Representing Negated Information in Healthcare Data Standards

**A report by the Patient Care, Vocabulary, and Clinical Quality Information work groups of HL7**

**Draft for Ballot, May 2017**

Contents

[Introduction 3](#_Toc476651727)

[Approach 4](#_Toc476651728)

[Examples 4](#_Toc476651729)

[Classification and Analysis 4](#_Toc476651730)

[Modeling 5](#_Toc476651731)

[Guidelines 5](#_Toc476651732)

[Analysis 5](#_Toc476651733)

[Desiderata 5](#_Toc476651734)

[Scope Boundaries 7](#_Toc476651735)

[Uses of Negation 8](#_Toc476651736)

[Contexts 9](#_Toc476651737)

[Guidelines 9](#_Toc476651738)

[Appendix A 10](#_Toc476651739)

[Appendix B 21](#_Toc476651740)

[Appendix C 23](#_Toc476651741)

[Use Cases diagram 23](#_Toc476651742)

[Actors 23](#_Toc476651743)

[Use Cases 24](#_Toc476651744)

[Processes 26](#_Toc476651745)

[Negation Domain Class Diagram 33](#_Toc476651746)

[Out of scope items diagram 36](#_Toc476651747)

## Introduction

The concept of negation raises complex questions in the world of data representation. These questions include

* Repetition: whether a negation of a negation is an involution that cancels itself out, as in algebra, or an intensifier, as is common in natural language,
* Explicitness: whether absence of a statement of presence is ever equivalent to a statement of absence,
* Scope: how to establish the boundary of what is negated—i.e., when negation is predicated of a class, which class properties are asserted to be absent, and which ones contextualize that assertion
* Modification: the problem of changing the underlying meaning of a class, and the need to ensure that such “modified” classes are understood by other parties, and
* Transformation: how can a negated concept be transformed from one formalism into another.

When these issues arise in natural language, as in a clinical note, patterns developed over the history of natural language generally provide tactics for addressing these issues, often in ways specific to an interpretive community. However, when representing information in a form intended to support automated processing, it is important to specify semantics in consistent ways that support predictable processing results.

All of these questions have arisen in discussions of standards for the representation of clinical data, and they have done so in diverse contexts. These efforts have produced divergent solutions. It is not always obvious how to transform data formed in one syntax into another syntax—or even that such transformations can always be performed accurately.

This project aims to provide a foundation for harmonization of these efforts

* First by providing a compendium of data instances regarded as “negations” in order to identify the specific semantics to be addressed,
* Second by assessing the uses of these instances in order to clarify the specific semantic function of the negation,
* And third by stating principles for information design that support the identified functions without introducing unnecessary complexity.

These principles should allow specification designers to produce designs that

* Ensure they have addressed all the known cases of negation,
* Avoid, to the extent possible, the issues listed above, and
* Support forward and backward compatibility with other specifications that follow the principles.

We also considered another benefit:

* Recommended patterns to ensure future solutions can be harmonized more easily.

However, it was deemed better to leave these patterns in the hands of the respective specification designers. Instead, it is hoped that this analysis model may provide the basis for a policy to support the creation of such patterns.

The team is under no illusion that any effort “to develop one universal standard that covers everyone’s use cases”[[1]](#footnote-1) will cause stakeholders to subjugate their local and emergent needs to the dictates of a document. We do hope that, by engaging known design specification teams and by providing the result as a living document, we can provide a tool that design teams may find useful, and that this usefulness may conduce to more commensurable patterns in the future.

## Approach

The analysis was conducted in stages.

### Examples

The first task was to confirm scope. We solicited examples and sources of examples of negated information from the participants, and include examples from

* FHIR change requests & chat threads
* Natural Language Processing specifications
* US Veterans Administration use cases
* Team meetings.

We compiled a list of these examples, provided in Appendix A. Many of the items in this list are deemed out of scope for various reasons.

### Classification and Analysis

The second task was to reduce the compiled list to a shorter list of kinds of negation. Any item in the first list should be represented by an example in the second. For example, “absent spleen” and “absent carotid artery” are both instances of assertions of the absence of normal anatomical features. Whether they may also require additional explanatory information (e.g., whether the absence is due to a congenital defect, excision, or trauma) is only relevant here to the extent to which it affects the representation of absence. We were able to reduce a list of 151 examples to 37 kinds of negation.

The third task was to analyze the examples. We used queries from known quality measures and decision support scenarios to assess which examples contained semantics that required explicit negatory semantics, and which could be handled without that complexity. For instance, in the “absent spleen” case, “asplenia” and “immunocompromise” are useful concepts in a problem list, but we could not find cases where a positive assertion of the presence of an anatomical feature was purposefully denied or where such denial was queried.

For those cases that might require explicit semantics, we wanted to characterize the semantics of negation consistently, which we did by modeling the examples in the SNOMED CT concept model for Situation with Explicit Context. This provided a clear division between the phenomenon of interest and the negating operation.

The classes so identified are also represented in Appendix B.

### Modeling

We then modeled the cases in UML in order to make assumptions about the classes explicit and to uncover associations among them. These diagrams may be easier for some stakeholders to review than the lists on which they are based.

The model diagrams and definitions are provided in Appendix C.

### Guidelines

Finally, we used these representations to assemble a set of design guidelines for representing negation in clinical information models. While **subject matter expert workgroups** are needed to ensure the lists and classifications are complete and correct, **standards development workgroups** can use the resulting guidelines to

* + confirm that their designs support the needs of the clinical community,
  + demonstrate recommended patterns for their specification,
  + identify out-of-specification patterns, and
  + demonstrate transformations between their designs and other widely adopted specifications.

We frame these guidelines to support the development of a policy that could be adopted to guide future standards development.

## Analysis

One of our earliest conclusions was that the term “negation” is misleadingly abstract for use in information models: we found no examples of clinical use of the term “negation.” However, we find “negation” and “not” useful as keywords for collecting related concepts. We define the related concepts as those identifying things that are absent and actions that are not done. We also include some abstract edge cases, such as “goal not held” or “risk not present.” The full list is presented in the requirements spreadsheet.

### Desiderata

The following principles arose out of the analysis as points we felt it important to agree on. Many of them are not met by existing specifications, and two are in elementary conflict, but they represent a baseline for negotiation.

1. Absence of evidence is not evidence of absence.

There is no general need to represent the results of an empty query: no specific information (viz., absence) can be derived from it other than that it is empty.

Clinical Quality Measures (CQMs) may present an exception. A rule may infer that a procedure was not done for the sake of calculating the measure and its financial impact, but such an inference should never be used for clinical purposes. There may be a need to record the inference of absence, but if such a record is made, it must be made in a way that cannot be mistaken for a positive absence; e.g., a measure may represent a procedure as “not found.”

1. Avoid excessive abstraction.

Use concrete concepts rather than “negation” where appropriate.

