Published in final edited form as:

Health Aff (Millwood). 2007 ; 26(6): 1564–1574.

Extending The P4P Agenda, Part 1: How Medicare Can Improve Patient Decision Making And Reduce Unnecessary Care:

An agenda for Medicare to help drive improvements through pay-for-performance and shared decision making

John E. Wennberg,

(john.e.wennberg@dartmouth.edu) is the Peggy Y. Thomson Chair in the Evaluative Clinical Sciences at the Dartmouth Institute for Health Policy and Clinical Practice (formerly the Center for the Evaluative Clinical Sciences) and is a professor of medicine and of community and family medicine at Dartmouth Medical School in Hanover, New Hampshire

Annette M. O'Connor,

Professor in the School of Nursing and Department of Epidemiology and Community Medicine and a Tier 1 Canada Research Chair at the University of Ottawa, in Ontario, Canada. She is also a senior scientist at the Ottawa Health Research Institute

E. Dale Collins, and

Director of the Comprehensive Breast Program, Norris Cotton Cancer Center, at Dartmouth-Hitchcock Medical Center, and an associate professor of surgery at Dartmouth Medical School

James N. Weinstein

Professor and chair of orthopaedics, Dartmouth-Hitchcock Medical Center, Dartmouth Medical School, and the director of the new Dartmouth Institute for Health Policy and Clinical Practice

Abstract

The decision to undergo many discretionary medical treatments should be based on informed patient choice. Shared decision making is an effective strategy for achieving this goal. The Centers for Medicare and Medicaid Services (CMS) should extend its pay-for-performance (P4P) agenda to assure that all Americans have access to a certified shared decision-making process. This paper outlines a strategy to achieve informed patient choice as the standard of practice for preference-sensitive care.

Pay-for-performance initiatives often focus on the underuse of therapies that are widely viewed as medically essential, such as beta-blocker drugs following a heart attack.¹ In this paper we recommend that pay-for-performance (P4P) be expanded to focus on discretionary surgery that is sensitive to patients' preferences—that is, surgery where there is no single right or wrong treatment option, but where the key issue is whether one option or another is right for the patient. For example, among women with early-stage breast cancer, both mastectomy and lumpectomy followed by radiation yield similar mortality benefit. Many women have strong preferences for one or the other, so quality of care extends beyond the surgeon's technical skills to the decision-making process.

Decisions that involve values trade-offs between the benefits and harms of two or more clinically appropriate alternatives should depend on the individual patient's informed choice. But in everyday practice, patients typically delegate decision making to their physicians, leading to some decisions that are made without good information on the patient's true preferences. Shared decision making, augmented by patient decision aids (PtDAs), has been shown to be an effective means for achieving informed patient choice.² Considerable progress has been made in developing the infrastructure to support informed patient choice.³

This paper proposes a strategy to address three major barriers to the rapid adoption of informed patient choice as the standard of practice for “preference-sensitive” care. (1) The standard for review of medical necessity now used by the Centers for Medicare and Medicaid Services (CMS) and private health plans is based on the physician as the sole judge of medical necessity. (2) The economic incentives of traditional Medicare and most other payers reward providers for utilization, not for participating in clinical processes that ensure informed patient choice. (3) The scientific basis for making informed patient choice the standard of practice for the broad array of decisions where patients' preferences are important is underdeveloped, and we know little about how to predict demand for preference-sensitive treatments when shared decision making is employed.

We believe that Medicare should take the lead in addressing these barriers and accelerate the transition to informed patient choice as the standard of practice for preference-sensitive care. The CMS should assure that beneficiaries have access to (objectively measured) high-quality shared decision-making processes. Because of the implications for costs and the harms caused by operating on the wrong patient, the initial emphasis should be on conditions involving expensive, invasive, discretionary surgical procedures for which clinical trials have demonstrated the effectiveness of PtDAs in improving the quality of clinical decision making. Finally, the CMS should establish a research agenda to improve the scientific basis for informed patient choice.

