**HL7 Patient Care Work Group**

**Allergy/Intolerance/Adverse Reaction Topic Sub-Group Meeting Minutes**

**Date: August 6, 2014**

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Co-Chairs: Stephen Chu/Elaine Ayres Scribe: Elaine Ayres

|  |  |
| --- | --- |
| **Name** | **Present on August 6, 2014** |
| Elaine Ayres | X |
| Stephen Chu | X |
| Kelly Verdin | X |
| Rob Hausam | X |
| Jean Duteau | X |
| Max Topaz | X |
| Lorraine Constable | X |
| Lisa Nelson | X |

**Agenda for August 6, 2014**

1. Review agenda
2. Approve Minutes for July 23
3. Review Clinical Models
4. PSS with Vocab re SNOMED terms
5. C-CDA Harmonization - with associated terminology
   1. Vote on criticality concept decision.
6. Agenda for August 20, 2014

Minutes July 16 and 23, 2014:

Move: Stephen/Lorraine Abstain: o Negative: o Approve - 6

Vote: Publish Stephen/Lorraine Abstain – 0, Negative – 0 Approved – 5

Elaine to send publication request to HQ.

**Clinical Models** – Lorraine – ballot comment on clarifying the difference between severity and criticality to the model. Used language from the DAM to the clinical model scenario. Referenced table in the DAM rather than put in the database. Need to add a small discussion of this issue to the model re clarifying the difference between severity and criticality. Will review and provide text and where it should sit. Need this and Jean’s walk-through for publication.

Recommended text to add to clinical model publication to differentiate between severity and criticality (taken from Appendix A in the DAM).

*Severity and criticality are two related but distinct concepts in the domain of allergic and intolerance reactions.*

*Severity is an attribute of a symptom or a sign that is part of a reaction or an attribute of the constellation of signs and symptoms that constitute an episode of a reaction. Since there are a variety of different signs or symptoms and a variety of different reaction types, it would not be plausible to have a single rating scale that could be applied to different symptoms or two different types of reactions.*

*As an example to contrast severity and criticality, an individual might have severe vomiting as an intolerance reaction for sulfa drugs. This reaction would be listed as a sulfa drug intolerance with low criticality, since the potential for serious injury from this is low. An individual who had a reaction immediately after a bee sting consisting of generalized itching, hives, and wheezing, which resolved without treatment would be considered to have had a mild anaphylactic episode. That individual's condition of anaphylactic sensitivity to bee stings would be considered of high criticality, because of the life-threatening potential. High criticality does not equate to a future severe reaction, but rather the potential for a severe and life-threatening reaction.*

*Add to publication as well as model walk through.*

**PSS with Vocab** –. Will cancel the project. Joint session on Tuesday Q3 with IHTSDO. Elaine will attend.

**OpenEHR** – CKM archetype review process for adverse reaction/allergy and intolerance now closed. Russ helping to review comments.

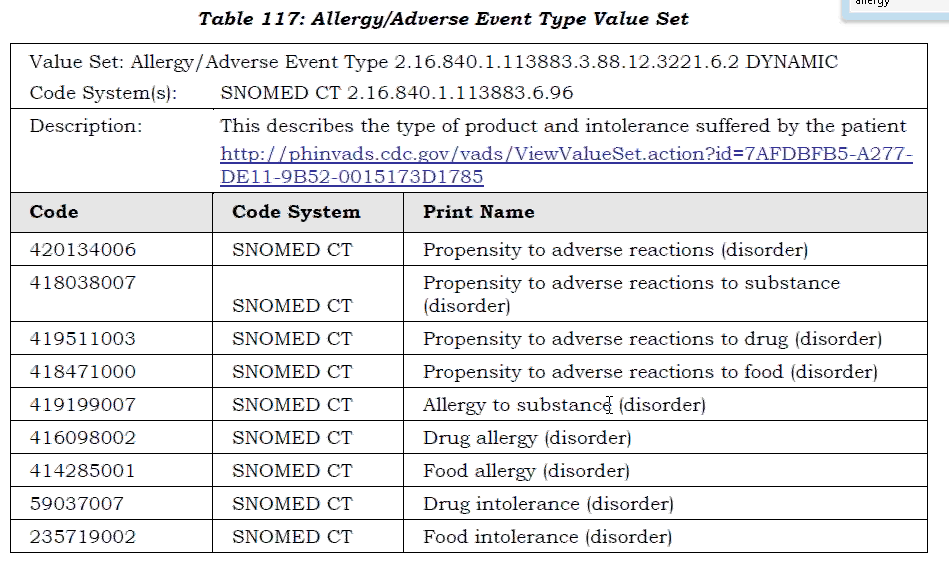
**C-CDA Harmonization:**

1. Address need for a Criticality Observation for the Allergy Intolerance Observation in place of current duplicate use of Severity template (on reaction and allergy observation) – 8/6/14
2. Allergy/Adverse event type value set – NAME: Allergy and Intolerance Type Value Set (7/16/14)
3. Concepts for value set: Use existing and add intolerance to substance, or come up with question and answer sets?
4. Null flavor concepts
5. Assertion?
6. Negation indicator
7. Review the entryRelationship type from allergy-intolerance Observation to reaction
8. Review entryRelationships
9. SAS: SubstanceAdministration
10. Subj: Medication Activity
11. Subj: Procedure
12. StatusCode versus Use of Allergy Status entryRelationship

