNORM, and LOINC by integrating their content and semantics, and normalizing the means to identify and version components, lexically search, logically define, semantically retrieve, and collaboratively extend.
SNOMED CT-US extension	Integrated SNOMED CT product, containing the US extension of terminology.
SNOMED CT-US-VA extension	Integrated SNOMED CT product, containing the US extension as well as the terminology from the VA extension.
SNOMED CT-US-VA extension	The Linux Standard Base [https://en.wikipedia.org/wiki/Linux_Standard_Base] (LSB) is a joint project by several Linux distributions under the organizational structure of the Linux Foundation to standardize the software system structure, including the filesystem hierarchy used in the Linux operating system. The LSB is based on the POSIX specification, the Single UNIX Specification (SUS), and several other open standards, but extends them in certain areas.
Node package manager	npm [https://en.wikipedia.org/wiki/Npm_(software)]is the default package manager for the JavaScript runtime environment Node.js.
MSA	Microservice architecture [https://smartbear.com/learn/api-design/what-are-microservices/] is a method of developing software applications as a suite of independently deployable, small, modular services in which each service runs a unique process and communicates through a well-defined, lightweight mechanism to serve a business goal.
SOA	A service-oriented architecture [https://en.wikipedia.org/wiki/Service-oriented_architecture] (SOA) is a style of software design where services are provided to the other components by application components, through a communication protocol over a network. The basic principles of service oriented architecture are independent of vendors, products and technologies.[1] A service is a discrete unit of functionality that can be accessed remotely and acted upon and updated independently, such as retrieving a credit card statement online.
Informatics Standards Architecture ACceleration	The VA ISAAC (InformaticS Architecture ACceleration) effort seeks a holistic approach to architecture that supports novelty within a rigorous—and vertically integrated—deployment pipeline that enables knowledge engineers, developers, testers, build managers, and operations personnel to work together effectively to deliver assets to the points of care and analysis. This technology stack must support integrated delivery of iterative revisions of specifications, services, and content which are today delivered by isolated silo organizations who place the implementation burden upon their consumers. This pipeline will be built from existing software-based best practices, and will embrace DevOps culture and practice by emphasizing collaboration and communication while automating the process of product delivery. ISAAC will promote standards and clarify the interoperability of terminologies for the workbench and Opentooling framework.
KnOwledge Management EnvironmenT	The VA ISAAC's KnOwledge Management EnvironmenT (KOMET) realizes the informatics architecture within a DevOps environment that integrates development, testing, publication, and delivery of specifications, content, and services into a vertically integrated environment that supports continuous delivery. See Also Informatics Standards Architecture ACceleration.

Semantic Operability using SNOMED CT, LOINC, and RxNorm	A single comprehensive terminology structure, populated with normalized content from SNOMED CT, LOINC and RxNORM terminologies. A single, integrated terminology will simplify the development and implementation of higher order models. The single terminology model is based on the data structures of the SNOMED RF2 model, which features comprehensive and consistent version representation, modularity of content with defined dependencies between modules, standardized processes for promoting content from one module to another, and standardized processes and structures for extending the provided content to meet system requirements. See Also Systematized Nomenclature of Medicine: Clinical Terms, Logical Observation Identifiers Names and Codes, RxNorm.
Project Information System and Management Environment	Environment to support common functionality required for project management, workflow, and system integration. For example, issue tracking, artifact versioning, and so forth.
Lightweight Expression of Granular Objects	Lightweight Expression of Granular Objects are reusable standards-based clinical data objects designed to protect clinicians from complex codes. LEGOs accurately capture clinical meaning and preserve clinical meaning between systems. They are looseley based on the IHTSDO Observables Model concept and comprised of self-contained units of knowledge, LEGOs transform patient data into a normalized consumable form. Ultimately, LEGO models can provide a foundation for the large-scale exchange of computer-processible medical information
Veterans Health Administration	The Veterans Health Administration is America's largest integrated health care system with over 1,700 sites of care, serving 8.76 million Veterans each year.
U.S. Department of Veterans Affairs	The US Department of Veterans Affairs provides patient care and federal benefits (financial, education, and so forth) to veterans and their dependents. (http://www.va.gov/) . There are three major administrative areas: Veterans Benefits Administration (VBA), Veterans Health Administration (VHA), and National Cemetery Administration (NCA).
Agency for Healthcare Research and Quality	The Agency for Healthcare Research and Quality (AHRQ) (formerly known as the Agency for Health Care Policy and Research) is an agency of the Department of Health and Human Services (HHS) whose mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work to make sure that the evidence is understood and used. AHRQ's priority areas of focus are to: * Improve health care quality by accelerating implementation of patient-centered outcomes research (PCOR). * Make health care safer. * Increase accessibility by evaluating Affordable Care Act (ACA) coverage expansions. * Improve health care affordability, efficiency, and cost transparency.
American Recovery and Reinvestment Act	The American Recovery and Reinvestment Act of 2009 (ARRA) (Public Law 111–5), commonly referred to as the Stimulus or The Recovery Act, was an economic stimulus package acted in the spring of 2009. While the primary purpose of ARRA was to stimulate the economy, it included the enactment of the Health Information Technology for Economic and Clinical Health Act, also known as the HITECH Act, which among other things codified the Office of the National Coordinator for Health Information Technology (ONC), and provided for health information technology investments and incentive payments meant to encourage the Meaningful Use of EHRs. This is important to VA as ONC has sponsored the development of standards which are then named in regulation as being necessary for Meaningful Use certification.

	See Also Health Information Technology for Economic and Clinical Health Act, Meaningful Use, Office of the National Coordinator For Health Information Technology.
Accredited Standards Committee X12	The Accredited Standards Committee X12 (ASC X12), is a Standards Development Organization (SDO) chartered by the American National Standards Institute (ANSI) in 1979. [The name "X12" is a sequential designator assigned by ANSI at the time of accreditation]. ASC X12 develops Electronic Data Interchange (EDI) standards for multiple industries. Of interest to the VA is the Insurance industry standards which includes healthcare eligibility and billing standards. These healthcare eligibility and billing standards are widely used, and their use is mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
American Society for Testing and Materials	ASTM International, known until 2001 as the American Society for Testing and Materials (ASTM), is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services. While ASTM is generally not involved in Healthcare IT standards, they developed a Continuity of Care Record (CCR) standard, which was included in Stage 1 of Meaningful Use.
Health Insurance Portability and Accountability Act	The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Public Law 104–191) contains two sections, the second of which directly affects the VA. Title I protects health insurance coverage for workers and their families when they change or lose their jobs. Title II, known as the Administrative Simplification (AS) provisions, requires the establishment of national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers. The AS provisions also address the security and privacy of health data. The standards are meant to improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in the U.S. health care system. The HIPAA AS provisions mandate, among other things, the use of ASC X12, HL7, and NCPDP messaging standards. Note that the HIPAA privacy provisions were strengthened in the ARRA legislation. See Also American Recovery and Reinvestment Act.
Health Information Technology for Economic and Clinical Health Act	The Health Information Technology for Economic and Clinical Health Act, abbreviated HITECH Act, was enacted under Title XIII of the American Recovery and Reinvestment Act of 2009. The HITECH Act provides funding to promote and expand the adoption of health information technology, including the creation of a nationwide network of electronic health records. The HITECH Act set meaningful use of interoperable EHR adoption in the health care system as a critical national goal and incentivized EHR adoption, and provides incentives for adoption of MU-certified EHR systems, which later become penalties for non-use of such systems. The Act officially established the Office of the National Coordinator for Health Information Technology (ONC), (which already existed under Executive Order 13335); as well as the The HIT Policy Committee which recommends a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information; and the HIT Standards Committee which recommends to the National Coordinator standards, implementation specifications, and certification criteria. The activities of these organizations are important to VA as they deal with the development of standards which are then named in regulation as being necessary for Meaningful Use certification and implemented in the Nationwide Health Information Network.

	See Also American Recovery and Reinvestment Act, Health Information Technology Policy Committee, Health Information Technology Standards Committee, Meaningful Use, Office of the National Coordinator For Health Information Technology.
Health Information Technology Policy Committee	A committee which will make recommendations to the National Coordinator for Health IT on a policy framework for the development and adoption of a nationwide health information infrastructure, including standards for the exchange of patient medical information.
Health Information Technology Standards Committee	A committee which is charged with making recommendations to the National Coordinator for Health IT on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information.

Source

<bibliomisc>http://www.healthit.gov/policy-researchers-implementers/health-it-standards-committee</bibliomisc>

Health Information Technology Standards Panel	A cooperative partnership between the public and private sectors for the purpose of harmonizing and integrating standards that will meet clinical and business needs for sharing information among organizations and systems.

Source

<bibliomisc>http://www.hitsp.org/</bibliomisc>

International Health Terminology Standards Development Organisation	The International Health Terminology Standards Development Organisation (IHTSDO) is an international non-profit standards development organization. Its mission is to develop, maintain, promote and deliver medical terminology products in order to improve the health in a global scale through the development and application of appropriately standardized clinical terminologies in general. In particular, the IHTSDO maintains and promotes SNOMED CT to ensure safe, precise and effective exchange of clinical and health related information. See Also Systematized Nomenclature of Medicine: Clinical Terms.
Logical Observation Identifiers Names and Codes	Logical Observation Identifiers Names and Codes (LOINC) is a standard for identifying medical laboratory observations. It was developed and is maintained by the Regenstrief Institute. LOINC was created in response to the demand for an electronic database for clinical care and management and is publicly available at no cost. LOINC applies universal code names and identifiers to medical terminology related to electronic health records. The purpose is to assist in the electronic exchange and gathering of clinical results (such as laboratory tests, clinical observations, outcomes management and research). LOINC has two main parts: laboratory LOINC and clinical LOINC. Clinical LOINC contains a subdomain of Document Ontology which captures types of clinical reports and documents. It is noted that there is some overlap between LOINC and SNOMED-CT. Recently LOINC and IHTSDO agreed to harmonize the two standards. See Also International Health Terminology Standards Development Organisation, Systematized Nomenclature of Medicine: Clinical Terms.
Office of the National Coordinator For Health Information Technology	A resource to the entire health system to support the adoption of health information technology and the promotion of a nationwide health information exchange to improve health care.

Source

<bibliomisc>http://www.healthit.gov/newsroom/about-onc</bibliomisc>

RxNorm	RxNorm, produced by the National Library of Medicine, provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, including those of First Databank, Micromedex, MediSpan, Gold Standard, and Multum. By providing links between these vocabularies, RxNorm can mediate messages between systems not using the same software and vocabulary.
Systematized Nomenclature of Medicine: Clinical Terms	The Systematized Nomenclature of Medicine: Clinical Terms (SNOMED CT) is the most comprehensive, multilingual clinical terminology in the world. It is a vital component for safe and effective communication and reuse of meaningful health information. See Also International Health Terminology Standards Development Organisation.
American Health Information Management Association	A professional organization for the field of medical record management.
Armed Forces Health Longitudinal Technology Application	The clinical documentation engine used by DoD Physicians to write their notes, input orders, document procedures performed and provide the basis of medical coding information.
Architecture Review Board (HL7)	The HL7 Architecture Review Board seeks to define a coherent architecture for HL7 work that defines the relationships among the HL7 work products and how they relate to other standards and components of local implementations. This architecture includes the Business Architecture by which these work products are produced and managed through their life cycle, the governance that will be enacted on these work products, and the scope of the standardization effort itself.
Bi-directional Health Information Exchange	A series of communications protocols developed by the VA used to exchange healthcare information between VA healthcare facilities nationwide and between VA healthcare facilities and DoD healthcare facilities.
Clinical Application Coordinator	The Clinical Application Coordinator (CAC) as a part of the Resource and Patient Management System (RPMS)-EHR implementation team provides ongoing operational support for certain RPMS packages that comprise and/or interface with the Electronic Health Record.
Compensation and Pension Record Interchange	CAPRI software was designed to promote efficient communications between VHA and VBA. It offers VBA Rating Veteran Service Representatives and Decision Review Officers help in building the rating decision documentation through on-line access to medical data.
Continuity of Care Document	An XML-based markup standard/specification intended to specify the encoding, structure, and semantics of a patient summary clinical document for exchange. The CCD is a constraint on the HL7 Clinical Document Architecture (CDA) standard specifying that the content of documents consist of a mandatory textual part for human interpretation and optional structured parts for software processing.
Consolidated Clinical Document Architecture	An ANSI-certified standard from Health Level Seven (HL7), which specifies the syntax and supplies a framework for specifying the full semantics of a clinical document. C-CDA defines a clinical document as having six characteristics; Per-

	sistence, Stewardship, Potential for Authentication, Context, Wholeness, and Human Readability.
Critical Care Data Interface	Interfaces which exchange information between VistA, the VA's computerized patient record and information system, and GE's QS(R) Critical Care Clinical Information System. These interfaces will enable VA Medical Centers nationwide to improve efficiency and accuracy by reducing duplicate data entry. In addition, they will support a national research data repository for patients treated in critical care and operating room environments.
Clinical Care Delivery Support System	A system that provides clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.

Source

<bibliomisc>http://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds</bibliomisc>

Clinical Context Object Workgroup	A vendor independent HL7 standard protocol designed to enable disparate applications to synchronize in real time at the user-interface level, which allows applications to present information at the desktop and/or portal level in a unified way.
Clinical Decision Support	Provision of pertinent knowledge and person-specific information to clinical decision makers to enhance health and health care.1 A required component of Meaningful Use. For further detail, review the CDS Content Delivery Roadmap.
Clinical Element Model	A small reusable representation of clinical information that is bound to a terminology system for its meaning. The CEM approach and repository of models was developed by Intermountain Healthcare and is used within their clinical systems.
Composite Health Care System	A module-based medical informatics system designed by Science Applications International Corporation (SAIC) and used by all DoD health care centers. Modules include RAD (radiology), LAB (Laboratory), PHR (Pharmacy), PAS (Patient Appointing and Scheduling), MCP (Managed Care Program; used to support TRICARE enrollees by enrolling them to Primary Care Managers), PAD (Patient Administration): MRT (Medical Records Tracking), MSA (Medical Service Accounting) medical billing, WAM (Workload Assignment Module), DTS (Dietetics), CLN (CLinical: Nursing, Physician, and Allied Health), DAA (Database Administration), ADM (Ambulatory Data Module) Medical Coding of outpatient visits, and TOOLS (FileMan).
Clinical/Health Data Repository	The Department of Defense (DoD) and the Department of Veterans Affairs (VA) in partnership, designed and implemented a Clinical Data Repository/Health Data Repository (CHDR) system that generates standards-based, computable electronic health records that can be exchanged and shared between the two agencies healthcare systems.
Clinical Information Modeling Initiative	An initiative established to improve the interoperability of healthcare information systems through shared implementable clinical information models
Computerized Patient Record System	A graphical user interface (GUI) for VistA. http://www.ehealth.va.gov/EHEALTH/CPRS_Demo.asp
Clinical Quality Measure	CQMs are tools that help many stakeholders, including CMS and health care providers themselves, measure and track the quality of health care services provid-

	ed by eligible professionals, eligible hospitals, and CAHs within our health care system. They measure many aspects of patient care including health outcomes, clinical processes, patient safety, efficient use of healthcare resources, care coordination, patient engagement, and population and public health.
Disability Benefits Questionnaire	DBQs are downloadable forms created for Veterans' use in the evaluation process for disability benefits. DBQs will help speed the processing of Veterans' disability compensation and pension claims. DBQs allow Veterans and Service members to have more control over the disability claims process by giving them the option of visiting a primary care provider in their community, at their expense, instead of completing an evaluation at a Department of Veterans Affairs (VA) facility. The streamlined forms use check boxes and standardized language so that the disability rating can be made accurately and quickly.
Electronic Data Interchange	The transfer of structured data, by agreed message standards, from one computer system to another without human intervention. EDI relies on primarily older technologies and point-to-point messaging.
Electronic Health Record	A systematic collection of electronic health information about individual patients or populations. See also Interagency EHR (iEHR)
Federal Health Information Model	A coordination of several partner agencies with the development of electronic medical records, information and terminology standards, including the coordination of agency efforts at relevant Standards Development Organizations (SDOs).

Source

<bibliomisc>http://www.fhims.org/</bibliomisc>

Fast Health Information Resources	Fast Healthcare Interoperability Resources (FHIR, pronounced "Fire") defines a set of "Resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. Technically, FHIR is designed for the web; the resources are based on simple XML or JSON structures, with an http-based RESTful protocol where each resource has predictable URL. Where possible, open internet standards are used for data representation.

Source

<bibliomisc>http://wiki.hl7.org/index.php?title=FHIR</bibliomisc>

Health Architecture Interagency Group	A component of the VA/DoD IPO structure.
Health Architecture Review Board	Serves as an advisory working sub-group to the VA/DoD Health Executive Council (HEC) that provides architecture oversight and approval due diligence for joint DoD/VA health programs to facilitate interagency cooperation and foster collaboration on enterprise architecture for interagency Health Information Technology (HIT) initiatives; activities that were previously the responsibility of the HEC IM/IT WG.
Health Level 7	A non-profit organization involved in the development of international healthcare informatics interoperability standards. The name "Health Level-7" is a reference to the seventh layer of the ISO OSI Reference model also known as the application layer, indicating that HL7 focuses on application layer protocols for the health care domain, independent of lower layers.

Health Management Platform	An IT platform for browser-based, clinical (nurse and physician) user-interface modules that are healthcare team-driven and enable functionality which decrease cognitive load, managing relationships between conditions, interventions and observations, acquire data (including documentation) as a by-product of workflow and support higher quality, safe patient care and clinician satisfaction.

Source

<bibliomisc>http://www.osehra.org/document/va-health-informatics-initiative-health-management-platform-virtual-patient-record</bibliomisc>

International Classification of Diseases	UN-sponsored WHO standard diagnostic tool for epidemiology, health management and clinical purposes.2 The ICD is revised periodically and is currently in its tenth revision. (ICD-10)
Interagency Electronic Health Record	A healthcare IT system currently under development which will integrate the Health IT resources of both the VA and the DoD to acquire next generation EHR capabilities for both departments.
Intermountain Healthcare	A non-profit healthcare system based in Salt Lake City, UT., which is the largest healthcare provider in the Intermountain West.
Integrating the Healthcare Enterprise	Associated with Patient Care Devices (PCD) and Pulse Oximetry (POI)
Interagency Program Office	IPO will act as a single point of accountability in the development and implementation of electronic health records systems or capabilities as well as accelerating the exchange of health care information to support the delivery of health care by both Departments. The IPO will also have responsibility for oversight and management of personnel and benefits electronic data sharing between the Departments.
Informatics Research and Design Center	A VA facility and operations base for the Knowledge Based Systems group, located in Nashville, TN
Joint Initiative Council	Formed to enable common, timely health informatics standards by addressing and resolving issues of gaps, overlaps, and counterproductive standardization efforts for international standardization needs.

Source

<bibliomisc>http://www.jointinitiativecouncil.org/</bibliomisc>

Javascript Object Notation	A text-based open standard designed for human-readable data interchange, used primarily to transmit data between a server and web application, serving as an alternative to XML.
Knowledge Based Systems	Office that extends past VA informatics by infusing clinical informatics expertise into VHA healthcare decision making, strategic planning, and delivery.
Model Driven Health Tools	An open source tooling project initiated and lead by VHA within the Open Health Tools (OHT) organization. VA is also one of the founding members of OHT.
Medical Domain Web Services	A suite of Service Oriented Architecture (SOA) middle-tier web services that exposes medical domain functionality, Medical Domain Objects (MDO). MDWS is

	equipped with the capacity to virtualize any legacy Veterans Health Information Systems and Technology Architecture (VistA) Remote Procedure Call (RPC) as a web service. A web service is an Application Programming Interface (API), which uses Simple Object Access Protocol (SOAP), the standardized protocol to communicate with subscribed client applications. http://osehra.org/group/mdws The MDWS Group at OSEHRA is intended to coordinate the further development and maintenance of MDWS as an Open Source project.
Meaningful Use	An incentive-based program to be rolled out in 3 planned stages over the period of approximately 2010 through 2016, which is designed to insure that providers show the use of certified EHR technology in ways that can be measured significantly in quality and quantity. The three core MU requirements for a certified EHR are: use in a meaningful manner, such as e-prescribing; the electronic exchange of health information to improve quality of health care; and utilization in submitting clinical quality and other measures.
National Council for Prescription Drug Programs	A not-for-profit, ANSI-accredited, standards development organization representing most sectors of the pharmacy services industry. The membership provides healthcare business solutions through education and standards focused on improving communication within the pharmacy industry.
National Drug File - Reference Terminology	The National Drug File - Reference Terminology (NDF-RT) is produced by the U.S. Department of Veterans Affairs, Veterans Health Administration (VHA). NDF-RT is an extension of the VHA National Drug File (NDF). It organizes the drug list into a formal representation. NDF-RT is used for modeling drug characteristics including ingredients, chemical structure, dose form, physiologic effect, mechanism of action, pharmacokinetics, and related diseases.
National Information Exchange Model	An XML-based information exchange framework representing a collaborative partnership of agencies and organizations across all levels of the U.S. government (federal, state, tribal, and local), as well as private industry. NIEM is designed to develop, disseminate, and support enterprise-wide information exchange standards and processes to enable automated information sharing.
National Library of Medicine	A division of the National Institutes of Health (NIH), representing the world's largest medical library. The NLM includes more than seven million books, journals, technical reports, manuscripts, microfilms, photographs and images on medicine and related sciences including some of the world's oldest and rarest works.
Notices of Proposed Rule Making	A notice of proposed rule making (NPRM) is a public notice issued by law when one of the independent agencies of the United States government wishes to add, remove, or change a rule or regulation as part of the rulemaking process. It is an important part of United States administrative law which facilitates government by typically creating a process of taking of public comment.
Office of Information and Analytics	An office that provides strategy and technical direction, guidance, and policy to ensure that IT resources are acquired and managed for the VA in a manner that implements various Federal laws and regulations.

