CIMI Modeling and Quality Guide

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1. Introduction

1.1. Background

The Clinical Information Modeling Initiative (CIMI) is an HL7 group that is defining a library of detailed clinical information models using a common modeling formalism. CIMI was established to improve the interoperability of healthcare information systems through shared implementable clinical information models that can be used to generate platform-specific model specifications such as FHIR profiles or CDA templates. These models are grouped into semantically equivalent (or 'isosemantic') families of clinical models, which capture the same clinical meaning using different combinations of concept pre-coordination and corresponding information model structure.

1.2. Purpose

The purpose of the CIMI Modeling and Style Guide is to allow the reader to understand the big picture behind the CIMI Models and to enlighten interested CIMI stakeholders regarding CIMI model terms, models, representations, and approaches among CIMI participants. In this document we begin with broad-brush stroke description of the basics of the CIMI models and follow with the more technical aspects of CIMI modeling including the modeling patterns.

1.3. Scope

This document presents the specification of the Clinical Statement Pattern and the Topic/Context Pattern that are used to create detailed clinical models (DCMs). The CIMI models consist of computer processable language syntaxes structured as high level patterns that are either complete or under development and include:

- Structured Data (Clusters).
- The Clinical Statement Pattern.
- Topic Patterns.
- Context Patterns.
- Terminology Bindings.

1.4. Audience

The intended audience for this document is anyone trying to understand, develop, and/or use CIMI models. This includes:

- Modelers creating new models.
- Modelers who have developed models in a different format and are transforming their existing models into CIMI models.
- FHIR profile developers who are transforming CIMI models into FHIR profiles.

2. Model Transformations

A key capability of CIMI will be to support the generation of implementable artifacts based on the clinical expertise captured in the ‘logical’ clinical models.The initial target artifacts are FHIR profiles but subsequent targets include CDA, openEHR, ISO 13606, DCM, and CEM through a common logical model intermediary. These targets are focused on interoperability but there is no reason not to support representations for persistence, user interfaces, decision support, or any other form that may be of use.

Tooling for these transformations is under development.

2.1. Iso-semantic Models

The CIMI Working Group recognizes it is unlikely a one-size-fits-all approach will accommodate the wide variety of clinical and implementation use cases. As such, the CIMI architecture supports isosemantic models. Isosemantic models are models that while different in structure represent the same semantic content. Isosemantic models facilitate alternate representations of the same information to address the requirements of specific use cases. While generally such variations in expressivity are not recommended (CIMI defines a ‘preferred’ set of models), it is sometimes inevitable. For instance, interface models may have different modeling requirements than messaging models.

CIMI intends to support the ability to transform models into their isosemantic counterparts. This implies the ability to recognize identical information constructed using different patterns and assumptions regarding the boundaries between terminology pre-coordination and structure.

Once identified, isosemantic model sets will be defined by the following:

- A ‘preferred’ model providing the most fully articulated representation of the information (note that model governance has not been defined; therefore, how ‘preferred’ is designated and governed is yet to be determined).
- Associated models with identical semantics but different structures.
- Formal rules for transforming the associated model features into the preferred model features such as: .
  - Turning a pre-coordinated concept (e.g., suspected Lyme disease) into a set of explicitly bound attributes (Lyme disease + suspected).
  - Turning a concept binding (sphygmomanometer) into an associated class characterized by that binding (device + type = sphygmomanometer)

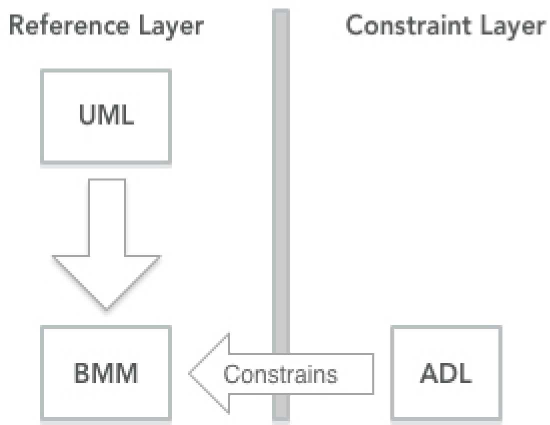
Isosemantic models varying in their degree of pre-coordination can generally be addressed at the archetype layer through attribute occurrence constraints. For instance, the AnatomicalLocation reference model pattern has a 'code' attribute to represent the body location and another 'laterality' attribute to indicate right or left. Two isosemantic models can be derived - one obtained by constraining out the 'laterality' attribue and only using the 'code' attribue with a valueset of codes that have the laterality concept pre-coordinated with the body location. The other isosemantic variant may only allow location codes that do not have a pre-coordinated laterality thus requiring the use of the builtin 'laterality' attribute.

3. Basics of the CIMI Model

The CIMI Model consists of two layers as shown in Figure 1, “CIMI Model Layers”. A reference model layer that defines the structural classes and named attributes, and a constraint layer which constrains these structural attributes by value, subtype, cardinality, and terminology. The basic modeling rule that CIMI follows is: new named attributes are added in the Reference Layer and the constraining of existing attributes occurs in the Constraint Layer.

The CIMI Reference Model layer is authored using Unified Modeling Language (UML). These class definitions may be viewed at http://models.opencimi.org/cimi_doc/.

Figure 1. CIMI Model Layers



The constraint layer is described using Archetype Definition Language (ADL). ADL is a formal language with a textual syntax for describing constraints on the classes described in the reference layer. A re-usable formal constraint model defined in ADL is called an Archetype. The full collection of CIMI Archetypes may be viewed at http://models.opencimi.org.

