

26 August 2010

Judith Sparrow
Office of the National Coordinator for HIT
Dept of Health and Human Services
Washington, DC

RE: HIT Standards Committee Vocabulary Task Force Hearing September 1-2, 2010

Dear Mrs. Sparrow,

Siemens Healthcare Health Services is pleased to submit our comments regarding the HIT Standards Committee Vocabulary Task Force Hearing to be held on September 1-2, 2010.

Siemens Healthcare Health Services (Siemens HS) is the information technology (IT) division of Siemens Healthcare, with worldwide headquarters in Malvern, Pa., employing about 5,000 individuals worldwide. Holding a leadership position in healthcare IT for over 35 years, Siemens HS is helping healthcare organizations achieve desired outcomes every day through the implementation of Siemens IT solutions.

In addition to providing in-house IT solutions for healthcare organizations, Siemens HS is a leading Application Service Provider (ASP) in healthcare, hosting data for over 1,000 of its customer organizations and operating one of the most sophisticated healthcare network operations centers.

We understand that some of the key objectives for the hearing on the use of value sets and subsets. Siemens HS strongly supports ONC's objectives, here. Our mission statement is to "passionately pursue solutions to healthcare's most complex challenges through remarkable innovations in IT."

In this context Siemens HS is pleased to submit the attached comments to help improve the quality and efficiency of healthcare delivery in the United States.

Sincerely,

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Overall Questions:

1. What are the requirements for a centralized infrastructure to implement “one-stop shopping” for obtaining value sets, subsets, and vocabularies for meaningful use?

Your detailed questions asking about maintenance, versioning, and distribution indicate that you are on the right track and asking the right kinds of questions. Below is an outline of important considerations that we see.

- a. Integration and alignment. All user perspectives of a particular value set or subset should be included and aligned. Specifically, the value set or subset should include metadata that identifies and aligns the:
 - i. Context of Data Entry. For each value set, or subset, it should be clear what the purpose of the value set, or subset, is (e.g., used for problem list vs. orderable lab tests), as well as who is expected to or allowed to enter and under what circumstances. It should also identify other users who are expected to review or validate the entered data, and where, how and when the review occurs. If the data capture may occur at multiple places at various times by a various users, the range of variability should be understood.
 - ii. Context of Data Use. Each value set or subset should identify who is expected to use the data and how. It should be clear where and how the value chosen by the user is expected to be used for a) clinical communication (and to what audiences), b) decision support, and/or c) quality reporting.
 - iii. Once the various stakeholders have been identified, then the subset or value set should be reviewed to ensure that all perspectives concerns have been addressed. For example, if a quality measure requires a particular value set of SNOMED codes from a problem list, does the Subset for the problems subset have the appropriate codes in it? These kinds of alignment issues are not currently being implemented.
- b. Content completeness. Value sets often fail to include exceptional values, synonyms, user interface terminologies, and maps needed to be used in the real world. Thus, most are incomplete. For example, if the subset or value set has a clinical audience that includes a patient (e.g. a problem list subset might be used at the point of discharge to communicate what happened during their hospitalization), does the concept have a label or map that can give this information in patient level language? RxNorm is also missing many needed concepts such as contraceptives.
- c. Content Quality. Despite good design and significant progress many of the larger terminologies and subsets still have significant quality problems, particularly with mappings. For example, there are many SNOMED codes which map as “type 1” (which is supposed to indicate that the terms are exactly the same) which imply directionality that the SNOMED code might otherwise be coded as that ICD9, but the reverse map does not hold so they should be codified “type 2”. Similarly we have run into issues with RxNorm to NDC maps
- d. Version controls. There need to be well understood responsibilities for senders as opposed to receivers on subset or value set interpretation. For example if an element has a value set which is marked as “Coded with exception” (data type of CWE in HL7 messages), are senders required to have the capability to send all values in the set at minimum? Similarly, are receivers required to have the capability to understand all values in the set at minimum? Details such as this recorded as metadata or as part of an overall model would help greatly in use and interpretation of the value set / subset. Similarly, for tightly controlled subsets and value sets, the sequence of how senders and receivers to move from one version to next needs definition.

