National Consensus Standards for Infectious Disease

Standing Committee Orientation

Melissa Mariñelarena, Senior Director
Christy Skipper, Project Manager
Mauricio Menendez, Project Analyst

January 18, 2017

Welcome and Introductions

NQF Project Team

- Melissa Mariñelarena, RN, MPA
  - Senior Director
- Christy Skipper, MS
  - Project Manager
- Mauricio Menendez, MS
  - Project Analyst

Agenda for the Call

- Standing Committee Introductions
- Overview of NQF, the Consensus Development Process, and Roles of the Standing Committee, co-chairs, NQF staff
- Overview of NQF's portfolio of Infectious Disease measures
- Review of project activities and timelines
- Overview of NQF's measure evaluation criteria
- Overview of SDS Trial Period
- Overview of eMeasure Approval for Trial Use
- SharePoint Tutorial
- Next steps

Infectious Disease Standing Committee

- Woody Eisenberg, MD **(Co-Chair)**
- Adam Thompson, B.A **(Co-Chair)**
- Emily Aaronson, MD
- Amesh Adalja, MD
- Esther Babady, PhD, D (ABMM)
- Nanette Benbow, MA
- Kathleen Brady, MD, MSCE
- Laura Evans, MD, MSc
- Piero Garzaro, MD
- Donald Goldmann, MD
- Jeffrey Hart, MS
- Michael Lane, MD, MSc, MPHS, CPPS
- Jeffrey Lewis, BA
- Melinda Neuhauser, PharmD, MPH, FCCP, FASHP
- Rocco Orlando, MD, FACS
- Jamie Roney, DNP, RN-BC, BSHCM, CCRN-K
- Pranavi Sreeramoju, MD, MPH, CMQ, FSHEA, FIDSA

The National Quality Forum: A Unique Role

Established in 1999, NQF is a non-profit, non-partisan, membership-based organization that brings together public and private sector stakeholders to reach consensus on healthcare performance measurement. The goal is to make healthcare in the U.S. better, safer, and more affordable.

Mission: To lead national collaboration to improve health and healthcare quality through measurement

- An Essential Forum
- Gold Standard for Quality Measurement
- Leadership in Quality

NQF Activities in Multiple Measurement Areas

- **Performance Measure Endorsement**
  - *600+ NQF-endorsed measures across multiple clinical areas*
  - *19 empaneled standing committees*
- **Measure Applications Partnership (MAP)**
  - *Advises HHS on selecting measures for 20+ federal programs, Medicaid, and health exchanges*
- **National Quality Partners**
  - *Convenes stakeholders around critical health and healthcare topics*
  - *Spurs action on patient safety, early elective deliveries, and other issues*
- **Measurement Science**
  - *Convenes private and public sector leaders to reach consensus on complex issues in healthcare performance measurement such as attribution, alignment, sociodemographic status (SDS) adjustment*

NQF Consensus Development Process (CDP)

7 Steps for Measure Endorsement

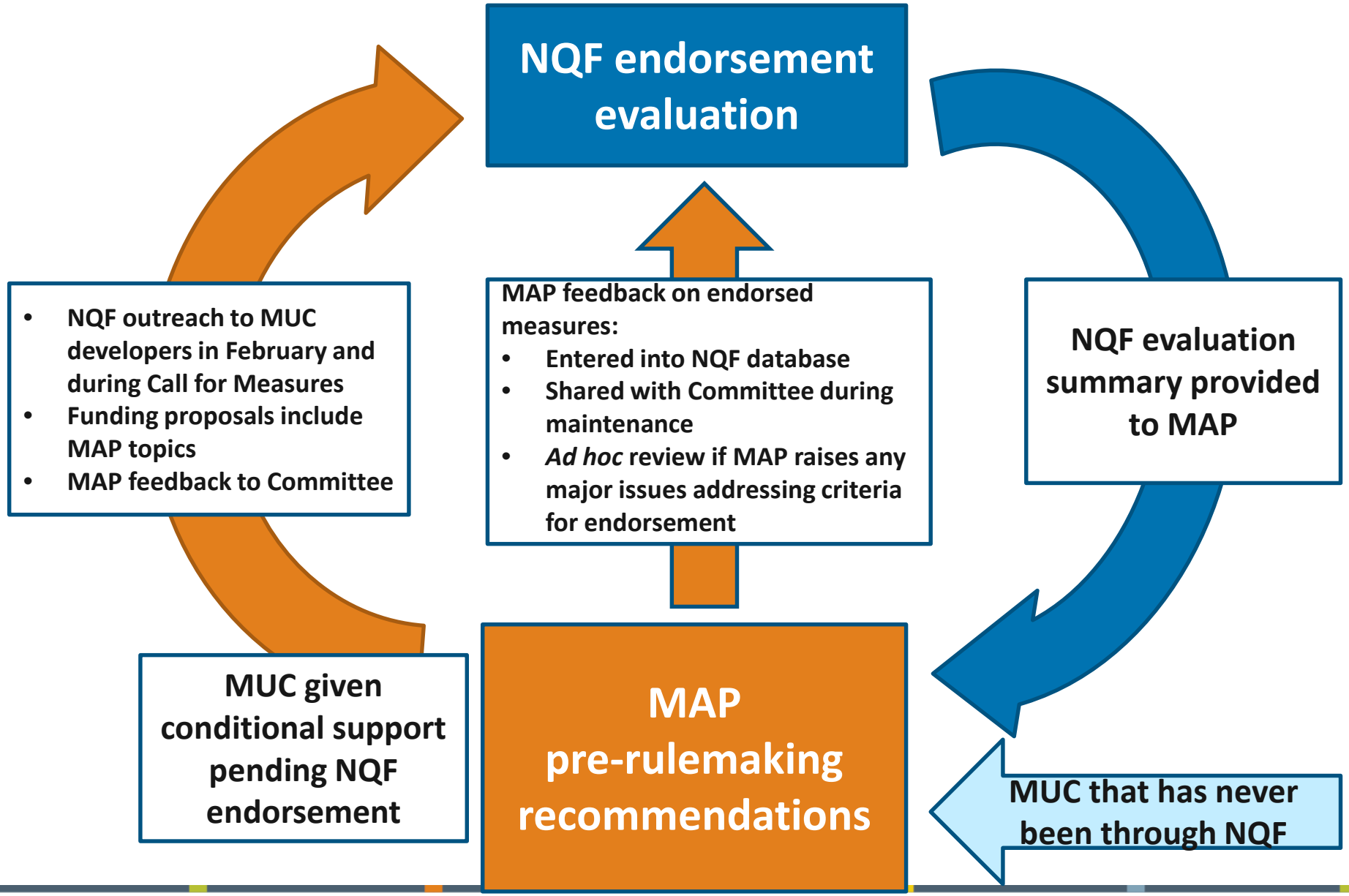
- Call for nominations for Standing Committee
- Call for candidate standards (measures)
- Candidate consensus standards review
- Public and member comment
- NQF member voting
- Consensus Standards Approval Committee (CSAC) ratification and endorsement
- Appeals

