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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.

Here, we introduce a new isosemantic representation that is designed to aid in the analysis of clinical information. This representation is called Analysis Normal Form (ANF).

1.2. Purpose

The purpose of this document is to inform the CIMI community about ANF and why it is needed as an additional standard isosemantic representation of models within CIMI.

1.3. Scope

This document will present the specification of the Analysis Normal Form (ANF), how it is used to create detailed clinical models (DCMs), and how it differs from CIMI's current standard modeling paradigm.

1.4. Audience

The intended audience for this document are all HL7 members.

2. Analysis Normal Form

2.1. Isosemantic Models

Ideally, clinical information is modeled in a manner that is most efficient for use. This is a problem because there are many different use cases for clinical information with a wide range of requirements. There is no single model that can be the most efficient model for all the various use cases. Maximum efficiency for each use case necessitates that any particular clinical information be available in multiple modeled forms. These models, although different in form, semantically model the same information, and are known as isosemantic models. Any particular detailed clinical model exists within a family of isosemantic siblings.

CIMI recognizes and supports the existence of isosemantic models and designates one isosemantic sibling as the CIMI 'preferred' model. The problem is that CIMI has not clearly stated for what use case this model is preferred. It could be the case that CIMI is mixing the multiple requirements of transformation, clinical data input, clinical data storage, clinical data querying, clinical data analysis, and modeler preference in the development of the CIMI 'preferred' model.

We feel it will be best for CIMI to clearly define the use case or use cases for any particular isosemantic family member. The moniker of 'preferred' could be sustituted with the actual use case. For example, if the intent of the model is to act as a common transformation pathway, then CIMI could use a term like the 'rosetta' member within an isosemantic family. Or if the intent for an isosemantic member is to support clinician data input, state that as the use case.

Here we address the use case of clincial data analysis and present the Analysis Normal Form (ANF) which will represent one member in each isosemantic family of detailed clinical models.

2.2. Clinical Statements – What are they, and *how are they used*?

A clinical statement represents an entry in the patient record that documents in a structured/computable manner clinical information related to the patient that is asserted by a particular source, recorded, and potentially verified.

Clinicians author clinical statements and enter them into their organization's electronic health record (EHR). Clinicians typically enter the information via a manner that we call here the clinical input form (CIF). However, the CIF is not a literal form that clinicians select and enter data in. Rather, it refers to the manner in which information is presented to the clinicians and how they enter the data, such as by constraining the information to allow only certain values to be entered, such as through a drop-down list or radio button, or breaking up large chunks of related information into smaller parts. For example, when a clinician orders a medication, rather than selecting this information all at once with a single item, they will choose the various parts of the medication order, such as:

- Kind of drug and strength (e.g., Acetaminophen 150 mg)
- Amount and how often the patient should take the medication (e.g., 1 tablet twice daily)
- Duration (2 days)
- Any constraints (e.g., do not exceed a total daily dosage of 600 mg)

Ideally, the way the information is presented to clinicians is in a manner that is most efficient for the clinicians to use. However, what is an efficient way for clinicians to select and enter data may not be the most efficient way for data analysts to use when they are querying data once it has been normalized and stored in a database, such as when creating a new CDS rule or compiling prevalence statistics. For this, the data is normalized using the *Analysis Normal Form (ANF)* and stored in a database. Again, the ANF is not necessarily a physical structure, but is how a data analyst might see the data when they are looking at it in a database, and not as clinicians would see it in the user interface (i.e., CIF).

- Clinician collects data ⇒ Clinical Input Form
- Data is normalized ⇒ Transformation process from CIF to ANF ⇒ Representable/storable in multiple types of databases.
- Data analyst who is using or querying the data (e.g., creating a CDS rule or working on prevalence statistics) ⇒ ANF (it is how the data is represented or stored in the database; must know enough about the data to know what is stored in the topic vs. what is stored as a result or detail)

The goal of ANF is to enable analysts to understand the data and how it is stored in lieu of having to teach them about the thousands of ways data can exist within an isosemantic family (i.e., CIF) and ensure the data that has to be expressed can be expressed in an operable and scalable way. The more that data is normalized, the simpler it will become to analyze, and the likelihood of analysis errors will be reduced. Without the ANF, the probability of patient safety risks is increased. Examples of problems that can occur are:

- **An inability to determine that two clinical statements are equivalent**
  - Taking two 250 mg acetaminophen tablets is the same as taking one 500 mg tablet but the analyst only queries for one of the statements, not both.
  - Presence of dot blot hemorrhage and 2 dot blot hemorrhages observed are equal in regard to presence and absence but the analyst queries only for presence vs. a quantitative finding of dot blot hemorrhages.
- **An inability to express something that is clinically significant**
  - We may not be able to express chest pain on inspiration, which can be a sign of pleurisy. The ability to differentiate cardiac chest pain from other types of chest pain is clinically important. An example of something that needs to be represented is *chest pain that worsens when you breathe, cough, or sneeze*.
- **An error is made in recording or in querying a repository for clinical statements**
  - On October 1, 2016, a provider enters a medication order for acetaminophen 250 mg for a patient to take 1 tablet twice daily for 2 days starting October 1, 2016
    - CIF: Provider enters the medication order
    - ANF: Analyst creates a CDS rule to identify all patients ordered acetaminophen during the period September 1 – December 31, 2016. However, while the analyst creates a query to search for a clinical statement (i.e., Request) where acetaminophen was the direct substance and was ordered during the period September 1 – December 31, 2016, the analyst did not include a Request topic of “Administration of drug or medication PO BID for pain.” Thus, the medication order would not be included in the query results.

