

# Developer Guidebook

## Two-Stage Consensus Development Process (CDP)

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NATIONAL  
QUALITY FORUM

# DEVELOPER GUIDEBOOK

## Two-stage Consensus Development Process (CDP)

### Table of Contents

<b>Overview of 2-Stage Consensus Development Process Redesign .....</b>	<b>3</b>
Why is NQF considering a change to its endorsement process? .....	3
What will the new process look like?.....	4
What are the benefits of the new process?.....	4
<b>Steward/Developer Roles and Expectations during Concept and Measure Evaluation .....</b>	<b>6</b>
Steward Participation in the Consensus Development Process .....	6
<i>Call for Concepts or Candidate Standards</i> .....	6
<i>Candidate Consensus Standard Review</i> .....	10
<i>Public and Member Comment</i> .....	11
<i>Member Voting (Stage 2 only)</i> .....	12
<i>Consensus Standards Approval Committee (CSAC) Decision</i> .....	13
<i>Board Approval or Ratification</i> .....	14
<i>Appeals (Stage 2 only)</i> .....	14
<b>Submitting Measures and Measure Concepts.....</b>	<b>16</b>
Measure Concept Agreement.....	16
Measure Steward Agreement.....	16
Harmonization and Competing Measures and Concepts .....	17
Online Measure and Concept Submission .....	18
<i>Measure Concept Submission</i> .....	18
<i>Measure Submission</i> .....	18
<i>What Good Looks Like?</i> .....	19
<i>Estimated Level of Effort</i> .....	19
Technical Review.....	19
<b>Maintenance and Measure Stewardship .....</b>	<b>22</b>
Stewardship .....	22
Approved Concepts.....	22
Concepts not Approved .....	22
Maintenance of Endorsed Measures .....	22
Annual Updates.....	22
<b>APPENDICES .....</b>	<b>24</b>
Appendix A: Guidance on Concept and Measure Submission and Review .....	25
Appendix B: Task Force Recommendations for Measure Maintenance, 2012.....	78
Appendix C: Measure Concept Agreement.....	80
Appendix D: Example of Exhibit A of the Measure Concept Agreement.....	86
Appendix E: Appendix A of Measure Steward Agreement .....	87
Appendix F: Example of Appendix A of the Measure Steward Agreement .....	88
Appendix G: Glossary .....	89

## National Quality Forum

### Overview of 2-Stage Consensus Development Process Redesign

In recent years, the healthcare field has become increasingly focused on performance measurement, quality improvement, and accountability, generating new opportunities for the measurement community – but also creating significant pressures and challenges for all those involved. NQF endorsement projects have increased in number and complexity while stakeholder expectations for the timeliness and effectiveness of the entire measure development, testing, and endorsement process have intensified.

NQF strives to continually improve its systems, policies, and processes, and is committed to seeking feedback to remain responsive to its stakeholders' needs. In response to requests from various stakeholders, NQF is examining a potential redesign of the Consensus Development Process (CDP) to accomplish two objectives: 1) to provide measure stewards with a determination of whether a “measure concept” satisfies the “importance to measure” endorsement criterion prior to full development and testing of the measure; and 2) once a measure concept has been approved, to provide greater flexibility for stewards to bring fully developed and tested measures back to NQF at any point in time to complete the endorsement process.

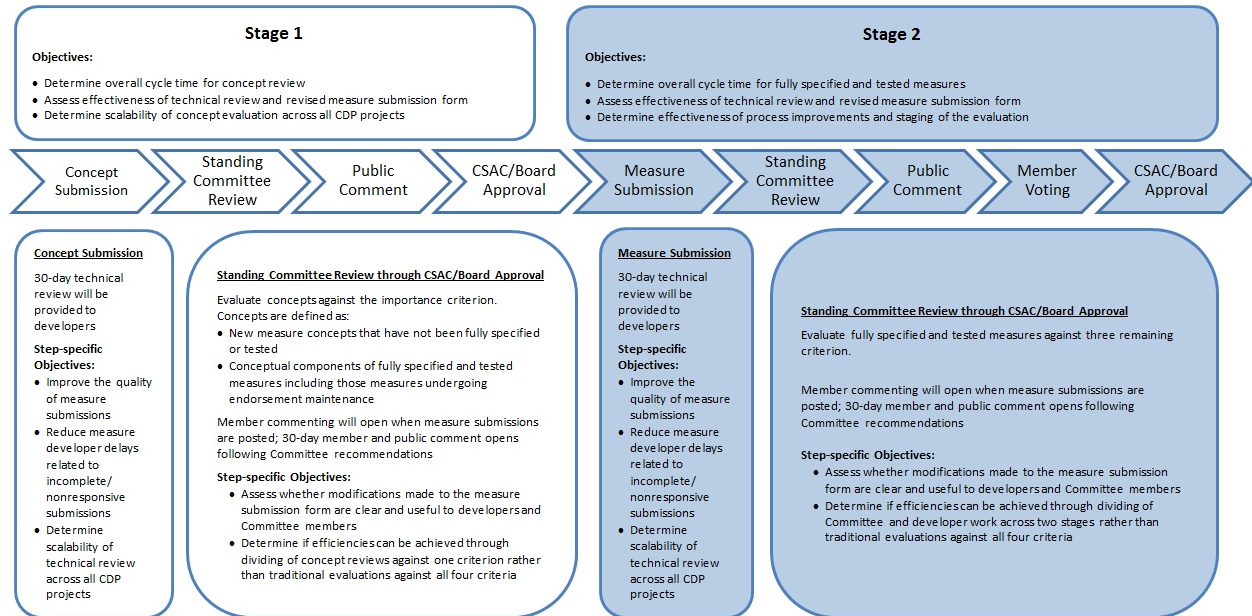
#### **Why is NQF considering a change to its endorsement process?**

To be endorsed, a measure submitted to NQF must satisfy four criteria—importance to measure and report (must pass), scientific acceptability of the measure properties (must pass), feasibility to implement, and usability of the measure results—and must be judged to be “best in class.” Often, measures do not make it past the importance criterion. Since measure stewards/developers are currently required to submit fully specified and tested measures for consideration, this leads to costly investments of steward/developers' time and resources to specify and test a measure that may not achieve NQF endorsement.

In recent months, NQF was asked to determine if the CDP could be modified to enable early review and approval of “measure concepts” against the importance criterion. Once a “concept” has passed the importance criterion, the steward would then be able to move forward with testing and further development of the measure having been assured by a steering committee that one of the criteria on which many measures to not passed has been achieved.

## What will the new process look like?

Figure 1: Proposed Two-Stage Endorsement Process



In the proposed redesign, the consensus development process would be conducted in two stages. As described in Figure 1 above, measure “concepts” against NQF’s importance criterion (addresses a high impact area, gap in care or opportunity for improvement exists, and evidence is sufficient to support the focus) would be evaluated in Stage 1. Potential related and competing measures would also be identified during this stage. All measures, regardless of their stage of development (e.g., concept, fully specified measure, fully specified measure with testing, undergoing maintenance review with NQF) would be required to undergo concept review.

Once the importance threshold has been met, a measure or concept could move into the second stage of the CDP. In the case of concepts, stewards would have up to 18 months to complete testing and full specification of their measures and bring back the measure for Stage 2 review.

Stage 2 would evaluate fully specified and tested measures against the remaining three criteria: scientific acceptability, usability, and feasibility. At the end of Stage 2, measures that are ratified by the Board will receive endorsement.

To accomplish these reviews, NQF will convene approximately 19 standing committees consisting of a mix of both clinical subject areas, like cardiovascular or perinatal care, and cross-cutting topics, like patient safety or care coordination. These committees would consider measure concepts and measures on a preset schedule throughout the year.

## What are the benefits of the new process?

The two-stage process could have a number of important benefits, including:

- **Better use of measure development resources.** Should stewards avail themselves of the measure concept approval option prior to specifying and testing a measure, it is less likely that measure development resources will be expended on the specification and testing of measures that would not pass the importance criterion.
- **Early opportunities for feedback.** The redesigned process will provide opportunities for feedback from NQF expert panels, as well as other key stakeholders such as consumers and purchasers, at the 'conceptual' stage, helping stewards refine measures at an early stage in their development.
- **Harmonization and best-in-class selection of measures.** The concept review stage will allow for early identification of harmonization and competing measure issues. Stewards/developers will have time to identify other measures that they should harmonize with, and to foster earlier collaboration with other stewards/developers.
- **More predictable schedules.** Establishing a system of standing committees meeting on regular, fixed timelines will increase the predictability of NQF's endorsement process, which will benefit all stakeholders. Measure stewards/developers will have a greater ability to plan their development efforts to correspond with the appropriate endorsement cycles; NQF members and the public will have a better sense of when measures will be available for comment and voting; and Steering Committee members, who participate on a volunteer basis and must balance their contributions to NQF projects with their already-busy work schedules, will be able to plan for in-person meetings, conference calls, and other NQF-related activities well in advance.

## Steward/Developer Roles and Expectations during Concept and Measure Evaluation

NQF evaluates measures against the standardized [Measure Evaluation Criteria](#):

- [Importance to Measure and Report](#) (PDF)
- [Scientific Acceptability of Measure Properties](#) (PDF)
- [Usability and Feasibility](#) (PDF)

In addition, composite measures are evaluated using the [Composite Evaluation Criteria](#) (PDF).

Information regarding the measure evaluation criteria as well as guidance documents can be found on the [Measure Evaluation Criteria](#) page on the NQF website.

In the two-stage CDP, measure concepts will be evaluated in the first stage against the Importance criteria, and the remaining criteria in stage two.

For more details on measure evaluation criteria, please see the following reports:

- [Evidence Task Force Report](#) (specifically for submission of concepts during Stage 1)
- [Measure Testing Task Force Report](#) including testing for eMeasures (specifically for submission of measures during Stage 2)
- [Harmonization Report](#) (related measures)
- [Competing Measures Report](#)
- [Reserve Status](#)

Evaluation and Concept/Measure Submission Guidance (presentation PDFs):

- [Guidance on Quality Performance Measure Construction](#)
- [Evidence and Importance to Measure and Report](#)
- [Measure Testing and Scientific Acceptability of Measure Properties](#)

### Steward Participation in the Consensus Development Process

Below are descriptions of the steps in the Consensus Development Process (CDP). This section provides detailed information of what occurs in each step and the role of the measure developer/steward.

#### *Call for Concepts or Candidate Standards*

At least two months before the start of a project, NQF issues a formal call for concepts or a call for candidate standards. Currently, there are two types of calls for standards: a call for measure concepts or measures and a call for practices. Based upon the scope and objective of the consensus development project, NQF may initially issue a call for practices, and issue a subsequent call for concepts and/or measures at a later date.

NQF's current understanding of the term performance measure draws heavily on the work of the Institute of Medicine (IOM). A performance measure, according to the IOM definition, is the "numeric quantification of healthcare quality." IOM defines quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Thus, performance measures can measure and quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality care.

Each candidate concept, measure or set of concepts or measures will have a measure steward who will assume responsibility for the submission of the concept for potential approval or measure for potential endorsement to NQF. The measure steward is responsible for making the necessary updates to the concept or measure, and for informing NQF about any changes that are made to the concept or measure. These changes are most often provided during the annual update process where developers attest whether there are changes to the measure and if so, what. Once a measure is endorsed, the measure steward is also responsible for providing the required information for the measure maintenance process that occurs approximately every three years.

NQF posts Concept Submission Forms and Measure Submission Forms for its projects on the website to obtain ongoing public input during the consensus development process.

### Measure Steward/Developer Expectations during Concept Submission/Measure Submission

1. Notify the appropriate NQF project staff that you plan on submitting a concept or a measure.
2. Familiarize yourself with the project timeline and submission deadline dates.
3. Create an [NQF account](#) if you do not already have one.
4. Review the resources provided to ensure your submission form(s) is complete and responsive:
  - a. NQF Measure Evaluation Criteria [web page](#)
  - b. [Composite Evaluation Criteria](#), if submitting a composite concept or measure
  - c. Guidance for Concept and Measure Submission and Review (Appendix A)
  - d. Task Force Recommendations for Measure Maintenance, 2012 (Appendix B)
  - e. [Evidence Task Force Report](#) (specifically for submission of concepts during Stage 1)
  - f. [Measure Testing Task Force Report](#) (specifically for submission of measures during Stage 2)
  - g. [Harmonization report](#) (related measures)
  - h. [Competing measures report](#)
  - i. Quality Positioning System (QPS): [Tool to search for endorsed measures](#)
5. Begin to complete the submission form(s)
  - a. **Note:** Allow adequate time to complete the submission forms. While the level of effort to complete the submission form will vary widely based on many factors (i.e., experience of submitter, complexity of measure, type of measure, developer resources), anticipate ~ 4 hours/concept submission form, and ~4-8 hours/measure submission form. Additional information can be found in the chapter on *Submitting Measures and Measure Concepts*.
  - b. **There will be one attachment required for each stage of the review.** In stage one, the evidence attachment is required and for stage two, it is the testing attachment.
6. Contact the appropriate NQF project staff if you have any questions while you are completing the submission form(s).



7. Submit your submission form(s) for technical review by the technical review deadline. Staff may identify areas in your submission form(s) that may not be responsive to questions or the measure evaluation criteria and ask that you make the necessary changes prior to the submission deadline.
  - a. **Note:** Any submitted attachments aside from the evidence (Stage 1) or measure testing (Stage 2) forms are considered supplemental information and review by the Committee is optional. All necessary and requested information to be reviewed by the Committee should be placed in the concept or measure submission form or on the evidence or measure testing forms.
8. Submit your submission form(s) by the submission deadline.

***Important Note:*** *If the submission is incomplete or not responsive so that there is insufficient information on which to evaluate any of the 4 criteria: Importance to Measure and Report, Scientific Acceptability of Measure Properties, Usability, and Feasibility, the concept or measure will not be accepted for consideration.*

9. Submit your measure steward agreement or measure concept agreement by the submission deadline:
  - a. For concepts (Stage 1 only): Submit a signed measure concept agreement—contact the appropriate NQF project staff to receive the agreement (see the chapter on *Submitting Measures and Measure Concepts* for more details).
  - b. For fully specified and tested measures (Stage 2 only): Submit a signed [measure steward agreement](#) (MSA) OR updated list of measures that includes the additional measure(s) that will be appended to the signed MSA. Contact the appropriate NQF project staff to receive the Appendix A document to update the list of measures if you currently have a signed MSA on file (see the chapter on *Submitting Measures and Measure Concepts* for more details).

### What Good Looks Like?

To review some examples of the type of information NQF is seeking in the concept and measure submission forms, review the related information for examples for evidence, measure testing and concept and measure submission items in Guidance for Concept and Measure Submission and Review ([Appendix A](#)).

#### *Candidate Consensus Standard Review*

After the close of a call for concepts or measures, the relevant project Steering Committee conducts a detailed review of all submitted concepts or measures, sometimes with the help of a Technical Advisory Panel. The duration of a Steering Committee's review of the concepts or measures for a given project can vary depending on the scope of the project, the number of concepts or measures under review, and the complexity of the concepts or measures.

Once the submission forms are posted on the project webpage, NQF members may begin commenting on the submitted concepts or measures. Comments received during the Committee evaluation period (prior to the in-person meeting) will be reviewed and discussed by the Committee at the meeting.

During this review process, the Steering Committee will meet in person two times (once for each stage) to discuss and evaluate the submitted concepts or measures. If there is a Technical Advisory Panel for the project, the Panel also may meet during this review process and provide specific technical advice to the Steering Committee. Both bodies may meet via conference call in addition to the scheduled in-person meetings.

Developers are strongly encouraged to participate in all calls and meetings of the Steering Committee. At the in-person meeting, each will be provided an opportunity to speak to their concepts/measures under consideration as well as on conference calls as needed.

All meetings and conference calls of a Steering Committee and any associated Technical Advisory Panel(s) are open to NQF members and the public. Information about each of these meetings, including the agenda and the location or the dial-in information is posted on the NQF website, through both the events calendar and the specific webpage for the project. Each meeting of a Steering Committee and of a Technical Advisory Panel features specific period(s) during which NQF members and interested members of the public may make comments regarding the Committee's deliberations.

During its evaluation of the concepts or measures submitted for NQF endorsement, a project Steering Committee is expected to achieve consensus on endorsement recommendations, as defined in the Office of Management and Budget (OMB) Circular A-119:

*General agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments (OMB Circular A-119, Section 4(a)(1) (1998)).*

### **Measure Developer Expectations during Steering Committee Review**

- Each Committee will meet for a 2-day in-person for a minimum of two times in a two-stage project.

#### *Prior to the In-Person Meeting:*

- Notify the appropriate project staff of who, from your organization, will be attending (in person or via phone) the in-person meeting and representing your concept(s) or measure(s).

#### *During the In-Person Meeting (2 days):*

- Attend the entire Steering Committee in-person meeting. Please be prepared to answer any questions from the Committee. Concepts and measures are usually grouped by topic area.
- At the in-person meeting, each measure developer will be given 3-5 minutes to briefly introduce their concept(s) or measure(s). Developers should focus their remarks on the rationale/intent behind the submitted concept(s) or measure(s) for consideration, their approach to measure development and testing, lessons learned from use of the measure (does not apply for concepts) and any unique issues.
- Developers are welcome to make comments during the NQF Member and Public Comment periods designated on the agenda.

#### *After the In-Person Meeting*

- If the Committee requested additional information from the developer, submit the requested information to project staff by the requested deadline.
- *(Stage 1 Only)* Developers will receive a checklist from NQF staff listing any items that should be addressed by the developers before an approved concept is resubmitted for stage 2 review. Stage 2 submissions will be checked against the checklist by NQF staff before passing submissions on to the Committee for review. Examples of checklist items may include Steering Committee recommendations for testing or reminders for NQF testing requirements.
- Developers can make general responses and comments during the NQF Member and Public Comment periods designated on the agenda.

#### *Public and Member Comment*

After a project's Steering Committee completes its initial review of the submitted concepts or measures, a draft of the Committee's recommendations--or "technical draft report"-- is posted on the NQF website for review and comment by members of NQF and the public. All concepts or measures regardless of the recommendation are posted for public and member comment.

As a part of the two-stage CDP, once the submission forms are submitted and subsequently posted, NQF members may begin commenting on the submitted concepts or measures. Comments received during the Committee evaluation period prior to the in-person meeting will be reviewed and discussed by the Committee at the meeting. All comments received after this meeting will be considered when comments on the technical report from the 30-day public and member comment period are reviewed.

When a commenting period opens, a notification is posted on the NQF website, and will be available through the event calendar and on the specific project page. NQF also sends out an email notification to NQF members and members of the public who have signed up for these notifications.

Both NQF members and interested members of the public can electronically submit comments on the Steering Committee's draft report via the NQF website. As part of NQF's commitment to transparency, all submitted comments will be posted on the NQF website, where they can be reviewed by any site visitor.

Following the conclusion of the public and member comment period, the project Steering Committee reviews all submitted comments. During its review, the Steering Committee may also seek out technical advice or other specific input from external sources, as needed.

After its review of the submitted comments, the Steering Committee may choose to revise its recommendations within the draft report in response to a specific comment or series of comments. Any revisions will be redlined in the revised draft report.

Should the Steering Committee gauge its revisions to be substantial in nature, a revised version of the draft report may be re-circulated for a second comment period for members and the public. If a revised version of the draft report is re-circulated for a second comment period, the review will follow the same process as the initial review and comment period.

#### **Measure Developer Expectations during Public Comment**

- Once the comment period opens, developers are encouraged to log in periodically throughout the comment period and review submitted comments. This will provide an opportunity to begin to think about how to respond to the comment(s).

#### *Following the Close of the Comment Period*

- Staff will notify developers and identify which comments require a developer response.
- Please submit developer responses to the comments by the deadline indicated by project staff. Staff will share the responses with the Steering Committee as well as post them on the project webpage during the NQF Member Voting period.
- Attend the Steering Committee conference call (~1-2 hours) to discuss the submitted comments. Be prepared to answer any questions from the Committee or public commenters.