One complexity that needs to be addressed here is that ADL can only be used to constrain reference classes defined in a lightweight proprietary UML like specification called Basic Meta-Model (BMM). For this reason, CIMI has developed tooling that transforms the CIMI UML models into the BMM specification. Although this complexity does exist, to ease understanding, the reader can simply imagine that ADL is directly constraining the UML classes.

The UML/BMM classes are more abstract and the archetypes are where specific semantics such as 'blood glucose' or 'diabetes present; are asserted.

3.1. Structures

The CIMI UML/BMM model has three concentric layers: a Core that defines datatypes and a root class, a Foundation that describes compositional patterns similar to ISO 13606, and a Clinical model layer constructed on top of the Foundation.

Most clinical specifications will be based on the Clinical Statement pattern defined in the Clinical model layer. But this pattern does employ structures built out of Foundation and Core classes, so familiarity with these layers will be helpful. For more information consult the CIMI Architecture Guide.

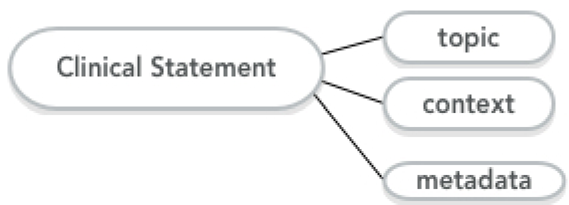
4. Clinical Statement Pattern

The central focus of the CIMI Reference Model is the Clinical Statement. A Clinical Statement represents structured electronic communication made about a patient typically documented as an 'entry' in the patient record. For example, Clinical Statement can be used to represent the following statements made about a patient.

- Patient has diagnosis of congestive heart failure.
- Patient has a family history of breast cancer.
- Patient has a goal of smoking cessation.
- Patient has an order for Physical Therapy.
- Patient has a lab result of Serum Sodium equals 130 mEq/L with delta flag.
- Patient had an appendectomy.

Clinical Statement, shown in Figure 2, “Clinical Statement”, has a ‘key’, ‘topic’, ‘context’, and ‘meta’. The ‘key’ is the terminology meaning binding for the entire Clinical Statement. The ‘topic’ is the clinical entity being described. The ‘context’ describes the circumstances that form the setting in which the ‘topic’ should be evaluated. Finally, ‘meta’ is the collection of metadata that is associated with the clinical statement: the who, where, why and when information.

Figure 2. Clinical Statement



Topic The ‘topic’ is the clinical entity described by the Clinical Statement. A few examples of topic include clinical assertions, evaluation results, and procedures. For each of these topics the information described is quite different. Therefore, CIMI describes topic types that contain the appropriate attributes to describe the required information for the given topic. The number of topic types will change as CIMI progresses. Currently the allowable topic types are EventTopic, ProcedureTopic and FindingTopic which has suptypes of EvaluationResultTopic and AssertionTopic.

Context The ‘context’ describes the circumstances that form the setting in which the ‘topic’ should be evaluated. CIMI describes context types that contain the appropriate attributes to describe the required information for the given context. The number of context types will change as CIMI progresses. Currently the allowable context types are EventContext, ActionContext, and FindingContext. ActionContext has subtypes with examples including RequestContext, OrderContext and PerformanceContext. FindingContext has subtypes with examples such as PresenceContext, AbsenceContext, and GoalContext.

Metadata ‘metadata’ is not actually an attribute of ClinicalStatement, but is intended here to represent the various attributes in clinical statement that represent metadata about the clinical statement. This includes attribution information relating to the statement itself such as who authored, verified, recorded, or signed the statement or more informally, the who, where, why, and when information. Other attributes of this nature are recordStatus and encounter.

4.1. Examples Using Topic and Context

Earlier, descriptive examples of Clinical Statements were given. Here we will represent a few of these examples using the Clinical Statement 'topic - context' paradigm. In Figure 3, "Patient has diagnosis of congestive heart failure.", the example for "Patient has diagnosis of congestive heart failure" is illustrated. The topic has been declared to be of type AssertionTopic stating "assertion of congestive heart failure", and the context has been declared to be of type PresenceAbsenceContext stating "Known Present". What may not be apparent in the figure is that when the topic is declared to be of type AssertionTopic then all the attributes of AssertionTopic are available for use. However, in the figure only the attribute named 'result' is shown for clarity.

In Figure 4, "Patient has an order for Physical Therapy.", the example for "Patient has an order for Physical Therapy." is shown. The topic has been declared to be of type ProcedureTopic stating "procedure of type physical therapy", and the context has been declared to be of type OrderContext. Again, the majority of attributes for ProcedureTopic and OrderContext are not shown for clarity.

Figure 3. Patient has diagnosis of congestive heart failure.

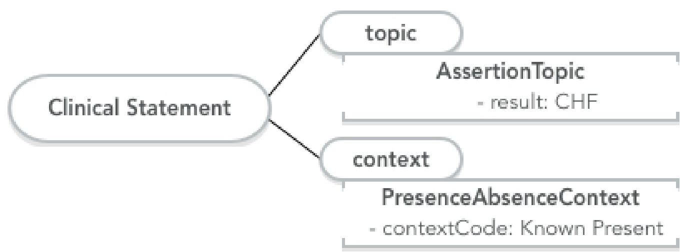
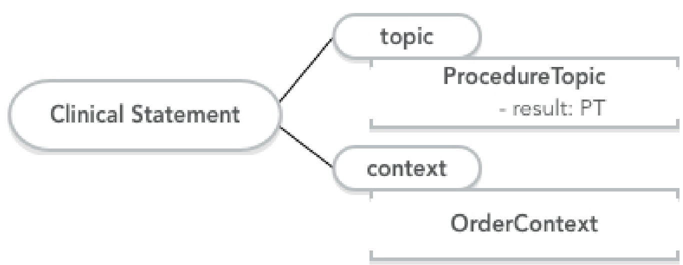


Figure 4. Patient has an order for Physical Therapy.



