NATIONAL QUALITY FORUM

NQF Testimony for Clinical Quality Hearing of the HIT Policy and Standards Committees

Panel 3: Measures

In order to better inform the Stage 3 Meaningful Use Program, NQF was asked to provide testimony on the role of measure development and infrastructure. Specifically, NQF was asked to respond to the following questions:

- How can the meaningful use program best foster innovation in measurement?
- What alternative strategies do you see for the creation of new measures in the field?
- What data and information do you need to create eMeasures and how can the meaningful use program help you get access to that?
- What factors will support evolution of quality measures from a focus on healthcare to a focus on health?

Since NQF is not a measure developer, we can only provide a high-level assessment of the process from the vantage point of the neutral evaluator and endorser of measures, as well as developer of tools and infrastructure that should help support the development of eMeasures. NQF can help as a coordinating body to facilitate both through its neutral convening role and innovations to its endorsement process. Through this work, we can move toward de novo development of eMeasures and strengthen new and valuable relationships between measure developers and EHR vendors.

NQF appreciates the opportunity to provide the HIT Standards and Policy Committees for the Clinical Quality Hearing. We stand ready and willing to work with you to help ensure quality is improved and costs are reduced across the health system through interoperability using a robust data platform to directly measure and improve health.

Question #1: How can the meaningful use program best foster innovation in measurement?

The meaningful use program can serve as an important source of innovation in measurement. The increased emphasis and adoption of EHRs provides an important opportunity to consider measure development in a new light. The shift away from retooling of existing quality measures to de novo measure development for electronic data sources presents important opportunities to foster innovation and also challenges. With the move toward measures based on high-quality data from electronic health records, performance measurement should make a quantum leap forward. The ability to incorporate clinical information, as well as patient-reported data, across the continuum of care should enable the next generation of performance measures.

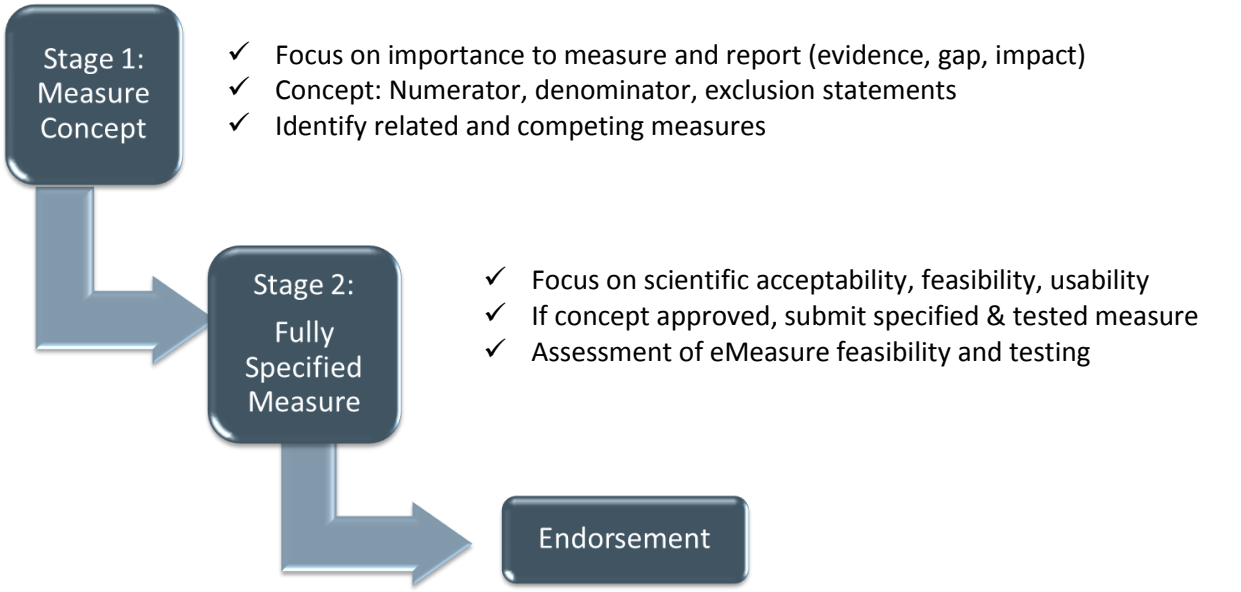
In order to leverage this opportunity, the measure development process must evolve to better use the data that will be available at the point of care through EHRs. To date, the current measure development

process has been very focused on the creation of measures based on the availability of data, often from claims without the benefit of high quality clinical data. In addition, some measures that were developed for paper medical records require significant data collection time and effort. Although the movement toward measures based on clinical registries provides a middle ground where higher quality clinical data on process and outcomes can be collected during the routine care, capturing and sending data to registries can still require additional clinician work effort. Measurement has also been limited by the inability to consider rich sources of information, including laboratory results, radiology results, clinician observations and patient-reported findings. The ability to move away from measures that have been developed with the end-data in mind and moving toward a more expansive view of what could and should be measured to improve care is a paradigm shift that measure developers and EHR vendors need to embrace.

