

National Standards for the Certification of Patient Decision Aids

FINAL REPORT

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NATIONAL
QUALITY FORUM

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EXECUTIVE SUMMARY

As people increasingly take a more active role in making decisions about their healthcare, many use decision aids. Decision aids are evidence-based tools designed to inform patients about their options (including known pros and cons) and help them to participate in making specific, deliberate choices among viable healthcare options. A large body of research shows that the use of decision aids to facilitate shared decision making (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 develop 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 shared decision making (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 (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 A](#)) 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 12 certifying criteria that assess the level to which a decision aid adequately facilitates decision making. 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.

BACKGROUND

Currently, routine clinical care rarely involves assessing and documenting patient goals. Instead, the existing 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 decision making. 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.¹ 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 decision making. As people take a more active role in making decisions about their care, many turn to decision aids to facilitate that process.

The Cochrane Collaboration defines a decision aid as an evidence-based tool designed to help patients to participate in making specific, deliberate choices among healthcare options. Patient decision aids supplement (rather than replace) clinicians' counselling about options. The specific aims of decision aids and the type of decision support they provide may vary, but in general, they explicitly state the decision that needs to be considered; provide evidence-based information about the health condition, the options for care, associated benefits, harms, probabilities, and scientific uncertainties; help patients recognize how their values relate to the decision; and to clarify the value they place on the benefits, harms, and scientific uncertainties.

Strong evidence demonstrates that using high-quality decision aids 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.² In addition, 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 to 21 percent reduction in costs.³

However, many tools and information resources that are labeled "decision aids" may or may not contain the content necessary for adequate decision support. The quality of these tools varies, and national standards are needed 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 ensuring care that focuses on a patient's health goals across physical, social, functional, and other dimensions.⁴ The lack of national standards, which limits the identification of evidence-based and reliable decision aids, also hinders increased adoption of decision aids. In addition, national accountability programs have not yet prioritized and meaningfully incorporated SDM using decision aids.

There are existing activities and sources of information that can help inform a potential certification process. First, the International Patient Decision Aids Standards (IPDAS) Collaboration has specified minimum standards for patient decision support interventions; however, IPDAS has not yet addressed how they might be used in national standards and criteria. Washington's Health Care Authority (HCA) has developed and implemented a decision aids certification process using a streamlined subset of IPDAS' criteria. HCA 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.

PROJECT OVERVIEW

As indicated in the commissioned white paper and briefly in the background section above, there is an opportunity to develop and more broadly implement decision aids across the healthcare sector; however, this will require standards or guidelines to ensure that the decision aids will support patients in becoming informed, engaged, and true participants in their healthcare. A potential national certification process may help by:

1. Promoting the use of decision aids that have received a quality “seal of approval” based on evidence and sound development protocols;
2. Clearly defining the basic features, standards, and attributes of tools that delineate a “good” decision aid;
3. Providing a baseline set of criteria that decision aid developers could use to develop and implement tools to meet or exceed a minimum standard; and
4. Providing guidance for use and potentially incentivizing widespread use of tools that meet set quality and safety standards.

Through a grant from the Gordon and Betty Moore Foundation, the National Quality Forum (NQF) built on the expertise and experience of IPDAS and Washington’s HCA 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 using decision aids.

NQF drew on its broad network of over 400 organizational members from the public and private sectors and its expertise in consensus building to accomplish the project’s activities, which are outlined below. More specifically, NQF:

- commissioned a white paper from the Dartmouth Institute for Health Policy & Clinical Practice to summarize decision aid quality

assessment and certification efforts to date, identify challenges to certifying decision aids, and 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 Patient Decision Aids Expert Panel to provide guidance and recommendations on a certification process.

The following sections of this report describe the findings from each of these activities as they relate to the development of 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 comprises the history, debates, and evidence related to the assessment of decision aid quality. The paper is the basis of this NQF project and establishes the rationale for certification of decision aids. In the white paper, the authors review the commonly used definitions of patient decision aids and how they differ from other kinds of tools and guidelines. They also describe the large body of research that has consistently shown that decision aids have a positive effect on patient outcomes. The authors further highlight the importance of creating standards as the risk of patients using low-quality decision aids increases with the increasing variety of decision making resources available.