The Nature Of The Problem

Traditionally, patients have delegated treatment decisions to their physicians: The physician determines medical necessity and diagnoses the patient's preference, and then the patient gives informed consent. Policymakers, in turn, have assumed that physicians' decisions reflect both medical need and patient demand. However, the remarkable degree of variation in the utilization rates of discretionary surgery raises questions about these assumptions. For example, among the 306 U.S. Hospital Referral Regions (HRRs) in 2002–03, the incidence of joint replacement for chronic arthritis of the hip and knee and of surgery for low-back pain varied 5.6-, 4.8-, and 5.9-fold, respectively, from the lowest to the highest region. The pattern of variation is remarkably stable over time, such that for most common procedures, variation among regions today is highly correlated with the pattern a decade ago. For example, among the 306 regions, surgery rates in 1992–93 and 2002–03 were $r = 0.89$, 0.86 , and 0.69 for hip, knee, and back surgery, respectively.⁴ Virtually every U.S. region, including those served by well-known academic medical centers, exhibits high rates of use for some surgical procedures and low rates for others. Assuming that most physicians are reasonably well informed about clinical guidelines and do not induce demand for self-serving reasons, such patterns of practice would be possible only if the number of clinically appropriate candidates for high-volume surgery in a region consistently exceeds the number operated upon.

There is growing evidence that the amount of surgery that can be justified on the basis of traditional practice guidelines actually exceeds the amount of surgery that patients want when fully informed. Several clinical studies have shown that some patients who meet professionally defined guidelines for appropriateness for surgery (based on symptoms and physiologic or pathologic deviance from a norm) do not want the procedure being recommended once they have been well informed about treatment options. In a population-based study conducted in two staff-model health maintenance organizations (HMOs), only 20 percent of patients with severe symptoms of prostatism chose surgery.⁵ In a recent population-based study to quantify the need for surgery for arthritis of the knee, only 15 percent of those with symptoms and x-ray evidence of degenerative changes indicating surgery actually wanted it after being fully informed.⁶ A number of clinical trials testing the effectiveness of decision aids have been conducted among patients considered by clinicians to be clinically appropriate candidates.

(Some trials were among patients on waiting lists for surgery.) A recent Cochrane review identified trials of seven conditions commonly treated surgically among the Medicare population: arthritis of the hip and knee; low-back pain from a herniated disc; chest pain (stable angina); enlarged prostate (benign prostatic hypertrophy, or BPH); and early-stage prostate and breast cancer.⁷ The review documented that although the uptake of surgery following shared decision making (compared to control groups) varied from study to study, a 21–44 percent decline was typical. Patients in shared decision-making arms of the trials were better informed about treatment options and made choices more consistent with their values.⁸

On the basis of such evidence, the CMS should take steps to ensure that Medicare beneficiaries facing discretionary surgery have access to high-quality shared decision making. The goal should be to establish the informed patient as the arbiter of medical necessity for clinically appropriate medical options and ensure that the rates for discretionary surgery reflect demand based on patient preferences.

Although the argument for informed patient choice is based on ethical principles of patient autonomy, the clinical trial data suggest that implementing high-quality shared decision making could also result in Medicare savings via a drop in utilization. The impact on the overall use and cost of medical care, however, needs to be measured over the longer term, with careful monitoring of outcomes. As the patient's condition worsens, as is typically the case for arthritis of the hip and knee, patient preference may change. On the other hand, as patients age, particularly those in the Medicare population, other medical problems may become more pressing. As we recommend below, long-term follow-up of patients who participate in shared decision making should be a research priority. Moreover, the unique challenges of implementing shared decision making in Medicare should be assessed and addressed as part of a pilot program.

We next discuss the components of a high-quality shared decision-making process, outlining our recommendations for attaining informed patient choice as the standard of practice and establishing a research agenda to accelerate progress.

