WHO KNOWS BEST?

The Challenges of Shared Decision Making

CYNTHIA TURNER

When a course of treatment is being considered, what needs to be incorporated into the discussion with your patients? In particular, how should you address issues such as brand-new technology, off-label applications, and out-of-pocket costs?

BY JEAN SHAW, CONTRIBUTING WRITER

A patient needs treatment. Either one of two similar procedures would be appropriate, yet one is significantly more expensive than the other. The patient is now sitting across from you, regarding you expectantly. How do you start the conversation?

That scenario plays out every day in ophthalmologists' offices. Consider this: Most new diagnoses of macular degeneration will lead to a discussion of Eylea (aflibercept), Lucentis (ranibizumab), and Avastin (bevacizumab), which raises the issue of off-label applications. And the presbyopic patient is faced with an ever-expanding array of IOLs to consider, complete with out-of-pocket costs. Similar examples can be found in other subspecialties. So how do you begin?

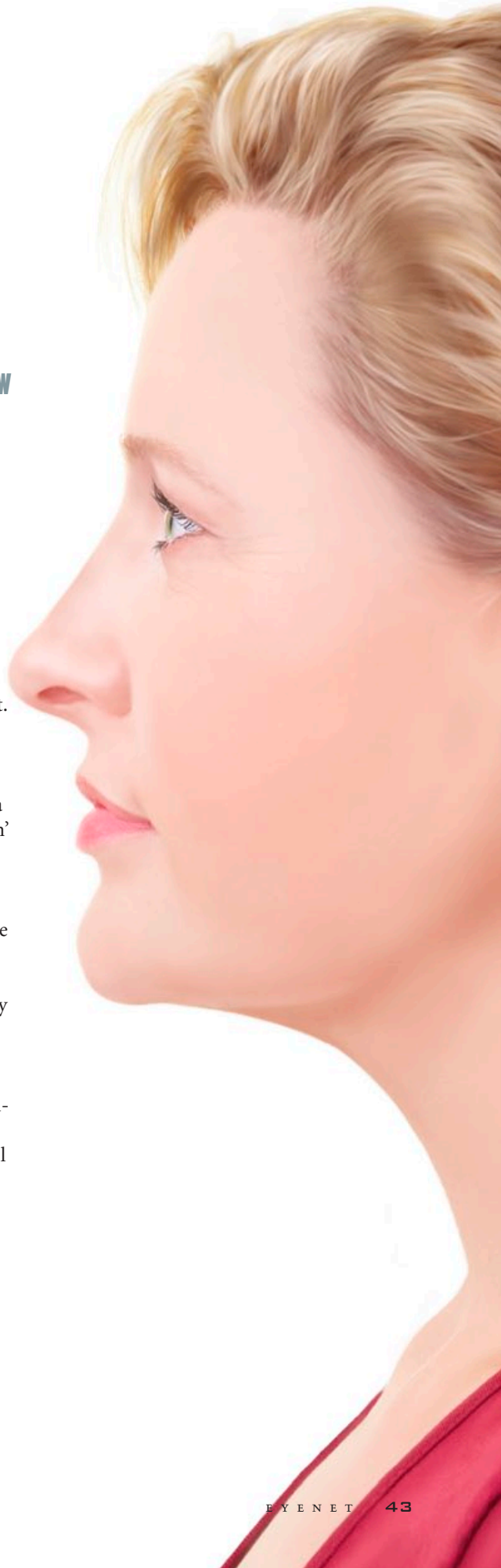
The TAO of Informed Consent

Today, more than ever before, clinical decision making needs to be *transparent, authentic,* and *open.* Call it the TAO of informed consent. The paternalistic approach—"doctor knows best"—is outmoded, and the pressure is on to adopt the model known as shared decision making, in which patients have a greater say.

"Transparency is the main issue," said Lisa B. Arbisser, MD, a cataract surgeon based in Iowa and Illinois. "With IOLs for presbyopic patients, for instance, the truth is our options aren't absolutely perfect. We're always dealing with trade-offs, and patients need to be fully informed." She added, "The Cadillac versus Yugo argument—the idea that there is an absolute 'best option' in any given situation, and that this 'best option' is the most expensive one—doesn't hold water with me. Sometimes the monofocal lens is the patient's best option."

