Partnership for Quality Measurement

Endorsement and Maintenance (E&M) Guidebook

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Introduction

The *Endorsement & Maintenance Process Guidebook (E&M Guidebook)* is a resource for measure stewards, measure developers, and organizations submitting measures to Battelle via the Partnership for Quality Measurement (PQM)™ for endorsement review. This guide provides information about the various steps of the endorsement and maintenance (E&M) process, including each phased review, possible endorsement decision outcomes, the appeals process, E&M policies and procedures, and the E&M committee structure.

The E&M Guidebook is organized to provide an overview of E&M goals, priorities, and resources; to guide measure developers and stewards through the six steps of the E&M process; and to provide key considerations for submitting measures to Battelle. The E&M Guidebook aims to do the following:

- Explain the measure submission and evaluation processes
- Describe the expectations for measure developers and stewards as participants in the process
- Serve as the main resource for E&M-related processes and policies.

The E&M Guidebook will be updated on a timely basis to maintain a current reference to assist measure developers and stewards in navigating the E&M process.

Who We Are

Battelle is the world's largest, independent, nonprofit, applied science and technology organization, with the objective of using science for the benefit of mankind. As a 501(c)(3) charitable trust, we are committed to translating scientific discovery and technology advances into societal benefits.

For over 20 years, we have been a leader in the science of health care quality measurement and improvement. Battelle is highly experienced in independent systematic evidence-based reviews of clinical quality measures (CQMs).

Battelle is a certified consensus-based entity (CBE) under the Centers for Medicare & Medicaid Services' (CMS) Qualified Entity (QE) Program developed to implement Section 10332 of the Affordable Care Act and the "Medicare Program; Availability of Medicare Data for Performance Measurement" Final Rule [CMS-5061-F]. As a certified CBE, Battelle meets the criteria of an independent CBE as mandated in federal statutes (SSA Section 1890 and 1890A).

To facilitate the execution of CBE tasks, we have formed the Partnership for Quality Measurement (PQM), which is comprised of all interested parties (formerly referred to as multi-stakeholder groups), including, but not limited to health care providers (e.g., clinicians, health plans, health systems), patients and caregivers, measure experts (e.g., developers, stewards, researchers), and health information technology specialists. Battelle's transparent, streamlined approach to consensus-building facilitates informed and thoughtful endorsement reviews of quality measures. Membership to PQM is free, and to serve on an E&M committee, individuals must be members of PQM.

Battelle's Portfolio of CBE Measures

Battelle organizes measures for E&M by five (5) project topical areas, each having an evaluation committee that oversees the portfolio of measures for the topic (Table 1). A project consists of measures submitted by measure developers/stewards and grouped by similar topic.

Table 1. Project Topical Areas

Project Title	Areas Covered	Example Measures*
Primary Prevention	Observable risk factors and behaviors	• CBE #0032 Cervical Cancer Screening • CBE #0431 Influenza Vaccination Coverage Among Healthcare Personnel

Project Title	Areas Covered	Example Measures*
Initial Recognition and Management	Signs and symptoms	• CBE #3592e Global Malnutrition Composite Score • CBE #2152 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling
Management of Acute Events, Chronic Disease, Surgery, Behavioral Health	Structural changes or functional impairment	• CBE #1879 Adherence to Antipsychotic Medications for Individuals with Schizophrenia • CBE #0061 Comprehensive Diabetes Care: Blood Pressure Control (<140/90 mm Hg)
End-of-Life Care, Rescue, Specialized Interventions	Advanced illness, end-stage disease	• CBE #2651 Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospice Survey • CBE #1423 Minimum spKt/V for Pediatric Hemodialysis Patients
Cost and Efficiency	Affordability and access	• CBE #2503 Hospitalizations per 1000 Medicare fee-for-service (FFS) Beneficiaries • CBE #3561 Medicare Spending Per Beneficiary – Post Acute Care Measure for Long-Term Care Hospitals

**CBE # is the former NQF identifying number, and Battelle will continue with this numbering system.*

Submission Tool and Repository

Key information about measure submissions, including endorsement status, are available via the Submission Tool and Repository (STAR). STAR enables measure developers to review and respond to public comment feedback in real time. STAR is updated regularly as new and maintenance measures are submitted to Battelle for endorsement review.

Beginning with the Fall 2023 cycle on October 1, 2023, developers/stewards may submit measures via STAR for endorsement review.

Endorsement and Review Process

Overview of and Enhancements to the Endorsement Process

The E&M process ensures measures submitted for endorsement are safe and effective, meaning use of the measure will increase the likelihood of desired health outcomes; will not increase the likelihood of unintended, adverse health outcomes; and is consistent with current professional knowledge.

Battelle's novel E&M process builds from the prior CBE processes and enables E&M decision-making in as few as six (6) months (from the Intent to Submit deadline until the end of the project [i.e., through the end of appeal proceedings]). Under this new process, measures reach their endpoint when an endorsement decision is rendered. This occurs when the E&M committees reach a final endorsement decision (Table 2). As part of the transparent E&M process, all decision outcomes will be displayed in STAR and made accessible to interested parties. This includes measures endorsed with conditions, measures not endorsed, and measures with endorsement removed.

Table 2. Endorsement Decision Outcomes

Decision Outcome	Description	Maintenance Expectations
Endorsed	**Applies to new and maintenance measures.** There is 75% or greater agreement for endorsement by the E&M committee.	Measures undergo maintenance of endorsement reviews every 3 years.± Developers/stewards may request an extension of up to 1 year (2 consecutive cycles).
Endorsed with Conditions*	**Applies to new and maintenance measures**. There is 75% or greater agreement that the measure can be endorsed as it meets the criteria, but there are recommendations/areas that committee reviewers would like to see when the measure comes back for maintenance. If these recommendations are not addressed, then a rationale from the developer/steward should be provided for consideration by the E&M committee review.	Measures undergo maintenance of endorsement reviews, which may require that the measures come back to Battelle in less than 3 years in order for the E&M committee to evaluate whether conditions have been met.
Not Endorsed	**Applies to new measures only**. There is 75% or greater agreement to not endorse the measure by the E&M committee.	None
Endorsement Removed	**Applies to maintenance measures only.** Either: • There is 75% or greater agreement for endorsement removal by the E&M committee; or • A measure steward retires a measure (i.e., no longer pursues endorsement); or • A measure steward never submits a measure for maintenance and there is no response from the steward after targeted outreach; or • There is no longer a meaningful gap in care, or the measure has plateaued (i.e., no significant change in measure results for accountable entities over time).	None

**Conditions are determined by the E&M committee.*

±Maintenance review cycles will be every 3 years, unless an emergency/off-cycle review is needed (See Emergency/Off-Cycle Reviews for more details).

The endorsement review process is designed to be conducted twice annually (i.e., Spring and Fall cycles; Figure 1). Measure developers can submit measures for PQM review at any point throughout the year, negating the need for a call for measures. Each cycle has a designated Intent to Submit deadline (i.e., approximately 1 month prior to full submission), before which measure developers must input key information (e.g., measure title, type, description, specifications) about their measure into STAR. Once all measures are submitted by the Intent to Submit deadline, the E&M staff use the measure information to determine the number and composition of E&M committees needed for that cycle. One month after the Intent to Submit deadline, measure developers submit their full measure information for E&M review. (See *Submitting Measures to Battelle* below for more details)

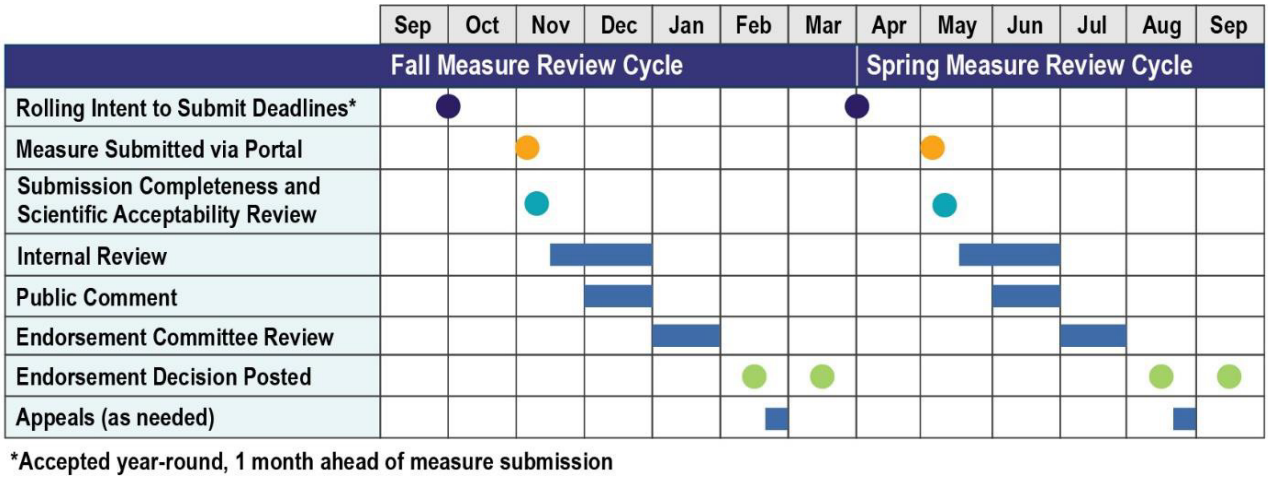


Figure 1. A 6-month endorsement review process.

To achieve a 6-month E&M process while maintaining high standards for transparency and rigor, Battelle has enacted several key enhancements: 1) leveraging the Scientific Methods Panel (SMP) to advance measure science, 2) retiring the Consensus Standards Approval Committee (CSAC), 3) establishing a more robust and transparent appeals process, 4) leveraging a Novel Hybrid Delphi and Nominal Groups (NHDNG) technique[1], 5) reducing the number of E&M committees, and 6) conducting the pre-evaluation public commenting concurrent with other necessary E&M activities.