#### *Member Voting (Stage 2 only)*

Once a project Steering Committee has reviewed all of the comments submitted during the public and member comment period and made any revisions to the draft report, members of NQF vote on the measures that are recommended by the Committee. All measures that are recommended by the Committee along with the results of member voting will proceed to the next step in the Consensus Development Process: review and recommendation by the Consensus Standards Approval Committee (CSAC).

Member voting will only occur in stage 2. Members will only vote on recommended measures; members will not vote on concepts recommended for approval by the Committee during stage 1.

All NQF member organizations are eligible to vote on any consensus development project. Each voting period is open for 15 days.

When a voting period opens, email notification is sent to NQF member organizations. Voting information is available on the NQF website.

Each NQF member organization may cast one vote in favor of or against approval of a Steering Committee's recommendations. A member organization may also abstain from voting on a particular consensus development project. All voting is conducted electronically and can be accessed via the email notification or the NQF website.

In rare instances, the Consensus Standards Approval Committee (CSAC) may request a second round of member voting. In such cases, NQF follows the same procedure to notify the membership and conduct the voting as outlined above.

#### **Measure Developer Expectations during Member Voting**

- Staff will notify developers of when the member voting period will open and close.
- At the close of member voting, staff will notify the developers of the voting results.

#### *Consensus Standards Approval Committee (CSAC) Decision*

The Consensus Standards Approval Committee (CSAC) reviews proposed concepts or measures for approval or disapproval and enhances NQF's Consensus Development Process. Members of the CSAC possess breadth and depth of expertise and are drawn from a diverse set of healthcare stakeholders with a simple majority of consumers and purchasers. Some CSAC members possess specific expertise in measure development, application, and reporting.

The CSAC holds three in-person meetings annually and convenes monthly by conference call. All convocations of the CSAC are open to NQF Members and the public. At each CSAC meeting, audience members have the opportunity to comment on the concepts or measures under consideration. Information about each CSAC meeting is available on the NQF website, including the meeting's agenda and materials and the physical location or dial-in information.

The CSAC reviews the recommendations of the Steering Committee, the public and member comments and their adjudication, and the results of NQF Member voting. After detailed review of a concept or measure, the CSAC determines if consensus has been reached across the various NQF Member Councils. The CSAC seeks further input from Council Leaders if there is a lack of consensus. On some occasions, the CSAC may also request a second round of Member voting on a particular measure or set of measures.

The CSAC can grant full approval or deny approval of a measure concept and recommend full endorsement or denial of endorsement of a measure.

An interested party may file a request for reconsideration of any measure (whether recommended or not during the NQF CDP) and this concern will be reviewed by the CSAC Chair and Vice Chair.

All of the CSAC's decisions regarding a concept, measure or measures are posted on the NQF website. In addition, all of the CSAC's recommendations are forwarded to the NQF Board of Directors for ratification.

The CSAC also serves in an advisory capacity to the Board of Directors and NQF management on ongoing enhancements to the Consensus Development Process and emerging issues in performance measurement.

#### **Measure Developer Expectations during CSAC Approval**

- Staff will notify developers when CSAC will review the submitted concepts or measures.
- Staff will provide developers with the materials for the CSAC call (agenda with dial-in information, CSAC memo, etc.).
- Developers are expected to attend the call (~1-2 hours) and answer any questions from members of CSAC.
- **Note:** A request for reconsideration of a measure can be submitted any time up until the CSAC review.

#### *Board Approval or Ratification*

CSAC decisions regarding concepts or measures are submitted to the [Board of Directors](#). The Board can affirm or deny a CSAC decision. All concepts or measures that are recommended must be ratified by the Board for approval (concepts only) or endorsement (fully specified and tested measures only).

After ratification by the NQF Board, the endorsement status of a measure is published on the NQF website. In addition, a searchable list of all NQF-endorsed<sup>®</sup> national voluntary consensus standards is available through the NQF [website](#).

#### *Appeals (Stage 2 only)*

After a measure has been formally endorsed by NQF, any interested party may **appeal the endorsement decision** with the NQF Board of Directors. An appeal may only be filed in response to NQF endorsement of a measure or set of measures; that is, an interested party *may not* file an appeal regarding the decision to not endorse a measure.

An appeal of an endorsed measure must be filed within 30 days of the endorsement decision by going to the project webpage or the [searchable list](#) of all NQF-endorsed<sup>®</sup> national voluntary consensus standards. For an appeal to be considered by NQF, the appeal must include written evidence that the appellant's interests are directly and materially affected by the measure recently endorsed by NQF, and that NQF's endorsement of this measure has had, or will have, an adverse effect on those interests.

All appeals are published on the NQF website.

Appeals are compiled and the CSAC reviews them and evaluates the concern raised is relevant and should warrant consideration of overturning the endorsement decision.

After discussions, the CSAC will make a recommendation to the NQF Board of Directors regarding the appeal. The Board of Directors will take action on an appeal within seven calendar days of its consultation with the CSAC.

The NQF Board of Directors' decision on an appeal of endorsement will be publicly available on NQF's website.

### **Measure Developer Expectations during Appeals**

- Staff will notify developers when the appeals period will open and close. An appeal can only be submitted for measures that have been endorsed by NQF. An appeal cannot be submitted for measures that were not recommended for NQF endorsement.
- At the close of the appeals period, staff will notify developers if any appeals were submitted on their measure(s).
- If an appeal was submitted, staff may request developers (if necessary) to provide a written response to the issues outlined in the letter of appeal.
- The letter of appeal will be discussed at the next CSAC in-person meeting or conference call. CSAC will review and discuss the letter of appeal and the developer's written response. The appellant will be asked to speak to their concerns and the developer will be provided an opportunity to respond. The developer will be asked to attend the CSAC call (~1-2 hours) and to answer any questions from CSAC.
- Following the CSAC call, staff will notify the developer of CSAC's recommendation to the NQF Board of Directors.

## Submitting Measures and Measure Concepts

**NQF uses an online Concept and Measure Submission Form.** The online submission form includes a variety of features and allows the user to:

- Gain secure access to the submission form from any location with an internet connection;
- Save a draft version of the form and return to complete it at his or her convenience; and
- Print a hard copy of the submission form for reference.

To review the questions included in the submission forms; review the online form (PDF) on the NQF website or review the Guidance on Concept and Measure Submission and Review ([Appendix A](#)). For more information on the function of the online submission form, please consult the Users' Guide to NQF's Online Measure Submission Form (PDF).

To submit a measure or concept, a steward must complete and electronically submit the online submission form for each concept and/or measure they wish to submit to NQF for consideration.

**Each submission to NQF, whether a concept, an endorsed measure undergoing maintenance review, or a new, fully specified and tested measure will now require a concept submission for initial evaluation against the criteria for Importance to Measure and Report.**

**A signed Measure Steward Agreement or Measure Concept Agreement must be submitted on or before the deadline for the measure or concept to be considered.**

### Measure Concept Agreement

Each steward who submits a concept to NQF must also submit a completed and signed Measure Concept Agreement (see [Appendix C](#)) on or before the concept submission deadline in order to be considered by the Committee. The measure concept agreement must include a completed Exhibit A, in which the steward provides information about the measure concept(s).

- A measure concept agreement must be submitting for the following:
  - A new measure concept that has not been fully specified or tested;
  - Conceptual components of a new, fully specified and tested measure; or
  - Conceptual components of a measure undergoing endorsement maintenance.
- Only one measure concept agreement is necessary for any one steward organization.
- Each concept submitted by the steward, must be listed in Exhibit A. The EXHIBIT A must include (see [Appendix D](#) for an example of how to complete Exhibit A of the measure concept agreement):
  - The name of the project in which the concept(s) was submitted for review and the date of submission.
  - The NQF measure number (if applicable), the measure title, measure description and type of measure concept must be listed for each concept submitted for review.

### Measure Steward Agreement

Each steward who submits a fully specified and tested measure to NQF in stage 2 must also submit a completed and signed [Measure Steward Agreement \(MSA\)](#) on or before the measure submission deadline in order to be considered by the Committee. The agreement is between NQF and the measure



steward. The MSA should be accompanied by the completed Exhibit A section of the MSA or a signed Appendix A listing the title and description of each measure submitted for review.

- Only one [MSA](#) is necessary for any one steward organization.
- If the steward is a governmental organization, an MSA is not required.
- A new measure steward who does not have an existing MSA with NQF must submit the MSA along with completing Exhibit A of the MSA, in which the steward must list all the measures (NQF measure number and measure title) being submitted for review.
- If a measure steward organization has an existing MSA with NQF, the organization will only need to submit Appendix A, as explained below (see [Appendix E](#)).

If there is an existing MSA with NQF, Appendix A must be completed so that additional measures submitted for review can be added to the MSA. **Appendix A must include** (see [Appendix F](#)) for an example of how to complete the document):

- The date in the first paragraph is the date the **ORIGINAL** Measure Steward Agreement was entered into. That date appears on the first page of the original MSA. NQF staff can assist you with the date if it is needed.
- The Steward's name must appear in the first paragraph next to the phrase -- "The Steward," which appears in parentheses after the Steward's name.
- The name of the project in which the measure(s) was submitted for review, date of submission the measure title and the measure description should all be entered above the sentence -- "All other provisions of the Agreement remain unchanged."
- The Steward's name MUST match the Steward's name on the underlying MSA. The individual signing Appendix A on behalf of the Steward need not be the same individual who signed the MSA.
- The document must be signed and dated by the steward. Electronic signatures are acceptable. "Signatures" in cursive font do not constitute an electronic signature, e.g.,

*Jane Doe.*

### Harmonization and Competing Measures and Concepts

It is the steward/developers' responsibility to determine if the concept or measure they plan to submit for NQF evaluation will need to be harmonized with similar NQF-endorsed measures or will be competing with an existing NQF-endorsed measure, **PRIOR** to submission.

- For convenience, please review the attached table of endorsed measures at the end of the Call for Concepts document to determine if the measure or concept you plan to submit is related or competing with existing endorsed measures.
- For guidance and definitions of measure harmonization and competing measures, review the [Measure Harmonization Report](#) and [Competing Measures](#) guidance.
- To search for similar and competing NQF-endorsed measures use the [NQF Quality Positioning System \(QPS\)](#).
- Concepts/measures identified as "similar" to endorsed measures, approved concepts, or to concepts/measures submitted in stage 2 will be returned to the steward/developer if harmonization was not achieved and will not be reviewed in that cycle.
- Concepts/measures identified as "competing" with endorsed measures, approved concepts, or with concepts/measures submitted during the same review cycle, must include a rationale in the submission for why the new concept/measure is superior.

## Online Measure and Concept Submission

To submit a measure or concept, a steward must complete and electronically submit the online submission form for each concept and/or measure they wish to submit to NQF for consideration.

- Each submission to NQF, whether a concept only, maintenance measure, or fully specified tested measure will require a concept submission for initial evaluation of the concept against the criteria for importance to measure and report.

### *Measure Concept Submission*

A measure concept submission will include the following information for newly created concepts or the information submitted to support the importance criterion for a fully specified measure, including maintenance measures:

#### Measure concept submission includes:

- Description of the measure concept including:
  - Measure Title
  - Brief Description
  - Numerator statement
  - Preliminary numerator details (not coding)
  - Denominator statement
  - Preliminary denominator details (not coding)
  - Exclusions under consideration
  - Preliminary exclusion details (not coding)
  - Risk adjustment variables under consideration
  - Proposed levels of analysis, data source, settings of care, topic area (taxonomy)
  - For outcome measures, proposed risk adjustment/stratification methodology
- Information to demonstrate that the criteria for importance to measure and report have been met
  - High impact (Importance subcriterion 1a)
  - Opportunity for improvement (Importance subcriterion 1b)
  - Evidence supporting the measure focus (Importance subcriterion 1c)
- Planned use/current use
- Identification of related and competing measures

### *Measure Submission*

For fully specified and tested measures (new or endorsement maintenance): Once a concept has been approved by the CSAC, staff will notify stewards when they may begin entering the remaining measure submission information.

For new concepts that are not yet fully specified and tested measures: Once a concept has been approved, the measure must be submitted within 18 months of the concept approval date.

#### Measure submission includes:

- Full specifications
- Measure testing (reliability and validity)
- Usability
- Feasibility
- Related and competing measures

### Submission Deadlines

- Deadlines for submitting concepts and measures are announced for each topic area **and will not be extended**.
- Deadlines for receiving technical review before the submission deadline also will be announced.
  - A minimum of one concept/measure from each steward must be submitted for review in the technical review period 3-4 weeks prior to the concept/measure submission deadline (see the Technical Review section below for more details).

### *What Good Looks Like?*

For examples of the type of information NQF is seeking in the concept and measure submission forms, review the related information on evidence, measure testing and concept and measure submission items in Guidance for Concept and Measure Submission and Review ([Appendix A](#)).

### *Estimated Level of Effort*

We strongly recommend allowing adequate time for accurate completion of the required submission forms.

These estimates are provided only as a guide and may vary greatly based on the submitters' experience with the NQF process and submission forms, availability of the information need to complete the form, submitters' resources and the complexity of the concept(s)/measure(s):

Measure Type	Estimated Time for Accurate Completion of Required Submission Form
New concept	~4 hours per concept
New measure	~8 hours per measure
Maintenance measure updates	~4 hours per maintenance measure

### **Technical Review**

1. Technical Review Period
  - a. During the CDP 2-stage pilot, measure stewards/developers will be **required** to submit at least one of each concept/measure type (process, health outcome, intermediate clinical outcome, process, structure, or composite) within the technical review period.
  - b. NQF staff will provide technical review to stewards/developers and **developers may submit** the concept/measure before the submission deadline based on updates required to enter the CDP process. Once the Call for Concepts or Measures opens, NQF staff will provide more detailed instructions on how to submit concepts/measures for technical review.
2. Concept and Measure Submission Deadline
  - a. Once the submission deadline has been reached, submitted concepts/measures will be reviewed by NQF staff. Concepts and measures that do not meet the requirements of the completeness and responsiveness review described below will be returned to the steward/developer. Stewards/developers **will not be allowed to resubmit** in the same review cycle, but will be invited to resubmit in the next review cycle.

Figure 1: Stage 1 - Overview of Technical Review/Evaluation Process

# 1) Technical Review Period

Concepts must be submitted 30 days prior to the submission deadline -

Edits will be encouraged within the technical review period

Completeness Review

Responsiveness Review



# 2) Concept Submission Deadline

No additional edits allowed. Incomplete or non-responsive submissions must be resubmitted in a subsequent review period

Completeness Review

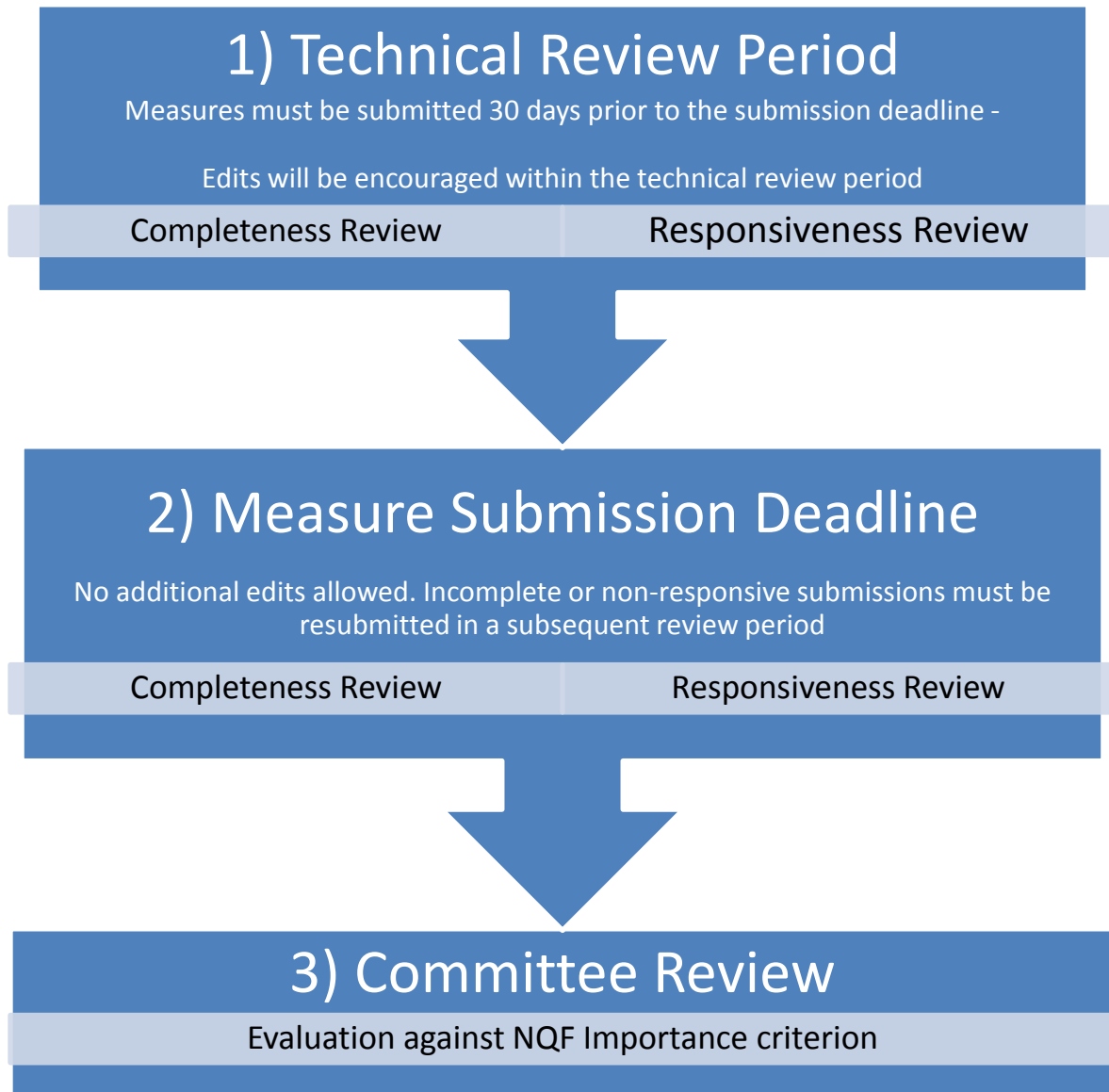
Responsiveness Review



# 3) Committee Review

Evaluation against NQF Importance criterion

Figure 2: Stage 2 - Overview of Technical Review/Evaluation Process



## Maintenance and Measure Stewardship

### Stewardship

- 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).
- Stewards may be contacted by the public and NQF membership related to 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 websites.

### Approved Concepts

- Once a concept has been approved, stewards will have 18 months to re-enter the process with the submission of the finalized measure specifications and testing data.
- Each steward will be given a checklist with important reminders and requirements for submission to stage two. The items on this checklist must be addressed prior to submitting for measure review in stage two.
  - The checklist with detailed responses to each of the Committee's recommendations must be uploaded to your online measure submission form as the first attachment.
  - If additional changes were made (which were not in reference to the Committee's recommendations on the checklist) to the approved concept, describe those changes and the rationale in item **2a1.02** of your online measure submission form.

### Concepts not Approved

- Stewards/developers are encouraged to review the feedback from the Steering Committee and staff and address any major issues identified before resubmitting.

### Maintenance of Endorsed Measures

As an endorsing body, NQF is committed to ensuring the performance measures endorsed continue to meet the rigorous NQF [measure evaluation criteria](#). NQF's measure endorsement - which includes this important three-year review of previously endorsed measures - is standardized in a regular cycle of topic-based measure evaluation. [NQF follows a three year schedule](#) that outlines the review and endorsement of measures in approximately 20 topic areas, such as cardiology, perinatal, care coordination, and patient safety. As the need arises, these topic areas may be revised to account for measures that may require a new or more appropriate topic area.