Components Of High-Quality Shared Decision Making

Implementation of shared decision making should be evaluated according to (1) the quality of the decision aids that are provided; (2) the training and proficiency of those who deliver decision support; (3) use of (validated) patient decision quality measures (properly implemented) to monitor performance, improve process quality, and score performance for public accountability; and (4) success in implementing clinical pathways to ensure high-quality shared decision making.⁹

Patient decision aids

Standards for identifying and certifying high-quality PtDAs are essential. Fortunately, the International Patient Decision Aids Collaboration has reached a consensus on the standards for development and evaluation.¹⁰ This consortium of more than 100 researchers, practitioners, patients, and policymakers from fourteen countries has rated quality criteria in the following domains: information, risk communication, values clarification, balanced guidance in deliberation, systematic development, evidence base, disclosure of sources of support and conflicts of interest, and evidence of positive effects on decision quality. Exhibit 1 lists the quality criteria rated by the collaboration as the most important in judging the quality of a patient decision aid. The Ottawa Health Decision Center at the University of Ottawa, Ontario, has demonstrated the feasibility of using the collaboration's criteria to rate more than 200 PtDAs.

Trained health professionals

Health professionals need to be trained in shared decision making and the use of PtDAs. The Ottawa Health Research Institute (OHRI) has evaluated training strategies that include autotutorial and skill-building workshops in decision support and the use of PtDAs; structured decision support protocols; and performance feedback with real or simulated patients.¹¹ These training programs have been adapted for use in primary care settings, nurse call centers, academic medical centers, and the National Health Service Urology Program in the United Kingdom.

Performance monitoring

Decision quality refers to the extent to which patients arrive at choices that are both informed and based on individual preference.¹² For accountability as well as good patient care, monitoring the quality of the decision process is essential. The Foundation for Informed Medical Decision Making is supporting the development of instruments to measure decision quality across multiple clinical decisions. They focus on assessing how well patients understand the key facts about treatment options and how consistent their choices are with their reported preferences for outcomes.

Delivery of shared decision making

A key requirement is that the shared decision-making process be integrated into everyday practice, embedded into well-defined clinical pathways to ensure that all eligible patients are given the opportunity to participate. Typically, the care pathway and the associated delivery of decision support involve some combination of clinical consultation and counseling, and PtDAs and coaching, all taking place at the “right moment.”¹³ However, the sequence, combination, and professionals involved will depend on the type of decision, patient population, and service context in which care is provided. For purposes of reporting on performance as well as caring for patients, shared decision making must be supported by information technology (IT) systems capable of managing both clinical information and information obtained directly from patients. Models for shared decision making are currently being evaluated in the United States, the United Kingdom, and Canada.¹⁴

Informed Patient Choice As The National Standard

Here we lay out a strategy for changing the standard of practice so that the definition of *medical necessity* for preference-sensitive treatments is made not solely by the physician or payer, but rather through informed patient choice. Although the content of the benefit package would still be determined by the payer, and clinical appropriateness would be defined by medical experts, medical necessity would be based on the patient's preference, established through high-quality shared decision making. The goal is to achieve this standard of practice throughout the United States, focusing first on conditions involving discretionary surgery and other costly interventions for which evaluated PtDAs are available.

A pilot program

The implementation of shared decision making within CMS populations should be pilot-tested to identify and address barriers and unintended consequences, and to build the infrastructure required for broad implementation. We envision a three-year grant-in-aid program for provider organizations that agree to implement high-quality shared decision making on a demonstration basis to develop templates for national diffusion. The grants-in-aid would support the design and evaluation of models for decision support in primary care and specialty practices, large group practices, solo practice, and hospitals, as well as community-based settings. The CMS would also analyze the costs associated with supporting shared decision making (so that

providers can be compensated fairly) and develop P4P models with providers to reward the delivery of high-quality care.