2.3. Types of Clinical Statements

The types of clinical statements represented in ANF are listed and described below. The rationale for selecting these types is: Clinicians basically do two categories of things with a patient that need to be documented as clinical statements:

1. **Performance of action**: Actions may include passive observation of a phenomenon related to patients and their health status or family history, and may also include active interventions, such as providing education or administering medications or documenting that a patient is participating in exercise to improve their overall health status.

2. **Request for action**: Requests for future actions may include defining goals, consultation with other providers, or active interventions.

NOTE: Given that this work is not yet finalized, it is possible that additional clinical statement types may be needed.

2.3.1. Performance Clinical Statements

A performance statement describes an action that has previously been performed, and – if applicable - the results of that action. As shown in the examples below, this can range from documenting that a subject of record:

- Was observed to have the presence or absence of a clinical phenomenon
- Underwent a specific test/screening or procedure, and its resultant value, if any
- Was administered a medication or other substance
- Was provided educational materials
- Has any other state or specific characteristic that is clinically relevant

If the performance statement:

- Regards a measurement that was taken, all information about that measurement will be included as part of the clinical statement, such as its value and unit of measure and any details about how the measurement was taken.
- Results in an order(s) placed during the same encounter that was made to learn more about the phenomenon or to monitor it, then a link will be made to the order(s).

Examples of performance clinical statements:

1. Systolic blood pressure of 120 mmHg taken from right brachial artery while seated and no more than 30 minutes after the patient last urinated
2. Diabetes mellitus is present
3. Diabetes mellitus is not present
4. Three dot blot hemorrhages
5. Dot blot hemorrhage is present
6. Patient taking one Acetaminophen 100 mg tablet by mouth daily as needed for pain
7. Positive screen for fall risk
8. Negative screen for PTSD and depression
9. Family history of colon cancer
10. Patient provided educational materials on pre-diabetes diagnosis
11. Patient counseled on the health risks of continuing smoking

2.3.2. Request Clinical Statements

A Request clinical statement describes a request for an action made by a clinician. Most of the times, but not always, the object of the request (e.g., lab test, medication order) will be fulfilled by someone other than the clinician (e.g., lab technician, pharmacist) making the request. All information about the request will be documented in this clinical statement, including information about details relating to the request, such as patient must fast for 12 hours before having a lipids blood test.

Examples of Request clinical statements:

1. Lipids panel for patient Jane Doe. Patient must fast for 12 hours prior to the blood test.
2. Head CT with contrast for patient John Doe.
3. Cardiology referral for patient Mary Smith.
4. Penicillin medication for patient Michael Smith to be taken twice a day by mouth with food for 10 days.
5. Advised to participate in group tobacco cessation counseling once a week.
6. Advised to lose 15 pounds within 3 months.

7. Advised to exercise at least 3 times a week for 30 minutes per day for 3 months.
8. Advised to decrease the number of packs smoked per day from 3 to 2 within 6 months by using a nicotine patch.

3. ANF Modeling Principles

A. **Separation of Concerns:**As defined by Wikipedia [1]: Separation of Concerns (SoC) is a design principle for separating a computer program into distinct sections, such that each section addresses a separate concern. A concern is a set of information that affects the code of a computer program. A concern can be as general as the details of the hardware the code is being optimized for, or as specific as the name of a class to instantiate. A program that embodies SoC well is called a modular program. Modularity, and hence separation of concerns, is achieved by encapsulating information inside a section of code that has a well-defined interface. Encapsulation is a means of information hiding. Layered designs in information systems are another embodiment of separation of concerns (e.g., presentation layer, business logic layer, data access layer, persistence layer). The value of separation of concerns is simplifying development and maintenance of computer programs. When concerns are well-separated, individual sections can be reused, as well as developed and updated independently. Of special value is the ability to later improve or modify one section of code without having to know the details of the other sections, and without having to make corresponding changes to those sections.

The use of immutable objects (see principle B Immutability below) is a technique that fulfills the Separation of Concerns principle.