Source

<bibliomisc>http://www.oit.va.gov/About_the_Office_of_OI_T.asp</bibliomisc>

Office of Information and Technology	OIT delivers available adaptable, secure and cost effective technology services to the Department of Veterans Affairs (VA) and acts as a steward for all VA's IT assets and resources.
Object Management Group	An international, open membership, non-profit computer industry standards consortium focused on modeling (programs, systems and business processes) and model-based standards. http://www.omg.org/
President's Council of Advisors on Science and Technology.	An advisory group of the nation's leading scientists and engineers who directly advise the President and the Executive Office of the President. PCAST makes policy recommendations in the many areas where understanding of science, technology, and innovation is key to strengthening our economy and forming policy that works for the American people. PCAST periodically produces reports on a number of technology subject areas, one of which is Networking and Information Technology Research and Development. Under this category, on December 8, 20, a "PCAST report was published titled "Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward." http://www.whitehouse.gov/sites/default/files/microsites/ostp/pcast-health-it-report.pdf
Patient Care Devices	A medical device used in the process of diagnosing, monitoring, treating, or preventing disease.

Source

<bibliomisc>http://www.ihe.net/resources/upload/ihe_pcd_user_handbook_2011_edition.pdf</bibliomisc>

Pulse Oximetry	Pulse Oximetry is a non-invasive method for monitoring a patient's O2 saturation using a pulse oximeter device.
IHE Patient Care Device Technical Framework Supplement - Pulse Oximetry Integration.	This supplement builds on existing integration profiles (i.e., PCD, DEC) and transactions (i.e., PCD-01) and specifies content constrained for exchanging pulse oximetry data
Requirements Analysis and Engineering Management	Management of those tasks that encompass determining the needs or conditions to be met for a new or altered product, including conflicting requirements of various stakeholders, analyzing, documenting, validating and managing software or system requirements.
Representational State Transfer	An architectural style that abstracts the architectural elements within a distributed hypermedia system. REST ignores the details of component implementation and protocol syntax in order to focus on the roles of components, the constraints upon their interaction with other components, and their interpretation of significant data elements.
Regenstreif Institute	A private, non-profit research organization founded in 1969, heavily involved in the field of medical informatics and health services research, which is affiliated with the Indiana University School of Medicine and based in Indianapolis.
Substance Abuse and Mental Health Services Administration	A branch of the U.S. Department of Health and Human Services, headquartered in Rockville, MD., charged with improving the quality and availability of prevention, treatment, and rehabilitative services in order to reduce illness, death, disability, and cost to society resulting from substance abuse and mental illnesses.3 www.samhsa.gov

Standards Collaboration Roadmap	A guide identifying the strategic partners, priorities, established objectives and evaluation criteria for interagency collaboration and joint standards architecture engagement. The roadmap will include both internal VA programs and external agency partner collaboration activities. The SCR is a revision-controlled document, updated as needed to reflect the dynamic nature of the healthcare IT environment.
Standards Development Lifecycle	A 6-step cycle used to define the process steps and stakeholders involved within the development and adoption of standards.
Standards Development Organization	An organization whose primary activities are developing, coordinating, promulgating, revising, amending, reissuing, interpreting, or otherwise producing technical standards that are intended to address the needs of a relatively wide base of affected adopters (e.g. Health IT). SDOs may be governmental, quasi-governmental or non-governmental entities. Quasi- and non-governmental standards organizations are often non-profit organizations.
System for the Mechanical Analysis and Retrieval of Text	An information retrieval system used within documentation and forms. The SMART (System for the Mechanical Analysis and Retrieval of Text) Information Retrieval System is an information retrieval system developed at Cornell University in the 1960s. Many important concepts in information retrieval were developed as part of research on the SMART system, including the vector space model, relevance feedback, and Rocchio classification.

Source

<bibliomisc>https://en.wikipedia.org/wiki/SMART_Information_Retrieval_System</bibliomisc>

Substitutable Medical Applications, Reusable Technologies (SMART) Platforms	SMART Health IT is an open, standards based technology platform that enables innovators to create apps that seamlessly and securely run across the healthcare system. Using an electronic health record (EHR) system or data warehouse that supports the SMART standard, patients, doctors, and healthcare practitioners can draw on this library of apps to improve clinical care, research, and public health. The SMART platform is composed of open standards, open source tools for developers building apps and a publicly accessible app gallery. To date, dozens of clinical applications have been built on this platform, and SMART applications are being used to provide clinical care at healthcare institutions, including Boston Children's Hospital and Duke Medicine. The project is run out of the not-for-profit institutions, Boston Children's Hospital Computational Health Informatics Program and the Harvard Medical School Department for Biomedical Informatics.

Source

<bibliomisc>http://smarthealthit.org/smart-on-fhir/</bibliomisc>

Subject Matter Expert	An individual who is broadly accepted as an expert in a particular area or topic.
A recursive acronym for SPARQL Protocol and RDF Query Language	A query language for databases, able to retrieve and manipulate data stored in Resource Description Framework format, which was made a standard by the RDF Data Access Working Group (DAWG) of the World Wide Web Consortium, and is recognized as one of the key technologies of the semantic web. SPARQL v1.1 was released in March, 2013.4

Source

<bibliomisc> http://www.w3.org/TR/sparql11-overview/</bibliomisc>

Standards Related Organization	An organization whose primary activities are directly inter-related or critically affected by the development, coordination, promulgation, revision, amendment, reissuance, interpretation, or production of technical standards.
Standards Steering Committee	A committee representing multiple organizations within VHA, chartered to refine and vet the Standards Life Cycle Process document and establish/maintain a governance process for prioritization and validation of standards and standards-related activities.
Standards and Terminology Service	To prepare standards specifying principles and methods for the preparation and management of language resources within the framework of standardization and related activities.5 (See also ISO/TC 37)
Unified Modeling Language	A standardized general-purpose modeling language in the field of object-oriented software engineering. UML was added to the list of OMG adopted technologies in 1997.
Veterans Benefit Management System	The VA's web-based, electronic claims processing solution. The first Generation of VBMS was deployed in January 2013. The integration of VBMS with the online portal eBenefits, provides an end-to-end digital filing capability.
VHA eHealth University	The online presence and training platform for the Office of Training Strategy. VeHU is used to promote collaboration of clinical staff, developers, and informatics staff to ensure VA resources are utilized in every possible capacity.
Veterans Integrated Service Networks	22 geographic based VA operating units or networks, allowing networks to manage themselves and adapt to the specific demographics of their location.
Veterans Information Systems and Technology Architecture	An enterprise-wide information system consisting of a range of over 150 integrated software modules designed for the support of clinical care, financial functions, and infrastructure management. A GUI developed for clinician use, Computerized Patient Record System (CPRS), provides a client-server interface that allows health care providers to review and update a patient's electronic medical record.
World Health Organization	A specialized agency of the United Nations (UN) that is concerned with international public health, established on 7 April 1948, and headquartered in Geneva, Switzerland.8
eXtensible Markup Language	A markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable. The design goals of XML emphasize simplicity, generality, and usability over the Internet.9
Multi-Enterprise Architecture of Networked Services	See HITSP 08 N 345 MEANS - A Multi-Enterprise Architecture of Networked Services standard. Note that this standard may be obsolete.

E. Parking lot/Ideas Discussed and Discarded

E.1. Confusion About Negation: “Absent” and “Not Present”

Negation as a logical concept is subject to many ambiguities and inconsistencies, in healthcare applications and general usage[1]. For example, the semantic distinctions between the statements “he didn’t say she was ill” and “he said she was not ill” are subtle and open to varying interpretations. When such distinctions appear in medical records and are used as the basis for inference or data retrieval, it’s important that a clear and formal semantic exists that is shared by those who record the information, those who later review the information and use it in medical decision making, and those who write software that aggregates, abstracts, infers, or performs other logical computations on the information.

One important distinction in medical documentation is that of a clinical phenomenon being documented as “absent” versus the phenomenon not being documented as “present.” For example, does the explicit documentation of “No abdominal tenderness” mean the same thing as no documentation of “abdominal tenderness”? Would the interpretation be different if the phenomenon were instead “jaundice” or “HIV”? Would it matter if the presenting complaint at the time that observation were documented were “vomiting” versus “ankle sprain”? Depending on the clinical context, the specific phenomenon in question, and the assumptions of individuals using the medical record, the interpretation of “absent” versus “not present” could be the same or quite different. Today’s representation and inferencing models for electronic health records do not provide enough clarity and control to safely interpret negation in these situations.

Finally, current ontology-based models for representing clinical observations sometimes result in gross errors when subsumption inferences are applied to negated clinical concepts. For example, the SNOMED-CT model incorrectly infers that the documentation of “No myocardial infarction” in a patient implies that the patient has “No heart disease” whatsoever. A model that correctly handles subsumption testing over negated clinical concepts is required to support correct (and safe) inferencing in electronic health records.

E.2. Potential Problems and Issues

Although it helps to solve the problems described Section ???, the models presented in this paper for consolidating “Findings” and “Observable Entities” into “Phenomena” and for normalizing the representation and querying of negated phenomena also entail certain challenges and limitations.

E.2.1. Negative Values for Phenomena

The model does not allow interval values that include negative real numbers. In rare cases, clinical phenomena require such values, for example the phenomenon of “Max ST deflection” in an EKG, which can be either positive or negative.

A potential solution in these cases is to change the modeling of certain phenomena so that they only take on positive numeric values. In the example above, this strategy would entail the specification of separate phenomena for “Max ST depression” and “Max ST elevation”. Further work is required to determine how

[1] Horn L. A Natural History of Negation. University of Chicago Press, 1989.

often phenomena with negative values occur and whether the proposed strategy is effective is all such cases.

E.2.2. Values from Enumerated Value Sets that are not Numeric or not Ordinal

Certain clinical phenomena have values that are simply not numeric, and to which the model for representing and processing interval values does not cleanly apply. The following phenomena and their corresponding enumerated value sets illustrate this point.

Eye-Color: Values = (Blue, Green, Brown, Black, …)

Eye-Color : Values = (1=Blue, 2=Green, 3=Brown, 4=Black, …)

Dysphagia: Values = (never, rarely, sometimes, frequently, always)

Patellar tendon reflex: Values = (1+, 2+, 3+, 4+)

To address the reality of such observations in the medical record, the assignment of interval values may need to be limited to only those phenomena whose values are naturally numeric or can be characterized as present, absent, or indeterminate (for which interval values are defined). An alternative would be to always assign such phenomena the interval value “(0,#]” (Present), and denote the property values using a different attribute (such as “color”, “frequency”, of “intensity” in the cases above).

E.2.3. Units of Measure for Non-Quantitative Values

Consolidating “Findings” and “Observable Entities” allows the use of a numeric interval value to denote the presence or absence of clinical observations that wouldn’t otherwise have numeric values, such as “nausea” or “dizziness.” Interval values also allow one to denote the presence and the cardinality of certain clinical phenomena using a single value, such as for “Daily cigarette use” or “Pressure ulcers”.

In both situations however, there is no natural unit of measure to associate with the interval values. To the degree that there’s benefit in consistently assigning a unit of measure to all values, this void presents a problem.

A possible solution is to have a “null” unit of measure, indicating that the value is not associated with any unit of measure. This strategy may not be unfamiliar to data modelers and data analysts, in that certain LOINC lab codes already include such a designation (such as for Urine Specific Gravity, a dimensionless measurement). Alternatively, one could create special-purpose units of measure to associate with dimensionless values. Again, this strategy has been adopted for certain LOINC lab codes, such as pH (which includes a special “[pH]” unit of measure) or manual cell count (which includes the special “per high powered field” unit of measure).

E.2.4. Subsumption over all Refining Attributes of Phenomena

As described in Section Section C.1.2, “Assigning Values to Phenomena That Include Refining Attributes”, correct application of the tri-valued model for querying phenomena requires that interval values be assigned to the entirety of each phenomenon (including all of its refining attributes). Further, the correct applications of the axioms in Section Section C.2.2, “A Formal Model of Negation with Subsumption Relationships” also require that subsumption testing between phenomenon (i.e., application of the “Is-A()” predicate within these axioms) include all of the refining attributes to which interval values have been

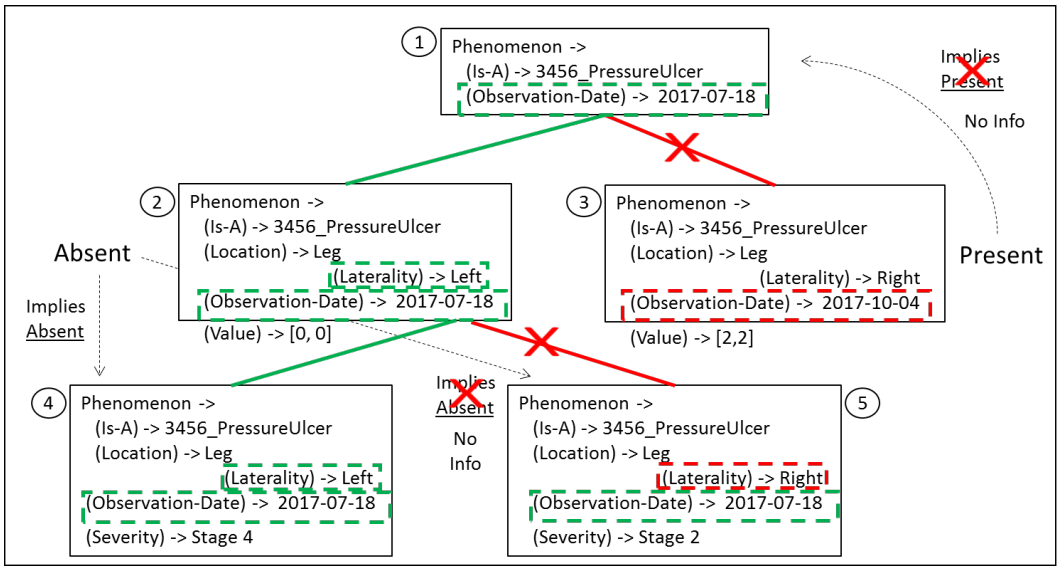
assigned. If subsumption testing is performed using only a subset of the attributes to which interval values are assigned, the axioms will produce incorrect results.

The point is illustrated through several examples shown in Figure E.1, “Examples of correct and incorrect application of subsumption testing involving post-coordinated phenomena.”.

Note, for example, that if subsumption testing between phenomenon 1 and phenomenon 3 excludes the “Observation-Date” value in phenomenon 3, and “Observation-Date” is within the scope of the attributes to which the interval value “[2,2]” has been assigned, then phenomenon 3 will be subsumed by phenomenon 1 and the axioms of Section Section C.2.2, “A Formal Model of Negation with Subsumption Relationships” will infer that phenomenon 1 is present. However, upon inspection, it is clear that the presence of two pressure ulcers in the right leg on Oct. 4, 2017 does not necessarily imply the presence of any pressure ulcers on July 7, 2017. Subsumption testing that correctly included the “Observation-Date” attribute would have prevented this incorrect inference and concluded that the existence of pressure ulcers on July 7, 2017 was indeterminate based on the available data.

Similarly, if subsumption testing between phenomenon 5 and phenomenon 2 excludes the “Laterality” attribute of the anatomical location of phenomenon 5 (a nested attribute), and “Laterality” is within the scope of the attributes to which the interval value “[0,0]” has been assigned, then phenomenon 5 will be subsumed by phenomenon 2 and the axioms of Section Section C.2.2, “A Formal Model of Negation with Subsumption Relationships” will infer that phenomenon 5 is absent. Again, however, intuition should make clear that the absence of a pressure ulcer on left leg on July 18, 2017 does not necessarily imply the absence of a pressure on the right leg on that same date. Inclusion of the “Laterality” attribute in the subsumption test would have prevented this incorrect inference, and caused the axioms of Section Section C.2.2, “A Formal Model of Negation with Subsumption Relationships” to conclude that the presence of a stage-2 pressure ulcer in the right leg on that date was indeterminate based on the data.

Figure E.1. Examples of correct and incorrect application of subsumption testing involving post-coordinated phenomena.



The point of these examples is to underscore the importance of including all of the refining attributes to which interval values are assigned in any subsumption tests that are later performed. In practice, however, this may not be a trivial undertaking. For example, subsumption testing between date values of different granularities (year vs. month vs. day) is not supported by standard description logic reasoners, so that a phenomenon observed in July 2017 may not correctly subsume the same observation observed on July 12, 2017. Further, the correct semantics of subsumption between date values when assigned to clinical

observations may not be straightforward. For example, assigning an Observation-Date value of “July 2017” to a phenomenon could mean that the phenomenon was observed at *some point* in July 2017, or it could mean that the phenomenon was observed throughout the duration of July 2017. The intended meaning has implications for whether a phenomenon with the Observation-Date value of “July 2017” should subsume a phenomenon with the Observation-Date value of “July 18, 2017” with respect to the application of the axioms in Section Section C.2.2, “A Formal Model of Negation with Subsumption Relationships”.

Similar questions arise regarding the scope of attributes to which interval values should be assigned, and which ones comprise refining attributes of the phenomenon itself (such as laterality, observation-date, severity, etc.), and which ones comprise meta-attributes that do not refine the phenomenon (such as identity of the observer, method of observation, purpose of the observation, etc.). Strictly speaking, meta-attributes should be excluded from the scope of interval-value assignments and (therefore) from subsumption testing, but in certain cases it may not be clear which attributes are truly refining attributes and which are meta-data, and that distinction may even be context specific. For example, method of observation may be a significant attribute of the observed phenomenon in certain cases, but not others. All of these issues remain to be examined and resolved before one can correctly and reliably apply the models presented here.

E.2.5. “Cognitive Dissonance”

The final challenge in using the models described here is the unintuitive nature of representing the values of all clinical observations using numeric intervals, as formalized in Section Section 12.2.6.2, “Phenomena and Interval Values”. The notion that entirely qualitative clinical observations such as “nausea” and “dizziness” have quantitative interval values may be difficult for those implementing and working with the proposed model to grasp and accept. Similarly, the model produces certain unintuitive characterizations of clinical observations that only have numeric values, such as the conclusion that a “Serum Potassium” observation is “Present” if it’s value is > 0, and otherwise is “Absent”. It remains to be seen whether those using the model can overcome potential “cognitive dissonance” in encountering such implications.

E.3. Compound Clinical Statements: Separable vs. Inseparable Components

Discussion:

- Do we think of clinical statements with “values” only as numerical values? Or would other statements be considered having values, e.g.
  - Patient position = sitting
  - Priority = routine
  - Route of Administration = sublingual

If statements can have values other than numerical values, the BP use case could look like the example below:

USE CASE	SEPARABLE STATEMENTS	INSEPARABLE COMPONENTS
BP of 120/80 mmHg on right brachial artery, patient in sitting position for at least 5 min., using adult BP cuff, urinary bladder voided within 30 min. before measurement	Systolic BP = 120 mmHg	
	Diastolic BP = 80 mmHg	
	Time since last urination = 30 min. or less	

	Measurement body site = right brachial artery	
	Device used = adult cuff	
	Body position = sitting	
	Sitting time before measurement = 5 min. or more	

The “panel” above would consist of the following statements:

1. Systolic BP = 120 mmHg
2. Diastolic BP = 80 mmHg
3. Time since last urination = 30 min. or less
4. Measurement body site = right brachial artery
5. Device used = adult cuff
6. Body position = sitting
7. Time in sitting position = 5 min. or longer

If statements can have values other than numerical values, the Medication use case could look like the example below:

USE CASE	**SEPARABLE STATEMENTS**	**INSEPARABLE COMPONENTS**
Administration of nitroglycerin 0.4 mg tablet sub-lingual every 5 minutes as needed for chest pain; maximum 3 tablets (routine)	Strength = 0.4 mg	Administration
	Frequency = every 5 minutes	Nitroglycerin
	Maximum dosage = 3 tablets	As needed
	Dose form = tablet	
	Route of Administration = sublingual	
	Indication = Chest pain	
	Priority = Routine	

The “panel” above would consist of the following statements:

1. Administration of nitroglycerin as needed
2. Medication strength = 0.4 mg
3. Frequency = every 5 minutes
4. Maximum dosage = 3 tablets
5. Dose form = tablet
6. Route of Administration = sublingual
7. Indication = chest pain

8. Priority = routine

After discussion, decision was made to only define separable components as components with numerical or pseudo-numerical values and components, that can have present/absent values, if these are directly related to the focus of the statement.

27. Maven

27.1. Debugging maven mojo execution

Set the following properties in Netbeans:

```
jpda.listen=maven
Env.MAVEN_OPTS=-ea -Xmx12g -Xms12g
```

Then set your breakpoints within the maven mojo or a dependent library, and then execute a normal clean install.

27.2. Debugging Maven builds

You can attach a debugger to a maven execution so that breakpoints on sections of code can be set, and varibles evaluated. Execute the following from the command line:

```
$ mvndebug clean install
Preparing to Execute Maven in Debug Mode
Listening for transport dt_socket at address: 8000
```

The console indicates that it is listening or transport dt_socket at address: 8000, attach your debugging session to this port from your favorite environment, and follow the methods applicable for that environment.

27.3. Docker

```
$https://whyistheinternetbroken.wordpress.com/2016/03/25/docker-mac-install-fails/
```

28. Source code managment

GitFlow

JGitFlow

28.1. GitFlow release

```
$ mvn jgitflow:release-start
```

28.2. Project refactoring

ISAAC & KOMET software packages are moving from organizational namespaces to project namespaces, so that organizational transitions will not require an additional refactoring step in the future. Two namespaces have been acquired for the refactoring: sh.isaac and sh.komet. The sh prefix can be thought of an acronym for *semiotic history*, since a foundational goal of ISAAC and KOMET is to enable evolutionary development of semiotic artifacts, in a way that supports version control and comprehensive audit trails with respect to these artifacts. Other useful interpretations of sh such as *short handle*, *super hero*, and *Sherlock Holmes* are possible, in addition to sh being the Internet country code top-level domain for *Saint Helena*. Saint Helena is one of the most remote islands in the world. In 1815, Napoleon was imprisoned on Saint Helena in exile by the British. He died there in 1821.