The logical concept of negation, with its Boolean value range, is rare in healthcare practice. Most of the things we refer to as negations are observations of *absence* or records that things were *not done*. Because the semantics of the Boolean value are so abstract (e.g., giving rise to substantial confusion despite its concrete and detailed exposition in the HL7 V3 RIM), we recommend that it be avoided in information modeling. Even the most fit example we could find for negation—a provider “refuting” a prior diagnosis—has a specific concrete term already in use. (Note that the ambiguous term “rule-out” should be recorded or defined as either “possible” or “refuted,” per the local context assumption.)

We do not argue with the Boolean type’s usefulness in programming; only its clarity in information modeling.

1. Handle negation as consistently as possible without violating clinical requirements.

Consistency has two faces: that of semantic consistency within a model and that of syntactical consistency across models.

For the first, models should not allow different properties to represent overlapping semantics. E.g., if a model has a way (e.g., “status”) to specify whether an activity is completed, it is unclear what information a Boolean “not done” flag provides. Rather than adding another element, it seems that the addition of a “not done” value to the status range meets the need without creating an opportunity for contradictory information.

For the second, the difficulty is in defining when things are similar enough in clinical practice to merit leverage of similar data structures, and when they are not (e.g., Finding “absent” vs Condition “refuted”). The catalog approach of this project is designed to provide cases to inform discussion of that concern.

A third issue may arise when using the SNOMED CT concept model to represent observation results. The model supports the association of observable entities with the findings that interpret them, but is also supports the assertion of “presence” in the situation model.

1. Avoid double negatives.

The semantics of double negatives are ambiguous.

Where double negation is unavoidable, its meaning should be specified clearly and explicitly. Furthermore, in that case, the preferred approach is "idempotent": any number of negations is equivalent to one negation. I.e., double negation should be an emphatic, not an inversion.

1. Support requirements with minimal transformation.

Transformation introduces risk and cost, and should be avoided, all else being equal. One approach to the principle articulated by the NPfIT project is to store data in a form as “close to user” as possible. This preserves the intended semantics of the user most clearly, and may be useful for future modifications (or even corrections) to any automated transformations.

Transformations will still be necessary, but, of the many guidelines and heuristics for determining where to perform them, this one militates for storing closer to capture and transforming closer to point of use.

1. Model negated properties as explicitly as possible to support unambiguous comprehension and automated use of semantics.

Semantic codes are more useful than text. Where negation is used for computation, it can be expressed in a “model-coordinated” fashion (e.g., with a separate field for “present” or “absent”) or in a “terminology-coordinated” fashion (e.g., a single field to contain both “present X” and “absent X”). The former requires less terminology maintenance and supports computation more directly; the latter is likely to be more often found in “close to user” forms.

Note that Desiderata 5 and 6 contain a conflict: a close-to-user form is likely to make use of pre-coordinated concepts, whereas a fully articulated model is not. One method of managing this difficulty is to allow a “close-to-user” form for user interfaces, storage, and interoperability as long as such a form can be logically disaggregated into constituent parts for processing. E.g., a “No allergy to latex” concept may be a “fully defined” situation, where the “absent” finding context can be dereferenced when needed for calculation. This approach implies a requirement for accessible terminology services.

### Scope Boundaries

We identify several related topics here in order to clarify that they are out of scope.

* There are other **Modifiers** that may affect the semantics of a data element. Risks and family history modifiers, e.g., may require handling similar to that recommended here.
* **Certainty** is an assessment of the confidence with which an assertion is stated. Degrees of certainty may imply complementary degrees of negation. SNOMED CT specifies flavors of “known present” including “confirmed present,” “definitely present,” and “probably present,” but “probably present” also shows up in the “known possible” branch alongside “probably not present,” which also appears in the “known absent” branch. This suggests that, were these concepts fully defined, they would contain distinct properties for presence and certainty.
* **Likelihood** refers to the probability that something is true. This may be distinguished from Certainty, which is a kind of Data Quality, and has to do with how well the evidence supports a conclusion. Likelihood values do actually impinge on presence/absence semantics: a likelihood of zero is equivalent to absence
* **Data quality** concerns seem to some to be related to negation. The knowledge that a certain percentage of assertions are incorrect invites comparison to negation of that cohort. However, as the cohort is unknown, no negative assertions can be made. Possible solutions may focus on processes of data capture and maintenance: the topic is not our focus here.
* **Provenance** has been suggested as another dimension of potential negation, however the concern has been with quality and certainty, addressed above.
* **Null values** represent a special case. While we maintain that null values in general are a separate topic from negation, the degree of interest in “no known allergies” makes it a key use case for our project.

### Uses of Negation

The kinds of statements we classify as negation are made for a variety of reasons. We find four general categories:

1. Absence of a phenomenon that might be suspected
   1. Refutation of a previously suspected or considered diagnosis
   2. Cataloging of “chart by exception” ruled-out phenomena
   3. Patient reports may require support, but no cases have been identified.
2. Checking for contraindications prior to taking action
   1. Allergy, pregnancy, bleeding disorders, medications, NPO, etc.
3. Criteria
   1. Decision points for starting or stopping interventions
4. Prohibition & rationale
   1. Instructions for planning purposes
   2. Consent or alignment of goals
   3. Rationale for not having performed an intervention suggested by a quality measure

Items in category 1 may benefit from explicitly modeled negation that can support negated logical expressions (e.g., “head injury without loss of consciousness”). The other categories may not.

Category 2 contains information that is asked as part of a procedural safety check: if there are subsequent procedures, these questions will be asked again. If answered in the negative, they are only recorded as an audit trail that the question was asked. These assertions will usually be recorded as question/answer pairs (evaluation patterns), where the negative semantics are represented in a clearly delineated “answer” portion. This answer may be transformed into a logical negation, but to do so would be unusual.

Category 3 includes plans and directives (and possibly protocols) that include some decision criterion (e.g., “Nothing to eat or drink until respiratory distress dissipates”). As with group 2, the prospective negation is in response to an explicit question, and it can be easily captured as the answer.

Category 4 describes procedures and interventions, both as records of inaction with reasons (for quality measure calculation) and as instructions to avoid action, also usually with a reason.

These two cases seem to harbor complexity:

* Patient not taking medication. Asserting “procedure not done” doesn’t seem to convey the habitual nature of the assertion.
* Specific vs class negation (e.g., no latex allergy vs no allergies). Does the use of the more general class (“allergy”) do what we need, or are there other considerations?