Prior to the scheduled three-year maintenance review, stewards of endorsed measures will provide NQF with any modifications to the measure specifications, current evidence supporting the measure, data supporting use of the measure, testing results, and other relevant information. NQF will also solicit stakeholder input on the use of the measure and changes in evidence, scientific soundness, and feasibility.

[NQF Endorsement Maintenance Policy](#) (PDF)

### Annual Updates

In the two years when an endorsed measure is not being re-evaluated for continued endorsement, measure stewards will submit a status report of the measure specifications to NQF. This report will either reaffirm 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 the three-year endorsement period, the measure steward is responsible for informing NQF immediately of the timing and purpose of the changes. An ad hoc review will be conducted if the changes materially affect the measure's original concept or logic.

### **Ad Hoc Review**

An ad hoc review may be conducted on an endorsed measure at any time if the evidence supporting the measure has changed, implementation of the measure results in unintended consequences, or material changes have been made to the measure. Ad hoc reviews can be requested at any time by any party, as long as there is adequate evidence to justify the review. When requesting an ad hoc review, requestors should indicate under which criterion they are requesting the ad hoc review and should provide in writing adequate evidence to justify the review.

The ad hoc review process follows a shortened version of the Consensus Development Process and includes a call for nominations for technical experts, review by the expert panel, a public and Member comment period of no less than 10 days, review by the CSAC, ratification by the NQF Board of Directors, and an appeals period.

If a measure remains endorsed after an ad hoc review, it is still subject to its original maintenance cycle.

# APPENDICES



## Appendix A: Guidance on Concept and Measure Submission and Review

### Key Points Sheet –

#### Review Concept and Measure Submissions for Completeness and Responsiveness

##### PROCESS

**Purpose/Objective:** To ensure that all information needed to evaluate the concept or measure against the NQF criteria is available for review and in the correct location to facilitate the ease and efficiency of evaluation by the Steering Committee. Concept and measure submissions that are either incomplete or unresponsive will not be forwarded on for Steering Committee evaluation.

##### Definitions

**Completeness:** All submission questions (items) are answered unless clearly not applicable.

**Responsiveness:** Information provided in the submission form corresponds to what was asked and is entered in the correct location.

**Note:** This review does not make a judgment about whether NQF evaluation criteria are met, just whether the requested information is provided and in the correct location of the form.

**Who:** All NQF Performance Measures staff may review submissions for completeness and responsiveness. Determination that a measure submission does not meet the condition that it is complete and responsive is approved by a Senior Director (project lead).

**Timing:** Submissions are reviewed as they are submitted. Generally submissions are reviewed for completeness and responsiveness at the same time by the same staff person.

##### Result of Review:

If the concept or measure submission is:

- Complete and responsive, the concept/measure is ready for Steering Committee review.
- EITHER incomplete OR unresponsive, the concept/measure is not ready for consideration by the Steering Committee. Opportunity for revision depends on timing of submission as follows:
  - If the submission occurs on or before the technical review deadline, staff will provide feedback to the steward/developer who will be able to revise the submission prior to the measure submission deadline.
  - If the submission occurs after the technical review deadline, there is no guarantee that staff will have time to review and provide feedback for measure steward/developers to make revisions before the measure submission deadline. Submissions that are incomplete or unresponsive are not accepted for consideration in the current project. Information on why the concept/measure will not be evaluated during the current project will be provided to the steward/developer who may revise and resubmit for a later project for that topic area.

##### CHECK THAT ALL CONDITIONS ARE MET TO EVALUATE CONCEPTS AND MEASURES

**Condition A.** Is the measure concept agreement (Stage 1 only) or measure steward agreement (Stage 2 only) signed or updated?

Measure steward agreements are required for all non-government organizations even if measure is made publicly and freely available.

Concepts only (this applies to all concepts submitted in Stage 1-measures not yet fully specified and tested, fully specified and tested measures and maintenance measures): Signed **measure concept agreement**

Fully specified and tested measures (Stage 2 only): Signed [measure steward agreement](#) (MSA) OR updated list (Appendix A of the MSA) of measures that includes the additional measure that will be appended to the signed MSA.

**Condition B:** For stage 2 measure submissions: The measure owner/steward verifies there is an identified responsible entity and a process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every three years.

**Condition C.** Use for accountability/public reporting and improvement – Check that either current or planned use includes both accountability (including public reporting) and performance improvement.

**Condition D:** For stage 2 measure submissions: The measure is fully specified and tested for reliability and validity.

**Condition E.** Related and Competing measures addressed – check that the questions on related and competing measures have been answered. Check the [NQF measures database](#) to identify potentially related and competing measures to make sure they are completely identified in the submission.

- Check against the list of all previously endorsed measures in the topic area (posted on the project page)
- Check against new concepts and measures submitted for the current review period
- Recommended search strategy: begin with taxonomy terms for subject/topic areas, then keyword search on terms for the subject/topic area and measure focus

**Condition F.** Measure submission information is **complete and responsive**.

- Refer to examples of “what good looks like” as needed. The examples are not the only way to respond; and if it’s unclear whether an answer is responsive, check with the Senior Director (project lead).
- Answers to questions asking for **data** should include numbers
- For endorsement maintenance, performance gap and disparities data should be provided for the measure as specified. This could be supplemented with data from the literature, but it is not required unless the measure is not in use.
- Make sure the **evidence form** is attached and completed properly.

If a **health outcome**

- Requires only 1c.1-1c.2 (A health outcome is an end-result (e.g., mortality, complication, function, health status; or sometimes a proxy for health outcome such as hospital admission))
- For all other measures (structure, process, intermediate outcome)

- Some items are required and some may not be needed.

**Required:**

- 1c.3 relationship of measure focus to desired outcomes

- 1c.8-1c.13 and questions regarding systematic review of body of evidence
- 1c.4 whether or not there is a guideline (if yes, 1c.4.1 -1c.5; If 1c.5 is yes, then 1c.5.1)
- 1c.6 whether or not there is another published systematic review (if yes, 6.2-6.3)

**Used only under certain conditions:**

- 1c.7-1c.7.3 only if no other systematic review from guideline (1c.5) or other published systematic review (1c.6)
- Make sure the **testing attachment form** is attached and completed properly.
  - Data used to test the measure should match the data source specified in the measure.
  - If the measure is specified for multiple data sources, testing must be completed on all data sources for which the measure is specified.
  - Testing can be completed at either the data element level or the measure score level or both, steward/developers should be sure to indicate clearly at which level the measure has been tested.
- If the submitted measure includes any proprietary components (e.g. risk adjustment model), the algorithm and pricing for the model must be disclosed in the feasibility section 4d.2.

**GENERAL PRESENTATION OF SUBMISSIONS**

- Make sure all URLs are active and correct.
- This review does not focus on spelling and grammar; however, if numerous mistakes impede readability and understanding then the steward/developer will be asked to correct the form.

**EXAMPLE RESPONSES FOR MEASURE SUBMISSION ITEMS**

The following examples are only for illustration of the type of information that that would be considered complete and responsive and ready for Steering Committee evaluation. Some of the examples are adapted from actual measure submissions and some were developed only as examples. The key point is to provide substantive information and data in the measure submission so that the Steering Committee can evaluate whether the NQF criteria are met.

<a href="#"><u>EXAMPLE — HIGH IMPACT (1a) AND OPPORTUNITY FOR IMPROVEMENT (1b)</u></a> .....	28
<a href="#"><u>EXAMPLE — HIGH IMPACT (1a) AND OPPORTUNITY FOR IMPROVEMENT (1b)</u></a> .....	29
<a href="#"><u>EXAMPLE — EVIDENCE, HEALTH OUTCOME</u></a> .....	35
<a href="#"><u>EXAMPLE — EVIDENCE, PROCESS #1</u></a> .....	42
<a href="#"><u>EXAMPLE — EVIDENCE, PROCESS #2</u></a> .....	51
<a href="#"><u>EXAMPLE — MEASURE CONCEPT SPECIFICATIONS</u></a> .....	60
<a href="#"><u>EXAMPLE — USABILITY AND USE</u></a> .....	67
<a href="#"><u>EXAMPLE — RELATED AND COMPETING MEASURES/CONCEPTS</u></a> .....	69
<a href="#"><u>EXAMPLE — MEASURE TESTING</u></a> .....	72

**EXAMPLE — HIGH IMPACT (1a) AND OPPORTUNITY FOR IMPROVEMENT (1b)**

## NATIONAL QUALITY FORUM—Concept Submission Items

### High Impact and Opportunity for Improvement

#### EXAMPLE — HIGH IMPACT (1a) AND OPPORTUNITY FOR IMPROVEMENT (1b)

*The following example is only for illustration of the type of information requested for the Steering Committee's evaluation of high impact and opportunity for improvement. The key point is to provide substantive information and data in the measure submission.*

**Note:** These items are in the online submission form and responses must be entered into the online form.

**EXAMPLE:** Adapted from measure about influenza vaccination in healthcare workers (NQF#0431, by CDC)

#### High Impact (1a)

##### 1a.1

*Demonstrated high impact aspect of healthcare*

[Selected from List]

##### **EXAMPLE:**

affects large numbers; patient/societal consequences of poor quality

##### 1a.2

*If "Other", please describe:*

##### 1a.3

Provide **epidemiologic or resource use data** that demonstrates the measure addresses a high impact aspect of healthcare. List citations in 1a.4.

#### Key Points

- Limit to half page
- Should include quantitative data (e.g., number of persons and percentage affected, dollar amounts), not just statements of conclusion
- Should relate to the target population (e.g., condition, specific procedure, etc.) and category for impact selected in 1a.1
- The online form does not accept formatting such as tables – use narrative or lists

##### **EXAMPLE:**

From 1976-2007, influenza virus infections caused an average of 23,607 influenza-related deaths with a wide yearly range of 3,349 to 48,614 deaths over 31 influenza seasons; approximately 90% of these

deaths occurred among persons aged 65 and older.(1) Healthcare personnel (HCP) can serve as vectors for influenza transmission because they are at risk for both acquiring influenza from patients and transmitting it to patients and HCP often come to work when ill.(2) One early report of HCP influenza infections during the 2009 H1N1 influenza pandemic estimated 50% of infected HCP had contracted the influenza virus from patients or coworkers in the healthcare setting.(3) Influenza virus infection is common among HCP: one study suggested that nearly one-quarter of HCP were infected during influenza season, but few of these recalled having influenza.(4) Therefore, all HCP are recommended to receive the seasonal influenza vaccine annually to protect themselves and their patients.(5)

Nosocomial influenza outbreaks in healthcare facilities result in longer stays and greater mortality for patients (6-9) and missed work for HCP.(2,9) Higher influenza vaccination coverage among HCP is associated with reductions in nosocomial influenza among hospitalized patients (8,10) and nursing home residents.(11-13) Influenza vaccination of HCP is also associated with decreased all-cause mortality among nursing home residents.(11-14).

#### 1a.4

*Citations for data demonstrating High Impact provided in 1a.3*

#### Key Points

- Limit to one page

#### EXAMPLE:

1. Thompson MG, Shay DK, Zhou H, et al. Estimates of deaths associated with seasonal influenza – United States, 1976-2007. *MMWR Morb Mortal Wkly Rep.* 2010; 59(33):1057-1062.
2. Wilde JA, McMillan JA, Serwint J, et al. Effectiveness of influenza vaccine in healthcare professionals: a randomized trial. *JAMA* 1999; 281: 908–913.
3. Harriman K, Rosenberg J, Robinson S, et al. Novel influenza A (H1N1) virus infections among health-care personnel – United States, April-May 2009. *MMWR Morb Mortal Wkly Rep.* 2009; 58(23): 641-645.
4. Elder AG, O’Donnell B, McCrudden EA, et al. Incidence and recall of influenza in a cohort of Glasgow health-care workers during the 1993-4 epidemic: results of serum testing and questionnaire. *BMJ.* 1996; 313:1241-1242.
5. Fiore AE, Uyeki TM, Broder K, et al. Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. *MMWR Recomm Rep.* 2010; 59(08): 1-62.
6. Cunney RJ, Bialachowski A, Thornley D, Smaill FM, Pennie RA. An outbreak of influenza A in a neonatal intensive care unit. *Infect Control Hosp Epidemiol.* 2000; 21:449-454.
7. Bridges CB, Kuehnert MJ, Hall CB. Transmission of influenza: implications for control in health care settings. *Clin Infect Dis* 2003; 37: 1094–1101.
8. Weinstock DM, Eagan J, Malak SA, et al. Control of influenza A on a bone marrow transplant unit. *Infect Control Hosp Epidemiol.* 2000; 21:730-732.
9. Sartor C, Zandotti C, Romain F, et al. Disruption of services in an internal medicine unit due to a nosocomial influenza outbreak. *Infect Control Hosp Epidemiol* 2002; 23:615–619.
10. Salgado CD, Giannetta ET, Hayden FG, Farr BM. Preventing nosocomial influenza by improving the vaccine acceptance rate of clinicians. *Infect Control Hosp Epidemiol* 2004; 25:923–928.
11. Hayward AC, Harling R, Wetten S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised

controlled trial. *BMJ* 2006; 333: 1241-1246.

12. Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of healthcare workers in long-term-care hospitals reduces the mortality of elderly patients. *J Infect Dis.* 1997; 175:1-6.

13. Lemaitre M, Meret T, Rothan-Tondeur M, et al. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial. *J Am Geriatr Soc.* 2009; 57:1580-1586.

14. Carman WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial. *Lancet* 2000; 355:93–97.

## Performance Gap – Opportunity for Improvement (1b)

### 1b.1

**Briefly** explain the rationale for this measure

#### Key Points

- Limit to half page
- Explain benefits (improvements in quality) envisioned by use of this measure
- Do not repeat information for impact, performance gap, or evidence

#### EXAMPLE:

Use of this measure to monitor influenza vaccination among HCP is envisioned to result in increased influenza vaccination uptake among HCP, because improvements in tracking and reporting HCP influenza vaccination status will allow healthcare institutions to better identify and target unvaccinated HCP. Increased influenza vaccination coverage among HCP is expected to result in reduced morbidity and mortality related to influenza virus infection among patients, as described above in Section 1a.3.

### 1b.2

Provide **data** demonstrating performance gap/opportunity for improvement (Variation or overall less than optimal performance across providers). List citations in 1b.3.

**For endorsement maintenance, provide performance data on the measure as specified (mean, std dev, distribution of scores by decile, min, max).** Describe who was included in the performance data in 1b.3.

#### Key Points

- Limit to two pages
- The online form does not accept formatting such as tables – use narrative or lists
- Should include quantitative data (e.g., number, percent), not just statements of conclusion
- Should be about the measure focus and target population
- If new concept or measure, data could be from literature, studies, or testing
- If endorsement maintenance, the data should be the performance scores on the measure as specified and for the specified level of analysis
- Should correspond to the level of analysis for the measure (e.g., variation across hospitals, or physicians, etc.)
- If limited variation, should discuss in context of impact or overall less than optimal performance

#### EXAMPLE:

(data from testing)

Among employees, the median influenza vaccination coverage rate among healthcare institutions participating in the field test was 63% (quartile 1: 44%, quartile 3: 79%).

Among credentialed non-employees, the median influenza vaccination coverage rate was 46% (quartile 1: 8%, quartile 3: 90%).

Among other non-employees, the median influenza vaccination coverage rate was 51% (quartile 1: 29%, quartile 3: 92%).

Reported influenza vaccination coverage rates vary noticeably by denominator group. In addition, all three estimates are substantially lower than the Healthy People 2020 goal of 90% influenza vaccination coverage among HCP, demonstrating substantial room for improvements.

### 1b.3

*Citations for data on performance gap provided in 1b.2.*

***For endorsement maintenance, describe who was included in the performance results reported in 1b.2, (number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include).***

#### Key Points

- Limit to one page
- Provide citations for data from literature
- For performance scores, describe data source as requested

#### EXAMPLE:

The measurement testing was conducted from October 2010 to March 2011 among 234 healthcare institutions from four jurisdictions, including 78 acute care hospitals, 59 long-term care facilities, 16 ambulatory surgical centers, 43 dialysis clinics, and 38 physician practices. This represents a 74% response rate from our initially recruited sample of 318 healthcare institutions (92 acute care hospitals, 89 long-term care facilities, 30 ambulatory surgical centers, 51 dialysis clinics, and 56 physician practices). Demographic and policy characteristics of participating institutions are further described in Section 2b5.1.

### 1b.4

Provide **data** on disparities by population group. List citations in 1b.5.

***For endorsement maintenance, provide performance data by population group on the measure as specified (e.g., mean, std dev). Describe who was included in the performance data in 1b.5.***

#### Key Points

- Limit to two pages
- The online form does not accept formatting such as tables – use narrative or lists
- Should include quantitative data (e.g., number, percent), not just statements of conclusion
- Should be about the measure focus and target population



- If new concept or measure, data could be from literature, studies, or testing
- If endorsement maintenance, the data should be the performance scores on the measure as specified and for the specified level of analysis

**EXAMPLE:**

Data on influenza vaccination in healthcare workers by population group is not available. Data on influenza vaccination rates by population group in general obtained from the Behavioral Risk Factor Surveillance System are as follows.

Influenza vaccination coverage, \* by race/ethnicity† --- Behavioral Risk Factor Surveillance System 2009-2010

Seasonal (only) influenza vaccination coverage

Reported in this order:

- 1) Children aged 6 mos--17 yrs (n = 159,652)
- 2) Adults at high-risk§ aged 18--49 yrs (n = 21,821)
- 3) Adults aged 50--64 yrs (n = 117,267)
- 4) Adults aged ≥65 yrs (n = 112,752)
- 5) All aged ≥6 mos (n = 514,785)

Reported as % (95% CI)

All:

- 1) Children aged 6 mos--17 yrs 43.7 (42.8--44.6)
- 2) Adults at high-risk§ aged 18--49 yrs 38.2 (36.9--39.5)
- 3) Adults aged 50--64 yrs 45.0 (44.4--45.6)
- 4) Adults aged ≥65 yrs 69.6 (69.0--70.2)
- 5) All aged ≥6 mos 41.2 (40.8--41.6)

White, non-Hispanic:

- 1) Children aged 6 mos--17 yrs 43.2 (42.3--44.1)
- 2) Adults at high-risk§ aged 18--49 yrs 39.9 (38.3--41.5)
- 3) Adults aged 50--64 yrs 46.5 (45.9--47.1)
- 4) Adults aged ≥65 yrs 71.7 (71.2--72.2)
- 5) All aged ≥6 mos 43.9 (43.5--44.3)

Black, non-Hispanic:

- 1) Children aged 6 mos--17 yrs 37.0¶ (34.4--39.6)
- 2) Adults at high-risk§ aged 18--49 yrs 34.8¶ (31.5--38.1)
- 3) Adults aged 50--64 yrs 40.3¶ (38.3--42.3)
- 4) Adults aged ≥65 yrs 55.2¶ (52.9--57.5)
- 5) All aged ≥6 mos 33.7¶ (32.5--34.9)

Hispanic:

- 1) Children aged 6 mos--17 yrs 46.9¶ (44.3--49.5)
- 2) Adults at high-risk§ aged 18--49 yrs 35.5 (31.6--39.4)
- 3) Adults aged 50--64 yrs 40.6¶ (37.9--43.3)

- 4) Adults aged ≥65 yrs 56.1¶ (52.8--59.4)
- 5) All aged ≥6 mos 33.6¶ (32.4--34.8)

Other, non-Hispanic\*\*:

- 1) Children aged 6 mos--17 yrs 53.6¶ (50.5--56.7)
- 2) Adults at high-risk§ aged 18--49 yrs 41.3 (35.5--47.1)
- 3) Adults aged 50--64 yrs 44.1 (40.6--47.6)
- 4) Adults aged ≥65 yrs 68.1 (64.9--71.3)
- 5) All aged ≥6 mos 42.4 (40.8--44.0)

Abbreviation: CI = confidence interval.

