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ONC HIT Standards Committee
Clinical Operations Workgroup – Task Force on Vocabulary
Panel 5: Level 1 Governance Value Sets

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THE NATIONAL QUALITY FORUM

Good Morning Chairs and Members of the Taskforce. Thank you for providing the National Quality Forum with the opportunity to provide comments on the production, maintenance, and oversight of value sets for use in quality measurement and clinical-decision support.

NQF is a public and private partnership with more than 400 members representing virtually every sector of the health care system. NQF operates under a three-part mission to improve the quality of American health care by:

- setting national priorities and goals for performance improvement;
- endorsing national consensus standards for measuring and publicly reporting on performance; and
- promoting the attainment of national goals through education and outreach programs.

NQF is recognized as a private sector standard-setting body under the National Technology Transfer and Advancement Act.

NQF endorsement, which involves rigorous, evidence-based review and a formal Consensus Development Process, has become the "gold standard" for health care performance measures. Major health care purchasers, including the Centers for Medicare & Medicaid Services, rely on NQF-endorsed measures to ensure that the measures are scientifically sound, relevant and help standardize and raise the bar for performance across the industry. To date, NQF has endorsed more than 500 measures.

NQF drives improvements in care by endorsing evidence-based measures of performance-- focusing on measurement for accountability and quality improvement. Measurement has the greatest impact on quality when it supports transparency and public reporting, but also provides actionable information to clinicians to make improvements in care delivery. To date, quality measurement and public reporting has been thought of as a secondary data use versus a driver of care. However, by setting standardized performance measures and properly designing and building HIT, it will now be possible to capture performance data as part of the care process and to provide immediate information feedback and clinical decision-support to clinicians to drive improvement.

Designing and building HIT to support performance improvement requires close collaboration between the "quality community" and the "HIT community." The "quality community" includes organizations that set practice guidelines, develop performance measures, and set standards for measurement. NQF plays a key role in the "quality community" as the national standard-endorsing body for performance measures and as a neutral convener of multiple stakeholders to set National Priorities for Improvement and advance the quality agenda. The "HIT community" includes HIT suppliers, standard-setting organizations, and users. The DHHS Office of the National Coordinator for HIT is leading the effort and working to establish a Nationwide Health Information Network.

Recognizing the importance of a close collaborative relationship between the “quality community” and the “HIT community,” in 2008, Congress directed HHS to contract with a consensus based organization, such as NQF, to endorse standardized performance measures and to “promote the development and use of EHRs that contain the functionality for automated collection, aggregation, and transmission of performance measure information.” NQF was awarded this contract in 2009 which provides for annual renewal for up to four years.

I commend the Standards Committee and the Task Force for focusing needed attention on how vocabulary subsets and value sets should be created, distributed and maintained in order to facilitate meaningful use of electronic health records.

1. Who should determine those that are needed?

Value sets are needed to enable quality measurement and clinical-decision support (CDS), as well as a variety of secondary uses, such as public health and disease surveillance, post-marketing drug surveillance, and comparative effectiveness. The “users” of value sets, including organizations that develop measures and CDS (e.g., Physician Consortium for Performance Improvement, accrediting organizations, and others), government agencies with responsibility for key secondary uses (e.g., CDC, FDA, AHRQ), and other stakeholders, must have input into the development process and are key to identifying what value sets are needed. A flexible, collaborative structure will be necessary to ensure that the value sets meet the needs of the end users.

During the last three years, NQF, in collaboration with others, has made considerable progress in establishing a “bridge” between the “quality community” and the “HIT community.” NQF’s Health Information Technology Expert Panel (HITEP), chaired by Paul Tang, MD, has reviewed over 500 performance measures endorsed by NQF and identified the requisite data requirements in EHRs and PHRs to support quality measurement and improvement. As part of its work to evolve measures from unstructured, human readable documents to computable formats, the NQF has begun to develop the Quality Data Set (QDS). The QDS is an information model that clearly and specifically defines concepts that are used by quality measures. For example, a measure of whether aspirin was administered in a timely fashion to a patient with symptoms of a heart attack upon arrival in the emergency department would be characterized with the RxNORM code for aspirin with a time stamp found in the EMR “section” for medications administered. The same code found in a historical medication list or as an allergy means something different.

To reduce the cost of measure development and maintenance, and promote greater consistency and harmonization of measures, it will be important to specify “value sets” that can be reused by many measure developers. For example, a value set that identifies the RxNORM codes for enteric coated aspirin and plain aspirin would be useful in specifying many different performance measures that seek to ascertain aspirin use.

