NATIONAL QUALITY FORUM

Report from the National Quality Forum: eMeasure Feasibility Assessment

DRAFT TECHNICAL REPORT

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Contents

INTRODUCTION

As quality measurement shifts to measures derived from electronic health records (EHRs), additional clarity about the testing is needed to assure that eMeasures can be used for a range of accountability applications, which require both precision and results that are reliable and valid. While the concepts of reliability and validity apply equally to measures derived from EHRs, the electronic health record presents additional challenges related to measure testing: widespread EHR data are not yet available for measure development and testing; there is a lack of comparability across vendor products; data elements needed for advanced measures currently may not be feasible to capture in EHRs; and provider-level variability in capture of needed data elements is likely.

Realizing the promise of EHRs as a tool for quality reporting will rest on the ability of providers, payers, certifiers, vendors and other users of the information to know that eMeasures provide valid and reliable data. During the public and member comment for the National Quality Forum's (NQF) eMeasure Review and Testing Proposal in early 2012, several organizations expressed support that eMeasure testing should incorporate the feasibility and clinical workflow requirements of data capture for the data elements utilized in addition to reliability and validity testing. This requirement is significantly hampered by the lack of clarity and definition in the field as to what constitutes feasibility assessment for EHRs.

PURPOSE

The purpose of the eMeasure Feasibility Assessment project was to assess the current state of feasibility assessment for new and retooled eMeasures and identify a set of principles and criteria for adequate feasibility assessment. Specifically, the goals of the project were to:

- conduct an environmental scan of approaches to feasibility assessment from measure developers, government contractors and EHR vendors to gather the current approaches used to assess measure feasibility; and
- review results of environmental scan and propose a set of feasibility recommendations, including a starter set of criteria for eMeasure feasibility assessment that will address the following considerations:
    - the timing of feasibility assessment in the course of measure development (e.g., iterative testing with development, feasibility testing of fully specified measures);
    - the potential differences in feasibility assessment requirements for de novo (new) eMeasures and re-specified eMeasures;
    - the number and diversity of EHRs used for testing and relation to comparability across EHRs in terms of data feasibility, validity, and reliability; and
    - the interrelationship of feasibility and validity testing of new measures.

This eMeasure feasibility report provides important guidance that can shape future measure development as well as product development and certification requirements.

To achieve these goals, NQF convened a 15-member Technical Expert Panel (TEP) which was comprised of measure developers, experts in measure development and testing, EHR vendors, and implementers. In addition to participating in several conference calls, the TEP also gathered for a one-day, in-person meeting in Washington, DC on December 7, 2012.

BACKGROUND

Several prior NQF activities provide the foundation for this present work on eMeasure feasibility assessment:

- NQF criteria for feasibility: Feasibility is one of four major criteria that NQF uses to evaluate measures for endorsement. Feasibility is defined as the *"extent to which the required data are readily available or could be captured without undue burden and can be implemented for performance measurement."* Sub-criteria further define how feasibility is evaluated:

  3a. For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).
  3b. The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.
  3c. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). [1]

- Health Information Technology Expert Panel (HITEP) Report (2008) The HITEP 1 report identified common data types to be standardized for automation in EHRs and health information exchanges. This report described a framework to assess the quality of each data type as it then existed in EHRs. The data quality framework provided an initial assessment of the availability and quality of a given data type.[2]

- NQF Testing Task Force Report (2011) The Testing Task Force report provides the guidance for rating the level of evidence for reliability and validity of EHR measures. The testing criteria for all eMeasures (de novo and re-specified) include specification in accordance with the Quality Data Model (QDM); and empiric testing of validity of the data elements and measure score. [3]

- NQF's Draft Requirements for eMeasure Review and Testing (2012) During public and member comment on the draft document, several organizations expressed a need to incorporate feasibility assessment of data capture for the specified data elements. The Consensus Standards Approval Committee (CSAC) agreed that feasibility assessment should be required for all eMeasures. The draft document concluded that further work is needed to define and standardize requirements for feasibility assessment.[4]

ENVIRONMENTAL SCAN

NQF conducted an environmental scan to identify approaches to feasibility assessment from measure developers, electronic health record (EHR) vendors, and providers. Each of the stakeholder groups was asked to respond to a series of questions. Up to nine organizations were queried in each of the three stakeholder groups.

NQF reached out to nine EHR vendors representing a cross section of inpatient and ambulatory electronic health record (EHR) companies. With the assistance of a technical expert panel (TEP) member, NQF worked with the HIMSS EHRA vendor group to distribute the questions to EHR vendors. Eight vendors responded. Four measure developers responded to NQF's request. All four are HHS contractors. Three develop inpatient measures and one develops ambulatory measures. The final group, providers, consisted of an ambulatory physician practice and two health systems which include inpatient and ambulatory sites.

Sample Environmental Scan Questions

- General approach to feasibility testing;
- Current efforts of collaboration or interrelationships with vendors, and/or measure developers and/or providers in regards to feasibility testing;
- How feasibility fits into their business cycle (vendor question)
- When testing occurs (measure developers)
- Impact to workflow to be addressed during development

NQF developed questions specific to each stakeholder group. Questions were based on their workflow and what their role was in the quality measure lifecycle. For example, it was important to ask EHR vendors how measure feasibility testing fit into their business development cycle, and to ask measure developers when feasibility testing occurs in their development cycle, and to ask providers to describe factors that impacted implementation and workflow issues that should be addressed or factored into the development of eMeasure. A full list of questions and a summary of responses from each stakeholder group can be found in Appendix 2.

Common themes emerged from each stakeholder group. Vendor responses had three common themes: 1) the need to assess measure requirements and analyze their EHR product for gaps, 2) the impact of measure requirements on EHR work flow, and 3) addressing identified gaps. Vendors also commented that not all data elements can be extracted from the EHR. Data may be stored in another system or stored as text. There were reports of collaboration among vendors and measure developers but this was not the general rule.