\* Coverage estimates are for persons with reported vaccination during August 2009--May 2010 who were interviewed during October 2009--June 2010.

† Race/ethnicity categories are mutually exclusive.

§ High-risk conditions include asthma, other lung problems, diabetes, heart disease, kidney problems, anemia, and weakened immune system caused by a chronic illness or by medicines taken for a chronic illness.

¶ Statistically significant difference at  $p < 0.05$  (t-test) in estimated vaccination coverage. Referent group was non-Hispanic whites.

\*\* Because of limited sample sizes, respondents who self-identified as Asians, American Indians/Alaska Natives, Native Hawaiians, Pacific Islanders, and persons of multiple races were classified in the non-Hispanic Other group.

## 1b.5

*Citations for data on Disparities provided in 1b.4*

***For endorsement maintenance, describe who was included in the performance results reported in 1b.4, (number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include).***

### Key Points

- Limit to one page
- Provide citations for data from literature
- For performance scores, describe data source as requested

### EXAMPLE:

Truman, B.I., et al. CDC Health Disparities and Inequalities Report, United States 2011. *MMWR Morb Mortal Wkly Rep.* 2011 Jan 14; Supplement **60(01);38-41.**

<http://www.cdc.gov/mmwr/preview/mmwrhtml/su6001a7.htm#tab>

**EXAMPLE — EVIDENCE, HEALTH OUTCOME**

## NATIONAL QUALITY FORUM—Evidence (1c) Pilot Submission Form

### EXAMPLE — EVIDENCE, HEALTH OUTCOME

*The following example is only for illustration of the type of information requested for the Steering Committee's evaluation of the evidence. The key point is to provide substantive information and data in the measure submission form so it is clear about the evidence that does or does not exist to support the measure focus.*

**Measure Title:** [30-day unplanned hospital readmission](#)

**Date of Submission:** 5/31/2012

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- Contact NQF staff for examples and resources, or questions.

### STRUCTURE-PROCESS-OUTCOME RELATIONSHIP

#### 1c.1. This is a measure of:

Outcome

- Health outcome: [30-day unplanned hospital readmission](#)
- Intermediate clinical outcome: [Click here to name the intermediate outcome](#)
- Process: [Click here to name the process](#)
- Structure: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

#### HEALTH OUTCOME MEASURE **If not a health outcome, skip to 1c.3**

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

#### 1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

##### Key Points

- A health outcome is an end-result (e.g., mortality, complication, function, health status; or sometimes a proxy for health outcome such as hospital admission).
- Should indicate the causal pathway – not just a general statement.
- Multiple processes may influence a health outcome – not all need to be included – focus on those with the strongest rationale.
- Do not include rationale or evidence in this item.

## EXAMPLE

Hospital readmission is considered a proxy for the health outcome of deterioration in health status.

Multiple care processes can influence deterioration in health status after discharge resulting in hospital readmission (e.g., appropriate treatment/intervention, medications, clinical stabilization, care coordination/transition).

Comprehensive care transition management/care coordination can lead to decreased hospital readmissions as described below.

### **Comprehensive care transition management/ care coordination**

Leads to ↓

Early reconnection to primary care; appropriate level of follow-up care; patient understanding of self-monitoring, self-management, & follow-up care

Leads to ↓

Continuity of treatment plan; early identification & intervention for adverse changes

Leads to ↓

Stable/improved health status

Leads to ↓

### **Decreased likelihood of readmission**

**1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.**

#### **Key Points**

- The rationale should support linkages described in 1c.2 above.
- The rationale should be based on evidence to the extent possible and/or logical conceptual relationships.
- If a health outcome, not required to complete other items about body of evidence.

## EXAMPLE (adapted from NQF # 1789, CMS)

Randomized controlled trials have shown that improvement in the following areas can directly reduce readmission rates: quality of care during the initial admission; improvement in communication with patients, their caregivers and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Evidence that hospitals have been able to reduce readmission rates through these quality-of-care initiatives illustrates the degree to which hospital practices can affect readmission rates. Successful randomized trials have reduced 30-day readmission rates by 20-40% [4-14].

Since 2008, 14 Medicare Quality Improvement Organizations have been funded to focus on care transitions, applying lessons learned from clinical trials. Several have been notably successful in reducing readmissions. The strongest evidence supporting the efficacy of improved discharge processes and enhanced care at transitions is a randomized controlled trial by Project RED (Re-Engineered Discharge), which demonstrated a 30% reduction in 30-day readmissions. In this intervention, a nurse was assigned to each patient as a discharge advocate, responsible for patient education, follow-up, medication reconciliation, and preparing individualized discharge instructions sent to the patient's primary care provider. A follow-up phone call from a pharmacist within 4 days of discharge was also part of the intervention [4].

Given that studies have shown readmissions to be related to quality of care, and that interventions have been able to reduce 30-day readmission rates, it is reasonable to consider an all-condition readmission rate as a quality measure.

#### References:

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2. Benbassat J, Taragin M. Hospital readmissions as a measure of quality of health care: advantages and limitations. *Archives of Internal Medicine* 2000;160(8):1074-81.
3. Medicare Payment Advisory Commission (U.S.). Report to the Congress promoting greater efficiency in Medicare. Washington, DC: Medicare Payment Advisory Commission, 2007.
4. Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med* 2009;150(3):178-87.
5. Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. *J Am Geriatr Soc* 2004;52(11):1817-25.
6. Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: a randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. *J Am Geriatr Soc* 2009;57(3):395-402.
7. Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomised controlled trial. *BMC Public Health* 2007;7:68.
8. Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. *J Hosp Med* 2009;4(4):211-218.
9. Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: a systematic metareview. *BMC Health Serv Res* 2007;7:47.
10. Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. *Ann Intern Med* 1994;120(12):999-1006.
11. Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: a randomized clinical trial. *Jama* 1999;281(7):613-20.

12. van Walraven C, Seth R, Austin PC, Laupacis A. Effect of discharge summary availability during post-discharge visits on hospital readmission. *J Gen Intern Med* 2002;17(3):186-92.
13. Weiss M, Yakusheva O, Bobay K. Nurse and patient perceptions of discharge readiness in relation to postdischarge utilization. *Med Care* 2010;48(5):482-6.
14. Krumholz HM, Amatruda J, Smith GL, et al. Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. *J Am Coll Cardiol*. Jan 2 2002;39(1):83-89.

**Note:** For health outcome measures, no further information is required

### STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE

If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).

**1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes.** (Do not summarize the evidence here.)

**1c.4.** Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No

If no, skip to #1c.6

If yes, answer 1c.4.1-1c.5.

**1c.4.1. Guideline citation** (including date):

**1c.4.2. URL** (if available online):

**1c.4.3. Identify guideline number and/or page number:**

**1c.4.4. Quote verbatim, the specific guideline recommendation:**

**1c.4.5. Grade assigned to the recommendation with definition of the grade:**

**1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation?** Yes  No  If no, skip to #1c.6

If yes, answer 1c.5.1. (**Note:** Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)

**1c.5.1. Grade assigned to the body of evidence with definition of the grade:**

**1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1? (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)**

Yes  No  If no, skip to #1c.7

If yes, answer 1c.6.1-1c.6.3. (**Note:** Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

**1c.6.1. Citation** (including date):

1c.6.2. URL (if available online):

1c.6.3. Grade assigned to the body of evidence with definition of the grade:

If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8

1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No

If yes, answer 1c.7.1-1c.7.3. (**Note:** Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)

1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?

1c.7.2. Grade assigned to the body of evidence with definition of the grade:

1c.7.3. Describe the process used for the systematic review:

If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.

#### FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS

(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)

1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: [Click here to enter date range](#)

#### QUANTITY AND QUALITY OF BODY OF EVIDENCE

1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

#### ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)

1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?

#### UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE



**1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence?** Yes  No  ***If no, stop***

If yes,

**1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**

**EXAMPLE — EVIDENCE, PROCESS #1**

**NATIONAL QUALITY FORUM—Evidence (1c) Pilot Submission Form**

**EXAMPLE — EVIDENCE, PROCESS #1**

*The following example is only for illustration of the type of information requested for the Steering Committee's evaluation of the evidence. The key point is to provide substantive information and data in the measure submission form so it is clear about the evidence that does or does not exist to support the measure focus.*

**Measure Title:** [Women with urinary incontinence who receive pelvic floor muscle training](#)

**Date of Submission:** 5/31/2012

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

**STRUCTURE-PROCESS-OUTCOME RELATIONSHIP**

**1c.1. This is a measure of:**

Outcome

- Health outcome: Click here to name the health outcome
- Intermediate clinical outcome: Click here to name the intermediate outcome
- Process: [pelvic floor muscle training for urinary incontinence](#)
- Structure: Click here to name the structure
- Other: Click here to name what is being measured

**HEALTH OUTCOME MEASURE** *If not a health outcome, skip to 1c.3*

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

**1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.**

**1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.**

*Note: For health outcome measures, no further information is required*

**STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE**

*If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).*

**Key Points**

- See NQF [guidance on evaluating evidence](#) and criteria for rating [Quantity, quality, consistency of body of evidence](#)
- A **systematic review** is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include quantitative synthesis (meta-analysis), depending on available data ([IOM,2011](#)).
- A body of evidence includes all the evidence for a topic, which is systematically identified, based on pre-established criteria for relevance and quality of evidence.
- Expert opinion is not considered empirical evidence, but evidence is not limited to randomized controlled trials
- There is variability in evidence reviews, grading systems, and presentation of the findings; however, the information should be reported as requested in this form so the Steering Committee can evaluate it according to NQF criteria and guidance.

**1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes. (Do not summarize the evidence here.)**

**Key Points**

- Should indicate the causal pathway – not just a general statement
- Do not discuss evidence in this item

**EXAMPLE**

Pelvic floor muscle training (PFMT) >>

Increases strength (the maximum force generated by a muscle in a single contraction); endurance (ability to contract repetitively, or sustain a single contraction over time); coordination of muscle activity or to suppress urge, or a combination of these lead to>>

Decreased urine leakage

**1c.4.** Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No   
*If no, skip to #1c.6*

*If yes, answer 1c.4.1-1c.5.*

**1c.4.1. Guideline citation (including date):** Incontinence in women. In: Schröder A, Abrams P, Andersson KE, Artibani W, Chapple CR, Drake MJ, Hampel C, Neisius A, Tubaro A, Thüroff JW. Guidelines on urinary incontinence. Arnhem, The Netherlands: European Association of Urology (EAU); 2009 Mar. p. 28-43.

**1c.4.2. URL (if available online):**

**Key Points**

- Make sure URL is active and correct

**EXAMPLE**

<http://www.uroweb.org/gls/pdf/Urinary%20Incontinence%202010.pdf>

<http://www.guideline.gov/content.aspx?id=16386&search=urinary+incontinence#Section424>

**1c.4.3. Identify guideline number and/or page number:**

**Key Points**

- If guideline recommendation is one of many from a single document, the specific guideline number and/or page number is necessary.

**EXAMPLE**

Guideline 5.2 Initial treatment of UI in women. p.29

**1c.4.4. Quote **verbatim**, the specific guideline recommendation:**

**Key Points**

- Do not summarize, paraphrase, or shorten

**EXAMPLE**

PFMT should be offered as first-line conservative therapy to women with stress, urgency, or mixed UI

**1c.4.5. Grade assigned to the recommendation with definition of the grade:**

**Key Points**

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for a recommendation

**EXAMPLE**

A - Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial

**1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation? Yes  No  **If no, skip to #1c.6****

*If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)*

**1c.5.1. Grade assigned to the body of evidence with definition of the grade:**

**Key Points**

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make

sure it is the appropriate grade for the body of evidence

- If specific details regarding systematic review of evidence for guideline not available, will need to identify another review of the body of evidence

#### EXAMPLE

The guideline document states that the recommendation is based on a systematic review of evidence, but the specific grade and summary of the body of evidence was not provided.

**1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1?** (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)

Yes  No  **If no, skip to #1c.7**

If yes, answer 1c.6.1-1c.6.3. (**Note:** Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)

1c.6.1. **Citation** (including date): Dumoulin C, Hay-Smith J; Pelvic floor muscle training versus no treatment or inactive control treatments for urinary incontinence in women; Cochrane Database of Systematic Reviews 2010, Issue 1. Art. No.: CD005654, DOI: 10.1002/14651858.CD005654.pub2.

1c.6.2. **URL** (if available online):

#### Key Points

- Make sure URL is active and correct

#### EXAMPLE

<http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005654.pub2/abstract;jsessionid=5B59498CFC062003F250C00B2B8CEFE.d01t03>

**1c.6.3. Grade assigned to the body of evidence with definition of the grade:**

#### Key Points

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for the body of evidence

#### EXAMPLE

An overall grade of methodological quality was not assigned. In the systematic review, individual study quality was graded on a scale for risk of bias – see section 8.

**If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8**

**1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No**

*If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer's systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)*

**1c.7.1. Who conducted the measure developer's systematic review of the body of evidence?**

**1c.7.2. Grade assigned to the body of evidence with definition of the grade:**

**1c.7.3. Describe the process used for the systematic review:**

**If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.**

#### **FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS**

##### **Key Points**

- Responses to the following items should NOT include a description of each individual study – the responses should include quantitative data from a synthesis of the entire body of evidence. If there is more than one systematic review, each should be reported separately (not combined by the submitter).
- May copy relevant sections from source(s) of systematic reviews cited in 1c.5, 1c.6, or 1c.7; include page number if possible; make sure it includes substantive, quantitative information not just conclusions

*(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)*

**1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: [1989-2008](#)**

#### **QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)**

##### **Key Points**

- Only enter number and type of study design here — discuss in 1c.10
- NQF does not require evidence be only randomized controlled trials
- Study design relates to quality of evidence but is insufficient by itself to judge quality

#### **EXAMPLE**

14 randomized controlled trials

**1c.10. What is the overall quality of evidence across studies in the body of evidence?** (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

**Key Points**

- Do not discuss each study individually — categorize by quality

**EXAMPLE**

The systematic review identified quality of evidence based on risk of bias. System for determining risk of bias was explained in Chapter 8 of Cochrane Handbook for Systematic Reviews for Interventions, 5.0.2, updated September 2009 <http://www.mrc-bsu.cam.ac.uk/cochrane/handbook502> .

Risk of bias	Interpretation	Within a study	Across studies
Low risk of bias.	Plausible bias unlikely to seriously alter the results.	Low risk of bias for all key domains.	Most information is from studies at low risk of bias.
Unclear risk of bias.	Plausible bias that raises some doubt about the results.	Unclear risk of bias for one or more key domains.	Most information is from studies at low or unclear risk of bias.
High risk of bias.	Plausible bias that seriously weakens confidence in the results.	High risk of bias for one or more key domains.	The proportion of information from studies at high risk of bias is sufficient to affect the interpretation of results.

Based on the reported adequacy of allocation concealment and blinding, two trials appeared to be at low risk (Bø 1999; Castro, 2008), six at moderate risk (Bidmead 2002; Burgio 1998; Burns 1993; Kim 2007; Miller 1998; ; Yoon 2003; ), and six at high or possible high risk of bias (Aksac 2003; Henalla 1989; Henalla 1990; Hofbauer 1990; Lagro-Janssen 1991; Wells 1999). Interestingly, the more recent trials tended to be of lower risk for bias based on the trial reports.” (p. 20)

Methodological quality was evaluated from the trial reports. Therefore, the quality of reporting might have affected the judgement of methodological quality. Two of the included studies were published only as abstracts (Bidmead 2002; Henalla 1990). Limited methodological detail was given, which made it particularly difficult to judge the quality of these trials. In addition, few data were reported.

In one way, it was disappointing that only two trials sufficiently described the randomisation process so that the review authors could be sure there was adequate concealment. On the other hand, it was encouraging, given the difficulties of blinding participants and treatment providers to PFMT, that eight of the 14 studies used blinded outcome assessors. Generally, the proportion of dropout and withdrawals was in the region of 0 to 20%. Sample sizes were small to moderate in 12 of the 14 studies, and only three trials reported an a priori power calculation. Two trials stated that intention to treat principles were used for the primary analysis, and one stated that intention to treat analysis did not change the findings of the primary analysis.

Sensitivity analysis on the basis of trial quality was not considered appropriate in view of the small number of trials contributing to each comparison. It is not known to what extent the variable quality of the trials has affected the findings of the review. It is interesting to note that of all the studies



contributing data to the analysis, the largest treatment effect (for cure and improvement, and leakage episodes) was observed in a trial at the high risk of bias. This might be an example of the apparent overestimation of treatment effect (about 30%) observed in trials with inadequate or unclear concealment of random allocation (Egger 2002).” (p. 20)

## ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

**1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence?** (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)

### Key Points

- Do not discuss each study individually — categorize by outcome studied

### EXAMPLE

Meta-analysis was not possible due to study heterogeneity.

Comparison of PFMT versus no treatment, placebo, or control was studied for a variety of outcomes as follows:

**Outcome: Patient Perceived Cure** – 2 studies with consistent direction in favor of PFMT but differences in magnitude of effect (risk ratio 2.34-16.80)

**Outcome: Patient Perceived Cure or Improvement** – 3 studies with consistent direction in favor of PFMT but differences in magnitude of effect (risk ratio 2.26-20.0). The authors concluded “Overall, the differences in likelihood of cure or improvement after PFMT compared to control suggested by the review are sufficient to be of interest to women.” (p.18)

**Outcome: QoL** – 2 studies

Hopkins Symptom Checklist, for psychological distress (SCL-90-R)

Global severity: 50.8 (12.8) vs. 51.4 (10.9); mean difference -0.6, 95% CI -5.3 to 4.1

Norwegian Quality of Life Scale

90.1 (9.5) vs. 85.2 (12.1); mean difference 4.9, 95%CI -1.1 to 10.9

The authors concluded “Based on evidence from single trials, there is improved condition specific QoL in women treated with PFMT compared to controls, but there might be less or no effect on generic QoL.” (p.18)

**Outcome: Leakage Episodes** – 5 studies with consistent direction in favor of PFMT but differences in magnitude of effect. “there were statistically significantly fewer leakage episodes (-0.77 to -2.92) with PFMT” (p.18)

**Outcome: Number of Voids per Day** – 1 study with significantly fewer (-3.1) with PFMT

**Outcome: Number of Voids per Night** – 1 study with no significant difference

**Outcome: Short pad Test Number Cured** – 3 studies with consistent direction in favor of PFMT but differences in magnitude of effect (risk ratios 5.54-16.24)

**1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?**

**Key Points**

- Information on harms may come from different studies than the treatment effectiveness studies, often from observational studies

**EXAMPLE**

Three of four studies that reported adverse events stated there were none with PFMT. The other trial recorded a few minor effects of PFMT (for example discomfort with training), and all of which were reversible with cessation of training. Although randomized trials are probably not the most appropriate way to address safety, neither these data nor the content of PFMT suggest that PFMT is likely to be unsafe. (p. 19)

The authors concluded that “PFMT is better than no treatment, placebo, drug, or inactive control for women with stress, urge, or mixed incontinence. Women treated with PFMT were more likely to report cure or improvement, report better QoL, have fewer leakage episodes per day and have less urine leakage on short pad tests than controls. (p.21)

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1c.13. Are there new studies that have been conducted since the systematic review(s) of the body of evidence?** Yes  No  *If no, stop*

If yes,

**1c.13.1. For each new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.**

**EXAMPLE — EVIDENCE, PROCESS #2**

## NATIONAL QUALITY FORUM—Evidence (1c) Pilot Submission Form

### EXAMPLE — EVIDENCE, PROCESS #2

*The following example is only for illustration of the type of information requested for the Steering Committee's evaluation of the evidence. The key point is to provide substantive information and data in the measure submission form so it is clear about the evidence that does or does not exist to support the measure focus.*

**Measure Title:** [Periconception folic acid supplementation](#)

**Date of Submission:** 5/31/2012

- Respond to all questions with answers immediately following the question.
- Maximum of 6 pages (*6 pages includes questions/instructions in the form*); minimum font size 11 pt
- All information needed to demonstrate meeting the [evidence criterion \(1c\)](#) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- See NQF [guidance on evaluating evidence](#). Contact NQF staff for examples, resources, or questions.

