Goals

1. Raise awareness of problematic vocabulary usage in CCAr2, and encourage others to make DSTU comments.

2. Stimulate discussion and ideas for next steps we can initiate with HL7 (and ONC?) to make the process more effective and efficient.

Specific CCDAr2 Issues and Recommendations

Advance Directives

Sections

2.3 Advance Directives Section (entries optional) (V2)
2.3.1 Advance Directives Section (entries required) (V2)

[RI Comments]

Recommendation: No problems here.

Rationale:

Both of these sections use an appropriate section code 42348-3:Advance directives:Find: Pt
:Patient:Nar. They contain an organizer and entry templates.

Organizer

3.3 Advance Directive Organizer

CCDA Description: This clinical statement groups a set of advance directive observations.
Recommendations:

1. Replace binding to 45473-6 with 75911-8.

Rationale:

This organizer template is inappropriately bound to an ordinal LOINC code (45473-6 Advance directive - living will [Minimum Data Set]) that has an answer list and meaning associated with the MDS instrument. This code 45473-6 does not represent an organizer concept.

We have created a new panel code to be used in this template:

75911-8  Advance directives panel::Pt::Patient::

LOINC Description:
Used to group together a set of advance directive observations, such as directives for medications, transfer of care, treatment, procedures, intubation and/or diagnostic tests. This term was created for, but not limited in use to, the Advance Directive Organizer within the HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm).

Now, it appears from the description of the Observation template (see below, Advance Directive Observation (V2) [p. 414]) that you meant to be able to represent a general category of directive (The existing template does not do this (it's a static binding to a single code). I would not recommend adding this arbitrary level of classification into the structure.

Entries

3.2  Advance Directive Observation (V2) [p. 414]
CCDA Description: This clinical statement represents Advance Directive Observation findings (e.g., “resuscitation status is Full Code”) rather than orders...The general category of the patient’s directive is documented in the observation/code element. The observation/value element contains the detailed patient directive which may be coded or text. For example, a category directive may be antibiotics, and the details would be intravenous antibiotics only.

[Risk Indication (RI) Comments]

**Recommendations:**

1. Replace binding to 75278-2 with 75320-2.
2. Create a specific value set for the subset of SNOMED CT codes that would be allowed as observation values. At a minimum you should at least fix the CONF:1098-32493 to read “If type is CD, then value SHOULD be drawn from SNOMED-CT.” and reference the SNOMED OID.
3. Remove this text
   1. The general category of the patient’s directive is documented in the observation/code element. The observation/value element contains the detailed patient directive which may be coded or text. For example, a category directive may be antibiotics, and the details would be intravenous antibiotics only.

**Rationale:**

This observation template is bound to the LOINC code: 75278-2 *Advance directive status* and has the Obs/value statement:

8. SHALL contain exactly one [1..1] value (CONF:1098-30804) such that it a. If type CD, then value will be SNOMED-CT (CONF:1098-32493).

The template is bound to the wrong LOINC code, the code created for this observation is 75320-2
Advance directive HL7.CCDAR2. [Recommendation 1]

The template says that the set of allowed answers (i.e. specific directives) should be drawn from SNOMED CT, but the wording of the conformance statement is weird. What you need is a specific value set of preferred SNOMED CT codes that should be used, if a standard code is going to be used. [Recommendation 2]

The description for the template implies that there is a specific mechanism for identifying the general class of directive and the specific directive, but there is no mechanism in the observation template structure/codes to do that. The template model is fine as is, just a simple question/answer model for representing the directive, which can be specified in as much detail as needed in the answer coding. The text from the observation template description that references a “general category” should be removed [Recommendation 3]. If you want to group observations of a particular “general category” together, you'll have to revisit the recommendations and guidance about how to use the AD organizer.

Mental Status

Section

The section appropriately uses the LOINC code 10190-7 Mental status Narrative.

Section contains these templates: Assessment Scale Observation, Mental Status Observation (V2), Mental Status Organizer (V2).

[RI Comments]

No issues here.
Organizer

3.52 Mental Status Organizer (V2)

CCDA Description: The Mental Status Organizer template may be used to group related Mental Status Observations (e.g., results of mental tests) and associated Assessment Scale Observations into subcategories and/or groupings by time. Subcategories can be things such as Mood and Affect, Behavior, Thought Process, Perception, Cognition, etc.

