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Toward the "Tipping Point" Decision Aids and Informed Patient Choice

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Toward The 'Tipping Point': Decision Aids And Informed Patient Choice

Access to high-quality patient decision aids is accelerating, but not at the point of clinical care.

by Annette M. O'Connor, John E. Wennberg, France Legare, Hilary A. Llewellyn-Thomas, Benjamin W. Moulton, Karen R. Sepucha, Andrea G. Sodano, and Jaime S. King

ABSTRACT: Preference-sensitive treatment decisions involve making value trade-offs between benefits and harms that should depend on informed patient choice. There is strong evidence that patient decision aids not only improve decision quality but also prevent the overuse of options that informed patients do not value. This paper discusses progress in implementing decision aids and the policy prospects for reaching a "tipping point" in the adoption of "informed patient choice" as a standard of practice. [*Health Affairs* 26, no. 3 (2007): 716–725; 10.1377/hlthaff.26.3.716]

Treatments with adequate scientific evidence about outcomes can be classified as "effective" or "preference-sensitive."[1] For "effective" treatments, the benefits far outweigh the possible harms, and the goal is to promote their uptake, using professional and patient education, organizational changes, and funding incentives. The best choice for "preference-sensitive" treatments, in contrast, depends on how patients value benefits versus harms. Although it is more difficult to judge the appropriate rate of uptake, Karen Sepucha and colleagues propose a benchmark of "decision quality"—that is, the consistency between eligible patients' treatment uptake rates and the underlying distributions of patients' informed values.[2]

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We know that decision quality resulting from standard counseling is inadequate.[3] Patients have unrealistic expectations of treatment benefits and harms, clinicians are poor judges of patients' values, and, as a consequence, there is overuse of treatment options that informed patients do not value. Indeed, the use of "preference-sensitive" surgical options (for example, hip replacement, prostatectomy, hysterectomy, mastectomy, discectomy, and coronary bypass) can vary two- to fivefold.[4] Patient decision aids (informational documents designed to help patients make decisions about treatment options), when used as adjuncts to counseling, improve decision quality and reduce the overuse of surgical treatments by 25 percent.[5] Decision aids differ from conventional educational materials by presenting balanced personalized information about "options" in sufficient detail for patients to arrive at informed judgments about the personal value of those options. The aim of a decision aid is to improve decision quality and to reduce related unwarranted practice variations by (1) providing facts about the condition, options, outcomes, and probabilities; (2) clarifying patients' evaluations of the outcomes that matter most to them; and (3) guiding patients in the steps of deliberation and communication so that a choice can be made that matches their informed values. Decision aids are delivered as self- or practitioner-administered tools in one-to-one or group sessions. The media for delivery vary (for example, print, video, computer disk, and Web).

This paper summarizes progress in implementing an infrastructure to support informed patient choice, as well as the policy initiatives required to reach the "tipping point" that assures widespread adoption of decision aids as the standard of practice for preference-sensitive care.

Infrastructure To Support Informed Patient Choice

Over the past decade or so, major progress has been made in developing the infrastructure needed to support a change in the standard of practice from delegated decision making to clinical decision making based on shared decisions. The efficacy of good-quality decision aids in improving the quality of clinical decision making has been established. The infrastructure for building and maintaining libraries of effective decision aids is growing and improving. International consensus standards for designing and testing these supports have been developed, as have several models for implementing decision support services. National certification standards are being developed to certify that health care organizations meet the requirements for informed patient choice. Measures of decision quality are under development to monitor performance and provide clinical feedback on the quality of clinical decision making for preference-sensitive treatment choices. And new methods for conducting the clinical evaluation of preference-sensitive treatments are under way. The following briefly summarizes the progress that has been made in each of these domains.

■ **Efficacy.** The Cochrane Collaboration has systematically reviewed more than

fifty randomized clinical trials (RCTs) of decision aids for preference-sensitive options.[6] The review confirms that decision aids help patients participate in decision making, leading to informed choices that are consistent with their values. Specifically, superior effects were shown in the form of (1) increased knowledge scores; (2) improvements in patients' realistic perceptions of the chances of benefits and harms; (3) lowered scores for decisional conflict; (4) smaller numbers of patients who are passive in decision making; (5) smaller numbers of patients who remain undecided after counseling; and (6) improved agreement between a patient's values and the option that is actually chosen. Moreover, several trials focused on decision aids about accepting or rejecting major elective surgery have demonstrated reductions in the more invasive surgical options by 25 percent, with no adverse effects on patient satisfaction or health outcomes.