StatementTopic and StatementContext are both collections of attributes and have the following characteristics:

1. They are reusable components that can be assembled to form clinical statements. For instance, one can coordinate the ProcedureTopic with the ProposalContext to represent a ProcedureProposal statement. Alternatively, ProcedureTopic may be paired with OrderContext to create a ProcedureOrder statement.

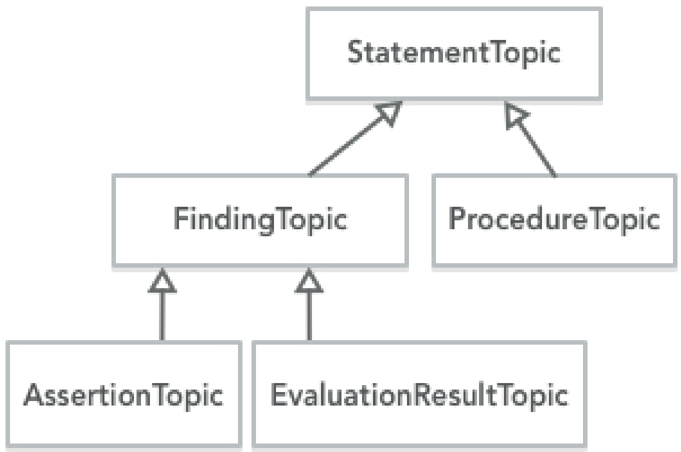
2. They represent groupings of attributes aligned with the SNOMED Clinical Terms (SNOMED CT) Concept Model. For instance, ProcedureTopic is aligned with the SNOMED CT Procedure Concept Model. PerformanceContext aligns with the Situation with Explicit Context Concept (SWEC) Concept Model.

3. They provide for a mechanism to state presence or absence of a finding as well as performance or non-performance of an action. For instance, the pairing of ProcedureTopic with NonPerformanceContext allows for the expression of a procedure that was not performed.

5. Topic Patterns

Topic Patterns include all the attributes required to fully describe a clinical entity. The topic patterns CIMI has developed to date include FindingTopic, ProcedureTopic, and EventTopic, wheith FindingTopic having children of AssertionTopic and EvaluationResultTopic. They are shown in Figure 5, "Topic Hierarchy" and are described in the following sections. Each of these topic subtypes contain a collection of attributes that describe the given pattern. These patterns provide the foundational structure for detailed clinical model (DCM) archetype instances that can be visualized at http://models.opencimi.org

Figure 5. Topic Hierarchy



5.1. AssertionTopic

The first topic type described here is the AssertionTopic pattern with its included attributes, as shown in Figure 6, "AssertionTopic". ConditionTopic, shown in Figure 7, "ConditionTopic" is a child of AssertionTopic which is used to represent a clinical finding such as the presence (or absence) of a condition in a patient. For example:

- ChestPainAssertion asserts the presence of chest pain.
- ChestPainAbsenceAssertion asserts the absence of chest pain.
- EdemaAssertion asserts the presence of edema.

Figure 6. AssertionTopic

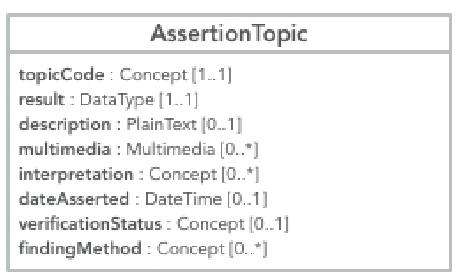


Figure 7. ConditionTopic

The assertion pattern for a clinical statement is as follows:

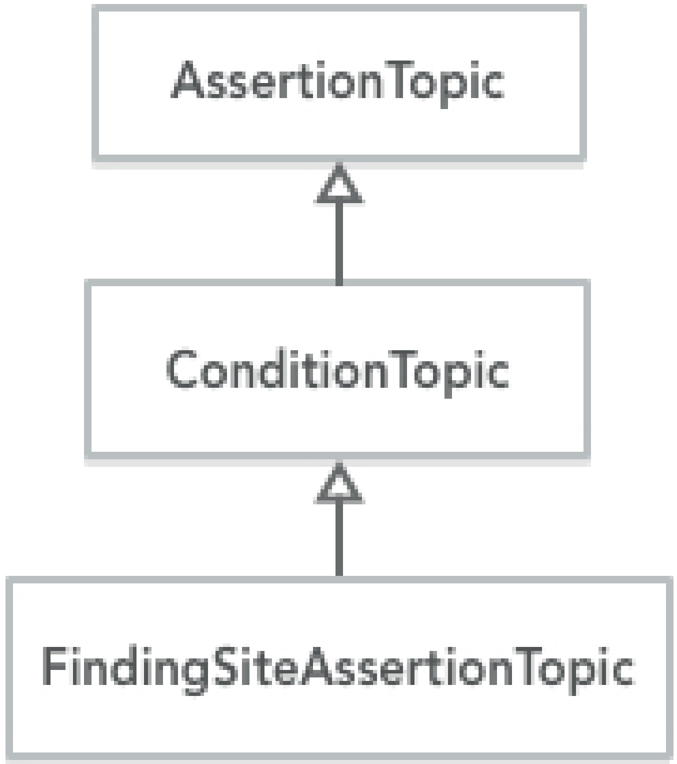
- topic.topicCode = a code meaning “assertion”.
- topic.result = a code representing what is being asserted (i.e., “rash”, “auto accident”, “hypertrophy”, etc.).

