ISAAC's KOMET and SOLOR

A Treatise on Symbolic Data Systems

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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

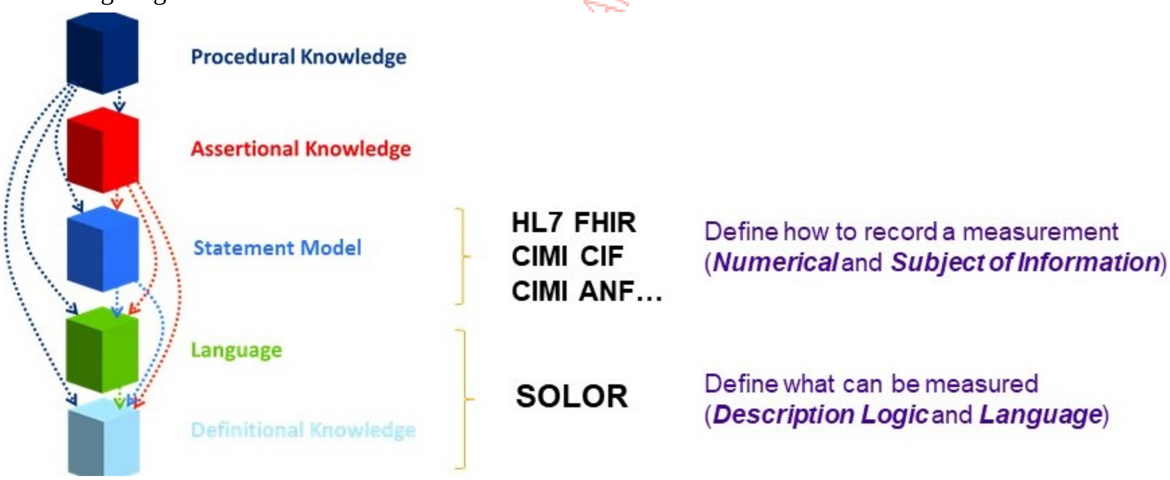
A recent whitepaper[2] cited that great strides have been made in healthcare data interoperability in the past decade… the vast majority of clinicians and patients have access to some portion of their health data in electronic format, thanks to the proliferation of electronic health record (EHR) systems 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 (13.7% of all documents), vital signs and results should use LOINC (9.2% of all documents), vital signs, and results should use unified code of units of measure (UCUM) for physical values (8.7% of all documents) and the inclusion of conflicting status information for medications (6.7% of all 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 quantitative or existential.

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



Current challenges include the following:

1. Further tooling and guidance needs 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

[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

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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.

1.4. 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

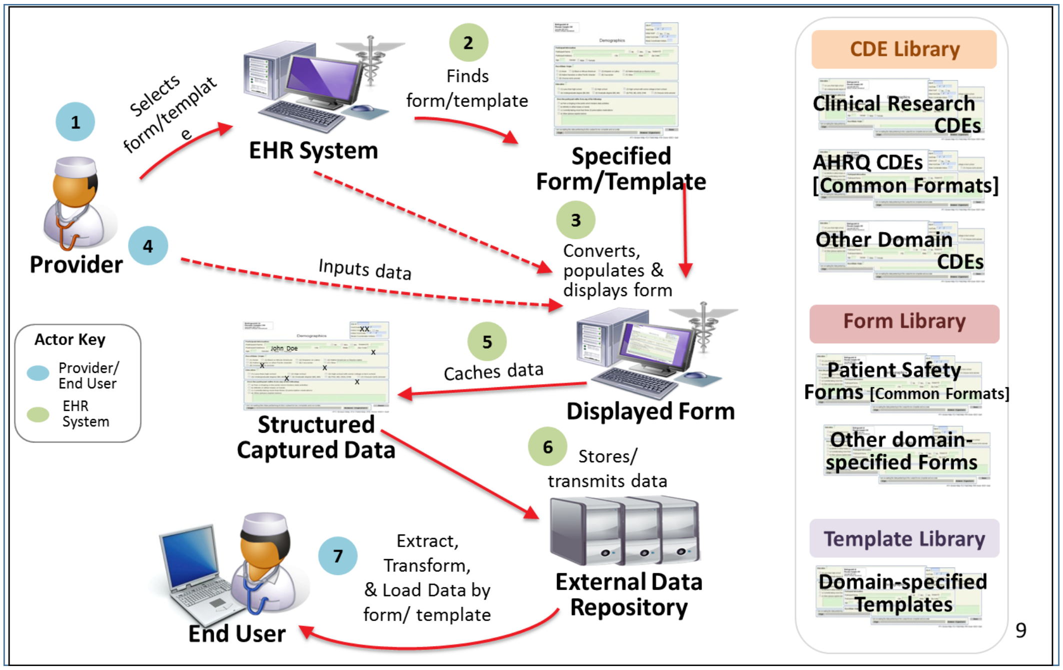
“Data element” is a longstanding concept used in information technology and data modeling[1]. Recently, the definition and use of data elements has been proposed as the basis for structured data capture within EHRs and other clinical applications.

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 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.



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

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
- 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):

[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

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

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 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.

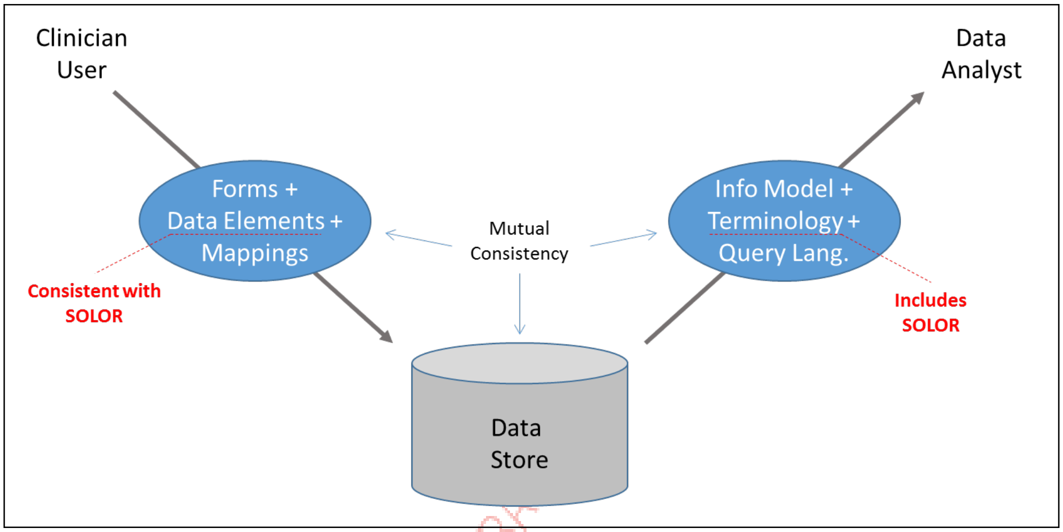
Examples of information models consistent with this approach include OpenEHR[5,6] and CIMI[7,8]. Examples of applicable terminology models include SNOMED-CT[9] and SOLOR[10].

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

[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/.

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.



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

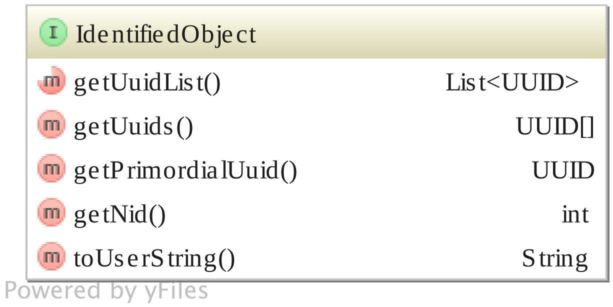
Documentation is a cross-cutting concern A well-documented system is inextricably linked to our ability to understand, maintain, and assure the quality of that system. Just as declarative knowledge layers derive from the ones below, the documentation must have the ability to derive selected content from 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

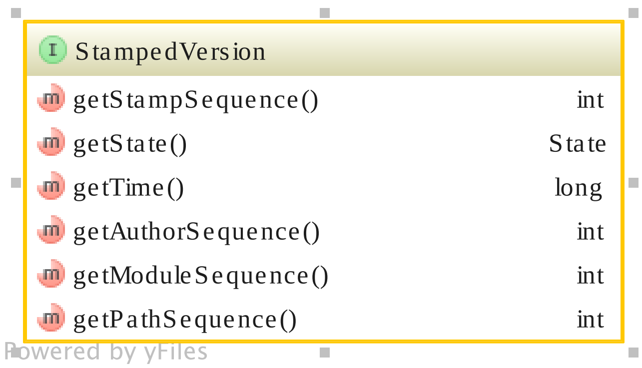


Figure 2.4. Latest Version

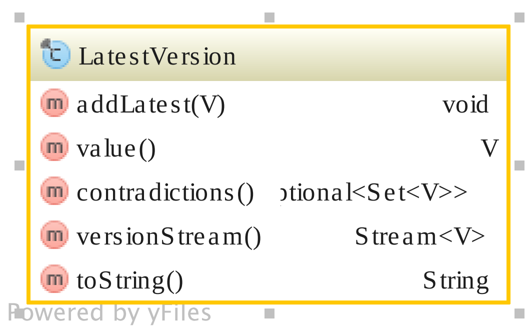
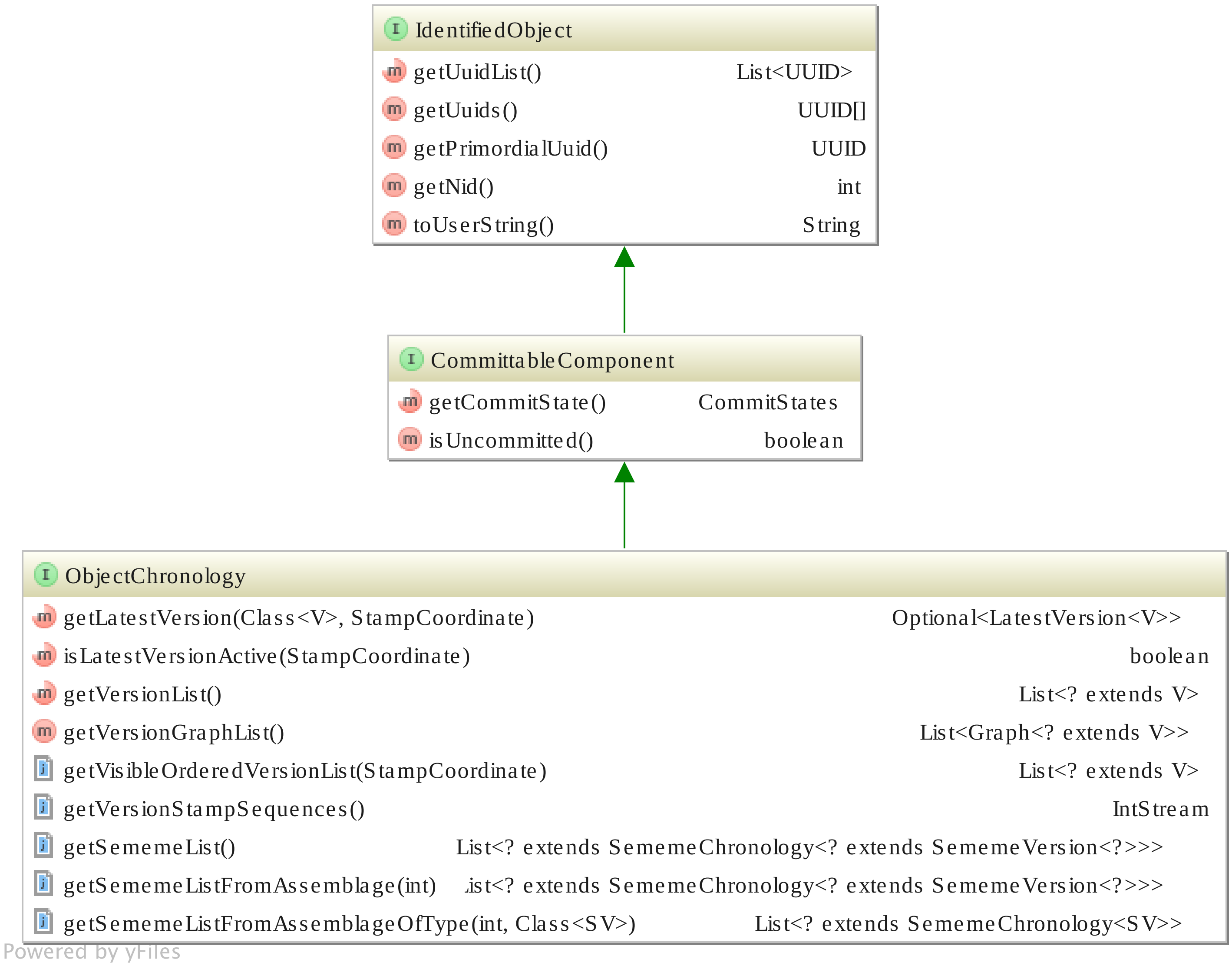


Figure 2.5. Object Chronology



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.