The code selected should indicate the category that groups the contained mental status observations (e.g., communication, learning and applying knowledge). SHOULD contain zero or one [0..1] code (CONF:1098-14378). a. The code, if present, SHOULD contain zero or one [0..1] @code (CONF:1098-14697). i. SHOULD be selected from ICF (codeSystem 2.16.840.1.113883.6.254) OR LOINC (codeSystem 2.16.840.1.113883.6.96) (CONF:1098-14698).

[RI Comments]
No issues here.

Observations

3.51 Mental Status Observation (V2)

CCDA Description: The Mental Status Observation template represents an observation about mental status that can come from a broad range of subjective and objective information (including measured data) to address those categories described in the Mental Status Section. See also Assessment Scale Observation for specific collections of observations that together yield a summary evaluation of a particular condition.

This template is bound to LOINC code 75275-8 Cognitive function HL7.CDAR2.

LOINC Description: A patient’s cognitive status (e.g., mood, memory, ability to make
decisions) and issues that limit cognition (e.g., amnesia, dementia, aggressive behavior). May include assessment scale observations, identify caregivers, and provide information about non-medicinal supplies.

Answer codes are to be drawn from SNOMED CT


[RI Comments].
No issues here per se. LOINC may want to rename this term to “mental status” vs. cognitive function. We actually have both a “mental function” term (75309-5 Mental function) and a “cognitive function” term (75275-8 Cognitive function) that were created at the same time. The LOINC term 75275-8 Cognitive function HL7.CCDAR2 was created for the “Cognitive Status Observation (V2)” template, not the Mental Status observation template. CCDAr2 renamed/merged the Cognitive Status Observation with the new/revised Mental Status Observation template. In my estimation it would be easier for implementers if we kept the 75275-8 term and deprecated the other, so we'll invoke that aspect of our deprecation policy. Because of the ambiguity around these terms, I am advocating that we anchor our definition of this term to the ICF notion of mental function, which is broader than cognition (cognitive functions).

Functional Status

Problem Type

Table 283: Problem Type has two rows that should be removed.

[RI Comments]
Recommendation:

1. Delete rows highlighted in figure above

Rationale:

There are two rows for both LOINC 75323-6 and 75319-4 one has an incorrect print name.

Functional Status Observations

3.30 Functional Status Observation (V2)

[RI Comments]

Recommendations:

1. Replace binding to 54522-8 with 75276-6.
2. Allow regular observations (9.61 Result Observation (V2)) and not just assessment scale observations to be linked to this general observation of a sensory status problem.

**Rationale**

This template is inappropriately bound to LOINC code 54522-8 Functional status. That code is a panel code, whose list of child elements were based on MDS v3. It is NOT a general purpose functional status observation. We did create a general-purpose functional status code: 75276-6 Functional status HL7.CCDAR2, so that is the code that should be used.

Many kinds of functional impairments are measured by clinical observations that don't fall in the rubric of “Assessment Scales” as defined by the CCDAr2 3.7 Assessment Scale Observation template (observation: identifier urn:oid:2.16.840.1.113883.10.20.22.4.69). For example, a patient might have difficulty walking, and that could be supported by an observation of the distance walked in 6 minutes, a measurement of a specific joint range of motion showing a major limitation, etc. These observations either individually or collectively are not conceived of as a “scale”.
Cultural and Religious Beliefs

Observation

3.17 Cultural and Religious Observation

7. SHALL contain exactly one [1..1] value (CONF:1098-28442). a. If value is CD, it SHALL be SNOMED-CT (CONF:1098-32487).

[RI Comments]

Recommendations

1. Create a specific value set for the subset of SNOMED CT codes that would be allowed as observation values. At a minimum you should at least fix the CONF:1098-32487 to read “If type is CD, then value SHALL be drawn from SNOMED-CT.” and reference the OID.

Rationale

Would be easiest for implementers to find the right SNOMED codes if there was a value set, but at least fix the wording to say that it should be selected from SNOMED CT. Current wording suggest that they should put a code that means “SNOMED CT” in the value.

Age at Event Onset

3.4 Age Observation

CCDA Description: This Age Observation represents the subject’s age at onset of an event or observation. The age of a relative in a Family History Observation at the time of that observation could also be inferred by comparing RelatedSubject/subject/birthTime with Observation/effectiveTime. However, a common scenario is that a patient will know the age of a relative when the relative had a certain condition or when the relative died, but will
not know the actual year (e.g., "grandpa died of a heart attack at the age of 50"). Often times, neither precise dates nor ages are known (e.g., "cousin died of congenital heart disease as an infant").