Measure Application Partnership (MAP)

In pursuit of the National Quality Strategy, the MAP:

- Informs the selection of performance measures to achieve the goal of improvement, transparency, and value for all
- Provides input to HHS during pre-rulemaking on the selection of performance measures for use in public reporting, performance-based payment, and other federal programs
- Identifies gaps for measure development, testing, and endorsement
- Encourages measurement alignment across public and private programs, settings, levels of analysis, and populations to:
  - *Promote coordination of care delivery*
  - *Reduce data collection burden*

CDP-MAP INTEGRATION – INFORMATION FLOW



Role of the Standing Committee
General Duties

- Act as a proxy for the NQF multi-stakeholder membership
- Serve 2-year or 3-year terms
- Work with NQF staff to achieve the goals of the project
- Evaluate candidate measures against the measure evaluation criteria
- Respond to comments submitted during the review period
- Respond to any requests from the CSAC

Role of the Standing Committee
Measure Evaluation Duties

- All members review all measures
- Evaluate measures against each criterion
  - *Indicate the extent to which each criterion is met and rationale for the rating*
- Make recommendations to the NQF membership for endorsement
- Oversee Infectious Disease portfolio of measures
  - *Promote alignment and harmonization*
  - *Identify gaps*

Role of the Standing Committee Co-Chairs

- Participate as an SC member
- Co-facilitate Standing Committee (SC) meetings
- Work with NQF staff to achieve the goals of the project
- Assist NQF in anticipating questions and identifying additional information that may be useful to the SC
- Keeps SC on track to meet goals of the project without hindering critical discussion or input
- Represent the SC at CSAC meetings

Role of NQF Staff

- NQF project staff will work with the Committee to achieve the goals of the project and ensure adherence to the CDP:
  - Organize and staff Committee meetings and conference calls
  - Guide the SC through the steps of the CDP and advise on NQF policy and procedures
  - Review measure submissions and prepare materials for SC review
  - Draft and edit reports for SC review
  - Ensure communication among all project participants (including SC and measure developers
  - Facilitate necessary communication and collaboration between different NQF projects and external stakeholders

Role of NQF Staff
Communication

- Respond to NQF member or public queries about the project
- Maintain documentation of project activities
- Post project information to NQF website
- Work with measure developers to provide necessary information and communication for the SC to fairly and adequately evaluate measures for endorsement
- Publish final project report

Questions?

Infectious Disease Portfolio of Measures

- This project will evaluate measures related to Infectious Diseases that can be used for accountability and public reporting for all populations and in all settings of care. The second phase of this project will address topic areas including:
  - *HIV/AIDS*
  - *Sepsis and Septic Shock*
- NQF solicits new measures for possible endorsement
- NQF currently has 12 endorsed measures within the area of Infectious Disease. Endorsed measures undergo periodic evaluation to maintain endorsement – "maintenance".

Infectious Disease Measures 2016-2017

Measure Title

- Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis (AAB)
- Appropriate Treatment for Children With Upper Respiratory Infection (URI)
- Hepatitis C: Confirmation of Hepatitis C Viremia
- Paired Measure: Hepatitis C Ribonucleic Acid (RNA) Testing Before Initiating Treatment (paired with 0396)
- Paired Measure: Hepatitis C Virus (HCV) Genotype Testing Prior to Treatment (paired with 0395)
- Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks after Initiation of Treatment
- Paired Measure: Hepatitis C: Hepatitis A Vaccination (paired with 0400)
- *HIV/AIDS: CD4 Cell Count or Percentage Performed*
- *HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) Prophylaxis*
- *HIV/AIDS: Tuberculosis (TB) Screening*
- *HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis*
- *Severe Sepsis and Septic Shock: Management Bundle*
- *HIV medical visit frequency*
- *Gap in HIV medical visits*
- *HIV viral load suppression*
- *Prescription of HIV Antiretroviral Therapy*
- *Sepsis Mortality Outcome Measure*

