Assessment of the National Quality Forum's Consensus Development Process

Final Report

December 2010

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EXECUTIVE SUMMARY

Project Purposes and Methods

This project sought to provide formative feedback on the Consensus Development Process (CDP)—the means that the National Quality Forum (NQF) uses to engage diverse public and private stakeholders to reach consensus on ways to operationalize, measure, and publicly report on national priorities for health care system performance. The assessment was conducted by Mathematica Policy Research under contract from NQF.

The assessment examined the timeliness, efficiency, and effectiveness of the CDP with a view toward identifying its strengths and weaknesses and where it might be improved. The assessment was based on three types of data and analysis:

- **Technical Process Analysis.** This analysis addressed the questions of how the CDP currently works and how the approval process functioned from 2008 through early 2010. We reviewed NQF's administrative records to learn how the process operates through its various stages and spoke with NQF staff to fill in gaps in the written record.
- **Stakeholder Analysis**. This analysis addressed the more qualitative yet critical issues associated with how different stakeholders (those more active or less active in the process) view the CDP. Through structured one-on-one discussions, we determined stakeholders' views on the current process, as well as those elements that should be retained, changed, or discussed further.
- **Scan of Comparative Alternatives.** The scan's goal was to provide an overall context for NQF as it considers changes in the CDP. We conducted both a general environmental scan of various types of evidence-based and collaborative processes and a targeted review and comparison of four examples of other consensus development processes having features that could provide insight into the NQF process.[1]

The key strengths of the assessment are its scope; use of multiple sources, information, and perspectives; and its focus on relatively current experience with the CDP. The methods used show the way the process should work, how it actually has worked, and how different stakeholders perceive it to work—three perspectives that may not always align fully with one another, especially as the external environment shaping the CDP and the CDP itself continues to evolve. In response, NQF continues to modify and make incremental changes in the CDP.

[1] They included: (1) The United Kingdom's (UK) National Institute for Health and Clinical Excellence (NICE) and its Centre for Public Health Excellence; (2) the Financial Accounting Standards Board (FASB) and Governmental Accounting Standards Board (GASB); (3) the U.S. Preventive Services Task Force (USPSTF) administered within the Agency for Healthcare Research and Quality (AHRQ), and (4) the American National Standards Institute (ANSI).

Key Findings

Most stakeholders viewed the CDP as working reasonably well overall, although they identified areas for improvement. Almost universally, those familiar with the CDP process in the past said that it had improved over time and was likely to improve further due to changes recently enacted or under development. Overwhelmingly, stakeholders saw the CDP's multi-stakeholder and open process as its key strength. A few stakeholders were more critical, although they acknowledged the CDP's strengths.

The analysis provides insight on performance related to the goals of timeliness, efficiency, and effectiveness, as well as opportunities for further improvements.

Timeliness of the CDP. The CDP cycle for an individual project varies substantially, with the average completed project taking about a year from initial to last steps. Stakeholders were split about how they viewed the current timeline, with half unequivocally perceiving it as too slowly paced and the rest feeling that it was about right. For the most part, stakeholders agreed with the steps in the CDP but wanted them to move more quickly. Our technical analysis of the process suggests some ways in which the timeline could be shortened. More dramatic change would require more fundamental revisions in the process.

Efficiency of the CDP. For the assessment, we defined the efficiency of the CDP in terms of how the processes it employs support transparency through its website and the use of reasonably easy means for stakeholder engagement. As to transparency, our analysis shows an improvement over time in the completeness of material posted on the public website, with more recent projects being more fully documented. Gaps in available information remain, however. Some stakeholders said that it was not always easy to find or use available information, so there is still room for improvement. As to ease of participation, we find that the CDP provides multiple opportunities for stakeholder participation, with stakeholders almost universally viewing the process as open to them. The CDP is a labor-intensive process, however, and there are ways NQF could further enhance ease of member participation.

Effectiveness of the CDP. We assessed effectiveness based on the CDP's ability to generate credible endorsements across projects, viewed mainly from the point of view of stakeholders. Through the CDP, the NQF has endorsed a large number of standards. Such endorsement is not automatic, with 19 percent to 90 percent of submitted standards endorsed in individual projects. Stakeholders viewed the addition of the Consensus Standards Approval Committee (CSAC), a standing committee of the Board overseen by the CDP, as working well. However, they said that the work of individual project steering committees is uneven across projects, showing some gaps in skills. Interviewees also noted that the CDP's effectiveness at times is limited by the number of available measures submitted for consideration. While it was beyond the scope of this assessment to examine the ultimate use of endorsed measures and their subsequent impact (which is the focus of other studies), interviewees also noted that the effectiveness of the CDP ultimately depends on such uses and impacts.

Insights from Comparative Analysis. We examined critical characteristics of several other consensus processes for potential insight into the CDP. We found similarities and differences in the goals of their organizational processes and how they structure these processes. As with NQF, each process incorporates projects that vary in their complexity and scope. Average timelines are lengthy and variable by project. All processes have faced issues of balancing scientific evidence and feasibility but handled them in different ways. Some organizations aim to eliminate conflicts,

whereas others, like NQF, aim to manage them. The organizations also differ in the level of resources available to support their work. Compared to others, NQF appears to have less independence and flexibility in planning its work and allocating funds. It also relies more heavily on volunteers and less on external analysis to support its committees' work. Thus, some issues faced by CDP are generic to consensus processes and can benefit from the experience of other organizations.

Conclusions and Recommendations

The assessment indicates that NQF's CDP is recognized as an important vehicle to achieve consensus on standards for supporting the nation's public reporting and quality improvement in health care. Stakeholders of different types perceive NQF as occupying a unique position in the "quality marketplace," with its processes allowing diverse interests and stakeholders to come together openly and transparently to make decisions about the metrics guiding societal efforts to measure and track health care system performance.

To support its work, we recommend that NQF and its stakeholders continue to refine and strengthen the CDP in ways that will enhance its ability to generate timely, efficient, and effective analysis and endorsements of standards.

Timeliness. While the CDP has defined steps and agreed upon timelines for specific tasks, there appears to be no consensus on how long the process *should* take overall, particularly as to alignment with the external demands on various stakeholders seeking to make use of endorsed measures. We recommend that participants review the findings of this assessment with respect to the timeline of the CDP and consider how best to align the process with the needs of participants and the constraints of those external processes using CDP-endorsed measures. Such a review would also be timely, given the shift to batched "best in class" review, since this change likely will call for modification of certain procedures.

Efficiency. Given its goals of transparency, NQF should continue its efforts to use its website to provide public information on its projects, their statuses, their results, and the rationale for those results. By increasing the consistency with which information is reported across projects and making written materials easier to locate and use, NQF can reduce the burden of participation on members and support member councils in involving members more fully. NQF also should continue to clarify its written policies and procedures, such as those relating to steering committee size and composition.

Effectiveness. The credibility of the CDP depends in large part on how well its members and other audiences perceive the way the review applies the diverse criteria relevant to endorsing measures. Through the CSAC, NQF has been working to develop clearer guidance and operational support for applying review criteria. Such efforts need continued priority in terms of development and effective implementation. We also recommend that NQF consider how to expand the analysis and expertise available to steering committee members in assessing proposed measures against criteria to identify "best in class" measures.

More broadly, we recognize that the policy environment is in transition. The Accountable Care Act (ACA) emphasis on national health reform and the Administration's pursuit of the "triple aim" are likely to enhance the relevance of NQF work while altering the environment in ways that will influence the demand and use of endorsed standards. Our assessment of the CDP must be considered in the context of these changes, with a view toward identifying how best to strengthen and position it for the future.

I. OVERVIEW OF PROJECT AND APPROACH

A. Overview of Goals

The Consensus Development Process (CDP) is central to the mission of the National Quality Forum (NQF). The voluntary consensus standards resulting from the CDP provide a means of developing consensus among stakeholders on how to put in place, measure, and publicly report on national priorities for the performance of the health care system. With the implementation of health reform and other emerging initiatives nationwide, NQF's priority setting and endorsement agenda will play an increasingly important role. It will therefore be important that the CDP be as effective and efficient as possible in support of this work.

This project assesses the timeliness, efficiency, and effectiveness of the CDP in order to provide formative feedback on how the CDP is working now and where it might be improved. For reasons articulated elsewhere (NQF 2009; IOM 2001), quality measurement and the subsequent use of standards for public reporting and quality improvement have become increasingly central to national health care policy and reform. This environmental context has over time shaped, constrained and expanded NQF's role. The amount and diversity of activity focused on performance measurement has expanded, and NQF's role has become increasingly central. Under the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), the Centers for Medicare & Medicaid Services (CMS) now uses NQF's measures for the Physician Quality Reporting Initiative (PQRI). As CMS has become committed to using NQF measures, other groups, such as the Ambulatory Quality Alliance, have decided to cease endorsement of quality measures on their own.[2] Recently enacted national health reform legislation contains several provisions for enhancing quality and controlling costs that will depend on sound performance measures (KFF 2010). The provisions are likely to create demand for NQF to focus on an increasingly broad set of measures to support major reforms. NQF is already planning to remain flexible and look ahead, as illustrated by its current work analyzing measures relevant to different modes of payment reform.

B. NQF Context

The CDP assessment recognizes NQF's characteristics, potentially competing needs, and long-term goals, as follows:

- Governance as a **complex public/private partnership** with over 400 member organizations that reflect a diversity of interests (for example, eight member councils). The credibility of NQF's CDP depends on the belief by all organizations that their interests have been acknowledged and that no one organization dominates.
- Authority enhanced by recognition as a **consensus body** under the National Technology Transfer and Advancement Act of 1995 (NTTAA) and OMB Circular A-119, both of which provide the authority needed for NQF to broker the public/private partnership effectively. (Any modifications to the CDP must allow NQF to retain its recognition under NTTAA.)

[2] For additional detail, see http://www.cms.hhs.gov/PQRI/Downloads/CMS_1413_P.pdf. See also http://input.qualityforum.org/docs/senate_07_09_08.pdf.

- **Broad scope of concern.** The CDP is relevant to a range of consensus projects whose end products include measures, frameworks, sets of practices, and explanatory text and documentation.[3] The content of individual CDP projects also is diverse, with a broad scope that covers the the range of interests identified in the Institute of Medicine's (IOM) landmark Quality Chasm report (IOM 2001) and address six key areas identified by the National Priorities Partnership (2008). This broad scope creates a large and growing workload for NQF overall and for the CDP as part of it. The CDP must cover a wide range of interests and expertise.

- **Inherent tensions** associated with NQF's funding streams and diversity of member organizations.[4] The priorities set by NPP aim to provide a shared vision of direction. However, differences persist; that is, some stakeholders, like providers, have a unique vision and a much greater stake in measure development than do other stakeholder groups. NQF views its role as managing, not eliminiating conflict. Historical funders of NQF have an obvious interest in having NQF pay swift attention and take positive action on their particular priorities, which may not be the same circumstance for other stakeholders and NQF partners. This was a bigger issue before NQF had access to HHS funding than it may be now.

C. Overview of Approach

This project has two phases, with this draft report summarizing the findings and conclusions from the first phase of that work. In phase 1, we completed three interrelated sets of analyses:

- **Technical Process Analysis.** The analysis addressed the questions of how the CDP currently works and how the approval process functioned in 2008 through early 2010. We reviewed NQF's administrative records to learn how the process operates as it moves through its stages, and spoke with NQF staff to fill in gaps in the written record.

- **Stakeholder Analysis.** The analysis addressed the more qualitative yet critical issues associated with the way different stakeholders (those active and those less active in the process) view the CDP. Through structured one-on-one discussions, we determined stakeholders' views on the current process as well as elements that should be retained, changed, and open to debate.

- **Scan of Comparative Alternatives.** The goal of the scan was to provide an overall context for NQF. We conducted both a general environmental scan of various types of evidence-based and collaborative processes and targeted review and comparison of four specific orgniazations with consensus processes that had features that could provide insight into issues of concern to NQF.

[3] The CDP does not apply to the full range of NQF activity, but only to those activities for which formal consensus is required.

[4] For much of its history, NQF has been constrained by the absence of a dedicated and flexible funding source, relying instead on a patchwork of public and private grants to complement member dues. Under authority of MIPPA, NQF now receives annual funding from the U.S. Department of Health and Human Services (HHS) to establish a portfolio of quality and efficiency measures.

Table I.1 summarizes the questions addressed by each of these analyses and subsequent work. Table I.2 provides additional detail on how the three analyses we have conducted together support our assessment of the performance of NQF's CDP against three criteria—timeliness, efficiency, and effectiveness (in terms of quality). We looked across the CDP and by each step in the process to identify areas where change is most desired. Based on this review, we identified aspects of the CDP that seem to perform well and areas that might benefit from improvement, including options that may be suggested by the analysis.

Table I.1. General Questions of Interest

Three Components of the CDP Analysis
Technical Process Analysis. How does the CDP generally work, and how did it work for specific projects recently under review (for example, timelines and steps in the process that seem most amenable to efficiency improvements, issues that have arisen, and process implications)?
Stakeholder Analysis. What do diverse stakeholders currently view as the strengths and weaknesses of NQF's CDP? What types of changes do they see as valuable or unacceptable? What concerns must be addressed by any change?
Scan of Comparative Alternatives. What can we learn from examining the literature that will be useful in evaluating and improving NQF's CDP? What can we learn from looking at other evidence-based processes involving multiple stakeholders, especially any complex processes with requirements similar to those of NQF?
Overall Evaluation and Suggestions for Change
Given the findings of the analysis, what are the strengths and weaknesses of NQF's current CDP? Which areas or issues appear relevant for possible improvement, and what options might be considered?
From the findings and reactions of NQF staff and key leadership of CSAC, what are the most important areas for changes that we recommend for NQF's consideration? What alternative options exist to address these areas and what are the advantages and disadvantages of each?

This report reflects processes in place over the time period studied, as well as how they were perceived externally. CDP continues to evolve. Some specific details discussed have subsequently been modified. However, we believe the assessment provides a generally current overview of the CDP today.

D. Report Organization

This report is organized in five chapters. Following this introductory chapter (Chapter I), we provide an overview of how the CDP process works, which projects fell within the time period and criteria for our assessment, and our general approach with stakeholders (Chapter II). We then provide a detailed assessment of the performance of the CDP against key goals relating to timeliness, efficiency, and effectiveness (Chapter III). The analysis in chapter III is based both on the technical process analysis and on the stakeholder interviews. In Chapter IV, we summarize the findings from the comparative analysis of alternative consensus development processes and identify relevant insights and potentially applicable lessons and options for the CDP. Finally, in Chapter V we summarize the key findings and conclusions from the analyses, and provide an initial review of areas the study suggests may be most valuable for future focus. Appendices provide additional documentation on the findings and methods used in this work.

Table I.2. Key Dimensions for Assessing CDP Performance and Relationship to Analytic Components

Criteria for Assessing CDP Performance and Application to Specific Analyses	**Timeliness.** How long does it take? Where is most time lost relative to requirements? How variable is experience across projects and why? Is timeliness getting better or worse? Does the whole process from start to finish seem to take a reasonable amount of time? If not, what or are the barriers or issues?	**Efficiency.** Is it staff- and user-friendly and not unduly burdensome? Is it transparent? Are staff resources being used efficiently to move the CDP forward in a meaningful way?	**Quality/Effectiveness.** Are topics and measures well bundled and focused within projects? Do reviewers have the needed mix of skills? Is CDP achieving what stakeholders expect or want from it?
Technical Process	Total and average time, where extra time is spent (versus mandated steps), variability across projects and over time	Mathematica's analysis of the completeness of documents on the web and ease of use; feedback from staff supporting the process on their experience and perceptions	Nature of comments that shed light on how stakeholders view projects and their assessments of different steps in the process
Stakeholder Interviews	Perceptions of timeliness and variability by stakeholder type	Views on ease of using website, understanding materials, conveying concerns	Perceptions of the quality of call, review, and resulting endorsement; perceptions of the skill set and orientation of people involved at NQF and on panel
Scan of Comparative Alternatives	How CDP compares to others with regard to structure, timing, and user perception	Ways other processes involve stakeholders in review and demands on them; how NQF's processes and use of resources compare to others	Perceived quality of review and outcomes (by a limited group); value of the products in terms of size and scope relative to resource inputs

II. HOW THE CONSENSUS DEVELOPMENT PROCESS WORKS

Although the CDP has evolved over time, we are not providing a historical review of the process development. Instead, this project focuses on assessing how the CDP process worked as it functioned in early 2010. For this purpose, we focused operationally on projects that were initiated in 2008 or later. In this chapter, we review the way the CDP worked over the period of our assessment, along with selected changes that are being introduced or considered. We then describe the criteria used to identify relevant projects over the time frame of our assessment and their characteristics. In the last section, we provide an overview of our key stakeholder interviews and their general thoughts on the current process overall to serve as context for the more detailed assessment that follows in Chapter III.

A. Description of the Current CDP

We base our description of the CDP on a review of documents on NQF's website and subsequent discussion with NQF. Following its evolution over the past 10 years, the current version of the CDP (version 1.8, approved May 9, 2007) uses nine steps that adhere to the five key elements of a voluntary consensus process for standards development as specified by NTTAA: openness, balance, due process, consensus, and an appeal mechanism (NQF 2009). OMB Circular A-119 defines consensus as "general agreement, not necessarily unanimity" so that attempts may be made to resolve objections and members have an opportunity to amend their votes after reviewing comments.

The CDP used by NQF is based, as many such consensus development processes are, around specific projects. These projects support a process designed to result in NQF endorsement of standards for monitoring and public reporting on the performance of the health care system on a specified topic. Such standards include frameworks, practices, measures, and their associated definitions. Once a project is approved for consideration, NQF's CDP triggers a multistep process that provides a structured opportunity for the engagement of diverse stakeholders and the public at each stage. In general terms[5], key steps in the CDP include the following:

1. **Call for Intent to Submit Candidate Standards.** NQF issues a public notice to advise stakeholders that a consensus development project is set to begin. The public notice describes the upcoming project and asks measure stewards to notify NQF if they plan to submit specific standards for consideration. This step was added to the process in April 2009 to make sure that the expertise of the project steering committee that is formed (see step 2) is aligned with the types of standards submitted.
2. **Call for Nominations.** NQF elicits suggestions for the membership of the steering committee that will oversee the technical review of candidate standards. Members of the steering committee are typically NQF members who are selected on the basis of their expertise and with the goal of balanced perspectives. Nominations may be submitted during a 30-day period, after which a draft roster is posted to NQF's website. Within the past year, NQF has provided the public and NQF members with a 14-day period in which to comment on the roster prior to finalizing the committee. Some projects also

[5] The CDP is an evolving process that has been refined over time. However its essential features follow this model.

have convened one or more technical advisory panels (TAP) to provide expert input though this mechanism is used less now as expertise is incorporated directly onto the steering committee. This step may occur concurrently with the call for candidate standards, but it may also precede both the intent to call for standards and the call for candidate standards. The purpose of doing so would be to allow the committee to assist in developing the calls for standards.

3. **Call for Candidate Standards.** The two types of calls for standards are calls for practices and calls for measures. A call for practices typically occurs when few—if any—measures are likely to exist in a given topic area and so will precede a call for measures. Anyone may respond to the call for standards, but each submission requires a steward who assumes responsibility for the measure and its update. Stewards who do not respond to the intent to submit standards may still respond to the call to submit standards. Before implementation of the intent-to-submit candidate standards, this was often the initial step, though sometimes occurred simultaneously with the call for nominations.
4. **Candidate Consensus Standards Review.** The steering committee, and any technical advisory panel(s), typically meets several times by telephone and once in-person to review submissions. NQF staff also review submissions and bring any issues to the attention of the steering committee's chair and co-chair. All steering committee and TAP meetings are open to the public.

Standards must first pass the following threshold requirements to be considered:

- A signed measure steward agreement must be in place for a non-governmental organization.
- Measure owners must verify that they are responsible for and will update measures.
- Measures must include their intended use for both public reporting and quality, not only for the latter, as was sometimes the case in the past.
- Measure submission form(s) must be complete

If submitted standards meet these requirements, the steering committee evaluates them in accordance with the criteria discussed in detail below. The steering committee either sends the standards on for further consideration, suggests modifications to the measure developers/stewards, or rejects the measures.

In August 2008, NQF adopted **new evaluation criteria for standards** in order to create (1) stronger links to priorities, (2) strengthen the emphasis on standards reflecting outcomes rather than processes of care, and (3) sharpen the focus on composites (Farquhar and Marinelarena n.d.; Burstin 2009). With these changes, current criteria now include:

- **Importance.** In reviewing any proposed standard, the steering committee will review evidence of a standard's importance not just technical soundness. For a standard to be approved, the steering committee must deem it important to the broad topic at hand and worth potential resources. Importance refers to the ability of a standard to make a difference by emphasizing aspects of care that are consistent with national priorities and also amenable to change. This "must pass" requirement is designed partly to weed out easily achieved measures that tend to

cluster at high levels of performance, making it difficult to distinguish the quality of providers. However it also addresses other concerns, including an emphasis on standards where practices vary and high costs may apply.

- **Scientific Acceptability.** NQF defines specific properties for judging acceptability of specified standards as reliable and valid performance standards that distinguish good from bad care. It also discourages exclusions of patient subgroups in measure definition because exclusions make it difficult to meet other goals.
- **Feasibility.** NQF places emphasis on the ability to rely on IT to construct a standard without causing undue burden. It prefers data that are collected as part of the care process and that are either electronically available or close to becoming so.
- **Usability.** NQF is looking for greater emphasis on harmony of standards. NQF's view is that it should not spend resources on the review of standards intended only for quality improvement if they are not to be publicly reported in some form. NQF also is placing new emphasis on the endorsement of composite measures that combine multiple dimensions of some aspect of performance.

5. **Comment Period by Public and Members.** The steering committee makes its report and recommendations available for review by the public, each member organization, and all eight member councils.[6] Members have 30 days for review and comment, and the public has 21 days (both reviews begin at the same time). NQF staff respond to every submitted comment and post their responses on the website. The steering committee uses the comments to make any revisions to its report. In the event that it makes major changes to the report, the steering committee may re-circulate the report. Based on public comment, measure specifications may be modified or the steering committee may change its decision to recommend endorsement or rejection of a given standard.
6. **Member Voting.** After the steering committee has reviewed comments and finalized its report and recommendations, each NQF member organization has an opportunity to vote on its recommendations; members vote for or against each standard that the steering committee has recommended for approval. Voting takes place over a 30-day period. The consensus process does not require unanimity, though it must involve a process of communication and attempts to resolve differences. Approval is based on a simple majority.
7. **Consensus Standards Approval Committee (CSAC) Decision.** The CSAC, one of three major standing committees, is responsible for reviewing all recommended standards after public and member comment and voting by NQF member organizations to make decisions subject to board ratification.[7] CSAC's members, appointed by the

[6] NQF expanded its member councils from four to eight in 2007. They include consumer, health plan, health professional, provider organization, public/community health agency, purchaser, quality measurement, research and improvement, and supplier and industry. A chair and vice chair oversee each council.

[7] CSAC was established in December 2006 as part of a revision of NQF's governance and committee structure. The chair and vice chair positions rotate annually and seek to balance consumer and provider perspectives, along with

NQF board, have expertise in performance measurement and quality improvement and represent the various perspectives of NQF member organizations. CSAC decisions guide NQF's board on the endorsement of standards. The CSAC votes on whether to recommend endorsement of each standard. It reviews the steering committee's recommendations and member votes, disaggregating votes by constituency and council. CSAC members serve a two-year term (renewable for an additional two years), with a staggered rotation. The committee includes representatives from the member councils and is structured so that members viewed as representing the interests of "consumers and purchaser" hold a simple majority.[8] CSAC meets three times a year in person and regularly by conference calls. NQF members and the public may comment at these meetings.

8. **Board Ratification**. Formal endorsement of a standard occurs once the board approves it. The board usually, though not necessarily always, follows CSAC's decision.
9. **Appeals.** Consistent with NTTAA, any interested party may appeal an endorsement decision to NQF's board. Appeals must be filed within 30 days and provide direct evidence that an endorsed standard directly and materially affects the appellant's interests. Appeals also appear on NQF's website for evaluation against scientific evidence. Appeals are reviewed by CSAC and CSAC then makes a recommendation to NQF's board. The board consults with CSAC and must act on the appeal within 30 days.

Historically, NQF has had no dedicated funding source, so the content of its projects was heavily driven by the interest and financing of external entities such as CMS, the Robert Wood Johnson Foundation (RWJF), or others. Based on requirements in MIPPA 2008, HHS now contracts with NQF for a broad set of activities that are defined on an annual basis.[9] With this core funding from HHS, NQF and HHS are now working jointly to establish projects that address national priorities. The infusion of HHS funds has stabilized the finances of NQF and allowed it to expand.

B. Changes Currently Being Considered or Introduced

The structural changes introduced at NQF in 2007 established the CSAC to strengthen the CDP and enhance the evidence base and expertise available to the review process. However, while major changes in the CDP have not been made over the recent period studied, the CDP continues to evolve. The current assessment findings reflect changes introduced since 2007, but not those just

(continued)
the perspective of others. In addition to its endorsement role, CSAC serves in an advisory capacity to the board and NQF staff on issues associated with enhancements of the CDP and other measurement issues.

[8] Recent analysis by NQF, prepared as background for the October 16, 2009, meeting of NQF's board, highlights the fact that, while significant splits by interest group are rare, stakeholder interests may differ and create challenges for building a multi-stakeholder consensus (Board Materials, Tab 3). Such an event occurred with the recent review of the Leapfrog Survival Predictors (Board Materials, Tab 1). (See http://www.qualityforum.org/About_NQF/Board/Board_of_Directors_ Meeting__October_16, 2009.aspx.)

[9] The four year contract covers the period January 14, 2009 through January 13, 2013 to support five duties: (1) recommendations on a national strategy and priorities; (2) endorse quality measures; (3) maintain endorsed quality measures: (4) promote electronic health records; and (5) report annually to Congress and the Secretary of HHS. Specific work in each area is defined with HHS on an annual basis. GAO (2010).

being introduced or considered. However, pending changes are relevant to this assessment because they will need to be factored into any recommendations for change that may come from it.

1. Standards of Evidence

One area that continues to receive attention relates to the criteria that should guide review of potential measures for endorsement and what should be required in the way of testing. As already mentioned, NQF provided more specific guidance in August 2008 on the criteria to be used in assessing candidate standards with importance as a threshold criteria every standard should meet to warrant further consideration, along with scientific acceptability, feasibility, and usability.

To provide further guidance for evaluating standards against the criterion of importance, NQF convened a Task Force that distributed for comment a draft document with Guidance for Evaluating the Evidence Related to the Focus of Quality Measurement in mid-May 2010. The report reviewed existing metrics for grading evidence. It recommended high standards of evidence for publicly reported measures. It also recommended that in the absence of strong certainty of net benefits, expert judgment must conclude that the potential benefits to patients clearly outweigh the potential harm to patients from the specific structure, intervention, or service.

To provide further guidance on assessing scientific acceptability, NQF established a Task Force on Measure Testing and they, in turn, issued draft guidance for Measure Testing and Evaluating the Scientific Acceptability of Measure Properties for comment in mid June 2010. The proposed recommendations include an expectation that there be empirical evidence of reliability and validity for measures endorsed by NQF. The recommendations also propose flexibility in application to accommodate current operational constraints expected to arise in testing reliability and validity, taking into account high, moderate, and low ratings on each of these criteria jointly. The goal is to inform expert judgment with a more thorough understanding of the nature of the evidence of scientific acceptability that does or does not exist. The draft report circulated for public comment also discusses NQF's intent to narrow the types of untested measures that would be considered for time-limited endorsements.[10]

2. Measure Maintenance and Endorsement Cycle

A second area that has received attention involves policies on measure review or maintenance and ways of addressing concerns about the equity of standards proposed for new and existing measures. Under NQF's historical policies, measure developers were responsible for annual measure maintenance updates to confirm existing specifications or make minor updates to them, with NQF conducting a three year review of the endorsement (shorter for measures receiving time-limited endorsement). However, this process for measure maintenance was modified by the NQF board in May 2010. Under the new process, NQF established a three year cycle for review of measures in 22 topic areas mapped to priority condition areas. Under the new policy, existing and new measures on a given topic would be reviewed simultaneously by a committee. The review would follow the nine-step process previously described. The intention is to generate a more even workload within a

[10] The intent is to focus on measures in new areas where there is a critical time line (for example, legislative mandate) and non-complex measure (that is, not a composite or not requiring risk adjustment). NQF indicates that this decision to narrow, while discussed in the Task Force document, reflects an earlier decision made by the Board of Directors.

structure that supports review of evidence, harmonization, and head-to-head comparisons that might better identify "best of class" measures.

While measure maintenance was not within the scope of the CDP assessment we were asked to pursue, this change is relevant to the assessment findings since it will affect the way both new and existing measures are reviewed within the CDP. The policy change also will likely make it easier for measure developers to anticipate at which point a particular topic will be considered.

All of these efforts are relevant to decisions about future refinements of the CDP in response to our evaluation of its timeliness, efficiency and effectiveness as it currently functions. The remainder of this chapter provides additional background on the way we structured the technical analysis and stakeholder interviews that guide our initial review of the CDP.

C. CDP Projects Included Within the Scope of Assessment

For the evaluation, we focused on projects initiated in 2008 or 2009, a time period sufficient to generate a meaningful set of experiences with projects that went through the process as revised in 2007.[11] The precise operational definition of projects is particularly relevant to the technical analysis, many of whose metrics were calculated from data on the included projects.

For purposes of this study, projects were defined as listed on the NQF website. To be included in the technical analysis, the project had to be intended to endorse a specific product, such as a framework or set of practices or measures on a given topic with the expectation that the review would result in a formal decision on endorsement. Some of these projects, though listed separately on the NQF website, were carved out of or added to existing NQF projects, using the existing steering committee to do the work.[12] This definition excludes NQF projects that are implemented outside the formal endorsement process. It also excludes projects, like those involved in review of existing endorsed standards that underwent a truncated review during 2008 and 2009 as part of measure maintenance. NQF requested the exclusion of this latter type of project because they raise different issues about changes in CDP policies. Further NQF was considering change in this process of measure maintenance and therefore did not feel it would be a good use of resources to include them. The projects to be assessed were identified in advance based on these criteria, leading to a list that was approved by NQF staff.[13]

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[11] The use of this definition meant that some CDP projects still ongoing that started before 2008 were excluded. These include: Additional Clinical Measures 2008; Composite Evaluation Framework and Composite Measures; Cultural Competency Framework & Practices; Emergency Care, Phase I; Emergency Care, Phase II; Health IT Structural Measures Influenza and Pneumococcal Immunizations; Laboratory Medicine: Patient Safety and Communication Practices; Perinatal Care 2008; Health IT Expert Panel I (HITEP-I); End-Stage Renal Disease (ESRD) Measures; Diabetes Measure Set: Value-Based Episodes of Care; and Cancer Measure Set: Value-Based Episodes of Care.

[12] Excluded projects involved white papers (on measuring continuing care for substance abuse, efficiency measures), four ad hoc reviews, a clinical decision support expert panel, a project involving prioritization of high impact conditions for health care performance measurement, NQF's patient safety advisory committee, several projects relating to Health Information Technology and e-measure format review, and methods based projects (involving harmonization, measure maintenance, and coding maintenance).

[13] NQF staff later questioned the inclusion of two project that did not involve new calls for measures and unique steering committees (ambulatory care: eyecare and melanoma; and hospital psychiatric care) and a third whose history as influenced by external factors (pressure ulcer framework). We show the projects in question but have not modified their

Table II.1 provides a list of the 23 projects ultimately included in the analysis. The projects included vary substantially. **Three types of projects are included under the CDP—developing endorsed measures, practices, and frameworks**. Most projects aim for endorsed measures on a particular topic but sometimes the state of the art is not sufficiently developed to support that. Frameworks are ways of conceptualizing a topic to support future work on standards for practices and measures. When knowledge is sufficient to identify practices to be followed but not metrics to quantify these practices, a project may lead to endorsement of practices rather than concrete measures.

Of the 23 projects included in this analysis, 2 involved preliminary work to develop an endorsed framework to guide future work (patient safety, pressure ulcers). One included both a review of proposed practices and then specific measures (care coordination); 2 involved only practices (safe practices 2009 and 2010). The rest focused exclusively on consideration of proposed measures. Most projects were funded either by CMS (10 of the 23 projects) or HHS (6 of the 23); various other groups funded the rest. HHS funds became more dominant in 2009, reflecting the funding mandates in MIPPA. At the point when they were selected for inclusion in the analysis, 10 projects had already been completed; the rest were at various points in the CDP process.

The scope and scale of projects studied vary substantially. Some are fairly narrow and focus on a single condition or area like eye care and melanoma, imaging efficiency, pressure ulcers, or stroke prevention. Others involve a single setting or area but include a potentially broad set of measures relevant to ambulatory care, home care, hospital care or patient safety. A few projects had a particularly expansive scope. For example, the project on care coordination practices and measures covered a diverse and still evolving area, with 78 measures and 35 practices considered. The patient outcomes project's scope (the Phase I and II project) included measures for 20 different conditions as well as cross-cutting measures. The project involving use of clinically enriched ambulatory care project data considered over 200 measures. This contrasts, for example, against the hospital psychiatric care that considered only 3 measures whose review was considered in meetings of the steering committee associated with the hospital outcomes project. The mean number of measures considered by the 18 projects for which these counts are relevant was 41, with a median of 26.

D. General Stakeholder Perspectives on the Current CDP

To complement the technical analysis, we interviewed 25 individuals spanning the range of participants and stakeholders in NQF's CDP process (see Table II.2). They included those involved with consumer and purchaser organizations, government and other funders, private measure developers, provider and professional organizations, health plans, and other perspectives. Many interviewees brought multiple perspectives. Many were physicians though they worked in a variety of settings and therefore brought different stakeholder perspectives. Many interviewees were highly involved in NQF activities, serving on the board, diverse member councils, project steering committees or CSAC. This selection was by design because these individuals are most familiar with how NQF operates and thus best positioned to provide operational feedback on it. While those closely involved with NQF include major stakeholder groups, participants may not necessarily be

(continued)
selection to avoid retrospective change and potential bias that might be introduced. Our analysis indicates that modifying this feature of the design would not have a major influence on the findings.

representative of the full spectrum of individuals with an interest in the outcomes of the CDP. To obtain complementary perspectives, we therefore also interviewed quality leaders with less day-to-day involvement in NQF and also requested NQF help us in assuring that the list included those with different perspectives, including those likely to have more critical comments. On average, interviews took an hour and followed a semi-structured protocol (see Appendix A). Respondents were told that the interviews were confidential and that comments would not be specifically attributed to them.