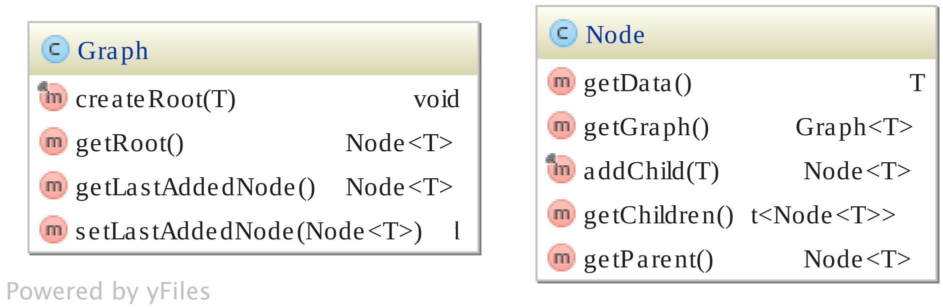
2.7.6.5. Module and/or path

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

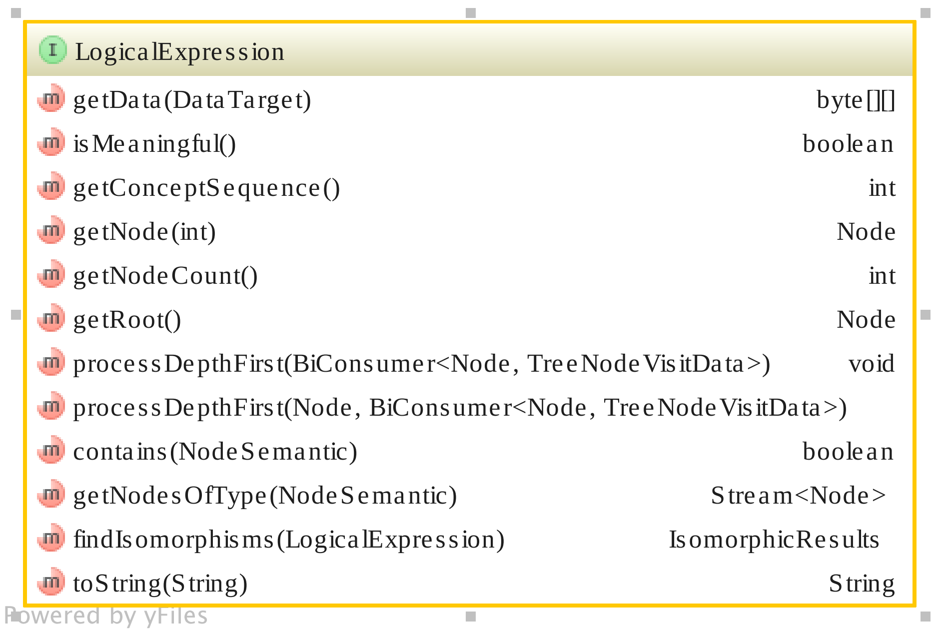


Figure 2.8. Logical Node

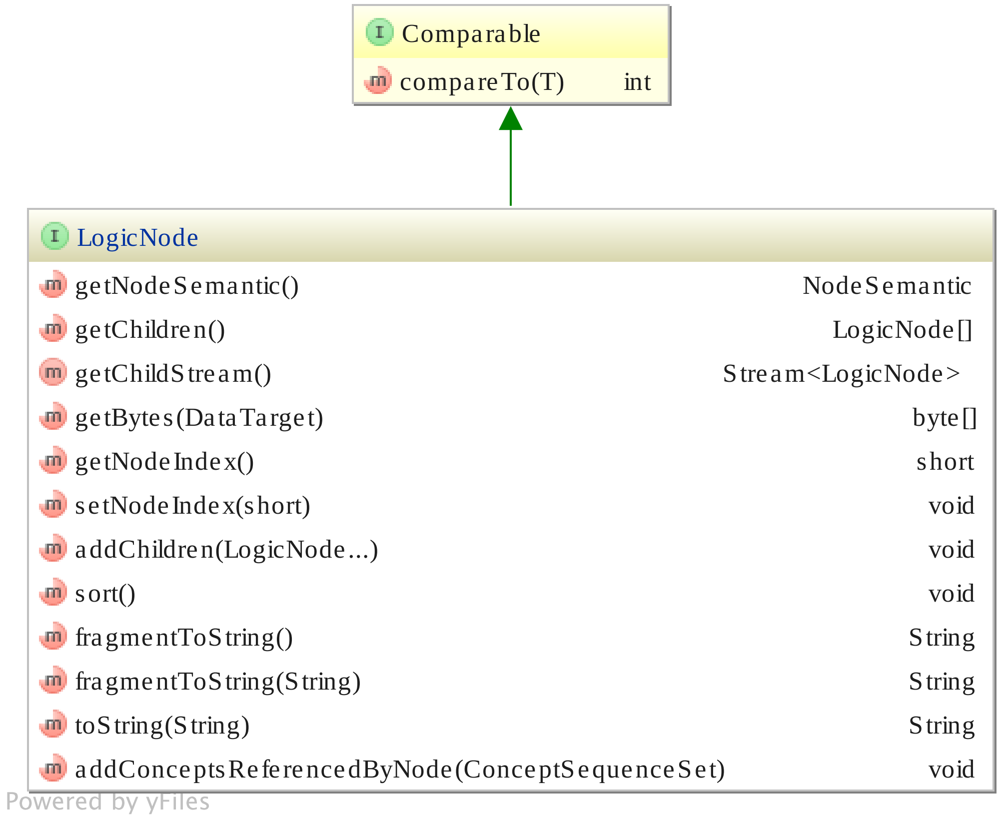
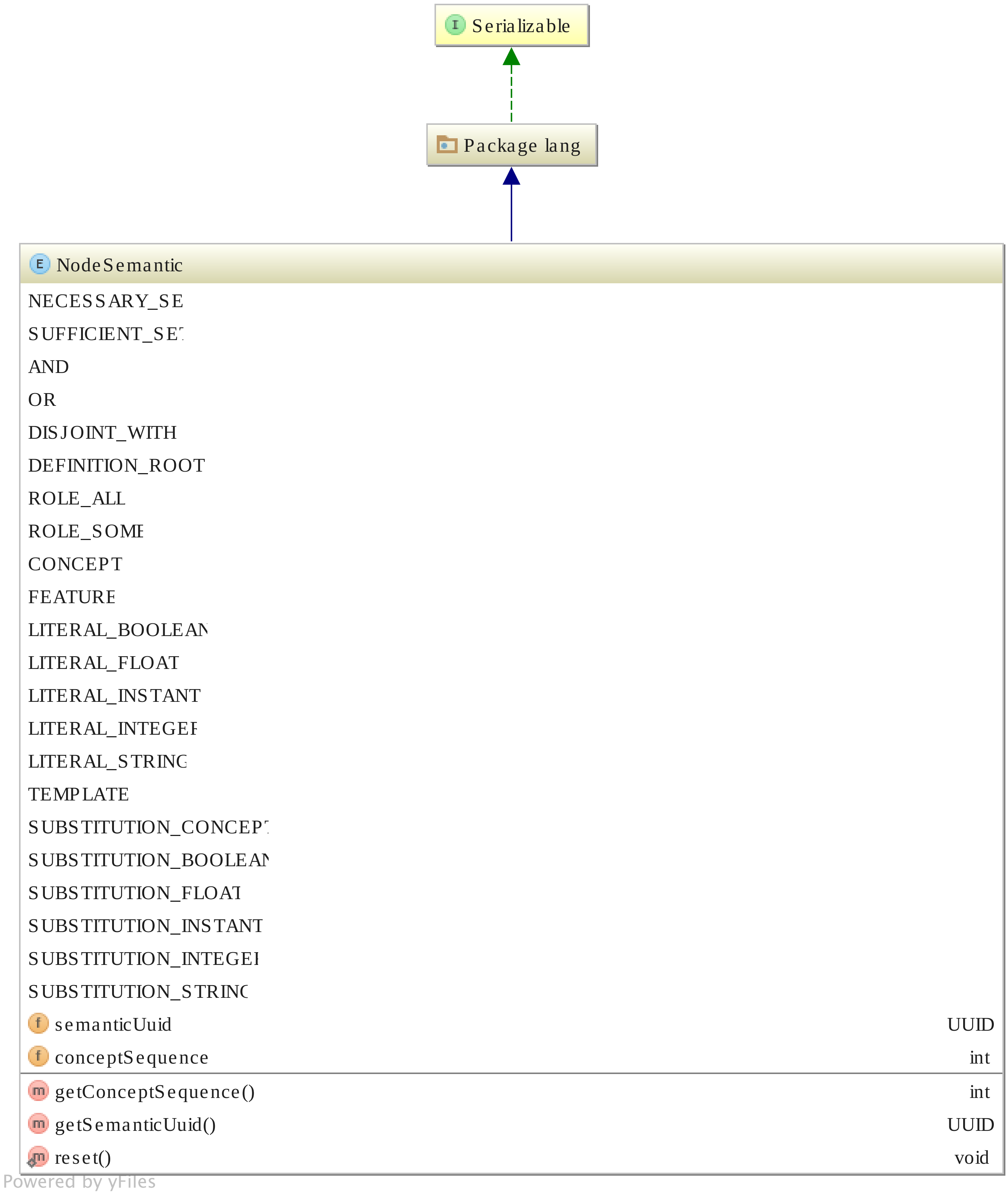


Figure 2.9. Node Semantic



2.9. Semantic

Text

Figure 2.10. Semantic object

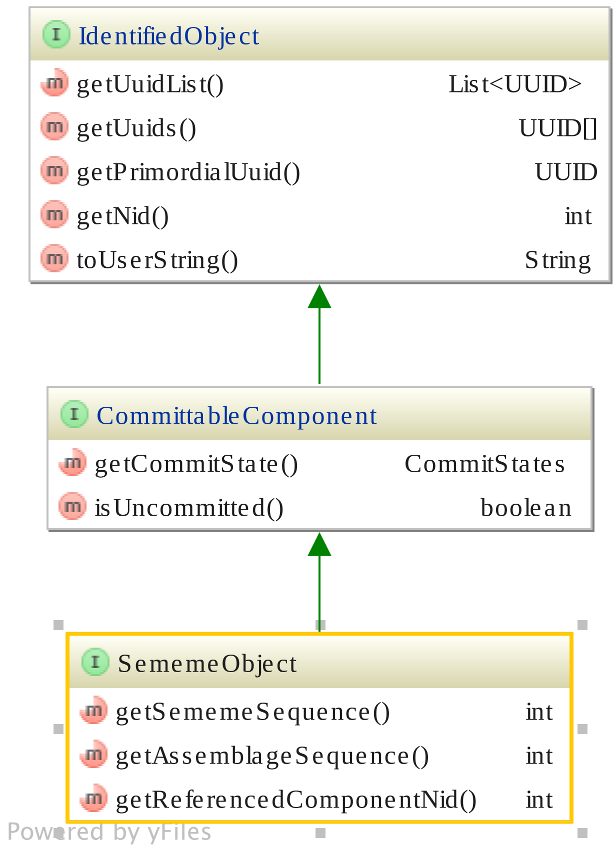
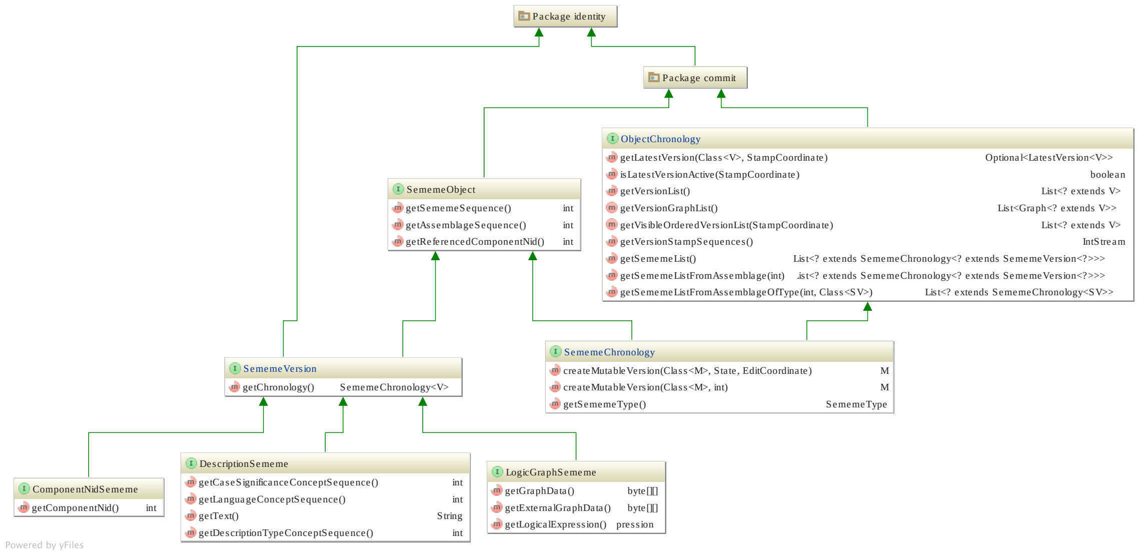


Figure 2.11. Semantic Chronology & Versions



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

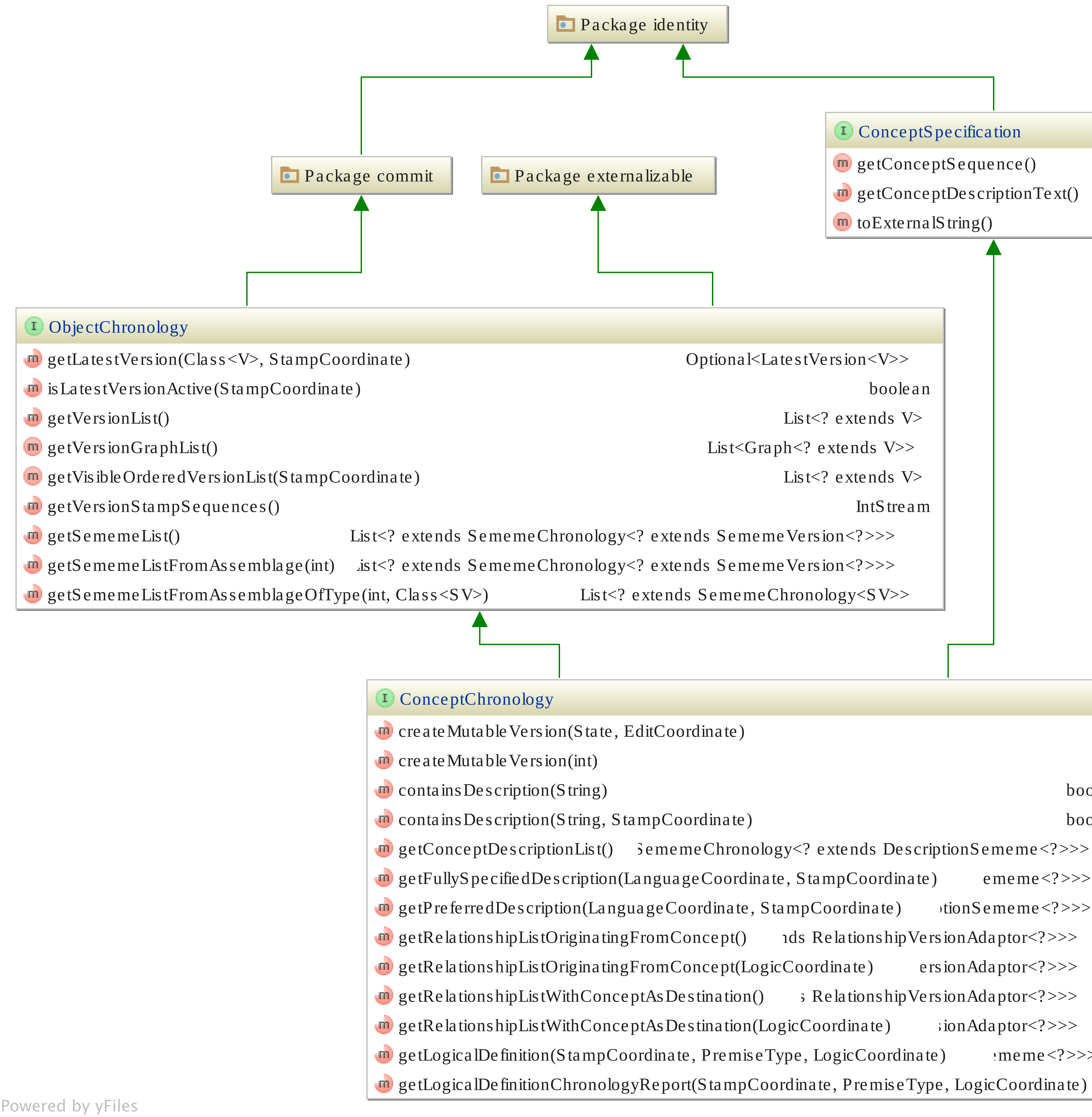
ConceptChronology extends ObjectChronology with specific methods to identify and describe concepts. All identifiable concepts used in higher layers must be present in this layer.

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.

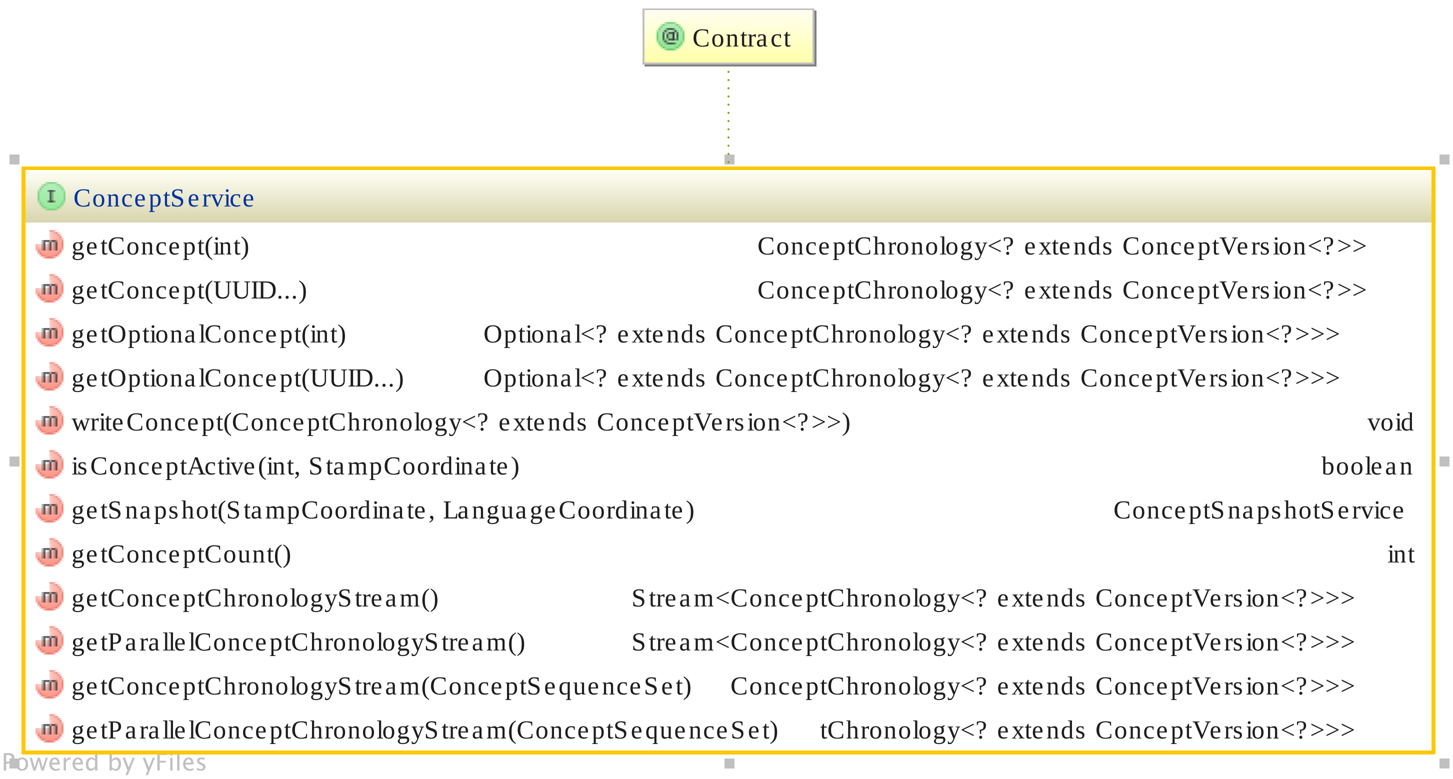

Package identity
Package commit
Package externalizable
ConceptSpecification
getConceptSequence()
getConceptDescriptionText()
toExternalString()
ObjectChronology
getLatestVersion(Class<V>, StampCoordinate) Optional<LatestVersion<V>>
isLatestVersionActive(StampCoordinate) boolean
getVersionList() List<? extends V>
getVersionGraphList() List<Graph<? extends V>>
getVisibleOrderedVersionList(StampCoordinate) List<? extends V>
getVersionStampSequences() IntStream
getSememeList() List<? extends SememeChronology<? extends SememeVersion<?>>>
getSememeListFromAssemblage(int) ist<? extends SememeChronology<? extends SememeVersion<?>>>
getSememeListFromAssemblageOfType(int, Class<SV>) List<? extends SememeChronology<SV>>
ConceptChronology
createMutableVersion(State, EditCoordinate)
createMutableVersion(int)
containsDescription(String) boo
containsDescription(String, StampCoordinate) boo
getConceptDescriptionList() ememeChronology<? extends DescriptionSememe<?>>>
getFullySpecifiedDescription(LanguageCoordinate, StampCoordinate) ememe<?>>>
getPreferredDescription(LanguageCoordinate, StampCoordinate) tionSememe<?>>>
getRelationshipListOriginatingFromConcept() nds RelationshipVersionAdaptor<?>>>
getRelationshipListOriginatingFromConcept(LogicCoordinate) ersionAdaptor<?>>>
getRelationshipListWithConceptAsDestination() RelationshipVersionAdaptor<?>>>
getRelationshipListWithConceptAsDestination(LogicCoordinate) ionAdaptor<?>>>
getLogicalDefinition(StampCoordinate, PremiseType, LogicCoordinate) meme<?>>
getLogicalDefinitionChronologyReport(StampCoordinate, PremiseType, LogicCoordinate)
Powered by yFiles

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

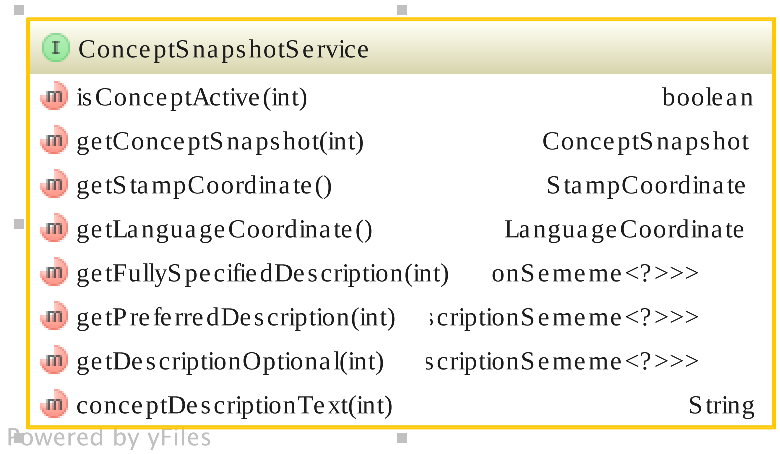
Figure 2.13. Concept service



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

ISAAC's KOMET is the KnOwledge Management Environment that enables building Linguistic, Definitional, Assertional, Statement, and Procedural representations using ISAAC's building blocks.

