Integrated Knowledge Management (IKM) Volume 4

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Part I. Foundational Architecture

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1. Terminology Knowledge Architecture (Tinkar) Overview

Over the past decades, biomedical terminologies have increasingly been recognized as key resources for knowledge management, data integration, and decision support. [1] Acceleration and development of Electronic Health Record (EHR) systems has precipitated the emergence of “standard terminologies” and their widespread adoption in the clinical community. These include Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), the Logical Observation Identifiers, Names, and Codes (LOINC®) and RxNorm. The availability of these clinical terminologies through the terminology services of Fast Healthcare Interoperability Resource (FHIR) is facilitating their usage in support of interoperability in healthcare.

Interoperability requires standardized semantics based on reference terminology provided by standards development organizations, professional organizations, or government agencies. These organizations publish their content with the intention of licensing it to health information technology (IT) vendors, providers, and research organizations. In the U.S., the core clinical reference terminology is based on SNOMED CT®, LOINC®, and RxNorm. Healthcare organizations must adopt and integrate subsets or modules of various reference terminology and manage references, dependencies, versions, and releases. It is important for the integrity of medical records that the change history of concepts and value sets can be managed and tracked to allow the exchange of either current or retrospective medical records. Therefore, enterprise terminology requires integrated terminology using a common representation and management.

Despite the need to use standard terminologies in a highly integrated way, there is no standard representation across SNOMED CT®, LOINC®, RxNorm, etc. Some partnerships have been created among development teams to facilitate interoperability and minimize duplication of effort. Further integration has been proposed but will require additional resources to bring these terminologies closer together. However, while this evolution leads to greater compatibility and interoperability, integration of SNOMED CT®, LOINC®, and RxNorm is non-trivial as these terminologies use different formalisms and tools for their representation. Various terminologies have different semantics, models, release cycles, and versioning mechanisms. [1] While there is recognition that terminologies are not standardized at the exchange level, there is no consensus about harmonized next steps to solve the challenges.

This document focuses on the need for – and logical specification of – a Terminology Knowledge Architecture (Tinkar). The Tinkar Reference Model is a logical model that describes the standardized model for terminology and change management. Tinkar provides an architecture that delivers integrated terminology to the enterprise and its information systems. In doing so, it addresses the differences in management and structure across reference terminology, local concepts, and code lists/value sets.

The Capability Maturity Model is a development model and can be viewed as a set of structured levels that describe how well the behaviors, practices, and processes of an organization can reliably and sustainably produce required outcomes. There are five levels defined along the continuum of the Capability Maturity Model (see below). The model provides a theoretical continuum along which process maturity can be developed incrementally from one level to the next. An implementation of the Tinkar Specification can provide a single representation for all terminologies required in the U.S. and other countries, while also providing a better foundation for maturing change management models as described by the Capability Maturity Model [2]:

1. **Initial** – Tinkar aims to reduce and eliminate challenges with management of changes to terminology being unpredictable, poorly controlled, and reactive.

2. **Repeatable** – Tinkar provides the foundation for robust configuration management and quality assurance for terminologies.

3. **Defined** – Tinkar allows terminologies to have standardized update and extension processes.

4. **Managed** – Tinkar represents updates and changes to terminologies so that the changes can be measured and controlled.

5. **Optimizing** – Tinkar aims to allow multiple stakeholders to apply and retrieve changes to shared terminology content with equivalent and harmonized results.

Tinkar aims to adhere to the following statement from a publication about developments in clinical terminologies in the 2018 Yearbook of Medical Informatics [1]: "The benefits of the integrated terminologies in terms of homogenous semantics and inherent interoperability should, however, outweigh the complexity added to the system." This specification provides the foundation of a knowledge architecture that is intended to integrate reference terminology from distributors (e.g., SNOMED CT®, LOINC®, RxNorm) with local concepts to support interoperable information semantics across the enterprise.

1.1. Motivation: Why Tinkar?

Information systems that are used across the healthcare enterprise record and manage clinical data using clinical statements and clinical terminologies in non-standardized ways. Interoperability specifications aim to require terminology bindings to concepts, code systems, and reusable value sets. Currently, there is variation in clinical data exchange across the enterprise, as existing payloads and clinical statements use inconsistent and highly variable enterprise terminologies. The management of the concepts, code systems, and value sets is non-trivial because developers, implementers, and end users are forced to manage "unnecessary complexity." For example:

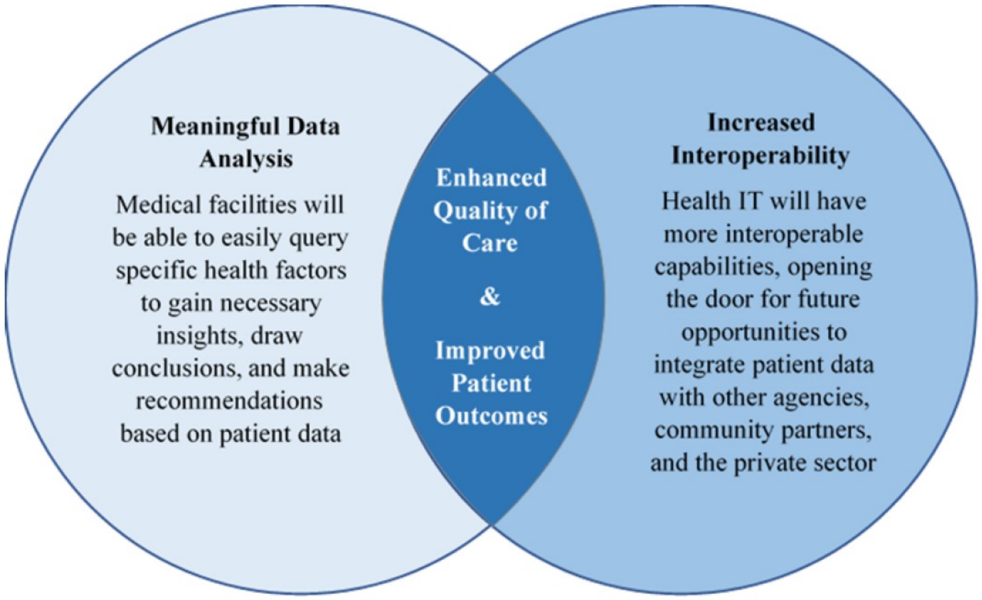
- Representation of medications: RxNorm codes overlap with CVX codes. Investigational vaccines from the U.S. Food and Drug Administration (FDA) are not represented in RxNorm, CVX, or SNOMED CT®.

- Representation of COVID-19 result codes are inconsistent and are not equivalent (e.g., detected, undetected, positive, negative, etc.).

As a result of these complexities, there are many ways to say the same thing using standard terminologies and standard formats. The Institute of Medicine report, *Health IT and Patient Safety: Building Safer Systems for Better Care*, highlighted the unintended consequences of health IT-induced harm that can result in serious injury and death due to dosing errors, failure to detect serious illnesses, and delayed treatment due to poor human-computer interactions, confusing clinical terminology, or unreliable data quality. [3] Despite the widespread understanding of the importance of the quality of clinical data, there is currently a lack of integration and management of clinical terminologies across the healthcare enterprise.

Tinkar intends to support integration of clinical terminology and local concepts to support increased data quality for interoperable clinical information. High-quality clinical data enables healthcare systems across the enterprise to conduct robust and meaningful data analysis and increase overall interoperability, which ultimately enhances quality of care across all medical facilities.

Figure 1.1. Why Tinkar?



Separation of concerns is an architectural design principle, whereby a system is divided into distinct sections, such that each section can address separate concerns. In this case, each architectural layer may build upon artifacts from lower layers.

1.2. The Problem Tinkar Addresses

The following four high level potential deficiencies related to poorly integrated terminology and inefficient change management describe preventable harm that Tinkar addresses:

1. **Inability to recognize equivalence.**
    - Difficulty with determining that codes/terms using standard terminologies from disparate health IT systems represent a common clinical idea/concept (e.g., "Feels Feverish" in the Temperature Symptoms SNOMED CT® hierarchy versus "Feels Hot/Feverish" in the Observation and Sensation SNOMED CT® hierarchy. Both concepts are Findings in SNOMED CT® but there is no unifying way to identify equivalence).
2. **Inability to represent a pertinent phenomenon.**
    - A new set of local terminology may be managed with value sets and concept gaps addressed in quick iterations (e.g., "COVID-19 negative test result" was needed in practical use before official Standards Development Organization (SDO) releases, or gaps like "mild anemia", which was proposed, but not accepted, by both the international and U.S. SNOMED CT® release).
3. **Flawed information.**
    - Incorrect usage or representation of clinical ideas/concepts from standard terminologies due to a lack of harmonization and multiple representations that currently exist (e.g., LOINC® and SNOMED CT® have overlapping concepts).
4. **Inability to reliably and safely evolve over time. [4]**

- There is a lack of clear, detailed descriptions of changes to terminologies over time so that changes can be understood by implementers. Terminologies often change in ways that are convenient for the creators, but complex for the users (e.g., redundancy, major name changes, code reuse, and changed codes).

Consider the following examples of implementations that have gone wrong: [5-8]

- **Computer error may have led to incorrect prescribing of statins to thousands of patients.**
  - Thousands of patients in England may have been incorrectly prescribed or taken off statins because of a major IT glitch.
  - Underlying cause: (1) code mapping errors, and (2) brittle means for determining equivalence.
- >**Alert for monitoring thyroid function when taking Amiodarone stopped working.**
  - Amiodarone is associated with several side effects, including thyroid dysfunction, which is due to amiodarone's high iodine content and its direct toxic effect on the thyroid.
  - Underlying cause: (1) the identifier for the drug amiodarone was changed in another system, and (2) uncoordinated means for determining equivalence.
- **62% of clinical decision support (CDS) malfunctions were attributable to changes in underlying codes or data fields.**
  - Change is a constant feature of providing healthcare.
  - Underlying cause: (1) poorly managed change.