Table II.1. CDP Projects Started Since 2008 Included in the Evaluation

Project Name	Year Started	Status at Selection	Funder	Measures Submitted
1. Ambulatory Care—Additional Outpatient Measures 2010	2009	In process	CMS	27
2. Ambulatory Care Measures Using Clinically Enriched Administrative Data	2008	Complete	Aetna*	206
3. Ambulatory Care: Eye Care and Melanoma Measures	2008	Complete	RWJF	10[a]
4. Care Coordination Practices and Measures	2008	In process	SAN**	113
5. Efficiency: Imaging Efficiency	2009	In process	CMS	17
6. Home Health: Additional Measures (2008)	2008	Complete	CMS	57
7. Home Health: Additional Measures 2008 Addendum	2008	Complete	CMS	57[b]
8. Hospital Care: Outcomes and Efficiency Measures Phase I	2008	Complete	CMS	3
9. Hospital Care: Outcomes and Efficiency Measures Phase II	2008	In process	CMS	21
10. Hospital Psychiatric Care	2009	In process	CMS	3
11. Medication Management Measures	2008	Complete	CMS	35
12. Nursing Homes	2009	In process	HHS	25
13. Outpatient Imaging Efficiency	2008	Complete	CMS	21
14. Patient Outcomes Measures: Phases I and II	2009	In process	HHS	43[c]
15. Patient Outcomes Measures: Child Health and Mental Health (Phase III)	2009	In process	HHS	57[d]
16. Patient Safety Measures	2009	In process	HHS	44
17. Patient Safety: Safety Reporting Framework	2009	In process	HHS	NA
18. Patient Safety: Serious Reportable Events in Health Care	2009	In process	HHS	[e]
19. Pediatric Cardiac Surgery	2009	In process	PCSC***	13
20. Pressure Ulcer Framework	2008	In process	CMS	NA
21. Safe Practices 2009	2008	Complete	NQF	[f]
22. Safe Practices for Better Health Care—2010 Update	2009	Complete	NQF	[f]
23. Stroke Prevention and Management	2008	Complete	CMS	19

Source: National Quality Forum, Consensus Development Projects, Current and Complete. Available at http://qualityforum.org/Projects.aspx. Accessed on April 16, 2010.

*Aetna Foundation, United Health Foundation, Wellpoint and Cigna

**Sanofi-Aventis, Wellpoint and Department of Veterans Affairs

***Pediatric Cardiac Surgery Coalition

[a]Review of revised and updated measures submitted in 2007; [b]no unique call for measures; [c]22 in Phase 1 and 21 in Phase 2; [d]30 for child health and 27 for mental health (numbers vary slightly from those on the NQF website); [e]step was not yet started. [f] Counts not available. Projects updated existing measures and considered additional ones.

Table II.2. List of Stakeholders Interviewed

Tanya Alteras, MPP, Consumer Support (National Partnership for Women and Families and Consumer/Purchaser Disclosure Project)
Bruce Bagley, MD, NQF Board, Vice Chair of CSAC (American Association of Family Practice)
Maureen Bisagnano, Quality Improvement and Measure Developer (President, Institute for Healthcare Improvement)
Dale Bratzler, MD, Measure Developer, (Oklahoma Quality Improvement Organization)
Paul Convery MD, Chair, Provider Organizations Council (Baylor Health System)
Patrick Conway, MD, (Formerly with the Office of the Secretary, U.S. Department of Health and Human Services)
Louis Diamond, MD, Chair, Quality Measurement, Research, and Improvement Council (Thomson Reuters)
Joyce Dubow, MS, Founding Chair CSAC (AARP)
David Gifford, MD, Chair, Public/Community Health Agency Council (Rhode Island State Health Department)
Kate Goodrich, MD, HHS Project Manager (Office of the Secretary, U.S. Department of Health and Human Services)
Sam Ho MD, Measure Developer, (United Healthcare)
David Hopkins, Ph.D, Vice Chair, Purchaser Council (Pacific Business Group on Health)
Karen Ignani, MBA (and staff), NQF Board (America's Health Insurance Plan)
George Isham MD, Previous Advisory Council Member, (Health Partners)
Charles Kahn, MPH (and staff) , NQF Board (Federation of America's Hospitals, Hospital Quality Alliance)
Karen Kmetik, Ph.D, Measure Developer (AMA's Physician Consortium for Performance Improvement)
Arthur Levin, MPH, NQF Board and CSAC Chair (Center for Medical Consumers)
Sam Nussbaum MD , NQF Board, (Wellpoint)
Greg Pawlson MD (and staff), Measure Developer (National Committee for Quality Assurance)
Mike Rapp MD (and staff), Funder and Measure Developer, (Centers for Medicare & Medicaid Services)
William Rich, MD, Chair Health Professions Council (American Academy for Ophthalmology)
Bernard Rosof, MD NQF Board and Chair Physician Consortium for Performance Improvement (Huntington Hospital)
David Shahian MD, Vice Chair, Health Professionals Council (Society of Thoracic Surgeons)
Anne Weiss, MPP, Funder, (Robert Wood Johnson Foundation)
Nancy Wilson, MD, Project Officer, (Agency for Healthcare Research and Quality)

The initial discussions in each interview provide an overview of stakeholders' general perspectives on the CDP. **In general, the interviews suggest most stakeholders review the CDP as working reasonably well overall but that there are areas that could be improved; a few were more critical** than others (Table II.3). Almost universally, those familiar with the past said that the CDP process had improved over time and was likely to be improved further by the changes currently being considered (as discussed earlier). Overwhelmingly, **stakeholders said the key strengths of the CDP related to the fact that it was a multi-stakeholder and open process**, though those features also had some downsides. (Table II.4) Respondents varied in how they perceived weaknesses and perspectives varied within as well as across groups. We analyze these and more detailed stakeholder assessments in chapter III to support our assessment of the timeliness, efficiency, and effectiveness of the process.

Table II.3. Stakeholder Assessment of the Overall CDP Process

- It is working better. Like anything you learn as you go. (Consumer)
- It is working as well as can be expected. NQF has created a place to have a conversation. I think people take it seriously and engage in it seriously. It is a place where different views can be discussed and worked out. (Consumer)
- It is serving its purpose pretty well from the perspective of serving diverse stakeholders. (Purchaser)
- It is working as well as can be expected….the reality is that the volume and nature of the work has been overwhelming. The majority of people…have other day jobs. (Measure developer)
- Over time, it has improved. It still feels a bit cumbersome and not always the most efficient process with communications flowing freely. (Measure developer)
- On a scale of 1 to 10, I'd give it about a five now—before it was 3. It's getting better but there's still not enough staff knowledge and control of the process and committees are variable and some get very out of the box and they start redesigning the world. (Measure developer)
- Concept of consensus is a good one and it probably necessary when it is going to be applied nationally to a variety of stakeholders. I think the diversity of viewpoints that has to be accommodated is often times a disadvantage though. (Professional)
- [It is] working fairly well, though I have concerns. (Measure developer)
- I think it is working really well given the political constraints it has to work under. The process of building consensus is hard in general. (Measure developer; general quality organization)
- Overall it is working well—the fact that it produces a product in today's world is an end that justifies the means. That said, NQF has worked continually for feedback for how to revise and change the process and I think the process could benefit from further improvement. (State government)
- The idea behind it is extremely good and it probably works well often but there are some concerns. (Government).
- It generally works ok. We are still struggling to get balance and some of the details right. It depends on who is staffing which project. (Provider organization)

Particularly Positive Respondents

- I think it is working beautifully. In fact, when issues come up, it is often because stakeholders are looking at their perspective and not nationally. (Health plan)

Particularly Critical Respondents

- I think there are huge problems. This is not just a professional sense but that of several [professional] societies. No one knows how to verbalize it. (Professional)
- I am not impressed with how the CDP is maintained and run. There is a lot of variance in the level of scrutiny that steering committees have during each project. NQF staff hasn't provided enough oversight to those committees. (Government)
- From policy perspective, I fail to see how the product that NQF is producing [the improved measures] is really driving change in the health system broadly speaking. The CDP process by nature is a consensus one and a low one. (Health plan)
- It is frustrating. [It is] slow, biased to more policy activities and doesn't actively support enough real world measures. (Health plan)
- It doesn't work very well…lack of standardization in actual operation and process…ranging from criteria use for selecting folks on committees to the kinds of measures that are approved or not approved. (Government)

Note: These are comments made by specific individuals intereviewed. The bracket at the end shows the category of respondent. Among individuals of a given type, opinions varied.

Table II.4. Stakeholder Views of the Main CDP Strengths

- The process has been tried and true. The strength is in the process. (Provider organization)
- Main strength is that it is open. (Professional)
- The fact that it is a formalized consensus process [that] follows existing ground rules for these kinds of processes…that kind of anchoring is important. (Consumer)
- Everyone from all across the country has the opportunity to give input. (Provider organization)
- It is a multi-stakeholder group trying to do the right thing. The process is a little goofy—strengths are apparent, processes drive people nuts.(Professional)
- It is open and transparent. From consumer/purchaser perspective, it provides an opportunity to go toe to toe [with other constituencies]. (Consumer)
- It brings together diverse perspectives from stakeholders from the provider side who are being measures to those wanting to get better measures….on CSAC, we all have transcend parochial perspectives. (Purchaser))
- Steering committees, though problematic,are necessary; also transparency, voting, public comment, and appeals. (Government)
- It provides a chance for all stakeholders to participate. (Measure developer)
- Trying to look for "best in class" and creating harmonization. (Measure developer)
- The consensus—the multi-stakeholder buy-in necessary to get acceptance by payers, buyers, and the consumer community. (Professional)
- Built into statute so a big strength is that after a measure has gone through the process and gone through endorsement you can feel comfortable the measure is useful for accountability. (Measure developer)
- Stakeholders are represented, it is a systematic way to get feedback, it is transparent, and it is great that the NQF publicizes each step, (Health plan)
- Review criteria stronger than [in the] past. (Consumer)
- Building agreement and awareness. People begin to see things in the same way even if they don't agree on it. Conversation is critical. (Measure developer/quality leader)
- I think that the measures have to be open to the public and that they make them very transparent. (State government)
- The best of NIH review processes. (Health plan)
- By nature of it being a consensus process, they do an excellent job of bringing in stakeholders, having criteria, and working in a standardized way. (Government)
- That it still exists. That is, that it is a consensus process and you have to give and take among the various entities in concerns over the measures. Sometimes you get to highest common denominators and sometimes you don't. I think it is a strength that you have buy-in. (Provider organization)
- It is multi-stakeholder. It takes into account the complexity of proprietary measures and software. It prioritizes measure development and approaches to gaps (in measures). The goals and connection with priority partnership are well intended. It is just the execution that is the drawback. (Health plan)

III. ASSESSMENT AGAINST KEY PERFORMANCE GOALS

This chapter assesses performance in turn on each of the three dimensions set for the CDP: timeliness, efficiency, and effectiveness—drawing on both the technical process analysis and the stakeholder interviews.

A. Timeliness

1. What the Technical Analysis Shows

Overall Project Duration. To analyze project timeliness, we created a database from NQF records showing start and completion date of each step in the CDP for each project.[14] The analysis is based on data for late June 2010. At that point of time, 12 projects were completed, 2 more were awaiting CSAC or board action on recommendations by the project steering committee, and 9 others were at various earlier stages. For the 12 completed projects, durations ranged from 203 to 489 days with a mean of 326 and a median of 377, or between 11-13 months.[15]

Figure III.1 shows the duration of each completed project. Obvious explanations exist for why some projects took particularly long or short times. The Hospital Care Outcomes and Efficiency Measures Phase I project, for example, which was the shortest (203 days), involved three measures (along with consideration of a few additional ones for hospital psychiatric care, listed on the website as a second project). Likewise, the 2010 update of the safe practices project (239 days) involved no new call for measures. On the other hand, the longest duration project (489 days) focused on ambulatory measures involving clinically enriched administrative data with a call generating over 200 proposed measures for consideration.

NQF staff report that specific circumstances delayed some projects that are still under way (Figure III.2). The pressure ulcer framework (620 days as of late June 2010) could not be finalized because of a release of a new national guideline requiring a rework of the measures that had been reviewed, a delay that, in turn, delayed completion of the home health measure project (completed after 396 days). The care coordination project (583 days as of late June 2010) involved a two phased process in which first practices and then measures were reviewed. As discussed in the Chapter II, projects vary considerably and this variation inevitably has some effect on project duration.

[14] The database was constructed using the project data posted on the NQF website for each of the relevant projects. (Available publicly at http://www.qualityforum.org/Projects.aspx). The "details" section of each project shows the status of work and dates relevant to each stage in the process. Note that the time frames of some steps overlap (such as calls for measures and calls for panel nominations). Also, there often are gaps between when one step ends and another takes place; this may be because work needs to be accomplished or for other reasons. For example, after the steering committee makes recommendations, there may be a delay while the draft report is prepared for member and public comment. Similarly, there typically is a lag between comments and voting because the steering committee needs to review the comments and decide whether to modify any of its recommendations in light of comments. Thus, the total duration of a project reflects the time between start and end date, and that duration typically will not be the same number of days as one would compute by adding the time involved in individual steps.

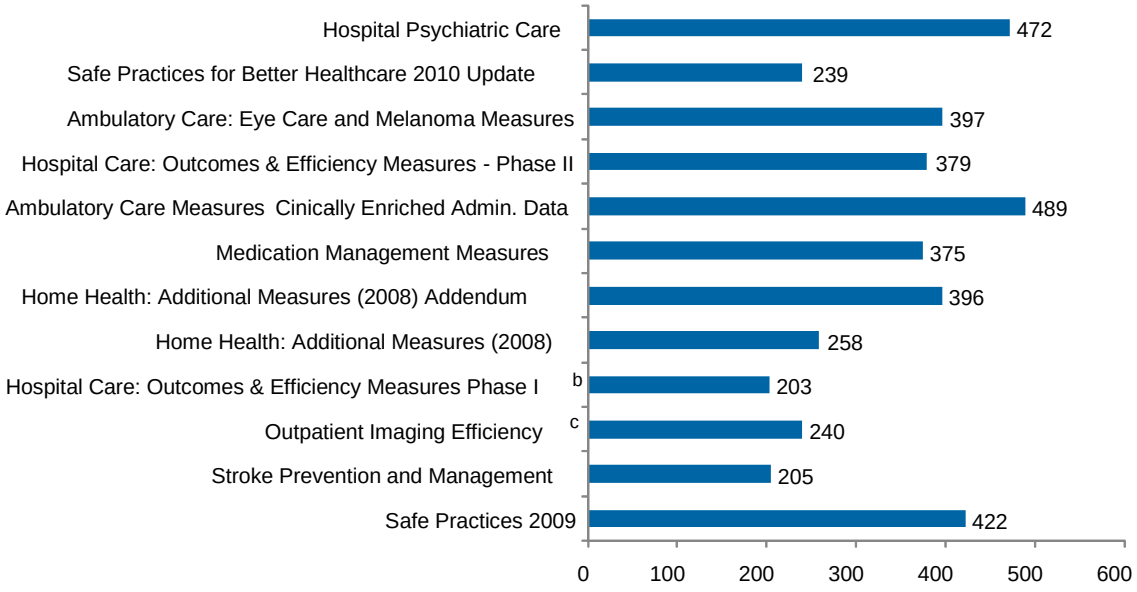
[15] Excluding the Hosptial Psychiatric Care and Ambulatory Care: Eye Care and Melanoma projects, both of which did not have a call for nominations for a call for measures, the mean length of projects was 321 days with a median of 317. The range does not change.

Table III.1. Project Duration (in Days) by Status in Late June 2010

Project Status and Type	Number of Projects	Mean Days from Call to Completeness or Cut Off Date	Minimum	25% Percentile	Median	75% Percentile	Maximum
Completed Projects	12	**326**	203	240	**377**	403	489
Projects Still Underway	11	**336**	186	226	**297**	374	620

Source: MPR analysis of a data from NQF's website on project time

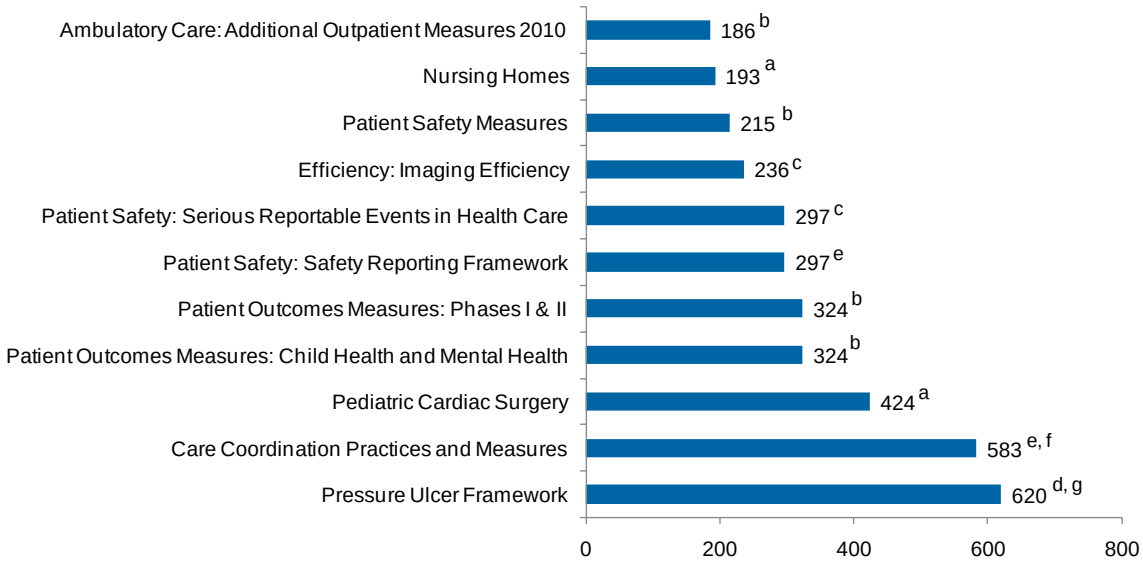
Figure III.1. Duration of Completed Projects (in Days)



Source: MPR analysis of data from NQF's website on project time.

Note: Hospital psychiatric care and eye care and melanoma projects had no new call for measures. Their duration was influenced by NQF's decision to have these measures reviewed by existing panels after they completed their other work.

Figure III.2. Project Duration, Projects Still Under Way (Days, as of Late June 2010)



Source: MPR analysis of a data from NQF's website on project time

Status:
[a] With Steering Committee
[b] Public Comment
[c] Member Voting
[d] CSAC
[e] Board
[f] Includes a call for practice and measures.
[g] Approval delayed by release of a new treatment guideline on March 3, 2010 (National Pressure Ulcer Advisory Panel).

Project Duration by CDP Step. To better understand the timing of the project review process across these diverse sets of projects, we pooled data across all the projects that had completed a certain step to learn more about how long each step takes, which steps are most variable, and whether there are lapses in time between steps that might contribute to total project duration. We also talked with NQF staff involved in the process about timeliness and what contributed to the timing of various steps.

Table III.2 shows the results of that analysis (detailed data on the timing of each individual project is included in the appendix (Appendix Table B.1)). The table shows the mean and median number of days from start to completion for each step, based on experience for included projects completing that step. We also show time associated with transitions between certain steps where they are most relevant. While the timing of some steps varied little across projects (usually because it was mandated), there was considerable variation across projects in the time in other steps. To give a sense of the "typical" time involved, we show the inter-quartile range (the span in days across the middle half of the distribution) along with the median and maximum time projects experienced. When medians are substantially different from means, it means that at least one project had a particularly long (or short) time frame that pulled up (or down) the average experience.

As we interpret the data in Table III.2, they show at least four key points.

First, the nine step CDP process as now defined inherently takes time. Mandated steps that seek stakeholder input and comment at critical stages, require 4 to 5 months time. Thus, the minimum time for the process would be six months. In reality, a minimum time of 9 months is more realistic, even if no delays or complications are encountered.

Second, the time associated with the steering committee's review of candidate consensus standards and recommendations typically takes the most time in the process and has the most variability. On average, this step takes over four months or around a third of the entire time frame. The duration also varies substantially across projects with, for example, over a 150 day difference between the duration of projects at the low and high end of the inter-quartile range. Projects vary in their scope and complexity. While NQF aims to have an in-person meeting for all projects to initiate the review of candidate standards, the number of follow-up meetings or calls varies substantially. In most cases there are another one or two meetings (for 2 to 3 meetings in total). However, it is not unusual to have 5-6 calls or meetings and, for some complex projects, substantially more. For example, the patient outcomes (phases I and II) project had 19 meetings or calls and the care coordination project had 13. All these counts include meetings of the technical advisory panel for projects that employ them. In addition to variation in the number of meetings, the review process also takes time because members of the steering committee are volunteers who have, as one interviewee said, "day jobs." This complicates scheduling and probably creates delays and potential inefficiencies. Staff say scheduling is a time consuming step. Recently, they have tried to set up fixed dates, at least for the initial meeting, well in advance and concurrent with the call for nominations. Unfortunately, the small number of projects and inherent variability of projects on many dimensions limited our ability to further provide insights on how characteristics of the process (like size of panels or available expertise) contribute to longer or shorter time frames

Table III.2. Summary of Duration of the CDP by Step, All Projects (in Days)

	Minimum Number of Days (if any)	Number of Applicable Projects	Mean	Median	25th Percentile	75th Percentile	Maximum
CDP Step							
1. Call for Intent to Submit Candidate Standards	14	7	34	14	13	22	139
2. Call for Nominations	30[a]	22	30	30	29	33	48
(Days between end of 1 and start of 3)	*14*	*7*	*23*	*41*	*29*	*37*	*64*
3. Call for Candidate Standards		19	41	30	29	47	137
(Days between end of step 3 and start of 4)		*14*	*-6[b]*	*6*	*-13[b]*	*38*	*299*
4. Candidate Consensus Standards Review[c]		15	135	135	52	210	305
5. Public and Member Comment	30	15	31	29	29	30	43
(Days between end of 5 and start of 6)[c]		*13*	*41*	*24*	*13*	*33*	*193*
6. Member Voting	30	13	29	29	29	29	32
7. CSAC Decision (from end of member voting)		11	18	12	7	24	50
8. Board Ratification (from CSAC decision)		12	37	29	18	49	111
9. Appeals	30	12	29	29	29	29	31
Total Project Duration–Finished Projects		12	340	377	240	403	489
Duration as of Completion or 6/26/2010 (all projects)		23	338	324	238	410	620

Source: MPR analysis of a database created from information on the time line of each project as recorded on the NQF website http://www.qualityforum.org/Projects.aspx as of late June 2010.

[a] An additional 14 days is involved in posting for comments the proposed rosters for panels.

[b] The term, "negative days" means that the step began while the proceeding step was still under way. In this case, the Review of Candidate Standards began while additional candidate measures were either elicited or while issues associated with their submissions were handled.

[c] Because member and public comment occurs during the review period and is considered by the panel, this duration can be complicated to calculate. To do so, we measured from the start to end dates for this task as listed on the website for the project. When a summary period was not listed, we identified the end based on the last meeting indicated under that step. The dates specified by NQF for some projects include follow up calls or meetings after public comment to finalize options and thus overlap step 5. Additional details on this anlaysis are available in Appendix Table B.1.

Third, a nontrivial amount of time intervenes between steps in the process. That, at least in part, is because operationally there is an internal process to support the external process and that in turn has certain steps that have to be undertaken to implement the various steps and oversee the work of staff. Common situations that take extra time include for example:

- **Constituting panels from nominees**. Staff say they get 50-80 nominations for a panel, but that there also may be critical gaps in expertise or perspective that require additional outreach which takes time. They also say some projects receive fewer nominations.[16] Panelists with a consumer, purchaser or public/community health, and supplier perspective are said to be particularly challenging to identify, with consumers a particular concern given NQF's strong interest in having consumers participate in all panels. Though NQF aims to anticipate needs of specific projects in its calling for nominations, some kinds of expertise may become obvious only after NQF learns more about the measures likely to be submitted and nominations also may fall short in particular areas of expertise. There also may be conflict of interest issues to resolve.[17]
- **Resolving proprietary and other issues associated with particular candidate measures.** The call for measures requires that measure developers provide specified information and assurances. However information on the submissions may not be complete and staff say they can spend a considerable amount of time assisting measure developers to propose measures and address requirements. Sometimes deadlines will be extended with the goal of adding to the completeness of the candidate measures available for review. When candidate practices, rather than measures, are considered, staff also say it takes time to explain what a practice is and what they are expecting from those making a proposal.[18] Also, time may be lost during the review process if issues arise with particular measures that warrant followup by staff with the measure developer.
- **Finalizing materials for external review.** NQF has an internal process that staff use in supporting the review committee and CDP process. Draft reports for public and member comment need to be prepared and reviewed internally. Comments need to be integrated into some form of document along with information on how the comment is being handled. Staff must revise draft reports as any changes are made in response to comments and as the recommendations move from steering committee to the CSAC and then to the board. The fact that voting and endorsement is on a measure specific basis makes projects more complex to document. Such documentation however is

[16] An analysis of 10 recent projects that had completed the voting stage showed some projects get substantially fewer nominations, perhaps 10-35 (Burstein and Bossley 2010). This could reflect differences in measurement with lower numbers showing the number of member organizations making nominations versus the total number of individuals nominated.

[17] NQF's current policy (dated January 14, 2010) calls for disclosure of interests but not necessarily disqualification because of those interests given the nature of the CDP and the fact that the interests may reflect the reasons a member has been selected for a committee. Conflicts of interest that could result in disqualification involve "those with any financial or other interest that could (1) significantly impede, or be perceived to impede a potential or current member's objectivity, or (2) create an unfair competitive advance for a person or organization associated with a potential or current member." Potential committee members must disclose interests in writing (and sometimes with additional oral disclosure) and these are considered at the initial meeting.

[18] For example, staff said that often a call for practices will generate submissions on particular programs or models in place whereas what NQF is seeking is a more general concept or preferred way of doing things that can be endorsed.

> important since it may ultimately influence endorsements that could affect both the way resources flow to providers (if used in payment incentive programs for example) and affect the business viability of measure developers. The efficiency with which these tasks are carried out obviously will influence the time line.

Finally, because of the nature of the topics addressed in projects, there does not appear to be a "typical project" or "time line." One NQF staffer involved in supporting the CDP said in an interview, "the CDP guides our work every day" but "since projects are unique, they don't happen in the same way." With respect to project duration, this means not only that projects are complex but that unique events, large and small, may occur that affect the time line. Probably the most critical variation relates to the tremendous diversity in scope, scale, and focus among projects that has already been discussed. However, individual projects also may pose other unique challenges. For example, staff described one project where the steering committee evaluation initially did not follow guidelines for the CDP process and had to be revisited. In another case, a conflict of interest arose after the review process had started and had to be addressed. Sometimes NQF staff may try to accommodate external stakeholder interests by integrating a measure into a project even though it does not fully fit and ensuing complications may delay work. The fact that NQF's workload is growing and staff recruitment is ongoing undoubtedly creates its own challenges in managing the staffing needed to support timely review.

2. Stakeholder Perspectives on Time Frame

The stakeholders we interviewed differed substantially in how they viewed the current timeliness of the CDP process. Of the 25 people interviewed, 24 responded to this question. From their responses, they appear split right down the middle between those largely comfortable with the process the way it now functions and those seeking change. Eleven unequivocally thought it was too slow, 9 that the current timing was about right, one that it had elements of both, one that it was too fast, and 2 others responded less in terms of its overall timeliness than in the ability to match external time lines. Perspectives on this issue did not neatly line up by stakeholder group. However, clinicians were more likely to be comfortable with a longer time frame and purchasers/government and health plans tended to want to see the process move more quickly. We review below the main perspectives that appear behind these general views.

Current Time Line Adequate. Those perceiving the current time line to be adequate for the most part argued that the task of developing endorsed measures was complex and it was better to be right than too speedy. One told us:

> "It [CDP] is a messy process and it takes time. You have to have time to allow discussions and people to engage, and as it is there are not endless discussions…those deadlines come up rapidly."

Another countered:

> "I would push back a bit on the question of timeliness and ask what the value is for timeliness. What is the balance between timeliness and the desire to get it right? I'm not sure why time lines matter, though of course there are parameters and some limits."

Some of those perceiving the current timeline as adequate were active in NQF leadership and potentially accommodating to what, in their experience, was the reality of the process. For consumers, a key concern relates to having the time to review measures and advise others in their

constituency on voting on issues that may be technically complex and not easily understood. They opposed shortening the process, particularly if it detracted from the time they had available to do their analysis and input.

Current Time Line Too Long. Support for a shorter time frame seems to be motivated by a at least two considerations—a general interest in more streamlined and quicker processes and specific concerns about aligning NQF processes with external requirements. As one said:

> "While the process has a system to it, it is very long and there are not many options for faster review of measures. It is a long process from when you do the calls for measures to when measures get reviewed to when you get an expert panel and the panel deliberates. The market is changing so fast we need to figure out [how to get] more rapid cycle review."

A member of a specialty society that had momentum behind a particular measure set they had endorsed were frustrated when the NQF time line for review did not align with theirs and their members did not understand why it could not move more quickly. When a specialty society has developed a measure on a topic that is not part of an upcoming call, these concerns are particularly likely. The move to scheduled reviews is likely to help societies plan but still will not obviate mismatches between the NQF calendar and when a particular group is motivated to move forward.

Interviewees critical of the time line also viewed the **alignment of the NQF time line and external requirements as especially problematic**. In terms of alignment, one interviewee noted, for example, that performance requirements typically were in contracts negotiated annually; a delay could mean an entire year was lost because measures were not ready to be incorporated into contracts. Another described a situation where a legislatively mandated time line led an agency that would have preferred getting NQF endorsement for a measure set it developed to skip that process because the time lines could not match and the agency felt it already had used a relatively robust process in developing the measures. Organizations that had already undergone relatively extensive development processes were at times frustrated that after all that work they were required to undergo another review with elements they felt involved some duplication. NQF's view is that they provide a multi-stakeholder process for reviewing measures that has broader application than other processes that may proceed it.

Federal mandates create particular challenges with respect to the CDP time line. Congress often enacts laws that have specified deadlines. Agencies like CMS also are required to follow regulatory rules in integrating endorsed measures into policies for reporting or payment. These agencies also may be conflicted if measures are dropped but regulations specify them. NQF has tried to accommodate external requirements by moving specific projects faster through the process, but special treatment for a major funder also can be a source of tension within a multi-stakeholder consensus process. Stakeholders perceived the shift to HHS core funding versus project by project funding had the potential to ease such tensions, but said that that also depended on the way HHS exerted its influence to support not just measure development for Medicare and Medicaid but for the nation overall. From our own experience with getting this evaluation approved to begin, we also perceive that the contracting structure, with its requirements for project specific reviews, could itself be a source of delays in the startup of projects even if they operate independently once begun.

Ways to Shorten the Process. Stakeholders for the most part agreed with the steps developed for the process and mainly wished they could move more quickly.[19] Though some suggested shortening each step, most concerned with a shorter time line were more concerned with the "front end" of the process involving project initiation through steering committee review. In general, respondents seemed accepting of the process (and associated time line) after steering committee work was done and also perceived a final appeal to provide assurance that concerns would be heard.

Few had concrete suggestions on how specifically to make the process proceed faster, noting that "measure developers needed a decent amount of time to submit their information and it takes time to get the nominations in" or that they were not really sure but thought it should be studied. One interviewee thought that the timing could be cut down in most steps but our sense is that those we interviewed likely would have problems with tightening the timing in many steps (especially member comment and voting). An experienced observer of the process said they thought that there was some room for streamlining in the review of measures because of the weeks in between meetings to cover a week of work, though they also noted that that "may be wishful thinking."

Our impression is that some of those comfortable with the current time frame did not actually know how long it took. Thus, it could be valuable once this analysis is shared to see whether there are additional insights or thoughts on the issue of timeliness. The relevant issue is to identify what the goal should be in terms of time line and how it should vary for different types of projects.

It also may be valuable to consider, as we discuss in chapter 5, whether there are ways to create more generic rules on when a particular project will be fast tracked. This could address specific concerns while creating more transparency and potential equity.

B. Efficiency

For purposes of this evaluation, the efficiency of the CDP is defined in terms of how well the processes employed support transparency and appropriate means for stakeholders to engage in the CDP within reasonable limits of time and resources. We review first what the technical analysis reveals about the transparency of the process and the extent of stakeholder engagement. We then consider what we learned from stakeholder interviews, complemented by conversations with NQF staff, about the staff and other support available for the CDP as it affects the ease and efficiency of participation and the process overall.

1. Transparency of the CDP Process

Technical Process Analysis. The primary means NQF employs to support the transparency of the CDP process increasingly is focused on the NQF website. The intent is to allow all interested parties to be able to access relevant documents on that site. NQF re-designed their website in August of 2009. As part of this effort, they increased efforts to post documents for public review.

To assess the extent of transparency, we examined the completeness with which key documents on each project were posted on the website. Because they are central to the CDP process, we focused the analysis on four types of documents relevant to projects; (1) steering committee

[19] NQF says it is currently working on a redesign that will address some of these concerns.

agendas; (2) summaries or transcripts of steering committee meetings; (3) documents indicating the public comments received and response to them; and (4) final reports for completed projects.[20] Because the website redesign occurred midway in the evaluation period, our analysis distinguishes between projects initiated before and after the policy change occurred. Twenty three projects in the total were analyzed. Fifteen of the projects analyzed began before the change in the website occurred, and 8 projects took place after. Our evaluation is based on a review of what was or was not available on CDP projects on NQF's website as of June 28, 2010.

Table III.3 presents the results of the analysis. Looking first at steering committee agendas, we find that more recent projects are more complete than earlier projects. Out of the 15 projects that began before the website redesign, only three had 100 percent of steering committee meeting agendas posted. Three of the earliest projects that began in February-May of 2008 had no meeting agendas posted. On average, 51 percent of meeting agendas were posted per project in this time period.[21] In comparison, 100 percent of meeting agendas are posted for 5 of the 7 relevant projects that occurred after the website change. (One project has not finished the steering committee step and is not included.) For this time period, there are no projects missing all meeting agendas, and the average percent of meeting agendas posted across projects is 87 percent.

In general, when looking at the availability of steering committee meeting summaries or transcripts, later projects are also more complete. Six projects from before the website change have no summaries or transcripts posted, only one project has materials for all meetings, and the average across project is 30 percent. For the period after the website change, only one project lacks any meeting summaries or transcripts, 4 have 100 percent of materials posted, and the average across projects is 82 percent. (One project has not finished the steering committee step and is not included.) NQF currently develops transcripts for in person meetings but not calls so the later require staff work to summarize.

The third area we analyzed was whether a response to all comments submitted was available either in a standalone document or as part of a draft or final report. The responses to comments are typically posted in a standalone Excel table organized by the topic of the comment. This table includes the full text of each submitted comment, and a response to each individual comment. Typical responses include that no action will be taken, that the comment will be incorporated into the report, and that the comment addresses an issue the steering committee also discussed. Comments are sorted into general comments about the project, and comments on particular measures. The name of the individual who made the comment and their organizational affiliation is listed. Out of the 15 projects evaluated that completed the public comment step, a response to comments was available in 11 cases. There are too few projects (one only) beginning after the

[20] Draft reports are produced to support public and member comment and updated/revised as the process proceeds. The final reports incorporate the final ratification by the board. Separately from this process, NQF maintains an electronic list of all endorsed measures. Some view this list as potentially more critical than the specific project reports. However, the project reports are the vehicle for transparency about the process and rationale leading to endorsement or non-endorsement. .

