TO: Consensus Standards Approval Committee

FR: Consensus Task Force

RE: Consensus Task Force Recommendations

DA: March 15, 2013

ACTION REQUIRED

Review attached draft report and approve the following:

- Preliminary recommendations report for a redesigned consensus development process to be shared with the Board of Directors and the NQF Members and Public.

BACKGROUND

The Consensus Task Force met in November 2012 and reviewed input from the focus groups and approaches of other standard-setting bodies as part of their effort to review approaches to establishing consensus and to identify the strengths and weaknesses of the current process. They made recommendations for process enhancements for NQF staff to roll out in the short term, as well as recommendations for NQF staff to hold a Lean Event to model potential processes for developing consensus to be presented to the Task Force at a meeting in February 2013. Using features of the various models presented by staff, the Task Force made a recommendation for a new process for consensus development, which will be outlined in this report.

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Background

Since the first version of the CDP approved in July 2000, NQF has refined the CDP to address the needs of NQF members and more broadly the needs of the healthcare industry. These refinements include: different types of endorsement, such as time-limited endorsement; efforts to maintain a current NQF-endorsed measures portfolio; and increased efficiency of the CDP (i.e. reducing voting from 30-days to 15-days).

These changes were themselves part of a broader process of continuous improvement in the structure and governance of NQF to reflect what we learned as the organization grew and to respond to concerns and requests of NQF members and more broadly of NQF's multi-stakeholder constituencies – hospitals, physicians and other clinicians, consumers, purchasers, health plans, public health organizations and agencies, suppliers and health industry companies, and quality improvement organizations.

The 2012 hospital-wide readmissions project raised questions about NQF's consensus process for making endorsement decisions. As a result, the Board approved a task force that would review and recommend enhancements for defining and achieving consensus within NQF's consensus development process (CDP). The Consensus Task Force (the "Task Force") was not constrained within the current consensus development process; the Task Force explored the meaning of consensus and different approaches for achieving it.

Composition and Charge

The NQF Board Executive Committee created a Task Force including members of the Board of Directors, Consensus Standards Approval Committee (CSAC), and individuals from the NQF membership (Appendix A).

Two non-voting, ex-officio members participated in the task force, including the CSAC chair as well as a representative of a standard-setting organization.

The charge to the Consensus Task Force was to:

1) Review different approaches to establishing consensus;
2) Identify the strengths and weaknesses of the current process; and
3) Recommend enhancements to the current process.

The Task Force sought input from NQF members regarding the current process through a variety of avenues including focus groups, asking for input on defining consensus and suggestions for improvement. The Task Force also reviewed approaches used by other standard-setting bodies in establishing consensus.

The Task Force met in November 2012 and reviewed input from the focus groups and approaches of other standard-setting bodies as part of their effort to review approaches to establishing consensus and to identify the strengths and weaknesses of the current process. They made recommendations for process enhancements for NQF staff to roll out in the short term (Appendix B), as well as recommendations for NQF staff to hold a Lean Event to model potential processes for developing consensus to be presented to the Task Force at a meeting in February 2013. Using features of the

various models presented by staff, the Task Force made a recommendation for a new process for consensus development, which will be outlined in this report.

Input from Focus Groups

NQF contracted with an external consultant to conduct focus groups with members to better understand the member perception of NQF's process to achieve consensus and their view of how stakeholder interests are balanced throughout the current CDP. In October 2012, four in-person focus groups and one virtual session were conducted in Washington, DC and Chicago. An additional virtual session was conducted in December 2012 to get input from a group of stakeholders whose membership was spread out across the United States, making it difficult to have an in-person focus group session. The focus groups included those organizations that typically participate in the CDP as well as those organizations that do not regularly participate in voting or other CDP activities such as commenting or nominating for Steering Committees.

Two in-person focus group sessions were held in Washington, DC, and targeted the Provider, Purchaser, and Consumer councils. Two in-person focus group sessions were held in Chicago, IL, and targeted the Quality Measurement, Research and Improvement and Health Professional councils. One virtual session included the Health Plan, Public and Community Health Agencies, and the Supplier and Industry councils; another virtual session included the Consumer and Purchaser councils. The organizations that participated in the focus groups appear in Appendix C.

The scope of the questions being asked of the focus groups was limited to NQF's process to achieve consensus through the CDP. The methodology for gaining these inputs focused on ensuring a diversity of responses, gaining insight from a representative group of stakeholders, getting an informative critique of the CDP as it stands, and receiving input on ideas for potential enhancements to the process.

The questions were divided into two sections: Achieving Consensus and Balance of Interests. The questions on Achieving Consensus focused on how to determine what stakeholders felt met the threshold for consensus throughout the CDP; the Balance of Interest questions focused on how the CDP met and represented the needs of the individual stakeholder, the NQF councils, the Steering Committees, the CSAC, the Board, and other vested stakeholders.

The input from the focus groups centered on three themes:

- Process Transparency and Consistency
- Member Engagement
- Balance of Interests

Regarding process transparency and consistency, members stated that achieving consensus should feel like consensus to the membership; the members need the opportunity to provide input, hear opinions from other stakeholders, and robustly discuss areas of disagreement. Members commented that it is important that when a measure either is or is not endorsed, that all stakeholders can understand why the decision was made even if they don't agree with it. Further, the members stated that the role of NQF should be to provide an opportunity for further deliberation between stakeholders who may disagree on whether a measure is suitable for endorsement.

With respect to member engagement, members stated that there was a need for a vigorous member engagement strategy from NQF. Members wanted to be notified of projects that they were interested in and educated on how to engage in NQF processes. Additionally, members commented that it was important that NQF switch from pushing information and relying on members to actively engage and instead move to a model where NQF provided members with information and encouraged participation in a focused way based on the member interests.

On the topic of balance of interests, members commented that the current process seems lopsided, as Steering Committees are not representative of the membership and provide a different perspective on measures early in the process than the membership may. Additionally, the input from the governing bodies (CSAC and Board) is provided much later in the process and also varies from the input of the Steering Committee and the membership. Steering Committees are largely seated by clinicians and health care providers and provide the initial endorsement recommendation; however, the CSAC and Board are constituted of a simple majority of consumers and purchasers and provide the final endorsement recommendation. The end result is that Steering Committees evaluate measures differently than the membership, and the CSAC and Board, with the opportunity for measures to make it through the entire CDP process only to be struck down by the CSAC or Board.

Input from Standard Setting Organizations

NQF staff collected information from other consensus-based standard setting organizations, exploring processes used by other organizations, particularly American National Standards Institute (ANSI) as most of the standard setting bodies in the United States are ANSI-accredited. As of October 2012, there are 228 ANSI-accredited standards organizations[1], all of which meet the guidelines for achieving consensus outlined in a document sent previously (NQF Consensus v ANSI Consensus.pdf). The majority of the ANSI-accredited organizations reviewed by NQF staff had flexible timelines for approving a standard, allowing for increased time for public input and a more iterative process for modifying standards than NQF's current process.

Other notable process points that vary from the NQF process include:

- Consensus is defined as "substantial agreement has been reached by directly and materially affected interests. This signifies the concurrence of more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, **and that an effort be made toward their resolution."** [2] NQF currently requires a simple majority.
- Voting must meet numerical requirements for consensus as described in a standard developer's accredited procedures. An example of the criteria for consensus includes a requirement that a majority of the consensus body cast a vote (counting abstentions) and at least two-thirds of those voting approve (not counting abstentions). [3] NQF currently has no requirements on what

[1] http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/ANSI%20Accredited%20Standards%20Developers/OCT12ASD_basic.pdf

[2] http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/2012%20ANSI%20Essential%20Requirements%20and%20other%20Updated%20Procedures/2012_ANSI_Essential_Requirements.pdf

[3] *IBID*

percentage of votes from eligible members are required, and requires that a simple majority of those voting approve (abstentions are omitted from the voting percentage calculation entirely).
- ANSI guidance places an emphasis on staff training, maintaining a basic training guide for new staff and for volunteers on committees.
- ANSI has several checks and balances in place, including:
    - An audit program to ensure procedures are consistent and a checklist which is submitted to demonstrate that process has been followed;
    - An annual review cycle to ensure compliance with processes and to provide any updates to the processes; and
    - Shared learning/recommendations for efficient standards development are provided to all standard development organizations, emphasizing consistency in process and in implementation of process.[4]

Input from the Two-Stage Pilot Project

The Task Force was also provided preliminary results on the evaluation of the proposed two-stage process, taken from an analysis of the Stage 1 Measure Concept pilot, the Gastrointestinal /Genitourinary project. Staff recommended that the Task Force review the analysis in conjunction with making recommendations on a model for developing consensus, as many lessons were learned in the development and piloting of the process.

The two-stage pilot was designed in response to a formal request from the American Medical Association (AMA), 38 medical specialty societies, and the Centers for Medicare and Medicaid Services (CMS) asking that NQF consider revising the current CDP so as to incorporate a staged process for measure evaluation that would allow for earlier review of measure topics and later review of measure specifications and testing results. An underlying motivation behind this request was that measures often do not make it past the Importance criterion. However, because measure developers are currently required to submit fully specified and tested measures for evaluation, developers may make costly investments of time and other resources to specify and test a measure that may not achieve NQF endorsement.

Because NQF strives to continually improve its own systems, policies, and processes, NQF staff explored a potential re-design of the CDP that would meet the following two objectives:
- Provision of a determination of whether a "measure concept" satisfies the Importance criterion prior to full development and testing of a measure; and
- Provision of more timely and flexible review of fully specified and tested measures.

The process allowed for "measure concept" review during Stage 1, and review of fully specified and tested measures in Stage 2 (Appendix D).

Several recommendations emerged from the analysis of the CDP re-design, which the Task Force was asked to consider when proposing a model for developing consensus. Those are:

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4 http://publicaa.ansi.org/sites/apdl/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/Recommendations%20for%20Efficient%20Standards%20Development%20FINAL.pdf

- **CDP improvement rather than CDP re-design**. The Stage 1 pilot has thus far revealed several limitations in the proposed 2-Stage re-design. Most of the design components in Stage 1 that were successful can be incorporated into the existing CDP. These include the following:
    - Earlier opportunity for multi-stakeholder input prior to evaluation of measures by the Steering Committee
    - Use of the Steering Committee and Developer Guidebooks
    - Continued improvement of the measure submission form, incorporating many of the ideas from the Evidence Attachment
    - More consistent and earlier—but still informal—upfront technical review, using tools and lessons learned from the formalized processes implemented in the pilot
- **Allow for concept review.**
    - Look for ways to allow for concept review at any point in time—both within and outside of scheduled CDPs
    - Do not insist that concept reviews be conducted as part of a formal process
    - Do not require approval for concepts or passing of criteria
    - Do not require concepts reviews for fully-specified and tested measures
    - Provide technical assistance and recommendations as part of concept review
- **Continue to look for ways to allow for more timely and flexible review of fully specified and tested measures.**
- **Continue to explore implementation of standing Steering Committees.**
- **Continue to elicit feedback from all stakeholders regarding the CDP process.**

Outline of the Current Consensus Development Process

As a consensus-based organization, NQF has modeled the CDP to satisfy the requirements of OMB Circular A-119, which establishes policies regarding Federal use and development of voluntary consensus standards, consistent with the National Technology Transfer and Advancement Act of 1995. OMB Circular A-119 defines a consensus-based organization as having the following attributes:

- Openness
- Balance of interest
- Due process
- Appeals process
- Consensus

OMB Circular A-119 defines consensus as "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."[5]

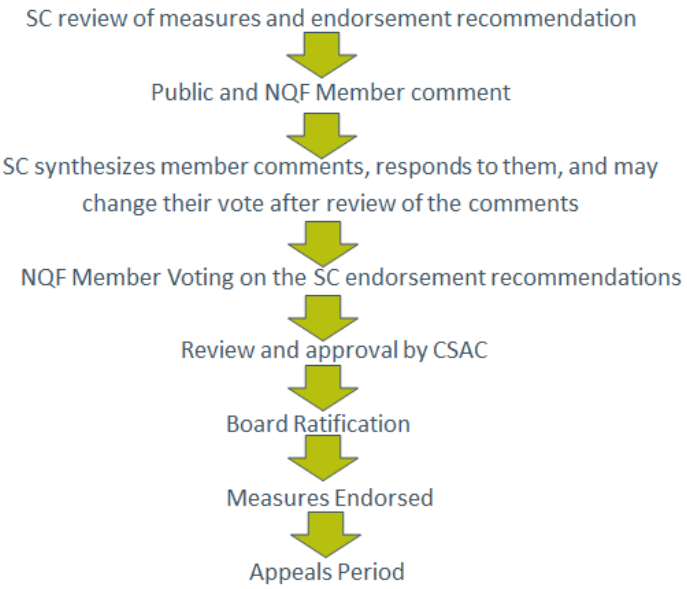
NQF currently satisfies the required attributes of a voluntary consensus standards body through an eight-step process that applies to all NQF CDP projects:

1. Call for Nominations

[5] OMB Circular A-119, § 4(a)(1)(v) (1998).