Tinkar addresses challenges and problems from the above implementation examples:

Challenge	Tinkar Solution
Uncoordinated or brittle terminology integration frequently breaks across systems	Standardize (and facilitate sharing) of terminology representation across systems
Management of change over time	Consistent representation and configuration management
SNOMED CT®'s proprietary aspects prevents use as a common format for LOINC® and similar	Build on existing SNOMED CT® foundation, rather than reinvent, using an open-source initiative approved permissive licenses (i.e., Apache 2)

1.3. About Tinkar

Tinkar provides the foundation of a knowledge architecture that is intended to integrate reference terminology from distributors (e.g., SNOMED CT®, LOINC®, RxNorm) with local concepts to support interoperable information semantics across the enterprise.

This specification introduces an agile approach to terminology design and formatting that promotes the use of self-describing data. It is a shift from hard-coded models that have been favored due to their prescriptive nature but have shown limited flexibility and extensibility. This specification is similar to FHIR as it places the focus on a self-describing, extensible approach to representing terminology. Therefore, Tinkar aims to be both self-describing and completely machine processed:

1. Self-describing machine-readable representation of terminology, such that if an application can process the metadata, it should be able to import the content/concepts and make it available to enterprise applications.

2. The machine-readable terminology could generate human-readable documentation so that business analysts and developers can understand and apply it correctly.

1.4. Tinkar Objectives and Purpose – Manage Terminology and Change

This specification describes the requirements and characteristics of systems required to manage terminology produced by a variety of organizations across a healthcare enterprise. This foundation must allow enterprise to extend terminology standards and implement extensions in a timely fashion.

This specification is intended to support healthcare organizations' standard terminology modules, value sets, and coding systems as well as local terms and equivalence mappings.

A standard-based Tinkar specification is necessary to support the operation of a variety of systems intended to deliver knowledge management for terminology to vendors, providers, and even standards-development organizations, like Health Level Seven (HL7).

1.5. Related Efforts

Previous efforts have attempted to create a common set of terminology capabilities and services by specifying a single predefined structure for managing terminology. Unfortunately, a hardwired structure that works for one standard may not work for another. The inability to integrate content across terminology standards is a barrier to implementing services and modules that can deliver integrated concepts, code lists, and value sets required by enterprise systems for treatment, research, business process automation, quality measures, and outcome analysis.

- Clinical applications require integrated terminology to create interoperable clinical statements that are organized into messages, documents, or resources.
- Data analysis and research require integrated terminology to analyze aggregated information. Interoperability, CDS, or other types of automation require common semantics based on a set of integrated models across reference standards (e.g., SNOMED CT®, LOINC®, RxNorm).

The Unified Medical Language System (UMLS) Metathesaurus is a compilation of multiple sources organized into 'concepts' that contain terms from many sources. The terms within a concept are declared synonyms by UMLS editors. However, its use in terminology systems has limited utility for several reasons. First, UMLS concepts are created on lexically-based rules and use very little of the additional information (relationships between concepts) that may be available from the source terminology. It does not permit classification to identify cases of possible missed synonymy. Second, issues of currency occur because of dyssynchrony of release dates between source terminologies and the UMLS itself. Third, the UMLS does not support a contribution model. That is, it is a static file that cannot be amended to support additional terms that may be required to fill gaps in existing terminologies subsumed by the Metathesaurus; it does not support extensions. Lastly, there is no efficient format for sharing integrated Metathesaurus content (though there is Rich Release Format [RRF]). The UMLS is not an architecture for terminology management. It may only serve as a reference, noting the aforementioned limitations. An implementation of Tinkar may help address these limitations.

Common Terminology Services 2™ (CTS2™) is an architecture for terminology management that supports history retrieval, though it does not support an arbitrarily granular change set model for versioning. The Tinkar specification, in contrast, provides that every new assertion, whether a new component or a change to an existing component, must have a precise version coordinate that govern granular change control. CTS2™ asserts a specific terminology model and does not support unanticipated properties with a self-describing model.

The U.S. Core Data for Interoperability (USCDI) is an amalgamation of various encoding standards. The standards being identified for specific data elements do not themselves provide consistency for how encoding is represented, how those encoding standards change over time, and how those encoding standards are distributed. As demonstrated by COVID-19 data needs, coordinated extension of content, timely distribution of updates, and consistency of representation are required to effectively respond to needs of public health and syndromic surveillance. Tinkar could help make it easier to standardize the representation, distribution, version and configuration management, and ability to share extensions to the USCDI as well as the underlying terminology systems themselves.

1.6. Benefits of Self-Describing Architecture

Tinkar is self-describing and completely machine-processed. A self-describing architecture is defined in a report from Queensland University of Technology as follows: "[t]he idea is that self-descriptions of data and other techniques would allow context-understanding programs to selectively find what users want, or for programs to work on behalf of humans and organizations to make them more scalable, efficient and productive." [9] Key advantages of a self-describing architecture (or metadata driven architecture) [10] include the following details:

Changes can be reviewed immediately – Every action or change by end users can be immediately previewed or tested, without needing any compilation or deployment process. The review can also be done before saving or publishing the changes, which makes it an interactive development environment for designers to create functionality in an iterative manner.

Version control with easy rollback – Every time any changes are made to published terminology artifacts, the historic versions of the metadata files are maintained. This enables easy version control and rollback when necessary. Every time a change is made to any artifact, the prior version that existed is archived. When a developer needs to roll back to the prior version, it can be achieved easily.

Any data source can be added – A self-describing architecture facilitates the ability for multiple types of terminology data sources to be connected to the system.

Define granular coordinates and configuration management – The functionality for defining granular, user-defined settings and controls for granular elements of clinical terminology management is supported. This includes create, read, and append settings, as well as management of individual elements, like fields or other controls.

Faster extensions – A benefit of a self-describing architecture is that it can abstract a lot of the deep internal complexities that makes development of standard terminologies complicated. This approach can improve processes around extensions to terminology.

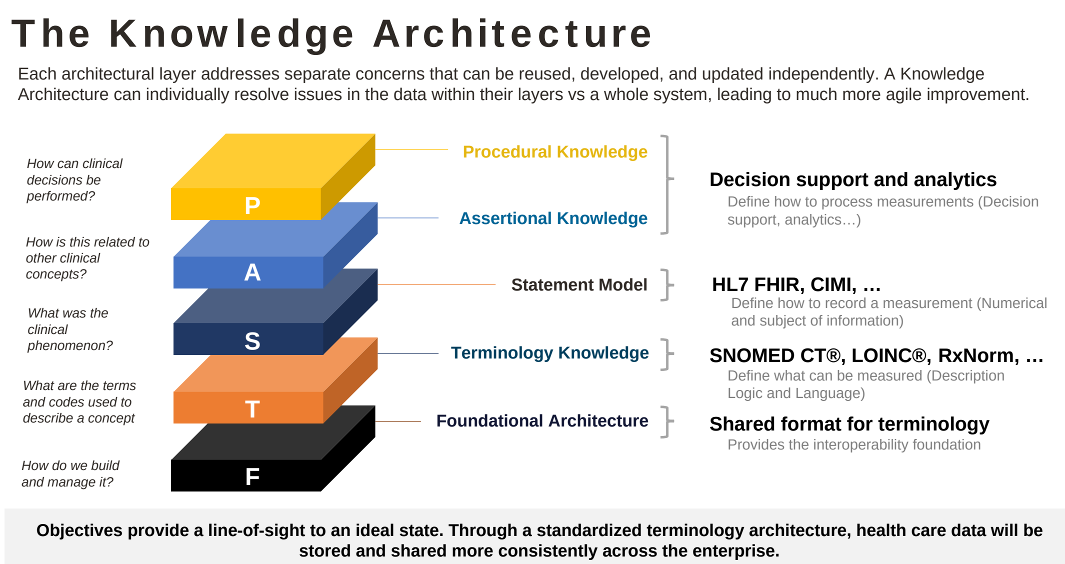
1.7. Approach - Architectural Separation of Concerns

Increased reliance on computerized health records, including EHR Systems, requires standardized medical terminology to encode health information consistently across systems and enterprises. Clinicians require not only objective quantitative measurements (e.g., 90 beats per minute for a patient's pulse), but also procedural context (e.g., pulse oximetry, manual) about past observations or requests for future interventions. While two quantitative measurements may be the same, the procedural information could indicate meaningful semantic differences and lead to different clinical interpretation and treatment. As information is exchanged across systems, the solution requires a common understanding of data, a method to support knowledge-representation, and clinical decision rules based on common terminology and statements. Each component must address an aspect, and together need to address the requirements of clinicians. Current

HL7 standard implementations rely on profiles and templates to disambiguate statement and terminology, and provide sufficient precision for transactions, documents, and standards-based application programming interface (APIs). Therefore, the architectural approach described here is applicable to standards organizations developing interoperability for enterprise and project-specific implementations in equal measure.

Functional decomposition—often referred to as a *Separation of Concerns* (SoC)—across components or sections with a specific purpose is a foundational design principle for complex system architecture. SoC allows a complete system to be subdivided into distinct sections or components with well-defined functionality and dependencies. If successful, this approach allows individual sections to be able to be *reused*, as well as designed, implemented, and updated *independently* to address emerging *requirements*. This is especially useful and important in a medical context given how many different health information and clinical terminology projects are ongoing at any given time. Efforts are often uncoordinated and led by disparate and unrelated standards development organizations. In these cases, SoC allows teams to work independently, in coordination with each other, and reuse the resulting artifacts.

Figure 1.2. Separation of Concerns: Knowledge Architecture



Separation of Concerns is an architectural design principle, whereby a system is divided into distinct sections, such that each section can address separate concerns. In this case, each architectural layer may build upon artifacts from lower layers.

Foundational Architecture – The Foundational layer of the Knowledge Architecture provides the common elements of interoperability, such as: object identity, versioning, modularity, and knowledge representation. It includes (a) the foundation and building blocks of the common model; (b) how the repeatable transformation process of disparate standards into the common model promotes interoperability with other environments; and (c) how the modules of the architecture are tightly version controlled over time. The Tinkar Reference Model belongs in this layer.