The paper also includes the history and growing interest in developing national standards for decision aids. The 2010 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 a means to facilitate SDM. One of the panel's recommendations was 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 further includes a summary of IPDAS' criteria development work and the HCA's effort to apply selected IPDAS criteria to a certification process in Washington State. The authors discuss potential certification issues 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 NQF's Patient Decision Aids Expert Panel. In the paper, the authors propose qualifying and certifying criteria, selected from the IPDAS criteria, that would be most appropriate for a national certification process. In addition, the authors present several potential implementation questions. 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 of measures used to assess the quality of decisions made through SDM, particularly those facilitated by decision aids. NQF assessed instruments (i.e., surveys/questionnaires/tools) and performance measures (the "measures"), as well procedure- and condition-specific measures that apply to patients, providers, and surrogate decision makers. NQF identified 13 performance measures and 64 instruments using a strict set of inclusion and exclusion criteria. NQF organized these measures by whether they assessed decision antecedents (e.g., preferences, health literacy, attitudes, and skills), decision making 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 performance measures and instruments identified in the scan are briefly summarized in a memo posted to the NQF Decision Aids project webpage. The memo also includes a description of the purpose of the environmental scan, methodology, and 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 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 Patient Decision Aids Expert Panel

NQF convened a multistakeholder panel of 21 experts (Appendix A) to support the goals of the project. NQF staff solicited nominations and conducted outreach to SDM experts to identify candidates and subsequently selected the Panel based on recommendations from NQF's members and the public. The appointed Panelists have expertise in SDM research, decision aid development, bioethics, health law, and device manufacturing. The Panel included 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 the June 2016 meeting, the Panel used the findings from 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 SDM using decision aids.

NQF DECISION AIDS EXPERT PANEL RECOMMENDATIONS

Overview

The Expert Panel's deliberations focused on two topics: increasing use of decision aids and criteria for a potential certification process. In their discussion about increasing use of high-quality decision aids, the Panel members recognized that certification is just one step toward achieving this goal. Provider buy-in is also essential to adopting certified decision aids in routine care, and providers will need to learn how to select and use them appropriately. Additionally, 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. There are also legal levers that can be used to increase the use of decision aids. A key element of SDM is informing patients of their choices, options, and the potential benefits and harms of those options. Consequently, the Expert Panel discussed the role of decision aids in improving the informed consent process (which could lead to increased use). Washington State, for example, 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.

The Panel's primary area of discussion was criteria for a potential certification process. Considering all of the background information provided, the Panel identified a set of standards composed of criteria specific to screening, certifying, and screening and diagnostic tests. It selected these criteria based on the IPDAS-developed standards proposed in the Dartmouth Institute for Health Policy & Clinical Practice white paper and the standards selected

by the Washington State Health Authority for its certification program.

The Panel's proposed certification criteria are meant to apply to "complete" patient decision aids, which are standalone, independent tools for patients facing a medical decision. "Incomplete" discussion guides require a clinician to add significant content to convey what patients need to know to make a decision. Once the criteria are applied to a certification process, the developer seeking certification would need to provide supporting information on how the submitted decision aid meets the criteria. The developer would submit an application, as well as the decision aid itself, and/or a supplemental document (depending on the type of decision aid). Some criteria could elicit a binary response (yes/no), and others could 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 did not address the actual scoring or rating of a decision aid based on the criteria.

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 proposed criteria are intended to set a bar high enough to ensure a basic level of safety and utility. The panel selected criteria that address the needs of patients, their families, and caregivers. The Panel views these criteria as 'version 1.0' and expects the criteria would 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 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 each should be interpreted. There was unanimous agreement on the criteria that address basic elements like a description of the target health condition or problem for which the decision is required and an explicit statement of the decision under consideration. There was considerable discussion about what should and should not be included in the screening criteria. Based on these conversations, the Panel developed high-level guidance for developers seeking to meet the screening criteria.

