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Health Policy

journal homepage: [www.elsevier.com/locate/healthpol](http://www.elsevier.com/locate/healthpol)



Health Reform Monitor

## A proposal for the development of national certification standards for patient decision aids in the US<sup>☆</sup>

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### ARTICLE INFO

#### Article history:

Received 19 July 2017

Received in revised form 9 February 2018

Accepted 20 April 2018

#### Keywords:

Patient decision aids

Shared decision making

National standards

Certification process

Patient engagement

Development and implementation

### ABSTRACT

Efforts to implement the use of patient decision aids to stimulate shared decision making are gaining prominence. Patient decision aids have been designed to help patients participate in making specific choices among health care options. Because these tools clearly influence decisions, poor quality, inaccurate or unbalanced presentations or misleading tools are a risk to patients. As payer interest in these tools increases, so does the risk that patients are harmed by the use of tools that are described as patient decision aids yet fail to meet established standards. To address this problem, the National Quality Forum (NQF) in the USA convened a multi-stakeholder expert panel in 2016 to propose national standards for a patient decision aid certification process. In 2017, NQF established an Action Team to foster shared decision making, and to call for a national certification process as one recommendation among others to stimulate improvement. A persistent barrier to the setup of a national patient decision aids certification process is the lack of a sustainable financial model to support the work.

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### 1. Introduction

In 2010, the ACA included a provision for a national certification process for decision aids, although no funding was allocated to the work [1]. In 2014, the Institute of Medicine convened an expert panel to consider the topic of patient decision aid certification and confirmed that a process of national certification should be established [2]. Other countries are also examining ways to ensure that patient decision aids (PDAs) meet agreed standards [3]. The National Health Service (NHS) England's Information Standard operates a certification scheme for producers of patient

information materials [4], while National Institute for Health and Care Excellence (NICE) accredits developers of clinical guidance [5]. A combination of these approaches has been proposed as the basis of NHS certification process for patient decision aids, but as yet no funds have been made available to cover the cost of its establishment. In Taiwan, a committee composed of healthcare professionals used the criteria and checklist of the International Patient Decision Aid Standards (IPDAS) Collaboration resulting in the accreditation of 57 tools [3].

With the push to increase value in health-care services, there has been greater interest in patient engagement and experience across episodes of care. Many clinical encounters will require decisions about procedures or investigations or set goals for the management of a chronic condition; all are areas where patient input and shared decision making (SDM) are being recommended. For example, in a coverage decision to approve the use of low-dose chest CT scans for smokers to screen for lung cancer, the Centers for Medicare and Medicaid Services (CMS) included a requirement that the patient-clinician discussion includes the use of a patient decision aid [6].

<sup>☆</sup> Open Access for this article is made possible by a collaboration between Health Policy and The European Observatory on Health Systems and Policies.

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<https://doi.org/10.1016/j.healthpol.2018.04.010>

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An announcement by CMS to incentivize shared decision making in Accountable Care Organizations and Decision Support Organisations stimulated even more interest in these patient-facing tools [7]. CMS specifically indicates that the use of patient decision aids can enhance the involvement of patients in decisions where two or more reasonable healthcare options are available [8]. For physicians, the CMS Quality Payment Program [9] includes selected improvement activities for physician practices, including “the use of evidence-based decision aids to support shared decision making.” The initiative fits into a broader plan to stimulate value-based purchasing on the part of CMS. These initiatives may also be taken up by private sector health plans as they introduce products with increasing deductibles and copayments. These plans expose patients to higher costs, and proponents claim that they will stimulate patients to make decisions based on cost-effectiveness [Box 1](#).

**Box 1: What are patient decision aids?**

Patient decision aids are evidence-based tools that have been designed to help patients participate in making choices among health care options. They can be in a range of media and contain summaries of scientific evidence that are designed to be accessible to patients. The goal of these tools is to supplement and facilitate rather than replace, clinicians’ counseling about options. In general, they explicitly state the decision that needs to be considered and provide information about the health condition, the options available and their associated benefits, harms, probabilities, and uncertainties. They help patients, implicitly or explicitly, become informed and to form preferences about decisions that they might face in health care settings [15]. There is strong evidence to show that using patient decision aids improves patients’ knowledge about options and their outcomes and that patients can assess risk much more accurately, and that patients using these tools make decisions that are better aligned with their informed preferences. There are also studies showing that in some situations, fewer people choose surgical options. Reductions in healthcare costs have been reported in association with the use of patient decision aids, although the evidence in support of cost-reduction requires further research [16].

