



## National Standards for the Certification of Patient Decision Aids

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*DRAFT REPORT FOR COMMENT*

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## Executive Summary

As people increasingly take a more active role in making decisions about their healthcare, many use decision aids—educational tools such as videos, pamphlets, and other online and print resources—to guide conversations with their providers about care options. A large body of research shows that the use of decision aids to facilitate shared decisionmaking (SDM) improves patient outcomes. However, several barriers impede widespread use, including the lack of national standards for the quality of decision aids. In the absence of standards, patients and their families may wonder which resources will really help them make decisions that reflect their personal health goals.

To address this issue, the National Quality Forum (NQF), through a grant from the Gordon and Betty Moore Foundation, aims to create multistakeholder guidance on national standards and a sustainable process for the certification of patient decision aids. In addition, NQF seeks to initiate the development and use of performance measures that can assess the quality of SDM. To support these goals, NQF

- commissioned a white paper from the Dartmouth Institute for Health Policy & Clinical Practice to summarize previous efforts and propose options for national standards for decision aids;
- conducted an environmental scan of performance measures and instruments related to assessing SDM quality; and
- convened a multistakeholder Expert Panel to provide guidance and recommendations.

The commissioned white paper includes a history of decision aid quality improvement efforts to date, including relevant policies and regulations. It also covers work by the International Patient Decision Aids Standards Collaboration (IPDAS) to develop criteria and an effort by the Washington State Health Authority's (HCA) to develop and implement a certification process. The paper proposes several options and considerations for NQF to contemplate when developing a national certification process.

NQF's environmental scan of measures supplemented the white paper by providing a snapshot of existing measures that are in development or currently in use to assess the impact of SDM. NQF identified 13 performance measures and 64 instruments. The results of the scan emphasize the need to develop performance measures to close gaps in measurement and empirically test existing instruments. The white paper and a summary of the environmental scan can be found on the NQF Decision Aids project webpage.

NQF convened a multistakeholder panel of 21 experts (Appendix X) to provide recommendations which built on the findings of the white paper and environmental scan. The Expert Panel proposed a set of criteria that could be incorporated into a national certification process. The Expert Panel identified seven [screening criteria](#) that assess if a decision aid is eligible for certification and thirteen [certifying criteria](#) that assess the level to which a decision aid adequately facilitates decisionmaking (certifying criteria). It also selected [six additional criteria](#) that pertain to decision aids that address screening and diagnostic tests. NQF explored several options for a certification process based on the Expert Panel's recommendations. The primary goal of certification is to initiate the use of decision aids that meet a minimum quality standard. Alongside that goal is the need to assess the impact of SDM. Resources will need to be invested in performance measure development and research to better understand best

practices for SDM. The Expert Panel will refine its recommendations after soliciting feedback from the public and NQF members.

## Background

The current healthcare paradigm focuses on disease-specific interventions and outcomes, despite widespread acknowledgement that patient goals, values, and preferences should play a key role in care planning and decisionmaking. The focus on disease states and clinical indicators is important, but not always the most meaningful for patients with multiple chronic conditions, severe disability, advanced illness, or for persons approaching end-of-life.<sup>1</sup> As people increasingly take a more active role in making decisions about their care, many turn to decision aids—educational tools such as videos, pamphlets, and other online and print resources—to guide conversations with their healthcare providers about care options. The Internet offers an enormous amount of information and an increasing number of tools being labeled as “decision aids.” However, there are no national standards to help patients and their families pick the best tools to support conversations and choices that reflect their personal health goals. National standards for these resources are necessary for advancing goal-based care (i.e., care that focuses on a patient’s health goals across physical, social, functional, and other dimensions).<sup>2</sup>

