

Informed Consent, Part One: Use of Staff, Brochures, DVDs and the Web

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One of the most powerful tools for advancing patient safety is the process of informed consent, said Fay A. Rozovsky, JD, MPH, a past-president of the American Society for Healthcare Risk Management. At the heart of this process is the conversation that takes place between the doctor and patient, and there are ways to enhance that dialogue without having to invest a great deal of extra time or money. This issue of *EyeNet* looks at the dos and don'ts of using staff members and patient education materials to support the consent process.

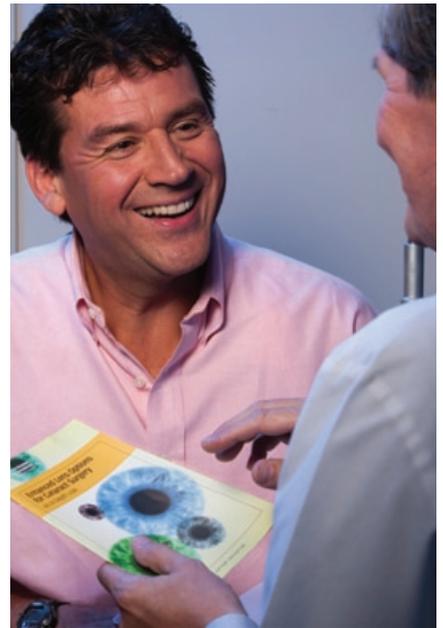
The Role of Staff Members

"Allied health professionals—now frequently referred to as physician extenders—should not be doing the informed consent process per se," said Ms. Rozovsky, who is principal of The Rozovsky Group, a health care risk management consultancy firm. "But ophthalmologists can make use of them during the consent process."

Staff can help with some of the initial screening. "Suppose you have a 65-year-old patient who has a per-

sistent problem with glaucoma," said Ms. Rozovsky. "He has had surgery, he is having acute glaucoma episodes, he has lost part of his vision and is being monitored on a regular basis. He also has cataracts and is a fragile diabetic. If the physician goes through all the usual questions on every visit, you're going to have a backed-up office. But if you have nurses, Advanced Practice RNs or PAs who are good communicators, they can be trained to run through a screening checklist. So each time this patient visits, he gets asked the same set of questions. These might include, for example, 'How are you doing today? Since you were here last month, have you seen any other care providers—including optometrists, dentists or any other specialists? Have you changed any of your medications or have any of your doctors changed your medications? Have you started taking any supplements or over-the-counter medications?'"

Staff can alert the physician to potential red flags. "When staff run through this checklist of questions, they are taking one component of the informed consent process—the intake of information—and are transferring it into a very powerful tool for patient safety," said Ms. Rozovsky. These very short discussions can reveal that particular patients may need more attention because, for instance, they are noncompliant or their drug plan



Dec. 1 to 7 is Patient Education Check-up Week. During the first week of December, the Academy and OMIC urge all ophthalmologists and practice managers to make sure their patient education materials and informed consent documents are up to date: 1) Visit www.aao.org/patiented/audit for a patient education checklist, 2) visit www.aao.org/patientedproducts to review peer-reviewed patient education materials and 3) visit www.omic.com to see OMIC's most recent informed consent documents.

This annual review of materials can help you prevent or minimize the impact of a malpractice lawsuit.

has changed their medications. “Some specialties regularly use this approach for certain patients, such as end-stage renal dialysis patients or pregnant women who are high-risk. These are patients for whom there are certain things that you want to look for, so you can rule-in or rule-out changes.”

Staff must have good communication and interpersonal skills. You should not delegate elements of the screening process to staff members unless you are comfortable with their communication skills and have supervised their patient interactions. “They may, after all, need to elicit sensitive, but important, information,” said Ms. Rozovsky. “This is truer than ever in the age of ‘recession risk management,’ when Medicare patients on a fixed income may be in the donut hole for Part D. You’ll want to find out which of your patients have modified their own care plan to try and stretch out their drugs by, for instance, only taking them every other day or intermingling them with over-the-counter drugs.” Attention to word-use and body language is valuable; patients may provide the answers they believe you want to hear and deny any difficulties they have had in, for instance, inserting drops or following directions.