Question #2: What alternative strategies do you see for the creation of new measures in the field?

This new paradigm for measure development will require new relationships and coordination between developers and EHR vendors. An earlier focus on the development and assessment of measure concepts should provide important opportunities for measure harmonization and early assessment of data availability and feasibility. The proposed shift toward a two-stage NQF endorsement process is intended to provide an endorsement process that better aligns with measure development.

The proposed two-stage endorsement process outlined in the diagram below would allow an early focus on the importance of a measure – including the evidence for the underlying measure focus, the potential impact of a measure, and a gap in care or variation across providers. This assessment can be done before a measure is specified and ready for testing. This is especially important for eMeasures since many of the measures with the greatest potential to impact patient care cannot yet be assessed in current EHRs. The opportunity to assess the measure concept while the developer and vendor communities assess the feasibility of the required data elements in EHRs should lead to a more efficient measure development process.



By identifying those concepts and clinical areas for which there is a strong evidence base and that have the potential for the greatest impact and opportunity for improvement, the next logical step will be to assess the feasibility to collect the needed information within the current electronic environment. This feasibility testing will begin to identify the requirements that must be built into EHR certification, alert EHRs vendors of the necessary modifications that may be required to collect the data, and allow an opportunity for the provider community to provide input into the necessary clinical workflow changes that may be required to implement the measures and track improvement at the point of care. It is hoped that this increased collaboration will lead to innovative measures and shared learning across the healthcare continuum with the overarching goal of improving the health and well-being of individuals.

It is also increasingly clear that measure development needs to move away from retooling of measures developed for a different data source, such as claims data and shift toward de novo development of clinical quality measures designed for the EHR platform. The recreation of existing measures in EHRs may lead to measures that are overly burdened by potentially unnecessary exclusions and complex measure logic that increases the complexity of data collection and negatively impacts clinical workflow at the point of care. The ability to look for multiple visits or drug claims data provided an opportunity to ensure that a patient was eligible for a population in claims-based measures. The presence of an up-to-date problem list in an EHR should remove some of these requirements and allow for more population-based views of care. For example, patients with hypertension should have their blood pressure controlled regardless of the number of visits to a provider in a given year.

Another paradigm shift in measure development is a movement toward outcome measures, rather than processes of care for which data are more easily available using claims. These outcomes should be linked to evidence-based processes that can drive improvement through clinical decision support systems. If process measures are considered, the focus should be on those processes most proximal to and with the greatest impact on patient outcomes. Personal health records, patient web portals, and

increasingly available smart phone apps should provide important opportunities for individuals to self-report on outcomes, as well as medication use, patient experience, and decision quality.

To achieve our new measurement goals in EHRs, it is also critical that measure testing be incorporated into the measure development and endorsement process. As detailed in the NQF Measure Testing Task Force report, all quality measures, including eMeasures should be tested for reliability and validity. Measures based on EHRs should also incorporate testing to assure the feasibility of data capture for the data elements utilized in the measure. It is becoming increasingly clear that there is a need for a set of definitions and standards for feasibility testing for eMeasures, and NQF welcomes the opportunity to work with measure developers, EHR vendors and others on this important issue.

As the neutral convener and evaluator of measures, NQF can serve an important role in building and facilitating relationships across key stakeholders in addition to identifying areas in which measurement should focus next.

Question #3: What data and information do you need to create eMeasures and how can the meaningful use program help you get access to that?

While EHRs have great promise as the source of both measurement and improvement, there is much work to be done to effectively leverage the capabilities of EHRs. The shift to EHRs introduces old and new methodological concerns that will need to be addressed in order to take full advantage of the greater capabilities for measurement. Measurement conventions will be needed to ensure consistency with new types of performance measures.

- Delta measures: There has been great interest in moving toward the use of "delta" measures that can track the change in outcomes across time (e.g., change in systolic blood pressure over 6 to 12 months for patients with initially elevated systolic blood pressure). To avoid ambiguous interpretation, the measure will need to specify which, among multiple systolic blood pressure results during an encounter, is used for measurement (e.g., the highest, lowest, or average performance).
- Incorporation of patient risk: EHRs provide an opportunity to better assess clinical risk in order to better risk adjust and/or stratify performance measures.
- Patient-reported information: The use of PHRs and web portals offers great potential for further incorporating the patient's voice into performance measures. Further work is needed to understand potential differences in measure performance depending upon mode of entry. For patient-entered clinical information, further work is needed to understand how best to reconcile conflicting information from patients and providers (e.g., medication lists).
- Measure evolution: Moving measures toward a fully interoperable electronic platform provides an opportunity for research to compare provider performance across different data platforms. Further methodological work exploring the differences found for the same providers across different data platforms would further understanding of the impact of data source. In the interim, results on performance measures generated from different data platforms should not be considered comparable.

