How to ensure the quality and safety of patient decision aids?

Towards a feasible certification process

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Content

Executive summary

The interest in producing information to support patients to become informed, engaged and true participants in their health care increases constantly, indicating the need to pay attention to the quality of the information that is prepared for such tasks. Patient decision aids are one example of such information sources, tools that are designed to describe alternative ways of managing an illness or health status, or choosing a treatment. The recent trial-based research on their effect has consistently shown that they have positive effects on patient knowledge, on the decisions made, and on a range of other outcomes.

As more developers enter the field, the risk that low quality or heavily biased patient decision aids are used is increasing. To reduce this recognized risk, there has been a consistent call that patient decision aids should meet agreed quality standards, given that they influence the decisions that patients make, either in partnership with their clinician, or acting alone. This call was given a high profile by its appearance in the 2009 Affordable Care Act in the US. The work of outlining criteria began with the work of the International Patient Decision Aids Standards Collaboration. It was the basis of a pioneering certification process established by the state of Washington in May 2016, which is currently being evaluated.

In this document, at the request of the National Quality Forum, we outline the relatively short history, the debates and relevant evidence that have appeared over the past decade in relation to the assessment of patient decision aid quality. We propose a process that takes into account the fundamental requirements to consider how best to summarize research evidence as well as control and minimize the risks of competing interests. In addition, such a process needs to ensure that the tools produced are as accessible, and as useful as possible to real end users – to people who need help to make good decisions.

1. Introduction

The aim of this paper is to describe the development of a potential certification process for patient decision aids in the US.

To achieve this goal, we define the core components of patient decision aids, noting that many other names have been used (shared decision making programs, decision support tools or interventions, and so forth). We describe how they are different from clinical practice guidelines and from patient versions of such guidelines. We explain why it is considered important to design and set up a certification process. We also provide a brief overview of the work done so far, to suggest a certification process for patient decision aids. Finally, we describe the remaining challenges for the possible set up of a certification process in the US and present a certification proposal.

To inform this discussion, we searched PubMed and PsycINFO for articles in peer-reviewed journals published between 2006 and February 2016. Search terms included: "patient decision aid" or "decision support techniques" combined with terms such as "certification", "accreditation", or "standard." Studies were eligible if they covered the development of quality standards for patient decision aids, proposed certification methods, or were commentaries on this topic. Our searches of digital databases identified 261 unique citations. From this set, we identified ten articles that met the inclusion criteria. The reference lists of these ten articles were screened, and an additional eight articles met the inclusion criteria. All citations were reviewed for eligibility by PS (1–18).

A draft of the proposal was sent on April 11, 2016 to the following consultants for review: Professor Angela Coulter, University of Oxford, UK; Deborah Collis and Victoria Thomas, National Institute for Health and Care Excellence, UK; Professor Bob Volk, MD Anderson Cancer Center, Texas, US; Dr. Angelo Volandes, Harvard Medical School, Boston, US; and Professor Dawn Stacey, University of Ottawa, Canada. Consultants were given two weeks to review the document and provide feedback. The draft report was sent to the National Quality Forum (NQF) in May 2016. An expert panel webinar was scheduled for May 18 and a stakeholder meeting planned for June 22, 2016.

1.1 What are patient decision aids?

The name 'patient decision aids' has become widely recognized in healthcare to describe "tools designed to help people participate in decision making about health care options, with the goal of promoting deliberation between patients, health care providers, and others about those options"(16). Patient decision aids "provide information about the options, and help patients to construct, clarify, and communicate the personal values they associate with the different features of the options" (16). Patient decision aids do not advise people to choose one option over another, nor are they meant to replace discussions with practitioners. Instead, they provide structured guidance in the steps of decision making and to prepare patients to make informed, values-based decisions with

their practitioner" (7,15,16,19).

Different types of tools have been produced, each with variable quantities of included information, variable quality of evidence synthesis, different target audiences, different features (e.g., explicit values clarification exercise), and different intentions in terms of *when* and *how* they are used. Definitions of 'patient decision aids' most often refer to the intention to present alternatives, either in terms of possible treatments or actions. This includes the attention given to ensuring that the information contained is scientifically accurate, balanced, accessible, and adopts the best methods for communicating risk, in terms of the probabilities that benefit or harm will occur. This is done by summarizing evidence from scientific studies. Patient decision aids also make an effort to help patients clarify their values and preferences either explicitly or implicitly so that patients are able to determine whether available options align with their own priorities or interests.

These interventions have been subject to research since the late 1980s, and by 2014, there had been over 115 randomized trials of these tools across a wide range of settings (16). Taken overall, the results of the trials provide a clear picture - research evaluations show that patients who use them become better informed, have less 'decisional conflict', and have more 'accurate risk perceptions'. There are reports that fewer patients are 'passive in decision making processes' and that 'patient-practitioner communication' is improved, but there are a limited number of studies that have been able to confirm this finding using observational methods (16). The studies that provide evidence from observational measures showing greater participation in decision making processes, i.e., in shared decision making, have mostly used tools designed for use in clinical encounters (20,21).

A systematic review conducted by Shay and Lafata (20) described patient outcomes that have been measured in relation to shared decision making and assess the link between the two. Affective cognitive outcome assessments comprised 51% of the 95 total unique patient outcomes that were evaluated, 28% were behavioral outcome assessments, and 21% were health outcome assessments. Fewer than half the assessments revealed a statistically significant and positive relationship between shared decision making and a patient outcome. When shared decision making was measured from the perspective of the patient, regardless of the outcome category, assessments were more likely to result in significant associations.

1.2 How are patient decision aids different from clinical practice guidelines?

The production of clinical practice guidelines has evolved substantially over the last few years. More recently, experts in the guideline field have recognized the need to consider moving beyond recommendations that recognize the existence of only one viable management option. In this regard, a dialogue has been initiated between those who develop patient decision aids and those who focus on a set of 'best practice' recommendations. Guideline producers have begun to consider how to include information about patient preferences and how to produce versions of guidelines that are suitable for patients (22). For this reason, we need to consider the differences and

similarities of patient decision aids and clinical practice guidelines where the common theme is to summarize evidence to guide decision making.