### Contexts

The four categories listed above map generally to the patterns in the model:

1. Absence of phenomenon: absence of phenomenon
   1. The context tends to be refutation of a suspected condition. See example 1, no CHF.
2. Contraindications: evaluation of characteristic
   1. These tend to be represented as questions for procedural review; their semantics has a very short shelf-life and they are unlikely to be used in prospective analysis. See example 92, not pregnant.
3. Criteria: absence of phenomenon
   1. When an instruction is given a criterion of absence, the phenomenon is best represented as explicitly negated. See example 133, “until distress dissipates.”
4. Prohibition: Prohibition
   1. Prohibitions are orders not to do things.

For **data entry** and **human review**, close-to-user forms are appropriate.

**Storage** form is a system architecture decision. It depends on the specific uses to which data will be put, as well as legal and audit needs.

**Quality measure** calculation can be performed *ex post facto* and should have minimal effect on clinical record formats.

Other uses include forms optimized for computation in **query** and **clinical decision support**. To the extent that this support is managed in business logic, it can be left to the business designers. To the extent that the analytics may depend on more general and cross-case representations, it becomes important to model logical negation explicitly.

\*\*\*Need use cases\*\*\*

## Guidelines

We recommend that specification designers follow these guidelines.

1. Follow the desiderata listed above.
2. Where there is conflict, e.g., between desiderata 5 and 6, specify the requirements and resulting direction.
3. Provide explicit instructions for how negated statements in your specification should be transformed from and to other widely adopted specifications. This can be done in a consolidated manner using the classes identified in the analysis model or on a case-by-case basis.
4. When you identify a use case that this model does not address, bring it up to the Patient Care or Vocabulary work group.