5.1.1. Assertion Hierarchy

The full hierarchy for AssertionTopic is shown in Figure 8, “Assertion Hierarchy”. AssertionTopic serves two important purposes: (1) it provides the core set of assertion attributes that are relevant in assertion of presence and absence; and (2) it is the parent type for the more specific assertions such as ConditionTopic and FindingSiteAssertionTopic. If additional attributes are identified as needed to properly model assertions they would either be added to one of the existing assertion types or a new type could be created with these attributes. This modeling decision would be based on whether adding these attributes make sense for existing assertions types or whether they should be used to create a new subset of assertions. Typically an attribute is added to the parent class if that attribute is relevant in all the subclasses derived from the parent class. If an attribute is only relevant in some of the subclasses then the attribute is introduced in these subclasses. This ensures that a class does not have an attribute that is incongruent and thus requires that attribute to be occasionally constrained out. For instance, it is viewed as bad practice to create an Animal class that contains arms, legs, and wings and then create a subclass of dog that constrains out wings since dogs do not have wings.

Note there are two ways to introduce an attribute that is not always used. A UML class specialization specifies a new class that has all of the attributes of its parent and may then specify additional attributes. An archetype may choose to use whichever class, parent or child, is appropriate. Or, the additional attribute may be added to the original class and the archetype may then use the attribute or "constrain it out" by setting its cardinality to zero. As previously state, CIMI modelers prefer the first approach, extension through UML class specialization, that avoids the need to constrain elements out of archetypes.

Figure 8. Assertion Hierarchy



5.1.2. Assertions

Assertions affirm or deny the existence of clinical conditions, diseases, symptoms, etc., in the patient. As just described, different varieties of assertion may extend an existing AssertionTopic class with any additional attributes necessary to fully represent this new group of assertions. Table 1 shows examples of clinical statements using the AssertionTopic class for the topic, and Table 2 shows examples of clinical statement using FindingSiteAssertionTopic for the topic. These examples show the ‘topic.topicCode’, ‘topic.result’, and ‘context.contextCode’ for each, with the addition of any extra attributes from the chosen topic needed to describe the clinical statement. Context will be discussed in depth later in this document. For now, be aware the chosen context is a full class with many attributes but here we are only showing the context code attribute that is common to all context types.

Example 1. The patient has diabetes mellitus type 1 which was diagnosed at age 24

```
DiabetesMellitusAssert
    topic.topicCode: Assertion
    topic.result: Diabetes mellitus type 1 (disorder)
    topic.ageAtOnset: 24 years
    context.contextCode: Confirmed present (qualifier value)
```

Example 2. The patient does not have diabetes mellitus type 1

```
DiabetesMellitusAbsentAssert
    topic.topicCode: Assertion
```

```
        topic.result: Diabetes mellitus type 1 (disorder)
        context.contextCode: Known absent (qualifier value)
```

Note, in the CIMI alignment with the SNOMED CT concept model, the AssertionTopic pattern corresponds to the Finding hierarchy as inflected by the Situation hierarchy.

Note AssertionStatement.topic.topicCode is not part of this construction. It is modeled with the fixed term "assertion" and is as semantically inert as we can manage.

Other attributes may also inflect the semantics; e.g., an AssertionStatment.topic.findingMethod that would align with the concept model's Finding.findingMethod.

5.1.3. Finding Site Assertions

A FindingSiteAssertionTopic is an assertion about a finding found on the body. This assertion is a "design by extension" assertion because it contains the additional attribute findingSite that is used to capture the body site affected by the condition. The FindingSiteAssertionTopic encourages post-coordination as shown in examples 3 and 4, and intentionally aligns with the SNOMED CT Clinical Findings concept model.

Example 3. The patient has a femur fracture in the right leg

```
    FractureAssert
        topic.topicCode: Assertion
        topic.result: Fracture of bone (disorder)
        topic.findingSite.code: Bone structure of femur
        topic.findingSite.laterality: Right (qualifier value)
        context.contextCode: Confirmed present (qualifier value)
```

Example 4. The patient has a stage two pressure injury on the right ischial tuberosity

```
    WoundAssert
        topic.topicCode: Assertion
        topic.result: Pressure ulcer stage 2 (disorder)
        topic.findingSite.code: Skin structure of ischial tuberosity
        topic.findingSite.laterality: Right (qualifier value)
        context.contextCode: Confirmed present (qualifier value)
```

5.2. Evaluation Result

The second topic pattern we will discuss is EvaluationResultTopic which is used to document a characteristic of a patient or a clinical value being observed. An EvaluationResultTopic may hold the name of a test in the 'topicCode' attribute (e.g., "heart rate evaluation", "serum glucose lab test", etc.) and the resulting value of the test in the 'result' attribute. Viewed another way, the EvaluationResultTopic topicCode holds a question (e.g., "what is the heart rate?", "what is the serum glucose?") and the 'result' holds the answer. Any clinical statement such as a laboratory test, a vital sign, or a questionnaire question that fits this pattern of a question and a resulting value is modeled with the EvaluationResultTopic pattern.

The evaluation result pattern for a clinical statement is as follows:

- topic.topicCode = what's being evaluated ("heart rate", "serum glucose", "breath sound", etc.).
- topic.result = the result of the evaluation ("72 bpm", "100 mg/dL", "rales")

The following is an isosemantic comparison of the evaluation result pattern to the previously described assertion pattern. In the previous section, we illustrated assertion models using rash, auto accident, and hypertrophy. Below we show what these assertion examples would look like if we hypothetically modeled them using the Evaluation Result pattern. Note, CIMI avoids creating models where the 'result' specifies "presence/absence" or "yes/no", so this is a clear indicator that the assertion pattern is preferred in these cases.