Packages and artifacts prefixed with sh.isaac are used for

Existing packages will be renamed according to the following table:

Table 28.1. Package refactor table

Old Package Prefix	New Package Prefix
gov.va.oia.terminology	sh.isaac
gov.va.isaac	sh.isaac
gov.vha.isaac	sh.isaac
sh.isaac.ochre	sh.isaac
gov.vha.isaac.ochre.commit.manager	sh.isaac.provider.commit
gov.vha.isaac.ochre.concept.provider	sh.isaac.provider.concept
gov.vha.isaac.ochre.coordinate.provider	sh.isaac.provider.coodinate
gov.vha.isaac.ochre.ibdf.provider	sh.isaac.provider.ibdf
gov.vha.isaac.identifier	sh.isaac.provider.identifier
gov.vha.isaac.ochre.logic.provider	sh.isaac.provider.logic
gov.vha.isaac.ochre.logic.csiro	sh.isaac.provider.logic.csiro
gov.vha.isaac.metacontent	sh.isaac.provider.metacontent
gov.vha.isaac.ochre.observable.provider	sh.isaac.provider.observable
gov.vha.isaac.ochre.path.provider	sh.isaac.provider.path
gov.vha.isaac.ochre.progress.provider	sh.isaac.provider.progress
gov.va.isaac.ochre.search	sh.isaac.provider.query.search
gov.vha.isaac.ochre.query.provider	sh.isaac.provider.query

Old Package Prefix	New Package Prefix
gov.vha.isaac.ochre.sememe.provider	sh.isaac.provider.sememe
gov.vha.isaac.ochre.stamp.provider	sh.isaac.provider.stamp
gov.va.isaac.sync.git	sh.isaac.provider.sync.git
gov.vha.isaac.taxonomy	sh.isaac.provider.taxonomy
gov.vha.isaac.ochre.workflow.provider	sh.isaac.provider.workflow

Maven artifact identifers shoud match the enclosing directory that contains the source code of the artifact. As part of the refactoring effort, Maven artifact coordinates, and the corresponding directory names will be renamed according to the following table:

Table 28.2. Artifact coordinate refactor table

Old Group Identifier	Old Artifact Identifier	New Group Identifier	New Artifact Identifier
gov.vha.isaac.ochre	isaac-parent	sh.isaac	isaac
gov.vha.isaac.ochre.modules	commit-provider	sh.isaac.provider	commit
	concept-provider	sh.isaac.provider	concept
	coordinate-provider	sh.isaac.provider	coordinate
	db-builder	sh.isaac.integration	db-builder
	db-config-builder	sh.isaac.integration	db-config-builder
	ibdf-provider	sh.isaac.provider	ibdf
	identifier-provider	sh.isaac.provider	identifier
	import-utils	sh.isaac.integration	import-utils
	integration-tests	sh.isaac.integration	integration-tests
	logic-provider	sh.isaac.provider	logic
	metacontent-store	sh.isaac.provider	metacontent
	metadata	sh.isaac.core	metadata
	metadata-source	sh.isaac.core	metadata-source
	observable-provider	sh.isaac.provider	observable
	ochre-api	sh.isaac.core	api
	ochre-mapping	sh.isaac.core	mapping
	ochre-model	sh.isaac.core	model
	ochre-mojo	sh.isaac.core	mojo
	ochre-mojo-log-config	sh.isaac.core	log-config
	path-provider	sh.isaac.provider	path
	progress-provider	sh.isaac.provider	progress
	query-provider	sh.isaac.provider	query
	sememe-provider	sh.isaac.provider	sememe
	stamp-provider	sh.isaac.provider	stamp
	sync-git	sh.isaac.provider	sync-git
	taxonomy-provider	sh.isaac.provider	taxonomy
	workflow-provider	sh.isaac.provider	workflow

28.2.1. Automation-enforced conventions

The ISAAC and KOMET projects aspire to have well-documented, structured, and readable source code to speeds up bug hunting and feature enhancements development. Predecessor projects suffered from lack of automation of coding conventions, resulting in wide variations of coding styles, as well as difficulty improving the quality of the source code without creating difficulty analyzing differences from one version to another. Going forward, these projects will have automated transformation of source code to ensure that the source code is well structured and readable. The automated transformation of source files will include:

1. Algorthmic tree-like sorting of all source code elements. By having all source files adhere to an automated sort order of classes, fields, variables, and other elements, we make it easier for developers to consistenty find what they are looking for, and to also minimize identification of non-semantic differences which would otherwise be caused by simple rearrangment of source content.

2. Use of 'this.' qualifier for all field accesses. Use of the 'this.' qualifier eliminates the need for other conventions such as an underscore prefix or suffix for field names such as _fieldName or fieldName_. These underscore conventions have been used inconsistently within the source in the past, and brings the code into consistency with most standard java coding conventions. The recommended style for handling method parameters that have the same name as fields is to use the 'this.' qualifier with paramaters of the same name, as in this example:

   ```
   public void setFoo(String foo) {
       this.foo = foo;
   }
   ```

   In addition, use of 'this.' qualifiers with 'that.' parameter names for equals, clone, and similar types of methods can lead to improved readibility of the code:

   ```
   public boolean isSame(MyClass that) {
       return this.uuid().equals(that.uuid());
   }
   ```

3. Elimination of inconsistent conventsions such as use of an underscore prefix or suffix for field names such as _fieldName or fieldName_

4. Template-driven JavaDoc insertion and completion to facitate consistency and ease of entry for JavaDoc comments.

5. Automated insertion, removal, indentation, and alignment of parantheses, braces, white space, declerations, assignments, and comments.

6. Add missing @override and @deprecation annotations.

28.2.2. Source code transformation

Unfortunately, we are not aware of any single, headless tool that can perform the automated transformation we describe above. Here we describe the steps in the refactoring and maintenance process of ISAAC and KOMET sources.

Fix order-sensitive elements

Summary

Identify any order sensitive references that may become illegal forward references when transformed.

Prerequisites

- Ability to checkout a project from git
- Ability to execute maven builds on project
- A licensed Jindent install on the computer where the transformation will be performed

1. Checkout the source of the project to be refactored.

```
$ mkdir origva
$ cd origva/
$ git clone https://[insert url here]/git/r/ISAAC.git
$ cd ISAAC/
```

2. Compile the project, and verify there are no compiler errors. If compiler errors are identified, work to resolve those problems with the original sources of the project, and restart at Step 1.

```
$ mvn clean install
[INFO] Scanning for projects...
...
[INFO] ------------------------------------------------------------------------
[INFO] BUILD SUCCESS
[INFO] ------------------------------------------------------------------------
[INFO] Total time: 46.207 s
[INFO] Finished at: 2017-03-12T08:57:18-07:00
[INFO] Final Memory: 414M/1626M
[INFO] ------------------------------------------------------------------------
$
```


3. Open project in NetBeans 8.2, and optimize imports. Note that optimization was attempted with Eclipse Neon.2 Release (4.6.2), and the optimization inappropriately removed imports for annotations, and thus the Eclipe optimize import routines cannot be used.

4. Apply the algorthmic sorting of all source code elements. In our case, we will use Jindent for this purpose.

    a. Add a profile for Jindent formatting to the top-level project pom

```
<profile>
    <id>refactor-transform</id>
    <activation>
        <activeByDefault>false</activeByDefault>
    </activation>
    <dependencies>
        <dependency>
            <groupId>one.isaac.jindent</groupId>
            <artifactId>isaac-conventions</artifactId>
            <version>1.0</version>
            <type>zip</type>
        </dependency>
    </dependencies>
    <build>
        <plugins>
            <plugin>
                <groupId>org.apache.maven.plugins</groupId>
```

```
                        <artifactId>maven-dependency-plugin</artifactId>
                        <version>3.0.0</version>
                        <executions>
                            <execution>
                                <id>extract-conventions</id>
                                <phase>generate-sources</phase>
                                <goals>
                                    <goal>unpack</goal>
                                </goals>
                                <configuration>
                                    <artifactItems>
                                        <artifact>
                                            <groupId>one.isaac.jindent</groupId>
                                            <artifactId>isaac-conventions</artifact
                                            <type>zip</type>
                                        </artifact>
                                    </artifactItems>
                                    <outputDirectory>${project.build.directory}/jin
                                </configuration>
                            </execution>
                        </executions>
                    </plugin>
                    <plugin>
                        <groupId>komet.one</groupId>
                        <artifactId>repackage-mojo</artifactId>
                        <version>1.0-SNAPSHOT</version>
                        <dependencies>
                            <dependency>
                                <groupId>one.solor</groupId>
                                <artifactId>jindent</artifactId>
                                <version>1.0</version>
                                <scope>system</scope>
                                <systemPath>/Applications/Jindent/lib/Jindent.jar</s
                            </dependency>
                        </dependencies>
                        <executions>
                            <execution>
                                <id>repackage</id>
                                <phase>process-sources</phase>
                                <goals>
                                    <goal>repackage</goal>
                                </goals>
                                <configuration>
                                    <inputDirectory>${project.basedir}</inputDirecto
                                </configuration>
                            </execution>
                        </executions>
                    </plugin>
                </plugins>
            </build>
        </profile>
```

b. **Transform sources**

```
$mvn -e --non-recursive -Prefactor-transform clean install
```

5. Compile the transformed project, and identify any compiler errors. These errors are a result of the sorting of field declerations within the classes.

```
$cd target/output/
$mvn clean install
...
[ERROR] Failed to execute goal org.apache.maven.plugins:maven-compiler-plugin:3
        on project import-utils: Compilation failure
[ERROR] import-utils/src/main/java/sh/isaac/converters/sharedUtils/ComponentRef
        illegal forward reference
...
$
```

6. **Fix compile errors**

   Identify the untransformed original source file responsible for failing to compile after transformation. Fix the issue that resulted in the compile error. In this case, the forward references was caused by implicit order dependent initialization of fields, prior to the constructor being called. Modify the initialization to take place in the constructor for the class, where order will be preserved.

7. Change back to the original directory, and repeat the transformation.

```
$ cd ../..
$ mvn -e --non-recursive -Prefactor-transform clean install
```

   Repeat Steps 4-6 until all compile errors are resolved.

8. Create a refactor branch, and commit pom changes, and source changes to to this branch. For subsequent integration of ongoing work from the unrefactored sources, changes will be merged against the refactor branch.

```
git checkout -b refactor
git commit -m "package refactoring"
```

9. Eclipse Mars; Install JAutoDoc, m2e; configure AutoDoc, cleanup.

   Set to external maven.

   Turn off build automatic.

   Open Eclipe. Select the menu item: File -> Import->existing project

   Use JAutoDoc to add comments to each project

   Cleanup to add this. to all variables...

   Class Artifact is an example of variables with

   After verifying that the Cleanup and JAutoDoc settings are proper, run the generation of the refactor project.

10. Create a new git repository from the refactored project in the target directory of the original project.

```
cd existing-project
git init
git add --all
git commit -m "Initial Commit"
git remote add origin http://kec@stash.informatics.com/scm/shisaac/isaac-sh.git
git push -u origin master
```

11. Open project in eclipse. Configure code cleanup to insert this. for all references to fields. Run code cleanup. Commit changes to repository so we have stepwise history, and easy ability to rollback.

    ```
    git commit -m "after code cleanup"
    ```

12. In eclipse, run JAutoDoc. Commit changes to repository so we have stepwise history, and easy ability to rollback.

    ```
    git commit -m "after JAutoDoc"
    ```

13. Open in NetBeans. Batch format with JIndent to make JAutoDoc changes consistent. Commit changes to repository so we have stepwise history, and easy ability to rollback.

    ```
    git commit -m "after JIndent format"
    ```

14. In NetBeans. Search for fields that match "_;", "_ ", " _", and then selectively refactor to remove prefix and suffix underscores from field names. Commit changes to repository so we have stepwise history, and easy ability to rollback.

    ```
    git commit -m "remove field underscore prefix and suffix to have consistent nam
    ```

15. In NetBeans, search for fields that match "_;", "_ ", " _", and then selectively refactor to remove prefix and suffix underscores from field names. Commit changes to repository so we have stepwise history, and easy ability to rollback.

    ```
    git commit -m "remove field underscore prefix and suffix to have consistent nam
    ```

16. In NetBeans, use inspect and transform to use enhanced for loops, String switch statements, and try with resources. Commit changes to repository so we have stepwise history, and easy ability to rollback.

    ```
    git commit -m "Move to enhanced for loops, String switch statements, try with r
    ```

17. Release the project. (put altDeploymentRepository in a profile named release-deploy)

    ```
    $ mvn -P release-deploy jgitflow:release-start jgitflow:release-finish
    ```

    If you know the release and development versions, you can specify them directly, so that you do not have to interactively enter them:

    ```
    $ mvn -P release-deploy jgitflow:release-start jgitflow:release-finish \
          -DreleaseVersion=3.08 -DdevelopmentVersion=3.09-SNAPSHOT
    ```

18. Push the entire repository to GitHub...

28.2.3. Jindent

JIndent is used to ensure that all Java sourcecode comples with a consistent format, and that content within the file are consistently sorted (method calls are sorted by features including the method name). This

formating is applied when sourcecode is checked into the git repository. This formatting and sorting of source code enables diff-tools to analyse differences more efficiently—only revealing real semantic diffs which will be recognized and commited. Changes in formatting, white space, order of methods will be eliminated by the formatting process.

JIndent can be used within many editors, as maven plugins developed by this project, and using the batch tools provided by the developer.

28.2.3.1. JIndent Maven plugins

JIndent provides java libraries that we have integrated into a maven mojo to process sources in a batch fashion as part of a maven project.

Deploying JIntent libraries to an artifact repository. Use a terminal to navigate to the JIndent install lib directory, and execute the following commands.

Jindent.jar

```
mvn deploy:deploy-file -DgroupId=jindent.java\
  -DartifactId=jindent \
  -Dversion=5.0.1 \
  -Dpackaging=jar \
  -Dfile=Jindent.jar \
  -DrepositoryId=central \
  -Durl=http://artifactory.informatics.com/artifactory/ext
```

JindentHelp.jar

```
mvn deploy:deploy-file -DgroupId=jindent.java\
  -DartifactId=jindent-help \
  -Dversion=5.0.1 \
  -Dpackaging=jar \
  -Dfile=JindentHelp.jar \
  -DrepositoryId=central \
  -Durl=http://artifactory.informatics.com/artifactory/ext
```

jhall.jar

```
mvn deploy:deploy-file -DgroupId=jindent.java\
  -DartifactId=jhall \
  -Dversion=5.0.1 \
  -Dpackaging=jar \
  -Dfile=jhall.jar \
  -DrepositoryId=central \
  -Durl=http://artifactory.informatics.com/artifactory/ext
```

l2fprod-common-all.jar

```
mvn deploy:deploy-file -DgroupId=jindent.java\
  -DartifactId=l2fprod-common-all \
  -Dversion=5.0.1 \
  -Dpackaging=jar \
  -Dfile=l2fprod-common-all.jar \
  -DrepositoryId=central \
  -Durl=http://artifactory.informatics.com/artifactory/ext
```

Once the libraries are deployed to an artifact repository, the maven plugins can depend on these artifacts, by including the following dependency information in the project pom:

```
<dependency>
```

```
    <groupId>jindent.java</groupId>
    <artifactId>jindent</artifactId>
    <version>5.0.1</version>
</dependency>
<dependency>
    <groupId>jindent.java</groupId>
    <artifactId>jindent-help</artifactId>
    <version>5.0.1</version>
</dependency>
<dependency>
    <groupId>jindent.java</groupId>
    <artifactId>jhall</artifactId>
    <version>5.0.1</version>
</dependency>
<dependency>
    <groupId>jindent.java</groupId>
    <artifactId>l2fprod-common-all</artifactId>
    <version>5.0.1</version>
</dependency>
```

28.2.3.2. JIndent settings.xml

JIndent requires a jindent-settings.xjs file to define formatting options, and this file is necessary to execute. We use a standard jindent-settings.xjs file (it is an xml file) to standardize options across users. This settings file is deployed as a standard maven artifact. First, zip the settings file, such as: isaac-java-conventions.xjs.zip. Navigate to the folder in which the zipped file is located, and then execute the following command:


```
mvn deploy:deploy-file -DgroupId=one.isaac.jindent\
  -DartifactId=isaac-conventions \
  -Dversion=1.0 \
  -Dpackaging=zip \
  -Dfile=isaac-java-conventions.xjs.zip \
  -DrepositoryId=central \
  -Durl=http://artifactory.informatics.com/artifactory/libs-release-local/
```

Once the artifact is available, it can be made available to projects that require it. First add the artifact as a dependency to the project:

```
<dependencies>
   <dependency>
      <groupId>one.isaac.jindent</groupId>
      <artifactId>isaac-conventions</artifactId>
      <version>1.0</version>
      <type>zip</type>
   </dependency>
</dependencies>
```

Then add the following plugin specification inside the project so that the file will be extracted into the default jindent directory:

```
<plugin>
     <groupId>org.apache.maven.plugins</groupId>
     <artifactId>maven-dependency-plugin</artifactId>
```

```
        <version>3.0.0</version>
        <executions>
            <execution>
                <id>extract-conventions</id>
                <phase>generate-sources</phase>
                <goals>
                    <goal>unpack</goal>
                </goals>
                <configuration>
                   <artifactItems>
                        <artifact>
                            <groupId>one.isaac.jindent</groupId>
                            <artifactId>isaac-conventions</artifactId>
                            <type>zip</type>
                        </artifact>
                   </artifactItems>
                   <outputDirectory>${project.build.directory}/jindent</outputDirecto
                </configuration>
            </execution>
        </executions>
    </plugin>
```

28.2.3.3. JIndent license

After the license is installed on your local computer

Then add the following plugin specification inside the project so that the file will be extracted into the default jindent directory:

28.2.4. yFiles for JavaFX

yFiles jar file needs to be installed in the developers local repository if yFiles development is planned.

```
mvn install:install-file -DgroupId=yfiles \
  -DartifactId=yfiles-for-javafx \
  -Dversion=3.0 \
  -Dpackaging=jar \
  -DcreateChecksum=true \
  -DgeneratePom=true \
  -DupdateReleaseInfo=true \
  -Dfile=yfiles-for-javafx.jar
```

29. DocBook

29.1. Steps to Convert Word Document to Doc-Book

Patrick O'Connor

Steps to convert a word document into a DocBook

General DocBook information can be found here: http://docbook.org/

After you have created a word document using a “stylized’ MS Word Template, use these simple steps to convert that DOCX file into an XML file:

Step 1:

Use an XML conversion tool, such as the free one located at URL: www.xmlmind.com/w2x/docx_to_docbook.html [http://www.xmlmind.com/w2x/docx_to_docbook.html]

NOTE: This will allow you to convert up to 3 times in any 24-hour period

Step 2:

Click Browse and navigate to your desired DOCX file that you wish to convert

Step 3

Choose the selected output format (such as DocBook v5.0 Article), and click convert

NOTE: If you want to integrate with ISAACS KOMET DocBook project later, you MUST convert it to a DocBook v5.0 format.

Measure	
getResolution()	Optional<fl
getLowerBound()	
getUpperBound()	
includeLowerBound()	boo
includeUpperBound()	boo
getMeasureSemantic()	LogicalExpres

This will download a zip file:

Step 4

Unzip the file; inside the newly unzipped file will be a directory. You will see an XML format version of your document inside. This will allow you to edit the XML file, and convert it to PDF, HTML, etc. for use in other documents.

NOTES:>

1. When you select the Text mode to view the actual XML, if all of the XML appears on one line OR if you receive a message stating, "this document contains long lines which may affect performance when opened in the text editor", then click the Format and Indent button. Then, it should display the formatted XML.

2. If there were any pictures in your document, they will be in another directory, inside the first.

Working inside an IDE, within the context of the larger document:

Things needed first:

- You need an integrated development environment installed, such as Eclipse.
- Install plugin from OxygenXML (provides tools to directly edit these types of documents)
  - https://www.oxygenxml.com/xml_editor/download_oxygenxml_editor.html?os=Eclipse
- Install plugin from GitHub (source code control repository, which is needed to view all current KOMET book materials)
  - https://eclipse.github.io/
- Check for or Install plugin for Maven (configuration management and build environment; generates PDFs, HTMLs, and archived versions from XML files)
  - http://www.eclipse.org/m2e/

30. Specifications

30.1. Knowledge Streaming Specification

30.1.1. Data format

ISAAC specifies a streaming data format. This streaming format is sutiable for durable storage on disk, for store-and-forward synchronization (as typically seen in distributed-version control systems that utilize change-sets such as Git), and for point-to-point streaming of changes in real-time. Version-control change sets are represented using this streaming data format.

The streaming data format consists of a repitition of 3 data elements:

1. A token indicating the object type next to be read from the stream

2. A numeric representation of the version of the object data written to the stream

3. The actual data of the object written to the stream.

Example 30.1. Streaming format element types

```
public enum IsaacExternalizableObjectType {
   /**
    * An external representation of a concept. An identifier with status. Descript
    * are provided as SEMANTICs.
    */
   CONCEPT((byte) 1),

   /**
    * An external representation of a semantic unit of meaning, associated with a
    */
   SEMANTIC((byte) 2),

   /**
    * An external representation of a stamp comment.
    */
   STAMP_COMMENT((byte) 4),

   /**
    * An external representation of a stamp alias.
    */
   STAMP_ALIAS((byte) 5),

   /**
    * An external representation of a stamp.
    */
   STAMP((byte) 6);
}
```

See the following classes for entry points to learn more:

- BinaryDataServiceFactory
- BinaryDataProviderFactory
- DataWriterService
- BinaryDataReaderService
- ConceptChronologyImpl
- IsaacExternalizable
- ConceptChronologyJsonWriter

30.1.2. Knowledge Archive Specification

The artifact format combines one or more data files into a zip file with appropriate metadata. Each artifact is uniquely identified by a group id [http://maven.apache.org/glossary.html#GroupId] and an artifact ID which is unique within a group, and may be stored on, and retrieved from, a standard maven artifact repository. Metadata will include a manifest.mf file, and a pom file that defines artifact licenses and dependencies.

In general, the zip entries are intended for ease of import into relational databases. The relational format utilizes UUIDs to identify all objects, and an alternative identifier file is provided for working with other types of identifiers.

30.1.2.1. Graph representation

When a datafield represents an explicit graph, GraphSON [http://tinkerpop.apache.org/docs/3.3.1/dev/io/#graphson] is used to represent the graph. GraphSON is a JSON-based [http://json.org/] format for individual graph elements (i.e. vertices and edges), and complete graphs.

30.1.2.2. Artifact Coordinate

We rely on Maven coordinates [https://maven.apache.org/pom.html#Maven_Coordinates] to define a set of identifiers which can be used to uniquely identify an artifact.

