



TO: eMeasure Feasibility Expert Panel
FR: Reva Winkler and Helen Burstin
DA: December 4, 2012
RE: December 7 eMeasure Feasibility meeting – additional materials

This memo provides draft guidance and principles for approaching eMeasure feasibility assessment derived from previous panel discussions as well as results from the environmental scan. Additional materials including a scoring system for data element feasibility as a “strawman” for the panel’s reaction will be forthcoming.

Project Goals

The goal of this project is to propose a set of feasibility assessment recommendations, as well as a starter set of criteria for eMeasure feasibility that will assess the feasibility of data capture for the data elements utilized in a structured format and address the following considerations:

- Timing of feasibility assessment in the course of measure development (e.g., iterative assessments with development, implementation of fully specified measures)
- Potential differences in feasibility assessment requirements for de novo measures and retooled measures;
- Number and diversity of EHRs systems used for assessment and relation to comparability across EHRs in terms of data feasibility, validity, and reliability; and
- Interrelationship of feasibility and validity assessment of data elements of new measures.

The deliverable from this effort, the eMeasure feasibility assessment guidance report, should provide important guidance that can shape future measure development contracts as well as certification requirements.

Guidance and Principles for eMeasure Feasibility Assessment

Overarching Areas:

- There is a spectrum of assessing feasibility rather than a simple yes/no.
- Feasibility should be considered early in the development process and tested throughout the entire continuum of measure development.

- Greater collaboration between measure developers, EHR vendors, and providers at all stages of development would enhance the assessment of feasibility.
- Testing for reliability and validity cannot begin without first assessing for feasibility at the data element level.
- Feasibility covers the following domain areas:
 - Data Representation (used to represent measure concepts and EHR content)
 - Clinical Workflow (Implementation and Impact on Clinical Care)
 - Data Communication (Interoperability)
 - Technical Tools
- Feasibility assessment should consider implementation factors (access to structured/coded data, heterogeneity of data across different EHR systems, data accuracy and completeness, ability to query data, mapping requirements, clinical decision support requirements, reporting complexity, and workflow factors).
- A feasibility scoring system can be used as a tool by all stakeholders responsible for developing eMeasures.

Data Representation (used to represent measure concepts and EHR content)

- Standardization of data elements, associated definitions and value sets, and mapping to the Quality Data Model (QDM) must be assessed for feasibility.
- Data elements must be well defined including terminologies or value sets to enable understanding of the measure intent and consistent interpretation by those implementing an eMeasure.
- The goal focuses on reliable and valid representation of the measure meaning and EHR representation.
- Further work is needed to explore the reliability and validity of the mappings of standard vocabularies to local terminologies.
- Profiling of the availability of data elements across electronic health record systems (EHRs) vendors should be incorporated into eMeasure feasibility.

Clinical Workflow (Implementation and Impact on Clinical Care)

- Providers and EHRs vendors should be involved in the measure development, testing and implementation of eMeasures.
- The degree of required potential end user customization of vendor products should be considered.
- Each structured data element increase implementation costs and the importance of the clinical component both to the provider and patient being measured should be weighed against them.

Data Communication (Interoperability)

- Important measures of care coordination based on exchange of information have failed on feasibility because little exchange is currently happening.
- Existing communication standards such as Continuity of Care Document (CCD) and Quality Reporting Document Architecture (QRDA) can be used to assess feasibility.
- QRDA is important because sometimes communications standards lag behind data standards.
- Known gaps in standards need to be taken into consideration when assessing feasibility.

Technical tools

- The ability to aggregate data and produce reports for internal and external use on eMeasure performance is integral.
- There is variation among interface data capture and coding in standard vocabularies versus using local codes. This may require the need for mapping tools.
- Clinical decision support should be a byproduct of eMeasure integration within EHRs.
- Providers should be able to view aggregate performance on eMeasures as well as be able to “drill down” to individual patient data as desired.

Discussion questions:

- What are the reference point(s), i.e., feasibility for whom and when?
- To what degree should feasibility assessment move beyond the data element level analysis to the measure score level?
- To what degree should feasibility assessment occur at a vendor level vs. the local implementation level (i.e., at the point of care)? How many vendors or sites are needed?
- eMeasure testing may be done in a simulated or real world environment. Are they equivalent? Does real world have more credibility than simulated?
- What should indicate whether a measure is intended for widespread, current use or whether the measure is future-oriented for guiding development of EHRs and may not be readily feasible in the near term?
- What are the feasibility characteristics or concerns attributable to the eMeasure rather than local implementation issues or EHRs functionalities?
- What does ‘good enough’ look like for feasibility? Is there a minimally acceptable level of feasibility for eMeasures for accountability and quality improvement?
- How should standardization of data elements be factored into feasibility assessments to leverage the likelihood of successful implementation of eMeasures across EHRs?

- How should expectations for feasibility assessment accommodate advanced measures to encourage EHRs to evolve in ways that meet the goals of the National Quality Strategy?
- Is an assessment that demonstrates sufficient feasibility a prerequisite for reliability and validity of the data elements? Can an eMeasure that is not feasible be valid?
- Is feasibility assessment in real world clinical settings distinct from reliability and validity assessment of the data elements?
- How should information from feasibility assessment be incorporated into reliability and validity testing (e.g., the effect of systematic missing data on validity?)

eMeasure Feasibility Assessment

Summary of Expert Panel Conference Call

October 30, 2012

NQF staff provided an introduction to the project goals and deliverables. NQF staff also reviewed the findings of an environmental scan of EHR vendors, measure developers and providers on current assessment of feasibility of eMeasures.

Expert Panel Discussion

eMeasure Feasibility

- There is a spectrum of assessing feasibility rather than a simple yes/no. Some members suggested that the goal is to determine the conditions under which an eMeasure measure could be feasible.
- Feasibility assessment should provide enough information for decision-makers to determine whether to move ahead with eMeasure development and implementation.
- Feasibility assessment should consider implementation factors (access to structured/coded data, heterogeneity of data across different EHR systems, data accuracy and completeness, ability to query data, mapping requirements, clinical decision support requirements, reporting complexity, and workflow factors).
- Feasibility assessment should be considered at several points during the development process from very early during the conceptual development through specification, testing and implementation.
- Measures that are re-specified are very challenging as found with the re-tooling for meaningful use Stage 2. An initial assessment of feasibility might determine the complexity associated with re-specification. It will be important to strike a balance between assessing feasibility in current versions of EHRs with other sources of electronic data. Focus should be on development of new eMeasures and re-thinking existing measure concepts in a way that takes advantage of the structure and logic of an EHR rather than trying to retool existing measures typically obtained from claims and administrative data sources.

Data representation (source, standardization, validity, and reliability)

- Some Panel members suggested that the definitions of many data elements are ambiguous. For example, specifications may not include terminologies or value sets for the definition of an office visit – does it mean face to face, with a nurse, with a doctor, either or all?
- The lack of standardized value sets for application across eMeasures was raised as a concern. For example, there are multiple smoking codes in SNOMED (tobacco smoking versus tobacco use) and specifies light, medium, heavy use but the value set does not provide enough clarity.
- Assessment of difficult data elements should be considered when evaluating the goal/value of the whole measure.

- GE described part of their assessment as data profiling that investigates real, in-use customer data statistics to see the candidate EHR terms are in use. Panel members were interested in hearing more about the profiling.
- Similarly a member reported that the American College of Cardiology looks at how frequently a data element is present in their registry to inform the measure specifications.

Workflow (getting the data)

- Each structured data element adds to costs and there is a need to be thoughtful about aggregate costs for multiple data elements and the return on the investment. Is the value of the measure sufficient to justify the costs of data capture?
- New EHR feasibilities will have an impact on providers. The question is whether the data is important for the care of the patient.
- The requirement to ask providers to provide rationales as to why they did or did not do a certain thing can create additional and unnecessary burden.
- The impact on feasibility of end user customization of vendor products should be considered.
- The role of customers and/or providers in feasibility testing was considered by some developers in the environmental scan.

Data communication (interoperability)

- There is variation among interface data capture and coding in standard vocabularies versus using local codes.
- Important measures of care coordination based on exchange of information have failed on feasibility because little exchange is currently happening.

Technical tools (CDS, mapping, queries, reporting, etc.).