The CMS funding announcement stated that these decision aids be of a high quality, balanced, and contain trustworthy summaries of evidence made accessible to patients. Yet, despite a decade of research into how to set standards for these types of decision aids, an institutional capacity to assess the quality and suitability of patient decision aids for wider use has not been achieved. There have, however, been significant developments in the United States of America (USA) with regard to patient decision aid certification at both state and national levels over the last two years. The timing of these developments should enable more rapid progress toward national standards to ensure that decision aids are accurate and unbiased. The goal of this article is to describe how the National Quality Forum (NQF) has proposed that National Certification Standards be developed and adopted for patient decision aids in the USA. Thus, the level of interest is likely to remain high despite recent notices by CMS cancelling the two SDM experiments it had recently proposed.

**2. Why is there a need for certification?**

The content and design of these tools clearly influence the decisions that patients make. Poor quality or misleading tools are essentially a risk to patient safety and well-being. It is, therefore, important that strict attention is focused on the content because inaccurate or unbalanced presentations could lead to poor qual-

ity decisions. The task of identifying and summarizing evidence so that it is accessible to patients is a specialized skill and keeping the content up to date requires vigilance, expertise, and resources. Entities who might stand to benefit could influence the presentation of options. There is also a risk that some organizations and clinicians may be using patient education programs that fall short of meeting the definition of a decision aid. As payer requirements for these patient tools increase, there is a risk that sub-optimal tools could be called patient decision aids and marketed as such, or that existing patient resources might be adapted without paying attention to the standards that have been developed to ensure that patients are given evidence-based information and supported in constructing informed preferences. Such lower quality tools may not achieve the value-based care goals that have been demonstrated by high-quality tools in the literature. Fortunately, a significant body of work has been done on how to set standards for these tools.

**3. Benefits of a national certification process**

The lack of a clear set of criteria and standards will likely lead to confusion in healthcare organizations that are trying to understand how to adopt patient decision aids as part of a strategy to adopt shared decision making. A set of national standards should provide clarity on tools that are “good enough” to meet evolving requirements for the use of decision aids. A national certification process should make it easier for payers and purchasers to incentivize the use of patient decision aids in advanced payment programs. Though Washington State’s Health Care Authority (HCA) approval process [10] has been successful, it would be duplicative to replicate state-based assessments of decision aids. In a time of state budget tightening, few states will have the expertise and resources to set up their own certification processes. It would also be difficult and costly for developers of decision aids to develop tools to meet differing standards.

**4. Previous work to develop quality standards**

The first effort to set standards was completed in 2006 by IPDAS, a multi-stakeholder process that led to the production of a self-assessment checklist that developers could use to assess published tools, or tools in development [11]. Further work led to a measure IPDASi [12] and a set of criteria that should be met to achieve a ‘minimum’ acceptable standard [13]. Washington’s HCA used a modified subset of these criteria to develop and implement a patient decision aid certification process. Washington’s HCA began accepting applications for the certification of patient decision aids in April 2016 and, by January 2018, had certified 9 patient decision aids, listed on their website [10]. The HCA anticipates that the use of certified patient decision aids by providers and delivery systems, coupled with ties to reimbursement and increased liability protections for physicians who utilize the tools, as provided for in Washington State law, will improve quality by actively engaging patients in their care decisions, see [Table 1](#) for a timeline of key events.

**5. Developing a national certification process**

Given growing interest in shared decision making in health care, there is an opportunity to build on Washington HCA’s experience. The key to a successful implementation of patient decision aids is the development of national quality standards for decision aids and a certification process to ensure that selected decision aids are reliable and safe for patient use.

A national certification process could help the adoption of decision aids by the following mechanisms:

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