### STRUCTURE-PROCESS-OUTCOME RELATIONSHIP

#### 1c.1. This is a measure of:

Outcome

- Health outcome: [Click here to name the health outcome](#)
- Intermediate clinical outcome: [Click here to name the intermediate outcome](#)
- Process: [Folic acid supplements for women who may become pregnant and in early pregnancy to prevent neural tube defects](#)
- Structure: [Click here to name the structure](#)
- Other: [Click here to name what is being measured](#)

#### HEALTH OUTCOME MEASURE **If not a health outcome, skip to 1c.3**

*If the measure focus identified in 1c.1 is a health outcome, answer 1c.2 and 1c.2.1.*

#### 1c.2. Briefly state or diagram how the health outcome is related to at least one healthcare structure, process, intervention, or service.

##### 1c.2.1. State the rationale supporting the relationship between the health outcome and at least one healthcare structure, process, intervention, or service.

**Note:** *For health outcome measures, no further information is required*

#### STRUCTURE, PROCESS, OR INTERMEDIATE OUTCOME MEASURE

If the measure focus identified in 1c.1 is a structure, process, or intermediate outcome answer all the following questions (except as indicated by skip pattern).

**Key Points**

- See NQF [guidance on evaluating evidence](#) and criteria for rating [Quantity, quality, consistency of body of evidence](#)
- A **systematic review** is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include quantitative synthesis (meta-analysis), depending on available data ([IOM, 2011](#)).
- A body of evidence includes all the evidence for a topic, which is systematically identified, based on pre-established criteria for relevance and quality of evidence.
- Expert opinion is not considered empirical evidence, but evidence is not limited to randomized controlled trials
- There is variability in evidence reviews, grading systems, and presentation of the findings; however, the information should be reported as requested in this form so the Steering Committee can evaluate it according to NQF criteria and guidance.

**1c.3. Briefly state or diagram how the measure focus is related to desired health outcomes and proximity to desired health outcomes.** (Do not summarize the evidence here.)

**Key Points**

- Should indicate the causal pathway – not just a general statement
- Do not discuss evidence in this item

**EXAMPLE**

Folic acid supplementation in women planning, or capable of becoming pregnant, and continued during the early weeks of pregnancy reduces the occurrence of neural tube birth defects.

**1c.4.** Is there a guideline recommendation supporting the measure focus identified in 1c.1.? Yes  No

If no, skip to #1c.6

If yes, answer 1c.4.1-1c.5.

**1c.4.1. Guideline citation (including date):**

U.S. Preventive Services Task Force. Folic Acid for the Prevention of Neural Tube Defects: U.S. Preventive Services Task Force Recommendation Statement. AHRQ Publication No. 09-05132-EF-2, May 2009.  
<http://www.uspreventiveservicestaskforce.org/uspstf09/folicacid/folicacidrs.htm>

Folic Acid for the Prevention of Neural Tube Defects: U.S. Preventive Services Task Force Recommendation Statement U.S. Preventive Services Task Force Ann Intern Med May 5, 2009 150:626-631.

American College of Obstetricians and Gynecologists (ACOG). Neural tube defects. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2003 Jul. 11 p. (ACOG practice bulletin; no. 44). [81 references]

The American College of Obstetricians and Gynecologists (ACOG) reaffirmed the currency of the guideline in 2008.

1c.4.2. **URL** (if available online):

**Key Points**

- Make sure URL is active and correct

**EXAMPLE**

USPSTF: <http://www.uspreventiveservicestaskforce.org/uspstf/uspsnrfol.htm>

ACOG: <http://www.guideline.gov/content.aspx?id=3994&search=folic+acid+supplement>

1c.4.3. **Identify guideline number and/or page number:**

**Key Points**

- If guideline recommendation is one of many from a single document, the specific guideline number and/or page number is necessary.

**EXAMPLE**

USPSTF: no numbering provided; date is May 2009

ACOG: practice bulletin no. 44

1c.4.4. **Quote *verbatim*, the specific guideline recommendation:**

**Key Points**

- Do not summarize, paraphrase, or shorten

**EXAMPLE**

USPSTF: The USPSTF recommends that all women planning or capable of pregnancy take a daily supplement containing 0.4 to 0.8 mg (400 to 800 µg) of folic acid.

ACOG: Periconceptional folic acid supplementation is recommended because it has been shown to reduce the occurrence and recurrence of neural tube defects (NTDs).

1c.4.5. **Grade assigned to the recommendation with definition of the grade:**

**Key Points**

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale

- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for a recommendation

### EXAMPLE

USPSTF: A recommendation - The USPSTF recommends the service. There is high certainty that the net benefit is substantial. Offer or provide this service.

ACOG: Level A - Recommendation is based on good and consistent scientific evidence

**1c.5. Did the guideline developer systematically review and grade the body of evidence for the specific guideline recommendation?** Yes  No  **If no, skip to #1c.6**

*If yes, answer 1c.5.1. (Note: Findings of the systematic review of the body of evidence for the guideline recommendation must be reported in 1c.8-1c.13.)*

**1c.5.1. Grade assigned to the body of evidence with definition of the grade:**

#### Key Points

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for the body of evidence
- If specific details regarding systematic review of evidence for guideline not available, will need to identify another review of the body of evidence

### EXAMPLE

USPSTF: High Certainty of Net Benefit - The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.

ACOG: The National Guideline Clearinghouse states recommendation based on systematic review of evidence, but the specific grade and summary not provided.

**1c.6. Is there another published systematic review of the body of evidence supporting the measure focus identified in 1c.1?** (other than from the guideline cited above, e.g., Cochrane, AHRQ, USPSTF)  
Yes  No  **If no, skip to #1c.7**

*If yes, answer 1c.6.1-1c.6.3. (Note: Findings of the systematic review of the body of evidence must be reported in 1c.8-1c.13.)*

**1c.6.1. Citation (including date):** Wolff T, Witkop CT, Miller T, Syed SB. Folic Acid Supplementation for the Prevention of Neural Tube Defects: An Update of the Evidence for the U.S. Preventive Services Task Force. Evidence Synthesis No. 70. AHRQ Publication No. 09-051132-EF-1. Rockville, Maryland: Agency for Healthcare Research and Quality. May 2009.

**1c.6.2. URL (if available online):**

**Key Points**

- Make sure URL is active and correct

**EXAMPLE**

<http://www.ncbi.nlm.nih.gov/books/NBK43412/>

**1c.6.3. Grade assigned to the body of evidence with definition of the grade:**

**Key Points**

- Should include BOTH grade and definition of the grade; if both not provided, reason should be explained
- Not all grades are on a letter or number scale
- Grades for recommendation and quality of evidence are often different (although related) – make sure it is the appropriate grade for the body of evidence

**EXAMPLE**

The evidence synthesis did not provide one overall grade. See prior section for USPSTF grade for the recommendation. See next section for summary of evidence.

*If a systematic review of the evidence was identified in either 1c.5 or 1c.6, skip to 1c.8*

**1c.7. If a systematic review of the body of evidence was not identified and reported in 1c.5 or 1c.6, did the measure developer perform a systematic review of the body of evidence supporting the measure focus identified in 1c.1? Yes  No**

*If yes, answer 1c.7.1-1c.7.3. (Note: Findings of the measure developer’s systematic review of the body of evidence must be reported in 1c.8-1c.13 and unpublished evidence review products such as evidence tables provided in an appendix.)*

**1c.7.1. Who conducted the measure developer’s systematic review of the body of evidence?**

**1c.7.2. Grade assigned to the body of evidence with definition of the grade:**

**1c.7.3. Describe the process used for the systematic review:**

*If no systematic review of the body of evidence identified in 1c.5, 1c.6, or 1c.7, the evidence criterion can not be met.*

**FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE FOCUS**

**Key Points**

- Responses to the following items should NOT include a description of each individual study – the responses should include quantitative data from a synthesis of the entire body of evidence. If there is more than one systematic review, each should be reported separately (not combined by the submitter).
- May copy relevant sections from source(s) of systematic reviews cited in 1c.5, 1c.6, or 1c.7; include page number if possible; make sure it includes substantive, quantitative information not just conclusions



*(Items 1c.8-1c.13 must be answered and should support the measure focus identified in 1c.1. If more than one systematic review was identified (1c.5, 1c.6, and 1c.7), provide a separate response for each.)*

**1c.8. What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range:** [1992-2009](#)

#### QUANTITY AND QUALITY OF BODY OF EVIDENCE

**1c.9. How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)**

##### Key Points

- Only enter number and type of study design here — discuss in 1c.10
- NQF does not require evidence be only randomized controlled trials
- Study design relates to quality of evidence but is insufficient by itself to judge quality

#### EXAMPLE

USPSTF: Initially 1 large randomized, controlled trial (RCT) for the 1996 review.

The recent evidence synthesis included 4 studies published since 1996: 1 cohort study, 2 case control studies, and 1 meta-analysis.

**1c.10. What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect due to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)**

##### Key Points

- Do not discuss each study individually — categorize by quality

#### EXAMPLE

USPSTF:

One cohort study rated as fair quality.

Studies will be graded "fair" if any or all of the following problems occur, without the fatal flaws noted in the "poor" category : Generally comparable groups are assembled initially but some question remains whether some (although not major) differences occurred with follow-up; measurement instruments are acceptable (although not the best) and generally applied equally; some but not all important outcomes are considered; and some but not all potential confounders are accounted for. Intention to treat analysis is done for RCTs.

Two case control studies – one rated fair quality and one rated good quality.

Good: Appropriate ascertainment of cases and nonbiased selection of case and control participants; exclusion criteria applied equally to cases and controls; response rate equally to or greater than 80

percent; diagnostic procedures and measurements accurate and applied equally to cases and controls; and appropriate attention to confounding variables.

Fair: Recent, relevant, without major apparent selection or diagnostic work-up bias but with response rates less than 80 percent or attention to some but not all important confounding variables.

One meta-analysis rated fair quality.

## ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE

**1c.11. What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence?** (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)

### Key Points

- Do not discuss each study individually — categorize by outcome studied

### EXAMPLE

USPSTF: The Czeizel cohort study reported that 1 NTD and 9 NTDs occurred in the supplemented and unsupplemented women, respectively, for an adjusted odds ratio (aOR) of 0.11 (95% CI, 0.01–0.91); the odds ratio (OR) was adjusted for birth order, chronic maternal disorders, and history of previous fetal death or congenital abnormality. The meta-analysis also found a protective effect of folic acid-containing multivitamins in NTDs with an OR of 0.67 (95% CI, 0.58–0.77) in case-control studies and an OR of 0.52 (0.39–0.69) in RCTs and cohort studies. Both the Czeizel study and the meta-analysis found a statistically significant association between folic acid supplementation and a reduction in cardiovascular congenital abnormalities. In addition, there was a significant effect of folic acid-containing multivitamin use on congenital limb defects in the meta-analysis. No consistent effect of folic acid-containing multivitamins, either on orofacial clefts or on urinary tract congenital abnormalities, was seen in the Czeizel study or the meta-analysis.

The 1995 case-control study reported an OR of 0.65 (95% CI, 0.45–0.94) for use of folic acid-containing supplements in the 3 months before conception, and an OR of 0.60 (95% CI, 0.46–0.79) for supplement use in the 3 months after conception. The 2003 study by Thompson and colleagues reported an OR of 0.55 (0.25–1.22) for regular use, and an OR of 0.92 (0.55–1.55) for some use of folic acid-containing supplements, but neither of these findings was statistically significant. Several differences in these case-control studies may explain differences in results. The 2003 Thompson study was smaller and adjusted for dietary folate intake. Additionally, the exposure timeframes were different: the Shaw study measured exposure in 2 time frames, 3 months before and 3 months after conception, while the Thompson study combined these same 6 months of periconception time into one measure of exposure.

**1c.12. What harms were studied and how do they affect the net benefit—benefits over harms?**

### Key Points

- Information on harms may come from different studies than the treatment effectiveness studies, often from observational studies

### EXAMPLE

USPSTF: The recommendation statement concluded: “Adequate evidence suggests that folic acid from supplementation at usual doses is not associated with serious harms. In its current review, the USPSTF found no evidence on drug interactions, allergic reactions, or carcinogenic effects.”

The evidence synthesis found one fair quality retrospective cohort study that addressed whether folic acid supplementation in women of childbearing age increases the risk of harmful outcomes for either the woman or the infant. After adjusting for age and parity, the authors reported an OR of 1.59 (95% CI 1.41–1.78) for twin delivery after preconceptional folic acid supplementation. In a subgroup analysis of women who did not report IVF, the risk of twinning was lower and non-significant (OR 1.13, 95% CI 0.97–1.33), as expected given the increase in multiple gestation associated with IVF and other assisted reproductive technologies. The odds of having twins of unlike sex, an outcome used as a proxy for dizygotic twinning, were increased in women taking folate, (OR 1.43, 95% CI 1.12–1.83). The authors then adjusted for both a 45% underreporting of supplementation as well as an estimated 12.7% of unidentified IVF pregnancies. When the likely underreporting for folic acid use and IVF were accounted for, the OR for twin delivery after preconceptional supplementation fell to 1.02, and was no longer statistically significantly greater than the risk for women who did not take folic acid (95% CI, 0.85–1.24).

ACOG: Risks of folic acid supplementation. The risks of higher levels of folic acid supplementation are believed to be minimal. Folic acid is considered nontoxic even at very high doses and is rapidly excreted in the urine. There have been concerns that supplemental folic acid could mask the symptoms of pernicious anemia and thus delay treatment. However, folic acid cannot mask the neuropathy typical of this diagnosis. Currently, 12% of patients with pernicious anemia present with neuropathy alone. With folic acid supplementation, this proportion may be increased, but there is no evidence that initiating treatment after the development of a neuropathy results in irreversible damage. A small number of women taking seizure medication (diphenylhydantoin, aminopterin, or carbamazepine) may have lower serum drug levels and experience an associated increase in seizure frequency while taking folic acid supplement. Monitoring drug levels and increasing the dosage as needed may help to avert this complication.

#### UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE

**1c.13.** Are there new studies that have been conducted since the systematic review(s) of the body of evidence? Yes  No  *If no, stop*

If yes,

**1c.13.1.** For **each** new study provide: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

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**EXAMPLE — MEASURE CONCEPT SPECIFICATIONS**

## NATIONAL QUALITY FORUM—Concept Submission Items

### Measure Concept Specifications

#### Key Points

- Measure concepts should be sufficiently specified so that it is clear how the concept will be measured

#### De.1. Measure Title

#### Key Points

- Briefly convey as much information as possible about the measure focus and target population

#### SUGGESTED FORMAT

[target population] who received/had [measure]

#### EXAMPLE

Patients with diabetes who received an eye exam

**De.2. Brief description of measure** (*including type of score, measure focus, target population, timeframe, e.g., percentage of adult patients aged 18-75 years receiving one or more HbA1c tests per year*)

#### Key Points

- Briefly describe the type of score (e.g., percentage, proportion, number) and the target population and focus of measurement.

#### SUGGESTED FORMAT

[type of score] of [target population] who received/had [measure focus]

#### EXAMPLE

Percentage of adult patients age 18-75 with diabetes who received a foot exam

**De.4. Subject/Topic Areas** (Check all the areas that apply): **[Taxonomy - select from list]**

**De.5. Cross Cutting Areas** (Check all the areas that apply): **[Taxonomy - select from list]**

#### Measure Specifications (**Measure evaluation criterion 2a1**)

**2a1.1. Numerator Statement** (*Brief, narrative description of the measure focus or what is being measured the target population, i.e., cases from the target population with the target process, condition, event, or outcome*)

#### Key Points

- Describe the measure focus—cases from the target population with the target process, condition,

event, or outcome based on the evidence.

- If the time frame is different than for identifying the target population, it should be specified.

#### SUGGESTED FORMAT

Patients [in the target population] who received/had [measure focus] {during [time frame] if different than target population}

#### EXAMPLE

Patients age 18-75 with diabetes in ambulatory care who received a foot exam

**2a1.3. Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*

**For new concepts**, describe how you plan to identify and calculate the numerator.

#### Key Points

- Define all key concepts
- Identify code/value sets (e.g., ICD-10) or standard data collection items (e.g., Minimum Data Set (MDS) that are or will be used for concepts
- Note that lists of individual codes with descriptors or specific data items and responses should be submitted with stage 2 measure submission

#### EXAMPLE

Identification of foot exam will require review of the medical record. The foot examination must include all the following: inspection, assessment of foot pulses, and testing for loss of protective sensation (LOPS) (10-g monofilament plus testing any one of: vibration using 128-Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold).

**2a1.4. Denominator Statement** *(Brief, narrative description of the target population being measured)*

#### Key Points

- Designate the broadest population based on the evidence for which the target process, condition, event, outcome is applicable target population should indicate age, setting, and time frame for identifying the target population.

#### SUGGESTED FORMAT

Patients [age] with [condition] in [setting] during [time frame]

#### EXAMPLE

Patients age 18-75 with diabetes in ambulatory care during a 12-month measurement period

**2a1.5. Target Population Category** (*Check all the populations for which the measure is specified and tested if any*): [Taxonomy - select from list]

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**2a1.7. Denominator Details** *(All information required to identify and calculate the target population/denominator such as definitions, timeframe, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format stage 2 measure submission)*

**For new concepts,** describe how you plan to identify and calculate the denominator.

**Key Points**

- Define all key concepts
- Identify code/value sets (e.g., ICD-10) or standard data collection items (e.g., Minimum Data Set (MDS)) that are or will be used for concepts
- Note that lists of individual codes with descriptors or specific data items and responses should be submitted with stage 2 measure submission

**EXAMPLE**

Diabetes is/will be identified using ICD-10 codes

**2a1.8. Denominator Exclusions** *(Brief narrative description of exclusions from the target population)*

**Key Points**

- Identify patients who would be in the target population, but who should not receive the process or are not eligible for the outcome for some other reason, particularly as indicated by the evidence

**SUGGESTED FORMAT**

Patients in the [target population] who [have some additional characteristic, condition, procedure]

**EXAMPLE**

Patients with diabetes who have gestational or steroid-induced diabetes

**2a1.9. Denominator Exclusion Details** *(All information required to identify and calculate exclusions from denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)*

**For new concepts,** describe how you plan to identify and calculate the exclusions.

**Key Points**

- Define all key concepts
- Identify code/value sets (e.g., ICD-10) or standard data collection items (e.g., Minimum Data Set (MDS)) that are or will be used for concepts
- Note that lists of individual codes with descriptors or specific data items and responses should be submitted with stage 2 measure submission

**EXAMPLE**



Gestational or steroid-induced diabetes is or will be identified using ICD-10 codes

**2a1.10. Stratification Details/Variables** (All information required to stratify the measure results including stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors should be provided in an Excel file in required format with stage 2 measure submission)

**For new concepts**, describe how you plan to stratify the measure results.

**Key Points**

- Do not describe development and testing of stratification approach here – this item is for specifications
- Identify stratification variables
- Define all key concepts
- Identify code/value sets used for concepts but lists of individual codes and descriptors should be submitted with stage 2 measure submission

**EXAMPLE**

In addition to overall hospital score compute score for each racial group.  
Stratification categories: white, black, Hispanic, and other.