- There is a need to assess the ability to aggregate the data, as well as the ability to package, send and report to an external entity.
- Paper medical record based measures use a human interface with detailed abstraction guides and testing for inter-rater reliability. For eMeasures, the challenge is using standardized vocabularies viewed in a standardized fashion and the validity and reliability of the mappings from local terminologies to standard vocabulary

Rating System for eMeasure Feasibility

Several Expert Panel members recommended the development of a quantitative scoring system to assess the feasibility of data elements. There is also a need to develop criteria for eMeasure feasibility. Members noted that the ability to assign feasibility scores to different data elements could provide a better understanding of overall eMeasure feasibility. Paul Tang suggested that this effort build on prior work done on data quality in the 2008 HITEP I report which was a precursor to the QDM. The 2008 HITEP I report was sent to the Expert Panel members electronically.



To: eMeasure Feasibility Testing TEP members

From: Reva Winkler, MD, MPH
Beth Franklin, MS, RN
Kathryn Streeter, MS

Date: December 4, 2012

Re: Environmental Scan, eMeasure Feasibility Testing

The National Quality Forum (NQF) conducted an environmental scan for the eMeasure Feasibility Testing project. The environmental scan was intended to identify approaches to feasibility testing from measure developers, government contractors, electronic health record (EHR) vendors, and providers. Each of the stakeholder groups was asked to respond to a series of questions. The questions are below. Responses were gathered via conference calls or through email. Attached are the raw data responses.

Questions asked of stakeholders for environmental scan:

Vendors

- Your general approach to feasibility testing for implementing eMeasures into (EHRs);
- How you assess the impact of eMeasure implementation and workflow issues;
- Assessment of short-term versus long-term feasibility of an eMeasure's implementation;
- How feasibility testing fits in to your business cycle and development of products; and
- Current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures.

Developers

- Your general approach to feasibility testing for implementing eMeasures into EHRs, including
 - your approach to feasibility testing of the data elements;
 - what decisions are made with regard to the eMeasure when testing identifies feasibility problems;
 - how feasibility testing relates to testing for reliability and validity;
 - at what point in the measure development process feasibility testing currently occurs; and
 - how testing for feasibility, reliability and validity is being handled across multiple vendor systems.
- Current efforts of collaboration or interrelationships with vendors and providers in regards to feasibility testing.



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Providers

- Your expectations of feasibility testing prior to implementation of eMeasures;
- Factors that impact your implementation and workflow issues that should be addressed or factored into the development of eMeasures; and
- Current efforts of collaboration or interrelationships with vendors and measure developers in regards to feasibility testing.

If you have any questions prior to the call about the scan please contact Kathryn (Katie) Streeter at kstreeter@qualityforum.org.

Thank you.

Approach to feasibility testing

eMeasure feasibility testing is not fundamentally different than traditional paper-based measures feasibility testing processes. In fact, the aim is largely the same: to determine the viability and practicality of implementing the measure. What is unique in eMeasure feasibility testing is that data sources are limited to structured and/or coded fields in the EHR, so the feasibility challenge is not only if the data are documented, but also how and where they are documented. This also impacts the composition of the participants involved in feasibility testing (i.e, EHR vendors need to be part of the discussion, as well as provider representatives and clinicians).

In addition, feasibility testing should not be regarded as an isolated step in the eMeasure development process, but rather considered from the moment core clinical concepts are identified and specifications are drafted. To this end, The Joint Commission is establishing HIT advisory panels to inform draft specification of eMeasures as well as feasibility testing. However, due to the known variability across EHR systems and installations, seeking a broader audience for feasibility testing purposes is critical. This will be achieved through public requests for comments on draft electronic specifications.

Evaluation of the data capture capability is assessed through structured questionnaires with ratings on a Likert scale, or approached in a table format, or by other approaches. Focus groups and structured interviews may also be used.

A complete assessment of data capture capabilities will cover:

- Data availability (data sources)
- Data accessibility (structured vs. unstructured fields)
- Data standardization (use of standard vocabularies vs. local vocabularies; conformity of data fields with QDM framework)
- Data quality viability (likelihood of documentation; workflow considerations)

In addition, other elements that are critical for eMeasure implementation need to be evaluated, including, but not limited to, alignment of eMeasure definition with data transmission capabilities (QDM/HQMF vs. QRDA).

Approach to resolving eMeasure representation issues when testing identifies feasibility problems

There is a fine line between simplifying a measure to enhance implementability and losing the clinical integrity and meaning that the measure is developed to represent. Resolving eMeasure representation issues requires consideration of a number of factors:

- Measure intent and supporting evidence-base
- Level of effort involved in EHR implementation of measure concepts not readily available in EHRs
- Differences in terms of data capture ability across EHR systems and installations
- Workflow issues and potential impact on the ability to receive data

Consideration of these factors often results in a trade-off resolution that retains the measure's viability, although not necessarily retaining the constructs of the original measure. While this can be acceptable to make a decision to move forward with the measure, additional testing, particularly validity and reliability testing, is absolutely critical. Essentially, when a measure is retooled, the feasibility and pilot test results obtained for the original measure constructs do not necessarily hold true for the retooled measures. The fundamentally different nature of an eMeasure vs. a paper-based measure requires full testing procedures for retooled measures.

In our experience, resolution of eMeasure representation issues will require:

- Looking for alternative, more feasible ways of capturing the information (different data source, alternate QDM element modeling, modeling an exclusion as an inclusion).
- Considering alternate vocabulary representations for particular clinical concepts.

For retooled measures, original paper-based data may be available to assess the potential impact of removing a certain concept from the measure. This type of what-if analysis with real-world data can inform the resolution of eMeasure feasibility issues by substantiating or contradicting a particular proposed solution.

On occasion, the resolution of eMeasure representation issues may not be possible, and that realization needs to be accepted as a possible outcome of eMeasure feasibility testing. This can be due to the difficulties in bridging the gap between EHR capabilities and sophisticated evidence-based measures, or issues with eMeasure representation frameworks (including the Quality Data Model, HL7's Health Quality Measures Format or Quality Reporting Document Architecture and the Measure Authoring Tool). In these situations, the root cause for the representation issue needs to be identified, and recommendations regarding the identified issues should be directed to the appropriate organizations.

How feasibility testing relates to testing for reliability and validity

Feasibility can provide a good foundation for the identification of major barriers to eMeasure implementation, and set the stage for real-world testing of electronically specified measures. However, while feasibility testing can inform the specification of measure constructs, it provides limited insight into potential issues related to how the measure actually performs in the real-world, particularly:

- Standardized data capture and data quality issues (e.g. variability in data sources, missing data in structured fields)
- Capture of standardized data (e.g. how data mapping may influence measure results)
- Value of structured and encoded data vs. other forms of documentation within the EHR (does the encoded data provide an accurate picture of a particular patient's care?)

Feasibility is a preamble for other forms of testing (including reliability and validity), and does not necessarily rely on real patient data. Reliability and validity testing using actual patient data are necessary to ensure that measure results are reliable and robust given the newly developed electronic specifications.

At what point in the measure development process feasibility testing currently occurs

Feasibility testing should not be an isolated step in the process of developing eMeasure specifications. Given the significant effort that goes into specifying eMeasures, including QDM element modeling, vocabulary representation of clinical concepts and eMeasure logic creation, the involvement of EHR vendors and users in the early stages of the process is critical to produce the best possible measure representation and to minimize rework downstream. Formal feasibility testing occurs after the draft electronic specifications are completed and before publishing draft specifications for public comment. Following these steps are validity and reliability testing.

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

We expect feasibility, reliability and validity testing results to vary across EHRs, both due to structural and sophistication differences. These differences may arise from distinct steps in the process of capturing and extracting data from EHRs, including:

- Structure and encoding of data on the interface (at the point of care)
- Mapping of local vocabularies to reference and standard terminologies
- Mapping of EHR data fields to data transmission formats (e.g. QRDA)
- Mapping of EHR data fields to QDM elements

The gold-standard of human abstraction has the necessary flexibility to ensure standardized data element abstraction for comparison with encoded EHR data. When differences are detected across providers, a determination needs to be made on what the root cause for the discrepancy was:

- Documentation practices within the organization, including misinterpretation or misuse of interface vocabularies and structured fields, and workflow issues
- EHR documentation structure
- Mapping issues in the data extraction process (e.g. QDM, vocabularies and QRDA)

In addition, other sources for reliability and validity issues need to be considered, including interpretation of eMeasure logic and issues with HQMF implementation.

From a data capture perspective, when it is determined that EHR functionality (e.g. inability to capture data in a structured or encoded format) is the cause for discrepancies, it is critical to determine whether this is a particular (found in a specific EHR system or installation) or a general issue (issue is found in most or all EHRs). While a particular issue needs to be addressed by the EHR vendor, the solution to more generalized implementation issues is, of course, not simple. The question becomes what is an acceptable EHR maturity level to support a particular electronically specified measure.