2. Which requirements or functionalities are urgent, i.e., absolutely required to support “meaningful use”? Which would be most useful immediately? What would be a staged approach over time to get to the desired end state?

The MU objectives are somewhat of a moving target presently, and even though the stage 1 requirements would have been helped by your efforts, these requirements are largely codified. Thus, the main infrastructure need is to support the evolutionary changes needed for later stages and to clarify and take over maintenance of standards listed in stage 1.

Content will be a significant concern for later stages. These include:

- a. Non-medication Allergies and allergen classes. Set of substances that can/should be recorded for allergy lists. Medication allergies should be aligned with terminologies required for medications (eg RxNorm). However there is particular need for alignment on how to handle substance other than medicine (e.g. eggs, latex, etc), or classes that have cross reactivity (e.g. Beta-Lactams)
- b. Problem Lists. Suggest guidance to the NLM CORE Subset + any additional terms needed to support various quality measures.
- c. Values for Structured Sig
 - i. Frequency Schemas (e.g. BID, q6hrs, etc)
 - ii. Routes Of Administration
 - iii. Dosing Forms
 - iv. Units Of Measure
- d. Procedures. Procedures were listed for stage 1 in various contexts (ie exchange of clinical data) but no standard list was given (CPT and ICD are designed more for billing purposes). A suitable subset for a "procedure list" that may be used for communication with another provider or patient as opposed to for billing.
- e. Alternative Medications. Rx Norm is missing many clinically relevant concepts including contraceptives, herbals, vitamins, and many brand names.
- f. Orderable Tests and Activities. Orderable lab tests and panels such as "CBC" for use in evidence based order sets. Specific sets of orders are needed for:
 - i. Lab.
 - ii. Radiology
 - iii. Nursing
- g. Laboratory tests and radiology reports as resulted (eg common LOINCs) that senders must be able to send and receivers must be able to receive.

Detailed Questions:

3. Where are you using value sets and subsets? For what domains? How many value sets and subsets?

This is difficult to answer since there are many, some are nested, and in general the systems are designed to be highly configurable, and not all concepts need to be represented at the national level. Below is a partial list that gives a flavor of the types of subsets and value sets in a clinical information system.

- a. Medication Substances. We use FDB primarily at the Routed Med and Package Med level. We also include maps to RxNorm at the SCD level. Customers then use this to pick (subset) which items they have on formulary.
- b. Allergies. We use FDB primarily for medication allergies and checking, but have customer defined values for non-med allergies and hardwired processing for Latex and IV contrast specifically. A list of Common Allergy Reactions may also be configured by the user.
- c. Problems. Our starter content for Problems is based on the NLM CORE subset, and ICNP nursing problems. Each problem may have a generic structure with customer defined content and also customer defined "parameters" which may qualify the problem. Parameters may be grouped into parameter sets. A parameter may be defined to have an attached value set. For example some of these value sets associated with problems include: Certainties (Probable, Certain, ...), Acuties (Acute, Chronic, ...), Judgments (Impairment, Delay, High, Low,..), Client (Patient, Brother, Father, ...), ExpectedOutcomes

(Improved, Within Limits, Effective,...), Status (Active, Erroneous, ...), BodyLocation (Abdomen, Chest, ...), Laterality (Left, Right, ...), Severity (Mild, Moderate, ...).