31. Services

31.1. Newton's Cradle

Chronicled Assertion Database of Logical Expressions

https://jaxenter.com/prometheus-2-0-new-storage-layer-boosts-monitoring-scalability-kubernetes-distributed-systems-134365.htmlTime series databases have their share of challenges. Fabian Reinartz, engineer/tech lead at CoreOS, explained in the blog post that “a time series system collects data points over time, linked together into a series. Each data point is a numeric value associated with a timestamp. A series is defined by a metric name and labeled dimension and serves to partition raw metrics into fine-grained measurements.”

31.2. Simulated patient data

Here are some URLs to explore the Synthetic Patient Database from MITRE that I mentioned in our CDS Grand Rounds call this afternoon: Synthea (synthetic patient database)

- About [https://syntheticheath.github.io/synthea/#home]
- Database [https://github.com/syntheticheath/synthea]
- Synthea Wiki [https://github.com/syntheticheath/synthea/wiki]

SyntheticMass (Synthetic Patient database mimicking the population of Massachusetts)

- Browse [https://syntheticmass.mitre.org]
- FHIR [https://syntheticmass.mitre.org/fhir/metadata]

Slide presentation (as .pdf) regarding Synthea (good overview and resource, authored by Jason Waslonoski from MITRE): https://www.hl7.org/events/fhir/roundtable/2017/03/pdfs/D-21_Jason-Walonoski.pdf

32. Tools

32.1. We work with these tools for the following reasons

To be completed.

32.2. KOMET

32.2.1. CSS Styling

Note, for a TreeTableCell, the Style is null by default, but the StyleClass list is: "cell", "indexed-cell", "tree-table-cell", and "table-column".

Descendant combinator

A descendant combinator is whitespace [https://www.w3.org/TR/selectors/#whitespace] that separates two sequences of simple selectors. A selector of the form "`A  B`" represents an element `B` that is an arbitrary descendant of some ancestor element `A`

Style Class

Each node in the scene graph has a **styleClass** variable, a List<String>. Styles for style classes can be specified using the **.styleclass** selector syntax in a style sheet. Note that a node may have more than one style class.

Style

An inline style for the node.

Child combinator

A child combinator, >, describes a childhood relationship between two elements. For example, **.titled-pane** > **.title** refers to a node with a style class of **title** that is a child of a node with a style class of **titled-pane**.

```
.titled-pane > .title {
    -fx-background-color: -fx-box-border, -fx-inner-border
    -fx-background-insets: 0, 1, 2;
    -fx-background-radius: 5 5 0 0, 4 4 0 0, 3 3 0 0;
    -fx-padding: 0.166667em 0.833333em 0.25em 0.833333em;
}
```

pseudo-class

a pseudo class can qualify a class. For example, the pseudo class **odd** can qualify **indexed-cell**, so that special formatting can be applied to odd rows in a table.

```
.indexed-cell:odd  {
   -fx-background-color: orange;
```

```
}
```

Need a pseudoclass for inactive state... http://www.guigarage.com/2016/02/javafx-and-css-pseudo-classes/

Table 32.1. KOMET Pseudo classes

pseudo-class	implementing classes		description
inactive	KometTreeTableCell		set if a version is inactive, so that appropriate consistent coloring can be used
uncommitted	KometTreeTableCell		set if a version is uncommitted, so that an appropriate consistent coloring can be used
uncommitted-with-error	KometTreeTableCell		set if an uncommitted version has an error that must be fixed prior to commit
superceded	KometTreeTableCell		a version may be active, but superceded by a different component, so not current in the display
description-version			
logical-definition-version			
concept-version			

Table 32.2. KOMET CSS Properties

CSS Property	Class	Default	Description
-fx-cursor	javafx.scene.Node	javafx.scene.Cursor.DEFAULT	Used to set the cursor when over a node.
-fx-background-color	javafx.scene.Node		Sets the background color of a node.
-fx-font	javafx.scene.text.Font	Font DEFAULT (12px system)	Sets the font to use by the style class

Table 32.3. KOMET CSS Classes

CSS Class		Description
komet-version-general-cell		
komet-version-status-cell		this cell contains the status for an ObservableCategorizedVersion
komet-version-author-time-cell		this cell contains the author and time for an ObservableCategorizedVersion
komet-version-module-path-cell		this cell contains the module and path for an ObservableCategorizedVersion
komet-version-what-cell		this cell indicates the type of the ObservableCategorizedVersion
komet-version-description-text-cell		this cell contains the description text for ObservableCategorizedVersion who are types of DescriptionVersions

CSS Class		Description
komet-version-logic-graph-cell		this cell contains a text representation of a logic definition for ObservableCategorizedVersion who are types of LogicGraphVersion
komet-version-identifier-cell		this cell contains a text representation of an identifier for ObservableCategorizedVersion who are members of an identifier Assemblage.
isaac-version		the row for this cell contains an isaac ObservableCategorizedVersion
versioned-tree-table-view		TreeTable that displays versioned components pointing to a parent versioned component
concept-detail-pane		
concept-label-toolbar		
komet-version-concept-cell		
component-panel		ComponentPanel
component-detail-background		VBox
component-badge		Node
component-version-what-cell		TextNode describing what type this component version is
component-text		
expand-control		
version-panel		
header-panel		

33. Content

The ISAAC infrastructure expects resources—such as terminology sources—to be avaible from a Maven-compliant artifact repository.

A repository manager is a dedicated server application designed to manage repositories of binary components. The usage of a repository manager is considered an essential best practice for any significant usage of Maven.

33.1. Purpose

A repository manager serves these essential purposes:

- act as dedicated proxy server for public Maven repositories
- provide repositories as a deployment destination for your Maven project outputs

33.2. Benefits and Features

Using a repository manager provides the following benefits and features:

- significantly reduced number of downloads off remote repositories, saving time and bandwidth resulting in increased build performance
- improved build stability due to reduced reliance on external repositories
- increased performance for interaction with remote SNAPSHOT repositories
- potential for control of consumed and provided artifacts
- creates a central storage and access to artifacts and meta data about them exposing build outputs to consumer such as other projects and developers, but also QA or operations teams or even customers
- provides an effective platform for exchanging binary artifacts within your organization and beyond without the need for building artifact from source

33.3. Publishing RF2 sources as Maven Artifacts

An example project that converts SNOMED RF2 zip distribution files into maven artifacts, and can publish those artifacts in a users local repository, or on an artifact repository is available on git hub. The project is named the SOLOR source artifact transformer, and is available at the following URL:

https://github.com/informatics-architecture/solor-source-artifact-transformer

This project contains example conversions for:

- The International Edition of SNOMED Clinical Terms
- The Australian Extension to SNOMED Clinical Terms
- The Spanish Extension to SNOMED Clinical Terms

- The LOINC Extension to SNOMED Clinical Terms
- The United Kingdom Clinical Extension to SNOMED Clinical Terms
- The United Kingdom Drug Extension to SNOMED Clinical Terms
- The United States Extension to SNOMED Clinical Terms

34. Collaboration

This section will include a guideline on how to collaborate and reference materials from GitHub READMEs, etc.

F. Requirements enumeration

F.1. Business-Specified Functional Requirements

F.1.1. Common tooling requirements

Users will develop CDS knowledge artifacts of varying types that conform to conform to the specifications in the HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3 (or later HL7 version or final standard if one has been released during the period of performance of the current effort). via an Integrated Development Environment with the following common features:

F.1.1.1. User Interface

Requirement F.1. insertRequirementTitle

insertRequrementShortId	All editors will be integrated into a common environment with a consistent user interface (UI).

Requirement F.2. insertRequirementTitle

insertRequrementShortId	There shall be a standard guide and protocol for the UI.

All components will follow established rules for icons, graphics, widgets, CSS stylesheets, etc. that all editors will in turn follow, to establish and insure a common look and feel.

Requirement F.3. insertRequirementTitle

insertRequrementShortId	All editors will be built following standards for user-centered design.

Requirement F.4. insertRequirementTitle

insertRequrementShortId	All editors will include consistent, user-friendly features, such as form fields (e.g., check boxes, pick lists, and text boxes), drag and drop functionality, intuitive advance searching, and help menus.

F.1.1.2. Editing and File Management

The user shall be able to perform typical editing and file management functions for all artifacts including:

Requirement F.5. insertRequirementTitle

insertRequrementShortId	Read/open artifact type instances from standard artifact repository

Requirement F.6. insertRequirementTitle

insertRequrementShortId Save versioned artifact to standard artifact repository

Requirement F.7. insertRequirementTitle

insertRequrementShortId Import and export standards-based artifacts

Requirement F.8. insertRequirementTitle

insertRequrementShortId Print artifacts

Requirement F.9. insertRequirementTitle

insertRequrementShortId Edit existing artifacts and save as new

Requirement F.10. insertRequirementTitle

insertRequrementShortId Save and return to incomplete work

Requirement F.11. insertRequirementTitle

insertRequrementShortId Perform automatic interim saving of an artifact, with versioning, while under construction.

Requirement F.12. insertRequirementTitle

insertRequrementShortId Track, undo and redo changes

Requirement F.13. insertRequirementTitle

insertRequrementShortId Drag/drop/cut/paste of both entire artifacts and sub-artifacts, both within and among artifacts. Operations shall be valid upon structured forms, text forms, graph forms, Graph ML.

Requirement F.14. insertRequirementTitle

insertRequrementShortId Copy content and save to an external source.

Requirement F.15. insertRequirementTitle

insertRequrementShortId Paste content from an external source.

Requirement F.16. insertRequirementTitle

insertRequrementShortId Start an instance of a new document while one document is already open and being constructed.

Requirement F.17. insertRequirementTitle

insertRequrementShortId Scroll vertically and horizontally.

Requirement F.18. insertRequirementTitle

insertRequrementShortId Delete a documentation template under construction, but with back-up copies automatically saved, versioned, and available for retrieval.

Requirement F.19. insertRequirementTitle

insertRequrementShortId Publish the documentation template to a database.

Requirement F.20. insertRequirementTitle

insertRequrementShortId Metadata management (described below)

Requirement F.21. insertRequirementTitle

insertRequrementShortId Permit annotation and comments of artifacts

Requirement F.22. insertRequirementTitle

insertRequrementShortId Dashboard for artifact tracking

Requirement F.23. insertRequirementTitle

insertRequrementShortId Support generic validation plugins (e.g. XML schema validation)

Requirement F.24. insertRequirementTitle

insertRequrementShortId	Central maintenance and coordination of content

Requirement F.25. insertRequirementTitle

insertRequrementShortId	Maintain and manage artifacts without dependence on software development resources

Requirement F.26. insertRequirementTitle

insertRequrementShortId	Life cycle management and versioning

Requirement F.27. insertRequirementTitle

insertRequrementShortId	Set artifact permissions regarding who can view, edit, delete a current artifact

F.1.1.3. Assistive Functions

The editor shall perform various assistive functions, including:

Requirement F.28. insertRequirementTitle

insertRequrementShortId	Syntax color coding/indenting

Requirement F.29. insertRequirementTitle

insertRequrementShortId	Alert/error identification

Requirement F.30. insertRequirementTitle

insertRequrementShortId	Present & resolve

Requirement F.31. insertRequirementTitle

insertRequrementShortId	At edit, comment, merge, import, continuous integration times

Requirement F.32. insertRequirementTitle

insertRequrementShortId	At each - allow for similarity search

Requirement F.33. insertRequirementTitle

insertRequrementShortId	Version comparison and contradiction

Requirement F.34. insertRequirementTitle

insertRequrementShortId	Review/merge capability; based on Graph Theory and similarity based on Graph edit distances

Requirement F.35. insertRequirementTitle

insertRequrementShortId	Context-sensitive help

Requirement F.36. insertRequirementTitle

insertRequrementShortId	Add and update existing artifacts, based on role permissions

Requirement F.37. insertRequirementTitle

insertRequrementShortId	Syntax checking as well as spell checking

Requirement F.38. insertRequirementTitle

insertRequrementShortId	Support various refactoring functions, e.g. - copy/paste detection, global renaming of a variable, etc.

Requirement F.39. insertRequirementTitle

insertRequrementShortId	Create artifacts from templates and include a template library that includes templates for commonly used constructs (i.e., trigger types, conditional expression clause types, and action types) and include domain-specific extensions to enable quick identification/distinction.

F.1.1.4. Collaboration and Workflow

The editing system shall support communication and collaboration among knowledge engineers and users, who are expert physicians, nurses, pharmacists, and other clinicians. These experts are not necessarily computer experts or experts in artifact type definitions. The goal of the editing system is to assist with the transfer of the experts' clinical knowledge into a valid computer representation based upon standards.

Types of collaboration tasks include peer-to-peer tasking (requesting and receiving assistance), support for authors to contract out sub-artifacts, to support an inter-expert review and validation process, and to

request new content (new component/subcomponent/term rapid turnaround…artifact rapid turnaround). Within these types of tasks, the software shall support:

Requirement F.40. insertRequirementTitle

insertRequrementShortId	User roles and both individual and role-based permissions.

Requirement F.41. insertRequirementTitle

insertRequrementShortId	Ability to request supporting artifacts, request collaboration, and manage and track these requests and responses by variables such as person, artifact type, review status, and other flags.

Requirement F.42. insertRequirementTitle

insertRequrementShortId	Use of modeled concepts to represent artifact or component or collaboration status: Sample states for artifact creation from Software Engineering Literature and Model and or HL7 KNART specification.

Requirement F.43. insertRequirementTitle

insertRequrementShortId	Internal review, quality assurance, and verification of artifacts.

Requirement F.44. insertRequirementTitle

insertRequrementShortId	Methods to view, manage, and prioritize items in a work queue, including by artifact, by requestor, by domain, by context, or other relevant categories.

Requirement F.45. insertRequirementTitle

insertRequrementShortId	Workflow manager capabilities to monitor and reassign workflow.

Requirement F.46. insertRequirementTitle

insertRequrementShortId	Ability to function within and across repositories, artifacts, and artifact types, and work with related repositories, platforms, and tools.

Requirement F.47. insertRequirementTitle

insertRequrementShortId	Model driven workflow.

Requirement F.48. insertRequirementTitle

insertRequrementShortId GITFlow paradigm for branch and merge.

Requirement F.49. insertRequirementTitle

insertRequrementShortId Check out versions and merge back together.

Requirement F.50. insertRequirementTitle

insertRequrementShortId New Collaborative node - can join any other node at any time in the future (see GitHub model).

Requirement F.51. insertRequirementTitle

insertRequrementShortId Computing operational metrics - editing/reproducing, etc.

Requirement F.52. insertRequirementTitle

insertRequrementShortId Integration with Issue Tracker.

Requirement F.53. insertRequirementTitle

insertRequrementShortId Communications between users via different channels (e.g., email, text, blogs) based on projects, roles and individual identities.

F.1.1.5. Search

The software shall support search capability between and within artifacts and sub-artifacts as described below.

Requirement F.54. insertRequirementTitle

insertRequrementShortId Search should function within and across repositories, artifacts, and artifact types, and work with related repositories, platforms, and tools.

Requirement F.55. insertRequirementTitle

insertRequrementShortId Terminology search: within artifacts, within standards, within value sets.

Requirement F.56. insertRequirementTitle

insertRequrementShortId	Search shall be context and rule-sensitive, for example restricted to certain terminologies required for a particular sub-element.

Requirement F.57. insertRequirementTitle

insertRequrementShortId	Search for artifacts with particular flags or metadata types, search for artifacts descended from other artifacts or associated with other artifacts.

Requirement F.58. insertRequirementTitle

insertRequrementShortId	Search for artifacts used in similar documents or templates in the past.

Requirement F.59. insertRequirementTitle

insertRequrementShortId	Semantic neighborhood search for terms based on hierarchies or class membership inferred from terminology.

Requirement F.60. insertRequirementTitle

insertRequrementShortId	Free text search criteria (similarity, normalized word searches, distance metric).

F.1.1.6. Metadata Management

Requirement F.61. insertRequirementTitle

insertRequrementShortId	Metadata should be model-driven

Requirement F.62. insertRequirementTitle

insertRequrementShortId	Metadata should include information about the artifact itself

Requirement F.63. insertRequirementTitle

insertRequrementShortId	STAMP metadata (Status, Time, Author, Module, Path)

Requirement F.64. insertRequirementTitle

insertRequrementShortId Metadata should include linkages from the artifact to:

Requirement F.65. insertRequirementTitle

insertRequrementShortId Other assets (i.e., dependencies)

Requirement F.66. insertRequirementTitle

insertRequrementShortId Literature (i.e., references)

Requirement F.67. insertRequirementTitle

insertRequrementShortId Organization (curation)

Requirement F.68. insertRequirementTitle

insertRequrementShortId Work processes

Requirement F.69. insertRequirementTitle

insertRequrementShortId Metadata linkages should be editable, configurable, and searchable

Requirement F.70. insertRequirementTitle

insertRequrementShortId Configurable logging

Requirement F.71. insertRequirementTitle

insertRequrementShortId Group artifacts by metadata tags (e.g., “order set”, “condition-based rule”, etc)

F.1.1.7. Terminology Integration

Requirement F.72. insertRequirementTitle

insertRequrementShortId Ability to handle terminology updates in a timely fashion including tracing all dependent constructs upon implementation of a new terminology version.

Requirement F.73. insertRequirementTitle

insertRequrementShortId	Ability to detect impact of terminology updates on existing rules (be able to triage as “no, minor or major impact” on rules).

Requirement F.74. insertRequirementTitle

insertRequrementShortId	Ability to search, navigate and select terminologies and concepts (e.g., terminology browser) directly from user interface.

Requirement F.75. insertRequirementTitle

insertRequrementShortId	Display concept names in the rules to make the rules readable and understandable and store the concept codes for the purpose of rule execution.

Requirement F.76. insertRequirementTitle

insertRequrementShortId	Ability to navigate semantic relationships between concepts.

Requirement F.77. insertRequirementTitle

insertRequrementShortId	Ability to define, display and search value sets or subsets of related terms.

F.1.1.8. Artifacts Publication

Requirement F.78. insertRequirementTitle

insertRequrementShortId	Artifacts need to be made available for execution within production clinical information systems.

Requirement F.79. insertRequirementTitle

insertRequrementShortId	Artifact specifications must be visible to users at enterprise level.

Requirement F.80. insertRequirementTitle

insertRequrementShortId	Executable representation must be available in human readable format for review by SMEs and other business people.

Requirement F.81. insertRequirementTitle

insertRequrementShortId	Artifacts must be publishable to testing and runtime environments without requiring manual re-entry.

F.1.1.9. Reporting

Requirement F.82. insertRequirementTitle

insertRequrementShortId	Comparison reports to identify when artifacts are dependent on each other, so they can be tested and managed together.

Requirement F.83. insertRequirementTitle

insertRequrementShortId	Usage reports to specify which applications consume the artifacts, so that future changes can be communicated to the relevant teams.

Requirement F.84. insertRequirementTitle

insertRequrementShortId	Audit reports to track artifacts changes, including who made the changes and why the changes were made.

Automated and Manual Quality Assurance (QA) support

Requirement F.85. insertRequirementTitle

insertRequrementShortId	Capability for running QA rules

Requirement F.86. insertRequirementTitle

insertRequrementShortId	Search for redundant content

Requirement F.87. insertRequirementTitle

insertRequrementShortId	Classification and consistency checks

Requirement F.88. insertRequirementTitle

insertRequrementShortId	Test artifact features in a sandbox.

F.1.1.10. Artifact Type Instances and Artifact Type Definitions

The Integrated Development Environement (IDE) will be configurable via import of an artifact type definition:

Requirement F.89. insertRequirementTitle

insertRequrementShortId	For each artifact type (e.g., order set, documentation template, or Event-Condition-Action rule) or component (e.g., ECA condition, behavior, expression) there should be an artifact type definition corresponding to the HL7 specification. Examples: e.g., event-condition-action rules, which have trigger elements, expression elements, condition elements, and behavioral elements, and action elements. (see page vii and referents to HL7 spec);

Requirement F.90. insertRequirementTitle

insertRequrementShortId	Users will use the editor to select the desired artifact type definition, and then create an artifact type instance based on that definition.

Requirement F.91. insertRequirementTitle

insertRequrementShortId	Users will be able to create new artifact type definitions either de novo or by importing, modifying and renaming an existing artifact type definition. For example, a user could select an order set artifact type definition and specialize it for some particular setting (e.g., intensive care unit order set type definition).

F.1.2. Documentation template editor requiremnts

Requirement F.92. insertRequirementTitle

insertRequrementShortId	The Documentation Template editor shall allow an end user to create Documentation Templates that are adherent to the standard stated in HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3, and the Government-defined extension.

Requirement F.93. insertRequirementTitle

insertRequrementShortId	The Documentation Template editor will be a seamless component of an integrated Knowledge Development Platform with other CDS artifact editors and essential supporting components such as terminology editors. Requirements common to all editors shall be included.

Requirement F.94. insertRequirementTitle

The Documentation Template editor must:

Requirement F.105. insertRequirementTitle

insertRequrementShortId	Produce documentation templates that are capable of branching logic; the forms created must be able to specify all the actions (such as action of type CollectInformationAction) within the HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3.

Requirement F.106. insertRequirementTitle

insertRequrementShortId	Perform automatic interim saving of a document, with versioning, while under construction.

Requirement F.107. insertRequirementTitle

insertRequrementShortId	Organize document concepts hierarchically or non-hierarchically as requirements for content may dictate.

Requirement F.108. insertRequirementTitle

insertRequrementShortId	Get documentation-specific metadata as well as all other metadata.

Requirement F.109. insertRequirementTitle

insertRequrementShortId	Access an expressions editor and consume the output of an expressions editor.

The Documentation Template editor must allow a user to:

Requirement F.110. insertRequirementTitle

insertRequrementShortId	Search for other templates with needed content, import portions of other document templates AND make sure there are not duplicate titles.

Requirement F.111. insertRequirementTitle

insertRequrementShortId	Create a new template.

Requirement F.112. insertRequirementTitle

insertRequrementShortId	Import and modify an existing template, selecting it from a library or list of existing templates.

Requirement F.113. insertRequirementTitle

insertRequrementShortId	Create or assign a Template Name or Document Title, and check for and disallow duplicate names or titles.

Requirement F.114. insertRequirementTitle

insertRequrementShortId	Create a Template Description including Category of Template, and select language for the description.

Requirement F.115. insertRequirementTitle

insertRequrementShortId	Define and impose required content on the documentation template.

Requirement F.116. insertRequirementTitle

insertRequrementShortId	Embed hyperlinks into the document template as may be clinically or operationally appropriate.

