



States Explore Shared Decision Making

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test in this population,” Carroll said. “We also think earlier and less frequent testing based on a man having a lower than median PSA level might reduce health care costs.”

In addition to lowering the age for determining a baseline PSA level, the best practice statement no longer recommends a single threshold value of PSA that prompts biopsy to confirm the

presence of cancer. It notes that multiple factors, such as free and total PSA, patient age, PSA velocity (the rate at which the number increases) and density, family history, ethnicity, prior biopsy history, and comorbidities, should be taken into account.

Carroll added that the 40-year baseline recommendation does not exist in a vacuum and that physicians should

have explicit discussions with their patients about both the benefits of early detection and the risks of overtreatment. To help promote such discussions between physician and patient, Brawley said, the ACS is developing a 1-page document aimed at patients, written at an eighth-grade level, that will make clear the benefits and risks of screening for prostate cancer. □

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HEALTH OFFICIALS IN WASHINGTON State are probing whether more actively involving patients in decision making will help improve patient care and satisfaction and perhaps lower costs associated with certain elective medical procedures.

In 2007, the state passed legislation that officially recognized shared decision making as a high standard of informed consent. The law also required a demonstration project, which is now under way, to gauge the effects of this model of informed consent for treating patients with “preference-sensitive conditions” that have multiple options for care. The project includes such conditions as osteoarthritis of the knee or hip, low back pain, abnormal uterine bleeding, fibroids, benign prostatic hyperplasia, chronic stable angina, early-stage breast cancer, and breast reconstruction after mastectomy.

Four other states are considering legislation that would mandate a pilot study of shared decision making. A federal bill proposing such an experiment in the Medicare program is also under consideration in the US Congress. The proposals come as state and federal governments grapple with how best to improve the quality of health care and reduce unnecessary costs.

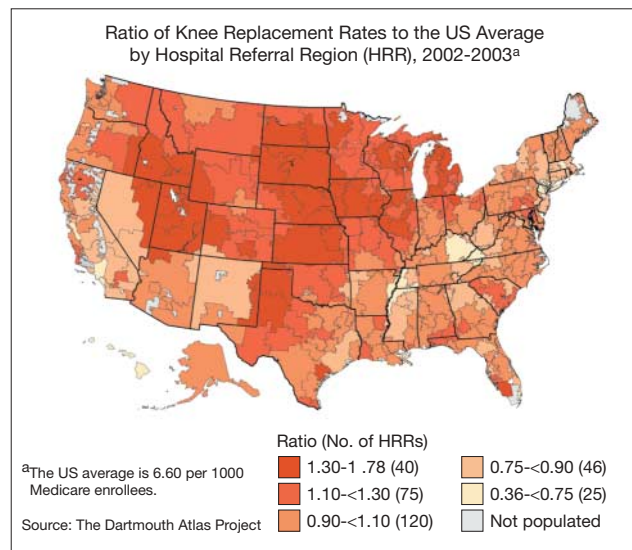
Some of the proposals build on evidence that the cost and delivery of health care vary substantially between differ-

ent geographic regions. Specifically, researchers have found that although physicians in both high-spending and low-spending regions were equally likely to follow clinical guidelines for care, when there are multiple acceptable options for treating a particular medical condition, physicians in higher-spending regions are more likely to recommend more expensive interventions, while physicians in lower-spending regions are more likely to recommend more conservative options (Sirovich B et al. *Health Aff [Millwood]*. 2008;27[3]:813-823).

Officials at Group Health Cooperative, a nonprofit health insurer and medical system that covers 580 000 individuals in Washington State, analyzed state-level data to determine whether such geographic differences

were also occurring locally. They found important differences in care for a variety of conditions. For example, men with benign prostatic hyperplasia in Wenatchee, Wash, are 5 times more likely to undergo transurethral resection of the prostate than men in Seattle, according to 2005 data on Medicare enrollees. They also noted that patients in some regions were about twice as likely to have knee replacement than those in other areas.

However, it was not clear why such variations were occurring, explained David Arterburn, MD, an assistant investigator at Group Health Cooperative’s Center for Health Studies. “We don’t think that knees are different [in these areas]; it might be differences in the way care is provided,” he said.