## Appendix A

List of example requirements,

| ID | **Source** | **Item** | **Category** | **Relevant** | **Note** | **Model class** |
| --- | --- | --- | --- | --- | --- | --- |
| 62 | CIMI CQI project | Absence of assertion of intent to breast feed | absence of assertion | Not relevant | absence of evidence is not evidence of absence | None |
| 64 | PC thread 2/25/16 | 2.       It is not the case (that I do know) that the Patient has problem X, | absence of assertion | Not relevant | null value | None |
| 147 | PQRS 258 | Percent of patients undergoing open repair of small or moderate sized non-ruptured abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7) i.e., who do not experience a major complication | absence of complication (derived) |  |  | Absence of phenomenon, derived |
| 148 | PQRS 259 | Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2) | absence of complication (derived) |  |  | Absence of phenomenon, derived |
| 150 | PQRS 384 | Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery. | absence of complication (derived) |  |  | Absence of phenomenon, derived |
| 48 | NegEx Lexicon | definiteExistence e.g., obvious | affirmative | Not relevant | affirmative, not negation | None |
| 54 | NegEx Lexicon | probableExistence e.g., evidence for, appears | affirmative | Not relevant | likelihood, not negation | None |
| 57 | NegEx Lexicon | pseudoHistorical e.g., history and examination | affirmative | Not relevant | history, not negation | None |
| 58 | NegEx Lexicon | pseudoNegation e.g., no change | affirmative | Not relevant | consistency, not negation | None |
| 63 | PC thread 2/25 | 1.       It is the case (that I do know) that the Patient has problem X, | affirmative | Not relevant | affirmative, not negation | None |
| 42 | HL7 PC Orlando 1/12/16 | Congenital absence of coronary artery | Anatomical deficit, congenital |  | need to distinguish? | Condition |
| 44 | HL7 PC Orlando 1/12/16 | Left leg amputated (not present) | Anatomical deficit, surgical |  |  | Condition or Procedure (Record of action) |
| 43 | HL7 PC Orlando 1/12/16 | Left kidney resected (absent) | Anatomical deficit, surgical |  |  | Condition or Procedure (Record of action) |
| 100 | invented 5/5/16 | Hand lost in accident | Anatomical deficit, traumatic |  |  | Condition |
| 47 | HL7 PC Orlando 1/12/16 | no spleen | Anatomical deficit, unspecified |  |  | Condition |
| 144 | PQRS 145 | Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available) | backup measure | Not relevant | absence is a condition, not a recorded fact | None |
| 60 | RadLex (Richard Esmond) | Radiology negative findings - get example list for chart by exception | Chart by exception |  |  | Absence of phenomenon |
| 104 | WGM 5/10/16 | [assert that a batch of stuff is absent] | Chart by exception |  |  | Absence of phenomenon |
| 1 | VA Use Case Angina 1 - EDCare 2.20.15 | m.   CXR: Normal. No mediastinal widening, valve disease, or CHF I.e., no CHF | Chart by exception |  |  | Absence of phenomenon |
| 105 | WGM 5/10/16 | [handle context conduction] | Collection (inheritance) | Not relevant | no concrete example found | None |
| 103 | WGM 5/10/16 | Ted: nested negation? See fhir dstu questionnaire | Collection (inheritance) | Not relevant | no concrete example found | None |
| 74 | 20160323 call | does not have diabetes (from MU test data - problem list) - provenance is important to consider i.e., no diabetes | Condition absent |  |  | Absence of phenomenon |
| 92 | Negation call 4/13 | patient not pregnant | Condition absent |  |  | Absence of phenomenon |
| 73 | 20160323 call | not allergic to clindamycin (from MU test data - allergy list) - provenance is important to consider | Condition absent |  |  | Absence of phenomenon |
| 67 | PC thread 2/25/16 | 5.       It is the case (that I do know) that the Patient has no problems (ie none). | Condition absent (generic) |  |  | Absence of phenomenon |
| 112 | openEHR exam pattern | No abnormality detected (BL) | Condition absent (generic) |  |  | Absence of phenomenon |
| 41 | HL7 PC Orlando 1/12/16 | my uncle does not have hemophilia | Condition absent (relation) |  | One might assume this is a risk factor for pt, not a condition for uncle. But some domains might model relation to uncle and absence of a condition. In this case, this is an absent condition like any other, just assigned to a different person. | Absence of phenomenon |
| 69 | PC thread 2/29/16 | clinicianAssertedStatus - confirmed/refuted - "Patient is/isn't allergic to penicillin" | Condition absent (sensitivity) |  |  | Absence of phenomenon |
| 70 | PC thread 3/1/16 | no allergy to latex | Condition absent (sensitivity) |  |  | Absence of phenomenon |
| 128 | FHIR Zulip 9/5 | "patient says that they have never had chicken pox" | Condition historically absent |  |  | Evaluation of characteristic |
| 101 | WGM 5/10/16 | [condition in remission] | Condition in remission | Not relevant | this is a problem status | None |
| 91 |  | Refute the absence of a condition | Condition not absent | Not relevant | no concrete example found | None |
| 102 | WGM 5/10/16 | [condition refuted] | Condition refuted | Not relevant | this is a problem status | None |
| 131 | PC 9/20/16 | healed fracture (no fracture) | Condition resolved | Not relevant | this is a problem status | None |
| 122 | Negation call 8/10 | need example. Probably out of scope, because semantically more like 'risk' or 'possibility,' but need to explain this. And that "rule out" is ambiguous: use "differential" or "not present" | Condition rule-out | Not relevant | differential or rule-out are ambiguous for two problem states: risk/possibility and refuted. Use those. | None |
| 53 | NegEx Lexicon | indication e.g., rule out | Condition rule-out | Not relevant | too abstract to evaluate | None |
| 136 | PQRS 69 | Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period [condition not in remission] | Condition status | Not relevant | this is a problem status | None |
| 130 | PC 9/20/16 | Patient does not consent to surgery | Consent |  |  | None |
| 50 | NegEx Lexicon | experiencer e.g., sister's | Context | Not relevant | subject context, not negation | None |
| 51 | NegEx Lexicon | future e.g., at risk for, concern for | Context | Not relevant | risk, not negation | None |
| 143 | PQRS 141 | Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre- intervention level, a plan of care was documented within 12 months | Criterion | Not relevant | threshold, not negation | None |
| 145 | PQRS 166 | Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours | Criterion | Not relevant | threshold, not negation | Condition |
| 97 | MM mail 4/5 | “NO KNOWN. CODEINE CAUSES NAUSEA” | criticality |  | combination of negative & criticality | condition |
| 82 | Negation call 3/30/16 | patient did not show up | Encounter not held |  | could be documented on appointment; might be documented as an act that did not occur. | Action not done |
| 39 | VA Use Case DM 4 Care Coordinator Telephone Follow Up 2.20.15 | a.     Patient notes that work has been busy, and that no time has been available to make the appointment | Encounter not to be held + reason |  |  | Action not done |
| 81 | Negation call 3/30/16 | follow up not needed | Encounter not to be held + reason |  |  | Prohibition |
| 55 | NegEx Lexicon | probableNegatedExistence e.g., fails to reveal | Evidence absent | Not relevant |  | Evaluation of characteristic |
| 108 | decomposition of other requirements 6/21 | no evidence of cancer (path) | Evidence absent (Pathology) |  | not condition absent; likely to be a question asked for certain patients | Evaluation of characteristic |
| 56 | NegEx Lexicon | pseudoExperiencer e.g., by her husband | Family member | Not relevant |  | None |
| 133 | VA Use Case CHF - ED 20150305 | 1.     Nothing to eat or drink until respiratory distress dissipates  [respiratory distress absent] | Finding absent |  |  | Absence of phenomenon |
| 71 | Kcampbelll | closed head injury without loss of consciousness i.e., no loss of consciousness | Finding absent (dependent) |  | two observations. Is conjunction in situation relevant? | Absence of phenomenon |
