PROPOSED

ANALYSIS NORMAL MODELING GUIDELINES

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# Introduction

The purpose of this document is:

1. To define a clinical statement.
2. To define the types of clinical statements and their attributes.
3. To provide a set of guidelines to model clinical statements.
4. To provide a validation framework for inter-modeler reliability when applied in the field.
5. To provide information on how clinical statements will be modeled for the KBS Clinical Decision Support (CDS) Knowledge Artifact (KNART) project. Once the models are approved, model slots bound to terminologies will be identified for subsequent terminology binding definitions proposed by the VA Terminology Team. Modeling of clinical statements outside of the CDS KNART project is currently beyond the scope of this effort.
   * KNART example: Consult request to Cardiology to evaluate chest pain. Certain information must be collected and stored as structured data, such as the reason for the consult.

These modeling guidelines were derived from several documented use cases. The main goal of this effort is to provide a reproducible and a principled approach to the formal capture of clinical knowledge within Information Models and their references to underlying Terminology Models. Currently, the proposal and examples are independent of any specific terminology.

These guidelines will be distributed to a variety of participants to contribute to a modeling exercise. After having read the guidelines, participants will be asked to access a survey where they will view a number of clinical statements and indicate how they would model them. ***When attempting the modeling exercise, it will be important to model per the guidelines specified in this document regardless of how existing terminologies, such as SNOMED-CT, may model these concepts***. In the future, an exercise to reconcile approaches may be conducted but is out-of-scope at this time.

# Modeling Principles

The modeling guidelines were developed in accordance with the principles shown below. These principles are defined in Appendix A.

* Separation of Concerns
* Immutability
* Composition Over Inheritance
* ANF Clinical Statements Represent the Minimum Disjoint Set
* ANF Classes Cleanly Separate Concerns
* Clinical Statement Model Stability
* Overall Model Simplicity
* Cohesion
* Reusability
* Assumption-free
* Design by Composition over class specialization.
* No False Dichotomies
* Model Should Avoid Semantic Overloading (semantic precision)
* Convention Over Configuration
* Model Consistency
* Model Symmetry
* Iterative development and validation using use cases

# 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 about a subject of information, such as a patient or a relative of the patient, and that is asserted by a particular source, recorded, and potentially verified.

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

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

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

* Clinician collects data 🡪 Clinical Input Form
* Data is normalized 🡪 Transformation process from CIF to ANF 🡪 Representable/storable in multiple types of databases, which could include VistA but a separate process would need to be performed to make that happen.
* Data analyst who is using or querying the data (e.g., creating a CDS rule or working on prevalence statistics) 🡪 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 be entered (i.e., CIF) and ensure the data we need 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.

# Types of Clinical Statements

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

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

**NOTE:** Given that this work is not finalized yet, it is possible that additional clinical statement types may need to be added in the event during creation of the KNARTs there are clinical terminology artifacts identified that do not fit into any of the types listed above.

Any statement that states or implies an “if/then” clause should be expressed and captured as an ECA rule

Example:

* + “Free-text reminder: Consider [ordering X procedure] for patients with suspected pericarditis, myocarditis, hypertrophic cardiomyopathy, or pulmonary hypertension.”
  + Implied “if/then” clause: **IF** pericarditis, myocarditis, hypertrophic cardiomyopathy, or pulmonary hypertension is suspected – **THEN** consider ordering X procedure.
  + Rather than capturing the above statement as a free text reminder, building an appropriate ECA rule should be considered.

## Action Clinical Statements

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

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

If the action statement:

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

Examples of Action clinical statements:

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

## 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.

## Clinical Statement Components

* + **Proposed Principle 1:** Clinical statements have separable and inseparable components; clinical statements with separable components are considered *compound* clinical statements
  + **Proposed Principle 2:** Separable components are statements, which require a value.
    - The values can be
      * numerical
      * pseudo-numerical, e.g. low/medium/high
      * Present/absent
  + **Proposed Principle 3:** Clinical statements with values can stand alone
  + **Proposed Principle 4:** Clinical statements with present/absent values can be components that play a role in the focus of the statement
  + **Proposed Principle 4:** Inseparable components of clinical statements do not require values

Compound clinical statements with separable components should be represented as “panels”, with each separable clinical statement as a “stand alone” statement, which can be referenced by multiple “panels”.