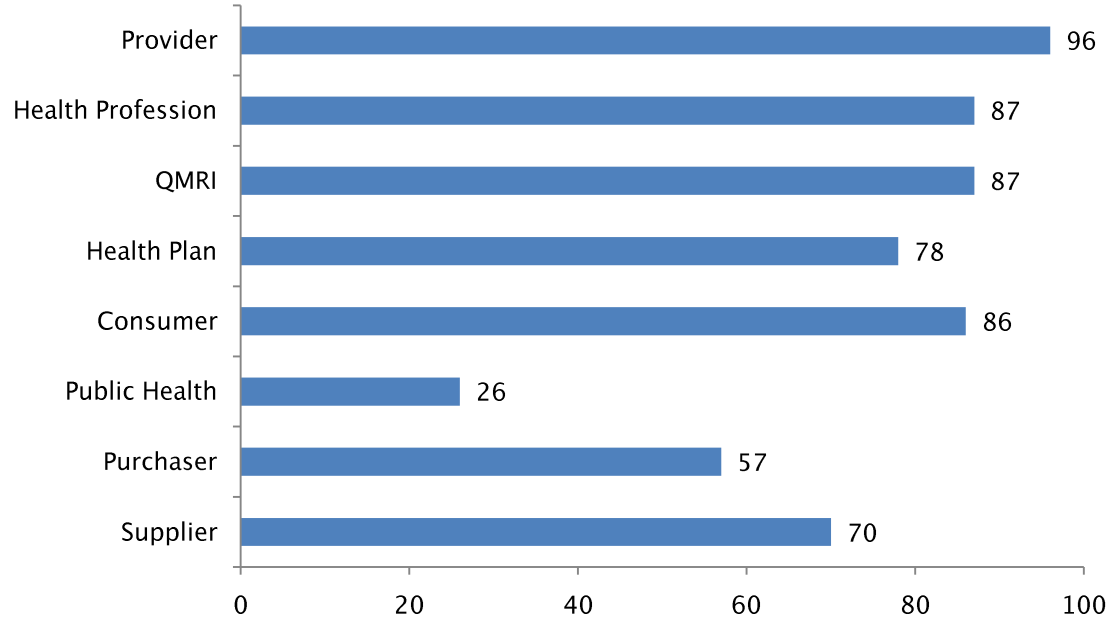
[21] This was calculated as the average of the percent of meeting agendas per project, not as the percent of total meeting agendas available. One project, Safe Practices 2009, is excluded as a percentage could not be calculated because the total number of steering committee meetings was not available.

Table III.3. Availability of CDP Materials on NQF's Website, Included Projects by Date of Start

Measure	Pre-August 2009	Post-August 2009
Total # of Relevant Projects	15	8
Agenda		
Mean % of Relevant Agendas Posted for a Project	51%	87%
Projects with 0 Available	3	0
Projects with Some Available	9	2
Projects with 100% Available	3	5
Committee Meetings with Summaries or Transcripts		
Mean % of Relevant Meetings Posted	30%	82%
Projects with 0 Available	6	1
Projects with Some Available	8	2
Projects with 100% Available	1	4
Response to Comments		
Number of Relevant Projects	14	1
Number with Materials Available	10	1
Number Without Materials Available	4	0
Final Report Available		
Number of Relevant Projects	11	0
Number with Materials Available	7	0
Number Without Materials Available	4	0

Source: MPR analysis of NQF website in late June 2010.

Figure III.3. Percentage of Project Steering Committees with Representation



Source: MPR analysis of a data spreadsheet provided by NQF.

website redesign to discern any pattern in completeness of postings pre- and post-policy. (Ten of 14 projects in the earlier period had a response to comments, and one of one in the later period had a response.)

A draft report was always available when a project reached the public comment step. However, in some cases a final report was not available for completed projects.[22] There are four projects that have been complete for at least two months in which no final report is available: Hospital Care: Outcomes and Efficiency Measures Phase I, Home Health: Additional Measures Addendum, Ambulatory Care Measures Using Clinically Enriched Administrative Data, and Hospital Care: Outcomes and Efficiency Measures Phase II. Hospital Care: Outcomes and Efficiency Measures. Phase I finished a year-and-a-half ago on November 27, 2008.

Overall, completeness of CDP materials is improving. The most recent projects frequently have all relevant materials posted, and typically have at least some materials available to the public. However, our ability to analyze fully the most recent projects is limited as only one project has reached the stage where responses to comments are posted and none of the projects are at the stage where a final report is posted. NQF views final reports as secondary to their goal of endorsing measures if NQF perceives that posting memos associated with CSAC and Board action are a better alternative than a final report, they should modify the website to remove the reference to a final report and change the title of the darft report (e.g., Decision Document for CSAC). With these refinements, outside users will have a more accurate source of how transparency is addressed.

The analysis just presented has certain inherent limitations. First, the analysis presents a snapshot in time of materials available, and thus does not show how timely the posting of materials was on the website at the appropriate steps of projects. Second, the analysis examines only availability, not the quality, thoroughness, or ease of use of posted documents. To address this issue, at least partially, we asked interviewees how accessible and valuable they found these documents and cover their responses later in this report.

Stakeholder Perspectives. The issue of transparency was discussed in general in the interviews. As discussed in Chapter II (see Table II.3), the inclusiveness of the CDP process and its overall transparency was viewed as an overwhelming strength of the process. For the most part, those actively engaged in the process have received information of the type discussed above from staff directly rather than through the web though this may change in the future. Interviewees said that staff were supportive in helping them gain access to information. However they identified some areas where the information provided could be enhanced.

The first involves ease of use (previewing a topic to be discussed later). Documents often were long and retrieval and printing algorithms did not necessarily make it easy or feasible for them to highlight a specific part of a report to print or share with staff (versus the report in its entirety).[23] Comments submitted in response to calls and the NQF responses to those comments were available

[22] Our analysis allowed for a two-month time period to complete the final report after a project finished. This impacted one project, Hospital Psychiatric Care, which was completed June 4, 2010 but which does not have a final report posted. The final report step was considered to be not applicable for this project

[23] For an example of what we believe interviewees were looking for, see the way PDFs are posted for the annual reports made to congress by the Medicare Payment Advisory Committee. Website visitors can access the entire report or particular chapters individually (www.medpac.gov).

typically in a spreadsheet format that was not necessarily easy to manipulate. Though most felt the website redesign improved access, some still found it difficult to locate documents. As discussed later, the organization of documents also did not always make it easy for users to take advantage of available materials.

The second involves timeliness and completeness of the materials presented. While comments and responses were provided at the end of the process, at least one interviewee felt that it would be useful to see submitted comments on a real-time basis. Such timely information would allow them to take other comments into consideration in their response. Measure developers said some measures were not specified in sufficient detail in written materials to support replication[24]. A number indicated that the available material on the website did not show the actual vote, particularly by constituency. Another thought that better transparency should also include showing better information on appeal rates and summary information on reviews over the last 12 months. In our follow-up discussions with NQF staff, we confirmed that this information is provided to the CSAC as part of their deliberations. NQF now posts voting results in memos to CSAC.[25]

2. Stakeholder Participation

Technical Process Analysis. Stakeholders have an opportunity to participate in the CDP in many ways, including serving on steering committees or technical panels, commenting on steering committee recommendations, and voting on their subsequent recommendations to the CSAC.

Steering Committees. Each project has an associated steering committee and some have a separate technical panel.[26] These committees vary in size but typically have 15-20 members (see Appendix Table B.2). Committees appear to have representation from a broad set of constituencies, though not all are represented on each committee.[27] Providers, health professions, measure developers, and consumers are on almost all committees (over 85 percent); health plans and suppliers are represented most of the time (78 percent and 70 percent, respectively). Public and community health, a council whose membership growth is only relatively recent, is represented only on about a quarter of all projects. This could mean some CDP projects are of less relevance to these groups or that individuals from these constituencies are harder to recruit. These counts relate to minimums; most steering committees have more members from some constituencies (for example, 4 providers versus one consumer).

In general, while CSAC by design has a majority of consumers and purchasers, steering committees are neither required nor expected to have this composition and indeed their focus probably means that they may not. To the extent members are voting as constituencies rather than

[24] Some gaps in information may reflect NQF's views that it is endorsing standards but not detailing how they are to be used in terms of things like minimum cut-offs and sample sizes (for surveys) or benchmarks. They and critical clients reason that many details will vary with the application.

[25] These were included in the Patient Outcomes Measures posting on CSAC states on October 2010.

[26] Technical panels typically are employed when a project needs specialized knowledge. In recent projects, NQF has attempted to streamline the process by including experts on steering committees so that technical panel use can be limited.

[27] Technical advisory panels, in contrast, appear more dominated by providers and the health professions. As with steering committees, they tend to be predominately NQF members.

individuals with a common charge, this has the structural potential to generate conflict as measures move across the steps in the process, though it may be unavoidable.

Eighty-seven percent of all steering committee members work at organizations that are members of NQF; some of the others may have been nominated by an NQF organization though they themselves do not work for an NQF member. A review of the non-members suggests that they represent a mix of different perspectives. Some are academics and researchers in public policy settings. Some are government officials that typically bring specialized expertise (health information technology, Medicaid). Some are specialists on a given topic (for example, speech rehabilitation, stroke, plastic surgery, pediatric hospitals) and others bring the consumer perspective relevant to that topic (for example, experience caring for those with Alzheimer's disease, parents of children with special needs). Nonmembers also may be appointed to allow continuity by including people who had participated in earlier steering committees though they may not be with a member organization now.

Member and Public Comment. A substantial number of organizations appear to participate in the CDP by commenting on steering committee projects, though most tend to focus only on particular projects of interest. To gain insight into this process within the constraints of available resources, we analyzed comments at the organization level for the 13 projects where a table of submitted comments was available in Excel.[28] Because entities commented on specific measures and unique individuals were hard to track, this analysis also excluded comments submitted by individuals without an organizational affiliation.

A total of 180 organizations submitted comments on at least some aspect of one or more projects (See Table III.4). In most cases, organizations are selective in their comments. Almost three quarters (73 percent or 131 of the 180) commented on a single project. At the other extreme, 7 organizations commented on half or more of the projects. Four were national associations representing the health professions and one was the major measure developer working with the medical profession. The other two were a national association representing health plans and a business coalition.

Other organizations commenting on three or more projects included: CMS and Childbirth Connection (six projects each), Pacific Business Group on Health (five projects), National Association for Healthcare Quality, the American Geriatrics Society, the American Heart Association, AdvaMed, the American Hospital Association, the American Society of Health System Pharmacists, the Federation of American Health Systems, and the Leapfrog Group (four projects each), and American Association of Neurological Surgeons, the American College of Physicians, the American College of Cardiology, Atlantic Health, the Societal of Hospital Medicine, Aetna, BJC Healthcare (a provider group), National Association of Children's Hospitals and Research Institute (NACHRI) and UW Hospitals and Clinics (three each).

[28] Four projects were excluded from this project because they have not reached the comment stage, and five were excluded because the submitted comments were not available in an accessible format. For Patient Outcomes Measures Phases I and II, comments from the first draft report were not available in an accessible format, and comments from the second draft report were not available by the time the comment period had closed. This analysis also excluded comments submitted by individuals without an organizational affiliation.

Table III.4. Number of Organizations Commenting on Projects

Number of Projects Included in Analysis[1]	13
Total Number of Organizations Commenting	180
Number of Organizations Commenting on One Project	131
Percent of Organizations Commenting on One Project	73%
Number of Organizations Commenting on >= 50% of Projects	7
Percent of Organizations Commenting on >= 50% of Projects	<1%
Organizations Commenting on >= 50% of projects	**Number of Projects Commented On**
America's Health Insurance Plan	11
American Nurses Association	11
American Medical Association	10
American Academy of Family Physicians	7
American College of Physicians	7
Healthcare 21 Business Coalition	7
Physician Consortium for Performance Improvement	7

Source: MPR Analysis of NQF website.

[1] Projects were included in this analysis when a table of submitted comments was available in Excel (as of July 19th, 2010). Four projects were excluded from this project because they have not reached the comment stage, and five were excluded because the submitted comments were not available in an accessible format.

Comments were received on all projects that have gone through this step, though the volume has varied across projects and the type of data available on different projects makes consistent tracking of these data difficult (see Appendix Table B.3).[29]

Voting. Each member association has an opportunity to vote on each measure that the steering committee recommends for endorsement. These votes are shared with CSAC (by council) to inform their decision making. Voting rates tend to be low across most membership councils though, the rate varies by project and its visibility and breadth of concern. NQF analyzed voting patterns for 10 projects included in our anlaysis for CSAC recently.[30] Table III.5 draws on that NQF analysis and shows the mean percentage of eligible member organizations voting per project, by council. On average, 15 percent of member organizations vote, with this varying from 6 percent (hospital psychiatric measures) to 24 percent (hospital outcomes and efficiency measures Phase II). Voting rates are highest among organizations in the health plan, health professions and purchaser councils than other councils though voting rates are not high in any council.

[29] The number of individuals commenting with no shown organizational affiliation was not analyzed due to the complexity of doing so with the available data.

[30] See March 8, 2010 memo from Helen Burstin and Heidi Bossley to CSAC on "Level of Involvement from NQF Membership Across CDP."

Table III.5. Rate of Voting Participation by Member Council, Percent of Eligible Members Voting Per Council

Council	Mean Rate	Minimum	Maximum	Median rate
Consumer	9%	0%	17%	8%
Health Plan	30%	15%	47%	31%
Health Professionals	24%	7%	34%	24%
Provider	11%	2%	26%	12%
Public and Community Agency	2%	0%	8%	0%
Purchaser	24%	4%	39%	25%
QMRI	14%	7%	22%	14%
Supplier and Industry	10%	0%	22%	10%
Total:	**15%**	**6%**	**24%**	**16%**

Source: MPR analysis of information in Burstin and Bossley (2010).

*10 projects used in analysis: Ambulatory Care Measures Using Clinically Enriched Administrative Data; Care Coordination Practices and Measures; Hospital Psychiatric Care; Home Health: Additional Measures (2008); Home Health: Additional Measures 2008 Addendum; Hospital Care: Outcomes and Efficiency Measures Phase I; Hospital Care: Outcomes & Efficiency Measures Phase II; Medication Management Measures; Outpatient Imaging Efficiency; Stroke Prevention and Management.

The eligible number of member organizations differs by council reflecting available organization and financing, as well as interest. Membership numbers also vary over time as members renew or join so each project vote has a specific (and often a different) number of eligible organizations. In general, the provider council is the largest of the 8 in NQF (over 125 member organizations), followed by the health professions (over 60 member organizations) and QMRI (measure developers, around 60). There are only around 25 eligible members each on the consumer, public and community agency, purchaser and supplier councils and about 15 purchasers. This means that the votes for some councils will reflect more organizations' perspectives than others. It also means that stratification by council (as NQF does) is important because otherwise the health professions, provider, and measure developer councils are likely to dominate the voting.

Stakeholder Perspectives. Almost universally, stakeholders that we spoke with who themselves participate or who are in organizations that do so perceived that the CDP process welcomed their engagement and was open to their feedback but they also said that being able to participate fully took time and there were ways NQF could make it easier for them to participate.

Interviewees perceived the consensus based CDP process as encouraging broad based participation. A key strength of the CDP said a consumer representative interviewed, is that the process is "open and transparent and, from a consumer purchaser perspective, it provides an opportunity to go toe to toe [with other constituencies]." "Everyone from all across the country has an opportunity to give input," said a provider organization representative in citing key strengths. Getting to consensus—"the multi-stakeholder buy in necessary to get acceptance by payers, providers, and the consumer community" was the CDPs' key strength, said a payer. From the perspective of a measure developer, it also is "built into the statute so a big strength is that after a measure has gone through the process and gone through the endorsement, you can feel comfortable the measure is useful for accountability." But while the process has improved over time, "it still feels

a bit cumbersome and [is] not always the most efficient process with communications flowing easily, said a [different] measure developer.

Demands of Participation. While the CDP process may be open to participation, stakeholders from across the spectrum note that participation takes work if they are to follow the review process and knowledgeably comment and vote. In one large provider system actively involved with NQF, they described having a master's level person that has as part of her job serving as liaison to the CDP so that the organization can make nominations for steering committees and participate in the process throughout. Such positions and responsibilities appear common across many of the major provider, professional, and health plan members participating in the CDP, particularly those that represent members nationally or feel their interests require a national presence. However, this magnitude of resource investment is unlikely to be feasible or supported in organizations that are less well financed or less dependent on the CDP for organizational success. One purchaser representative who spends a lot of time on the process said that it is:

> "Very tough for purchasers. If you want to be a responsible voter on measures that are proposed for NQF endorsement, you have to set aside a fair chunk of time to study information given to you by the steering committee…Purchasers…have very lean staff…[many people also have been] laid off in the recession so there are not many able to devote time to this."

A similarly active consumer group member observed:

> "It is not the easiest process to participate in if you are in the public realm…for the consumer to really delve into the process and read the reports and make comments is difficult. It is a very technical process…I often have to translate [for other consumers)] and sometimes I also need a translator…This is a huge barrier."

The time involved in participation was a barrier not just for consumers and purchasers. For example, both health professions and provider council leadership were aware of low voting rates from their councils and considering whether they could effectively generate participate outside the small number of large organizations with strong expertise that they relied on. However, they also pondered whether that lower level of participation by experienced members should suffice in representing the interests of their council members.

The nature of the CDP probably makes some of the burden of participation inevitable but there likely are some ways in which participation could be better supported. Several interviewees suggested work on the way materials are presented to make them easier to review. An interviewee, familiar with the role some NQF members play in informing others about the process, reinforced the previously noted suggestion that materials be posted in ways that allow selective content to be shared internally but not publically during a CDP project. Another suggested the value of layering that with a format analogous to peeling an onion, with more consideration given to how to present "the measures in any easy and rapidly digestible way for members to look at and review." As well as reorganization, simpler things, like use of larger fonts and summaries of which boxes a measurer had checked off (versus making members do that assessment themselves), could be a help, one said.

While most said the redesigned website was much improved and helpful to their participation, some thought additional work to help members locate material on the website would be useful. For example, some said, they found gaps or inconsistencies in the way current project deadlines are shown in the calendar, home page, and other sources or had trouble locating nomination forms in

response to project calls for steering committee members. Some of these instances may reflect shortcomings of the website itself, whereas others may reflect variable knowledge of how to effectively negotiate it. NQF staff seem to be willing to take the time, when asked, to help with problems of the latter sort, but obviously the process would be more efficient for all if need for such help were minimized.

Ease of Measure Submission. Given that consensus on appropriate practices and measures is central to the CDP, the ease with which measure developers can submit candidate standards for review and efficiently engage in the process is of particular importance. Almost all of those we interviewed with a role in the standard submission process said there was room for improvement, though their specific suggestions appear to vary, partly with how they keep their own information internally and would therefore find most useful. The later issues are particularly relevant for large scale measure developers that have their own internal documentation process. They told us:

> "The physical way we fill out these forms [measure submissions] is extremely frustrating [though it is evolving]. The form are rigid… [the system] needs to be a database structure rather than forms."
>
> "[There needs] to be a better way to submit measures. Many hours of labor [are required] and [there is] inconsistency in the use of forms over time."
>
> "The current forms [for submitting measures] are a bit clumsy. It is not always clear what they are looking for…they need to be clearer in [the] measure submission template; that would save a lot of back and forth to figure out what they are looking for on our end. Some of my colleagues describe these…'as a moving document.'"

While consistency seems to be a critical concern, there are likely to be tensions between consistency over time and efforts that aim to expedite submissions. NQF staff indicated they are moving to a web-based platform, but at least one interviewee with experience under this system suggests that the shift itself would be unlikely on its own to resolve all issues since they found it "hard to submit measures on the web."

One developer noted that the while it sometimes is "difficult to plug in a measure to existing forms" the "extensive document is good" and he didn't "have major issues with it." But he also perceived only so much should be expected of forms, noting that it is vital to have the measure developer or someone who understands the measure in the room because "the forms themselves don't give enough information to make meaningful decisions."

The issue of standard submission is one that also adds to the NQF staff workload and has the potential to delay work. In our staff interviews, we heard that staff (and NQF in general) tries to be as helpful and responsive to developers as possible and to encourage submissions. That means that rather than reject a measure outright because a submission is incomplete or poorly documented (as staff say at least some steering committees may suggest), they will work with measure developers to address gaps and, often more frequently, modify information that is not responsive to the question raised. Staff also point out that while a measure developer may want to submit an attachment (instead of inputting data directly in a place on the form), steering committee members look for information in a particular place and therefore attachments are cumbersome and may mean they don't see important information. Sometimes steering committee reviews have been delayed while issues are addressed with outstanding measures, though sometimes committees have begun before the complete set of measures is available. That approach is likely to be less acceptable under the new

process of measure review in which existing and potential new measures on a specific topic are reviewed on a head to head basis to identify "best in class."

Hence, the efficiency and the effectiveness of the CDP is likely to be enhanced to the extent that NQF staff and measure developers can identify ways to improve the candidate standards submission process so that it can be more automated without undue burden on either developers or staff.

Efficiency of Individual Projects. Some interviewees did not perceive that projects varied substantially in "how well they worked." However, most said projects differed, including recent projects.[31] One interviewee noted that some measure sets are just more complex than others. One said, "One project I was on was fantastic. We had a great mix of people very devoted to the process and the QI enterprise in general. On another project however, it was a different experience. Everyone was equally committed but there were more turf issues." Another said that the chair, composition, and staffing of the steering committee made a difference with projects running better when "chairs and committee (members) knew and trusted each other and there were good staff." From their perspective, a well performing project required members to understand the process, park preconceived biases at the door, basically know how to run a meeting and what constituted an effective committee composition. Another agreed that panel makeup makes a difference because one person with strong views (especially if they are chair) can influence the conversation; the NQF staff need to work with chairs to remain in the discussion. Another observed:

> "There are so many factors. Is it a well conceived measure to begin with? Is it easy to analyze? What is the mix of people on the steering committee and their level of expertise? All these things have to line up for it to be a really good project."

Another interviewee who generally saw little variation across projects said when it occurred it:

> "…usually centers around the project director. How well organized they are, how well they explain things, how well they are able to keep you up to date, how well they understand the process and how it fits into the picture. I mean basically how well they are organized."

Staff Support for the CDP. The CDP is a labor intensive process. Staff say they try to ease the burden on steering committee chairs by doing all the organizational work on associated projects. CDP leadership within NQF assigns a three member team to each project including a senior director who guides the work. NQF has developed internal materials that document the way each step in the process is to be supported and reviewed.[32] Staff typically have multiple projects under way

[31] We encouraged users to focus on recent experience by making that point at the beginning of each interview and also by probing, when specific issues were noted, whether this was a recent project or instance. In these situations there is always a danger of "telescoping" where individuals see projects as more recent that they in fact are. Also, perceptions may lag changes in reality. However, while this might explain some of the comments, we believe that it is unlikely to explain them all because of the probing we included.

[32] Because our project was not intended as an audit or internal evaluation, we did not ask for or review most of these internal documents and instead relied on staff discussions to learn about the process and stakeholder perspectives to learn about how well they perceived it worked.

concurrently and they may also work on tasks beyond those in the formal CDP. NQF's senior staff typically oversee major decisions and play a critical role in helping project managers support work at major meetings of the steering committee.

Because the workload has been growing, NQF has been adding staff and employing them across a wider range of projects both within and outside the CDP. There also has been natural turnover, possibly accelerated as NQF's leadership and the expectations for the CDP have changed over time and with it the expectations for staff. The transition means that experienced staff are assets (because of that experience) but may also not be as flexible as new staff on making changes in past practices that NQF seeks. Some experienced staff also sometimes now work elsewhere in the NQF organization leading other critical work.

In our stakeholder interviews, we heard mixed feedback on the way NQF staff are able to support the CDP. Virtually universally, interviewees said staff were supportive but their skills varied considerably. On the one hand, newly available HHS resources have stabilized NQF's funding and allowed it to build the staff. Some give high marks to staff for their ability to be knowledgeable and keep things moving. Others commend the intellectual capital of NQF's leadership and senior staff but say that staff shortages at the project manager level and variability in staff knowledge is a problem. One interviewee commented, "NQF staff doesn't always have the content knowledge necessary," with new staff sometimes not "as educated or trained as they should be," possibly because the staff has had to expand so quickly. Another perceived that the staffing as "having some problems bringing it up a notch to conceptualize issues at a higher level." Gaps in knowledge of specific subjects under review by a project and measure development expertise appear to be among skills found to be most variable or lacking.

Beyond the substance, we also heard a few expressions of concern (more prevalent for some projects than others) over disorganization, with materials provided "at the last minute" and what seemed to them like "a half dozen staff that email on different topics" including two on the same project in calls that were uncoordinated.

It is our understanding that NQF's senior staff are aware of at least some of these concerns and are attempting to respond to them. A few months ago, they hired an experienced senior staffer from the Physician Consortium for Performance Improvement to oversee day-to-day operations of the CDP. NQF also continues to recruit staff and get input from existing staff on training and other needs. Staff say that the skills required for this type of support mean that successful hires need not just technical skills but organizational and interpersonal ones that allow them to function well and enjoy the kind of environment inherent in consensus processes. The demand for substantive skills and a particular kind of orientation probably complicates the task of successful staff recruitment and means that as staff self select, some turnover is inevitable.

Perspectives on Voting Rates. Staff and stakeholders have said that the low rate of participation in recent votes is not a new issue for NQF. They perceive that this is inevitable because members joined for different reasons, some mainly to stay abreast of the process versus participate in it. Interests also vary across projects, which influences who votes on which measures. Some members have very targeted concerns.

A number of the member councils said they were considering what they could do to enhance the participation by members in their council, though taking any action would likely require support from NQF staff. For example, one council leader requested a report from NQF on all measures currently considered so that relevant ones could be discussed in conference calls and assignments

made for tracking. Another council's effort encountered difficulties because confidentiality concerns reportedly precluded NQF staff from sharing email addresses. A member who helped advise other members on the issues associated with particular votes said, "I wish there was more time…I think people don't get the [our] recommendations in time. Other times even with our recommendations they don't know enough still or don't care."

How to interpret low rates of voting is unclear. While individual council leadership was considering how they could enhance member participation, most seemed to accept low rates of voting as a current, though less than desirable, reality. But one interviewee chairing a council said the point really related to what responsibilities were associated with membership and what the benchmark for participation should be. In a follow up discussion they said:

> "Participation tends to be low…it is quite low on all the councils[…Yes, some people join to follow the process only] but it [the volume of activity] is also an overload. They all have day jobs and often don't respond because they don't have the expertise to respond [in terms of the benefits and loss and whether it matters]. We are meant to be a consensus driven organization. If we are to be this, than having maximum participation is important. If we find ourselves with low levels of participation, can we still call ourselves a consensus driven organization? That makes me uncomfortable. Secondly, we don't know what we don't know. If they made it more user friendly, we may get comments from really smart people on things we don't know we are missing. We need to have ownership of the process as it unfolds."

Several interviewees said they would like to get voting results by council (a topic discussed previously). Interviewees on the CSAC say they get that information and use it to understand which measures or practices may pose issues as reflected in split votes or wide differences across councils. At least a few interviewees not on CSAC wondered if votes were even considered so there appears to be room for improvement in communication with member councils on the voting process.

C. Effectiveness

We review here the outcome of the endorsement process and then what stakeholders say about the effectiveness of the review process and ultimate outcomes. We also discuss at the end bigger picture issues raised by stakeholders. Though potentially beyond the scope of this project and not under control of the CDP, these big picture issues are perceived by stakeholders as influencing its effectiveness, such as the measure pipeline, use of measures, and resource constraints.

Readers will note that this section relies more extensively than others on stakeholder interviews rather than technical analysis. The CDP is a consensus based process and there does not exist a technically correct outcome that an outsider can validly use as a benchmark for how well the process balances the four criteria and handles gaps in available information in applying criteria. In addition, over the period of our study, review criteria were still being refined as were the processes used for review in the steering committee. Our evaluation also was not intended as an audit and did not involve a measure by measure review of the specific review process for each of the individual measures included in the projects we examined. We understand that other projects under way at NQF will look further at effectiveness as assessed by the uses made of endorsed standards and the priorities set for review of candidate standards, each of which is important to assessment of the results of the CDP. Readers who wish to see a specific list of frameworks, practices, and measures endorsed in the projects reviewed here can find it in Appendix Table B.5. In addition, in Chapter IV

we compare the CDP to other consensus projects on this and other dimensions to gain insight on options.

1. What the Technical Analysis Shows

As part of the CDP, candidate standards are reviewed against criteria relating to importance, scientific acceptability, feasibility, and usability. Over time, NQF has continued to refine how these criteria should be interpreted and assessed. Staff say that steering committee meetings involve a systematic walk through of each proposed standard to assess how well it meets the criteria. Specific steering committee members will be asked to take the lead in review of particular measures though all members are expected to review each measure. On some more recent projects, NQF has requested each member of the steering committee to submit electronically in advance assessments of standards against criteria so that the results can be used to get an initial indication of where panel members agree and disagree so that this information can be considered in identifying up front how best to allocate discussion time. Standards that are endorsed by the steering committee are voted on individually by members and submitted to CSAC whose decision is ultimately subject to board ratification.

The output of the CDP process consists of endorsed frameworks, practices, and measures. Thirteen projects included in this analysis had completed the endorsement process, including 10 with specific practices/measures (see Appendix Table B.4). The number of practices/measures endorsed ranged from 2 (Hospital Care Outcomes and Efficiency I, and Hospital Psychiatric care) to 70 (care coordination), reflecting both differences in the number of measures considered in each project and other factors.

The percentage of submitted measures endorsed varied from 19 percent to 90 percent. High rates of endorsements occurred on smaller and more focused projects but the review process appears to involve more sorting for the larger projects, particularly those that are complex projects with many submitted measures, often in diverse areas. Seventy of the 206 submitted measures (34 percent) were endorsed in the project involving clinically enriched data on ambulatory care. The care coordination project led to endorsements for only 10 of the 78 submitted measures, though 25 of the 35 practices were endorsed. In some cases, measures are moved across projects making tracking more difficult. For example, the home health project included both a basic and addendum set of measures. Though these tended to be shown as separate projects, measure counts sometimes were combined across them as reflected in Appendix Table B.4.

Steering committee decisions play a central role in what ultimately gets endorsed. The record indicates times when their votes are influenced by the public and member comments. In the Ambulatory Care: Eye Care and Melanoma Measures Project, the steering committee, we were told, hesitated to endorse a cataract measure (improvement in vision 90 days after surgery) out of concern it did not meet the importance criterion. However, they subsequently recommended it after many comments favorable to the measure were received that noted the importance of outcome measures, the high volume of cataracts, and the lack of data on current performance. The steering committee also responded to comments on the Ambulatory Care Measures Using Clinically Enriched Administrative Data by reconsidering six measures, two of which it ultimately endorsed.[33] In the

[33] The identity of these is not clear from the voting and final report posted.

Safe Practices 2009 project, many changes were made in the language of the report based on comments.

For the most part, CSAC members carefully review the report from the steering committee and the outcome of the voting on each measure. By in large, CSAC has agreed with the steering committee, but not always. For example, on the Hospital Care: Outcomes and Efficiency Measures Phase II project, CSAC voted to endorse only 10 of the 11 measures recommended by the steering committee, citing lack of harmonization with existing measures as the reason one measure was not endorsed. A similar rationale was given by CSAC in endorsing only 16 of the 17 measures recommended by the steering committee on the Stroke Prevention and Management Project. The recommended measure on smoking cessation was rejected because CSAC had a strong preference for a single harmonized measure on smoking cessation versus many condition specific measures.

CSAC was formed as a way to add expertise to the review process and reduce the burden on the board of measure-by-measure review so that they could focus on more strategic issues. While the board is charged with ratifying CSAC action, most often they agree with CSAC. In most reviewed projects, the board ratified CSAC recommendations unanimously. On the Medication Management project, 2 of the 19 board members voted in opposition. To our knowledge, the most substantial difference between CSAC and the board occurred in the Hospital Care: Outcomes and Efficiency Measures Phase II Project. In ratifying 4 of the 10 CSAC recommendations, the board deferred a decision on six measures (up to October 2010) pending further study. The deferred measures were ones that the steering committee and CSAC had voted in favor of but the technical committee had opposed. In deferring a decision, the board said that it viewed the issues raised as generating fundamental questions about the CDP that warranted attention before they should act.

One project resulted in appeals that were reviewed again by CSAC and then the board. In both cases the original recommendations were upheld.

2. Stakeholder Perspectives

Accountability in the Current Process. Under the current CDP process, CSAC and the board is ultimately accountable for the review process and its results but much of the work of review takes place in the steering committees. Interviewees fairly universally perceived that the relatively new role for CSAC within the CDP was working well and enhanced the CDP process. CSAC leadership told us they view its role as ensuring that the process has been carried out effectively. Current efforts to clarify how scientific acceptability is to be judged evolved with CSAC leadership to address general issues they perceived were relevant across projects. Those in CSAC leadership note that they still face ongoing challenges that involve helping members try "to resist going back and redoing the steering committee's work." As another observed, "It is hard to get people with methodological knowledge not to redo a measure but that is not their role." Similar issues we were told sometimes arise at the board level, particularly when new members are added. Though a few interviewees (often with rejected measures) were critical that the CDP can generate late stream changes after several layers of review, most were more focused on activity before this stage in the process and the work of the steering committees.

Perceptions of Steering Committees and Their Review. In general, as discussed in Chapter II (Table II.3), interviewees perceive the CDP works from the perspective of diverse stakeholders with one noting, "The fact that it produces a product in today's world is an end that justifies the means." When probed more deeply, some have very positive things to say about the steering committee expertise relevant to review. "They bring in top notch people," said one interviewee. But

even if they supported the process and thought it worked well, many were concerned about unevenness within the committees, potential gaps in important skills that could benefit from attention to enhance the CDP, and what they viewed as the lack of standardization in how reviews were addressed.[34] One of the more critical interviewees told us:

> "NQF does not put the correct people on the steering committee. These people do not have expertise in the area. Developers also need a greater presence…Certain people on the committee have fixed ideas and often too much influence over other people."

One interviewee experienced with measure development processes perceived that the CDP steering committees were not as cross-disciplinary as others in which they were engaged and another suggested more outreach to complement those nominated voluntarily. The rigor of review was perceived by several to vary across committees. A few interviewees expressed concern about potential conflicts of interest within the steering committee that could either make it hard to recruit members or encourage low bar endorsements for "measures that aren't that great." Some of those whose work was locally focused expressed concern that the review committees include "inside baseball players," dominated with quality measurement experts and people who had worked in the area for a long time rather than front liners, such as clinicians, payers at the local or regional levels, and "real world" people, such as "self funded employers that do measure development or health plans."

