NATIONAL QUALITY FORUM

TO: NQF Members

FR: Karen Pace, PhD, RN

RE: Review of *Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties*

DA: June 14, 2010

Background

The National Quality Forum (NQF) relies on four criteria for evaluating the suitability of quality measures for endorsement as voluntary consensus standards. The second criterion, *Scientific Acceptability of Measure Properties,* is an important aspect of the successful use of publicly reported measures to improve performance. Scientific acceptability of measure properties refers to the reliability and validity of measures. In evaluating a measure, both empirical evidence and expert judgment play a role. However, judgment can best be applied when those evaluating a measure have a thorough understanding of the evidence of scientific acceptability that does or does not exist. Evidence that a clearly specified measure produces credible results on performance comes from the basic measurement principles of reliability and validity.

The NQF Task Force on Measure Testing was asked to address the following tasks.

- Identify the type of testing that should be conducted for various types of measures and data sources, and determine whether there are any acceptable alternatives to formal testing.
- Identify the type of testing that should be required prior to endorsement of measures specified for electronic health records (EHRs), both measures originally developed using other data sources besides the EHR and measures developed de novo for EHRs.
- Develop guidance for measure stewards/developers and NQF technical advisors and steering committees on adequate measure testing, interpretation of results, and information about testing that should to be provided in the measure submission.
- Make recommendations for potential enhancements to the evaluation criteria.

The Task Force's recommendations are included in the draft document, *Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties*. The draft report is posted on the NQF web site for review and comment only—not voting.

You may post your comments and view the comments of others on the NQF website.

NQF Member comments must be submitted no later than 6:00 PM ET, July 13, 2010; public comments are due 6:00 PM ET, July 6, 2010.

NQF is now using a program that facilitates electronic submission of comments on this draft report. **All comments must be submitted using the online submission process.**

Supporting documents related to your comments may be submitted by e-mail to performancemeasures@qualityforum.org with "Measure Testing Report" in the subject line and your contact information in the body of the e-mail.

Thank you for your interest in the NQF's work. We look forward to your review and comments.

NATIONAL QUALITY FORUM

Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties

Draft Report for Review and Comment

June 14, 2010

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INTRODUCTION AND CHARGE

The National Quality Forum (NQF) relies on four criteria for evaluating the suitability of quality measures for endorsement as voluntary consensus standards. The second criterion, *Scientific Acceptability of Measure Properties*, is an important aspect of the successful use of publicly reported measures to improve performance. Scientific acceptability of measure properties refers to the reliability and validity of measures. The use of measures that are unreliable or invalid undermines confidence in measures of both the providers of healthcare and the consumers of the information. The goal of this document is to provide recommendations on what constitutes scientific acceptability of measures to assist those participants in the measure evaluation process, including steering committees and technical advisory panel members, as well as measure developers. Guidance on scientific acceptability will facilitate a shared understanding of this complex and highly specialized subject.

In evaluating a measure, both empirical evidence and expert judgment play a role. However, judgment can best be applied when those evaluating a measure have a thorough understanding of the evidence of scientific acceptability that does or does not exist. Evidence that a clearly specified measure produces credible results on performance comes from the basic measurement principles of reliability and validity. Although reliability and validity have always been included in NQF evaluation criteria, the criteria have not included specific guidance on 1) the scope of testing, 2) what tests of reliability and validity could be performed, and 3) how to weigh the results of this testing.

Task Force Charge

The NQF Task Force on Measure Testing was asked to address the following tasks.

- Identify the type of testing for scientific acceptability that should be conducted for various types of measures and data sources, and determine whether there are any acceptable alternatives to formal testing.
- Identify the type of testing that should be required prior to endorsement of measures specified for electronic health records (EHRs), both measures originally developed using other data sources besides the EHR and measures developed de novo for EHRs.

- Develop guidance for measure stewards/developers and NQF technical advisors and steering committees on adequate measure testing, interpretation of results, and information about testing that should be provided in the measure submission.
- Make recommendations for potential enhancements to the evaluation criteria.

BACKGROUND

NQF endorses quality measures intended for quality improvement as well as public reporting. Measure scores are used to make decisions about selecting and rewarding healthcare providers (e.g., by consumers and purchasers) and identifying opportunities for quality improvement (e.g., by providers). The level of confidence one can have in conclusions about quality based on the measure scores is a function of the reliability and validity of measurement, as well as the display used to report performance on the measure.

The NQF measure evaluation criteria can be viewed as a hierarchy for evaluating measures.

> "If a measure is not important, its other characteristics are less meaningful. If a measure is not scientifically acceptable, its results may be at risk for improper interpretation. If a measure is not interpretable [usable] we probably do not care if it is feasible. If a measure is not feasible, alternative approaches to acquiring important information should be considered (p. I-40)."[1]

Once a measure has been determined to meet the criterion of *Importance to Measure and Report*, it is evaluated on the criterion, *Scientific Acceptability of Measure Properties*. This criterion addresses the basic measurement principles of reliability and validity. The NQF evaluation criteria parallel best practices for measure development, which include testing reliability and validity. [2, 3]

NQF's measure evaluation criteria include a variety of types of evidence as indicated in Table 1. The criterion, *Scientific Acceptability of Measure Properties*, addresses ***how*** the healthcare quality concept is measured. This criterion includes reliability (2b) and validity (2c), as well as precision of specifications (2a) and potential threats to valid conclusions about quality related to exclusions (2d), risk adjustment for outcome and resource use measures (2e), methods to

discriminate performance (2f), and comparability of results from different data sources (2g). The other subcriteria include specifications to detect disparities (2h).

Table 1. Measure Evaluation Criteria and Type of Evidence

Evaluation Criteria	Sources of Evidence
1.Importance to Measure and Report 1a. High impact	Epidemiologic data Health services research
1.Importance to Measure and Report 1b. Opportunity for improvement	Epidemiologic data Health services research
1.Importance to Measure and Report 1c. Evidence that supports the focus of measurement	Clinical research Health services research
2.Scientific Acceptability of Measure Properties 2a-h. Reliability and validity	Psychometric testing—reliability and validity, adequacy of risk adjustment, etc.
3. Usability 3a. Demonstration of understanding and usefulness for public reporting and quality improvement	Data and/or qualitative information demonstrating understanding and usefulness for public reporting and quality improvement
4. Feasibility 4e. Demonstration the measure can be implemented	Data and/or qualitative information demonstrating the measure can be implemented

Reliability and Validity

A quality measure is a numeric quantification of the relatively abstract construct of quality of healthcare, which is measured imperfectly. Reliability refers to the ***repeatability and reproducibility of measure scores for the same population in the same time period***. Validity refers to the ***correctness of conclusions about quality*** that can be made based on the measure scores. Over the past four to five decades numerous methods have been devised to test measures and thus address the measure performance issues inherent to all measurement. These approaches provide empirical evidence of the properties of reliability and validity. Examples of approaches to reliability and validity testing can be found in Table A-1 (Appendix A).

A measure score reflects a theoretical 'true score" plus error (or noise): The more error, the less reliable and valid is the measurement. Random or chance errors affect the reliability or repeatability of measurement and systematic errors affect the validity or correctness of the

conclusions one can make based on the measure score. Threats to reliability include ambiguous measure specifications (including definitions, codes, data collection, and scoring) and statistical issues such as sampling and small case volume. Threats to validity include unreliability and other aspects of the measure specifications and data such as inappropriate exclusions, lack of appropriate risk adjustment or risk factors for outcomes and resource use, specifications for multiple data sources or methods that result in different scores and conclusions about quality, and systematic missing or "incorrect" data. Most importantly, a measure may be invalid because the measurement has not correctly captured the concept of quality it was intended to measure.