Terminology Knowledge - The Terminology Knowledge layer is responsible for structured sets of medical terms and codes that *define* concepts of interest, including descriptions, dialects, language, and semantic hierarchy. SNOMED CT®, LOINC®, and RxNorm are part of this layer. It defines what valid codes or expressions may be used by higher level layers.

Statement Model – The Statement Model layer is responsible for defining how data elements are combined to create a statement. This layer reuses the artifacts defined in the Terminology Knowledge layer. The analysis normal form (ANF) Reference Model [11] belongs in this layer.

Assertional Knowledge – The Assertional Knowledge layer makes use of the Terminology Knowledge layer concepts to specify *non-defining* facts that may be used by procedural knowledge algorithms. An example fact might be that “thiazide diuretics treat hypertension.” Assertional Knowledge may also indicate what symptoms may be associated with a disorder.

Procedural Knowledge – The Procedural Knowledge layer, also known as *imperative knowledge*, is the knowledge exercised in the performance of some task. An example would be determining a hypertension treatment plan by analyzing a combination of a patient’s clinical statements and the available assertional knowledge. The procedural knowledge is responsible for information about standard ways to carry out specific procedures, as well as other procedural guidelines, (e.g., treatment protocols for diseases and order sets focused on certain patient situations). Procedural knowledge, together with assertional knowledge, enables clinical decision support, quality measurement, and patient safety. This layer relies on the architectural foundation and terminology layers, incorporates the statement model for information retrieval, and uses the assertional knowledge. Procedural knowledge artifacts may include clinical alert rules, reminders, etc., that trigger actions or recommend interventions.

Examining a clinical procedure for controlling hypertension illustrates each of the layers of the informatics architectural separation of concerns.

- At the Terminology Knowledge layer there may be various codes and terms from disparate source terminologies to define a concept (e.g., hypertension). Ideally, these overlapping codes and terms would be oriented to the same parent concept during the transformation and integration process at the Foundational Architecture layer.
- The Statement Model layer enables representation of blood pressure measurement values (e.g., systolic BP = 140 mmHg), or the categorical data (e.g., pregnancy induced hypertension vs. renal hypertension) within a standard data structure to facilitate information exchange or retrieval, such as within a standards-based clinical statement (i.e., Clinical Information Modeling Initiative [CIMI], Clinical Document Architecture [CDA], FHIR, ANF, etc.).
- The Assertional Knowledge layer represents non-procedural statements, or facts, such as “Stage 2 high blood pressure is over 140 systolic or 90 diastolic,” or “beta-blockers and ACE inhibitors may be used to treat hypertension”, or “beta-blockers are contraindicated in patients with a diagnosis of reactive airway disease.”
- Finally, the Procedural Knowledge layer provides algorithms to analyze clinical statements about a patient, in combination with the Assertional Knowledge, to recommend a treatment protocol for different kinds of hypertension, including the considerations of, (e.g., patient age, co-morbidities etc., which can be generated by an electronic clinical decision support system [Statement + Assertional layers]). This layer adds support for workflow and conditional logic (i.e., if-then-else).

A clear separation of concerns enables the isosemantic transformation of standards-based clinical statements to normal form in the Statement Model layer by decoupling structure from semantics and workflow.

HL7 relies on implementation guides (for V2, CDA, and FHIR) to add sufficient terminology knowledge to standards-based clinical statements. Terminology constraints documented as profiles or templates are the mechanism to create interoperable implementation guides from health IT standards. Only after the Terminology Knowledge is fully defined can the standards-based statements be used to support business and workflow decision points consistent with the Assertional and Procedural layers described above.

1.8. About this Document

This document describes how encoded clinical data can be improved with a terminology management model. This terminology can be unified for HL7 and non-HL7 systems. The Terminology Knowledge Architecture, known as Tinkar, treats terminology in a common way for managing enhanced patient care and improved record keeping. The unification of models such as SNOMED CT®, LOINC®, and RxNorm will allow more robust computable medical records. The following sections contain the Tinkar Reference Model, along with illustrative examples as to the complexity and necessity of type of structure.

Tinkar will take different language sources and cohesively manage terminology data. Section 2 lays out the specific business requirements necessary for this task. The model representation is outlined in Section 3. Section 4 shows how Tinkar brings together the biomedical terminologies by a common description format. An implementation of the Tinkar specification can be used to fill the gaps between the common HL7 Terminologies and other systems like SNOMED CT®, RxNorm, Unified Code for Units of Measure (UCUM), etc. The result is the distribution and sharing of cohesive data across all platforms.

2. Business Requirements

This section details specific business requirements for a Tinkar logical model.

2.1. Clinical Requirements

The ultimate goal of this effort is to support the coordination of safe, effective medicine (Requirement 1). This goal requires quality information in the patient record (Requirement 2), wherever it comes from, and the increasingly distributed nature of care that requires commonly understood data standards (Requirement 3) to ensure mutual comprehension across the care team and over time. There are four outlined clinical use cases:

- **Record Patient Data**

A care provider, already authenticated and authorized to the system and using the appropriate context to ensure the system records the data for the correct patient, adds or modifies information in the patient record. This may include signs, symptoms, impressions, diagnoses, orders, notes, or other assets.

This operation may initiate workflow processes or automated processes such as clinical decision support suggestions.

For structured data using standard terminologies, the terms available are appropriate (Requirement 4) for the clinical context, for the role (i.e., terms may differ for different kinds of users), and for the data context (e.g., data entry fields may not support inactive or deprecated terms that would be allowed in search or analytical contexts).

If the available terminology does not support the provider's needs, the provider may assert a need for a new term.

- **Propose Terminology Change**

If a provider attempts to enter a term that is not supported by the enterprise terminology, the effort will be captured as a proposed term (Requirement 5).

Systems may capture this information unobtrusively as text, or prompt further information from the clinician to assist the authoring process. The system will convey at least the text and the identity of the clinician to the terminologist.

- **Review Patient Data**

A provider, already authenticated and authorized to the system and using the appropriate context to ensure the system records the data for the correct patient, finds and reviews information in the patient record.

For structured data using standard terminologies, the terms available are appropriate for the clinical context, for the role (i.e., terms may differ for different kinds of users), and for the data context (i.e., data entry fields may not support inactive or deprecated terms that would be allowed in search or analytical contexts).

Changes to the terminology that could affect record interpretation will be indicated (Requirement 6), along with a way to identify the change and its effect.

- **Review Knowledge Base Changes Relevant to Record**

If the system identifies a relevant change, the provider may request further information.

This will include the ability to see available values and CDS results for specific dates and contexts (Requirement 7), including those under which the data was recorded or specific decisions were made.

Clinical Use Cases

The key capability for a clinician should be to record and review data quickly and accurately (Requirement 8), taking advantage of up-to-date classifications and decision support rules. This should be accomplished by knowing when a change in the knowledge base might affect a record. The change management capability that supports these operations should be as unobtrusive as possible to patients and care providers, and always readily available.

These operations depend on the availability not only of currently accurate terminology assets, but also assets from prior points in time (Requirement 7). These may include assets as defined or refined by different stakeholders with different sets of assumptions. For instance, whether a disorder meets a criterion defined by a standard terminology, a payor, a professional society, or a locally chartered board of specialists.

To support these needs, the Enterprise Terminology that supports the clinical systems must manage change systematically (Requirement 9), and it must do so for both internally-managed and externally-sourced assets.

2.2. Asset Curation Requirements

Curation of these assets requires detailed change data. The evolution and maturation of knowledge happens at different times and places. Keeping standards and relationships to standards current is a complex undertaking. A health system may subscribe to dozens of standard and commercial terminologies, each of which may publish scheduled updates several times a year, and any of which may push out an emergency update at any time. All these assets have different designs, so ensuring continued cohesion is expensive and time-consuming, and the necessary transformations introduce risk. Systematic management of change requires granular representation of the assets and associated asset changes.

There are best-practice capabilities in knowledge asset maintenance. The following is proposed for clinical data standards:

- Unique object identification (Requirement 10): Every object under version control must have a unique identifier, and the identifier must remain unchanged as the object is modified and different versions of it are created and saved.
- Version history retention (Requirement 11): Each version of an object must be persisted as the object changes over time, along with metadata indicating its version identifier, time of creation, creating author, and branch of the version control system on which it was created. Further, every version of each object must remain available for retrieval and inspection.
- Version comparison (Requirement 12): It must be easy to compare two versions of the same object and identify all differences between them. Among other things, this capability is important to determine whether updates to a sub-artifact have changed its semantics in a way that may affect the behavior of one or more of its parent artifacts. Ready comparison is also important when merging two or more concurrent development efforts involving the same knowledge artifacts.
- Branching capabilities (Requirement 13): It must be possible to create a virtual copy of the entire version-control configuration, or a defined subset, in a new “path,” such that changes made to objects in this branch do not appear in the original configuration. This capability allows individual knowledge engineers to make and test changes to knowledge artifacts without affecting the work of other knowledge engineers or the integrity of knowledge artifacts currently in production. This facility is critical to the orderly and safe management of a clinical decision support system.

- Merging capabilities (Requirement 14): It must be possible to incorporate all the changes made on one branch of the version-control repository into another branch, such that any conflicts between different versions of the same objects are detected and resolved. This capability is important to enable work done by multiple knowledge engineers concurrently to be combined and incorporated into the main branch of the repository. The merging capability is also important to allow knowledge engineers to update their local branches of the repository with changes that may have been made by others to the main branch, thus ensuring that changes will remain compatible with the latest version of the system.

These core properties support authoring and maintenance operations: at a high level, this means modifying the enterprise terminologies (Requirement 15), importing standard terminologies (Requirement 16), and publishing the enterprise terminologies (Requirement 17) to the client clinical systems. The standard terminology publisher has the same needs around modification and publishing as the enterprise, and some standards import other standards as well (e.g., Medication Reference Terminology [MedRT], which publishes relationships among other standards).