Decisions on steering committee composition may involve balancing representation of constituent members and subject matter/measurement knowledge, to the extent these conflict.[35] While NQF staff told us that the breadth of its membership limit the need for trade-offs, some interviewees were not so sure. One stakeholder said:

> "The members try to get representation of constituent groups, which is both a strength and a weakness. But sometimes they don't get people who understand the measures, so you are really getting a vote on the importance of the topic and not on the measure itself."

Another observed:

> "In the discussions I have been involved in, there are variable levels of expertise represented. This is not unique to NQF…some of the people are there because they represent X organization not because they are knowledgeable.[36] We should try to populate these groups with people more knowledgeable about measure development and criteria [but I don't know] if these individuals can be found and still have representation of all stakeholders. [It is] apparent on some panels that folks just don't understand the measure."

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[34] Readers should be aware that the concerns expressed were not necessarily consistent with one another. Also, some may reflect differences in perspective and experience with individual projects versus the CDP overall.

[35] NQF's policies specify that committee members serve as individuals and not as representatives of an orgniazation. However, NQF still seeks to balance the diverse perpectives of its members.

[36] See prior note.

These individuals came from different perspectives but seemed to see similar tensions. One interviewee went further, suggesting that with the shift in NQF's funding stream to public sources, NQF membership should play less of a role or no role in determining membership on steering committees.[37]

Perceptions of Steering Committee Results. In some ways, perspectives on the results of the CDP mirror those of the process, with some relatively satisfied with the results given the context in which NQF works and with others desiring more. The difference, it would appear, involves potential **trade-offs in the weight to be given to scientific acceptability versus importance**.

In the scientific camp, one extreme would dismiss any measure that is not positively recommended by the technical advisory panel to the steering committee (in place on some but not all projects). At a minimum, these stakeholders say there should be a consistent standard for evidence and testing, with more reliance on experts and technical characteristics of measures and their evidence base. They feel NQF could be more rigorous. Providers, health professions, and measure developers are more likely to have this view but, notably, there is not unanimity across groups—a fact that probably reflects their acceptance of the consensus process and desire for a broad-based buy-in in an environment in which others have different views.

Consumers and purchasers appear to give more emphasis to importance in assessing standards. One purchaser asked, "Is there more weight given to scientific precision than to recognizing that we are in a world where it might be ok to have less scientific precision? High precision versus acceptability are two different things." The tension was perceived by a consumer interviewee to be one of "what is good enough?" From her perspective, "If there are serious concerns, everyone pays attention. When there is uncertainty, it is more a gray area"

More detailed guidance to steering committee members on what is expected from review (building on what CSAC is now developing) could be a middle ground on which stakeholders from diverse perspectives can agree. Several interviewees perceived that "steering committee instructions are not standardized," as one interviewee put it. Suggestions included more clear guidelines for policies NQF has set for reviews (like those involving how risk adjustment is to be handled), two page summaries of what the role of committee members is at different points in the process, and appropriate ways to balance perspectives of organizations and the process itself. This would enhance the process of establishing ground rules and defining the scope of review.

In assessing the CDP, some stakeholders viewed their perspectives as grounded in what they perceived to be the ultimate goals of the CDP and the standards it was created to endorse. One interviewee with national quality improvement experience wondered whether a process "of having so many voices in the room and everyone needs to be heard results in a list of too many measures versus more actionable ones." On the other hand, some of the processes that are supported by the CDP (like CMS's work on Medicare PQRI) seem to require endorsement of a large number of specialty specific measures.

Limitations of the Pipeline. Though we did not directly ask about pipeline issues because they were beyond what NQF viewed as the scope of work for this project, nonetheless, interviewees

[37] NQF staff note that member fees are still an important source of organizational revenue.

raised it as an issue. Their concern was that limitations in the pipeline of measures available and submitted serve to constrain what the CDP can accomplish. As one measure developer said, "[We] only get what is offered and that will be harder as we go along."

One concern among interviewees involves the ability to get relevant measures submitted when they are available so that recommendations could truly focus on "best of class." As one developer commented, "It is time-consuming to submit a measure and I can see why some would not choose to submit because it is not part of their core business." A measure developer might "have to spend millions and then maintenance," observed another. We followed up with a number of interviewees to get their reaction to these points. The general sense appears to be that while in many cases the desired measures are not yet developed, somewhat more exist than are proposed to NQF. The disparity exists because some measures are developed within organizations that are not ready to take on the costs and trade-offs associated with NQF endorsement, whether that relates to tests, maintenance, or loss of certain proprietary rights. This was a concern of interviewees, particularly as NQF moves forward to measures in areas that are less well established.

A second concern of interviewees involves measure gaps and who is going to fill them. One interviewee observed:

> "A main weakness is about the measure pipeline. Who is developing measures that can submit to NQF? It seems there are not sufficient efforts under way out there in measurement developer land to develop the type of measures we are looking for, like patient reported measures."

Measure developers observed that funds to support measure development and maintenance have historically been scarce. They thought health reform could enhance available funding but leave maintenance costs still an issue, particularly for private sector measure stewards. Several individuals also were concerned that the emphasis to date on Medicare measures, while valuable, meant that measures relevant to the millions of Americans now under age 65 and now covered by private insurance or Medicaid received too little attention. From their perspective, NQF could push more aggressively in this area. We understand that at least some of these issues are being considered by NQF activities outside the CDP, driven at least in part by the requirements of the Patient Protection and Affordable Care Act (ACA).

Desired Outcomes from the CDP. Several interviewees noted that the evaluation of the CDP process (and particularly the consideration of any changes) probably cannot ultimately be separated from its goals. NQF's work is particularly important in today's environment with national health reform. Interviewees coming from diverse comments posed questions like these:

> "The overall question is does this entire enterprise make a difference? Are we really improving care? There are very large questions we don't have answers to so we end up looking very narrowly." (consumer group)
>
> "NQF is adopting measures, not measure sets…we need more cohesion when we review measures, or at least articulate where the gaps are better at the same time as we release measures." (measure developer)
>
> "When we endorse measures, what happens and which ones really mattered? There needs to be a feedback loop." (funder)

How to blend national goals with local market variation was another related concern. This point was argued forcibly by one of our interviewees, a leader of a large system. He said:

> "I fail to see how the product that NQF is producing (the improved measures) is really driving change in the health system broadly speaking. For a lot of the health care system, especially hospitals, it is like a 'checkbox function.' The quality problem in this country really needs a robust quality measure system. The basic mission we have for NQF is on target. [But] when you get to the consensus part of it, political consensus processes at the national level tend to be influenced by a host of other political factors…and when we look across the country, we have vastly different types of situations in terms of capabilities of different health systems. There are a host of strategies out there for rolling out standards and our current CDP seems to be 'one size fits all.' And that kind of ends up, not intentionally, as a low common denominator." One interviewee suggested that it wasn't clear what question is behind the measures NQF is endorsing:
>
> "Are they asking is this measure useful in all contexts for all people at all times? A measure is never that useful. They're not thinking about a specific program."

Another observed:

> "NQF isn't really driving the measures. They should start pushing an agenda to get measures out there and they are not doing that now. I have been on a couple of NIH consensus panels and it turns out that the biggest part is the last section of the report on future directions and where NIH funding should go. These panels should have the same thing."

Thus the effectiveness of the CDP ultimately cannot be separated from the rationale for measurement. As NQF moves forwards with its separate work to define priorities, gaps in measures, and better monitor how measures are used, this work can be used to provide valuable feedback to the CDP process that can inform its goals and help ensure processes are set up to accomplish them in a timely, efficient, and effective way.

In the next chapter (IV) we review for point of comparison what case studies reveal about how selected other consensus processes address issues of common concern. In Chapter V, we consider the strengths and weaknesses in the current CDP process and what this means for subsequent work to consider changes in the CDP.

IV. COMPARATIVE ANALYSIS

A. Overview of this Component of the Analysis[38]

The Comparative Analysis was designed to complement the assessment of the CDP by analyzing the experience of other types of consensus processes. The intent was to learn about how different processes approach common issues, particularly transparency, balance and composition of consensus panels, policies to manage bias, and methods to balance stakeholders' preferences and scientific evidence.

The comparative analysis has two parts, with an emphasis on the second. First, we conducted a limited review of the literature to learn about what is known about how to structure consensus development processes and to review specific requirements under the NTTAA and the related OMB circular A-119. Second, we identified four organizations that engage in consensus-like processes and developed case studies focusing on issues likely to be of general interest, even though the cases involved substantially different work from that of the CDP.

The goal of these two tasks was to identify potential avenues for improvement to NQF's CDP. In turn, we summarize here the findings from the literature review and then case studies, ending with an analysis of potentially applicable lessons and options that may be useful to consider as NQF and its stakeholders move forward in considering change in the CDP.

B. Literature Review

1. Methods

The purpose of the literature review was two-fold. First we wanted to understand the requirements that apply to the CDP as an approved standards organization. Towards this end, we reviewed the NTTAA and the OMB Circular A-119, and Federal Advisory Committee Act (FACA) rules. Second, we wanted to learn whether the literature had identified any "best practices" or other guidance for developing consensus processes relevant to goals like those of CDP, though we expected it did not. Toward this end, we conducted a brief search of PubMed and Google Scholar for articles on consensus development processes. Key words included in our searches included "consensus development," "consensus method," "consensus process," and "consumer AND consensus." Both PubMed and Google Scholar returned hundreds of hits; we searched through the first hundred hits for relevant articles. We also reviewed reference lists of relevant articles for additional papers that might be useful.

2. Relevant Federal Regulations

Under the NTTAA,[39] federal agencies are required to use voluntary consensus standards rather than government-developed standards, unless "inconsistent with the law or otherwise impractical."

[38] Kate Stewart was the main author for this chapter and responsible for this task. Stephanie Peterson conducted the ANSI case study and worked on the task with Kate.

The key reasons stated for using voluntary consensus standards were to minimize taxpayer-funded expenditures and to allow private industry to develop standards that best facilitate competition and efficiency while meeting both public and private needs.

Subsequent to passage of NTTAA, OMB issued Circular A-119 to clarify guidance to federal agencies and voluntary consensus standard organizations on NTTAA.[40] This guidance, last revised on February 10, 1998, reviewed the goals of voluntary consensus standards and defined their reach and application. The circular defines a standard as including each of the following:

1. Common and repeated use of rules, conditions, guidelines or characteristics for products or related processes and production methods and related management systems practices.
2. The definition of terms: classification of components, delineation of procedures; specifications of dimensions, materials performance, designs or operations; measurement of quality and quantity in describing materials, processes, products, systems, services or practices; test methods and sampling procedures; or descriptions of fit and measurements of size and strength.

These measures are "performance standards" when they focus on results with criteria for verifying compliance but without stating specific methods for achieving the desired result.

The circular clarifies that "a voluntary consensus standards body must be defined by the following attributes: (i) openness; (ii) balance of interest; (iii) due process; (iv) an appeals process; and (v) consensus, which is defined as general agreement, but not necessarily unanimity…" The circular does not define these terms in detail, presumably to allow agencies to take advantage of a variety of forms of consensus activity that fall under this circular. Federal agencies are allowed and encouraged to participate in voluntary consensus standard processes as relevant to their missions and goals and as in the public interest (subject to any applicable laws and regulations). They may also provide financial, administrative, and technical support as well as engage in joint planning with consensus organizations.

Other bodies that may use some variant of consensus processes include federally established advisory committees; these may be established by Congress, the Office of the President or federal agency heads to advise the government on specific issues. Advisory committee procedures are guided by the FACA, which generally states that committee meetings must be open to the public (except when concerning national security) and allow for reasonable participation; the public shall have access to documents prepared by the committee as well as those reviewed as part of committee work; detailed minutes of the meetings must be kept and certified by the chairman of the advisory committee; a designated officer or employee of the federal government must chair or attend each meeting, and the advisory committee cannot meet without the designated person; and, unless otherwise specified, transcripts of meetings shall be publicly available. However, unlike OMB

(continued)

[39] For additional details on this Act, see: http://ts.nist.gov/standards/information/113.cfm. Further NTTAA-related documents, including OMB Circular A-119 and implementation reports are available at http://ts.nist.gov/Standards/Conformity/pubs.cfm. Accessed July 31, 2010.

[40] OMB. "Circular No. A-119 Revised" February 10, 1998. Available at http://www.whitehouse.gov/omb/circulars_a119 . Accessed August 11, 2010.

Circular A-119, FACA does not provide guidance on the characteristics of advisory committees processes.

3. Literature Review on Consensus Processes

The vast majority of the literature on health-related consensus processes focuses on development of clinical guidelines. This literature describes the various methods and outcomes associated with consensus development among professional groups, using techniques such as the Delphi method, Nominal Group Process, Glaser's Approach, and the Rand method (Rycroft-Malone 2001; Fink et al. 1984; Hutchings and Raine 2006; Fretheim et al. 2006; Elwyn et al. 2006; Brook et al. 1991; Lomas 1991). Other studies have also reviewed the NIH Consensus Development Program (see Lomas 1991 and Portoney et al. 2007). Most of this literature appeared to be of limited use to NQF, as it primarily involved medical experts reviewing the evidence and making decisions. Almost none included consumers in the process or focused on key parameters of the NQF CDP such as consumer involvement, due process and a mechanism for appeals. However, several of the studies acknowledged the limited use of consumer participation in these processes (Schunemann et al. 2006; Gagnon et al. 2009).

One study presented a conceptual framework for developing a consensus approach among policymakers, providers and consumers related to providing mental health services that may be of interest to NQF. This paper discusses how new policies can be developed through a consensus process including researchers, practitioners, and community members that empowers all relevant parties through shared knowledge and collaborative participation (Broner et al. 2001). The model presented in this paper identifies prerequisites to developing consensus among relevant parties, including "bridgers," those persons or institutions, like NQF, who bring together the diverse parties. In addition, these "bridgers" need to identify and assemble a broad array of key stakeholders to the consensus process to ensure there is community ownership of the consensus, develop a consensus process, and allow for ongoing collaboration and discussion among key stakeholders, including information dissemination, after initial consensus has been reached.

Broner et al. (2001) conceptualize the consensus process into nine steps based on Donabedian's quality framework of structure, process, and outcomes (see Table IV.1). In this model, structure includes the facilities, staff, equipment and collaborative relationships, process includes the activities, procedures, protocols and methods to develop consensus and outcomes include the results of the consensus process. Analyzing each of these components separately can help to identify gaps in the consensus process and areas for improvement.

4. Conclusions

Federal requirements for voluntary consensus processes are relatively general, giving organizations like NQF and other voluntary standards developers discretion in how they address them. There was also limited research on consensus development processes that include a broad array of stakeholders and that have rigorous due process and appeals requirements. Most of the existing literature focuses on the development of clinical guidelines based on expert reviews of the literature or experts coming to agreement on best practices. While the Broner et al. (2001) paper may provide a useful framework to conceptualize various steps required as part of a consensus process, it does not provide insights into key factors that might improve the current NQF CDP. We found no studies that tested specific characteristics of consensus processes that would provide NQF with better guidance on how to improve its CDP.

Table IV.1. Framework for Conceptualizing Consensus Development (Broner and Colleagues)

Structure
1. Infrastructure Issues: Identify issues and stakeholders and ensure the infrastructure is available to support the consensus process.
2. Consensus Process Structure: Form the collaboration, including identification of the group leader, define mission and scope, develop communication plans and processes to resolve disputes and procedures to evaluate project activities and products.
3. Articulate Vision. Articulate a vision for the consensus project, including goals and objectives, and evaluate costs and benefits of the proposed project.
Process
4. Evaluate Current State. Analyze current state and required inputs, outputs, and outcomes of the process for a successful project as well as develop work groups to address the process.
5. Identify Barriers. Identify barriers to implementation and any stakeholders associated with barriers.
6. Identify Solutions. Develop solutions to these barriers.
7. Develop Implementation Plan. Develop an implementation plan, including pilot tests of outcomes of the consensus process.
Outcome
8. Implement and Evaluate Plan. Implement and evaluate the pilot and refine, as necessary.
9. Ongoing Monitoring. Monitor progress and institutionalize the process, including developing operations or procedures manuals and performance measures.

Source: Summary of pages 88–99 and Table 1 in Broner et al. (2001).

C. Case Studies

Given limitations in the research on consensus processes viewed broadly, the four case studies developed as part of this assessment provide otherwise unavailable insight into how various consensus projects address different issues. We review first the methods used to identify the processes we studied, then the study results, and a comparison between what NQF and these organizations do and the potential lessons that may be applicable.

1. Methods

Our goal in selecting case studies was to identify well established consensus-based processes in any field that could provide insight on ways of structuring such processes consistent with the requirements of such bodies. We did not require that all organizations considered for case studies operate within the realm of the federal guidelines. We did look for a mix of organizations and attention to multi-stakeholder concerns. While all aspects of the organization were not expected to be relevant, we were looking for a balance of organizations with different processes that might contrast with one another and provide a range of insights relevant to thinking about the CDP.

We identified potential organizations for case studies based on web searches of organizations engaged in consensus processes and standards development as well as through discussions with NQF. For all potential case study candidates, we reviewed each organization's website and summarized any pertinent information on their consensus processes, including composition of members making consensus decisions and overarching principles and specific processes that the organizations developed for consensus. We also evaluated whether the consensus processes appeared to meet NQF-relevant criteria such as transparency, balance, and composition of consensus panels, policies to manage bias, and methods to balance stakeholders' preferences and scientific evidence. Based on these analyses, we highlighted the strengths and weaknesses of each organization as a potential case study, and made recommendations about which organizations to study. We reviewed the potential case study summaries and recommendations with NQF and made collaborative decisions about which organizations to study. (Appendix C includes information on organizations reviewed but not selected.)

For those organizations we decided to study, we conducted telephone interviews with three to four key persons involved in the relevant consensus processes, including staff members and stakeholders, to further understand the mechanics of each organization's consensus processes. We sought to understand issues such as the steps involved in developing consensus, consensus panel membership, conflict of interest policies, evidence reviews, processes for stakeholder participation, time lines, resources required, and funding sources, as well as insights on how organizations address many of the issues NQF must address, including transparency, balance and composition of consensus panels, policies to manage bias, and methods to balance stakeholders' preferences and scientific evidence. Interviews used semi-structured protocols that were modified, as appropriate, to ask specific questions about each organization's consensus processes based on our reviews of each organization's website. Based on the documents and interviews, we developed individual case study

reports of each organization that details their consensus processes and insights learned through our interviews (see Appendix D).[41]

2. Results

Organizations Profiled as Case Studies. For this analysis we examined four organizations and the consensus processes in which they were engaged.

- **National Institute for Health and Clinical Excellence (NICE): Centre for Public Health Excellence.** The National Institute for Health and Clinical Excellence (NICE) is responsible for developing recommendations related to medical care and preventive and public health services to the British government and National Health Service (NHS). The Centre for Public Health Excellence develops recommendations for population-based programs and interventions to improve public health. NICE processes to develop recommendations are guided by rigorous evidence reviews, as well as principles of transparency, collaboration, and involvement of stakeholders. The Centre for Public Health Excellence also conducts field work to test the practicability and feasibility of recommendations.
- **Financial Accounting Standards Board (FASB) and Governmental Accounting Standards Board (GASB).** The FASB and GASB develop and improve accounting standards for private sector corporations and state and local governments, respectively. Both FASB and GASB are run by the Financial Accounting Foundation (FAF), a private, not-for-profit organization. Both FASB and GASB follow the same general procedures to identify standards topics to address and to develop and modify related standards, though a few details may vary. The FASB and GASB processes are characterized by openness, balance, and fairly high transparency. For some projects, FASB and GASB also engage volunteers to field test the proposed standards.
- **Agency for Healthcare Research and Quality (AHRQ): U.S. Preventive Services Task Force (USPSTF).** The USPSTF develops recommendations for delivery of preventive and primary care services based on a rigorous evaluation of the scientific evidence. The USPSTF is convened by AHRQ, which also provides administrative, programmatic, and technical support to the task force. To support the task force in making specific recommendations, AHRQ's evidence-based practice centers (EPCs) conduct systematic evidence reviews of published literature on a particular topic once it has been selected. In addition, the task force collaborates with various partner organizations, including federal health agencies, medical societies, and population and policy-based organizations to help the task force clarify and disseminate the guidelines. The USPSTF process is predicated on rigorous evidence reviews.

[41] We shared a draft of the case with the lead interviewee from the main organization responsible for the consensus process in each case to verify its accuracy.

- One important consideration for NQF with respect to the USPSTF is that *the USPSTF does not consider itself a consensus body*. Several interviewees noted that consensus-based recommendations are those based primarily on expert opinion and not on the strength of the evidence. They noted that such consensus decisions related to clinical guidelines are generally of poor quality. In contrast, the USPSTF is responsible for assessing the strength of the evidence. While the USPSTF must come to consensus on grading the evidence of specific services, they still maintain that they are evidence-based and not a consensus organization.

- **American National Standards Institute (ANSI).** ANSI establishes guidelines for voluntary consensus processes and accredits Standards Developing Organizations (SDOs) who use these guidelines. Over 200 accredited SDOs, representing various industries, follow ANSI's guidelines for voluntary consensus processes. Standards developed through these SDOs using ANSI consensus process guidelines can become American National Standards. ANSI also represents the U.S. in various international standards organizations, including the International Organization for Standardization (ISO). Further, ANSI collaborates closely with the National Institute for Standards and Technology (NIST), a federal agency, to facilitate new standards development by SDOs and to develop U.S. positions related to international standards. We chose to study ANSI not only to understand its requirements related to voluntary consensus development, but also to study it as a potential business model for NQF as an organization that accredits other organizations to develop standards.

3. Unique Features of Organizations' Consensus Processes

This section describes characteristics of these processes that may be relevant for NQF. Detailed descriptions of each organization's consensus processes are included in the individual case studies in Appendix D.

Topic Selection. Anyone can suggest topics to NICE and FASB and GASB. The USPSTF task force identifies topics through period notices in the *Federal Register*, solicitation of partner organizations and suggestions from task force members. ANSI and the accredited standard development organizations identify needs for standards and, in addition, ANSI coordinates with federal agencies and state and local governments to achieve greater reliance on voluntary standards and lessened dependence on in-house standards. However, the process through which these organizations decide on which topics to pursue varies.

- NICE develops detailed briefing papers on proposed topics that are reviewed by an independent "topic selection panel" of health professionals and lay persons. The panel makes recommendations about which topics to pursue, and sends their recommendations to the government. The government makes the final decision about which topics should be studied.

- The USPSTF task force has a topic prioritization workgroup composed of task force members and AHRQ staff who recommend which topics the USPSTF should review. However, agreement must be made among the full task force on the topics selected. Prioritization of topics is based on: 1) relevance to prevention and primary care; 2) public health importance; and 3) potential impact of USPSTF recommendations on clinical practice.

- The FASB and GASB chairs decide whether to add a project to the technical agenda, subject to oversight by the foundation's board of trustees, and after appropriate consultation with FASB and GASB advisory councils, and other board members and staff.
- In cooperation with the accredited standard development organizations, ANSI identifies the need for standards, which are published on ANSI's website and receive a public comment period for input from the larger community. ANSI also coordinates with all levels of government when they have a need for a new standard. ANSI will hold a forum with relevant SDOs to identify what is needed, fact-find what exists, and how to best address the new standard.

Evidence-based Processes. As interviewees describe it, NICE and USPSTF rely on rigorous evidence reviews to develop recommendations, whereas FASB and GASB deal with accounting conventions that attempt to communicate economic reality and balance between theory and practice. ANSI relies on the *United States Standards Strategy* which is a document that details a central framework for standard development that was approved by ANSI's board and developed by a diverse group of constituents representing stakeholders in government, industry, standard development organizations, consumer groups, and academia.

- NICE typically contracts with outside research organizations, primarily academic departments, to conduct reviews of the evidence. These include effectiveness review of the evidence and economic modeling. Economic modeling includes both cost-effectiveness and cost-utility analyses.
- AHRQ contracts with evidence-based practice centers (EPCs) to conduct systematic evidence reviews of published literature on a particular topic once it has been selected. These reviews are the basis of all USPSTF recommendations.
- For FASB and GASB, accounting standards are conventions rather than having a hard evidence base. Both organizations rely on analyses prepared by individuals with accounting expertise in different areas that the boards use to base their decisions and to balance theory and practice. All analyses are conducted by in-house professional staff.
- ANSI uses the *United States Standards Strategy* document as a central framework for standard development. Because the U.S. standards system is so diverse, this central framework provides key components that ensures public health and promotes global competitiveness among the large and diverse sectors developing standards.

Opportunities for Stakeholder Participation. NICE, FASB, GASB, and ANSI provide opportunities for all stakeholders to comment and participate in the consensus process. Historically, USPSTF has only invited participation from specific partner organizations. However, USPSTF is currently pilot-testing procedures for public comment which it intends to incorporate into future reviews; the rationale for limiting public participation was to focus recommendations on the evidence and not allow advocates to sway recommendations.

- For each project, NICE requires that persons and organizations who want to participate register as stakeholders. Once registered, stakeholders are sent both draft recommendations and evidence reviews for comment. NICE responds to all comments, posting both comments and responses on their website. Most NICE meetings are open to the public.

- FASB and GASB generally provide more than one opportunity for stakeholder comments. The Foundations By Laws require that once the boards have established draft standards, they release these as an Exposure Draft for public comment. In some cases, comments may be solicited prior to this point. A common mechanism for doing so is a "Preliminary Views" document that describes the project, initial analyses and the board's initial position on the project. An alternative is a "Discussion Document" that includes analyses but no recommendations. If necessary, the boards will also hold public roundtable meetings on the draft standards. All board meetings are open to the public. FASB and GASB staff review and respond to all comment letters
- ANSI provides opportunities for stakeholder comments by posting all proposals for new, revised, reaffirmed, or withdrawn standards on its website for a public comment period. In addition, the consensus body's developed by each SDO for voting on a standard must be open to all persons who are directly and materially affected by the activity in question with no undue financial barriers to participation.
- The USPSTF collaborates with various partner organizations, including federal health agencies, medical societies, and population and policy-based organizations. Partner organizations do not participate in development of task force recommendations, but they attend task force meetings and receive copies of draft evidence reports and draft guidelines. In general, partner organizations are not engaged to help the task force clarify and disseminate the guidelines. The ultimate goal of engaging partner organizations is to understand criticisms and nuances of the proposed guidelines that the task force may not have considered.

Fieldwork. NICE, FASB, and GASB incorporate field work into their consensus processes.

While NICE draft recommendations are open for stakeholder comments, NICE contracts with research organizations to conduct focus groups and interviews with persons and organizations that would be responsible for implementing the recommendations. The goal of this field work is to identify practical issues the committees may have overlooked that need to be incorporated into the recommendations. There was some disagreement over the usefulness of the field testing process among our NICE interviewees. While two interviewees noted that input from implementers have led committees to re-think and revise recommendations, another noted that most of the input from field testing repeated information that was obtained from stakeholders during the consensus process.

FASB and GASB may solicit volunteers to conduct field testing of proposed standards. Field testing usually involves application of proposed accounting standards to historical financial data to see how challenging it may be to apply the proposed standards. Field testing includes cost-benefit analyses of implementing the proposed standards. Further, the boards may select key experts in the field to review the proposed standards.

Formal Versus Informal Votes to Develop Consensus. FASB, GASB, USPSTF, and ANSI all use voting procedures to develop recommendations, while NICE uses more informal processes to come to consensus.

- FASB and GASB require a simple majority to develop accounting standards.
- USPSTF require two-thirds majority to make recommendations.

- ANSI requires that a majority of the consensus body cast a vote and at least two-thirds of those voting approve.
- NICE committees come to broad agreement over the recommendations during meetings and through email while finalizing the wording of recommendations in the written drafts. While it would be possible for NICE to vote on recommendations, this is rarely done.

Panel Membership. The panels or committees used to make decisions vary along many dimensions across these organizations. Table IV.2 highlights some of the differences in panels related to size, term limits, expertise required, time commitment, compensation and criteria for selection.

Each of the organizations is designed to support a decision-making body and technical work related to specific projects either as consultants (NICE and USPSTF) or staff (FASB and GASB). Among organizations, FASB and GASB also are unique in that their decision makers, or boards, are salaried (in full or in part and with fixed terms). This arrangement probably reflects the strong interest in avoiding financial conflicts of interest by having decision makers work for organizations that stand to benefit financially from the decision made.[42] The others with set procedures (ANSI's varies across the organizations it accredits) use committees that may be either fixed by term (USPSTF) or project (NICE, but complemented with standing committees). In these instances, committee members work elsewhere; most volunteer, but some may be paid either because more is expected of them (chairs, for whom time is bought out) or to offset the opportunity costs or needs (self employed and consumers). At least two of the groups (GASB and NICE) require part-time staff or committee members to formally agree that they are representing themselves rather than organizations.

NICE's use of both permanent and rotating committees to develop recommendations provides a good opportunity to compare the two. For public health interventions that involve treating individual patients (for example, recommendations for specific treatments for smoking cessation), NICE has established a permanent public health interventions advisory committee (PHIAC) with a relatively large membership of 33. For considering public health programs that involve population based strategies (for example, strategies to reduce obesity in the population), NICE establishes a new committee called the Programme Development Group (PDG) to develop recommendations for each public health program project with a somewhat smaller membership. Interviewees thought that neither model was superior to the other and that both had been successful at delivering high quality, evidence-based recommendations on time. But they each bring their strengths and weaknesses as do differences in committee size between the two.

In Table IV.2, we summarize the perceived relative strengths and weaknesses of these two approaches to developing consensus panels based on insights from the three interviewees. Generally, permanent committees allow greater continuity and lower training costs but mean that expertise may not be as efficiently tied to specific projects. On the other hand, recruitment may be easier for projects with a more specific focus or term and a project structure allows greater flexibility in addressing skills. When committees are very large, coming to agreement may be more difficult.

[42] GASB uses part-time staff but deals with conflicts by employing only retired individuals when their expertise could be in conflict.

Table IV.2. Comparison of Case Study Committees' Characteristics

	FASB and GASB		NICE		USPSTF	ANSI
Consensus Panel/ Committee	FASB	GASB	Permanent committee (PHIAC)[a]	Rotating committee (PDG)[b]		
Number of Members	5	7	33	20	16	Varies by SDO
Term; Term Limit	5-year term; Limit 2 terms	5-year term; Limit 2 terms	3-year term; Limit 10 years	Approximately 14 to 21 months (i.e., length of time to develop the guidance)	4-year term; possible extension for 1-2 years	Varies by SDO
Time Commitment and Pay	Full-time, salaried	Full-time and salaried chair; other board members part-time and paid; meet 2.5 days every 6 weeks with 1/2-day phone call time in between	Part-time (chair has time bought out; committee members are volunteers but self-employed, and consumer members receive some payment)	Part-time (chair has time bought out; committee members are volunteers-paid otherwise by the NHS--but self-employed; consumer members receive some payment	Part-time (committee members are volunteers; meet 3 times a year (1.5-day meetings); expenses paid)	Varies by SDO
Composition	One member from academia, 2 CPAs, one issuer, and one investor.	Persons with experience working for state and local governments, one member from academia, and a retired CPA from one of the big four accounting firms	Medical, scientific, and public health experts and lay representatives	Topic experts and lay representatives	Medical practitioners in primary and preventive care, epidemiologists, health economists, decision-modelers, and experts in health care evaluation	Must include broad participation from materially affected and interested persons

Table IV.2 *(continued)*

	FASB and GASB	NICE		USPSTF	ANSI
Selection Criteria	Technical expertise and strong interest in investor and public policy (not because of narrow expertise in specific areas)	Professional members must represent varied expertise in medicine, social sciences and public health; all members must agree to serve in an individual capacity and not as representatives of any organization.	Professional members are experts on the specific topic; all members must agree to serve in an individual capacity and not as representatives of any organization.	Medical generalists rather than specialists to ensure recommendations are based on the evidence rather than professional societies' expectations. Persons who will be committed to the process and who are not affiliated politically.	Varies by SDO; each developer must state specifically how consensus will be determined. ANSI approves the consensus body during the accreditation process of the organization.

[a] NICE uses permanent committees for recommendations for public health interventions; these are typically targeted at specific populations and are generally small in scope. For example, public health intervention–related recommendations may focus on specific treatments for smoking cessation.

[b] NICE uses rotating committees for public health programs, which are more broadly targeted to the broader population, such as methods to reduce obesity or cardiovascular risk in the general population.

Different groups however differ in how much expertise they believe is desirable. The USPSTF deliberately aims for generalists, perceiving the specialists may find it harder to separate professional opinion from evidence.

Workload and Resources. All organizations reported that they were resource-constrained and would like to do more work if they had additional funds. In Table IV.3, we compare the level of productivity and resources required for each of these organizations' consensus processes. Because there are no standards for project size and resource needs and because some organizations use staff for multiple functions (USPSTF and ANSI), it can be difficult to make head-to-head comparisons.

While the number of projects varies across organizations, this does not seem to reflect the resources available to organizations or the time required to complete the work—probably reflecting differences in the definition of a project across organizations. Each organization appears to take a substantially long time to complete its project work. NICE has the largest budget followed by FASB. The USPSTF has the smallest budget.

FASB's support is guaranteed through a dedicated funding stream authorized in the Sarbanes/ Oxley Act designed to make the work on accounting standards independent of industry. FASB submits an annual budget to the SEC, which includes its annual work plan for the year but the agency is not constrained by that and can change the work priorities and reviews. GASB has not had access to such a funding stream before and is substantially smaller, though its processes work similarly to those of FASB. The 2010 financial reform bill enacted by Congress will align FASB and GASB financing by authorizing GASB funding through bond revenue.

Table IV.3. Relative Strengths and Weaknesses of Permanent Versus Rotating Consensus Committees

	Strengths	Weaknesses
Permanent Committee	• Committee understands how the consensus process works and does not require ongoing training. • High degree of expertise in types of questions asked. • Dynamic energy and familiarity among committee members. • Little burden on any one committee member.	• Members' expertise in some topics may be limited; may need to bring in outside experts. • Commitment to meetings is lower because of large size; members often only show if the issues being discussed are interesting to them. • Difficult to write recommendations as a group with so many members; the organization's staff and the chair to do most of the writing.
New Committee for Each Project	• Each committee includes leading experts who have extensive knowledge on the evidence before the process begins; the committee brings "high intellectual capital." • Commitment to meetings is greater because it is a fixed-term commitment.	• The organization must train each committee about the organizational procedures and how the committee should work; this results in considerable work and cost to organization.

NICE functions independently of government, though its funds come from Parliament and hence may be affected in the future by austerity policies in the UK. While topics must be approved by the government, NICE is not required to report how specific funds are used across projects, giving leadership discretion such a decision. The USPSTF's support, in contrast, which is through AHRQ and budget constrained, is much smaller. However, the task force is granted substantial autonomy in its work.