**2a1.13. Statistical risk model method and variables** (Name the statistical method - e.g., logistic regression, list all the risk factor variables. Note - risk model development should be addressed in measure testing in the stage 2 measure submission)

**For new concepts**, describe how you plan to adjust for differences in case mix/risk across measured entities

**Key Points**

- Do not describe risk model development and testing here – this item is for specifications
- Identify statistical method for risk adjustment
- Identify risk factor variables but the coefficients and code lists should be provided in Excel file with stage 2 measure submission
- Define all key concepts
- Identify code/value sets used for concepts but lists of individual codes and descriptors should be submitted with stage 2 measure submission

**EXAMPLE**

Logistic regression model

Risk Factors:

Age

Functional status

Prior hospitalization

Co-morbid conditions of diabetes, CHF, CAD

**2a1.25. Data Source** *(Check only the sources for which the measure is specified and tested)*

**If other, please describe in 2a1.26.**

**For new concepts, check the planned data sources. [Taxonomy - select from list]**

**2a1.26. Data Source or Collection Instrument** *(Identify the specific data source or data collection instrument (e.g. name of database, clinical registry, collection instrument, etc.)*

#### **EXAMPLES**

[Outcome and Assessment Information Set \(OASIS\)](#)

[MedPAR database](#)

**2a1.33. Level of Analysis** *(Check only the levels of analysis for which the measure is specified and tested):*

**For new concepts, check the planned levels of analysis. [Taxonomy - select from list]**

**2a1.34. Care Setting** *(Check only the settings for which the measure is specified and tested):*

**For new concepts, check the planned settings. [Taxonomy - select from list]**

**DRAFT**

**EXAMPLE — USABILITY AND USE**

## NATIONAL QUALITY FORUM—Concept Submission Items

### Usability and Use

#### 4.1. Current and Planned Use

Performance results from NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement (in addition to use for performance improvement).

*(Check only the current and planned uses; for any current uses that are checked, provide a URL for the specific program)*

**[Taxonomy - select from list]**

#### Key Points

- NQF endorses measures for use in accountability/public reporting, in addition to performance improvement
- Measures do not need to be in use at the time of initial endorsement
- Only check an applications is planned when there is or will be a specific plan for implementation (plan must be submitted with measure submission for stage 2)
- See [Usability Task Force report](#)

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**EXAMPLE — RELATED AND COMPETING MEASURES/CONCEPTS**

## NATIONAL QUALITY FORUM—Concept Submission Items

### Related and Competing Measures

#### Relation to Other NQF-endorsed® Measures (Measure evaluation criterion 5)

**5.1.** If there are related measures (either same measure focus or target population) or competing measures with the same measure focus and same target population), list the NQF # and title of all related and/or competing measures. NOTE: Can search and select measures.

##### Key Points

- Measure harmonization and competing measures must be resolved by developers prior to measure submission in stage 2
- Related and competing measures include those from other developers
- Check the list of all previously endorsed measures in the topic area posted to the project page

#### Harmonization (Measure evaluation criterion 5a)

**5a.1.** If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized?

**For new concepts, skip to 5a.2.**

Yes  
No

##### Key Points

- Completely harmonized means exactly the same specifications

**5a.2.** If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

**For new concepts, describe why another measure is needed and plans to harmonize measure specifications**

##### Key Points

- Measure harmonization must be resolved by developers prior to measure submission in stage 2
- NQF prefers to endorse measures with the broadest applicability supported by the evidence. Explore the possibility of combining measures.
- Describe actions taken to achieve harmonization including developers contacted and result of that communication
- See [Measure Harmonization report](#).

#### Competing Measure(s) (Measure evaluation criterion 5b)

**5b.1.** If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid

or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

**For new concepts, describe how a new measure will be superior to existing endorsed measures or why additional measure is needed.**

**Key Points**

- Competing measures must be resolved by developers prior to measure submission in stage 2
- NQF prefers to endorse measures with the broadest applicability supported by the evidence. Explore the possibility of combining measures
- Describe actions taken to prevent multiple measures including developers contacted and result of that communication
- See [Competing Measures report](#).

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**EXAMPLE — MEASURE TESTING**



## Measure Testing to Demonstrate Scientific Acceptability of Measure Properties

**Measure Title:** [Click here to enter measure title](#)

**Date of Submission:** [Click here to enter a date](#)

**Type of Measure:**

<input type="checkbox"/> Composite	<input type="checkbox"/> Outcome
<input type="checkbox"/> Cost/resource	<input type="checkbox"/> Process
<input type="checkbox"/> Efficiency	<input type="checkbox"/> Structure

This Word document template must be used to submit information for measure testing.

- **For all measures, sections 1, 2a2, 2b2, 2b3, 2b5 must be completed**
- **For outcome or resource use measures, section 2b4 also must be completed**
- If specified for **multiple data sources** (e.g., claims and medical records), section **2b6** also must be completed
- Respond to all questions with answers immediately following the question (*unless meet the skip criteria or those that are indicated as optional*).
- Maximum of 10 pages (*including questions/instructions; do not change margins or font size; contact project staff if need more pages*)
- All information on testing to demonstrate meeting the [criteria for scientific acceptability of measure properties \(2a,2b\)](#) must be in this form. An appendix for *supplemental materials* may be submitted, but there is no guarantee it will be reviewed.

### 1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

*Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. If there are differences by aspect of testing, (e.g., reliability vs. validity) be sure to indicate the specific differences in question 7.*

**1.1. What type of data was used for testing?** (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for all the types of data specified and intended for measure implementation*)

Measure Specified to Use Data From:	Measure Tested with Data From:
<input type="checkbox"/> abstracted from paper record	<input type="checkbox"/> abstracted from paper record
<input type="checkbox"/> administrative claims	<input type="checkbox"/> administrative claims
<input type="checkbox"/> clinical database/registry	<input type="checkbox"/> clinical database/registry
<input type="checkbox"/> abstracted from electronic health record	<input type="checkbox"/> abstracted from electronic health record
<input type="checkbox"/> eMeasure implemented in electronic health record	<input type="checkbox"/> eMeasure implemented in electronic health record
<input type="checkbox"/> other: <a href="#">Click here to describe</a>	<input type="checkbox"/> other: <a href="#">Click here to describe</a>

**1.2. If used an existing dataset, identify the specific dataset** (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured;*

*e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).*

**1.3. What are the dates of the data used in testing?** [Click here to enter date range](#)

**1.4. What levels of analysis were tested?** (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

individual clinician    group/practice    hospital/facility/agency    health plan  
 other: [Click here to describe](#)

**1.5. How many and which measured entities were included in the testing and analysis (by level of analysis and data source)?** (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

**1.6. How many and which patients were included in the testing and analysis (by level of analysis and data source)?** (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

**1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.**

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## 2a2. RELIABILITY TESTING

**Note:** *If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – report validity of data elements in 2b2*

**2a2.1. What level of reliability testing was conducted?** (*may be one or both levels*)

Critical data elements used in the measure (*e.g., inter-abstractor reliability*)  
 Performance measure score (*e.g., signal-to-noise*)

**2a2.2. For each level checked above, describe the method of reliability testing and what it tests** (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

**2a2.3. For each level checked above, what were the statistical results from reliability testing?** (*e.g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis and association with case volume*)

**2a2.4 What is your interpretation of the results in terms of demonstrating reliability?** (*i.e., what do the results mean and what are the norms for the test conducted?*)

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## 2b2. VALIDITY TESTING

**2b2.1. What level of validity testing was conducted?** (may be one or both levels)

Critical data elements

Performance measure score

Empirical validity testing

Systematic assessment of face validity of performance measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance quality or resource use and can distinguish performance)

**2b2.2. For each level checked above, describe the method of validity testing and what it tests** (describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)

**2b2.3. What were the statistical results from validity testing?** (e.g., correlation; t-test, ANOVA)

**2b2.4. What is your interpretation of the results in terms of demonstrating validity?** (i.e., what do the results mean and what are the norms for the test conducted?)

---

### **2b3. EXCLUSIONS ANALYSIS**

NA  no exclusions — skip to #2b5

**2b3.1. Describe the method of testing exclusions and what it tests** (describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used)

**2b3.2. What were the statistical results from testing exclusions?** (include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores)

**2b3.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results?** (i.e., the value outweighs the burden of increased data collection and analysis. *Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)

---

### **2b5. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE**

**2b5.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified** (describe the steps—do not just name a method; what statistical analysis was used)

**2b5.2. What were the statistical results from testing the ability to identify differences in performance measure scores across measured entities?** (at a minimum, the distribution of performance measure

scores for the measured entities by decile/quartile, mean, std dev; preferably also number and percentage statistically different from mean or some benchmark, different from expected, etc.)

**2b5.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and clinically/practically meaningful differences in performance across measured entities? (i.e., what do the results mean and what are the norms for the test conducted?)**

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**If not an intermediate or health outcome or resource use measure, this section can be deleted**

## **2b4. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES**

**2b4.1. What method of controlling for differences in case mix is used?**

- Statistical risk model with** [Click here to enter number of factors](#) **risk factors**
- Stratification by** [Click here to enter number of categories](#) **risk categories**
- No risk adjustment or stratification**
- Other,** [Click here to enter description](#)

**2b4.2. If an outcome or resource use measure is not risk adjusted or stratified, provide rationale and analyses to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.**

**2b4.3. Describe the conceptual/clinical and statistical methods and criteria used to select factors used in the statistical risk model or for stratification by risk (e.g., potential factors identified in literature and/or expert panel; regression analysis; statistical significance of  $p < 0.10$ ; correlation of  $x$  or higher)**

**2b4.4. What were the statistical results of the analyses used to select risk factors?**

**2b4.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used)**

*Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.*

**if stratified, skip to 2b4.9**

**2b4.6. Statistical Risk Model Discrimination Statistics:**

**2b4.7. Statistical Risk Model Calibration Statistics:**

**2b4.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:**

**2b4.9. Results of Risk Stratification Analysis:**

**2b4.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.e., what do the results mean and what are the norms for the test conducted)**

**\*2b4.11. Optional Additional Testing** (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods*)

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**If only one set of specifications, this section can be deleted**

## **2b6. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS**

**Note:** *This criterion is directed to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical records and a different set of specifications for claims). It does not apply to measures that use more than one type of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).*

**2b6.1. Describe the method of testing conducted to demonstrate equivalence of performance scores for the same entities across the different specifications** (*describe the steps—do not just name a method; what statistical analysis was used*)

**2b6.2. What were the statistical results from testing comparability of performance scores for the same entities when using different specifications?** (*e.g., correlation, rank order*)

**2b6.3. What is your interpretation of the results in terms of demonstrating comparability of performance measure scores for the same entities across the different specifications?** (*i.e., what do the results mean and what are the norms for the test conducted*)

## Appendix B: Task Force Recommendations for Measure Maintenance, 2012

Two recent NQF Task Force reports have provided more detailed guidance and expectations for evaluating measures against the four main criteria:

[Evidence Task Force Report](#)  
[Measure Testing Task Force Report](#)

In each report, the Task Force has established specific guidance and expectations for measures undergoing maintenance review as well as new measures. Submissions must respond to the specific requests appropriate for measure maintenance:

### Importance to Measure and Report: Opportunity for Improvement

- **Section 1b.2 Summary of Data Demonstrating Performance Gap** (*Variation or overall less than optimal performance across providers*):  
**For Maintenance** – *Descriptive statistics for performance results **for this measure** - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*
- **Section 1b.3 Citations for Data on Performance Gap**  
**For Maintenance** – *Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*
- **1b.4 Summary of Data on Disparities by Population Group**  
**For Maintenance** – *Descriptive statistics for performance results **for this measure** by population group*
- **1b.5 Citations for Data on Disparities Cited in 1b.4**  
**For Maintenance** – *Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*

### Reliability and Validity Testing Required for Maintenance of Endorsement

- Endorsed measures are reviewed for maintenance of endorsement every three years along with new measures.
- Both new and endorsed measures are required to meet the measure evaluation criteria, including reliability and validity (see table 6).
- Reliability and validity testing should:
  - Use data from implementation of the endorsed measure as specified and,
  - Focus on the measure score rather than on the data elements (i.e. information on the accuracy of any classification based on the measure results).
- If an endorsed measure has not been implemented, then expanded testing in terms of scope and levels is required.
- As with initial endorsement, all the other criteria also will be used to determine whether a measure warrants continued endorsement

**Table 6: Scope of Testing Required at the Time of Review for Endorsement Maintenance**

	<b>First Endorsement Maintenance Review</b>	<b>Subsequent Reviews</b>
Reliability	<p><b>Measure In Use</b></p> <ul style="list-style-type: none"> <li>Analysis of data from entities whose performance is measured</li> <li>Reliability of measure scores (e.g., signal to noise analysis)</li> </ul> <p><b>Measure Not in Use</b></p> <ul style="list-style-type: none"> <li>Expanded testing in terms of scope (number of entities/patients) and/or levels (data elements/measure score)</li> </ul>	Could submit prior testing data, if results demonstrated that reliability achieved a high rating
Validity	<p><b>Measure in Use</b></p> <ul style="list-style-type: none"> <li>Analysis of data from entities whose performance is measured</li> <li>Validity of measure score for making accurate conclusions about quality</li> <li>Analysis of threats to validity</li> </ul> <p><b>Measure Not in Use</b></p> <ul style="list-style-type: none"> <li>Expanded testing in terms of scope (number of entities/patients) and/or levels (data elements/measure score)</li> </ul>	Could submit prior testing data, if results demonstrated that validity achieved a high rating

Usability (new 2012 guidance will be implemented in 4th quarter 2012)

- 3a.1. Use in Public Reporting - disclosure of performance results to the public at large** (*If used in a public reporting program, provide name of program(s), locations, Web page URL(s)*). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement:

**For Maintenance** – *If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*
- 3b.1. Use in QI.** If used in quality improvement program, provide name of program(s), locations, Web page URL(s)

**For Maintenance** – *If not used for QI, indicate the reasons and describe progress toward using performance results for improvement.*

## Appendix C: Measure Concept Agreement



### **Measure Concept Agreement**

This Measure Concept Agreement (the “Agreement”) is entered into by and between National Quality Forum (“NQF”) and \_\_\_\_\_ (“Steward”), on <insert date>.

**WHEREAS**, NQF wishes to offer Stewards the opportunity to participate in a two-stage Consensus Development Process (“CDP”); and

**WHEREAS**, NQF wishes to make this opportunity available to Stewards bringing forward measure concepts only, new fully tested and specified measures, and measures undergoing endorsement maintenance; and

**WHEREAS**, Steward wishes to avail itself of this opportunity with respect to the measure concept(s), new measure(s), or measure(s) undergoing endorsement maintenance listed in this Agreement;

**NOW, THEREFORE**, in consideration of the foregoing, Steward and NQF hereby agree as follows:

1. **Definition of Measure Concept.** A Measure Concept consists of the following elements:
  - A. a numerator statement;
  - B. a denominator statement;
  - C. exclusions under consideration;
  - D. preliminary detailed specifications, which may or may not include coding;
  - E. proposed levels of analysis, data source, and settings of care; and
  - F. for outcome and other measures when indicated, description of proposed risk adjustment/stratification methodology and risk factors under consideration.
  
2. **Submission of Measure Concept.**



A. **Types of Submissions.** Steward may submit a Measure Concept to NQF for review in any of the following formats, which must include the elements specified in Section 1, Definition of Measure Concept, of this Agreement:

- (1) a new measure concept that has not been fully specified or tested;
- (2) conceptual components of a new, fully specified and tested measure; or
- (3) conceptual components of a measure undergoing endorsement maintenance.

B. **List of Submissions.** Steward is submitting the Measure Concept(s) listed in Exhibit A, which is attached to and incorporated by reference into this Agreement, for review by NQF.

### **3. NQF Review of Measure Concept.**

A. NQF will evaluate the Measure Concept for “Importance to Measure and Report,” (“Importance”), as defined by NQF’s Measure Evaluation Criteria and according to Stage One of the Two-Stage CDP, as both may be amended from time to time.

B. The determination of whether to approve a Measure Concept, and if applicable, whether to withdraw approval is in NQF’s sole discretion. Steward has no right to challenge a decision on a Measure Concept except through NQF’s reconsideration process. The result of reconsideration of a Measure Concept is final, and Steward waives any claim against NQF arising from a decision not to approve a Measure Concept or to withdraw approval of a Measure Concept.

C. Approval of a Measure Concept applies for 18 months following the date of approval. Steward must submit a fully specified and tested measure during this 18-month window in order to complete the measure endorsement process. If Steward does not submit a fully specified and tested measure within the 18-month window, the approval of the Measure Concept expires.

D. NQF’s approval of a Measure Concept applies solely to the Steward who seeks evaluation of such Measure Concept, unless Steward assigns the Measure Concept and approval to another party and that party does not alter the Measure Concept.

E. If NQF proposes changes to a Measure Concept prior to approval, NQF shall notify the Steward of the proposed changes, and the Steward shall have the right to accept such changes or reject such proposed changes and withdraw the Measure Concept from consideration for approval. If Steward withdraws the Measure Concept, NQF shall have no right to approve the original or modified Measure Concept unless Steward elects to re-submit the original or modified Measure Concept.

F. If Steward changes a Measure Concept following approval, Steward must notify NQF as soon as practicable. A material change in a Measure Concept may result in NQF requiring that the Steward re-submit the Measure Concept for review.

G. If Steward abandons a Measure Concept, Steward shall notify NQF as soon as practicable.

H. If a Measure Concept is approved by NQF, Steward may state that the Measure Concept is NQF-approved. Steward may not state that the Measure Concept is NQF-endorsed.

#### **4. Disclosure for Measure Concept Review.**

A. Steward agrees to disclose to NQF the information outlined in Section 1, Definition of Measure Concept, so that NQF may evaluate the Measure Concept for Importance. Steward is also required to complete and disclose a Measure Submission Form. Steward's disclosure to NQF as described in Section 4.A. includes disclosure to NQF staff, committees, officers, directors and agents as deemed appropriate by NQF.

B. Steward agrees that NQF may publicly disclose all information necessary to evaluate the Measure Concept and for purposes of public review and comment, including but not limited to:

- A. a numerator statement;
- B. a denominator statement;
- C. exclusions under consideration;
- D. preliminary detailed specifications, which may or may not include coding;
- E. proposed levels of analysis, data source, and settings of care;
- F. for outcome and other measures when indicated, description of proposed risk adjustment/stratification methodology and risk factors under consideration; and
- G. Measure Concept submission form.

C. Steward agrees that NQF may publicly disclose all of the information listed in Section 1, Definition of Measure Concept, and the Measure Submission Form, following approval or rejection of the Measure Concept.

**5. Term and Termination.**

A. This Agreement is effective as of the date above written, and shall have a term ending 18 months after the date a given Measure Concept is approved.

B. NQF may terminate this Agreement with respect to a given Measure Concept upon ten (10) days written notice of its decision to withdraw approval of such Measure Concept. NQF shall notify Steward of the reasons for withdrawing approval of the Measure Concept and provide Steward with a reasonable opportunity to address the reasons for withdrawing approval. The determination of whether Steward has sufficiently addressed such reasons shall be made in NQF's sole discretion.

C. Steward may terminate NQF's approval of a given Measure Concept and this Agreement upon ten (10) days written notice to NQF.

D. Upon termination of this Agreement with respect to a given Measure Concept, Steward shall cease any reference to NQF's approval of such Measure Concept.

**6. Indemnification.** Steward shall hold NQF harmless and indemnify NQF for any and all liability, loss, damages, cost and expenses, including reasonable attorneys' fees, arising out of or connected with: (i) any claim of infringement or misappropriation of any intellectual property right or proprietary right of any third party and related to the Measure Concept, and (ii) any claim by a third party related to the Measure Concept except to the extent that NQF has been grossly negligent or engaged in willful misconduct.

**7. Miscellaneous.**

A. Any notice or other communications under this Agreement must be in writing and will be considered given on the date delivered to the other party through a method capable of tracking. Notices shall be sent to:

National Quality Forum  
1030 15<sup>th</sup> Street, NW  
Suite 800  
Washington, DC 20005  
ATTN: Performance Measures

<TO STEWARD>

B. This Agreement may only be amended in writing through a document signed by both parties.

C. The parties will attempt to resolve any disputes between them through negotiation or other informal means. In the event that a dispute cannot be resolved in this manner, the parties will submit to binding arbitration in accordance with the rules of the American Arbitration Association.