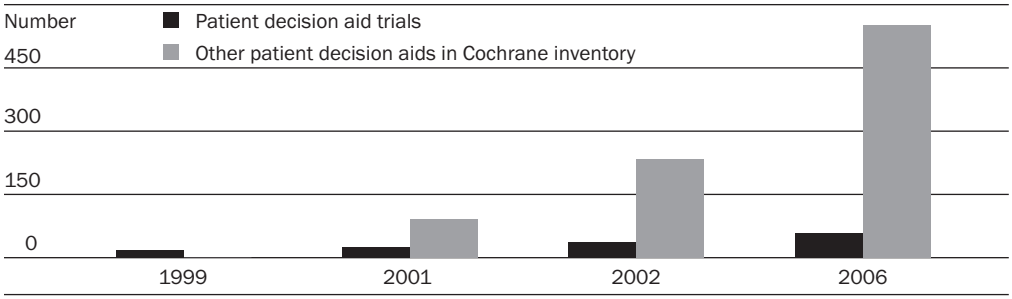
■ **Cost-effectiveness.** Three trials have measured the economic impact of using patient decision aids. One U.K. trial evaluated the cost-effectiveness of aids to reduce hysterectomy rates in cases of heavy menstrual bleeding.[7] The mean total costs and quality-adjusted life-years (QALYs) were superior for groups exposed to decision aids or the combination of aids with nurse coaching as follows: (1) standard care: U.S.$2,751 per patient, 1.572 QALY; (2) aid video alone: U.S.$2,026, 1.567 QALY; and (3) aid video plus nurse coaching (involving eliciting values for outcomes): U.S.$1,566, 1.582 QALY. Two other cost-minimization trials of decision aids for prostate enlargement treatment and menopausal hormones reported that the aid would have been cost-neutral if less costly delivery methods were used (for example, the Internet rather than supplying equipment for interactive videodisks).[8]

■ **Libraries of decision aids.** The Cochrane Collaboration has catalogued and evaluated the quality of a growing number of decision aids, created by a wide range of developers (Exhibit 1).[9] Examples of developers include the Foundation for Informed Medical Decision Making and its commercial partner, Health Dialog; Healthwise; the Mayo Clinic; and the Ottawa Health Research Institute. U.S. organizations that have compiled and are managing clearinghouses of decision aids include the National Cancer Institute and the Centers for Disease Control and Prevention.

■ **International standards.** The International Patient Decision Aid Standards (IPDAS) Collaboration is a network of more than 100 researchers, practitioners, patients, and policymakers from fourteen countries.[10] These collaborators have developed quality criteria in the domains of essential content (providing information, presenting probabilities, clarifying values, and guiding deliberation and communication); development (systematic development process, balance, evidence base, plain language, and disclosure); and evaluation (decision quality). The endorsed criteria are summarized in a checklist for users, to guide payers, practitioners, patients, developers, and researchers.

■ **Models for implementing decision-support services.** Models include call-center models at the health plan level (for example, Health Dialog in the United States; BC Healthguide in Canada; and Australia Cancer Call Centers) as well as

EXHIBIT 1
Growth In Number Of Patient Decision Aid Trials And Number Of Patient Decision Aids Registered In The Cochrane Collection Library, Selected Years 1999–2006



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

models that integrate decision aids into clinical practice. The use of decision aids in call centers and public or health plan portals has expanded rapidly. For example, high-volume decision-aid producers estimate that decision aids were accessed about nine million times in 2006, mostly via the Internet.[11]

Barriers and facilitators. The use of decision aids as part of clinical care has had a much slower rollout. A recent systematic review identified health professionals' most commonly perceived barriers to implementing shared decision making: lack of applicability because of patient characteristics; time constraints; lack of applicability due to the clinical situation (for example, emergency situations); and perceived patient preferences for a model of decision making that did not fit a shared decision-making model.