Part II. Language representation

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4. Language

Language is used to describe identified components.

4.1. Language Layer Concerns

4.1.1. Language

4.1.2. Dialect

4.2. Cross Cutting Concerns

4.2.1. Understandability, Reproducibility, and Utility

4.2.2. Query

4.3. Concordance

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

4.4. KOMET support for Language

DRAFT

5. SOLOR language representation

6. KOMET support for language

Part III. Definitional representation

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DRAFT

7. Definitional

7.1. Definitional Layer Concerns

7.1.1. EL++ definitions of concepts

7.2. Definitional Layer Exclusions

7.2.1. Logical negation

7.2.2. Measurement

7.3. Crosscutting Concerns

7.3.1. Understandability, Reproducibility, and Utility

7.3.2. Query

7.4. 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]

7.4.1. Conjunction

7.4.2. Disjointness

7.4.3. Reflexive roles

7.4.4. 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

7.4.5. Necessary axioms

7.4.6. Sufficient axioms

7.4.7. Defining relationships

Role relationship are represented as existential restrictions

7.4.8. 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.

7.4.9.

7.5. Principles

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

7.5.1. 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.

7.5.2. 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

7.5.3. 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

7.5.4. 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].

7.5.5. 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?

7.5.6. 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 7.1. 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

7.5.7. 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."

7.5.8. 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.

7.5.9. 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.

7.5.10. 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.

7.5.11. 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.

7.5.12. 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.

7.5.13. Principle 13:Reusability

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

7.5.14. 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.

7.5.15. 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

7.5.16. 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.

7.5.17. 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).

7.5.18. 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.

7.5.19. 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).

7.5.20. Principle 20: Model Symmetry

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

7.6. 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").

7.6.1. Concern 1: Phenomenon Measurement

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

7.6.1.1. 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

7.6.2. Concern 2: Identification of Equivalent Observation Results

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

7.6.2.1. 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.

7.6.2.2. 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.

7.6.2.3. 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.

7.6.2.4. 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

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

Need to insert description here.

7.6.2.6. Technique 2.6: Concrete Domains

Need to insert description here.

7.6.3. Concern 3: Identification of Logical Inconsistencies

Need description for this concern.

7.6.3.1. Technique 3.1 Disjoint Concepts

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

7.7. "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.

7.7.1. 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?

8. SOLOR definitional knowledge

8.1. Top Level Categories

8.1.1. Phenomenon

8.1.2. Action

Procedure + event?

8.1.3. Organism

8.1.4. Substance

Food?

8.1.5. Physical object

Pharmaceutical / biologic product

8.1.6. Specimen

8.2. Accepted relationship types

8.2.1. 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.

8.2.2. 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.

8.2.3. 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]

8.2.4. 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.

8.2.5. 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.

8.2.6. 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.

8.2.7. Severity

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.

[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

8.3. Undetermined relationship types

8.3.1. 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.

8.3.2. 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.

8.3.3. 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.

8.3.4. 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.

8.3.5. 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.

8.3.6. 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.

8.3.7. 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.

8.4. Excluded relationship types

8.4.1. 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.

8.4.2. 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.

8.4.3. 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.

8.4.4. 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.

8.4.5. 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.

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

8.5.1. 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.

8.5.2. 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.

8.5.3. Concepts Including Negation

“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.

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.

8.5.3.1. 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.

8.5.3.2. 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)"*

8.5.3.3. 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.

8.5.3.4. 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/Specin record.
373880007	Specimen rejected / not processed (finding)	✔	
284348003	Excision of rejected transplanted kidney (procedure)	⊗	"**rejected**" is **not about the p**

8.5.4. 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.

8.5.4.1. 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)

8.5.4.2. 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.

8.5.4.3. 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)**	✓	
185412005	**Father made appointment (finding)**	✓	Although it is the patient’s “Moth about the “***Mother***”, “***Father***” or “
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

8.5.5. 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.

8.5.5.1. 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)*

8.5.5.2. 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)	✓	
120608000	Blister with infection (disorder)	✓	Concepts describe more than
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)	✓	
1409210001 19102	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)	⊗	

8.5.6. 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.

8.5.6.1. 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

8.5.6.2. 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.

8.5.7. 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.

8.5.7.1. 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)”.

8.5.7.2. 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.***

8.5.7.3. 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

8.5.8. 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)

8.5.8.1. Sensitivity and Specificity of Keywords for “Negation”

Sensitivity of 73% and Specificity of 95%

8.5.8.2. Sensitivity and Specificity of Keywords for “Patient not Subject of Information”

Sensitivity of 75% and Specificity of 99%

8.5.8.3. Sensitivity and Specificity of Keywords for “Compound Observation”

Sensitivity of 93% and Specificity of 94%

8.5.9. 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.

8.6. Concrete Domains

8.6.1. 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.

8.6.2. 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.

8.6.3. 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

8.6.4. 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|

8.7. Disjoint Content

8.7.1. Introduction

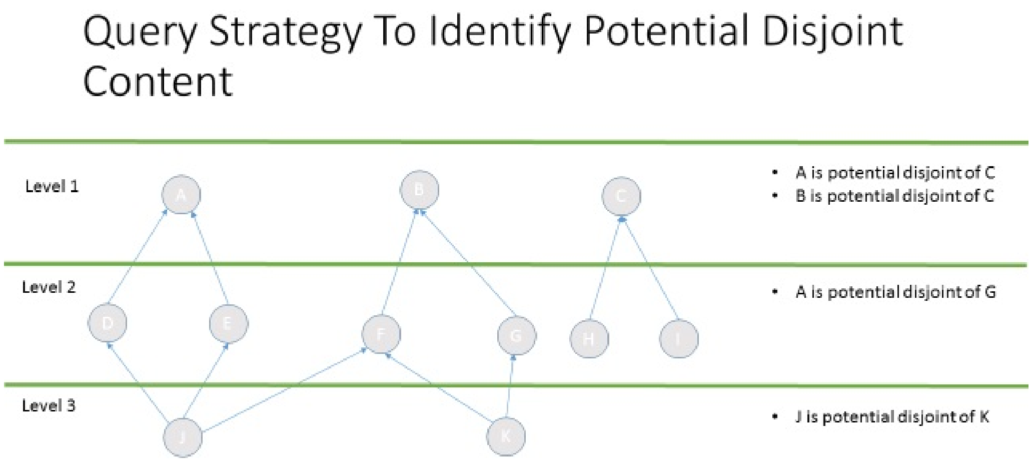
Classes are disjoint if they cannot have common instances. In an ontology, all classes are assumed to have potential overlapping instances unless they are explicitly stated to not have them. The current modeling of SNOMED CT does not contain any such statements, therefore all concepts are considered 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.

8.7.2. 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.

8.7.3. 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.



8.7.4. 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.

8.7.5. 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.

8.8. Meronomy / Partonomy

8.8.1. 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.

8.8.2. 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.

8.8.3. Body Structure Concepts

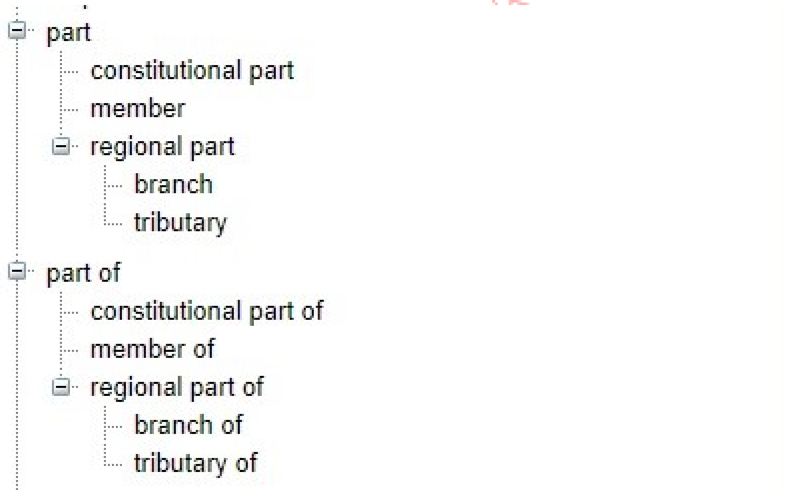
There are currently 42,596 *Part-of* Relationships assigned to Body Structure concepts remaining from the 2003 decision to transform them to non-defining.

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:



8.8.3.1. 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.

8.8.4. 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.

8.8.4.1. 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.

8.8.5. 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.

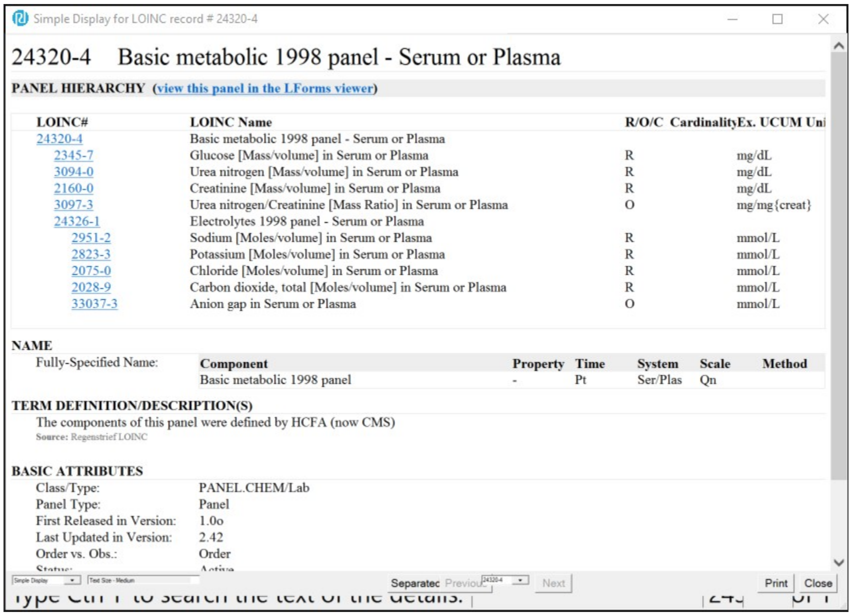
24331-1 Lipid 1996 panel - Serum or Plasma

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

8.8.5.1. 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

Separated Previous 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. KOMET support for description logic

9.1. Graphical representation

Part IV. Assertional representation

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10. Assertions

11. SOLOR assertional knowledge

12. KOMET support for assertions

Part V. Statement representation

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13. 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.

13.1. Clinical Observation Modeling

Supporting Domain Semantics, Flexibility, and Interoperability

Walter Sujansky

13.1.1. 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.

13.1.2. 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.

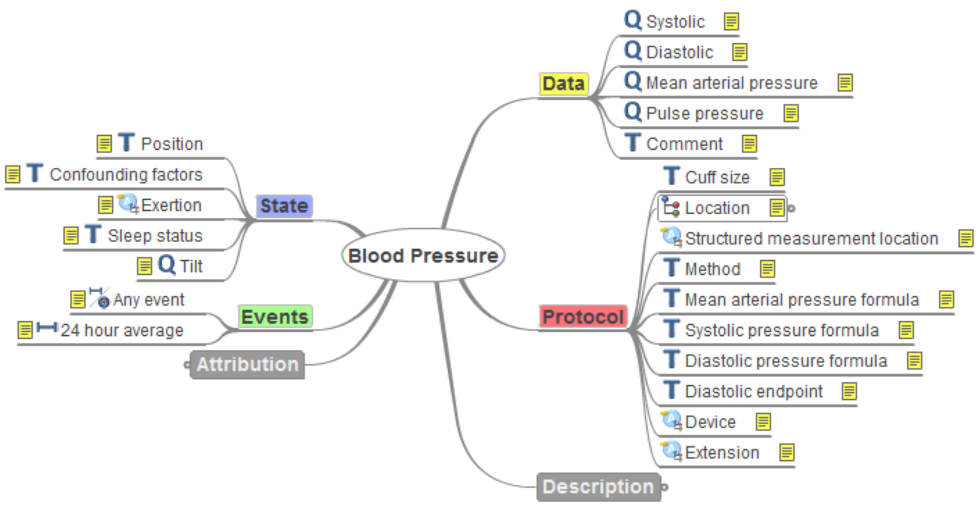
statement models define the structure and semantics of discrete clinical observations as formal "types" that are later instantiated to represent specific recorded observations that apply to particular patients. Like object types in programming languages, these type definitions include enumerations of 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 13.1 shows the graphical depiction of an example statement model for a blood pressure measurement.

Figure 13.1. Example clinical object model for a blood pressure measurement



13.1.2.1. The Role of Clinical Observation Models

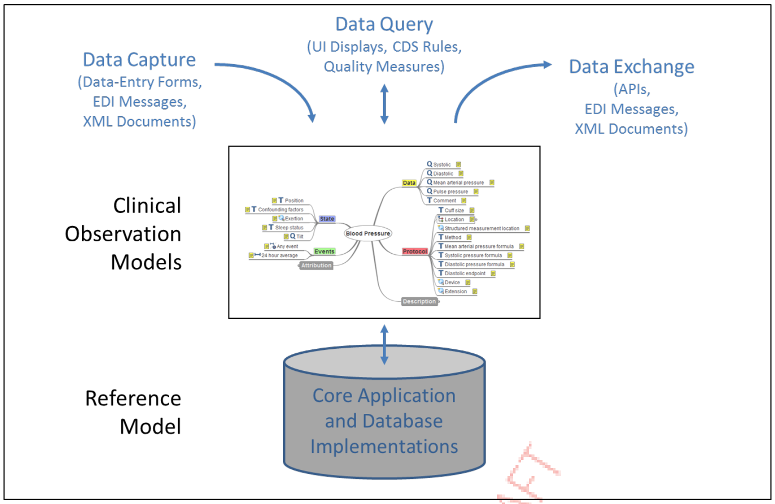
In general, clinical observation models serve at least two purposes.

1. statement models *standardize* the capture, retrieval, and exchange of clinical observations within and between information systems. As seen in Figure 13.1, 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 13.2 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*.

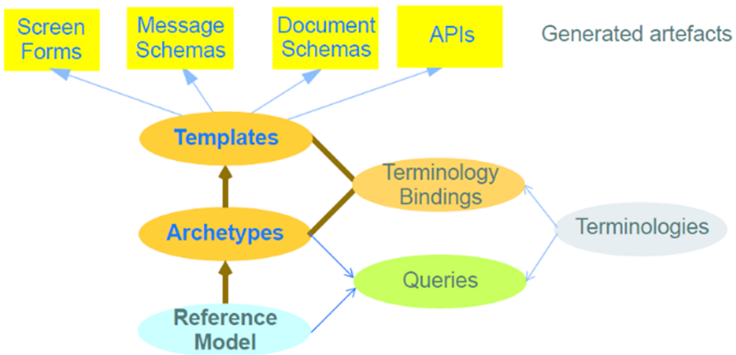
Figure 13.2. The role of clinical observation models in electronic health record systems



13.1.3. 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 13.3 illustrates the components of the OpenEHR architecture, which are further described below.