The Panel recommended that the decision aid specify the target user (including surrogate decision makers) 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. Two broad classes of information are important and should be included in the list of options: (1) the experience of undergoing each option and the implications for one's ongoing quality of life, and (2) clinical benefits and harms that are more likely with each option based on the best available research. The Panel also noted 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 use of a decision aid

helps identify these preferences can be implicit or explicit (i.e., providing information necessary to consider values or having a values clarification exercise) 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 a decision aid should meet the following seven screening criteria before considering it for certification:

1. The patient decision aid describes the health condition or problem for which a decision is required.
2. The patient decision aid identifies the target user.
3. The patient decision aid explicitly states the decision under consideration.
4. The patient decision aid describes the options available for the decision, including nontreatment when appropriate.
5. The patient decision aid describes the positive features of each option.
6. The patient decision aid describes the negative features of each option.
7. The patient decision aid 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 decision making. The Panel noted that not all 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 judgments and/or may require content-specific expertise to determine if the criterion is met. Reviewers will need to make such judgments 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 decision options; in addition, these options should be a full and balanced accounting of best evidence about each of the options under consideration. 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 for the performance measure endorsement process, which requires a summary of the quality, quantity, and consistency of the evidence supporting a measure (including levels of uncertainty). These criteria could be adapted to judge the level of evidence reflected in a decision aid. There are also standards for clinical practice guideline development 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. User testing should include patients with lower health literacy and numeracy. The Panel did not select a threshold for the level of readability, as this would be determined based on the intended user. Qualified health professionals should be involved in determining the necessary clinical content. The Panel recognized that these criteria would be further defined and could include sub-criteria once they are tested for use. The Expert Panel agreed that the following 12 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 provides a publication date.
6. The patient decision aid or supporting document provides information about the update policy and next expected update.
7. The patient decision aid provides information about the funding sources used for development.
8. The patient decision aid or supporting document provides information about competing interests and/or policy.
9. 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.
10. The patient decision aid or supporting document provides information about user

testing with target patients and health professionals.

11. The patient decision aid or supporting document reports readability levels.
12. 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 intended to help a patient choose between treatment options (or nontreatment). These criteria require screening and diagnostic test decision aids to inform patients what their results mean and the next steps. The Panel discussed how information on test results should be displayed. It 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. These values would need to be presented in a manner

that is easily understood by the target user. 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 a 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 in general. The Panel recognized that if NQF adopts the criteria for a potential certification process, some criteria might need to be refined, and subcriteria might need to be created to operationalize certain concepts. There are also several considerations that would need to be addressed before implementation. The panel noted that the name of these criteria could be reconsidered upon the implementation of a potential certification program to avoid confusion with the “screening criteria.”

NQF CERTIFICATION PROCESS

Sources Informing Development of a Certification Process

In addition to seeking expert opinion on the certification criteria, NQF solicited recommendations on a potential certification process. The Panel's deliberations led to identification of three main sources that could inform the process. First, NQF would draw from its experience using multistakeholder expert panels in the current Consensus Development Process (CDP), but would not duplicate it for certification of decision aids. Further, since NQF does not currently endorse instruments/surveys/tools, the new certification process would require the creation of a new application and procedures for review. The Expert Panel supported building a decision aid certification process that closely aligns with NQF's Consensus Development Process (CDP), but also recognized the importance of ensuring that a certification process is neither unduly burdensome on the decision aid development community, nor too costly to be sustained.

Second, as previously described, the Washington's HCA has piloted a certification process for patient decision aids. NQF would also use lessons learned from the HCA's certification process to inform the potential creation of a national process for decision aids.

Third, in addition to recommending that NQF learn from Washington State's approach, 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. In response to the first proposed

requirement, 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 also suggests in a second requirement that—in addition to certifying individual decision aids—NQF could certify developer organizations within the following parameters: (1) developers actively maintaining five or fewer products for use by patients should have all their tools subject to certification, and (2) developers actively maintaining six or more tools would be eligible to become a certified decision aid developer. To become a 'certified developer,' NQF would certify an organization's decision aid development process. A random sample (size to be determined) of an organization's repository of decision aids would be selected to test using 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. This would provide an opportunity for NQF to learn from that process and 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.