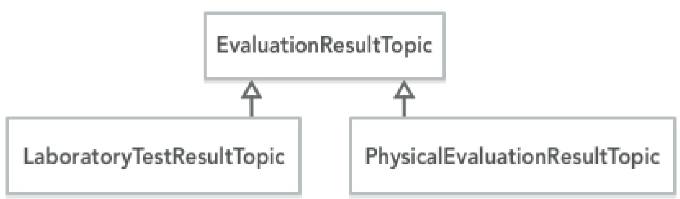
Assertion	• topic.topicCode = a code meaning "assertion" • topic.result = a code representing what's being asserted ("rash", "auto accident", "hypertrophy", etc.)
EvaluationResult (This is hypothetical)	• topic.topicCode = what's being evaluated ("rash", "auto accident", "hypertrophy", etc.) • topic.result = "present" or "yes"

Like Assertion, Evaluation Result corresponds to the SNOMED CT concept model. The EvaluationResultStatement.topic.topicCode attribute corresponds to the observation being evaluated.

5.2.1. Evaluation Result Hierarchy

EvaluationResultTopic currently has two subtypes; LaboratoryTestResultTopic (that includes additional attributes necessary to describe laboratory tests) and PhysicalEvaluationResultTopic.

Figure 9. Evaluation Result Hierarchy



5.2.2. Modeling in the Constraint Layer

This section will use LaboratoryTestResultTopic, which exists in the Reference Model Layer, to further describe modeling in the Constraint Layer. There are different categories of laboratory tests that differ in their resulting data type, such as quantitative labs and nominal labs, where the former would have a QUANTITY result and the latter would have a CODED_TEXT result. For the different lab categories there is not a need for new named attributes only a need to constrain the result to the appropriate datatype. The modeler has a choice to make in this situation as the datatype could be constrained in a new class subtype in the reference layer or as an archetype in the constraint layer. Since a new named attribute is not required the style CIMI has adopted as the constraint would occur in the constraint layer and an ADL Archetype would be created for both QuantitativeLaboratoryTestResult and NominalLaboratoryTestResult.

5.2.3. Evaluation Result Subtypes

LaboratoryTestResultTopic	LaboratoryTestResultTopic contains attributes specific to the lab evaluation process. These include information about the physical process (e.g., specimen) plus process management information (e.g., status).

PhysicalEvaluationResultTopic	PhysicalEvaluationResultTopic contains attributes specific to the clinical evaluation process. These include information about the physical examination process (e.g., patient position, body site).

Example 5. The patient's skin turgor is friable

```
SkinTurgorEval
    topic.topicCode: Skin turgor (observable entity)
    topic.result: Fragile skin (finding)
    topic.evaluationProcedure: Inspection (procedure)
    context.contextCode: Confirmed present (qualifier value)
```

Example 6. The patient's systolic blood pressure is 120 mmHg

```
SystolicBloodPressureEval
    topic.topicCode: Systolic arterial pressure (observable entity)
    topic.result: 120
        unitsOfMeasure: Millimeter of mercury (qualifier value)
    topic.evaluationProcedure: Auscultation (procedure)
    context.contextCode: Confirmed present (qualifier value)
```

5.2.4. Guideline: Assertion versus Evaluation

In most cases the decision between using the evaluation result pattern and the assertion pattern is intuitive and straightforward. "Urine color", for example, is clearly best modeled as an evaluation result because the attribute being evaluated is the color of the patient's urine and the result of the evaluation is the set of codes representing the colors that may be observed. To model urine color as an assertion would require the creation of a large number of pre-coordinated concepts. The key would be "assertion" and result would be populated with a code from a set of codes such as "amber urine" (meaning "the patient has amber urine"), "clear urine", etc.

However, this highlights any evaluation model may be transformed into an assertion model. (Conversely, any assertion model may be transformed into an evaluation model.) In the case of urine color, the decision is intuitive. In other cases the decision is less clear.

For example, "heart rhythms" (bradycardic, tachycardic, etc.) may be modeled as multiple assertion models (bradycardia, tachycardia, etc.) or as a "heart rhythms" evaluation model whose data is constrained to a value set (containing "bradycardic", "tachycardic", etc.).

The general guideline is if it is natural to think of the concept as a noun, as a condition or state that exists in the patient, model as an assertion or set of assertions. If the statement about the patient is thought of as a name/value pair (i.e., a noun representing the attribute and an adjective representing the value), such as "hair color" = ("black", "brown", "blonde"), then model it as an evaluation. However, it is important to note both styles are allowed and the true determinant of their use is whether a result for a given criteria other than true/false or present/absent is specified.

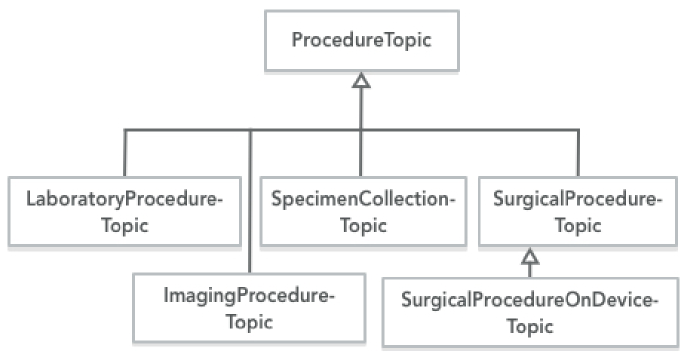
This discussion highlights the importance of isosemantic models. Even if one model or set of models can be agreed upon as the preferred storage model (e.g., assertion models for "bradycardia" and "tachycardia" instead of an evaluation model with "bradycardic" and "tachycardic" as values), inevitably there will be use cases (e.g., data entry, messaging, reporting, etc.) for the other model and a need to identify use cases where different modeling patterns describe semantically identical phenomena. These patterns are isosemantic. An essential (as of now unfulfilled) requirement is for a mechanism of identifying isosemantic models, managing isosemantic groups, and transforming between them. We expect a great deal of this work to be facilitated by the semantic underpinnings of the models supporting the ability to classify the content of two models and determine their logical relations (equivalent, subsumed, disjoint).

