Informed Consent

By Jeffrey A. Woods, JD

Where there is a bad outcome in claims, we frequently find the consent process, or at least, documentation of that process, was lacking. Plaintiffs' attorneys are eager to assert the old adage that, "if it's not documented, it wasn't done." While that is not necessarily true, it is certainly more difficult to prove that it *was* done if it wasn't documented.

Lack of informed consent can be a sole basis for a negligence claim or can be asserted as an additional claim in connection with other alleged acts of negligence. In the event of such a claim, thorough documentation of the informed consent discussion may prove to be the defining factor of a successful defense.

While informed consent is rarely the central issue in a lawsuit, it is almost always included as an allegation. In claims we have reviewed in which consent was an issue, it was related to the failure to review specific risks, benefits, and alternatives associated with a proposed procedure, as well as to ensure the patient had an opportunity to have his or her questions answered. It's well-settled that physicians have a legal and ethical obligation to provide patients with enough information with which they can make an informed election about the course of their medical treatment. What frequently gets overlooked in the informed consent process is that this discussion is an additional opportunity to establish or solidify rapport with patients, because it involves them in their medical care and helps to set realistic expectations regarding the proposed treatment plan or procedure. Many physicians seem to view informed consent as merely a necessary formality, a time to obtain the patient's signature on a form in order to allow a specific procedure to be performed or treatment or medication to be administered. In actuality, it is often the most important discussion a physician will have with the patient. It lets the patient know that

complications can and do occur.

Generally, it is the duty of the physician who performs the medical test or procedure in question to disclose pertinent information to the patient and ensure that valid consent is obtained. The physician may also be assisted by other healthcare professionals in providing patient education information or obtaining a signature on the consent form, but the individual who renders the care bears the ultimate responsibility for obtaining informed consent.

To be valid, the process must include adequate opportunity for the patient to have direct and meaningful dialogue with the physician and to be afforded the opportunity to ask and have questions answered to his or her satisfaction. The discussion should consist of language appropriate to the patient's level of understanding (i.e. in lay terms) rather than using complex medical terminology. It should be accomplished in an atmosphere that allows the patient to make thoughtful, well-considered decisions regarding his or her healthcare, which means the process should not take place after certain medications have been administered or in a rushed fashion just prior to a procedure. It is also important to remember that false reassurances intended to calm anxious patients may create unrealistic expectations.

The American Medical Association's (AMA) Ethical opinion E-8.08[1] sets forth the obligation of a physician to give a patient adequate information so that he/she may effectively exercise a right of self-decision. A patient may bring a lawsuit against a healthcare provider based solely on the allegation that he/she did not give consent to be touched. This type of claim is called a "battery." Examples would be the extension of surgery beyond what was authorized or operating on a part of the body other than that which was consented to by the patient. A second, and much more common, legal claim is that consent was not given based upon proper and adequate information. This is a "lack of informed consent" claim. Informed consent allegations are usually found as part of a typical medical malpractice action and arise from all types of medical situations in virtually every area of specialization. Thus, from a risk management perspective, the informed consent process plays a vital role in minimizing exposure to medical negligence lawsuits.

Informed consent may be either "express" or "implied." Express consent is given in writing or verbally and, generally speaking, is required for surgery, anesthesia, invasive treatments, and those situations specifically defined by statute as requiring consent (for example, HIV testing). Consent not given by a patient in writing or verbally, but understood from the circumstances surrounding the procedure or treatment at issue, is known as implied consent. Implied consent normally is given in routine office practice. Implied consent may be inferred when a patient seeks treatment or shows a willingness to go through with a particular course of treatment. For example, if a patient, without speaking, rolls up his or her sleeve and holds out an arm in response to a request to take a blood pressure reading, that conduct indicates implied consent to the process.

Consent is also implied in emergency medical situations. Typically, the patient must have a life- or health-threatening medical condition, and it must be severe enough that any

delay in treatment would have a serious negative impact on the health and well-being of the patient. Also, the patient must be so incapacitated that he or she cannot be expected to make an informed choice regarding treatment. Under these circumstances, a physician is justified in undertaking medical treatment without consent. However, if there is a spouse (unless legally separated), parent, adult child, adult sibling, or grandparent available, it is advisable that consent be obtained from that person.

A competent adult or parent may consent to treatment. If the patient does not possess the mental capacity to understand the nature and consequences of authorizing treatment, someone who holds a durable healthcare power of attorney may consent. In the absence of such individual, the next course would be to turn to a surrogate decision maker – spouse (unless legally separated), adult child, parent, adult sibling, or grandparent.