Requirement F.117. insertRequirementTitle

insertRequrementShortId	Assemble non-user interface components for the documentation template, such as:

Requirement F.118. insertRequirementTitle

insertRequrementShortId	Questions and answers

Requirement F.119. insertRequirementTitle

insertRequrementShortId	Section headers

Requirement F.120. insertRequirementTitle

insertRequrementShortId	Create sections and sub sections.

Requirement F.121. insertRequirementTitle

F.1.3. Event condition action rule editor requirements

The ECA Rules editor must meet the requirements described below. As previously mentioned, the editor must generate ECA Rule knowledge artifacts that conform to the HeD Knowledge Artifact schema, per the HL7 Version 3 Standard: CDS Knowledge Artifact Specification, Release 1.3 and the Government-defined extension. Page 32 of the specification includes an illustration of the ECA rule knowledge artifact in Figure 2, as show below.

ECA RULE TEMPLATE – CONCEPTUAL OVERVIEW

As depicted in the preceding diagram and described in the HL7 specification, the ECA Rules editor shall allow a user to create an individual ECA rule that has the following characteristics and behaviors when implemented:

1. The ECA rule is activated when a defined triggering event occurs (e.g., an encounter with a primary care provider).

2. Conditions are evaluated following rule activation. Conditions may reference external data, and conditions may be composed of named, reusable expressions.

o Example: Patient is 65 years of age or older AND the patient has never had a pneumococcal vaccination.

♣ The patient's medical record would be checked for these two conditions.

♣ Additionally, a value set would be checked, such as an existing non-VA value set or a VA-defined value set, which contains the standard codes that define a pneumococcal vaccination.

3. If the Condition is true, then the action(s) specified in the "action" part of the rule are executed (e.g., recommend the patient receive a pneumococcal vaccination, document a reason why the patient should not have a pneumococcal vaccination).

4. Actions may be grouped and structured hierarchically using action groups and behaviors to specify how the actions should be shown to a clinical provider and to place restrictions on how a provider chooses from the available set of actions (e.g., choose no more than one, select all).

5. Actions may be orders that are shown to a clinical provider. However, not all actions must be orders. For example, actions may be the creation of a new event that triggers another rule, a future encounter, or the creation of a state description of the patient.

6. Accommodate creation of ECA knowledge artifacts (e.g., medication and clinical reminder rules) in all applicable clinical domains.

7. Accommodate, indicate, and list/display ECA rule based on metadata regarding care setting, such as women's health, geriatric care, inpatient or ambulatory, and based on specific diseases, such as hypertension or diabetes, as well immunizations that are due.

8. Indicate the clinical system of the ECA rules, such as standalone, embedded in ambulatory EHR, or standalone web-based application.

9. The ECA Rule editor must be able to specify all of the components, as noted in the HL7 specification, including events, conditions, expression, actions, and behaviors.

10. Express different types of clinical knowledge, including complex relationships and constraints. For example, an ECA rule may have multiple conditions that have conditions within those conditions that, when met, result in multiple actions to be taken.

11. Ability to notify user when two or more rules potentially conflict with each other, such as two methods for identifying patients with diabetes, such as by problem list and by lab results.

12. Topic specific visualization

13. Time pattern visualization.

14. Runtime simulation for rule execution, including time patterns.

15. ECA-specific refactoring function.

16. The system should be able to display the cost of acquiring any given piece of information to enable the user to make cost efficient ECA rules.

17. ECA-unique metadata read/edit.

18. Ability to check to duplicate or overlapping rule logic.

19. Ability to construct rule artifacts such as decision tables and rule flows.

20. Provide analytical reports to identify conflicting rules, incomplete rule coverage or rule redundancy.

Test Rules

A. Allow rule logic to be validated independently from the upstream or downstream services and applications.

B. Eventually integrate with upstream and downstream services and applications in order to perform integration and user acceptance testing activities.

C. Develop and maintain test patient data to support the rule logic.

D. Identify redundancy and overlapping rule logic.

E. Identify missing conditions and actions.

F. Identify conflicts with existing rules.

F.1.4. Condition Editor requirements

The user must be supported in creating Condition components that support CDS knowledge artifacts of varying types that conform to conform to the specifications in the HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3 (or later HL7 version or final standard if one has been released during the period of performance of the current effort).

F.1.5. Expression Editor requirements

The user must be supported in creating Expression components that support CDS knowledge artifacts of varying types that conform to conform to the specifications in the HL7 Version 3 Standard: CDS Knowledge Artifact Specification, DSTU Release 1.3 (or later HL7 version or final standard if one has been released during the period of performance of the current effort).

F.1.6. Action Editor requirements

The user must be supported in creating Action components that support CDS knowledge artifacts of varying types that conform to conform to the specifications in the HL7 Version 3 Standard: CDS Knowledge

Artifact Specification, DSTU Release 1.3 (or later HL7 version or final standard if one has been released during the period of performance of the current effort).

F.1.7. Order set editor requirements

• The editor will allow an end user to create orders and order sets that are adherent to the HL7 CDS Artifact specification with government defined extensions.

• The editor will be a seamless component of an integrated Knowledge Development Platform with other CDS artifact editors and essential supporting components such as terminology editors. Requirements common to all editors will be included.

• Orders and order sets applicable to both inpatient and outpatient scenarios must be supported. The types of orders that must be supported include the following:

o Medication

o Laboratory

o Diagnostic Imaging

o Diet

o Nursing

o Activity

o Consult

o Procedures

o Blood Bank

o Clinic Scheduling

• The editor will allow a user to:

o Create an individual order.

o Create an order set comprised of both individual orders and order sets within user defined sections and subsections.

o Define any data input component of an individual order as required or optional.

o Define any order set or order within an order set as required or optional.

o Define a set of orders as either mutually exclusive or not mutually exclusive.

o Define order and order set metadata including artifact provenance, status, version, description, applicable care context, etc.

o Add text statements to any part of an order or order set (e.g. a statement giving instructions to “choose one order from the following list”).

o Add external data elements to any part of an order or order set, including data pulled from a patient’s medical record.

o Associate references and documents with an order or order set (? How to manage documents).

o Identify the sequence of the orders within an order set, such as this is order #1, this is order #2…

o Group orders and order sets, such as separate group for medications and laboratory tests and sub-groups within the groups, such as group for medication orders and a sub-group for beta blocker orders.

F.1.8. Aggrigate artifact editor

The Aggregate Artifact editor will perform subcomponent integration consisting of several steps that the tools must support including:

1. Subcomponent assembly: The aggregate artifact editor must be able to gather the KNART artifacts necessary for creating the composite artifact such as documentation templates, order sets, expressions, actions and references into a single specification

2. Harmonization: The editor must support refactoring of included subcomponents including identification and elimination of duplicate subcomponents, location and rationalization of near-duplicates.

3. Integration: The editor must support the integration of component pieces via expressions and actions that control the behavior of the composite whole. The user must be able to test the integration with support from the editing environment

F.1.9. Presentation layer editor

The DTPLE (document template presentation layer editor) will be able to import HL7 documentation template artifacts and output executable packages of HTML5 and DRL.

The DTPLE will Support:

• Widget Binding

o Support the binding of HL7 artifact components, such as questions and permitted answer sets to appropriate HTML5 widgets such as radio buttons, check boxes and drop down lists.

o Support the storage of bound widgets and artifacts in a common repository

o Support the search, retrieval and reuse of bound widgets from the repository

o Support the same for collections of bound widgets and user interface contrivances

• Layout and Design Support (e.g., see Google web designer)

o Support the drag and drop placement and movement of bound widgets on an HTML5 form

o Support the drag and drop placement of other user interface components, such as frames and images supported by HTML5

o Support fonts, colors, alignment, borders and other design tools

o Support outputs optimized for various form factors

• Expression Language Conversion

o Conversion of CQL statements to DRL

o Need help here.

• Application Execution Simulation and Debugging Support

• Creation of Executable Artifacts that are/can be integrated with other execution System components such as data read, data write and data updates

• Include other General Editing Environment tools as well….

F.1.10. Governance workflow requirements

1. Must be model-driven at all levels and be flexible and adaptable

2. Artifacts may undergo organization review by zero or more governance groups

3. Review results must be rationalized, either by harmonization or versioning. This decision is itself a governance process.

4. Review results include status such as:

a. Approved for implementation (full, partial, pilot)

b. Approval pending resolution of issues

c. Rejection with invitation to resubmit

d. Rejection without invitation to resubmit (core idea rejected, no remediation acceptable) Governance Groups

1. Organizational home and authority (need org models here)

2. Members – have one or more members

3. Processes (model-driven)

4. Artifact Review Assignments

a. Receive Assignments

b. Return and Reassign Assignments

c. Track Group assignments

d. Process Assignments

i. Delegation to members

1. Give members assignments

2. Track members assignments

3. Review members work products

ii. Group Performance

1. Review artifacts

2. Create comments

3. Identify issues

4. Propose resolutions

e. Make disposition of assignments – approve, return for modification, terminate etc.

f. Monitor and track work process and products

Governance Group Members

1. Belong to Governance groups in one or more roles

2. Monitor Work queues

3. Artifact Review Assignments

a. Receive assignments

b. Return or reassign assignments

c. Review artifacts

d. Create comments regarding the artifact or other members reviews

e. Identify issues

f. Propose resolutions

g. Submit review work product to committee

Governance Issue Management

Issues are generated when reviewing groups or group members have concerns, questions, comments or other inputs regarding an artifact under review.

1. Issue Generating Person

a. Create Issue

i. Must provide description of issue linked to either a portion of the artifact or to the artifact as a whole

ii. Assign severity level – issue severity could range from trivial to fatal. Required responses may vary with severity.

iii. Linked to artifact version

iv. Propose resolution

v. Propose receiver of issue (default is review committee?)

b. Review response to issue and adjust status

c. Status flags modeled per general requirements

d. Track issue status by artifact, governance group, governance group member and probably other stuff too.

2. Issue Resolving Person

a. Reviews issue and proposed resolution

b. Collaborates with issue generating person to arrive at acceptable solution

c. Implements solution in artifact

d. Provides next version of artifact to governance committee (probably in batches)

F.1.11. Project Information System and Management Environment (PRISME)

F.1.11.1. General Requirements

The Project Information System and Management Environment (PRISME) will provide the general requirements listed below. Additional specific requirements are shown in the sections that follow.

Requirement F.134. Enable comprehension of the complete state of the development environment

FC-1 PRISME complete state of the development environment in the shortest amount of time. PRISME shall make specification and execution of the project build process easy, shall provide a uniform build system, shall provide quality project information, shall provide guidelines for best practices development, and shall allow transparent migration to new features of PRISME.

Requirement F.135. Provide project dashboards

FC-2 PRISME *(FC-1 above)* shall provide a dashboard that shows all the projects known to PRISME, shows summary statistics for those projects, and shall provide links to more detailed project information including detailed build metrics generated by the Continuous Integration Service *(ETS-F-54 below)*, the Tracker for each project *(ETS-F-36 below)*, the artifacts deployed to the Artifact Repository *(ETS-F-27 below)* for each project, and the version control system *???(see section 5.1.6 below)* for each project's sources and generated website.

Requirement F.136. Use declarative specifications with version-controlled POM

FC-3 PRISME *(FC-1 above)* shall use declarative specifications of a project's build, deployment, release, reporting, and documentation within a version-controlled Project Object Model (POM) file. This POM file shall contains the Uniform Resource Locator (URL) locations of the version control system which hosts the project's POM file as well as any configuration files, data files, and source files and shall also specify the project's dependencies, the developers involved and the roles they play, the defect tracking system, the continuous integration system, the organizations participating in the project, and the licenses associated with artifacts generated by the project.

Requirement F.137. Automated change log

FC-4 PRISME *(FC-1 above)* shall provide automated change log documentation created directly from source control.

Requirement F.138. Automated release management process

FC-5 PRISME *(FC-1 above)* shall ensure reproducibility, accountability, and immutability of all aspects of a project's release by ensuring that the release management process is fully automated, that all sources must be under version control, that all dependencies must be released, that no manual processes can participate in the release process, and that any subsequent modifications to release artifacts can be repudiated. The only way to change the release process shall be to modify the POM file and project sources, and to then check those changes into the project's version control system and then to request a project release from PRISME.

Requirement F.139. Integrate with issue tracking systems

FC-6 PRISME *(FC-1 above)* shall integrate with issue tracking systems and will provide automated reports of open issues and resolved issues at any time, and for any release.

Requirement F.140. Provide cryptographic checksums for all artifacts

FC-7 PRISME *(FC-1 above)* shall provide cryptographic (MD4 and SHA1) checksums for all artifacts to ensure their integrity.

Requirement F.141. Accessible over public Internet

FC-8 PRISME *(FC-1 above)* shall be accessible over the public Internet so that our collaborators (United States National Library of Medicine, DoD, The Centers for Medicare and Medicaid Services [CMS], Office of the National Coordinator, Intermountain Healthcare, Kaiser Permanente, the IHTSDO, and others) may participate in, or subscribe to, PRISME supported projects.

F.1.11.1.1. Workflow Management Service

PRISME will provide a workflow management service that is based on the **Business Process Model and Notation (BPMN) 2.0** specifications and supports the entire life cycle of the business process (from authoring through execution to monitoring and management). Java Business Process Model (jBPM)1 is an open-source (Apache 2) prototypical example of such a workflow management service.

Requirement F.142. Provide workflow management service

FC-9 PRISME *(FC-1 above)* shall provide a workflow management service able to create, load, and execute rules, and able to coordinate workflows between FAR client applications.

Requirement F.143. Run workflow management service engine within Java 8 SE

FC-10 The workflow management service engine must be able to run embedded within the default Java 8 Standard Edition (Java 8 SE) application platform *>(FC-A-1 below)*

Requirement F.144. Deploy web service on Java

FC-11 The Workflow Management Service *(FC-9 above)*shall run as a web service deployed on a Java EE 7/Java 8 SE server

Requirement F.145. Access through REST API

FC-12 The Workflow Management Service *(FC-9)* shall provide access to workflow services through a Representational State Transfer (REST) Application Program Interface (API) *(FC-A-4).*

Requirement F.146. Provide web services human task management capabilities

FC-13 The Workflow Management Service *(FC-9)* shall provide Web Services Human Task (WS-HumanTask)(http://docs.oasis-open.org/bpel4people/ws-humantask-1.1.html)management capabilities, which shall include the ability to define the type of task, the priority of the task, the data associated with the task, and the ability to assign a task to an individual or a group.

Requirement F.147. Use of POM file

ETS-F-3 PRISME *(ETS-F-1 above)* shall use declarative specifications of a project's build, deployment, release, reporting, and documentation within a version-controlled Project Object Model (POM) file. This POM file shall contains the Uniform Resource Locator (URL) locations of the version control system which hosts the project's POM file as well as any configuration files, data files, and source files and shall also specify the project's dependencies, the developers involved and the roles they play, the defect tracking system, the continuous integration system, the organizations participating in the project, and the licenses associated with artifacts generated by the project.

Requirement F.148. insertRequirementTitle

ETS-F-4 PRISME *(ETS-F-1 above)* shall provide automated change log documentation created directly from source control.

Requirement F.149. insertRequirementTitle

ETS-F-5 PRISME *(ETS-F-1 above)* shall ensure reproducibility, accountability, and immutability of all aspects of a project's release by ensuring that the release management process is fully automated, that all sources must be under version control, that all dependencies must be released, that no manual processes can participate in the release process, and that any subsequent modifications to release artifacts can be repudiated. The only way to change the release process shall be to modify the POM file and project sources, and to then check those changes into the project's version control system and then to request a project release from PRISME.

Requirement F.150. insertRequirementTitle

ETS-F-6 PRISME *(ETS-F-1 above)* shall integrate with issue tracking systems and will provide automated reports of open issues and resolved issues at any time, and for any release.

Requirement F.151. insertRequirementTitle

ETS-F-7 PRISME *(ETS-F-1 above)* shall provide cryptographic (MD4 and SHA1) checksums for all artifacts to ensure their integrity.

Requirement F.152. insertRequirementTitle

ETS-F-8 PRISME *(ETS-F-1 above)* shall be accessible over the public Internet so that our collaborators (United States National Library of Medicine, DoD, The Centers for Medicare and Medicaid Services [CMS], Office of the National Coordinator, Intermountain Healthcare, Kaiser Permanente, the IHTSDO, and others) may participate in, or subscribe to, PRISME supported projects.

F.1.11.2. Workflow Management Service

PRISME will provide a workflow management service that is based on the **Business Process Model and Notation (BPMN) 2.0** specifications and supports the entire life cycle of the business process (from authoring through execution to monitoring and management). Java Business Process Model (jBPM) (http://jboss.org) is an open-source (Apache 2) prototypical example of such a workflow management service.

Requirement F.153. insertRequirementTitle

ETS-F-9 PRISME *(ETS-F-1 above)* shall provide a workflow management service able to create, load, and execute rules, and able to coordinate workflows between FAR client applications.

Requirement F.154. insertRequirementTitle

ETS-F-10 The workflow management service engine must be able to run embedded within the default Java 8 Standard Edition (Java 8 SE) application platform *(ETS-A-1 below)*.

Requirement F.155. insertRequirementTitle

ETS-F-11 The Workflow Management Service *(ETS-F-9 above)* shall run as a web service deployed on a Java EE 7/Java 8 SE server *(ETS-A-3 below)*.

Requirement F.156. insertRequirementTitle

ETS-F-12 The Workflow Management Service *(ETS-F-9 above)* shall provide access to workflow services through a Representational State Transfer (REST) Application Program Interface (API) *(ETS-A-4 below)*.

Requirement F.157. insertRequirementTitle

ETS-F-13 The Workflow Management Service *(ETS-F-9 above)* shall provide Web Services Human Task (WS-HumanTask) *(http://docs.oasis-open.org/bpel4people/ws-humantask-1.1.html)* management capabilities, which shall include the ability to define the type of task, the priority of the task, the data associated with the task, and the ability to assign a task to an individual or a group.

Requirement F.158. insertRequirementTitle

ETS-F-14 The Workflow Management Service *(ETS-F-9 above)* shall manage the life-cycle of human tasks, including task creation, reservation, execution, completion, delegation, revocation, suspension, stopping a task in progress, skipping a task, and managing error states of human tasks.

Requirement F.159. insertRequirementTitle

ETS-F-15 The Workflow Management Service *(ETS-F-9 above)* shall enable project managers to view and edit workflow definitions using the BPMN 2.0 standard *(http://www.omg.org/spec/BPMN/2.0/)*

Requirement F.160. insertRequirementTitle

ETS-F-16 The Workflow Management Service *(ETS-F-9 above)* shall enable workflow definitions that can coordinate work across independent projects. For example, when a new concept is created in one project, a workflow process may be transmitted to a second project to translate that concept's description into another language, and another workflow process may be transmitted to a third project to ensure that the new concept is properly mapped to International Classification of Diseases, Tenth Edition, Clinical Modifications (ICD-10-CM).

Requirement F.161. insertRequirementTitle

ETS-F-17 The Workflow Management Service *(ETS-F-9 above)* shall enable "store and forward" execution of human tasks by client systems. The client systems would reserve a collection of tasks, which would then be executed offline, with the results transmitted back to the Workflow Management Service when the client comes back online.

Requirement F.162. insertRequirementTitle

ETS-F-18 The Workflow Management Service *(ETS-F-9 above)* shall provide reporting capabilities that provide summary statistics regarding process execution, as well as detailed information regarding the status of individual processes.

Requirement F.163. insertRequirementTitle

ETS-F-19 The Workflow Management Service *(ETS-F-9 above)* shall provide a reliable audit trail for all workflow task execution.

Requirement F.164. insertRequirementTitle

ETS-F-20 The Workflow Management Service *(ETS-F-9 above)* shall publish workflow processes as Maven artifacts *(ETS-A-6 below)* on the Artifact Repository Service *(ETS-F-27 below)*.

Requirement F.165. insertRequirementTitle

ETS-F-21 The Workflow Management Service *(ETS-F-9 above)* shall provide support for guided development of workflow processes by project managers.

F.1.11.3. Identity and Access Management Service

ETS-F-22 PRISME *(ETS-F-1 above)* shall provide for a single-sign-on capability so that users only have to log on once to PRISME and all role-based access control is managed from this single-sign-on.

ETS-F-23 The Identity and Access Management service *(ETS-F-22 above)* will support publication of a terminology system that consists of users and their roles, so that terminology development environments can use those concepts to identify editing actions of users, and to determine roles assigned to individual users.

ETS-F-24 The system will allow stratification of users by level of expertise. Access to particular user functions and work flows may be granted or denied based on level of expertise.

ETS-F-25 The system will allow stratification of users by level of domain knowledge expertise. Access to particular user functions and work flows may be granted or denied based on level of domain knowledge expertise.

ETS-F-26 The system will allow stratification of user's assigned role (e.g., modeler, quality assurance, reviewer, mentor). Access to particular user functions and work flows may be granted or denied based on user role.

F.1.11.4. Artifact Repository Service

PRISME will provide an artifact repository service. Artifactory[1] Apache Archiva[2] and Sonotype Nexus[3] are prototypical examples of artifact repository services.

Requirement F.166. insertRequirementTitle

ETS-F-27 PRISME *(ETS-F-1 above)* shall provide an Artifact Repository Service to which project artifacts are published and from which project dependencies are obtained by developers and/or continuous integration servers.

Requirement F.167. insertRequirementTitle

ETS-F-28 The Artifact Repository Service *(ETS-F-27 above)* shall be able to proxy artifact repositories from other organizations, and shall be able to be proxied by artifact repositories hosted by other organizations.

[1] http://www.jfrog.com/home/v_artifactory_opensource_overview
[2] http://archiva.apache.org/index.cgi
[3] http://www.sonatype.org/nexus/

Requirement F.168. insertRequirementTitle

ETS-F-29 The Artifact Repository Service *(ETS-F-27 above)* will identify artifacts by a group identifier, an artifact identifier, and a version.

Requirement F.169. insertRequirementTitle

ETS-F-30 The Artifact Repository Service *(ETS-F-27 above)* will classify artifacts with a classifier that describes the type and format of a project artifact. An example classifier, such as “RF2” would indicate that the artifact contained terminology content represented as Systematized Nomenclature of Medicine (SNOMED) Release Format 2 files.