Infectious Disease Portfolio –Deferred

Measure	Status
Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis (AAB)	Deferred
Appropriate Treatment for Children With Upper Respiratory Infection (URI)	Deferred
HIV/AIDS: Pneumocystis jiroveci pneumonia (PCP) Prophylaxis	Deferred
HIV/AIDS: Sexually Transmitted Diseases – Screening for Chlamydia, Gonorrhea, and Syphilis	Deferred

Infectious Disease Portfolio - Withdrawn

Measure	Status
Hepatitis C: Confirmation of Hepatitis C Viremia	Withdrawn/Endorsement Removed
Paired Measure: Hepatitis C Ribonucleic Acid (RNA) Testing Before Initiating Treatment (paired with 0396)	Withdrawn/Endorsement Removed
Paired Measure: Hepatitis C Virus (HCV) Genotype Testing Prior to Treatment (paired with 0395)	Withdrawn/Endorsement Removed
Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks after Initiation of Treatment	Withdrawn/Endorsement Removed
Paired Measure: Hepatitis C: Hepatitis A Vaccination (paired with 0400)	Withdrawn/Endorsement Removed
HIV/AIDS: CD4 Cell Count or Percentage Performed	Withdrawn/Endorsement Removed
HIV/AIDS: Tuberculosis (TB) Screening	Withdrawn/Endorsement Removed

Infectious Disease Portfolio – Submitting

Measure	Status
Severe Sepsis and Septic Shock: Management Bundle	Under Review: Maintenance
HIV medical visit frequency	Under Review: Maintenance
Gap in HIV medical visits	Under Review: Maintenance
HIV viral load suppression	Under Review: Maintenance
Prescription of HIV Antiretroviral Therapy	Under Review: Maintenance
Sepsis Mortality Outcome Measure	Under Review: Maintenance – Possibly Submitting TBD

Infectious Disease Portfolio – New

Measure	Status
HIV viral load suppression (E-measure)	New
HIV medical visit frequency (E-measure)	New
Prescription of HIV Antiretroviral Therapy (E-measure)	New

Activities and Timeline

Meeting	Date/Time
Orientation Call	January 18, 2017, 1:00 – 3:00 PM EST
Measure Evaluation Q & A Call	February 7, 2017, 2:00 – 4:00 PM EST
Workgroup Calls	Group 1: February 28, 2017, 11:00AM – 1:00PM EST Group 2: March 1, 2017, 1:00 – 3:00PM EST
In-Person Meeting (1 day in Washington, D.C.)	March 14, 2017 at 8:30AM – 5:00PM EST
Post-Meeting Conference Call	March 23, 2017, 1:00PM – 3:00PM EST
Post Draft Report Comment Call	June 1, 2017, 1:00 – 3:00PM EST

Measure Evaluation Criteria Overview

NQF Measure Evaluation Criteria for Endorsement

NQF endorses measures for accountability applications (public reporting, payment programs, accreditation, etc.) as well as quality improvement.

- Standardized evaluation criteria
- Criteria have evolved over time in response to stakeholder feedback
- The quality measurement enterprise is constantly growing and evolving – greater experience, lessons learned, expanding demands for measures – the criteria evolve to reflect the ongoing needs of stakeholders

Major Endorsement Criteria
Hierarchy and Rationale (page 31)

- ***Importance to measure and report**: Goal is to measure those aspects with greatest potential of driving improvements; if not important, the other criteria are less meaningful (**must-pass**)*
- ***Reliability and Validity-scientific acceptability of measure properties** : Goal is to make valid conclusions about quality; if not reliable and valid, there is risk of improper interpretation (**must-pass**)*
- ***Feasibility**: Goal is to, ideally, cause as little burden as possible; if not feasible, consider alternative approaches*
- ***Usability and Use**: Goal is to use for decisions related to accountability and improvement; if not useful, probably do not care if feasible*
- ***Comparison to related or competing measures***

Criterion #1: Importance to Measure and Report (page 33-41)

1. **Importance to measure and report -** Extent to which the specific measure focus is evidence-based and important to making significant gains in healthcare quality where there is variation in or overall less-than-optimal performance.