| 4 | VA Use Case Angina 1 - EDCare 2.20.15 | b.    CV: Chest pressure 5 out of 10 after 3 SL-NTG tablets, S1S2, No murmurs or gallop Exam: No murmur | Finding absent (exam) |  |  | Absence of phenomenon |
| 23 | VA Use Case Depression - Outpatient Follow-up 2.26.15 | Extremities: No swelling, pedal pulses strong. I.e., No swelling | Finding absent (exam) |  |  | Absence of phenomenon |
| 33 | VA Use Case DM 2 Follow Up Outpatient Visit 2.20.15 | Extremities: No swelling, bilateral pedal pulses +2, I.e., No swelling | Finding absent (exam) |  |  | Absence of phenomenon |
| 37 | VA Use Case DM 3 - Referral for Annual Podiatry Screening 2.20.15 | 5. Wound assessment: Medial portion of right big toe (approx. 5 mm x 5mm) at top of toenail is slightly red. No breakdown. No sign of infection.  I.e., No breakdown | Finding absent (exam) |  |  | Absence of phenomenon |
| 38 | VA Use Case DM 3 - Referral for Annual Podiatry Screening 2.20.15 | Provider removes ingrown toenail without complications. No infection noted. Skin intact, with slight inflammation. I.e., No infection noted | Finding absent (exam) |  |  | Absence of phenomenon |
| 11 | VA Use Case Angina 2 TelemetryCare 2.20.15 | a.     Begin light exercise (walking on a level surface for 5 minutes, 3 times a day). Add 1 minute to each session, each day until able to complete 10-15 minutes in each session without cardiac symptoms. cardiac symptoms absent | Finding absent (exam) |  | Record "absent"; we do not recommend relying on absence of positive assertion to record achievement of a goal | Absence of phenomenon |
| 24 | VA Use Case Depression - Outpatient Follow-up 2.26.15 | b. Adverse effects from the medication  a. None noted | Finding absent (general) |  |  | Absence of phenomenon |
| 22 | VA Use Case Depression - Outpatient Follow-up 2.26.15 | Abdomen: Soft, benign. No GI/GU issues. I.e., No GI/GU issues | Finding absent (general) |  | this is very similar to chart by exception | Absence of phenomenon |
| 20 | VA Use Case Depression - Outpatient Follow-up 2.26.15 | a.     AUDIT-C - Score: 0 (No symptoms of abuse) | Finding absent (instrument) |  |  | Evaluation of characteristic |
| 32 | VA Use Case DM 1 Diagnosis of Diabetes 2.20.15 | Patient completes alcohol use screening  l. Result: 2 (Negative) | Finding absent (instrument) |  |  | Evaluation of characteristic |
| 31 | VA Use Case DM 1 Diagnosis of Diabetes 2.20.15 | Patient completes PTSD screening k. Results: Negative | Finding absent (instrument) |  |  | Evaluation of characteristic |
| 9 | VA Use Case Angina 2 TelemetryCare 2.20.15 | Cardiologist evaluates the reading and enters the interpreted result in the EHR. Result: Normal echocardiogram. No cardiomegaly or effusion. Good valve function. Ejection Fraction: 58% I.e., No cardiomegaly | Finding absent (interpretation) |  |  | Absence of phenomenon |
| 10 | VA Use Case Angina 2 TelemetryCare 2.20.15 | Reviews ECG reading and enters the interpreted result in the EHR. Result: SR 76. No ectopy. No hypertrophy.  I.e., No hypertrophy | Finding absent (interpretation) |  |  | Absence of phenomenon |
| 8 | VA Use Case Angina 2 TelemetryCare 2.20.15 | a.     Notes cardiac rhythm: Sinus rhythm without ectopy, HR 84 I.e., No ectopy | Finding absent (interpretation) |  |  | Absence of phenomenon |
| 13 | VA Use Case CHF - ED 20150305 | o    Cardiac rhythm (ECG): Sinus tachycardia (ST) without ectopy  I.e., No ectopy | Finding absent (interpretation) |  |  | Absence of phenomenon |
| 108 | decomposition of other requirements 6/21 | no mrsa found (lab) | Finding absent (lab) |  |  | Evaluation of characteristic |
| 7 | VA Use Case Angina 2 TelemetryCare 2.20.15 | a.     History of Tobacco use: No | Finding absent (patient report) |  |  | Evaluation of characteristic |
| 17 | VA Use Case CHF - ED 20150305 | a.     Smoking history: No tobacco use | Finding absent (patient report) |  |  | Evaluation of characteristic |
| 19 | VA Use Case CHF - IMC 20150305 | 1.     History of Tobacco use: No | Finding absent (patient report) |  |  | Evaluation of characteristic |
| 29 | VA Use Case DM 1 Diagnosis of Diabetes 2.20.15 | a.     Smoker: No | Finding absent (patient report) |  |  | Evaluation of characteristic |
| 30 | VA Use Case DM 1 Diagnosis of Diabetes 2.20.15 | a.     Substance Use: No | Finding absent (patient report) |  |  | Evaluation of characteristic |
| 35 | VA Use Case DM 3 - Referral for Annual Podiatry Screening 2.20.15 | a.     Smoker: No | Finding absent (patient report) |  |  | Evaluation of characteristic |
| 36 | VA Use Case DM 3 - Referral for Annual Podiatry Screening 2.20.15 | b.     Alcohol Use: No | Finding absent (patient report) |  |  | Evaluation of characteristic |
| 3 | VA Use Case Angina 1 - EDCare 2.20.15 | d.    Smoking history: No tobacco use | Finding absent (patient report) |  |  | Evaluation of characteristic |
| 5 | VA Use Case Angina 1 - EDCare 2.20.15 | e.     GU: Verbalizes no problems with voiding | Finding absent (patient report) |  |  | Evaluation of characteristic |
| 89 | NEMSIS | No bleeding disorders | Finding absent (patient report) |  | safety process; not on condition list | Evaluation of characteristic |
| 45 | HL7 PC Orlando 1/12/16 | No vision in right eye | Functional deficit |  |  | Condition |
| 46 | HL7 PC Orlando 1/12/16 | no menses | Functional deficit |  |  | Condition |
| 49 | NegEx Lexicon | definiteNegatedExistence e.g., patient was not | general | Not relevant | too abstract to evaluate | None |
| 80 | Negation call 3/30/16 | 5-year survival is not my goal | Goal not held |  |  | Evaluation of characteristic |
| 79 | Negation call 3/30/16 | Quitting smoking is not my goal | Goal not held |  |  | Evaluation of characteristic |
| 76 | Negation call 3/23 | Goal was not met | Goal status | Not relevant | status of tracked goal | None |
| 14 | VA Use Case CHF - ED 20150305 | 1.     Sinus tachycardia (ST) Q waves in the inferior leads, inferolateral ST- and T-wave changes (This is unchanged from the previous admission-3 months ago). | Inference | Not relevant | 'no change' can be inferred from any pair of items | None |
| 52 | NegEx Lexicon | historical e.g., changing, previous | Inference | Not relevant | prior change is not a negation | None |
| 25 | VA Use Case Depression - Outpatient Follow-up 2.26.15 | i.    Provider notices that the patient did not tolerate Prazosin in the past (which was started to address difficulty sleeping) | Intolerance | Not relevant | intolerance is a condition | Condition |
| 12 | VA Use Case CHF - ED 20150305 | Allergies: No known drug allergy | No known allergy |  |  | Absence of phenomenon |
| 16 | VA Use Case CHF - ED 20150305 | a.     Confirms allergies: No known drug allergy | No known allergy |  |  | Absence of phenomenon |
| 93 | MM mail 4/5 | “No Known Medicine Allergies, mom sts food Allergies” | No known allergy |  |  | Absence of phenomenon |
| 94 | MM mail 4/5 | “no known med allergies but has food other allergies” | No known allergy |  |  | Absence of phenomenon |
| 2 | VA Use Case Angina 1 - EDCare 2.20.15 | b.    Confirms allergies: No known drug allergy | No known allergy |  |  | Absence of phenomenon |
| 95 | MM mail 4/5 | “Father states pt has no known allergies, but states close family members have had severe reactions to:  PCN, succinylcholine chloride, anectine, and quelizine” | No known allergy with FH |  |  | Absence of phenomenon |
| 21 | VA Use Case Depression - Outpatient Follow-up 2.26.15 | Head/Neuro: WNL Heart: S1S2, BP normal | Normal | Not relevant | WNL can be used to support chart by exception, but is not here | Evaluation of characteristic |
| 34 | VA Use Case DM 2 Follow Up Outpatient Visit 2.20.15 | Head/Neuro: WNL | Normal | Not relevant |  | Evaluation of characteristic |
| 129 | FHIR Zulip 9/5 | not currently taking | Not on medication |  |  | Not currently taking medication |
| 90 | NEMSIS | Not on anticoagulants or thinners | Not on medication (patient report) |  |  | Not currently taking medication |
| 6 | VA Use Case Angina 1 - EDCare 2.20.15 | b.    Since chest pain started 45 minutes ago, it is too early to see any elevation in cardiac enzymes (Troponin, CK-MB) | Null flavor | Not relevant | null value | None |