The certification of PtDAs and health care organizations is an important feature in our proposal. Efforts to certify PtDAs are already under way. The Washington State legislature recently passed a bill (ESSB 5930) that provides a higher standard of immunity for providers who use PtDAs from litigation based on failure to inform; it has called for a national accrediting agency to implement a certification process.¹⁵ The standards developed by the International Patient Decision Aids Collaboration should facilitate this process. An important additional task is developing a process for certifying providers. During the pilot phase, the CMS would work with participating providers and accrediting agencies to ensure that a certified provider has the key components for supporting high-quality shared decision making, including public reporting of results.

Changing the standard for medical necessity

In the fourth year, the CMS would initiate a P4P demonstration to support a national effort to change the standard for defining *medical necessity*. Hospitals (and ambulatory surgery centers) would be encouraged to voluntarily implement certified shared decision making and participate in the CMS's P4P program. All U.S. hospitals (and surgery centers) would be eligible to participate, as would solo, small, and group practices capable of supporting shared decision making.

First, all participating hospitals would be compensated for establishing and maintaining a certified shared decision-making process that adapts into their local environment the clinical pathways developed in the pilot program. The goals are to ensure that all patients that meet clinical appropriateness for surgery or other high-cost treatments have the opportunity to participate in shared decision making; that patient decision-quality measures are incorporated into medical records and made available to the patient and relevant caregivers in the decision process; and that information on decision quality is aggregated for public reporting of decision-quality scores at appropriate intervals. Hospitals would be compensated fairly for maintaining the shared decision-making process according to cost estimates obtained by pilot research.

Second, participating hospitals with (audited) high-quality patient decision scores would be given a bonus over estimated real costs according to a formula established by the CMS. The amount should be determined by the extent to which (compared to other participating hospitals) a hospital achieves high-quality shared decision making as measured by scores on decision-quality instruments and success in enrolling eligible patients into the decision-making process.¹⁶

National standard

Ultimately, the CMS would ensure that all Medicare patients have access to shared decision making. Providers would be paid a fair price for offering it, and high performance on decision-quality measures would be rewarded. However, providers that fail to comply with the new standard for defining *medical necessity* for preference-sensitive, costly, invasive treatments would no longer be reimbursed for performing those treatments. Compliance would be defined by the presence of a certified shared decision-making process and satisfactory scores on (audited) decision-quality measures. We suggest a target date for these requirements of five years after the P4P demonstration begins.

Programmatic Research Agenda For Clinical Appropriateness And Shared Decision Making

The transition from delegated decision making to informed patient choice requires a shift in federal research priorities. Patients and providers need up-to-date information on the risks and benefits of treatment options and the importance of patients' preferences in guiding choice. Experts responsible for defining which treatments are clinically appropriate for inclusion in Medicare need better information on effectiveness of care, while policymakers need to better understand and predict demand for costly preference-sensitive treatments.

Here we identify four priority research areas for the national program, which should begin as soon as possible and continue indefinitely.

Ongoing, up-to-date assessment of treatment options

Rational decision making requires an accurate assessment of outcomes that matter to patients. Such research is essential for defining *clinical appropriateness*, for making coverage decisions, for constructing and updating PtDAs and modifying decision quality measures, and, foremost, for promoting a dynamic health care economy that values progress. Today such research is pursued only haphazardly. An organized research agenda is needed for the continuous evaluation of the clinical theories and supporting evidence that justify interventions offered.

Fundamental research in patient decision making

Shared decision making should be based on advanced understanding of the psychology of patient decision making and the underlying mechanisms of the effects of PtDAs.¹⁷

Practical tools for decision support

Although fundamental research will make an important contribution, the research agenda should also focus on advancing the art and science for constructing PtDAs, decision-quality measures, and other tools. The research would compare, for example, alternative designs for decision aids (written, video, and interactive Internet applications); the use of nurse coaches; and the effects of ethnicity, educational attainment, age, mental health status, and diagnosis on the patient's role in informed choice. It would also focus on developing and advancing criteria for PtDA certification to keep the certification process current with the design of decision-support tools.