Under contract with DHHS, NQF is currently overseeing the development of e-specifications for 110 performance measures included in the meaningful use notice of proposed rule making (NPRM). NQF has subcontracted with leading measure developers to "retool" their performance measures using a Measure Authoring Tool. The Measure Authoring Tool allows developers to describe their measures in a highly structured format using the QDS and healthcare industry standards code sets. This undertaking represents the first widespread application of the QDS and is expected to produce the first generation of Value Sets needed to support quality measurement and improvement.

2. Who should produce them?

Value sets to support quality measurement and CDS should be produced through a collaborative effort involving NQF and the leading developers of performance measures and CDS, and supported by terminology experts. The role of measure developers in this process is essential as they best understand the quality concepts represented in a performance measure or CDS rules, and the issues that need to be considered when selecting appropriate codes from a taxonomy and building the value set.

However, a coordinated process across all measure developers is needed. The current practice is that each measure developer employs or develops expertise to build value sets. Although several measures originating from one steward may reuse value sets, another measure steward creates value sets for the same concept used in its own quality measures. The frequency with which measure stewards maintain their value sets varies even though the underlying taxonomy may be updated frequently. The status quo can allow inconsistency in the quality and currency of value sets leading to variability in the quality and comparability of performance reporting. Additionally, the cost to *develop* value sets and *maintain* them for each measure developer is significant. The cost is multiplied over many measure stewards and also developers of clinical decision support rules, much of which is duplicative since many value sets are created many times by different groups. This sort of distributed approach is costly to the measure development enterprise and to the health care system as a whole.

A more coordinated approach to the development and maintenance of value sets, with more structured input by experts in the respective taxonomies, would be a more effective and efficient process.

3. Who should review and approve them?

A government agency should be designated to take the lead in establishing an overall governance structure and "rules of the road" for the review and approval of various types of value sets. For each domain area (i.e., quality measurement and CDS; public health; post-marketing drug surveillance; comparative effectiveness), a lead entity might be designated to coordinate development and to review and approve of value sets.

Starting in 2011, NQF will be requiring measure developers to maintain e-specifications as a condition of continued NQF-endorsement of their measures. These eMeasures will need to be specified using NQF's measure authoring tool and the QDS as a foundation. Our plan is to continue developing QDS to include value sets specified in collaboration with measure developers. It is important to note that there is considerable overlap between value sets needed for performance measurement and those needed for CDS (i.e., practice guidelines developed primarily by specialty societies are the source of many performance measures and the associated CDS rules).

While domain-specific efforts that are closely tied to real-life use cases (e.g., NQF-endorsed performance measures in use) are critical to making sure that the value sets support the end uses, we recognize that value sets must support a variety of secondary uses and there are parallel efforts underway in other domains (e.g., CDISC, National Cancer Institute, Public Health Information Network). A government agency charged with providing overall coordination and developing guiding principles applicable to all domains would lead to greater consistency and efficiency. This government entity might also be charged with ongoing maintenance of a central repository of value sets.

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

In order to maximize the ability for reuse of value sets, the description and metadata has to be carefully specified. There is existing precedent outlined by various experts in the field to describing value set metadata. A Vocabulary Summit of experts occurred in 2007, the findings of which were adopted by the HITSP Data Architecture Tiger Team in 2009 in Technical Note # 903. That document describes the specific metadata information that will encourage maximum reuse (e.g., specific identifier, version number, taxonomy from which is it derived, originating organization, purpose and intended use).

Existing efforts by the National Cancer Institute (NCI) Shared Health and Clinical Research Electronic Library (SHARE) and public health value sets maintained with the Public Health Information Network Vocabulary Access Directory (PHIN VADS) may also offer valuable insights into metadata requirements.

5. In what format(s) and via what mechanisms should they be distributed?

The lead government agency should be responsible for establishing a value set format and a central registry to enable widespread distribution of value sets free of charge to all potential users. Value sets promulgated from the various domain-specific initiatives should be registered in a central registry site.

The value set format should be consistent with existing standards for value sets as highlighted by standard development organizations such as HL7 which also has standards for sharing and interoperability of value sets that have been vetted or balloted through that organization. Establishment of such 'rules of the road' is essential to successfully accomplish the goal of a shared value set resource.

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

The maintenance processes for value sets will need to include:

- Routine maintenance. Value sets need to be updated to reflect changes in the underlying taxonomies and code sets.
- Ad hoc maintenance. There will need to be a mechanism to respond to ad hoc concerns raised about a particular value set (e.g., not performing as intended, unintended consequences).
- Major periodic review. All value sets should undergo a careful review and evaluation every few years to assess whether the value set should be significantly modified (e.g., re-specified using SNOMED terminology instead of ICD-10) or retired altogether.

The lead government agency is best positioned to handle routine maintenance, while domain-specific initiatives might handle ad hoc and major periodic reviews, both of which are more closely linked to “content” and end user issues. The lead government agency should also be responsible for versioning and notification of all users of each value set when new versions are available.

