The Joint Commission

Written Comments Submitted to the
ONC HIT Standards Committee
Clinical Operations Workgroup – Task Force on Vocabulary
March 23, 2010

Panel 5: Level 1 Governance Value Sets

The Joint Commission appreciates the opportunity to provide comments on the "rules of the road" for vocabulary subsets and vocabulary value sets. We believe our comments will facilitate meaningful use of electronic health records. Founded in 1951, The Joint Commission is an independent, not-for-profit organization whose mission is to continuously improve the safety and quality of care provided to the public by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

While The Joint Commission has its roots in hospital accreditation, over the years it has developed evaluation programs for a diverse array of health care settings. Today, The Joint Commission evaluates and accredits more than 17,000 health care organizations and programs in the United States, including ambulatory care, behavioral health services, durable medical equipment providers and suppliers, home care, hospices, hospitals and critical access hospitals, laboratories and long term care facilities.

Since the mid-1980s, the Joint Commission has been a nationally recognized leader in performance measurement and, as such, has gained extensive experience and expertise in the identification/development, specification, testing and implementation of performance measures. The Joint Commission developed and field-tested the first ever sets of standardized performance measures (perioperative care, obstetrical care, trauma care, oncology care, infection control and medication use). In the mid-1990s, the Joint Commission embarked on a second effort to implement standardized performance measures (i.e., core measures), known as the ORYX initiative, as an accreditation requirement for hospitals (and other types of accredited organizations). Hospitals seeking accreditation (representing approximately 96% of all U.S. hospital beds) are currently required to select from 10 standardized measure sets to meet accreditation requirements.

The ORYX initiative has evolved over the last decade to become a technologically sophisticated, state-of–the-art process for performance measure implementation and ongoing data collection, transmission, analysis and

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reporting. Joint Commission developed core performance measures, approximately 50 vendors, and a highly developed technical infrastructure support data collection and transmission for nearly 4,000 hospitals today. The Joint Commission has nearly 25 years of experience in evidence-based measure development, including both de novo development and adaptation of existing measures. To date, measure sets have been developed across more than 25 clinical areas for use in accreditation, certification, quality improvement initiatives, public reporting, monographs, etc.

These comments draw from The Joint Commission's considerable experience and expertise in developing and testing measures, including recent experience in retooling inpatient measures for EHR Data Collection. HITSP received funding from the U.S. Department of Health and Human Services for a Centers for Medicare & Medicaid Services (CMS) sponsored project to retool the Joint Commission developed venous thromboembolism (VTE) and stroke measures and CMS' emergency department measures so that quality data can be collected from within an EHR as a by-product of patient care. The Joint Commission, a HITSP member, participated with the Tiger Team on the retooling of the VTE and Stroke measures. In addition, the Joint Commission participated with the Tiger Team to update HITSP's Quality Standard (IS06) and in the decision-making concerning general EHR data collection concepts as they relate to quality measures.

The Joint Commission's evaluation criteria used in identification and implementation of quality measures include the requirements that each measure targets improvement in the appropriate patient population(s); is precisely defined and specified; interpretable; useful in the accreditation process; and is publicly available. In addition, to be applicable for their intended use, individual quality measures must meet a number of strict requirements, including having established reliability and validity.

Our chart-based measures are defined and specified using ICD-9-CM diagnosis and procedure code tables, medication code tables, precisely defined data elements, and step-by-step programming algorithms. Our work with HITSP in the retooling of our Stroke and VTE measure sets has indicated that our existing code tables will become value sets containing nationally identified vocabulary; our programming algorithms will be the logic depicted within the eMeasure specification; and our existing data element definitions will be modified into value sets linked to a specific location within the electronic record (e.g., problem list or discharge summary).

1. Who should determine which value sets are needed?

As is evident in our existing chart-based performance measures, The Joint Commission supports, when appropriate, the reuse of value sets among measures and measure sets. The Joint Commission has been a strong proponent and leader in measure standardization. With the move towards the usage of standardized vocabularies, it only makes sense that measure developers will begin to make use of value sets defined by other measure developers or perhaps even use subsets defined by medical specialties.

However, we believe that value sets must be matched to their intended use. The determination of which value sets to use and what vocabulary codes should comprise each value set will play a major role in ensuring that future quality measures are reliable, valid, and support the clinical intent of the measure. While a reviewer not involved in performance measure development may think two value sets are sufficiently similar and should be combined, or the second one not be created, it is the measure developer that understands the intent of the measure in which the value set will be used. Restriction to the creation of value sets may be counterproductive to the development of clinically meaningful performance measures.

2. Who should produce the value sets?

The Joint Commission understands that vocabulary experts will have a very important role in the adoption and usage of standardized vocabulary. Today, the Joint Commission employs staff with expertise to validate the ICD-9-CM codes utilized in our chart-based measures and it is the Joint Commission's intent to identify individuals with requisite knowledge respecting future standardized vocabularies so we can continue to define reliable and valid quality measures.