Studies of patient demand for preference-sensitive care

Understanding the implications of the shift in decision making from delegated to informed patient choice on the health care economy should be included in the research agenda. The first priority should be to understand and predict demand for preference-sensitive treatments under informed patient choice. The study of osteoarthritis of the knee described above distinguishes clearly between clinically appropriate need (defined by medical experts) and preference-defined need (defined by patients). Similar studies are needed for other conditions. The second priority is to understand the effects of copayment and other forms of patient cost sharing on patients' preferences.

Discussion

This paper calls on the CMS to take the lead in promoting the transition to a new standard of practice for defining *medical necessity* for many discretionary treatments based on informed patient choice. Here we discuss the limitations of our proposal and some concerns that need to be addressed.

A large-scale national roll-out will not succeed without careful attention to barriers or facilitators that could affect implementation and sustainability.¹⁸ In a recent systematic review among health professionals, the most commonly perceived barriers to implementing shared decision making were lack of applicability because of patient characteristics; time constraints; lack of applicability because of the clinical situation (for example, emergencies); and the belief that patients would rather leave decisions up to their physicians. Factors that facilitated implementation were the perception that shared decision making will improve clinical processes and patient outcomes; patients' preferences for decision-making roles that fit the informed-patient-choice model; the motivation of health professionals; the perception that the approach is useful/practical; and the characteristics of the patient.¹⁹ Concerns such as these would presumably be addressed (and practical solutions would evolve) during the pilot phase.

Political feasibility

Major questions remain about political feasibility. Support from the medical profession as well as key legislators will be critical.²⁰ A central task will be to mobilize professional support. Shared decision making fits well with the American College of Physicians' concept of the Advanced Medical Home.²¹ Several academic medical centers and large group practices are already implementing shared decision making. During the pilot phase, it will be important to broaden support among academic medical centers, and we recommend that the CMS recruit others to participate.

The feasibility of our proposal would be greatly increased if private insurers, employers, and business coalitions were to unite in encouraging Congress to ensure that the CMS takes the lead. Employers and private-sector payers are rapidly developing policies to encourage patients to participate actively in health care decisions, foremost through changes in health insurance benefit packages such as health savings accounts (HSAs) and increased cost sharing. They have a large stake in the movement to establish informed patient choice as the standard of practice, and they should welcome a national strategy that gives patients access to certified shared decision-making processes, particularly if the conditions were expanded to include common, costly procedures affecting the nonelderly population. Support will also be needed from patient advocacy groups and patients themselves, who have the most at stake.

Additional limitations

Our proposal has additional limitations. Its focus on conditions with invasive treatment options is admittedly a limited one. A number of other treatment choices should be based on informed patient choice (for example, prostate-specific antigen, or PSA, and other screening tests). However, the principles as well as the infrastructure for making the transition to a new standard for defining *medical necessity* are best illustrated by conditions involving discretionary surgery. Moreover, since these must be performed in a hospital or surgery center, the provider who should be accountable for participating in the process is obvious. Further, if shared decision making can be implemented for these high-profile decisions, extension of the new standard for decision making should be easier for other conditions, and decision aids for those would presumably be introduced during the implementation phase.

Call for research

We also recognize the inherent difficulties in establishing “true” preference, and we call for fundamental research to develop our understanding of the psychology of patient decision making. The research should include a concentrated effort to understand issues affecting the use of procedures by minority groups. Possible reasons for the low use of surgery by African American males range from their distrust of the health care system to providers' failure to offer surgery to patients that could benefit from it. The contribution of such factors needs to be taken into account in designing decision aids and building the clinical pathways to make sure that

all patients who meet clinical guidelines are offered the range of clinically appropriate treatment options.