Figure 13.3. OpenEHR architecture

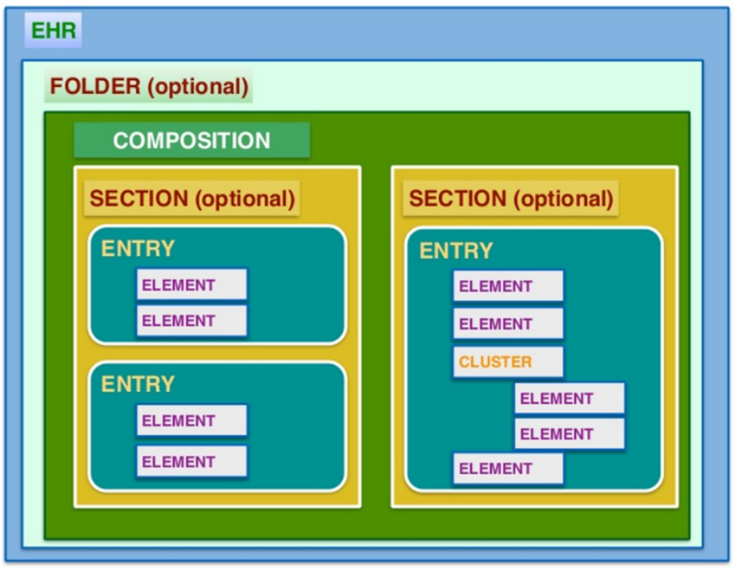


[3]Demski H, Garde S, Hildebrand C. Open data models for smart health interconnected applications: the example of openEHR. BMC Med Inform Decis Mak. 2016 Oct 22;16(1):137. (available at https://www.ncbi.nlm.nih.gov/pubmed/27770769).
[4]http://www.openehr.org/what_is_openehr.

13.1.3.1. 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 13.4 shows the constructs of the OpenEHR reference model and how they are hierarchically organized to create the “scaffolding” for patient records.

Figure 13.4. 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.”

13.1.3.2. OpenEHR Archetypes

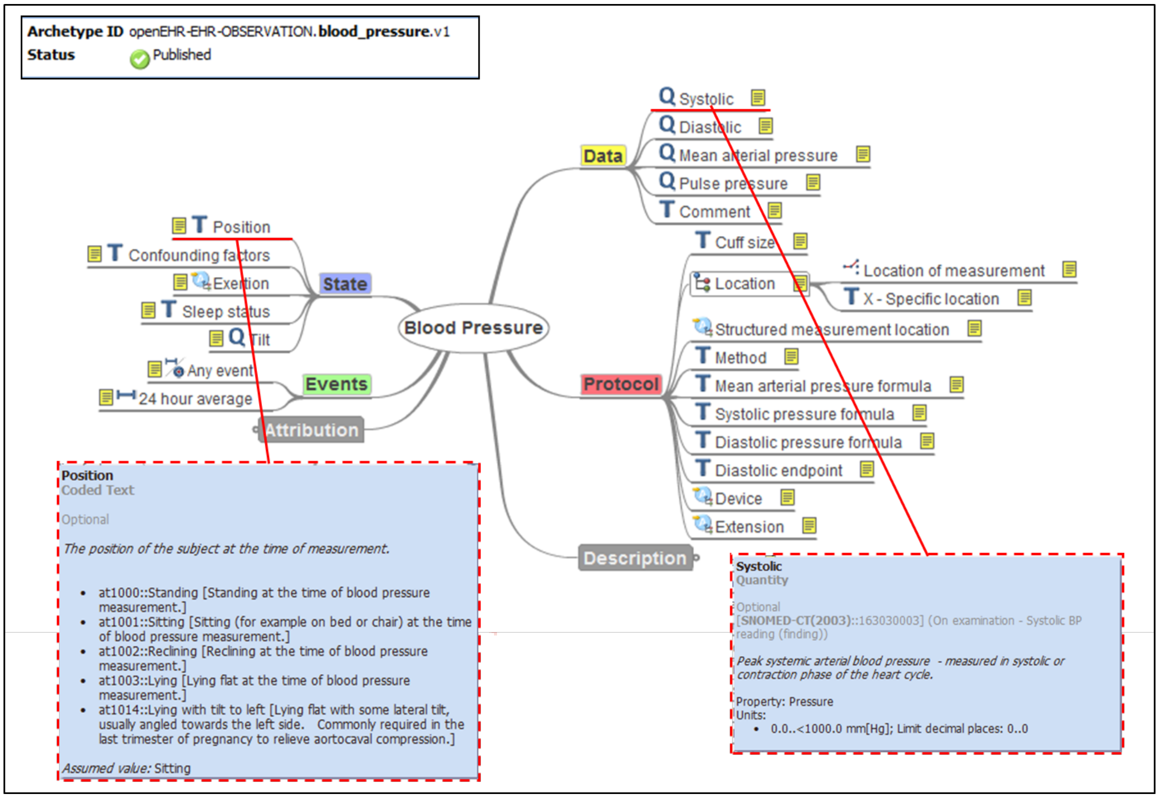
Archetypes are clinical object models that specify:

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 13.5 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 13.5. 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 13.5. Example of an OpenEHR Archetype



OpenEHR Archetypes must be defined using only the constructs of the underlying Reference Model, as shown in Figure 13.3. 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 13.5 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.

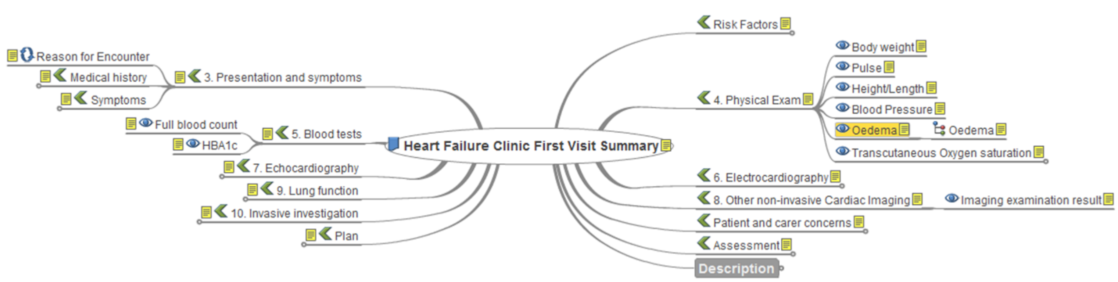
OpenEHR currently includes several hundred Archetypes[5], including many for clinical observations. The framework, however, remains very much a work in progress, and many Archetypes remain in draft form.

13.1.3.3. 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 13.3).

Figure 13.6 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 13.6. Example of an OpenEHR Template

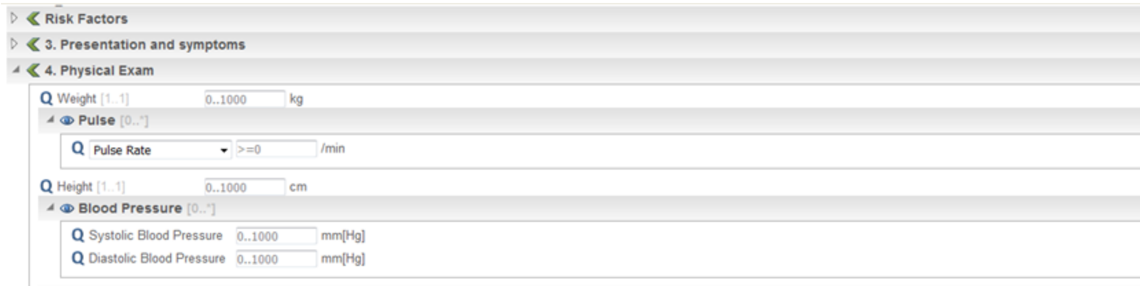


Although not shown in Figure 13.6, Templates may also include additional constraints applied to their constituent Archetypes. Such constraints may entail the inclusion of only a subset of the Archetype's Elements, the allowance of only a subset of the coded values specified for an Element, the designation 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 13.7 shows a graphical user interface ("Screen Form") for data entry generated from the heart-failure Template in Figure 13.6. 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 13.5), 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 13.6 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.

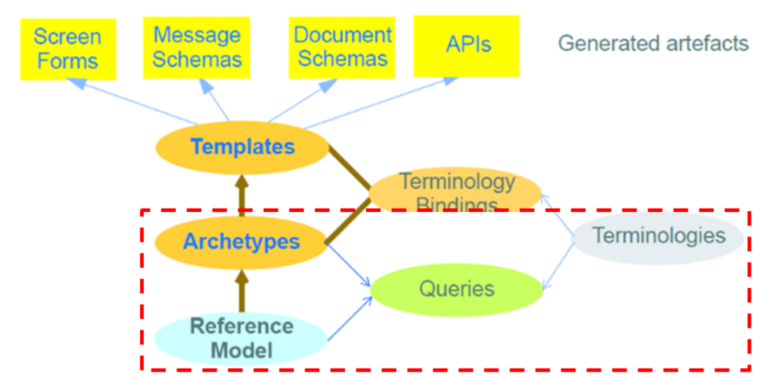
Figure 13.7. Example of a Screen Form generated from an OpenEHR Template



13.1.3.4. 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 13.8 for a graphical representation of these dependencies).

Figure 13.8. 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 13.6) 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 13.1.3.1).

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” concept with the specific disease concepts (such as “Atherosclerosis”) that are actually referenced in defined Archetypes.

13.1.4. 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.

13.1.4.1. 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”.

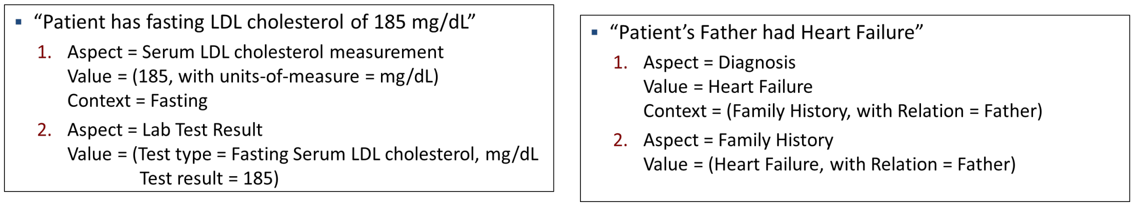
The aspect and the value/magnitude of an observation may, themselves, be further modified or qualified to denote the complete semantics of the observation. For example, the aspect “Systolic Blood Pressure” in the example above could be further qualified by the date/time that the measurement was taken 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 13.9 show reasonable variations in the use of aspect, value, and context to represent the same observation semantics.

Figure 13.9. Example variations in modeling of clinical observations



13.1.4.2. 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.

13.1.4.3. 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 13.2, 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.

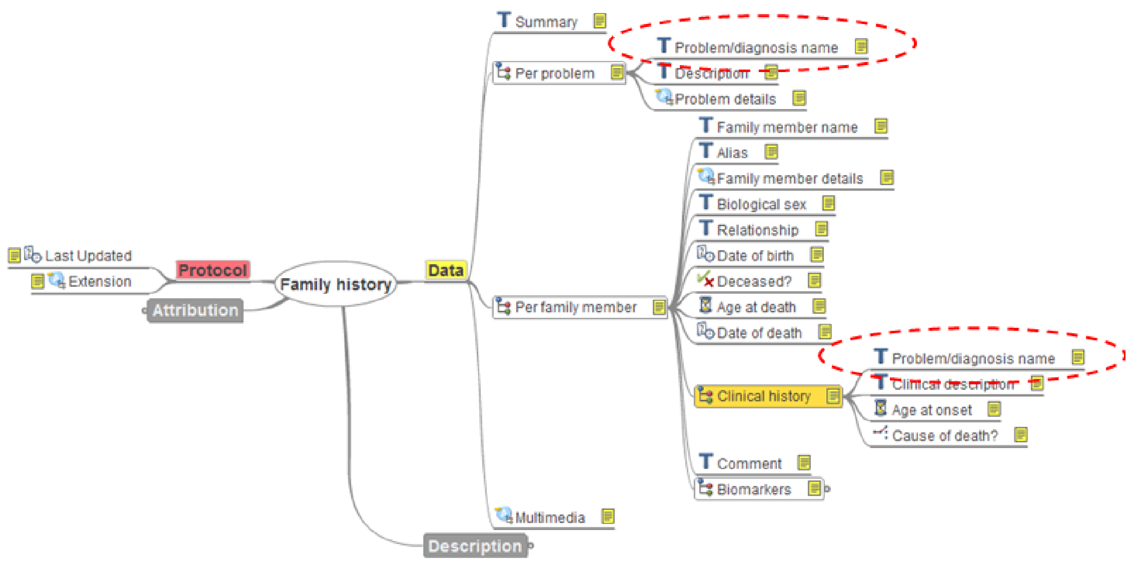
To help ensure reproducibility, modelers should follow at least two guidelines when creating clinical observation models: Avoid arbitrary variation and explicitly represent clinically relevant distinctions. Figure 13.10 illustrates relevant examples and counterexamples of these guidelines. Note that 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 13.10. Guidelines for designing clinical observation models

- Avoid arbitrary variation, such as
  1. Aspect = NULL
     Value = Regular pulse vs.
  2. Aspect = Skin Turgor
     Value = Normal vs.
  3. Aspect = Physical Exam Finding
     Value = Brisk Knee Reflex
- Explicitly represent clinically relevant distinctions, such as
  1. Aspect = Patient-Reported Symptom
     Value = Weakness in Right Arm vs.
  2. Aspect = Physical Exam Finding
     Value = Weakness in Right Arm

Figure 13.11 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 13.11. A poorly designed clinical observation model



13.1.4.4. 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 13.1.4.2). 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 13.1.4.2.

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.

13.2. 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 13.1. General Statement Model

Statement
Narrative:
Topic:
Subject of information:
Statement time:
Act:

Editorial Rule 13.1. 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 13.2. 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 13.3. 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 13.4. Act

The Act is information that details the act related to the topic, either a request act, or a performance act.

13.2.1. Statement Layer Concerns

The statement layer is primarily concerned with representation of instance data.

13.2.1.1. Measurement

13.2.1.2. Reporter

13.2.1.3. Performer

13.2.1.4. Subject of information

13.2.2. Crosscutting Concerns

13.2.2.1. Query

13.2.3. Understandable, Reproducible, and Useful

Given a narrative, fill out the form

Example 13.1. 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 13.2. 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 13.5. 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 13.6. Reproducible

Independent observers encountering a topic and equivalent circumstances will record equivalent statements

Editorial Rule 13.7. Useful

The representation must be useful for the purposes that the modeling is intended to support.

13.2.4. 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 13.2. 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

13.2.4.1. 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 13.3. Pulse Measurement Statement

Performance Statement		
Narrative:		
Topic:		
Subject of information:		
Statement time:		
Performance Act:	Circumstance:	Timing:
	Result:	120 beats per minute

Table 13.4. Pulse Request Statement

Request Statement		
Narrative:		
Topic:		
Subject of information:		
Statement time:		
Request Act:	Circumstance:	Timing:
		Repetition:
	Requested result:	< 70 beats per minute

13.2.4.2. Measurement

Editorial Rule 13.8. Measurement

Define measurement

Editorial Rule 13.9. 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 13.10. 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 13.11. 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 13.12. 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 13.13. Resolution

An optional numeric representation of the resolution of this measurement, using the same semantics as the measurement itself.

Editorial Rule 13.14. Measure semantic

A concept that defines the semantic interpretation of the upper and lower bounds of this measurement.

13.2.5. 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.

13.2.5.1. 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

13.2.5.2. 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.

13.2.6. Statement Building Blocks

The following components are used in multiple places within clinical statements.

13.2.6.1. Stamp Coordinate

The stamp coordinate represents the versions of the integrated terminology and statement model used to represent a clinical statement.

13.2.6.2. 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 13.5, "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 13.5. 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”

13.2.6.2.1. 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,∞], [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 | ∞]

The semantics of this grammar are as follows:

‘[‘ and ‘]’ : Inclusive boundary (i.e. >= and <=)

‘(‘ and ‘)’ : Exclusive boundary (i.e., > and <)

∞: 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 ∞, the meaning is that the value of the phenomenon is > *n* or >=*n*, depending on whether the interval is open or closed.

(0,∞] : > 0 ; [10,∞] : >= 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 13.12, “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 13.12. The semantics of interval values assigned to phenomena, as shown through examples.

13.2.6.2.2. 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], $(0,\infty]$) => TRUE

IsWithin([0,2], $(0,\infty]$) => UNKNOWN

IsWithin((0,2], $(0,\infty]$) => TRUE

IsWithin([0,0], $(0,\infty]$) => FALSE

IsWithin([0,0], [0,0]) => TRUE

13.2.6.3. 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.

13.2.6.3.1. UUID

The UUID is the means by which all clinical statement items that require unique identifiers are identified.

13.2.6.3.2. Logical Expression

13.2.6.3.3. Stamp Coordinate

13.2.6.4. Compound Statements

13.2.6.4.1. 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 13.6. 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 13.7. 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

13.2.6.4.1.1. 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 <u>all</u> components, which <u>play a role</u> and are therefore separable components.

Examples:

Table 13.8. 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

13.2.6.4.1.1.1. 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*

13.2.6.5. Encoded Statements

13.2.6.5.1. Procedures

13.2.6.5.2. Finding, Observation, and Phenomenon

13.2.6.6. Statement Models

Analysis normal form and clinical input form

13.2.7. 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.