1. **Leveraging SMP to Advance Measure Science:** While each measure will continue to be reviewed for scientific rigor, the expertise of the SMP will be utilized across the entirety of the E&M process rather than on a measure-by-measure basis. While this does assist in reducing the overall endorsement timeline, more importantly it allows the SMP to provide

[1] Davies S, Romano PS, Schmidt EM, Schultz E, Geppert JJ, McDonald KM. Assessment of a novel hybrid Delphi and nominal groups technique to evaluate quality indicators. Health Services Research. 2011 Dec;46(6pt1):2005-18. https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1475-6773.2011.01297.x

guidance that will enhance all measures by focusing on novel and the most difficult methodological challenges faced by measure developers.

2. **Retiring the Consensus Standards Approval Committee:** To empower E&M committees and to increase patient and consumer voice in the process, the CSAC review will be retired. Through PQM, endorsement decisions are made by E&M committees and are considered final unless an appeal is requested within three (3) weeks of the decision being posted to the PQM website. While this does assist in reducing the overall endorsement timeline, with this change, we have also increased patient community (i.e., patients, caregivers, advocates) and purchasers of health care (e.g., state, federal, private) engagement in the E&M process. In particular, at least three members from the patient community are seated on each committee, increasing the reach to all interested parties, including patients and purchasers through our partnerships with IHI, Rainmakers, and PQM membership overall.
3. **Establishing a More Robust and Transparent Appeals Process:** When an appeal is received, the E&M team conducts a preliminary review of the appeal to determine if a re-review is appropriate, at which point an ad-hoc Appeals Committee is convened to review the appeal. The Appeals Committee consists of E&M team (i.e., technical leaders from PQM and our partners) and the chairs from that cycle's E&M committees. If additional perspectives are needed, we send ad-hoc requests to the PQM membership. This structure ensures these meetings can be convened quickly and as needed, and the inclusion of E&M staff and committee chairs reduces the risk of duplicative or contradictory discussions.
4. **Leveraging the Novel Hybrid Delphi and Nominal Groups Technique:** To promote consistency in measure evaluation reviews and to ensure there is focused, facilitated discussion that is inclusive of all interested party perspectives, Battelle uses a NHDNG technique to build consensus among E&M committee members and leverage experienced and trained facilitators. The NHDNG technique is a hybrid technique that utilizes a multi-step process meant to increase engagement of all committee members and structure facilitation by using standard measure evaluation criteria and practices.
5. **Reducing the Number of E&M Committees:** Measures submitted to Battelle for review will be evaluated by one of the five E&M project committees (Table 1). Maintenance of fewer, more generalized committees enables a more equitable distribution of effort. These committees have a diversity of expertise to address a range of topic areas in a more flexible approach that maximizes engagement during each cycle. Subject matter experts are recruited as needed from PQM membership to provide more specific clinical knowledge when called for by the measure under review.
6. **Conducting the Pre-evaluation Public Commenting Concurrently with Staff Assessments:** For each measure evaluation cycle, public comment happens twice. The first occurs prior to the E&M committee endorsement meeting (i.e., pre-evaluation commenting), and the second occurs after an endorsement decision has been made by the committee (i.e., post-evaluation commenting). The first comment period has the lengthier public comment window of 30 days, which enables 1) public comment to happen concurrent with an internal E&M team review and assessment (formerly Preliminary Analysis); and 2)

the compilation and synthesis of comments received, which is integrated into the NHDNG process for review during the E&M committee meetings before members make their final endorsement decisions about the measure(s).

For the second public comment period, endorsement decisions made during committee meetings are shared via the public facing PQM website for three (3) weeks, which represents the Appeals period, during which any interested party may request an appeal of any E&M committee endorsement decision rendered for that cycle.

Battelle is dedicated to evaluation of the E&M process and integrating interested party input across the cycles. Therefore, the process and the E&M Guidebook may evolve over time. Proposed changes to the E&M process or criteria undergo a formal public comment period and before any changes are implemented, educational resources (e.g., webinars, informational guides) are made available. Any changes in the E&M process or measure evaluation criteria will not be applied to any measure that is currently going through the E&M process.

E&M Committee Composition, Roles, Responsibilities

As a CBE, we seat individuals from the PQM membership into committees to participate in the E&M process. E&M committees are composed of diverse members representing all facets of the health care system. There are five projects each cycle, each having a committee that evaluates, discusses, and assigns ratings for measures under endorsement review (see Table 1). We will ensure diversity of E&M committee membership through a formal nominations process (See *E&M Committee Nominations* for more details) to fill gaps in expertise and perspective needed for the E&M committee. This structure of membership organization enables use of the NHDNG technique, which maximizes member engagement and promotes consistent application of evaluation criteria.

Each project uses the Novel Hybrid Delphi (Advisory) and Nominal (Recommendations) Groups technique for measure endorsement reviews. Within each E&M project committee, there is a Foundational Group and a Reconciliation Group (Figure 2).

- **Advisory (Delphi) Group**: Members in this group review and provide ratings and written recommendations on measures prior to the Recommendations Group endorsement meeting. These inputs ensure that a larger number of voices contribute to the consensus-building process. The Advisory Group members are encouraged to attend the Recommendations Group endorsement meeting to listen to the Recommendations Group discussions and to revote on measures during the meeting.
- **Recommendations (Nominal) Group**: Members in this group also review and provide ratings and written recommendations on measures prior to the Recommendations Group endorsement meeting. Areas of disagreement (i.e., lack of consensus) identified from the initial measure ratings from both groups will inform the Recommendations Group discussions during the endorsement meeting (See *Endorsement Committee Review* for more details). Recommendations Group members will also revote on measures during the meeting.

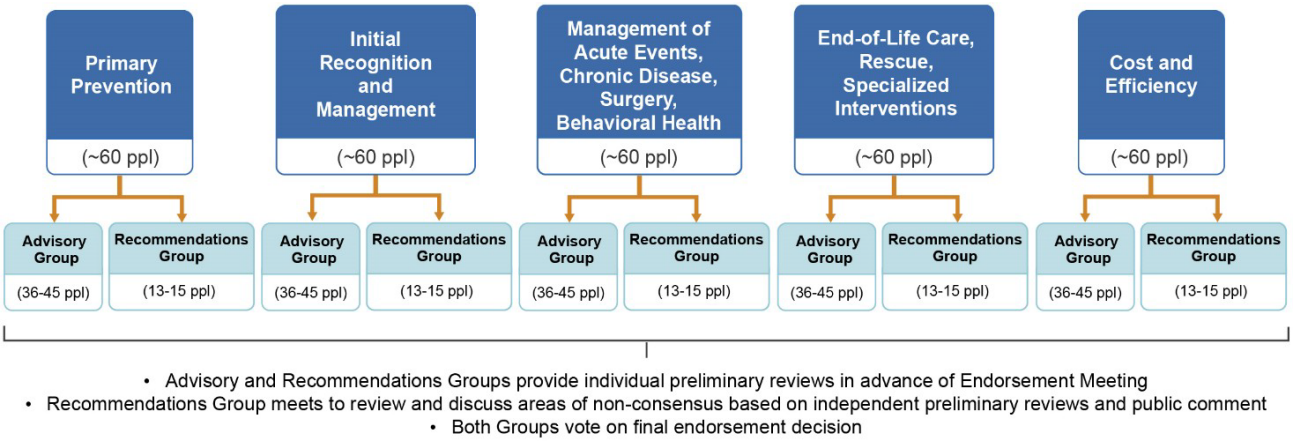


Figure 2. Recommendations and Advisory Group Structure

The Recommendations and Advisory Group members consist of interested parties from PQM membership, who evaluate, discuss, and rate the measures undergoing endorsement review. Each E&M project committee (Recommendations Group plus the Advisory Group) has two co-chairs. The co-chairs' responsibilities are to:

- Co-facilitate meetings, along with E&M project staff
- Work with E&M staff to achieve the goals of the project
- Assist E&M staff in anticipating questions and identifying additional information that may be useful to the committee
- Participate as a full voting member
- Represent the committee at *Appeals Committee* meetings or calls

To ensure representation of the population of interested parties, up to 60 members are seated on an E&M project committee through a formal nominations process (See *E&M Committee Nominations* for more details) that is conducted annually to fill gaps in expertise and roster categories (Table 3). To serve on an E&M committee, individuals must also be PQM members. We seat PQM members based on the expertise needed for the E&M project, ensuring adequate representation and perspectives across roster categories. Each year, committee members are randomly assigned, within roster categories, to either the Advisory Group (36-45 individuals) or the Recommendations Group (13-15 individuals), except for co-chairs. This means that yearly Advisory and Recommendations Group assignments are mutually exclusive and will not change for up to two cycles (Fall and Spring).

On an as-needed basis, the membership of the Recommendations Group may be augmented with individuals with specialized expertise, which is determined after each cycle's Intent to Submit deadline. For example, if a health care cost measure for a specific disease state or condition is under consideration for review by the Cost and Efficiency committee, researchers and experts of that disease state or condition are invited to provide subject matter expertise for

the committee's consideration during the Recommendations Group meeting. These subject matter experts are non-voting participants and will only provide input on relevant measures.