Goal-based care has the potential to support personalized, individualized care for patients. Meaningfully incorporating individuals’ goals, values, and preferences into care planning requires respectful and compassionate conversations between providers and patients. These discussions should elicit patients’ goals and values as well as encourage patients and caregivers to be partners in decisionmaking. Currently, clinical practice and electronic health records rarely assess and capture patient goals. Strong evidence demonstrates that shared decisionmaking (SDM) facilitated through the use of decision aids has improved patients’ knowledge about options and their outcomes, increased accurate risk perception, resulted in a better match between values and choices, reduced decisional conflict, and decreased the number of people who remain undecided about treatment.<sup>3</sup> A study reviewing the use of decision aids and hip and knee surgery rates found that patient decision aids were associated with 26 percent fewer hip replacement surgeries, 38 percent fewer knee replacements, and 12-21 percent reduction in costs.<sup>4</sup>

Multiple barriers hinder implementation of strategies to increase the adoption of decision aids. These barriers include the lack of national standards, which has limited the identification of evidence-based and reliable decision aids. In addition, national accountability programs have not yet prioritized and meaningfully incorporated SDM through the use of decision aids. The International Patient Decision Aids Standards (IPDAS) Collaboration has conducted work to specify minimum standards for patient decision support interventions; however, IPDAS has not yet applied this work to national standards and criteria. Washington’s Health Care Authority (HCA) adapted a streamlined subset of criteria developed by IPDAS. HCA has developed and implemented a process to certify decision aids, and began accepting applications for the certification of aids in April 2016. The state envisions that the use of certified decision aids by providers and delivery systems will improve healthcare quality and reduce avoidable costs by actively engaging patients in their care decisions. The certification of evidence-based decision aids represents a first step towards this vision.

## Project Overview

To build upon the expertise and experience of both IPDAS and Washington's HCA, the National Quality Forum (NQF), through a grant from the Gordon and Betty Moore Foundation, aims to create multistakeholder guidance on national standards and a sustainable process for the certification of patient decision aids, identify approaches to measure the quality of SDM, and provide guidance to support the development of measures that can assess the impact of SDM, through the use of decision aids. To support these goals, NQF

- commissioned a white paper from the Dartmouth Institute for Health Policy & Clinical Practice to summarize quality assessment and certification efforts to date, to identify challenges to certifying decision aids, and to propose a set of criteria and a process for certification based on previous efforts;
- conducted an environmental scan of performance measures and instruments related to SDM quality that are in development or currently in use; and
- convened a multistakeholder Expert Panel to provide guidance and recommendations.

The following sections describe the findings from each of these activities as they relate to the development of draft certification criteria and a potential certification process for decision aids.

### White Paper

NQF commissioned a [white paper from the Dartmouth Institute for Health Policy & Clinical Practice](#) that outlines the history, debates, and evidence related to the assessment of decision aid quality. The paper reviews the commonly used definitions of patient decision aids and how they differ from other kinds of tools and guidelines. It describes the large body of research that has consistently shown that decision aids have a positive effect on patient outcomes. It also highlights the importance of creating standards as the risk of patients using low-quality decision aids increases with the increasing variety of decisionmaking resources available.

The paper also describes the history and growing interest in developing national standards for decision aids. The 2009 Affordable Care Act, for example, included a provision for a national certification process for decision aids. The provision has led several organizations to discuss the impact of decision aids on improving healthcare and to seek potential certification models. In 2014, the Institute of Medicine convened an expert panel to consider patient decision aids as means to facilitate SDM. Among the panel's recommendations was a call to certify decision aids. The panel stressed the need to ensure the accuracy of a decision aid's content and the availability of certified decision aids for a wide range of patient populations.

The paper also summarizes IPDAS' criteria development work and the HCA's effort to apply selected IPDAS criteria to a certification process in Washington State. It discusses the potential issues of certification like managing decision aid developer disclosures/competing interests, legal considerations, and appropriately evaluating the evidence that supports the decision aid's content. The authors solicited input from national and international leaders in standards for decision aids and incorporated their feedback into the draft paper shared with the committee. In the paper, the authors propose qualifying

and certifying criteria that would be most appropriate for a national certification process selected from the IPDAS criteria. In addition, the authors present several potential implementation issues which are posed as questions in the paper's conclusion. The full paper can be found on the NQF Decision Aids project webpage.