Reliability and validity are not all-or-none properties; rather, measures of reliability and validity produce graduated results. Therefore, results of measure testing always require interpretation. Reliability and validity are not static; they are influenced by the conditions under which the measures are used. A discussion of measurement concepts can be accessed in an online research methods knowledge base.[4] Rubin et al.[3] describe reliability and validity testing in quality measure development. Examples of validity testing of healthcare quality measures also are reported in the literature.[5, 6]

The concept of reliability can be applied to both the computed performance measure score (e.g., rate, proportion, average) and the individual data elements used in a measure (e.g., diagnosis, medication, admission date, birth date). Reliability is considered necessary, but not sufficient, for achieving a valid measure. A measure could be repeatable, but lead to incorrect conclusions and would therefore be invalid. In addition, if a measure is not repeatable, a valid conclusion about quality would not be possible.

Evaluation of the scientific acceptability of a measure does not occur in a vacuum. The Task Force was aware of factors within the current environment impacting their deliberations. The recommendations of the Task Force would have implications for both measure developers and healthcare providers. For example, some observers have suggested that existing measure evaluation criteria are too stringent (the perfect being the enemy of the good) while others have suggested that the criteria are not rigorous enough. Some contend that providers use adherence

to the measure evaluation criteria as a barrier to making performance information available; others maintain that unless a measure has adequate measure properties it cannot provide useful information. Nonetheless, the consequences of using unreliable or invalid measures can at times be significant for those being measured as well as those who use the information to select a healthcare provider. Resources may be wasted or misdirected; and there is potential for invalid measures to result in misinformation and misdirection of patients or potential unintended harmful consequences. As the stakes around quality measurement are raised, the potential for conflicts among these perspectives increases. The Task Force therefore made a deliberate attempt to make recommendations that balanced the requirement for insuring that NQF endorsed measures would be both sufficiently reliable and valid to make them meaningful and minimize unintended consequences, with requirements for testing that were not so high as to stifle measure development and innovation.

Reporting of Measure Scores and Scientific Acceptability

NQF does not determine the specific use or reporting formats of the measures it endorses. Nonetheless, the scientific acceptability of a measure can be related to the context in which the measure is used and the choices made in reporting performance measure scores. For example, Kaplan and colleagues [7] demonstrated that the number of categories chosen for performance reporting (e.g., high/medium/low) influences the likelihood of misclassification. Misclassification is, by definition, an invalid reporting of performance. Reporting performance from highest to lowest without information on margin of error and meaningful differences limits and may misrepresent the knowledge to be gained from measures. Further, those choosing to report measures may decide to combine the measures in order to simplify reporting, making the metrics more accessible and usable for consumers. These combined measures also have potential to be misleading. [8] Because NQF endorsement does not dictate how the measures are used, the Task Force was not asked to make recommendations on reporting but these issues are highlighted for further discussion and assessment.

Measure Testing Issues Identified with Measures Submitted to NQF

The Task Force understood their charge as emerging from several years of NQF experience with measure evaluation. This experience, enumerated below in six points, informed the Task Force's

recommendations. First, the NQF portfolio of endorsed measures shows considerable variation in the level of rigor used in measure testing. Measure developers are currently expected to address these requirements in a way that is most appropriate and feasible for the measure and data source involved. Nonetheless, some developers submit limited information on reliability or validity testing perhaps due to a lack of expertise or resources. On the other hand, other measure developers have conducted formal reliability and validity testing and have demonstrated that a proposed measure generates reproducible results and credible conclusions about quality.

Second, when reliability and validity testing results have been submitted, there has been variability in the scope of testing and the rigor of methods and statistical analysis. For example, reliability of categorical data elements may be assessed only as the percentage of agreement between raters versus using the kappa statistic, which adjusts for chance agreement. In some cases, the testing was conducted with a particular data source, such as the paper medical record, while the measure was specified using a different data source, such as electronic health record.

Third, there also has been some confusion regarding what is considered testing of scientific acceptability. Terms such as "measure testing," "pilot testing," and "field testing" are commonly used in the discipline of measure development and include reliability and validity testing, as well as other aspects of measure development. For example, measure submissions may include descriptive statistics that demonstrate the data are available and can be analyzed to produce scores, but do not specifically address reliability or validity.

Fourth, some submissions rely on an assumption of reliability and validity. This assumption may be based on prior use of the measure or some aspects of the measure specifications (e.g., diagnosis codes are relatively well defined and used in accordance with coding rules). In some cases an argument is made that a data source would become more reliable and valid if a quality measure was implemented and publicly reported.

Fifth, measure developers rarely submit analyses justifying exclusions or demonstrating comparability of different methods of data collection.

Sixth, steering committees may variably weigh the strengths and weaknesses of the evidence for reliability and validity in their recommendation for endorsement. In summary, while NQF has been raising the bar of expectations and introducing greater rigor and standardization to the evaluation process, the NQF portfolio of endorsed measures still includes varying levels of methodological rigor.

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 electronic health records 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, and 3) decrease the burden of the data collection through automated collection and aggregation.

While the concepts of reliability and validity apply equally to measures derived from EHRs, the electronic health record also presents additional issues related to measure testing. Widespread EHR data are not available for measure development and testing. In addition, the numerous vendors and home grown EHR systems presents the additional challenge of insuring that the selected data fields of interest for any particular measure are comparable among different EHRs. Recommendations regarding testing and evaluation of EHR measures is addressed in Section III.

Summary of Background

- There are no perfect quality performance measures and there will be some error in all measurement. Performance measurement science is an imperfect science.
- Measurement principles of reliability and validity apply to quality performance measures regardless of data source.

- Reliability and validity are not all-or-none properties and involve a matter of degree.
- Reliability and validity can apply to individual data elements used in a measure, as well as the computed measure score.
- Reliability is necessary but not sufficient for validity (i.e., reliability is about repeatability of data or scores (even if incorrect); validity is about the "true" or correct values for data elements and conclusions about quality). Measure scores that are mainly determined by random error (noise) are misleading and lead to unwarranted conclusions about quality.
- NQF is ultimately concerned with endorsing measures that produce scores from which valid (i.e., correct) conclusions about the quality of care can be made.
- A measure that is not a valid indicator of quality is not useful for making decisions about selecting healthcare providers based on quality or investing time and resources into improvement.
- There is no one definitive test for reliability or validity because reliability and validity testing results can vary under the conditions of implementation.

RECOMMENDATIONS

The recommendations in this report are intended to provide additional guidance and clarification regarding the NQF criteria related to measure testing. They are not intended to provide a detailed primer on methods for measure testing. The recommendations also are not intended as a definitive scoring system for measure evaluation. Evaluation still requires judgment regarding the adequacy of the empirical testing evidence. The recommendations should promote greater consistency in applying the NQF criteria, while maintaining consideration of multi-stakeholder perspectives during the evaluation.

I. Recommendations for Empirical Evidence of Reliability and Validity

Before developing guidance on the specific testing criteria, the Task Force was asked to consider a fundamental question of whether reliability and validity need to be demonstrated empirically or could be assumed or agreed upon through various review or consensus processes. The Task Force recommended that ***empirical evidence of reliability and validity should be expected for measures endorsed by NQF***.

Although precise specifications provide a foundation for consistent implementation and thus increase the likelihood of reliability, reliability cannot be assumed. Although evidence for the measure focus (NQF criterion 1c) provides a foundation for the validity (NQF criterion 2c) of the measure as an indicator of quality, the way a measure is specified can affect the validity of the conclusions about quality.

Implementation and reporting of measures is expected to lead to improvements in documentation, data coding, and data capture and thus reliability and validity. This assumption of improved reliability and validity over time applies to all measures regardless of data source; however, it does not negate the need for reliability and validity to be demonstrated empirically when a measure is being considered for endorsement.