We distinguish between the Enterprise Terminologist and the SDO Terminologist. The Enterprise Terminologist is responsible for ensuring that the terminology resources provided to clinical systems are current and accurate. This involves managing the consumption of external terminologies as well as maintenance of assets defined within the enterprise. The SDO Terminologist is responsible for ensuring that the terminology resources provided to other terminology systems are current and accurate. This may involve managing the consumption of external terminologies as well as maintenance of assets defined within the SDO.

- **Modify Enterprise Terminology**

A user adds, modifies, or deactivates content in the terminology assets of the enterprise, including assets provided to clinical systems as well as management data used only within the knowledge base.

- **Publish Enterprise Terminology**

A user manages the publication process that supports the automated provision of terminology content to clinical systems.

- **Import Standard Terminology**

A user incorporates a new standard terminology or new version of a standard terminology into the enterprise terminology. During this process, functionality supports the assessment and management of impacts on existing enterprise assets.

- **Publish Standard Terminology**

A user manages the publication process that supports the automated provision of terminology content to client terminology servers.

- **Modify Standard Terminology**

A user adds, modifies, or deactivates content in the terminology assets of the standard, including assets provided to client terminology systems as well as management data used only within the knowledge base (e.g., changing SNOMED CT® relationships, inserting a concept in between two existing concepts). *Note that a standard can only be modified by the standard owner*. A client enterprise may add to or modify the content in an “overlay,” but those changes are part of the local enterprise assets. The client enterprise cannot actually modify the standard.

Asset Curation Use Cases

Today, clinical systems consume terminologies, but the interfaces are point-to-point. To assert or assess new information, the tools must already understand all relevant interface models. Since an external organization may modify that model at any time, the ability to consume external assets involves ongoing manual efforts to understand or confirm the model and the design of transformations to support consumption. This is potentially expensive and risky.

We propose a “data-driven” architecture to support self-describing terminology assets. All changes can be programmatically managed with a globally consistent design. Management may involve human review, but it can leverage pattern-based recognition of specific change types for automated handling, leaving a smaller number of cases that require human judgment. This information design will support a common representation of all terminologies. There are two key requirements for this design:

1. A complete record of all changes, including relevant change context information (Requirement 11)

2. A single syntax to support the representation of all terminology assets, known and future (Requirement 18)

The context information of the first requirement includes the following:

1. The Status of the asset: whether it should be considered active or inactive in the context of these other attributes (Requirement 19). For systems that do not support status, the default will be “active.”

2. The Time of the change, specified with a time zone and at an appropriate precision (Requirement 20). For systems that do not provide a time, the default will be the release time.

3. The Author of the creation or change, unambiguously identified (Requirement 21). For systems that do not provide an author, a default author will be created for the system.

4. The domain or organizational name of the larger asset within which the component is meaningful, such as code system or edition (a.k.a., Module) (Requirement 22). For systems that do not provide a module, a default module will be created for the system.

5. The production branch of that organization, e.g., for distributed development, testing, staging, or production (a.k.a., Path) (Requirement 23). For systems that do not provide a path, a default path will be created for the system.

These elements together are referred to by the acronym “**STAMP**.” Every new assertion, whether a new asset or a change to an existing asset, must have a STAMP to determine when it is to be used. The STAMP properties support the ability to apply terminology assets for specific purposes. For example:

- “Path” can be used to test provisional content without physically swapping out systems.

- “Modules” are used to organize content for maintenance and publication purposes. Modules are the domain or organizational name of the larger asset within which the component is meaningful, such as code system or edition. Modularity for terminologies should follow a similar design to modularity in software engineering. Deciding what belongs in certain modules or extensions within certain terminologies is a difficult subject that is out of scope for this document, but having support for the ability to create modules, recognize redundancy, and merge or retire concepts are important requirements that must be supported. [12-14]

- “Time” supports the ability to apply CDS rules as they would have looked in the past.

A further requirement is that not only must the architecture support these properties, but that it must require the properties for all assets under curation. Without consistent application of this rule, the foundational capability of detailed version management is more difficult.

Additionally, for an asset to support a record of changes, each asset must itself be identifiable (Requirement 10).

The “single syntax” requirement is harder to satisfy. One approach would be to define a syntax that addresses the data elements of all known terminologies. This would be a heavy specification, that would be difficult to maintain, and could fail to capture new elements as terminologies are added in the future.

The other approach is to use a “self-describing” or “meta-modeling” approach, where the syntax defines not only the content but also what the content means. “Rigid” or “brittle” specifications determine in advance where information belongs: a database may use column names to suggest what belongs in a column, but there is no way to determine whether the name is a good one, or whether an instance value meets the criterion implied by the name. But flexible specifications support data definition. Extensible Markup Language (XML) (a subset of Standard Generalized Markup Language [SGML]) provides a way to specify types of data and structural (not semantic) relationships. Resource Description Framework (RDF) goes one step further by making the relationship between an element and its containing class an explicit part of every triplet. If this relationship is specified in a controlled terminology, then assertions can be tested for validity. For example, if an RDF Schema Specification (RDFS) asserts that the finding site of a lesion must be an anatomical feature, then assertions about actual lesions can be tested for valid finding sites. Furthermore, this logic specifies a “range” in the same syntactic structure as the instance assertion: changes to the knowledge base do not affect the syntactical representation of the knowledge. Systems that adopt this approach will require effort to take advantage of new features of terminologies, without having to rebuild their infrastructure when changes are made.

Having change data in discrete tagged change sets will allow the software to hide most of the complexity of version management from the human managers, allowing them to focus on significant decisions.

2.3. Configuration Requirements

A granular self-describing model will support any statement that can be made using concepts in a subject-predicate-object structure, and its compositional aspect permits compound predicates. It is difficult to imagine a proposition that cannot be supported, however, this means that there are multiple ways to support any specific kind of statement that a terminology knowledge base must support. This section addresses best practices for these cases.

2.3.1. Operations

<u>Import</u>: A user may identify content from another system and write it into the Terminology Repository. When this happens, the new content will be recorded in the common, self-describing format. When a set of content is imported, rules asserted by the source steward or the Terminology Repository steward may be used to assert structural equivalence in the repository (i.e., different source concepts may be represented as alternate representations of the same root concept). During importation of subsequent versions of a system, changes to assets on which other enterprise assets depend must be identified and managed as directed by documented policies. The import operation will usually identify sets of such changes which require prioritization to prevent redundant processing.

<u>Search (Requirement 24)</u>: A user may use lexical or concept-based parameters to search for a set of matching assets.

<u>View (Requirement 25)</u>: A user may view an asset, the view consisting of related information associated in visually appropriate ways. This view may omit information not appropriate to the user’s context.

<u>Compare (Requirement 12)</u>: A user may view related assets, including versions of component, in a form designed to support analytical comparison (e.g., side-by-side display).

<u>Authoring/Maintenance</u>: A user may modify existing content or add new content. To preserve prior states, all modifications are recorded as new versions of content: prior versions will remain unchanged. Any time a change is made, the system will identify dependent assets and rules for handling these changes.

- An addition (Requirement 26) is a new version with a new asset UUID (universally unique identifier). Patterns may assert constraints for additions, which may be specific to context (Modules, Paths, Languages, etc.).
- An inactivation (Requirement 27) is a new version of an existing asset with status set to "inactive." Patterns may assert rules for deletions, which may be specific to context.
- A change (Requirement 28) is a new version of an existing asset with the new value(s), distinguishable by STAMP value. A change may involve only a STAMP value. For example, deactivation, or import of a concept to a new module or path.

Classify (Requirement 29): A user may select a logical profile and classifier and use classification logic to test equivalence and subsumption of identified assets, or to generate a set of inferred relationships from a set of stated relationships. An inferred set may be persisted.

Publish (Requirement 30): A user may promote content into a "publication" path and produce a transmissible payload of content that can be consumed by other repositories. This promotion is a change and may require resolution of constraints on membership in that path.

2.3.2. Patterns for Representing Various Assets

The data architecture must support patterns for the representation of many kinds of assets. A minimal list includes the following:

1. A **term** must have:
    a. A string representation
    b. A language, possibly including refinements
    c. An indicator of case sensitivity
    d. A type used to represent whether a term is a synonym, fully qualified name (for example: SNOMED CT® Fully Specified Name or LOINC® Long Common Name), definition, etc.
2. A **concept** must have:
    a. At least one term
    b. At least one parent, except for root concepts or terminologies that are not hierarchical
3. A **logical definition** must have:
    a. A definitional status
4. **STAMP values must include**:
    a. "Active" and "inactive" status concepts
    b. At least one "default" author
    c. At least one "root" module
    d. Paths supporting "development" and "publication"
5. An **inferred classification** must indicate:

   a. The classifier used for its generation

   b. The logic profile used for its generation

   c. The stated asset(s)

6. The **module dependency** graph:

   a. Identifies the root module

   b. Lists all other modules, indicating dependency

   c. Must be acyclical

Many other patterns may be present. Implementations are expected to support:

7. **Any assembly of relationships** associating one concept with another which must have:

   a. At least one default rule (constraint) for handling changes (e.g., whether assets dependent on changed assets can be automatically handled or require intervention)

8. **Any assembly of relationships** may include components that are themselves semantics

9. **Value sets** may include:

   a. Rule-based member inclusions

   b. Enumerated members

10. System-specific **import rules**:

    a. System equivalences for Tinkar attribute and other infrastructure concepts

    b. Specified exclusions of logical assertions to support equivalence-on-import inferences irrespective of administrative metadata

11. **Maps**:

    a. Relationships for equivalence assertions

    b. Relationships for subsumption assertions

    c. Relationships for other functions (e.g., U.S. Center for Disease Control and Prevention (CDC) Reportable Condition Mapping Table)

12. **Constraints** on asset patterns, including:

    a. Logical composition constraints on concepts (e.g., the SNOMED CT® concept model)

    b. Syntactic compositional constraints on strings (e.g., Multipurpose Internet Mail Extension [MIME] types, International Organization for Standardization [ISO] languages, or UCUM units)

    c. Pattern constraints, e.g., presence of exactly one name classified as “fully specified,” or names in specified languages

    d. Rules that may govern modifications to other assets (e.g., incremental addition of effort estimates based on known problematic terms).