Table 3. Roster Categories and Target Number of Individuals

Roster Category	Advisory Group Targets*	Recommendations Group Targets*
Patients, families, caregivers, patient advocates	9	3
Clinicians, including physicians, nurses, pharmacists, physical therapists, etc.	6	2
Facilities/institutions including accountable care organizations, hospitals or hospital systems, and post-acute/long-term care facilities	6	2
Purchasers and plans (state, federal, and/or private)	6	2
Rural health experts	3	1
Health equity experts	3	1
Researchers in health services, alternative payment models, population health	6	2
Other Interested Parties (representatives of electronic health record [EHR] vendors, provider and facility associations, and experts in areas such as quality improvement/ implementation science, care coordination, patient safety, behavioral health, and national policy makers)	6	2
TOTAL	**45**	**15**

**Note: one-third (1/3) of the individuals on the rosters rotate off these groups annually, and new committee members are seated through a formal nominations process. If we do not fill the number of seats listed for a given roster category, we will determine if remaining seats can be distributed to other roster categories, based on the expertise needed within the committee.*

Term of Appointment

Committee members are appointed to a three-year term. Each year, we host a nominations process to recruit PQM members into the E&M project committees, ensuring adequate representation across roster categories (Table 3). Committee co-chairs are appointed to a three-year term with an option to extend for one additional two-year term. A third of the members end their terms every year, as newly seated members join. Currently serving members rotate between Advisory and Recommendations Groups (except for co-chairs), annually. For the Fall 2023 cycle, we will assign members (except co-chairs) to different term

lengths of 1, 2, or 3 years—this ensures continuity by preventing all members from ending their terms simultaneously. See *Endorsement Committee Review* below for more information.

E&M Committee Nominations

Battelle staff conduct a review of committee member appointments annually, which includes internal re-calibration of the membership, a call for nominations, and targeted outreach. A call for nominations is published on the PQM website and an announcement is sent out to all PQM members. Nominations are submitted via the PQM website. Self-nominations are welcome. Third-party nominations must indicate that the individual has been contacted and is willing to serve. Nominees must be PQM members (which is free), and they must complete an application form and a Disclosure of Interest (DOI) form (*Appendix B*). Before finalizing the appointments, a draft roster of nominees is published for public comment for transparency and for garnering input that the E&M roster has the expertise needed for the given E&M project.

Nominees commit to participating in scheduled calls and meeting dates, providing timely responses to requests for feedback, and being available for ad-hoc meetings and conference calls. To be eligible for participation, nominees should (1) have relevant expertise and demonstrated experience related to the use of quality and efficiency measures and/or (2) belong to at least one of the following categories:

- Patients, caregivers, and patient advocates
- Clinicians, including physicians, nurses, pharmacists, physical therapists, etc.
- Facilities/institutions including accountable care organizations, hospitals or hospital systems, and post-acute/long-term care facilities
- Purchasers and plans (state, federal, and/or private)
- Rural health experts
- Health equity experts
- Researchers in health services financing, alternative payment models (e.g., bundled payment, shared savings, all-payer models, etc.), population health, or implementation science methodology
- Other Interested Parties (representatives of electronic health record [EHR] vendors, provider and facility associations, and experts in areas such as quality improvement/ implementation science, care coordination, patient safety, behavioral health, and national policy makers.

Committee members are responsible for notifying the E&M project team if he/she:

- Changes employers or contact information;
- Is unable to attend a scheduled meeting; and/or
- Has a prolonged conflict that emerges during his/her term that will interfere with meeting the obligations of E&M committee membership, in order to determine whether ongoing membership on the committee is warranted or if inactive status can be granted for a cycle.

We understand that plans and demands of E&M committee members change. Therefore, members may shift to inactive status for a give review cycle or end his/her term early. E&M committee members with inactive status are not permitted to vote and are therefore not counted in the denominator when determining quorum and voting thresholds. A committee member may be granted inactive status at any time during their term and at any given point before the measure endorsement meeting.

If a member has poor attendance or participation, Battelle staff will contact the member and ask if he/she would like to resign. Battelle reserves the right to remove any member for persistent poor attendance or lack of participation.

Conflict of Interest Policy

As a Consensus Based Entity (CBE) on contract 75FCMC23C0010 with CMS, Battelle Memorial Institute ("Battelle") convenes several committees of Interested Parties (IPs) to provide input on (1) measure endorsement decisions of quality performance measures, (2) the selection of quality measures for a pre-rulemaking process, which is required by Social Security Act Sections 1890(b)(7) and 1890A, and (3) a measure removal process. This Conflict of Interest Policy (the "Policy") is applicable to such committees to ensure the committee performs its functions in a manner free from bias and undue influence. All committee members must attest that they will follow this policy and provide the requisite information necessary to conduct a conflict of interest (COI) review by Battelle.

The term "conflict of interest" means any financial or other interest that could actually or be perceived to (1) significantly impede your objectivity, or (2) create an unfair competitive advantage for you or an organization associated with you. Disclosure of a financial interest does not automatically mean a COI exists but may warrant further discussion and review.

To complete the COI analysis, each IP serving on a committee that evaluates measures for endorsement and/or for providing recommendations for pre-rulemaking will be required to complete a Disclosure of Interest Form for each measure, or batch of measures, assigned to that committee (*Appendix C*). This form will contain questions relevant to the specific measure(s) being reviewed. Battelle will provide the Disclosure of Interest Form to committees at the start of each cycle. The form will contain questions regarding the member's financial interests and business associations that may present a perceived or actual COI.

The questions in the Disclosure of Interest Form will focus on whether:

(1) You contributed directly and substantially to the development of a measure or measures being considered for endorsement or measure or measures under consideration for selection or removal. For example,

- You worked on the measure as an employee of the measure development organization.
- You directly collaborated with the measure development organization to create or refine the measure.
- You worked on the measure as a consultant for the measure development organization.

(2) You or your spouse, domestic partner, or child could receive a direct financial benefit

(3) from a measure being recommended for selection or removal or endorsement. For example,

- You own stock in a company that has a financial interest in the measure being endorsed or not endorsed.

(4) In the last 5 years you have received an indirect financial benefit, i.e., not related to the measure under review, of $10,000 or more from a measure developer whose measure is under review, or an indirect financial benefit of $10,000 or more, in the aggregate, from an organization or individual that may benefit from a measure being endorsed or not endorsed or being considered for the selection or removal process. For example,

- You have received $20,000 in consulting fees from the measure developer in the last 5 years for work unrelated to the measure being reviewed.

(5) You are currently employed by the measure developer and the developer has created the measure(s) under review, has created measure(s) in the topical area under review, or has created measure(s) that compete with measure(s) created by another developer and under review.

By participating as a committee member, each member consents to public disclosure of general information about the member's financial or business interests, professional associations, and experiences that may be of interest to the public regarding COI. They must also announce their organizational affiliation and any organizational conflicts of interest. Unless legally required to do so by an authoritative entity, such as CMS, specific financial information will not be provided to the public, but financial relationships may be subject to disclosure.

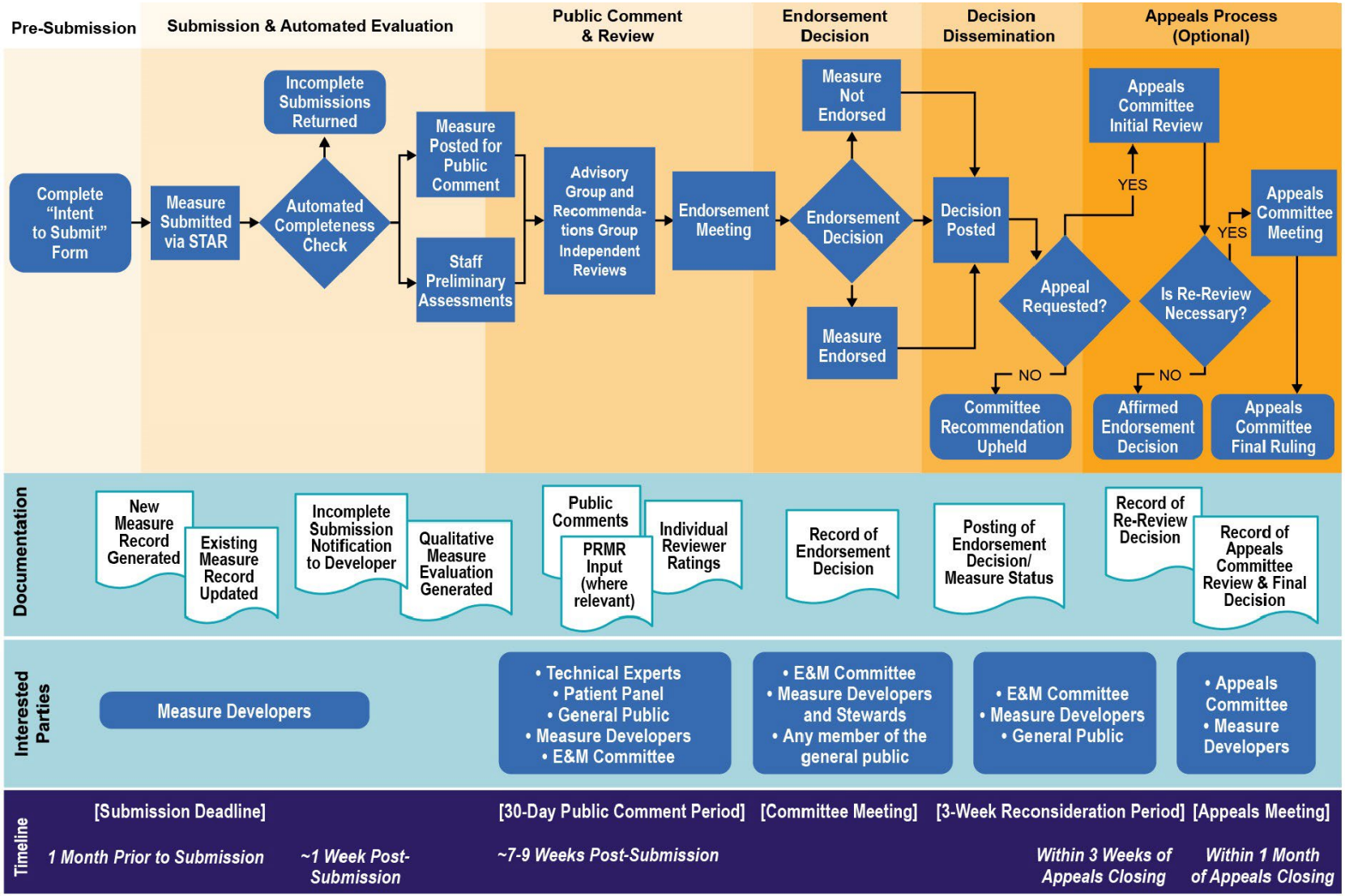
If you provide information that creates a perceived or actual COI, Battelle requires that you recuse yourself from the discussion and any voting regarding the applicable measure or measures, and in some instances, competing and related measures. Committee members who have conflicts with specific measures, as determined by the measure-specific questionnaire, must publicly recuse themselves from discussion and any voting associated with those measures. However, this does not prohibit the committee member from submitting public comments for the committee's considerations.

