



**Written Comments Submitted to the ONC HIT Standards Committee
Clinical Operations Workgroup – Vocabulary Task Force
September 1-2, 2010
Panel 1: Measure Developers Value Set Creators
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The American Medical Association is pleased to provide comments on the management and implementation of value sets. We feel our comments are valuable in advancing the integration of performance measures within electronic health records.

The AMA-convened Physician Consortium for Performance Improvement[®] (PCPI), staffed by the Performance Improvement division of the AMA develops quality measures. The PCPI includes over 170 member organizations and since its inception in 2000, has developed over 260 quality measures in 42 different clinical topics. Our measures are included in national programs such as the CMS PQRI program and the CMS EHR Incentive Program (meaningful use regulation). They are also used by private payers and as medical boards in their certification process. Given the volume, scope and adoption of measures developed to date, we have created hundreds of value sets. We are pleased to report that the PCPI's use and structure of value sets and subsets is aligned with the definitions put forth by the Vocabulary Task Force and offer the following comments and recommendations based on our experience.

With respect to our internal processes and within in the context of one stop shopping," we believe the implementation and management of value sets requires a coordinated effort with a broad spectrum of expertise that includes but is not necessarily limited to the following:

- Medical specialties, clinicians and specialists to ensure clinical relevance;
- Informaticists and subject matter experts to provide the HIT discipline
- IT and technical expertise to implement requirements and produce deliverables
- Skilled measure development professionals (e.g. policy and functional analysts) that serve as critical liaisons between technical, clinical and terminology experts.

We recommend that the committee consider the value set endeavor from two perspectives: infrastructure and content. Both requirements are equally important; we stress the importance of isolating the issues related to each.



The PCPI value sets are part of the quality measure specifications. We are committed to ensuring the specifications and relevant value sets are publicly available. We post them to our website. We are also committed to ensuring that our specifications and value sets can be used electronically. In the context of infrastructure, we believe that value sets should reside within a registry provided via web services. That registry should be developed in close collaboration with value set developers.

From a content perspective, we recommend the use of structurally defined value sets and subsets versus enumeration or “cherry picking” to identify members of subsets and value sets. This recommendation is based on lessons learned as they relate to the requirements for effective change management. The release of a new version of vocabularies, terminologies and code sets presents a considerable impact on our maintenance process. Using the SNOMED CT release as an example, we are able to track and identify revisions to existing SNOMED concepts that are members of our value sets and subsets. However, identifying concepts that are new for the most recent release of SNOMED that should also be members of our value sets and subsets can be quite challenging because historically, our value sets have been developed using enumeration or without the use structured rules or semantics. Our goal is to incorporate structured rules and semantics to the extent possible to facilitate effective change management. We recommend that the value set infrastructure support structured definitions as well. We also recommend facilitating a change management report via a web site that would also include a submission or feedback mechanism.

Careful and comprehensive review of the issues related to value sets are essential for re-tooling performance measures for electronic systems and meaningful use of electronic health records. We appreciate the opportunity to contribute to the committee’s deliberations.



Responses to detailed 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?

PCPI as a stakeholder in the development of a value set registry recommends that the infrastructure for the end solution include the following:

- a. **Data Access:** A web based solution for both access and management. It is recommended that an API is published for solution users for data access and metadata services. The solution must support access via standard browsers and support new versions of browsers as they are released.
- b. **User Interface:** An easy to use interface should be developed that allows for, but is not limited to, versioning, import and export of data, workflows for the input, review and publication of value sets. It is recommended that solution design includes an interface design to which stakeholders, including the AMA-PCPI, contribute. Moreover, it is recommended that the usability testing of a prototype be conducted to validate the solutions functionality with each stakeholder.
- c. **Security:** It is recommend that the solution be designed using multi-tenant architecture and a security model with security assurance which will prevent loss, inaccuracy, alteration, unavailability, or misuse of the data and resources that the solution and its users use, control, and protect. It is also recommended that the security model allows for access control so that value sets can be secured for review and testing prior to becoming publicly available.
- d. **Performance:** The solution needs to be reliable with Service Level Agreements in place for uptime and scheduled maintenance. It is also recommended that the solution be scalable and able to handle peak loads.
- e. **Usability:** It is recommended that the solution has built in version control and logging. Additionally, notifications would be particularly helpful to alert users of value sets of changes.
- f. **Business Continuity:** A business continuity plan should be in place with a full disaster recovery plan completed.
- g. **Monitoring:** We recommend that registration and metering of usage be built into the solution, as well as error reporting and validity checks.

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?