While it seems intuitive that a certain level of functionality should support a particular quality measure, we believe that functionality thresholds need to be better defined. ONC certification of EHR technology could provide a minimum functionality expectation, however, 2014 Edition EHR Certification Criteria pertaining to clinical quality measures data capture and export – particularly, 170.314(c)(1)(i) – may be both too

specific and too broad. On one hand, this certification criterion requires that a certified EHR is capable of capturing data elements as required for each and every CQM for which the technology is to be certified. While this is very specific for the clinical quality measures included in Meaningful Use, it provides no leverage for other measures; hence it may be too narrow of a requirement to be useful for determining eMeasure feasibility outside of the scope of Meaningful Use Stage 1 and 2. On another hand, the certification criterion does not provide direction on how and where these data elements would be captured, making it also very broad.

An alternative way a threshold (or multiple thresholds) could be defined is using HIMSS EMR Adoption Model to categorize measures according to required EHR functionality. However, because some measures are specialty-specific, the EMR Adoption Model may not provide sufficient detail to determine the maturity level required for a particular quality measure. An adaptation or expansion of this model could, however, provide direction to both EHR vendors and measure developers by creating definitive expectations on EHR functionality by stages.

More than what the specific results of eMeasure testing across multiple vendor systems, it is important that measures are developed to a particular level of expected functionality in EHRs. It is also important to understand that the gap between eMeasure specifications and EHR capabilities:

- is not necessarily common to all EHRs
- is data-element dependent, and potentially specialty-specific
- is not necessarily resolved by simplifying eMeasure specifications

Potential approaches to resolving feasibility/validity/reliability issues for a given measure, as opposed to a simple pass/fail approach (i.e., this eMeasure is not feasible in all EHRs, hence it should not be implemented), include the specification of measures targeted for a particular level of EHR maturity, with the possibility of the same measure being specified for more than one EHR maturity level.

It may well be the case that a measure is not feasible at any level of EHR maturity, due to the documentation specificity required. In these cases, working with clinicians and professional societies to define data standardization and “minimum data sets” to be embedded in EHR documentation is a necessary step before a measure can be accurately implemented. This is where standardization of EHR documentation comes into play to narrow the gap between EHR capabilities and sophisticated clinical quality measures.

Another take on the nature of your original question may be how testing is handled when a provider relies on multiple vendors for its electronic data. Joint Commission measures are provider-focused measures, and hold providers accountable for individual patient care. From this perspective, feasibility, reliability and validity testing of an eMeasure must consider all available electronic sources for patient data that could be considered as part of the patient's medical record. Multiple vendor systems pose additional challenges in terms of data interoperability, but a measure cannot be tailored to include only partially available information from single system. This would create issues for providers as well as vendors who provide comprehensive solutions (the measure should not be “blind” to certain components of such systems).

Current efforts of collaboration or interrelationship with vendors and providers in regards to feasibility testing

The Joint Commission is leading its own eMeasure pilot project and working with CMS staff to ensure our respective projects are substantially similar as to allow the most participation possible in both pilots. Initially the Joint Commission's pilot will focus on the ability for our ORYX vendors that have obtained ONC certification to transmit eMeasure data to the Joint Commission and for us to be able to receive and process the data. Once our technical infrastructure for eMeasurement has been developed and tested, our pilot will evaluate issues surrounding data quality and data completeness as it relates to our ORYX vendors, EHR vendors, and the hospitals' processes and procedures. The goal is to develop confidence that electronically derived measures are of sufficient quality that they can be used within the Joint Commission's accreditation and certification activities and for public reporting purposes.

In an effort to evaluate and address the challenges associated with EHR-based outcome measurement, The Joint Commission convened a two-day meeting in the spring of 2012 that assembled some of the nation's foremost authorities on outcome measurement, risk adjustment and the adoption and standardization of the EHR (funded through the AHRQ Small Conference Grant: #1R13HS021051-01). There was consensus at the meeting that the next step should be to conduct a robust demonstration project to assess the ability of disparate EHRs, implemented across multiple hospitals, to collect standardized, risk adjusted and clinically relevant outcome measures. The Joint Commission, along with our certified EHR vendor partners and another nationally recognized clinical outcome measure developer, is in the process of developing a project proposal to secure funding to conduct this demonstration project.

In addition, The Joint Commission is engaging EHR vendors to serve on Technical Expert Panels to support the specification and testing of electronic measures as discussed above.

Developer: Mathematica Policy Research

10/16/2012

Reasons for feasibility testing:

- To determine suitability for MU – can it be implemented and used in incentive program?
- To meet NQF criteria for feasibility

Feasibility is an evolving approach – two approaches for re-specified measures; anticipate a different approach for de novo eMeasures integrating feasibility with reliability and validity

1. Feasibility of re-specified measures for MU2

- measures have already been tested for reliability and validity from paper-based records
- necessarily came after prior testing for R/V and at the same time as entering into MAT
- used data element table (DET) with permission from PCPI for testing
- 8 testing sites; 6 EHR vendor products – selected sites generally more familiar with quality measurement – not necessarily representative of all sites
- Two assessments:
 - i. How EHR system was structured
 - ii. Subjective assessment of feasibility by clinicians: workflow issues; measure integrity; face validity
- Never collected patient data – just evaluated the capacity of the EHR system
- Limited by deadlines for rule-making
- Some small modifications to measure specifications were made

LESSONS:

- Feasibility is not Yes/No but a continuum; developed a 5 point grading scale so CMS could evaluate for MU
- The results pertained to specific sites and not necessarily representative though the results could inform others
- Important to consider structure and feasibility of individual data elements as well as overall measure feasibility
- The mere existence of a data element was not enough – workflow is very important
- Qualitative feedback indicated that the complexity of the measure is also important

2. Feasibility of re-specified measures for Pediatrics

Three components:

- Looked at structured information about 4 EHRs in 6 sites to see whether data elements could be collected
- Semi-structured interviews with clinicians focusing on workflow and collecting the data elements
 - Very valuable; “we don’t always actually use these structured data fields”
 - Likelihood improved use of data fields if meaningful for clinical care – likely pushback if not considered meaningful; example – denominator exclusions that aren’t applicable to the individual patient
 - The number of clicks during a patient visit important
- Phone interviews with the 4 EHR vendors
 - Technology is changing so rapidly – must think ahead to future feasibility considerations

OVERALL LESSONS

- Feasibility is contingent: If _____ (ex: provider did X or Y), then feasible.
- Feasibility is endogenous: if CMS or ONC requires a data element not in an EHR system, the vendor will put it in within 6 months
- The presence of a data field does not mean it is populated.
- Need better ability to read unstructured data.

Yale eMeasure Development Process: Assessment of Data Element Feasibility

Overview

This document describes Yale’s feasibility assessment process during the development of a hospital 30-day all-cause risk-standardized mortality eMeasure for acute myocardial infarction (AMI) hospitalizations. Our team approached measure development with the goal of developing a *de novo* measure that could be feasibly implemented in the current electronic health record (EHR) environment without necessitating changes to current clinical practice or EHR implementation. Specifically, we sought to develop a measure that would not add additional processes to routine clinical care solely for measurement purposes, nor rely on future capabilities of EHRs. To do so, we developed a set of criteria against which all potential data elements in our measure were evaluated based on the feasibility of their use in an eMeasure.

Consideration of feasibility in the current EHR environment was an integral goal incorporated from the beginning of measure development, rather than a post-development testing process.

Approach to Measure Development

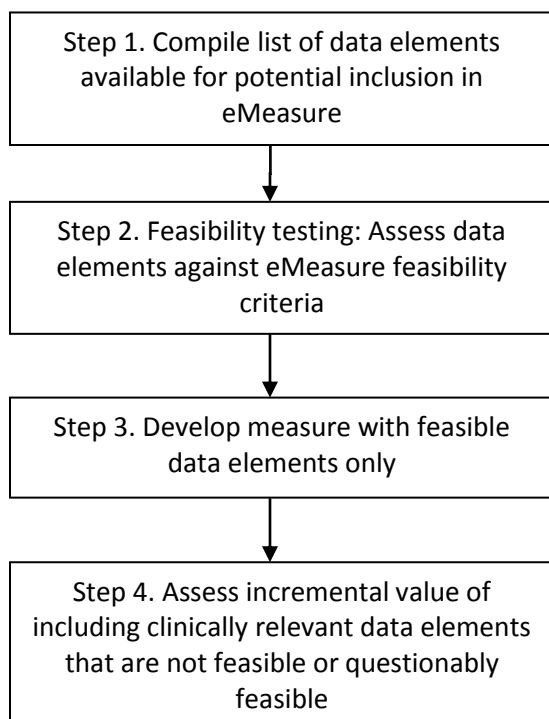
A. Data Source

Our data source for model development was a national clinical registry. This registry provided a source of clinical data elements obtained in a standard fashion from multiple hospitals, allowing us to adequately assess the importance of risk-adjustment variables in predicting a hospital’s risk-standardized mortality rate.