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

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

Figure 1. Architectural Separation of Concerns

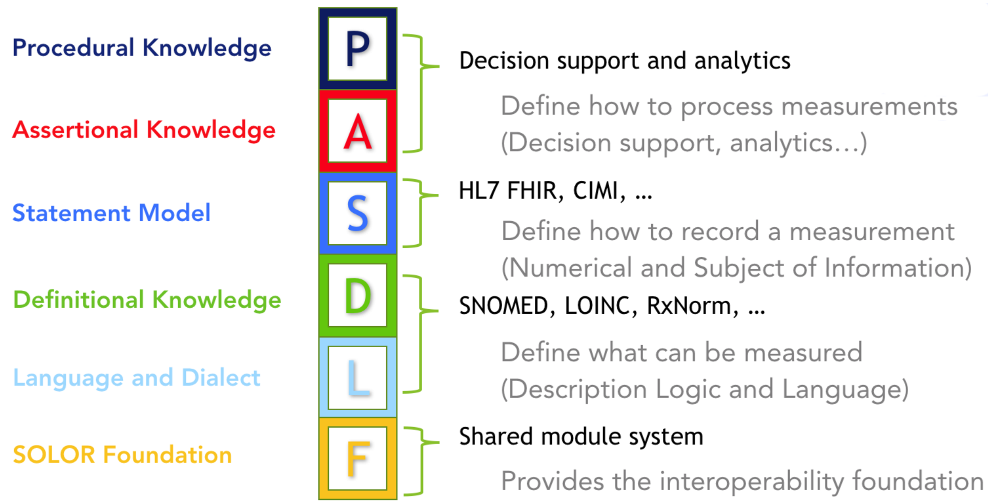


Figure 1, "Architectural Separation of Concerns" shows the Statement layer is separate from Terminology layers, yet most CIF statement models mix terminolgy concerns into the structural attributes of the statement model. ANF attempts to maintain a clean separation between these layers. The Language

[1] https://en.wikipedia.org/wiki/Separation_of_concerns

and Definitional layers are used to define what is being measured, such as Dot-blot hemorrhage of the retina or Type 1 diabetes.

B. **Immutability:** An Immutable Object as defined by Wikipedia [2]: Used in object-oriented and functional programming, an immutable object is something that cannot be changed after it is created, in contrast to mutable objects that can be changed after they are created. There are multiple reasons for using immutable objects, including improved readability and runtime efficiency and higher security.

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

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

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

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

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

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

D. **ANF Clinical Statements Represent the Minimum Disjoint Set:** Analysis Normal Form (ANF) clinical statements represent the minimum disjoint set of statement topic, result, and circumstance and may not be further specified.

E. **ANF Classes Cleanly Separate Concerns:** Analysis Normal Form (ANF) classes must cleanly separate the concerns of concept definition and the concerns of domain models.
   - ***NOTE:*** *Need to define the domain models thoroughly here.*The strawman description is that domain models use concept definitions as a building block to define non-defining relationships or associations between concepts. The domain model represents cardinality, optionality, and other constraints.
     - **Example:**Laterality should be a concern of either the concept definition or the domain model, but not both. We can relax this principle for the Clinical Input Form (CIF) but for ANF we need a clean and invariant separation of concerns.
   - ***NOTE:*** *Need to determine better names for "concept definition" and "domain models."*

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

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

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

G. **Overall Model Simplicity:** In cases where different principles collide, we shall favor the enhancement of simplicity of the entire system over simplicity in one area of the system.
H. **Cohesion:** Related classes should reside in the same module or construction. The placement of a class in a module should reduce the dependencies between modules.
I. **Reusability:** Architectural patterns should encourage class reusability where possible. Reusability may further refine encapsulation when composition is considered.
J. **Assumption-free:** Implied semantics must be surfaced explicitly in the model.
   - **Example:** Implicit in the statement, "I order a book from Amazon" are: paying for the book, delivery of the book to some location, and the transfer of ownership of the book from the vendor to the client.
K. **Design by Composition and/or Class Specialization:** The capture of additional model expressivity must be captured by composition and/or by class specialization. The modeling approach should avoid the use of design by constraint (except for terminology binding and attribute type constraints) as it violates proper decoupling and encapsulation. An example of design by constraint is to create a single procedure class containing all attributes for all known procedures and constraining out irrelevant attributes in a more specialized model. This approach is very difficult to implement and violates numerous object-oriented best practices.
L. **No False Dichotomies:** Dichotomies that are not completely disjoint (mutually exclusive) lead to arbitrary classification rules and result in ambiguity based on different assumptions about the domain. These must be avoided.
M. **Model Should Avoid Semantic Overloading (semantic precision):** Semantic overloading occurs when a model attribute's meaning changes entirely, depending on context. While the refinement of the semantics of an attribute in a subclass is acceptable, a change of meaning is problematic. For instance, in FHIR, the Composition class defines an attribute called Subject. In some subclasses, the attribute may be the entity that this composition refers to (e.g., the patient in a medical record). In other cases, it is the topic being discussed by the composition (e.g., a medication orderable catalog).
N. **Convention Over Configuration:** Convention over configuration (also known as coding by convention) is a software design paradigm used by software frameworks that attempt to decrease the number of decisions that a developer using the framework is required to make without necessarily losing flexibility.
O. **Model Consistency:**Patterns should allow the consistent representation of information that is commonly shared across models. For instance, attribution and participation information should be captured consistently. Failure to do so forces implementers to develop heuristics to capture and normalize attribution information that is represented or extended differently in different classes (e.g., FHIR).
P. **Model Symmetry:** There should be symmetry in the models wherever we can have it.
Q. **Iterative development and validation of model using use cases:**TBD

4. ANF Reference Model

The ANF Reference Model is a small static model that can easily be described with UML, OpenEHR BMM, or FHIR StructureDefintion. Detailed Clinical Models are then described as contraints of this reference model. The core of the model is the class ClinicalStatement seen in Figure 2, "ClinicalStatement".