Measure developer responses mentioned that feasibility testing is an evolving process and the approach to testing must be different for re-specified measures and de novo (new) measures. Workflow, test site experience and structure also impact the testing. Developers also suggested that when feasibility testing identifies a problem they need to look for alternatives for capturing the data or consider alternate representation for clinical concepts. One measure developer stated that feasibility testing is a continuum, it does not occur just once in the measure cycle, so they developed a five (5) point scale for testing and evaluating the feasibility. This concept of using a scale to rate feasibility has generated great discussion among the project TEP.

The final stakeholder group, providers, stated that testing of measures should occur with all major EHR vendors and in as many settings as possible: large, small, solo providers, multispecialty, academic, etc. They also suggested a test dataset to improve the process. Two other themes emerged from this group: the importance of workflow and the need to share data among disparate systems.

PRINCIPLES AND GUIDANCE

The following key principles were identified by the TEP that guided their recommendations for eMeasure feasibility assessment:

Definitions/Terminology

- **Clinical Quality Measures (CQM):** A mechanism used for assessing the degree to which a provider competently and safely delivers clinical services that are appropriate for the patient in an optimal timeframe. [5]

- **Electronic health record (EHR)** (also electronic patient record, electronic medical record, or computerized patient record): As defined by Healthcare Information Management and Systems Society (HIMSS), the electronic health record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and imaging reports.[6]

- **eMeasure:** As defined by Health Level Seven (HL7), an eMeasure is a health quality measure encoded in the Health Quality Measures Format (HQMF) format. The HQMF is a standard for representing a health quality measure as an electronic document. Through standardization of a measure's structure, metadata, definitions, and logic, the HQMF provides for quality measure consistency and unambiguous interpretation.[7]

- ***De novo* eMeasure**: A new performance measure developed for use in EHRs; it is not re-specified from an existing measure based on other data sources.

- **eMeasure feasibility**: The extent to which the required data are readily available or could be captured without undue burden and can be implemented for performance measurement in EHRs.

- **Data element, quality:** A quality data element is a single piece of information that is used in quality measures to describe part of the clinical care process, including both a clinical entity and its context of use (e.g., diagnosis, active). [8]

    - **Data element, critical** Among quality data elements those elements that contribute most to the computed measure score, that is, account for identifying the greatest proportion of the target condition, event, or outcome being measured (numerator); the target population (denominator); population excluded (exclusions); and, when applicable, risk factors with the largest contribution to variability in outcome.[9]

- **Quality Data Model (QDM):** The QDM (formerly referred to as the Quality Data Set or QDS) is an information model that defines concepts used in quality measures and healthcare. It is intended to enable automation of structured data capture in EHRs, PHRs, and other electronic clinical sources. It provides a structure to describe clinical concepts contained within quality measures in a standardized format so individuals (i.e., providers, researchers, or measure developers) monitoring clinical performance and outcomes can concisely communicate necessary information. The QDM also describes information so EHRs and other health IT systems can consistently interpret and easily locate data required for quality measurement.[10]

- **Health Quality Measures Format (HQMF**): A standard for representing a health quality measure as an electronic document.[11]

- **Quality Reporting Document Architecture (QRDA):** A standard for communicating health care quality measurement information in support of calculation of eMeasures.[12]

Overarching Principles

- There is a spectrum of eMeasure feasibility that depends on the maturity of EHR systems and the context for the eMeasure implementation. EHR vendors indicate that all data elements could be ultimately integrated into an EHR; however, the questions are whether the importance of the measure results justifies the cost and the time required for development and whether clinical workflow can efficiently capture the necessary data as a byproduct of the provision and documentation of patient care. Until agreement is reached that everyone must achieve the same level of interconnection and maturity, feasibility will be variable across all EHR implementations.

- The feasibility assessment is different than reliability and validity testing of an eMeasure. Feasibility should be assessed in several domains: data availability including heterogeneity across different EHR systems and mapping requirements; data accuracy and completeness; data standards (access to structured and coded data); workflow; measure logic; measure aggregation and reporting. Although there is overlap between some domains of feasibility and validity, the intent of feasibility assessment is to guide measure development prior to formal testing for reliability and validity.

- The fundamental goal of performance measurement is to improve the quality of care delivered. As such, there are some aspects of care that are sufficiently important to merit changes in workflow, i.e., changing behaviors to align with best practices. The balance between feasibility and validity and reliability and the usefulness of the measure for care improvement is critical. The value of an eMeasure reflects a balance between the quality improvement potential in the eMeasure and the feasibility, including costs.

- In this dynamic and rapidly evolving environment feasibility assessment should not restrict the development of new quality measures that capitalize on the features of EHRs or address important areas of measures such as care coordination and patient reported outcomes that may be challenging at the present time. Data elements that seem less feasible in the near term can become feasible in 3-5 years with specific guidance to EHR vendors, certification bodies and other stakeholders. While there is a need for prioritization of expectations for EHR vendors,

measure developers are encouraged to be forward thinking and develop new types of innovative measures that capture important, new aspects of quality care .

- A great deal of innovation is occurring in the local settings, particularly in high-performing organizations. Providers are using EHR products in creative ways that inform future product development. Collaborative measure development efforts should seek out innovation in the field and learn from high quality organizations. Providers are creating useful and meaningful measures for quality improvement that may be suitable for use as accountability measures.

RECOMMENDATIONS

RECOMMENDATION 1: Assess feasibility throughout eMeasure development

Feasibility should be considered early in the eMeasure development process and assessed throughout the entire duration of measure development as an agile, iterative process. Greater collaboration among measure developers, EHR vendors, and providers at all stages of development would promote more rapid evolution in EHR functionality for current measures as well as to build the capability for more complex, EHR enabled eMeasures in the future.