B. Incorporating Data Element Feasibility Assessment into Measure Development

We sought to include in the final model only those data elements that would be feasible in an EHR environment, or “eMeasure feasible.” Early in the development process, we assessed the feasibility of each data element available for potential inclusion in the model against a set of criteria specifically developed for the purpose of assessing feasibility in an eMeasure. See Figure 1 below.

Figure 1. Candidate Data Elements Selection Process Flow Chart



C. Feasibility Criteria and Process for Assessment

In collaboration with EHR experts, including a vendor and clinicians with experience in multiple EHR systems, the Yale team developed the following criteria to assess data element feasibility. Data elements deemed to fulfill feasibility requirements must be:

1. Consistently obtained in the target population based on current clinical practice,
2. Captured with a standard definition and recorded in a standard format, and
3. Entered in structured fields that are feasibly retrieved from current EHR systems.

Through a consensus process with our working group and EHR experts, and in consultation with representatives from the Office of the National Coordinator for Health Information Technology (ONC), we assessed each inclusion criterion, exclusion criterion, and candidate risk-adjustment variable using these criteria. Data elements satisfying all three criteria were deemed feasible for inclusion in an eMeasure given the current EHR environment. Data elements clearly not fulfilling one or more of the criteria were deemed not feasible in an eMeasure given the current EHR environment. Some data elements were deemed to be questionably feasible. See the examples provided in the table below.

Table 1. Examples of Feasibility Assessment of Candidate Risk-Adjustment Variables

Variable	Consistently obtained in target population based on current clinical practice	Captured with a standard definition and recorded in a standard format	Entered in structured fields that are feasibly retrieved from current EHR systems
1. Candidate variables deemed to fulfill all three criteria required for eMeasure feasibility			
Age	✓	✓	✓
Heart Rate at First Medical Contact (bpm)	✓	✓	✓
2. Candidate variables deemed to have questionable feasibility in current EHR environment			
History of Hypertension (No/Yes)	✓	✓	?
Prior MI (No/Yes)	✓	✓	?
3. Candidate variables deemed not feasible for use in eMeasures given current EHR environment			
ST Segment Elevated Myocardial Infarction (STEMI) or STEMI Equivalent (No/Yes)	✓	×	×
Brain Natriuretic Peptide (BNP) (pg/mL)	×	✓	✓

D. Model Development Using Feasible Data Elements

Model development (i.e., cohort definition and risk-adjustment variable selection) proceeded using those data elements found to be feasible for inclusion in an eMeasure.

We assessed the incremental value of including questionably feasible data elements in the risk-adjustment model by comparing model performance with and without them. The minimal improvement in model performance that resulted was not sufficient to warrant including these elements in the model, given their questionable feasibility.

E. Testing of Clinically Relevant Data Elements Not Meeting Feasibility Criteria

During model development, we aimed to develop the best possible measure that could be feasibly implemented without necessitating major changes to clinical processes or current EHR structures. As a means of fully assessing the performance of the eMeasure, we completed further data element testing following measure development. Specifically, we identified certain variables – for example, electrocardiogram findings – that were deemed clinically important but did not meet the feasibility criteria for eMeasure feasibility. We performed quantitative and qualitative analysis to determine the effect of adding these variables to the risk-adjustment model. Because model performance did not differ meaningfully when limited to feasible data elements only, this final step confirmed that the inclusion of elements that did not meet the feasibility criteria was not warranted. If such data elements had proven to be critical for measure performance, we would have recommended delaying implementation of the measure until such elements could be feasibly retrieved from the EHR. Alternately, NQF allows that standards for feasibility can be met if a credible, near-term path to electronic collection is specified.

Relation of Feasibility Process to Reliability and Validity Testing

A. Data Element Reliability Testing

According to NQF's Draft Requirements for eMeasure Review and Testing, "data elements extracted from EHRs using computer programming are by virtue of automation repeatable (reliable)." To further ensure the reliability of the data elements, our second feasibility criterion requires that data elements be "captured with a standard definition and recorded in a standard format."

As an example, heart failure on admission and cardiogenic shock on admission are consistently obtained in current clinical practice, but definitions of these variables are inconsistent (i.e., they are not captured with a standard definition or recorded in a standard format). Thus, their reliability is limited. During model development, these variables were deemed questionably feasible and were not included in the model. Future models may consider the inclusion of these variables if they become more eMeasure-feasible over time.

B. Data Element Validity Testing

According to NQF's Draft Requirements for eMeasure Review and Testing, validity testing should "analyze agreement between data elements and scores obtained with data exported electronically using the specifications to those obtained by review and abstraction of the entire EHR." During eMeasure testing, which will be performed by another entity subcontracting with CMS, the electronic output of the EHR will be compared to data abstracted by nurse reviewers. This assessment will be done at four to five institutions with different EHR vendors. The incorporation of early feasibility testing increases the likelihood that the model data elements will be validly extracted from current EHRs, and validity testing will confirm that.

C. Inclusion of Multiple Vendor Systems

During model development, multiple EHR experts (including clinicians and representatives from an EHR vendor and the Office of the National Coordinator for Health Information Technology (ONC)) provided input regarding the feasibility criteria and the eMeasure feasibility of each individual data element.

In addition, the validity testing process during eMeasure testing will include four to five hospitals with multiple different EHR vendors, covering a variety of vendor types and a majority of the EHR market.

Environmental Scan – Developer

Developer: Abt Associates

Project Background:

- Develop, retool, and maintain hospital clinical quality measures (CQMs) that can be used by eligible hospitals and critical access hospitals (CAHs) to demonstrate Meaningful Use of certified electronic health record (EHR) systems, as part of the Medicare and Medicaid EHR Incentive Program
- Abt Associates and its partners:
 - Health Services Advisory Group, Inc. (HSAG)
 - Lantana Consulting Group
 - Oklahoma Foundation for Medical Quality (OFMQ)
 - Qualidigm
 - Stepwise

Testing Objectives:

- Feasibility of eMeasure implementation given hospital EHR system constraints

Feasibility Testing

- Testing Design
 - EHR Vendor Feasibility Survey
 - Subjective assessment by nine EHR vendors of ability to capture data in structured format
 - 122 items, consisting of data types and their attributes, as defined by the QDM
 - EHR vendor comments
- Emphasized ability to capture required data by Stage 2 (vs. now)
- Testing Methods
 - Quantitative Analyses
 - Highly feasible data items
 - Level of feasibility for a particular item
 - Potentially difficult data items
 - Qualitative Analysis
 - EHR vendor comments

Results: Feasibility Testing

- Quantitative Findings
 - For ALL data items, a majority of vendors indicated that the item could be developed as a structured field within 18 months (or that they already included it)
 - Negation and negation rationale were most commonly identified as potentially difficult data items to capture

- **Qualitative Findings**
 - Concept that the item is intended to capture is unclear to the vendors in some cases
 - In other cases, concept that the data element is intended to capture is clear; however, it is unclear how the concept could be operationalized
 - Capturing certain data elements in a structured format would require data model changes in the EHR beyond simply adding an attribute to an existing table
 - Although structured formats may be available (or could be provided) in the EHR in some cases, clinicians may not use them because of the impact on workflow
- **Lessons Learned**
 - Vendors may require more guidance and education about what is intended to be captured by certain difficult-to-understand concepts
 - Education and guidance to the hospital industry, as well as suggested or example workflows could be provided to the hospital industry and clinicians to assist in adjusting workflow patterns
 - Issues identified with collecting certain data types in existing EHR systems could be shared with EHR vendors and related stakeholders to work towards creating future versions of EHR systems that address these problems

Potential Next Steps

- **Feasibility Testing**
 - Additional research could be conducted to further identify potential data gaps that exist between the common EHR systems and the data elements required to support the calculation of eMeasures
 - Given the known variation that exists in clinical and data workflow, it may be beneficial to conduct further testing of feasibility specifically focused on the measure implications of this variation. As part of this assessment, issues with coordination across multiple data systems could also be addressed