More details needed

At this stage in its development, our proposal is necessarily sketchy. It is the task of the pilot project to develop the template for the national program, including details regarding clinical pathways, procedures for certifying shared decision-making processes, the implementation of new payment methods, the development of P4P models to reward providers who achieve high-quality shared decision making, and strategies for overcoming barriers to implementation. The programmatic research and development plan is only an outline. Details concerning the budgets and organizational relationships and methodologies for launching the scientific endeavor need to be worked out. Our goal has been to lay out what we hope is a coherent strategy for coming to terms with the problem of unwarranted variation and to set up a framework for considering next steps.

In this paper we have outlined a strategy for the CMS to take the lead in establishing informed patient choice as the standard for determining medical necessity for clinically appropriate, preference-sensitive care. We suggest that the CMS focus first on expensive, invasive treatments. Health services research has built the body of knowledge that provides the foundation for this reform. The implications for the health care economy seem to be favorable: Informed patients appear to demand less surgery than the amount now being performed. But above all, it is the ethically right thing to do: Paternalism is reduced, autonomy is enhanced, and the risk for a serious medical error occasioned by providing an unwanted therapy is greatly diminished.

Acknowledgements

Annette O'Connor and E. Dale Collins receive research funds from the Foundation for Informed Medical Decision Making (FIMDM). The FIMDM, a nonprofit, has a licensing agreement with Health Dialog, a commercial company that promotes the use of patient decision aids. John Wennberg is a consultant for the FIMDM and has a financial interest in Health Dialog. This research is also funded by the National Institute on Aging (Grant no. 2 P01 AG019783). The authors thank Shannon Brownlee and Martha M. Smith for editorial assistance.

NOTES

1. Wennberg JE, Fisher ES, Skinner JS. Geography and the Debate over Medicare Reform. *Health Affairs* 2002;21:w96–w114. [PubMed: 12703563] published online 13 February 2002; 10.1377/hlthaff.w2.96
2. O'Connor AM, et al. Decision Aids for People Facing Health Treatment or Screening Decisions. *Cochrane Database of Systematic Reviews* 2003;(no 2):CD001431.
3. O'Connor AM, et al. Toward the Tipping Point: Decision Aids and Informed Patient Choice. *Health Affairs* 2007;26(no 3):716–725. [PubMed: 17485749]
4. Weinstein JN, et al. Trends and Geographic Variations in Major Surgery for Degenerative Diseases of the Hip, Knee, and Spine. *Health Affairs* 2004;23:VAR-81–VAR-89. [PubMed: 15471768] published online 7 October 2004; 10.1377/hlthaff.var.81
5. Wagner EH, et al. The Effect of a Shared Decisionmaking Program on Rates of Surgery for Benign Prostatic Hyperplasia: Pilot Results. *Medical Care* 1995;33(no 8):765–770. [PubMed: 7543638]
6. Hawker GA, et al. Determining the Need for Hip and Knee Arthroplasty: The Role of Clinical Severity and Patients' Preferences. *Medical Care* 2001;39(no 3):206–216. [PubMed: 11242316]
7. The SPORT studies demonstrate the importance of patient preference in determining the need for surgery for low-back pain. See, for example, Weinstein JN, et al. Surgical versus Nonoperative Treatment for Lumbar Disc Herniation: The Spine Patient Outcomes Research Trial (SPORT) Observational Cohort. *Journal of the American Medical Association* 2006;296(no 20):2451–2459. [PubMed: 17119141]
8. O'Connor, et al. Decision Aids.
9. O'Connor, et al. Toward the Tipping Point.