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

separation

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:

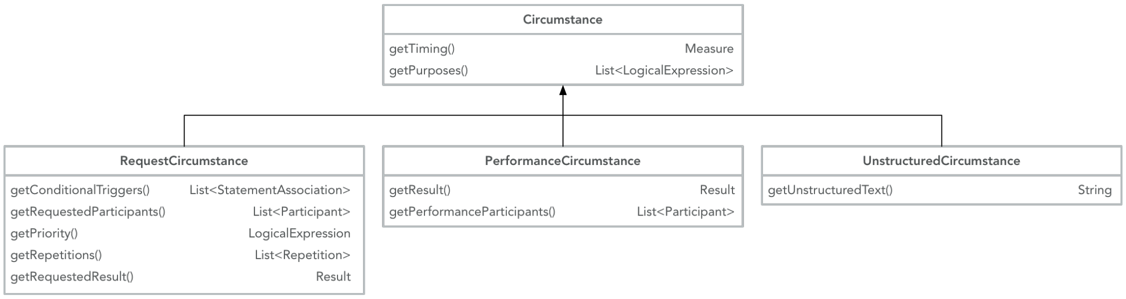
- Observation of congestive heart failure
- Observation of history of malignant neoplasm of bone
- Observation of numbness of left arm
- Observation of history of cognitive behavioral therapy

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



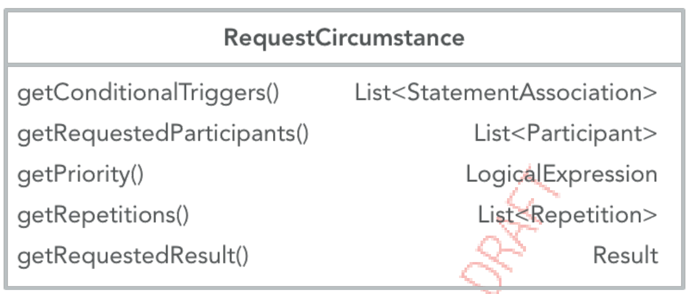
Circumstances can describe **HOW**, **WHY** and **WHEN** a requested or performed action will be or was carried out. Requests and performances have some shared circumstances:

- 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:**

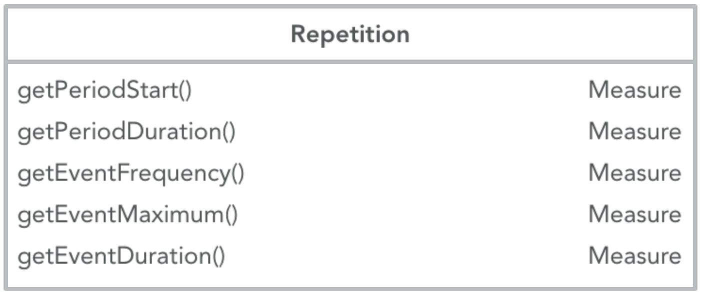
- Cardiology consultation with Chief Cardiologist
- Smoking cessation education with patient and patient's spouse

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.

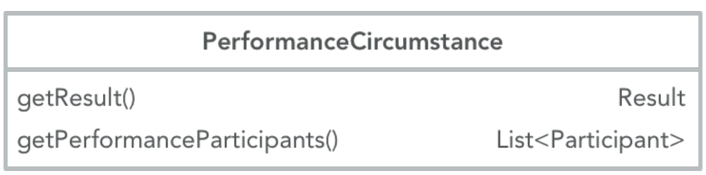
Examples:

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

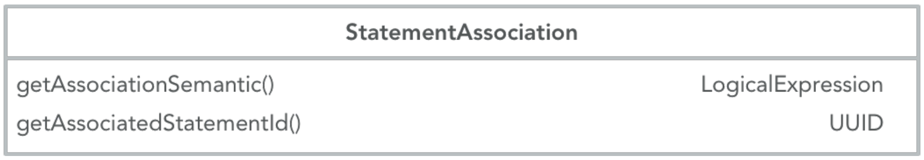
Participants in performing the action, e.g. technician, nurse

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

14.3.14.1.1. 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, RxNorm and LOINC) 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 are described in the HL7 KNART Specification3):

- 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

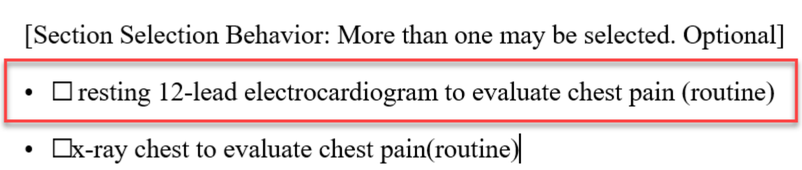
ECA Rules are used in Clinical Decision Support to trigger a defined action after a distinct event occurred. Example: Notify clinician if laboratory test result with “abnormal” flag has been received.

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.

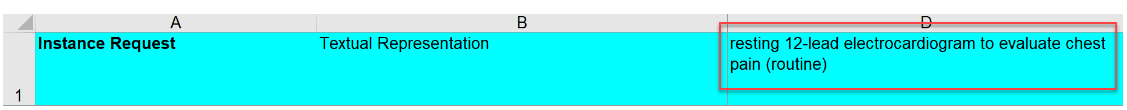
The example below shows orders as they potentially appear in a KNART:

Figure 14.7. Order Example (Cardiology Order Set)



The order from the KNART above appears in the TSR as an Instance Request:

Figure 14.8. Order Set Instance Request in TSR Template



14.6. KNART Information Modeling Overview

The Analysis Normal Form (ANF) provides a set of guidelines to model clinical 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 asserted by a particular source, recorded, and potentially verified.

The Analysis Normal Form (ANF) constitutes a model for defining the components of data elements from KNARTs on a general level, independent of any specific terminology. The ANF defines the principles, which distinguish the “topic” of clinical statements from the “circumstances” of e.g., an action request. The topic describes the “what” whereas the circumstances describe the “how”.

Details of the ANF model for clinical statements and their components have been discussed in previous sections of this document.

14.7. 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 will 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.

14.7.1. Instance Request (Request and Performance)

Represents the clinical statement to be modeled.

14.7.2. statementID (Request and Performance)

Not for modeling. ID will be assigned by KNART developers.

14.7.3. 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

14.7.4. METADATA: model fit (Request and Performance)

Currently not in use.

14.7.5. METADATA: model fit comments (Request and Performance)

Currently not in use.

14.7.6. 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)|

14.7.7. 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.

14.7.8. 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

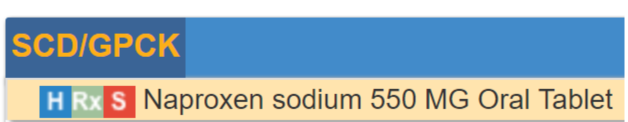
Post-coordinated expression with *conceptual graph* [1] syntax:

```
[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)]
```

Notes:

1. The IR is specific enough regarding strength and dose form. Therefore, the RxNorm SCD code can be applied

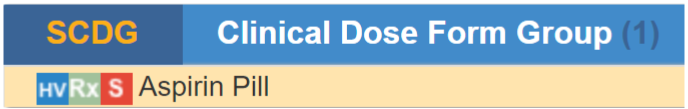
Figure 14.9. RxNorm SCD Code



[1] https://en.wikipedia.org/wiki/Conceptual_graph#Graph-based_knowledge_representation_and_reasoning_model

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:

   → 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.

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.

14.7.9. 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:

       [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

14.7.10. 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)];
```

14.7.11. Unstructured (Request and Performance)

Format: Plain text

Currently used to capture textual information for which there is no model at this time.

14.7.12. statementAssociation.semantic (Request and Performance)

Format: Logical Expression

Terminology: TBD Currently not in use

14.7.13. statementAssociation.statementId (Request and Performance)

For use by KNART developers.

14.7.14. 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

[2] https://en.wikipedia.org/wiki/ISO_8601

- 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
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.

14.7.15. 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.

14.7.16. 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)|

14.7.17. conditionalTrigger (Request)

Format: Logical Expression

Terminology: TBD

Currently not in use.

14.7.18. conditionalTrigger.statementId (Request)

UUID as identifier for the conditionalTrigger statement.

14.7.19. 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

14.7.20. 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

14.7.21. 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 measureSemantic are used as in all other timing related circumstances.

14.7.22. 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)|

14.7.23. 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.

14.7.24. repetition.eventSeparation (Request)

Currently not in use.

14.7.25. 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

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].

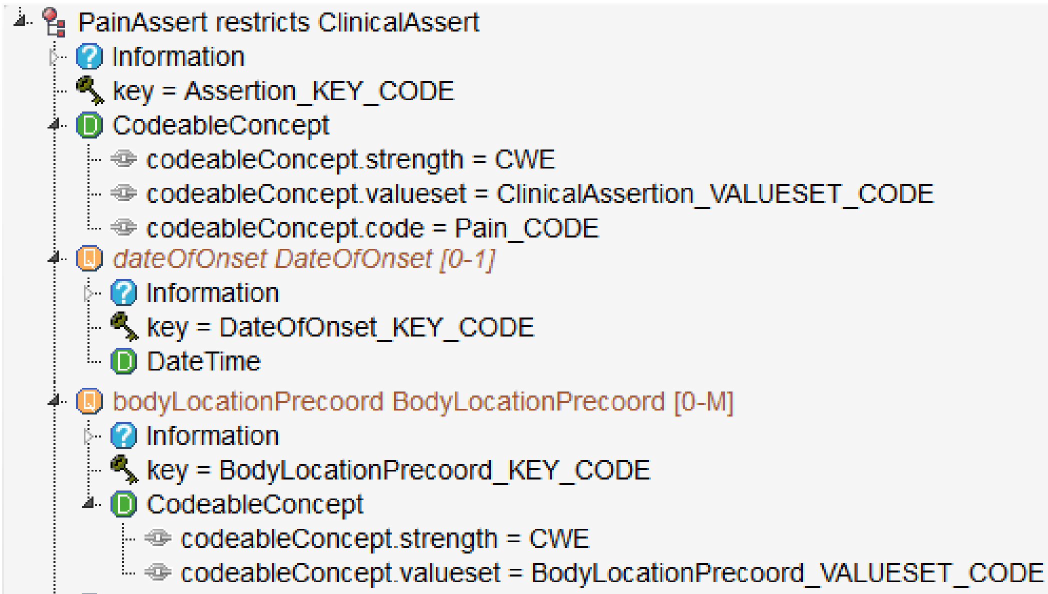
[1]http://models.opencimi.org/cimi_doc/CIMIArchitectureGuide/CIMIArchitectureGuide.html

[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.)

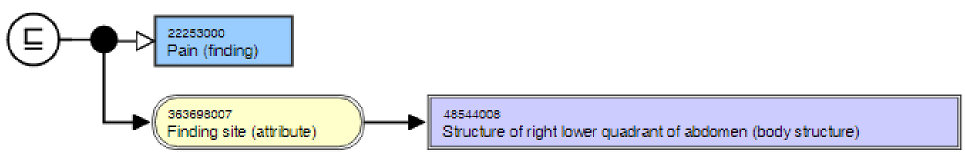
The exhaustive inclusion of all such abdominal sub-parts and sub-sub-parts in every query that needs to specify the abdominal area would be onerous, as well as subject to error as the coded terminology representing these sub-parts changes over time. Further, formulation of queries with respect to CIMI 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. ".

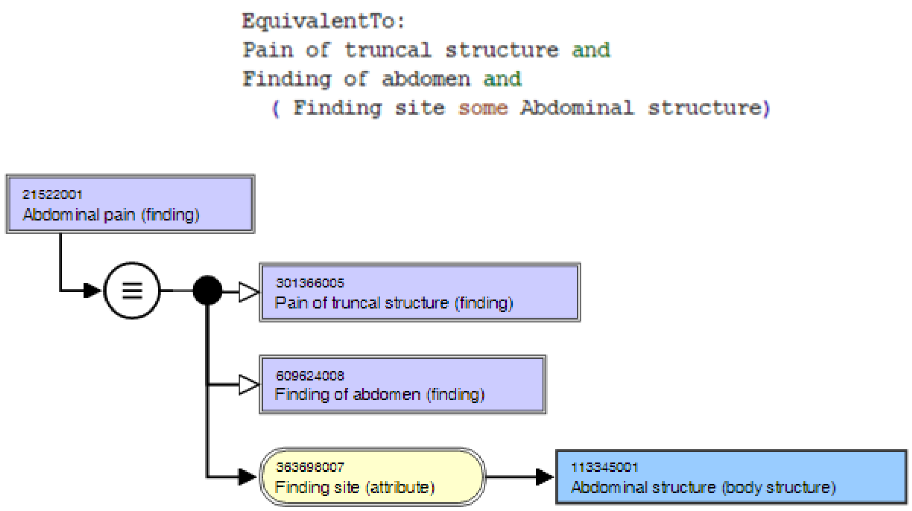
```
SubClassOf:
Pain and
  ( Finding site some Structure of right lower quadrant of abdomen)
```



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.”

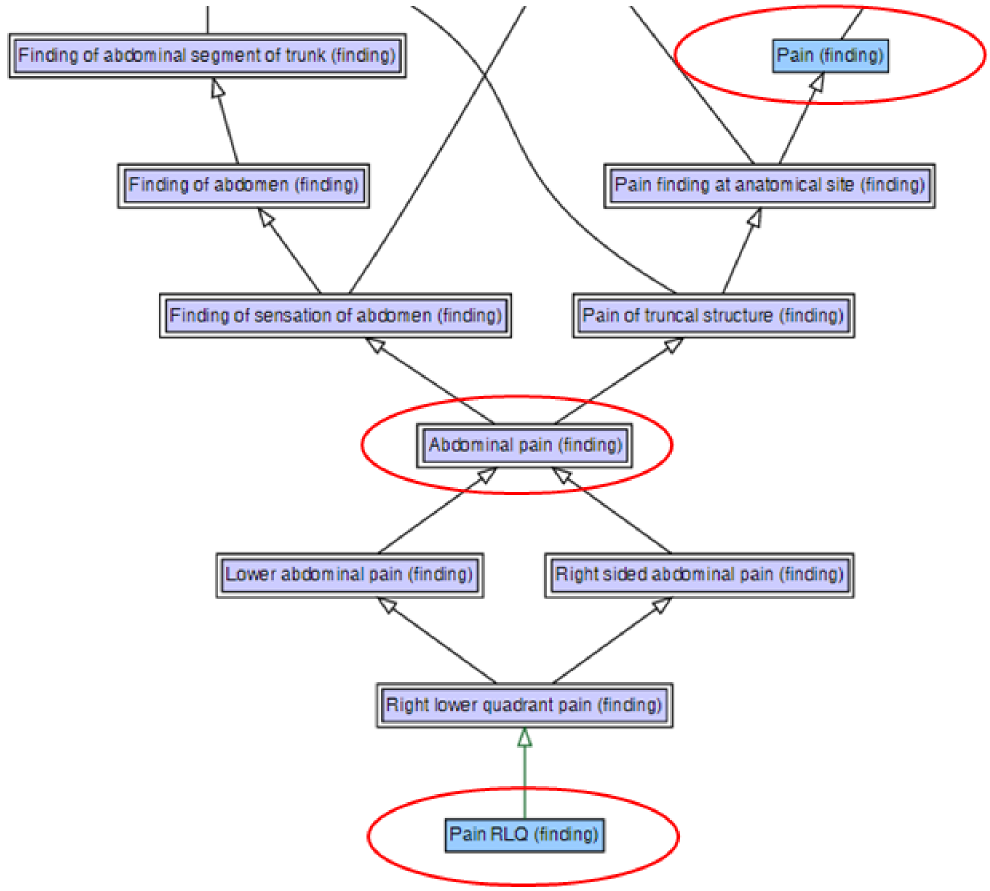


Based on this logical definition of “Abdominal Pain,” on the DL definitions of several other clinical concepts, and on formal rules of logic, a SOLOR reasoner can infer that the DL expression for “Pain in right lower quadrant” is subsumed by “Abdominal Pain.” In fact, the reasoner can correctly classify 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

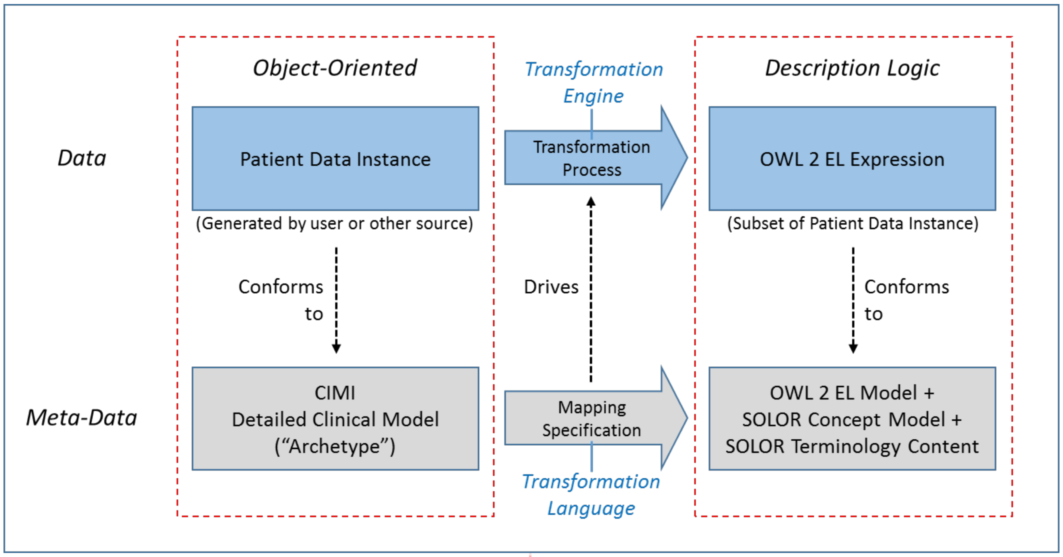
Figure 16.6, "Architectural framework for transforming CIMI DCM instances to DL expressions." summarizes the transformation process to convert CIMI DCM data instances to SOLOR post-coordinated DL expressions[6]. At the instance ("Data") level, the task must automatically and faithfully transforms data 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
<?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.

