



February 19, 2010

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HIT Standards Committee

Clinical Operations Workgroups – Task Force on Vocabulary

Re: Tuesday, February 23, 2010 Meeting

Dear Vocabulary Task Force;

NCPDP is submitting the following responses to the questions posed on 02/11/2010.

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization (SDO) consisting of more than 1,500 members who represent computer systems organizations, drug manufacturers and wholesalers, pharmacy chains, mail order and independent pharmacies, health insurers, claims processors and pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties involved in the standardization of data and transactions within the pharmacy services sector of the health care industry.

Thank you for the opportunity to provide input.

*With reference to definitions in Attachment 2, please respond to at least four of the following questions about convenience subsets and/or value sets that are needed to facilitate meaningful use of EHRs. Be sure to specify which questions you are answering and to which categories of subsets and value sets your comments apply.*

- 1) *Who should determine subsets and/or value sets that are needed?*
- 2) *Who should produce subsets and/or value sets?*
- 3) *Who should review and approve subsets and/or value sets?*
- 4) *How should subsets and/or value sets be described, i.e., what is the minimum set of metadata needed?*
- 5) *In what format(s) and via what mechanisms should subsets and/or value sets be distributed?*
- 6) *How and how frequently should subsets and/or value sets be updated, and how should updates be coordinated?*
- 7) *What support services would promote and facilitate their use?*
- 8) *What best practices/lessons learned have you learned, or what problems have you learned to avoid, regarding vocabulary subset and value set creation, maintenance, dissemination, and support services?*
- 9) *Do you have other advice or comments on convenience subsets and/or value sets and their relationship to meaningful use?*
- 10) *What must the federal government do or not do with regard to the above, and/or what role should the federal government play?*

**NCPDP general response on value sets:**

Based on the definitions provided - “Subset - a set whose members are members of another set; a set contained within another set” and “Value set – the set of all possible values for a given purpose” - we recommend the industry stakeholders should provide input for what is needed via an open collaborative environment.

Understanding value sets caused some confusion. Originally reviewers thought value sets are the values for a concept – for example the values of Administrative Gender might be M = Male, F = Female, and U = Unknown, making up the value set. However, upon requesting clarification, the example of a value set was “allergies” that would contain drugs from one vocabulary, foods from another and other items like dust or bee stings from another vocabulary. So there was concern that this term “value set” might be misunderstood.

In another example, a value set might be the definition of medication concepts from a *prescriber’s* point of view? The drug concept would come from RxNorm, the strength from a vocabulary, the route of administration from a vocabulary, etc. This value set is similar, but different than a value set for the definition of medication concepts from a *pharmacy’s dispensing* point of view where the drug concept would come from NDC or UPC or HRI, the route of administration might/not come from the same vocabulary as the prescriber example, the route of administration might/not come from the same vocabulary. Would it be better to define a value set that is the union of both of these and somehow differentiate that when prescribing RxNorm is used, but when dispensing NDC or UPC or HRI is used? It would seem that we might have thousands of value sets, depending on the number of use cases? Not only do we need to consider the purpose of that exchange, but also the further use of that information. It seems daunting to define value sets, but then again, we do have to determine this to exchange transactions.

1) *Who should determine subsets and/or value sets that are needed?*

**NCPDP response:**

Some entity has to be the owner/maintainer of a given vocabulary and the subsets generated from that given set. It appears that entity would need to feed their vocabulary or subset into the requirements for value sets. The industry must be able to come together and provide input as to what is needed. Going forward, the industry will provide requests for enhancements to the set as business requirements evolve.

Based on defined criteria, the industry stakeholders will need to determine if subsets are needed. It may be difficult to determine the criteria until there is more industry experience. While it is recognized that an implementer may not need 100,000 possible concepts for a given data element to be exchanged, it is difficult until there is sufficient industry experience to determine what appropriate subsets are.