- d. ICD9 or 10 are used for billing diagnoses.
- e. Procedures are coded with CPT codes and CPT modifiers
- f. Immunizations are coded with CVX codes
- g. Displays may be organized into “flow sheets” (e.g. “Labs”) which are sets of “display groups” (e.g., “Hematology”) which may contain sets of findings or other display groups. This is of particular note even at the national level since the organizational display of values and subsets plays an important role in the usability of certain sets, particularly larger ones. Sequencing and grouping matters. For example, this is where a panel of blood chemistries would be defined.
- h. Orders may be grouped by “favorite groups” (eg “Radiology”), “convenience sets” (eg GI prep) and “order sets” (eg “Pneumonia Admit Orders”). Orders have a variety of parameters such as status, Priority, etc each with an associated value set. Depending on the order type, a orderable service may have many other parameters and therefore value sets associated with them. For example a radiology order for a chest xray may have a parameter view which has a value set with values such as (“AP”, “Lateral”, Oblique”). There are hundreds of these. At the national level, this is where ‘evidence based order sets’ would be defined. ‘Evidence based ordersets’ depends on a common understanding of orders first.
- i. Similarly, medication orders need a type (Simple, Combination, SlidingScale, ...) to determine parameters and associated value sets. Some of these are RoutesOfAdministration (eg Oral, IV, SubQ,...) SubstanceForms (eg Tablet, Solution, ...) IVMethod(eg Irrigation, KVO, Push, ...).
- j. Clinical Documentation templates may have numerous customer definable findings and value sets. Examples might include an admission nursing assessment that has a finding of SmokingStatus (eg Current Smoker, Prior Smoker, ...) or TobaccoUseType (Cigarettes, Pipe, Chew Tobacco, ...) There are probably thousands of these small value sets.
- k. There are several cross purpose value sets that are more difficult to classify. These include concepts such as:
 - i. UnitsOfMeasure (mg, ml, g/dl, ...)
 - ii. Age Ranges (infant, child, adult, ...)
 - iii. FrequencySchemas (Daily, BID, ...)
 - iv. Events (Admit, Pre-op, Post-op, Discharge,...)
 - v. Commonly chosen reasons and Comments: Eg ReasonsForAlertOverride, ReasonsForRequest, ReasonsForDelay, ReasonsForRevision, ...
 - vi. Specimen Related: Containers, SpecimenTypes, CollectionMethods, AbnormalityIndicators
 - vii. User Groups/Security related: e.g. PreferenceGroups, SecurityRoles, SecurityUserGroups Specialities, CoverageGroups, Titles (Mr., Mrs, Dr., RN, LPN, ...), LicencingAuthorities,
 - viii. Locations: Cities, States, Countries, Counties, Communities, Nationality, Municipalities, BusinessEntities, UnitTypes, NursingUnits, ExternalSystems
 - ix. Financial Account Related: AccountStatuses, FinancialClasses, IDTypes, PlanCode, PlanType
 - x. Misc: e.g. Languages, RaceCodes, Ethnicities, Currencies, MaritalStatus, Religions, LivingArrangements, LivingWillStatuses, CodeStatuses, CommentLevels, ConditionsAtAdmissionDischarge, Devices, DischargeDisposition, DischargeTo, LocationAtDeath, IsolationIndicators, JobStatuses, TransportMethod, VisitCategory, RoomTypes,

4. In your experience with creating, disseminating, updating or using value sets, subsets and entire vocabularies, what works and does not work?

Organizing and disseminating values and sets by concept type such as “problem” or “document” or “order”, works better than organizing by particular purpose or specialty such as ‘sets needed for quality measures’ or sets needed by the ‘emergency room’. Eventually the purposes and specialties run into one another where structural types tend to stay distinct. Often the same value may be needed by quality reporting and a rule, and also may be needed by a nurse the emergency room or a physician in the ICU. When value sets or

subsets are managed in isolation for a single purpose rather than examining all purposes they create workflow issues for other users of the data.

Also, for larger subsets, identifying the correct granularity of coding is difficult, but it is important to identify the needed granularity early on in projects. Without this clarity many will attempt to code extremely rare minutia that has no identified downstream purpose which detracts from higher priority issues. Coding at very granular level also creates usability problems as terminologies grow to excessive size and it becomes very difficult to find any particular concept or differentiate it from other similar content. Coding with insufficient granularity makes it difficult to partition the data correctly for downstream users. Thus, it is instructive to look at real world data and prioritized uses of the data before establishing the granularity, then setting mechanisms to allow free text entry to capture additional detail in more rare cases.