One other feature is the set of concepts that the application will use to determine how to present the data to the user. A key dimension is the STAMP information defined above. In addition, three other "coordinates" are required for managing the presentation:

13. **Language**: A user may assert a required or preferred language, or a set of ranked language priorities.

14. **Logic**: A user may select the parameters for logical classification.

15. **Navigation**: A user may select the parameters for presentation of the logical classification

Like other concepts, these can be represented by the core data architecture. The application implementing the Tinkar specification must be able to identify those concepts appropriate for these uses.

2.3.3. Constraints

Constraints are required to:

1. Ensure that the appropriate level of detail for standard terminologies are represented within Tinkar

2. Create terminology extensions that conform to the requirements of the standard(s) the extension is based on

3. Perform general quality assurance

For example, constraints would be used to represent standard terminology artifacts, like the SNOMED CT® Machine Readable Concept Model. Additionally, constraints could be used to ensure that the terminologies represented within a Tinkar implementation are completely and consistently queried and displayed.

These same constraints can be used to create new content within a Tinkar implementation to specify the minimally viable data that would be required. For example:

4. All concepts must have at least one Fully Qualified Name within at least one Language or Dialect

5. All concepts must have at least one Name specified as Preferred within at least one Language or Dialect

6. All concepts must have at least one parent, unless it is a root concept

Constraints can be applied (or not applied) based on various criteria to perform Quality Assurance on content that is represented within a Tinkar implementation. For example:

7. SNOMED CT® Fully Specified Name hierarchy tags are applied based on where a concept exists in a hierarchy

8. Relationships between concepts have domain (based on hierarchy) and range (the hierarchy(s) of values that a relationship takes)

9. Modeling templates can be specified to ensure that new content that is created under a certain node in a hierarchy uses similar wording and relationships

Since some Quality Assurance Constraints do not always indicate an error, an Allow List could also be represented as a Semantic to record concepts that are allowed to not conform to a constraint. Constraints would be represented using semantics as they are self describing and can support multiple different representations for constraints (SNOMED CT® Expression Constraint Language, Drools, etc.). Representing Constraints as a Semantic also ensures STAMP. STAMP is versioned over time, capturing author information and allowing for tests and progress over different modules and paths.

Implementing Constraints would depend upon how the Constraints are written and formatted. For example, implementers could utilize a Rete algorithm through something like Drools to implement Constraints.

2.3.4. Minimally Required Content

A Tinkar implementation must be furnished with the following content:

1. One root concept
2. One module dependency graph
3. Infrastructure concepts a.k.a Tinkar Model Concepts to support the core patterns listed above
4. Import rules to support import of standard terminologies, including:
    a. Equivalences to support semantic integration of terminologies (e.g., that a LOINC® “system” instantiates the same relationship concept as the SNOMED CT® “inheres in” attribute)
    b. Exclusions to support removal of non-semantic properties from classification (e.g., RxNorm Translated CDs)

2.4. List of Requirements

ID	Requirement	Level	Clinical System	Terminology Management	Information Design
1	Support the practice and coordination of safe, effective medicine	Need	x		
2	Provide quality information in the patient record	Need	x		
3	Represent information in commonly understood data standards	Feature	x	x	x
4	Provide terms appropriate to the context	Feature	x	x	x
5	Capture terminology suggestions from point of care	Function	x		
6	Indicate data for which changes to the terminology could affect record interpretation	Function	x	x	x
7	View available terms and decision support recommendations for specified dates and contexts	Function	x	x	x
8	Support rapid and accurate recording and review of record data	Need	x		
9	Manage change systematically	Feature		x	x
10	Identify assets uniquely	Function		x	x
11	Retain all prior versions	Function		x	x
12	Support comparison of versions	Function		x	x
13	Support branching of sets of assets for independent development	Function		x	x

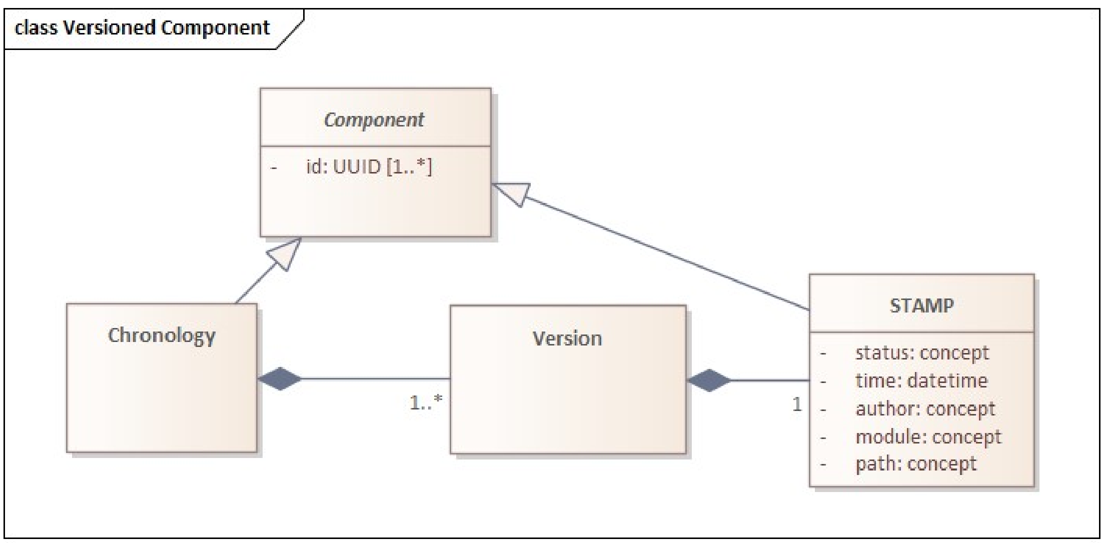
ID	Requirement	Level	Clinical System	Terminology Management	Information Design
14	Support controlled merging of branches by identifying and addressing conflicts with defined rules	Function		x	x
15	Modify enterprise terminology by creating, modifying, or deactivating assets and relationships	Function		x	x
16	Import standard terminologies, including merging capability for assets referring to prior versions of the standard	Function		x	x
17	Publish enterprise terminologies, including application and resolution of constraints specific to the publication path	Function		x	x
18	A self-describing method for representing terminology assets from diverse and mutable models	Feature			x
19	Represent the status of the asset in a context	Function		x	x
20	Represent the time at which a change is recorded	Function		x	x
21	Represent the author of a change	Function		x	x
22	Represent the system or sub-system of an asset	Function		x	x
23	Represent the path or branch of an asset version	Function		x	x
24	Support search using lexical or logical criteria	Function		x	
25	Support detailed view of assets and diverse properties, filtering content not relevant to the chosen context	Function		x	
26	Add terminology assets, including concepts, terms, relationships, definitions, value sets, maps, and others	Function		x	x
27	Deactivate assets, preserving their original form	Function		x	x
28	Modify assets, preserving their original form	Function		x	x
29	Classify assets using identified tools and logical profiles in chosen contexts, with the option to persist the inferred assets	Function		x	
30	Process a set of content for publication, including identification and resolution of unresolved constraints	Function		x	

3. Tinkar Reference Model

The Tinkar Reference Model is a logical model described herein using the *Object Management Group (OMG) UML 2.0* notation to describe the structure of integrated data representation and change management for biomedical terminologies. Tinkar provides an architecture that delivers integrated terminology to the enterprise and its information systems. In doing so, it addresses the differences in management and structure across reference terminology, local concepts, and code lists/value sets. This section describes classes of objects that support a common foundational framework for terminology and knowledge base systems (e.g., SNOMED CT®, LOINC®, RxNorm, HL7). An implementation of Tinkar can provide a single representation for all terminologies required in the U.S. and other countries, while also providing a better foundation for managing change. Tinkar could support the operation of a variety of systems intended to deliver knowledge management for terminology to vendors providers, and standards-development organizations like HL7.

3.1. Standard Class Model

Figure 3.1. Versioned Component



Versioned Component

The Tinkar Reference Model fulfills the requirement of capturing a complete record of all changes, including relevant context information. This is captured via the STAMP class using the following fields:

1. **Status:** A status is identified by a concept, which may be annotated with other identifying information. For example: active or inactive (???Requirement_19)

2. **Time:** Timestamps must employ a common standard, which must support precision and time zone. (???Requirement_20)

3. **Author:** An author is identified by a concept, which may be annotated with other identifying information as required. (???Requirement_21)

4. **Module:** Assignment to the appropriate terminology (e.g., LOINC®) or terminology component (e.g., SNOMED CT®, US Extension). A module is identified by a concept, which may be annotated with other identifying information. (???Requirement_22)

5. **Path:** Specification of an object under version control within a terminology development lifecycle, e.g., for distributed development, testing, staging, or production. A path is a common synomyn for "branch" as used in current software version control best practices/literature. A path is identified by a concept, which may be annotated with other identifying information. A core set of paths is necessary to support publication to external organizations. (???Requirement_23)

These elements together are referred to by the acronym "**STAMP**," as described previously. Every new assertion, whether a new component or a change to an existing component, must have a STAMP to determine when it is to be used. The STAMP properties support the ability to apply terminology components for specific purposes. For example,

- "Path" can be used to test provisional content without physically swapping out systems.
- "Module" can be used to filter out work that has not been authorized by the enterprise.
- "Time" supports the ability to apply CDS rules as they would have looked in the past.

The Tinkar Reference Model does not merely support the ability to "STAMP" components; it asserts a requirement that all changes have a STAMP. STAMP assertions are unversioned IdentifiedComponents that are referenced by the components they scope. Since STAMP uses versioned concepts (that have a STAMP), having the STAMP as a versioned component would lead to an infinite regress.