Recommendations for measures specified for EHRs are addressed in a separate section (Section III) because they are newer and there are several differences from other data sources. For example, the clinician is often the source of data in EHRs and the data are intended for use in care management. However, these distinctions are not absolute and the same issues of demonstrating scientific acceptability apply to EHR measures, as well as measures based on other data sources. Administrative claims data and EHR data are often combined to assess performance and may be viewed as complementary sources of information, each with their own strengths and limitations.

Although the Task Force was clear about the recommendation for empirical evidence of reliability and validity, it also recognized the practical implications of this assertion for measure developers. The Task Force therefore, further recommended some strategies that could minimize the burden of testing as follows.

- Evidence for reliability and validity may be accumulated over time and evaluators should remain flexible with regard to the extent of evidence submitted. The scope of testing may be on a relatively small scale for initial endorsement, followed by further analyses to support continued endorsement at the time of review for maintenance of endorsement.

- Reliability and validity testing may be conducted on a sample of the measured entities. The analytic unit of the particular measure (e.g., physician, hospital, home health agency) determines the sampling strategy for scientific acceptability testing. The sample should represent the variety of entities whose performance will be measured. The sample should include adequate numbers of units of measurement and patients to answer the specific reliability or validity question with the chosen statistical method. Testing requirements for maintenance of endorsement are addressed in Section V.
- Reliability and validity testing may be conducted for either the data elements used to calculate the measure score or the computed measure score to achieve an acceptable rating for endorsement. Although ideally testing is conducted for both the critical data elements and the computed measure score, only one level of testing would be required for endorsement.
- Reliability testing of data elements could be bypassed if empirical validity testing of the data elements demonstrates acceptable validity.
- Prior evidence of reliability or validity of data elements for the data source specified in the measure (e.g., hospital claims) can be used as evidence for those data elements.
- Because validity testing of measure scores can be quite burdensome, a formal and systematic testing of face validity of the measure score as an indicator of quality (see Table A-2) could be acceptable for validity of measure score.

The Task Force further acknowledged that there are degrees of reliability and validity and the following guidance distinguishes ideal testing and evidence from what is acceptable for endorsement by NQF. Measures without empirical testing of reliability and validity should be considered untested measures and subject to NQF's conditions for considering untested measures for endorsement. Untested measures are addressed in Section IV.

II. Recommendations for the Type of Testing and Results Needed to Demonstrate Scientific Acceptability of Measure Properties

As noted in the first set of recommendations, the Task Force recommended that empirical evidence of reliability and validity are required for measures considered for NQF endorsement. How should participants in the evaluation process assess the evidence provided when

measures are submitted? The Task Force chose to provide guidance on measure testing through the development of criteria to rate the reliability and validity of measures being considered for endorsement. This approach requires well-defined descriptions of the rating scheme to reduce ambiguity and miscommunication. While the Task Force has tried to achieve this precision, it recognizes that there will inevitably be some ambiguity and room for interpretation. In addition, the descriptions may require further clarification and/or revision. Finally, the Task Force was not able to fully assess the impact of the proposed rating system on the measure endorsement process. So, this proposed approach to evaluating scientific acceptability of measure properties should be monitored to ensure it achieves the intent of endorsing reliable and valid measures and does not unduly impede endorsement of measures.

The Task Force chose to provide guidance on evaluating *Scientific Acceptability of Measure Properties* using a two-step process. First, guidance is provided on how to rate the evidence for reliability and validity. Second, guidance is provided on how to use the ratings to determine if the criterion of *Scientific Acceptability of Measure Properties* is met.

Table 2 provides the guidance for rating the level of evidence for reliability and validity, which is classified as high, moderate, or low. The ratings depend on both the type of testing conducted and the results of testing meeting acceptable norms.

The rating scheme is structured around a distinction between testing the data elements used to calculate a measure (e.g., diagnosis, procedure, age) and the computed measure scores (e.g., rate, proportion, average). Some measures rely on many data elements. Testing at the data element level does not necessarily need to be conducted for every single data element, but should include those elements that are most critical to the computed score.

Testing at either the level of data elements or the computed measure score with acceptable results is rated moderate and would be acceptable for endorsement. Testing at both levels of data elements and computed measure score with acceptable results is rated high. The low rating represents inadequate testing or inadequate testing results. As noted previously, untested

measures would not be rated on reliability and validity and special considerations for untested measures are addressed in a separate section (see Section IV).

Table 3 presents the Task Force's recommendation on how the ratings for reliability and validity are used to determine whether a measure adequately meets the criterion of *Scientific Acceptability of Measure Properties*. Moderate ratings for both validity and reliability as described in Table 2 would be required to pass this criterion and be acceptable for endorsement.

335 Table 2. Evaluation Ratings for Reliability and Validity

Rating	Reliability	Validity
High	All measure specifications (e.g., numerator, denominator, exclusions, risk factors, scoring) are unambiguous and likely to consistently identify who is included and excluded from the target population and the event, condition, or outcome being measured; how to compute the score, etc.; **AND** Empirical evidence of reliability of both data elements and measure score: • Data element reliability statistics for critical data elements and measure score are within acceptable norms (tested, or reported in the literature for the same data source); **OR** commonly used data elements with little question of reliability (e.g., gender, age, date of admission); **OR** *may forego data element reliability testing if data element validity demonstrated*; **AND** • Measure score reliability (precision) 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: • Data element validity statistical testing results are within acceptable norms; **AND** • Measure score validity testing demonstrates a statistically significant result for the hypothesized performance of the measure score; **AND** Identified threats to validity (lack of risk adjustment/stratification, multiple data sources/methods, systematic missing or "incorrect" data, statistical methods) are empirically assessed and adequately addressed in measure specifications
Moderate	All measure specifications are unambiguous as noted above **AND** Empirical evidence of reliability 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 for either data elements **OR** measure score as noted above; **OR** Systematic assessment of face validity of measure score as a quality indicator 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 empirically assessed and adequately addressed in measure specifications
Low	One or more measure specifications (e.g., numerator, denominator, exclusions, risk factors, scoring) are ambiguous with potential for confusion in identifying who is included and excluded from the target population, or the event, condition, or outcome being measured; or how to compute the score, etc.; **OR** Empirical evidence of low reliability for either data elements **OR** measure score – reliability statistics outside of acceptable norms	The measure specifications (numerator, denominator, exclusions, risk factors) do not reflect the quality of care problem (1a,1b) and evidence cited in support of the measure focus (1c) under Importance to Measure and Report; **OR** Empirical evidence of low validity for either data elements **OR** measure score **OR** Inadequate assessment of face validity: • Face validity assessed only by the developer or one group; **OR** • Face validity did not explicitly address the question of whether 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 **OR** Threats to validity as noted above are considered likely and are NOT empirically assessed

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Table 3. Evaluation of Scientific Acceptability of Measure Properties Based on Reliability and Validity Ratings

Validity Rating	Reliability Rating	Pass *Scientific Acceptability of Measure Properties* for initial endorsement	
High	**Moderate-High**	**Yes**	Evidence of reliability and validity
	Low	No	Represents inconsistent evidence—reliability is necessary for validity
Moderate	**Moderate-High**	**Yes**	Evidence of reliability and validity
	Low	No	Represents inconsistent evidence—reliability is necessary for validity
Low	Any rating	No	Validity of conclusions about quality is the primary concern. If evidence of validity is low, the reliability rating will usually also be low. If validity is low and reliability is moderate-high, it represents inconsistent evidence.

Common approaches to testing reliability and validity for the data elements as well as the computed measure score that can be applied to quality performance measures are provided in Appendix A (Tables A-1 and A-2). The type of testing mentioned is those that ***could*** be performed—not what is required. Measure developers should select the testing that is appropriate and feasible for the measure under consideration and that will meet the moderate rating as described in Table 2. Table A-2 also addresses potential testing and analysis related to the threats to validity represented by other subcriteria under *Scientific Acceptability of Measure Properties*. Measure developers should identify the potential threats to validity for the specific measure and conduct analyses to demonstrate adequate control. Information on interpretation of the common statistical tests used to demonstrate reliability and validity also are provided in Appendix A (Table A-3); however, those norms provide only general guidelines and testing results must be interpreted within the unique context of the specific measure.