**Examples:**

|  |  |  |
| --- | --- | --- |
| **USE CASE** | **SEPARABLE STATEMENTS** | **INSEPARABLE COMPONENTS** |
| BP of 120/80 mmHg on right brachial artery, patient in sitting position for at least 5 min., using adult BP cuff, urinary bladder voided within 30 min. before measurement | Systolic BP = 120 mmHg | Using adult BP cuff |
| Diastolic BP = 80 mmHg | Right brachial artery |
| Time since last urination = 30 min. or less | Sitting position |
| Time in sitting position = 5 min. or more |  |

Table : Separable/Inseparable Statements - Blood Pressure Measurement Use Case

The “panel” above would consist of the following statements:

1. Blood pressure on right brachial artery, using adult cuff, with patient in sitting position
2. Systolic BP = 120 mmHg
3. Diastolic BP = 80 mmHg
4. Time since last urination = 30 min. or less
5. Time in sitting position = 5 min. or more

|  |  |  |
| --- | --- | --- |
| **USE CASE** | **SEPARABLE STATEMENTS** | **INSEPARABLE COMPONENTS** |
| Administration of nitroglycerin 0.4 mg tablet sub-lingual every 5 minutes as needed for chest pain; maximum 3 tablets (routine) | Strength = 0.4 mg | Administration |
| Frequency = every 5 minutes | Nitroglycerin |
| Maximum dosage = 3 tablets | Tablet |
|  | As needed |
|  | Sublingual |
|  | For chest pain |
|  | Routine |

Table : Separable/Inseparable Statements - Administration of Nitroglycerin Use Case

The “panel” above would consist of the following statements:

* Administration of nitroglycerin tablets as needed, sublingual, for chest pain, routine priority
* Medication strength = 0.4 mg
* Frequency = every 5 minutes
* Maximum dosage = 3 tablets

**Pseudo-numerical values** are qualitative scales, e.g.

* Low/medium/high
* Mild/moderate/severe
* Tumor staging and grading
* + pos./++ pos./+++ pos.

**Statements with absent/present values** are considered **inseparable** components, if they are **part of** the focus of the statement.

*Example statement*: Patient has warm skin and blue eyes.

Warm skin and blue eyes are the focus of this statement; both components have a value of “present” and they are **part of** the focus of the statement and are therefore considered inseparable:

* Blue eyes = present
* Warm skin = present

Other components, such as *right brachial artery* or *adult BP cuff* in the BP measurement use case are considered separable, although they may appear to be able to stand alone and have values of present/absent.

*Example action statement:* SystolicBP 120 mmHg taken on right brachial artery, using adult BP cuff

The right brachial artery and the adult BP have (implied) values of “present”, but they are **not part of the focus** of the statement (Blood pressure). Therefore, they are considered separable.

* Right brachial artery = present
* Adult BP cuff = present

The right brachial artery **plays a role** as the site of the blood pressure. Similarly, the adult BP cuff **plays a role** as the device used to perform the measurement.

*Example request statement:* BP measurement to take on right brachial artery, using adult BP cuff

The right brachial artery and the adult BP have (implied) values of “present”, but they are **not part of the focus** of the statement (blood pressure). Therefore, they are considered separable.

* Right brachial artery = present
* Adult BP cuff = present

The right brachial artery **plays a role** as the site of the blood pressure measurement. Similarly, the adult BP cuff **plays a role** as the device used to perform the measurement.

The two examples above show, that the focus of the statements does not change. It is in both cases the blood pressure. The roles of the right brachial artery and the adult BP cuff consequently do not change, either.

The separable components of a clinical statements are also variables. BP measurement can be performed at a different body site (e.g. left brachial artery) or using a different device (e.g. digital BP machine). However, the focus of the statement remains the same.