## Environmental Scan of Measures

To gain a better understanding of the performance measurement landscape, NQF conducted an environmental scan to identify measures that are used to assess the quality of decisions made through the use of SDM, particularly those facilitated by decision aids. The scan included instruments (i.e., surveys/questionnaires/tools) and performance measures. These measures were organized by the constructs of decision antecedents (e.g., preferences, health literacy, attitudes, and skills), decisionmaking processes (e.g., level of patient engagement, topics included in SDM process, and tools used), and decision outcomes (e.g., knowledge, concordance between goals and treatment, and quality). The scan included procedure- and condition-specific measures that apply to patients, providers, and surrogate decisionmakers. NQF identified 13 performance measures and 64 instruments using a strict set of inclusion and exclusion criteria. The performance measures and instruments identified in the scan are briefly [summarized in a memo](#) posted to the NQF Decision Aids Project page. The memo describes the purpose of the environmental scan, the methodology, and the results. The instruments and performance measures captured in the scan provide a snapshot of the current state of measurement of SDM. The results of the scan point to the need to develop performance measures in order to incentivize widespread use of decision aids and close gaps in measurement, as well as the need to expand empirical testing of existing instruments to establish reliability and validity.

## NQF Decision Aids Expert Panel

NQF convened a multistakeholder panel of 21 experts ([Appendix A](#)) to support the goals of the project. The appointed Panel represents expertise in SDM research, decision aid development, bioethics, health law, and device manufacturing. The Panel includes healthcare providers, researchers, caregivers, and patients (including patient advocates). NQF convened the Panel for an orientation webinar in May 2016 to provide a project overview and review the Washington State HCA's decision aid certification process development and implementation efforts. This webinar set the stage for the Panel's in-person meeting held on June 22-23, 2016. During June 2016 meeting, the Panel used the findings of the white paper and environmental scan to develop recommendations on national standards for decision aids, a sustainable process for decision aid certification, and ways to advance measurement of the use of SDM facilitated by the use of decision aids.

## NQF Decision Aids Expert Panel Recommendations

The Expert Panel recognized that certification is just one step toward increasing the use of high-quality decision aids. Provider buy-in is essential to adopting certified decision aids in routine care, and providers will need to learn how to select and use them appropriately. Policymakers will need to incentivize the use of decision aids through payment programs and regulations. Most importantly, patients and caregivers will need to understand the purpose and the usefulness of decision aids in helping them make more informed healthcare decisions.

Some legal levers can be used to incentivize the use of decision aids. The Expert Panel discussed the role of decision aids in improving the informed consent process. A key element of SDM is informing patients of their choices, options, and the potential benefits and harms of those options. Washington State passed legislation in 2007 that recognizes SDM as an enhanced method of obtaining informed consent for preference-sensitive conditions if the provider uses a “certified decision aid.” This led to the 2012 legislation allowing the Washington State Health Authority to become a certifying entity. The Panel noted the potential for similar legislation at the national level. Considering these factors, the Panel identified a set of standards categorized by: screening, certifying, and screening and diagnostic test specific criteria. The process involved adapting standards developed by IPDAS proposed for use in the Dartmouth Institute for Health Policy & Clinical Practice white paper and standards selected by the Washington State Health Authority for its certification program.

The Panel’s proposed certification criteria are meant to apply to pre-encounter patient decision aids, which act as independent tools for patients before a clinical encounter, as well as encounter patient decision aids, which help guide the conversation between a patient and a provider. Once the criteria are applied to a certification process, the developer seeking certification will need to provide supporting information on how the submitted decision aid meets the criteria. Much of the information can be included in the decision aid itself, within a supplemental document, or both (depending on the type of decision aid). Other information will be obtained through an application. The actual scoring or rating of a decision aid based on the criteria has yet to be determined. Some criteria may elicit a binary response (yes/no), and others may require a rating scale similar to the scales NQF employs for considering performance measures for endorsement. For example, a reviewer could rate the evidence provided for a decision aid as low, medium, or high. The Panel expressed the importance of first setting a standard for decision aids and evaluating the impact before trying to differentiate the varying levels of quality among them. The Panel’s criteria are intended to set bar high enough to ensure a basic level of safety and utility. Criteria were selected in recognition of the needs of patients, their families, and caregivers. The Panel envisions that the criteria will evolve over time as they are tested through use and collaboration with developers, the certifying entity, and other stakeholders.