The information on approaches to testing is not meant to provide an exhaustive list of methods. Other approaches to testing may be appropriate and could be used if the method and rationale are explained and judged to be appropriate. For example, if agreement on data elements between two time periods is proposed as a test of reliability, the rationale for expecting stability (rather than change) over the time period is important to discuss. Stability over time might be more plausible for the characteristics of patients served than for interventions provided. However, calculation of measures scores and descriptive statistics, or the fact that a measure has been in use do not constitute empirical evidence of reliability or validity. Such information may

be relevant to the criteria of opportunity for improvement (1b) and usability of the measure (3a); but alone does not provide information about the reliability or validity of the measure scores.

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 are entered directly into standardized computer readable fields, the EHR will be considered the authoritative source of clinical information and legal record of care. Quality measures based on EHRs require exporting clinical information recorded by healthcare clinicians from discrete computer readable fields; therefore, measurement errors due to manual abstraction, coding by persons other than the originator, or transcription are eliminated. The potential sources of error that pose threats to the reliability and validity of data elements and measure scores for EHR measures include: 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; and 4) incorrect parsing of data by natural language processing software used to analyze information from text fields. All of these potential errors except those from parsing technology 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. Just as for other measures, Table 3 indicates how the ratings are used to make a determination if the criterion, *Scientific Acceptability of Measure Properties* has been met for EHR measures. Testing approaches for reliability and validity of the EHR measure score are the same as for any measure as noted in Tables A-1 and A-2.

There are two differences highlighted in Table 4. First, EHR measures must be specified in accordance with the Quality Data Set (QDS). [9] The QDS will be updated on a regular basis so if

a measure needs a quality data element not currently available, there will be a process to consider additional quality data elements.

Second, data elements for quality measures, which are extracted from EHRs using computer programming, are by virtue of automation repeatable (reliable); therefore, testing at the data element level should focus on validity as discussed below. This would be consistent with the rating system presented for Table 2, where reliability of data items may be bypassed if validity of data items is demonstrated.

An approach to testing validity of data elements analyzes 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 literature [10-12] and by HealthPartners in a Commonwealth report [13] on performance measures and EHRs. 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 that should return the known values of the data elements and scores in the simulated data set.

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, they 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, the error would not amenable to changes to the EHR measure specifications but may necessitate the need for further evaluation and refinement of the measure.

The recommended approach for evaluating reliability and validity of data elements for EHR measures takes into account the current environment in which standards for EHRs and EHR measures are under development and widespread adoption is not yet reality. Therefore, testing sites are limited and testing in a sample of EHR systems may not be representative of others.

However, this is no different than testing of data elements for measures based on other data sources in a sample of the measured entities. 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 should be true to the principles of scientific acceptability. EHRs and EHR measures are new and will most likely require some adjustment of local EHR structures and recording practices to meet standards. Therefore, two recommendations regarding implementation are offered.

- There should be a period of time when measure scores are reported only to providers so that they correct any discrepancies in their systems and practices before public reporting begins.
- 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 specification for EHRs. Although these endorsed measures should have already been tested for reliability and validity, the EHR measure specifications require some assessment of 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 is needed.

443 Table 4. Evaluation of Reliability and Validity of Measures Specified for EHRs

	New Measure Specified for EHR		Modifications for Endorsed Measures Re-specified for EHRs
Rating	Reliability Description and Evidence	Validity Description and Evidence	
High	The EHR measure specifications use only data elements from the quality data set (QDS) * and include quality data elements, code lists, and measure logic; **AND** Empirical evidence of reliability of both data element and measure score: • Data element reliability (repeatability) assumed with computer programming – should test data element validity **AND** • Measure score 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: • Data element validity demonstrated by analysis of agreement between data elements (and computed scores) exported electronically and data elements (and computed scores) 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 computed measure score; **AND** • Measure score validity testing demonstrates a statistically significant result for the hypothesized performance of the measure score; **AND** Identified threats to validity (lack of risk adjustment/stratification, multiple data sources/methods, systematic missing or "incorrect" data, statistical methods) empirically assessed and adequately addressed in measure specifications	The EHR measure specifications use only data elements from the quality data set (QDS) * and include quality data elements, code lists, and measure logic; **AND** Crosswalk of the EHR measure specifications (QDS quality data elements, code lists, and measure logic) to the endorsed measure specifications confirms 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
Moderate	The EHR measure specifications use only data elements from the QDS as noted above; **AND** Empirical evidence of reliability for either data elements **OR** measure score as noted above	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 for either data elements **OR** measure score as noted above; **AND** Identified threats to validity noted above empirically assessed and adequately addressed in measure specifications	The EHR measure specifications use only data elements from the QDS as noted above **AND** Crosswalk of the EHR measure specifications (QDS data types, code lists, and measure logic) to the endorsed measure specifications confirms that they represent the original measure, which was judged to be a valid indicator of quality **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.
Low	The EHR measure specifications do not use only data elements from the QDS; **OR** Empirical evidence of low reliability for either data elements **OR** measure score – reliability statistics outside of acceptable norms	The EHR measure specifications (numerator, denominator, exclusions, risk factors) do not reflect the quality of care problem (1a,1b) and evidence cited in support of the measure focus (1c) under Importance to Measure and Report; **OR** Empirical evidence of low validity for either data elements **OR** measure score **OR** Threats to validity as noted above are considered likely and are NOT empirically assessed	The EHR measure specifications do not use only data elements from the QDS; **OR** Crosswalk of the EHR measure specifications to the endorsed measure specifications identifies 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

444 ***QDS elements should be used when available. When needed quality data elements are not yet available in the QDS,**
445 **they will be considered for addition to the QDS.**

IV. Recommendations Related to Untested Measures

Measures without empirical evidence of reliability and validity are considered untested. Untested measures are only eligible for time-limited endorsement if the conditions for considering time-limited endorsement are met.

- An incumbent measure does not address the specific topic of interest in the proposed measure;
- A critical timeline must be met (e.g., legislative mandate); and
- The measure is not complex (e.g., composite, requires risk adjustment).

In addition to passing the criterion, *Importance to Measure and Report*, untested measures must demonstrate an adequate foundation for both reliability and validity as follows. Measures that do not meet these minimum requirements are not ready for testing and should not be recommended for time-limited endorsement.

Table 5. Minimum Requirements for Untested Measures under Scientific Acceptability of Measure Properties

Foundation for Reliability	Foundation for Validity
All measure specifications (e.g., numerator, denominator, exclusions, risk factors, scoring) are unambiguous and likely to consistently 1) identify who is included and excluded from the target population; 2) identify the event, condition, or outcome being measured; 3) compute the measure score; etc.	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*

V. Recommendations for Additional Testing Required for Maintenance of Endorsement

The above guidance on testing and evidence of reliability and validity is for initial endorsement decisions. With the new system of endorsement cycles, currently endorsed measures will be reviewed for maintenance of endorsement every three years along with new measures. Both new and endorsed measures will be required to meet the measure evaluation criteria, including reliability and validity. Recognizing that reliability and validity are not static properties, no one test is definitive, evidence is accumulated over time, and the proposed rating system allows endorsement for measures with limited evidence of reliability and validity, the Task Force agreed that reliability and validity should be evaluated when measures are reviewed for

continued endorsement. For measures that are already endorsed, the evidence needed for reliability and validity may vary based on the following considerations:

- whether data are available from implementation;
- and the extent of testing and evidence provided at the time of initial endorsement.