**Other examples:**

* Head CT with contrast: Contrast media plays a role as an imaging substance used
* Dobutamine stress echocardiogram: Dobutamine plays a role as a substance to induce cardiac stress
* BP measurement taken at doctor’s office: The office plays a role as an environment
* Body temperature reported by nurse: The nurse plays a role as the finding informer

## Details

* + **Proposed Principle 1:** Details refine or further qualify the topic. Topic type and topic focus together with the details sufficiently define instance requests.
  + **Proposed Principle 2:** Not every action or request requires details to be sufficiently defined.
  + **Proposed Principle 3:** A detail has a key and a value, where the value can be a concept or a numeric range with unit.
  + **Proposed Principle 4:** A detail can be a separable or inseparable part of a complex clinical statement.

**The criteria for identifying the focus and details that are not part of the focus, but play a role in a clinical statement suggest that “details” are all components, which play a role and are therefore separable components.**

**Examples:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Detail** | **Description** | **Has (Pseudo-) Numeric Value** | **Has Present/Absent Value** | **Part of Focus of Statement** | **Plays Role** | **Separable/**  **Inseparable** |
| Actor | Person making the request or documenting/reporting the action | no | yes | no | yes | separable |
| Approach/Access Route | Passage used to reach the procedure site or take a measurement | no | yes | no | yes | separable |
| Body position | Position of the body during a procedure/test | no | yes | no | yes | separable |
| Priority | Priority of the request, e.g. Stat or Routine | yes | yes | no | yes | separable |
| Indication | Reason that a request was made or an action taken | no | yes | no | yes | separable |
| Duration | A length of time, such as for 7 days, within 24 hours, or as needed | yes | yes | no | yes | separable |
| Frequency | How often something must be done, such as daily, twice per day | yes | yes | no | yes | separable |
| **Detail** | **Description** | **Has (Pseudo-) Numeric Value** | **Has Present/Absent Value** | **Part of Focus of Statement** | **Plays Role** | **Separable/**  **Inseparable** |
| Route of Administration | Way in which something, such as a medication, is given to a patient, such as by mouth/oral, intravenously, sublingual | no | yes | no | yes | separable |
| Strength | Strength of a unit of the medication/drug itself, such as 25 mg | yes | yes | no | yes | separable |
| Amount | Amount of the medication/drug that is to be taken at a given time, such as 2 tablets | yes | yes | no | yes | separable |
| Dosage | Equals strength multiplied by amount, e.g. 2 tablets of 25mg equals 50mg | yes | yes | no | yes | separable |
| Projection | The path taken by an x-ray beam or ultrasonographical wave as it passes through the body | no | yes | no | yes | separable |
| Substance used | Substance such as contrast media for imaging or catecholamine for stress induction | no | yes | no | yes | separable |
| Device used | Device used to perform something, such as using a BP cuff to measure blood pressure | no | yes | no | yes | separable |
| Device setting | Specific settings for a device used to perform a procedure, such as O2 Flow Rate 5 to 12 L/min | yes | no | no | no | separable |
| Informer | Person who reports a test result or gives information about the patient | no | yes | no | yes | separable |
| **Detail** | **Description** | **Has (Pseudo-) Numeric Value** | **Has Present/Absent Value** | **Part of Focus of Statement** | **Plays Role** | **Separable/**  **Inseparable** |
| Performer | Person who performs an action | no | yes | no | yes | separable |
| Assessment Scale | Reference scale use for scoring | no | yes | no | yes | separable |