Additionally, committee members must orally disclose relevant interests at a public committee meeting. The disclosure usually occurs at a committee's first public meeting. Senior staff will lead this disclosure and instruct committee members regarding information that should be disclosed. Following oral disclosure by committee members, Battelle program staff will invite committee members to ask and respond to questions of each other or Battelle staff regarding any disclosures made by committee members.

Finally, all committee members have an ongoing duty to monitor for COI issues of themselves and fellow committee members and raise or disclose any issues either in a committee meeting, to the committee chair, the Battelle program team, or the Battelle legal department. Committee members should take a proactive approach and report any instances if a fellow committee member appears conflicted or is acting in a biased manner.

Submitting Measures to Battelle

The E&M process consists of six (6) stages, starting with Intent to Submit and cascading to the Appeals period (Figure 3). During each stage, the E&M staff work closely with developers and stewards, committee members, and other interested parties to address questions regarding process and/or criteria. The E&M team also conducts the endorsement meetings and provides all relevant materials and documentation of the endorsement deliberations and decisions, including committee rationales. The E&M team informs all interested parties of the status of measures going through the process and welcomes public comment on the measures and endorsement decisions throughout the review cycle. Lastly, all information pertaining to the E&M committee meetings, the measures being reviewed, and the E&M meetings themselves are made public.



**Measures submitted for maintenance follow the same process as new measures but have different criteria for endorsement at internal measure review & committee review stages.*
PRMR: Pre-rulemaking measure recommendations

Figure 3. Process map of one, 6-month E&M cycle.

Intent to Submit

The Intent to Submit period is on a rolling basis. Measure developers and stewards submit key information about the measure via STAR at least one (1) month prior to the full measure submission deadline of the intended review cycle (Fall or Spring). For all measures (new and maintenance), stewards/developers must submit the following information during Intent to Submit:

- Measure Title
- Measure Description
- Measure Type (e.g., structure, process, outcome)
- Measure Specifications (e.g., numerator, denominator, exclusions)
- Intended Measure Review Cycle
- Contact information and affiliation
- Quality Measure Developer and Steward Agreement (QMDSA) (see *Appendix A*).

Additionally, developers and stewards may also indicate the need for technical assistance, which the E&M team provides (see *Technical Assistance* section).

Full Measure Submission

Completeness Checks

After one (1) month from Intent to Submit, developers/stewards must submit all the measure information via the online measure submission tool, STAR. The E&M team conducts completeness checks (see *Measure Submission Completeness Checklist* below) to determine if all required responses and measure information have been submitted. The E&M team notifies measure developers/stewards of any issues identified and request developers/stewards address the completeness check feedback within 2 business-days. Following completeness checks, measures are posted for a 30-day public comment period (see *Two Public Comment Opportunities Section* below), while simultaneously undergoing an internal measure review by E&M staff and by E&M committee members.

Submission of Electronic Clinical Quality Measures (eCQMs)

The following clarifications that are specific to eCQMs:

- A new eCQM version of an endorsed measure is not considered an endorsed measure until it has been specifically evaluated and endorsed by Battelle. An eCQM should be submitted as a separate measure even if the same or a similar measure exists.

- Measure specifications should use the latest accepted versions of the following industry eCQM technical specifications: Health Quality Measure Format (HQMF), Quality Data Model (QDM), and Clinical Quality Language (CQL). Use of the CMS Measure Authoring Tool (MAT) ensures that the measure uses these technical specifications; however, the MAT is not required to produce HQMF.
- eCQM developers must use value sets that are published through the National Library of Medicine's Value Set Authority Center (VSAC). This helps reduce implementation issues related to value sets and code system validation and encourages the use of harmonized value sets. If an eCQM does not have a published value set, then the measure developer must look to see if there is a published value set that aligns with the proposed value set within its measure. If such a published value set does not exist, then the measure developer must demonstrate that the value set is in draft form and is awaiting publication to VSAC.
- Documentation of testing on more than one electronic health record (EHR) system from more than one EHR vendor is required to establish Scientific Acceptability (i.e., reliability and validity), indicating that the measure data elements are valid and that the measure score can be accurately calculated.
- Submissions require a feasibility assessment, including the eCQM Feasibility Scorecard. This assessment identifies data elements feasibility issues. Simulated data set results allow assessment of each branch of the measure logic to ensure the logic can be processed technically by other eCQM-capable reporting tools.
- Demonstration of data element reliability is required for unstructured data fields and data element validation is required for all eCQMs. If data element testing is not possible, justification is required and must be accepted by the E&M committee.

Measure Submission Completeness Checklist

Developers/stewards are also encouraged to follow the checklist below to ensure the measure submission is complete and responsive prior to E&M committee consideration. The E&M team will review measure submissions for completeness. If issues have been identified, the E&M team will notify developers/stewards within one week after the measure has been submitted. Developers/stewards will have 2-business days to address the issues identified. If developers/stewards are unable to do so, then the measure may need to be resubmitted at a future cycle.

☐ QMDSA is completed, signed, and attached to the submission.

☐ Health conditions (i.e., disease states) of the measures are indicated.

☐ Responses received for all relevant fields on the measure submission form.

☐ Testing is conducted for the data source(s) and level(s) of analysis for which the measure is specified; information for data source and level of analysis is consistent across the specifications and testing items.

☐ Attachments include electronic clinical quality measure (eCQM) specifications and data dictionary/code lists, if appropriate.

☐ All URLs are active and accurate.

☐ Evidence that a search for potential related/competing CBE measures and either a plan for harmonization or a rationale is provided for identified measures.

☐ Paired measures are submitted on separate forms.

☐ An eCQM has a feasibility score card submitted along using eCQM industry technical specifications including HQMF, QDM, and CQL.

☐ ICD-10 (International Classification of Diseases) codes are used and included, if applicable.

E&M Team and Individual Committee Member Review and Assessment

The E&M team reviews each measure submission using the PQM Measure Evaluation Rubric (*Appendix D*). Measures are evaluated on five criteria domains (Importance, Feasibility, Scientific Acceptability [i.e., Reliability and Validity], Equity, and Use and Usability. For each domain, reviewers indicate if a measure has "Met", "Not Met but Addressable", or "Not Met" the criterion, based on specific evaluation considerations for each area. The E&M team shares these preliminary assessments (formerly Preliminary Analysis) with developers for a 2-business-day, factual review prior to sharing with the E&M committee. This factual review is to ensure that the team's preliminary assessments include accurate results from the measure submission. For example, when summarizing the testing results of a measure, has the E&M team accurately reflected the testing results? This factual review *is not* intended to provide an opportunity for developers/stewards to disagree with the E&M staff measure ratings. These preliminary assessments are preliminary, as the E&M committee ultimately will determine the final ratings and endorsement decisions of measures.

At least 3 weeks prior to an E&M committee endorsement meeting (referred to as "Endorsement Meeting" in Figure 4), the Recommendations Group and the Advisory Group receive a packet of information (e.g., measure submission, endorsement rating rubric, E&M team preliminary assessments) related to each measure up for review. First, members of both groups are asked to rate each measure, independently, using the PQM Measure Evaluation Rubric (referred to as "Independent Measure Review" in Figure 4). Committee members are also asked to assign an endorsement decision (Table 1), based on their rubric assessments. The E&M team aggregates and summarizes the results and distributes them back to the members for review prior to the endorsement meeting.