Name of Value Set:

Currently: Allergy/Adverse Event Type

Use various value sets for type of substance. Categorize at least to select the correct value sets. If A – use this value set, …..



*FROM conversation on 6/26/14 – Ayres/Hausam/Leftwich*

***Table Name: Allergy and Intolerance ~~Classification~~ Type Value Set – APPROVED on 7/16/14***

*Propensity to adverse reactions to a substance (undifferentiated allergy or intolerance (synonym))*

*Allergy to substance – ok as is*

*Intolerance to substance – need to add as SNOMED concept*

*Discussed use of LOINC as alternative – as observations these values should remain as SNOMED.*

This is the relationship of these concepts:

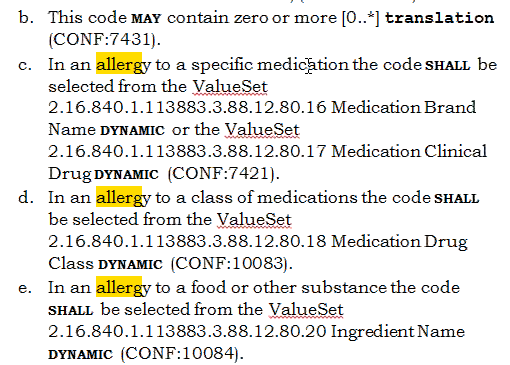
* 1. Propensity to adverse reactions
     1. Hypersensitivity disposition
     2. Propensity to adverse reaction to a substance
        1. Allergy to a substance (\*\*two parents)
           1. Drug Allergy\*\*
           2. Food Allergy\*\*
        2. **ADD Intolerance to substance**
        3. Propensity to adverse reaction to a drug
           1. Drug Allergy\*\*
           2. Drug Intolerance
        4. Propensity to an adverse reaction to food
           1. Food Allergy\*\*
           2. Food Intolerance

Do we need a separate value set for a “Known Allergy”?

What is the concept of certainty? In the allergist community there is a patient report reaction, vs a reaction that is observed by a physician. The latter is more certain.

Another use case – multiple meds with a reaction, but which is causing. There is uncertainty about which drug, but how to you record? Are you allergic to all, or might be allergic to all three?

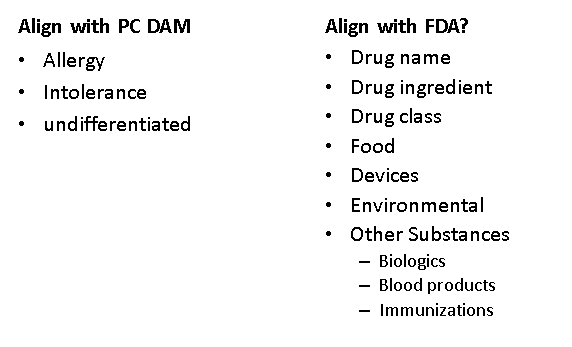
Possible concepts – current:



What is the value set designed to accomplish? Allergy Problem Act – (or concern act). Problem Observation or other problem observation related to the concern. Clinical Statement (the act) allergy or adverse reaction exists or does not exist. The code (SNOMED) is an assertion carried in the terminology. What type of allergy is this??? The causative agent is noted as a specific entity.

Suggested: Allergy and Intolerance Category

Need a concept to tell us what category we are in….a medication, a class of medications, or a food or other substance. Would need categories that do not overlap.



V3 has a codable concept of ObservationIntoleranceType

Question and Answer table: use same value set for each question.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Allergy?** | **Intolerance?** | **~~Undifferentiated?~~**  **Undetermined** | **Value Set** |
| Drug Name | Code– Allergy to named drug? | Code – Intolerance to named drug? | Code – allergy or intolerance to a named drug? | Value set of drug names |
| Drug Ingredient |  |  |  |  |
| Drug Class |  |  |  |  |
| Food |  |  |  |  |
| Devices | May be in RxNorm |  |  |  |
| Environmental |  |  |  |  |
| Other Substances |  |  |  |  |
| … |  |  |  |  |

Code in cell/Fifth column with a value set of substances.