Table : Separable/Inseparable Statements – Details

### Details/Roles in the Context of Use Cases

* **Role: Approach/Access Route**
  + Passage used to reach the procedure site or take a measurement.
    - Excision of rib by *cervical approach*
    - Administration of enema via *rectal route*
* **Role: Body Position**
  + The position of the body during a procedure/test.
    - Colonoscopy in *right lateral position*
    - Blood pressure measurement in *seated position*
    - ECG in *lying position*
* **Role: Body Site**
  + The body site of a finding or a procedure
    - Blood pressure measurement on *right brachial artery*
    - Removal of tattoo from *left upper arm*
* **Role: Priority**
  + The priority of the request, such as Stat or Routine.
    - Blood sugar measurement 3 times/day, *routine*
* **Role: Indication**
  + The reason for a request made or an action taken.
    - ECG to evaluate *chest pain*
    - X-ray of hands to evaluate *rheumatoid arthritis*
    - Patient placed in observation status due to *suicidal thoughts*
* **Role: Duration**
  + A length of time, such as for 7 days, within 24 hours
    - Physical therapy for *3 weeks*
    - Administration of Aspirin 200mg oral tablets for pain as needed for *2 days*
* **Role: Frequency**
  + How often something must be done, such as daily, twice per day or once in a 24-hour period.
    - Chest x-ray *once daily* to evaluate pneumonia
    - Psychiatric evaluation *bi-weekly* for PTSD
* **Role: Route of Administration**
  + The way in which something, such as a medication, is given to a patient.
    - Patient taking two Acetaminophen 100mg tablets *by mouth*
* **Role: Strength**
  + The strength of the medication/drug
    - Patient taking two Acetaminophen *100mg* tablets by mouth
* **Role: Amount**
  + The amount of the medication/drug that is to be taken at a given time, such as 2 tablets.
    - Patient taking *two* Acetaminophen 100mg tablets by mouth
* **Role: Dose Form**
  + The form of preparation of a medication
    - Patient taking *two* Acetaminophen *100mg* *tablets* *by mouth*
* **Role: Dosage**
  + Equals strength multiplied by amount.
    - Patient taking two tablets of Acetaminophen 100mg each = *amount of 200mg*.
* **Role: Projection**
  + The path taken by an x-ray beam or ultrasonographical wave as it passes through the body
    - MRI of brain *sagittal and transversal*
    - *Transthoracic* echocardiogram
* **Role: Substance Used**
  + Substance such as contrast media for imaging or catecholamine for stress induction
    - Head CT with *contrast*
    - *Radioisotope* study of musculoskeletal system
    - *Dye* test of fallopian tube
* **Role: Device Used**
  + A device used to perform an action, such as using a sphygmomanometer to measure blood pressure or a ventilator to help a patient breath.
    - Lithotripsy using *laser*
    - Biopsy using *Watson capsule*
* **Role: Device Setting**
  + Specific settings for a device used to perform a procedure, such as
    - Oxygen therapy, *O2 Flow Rate 5 to 12 L/min.*
    - Electrode setting for electro-surgery *12 watts*
* **Role: Family Member**
  + Blood relative of the patient, such as mother, maternal grandfather. This information is used to identify which family member(s) have a history of certain phenomena.
    - *Maternal* pyrexia
    - Drug misuse by *father*
* **Role: Informer**
  + Person reporting/documenting an action result or giving information about the patient.
    - Patient medical history reported by *spouse*
    - Bedside blood sugar measurement reported by nurse
* **Role: Performer**
  + Person performing an action
    - Blood pressure measurement taken by *physician*
    - Diabetes education given by *dietician*

# Topic

* + **Proposed Principle 1**: The topic defines the action being represented or requested.
  + **Proposed Principle 2:** The topic has to be able to exist on its own and still retain clarity of meaning.
  + **Proposed Principle 3:** The topic includes what is being measured or observed.
    - Guidelines:
      * Each clinical statement may only have one topic.
      * Each topic contains:
        + An action *type*, defined as the kind of action that is to be or has been performed, such as ‘observation-of’, ‘measurement-of’, administration-of’, or ‘imaging-of’.
        + A *domain,* defined as the range of allowed focus concepts, such as ‘medication’, imaging’ or ‘laboratory test’
        + A *focus* concept defined as the actual procedure requested or performed, such as ‘systolic blood pressure’ or ‘Aspirin’.
      * The action type in combination with the focus concept allows the representation of topics such as “measurement-of systolic blood pressure” or “administration-of Aspirin”.

In summary, the Topic is comprised of the following:

* + - **Type:** The type of action such as observation-of’, ‘measurement-of’, ‘administration-of’, or ‘imaging-of’.
    - **Focus:** A concept or expression representing the focus of the action such as ‘systolic blood pressure’, ‘nitroglycerin’, or “head’.
    - **Domain:** A domain that encompasses the range of possible focus concepts.