2. Call for Candidate Standards
3. Candidate Consensus Standard Review
4. Public and Member Comment
5. Member Voting
6. CSAC Decision
7. Board Ratification
8. Appeals

Figure 1: Current CDP Process Model Flow



Since the first version of the CDP approved in July 2000, NQF has refined the CDP to address the needs of NQF members and more broadly the needs of the healthcare industry. These refinements include: different types of endorsement, such as time-limited endorsement; efforts to maintain a current NQF-endorsed measures portfolio; and increased efficiency of the CDP (i.e. reducing voting from 30-days to 15-days).

These changes were themselves part of a broader process of continuous improvement in the structure and governance of NQF to reflect what we learned as the organization grew and to respond to concerns and requests of NQF members and more broadly of NQF's multi-stakeholder constituencies – hospitals, physicians and other clinicians, consumers, purchasers, health plans, public health organizations and agencies, suppliers and health industry companies, and quality improvement organizations.

Over the life of the CDP, the most significant refinements to the process have focused on being responsive to an increased desire for member involvement and input into the process.

NQF Staff Lean Event: Process Modeling

As a result of the Task Force recommendations in November 2012, NQF Staff participated in a one week long process modeling event to develop models for achieving consensus to present to the Task Force members at their February 2013 meeting. The aim was for staff to develop several models for the Task

Force to review, allowing the Task Force to select a model as presented or to modify or combine the models in order to develop a process for achieving consensus.

Staff worked to define and document potential solutions to a defined problem statement, that "currently concerns exist that the NQF consensus development process does not adequately address achieving consensus and ensuring a balance of interest (under variable conditions and for various stakeholders) through well-defined and transparent processes (understood internally and externally)." Staff was encouraged to develop process models that addressed focus group comments, met the criteria for consensus organizations as defined in OMB Circular A-119, and would result in sound, usable measures for the NQF membership and public. Further, the models referenced approaches of other standard setting organizations and also addressed key areas of importance for NQF, such as increasing the value of NQF membership.

As part of developing these models, staff laid out criteria that each of the models should meet based on the OMB Circular A-119 definition, the focus group input, and the areas of importance for NQF. Each model was evaluated against these criteria to ensure that all were addressed (Appendix E). As staff began to work on model design and defining factors of consensus, several key elements were identified that were tenets of all proposed models. Those were:

- Technical review process for measures (objective process for evaluation of measure evaluation criteria)
- Defined consensus bodies
- Balance of stakeholder interest within the consensus body
- Consumer/Purchaser/Patient emphasis
- Identification of when consensus is or is not achieved (defined through quorum of votes and thresholds for approval)
- A process for additional deliberation when it is unclear whether consensus has been achieved
- Opportunities for public comment and member comment with straw poll indication of support
- Oversight Committee to ensure process was followed
- Appeals process

The differences between the models center on the process for technical review of the measures and the defined consensus body, within which stakeholder interests may be balanced differently. Consumer/Purchaser/Patient emphasis, identification of when consensus is or is not achieved (through quorum of votes and thresholds for approval), the process for additional deliberation, and the opportunities for public comment and member comment with support rationale were consistent throughout the proposed models. Details of the staff process for developing consensus models, explanation of the process elements, and the staff proposed process models can be found in Appendix F.

Of note, all proposed models re-envision the role of the Consensus Standards Approval Committee (CSAC) and the Board of Directors in the measure evaluation and consensus development process.

Consensus Task Force Discussion and Recommendations

The Consensus Task Force met on February 19 and 20, 2013, to review the proposed process models and either to make recommendations for enhancements to the current CDP model or to propose a new model for developing consensus.

To do this, the Consensus Task Force first reviewed all of the input from the focus groups, the criteria required by OMB Circular A-119 for a consensus organization, and the key areas of importance for NQF when developing a consensus process.

Staff presented the proposed process models to the Task Force, emphasizing the ability of the Task Force to develop an original model by viewing the technical review process options, the proposed consensus body options, and the member and public commenting options as process building blocks that can be put together in many different ways. The Task Force evaluated the models by reviewing each of the building blocks to determine which proposed option would best serve the overall goal of creating a process where measure criteria was reviewed objectively, all stakeholders were able to provide input throughout the process, and a forum to enable the discussions that allow consensus to be reached throughout the process.

Technical Review Process

The technical review process is defined as a process to ensure an objective and consistent review for measure evaluation criteria (e.g. evidence, reliability, validity, eMeasure specs, etc.). The input from the technical review process **would not** serve as a recommendation for endorsement; instead, it would be provided to the consensus body as an objective rating of how the information provided in the submission form met or did not meet the NQF measure evaluation criteria. The purpose of this was twofold; first, to enable informed input on the measures from all stakeholders regardless of methodological expertise, and second, to allow the consensus body to make a recommendation on the measure with technical review as input to a broader multistakeholder perspective.

Task Force members first discussed the merits of each of the technical review process options:

- Convene a technical, methodological expert panel: comprised of a stable of methodological experts who would meet to vet the measures based on the criteria
- Utilize peer reviewers (blinded process): staff would parse out relevant portions of measures for vetting by peer reviewers (e.g., evidence would be reviewed by evidence reviewers, reliability and validity testing by methodological experts)
- Technical expert review (individual reviewers): staff would send measures to reviewers with relevant topic expertise to the measure being vetted; reviewers would review the measure in its entirety as individuals rather than through a convened group activity

Task Force members stated that, with the goal of increasing the speed of the process for developing consensus while also allowing for more consistent and objective review of the measure evaluation criteria, utilizing some form of peer review or individual technical review would be the superior option for technical review. The Task Force noted that much of the perceived inconsistency in application of the measure evaluation criteria may happen because convened expert panels may have dominant individuals who sway the recommendation of the committee; use of individual reviewers eliminates this bias. Further, the time needed to convene an expert panel would almost certainly exceed the time needed to send measures to individual reviewers; consequently, using individual reviewers would shorten the time needed for this review.

With respect to using either peer reviewers who reviewed measure criteria relevant to the reviewers' expertise or experience versus utilizing technical experts with topic expertise to review the measure in its entirety, the Task Force questioned which model would lead toward improved consistency and objectivity of the application of the measure evaluation criteria. Task Force members stated that the

peer review model acknowledges that not every individual with expertise in a clinical field also has methodological expertise as relates to measure construction and scientific soundness. Additionally, the Task Force noted that members had indicated during the focus group sessions the desire for easily understandable translation of the methodology underlying each measure, in order to allow all members to comment and provide input on measures earlier in the process. Further, by allowing member commenting to occur simultaneously with the technical review, NQF can elicit important and early feedback from end users of the measure which can serve as input to the Consensus Body. Task Force members stated that the peer review model allows for input tailored to the expertise of the reviewer, while also allowing early feedback on the operationalization of the measure in a healthcare setting.

The Task Force recommended that the peer review model for the technical review process be used in the consensus model. The Task Force agreed that this review should be double blinded, with the reviewer unaware of the developer of the measure and vice versa.

Consensus Body

The consensus body is defined as the group of individuals who make a preliminary vote and make the final decision to approve standards after reviewing all comments received. This is in line with the OMB Circular A-119 definition, which requires that "the consensus body members are given an opportunity to change their votes after reviewing the comments."[6]

Task Force members discussed the various consensus body options:

- Council leadership as representatives of the membership as consensus body: council representatives would act as the consensus body, with the chair and vice chair serving as voting representatives for each stakeholder council. Interest would be balanced along the current 8 member council stakeholder groups.
- Subset of membership as consensus body: comprised of members who self-designate interest in a specific topic area or measure, or participate in the commenting period. Interest would be balanced by categorizing membership into three different interest categories, adapted from ANSI accredited organizations explained below and in Appendix F:
    - Those being measured
    - Those using measures
    - Other interested parties
- Elected subset of the membership as consensus body: NQF would call for nominations to seat members on several consensus bodies. Potential candidates would be submitted for member vote within a designated interest group, with individuals being elected by their interest groups to serve as representatives of their respective interest groups. Interest would be balanced by categorizing membership into three different interest categories, adapted from ANSI accredited organizations explained below and in Appendix F:
    - Those being measured
    - Those using measures
    - Other interested parties

Task Force members reiterated the importance of allowing the full membership the opportunity to weigh in and state support or lack thereof for a measure in a consensus development process; the Task Force wanted to maintain the membership's ability to state support at any point in the process, without

[6] OMB Circular A-119, § 4(a)(1)(v) (1998).

having to designate interest in a project upfront or participate on a consensus body. However, the Task Force debated whether that needed to be through traditional voting as occurs in the current CDP or whether that input could come through an enhanced commenting period allowing members to indicate support for a measure. The Task Force stated that given the low numbers of members voting in the current process and the relatively higher number of members who comment in the current process, it is very feasible to get member input and indication of support through an enhanced commenting period. Further, by ensuring that this commenting period is an input into the consensus body prior to making an endorsement recommendation, it increases the importance and impact of the member voice and support indication. As such, the Task Force felt comfortable selecting a process model with the consensus body as a smaller, defined group of the membership such as proposed above (self-designated subset of the membership, council-based representatives, and elected subset of the membership).

The Task Force discussed the qualities of the council leadership as the consensus body, taking advantage of the current NQF member council structure and stakeholder divisions. The Task Force noted that by design, interests of the stakeholders would be balanced, assuming that the current council structure maintains relevancy. The Task Force stated concern that this structure may pose an insurmountable challenge with respect to measure volume; the number of measures reviewed annually would likely far exceed the ability of the 8 council chairs and vice chairs to provide informed review of the measures. Further, this structure assumes that the stakeholder councils share common interests and support like measures, which may not be a factual assumption. The Task Force also stated that this option places a significant responsibility on a very small number of people, as in addition to reviewing all measures, the council leadership would need to get input from their councils in order to adequately represent the council viewpoint when voting. Consequently, the Task Force discarded this option.

The Task Force next discussed the virtues of the self-designated subset of the membership serving as the consensus body, a proposed option which acknowledged that not all members are interested in all measures or measure topic areas. The Task Force noted that this option also would allow for an enhanced member engagement strategy tailored to the interests of each individual membership organization, an effort that is ongoing throughout NQF. However, the Task Force stated that there were several implementation issues with this option, including a potential inability to balance stakeholder interests as composition of the consensus body relies upon self-designation of interest. There is significant potential for an imbalance in member organizations interested in a given topic area by stakeholder group. Additionally, there is potential for different consensus bodies for every measure that comes through NQF, depending on how members designate interest in a measure or topic area. The IT infrastructure to coordinate all of these consensus bodies may pose an insurmountable challenge. The Task Force also stated unease with setting a cutoff point for when members could self-designate interest in a topic area or measure, as many members may not be able to keep up with the many measures coming through NQF at a given time and thus may miss an opportunity to participate on a measure of importance. Finally, the Task Force acknowledged that setting a quorum for participation of the consensus body members and a threshold for approval of a measure may present a challenge, as NQF does not serve in a role to obligate members to vote on projects; voting is an opportunity for members to engage.

The Task Force then discussed the merits of the elected subset of the membership as the consensus body, an option which uses members to serve as representatives of their interest groups. The Task Force appreciated the transparency and openness associated with this option, as the membership would elect the consensus body members to represent them within an interest category and then would provide indications of support or lack thereof to the consensus body prior to an endorsement

recommendation. This would result in a process where the elected consensus body members would be informed of the comments and support or objections of their interest group and thus accountable to their interest group when making endorsement decisions. This option also acknowledges that not all members are interested in all measures or topic areas, allowing the membership at large to participate when measures of interest are being reviewed. Additionally, by utilizing an election process for membership to the consensus body, the consensus body will have a balance of stakeholder interest by design, as seats can be designated for a particular interest group. The Task Force stated the need for multiple consensus bodies to be seated in order to accommodate the volume of measures anticipated; the process for these multiple consensus bodies will be explained below. The Task Force also acknowledged the importance of utilizing a full disclosure of interests model as a foundational element in composing the consensus body. The Task Force did acknowledge that an election process may be complex; however, this was not envisioned to be any more complex than the current process of seating Steering Committee members.

