

## Written Testimony for the HIT Standards Committee Vocabulary Task Force, February 23, 2010

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

#### Short Answer:

The determination of 'if' a subset/value-set should exist should be driven by use cases. The government (HHS or ONC) should fund a registry of subsets/value-sets, define and manage a process for arbitration, and rules of governance. It should not to worry about if a particular value-set of subset exists or does not except as it relates to a higher level goal.

#### Long Answer and Explanation:

Note: I assume this question is meant to say "who should determine IF a subset/value-set is needed or should be required" to distinguish it from the question #2 of "what" content the subset/value-set should contain.

It is important to consider that subsets and value-sets must be matched to their particular use in a particular context. These contexts may be similar and overlap, but other times important differences in context need to be considered. Forcing the use of an inappropriately defined subset/value-set or the use of a good subset/value-set in an inappropriate context may be worse than having no value-set at all.

For any given use case, the need for a particular subset/value-set, and therefore influences who should be involved in determining subset/value-sets, may arise from assumptions embedded in:

- The structural model.
  - The value list may depend on a particular question context, or other information or qualification may be passed separately in that model.
  - For example, if the model has separate fields for "body-part?" and "laterality?", the appropriate value sets might be ("hand", "foot", ...) and ("left", "right", "bilat", "NA"). The value-set is different if there is only one field "body-part?" which might pre-coordinate the values in the value-set ("left hand", "right hand", "both hands", ...)
  - Other Standards Development Organizations (SDO's) such as HL7 or X12 therefore have a stakeholder interest in assigning or constraining value-sets.
- Technical considerations of the applicable terminology.
  - The terminology size, scope, or structural requirements may affect how subsets are managed. For example SNOMED-CT includes many concept types so including a subset of just the "Medical problems applicable for problem lists" makes sense. The methods used to create, maintain and use this subset may be different from the way a subset might work for LOINC. Additionally, SNOMED-CT has formal methods for post-coordination which interact with the structural model above.
  - Terminology Standards developers therefore have a stakeholder interest in assigning or constraining value-sets.
- The relationship to other terminologies and subsets.
  - The need for a subset or value-set may cross domains and terminologies. For example, the indication for a particular RxNorm Ingredient may require a subset of SNOMED-CT coded problems.
  - Subsets can not always be managed by one SDO and may joint stakeholder ownership of subsets.
- The Clinical Context of the Primary Use Case, and data entry.
  - The relations and clinical purpose for the subset may vary dramatically. This often creates overlapping needs that cross cut structural or terminology standards. For example

- an order for a ‘CBC’ may require a value-set of findings that are expected to be in the result or that order, or it may require a list of valid reasons for a ordering a ‘CBC’.
- Users entering the information have needs to help them speed entry, but also need value-sets that are relevant and small enough to do their jobs. For example, a nursing problems subset would have different content and requirements than a physician problems subset.
- End users have a stakeholder interest in assigning or constraining value-sets and subsets.
- Downstream Users of the Information.
  - Codified information is generally required to help support some other function such as billing, decision support, or quality reporting. The granularity and concept coverage of the responses may be affected by the need to drive a particular need of someone other than the end user entering the data.
  - Payers, Quality Reporting and Public Health Agencies all have stakeholder interest in assigning or constraining value-sets and subsets.
- The Need to Support Legacy Products and Workflow.
  - The interpretation of the subset must be clear, so that products know what they must support, when, and how migration of legacy will occur.
  - Vendors and implementers have stakeholder interest in constraining value-sets and subsets.
- Local/State or International needs.
  - Regional considerations may impose addition needs for subset/value-set creation.
  - Other governmental bodies may have stakeholder interest in creating or constraining subsets/value-sets.
- The Need for Alignment.
  - With many different groups that have vested and sometimes competing interests, there may be need to simplify and standardize on common approaches.

The examples above are included to highlight that the decision to use any particular subset/value-set is relatively complicated, and must typically be managed at very low levels because of technical implementation details and the many stakeholder interests. Thus, decisions about definition or use of any particular subset/value-set should NOT be handled through high level committees or governmental rules. The easy answer is then to leave this as part of the technical requirements of particular standards or implementation guidance a particular use case is formally outlined.

However, uncontrolled, groups that define different use cases will overlap in requirements and are likely to be ignorant of the needs and work proceeding in other groups, As a result, they will arrive at different value-sets that should ideally be aligned to one. This is not only the current situation, but also likely to continue under almost any circumstance.