Historically, none of these groups is funded in the project-by-project fashion of NQF and in all three cases, the funders have more flexibility in deciding how to use funds than NQF appears to have, even under the new HHS contract. ANSI, however, like NQF, is a membership driven organization with its members representing industry efforts at voluntary standards. We do not know how member organizations accredited to conduct consensus projects are financed, but this likely varies.

Table IV.4. Workload and Resource Use of the Case Study Organizations

	FASB & GASB	NICE	USPSTF	ANSI
Number of Projects Conducted Per Year	Typically 8–11 projects active at any time	15–22 projects	Approximately 11 topics at any time	The number accredited per year varies between 3 and 15; they usually accredit between 5 and 7 SDOs per year.
Time Per Project	In rare cases, projects can be completed in 90 days; typically, projects take anywhere from 6 months to 5 to 7 years. Some projects have extended beyond 10 years.	Typically, projects take from 17 months to about 3 years.	Approximately 2–3 years total, including 12 to 18 months to conduct evidence reviews and make recommendations	The accreditation process usually takes 3–4 months.
Frequency of Updating Recommendations/ Standards	N/A	Every 3 years	Every 5 years	N/A
Staff Size	FASB: 65; GASB: 21 (The later may change in the future as the financial reform bill includes a dedicated funding stream from bond revenue to support GASB (FASB already has one through equities).	30 staff, primarily post-doctoral scientists who provide technical support; Administrative and clerical staff; Project managers; 5 deputies	Staff support through AHRQ; staff supporting the USPSTF including a nonphysician director, chief medical officers, 3 medical officers, higher level administrator who is in the CP3 AHRQ center, and other support for communications services.	Stephanie, can you look this up?
Sub-contractors	None mentioned	Academic centers typically conduct the evidence reviews	Evidence-based Practice Centers (EPCs)	None mentioned
Committee Training Required	No formal training mentioned for board members, but interviewees noted it takes about one year for members to become effective.	Lay members receive training on systematic evidence reviews. Each rotating committee and new members of the permanent committee require training, including professionals and lay persons.	None specifically discussed	None specifically discussed

Table IV.4 *(continued)*

	FASB & GASB	NICE	USPSTF	ANSI
Overall budget	FASB has an annual budget of $31 million per year and GASB has a budget of $6 to $7 million.	The annual budget for NICE is 61 million pounds. 50% budget goes to academic centers for evidence reviews; remaining 50% covers all other expenses.	USPSTF has a total budget between $1.5 and $2 million per year. This covers the reviews conducted by the EPCs, travel and meeting expenses, salaries for AHRQ staff, and services from AHRQ's Office of Communications and Knowledge Transfer.	ANSI has a total annual budget of $22 million. ANSI says that resources used for accrediting SDOs are much lower than what might be expected because work is conducted by a relatively small group of people who have been with ANSI a long time and have a lot of institutional knowledge. (Most of ANSI's budget supports other purposes.)
Funding Source	**FASB:** Fees charged by SEC to publicly traded companies based on their market capitalization. Revenues from publications and subscriptions **GASB:** Contributions from state and local governments**.** Revenues from publications and subscriptions (financial reform bill has dedicated bond based funding)	Parliament	Federal government	60 % of ANSI revenues are from publication sales; 18 % are from membership dues; 16 % are from accreditation services.

*NICE reimburses any physicians on the committees for costs incurred to pay other physicians to cover their practice while attending meetings.

Balance and Composition of Committees. Organizations had different goals in terms of balance and composition of the committees.

- By design, the USPSTF is composed of medical generalists and persons with specific methodological expertise (for example, epidemiologists and health economists). The task force is often criticized for not having representation from specialist groups among its members. However, interviewees noted that excluding these groups is appropriate because their incentive is to justify current practices, not to look objectively at the evidence. One interviewee noted that it makes sense for the task force to exclude groups "with skin in the game."
- NICE committees include both professional and lay members. Any needed expertise not included on the committees can be incorporated through expert testimony. A critical aspect of committee work is that members of the committees serve in an individual capacity. They are not on the committee to represent any organization. To facilitate lay members' participation on the committees, lay members receive training from NICE's patient and public involvement group on systematic evidence reviews.
- FASB and GASB seek balance in terms of expertise and understanding of stakeholder perspectives; specifically, they seek board members who have broad knowledge of accounting rather than specialized expertise in a limited area. Members are selected to bring different kinds of expertise and knowledge across the span of the work. However, each board member is responsible for representing public interest in terms of developing high quality and transparent accounting standards, not particular constituencies.
- ANSI seeks to balance ensuring that no single interest category constitutes more than one-third of the membership of a consensus body dealing with safety-related standards or no single interest category constitutes a majority of the membership of consensus body dealing with other than safety-related standards. Categories must cover all materially affected parties and consideration must involve at least the producer, user, and general interest. In addition, ANSI board members are composed of a diverse group of individuals from various sectors including government, industry, SDOs, trade associations, among other organizations. ANSI requires that certain thresholds be reached in voting, a process designed, we expect, to further limit potential domination by a single group.

Balance Between Scientific Evidence and Stakeholders. This issue is primarily relevant to NICE and USPSTF, both of which use rigorous evidence reviews to develop recommendations. Both organizations are committed to developing evidence-based guidelines that are not influenced by patient advocacy or other outside interests. A striking difference between the two organizations is NICE's openness to stakeholder participation in the process and limited opportunities for stakeholders to participate in USPSTF's decision-making processes. Specific differences between NICE and USPSTF include:

- All registered NICE stakeholders receive an emailed copy of the draft recommendations for comment. The committee reviews and responds to all comments. NICE publishes both stakeholder comments and committee responses on their website. To address stakeholder disagreements with the recommendations, the committees focus their replies on the evidence used to develop the recommendations. Other times, stakeholders provide feedback on issues of practicability and feasibility. All interviewees noted the importance of stakeholder comments, particularly for public health, where stakeholders

encompass a broad set of organizations and populations (for example, restaurants, safety equipment manufacturers, charities, and so forth) beyond traditional health care stakeholders.

- The USPSTF generally focuses on the available evidence and aims to avoid, it says, being influenced by advocacy and admonitions from consumers and medical specialties. Partner organizations are engaged to help the task force understand how to appropriately craft the message of the guidelines and to disseminate the guidelines; they are generally not engaged to debate the task force's recommendations. The task force has recently piloted a public comment period on draft recommendations. The goal is to use public comments to help improve the recommendations, for example, where the USPSTF may have missed relevant evidence or how they could better word the recommendations. The USPSTF says it has decided to incorporate such comments in future reviews but they are still determining the best way to do so and implementation will require adding staff support.

For FASB and GASB, the broader issue is that accounting is driven by conventions that aim to balance concepts with operational considerations in order to reflect economic reality. Because accounting is not a hard science, there is no absolute truth or scientific evidence to guide its work; rather, the boards try to establish conventions. They try to balance theory and practice, going as far to conduct cost-benefit analyses of many proposed standards to understand the conceptual benefit of a proposed standard versus the cost to implement it. There is tension at times over the balance in establishing practical versus accurate accounting conventions.

Managing Bias. All of the case study organizations studied had processes in place to address potential bias, although some were stronger than others. For example:

- The USPSTF has strict policies governing conflicts of interest. Members must declare any financial, intellectual, or other conflicts of interest prior to each meeting. Members' declaration of conflict of interest is graded by the chair, vice, and AHRQ staff prior to each meeting. Conflict of interest grades range from "A," which means that the member has no conflict of interest and can participate in all aspects of the task force work on the topic to "D," which means that the member cannot participate in any aspect of the recommendation (that is, the member may not be a topic lead and must leave the room for all discussion and voting on the topic; in addition, publicly released recommendations will note that the member was recused from participating on the guideline).
- NICE also requires committee members to declare conflicts at each meeting that may preclude participation, but does not have a grading system similar to USPSTF.
- FASB and GASB manage biases by requiring that the boards function independently from stakeholder organizations. FASB members must sever ties to previous employers once they are appointed to the board. Because GASB members are part-time (except for the GASB chair), they cannot require members to sever all employment ties. However, conflict of interest factors into selection, with members generally working for government agencies or universities or retirees, not employees of firms likely to be influenced by the decisions of the board. In addition, interviewees noted that GASB's commitment to due process and transparency helps manage bias because all meetings are open to stakeholders who can observe the process and draw the board's attention to any perceived biases.

- ANSI also has conflict of interest policies for both the standard development organizations as well as for the boards voting on accreditation of organizations and on proposed standards. Guidelines define relevant conflicts for Board consideration; the Board then will vote on whether the conflict is sufficient to disqualify members from voting.

Transparency. NICE, FASB, and GASB processes were rated as highly transparent by interviewees associated with both organizations.

- NICE posts meeting minutes, evidence reviews, and other committee documents on their website. Most committee meetings are open to the public. Registered stakeholders are welcome to comment on recommendations, and NICE posts its responses to all comments on its website.
- FASB and GASB technical decisions are made during board meetings, and all board meetings are open to stakeholder organizations and the public, although stakeholders and members of the public do not actively participate during the meetings. In addition, meetings are recorded and broadcasted on the FASB and GASB websites for those unable to attend. The boards invite public comment on all proposed standards, both at the preliminary view and exposure draft stages, and anyone is allowed to comment. All comments and responses to comments are posted on the FASB and GASB websites. All board meetings are required to be public.

One area where FASB and GASB have purposefully limited transparency is with staff analyses; FASB does not make these publicly available and GASB makes only final analyses available. The rationale is to allow for free exchange of ideas and opinions among board members and staff. By not publicly releasing staff analyses, or preliminary analyses for GASB, the boards do not have to be concerned about offending any particular stakeholder groups while evaluating and debating the merits of proposed standards. Interviewees noted that this allows staff and board members to have more candid exchanges about proposed standards and their implications. They also said that if (preliminary) staff analyses are made public, the boards could be accused of either not listening to stakeholders (when stakeholders disagree) or pandering to stakeholders (when some stakeholders agree), so it can be a lose-lose situation. When GASB releases final staff analyses, they do attempt to be diplomatic in how they word analyses, although they do not change the content or conclusions in the papers.

Transparency is an area where the interviewees were somewhat critical of the USPSTF process.

- The task force meetings are not open to the public, and even some portions of meetings are closed to partners. There are meeting minutes for all task force meetings, although these are not very detailed and not made publicly available. Although procedures are posted on the website, it is not easy to find information. All interviewees noted that after the recent mammography screening guidelines were released, some of the criticisms leveled at the USPSTF clearly demonstrated that critics do not understand the process and how the guidelines were developed. However, some of the lack of transparency in USPSTF procedures is by design; in particular, the process is intended to protect the task force from advocacy. They believe it may be difficult to remain objective if there are advocates in the room. Interviewees noted that the task force is working to improve

transparency in certain areas. For example, it is working to make more documents publicly available.

ANSI produces a web-based weekly publication called *Standards Action*, which contains proposals for new standards, as well as revisions, reaffirmations, and withdrawals of existing standards. It also includes proposed revisions to ANSI's procedures and to ISO proposals and developments. The public is allowed to comment on each of these topic areas.

Political Independence. Each of the organizations studied function independent of government agencies, although they often work closely with government agencies. NICE and USPSTF are funded by the government. Political independence benefits both the organizations and the government. Specifically, these organizations may make politically unpopular recommendations, and this provides government officials opportunity to distance themselves from such recommendations. At the same time, government officials value independent, non-politically derived recommendations and guidelines.

3. Summary of Findings in the NQF Context

In Table IV.5, we summarize key features of NQF and each of the comparison case studies. In terms of focus, NQF, NICE, and USPSTF are most similar in that they are health focused whereas FASB and GASB focus on financial standards for accounting in private and public organizations. ANSI focuses on a range of standards, typically based in industry and reflecting the engineering routes of the organization.

The criteria used by organizations differ. At one extreme, the USPSTF is focused exclusively on rigorous evaluation of scientific evidence in a relatively closed process. In contrast, NICE is concerned with evidence, but also aims to obtain input from a variety of stakeholders and take into consideration the practicability and feasibility of what is intended. FASB and GASB may use formal field tests at times to assess the practicability of proposed accounting standards or to identify unanticipated effects.

In terms of workload and timeliness, the comparison highlights the potential irrelevance of the concept of "project" as a standardized metric in assessing time requirements. The number of active projects per year differs substantially across these organizations in ways that appear unrelated to available resources. All experience considerable variability in the time frame it takes to complete a project. NQF's time frame is on the shorter end of spectrum. However it is difficult to make sense of these data without understanding more about what given projects entail.

The organizations differ in how they view and handle the concept of consensus. At one extreme, the USPSTF rejects even a "consensus" label because they perceive themselves rating and applying evidence, a marked departure to what they view as the historical practice of consensus bodies. FASB, GASB, and NICE view themselves as coming to agreements that take into account a variety of perspectives (including the public interest or lay representatives respectively).

The resources available to the organizations differ along with the support they provide for assessing evidence. The USPSTF appears to operate with limited funds (albeit support from evidence-based practice centers). NICE, FASB, and GASB appear to have much more stable and supportive financing streams. NICE's funds come from Parliament and it has been relatively well

Table IV.5. Summary of NQF and Selected Other Consensus Processes on Selected Dimensions

Dimension	NQF	NICE	FASB and GASB	USPSTF	ANSI
Focus	Endorsed frameworks, practices and measures for public reporting on the performance of the U.S. health care system	Recommended population based programs and interventions to improve public health	Develop and improve accounting standards for private sector corporations (FASB) and state and local government (GASB)	Recommendations for delivery of preventive and primary care services	Primary administrator and coordinator of U.S. private sector voluntary standards program to enhance global competitiveness of business and U.S. quality of life; accredits qualified standards development organizations (SDOs)
Criteria for Decision	Importance, scientific acceptability, feasibility and usability	Review of evidence and economic modeling, expert testimony, internal review of stakeholder comments on practicability, feasibility, and so forth	Accounting standards are "conventions" based on experience to balance theory and practice; may include volunteer field tests of practicability of application	Rigorous evaluation and rating of scientific evidence (does not view itself as a consensus body)	NA
Standard for Approval	Majority (usually more)	Broad agreement, no voting	Simple majority	Two-thirds majority	Majority votes and 2/3 of voters
Consensus Body	Volunteers, multi-stakeholders; individual project committees to recommend with standing committee to decide	Mix of experts and lay representatives (later and new members receive training)[a]	Appointed term limited salaried commission[b]	Appointed, term limited expert volunteers (generalists versus specialists on a particular topic)	Varies across SDOs but no single interest category can be more than 1/3 of body for safety standards or the majority for other standards.
Active Projects Per Year	12-15?	15-22	8-11	11	NA[b]
Project Length	Varies, 12 month average	From 17 months to 3 years	Varies from 6 months to 5-7 years, some longer	2-3 years, with 12 to 18 months for evidence reviews and recommendations	Varies across accredited organizations (3-4 months for accreditation)
Support for Decision	Staff focused mainly around support for process; reviews have no formal staff documents	Academic centers conduct reviews; NICE staff include full-time scientists	Full-time staff with accounting expertise prepare papers	Evidence-based practice centers conduct reviews; staff support from AHRQ	NA
Funding	Mix of member dues and public/private sector funding ($10 million per year HHS contract since 2009 for multiple uses)	Parliament ($61 million; half to academic centers)	FASB: fees assessed on publicly traded companies by SEC[c] (FASB $31 million and GASB $6-7 million)	Federal government ($1.5 million to $2 million budget including EPC work)	Publication sales, membership dues, accreditation services ($22 million budget for multiple uses)

Table IV.5 *(continued)*

Dimension	NQF	NICE	FASB and GASB	USPSTF	ANSI
Managing Bias (Conflict of interest)	Conflict of interest policy with management to minimize confict	Disclosure at each meeting that may preclude participation (no grading). Members must agree to participate in an individual capacity.	Handled as part of appointment; members required to function independently from perspective of investor and public policy versus as stakeholders	Strict policies for disclosure each meeting with grading of disclosure and rules for participation	Conflict of interest policy required of SDOs and ANSI; ANSI operates final level of appeal.
Transparency and Public Participation	Materials posted; meetings open; comments elicited both from members and public at large; members given preference in committees	Registered stakeholders can comment and receive material; materials posted; most meetings open	All decisions at meeting open to public; no public participation; comments elicited; most staff documents not public	Meetings are not public; minutes are not detailed or publicly available; limited transparency is by design to limit advocacy. USPSTF has partner organizations but members from these organizations attending meetings do not participate in decision making.	SDOs must open process to all directly and materially affected with no undue financial barrier; ANSI publishes weekly proposals for new and proposed standards. Public can comment; participation not dependent on membership
Political and Operational Independence	Independent body; funding constraints have tied topics to funder interest; HHS contract is broader but involves detailed oversight; membership organization of 8 types	Independent; topics recommended, by panel but recommendations must be approved by government	Independent; board submits budget to SEC but is not bound by projects listed and does not report spending by project	Independent federal advisory panel with history of government support for this role; topics approved by task force based on relevance, importance, and potential impact	Independent; membership organization of 1,000 diverse entities of 6 types

[a] NICE has a 33 member permanent committee for interventions and 20 member project committee for programs. Chairs have some time bought out; experts are volunteers assuming NHS support from employer, and lay representatives (and self employed) receive payments.

[b] FASB has 5 members all full time and salaried; GASB has 7, with a full-time chair and others part time

[c] GASB relies on state and local government contributions and revenues from publications and subscriptions; financial reform bill has dedicated bond based funding.

endowed, though that funding may be affected by the UK's change in leadership and new austerity measures. NICE absorbs some labor costs associated with participants in their processes (notably lay representatives and buyout of time for those leading the work) and contract with academic centers to do evidence reviews to support their work. FASB and GASB do not rely on volunteers at all, with full- or part-time paid boards that are supported by the analytical work of seasoned accounting staff and independent secure funding streams designed to allow them to stay independent of industry. NQF relies much more heavily on volunteers than the other organizations and also makes more limited use of contracting experts or senior staff to conduct analyses relevant to particular projects that are part of the CDP.[43]

NQF's funding appears to limit its ability to set priorities more than other organizations. Historically, NQF has had to solicit funds on a project-by-project basis that limited its flexibility to set priorities. HHS funds have potential to change that, but specific projects are approved annually (US GAO 2010). NQF's ability to plan and spend these funds in a timely manner is also limited by federal contracting, reporting, oversight, and approval processes that apply to individual projects and tasks as well as the contract oversall. This contrasts, for example, with FASB, which submits an annual budget to the SEC that includes a work plan but does not constrain them in initiating projects or require detailing later reporting. We are uncertain where ANSI falls on this spectrum given their complex mission. As a member organization, ANSI, like NQF, probably needs to balance stakeholder interests and protect itself against undue influence by its most well endowed members.

4. Lessons for NQF

The case studies provide what to us appear to be valuable contrasts that highlight relevant decisions associated with structuring consensus processes that may be of value in informing the structure of the CDP going forward. They provide both insights on how particular steps in the CDP might be refined and also illustrate more fundamental differences in conceptual approach. We review in turn particular lessons that seem potentially relevant to issues of timeliness, efficiency, and effectiveness, and then some broader issues.

Timeliness. Like NQF, each of the processes we reviewed took considerable time and that time varied across projects. While our review of these processes did not have the depth of analysis and interviews as that of NQF, it appears that those overseeing these processes, like those of NQF, justify long time frames by the stakes associated with the results. NICE's approach to scheduling and implementation also could be useful to exam as it appears the most highly organized and tightly structured of those reviewed. However, NICE also has more resources than NQF, which is an important caveat because staff availability may be a criterion to moving processes faster.

Efficiency. The comparison processes reviewed used a diversity of features, some of which could be considered to enhance the efficiency of the CDP. This includes approaches to deciding on an optimal size for steering committees, the way expertise is obtained, and how registration or handling of stakeholders is used to enhance stakeholder communication. A review of other processes also provides food for thought about the points at which stakeholder feedback is relevant. For example, though all (except the USPSTF) obtain comments on proposed approaches and final

[43] This appears to still be the case even thought NQF recently has begun to contract for statistical advice.

recommendations, NQF appears to go further than most of the others in garnering stakeholder input at each stage in the process (for example, allowing comments on proposed panels after nominations have been received). As someone interviewed for a case study noted, the risk in structuring feedback is that the process itself can become the goal. Hence continuous reinforcement of the ultimate goal of measures may be important in keeping processes on track

ANSI's history may have relevant insights into how to handle review of standards or expedited review of process that already have been informed by some type of external review if not formal consensus process that meet certain established criteria. Currently, it appears that NQF does not take advantage of comments or analysis prepared as part of developing measures. While use of such information may need to be controlled to ensure an independent CDP review, there may be more efficient and effective ways of handling the more formal process of selecting and approving topics for review.

Effectiveness. Each process, with the possible exception of the USPSTF, has to balance evidence against other criteria, including acceptability and feasibility. From our review, we did not perceive that NICE necessarily was less evidenced based than the USPSTF, even though NICE sought to formally take into account operational considerations in its review. NICE, FASB, and GASB used formal methods of field testing or gaining input; NQF may want to consider these either as part of its review or as submissions it accepts. Each of the other processes (except possibly ANSI) seemed to do more to complement the work of volunteer or part-time committees with expertise (either through in-house staff or consultants) to assist them in better addressing the issues of scientific acceptability, as well as other issues, like feasibility, than committee members may be less well positioned to understand.

Although ANSI does not lead consensus development processes for standards, they are the intellectual force behind consensus development for most engineering, consumer products, health, and other standard organizations. Elements of this model could be useful for NQF to think about, particularly as need for more and more health care-related quality measures grow.

V. CONCLUSIONS AND RECOMMENDATIONS

This assessment shows that the CDP operated by the NQF is a recognized focus for work on measurement to support public reporting and healthcare quality improvement in this nation. Those interviewed perceived NQF to occupy a unique position in the "quality marketplace," with processes that allowed diverse interests and stakeholders to come together in an open and transparent manner to make decisions about the metrics guiding societal efforts to measure and track performance of the health care system in this country. As one interviewee observed, the fact that the CDP has survived and continues to generate endorsed standards through a multi-stakeholder consensus process, despite the inherent challenges in achieving that goal, is itself a measure of its effectiveness.

Nonetheless, NQF can in many ways be viewed as a young organization. Its procedures for endorsing standards are evolving and being refined. The external environment also has been anything but stable. Key features that define an effective set of standards—like shared agreement on ultimate goals and an incentive to align metrics defining those goals with incentives for health care delivery—have not, to date, existed across the public and private sector to frame the work of the CDP, but may now be emerging as a result of private sector work through the NPP and new requirements of the Patient Protection and Accountable Care Act or ACA.

We identify here what we view as the most significant areas for attention to enhance timeliness, efficiency, and effectiveness given the evaluation findings. From the prior chapters the reasons for highlighting these issues should be clear, along with selected actions that various stakeholders have suggested or might find responsive to their concerns. The specific actions related to these areas are further detailed in Table V.1 (at the end of this Chapter).

A. Timeliness

Adoption of Time Line Targets. It is impossible to evaluate the timeliness of the CDP without a benchmark, or at least some indication about how benchmarks should be considered.[44] Currently the process averages 12 months, but it varies considerably across projects. Even those closely involved in the process do not seem to have a shared vision for the current time line and what its goal should be. It could be useful for NQF and the key users of the standards it endorses to consider whether it is worthwhile to develop an explicit consensus standard with respect to timeliness of review that the CDP should attempt to reach, what differences in targets might be important for projects of different types, and how much allowance should be granted for random events and complications. We suggest that NQF's leadership, working with CSAC and key users of endorsed standards, meet to review the findings from this study against user needs and attempt to set goals to drive internal planning.

Target time lines probably will not fully address the issue of alignment of the NQF with external requirements (fixed by legislation, contract, or organizational membership expectations). NQF's new policy on staggered topic based reviews provides an opportunity to identify potential conflicts in advance and deal with them to better align specific projects with external requirements and also help stakeholders plan for their own use of standards. This likely will require NQF to have

[44] The CDP timeline specifies time for specified steps but includes no explicit public analysis of how long the process should take from start to finish.

flexibility to forward plan over several years rather than on a year-to-year or project-to-project basis, requiring HHS (as major funder) to employ a longer time horizon and more flexibility in funding. Government agencies and other users also could review their own internal procedures to see what flexibility they might have to better align their own internal processes with the time line of NQF.

Review CDP Procedures Given New Board Policy on Batching. As NQF implements the new board policy on batched review of existing and new measures around specific topic areas, some current procedures are likely to change and opportunities may be created to enhance the timeliness, efficiency, and effectiveness of the process. While interviewees told us they liked the new step of notification of new projects that has been part of the CDP recently, staff indicated that the new first step also has added time to the process. If a three year calendar is established, it may be feasible to substitute general publicity about that calendar for the specific notification in step 1 of the CDP. With advanced notice, there may also be opportunities to constitute and schedule advisory committees in advance, thus generating some time savings.

Some interviewees were disappointed that the CDP process now does not take into account more of the history or developmental work on measures. Currently the CDP does not, by design, consider analyses or public comment generated outside the CDP such as those used in measure development by NCQA, AHRQ or PCPI. While batched review is better suited to identifying best in class measures, it may complicate efforts to take advantage of informaton available on some but not all measures in that class. Batching also is likely to raise issues about the weight to be placed on established versus new measures in identifying "best of class". These are not enormous issues but they are important to consider and address in moving to the new system.

With changes in the scheduling of reviews and new staff overseeing the CDP, it also could be a good time to review the way NQF staffs CDP projects and internal procedures used to guide and oversee staff in supporting the effort. The role of project manager for a CDP project is a relatively challenging one and finding individuals with the right blend of substantive, organizational, and interpersonal skills suited to the role is undoubtedly challenging. It also could be useful to review the internal procedures that apply to the CDP to see if there are ways they can support a more consistent approach to the work without adding time to the process. We do not have detailed solutions to the issues raised about staff knowledge and variability but we believe they are important to address. Stakeholders also need to recognize that to do so fully NQF may require a more stable and secure funding stream than it has to date had available.

B. Efficiency

Continue Efforts to Improve Transparency through the Website. While the evaluation shows improvements in public availability of information on details of the CDP process for individual projects, there remains room for improvement even when measured in the most recent projects. Some projects are still not completely documented. Documentation historically has excluded some important information, such as the vote totals by constituency. Formats do not necessarily support users in easily identifying how standards were assessed against criteria and how comments were handled. There also appear to be lags in how long it takes some information to be posted, such as final reports.

Review Criteria for Steering Committee Size and Composition. NQF criteria for steering committee composition currently are fairly generic. Expertise relevant to individual projects is solicited and efforts are made to make sure a committee formed from nominees is balanced across constituencies and does not lack specific skills or representation. Steering committees also tend to be

relatively large, which probably adds to the scheduling difficulties because of the need to coordinate calendars across many busy people. It could be valuable to review the rationale for the steering committee and how it should be constituted. For example, is there a certain level of expertise with measurement all members require or need training to understand? What does representation mean in this context? With a smaller steering committee, it could be feasible to more adequately balance different points of view while creating more consistency in the expertise and perspective brought to the committee. The other review processes included in our assessment would seem to provide examples of different ways of restructuring committees.

As part of this review, it also would be valuable to communicate more clearly with constituencies the role separate technical advisory committees play in the process. Currently, some projects have them and others do not, based presumably on need for unique expertise. NQF says use of separate panels is being phased out in favor of integrating expertise directly on the steering committee. However our interviews suggest this policy change is not necessarily well known.

Enhance Consistency in Format and User Friendliness of Written Material. The format of materials available for different projects differs, though each is expected to address common issues of concern and there is some consistency across projects. The volume of material available in individual CDP projects also is not necessarily designed to support the different needs of users. It would be useful to review the main documents generated at NQF to increase the standardization of formats, expand use of layering with summaries and separate access to material at different levels of detail, and other changes to the way current documents are provided and can be accessed. Consistent templates would help users learn where they can look to find particular kinds of information. Summaries that cover specific topics of general interest could help council leaders seeking to educate and encourage their members about participation. A PDF with comments and responses, by category, could be easier for many users to use than an Excel spreadsheet

C. Effectiveness

Enhance the Availability of Expert Analysis to Support Review. The new board policy on batching projects by topic could provide an opportunity to support the quality of the steering committee's review with analysis, potentially prepared in advance by experts, on current measures and what is known in a particular field. As noted in Chapter IV, the other processes we reviewed include more analytical support for reviews than NQF currently offers. Commissioning a paper to lay out issues for batched topical reviews could enhance the focus on identification of "best in class" measures and gaps.[45] Such a paper would provide a comparative review of alternative measures and on a given topic that could serve as an analytical base for committee discussions.

Enhance Guidance on Criteria for Endorsement. NQF has established criteria for endorsement but interviewees expressed concern that they are not necessarily applied in a consistent way across projects. To some extent, consistency is challenging given gaps in evidence and the uneven development of measures. Yet it is important that NQF endorsement be viewed to follow consistent principles. CSAC's work to develop clearer guidance on the role of evidence in review already is poised to address some of the concerns raised. We suggest that NQF staff work with

[45] This would parallel the evidence based reviews by NICE and the USPSTF and staff analysis prepared for FASB and GASB.

CSAC to further build on the work they are overseeing with the goal of using the insight developed to generate a brief, 2-3 page summary of what the criteria mean and how they should inform decision making in different situations.

Link Decisions on the CDP to Broader NQF and National Priorities. Such action should focus particularly on the issues of scientific acceptance and importance. The CDP does not exist in a vacuum. Its effectiveness depends on its ability to generate an endorsed set of measures that match the needs users have and the ways people seek to use those measures to enhance the performance of the health care system. Historically, measurement work has been impeded by both limited resources and a lack of national vision or infrastructure for generating consensus on ways to move forward. NQF's work in partnership with public and private sector members has started to fill that gap through the National Priorities Partnership and expanded use of public reporting. The national health reform legislation provides further guidance on building an infrastructure to support performance monitoring, measurement, and improvement. The CDP will be more effective to the extent it can build on agreed upon priorities and ways of using measures to improve performance. Hopefully this evaluation will not be viewed in isolation from the broader activity and any subsequent changes will be used to inform the evolution of the CDP and its vision.

Table V.1. Suggested Areas and Actions for Consideration to Strengthen the CDP

Action	Responsible Organization/Staff
DEVELOP TIME LINE TARGETS FOR THE CDP THAT ARE FEASIBLE AND ACCEPTABLE TO MEASURE USERS	
Develop consensus on targets for time line. What reaction do key users of standards have to the data presented here showing an average of a year for the process? Realistically, what should be the goal for how long an average project should take and how much flexibility should be provided for variation based on project characteristics of random factors? What policies should apply to fast tracking of projects to address external constraints, including eligibility criteria and review criteria? Identify whether there are ways to take advantage of analyses conducted in measure development to facilitate the CDP review process.	NQF leadership in consultation with core users of the standards HHS: Analysis of ways of structuring HHS authority and processes to minimize misalignment of legislative and regulatory requirements in Medicare and Medicaid and multi-stakeholder targets for review timeliness. NQF/HHS: Ways of balancing HHS requirements and the constraints of a consensus based voluntary process that works equitably across public/private stakeholders.
REVIEW CURRENT PROCEDURES FOR THE CDP IN CONTEXT OF THE NEW PROCEDURES FOR BATCHED REVIEW	
Identify how procedures will or should be affected by the new batched policies for review and its emphasis on "best in class". Are there opportunities to save time by advance formation and scheduling of steering committees? Are there ways of enhancing information available to the process to better support a head-to-head comparison of "best in class?" What ways, if any, exist to enhance consistency and quality of staff support across projects and provide efficient oversight?	NQF Staff with CSAC: Review what new board policy means for operational issues associated with early steps in the CDP like panel formation and notification requirements of upcoming reviews. Adopt and target time line for steps associated with the three year schedule defining areas to be covered by projects. NQF Staff with CSAC: Consider whether it could be valuable to contract in advance for cross cuttomg analysis of existing and potential new measures to support work by steering committee under "best in class" review. NQF Staff Responsible for the CDP: Review current staffing policies and CDP procedures to identify ways of enhancing the consistency and quality of the work and provide efficient oversight.
CONTINUE EFFORTS TO IMPROVE TRANSPARENCY THROUGH THE WEBSITE	
While the evaluation shows improvements in public availability of information on details of the CDP process for individual projects, there remains room for improvement even when measured in the most recent projects.	NQF Staff: Monitor completeness and timeliness of posting materials on the web for each current project. Improve means to make voting transparent. Review formats to encourage transparency about how submitted standards match against the criteria set for endorsement.
REVIEW CRITERIA FOR COMPOSITION OF STEERING COMMITTEES AND USE OF EXPERTS	
Though NQF aims to structure panels to meet specific needs of different projects, there appear to be limited formal criteria to guide selection. How big should they be? What balance is desired between expertise and broad representation? Does the current way of structuring the process provide the best protection against "provider capture" and broad representation to address public policy interests? What form of orientation or training should new participants receive? What technical guidance should some or all get on key concepts related to their role and the requirements for review?	NQF Staff: Clarify current policy. Review comparison case studies to identify alternatives that work in the NQF context. Identify any potential changes that warrant CSAC involvement.

Table V.1 *(continued)*

Action	Responsible Organization/Staff
IMPROVE WRITTEN DOCUMENTS TO BETTER FACILITATE USER PARTICIPATION	
Review current standards for formatting individual common documents and develop templates supporting more standardized formats. Review formats with users to make modifications that better address their needs by using layering, ability for sharing summary information, and so forth.	NQF Staff: Review of current policies and templates for standardization. Discuss with chairs of member councils information they would find useful to help their members participate and what modifications might be valuable to introduce in formatting.
INCREASE TECHNICAL SUPPORT TO STEERING COMMITTEES	
Communicate with members the effort to incorporate technical advisory committee expertise directly on the steering committee. Identify other ways to provide technical input on a timely basis (e.g. providing expert testimony and contracted analysis and synthesis of existing research and analysis of measures.).	Take advantage of new process of batching reviews to generate expert briefing materials for each committee.
ENHANCE GUIDANCE ON CRITERIA FOR ENDORSEMENT	
Continue and build on work by CSAC dealing with the role of evidence in review. Refine the statement of evaluation criteria to support more consistent application of criteria across committees.	CSAC: Build on current work to better address the role of evidence in review to create user friendly guidance on how criteria are to be interpreted in review.
LINK CDP TO NATIONAL PRIORITIES AND OTHER ONGOING EVALUATIONS	
NQF is evaluating the use of measures and the National Priorities Partnership simultaneously through separate projects independent from this evaluation. Further, as part of its ongoing work, NQF is meeting with HHS and others to talk about requirements specified in the ACA and how they will be met. Expected changes that result from these diverse accounts will need to be leveraged and aligned to enhance the effectiveness of the CDP and NQF overall.	NQF Leadership. Review guidance and vision for what the CDP seeks to achieve within the entire context of NQF goals as national health reform is implemented.