## Screening Criteria

The Expert Panel identified screening criteria, separate from the certifying criteria, to allow an applicant or reviewer to determine whether or not a patient decision aid is eligible for certification. These criteria correspond with the existing definitions of decision aids. They are meant to allow a reviewer to determine if the decision aid includes the required information or not. The screening criteria are not meant to determine the adequacy of the content or how the information is presented. A tool that does not meet these screening criteria would not be reviewed for certification. The Panel discussed the nuances of each criterion and how they should be interpreted. There was unanimous agreement on the criteria that require basic elements like a description of the target health condition or problem for which the decision is required and an explicit statement of the index decision under consideration. There was considerable discussion what should and should not be included in the screening criteria. Through these conversations, the Panel provided high-level guidance for developers seeking to meet the screening criteria.

The Panel recommended that the decision aid specify the target user (including surrogate decisionmakers) because decision aids are often developed and tested for a specific group of patients. The target user should be defined clinically as well as by other factors (e.g., ethnicity, language, education level, etc.) that help identify the population for which the decision aid would be most effective. The Panel agreed that the decision aid should present the full range of options available for the decision and specifically highlighted the need for an option that informs patients that they can choose not to receive a clinical intervention, testing, or screening. The Panel also expressed that one of the distinguishing features of a decision aid is its ability to facilitate the identification of a patient's values. The extent to which a decision aid obtains these preferences can be implicit or explicit at the screening stage. However, a reviewer would determine which is most appropriate when the decision aid is under review for certification. The Panel agreed that the following seven criteria should be met before considering a decision aid for certification.

1. Describes the health condition or problem for which the index decision is required
2. Identifies the target user of the patient decision aid
3. Explicitly states the index decision under consideration
4. Describes the options available for the decision, including nontreatment
5. Describes the positive features of each option
6. Describes the negative features of each option
7. Clarifies patient values for outcomes of options by:
  - a. asking patients to consider or rate which positive and negative features matter most to them; and/or
  - b. describing the features of options to help patients imagine the physical and/or social and/or psychological effects

## Certifying Criteria

The certifying criteria are intended to assist a reviewer in determining the level to which a decision aid facilitates decisionmaking. The Panel noted that not all of the criteria would apply to all decision aids in all situations. In these cases, developers would have to provide a rationale for why a criterion does not apply. Many of the criteria are objective (e.g., includes publication date) but others require subjective judgements and/or may require content-specific expertise to determine if the criterion is met.

Reviewers will need to make such judgements when evaluating the adequacy of the evidence to support the content, presentation of options and probabilities, methods used to test the decision aid, and level to which the decision aid is understandable by the target user.

The Panel recommended that a decision aid should not only contain the options for the index decision under consideration but that these options should be balanced (i.e., balanced detail). A balanced presentation of options could be determined through user testing and input from providers. Panel members also stressed the importance of ensuring that the content of a decision aid is based on a rigorous evidence synthesis method. They discussed adopting NQF's evidence criteria, used for the performance measure endorsement process that requires a summary of the quality, quantity, and consistency of the evidence supporting a measure (including levels of uncertainty). This criterion could be adapted to judge the level of evidence provided for a decision aid. There are also standards

developed to create clinical practice guidelines that may be applicable when conducting an evidence synthesis to support a decision aid's content.