4.1. Clinical Statement

Figure 2. ClinicalStatement

Name	Flags	Card.	Type
ClinicalStatement			
statementTime		1..1	http://opencimi.org/cimi/StructureDefinition/Measure
statementId		1..1	uuid
subjectOfRecordId		1..1	uuid
statementAuthor		0..*	http://opencimi.org/cimi/StructureDefinition/Participant
subjectOfInformation		1..1	CodeableConcept
statementType		1..1	CodeableConcept
topic		1..1	CodeableConcept
circumstance		1..1	http://opencimi.org/cimi/StructureDefinition/Circumstance
statementAssociations		0..*	http://opencimi.org/cimi/StructureDefinition/StatementAssociation

Clinical Statement is the main class which describes an entry of clinial information into the patient record. Most importantly it contains the 'topic' which describes what this statement is about, and the 'circumstance' which will contain either request or result information regarding the 'topic'.

4.1.1. statementTime

Statement Time describes when the statement was documented in ISO 8601 Date/Time Standard Format

4.1.2. statementId

Statement Identifier is a unique identifier for the statement represented by a UUID.

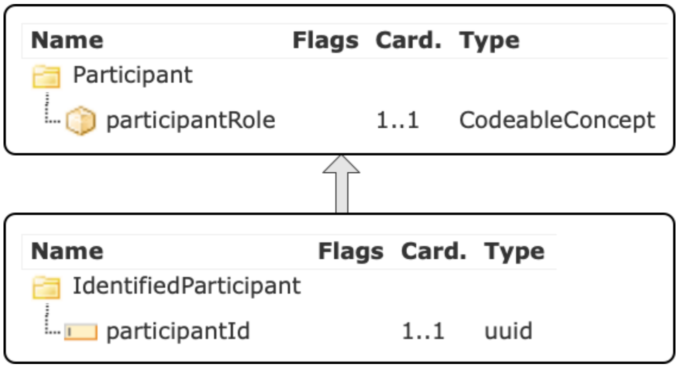
4.1.3. subjectOfRecordId

A patient's clinical record will contain many statements. The subjectOfRecordId is a uuid which identifies the patient clinical record in which this statement is contained. If this statement is in John Doe's patient record, then John Doe is the subject of record and the subjectOfRecordId is a uuid that identifies John Doe.

4.1.4. statementAuthor

Statement author is an optional list of authoring participants (Figure 3, “Participant”). Either a Participant or its subclass IdentifiedParticipant can be used. Participant includes a coded *participantRole* for values such as 'Healthcare professional', 'Nurse', or 'Requestor'. IdentifiedParticipant adds the additional attribute *participantId* which is a UUID to uniquely identify the participant.

Figure 3. Participant



4.1.5. subjectOfInformation

Subject of Information is a coded field used to express **WHO** the clinical statement is about. A patient's clinical record may contain statements not only about the patient, but also statements about children, relatives and donors. Thus, some possible values for subjectOfInformation, would include codes for 'subject of record' (the patient), 'family member', or 'donor'. The majority of statements will have a subjectOfInformation with a value of 'subject of record', since most statements in a patient record will be about the patient.

4.1.6. statementType

Statement Type distinguishes between a performance ('performed') and a request ('requested'). Performances may be observational performances, e.g. the observation of a clinical finding or disorder being present or absent. They can also be a procedure or intervention which has been performed on the subject of record in the past, e.g. "a procedure using a 12-lead electrocardiogram". Performances can – but do not have to – include quantitative or qualitative results, e.g. "3 dot blot hemorrhages" or "Hepatitis A antibody positive".

4.1.7. topic

Topic is the expression of **WHAT** is being requested or what was performed. For both clinical statement types (request or performance) a pre-coordinated or post-coordinated SOLOR "procedure" concept as a logical expression is required to sufficiently capture the action, which is either requested or performed.

Requests for actions can be requests for actions such as procedures or interventions:

- Stress echocardiogram
- Administration of Aspirin 81 mg oral tablet
- Systolic blood pressure measurement

Performances of actions can be performed procedures like the examples above. They can also be observational procedures, describing the absence or presence of clinical findings or disorders. In these cases, the observation action of the clinical findings and disorders is performed:

- Congestive heart failure
- History of malignant neoplasm of bone
- Numbness of left arm
- History of cognitive behavioral therapy

The topic is the central component of clinical statements. The following are proposed principles for the topic of a clinical statement.

- **Proposed Principle 1:** The topic defines the action being performed or requested.
- **Proposed Principle 2:** The topic has to be able to exist on its own and still retain original intent and clarity of meaning.
- **Proposed Principle 3:** The topic includes what is being measured or observed.
- **Proposed Principle 4:** Each clinical statement may only have one topic.

4.1.8. circumstance

Figure 4. Circumstance and subtypes

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

- Timing: **WHEN** a requested action should be performed or **WHEN** an observed finding or disorder was present or absent.
  - Examples:
    - Cardiology Consult in 2 weeks
    - Breast cancer screening 3 months ago
- Purpose: **WHY** an action was requested or performed
  - Examples:
    - Echocardiogram to evaluate arrhythmia
    - Education about allergens for anaphylaxis management

Other circumstances are specific to requests or performances.

4.1.8.1. RequestCircumstance

Request circumstance further specifies **HOW** a requested action is to be performed, e.g. how often or how long.