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APPENDIX A

LIST OF GENERAL TOPICS FOR STAKEHOLDER DISCUSSION

Table A.1. List of General Topics for Stakeholder Discussion

Background for Respondents. We are focused specifically on the formal Consensus Development Project and how it works now. Our focus is on projects that involve calls for measures, standards, or (less frequently now) frameworks. We are looking only at the most recent period (projects begun in 2008 or later). We also want to distinguish between issues that occur across all projects versus issues specific to individual projects. We also know that the CDP evolves; therefore, we are interested in your views on ***how it works now.***

Background

1. To understand your perspective, will you briefly review your/your organization's history of involvement with NQF?
2. Have you been closely involved in particular projects versus generally involved in all projects? Which?
3. To what extent are you involved *now* in CDP and familiar with how it currently works?

Overall Feedback

4. What is your overall sense of how well NQF's CDP is now working?
5. What do you see as the CDP's main strengths?
6. What do you see as the CDP's main weaknesses or areas in need of improvement?

Assessment of Key Attributes of Performance

7. How would you assess the current *timeliness* of the CDP? Within the legal constraints relevant to NQF's CDP, what suggestions do you have for improving the process's timeliness? Which steps can be most improved?
8. How would you assess the current efficiency of the CDP? By efficiency, we mean the relative ease with which you or your organization can participate in the process, how you perceive the CDP's receptivity to feedback, and how well administrative support, such as the website or staff, enhances the process. Within the legal constraints relevant to NQF's CDP, what suggestions do you have for improving its efficiency?
9. How would you assess the current effectiveness of the CDP? By effectiveness, we mean that the review is high quality. That, in turn, means that topics and measures are well bundled and focused, that reviewers have the appropriate mix of skills, and that the CDP achieves what stakeholders expect or want from it. Within the legal constraints relevant to NQF's CDP, what suggestions do you have for improving the CDP's effectiveness?

Feedback on Variability and Particular Steps in the Process

10. Are there certain characteristics that distinguish projects that went better than others? What are these characteristics?
11. Which steps in the CDP seem to work best? Which are the most problematic?

    - Announced project
    - Call for nominations/panel development, call for measures
    - Review of measures
    - Public comment and voting
    - CSAC review
    - NQF board review
    - Appeal

Suggestions for Change

12. What are your perceptions of the most significant issues to be addressed in any revision of NQF's CDP?
13. What aspects of the CDP *should not change*, and why?
14. What aspects of the CDP *should change*, and why?
15. Are you familiar with other consensus development processes? How does NQF's compare? Are there particular features of the other processes that may be considered for incorporation into the CDP? Anything to avoid?

Summing Up

16. Did we omit a particular aspect of or issue with the CDP that demands our consideration?
17. How would you identify the most important issue that we need to consider in evaluating the CDP?

APPENDIX B

ADDITIONAL TABLES FROM THE TECHNICAL ANALYSIS

Table B.1. Project Duration by Step, Individual Projects

	1. Intent to Call for Standards	2. Call for Nominations	3. Call for Measures/ Candidate Standards	4. Committee Review	5. Public Comment	6. Member Voting	7. CSAC Review – Number of Days Following Close of Member Voting	8. Board Ratification – Number of Days Following CSAC Review	9. Appeal	Total Duration (includes delays between steps)
Ambulatory Care: Eye Care and Melanoma Measures	N/A	N/A[a]	0[b]	171	29[c]	29	50	50	29	397
Ambulatory Care – Additional Outpatient Measures 2010	13	29 (simultaneous)		--	--	--	--	--	--	--
Ambulatory Care Measures Using Clinically Enriched Administrative Data	N/A	30 (simultaneous)		213	43	29	9	29	29	489
Care Coordination Practices and Measures	N/A	29	137[d]	267	29	32	23	83	--	--
Efficiency: Imaging Efficiency	14	29 (simultaneous)		62	31	--	--	--	--	--
Home Health: Additional Measures (2008)	N/A	48	60[e]	60	29	29	12	21	29	258
Home Health: Additional Measures (2008) Addendum	N/A	48	29[f]	43	29	29	22	48	29	396
Hospital Care : Outcomes and Efficiency Measures Phase I	N/A	32	N/A	0[g]	29	29	N/A	N/A	30	203
Hospital Care: Outcomes and Efficiency Measures – Phase II	N/A	30	50[h]	241	40[i]	29	7	20	30	379
Hospital Psychiatric Care	N/A	no date	no date	135	29	29	9	111	29	472

	1. Intent to Call for Standards	2. Call for Nominations	3. Call for Measures/ Candidate Standards	4. Committee Review	5. Public Comment	6. Member Voting	7. CSAC Review – Number of Days Following Close of Member Voting	8. Board Ratification – Number of Days Following CSAC Review	9. Appeal	Total Duration (includes delays between steps)
Medication Management Measures	N/A	33 (simultaneous)		202	31[j]	30	36	46	31	375
Nursing Homes	13	39	63[k]	--	--	--	--	--	--	--
Outpatient Imaging Efficiency	N/A	30 (simultaneous)		30	29	29	5	10	29	240
Patient Outcomes Measures: Child Health and Mental Health – Phase III	139	29[l]	29	--	--	--	--	--	--	--
Patient Outcomes Measures: Phases I and II	13	29[m]	71	--	--	--	--	--	--	--
Patient Safety Measures	14	29 (simultaneous)		--	--	--	--	--	--	--
Patient Safety: Safety Reporting Framework	N/A	43 (simultaneous)		--	--	--	--	--	--	--
Patient Safety: Serious Reportable Events in Health Care	N/A	43	29	--	--	--	--	--	--	--
Pediatric Cardiac Surgery	30	31 (simultaneous)		--	--	--	--	--	--	--
Pressure Ulcer Framework	N/A	30	N/A[n]	206	29[o]	29	--	--	--	--
Safe Practices 2009	N/A	29	29[p]	305	29[q]	29	35	32	29	422
Safe Practices for Better Health Care 2010 Update	N/A	0	N/A	16	29	N/A	--	29	29	239
Stroke Prevention and Management	N/A	30 (simultaneous)		77	29[r]	31	24	5	27	205

Source: MPR analysis of NQF website.

[a] From website: As a continuation of NQF's multi-year Ambulatory Care project, members of the original Ambulatory Care Steering Committee were asked to guide this project. The call for nominations for the Ambulatory Care Steering Committee and technical advisors was issued in November 2004.

[b] Four revised or updated skin care (melanoma) measures and six eye care measures were submitted to NQF to fill important gaps in the ambulatory care measure set. These 10 measures considered by the Steering Committee were revised and updated versions of measures originally submitted to NQF in 2007 as a part of the Ambulatory Care: Specialty Clinician Performance Measures project.

[c] The Public Comment step occurred within the time frame of the Committee Review step.

[d] The Call for Candidate standards step started before the Call for Nominations step ended. There were 18 days of overlap.

[e] The Call for Candidate standards started at the same time as the Call for Nominations, but ended 12 days later. In addition, the Review of Candidate standards started 13 days before the Call for Candidate Standards ended (and 1 day before the Call for Nominations ended).

[f] The Call for Candidate standards step started before the Call for Nominations step ended. There were 17 days of overlap. In addition, the Review of Candidate standards started 13 days before the Call for Candidate Standards ended (and one day before the Call for Nominations ended).

[g] Only 2 measures endorsed--looks like they only had one meeting.

[h] The Call for Candidate standards step started a day after the Call for Nominations step. There were 29 days of overlap. In addition, the Review of Candidate Standards started 18 days before the Call for Candidate Standards ended.

[i] The Public Comment step occurred within the time frame of the Committee Review step. In addition, Member voting started before the Review of Candidate standards step ended. There were 22 days of overlap.

[j] The Public Comment step occurred within the time frame of the Committee Review step.

[k] The Call for Candidate standards started at the same time as the Call for Nominations. There were 39 days of overlap.

[l] The Call for Nominations started 11 days after the Intent to Call for Standards. There were 29 days of overlap.

[m] The Call for Nominations started 11 days after the Intent to Call for Standards. There were 29 days of overlap.

[n] An environmental scan step occurred instead of this step.

[o] The Public Comment step occurred within the time frame of the Committee Review step.

[p] The Call for Candidate standards step started before the Call for Nominations step ended. There were 15 days of overlap.

[q] The Public Comment step occurred within the time frame of the Committee Review step.

[r] The Public Comment step occurred within the time frame of the Committee Review step.

Table B.2. Involvement of Steering Committees in Projects

Project	# Of Steering Committee Members	Use of Separate Technical Advisory Committee
Ambulatory Care Additional Outpatient Measures 2010	17	
Ambulatory Care Measures Using Clinically Enriched Administrative Data	22 (2 dropped out during the project)	
Ambulatory Care: Eye Care and Melanoma Measures	n/a – this was based on the existing Ambulatory Care Steering Committee	Yes
Care Coordination Practices and Measures	27	
Efficiency: Imaging Efficiency	20	
Home Health: Additional Measures (2008)	20	
Home Health: Additional Measures (2008) Addendum	20	Yes
Hospital Care: Outcomes and Efficiency Measures Phase I	21	
Hospital Care: Outcomes and Efficiency Measures – Phase II	21	Yes
Hospital Psychiatric Care	21	Yes
Medication Management Measures	17	
Nursing Homes	20	
Outpatient Imaging Efficiency	15	
Patient Outcome Measures Phases I and II	24	Yes (multiple)
Patient Outcomes Measures: Child Health and Mental Health Phase III	18	
Patient Safety Measures	20 proposed	
Patient Safety: Serious Reportable Events in Health Care	20	
Patient Safety: Safety Reporting Framework	16	
Pediatric Cardiac Care	12	
Pressure Ulcer Framework	20	
Safe Practices 2009	14	
Safe Practices for Better Health Care 2010 Update	14	
Stroke Prevention and Management	17	

Table B.3. Volume of Comments Received in Member/Public Comment Period, by Project and Status (as of June 2010)

Project	Comments
Ambulatory Care – Additional Outpatient Measures 2010	Step had not occurred
Ambulatory Care Measures Using Clinically Enriched Administrative Data	800 comments from 37 responders
Ambulatory Care: Eye Care and Melanoma Measures	64 comments from 30 responders (19 NQF member organizations and 11 non member organizations or individuals)
Care Coordination Practices and Measures	464 comments from 50 responders *35 NQF member organizations and 15 non member organizations
Efficiency: Imaging Efficiency	no comments had been submitted yet (6/3/2010)
Home Health: Additional Measures (2008)	92 comments from 22 NQF member organizations
Home Health: Additional Measures (2008) Addendum	22 comments from 13 NQF member organizations
Hospital Care : Outcomes and Efficiency Measures Phase I	35 comments from 22 entities including 20 NQF member organizations and 2 non member organizations or individuals
Hospital Care: Outcomes and Efficiency Measures – Phase II	171 comments from 34 NQF member organizations and 7 non members
Hospital Psychiatric Care	63 comments from 30 responders
Medication Management Measures	266 comments from 36 NQF member organization s and 8 non member organizations
Nursing Homes	Step had not occurred
Outpatient Imaging Efficiency	205 comments from 33 responders including 24 NQF members and 9 non member organizations
Patient Outcomes Measures: Child Health and Mental Health – Phase III	Mental health: step is in process (to close on June 29) child health: has not happened yet (scheduled for July 12)
Patient Outcomes Measures: Phases I and II	Comments had been submitted for Phase 1, comment period just started for phase 2
Patient Safety Measures	step had not occurred
Patient Safety: Safety Reporting Framework	Comments had not been summarized
Patient Safety: Serious Reportable Events in Healthcare	step had not occurred
Pediatric Cardiac Surgery	step not completed
Pressure Ulcer Framework	24
Safe Practices 2009	22 according to draft report, but only 14 present in comment chart
Safe Practices for Better Healthcare 2010 Update	Not available
Stroke Prevention and Management	87 organizations, including 19 NQF members

Source: Most from Burstin and Bossley memo to CSAC on 10 projects (March 8, 2010). Others from website and spread sheet with comments

Appendix Table B.4. Number of Submitted and Endorsed Measures by Project (as of late June 2010)

Project	Number of Measures Submitted During Call for Measures	Number of Measures Endorsed	Percentage of Submitted Measures Endorsed
Ambulatory Care Additional Outpatient Measures 2010	27	Step had not completed	N/A
Ambulatory Care Measures Using Clincally Enriched Administrative Data	206	70	34%
Ambulatory Care: Eye Care and Melanoma Measures	10 (revised & updated measures that were submitted in 2007)	6	60%
Care Coordination Practices & Measures	78 measures and 35 practices	10 measures and 25 practices	33% (13% measures, 72% practices)
Efficiency: Imaging Efficiency	17	N/A	N/A
Home Health: Additional Measures (2008)	57	24[a]	42%
Home Health: Additional Measures (2008) Addendum	N/A	N/A	N/A
Hospital Care: Outcomes & Efficiency Measures Phase I[b]	3	2	67%
Hospital Care: Outcomes & Efficiency Measures – Phase II	21	4	19%
Hospital Psychiatric Care	3	2	67%
Medication Management Measures	35	19[c]	54%
Nursing Homes	25	Step has not occurred	N/A
Outpatient Imaging Efficiency	21	8	38%
Patient Outcome Measures Phases I and II	22 for Phase 1 and 21 for Phase 2	Step has not occurred	N/A
Patient Outcomes Measures: Child Health and Mental Health Phase III	30 for child health (website says 31) and 27 for mental health (website says 24)	Step has not occurred	N/A
Patient Safety Measures	44	Step has not occurred	N/A
Patient Safety– Serious Reportable Events in Healthcare	N/A	Step has not occurred	N/A

Table B.4 *(continued)*

Project	Number of Measures Submitted During Call for Measures	Number of Measures Endorsed	Percentage of Submitted Measures Endorsed
Patient Safety: Safety Reporting Framework	N/A	Step has not occurred	N/A
Pediatric Cardiac Care	13	Step has not occurred	N/A
Pressure Ulcer Framework	N/A	Step has not occurred	N/A
Safe Practices 2009	Not Available	34	N/A
Safe Practices for Better Healthcare 2010 Update	Update of previous practices	34	N/A
Stroke Prevention and Management	19	17	90%

[a] 24 is the number given in the final report, which includes both this project and the Addendum.

[b] The home health addendum standards were integrated with the core home health project in reports.

[c] 19 Endorsed according to the final report. The website reports 18 measures.

Table B.5. List of Practices, and Measures Endorsed by Project (Current as of late June 2010)

Ambulatory Care Using Clinically Enriched Administrative Data	
1	EC-234-08 Asthma-Short-Acting Beta Agonist Inhaler for Rescue Therapy
2	EC-016-08 Use of Spirometry Testing in the Assessment and Diagnosis of COPD
3	EC-255-08 COPD with Exacerbations- Adding a Long-Acting Bronchodilator
4	EC- 227-08 High Risk for Pneumococcal Disease - Pneumococcal Vaccination
5	EC-089-08 New Rheumatoid Arthritis Baseline ESR or CRP within Three Months
6	EC-060-08 Rheumatoid Arthritis Annual ESR or CRP
7	EC-056-08 Rheumatoid Arthritis New DMARD Baseline Serum Creatinine
8	EC-057-08 Rheumatoid Arthritis New DMARD Baseline Liver Function Test
9	EC-059-08 Rheumatoid Arthritis New DMARD Baseline CBC
10	EC-049-08 Hydroxychloroquine Annual Eye Exam
11	EC-079-08 Methotrexate: LFT within 12 Weeks
12	EC-080-08 Methotrexate: CBC within 12 Weeks
13	EC-213-08 Steroid Use -Osteoporosis Screening
14	EC-081-08 Methotrexate: Creatinine within 12 Weeks
15	EC-283-08 Osteoporosis-Use of Pharmacologic Treatment
16	EC-281-08 Osteopenia and Chronic Steroid Use – Treatment to prevent Osteoporosis
17	EC-028-08 Annual Cervical Cancer Screening for High Risk Patients
18	EC-240-08 Breast Cancer-Cancer Surveillance
19	EC-007-08 Follow-Up after Initial Diagnosis and Treatment of Colorectal Cancer: Colonoscopy
20	EC-248-08 Prostate Cancer – Cancer Surveillance
21	EC-071-08 Post MI: ACE Inhibitor or ARB Therapy
22	EC-208-08 MI-Use of Beta Blocker Therapy
23	EC-054-08 Stent Drug-Eluting Clopidogrel
24	EC-272-08 Secondary Prevention of Cardiovascular Events- Use of Aspirin or anti-platelet therapy
25	EC-202-08 Heart Failure - Use of ACE Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) Therapy

Table B.5 *(continued)*

26	EC-215-08 Congestive Heart Failure-Use of a Beta Blocker
27	EC-083-08 New Atrial Fibrillation: Thyroid Function Test
28	EC-244-08 Atrial Fibrillation - Warfarin Therapy
29	EC-256-08 Male Smokers or Family History of Abdominal Aortic Aneurysm (AAA) Screening for AAA
30	EC-099-08 [Hypertension] patients with a serum creatinine in the last 12 months
31	EC-037-08 Deep Vein Thrombosis Anticoagulation >= 3 Months
32	EC-061-08 Pulmonary Embolism Anticoagulation >= 3 Months
33	EC-053-08 Tympanostomy Tube Hearing Test
34	EC-006-08 Chronic Kidney Disease: Monitoring Parathyroid Hormone
35	EC-012-08 Chronic Kidney Disease: Monitoring Calcium
36	EC-005-08 Chronic Kidney Disease: Monitoring Phosphorous
37	EC-251-08 Chronic Kidney Disease – Lipid Profile Monitoring
38	EC-252-08 Chronic Kidney Disease with LDL Greater than or equal to 130 – consider adding a lipid lowering agent
39	EC-238-08 Non-Diabetic Nephropathy – consider adding and ACEI or ARB
40	EC-096-08 Adult(s) with diabetes that had a serum creatinine in the last 12 reported months
41	EC-095-08 Adults(s) taking insulin with evidence of self-monitoring blood glucose testing
42	EC-274-08 Primary prevention of cardiovascular events in diabetics older than 40 years – Use of aspirin or antiplatlet therapy
43	EC-231-08 Diabetes with LDL greater than 100 – Use of a lipid lowering agent
44	EC-232-08 Diabetes with Hypertension or Proteinuria - Use of an ACE Inhibitor or ARB
45	EC-262-08 Diabetes and elevated HbA1c – Use of diabetes medications
46	EC-013-08 Comprehensive diabetes care: HgA1c control (<8%) © NCQA
47	EC-239-08 GERD - Upper Gastrointestinal Study in Adults with Alarm Symptoms
48	EC-002-08 Appropriate Work Up Prior To Endometrial Ablation Procedure
49	EC-285-08 Chronic Liver Disease - Hepatitis A Vaccination
50	EC-046-08 Hepatitis C: Viral Load Test

Table B.5 *(continued)*

51	EC-009-08 HIV Screening: Members at High Risk of HIV
52	EC-003-08 Appropriate Follow-up for Patients with HIV
53	EC-203-08 Hyperlipidemia (Primary Prevention)- Lifestyle Changes and/or Lipid Lowering Therapy
54	EC-004-08 Adherence to Lipid Lowering Medication
55	EC-041-08 Dyslipidemia New Med 12-Week Lipid Test
56	EC-217-08 Atherosclerotic Disease- Lipid Panel Monitoring
57	EC-288-08 Atherosclerotic Disease and LDL Greater than 100-Use of a Lipid Lowering Agent
58	EC-119-08 Lithium Annual Creatinine Test in the ambulatory setting
59	EC-076-08 Lithium Annual Lithium Test in ambulatory setting
60	EC-077-08 Lithium Annual Thyroid Test in ambulatory setting
61	EC-051-08 Warfarin PT/ INR Test
62	EC-204-08 Warfarin - INR Monitoring
63	EC-027-08 Ambulatory Initiated Amiodarone Therapy: TSH Test
64	EC-014-08 Follow-Up After Hospitalization for Mental Illness
65	EC-032-08 Bipolar antimanic agent
66	EC-093-08 Adult(s) with Frequent Use of Acute Medications that also Received Prophylactic Medications
67	EC-039-08 Diabetes and Pregnancy: Avoidance of oral hypoglycemic agents
68	EC-112-08 Pregnant women that had HBsAg testing
69	EC-107-08 Pregnant women that had HIV testing
70	EC-110-08 Pregnant women that had syphilis screening
Ambulatory Care: Eye Care and Melanoma Measures	
1	0561 Melanoma coordination of care (AAD/AMA PCPI/NCQA) *AED-003-08*
2	0562 Melanoma: appropriate use of imaging studies (AAD/AMA PCPI/NCQA) *AED-004-08*
3	0563 Primary open-angle glaucoma: reduction of intraocular pressure by 15 percent or documentation of a plan of care (AAO/AMA PCPI/NCQA) *AED-005-08*

Table B.5 *(continued)*

4	0564 Cataracts: complications within 30 days following cataract surgery requiring additional surgical procedures (AAO/AMA PCPI/NCQA) *AED-007-08*
5	0565 Cataracts: 20/40 or better visual acuity within 90 days following cataract surgery (AAO/AMA PCPI/NCQA) *AED-008-08*
6	0566 Age-related macular degeneration (AMD): counseling on antioxidant supplement (AAO/AMA PCPI/NCQA) *AED-010-08*
Care Coordination: Practices and Measures	
1	The patient shall be provided the opportunity to select the healthcare home that provides the best and most appropriate opportunities to the patient to develop and maintain a relationship with healthcare providers.
2	Healthcare home or sponsoring organizations shall be the central point for incorporating strategies for continuity of care.
3	The healthcare home shall develop infrastructure for managing plans of care that incorporate systems for registering, tracking, measuring, reporting, and improving essential coordinated services.
4	The healthcare home should have policies, procedures, and accountabilities to support effective collaborations between primary care and specialist providers, including evidence-based referrals and consultations that clearly define the roles and responsibilities.
5	The healthcare home will provide or arrange to provide care coordination services for patients at high risk for adverse health outcomes, high service use, and high costs.
6	Healthcare providers and entities should have structured and effective systems, policies, procedures, and practices to create, document, execute, and update a plan of care with every patient.
7	A systematic process of follow-up tests, treatments, or services should be established and be informed by the plan of care.
8	The joint plan of care should be developed and include patient education and support for self-management and resources.
9	The plan of care should include community and nonclinical services as well as healthcare services that respond to a patient's needs and preferences and contributes to achieving the patient's goals.
10	Healthcare organizations should use cardiac rehabilitation services to coordinate care for patients with a recent cardiovascular event, where available, appropriate, and accessible.
11	The patient's plan of care should always be made available to the healthcare home team, the patient, and their designees.
12	All healthcare home team members, including patients and their designees, should work within the same plan of care and share responsibility for their contributions to the plan of care and achieving the patient's goals.
13	A program should be used that incorporates a care partner to support family and friends when caring for a hospitalized patient.
14	Assess and document the provider's perspective of care coordination activities.
15	Standardized, integrated, interoperable electronic information systems functionalities essential to care coordination decision support, quality measurement and practice improvement should be used.
16	An electronic record system should allow the patient's health information to be accessible to caregivers at all points of care.
17	Regional health information systems governed by public/private partnerships should enable healthcare home teams and to access all patient information.

Table B.5 *(continued)*

18	Decisionmaking and planning for transitions of care should involve the patient, and, according to patient preferences, family and caregivers (including the healthcare home team). Appropriate follow-up protocols should be used to assure timely understanding and endorsement of the plan for patient and their designees.
19	Patient and their designees should participate directly in determining and preparing for ongoing care during and after transitions.
20	Systematic care transitions programs that engage patients and families in self-management after being transferred home should be used whenever available.
21	The Transitional Care Model should be deployed for chronically highrisk older adults.
22	Healthcare organizations should develop and implement a standardized communication template for the transitions of care process, including a minimal set of core data elements that are accessible to the patient and their designee during care
23	Healthcare providers and healthcare organizations should implement protocols/policies for a standardized approach to all transitions of care. Policies and procedures related to transitions and the critical aspects should be included in the standardized approach.
24	Healthcare providers and healthcare organizations should have systems in place to clarify, identify, and enhance mutual accountability (complete/confirmed communication loop) of each party involved in a transition of care.
25	Healthcare organizations should evaluate the effectiveness of transition protocols and policies, as well as evaluate transition outcomes.
1	Cardiac rehabilitation patient referral from an inpatient setting
2	Cardiac rehabilitation patient referral from an outpatient setting
3	Patients with a transient ischemic event er visit who had a follow-up office visit
4	Biopsy follow-up
5	Reconciled medication list received by discharged patients (inpatient discharges to home/self care or any other site of care)
6	Transition record with specified elements received by discharged patients (inpatient discharges to home/self care or any other site of care)
7	Timely transmission of transition record (inpatient discharges to home/self care or any other site of care)
8	Transition record with specified elements received by discharged patients (emergency department discharges to ambulatory care [home/self care])
9	Melanoma continuity of care – recall system
10	3-Item Care Transitions Measure (CTM-3)
Home Health: Additional Measures (2008)	
1	Timely initiation of Care
2	Improvement of management of oral medications
3	Diabetic foot care and patient education implemented
4	Drug education on medications provided to patients/caregiver during episode
5	Influenza immunization received for current flu season
6	Pneumococcal polysaccharide vaccine (PPV) ever received
7	Depression assessment conducted
8	Pain assessment conducted
9	Pain interventions implemented
10	Improvement in pain interfering with activity
11	Improvement in dyspnea

Table B.5 *(continued)*

12	Heart failure symptoms addressed
13	Improvement in status of surgical wounds
14	Increase in the number of pressure ulcers
15	Pressure ulcer included in pain of care
16	Pressure ulcer prevention plans implemented
17	Pressure ulcer risk assessment conducted
18	Improvement in ambulation/locomotion
19	Improvement in bathing
20	Improvement in bed transferring
21	Multifactor fall risk assessment conducted
22	Emergency department use: with and without hospitalizations
23	Acute care hospitalization
24	Home health CAHPS
Hospital Care : Outcomes & Efficiency Measures Phase I	
1	0505 Thirty-day all-cause risk standardized readmission rate following acute myocardial infarction (AMI) hospitalization. (CMS) (HOE-001-08)
2	0506 Thirty-day all-cause risk standardized readmission rate following pneumonia hospitalization. (CMS) (HOE-002-08)
	Hospital Care Outcomes and Efficiency Phase II
1	HOE-010-08: 30-Day All Cause Risk-Standardized Percutaneous Coronary Intervention (PCI) Mortality Rate for Patients with ST Segment Elevation Myocardial Infarction (STEMI) or Cardiogenic Shock
2	HOE-009-08: 30-Day All Cause Risk-Standardized Percutaneous Coronary Intervention (PCI) Mortality Rate for Patients Without ST Segment Elevation Myocardial Infarction (STEMI) and Without Cardiogenic Shock
3	HOE-008-08: Hospital-Specific Risk-Adjusted Measure of Mortality or One or More Major Complications Within 30 Days of a Lower Extremity Bypass (LEB)
4	HOE-015-08 Postoperative Respiratory Failure (PSI#11)
Hospital Psychiatric Care	
1	Hours of Physical Restraint
2	Hours of Seclusion
Medication Management Measures	
1	0541 Proportion of days covered (PDC): 5 rates by therapeutic category
2	0542 Adherence to chronic medications
3	0543 Coronary artery disease and medication possession ratio for statin therapy
4	0544 Use and adherence to antipsychotics among members with schizophrenia
5	0545 Diabetes mellitus and medication possession ratio (MPR) for chronic medications
6	0546 Diabetes suboptimal treatment regimen (SUB)
7	0547 Diabetes and medication possession ratio for statin therapy
8	0548 Asthma control—suboptimal asthma control (SAC) rate (rate 1) and asthma control—absence of controller therapy (ACT) rate (rate 2)
9	0549 Pharmacotherapy management of COPD exacerbation (PCE): two rates are reported
10	0550 Chronic kidney disease, diabetes mellitus, hypertension and medication possession ratio for ACEI/ARB therapy

Table B.5 *(continued)*

11	0551 ACE inhibitor/angiotensin Receptor blocker use and persistence among members with coronary artery disease at high risk for coronary events
12	0552 HBIPS-4: patients discharged on multiple antipsychotic medications AND HBIS-5: patients discharged on multiple antipsychotic medications with appropriate justification
13	0560 HBIPS-5: patients discharged on multiple antipsychotic medications with appropriate justification
14	0553: Care for older adults—medication review (COA)
15	0554: Medication reconciliation post-discharge (MRP)
16	0555 Monthly INR monitoring for beneficiaries on warfarin
17	0556 INR for beneficiaries taking warfarin and interacting antiinfective medications
18	0557 HBIPS-6: post discharge continuing care plan created
19	0558 HBIPS-7: post discharge continuing care plan transmitted to next level of care provider upon discharge
Outpatient Imaging Efficiency	
1	0507 Stenosis measurement in carotid imaging studies
2	0508 Inappropriate use of "probably benign" assessment category in mammography screening
3	0509 Reminder system for mammograms
4	0510 Exposure time reported for procedures using fluoroscopy
5	0511 Correlation with existing imaging studies for all patients undergoing bone scintigraphy
6	0512 Percentage of patients undergoing cervical spine radiographs in trauma who do not have neck pain, distracting pain, neurological deficits, reduced level of consciousness, or intoxication
7	0513 Use of contrast: thorax CT
8	0514 MRI lumbar spine for low back pain
Safe Practices (2009/2010)	
1	Leadership Systems and Structures
2	Culture Measurement, Feedback, and Intervention
3	Teamwork training and skill building
4	Identification and Mitigation of Risks and Hazards
5	Informed consent
6	Life-sustaining treatment
7	Disclosure
8	Care of the caregiver
9	Nursing workforce
10	Direct caregivers
11	Intensive Care Unit care
12	Patient care information
13	Oral read-back and abbreviations
14	Labeling of diagnostic studies
15	Discharge systems
16	Safe adoption of computerized prescriber order entry
17	Medication reconciliation
18	Pharmacist leadership structures and systems

Table B.5 *(continued)*

19	Hand hygiene
20	Influenza prevention
21	Central line-associated bloodstream infection prevention
22	Surgical-site infection prevention
23	Care of the ventilated patient
24	Multi-drug resistant organism prevention
25	Catheter-associated urinary tract infection prevention
26	Wrong-site, wrong-procedure, wrong-person surgery prevention
27	Pressure ulcer prevention
28	Venous thromboembolism prevention
29	Anticoagulation therapy
30	Contrast media-induced renal failure prevention
31	Organ donation
32	Glycemic control
33	Falls prevention
34	Pediatric imaging
Stroke prevention and Management	
1	Deep vein thrombosis (DVT) prophylaxis
2	Discharged on antithrombotic therapy
3	Patients with atrial fibrillation receiving anticoagulation therapy
4	Thrombolytic therapy administered
5	Antithrombotic therapy by end of hospital day two
6	Discharged on statin medication
7	Stroke education
8	Assessed for rehabilitation
9	Functional communication measure: writing
10	Functional communication measure: swallowing
11	Functional communication measure: spoken language expression
12	Functional communication measure: spoken language comprehension
13	Functional communication measure: reading
14	Functional communication measure: motor speech
15	Functional communication measure: memory
16	Functional communication measure: attention
17	Acute stroke mortality rate

APPENDIX C

ORGANIZATIONS NOT SELECTED AS CASE STUDIES

AHRQ's National Advisory Council for Health Care Research and Quality. The National Advisory Council provides advice and recommendations to the AHQR Director and Secretary of Health and Human Services on priorities for health services research.[46] The council includes representatives from private sector and federal agencies. Beyond this description of the general composition of the National Advisory Council, there was little information on the consensus processes, if any, used by the Council and whether outside stakeholders had opportunity to participate. As a result, we recommended against developing a comparative case study of the National Advisory Council.

Health Level Seven International (HL7). HL7 is a not-for-profit organization that develops standards related to the exchange, integration, sharing and retrieval of electronic health information. HL7 is also an ANSI-accredited SDO. We assumed that HL7 follows ANSI regulations for voluntary consensus processes, and would learn about these processes through the ANSI case study.

NIH Consensus Development Program. The NIH Consensus Development Program includes systematic reviews of medical evidence by an unbiased panel (that is, a panel that excludes persons with financial or career interests in the topic) to develop evidence-based recommendations for various medical conditions. The panel includes 12 to 16 members, most with professional degrees in medicine, biostatistics, epidemiology, ethics, and economics, as well as persons representing the public. There appears to be limited opportunity for outside stakeholders to participate. In addition, the NIH consensus process uses AHRQ's Evidence-based Practice Centers (EPCs) to conduct the same type of evidence reviews as used by the USPSTF. Because the NIH Consensus Development Program looked similar to AHRQ's USPSTF processes (that is, similar focus on strength of evidence and use of systematic reviews conducted by the EPCs), we decided to only go forward with the USPSTF case study to maximize our ability to learn from diverse consensus processes.

Oregon Health Plan (OHP). The OHP provides coverage to Medicaid beneficiaries. OHP developed a system to provide comprehensive medical care for all Medicaid beneficiaries by limiting services and treatments to specific conditions and procedures on a prioritized list. A commission composed of physicians, nurses, and public representatives developed the list, allowing for public comment on the prioritization. There was limited information on the OHP website about any consensus processes used to develop the list or any of the relevant NQF-related characteristics, such as balance, transparency, and management of bias. As a result, we recommended that we not go forward with a case study on OHP.

Picker Institute. The Picker Institute is a non-profit institution that sponsors education and research in the field of patient-centered care, including the development of new surveys of patient experiences. We did not find any evidence on the Picker Institute website that it uses any form of consensus development process, and recommended that we drop it as a potential case study.

Underwriters Laboratories (UL). UL is one of the leading organizations that set standards for safety. We initially planned to conduct an in-depth review of the UL website as a potential case study organization, but learned that UL is an ANSI-accredited SDO. We assumed that UL follows ANSI

[46] For further information, see http://www.ahrq.gov/about/council.htm

regulations for voluntary consensus processes, and would learn about these processes through the ANSI case study.

U.S. Food and Drug Administration (FDA). We initially reviewed the FDA's website for information on standards for medical devices developed by the FDA's Center for Devices and Radiological Health (CDRH), as the CDRH includes staff responsible for facilitating use of medical device consensus standards. However, we learned through further research that the FDA itself does not develop standards or otherwise engage in consensus development processes. The FDA works with existing standards developing organizations (SDOs) to expand use of relevant standards. In addition, if the FDA identifies specific needs for standards, it would notify the National Institute for Standards and Technology (NIST) about these needs, and NIST would in turn notify ANSI. Thus, FDA-related standards are covered through our analyses of ANSI and ANSI's role as an intermediary between the federal government and SDOs.