**Result**

The result of an action. This applies to Action clinical statements and not Requests. The result is comprised of the following:

* + - **Value:** A numeric range with a lower and upper bound, such as 120 - 125. The range can also be used to represent presence and absence.
    - **Unit:** A coded field used to represent various units of measure, such as grams, mmHg, inches, and percentage. There is also a special type of unit called “count,” which is an integer count of what is specified in the topic. For example, if the topic is “Dot blot hemorrhage” and the result unit is set to “count,” then the result value can be used to specify the integer range of “dot blot hemorrhages” observed, such as 3 or 5.
    - **Precision:** The precision defines the precision of the result value, such as constraining the value to integer or decimal values.

Each clinical statement will have:

A topic, consisting of an action type, focus, and focus domain.

For Action statements only, there is a result that contains the measurement according to the upper bound/lower bound, unit of measure, and precision.

A set of details in the form of key/value pairs where the value can be a numeric range or coded expression.

# Examples of Modeling Action Clinical Statements NEEDS UPDATE WHEN WE KNOW MORE

| **Action Clinical Statement Examples** | **Topic** | **Result** | **Details** |
| --- | --- | --- | --- |
| 1. Systolic blood pressure of 120 mmHg taken from right brachial artery while seated and no more than 30 minutes from when the patient last urinated | measurement-of Systolic blood pressure | **Value:** 120  **Unit:** mmHG  **Precision:** (integer) | **Approach/Access Route:** Right brachial artery (technique)  **Body Position:** Seated (technique)  **Activity**: Rested for at least 10 minutes (technique)  **Prerequisite**: Urinated within 30 minutes of BP being taken |
| 1. Patient has systolic blood pressure of 122 mmHg while patient is seated, right brachial artery | measurement-of Systolic blood pressure | **Value:** 122  **Unit:** mmHG  **Precision:** (integer) | **Approach/Access Route:** Right brachial artery (technique)  **Body Position:** Seated (technique) |
| 1. Patient has systolic blood pressure of 130 mmHg, while patient is seated, adult cuff, automated cuff, 30 minutes or less after emptying bladder, at patient’s home, taken by patient | measurement-of Systolic blood pressure | **Value:** 130  **Unit:** mmHG  **Precision:** (integer) | **Device Used:** Adult cuff (technique)  **Device Used:** Automated cuff (technique)  **Body Position:** Seated (technique)  **Prerequisite:** 30 minutes or less after emptying bladder  (Not a detail: At patient’s home  Taken by patient – not a detail, but instead attribution information) |
| 1. Patient has systolic blood pressure of 125 mmHg, while patient is seated, adult cuff, 30 minutes or less after emptying bladder, at doctor’s office | measurement-of Systolic blood pressure | **Value:** 125  **Unit:** mmHG  **Precision:** (integer) | **Device Used:** Adult cuff (technique)  **Body Position:** Seated (technique)  **Prerequisite:** 30 minutes or less after emptying bladder  (Not a detail: At doctor’s office – not a detail, but instead attribution information) |
| 1. Patient has thromboembolism history | observation-of thromboembolism | **Value:** [0, inf)  **Unit:** count  **Precision:** (integer) |  |
| 1. Diabetes Mellitus present | diagnosis-of Diabetes Mellitus | **Value:** [1, inf)  **Unit:** count  **Precision:** (integer) |  |
| 1. Diabetes Mellitus not present | diagnosis-of Diabetes Mellitus | **Value:** [0,0]  **Unit:** count  **Precision:** (integer) |  |
| 1. Three dot blot hemorrhages | observation-of Dot blot hemorrhage | **Value: [**3,3]  **Unit:** count  **Precision:** (integer) |  |
| 1. Dot blot hemorrhage present | observation-of Dot blot hemorrhage | **Value:** [1, inf)  **Unit:** count  **Precision:** (integer) |  |
| 1. Patient taking one Acetaminophen 100 mg tablet by mouth daily as needed for pain | administration-of Acetaminophen | **Value:** [1, inf)  **Unit:** count  **Precision:** (integer) | **Strength:** 100 mg (technique)  **Amount:** 1 tablet (technique)  **Route of Administration:** Oral (technique)  **Frequency:** Daily  **Indication:** Pain |
| 1. Positive screen for fall risk | observation-of fall risk | **Value:** [1,1]  **Unit:** count  **Precision:** (integer) |  |
| 1. Family history (mother) of colon cancer | observation-of colon cancer | **Value:** [0, 1]  **Unit:** count  **Precision:** (integer) | (Not a detail: Subject of Information is Mother) |
|  |  |  |  |

