

Extending the Pay-for-Performance Agenda: Part One

**How Medicare Can Improve the Quality of
Patient Decision Making and
Reduce Unnecessary Care**

A Synopsis

John E. Wennberg, MD, MPH

Annette M. O'Connor, PhD

E. Dale Collins, MD, MS

James N. Weinstein, DO, MS

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Patients who are offered discretionary surgery face a welter of information and choices. Is surgery more effective than non-surgical treatments? Will having surgery sooner produce a better outcome than watchful waiting? Is one surgical technique safer or more effective than another? The answers to such questions should depend not only on the availability of valid clinical science, but also on the values and preferences of individual patients.

Yet all too often, patients are not given the information they need—in a way they can absorb—nor are they encouraged to make a truly informed choice. Personal values as well as a patient’s perception of competing risks and benefits must be part of a fully informed decision. For a woman with early-stage breast cancer, for instance, the decision to undergo mastectomy versus lumpectomy with radiation, treatments with similar long-term outcomes, should depend on how much she cares about preserving her breast versus how much she values not having to undergo continued surveillance should she choose lumpectomy. In routine practice, however, vital information about what is at stake often fails to be conveyed and a patient’s decision to undergo discretionary surgery is often unduly influenced by physician opinion, leading in some cases to interventions that the patient would not have wanted, had he or she been fully informed about the options.

Shared decision making, augmented with patient decision aids, has been shown to be an effective means for achieving informed patient choice; and considerable progress has been made in developing the infrastructure to support informed patient choice.ⁱⁱ Widespread adoption of shared decision making and patient decision aids would improve the quality of health care and probably cut costs. However, significant barriers to their rapid adoption as the standard of practice remain.

We propose an eight-year, phased-in program to foster the adoption of informed patient choice as a standard of care. This program would have the Centers for Medicare and Medicaid Services (CMS) extend its pay-for-performance agenda to assure that all Americans have access to a certified shared decision making process for common conditions involving “preference-sensitive care,” or care where there is no single right or wrong treatment option, but where the key issue is whether the treatment is right

for the individual patient. We recommend focusing on ten conditions that together account for 40 percent of Medicare spending for inpatient surgery. If implementing shared decision making results in reductions in the rate of discretionary surgery of at least 20 percent (as clinical trials suggest it might), Medicare would save \$3.5 billion annually in 2006 dollars.

The nature of the problem

Per capita rates of many surgical procedures vary widely in different parts of the country. The rate of knee replacement for arthritis, for example, varied nearly five-fold between regions with the highest and lowest rates in 2002-2003. The incidence of surgery for low back pain varied nearly six-fold. There's no evidence that this variation is due to underlying differences in rates of illness in the population. Rather, it reflects the "surgical signature" of different regions, or variations in practice patterns among different groups of specialists.

The patterns of variation are such that virtually every region of the country, including some served by well-known academic medical centers with strong national reputations for excellence, exhibits high rates of use for some procedures. Surprisingly enough, the variation in surgery rates among regions is not closely associated with the supply of surgeons qualified to perform the surgery. And the pattern of variation is remarkably stable over long periods of time, such that for most common procedures, the variation among regions seen today is highly correlated with the variation seen a decade ago.

The wide differences in surgical signatures, the stability of that variation over time, and evidence from clinical trials all point to the same conclusion: the amount of surgery that can be justified on the basis of traditional practice guidelines exceeds the amount of surgery that patients might actually want, if they were fully informed of the risks and benefits of their different treatment options. Research has shown that many patients who meet clinical guidelines for appropriateness for surgery do not, in fact, want the procedure when they are able to choose among treatment options in an environment that supports shared decision making. Among patients with severe symptoms of an enlarge prostate, less than 1 patient out of 4 choose surgery, once they were informed about the negative impact of surgery on sexual function. In a recent population-based study designed to quantify the need for surgery for arthritis of the knee, only 16% of those with symptoms

and x-ray evidence of degenerative changes warranting surgery actually wanted the surgery when informed about their options.ⁱⁱⁱ In clinical trials, the rate of decline in uptake of discretionary procedures following shared decision making (compared to control groups) varies from study to study, but a 21-44% drop is typical.^{iv}

There are many reasons why the amount of care that physicians can justify on the basis of practice guidelines may be more than the amount patients want. For some surgeries, there is little valid evidence for outcomes, leaving patients and physicians to base treatment decisions not on solid evidence but on “usual practices” or local standards of care. (Spinal fusion for low back pain is an example.) Even when there is valid evidence for the outcomes of various treatments, as is the case for mastectomy versus lumpectomy, not all patients will place the same value on the tradeoffs between the various risks and benefits. Finally, current reimbursement schemes reward physicians for utilization, not for participating in clinical processes that assure informed patient choice, and their insured patients rarely pay more out of pocket for procedures that cost more than other clinically appropriate alternatives.