There needs to be alignment in the context of use of value sets across standards, whether those standards are named within the final meaningful use and certification rules or used in practice. From a quality measures perspective, harmonization is necessary related to value set vocabulary definitions across standard setting entities such as HL7, HITSP and NQF.

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

The PCPI’s use and structure of value sets and subsets is aligned with the definition of value sets and subsets put forth by the Vocabulary Task Force. A value set used within a quality measure is designed to represent a given data element within a quality measure. The PCPI uses value sets and subsets to specify the required data elements for quality measures developed by the PCPI. The data elements are specified in accordance with the standards named in the ONC final rule for Standards, Implementation Specifications, and Certification Criteria for EHR Technology. For a given data element (eg, diagnosis or procedure), there may be more than one subset within a value set for a given data element. For example, a quality measure for Heart Failure will have a value set for “Heart Failure-Diagnosis”. This value set is comprised of 3 subsets—ICD-9 CM, ICD-10 CM, and SNOMED-CT. We strongly believe there should be no limit on the number of allowable value sets. Instead, that number is commensurate with the number of quality specified and used.

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

With respect to disseminating value sets, the process the PCPI currently uses for our quality measures is to publish the value sets on our website. Users can download the value sets from the website. We acknowledge that this process is not optimal and recommend that value sets are available online and via web services, with notifications sent via email to registered users when updates are made.

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?**

We believe the implementation and management of value sets requires a coordinated effort with a broad spectrum of expertise that includes but is not necessarily limited to the following:

- **Medical specialities, clinicians and specialists to ensure clinical relevance;**
- **Informaticists and subject matter experts to provide the HIT discipline**
- **IT and technical expertise to implement requirements and produce deliverables**
- **Skilled measure development professionals (e.g. policy and functional analysts) that serve as critical liaisons between technical, clinical and terminology experts.**

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?**

See response for question 7

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

The PCPI value set maintenance is part of a larger process to maintain the PCPI quality measures. The quality measure maintenance process includes major and minor revisions. Major revisions include a complete review of the clinical guidelines and evidence, with revised measures going through the full measure development process—including public comment, re-specification (including update of value sets), and approval by the PCPI. Major revisions typically occur on a three year cycle.

Minor revisions include updates to the coding and taxonomies to reflect current releases. For example, each year, the ICD-9 CM and CPT® codes are updated to ensure that the value sets include only current valid codes. As new codes are released, coding experts on the measure development team review to determine if the codes are appropriate for inclusion in the value sets—making sure that the original intent of the data element and corresponding value set—is preserved. Minor revisions occur on an annual basis—typically after ICD-9 CM and CPT are released in October for the upcoming calendar year, and include the most recent versions of SNOMED-CT, RxNorm, and LOINC at that time.



One of the challenges with respect to harmonization of maintenance schedules is that the taxonomies and coding systems used in quality measure specifications have different release schedules and frequencies. We encourage harmonization at the national level for release cycles.

Additionally we recommend the use of structurally defined value sets and subsets versus enumeration or “cherry picking” to identify members of subsets and value sets. This recommendation is based on lessons learned as they relate to the requirements for effective change management. Our goal is to incorporate structured rules and semantics into the definition of PCPI value sets and subset to the extent possible to facilitate our maintenance process. We recommend that the infrastructure support the use of those definitions as well.

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

1. Unique id for the value set
2. PCPI measure topic
3. Measure number within the measure topic
4. Measure component to which members of the value set belong
5. Value set name-the English term used to describe the value set
6. The coding system to which the subset members belong
7. The numerical representation for a concept
8. The English language description of a concept
9. Version – the terminology version
10. OIDS for data elements

Version management is performed manually at the measure level. When new or updates to value sets are available a new value set document is posted to our website.

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?

We defer to EHR vendors.

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

We defer to EHR Vendors as this is an architecture dependent question.

- 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? How is the English language intent of the value set context documented and maintained?**

The PCPI value sets include unique identifiers to link the value set to the corresponding data element in the quality measure. The English language intent of the value set is linked to how the data element is specified, and to the specific attributes of the data element. One tool that has facilitated the standardization of data elements is the NQF Quality Data Set—a framework to identify the type of information included in quality measures, and a standard way to represent the data elements.

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

Not applicable to the AMA

- 13. How do you manage distribution of updates to multiple sites?**

Currently PCPI values sets are distributed , via Microsoft Excel Worksheets that are published to our website. Vendors can proactively obtain the information by visiting the website and downloading the coding spreadsheet(s) .

- 14. Where is local customization appropriate and how much customization is acceptable?**
From a content perspective, we believe customization is most appropriate at the national level.

Not applicable to the AMA

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

Not applicable to the AMA

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

We defer to EHR Vendors as this is an architecture dependent question.



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

The need for structured semantic value set definitions