   1a. Evidence: *the measure focus is evidence-based (page 34-39)*

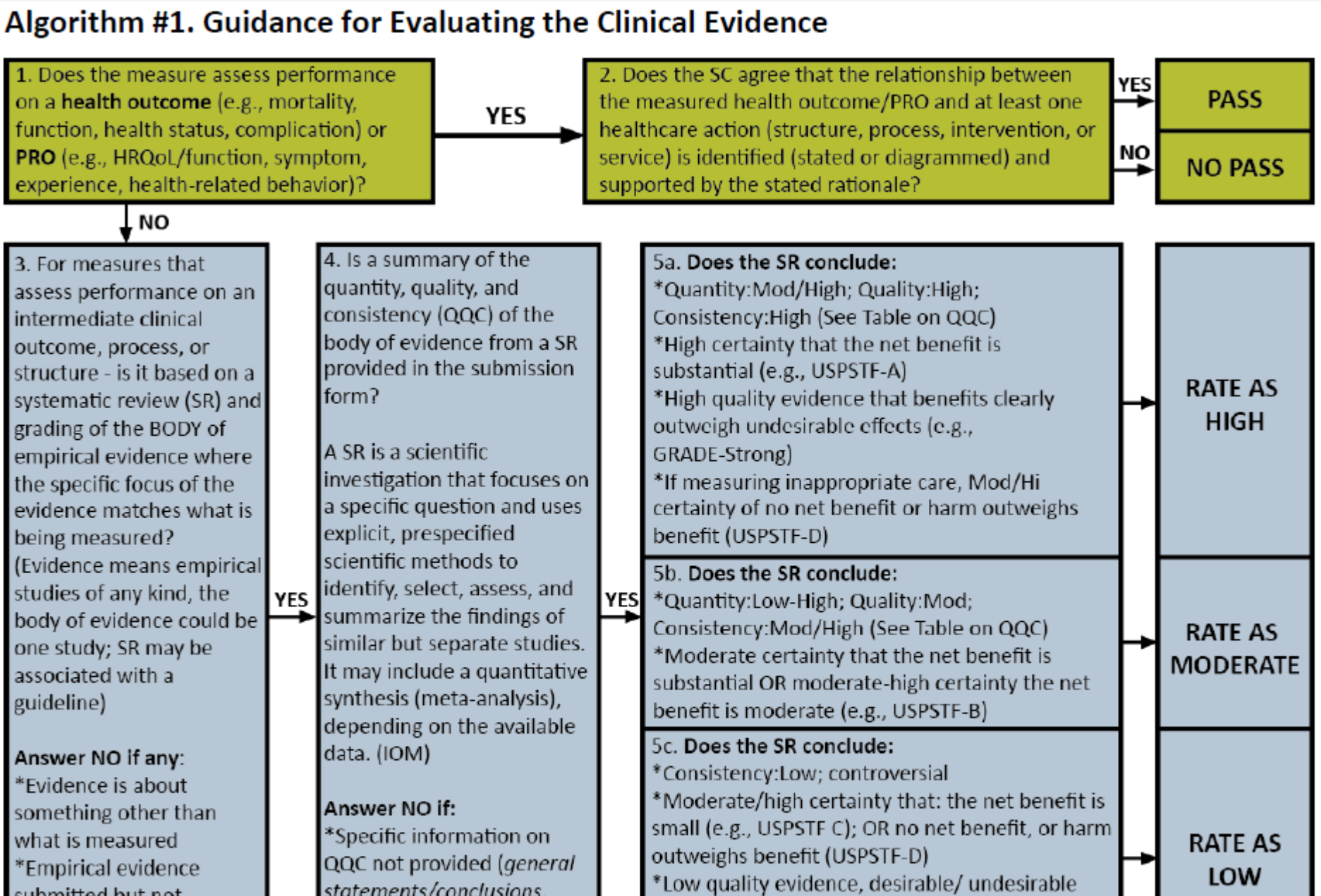
   1b. Opportunity for Improvement: *demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or disparities in care across population groups (pages 41-42)*

   1c. Quality construct and rationale *(composite measures only)*

Subcriteron 1a: Evidence (page 34-39)

- Outcome measures
  - *A rationale (which often includes evidence) for how the outcome is influenced by healthcare processes or structures.*
- Structure, process, intermediate outcome measures
  - *The quantity, quality, and consistency of the body of evidence underlying the measure should demonstrate that the measure focuses on those aspects of care known to influence desired patient outcomes*
    - » Empirical studies (expert opinion is not evidence)
    - » Systematic review and grading of evidence
      - *Clinical Practice Guidelines – variable in approach to evidence review*

Rating Evidence: Algorithm #1 – page 36



Criterion #1: Importance to measure and report Criteria emphasis is different for new vs. maintenance measures

New measures	Maintenance measures
• Evidence – Quantity, quality, consistency (QQC) • Established link for process measures with outcomes	**DECREASED EMPHASIS**: Require measure developer to attest evidence is unchanged evidence from last evaluation; Standing Committee to affirm no change in evidence IF changes in evidence, the Committee will evaluate as for new measures
• Gap – opportunity for improvement, variation, quality of care across providers	**INCREASED EMPHASIS**: data on current performance, gap in care and variation

Criterion #2: Reliability and Validity– Scientific Acceptability of Measure Properties (page 41 - 51)

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of health care delivery

2a. **Reliability (must-pass)**

2a1. Precise specifications including exclusions

2a2. Reliability testing—data elements or measure score

2b. **Validity (must-pass)**

2b1. Specifications consistent with evidence

2b2. Validity testing—data elements or measure score

2b3. Justification of exclusions—relates to evidence

2b4. Risk adjustment—typically for outcome/cost/resource use

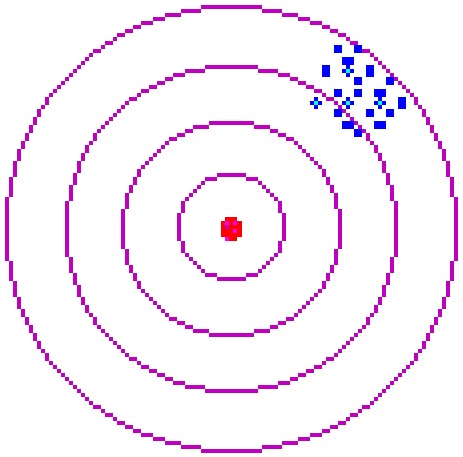
2b5. Identification of differences in performance