The Task Force recommended that an elected subset of the membership serve as the consensus body, with several consensus bodies created in order to accommodate measure volume.

Consensus Task Force Proposed Consensus Process

After selecting the technical review process and the consensus body, the Task Force then began to develop process models utilizing these two components while also satisfying the criteria required by OMB Circular A-119 for a consensus organization, and the key areas of importance for NQF when developing a consensus process.

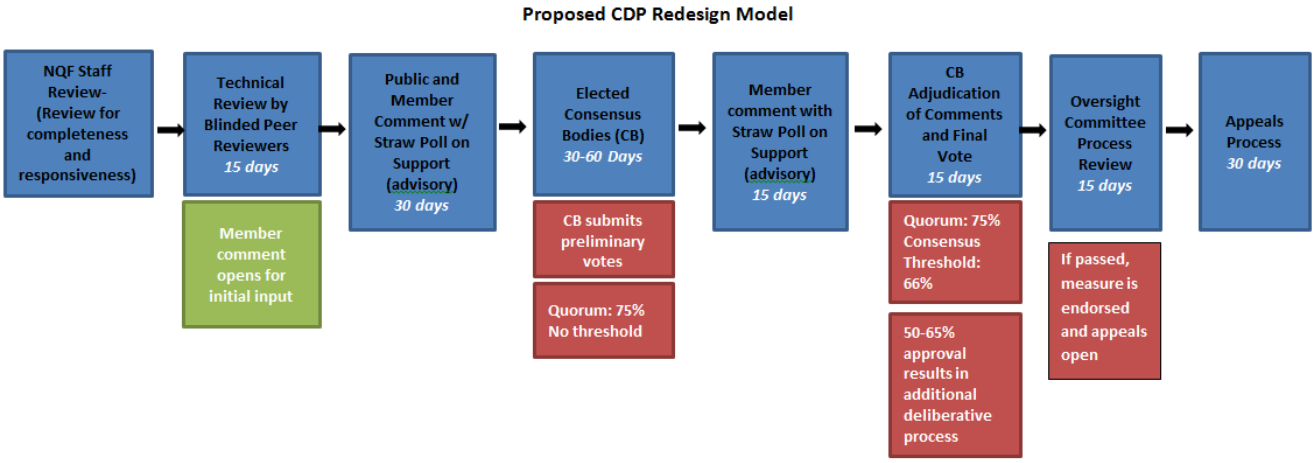
The Consensus Task Force recommended a redesigned consensus development process to address all measures that come through NQF for endorsement (new measures, maintenance measures, review of time-limited measures, ad-hoc reviews, etc.). Once the proposed process for achieving consensus is finalized, process mapping and build out of the process will take into account harmonization processes recommended by the harmonization task force and address related and competing measures. The proposed process re-envisions the role of the membership, the review committees, and the Board of Directors in the measure endorsement process.

The Task Force developed a process model that incorporated the peer review technical review process and the elected subset of the membership as the consensus body, along with the following elements:

- The Task Force assigned staff to review measure submission forms for completeness and responsiveness, and return them to developers if they did not meet minimum criteria for this prior to the measure entering the peer review and consensus process.
- As mentioned previously, the Task Force acknowledged the importance of seeking member input early in the process in order to inform the consensus body endorsement recommendations. This comment period with the opportunity for members to indicate "support," "can live with," or "do not support" was placed in the process prior to the consensus body preliminary endorsement recommendation.
- The Task Force acknowledged the need for technical review of measure evaluation criteria to serve as an input to the membership and public and also to the standing committees serving as the consensus bodies.
- The Task Force recommended creation of five to seven standing committees to serve as the consensus bodies for review of all measures, with the focus of the consensus bodies tied to the National Quality Strategy priority areas.

- The Task Force identified a quorum for participation of the consensus body members and a threshold for approval of a measure to ensure that consensus is achieved.
- A process for additional deliberation when it is unclear whether consensus has been achieved was developed.
- The Task Force created an Oversight Committee to ensure process was followed, as well as to propose modifications to the CDP as needed.
- An appeals process was established.

Figure 6: Consensus Task Force Proposed Consensus Model



Each element of the proposed process is further described below.

NQF Staff Review

Measures submitted by developers will enter the CDP in a "single flow" process. This process does not rely on the traditional project and "call for measures" structure. Measure developers will have greater flexibility and freedom to submit measures when they are ready for review rather than waiting for the next project in that content area. Under the current structure, measure developers may wait as long as 3 years for the submission opportunity. This wait time between projects has negative consequences for both NQF and Measure Developers. NQF has been more willing to accept incomplete and unresponsive measures and deliver these measures to the committee because the next project in that area may be as far as 3 years in the future. Conversely, developers are more likely to rush the development and testing of measures to meet NQF project timelines. This process proposes that NQF staff have the authority to reject measures that do not meet minimum criteria for completeness and responsiveness to questions on the submission form. Accepting measures into the process only when they are ready for review, rather than compromising or rushing to meet deadlines, will have positive benefits for all parties.

Technical Review by Blinded Peer Reviewers

Following submission by measure developers, NQF staff will triage the measure submission and select appropriate reviewers from a stable of vetted experts on certain criterion. These reviews will be "blinded." Measure reviewers will not be provided with information about the measure developer. This

will allow for an un-biased review based solely on the information submitted and not on any pre-conceived opinion of the developer or measure. Evaluations of the NQF criteria (e.g. Evidence, Reliability, Validity) will be aggregated by NQF staff and provided for a preliminary member/public comment period and Consensus Body review.

Member commenting will be open on all measures while peer review is ongoing, eliciting early input from users of the measures including community, facility or healthcare setting, and state implementers of measures. Public commenting will open once the aggregated peer review evaluations have been posted.

Public Comment and Member Comment with Straw Poll on Support

Following the posting of the aggregated peer review evaluations, NQF Members will have a 30-day period to provide comments and indications of support for all measures under consideration. Members will have the opportunity to comment and indicate "support," "can live with," or "do not support" with respect to each measure. All NQF member organizations are eligible to comment and indicate support for any measure being reviewed. This input will be compiled and presented to the consensus body as an advisory input prior to the consensus body making an initial endorsement recommendation for a measure.

The opportunity for member commenting with straw poll on support, which opens while measures are undergoing technical review, will remain open for the duration of the 30-day commenting period. The public commenting period will last 30 days and will open once the aggregated peer review evaluations have been posted. The public will provide comments on the measures without the opportunity to participate in the straw poll on support of the measure.

Standing Committees: Elected Consensus Body Composition and Review of Measures

The Task Force recommended the creation of five to seven standing committees to form the consensus bodies to review measures against the measure evaluation criteria, review input from the membership and the public, and to make endorsement decisions on measures.

Composition of Consensus Bodies

The Task Force recommended that stakeholder interest be balanced within each of the elected consensus bodies using categories adapted from ANSI accredited standard setting organizations. The ANSI accredited standard setting organizations use the categories of user, producer, and general interest. This model proposes placing NQF members into one of three interest categories:

- Those being measured
- Those using measures
- Other interested parties

The process for designating member organizations into one of these interest categories would require consideration of the primary function of the member organization, as well as consideration of the organization preference of interest category and justification for that preference. **This effort has not yet been undertaken, and assignment of member organizations to these defined interest categories will include consultation with the member organizations.** However, for the purposes of this model, staff has placed stakeholder councils into the following categories:

Those being measured

- Health Professionals Council (100 member organizations)
- Provider Organizations Council (125 member organizations)

Those using measures
- Consumer Council (33 member organizations)
- Health Plan Council (19 member organizations)
- Purchaser Council (20 member organizations)

Other interested parties
- Public-Community Health Agency Council (30 member organizations)
- QMRI Council (80 member organizations)
- Supplier-Industry Council (40 member organizations)

The Task Force acknowledged that NQF as an organization was created with a vision to serve the consumer, purchaser, and patient. These voices had been underrepresented in the discussions around improving the quality and safety of healthcare delivery; NQF was created to serve as a platform for these stakeholders to provide input into the discussion and to make decisions about important drivers for improvement. Additionally, the number of organizations focused on the consumer, purchaser, and patient are small in number when compared with other stakeholders, reinforcing the need to ensure that these voices are heard. As such, the Task Force stated the importance of preserving the emphasis on the consumer, purchaser, and patient voices as part of the consensus body.

The Task Force recommended that each of the five to seven consensus bodies be composed of a total of 18 members, with 1/3 those using measures (consumers, purchasers, health plans); 1/3 those being measured (providers, health professionals); and 1/3 interested parties (QMRI, supplier and industry, public and community health agencies). For a measure to be endorsed, 66% of the members of the consensus body as a whole must approve the measure. In line with the intent of the NQF Bylaws regarding consumer and purchaser representation in the process, the Task Force recommended that the consumer and purchaser voices are maintained by requiring approval of measures by a simple majority (4 of the 6 members) of the "those using measures" category, in addition to the requirement for overall approval by 66% of the members of the consensus body. Failure to achieve a simple majority of approval from the "those using measures" category would trigger the additional deliberative process. Additionally, those measures approved by 50%- 65% of the elected consensus body will also be reconsidered through an additional deliberative process in order to foster a greater degree of consensus.

Focus of Consensus Bodies

The Task Force stated that flexibility both in the number and focus of the elected consensus bodies will enable better representation of the NQF membership and the review of measures within a reasonable timeframe (i.e., 1-2 months following submission). Given the objective technical review through the use of peer reviewers, it is assumed that those who are elected to a consensus body would not need technical expertise in a given areas but should meet the following requirements: 1) be from an NQF member organization and 2) have experience related to the stakeholder group's focus (e.g., from a provider organization who implements measures). Additionally, it is considered foundational that all members of the consensus body participate in full disclosure of interests in order to move forward with this model.

While a model where each consensus body would address a given topical area or National Quality Strategy (NQS) priority may be viewed as optimal, it also has limitations in enabling review of measures efficiently and ensuring a stable "flow" of measures across the various consensus bodies. For this reason, the Task Force recommends that each group would be not dedicated to one NQS priority or topic area but that each may be charged with addressing two or more NQS area and/or clinical topics. This broader scope will allow measures to be distributed in a targeted manner, ensuring that multiple measures within a given area or topic are reviewed by the same group but also allowing staff to distribute measures as they are submitted efficiently. The Board of Directors will oversee the implementation of the consensus bodies, providing recommendations on the type and number of consensus bodies to be seated with an expectation of operationalizing five to seven consensus bodies. Decision rules similar to how measures are assigned to review committees now would be developed and refined over time.

Review Process
Each consensus body will be charged with reviewing the measures themselves, the aggregated peer reviews on the ratings of the technical measure evaluation criteria, and all of the input from the commenting period including the membership indications of support. These inputs will inform the consensus body measure endorsement recommendations.

The consensus body members will submit preliminary votes on endorsement for each of the measures under review. The preliminary vote will require participation from 75% of the elected consensus body to achieve quorum and to be considered valid. There is no threshold for approval, as this is unnecessary for a preliminary vote.

Member Comment with Straw Poll on Support

Following the elected consensus body's preliminary votes on measure endorsement, NQF Members will have a 15-day period to again provide comments and indications of support for all measures under consideration. Members will have the opportunity to comment and indicate "support," "can live with," or "do not support" with respect to each measure. All NQF member organizations are eligible to comment and indicate support for any measure being reviewed. This input will be compiled and presented to the consensus body as an advisory input prior to the consensus body making a final endorsement recommendation for a measure.

Consensus Body Adjudication of Comments and Final Vote

Each consensus body will review all member comments and indications of support, with the opportunity for additional deliberation for a measure where comments suggest a lack of consensus. The consensus bodies will respond to all objections as part of this process.

The consensus body will have 15 days to submit their final votes on measures under consideration for NQF endorsement. The final vote will require participation from 75% of the elected consensus body to achieve quorum and to be considered valid. Measures must be approved by 66% of the elected consensus body in order to be NQF-endorsed and also approved by a simple majority (4 of the 6 members) of the "those using measure" category. Measures approved by 50%- 65% of the elected consensus body or approved by less than a simple majority (4 of the 6 members) of the "those using measures" category will be reconsidered through an additional deliberative process in order to foster a greater degree of consensus.

Deliberative Process

The deliberative process is followed when the measure does not meet the threshold for approval; however, it is unclear whether consensus has been reached on the measure. The trigger for this process is when a measure has been approved by 50%-65% of the elected consensus body, or when less than a simple majority (4 of the 6 members) of the "those using measures" category approves the measure. This process is intended to be outside of the consensus development process and only utilized for measures where it is unclear whether consensus has been reached.