Clinical practice guidelines are known to most as summaries of evidence designed for use by healthcare professionals and policy makers to support clinicians to make the most appropriate decisions with their patients. The common ground they share with patient decision aids is their intention to distil many studies about the effectiveness of treatments and tests into recommendations that can guide decisions, typically the decisions of clinicians. This intention to 'recommend' also reveals a difference in the stance taken by most groups that develop clinical practice guidelines. There is typically much less effort in clinical practice guidelines to compare alternative treatments or to present a comparison between the possible harms and benefits, although there are indications that this is changing (23). The role of patients' preferences is not usually made prominent in clinical practice guidelines. These tools are more likely to consist of a set of 'best practice' recommendations. It is important to note that patient-facing versions of clinical practice guidelines have been developed by many organizations. Yet, most of those tools aim to summarize a recommendation rather than compare options. There are exceptions, however, and the Consumer Summary Guides from the Agency of Healthcare Research and Quality (AHRQ) are a good example of an effort to compare management options (24).

Over the years, the volume and range of clinical practice guidelines have increased dramatically. Many organizations have developed guidelines, covering a multitude of clinical topics, so much so that many clinicians have commented that there is confusion as to the most authoritative version, especially when the recommendations vary from document to document (25).

To address concerns of this nature, systems have been proposed to ensure that clinical practice guidelines adopt a rigorous approach to the synthesis of scientific evidence, ensuring that searches for studies are well conducted and that the summaries are based on sound analytical steps. In the US, systems have been developed by the Evidence-Based Practice Centers who conduct Comparative Effective Reviews (26). The US Preventive Services Task Force uses the Evidence-Based Practice Center reviews to inform their clinical preventive services, and the American Cancer Society as well as the American Society of Clinical Oncology have been using rigorous evidence review processes in preparing their cancer-related guidelines. The Task Force makes an assessment of net benefit in its recommendations. These recommendations are particularly relevant because they are linked to patient copayment requirements (and hence policy) for A and B recommendations, high certainty or moderate net benefit respectively (27). An additional concern about clinical practice guidelines has been the potential for commercial and other competing interests to influence guideline panels as they summarize the evidence at their disposal (28), a concern which we will address further.

The most prominent and widely used system at an international level is known as the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) - used by 92 organizations worldwide as a method to reassure end-users of the quality of

the guidelines that are eventually published. Appraisal of Guidelines, Research and Evaluation (AGREE) II is a tool used to assess the quality of clinical practice guidelines (29).

Given this emphasis on evidence appraisal and synthesis, it is worth noting that the National Quality Forum (NQF) considers and endorses performance measures that are suitable for accountability applications (e.g., public reporting, accreditation, performance-based payment, network inclusion/exclusion, etc.) or for internal quality improvement efforts (30). Patient reported outcomes (PROs) include health-related quality of life or functional status, symptom and symptom burden, experience with care, and health-related behaviors. Setting up an endorsement process entailed developing a process for working at a national level in a way that has been deemed acceptable to set quality standards. To accomplish the work, NQF set up a Consensus Standards Approval Committee (CSAC), as well as multidisciplinary stakeholder panels that included clinical expertise when relevant, as an addition to the conduct of a clinical evidence review, that cites the relevance of USPTSF (A) levels and GRADE (Strong category) and conduct a measure testing review. It is worth noting, therefore, that the established endorsement process for measures evaluates the *strength* of the evidence using a systematic approach to the relevant literature (as well as the type, suitability, and quality of testing conducted). This is consistent with the standards established by the Institute of Medicine (IOM) for systematic reviews and guidelines. The CSAC recognized that there could be room for exceptions, where giving attention to important measurement constructs would require some exceptions where research evidence was not yet available. In summary, NQF has established a process for evidence and content review that has led to an endorsement process for measures. It would seem feasible to leverage this experience.

1.3 Why is it considered important to ensure the quality and safety of patient decision aids?

Many reports and articles about patient decision aid 'certification' argue that a need exists to ensure that information given directly to patients needs to achieve an agreed upon standard, against a range of criteria (31,32). The need to ensure that patient decision aids were developed and certified was contained in the Affordable Care Act, although resources were not allocated to that goal (33).

The arguments for setting standards are as follows:

Patient decision aids, as shown by many scientific trials, if used, increase the knowledge individuals have about healthcare options, improve accurate risk perception, reduce uncertainty and decisional conflict, and accordingly influence patients' decisions. Making decisions based on inaccurate information, or on information that has been influenced by poor presentation, low-quality risk communication formats, or by commercial and other interests would be a threat to patients' safety.

In addition, there is confusion about what constitutes a 'patient decision aid', and especially about the boundary between these tools and patient information leaflets,

booklets, and websites. Organizations alerted to the possible need to use patient decision aids in order to obtain rewards or reimbursements have been known to regard patient education material or information leaflets as patient decision aids, to develop their own versions, or adopt and modify tools made by others (34). Incentivizing the use or dissemination of patient decision aids, as has been proposed in many policy documents (35), places an urgent need to define and ensure adherence to an agreed upon standard.

A system is therefore required to ensure that patients are not exposed to information that is either of low quality, or worse, biased towards or away from the choice that people informed by *reliable, trustworthy* sources, would make. It is a matter of patient safety as well as one of quality.