2b6. Comparability of data sources/methods

2b7. Missing data

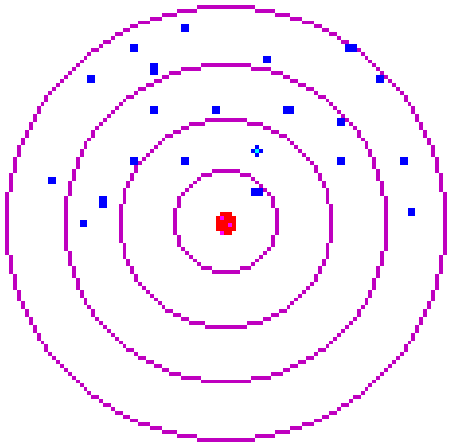
Reliability and Validity (page 42)

Assume the center of the target is the true score…



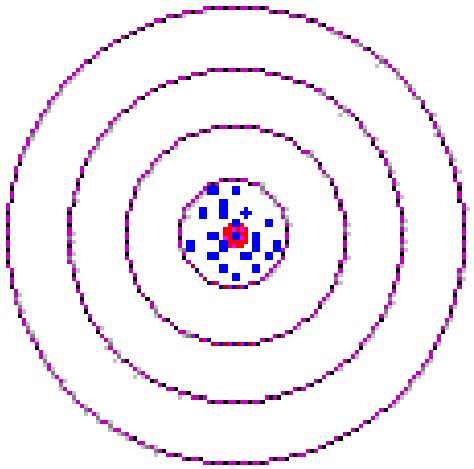
Reliable Not Valid

Consistent, but wrong



Neither Reliable Nor Valid

Inconsistent & wrong



Both Reliable And Valid

Consistent & correct

Measure Testing – Key Points (page 43)

Empirical analysis to demonstrate the reliability and validity of the *measure as specified,* including analysis of issues that pose threats to the validity of conclusions about quality of care such as exclusions, risk adjustment/stratification for outcome and resource use measures, methods to identify differences in performance, and comparability of data sources/methods.

Reliability Testing (page 43)
Key points - page 44

- Reliability of the ***measure score*** refers to the proportion of variation in the performance scores due to systematic differences across the measured entities in relation to random variation or noise (i.e., the precision of the measure).
  - *Example - Statistical analysis of sources of variation in performance measure scores (signal-to-noise analysis)*

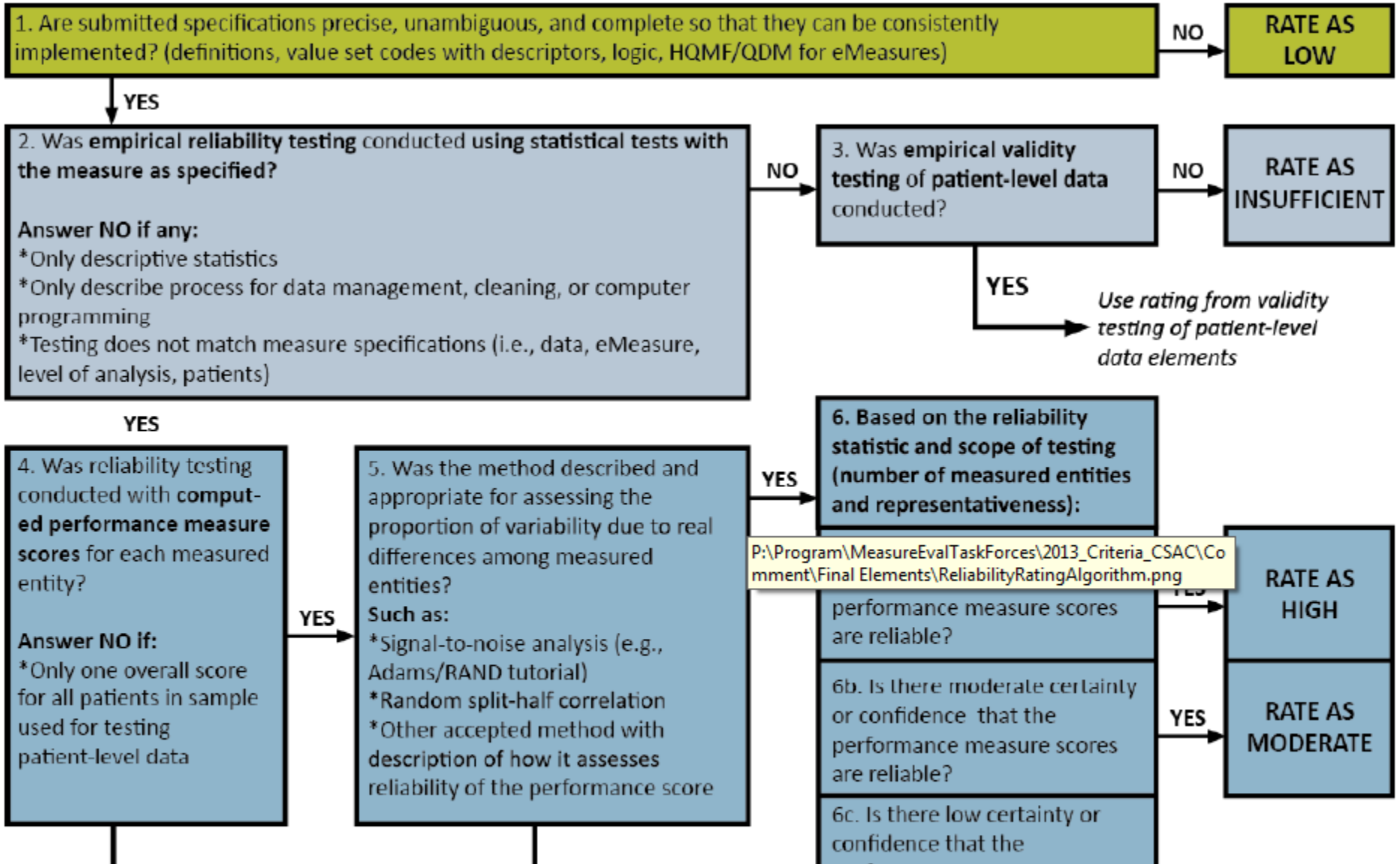
- Reliability of the ***data elements*** refers to the repeatability/reproducibility of the data and uses patient-level data
  - *Example –inter-rater reliability*