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

Many factors will contribute to widespread use of value sets including:

- Linkages to end uses. As noted above, value sets should not be developed in a vacuum. The development of value sets should be closely linked to the actual end uses.

- Trusted source and transparent processes. Value sets should be developed, maintained and distributed through trusted sources and credible transparent processes. For example, public vetting of proposed value sets through a credible consensus process would build trust and encourage more widespread use.

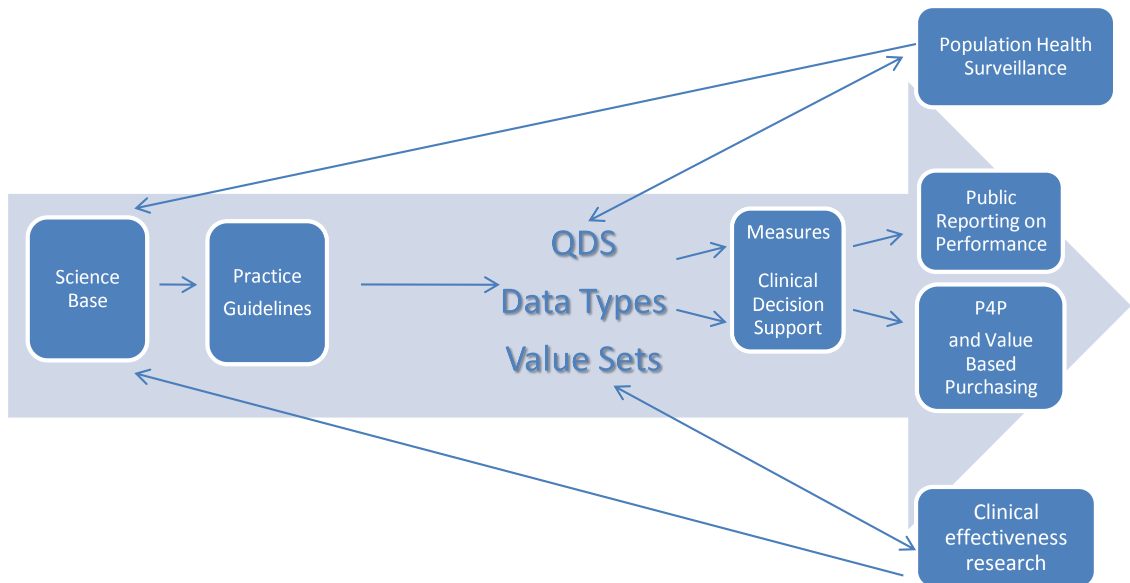
- Technical credibility and currency of updates. The processes should instill confidence in end users that the value sets in the registry are correct and up to date at all times.

- Accessibility. Free access and easy search capabilities will be critical to promoting widespread use. To more effectively allow automated access and reuse, compliance with existing standards for value set interoperability transactions (e.g., the sharing value set specifications identified by HITSP) will further promote use.

- Trouble-shooting. There should be appropriate mechanisms for responding to user concerns of all types.

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?

The development and specification of value sets to support quality measurement and improvement is one link in a long supply chain of inter-related activities that must be coordinated to achieve the intended result of improving quality. See graphic below.



Value sets should not be developed in a vacuum. All stakeholders must be engaged

through a collaborative process and careful attention must be paid to the inter-related nature of these activities.

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

QDS is an essential building block to the specification of meaningful value sets. Value sets developed in isolation will have limited use and applicability. The QDS is an information model that includes both the data elements that need to be captured to calculate measures and additional contextual information that makes the performance data most useful.

In the AMI example above, the data element is aspirin, while the contextual information that needs to be captured includes whether the aspirin was prescribed, dispensed or administered. Value sets must be specified to reflect both the necessary data elements and relevant contextual information to be useful for building performance measures or CDS rules.

By connecting, or binding these value sets to their expected uses, the quality measure or the clinical decision support rule can inform the EHR *meaningfully* what only computer savvy implementers could do in the past after reading through guidelines.

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

The federal government should provide leadership but it should not act alone. A lead agency should be designated to provide coordination, specify "rules of the road," and maintain the registry.

Domain-specific initiatives should be established which engage end users of value sets in the process of setting the agenda and developing a parsimonious portfolio of value sets that best meets their needs.

A high priority should be based on building on existing efforts, and not recreating the wheel. The federal government can contribute significantly by leveraging the work that has been done and working in close collaboration with other organizations, for example, CDISC, NQF, the National Cancer Institute and the Public Health Information Network.

11. Some have expressed concerns about intellectual property with respect to the specific value sets (i.e., value sets developed from proprietary code sets). How do you envision sharing value sets while accounting for these intellectual property issues?

Value sets impart specific meaning of a concept so in order to allow sharing and comparability, these value sets need to be freely and publicly available and non proprietary.