| 40 | HL7 PC Orlando 1/12/16 | do not know whether uncle has/had colon cancer | Null flavor | Not relevant | null value | None |
| 65 | PC thread 2/25 | 3.       It is the case that I don’t know if the Patient has problem X, | Null flavor | Not relevant | null value | None |
| 66 | PC thread 2/25 | 4.       It is the case that I don’t know if the Patient has any problems (ie any). | Null flavor | Not relevant | null value | None |
| 96 | MM mail 4/5 | “no known allergies but has problems with ingesting some meds” | Null flavor | Not relevant | null value | None |
| 59 | NegEx Lexicon | uncertain e.g., either | Null flavor | Not relevant | null value | None |
| 107 | decomposition of other requirements 6/21 | No next of kin | Party absent (persistent) |  | could be n/a or negated or a second question with "no" or "none" as the answer | Evaluation of characteristic |
| 106 | WGM 5/10/16 | no family; no home; transportation; POA I.e., no family | Party absent (persistent) |  |  | Evaluation of characteristic |
| 72 | Unknown | mother not present | Party absent (point) | Not relevant | Provenance | None |
| 61 | CIMI CQI project | Assertion of intention not to breast feed | Patient intent to abstain |  |  | Evaluation of characteristic |
| 75 | Negation call 3/23 | Preference that an action not be done: [Margaret] | Patient preference to abstain |  |  | Evaluation of characteristic |
| 132 | PC 9/20/16 | Patient is not NPO | Precondition not met |  |  | Evaluation of characteristic |
| 78 | Negation call 3/30/16 | reason for discontinuing medication | Procedure discontinued + reason |  |  | Action aborted |
| 27 | VA Use Case Depression - Outpatient Follow-up 2.26.15 | and was discontinued due to irregular heartbeats and restlessness | Procedure discontinued + reason |  |  | Action aborted |
| 115 | CQI - The Joint Commission Measure VTE-3 | Reason for discontinuation of parenteral anticoagulation therapy | Procedure discontinued + reason |  |  | Action aborted |
| 26 | VA Use Case Depression - Outpatient Follow-up 2.26.15 | *xxxx* and was discontinued due to irregular heartbeats and hyperventilation | Procedure discontinued + reason |  |  | Action aborted |
| 135 | PQRS 65 | Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode | procedure not done |  |  | Action not done |
| 137 | PQRS 93 | Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy | procedure not done |  |  | Action not done |
| 138 | PQRS 102 | Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer | procedure not done |  |  | Action not done |
| 139 | PQRS 116 | Percentage of adults 18 through 64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or 3 days after the episode | procedure not done |  |  | Action not done |
| 140 | PQRS 121 | Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period | procedure not done |  |  | Action not done |
| 141 | PQRS 122 | Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care | procedure not done |  |  | Action not done |
| 146 | PQRS 243 | Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program | procedure not done |  |  | Action not done |
| 149 | PQRS 312 | Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis. | procedure not done |  |  | Action not done |
| 151 | PQRS 419 | Percentage of patients with a diagnosis of primary headache disorder for whom advanced brain imaging was not ordered. | procedure not done |  |  | Action not done |
| 99 | Negation call 4/20 | hearing screening not done - needed for quality measure | Procedure not done |  |  | Action not done |
| 113 | CQI call 8/5 | Represent inference of "absence" from empty query - specific use not yet determined, but, e.g., CDS logging | Procedure not done - inference |  |  | Action not done (derived) |
| 28 | VA Use Case Depression - Outpatient Follow-up 2.26.15 | Patient still refuses cessation treatment despite motivational interventions | Procedure not done + reason |  |  | Action not done |
| 87 | FHIM call 4/1/16 | did not do a variety of things for reason X | Procedure not done + reason |  |  | Action not done |
| 114 | CQI - The Joint Commission Measure AMI-7a | Reason for delay in fibrinolytic therapy | Procedure not done + reason |  |  | Action not done |
| 116 | CQI - The Joint Commission Measure STK-4 | Reason for delay in initiation of IV thrombolytic | Procedure not done + reason |  |  | Action not done |
| 117 | CQI - The Joint Commission Measure VTE-3 | Reason for not providing overlap medication (IV or subcutaneous anticoagulation therapy and warfarin on the same day) | Procedure not done + reason |  |  | Action not done |
| 118 | CQI - The Joint Commission Measure TOB-2, TOB-3 | Reason for not providing tobacco cessation medication at discharege | Procedure not done + reason |  |  | Action not done |
| 119 | CQI - The Joint Commission Measures STK-1, VTE-1, VTE-6 | Reason for not providing Venous thromboembolism therapy or prophylaxis (medication or antithrombotic device use | Procedure not done + reason |  |  | Action not done |
| 120 | CQI - The Joint Commission Measure STK-6 | Reason for not providing statin medication at discharge | Procedure not done + reason |  |  | Action not done |
| 121 | CQI - The Joint Commission Measure PC-03 | Reason for not initiating antenatal steroids | Procedure not done + reason |  |  | Action not done |
| 77 | Negation call 3/30/16 | won't admin flu vaccine due to egg allergy | Procedure not done + reason |  |  | Action not done |
| 83 | Negation call 3/30/16 | procedure not done because patient ate | Procedure not done + reason |  |  | Action not done |
| 86 | Negation call 3/30/16 | did not provide vaccine because out of stock | Procedure not done + reason |  |  | Action not done |
| 134 | PQRS 47 | Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. | Procedure not done + reason |  |  | Action not done |
| 124 | FHIR Gforge comment | [do not turn patient](http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=9335) | Procedure not to be done |  |  | Prohibition |
| 126 | FHIR Gforge comment | do not flush central line | Procedure not to be done |  |  | Prohibition |
| 127 | FHIR Gforge comment | do not take blood pressure on left arm | Procedure not to be done |  |  | Prohibition |
| 18 | VA Use Case CHF - ED 20150305 | 1.     Nothing to eat or drink until respiratory distress dissipates | Procedure not to be done |  |  | Prohibition |
| 125 | FHIR Gforge comment | do not give blood or blood products | Procedure not to be done |  |  | Prohibition |
| 68 | PC thread 2/29/16 | patientAssertedStatus - unconfirmed/excluded - scope of "I'm allergic to penicillin" | Provenance | Not relevant | How to interpret the focal concept (drug, product, class) is orthogonal to negation | None |
| 123 | FHIR list, 8/23 | to exclude a search result for specific code system | Query | Not relevant |  | None |
| 85 | Negation call 3/30/16 | did not supply electric wheelchair | Supply not provided |  | consider pattern of process status - GF | Action not done |
| 84 | Negation call 3/30/16 | did not use antithrombotic device on legs (supply) | Supply not provided |  |  | Action not done |
| 110 | decomposition of other requirements 6/21 | no family; no home; transportation; POA | Support deficit |  |  | Evaluation of characteristic |
| 111 | decomposition of other requirements 6/21 | no family; no home; transportation; POA | Support deficit |  |  | Evaluation of characteristic |
| 109 | decomposition of other requirements 6/21 | no family; no home; transportation; POA | Support deficit |  |  | Evaluation of characteristic |
| 142 | PQRS 137 | Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes:  • A target date for the next complete physical skin exam, AND  • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment | system characteristic | Not relevant |  | None |
| 15 | VA Use Case CHF - ED 20150305 | i.    If the patient does not produce 250ml urine in first 30 minutes, furosemide 40mg IV x1 should be administered | Threshold | Not relevant |  | None |
| 98 | MM mail 4/5 | “Allergic to antibiotics but no known which class” | Vague |  | question | None |