Figure 5. RequestCircumstance

RequestCircumstance		
conditionalTrigger	0..*	http://opencimi.org/cimi/StructureDefinition/ClinicalStatement
requestedParticipant	0..*	http://opencimi.org/cimi/StructureDefinition/Participant
priority	1..1	CodeableConcept
repetition	0..*	http://opencimi.org/cimi/StructureDefinition/Repetition
requestedResult	1..1	http://opencimi.org/cimi/StructureDefinition/Result

4.1.8.1.1. conditionalTrigger

TBD

4.1.8.1.2. requestedParticipant

Requested participants is an optional list of either specific persons or roles who perform an action, assist in performing an action or are targets of an action.

Examples:

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

4.1.8.1.3. priortity

Priority expresses the priority with which a requested action has to be carried out, e.g. “routine” or “stat”.

4.1.8.1.4. repetition

Figure 6. Repetition

Name	Flags	Card.	Type
Repetition			
periodStart		1..1	http://opencimi.org/cimi/StructureDefinition/Measure
periodDuration		1..1	http://opencimi.org/cimi/StructureDefinition/Measure
eventFrequency		1..1	http://opencimi.org/cimi/StructureDefinition/Interval
eventSeparation		1..1	http://opencimi.org/cimi/StructureDefinition/Measure
eventDuration		0..1	http://opencimi.org/cimi/StructureDefinition/Measure

Repetition is used to describe when an action is requested for more than a single occurrence

- When the repeated action should begin (periodStart), e.g. NOW
- How long the repetitions should persist (periodDuration), e.g. for 3 weeks

- How often the action should occur (eventFrequency), e.g. 3 times per week
- How long between actions (eventSeparation), e.g. for 2 weeks
- How long every action should last (eventDuration), e.g. for 5 minutes

4.1.8.1.5. requestedResult

A requested result is a patient goal to be achieved. It can include specified or quantified details of an action that is to be performed, such as '3 times daily'.

Examples:

- Narrative: Administration of Metoprolol tartrate 50 mg oral daily 2 times to lower systolic blood pressure to <130 mmHg
- Narrative: Diltiazem 30 mg, one tablet oral daily 4 times

4.1.8.2. PerformanceCircumstance

Performance Circumstance specifies the result of the performance.

Figure 7. PerformanceCircumstance

Name	Flags	Card.	Type
PerformanceCircumstance			
result		1..1	http://opencimi.org/cimi/StructureDefinition/Result
performanceParticipant		1..*	http://opencimi.org/cimi/StructureDefinition/IdentifiedParticipant

4.1.8.2.1. result

Result of diagnostic or observational procedures. There are two types of results shown in Figure 10, "Result Hierarchy" which are InterventionResult and ObservationResult.

Examples:

- Narrative: Systolic blood pressure 120 mmHg
- Narrative: Body weight 165 pounds

4.1.8.2.2. performanceParticipant

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

4.1.8.3. UnstructuredCircumstance

Unstructured Circumstance is used to document additional parts of clinical statements, which are not necessary for accurate data coding or retrieval.

Figure 8. UnstructuredCircumstance

Name	Flags	Card.	Type
UnstructuredCircumstance			
unstructuredText		1..1	string

4.1.8.3.1. unstructuredText

Text field to document unstructured circumstances.

4.1.9. statementAssociation

Statement associations enable the clinical statement to link to other clinical statements. They are part of the narrative, but are not considered part of the topic. They can further specify, e.g. instructions that apply to the performance of an action. If the topic is a laboratory result panel, each association would point to another statement which is a laboratory result.

Figure 9. StatementAssociation

Name	Flags	Card.	Type
StatementAssociation			
associationSemantic		1..1	CodeableConcept
associatedStatementId		1..1	uuid

4.1.9.1. associationSemantic

Association semantic is a logical expression to capture how the target statement is associated.