2. Quality assessment and certification efforts to date

2.1 Standard setting for patient decision aids: the work of the International Patient Decision Aids Standards (IPDAS) Collaboration

2.1.1 Development of the IPDAS checklist and quality criteria framework (2003-2006)

The IPDAS collaboration was established in 2003 to develop a quality framework and quality criteria for the assessment of patient decision aids (7). To this effect, a two-round international online Delphi survey was conducted where selected participants were asked to rate the importance of 83 quality criteria in 12 quality dimensions. One hundred and twenty-two nominated participants representing 14 countries (researchers, patients, practitioners, and policy makers) took part in the first round of the Delphi survey (with 104 completing both rounds). Out of 83 quality criteria presented to participants in round one, 74 were retained. This constituted the first iteration of the IPDAS checklist for appraising the quality of patient decision aids.

2.1.2 Development of the IPDAS instrument (2006-2009)

The IPDAS checklist enabled users to determine (by ticking all relevant boxes) whether a patient decision aid included suggested components and 'met' agreed upon quality criteria across various dimensions (e.g., development process, evaluation etc.). However, it did not provide a precise, quantitative assessment of the decision aid's quality. To fill this gap, the IPDAS instrument (IPDASi) was developed and validated between 2006 and 2009, comprising four stages: 1) refinement and preparation of version 1.0 of IPDASi, 2) confirmation of items and development of version 2.0 of IPDASi, 3) validation study of IPDASi 3.0, 4) development of IPDASi short form (19 items) (4). The IPDAS instrument was used by calibrated assessors and does not rely on self-reported assessments by developers.

In summary, IPDASi version 3.0 included 47 items divided into ten dimensions, providing an overall quality score out of 100. As part of the validation study, IPDASi scores of 30

selected decision aids ranged from 33 to 82, thus permitting discrimination. IPDASi short-form (19 items) was developed using all criteria that received an equimedian score of 9 in the Delphi survey. The scores obtained using IPDASi short-form were very similar to those obtained with IPDASi V3.0, suggesting a high correlation between IPDASi short form and IPDASi V3.0. However, the findings also highlighted the potential to improve inter-rater reliability.

2.1.3 Developing minimum standards for certifying patient decision aids

In order to develop standards for the certification of patient decision aids, Joseph-Williams et al. conducted a modified two-stage Delphi survey using items from IPDASi V3.0 to identify minimum standards that could contribute to certifying patient decision aids (8). Based on the results of the Delphi survey and expert discussions, three categories of minimum standard criteria emerged:

- Qualifying criteria
- Certification criteria
- Quality criteria

2.1.3.1 Qualifying criteria

The purpose of developing 'qualifying' criteria was to ensure eligibility - that tools would meet the core requirements for classification as patient decision aids. Six criteria were proposed, closely aligned with existing definitions of patient decision aids. According to the specified criteria (8), to be eligible for certification, tools should

1) consider 'a specific decision'.
2) help patients compare and select options.
3) have information about relevant health outcomes that include 'positive and negative' aspects of options.
4) describe outcomes that are relevant to health status.
5) avoid promoting compliance with a *recommended* option.
6) help patients to clarify preferences.

2.1.3.2 Certification criteria

The suggestion made in the minimum standards article was that patient decision aids would be considered 'certified' if they were scored positively against 10 criteria (see Box 1). Each criterion was to be scored on a four-point scale [strongly disagree (score 1) to strongly agree (score 4)], and tools should score 3 or 4 (on a 1 to 4 scale) on each certification criterion in order to satisfy certification standards.

2.1.3.3 Quality criteria

A total of 28 criteria were categorized as being optional and outside the remit of a certification process. They could be scored (using a four-point scale) and considered to be *desirable but not essential*, and therefore considered as an indicator of quality rather than as minimum standards that had to be achieved. The criteria fall into nine categories including information, probability statements, value/preference clarification, decision guidance, tool development, evidence synthesis, disclosure of interests, plain language, and evaluation.

Box 1 Certification Criteria (8)

1. The patient decision aid shows the negative and positive features of options with equal detail (e.g., using similar fonts, sequence, presentation of statistical information).
2. The patient decision aid (or associated documentation) provides citations to the evidence selected.
3. The patient decision aid (or associated documentation) provides a production or publication date.
4. The patient decision aid provides information about the update policy.
5. The patient decision aid provides information about the levels of uncertainty around event or outcome probabilities.
6. The patient decision aid provides information about the funding source used for development.
7. The patient decision aid describes what the test is designed to measure.
8. If the test detects the condition or problem, the patient decision aid describes the next steps typically taken.
9. The patient decision aid describes the next steps if the condition or problem is not detected.
10. The patient decision aid has information about the consequences of detecting the condition or disease that would never have caused problems if screening had not been done (lead time bias).

As a follow up to setting these minimum criteria, Durand et al. assessed the feasibility and application of the proposed minimum standards (10). Trained raters used the minimum standard criteria to score 30 patient decision aids included in the 2009 Cochrane systematic review (and all supporting documentation provided by the decision aid developers). Twenty-five out of thirty decision aids met the qualifying standards, but only three of the 30 tools met the proposed certification criteria. Failure to certify was most often due to the omission of information (e.g., update policy, funding source), which could be easily rectified. Their findings suggested that using minimum standards would be a feasible exercise.

The exercise also highlighted that designing a future certification process would require resolving several challenges. There was considerable variation between independent

raters' assessments. Further attention to agreed descriptions of the criteria and how assessors would apply the scoring manual would be required if this method were adopted by a formal process. Further, it was unclear whether the proposed minimum standards could be applied in the same manner to patient decision aids that have been designed for different goals. For example, how might certification criteria address patient decision aids that are designed to support *collaboration* in clinical interactions rather than act as independent information sources for patients before or after clinical encounters. Such encounter tools are typically brief and rely on the contribution made by a clinician during a clinical visit.

2.1.4 Debates about IPDAS

Several commentators have critiqued the IPDAS work. In 2010, Bekker questioned whether unconditional adherence to the IPDAS checklist could threaten the validity of patient decision aids (36). While the author recognizes that the checklist will reduce variation in the quality of decision aids, she argues that the IPDAS criteria do not guarantee that interventions that meet IPDAS standards necessarily enable good patient decision making. She raises concerns about the lack of understanding of active ingredients that facilitate decision making and associated theoretical contributions from decision sciences. This set of criteria may, therefore, deter future research and understanding, both from developers and academics, of decision aid components that are most active and effective in facilitating high quality decisions.