In addition, as part of our preparation for the October 2013 conversion from ICD-9-CM to ICD-10-CM Joint Commission staff participate on the National Quality Forum Measure Specification Coding Maintenance Expert Panel. The NQF is currently in the process of obtaining public comment on the Code Maintenance Framework and Operational Guidance as put forth by the Expert Panel This framework identifies best practices for approaching the measure conversion process and discusses recommendations and guidance to NQF maintenance operations for the coding transition process.

We strongly believe that each measure developer should continue to have the latitude to define the value sets related to the measures it develops as well as the business model it utilizes to gain access to the needed vocabulary expertise.

3. Who should review and approve value sets?

The Joint Commission intends to continue our policy of soliciting public comment on all our measures, including value sets, before they are implemented. Rather than focusing on "who" should be allowed to review and approve value sets, The Joint Commission believes that a process must be created to provide control around the creation and maintenance of the value sets. We believe this process should include a single, centralized value set registry which would facilitate the sharing and reuse of value sets.

Part of the process could include the value set owner attesting that it reviewed the existing value sets in the registry and found no value set that would meet the intent of the measure in which the value set will be used. Individuals that wish to review value sets could subscribe to the registry so they would be notified when a new value set is added or one is modified and the timeframe in which the review must be performed.

There would need to be a process for the owner to follow as outlined below in (A) before approving a value set and a process as outlined in (B) for an adopter that desires to reuse an existing value set.

(A) The Joint Commission recommends that the owner would be required to perform the following before approving the value set for inclusion in the centralized registry:

- Evaluate all reviewers' comments and provide explanations as to why a comment was not acted upon or was acted upon differently than suggested.
- Add the results of pilot tests conducted with real data to show that the value set identifies the expected group of patients from the appropriate location within the EHR (e.g., problem list versus discharge summary).
- The value set owner will identify its quality measure(s) that will utilize the new value set, including the start and end timeframes for the value set (e.g., 1/1/2011 discharges) for each measure.

(B) Other measure developers should be allowed to adopt a value set that they do not own for usage within their own quality measures. This identification should be made within the value set registry and should include the start and end timeframes appropriate for these measures. Measure developers that use value sets owned and maintained by another developer would automatically be enrolled as reviewers of the value set. If the owner of a value set modified it in such a way that it is no longer valid for the "adopting" measure developer, the "adopting" measure developer should be allowed to continue to use an 'older' version of a value set. At that time, perhaps, one of the "adopting" measure developers continuing with the 'older' version of the value set should be become the owner so there would still be an entity responsible for maintaining the value set as the associated vocabulary is updated.

Over time, the process of linking quality measures to value sets will become less cumbersome as the value set registry expands with approved value sets available for adoption.

4. How should value sets be described, i.e., what is the minimum set of metadata needed?

At a minimum, value set metadata need to define the following information:

- The owner and maintainer of the value set
- Attestation that there are no existing value sets that meet the intent of the usage of the set
- The purpose of the value set (how this value set will be used)
    - Quality measurement, clinical decision support, public health population identification
    - This should not get into the specifics of a given quality measure and whether it will be used for numerator, denominator, or exclusion criteria, as this usage can vary for different measures.
- The intent of the value set (i.e., the reason these codes were selected)
- Timeframes for the value set
    - When the value set was created
    - When the value set was retired
- The version of the value set (updated whenever the value set is modified)
    - Reason for the value set update
- The vocabulary (e.g., SNOMED, LOINC, RxNorm) that comprises the value set

If a decision is made to not create a value set registry that can link the value sets to quality measures, the following additional information should be captured within the metadata:

- A list of all quality measure(s) that are linked to the value set, whether by the value set owner or adopter.
- The time frames in which each quality measure utilizes the value set.

Also, the information described above in question #3 must be included in metadata for each value set. This information would not need to be distributed with the value sets, but should be available as needed.

5. In what format(s) and via what mechanism should value sets be distributed?

The Joint Commission believes that convenience subsets and value sets will be key components to the success of the electronic health record (EHR), as many portions of the EHR will utilize them. We believe that sharing value sets between a measure developer and EHR certified software is just the beginning of distribution needs. In the future, perhaps medical specialties will define subsets and value sets which will be utilized by all EHR certified software for clinical decision support purposes. In addition, health care

organizations may choose to share clinical decision support logic that they have successfully implemented and will need to share the subsets and value sets that support the logic.

We believe that the Secretary of Health and Human Services should adopt health information technology standards that define the technical formats that will be used, the required and optional metadata, how individuals/organizations can subscribe to specific subsets and value sets, and how the publishing of the subsets and value sets should occur. The adopted standards need to be defined in such a manner that not only EHR vendors can work with them, but also that everyone in the health care industry producing a value set can adopt.

Implementing a single value set registry would assist in bringing the health information technology requirements within grasp of the entire health care community. This will occur if the implementation is done in such a way that owners do not perceive they are being dictated to as to when a subset or value set may be created and/or maintained.