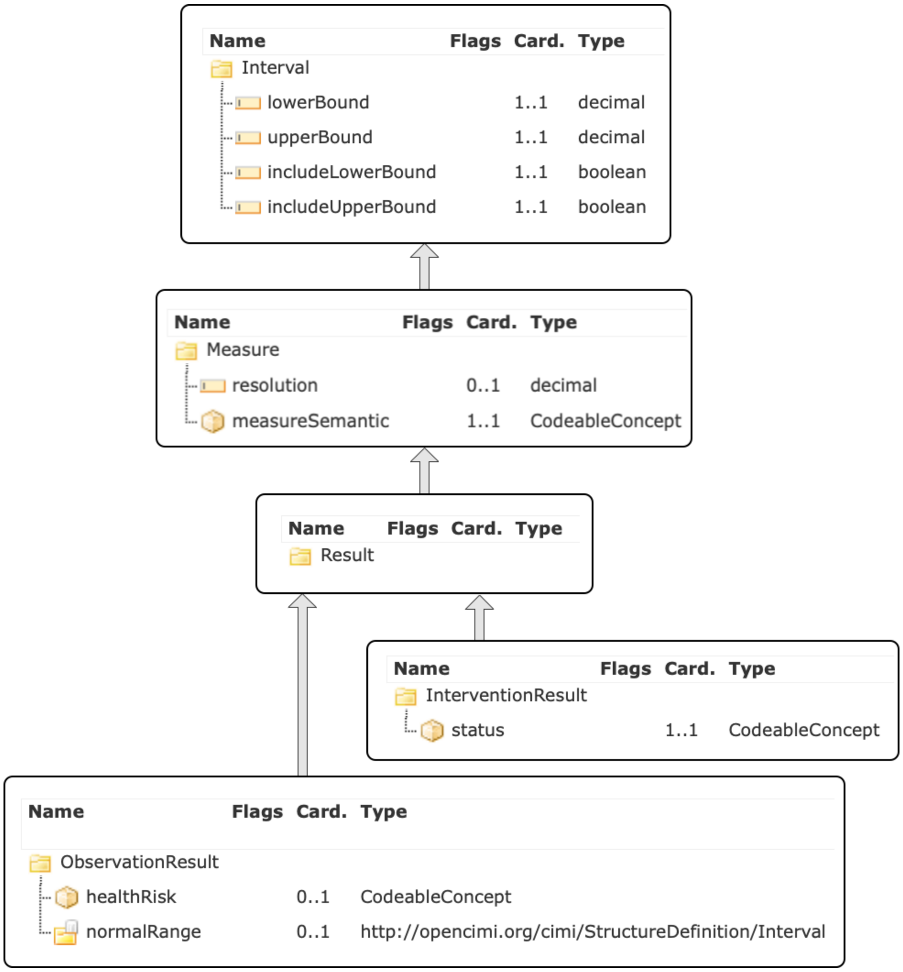
4.1.9.2. associatedStatementId

Associated Statement Id is a UUID to identify associated statements. This UUID is the statementId of the target ClinicalStatement

4.2. Measure and Result

A unique aspect of the the ANF Model is that all measures and results are numeric ranges. The hierarchy of classes to represent these is shown in Figure 10, “Result Hierarchy”. An important point to notice in this class diagram is that the ANF Model does not allow coded results, only a numeric interval is possible.

Figure 10. Result Hierarchy



4.2.1. Measure

Measure captures measurable elements of clinical statements, e.g. the results of test procedures, time periods, frequencies of repetitions for procedures or medication administrations. Note that the inherited attributes from the Interval class will be discussed here.

4.2.1.1. lowerBound

Lower bound represents the lower bound of a measurable element. This can be the lower bound of a range: For the “Administration of 25 to 50 mg of medication X” the lower bound is 25. For a test result, which is not a range, lower and upper bound are the same. Example: systolic blood pressure 110 mmHg. The lower and upper bound are both 110 mmHg.

4.2.1.2. upperBound

Upper bound represents the upper bound of a measurable element. This can be the upper boundary of a range: For the “Administration of 25 to 50 mg of medication X” the the upper bound is 50 mg. In cases, where the measurable element does not represent a range, upper and lower bound have the same value.

4.2.1.3. includeLowerBound

Include lower bound states whether the lower bound in the interval is included in the interval. In the medication examples above, the lower bound would be included. The lower range dose of 25 mg of medication X dose can be administered.

The inclusion or exclusion of lower bound is needed to express measurable elements which include relative properties, such as “greater than”, “less than” and others. Example: “Persistent cough for more than 10 days”. If a lower bound of “10” is chosen, it would not be included, because the example states: more than 10 days. Choosing “11” would require to include the lower bound.

4.2.1.4. includeUpperBound

Include upper bound states whether the upper bound in the interval is included in the interval. Similar to lower bound, where the measurable element has relative properties, the same rules apply. If the upper bound of a measure is not defined, e.g. “blood glucose measurement daily for at least 2 weeks”, the upper bound will be captured as “inf” (infinite). Infinite as an upper bound is never included.

4.2.1.5. resolution

The Resolution within a measure defines the possible or allowed increments in which the measured “thing” can be counted. In the example of the systolic blood pressure of 110 mmHg, the resolution is “1”, because the blood pressure measurement result can be counted in 1 mmHg increments. The Resolution is not always defined or known. Example: a clinical statement like “History of breast cancer” implies an undefined amount of time in the past and it is not stated, if it is years, months, etc.

4.2.1.6. measureSemantic

Measure semantic represents the unit of measure. It is described using a logical expression. In systolic blood pressure, the unit of measure is millimeters of mercury, and thus the measure semantic is a SNOMED CT concept: 259018001 |Millimeter of mercury (qualifier value). For blood glucose measurement daily for 2 weeks, the measure semantic would be “258705008 |week (qualifier value)”. In cases where the measure pertains to something relative to the statement time, as in the example above of “History of breast cancer” the standardized time/date format ISO 8601 is used for the measure semantic: ISO 8601 prior to statement time.

4.2.2. InterventionResult

Intervention Result is a result, thus inheriting all the attributes of Result, and adds the attribute *status*, which is a coded value representing the current status of the intervention.

Figure 11. Result Hierarchy

Name	Flags	Card.	Type
InterventionResult			
status		1..1	CodeableConcept

4.2.3. ObservationResult

Observation Result is a result, thus inheriting all the attributes of Result, and adds the attributes *healthRisk* and *normalRange*. Health Risk is used to flag a result with coded values such as 'low', 'normal', high', and 'critical'. Normal Range is the interval of values that are normal.