Requirement F.170. insertRequirementTitle

ETS-F-31 The Artifact Repository Service *(ETS-F-27 above)* will enable users to search the repository via a Graphical User Interface (GUI) for artifacts by checksum, group id, artifact id, classifier, version, license, and by full text search of selected project content, minimally including the project POM file.

Requirement F.171. insertRequirementTitle

ETS-F-32 The Artifact Repository Service *(ETS-F-27 above)* will allow clients to programmatically obtain lists of artifacts filtered by regular expression pattern matching, checksum, group identifier, artifact identifier, classifier, version, license, and by full text search of selected project content, minimally including the project POM file.

Requirement F.172. insertRequirementTitle

ETS-F-33 The Artifact Repository Service *(ETS-F-27 above)* shall provide control over what artifacts are used by PRISME projects. The Artifact Repository Service must enable the organization to standardize on a specific version of a dependency, and to enforce this standardization by only providing access to a specific version of an artifact in a repository manager.

Requirement F.173. insertRequirementTitle

ETS-F-34 The Artifact Repository Service *(ETS-F-27 above)* shall provide control over the licenses of artifacts allowed in the repository, and shall provide reporting of the licenses used by each artifact currently within the repository.

Requirement F.174. insertRequirementTitle

ETS-F-35 The Artifact Repository Service *(ETS-F-27 above)* shall allow client applications, such as the PRISME Project Creation Application *(ETS-F-61 below)* to remotely query the artifact repository, and to remotely download selected artifacts.

F.1.11.5. Tracker Service

The PRISME environment shall provide a tracker service. A prototypical example of a tracker service would be Atlassian's JIRA tracker.[4] JIRA is used by Open Source Electronic Health Record Alliance (OSEHRA)[5] and synergism and/or integration with OSEHRA is worth considering.

Requirement F.175. insertRequirementTitle

ETS-F-36 PRISME *(ETS-F-1 above)* shall provide a Tracker Service for each project.

F.1.11.6. Service Desk

The PRISME environment shall provide a service desk. A prototypical example of a service desk would be Atlassian's Service Desk extension to JIRA.[6] JIRA is used by OSEHRA,[7] and synergism and/or integration with OSEHRA is worth considering.

Requirement F.176. insertRequirementTitle

ETS-F-37 PRISME *(ETS-F-1 above)* shall provide a Service Desk Portal to allow users to log service requests that relate to PRISME Services and Terminology Tooling.

Requirement F.177. insertRequirementTitle

ETS-F-38 The Service Desk *(ETS-F-37 above)*shall support Service Level Agreements that are automatically associated with user requests, and will enable real-time generation of performance metrics.

F.1.11.7. Version Control Service

PRISME shall provide a version control service. A prototypical example of this version control service would be Git[8] or Apache Subversion[9]. Git is used by OSEHRA[10] and synergism and/or integration with OSEHRA is worth considering.

Requirement F.178. insertRequirementTitle

ETS-F-39 PRISME *(ETS-F-1 above)* shall provide a Version Control Service.

Requirement F.179. insertRequirementTitle

ETS-F-40 The Version Control Service *(ETS-F-39 above)* shall be available on the Public Internet.

[4] https://www.atlassian.com/software/jira
[5] http://issues.osehra.org/secure/Dashboard.jspa
[6] https://www.atlassian.com/software/jira/jsd
[7] http://issues.osehra.org/secure/Dashboard.jspa
[8] http://Git-scm.com
[9] http://subversion.apache.org
[10] http://www.osehra.org/page/osehra-code-repository

Requirement F.180. insertRequirementTitle

ETS-F-41 The Version Control Service *(ETS-F-39 above)* shall allow single-sign-on and role-based access control via the Identity and Access Management Service *(ETS-F-22 above)*.

Requirement F.181. insertRequirementTitle

ETS-F-43 The Version Control Service *(ETS-F-39 above)* shall be available on the Public Internet so that developers and collaborators with no access to the VA intranet can access the service.

Requirement F.182. insertRequirementTitle

ETS-F-44 The Version Control Service *(ETS-F-39 above)* shall have the necessary storage, configuration, and bandwidth to support version control of large textual data sources, such as a complete history of all SNOMED release files (Systematized Nomenclature of Medicine Clinical Terms [SNOMED CT] is released biannually, and the data files of the release are ~1.3 GB, compressible to ~200 MB).

Requirement F.183. insertRequirementTitle

ETS-F-45 The Version Control Service shall have one master repository for each terminology system or independent module of a terminology system that is used within VA, or are of collaborative importance. Today these terminology systems include, but are not limited to: SNOMED CT International Edition, SNOMED CT US Extension, SNOMED CT Spanish Edition, Logical Observation Identifiers, Names, and Codes (LOINC), International Classification of Diseases, Ninth Edition, Clinical Modification (ICD-9-CM), ICD-10-CM, RxNorm, National Drug File (NDF), National Drug File-Reference Terminology (NDF-RT), Current Procedural Terminology (CPT), Healthcare Common Procedure Coding System (HCPCS), Diagnosis Related Group (DRG), and VHA Terminology (VHAT).

Requirement F.184. insertRequirementTitle

ETS-F-46 The Version Control Service *(ETS-F-39 above)* shall support hosting of project websites generated by the continuous integration service *(ETS-F-54 below)* and will thereby provide for historical records of all project metrics published via the website.

F.1.11.8. Quality Management Platform

PRISME shall provide a quality management platform that will support traditional java-based software projects and can be extended specifically to support terminology quality metrics. A prototypical example of such an open-source (LGPL) quality management platform is SonorCube.[11]

[11] www.sonorcube.org

Requirement F.185. insertRequirementTitle

ETS-F-47 PRISME *(ETS-F-1 above)* shall provide a quality management platform that will enable tracking of quality metrics for each project over time.

Requirement F.186. insertRequirementTitle

ETS-F-48 The Quality Management Platform *(ETS-F-47 above)* shall provide trend analysis tools to monitor quality evolution and milestones.

Requirement F.187. insertRequirementTitle

ETS-F-49 The Quality Management Platform *(ETS-F-47 above)* shall provide detailed reporting of complexity, compliance, and coverage metrics.

Requirement F.188. insertRequirementTitle

ETS-F-50 The Quality Management Platform *(ETS-F-47 above)* shall be extensible by writing plugins that can support terminology specific metrics.

Requirement F.189. insertRequirementTitle

ETS-F-51 The Quality Management Platform *(ETS-F-47 above)* shall provide Individual-level, team-level and project-level monitoring of metrics.

Requirement F.190. insertRequirementTitle

ETS-F-52 The Quality Management Platform *(ETS-F-47 above)* shall support rule-based defect detection, and shall support white listing of rule violations, that are identified as allowed exemptions to the rule after a manual review of the rule violations.

Requirement F.191. insertRequirementTitle

ETS-F-53 The Quality Management Platform *(ETS-F-47 above)* shall support rule-based defect detection and shall support a comprehensive audit trail of all white listing activities.

F.1.11.9. Continuous Integration Service

PRISME shall provide a continuous integration service capable of building traditional software projects, as well as building terminology projects. Prototypical examples of such continuous integration services include: Apache Continuum,[12] Bamboo,[13] Hudson,[14] Jenkins,[15] and TeamCity.[16]

[12] http://continuum.apache.org/
[13] http://www.atlassian.com/software/bamboo/
[14] http://hudson-ci.org
[15] http://jenkins-ci.org
[16] http://www.jetbrains.com/teamcity/

Requirement F.192. insertRequirementTitle

ETS-F-54 PRISME *(ETS-F-1 above)* shall provide a continuous integration service that is able to build and test projects as defined by the project's POM.

Requirement F.193. insertRequirementTitle

ETS-F-55 The Continuous Integration Service *(ETS-F-54 above)* shall support feature branching or a branch-per-issue workflow by automatically detecting new project branches in the Version Control Service *(ETS-F-39 above)* project repository, and then to automatically apply the main line's continuous integration scheme to the new branches, so that branch metrics are automatically generated and available from the Dashboard.

Requirement F.194. insertRequirementTitle

ETS-F-56 The Continuous Integration Service *(ETS-F-54 above)* shall be configurable to listen to commit triggers from the Continuous Integration Service *(ETS-F-54 above)*, and to enable those triggers to initiate a project build on the continuous integration server.

Requirement F.195. insertRequirementTitle

ETS-F-57 The Continuous Integration Service *(ETS-F-54 above)* shall ensure the integrity of all dependent artifacts used in a project build by verifying the cryptographic checksums of all artifacts. If checksums do not match, the Continuous Integration service must force the build to fail.

F.1.11.10. Project Creation Application

The project creation application will guide the selection of options necessary to create a project POM and to create the necessary infrastructure components (version control repository, continuous integration server setup, web site deployment location, issue trackers) and to select the proper project options. The goal of the project creation application is to enable technical users to create projects more efficiently and to also enable non-technical project managers to be able to set up their own projects with guidance from the application.

Requirement F.196. insertRequirementTitle

ETS-F-58 PRISME *(ETS-F-1 above)* shall provide a Project Creation Application, which will enable a PRISME project administrator to create and deploy new projects.

Requirement F.197. insertRequirementTitle

ETS-F-59 The Project Creation Application *(ETS-F-59 above)* shall automate the creation and initialization of the Version Control Service *(ETS-F-39 above)* repository for a project, and check in initial project sources into the Version Control Service.

Requirement F.198. insertRequirementTitle

ETS-F-60 The Project Creation Application *(ETS-F-59 above)* shall automatically configure the Continuous Integration Service *(ETS-F-54 above)* to check out the project from the Version Control Service *(ETS-F-39 above)*, build the project, and then deploy the project to the Artifact Repository Service *(ETS-F-27 above)*.

Requirement F.199. insertRequirementTitle

ETS-F-61 The Project Creation Application *(ETS-F-59 above)* shall allow a project administrator to select filtered project dependencies (such as a version of SNOMED or LOINC) from a list of dependencies of the proper classification (java library, terminology content, etc.) obtained from searching the PRISME Artifact Repository Service *(ETS-F-32 above)* in real time.

Requirement F.200. insertRequirementTitle

ETS-F-62 The Project Creation Application *(ETS-F-59 above)* shall allow a project administrator to create an archetype[17] from a configured project and to configure all necessary services to version control, test, and release the archetype.

Requirement F.201. insertRequirementTitle

ETS-F-63 The Project Creation Application *(ETS-F-59 above)* shall allow a project administrator to update an existing archetype and to commit that update to version control and to release the updated archetype.

Requirement F.202. insertRequirementTitle

ETS-F-64 The Project Creation Application *(ETS-F-59 above)* shall allow a project administrator to create projects from selectable list of available archetypes.

Requirement F.203. insertRequirementTitle

ETS-F-65 The Project Creation Application *(ETS-F-59 above)* shall allow a project administrator to select workflow processes that will be available within a project.

F.1.12. Content Management Capabilities

Content management capabilities are discrete functions that may be aggregated together to form an application. For example, a comprehensive editing environment would have all the content management capa-

[17] http://maven.apache.org/guides/introduction/introduction-to-archetypes.html

bilities available within a single environment. A web application may only use selected content management capabilities to efficiently serve the needs of a single user community with minimal setup and training.

F.1.12.1. Status Time Author Module Path (STAMP) Versioning Component Database

Requirement F.204. insertRequirementTitle

ETS-F-66 All ETS content (concepts, definitions, maps, rules, Refsets[18]) will be given immutable component identifiers, and will be version controlled by indicating the Status, Time, Author, Module, and Path of every change to ETS content. This includes the need to address a VA Extension identifier such as namespace adn partition idenifiers. (

Requirement F.205. insertRequirementTitle

ETS-F-67 An embeddable (runs within the same Java Virtual Machine [JVM] memory space) STAMP versioning component database will be available to support the Java stand-alone environment, available under an Apache 2 license.

Requirement F.206. insertRequirementTitle

ETS-F-68 A client server STAMP versioning database will be available to support client server environments. This database will use Java Persistence API (JPA) 2.0 as the persistence mechanism.

F.1.12.2. Taxonomy viewing

Figure F.1. Taxonomy View

Requirement F.207. insertRequirementTitle

ETS-F-69 Content management environments must have a taxonomy-viewing component available that can display configurable information *(as shown in Figure 1)* to meet the needs of a particular application. Minimally, the taxonomy view must support displaying concepts parentage, when more than one parent is present and enabling navigation of the entire parentage and lineage of a concept.The taxonomy must also show all descendants (immediate and distant subtypes) of a concept. Custom shapes and colors may be shown based on different terminology characteristics and colors may display what path or module a component is part of. Likewise, the taxonomy viewer must indicate whether a concept has subtypes through the use of icons (e.g.,*in the image above*, the arrows to the left of some concepts indicate the presence of subtypes).

[18]Refsets is a name for a flexible, extensible SNOMED CT file structure with many actual uses and many other potential uses (http://www.hl7.org/documentcenter/public_temp_066EC5A2-1C23-BA17-0C4B712003699BE3/wg/vocab/presentations/SnomedCt_Rf2andRefsets_20120118.pdf)

Requirement F.208. insertRequirementTitle

ETS-F-70 The taxonomy viewer must be configurable to display the preferred, or fully specified name in a specified dialect and language.

Requirement F.209. insertRequirementTitle

ETS-F-71 The taxonomy viewer must be configurable to display an appropriate icon based on membership of a concept in a reference set.

Requirement F.210. insertRequirementTitle

ETS-F-72 The taxonomy viewer must have the ability to show inferred relationships, stated relationships, and a summation of views.

Requirement F.211. insertRequirementTitle

ETS-F-73 The taxonomy viewer must have the ability to show concepts that have non-hierarchical relationships within the viewer. For example, mapping relationships may show SNOMED codes as children of CPT codes, with an icon indicating the nature of the mapping relationship.

Requirement F.212. insertRequirementTitle

ETS-F-74 The taxonomy viewer must have the ability to navigate a hierarchy that is represented as refsets, so that navigation can be specified outside of logical subsumption when desired.The taxonomy viewer must also display the definition status of each concept (i.e., whether the concept is fully defined or primitive). This can be accomplished through the use of icons.*The incorporation of a "focused taxonomy browser" (a view limited to one concept and only its immediate subtypes and supertypes) would be especially helpful.*

F.1.12.3. Component Request Service

The Component Request Service will enable users (such as application developers, re-engineering teams, mapping groups, etc.) to request new components for various applications. These components may be new terms added to one of the SNOMED LOINC and RxNorm (SOLOR) terminologies, new CDS or Knowledge Artifacts, new automation rules for scripting the behavior of an application, new rules for confirming the quality or correctness of an editing action, or batch quality assurance and related components managed as part of the ETS.

Requirement F.213. insertRequirementTitle

ETS-F-75 PRISME *(ETS-F-1 above)* shall provide a Component Request Service.

Requirement F.214. insertRequirementTitle

ETS-F-76 The Component Request Service *(ETS-F-75 above)* will allow users to enter component requests independent of a particular project.

Requirement F.215. insertRequirementTitle

ETS-F-77 The Component Request Service *(ETS-F-75 above)* will allow project administrators to assign component requests to a specific project's tracker service *(ETS-F-36 above)* and to initiate workflow processes related to that request as defined by the workflow management service *(ETS-F-9 above)*.

Requirement F.216. insertRequirementTitle

ETS-F-78 The Component Request Service *(ETS-F-75 above)* will support custom forms for each type of component request. These custom forms will enable dynamic form population and may utilize all the knowledge base and quality assurance capabilities of the stand-alone editing environments to help requestors potentially completely model their requests, leaving only a central quality assurance function.

Requirement F.217. insertRequirementTitle

ETS-F-79 The Component Request Service *(ETS-F-75 above)* will provide the entering user with an immediate Universal Unique Identifier (UUID), as well as a skeletal definition that they can import into their system and immediately use while the component is being quality assured centrally.

F.1.12.4. Query Capabilities

Requirement F.218. insertRequirementTitle

ETS-F-80 The user shall be able to construct standard queries using a graphical interface that supports drag and drop of concept into the query specification, as well as type-ahead completion for selecting concepts for use in the query specification. The user shall be able to enter words or fragments in any order to retrieve all appropriate results.

Requirement F.219. insertRequirementTitle

ETS-F-81 The user shall be able to construct advanced queries using the standard For, Let, Where, Order, Return (FLWOR) statements defined by XQuery. The FLOWR statement construction shall support drag and drop of concept into the FLOWR statement, and shall also support type-ahead completion for selecting concepts for use in the FLOWR statement.

Requirement F.220. insertRequirementTitle

ETS-F-82 The user shall be able to save, retrieve, share, browse, and modify queries.

Requirement F.221. insertRequirementTitle

ETS-F-83 Content management environments must have access to comprehensive ad-hoc searching capabilities. These capabilities must include standard Lucene and Regex lexical searches, and must also include semantics searches such as kind-of, has rel-type, has rel-type with restriction structural searches such as, all components with a version modified by a particular author and temporal searches, such as all components that were members of this refset 1 year ago, but are not members of this refset today. This includes the ability to search by numeric identifiers, by fully specified name or other description, by active/inactive status, and the ability to search using multiple parameters simultaneously, etc.

Requirement F.222. insertRequirementTitle

ETS-F-167 The terminology tooling shall support the following search-related capabilities:

- Save/export search results
- Sort search results by various criteria such as alphabetical by FSN or by source (SNOMED CT International Release, US Extension, LOINC, Refset content, etc.)
- Provide numerical counts of search results

Requirement F.223. insertRequirementTitle

ETS-F-168 The terminology tooling shall be able to generate reports based on query specifications such as: all new concepts and their identifiers newly created in a release period, all concepts with definition changes in a given period, all concepts in a given Refset, etc. The reports should be able to be exported in an easily viewed format (e.g., tab-delimited text files).

F.1.12.5. Refset Capabilities

Requirement F.224. insertRequirementTitle

ETS-F-84 The user shall be able to convert the results of any query into an enumerated Refset.

Requirement F.225. insertRequirementTitle

ETS-F-85 The user shall be able to covert a query specification into a Refset specification from which the Refset members can be automatically computed.

Requirement F.226. insertRequirementTitle

ETS-F-86 The Refset specification associated with a refset will be STAMP versioned and stored as annotations on the concept that identifies the refset.

Requirement F.227. insertRequirementTitle

ETS-F-166 Authoring includes the ability to create new Refsets and the ability to have multiple authors of the same Refset.

Requirement F.228. insertRequirementTitle

ETS-F-169 The terminology tooling shall allow the user to enter Refset member annotations (e.g., for a Refset member concept, the ability to enter a mapping to a VHAT or standardized terminology code or comment which other users can view).

Requirement F.229. insertRequirementTitle

ETS-F-170 The terminology tooling shall provide the ability to view, add, and inactivate Refset members in one editing window.

Requirement F.230. insertRequirementTitle

ETS-F-185 The terminology tooling shall allow for Refset integration with existing VA systems, to allow for the import and export of Refsets.

Requirement F.231. insertRequirementTitle

ETS-F-186 The termiology tooling shall allow for the ability to publish Refsets for VA national use or by external partners.

F.1.12.6. Document Generation Capabilities

Requirement F.232. insertRequirementTitle

ETS-F-87 Darwin Information Typing Architecture (DITA) documentation may be associated with all terminology components.

Requirement F.233. insertRequirementTitle

ETS-F-88 Document generation tooling must be available to extract the terminology component DITA documentation and generate a DITA map which can in turn be used to generate Portable Document Format (PDF) or Hypertext Markup Language (HTML) documentation from that DITA content.

Requirement F.234. insertRequirementTitle

ETS-F-89 Document generation tooling must be available to extract the terminology component DITA documentation and integrate those DITA sources into DocBook 5.1 files, which can in turn be used to generate PDF or HTML documentation, or used for other data transformations.

Requirement F.235. insertRequirementTitle

ETS-F-90 Document generation tooling must be able to embed results from any query into tables and body text of DITA and DocBook documents.

F.1.12.7. Scripting Capabilities

Requirement F.236. insertRequirementTitle

ETS-F-91 The rich client tools will support scripting using the Oracle Nashorn JavaScript libraries

F.1.12.8. Description Logic

Requirement F.237. insertRequirementTitle

ETS-F-92 The terminology tools will support viewing concept definitions using the SNOMED diagramming standard.[19]

Figure F.2. SNOMED Diagramming Standard

Requirement F.238. insertRequirementTitle

ETS-F-93 The terminology tools will support drag and drop editing using the SNOMED diagramming standard.

Requirement F.239. insertRequirementTitle

ETS-F-94 The terminology tools will support type ahead completion of description logic definitions in any of the Web Ontology Language (OWL) 2 specified syntaxes.

Requirement F.240. insertRequirementTitle

ETS-F-95 The terminology tools will support drag and drop editing onto description logic definitions in any of the OWL 2 specified syntaxes.

[19] http://www.ihtsdo.org/fileadmin/user_upload/Docs_01/Publications/SNOMED_CT_Diagramming_Guideline.pdf

Requirement F.241. insertRequirementTitle

ETS-F-96 The terminology tools will support the complete OWL 2 in addition to supporting the OWL 2 EL profile.

Requirement F.242. insertRequirementTitle

ETS-F-171 The terminology tooling shall provide classifier functionality for the SOLOR Terminologies (SNOMED CT, LOINC, and RxNorm), VA Extension content, post-coordinated expressions, and LEGO content.

Requirement F.243. insertRequirementTitle

ETS-F-172 The terminology tooling shall display incremental changes that have occurred with each classification and will allow the user to sort the results by type of relationship change. The tooling shall also display the loss or gain of parent and child concepts when this occurs.

Requirement F.244. insertRequirementTitle

ETS-F-173 The terminology tooling shall detect and display concepts in equivalency and cycle errors as well as provide a means for the concepts to be transferred to editing panels for error correction.

F.1.12.9. Mapping Capabilities

Requirement F.245. insertRequirementTitle

ETS-F-163 The system must be able to support mapping between and among terms and knowledge artifacts.

Requirement F.246. insertRequirementTitle

ETS-F-164 The system must support users in creating, maintaining, updating and versioning mappings between and among terms and knowledge artifacts.

Requirement F.247. insertRequirementTitle

ETS-F-165 The system must support users with mapping decision support capabilities. This must include the ability to suggest mappings for a target object based on its syntactic, lexical and sematic properties and utilizing decision support modalities such as rules, heuristics and machine learning. Other types of mapping decision support, as described under modeling decision support, may also be required. The mapping decision support system must be able to track if its suggestions were accepted and to continually improve based on final modeler decisions.