```
PainAssert restricts ClinicalAssert
  Information
  key = Assertion_KEY_CODE
  CodeableConcept
    codeableConcept.strength = CWE
    codeableConcept.valueset = SCT-40468400 [Clinical Finding (finding)]
    codeableConcept.code = SCT-22253000 [Pain (finding)]
  dateOfOnset DateOfOnset [0-1]
    Information
    key = DateOfOnset_KEY_CODE
    DateTime
  bodyLocationPrecoord BodyLocationPrecoord [0-M]
    Information
    key = BodyLocationPrecoord_KEY_CODE
    CodeableConcept
      codeableConcept.strength = CWE
      codeableConcept.valueset = SCT-91723000 [Anatomical structure (body structure)
  associatedPrecondition AssociatedPrecondition [0-M]
  duration Duration [0-1]
    Information
    key = Duration_KEY_CODE
    Quantity
  painRadiation PainRadiation [0-M]
  exacerbatingFactor ExacerbatingFactor [0-M]
    Information
    key = ExacerbatingFactor_KEY_CODE
    CodeableConcept
```

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

<table>
<tr><th>Defining Attribute</th><th>Subsumed Attribute</th><th>Allowable Values</th></tr>
<tr><td>| FINDING SITE |</td><td></td><td>| Anatomical or acquired body structure | 442083009 (<<)</td></tr>
<tr><td>| ASSOCIATED MORPHOLOGY |</td><td></td><td>| Morphologically abnormal structure | 49755003 (<<)</td></tr>
<tr><td>| ASSOCIATED WITH
|</td><td></td><td>| Clinical Finding | 404684003 (<<)
| Procedure | 71388002 (<<)
| Event | 272379006 (<<)
| Organism | 410607006 (<<)</td></tr>
<tr><td>| SEVERITY |</td><td></td><td>| Severities | 272141005 (<=)(< Q)</td></tr>
<tr><td>| CLINICAL COURSE |</td><td></td><td>| Courses | 288524001 (<=)(< Q)</td></tr>
<tr><td>| EPISODICITY |</td><td></td><td>| Episodicities | 288526004 (<=)(< Q)</td></tr>
<tr><td>| HAS DEFINITIONAL MANIFESTATION |</td><td></td><td>| Clinical finding | 404684003 (<<)</td></tr>
<tr><td>| OCCURRENCE |</td><td></td><td>| Periods of life | 282032007 (<)</td></tr>
<tr><td>| FINDING METHOD |</td><td></td><td>| Procedure | 71388002 (<=)</td></tr>
<tr><td>| FINDING INFORMER |</td><td></td><td>| Performer of method | 420158005 (<<)
| Subject of record or other provider of history | 419358007 (<<)</td></tr>
</table>

Meaning of Allowable Values (*Range*) notations:

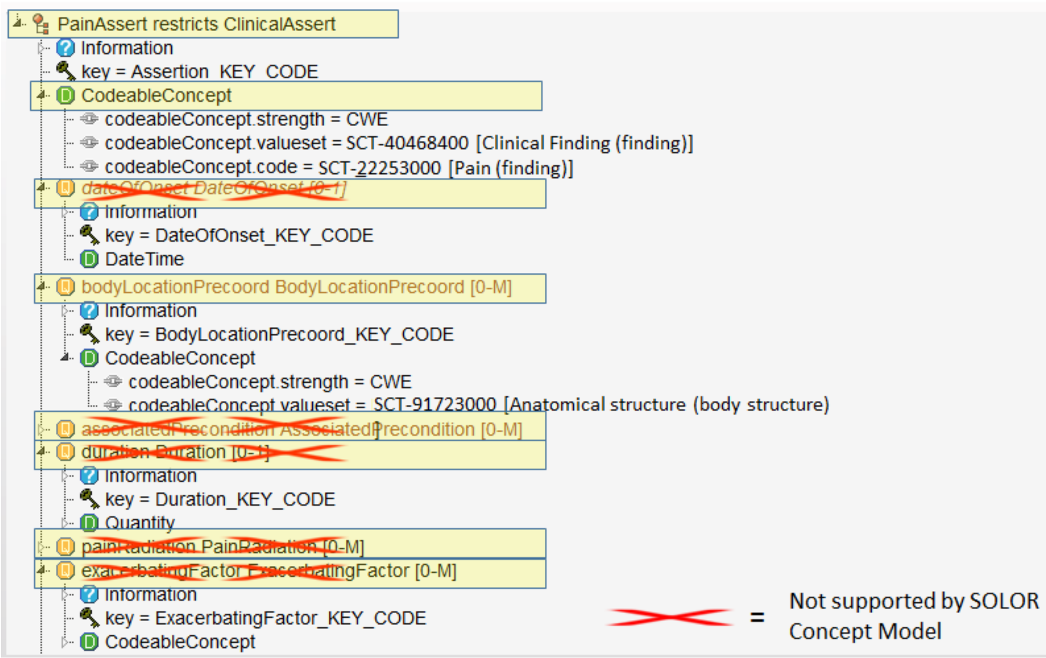
(<<) this code and *descendants*,
(<) *descendants* only,
(<=) *descendants* only (stated) except for supercategory groupers,
(==) this code only,
(< Q) *descendants* only when in a qualifying *Relationship*,
(< Q only) *descendants* only, and only allowed in a qualifying *Relationship*.

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.

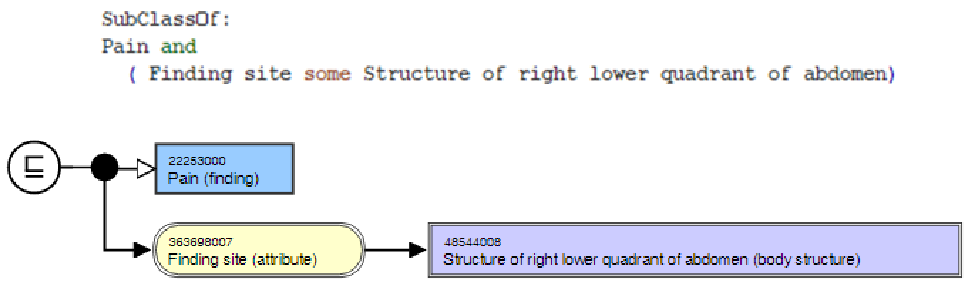
3. SOLOR Terminology Content. Lastly, the transformed CIMI DCM instance can only include references to codes and concepts that already exist within the SOLOR Terminology Model. For example, the value of the “BodyLocationPrecoord” attribute (“Right lower quadrant of abdomen” in the example of Figure 16.7, “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. ”.



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

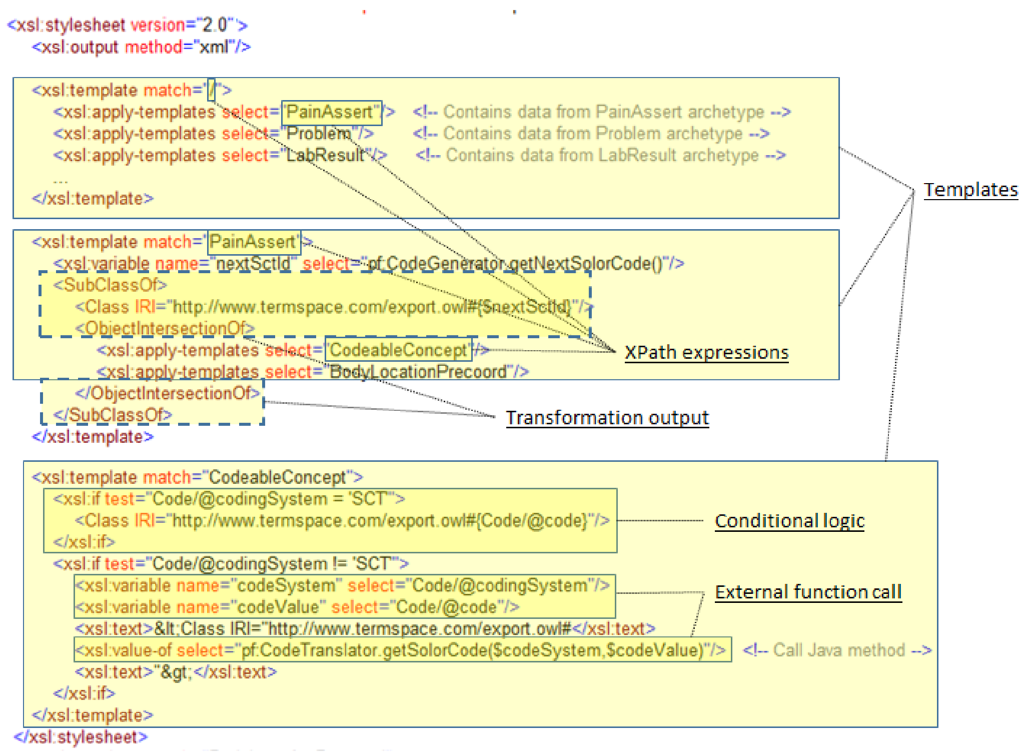
[8] https://en.wikipedia.org/wiki/XSLT (Accessed 9/30/2017).
[9] https://en.wikipedia.org/wiki/XPath (Accessed 9/30/2017).

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.



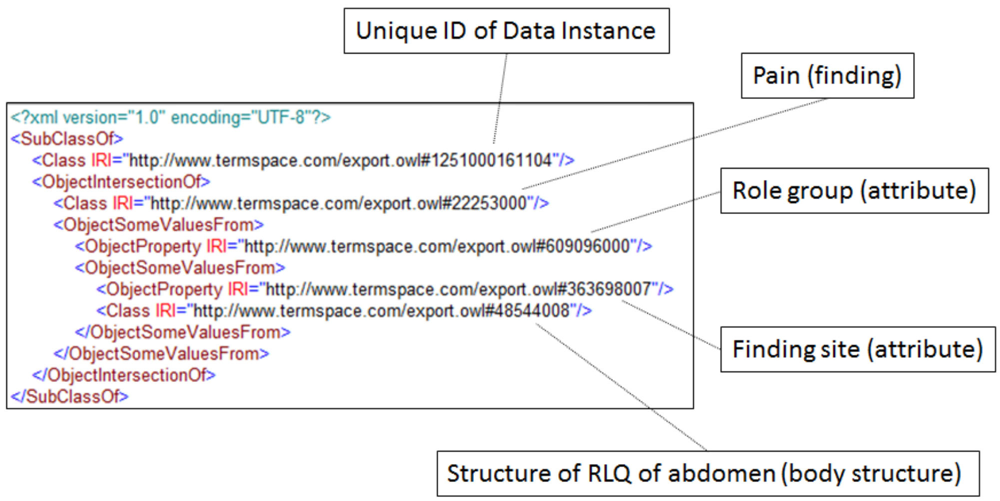
16.1.4.1.2. Example Transformation

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.

```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

Part VI. Procedural representation

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19. Procedural knowledge representation

20. KNART procedural representation

21. KOMET support for procedural knowledge

Part VII. Instance representation

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22. 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/

23. Instance persistence

Walter Sujansky

23.1. 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.

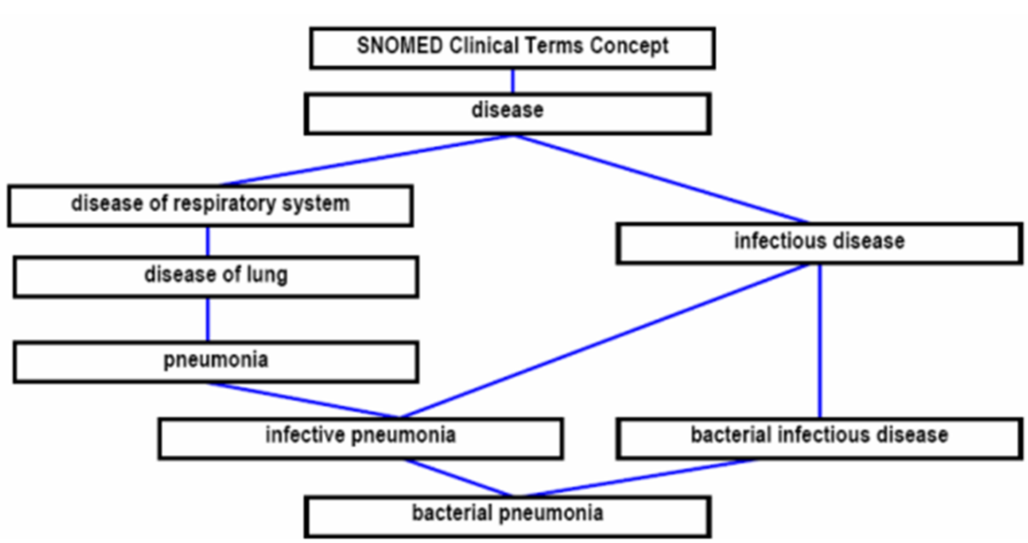
This document first provides a brief background on post-coordination in SCT and describes the scope of our analysis. The report next describes the requirements for managing clinical observations that were used to inform the analysis. The following section presents a set of relevant design dimensions 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.

23.2. 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 maintaining 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

23.3. 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.

23.3.1. 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.

23.3.2. 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 23.3.3, "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.

23.3.3. 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 23.4.4, "Computation of Transitive Closure" - Section 23.4.6, "Partial Subsumption Testing of Post-Coordinated Expressions").

23.3.4. 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.

23.3.5. 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.

23.4. 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 23.5, "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.

23.4.1. 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.

23.4.1.1. 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”)

23.4.1.2. 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.

23.4.2. 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

<table>
<tr><th>InstanceID</th><th>ProblemExpression</th></tr>
<tr><td>1</td><td>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</td></tr>
</table>

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

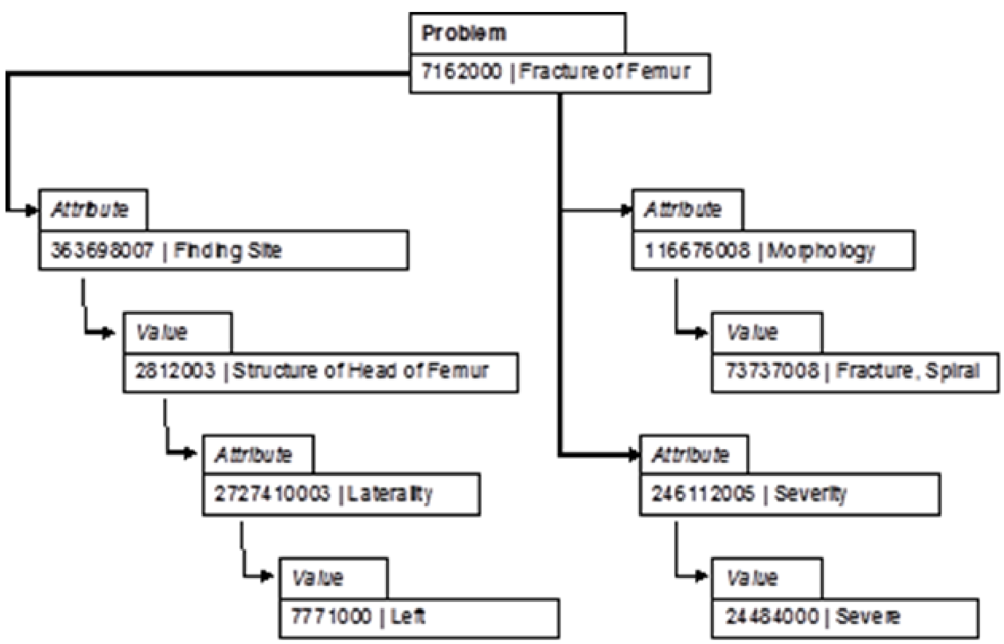
InstanceID	ParentInstanceID	SCT_AttributeID	SCT_AttributeDesc	SCT_ValueID	SCT_ValueDesc
1				7162000	Fracture of Femur
2	1	363698007	Finding Site	2812003	Structure of Head of Femur
3	2	2727410003	Laterality	7771000	Left
4	1	116676008	Morphology	73737008	Fracture, Spiral
5	1	246112005	Severity	24484000	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 23.3, “Requirements and Assumptions” The discussion first addresses representation in a relational database, and then covers representation in an object-oriented database (such as Caché).

23.4.2.1. 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.

23.4.2.2. 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 23.4.2.1, "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.

23.4.2.3. 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.

23.4.2.4. 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 23.4.2.1, “SNOMED Compositional Grammar” - Section 23.4.2.3, “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.

23.4.2.4.1. 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.

23.4.2.4.2. 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	SiteLateralityValueDesc	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.

23.4.3. 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.

23.4.3.1. 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").

23.4.3.2. 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.