We recently discussed at NCPDP meetings whether subsets for strength and unit of measure should be created based on some questions from NCI. While it was recognized that there are many possible values in the full list, it is also difficult to determine how to subset the lists (*Do you try to create a subset of only “human” based prescriptions? What about veterinary prescriptions? What if one entity needs to use a value from the full list, but the other entity only uses a subset?*) It was also recognized that software vendors would be working with their customers to determine “pick lists” which in effect creates a local subset. And related to medication information, there is a strong use in the industry on drug knowledgebase companies, who based on the products listed in their databases, would also provide some aspect of subsets based on products and use. The NCPDP attendees decided to recommend to NCI to take their “best guess” at creating some subsets, to provide

links to both the full list and the subset list, and to ask the industry to continue to gain experience and feed that information to the terminology owner.

2) *Who should produce subsets and/or value sets?*

**NCPDP response:**

At this point, NCPDP recommends that the owner/maintainer of the vocabulary (or their designee) be responsible for subsets. They (or their designee) would provide the timely updates based on publications and provide support for the products.

A possibility could be that the owners would still own the concepts with a “central authority” providing a mechanism for subsetting and access to the subsets/value sets. This implies a strong collaboration between owners and the central authority.

In our industry, the use of drug knowledgebase vendors has provided “one view” for a customer to pull from one source, even though the database products obtain content from many sources.

As for value sets – wouldn’t the owner/maintainer of the vocabulary be responsible for maintaining their content in a value set? Is the suggestion that there be entity(ies) that take the vocabularies (and updates) and somehow repurpose them to be a value set? Or would the entity(ies) just list the various vocabularies in the value set?

It is important for the industry to know where to go to for the authoritative source for that set, subset, or value set. This does not mean there is one site for the universe of every set and subset and value set ever published. Rather that there is a site known where to submit additions/modifications for that set, where to obtain subsets and value sets as available. A document/website listing the sources would be very helpful. For example, there is confusion about whether to go to IHTSDO, to NCI, to NLM, or to other sites for what and why. In the NCPDP External Code List document, we would like to point the implementer to the website where they can obtain the concepts that can be used in a given data element.

There must be a defined process for industry stakeholders to submit additions/changes to the subset/value set, or the definition of a new subset/value set.

3) *Who should review and approve subsets and/or value sets?*

**NCPDP response:**

What subsets or value sets are defined should be based on industry input and experience. If clear rules can be established of what a subset is to consist of, and the owner/maintainer of the vocabulary can actually implement the criteria, those rules can be published for the industry and the owner/maintainer would dynamically manage the subset. But it may be difficult to determine the subset criteria until there is more experience. As noted above, value sets may be more difficult.

4) *How should subsets and/or value sets be described, i.e., what is the minimum set of metadata needed?*

**NCPDP response:**

If subsets and/or value sets can be established, the description should be as clear as can be established, listing criteria for what is in versus what is not, list examples that satisfy the criteria, as well as describing examples that did not satisfy the criteria and why they are not included.

For consideration:

The following should be considered as metadata for subsets/value sets: subset name and identifier, version or revision identifier, access information (e.g., where can

the [updated] subset/value set be found and retrieved), update frequency, source information set(s) with version/revision (value sets may include concepts from different information sets), source information set owner/maintainer(s), subset/value set definition authority (who created/defined the subset/value set), subsetting criteria (if defined).

- 5) *In what format(s) and via what mechanisms should subsets and/or value sets be distributed?*

**NCPDP response:**

The subsets and/or value sets should be distributed in the same way as the full sets for consistency, but at the least include the formats the industry is expecting. At this time it appears that CSV, Excel, tab delimited text are popular choices for implementers. Given current IT industry usage, a standardized XML format (including metadata) should also be considered.

- 6) *How and how frequently should subsets and/or value sets be updated, and how should updates be coordinated?*

**NCPDP response:**

The subsets and/or value sets must be available dependent on their expectation for modifications. The subsets and/or value sets must be available timely. Some sets would be expected to be available prior to general industry use. If sets are implemented based on a distribution hierarchy (for example medication information would need to be available for drug knowledgebase companies who distribute to their customers before the products are on the market), they must be available timely. Depending on the usage, sets may require near real-time updating and availability, if the information is in use in real-time processing such as eligibility checking or claims processing.