F.1.12.10. Browse a Set of Approved, Suggested or Similar Models

Requirement F.248. insertRequirementTitle

ETS-F-97 System must be able to develop and maintain a library of approved models and descriptions that can be linked to modeling assignments.

Requirement F.249. insertRequirementTitle

ETS-F-98 System must be able to suggest exemplar models based on modeling task, progressive user input, typical user modeling patterns, user “favorites” and other characteristics.

Requirement F.250. insertRequirementTitle

ETS-F-99 System must allow exemplar model sets to evolve as modeling task progresses.

F.1.12.11. Template Based Modeling

Requirement F.251. insertRequirementTitle

ETS-F-100 The system shall allow description logic substitution templates to be included in concept definitions, and the substitution values for individual concepts shall be stored as refsets.

Requirement F.252. insertRequirementTitle

ETS-F-101 The refset values associated with substation templates can be edited with the concepts definition, and within a spreadsheet style format so that entire collections of concepts can be viewed and edited at once.

Requirement F.253. insertRequirementTitle

ETS-F-102 Template based modeling will support the SNOMED diagramming standard for [20] specification of templates. These templates will be stored as versioned annotations on the refset that is used to populate the template.

Figure F.3. Template Based Modeling Diagram

[20] http://www.ihtsdo.org/fileadmin/user_upload/Docs_01/Publications/SNOMED_CT_Diagramming_Guideline.pdf

F.1.12.12. Modify Existing

Requirement F.254. insertRequirementTitle

ETS-F-103 The system must allow the modeler to select an exemplar model and to use it as a starting point to modify for a new modeling task from their work queue.

F.1.12.13. Specialize From Existing

Requirement F.255. insertRequirementTitle

ETS-F-104 The system must allow the modeler to specialize an existing model by adding to it without changing the base model construction.

F.1.12.14. Steal Pieces and Re-use in a New Model

Requirement F.256. insertRequirementTitle

ETS-F-105 The system must allow the modeler to select components of an existing model to be re-used in the creation of a new model. Methods of selection and re-use should be highly useable and easily understood. For example, using graphical elements.

Requirement F.257. insertRequirementTitle

ETS-F-106 Power Builder: System must have modeling “mail merge” capability, e.g., allow the modeler to select a piece of an exemplar model and designate it as “variable”. The system should allow the modeler to create/maintain a list of elements that would then be merged one at a time into the variable component of the exemplar model, with each merger creating a new draft model for review.

F.1.12.15. Rules Driven Modeling

Requirement F.258. insertRequirementTitle

ETS-F-107 The System must support the creation of models based on rules-based system feedback and constraints. Rules will be able to specify terminologies or terminology components, preferred and allowed semantic types, and other modeling style guides.

Requirement F.259. insertRequirementTitle

ETS-F-108 The system should be able to implement rules that limit the complexity of modeling by factors including task and/or modeler expertise. For example, no more than one post coordination or only terms from these trees. Modelers and Quality Assurance (QA) reviewers should be notified when limit boundaries are encountered.

Requirement F.260. insertRequirementTitle

ETS-F-109 The system must support the creation, versioning, and maintenance of rules to guide modeling efforts using open source tools in an externalized environment that does not create “hard coded” rules.

Requirement F.261. insertRequirementTitle

ETS-F-110 The system will allow rules to be created for various use scenario components including model domain, modeler domain expertise, and modeler modeling expertise.

Requirement F.262. insertRequirementTitle

ETS-F-111 The system must support access to modeling rules by various other functional components specified elsewhere (e.g., Interview driven modeling).

F.1.12.16. Interview Driven Modeling

Requirement F.263. insertRequirementTitle

ETS-F-112 The system will step user through a series of questions that guides model creation that complies with modeling rules.

Requirement F.264. insertRequirementTitle

ETS-F-113 The questions will be tailored to the initial modeling task and be refined by each successive answer from the human modeler.

Requirement F.265. insertRequirementTitle

ETS-F-114 The choices presented to the modeler should have explanations and context sensitive help as appropriate.

Requirement F.266. insertRequirementTitle

ETS-F-115 The modeler should be allowed to move backwards to revisit or reconsider earlier questions and answers as well as to cancel the interview entirely.

Requirement F.267. insertRequirementTitle

ETS-F-116 Resulting models must conform to modeling rules and styles.

F.1.12.17. Rules Driven QA

Requirement F.268. insertRequirementTitle

ETS-F-117 The system will be able to execute a rules evaluation batch mode to when new base terminologies are entered or other conditions that change substrate of lower level components or knowledge objects with dependencies.

F.1.12.18. Semi-Automated Modeling

Requirement F.269. insertRequirementTitle

ETS-F-118 The system should be able to accept an input string (up to a sentence) and generate a suggested term modeling the input string.

Requirement F.270. insertRequirementTitle

ETS-F-119 The system should be able to form post-coordinated expressions of at least 3 SNOMED terms and relations.

Requirement F.271. insertRequirementTitle

ETS-F-120 The system should be able to suggest models that correctly represent negation and uncertainty.

F.1.12.19. Alerts

Requirement F.272. insertRequirementTitle

ETS-F-121 The system should have the ability to notify users of various types about alert conditions and these alert conditions will be triggered by a rule-based system.

Requirement F.273. insertRequirementTitle

ETS-F-122 Conditions triggering alerts should include rule violations, errors, etc.

F.1.12.20. Human Consults

Requirement F.274. insertRequirementTitle

ETS-F-123 The workflow system shall allow the modeler to send a request for modeling assistance to a user or user type.

ETS-F-124 The system should have configurable workflows capable of directing model review after model creation.

F.1.12.21. Context-sensitive help

Requirement F.275. insertRequirementTitle

ETS-F-125 The system should be able to provide Context-sensitive infobuttons linked to terminology and modeling guidelines.

Requirement F.276. insertRequirementTitle

ETS-F-126 The system should build upon available open source infobutton tools that VA already has in place or development.

F.1.12.22. Workflow

Requirement F.277. insertRequirementTitle

ETS-F-127 Appropriate tools will have a workflow inbox from which users can manage their work.

Requirement F.278. insertRequirementTitle

ETS-F-128 All tools must have the ability associate workflow processes with edits and commits to content.

Requirement F.279. insertRequirementTitle

ETS-F-155 The terminology tooling must incorporate an agreed upon workflow algorithm which includes adding and allowing authors at increasing levels of authoring permissions (i.e., modeler, reviewer, approver, etc.).

Requirement F.280. insertRequirementTitle

ETS-F-156 The terminology tooling must also be able to support the workflow integration of terminology authors external to the KBS team, and potentially external to the VA.

Requirement F.281. insertRequirementTitle

ETS-F-157 The terminology tooling needs to provide a means of conflict adjudication / resolution in the event that more than one author models the same concept.

Requirement F.282. insertRequirementTitle

ETS-F-158 The terminology tooling should also support workflow for exporting content to VA partners and for submitting content requests to the United States SNOMED CT Content Request System (USCRS).

Requirement F.283. insertRequirementTitle

ETS-F-174 The terminology tooling shall be able to display all workflow history for a concept in a given release period.

Requirement F.284. insertRequirementTitle

ETS-F-175 The terminology tooling shall provide a means to search workflow to identify concepts in various stages of workflow using parameters such as: current workflow state (assigned, for review, approved), current editor, etc.

F.1.12.23. Quality Assurance

Requirement F.285. insertRequirementTitle

ETS-F-129 All terminology tooling will utilize rule-based system to perform real-time quality assurance. The rule-base used by the IHTSDO is a starting point for VHA quality assurance rules.

Requirement F.286. insertRequirementTitle

ETS-F-130 The tooling will provide capabilities for users to add and edit QA rules, in a graphical manner, using domain specific languages where appropriate.

ETS-F-176 The terminology tooling shall provide a means of viewing all QA rules (within the tool and by export to a document) as well as all concepts within the terminology which violate those rules (i.e., as currently provided by the IHTSDO Workbench QA Case Manager). The tooling shall provide a means for the concepts to be transferred to editing panels for error correction.

F.1.12.24. Additional Considerations

Requirement F.287. insertRequirementTitle

ETS-F-159 The terminology tooling must allow the modeler to create new concepts within the SOLOR terminology. New concepts may be created through a semi-automated process (which includes functionality such as pre-populating preferred terms and auto-correction of spelling errors or inadvertent extra spaces).

Requirement F.288. insertRequirementTitle

ETS-F-160 The terminology tooling must allow the modeler to retire concepts according to specified editorial policy. Concepts may be retired through a semi-automated process which retires all of the concept components and creates “pointers” to active concepts as substitutions as defined by editorial guidelines.

Requirement F.289. insertRequirementTitle

ETS-F-161 The terminology tooling must allow the modeler to see a given concept’s history (all previous versions of the concept) in an easily viewable format. The modeler should be able to revert to a previous version of the concept in the event of a modeling error or conflict between authors.

Requirement F.290. insertRequirementTitle

ETS-F-162 The terminology tooling must have a means of indicating the origin of concepts, Refsets, and other content (i.e., the capability to distinguish which content is created by the KBS terminology authoring team and which content has been created outside of KBS and by whom).

F.1.13. End User applications

F.1.13.1. Stand-Alone Terminology Integrated Development Environment

Requirement F.291. insertRequirementTitle

ETS-F-131 High-performance stand-alone terminology editing environment, deployed as a Java Web-Start rich internet application[21] able to efficiently run on a laptop computer that comfortably supports the runtime environment defined by 0 below.

Requirement F.292. insertRequirementTitle

ETS-F-132 The Stand-alone Terminology Integrated Development Environment (TIDE) must support all the capabilities currently supported by the IHTSDO workbench, in addition to all the potentially additional content management capabilities described here. The emphasis on the stand-alone TIDE required by this effort is an improvement in overall system quality, performance, and user interaction.

Requirement F.293. insertRequirementTitle

ETS-F-133 The stand-alone editor will use Java WebStart to support a simple install and update process.

[21] http://www.oracle.com/technetwork/java/javase/overview-137531.html

Requirement F.294. insertRequirementTitle

ETS-F-134 Users can customize screen layout and arrangement of features using an embedded Java FX 2.0 Scene Builder.

Requirement F.295. insertRequirementTitle

ETS-F-135 The Stand-alone TIDE *(ETS-F-131) above)* must support use of a central repository for collaborative projects and must also provide each developer with a complete history of all development work for that project on their local within their local environment. This support for a central repository supports collaborative work, and the provision of each developer with a complete history of all changes, guarantees that all developers can get work done regardless of their current Internet or Virtual Private Network connectivity. Support for distributed development is a standard feature of typical IDEs, and current version of the IHTSDO workbench supports such collaborative and distributed development.

Requirement F.296. insertRequirementTitle

ETS-F-136 The stand-alone TIDE must have fast and reliable support for creating different working sets, known as *branches*, within a project and sharing changes across them, known as *merges*. Branches make it easy to support different versions of a terminology package, regardless of whether those versions are permanent or were created for experimentation. Merges are a key aspect of a source code control system

Requirement F.297. insertRequirementTitle

ETS-F-137 The stand-alone TIDE must ensure *immutability* of committed changes. Immutability requires that once changes are committed to a repository, they shall be a permanent part of a project's historical record. Even though changes can subsequently be un-done (by *reverting*), both the changes and the replacement code that undoes those changes are a permanent part of project history.

Requirement F.298. insertRequirementTitle

ETS-F-138 The stand-alone TIDE must ensure *accountability*. Accountability requires that it is easy to determine who made a specific change and when that change was made.

Requirement F.299. insertRequirementTitle

ETS-F-139 The stand-alone TIDE must make it easy for developers to share in-progress branches and terminology changes between subsets of developers without requiring that those changes first be checked in to the central repository. Changes shared in this manner must preserve the immutability and accountability aspects of the shared changes.

Sharing capabilities as described here are standard features of distributed version control systems such as Git.

F.1.13.2. Client-Server Terminology Integrated Development Environment

Requirement F.300. insertRequirementTitle

ETS-F-140 The Client-server Integrated Development Environment will have all the functions of the standalone IDE, but will not store data locally.

Requirement F.301. insertRequirementTitle

ETS-F-141 The Client-server Integrated Development Environment will use the same simple install and update process as the standalone IDE.

F.1.13.3. Terminology Web Application Environment

Requirement F.302. insertRequirementTitle

ETS-F-142 Web Application Environment will be configurable to provide selected content management capabilities.

F.1.13.4. New concept request application

Requirement F.303. insertRequirementTitle

ETS-F-143 Any tools that support new concept requests shall integrate with request submission systems such as the National Library of Medicine (NLM) request submission system via the workflow service.

F.1.14. Knowledge Types

F.1.14.1. Stratified by Domain

Requirement F.304. insertRequirementTitle

ETS-F-144 The system will support efficient editing and curation of knowledge artifacts across all knowledge domains, such as pharmacy, lab, and ophthalmology in a flexible fashion for all required areas.

Requirement F.305. insertRequirementTitle

ETS-F-145 The system will utilize rule-bases to provide customized behavior based on domain and context within the tooling environments.

F.1.14.2. Stratified by Architectural Level

Requirement F.306. insertRequirementTitle

ETS-F-146 The system will support knowledge types at architectural levels as specified in the Informatics Architecture (terminology layer, knowledge base layer, clinical context layer, and rules layer).

F.1.15. Inputs into System

Requirement F.307. insertRequirementTitle

ETS-F-177 The terminology tooling shall support information models derived from medical devices – in particular, integration of Model Driven Health Tools components for UML model viewing (Catherine made this suggestion as a result of recent meetings with business architects.)

Requirement F.308. insertRequirementTitle

ETS-F-182 The terminology tooling shall have the ability to incorporate and import additional imputs from the following sources:

- Veterans Enterprise Terminology System (VETS)
- VHA Terminology (VHAT)
- VHA Unique Identifiers (VUIDs)
- Lexicon
- Lightweight Expression of Granular Objects (LEGO)

F.1.15.1. Terminology Releases from Standards Development Organizations (SDO)

Requirement F.309. insertRequirementTitle

ETS-F-147 The system will be able to accept, process, integrate, and version electronic releases of terminologies from SDO, the NLM and other authoritative sources. At a minimum this includes SNOMED CT, LOINC, RxNORM, Code for Vaccine Administered (CVX), and To Be Determined (TBD).

F.1.15.2. Terminology Releases from Knowledge Sharing Partners

Requirement F.310. insertRequirementTitle

ETS-F-148 The system will be able to accept, process, integrate, and version electronic releases from terminology knowledge sharing partners. At a minimum, this includes SNOMED CT extensions and ref sets.

F.1.15.3. Clinical Decision Support (CDS) and Knowledge Related Artifacts

Requirement F.311. insertRequirementTitle

ETS-F-149 The system will support searchable, shareable Extensible Mark-up Language (XML) structures. Such structures shall be composed of standard terminologies such as the SNOMED CT and LOINC. The structures will be used to define essential building blocks for medicine, including clinical observations (e.g., notation of “chest pain radiating to the left arm”), order sets (e.g., “Give one nitroglycerin tablet sublingually and call M.D.”), and decision support (e.g., “If chest pain with left arm radiation then do nitroglycerin order set”). The tools will provide a single consistent way of creating these knowledge artifacts and a seamless flow between documentation, decision support, and ordering at the point of care

F.1.15.4. XML Transforms

Requirement F.312. insertRequirementTitle

ETS-F-150 The system must support the automated transform between XML models of various knowledge artifacts. The transforms should be built on a common model transform methodology available in open source, such as Model Driven Health Tools.

F.1.16. Outputs from System

Requirement F.313. insertRequirementTitle

ETS-F-151 The system will be able to export terminology content and knowledge artifacts in a variety of formats for internal and external consumption. Exports must support Versioning, Error checking, tracking, Publish/ Subscribe paradigms.

Requirement F.314. insertRequirementTitle

ETS-F-152 Internal consumers will include application builders, terminology technical services (STS).

Requirement F.315. insertRequirementTitle

ETS-F-153 External consumers include SDO, the NLM US realm/NLM, Healthcare and Health IT partners and other authoritative sources.

Requirement F.316. insertRequirementTitle

ETS-F-154 The terminology tooling system must have the ability to export content requests directly to the United States SNOMED CT Content Request System (USCRS).

F.1.16.1. Publishing Output Content (VETS)

Requirement F.317. insertRequirementTitle

ETS-F-178 ETS shall support a mechanism for integrating data from the Terminology Tooling (from both Workbench and ISAAC) with existing (current) VA systems.

Requirement F.318. insertRequirementTitle

ETS-F-179 The Export Process from the Terminology Tooling will involve the following components:

- Ability to export content from the tooling as IHTSDO Standard Release Format 2 (RF2) SNOMED CT Identifiers (SCT Ids) or Universally Unique Identifiers (UUIDs).
- Mapping VHA Unique Identifier (VUIDs) to the components as an individual Reference Set (Refset) within the RF2.
- Upon export, any component that doesn't already contain a VUID will be assigned one from a pool of VUIDs made available by VA and stored in the Workbench.
- VUID assignment will be within a dedicated VUID Refset.

Requirement F.319. insertRequirementTitle

ETS-F-180 The Import Process from the Terminology Tooling will involve the following components:

- A separate program (via Maven) will import VA/VistA based content into the Workbench.
- Import process will create a Workbench Changeset.
- Workbench Import Program will retrieve content via Archiva.
- VUID assignment
  - If the VistA concept has a SNOMED CT Id, then process will add that concept's VUID to a SNOMED CT concept.
  - If the VistA concept does not have a SNOMED CT Id, then the process will generate a UUID from the VUID within the Workbench, and then add it to the VA extension to SNOMED CT.
- At release, all content developed within the Workbench will be assigned a VUID for the VUID collection delivered by VA.

Requirement F.320. insertRequirementTitle

ETS-F-181 ETS must support the development, maintenance, and publication of a VA Extension and its integration with existing VA systems. This includes providing for tooling training and terminology authoring training.

Requirement F.321. insertRequirementTitle

ETS-F-183 ETS must be able to output VA extension releases or release packages.

Requirement F.322. insertRequirementTitle

ETS-F-184 ETS must be able to export content requests to NLM US Content Request System.

F.2. Business-Specified Architectural Requirements

Clinical and technical tooling to support a comprehensive ETS will build on existing open-source terminology tooling projects currently either under development at, or in use at, the IHTSDO, the NLM, Kaiser Permanente, Sweden's national release center, Denmark's national release center, and VHA. This section defines the default platform currently used by these development efforts, and will therefore define the default platform for all new development.

Requirement F.323. insertRequirementTitle

ETS-A-1 The default platform for all software development beneath the presentation layer development will be Oracle 64 bit Java 8 SE.

Requirement F.324. insertRequirementTitle

ETS-A-2 The default framework for all web application presentation layer development will be done in HTML5 markup, with JavaScript as the Document Object Model (DOM) scripting language, and with support for high-resolution display devices. Scaled Vector Graphics (SVG) images are the preferred means for scalable image representations to support high-resolution display devices. Alternatively, when SVG imagery is not appropriate, developers may use the image-set() CSS capability *(http://dev.w3.org/csswg/css-images-4/)* for raster images.

Requirement F.325. insertRequirementTitle

ETS-A-3 The default framework for all Java Rich Internet Application (RIA) development will be JavaFX 8.

Requirement F.326. insertRequirementTitle

ETS-A-4 REST is the default architectural style for providing web services.

Requirement F.327. insertRequirementTitle

ETS-A-5 Apache Jersey 2.6 *(https://jersey.java.net)* is the default framework for implementing web services.

Requirement F.328. insertRequirementTitle

ETS-A-6 All project artifacts shall be managed by an Apache Maven compatible repository manager, and will have an associated POM file that contains all the elements required for deployment of artifacts to the Maven central repository. For this specification, an artifact is a resource used by—or produced from—the development process, whether it is documentation, data, or an executable file.

F.3. Terminology Project Information System and Management Environment

PRISME *(ETS-F-1 above)* will utilize Apache Maven *(http://maven.apache.org)* for project definition, project build specification, project quality reporting, and project deployment.

PRISME *(ETS-F-1 above)* will extend Apache Maven with plugin extensions *(http://maven.apache.org/plugin-developers/index.html)* to managing terminology project processing, quality determination, release, and deployment.

PRISME *(ETS-F-1 above)*will preferentially use open-source source software when such software meets project functional requirements, or may be reasonably extended to meet project functional requirements.

PRISME *(ETS-F-1 above)* development efforts will preferentially contribute to existing open-source projects in ways that improve their quality, functionality, and performance as part of assuring the quality, functionality, and performance of PRISME projects themselves.

Maven is currently the foundation of the environment used by the IHTSDO for its managed services, which is used by IHTSDO member countries for managing their SNOMED extensions, and for managing IHTSDO international development. The IHTSDO has many maven plugins available that support content conversion, content publication, Release Format 2 (RF2) file generation, and batch quality assurance. The business owners require that this effort extends and contributes to this collaborative work.

The POM of PRISME *(ETS-F-2 above)*, shall be the Maven Project Object Model 4.0.0 *(http://maven.apache.org/pom.html)*.

The reporting capabilities of PRISME *(ETS-F-1 above)*, as specified by ETS-F-6 above, shall either utilize existing Maven reporting plugins *(http://maven.apache.org/plugins)* or shall utilize Terminology-PRISME-specific reporting plugins that are written in Java by extending the AbstractMavenReport plugin *(http://docs.codehaus.org/display/MAVENUSER/Write+your+own+report+plugin)*.

Utilizing the standard Maven reporting capabilities ensures that PRISME can integrate reporting capabilities into the continuous integration and release processes, and can distribute reports as artifacts with a standard means to assure their integrity using cryptographic checksums. In addition, the extension of—and contribution to—collaborative work is more likely when adhering to this Maven standard practice.

The runtime environment for the stand-alone TIDE *(ETS-F-131 above)* and for server-side components of the client-server TIDE *(ETS-F-140 above)* and the Web Application Environment *(ETS-F-142 above)*shall be Oracles 64 bit version of Java 8.

Java 8 is necessary to best support JavaFX GUI components within the standalone or client-server environment. Additionally Java 8 on the server is necessary to support optional constructs within the API, to support observable properties within server-side code, and to support improved performance and simplified development via use of concurrent streams, and concurrent use of lambda functions.