RECOMMENDATION 2: Framework for eMeasure feasibility assessment

The TEP agreed that a framework for assessing eMeasure feasibility would provide a common language and provide decision-makers with valuable information about the technical feasibility of eMeasures. Building on the work from the HITEP 1 report, this proposed framework addresses assessment of technical feasibility of data collection only and does not address the value of the data element or eMeasure. Assessment of the feasibility of data elements while a measure is being conceptualized and specified can identify significant feasibility issues before the measure is field tested. A feasibility assessment should address both the data elements and subsequently the measure logic, aggregation and reporting.

2.1 Data element feasibility assessment

The goal of data element feasibility assessment is to guide and assist measure developers to better understand what is more feasible in the near term or whether a longer timeframe is required to achieve changes in EHRs or workflow to capture the data. Measure developers can consider alternative approaches to specify a measure based on the feasibility assessment. Measure development sponsors and potential implementers can use the feasibility assessment to make decisions on proceeding with development of a new measure or re-specifying an existing measure and determine the likely timeframe when a measure might be ready for implementation. Providers and organizations who would implement the eMeasure would have more information to provide meaningful input during measure development.

A report on the feasibility assessment of the data elements should address the following characteristics:

- Data availability – the extent to which the data is readily available in a structured format across EHR systems. EHR vendors can determine how often data is captured (data profiling) among current users. A major challenge is data exchange and the ability to link independent data sources such as inpatient and ambulatory data, inpatient and long-term care data, or emergency department and inpatient data. The capability for data exchange is quite

variable. When difficulties with availability of critical data elements in valuable eMeasures are identified, the steps required to improve data availability should be proposed.

- Data accuracy - the extent to which the information contained in the data is correct. This would include whether the most accurate data source is used and/or captured by the most appropriate healthcare professional or recorder. The HITEP 1 report stated "the authority and accuracy of data are often interrelated (e.g. lab results coming from a laboratory interface are both authoritative and accurate). While there are examples of data from an authoritative source (e.g. clinician) that are not always accurate (e.g. subjective historical findings) and vice versa, these two were considered an aggregate as they both assess the soundness of the data source." [13]

- Data standards – the extent to which the data element is coded using a nationally accepted terminology standard. Standard data elements, associated definitions and code sets, and mapping to the Quality Data Model (QDM) are expected.

- Workflow - the extent to which capturing the data element fits the typical workflow for that user. The HITEP 1 report indicated that "in order for quality data to be recorded at the point of care by authoritative sources, it needs to fit into the clinical workflow. For example, it is of little benefit to have the capability of capturing certain patient symptoms if it requires five clicks and three screens during a busy clinical encounter, for the end result will likely be missing data."

Data element feasibility scorecard

A standard score card for assessing feasibility of data elements can provide a basic summary about overall feasibility of an eMeasure. Assessing feasibility requires identifying the assumptions made and the reference point against which feasibility is being assessed. For example, is the assessment made for EHRs that meet certification requirements, the average EHR, or 50% or 80% of EHRs? It may be necessary to compute the score against a matrix of different assumptions in terms of interconnectivity and maturity of the EHR.

The assessment would be made based on current implementation capabilities and future (3-5 years) implementation for data elements that have a current low score for feasibility:

Current –Rate the characteristics of the data element using the 1-3 scale for current feasibility based on the assumptions and reference indicated.

Future – Rate the characteristics of the data element using the 1-3 scale for feasibility in 3—5 years and indicate what is required to reach the future state if necessary.

The assessment should use quantitative methods whenever possible. For example, data profiling; structured interview surveys and questionnaires from providers in a variety of settings. These assessments should be a collaborative effort of measure developers, EHR vendors, and providers. NQF should provide a standard set of assumptions and reference points against which all data elements are rated.

Feasibility assessments should provide transparent detail on how the assessment was made including:

- the number of EHR systems assessed and the percentage of EHR market coverage for that clinical domain; and
- who performed the assessment (e.g., the number of EHR vendors and/or user groups; the number and variety of provider/sites or user groups).

During measure conceptualization and development, the assessments may evolve by incorporating more feedback and iterative assessments by a wider audience as the measure development progresses.

Data element:		
Measure Title:		
Data element definition:		
Assumption(s) when rating this data element:		
Who performed the assessment:		
Number of EHR systems assessed and the percentage of EHR market coverage for that clinical domain:		
	Current (1-3)	Future* (1-3)
Data Availability – Is the data readily available in structured format, i.e., resides in fixed fields within EHRs? Scale: 3 - One of the following: a. Data element is routinely collected as part of the care process and exists in the majority of EHRs or b. Data element is currently collected as part of the care process and exists in some EHRs and/or some health systems 2 – Data element is currently not collected but the ability to collect data element is required for certified EMR 1 – Ability to collect data element is not required for certified EHR and is currently not widely collected		
Data Accuracy – Is the information contained in the data element correct? Are the data source and recorder specified? Scale: 3 – The information is from the most authoritative source and is highly likely to be correct. (e.g., laboratory test results transmitted directed from the laboratory information system into the EHR). 2 – The information may not be from the most authoritative source and/or has a moderate likelihood of being correct. (e.g., self-report of a vaccination). 1 – The information may not be correct. (e.g., a check box that indicates medication reconciliation was performed).		

Data Standards – Is the data element coded using a nationally accepted terminology standard? Scale: 3 – Always coded in nationally accepted standard 2 – Standards currently available, but not widely adopted 1 – No standards currently available		
Workflow – Is the data captured during the course of care and fits the typical EHR workflow for that user? Scale: 3 – Requires no additional data entry from clinician solely for the quality measure and no EMR user interface changes. Data element is available as a byproduct of routine care. Examples would be lab values, vital signs, referral orders, or problem list entry. 2 – Additional time and effort over and above routine care is required, but some perceived to be of benefit 1 – Additional time and effort over and above routine care is required but without immediate benefit to care		
DATA ELEMENT FEASIBILITY SCORE		

*For data elements that score low on current feasibility, indicate what is required to improve the feasibility score in 3-5 years.