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October 16, 2012

RE: eMeasure Spec Response

TO: Kathryn Streeter
National Quality Forum

Thank you for reviewing our response below:

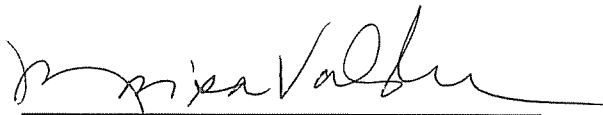
- Your expectations of feasibility testing prior to implementation of eMeasures:
 - Need a test data set – e.g. population of 100 patients with associated score with expected test result data included in the specifications
 - Need testing with all major EHR vendor products
 - Need testing at hospitals with disparate Information Systems (e.g. Certified EHR (Eclipsys), EDIS, surgery systems, L&D system, etc.) that have various data components required for the makeup of an eMeasure
 - Need testing of multiple facility types (small and large hospital systems, rural hospitals, systems that have providers that are employees as well as systems where providers are not employed by the system)
 - Need a published report of the testing experience that discusses challenges in the implementation and recommendations for addressing these challenges
 -
- Factors that impact your implementation and workflow issues that should be addressed or factored into the development of eMeasures:
 - Analysis is needed for workflow implications of retooling abstracted measures to eMeasures (i.e. impact of changes on the reporting of abstracted measures)
 - Impact to clinical workflow (e.g. physicians having to document discrete data elements for certain measures as opposed to narrative/dictated reports)
 - Workflow issues related to disparate IS systems (e.g. CQM: Exclusive Breast Milk Feeding for systems that have a separate L&D information system, SCIP measures with separate surgical IS, and ED throughput measures with separate EDIS)
 - Analysis around measures not typically associated with acute care setting (tobacco, alcohol measures, LTACH, ASE)
 - For large hospital systems that include multiple specialty hospitals, the number of CQMs that must be reported across the system could approach the total of 29 CQMs if required to report on CQMs that are most applicable to each hospital's patient population; this will result in possibly having to develop and report double the Stage 2 required number of CQMs (16) across the large systems
 - Physician adoption of discrete data documentation continues to be poor, if not rejected entirely; many health care systems continue to struggle with implementing electronic physician documentation in general, but particularly when documentation of discrete data is required; this does not fit physician workflow and is a major provider dissatisfier. More time is needed to develop acceptable provider documentation solutions

•

- Current efforts of collaboration or interrelationships with vendors and measure developers in regards to feasibility testing.
 - Vendor testing of CQMs in coordination with NQF should include testing at multiple client sites of varying sizes and with varying product use (e.g. hospitals with disparate information systems)
 - Propose that NQF recommend that ONC require vendors to certify for all eMeasures
 - Consideration of incentives to vendors for working with NQF and other vendors (not necessarily financial)



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Environmental Scan – Provider

Phone Interview

A vertically integrated multispecialty group of 70 providers; qualified as Level 3 medical home

Allscripts EHR system for 5 1/2 years; each department has selected 3 quality measures – generally from NQF/PQRS/NCQA; some internal measures

Measures from own queries and ad hoc reports; some vendor packages

No interface with hospitals

Clinical workflow issues: clinicians only responded to financial incentives

Vendor was more helpful when it was smaller

Recommendations: Pilot test measures in multiple practice types: solo, medium, large, multispecialty, academic

Would consider being a test site if given some compensation or manpower assist/support

Integrated system: more than 400 clinics and hospital locations in 4 states; fully integrated EMR; core measure, PQRS, MU – intends to meet all measures and requirements

Central EMR (EPIC): Implementation of MU1

- Analysis of discrete data elements
 - For some measures chose more strict standards
 - Manually developed additional specificity
- To comply required workflow changes and some manual abstraction
- Limited impact on workflow;
- lots of physician pushback – not using discrete data fields
 - Restructured user interface
- For MU2 – trying to move away from any manual abstraction

Other quality and safety measures:

- Interest in areas where there are no measures – create their own if necessary; challenging
 - Example: blood loss as a complication of surgery
 - Where documented- no central location; acute or chronic; is it truly a complication?
- Implementation often gets lost in the weeds of caveats, “minor criteria” (often exclusions); can’t always figure out a way to automate it and so rely on manual abstractors
- Limited help from vendors – they are focused on meaningful use
- Experience with vendor products—did not meet their needs
 - Lucky to have resources to develop own software to abstract data and present it in meaningful ways
 - Need data governance structure

Large integrated system

- bringing together multiple information systems that have all been tweaked is an overwhelming mapping exercise
- Lab info system brought into the EMR
- Example: Ejection fraction result is in a specific information system – struggle to integrate into the EMR – still a manual process; trying to figure out the cost-effective approach – major technological investment to integrate disparate systems or changes in workflow – not yet resolved

Moving to ACOs

- Their system can move data from the office to the hospital
- Challenges with getting data from remotely managed patients

- Vast differences in technological capabilities in the rural setting
- Limits on data allowed from FDA certified devices – not readily compatible with EMR

What do they need from eMeasures?

- Clear data elements – to be able to translate to a discrete location
- Standardization of data: ex – mammogram – claims is what is paid for but quality wants more: done, read, responded to
- Would love “plug and play” measures from the vendors

HIT Standards

- HL7 messages lack standardization
- Struggles with sharing data from different vendors – different philosophies and willingness to cooperate
- Standards are only recommendations

Vendor: Allscripts

Contact: Leigh Burchell, Vice President, Government Affairs

1. Your general approach to feasibility testing for implementing eMeasures into (EHRs)

Within the Allscripts organization, eMeasures serve as the guiding templates for establishing defined workflows within the EHR, provide mandates around the specific codes required from a calculation standpoint, and overall are the backing documents to support our general user community. As measures are developed, consistent data definitions and complete code set/code identification is critical to implementation within the EHRs.

2. How you assess the impact of eMeasure implementation and workflow issues

Because each eMeasure has unique characteristics as it relates to code sets and descriptions, each one is carefully reviewed by both clinical specialists and software developers to evaluate any potential gaps between the required code sets in the eMeasure and the existing functionality and data within the EHR. Each measure is then mapped to the workflow within the EHR. Through the mapping process, the clinical specialist then identifies the intricacies of each measure and defines a best practice approach for coding the measure calculation. He or she also outlines a best practice approach for clinicians to implement that eMeasure into their day-to-day workflows.

3. Assessment of short-term versus long-term feasibility of an eMeasure's implementation

From a short term standpoint, eMeasures play a critical role in the success of developing and deploying a set of measures for a given program. Having immediate reference to the measures to assess EHR gaps, identify the level of effort and allocate resources to build a program based on measures is a priceless asset.

From a long term standpoint, there are a variety of concerns with continuing to use eMeasures. Although having a singular platform that allows for measure consumption and validation across all EHR settings is essential to the success of developing quality measures, the seemingly continual change of quality measures is challenging to follow and resource accordingly. Our clients expect to remain consistent with the best practice workflows, but at the same time, they tell us that changes in the measure definitions and calculations cannot require changes in the day-to-day workflow within the EHR. We strongly support the need to align measures across federal and private sector program by using the same or harmonized measures. This alignment must, however, also include the technical data definitions. We would like to see this theme further developed in the future.

4. How feasibility testing fits in to your business cycle and development of products

Feasibility testing is a routine part of an eMeasure implementation from review to deployment. Prior to presenting eMeasures to developers for build, clinical specialist identify the impact of each measure to

be able to begin discussing the forthcoming changes with clients. Prior to deployment, each developed measure will go through a rigorous quality control cycle to ensure the established workflows (through the eMeasure review) are followed and the expected results are rendered. In addition to the quality control cycle, each eMeasure goes through an early adopter and early validation process that involves our clients.

5. Current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures.

A large part of our success with providers and users is the solicitation of feedback through our early adopter and early validation programs. Through these programs, providers and users alike have an opportunity to test the developed eMeasures and provide feedback, allowing optimization of the measures and identification of ways to better fit newly developed workflows into a provider's day-to-day practices. Within each program, all respective parties (product developers, QC, product owners) are involved with the feedback process.