It should be noted the Assertion vs. Evaluation topic is solely concerned with the structure and schema pattern used to capture clinical information. Choosing Assertion vs. Evaluation patterns has nothing to do with whether the information being captured is subjective vs. objective.

5.3. ProcedureTopic

Procedure models are used to represent actions taken related to the care of a patient such as a cholecystectomy, peripheral IV placement, delivery of a warm blanket, dressing change, ambulation, patient education, etc. The CIMI ProcedureTopic, as shown in Figure 10, “Procedure Hierarchy”, is a base class for a number of specializations such as surgical, imaging, and laboratory procedures. The CIMI Procedure Model is aligned with the SNOMED CT Procedure Concept Model when such an alignment exists.

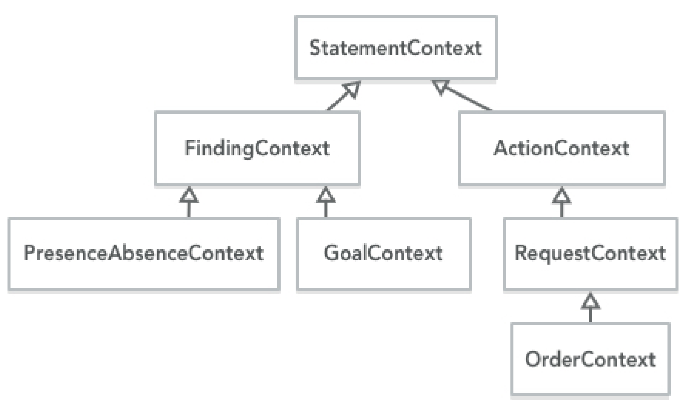
Figure 10. Procedure Hierarchy



6. Context Patterns

When a Clinical Statement is defined it will be modeled as a combination of a topic and a context. The ‘context’ describes the circumstances that form the setting in which the ‘topic’ should be evaluated. Specializations within the context hierarchy, shown in Figure 11, “Procedure Hierarchy”, add important attribution information for the situation being described.

Figure 11. Procedure Hierarchy



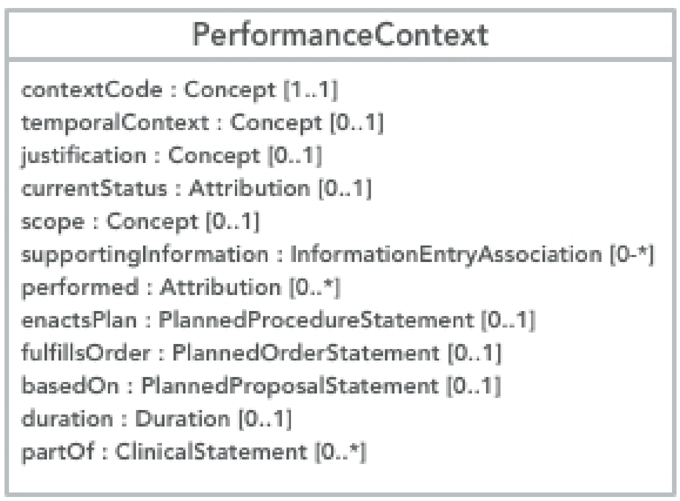
The StatementContext abstract class has the following three specializations:

FindingContext The FindingContext class aligns with the SNOMED Situation with Explicit Context for findings and provides the context for either the EvaluationResultTopic or AssertionTopic of a clinical statement. For instance, a context about a finding may state that the finding was present or absent.

ActionContext The ActionContext class aligns with the SNOMED Situation with Explicit Context for procedures and provides the context for the Act topic of a clinical statement. For instance, a statement about a procedure may specify the procedure has been proposed, ordered, planned, performed, or not performed. Each action context, in turn, has its own lifecycle. An example of the PerformanceContext class is shown in Figure 12, "PerformanceContext".

EventContext Not shown in the above diagram, EventContext is a child of StatementContext. At this time specializations of EventContext have not been defined. It is anticipated that EventOccurrence and EventNonOccurrence specializations will be introduced.

Figure 12. PerformanceContext



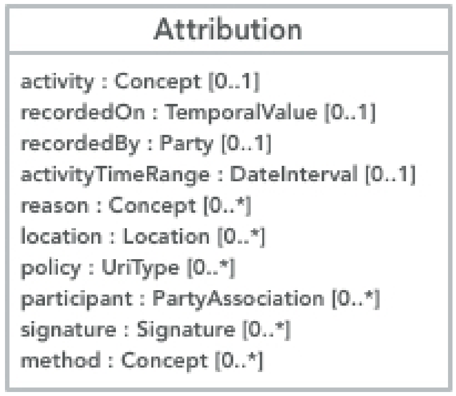
7. Metadata

The final division of the Clinical Statement pattern is the metadata which is a collection of attribution/provenance information regarding the topic/context being described by the clinical statement.

7.1. The CIMI Attribution/Provenance patterns

In the CIMI model, provenance information is represented by the Attribution class shown in Figure 13, "Attribution Class". The Attribution class provides a pattern for the capture of provenance information such as the what, who, when, where, why, and how associated with a particular activity – e.g., provenance attributes about the verification of a clinical statement (e.g. the provider performing the surgery in O.R. suite 6).