The Task Force requests comments on what evidence of reliability and validity should be required for review for maintenance of endorsement.

VI. Recommendations for Modifications to the NQF Evaluation Criteria

The suggested changes to the evaluation criteria reflect the recommended guidance. Criterion 2, *Scientific Acceptability of Measure Properties*, is primarily about reliability and validity and threats to reliability and validity. This criterion is simplified by focusing on the concepts of reliability and validity and arranging the subcriteria to reflect their relationship to reliability or validity as follows. The changes to the current criteria are redlined.

Reliability

Precise specifications (2a) including exclusions (2d)

Reliability testing (2b)—data elements or measure score

Validity

Validity testing (2c)—data elements or measure score

Justification of exclusions (2d)—relates to evidence

Risk adjustment (2e)

Comparability of data sources/methods (2g)

Identification of differences in performance (2f)

Disparities (2h)

2. Scientific acceptability of the measure properties: Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. [See footnotes below the criteria]

2a. Reliability

2a1. The measure (with exclusions) is well defined and precisely specified [6] so that it can be implemented consistently within and across organizations and allow for comparability. ~~The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP).~~ EHR measure specifications are based on the quality data set (QDS). [7]

~~2b~~2a2. Reliability testing [8] demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

2b. Validity

2b1. The measure specifications [6] are consistent with the evidence presented to support the focus of measurement under criterion 1c. The measure is specified to capture the most inclusive target population indicated by the evidence.

2~~c~~b2. Validity testing [9] demonstrates that the measure correctly reflects the quality of care provided, adequately ~~distinguishing~~ identifying good and poor quality. ~~If face validity is the only validity addressed, it is systematically assessed.~~

2~~e~~b3. For outcome measures and other measures (e.g., resource use) when indicated:

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care; [11,13] and has demonstrated adequate discrimination and calibration

OR

- rationale/data support no risk adjustment.

2~~f~~b4. ~~Data a~~Analysis of computed measure scores demonstrates ~~that methods for scoring and analysis of the specified measure allow for identification of~~ statistically significant and practically/clinically meaningful [14] differences in performance OR overall poor performance. ~~[does this fit with reliability (small case volume, rare event issues), or validity, neither?]~~

2~~g~~b5. If multiple data sources/methods are ~~allowed~~ specified, there is demonstration they produce comparable results.

2b6. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);
OR
rationale/data justifies why stratification is not necessary or not feasible.

2~~d~~c. ~~Clinically necessary~~ If measure exclusions are ~~identified and must be:~~ not indicated by the clinical evidence (1c, 2b.1), they are supported by evidence [10] of sufficient frequency of occurrence so that results are distorted without the exclusion;

~~AND~~

~~•a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus [11];~~

AND

- ~~precisely defined and specified:~~
  - ~~if there is substantial variability in exclusions across providers, the measure is specified so that~~ Specifications for scoring include computing exclusions ~~are computable and~~ so that the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);

AND

  - ~~i~~If patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent [12] (e.g., numerator category computed separately, denominator exclusion category computed separately).

~~**2h.** If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);~~
~~OR~~
~~rationale/data justifies why stratification is not necessary or not feasible.~~

Evaluation Criteria Footnotes

6 Measure specifications include the target population (~~e.g.,~~ denominator) to whom the measure applies, identification of those from the target population who achieved the specific measure focus (~~e.g.,~~ numerator, target condition, event, outcome), measurement time window, exclusions, risk adjustment/stratification, definitions, ~~data elements,~~ data source, code lists with descriptors, ~~and instructions,~~ sampling, scoring/computation.

7 EHR measure specifications include data type from the QDS, code lists, EHR field, measure logic data flow diagram, original source of the data, recorder, and setting.~~The HITEP criteria for high quality data include: a) data captured from an authoritative/accurate source; b) data are coded using recognized data standards; c) method of capturing data electronically fits the workflow of the authoritative source; d) data are available in EHRs; and e) data are auditable. NQF. *Health Information Technology Expert Panel Report: Recommended Common Data Types and Prioritized Performance Measures for Electronic Healthcare Information Systems*. Washington, DC: NQF; 2008.~~

8 Reliability testing ~~may address~~applies to both the ~~data item~~data elements ~~or~~ and ~~final~~ computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

9 Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the information. Examples of validity testing of the measure score include, but are not limited to~~:~~ testing hypotheses that the measures scores indicate quality of care, e.g., ~~determining if~~ measure scores ~~adequately distinguish between~~ are different for ~~providers~~ groups known to have ~~good or poor~~ differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures).~~ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests~~. ~~Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality).~~ If face validity is the only validity addressed, it is systematically tested using a modified Delphi or other process that is open to peer review, e.g., RAND Appropriateness Method, ACC/AHA method) ~~assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic~~.

10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

11Risk factors that influence outcomes should not be specified as exclusions.

12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

VII. Recommendations for the Measure Submission

Following are suggested modifications to the information that is currently requested on the measure submission form based on the recommended guidance and questions and issues that have arisen with the current submission form. The changes to the current submission items are redlined.

Measure Specifications (Measure evaluation criterion 2a)

2a.1. Numerator Statement *(Brief ~~text~~ narrative description of the numerator - what is being measured about the target population, e.g., target condition, event, or outcome)*

2a.2. Numerator Time Window *(The time period in which cases are eligible for inclusion in the numerator)*

2a.3. Numerator Details *(All information required to collect the data~~or~~ required to calculate the numerator, including definitions and all codes with descriptors~~, logic, and definitions~~)*

2a.4. Denominator Statement *(Brief narrative~~text~~ description of the denominator - target population being measured)*

2a.5. Target Population Gender

Female Male

2a.6. Target Population Age Range

2a.7. Denominator Time Window *(The time period in which cases are eligible for inclusion in the denominator)*

2a.8. Denominator Details *(All information required to collect the data~~or~~ required to calculate the denominator~~, - the target population being measured -~~ including definitions and all codes with descriptors~~, logic, and definitions~~)*

2a.9. Denominator Exclusions *(Brief ~~text~~ narrative description of exclusions from the target population)*

2a.10. Denominator Exclusion Details *(All information required to collect the data required for exclusions to the denominator, including all definitions and codes with descriptors~~, logic, and definitions~~)*

2a.11. Stratification Details/Variables *(All information required to stratify the measure including the stratification variables, all definitions and codes with descriptors~~, logic, and definitions~~)*

2a.12. Risk Adjustment Type

No risk adjustment necessary – measure is not an outcome or resource use measure
No risk adjustment necessary – rationale and analysis provided in Section 2e
stratification/analysis by subgroup – see variables in 2a.11
statistical risk model – specifications 2a.14
~~case-mix adjustment~~
~~paired data at patient level~~
~~risk-adjustment devised specifically for this measure/condition~~
~~risk-adjustment method widely or commercially available~~
Other (specify)

2a.14. Specifications for Statistical Risk Model and ~~Adjustment Methodology/~~Variables *(Name the statistical method (e.g., logistic regression) and ~~L~~list the risk ~~adjustment~~ model variables all definitions and codes with descriptors. ~~and describe conceptual models, statistical models, or other aspects of model or method~~ Development and testing are reported in Section 2e)*

2a.15. Detailed Risk Model *(Please provide a web page URL or attachment. NQF strongly prefers URLs. Attach documents only if they are not available on a web page and keep attached file to 5 MB or less.)*

2a.18. Type of Score

count
frequency distribution
non-weighted score/ composite/scale
rate/proportion
ratio

weighted score/ composite/scale
categorical
continuous variable
Other (please indicate)

2a.20. Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

better quality= higher score
better quality = lower score
better quality = score within a defined interval
passing score defines better quality

2a.21. Measure Score Calculation Algorithm *(Describe the calculation of the measure score as a ~~flowchart or~~ series of steps, including identification of denominator, exclusions, identification of numerator, stratification or adjustment, and classification category)*

2a.22. Measure Algorithm or Flow Diagram *(Please provide a web page URL or attachment. NQF strongly prefers URLs. Attach documents only if they are not available on a web page and keep attached file to 5 MB or less.* ~~**Describe the method for discriminating performance** *(E.g., significance testing)*~~

2a.23. Sampling (Survey) Methodology

If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey, and guidance on minimum sample size (response rate).