In addition, the Panel discussed several issues related to how a decision aid articulates outcome probabilities and the level to which it employs proper risk communication principles. Panel members expressed the need to delineate the risks and benefits of outcomes and how they may differ between populations. The Panel recognized that information on probability is not always available. The Panel recommended that decision aid developers provide a rationale for including or not including outcome probabilities. The rationale should also provide information on the degree to which social or physical factors (age, gender, ethnicity, etc.) influence those outcome probabilities. The Panel also expressed the importance of user testing in the development of the decision aid. Qualified health professionals should be involved in determining the necessary content and the suitability for the target user. The Panel recognized that these criteria will be further defined and may include subcriteria once they are tested for use. The Expert Panel agreed that the following 13 criteria should be required for certification:

1. The patient decision aid provides a balanced presentation of options.
2. The patient decision aid content is based on a rigorous and documented evidence synthesis method.
3. The patient decision aid or supporting document provides information about the evidence sources used.
4. The patient decision aid or supporting document provides key outcome probabilities, adopting risk communication principles.
5. The patient decision aid or supporting document provides information about levels of uncertainty.
6. The patient decision aid provides a publication date.
7. The patient decision aid or supporting document provides information about the update policy and next expected update.
8. The patient decision aid provides information about the funding sources used for development.
9. The patient decision aid or supporting document provides information about competing interests and/or policy.
10. The patient decision aid or supporting document provides information about the patient decision aid development process, including information about participation from target users and health professionals.
11. The patient decision aid or supporting document provides information about user testing with target patients and health professionals.
12. The patient decision aid or supporting document reports readability levels.
13. There is evidence that the patient decision aid follows plain language guidelines, to ensure understanding of people with low literacy and/or low health literacy skills.

## Screening and Diagnostic Test Criteria

A screening test is a preventive tool that assesses the presence or absence of a disease in asymptomatic individuals. A diagnostic test is conducted after a screening test identifies the presence of a disease or for a symptomatic patient to make a definitive diagnosis. The Expert Panel selected criteria specific to screening and diagnostic tests because these decisions typically require additional information that may not be included in a standard decision aid where the patient is choosing between treatment options (or nontreatment). These criteria require screening and diagnostic test decision aids to inform the patient of what their results mean and the next steps. The Panel discussed how information on test results should be displayed. For example, they recommended that developers use positive and negative predictive

values because patients are more concerned about how likely they are to have a disease if the test is positive or negative. The Panel agreed that the following six criteria should be required for certification for decision aids that pertain to screening and diagnostic tests:

1. Describe what the test is designed to measure.
2. Describe next steps taken if test detects a condition/problem.
3. Describe next steps if no condition/problem detected.
4. Describe consequences of detection that would not have caused problems if the screen was not done.
5. Include information on the test's positive predictive value.
6. Include information on the test's negative predictive value.

The Expert Panel also discussed the feasibility of implementing the criteria specific to screening and diagnostic tests as well as the screening and certifying criteria. The Panel recognized that if NQF adopts the criteria for a certification process, some criteria may need to be refined, and subcriteria may need to be created to operationalize certain concepts. There are also several considerations that will need to be addressed before implementation. Therefore, the criteria are considered a draft. The Panel will continue to refine them after obtaining input from the public and NQF members.

## NQF Certification Process

In addition to seeking expert opinion on the certification criteria, NQF solicited recommendations on a potential certification process. Ultimately, NQF would build a process similar to its current Consensus Development Process (CDP) (i.e., or measure endorsement process). As previously described, Washington State's HCA, working with numerous stakeholders and building on the work of IPDAS, developed a process to certify decision aids. According to the HCA, certification plays a significant role in assuring the quality of decision aids used by consumers, providers, and payers. Washington State's leadership in creating a process to certify patient decision aids (PDAs) provides a model that other states and organizations can adopt. NQF intends to use lessons learned from the HCA's certification process to inform the creation of a national process for decision aids. However, since NQF does not currently endorse instruments/surveys/tools, the new certification process would involve the creation of a new application and procedures for review. The authors of the Dartmouth white paper presented two key requirements for a successful certification process:

1. Provide a clear definition of patient decision aids, inclusive of essential components with flexibility to allow tools of different types, intentions, and formats
2. Be inclusive of individual decision aids AND developer organizations

The Expert Panel discussed both requirements at length. Specifically, the Expert Panel encouraged NQF to be flexible regarding the decision aid's format (e.g., paper, online, video, etc.) to encourage development of innovative decision aids that meet the proposed criteria. This flexibility will also promote additional research on which formats produce the best outcomes, an area of research that can be strengthened.