Dr. Arbisser said, "It is difficult that, for financial reasons, not every patient has access to their preference. With automobiles, the Yugo owner can work hard and buy a Cadillac later on; with IOLs, the implant is there to stay."

SHARED DECISION MAKING. In theoretical terms, what does shared decision making look like? Essentially, this model recognizes that it's primarily the physician's responsibility to identify the medical problem and lay out the reasonable choices for treatment—and that it's the patient's responsibility to identify his or her personal goals and concerns in light of those choices.[1]

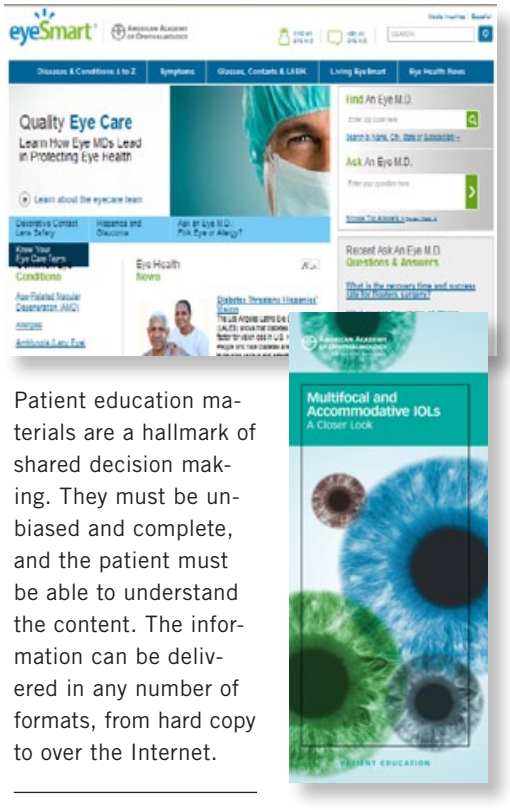


THE FRAMEWORK. One of the core principles of shared decision making is that the acceptable balance between the risks and benefits of any treatment should be considered by the person who has to live with them. But for patients to have a meaningful say in this process, three conditions must be met.[1]

- Patients must be informed, via an "objective, unbiased presentation of reasonable options to consider and the pros and cons of those options."
- They must have time to consider any personal issues and evaluate how those issues might play out with regard to the various treatment alternatives.
- They must be encouraged to share their personal goals and concerns with their physician, and those goals and concerns must then be incorporated into the decision-making process.

THE PUSH FOR ADOPTION. At the federal level, the Affordable Care Act of 2010 includes a provision that supports putting patients at the center of clinical decision making.[2] In addition, a growing number of states are adopting policies that support the shared decision-making model.[3]

One of the drivers behind the adoption of this model is the change in the cultural climate. Patients who prefer the authoritarian model, in which physicians unilaterally make all clinical decisions, are in the minority.



Patient education materials are a hallmark of shared decision making. They must be unbiased and complete, and the patient must be able to understand the content. The information can be delivered in any number of formats, from hard copy to over the Internet.

A second, increasingly powerful driver is the hypothesis that shared decision making can simultaneously improve the quality of health care and lower its costs. In particular, the thinking is that it will reduce the incidence of overdiagnosis and overtreatment.

Indeed, a study published in September found that the use of patient decision aids (patient education materials that are a hallmark of the shared decision-making model) in a large health system led to a significant reduction in the rate of elective hip and knee surgeries. The findings "support the concept that patient decision aids for some health conditions, for which treatment decisions are highly sensitive to both patients' and physicians' preferences, may reduce rates of elective surgery and lower costs," the researchers concluded.[4]

"In the eyes of professionals, cost may not be part of the discussion, but in the eyes of society, cost is one of the components of good quality care," said William L. Rich III, MD, the Academy's medical director of health policy. "It's a component of the equation and is going to continue to be a part of our professional interaction with patients."

ON THE RAZOR'S EDGE. "This is a complicated and controversial issue," said Jeffrey S. Heier, MD, associate professor of ophthalmology at Tufts University and clinical instructor of ophthalmology at Harvard Medical School. When it comes to discussing treatment options with patients, he said, "Physicians have two responsibilities." The first is to the patient: "Safety and efficacy trump all."