The case for reducing variation

Increasing the availability of patient decision aids and fostering shared decision making will improve the quality of care, since operating on a patient who would otherwise not choose surgery represents a form of medical error. Shared decision making may also bring down costs. Fully 40 percent of Medicare reimbursements for inpatient surgery go toward ten discretionary procedures that are preference-sensitive and whose surgical signature varies widely in different regions.

We believe that Medicare should exercise decisive leadership to accelerate the transition to informed patient choice as the standard of practice for preference-sensitive care. The agency should assure that all Medicare enrollees have access to (objectively measured) high quality shared decision making within a decade. Because of the implications for costs, and the harms caused by operating on the wrong patient, the CMS should concentrate first on promoting informed patient choice for conditions involving expensive, invasive discretionary surgical procedures and reducing overuse of those procedures. Finally, the CMS should establish a directed (and budget-neutral) research program to improve the scientific

basis for achieving informed patient choice. The goal is to achieve this standard of practice throughout the United States within eight years for the ten priority conditions involving discretionary surgery.¹

Proposal

The goal is to establish the informed patient as the arbiter of medical necessity for clinically appropriate medical options and, as a consequence, assure that the rates for discretionary surgery reflect demand based on patient preferences. Implementing high quality shared decision making will depend upon: (1) the quality of the decision aids that are provided; (2) the training and proficiency of the health professionals who deliver decision support; (3) the use of (validated) patient decision quality instruments to monitor performance, improve process quality, and score performance for public accountability purposes; and (4) the development of protocols for integrating shared decision making into clinical practice.

1) High Quality Patient Decision Aids Standards for identifying and certifying high quality decision aids are essential. The International Patient Decision Aids Collaboration² has reached a consensus on standards for development and evaluation of decision aids.² The Ottawa Health Decision Center, at the University of Ottawa, Canada, has demonstrated the feasibility of using the Collaboration's criteria to rate over 200 patient decision aids.

2) Trained Health Professionals Health professionals need to be trained in shared decision making and the use of patient decision aids. The Ottawa Health Research Institute³ has evaluated training strategies such as auto-tutorial and skill-building workshops; structured decision support protocols; and performance feedback with real or simulated patients. These training programs have been successfully adapted for use in primary care, nurse call centers, and health care centers.

¹ These conditions include gallstones; angina; osteoarthritis of the knee and hip; claudication, or exertional leg pain; carotid stenosis; early stage prostate cancer; benign prostate hyperplasia; and early-stage breast cancer.

² This consortium of over 100 researchers, practitioners, patients and policy makers from 14 countries have rated patient decision aids for such qualities as information content; risk communication; values clarification; and evidence for positive effects on decision quality.

3) Performance Monitoring of Decision Quality Decision quality refers to the extent to which patients arrive at choices that are informed and preference-based.vii The Foundation for Informed Medical Decision Making is supporting the development of instruments to measure decision quality. The instruments focus on assessing the extent of the patient’s understanding of the key facts about the decision, and the extent to which their choices are consistent with their reported preferences. They measure the outcomes of the shared decision making process and are useful for clinical process improvement as well as for public reporting that evaluates how well providers are proceeding in establishing informed patient choice as a standard of practice.

4) Integrating Shared Decision Making The goal of this plan is to make shared decision making an integral part of everyday practice, beginning at the primary care level. Ideally, shared decision making involves some combination of clinical consultation and counseling, along with patient decision aids and coaching, all of which take place at the “right moment” in the progression of a patient toward a treatment choice.viii For the purposes of reporting on performance as well as managing individual patients, this process must be supported by IT systems capable of managing data obtained directly from patients as well as traditional clinical information that comes from providers. Delivery models are currently being evaluated in the U.S., U.K., and Canada.