The deliberative process allows for an opportunity for all objectors to provide concise statements of opposition/objection to the measure as well as advocates of the measure to provide statements of support, a conference call open to the public for the consensus body to discuss the objections and statements of support, and a second round of voting by the consensus body. If the threshold for approval is not met after the second round of voting, the measure will not be endorsed.

Oversight Committee Process Review

Currently the oversight of the consensus development process is under the responsibility of the Consensus Standards Approval Committee and the Board of Directors. In the proposed redesign, this responsibility would move to the Oversight Committee and the scope would be narrowed and would not include ensuring that those standards endorsed meet the criteria and are appropriate for endorsement, which would be within the charge and responsibility of the elected consensus bodies.

The proposed charge of the Oversight Committee would be to:

- Address concerns raised that process was not followed (e.g., a comment was not adjudicated);
- On a quarterly basis, ensure that the steps of the CDP were followed (e.g., no step was missed or not completed); that all quorums and consensus thresholds were met; and that all comments were adequately adjudicated;
- Consult on appeals received as requested by the Board of Directors; and
- Provide periodic review of the CDP and provide recommendations to the Board of Directors for ongoing improvement (including review of whether the new consensus model results in the desired outcome of strong member participation during commenting periods and results in endorsement of high priority measures that fill gap areas).

The Oversight Committee would be a Board appointed committee composed of no more than 10-12 individuals independent of the elected consensus bodies who are both knowledgeable of the CDP and from member organizations of NQF and including a representative of the Board of Directors. NQF staff would provide input and materials to demonstrate that the process was followed, quorums and consensus thresholds were met, and all comments adequately adjudicated. In addition, NQF staff would propose modifications to the CDP based on experience to this committee for their discussion and approval and subsequent approval by the NQF Board of Directors. The Oversight Committee would review the CDP as well as any proposed modifications on an annual basis.

The Oversight Committee's work would primarily be conducted electronically to ensure that the CDP was followed and would also be convened either via phone or in person to evaluate the CDP and propose modifications.

Appeals Process

NQF's Board of Directors will hear appeals on all endorsement decisions. Any interested party may appeal the endorsement decision if there were process concerns and/or there are new measurement issues or evidence that was not addressed during the consensus process.

Appeals must be submitted in writing with the grounds for the appeal clearly stated. NQF staff will review each appeal and then forward the appeal and an analysis of the appeal to the Board of Directors. The Board of Directors may delegate the analysis of the appeal to a Board appointed committee (e.g., process issue analysis by Oversight Committee; measurement issue analysis by measurement Advisory Committee); however, the Board of Directors will issue the final decision on the appeal.

All appeals will be decided based on the written materials submitted. The Board of Directors will issue a written decision on each appeal.

Measurement Advisory Committee

The Task Force acknowledged that there is an ongoing need for a committee with measurement expertise to advise on strategic measurement issues and update the measure evaluation criteria outside of the measure endorsement process. As such, the Task Force recommends the creation of a Measurement Advisory Committee to serve in this role.

The Measurement Advisory Committee (MAC) will take on some of the critical functions of the CSAC. It may also encompass some of the current roles of the Health IT Advisory Committee (HITAC). The MAC would be comprised of 15-17 individuals, mirroring the composition of the current CSAC and Board of Directors with a majority being users of measures while also inclusive of representatives from all stakeholders. Like the CSAC, the MAC will include individuals drawn from a diverse set of stakeholder perspectives, including individuals with methodological expertise in measure use, development, and reporting.

Proposed charge for the Measurement Advisory Committee would include:

- Provide measurement expertise and guidance to NQF staff and committees on emerging issues in performance measurement and eMeasurement; and
- Provide periodic review of the measure evaluation criteria and provide recommendations for modifications to the criteria.

Next Steps

The Task Force recommendations and proposed process model will be reviewed by the CSAC at their March 20-21, 2013 in-person meeting. The proposed recommendations will then be reviewed by the Board of Directors on a conference call in late March or early April 2013.

The Task Force recommendations and proposed consensus process will be posted to the NQF website for a comment period. During this time, NQF staff will be participating in a series of listening sessions with the membership to get feedback on the proposed consensus process and answer any questions. Upon completion of the comment period, the Task Force will review and address all comments.

The Task Force proposed process model will then be presented to the Consensus Standards Approval Committee and the Board of Directors for final approval in late Spring to mid-Summer 2013.

Appendix A: Consensus Task Force Members and NQF Staff

Consensus Task Force Members

Lawrence Becker (Co-chair)
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Frank Opelka, MD, MPH (Co-chair)
Louisiana State University, New Orleans, LA

JudyAnn Bigby, MD
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William Conway, MD
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Rita Munley Gallagher, PhD, RN
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Carol Herman
Association for the Advancement of Medical Instrumentation, Arlington, VA

Ann Monroe, MA
Health Foundation for Western and Central New York, Buffalo, NY

Arthur Levin, MPH
Center for Medical Consumers, New York, NY

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Taroon Amin, MA, MPH
Senior Director, Performance Measures

Lindsey Tighe, MS
Project Manager, Performance Measures

Appendix B: Task Force Short Term Recommendations

Steering Committee

In response to discussion regarding the consistency of Steering Committee selection:
• Review steering committee composition and process for seating members
  o Transparent criteria for SC selection: number of members desired, expertise being sought (balance of interest)
  o Terms and COI policy for standing committees
• Begin roll out of standing committees as funding allows
 	
In response to discussion regarding the transparency of Steering Committee selection:
• Develop metrics on Steering Committee composition
• Develop criteria/checklist for transparency, which would be posted to the project page (number of nominations received, expertise desired, councils who submitted, etc.)
 	
STATUS: Staff has begun developing templates for posting to the project page at the time of nominations indicating the desired composition and expertise for the SC. A planning team is currently drafting final plans for standing committees if still approved. These efforts will be informed by Task Force recommendations on committee compositions.

In response to discussion regarding the consistency of the Steering Committee review of the measures:
• Determine the role and responsibility of the facilitator for the Steering Committee meetings
  o Define who should receive training as the facilitator (staff, SC chairs, outside facilitator)
  o Look at ANSI materials/training for facilitators
 	
STATUS: Staff has had preliminary discussions regarding who should facilitate meetings, with consideration given to expertise, expense, training time, etc. A recommendation will be finalized within the next month.

In response to discussion regarding process questions: • Education of NQF membership and public on the CDP • Develop a guidebook that is published to the NQF website for easy access by the membership and public **STATUS: Staff has developed draft Committee, Developer and Member guidebooks, currently undergoing internal approvals and with plans to be piloted in Spring 2013.**
Member Engagement

In response to discussion seeking clarity in how to engage in the CDP projects:
• CDP-specific communications to be sent out to the membership and the public
  o Publicly shared timelines for upcoming projects
  o Explore expanding CDP projects on the NQF web site-increase accessibility from the home page
  o Increase Council awareness and discussions on CDP projects
• Develop broader strategy on member engagement across NQF for implementation within next 3 months

STATUS: Staff is participating in an organization wide member engagement strategy, with a work plan proposed on February 15th. This effort will be informed by Task Force recommendations on the function and appropriate balance of stakeholder groups.

Comment Period

In response to discussion seeking clarity in how comments are adjudicated:

- Explore ways to further allow granularity in comments against criteria, seeking comments on the measures specific to the measure evaluation criteria
    - need to determine how quickly could implement-change the commenting field or have staff sort the comments by criteria
- Look at how comments are adjudicated and presented to ensure that comments are easily attributable to the organizations that have made them
- Provide the table of comments and responses directly back to those who commented
- Provide information regarding the SC call to discuss comments directly back to those who commented

STATUS: Staff have had preliminary discussions regarding IT capabilities and possible layouts. This effort will be informed by Task Force recommendations on the role of commenting.

Appendix C: Organizations that Participated in Focus Groups

Focus Group #1, Consumer and Purchaser Councils (4 Attendees)	Focus Group #2, Providers Council (8 Attendees)	Focus Group #3, Health Professionals Council (7 Attendees)	Focus Group #4, Quality Measurement, Research & Improvement Council (4 Attendees)	Focus Group #5, Public and Community Health Agencies, Health Plan, and Supplier and Industry Councils (7 Attendees)	Focus Group #6, Consumer and Purchaser Councils (9 Attendees)
AARP	American Hospital Association	American Academy of Pediatrics	American Board of Medical Specialties	Aetna	The Alliance
CMS	American Association of Medical Colleges	American Association of Nurse Anesthetists	The Joint Commission	America's Health Insurance Plans	AFT Healthcare
National Business Coalition on Health	National Association of Children's Hospitals and Related Institutions	American College of Surgeons	University HealthSystem Consortium	Pfizer	Childbirth Connection
National Partnership for Women and Families	National Association of Public Hospitals and Health Systems	American Health Information Management Association	American Medical Association-Physician Consortium for Performance Improvement	Advamed	Connecticut Center for Patient Safety
	The Alliance for Home Health Quality and Innovation	American Osteopathic Association		Lilly	Consumer Coalition for Quality Health Care
	National Association of Psychiatric Health Systems	Emergency Nurses Association		GlaxoSmithKline	Health Watch USA
	Premier Inc.	Society of Thoracic Surgeons			St. Louis Business Health Coalition
	Federation of American Hospitals				Pacific Business Group on Health
					Lamaze International

Appendix D: 2-Stage CDP Process: Evaluation Results for Stage 1 Excerpts from Draft Report

2-Stage CDP Process: Evaluation Results for Stage 1

EXCERPTS FROM DRAFT REPORT

Introduction

Stakeholder recommendation for CDP re-design

In the fall of 2011, the American Medical Association (AMA), 38 medical specialty societies, and the Centers for Medicare and Medicaid Services (CMS) formally requested that NQF consider revising the current CDP so as to incorporate a staged process for measure evaluation that would allow for earlier review of measure topics and later review of measure specifications and testing results. An underlying motivation behind this request is that measures often do not make it past the Importance criterion. However, because measure developers are currently required to submit fully specified and tested measures for evaluation, developers may make costly investments of time and other resources to specify and test a measure that may not achieve NQF endorsement.

The above organizations also asked that NQF consider more flexible CDP scheduling so that so that new measures could be evaluated outside of the 3-year cycle typically used for the measure maintenance process. Under the current CDP timelines, developers could wait two or more years to submit a measure for next maintenance cycle if testing data are not available by the project submission deadline.

Because NQF strives to continually improve its own systems, policies, and processes and is committed to seeking feedback on its processes and responding to stakeholders needs, many *incremental* changes to various processes and procedures within the CDP have been implemented over the past several years. In response to the above-mentioned letter, however, NQF began to formally explore a potential *re-design* of the CDP in late fall 2011.

The following two key objectives were deemed to be essential elements for any proposed re-design of the CDP:

- Provision of a determination of whether a "measure concept" satisfies the Importance criterion prior to full development and testing of a measure; and
- Provision of more timely and flexible review of fully specified and tested measures.

Proposed CDP Re-Design: A 2-Stage Process

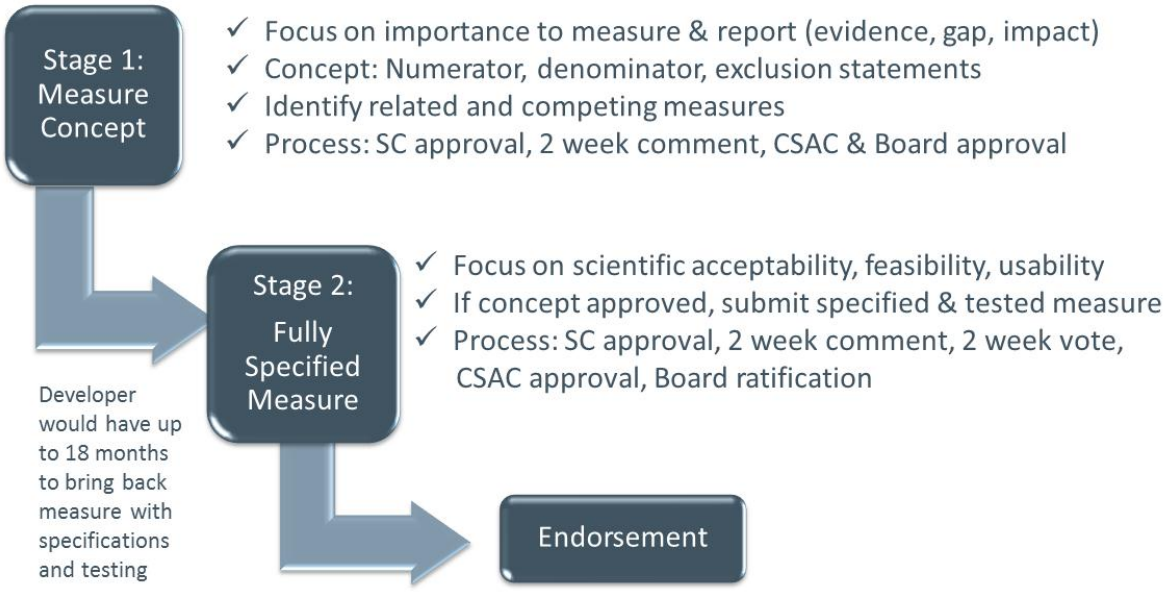
To accomplish these key objectives, NQF staff embarked on a 4-month endeavor to re-design the CDP. Staff used the AMA/CMS/AMA/medical society recommendation for a staged process as the basis for the proposed redesign.