Proposed Certification Process

Another important component of a potential certification process is the specific structure and steps that would support review and certification. One option would be for NQF to pursue an approach similar to the endorsement of performance measures, in which 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 would not use its existing committees to review decision aids due to funding restrictions. This presents another reason why the endorsement and certification processes would require separate structures. A potential process for the certification of decision aids follows in Exhibit 1.

EXHIBIT 1. 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
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As outlined in Exhibit 1, NQF staff would ensure that the application and supporting documentation are complete and conduct the initial assessment of the decision aids against the proposed screening criteria. Staff would determine whether the submitted decision aid meets the screening criteria and therefore is eligible for certification. If so, the decision aid would move on to review for certification. The expert review committee could then focus on applying the more subjective certification criteria and could address any contentious issues or topics requiring clinical expertise.

Next Steps

As noted previously, the authors of the Dartmouth white paper presented several considerations and questions that require additional deliberation 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, there will be

further questions. Some of these procedural questions may be best addressed by a pilot test of the process, which NQF is pursuing as a potential next step. Some possible topics that would need consideration before the release of a final certification process follow:

- How would we manage ambiguity and review a decision aid fairly and reliably?
- Would additional training or expertise be needed for the initial review of applications (i.e., application of the screening criteria)? What would be the required qualifications for the external certification review panel?
- Would assessment of different types of decision aids require different processes? Should pre-encounter and encounter decision aids be assessed differently? Should screening/diagnostic aids have a different process or committee?
- Who would judge the accuracy of the evidence and information provided? Would supplementing the external certification review committee with topic-specific clinical experts be adequate?
- Should the evidence synthesis method be specified/agreed upon by the certification agency? For example, could a decision aid developer rely on a previously-conducted systematic review? Would the developer be required to conduct a systematic review if no relevant systematic review exists?
- Should each developer evaluate the effectiveness of its patient decision aid and provide evidence about evaluation? What would be considered enough research evidence to demonstrate 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 would have the benefit of observing and learning from the Washington State HCA's process and working collaboratively to identify the best approach.

BUSINESS MODEL OPPORTUNITIES

Another key consideration in the implementation of a process to certify decision aids is how such an endeavor would be funded and sustainable. NQF developed preliminary options and gathered some input from decision aid experts, but would have to conduct additional research and vetting to finalize an approach. The table below describes potential funding approaches, considerations for each approach, and some high-level challenges and opportunities.

Exhibit 2 represents some possible approaches to

funding, but a hybrid, or an alternative approach may also work. NQF is exploring options to fund a pilot project to test an application and review process. The pilot project would help NQF identify a sustainable funding approach; it would provide a better understanding of what might be the overall resources required to implement the certification process and potential for economies of scale. Additionally, avoiding conflicts of interest and undue influence from supporting entities would need to be addressed in the design of any funding mechanism for a national certification process.

EXHIBIT 2. POTENTIAL FUNDING APPROACHES

Potential Funding Approach	Considerations, Challenges, and Opportunities
Federal funding	<ul style="list-style-type: none"> • Certification of the decision aids is a first step in moving toward performance measurement approaches • While included in the Affordable Care Act, funds have not been appropriated • Person- and family-centered measurement—specifically including the values and goals of patients, families, and caregivers—is a priority area for CMS • Established relationships and multistakeholder processes that will contribute to success of the certification process
Decision aid industry payment for certification review	<ul style="list-style-type: none"> • Currently, there are fewer than 10 decision aid developers that contribute significantly to the creation of aids which creates concerns about sustainability of an ongoing certification process if a “pay per aid” approach is employed. • Nontraditional decision aid developers (e.g., researchers/university/provider organizations) may not have funding capacity to pay for certification of individual aids. • NQF’s current measure endorsement process does not charge the measure developer/steward for measure evaluation given that it is otherwise funded; however, significant staff resources would be required to support this process.
Private philanthropic organization support	<ul style="list-style-type: none"> • While a private organization may contribute some “seed” money, it is unlikely that a philanthropic organization would sustain ongoing operations. • There is potential to seek funding for a targeted pilot project, potentially limited to a topic area of interest to the funder, which would lead to more information about implementation and funding requirements.
Private industry contributions	<ul style="list-style-type: none"> • Would require creation of a general funding mechanism where pharmaceutical or device manufacturers, for example, could contribute funds to cover general costs of certification, but could not specify further how they would be applied and would not be involved in the certification process. • NQF could establish an “industry council” with a participation fee, which could allow contributors to receive early updates on projects and other benefits, but would not allow them to be involved in certification decisions.