- Measure harmonization: The shift to an electronic platform provides an opportunity to harmonize relatively simple conventions that were previously embedded in the measurement process but require clear definitions for measurement by electronic queries. Some examples that seem straightforward but require careful definitions include calculation of age and period of measurement. There has been some central coordination of these issues for measures developed under HHS contracts through the eMeasure Implementation Group (eMIG) but much work remains.
- Use of measures across EHRs: Standardization of EHR capture and reporting of data required for measurement will help resolve methodological issues that may emerge when measures developed for use within a specific EHR, often homegrown systems, are generalized to a broader set of commercial products. Many of the leading systems have built on years of development and refinement.
- Moving toward interoperability: While many innovative measures can be constructed using interoperable EHRs, some health systems and practices may not have achieved fully interoperable EHRs. Matching the measure's required data needs to the capacity of the health system or practice using the performance measure will be important. Interoperability also plays a significant role in making historical data available for measure inclusion and exclusion criteria.

The further expansion of the types and quality of information captured within an EHR will enable increased access to data including patient-reported information (e.g., previous history, patient/family risk factors) that has not been widely available at the point of care to date. In addition, it will further the goal to improve patient care with real-time feedback and information on measures that are clinically relevant, evidence based, and have identified opportunities for improvement.

In addition, the measurement infrastructure and data can itself be leveraged to encourage standardized data, coding, and tools across the healthcare continuum in a manner that has not yet been seen. This can occur through use of a standardized data model and standardized value sets.

Standardized data model

The Quality Data Model (QDM) provides a common technological framework for defining clinical data necessary to measure performance and accelerate improvement in patients' quality of care. By providing a common language to describe the information within quality measures, the QDM enables quality measurement from a variety of electronic sources, including electronic health records (EHRs), personal health records (PHRs), registries, and health information exchanges (HIEs). The QDM is applicable to all care settings a patient is likely to interact with his or her lifetime. The QDM enables versioning, growth, and expansion to meet future needs for measurement and guideline implementation.

A. QDM was created to allow measure developers to express content for measures at the patient level, the provider level and the population level. Some components of the QDM, while

important for measurement using electronic data, are not appropriate for the EHR as the sole source of information.

To address the feasibility of finding QDM components in EHRs, NQF will publish a QDM Style Guide later this month. The QDM Style Guide provides guidance about which information can be expected in structured form in EHRs that use certified components and which information may be important to measures but would likely require additional effort if certified EHRs are used as the only source of data.

B. Measure developers should create measures for EHRs de novo rather than re-tooling measures created for other data platforms. For future measures, there are two approaches which must be balanced:
    a. Measure developers should be guided to data that can be reasonably expected in existing EHRs.
    b. Where data requirements extend beyond existing standard EHR capabilities to manage data, they should be prioritized based on their impact on clinical outcomes and certification requirements should be enhanced to accommodate capture and use of such data.

    It is important to improve the availability of structured data essential for high priority clinical care concepts to avoid the need for EHR vendors to adjust the user workflow merely for the purpose of collecting measure data. The QDM Style Guide is not intended to restrict quality measure development for the purpose of testing and evaluation for more advanced EHR implementations. The first version of the QDM Style Guide is intended to provide direction to measure developers about the floor of feasibility and availability for specific data within an existing EHR. This guide will help measure developers or others seeking data directly within EHRs meeting certification standards to focus on readily available data as they consider data elements to define measure content. Efforts such as the eMeasure Learning Collaborative provide an excellent opportunity to enable such communication with a wide, multi-stakeholder audience.

C. Data required to manage evidence-based high priority clinical care concepts should be standardized to improve care concurrently and to enable more clinically relevant clinical quality measures that use the same data. Some examples of data that have been problematic to capture and evaluate yet are critical to provide clinicians and EHRs to manage the quality of care and measurement, include:
    1. Cardiac ejection fractions in cardiac imaging reports.
    2. Estimated gestational age of a fetus based on imaging.
    3. Quantitative measures of vessel lumen diameters.
    4. Explicit staging of cancers or structured data used to stage cancer.