Figure 13. Attribution Class



CIMI currently includes two attribution patterns:

1. Attribution information as a part of the clinical statement – In this pattern, the ClinicalStatement pattern contains a number of attributes of type Attribution (e.g., ClinicalStatement.authored and ClinicalStatement.verified). This pattern provides a consistent way to capture attribution information that extends beyond simply the agent of an activity (e.g., the author). When attribution is part of the ClinicalStatement model, any change to the attribution for an activity will result in a version change.

2. Attribution information external to the clinical statement - CIMI allows the capture of provenance information external to the clinical statement through the Provenance class. The provenance class contains the Attribution class and provides pointers to one or more clinical statements (e.g., the Provenance.target attribute). This pattern allows the addition and modification of provenance information associated with a clinical statement without impacting its version.

8. CIMI Model Quality Criteria

The following quality criteria have been proposed for all CIMI models:

- Shall satisfy the URU principles – that is, they will be:
  - Understandable (cohesive and coherently expressed).
  - Reproducible (consistent).
  - Useful (fit for purpose)
- Shall be clinically accurate as deemed by clinicians.
- Shall be evidence-based, as demonstrated by peer reviewed studies whenever possible.
- Shall be adequate to express required clinical statements when tested using use cases.
- Shall be developed with robust versioning and review controls.

The application of these criteria to CIMI models will be assessed through clinical and technical reviews and through pilot implementations and revised as needed.

9. Semantic Model Terminology Binding

Information models are often developed independently of clinical ontologies. As a result, many information models align poorly with the terminologies or ontologies upon which they ultimately depend for their formal semantics. Moreover, by not explicitly specifying the model's semantics the meaning of the model is left open for interpretation during implementation further hindering interoperability. CIMI's goal is to have formal terminology bindings to standard terminologies.

Terminology binding refers to “the assertion of a relationship between the information model and the terminology”. This binding involves attaching terminology concepts, reference sets, or expressions to an attribute in an information model.

There are four main use cases motivating terminology binding to CIMI models:

1. To support data validation and semantic interoperability (e.g., exchanging data between systems that use different native information structures)
   - By confirming instance data conforms to the semantic specification.
   - By supporting the construction of valid description logics for instance classification and application of decision support and other analytic tools.

2. To support the management and quality control of clinical model libraries, including:
   - Searching model libraries (using the meaning of the models and their contents).
   - Identifying semantic overlap between models.
   - Identifying inconsistency of model interdependencies (e.g. the meaning of a constrained archetype is not subsumed by the meaning of the base archetype).

3. To determine the isosemanticity of two or more instances of models that are semantically equivalent, but structurally different; and to be able to transform between these isosemantic representations, including:
   - Models using a different level of pre-coordination versus structure.
   - Models making different modeling design choices (e.g., representing a laboratory test method as a single attribute, versus a CLUSTER containing many attributes).

4. To enable querying over data instances of iso-semantic model representations (as described above)

5. To enable querying over data instances of isosemantic model representations (as described above)

It is proposed these use cases be met by the fulfilment of the following requirements:

- A standard, reproducible methodology for defining the meaning of each node in the model using an association with a terminology.
- A standard, reproducible methodology for defining the valid set of values of each coded data element in the model (either explicitly or as a constraint expression).
- A standard, reproducible methodology for establishing semantic relationships between nodes in the same model, such as through SNOMED-CT Template syntax.
- Terminology bindings allowing the values to be represented in a way agnostic to the degree of pre-coordination versus structure.
- Terminology bindings enabling the transformation between iso-semantic representations of the same model.
- Terminology bindings allowing consistency to be checked within models and between models related by specialisation or slot filling.

CIMI aligns closely with the SNOMED CT Concept Model with particular emphasis on the Situation with Explicit Context expression semantics. If the CIMI attribute aligns with the SNOMED CT concept model, attributes are bound to descendants of Concept model attribute ID 410662002 | Concept model attribute (note, children of Unapproved attribute (attribute) ID 408739003 should not be used). If there is no attribute binding (e.g. temporal attributes such as “start time”) then CIMI may:

- Use a name/value pattern (e.g., evaluation result) to capture element data.
- A standard, reproducible methodology for defining the valid set of values of each coded data element in the model (either explicitly or as a constraint expression).
- Proceed without semantic bindings in the short term.
- Create new attributes in an extended concept model to support these elements.
- Investigate patterns for associating name/value patterns generically in the concept model (i.e., supporting LOINC or Observable Entity values as attribute bindings under defined circumstances).

To support terminology bindings to SNOMED CT components not available in the international release CIMI will develop SNOMED CT content. Currently, plans are to develop this content in the HSPC extension of SNOMED CT in the SOLOR namespace. SOLOR is designed to coordinate SNOMED CT, LOINC, and RxNorm (and, in future, international drug terminologies) in order to support description logic classification of information spanning those systems and potentially others as well.

Attribute bindings will use SNOMED CT wherever possible except for laboratory, vital signs, and anthropomorphic measurements that will be bound to LOINC terms. When the values are outside the scope of SNOMED CT or LOINC other terminologies (e.g. LOINC answers) may be selected (on a case-by-case basis). Table 1, "Terminology bindings for Assertion" illustrates the terminology bindings for Assertion.