The Dartmouth white paper suggests that—in addition to certifying individual decision aids—NQF could certify developer organizations within the following parameters: (a) developers actively maintaining five or fewer products for use by patients should have all of their tools subject to certification, and (b) developers actively maintaining six or more tools would be eligible to become a certified decision developer. NQF could certify the decision aid development process of organizations. A random sample (size to be determined) of an organization’s repository of decision aids would be selected to test whether or not they meet the criteria. If all attain certification, the organization would become a ‘certified developer’ for a predetermined amount of time. The Expert Panel recommended that NQF might be best informed by starting with the certification of individual aids, learn from that process, and then assess the variation in quality among decision aids developed by the same developer. If the quality is consistent, there may be a case for organizational certification. The Expert Panel supported building a decision aid certification process that closely aligns with NQF’s Consensus Development Process (CDP). Exhibit 1 depicts the key process steps for the CDP or measure endorsement process.

#### **Exhibit 1. NQF Consensus Development Process Steps**

1. Call for nomination for standing committee
2. Call for candidate standards (measures)
3. Candidate consensus standard review
4. Public and member comment
5. NQF member voting
6. Consensus Standards Approval Committee (CSAC) decision/Board Review
7. Appeals

NQF currently has 18 seated multistakeholder Committees that provide recommendations on measurement with topics ranging from cardiovascular disease, behavioral health, neurology, and cancer, in addition to cross-cutting areas such as person- and family-centered care, patient safety, and care coordination. NQF could pursue a similar approach where a Committee would be convened with expertise specific to the decision aids under review. Alternatively, NQF could convene a committee with general expertise in SDM that would draw condition-specific expertise from NQF member networks. NQF is unable to use its existing Committee’s to review decision aids because of funding restrictions. The endorsement and certification processes would thus require separate structures. Exhibit 2 describes a potential process for the certification of decision aids.

#### **Exhibit 2. Potential Decision Aid Certification Process**

1. Appoint review committee and identify supplemental expertise needed
2. Call for candidate decision aid application packets with supporting materials
3. Certification step 1: Evaluation of screening criteria (NQF staff)
4. Certification step 2: Review of certification criteria (review committee)
5. Public comment period
6. Certification approval

As outlined in Exhibit 2, NQF staff would conduct the initial assessment of the decision aids against the proposed screening criteria, after ensuring that the application and supporting documentation are complete. Staff would assess whether the submitted decision aid meets the screening criteria and is eligible for certification. If so, the decision aid would move on to review for certification. The review committee could then focus on the certification criteria, which are more subjective, and any contentious issues or areas requiring clinical expertise.

As noted previously, the authors of the Dartmouth white paper presented considerations and questions that require additional input prior to the finalization of a certification process. In addition, as NQF begins to translate the recommendations of the Expert Panel into an application and review process, it is anticipated that additional questions will be identified. Some of these procedural questions may be best informed by a pilot test of the process. NQF is pursuing this as an option. The following questions have not yet received input from the Expert Panel but are examples of topics that will be considered before the release of a final certification process.

- How do we manage ambiguity and review a decision aid fairly and reliably?
- Is additional staff training or expertise needed for the initial review of applications (i.e., evaluation of the screening criteria)? What are the desirable qualifications for staff assessors and the larger certification review panel?
- Are there process implications for different types of decision aids? Should pre-encounter and encounter decision aids be assessed differently? Should screening/diagnostic aids have a different process or committee?
- Who will judge the accuracy of the evidence and information provided? Will supplementing the larger certification review committee with topic-specific clinical expertise be adequate?
- Does the evidence synthesis method have to be specified/agreed upon by the certification agency? For example, can a decision aid developer rely on a systematic review that has already been conducted? Is it required to conduct a systematic review if no relevant systematic review exists?
- Does each developer need to evaluate the effectiveness of its patient decision aid and provide evidence about evaluation? What is considered a sufficient amount of research evidence to determine effectiveness?