6. How and how frequently should value sets be updated, and how should updates be coordinated?

Owners should evaluate their value sets whenever the associated vocabulary (e.g., SNOMED) is modified. In addition, owners should be given the latitude to determine if a given value set should be modified based on changes in the supporting clinical evidence or guidelines. When updates are made, the owner would need to provide the time frame describing when the old version ends and the new version begins and the reason for making the update.

Implementing a single value set registry would help ensure that subscribers to a subset or value set would be notified of the update and ensure that it would be published according to the timeframes specified by the value set owner.

7. What support services would promote and facilitate their use?

A value set registry could contain functionality that would help to ensure proper control of the sets and decrease burden on both owners and adopters. This registry could:

- Use a subscription method that would notify those interested in either reviewing or using specific value sets that a new version has been created.
- Notify owners that they need to review specific value sets because the associated vocabulary or subset(s) have been modified.
- Support measure developers that want to use a value set maintained by another developer by allowing them to link their measures to these value sets within the registry.

- Use a standardized publishing method that supports individuals accessing the value sets manually and would support automatic software updates or automatic value set "shipping" to end-users so they could manually update their software.

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

As we have stated, the code tables that are utilized in The Joint Commission's core measures are similar in concept to the value sets that will be used in eMeasures. Two important lessons-learned are outlined below:

(A) Very early on in creating and using code tables, we discovered that having multiple terminologies (i.e., ICD-9-CM Diagnosis Codes, ICD-9-CM Procedure Codes, and Medications) in one table reduced our ability to reuse a code table among multiple measures and measure sets. In addition, we realized that creating code tables using only one type of terminology per table decreased the complexity of the computer programming required to read the code table. When multiple vocabularies are used in one code table, the required number of programming objects is multiplied or complex inter-relationship between the programming objects must be created, thereby increasing the probability that software defects might occur.

(B) We also discovered that measure developers should be restricted from defining terminology codes (i.e., value sets) directly within measures. Our applications are programmed with the assumption that all code tables will be maintained within a database using version control linked to the measures. If a terminology code(s) appears directly in the measure logic, then we either have to create an internal code table that can be data based or we have to write logic specific to the measure to handle this terminology code. Over the years, we have adopted the standard of creating internal code tables when this occurs so that we can use our existing programming objects and, thereby, not increase the possibility of software defects.

9. Do you have other advice or comments on value sets and their relationship to meaningful use?

Through he Joint Commission's experience in working with the HITSP Quality Tiger Team to re-tool chart-based VTE and stroke measures, we have learned that restrictions as to the composition of value sets by external entities are not appropriate or realistic. Measure developers must have the discretion to compose value sets using the standardized vocabularies and methods that they feel are most appropriate to accurately portray the clinical meaning of the measure. For example,

while all efforts should be made by measure developers to use value sets of minimal complexity, there are times when simple query-based specification definitions are not sufficient to adequately capture the clinical meaning of a concept, and instead post coordination of the clinical concept may be required.

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

(A) The federal government should not dictate who is allowed to determine the need for value sets, or who can produce and approve them. Instead, ONC should work with the health care community to create a process that provides control around the creation and maintenance of the value sets.

(B) The federal government should identify an entity, such as the National Library of Medicine, that would be designated as a reviewer of all value sets. This designation would not preclude others from reviewing and providing comments on specific value sets, but would ensure there is at least one reviewer for each set and would help ensure consistency between and reduce redundancy of value sets.

(C) The Joint Commission recommends that CMS and ONC do not specify proprietary standardized vocabulary for use within hospital-based EHRs. All vocabularies used in value sets should be in the public domain.

(D) To support interoperable HIT, ONC must specify the technical standards surrounding value sets in how they are formatted and disseminated. In addition, the technical standards should be in the public domain.

(E) ONC should evaluate the feasibility of developing a single value set registry that supports the needed technical standards and documentation requirements. This registry should be agnostic as to EHR vendor and should be implemented with the future vision of value sets being created and maintained for many purposes beyond quality measures.

11. **Some have expressed concerns about intellectual property with respect to the specific value sets (i.e., the effort and expertise required to create them), and regarding the specific codes used (i.e., value sets developer from proprietary code sets). How do you envision sharing value sets while accounting for these intellectual property issues?**

Today, the Joint Commission's performance measures and associated code tables are in the public domain, available to the entire health care community for its review and use. We know that other entities have adopted our measures and use the specifications as we define them, and we encourage this practice. We feel that to do otherwise would result in

proliferation of similar, though not identical performance measures, and would have a chilling effect on the comparability of performance data nationwide.

Our concern about the intellectual property surrounding our value sets is the same as our concern about our quality measures. As a measure developer and steward, and as a leader in health care quality, we value the autonomy to develop and maintain value sets as needed to ensure the intent and integrity of our measures are met and that the measures are reliable and valid.