Data element feasibility score

The data element score can be summarized in several ways. A validation pilot study should determine the best summary score (sum, weighted sum, average or weighted average or other) that provides the best discrimination about feasibility. However, regardless of summary score, if any component is rated a "1", the feasibility is low for that data element.

2.2 eMeasure feasibility assessment

The TEP emphasized that feasibility is not solely about the data elements. The measure specifications and the calculation logic are important to understanding the intent of the measure which can influence what data must be collected. The number of data elements increases complexity of the measure which is more costly for development and testing. Each structured data element increases implementation burden and the importance of the clinical component both to the provider and patient being measured should be weighed. For example, if the logic of an eMeasure is quite complex or some data elements score low on feasibility consideration of a different approach may be warranted. During the environmental scan some developers reported having studied the incremental effect of adding a data element. Such an approach to feasibility assessment requires more analysis and perhaps more quantitative assessment.

The ability to aggregate data and produce reports for internal and external use on eMeasure performance is integral. Existing communication standards such as Consolidated CDA (Clinical

Documentation Architecture) and Quality Reporting Document Architecture (QRDA) can be used to assess additional aspects of feasibility related to exchange and reporting of quality data. Ensuring that data can be captured through QRDA is important because communications standards can, at times, lag behind data standards.

In addition to the scores for the individual data elements, the eMeasure feasibility assessment report should include:

- assessment of the feasibility of the aggregate data elements:
    - Do any critical data elements (those elements that contribute most to the computed measure score such as numerator, denominator) score low on feasibility?
    - How many data elements are required and are all data elements essential to the eMeasure? For examples, do data elements for exclusions impact the measure score significantly?
- assessment of the measure logic:
    - Does the calculation algorithm work in multiple EHR systems?
    - How complex is the logic?
    - How easy is it to explain to providers?

The feasibility assessment of the measure score (data aggregation) is naturally addressed by testing for reliability and validity at the level of the eMeasure score. TEP members provided examples of feasibility scoring using the scorecard in Appendix D.

RECOMMENDATION 3: Validating the data element feasibility scoring

The proposed data element feasibility scoring system must be validated which is outside the scope of this project. The scoring system should be piloted by several measure developer/EHR vendor/provider collaboratives and the results provided within 6-12 months. TEP members suggested that a pilot could validate the data elements from the CQMs proposed and selected for Meaningful Use Stage 2 and score them against the certified EHR technology (CEHRT) requirements. The 'current' state could be calibrated against Meaningful Use Stage 1 CEHRT requirements, and the future state against the Meaningful Use Stage 2 CEHRT requirements.

RECOMMENDATION 4: Data element feasibility catalogue/repository

In order to leverage the work of others and avoid duplication of efforts, the results of the data feasibility assessments should be catalogued in a repository available to all stakeholders and reviewed annually. Measure developers would then be able to consult the catalogue to determine feasibility of previously used data elements and only expend resources to assess feasibility of new data elements or to provide new information on how the data element is performing. The catalogue would also allow standardization of how data elements are represented in the QDM.

RECOMMENDATION 5: NQF evaluation for endorsement

The results of the feasibility assessment(s) conducted during measure development would provide useful information to address NQF's endorsement criteria and sub-criteria, particularly in the areas of Scientific Acceptability (Appendix C, Table 4) and Feasibility.

For eMeasures, the TEP recommends these modified criteria when considering an eMeasure for NQF endorsement:

- The description of the feasibility criteria is better expressed by ""extent to *which specifications and logic require data that* are readily available or could be captured without undue burden and can be implemented for performance measurement."

- The results of the eMeasure feasibility assessment will be included in the measure submission to NQF for consideration of endorsement. The feasibility assessment information will include:
    - a description of the assessment;
    - feasibility scores for all data elements; and
    - explanatory notes for all data element components scoring a "1" with plans for improving the scores.

- A formal analysis of missing data for all data elements should be included as a sub-criterion under Feasibility for eMeasures. The analysis for missing data may use data profiling by EHR vendors and current installations or from data generated during formal testing for reliability and validity. The number of EHR systems and provider/sites analyzed must be reported.

The TEP discussed possible thresholds for the number of EHR systems and installations that should be included in a feasibility assessment. The TEP emphasized a need for transparency in conveying the details of how the feasibility assessment was performed. As a guide to Steering Committees, the TEP suggested that assessment of fewer than three EHR systems and 10 installations would not provide sufficient information to evaluate the feasibility of an eMeasure.

RECOMMENDATION 6: Composite measures

NQF is currently updating the guidance for composite measures in the Composite Evaluation Guidance Reassessment Project. Since the growing interest in composite measures extends to eMeasures, the guidance should assist eMeasure developers also. The composite guidance notes that "feasibility of the composite measure will be influenced by the least feasible of the component measures." The data element feasibility scoring system proposed here will assist development of composite measures by assessing the feasibility of the component measures and all of the data elements. A critical data element with low feasibility will affect the overall feasibility of the composite as well as the individual component measure.

RECOMMENDATION 7: Greater collaborative efforts are needed for eMeasure development and implementation

The eMeasure Feasibility Assessment recommendations emphasize the need for greater collaborative efforts among all stakeholders. Collaborative efforts such as the eMeasure Learning Collaborative that "seeks to create a learning environment for advancing knowledge and promoting best practices related to developing and implementing eMeasures" provides an opportunity for stakeholders to work together. All stakeholders must play an active role in the development and implementation of eMeasures. In addition to measure developers and EHR vendors, providers must be involved at all stages of eMeasure development to provide critical input on feasibility. Working through their health systems or professional communities, providers should take a more proactive role in the development of eMeasures. The Quality Data Model (QDM) User Group offers an additional opportunity for

stakeholders from measure development, measure implementation and vendor communities to come together to directly affect the QDM and eMeasure representation.