Table 1. Terminology bindings for Assertion

<table>
<tr><th>Attribute</th><th>Code</th><th>Display</th><th>Term</th><th>Range</th></tr>
<tr><td>Assertion</td><td>246090004</td><td>Associated Finding</td><td>SNOMED CT</td><td><< 404684003 |Clinical finding (finding)| OR << 272379006 |Event (event)|</td></tr>
<tr><td>Due to</td><td>42752001</td><td>Due to</td><td>SNOMED CT</td><td><< 404684003 |Clinical finding (finding)| OR << 272379006 |Event (event)| OR << 71388002 |Procedure (procedure)|</td></tr>
<tr><td>Severity</td><td>246112005</td><td>Severity</td><td>SNOMED CT</td><td><< 272141005 |Severities (qualifier value)|</td></tr>
<tr><td>Clinical Course</td><td>263502005</td><td>Clinical Course</td><td>SNOMED CT</td><td><< 288524001 |Courses (qualifier value)|</td></tr>
<tr><td>Associated Precondition</td><td>47429007</td><td>Associated with</td><td>SNOMED CT</td><td><< 410607006 |Organism (organism)| OR << 105590001 |Substance (substance)| OR << 260787004 |Physical object (physical object)| OR << 78621006 |Physical force (physical force)| OR << 373873005 |Pharmaceutical / biologic product (product)| OR 138875005 |SNOMED CT Concept (SNOMED RT+CTV3)|</td></tr>
<tr><td>Periodicity</td><td>new</td><td></td><td>SNOMED CT</td><td><< 442083009 |Anatomical or acquired body structure (body structure)|</td></tr>
<tr><td>Alleviating factor</td><td>new</td><td></td><td>SNOMED CT</td><td>|Device| 49062001 (<=) |Pharmaceutical / biologic product| 373873005 (<< Q only) | Procedure (procedure)|71388002 (<=)</td></tr>
<tr><td>Exacerbating factor</td><td>new</td><td></td><td>SNOMED CT</td><td>|Device| 49062001 (<=) |Pharmaceutical / biologic product| 373873005 (<< Q only) | Procedure (procedure)|71388002 (<=)</td></tr>
<tr><td>Causative agent</td><td>246075003</td><td>Causative agent</td><td>SNOMED CT</td><td>|Organism| 410607006 (<<) |Substance| 105590001 (<<) |Physical object| 260787004 (<<) |Physical force| 78621006 (<<) |Pharmaceutical / biologic product| 373873005 (<< Q only) |SNOMED CT Concept| 138875005 (==)</td></tr>
<tr><td>Finding site</td><td>363698007</td><td>Finding Site</td><td>SNOMED CT</td><td>|Anatomical or acquired body structure| 442083009 (<<)</td></tr>
</table>

9.1. Terminology Binding Guidelines

All finalised CIMI Clinical Models shall:

- Include a semantic “concept binding” for each attribute in the model to a terminology concept (expression or pattern) that represents the meaning of the attribute. (Note the development of the concepts in the terminology will take time: whether models may be finalized prior to this has yet to be determined.)
- Include a “value binding” from each attribute of type Concept to a terminology reference set indicating the valid values for the attribute – either defined intentionally using a constraint expression, or extensionally as a list of terminology components

All finalized CIMI Clinical Models should be suitable for the generation of equivalent SNOMED CT logical expressions based on their key and attribute concept bindings and the relationships defined in the SNOMED CT concept model -- possibly via the Machine Readable Concept Model (MRCM). It may be necessary or appropriate, in addition to this “self-generated expression” capability, to include “constructor binding” on appropriate container-type attributes in the form of terminology expressions to help determine its isosemanticity with other model representations. Where such bindings might conflict with the generated expressions these artifacts may be either redundant and inadvisable or a valid and useful check on construction.

9.1.1. Semantic Model Value Set Binding

Work is currently being done within the HL7 Vocabulary work-group to define terminology binding semantics that remain valid across multiple implementation domains (V2, V3, C-CDA, FHIR and CIMI). CIMI is an active participant in these efforts and it is our intent to align CIMI Value Set bindings as closely as possible to this effort.

10. Appendix A - Glossary

Table 2. Glossary

Term	Acronym	Definition
Archetype		A re-usable, formal model of a concept expressed as a computable constraint model defined in ADL
Archetype Definition Language	ADL	ADL is a formal language for expressing archetypes. It provides a formal, textual syntax for describing constraints on any domain entity whose data is described by an information model
Attribute		A field in any class
Clinical Information Modelling Initiative	CIMI	An initiative established to improve the interoperability of healthcare information systems through shared implementable clinical information models
Clinical Statement		Structured electronic communication made about a patient typically documented as an 'entry' in the patient record
Complex Clinical Statement		A statement that is composed of parts where each part can only be fully understood in the context of its parent
Compound Clinical Statement		A clinical statement composed of one or more clinical statements that may exist outside of the containing parent statement
Constraint Model		A formal specification used for describing constraints on an Underlying Reference Model. The Constraint Model is used to express clinical information models (i.e. archetypes)
Context		The circumstances that form the setting in which the ‘topic’ should be evaluated

Term	Acronym	Definition
Detailed Clinical Model	DCM	A relatively small, standalone information model designed to express a precise clinical concept in a standardized and reusable manner
Governance		The use of a set of processes, customs, policies, laws and institutions to direct the way people administer
Isosemantic Models		A model that, while different in structure, represents the same semantic content as a second model
Key		The main concept of interest in a clinical statement, about which the other attributes and relationships provide additional information
Meta		Attribution information relating to the statement itself such as who authored, verified, recorded, or signed the statement. Meta includes the who, where, why and when information
Terminology Binding		The assertion of a relationship between the information model and the terminology
Topic		The clinical entity described by the Clinical Statement e.g. clinical assertions, evaluations results, and procedures
Topic Pattern		Attributes required to fully describe a clinical entity