Vendor: EPIC

Contact: Sasha TerMaat

Your general approach to feasibility testing for implementing eMeasures into (EHRs)

Staff members (both software developers and clinicians) familiar with the capabilities of our software and common use of our software review measure specifications for what data elements are required to compute the measure. We ask these questions:

1. Are all of the data elements required by the measure logic currently captured in common EHR workflows? If yes, then the measure is feasible. If no, continue to question 2.
2. Can the data elements required by the measure logic be computed by the EHR based on data elements currently captured in common EHR workflows? If yes, then the measure is feasible. If no, continue to question 3.
3. Is there a natural place to add necessary new data elements required for the measure logic in existing common EHR workflows? If yes, the measure will be feasible once such data elements can be developed, implemented, and trained (likely 1-2 years). If not, then the measure will not be feasible for at least 2 years.
4. Some data elements are things that must be manually abstracted based on other information (for example, “has the patient ever had an unexplained terminated pregnancy?”) or that are not going to be stored in an EHR (for example, information about healthcare staffing levels). Measures including such elements will never be feasible for EHR reporting.

There are many measures we are pressured to implement regardless of feasibility assessments. For example, measures that are part of high priority or required programs for our users, such as Meaningful Use or PQRS, are often implemented in the EHR even if the data elements required do not fit well into existing common EHR workflows and are burdensome to clinical users.

How you assess the impact of eMeasure implementation and workflow issues

Staff assess as described above. Workflow issues are generally obvious. We recommend to our users workflows that we think will be as minimally burdensome as possible. We also receive frequent feedback from clinician users of our software regarding their use of the documentation tools and quality reports.

Assessment of short-term versus long-term feasibility of an eMeasure’s implementation;

Occasionally we assess that a quality measure might be challenging in one earlier version of our software and easier in a later version.

How feasibility testing fits in to your business cycle and development of products; and

Feasibility assessment is not generally related to our business cycle and development of products. It is performed in relation to the release of new quality measure specifications and the deadlines for implementation of new or updated measures, as we complete designs for how the measures will be developed and create workflow recommendations for the measures for our users.

If we are considering support for a net new measure set, one factor considered in prioritization of supporting new measures is the feasibility of capturing the required data.

Current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures.

We are occasionally contacted by measure developers or their contractors with questions or to provide feedback on whether measures being developed are feasible for EHR implementation. We appreciate being consulted for our feedback and would like to be able to help measures selected for federal programs be more EHR feasible. However, participation is often challenging.

1. It is not always clear to us in advance when our input will be solicited.
2. Our input is often requested on a short timeline.
3. Each time our input seems to be solicited in a different format. There is not consistency in what we are asked to evaluate or how we should evaluate it.
4. Sometimes our input is solicited at the wrong point in the measure development. For example, if our input is requested early in the development of a measure, not all of the data elements might be available for us to evaluate, and this can be key to assessing feasibility. However, if our input is requested late in the development of a measure, it might be too late for the measure to be significantly revised based on feedback.
5. Finally, we do not always see that our efforts in this area have impact.

Sometimes users of our software are requested to participate in feasibility testing. Such requests can be challenging for our users to accommodate, especially if the expectation is that they test the measure with real EHR data.

Given our experience with quality measurement reporting, we suggest the following approach for feasibility assessment.

First, identify a particular set of data elements that are currently commonly captured in EHR workflow. This might build upon work already done in comparing the QDM Style Guide to meaningful use requirements for certification, for example. Measures using only data elements that are part of that “2014 Common Set” could be established as feasible for users of 2014 certified software.

Second, identify the set of data elements that are not already currently captured in EHR workflow but are desired for reporting certain measures. With industry input from clinicians and EHR vendors, prioritize such data elements into categories. For example, some such elements might be added to 2016 EHR certification. Other such data elements might be designated as appropriate for specialty modules but not appropriate for general EHR certification. This work would allow EHR developers to plan development of their systems to gradually enlarge the set of feasible and supported measures. EHR developers could also competitively differentiate based on support of certain specialty data sets or early support of data sets not required until future certification stages.

In this way, we suggest that feasibility assessment be of the data elements required to be captured or computed by the EHR, and not specific to individual measures being proposed. Assessment could be performed initially based on the list of data elements and then applied to new measures as developed.

Vendor: GE Healthcare

Contact: Mark Segal

Responses from GE Healthcare. Mark noted “that in general, the questions were more suited to measure developers. We do not have formal processes for ‘feasibility testing’ for eMeasures. The below reflects how we are approaching feasibility issues.”

Your general approach to feasibility testing for implementing eMeasures into (EHRs):

1. Data Mapping: Reverse mapping of value set code to EHR internal vocabulary to see if there is any candidate EHR terms representing the eMeasure data element.
2. Data Profiling: Investigate real in-use customer data statistics to see the candidate EHR terms are in use.
3. Traceability of Workflows that may capture data using these internal EHR terms.
4. Concepts must be “map-able” to standard taxonomies to support export requirements. This is both a mapping issue and a pre-coordination issue (mapping to precise terms).
5. State transitions must be preserved along with timing information. This raises the bar for tracking and extracting historical information (that’s not to mention any issues related to corrections to historical data).
6. Timing is often subjective and sometimes not available – when did you first experience this problem? “Fuzzy” dates, an uncooperative or unconscious patient, etc.

How you assess the impact of eMeasure implementation and workflow issues:

1. If there are existing appropriate workflows that capture the required eMeasure data, assess the impact on guiding users to use those workflows.
2. If there is no existing workflow, assess the appropriate way to introduce new/to modify existing in order to capture the data.

Assessment of short-term versus long-term feasibility of an eMeasure’s implementation

1. Short-term feasibility: eMeasure data elements are captured through current existing EHR terms and workflows. The existence and appropriateness of the term and workflow are the targets of assessment.
2. Long-term feasibility: eMeasures that users may consider important to their practices and willing to capture related data elements in their workflows.

How feasibility testing fits in to your business cycle and development of products

1. There is no formal ‘feasibility testing’. We have validation testing that determines whether the developed products meet the user’s need and intended use.

Current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures

1. User collaboration meetings on measure preference and internal EHR term identification/mapping.

Vendor: Greenway Medical

Contact: Jason Colquitt, Vice President, Data Services

Your general approach to feasibility testing for implementing eMeasures into (EHRs)

1. We assess the individual data elements of the measure.
2. Analysis per element takes place on if gap exist, unstructured data may exist in the various workflows, or if data is discretely captured in order to calculate from.

How you assess the impact of eMeasure implementation and workflow issues

1. We analyze each workflow per the data element and document those so that users are clear as to how we are processing the measure.
2. If a gap or clarity needs to be gained we many times have new functionality to create.

Assessment of short-term versus long-term feasibility of an eMeasure's implementation

1. I assume the meaning for short-term versus long-term feasibility here is allowing a certain workflow that may not be optimal until the new functionality can be released.
2. This is determined by the lead time given until the measure needs to be in production.

How feasibility testing fits in to your business cycle and development of products

1. This is the first step in our development iterations and informs the latter development iterations

Current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures

1. We have been engaged with several measure developers in relation to their MU 2 feasibility testing.
2. We are also engaged through the EHRA to collaborate on any EHR specific industry issues that need to be addressed.
3. We are active with PCPI, NQF, and HITSC in regards to emeasurement activities.

Vendor: McKesson
Contact: Ginny Meadows

**NQF eMeasure Feasibility Environmental Scan
Responses 10/22/2012**

The National Quality Forum (NQF) is launching a new project to assess the current state of feasibility testing for new and retooled eMeasures, and identify a set of principles and criteria for adequate feasibility testing. As part of the project, NQF is conducting an environmental scan of approaches to feasibility testing from measure developers, government contractors, electronic health record (EHR) vendors, and providers.

NQF would appreciate your input and asks you to answer the following:

1. Your general approach to feasibility testing for implementing eMeasures into (EHRs);

The steps that McKesson follows when implementing eMeasures are explained in our response to question #2, where we describe our process to assess the impact of implementing each eMeasure to both the EHR and to the provider workflow. However, at that point in the eMeasure development and implementation process, it is much too late to assess the actual feasibility of the eMeasure, as this should take place during the measure development process. Through our experience in implementing eMeasures, and working with measure developers, providers, and other stakeholders, we offer our recommendations on the actual feasibility testing that should be performed during the measure development phase.