RECOMMENDATION 8: Need for testing partners

During measure development there is a constant need for testing partners and pilot participants that could be facilitated by ongoing collaboratives focused on developing and implementing eMeasures. Greater participation and collaboration by providers and health systems includes a willingness to participate in testing new eMeasures.

NOTES

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Appendix A - eMeasure Feasibility Assessment Technical Expert Panel Roster

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Appendix B – Environmental Scan

EHR Vendor questions and responses:

What is your general approach to feasibility assessment for implementing eMeasures into EHRs?

- Review of specifications and value sets to identity what is to be captured.
- Assess to ensure required data elements for eMeasures are in the EHR; if gaps, where in workflow to add?
- Build detailed workflow documents
- Assess impact to provider workflow
- Evaluate that accurate and consistent calculations are achieved
- Work with customers to provide input on workflows and system changes
- Recommend that early in measure development process eMeasures be evaluated to ensure clinical workflow can capture the necessary data
- Encourage collaboration between measure developers, EHR vendors and providers during the development process

How do you assess the impact of eMeasure implementation and workflow issues?

- Gap analysis by clinical specialist and software developers to identify gaps in workflow
- Create new functionality if gap analysis identifies a deficit
- Identify workflow best practices for users
  - Vendor knowledge experts
  - Customers

Assessment of short-term feasibility of implementation:

- Assessment of eMeasures to ensure current system captures the data needed for calculations
- Identifying best practice workflows to capture the data – workflow may not be optimal but is a means to an end
- Interoperability and data exchange required for the measure are currently unavailable
- Resource constraints are a challenge for short-term development

Assessment of long-term feasibility of implementation:

- Develop and release new functionality as required for collection of data elements
- Assess lead time to develop and implement into system
- Feasibility assessment used in multiple phases of development (iterations)
- Align measures across federal and private sector programs and include technical data definitions
- Longitudinal data often requires data not controlled by the provider; attribution of data can be difficult to trace
- Enhance reporting tools to ease adoption for customers
- Improve data analytics

How does feasibility assessment fit in to your business cycle and development of products?

- Assessment of measure impact on EHR including review of established workflows to ensure desires results are attained
- Testing performed with release of new/updated quality measure specifications and implementation of e-measures
- No formal ‘feasibility testing’; validate that product meets user’s needs

- Used in multiple phases of development (iterations)
- Involve stakeholders as early adopters of eMeasures (field testers, pilot sites, early validation process, etc.)
- Developed flexible tool sets for data capture
- Include EHR vendors on technical expert panels (TEP) when commencing development of new eMeasures
- Feasibility testing is part of the business or development cycle; implementation of measure requirements occurs after the regulatory requirements are communicated

What are your current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures?

- Early adopter and early validation program
  - Allows users/providers to test the measure, provide feedback and identify workflow best practices
- Work with customers and vendor partners to identify data capture best practices
- Engage measure developers and providers in testing
- Engaged by measure developers to participate in testing
- Work with industry groups to address measurement issues
- Timing of request to participate in measure testing can be problematic
- Collaboration among stakeholders (measure developer, EHR vendors, providers) to provide cross education on measure development, EHR development cycle, clinical workflow, etc.

Measure Developer questions and responses

What is your general approach to feasibility testing for implementing eMeasures into EHRs?

- Starts when core clinical concepts are identified and specifications drafted
- Establish Health IT advisory panels
- Seek publish comment on draft specifications
- Assess data capture capabilities
- Align eMeasure definition with data transmission capabilities (QDM/HQMF/QRDA)
- Feasibility testing is an evolving process
- Testing approaches different for re-specified and de novo measure
- Developed a five point grading scale for CMS to evaluate Meaningful Use (MU) of measures
- When testing a measure for feasibility must consider:
  - Structure of individual data elements
  - Overall measure including complexity
  - Workflow
- Just because a data field exists does not mean it gets populated
- Developed criteria to assess data element feasibility: target population obtained with data element(s), captured with a standard definition and recorded in a standard format; and data in structured field in the HER and are feasibly retrieved.

What decisions are made with regard to the eMeasure when testing identifies feasibility problems?

- Assess the impact of removing a concept – does it change the intent of the measure?
- Look for alternatives for capturing data

- Consider alternate representations for clinical concepts
- Include CMS/funder in decision making process
- Structure of data elements: 'just because the field exists doesn't mean it is populated'
- Issue resolution may not possible

At what point in the measure development process does feasibility assessment currently occurs?

- After the draft electronic specifications are completed but before publishing draft specs for public comment
- Testing is a continuum

How is testing for feasibility, reliability and validity handled across multiple vendor systems?

- Testing of measures occurred at multiple sites using 6 EHR vendor products
- Need to consider workflow in testing
- Results will vary based on structural and site experience and workflow

What are your current efforts of collaboration or interrelationships with vendors and providers in regards to feasibility testing?

- Pilot project with ONC-certified ORYX vendors to transmit eMeasure data (TJC)
- Future project: "…assess ability of disparate EHRs …to collect standardized, risk adjusted and clinically relevant outcome measures" (TJC)
- Testing at multiple sites with different EHRs
- Convene multidisciplinary TEPs to provide guidance

Provider questions and responses:

What are your expectations of feasibility testing prior to implementation of eMeasures?