Some of the questions above are critical to finalizing a process, and others are more targeted at implementation of the criteria. As indicated earlier, NQF has the benefit of observing and learning from the Washington State HCA's process and working collaboratively to identify the best approach.

## **Business Model Opportunities**

A key consideration in the implementation of a process model to certify decision aids is how such an endeavor would be funded and how to make the process sustainable. NQF has discussed this subject internally and has had some input from decision aid experts, but requires additional research and vetting to finalize an approach. The table below describes potential approaches, considerations for each approach, and some high-level challenges and opportunities.

### Exhibit 3. Potential Funding Approaches

Potential Funding Approach	Considerations, Challenges, and Opportunities
Federal Task Order/Contract Vehicle	<ul style="list-style-type: none"> <li>• Longer process to obtain funding</li> <li>• NQF cannot “fit” decision aid certification into its current endorsement funding vehicle</li> <li>• Certification of the decision aids is a first step in moving toward performance measurement approaches</li> <li>• While included in the Affordable Care Act, funds have not been appropriated</li> <li>• Person- and family-centered measurement—specifically including the values and goals of patients, families, and caregivers—is a priority area for CMS measure development</li> <li>• Established relationships and multistakeholder processes that will contribute to success of process</li> </ul>
Decision Aid Industry Pay for Certification	<ul style="list-style-type: none"> <li>• Currently, there are fewer than 10 decision aid developers that contribute significantly to the creation of aids which creates concerns about sustainability of ongoing certification process if a “pay per aid” approach is employed.</li> <li>• Nontraditional decision aid developers (e.g. researchers/university/provider organizations) may not have funding capacity to pay for certification of individual aids</li> <li>• NQF’s current measure endorsement process does not charge the measure developer/steward for the measure evaluation; however, significant staff resources are required for the process.</li> </ul>
Private Philanthropic Organization	<ul style="list-style-type: none"> <li>• While a private organization, such as the Gordon and Betty Moore Foundation, may contribute some “seed” money, it is unlikely that ongoing budgets could sustain the process over time.</li> <li>• Potential to seek funding via this route for a pilot project with area of interest to the funder to promote understanding of the implementation of the process model and funding requirements</li> </ul>
Industry Contributions	<ul style="list-style-type: none"> <li>• Would require a “general funding” account where pharma or device manufacturers could contribute to cover costs of certification, but be fire-walled from involvement</li> <li>• NQF could establish an “industry council” where contributors would receive early updates on projects and other benefits, but could not be involved in certification decisions</li> <li>• Would require dedicated staff for industry relations, project management</li> </ul>

Exhibit 3 represents some possible approaches to funding, but a hybrid approach may also work. NQF is exploring options to fund a pilot project to test an application and review process. The pilot project will allow NQF to identify a sustainable approach by determining overall costs to implement the certification process, level of staff effort, and if there may be economies of scale that could reduce costs. Conflicts of interest in funding mechanisms are of extreme importance; any potential funding stream must be free of any undue influence from the supporting entities.

## Opportunities and Challenges in Performance Measurement

The Expert Panel discussed the need to identify and develop performance measures to improve the quality of SDM and close measurement gaps. The Panel emphasized that the primary goal for setting standards is to ensure patients are well informed, meaningfully involved in their care, and that their choice of treatment (or nontreatment) reflects their goals and preferences. There have been several systematic reviews (including dozens of randomized control trials) that have documented the measures that exist to assess the quality of decisionmaking facilitated through SDM. The majority of existing measures are instruments developed for research-specific aims rather than to inform practice. There are others like the decisional conflict scale with multiple versions that can be applied in research and practice. Instruments that assess clinical practice are promising sources of data for performance measures. Performance measures are critical to comparing entities and understanding variability across settings where SDM is in use and is driving improvements in quality of care. Once national standards and a certification process exist, the healthcare system can begin incentivizing the use of ‘certified’ decision aids. Data should be collected on the use of decision aids to measure their impact. Measurement can also stimulate the use of decision aids.