5. What human resources does it take to implement and manage value sets, subsets, and entire vocabularies? Informaticists? Clinicians? IT people? How are you organized?

This requires a team with a variety of roles. A product manager is needed to define priorities and plan overall content needs. A project manager is needed to work progresses according to scheduled timelines, and ensure appropriate quality checkpoints have been met. Product analysts are needed to determine detailed content use cases and requirements. Once content has been started, content curators are required to maintain the content and ensure consistency over time. A DBA is required to logically structure the content. Developers are required to build tools. Resource managers are needed to ensure staffing is appropriate and skill sets are aligned with job functions. A contract manager is needed to keep business relationships with content providers. Release managers and beta managers are needed to establish appropriate real world testing prior to general release.

6. What national resources and services could be leveraged to reduce the level of effort required for local implementations? What is the irreducible minimum of local work at an implementation site or within an organization or system?

There is no single answer to this. Localization is needed because the people, the services, and structural locations are not the same at different sites. This drives medicine to be practiced differently. Additionally, the level of abstraction where commonality to another site may be achieved is -- and likely always will be -- a changing and fuzzy line. Thus, an intent to cover 90% of a particular domain (the commonality of 90% of sites), with allowance for graceful failover to cover the remaining 10% is appropriate.

Strategies to account for local variation might range from:

- o Local filtering of a larger superset of concepts (e.g. a formulary selection from all drugs)
- o Locally defined concept labels (e.g. some hospitals use "chem7" others use "BMP")
- o Allowance for free text exceptions (e.g. a rare problem in a problem list)
- o Mapping to local terms (e.g. known by my lab system here as "HgbA")
- o Allowance for locally defined concepts in addition to standard content (e.g. Most hospitals have plain x-ray, few outside the Mayo clinic may distinguish between "Imitron" and "spiral" CT scans)
- o Entire sets composed of local definition (e.g. the nursing stations in a particular hospital)

The solution and "acceptability" of customization is dependant on the particular value set or subset in question.

It is also important to keep in mind that many vendors have international customers that they must support. Thus, for these vendors there must be ways to separate what has applicability in the US market only (e.g. medication content is substantially different in other countries), and content that may have specific licensing restrictions (e.g. SNOMED-CT). US National resources could be used to substantially reduce the burden to bring content in foreign markets however, and to do so is in the advantage of the US. For example, bringing content to a foreign market may involve providing user interface terms in different languages. Including alternative languages such as Spanish might be help other markets, but is also relevant for the US market in

part to help with consumer empowerment, but also when exchange of health information does need to cross borders.

7. What is your maintenance process? How do you manage updates?

This depends greatly on the subset or value set. For example, medication content is maintained primarily by a 3rd party provider (FDB), with timing aligned at Siemens such that it is distributed to customers for release across all our products on the same day. Some content may be delivered or upgraded with release of new software versions. Other content is delivered as a 'starter' database to get customers running quickly (80% guess at common functionality) from which the customer then adapts to their local environment and take on maintenance from that point forward. Other content has a mixed flavor.

8. What metadata do you maintain and how do you maintain versioning?

See question 10.

9. Is there a difference between versioning for clinical documentation vs. versioning for reported measures, i.e., when do you go live with a change in the EHR vs. when do you use the new version for measures?

Content versioning and code versioning is different. Values, value sets, and subsets have a dependency on code functionality, and therefore particular releases. However, the content often changes more frequently than the software code and in general does not need to be bound to a release. It may depend on a minimum version to ensure that certain functionality is in place.