Thus, I think rather than describing “who determines” a better question might be “what is the process control.” Such a process control should be efficient in allowing adequate review and alignment while not overloading groups with administrative overhead to get approval. It should encourage sharing and reuse where it is feasible and appropriate, but only where it is feasible and appropriate.

My suggestion here would be for ONC to fund and maintain a central registry of subsets/value-sets (perhaps as an extension of USHIK or PHINVADS) and achieve process control through rules of access and arbitration of disputed of items in this registry. It should also work to maintain this database by ensuring that it does not become cluttered with stale data.

Oversight of this registry from the HITSC could come in the form of:

- 1) **Assignment of an ‘owner’ for each subset/value-set.** An ‘owner’ should be responsible for coordination of the users of the set and arbitration of content and versioning. Owners of subsets and value-sets may adopt a similar process of arbitration and checks of stale data to manage their respective content, but this may depend on the nature of the content.
- 2) **Registration of users of the value-set.** This is needed to ensure that value-set owners can manage the set properly and notification can occur if the subset/value-set becomes orphaned or arbitration determines that a harmonization must occur.

- 3) **Control on creation.** Any group asking to register a subset/value-set for a given use-case should provide some sort of attestation that they have reviewed related subsets in the registry and could not use them.
- 4) **Rules for how orphaned subsets/value-sets are deprecated.** For example, there should be regular checks (e.g., once a year) in place to ensure that owners still exist and the value-set is being used so that the registry does not fill up with “dead links”. Registered users should be notified if the subset/value-set is ownerless and a period of time should be given where notified users have chance to take ownership, otherwise the subset/value-set should be marked as obsolete.
- 5) **Establishment of an arbitration process** to determine when there is dispute over the need to align between different owners of subsets/value-sets. This process should include at minimum:
  - a. Reporting. A mechanism for registered users to report that 2 or more subsets overlap and need to be combined.
  - b. Notification. A mechanism to notify owners and the reporting user to see if agreement can be reached without formal arbitration.
  - c. A court. A mechanism to place the issue as a case before an arbitration committee to formally decide the issue.

The phrase ‘some sort of attestation’ is deliberate. The level detail in this attestation may need to be tailored as needed to achieve process control. However, as long as the work to register and maintain a new subset/value-set is greater than the work to register use of an old one, there is incentive to do the right thing. A simple checkbox attestation may be sufficient. If and when problems and abuses occur, requiring more evidence of review will provide incentive to use existing sets rather than fragmenting and creating your own.

In addition to being a source of subsets/value-sets in the role of assigning appropriate implementation guidance, HITSP is an appropriate choice for an arbitration committee. Its “Data Architecture Tiger Team” was an initial attempt to address alignment across different groups and use cases. Continuation of such an effort is desirable, but its scope should be focused on a manageable number of prioritized vocabularies and subsets, rather than attempting to boil the ocean. In addition, consistency in the direction is very important.

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

Potentially, anybody.

See the answer to Question #1. There are necessarily many sources and the content needs should not be restricted. SDOs, quality metric organizations, and implementation guide providers all have rational reasons and need to create subsets and value-sets and the content of subsets/value-sets often needs to be closely aligned to structural models or particular characteristics of the use case.

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

**Short Answer:** Approval of subsets and value-sets should be included as part of the approval of the higher level use cases and implementation guidance. ‘Approval’ should not come until pilots with real patient data are completed.

### **Long Answer and Explanation:**

Subsets and value-sets are just one part of the job of defining the technical implementation guidance for a use case, and any approval should be considered outside of the appropriate use scope of that subset/value-set. Thus, it should fall as a natural part of approving the implementation guidance. However, in my opinion, the ‘approval’ process is broken, and fixing it is critical before any meaning of ‘approval’ can be applied.

Prior to HITECH, AHIC played a role of defining use cases, HITSP assigned relevant standards to those use cases, HHS approved these, and CCHIT verified that products had these capabilities. Thus the ‘approval’ in this context has been interpreted by many as implying some sense of readiness – for example for certification. If not for this purpose who should care if an item is ‘approved’ and what does ‘approval’

mean? For example, surely it does not imply that a customer is prevented from using a subset/value-set that is not approved.