APPENDIX D

COMPARATIVE ANALYSIS CASE STUDIES:

FASB and GASB
NICE
USPSTF
ANSI

FINANCIAL ACCOUNTING STANDARDS BOARD (FASB) AND GOVERNMENTAL ACCOUNTING STANDARDS BOARD (GASB)

Prepared by Kate Stewart with the support of Stephanie Peterson

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Background

The Financial Accounting Standards Board (FASB) and Governmental Accounting Standards Board (GASB) develop and improve accounting standards for nongovernmental entities and state and local governments, respectively. Both FASB and GASB are the standards-setting bodies established and overseen by the Financial Accounting Foundation (FAF), a private, non-for profit organization.[1] FASB is primarily funded by "accounting support fees," which are fees assessed on publicly traded companies based on their market capitalization. The Public Company Accounting Oversight Board serves as the FASB's collection agent, handling billing and collection on behalf of the FAF. GASB receives contributions for its work primarily from state and local governments. In addition, the FAF sells subscriptions and publications on the FASB and GASB websites. Funds from publications and subscriptions also fund FASB and GASB, particularly GASB, as contributions covered about 20 percent of GASB total expenses in 2009.[2]

The FAF was established in 1972; it in turn founded the FASB in 1973 and GASB in 1984.[3] As part of the Securities and Exchange Act of 1934, Congress established the Securities and Exchange Commission and gave it the responsibility and authority for establishing accounting standards for public companies. In the later 1930s, the SEC decided to look to the private sector to develop accounting standards (rather than doing so itself). Through the early 1970's,FAF, accounting standards for nongovernmental entities were developed by the Boards and Committees of the American Institute of CPAs (AICPA) and Councils and Committees of the Government Finance Officers Association. However, there was a general perception that AICPA and the GFOA, as industry associations, were not independent in its standards setting. In the late 1960's/early 1970s, there was a study of the standards setting process in the United States, the outcome of which was a recommendation to establish a separate, independent standards-setting body. The FAF and FASB were created as a direct result of that recommendation.

Under the supervision of the FAF, FASB[4] and GASB develop and improve accounting standards independent from government or industry entities. The issuance of authoritative standards of accounting and reporting require the approval of a majority (rather than unanimous consent) of the FASB or GASB members. In 1984, the FASB established the Emerging Issues Task Force (EITF). The EITF's primary mission is to reduce diversity in practice on a timely basis through the development of implementation guidance within the framework of existing authoritative literature. The EITF operates under the direct supervision of the FASB; since 2002 all consensus guidance of the EITF must be approved for issuance by a majority of the FASB.[5] Although the GASB has the authority to establish an implementation task force like the EITF, it determined that such a task force has not been necessary to this point.

Both Boards are supported by professional staff. Table 1 describes similarities and differences between FASB and GASB, which are also described further in the following sections.

Table 1. FASB and GASB Comparison

	Financial Accounting Standards Board (FASB)	Governmental Accounting Standards Board (GASB)
Sets Standards for…	Nongovernmental entities	State and local governments
Funding Sources…	• Fees charged by SEC to publicly traded companies based on their market capitalization. • Revenues from publications and subscriptions	• Contributions primarily from state and local governments • Revenues from publications and subscriptions
Board		
Size	5 members	7 members
Full time vs. part time	All 5 board members are full-time	Only the chair is full-time. The other 6 members are part-time.
Term Limits	5-year term; limit 2 terms	5-year term; limit 2 terms
Staff Size	65	21
Timeline for projects	Varies from 90 days to 10+ years	Varies from 90 days to 10+ years
Field-testing for some proposed standards	Yes	Yes

Overview of Standards Development Process

FASB and GASB follow the same general procedures to establish standards topics (usually referred to as 'due process'). The objective for both is to encourage and facilitate the free expression of opinion by all stakeholders in the financial reporting system, at all stages of the process. The general process for developing standards includes:

1. **Topic Selection**. The Boards receive requests and recommendations for new standards development and reconsideration of existing standards from various sources, including institutional analysts and investors/creditors, advisory councils and committees, the SEC, financial statement preparers and accounting firms. Suggestions are typically based on perceived deficiencies in Generally Accepted Accounting Principles (GAAP). The FASB and GASB Chairmen have the authority to decide whether to add a project to the technical agenda, subject to oversight by the Foundation's Board of Trustees and after appropriate consultation with FASB and GASB advisory councils, other Board Members, and staff.
2. **Preliminary Analysis and Deliberation**. Staff members conduct initial analyses and the Board deliberates at one or more public meetings the various issues identified and analyzed by the staff.
3. **Exposure of Draft Standards for Public Comment.** The Foundation's By-Laws require that proposed standards of accounting and reporting be exposed for public comment (referred to an \"Exposure Draft"). The Exposure Draft contains the proposed standards and the basis for the Board's conclusions. The length of the comment period depends on the nature and complexity of the proposal. In some cases, the Board may decide to solicit input on a technical project before finalizing an Exposure Draft. It can solicit that input in a number of different ways. Two common ways are by publishing a "Preliminary Views" that describes the Board's tentative conclusions on some or all issues. Another way is to issue a neutral discussion document that describes the financial reporting issues and alternative ways of addressing those issues without expressing any conclusions. Approval of the majority of the Board is required to issue an Exposure Draft

4. **Public Forums.** If necessary, the Board will hold a public forum to discuss financial reporting issues with stakeholders. An Exposure Draft is often the basis for such forums, which may take the form of a roundtable meeting or a public hearing.
5. **Redeliberation of Proposed Standards**. After the public comment period has closed, the Board re-deliberates the proposed provisions at a series of public meetings. The basis for those redeliberations are staff analysis of comment letters and other forms of stakeholder input.
6. **Standards Updated.** The Board issues final standards, subject to the approval of at least a majority of the Board.

In addition to the steps broadly described above, the Board may seek information about the benefits, costs, and operationality of its proposals through means other than the public exposure process. One of those ways is field-test proposed standards. Field-testing usually involves application of proposed standards to historical data to see how challenging it may be to apply the proposed standards. Field testing includes cost-benefit analyses of implementing the proposed standards. The Board may also conduct field tests, which includes an in-depth discussion of the proposal with selected stakeholders. For major projects, the Board may also develop a resource group or task force that includes preparers, auditors, and users of financial information who are experts on the subject to provide insights from stakeholder perspectives about the project.

Board Membership and Support Staff

FASB currently consists of 5 full-time, salaried board members and about 65 staff members. FASB board members are selected by the FAF board of trustees for a 5-year term and can be re-appointed for one additional 5-year term. An executive search firm helps to identify candidates for FASB through recommendations from various organizations, including the SEC. All FASB board members go through an interview process with SEC. The FAF Trustees selects FASB members based on their criteria established in the organization's by-laws, which include technical expertise and strong interest in investor and public policy. The By-Laws require that the FASB and GASB as a whole be balanced in the sense that the collective group has sufficient understanding of business, accounting, finance, accounting education and research. Currently, the FASB consists of one member from academia, 2 from public accounting, 1 issuer and 1 investor.

Once appointed, FASB board members must relinquish all ties to the organizations in which they worked. This ensures independence of Board members. Prior to July 1, 2008, the FASB board consisted of 7 full-time members who collaboratively set the agenda.[6] However, there was a perception that this process was slowing the work of the FASB, and the number of Board members was reduced to 5 and the FASB Chair was given responsibility for setting the agenda, in consultation with the other 4 board members.

GASB consists of 7 members supported by 21 staff members. Only the GASB Chair is full-time; the remaining 6 members are part-time. An executive search firm helps to identify candidates for GASB through recommendations from various organizations. The FAF also attempts to achieve balance within GASB by ensuring representation from academia, as well as representation from persons with state government, local government, state audit, local audit and public accounting experience. GASB currently includes members working for state and local governments, a university professor, an analyst, and a retired CPA from an accounting firm.

To ensure transparency of the standards-setting process, the rules of procedure of the GASB and FASB require that all discussions of technical accounting and reporting issues involving a majority of the Board be held in public meetings that are open to public observation. The FASB generally holds public Board meetings weekly. GASB public meetings are generally held in person every 6 weeks for 2.5 days. In between meetings, GASB holds teleconferences for one half-day. FASB public meetings are also audio-webcast.

Interviewees thought the 5-year terms for FASB and GASB were reasonable, as it takes at least one year to understand the process and become effective. However, one thought that 10 years was too long and that FAF could consider shortening the potential second term to 3 years, for a maximum of 8 years.

Both FASB and GASB staff are responsible for objective and neutral analysis. This helps facilitate debate among Board members when reviewing analyses of proposed standards. In addition, staff is responsible for reviewing and addressing stakeholder comments on preliminary view and exposure drafts. They summarize all comments by type and volume, including basic statistical analyses of comments; all comments and responses to comments are made publicly available on the FASB and GASB websites.

For each project, there is a staff member who functions as project manager. The project manager has overall responsibility for the analyses and putting forth recommendations to the Board. In addition to conducting conceptual and qualitative analyses of accounting issues and alternatives, staff often hold discussions with financial statement preparers, auditors and other stakeholders to better inform the Board of potential implications of proposed standards. Project managers typically have at least 10 years experience as an auditor or preparer of financial statements (FASB) or 10 years experience with public accounting or experience in state and local government (GASB). FASB staff also includes 2 senior investors who provide insights from investors' perspectives.

Timeline and Number of Projects per Year

The timeline and number of ongoing projects each year varies for both FASB and GASB. At any one time, FASB and GASB have about 8 to 11 active projects. Projects to address narrower practice issues or to enhance disclosures can be completed in 90 days to a year. Projects to fundamentally reconsider major areas of financial accounting and reporting often range in duration from 5 to 7 years. Some particularly complex or controversial projects have extended beyond 10 years. During the financial crisis in 2008, FASB issued about half a dozen accounting standards in 6 months to address issues of fair value and financial instruments. They were able to develop standards so quickly in response to the crisis by shortening the public comment periods.

Resources Required

All interviewees noted that FASB and GASB are resource-constrained, in the sense that there are practical limits to the number of projects a five or seven-member board can address at any one time. As noted earlier, contributions primarily from state and local governments to GASB cover approximately 20 percent of GASB's costs. The recently passed financial reform act provides the ability to establish a fee that would create a source of guaranteed funding for GASB, similar to the fees charged to publicly held companies for FASB, which may increase available resources for GASB. Currently, the FAF must use revenues from publications and subscriptions sales to cover remaining GASB expenses.

Although FASB's costs are primarily covered by fees from publicly traded companies, supplemented by some funds from publication and subscription sales, an interviewee noted that there is always more work FASB and GASB could be doing. FASB and GASB develops its annual budget in the fall, and the FASB budget is submitted to the SEC for review. The budget is based on planned technical activities for the year, however, the FASB budget does not constrain in the projects it may undertake; the Board may decide to work on other projects during the year.

Staff, FASB members and GASB chair are full-time salaried positions. The remaining GASB members are paid for one-third of their time. Field testing and fatal flaw analyses are conducted by unpaid volunteers. Board members and staff typically recruit former colleagues as well as employees of organizations that they think would be affected by the proposed standards.

Insights on Selected Issues Discussed with Interviewees

1. Transparency

FASB and GASB procedures are guided by principles of due process and transparency. Technical decisions are made during Board meetings, and all Board meetings are open to stakeholder organizations and the public, although stakeholders and members of the public do not actively participate during the meetings. In addition, FASB meetings are audio-webcast and archived on the FASB website for those unable to attend in person. The Boards invite public comment on all proposed standards, both at the preliminary view and exposure draft stages, and anyone is allowed to comment. All comments and responses to comments are posted on the FASB and GASB websites. One interviewee noted that stakeholders are more likely to accept standards if they feel the Board heard and considered their perspectives.

The Board's deliberations of a due process document (for example, Exposure Draft), based on stakeholder input, can result in significant changes. If the standard changes substantially due to comment letters, the Board will often develop a new exposure draft and allow for a new round of public comment. If the comment letters only result is minor tweaking of proposed standards, those proposed standards will not be re-exposed.

One interviewee clarified that while transparency and due process are critical to understanding strengths and weaknesses of proposed standards from various stakeholders' perspectives and to developing well-accepted standards, it is important that the due process system and commitment to transparency not hinder the development of standards. It can be easy to fall into the trap of seeing the process as the end in itself when the end is the development or modification of standards that achieve the overall missions of the board.

A majority of the Board members are not allowed to discuss a project that is currently on the technical agenda outside a publicly announced Board meeting as all Board meetings are required to be public, and it might be construed as "meeting behind closed doors." However, one area where FASB and GASB have purposefully limited transparency is with staff analyses; FASB does not make these publicly available at all and GASB only makes the papers provided to the Board members available. The rationale is to allow for free exchange of ideas and opinions among Board members and staff. By not publicly releasing staff analyses (or, preliminary analyses for GASB), the Boards do not have to worry about offending any particular stakeholder groups while evaluating and debating the merits of proposed standards. Interviewees noted that this allows staff and Board members to have more candid exchanges about proposed standards and their implications. They also said that if (preliminary) staff analyses are made public, the Boards can be accused of either not listening to

stakeholders (when stakeholders disagree) or pandering to stakeholders (when some stakeholders agree), so it can be a lose-lose situation. When GASB releases final staff analyses, they do attempt to be diplomatic in how they word analyses, although they do not change the content or conclusions in the papers.

2. Balance and Composition of the Boards

There was controversy around the reduction of FASB from 7 to 5 members, as various stakeholders were concerned that this move would concentrate power among too few members. The extent to which various stakeholder groups continue to hold this view is unknown. Interviewees noted that a benefit of having 7 board members on GASB compared to only 5 on FASB is that the 7 likely bring more diverse perspectives and backgrounds. It was unclear whether the reduction from 7 to 5 FASB members increased productivity of the board. As described above, the FAF attempts to ensure FASB and GASB are balanced in terms of expertise and understanding of stakeholder perspectives; in addition, the FAF seeks to identify board members who have broad knowledge of accounting rather than specialized expertise in a limited area. All board members are responsible for representing public interest in terms of developing high quality and transparent accounting standards, not particular constituencies.

Interviewees noted that the GASB has less time to work on standards compared to FASB because GASB members, with the exception of the Chair, are part-time and have other responsibilities. Interviewees thought it would be preferable for GASB to be full-time as well, but are constrained by resources.

3. Balance between Scientific Evidence and Stakeholders

One interviewee clarified that accounting standards are developed based on reasoning from conceptual and practical considerations rather than from empirical analysis. Because accounting is not a hard science, there is no absolute truth; rather, accounting standards are conventions that try to communicate underlying economic reality. They try to balance theory and practice, going as far to conduct cost-benefit analyses of many proposed standards to understand the conceptual benefit of a proposed standard versus the cost to implement it. However, one interviewee noted that it is challenging to quantify the benefits of good accounting standards, other than the fact that having solid accounting standards is central to efficient and effective capital markets. They have to find indirect measures of the benefits and develop some conclusions about the extent to which external financial statement users value the standards. That is, there is tension at times over the balance in establishing practical versus purely conceptual accounting standards.

4. Managing Bias

Interviewees acknowledged that all Board members and staff have biases based on their prior professional experiences. FASB and GASB manage these biases by requiring that the Boards function independently from stakeholder organizations, and having staff conduct analyses. Board members are then cognizant of staff biases and can acknowledge and address any such biases when discussing proposals. In addition, FASB's and GASB's commitment to due process and transparency helps manage bias because stakeholders can observe the process and draw the Board's attention to any perceived biases.

5. Political Independence

Although the SEC has oversight of FASB, FASB and GASB operate independently. This is critical, interviewees noted, as FASB accounting standards can move billions of dollars of capital. The SEC has been very committed to maintaining FASB's independence; even if the SEC was unhappy with FASB, it would not be allowed to withhold FASB funding in any circumstances. As a result, FASB operates independently from government and industry. The only way that FASB could lose its funding is if Congress changed the law. However, FASB is not insulated from political pressure and it is often a high-pressure job; for example, in April 2009, the FASB Chair was called before Congress and told to fix fair value accounting or Congress would do it for them.

One interviewee contrasted FASB with the International Accounting Standards Board (IASB). IASB does not have a guaranteed revenue stream, and contributing governments often try to dictate what they want from IASB. As a result, IASB is sometimes perceived to have less power because governments, such as France and Germany, make specific demands on IASB related to accounting standards. There has been debate in the US about the extent to which US collaborate with IASB to develop joint accounting standards. An interviewee further noted that one of the reasons that the cost of capital is typically cheaper in the US relative to the rest of the world because the US has the most transparent accounting standards; investors do not need to pay a capital risk premium for investing in the unknown.

References

[1] Information for this case study were derived from review of the FASB and GASB websites as well as interviews with a senior FASB staff member, a senior GASB staff member and a representative from a FASB stakeholder group. To protect interviewees' confidentiality, we do not attribute quotes directly to any interviewee. The FASB website can be found here: http://www.fasb.org/home. The GASB website can be found here: http://www.gasb.org/. Last accessed July 25, 2010.

[2] GASB Statement of Budgeted Revenues and Expenses for the Year Covering December 31, 2010 (Compared to 2009 Actual and 2009 Budget). Available at: http://www.gasb.org/jsp/GASB/Document_C/GASBDocumentPage&cid=1176156808953. Last accessed July 26, 2010.

[3] Financial Accounting Foundation 2009 Annual Report. Available at: http://www.fasb.org/cs/BlobServer?blobcol=urldata&blobtable=MungoBlobs&blobkey=id&blobwhere=1175820588436&blobheader=application%2Fpdf. Last accessed July 26, 2010.

[4] The FASB also works under the supervision of the SEC.

[5] We initially proposed to study FASB and EITF as standards setters. However, our interviewees clarified that the EITF is not a standards-setting body, and we did not pursue further analyses of the EITF.

[6] The Financial Accounting Foundation Board of Trustees Approves Changes to Oversight, Structure and Operations of the FAF, FASB, and GASB: Changes are Designed to Protect and Maintain the Efficiency, Effectiveness and Independence of the Standards-Setting Process. Press Release, February 26, 2008. Available at: http://www.fasb.org/faf/nr022608.pdf. Last accessed July 26, 2010.

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE): CENTRE FOR PUBLIC HEALTH EXCELLENCE[1]

Prepared by Kate Stewart with the support of Stephanie Peterson

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Background

The National Institute for Health and Clinical Excellence (NICE) is responsible for developing recommendations related to medical care and preventive and public health services to the British government and National Health Service (NHS).[2] NICE is funded by Parliament, and except for working collaboratively with the government on public health and clinical guidelines topic selection, NICE operates independently from the government and the NHS.[3]

The Centre for Public Health Excellence at the National Institute for Clinical Excellence (NICE) develops recommendations for population-based programs and interventions to improve public health. The two (interventions and programs) differ in that public health interventions are typically targeted at specific populations and are generally smaller in scope than public health programs, which are more broadly targeted to the broader population. For example, public health intervention-related recommendations may focus on specific treatments for smoking cessation, whereas program-related recommendations may focus on methods to reduce obesity or cardiovascular risk in the general population.

The consensus processes NICE uses to develop recommendations for public health interventions and programs are generally similar.[4] The most substantive difference between the two processes is the establishment of the panels that make the recommendations. For considering interventions, there is a permanent public health interventions advisory committee (PHIAC), comprised of 33 members representing the medical, scientific, and public health communities as well as the general public. Members of the PHIAC are appointed for a term of 3 years, with a 10-year limit. For considering programs, NICE establishes a new committee called the Programme Development Group (PDG) to develop recommendations for each public health program project. The PDG includes 20 members, including experts on the particular topic and representatives of the public.

Consensus Process

NICE processes to develop recommendations are guided by principles of transparency, collaboration and involvement of stakeholders. Below we list the basic steps of the processes used to develop recommendations for public health interventions and programs:

1. **Topic Selection.**[5] Anyone can suggest a topic to the Centre for Public Health Excellence for public health interventions or programs. The Centre often receives topics from public health professionals and public health leads through broad discussions with these groups. In addition, NICE may hold topic workshops where researchers and leaders in specific public health areas present on the issue. NICE reviews and evaluates the topics internally, and develops detailed briefing papers on the proposed topics. The briefing papers may be small or large. NICE has a topic selection panel comprised of health professionals and lay persons that reviews the briefing

papers, debates the proposed topics and makes recommendations, including which topics to prioritize and the key substantive areas within topics.[6] These recommendations are sent to the government for review by ministers and knowledgeable staff members (i.e., civil servants), who return to NICE 2-to-3-lines with instructions on which topic(s) to develop recommendations.

2. **Post-referral Clarification and Scope Development.** Once NICE receives instructions from the government, staff at the Centre for Public Health Excellence develops the scope of the work, including inclusion and exclusion parameters, key research questions to be answered, and the framework and logic model of the topic. The staff develops a "topic scope" document that goes out for public consultation.[7]

3. **Stakeholders Register Interest.** Anyone can register with NICE as a stakeholder for any project. For public health interventions and programs, stakeholder groups may include professional groups, local public health departments, charities, as well as the Department of Health and other government departments.

4. **PDG Established (for topics assigned to public health programs only).** As described above, a new PDG is established for each topic assigned to public health program process. Any topics assigned to public health interventions process are led by the permanent PHIAC.

5. **Scope Finalized.** Based on comments from stakeholders, the PDG/PHIAC finalizes the scope, including which research questions can be answered from the published literature to develop recommendations

5. **Evidence Reviewed.** NICE typically contracts with outside research organizations, primarily academic departments, to conduct reviews of the evidence. These include effectiveness review of the evidence and economic modeling. Economic modeling includes both cost-effectiveness and cost-utility analyses.

6. **Call for Evidence.** To address gaps in the evidence, the PHIAC and PDG may invite experts to testify on their knowledge and experience in these areas.

7. **Draft Recommendations Developed.** Based on review of the evidence, expert testimony and internal discussion among the relevant PDG/PHIAC committee, the committee develops preliminary recommendations. These are initially drafted by NICE staff and the committee chair, and circulated to all committee members for internal comment. The comment process is typically conducted remotely over email, although the committees can be reconvened if there is disagreement or new issues arise. Once general agreement is reached on the draft document, the draft recommendations are released for public comment.

8. **Stakeholders Comment on Draft Recommendations.** Stakeholders may comment both on the draft recommendations and the evidence reviews used to develop the recommendations.

9. **Fieldwork Conducted.** While draft recommendations are open for stakeholder comment, the Centre for Public Health Excellence contracts with research organizations to conduct focus groups and interviews with persons and organizations who would be responsible for implementing the recommendations. The goal of this field work is to identify practical issues that the committees may have overlooked that need to be incorporated into the recommendations.

10. **Final Recommendations Developed.** After the period for stakeholder comments has closed and fieldwork report is completed, the PHIAC/PDG meets again, debates any remaining issues and finalizes the recommendations.
11. **Recommendations Issued.** Final recommendations are reviewed by a final arbitrary at NICE, the Guidance Executive, which is comprised of NICE executive directors, guidance centre directors and the communications director[8] and which is legally responsible for recommendations that are issued by NICE. Upon approval from the Guidance Executive, the recommendations are published.

Consensus Project Timelines

Overall, the full process may take anywhere from 17 months to about 3 years. The first five steps of the consensus process, from topic selection to agreement on the final scope of the project, require anywhere from 3 months to more than one year. Steps six through twelve, from evidence reviews through final issue of recommendations take approximately 14 and 21 months, respectively for public health interventions and public health programs. At times, delays may occur for strategic reasons; for example, one interviewee noted that NICE delayed publication of a recent recommendation during the general election so that the recommendations did not get overlooked by the press. Other times, delays may occur if the evidence reviews do not fully address the research questions.

There is a process for updating recommendations every 3 years. Typically, NICE staff reviews the literature for any new evidence that may change existing recommendations. Only if NICE believes that new evidence will affect recommendations do they re-convene the PHIAC or PDG; otherwise, NICE staff confirm that there is no change to the existing recommendations, and incorporate any new evidence to support the recommendations.

Number of Projects per Year

There are 15 major projects, including both public health interventions and programs, in progress at any time during the year. Because the length of time required for projects may vary and differences in starting dates of projects, there are typically 22 public health projects in progress at any time. The Centre for Public Health Excellence published its first recommendation in 2006 and recently published their 26th recommendation.

Resources for Consensus

The Centre for Public Health Excellence includes approximately 30 staff members, the bulk of whom are post-doctoral scientists who provide technical support – for example, staff draft initial recommendations and brief the research organizations conducting the field work. There are also administrative and clerical staff, project managers and five deputies to help keep projects moving along. The biggest expense associated with developing public health recommendations is the academic research to develop the evidence reviews; this work comprises approximately 50 percent of the Centre's budget. The remaining 50 percent covers staff salaries, field work and committee-related expenses.

With the exception of the chairs of the PHIAC and PDG, all other committee members are volunteers. However, NICE reimburses any physicians on the committee for costs incurred to pay other physicians to cover their practice while attending meetings. NICE also provides an honorarium to lay persons who serve on the committees. Travel and meals associated with

committee meetings are also reimbursed. Within the various medical, scientific and academic professional communities, participation on PHIAC and PDG is generally considered prestigious and resume-enhancing; NICE does not have difficulties obtaining participation on these committees. Further, for physicians and employees in the NHS, the NHS considers committee-work at NICE part of public service and does not require additional payment.

Both PHIAC and PDG meet monthly. The Chair's responsibilities include working with NICE staff on topic selection activities, leading meetings, developing and editing documents with NICE staff, and giving presentations to various groups about the Centre for Public Health Excellence's work.

Insight on Selected Issues Discussed with Interviewees

1. Consensus Panels: Use of Permanent vs. Changing Committees and Differences in Size

The use of both permanent and changing committees within the Centre for Public Health Excellence reflects historical precedent within NICE. Specifically, the Centre for Public Health Excellence was founded subsequent to the Centres for Health Technology Evaluation and Clinical Practice. The Centre for Health Technology Evaluation, which develops recommendations for use of medical care technologies, uses permanent committees, while the Centre for Clinical Practice, which develops treatment guidelines, uses rotating committees. The PHIAC was modeled after the Centre for Health Technology Evaluation and the PDG after the Centre for Clinical Practice.

Both the permanent PHIAC and rotating PDG have been successful at delivering high-quality, evidence-based recommendations on time. None of the interviewees thought one approach was superior to the other, but recognized that each has its strengths and weaknesses. There are also strengths and weaknesses associated with the different size committees. Table 1 summarizes the perceived relative strengths and weaknesses of these two approaches to developing consensus panels based on insights from the three interviewees.

2. Informal Consensus Processes within PHIAC/PDG

The PHIAC and PDG come to broad agreement over the recommendations during meetings and over email while finalizing the wording of recommendations in the written drafts. Neither committee uses formal consensus processes, such as use of Delphi or nominal group methods to achieve consensus. It is possible for the committees to vote on recommendations, but this is rarely done. Mostly, the committees come to general agreement through discussion and debate at meetings and via email exchanges. One interviewee noted that it would be feasible for NICE to develop more formal processes for developing consensus, but this would require more resources, and the process is already relatively expensive; in addition, people complain that NICE is currently too slow developing recommendations, and implementing more formal consensus processes would further slow the process.

3. Field Testing

The Centre for Public Health Excellence is the only NICE Centre that conducts field-testing of draft recommendations. The rationale behind field testing is to conduct a "reality check" that the evidence-based recommendations are practicable. There was some disagreement over the usefulness of the field testing process among interviewees. While two interviewees noted that input from implementers have led committees to re-think and revise recommendations, another noted that

Table 1. Relative Strengths and Weaknesses of Permanent Versus Rotating Consensus Committees

	Strengths	Weaknesses
Permanent Committee with 33 members (PHIAC)	• The PHIAC understands how NICE works, and does not require on-going training • High degree of expertise in types of questions asked • Dynamic energy and familiarity among committee members • Little burden on any one committee member	• Members' expertise in some topics may be limited; may need to bring in outside experts • Commitment to meetings is lower because of large size; members often only show if the issues being discussed are interesting to them • Difficult to write recommendations as a group with so many members; PHIAC relies on NICE staff and the Chair to do most of the writing
New Committee for each Public Health Program project with 20 members (PDG)	• Each committee includes 20 leading experts who have extensive knowledge on the evidence before the process begins; the committee brings "high intellectual capital"	• NICE must train each PDG about NICE processes and how the committee should work; this results in considerable work and cost to NICE • Commitment to meetings is greater because it's a fixed-term commitment

most of the input from field testing repeated information that was obtained from stakeholders during the consensus process.

4. Balance and Composition of PHIAC and PDG committees

As noted above, both PHIAC and PDG include professional and lay members, including persons representing patients and caregivers. Any needed expertise not included on the committees can be incorporated through expert testimony during the call for evidence (step 8 of the consensus process above). A critical aspect of committee work is that members of the committees serve in an individual capacity. They are not on the committee to represent any organization. In addition, NICE has a "declaration of interest" procedure at each meeting where members must declare outside interests that might influence their decisions. Because there is relatively little money in public health, financial conflicts of interest tend to be rare among PHIAC and PDG members. To facilitate lay members' participation on the committees, lay members receive training from NICE's patient and public involvement group on systematic evidence reviews.

5. Balance between Scientific Evidence and Stakeholders

NICE public health recommendations are guided by the scientific evidence. However, one of our interviewees noted that there is a distinction between empirical information reported in the scientific literature and how this information is interpreted and transformed into recommendations. NICE tries to clarify which information is being interpreted and how it is interpreted – for example, through theoretical, clinical or practical viewpoints. This type of evidence and interpretation differs from rationale knowledge based on anecdotal experience or opinion. NICE tries to minimize the influence of anecdotes and opinions on recommendations, but their ability to do so varies with the

strength of the evidence base. For issues where the scientific evidence base is solid, there is little room for anecdote or opinion; in contrast, when the science base is limited and experts are invited to provide expert opinion, the committees have to make judgments on how heavily to weight expert opinion. Another interviewee noted that NICE tries to stretch the evidence as far as they can and listen to experts, but it can be a challenge to reconcile both.

All registered stakeholders receive an emailed copy of the draft recommendations for comment. The committee reviews and responds to all comments. NICE publishes both stakeholder comments and committee responses on their website. To address stakeholder disagreements with the recommendations, the committees focuses its replies on the evidence-base used to develop the recommendations. Other times, stakeholders provide feedback on issues of practicability and feasibility. All interviewees noted the importance of stakeholder comments, particularly for public health, where stakeholders encompass a broad set of organizations and populations (e.g., restaurants, safety equipment manufacturers, charities, etc.) beyond traditional health care stakeholders.

6. Managing Bias

Interviewees thought NICE did a solid job managing bias among committee members and stakeholders. NICE has specific guidelines for declarations of conflicts of interest, and requires committee members to declare conflicts at each meeting. In addition, recommendations are developed on the strength of the evidence base, and this helps to minimize individuals' biases. One interviewee noted that throughout the consensus process, committee members become aware of other committee members' personal biases and can take those into account when discussing the evidence. Similarly, stakeholders register interest for a reason, and committees can account for stakeholders' positions.

7. Transparency

All interviewees noted that NICE consensus processes are very transparent. NICE posts meeting minutes posts meeting minutes, evidence reviews and other committee documents on their website. Most committee meetings are open to the public. [9]

8. Political Independence

As noted above, NICE is funded by the British Parliament, but operates as an independent entity from the government and the NHS, with the exception of the topic selection process. This arrangement is beneficial to all parties, as the government seeks independent advice on these topics. NICE has provided recommendations that are politically unpopular, and this insulates government ministers from having to take responsibility for the recommendations. However, there is concern that current 'austerity measures' may lead to cuts in NICE funding. It is unclear whether or the extent to which this may happen, since the government has been dedicated to identification and use of cost-effective medicine and public health programs.

References

[1] Information for this case study comes from a review of the NICE website as well as interviews with 3 individuals associated with the NICE Centre for Public Health Excellence, including one NICE employee. To protect interviewees' confidentiality, we do not attribute quotes directly to any interviewee. The NICE website can be found here: http://www.nice.org.uk/

[2] See Kelly, M.P., Morgan, A., Ellis, S., Younger, T., Huntley, J., Swann, C. (2010) Evidence based public health: A review of the experience of the National Institute of Health and Clinical Excellence (NICE) of developing public health guidance in England , *Social Science and Medicine*, 71 :1056 - 1062 http://dx.doi.org/10.1016/j.socscimed.2010.06.032 for more detail as this is quite complex because the relationships vary depending on whether the jurisdiction is England, Wales, Scotland or Northern Ireland

[3] For additional information, see the NICE website: http://www.nice.org.uk/

[4] For additional information on guideline development process, see: http://www.nice.org.uk/aboutnice/howwework/developingnicepublichealthguidance/developing_nice_public_health_guidance.jsp

[5] Additional information on public health topic selection can be found here: http://www.nice.org.uk/media/96A/B2/TopicSelectionProcessManualv25.pdf

[6] For additional details, see: http://www.rcplondon.ac.uk/media/noticeboard/Documents/NICE-information-pack-for-applicants-professional.pdf. Last accessed July 31, 2010.

[7] For examples of draft scope documents, follow the link to any of the projects listed on this page: http://www.nice.org.uk/guidance/index.jsp?action=byType&type=5&status=2

[8] See http://www.nice.org.uk/aboutnice/whoweare/guidanceexecutive/guidance_executive.jsp. Last accessed July 31, 2010.

[9] PHIAC is open to the public. PDGs are not.

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY: US PREVENTIVE SERVICES TASK FORCE (USPSTF)[1]

Prepared by Kate Stewart with the support of Stephanie Peterson

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The US Preventive Services Task Force (USPSTF) develops recommendations for delivery of preventive and primary care services based on a rigorous evaluation of the scientific evidence. The USPSTF is convened by the Agency for Healthcare Research and Quality (AHRQ), which also provides administrative, programmatic and technical support to the task force.[2]

Background

The USPSTF was first convened in 1984; it was modeled after a Canadian task force established in the 1970's to provide evidence-based recommendations for preventive medicine. The goal of the Canadian task force was to move medical care recommendations away from a consensus-driven approach to an evidence-based approach. In this context, consensus-based recommendations are those based primarily on expert opinion about how to manage conditions and not based on the strength of the evidence. This history is pertinent to the current USPSTF because *the USPSTF does not consider itself a consensus body*. At the same time, the USPSTF is responsible for assessing the strength of the evidence, and must come to consensus on grading the evidence for delivery of specific services. One can argue that the USPSTF makes consensus decisions based on the strength of the evidence.[3] Their strong believe that they are not a consensus body probably represents a reaction of concern over the quality of decisions made by previous expert consensus panels.

Task Force Membership, Supporting Organizations and Partners

The task force is comprised of 16 members with expertise in primary care and preventive care (e.g., internists, family practitioners, pediatricians, obstetricians/gynecologists, geriatricians, behavioral medicine practitioners and nurses), epidemiology, health economics, decision-modeling, and evaluation studies. Members are selected by the AHRQ director and typically serve 4-year terms, which may be extended for 1 to 2 years. To identify candidate task force members, the USPSTF Chair and AHRQ staff recruit members through notices in the Federal Register or specific and individualized recruitment tactics designed to locate particular essential areas of expertise. For example, if a pediatrician's term is near completion, they often look to replace that member with another pediatrician. During the process of vetting candidates, they try to identify persons who will be committed to the process and who are not political. The Chair and AHRQ staff put together a list of possible candidates for the AHRQ Director. By design, task force members are selected to be medical generalists rather than specialists to ensure recommendations are based on the evidence rather than professional societies' expectations.