There is growing interest in using performance measures that assess the use of SDM in quality improvement and accountability programs. Adopting performance measures for these purposes will require collaborative and collective effort across multiple stakeholder groups including providers, consumers, purchasers, measure developers, researchers, and others. First, SDM performance measures have not been widely adopted for clinical use outside research settings in the United States. For that reason, many health professionals, payers, and provider institutions may not be familiar with such measures. Steps will be needed to raise awareness of the utility of SDM in improving patient outcomes. Second, there are several method-related challenges such as aggregating patient data on decision aids to measure performance at multiple levels of analysis (e.g., individual, group practice, organization) and use of proxy respondents.<sup>5</sup>

The Panel acknowledged the difficulty of measuring the outcomes of SDM that matter most to patients and caregivers. Assessing patient’s values, for example, is a critical component of SDM, but a patient’s values are not static. They continuously change over time with more information and new experiences. Other outcomes, like knowledge, are important but are only one piece of assessing quality. The Panel discussed building a conceptual model that focuses on patient outcomes (primarily what is most important to patients). The Panel also cited the limitations of existing data. Often, only decision outcomes for patients who chose a treatment can be assessed. Patients who did not choose an intervention are typically not documented, which can introduce bias into measurement.

A few promising performance measures have recently been submitted to NQF for endorsement. For example, measure 2958: Informed, Patient Centered (IPC) Hip and Knee Replacement Surgery is a patient-reported outcome measure that assesses adequate knowledge and preference for surgery. This measure is generated from data collected using the Decision Quality Instruments (DQI) developed by Massachusetts General Hospital. Measure 2962: Shared Decision Making Process is another patient-reported outcome measure that assesses the extent to which providers involve patients in the decisionmaking process. These measures are currently being reviewed through NQF's Consensus Development Process and have been recommended for endorsement. Some promising measures related to SDM are already endorsed. For example, measure 2483: Gains in Patient Activation Scores at 12 Months assesses an individual's knowledge, skill, and confidence for managing his or her health and healthcare.

The markers of a strong performance measure include the measure's importance (demonstrated through evidence and a gap in performance, scientific acceptability (reliability and validity), feasibility to implement, and usability by stakeholders. A strong performance measure will be based on valid instruments or evidence-based decision aids as they provide the basis for measurement. Because the field of SDM is somewhat in its infancy there are challenges to creating performance measures. However, many of these challenges can be eliminated once certified decision aids are in use and performance measurement is prioritized. Resources will need to be invested in performance measure development which will allow the healthcare system to assess the impact of SDM as well as resources for research to better understand best practices for SDM. Resources will be needed both to develop performance measures to assess the impact of SDM and to research best practices for SDM.

## Next Steps

Selecting national standards for the certification of decision aids is one step towards achieving a national certification process for decision aids. The criteria for certification of decision aids will need to be tested to assess feasibility for implementation. This will require fully developing a certification process which will partly depend on identifying a sustainable funding source. The criteria recommended by the Expert Panel are considered a draft. This report will be available for the public and NQF members to provide input on the proposed criteria and certification process options until Oct 14. These comments will be publicly available. The Expert Panel will review the comments received and use them to refine the final recommendations. A final report will be available in December 2016.

## References

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<sup>5</sup> National Quality Forum (NQF). Patient Reported Outcomes (PROs) in Performance Measurement. Washington, DC: NQF, 2013. Available at [http://www.qualityforum.org/Publications/2012/12/Patient-Reported\\_Outcomes\\_in\\_Performance\\_Measurement.aspx](http://www.qualityforum.org/Publications/2012/12/Patient-Reported_Outcomes_in_Performance_Measurement.aspx). Last accessed June 2016.

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