- Test data set
- Testing
  - Occurs with all major EHR vendor products
  - At hospitals with disparate information systems that have data required for the eMeasure
  - Of multiple facility types
- Pilot test measures in multiple practice types: solo, medium, large, multispecialty, academic
- Clearly defined data elements

What factors impact your implementation and workflow issues that should be addressed or factored into the development of eMeasures?

- Workflow
  - Impact of moving from abstracted to re-tooled measures
  - Issues related to disparate systems
- Physician adoption of discrete data documentation is poor
- Standardization of data
- Clearer data elements

What are your current efforts of collaboration or interrelationships with vendors and measure developers in regards to feasibility assessment?

- eMeasure testing at multiple sites of various sizes with various products
- Recommend ONC require all vendors to certify for all eMeasures
- Improved data sharing from disparate vendors
- Compensate test sites financially or with assistance/support

Appendix C – NQF Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties (2010)

Electronic Health Records and Electronic Measures

Development and implementation of electronic health record (EHR) systems hold great promise for the efficient collection of clinical data that can be used for quality measurement. National initiatives call for the adoption of EHRs that include the capability for quality measurement, and NQF has made endorsing quality measures specified for EHRs an important goal. Data stored in EHRs facilitate reporting of quality measures because EHR data 1) are clinically specific, 2) include a large variety of data types including physiologic data such as laboratory values, and 3) decrease the burden of data collection through automated identification, extraction, computation, and aggregation.

Although the concepts of reliability and validity apply equally to measures derived from EHRs, the EHR presents additional issues related to measure testing. Widespread EHR data are not yet available for measure development and testing. In addition, because there are numerous EHR vendors and home-grown EHR systems, it can be difficult to insure that the selected data fields of interest for any particular measure are comparable among different EHRs. Recommendations regarding testing and evaluation of EHR measures are addressed in Section III.

III. Recommendations for Measures Specified for EHRs

The EHR holds significant promise for improving the measurement of healthcare quality. The availability of a broad range of reliable and valid data elements for quality measurement without the burden of data collection is widely anticipated. Because clinical data can be entered directly into standardized computer readable fields, the EHR will be considered the authoritative source of clinical information. Quality measures based on EHRs use clinical information recorded by healthcare clinicians in discrete computer readable fields; therefore, measurement errors due to manual abstraction, coding by persons other than the originator, or transcription could be eliminated. Despite these potential advantages over current data sources, several potential sources of error pose threats to the reliability and validity of data elements and computed measure scores for EHR measures including: 1) incorrect measure specifications, including code lists, logic, or computer readable programming language; 2) EHR system structure or programming that does not comply with standards for data fields, coding, or exporting data; 3) difference in use of data fields by different users or entry into the wrong EHR field; 4) entry of incorrect information; and 5) incorrect parsing of data by natural language processing software used to analyze information from text fields. All of these potential errors are analogous to sources of error with measures based on other data sources.

Table 4 provides the guidance for rating the level of evidence for reliability and validity of EHR measures, and it is analogous to the ratings in Table 2 [for traditional measures]. Table 3 indicates how the ratings are used to make a determination if the *Scientific Acceptability of Measure Properties* criterion has been met for EHR measures. Approaches to testing the reliability and validity of the EHR measure score are the same as for any measure as noted in Tables A-1 and A-3.

Tables 2 and 4 differ in two ways. First, EHR measures must be specified in accordance with the Quality Data Model (QDM, formerly called the QDS).14 The reason for requiring specifications using the QDM is

twofold: 1) the QDM can be translated to computer-readable specifications that can be applied to EHRs; and 2) the structure of the QDM will help fulfill the criterion for precise specifications. The QDM will be updated on a regular basis; therefore, if a measure needs a quality data element that is not currently available, then there will be a process to consider additional quality data elements so that the measure could achieve a moderate or high rating.

Second, data elements for quality measures, which are extracted from EHRs using computer programming, are by virtue of automation repeatable (reliable); however, they can be wrong (invalid). Different uses of an EHR data field by clinicians or different data processing or extraction protocols in different EHRs can result in incorrect or missing data and produce different performance scores. Therefore, testing at the data element level should focus on validity as discussed below. Focusing on validity testing of data elements is consistent with the rating system for all measures presented in Table 2—that is, if empirical validity testing of the data elements is conducted, then separate reliability testing of the data elements is not required.

An approach to testing the validity of data elements analyzes the agreement between data elements and scores obtained with data exported electronically using the EHR measure specifications to those obtained by review and abstraction of the *entire* EHR, preferably using EHRs that comply with standards. This approach has been reported in the literature15-17 and by HealthPartners in a Commonwealth Fund report18 on performance measures and EHRs. As with measures for other data types, testing may be conducted on a sample of the measured entities (see Section I).

Because EHR databases may not be available for such testing, another approach is to apply the EHR measure to a simulated data set that reflects standards for EHRs and includes sample patient data with the elements needed for the specified measure. Because the simulated data set is constructed, the values for the data elements and scores are known. When the EHR specifications are applied to the simulated data set, they should return the known values of the data elements and scores.

With either approach, when the results obtained for the EHR measure do not match the known values in the simulated data set or the abstracted data, an analysis is conducted to determine the source of error. If the error is related to the measure specifications, including code lists, logic, and computer readable programming language, then it would be corrected before submission for endorsement. If the source of error is due to clinical data entry practices and EHR structures unique to specific organizations, then the error would not be mitigated by changes to the EHR measure specifications, but it could indicate the need for further evaluation of feasibility and for alternative data fields.

The recommended approach to evaluating reliability and validity of data elements for EHR measures accounts for the current environment in which standards for EHRs and EHR measures are under development and have not yet been widely adopted. Therefore, testing sites are limited, and testing in a sample of EHR systems may not be representative of all systems. However, this is no different from testing the data elements for measures based on other data sources in a sample of the measured entities whose data practices may vary. As noted in the Background, reliability and validity are not static properties, and no one test is definitive.