We compute quality measures in a separate module that is designed to be used by a chart abstractor. This module can receive data (structured and unstructured text) from multiple systems as a typical customer does not only have our systems. This further provides for the ability to align/normalize data across these systems. All data is provided as "evidence" to a user who reviews and asserts the answer to the question asked by the measure (e.g. does this patient have exclusion). A newer version of the quality measure involving an updated value set might require updates to rules to gather relevant data, or which patients might meet inclusion/exclusion criteria. Hospital workflow and policy would determine if a change to the clinical documentation is required to ensure that evidence can be captured (e.g., adding a new finding to a nursing assessment). In determining the documentation change, it not only involves adding new findings with associated value sets, but also potential process changes to determine who who, where, and how it will be captured (e.g. will this be on the triage form, or daily assessment or in a dictated document). This process may take several months to prepare and execute.

Clearly, using the new version of the measure cannot occur until the source system (EHR or other HIT module) has been updated and users have started to populate the new data requirements, unless all the relevant data is already available.

10. How do you manage versioning in clinical decision support vs. changes in value sets?

We have recently been moving toward delivering more of some types of content in bulk form, where instead of the customer modifying/syncing with our content, the customer derives their local content from our content in the form of overrides and local extensions. This moves versioning of content into larger blocks that are easier to work with. In these bulk updates, much of the decision support (in particular regarding medication duplication, drug/dose, and allergy checking) is therefore updated by providing updated versions of a database that contains all of this content.

For example, we provide a database of medication content (including all relevant subsets, value sets for routes, frequencies, and concept relationships such as drug-drug interactions). User overrides, local content and configuration (e.g. which drug-drug interactions they do not want to use, which items on formularies, maps to local terms) are managed separately in another database and software applies the customer overrides at runtime. This greatly simplifies version control because the database can be switched to a different version by simply pointing at a different (newer) database. Concepts in the medication database

are retained forever, but may be marked obsolete which may prompt changes to local content that has dependencies. This works well for us because as a software vendor we can control both the content and the software bindings. It is not clear that a similar strategy could work for ONC.

Other decision support may be written by the customer in the form of custom rules or workflows and this requires maintenance independently. If content is controlled this way, it generally requires a dependency tree and meta-data identifying where value sets are being used. When a value is changed in a value set or subset, it should trigger that the dependent content needs to be retested.

11. How does an application know which value set is for which purpose? How is the specific context for a value set maintained at the message data element level of specificity?

This largely depends on the type of value set and how it is intended to be used. In general there are relationships between concepts and particular value sets. See the above description of problem parameters (question 3, point c) as an example. In some cases “applicability criteria” (e.g if female then show breast exam, if male show prostate exam, etc) are applied which change the associated forms, parameters or value sets depending on the context of use.

12. How is the English language intent of the value set context document and maintained?

Again, this may vary depending on the specific content type. However, as a general rule we provide additional long text description areas where concepts (including value sets and subsets) may contain information to clarify purpose.

13. What are lessons learned about web links vs. storage of the vocabulary or other artifact in a physical repository?

URL links can work for some kinds of content such as looking up evidence on medical sites (where the evidence may change rapidly) as long as there is no critical path dependency for patient care, and there is mechanism for graceful exception handling. URL links generally fail when the link must include static references such as what a particular piece of information meant at a particular point in time, or a particular versioned object.

For the purpose of content distribution, we would advise locally control of content where feasible. For example, define the values of a value sets or subsets to be static within a particular version. If weblinks are included in particular forms of content they should undergo regular review to ensure that the links have not broken.

14. How do you manage distribution of updates to multiple sites?

Delivery of medication updates is pushed to the customer. Other content generally is made available via a customer share point. Customers are generally responsible for application in local environments.

15. Where is local customization appropriate and how much customization is acceptable?

See question 6

16. How do you manage distribution of updates with local variations and optionality? Unique subsets? Local mappings?

See questions 6 and 10.

17. What has to be local in an EHR implementation vs. what can be external in a vocabulary repository?

See question 6 and 10.

18. What functions are required that users have not yet appreciated?

I believe that there is a critical mass (which most users have not achieved) where there is enough data in the system (especially problem lists) and configuration is sufficiently mature (especially user templates) that it

becomes easier and faster to enter and maintain the data in the computer than it is to use paper. This tipping point is critical for realistic decision support and analytics, and these functions will have limited usefulness until this happens.