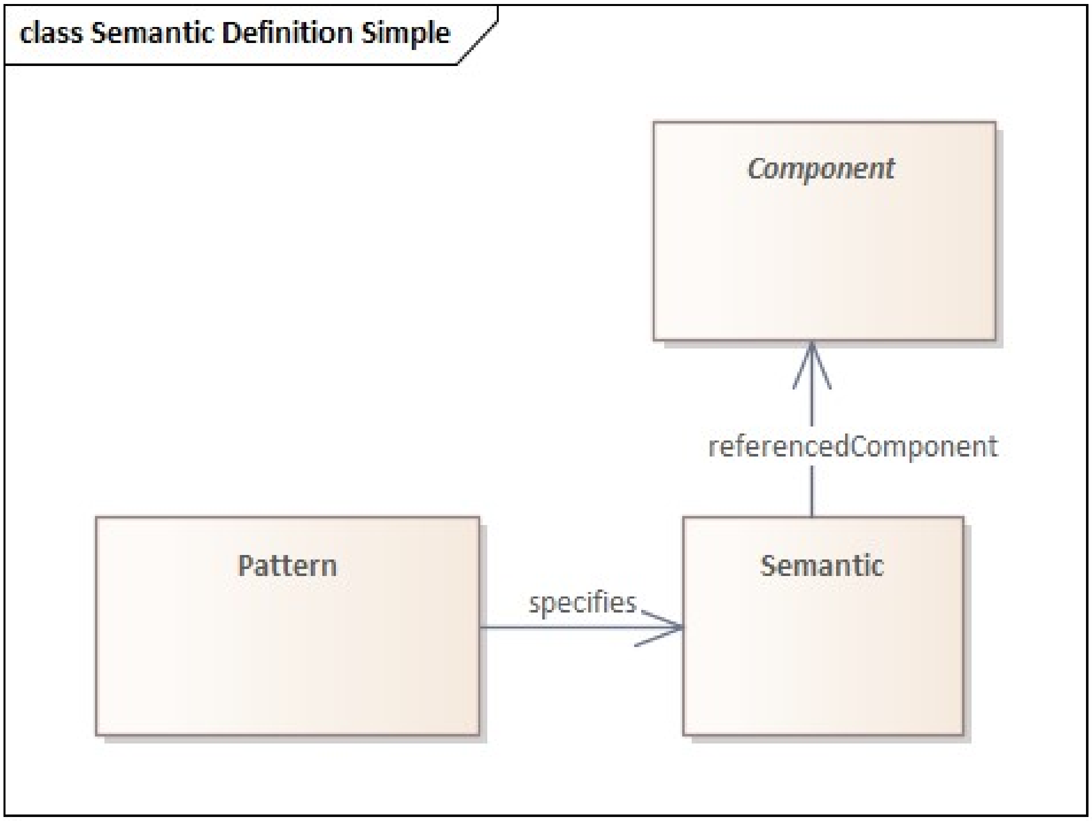
Not all terminology systems contain all the information recorded in STAMP, but defaults can be used in cases where it is missing. For example, SNOMED CT® contains the Status, Time, and Module but do not distribute the Path or Author. Since most terminologies only release a Production path, the Path could be defaulted to Production Path and the Author could be defaulted to SNOMED CT® Author.

All IdentifedComponents in the knowledge base will consist of a series of change records, called ComponentVersions, (beginning with the "Create" version), all associated to an underlying ComponentChronology.

A Components Chronology only has properties attributed to it by its versions. Looking at the IdentifiedComponent through different sets of changes (published version, geographically defined set of modules, historical timestamp) may reveal substantially different IdentifedComponents.

3.2. Component Types

Figure 3.2. Component Types



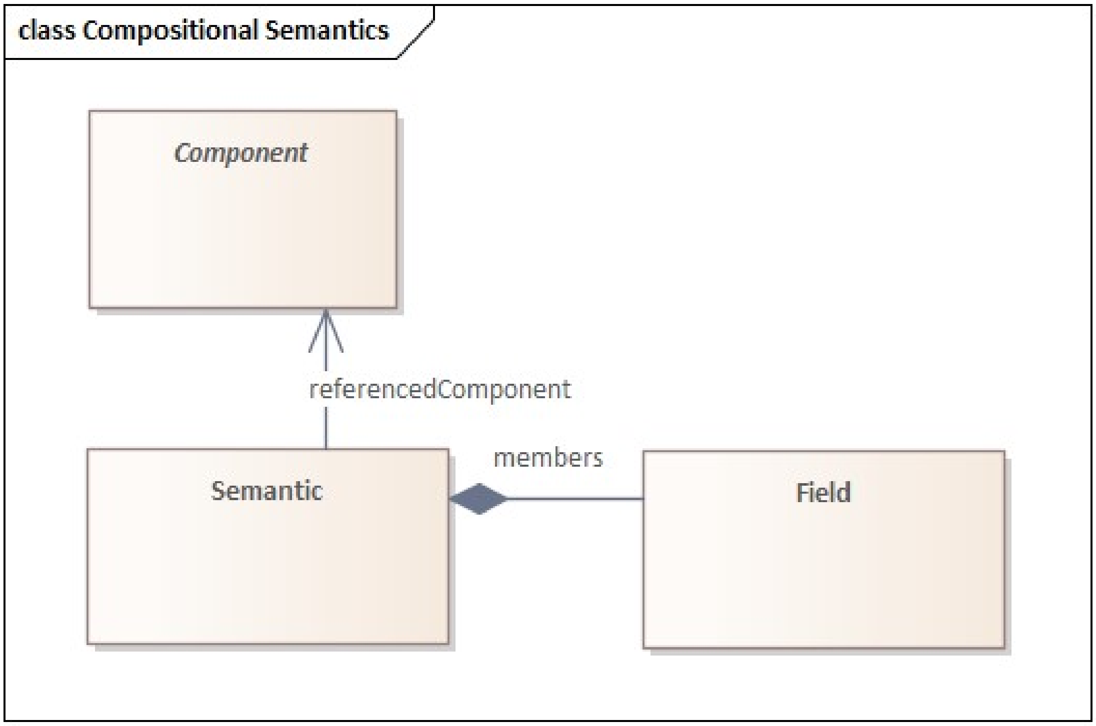
Component Types

All Components in Tinkar are uniquely identified using UUID. A Component will be represented by an array of UUIDs with at least one UUID, but can be represented by more than one UUID in the case of a concept being derived from multiple sources. For example, the concept Acetaminophen (which exists in SNOMED CT®, LOINC®, and RxNorm) could have a UUID from each terminology and be represented as an array of UUIDs for this single concept within a Tinkar implementation.

A Concept is identified using UUIDs and contains no information. To assemble groups of assertions and to provide information about Concepts, Tinkar uses a construct called a **Semantic**. A Semantic is a class containing a set of predicates and objects about a subject. A semantic adds meaning to the components it references, through the fields it contains. A Semantic supports the specification of value sets, compositional definitions, and other components requiring internal structure, and it specifies the nature of the compositional relationship explicitly.

The Semantic class uses a Concept to define the relationship between the value(s) and the Concept; the value itself may be either a concept or some other kind of data type, such as a string. This creates the ability to assemble assertions into more complex structures.

Figure 3.3. Compositional Semantics



Compositional Semantics

As discussed earlier, if an author makes a change to an IdentifiedComponent, the prior Version is unchanged, but a new version – with the appropriate STAMP information – is recorded. Users viewing the Concept and associated Semantics in the prior context (i.e., as of the prior time, if no other STAMP element has changed) will see the old values; users viewing the Concept and associated Semantics in the new context will see the new values.

Since it is versioned, a Semantic is manifested as a **SemanticChronology**, containing a set of **SemanticVersions**. SemanticVersion is a single instance of a Semantic with a STAMP, and a SemanticChronology is the set of versions having a STAMP for a Semantic. Concepts, too, are manifest as collections: a **ConceptChronology** consisting of a set of **ConceptVersions**. ConceptVersion is a single instance of an identifier for a concept with a STAMP and the ConceptChronology is the set of versions having a STAMP for a concept. A concept identifier specifies a ConceptChronology; specifying a ConceptVersion requires a rule or parameter for selecting among STAMP values.

If other IdentifiedComponents depend on the changed concept, these IdentifiedComponents can be identified by relationships in the Semantics. The Semantics can assert rules for how to manage these changes. A Semantic defining a value set for data entry might automatically accept any deactivations from the source system authority, while a Semantic defining a value set for research might automatically decline to adopt deactivations, or do so based on whether there are extant operational values. Escalating such decisions for human adjudication or review at multiple levels is also always an option. Systems might adopt any number of methods for dealing with identified changes: the important thing is to ensure the changes can be identified consistently.

3.3. Field Data Types

Tinkar supports the following field data types for use with Semantics.

1. String - a sequence of characters, either as a literal constant or as a variable. Strings could be used to represent terms from code systems or URLs, textual definitions, etc

2. Integer - data type that represents some range of mathematical integers

3. Float - represents values as high-precision fractional values

4. Boolean - represents the values true and false

5. Byte Array - an array of 8-bit signed two's complement integers

6. Directed Graph or Digraph - a graph whose edges are ordered pairs of vertices. Each edge can be followed from one vertex to another vertex

7. Instant - models a single instantaneous point on a timeline

8. Planar Point - position in a two-dimensional space (a plane)

9. Spatial Point - position in a three-dimensional space

10. Component ID List - an ordered list of Component IDs

11. Component ID Set - an unordered list of Component IDs

12. UUID - A 128-bit number used to identify information in computer systems

13. Directed Tree or Ditree - a graph obtained from an undirected tree by replacing each undirected edge by two directed edges with opposite directions

14. DiGraph - A graph in which a set of objects are connected where all the edges are directed from one vertex to another

15. Vertex - The fundamental unit of data that makes up a graph or tree

    a. In Tinkar, property graphs are used as a general-purpose data pattern to represent an abstract syntax tree (AST), such as Web Ontology Language (OWL) EL++. This allows for data types without requiring custom nodes.

        i. An AST may be used "during semantic analysis, where the compiler checks for correct usage of the elements of the program and the language. The compiler also generates symbol tables based on the AST during semantic analysis. A complete traversal of the tree allows verification of the correctness of the program. After verifying correctness, the AST serves as the base for code generation. The AST is often used to generate an intermediate representation, sometimes called an intermediate language, for the code generation." [15]

        ii. An AST is made up of nodes and branches. In Tinkar, every tree will always have roots, but they are specific: "An OWL EL root" vs. a "BPMN root", etc. Each node must have 0 or more children.

    b. Here is an example of Tinkar output of semantics that reference multiple concepts.