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 decision making facilitated through SDM. Most 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 to driving improvements in quality of care. National standards and a certification process may help increase 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. Strategies to raise awareness of the utility of SDM in improving patient outcomes will be needed. 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.⁵

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 based performance measure (PRO PM) 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 PRO PM that assesses the extent to which providers involve patients in the decision making process. These measures are currently under

review through NQF's Consensus Development Process and have been recommended for endorsement. Additional 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.

PUBLIC COMMENTS

NQF received dozens of comments from advocacy and trade organizations, special interest groups, researchers, and patients on the Expert Panel's recommendations. The Panel convened on October 25, 2016, to discuss these comments and finalize its recommendations. Most comments supported the Panel's work. Generally, comments were related to emphasizing the importance of this work and providing a clear rationale for a certification process. There were many comments that requested additional detail on the concepts presented in the screening, certifying, and screening and diagnostic specific criteria. NQF clarified that this level of detail would be included in a guidebook and application materials for developers who submit decision aids for certification. The guidebook would contain a detailed explanation of the certification process, including how decision aids are evaluated based on the criteria (e.g., rating scales), how to submit a decision aid for certification, what is involved in each step of the process, and how to maintain certification. It would also include information on conflict of interest and proprietary issues. Developing the guidebook would be a key element of the next phase of this work. The Panel supported this approach and agreed to serve in an advisory capacity if and as the work progresses.

Several comments focused on the use of explicit versus implicit values clarification and cited examples why it may or may not be appropriate to require all decision aids to include explicit values clarification. The Panel decided that until there is stronger evidence to support one approach over the other, decision aids can be certified with either an implicit or explicit values clarification, and this is captured in screening criterion 7. There were also comments related to the suitability of requiring a nontreatment option in a decision aid. The Panel adjusted this criterion to include discussion of nontreatment options *only* when it is appropriate. In addition, there were suggestions to reorganize, remove, and consolidate some of the criteria. The Panel considered these comments and removed a criterion that would require a decision aid or supporting document to provide information about the uncertainty of clinical evidence. Lastly, there were comments disputing the necessity of a certification process and the potential burden on decision aid developers. The Panel noted that a certification process is necessary to ensure developers have a minimum standard to substantiate the quality of decision aids and that patients are using aids that promote quality and patient safety.

PATH FORWARD

Selecting national standards for the certification of decision aids is one step towards achieving a national certification process for decision aids. However, the certification criteria will need to be tested in a pilot project to assess feasibility for implementation. A future pilot project could focus on assessing the process, structure, and technical resources required to implement a national certification process. It would also identify potential rating systems for reviewers and guide the development of decision aid developer and evaluation guidelines. It would also provide

additional information to inform a potential funding model. However, the first step will be to identify a funding source for continuing this work. Additionally, NQF hopes to build on the work of the Panel through the 2017 National Quality Partners Shared Decision Making Action Team. This related initiative will support and stimulate broader implementation of decision aids, further focus national attention on patient preferences and values, and suggest measures and best practices to promote shared decision making as a standard of care.

ENDNOTES*

1 Reuben DB, Tinetti ME. Goal-oriented patient care—an alternative health outcomes paradigm. *N Engl J Med.* 2012;366:777-779.

2 Stacey D, Légaré F, Col NF, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev.* 2014;1:CD001431.

3 Arterburn D, Wellman R, Westbrook E, et al. Introducing decision aids at Group Health was linked to sharply lower hip and knee surgery rates and costs. *Health Aff (Milwood).* 2012;31(9):2094-2104.

4 Reuben DB, Tinetti ME. Goal-oriented patient care—an alternative health outcomes paradigm. *N Engl J Med.* 2012;366:777-779.

5 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. Last accessed June 2016.

*The full list of references that form the basis of this work is included in the white paper produced by the Dartmouth Institute for Health Policy & Clinical Practice.

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