The IPDAS instrument has also been criticized for its inability to assess the quality and clinical accuracy of the decision aid content (personal communications). Others have highlighted the need for additional criteria surrounding the issue of competing interests and suggested a more rigorous approach to the disclosure of competing interests in patient decision aid development (37).

Most recently, McDonald et al. have criticized the conceptual clarity and evidence base underlying the IPDAS checklist (38). They analyzed the probability information domain of the checklist using their own framework for the evaluation of patient decision aids and identified gaps in the empirical and theoretical basis for this domain and associated criteria.

2.2 Certification efforts

2.2.1 Initiatives in the US

2.2.2 The Affordable Care Act

Section 3506 of the Patient Protection and Affordable Care Act in 2010 discusses the establishment of a program that "develops, tests and disseminates" *certified* patient decision aids to help improve patient-clinician communication in order to elicit patient preferences (33). Funding to achieve this part of the Act was not appropriated.

2.2.3 Report by the New America Foundation

The US has led the discussion about the need to certify patient decision aids (31). In 2012, The New America Foundation hosted a meeting at the instigation of the Foundation for Informed Medical Decision Making. This Foundation has since renamed itself the Informed Medical Decision Making Foundation and has merged with Healthwise, a major developer of patient decision aids. The report summarized the work that had been done by IPDAS to date and made recommendations that a process be set up to certify patient decision aids (39).

2.2.4 Institute of Medicine Roundtable

In 2014, the Institute of Medicine organized a roundtable on value and science-driven healthcare gathering 14 experts to consider patient decision aids as a means to *facilitate* shared decision making, drawing attention to the distinction between the two terms. A Discussion Paper was published in September 2014 and made the following recommendations (28):

1) *Need to certify decision aids.* The report concluded that a certification process should be initiated, and emphasized the need for up-to-date accurate information as well as ensuring that the tools be available to as wide a range of populations as possible.

2) *Set quality standards for shared decision making.* The report suggested that patients' knowledge be tested as part of an effort to measure 'decision quality'.

3) *Use information technology.* The report highlighted the *potential* of technology to deliver patient decision aids, to record that they have been used, and to document patients' informed preferences.

4) *Highlight the role of employers and payers.* The report suggested that insurers and employers, via their health insurance role, offer patient insurance that includes access to certified patient decision aids.

2.2.5 State of Washington initiative

In 2007, the state of Washington passed legislation in the Blue Ribbon Commission bill (Chapter 259), which they called a "shared-decision making pilot" (40). The law was intended to "broaden the development, certification, use, and evaluation of effective decision aids" and called for a "shared decision making pilot" to be set up. The drafting seemed to imply that the use of patient decision aids was *equivalent* to achieving shared decision making. While there is evidence that patients *report* improved communication processes, further work is required to confirm whether the use of patient decision aids leads to a process of shared decision making (16).

In 2012, the state of Washington addressed the issue of informed consent in a new legislation (41). The legislation stated that the use of a patient decision aid would provide a higher level of evidence that informed consent would have been achieved. In

addition, if there was proof that a patient decision aid had been used, then the "patient has the burden of rebutting this by a preponderance of the evidence". In other words, using a certified patient decision aid would provide a clinician with a higher degree of liability protection. The legislation goes on to describe that a 'patient decision aid' means a written, audiovisual, or online tool that provides a balanced presentation of the condition and treatment options, benefits, and harms, including, if appropriate, a discussion of the limits of scientific knowledge about outcomes, for any medical condition or procedure (41).

Tied to this informed consent legislation were the following clauses about 'certification':

- A tool can be 'certified' by one or more national certifying organizations recognized by the medical director of the Health Care Authority (HCA).

- A tool that has been evaluated by the international patient decision aid standards by an organization located in the US or Canada and has a current overall score satisfactory to the medical director of the HCA would certify.

- If a current evaluation is not available from an organization located in the US or Canada, the medical director of the HCA can independently assess and certify based on the International Patient Decision Aid Standards. In other words, the medical director can decide whether or not a patient decision aid meets the required quality threshold.

No further legislation has been passed either in Washington, or elsewhere in the US with regard to patient decision aid certification.

In 2012, Washington's legislature therefore amended its state law to enable certification at the state level by the medical director of the Health Care Authority (HCA), specifying these independent state certification standards must be based on the International Patient Decision Aids Standards (41). Washington has therefore developed a certification process for patient decision aids that was launched in April 2016.

To summarize, the state of Washington is promoting the use of patient decision aids by developing a formal proposal to a) certify a set of tools, b) provide liability protection to clinicians with regard to informed consent if they use such tools, and c) to use the 'power of their purse' to require that HCA contractors use certified tools.

In 2015, supported by an award from the Gordon and Betty Moore Foundation, the state of Washington convened convened local, and national stakeholders and IPDAS experts to advise state leaders on state certification standards and processes. As stated, the state of Washington had legislation encouraging the use of patient decision aids (40), and there was, therefore, a perceived need to consider how to ensure that patient decision aids would be of a sufficient quality to be recognized as 'fit for purpose'. After the meeting, a report was produced to achieve Healthier Washington's vision of certifying patient decision aids to improve healthcare quality while reducing avoidable costs (41). After a consultation and review process, certification criteria and a certification process was proposed in early 2016 (42).

In launching its certification process, Washington determined it would prioritize selected high priority clinical topic areas for certification, particularly for the first few review cycles. It has now developed and implemented a multi-step process for the certification of patient decision aids, which we summarize here:

Step 1 Selection and initial steps
Washington's lead state agency, the Health Care Authority (HCA), determines and announces its priority clinical areas, and issues a call for application submission. Developers must submit complete an application that includes questions and supporting documentation about the developer, features of their decision aid, supporting evidence using a prescribed evidence table, development process, and evaluation methods as well as provide a copy of the tool.