The proposed 2-Stage process

The proposed 2-stage CDP is shown in Figure 1. In Stage 1, measure concepts would be evaluated against NQF's importance criterion[7]. Potential related and competing measures also would be identified during this stage. All measures, regardless of their stage of development (i.e., concepts, fully specified measures, fully specified measure with testing, measures undergoing maintenance review) would be required to undergo concept review.

Once the importance threshold has been met, a measure or concept would be eligible to move to Stage 2 of the process. In Stage 2 of the process, fully specified and tested measures would be evaluated against the remaining three evaluation criteria: scientific acceptability, usability, and feasibility. Measure stewards would have up to 18 months to fully specify and complete testing of their approved concepts before bringing the measure forward for Stage 2 review. Measures that are already fully specified and tested could proceed immediately to Stage 2. At the end of Stage 2, measures ratified by the Board would receive endorsement.

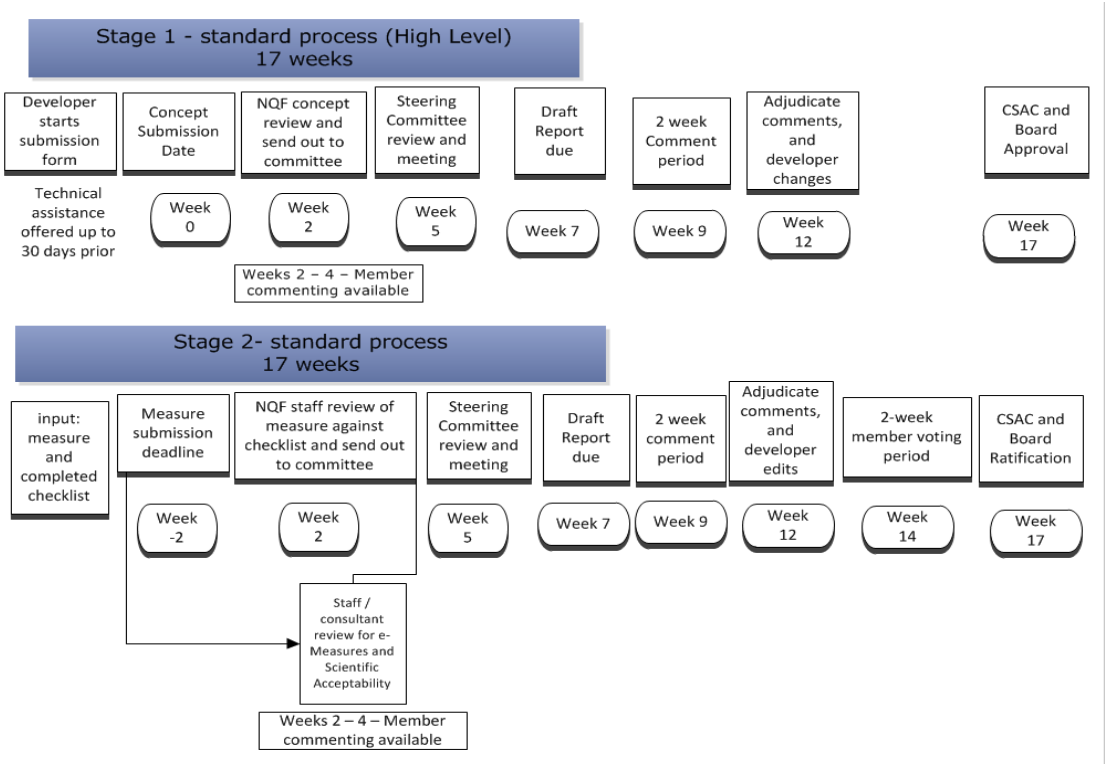
Figure 1: Proposed Two-Stage Endorsement Process



Each stage of the 2-Stage process would take 17 weeks for completion (see Figure 2). Initiation of CDP projects would be staggered so as to ensure adequate staffing for projects and feasible timelines for external stakeholders (e.g., public and member commenting, voting, etc.).

[7] The three subcriteria under the Importance to Measure and Report criterion included—at the time of the CDP re-design—the following: high impact (1a); performance gap/opportunity for improvement (1b); and evidence supports measure focus (1c).

Figure 2. Timeframe for Stage 1 and Stage 2



Key objectives of the proposed 2-Stage process

The proposed 2-Stage process has six key objectives, each of which can be categorized under the two key CDP re-design objectives (see table 1). Each of these six objectives is described more fully below.

Table 1. Objectives of the 2-Stage CDP redesign

	Key objectives of CDP re-design	
	Evaluation of measure concept prior to full measure development/testing	**More timely and flexible review of fully specified and tested measures**
Key objectives of the 2-stage process	Better use of measure development resources	More frequent endorsement cycles
	More efficient use of NQF resources	More predictable schedules
	Earlier and more balanced opportunities for stakeholder feedback	Earlier identification competing measures/harmonization issues

Better use of measure development resources

Measure stewards who avail themselves of the measure concept approval option prior to fully specifying and testing a measure would not have to expend time, effort, and financial resources on specification and testing of measures that do not pass the importance criterion.

More efficient use of NQF resources

For those concepts that do not pass the importance criterion, review and evaluation of the fully specified and tested measure against the remaining criteria would not be necessary, thus saving time and effort for both NQF staff and volunteers (i.e., Steering Committee members, NQF members, CSAC members, the Board, and members of the public).

Earlier and more balanced opportunities for feedback

Review of measure concepts would allow for multi-stakeholder input (e.g., NQF expert panels and other key stakeholders such as consumers and purchasers) earlier in the measure development process. Such feedback could potentially aid stewards and developers to refine their measures prior to full evaluation and may increase the likelihood that such a measure would be endorsed.

More frequent endorsement cycles

Instead of NQF's current three-year cycle of projects in measure endorsement topic areas, there would be at least two opportunities for measure stewards to submit measure concepts and/or measures into a topic area each year. Having more frequent endorsement cycles also should eliminate the need for time-limited endorsement of untested measures.

More predictable schedules

Use of standing steering committee will allow for the establishment of regular, fixed timelines for concept/measure evaluation, thus increasing the predictability of all facets of the endorsement process. Measure 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.

Earlier identification of issues related to competing measures and measure harmonization

Harmonization and competing measure issues will be identified in Stage 1 of the proposed CDP, rather than towards the end of the endorsement process, currently occurs. If competing measures or concepts are identified, the measure steward may decide to suspend further development of the measure, thus conserving developer resources needed for measure specification and testing. Earlier identification would also allow for earlier collaboration, if desired, between developers for the purposes of measure harmonization or joint measure development.

Piloting the 2-Stage Process

Because the proposed 2-Stage re-design of the CDP represents a substantial departure from the current CDP, NQF leadership recognized the need to pilot both stages of the proposed process prior to recommending its adoption by the NQF Board of Directors. Piloting the proposed 2-Stage process will allow NQF to obtain tangible experience with many of the new processes from the perspectives of measure developers, Steering Committee members, membership, NQF staff, and other stakeholders. Ideally, results from the pilot will inform NQF leadership regarding the success in fulfilling the objectives of the proposed 2-Stage process, and, more broadly, of the attainability of the overall objectives of the CDP re-design effort.

The pilot project: Gastrointestinal / Genitourinary (GI/GU) Measure Endorsement

While several previously-scheduled endorsement projects could have served as the pilot project for the proposed 2-Stage process, the GI/GU project was chosen because it was scheduled to begin soon after the 2-Stage process was formulated (i.e., in the summer of 2012), both concepts and fully specified and tested measures were available for review within the project, and the project had a relatively small number of concepts/compared to other scheduled projects.

The specific goals of the GI/GU pilot were twofold:

1. To assess the process steps, the estimated timeline for projects, and the tools and materials needed to implement core components of the proposed 2-Stage CDP.
2. To allow NQF to identify and assess the scalability of the proposed 2-Stage process, including the implications of the redesigned process on staffing and relevant infrastructure supports.

Because of budgetary and internal process constraints, not all of the components and assumptions of the proposed 2-Stage CDP could be tested directly through the pilot project. Specifically, two key components of the proposed re-design were not implemented: the standing steering committee structure and a process to enable measure developers to submit fully specified and tested measures within 12-18 months of the initial submission and review of their measure concepts.

The consensus process used in the pilot project was consistent with, but not identical to, NQF's current CDP (version 1.9). Specifically—in addition to the staging of the evaluation process to evaluate measure concepts separately from evaluation of the fully specified and tested measures against remaining criteria—the consensus process that was implemented for in Stage 1 of the pilot differed from the current CDP in the following ways:

- **Upfront technical review**. NQF staff provided an upfront technical review[8] of concept/measure submissions prior to making the materials available to the Steering Committee. These required reviews were intended to ensure that submission materials were complete and responsive to the questions needed for concept evaluation and to provide individualized support to those developers who needed assistance with the submission process.

[8] Measure developers were asked to submit at least one measure concept through NQF's upfront technical review process prior to the SC's review. This upfront technical review consisted of two levels of review (L1=assessment of completeness of submission; and L2-assessment of responsiveness of submission). Of the 18 measure concepts submitted for evaluation in Stage 1 of the pilot, 14 were submitted for upfront technical review.

- **Earlier opportunity for comment**. A two-week comment period was opened to NQF members prior to the in-person Committee meeting to allow the opportunity to submit comments for consideration and discussion by the Committee at the in-person meeting.
- **Development of additional tools.** Several tools were developed to provide additional information and guidance to developers and the Steering Committee regarding NQF's evaluation criteria and to facilitate review of measure concepts. These tools included a Developer Guidebook, a Steering Committee Guidebook, a concept submission form, an evidence attachment, and a measure tracking log (the latter for internal staff use); these tools are described more fully later in the report.
- **Approval of measure concepts**. For Stage 1 of pilot, the Steering Committee recommended "approval" (or not) of measure concepts (rather than a recommendation regarding endorsement as in the current CDP). Developers whose concepts were approved in Stage 1 have up to 18 months to fully develop, specify, and test their measure(s) before submitting it for Stage 2 review against the remaining NQF criteria. Endorsement of a measure will not be granted until a measure has passed all four NQF criteria at the end of Stage 2.
- **Provision of developer checklists**. A checklist was provided to each developer following the Committee's review and recommendations for concepts in Stage 1. These checklists summarize the Committee's recommendations for improving the concept(s) and considerations for specifying and testing the measure that must be addressed prior to submission to Stage 2 of the pilot.[9]

Five tools were developed specifically to aid in the upfront review process (and, by extension, to help improve the quality of concept/measure submissions). These tools included the following:

- **Concept submission form.** Because the measure submission form used for measures submitted under the current CDP is designed for fully specified and tested measures, a form was needed to elicit only the information needed to evaluate measure concepts. This form is an abbreviated version of the current measure submission, modified as needed to provide guidance to developers to describe their measure concepts. As with the current measure submission form, data were entered data into the concept submission form electronically through the usual NQF measure submission interface.
- **Evidence attachment form**. Past experience with the current measure submission form indicates that developers often are unsure how to respond to the items needed for evaluation of the evidence subcriterion and Steering Committee members often have trouble assimilating the information. Staff designed the evidence attachment to elicit this needed information from developers in a way that is more logical and less repetitive than the current measure submission form, with the hope that the new layout would assist developers in addressing the questions and facilitate Steering Committee member understanding of the information provided. For the pilot, this form was not implemented as part of the concept submission form but was instead distributed as an "attachment" to the form.
- **Measure tracking log**. This tool was created to track and communicate the progress of a concept/measure through the entire evaluation process, from initial submission, through upfront technical review, hand-off to the CDP activities team, and evaluation of the

[9] The developer checklists can be considered either tools or infrastructure supports for Stage 2 of the proposed re-design process; the utility of these checklists will be included as part of the evaluation of Stage 2 of the pilot.

concept/measure by the Steering Committee. Staff used this log to document the feedback and interaction with developers that was provided as part of the upfront review process, to track what changes developers made based on this feedback, to record the time needed for the review process, and to flag which concept submission items were the most difficult for developers to answer.