D. This Agreement will be governed by and construed in accordance with the laws of the District of Columbia, without reference to conflicts of law provisions.

E. The undersigned each respectively represent that each part is authorized to sign this Agreement on behalf of the parties to this Agreement.

**NATIONAL QUALITY FORUM**

**<NAME OF STEWARD>**

\_\_\_\_\_  
Signature of Authorized Representative

\_\_\_\_\_  
Signature of Authorized Representative

\_\_\_\_\_  
Name of Authorized Representative

\_\_\_\_\_  
Name of Authorized Representative

\_\_\_\_\_  
Title of Authorized Representative

\_\_\_\_\_  
Title of Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

**EXHIBIT A**

**List of Measure Concepts**

For each Measure Concept, indicate whether you are submitting:

1. a new measure concept that has not been fully specified or tested;
2. conceptual components of a new, fully specified and tested measure; or
3. conceptual components of a measure undergoing endorsement maintenance.

Additional information, including the elements of the Measure Concept, will be collected separately by NQF.

***Project Name:***

***Date of Submission:***

<b>NQF Measure Number (if applicable)</b>	<b>Measure Concept Title</b>	<b>Measure Concept Description</b>	<b>Type of Measure Concept</b>

**Appendix D: Example of Exhibit A of the Measure Concept Agreement**

**EXHIBIT A**

**List of Measure Concepts**

For each Measure Concept, indicate whether you are submitting:

1. a new measure concept that has not been fully specified or tested;
2. conceptual components of a new, fully specified and tested measure; or
3. conceptual components of a measure undergoing endorsement maintenance.

Additional information, including the elements of the Measure Concept, will be collected separately by NQF.

**Project Name:** *National Voluntary Consensus Standards: Gastrointestinal and Genitourinary Endorsement Maintenance Pilot 2012*

**Date of Submission:** *July 16, 2012*

NQF Measure Number (if applicable)	Measure Concept Title	Measure Concept Description	Type of Measure Concept
0622	GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms	The percentage of adult patients with gastroesophageal reflux disease (GERD) with alarm symptoms who have had an upper gastrointestinal study.	conceptual components of a measure undergoing endorsement maintenance
C2059	IBD preventive care: corticosteroid sparing therapy	Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroid* greater than or equal to 10mg/day for 60 or greater consecutive days that have been prescribed corticosteroid sparing therapy in the last reporting year.	a new measure concept that has not been fully specified or tested

**Appendix E: Appendix A of Measure Steward Agreement**

**APPENDIX A**

**MEASURE INFORMATION**

In accordance with Section 1.a. of the Measure Steward Agreement (the “Agreement”), entered into on \_\_\_\_\_, by \_\_\_\_\_ (the “Steward”) and the National Quality Forum (“NQF”), the Steward hereby submits as Appendix A to the Agreement the following additional Measures for consideration for endorsement by NQF:

All other provisions of the Agreement remain unchanged.

An authorized signatory of each party to the Agreement hereby signs below to indicate acceptance of this Appendix A and its incorporation into the Agreement.

**MEASURE STEWARD**

**NATIONAL QUALITY FORUM**

\_\_\_\_\_  
Signature of Authorized Representative

\_\_\_\_\_  
Signature of Authorized Representative

\_\_\_\_\_  
Name of Authorized Representative

\_\_\_\_\_  
Name of Authorized Representative

\_\_\_\_\_  
Title of Authorized Representative

\_\_\_\_\_  
Title of Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

**Appendix F: Example of Appendix A of the Measure Steward Agreement**

APPENDIX A

MEASURE INFORMATION

In accordance with Section 1.a. of the Measure Steward Agreement (the “Agreement”), entered into on January 15, 2010, by Ace Measure Developer (“the Steward”) and the National Quality Forum (“NQF”), the Steward hereby submits as Appendix A to the Agreement the following additional Measures for consideration for endorsement by NQF:

*National Voluntary Consensus Standards for Patient Outcomes Project: Mental Health Outcomes*

*Submitted Tuesday, February 2, 2010*

**Measure Title:** Services offered for psychosocial needs

**Measure Description:** Proportion of patients with a New Treatment Episode (NTE) and have evidence of need/deficit for Housing or Employment status who are offered services for their needs.

All other provisions of the Agreement remain unchanged.

An authorized signatory of each party to the Agreement hereby signs below to indicate acceptance of this Appendix A and its incorporation into the Agreement.

**ACE MEASURE DEVELOPER**

**NATIONAL QUALITY FORUM**

\_\_\_\_\_  
Signature of Authorized Representative

\_\_\_\_\_  
Signature of Authorized Representative

\_\_\_\_\_  
Name of Authorized Representative

\_\_\_\_\_  
Name of Authorized Representative

\_\_\_\_\_  
Title of Authorized Representative

\_\_\_\_\_  
Title of Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date



## Appendix G: Glossary

**Access** - The ability to obtain needed healthcare services in a timely manner including the perceptions and experiences of people regarding their ease of reaching health services or health facilities in terms of proximity, location, time and, ease of approach. Examples may include, but are not limited to, measures that address timeliness of response or services, time until next available appointment, and availability of services within a community.

**Accountability** - An obligation or willingness to accept responsibility for performance.

**Accountability Applications** - Use of performance results about identifiable, accountable entities to make judgments and decisions as a consequence of performance, such as reward, recognition, punishment, payment, or selection (e.g., public reporting, accreditation, licensure, professional certification, health information technology incentives, performance-based payment, network inclusion/exclusion).

**Ad Hoc Review** - An ad hoc review may be conducted on an endorsed measure, practice, or event at any time with adequate justification to substantiate the review. Requests for ad hoc reviews will be considered by NQF on a case-by-case basis and must be justified by specific criteria. NQF can initiate an ad hoc review without an external request when material changes are made to a measure or emerging evidence suggests the need for a review. The ad hoc review process follows a shortened version of the Consensus Development Process. If a measure remains endorsed after an ad hoc review, it is still subject to its original maintenance cycle.

**Administrative Claims** - Data derived from administering and/or reimbursing patient care.

**Adverse** - Describes a consequence of care that results in an undesired outcome. It does not address preventability.

**Agency for Healthcare Research and Quality (AHRQ)** – The lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of and effectiveness of health care for all Americans.

**Ambulatory Care** - Healthcare services that do not require a hospital admission. These may be provided in an ambulatory surgery center, clinician office, or clinic/ urgent care setting.

**Ambulatory Surgery Center (ASC)** - Setting where outpatient surgical services are provided.

**Annual Measure Maintenance Update** - On an annual basis, measure stewards are responsible for submitting information to NQF that affirms the detailed measure specifications of the endorsed measure have not changed or, if changes have been made, the details and underlying reason(s) for the change(s). A full review of the NQF evaluation criteria will occur only at the three-year review. The annual maintenance for measures is staggered throughout the year, and the process typically last one quarter (three months) to complete.

**Attribution** - Identifying and assigning of a responsible provider or entity (e.g., health plan) for the care delivered for an episode or population.

**Behavioral Health/Psychiatric** - Behavioral health/psychiatric services may include, but are not limited to, diagnostic, therapeutic, and preventive mental health services, therapy and/or rehabilitation for substance-dependent individuals, and the use of community resources, individual case work, or group

work to promote the adaptive capacities of individuals in relation to their social and economic environments.

**Benchmarking** - The process of comparing the performance of accountable entities with that of their peers or with external best practice results. In developing comparative estimates, results should be risk adjusted for patient-level attributes to support the valid comparisons of these accountable entities.

**Cancer** - Cancer may include, but is not limited to, bladder, breast, colorectal, gynecologic, hematologic, liver, lung, esophageal, pancreatic, prostate and skin.

**Cardiovascular** - Cardiovascular may include, but is not limited to, acute myocardial infarction, atrial fibrillation, congestive heart failure, hyperlipidemia, hypertension, ischemic heart disease, coronary artery disease, and percutaneous coronary intervention (PCI).

**Care Coordination** - Ensuring patients receive well-coordinated care within and across all healthcare organizations, settings, and levels of care. Examples may include, but are not limited to, measures that address care management across settings, care transitions, plan of care and follow up, and handoff communication.

**Care Setting** - Settings or services for which the measure applies and is assessed.

**Carve-outs** - The outsourcing of services, such as behavioral health or pharmacy claims, to specialty health plans or claims processing entities or organizations.

**Center for Medicare and Medicaid Services (CMS)** - The US federal agency which administers Medicare, Medicaid, and the State Children's Health Insurance Program

**Children's Health** - Individuals aged 17 years and younger.

**Classification** - In QPS, NQF-endorsed measures are classified into several categories by which the user can search (care setting, conditions, cross-cutting area, data source, level of analysis, measure type, purpose/use, target population).

**Clinical Hierarchy** - An arrangement of clinical conditions that are ranked according to severity, as "high," "below," or "at the same level." For example, if a patient has COPD and develops bronchitis, COPD would be assigned a greater weight than bronchitis.

**Clinical Practice Guidelines** - Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.

**Clinician** - Various types of healthcare practitioners/providers, which may include but is not limited to, physicians, nurses, and allied health professionals.

**Clinician Office** - Setting in which outpatient healthcare services are provided by physicians or other healthcare providers, including but not limited to, primary care, family practice, general internal medicine, and faculty practice plans.

**Clinic/Urgent Care** - Setting in which urgent care services are provided. Urgent care services are medically necessary services which are required for an illness or injury that would not result in further disability or death if not treated immediately, but require professional attention and have the potential to develop such a threat if treatment is delayed longer than 24 hours.

**Code Set** - The codes belonging to a specific value set. See Value set.

**Community** (as a population) - A group of individuals within a community.

**Competing Measures** - Measure that have the same concepts for the measure focus (target process, condition, event, outcome) AND the same target population being measured

**Complex Measure** - A measure that requires the use of a proprietary (non public domain) grouper, risk adjustment or other similar methodology that is essential to calculating the result of the measure.

**Complications** - Any harm (injury or illness) caused by medical care resulting in an undesirable clinical outcome. This includes measures that may address adverse events.

**Composite** - A combination of two or more individual measures into a single measure that result in a single score.

**Condition** - Health conditions or topics intended to be measured.

**Consensus** (as defined by Office of Management and Budget) - General agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.

**Consensus Development Process** - NQF's formal process to evaluate and endorse consensus standards, including performance measures, best practices, frameworks, and reporting guidelines. The Consensus Development Process is designed to call for input and carefully consider the interests of stakeholder groups from across the healthcare industry.

**Consensus Standard** - A quality performance measure or practice that has been endorsed by NQF.

**Consensus Standards Approval Committee (CSAC)** - The Consensus Standards Approval Committee (CSAC) considers all measures recommended for endorsement by NQF. Members of the Committee possess breadth and depth of expertise in healthcare quality improvement and performance measurement and are drawn from a diverse set of stakeholder perspectives. After their detailed review of a measure, the CSAC submits decisions regarding endorsement to the Board of Directors. The Board can affirm or deny CSAC's decisions.

**Cost of Care** - A measure of the total healthcare spending, including total resource use and unit price(s), by payor or consumer, for a healthcare service or group of healthcare services, associated with a specified patient population, time period, and unit(s) of clinical accountability.

**Cost/Resource Use** - Counting the frequency of units of defined health system services or resources; some may further apply a dollar amount (e.g., allowable charges, paid amounts, or standardized prices) to each unit of resource use (i.e., monetize the health service or resource use units).

**Cross-Cutting Area** - Measures that can be applied across conditions, settings, and/or the episode of care.

**Data Source** - Source(s) from which data are obtained for measurement.

**Data Element, Critical** - Quality performance measures are based on many individual items of information. The data elements are often patient-level information on individual patients (e.g., blood pressure, lab value, medication, surgical procedure, death). Testing at the data element level should include those elements that contribute most to the computed measure score, that is, account for identifying the greatest proportion of the target condition, event, or outcome being measured (numerator); the target population (denominator); population excluded (exclusions); and when applicable, risk factors with largest contribution to variability in outcome. Structural measures generally are based on organizational information rather than patient-level data.

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

**Data Types** - A grouping of information that indicates the circumstance of use for any individual standard data type (e.g. outcome, process, composite)

**Denominator Statement** - A brief text description of the target population being measured.

**Dialysis Center** - Setting in which dialysis services are furnished to patients.

**Disparities** - Differences in the quality of healthcare that are not due to access-related factors or clinical needs, preferences, or appropriateness of intervention. Examples may include, but are not limited to, measures that address variation in care related to race, ethnicity, socioeconomic status, sexual orientation, cognitive or physical disabilities, and age.

**Efficiency** (Measure Type) - The cost of care associated with a specified level of health outcomes.

**Efficiency of Care** – A measure of cost of care associated with a specified level of quality of care. “Efficiency of care” is a measure of the relationship of the cost of care associated with a specific level of performance measured with respect to the other five IOM aims of quality.

**Electronic Clinical Data** (Data Source) - Data derived from a repository of electronically maintained information about healthcare.

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

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

**Empirical Evidence** - Data or information resulting from studies and analyses of the data elements and/or scores for a measure as specified, unpublished or published.

**Emergency Medical Services/Ambulance** (Care Setting) - First responder care specifically designed, equipped, and staffed for lifesaving procedures and transporting the sick or injured.

**Endocrine** - Endocrine may include, but is not limited to, diabetes and thyroid disorders.

**Endorsement Date** - The date that the measure was endorsed.

**Endorsement Type** - There are three endorsement types: endorsed, time-limited endorsed, or endorsed with reserve status.

**ESRD** - End State Renal Disease

**Environmental Scan** - systematic collection of external information to identify new ideas or concepts such as measures or practices

**Episode of Care** - A series of temporally contiguous healthcare services related to the treatment of a given spell of illness or provided in response to a specific request by the patient or other relevant entity.

**Event** - A discrete, auditable, and clearly defined occurrence.

**Exclusions** - A brief text description of exclusions from the target population.

**Exclusion Criteria** - Criteria applied before a measure is tested in order to remove any individuals with conditions that may skew the final measure score.

**Facility** (Level of Analysis) - A single entity that provides healthcare, which may include but is not limited to, a hospital, nursing home, dialysis center, and home health agency.

**Functional Status** (Cross-Cutting Area) - The level of activities performed by an individual to meet needs of daily living in many aspects of life including physical, psychological, social, spiritual, intellectual, and roles. Examples may include, but are not limited to, measures that address a patient's ability to perform activities of daily living (e.g. bathing, toileting, dressing, eating) or instrumental activities of daily living (e.g., medication management, shopping, food preparation).

**Functional Status** - A patient's ability to perform activities of daily living (e.g., bathing, toileting, dressing, eating) or instrumental activities of daily living (e.g., medication management, shopping, food preparation) due to musculoskeletal conditions.

**GI** - Gastrointestinal (GI) may include, but is not limited to, cirrhosis, gallbladder disease, GI bleeding, gastroenteritis, gastro-esophageal reflux disease (GERD)/peptic ulcer, and polyps.

**Group/Practice** - Two or more healthcare clinicians/providers who practice together, either at a single geographic location or at multiple locations.

**GU/GYN** - Genitourinary (GU)/Gynecologic (GYN) may include, but is not limited to, male and female reproduction and incontinence.

**Harmonization** - The standardization of specifications for related measures with the same measure focus (e.g., influenza immunization of patients in hospitals or nursing homes); related measures with the same target population (e.g., eye exam and HbA1c for patients with diabetes); or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless

differences are justified (e.g., dictated by the evidence). The dimensions of harmonization can include numerator, denominator, exclusions, calculation, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

**Health IT (Infrastructure Supports)** - The presence and use of HIT (a global term that encompasses electronic health records and personal health records and indicates the use of computers, software programs, electronic devices, and the internet to store, retrieve, update, and transmit information about patients' health) to support comprehensive management of medical information and its secure exchange between healthcare consumers and providers to facilitate quality improvement and care coordination.

**Health IT Advisory Committee (HITAC)** - The Health IT Advisory Committee (HITAC) provides ongoing guidance to NQF's HIT portfolio and offers specific expertise on HIT projects, including specification of testing requirements for eMeasures and maintenance of the quality data set. HITAC is a standing committee of the Board of Directors and was created in December 2009.

**Health Information Technology Expert Panel (HITEP)** - An Agency for Healthcare Research and Quality-funded panel convened by NQF.

**Health Information Technology Standards Panel (HITSP)** - A cooperative partnership between the public and private sectors, formed in 2005 for the purposes of harmonizing and integrating standards that will meet clinical and business needs for sharing information among organizations and systems.

**Healthcare Associated Infections** - Infections that patients acquire during the course of receiving treatment for other conditions.

**Healthcare Provider Survey (Data Source)** - Data derived from surveys (computerized, pencil-and-paper, verbal, etc.) of healthcare clinicians/providers.

**Healthcare Setting** - Any facility or office, including a discrete unit of care within such facility, that is organized, maintained, and operated for the diagnosis, prevention, treatment, rehabilitation, convalescence or other care of human illness or injury, physical or mental, including care during and after pregnancy. Healthcare settings include, but are not limited to, hospitals, nursing homes, rehabilitation centers, medical centers, office-based practices, outpatient dialysis centers, reproductive health centers, independent clinical laboratories, hospices, ambulatory surgical centers, and pharmacies. The boundary of a healthcare setting (the "grounds") is the physical area immediately adjacent to the setting's main buildings. It does not include nonmedical businesses such as shops and restaurants located close to the setting.

**Health Plan** - An organization that acts as an insurer for an enrolled population.

**HEENT** - Head, Eyes, Ears, Nose, and Throat (HEENT) may include, but is not limited to, dental, ear infection, hearing, pharyngitis, and vision.

**HL7 (Health Level 7)** - A standards-developing organization that provides standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services.

**High Quality Data** - HITEP criteria for high quality data includes a) data are captured from an authoritative/accurate source; 2) data are coded using recognized data standards; c) method of capturing data electronically fits the workflow of the authoritative source; d) data are available in EHRs; and e) data are auditable.

**Home Health (Care Setting)** - Limited part-time or intermittent skilled nursing care and home health aide services, physical therapy, occupational therapy, speech-language therapy, medical social services, durable medical equipment (such as wheelchairs, hospital beds, oxygen, and walkers), medical supplies, and other services that are provided to a patient in his/her home or place of residence.

**Hospice (Care Setting)** - Palliative services provided to terminally ill patients and their families/caregivers in the patient's place of residence or in an inpatient facility.

**Hospital/Acute Care Facility (Care Setting)** - Setting in which healthcare services, including but not limited to, diagnostic, therapeutic, medical, surgical, obstetric, and nursing are provided, by or under the supervision of physicians, to patients admitted for a variety of health conditions.

**HVBP - Hospital Value-Based Purchasing** - A program implemented by CMS to update payment policies and payment rates for hospitals beginning in October 2012.

**Imaging/Diagnostic Study (Data)** - Data derived from an imaging/diagnostic study.

**Imaging Facility (Care Setting)** - Setting with the equipment to produce various types of radiologic and electromagnetic images and the necessary healthcare staff to interpret the images obtained.

**Infectious Diseases** - Infectious diseases may include, but are not limited to, hepatitis, respiratory infections, tuberculosis, and sexually transmitted infections.

**Informed Consent** - A process of shared decision-making in which discussion between a person who would receive a treatment, including surgery or invasive procedure, and the caregiver/professional person who explains the treatment, provides information about possible benefits, risks and alternatives, and answers questions that result in the person's authorization or agreement to undergo a specific medical intervention. Documentation of this discussion should result in an accurate and meaningful entry in the patient record, which could include a signed "consent form." Signing a consent form does not constitute informed consent; it provides a record of the discussion.