Step 2 State review
Applications are first assessed by internal staff for eligibility, and timeliness, completeness and clarity of the submitted materials. The HCA medical director may then refer the decision aid and associated materials to an evidence based practice center to advise on the validity or presentation of the evidence or other elements of the decision aid or development methods. Accepted applications together with the results of the external evidence review (if any) are then considered by an expert advisory panel, using the agency's cerfication critieria. The review panel recommendation together with the complete review packet is then submitted to the medical director, who has the authority to certify the patient decision aids.

Step 3 Decision to certify or revise
The HCA medical director assesses the decision aid and the application materials together with the comments and reports from the reviews, and decides whether to certify, provide the developer with an opportunity to remedy any deficiencies in its application, or decline certification. Patient decision aids that are certified are be included on a webpage listing of certified products.

Step 4 Withdrawal or suspension
The Washington state proposal contains the potential to re-review and withdraw certification if new material or information has become available that may compromise the accuracy of the tool's content. The decision aid producer may update the decision aid and supporting material and re-submit for review.

Step 5 Recertification
The Washington state process suggests that certification should be valid for two years and has further details about timetables for the application process.

Step 6 Quality checks
The Washington state process suggests that 'certified developers' would be subject to random quality checks as part of the certification process.

2.3 Initiatives in other countries

2.3.1 Initiatives in the United Kingdom

As far as we are aware, the only other country to have considered developing a certification process for patient decision aids is England in the United Kingdom. In 2012, The National Institute for Health and Care Excellence (NICE), in collaboration with The Information Standard, investigated the scope, criteria, and process issues associated with the accreditation of patient decision aids. They conducted a short pilot of a possible accreditation scheme. In parallel, they convened a working group of experts in this area to review an analysis of possible options for accrediting the quality of patient decision aids. They reviewed the suitability of 1) current NICE accreditation criteria (initially developed for the accreditation of clinical guidance), 2) The Information Standard certification process designed for all types of written information for patients, and 3) IPDASi, to be used alone or in combination. Their analysis suggested that elements of NICE accreditation of organizations producing clinical guidelines, the Information Standard's certification of organizations producing patient information materials, and IPDASi were all considered suitable for accrediting patient decision aids. A combination of these processes was also feasible. The process would be similar to that adopted for the Information Standard certification, in which organizations applying to be certified submit a description of their processes, together with samples of their material. These are to be externally reviewed for independent scrutiny by professional certification bodies and organizations specializing in medical evidence reviews, such as BMJ Evidence or Bazian.

To test the above proposal, NICE conducted a pilot evaluation of *Totally Health* decision aids (commissioned by the Right Care program in 2012). Three decision aids were tested by the NICE accreditation team and Information Standard. Limited development process information was provided. The results suggested that NICE accreditation criteria, or Information Standard criteria, could be used to assess the patient decision aid development process. Issues associated with the amount of development process information the decision aid developer was able to provide were identified. The report does not indicate which criteria (NICE or Information Standard) may be best suited to accredit patient decision aids. The pilot findings confirmed their initial proposal, where a combination of 1) NICE accreditation and IPDASi criteria or 2) Information Standard and IPDASi criteria could be used.

Building on the above findings, recommendations were made to develop an accreditation program. Since then, no concrete steps have been taken to fund and implement this proposal, although further consideration is being given in 2016 to the steps necessary to promote the wider use of patient decision aids.

In 2014, NICE launched an endorsement program, which formally endorses guidance support resources (including patient decision aids) developed by organizations external to NICE. However, this program only endorses information resources that are aligned with and support recommendations from NICE guidance and does not certify or accredit patient decision aids.

This agenda arose again when in 2015 NICE held two international Shared Decision Making Collaborative Forums. One of the outcomes of these meetings was the development of a consensus statement to support shared decision making in health care systems, primarily in the UK's National Health Service (NHS). One of the recommendations in this consensus statement was,

"NICE, in collaboration with The Information Standard and the IPDAS collaboration, should establish a national endorsement process that enables users to identify up to date evidence-based patient decision aids meeting a minimum quality threshold. These should be available via a single point of online access."

NICE is working with NHS England to explore options for taking forward this concept of a repository of quality assured decision aids.

3. Current challenges

As this report illustrates, the mention of 'patient decision aids' in the Affordable Care Act (33) stating that 'certified' versions should be used in clinical settings has generated many meetings and reports.

However, progress towards developing a certification process has been slow. IPDAS, an informal international alliance of researchers, has published a series of articles that have provided a basis for the 'content', and some aspects of the development of patient decision aids to be considered. IPDAS has been unable, however, to address how to verify the rigor of evidence synthesis, the influence of potential conflicts of interests and clinical accuracy of the content. Although IPDAS has considered the topic of competing interests, the guidance is relatively weak, when examined systematically (1,2,4,5,7).

The state of Washington has introduced legislation (40,41) and has made considerable progress towards a process that is currently piloted and evaluated (May 2016).

Nevertheless, despite the progress made by the state of Washington, many unresolved challenges remain. These challenges are not new; they have been present throughout the work that IPDAS has undertaken and will be areas that require careful consideration if certification is to occur at a federal or national level in the US. These challenges include the following concerns:

3.1 Evidence synthesis. Who will judge the accuracy of the evidence and information presented?

Developers of clinical practice guidelines have faced similar challenges when faced with the task of verifying evidence synthesis methods. Whilst there remains debate about how best to ensure a rigorous process, it seems that an agency charged with the task of certifying patient decision aids should stipulate the kind of evidence synthesis processes that would be deemed acceptable. There are a number of potential methods that could be considered appropriate. As mentioned, in the US, Comparative Effective Reviews

(26) and other methods have been recognized as rigorous approaches to evidence synthesis. The Task Force has published its recommendations for guideline development (43) and has aligned its processes with those published by the National Academy of Medicine's (formerly the Institute of Medicine) recommendations for guideline development (44).