- **A Developer Guidebook**. The purpose of this guidebook was to orient concept/measure developers to the proposed 2-Stage process, to explain the roles and expectations for measure steward/developers during the evaluation process, and to provide in-depth guidance on submitting concepts and measures for evaluation
- **A Steering Committee Guidebook**. The purpose of this guidebook was to orient Steering Committee members to NQF and to the measure evaluation process, to document NQF criteria and guidance for measure evaluation criteria, and to introduce the proposed 2-Stage CDP.

A notable feature included in both guidebooks is an Appendix with examples of "What Good Looks Like." The examples included in this section of the guidebooks are meant to illustrate the type of information that would be considered both complete and responsive to the submission items, and thus, ready for Steering Committee evaluation. Some of the examples were adapted from actual measure submissions and some were developed by NQF staff.

Also, the pilot was staffed somewhat differently than typical CDP projects, with five staff assigned to the pilot rather than three as is currently done. Two staff members (one senior director and one senior project manager) were assigned responsibility for the upfront technical review, while three staff members (one senior director, one senior project manager, and one project analyst) handled the remaining aspects of the CDP.

On August 27-28, the GI/GU Steering Committee met to evaluate 18 measure concepts that were submitted by 8 developer organizations. The Steering Committee ultimately recommended 14 concepts for approval, 12 of which were subsequently approved by the Consensus Standards Approval Committee (CSAC) and the Board of Directors.

Evaluation Methodology

In order to assess the overall scalability and success of the proposed 2-Stage process, a formal evaluation of the pilot project was initiated. The intent of the evaluation of Stage 1 of the pilot is to capture stakeholders' perspectives of the process midway through the proposed 2-Stage process, and to assess the effectiveness of both the upfront technical review process and tools developed for use in Stage 1. Unfortunately, not all of the components, assumptions, and processes of the proposed 2-Stage CDP can be tested directly through the pilot project; further, a full evaluation of many of these components, assumptions, and processes can be performed only once both stages of the pilot have been completed.

The bulk of the evaluation of Stage 1 of the pilot was accomplished through a content analysis of qualitative data that were collected via surveys and structured discussions with NQF staff, the project Steering Committee, the CSAC, NQF membership, and measure developers, as follows:

- **NQF staff: Technical Review team**. Both team members tasked with upfront technical review participated in two 30-minute individual interviews and one 45-minute group interview.
- **NQF staff: CDP activities team.** All three team members participated in three 30-minute individual interviews and one 45-minute group interview.
- **Project Steering Committee.** Fourteen of the 17 Steering Committee members responded to a written survey and then participated in a 45-minute structured discussion during second day of the pilot project's in-person meeting.
- **Measure developers.** An online survey was distributed to those developer organizations that submitted concepts for the upfront technical review process. All staff members involved in the review process were invited to participate in the survey (a total of 30 individuals from seven developer organizations). The individual response rate was 30 percent.

All individual and group interviews with NQF staff were conducted by an experienced qualitative researcher external to the Performance Measures group. The structured discussion with the project Steering Committee was led by the senior director from the CDP activities team.

Quantitative data also were used to inform the evaluation of Stage 1 of the pilot. These data were collected through detailed tracking of project milestones and activities and through the surveys described above.

Conclusions Based on Stage 1 Evaluation Results

Several conclusions regarding the success of the pilot itself, as well as the success of the 2-Stage process as implemented in the pilot, can be made based on the evaluation of Stage 1 of the pilot.

First, the goals for Stage 1 the GI/GU pilot were, for the most part, met. Many of the process steps of the proposed 2-Stage process were implemented and evaluated through the pilot project. Also, several new tools needed for implementation were developed and evaluated as part of the pilot. Similarly, even though the pilot project was delayed, and the timelines were somewhat compressed, NQF staff were relatively successful in adhering to the timeline that was developed for completion of Stage 1 of the pilot. Finally, the pilot allowed for testing of staffing requirements for staffing and infrastructure supports, which allows for an assessment of the scalability of the proposed 2-Stage process.

However, as noted earlier, two key components of the proposed re-design were not implemented in the pilot project. The lack of ability to utilize a standing steering committee structure has made it impossible to assess whether the objective of having more predictable schedules can be met through the proposed 2-Stage process. Also, the pilot was designed to allow for only one full measurement cyde (i.e., only one round each of Stage 1 and Stage 2 is included in the pilot). Thus, the pilot was unable to allow measure developers to submit fully specified and tested measures within 12-18 months of the initial submission and review of their measure concepts. Any savings of developer resources that could potentially occur due to this design component cannot be assessed through the pilot. Further, the back-to-back design for implementation of Stage 1 and Stage 2 of the pilot impacted the ability of NQF staff to reject incomplete or non-responsive submissions from the pilot. Thus, a full understanding of whether the proposed 2-Stage process can help to achieve more frequent measurement cycles and help to avoid project delays is not possible through this pilot.

Second, results from the evaluation of the pilot suggest that the proposed 2-stage process should enable increased efficiencies for NQF staff and Steering Committees. In this pilot, one-third of the measure

concepts were judged not to meet the Importance criterion, and thus, further review and evaluation against the remaining criteria will not be needed. Typically, Committee members spend the majority of their time on the Importance and Scientific Acceptability criteria; conservatively, therefore, the rejection of one-third of the measure concepts could result in 16 percent less time needed for complete review of measures by staff and Steering Committees over the life of the project.

However, results from the evaluation of the pilot suggest that the proposed 2-stage process may not enable increased efficiencies for the CSAC and Board—and in fact may increase the workload for these groups. Specifically, as designed and implemented in the pilot, there will potentially be a need for a second round of CSAC and Board reviews for two-thirds of the measure concepts that were reviewed in Stage 1 of the pilot (assuming the associated measures meet the remaining evaluation criteria). Although different issues would be considered in this second round, at least some overlap in the two rounds would be expected.

Perhaps most enlightening, however, was how the CSAC process for Stage 1 played out in the pilot. Per the design of the 2-Stage process, the CSAC has the option of disapproving measure concepts, even if approved by the project Steering Committee. In the pilot, two concepts that were approved by the Committee were later overturned by the CSAC. Comparatively, this reversal rate is quite high, given that the CSAC may typically overturn Committee decisions only 2-3 times per year. The reasons why the Steering Committee allowed these two concepts that the CSAC ultimately did not move forward were based on their concerns with lack of evidence linking the concepts to outcomes and lack of importance to the overall measure portfolio.

Third, the evaluation of Stage 1 of the pilot suggests that upfront technical review can help to improve the quality of submissions. However, this finding is tempered by the reality that upfront technical review and associated feedback did not seem to be equally embraced or acted upon by all the developers involved in the pilot.

Fourth, the tools developed for the upfront technical review were found to be beneficial, even though the evaluation uncovered the need for some reorganization of the concept submission form, and some potential additions to the evidence attachment. The evaluation also uncovered the need for some modifications to the measure tracking tool that would help to improve the "hand-off" process between the technical review team and the CDP activities team and minimize the amount of "re-work" associated with the tracking process.

Fifth, there were no substantial delays in the project timeline once the pilot began. However, this result cannot be attributed to the provision of upfront technical review, particularly given that staff were not able to implement the option to reject consideration of submissions that were deemed incomplete or non-responsive.

Sixth, experience from the pilot project suggests that the upfront review process is scalable, at least in terms of having an adequate number of staff members with the skill set required to conduct the upfront technical review. There is still some question as to whether the process is scalable in terms of the time requirements needed for the process. The pilot project included a relatively small number of measure concepts (18 instead of the 25-30 measures that are more typically evaluated in a CDP project). Further, the staff time needed to accomplish the reviews was more than was originally anticipated. However, these findings should be considered in light of the fact that a review process for measure submissions already occurs—albeit on a much more informal basis—in current CDP projects. Also, time needed for the upfront review may decrease somewhat as staff becomes more familiar with the process itself and

with the tools used in the process—particularly if the hand-off process from the upfront review to the remainder of project activities is improved.

Seventh, results of the evaluation suggest that the guidebooks developed for the pilot—particularly the sections that give examples of "What Good Looks Like"— would be a valuable addition to the educational materials provided to developers and steering committees going forward.

Eighth, the provision of earlier opportunities for feedback was shown to be at least somewhat successful during Stage 1 of the pilot project. Although only two organizations took advantage of this opportunity, the response indicates that at least some NQF member organizations would be interested in providing earlier feedback. Further, some of the feedback offered related specifically to measure specifications and to concerns around feasibility of data collection—feedback that might be particularly useful to developers who are putting forward true measure concepts and have not yet fully specified the associated measures.

Finally, the pilot also demonstrated that identification of competing and/or related concepts/measures can be done earlier in the CDP process than is currently the case. However, because the pilot is being implemented for only one full measurement cycle with back-to-back stages, the utility of earlier identification of competing measures and/or harmonization issues—for example, earlier collaboration between developers, effects on subsequent measure development, and potential avoidance of project delays—cannot be evaluated.

Implications for the 2-Stage Process and the CDP redesign

Several implications regarding the proposed 2-Stage process and the overall CDP redesign effort can be made based on the results of the evaluation of Stage 1 of the pilot project, as follows.

First, while there does seem to be value in allowing for review of measure concepts, the complete re-design of the CDP as a 2-Stage process to facilitate concept review seems ill-advised. Many of the measures that will be evaluated in future CDP projects have been previously endorsed (and thus are already fully specified and tested). For stewards of these measures, the 2-Stage process will actually increase the workload (i.e., two measure submission processes, two in-person meetings, two rounds of responding to comments), but without any of the attendant savings that could come from not having to specify/test measures that do not pass the Importance criterion. Similarly, while there would be savings in time and resources for NQF staff, steering committees, the CSAC, and Board when subsequent review against the remaining evaluation criteria in Stage 2 is not necessary, those savings would likely be offset due to the duplicative nature of the processes in the two stages, as well as to the required staff resources needed for the upfront technical review process.

Second, the benefits derived from the formal upfront technical review process do not appear to be worth the time and resources required. Although successful to some extent—particularly for developers new to the NQF endorsement process—the desired outcome of higher quality concept submissions did not automatically materialize as a result of the review process. Instead, the success of the review process seemed related more to the acceptance of the given feedback rather than to the existence or quality of that feedback. It remains to be seen whether the upfront technical review process in Stage 2 (where the bulk of the feedback likely will address measure testing) will improve measure submissions.

Third, the information required for the concept review and the criteria used to evaluate that information was not sufficiently in sync to provide proper feedback to the measure steward. Specifically, information regarding the numerator, denominator, and exclusions for the measure concept was adequate to flag potential issues around competing or related measures; however, because precise specifications were not required, it is unclear to what extent measure harmonization could be accomplished. The provision of some information on measure specifications did allow the Steering Committee to offer feedback on those specifications. However, if those specifications did not really adhere to the evidence as presented for the measure concept, there was no criteria available for the Committee to use to justify not recommending the measure (that specifications are in line with evidence is covered under criteria 2b, which is part of the Stage 2 evaluation).