**Infrastructure Supports** - Community and system capacity, health information technology, and workforce development. Examples may include, but are not limited to, measures that address the physical buildings of hospitals, clinics, and office components; the informational capabilities comprising paper records, electronic data, voice, and visuals; and the participating physicians, nurses, and support staff.

**Inpatient** - A patient admitted to a hospital or other facility

**IRF** - Inpatient Rehabilitation Facility

**Integrated Delivery System** - A healthcare entity that may include a variety of facilities and/or services including, but not limited to, hospitals, medical groups, skilled nursing facilities, home health, and/or insurance vehicles. This includes delivery systems that assume responsibility across settings for the complete patient-focused episode of care, such as accountable care organizations.

**Laboratory (Care Setting)** - Setting certified to test or evaluate specimens for clinical and/or diagnostic results.

**Laboratory (Data)** - Data derived from a laboratory.

**Last Updated Date** - The date that the measure was last reviewed and updated.

**Level of Analysis** - Level(s) at which measurement is assessed.

**LTCH** - Long-Term Care Hospital

**Management Data** - Data derived within an organization's management systems such as facility census, staffing ratios or payroll.

**Maternal Care** - Women during preconception, pregnancy, childbirth and/or the postpartum period.

**Measure** - A standard: a basis for comparison; a reference point against which other things can be evaluated; "they set the measure for all subsequent work." v. To bring into comparison against a standard.

**MAP (Measure Application Partnership)** - The Measure Applications Partnership (MAP), convened by NQF in 2011, is a public-private partnership created to provide input to the Department of Health and Human Services (HHS) on the selection of performance measures for public reporting and performance-based payment programs. In convening MAP, NQF brings together stakeholder groups in a unique collaboration that balances the interests of consumers, businesses and purchasers, labor, health plans, clinicians and providers, communities and states, and suppliers.

**MU (Meaningful Use)** - The American Recovery and Reinvestment Act authorizes the Centers for Medicare & Medicaid Services (CMS) to provide a reimbursement incentive for physician and hospital providers who are successful in becoming "meaningful users" of an electronic health record (EHR). These incentive payments begin in 2011 and gradually phase down. Starting in 2015, providers are expected to have adopted and be actively utilizing an EHR in compliance with the "meaningful use" definition, or they will be subject to financial penalties under Medicare.

**Measure Description** - A brief text description of the measure that includes the type of score, measure focus, target population, or time.

**Measure, EHR** - An EHR measure is a healthcare quality measure specified for use with electronic health records; it is composed of data elements from the quality data set (see below), including code lists and measure logic, and can be translated to computer-readable specifications.

**Measure, Quality** (also quality performance measure) - Numeric quantification of healthcare quality for a designated healthcare provider, such as hospital, health plan, nursing home, clinician, etc.

**Measure Endorsement Maintenance** - Every three years, endorsed measures in a topical area, as well as newly submitted measures, will undergo the nine-step consensus development process, including review against updated NQF evaluation criteria. In addition to ensuring currency of specifications, endorsement maintenance provides the opportunity to harmonize specifications and to ensure that an endorsed measure represents the "best in class."



**Measure Evaluation Criteria** - Candidate measures are evaluated for their suitability based on four sets of standardized criteria in the following order: 1) importance to measure and report, 2) scientific acceptability of measure properties, 3) usability, and 4) feasibility.

**Measure Score** - The numeric result that is computed by applying the measure specifications and scoring algorithm. The computed measure score represents an aggregation of all the appropriate patient-level data (e.g., proportion of patients who died, average lab value attained) for the entity being measured (e.g., hospital, health plan, home health agency, clinician, etc.). The measure specifications designate the entity that is being measured and to whom the measure score applies.

**Measure Specifications** - Include the target population to who the measure applies, identification of those from the target population who have achieved the specific measure focus, measurement time window, exclusions, risk adjustment, definitions, data elements, data source and instructions, sampling scoring/computation.

**Measure Steward** - An individual or organization who is the intellectual property (IP) owner of a measure and is responsible for maintaining the measure.

**Measure Testing** - 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.

**Measure Type** - A domain of measurement such as process, outcome or patient experience with care.

**Measure Under Review** - There are four different types of review a measure could be under-going: ad hoc review, annual update review, time-limited review or endorsement maintenance.

**Medical Device** - An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which is recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

**Medication Error** - Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

**Medication Safety** - Any process or event surrounding medication use that may cause or lead to patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Examples may include, but are not limited to, measures that address prescribing, order communication, product labeling, and medication administration.

**Mental Health** - Mental health may include, but is not limited to, depression, serious mental illness, suicide, substance (alcohol and other drugs) use/abuse, and domestic violence.

**Misclassification** - An invalid reporting of performance

**Musculoskeletal** - Musculoskeletal may include, but is not limited to, osteoarthritis, rheumatoid arthritis, hip/pelvic fracture, joint surgery, low back pain, osteoporosis, and functional status related to musculoskeletal conditions.

**National** (e.g., Level of Analysis: Population) - A group of individuals within a single national entity (e.g., United States).

**National Priorities Partnership (NPP)** - The National Priorities Partnership (NPP), convened by NQF in 2008, is a collaborative effort of 51 major national organizations that collectively influence every part of the healthcare system. By focusing on high-leverage Priorities and Goals and taking collective action to reach them, the Partners aim to transform healthcare from the inside out—where it has the best chance to succeed.

**National Quality Strategy (NQS)** – The health reform law the law requires the Secretary of the Department of Health and Human Services (HHS) to establish a National Strategy for Quality Improvement in Health Care (the [National Quality Strategy](#)) that sets priorities to guide this effort and includes a strategic plan for how to achieve it.

**Neurology** - Neurology may include, but is not limited to, dementia, delirium, stroke and transient ischemic attack (TIA).

**NQF Endorsement** - NQF endorsement, which involves a rigorous, evidence-based review and a formal Consensus Development Process, has become the "gold standard" for healthcare performance measures.

**NQF Number** - A unique number is assigned to a measure once it is submitted to NQF.

**Numerator Statement** - A brief text description of what is being measured within the target population.

**Nursing Home/Skilled Nursing Facility** - Setting in which healthcare services are provided under medical supervision and continuous nursing care for patients who do not require the degree of care and treatment which a hospital provides and who, because of their physical or mental condition, require continuous nursing care and services above the level of room and board.

**Outcome** (Measure Type) - The health state of a patient (or change in health status) resulting from healthcare— desirable or adverse.

**Overuse** (Cross-Cutting Area) - Where the “the potential for harm exceeds the possible benefits of care”. Examples may include, but are not limited to, measures that address inappropriate and excessive care (tests, drugs, procedures and visits), preventable emergency department visits and hospitalizations, and harmful preventive services with no benefit.

**Paired Measures** - Two or more individual measures that are endorsed for use together as a unit of measures but results in individual scores.

**Palliative Care and End-of-Life Care** - Appropriate and compassionate care for patients with serious, advanced illnesses. Examples may include, but are not limited to, measures that address the evaluation and effective management of physical symptoms (e.g., pain, shortness of breath, nausea) and

psychological, social, and spiritual needs; effective communication, and access to palliative and hospice care services.

**Paper Records** (Data Source) - Data derived from manual abstraction from a medical record.

**Patient and Family Engagement** (Cross-Cutting Area) - Engaging patients and families in managing and evaluating their health and healthcare, and in making decisions about their care. Examples may include, but are not limited to, measures that address if patients are asked for feedback on their experience with care, have access to tools and support systems enabling them to navigate and manage their care, and have access to information, and assistance that enables them to make informed decisions.

**Patient Engagement/Experience** (Measure Type) - The use of feedback from patients and their families/caregivers about their experience and/or engagement in decision making around care (e.g., CAHPS, other patient surveys).

**Patient Reported Data/Survey** (Data Source) - Data derived from surveys (computerized, pencil-and-paper, verbal, etc.) of patients and/or caregivers.

**Payment Program** - Intended for use in payment programs (e.g. P4P, shared savings programs, etc.)

**Peer Groups** - The ways in which [resource use] measures ensure providers and health plans are compared to similar providers and health plans.

**Per Capita Measure** - Counts all services provided to a person within a specific population, regardless of condition or encounters with system.

**Per Episode Measure** - Counts resources based on bundles of services that are part of a distinctive event provided by one or multiple entities (e.g., health services provided associated with an event or series of events for acute myocardial infarction).

**Perinatal** - May include, but is not limited to, conditions affecting women and/or fetuses/newborns during pregnancy, childbirth, newborn and post-partum periods as well as during the pre-pregnancy period.

**Pharmacy** (Care Setting) - Setting where medications and other medically related items and services are sold, dispensed or otherwise provided directly to patients.

**Pharmacy** (Data) - Data derived from a pharmacy.

**PQRS (Physician Quality Reporting System)** - A voluntary reporting program implemented by CMS. The program provides an incentive payment to practices with eligible professionals (identified on claims by their individual National Provider Identifier [NPI] and Tax Identification Number [TIN]) who satisfactorily report data on quality measures for covered Physician Fee Schedule (PFS) services furnished to Medicare Part B Fee-for-Service (FFS) beneficiaries

**Population** (Level of Analysis) - A group of individuals defined by geography.

**Population Health** - Improving the health of the population through the delivery of effective preventive services, the promotion of healthy lifestyle behaviors, the use of community indices of health, and the assessment of environmental factors. Examples may include, but are not limited to, measures that

address whether communities foster health and wellness as well as reflect national, state, and local systems of care that are reliable and effective in the prevention of disease, injury, and disability.

**Post-Acute/Long-Term Care Facility** - A variety of services that help people with health or personal needs and activities of daily living over a period of time. Long-term care can be provided in the community or in various types of facilities, including but not limited to nursing homes, skilled nursing facilities, rehabilitation facilities, and assisted living facilities.

**Prevention** - Prevention may include, but is not limited to, wellness, child development, immunization, malnutrition, obesity, physical activity, tobacco use and health screening.

**Process** (measure type) - A healthcare service provided to, or on behalf of, a patient. This may include, but is not limited to, measures that may address adherence to recommendations for clinical practice based on evidence or consensus.

**Professional Certification or Recognition Program** - Intended for use in professional certification or recognition programs.

**Public Reporting** - Making comparative performance results about identifiable, accountable entities freely available (or at nominal cost) to the public at large (generally on a public website).

**Public Health/Disease Surveillance** - Intended for public health and disease surveillance.

**Pulmonary/Critical Care** - Pulmonary/critical care may include, but is not limited to, asthma, chronic obstructive pulmonary disease (COPD), dyspnea, and pneumonia.

**Purpose/Use** - The purpose(s)/use(s) for which the measure is intended.

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

**Quality Improvement** (internal to the specific organization) - Intended for quality improvement with internal benchmarking.

**Quality Improvement with Benchmarking** (external benchmarking to multiple organizations) - Intended for quality improvement with external benchmarking.

**Quality of Care** - A measure of performance on the six Institute of Medicine (IOM) specified healthcare aims: safety, timeliness, effectiveness, efficiency, equity, and patient-centeredness.

**Quality Positioning System (QPS)** - The Quality Positioning System (QPS) is a web-based tool to help people more easily select and use NQF-endorsed® measures. You and others will be able to create your own lists of NQF-endorsed measures in customized portfolios to fit your specific interests or needs, share your portfolios with others, and view and copy portfolios that others have generated.

**Random Error** - Errors that are not systematic and create “noise” in the measure results.

**Rationale** - Succinct statement of the need for the measure. Usually includes statements pertaining to Importance criterion: impact, gap in care and evidence.

**Regional** - A group of individuals within a geographical area that exists within or across one or more states (e.g., Northeast, QIO).

**Registry (data)** - Data derived from a registry.

**Regulatory and Accreditation Programs** - Intended for use in regulatory and accreditation programs.

**Rehabilitation** - Setting in which long-term, comprehensive rehabilitation services are provided to patients for the alleviation or amelioration of the disabling effects of illness. These services are provided by various health professionals including, but not limited to, nurses and physical, occupational, and speech therapists.

**Related Measures** - Measures that have either 1) the same target population being measured but a different concept for the measure focus (process, condition, event, outcome) OR the same concept for the measure focus (process, condition, event, outcome) and a different target population being measured

**Reliability** - The repeatability or precision of measurement. Reliability of data elements refers to repeatability and reproducibility of the data elements for the same population in the same time period. Reliability of the measure score refers to the proportion of variation in the performance scores due to systematic differences across the measured entities (signal) in relation to random variation or noise.

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

**Reliability, Threats** - Some aspects of the measure specifications or the specific topic of measurement can affect reliability. Ambiguous measure specifications can result in unreliable measures. Small case volume or sample size, or rare events can affect the precision (reliability) of the measure score. **Renal** - Renal may include, but is not limited to, chronic kidney disease (CKD) and end stage renal disease (ESRD).

**Reserve Status** - Highly credible, reliable, and valid measures that have high levels of performance due to quality improvement actions. The purpose of reserve status is to retain endorsement of reliable and valid quality performance measures that have overall high levels of performance with little variability so that performance could be monitored in the future if necessary to ensure that performance does not decline.

**Resource Use Measures** - Comparable measures of actual dollars or standardized units of resources applied to the care given to a specific population or event—such as a specific diagnosis, procedure, or type of medical encounter.

**Resource Use Service Categories** - Categories of resource units or services provided care for a patient or population. Resource units are generally identified through claims data and grouped into categories

with similar types of claims (e.g., x-rays grouped into imaging category). Categories are generally are and measured in terms of dollars, but also can also include resources not captured on a claim (e.g., nursing hours).

**Risk Adjustment** - The method of adjusting for clinical severity and conditions present at the start of care that can influence patient outcomes for making valid comparisons of outcome measures across providers. A corrective approach designed to reduce any negative or positive consequences associated with caring for patients of higher or lower health risk or propensity to require health services.

**Risk Factors** - Patient-related attributes or characteristics that contribute to outcomes

**Risk Model** - A statistical tool to account for patient risk factors to compare outcomes. Use of a risk model generates the expected outcome under typical care, given the patient's health status and risk factors. Patient-level outcome risk is assessed using some type of multiple variable regression model (e.g., standard logistic regression models, Bayesian models, hierarchical linear models, etc.).

**Safety** - The reduction and mitigation of unsafe acts within the healthcare system. Examples may include, but are not limited to, measures that address reduction in healthcare-associated infections, serious adverse events, readmissions, and mortality rates.

**Selection** - Use of performance results to make or affirm choices regarding providers of healthcare or health plans (e.g., an individual choosing a surgeon; an employer choosing a health plan to offer; a health plan choosing specialists to empanel; a family doctor choosing an oncologist to refer a cancer patient; an employee or Medicaid enrollee choosing a health plan during open enrollment).

**Serious Reportable Events (SRE)** - Events endorsed by NQF that are unambiguous, largely preventable, and serious, as well as adverse, indicative of a problem in a healthcare setting's safety systems, or important for public credibility or public accountability.

**Severity Levels** - Pre-determined levels of acuity used to rank and assign patients based on an assessment of the aggregate of their conditions/diagnosis codes.

**Standardized Pricing** - Pre-established uniform price for a service, typically based on historical price, replacement cost, or an analysis of completion in the market; removes variation in resource costs due to differences in negotiated prices or geographic differences based on labor or other input costs.

**Stratification** - Division of a population or resource services into distinct, independent strata, or groups of similar data, enabling analysis of the specific subgroups. This type of adjustment can be used to show where disparities exist or where there is a need to expose differences in results.

**Structure** (as a measure type) - Features of a healthcare organization or clinician relevant to the capacity to provide healthcare. This may include, but is not limited to, measures that address health IT infrastructure, provider capacity, systems, and other healthcare infrastructure supports.

**Structured Rules** - Widely accepted clinical recommendations expressed as coded logic statements made freely available via the Internet, developed by the AHRQ funded Structuring Care Recommendations for CDS project. These statements, or eRecommendations, will be structured in a standard fashion and use standard codes to identify patients for whom the recommendation applies and the actions that should be taken. Such logic statements can then be further adapted by clinical

information system suppliers and care providers to generate automated reminders for specific clinicians and/or patients within deployed systems.

**Surgery** - Surgery may include, but is not limited to, general surgery, perioperative, thoracic, cardiac and vascular.

**System Capacity** - The physical capacity, workflow and throughput of facilities. Examples may include, but are not limited to, measures that address the presence or number of certain types of rooms or beds at a facility and the length of time between arrival and departure from the emergency department.

**Target Population** - The population intended to be measured.

**Taxonomy** - Generally, a model with hierarchy and classification assembled with a descriptive purpose.

**Team** - Two or more healthcare clinicians/providers, at one location or across different settings, who collaborate together for the care of a single patient or multiple patients.

**Time-Limited Endorsement** - A measure that has not been tested for reliability and validity is only potentially eligible for time-limited endorsement if all of the following conditions are met: 1) the measure topic is not addressed by an endorsed measure; 2) it is relevant to a critical timeline (e.g., legislative mandate) for implementing endorsed measures; 3) the measure is not complex (requiring risk adjustment or a composite); and 4) the measure steward verifies that testing will be completed within 12 months of endorsement. Please refer to the "Measure Evaluation Criteria" on the NQF website for more information.

**Transparency** - Extent to which performance results about identifiable, accountable entities are disclosed and available outside of the organizations or practices whose performance is measured. The degrees of transparency are described in Table 2 and range from making performance results available only to a few selected staff within an organization to reporting the results to the public at large. The capability to verify the performance results adds significantly to measure transparency.

**Validation** - Process (testing) to determine if a measure has the property of validity. The term validation is often used in reference to the data elements and is another term for validity testing of data elements. Validation also is used in reference to statistical risk models where model performance metrics are compared between two different samples of data called the development and validation samples.

**Validity** - Validity refers to the correctness of measurement. Validity of data elements refers to the correctness of the data elements as compared to an authoritative source. Validity of the measure score refers to the correctness of conclusions about quality that can be made based on the measure scores (i.e., a higher score on a quality measure reflects higher quality).

**Validity Testing** - Empirical analysis of the measure as specified that demonstrates that data are correct and/or conclusions about quality of care based on the computed measure score are correct. Validity testing focuses on systematic errors and bias. It involves testing agreement between the data elements obtained when implementing the measure as specified and data from another source of known accuracy. Validity of computed measure scores involves testing hypotheses of relationships between the computed measure scores as specified and other known measures of quality or conceptually related aspects of quality. A variety of approaches can provide some evidence for validity. The specific terms and definitions used for validity may vary by discipline, including face, content, construct, criterion, concurrent, predictive, convergent, or discriminant validity. Therefore, the proposed conceptual

relationship and test should be described. The hypotheses and statistical analyses often are based on various correlations between measures or differences between groups known to vary in quality.

**Validity, Threats** - In addition to unreliability, some aspects of measure specifications and data can affect the validity of conclusions about quality. Potential threats include patients excluded from measurement; differences in patient mix for outcome and resource use measures; measure scores generated with multiple data sources/methods; and systematic missing or “incorrect” data (unintentional or intentional).

**Value of Care** - A measure of a specified stakeholder’s (such as an individual patient’s, consumer organization’s, payor’s, provider’s, government’s, or society’s) preference-weighted assessment of a particular combination of quality and cost of care performance.

**Value Set** - A set or collection of concepts from one or more vocabulary code systems and grouped together for a specific purpose. A value set is a uniquely identifiable set of valid concept representations. A value set may be a simple flat list of concept codes drawn from a single code system, or it might be constituted by expressions drawn from multiple code systems (a code system is a system consisting of designations and meanings, for example LOINC, SNOMED-CT, ICD-10, or ISO 639 Language Codes).

**Venous Thromboembolism** - The prophylaxis of two related conditions: deep vein thrombosis (DVT) and pulmonary embolism (PE).

**Workforce** - All disciplines of healthcare professionals as well as others working in healthcare facilities. Examples may include, but are not limited to, measures that address the composition and characteristics of the workforce, staffing and skill mix, accreditation/certification, and workforce satisfaction surveys.