The rate of elective surgeries such as knee replacement varies geographically. To reduce such unwarranted variation, some states are proposing methods to better educate patients about treatment options.



INFORMED DECISION MAKING

Ideally, when multiple options for care are available, patients should be fully aware of their options and physicians should know which option the patient would prefer. However, physicians often do not share with their patients the information needed to make an informed decision. In fact, in a study of more than 1057 recorded patient encounters involving 3552 clinical decisions, only 9% of the decisions met criteria for informed decision making (Braddock CH et al. *JAMA*. 1999; 282[24]:2313-2320). In a more recent study of 51 conferences between physicians and families regarding major end-of-life decisions, only 2% met all the criteria for shared decision making (White DB et al. *Arch Intern Med*. 2007;167[5]:461-467).

To address this information gap and promote shared decision making, some individuals and groups are advocating the use of decision aids—often Web-based videos—to walk patients through information about their treatment options and to encourage them to incorporate their own values and preferences in the decision-making process.

A Cochrane Collaboration review of 55 randomized controlled trials of shared decision making found that patients who used such decision aids had greater knowledge about their treatment options, were more actively involved in the process of deciding on a treatment, and were more satisfied with their decision and the process (O'Connor AM et al. *Cochrane Database Syst Rev*. 2003;[1]:CD00143). Aids that provided greater detail were more effective than aids that were less thorough. Additionally, patients who used decision aids were about 20% less likely to chose invasive surgical options over more conservative ones, without a negative effect on outcomes.

LEGISLATION

Washington State's shared decision-making law does not require that physicians use shared decision making instead of a more standard informed consent procedure, Arterburn ex-

plained. But using shared decision making may provide a greater level of liability protection because the state has recognized it as a higher standard, according to Arterburn.

In January, the state's 2-year demonstration project began. Participants include the Washington State Health Care Authority (which oversees the effort) and several organizations, including the Group Health Cooperative; the Everett Clinic (a multispecialty medical group); the Virginia Mason Medical Center, in Seattle; the Puget Sound Health Alliance (a Seattle-based health care quality improvement organization representing employers, patients, health plans, and hospitals); the Carol Millard Breast Cancer Center in Tacoma; and the Multicore Medical Center (a nonprofit health care organization based in Tacoma that includes hospitals, clinics, and multispecialty centers). The University of Washington secured a grant from the Foundation for Informed Medical Decision Making (<http://www.informedmedicaldecisions.org/>), a nonprofit group that promotes shared decision making and makes decision aids to help fund the project.

Lawmakers in Connecticut and Vermont are also considering similar laws and demonstration projects, according to the Foundation for Informed Medical Decision Making. Minnesota is contemplating legislation that would require clinicians treating state-insured employees or recipients of state medical assistance to use shared decision making in order to be reimbursed for certain procedures, including abnormal uterine bleeding, benign prostatic hyperplasia, chronic back pain, early stage breast cancer, urinary incontinence, and gastroesophageal reflux disease. Maine is considering legislation that would require health insurers and the state insurance program to implement shared decision making. On the federal level, US Senator Ron Wyden of (D, Ore) has proposed federal legislation that would require a pilot study of shared decision making for Medicare beneficiaries.

Karen Merrikin, JD, executive director of public policy at the Group Health Cooperative, said many lawmakers find shared decision making appealing because it has been shown to reduce the number of surgeries when some patients opt for more conservative, and likely less costly, interventions.

"Lawmakers are interested in an approach that could address the sweet spot of good outcomes and better value in health care," Merrikin said.

A PARTNERSHIP

Although physicians generally support the *idea* of making patients more involved in the decision-making process, a variety of factors often stand in the way of following this standard of care in their practice, said Clarence H. Braddock III, MD, MPH, of Stanford University School of Medicine. For example, physicians often say they do not have sufficient time or that their patients do not really want to be presented with options. Some may worry that shared decision making takes the decision completely out of their hands.

"What a lot of physicians hear, mistakenly so, is that the goal [of shared decision making] is to give patients information and let them decide what is the best treatment for them," Braddock said. But the goal, he said, is to first give a patient sufficient information to allow his or her personal values and preferences inform the decision and then the patient and the physician work together to arrive at the best option for that patient.