Figure 3.4. Multi-Concept Tinkar Output

```
Field 1: [
EL++ Stated terminological axioms: DiTreeEntity{
   [0]→[8] Definition root
      [8]→[7] Necessary set
         [7]→[5,1,6] And
            [5]→[4] Role type: Role group
               •Role operator: Existential restriction
               [4]→[3] And
                  [3]→[2] Role type: Is modification of
                     •Role operator: Existential restriction
                     [2] Concept reference: Acetylsalicylic acid
            [1] Concept reference: Salicylate
            [6] Concept reference: Antiplatelet agent
}]
```

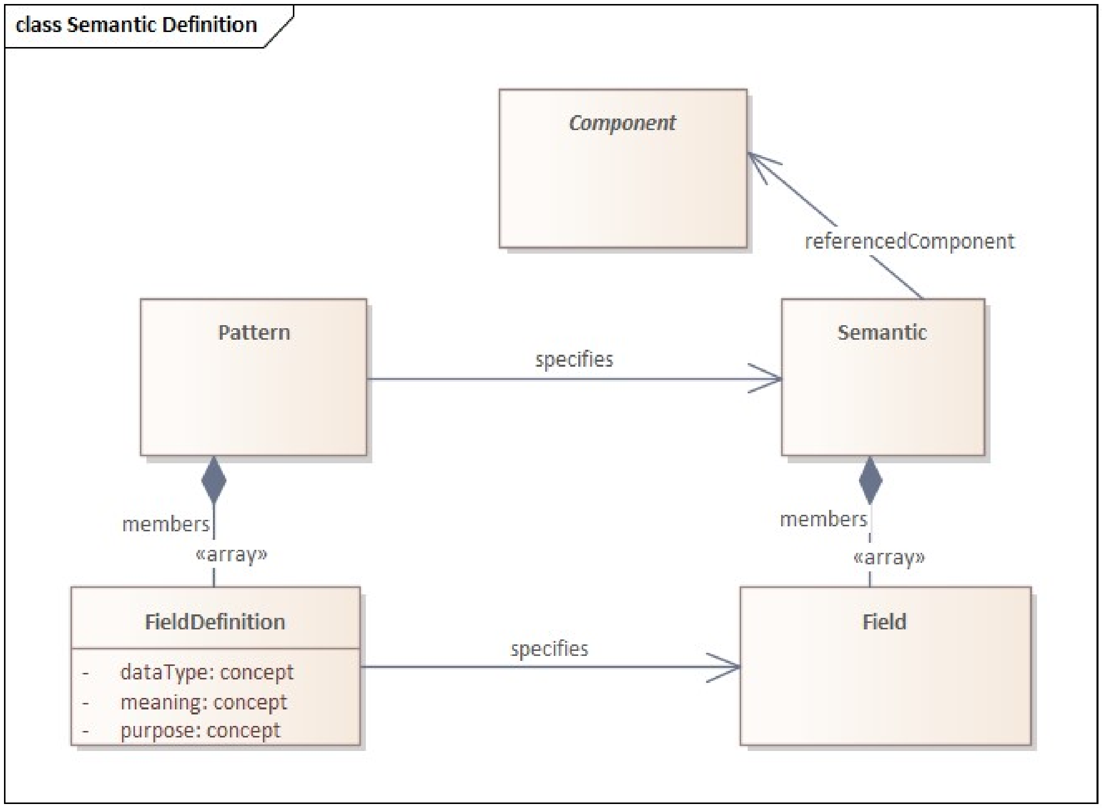
In this output, one can see a sufficient set and necessary set. Bulleted items are properties in the node. The output is printed as a "depth first search." Each depth adds 3 characters of padding and shows how OWL EL++ definitions, using only terminology and a standard property graph data structure, are represented. The 1st one is node index 0 which has a child of node index 8. Node index 0 is the OWL EL++ definition root. Node 8 points to Node 7, and the meaning of Node 8 is that it is a necessary set. Node 7 is 'And' and points to Node 5,1,6. Node 5's meaning is 'Role Type', Value is 'Role group', and its other property is 'Role Operator.' Node 5 points to Node 4. Node 4 is 'And.' Node 3 is 'Role Type.' Node 2 is Concept Reference. 7 also points to 1 and 6 (Concept References).

c. The property graph model demonstrates that each vertex has a meaning. Tinkar can use concepts to represent anything end users might need at nodes. This allows for data types without requiring custom nodes. With no changes to the underlying data structures, Tinkar can represent more than OWL EL++. With updates to terminology, Tinkar can represent any parsable standard, such as Business Process Model and Notation (BPMN) and Decision Model and Notation (DMN), using this property graph model and a proper set of terminology concepts and semantics represented using Tinkar.

3.4. Pattern (For Semantics)

The Tinkar Reference Model defines a first-class feature of the model, the **Pattern** (**PatternVersion** and **PatternChronology**). A Pattern is a class defining a set of predicates and object types that can be asserted about a class of subjects. All Semantics follow Patterns. A PatternVersion is a single instance of a pattern with a STAMP and a PatternChronology is the set of versions having a STAMP for a pattern. This feature asserts patterns that Semantic components can follow, like an XML or RDF Schema.

Figure 3.5. Pattern

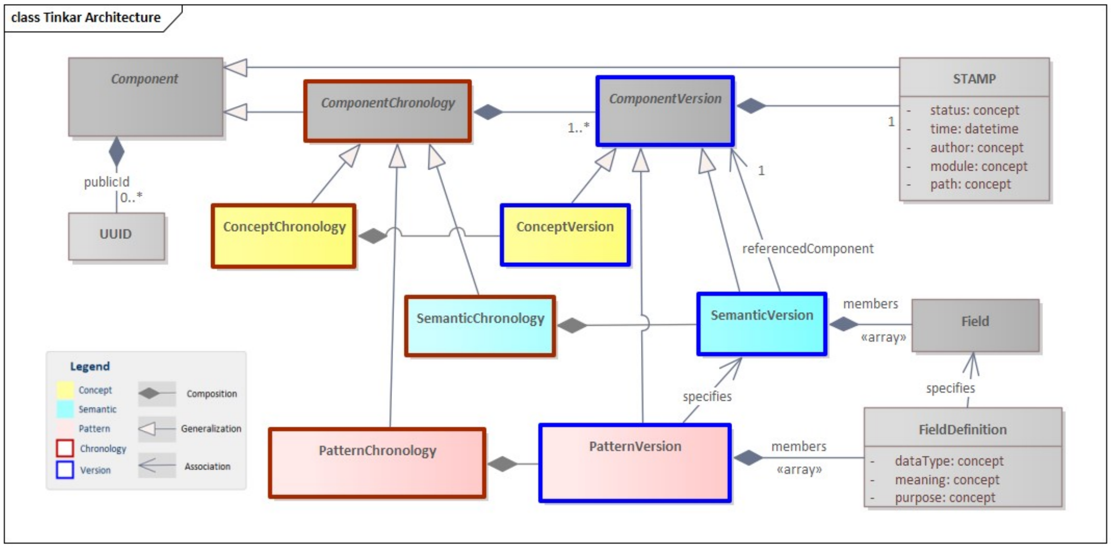


Pattern

Using the Pattern, Semantics with varying fields and data types can be specified to represent any structure needed to provide meaning to a concept. For example, if a field within a semantic is used to describe an SDO’s website, the Meaning would be “URL,” DataType of “String,” and Purpose of “Website.” The Pattern would then contain an array of these FieldDefinitions.

3.5. Overall Tinkar Architecture

Figure 3.6. Overall Tinkar Architecture



Overall Tinkar Architecture

Class Definitions
Concept - An identifier for a concept or instance. The identifier contains no information; all information specifying or describing the concept is asserted with Semantics. **ConceptVersion** - A single instance of an identifier for a concept with a STAMP. **ConceptChronology** - The set of versions having a STAMP for a concept. A concept identifier specifies a ConceptChronology; specifying a ConceptVersion requires a rule or parameter for selecting among STAMP values. **Semantic** - A class containing a set of predicates and objects about a subject. Semantics perform the descriptive work in Tinkar. **SemanticVersion** - A single instance of a Semantic with a STAMP. **SemanticChronology** - The set of versions having a STAMP for a Semantic. **Pattern** - A class defining a set of predicates and object types that can be asserted about a class of subjects. All Semantics follow Patterns. **PatternVersion** - A single instance of a pattern with a STAMP. **PatternChronology** - The set of versions having a STAMP for a pattern.

3.6. Coordinate

The Tinkar Reference Model supports and encourages the storage of time series data that utilizes multiple coordinates, for example, STAMP, Language, Dialect, clinical domains, etc. The ability to efficiently search, display, and navigate concepts and semantics requires the ability to calculate combinations of content based on one or more of these different coordinates.

In order to facilitate the computability of various, complex coordinates, including time series data, a graph structure is commonly used in software versioned control systems. A particular type of graph structure that is commonly used is a “version graph,” such as a directed acyclic graph. A version graph would enable a Tinkar implementation to recover the state of the graph at a particular point in time. Most graph databases do not support versioning as a first-class concept. It is possible, however, to create a versioning scheme inside the graph model whereby nodes and relationships are timestamped and archived whenever they are modified. The downside of such versioning schemes is that they leak into any queries written against the graph, adding a layer of complexity to even the simplest query.