The quality measurement community in general is still in the early stages of transforming from manual to eMeasurement, and is retooling measure specifications designed for manual data capture. There are two main components to a measure – the measure narrative supported by scientific evidence and the measure specification supported by clinical concepts and statistical logic. As part of the NQF endorsement process, these components are reviewed and endorsed as a whole. The endorsed measure, both intent and specifications as written are the property of the measure developer. Original specifications include value definitions for clinical concepts and statistical logic instructions for use with manually abstracted records. These instructions are interpreted by medical record professionals to perform this reporting. To adapt to the world of automated abstraction through electronic medical records, the measure developers, having invested significant time, labor and financial resources to achieve endorsement, may conform or “retool” these existing endorsed specifications to simply make the current value sets and logic machine-readable. Unfortunately, electronic health records require specifications and instructions that recognize the specific code sets and documentation workflows required of these systems. Measure developers must be allowed the ability to create EHR-readable specifications without jeopardy to their measure endorsement status. Each measure developer designs data models independently and debate is ongoing as it relates to competing approaches such as

whether to use an exception or an exclusion model for measure specifications. As a result, measures are not yet optimized for automation and inclusion within an EHR. The creation of “de novo” eMeasures should be strongly encouraged in order to avoid some of these challenges and ambiguities in retooling abstracted or claims-based quality measures.

In general, we recommend that early in the measure development process, eMeasures should be evaluated to ensure that clinical workflows can efficiently and accurately capture the necessary data as a byproduct of the routine provision and documentation of patient care. We encourage the collaboration between measure developers, providers and vendors during the measure development process to help validate this process, and in our response to question #5, we speak more specifically about our experience with such collaborative pilots.

In addition, the Quality Data Model (QDM) Style Guide was created as a companion document to the Quality Data Model (QDM) Update (June 2012) to specifically address the feasibility of QDM components in EHRs certified for the 2014 EHR Certification Program. We are encouraged by the intent of this document to provide direction to measure developers on the feasibility and availability of specific data elements within a 2014 Certified EHR, and hope that it is utilized by all measure developers during the eMeasure development process.

We also recommend that each eMeasure specification include expected/exemplar workflows and data sources. This would help define expectations both in single practice physician offices and community hospitals as well as within integrated delivery networks. Such guidance would not only assist in the interpretation and implementation of the measures by providers and EHR developers, but would provide a quality check on the logic itself as well as a “sniff test” for reasonableness and alignment with clinical and operational workflows.

eMeasures should undergo a rigorous test process prior to including them in Meaningful Use criteria. As defined in the Healthcare Information Management System Society (HIMSS) eMeasures recommendations sent to HHS in January 2012, both controlled testing and field testing of the eMeasure specification should be part of the measure development and endorsement process. Controlled testing of the eMeasure specification should ensure the feasibility, validity and accuracy of each eMeasure when implemented in an EHR.

Field testing of the eMeasure specification should be done in order to validate at least the following:

- The eMeasures specifications are accurate, with the correct clinical category defined and mapped to the correct vocabulary standards (taxonomy) and codes, along with the correct attributes and state(s).
- The eMeasures are tested for validity and reliability against the measure’s intent.
- Required data elements can be efficiently and accurately gathered in the healthcare provider workflow, if at all possible using data elements that are already collected as a byproduct of the care process and stored in the EHR.
- CQM reports based on eMeasures accurately reflect the care given by the applicable healthcare provider(s).

2. How you assess the impact of eMeasure implementation and workflow issues;

We will answer this from the perspective that we have as a measure implementer, and the steps we follow to assess the impact of implementing each eMeasure specification to both the EHR and to the provider workflow. As we pointed out in our response to question #1, at this point in the eMeasure development and implementation process, it is much too late to assess the actual feasibility of the eMeasure. However, because we are not participants in the eMeasure development process, we have no ability to do any assessment of the eMeasure until we have the detailed specifications, which come very late in the overall measure development and implementation process.

We follow several processes when evaluating the eMeasure specification:

1. Evaluation of specific components of the specification, including the HQMF and measure logic, to ensure we can consume the measure into our measure engine, and calculate the measure result with consistency and accuracy.
2. Evaluation to ensure that the required data elements are available in our existing EHR(s), using the correct terminology and value sets
 - This includes the evaluation of any exclusion or exception logic to ensure that the expected data is available, and does not require suboptimal data collection processes from the provider in order to satisfy the logic.
 - During this process, we build detailed data flow documents that replicate both the measure logic and the different EHR products that contain the required data elements.
3. Impact to provider workflow, and consideration of the most optimal data collection methods in order to satisfy the measure data requirements.
 - During this process, we build extensive “user guides” for our customers

In general, we were challenged by many of the Stage 1 measure specification requirements, and are hopeful that we will see improvements in the feasibility area of the Stage 2 measure specifications, although they are not yet available. For example, only an extremely robust and fully integrated billing/medical records/EHR product could actually capture all of the required data elements for the Stage 1 inpatient measures. To illustrate some of challenges, we cite 3 measures, with supporting examples:

- NQF 0495: ED 2.3 Emergency Department Throughput Stratified by Diagnosis (Stage 1 inpatient measure)
 - While seemingly simplistic and easily supported by either a complete EHR, or an Emergency Department Information System (EDIS) certified as modular EHR technology, as illustrated, this measure in fact requires information from multiple products: hospital billing/medical records system, inpatient EHR, and an EDIS or ED module of a complete EHR. An EDIS alone would not support either the required inpatient admission time or the discharge diagnosis for this measure.
- NQF 0036: Use of Appropriate Medications for Asthma (Stage 1 EP measure)

- While listed as a single measure, this is actually 4 different specifications, each of which is reported as 3 age stratifications. The full specification references over 600 RxNorm codes to be administered in a range of combinations.
- NQF 163: Primary PCI Received Within 90 Minutes of Hospital Arrival (Finalized for Stage 2)
 - We do not believe that the QDM today supports the level of granularity required for some of the measure logic.
 - Much of the source data for this measure is derived from cardiology information systems, which are not routinely well integrated into the EHR, and may not be using the coding standards required by the EHR incentive program. While the base EHR may include the necessary QDM data elements to capture or incorporate the cardiology data, this would not represent a normal workflow.
 - The current version of the specification, which we realize is not the final one, mixes billing and EHR data, and seems to expect indications of ordinality for procedures which are not available within the EHR itself.

3. Assessment of short-term versus long-term feasibility of an eMeasure's implementation;

McKesson is assuming that this question refers to the current capabilities and adoption of EHRs versus the future capabilities and adoption levels. Using that definition, we will first address eMeasures that depend on longitudinal data. While McKesson recognizes the value in being able to measure outcomes longitudinally, this requires a level of inter-operability and health information exchange well in excess of the current state of technology adoption and deployment. Most longitudinal measures depend on either robust information exchange or on the availability of a comprehensive longitudinal record that may include a mixture of both EHR and claims data. Health information exchange offers a way to bridge providers and ownership issues, but at present are limited in utility due to limited availability of data exchange, and are subject to the boundaries of a patient or provider's participation in a given information exchange.

An additional concern regarding the use of longitudinal measures is that, for programs such as meaningful use, the measures are used to evaluate the quality of care demonstrated by a healthcare provider. Longitudinal measures often require data that is not produced by or under the control of the care provider. While technical solutions are being developed for the exchange of health information among providers, there is no governance regarding the responsibility for the integrity or security of the patient data across multiple health care settings and providers. In addition, some measures assume availability of EHR functionality and data codification that are not commonly in use today. For example, some of the radiology measures assume the availability of structured radiology results coded in SNOMED. Radiology information systems were not included in the Stage 1 objectives for meaningful

use, and do not universally support such coding. Even where SNOMED coding is supported, it is still not widely adopted.

Measures that span both settings of care and providers also raise the question of attribution and data ownership. In the inpatient setting today, hospitals struggle with issues of attribution for manually abstracted measures. Where care is rendered across multiple shifts under the direction of hospitalist physicians, questions arise over which physician is responsible for compliance or non-compliance with a measure. This is even more complex in the ambulatory setting, where a typical Medicare patient may see more than five physicians in a given time period. Many of the proposed eMeasures raise complex methodological and attribution issues which further complicate the data sharing concerns. For example, NQF measure 004 looks at initiation and continued treatment for substance abuse across multiple providers and settings. Yet it is unclear from the measure logic which provider is responsible for reporting and how data is to be reliably shared across what may be multiple providers, who may, in fact, be competitors, may use different EHRs, and today may not have any kind of information exchange with one another.

It appears that some measure developers have tried to address the issue of attribution by moving reporting responsibility to individual physicians. While commendable, the result is a problematic workflow burden. For example, measure 270, *Perioperative Care: Timing of Prophylactic Antibiotics*, is currently a manual inpatient measure for which a hospital is responsible. The proposed retooled measure moves the ownership to the individual surgeon. As written, this will require the physician's office to take on the burden of data collection and reporting for data largely collected in the inpatient setting. In fact, the guidance for the measure indicates that it will require an abstract from the inpatient record.