2a.24. Data Source *(Check the sources for which the measure is specified and tested)*

Documentation of original self-assessment
Electronic administrative data/claims
Electronic clinical data
Electronic Health/Medical
External audit
Lab data
Management data
Organizational policies and procedures
Paper medical record/flow-sheet
Pharmacy data
Public health data/vital statistics
Record Registry data
Special or unique data
Survey: Patient
Survey: Provider

2a.25. Data Source or Collection Instrument *(~~Identify~~ Name the specific data source or data collection instrument, E.g. name of database, clinical registry, collection instrument, etc.)*

2a.26. Data Source or Collection Instrument Reference *(Please provide a web page URL or attachment. NQF strongly prefers URLs. Attach documents only if they are not available on a web page and keep attached file to 5 MB or less.)*

2a.29. Data Dictionary or Code Table *(Please provide a web page URL or attachment. NQF strongly prefers URLs. Attach documents only if they are not available on a web page and keep attached file to 5 MB or less.)*

2a.32. Level of Measurement/Analysis *(Check the level for which the measure is specified and tested)*

Clinicians
Individual
Group
Other
Facility/agency
Health plan
Integrated delivery system
Multi-site/corporate chain

Population
National
Regional/network
States
Counties or cities
Prescription drug plan

Program
Disease management
Quality improvement organization (QIO)
Other

Can be measured at all levels
Other

2a.36. Care Setting *(Check the settings for which the measure is specified and tested; check all that apply.)*

Ambulatory Care Home
Ambulatory surgery center Hospice
Office Hospital
Clinic Long term acute care hospital
Emergency Department Nursing home (NH) /skilled nursing facility (SNF)
Hospital Outpatient Rehabilitation facility
Assisted living
Behavioral health/psychiatric unit All settings
Dialysis facility Unspecified or "not applicable"
Emergency medical services/ambulance
Group homes
Other

2a.38. Clinical Services *(Healthcare services being measured; check all that apply.)*

Behavioral Health
Mental health
Substance use treatment
Other

Clinicians (*Continued*)
Podiatrist
Psychologist/LCSW
PT/OT/Speech

Clinicians
Audiologist
Chiropractor
Dentist/Oral surgeon
Dietician/Nutritional professional
Nurses
Optometrist
PA/NP/Advanced Practice Nurse
Pharmacist
Physicians (MD/DO)
Respiratory Therapy
Other

Dialysis
Home health
Hospice/palliative care
Imaging
Laboratory
Other

Reliability Testing (Measure evaluation criterion 2b)

2b.1. Data Sample *(Description of data sample and size)*
2b.2. Analytic Methods *(~~Type~~ Method of reliability testing and rationale~~, method for testing~~)*
2b.3. Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*

Validity Testing (Measure evaluation criterion 2c)

2c.1. Data Sample *(Description of data sample and size)*
2c.2. Analytic Method *(~~Type~~ Method of validity testing and rationale~~, method for testing~~)*
2c.3. Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted)*

Measure Exclusions (Measure evaluation criterion 2d)

2d.1. Summary of Evidence Supporting Exclusion(s)
2d.2. Citations for Evidence
2d.3. Data Sample *(Description of data sample and size)*
2d.4. Analytic Method *(Type of analysis and rationale)*
2d.5. Testing Results *(~~E~~e.g., frequency, variability, sensitivity analyses of impact on measure scores)*

Risk Adjustment Strategy (Measure evaluation criterion 2e)

2e.1. Data Sample ~~from Testing or Current Use~~ *(Description of data sample and size used for development and validation)*
2e.2. Analytic Method *(~~Type of risk adjustment, analysis and rationale~~Describe methods for development and testing of risk model including selection of risk factors)*
2e.3. Testing Results *(Quantitative assessment of relative contribution of model risk factors; Risk model performance metrics including cross-validation calibration and discrimination statistics, and assessment of adequacy in the context of norms for risk models. Provide calibration curve and risk decile plot in attachment.)*
2e.4. If outcome or resource use measure is not risk adjusted, provide rationale

Identification of Meaningful Differences in Performance (Measure evaluation criterion 2f)

2f.1. Data Sample from Testing or Current Use *(Description of data sample and size)*
2f.2. Methods to Identify Statistically Significant and Practical or Meaningful Differences in Performance *(Type of analysis and rationale)*
2f.3. Measure Scores from Testing or Current Use *(Description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance. If no variability, discuss rationale for performance measurement, e.g., benchmark for determining overall poor performance.)*

Comparability of Multiple Data Sources/Methods (Measure evaluation criterion 2g)

2g.1. Data Sample *(Description of data sample and size)*

2g.2. Analytic Method *(Type of analysis and rationale)*
2g.3. Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted~~E.g., correlation statistics, comparison of rankings~~)*

Disparities in Care (Measure evaluation criterion 2h)

2h.1. If measure is stratified to identify disparities, provide stratified results *(Scores by stratified categories/cohorts)*
2h.2. If disparities have been reported/identified but measure is not specified to detect disparities, provide follow-up plans

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APPENDIX A – COMMON APPROACHES TO TESTING

Tables A-1 and A-2 provide information on the various types of reliability and validity testing that ***could*** be performed. Table A-2 also addresses testing and analysis related to the threats to validity represented by other subcriteria under *Scientific Acceptability of Measure Properties*. The information in the following tables is not meant to provide an exhaustive list of methods. Other approaches to testing may be appropriate and could be used if the method and rationale are explained and judged to be appropriate. Measure developers should select the testing that is appropriate and feasible for the measure under consideration and that will meet at least the moderate rating as described in Table 2. Likewise, measure developers should identify the potential threats to validity for the specific measure and conduct analyses to demonstrate adequate control.

The Task Force requests suggestions for references and resources on testing approaches and interpretation of results.

873 Table A-1. Common Approaches to Testing Reliability Applied to Quality Measures

Reliability Testing – Data elements	
Data Source for Computing Score	Aspect of Reliability/Test
Retrospective chart abstraction (including registry data abstracted retrospectively from medical records)	**Inter-rater reliability between abstractors** Analysis of agreement using appropriate statistical tests (e.g., kappa, ICC) with 2nd abstractor on each critical data element and computed measure score
Codes that are used to represent the primary clinical data (ICD, CPT, CPT-II/G)	**Inter-rater reliability between coders** Analysis of agreement using appropriate statistical tests (e.g., kappa, ICC) with a 2nd coder on each critical data element and computed measure score;
Standardized clinical patient information (MDS, OASIS, registry, potentially some aspects of EHRs) collected by an authoritative source concurrently with care delivery (not abstracted, coded, or transcribed by another person)	**Inter-rater reliability between assessors** Analysis of agreement using appropriate statistical tests (e.g., kappa, ICC) with 2nd assessor on each critical data element and computed measure score
EHR clinical record information	Data elements obtained with EHR specifications and data exported electronically from EHRs according to standards are repeatable (reliable) when applied to the same population in the same time period
Instrument/scale	**Internal consistency reliability (Cronbach's alpha)** Analysis of the extent to which item responses obtained at the same time correlate highly with each other
Survey—single items	Test-retest reliability Analysis of agreement between two administrations of the same items (time frame long enough so as not to remember and short enough so as not to have changed)
Other data source	Rationale should be provided for method chosen to demonstrate reliability
Reliability Testing—Measure Score	
Data	Aspect of Reliability/Test
Computed measure scores and individual patient-level data for a sample of measured entities Reliability testing of the computed measure scores does not vary by data source or type of measure	**Statistical reliability (precision) of sample average as an estimate of the underlying population average** Analysis of the relative value of variation in measure scores due to signal (i.e., variation between measured entities) versus noise (i.e., variation within measured entities) using statistical tests such as Analysis of Variance (ANOVA) or Intraclass Correlation Coefficient (ICC) Generalizability analysis based on generalizability theory on the sources of variation Other methods may be appropriate and rationale for method chosen should be provided