The need to define use cases and implementation guidance that are aligned with national priorities is still valid, but the process has been problematic because it takes far less time to define a use case than it does to assign technical details such as implementation guidance, subsets and value-sets, and in turn assigning technical details takes far less time than implementing those details, and implementing details takes less time than making end solutions work in real life. As a result, far more use cases and implementation guides were produced than could actually be implemented or put into production. These use cases and implementation guides ARE a good start, however victory is being declared too early. These documents may perhaps be 'accepted for trial' but should not be considered 'approved' (as in ready for widespread use or potentially criteria for certification). The quality has not been adequately checked.

Currently there is assumption that it is somebody else's job to tracking the process as a whole to ensure that the solution is working. For example, once AHIC defined a use case, HHS has typically 'approved' them, and AHIC's role was considered completed. Instead, there should be understanding that the use case definers job is not completed until end users are using the tools and achieving outcomes as expected. In between, there are steps missing. In particular, there is a process management that tracks to determine what problems are blocking the completion of the job, and what plans are in place to ensure that the problems are being solved in real life. A 30 day comment period of review hardly suffices as a quality checkpoint.

My suggestion is to entirely reconsider governmental objectives individually as projects and the approval of subset/value-sets will naturally fall out as a by product of approval of the larger needs. Each government objective may include multiple supporting use cases a subproject, where each use case is managed and tracked to complete implementation. The first step in that process still includes a use case definition to define the solvable problem and sketch the solution. But, once a use case is sketched it may seem like a great idea and look feasible and correct, but in fact may not be. In short, it isn't complete, and should not be considered 'accepted' until it is proven that it is feasible and correct in real life. Until then it remains an opinion that it works.

If a use case is defined, but not implemented, the next logical step is to identify barriers to implementation and begin solving them. In that process it is likely that there will be blocking steps that require implementation guidance and specification harmonization such as which subsets or value-sets apply. This in itself may be come a subproject of the larger use-case project. It may be handed off as to another organization that has expertise (for example to HITSP) with a defined objective, not just to define guidance or which subset/value-set to use, but also to follow through that subset/value-set (or other guidance) has been tested to work.

If in developing the implementation guidance it is identified that a blocking step is that the identified that a subset or value-sets is needed but don't exist, then this may too be a subproject that is managed by giving work to another group such as an SDO.

At each step, each group should manage their project by declaring the intended direction and roadmap, perhaps defining interim solutions and reporting this to their parent project as defined deliverables. Each parent project should update their timelines and project plan to reflect the new status of subprojects. But also they should not accept the child organizations deliverable until they are sure it works as intended. Only after the work has passed pilot with live data on real patients at multiple sites and all corrections made should it be considered for 'approval'. Until then, it will almost certainly contain errors.

Thus, 'approval' of subsets and value-sets occurs potentially at many levels, but always in relation to a larger desired goal and always proven to work in real life.

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

HITSP T903 has excellent information that may provide a very good start. It is likely not robust enough to provide the management infrastructure described in question 1. I attached an appendix of metadata items which I believe could be added in.

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

For distribution to vendors a flat file suitable for load into a database (e.g., bar delimited). XML is acceptable also. Consistency and more important than a particular format (e.g., tab vs. comma delimited, etc). It is important to standardize on encodings. That might be a rule of process control in question 1.

Eventually, perhaps a real time source such as those recommended by HITSP T66 (IHE Sharing Value Sets (SVS) profile and/or the HL7 Common Terminology Service (CTS)) might be appropriate, but for now DISTRIBUTION of subset/value-set content probably needs to be included with product delivery. As such, web services or java API's are not needed. A simple web download is sufficient.

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

This depends on the subset/value-set. For example, subsets based on RxNorm ingredients will need more frequent updates than sets based on a route of administration. I recommend a push notification when sets change as described above.

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

The biggest problem is project management such as described in question #3.

Other considerations include:

- o Mapping tools. Help is needed for customers to upgrade legacy codes and value-sets and incrementally get them to standard terminologies. For example, availability of a RELMA like tool, but with better capability to see what is common, and what is rare.
- o Search tools. For finding sets in the registry and for finding items in the set.
- o Associated Content related to the subset/value-set. Implemented in real life a large subset isn't just a flat list – it generally will need a lot of massaging and information from the source terminology. Especially when dealing with names on the user interface, there are many details to manage and bindings to make it implementable. Examples include naming variants (e.g., short names with 8, 16, 32 characters or less when talking to some systems or for use with constrained real estate such as PDA's; variants that only have ascii characters, foreign language equivalents, etc), keywords and synonyms to help facilitate search, hierarchies limited to that subset, maps and relationships to other code systems, etc). Although this is mostly grunt work, it consumes significant resource time. It would be nice to share this related content also. Most vendors do not want to compete on this.
- o Remove licensing restrictions where possible.