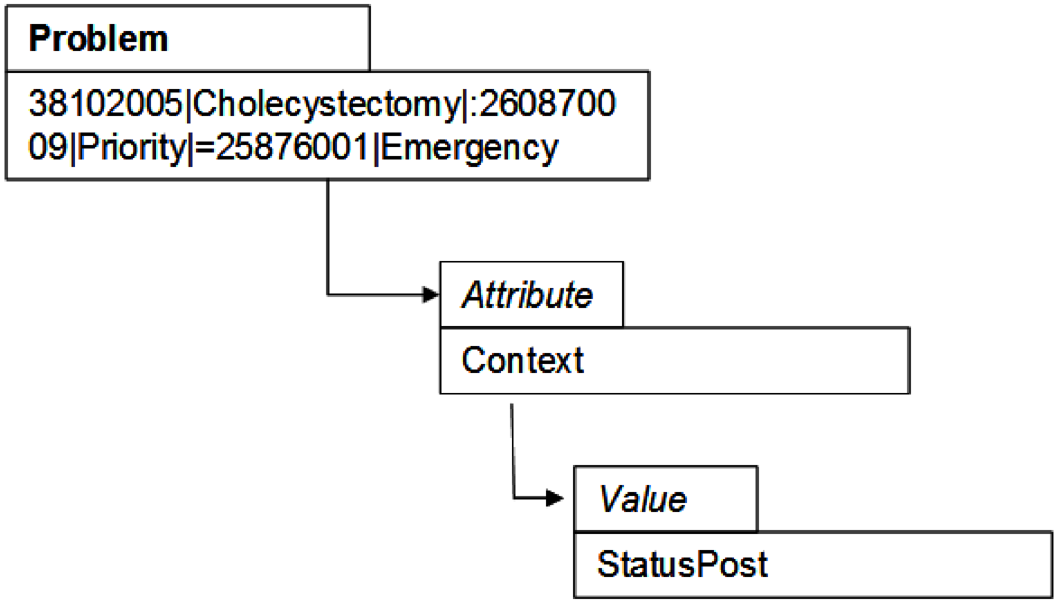
23.4.3.3. Relational Context Model

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.

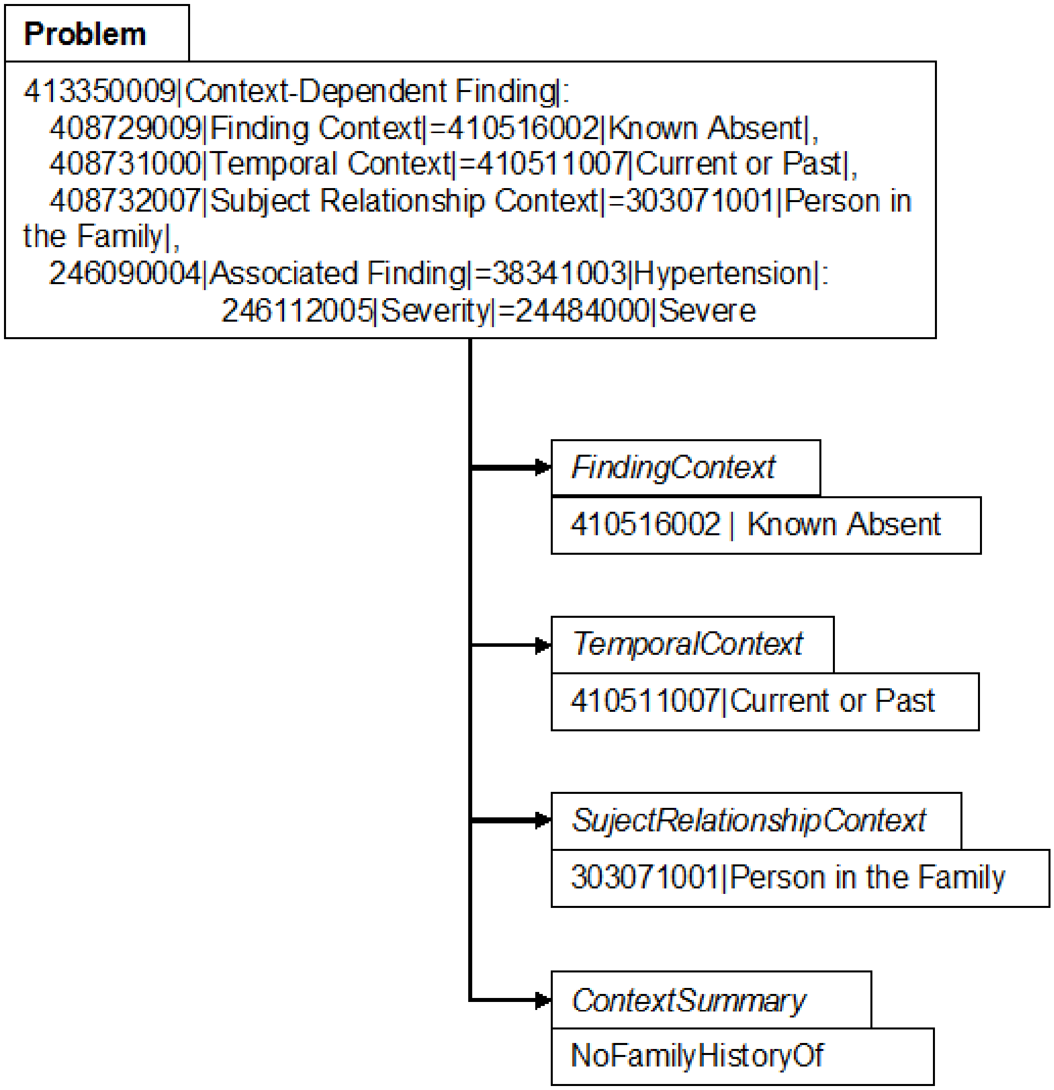
23.4.3.4. Combination of Approaches

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

<table>
<tr><th>InstanceID</th><th>ProblemExpression</th><th>FindingContext</th><th>TemporalContext</th><th>SubjectRelationshipContext</th><th>ContextSummar</th></tr>
<tr><td>1</td><td>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</td><td>Known Absent</td><td>Current or Past</td><td>Member of Family</td><td>NoFamilyHistoryOf</td></tr>
</table>

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.

23.4.4. 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 23.4.1.1, " 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 23.2, "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:

23.4.4.1. 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.

23.4.4.2. 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.

23.4.4.3. 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.

23.4.5. 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 23.4.4, “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 23.4.4, “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.

23.4.5.1. 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.

23.4.5.2. No Implementation of Just-in-Time Pre-Coordination

PROS and CONS: The opposite of those described in the section above.

23.4.6. 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 23.4.4, “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 23.4.4, “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 23.4.3.1, “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.

23.5. Recommendations

23.5.1. 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.

23.5.2. 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 23.4.2, “Structure and Syntax for Persistence”), depending on the technical capabilities of Caché.

23.5.3. Representation of Context

I recommend the hybrid approach described in Section Section 23.4.3.4, “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.

23.5.4. 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.

23.5.5. 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 23.4.4, “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).

23.5.6. Partial Subsumption Testing

Partial subsumption testing of post-coordinated expressions, as described in Section Section 23.4.6, “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

23.5.7. Summary of Recommendations: An Example

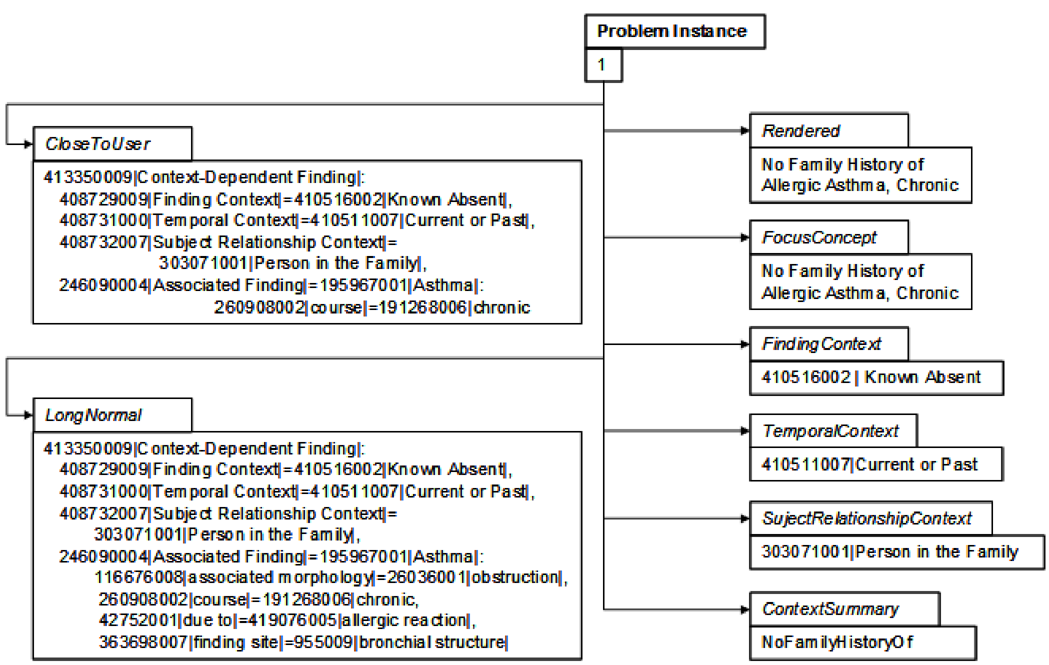
Based on each of the preceding recommendations, this section presents the representation of a single post-coordinated expression in the recommended persisted form. The expression represents the entered observation:

“No family history of chronic allergic asthma”

Relational Representation:

<table>
<tr><th>InstanceID</th><th>Problem_Rendered</th><th>Focus_Concept</th><th>Problem_CloseToUser</th><th>Problem_LongNormal</th><th>FindingContext</th><th>TemporalContext</th><th>ubjectRelationshipConte</th><th>ContextSummary</th></tr>
<tr><td>3875903</td><td>No Family History of Allergic Asthma, Chronic</td><td>389145006|
Allergic asthma</td><td>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</td><td>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|</td><td>410516002|
Known Absent</td><td>410511007|
Current or Past</td><td>303071001|
Person in the Family</td><td>NoFamilyHistoryOf</td></tr>
</table>

Caché Hierarchical Representation:



Part VIII. Appendices

Table of Contents

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=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]
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. <u>SNOMED-CT</u> [http://browser.ihtsdotools.org/] b. <u>LOINC</u> [http://search.loinc.org/search.zul?query=BMI] c. <u>RXNORM</u> [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. <u>SNOMED-CT</u> [http://browser.ihtsdotools.org/] b. <u>RXNORM</u> [http://www.nlm.nih.gov/research/umls/rxnorm/]
	Appendix	Refer to: <u>Exercise and Activity after a Heart Attack</u> [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

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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=X3oDMTByNW1iMWN2BHNlYwNzcgRwb3MDM 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 <u>education for managing chronic heart failure</u> [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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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

   viii. blood urea nitrogen (BUN)=13 mg/dL

   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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8.12. Additional References

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United States Department of Veterans Affairs. (2014). *VA/DoD Clinical Practice Guidelines. Screening and Management of Overweight and Obesity Pocket Card*. Retrieved from http://www.healthquality.va.gov/guidelines/CD/obesity/VADoDOBECPGPocketCardFINAL070314.pdf

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

American Diabetes Association. (2013). *Standards of medical care in diabetes—2013*. Retrieved from http://care.diabetesjournals.org/content/36/Supplement_1/S11.full

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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:

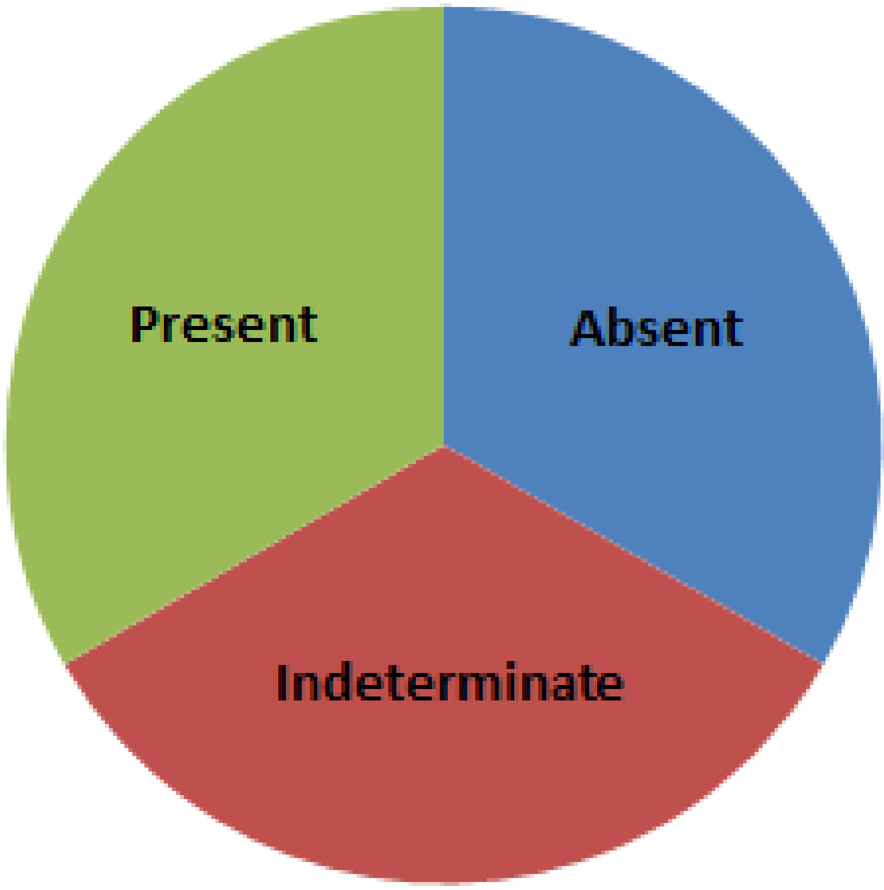
Present”: The phenomenon is explicitly documented as present or can be logically inferred to be present

“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 13.12, “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.

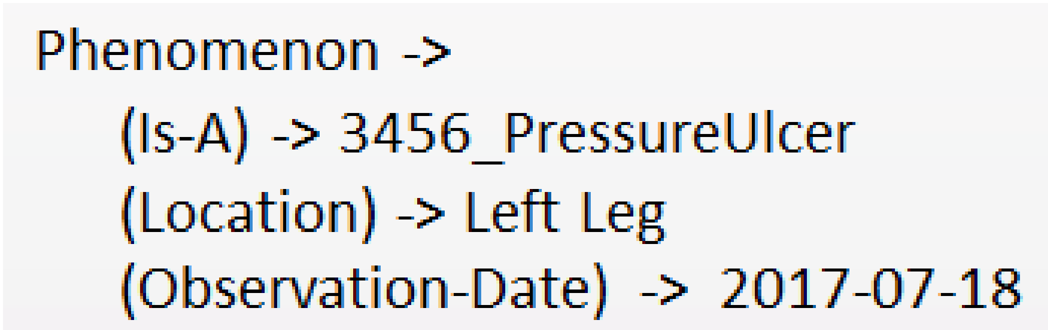
Figure C.2. Example assignments of present, absent, and indeterminate based on various interval values

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 13.2.6.2, "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.

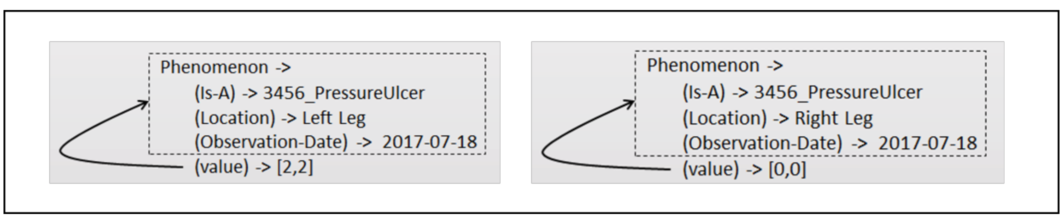
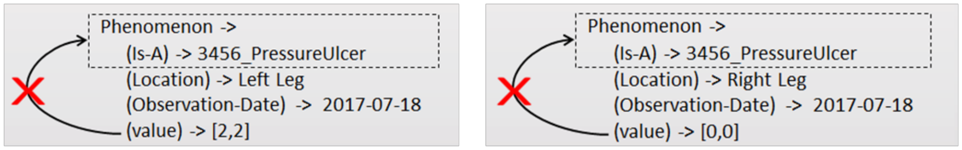


Figure C.5, "The incorrect assignment of interval values to post-coordinated phenomena. " illustrates the problems that may occur when interval values are erroneously assigned to just a subset of the post-coordinated expressions used to document phenomena. In this case, the interval values are assigned 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.