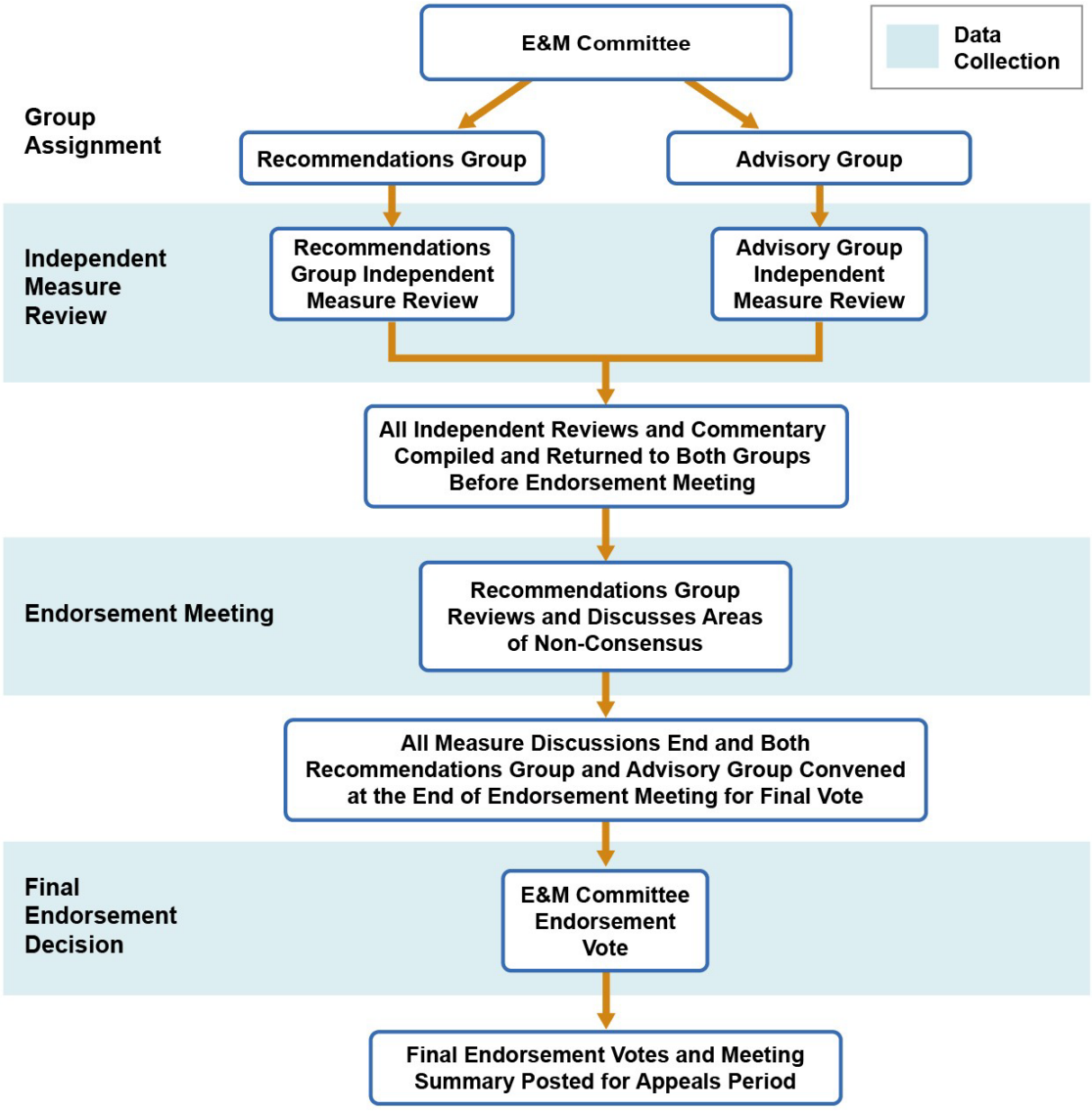


Figure 4. Advisory and Recommendations Group Measure Review Process

Public Commenting

Two Public Comment Opportunities

For each measure evaluation cycle, public comment happens twice during the process, the first happening prior to the E&M committee endorsement meeting (i.e., pre-evaluation commenting), and the second occurring after an endorsement decision has been made by the committee (i.e., post-evaluation commenting). The first comment period has the lengthier public comment

window of 30 days, which enables 1) the compilation and synthesis of comments received, which are integrated into the NHDNG process for review during the E&M committee meetings; and 2) public comment to happen concurrent with the internal staff review. During the initial 30-day public comment period, committee members have at least 3 weeks to review measure materials and to complete the PQM Measure Evaluation Rubric provided by the E&M team. These ratings are compiled and used by trained facilitators to guide committee discussions, which are held following the public comment period once comments have been compiled and synthesized for review during the meeting.

For the second public comment period, endorsement decisions made during committee meetings are shared via the public facing PQM website for 3 weeks, which represents the appeals period, during which any interested party may request an appeal of a committee endorsement decision (See *Appeals* section).

Endorsement Committee Review

Novel Hybrid Delphi and Nominal Groups Technique

At the conclusion of the pre-evaluation commenting period, the Recommendations Group meets for the endorsement meeting. One endorsement meeting is held per project, and all meetings are held virtually and open to the public. Foundational Group members will also join the call to listen to the Recommendations Group discussions.

During the meeting, the Recommendations Group discusses any issues/concerns raised during the pre-evaluation public comment period and any areas where consensus is lacking regarding the measure(s), based on the results from the pre-evaluation independent reviews. This is determined by the aggregated ratings from the independent reviews from both Groups. Consensus is determined to be 75% or higher agreement among members. Consistent with our goal to add rigor to all aspects of the consensus development process, Battelle will rely on an evidence-based consensus measure to determine whether consensus has been reached in committee votes. Analogous to inter-rater reliability, the consensus measure allows our team to assess the degree of disagreement (or lack of consensus) in committee votes. This approach is advantageous compared to other metrics based on variance, in that it takes into consideration the different sizes of the voting groups and different ratings across groups. See *Appendix F* for a description of the consensus measure.

The **evidence-based consensus measure** takes into consideration different sizes of voting groups and different ratings across groups.

The E&M team shares these preliminary results with both Groups for review prior to the endorsement meeting. The Recommendations Group does not discuss measures that have reached consensus (75% or greater) based on the aggregated independent reviews.

At the end of meeting, the E&M committee chairs summarize the deliberations of the Recommendations Group, and both the Advisory and Recommendations Group members will vote on the measure(s) for a final endorsement decision (Table 2). If a measure still does not

reach consensus, then it is not endorsed. After the meeting, the E&M team posts a meeting summary, including the final endorsement decisions to the PQM website for a 3-week appeals period.

The E&M team coordinates all communications with the Recommendations and Advisory Groups and facilitates all meetings. The team also summarizes, in a meeting summary and final technical report, the endorsement meeting discussions, final voting results, public comments received, and any dissenting views.

A crucial aspect of a successful consensus-based process is effective and organized meeting facilitation that ensures discussions remain productive, within scope, and inclusive of all voices. At E&M committee meetings, our facilitators confirm quorum and engage committee members in robust discussion to build consensus recommendations about each measure under review. The NHDNG is a comprehensive, adaptable tool that is employed to build consensus among E&M committee members and leverage experienced and trained facilitators. Further, the NHDNG technique is a hybrid technique that utilizes a multi-step process meant to increase engagement of all committee members and structure facilitation by using standard measure evaluation criteria and practices.

The **consensus-based process** ensures:

- Productive discussions
- Discussions within scope
- Inclusion of all voices
- Increased engagement
- Efficient information exchange

This structured approach allows for efficient information exchange among E&M committee members, which is particularly important when members offer unique points of view. The use of independent preliminary committee ratings anchors opinions based on each individual's knowledge and limits the likelihood that a vocal few impart too much bias on the results. Furthermore, this approach ensures all members have access to the same information prior to final evaluation.

Quorum

Having a quorum for meeting attendance and voting is critical to ensure the discussion and the vote is robust and reflective of all perspective represented on the E&M committee. Meeting quorum requires that 60% of the Recommendations Group members are present during roll call at the beginning of the meeting. If there is less than 60% attendance, then the Recommendations Group will not discuss the measures and a back-up meeting will be held.

Voting quorum is at least 80% of active committee members (Recommendations Group and Advisory Group), who have not been recused (see *Conflict of Interest Policy* for more details). If the voting quorum is not met prior to voting, members that are present vote live during the meeting, but final votes will not be displayed. Those members not present for voting will have 48 hours (2 business days) after the meeting to vote off-line.

We promote high attendance among voting members by engaging them early and often, including providing meeting notices well in advance of scheduled meetings and sending detailed agendas and information packets for rating with sufficient time for review.

Endorsement Decision Posted

Endorsement decisions made by E&M committee meetings are shared via the public facing PQM website for three (3) weeks, which represents an Appeals period, during which any interested party may request appeals regarding any E&M committee endorsement decisions.

Appeals

If preliminary review of a submitted appeal request finds re-review is appropriate, Battelle convenes a designated Appeals Committee to review the decision along with any new information to either uphold or overturn the original decision. When an appeal is received, the E&M team conducts a preliminary review of the appeal to determine if a re-review is appropriate, at which point an ad-hoc Appeals Committee is convened to review the appeal and vote to uphold or deny the appeal.

If a measure's endorsement is being appealed, the appeal must:

- Cite evidence that the appellant's interests are directly and materially affected by the measure, and that the CBE's endorsement of the measure has had, or will have, an adverse effect on those interests; and
- Cite the existence of a CBE procedural error or information that was available by the cycle's Intent to Submit deadline but was not considered by the E&M committee at the time of the endorsement decision, which is reasonably likely to affect the outcome of the original endorsement decision.

In the case of a measure not being endorsed (formerly a "reconsideration request"), the appeal must be based on one of two rationales:

- The CBE's measure evaluation criteria were not applied appropriately. For this rationale, the appellant must specify the evaluation criteria they believe was misapplied.
- The CBE's E&M process was not followed. The appellant must specify the process step, how it was not followed properly, and how this resulted in the measure not being endorsed.

The Appeals Committee consists of E&M team staff (i.e., technical leaders from Battelle and our partners, IHI and Rainmakers) and the chairs from each E&M committee of that cycle. If additional perspectives are needed, we send ad-hoc requests to the PQM membership. This structure ensures these meetings can be convened quickly and as needed, and the inclusion of E&M staff and committee chairs reduces the risk of duplicative or contradictory discussions. To promote transparency and accountability, Appeals Committee meetings are open to the public, and a meeting summary is shared publicly via the PQM website. All Appeals Committee decisions are final.

Final Technical Report

The E&M team develops and publishes a technical report for each project, upon completion. Each technical report includes the following information:

- A summary of the scope of review conducted under the E&M project
- A list of the performance measures submitted and evaluated under the E&M project
- A list of the performance measures endorsed and not recommended for endorsement under the E&M project
- A list of measure concepts submitted during Intent to Submit for measures under the E&M project
- A summary of the public comments received during the E&M process for the E&M project
- A summary of any potential high-priority gap areas for measure developers to consider for future development, identified during the E&M project
- A summary of any major concerns or methodological issues raised during performance measure evaluation of the E&M project.