Types of Coordinates:

1. STAMP coordinates are the most basic type of coordinate on which all content should be filtered. Examples of STAMP coordinates are:
    a. Most recent version
    b. Set of data from several versions
    c. All active components only
2. Language coordinates are used to control the terms that should be displayed. Examples of Language coordinates are:
    a. Displaying terms based on a language and/or dialect
    b. Prioritized list of synonyms based on a particular clinical domain
3. Logic coordinates are used to identify the various results from Description Logic Classifiers as well as the different versions of the output over time:
    a. Result from various Description Logic Classifiers
4. Navigation coordinates are used to assist in viewing and searching for a particular concept. Examples of these would be:
    a. Stated vs. inferred relationships from SNOMED CT®
    b. Concepts inclusion/exclusion for a particular domain

As the Tinkar specification evolves towards a Draft Standard for Trial Use (DSTU) and Connectathons, more coordinates and detailing will be provided.

3.6.1. Calculating Coordinates

The ComponentChronology contains all the versions of a component from the date it was instantiated until the most recent version. Components only get a new version whenever something about the component changes. To calculate the latest version requires the ability to find the most recent version of each component. Utilizing the STAMP Coordinates supports calculating all other coordinates:

1. Identify the Module(s) the user would like to view/search/modify.
2. Identify the Path the user would like to view/search/modify.
3. Identify the Status or Statuses the user would like to view/search/modify.

4. If relevant, identify the Author(s) the user would like to view/search/modify.
5. The last piece of the STAMP coordinate (time) is the most difficult to calculate. In most cases the user will need to find the most recent version of the component as of the current time to calculate this point of the coordinate. However, since Tinkar supports and encourages the representation of historical, the user may need to calculate the most recent version as of a different point in time.

After the STAMP Coordinates have been calculated, additional coordinates can then be applied as well. For example, applying a language and dialect coordinate will be important not only for viewing and searching, but also to determine the appropriate preferred name for displaying a hierarchy.

3.6.2. Next Steps Around Coordinates

As the Tinkar specification evolves towards a DSTU and Connectathons, more coordinates and detailing will be provided.

3.7. Future Iterations

The current Tinkar Reference Model is expressive enough to be able to represent any terminology. Future iterations of the Tinkar specification will require harmonized implementation guides to be created for each terminology. Doing so will ensure that implementers will be able manage terminology produced by a variety of organizations across a healthcare enterprise. Harmonized implementation guides will also support healthcare organizations' standard terminology modules, value sets, and coding systems as well as local terms and equivalence mappings.

Additional metadata from standards like Dublin Core or FHIR that may not currently be supported with the current Tinkar Reference Model could be supported using Concepts and Semantics. However, further changes to the Tinkar Reference Model may be needed if they cannot be supported using the current model.

4. Next Steps

Tinkar is a logical model and therefore may be implemented using relevant implementable models and technology. This section will focus on the use of Tinkar alongside preexisting HL7 exchange standards. In practice, the Tinkar logical model can be used to create practical implementation guidance in the future (e.g., implementation guides, profiles, value sets), and can be applied to design change management solutions.

4.1. Tinkar Serialization Data

Tinkar will include a serialization format that will serialize any or all the information stored in a Tinkar implementation. This serialization format will allow third parties to read data created by a Tinkar compliant implementation. A serialized Tinkar file can also be used to transfer information between different Tinkar implementations. This will ensure that no Tinkar data is lost.

C# and Java code implementations of the Tinkar Data Model will be made available to integrators, allowing third parties to more easily use Tinkar.

Specifically, third party implementers can use Java or C# to:

1. Read Tinkar data into memory.
2. Manipulate and modify Tinkar data using Tinkar data structures.
3. Write Tinkar data out to a serialized file.

4.2. Tinkar interfacing with Fast Healthcare Interoperability Resource (FHIR)

Tinkar data can be used to create FHIR compliant data. Tinkar data can be used to generate FHIR data. Only a subset of the Tinkar data model would be converted to FHIR. Roundtripping of data between Tinkar and FHIR back and forth is likely to result in Tinkar data loss.

Tinkar data items lost in FHIR conversion:

1. STAMP data: Loss of the STAMP data means that the ability to look at terminology at a specific point in time is lost. The FHIR data is a snapshot at a fixed point in time.
2. Semantic data: FHIR data does not contain a concept similar to Tinkar's semantic relationships.

There are two main areas in which Tinkar and FHIR are expected to interface, as described in the subsequent sections: "Dynamic FHIR Terminology Servers" and "Static FHIR CodeSystem and ValueSet Resources."

4.2.1. Dynamic FHIR Terminology Servers

FHIR terminology servers are designed to provide knowledge artifacts in real time to support clinical system operations. A system may request $expand on a ValueSet, for instance, to populate a drop-down list in a user interface, or $validate-code to confirm content in an interface conforming to a profile; a request for $subsumes on a CodeSystem or on a ConceptMap can be used to translate codes when transforming native records to a standard format, and so forth.

FHIR queries against the FHIR terminology server could use Tinkar originated terminology data as well as other non-Tinkar generated terminology to fulfill the requests.

The serialization file described above would be one way to import data from a Tinkar system to a FHIR terminology server. Implementers for each FHIR Terminology Server would have to write code specific to their implementation to import Tinkar data into their own implementation dependent data storage.

The Tinkar C# and Java libraries could be used by the FHIR Server Implementors to help support that import process.

4.2.2. Static FHIR CodeSystem and ValueSet Resources

FHIR CodeSystem and ValueSet records are designed to provide knowledge artifacts to support clinical system operations. Terminology data contained in FHIR CodeSystem and ValueSet resources are fixed at the time that the resource instances are generated.

It is expected that some automated means of creating FHIR ValueSet and CodeSystem records from Tinkar will be developed. The automated system could import data from a Tinkar system using the serialization format described above, and output desired CodeSystem and ValueSet instances. Modifications to the Tinkar data would require regeneration of the FHIR artifacts and subsequent transmission to interested users of those resource instances.

4.3. Tinkar interfacing with HL7 Unified Terminology Governance (UTG), HL7 Terminological Content (THO), and HL7 Terminology Authority (HTA)

The three HL7 processes for maintaining and distributing HL7 terminology content are Unified Terminology Governance (UTG), HL7 Terminological Content (THO), and HL7 Terminology Authority (HTA). Our understanding of these HL7 Areas:

- **UTG**: A process with associated tooling to support the process strictly for governance of HL7 terminological content. UTG is the maintenance process to keep it up to date and manage change.
- **THO**: HL7 Terminological Content refers to terminology.HL7.org (THO) which is the domain address of the entry point for the published content. HL7 terminology or THO refers to an enormous corpus of coded content that varies in quality and that has been developed in HL7 for about 30 years.
- **HTA**: The HTA's primary purpose is to deal memorandum of understanding and publication interfaces with non-HL7 publishers and maintainers of terminological content.

The aim of these HL7 groups, to provide standardized HL7 terminology in a consistent format, is consistent with the goal of Tinkar.

If HL7 so desired, Tinkar could be used as the format by which all HL7 terminology is exported. It is believed that current HL7 content can be converted to Tinkar with no loss. Further work would need to be done to verify that if HL7 was interested in that path.

Conversion of HL7 common terminology data to Tinkar would allow:

1. Use of tools like KOMET to import, export, maintain and validate HL7 terminology data

2. Use of Tinkar serialization format for serialization and distribution format

3. Use of Tinkar and third-party tooling to convert Tinkar serialized data to FHIR records and import to FHIR terminology servers

5. Key Takeaways

1. Terminology Knowledge Architecture (Tinkar) intends to integrate clinical terminology and local concepts to support increased data quality for interoperable clinical information. Quality clinical data enables healthcare systems across the enterprise to conduct robust and meaningful data analysis and increase overall interoperability, which ultimately enhances quality of care across all medical facilities.

2. A Tinkar specification provides a standardized model for terminology and change management.

3. The Tinkar Reference Model could provide a single representation for all terminologies required in the U.S. (e.g., SNOMED CT®, LOINC® , RxNorm).

4. Tinkar provides the foundation of a knowledge architecture that delivers integrated terminology to the enterprise and its information systems. In doing so, it addresses the differences in management and structure across reference terminology, local concepts, and code lists/value sets.

5. Tinkar aims to be both self-describing and completely machine processed:

    a. Self-describing machine-readable representation of terminology, such that if an application can process the metadata, it should be able to import the content/concepts and make it available to enterprise applications.

    b. The machine-readable terminology could generate human-readable documentation so that business analysts and developers can understand and apply it correctly.

6. If HL7 so desired, Tinkar could be used as the format by which all HL7 terminology is exported. It is believed that current HL7 content can be converted to Tinkar with no loss; further work would need to be done to verify that if HL7 was interested in that path.

7. In practice, the Tinkar logical model can be used to create practical implementation guidance in the future (e.g., implementation guides, profiles, value sets), and can be applied to design change management solutions.

6. Foundational Architecture

6.1. Foundational Architecture Challenges

Integrated Knowledge Management (IKM) will be composed of an integrated clinical transformation process to represent and bring together disparate terminology standards by using a single model that can encompass any customized content. We understand that health IT systems must address the following antipatterns:

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

6.1.1.1. 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 use to identify what organization created the components that were 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.

6.1.1.2. 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 organization's namespace. Furthermore, there is the need for the 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.

6.1.1.3. 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.

6.1.1.4. 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.

6.1.2. Design by Committee

A project that has many designers involved but no unifying plan or vision.

6.1.2.1. 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.

6.1.2.2. Interoperability at the Expense of Operability

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

6.1.2.3. 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.

6.1.3. Stovepipe

The Stovepipe Enterprise antipattern is characterized by a lack of coordination and planning across a set of systems. If every subsystem has a unique interface, 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.

6.1.3.1. 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® both 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-user's 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®), and the NLM (owners of RxNorm) will change the coordination of these 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 identifies over 150 sources, most of which are uncoordinated, and have independent models. These overlapping and unreconciled models create an unnecessary burden for the implementer.

6.1.3.2. 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 International Classification of Diseases Tenth Revision Clinical Modification (ICD-10-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?

6.1.3.3. 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 relatively nascent, and pharmacy, laboratory, and clinical systems are poorly integrated. However, if we successfully create compelling decision support on an integrated and shareable 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.

Here we propose leveraging opportunities that are helping to break down these barriers. 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.

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