4. SHALL contain exactly one [1..1] code (CONF:81-7615). a. This code SHALL contain exactly one [1..1] @code="445518008" Age At Onset (CONF:81-16776). b. This code SHALL contain exactly one [1..1] @codeSystem="2.16.840.1.113883.6.96" (CodeSystem: SNOMED CT 2.16.840.1.113883.6.96) (CONF:81-26499).

[RI Comments]

Recommendations

1. Replace CONF:81-16776 and CONF:81-26499 with two criteria. If reporting age of the patient, use LOINC 75272-5 Age at event onset HL7.CCDAR2. If reporting age of the family member, use LOINC 75273-3 Age at event onset family member HL7.CCDAR2.

Rationale

This template fits the criteria for resolution of the LOINC Block ballot comments, but was not implemented. As part of the reconciliation process we created two new codes, depending on whether you are reporting the patient's age or a family member's age. As a side note, the template definition doesn't give any specifics about how to report age of a family member such as is mentioned in the text “grandpa died of a heart attack at the age of 50”.

Pressure Ulcer Stage

Not an error per se, but a recommendation.

[RI Comments]
**Recommendation**

1. Replace assertion observation type with separate NPUAP stage observation (72527-5 *Pressure ulcer stage NPUAP*). SNOMED CT value set used in the assertion is the same as it would be for values to the coded observation.

**Rationale**

This template doesn't fully align with FHIM (which was my ballot comment found persuasive) because it drops the specific observation for pressure ulcer stage and models it instead with assertions onto the pressure ulcer count variable. This approach drops the fact that in FHIM the staging is specifically the NPUAP and is captured as the value of the observation represented by LOINC 72527-5 *Pressure ulcer stage NPUAP*. To fully align, the NPUAP stage should be represented as a separate linked observation.
Sensory Status

3.94 Sensory Status

4. SHALL contain exactly one [1..1] code, which SHOULD be selected from ValueSet Sensory Status Problem Type 2.16.840.1.113883.11.20.9.50 DYNAMIC (CONF:1098-27962).

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Code System OID</th>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>47078008</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 Hearing</td>
<td></td>
</tr>
<tr>
<td>40518003</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 Sensory function status: vision</td>
<td></td>
</tr>
<tr>
<td>37541005</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 Sensory perception</td>
<td></td>
</tr>
<tr>
<td>30732001</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 Taste, function</td>
<td></td>
</tr>
<tr>
<td>30746008</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 Sense of smell, function</td>
<td></td>
</tr>
<tr>
<td>30752008</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 touch sensation, function</td>
<td></td>
</tr>
<tr>
<td>30764008</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 speech hearing function</td>
<td></td>
</tr>
<tr>
<td>26050006</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 ability to perform functions for speech</td>
<td></td>
</tr>
</tbody>
</table>

SHEALL contain exactly one [1..1] value with @xsi:type="CD", where the code SHOULD be selected from ValueSet Mental and Functional Status Response 2.16.840.1.113883.11.20.9.44 DYNAMIC (CONF:1098-27974).

<table>
<thead>
<tr>
<th>Code</th>
<th>Code System</th>
<th>Code System OID</th>
<th>Print Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>11163003</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 Intact</td>
<td></td>
</tr>
<tr>
<td>26037002</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 Impaired</td>
<td></td>
</tr>
<tr>
<td>27252006</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 degree findings</td>
<td></td>
</tr>
<tr>
<td>250004</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 decreased</td>
<td></td>
</tr>
<tr>
<td>18043004</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 thin</td>
<td></td>
</tr>
<tr>
<td>18307000</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 altered</td>
<td></td>
</tr>
<tr>
<td>20572008</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 good</td>
<td></td>
</tr>
<tr>
<td>30714006</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 resistant</td>
<td></td>
</tr>
<tr>
<td>30105006</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 increased</td>
<td></td>
</tr>
<tr>
<td>41277001</td>
<td>SNOMED CT</td>
<td>2.16.840.1.113883.6.96 lacking</td>
<td></td>
</tr>
</tbody>
</table>

MAY contain zero or more [0..*] entryRelationship (CONF:1098-27984) such that it
a. SHALL contain exactly one [1..1] @typeCode="COMP" has component (CodeSystem: HL7ActRelationshipType 2.16.840.1.113883.5.1002 STATIC) (CONF:1098-27985).

b. SHALL contain exactly one [1..1] Assessment Scale Observation (identifier: urn:oid:2.16.840.1.113883.10.20.22.4.69) (CONF:1098-27986).