Figure 12. Result Hierarchy

Name	Flags	Card.	Type
ObservationResult			
healthRisk		0..1	CodeableConcept
normalRange		0..1	http://opencimi.org/cimi/StructureDefinition/Interval

5. Differences between ANF and CIF

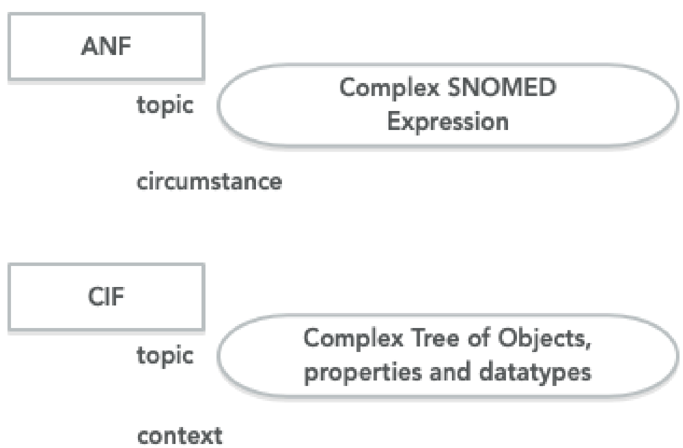
There are two fundamental differences between the ANF and CIF approach. The first is the representation of topic, and the second is the representation of results.

1. The representation of topic.
2. The representation of results.

5.1. The Representation of Topic

In the ANF model, the topic is represented by a single field containing a simple to complex SNOMED expression whereas in the CIF model, all the pieces of information that make up the topic are broken out and structured as needed into multiple properties with property names and appropriate datatypes.

Figure 13. Topic comparison for a complex topic



One implication of this is that the ANF is using two formalisms to represent the detailed clinical model. First it uses the formalism that represents the ANF reference model and constraints such as HL7's StructureDefinition syntax or OpenEHR's BMM/ADL syntax. Second, it uses SNOMED's syntax for post-coordinated SNOMED expressions. Tools for authoring and analysis would be required to parse and process both syntaxes.

The CIF model, on the otherhand, would be fully represented using the formalism that represents the CIF reference model and contraints such as HL7's StructureDefinition syntax or OpenEHR's BMM/ADL syntax.

5.2. The Representation of Results

In the CIMI CIF model, EvaluationResult and Assertion models are used to represent results. EvaluationResult has a topic representing what is being observed, and a result represented by a choice of datatypes.

An Assertion on the otherhand, has simply a topic with a value of 'assertion', and a result stated what is being asserted.

In the ANF model, the topic represents what is being observed and the result may only be a range of either a count or quantity. No coded results are allowed.

In the CIF model, when creating a model with a numeric result, the choice is quite clear and the choice will be an EvaluationResult, such as a topic of 'SerumSodium' and result with a numeric quantity. In this case, the CIF and ANF model are very aligned, except for the fact that the ANF model will use a range of that quantity.

But when a CIF model has a potential coded result, the choice between EvaluationResult and Assertion becomes muddied. For example, a model for Breath Sound could be an EvaluationResult with a topic of 'breath sound' and a coded result with the following valueset. Thus any of the breath sounds within the valueset can act as a result for this model. The other option, is that each of the breath sounds in the valueset is modeled as an Assertion with a topic of 'assertion', and a result of each particular code. To decided which model is better, usually we ponder how the clinician thinks about the data, or how it will be collected, or how it will be queried.

The ANF model cannot do an EvaluationResult style model as it doesn't allow coded results. Thus ANF is forced to make one and only choice, which is an assertion style where the particular breath sound is the topic, and the result will be numeric count indicating presence or absence.

- Absent
- Audible
- Clear
- Coarse Breath Sounds
- Coarse Crackles
- Crackles
- Diminished
- Expiratory wheezing
- Faint
- Fine Crackles
- Forced
- Inspiratory wheezing
- Left Ventricular Assist Device Noise
- Markedly Decreased
- Moderately Decreased
- Pleural Rub
- Prolonged Expiration
- Rhonchi
- Slightly Decreased
- Stridor
- Tubular Breath Sounds
- Upper Airway Congestion
- Wheeze

When querying instance data, the Assertion or ANF style is much more difficult for things like breath sounds. To query any breath sound instances, you must have knowledge of all possible breath sound topics and query for each. With the EvaluationResult style, querying is simpler as you simply query for a topic of 'breath sound', and the code result tells you what type of breath sound it is. Thus you do not have to know all the members of the valueset apriori to form the query.