10. Elwyn G, et al. Developing a Quality Criteria Framework for Patient Decision Aids: Online International Delphi Consensus Process. *British Medical Journal* 2006;333(no 7565):417. [PubMed: 16908462]
11. Légaré, F. Doctoral dissertation. University of Ottawa; 2005. Implementation of the Ottawa Decision Support Framework in Five Family Practice Teaching Units: An Exploratory Trial.
12. Sepucha KR, Fowler FJ Jr, Mulley AG Jr. Policy Support for Patient-Centered Care: The Need for Measurable Improvements in Decision Quality. *Health Affairs* 2004;23:VAR-54–VAR-62. [PubMed: 15471772]published online 7 October 2004; hlthaff.var.54
13. O'Connor, et al. Toward the Tipping Point.
14. The breast cancer program at Dartmouth-Hitchcock Medical Center has integrated the components of decision support. Readers may access a virtual tour of the shared decision-making program at <http://www.hitchcock.org/dept/csdm> (accessed 23 July 2007).
15. For more information on Engrossed Second Substitute Senate Bill (ESSB) 5930, chap. 259, Laws of 2007, see RedOrbit NewsWashington Becomes First State to Endorse Shared Medical Decision Making. Press Release, 2 May 2007, <http://www.redorbit.com/news/display/?id=92240411> September 2007; and Washington State LegislatureSB 5930—2007–08. <http://apps.leg.wa.gov/billinfo/summary.aspx?bill=5930&year=200711> September 2007
16. The bonus could be designed to compensate hospitals for loss of revenue resulting from a drop in surgery.
17. Holmes-Rovner M, et al. Are Decision Aids the Best Way to Improve the Quality of Clinical Decision-Making? *Medical Decision Making* (forthcoming).
18. National Health Service, Institute for Innovation and Improvement. NHS Sustainability Model and Guide. [15 August 2007]. http://www.institute.nhs.uk/option.com_joomcart/Itemid,26/main_page,document_product_info/products_id,291.html
19. Gravel K, Légaré F, Graham ID. Barriers and Facilitators to Implementing Shared Decision-Making in Clinical Practice: A Systematic Review of Health Professionals' Perceptions. *Implementation Science* 2006;1(no 6):16–30. [PubMed: 16899124]
20. W. Hugh Maloney, president, Washington State Medical Association, testimony before the Washington State Senate Committee on Health and Long-Term Care, 2 February 2007.
21. American College of Physicians. The Advanced Medical Home: A Patient Centered, Physician-Guided Model of Health Care. Policy Monograph. 2006 [15 August 2007]. http://www.acponline.org/hpp/adv_med.pdf

EXHIBIT 1**Patient Decision Aid (PtDA) Quality Checklist For Treatment Decisions From The International Patient Decision Aids Collaboration**

-
1. Provide information about options in sufficient detail for decision making?
 - Does the PtDA describe
 - The health condition
 - The natural course without options
 - The decision
 - The options
 - Procedures involved with each option
 - Positive and negative features of options
 - Chances of positive/negative outcomes
 2. Present probabilities of outcomes in an unbiased and understandable way?
 - Use event rates specifying the population and time period
 - Compare outcome probabilities using the same denominator, time period, and scale
 3. Include methods for clarifying and expressing patients' values?
 - Ask patients to consider which positive and negative features matter most
 4. Provide balanced and clear guidance in deliberation?
 - Able to compare positive/negative features of options
 - Show negative/positive features with equal detail (fonts, order, statistics display)
 - Report readability levels
 5. Have a systematic development process?
 - Find out what patients need to discuss options
 - Is reviewed by patients who have faced the decision previously
 - Field tests with patients facing the decision show that the patient decision aid is: (a) acceptable; and (b) balanced for undecided patients
 6. Use up-to-date scientific evidence that is cited in a reference section or technical document?
 - Provides references to evidence used
 - Report date of last update
 7. Disclose conflicts of interest?
 - Report whether authors or their affiliations stand to gain or lose by choices patients make after using the patient decision aid
 8. Ensure decision making is informed and values based?
 - There is evidence that the PtDA
 - Helps patients to know options and their features
 - Improves the match between the chosen option and the features that matter most to the informed patient
-

SOURCE: Adapted from International Patient Decision Aids (IPDAS) Collaboration, "IPDAS 2005: Criteria for Judging the Quality of Patient Decision Aids," Table 3, http://ipdas.ohri.ca/IPDAS_checklist.pdf (accessed 10 September 2007).

NOTE: Items shown here were rated as "very important" quality criteria (median rating 9/9).