- Consider whether testing used an appropriate method and included adequate representation of providers and patients and whether results are within acceptable norms

- Algorithm #2 – page 48

Rating Reliability: Algorithm #2 – page 45

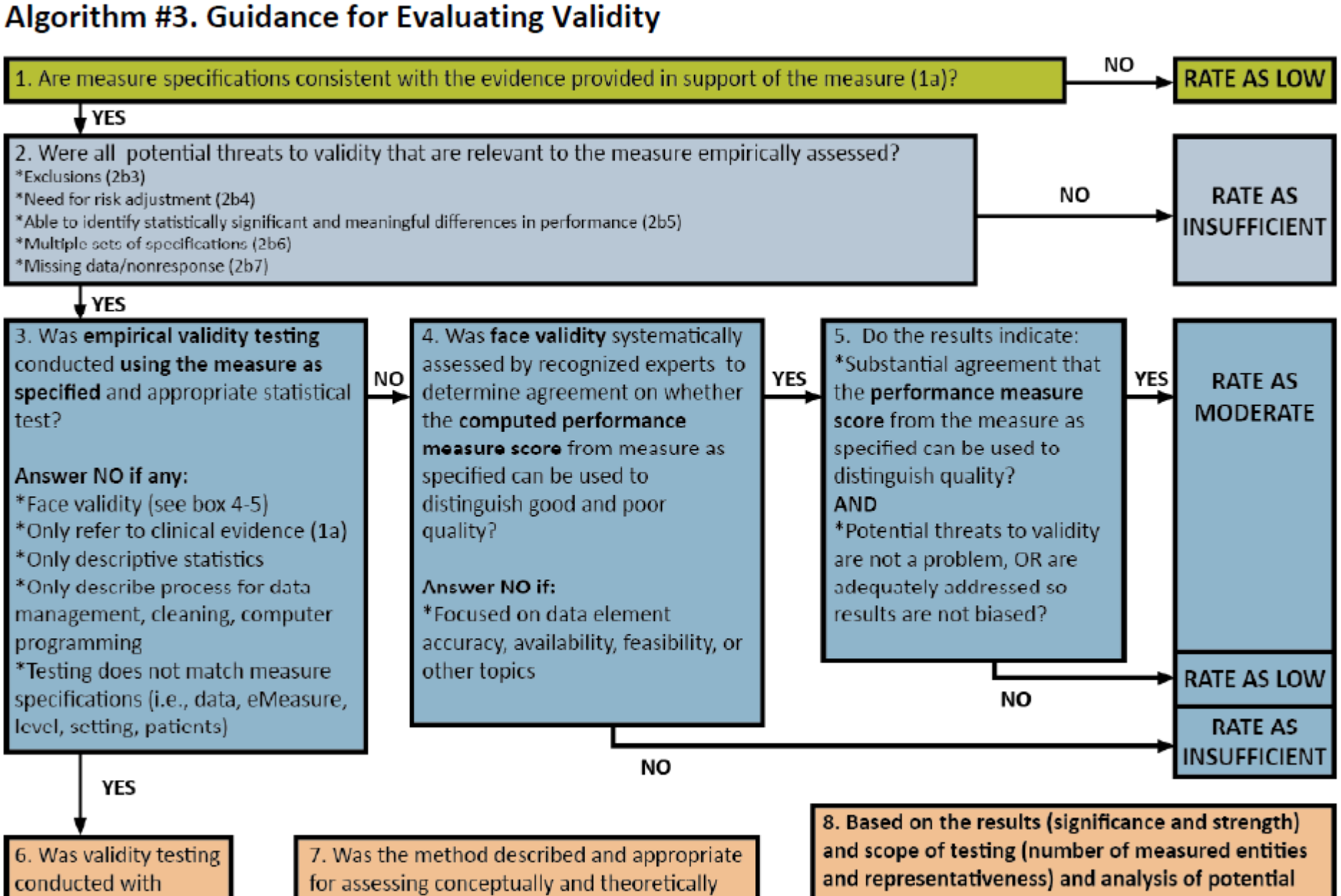
Algorithm #2. Guidance for Evaluating Reliability