Harmonization

The current quality landscape contains a proliferation of measures, including some that could be considered duplicative or overlapping and others that measure similar but nonidentical concepts and/or define patient populations somewhat differently. Such duplicative measures and/or those with similar but not identical specifications may increase data collection burden and create confusion or inaccuracy in interpreting performance results for those who implement and use performance measures. Resolving issues around harmonizing measures and handling competing measures is one of the key challenges. Developers/stewards must respond to the questions about harmonization in their measure submission.

ICD-10

The Department of Health and Human Services implemented conversion to ICD-10 coding on October 1, 2015. Further details explaining the changes can be accessed at http://www.cms.gov/Medicare/Coding/ICD10/index.html?redirect=/icd10. Battelle requires ICD-10 codes to replace any ICD-9 codes for all new submissions, measures undergoing endorsement maintenance, and measures due for annual update.

Technical Assistance

The E&M project staff provides technical assistance to measure developers and stewards at any time before or during the measure submission process. Contact PQMsupport@battelle.org with any questions about PQM's Measure Evaluation Rubric, how to answer the questions in the form, any technical issues with the online submission process, or anything else.

Additional Developer Resources

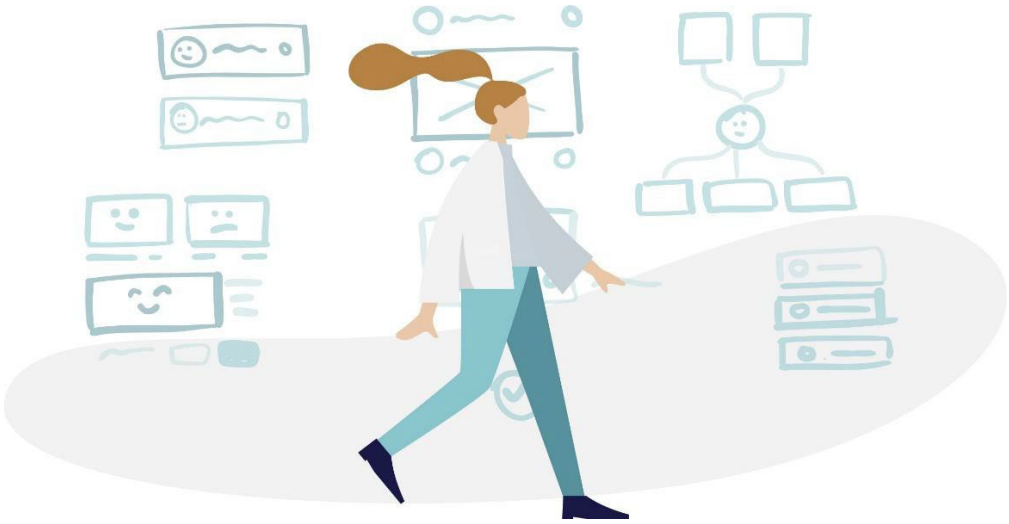
Battelle engages measure developers extensively to foster discussion and engagement with those who submit measures for E&M review. Materials, webinars, and discussions with

measure developers and stewards are intended to promote transparency and a collaborative environment that benefits all interested parties. As a CBE, Battelle cannot engage in measure development. However, each year we host a virtual Measure Developer Workshop, with the intent of engaging measure developers in cutting-edge topics relevant to measurement and E&M. For example, we share recommendations about measure evaluation criteria or testing requirements with measure developers to (1) obtain feedback on the recommendations; and (2) make developers aware of potential changes to future cycles. This more deeply engages measure developers in the refinement of processes and requirements; gives interested parties a "heads-up" as to what is coming at every stage, with the intention of improving overall openness to the changes; and contributes to consensus-building by providing an opportunity for us to gather in-depth input and recommendations on improvements to the process.

In addition, Battelle staff, who have measurement expertise, are able to assist developers through the submission and review process. The Battelle team can serve as a resource to developers through deep and nuanced understanding of the quality measure lifecycle, the tools and resources required to develop measures, the underlying measure science that guides measure development, and the time and resource constraints that impact measure development.

Maintenance of Endorsement

Maintenance of endorsement encompasses several processes: (1) annual updates to measure specifications of endorsed measures, (2) evaluations for endorsement maintenance (3) emergency/off-cycle reviews, (4) analysis and guidance for methodological and technical challenges, and (5) education and technical assistance to measure developers on endorsement maintenance activities. As the science of measurement and the uses of measures have evolved, Battelle has worked continually to launch its evaluation and endorsement processes to meet the needs of interested parties involved in performance measurement and improvement.



Annual Updates

Every year, when an endorsed measure is not being re-evaluated for continued endorsement, measure stewards have the option to submit a status report of the measure specifications to Battelle. This report either reaffirms that the measure specifications remain the same as those at the time of endorsement or last update or outline any changes or updates made to the endorsed measure.

If changes occur to a measure at any time in between the measures last endorsement review and its maintenance endorsement review (typically 5 years from its last endorsement review), the measure steward is responsible for informing Battelle immediately of the timing and purpose of the changes. An early maintenance review is conducted if the changes materially affect the measure's original concept or logic (see *Emergency Review/Off-Cycle Reviews* below).

Emergency Review/Off-Cycle Reviews

An emergency or off-cycle review is a formal measure evaluation and endorsement consideration that occurs prior to the previously scheduled maintenance of endorsement date. An early maintenance review follows the same process as a maintenance of endorsement evaluation.

An emergency or off-cycle review is triggered by a variety of ways:

- Request by a developer/steward due to a material change to an endorsed measure during an annual update. A material change is defined as any significant modification to the measure specifications that significantly affects the measure results such as:
    - Changes to the population being measured (e.g., changes in age inclusions, changes in diagnoses or other inclusion criteria, changes in excluded populations, from one type of insured population to all-payer population);
    - Changes to what is being measured (e.g., changes in target values like blood pressure or lipid values);
    - Inclusion of new data source(s); or
    - Expansion of the level or changing unit of analysis or care setting(s) (e.g., adding clinician-level to a measure that is endorsed at practice-level).
- Request by an interested party because of a perceived unintended negative consequence associated with the measure, a change in the clinical guideline driving the measure, or a significant implementation issue. The interested party may be a measure developer/steward, E&M committee member, or any other type of interested party.

We restrict the scope of the emergency or off-cycle review to the immediate issue (i.e., concern with the measure's evidence) and not an all-encompassing review. An early maintenance review can be requested by any party, if there is adequate, high quality, and consistent evidence to justify the review. To initiate the review, the interested party must send an email to PQMSupport@battelle.org with the subject "Emergency/Off-cycle Review Requested," which

alerts the E&M project team. The project team and respective E&M committee co-chairs review the request to see whether it is significant and emergent; for example, if the clinical practice underlying the measure is causing harm to patients directly or as a result of an unintended consequence. If deemed significant and emergent, the project team notifies the developer/steward (if they are not the requester of the emergency review) and pulls the measure off its maintenance cycle to be reviewed by the E&M committee during the next immediate cycle.

The project team recruits additional subject matter experts, ensuring an appropriate combination of perspectives, from PQM and from our partners, IHI and Rainmakers. The E&M committee determines whether the measure needs immediate attention, such as a change to the specifications, and shares this information with the measure developer/steward. If the change is not feasible, the committee may decide to give remove the measure's endorsement. If the measure does not need immediate attention, the measure developer/steward should document the issue for consideration in the next round of full review. The project team informs the requester of the emergency review of the final decision with justification.

Appendix A: Quality Measure Developer and Steward Agreement

Each candidate measure or set of measures has a measure steward who assumes responsibility for the submission of the measure to Battelle for potential endorsement. The measure steward is responsible for making necessary updates to the measure and informing Battelle about any changes made to the measure. In addition, the measure steward is responsible for providing the required measure information during the measure maintenance process:

- The measure steward organization is required to identify a single point of contact who will be notified of any upcoming maintenance deadlines or requirements related to the endorsed measure(s). If there is a change in point of contact, then the steward should notify Battelle of the new point of contact.
- Stewards may be contacted by PQM members or other members of the public with inquiries about specifications, updates, and implementation of the endorsed measure(s)
- Stewards are also responsible for maintaining measure details and specifications on any publicly available website.

Each steward who submits a fully specified and tested measure to Battelle must submit a completed and signed Quality Measure Developer and Steward Agreement (QMDSA) on or before the project's measure submission deadline in order for the measure to be considered by the Committee. The agreement is between Battelle and the measure steward and only shared between these parties:

- For new measure stewards, the QMDSA should be accompanied by the completed addendum, in which the steward must list all the measures (measure number and measure title) being submitted for review.
- For existing measure stewards, only a signed addendum is needed and will be appended to the existing MSA; a new MSA is not required. Contact Battelle project staff to obtain the addendum.

Only one QMDSA is necessary per measure steward. If the steward is a governmental organization, a QMDSA is not required. For more information about how to complete the QMDSA, please see the QMDSA Submission Instructions.

Battelle will work with all measure stewards to transition to this QMDSA. Measure stewards will only need to fill out the QMDSA form if they are a new developer/steward or have an expired NQF measure steward contract. All active NQF contracts will be honored until their 3-year expiration date. Upon expiration of the NQF contract the QMDSA form will need to be completed. Those who have measures up for maintenance or wish to add additional measures to their current QMDSA will need to complete an Additional and Maintenance Measures Form. Each QMDSA will stand for five (5) years from its effective date.

The QMDSA and Additional and Maintenance Measures Forms are contractual agreements that must be signed by Battelle and any QMDSA Steward that is submitting one or more measures to be evaluated for endorsement.