Recommendations

Based on the findings of the evaluation of Stage 1 of the pilot, the following recommendations for CDP re-design and improvement are presented:

- **CDP improvement rather than CDP re-design**. As noted above, the pilot has thus far revealed several limitations in the proposed 2-Stage re-design. Most of the design components in Stage 1 that were successful can be incorporated into the existing CDP. These include the following:
    - Earlier opportunity for multi-stakeholder input prior to evaluation of measures by the Steering Committee
    - Use of the Steering Committee and Developer Guidebooks
    - Continued improvement of the measure submission form, incorporating many of the ideas from the Evidence Attachment
    - More consistent and earlier—but still informal—upfront technical review, using tools and lessons learned from the formalized processes implemented in the pilot
- **Allow for concept review.**
    - Look for ways to allow for concept review at any point in time—both within and outside of scheduled CDPs
    - Do not insist that concept reviews be conducted as part of a formal process
    - Do not require approval for concepts or passing of criteria
    - Do not require concepts reviews for fully-specified and tested measures
    - Provide technical assistance and recommendations as part of concept review
- **Continue to look for ways to allow for more timely and flexible review of fully specified and tested measures.**
- **Continue to explore implementation of standing Steering Committees.**
- **Continue to elicit feedback from all stakeholders regarding the CDP process.**

Appendix E: Consensus Process Model Criteria Elements

Comparative Model Criteria	Criteria Category	Focus Group Alignment
Comment	OMB Circular A-119	Member engagement
Vote	OMB Circular A-119	Member engagement and balance of interest
Process for attempting to resolve objections by interested parties	OMB Circular A-119	Achieving consensus
Comments fairly considered and each objector is advised of disposition	OMB Circular A-119	Achieving consensus
Have opportunity to change vote following review of comments	OMB Circular A-119	N/A
Consensus body defined	OMB Circular A-119	Process consistency
Openness	OMB Circular A-119	Member engagement
Balance of interest	OMB Circular A-119	Balance of interest
Due process	OMB Circular A-119	Process consistency
Appeals	OMB Circular A-119	Process consistency
Consensus	OMB Circular A-119	Achieving consensus
Process check/oversight	OMB Circular A-119	Process consistency
Quorum	Regulatory Requirement	Achieving consensus
Consumer purchaser emphasis	NQF must have	N/A
Consensus thresholds	NQF must have	Achieving consensus
Trigger for more robust hashing out	NQF must have	Achieving consensus
Consensus body formation (election/selection)	NQF must have	Process consistency
Consensus body balance of interests	NQF must have	Balance of interest
Review of criteria (who)	NQF must have	N/A
Technical review	NQF must have	N/A
Value to membership	NQF must have	Member engagement
Defined process for what happens if consensus threshold is not reached	NQF must have	Process consistency

Appendix F: NQF Staff Process Modeling-Explanation, Definitions, and Proposed Process Models

Technical Review Process

The technical review process is defined as a process to ensure an objective and consistent review for measure evaluation criteria (e.g. evidence, reliability, validity, eMeasure specs, etc.). The input from the technical review process **would not** serve as a recommendation for endorsement; instead, it would be provided to the consensus body as an objective rating of how the information provided in the submission form met or did not meet the NQF measure evaluation criteria. The purpose of this was twofold; first, to enable informed input on the measures from all stakeholders regardless of methodological expertise, and second, to allow the consensus body to make a recommendation on the measure without bias as relates to the measure evaluation criteria.

In the current process, technical review is done by a Steering Committee, composed of experts in a particular condition or topic area. The Committees are largely seated by clinicians with relevant expertise. However, during focus group sessions, members commented that the types of discussion and application of criteria by the Committees seems to vary widely, leaving members with the perception that there is a need for greater consistency in measure evaluation. Taking this into account, staff proposed four configurations for a technical review process; three were put forth in process models. The four different configurations for technical review are:

- Convene a technical, methodological expert panel
- Utilize peer reviewers (blinded process)
- Technical expert review (individual reviewers)
- Utilize a combination of NQF staff and consultants

Taking into account member comments outlined above and heard during focus group sessions, as well as staff assessment of feasibility of each of the technical review processes, the following three were utilized in proposed process models:

- Convene a technical, methodological expert panel: comprised of a stable of methodological experts who would meet to vet the measures based on the criteria
- Utilize peer reviewers (blinded process): staff would parse out relevant portions of measures for vetting by peer reviewers; evidence would be reviewed by evidence reviewers, reliability and validity testing by methodological experts, and usability/use and feasibility by users of the measure
- Technical expert review (individual reviewers): staff would send measures to reviewers with relevant topic expertise to the measure being vetted; reviewers would review the measure in its entirety as individuals rather than through a convened group activity

Consensus Body

The consensus body is defined as the group of individuals who make a preliminary vote and make the final decision to approve standards after reviewing all comments received. This is in line with the OMB Circular A-119 definition, which requires that "the consensus body members are given an opportunity to change their votes after reviewing the comments."[10] As defined in the current CDP model, the consensus body is the entirety of the NQF membership. However, as was heard from members who

[10] OMB Circular A-119, § 4(a)(1)(v) (1998).

participated in focus groups and evident in the pattern of declining participation in voting by the membership, this did not account for the reality that many members are not interested in or affected by measures in all clinical topic areas for which there are CDP projects. Taking this into account, staff proposed five different types of consensus bodies; however, only three were put forth in process models. The five different types of consensus bodies are:

- Entire membership as consensus body (current model)
- Subset of membership as consensus body
- Council leadership as representatives of the membership as consensus body
- Steering Committees as consensus bodies
- Elected subset of the membership as consensus body

Taking into account member comments outlined above and heard during focus group sessions, as well as staff assessment of feasibility of each of the consensus bodies, the following three were utilized in proposed process models:

- Subset of membership as consensus body: comprised of members who self-designate interest in a specific topic area or measure, or participate in the commenting period
- Council leadership as representatives of the membership as consensus body: council representatives would act as consensus body, with the chair and vice chair serving as voting representatives for each stakeholder council
- Elected subset of the membership as consensus body: NQF would call for nominations to seat members on the consensus body. Potential candidates would be submitted for member vote within a designated interest group, with individuals being elected by their interest groups to serve as representatives of their respective interest groups.

Balance of stakeholder interest within the consensus body

Balance of interest within the consensus body was an important theme heard during the focus group sessions. Members stated that under the current process, the differing constitutions of the Steering Committee, the membership as a whole, and the CSAC and Board of Directors resulted in the process feeling unbalanced as different perspectives were emphasized depending upon which body was reviewing the measure.

To address this, staff proposed two options for balancing interest within the consensus bodies. These are:

- Balance of interest using the current 8 council structure, with equal representation from each member council on the consensus body
- Balance of interest using categories adapted from ANSI accredited standard setting organizations, with equal representation from each interest category.

Balance of interest using the current 8 council structure utilizes the following stakeholder councils:

- Consumer Council
- Health Plan Council
- Health Professionals Council
- Provider Organizations Council
- Public-Community Health Agency Council
- Purchaser Council
- QMRI Council
- Supplier-Industry Council

Balance of interest using categories adapted from ANSI accredited standard setting organizations. The ANSI accredited standard setting organizations use the categories of user, producer, and general interest. This model proposes placing NQF members into one of three interest categories:

- Those being measured
- Those using measures
- Other interested parties

The process for designating member organizations into one of these interest categories would require consideration of the primary function of the member organization, as well as consideration of the organization preference of interest category and justification for that preference. **This effort has not yet been undertaken, and any strategy for assigning member organizations to these defined interest categories will be extensively vetted prior to implementation.** However, for the purposes of the models that use these categories to balance the interest of the consensus body, staff have placed stakeholder councils into the following categories:

Those being measured

- Health Professionals Council (100 member organizations)
- Provider Organizations Council (125 member organizations)

Those using measures

- Consumer Council (33 member organizations)
- Health Plan Council (19 member organizations)
- Purchaser Council (20 member organizations)

Other interested parties

- Public-Community Health Agency Council (30 member organizations)
- QMRI Council (80 member organizations)
- Supplier-Industry Council (40 member organizations)

Consumer/Purchaser/Patient emphasis

NQF as an organization was created with a vision to serve the consumer, purchaser, and patient. These voices had been underrepresented in the discussions around improving the quality and safety of healthcare delivery; NQF was created to serve as a platform for these stakeholders to provide input into the discussion and to make decisions about important drivers for improvement. Additionally, the number of organizations focused on the consumer, purchaser, and patient are small in number when compared with other stakeholders, reinforcing the need to ensure that these voices are heard. As such, all models preserve the emphasis on the consumer, purchaser, and patient voices.

Identification of when consensus is or is not achieved

Each proposed process model requires a quorum of votes by the consensus body members and a threshold for approval of a measure. This varies based on the composition of the consensus body; however, at a minimum a simple majority of the consensus body is required as quorum when voting on a measure, and a minimum of two-thirds of the consensus body must approve a measure for it to be endorsed. The specific quorums and thresholds for each model will be defined within the process model lay out.

Process for additional deliberation

Each proposed process model has a pathway for additional deliberation for measures where it is unclear whether consensus has been reached. This process is intended to be outside of the consensus development process and only utilized for measures where there is significant disagreement along stakeholder lines or when there is a vote for approval of a measure that results in greater than a simple majority of the consensus body approving but not at the threshold for consensus as defined in each process model. The triggers for this additional deliberation process will be defined with the process model lay out.

The additional deliberation process for each model will involve an opportunity for all objectors to provide concise statements of opposition/objection to the measure, a conference call open to the public for the consensus body to discuss the objections, and a second round of voting by the consensus body. If the threshold for approval is not met after the second round of voting, the measure will not be endorsed.

Public comment and member comment with support rationale

Each proposed process model has at least one, if not several, opportunities for the public to comment and the membership to comment while indicating support of the measure. As part of commenting, the membership will be given the opportunity to indicate support rationale of the measure with the following statements:

- Support
- Can live with
- Do not support

Each model utilizes a comment period prior to the consensus body preliminary endorsement recommendation, to allow for member comment and indication of support to inform the endorsement recommendation. This was proposed in response to focus group input stating the importance of earlier member commenting to inform endorsement recommendations.

Oversight Committee to ensure process was followed

The Oversight Committee would be no more than 5-7 individuals independent of the elected consensus bodies and Board of Directors who were knowledgeable of the CDP and from member organizations of NQF. NQF staff would provide input and materials to demonstrate that the process was followed, quorums and consensus thresholds were met, and all comments adequately adjudicated. In addition, NQF staff would propose modifications to the CDP based on experience to this committee for their discussion and approval and subsequent approval by the NQF Board of Directors. These proposed modifications would be made on an annual basis with a set timeline for implementation that is published on the NQF web site.

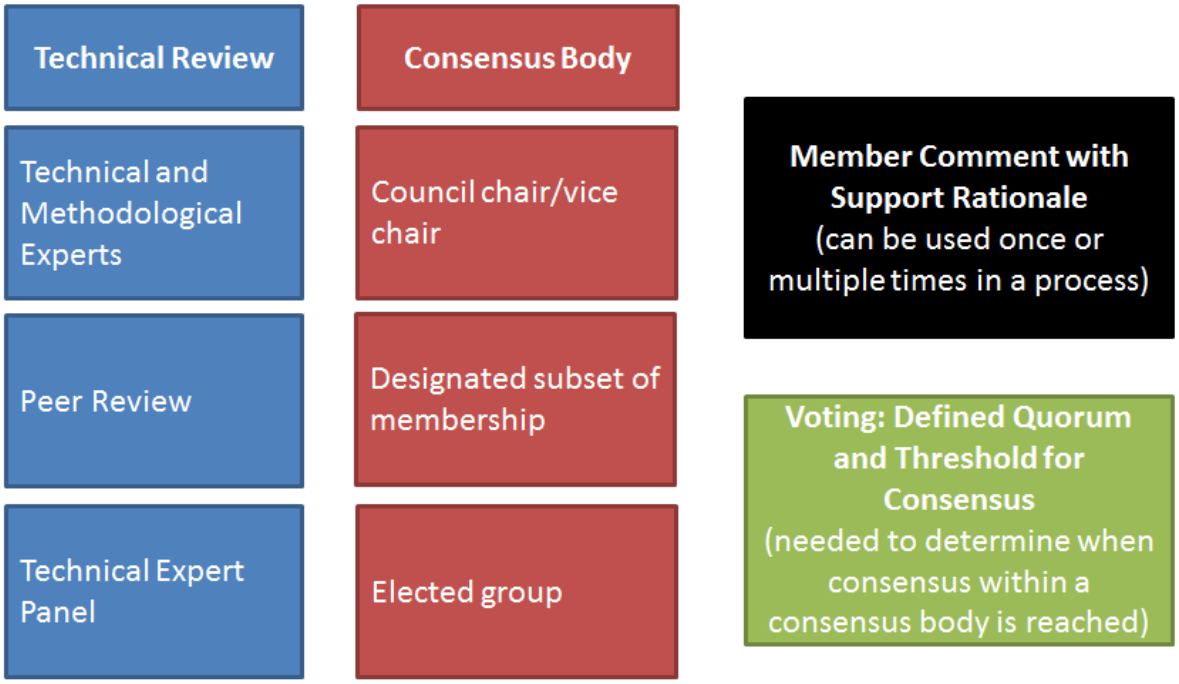
Appeals process

NQF's Board of Directors will hear appeals of endorsement decisions. Any interested party may appeal these decisions solely on the basis that process was not followed. Appeals must be submitted in writing with the grounds for the appeal clearly stated. NQF staff will review each appeal and then forward the appeal and an analysis of the appeal to the Board of Directors. All appeals will be decided based on the written materials submitted. The Board of Directors will issue a written decision on each appeal.

NQF Staff Proposed Process Models

By first combining a technical review process with a defined consensus body, staff were then able to build out three process models that satisfied the OMB Circular A-119 requirements, addressed input from the focus groups, and met the key areas of importance for NQF.