Validity testing (pages 46 - 50)
Key points – page 49

- **Empirical testing**
  - *Measure score* – assesses a hypothesized relationship of the measure results to some other concept; assesses the correctness of conclusions about quality
  - *Data element* – assesses the correctness of the data elements compared to a "gold standard"
- **Face validity**
  - *Subjective determination by experts that the measure appears to reflect quality of care*

Rating Validity: Algorithm #3 – page 50



Threats to Validity

- Conceptual
  - *Measure focus is not a relevant outcome of healthcare or not strongly linked to a relevant outcome*
- Unreliability
  - *Generally, an unreliable measure cannot be valid*
- Patients inappropriately excluded from measurement
- Differences in patient mix for outcome and resource use measures
- Measure scores that are generated with multiple data sources/methods
- Systematic missing or “incorrect” data (unintentional or intentional)

Criterion #2: Scientific Acceptability

New measures	Maintenance measures
• Measure specifications are precise with all information needed to implement the measure	NO DIFFERENCE: Require updated specifications
• Reliability • Validity (including risk-adjustment)	**DECREASED EMPHASIS**: If prior testing adequate, no need for additional testing at maintenance with certain exceptions (e.g., change in data source, level of analysis, or setting) Must address the questions for SDS Trial Period

Criterion #3: Feasibility (page 51)
Key Points – page 52

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement.

3a: Clinical data generated during care process

3b: Electronic sources

3c: Data collection strategy can be implemented

Criterion #4: Usability and Use (page 52)
Key Points – page 53

Extent to which potential audiences (e.g., consumers, purchasers, providers, policymakers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a: Accountability and Transparency: Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement

4b: Improvement: Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated

4c: Benefits outweigh the harms: The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4d: Vetting by those being measured and others: Those being measured have been given results and assistance in interpreting results; those being measured and others have been given opportunity for feedback; the feedback has been considered by developers.

Criteria #3-4: Feasibility and Usability and Use

New measures	Maintenance measures
Feasibility	
• Measure feasible, including eMeasure feasibility assessment	NO DIFFERENCE: Implementation issues may be more prominent
Usability and Use	
• Use: used in accountability applications and public reporting	**INCREASED EMPHASIS**: Much greater focus on measure use and usefulness, including both impact and unintended consequences
• Usability: impact and unintended consequences	

Criterion #5: Related or Competing Measures (page 53-54)

If a measure meets the four criteria and there are endorsed/new related measures (same measure focus or same target population) or competing measures (both the same measure focus and same target population), the measures are compared to address harmonization and/or selection of the best measure.

- 5a. The measure specifications are harmonized with related measures **OR** the differences in specifications are justified.
- 5b. The measure is superior to competing measures (e.g., is a more valid or efficient way to measure) **OR** multiple measures are justified.

Evaluation process

- **Preliminary analysis**: To assist the Committee evaluation of each measure against the criteria, NQF staff will prepare a preliminary analysis of the measure submission and offer preliminary ratings for each of the criteria.
  - *These will be used as a starting point for the Committee discussion and evaluation*
- **Individual evaluation assignments:** Each Committee member will be assigned a subset of measures for in-depth evaluation.
  - *Those who are assigned measures will lead the discussion of their measures with the entire Committee*

Evaluation process (continued)

- **Workgroup calls for new Committees:** To assist Committee members with their first evaluations, Committee members and measures will be divided into groups for preliminary calls to discuss measures and share initial thoughts
  - *Ensures initial familiarity with measures*
  - *Allows "practice" with NQF criteria and processes*
  - *Gives early feedback to developers of Committee questions or concerns*
- **Measure evaluation and recommendations at the in-person meeting:** The entire Committee will discuss and rate each measure against the evaluation criteria and make recommendations for endorsement.

Recommendation for Endorsement and Endorsement +

- The Committee votes on whether to recommend a measure for NQF endorsement.
- Staff will inform the Committee when a measure has met the criteria for possible "Endorsement +" designation:
  - *Meets evidence criteria without exception*
  - *Good results on reliability testing of the measure score*
  - *Good results on empirical validity testing of the measure score (not just face validity)*
  - *Well-vetted in real world settings by those being measured and others*
- Committee votes on recommending the "Endorsement +" designation, indicating that the measure exceeds NQF criteria in key areas.

SDS Trial Period Overview

Background

- During a **two-year trial period,** adjustment of measures for socio-demographic (SDS) factors **will no longer be prohibited**
- Each measure must be assessed individually to determine if SDS adjustment is appropriate (included as part of validity subcriterion)
- The Standing Committee will continue to evaluate the measure as a whole, including the appropriateness of the risk adjustment approach used by the measure developer
- Efforts to implement SDS adjustment may be constrained by data limitations and data collection burden

Standing Committee Evaluation

- The Standing Committee will be asked to consider the following questions:
  - *Is there a conceptual relationship between the SDS factor and the measure focus?*
  - *What are the patient-level sociodemographic variables that were available and analyzed during measure development?*
  - *Does empirical analysis (as provided by the measure developer) show that the SDS factor has a significant and unique effect on the outcome in question?*
  - *Does the reliability and validity testing match the final measure specifications?*

Questions?