Appendix B: Personal/Organizational Disclosure of Interest Form

1. Name:

   Organization Affiliation:

   Committee Name:

   Year:

NOTE: *This form will be renewed annually, please denote the year this disclosure will cover (ex. 2023) If you fill this form out in August of any given year, you will need to submit a new form January of the following year.*

2. Describe any personal or organizational relationships subject to disclosure. If None, check here: ☐

3. Describe any personal or organizational financial interests subject to disclosure. If None, check here: ☐

4. Electronic Certification
   By executing this Electronic Certification, I certify that I have reviewed the Personal/Organizational Disclosure of Interest Form, and the information given above is true to the best of my knowledge.

Name: _____ **Signature:** _____

Date: _____

All persons and organizations must be free of any conflicts of interest financially for this effort. If at any time you believe that a potential or actual conflict exists, you must notify Battelle immediately. “Conflict of Interest” means because of other activities or relationships with other persons or organizations you are unable or potentially unable to (1) render impartial assistance or advice; (2) perform due to the impairment of or the possibility of the impairment of your objectivity; or (3) perform because you have or might acquire an unfair competitive advantage.

Appendix C: Measure Disclosure of Interest Form

1. Name:

   Organization Affiliation:

   Committee Name:

   Cycle (ex. Fall 2025):

2. Describe any personal or organizational measure conflicts. If None, check here: ☐
   a. Measures under review:

CBE #	Measure Title	Measure Developer/Steward
####	[insert title]	[insert developer and steward]
####	[insert title]	[insert developer and steward]
####	[insert title]	[insert developer and steward]

      i. If you have worked as an employee, collaborator, or consultant of the measure developers/stewards listed *OR* contributed to the development of the measures listed, in any capacity, in the past five (5) years, check here: ☐

   b. Competing Measures:

CBE #	Measure Title	Measure Developer/Steward
####	[insert title]	[insert developer and steward]
####	[insert title]	[insert developer and steward]
####	[insert title]	[insert developer and steward]

      i. If you have worked as an employee, collaborator or consultant of the measure developers/stewards listed *OR* contributed to the development of the measures listed, in any capacity, in the past five (5) years, check here: ☐

   c. If you checked either box under 2a. or 2b. above, please provide a detailed description of the involvement. (Include CBE ID number, Measure Title, Cycle, and Steward Name:)

(continued on next page)

3. Electronic Certification

   By executing this Electronic Certification, I certify that I have reviewed the Measure Disclosure of Interest Form, and the information given above is true to the best of my knowledge.

Name: _____ **Signature:** _____

Date: _____

All persons and organizations must be free of any conflicts of interest for measures under this effort. If at any time you believe that a potential or actual conflict exists, you must notify Battelle immediately. "Conflict of Interest" means because of other activities or relationships with other persons or organizations you are unable or potentially unable to (1) render impartial assistance or advice; (2) perform due to the impairment of or the possibility of the impairment of your objectivity; or (3) perform because you have or might acquire an unfair competitive advantage.

Appendix D: PQM Measure Evaluation Criteria

Note: Rubric items correspond to items in the measure submission form and identify which items in the submission provide the information needed to evaluate each criterion.

Importance
Attach a logic model depicting the relationship between structures and processes and the desired outcome.
Summarize evidence of measure importance from the literature linking the structure/process/intermediate outcome to the outcome
[For initial endorsement] If implemented, what is the measure's anticipated impact on important outcomes?
[For maintenance] Provide evidence of performance gap or measurement gap by providing performance scores on the measure as specified (current and over time) at the specified level of analysis
Explain why existing measures/quality improvement programs are insufficient for addressing this health care need?
Provide evidence the target population (e.g., patients) values the measured outcome, process, or structure, and finds it meaningful. Describe how and from whom you obtained input.

Not Met:

- Evidence is about something other than what is measured OR
- Empirical evidence submitted without systematic review or grading OR
- Empirical evidence includes only selected studies OR
- Evidence is not graded high quality or strong recommendation OR
- Systematic review conclusion is that consistency is low or controversial; moderate/high certainty that the net benefit is null or small; or grade of weak OR
- There is low confidence/certainty that there is an adequate business case (adequate=there is a net benefit to measurement) OR
- There is low confidence/certainty that there is evidence of a performance gap OR
- There is no description of other existing measures or programs or no search conducted to identify other existing measures or programs OR
- Proposed measure has the same measure focus and target population as existing measures and offers no advantage in terms of addressing disparities, feasibility, potential use, or scientific acceptability OR
- Patient input does not support the conclusion that the measured outcome, process, or structure is meaningful or it does so with a low degree of certainty.

Not Met but Addressable:

- Criterion is not met (see above), but the reviewer can identify changes to specifications that may strengthen the measure's importance such that the criterion could be met.

Met:

- Systematic review concludes with at least moderate certainty that net benefit is at least moderate AND
- There is at least moderate confidence/certainty that there is an adequate business case (adequate=there is a net benefit to measurement) AND
- There is at least moderate confidence/certainty that there is evidence of a performance gap AND
- Description of existing measures or programs justifies the proposed measure's focus among the proposed measure's target population and/or the proposed measure is superior to identified related or competing measures AND
- Description of patient input supports the conclusion that the measured outcome, process, or structure is meaningful with at least moderate certainty.

Feasibility
[For Initial Endorsement] Describe the feasibility assessment showing you considered the people, tools, tasks, and technologies necessary to implement this measure. Please attach your completed feasibility scorecard.
Describe how the feasibility assessment informed the final measure, indicating any decisions made to adjust the measure in response to data availability.
Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm.

Not Met:

- Feasibility assessment not systematically conducted or described OR
- Long-term or no path is specified to support routine and electronic data capture with an implementable data collection strategy.

Not Met but Addressable:

- Criterion is not met (see above), but the reviewer can identify changes to specifications that may improve feasibility such that the criterion could be met.

Met:

- Near-term paths are specified to support routine and electronic data capture with an implementable data collection strategy OR
- Required data are routinely generated and used during care, required data are available in EHRs or other electronic sources, and the data collection strategy can be implemented.

Scientific Acceptability
Describe the data or sample used for testing (include dates, source). If you used multiple data sources for different aspects of testing (e.g., reliability, validity, risk adjustment), identify how the data or sample are different for each aspect of testing.
Provide descriptive characteristics of measured entities included in the analysis (e.g., size, location, type). If you used a sample, describe how you selected entities for inclusion in the sample.
Identify the number and descriptive characteristics (e.g., age, sex, race, diagnosis), of the unit of analysis, for example, patient, encounter or episode, separated by level of analysis and data source. If you used a sample, describe how you selected the patients for inclusion in the sample. If there is a minimum case count used for testing, you must reflect that minimum in the specifications.
If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), please identify how the data or sample are different for each aspect of testing.
Select the level of reliability testing conducted. ☐ Patient or Encounter-Level (e.g., inter-abstractor reliability) ☐ Accountable Entity Level (e.g., signal-to-noise analysis)
For each level of reliability testing conducted, describe the method of reliability testing and what it tests.
Provide the statistical results from reliability testing at the unit of analysis and the accountable entity level
Select the level of validity testing conducted ☐ Patient or Encounter-Level (e.g., inter-abstractor reliability) ☐ Accountable Entity Level (e.g., signal to noise analysis)
Select the type of validity testing conducted. ☐ Empirical validity testing ☐ Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., the score is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance).
For each level of testing conducted, describe the method of validity testing and what it tests.

Scientific Acceptability
Provide your interpretation of the results in terms of demonstrating validity (i.e., How do the results support an inference of validity for the measure?)
Check all methods used to address risk factors ☐ Statistical risk model with risk factors ___Specify number of risk factors) ☐ Stratification by risk category ___Specify number of categories) ☐ Other ___Specify ☐ No risk adjustment or stratification
Attach a conceptual model that illustrates the pathway between the social and/or functional status-related risk factors, patient clinical factors, quality of care, and the measured outcome. Explain the rationale for the model.
Provide descriptive statistics on the distribution across the measured entities of the risk variables identified in the conceptual model.
If using statistical risk models, provide detailed risk model specifications (query or algorithm), including the risk model method, risk factors, risk factor data sources, coefficients, equations, codes with descriptors, and definitions.
Detail the statistical results of the analysis used to test and select risk factors for inclusion in or exclusion from the risk model/stratification.
Provide the approach and results of calibration and discrimination testing. Describe any over- or under-prediction of the model for important subgroups.
If an outcome or resource use measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate there is no need to control for differences in patient characteristics (i.e., case mix) to achieve fair comparisons across measured entities.

Not Met:

Sampling

- Sampling is used and sampling strategy is not determined by the measure's analytic unit OR sample does not represent variety of entities whose performance will be measured OR sample does not include adequate numbers of units of measurement for the selected statistical method OR

For Patient or Encounter Level Reliability

- Internal consistency < 0.7 OR
- Inter-rater agreement < 0.4 OR
- Test-retest reliability (ICC or Pearson correlation) < 0.5 OR
- Linear relationship < 0.6 OR

For Accountable Entity Level Reliability

- Signal to noise/Inter-unit Reliability < 0.6 OR
- Split-half reliability (ICC) < 0.6 OR

Validity

- Face validity is inadequate or is the only type of validity discussed and the measure is undergoing maintenance review OR
- Reviewer determines that the methodology to assess validity is inadequate/inappropriate OR the analytic approach is inadequate/inappropriate OR
- Reviewer disagrees with the assertion that the measure can distinguish quality with limited or no threats to validity present OR

Risk Adjustment

- Factors in the risk model do not influence the measured outcome or are not present at the start of care OR risk model includes factors that are associated with differences or inequities in care without sufficient rationale based on a conceptual model OR
- Analysis does not demonstrate:
    - Variation in prevalence of risk factors across measure entities AND
    - Contribution to unique variation in the outcome AND
    - Impact of risk adjustment for providers at high or low extremes of risk OR
    - Results do not demonstrate acceptable model performance.