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875 Table A-2. Common Approaches to Testing Validity Applied to Quality Measures

Validity Testing – Data elements	
Data Source	Aspect of Validity/Test
Retrospective chart abstraction (including registry data abstracted retrospectively from medical records)	**Validity of data elements abstracted from medical record as compared to some criterion source of the same data ("gold standard")** Analysis of agreement using appropriate statistical tests (e.g., kappa, ICC) with some other source of the same information considered to be valid (e.g., original data collection such as survey or observation, vital statistics)
Codes that are used to represent the primary clinical data (ICD, CPT, CPT-II/G)	**Validity of coded data from claims as compared to some criterion source of the same data ("gold standard")** Analysis of agreement using appropriate statistical tests (e.g., kappa, ICC) with manual abstraction from the full medical record as the "gold standard"
Standardized clinical patient information (MDS, OASIS, registry, potentially some aspects of EHRs) collected by an authoritative source concurrently with care delivery (not abstracted, coded, or transcribed by another person)	**Validity of data elements from standardized assessment instruments as compared to some criterion source of the same data ("gold standard")** Analysis of agreement using appropriate statistical tests (e.g., kappa, ICC) with "expert" assessor (conducted at approximately the same time)
EHR clinical record information	**Validity of data elements extracted from specified fields in EHRs as compared to some criterion source of the same data ("gold standard")** Analysis of agreement using appropriate statistical tests (e.g., kappa, ICC) with data elements abstracted from the entire EHR (not just the fields where the data are expected) Demonstration of agreement between data elements and scores obtained by applying the EHR measure specifications to a simulated test EHR data set and the known values for the critical data elements and computed measure score
Survey – single items	**Validity of data elements from survey as compared to some criterion source of the same data ("gold standard")** Analysis of agreement using appropriate statistical tests (e.g., kappa, ICC) with some other source of the same information considered to be valid (e.g., medical record, vital statistics)
Instrument/scale	**Validity of the content of the items in an instrument or scale** Systematic assessment by subject matter experts that the content of the instrument/scale is representative of the domain being measured Confirmatory factor analysis
Other	Rationale should be provided for method chosen to demonstrate reliability

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879 Table A-2 Cont. Common Approaches to Testing Validity Applied to Quality Measures

Validity Testing—Measure Score	
Data	Aspect of Validity/Test
Computed measure scores for a sample of measured entities and other data as necessary for the chosen validity study Validity testing of the computed measure scores does not vary by data source or type of measure	**Evidence that supports the intended interpretation of measure scores for the intended purpose—making conclusions about the quality of care** Systematic testing of face validity of the measure score as a quality indicator by experts, explicitly addressed the question of whether ***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*** (using a modified Delphi or other process that is open to peer review, e.g., RAND Appropriateness Method[14], ACC/AHA method)[15] Studies to check the performance of the computed measure score against some criterion. These studies are based on a prediction about how the operationalization of the measure will *perform* based on the theory of the construct. ***Predictive*** - assess the ability of the measure score to predict something it should theoretically be able to predict ***Concurrent*** – assess the ability of the measure score to distinguish between groups that it should theoretically be able to distinguish between ***Convergent*** - examine the degree to which the measure score is similar to (converges on) other measures of the same construct or that it theoretically should be similar to ***Discriminative*** - examine the degree to which the measure score is not similar to (diverges from) other measures that it theoretically should be not be similar to
Threats to Validity—Measure Score	
Data Needed	Aspect of Validity/Test
Patient level data divided into development and validation samples	**Threat that differences in measure scores are due to differences in severity of patients served rather than differences in quality** For outcome and resource use measures, empirical evidence for the adequacy of controlling for patient factors (analysis of risk factors, discrimination and calibration of risk models); **OR** evidence that risk adjustment/ stratification is not necessary for fair comparisons (patient outcomes do not vary by patient characteristics)
Computed measure scores for each specified data source	**Threat of bias from differences in data source and/or differences in data collection practices** If multiple data sources (e.g., medical record and claims) or methods (e.g., mail survey and interview) are specified, empirical evidence that resulting measure scores are comparable (analysis of agreement between scores based on different data sources)
Patient level data	**Threat of bias from missing or "incorrect" data** Sensitivity analysis of the impact of missing or "incorrect" data on resulting measure scores (analysis of patterns of missing data; simulate missing data or "incorrect" data and analyze impact on measure scores)
Patient level data and computed measure scores	**Threat of misclassification or inability to distinguish comparative quality from measure scores related to statistical methods** Analysis of computed measure scores demonstrates the ability to identify statistically significant and practically or clinically meaningful differences in performance or overall poor performance

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882 Table A-3. Interpretation of Statistical Results

Test	Interpretation
Kappa [16, 17] Measure of agreement between two raters that adjusts for chance agreements for categorical data (nominal, ordinal)	Kappa values range between 0 and 1. 0 and are interpreted as degree of agreement beyond chance
	0 No better than chance 0.01-0.20 Slight 0.21-0.40 Fair 0.41-0.60 Moderate 0.61-0.80 Substantial 0.81-1.0 Almost perfect
ICC Alternative measure of agreement when more than two raters or quantitative data (interval, ratio)	ICC values range between 0 and 1.0 Interpretations are similar for kappa noted above ICC approaches 1.0 only if there is no variance due to raters
ANOVA or ICC Used for signal-to-noise analysis for estimated mean (or proportion) – analysis of variance between the measured entities (signal) to variance within the measured entities (noise)	F test of equality of means for measured entities; F-1 is an estimate of the ratio of signal to noise, and [1-(1/F)] estimates the fraction of total variance that is due to signal (real variation among measured entities), referred to as interunit reliability (IUR). When F is large, IUR is close to 1 indicating almost all signal and no noise. Zaslavsky [18] demonstrated that value of **F should be 10 or greater**
Cronbach's alpha Measure of the average correlation of the items comprising a scale or subscale	A widely-accepted cut-off is **.70 or higher** for a set of items to be considered a scale, but some use .75 or .80 while others are as lenient as .60. That .70 is as low as one may wish to go is reflected in the fact that when alpha is .70, the standard error of measurement will be over half (0.55) a standard deviation.
Pearson Correlation Measure of the degree of association (not agreement) between two quantitative variables	Interpretation depends on significance, size, and context. Values range from -1 to +1 The squared correlation represents the proportion of variance shared by the two variables (e.g., correlation of 0.5 represents 25% shared variance).

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APPENDIX B – TASK FORCE MEMBERS

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APPENDIX C – GLOSSARY

Data element, critical: Quality performance measures are based on many individual items of information. Testing at the data element level should include those elements that contribute most to the computed measure score (e.g., 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 largest contribution to variability in outcome.

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) [9]

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 secure, real-time, point-of-care, patient-centric information resource for clinicians.

EHR measure: An EHR measure is specified for use with electronic health records and composed of data elements from the quality data set (see below), measure logic, and machine readable specifications.

eMeasure: As defined by Health Level Seven (HL7), an eMeasure is a health quality measure encoded in the Health Quality Measures Format (HQMF) format is referred to as an "eMeasure." 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.