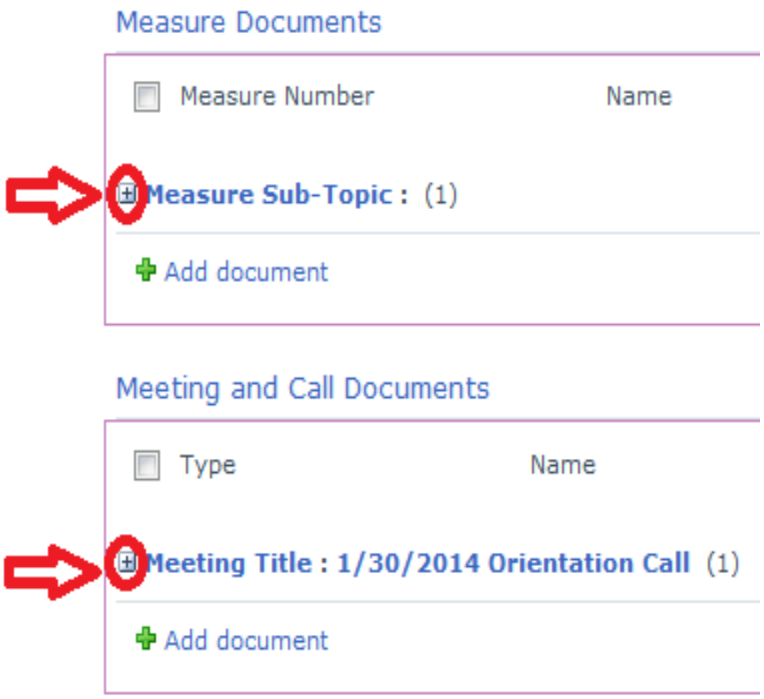
SharePoint Overview

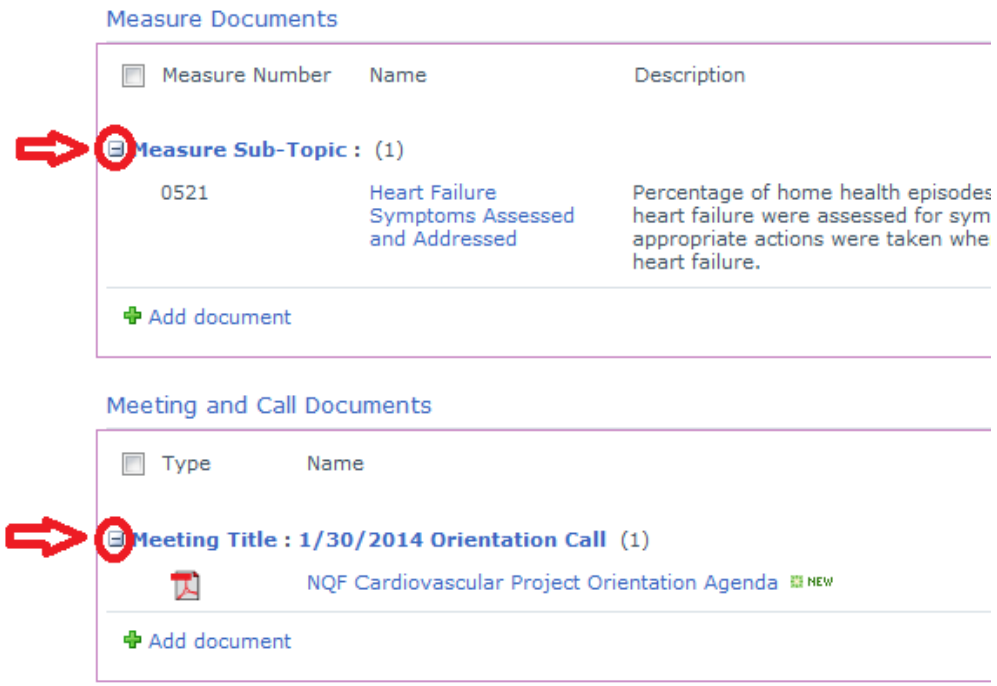
SharePoint Overview

- Accessing SharePoint
- Standing Committee Policy
- Standing Committee Guidebook
- Measure Document Sets
- Meeting and Call Documents
- Committee Roster and Biographies
- Calendar of Meetings

SharePoint Overview

- Please keep in mind:
  - + and – signs :





Measure Worksheet and Measure Information

- Measure Worksheet
  - Preliminary analysis, including eMeasure Technical Review if needed
  - Pre-evaluation comments
  - Public comments
  - Information submitted by the developer
    - » Evidence and testing attachments
    - » Spreadsheets
    - » Additional documents

Next Steps

Meeting	Date/Time
Orientation Call	January 18, 2017, 1:00 – 3:00 PM EST
Measure Evaluation Q & A Call	February 7, 2017, 2:00 – 4:00 PM EST
Workgroup Calls *(you will be assigned to one of these two calls)*	Group 1: February 28, 2017, 11:00AM -1:00PM EST Group 2: March 1, 2017, 1:00 – 3:00PM EST
In-Person Meeting (1 days in Washington, D.C.)	March 14, 2017 at 8:30AM – 5:00PM EST
Post-Meeting Conference Call	March 23, 2017, 1:00PM – 3:00PM EST
Post Draft Report Comment Call	June 1, 2017, 1:00 – 3:00PM EST

Project Contact Information

- Email: infectiousdisease@qualityforum.org
- NQF Phone: 202-783-1300
- Project page: http://www.qualityforum.org/Infectious_Disease_Project_2016-2017.aspx
- Share Point: http://share.qualityforum.org/Projects/Infectious%20Disease/SitePages/Home.aspx

Questions?