As mentioned earlier, GRADE is a system of evidence assessment that is used at an international level and increasingly recognized by US agencies (see Box 2).

Box 2 GRADE: assessing the quality of evidence synthesis (45)

In the GRADE system, randomized controlled trials (RCTs) represent the high-quality evidence end of the spectrum versus observational studies that are of lower quality. Guideline authors decide which outcomes are critical or important and rate the overall quality of evidence. The level of outcome desirability and the application of patient values and preferences provide direction for developers and the quality of evidence provides the strength (46).

AGREE II (mentioned previously) is another tool used to assess the quality of clinical practice guidelines (29).

Box 3 AGREE II (29)**: assessing the quality of guideline development**

AGREE II: Six quality domains for guideline development

Domain 1. Scope and purpose

Domain 2. Stakeholder involvement

Domain 3. Rigor of development

Domain 4. Clarity of presentation

Domain 5. Applicability

Domain 6. Editorial independence

Developers of patient decision aids have different approaches to evidence synthesis. Some rely on published guidelines or existing systematic reviews; some undertake their own assessment of the literature. Some developers do not provide much detail of how

they arrive at their content and rely on clinical experts. So far, there have been no detailed analyses of how patient decision aid developers achieve evidence synthesis.

3.2 Disclosure and management of competing interests

In parallel to ensuring rigorous evidence synthesis is the need to manage competing interest, both at organizational and individual levels (37). Again, in the domain of clinical practice guidelines, this issue has been repeatedly highlighted as a threat to trustworthy products. Investigations into the membership of clinical practice guidelines have revealed close ties between panel experts and companies that would have a direct interest in the nature of the recommendations (47). Producing trustworthy evidence for patient decision aids is a similar challenge and, in fact, may be harder to accomplish given that there are typically fewer data available about side effects, harms, and long-term adverse events. A recent review of the competing interest policies of 25 known patient decision aid producers indicated that 12 organizations were willing to share data, 11 did not respond, and 2 declined to provide data. Of the 12 that provided data, less than a handful had stringent competing interest policies, and most did not have processes that reliably disclosed and/or excluded the influence of competing interests (48).

Given that it is impossible to entirely exclude the influence of competing interests, decisions would be required about the acceptable level of risk that could be tolerated when competing interests are identified. For example, how does one consider the production of a patient decision aid funded by a company who might directly benefit from the portrayal of treatment options, or the inclusion of a clinical expert with extensive financial income from a company related to the topic area covered by the patient decision aid?

3.3 Certify individual decision aids or certify developer organizations?

Across the globe, there are relatively few patient decision aid organizations that actively maintain five or more tools. We estimate the number to be approximately 15, with about 8 that are based in the US. On the other hand, a very large number of patient decision aids have been produced, either by academic groups or small organizations with an interest in an emerging marketplace. The Ottawa A-Z Inventory provides a list of tools (49).

A certification process will be of most interest to those organizations who have invested time, money, and effort into creating a suite of tools, and who have a business model that relies on income derived from licenses or agreements for the use of such tools. If we focus on the US, the number of such organizations is limited. We estimate that there are only eight or so organizations that actively maintain 30 or more patient decision aids.

A certification body would need to decide whether or not the process applies to individual patient decision aids, or to a producer organization as a whole, or a hybrid of

both. An organization that produces more than a 100 tools would likely argue that all their tools have been developed using similar processes, and might be resistant to the cost of certifying each patient decision aid individually. A certification body might consider a hybrid process in such situations, where a random sample of tools is individually certified, with attention paid to the key steps in a published development procedure.

3.4 Evaluation data - required or not?

Following best practice in developing evidence-based content for patients is a complex process. It requires attention to evidence synthesis, to the exclusion of competing interests and user-centered design, recognizing that the users are patients as well as many other stakeholders, including clinicians (50). Towards the end of a development process, there is a gray area where pilot use and field-testing are recommended. This step is sometimes followed by quantitative evaluation in experimental trials to assess efficacy or effectiveness. A certification process will need to determine what level of evaluation data is sufficient. If a developer has data from a series of existing studies, would they be required to repeat such studies for a similar tool albeit covering different topics? This is an area where it might be best to take a pragmatic approach.

3.5 Different types of patient decision aids

Most patient decision aids developed to date have been introduced to patients *ahead* of clinical encounters; therefore, we suggest the term *pre-encounter* decision aids. They have focused on providing extensive information, via various media, such as video or more recently web-based (16). Extensive research has shown that although decision aids improve outcomes in controlled settings, with largely literate audiences, sustained use in routine care remains difficult to achieve because of implementation resistance (51).

Patient decision aids have also been designed for use in clinical encounters — encounter decision aids. These tools have not been the subject of as much research as pre-encounter decision aids (21). An encounter decision aid is designed to facilitate conversations about available options between patients and healthcare professionals (and caregivers or close relatives) *during* the clinic visit (52–55). They are intended to support a process of collaboration and preference elicitation and to enable clinicians to tailor information to patients' needs and characteristics. By necessity, there is less information contained in these kinds of tools - they typically contain pictures, short phrases, or icon arrays and are designed for assimilation in a few minutes, often used as a scaffold for a conversation between a clinician and a patient.

Nevertheless, these tools are indeed patient decision aids and their content, however brief, should be subject to the same certification standards as other tools, especially in terms of development, evidence synthesis, and the declaration of competing interests. There is however a need to discuss whether it is possible to apply the same standards

to the content of the tool, given that encounter tools are specifically designed to be catalysts for conversations rather than information for independent use. We, therefore, suggest that the certification of encounter decision aids be based on supporting documentation as well as the tool itself, where it is not practical that all information could be directly displayed on the encounter decision aid itself.