**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?**

- o Legacy is an uncomfortable reality and cannot be ignored. In particular, for the Hospital environment, incentives to make changes when the system “isn't broken” are very low. It is also a challenge to change several hospital systems (which might come from different vendors) simultaneously, and requires a high degree of coordination. Any downtime can impact patient care, and therefore must be minimized or prevented. For safety reasons full systems tests should occur before placing the new system into production. This takes significantly more time than most would anticipate. The result is a tendency towards continuing to use old locally coded values

- when upgrading. Starter content works for “starting” but not so much if already live. For example, there is low incentive to upgrade the hospital information system (HIS) to support LOINC if the local codes are generated by Lab system and also used by the Pharmacy and ER systems. Likewise there is low incentive to upgrade the lab to support LOINC, when the HIS, Pharmacy, and ER are still only accepting local codes. Upgrading all systems at once is difficult because it may introduce many unanticipated errors in a complex system.
- Mapping sounds easy, but isn’t. Small differences in the meaning of terms are the rule. Mapped content often loses information, and sometimes just isn’t possible. At times, mapping can create strange behaviour and results because of these subtle differences. Getting everybody to the same semantics needs to be the goal, but it’s harder than most believe.
  - Term maintenance is harder than first definition. How content will be maintained needs to be considered from the beginning.
  - Implemented in real life a large subset isn’t just a flat list. As listed above, it generally will need a lot of information from the source terminology and massaging before it can be included in a product.
  - Naming consistency is both a blessing and a curse. Always allow for many ways to name concepts that may be used in slightly different context.
  - Usage statistics are helpful. In large sets like problem lists or med lists rare things can and should failover to freetext to account for exceptions. Even for smaller sets it’s nice to help facilitate better usability. In our examples, it’s nice to know things like the fact that “Oral” is a more common route than “intrathecal”, so you can put common things at the top of the list.

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

- The use cases that define several of the referenced standards need more clarification about who, what, when and how the referenced data is created, and who, what, when, and how users are intended to receive it. For example, a use case for “submission” of lab results to public health should specify, which labs under what conditions, when (batch or real time), who (is it directly the lab, or must be through an EHR). This detail may not be included in the rule because it is subject to more extensive change, but it should be referenced in the rule where further details on exactly how the flow is intended to work can be found. That referenced place (perhaps HITSP documents) should be inclusive of implementation guidance to the level of subsets and value-sets.
- Procedures are referenced in Meaningful Use, but CPT coding of procedures is primarily for billing, yet the context of use is to record the list of procedures for the patient at the point of discharge. This is a disconnect because I don’t think patients want to see procedure codes for every vena-puncture or chest x-ray they had, they want to know the ‘major procedures’ meaning the surgeries, cardiac catheterization, etc. A subset is needed for this.
- There needs to be more clarity over what it means to “Enable a user to record, ... in accordance with ... <terminology standard>.” Does this mean that the system must be able to record ‘at least one’ concept in that standard, or ‘every possible concept in that standard’. Assuming the latter this is particularly problematic for large terminologies such as SNOMED-CT for problem lists because it contains over 350,000 concepts, when a relevant subset like CORE is ~5000, and VAKP contains ~17000, and BIDMC contains ~1000. Specification of subsets here would help to determine what is expected.
- A subset is needed for non medication Allergens (2013). UNII has been listed in the past, creating ambiguity about the need to support all of UNII for the few items that might be considered allergens.
- A terminology and subsets are needed to represent common non-medication Orders (ie radiology orders, patient care orders) for quality metrics. For example, it is difficult to implement automatic capture of a quality metrics such as ‘if VTE prophylaxis was started’ if there is no standard content for the order of sequential compression devices. All hospitals must create unique sets of their local orders that define “application of mechanical device”. Likewise it is difficult to recommend the correct indications for a MRI of the brain if there is no standard terminology for

that. Though result codes exist for radiology orders, LOINC does not, nor is it really intended to, represent the order.

- It is unclear which subset of lab results must be sent to public health agencies.

Other subsets needed, but not referenced in the IFR or NPRM.