6. Clinical Statement Examples

6.1. Request : Medication Order

Table 1. Example of a Medication Order

<table>
<tr><th colspan="3">Clinical Statement</th></tr>
<tr><td colspan="3">Narrative: Ibuprofen 400 mg tablet oral every 6 hours as needed for back pain; may increase dose frequency to one tablet every 4 hours

Statement type: <u>[Request]</u>

Subject of info: [410604004 |Subject of record]

Authors: [223366009|Healthcare professional]

Topic: [71388002|Procedure]-

(260686004|Method) [129445006|Administration - action]

(363701004|Direct substance) [197805|Ibuprofen 400 MG Oral Tablet]

(410675002|Route of administration) [260548002|Oral]</td></tr>
<tr><td rowspan="5">Circumstance:</td><td colspan="2">Request Circumstance</td></tr>
<tr><td colspan="2">Timing: <code>[2007-04-05T14:30Z, 2007-04-05T15:00Z]±P5M</code> [ISO 8601]

Purposes: [161891005 |Backache (finding)]

Triggers: associate statement backache present Participants: [410604004 |Subject of record]

Priority: [50811001 |Routine (qualifier value)]</td></tr>
<tr><td rowspan="2">Repetitions:</td><td>Repetition</td></tr>
<tr><td>Start: Duration: Frequency: Maximum: Duration:</td></tr>
<tr><td colspan="2">Result: 4</td></tr>
<tr><td colspan="3">Associations:

Statement time: <code>[2007-04-05T14:30Z, 2007-04-05T15:00Z]±P5M</code> [ISO 8601]

Stamp coordinate: [SOLOR Module] , [Release Path] , 2007-04-05T14:30Z Statement id: a3b46565-f8cd-4354-b4b6-3dff42d33496

Subject of record ID:</td></tr>
</table>

6.2. Examples of Modeling Performance Clinical Statements

6.2.1. Performance Statement Example 1

Narrative	Systolic blood pressure of 120 mmHg taken from right brachial artery while seated, rested for at least 10 minutes, and no more than 30 minutes from when the patient last urinated.
Topic	Observation of systolic blood pressure on right brachial artery.
Circumstance	***Observation Result***
	Value: [120, 120]
	Unit:mmHg
	Resolution:1
Associated Statements	Seated
	Rested for at least 10 minutes
	Urinated within 30 minutes of BP being taken

6.2.2. Performance Statement Example 2

Narrative	Patient has systolic blood pressure of 122 mmHg while patient is seated, right brachial artery.
Topic	Observation of systolic blood pressure on right brachial artery.
Circumstance	***Observation Result***
	Value: [122, 122]
	Unit:mmHg
	Resolution:1
Associated Statements	Seated

6.2.3. Performance Statement Example 3

Narrative	Patient has systolic blood pressure of 125 mmHg, while patient is seated, adult automated cuff, 30 minutes or less after emptying bladder, at doctor’s office.
Topic	Observation of systolic blood pressure.
Circumstance	***Observation Result***
	Value: [125, 125]
	Unit:mmHg

Resolution:1

Associated Statements Adult automated cuff used

Seated

Urinated within 30 minutes of BP being taken

Taken at Doctor’s office

6.2.4. Performance Statement Example 4

Narrative Patient has thromboembolism history.

Topic Observation of thromboembolism.

Circumstance ***Observation Result***

Value: [1, inf)

Timing

Value: [1, inf)

measureSemantic: ISO 8601 prior to statement time

6.2.5. Performance Statement Example 5

Narrative Diabetes Mellitus present.

Topic Observation of Diabetes Mellitus.

Circumstance ***Observation Result***

Value: [1, inf)

6.2.6. Performance Statement Example 6

Narrative Diabetes Mellitus not present.

Topic Observation of Diabetes Mellitus.

Circumstance ***Observation Result***

Value: [0,0]

6.2.7. Performance Statement Example 7

Narrative Three dot blot hemorrhages.

Topic Observation of Dot blot hemorrhage.

Circumstance ***Observation Result***

Value: [3,3]

Unit:count

6.2.8. Performance Statement Example 8

Narrative	Dot blot hemorrhage present.
Topic	Observation of Dot blot hemorrhage.
Circumstance	***Observation Result***
	Value: [1, inf)

6.2.9. Performance Statement Example 9

Narrative	Patient observed to have fall risk.
Topic	Observation of fall risk.
Circumstance	***Observation Result***
	Value: [1,1]
	Unit:count

6.2.10. Performance Statement Example 10

Narrative	Family history (mother) of colon cancer.
Subject of Information	Mother.
Topic	Observation of colon cancer.
Circumstance	**Value:** [1,inf)]
	measureSemantic: ISO 8601 prior to statement time

6.3. Examples of Modeling Request Clinical Statements

6.3.1. Request Statement Example 1

Narrative	Request for Administration of Acetaminophen 100 mg tablet by mouth daily as needed for pain.
Topic	Administration of Acetaminophen 100 mg tablet oral.
Circumstance	***Requested Result***
	Value: [1,1]
	Resolution:(1)
	measureSemantic: Oral tablet
	Frequency
	Value: [1,inf)

Resolution:1

measureSemantic:day

Purpose

Therapeutic; Pain

6.3.2. Request Statement Example 2

Narrative	Request for x-ray chest to evaluate chest pain (routine).
Topic	Performance of Chest x-ray.
Circumstance	**Priority:**Routine
	Purpose: Evaluation; chest pain

6.3.3. Request Statement Example 3

Narrative	Request for administration of nitroglycerin 0.4 mg tablet sub-lingual every 5 minutes as needed for chest pain; maximum 3 tablets (routine).
Topic	Administration of nitroglycerin 0.4 mg tablet sublingual.
Circumstance	***Requested Result***
	Value: [1,1]
	Resolution:(1)
	measureSemantic: Sublingual tablet
	Frequency
	Value: [5,15]
	Resolution:5
	measureSemantic:minute
	Purpose
	Therapeutic; chest pain
	Priority: Routine