Measure testing requirements should not impede the adoption of EHRs and EHR measures, but they should be true to the principles of scientific acceptability of measure properties. EHRs and EHR measures are new and will most likely require some adjustment of local EHR structures and recording practices to

meet standards. Therefore, providers should be encouraged to conduct their own internal reliability studies.

Previously endorsed measures specified for chart abstraction or administrative claims data may be appropriate for re-specification for EHRs. Although these endorsed measures should have already been tested for reliability and validity, the EHR measure specifications must be assessed for similarity to the original specifications, which also is addressed in Table 4. In some cases, the EHR specifications will represent a substantive change to the measure so that an assessment of reliability and validity of the EHR measure also is needed.

Table 4: Evaluation of Reliability and Validity of Measures Specified for EHRs [13]

	New Measure Specified for EHR		
Rating	**Reliability Description and Evidence**	**Validity Description and Evidence**	**Modifications for Endorsed Measure *Re-specified* for EHRs**
High	All EHR measure specifications are unambiguous[+] and include only data elements from the Quality Data Model (QDM)***** including quality data elements, code lists, and measure logic; **OR** new data elements are submitted for inclusion in the QDM; **AND** Empirical evidence of reliability of both data element **AND** measure score within acceptable norms: • Data element: reliability (repeatability) assured with computer programming—**must test data element validity** **AND** • Measure score: appropriate method, scope, and reliability statistic within acceptable norms	The measure specifications (numerator, denominator, exclusions, risk factors) reflect the quality of care problem (1a,1b) and evidence cited in support of the measure focus (1c) under *Importance to Measure and Report*; **AND** Empirical evidence of validity of both data elements **AND** measure score within acceptable norms: • Data element: validity demonstrated by analysis of agreement between data elements electronically extracted and data elements visually abstracted from the entire EHR with statistical results within acceptable norms; **OR** complete agreement between data elements and computed measure scores obtained by applying the EHR measure specifications to a simulated test EHR data set with known values for the critical data elements; **AND** • Measure score: appropriate method, scope, and validity testing result within acceptable norms; **AND** Identified threats to validity (lack of risk adjustment/stratification, multiple data types/methods, systematic missing or "incorrect" data) are empirically assessed and adequately addressed so that results are not biased	The EHR measure specifications use only data elements from the Quality Data Model (QDM)***** and include quality data elements, code lists, and measure logic; **AND** Crosswalk of the EHR measure specifications (QDM quality data elements, code lists, and measure logic) to the endorsed measure specifications demonstrates that they represent the original measure, which was judged to be a valid indicator of quality; **AND** Analysis of comparability of scores produced by the retooled EHR measure specifications with scores produced by the original measure specifications demonstrated similarity within tolerable error limits
Moder-ate	All EHR measure specifications are unambiguous[+] and include only data elements from the QDM;* **OR** new data elements are submitted for inclusion in the QDM; **AND** Empirical evidence of reliability within acceptable norms for either data elements **OR** measure score as noted above	The measure specifications reflect the evidence cited under *Importance to Measure and Report* as noted above; **AND** Empirical evidence of validity within acceptable norms for either data elements **OR** measure score as noted above; **OR** Systematic assessment of face validity of measure score as a quality indicator (as described in Table A-3) explicitly addressed and found substantial agreement that ***the scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality*** **AND** Identified threats to validity noted above are	The EHR measure specifications use only data elements from the QDM as noted above **AND** Crosswalk of the EHR measure specifications as noted above demonstrates that they represent the original measure **AND** For measures with time-limited status, testing of the original measure and evidence ratings of moderate for reliability and validity as described in Table 2.

	New Measure Specified for EHR		Modifications for Endorsed Measure *Re-specified* for EHRs
Rating	**Reliability Description and Evidence**	**Validity Description and Evidence**	
		empirically assessed and adequately addressed so that results are not biased	
Low	One or more EHR measure specifications are ambiguous[+] or do not use data elements from the QDM*; **OR** Empirical evidence of unreliability for either data elements **OR** measure score—i.e., statistical results outside of acceptable norms	The EHR measure specifications do not reflect the evidence cited under *Importance to Measure and Report* as noted above; **OR** Empirical evidence (using appropriate method and scope) of invalidity for either data elements **OR** measure score— i.e., statistical results outside of acceptable norms **OR** Identified threats to validity noted above are empirically assessed and determined to bias results	The EHR measure specifications do not use only data elements from the QDM; **OR** Crosswalk of the EHR measure specifications as noted above identifies that they do not represent the original measure **OR** For measures with time-limited status, empirical evidence of low reliability or validity for original time-limited measure
Insufficient evidence	Inappropriate method or scope of reliability testing	Inappropriate method or scope of validity testing (including inadequate assessment of face validity as noted above) **OR** Threats to validity as noted above are likely and are NOT empirically assessed	Crosswalk of the EHR measure specifications as noted above was not completed OR For measures with time-limited status, inappropriate method or scope of reliability or validity testing for original time-limited measure

[+]Specifications are considered unambiguous if they are likely to consistently identify who is included and excluded from the target population and the process, condition, event, or outcome being measured; how to compute the score, etc.
*QDM elements should be used when available. When quality data elements are needed but are not yet available in the QDM, they will be considered for addition to the QDM.