# Examples of Modeling Request Clinical Statements

| **Orders Clinical Statement Examples** | **Topic** | **Result** | **Details** |
| --- | --- | --- | --- |
| 1. Request for x-ray chest to evaluate chest pain (routine) | performance-of Chest x-ray |  | **Indication**: Evaluate chest pain  **Priority**: Routine |
| 1. Request for administration of nitroglycerin 0.4 mg tablet sub-lingual every 5 minutes as needed for chest pain; maximum 3 tablets (routine) | administration-of nitroglycerin |  | **Strength**: 0.4 mg tablet (technique)  **Dosage**: 1 (technique)  **Frequency**: Every 5 minutes (technique)  **Duration**: As needed (technique)  **Route** of Administration: Sub-lingual (technique)  **Indication**: Chest pain  **Priority**: Routine  **Constraint**: Maximum 3 tablets |
| 1. Request for prescription of Synthroid 50mcg, QD, 1 hour before meals | prescribing-of Synthroid |  | **Strength**: 50mcg (technique)  **Frequency**: QD (technique)  **Instruction**: 1 hour before meals |

# Appendix A: Modeling Principles Definitions

1. **Separation of Concerns:** As defined by Wikipedia[[1]](#footnote-2): 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.

1. **Immutability:** An Immutable Object as defined by Wikipedia[[2]](#footnote-3): 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.

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

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

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

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

1. **ANF Clinical Statements Represent the Minimum Disjoint Set:** Analysis Normal Form (ANF) clinical statements represent the minimum disjoint set of statement topic, result, and details and may not be further specified.
2. **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.”

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

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

1. **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.
2. **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.
3. **Reusability:** Architectural patterns should encourage class reusability where possible. Reusability may further refine encapsulation when composition is considered.
4. **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.

1. **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.
2. **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.
3. **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).
4. **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.
5. **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).
6. **Model Symmetry:** There should be symmetry in the models wherever we can have it.
7. Iterative development and validation of model using use cases: TBD

# Appendix B: Use Case for Modeling of Clinical Statements Using Analysis Normal Form

**USE CASE 1: DEPRESSION: FOLLOW-UP OUTPATIENT VISIT (SLIGHTLY ADAPTED FROM THE IA USE CASE)**

**ACTORS**

* Patient
* Medical Office Assistant
* Provider

**PRECONDITIONS**

This is a 32-year old male with a 6-month history of major depression on Zoloft and receiving group psychotherapy. Risk assessment scores from the last visit 1 month ago: PHQ-9 (15), PCL (16), AUDIT-C (0), ASSIST (10) for tobacco only. No suicidal ideation or risk of violence towards others.

* **PMH:** Patient had right above the knee amputation (AKA) 6 months ago and has prosthesis. Denies substance use of medications. Smokes 2 ppd. Patient does not have a traumatic brain injury (TBI).
* **Psychosocial:** Patient is S/P 2 deployments to Afghanistan, is estranged from family, has no close friends, lives alone, and is unemployed. His best friend died during their last deployment together, when the patient was injured. He attends AA meetings daily, is undergoing vocational rehabilitation and has been seen by a community social service agency.