4. How feasibility testing fits in to your business cycle and development of products; and

We welcome the opportunity to work with the measure developers, and have found this to be a very effective means of collaboration in the development of health IT-enabled measurement. There are several ways that this can happen. First, as technical expert panels (TEPs) are formed to begin the development of new measures, vendor representatives should be included on those panels. In addition, vendors should be involved in the field testing and piloting of the measures. Collaboration between the measure developers and EHR developers provides a critical step in the successful development of de novo eMeasures, and provides the opportunity for education among different stakeholders. EHR vendors and the customers they support may well be open to participation in feasibility testing in order to improve measure functionality.

5. Current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures.

Health IT vendors already play an active role in relevant standards development efforts, including the S&I framework and the HL7 Structured Documents workgroup. We believe we can also provide essential education and support to measure developers. We have found that measure developers are not always knowledgeable about technical aspects and practical workflow of EHRs, which hinders effective insight into measure development. For example, some of the measure developers participating in the NQF eMeasure Learning Collaborative have indicated they have little knowledge of the relevant taxonomies and code sets required for use in an EHR or how to use them effectively in measures. Our discussions with measure developers reveal a need for more education and understanding on their part about the development and use of EHRs. In turn, we could benefit from earlier participation in the measure development process with a greater understanding of the measure's intent and logic, and gain valuable education and insight to the process.

Funding measure developers to develop new "de novo" eMeasures should be a high priority, and CMS has already taken steps in this direction by awarding contracts for development of some de novo measures. One such contract, through Abt Associates, was for the development of five new Meaningful Use Stage 2 measures for the inpatient setting. Abt worked with both a technical expert panel and EHR vendor participants to help guide the development of the eMeasure specifications.

This type of collaboration between the measure developers and other stakeholders, such as EHR developers, standards organizations, and providers, is critical to the successful development of eMeasures, and provides the opportunity for education between the different stakeholders. McKesson welcomes the opportunity to assist with these collaborative efforts to provide the perspective and experience that we have as EHR developers and implementers.

In addition, vendors actively participate in professional associations such as HIMSS, AMIA and AHIMA to support clinical quality initiatives. Through these venues, multidisciplinary perspectives are heard and through a collaborative process recommendations for improvement are developed. These organizations provide a ready audience for rapid turnaround response to questions as they arise.

Fundamentally, we need to provide tools, education, and knowledge-sharing to support both the development of de novo measures, and the retooling of existing measures so that measure developers are fully aware of the unique opportunities and challenges associated with health IT-based measures, and the clinical workflow implications that may be introduced. Organizations like the National Quality Forum (NQF) and CMS, that use measures, should strongly encourage measure developers to develop de novo e-measures, and should facilitate feedback to the measure developers that reinforces the value provided by the measures.

Vendor: MEDITECH

Contact: Melissa Swanfeldt, Associate Vice President

Your general approach to feasibility testing for implementing eMeasures into (EHRs)

MEDITECH's experience with e-measure testing is related exclusively to Meaningful Use. We follow these steps.

1. Comprehensive review of e-measure specifications and value sets to determine the data to be captured
2. Identify workflow for data capture within the EHR and clinical applications such as physician documentation, nursing documentation, pharmacy, laboratory etc
3. Work with a panel of customers (clinicians) to review workflows and provide input into data capture process. (goal is to embed data capture into the clinician workflow with as much ease as possible)
4. Map workflow/data capture process to appropriate nomenclature standards
5. Create SQL report and test calculations with test set of patients

How you assess the impact of eMeasure implementation and workflow issues

Meditech has an interdisciplinary team that includes MEDITECH knowledge experts, and customer clinical experts that review the specifications and defines best practice workflows for data capture.

Assessment of short-term versus long-term feasibility of an eMeasure's implementation

Short term assessment includes review of all e-measures proposed for Meaningful Use to insure that MEDITECH's clinical products have the capabilities to capture the data needed for measure calculation including creating best practice workflows and improving our nomenclature mapping tools so that our system can be flexible as new nomenclature standards and value sets are introduced. Long term goals are to create streamlined reporting tool that make e-measure adoption simpler for our customer base.

How feasibility testing fits into your business cycle and development of products

As part of our meaningful use product enhancements we have created flexible tool sets that allow for streamlined data capture that is embedded into clinician's workflow, we feel our tool sets can support a large spectrum of data capture and are flexible to support changes in e-measures as well as de novo measures.

Current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures

Our efforts have focused exclusively on meaningful use measure preparedness. In addition to our customer panel we also work with Medisolv, a strategic alliance of MEDITECH on data capture best practice workflows. For

nomenclature mapping standards we work with IMO (Intelligent Medical Objects) to insure comprehensive coverage of nomenclature/value sets in our systems.

Vendor: NextGen

Contact: Sarah Corley, MD, Chief Medical Officer

Per Dr. Corley: “the main issue on failure to get responses is that no one is really providing us with consumable eMeasures right now so we really can’t answer these questions all that well.”

Your general approach to feasibility testing for implementing eMeasures into (EHRs)

Feasibility testing would probably go through 2 phases. The first would be to have a user import the eMeasure using our current tool used for creating a new measure native to our application. Gaps in the data element inclusion would need a development effort to include these, as well as a development effort to capture any data elements not currently available to report on. The second phase would most likely be an automated import of the measure after a review of the appropriate medical staff. A comparative analysis would be needed to compare the manual entry to the automated (dual reports) for accuracy.

How you assess the impact of eMeasure implementation and workflow issues;

Not sure. Currently a lot of effort goes into analyzing measures, mapping to appropriate fields, and assuring we have the required code sets before we can code the measure and calculate it. Anything that could speed that up would be helpful but we have not yet seen anything that we can consume without developing something new.

Assessment of short-term versus long-term feasibility of an eMeasure’s implementation;

Current resource constraints on development resources would make it difficult to take on any new tasks related to measure development that could not be immediately plugged into place. Data analytics of eMeasure calculations would need to be run against a baseline for current adherence to a manual generation (current measure calculation and alerts to users) to see if any additional value was gained in patient health over a population. It is feasible that the benefits of importing eMeasures is efficiency at the Practice (and EHR Development) as opposed to population health being improved. Those efficiencies would have to have a positive ROI on development efforts.

How feasibility testing fits in to your business cycle and development of products; and Current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures.

With ICD10 and MU2, resources are strained at most EHR companies. I don’t see how this would be prioritized in the short term.

Vendor: Siemens**Contact: Karen Nielsen**

We realize that there are multiple types of feasibility testing:

- Is this a test that is done before a measure is fully defined to understand its feasibility?
- Is this a test for identifying if an existing measure is a viable candidate for re-tooling as eMeasure?
- Is this for existing measures that are already mandated?

As an EHR vendor, we believe eMeasure Feasibility is determined by

1. if data elements are routinely captured by most providers in the routine course of care & captured for patients for which these data are needed;
 2. at what point in the care process are they collected;
 3. is the data structured or unstructured;
 4. is the data derived or does it require inference;
 5. did the measure author conceptualize the data and way the EMR conceptualizes the data match?
- I. Your general approach to feasibility testing for implementing eMeasures into (EHRs):
 - We would perform a generic assessment of how likely the data elements are to be captured in "our" system
 - and evaluate our customer's processes that would be impacted
 - II. How you assess the impact of eMeasure implementation and workflow issues;
 - We would have to look at any data elements that are not routinely captured and assess how they could be captured and what that would require on our behalf and on our customer's behalf.
 - III. Assessment of short-term versus long-term feasibility of an eMeasure's implementation;
 - Discrete value available in electronic format but usually in devices or standalone special software systems.
 - EF from Echocardiogram and PR or QT intervals in EKG
 - Structured data captured but available in a different setting of care/EHR system
 - Retail Pharmacy dispensing data
 - Data usually captured on paper and not electronically
 - Ambulance/EMT records
 - IV. How feasibility testing fits in to your business cycle and development of products; does not currently fit. We implement after the regulatory requirements are communicated
 - V. Current efforts of collaboration or interrelationships with developers and providers in regards to feasibility testing of eMeasures. none ~ vendors have not traditionally participated in measure development or testing

From a testing perspective, eMeasures would ideally have:

- eMeasures must have HQMF supplied for feasibility testing
 - no information should be provided in the Guidance with respect to measure calculation that is not accounted for in the HQMF
- Value Sets
 - vocabulary of the value sets should be provided
 - sample values within the value sets should be provided
- Calculation
 - sample data and expected result should be provided, either in QRDA level 1 format or as documentation of the values in the QDM