Strategy for Change

While the content of benefit packages would still be determined by payers, and clinical appropriateness would still be defined by medical experts, medical necessity would be determined by informed patients who have participated in a high quality shared decision making process. The goal is to make informed patient choice the standard of practice throughout the United States within eight years for the ten priority conditions involving discretionary surgery (and not just for Medicare beneficiaries, but for all patients). Changing the standard for defining medical necessity for preference-sensitive treatments to informed patient choice requires a multi-stage approach, with Medicare leading the way.

During the first three years, the CMS would offer grants-in-aid to provider organizations that agree to implement high-quality shared decision making

on a demonstration basis. The grants-in-aid would support the design and evaluation of clinical practice protocols for delivering decision support in various care settings, including primary care, specialty care, large group practices, solo practice, community-based settings, hospitals, and ambulatory surgery centers. The CMS would also support the analysis of costs of implementing shared decision making so providers can be compensated fairly, and pay-for-performance models can be developed to reward providers that implement high-quality shared decision making.

An important additional task is to develop a process for certifying the shared decision making programs of hospitals and ambulatory surgery centers. During this pilot phase, the CMS would work with participating providers and accrediting agencies to assure that a certified provider has in place the key components for supporting shared decision making, included public reporting of results.

Changing the Standard for Medical Necessity

Beginning with the fourth year, the CMS would initiate a five-year program to support a national effort to change the standard for defining medical necessity. On a voluntary basis, hospitals and ambulatory surgery centers would be encouraged to participate in a pay-for-performance program to implement shared decision making.³ All U.S. hospitals that provide discretionary surgery for one or more of the ten conditions would be eligible to participate in a program that would:

- 1) compensate hospitals for establishing and maintaining a certified shared decision making process. The goal is to ensure that all patients who are deemed clinically appropriate candidates for discretionary surgery have the opportunity to participate in a shared decision making process; that patient decision quality measures are incorporated into medical records; and that information on decision quality is aggregated for public reporting.

- 2) give participating hospitals with (audited) high quality patient decision scores a bonus over estimated real costs, according to a formula established by the CMS (based on research conducted during the initial

³ If shared decision making does not result in the anticipated drop in discretionary surgery, the CMS could implement a cost-sharing plan so that patients who chose expensive surgical options would bear some of the cost.

three years of the program). The bonus could be designed in part to compensate participating hospitals for loss of revenue due to the anticipated drop in demand for surgery. Hospitals with high quality patient decision scores that experience a drop in aggregate demand for surgery could thus be identified as eligible to share in the savings. A bonus would also be given to differentially reward hospitals that achieve high quality status according to publicly reported decision outcomes.

At the end of eight years, Medicare would take the final steps to assure that all Medicare patients would have access to shared decision making: it would no longer reimburse hospitals for discretionary surgery if they fail to comply with the new standard for defining medical necessity for the ten conditions. Compliance would be defined by presence of a certified shared decision making process and satisfactory scores on (audited) decision quality measures.

Research Agenda for Clinical Appropriateness and Shared Decision Making

The transition to informed patient choice requires a shift in research priorities toward improving the scientific basis for clinical decision making. We identify four high priority areas for a national research program:

Ongoing, up-to-date assessment of treatment options Both providers and patients need to know what works, what doesn't, and for which patients. Such information is essential for defining clinical appropriateness, for making coverage decisions, for constructing and updating decision aids, and for promoting a dynamic health care economy that values progress. Recent clinical studies challenging the conventional wisdom concerning the value of surgery for low back pain and angioplasty with stenting for stable angina (chest pain) underscore the importance of an ongoing research agenda to systematically evaluate new as well as established treatments.ix

Research in Patient Decision Making The transition to informed patient choice should be based on a deep understanding of the psychology of patient decision making and the underlying mechanisms of patient decision aids.x

Practical Tools for Decision Support In addition to basic research on how patients make decisions, we need research that will advance the practical application of decision aids. Such research would focus, for

example, on alternative designs for decision aids—written, video, interactive internet applications; the use of nurse coaches; the effects of ethnicity, educational attainment, age, mental health status and diagnosis, and other important factors that relate to the patient’s role in informed patient choice.

