Information plus documentation a must for informed consent

By Stacey Butterfield

Informed consent saved my bacon,” urologist James E. Gottesman, MD, told attendees at the Medical Group Management Association’s 2011 annual meeting, held in Las Vegas in October.

In 1996, Dr. Gottesman was sued for late diagnosis of a patient’s prostate cancer. He won the case, and one of the jurors told him that the deciding factor had been informed consent documentation showing that the patient had been warned that a biopsy could miss cancer.

“Documentation deflected my negligence case. Documented informed consent is a must,” Dr. Gottesman said.

Good informed consent should be a concern for not only specialists but any physician who performs a procedure with risks, he said. “If you’re sticking a needle in somebody draining a joint, could they bleed? Might you not make the right diagnosis? Even with a Pap smear, it can’t hurt,” said Dr. Gottesman.

Dr. Gottesman has been a believer in thorough informed consent since residency, when he got his first computer and used it to create templates for consent documentation. “For the past 25 years, literally everything I did had a consent form that documented what I discussed with the patient,” Dr. Gottesman said. His template includes a different form for every procedure that lists, in plain language, all of the risks that would be covered in an informed consent conversation.

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Although he thinks all medical practices should be using something similar to his templates, many aren’t, he said. Some physicians may believe incorrectly that the patient has been warned that a biopsy couldn’t miss cancer. “The problem is we’ve been told that forever and yet it hasn’t worked,” he added.

Based on his experience, and situations he’s witnessed involving other physicians, Dr. Gottesman believes standardized informed consent forms are a better solution. “An awful lot of practices and some hospitals, they’ve got great consents for the procedures we do constantly. The procedures that are done rarely don’t have consents at all,” Dr. Gottesman said.

Electronic health records (EHRs) seem like a natural answer to the need for standardized forms, but so far they haven’t included them. “The bad news is that not one EHR provider has addressed or adopted consent forms. They don’t want to touch it because it’s litigious,” he said.

Until standardized, specific forms are available on a widespread basis, Dr. Gottesman recommends that physicians create them themselves. “You know the risks for every procedure. List them,” he said. “A product designed by Dr. Gottesman, called iMedConsent, can be used to produce procedure-specific consent forms. It’s sold by Dialog/Medical. Dr. Gottesman disclosed that he has no financial interest in the company beyond consulting and reviewing forms.”

Patient communication

Dr. Gottesman also offered some advice on discussing consent with patients. “Biography can be administered independently, a process of sitting down with the patient and family,” he said. Having at least one member of the patient’s family present for the discussion is important because he or she may be more able to focus on the consent. “Sometimes the patients are off in another world,” Dr. Gottesman said.

If the patient has any particular impediments to understanding, it’s even more crucial to have a second listener, he added. “If they can’t speak English very well, or if you don’t think they’re very smart, bring in somebody else from the family.”

Many communication experts recommend the teachback method of explanation, in which patients repeat back what they’ve understood from the conversation, but Dr. Gottesman doesn’t always find that to be necessary. “As a physician, you’ve got a pretty good idea when somebody’s understanding,” he said.

A technique that he’s found successful is telling patients at the start of the conversation that you’re going to ask them questions at the end, in order to increase the likeliness that they’ll pay attention. “You don’t have to ask the questions. Just telling them that is enough,” Dr. Gottesman said.

For serious procedures, it’s also important to schedule this conversation far enough ahead that the patient has an actual opportunity to think it over. “If I had a person who would hem and haw, I gave them the consent form to take home,” Dr. Gottesman added.

The result of this process should be well-informed patients and fewer malpractice judgments, he concluded. Dr. Gottesman noted that apologies for adverse events have become popular, but he suggested that warning patients about negative outcomes before they happen can reduce patient unhappiness and lawsuits even more effectively.

“I do agree with apology and taking responsibility but ... proactive disclosure is ... a lot better,” he said.

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sioned in the Centers for Disease Control and Prevention’s Interim Guidance on Health Risk. Therefore, CMS has increased the total RVUs for annual wellness visits.

CMS had originally proposed to maintain the current relative values for the annual wellness visits, based on crosswalked values from the HCPCS G0438 and G0439 codes. However, in light of the comments received from ACP and other organizations, CMS is adding additional clinical staff time (and its associated Practice Expense [PE] RVUs) to the annual wellness visits.

The College strongly recommended that the health risk assessment should receive additional RVUs because of the additional work and practice expense it will require.

The reimbursement for the health risk assessment will be included in the reimbursement for the annual wellness visit. The new values are based on the level 4 evaluation and management codes 99204 and 99214 with an additional 10 minutes of clinical staff time for G0438 and an additional 5 minutes of clinical staff time for G0439.

In “subsequent annual wellness visits providing personalized prevention plans” certain elements should be updated based on information developed during the first annual wellness visit (for example, lists of risk factors and screening schedules).

Since all visits that follow the first one are considered subsequent annual wellness visits, the health professional should update elements that were developed during the previous visit if there have been changes.

The Agency for Healthcare Research and Quality describes the key features of health risk assessments, associates them with successful health risk assessments, and discusses their applicability to the Medicare population. ACP commends CMS for including this guidance on the content and conduct of health risk assessments.

By definition, a “health risk assessment” is an evaluation tool that collects self-reported information about the beneficiary or administered independently by the beneficiary or administered by a health professional before or as part of the annual wellness visit encounter, is approxi-