Risk Management Hotline

Clarification of Roles During the Informed Consent Process

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Recently, OMIC revised its sample consent form for cataract surgery, partly in response to the new "multifocal IOLs" and partly to better prepare patients for the procedure and defend ophthalmologists against allegations of lack of informed consent. Soon after the form revision was announced in our *E-Bulletin* and the *AAO Express*, policyholders began calling with questions about the roles they, their office staff, and the ASC play in the informed consent process.

Q I just reviewed OMIC's new cataract consent form. Do you really expect me to review all six pages with each of my patients?

A The short answer is no. A more complete response should help clarify the phases of the informed consent process and the roles played by various members of the health care team. As the surgeon, you have a legal duty to obtain the patient's informed consent, which is best understood as an oral agreement you reach with the patient after the informed consent discussion. This face-to-face talk addresses the ophthalmic condition and the risks, benefits, and alternatives—including no treatment—of the proposed procedure. The discussion must always take place before the patient signs any consent form, while the patient is awake and aware, and free from the effects of any medication that could interfere with his or her ability to participate in the decision-making process. The form itself serves to document and verify that the informed consent *discussion* with you took place. Neither the form nor any video or teaching aids can substitute for the face-to-face talk with the surgeon.

Q Do I have to mention all known risks during my discussion?

A No. The standard discussion most ophthalmologists conduct is rarely as detailed as a procedure-specific consent document and usually consists of a summary of this information. You do, however, need to address any particular concerns of the patient as well as any condition that puts the patient at increased risk, and then write a brief note in the medical record. To help educate the patient and provide more details about the surgery, OMIC recommends that you give patients a copy of the procedure-specific consent form. Some practices ask the patient to read it before the preoperative meeting with the surgeon; others have a staff member go over it with the patient afterwards.

Q Can my staff members witness the patient's signature even if they were not present during the discussion?

A Yes, since what is being witnessed is the patient's signature. While they cannot obtain the patient's informed consent, staff members play an invaluable role in patient education. As a risk management measure, staff members should ask patients what procedure will be done and why before asking them to sign the form. If the patient does not appear to understand, staff members should inform you so that you can discuss the procedure again and clear up any confusion or misunderstanding. Staff members can then document that you discussed the procedure again with the patient and that the patient appeared to understand and signed the consent.

Q Can I just use the consent form at the hospital or ambulatory surgery center (ASC)?

A No, since that form's primary purpose is to document that the ASC or hospital has fulfilled its own, separate legal duties. The ASC or hospital cannot obtain the patient's informed consent for the procedure you are performing; only the ophthalmologist can do that. Hospitals and ASCs must *verify*, however, that the surgeon obtained informed consent before allowing the procedure or surgery to take place. ASCs and hospitals also have a separate duty to obtain what is known as general consent for the care and treatment provided at their facility by their employees and other providers, e.g., the anesthetist. There is no discussion of specific risks or benefits of the ophthalmic procedure when obtaining this general consent. ASCs and hospitals often use a single form both to verify that the surgeon obtained informed consent and to obtain general consent for care rendered at their facility. The patient is usually given this form to sign by a facility employee during the registration or admission process. To protect themselves against allegations of lack of informed consent, therefore, ophthalmologists should have the patient sign the procedure-specific consent form in their office and place it in the patient's medical record.