Standardized value sets

We commend the Quality Measure Essential Components Tiger Team of the HIT Standards Committee Clinical Quality Workgroup for its recommendations to improve value set development and maintenance for the quality measurement enterprise:

Value sets consist of codes from standardized vocabularies that unambiguously define clinical concepts…A mechanism for value set validation…and an authoritative source for distribution of Stage 2 Clinical Quality Measure value sets are needed to support Meaningful Use Stage 2 readiness.

Recommendation 1: Establish NLM as a single authority for the validation of value sets used in Stage 2 quality measures. NLM should serve as a single source of truth for MU2 value sets, and should publish periodic updates to reflect changes within the underlying vocabularies and/or changes made by value set stewards.

Recommendation 2: ONC should expedite recommendations of the Implementation Workgroup (January 2012) and Vocabulary Task Force (April 2010) related to establishment of a publicly available value set repository.

Recommendation 3: The value set repository established by NLM should build on the IHE Sharing Value Sets (SVS) profile for storing and serving value sets, and incorporate Common Terminology Service 2 (CTS2) methods for managing vocabularies referenced by value sets.

Recommendation 4: Establish a web service for human and machine consumption of Meaningful Use 2 value sets. Consider NLM, AHRQ, or CDC as the Internet host of validated value sets.

Value set management requires three functions and related infrastructure:

A. *Value set development*: It is essential that measure developers have access to code systems that allow them to develop valid, complete, and reusable sets of codes. This requires functional knowledge of the evidence and a clear understanding of the intent, or meaning, of the data element and measure; clearly, the purview of the measure developer. It also requires an infrastructure to either find an existing value set that has the appropriate meaning, or the ability to appropriately search for the right values using the appropriate code system as it was intended to be used. The recommendations presented to the HIT Standards Committee on May 24, 2012 address this requirement.
B. *Value set curation*: It is further essential that value sets created by measure developers are evaluated and kept current with respect to the integrity of the code system from which they are created. For example, such referential integrity including assuring that value sets for laboratory tests use codes for the test itself (also known as the observable entity) rather than the finding that is the result of the test. Curation can also evaluate for changes in code systems over time, to be sure that value sets appropriately address new and newly retired codes. Curation can also identify similar value sets, those with a high number of identical values, to assist with harmonization of concepts and limit an overabundance of nearly identical value sets. Each measure developer performs curation tasks now, leading to duplicate efforts among, and also value sets that are not harmonized. The infrastructure requirement is a continuously updated

value set registry available to measure developers as well as EHR vendors and implementers and those using existing data for other secondary uses.

C. *Value set validation*: Curation is an essential service to manage value sets for routine use in electronic data systems. However, it is important to validate the content across stakeholders to determine the appropriateness of the content for the intended use, and also to convene all users to harmonize value sets used for the same meaning across measure developers. Value sets are the atomic particles used to define the molecular measures components (numerator, denominator, exclusions). Consistent use of standard, validated value sets will enable greater uniformity for performance measurement. Such validation should be a continuous harmonious process to enable a quick turnaround for measure developers to use the most appropriate and standardized value sets for each of the elements in their measures. Validation can also accommodate parsimony among other uses of the same value set for primary data collection and other secondary uses.

Question #4: What factors will support evolution of quality measures from a focus on healthcare to a focus on health?

Electronic health records can open up new frontiers in measurement, with respect to the individual patient, a specific focus on outcomes, and use of rich information generated in clinical environments. Using the collective push to achieve the National Quality Strategy goals, the meaningful use program should encourage the continued evolution of measures toward health, rather than only healthcare.

The greater focus on patient-centered outcomes and patient engagement should encourage a shift to health-oriented measures. New health-focused measures will require information directly from patients about functional status and risk evaluations. These concepts are good examples of the need for the use of validated instruments to provide clear, unambiguous, comparable results over time for the same patient, and among patients receiving care from the same provider or organization. Validated instruments allow measure developers to address required concepts more parsimoniously and EHRs to manage the tools and observations (results) in a more standardized manner. The work of the Patient Reported Outcomes Measurement Information System (PROMIS) should be supported and encouraged as important substrate for measure development.

The greater focus on population health and the health of communities can also be an important factor in the shift toward measures of health. There are many opportunities to harmonize measures currently used to assess patient health in a geographic area (e.g., Behavioral Risk Factor Surveillance System) to those items used to assess the health of patients within practices, health systems, and accountable care organizations. The ability of measures to flex up and down within a broader electronic infrastructure and health information exchanges should provide targeted opportunities for quality improvement activities.

Data on the determinants of health (e.g., social and physical environments) has not been available at the point of care but bring a new focus and context to providing care. While this data may not be generated

from an EHR, it has the potential for being made available to providers through these systems to enable that broader focus toward the overall health and well-being of the individual. As interoperability capabilities continue to evolve, this type of information should become more accessible and useful.