Brochures, DVDs and the Web Your educational efforts may be more effective if you use a combination of different approaches—including face-to-face discussions, written materials and audiovisual aids—rather than just one type of resource.¹ But you should make sure that your educational materials avoid some potential pitfalls, said Ms. Rozovsky.

From advanced language to computer literacy, are you asking too much of your patient? For older patients in particular, the Academy urges you to make sure that your written materials are easy-to-read and are written in plain language using familiar words and short sentences. “The sophistication of your brochures and DVDs is definitely an issue,” said Ms. Rozovsky. “But for me, an even bigger concern is the expectation that older

patients have computer literacy skills. There are firms providing wonderful Web sites with beautiful graphic interfaces, and physicians can tell patients, “When you get home, review this Web site and use the online tool to answer the questions at the end.” If patients are computer-literate, such Web sites can be a great educational resource. But when patients aren’t comfortable with computers, such an approach can short-circuit the consent process. “Suppose, for example, an elderly patient is struggling with the online interface for answering questions. At this juncture his 15-year-old grandson offers to help, and answers the questions on the grandfather’s behalf. If the ophthalmologist relies on those answers as confirmation that the patient understood the information on the Web site, then the exercise has been far from helpful,” said Ms. Rozovsky.

Are you providing information that is out-of-date or inconsistent? As a risk management consultant, Ms. Rozovsky regularly visits physicians’ practices. Two problems that she looks for are the timeliness and consistency of the patient education materials. “For instance, a device manufacturer or pharmaceutical company may have provided the practice with a great-looking brochure,” she said. “It is well-written, has nice graphics, and is easy to read and understand—but it doesn’t reference the same risks, benefits and alternatives as the consent document that the care provider provides. So instead of informing the patient, these incongruities confuse the patient. And to compound the problem, the clinic or tertiary care center may have a ‘fill in the blank’ document that lists yet a different set of factors.”

Review and document your materials. “At least once a year, your practice needs to review all the materials that it provides to patients,” said Ms. Rozovsky. “It is very important to make sure each item is up-to-date and that there are no incongruities between the various items. For each item, there should be an identifying version number and you need to keep a record of when it was last reviewed.”

For each patient, document which materials were used. “In the patient record, you should reference what educational items were used as part of the consent process,” said Ms. Rozovsky. “I’ve had clients who use a matrix. This is a brief checklist built into the patient record. They can then quickly check off that the patient was given a particular DVD and a particular brochure, and the version numbers of those items are also included.”

Keep a copy of every item, even ones you no longer use. “If, heaven forbid, there is a lawsuit several years from now, the fact that the medical record documents that a patient reviewed a particular version of the brochure won’t necessarily be very helpful unless you also have a copy of that brochure,” said Ms. Rozovsky.

The Physician’s Role Is Key “Tools are supportive only,” said Ms. Rozovsky. “They are not a replacement for the most powerful part of consent, which is the communication between the care provider and patient or surrogate—that is the critical piece.” In 2010, *EyeNet* will focus on key issues in the physician-patient dialogue—such as managing patient expectations and explaining statistics—and will compare different approaches to documenting informed consent.

1 U.S. Preventive Services Task Force. *Guide to Clinical Preventive Services, 2nd Ed.* (Washington, D.C.: U.S. Department of Health and Human Services, 1996).

Further Resources

Read four case studies that illustrate the consent process: Go to www.aao.org/ethics and select “Advisory Opinions” and then “Informed Consent.”

For tips on patient education, visit www.aao.org/patiented and select “Effective Patient Education.”

Visit the Web site of the Ophthalmic Mutual Insurance Company to download dozens of informed consent documents: Go to www.omic.com and select “informed consent.”