**WORKFLOW**

* After patient arrives to the clinic and is checked in, he uses a VA tablet to complete risk assessments and the tablet is synced to the EHR. Patient’s scores are:
  + PHQ-9: 17
  + PCL: 15
  + AUDIT-C: 0
  + ASSIST: 10 for tobacco only
* Patient is taken to a room and the MOA asks patient for their chief complaint (CC) and any updates to their psychosocial and medical history. MOA reviews and validates the reason for visit is a routine outpatient visit for depression and PTSD management. Patient has no updates to psychosocial history.
* MOA validates patient’s medication history has not changed. Patient is taking 1 Zoloft 150 mg p.o. daily.
* MOA takes patient’s vital signs:
  + Height = 72”
  + Weight = 176 lbs
  + BMI = 23.9
  + Heart rate = 80 bpm
  + Respirations = 18 / min
  + Blood Pressure = 124/74 mmHg
  + Temperature = 98.2F
* Provider reviews the patient record prior to entering the room, including seeing that the PHQ score has increased from 15 from a month ago, to 17 today.
* Provider asks the patient how he is feeling, along with his concerns. Patient: “I’m not very good. I’m so tired all the time. I’m not sleeping well and I have trouble concentrating. I go to my AA meetings, but that is about it.” After discussion with the patient, the provider also learns the patient is concerned about long term living accommodations and won’t be able to afford rent beyond the next 4 months.
* Provider completes a psychiatric evaluation. Patient’s mental status is assessed as:
  + Appearance: Poorly groomed, patient slouching
  + Behavior: Subdued
  + State of Consciousness: Alert and oriented x 3
  + Attention: Slow to respond, shrugs shoulders in response to some questions
  + Speech: Soft, coherent
* Provider performs medication reconciliation and validates that patient is taking Zoloft 150 mg p.o. daily.
* Provider completes a head to toe assessment:
  + Head/Neuro: WNL
  + Heart: S1S2, BP normal
  + Lungs: Clear
  + Abdomen: Soft, benign. No GI/GU issues.
  + Extremities: No swelling, pedal pulses strong.
* After discussion about the patient’s worsening depression and the need to adjust treatment to better manage the patient’s condition, Provider and patient agree upon the following changes to the care regimen, which are documented in the Care Plan:
  + Continue Zoloft 150 mg p.o. daily / Immediately
  + Start Venlafaxine 37.5 mg daily x 4 days, then increase to 37.5 mg twice daily / Immediately
  + Referral for weekly individual psychotherapy (provider responsibility; 20 sessions; diagnosis=depression, PTSD; reason=worsening depression) / Now
  + Make appointment for weekly individual psychotherapy (patient responsibility) / Immediately
  + Continue weekly group psychotherapy / Ongoing
  + Referral to Supported Housing Services provided. Patient to follow-up / Immediately
  + Continue Vocational Rehabilitation Training / Ongoing
  + Follow-up in 2 weeks to evaluate for medication side effects
* Provider discusses with patient the patient’s goals to manage his health. The patient states he would like to complete the Vocational Rehabilitation Training. He feels that he can complete it within 6 months, if his housing situation is resolved and he won’t be homeless.