Figure 2: Building Blocks for the Proposed Process Models



Several assumptions underlie all proposed process models:

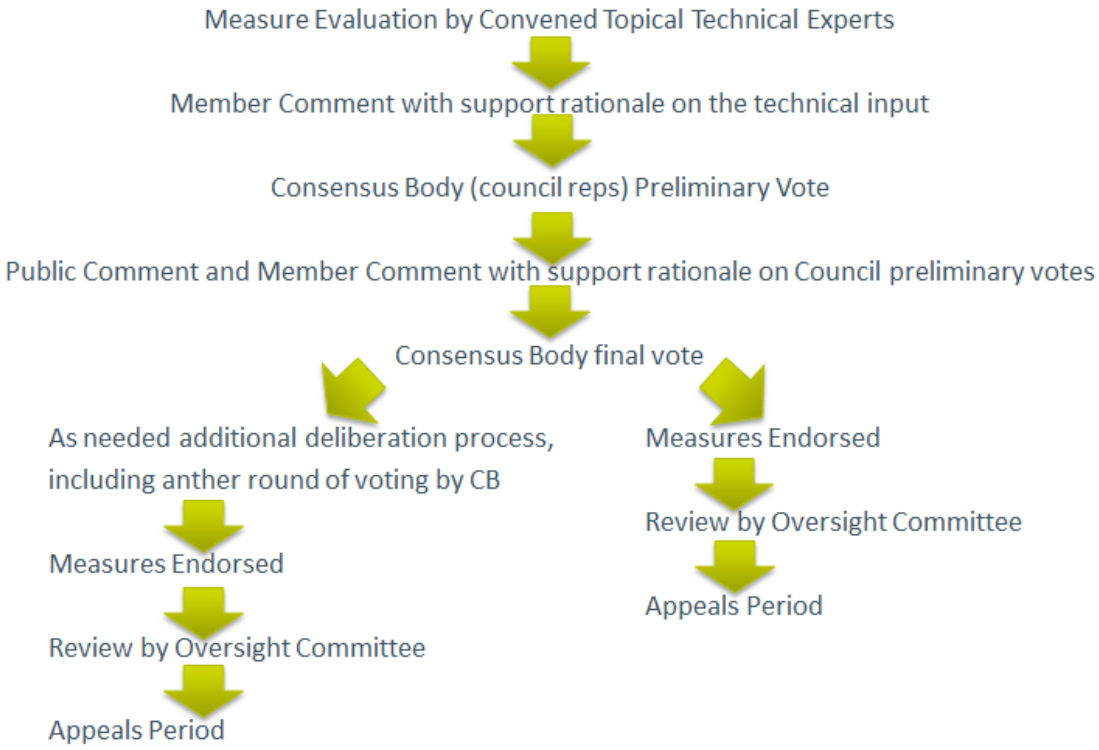
- There is flexibility in selecting features to create a model; the models proposed can be altered in many different, logical ways
- The models proposed eliminate the current roles for endorsement recommendation and ratification by the CSAC and BOD; this was done to streamline the process.
    - Consumer/Purchaser/Patient voice was built into the models to mirror these roles since they are not included
- It is critical to have input and buy-in from all of our membership for the process models to function as intended
- Any proposed model requires a culture change in NQF's member engagement strategy across the organization- needs to be strengthened and broadened
- Any proposed model requires engagement from the membership throughout the entire CDP process
- Further exploration is needed to operationalize a new process and to establish potential timelines for the process

Council-based Model

The council-based model defines the consensus body as the chair and vice chair serving as voting representatives for each stakeholder council. To balance stakeholder interests, this utilizes the current 8 member stakeholder council structure with equal representation from each member council.

The technical review process selected for this model is the convened technical, methodological expert panel. This panel would be comprised of a group of technical, methodological experts with relevant expertise to the measure topic who would meet to review the measures against the measure evaluation criteria.

Figure 3: Council-based Model Flow



This model contains two opportunities for members to comment with support rationale and one public commenting period.

Voting Quorum and Threshold for Approval:

- Preliminary Vote
  - Quorum: All councils must submit preliminary votes
  - Threshold: Not required
- Final Vote
  - Quorum: All councils must submit final votes
  - Threshold: 6/8 councils must approve, including the consumer and purchaser councils

If the threshold for consensus is not met during the final vote, the trigger for the additional deliberation process would be approval of the measure by 4 or more councils.

Designated Subset of the Membership Model

The designated subset of the membership model defines the consensus body as a self-designated subset of the membership. Members self-designate interest in a given topic or measurement area through an enhanced member engagement strategy, and/or by participating in the first round of comment with support rationale.

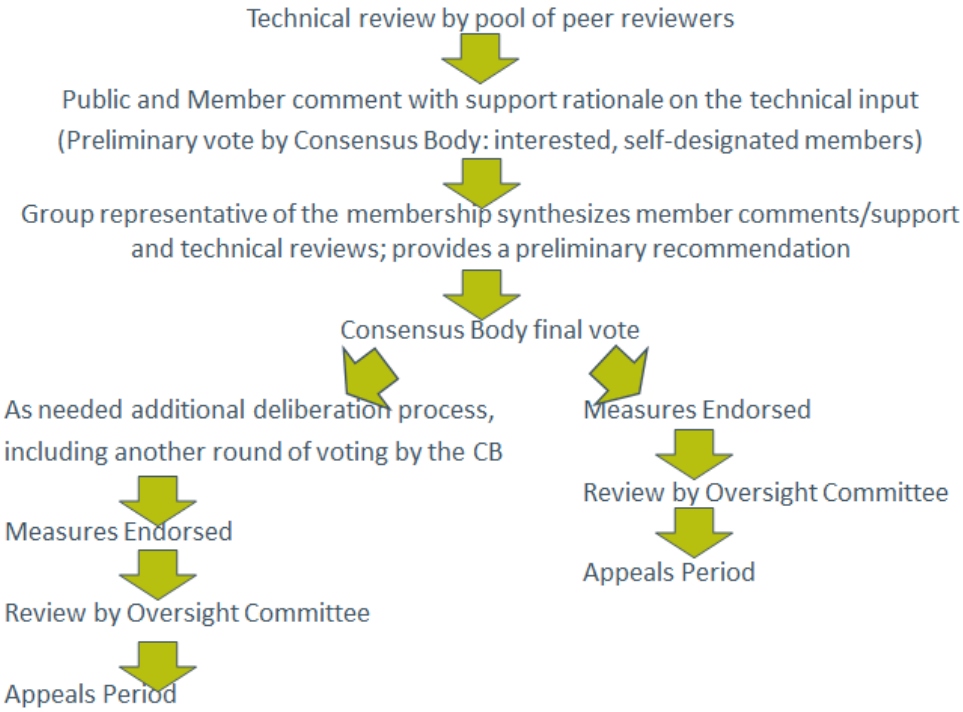
To balance stakeholder interests, membership will be categorized into three different interest categories, adapted from ANSI accredited organizations detailed earlier in this paper:

- Those being measured
- Those using measures
- Other interested parties

The technical review process for this model is use of blinded peer review. The peer reviewers would be responsible for one section of the criteria based on their expertise (i.e., evidence would be reviewed by evidence rating experts and clinicians; scientific acceptability would be reviewed by methodologists; usability/use and feasibility would be reviewed by end users of the measure).

Because the consensus body is composed of the membership who indicate an interest in the topic area, it would not be feasible to convene this entire group, which may vary based on measure or topic area, to synthesize information and respond to comments. As such, there is a need for a group to collate the various inputs for the measures and provide a preliminary recommendation for the self-designated members of the consensus body to vote on. This model proposes that a group representative of the membership would serve to synthesize member preliminary vote and comments with the technical peer reviews and provide that preliminary recommendation.

Figure 4: Designated Subset of the Membership Model Flow



This model contains two opportunities for members to comment and vote, and one opportunity for the public to comment.

Voting Quorum and Threshold for Approval:

- Preliminary Vote
  - Quorum: Not required, as the designated subset would be defined at this point
  - Threshold: Not required
- Final Vote
  - Quorum: 51% of the consensus body must vote
  - Threshold: 2/3 interest categories must approve, including the "those using measures" category

If the threshold for consensus is not met during the final vote, the trigger for the additional deliberation process would be approval of the measure by 4 or more councils. If the threshold for approval is not met after the second round of voting completed during the additional deliberation process, the measure will not be endorsed.

Elected Subset of the Membership Model

The elected subset of the membership model defines the consensus body as a group of elected peers serving as representatives of their interest groups. The consensus body would be seated first with NQF posting a call for nominations to seat members on the consensus body. Potential candidates would be submitted for member vote within a designated interest group, with individuals being elected by their interest groups to serve as representatives of their respective interest groups.

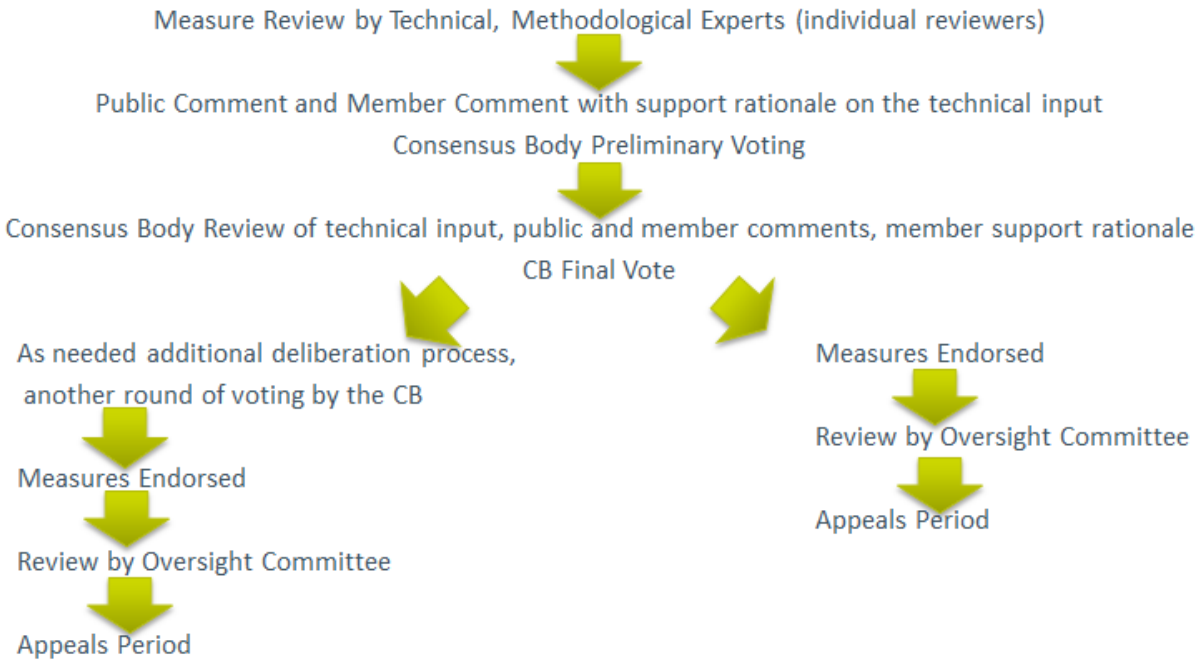
To balance stakeholder interests, membership will be categorized into three different interest categories, adapted from ANSI accredited organizations detailed earlier in this paper:

- Those being measured
- Those using measures
- Other interested parties

The technical review process for this model utilizes technical expert review (individual reviewers). Staff would send measures to reviewers with relevant topic expertise to the measure being vetted; reviewers would review the measure in its entirety as individuals rather than through a convened group activity.

This model proposes that the members, the public, and the consensus body all be provided with the technical review of the measure. At this time, the public will comment on the measures, the members will comment on the measures and provide support rationale, and the consensus body will provide preliminary votes on the measures. This is different from the other models which allow for public comment and member comment with support rationale to occur prior to consensus body preliminary votes; this was proposed as a method to streamline the process.

Figure 5: Elected Subset of the Membership Model Flow



This model contains one opportunity for member comment with support rationale, and one opportunity for public comment.

Voting Quorum and Threshold for Approval:

- Preliminary Vote
  - Quorum: 75% of the consensus body must vote
  - Threshold: Not required
- Final Vote
  - Quorum: 75% of the consensus body must vote
  - Threshold: 2/3 interest categories must approve, including the "those using measures" category

If the threshold for consensus is not met during the final vote, the trigger for the additional deliberation process would be failure to approve the measure by the "those using measures" category AND at least 51% approval of the consensus body members. If the threshold for approval is not met after the second round of voting completed during the additional deliberation process, the measure will not be endorsed.