- A subset is needed for allergic reactions. Traditionally HITSP has recommended the use of the VAKP subset, but this is far too general. Never have the vast majority of 17,000 VAKP terms been reactions to allergies.
- A terminology and subset is needed for common frequency schemas as used in orders and prescriptions (for example Daily, BID, QID, etc). This needs to be mapped to HL7 GTS, but >95% of all prescriptions fall in just a few schemas and mapping from the infinite granularity of GTS back to a common term is next to impossible.
- Better terminology bindings are needed for Drug(RxNorm)<=>Disease(SNOMED-CT) indications and contra-indications in particular. This needs to include sets on both sides to account for drug classes and disease groups.

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

As per above. The government should manage the process, but not dictate the details. However, the government should commission others to specify use cases with implementation guidance in appropriate levels of detail, test that guidance in pilots, and provide roadmaps to allow adequate lead time to anticipate direction and implement. Value-sets are part of implementation guidance.

## **Appendix: Possible additional metadata considerations for a Common Subset/Value-set repository in addition to the items listed in HITSP TN903.**

- Keywords
  - Used to index the subset/value-set for a search to find it
  - E.g., Route, Prescribing, Ordering, ...
  - Optional
- Change History
  - Date, author, change and Reason.
  - Including approval status
  - Required
- Deprecated
  - Y/N,
  - Required
- Replace by
  - If deprecated, is there another set which replaces it
  - Optional
- Owner
  - The person officially responsible for maintenance of the set.
  - Should include contact information.
  - Required
- Subscribed Users
  - Any interested party that has stakeholder interest in this set. If set is about to change or set becomes orphaned, this list is notified.
  - Required to maintain, but obviously could have nobody interested.
- Registered Use Cases
  - Any use cases that reference this set. May have distinction of primary use and secondary use
  - Optional
- Children Subsets
  - List of other subsets/value-sets that are dependent on any changes in this subset. May be used to further constrain the set for variations in use such as the distinction between what is required for senders vs required for receivers. Changes in this set should send notification to owners of these other sets.
  - Optional
- Parent Subsets
  - Potentially derived from the HITSP TN903 “Definition” as the list of parent subsets (the union or intersection of terms that this set is guaranteed to be in). Different in that this should subscribe this set as child of the parent to receive notification of changes in parents.
  - Optional.
- Other Related Subsets
  - Subsets that may have similar but different values for different use cases
  - E.g., PatientInstructionRoutes, SubstanceRoutes
  - Optional
- Related content
  - User sharing of additional content related to that subset. For example, Foreign languages, etc.
  - Optional.
- Licensing Restrictions
  - For the dependent terminologies and also for the set itself. Hopefully, anything that ends up in MU requirements should not be encumbered by licensing.
  - Required
- Terminology Dependency
  - Any coding systems referenced by the set. Including version.

- For terminologies that have concept permanence, the assumption is that version forward. For those terminologies that do not have concept permanence (e.g., ICD), assumption is that version is exact.
- E.g., SNOMED-CT >2009-01-31
- Required
- Structural and Contextual Assumptions
  - Freetext description of any structural assumptions made in the subset such as post-coordination of qualifiers in the model or only valid under particular conditions.
  - Optional
- Is Sequence Important?
  - Yes or No, must the ordering be maintained.
  - Required
- Encoding:
  - Information on which encodings were used (e.g. UTF8)
  - Required if not standardized. Delete if standardized.
- Predicate Question.
  - What is the immediate question that predicates this set? May be implied by intended purpose.
  - E.g., What is the Route of Administration? What Type of Tobacco?
  - Optional
- Intended Downstream User and Purpose
  - E.g., pharmacists to write Sig, Nurses not know which route to give
  - Optional
- Intended User Source For Data Entry
  - E.g., ordering/prescribing provider in cope or eRx system.
  - Optional
- Related Mappings.
  - Any information on mapping this set to other terminologies
  - Optional.

Related question – in addition to requirements from TN903, what is minimum data in each item.

- sequenceNo
  - Ordering identifier
  - Optional
- useFrequency
  - How frequently is this term chosen relative to others in the set as of this version.
  - Optional
- Addition Date
  - Date when item was added to set
  - Required
- Deprecation flag
  - Y/N – this item was once part of the set, but is no longer active.
  - Required
- Deprecation Date
  - Date when item was removed from set
  - Required