Identified factors that facilitated shared decision making included the perception that it would lead to a positive impact on patient outcomes or the clinical process, or both; patients' preferences for decision-making roles fit a shared approach; health professionals were motivated to use the aids; and the perception that shared decision making is useful or practical.[12]

Successful uptake of decision aids will also depend on the development of electronic infrastructures to support triggering of the aids, plus secure messaging and patient health records to deliver them to patients. The Center for Information Therapy is working with electronic medical record (EMR) developers and health information producers and health care providers to define electronic "moments of care" and provide just-in-time information before, during, and after clinical encounters.[13]

Care sites using decision aids. Despite the aforementioned barriers to uptake, several sites of care are developing models for delivering decision aids. For example, more than twenty Massachusetts cancer centers are using decision aids to help patients make treatment decisions; Massachusetts General Hospital has started an "ePrescribe" effort, where primary care physicians can prescribe decision aids through the hospital's EMR system; Dartmouth-Hitchcock Medical Center

(DHMC) and White River Junction Veterans Affairs Medical Center are using decision aids as part of a larger reengineering initiative in primary care; ten community-based primary care practices at the University of California, Los Angeles (UCLA), are using patient decision aids; and UC San Francisco and Allegheny General Hospital are incorporating aids into routine breast cancer care, and the University of North Carolina is incorporating them into colorectal cancer screening.

Key role of IT systems. An important element of these practice models is the key supportive role played by specially designed IT systems. For example, the DHMC breast cancer program is attempting to improve clinical care quality by incorporating IT to screen patients, inform physicians, cue the decision aid, assess naïve and informed preferences, flag emotional distress, and monitor decision quality. Typically, the delivery of decision support involves some combination of clinical consultation and counseling, decision aids, and coaching. The sequence, combination, and professionals involved depend on the type of decision, patient population, and service context in which care is provided; these are being spelled out in clinical and care pathways.[14]

International examples. Examples of implementing decision support also exist outside the United States. Several urology centers in the U.K. National Health Service (NHS) have care pathways for benign prostatic hyperplasia and early-stage prostate cancer treatments. These involve a medical consultation with the urologist to confirm the diagnosis and to clarify the options and roles in decision making; referral to the urology nurse specialist, who provides a decision aid about relevant treatments and a personal decision form that elicits decision quality (knowledge, values, and preferred treatment) and unresolved decisional conflict; and a follow-up coaching visit with the nurse specialist to discuss the patient's decisional needs and next steps.[15]

In Canada, Ottawa Hospital is beginning to embed decision support for cancer and obstetrical services into its care pathways as part of the informed-consent process. In Quebec City, the implementation process of shared decision making is being evaluated in five large family medicine sites. This program is closely associated with a residency program in family medicine. Training workshops on shared decision making take place in each teaching site. Simple clinical tools eliciting patients' decisional needs are disseminated through small-group learning sessions occurring throughout the residency, and an annual three-hour training session for clinical teachers is offered.

Developing National Certification Standards

The practice models described above can also be used as examples for developing two kinds of national standards—one for health professionals and the other for health care organizations.

Certification for professionals would involve strategies such as the credential-

ing of professional skills through completion of training programs. For example, the Ottawa Health Research Institute has evaluated strategies that include auto-tutorial and skill-building workshops in decision support and the use of decision aids; structured decision-support protocols; and performance feedback with real or simulated patients. Dawn Stacey and colleagues demonstrated that when this strategy was used in a general nurse call center and in a cancer call center, practitioners' knowledge and skills in decision support improved, particularly in assessing decisional needs, clarifying values, and addressing support needs.[16]

France Legare and colleagues have monitored the implementation of shared decision making in the practices of 122 primary care providers. The exposure to a training workshop, feedback, and reminder at the point of care explained a major proportion of the behavioral intention of interest in a dose-response manner.[17]

In one U.K. study, primary care physicians were able to acquire the skills of shared decision making and use risk communication aids after two sets of two three-hour training sessions.[18] The U.K. Urology Service has adapted the Ottawa training program with its service teams; the program also includes performance feedback on decision quality and addresses barriers to implementing decision aids in clinical care pathways.

These training initiatives can be adapted for national roll-out. There would need to be capacity building in training clinical teachers in shared decision making. Integration of shared decision making would need to occur in the certification processes of faculties of health sciences, including medicine and residency programs, and continuing medical education (CME) activities.