To support the task force in making specific recommendations, AHRQs' Evidence-based practice centers (EPCs) conduct systematic evidence reviews of published literature on a particular topic once it has been selected. In addition, the task force collaborates with various partner organizations, including federal health agencies (e.g., the Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, Food and Drug Administration, etc.), medical societies (e.g., American Academy of Pediatrics, American Academy of Family Physicians,

American College of Obstetricians and Gynecologists, etc.) and population and policy-based organizations (e.g., AARP, National Committee for Quality Assurance, and America's Health Insurance Plans). Partner organizations do not participate in development of task force recommendations, but they attend task force meetings and receive copies of draft evidence reports and draft guidelines.

In general, partner organizations are not engaged to debate the recommendations, but to help the task force clarify and disseminate the guidelines. The ultimate goal of engaging partner organizations is to understand criticisms and nuances of the proposed guidelines that the task force may not have considered. The federal partners' primary role is to help clarify the language included in the guidelines and to provide feedback on how guidelines may affect certain populations; for example, researchers from CMS and NIH often provide feedback on potential ramifications of guideline recommendations on Medicare, Medicaid and other relevant populations. AARP was recently added as a partner organization to get more feedback on consumer perspectives. The medical and professional societies provide feedback to the USPSTF on how members are likely to react to guidelines. These societies also play a large role in disseminating and implementing the guidelines among members, and provide critical insights to the task force on how to word recommendations.

Overview of Guideline Development Process

Below, we provide a brief overview of the USPSTF guideline development process.[4]

1. **Topic Selection.** The task force identifies topics through period notices in the *Federal Register*, solicitation of partner organizations and suggestions from task force members. A topic prioritization workgroup (comprised of task force members And AHRQ staff recommends which topics the USPSTF should review, but agreement must be made among the full task force on the topics selected. Prioritization of topics is based on: 1) relevance to prevention and primary care; 2) public health importance; and 3) potential impact of USPSTF recommendations on clinical practice.
2. **Work Plan Development.** For each topic, a small team of 3 to 4 members from the USPSTF leads the work plan development, including collaboration with AHRQ staff and the EPC (which drafts the work plan)[5] to develop and refine the scope of the project. Oftentimes, draft work plans are circulated to several outside experts for additional comment. The final work plan is approved by the full task force.
3. **Draft Evidence Report.** Based on the final work plan, the EPC conducts a systematic review of the relevant evidence, and presents findings to the task force.
4. **Review Evidence Report.** The full task force, any needed outside experts, six federal partners (i.e., CDC, CMS, FDA, IHS, NIH and VA), and other relevant partners review and comment on the evidence report.
5. **Draft Recommendation Statement.** The small group of 3 to 4 task force leads on the particular topic and AHRQ staff draft recommendation statements based on the evidence report that are circulated to the full task force for discussion. The recommendations are graded as:

    A. = Strongly Recommends
    B. = Recommends
    C. = Recommend against routine use

D. = Recommends Against
I. = Insufficient Evidence to Recommend For or Against

6. **Vote on Recommendation Statement.** At the next task force meeting, the full task force reviews the draft recommendation statement, debates the recommendations, and votes on various formulations of the recommendation statement until one version gains a supermajority (i.e., two-thirds) vote.
7. ***Final Evidence Report***. The EPC revises their evidence report, as appropriate, based on comments from partners and outside experts. The EPC documents the changes made to the report and why. It also drafts a manuscript for publication in a peer-reviewed journal. This often happens concurrently with steps 5 and 6 above.
8. **Draft Recommendation Statement Review and Revisions.** The draft recommendation statement is circulated to partner organizations for review and comment; as appropriate, these comments are incorporated into the recommendation.
9. **Approval of Final Recommendation Statement and Publication of Recommendation Statement and Evidence Report.** The small group of task force leads and the AHRQ staff make any revisions to the recommendations based on partner comments; the statement then may or may not be re-circulated to the entire task force for additional comment. Arrangements are made with appropriate peer-reviewed journals to publish the recommendation statement and manuscript based on the evidence report.

Timeline and Number of Projects per Year

In July 2010, the USPSTF was working on 11 topics.[6] Overall, it has a portfolio of 105 topics on which it has developed guidelines. These guidelines are updated every 5 years. The process of developing initial recommendations on a topic can take 2 to 3 years in total, including approximately 12 to 18 months to conduct the evidence reviews and make recommendations. In addition, the task force reviews recommendations approximately every 5 years. Reviews of existing recommendations are often conducted as "expedited" or "targeted" reviews. For expedited reviews, USPSTF reviews evidence published since the last recommendation to identify any new evidence that might affect recommendations. For targeted reviews, USPSTF identifies gaps in the evidence of existing recommendations (e.g., where recommendations are graded with an "I") and searches for evidence published since the last recommendation that might fill in those gaps. One interviewee thought that the task force could consider reviewing their processes for evidence reviews and identifying places where the evidence review process might be streamlined without compromising its quality.

Task Force Time Commitment and Overall Resources Required

Task force members are volunteers, including the Chair. There are 3 one and a half day in-person meetings at AHRQ's offices in Rockville, MD each year. During these meetings, the task force listens to evidence reports, votes on recommendations and crafts recommendation statements. In addition, task force members participate on one of three standing work groups that have monthly conference calls, including 1) a methods workgroup that is continually working on updating and improving methods for evidence reviews; 2) a topic prioritization workgroup that focuses on which topics should be reviewed by the USPSTF; and 3) a dissemination and implementation work group to help improve guideline dissemination. The USPSTF Chair has a greater time commitment, including bi-weekly phone calls with senior staff at AHRQ,[7] calls with EPCs to help provide

direction for evidence reviews, one to two "course correction" calls with AHRQ staff, USPSTF members and EPCs, as needed, during the process, and media calls.

The USPSTF has a total budget between $1.5 and $2 million per year. This level of funding covers the reviews conducted by the EPCs, travel and meeting expenses, as well as salaries for the AHRQ staff that supports the USPSTF, including a non-physician director, a chief medical officer, 3 medical officers, a higher level administrator, the Primary care, Prevention and Clinical Practice center (P3 Center) Director, and services from AHRQ's Office of Communications and Knowledge Transfer. Several interviewees noted that the level of funding for the task force is low for the number of guidelines developed and updated each year; these limited resources to support the task force are often an issue when priorities are established and conducting work, as the task force would like to do more than current resources allow.

Insights on Selected Issues Discussed with Interviewees

1. Rating the Evidence

According to interviews with representatives from two partner organizations, the USPSTF develops the most scientifically sound guidelines because of its strong focus on the evidence. Both interviewees noted that other medical societies' guidelines on the same topics may not use the same level of rigor to assess the evidence and may be influenced by lack of methodological sophistication in reviewing the evidence, desire to justify current practices, patient advocacy as well as concerns about the impact of guidelines on members' income. In addition, one interviewee noted that the USPSTF weighs the potential harms and benefits of interventions, whereas many professional organizations do not weigh potential harms of interventions. Limitations of the evidence reviews noted during our interviews included the limited amount of evidence available on important sub-populations, and the greater focus on the internal validity of studies compared to external validity.

A unique characteristic of the USPSTF recommendations is the use of the "I" rating for insufficient evidence to recommend for or against. This can be frustrating to guideline users who want a more definitive statement, but it also highlights gaps in the evidence base for future research. It also allows the USPSTF to recommend counseling and shared-decision-making with patients.

2. Transparency

Transparency is one area where the interviewees were somewhat critical of the USPSTF process. The task force meetings are not open to the public, and even some portions of meetings are closed to partners. There are meeting minutes for all task force meetings, although these are not very detailed and not made publicly available. Although procedures are posted on the website, it is not easy to find information. All interviewees noted that after the recent mammography screening guidelines were released, some of the criticisms leveled at the USPSTF clearly demonstrated that critics do not understand the process and how the guidelines were developed.

Some of the lack of transparency is by design; in particular, the process is intended to protect the task force from advocacy. They believe it may be difficult to remain objective if there are advocates in the room. Interviewees noted that the task force is working to improve transparency in certain areas. For example, it is working to make more documents publicly available. Partners said that the task force is usually very responsive to any questions about evidence used to make a decision. However, it is unclear how responsive the task force would be to a non-partner organization or individual. The evidence reports generated by the EPCs have increased in length and

detail over time, which also helps the task force demonstrate transparency in making evidence-based recommendations.

3. Balance and Composition of the Task Force

By design, the task force is comprised of medical generalists and persons with specific methodological expertise (e.g., epidemiologists and health economists); the task force is often criticized for not having representation from specialist groups on the task force. For example, with the recent mammography screening guideline recommendations, many groups criticized the task force for making recommendations without relevant specialists who conduct mammography and treat breast cancer patients. However, several interviewees noted that excluding these groups is appropriate because their incentive is to justify current practices, not to look objectively at the evidence. One interviewee noted that it makes sense for the task force to exclude groups "with skin in the game."

4. Balance between Scientific Evidence and Stakeholders

4a. Developing and Crafting Guidelines

The task force generally ignores advocacy and admonitions from consumers and medical specialties, and focuses on the available evidence. As an example, one interviewee noted that the task force may find no evidence that use of a screening test reduces mortality; however, patients may testify that having the screening test gave them "peace of mind" and motivated them to make healthier choices. In these cases, the task force may note a "postulated benefit" of the screening test, but note that further research is necessary to prove this benefit exists. Partner organizations said that the task force sends copies of draft guidelines for comment, but the comments are generally expected to focus on the "message" and how their members will interpret the recommendations, but they are not asked to comment on the conclusions made by the task force.

The task force has recently finished a pilot for a public comment period on draft recommendations and is now committed to using public comment, with outreach to professional societies, with all future releases. The goal is to use public comments to help improve the recommendations, for example, where the USPSTF may have missed relevant evidence or how they could better word the recommendations. The task force is in the process of adding new staff to help with this effort.

4b Disseminating Guidelines

As noted above, the task force typically sends draft recommendation statements to those professional organizations whose members will be most affected by the guidelines to uncover potential problems with the way in which the guideline recommendations are crafted. In addition, for potentially controversial guidelines, such as the mammography guidelines and guidelines for prostate cancer screening, the USPSTF has also sent draft guidelines to patient and provider organizations such as the American Cancer Society (ACS) to get their feedback. The goal is to understand how these organizations receive the guidelines what types of criticisms might be leveled at the USPSTF once they are published. However, this strategy can backfire on the USPSTF if these organizations disagree with the task force recommendations; in particular, there is a long lag-time between development of the recommendations and publication in a peer-reviewed journal. This provides organizations like the ACS with time to develop their own guidelines and pre-empt the task force guidelines. When USPSTF guidelines conflict with professional societies' guidelines, physicians

tend to follow their professional society guidelines. In these cases, it is unclear how the USPSTF can overcome these conflicts to give their guidelines more prominence.

5. Managing Bias

All interviewees noted that USPSTF has strict policies governing conflicts of interest.[8] Members must declare any financial, intellectual or other conflicts of interest prior to each meeting. Members' declaration of conflict of interest are graded by the Chair, Vice Chair and AHRQ staff prior to each meeting. Conflict of interest grades range from "A" which means that the member has no conflict of interest and can participate in all aspects of the task force work on the topic to "D" which means that the member cannot participate in any aspect of the recommendation (i.e., the member may not be a topic lead and must leave the room for all discussion and voting on the topic; in addition, publicly released recommendations will note that the member was recused from participating on the guideline). Partner organizations were particularly satisfied with the USPSTF conflict of interest policies and procedures.

6. Political Independence

The USPSTF is a non-federal advisory panel and AHRQ has always been committed to preserving the independence of the task force. This independence is important for both sides; the task force can make recommendations based solely on the evidence without any pressure to conform to political pressures, and AHRQ and other federal agencies can distance themselves from any unpopular recommendations. For example, when the task force released their revised recommendations on mammography screening in 2009, Secretary Sebelius released a statement distancing the government from the USPSTF and these recommendations.[9] An interviewee also noted that when the first guide to preventive services was released, AHRQ staff was not allowed to attend any briefings; the rationale was to let the task force and not the government "do the talking." Further, when we contacted AHRQ to request interviews with AHRQ key staff, task force members and partners for this study, AHRQ staff provided us the names of our four interviewees, but did not offer to speak to us themselves. One of our interviewees thought this was further indication of AHRQ's commitment to allowing the task force to speak for itself.

References

[1] Information for this case study comes from a review of the USPSTF website as well as interviews with 4 individuals associated with the USPSTF, including one current member, one former member and representatives from 2 partner organizations. To protect interviewees' confidentiality, we do not attribute quotes directly to any interviewee. The USPSTF website can be found here: http://www.ahrq.gov/clinic/uspstfix.htm. Last accessed July 20, 2010

[2] For additional information on the USPSTF, see: http://www.ahrq.gov/clinic/uspstfix.htm. Last accessed July 20, 2010

[3] Brief history of the USPSTF kindly provided by former member of the USPSTF interviewee.

[4] Additional details on the guideline development can be found in the USPSTF procedure manual: http://www.ahrq.gov/clinic/uspstf08/methods/procmanual.htm. Last accessed July 20, 2010.

[5] AHRQ primarily works with a single EPC that bids for a specific USPSTF contract.

[6] http://www.ahrq.gov/clinic/uspstf/topicsprog.htm. Last accessed July 20, 2010.

[7] USPSTF Vice Chair also participates in these biweekly meetings as well. However, in 2010 this position has been vacant.

[8] For additional information, see AHRQ procedures manual. http://www.ahrq.gov/clinic/uspstf08/methods/procmanual1.htm. Last accessed July 23, 2010.

[9] News Release. Secretary Sebelius Statement on New Breast Cancer Recommendations. November 18, 2009. http://www.hhs.gov/news/press/2009pres/11/20091118a.html. Last accessed July 23, 2010.

AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)[1]

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Background

ANSI was founded in 1918 by five engineering societies and three government agencies. It is a private, nonprofit membership organization supported by a diverse constituency of private and public sector organizations. It states its mission is to 'enhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems, and safeguarding their integrity'.[2]

Like NQF, ANSI is a recognized consensus body under NTTAA/OMB Circular A-119. However, ANSI does not develop standards itself but instead serves as the primary administrator and coordinator of the United States private sector-led voluntary standardization system. It represents the U.S. interests in regional and international standardization activities. (For example, it is the sole U.S. representative to the International Organization for Standardization (ISO)). It also coordinates with the National Institute of Standards and Technology (NIST) on private sector standards (see Figure 1 for more detail). ANSI uses this model because of the wide span encompassed by activities under this jurisdiction

To support the standards development function, ANSI accredits qualified organizations, whose standards development process meets all of ANSI's requirements, to develop American National Standards. ANSI is the only accreditor of U.S. voluntary consensus standards developing organizations and has accredited approximately 220 standard organizations in numerous different sectors (including the American Dental Association (ADA) and Health Level Seven (HL7)).[3] Accreditation by ANSI signifies that the procedures used by the standards organization in connection with the development of ANS meet ANSI's requirements for openness, balance, consensus and due process. ANSI has approved over 10,000 ANSs. Most organizations that have been accreditated appear to focus on standards that underlie the operation of specific products (often manufactured) to enhance safety, performance, and interoperability.

ANSI Membership

The ANSI Federation of members is comprised of nearly 1,000 U.S. businesses, professional societies and trade associations, standards developers, government agencies, institutes and consumer and labor interests.[4] ANSI members participate in a number of boards and councils, panels or coordinating and policymaking committees. Broadly categorized, ANSI has six types of members: government, consumer interest, company and organizational, educational and international.

Relevance to NQF

ANSI consensus procedures, like those of NQF, follow NTTAA/OMB. This case study was selected to understand better the delegated business model behind ANSI's operations. Specifically, in this case study we detail how SDOs become ANSI-accredited, including some detail on consensus requirements and how ANSI works with the government and international organizations.

ANSI Organization[5]

ANSI is comprised of nearly 100 employees across both their NY operations and DC headquarters offices (Figure 1).

- ANSI's Board of Directors is comprised of approximately 50 members from diverse backgrounds. ANSI members are invited, annually, to nominate a candidate from their organization to serve on the ANSI Board of Directors. Terms are staggered so that no more than eleven positions expire at the end of any calendar year. Board members can serve a maximum of two consecutive three-year terms.
- The Appeals Board's major responsibility is considering appeals by directly and materially affected persons (organizations, companies, government agencies, individuals etc) who believe they have been, or will be, adversely affected by a decision of ANSI. The Appeals Board is the final level of appeal within ANSI.
- The Board of Standard's Review major responsibility is the approval and withdrawal of ANSs.
- The ANSI Executive Standards Council's (ExSC) major responsibilities include developing and maintaining the criteria and procedures for the development and coordination of ANSs and for the development and coordination of U.S. positions in international standards activities for auditing such activity. They also establish and supervise groups as are needed to plan and coordinate the development of ANSs and to determine U.S. positions in international standards activities.
- Procedures and Standards Administration (PSA) ANSI's Procedures and Standards Administration area falls under ANSI's Accreditation Services department. The Executive Standards Council, Board of Standards Review and Appeals Board fall under the National Policy Committee (NPC) – and the PSA provides administrative support to these groups.

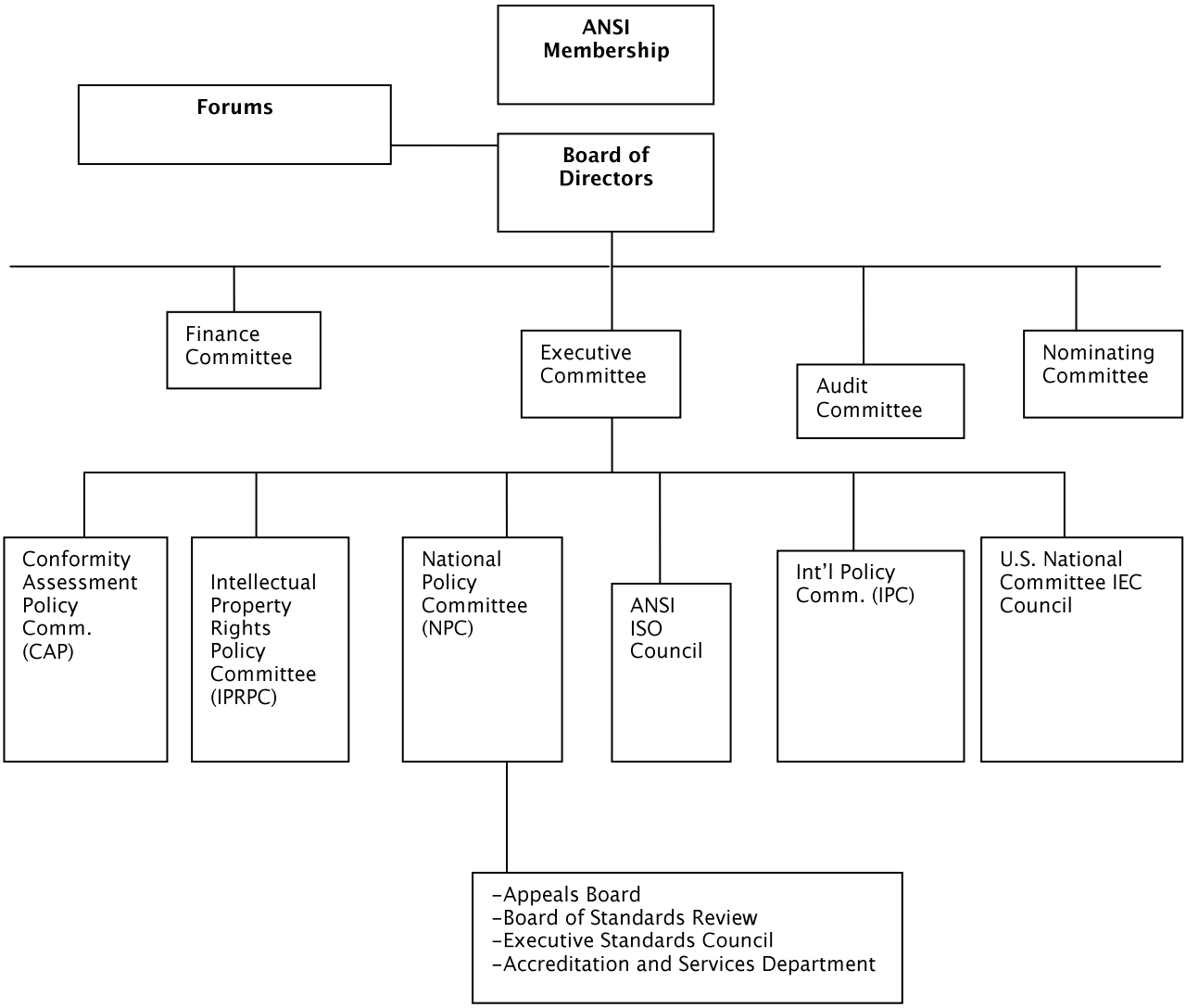
How ANSI works

1. Accreditation Process

All standard developers interested in becoming accredited by ANSI must follow the process detailed in the *ANSI Essential Requirements,* which is a set of requirements/procedures that govern the consensus development process.[6] Following successful completion of the application (which includes a fee and a detailed documentation of its proposed procedures for standard development), the organization will become an ANSI-accredited standards developer (ASD) and will then be able to submit standard(s). The steps to the accreditation process are as follows:

1. Any organization that wishes to become accredited as an ANSI-accredited developer of American National Standards must first submit an application. The application includes a section for the developer to identify its scope and rationale of any proposed standards development activities, its operating procedures, certification that it meets or exceeds ANSI's procedural requirements for openness, balance, consensus and due process as outlined in ANSI's *Essential Requirements document* and list any conflicts of interest of members on the Executive Standards Council.[7] The standard developer must also pay an accreditation fee of $4,000.

Figure 1. ANSI Organization Chart,
Highlighting relevant bodies pertinent to National and International Accreditation Processes



2. An announcement that the application was received and is available for public review is placed on ANSI's website, in the *Standards Action* (which is a weekly publication containing proposals for new standards as well as revisions, reaffirmations and withdrawals of existing standards in addition to applications received by organizations seeking accreditation).[8] The public review period is typically 60 days. Anyone is allowed to submit public comments.[9] In addition, ANSI offers a free e-mail service alerting subscribers when the most recent edition of the *Standards Action* becomes available.
3. Concurrent with the public review period, ANSI's Board of Standards Review (whose primary responsibility is reviewing SDO documents after accreditation to make sure that SDOs followed accredited procedures) and any relevant ANSI standards panel are also notified of the application and given an opportunity to comment.
4. The applicant must attempt to resolve any comments made which includes writing a formal response to each commenter.
5. The application is circulated to ANSI Executive Standards Council for a three week review and screening period. The primary purpose of this review is to ascertain procedural compliance with ANSI requirements. Any comments the applicant receives from the Subcommittee it must respond to and try to resolve. The developer may make changes to its application and/or procedures at the direction of the ExSC. Depending on how significant and/or substantive these changes are, the ExSC may request an additional public review at the ExSC discretion.
6. Following this review, the completed application, procedures, and the Subcommittee's recommendation are sent to the Executive Standards Council for final approval. They have one month to vote via a letter ballot which 2/3rds of the total ExSc must approve.
7. If any member of the Executive Standards Council offers negative comments on the application, the SDO is to attempt to resolve the issues and, if necessary, a recirculation ballot is distributed (i.e. if a yes vote is contingent on something that the SDO changes). (In the accreditation application, in general, negative comments received from the Executive Standards Council often consist of a lack of balanced representation on a proposed consensus body. As noted below, in the challenges section, applicants are often confused to what a consensus body means).

1a. Timeline for accreditation

The process usually takes 3-4 months. Because the SDOs have to develop procedures manuals when submitting their application and then put them out for public review, there is usually some back and forth (between SDOs, the Executive Council and the sub-committee on accreditation).

1b. Maintenance of Accreditation

All accredited standards developers are required to be in conformance with the current version of the *ANSI Essential Requirements*. If any changes to these requirements are made by the ANSI Board of Directors, the Executive Standards Council sets reasonable time limits for an accredited standards developer to make any necessary changes to their procedures for submitting standards.[10]

1c. Number of Projects per Year

The number accredited per year varies between 3 and 15; usually they accredit between 5 and 7 SDOs.

2. Resources

Revenues:

ANSI's revenue last year was 30.5 million. About 55 percent were from publication sales, 16 percent were from membership dues, 14 percent were from accreditation services and 12 percent were from fee-based programs.[11]

Expenses:

ANSI's total expenses across the entire organization last year were $30.3 million, and less than 5 percent were attributable to accrediting SDOs. Other expenses included 31 percent from publications; 15 percent on management and 12 percent on international standards programs.

The total budget for accreditation services (i.e. the department within which the Procedures and Standards Administration (PSA) is located which is where most standards-related activities are conducted) is about 14 percent of the ANSI budget. In particular, PSA is a relatively small group of people that have been with ANSI a long time and have a lot of institutional knowledge. Thus, we were told in our discussion with ANSI staff that the resources that are used for accrediting SDOs are much lower than what might be expected.

3. Standards Development

Once an organization becomes an accredited standard developer it may develop ANS standard(s).

2a. Consensus Process

As part of the procedures that must be completed in the accreditation application to develop ANS standards, the standard developer must put together a proposed consensus body for voting on standards. This consensus body must include broad participation from materially affected and interested persons. It must be open to all that want to participate and the developer must define categories of interested parties and include both documentation of this and documentation on its voting outcomes. It must also document all outreach activities. The criteria for consensus includes that a majority of the consensus body cast a vote and at least two-thirds of those voting approve.

2b. Appeals

ANSI has developed a system that allows for appeals at multiple levels. Every SDO has its own appeals policies as outlined in its application procedures. If someone submitted comments and/or asked to be on the consensus body and was denied, they can appeal to the SDO. They can also appeal to the ANSI Board of Standards Review, and if not satisfied, can take it to the highest level, the ANSI appeals board. Members of the ANSI appeals board represent a cross-section of the ANSI membership.

In sum, ANSI accredits organizations to conduct the appeal but concurrently verifies that the processes employed follow ANSI standards and operates a final appeal system for issues that cannot be resolved by accredited affiliates through their own internal appeal systems.

Additional Findings

1. Biggest Challenges

One of the biggest challenges mentioned during the interview process is that sometimes SDOs think they are following ANSI rules when they are not, so ANSI has to educate SDOs on what it means to follow ANSI procedures. For example, ANSI standards require that voting membership be open to all materially affected interests. If an SDO identifies a consensus body in its documentation that is really their board or requires that only members be a part of the consensus body, neither of these criteria would meet ANSI standards.

2. Openness

As mentioned above, the standards development process is required to be open to all directly and materially affected persons. ANSI's requirements for developers states that no undue financial barriers to participation shall exist. In addition, participation in the standards development process shall not be conditional upon membership in any organization.

In addition, public comment also allows individuals to have their comments considered as does the right to appeal.

3. Managing Bias

Within each organization's operating procedures, the organization must include language on conflict of interest. In addition, the executive standards council (ExSC) and the Board of Standards Review have their own conflict of interest policies which are similar. The ExSC's policy is defined as the following:

> "A conflict of interest can arise from involvement by an ExSC member with the subject matter of a dispute under consideration by the ExSC or from any relationship between the ExSC member and a party to an action before the ExSC, whether past or present, that reasonably raises a question of an ExSC member's impartiality.
>
> "Typically a potential conflict of interest arises when a member of the ExSC participated in activities integral to the particular issue under review or that person is employed by, or a member of the governing body of, the relevant standards developer or other entity as applicable. Similarly, a conflict of interest usually does not exist by virtue of the fact that a member of the ANSI committee participated in the development of standards by a particular standards developer or is a member of that standards developer."[12]

If a conflict of interest is found to exist by the Board, the Board will take a vote to determine whether or not to authorize or reject the issue at hand and take any other action deemed necessary to address the conflict and protect ANSI's best interests (including a vote sufficient for the issue at hand without counting the vote of the director with the conflict of interest).

4. Transparency

ANSI produces a web-based weekly publication called *Standards Action* that contains proposals for new standards, as well as revisions, reaffirmations and withdrawals of existing standards. It also includes proposed revisions to ANSI's Procedures and to ISO proposals and developments. ANSI

also has an email listserve alerting subscribers to new postings.[13] In the interview process we heard that ANSI is in the process of redesigning its website to make it more user-friendly.

5. Balance

By design, the ANSI board is comprised of a diverse group of individuals. The consensus body also must be comprised of a diverse group of individuals

6. Political Independence

ANSI works closely with the government in the standards development process, but is not a government agency. Its governance board consists of representatives from government agencies, SDOs, individuals, consumers and private companies.

ANSI includes representatives from a number of U.S. government agencies. The National Technology Transfer and Advancement Act put into place in 1996 has helped to encourage federal agencies both to rely upon and participate in the ANSI voluntary standards process. In addition, the National Institute for Standards and Technology (NIST) within the Department of Commerce has publically recognized ANSI as representative to ISO as well as regional standards organizations.

ANSI's Role Addressing Government-Requested Standards

When ANSI receives a request from a government agency noting they have a need for a new standard or area of standardization activity, ANSI may coordinate a forum with relevant SDOs working in that area. The Forum members will 'hoist the flag on the issue' during a kickoff meeting and then fact-find on what exists on the topic. The forum members also develop a 'standards roadmap' that outlines what standards currently exist, what is needed (considering both government's request and international standards/issues), and how to best address the need. This may include modification of existing standards or coming up with new standards. Both during this process and after this point, each SDO makes a business decision about going forward with standard development or not. One SDO typically takes the lead on developing the standard, however, sometimes the SDOs work jointly.

ANSI's Role with the International Organization for Standardization (ISO)

ANSI is the official U.S. representative to the International Organization for Standardization (ISO) and, via the U.S. National Committee, the International Electrotechnical Commission (IEC). It is also a member of the International Accreditation Forum (IAF). ANSI participates in almost the entire technical program of the ISO and IEC, and administers many key committees and subgroups. Part of ANSI's responsibilities as the U.S. member body to the ISO includes accrediting U.S. Technical Advisory Groups (U.S. TAGs). The primary purpose of these TAGs is to develop and transmit, via ANSI, the U.S. position on technical matters before ISO technical committees, subcommittees, and working groups.[14]

If a U.S. standards developer wants to put forward their standard to ISO, they would follow one of two tracks:

1. If the proposed standard relates to an existing project, the developer would need to become engaged in the U.S. TAG for that activity. This is administered by ANSI who will help the organization proposing the standard become a part of the necessary TAG.

If the U.S. TAG supports the proposal of the developer, then ANSI will submit the proposal to the relevant ISO committee. The ISO committee will conduct a vote over three-months to determine if international support warrants this project to move forward. If there is support, then the project goes into production to develop the standard (which takes about three years)[15] and the US TAG determines the US experts to be involved.

2. If the proposed standard does not relate to any existing ISO projects, then ANSI must go through a public review period. Based on the public review and comments, the ANSI ISO Council will make a decision as to whether the proposal should be submitted to ISO. If the ANSI ISO Council decides to support the proposal, it will be submitted to ISO. Again, the relevant ISO committee will conduct a three-month vote to determine if international support warrants this project to move forward. If there is support, then the project goes into production to develop the standard (which takes about three years)[16] and in this case, both a new ISO committee and a new US TAG will be formed and determine the US experts to be involved.

Fast Track Process

The U.S. may submit a nationally accredited standard through the ISO's fast track process. Because it is already nationally accredited it can circumvent some of the ISO committees and instead receives a consensus vote by ISO members. For the ISO to adopt the ANS, a two-thirds majority of the ISO members voting in favor is required. This process typically takes 3-4 months. However, as mentioned in discussions with ANSI staff, a good rule of thumb for an organization successfully getting their standard approved through the fact track is if it has already gained good acceptance in the community of interest (otherwise it ends up being part of one of the regular standard tracks).

References

[1] Information for this case study comes from a review of the ANSI website and documents as well as short interviews with several persons at ANSI.

[2] ANSI does not limit the technical content of proposed American National Standards but can also specify product or performance characteristics, describe a management system or specify terminology. The most recent proposed standards have been from engineering organizations (such as the American Society of Mechanical Engineers, ASME; and the American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc, ASHRAE, as recorded in ANSI's weekly *Standards Action* publication, which includes a list of all proposed new standards.

[3] A basic listing of ANSI Accredited organizations as of July 2010 is on the ANSI website at: http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=http%3a%2f%2fpublicaa%2eansi%2eorg%2fsites%2fapdl%2fDocuments%2fStandards%20Activities%2fAmerican%20National%20Standards%2fANSI%20Accredited%20Standards%20Developers

[4] A full list of members is listed on ANSI's website at: https://eseries.ansi.org/Source/directory/Search.cfm

[5] The full ANSI organization chart is located at: http://www.ansi.org/about_ansi/organization_chart/chart.aspx?menuid=1

[6] www.ansi.org/essentialrequirements

[7] ANSI's application for accreditation is on its website at: http://www.ansi.org/standards_activities/domestic_programs/accreditation_as_developer/accredit.aspx?menuid=3

[8] Notification in the *Standards Action is at:* http://www.ansi.org/news_publications/periodicals/standards_action/standards_action.aspx?menuid=7

[9] New, revised, reaffirmed and withdrawn ANS are announced in ANSI's Standards Action for public review – these announcements direct all commenters to the appropriate contact at the relevant standards developer. The actual process may be directed by the standards developer – Email; hard copy; web portal responses represent a good portion of comments received.

[10] There is no specified timeline for changes to the ANSI *Essential Requirements*. Changes are considered throughout the year in response to comments/proposals from the public; ASDs; staff; etc. These are discussed at ExSC meetings and if approved, are announced for public review; all resulting comments are discussed and responded to by the ExSC; and forwarded to the NPC for final approval. A new version of the ANSI *Essential Requirements* is published each year (usually in January), incorporating all approved changes from the previous year.

[11] Detailed revenue and expense data is available on ANSI's annual reports. http://publicaa.ansi.org/sites/apdl/Documents/News%20and%20Publications/Brochures/Annual%20Report%20Archive/2008-2009%20Annual%20Report.pdf

[12] All SDOs have their own operating procedures which include language on conflict of interest. In addition, the executive standard's council and the Board of Standards Review have their own conflict of interest policies which are similar. The executive standard's council and the Board of Standards Review policies on conflict of interest is at:http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=%2fsites%2fapdl%2fDocuments%2fStandards%20Activities%2fAmerican%20National%20Standards%2fProcedures%2c%20Guides%2c%20and%20Forms%2f2010%20ANSI%20Essential%20Requirements%20and%20Related&View=%7b21C60355%2dAB17%2d4CD7%2dA090%2dBABEEC5D7C60%7d

[13] The web address for the weekly publication is at: www.ansi.org/standarsaction

[14] More information on the technical advisory groups is available at: http://www.iso.org/iso/about/structure/strategic_and_technical_advisory_groups.htm

[15] For more information on the ISO process, see: http://www.iso.org/iso/about/how_iso_develops_standards.htm

[16] For more information on the ISO process, see: http://www.iso.org/iso/about/how_iso_develops_standards.htm