3.6 Legal considerations

Organizations that produce patient decision aids will naturally pay attention to the standards set by a certification body. They will also scrutinize the legal provisions in relation to certification. We should, therefore, examine where the law stands at this point in time across the US. In 2010, the term 'certified decision aid' was used in the Affordable Care Act (33), but as stated earlier, the recommendation was not funded.

Patient decision aid producers are likely to ask the following questions:

1. What would be the consequences of achieving or not achieving certification?

2. If clinics were to continue to use 'uncertified' tools, perhaps 'homegrown' or other tools that are found to be popular but which do not seem to meet minimum standards, would there be any legal force to forbid such use?

3. If a certification process is achieved at a US level, what would be the rewards or sanctions for individuals or organizations that were not willing to use certified tools?

4. Would there be a financial consequence, reward, or penalty to using or not using a tool that had achieved certification?

The Affordable Care Act seems to imply as much, but much is left open to debate (35).

4. A patient decision aids certification proposal

This proposal is meant to generate discussion about the key elements of such a method. We do not presume to arrive at a definitive detailed description--that level of detail is beyond the scope of this report.

First, we propose to build the certification program around the following prerequisites:

A. Definitions of patient decision aids

The *definition* should be based on existing agreements about the essential components, yet, also flexible enough to allow tools of different types, intentions, and formats to be considered eligible.

For encounter decision aids that by design are intended to be brief, the assessment should be based on both the content of the decision aid and on their supporting documents.

B. Certify individual patient decision aids as well as developer organizations

We propose that developers who are actively maintaining five or fewer products for use by patients should have *all their tools* subject to certification. For developers who are actively maintaining five or more tools, we propose that the organization as a whole be subjected to a certification of its development process, and, in addition, that a random sample (% to be determined) of the total available patient decision aids be subjected to certification. This would require a certification process that can be applied to both specific patient decision aids and to organizational development procedures, such as development processes, stakeholder involvement, user-centered design, evidence synthesis procedures, and policies for managing competing interests. This issue is likely to be the subject of debate.

A possible process could be as follows: if all patient decision aids, selected at random from a developer's catalog successfully attain certification, the organization becomes a 'certified developer', for a time period to be determined. If one or more of a developer's patient decision aids fail to accomplish certification, the organization would be required to address the deficiencies, and after a specified period of time, reapply for certification so that a further random sample of patient decision aids is assessed. Iterative processes would be required before organizations are given certified developer status.

C. Assessment process

We propose that the evaluation of the patient decision aids submitted for certification be based on the content of the decision aid, on an application form, as well as on supporting documents. In other words, decision aid developers who wish to certify their patient decision aid will be required to:

1. Provide a copy of the latest version of the patient decision aid;

2. Provide copies or web links to relevant supporting documents (e.g., relevant publications, reports, development procedures and standard operating procedures, competing-interest policy, competing-interest disclosure forms, relevant web pages that provide information about the decision aid and its development process);

3. Complete an application form describing the organization that developed the decision aid, listing all supporting documents provided and answering a series of five to ten questions about the patient decision aid development process (evidence synthesis, needs assessment, field testing, evaluation). We suggest that all materials will be reviewed by two independent assessors who

- have been trained in conducting this type of evaluation,

- have research experience and/or training, and
- have declared no relevant intellectual or financial competing interests.

It might be necessary to consider whether one of the assessors should be a clinician, perhaps with expertise that corresponds to the subject area of the patient decision aid under assessment.

We suggest that independent assessments should be compared and disagreements resolved by discussion. Processes should be developed to deal with disagreements that cannot be resolved.

Similar to processes established by NQF for measure endorsement, a certification review group should have stakeholders from multiple perspectives, including patients, and, when relevant, recruit expertise in clinical topic content. The review committee could be allocated the task of reviewing contentious issues and ratifying assessor evaluations and recommendations. Review committee members will be required to complete a competing interest declaration form and adhere to an agreed policy with regard to exclusion because of financial and intellectual conflicts of interest.

D. Assessment domains and criteria

The work of IPDAS has enabled significant progress to be made in this area, and it has led to the proposal of a set of minimum criteria that can be applied to patient decision aids and their supporting documentation. As is the case in the state of Washington, modifications to the suggested minimum criteria will be necessary (see Table 2 below). A distinction may need to be made between decision aids that address screening or treatment decisions, given the need to describe different concepts.

Based on the collective work of many contributors to this area, we propose that a national level patient decision aid certification process in the US should consist of the following domains, adapted from the IPDASi minimum standards work, and complemented by assessment criteria that have been found to be missing or criticized in past efforts to assess and accredit patient decision aids (not restricted to IPDAS criteria).

4.1 Qualifying criteria

We anticipate that qualifying criteria will be derived from IPDASi minimum standards and will apply to the patient decision aid tools--in physical or digital format. The selection and phrasing of these six qualifying criteria (Table 1) were undertaken so that they could be applied to all types of patient decision aids.

Table 1 Provisional selection of qualifying criteria

Item	Description *The patient decision aid …*	Domain
Item 1	states the health condition or problem for which index decision is required.	Information
Item 2	explicitly states the index decision under consideration.	Information
Item 3	describes options available for the index decision.	Information
Item 4	describes positive features of each option.	Information
Item 5	describes negative features of each option.	Information
Item 6	describes features of options to help patients imagine the physical and/or social and/or psychological effects.	Preferences and Values

4.2 Certification criteria

We propose to adapt the IPDAS minimum standards certification criteria (see table 2). These criteria can be applied to the content of the patient decision aid where relevant, or to the supporting documentation that should accompany each patient decision aid, providing the information considered necessary for certification purposes. Additional criteria may be required for decision aids that consider screening or diagnostic tests.