An example of certification for health care organizations is the convening of a panel of experts by the National Committee for Quality Assurance (NCQA) to work on credentialing for cancer care. The panel's work is still in its early stages and will focus on using available data to devise its first set of standards. The main work to date has been developing measures to indicate the level at which an institution has implemented decision support, assessing the reliability or validity of those measures, and piloting their inclusion in a certification process.

■ **Measures of "decision quality."** Measures of patients' decision quality are also under development.[19] *Decision quality* refers to the extent to which patients arrive at choices that are informed and preference-based. The Foundation for Informed Medical Decision Making (FIMDM) is supporting research into the development of decision-specific instruments to measure decision quality across multiple domains. The instruments focus on assessing the extent to which patients understand the key facts about the decision and the extent to which their choices are consistent with their reported preferences for the good and bad outcomes of the options.

Work is under way to supplement these decision-specific measures with generic items to assess the quality of the process; both types of measures reflect the consensus recommendations of the IPDAS collaboration. These measures will serve as important outcome criteria for evaluating the effectiveness of providers'

and organizations' decision-support interventions. An NCQA expert panel is developing and piloting these kinds of measures, to demonstrate that they are valid and reliable and can be considered for inclusion in evaluative work.

In addition, several programs have been using the measures as a screen to reveal knowledge deficits and patients' values before a consultation. The programs testing and using both generic and decision-specific decision-quality measures include the breast cancer program and the Spine Center at the DHMC, as well as the NHS urology services. The breast cancer centers at UCSF and at the Allegheny General Hospital are also starting to use decision-quality measures, along with video-based decision aids.

■ **Clinical evaluation of preference-sensitive treatments.** This refers to the use of decision aids and patient registries in "everyday practice" for long-term follow-up studies that compare the outcomes of different treatment options when the treatment choice has been based on patients' preferences. The Spine Patient Outcomes Research Trial (SPORT) of back surgery is an example that includes both an RCT and preference-based observational arms based on informed patient choice. This work rests on the ethical principle that trial entry for preference-sensitive treatments should be based on informed patient choice. The rich database generated by SPORT is providing Dartmouth investigators with the opportunity to assess outcome probabilities under active choice versus randomization.[20]

Toward The 'Tipping Point': Emerging Opportunities For Accelerated Change

Although progress has been made in building the infrastructure to support shared decision making, cultural, regulatory, legal, and economic barriers must be overcome to make informed patient choice the standard of practice for preference-sensitive treatments. Cultural resistance resides primarily in the change required in the doctor-patient relationship—that is, replacing the traditional reliance on the physician's opinion to define *medical necessity* with the shared decision-making model, which defines new roles for both patient and physician. The good news is that the research and development agenda described above has established that patients and physicians who participate in shared decision making make better decisions and are comfortable in their new roles. The bad news is that shared decision making remains the exception, not the rule.

To take the next steps to the "tipping point," the health policy community needs to develop new standards for defining the medical necessity of preference-sensitive treatment options. Health plans and employers need to develop new payment strategies that encourage both patients and providers to participate in shared decision making. The legal profession needs to recognize the limitations of traditional informed consent in assuring shared decision making and adopt a new standard based on the requirements for achieving informed patients through shared decision making. Each of these changes is amplified below.

■ **New standards for medical necessity.** The standard for review of medical necessity now commonly exercised by the Centers for Medicare and Medicaid Services (CMS) and private health plans is based on the physician as the determinant of medical necessity. We envision a different standard based on the assertion that the informed patient is the final arbiter of the necessity of preference-sensitive treatment. Under our recommendation, the medical profession would continue to determine which options are reasonable, and health plans would determine which options are covered. The process of informed patient choice should be well defined, transparent, and subject to review (along the lines discussed above). Decision aids should be assessed by external standards to ensure that they provide evidence-based, up-to-date, balanced information on all relevant treatment options and that they promote the clarification of values. Quality should be evaluated and reported using appropriate patient decision-quality measures. This process would also be certified or accredited.[21]

■ **New payment strategies.** The economic incentives embedded in traditional Medicare and most other payers reward providers for utilization, not for informed patient choice. Pay-for-performance (P4P) models that reward providers who implement shared decision making need to be designed and tested through demonstrations.[22] The effectiveness of health savings accounts (HSAs) and other "consumer-choice" strategies for involving patients in choice of discretionary treatments should increase patients' demand for shared decision making, but these models need to be tested. We believe that the existence of certification processes and decision-quality measures would provide the basis for qualifying providers for reimbursement and for monitoring the outcomes of the decision process.