The second is a "global health care issue," said Dr. Heier, who also directs the vitreoretinal service at Ophthalmic Consultants of Boston. "I do want to be fiscally responsible. If one treatment is significantly less expensive, I'd prefer to use that. I do have a responsibility to health care as a whole. But I won't sacrifice safety and efficacy for a price difference."

Talking Points

In practical, everyday terms, what does shared decision making mean for you and your staff?

THE LATEST AND GREATEST. As a recent issue of the *OMIC Digest* noted, the rapid pace of medical innovation means that ophthalmologists are continually assessing whether they want to be among the "early adopters" of a new technology or procedure.[5]

Although it can be challenging to balance the accepted standard of care against the rapidly changing standard of practice in your particular geographic area, "Don't oversell something new," advised Anne M. Menke, RN, PhD, OMIC's risk manager. "And be sure to disclose your experience or lack thereof" with any new procedures or medications, she said.

"I think it's important to avoid upselling," Dr. Arbisser agreed. For instance, the femtosecond laser is a hot-button issue in cataract surgery at the moment. But based on the available evidence, she said she doesn't see a clear advantage to using it at this time. Currently, "the patient is not significantly disadvantaged no matter what they can or cannot afford. This may become more difficult in the future, as evidence mounts as to better safety or efficacy of techniques that require out-of-pocket expenses."

Overall, Dr. Arbisser said, "The 'Would you have your mother choose this?' standard has always been one I have followed."

THE EXPERIMENTAL ANGLE. If you are presenting multiple

treatment options, and one is not approved by the FDA, "You must bring that into the discussion and check it off on the consent form," said Hans Bruhn, MHS, senior risk management specialist with the Ophthalmic Mutual Insurance Company (OMIC).

It's also essential to disclose whether you're providing treatment as part of a study, said Christie L. Morse, MD, chairwoman of the Academy's Ethics Committee and a pediatric ophthalmologist in Concord, N.H.

Ophthalmology is replete with examples of off-label use of drugs, with Avastin as a leading case in point. Dr. Heier offered an overview of how—before Eylea became available—he discussed Lucentis and Avastin with AMD patients. "I was very careful to review the two medications in light of all the treatment options and research evidence. I was also very careful to mention that one is used off label—and to describe what off label means—and to note the price differential." He told patients that he considered it a "reasonable course of action to start with Avastin and to follow them carefully—and that I had a low threshold for switching them to the more-expensive drug if they were not responding."

The converse applied as well, Dr. Heier said. "If patients desired to use the FDA-approved drug first and didn't respond as expected, it was reasonable to switch them to non–FDA-approved therapies to try to achieve greater efficacy." In November 2011, Eylea received FDA approval, and it may offer advantages in terms of dosing frequency as well as efficacy in hard-to-treat patients, said Dr. Heier. "My discussion of therapies now includes all three agents, and I am careful to highlight the advantages, and potential disadvantages, of each agent."

THE ISSUE OF MONEY. Whether or not a drug or procedure is covered by insurance, "It is incumbent upon the physician to discuss financial issues with the patient," said Dr. Rich, who practices in Fairfax, Va. "Even if a patient demurs and says, 'Oh, I'm covered,' that isn't the end of the discussion."

For instance, there may be additional costs to the patient in the form of greater co-pays. In addition, recent changes in reimbursement mean that physicians will be penalized under certain circumstances, said Dr. Rich. "In the past, when we practiced under a pure fee-for-service payment methodology, we were financially rewarded for providing a higher volume of services. Not now. Physicians now will be paid for the volume but also for the quality of the services and the efficiency with which they are provided."

Even when a patient is willing to pay out of pocket, "We still need to have the discussion," Dr. Rich said. "You explain the options, the pros and cons, and the outcomes—and you also discuss the added costs for some services. You need to give a fair representation of all options and any financial conflicts. Don't be a salesman."

Dr. Rich added, "I don't think this is a hard discussion to have; it's just something that we have not done with any regularity. We've discussed outcomes and risks with our patients, but we haven't discussed relative costs."

Additional Challenges

WHAT ABOUT TIME? All of this presents a significant real-world challenge with regard to time: You need to find out what matters most to your patients, reconcile their goals with your clinical experience, and cover issues of cost and medical innovation—and you need to do so within a limited amount of time.