Generally, a physician is required to disclose information that the average patient would need to know in order to be an informed participant in the decision. This "reasonable patient standard" is applicable in a majority of states, including Tennessee, Arkansas, Kentucky, Alabama, Mississippi, Georgia, North Carolina, and Oklahoma. Virginia's standard for informed consent, however, is a "reasonable *physician* standard".[2] Regardless of which standard applies, a physician need not disclose all of the risks or complications that may occur, but he/she should discuss those risks most commonly associated with the procedure or treatment and which have a reasonable chance of occurring, as well as those risks which have a small chance of occurring but have grave consequences.

A thorough consent process optimizes patient care and rapport and helps to minimize medical malpractice exposure, which is a win-win situation for all involved. Engage in a full and clear discussion with patients about the nature of their medical condition, the recommended treatment plan, and the risks, benefits, and alternatives. Doing so not only discharges your legal and ethical obligation to provide patients with sufficient information with which to make an educated election about the course of their medical care but may also help create realistic expectations on the patient's part as to the outcome of treatment. Be careful not to educate above a patient's comprehension level.

Risk Management Tip: Be sure the details of all discussions with patients are documented in your office record rather than relying on hospital consent forms that are not procedure-specific and may not capture all details of the conversation.

In the next issue, we will discuss best practices with documentation of the consent process.

[1] Ethical opinion E-8.08

[2] This reasonable physician standard requires disclosure of the information that a typical physician would give about the treatment, procedure, or surgery.

No Perfect Cases

By John T. Ryman, JD

On June 1, a 24-year-old obese female patient at 11 weeks gestation presented to the OB-GYN clinic to see Dr. Smith.[1] She had been treated at the clinic for her three prior pregnancies. At the patient's visit on September 3, Dr. Smith scheduled the patient for a three-hour glucose tolerance test (GTT), which was performed on September 12. According to those test results, the patient did not meet the criteria for gestational diabetes. The patient was seen at the clinic on October 6 and again on October 23, and at the latter visit, the patient was found to have lost nine pounds and had 3+ glycosuria. The patient reported that she had been suffering from a stomach bug and had been drinking a high-sugar content sports drink while in the waiting room. The weight loss was consistent with the reported illness, and glycosuria was attributed to consuming the sports drink. The patient also had a history of late-term weight loss in a prior pregnancy.

On October 28, the patient presented to the small local hospital with complaints of nausea, vomiting, and shortness of breath, and she was transferred to a regional hospital with a diagnosis of severe diabetic ketoacidosis. The patient was induced, resulting in a stillborn male at approximately 33 weeks. The autopsy report stated multiple causes of the stillbirth, with the mother's diabetes being the most likely cause.

The patient filed a lawsuit alleging that Dr. Smith failed to properly diagnose and treat her blood glucose levels, resulting in the death of her child. She sued for medical expenses, loss of earnings and earning capacity, loss of income, burial expenses, and non-economic damages for loss of love and companionship.

The plaintiff's OB-GYN expert opined that the child should have been delivered by

Caesarean section on October 23. His opinion was based on the patient's numerous health issues including obesity, excessive weight gain, and a family history of diabetes, yet he could not cite any medical authority for his opinions.

The plaintiff claimed non-economic damages, which were capped by state law, and economic damages of approximately $950,000. The economic damages claims were supported by the testimony of an economist expert for the plaintiff.

Dr. Smith's defense theme included that he appropriately and timely performed testing for gestational diabetes with negative results. The subsequent weight loss and finding of 3+ glycosuria was not indicative of development of gestational diabetes, and the evaluation at the October 23 office visit was reasonable based on the patient's report of illness and drinking a sugary sports drink in the waiting room. Absence of documentation from the October 23 visit, and the report of recent illness or of drinking a sports drink while waiting for her appointment complicated the defense. Dr. Smith recalled the information and testified to this in his deposition, but better documentation would have strengthened the defense. However, the defense theme was supported by multiple standard of care experts.

A placental pathologist disputed the conclusion in the autopsy report and reported that the autopsy slides indicated that the child did not die as a result of gestational diabetes. There were signs of maternal vascular issues, but the placenta was not typical for a diabetic mother. The expert opined that the most likely cause of fetal demise was placental abruption.

A maternal-fetal medicine (MFM) specialist who reviewed the case for the defense opined that Dr. Smith complied with the standard of care. There was no requirement to repeat the GTT. He believed that the patient suffered from either a UTI or gastroenteritis, which sent the patient into ketoacidosis. Earlier delivery on October 23 would probably have resulted in a stillborn or severely impaired baby.

Another maternal-fetal specialist reviewed the case and concluded the patient was not a chronic diabetic and did not develop gestational diabetes. Further, Dr. Smith appropriately screened the patient for gestational diabetes. Considering the findings of the placental pathologist, this MFM reviewer opined that an unrecognizable placental abruption led to death of the unborn child. According to this reviewer, all care by Dr. Smith was appropriate and within the standard of care.