Some sets may not change very often and may be at a different maintenance schedule, depending on industry use.

As to the coordination of updates, it would seem to be a requirement that if the full vocabulary set is updated, the subsets would be on that same schedule for consistency.

It would be expected that the owner/maintainer would have rigor of criteria for addition/modification/sunseting of values. They would be expected to have publication schedules and rigor for maintaining the subsets in sync with the larger vocabulary. They would be expected to have customer support for industry questions and requests.

- 7) *What support services would promote and facilitate their use?*

**NCPDP response:**

NCPDP recommends that the owner/maintainer must provide the same full suite of services that companies must maintain for their products for good customer support. These services include but are not limited to

- Educational information on the use of the products
- Distribution schedules reflecting industry needs
- Published production distribution schedules
- Ease of access to obtaining products
- Customer support to handle general industry inquiries timely
- Account management functions for the timely support of technical and business users (e.g. SDOs, drug knowledgebase entities, corporate headquarters, large provider groups, vendors, etc)

- A defined process and ease of access for industry stakeholders to request enhancements or modifications to the sets
  - A wish list item would be for this process to be standardized, rather than each owner/maintainer having a different input scheme.
- Escalation procedures for emergency needs (what to do if a value is not available)

8) *What best practices/lessons learned have you learned, or what problems have you learned to avoid, regarding vocabulary subset and value set creation, maintenance, dissemination, and support services?*

**NCPDP response:**

NCPDP suggests that the terminology organizations may best answer this question. While the NCPDP standards contain code lists for data elements, we do not purport to have the rigors and requirements on these code lists that a professional terminology organization would impose.

We have learned over the years that descriptions of the code values are very important, but even a description can generate further questions as the industry brings forward new products or services and interprets the use of a given code value. It can also be very difficult to define an item clearly as the English language sometimes gets in the way.

We have also learned that our code sets must be able to be updated timely – for industry use - while within the requirements of regulations (e.g. HIPAA, MMA). To support this, the NCPDP *External Code List* was created. This document may be updated and published on a quarterly basis (if new code values are needed). This allows the industry to be able to respond to new business needs which can be met by adding new values to existing data elements while the standard implementation guide (e.g. Telecommunication, Batch, Medicaid Subrogation, SCRIPT, Formulary and Benefit, etc), are “frozen” in version by the regulations.

9) *Do you have other advice or comments on convenience subsets and/or value sets and their relationship to meaningful use?*

**NCPDP response:**

It is unclear what role the pharmacy will have in the specific requirements for meaningful use. It is recognized that pharmacy is a valuable participant, but pharmacy is not cited for specific measures. The industry is requesting caution in regulation until experience is gained in the vocabularies cited.

10) *What must the federal government do or not do with regard to the above, and/or what role should the federal government play?*

**NCPDP response:**

In the vocabularies that have been named in regulations, it is very important to provide more guidance on the use of the vocabularies. There is a gap between the terminologists, the standard message exchanges, and the implementers. The terminologist maintains rigor and consistency in the vocabulary. The SDO seeks to exchange data elements in messages and to point the implementer to where they should obtain the set. The implementer needs to know what code list to use in a data element when exchanging x message. They wish to understand how to use the set in their products.

We have an alphabet soup of vocabularies and agencies that are involved in these vocabularies and difficulty understanding who is who and who maintains what.

NCPDP Response to Clinical Operations Workgroups – Task Force on Vocabulary Tuesday,  
February 23, 2010 Meeting

As an SDO, NCPDP is trying to wade through this same information. While there is a great overview on the NCI site about FMT (<http://evs.nci.nih.gov/ftp1/FMT/FMT%20FHA%20Presentation.ppt>), it is still difficult to understand what code set to put in the standards for a data element when exchanging x message, where to point the implementers to, how the different agencies and vocabularies may/may not interact or intersect. We noticed in the HITECH regulations that a reference was not given of where specifically to obtain UCUM. It would be helpful to have diagrams and a presentation that explains how the code sets listed in the regulation “fit together” and then to expand to other code sets not listed in the regulation, but appearing in vocabulary discussions.

Sincerely,



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