Studies of Patient Demand for Preference-Sensitive Care The shift from delegated decision making to shared decision making will upset the current disequilibrium between supply and utilization, creating a new economy in which demand is based on informed patient choice. Anticipating the implications of the resulting shift should be a major research priority. Studies cited above suggest that implementing shared decision making will lessen demand, but such studies need to be systematically replicated in other geographic regions and for other conditions. It is also important to understand the effects of co-payment and other forms of patient cost-sharing on patient preferences for the more expensive treatment option.⁴

Conclusion

Support for our proposal can be found in existing legislation: provisions under Section 646 of the Medicare Modernization Act of 2003 identify unwarranted variation in preference-sensitive treatments as a priority for reform, and shared decision making as a strategy for achieving this goal. To encourage implementation, Section 646 calls for new pay-for-performance models. It also identifies the importance of reducing scientific uncertainty and calls for investment in research and development by the National Institutes of Health and the Agency of Healthcare Research and Quality.

What has been missing from the 646 program is a budget-neutral way of paying for the needed research. In this proposal, budget neutrality is addressed in two ways. First, available evidence from clinical trials predicts a reduction in demand under shared decision making. Second, if this proves

⁴ This research will be essential if an unforeseen increase in patient demand requires policy makers to initiate patient cost-sharing as a factor influencing patient preference for high cost, invasive treatments.

incorrect—if demand under the new strategy exceeds the amount Medicare is willing to pay—differential prices based on comparative cost of alternative treatments could be introduced to influence patient choice.

There are many other conditions beyond the ten identified here whose treatment should be based on informed patient choice. By making the transition to a new standard for defining medical necessity for these ten conditions, and holding providers accountable for implementing shared decision making, Medicare can forge a new model for care. Health services research has built the body of knowledge that provides the basis 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 delivered. Implementing informed patient choice is also the right thing to do. It reduces paternalism, enhances patient autonomy, and diminishes the risk for serious medical error occasioned by providing an unwanted treatment.

ⁱ A.M. O'Connor, et al., "Decision Aids for People Facing Health Treatment or Screening Decisions." *Cochrane Database Syst Rev*, no. 2 (2003): CD001431.

ⁱⁱ A.M. O'Connor, et al., "Toward the Tipping Point: Decision Aids and Informed Patient Choice." *Health Affairs* 26, no. 3 (2007).

ⁱⁱⁱ G. A. Hawker et al., "Determining the Need for Hip and Knee Arthroplasty: The Role of Clinical Severity and Patients' Preferences," *Medical Care* 39 (March 2001): 206–16.

^{iv} A. M. O'Connor et al., "Decision Aids for People Facing Health Treatment or Screening Decisions", *Cochrane Database Syst Rev*, no. 2 (2003): CD001431.

^v G. Elwyn, et al., "Developing a Quality Criteria Framework for Patient Decision Aids: Online International Delphi Consensus Process." *British Medical Journal* 333, no. 7565 (2006): 417.

^{vi} D. Stacey, et al., "Barriers and Facilitators Influencing Call Center Nurses' Decision Support for Callers Facing Values-Sensitive Decisions: A Mixed Methods Study." *Worldviews Evidence Based Nursing* 2, no. 4 (2005): 184-95.

F. Légarè, "Implementation of the Ottawa Decision Support Framework in Five Family Practice Teaching Units: An Exploratory Trial" (Doctoral dissertation, University of Ottawa, 2005).

^{vii} K.R. Sepucha, F.J. Fowler Jr., and A.G. Mulley Jr., "Policy Support for Patient-Centered Care: The Need for Measurable Improvements in Decision Quality," *Health Affairs*, 7 October 2004, [content.healthaffairs.org/cgi/content/abstract/hlthaff.var. 54](http://content.healthaffairs.org/cgi/content/abstract/hlthaff.var.54) (1 November 2006).

^{viii} A.M. O'Connor, et al., "Toward the Tipping Point: Decision Aids and Informed Patient Choice." *Health Affairs* 26, no. 3 (2007).

J.N. Weinstein, et al., "Informed Patient Choice: Assessment of Risk/Benefit Trade-offs for Surgical Procedures and Medical Devices." *Health Affairs* (2007).

^{ix} R.A. Deyo et al., "The Messenger under Attack -- Intimidation of Researchers by Special-Interest Groups", 1997 *New England Journal of Medicine* 336: 1176-1180.

^x M. Holmes-Rovner et al., "Are Decision Aids the best way to improve the quality of clinical decision making?", The SMDM 2006 IPDAS Symposium. *Medical Decision Making*, 2007 (Forthcoming July/August).