■ **Informed patient choice as the legal standard.** We concur with several legal commentators who have suggested that the states should rethink current informed-consent requirements and adopt shared medical decision making as a prerequisite to valid, informed patient choice. The states are largely divided between two categories of informed-consent standards: physician-based and patient-based. In physician-based states, physicians must provide patients with the same information that a reasonable physician would under similar circumstances.[23] In patient-based states, physicians must provide patients with all of the information that an objective, reasonable patient would want under similar circumstances.[24]

Both standards prove insufficient, but for different reasons. The physician-based standard does not acknowledge that often no true objective standard for physicians exists.[25] In fact, reasonable physicians exhibit wide variations in practice patterns even within the same region. Likewise, the objective patient standard used in nearly all patient-based states does not go far enough to protect a patient's right to make medical decisions.[26] It fails to acknowledge that patients' values and preferences vary widely. In many cases, a patient's lifestyle, values, and preferences should dictate what course of treatment to follow. Under the objective patient standard, to the extent that the person's preferences do not correspond

with those of a "reasonable" patient, however defined, that person may be denied information that he or she would deem relevant to making the treatment decision.[27] Shared medical decision making offers a promising alternative to our current informed-consent system. It allows both physicians and patients to honor the values and preferences of the patient, while also permitting the physician to provide medical expertise to promote the patient's health. In fact, evidence suggests that shared medical decision making strengthens the therapeutic alliance between the physician and patient and improves patient satisfaction.

Critics of the shared decision-making approach have questioned the feasibility of proving that a true shared process had occurred, but the certification processes of care and decision quality measures discussed previously should provide transparent ways of measuring whether the standard of informed choice has been met.

TO REACH THE TIPPING POINT, we need to make the use of high-quality decision aids unavoidable and a part of the informed-consent process. The best way to accomplish the ease of prescription is to embed high-quality decision aids within EMR systems. At the national policy level, we need to design and introduce model legislation about informed patient choice, as well as to convene payer groups under the leadership of the CMS to redefine the patient's role in determining medical necessity and claims review. National policies focused on informed consent, a redefinition of *medical necessity*, and new payment strategies should accelerate adoption of informed patient choice as the standard for practice, with resulting benefits to patients, physicians, and the health care community.

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NOTES

1. J.E. Wennberg, "Unwarranted Variations in Healthcare Delivery: Implications for Academic Medical Centres," *British Medical Journal* 325, no. 7370 (2002): 961–964; and R.P. Harris et al., "Current Methods of the U.S. Preventive Services Task Force: A Review of the Process," *American Journal of Preventive Medicine* 20, no. 3 Supp. (2001): 21–35.
2. 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* 23 (2004): VAR-54–VAR-62 (published online 7 October 2004; 10.1377/hlthaff.var.54).
3. A.M. O'Connor et al., "Decision Aids for People Facing Health Treatment or Screening Decisions," *Cochrane Database of Systematic Reviews* no. 2 (2003): CD001431.
4. J.E. Wennberg and M.M. Cooper, "The Surgical Treatment of Common Diseases," in *The Dartmouth Atlas of Health Care, 1998* (Chicago: American Hospital Publishing, 1998), 108–111.
5. O'Connor et al., "Decision Aids."
6. Ibid.
7. A.D. Kennedy et al., "A Multicentre Randomised Controlled Trial Assessing the Costs and Benefits of Using Structured Information and Analysis of Women's Preferences in the Management of Menorrhagia," *Health Technology Assessment* 7, no. 8 (2003): 1–76.