Building an effective team can help with the time crunch, said Dr. Menke. "For instance, staff can begin the informed consent process. They can provide educational materials and any other information, including the actual consent form." However, she cautioned, "Only the surgeon may obtain the patient's actual informed consent." This is analogous to the situation with test results, she said. Even though staff may convey test results, only the physician may provide the interpretation.

A recent *OMIC Digest* article, "The Pressures and Risks of Keeping Current," discusses the issues that physicians should consider before adopting new technologies and techniques.[5]

A note on educational materials: Information should be unbiased, complete, and presented in a form that your patients can understand. It can be delivered in a variety of formats, from hard copy to over the Internet.

WHAT ABOUT MALPRACTICE CLAIMS? Some physicians have expressed concern that involving patients in treatment decisions would increase their vulnerability to malpractice claims. But if handled in a genuine and thorough manner, the opposite may prove to be the case.

"It's important to use the informed consent process," said Mr. Bruhn. "It really is about the discussion. You need to provide patients with complete information and give them the opportunity to ask questions."

Mr. Bruhn added, "As long as the patient knows what to expect, and surprises are minimized, you tend to be okay." And the paper trail benefits both the patient and the physician, he pointed out. "It's when patients don't recall [the points you've discussed] that you're in trouble. The process goes downhill from dissatisfaction to lack of trust to allegations of negligence."

OMIC experience has shown that there can be a greater risk of miscommunication—and a greater risk of claims—in areas "where there are out-of-pocket expenses for the patient, such as cosmetic procedures," said Mr. Bruhn. Complex disease conditions also have the potential for miscommunication, he said. "The more complex the disease is and the more critical the follow-up timelines are, the greater the opportunity for problems to occur."

Apply the Rules of Ethics

Given the complexity of delivering care today, the way forward will include numerous bumps in the road. "But the truth is, all of our treatment discussions really should begin with core ethical tenets," said Dr. Morse. If you look at the Rules of Ethics in the Academy's Code of Ethics (www.aao.org/ethics), you'll see that several of them dovetail nicely with the shared decision-making model, she said.

PRETREATMENT ASSESSMENT. Rule 6 reminds ophthalmologists that "we need to consider multiple factors of a patient's life," she said. Specifically, the rule notes that treatment should be recommended only after "careful consideration of a patient's physical, social, emotional, and occupational needs."

INFORMED CONSENT. Rule 2 succinctly states that informed consent must be obtained before any treatment. But this "involves much more than just getting a signature on a piece of paper," Dr. Morse cautioned. For instance, she said, "If one treatment is more expensive than another, why? You need to tell the patient, especially if they will have out-of-pocket expenses other than routine co-payments. Is it because of equipment? The surgeon's training? Reimbursement issues? All of the above?"

Moreover, she said, "Is this a new procedure for the ophthalmologist? Now the learning curve comes into play; you must disclose the extent of your surgical training and experience."

CLINICAL TRIALS. Rule 3 addresses clinical trials. Dr. Morse noted that it applies to more than formal IRB-approved trials. "Are you gathering data on a new treatment, perhaps for a case study or a meeting presentation? That needs to be disclosed and, ideally, should be part of the informed consent process."

CONFLICTS OF INTEREST. Finally, Rule 15 "covers not only financial but also professional conflicts of interest," Dr. Morse said.

"The bottom line is you need to lay out all the pros and cons, both real and perceived," said Dr. Morse. "And you need to be aware of the ways in which a patient might have been influenced—by advertising or by conversations with others, including other ophthalmologists."

1 Fowler FJ et al. *Health Aff.* 2011;30(4):699-706.
2 U.S. Department of Health and Human Services. National Strategy for Quality Improvement in Health Care. March 2011. www.healthcare.gov/law/resources/reports/nationalqualitystrategy032011.pdf. Accessed Oct. 1, 2012.
3 Frosch DL et al. *Health Aff.* 2012;31(5):1030-1038.
4 Aterbun D et al. *Health Aff.* 2012;31(9):2094-2104.
5 Menke AM. The pressures and risks of keeping current. www.omic.com/new/digest/Digest_Spring2012.pdf. Accessed Oct. 1, 2012.

More on Informed Consent. Visit www.eyenet.org/archives and look for the November/December 2009 and January 2010 articles on improving the process.

MEET THE EXPERTS



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