[RI Comments]

Recommendation

1. Change the sensory status template to follow the pattern of the Functional Status Observation (with changes noted in my prior comment)
   1. Specifically, this means replacing the value set in CONF:1098-27962 with a single (to be created) nominal LOINC code for “Sensory or speech status”
   2. The observation code should takes as values a SNOMED CT code (or perhaps an ICF code) indicating the sensory problem, not the value set specified in CONF:1098-27974
2. Allow regular observations (9.61Result Observation (V2)) and not just assessment scale observations to be linked to this general observation of a sensory status problem.

Rationale

The selection of a value set of SNOMED CT observables contradicts the HITSC recommendations and quality measure rules for using LOINC codes for this purpose. SDWG found the ballot comments on this persuasive, but failed to implement it as a change for this template. But, there is a deeper problem with this template in that the list of these high level functions seems to be selected based on a convenience set of what was already in SNOMED rather than a deliberate set of top-level functions. It doesn't appear to me to be based on an underlying framework (e.g. like ICF or something similar). They also don't reflect common practice in sensory testing. For example, typically you test vestibular functions like sense of position, balance, etc, and proprioception, temperature, vibration, pressure, etc.
Many kinds of sensory impairments are measured by clinical observations that don't fall in the rubric of "Assessment Scales" as defined by the CCDAr2 3.7 Assessment Scale Observation template (observation: identifier urn:oid:2.16.840.1.113883.10.20.22.4.69). For example, a patient might have a visual impairment that could be supported by observations of visual acuity, keratometry, refraction, etc. These observations either individually or collectively are not conceived of as a "scale".
Prognosis Observation

3.84 Prognosis Observation

This template represents the patient’s prognosis, which must be associated with a problem observation. It may serve as an alert to scope intervention plans.

The effectiveTime represents the clinically relevant time of the observation. The observation/value is not constrained and can represent the expected life duration in PQ, an anticipated course of the disease in text, or coded term.

1. This code SHALL contain exactly one [1..1] @code="75328-5" Prognosis (CONF:1098-29468).

[RI Comments]

Recommendation

1. Remove the sentence “The observation/value is not constrained and can represent the expected life duration in PQ, an anticipated course of the disease in text, or coded term.”

2. Make the data type a “CWE” so that the response values can be coded or text (but not a numeric quantity).

Rationale

Mixing coded, free text, and quantitative responses in a single observation variable is a bad idea. The LOINC code (75328-5) for this observation fits perfectly well as a CWE variable, and this is how I suspect most systems would record and transmit prognosis information. It would violate the meaning of the LOINC code to use a categorical variable identifier (scale:Nom) for a numeric result. If you wanted to exchange a numeric estimate of the life expectancy, you would use LOINC code
75327-7 Life expectancy [Time] Estimated instead, which has a Scale:Qn. I would also note that the SNOMED CT codes used in the example are “categorical” variables but express a probability of death within a certain time period. This further suggests that you don’t need a PQ variable.

Family History Observation

3.28 Family History Observation (V2)

5. SHALL contain exactly one [1..1] code, which SHOULD be selected from ValueSet Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 STATIC 2014-09-02 (CONF:1098-32427).

[RI Comments]

Recommendation

3. Replace the binding to ValueSet Problem Type with a binding to a value set of the equivalent LOINC codes that specify a System of “^family member”

Rationale

The current template binds to the general Problem Type value set which includes both observations about the patient and family members. Neither the definition of the value set (except by example of the codes included in the short list) nor the template text clarify that you should only select codes with a System of “^family member” when making observations about that family member that are recorded in the patient’s record. Likewise, you should not choose a LOINC code with the System of “^Patient” when you’re recording an observation about a family member. It would be cleaner and simpler for implementers if these were two separate value sets. Here are some of the codes that would be in the family member value set:
DIR Findings Section

2.19 Findings Section (DIR)

2. This section SHOULD contain only the direct observations in the report, with topics such as Reason for Study, History, and Impression placed in separate sections. However, in cases where the source of report content provides a single block of text not separated into these sections, that text SHALL be placed in the Findings section (CONF:81-8532).

[RI Comments]

Recommendation

1. Add a conformance statement about the code required for this section (LOINC 18782-3)

Rationale

For some reason, this section template doesn't specify a code. The general rule for the DIR sections is to use LOINC codes where possible (e.g. “The section/code should be selected from LOINC or DICOM for sections not listed in this table.”). Although the template doesn't specify a code, the
example uses a DCM one. Previously, in CCDAr1, LOINC code 18782-3 was listed in the section title and several tables (but curiously not in a conformance statement).