## Appendix B

List of requirement kinds, with proposed “situation” model representations

| ID | **Item** | **Category** | **Associated finding/procedure** | **Timing** | **context** | **subject** |
| --- | --- | --- | --- | --- | --- | --- |
| 150 | Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery. | absence of complication (derived) |  |  |  |  |
| 42 | Congenital absence of coronary artery | Anatomical deficit, congenital | Finding | Current | Present | Patient |
| 44 | Left leg amputated (not present) | Anatomical deficit, surgical | Finding | Current | Present | Patient |
| 1 | m.   CXR: Normal. No mediastinal widening, valve disease, or CHF I.e., no CHF | Chart by exception | Finding | Current | Absent | Patient |
| 92 | patient not pregnant | Condition absent | Finding | Current | Absent | Patient |
| 67 | 5.       It is the case (that I do know) that the Patient has no problems (ie none). | Condition absent (generic) | Finding | Current | Absent | Patient |
| 70 | no allergy to latex | Condition absent (sensitivity) | Finding | Current | Absent |  |
| 128 | "patient says that they have never had chicken pox" | Condition historically absent | Finding | Current | Absent | Patient |
| 82 | patient did not show up | Encounter not held | Encounter | Current | Not done | Patient |
| 81 | follow up not needed | Encounter not to be held + reason | Encounter | TBD | Not to be done | Patient |
| 108 | no evidence of cancer (path) | Evidence absent (Pathology) | Finding | Current | Absent | Patient |
| 133 | 1.     Nothing to eat or drink until respiratory distress dissipates  [respiratory distress absent] | Finding absent | Finding | TBD | Absent | Patient |
| 71 | closed head injury without loss of consciousness i.e., no loss of consciousness | Finding absent (dependent) | Finding | Specified time | Absent | Patient |
| 23 | Extremities: No swelling, pedal pulses strong. I.e., No swelling | Finding absent (exam) | Finding | Current | Absent | Patient |
| 24 | b. Adverse effects from the medication  a. None noted | Finding absent (general) | Finding | Current | Absent | Patient |
| 20 | a.     AUDIT-C - Score: 0 (No symptoms of abuse) | Finding absent (instrument) | Finding | Current | Absent | Patient |
| 10 | Reviews ECG reading and enters the interpreted result in the EHR. Result: SR 76. No ectopy. No hypertrophy.  I.e., No hypertrophy | Finding absent (interpretation) | Finding | Current | Absent | Patient |
| 108 | no mrsa found (lab) | Finding absent (lab) | Finding | Current | Absent | Patient |
| 7 | a.     History of Tobacco use: No | Finding absent (patient report) | Finding | Current | Absent | Patient |
| 89 | No bleeding disorders | Finding absent (patient report) | Finding | Current | Absent | Patient |
| 46 | no menses | Functional deficit | Condition | Current | Present | Patient |
| 79 | Quitting smoking is not my goal | Goal not held | Goal | Current | Absent | Patient |
| 25 | i.    Provider notices that the patient did not tolerate Prazosin in the past (which was started to address difficulty sleeping) | Intolerance | Condition | Current | Present | Patient |
| 12 | Allergies: No known drug allergy | No known allergy | Condition | Current | Absent | Patient |
| 34 | Head/Neuro: WNL | Normal |  |  |  |  |
| 129 | not currently taking | Not on medication | Procedure | Current or past | Not done | Patient |
| 106 | no family; no home; transportation; POA I.e., no family | Party absent (persistent) | Finding | Current | Absent | Patient |
| 61 | Assertion of intention not to breast feed | Patient intent to abstain | Goal | Current | Absent | Patient |
| 75 | Preference that an action not be done: [Margaret] | Patient preference to abstain | Goal | Current | Absent | Patient |
| 132 | Patient is not NPO | Precondition not met | Finding | Current | Present | Patient |
| 27 | and was discontinued due to irregular heartbeats and restlessness | Procedure discontinued + reason | Procedure | Current | Discontinued | Patient |
| 137 | Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy | procedure not done | Procedure | Current | Not Done | Patient |
| 113 | Represent inference of "absence" from empty query - specific use not yet determined, but, e.g., CDS logging | Procedure not done - inference | Not for inference | | | |
| 28 | Patient still refuses cessation treatment despite motivational interventions | Procedure not done + reason | Procedure | Current | Not done | Patient |
| 124 | [do not turn patient](http://gforge.hl7.org/gf/project/fhir/tracker/?action=TrackerItemEdit&tracker_item_id=9335) | Procedure not to be done | Procedure | Current | Not to be done | Patient |
| 85 | did not supply electric wheelchair | Supply not provided | Procedure | In the past | Not done | Patient |
| 110 | no family; no home; transportation; POA | Support deficit | Finding | Current | Absent | Patient |

## Appendix C

Domain analysis model representing common negation use cases and classes to support them, based on requirements list.

### Use Cases diagram



1. Use Cases

### Actors

#### Automated Agent

A system that uses record data in an automated fashion.

#### Clinical decision support system

A system designed to recommend clinical advice based on a patient's record data.

#### Initial care provider

A care provider who records information that will be used later.

#### Quality system

A system designed to calculate quality measures based on existing medical record data.

#### Subsequent care provider

A provider who uses information recorded previously.

Note that a subsequent provider may simply be the initial provider at a later point in time.

### Use Cases

Package in package 'Use Case Model'

Use Cases

Version 1.0 Phase 1.0 Proposed

created on 11/30/2016. Last modified 2/8/2017

#### Confirm checklist

Certain actions require confirmation of appropriateness. Some questions may confirm whether or not there are contraindications to a procedure (pregnancy, latex allergy), and some may confirm the patient's state of mind (goals, permissions). When these questions are answered in the negative, the 'gated' action will typically not proceed.

#### Direct that procedure not be done

Instruction that a procedure not be performed on a specific patient, usually with a reason for the prohibition.

#### Find absent phenomena

Discover phenomena documented as absent in the patient. This case supports both human review and automated processes (CDS and quality measure calculation).

#### Find procedures not done

Discover procedures documented as not performed on the patient. This case supports both human review and automated processes (CDS and quality measure calculation).

#### Order Procedure

Indicate that a procedure should be performed. This is included here in order to demonstrate linkage to the prior assertion that the procedure not be performed.

#### Record absent intent

Intents include goals and permissions. A patient may not share a clinician's concern or statement of goal such as quitting smoking; and the patient may decline to give permission to perform procedures.

#### Record absent phenomenon

Record that a phenomenon is not observed in a patient. This typically implies that the method used to determine the presence of the phenomenon is normally sufficient to do so.

#### Record negative answer to question

A negative value is recorded in response to a specific evaluative question.

Two common cases include negative results (e.g., negative strep test) and questions confirming absence of contraindications to a procedure (e.g., patient not pregnant).

#### Record procedure not done

Document that a specific procedure was not performed on the patient, usually to ensure that other providers understand that the gap is intentional. Such a record implies a scope of time, typically the encounter.

#### View absent phenomenon

View problems or other conditions found to be absent in the patient. This is commonly used in 'chart by exception' cases.

#### View procedure not done

Discover details about a procedure documented as not done, typically with a reason.

### Processes

#### Apply Checklist diagram



1. Apply Checklist

#### Apply Measure diagram



1. Apply Measure

#### Apply Rule diagram



1. Apply Rule

#### Find Absent Phenomenon diagram



1. Find Absent Phenomenon

#### Order Check diagram



1. Order Check

#### Apply Rule

Rules take input data and determine an output. These are typically clinical recommendations for treatment, given a set of patient characteristics.

#### Begin Order

A provider begins to enter an order. The procedure may or may not be countermanded.

#### Calculate Quality Measure

Use defined rules to calculate a ratio of cases meeting a positive or negative criterion to cases in a defined population.

#### Confirm checklist

The checklist "gates" the proposed action. Certain answers may prevent the execution of the action.