8. E. Murray et al., "Randomised Controlled Trial of an Interactive Multimedia Decision Aid on Benign Prostatic Hypertrophy in Primary Care," *British Medical Journal* 323, no. 7311 (2001): 493–496; and E. Murray et al., "Randomised Controlled Trial of an Interactive Multimedia Decision Aid on Hormone Replacement Therapy in Primary Care," *British Medical Journal* 323, no. 7311 (2001): 490–493.
9. For an inventory of decision aids and the Cochrane Review, see Ottawa Health Research Institute, "A–Z Inventory of Decision Aids," http://decisionaid.ohri.ca/AZinvent.php (accessed 24 October 2006); a Web search on 30 October 2006 for "decision aid" produced 960 hits at the NIH site, http://www.cancer.gov, and 29,789 hits at the CDC site, http://www.cdc.gov.
10. 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; and 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 9 February 2007).
11. Don Kemper, chief executive officer, Healthwise, personal communication, January 2007; David Wennberg, president and chief operating officer, Health Dialog Analytic Solutions, personal communication, January 2007; and Anton Saaramaki, computer systems analyst, Ottawa Health Research Institute, personal communication, January 2007.
12. K. Gravel, F. Legare, and I.D. Graham, "Barriers and Facilitators to Implementing Shared Decision-Making in Clinical Practice: A Systematic Review of Health Professionals' Perceptions," *Implementation Science* no. 1 (2006): 16.
13. For more information, see the Center for Information Therapy home page, http://www.informationtherapy.org.
14. For more-in-depth discussion of pathways, see J.N. Weinstein, K. Clay, and T.S. Morgan, "Informed Patient Choice: Patient-Centered Valuing of Surgical Risks and Benefits," *Health Affairs* 26, no. 3 (2007): 726–730.
15. National Steering Group for Decision Support Aids in Urology, *Implementing Patient Decision Aids in Urology—Final Report*, October 2005, http://www.pickereurope.org/Filestore/Research/Urology_steering_group_report.pdf (accessed 26 October 2006). See also E. Wirrmann and J. Askham, *Implementing Patient Decision Aids in Urology*, September 2006, http://www.pickereurope.org/Filestore/Downloads/UrologyFINALREPORTSep06.pdf (accessed 12 February 2007).
16. D. Stacey et al., "Barriers and Facilitators Influencing Call Center Nurses' Decision Support for Callers Facing Values-Sensitive Decisions: A Mixed Methods Study," *Worldviews on Evidence-Based Nursing* 2, no. 4 (2005): 184–195; and D. Stacey et al., "Addressing Barriers Influencing the Provision of Telephone-Based Patient Decision Support by Cancer Helpline Professionals" (Presentation at the Fourteenth International Conference on Cancer Nursing, Toronto, Ontario, 27 September–1 October 2006).
17. F. Legare, "Implementation of the Ottawa Decision Support Framework in Five Family Practice Teaching Units: An Exploratory Trial" (Doctoral dissertation, University of Ottawa, 2005).
18. G. Elwyn et al., "Achieving Involvement: Process Outcomes from a Cluster Randomized Trial of Shared Decision Making Skill Development and Use of Risk Communication Aids in General Practice," *Family Practice* 21, no. 4 (2004): 337–346.
19. Sepucha et al., "Policy Support for Patient-Centered Care"; and K. Sepucha et al., "An Approach to Measuring the Quality of Breast Cancer Decisions," *Patient Education and Counseling* 65, no. 2 (2007): 261–269.
20. N.J. Birkmeyer et al., "Design of the Spine Patient Outcomes Research Trial (SPORT)," *Spine* 27, no. 12 (2002): 1361–1372.
21. J.E. Wennberg and P.G. Peters Jr., "Unwarranted Variations in the Quality of Health Care: Can the Law Help Medicine Provide a Remedy/Remedies?" *Wake Forest Law Review* no. 37 (2002): 925–941.
22. J.E. Wennberg, E.S. Fisher, and J.S. Skinner, "Geography and the Debate over Medicare Reform," *Health Affairs* 21 (2002): w96–w114 (published online 13 February 2002; 10.1377/hlthaff.w2.96).
23. *Tashman v. Gibbs*, 556 S.E.2d 772, 777 (VA 2002).
24. *Canterbury v. Spence*, 446 F.2d 772, 784 (DC 1972).
25. J.S. King and B. Moulton, "Rethinking Informed Consent: The Case for Shared Medical Decision-Making," *American Journal of Law and Medicine* 32, no. 4 (2006): 429–501.
26. Ibid.
27. Ibid.