Not Met but Addressable:

- Criterion is not met but the reviewer can identify:
    - Improvements to the sampling methodology OR
    - Changes to the methodology/analytic approach that could improve assessment of reliability OR
    - Changes to the methodology/analytic approach that could improve assessment of validity OR
    - Changes to the specifications that could improve validity and/or address threats to validity OR
    - Changes to the risk model that could improve model appropriateness or performance.

Met:

Sampling

- If a sample is used, the sampling strategy is determined by the measure's analytic unit AND sample represents the variety of entities whose performance will be measured AND sample includes adequate numbers of units of measurement for the selected statistical method AND

For Patient or Encounter Level Reliability

- Internal consistency ≥ 0.7 OR
- Inter-rater agreement ≥ 0.4 OR
- Test-retest reliability (ICC or Pearson correlation) ≥ 0.5 OR
- Linear relationship ≥ 0.6 AND

For Accountable Entity Level Reliability

- Signal to noise/Inter-unit Reliability ≥0.6 OR
- Split-half reliability (ICC) ≥ 0.6 AND

Validity

- Face validity is adequate, and the measure is undergoing initial review OR
- Reviewer determines methodology employed is adequate and the analytic approach presented is appropriate and thorough AND
- Reviewer determines that results of empirical testing adequately demonstrate that the measure is valid AND
- Reviewer determines the interpretation of the empirical results supports an inference of validity AND

Risk Adjustment

- Factors in the risk model influence the measured outcome and are present at the start of care AND risk model does not include factors that are associated with differences or inequities in care unless justification provided based on a conceptual model AND
- Analysis demonstrates:
    - Variation in prevalence of risk factors across measured entities AND
    - Contribution to unique variation in the outcome
    - Impact of risk adjustment for providers at high or low extremes of risk AND
    - Results demonstrate acceptable model performance.

Equity
Describe how this measure contributes to efforts to address inequities in health care. Provide a description of your methodology and approach to empirical testing of differences in performance scores across multiple sociocontextual variables (e.g., race, ethnicity, urbanicity/rurality, SES, gender, gender identity, sexual orientation, age). Provide an interpretation of the results, including interpretation of any identified differences and consideration of negative impact or unintended consequences on subgroups.

Not Met:

- Reviewer determines that equity is not sufficiently assessed OR that measure does not contribute to efforts to address inequities in health care.

Not Met but Addressable:

- Criterion is not met but reviewer can identify changes to the assessment of equity OR changes to the measure specifications that would address inequities in health care.

Met:

- Reviewer determines sufficient assessment of equity was conducted (i.e., methodology provided, differences in scores tested across multiple categories, and interpretation of results) AND that the measure contributes to efforts to address inequities in health care.

Use and Usability
[For initial endorsement] Check all planned uses and provide the name of the program and sponsor, URL, purpose, geographic area and percentage of accountable entities and patients included, and level of analysis and care setting. ☐ Social Security Act modifications under the Patient Protection and Affordable Care Act and related accountability applications ☐ Quality Payment Program (QPP) Merit-based Incentive Payment System (MIPS) and Qualified Clinical Data Registries (QCDRs) ☐ Specialty society clinical data registrations ☐ Certification programs ☐ Employer insurance plans

☐ Medicaid ☐ Other use:
[For maintenance review] Check all current uses. ☐ Social Security Act modifications under the Patient Protection and Affordable Care Act and related accountability applications ☐ QPP MIPS and QCDRs ☐ Specialty society clinical data registrations ☐ Certification programs ☐ Employer insurance plans ☐ Medicaid ☐ Other (specify):
What are the actions measured entities must take to improve performance on this measure? How difficult are those actions to achieve?
[For maintenance only] Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how you obtained feedback.
[For maintenance only] Describe how you considered the feedback when developing or revising the measure specifications or implementation, including whether you modified the measure and why or why not.
[For maintenance only] Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality health care, geographic area, number and percentage of accountable entities and patients included). If use of the measure demonstrated no improvement, provide an explanation.

Not Met:

For initial endorsement

- There is no plan for use in at least one accountability application within 3 years of initial endorsement OR
- Performance scores do not yield actionable information that can be used to improve performance among measured entities.

For maintenance

- The measure is not currently in use in at least one accountability application OR
- Performance scores do not yield actionable information that can be used to improve performance among measured entities OR
- Reviewer determines that based on the information provided regarding feedback on measure performance that the measure is not usable.

Not Met but Addressable:

For initial endorsement and maintenance

- Criterion is not met (see above), but the reviewer can identify changes to specifications that may strengthen the measure's ability to yield actionable information or usability.

Met:

For initial endorsement

- There is a plan for use in at least one accountability application within 3 years of initial endorsement AND
- Performance scores yield actionable information that can be used to improve performance among measured entities.

For maintenance

- The measure is currently in use in at least one accountability application AND
- Performance scores yield actionable information that can be used to improve performance among measured entities.
- Reviewer determines that based on the information provided regarding feedback on measure performance that the measure is not usable.

Appendix E: Guidance to Make Submissions 508 Compliant (required)

The E&M team ensures that all public facing materials are 508 compliant. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), ensures those with disabilities have equal access to government information as contained on information and communications technology (ICT), and thereby to the government employment, programs and services to which all citizens are entitled. The following steps should be taken during the measure submission process to maintain Section 508-compliance:

- Creating tables with row and column headers and proper reading order. Tables must be properly created to be Section 508-compliant. The table feature of the software must be employed, rather than tabs and drawn lines. Row and column headers must be identified as such. Tables must be set up such that the reading order is left to right and top-down in order to be read correctly by read-aloud software. Tables should avoid any merging or splitting of cells. Table rows should not split/break across pages. Repeat the column and row headers to avoid merging cells and issues with splitting/breaking rows across pages.
- Providing alternative text (alt-text), a text equivalent that describes images, graphics, and exhibits that can be used by text-to-speech programs. Developers/stewards should provide alt-text of the image, chart, or graphic that describes all the information important for understanding the image for the visually impaired web user. All of the relevant information in charts, graphs, and diagrams should be included in the alt-text. Images or graphics that are added for design or layout only (that is, add no meaning to the document) can be described briefly, as in “bullet” or “empty cell.”
- Using color appropriately. There must be enough color contrast in graphics to prevent those individuals with color vision deficiencies from having problems understanding the graphic. Color alone cannot be used to convey information or meaning.
- Creating hyperlinks using a description of the link destination rather than vague or confusing text such as “click here.”

The E&M team provides a checklist of 508 compliance criteria for developers/stewards to consider when submitting measures to Battelle (see below).

508 GUIDANCE CHECKLIST

Version: 1.0; Generated: 14 April 2023

These guidelines apply to all parts of your measure submission including all fields and attachments used within the measure submission forms.

Text

- ☐ Is all my text black, not using any other colors?
- ☐ Am I reserving underlined text for **hyperlinks** only and creating emphasis using *italic,* **bold,** and ***bold-italic*** text instead of using underlining?
- ☐ Am I avoiding multiple hard and soft returns?
- ☐ Are all my hyperlinks working, linked to their correct destination, and using a distinct style to set them off from regular text?
- ☐ Do all my bulleted or numbered lists use the built-in bulleting or numbering options?

Tables

- ☐ Are my tables actual tables and **not** images or screenshots of a table?
- ☐ Am I using the MIMS table creation tool or a attaching a Word *Table Design Style* table?
- ☐ Am I repeating the column and row headers in individual cells to avoid merged table cells?
- ☐ Do my empty table cells contain a symbol like * with the note: **Cells intentionally left empty,* at the bottom outside of my table?
- ☐ Did I write a brief description of what the table conveys using the Table Caption option?
- ☐ Is the table converted to paragraph text if it is too long to fit all of one column on a single page and flows over to the next page?
- ☐ Does my attached Word table have *Allow row to break across pages* turned **off** for all rows and *Repeat as header row at the top of each page* turned **on** for the first row?

Images, Figures, Graphs, Charts, and Pictures

- ☐ Do my images include clear concise alt-text descriptions of what they represent using the image caption option, or Edit/Alt-text option for Word attachments?

Appendix F: Measure of Consensus

- Variance is used as a metric to assess disagreement (lack of consensus)
- However, variance alone is insufficient when comparing different sizes of groups or groups that have different means
- The measure of consensus is the complement of the index of disagreement, which is based on the variance of the responses scaled by the total available range of variance conditional on the mean response.

Number of respondents	Evidence complete and adequate	Evidence not complete nor adequate, but will path forward	Evidence not complete nor adequate, and no path forward	Measure of Consensus
40	0.000	0.250	0.750	1.00000
40	0.125	0.125	0.750	0.99429
20	0.000	0.250	0.750	1.00000
20	0.125	0.125	0.750	0.95170
40	0.125	0.750	0.125	0.99707
20	0.150	0.750	0.100	0.97065
40	0.250	0.000	0.750	0.94527
20	0.250	0.000	0.750	0.95110
40	0.500	0.000	0.500	0.81789
20	0.500	0.000	0.500	0.80713

Measure of Consensus = 1 – Index of Disagreement

Index of Disagreement = Response variance / Total available range of variance

Threshold for “consensus” is 0.95000

References

M. A. Rahem and M. Darrah, “A geometric approach for computing a measure of consensus for groups,” International Mathematical Forum, vol. 11, pp. 961–973, 2016.

M. A. Rahem and M. Darrah, "Using a Computational Approach for Generalizing a Consensus Measure to Likert Scales of Any Size." International Journal of Mathematics and Mathematical Sciences, 2018.

Y. Akiyama, J. Nolan, M. Darrah, M. A. Rahem, and L. Wang, “A method for measuring consensus within groups: an index of disagreement via conditional probability,” Information Sciences, vol. 345, pp. 116–128, 2016.

Y. Tsuchiya and N. Hiramoto, “Measuring consensus and dissensus: a generalized index of disagreement using conditional probability,” Information Sciences, vol. 439/440, pp. 50–60, 2018.

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