Terminology development is a collaborative international effort, where collaborative participants may chose a variety of hardware and software environments based on individual circumstances and preferences.

The install and update mechanism *(ETS-F-133 above)* used for the Standalone IDE *(ETS-F-131 above)* will use the Java Web Start version compatible with Java Development Kit, Version 8 (JDK 8).

Java Web Start is currently being added to the IHTSDO workbench, to simplify the user install and update experiences. Further information about JDK 8 Java Web Start can be found at this URL: *http://docs.oracle.com/javase/8/docs/technotes/guides/javaws/index.html*

The install and update mechanism *(ETS-F-141 above)* for the Client-server IDE *(ETS-F-140 above)* will use the same install and update mechanism defined in 0.

Using the same install and update mechanism will simplify software development, testing, documentation, and training; decreasing project cost and risk.

F.4. Performance, Capacity, and Availability Requirements

F.4.1. Performance

The system shall remain responsive at all times, with no more than 2 second lags between user action, and system response to action.

Editing environments that support classification must be able to classify the entire terminology in 30 seconds or less, and to incrementally classify additive changes to the terminology in 500 milliseconds or less.

Refset environments must support Refset computation of a 150,000 member set, and computation of parent Refsets in less than 10 seconds.

Table F.1. Performance Analysis

If this is a system modification, how many users does the current system support?
The current system supports 8-10 users (STS and KBS staff).
How many users will the new system (or system modification) support?
The web application components of the system are expected to support 5,000 registered users, and 600 concurrent users. This includes STS staff, KBS staff, contractors, field staff, etc.
What is the predicted annual growth in the number of system users?
Annual growth is expected to average 10-15%. Initially, growth may be as high as 20% (specifically related to VistA Evolution and Connected Health initiatives). However, it is expected to plateau.

F.4.2. Capacity

The web application components of the system shall support 5,000 registered users, and 600 concurrent users.

Table F.2. Capacity Analysis

What is the predicted size (average) of a typical business transaction?
Refset environments must support Refset computation of a 150,000 member set.
What is the predicted number of transactions per hour (day, or other time period)?
Nightly builds occur on all changes computed for that day. The number of these types of transactions varies based on workload and project needs. The types of changes include but are not limited to: maintaining and creating terminology, adding new terms, batch uploads, and new updates necessary when new terminology is released.
Is the transaction profile expected to change (grow) over time?
Yes, the transaction profile is expected to grow. As terminology is added, so does the increased burden of maintenance.
What is the process for planning/adjusting capacity?
As new projects are added, capacity changes will be addressed proactively. Additionally, the Program Office will assess capacities (i.e., server size, number of users [within 90% of target expected users], etc.) periodically and prepare to make adjustments, as appropriate.

Does the update require a surge capacity that would be different from the base application?
Increased activities are experienced when updated code sets are released. • ICD – October • CPT/HCPCS – January • LOINC – January/June • SNOMED CT – January/July • SNOMED US extensions – March/October

F.4.3. Availability

Table F.3. Availability Description

Describe when the envisioned system will need to be available (business hours only, weekends, holidays, etc.) to support the business.
The system shall be 99.9% available Monday-Friday, 6:00 AM ET to 3:00 AM ET. The system shall be 98% available on an annual basis. Build (system implementation) shall be scheduled during off peak hours or in conjunction with relevant maintenance schedules. Maintenance, including maintenance of externally developed software incorporated into the application, shall be scheduled during off peak hours or in conjunction with relevant maintenance schedules. The business owner should provide specific requirements for establishing system maintenance windows when planned service disruptions can occur in support of periodic maintenance.

F.5. Business-Specified Non-Functional Requirements

The system must be **provably** highly usable in a safe, efficient fashion. The business expects to be involved in iterative cycles of usability planning, evaluation, and improvement.

F.5.1. User Centered Design

User centered design (UCD) is an approach to design that grounds the process in information about the people who will use the product. UCD processes focus on users through the planning, design and development of a product.

Usability is defined as the “extent to which a system, product, or service can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” (International Organization for Standardization [ISO] 9241:210).[22] For clinical systems, organizations such as the Office of the National Coordinator (ONC) through its regulation - 170.314(g)(3): Safety Enhanced Design certification program[23] and its Health IT Policy Committee;[24] as well as the Institute of Medicine

[22]ISO 9241:210 (2010). Ergonomics of human-system interaction - Human-centered design for interactive systems.
[23]http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method
[24]Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology, Final Rule.

(IOM) through its November 2011 report titled ‘‘Health IT and Patient Safety: Building Safe Systems for Better Care’’,[25] call for a focus on improved usability outcomes in conjunction with improved safety, risk management, and safety culture. A UCD process is a framework aimed at optimizing the usability of a system, product, or service, while at the same time including human factors activities focused on areas impacting patient safety.

UCD standards provide alternative frameworks for integrating UCD into the design and development of software systems. Just as software projects can call for similar but slightly different design and/or development approaches to assure a successful system, projects can also call for similar but slightly different UCD processes. Characteristics that might result in one UCD process being used over another UCD process include requirements defining the rigor with which UCD activities must be carried out or the specificity required for traceability from UCD activities to impact on the product.

Aspects of the ISO 9241:210 (Ergonomics of human-system interaction - Human-Centered Design for Interactive Systems) and National Institute of Standards and Technology (NIST) 7741 (Guide to the Processes Approach for Improving the Usability of Electronic Health Records)[26] UCD standards are the foundation for the process described in this document. For regulatory purposes, for example ONC's 170.314(g)(3): Safety Enhanced Design certification, both of these standards as well as other standards are acceptable.

The ISO 9241-210 (Human- Centered Design for Interactive Systems) describes four primary activities that are to be carried out in iterative fashion until defined usability objectives are obtained. The National Institute of Standards and Technology Interagency Report (NISTIR) 7741 (NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records [EHR]) describes activities to be carried out during the development of EHR applications. This standard focuses on methods relating to UCD and usability testing.

Content Management capabilities and integration of those capabilities into applications will be done according to the principles of User Centered Design as defined in ISO 9241:210 (Ergonomics of human-system interaction - Human-Centered Design for Interactive Systems) and NIST 7741 (Guide to the Processes Approach for Improving the Usability of Electronic Health Records).[27]

Design of Content Management capabilities and integration of those capabilities will meet ONC's 170.314(g)(3): Safety Enhanced Design certification standards.

F.5.2. Life Critical Systems Approach

As business owners with the clinical responsibility to assure the safety of the veterans we serve, we require that development be performed, to the extent reasonably possible, in accordance with International Electrochemical Commission (IEC) 62304 Medical device software – Software life cycle processes. For the purposes of this BRD, the terminology content itself will be treated as software, and must also be managed in accordance with IEC 62304. Examples of terminology content subject to IEC 62304 include SNOMED, LOINC, RxNorm, and similar terminology systems used within VA health information systems.

We recognize that achieving full compliance with IEC 62304 is a mid-term objective of this effort, and that immediate compliance with all aspects of IEC 62304 is unreasonable, and may itself cause harm secondary to delays in improvements to existing systems that are not IEC 62304 compliant. In lieu of immediate compliance for any component for which a risk assessment demonstrates acceptable risk for deferring full compliance, progress toward full compliance must be measurable, and must proceed according to a compliance plan approved by the business owners.

Clinical decision support capabilities are a type of life-critical system—a system where failure can mean not delivering life and/or safety critical information a timely manner so that it could be acted on to the

[25]IOM. 2012. Health IT and Patient Safety: Building Safer Systems for Better Care. Washington, DC: The National Academies Press.
[26]NIST 7741 (2010). Guide to the Processes Approach for Improving the Usability of Electronic Health Records.
[27]NIST 7741 (2010). Guide to the Processes Approach for Improving the Usability of Electronic Health Records.

benefit of life or safety of patients we serve, or can mean delivering incorrect information that is acted on to the detriment of life or safety of the patients we serve.

Techniques commonly applied to the design, development, and maintenance of life-critical systems are underutilized in traditional health IT practice. This effort seeks to remedy this underutilization by bringing in external experts to perform Probabilistic risk assessments for core components of the informatics architecture. These risk assessments should look comprehensively at the defect reporting systems, development processes, automated and interactive testing proc¬esses, publication processes, and other aspects deemed appropriate by the external experts. This analysis should be performed with the assumption that clinical SOLOR System terminology content, and declarative or procedural rules (e.g., Drools) that use that content are types of software, and appropriate software best practices and existing software development tools should be directly applied where possible—make use of unit test frameworks (e.g., JUnit), defect reporting systems (e.g., Jira), version-control systems (e.g., Git), configuration management systems (e.g., Maven), continuous integration environments (e.g., Hudson)—or where not possible these existing development tools should be extended to meet requirements. At least the following components should be evaluated:

- The Informatics Architecture Speification (From VA)
- The SOLOR System terminologies:
  - SNOMED CT (From IHTSDO)
  - RxNorm (From NLM)
  - LOINC (From the Regenstrief Institute)
  - VA extensions made to these terminologies
- Open Tooling Framework (OTF) tooling (From IHTSDO)
- The Informatics Architecture Acceleration (ISAAC) editor built using OTF (From VHA)
- The Commonwealth Scientific Research Organization (CSIRO) classifier used for terminology management by the VHA
- The Lightweight Expression of Granular Objects (LEGO) development environment (From the VHA)
- The process of upgrading a system to new versions of any of the SOLOR terminologies, considering all the implications that upgrade may have on existing patient data, existing decision support capabilities, and existing reporting capabilities.
- All software library dependencies of any software used within the clinical and technical terminology tooling.

All components (terminology and software) of the terminology tooling must be evaluated with respect to IEC 62304. This analysis must include a probabilistic risk assessment for patient morbidity and mortality cause by improper functioning of software. The defect rate (errors of omission and commission) within the existing terminology content must be determined. The error rate must be stratified by content areas (over the counter medications, Prescription (Rx) only medications, antineoplastic substances, skin findings, surgical procedures, morphologic findings, etc.), so that probabilities of errors can be correlated with the magnitude of morbidity or probability of mortality associated with identified types of errors.

All aspects of human interaction with the terminology tooling must be evaluated with respect to IEC 62304. This analysis must include a probabilistic risk assessment for patient morbidity and mortality cause by human error when using the software.

All aspects of workflow design within the terminology tooling must be evaluated with respect to IEC 62304. This analysis must include a probabilistic risk assessment for probability of morbidity and mortality that could be prevented by changes in workflow (for example requiring dual independent review of existing or new content).

In above to the above evaluations, if any area is found to have significant deficits with respect meeting standards for life-critical systems, we must also develop:

- A roadmap describing the best sequence to rectify any deficits
- Quality improvement plans to ensure that once the deficits are resolved, there is sufficient ongoing system improvement such that the system does not regress

A roadmap and quality improvement plan will be developed for any components of the tooling environment that are found to have significant deficits with respect to meeting standards for life critical systems.

Commercial-Off-The-Shelf (COTS) tools, such as Parasoft's JTest, or AGitarOne, or suitable open source equivalents may help rapidly improve test coverage and related quality aspects of dependent software modules. These tests should result in artifacts that can be used by the respective projects, and should seek to be comprehensive over the scope of the evaluated software.

All dependent open source libraries will be built from source, and comprehensive quality metrics will be obtained to assess their quality.

COTS unit-test generation tools augmented with manually generated unit-test cases and integration tests will be used to create 95% source code coverage of the terminology tools.

The terminology tool code coverage will be used to determine how much of the source code from dependent libraries is actually used, and to use that analysis to determine if the number of dependent libraries can be reduced, or if only selected classes from those libraries should be used.

COTS unit-test generation tools augmented with manually generated test cases will be used to create 95% source code coverage of the terminology libraries.

Test coverage information of terminology tools, the terminology libraries will be analyzed to determine what areas of the software need specific efforts to improve quality and correctness.

The comprehensive unit tests shall be combined to create a regression test suite to be used as part of ongoing development.

The comprehensive unit tests shall be contributed back to the open source community for libraries for which they are generated. Any fixes or recommendations for improvement shall be discussed with the project owners.

If significant areas of quality deficiency are identified with necessary open-source libraries, we will contribute development resources to those projects to rectify those quality deficiencies.

F.5.2.1. System Acceptance Testing

The following examples are different types of testing that should be considered during system acceptance testing:

- Graphical user interface testing
- Usability testing
- Software performance testing

- Compatibility testing
- Exception handling
- Load testing
- Volume testing
- Stress testing
- Security testing
- Scalability testing
- Sanity testing
- Smoke testing
- Exploratory testing
- Ad hoc testing
- Regression testing
- Installation testing
- Maintenance testing
- Recovery testing and failover testing.
- Accessibility testing, including compliance with:
  - Americans with Disabilities Act of 1990
  - Section 508 Amendment to the Rehabilitation Act of 1973
  - Web Accessibility Initiative (WAI) of the World Wide Web Consortium (W3C)

F.5.3. Known Interfaces

This is the business community's best understanding of known interfaces and may not be a comprehensive listing.

Table F.4. Known Interfaces

Name of Application	Description of current application	Interface Type	Existing Functionality	Deliverables
VHA Enterprise Terminology Services (VETS) (includes New Term Rapid Turnaround (NTRT)	Suite of products that deliver standardized terminology content for use across the VA enterprise; including VistA	Automated	Yes, but not to enterprise requirement's level	Rapid and accurate issuance of terms, updates of existing terms, and deployment of solutions over a browser to multiple applications.

Name of Application	Description of current application	Interface Type	Existing Functionality	Deliverables
	and Clinical / Health Data Repository (CHDR).			
Connected Health/Mobile Applications	Provides mobile access to VA healthcare information	Automated	Limited; applications are being developed	Data would be shared, as needed.
Corporate Data Warehouse (CDW)	National data repository that pulls from several VHA clinical and administrative systems, primary VistA.	Automated	Yes	Data would be shared, as needed.
Registries	Supports the maintenance of local and national registries for clinical and resource tracking of care for patients with certain clinical conditions.	Automated	Yes	Data would be shared, as needed.

F.5.4. Related Projects or Work Effects

PRISME will enable developers and managers to comprehend the complete state of the development environment in the shortest amount of time. PRISME shall make specification and execution of the projects build process easy, shall provide a uniform build system, shall provide quality project information, shall provide guidelines for best practices development, and shall allow transparent migration to new features of PRISME.

NSR #20120905 Mobile Applications

http://vista.med.va.gov/nsrd/Tab_GeneralInfoView.asp?RequestID=20120905

The Mobile Development project is focused on the development of simple and complex applications and treats these applications as functions being released to the App Store. This project manages the development of mobile applications and plans for cyclic release of applications over the course of 4, 6 month increments.

NSR #20130905 VistA Evolution (VE)

http://vista.med.va.gov/nsrd/Tab_GeneralInfoView.asp?RequestID=20130905

The VistA-4 Project will be the first project in the VistA Evolution Program. VistA-4 will focus on syntactic, semantic, and process interoperability, care coordination, the integration of ancillary services, and

meaningful use. VistA-4 will rely upon infrastructure components, data models, and services that support an open, modular, extensible EHR platform allowing VA to provide high-quality solutions at increased speed and decreased cost. The resulting system will be flexible and agile, accommodating new technology advances and achieving optimal results more efficiently.

NSR #20140509 VA/DoD Data Standardization

http://vista.med.va.gov/nsrd/Tab_GeneralInfoView.asp?RequestID=20140509

VA is collaborating with the DoD and the IPO to improve the interoperability of data contained in the VA and DoD health care systems. Data standardization is the key. As part of the improvement process, this request will provide the framework for expectations related to sharing standardized clinical data between VA and its health care deliver partners (namely DoD).

NSR #20080407 Standard Computable Data in Documents

http://vista.med.va.gov/nsrd/Tab_GeneralInfoView.asp?RequestID=20080407

This request seeks to standardize objects in documents so that they are computable and available for all document types.

NSR #20110408 Certification of VistA for Meaningful Use

http://vista.med.va.gov/nsrd/Tab_GeneralInfoView.asp?RequestID=20110408

This NSR seeks to bring VistA into compliance with the Stage 1 Meaningful Use of EHR Technology certification criteria, enabling VA to meet its commitment to the Meaningful Use objectives. The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act (ARRA) of 2009, was signed into law on February 17, 2009, to promote the adoption and meaningful use of certified health information technology. In July of 2010, CMS announced a final rule to implement provisions of ARRA that include criteria for achieving meaningful use of health information technology. This final rule defined meaningful use adoption criteria in stages of adoption. In an effort to further codify the relationship between the aforementioned legislation, OMB issued a memorandum on September 17, 2010, requiring that selected federal agencies, including VA, achieve five HIT Principle Processes by the end of FY12.

F.6. Other Considerations

F.6.1. Alternatives

No alternatives have been identified for this request. The enhancements requested are imperative. Without them, we won't achieve interoperability and will fail to meet legislative mandates (NDAA FY14 [requires interoperability of all data specifically terminology and computability of the terminology], NDAA FY15 [under review; references terminology to be shared between VA and DoD], H.R. 4486 Military Construction Budget [which includes VA], and VE).

F.6.2. Assumptions

To meet the aggressive implementation timeline, staffing and funding will be provided at the necessary levels to achieve the goals.

F.6.3. Dependencies

Availability of staff (SMEs and developers) that possesses the prior knowledge of the processes and systems impacted for this long-term effort.

- Time commitments from SMEs and developers to implement functionality.
- Financial resources for development and ongoing maintenance will be available. (This new system will have ongoing costs to VA related to sustainment and maintenance.)
- Access to data.

F.6.4. Constraints

- The new system must be in place by October 1, 2014 to meet legislative requirements.
- Hardware utilized by staff must include the appropriate memory on computers to support the functionality requested.

F.6.5. Business Risks and Mitigation

Table F.5. Business Risks and Mitigation

Business Risks	Mitigation
If there is insufficient funding to support development or acquisition, then necessary immunization data will not be collected	Coordinate with Business Owners and leadership to ensure project funding.
If resources are not available, then the deployment of enhancements may be delayed.	Coordinate with stakeholders, to ensure understanding of requirements as part of their scope.
Due to the compressed time frame in which implementation is expected, there is an inherent risk that the deadline will be missed.	Work with Product Development (PD) to create and monitor development milestones. Obtain additional resources and funding to meet timelines.
Due to the compressed time frames used to elicit and document the requirements for this NSR, there is the inherent risk that the requirements do not capture the full scope of the request.	Ensure requirements are designed and developed via agile methodology and derived during high-level discovery meetings. Requirements elaboration is documented and mitigation plans are provided.

F.7. Requirements fromIHTSDO...

Concurrent Transactions in Single Workspace
Assumptions:
Translation is not in scope and is not supported in this collaborative environment.

The work package is for a backend that would make it possible to support the following use-cases.

All edits are happening in real-time. Uncommitted changes are visible to all users in real-time.

Committed changes are visible to all users in real-time.

Collaborative environment is a Web-based application.

Use Cases
As an editor, I want the ability to commit all of my, and only my, changes as a group.

As an editor, I want the ability to commit all of my, and only my, changes on a single concept.

As an editor, I want the ability to edit in real-time.

As an editor, I want to be notified when the concept I am editing in real-time is also being edited by others in real-time.

As an editor, I want to be notified if a change of mine has caused a contradiction.

As an editor, I want to see a contradiction when a concept has published changes that have occurred concurrently.

As an editor/reviewer, I want the ability to add a comment to my commits.

As an editor/reviewer, I want the ability to revise my comments.

As a reviewer, I want my review (edits, comments, etc.) to be visible in real-time to the original editor (and other users in the environment).

Multiple Workspaces (e.g. sandbox)

Additional assumptions:

Real-time: commit button = commit + publish

Sandbox: commit button = commit only. Changes are published later using a different mechanism.

Basic
As an editor, I want to be be able to commit and preview the effects of my changes without sharing the changes with others (sandbox).

As an editor, I want the ability to commit all of my, and only my, changes as a group in my sandbox.

As an editor, I want the ability to commit all of my, and only my, changes on a single concept in my sandbox

As an editor, I want the ability to publish changes from my sandbox.

As an editor, I want the ability to create a sandbox.

As an editor, I want the ability to edit in a sandbox.

As an editor, I want the ability to discard a sandbox.

As an editor, I want the ability to publish a sandbox.

As an editor, I want the ability to classify in my sandbox.

As an editor, I want the ability to abandon all of my changes in my sandbox and not have them be visible again to me or others.

As an editor, I want a searchable, sortable list of my changes that have occurred in my sandbox, organized by concept.

As an editor, I want the ability to use workflow from within my sandbox, e.g. promote concepts.

As an editor, I want the to be notified if any of my changes in my sandbox would cause a contradiction.

As an editor, I want to be prevented from publishing my changes, if they would cause a contradiction, until all potential contradictions are resolved.

Intermediate
As an editor, I want the ability to abandon some of the changes in my sandbox and not have them be visible again to me or others.

As an editor, I want the ability to see what other changes have been published that are not part of my sandbox.

As an editor, I want the ability to choose when to apply others' changes to my sandbox. (Note: This should be mandatory at some point, e.g. before a push.)

Advanced

As an editor, I want to be able to share my sandbox with select others, without sharing my changes with everyone.

As an editor, I want the ability to publish changes from a sandbox that I am a part of.

As an editor, I want changes in a sandbox I am a part of to be visible to all other members in real-time.

As an editor, I want the ability to include/exclude changes for publication from my sandbox at a component l

As an editor, I want to the ability to see if any of the components included for publication are dependent on any of excluded components.

As an editor, I want a searchable, sortable list of my changes and other changes that have occurred in a sandbox, organized by concept.

As an editor, I want the ability to subscribe to published changes from another collaborative editing environment, e.g. a member country can subscribe to IHTSDO changesets.

As an editor, I want the ability to control how the changes from my subscriptions are applied.

As an editor, I want the ability to have multiple sandboxes.

—IHTSDO

G. SOLOR References

Observations

¦Systolic blood pressure¦	Systolic blood pressure is a primitive child of Blood Pressure. See Also ???TITLE???.
¦Diastolic blood pressure¦	Diastolic blood pressure is a primitive child of Blood Pressure See Also ¦Systolic blood pressure¦.

Procedures

Procedure 1	Some reasonable definition here. Include human readable description logic definition. See Also Procedure 2.
Procedure 2	Some reasonable definition here. Include human readable description logic definition. See Also Procedure 2.