Empirical evidence: Analyses of data for the measure as specified, unpublished or published

Measure Testing: Empirical analysis to demonstrate the reliability (2b) and validity (2c) of the measure as specified including analysis of issues that pose threats to the validity of conclusions

about quality of care such as exclusions (2d), risk adjustment/stratification for outcome and resource use measures (2e), methods to identify differences in performance (2f), and comparability of data sources/methods (2g).

Quality Data Set (QDS): Clinical data necessary to measure quality performance. The QDS framework contains three levels of information: standard elements, quality data elements, and data flow attributes. Standard elements (e.g., diagnosis) represent the atomic unit of data identified by a data element name, a code set, and a code list composed of one or more enumerated values. The quality data element includes the standard element plus quality data type or context (e.g., diagnosis active). Data flow attributes include source (originator), recorder, setting, and health record field. [9]

Reliability: Measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period

Reliability testing: Empirical analysis of the measure as specified including the data elements and/or the computed measure scores that demonstrate repeatability and reproducibility of the data elements and computed measure scores in the same population in the same time period. Reliability testing focuses on random error in measurement and generally involves testing the agreement between repeated measurements of data elements (often referred to as inter-rater or inter-observer, which also applies to abstractors and coders); and the amount of error associated with the computed measure scores.

Reliability, threats: Some aspects of the measure specifications or the specific topic of measurement can affect reliability. Ambiguous measure specifications can result in unreliable measures. Statistical issues, such as small case volume or sample size or rare events can affect the precision (reliability) of the measure score.

Untested Measure: Measure without empirical evidence of reliability and validity. Untested measures are only eligible for time-limited endorsement if the conditions for considering time-limited endorsement are met.

Validation: Activity (testing) to determine if a measure has the property of validity. The term validation is most often used in reference to the data elements.

Validity: Measure results correctly reflect the quality of care provided, adequately distinguishing good and poor quality. A measure cannot be valid without being reliable.

Validity testing: Empirical analysis of the measure as specified including the data elements and/or the computed measure scores that demonstrate that data are correct and conclusions about quality of care based on the computed measure score are correct. Validity testing focuses on systematic errors and bias. It involves testing agreement between the data elements obtained when implementing the measure as specified and data from another source of known accuracy. Validity of computed measure scores involves testing hypotheses of relationships between the computed measure scores as specified and other known measures of quality or conceptually related aspects of quality. A variety of approaches can provide some evidence for validity. The specific terms and definitions used for validity may vary by discipline, including face, content, construct, criterion, concurrent, predictive, convergent, or discriminant validity. Therefore, the focus should be on describing the proposed conceptual relationship and test. The hypotheses and statistical tests often are based on various correlations between measures or differences between groups known to vary in quality.

Validity, threats to of conclusions about quality: In addition to unreliability, some aspects of measure specifications and data can affect the validity of conclusions about quality. Potential threats include patients excluded from measurement; differences in patient mix for outcome and resource use measures; measure scores generated with multiple data sources/methods; specifications that obscure disparities in care; systematic missing or "incorrect" data (unintentional or intentional); statistical methods used to produce estimates or identify differences in performance.

NATIONAL QUALITY FORUM

Measure Evaluation Criteria
December 2009

Conditions for Consideration
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:
A. The measure is in the public domain or an intellectual property agreement is signed.
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years.
C. The intended use of the measure includes both public reporting and quality improvement.
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 24 months of endorsement.

Criteria for Evaluation
If all four conditions for consideration are met, candidate measures are evaluated for their suitability based on four sets of standardized criteria: importance to measure and report, scientific acceptability of measure properties, usability, and feasibility. Not all acceptable measures will be strong—or equally strong—among each set of criteria. The assessment of each criterion is a matter of degree; however, all measures must be judged to have met the first criterion, importance to measure and report, in order to be evaluated against the remaining criteria.

1. Importance to measure and report: Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. ***Candidate measures must be judged to be important to measure and report*** *in order to be evaluated against the remaining criteria.*

1a. The measure focus addresses:
- a specific national health goal/priority identified by NQF's National Priorities Partners; OR
- a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

1b. Demonstration of quality problems and opportunity for improvement, i.e., data[1] demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

1c. The measure focus is:

[1] Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed[2];
  OR
- if an intermediate outcome, process, structure, etc., there is **evidence**[3] that supports the specific measure focus as follows:
  - o Intermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - o Process – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
    if the measure focus is on one step in a multi-step care process[4], it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - o Structure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - o Patient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
  - o Access – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - o Efficiency[5] – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

If not important to measure and report, STOP.

2. Scientific acceptability of the measure properties: Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented.

2a. The measure is well defined and precisely specified[6] so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) [7] .

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[2] Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, "never events" that are compared to zero are appropriate outcomes for public reporting and quality improvement.

[3] The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system – grade definitions and methods). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

[4] Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

[5] Efficiency of care is a measurement construct of cost of care or resource utilization associated with a specified level of quality of care. It is a measure of the relationship of the cost of care associated with a specific level of performance measured with respect to the other five IOM aims of quality. Efficiency might be thought of as a ratio, with quality as the numerator and cost as the denominator. As such, efficiency is directly proportional to quality, and inversely proportional to cost. (NQF's Measurement Framework: Evaluating Efficiency Across Episodes of Care; based on AQA Principles of Efficiency Measures).

2b. Reliability testing[8] demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

2c. Validity testing[9] demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

2d. Clinically necessary measure exclusions are identified and must be:

- supported by evidence[10] of sufficient frequency of occurrence so that results are distorted without the exclusion;

AND

- a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus[11];

AND

- precisely defined and specified:
  - if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
  - if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent[12] (e.g., numerator category computed separately, denominator exclusion category computed separately).

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[6] Measure specifications include the target population (e.g., denominator) to whom the measure applies, identification of those from the target population who achieved the specific measure focus (e.g., numerator), measurement time window, exclusions, risk adjustment, definitions, data elements, data source and instructions, sampling, scoring/computation.

[7] The HITEP criteria for high quality data include: a) data captured from an authoritative/accurate source; b) data are coded using recognized data standards; c) method of capturing data electronically fits the workflow of the authoritative source; d) data are available in EHRs; and e) data are auditable. NQF. *Health Information Technology Expert Panel Report: Recommended Common Data Types and Prioritized Performance Measures for Electronic Healthcare Information Systems*. Washington, DC: NQF; 2008.

[8] Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

[9] Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

[10] Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

[11] Risk factors that influence outcomes should not be specified as exclusions.

[12] Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

2e. For outcome measures and other measures (e.g., resource use) when indicated:

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care[11,13]

OR

- rationale/data support no risk adjustment.

2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful[14] differences in performance.

2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);
OR
rationale/data justifies why stratification is not necessary or not feasible.

3. Usability: Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making.

3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for <u>both</u> public reporting (e.g., focus group, cognitive testing) <u>and</u> informing quality improvement (e.g., quality improvement initiatives)[15]. An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

3b. The measure specifications are harmonized[16] with other measures, and are applicable to multiple levels and settings.

3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a

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[13] Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

[14] With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.

[15] Public reporting and quality improvement are not limited to provider-level measures – community and population measures also are relevant for reporting and improvement.

[16] Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., ***influenza immunization*** of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for ***patients with diabetes***), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare).
4. Feasibility: Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. **4a.** For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. **4b.** The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record. **4c.** Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity. **4d.** Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified. **4e.** Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality[17], etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).
If a measure meets the above criteria <u>and</u> there are competing measures (either endorsed measures, or other new submissions that also meet the criteria), compare measures on: Scientific acceptability of measure properties, Usability, and Feasibility to determine best-in-class. **5.** Demonstration that the measure is superior to competing measures – new submissions and/or endorsed measures (e.g., is a more valid or efficient way to measure).

[17] All data collection must conform to laws regarding protected health information. Patient confidentiality is of particular concern with measures based on patient surveys and when there are small numbers of patients.