What is the issue (Code) – and then name the thing (Substance).

Elaine will fill in the table (need LOINC) as well as desired coding system for substances.

Are pre-coordinated concepts required? Should allow both specific drug and a class.

Meaningful use – classified allergy as an immunological reaction. Everything else is an intolerance (these have a variety of mechanisms). Both are unique to the individual.

In the C-CDA – Allergy Problem Act, there is a LOINC code to call out an allergy, adverse reaction or alert, or you can put “concern”. The substance is noted as manufactured product with a code.

Need 21 variants of the concepts across to make the case statement work. Need a coded value. Use qualifiers? Need to come up with the terms of the value set, and the representation of the allergy, intolerance and undifferentiated classes.

ACTION – determine concepts and complete grid. Complete seven rows.

Note there is a reaction template and a severity template as well. There may be a reaction noted, and there may need a high level concept that notes there is some sort of allergy/tolerance. There might not be a substance – need a null flavor.

Discuss -- How do you differentiate between allergies and intolerances? Cannot always tell which it is. What if an allergist wants to say something very specific? Can we model this? Need to enable decision support via an accurate allergy and intolerance list.

ACTION – work on Allergy/AdverseEvent Value Set

Look at the correct set of answers

Then look at the answers

Look at assertion – should these be LOINC codes vs. SNOMED?

TermInfo – structural vs. terminology – mixing models and terminology. Assert and then provide a value set. The use assertion pattern makes coupling of concepts impossible – e.g. a question and an answer. Need to move beyond the assertion pattern. Suggest – not use the assertion pattern – rather use the code to represent a question and a code to represent the answer.

**Criticality discussion**: (on 7/2/14 with Russ, Rob and Elaine)

Current FHIR value set (Allergy and Intolerance).

1.14.2.1.33.1 Criticality

The criticality of an adverse sensitivity

This value set defines its own terms in the system http://hl7.org/fhir/criticality

|  |  |  |
| --- | --- | --- |
| **Code** | **Display** | **Definition** |
| fatal |  | Likely to result in death if re-exposed. |
| high |  | Likely to result in reactions that will need to be treated if re-exposed. |
| medium |  | Likely to result in reactions that will inconvenience the subject. |
| low |  | Not likely to result in any inconveniences for the subject. |

These codes are used in the following places:

* [AllergyIntolerance.criticality](http://www.hl7.org/implement/standards/FHIR-Develop/allergyintolerance.html#def) ([Fixed](http://www.hl7.org/implement/standards/FHIR-Develop/terminologies.html#code))

The OID for the value set is 2.16.840.1.113883.4.642.2.33 33 (OIDs are not used in FHIR, but may be used in v3, or OID based terminology systems).

See [the full registry of value sets](http://www.hl7.org/implement/standards/FHIR-Develop/terminologies-valuesets.html) defined as part of FHIR.

In FHIR – do not have to have a value. So look at concepts for probability:

1. Flag for criticality – 0 or 1
2. High or Low or No code (leave blank)
3. High or Low or Unable to Determine or Unknown (e.g. from another system)
   1. Currently has 0..1
   2. Change cardinality to 1..1 (? FHIR) (need to be sure that codes convey definitions.

Code for HIGH - Definition: Exposure to substance may result in a life threatening or organ system threatening outcome.

Code for LOW – Definition: Exposure to substance unlikely to result in a life threatening or organ system threatening outcome.

Unable to Determine – Definition: Unable to assess with information available. (Actual coded concept not a null flavor code)

Unknown – Definition: No information (Null) (Value set in FHIR, flavors of null in C-CDA (UNK))(this may work but may need to be reconsidered)

Suggested coding system – if in SNOMED would need fully specified name. Will need the concept of criticality in LOINC as on observation in V3 and C-CDA.

Unable to determine – a coded value.

Rob – ok with this. Use the concept with associated with definition.

V3 does not yet bind to a value set. Currently just have the concept.

Name for value set – Criticality Observation data entry level template there value set should be call Allergy and Intolerance Criticality Value Set.

FHIR may not like the 1..1 cardinality – will probably suggest 0..1. 1…1 is only at the profile level.

Vote to approve value set and value set name for use in C-CDA and FHIR. Note that terms must be developed in standard terminology (SNOMED and LOINC).

Move: Stephen/Lisa Abstain – 0 , Negative – 0, Approve – 6

Update the ObservationIntolerance in RoseTree need a harmonization proposal.

**Agenda for August 20, 2014**

1. Review agenda
2. Approve Minutes for August 6
3. C-CDA Harmonization - with associated terminology
   1. Proposed template language.
4. Agenda for September 3, 2014