#### Direct Procedure Not Be Done

A provider indicates that a procedure should not be performed on a patient, and may provide a reason for this statement--as well, incidentally, as a reason why it should. This direction may have specific temporal or organizational scope.

#### Find Absent Phenomena

Certain rules and measures need to know whether a specific phenomenon has been asserted to be absent. A head injury will be treated differently if it is without loss of consciousness, but this absence cannot be inferred: it must be stated in the record to qualify for use in the rule.

#### Find Phenomena

A rule will typically determine whether a patient fits into a cohort of interest by asking whether they have certain conditions or characteristics.

#### Find Procedures Not Done

Measures and some rules merely need to know whether a procedure has been performed.

Some rules, e.g., order checks, include a check for records indicating that a procedure should not be performed on this patient.

#### Find Quality Measure Procedures Not Done

Search for records asserting that a specific procedure was not done.

Some procedures are explicitly asserted as not done in the clinical domain. This is typically done in order to provide a rationale for not being done to support exceptions in quality measure calculation.

A procedure may also be recorded as not done for clinical reasons, typically because it is indicated by a protocol but contraindicated by some other factor, and the provider making this decision wants to ensure that other providers don't interpret the gap as an oversight.

#### Find Specified Procedures

Search the record for procedures relevant to the quality measure or rule. A measure will typically assess how often a recommended procedure is done for a specified class of patient. A rule may need to know whether an action has been taken, but may only suggest action.

#### Infer Procedures Not Done

If a relevant procedure record is not found, a quality measure has no option other than to infer that the procedure was not done. The resulting assertion that something was not done cannot be used for clinical care; it may be persisted only for quality measure calculation and audit.

#### Record absent intent

Intents are a special case of negative state questions, typically used for care planning as well as confirming specific interventions. Statements about goals, for instance, may persist beyond a specific encounter, while permissions are typically solicited for each encounter.

#### Record absent phenomenon

If phenomenon of interest is identical to that recorded, this is no different from finding present phenomena.

Otherwise, the logic of aggregation is modified from normal operation, whether by description logic or by query.

* If the phenomenon of interest is more general than that recorded, it cannot be ruled out: e.g., a record of 'no subdural hematoma' does not imply no cerebral hemorrhage.

If the phenomenon of interest is more specific than that recorded, it can be: e.g., a record of 'no cerebral hemorrhage' does imply 'no subdural hematoma.'

#### Record negative answer to question

Absences that are otherwise of no interest may be of interest in certain cases. Pregnancy, NPO status, and other states may be relevant to planned interventions, and may be explicitly interrogated. Answers may not be recorded to support extended management (e.g., as, conditions), but will be kept at hand to support decisions around interventions and to audit these decisions.

#### Take Checklist-Gated Action

Certain actions require confirmation of appropriateness. Some questions may confirm whether or not there are contraindications to a procedure (pregnancy, latex allergy), and some may confirm the patient's state of mind (goals, permissions). When these questions are answered in the negative, the 'gated' action will typically not proceed.

#### View Countermanded Procedure

The provider views the record countermanding the procedure. This is not necessarily a rule: the provider may determine that the procedure should be performed anyway; it only informs the provider of the prior decision.

#### View absent phenomenon

### 

### Negation Domain Class Diagram



1. Negation Domain Diagram

#### Indicative statement

A statement of fact, as opposed to an instruction (imperative), possibility (subjunctive), or question (interrogative).

#### Absence of phenomenon

An assertion that a phenomenon is not observed in the patient, implying but not specifying that the observation process used should be sufficient to detect the phenomenon were it present.

This is a common pattern in "chart by exception" scenarios.

Also note that any negative evaluation of presence statement may also be represented as an "absence of phenomenon."

#### Action not done

Actions not done are typically captured in order to explain why they were not done.

#### Action not done derived from 'not found'

Quality measures may need counts of actions done and not done, and they will necessarily count actions not found as not done. These derived facts can be used for quality measure calculation and persisted for audit, but they cannot be relied upon for clinical use.

#### Evaluation of characteristic

A statement of the value of a property or attribute of the patient, typically expressed as a question/answer or name/value pair.

E.g., blood pressure = 120/90, breath sound quality = normal, smoking status = smoker.

Whether the indicative statement should contain the question/name as well as the answer/value (rather than refer to it) is a design question.

Also note that any "absence of phenomenon" statement may also be represented as an evaluation, given a defined question with which to do so.

#### Imperative direction

A request, demand, suggestion or prohibition that an act be performed in the future.

Such direction may include reasons for doing it and reasons for not doing it, whether it is a demand or a prohibition.

#### Indicative statement

A statement of fact, as opposed to an instruction (imperative), possibility (subjunctive), or question (interrogative).

#### Intent absent

Two kinds of intent have been identified.

A patient may grant or withhold permission to conduct a procedure. This is typically captured as the answer to an explicit questions.

A patient may also concur or disagree with a goal assertion. Goal assertions may be captured as independent phenomena, but can be captured in response to care planning questions. Denial of a goal is typically a response to a proposed goal.

#### Interrogative question

A question, typically about a characteristic of a patient, for which the answer is the indicative statement. The question may take the form of the name of a property, implying the question 'what is the value of this property?'

E.g., blood pressure, breath sound quality, smoking status.

#### No known drug allergy

Assertion that no drug allergy is known to be present in the patient. This can be understood as an explicit negation, with the scope of substances to which the patient has been exposed, or as a null value with respect to other substances.

#### Not currently taking medication

Observation that a patient has not recently taken a medication, without reference to any specific administration. This can be a generic statement, as in "not on any medications" or a specific observation, such as "not on any blood thinners."

Does the concept of 'habitual' obtain here, or only recency?

#### Order

Instruction to take action. This class represents an intent that action be taken irrespective of strength or workflow; i.e., it includes suggested and planned as well as ordered procedures.

#### Presence of phenomenon

A statement asserting that a phenomenon is observed in the patient. This is typically used for phenomena understood as 'conditions' -- enduring physiological states about which a patient or caregiver may have appropriate concern.

E.g., diabetes mellitus, pregnancy, hypertension.

Whether these phenomena can be categorically differentiated from "evaluation" values (characteristics to be evaluated, typically as a question/answer or name/value pair) is a vexed question, but usage requires that we address both.

#### Prohibition

Indication that a procedure is to be avoided.

#### Record of action

A statement about an action. The action might be in any state -- performed, planned, prohibited, not done, etc.

An action may have reasons for and against execution. If there is no actual order from which to derive these values, they belong in the record statement itself.

Whether the act is in fact performed cannot be inferred from the pro and con reasons: it must be explicitly stated (whether in an attribute or in a class definition).

### Out of scope items diagram



1. Out of scope items

1. https://xkcd.com/927/ [↑](#footnote-ref-1)