As part of this process to ensure that the decision the physician and patient reach together is consistent with the patient's values, Arterburn explained, after a patient has viewed a decision aid, the physician may ask the patient how they feel about the risks and benefits associated with each option and how various options might affect the patient's life. For example, for those women with breast cancer who may place a high value on preserving their breast, lumpectomy with radiation might better fit this value than mastectomy.



Some physicians may also take issue with the content of the decision aids, but may become more comfortable with such aids as more of them become available and studies are conducted to assess and compare them, said Arterburn. In the meantime, the International Patient Decision Aid Standards Collaboration is creating a set of criteria that can be used to judge whether decision aids are evidence-based and free of bias or conflict.

Although no data are yet available, the Group Health Cooperative has been using decision aids produced by the Foundation for Informed Medical Decision Making (which are reportedly based on systematic reviews of the evidence and focus groups and inter-

views about patient preferences) and has received some positive anecdotal feedback, Merrikin said. For example, some orthopedic surgeons have commented that patients are better prepared to discuss the options, are more knowledgeable, and ask more sophisticated questions—factors that have helped reduce the amount of time necessary for such discussions. There also is evidence in the literature that patients who go through the shared decision-making process are more likely to adhere to the selected therapy, Braddock said.

However, there may be financial disincentives that might discourage physicians from taking time for shared decision making. For example, Braddock

said, physicians are reimbursed more for performing procedures than for consultations. Some of the state bills do require reimbursement for shared decision making, however, which may help address this potential barrier.

Whether adopting shared decision making will actually cut costs remains to be seen. Patients faced with various options that produce a similar outcome may not necessarily choose the less expensive one. In any case, Braddock and Arterburn said, physicians have an ethical obligation to ensure that their patients are fully informed and given a say in what happens to their bodies.

“It’s the right thing to do,” Braddock said. □

FDA Tells Drug and Device Makers to Give Balanced Picture of Risks in Ads, Labels

Bridget M. Kuehn

THE US FOOD AND DRUG ADMINISTRATION (FDA) is advising the makers of medications and medical devices to avoid misleading consumers with marketing strategies that deemphasize the risks of these products.

Promotional materials that omit or minimize risk information are the most frequent reason the agency issues enforcement letters to companies, and the FDA says it has received requests from industry for clarification about what it considers a violation. In the new guidance (<http://www.fda.gov/cder/guidance/7427dft.pdf>), the agency emphasizes that simply including risk information is not enough to satisfy its requirements; rather, the agency weighs whether marketing materials leave consumers or clinicians with a balanced impression of a product’s risks and benefits.

In addition to providing physicians with the information they need to know to safely prescribe medical products, appropriate risk disclosures in advertise-

ments help consumers decide whether a product may be appropriate for them. Such disclosures also inform patients about what they should discuss with their clinician before using a product, warn about adverse events they might experience, and highlight safety precautions, such as not driving, which should be taken while using the product, according to the guidance.

Currently, advertisements and labels for medical products frequently fail to meet these critical objectives. In 1999 and 2002, the FDA surveyed nearly 2000 US adults by telephone to assess their impressions of direct-to-consumer advertisements of prescription drugs and found that 60% believe that the advertisements do not provide enough information about risks (<http://www.fda.gov/cder/ddmac/Final%20Report/FRfinal111904.pdf>). Results from a 2002 survey of 500 US physicians published in the same report reveal that 60% of physicians say the patients develop little or no understanding about drug risks and 72% say patients fail to understand who should

not use the drugs, based on their exposure to the product advertising.

In its guidance, the FDA discourages companies from using visual, audio, and other marketing techniques that may leave consumers or physicians with a distorted view of product risks and gives numerous examples of such misleading advertising. In one example, a television advertisement for a cholesterol-lowering drug, as the announcer accurately describes the medication’s risks, images depicting patients benefiting from the drug are shown on the screen and loud, upbeat music plays. In another example, the FDA cites a print advertisement in a medical journal for an arthritis drug in which large, bold headlines set off by white space trumpet that the drug is proven safe and effective for arthritis pain and stiffness, that the product’s gel formulation is easy to use, and that it is the most frequently prescribed drug in the United States; risk information, on the other hand, is relegated to cramped, non-bold, small type at the bottom of the page. □