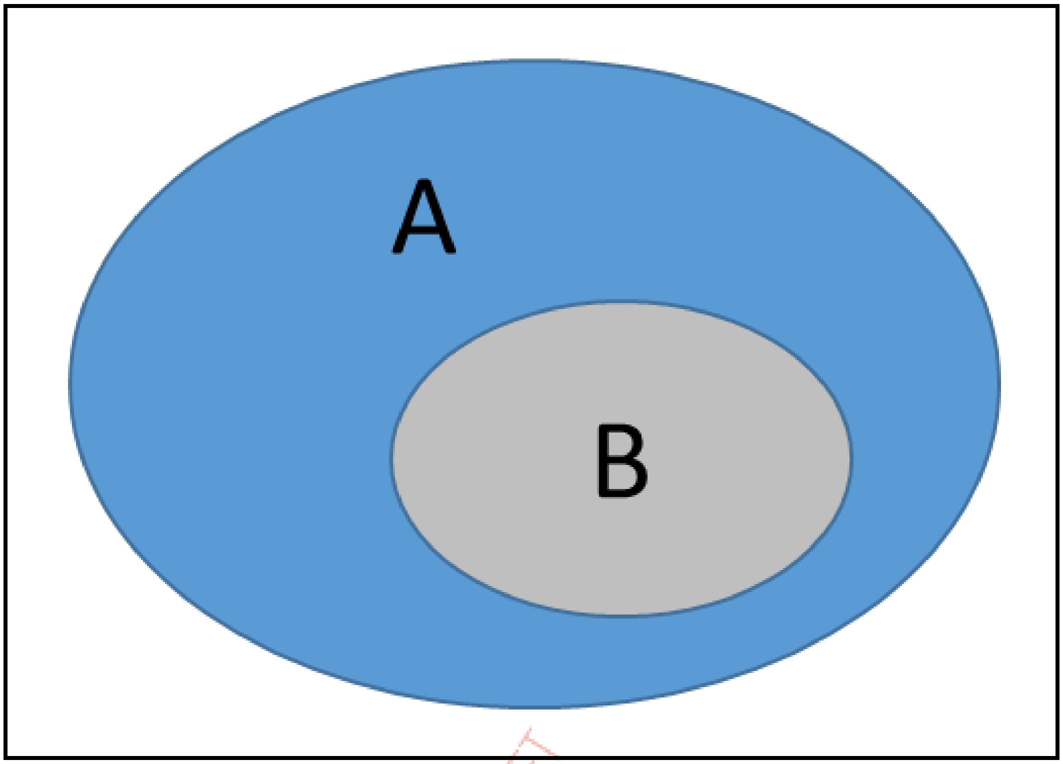
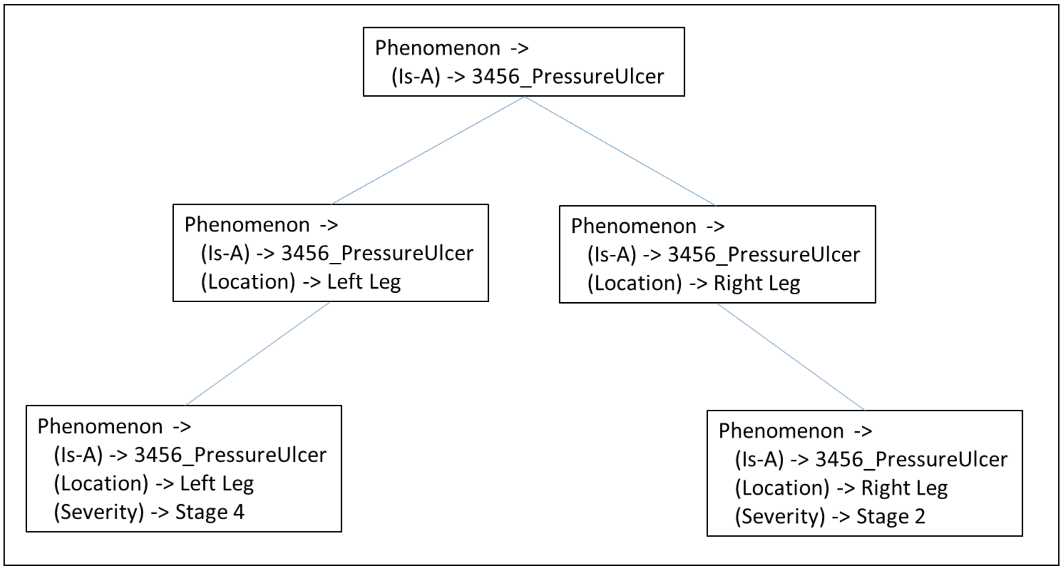


Figure C.7, “An example subsumption hierarchy for post-coordinated phenomena in the clinical domain. ” shows how subsumption relationships can apply to clinical observations. Specifically, the figure shows a subsumption hierarchy involving various types of pressure ulcer phenomena in which each parent 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:

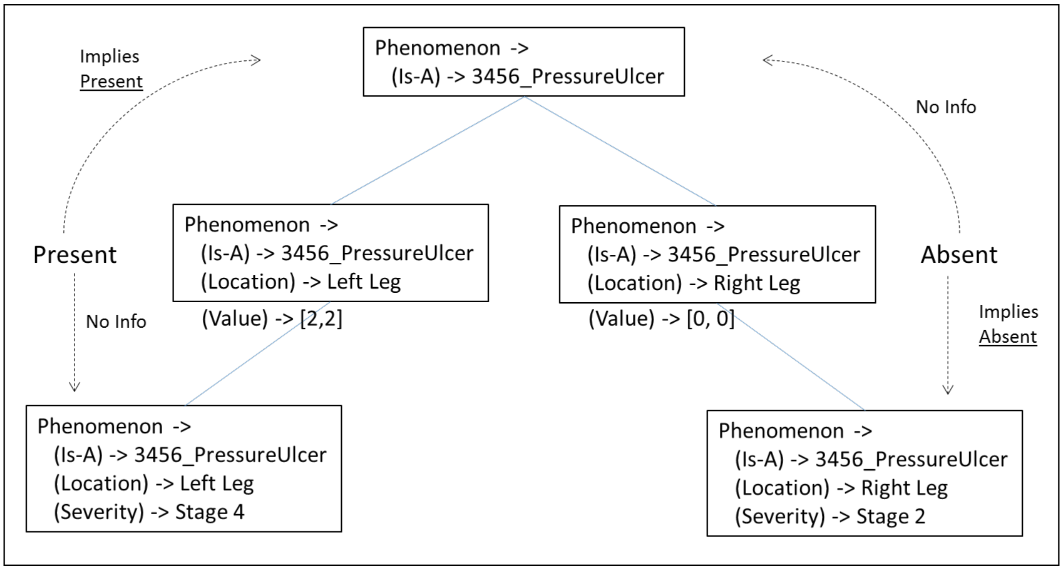
3. IF Member-Set-A(i) THEN Member-Set-B(i)

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,∞]) = 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,∞]) = 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,∞]) = 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,∞]) < > 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 13.12, “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 13.12, “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:

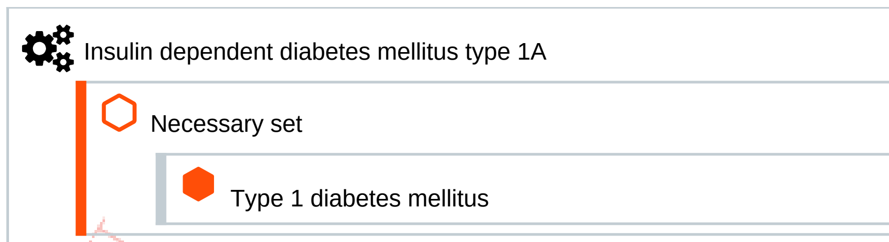
UUID: cc0759c3-623e-3417-badb-8dbad681e0f5

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:

- Pulse rate
  - Sufficient set
    - Cardiac feature
    - Cardiovascular measure
    - Pulse characteristics
    - Role group
      - ∃ (Characterizes)→ [Cardiac process]
    - Role group
      - ∃ (Process output)→ [Entire cardiac cycle process]
    - Role group
      - ∃ (Property type)→ [Number rate]
    - Role group
      - ∃ (Scale type)→ [Quantitative]
    - Role group
      - ∃ (Direct site)→ [Systemic arterial structure]
  - Necessary set
    - Heart rate
    - Pulse characteristics

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

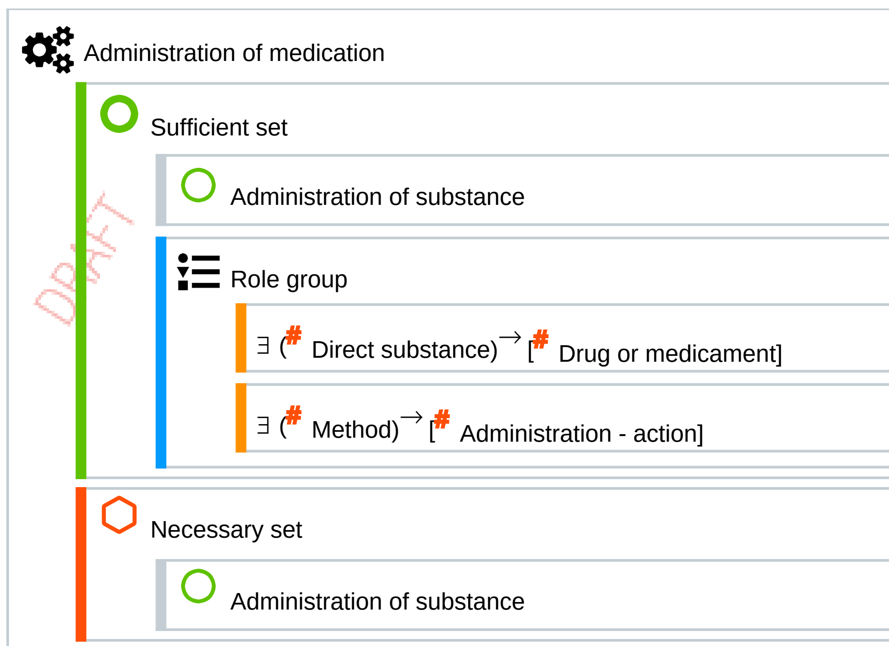
Codes:

- 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:

Peripheral pulse taking

- Necessary set
  - Examination of cardiovascular structure
  - Examination of limb
  - Palpation
  - Procedure on artery
  - Pulse taking
  - Role group
    - ∃ (Method)→ [Palpation - action]
    - ∃ (Procedure site - Direct)→ [Structure of artery of extr

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:

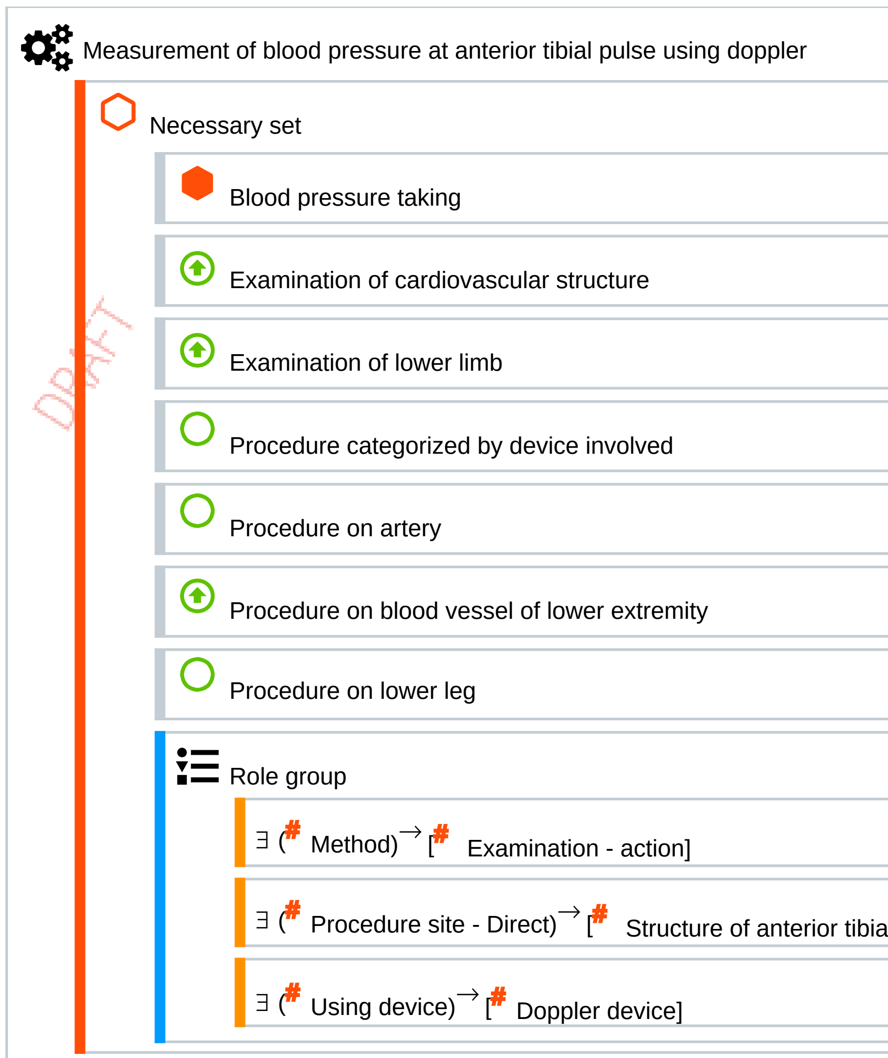
UUID: 697518a2-7d28-3bc3-8213-e5e7b3b86b99

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:

O/E - pulse rate

- Necessary set
  - O/E - specified examination findings
  - Pulse rate finding
  - Role group
    - ∃ (# Finding informer)→ [# Performer of method]
  - Role group
    - ∃ (# Finding method)→ [# Physical examination]
  - Role group
    - ∃ (# Interprets)→ [# Pulse rate]
  - Role group
    - ∃ (# Interprets)→ [# Pulse]
  - Role group
    - ∃ (# Finding site)→ [# Structure of cardiovascular system]

Measurement of blood pressure using cuff method

Descriptions:

Measurement of blood pressure using cuff method (procedure)

Measurement of blood pressure using cuff method

Codes:

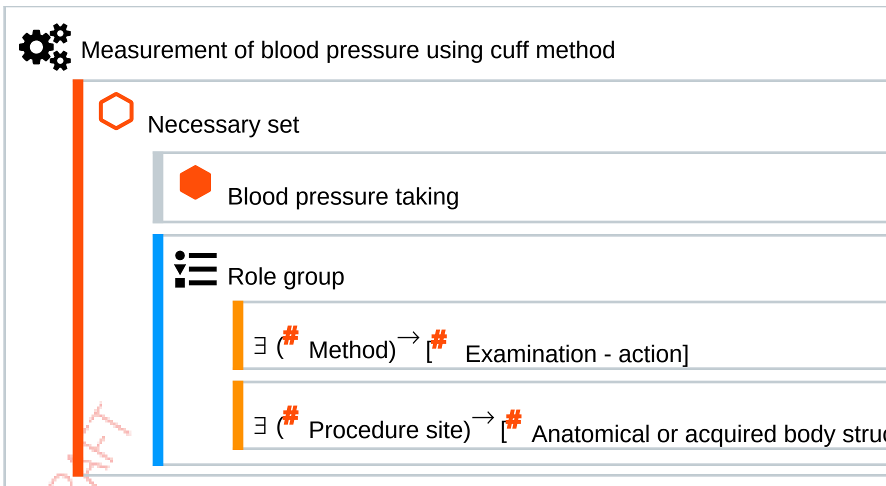
UUID: 74374092-8c3a-328c-9370-ba1ecba7a0d0

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:

Blood pressure taking

- Necessary set
  - Taking patient vital signs
  - Role group
    - ∃ (# Method)→[# Examination - action]
    - ∃ (# Procedure site)→[# Anatomical or acquired body struc

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

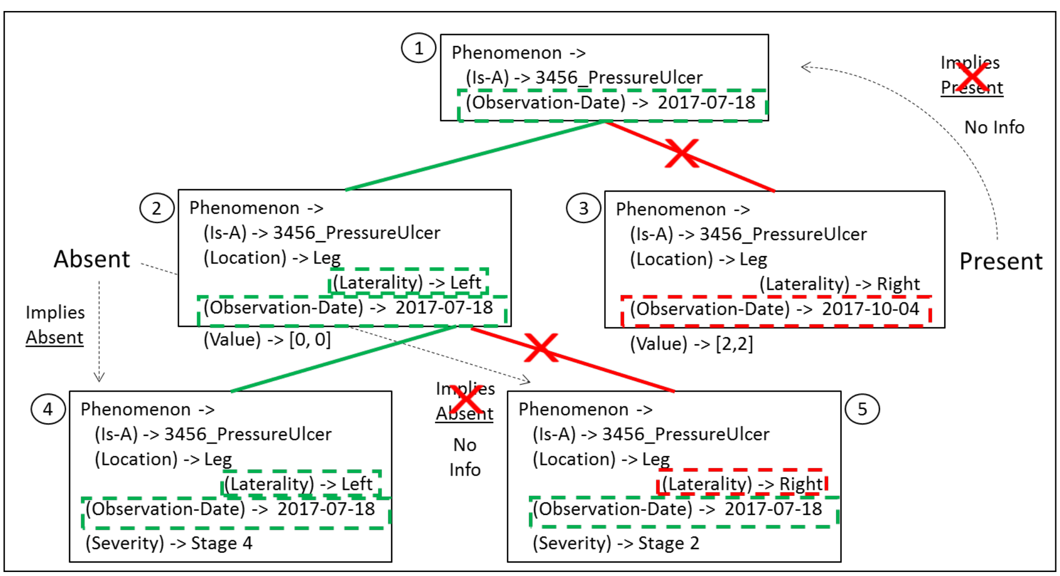
As described in Section Section C.1.2, "Assigning Values to Phenomena That Include Refining Attributes", correct application of the tri-valued model for querying phenomena requires that interval values be assigned to the entirety of each phenomenon (including all of its refining attributes). Further, 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 13.2.6.2, “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.