Table 2 Proposed certification criteria

Item	Description	Domain
Item 1	The patient decision aid attempts to provide a balanced presentation of options.	Information
Item 2	The patient decision aid content is based on a rigorous and documented evidence synthesis method.	Evidence synthesis
Item 3	The patient decision aid or supporting document provides information about	Evidence

	the evidence sources used.	
Item 4	The patient decision aid or supporting document provides outcome probabilities, adopting risk communication principles.	Probability
Item 5	The patient decision aid or supporting document provides information about levels of uncertainty.	Probability
Item 6	The patient decision aid provides a publication date.	Evidence
Item 7	The patient decision aid or supporting document provides information about the update policy and next expected update.	Evidence
Item 8	The patient decision aid or supporting document provides information about the funding sources used for development.	Disclosure
Item 9	The patient decision aid or supporting document provides information about competing interests and/or policy.	Disclosure
Item 10	The patient decision aid or supporting document provides information about the patient decision aid development process, including information about needs assessment conducted with both target patients and health professionals.	Development
Item 11	The patient decision aid or supporting document provides information about user testing with target patients and health professionals.	Development
Item 12	The patient decision aid or supporting document reports readability levels (Grade 7 or below).	Language
Item 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.	Language

4.3 Issues to be discussed

We present below a list of issues that require further discussion.

1. One of the greatest challenges of IPDAS is the issue of inter-rater reliability and degree of ambiguity inherent to many IPDASi and IPDASi minimum standards items.

How do we manage this ambiguity and ensure that raters are able to rate each patient decision aid fairly and reliably against a set of unambiguous requirements? For example, one of the proposed qualifying criteria is: "The patient decision aid describes positive features of each option." Does a rater consider that this criterion is met if the decision aid describes one positive feature, or several positive features, of each option? Or does the rater need to be a clinical expert in the decision aid topic area to determine whether all relevant positive features associated with this option have been described? This was an unresolved issue met by the assessors that used IPDASi and may be a challenge that will be met by the state of Washington certification scheme as well.

1a. What qualifications do assessors need?

1b. How much assessor training is required? And how will it be delivered? By who?

1c. Are assessors remunerated, employed, or expected to do it on a voluntary basis, as is the case with most journal peer-review procedures.

1d. The National Quality Forum uses multi-stakeholder committees to evaluate measure quality (e.g., evidence and user testing). Leveraging existing committees and related resources to determine (against the proposed criteria) whether or not a patient decision aid can be certified would bypass most, if not all, of the above issues. How would a multi-stakeholder committee change the rating process?

2. Does each developer need to evaluate the effectiveness of their patient decision aid and provide evidence about evaluation, although there is a large body of existing evidence (e.g., Cochrane reviews)?

2a. If so, what is considered a sufficient amount of research evidence to determine effectiveness; and does it directly determine whether or not a decision aid or organization becomes certified?

3. If larger organizations are certified, do we need to assess the development process independently, as well as undertake the certification of a proportion of their decision aids (and existing questions about development process included in each individual decision aid assessment)?

4. Does the evidence synthesis method have to be specified / agreed by the certification agency? For example, can a decision aid developer rely on a systematic review that has already been conducted? Are they required to conduct a systematic review if no relevant systematic review exists?

5. In order to simplify the certification process and address some of the challenges raised by the minimum standards' feasibility exercise, we suggest that quality items included in the minimum standards proposal are removed. Some of those items (deemed most important) have been included in the certification criteria, and others

have been removed entirely. Is there a concern that quality items should be retained and rated separately, as was proposed for the minimum standards?

6. Should the certification process result in a pass or fail status, or should certification items be scored along a scale, such as low/moderate/high "evidence exists that the certification criterion is met"? The latter is the approach currently followed by the NQF multi-stakeholder process for measurement endorsement.

7. How long is certification valid for? In other words, does each certified patient decision aid require re-assessment every few years, to ensure that the content is current and accurate?

8. How is failure or success with certification determined? Does the patient decision aid need to meet every single qualifying as well as certification criterion? For example, if a decision aid meets all qualifying and certifying criteria except for one or two, could we consider granting provisional certification provided the two criteria are met within an agreed timeframe? Or is the patient decision aid developer required to submit a new application form once the changes have been made and cover the cost of assessment twice?

9. For the qualifying criteria, can the information be provided on supporting documents?

10. How about certification criteria? Do we accept (and this is particularly relevant for brief encounter decision aids) that the information required according to certain criteria appears either on the patient decision aid itself or on supporting documents?

11. The proposed certification criteria do not, as yet, cover specific features of patient decision aids addressing screening or decisions to use tests, as is the case with IPDASi, IPDASi minimum standards and the Washington state certification. Are those criteria necessary? If so, should they be added as optional certification (or qualifying?) criteria that only have to be met by patient decision aids that cover screening / testing decisions?

12. Evidence from implementation projects suggests that some of the most popular and widely adopted patient decision aids do not meet IPDAS standards (e.g., do not provide detailed numerical outcome probabilities), because such tools meet less clinician and organizational implementation resistance. How should a certification proposal deal with this pragmatic issue?

13. Assuming that several patient decision aids covering the same topic or decision achieve certification, should NQF rank the certified tools (a list of 'best in class") according to their quality and proposed use?

4.4 Excluded areas

Research into patient decision aids has indicated that some areas have less evidence to support their inclusion in patient decision aids. The inclusion of narrative elements, such

as patient stories or testimonials, has led to debate. Although often considered helpful and viewed as valuable components by patients and others, the risk of biasing decisions is considered to be too high. Consensus on this issue has not emerged and there is insufficient research on which to draw conclusions (56). Similarly, research on the inclusion of differing preference elicitation exercises has shown inconsistent results (57). Given these concerns, it does not seem necessary to include these areas as necessary components of a certification process.

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Author competing interests

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List of abbreviations

AHRQ	Agency of Healthcare Research and Quality
AGREE	Appraisal of Guidelines, Research and Evaluation
GRADE	Grading of Recommendations Assessment, Development & Evaluation
HCA	Health Care Authority
IPDAS	International Patient Decision Aids Standards
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NQF	National Quality Forum

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