Appendix D – Examples of Feasibility Assessment Scoring

Scorecard Ratings

Data Availability – Is the data readily available in structured format, i.e., resides in fixed fields within EHRs? Scale: 3 - One of the following: a. Data element is routinely collected as part of the care process and exists in the majority of EHRs or b. Data element is currently collected as part of the care process and exists in some EHRs and/or some health systems 2 – Data element is currently not collected but the ability to collect data element is required for certified EMR 1 – Ability to collect data element is not required for certified EHR and is currently not widely collected
Data Accuracy – Is the information contained in the data element correct? Are the data source and recorder specified? Scale: 3 – The information is from the most authoritative source and is highly likely to be correct. (e.g., laboratory test results transmitted directed from the laboratory information system into the EHR). 2 – The information may not be from the most authoritative source and/or has a moderate likelihood of being correct. (e.g., self-report of a vaccination). 1 – The information may not be correct. (e.g., a check box that indicates medication reconciliation was performed).
Data Standards – Is the data element coded using a nationally accepted terminology standard? Scale: 3 – Always coded in nationally accepted standard 2 – Standards currently available, but not widely adopted 1 – No standards currently available
Workflow – Is the data captured during the course of care and fits the typical EHR workflow for that user? Scale: 3 – Requires no additional data entry from clinician solely for the quality measure and no EMR user interface changes. Data element is available as a byproduct of routine care. Examples would be lab values, vital signs, referral orders, or problem list entry. 2 – Additional time and effort over and above routine care is required, but some perceived to be of benefit 1 – Additional time and effort over and above routine care is required but without immediate benefit to care

Example 1

Data element: **Oral medication dispensing event**			
eMeasure Title: Asthma Medication Ratio (AMR) from HEDIS© 2013. Medication dispensed data would include medication code, dispense date, and days supply.			
Data Element Definition: Oral medication dispensing event: One prescription of an amount lasting 30 days or less. To calculate dispensing events for prescriptions longer than 30 days, divide the days supply by 30 and round down to convert. For example, a 100-day prescription is equal to three dispensing events (100/30 = 3.33, rounded down to 3). The organization should allocate the dispensing events to the appropriate year based on the date on which the prescription is filled. Multiple prescriptions for different medications dispensed on the same day are assessed separately. If multiple prescriptions for the same medication are dispensed on the same day, sum the days supply and divide by 30. Use the Drug ID to determine if the prescriptions are the same or different. Refer to the definition of Oral medication dispensing event in ASM for examples.			
Reference Point: Global assessment			
COMPONENT	**Current**	**Future**	**COMMENTS**
Data Availability – Is the data readily available in structured format , i.e., resides in fixed fields in EHRs?	1	2	Medication fill/dispense data in EHRs is available in some integrated settings, is not widely implemented. The technical fundamentals for this type of information exchange exist, but these are not part of current ONC CEHRT certification criteria. Rated a 2 for near future state because it is likely it will become part of certification criteria before it becomes routinely collected.
Data Accuracy – What is the accuracy of the data element in EHRs under normal operating conditions? Are the data source and recorder specified?	1	2	Uncertain how to rate this component given the low likelihood of data availability. Electronic dispense data would be at least generally accurate in the future
Data Standards – Is the data element coded using a nationally accepted terminology standard?	2	3	Drug codes are certainly available and can be mapped to RxNorm. Not clear how widely these standard drug codes are currently used in medication dispense records, but they are currently good enough for claims-based reporting. Likely to improve in the future.
Workflow – Is the data captured during the course of care and fits the typical EHR workflow for that user?	1	2	This represents a challenge to score. Providers would benefit from knowing what was dispensed. However, it is not clear that it would be perceived to be worth the effort to capture all of the attributes that this data element requires: medication code, date, days supply.
FEASIBILITY SCORE	LOW		Multiple components scoring “1”

Example 2

Data element: **Medication, Administered: Prophylactic antibiotics**			
eMeasure Title: Measure: Perioperative Care: Timing of Prophylactic Antibiotics - Ordering Physician (NQF 0270), American Medical Association - Physician Consortium for Performance Improvement			
Data Element Definition: Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics who have an order for an antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours) prior to the surgical incision (or start of procedure when no incision is required) The appropriate timing of administration of prophylactic antibiotics has been demonstrated to reduce the incidence of surgical wound infections. Specifying the time of administration in the order is critical as available evidence suggests that the drug should be received within one hour before incision for maximum antimicrobial effect**. Data elements required for the measure can be captured and the measure is actionable by the physician.** **For this measure, the source of the clinical data will be located in both the hospital EHR and the physician practice EHR**. The denominator is identified by the procedures that are performed by the physician, whereas the clinical data required for the numerator and exceptions will be located in the hospital EHR. In order to calculate the measure**, there may be some abstraction required from the inpatient record to the ambulatory (physician) EHR before the measure can be calculated**. The intent of this measure is to assess whether or not the provider ordered the prophylactic antibiotic to be administered within one hour prior to incision (or within 2 hours if vancomycin or fluoroquinolones). As some procedures (e.g., endoscopy) have no incision, the measure provides the option of using incision time OR start time. The 'start time' is to be used only for those procedures that have no 'incision.' Although the eMeasure specifies "medication administered," this should also include the intent to administer the medication in the absence of actual administration. For example, if the provider orders the medication to be administered within one hour prior to incision (or within 2 hours if vancomycin or fluoroquinolones), yet it is not administered, the provider would still be compliant with the numerator.			
Reference Point: Global assessment			
COMPONENT	**Current**	**Future**	**COMMENTS**
Data Availability – Is the data readily available in structured format , i.e., resides in fixed fields in EHRs?	1	2	
Data Accuracy **–** What is the accuracy of the data element in EHRs under normal operating conditions? Are the data source and recorder specified?	1	1	Rated a "1" for future state 1 – 3 years, as even though the medication might be available, the actual time of administration being sent on a CCDA is questionable.
Data Standards **–** Is the data	3	3	Data Availability outweighs all of these other

element coded using a nationally accepted terminology standard?			categories. If the data was there, it would be coded using a standard.
Workflow – Is the data captured during the course of care and fits the typical EHR workflow for that user?	1	2	
FEASIBILITY SCORE	LOW		Multiple components scoring “1”