**BREAKDOWN OF ENCOUNTER INTO CLINICAL STATEMENTS**

* Requests
  1. **Medication:** 1 Venlafaxine 37.5 mg tablet daily x 4 days, then increase to 37.5 mg twice daily
     + **Topic:** Venlafaxine
     + Details:
       - Category/Type: Medication
       - Strength: 37.5 mg
       - **Dosage:** 1 tablet
       - Frequency: Daily
       - Duration: 4 days
       - **Instructions:** After 4 days, increase to 37.5 mg twice daily
  2. **Referral:** Weekly individual psychotherapy, 20 sessions, diagnosis = depression, PTSD, reason=worsening depression
     + **Topic:** Individual Psychotherapy
     + Details:
       - Category/Type: Referral
       - Value: 20
       - **UOM:** Sessions
       - **Indication:** Worsening depression, PTSD
  3. **Referral:**  Supported Housing Services
     + **Topic:** Supported Housing Services
     + Detail:
       - Category/Type: Referral
* Action (These need to be split out by topic, result, and details)
  1. Height: value = 72; UOM = inches
  2. Weight: value = 176; UOM = pounds
  3. BMI: value = 23.9; UOM = ???
  4. Heart rate: value = 80; UOM = bpm
  5. Respirations = value = 18; UOM = minute (is this correct for representing it?)
  6. Systolic BP: value = 124; UOM = mmHg
     + Where to put details, such as position (e.g., seated, lying down), laterality, preconditions (e.g., patient urinated at least 30 minutes before BP taken), etc.?
  7. Diastolic BP: value = 74; UOM = mmHg
  8. Temperature: value = 98.2; UOM = F
  9. Appearance: result (coded) = poorly groomed, patient slouching
  10. Behavior: result (coded) = subdued
  11. State of consciousness: result (coded) = Alert and oriented x 3
  12. Attention: result (coded) = Slow to respond, shrugs shoulders in response to some questions
  13. Speech: result (coded) = Soft, coherent
  14. Head/Neuro exam: result (coded) = WNL
  15. Heart exam: values = S1S2, BP normal
  16. Lungs exam: value = Clear
  17. Abdomen exam: value = Soft, benign. No GI/GU issues.
  18. Extremities exam: No swelling, pedal pulses strong.
  19. Patient attending weekly group psychotherapy
  20. Patient enrolled in Vocational Rehabilitation Training
  21. Goal = Complete Vocational Rehabilitation Training within 6 months, provided his housing situation is resolved and he won’t be left homeless

# Appendix C

## Ideas Discussed and Discarded

### Compound Clinical Statements: Separable vs. Inseparable Components

**Discussion:**

* Do we think of clinical statements with “values” only as numerical values? Or would other statements be considered having values, e.g.
  + Patient position = sitting
  + Priority = routine
  + Route of Administration = sublingual

If statements can have values other than numerical values, the BP use case could look like the example below:

|  |  |  |
| --- | --- | --- |
| **USE CASE** | **SEPARABLE STATEMENTS** | **INSEPARABLE COMPONENTS** |
| BP of 120/80 mmHg on right brachial artery, patient in sitting position for at least 5 min., using adult BP cuff, urinary bladder voided within 30 min. before measurement | Systolic BP = 120 mmHg |  |
| Diastolic BP = 80 mmHg |  |
| Time since last urination = 30 min. or less |  |
| Measurement body site = right brachial artery |  |
| Device used = adult cuff |  |
| Body position = sitting |  |
| Sitting time before measurement = 5 min. or more |  |

The “panel” above would consist of the following statements:

1. Systolic BP = 120 mmHg
2. Diastolic BP = 80 mmHg
3. Time since last urination = 30 min. or less
4. Measurement body site = right brachial artery
5. Device used = adult cuff
6. Body position = sitting
7. Time in sitting position = 5 min. or longer

If statements can have values other than numerical values, the Medication use case could look like the example below:

|  |  |  |
| --- | --- | --- |
| **USE CASE** | **SEPARABLE STATEMENTS** | **INSEPARABLE COMPONENTS** |
| Administration of nitroglycerin 0.4 mg tablet sub-lingual every 5 minutes as needed for chest pain; maximum 3 tablets (routine) | Strength = 0.4 mg | Administration |
| Frequency = every 5 minutes | Nitroglycerin |
| Maximum dosage = 3 tablets | As needed |
| Dose form = tablet |  |
| Route of Administration = sublingual |  |
| Indication = Chest pain |  |
| Priority = Routine |  |

The “panel” above would consist of the following statements:

1. Administration of nitroglycerin as needed
2. Medication strength = 0.4 mg
3. Frequency = every 5 minutes
4. Maximum dosage = 3 tablets
5. Dose form = tablet
6. Route of Administration = sublingual
7. Indication = chest pain
8. Priority = routine

After discussion, decision was made to only define separable components as components with numerical or pseudo-numerical values and components, that can have present/absent values, if these are directly related to the focus of the statement.

1. <https://en.wikipedia.org/wiki/Separation_of_concerns> [↑](#footnote-ref-2)
2. <https://en.wikipedia.org/wiki/immutable_object> [↑](#footnote-ref-3)