Defense counsel recommended defending the case through trial; Dr. Smith wanted to defend his care and did not give consent to settle. Trial started nearly five years after Dr. Smith treated the patient and lasted a total of five days. The plaintiff was a likable person and made a good and sympathetic witness. Her case was primarily based on sympathy; however, the medical and factual evidence at trial strongly favored Dr. Smith. Dr. Smith and his three experts were all strong witnesses, appearing in-person at trial. They effectively refuted the plaintiff's claims with facts and medical science, explaining the standard of care and how Dr. Smith met that standard. Further, they were able to offer a plausible alternative theory for the cause of the death. At the end of the five-day trial, after

about two hours of deliberation, the jury returned a verdict in favor of Dr. Smith.

There are no perfect cases for either the plaintiff or the defendant. Perfect cases never get to the courtroom. Thus, trial is always somewhat risky, and it is unlikely that there are any doctors who enjoy being the defendant in a trial. The outcome of a fight is rarely certain. However, this case is an example of when a good doctor fought to defend his care and prevailed, despite the tragic outcome.

[1] All names have been changed.

Managing the Quality of Patients' Wait

By Elizabeth Woodcock, MBA, FACMPE, CPC

Patients now wait 24 days to see a specialist, up 30 percent since 2014, according to a survey of specialists in the 15 largest U.S. metro areas.[1] As patients wait longer just to get open appointments to see their physicians, making them linger another 30-plus minutes in the reception area on the day of the visit could seem like an additional insult. Yet, eliminating all wait time — whether to the next open appointment or on the day of the visit — is next to impossible in many physician practices. Patients may intellectually accept the difficulty of delivering a service as complex as medical care on a time schedule — one patient might take 30 minutes, the next one just five minutes — but that knowledge does little to erase negative emotional responses to delays. Making matters worse, the longer the *perceived* wait, the more patients expect from you and your staff.

Assuming you have, or plan to, consider more complex approaches to improve overall access — offering express clinics, self-scheduling, group visits, and so on — let's take a look at one portion of the waiting experience that you can quickly improve: the *quality* of the wait, specifically, what the patient experiences at the time of the visit. Your efforts to improve the quality of patients' wait times not only can reduce frustration, but it could also make a positive impression on patients.

Be aware of wait times. Make tracking wait times a key function of your receptionists' responsibilities. They can use the patient arrival function in your practice management system to keep track of the time of each patient's entrance and (ideally) when they are escorted to the clinical area. Lacking an automatic method, use small, inexpensive timers with magnets on the back. Get a magnetized white board, recording patients' names as they check-in. Place the timer adjacent to the name (and start it), allowing the receptionist

to track the wait time of each patient. Erase each name as the patient is roomed. This white board – viewable only to staff – would be constantly changing, but it would serve the purpose of keeping you cognizant about waits.

Keep patients informed. To prevent discontent over delays from reaching a boiling point, plan to intervene at about the 20-minute mark. Once a patient has waited 20 minutes, communicate with him or her about the wait. Start with an apology for the delay. Then explain the cause in very general terms: "your doctor's patient visits are running longer than we expected this afternoon," or "your physician was called to an emergency offsite this morning," and so on.

Offer to reschedule. After a certain time period – let's say an hour of waiting – it may be helpful to offer patients the opportunity to reschedule. From a clinical perspective, this may not be an option for all patients, but it may be a viable (and appreciated) alternative for some. From a practical perspective, you'll do no good proposing a new appointment time that is many weeks away. Even if it requires a manager's intervention into the scheduling process, find places to quickly fit in the rescheduled patients. If rescheduling isn't an option, when the wait time becomes significant (say, that hour mark), the physician's nurse or medical assistant should come out to speak with patients about the delay. Meanwhile, the reception staff can telephone patients scheduled for the remainder of the day's session to offer new arrival times or, perhaps, to reschedule their appointments. Maintain gift cards at the front office for a complimentary beverage or snack at an onsite cafe or nearby business; offer them to patients when wait times become excessive.

Convert the "waiting room" into a "reception area." Sure, renaming the area where patients wait to be seen seems like window dressing, but it's a start on creating a new attitude for you and your patients. Instead of giving patients the perception that you expect them to wait, your practice will be saying, "we're ready to receive you."

Make the "reception area" receptive. It may require a small investment, but items like natural (or natural-like) lighting; soft, soothing music; comfortable furniture; an agreeable temperature; clean, accessible restrooms; and a comforting color palette tell patients that you do care about their experience. Stocking the room with current magazines and a television also helps, but don't stop there. Here are more ways to make waiting a little less annoying in your practice:

Refreshments. Offer water or a coffee bar. Install a machine that provides self-serve specialty coffee and hot water for tea (but not if your practice serves small children).

Wireless Internet. Nearly every patient has a device that can log onto the Internet, so why not offer the amenity of access to them, particularly if you don't want them chatting on their cell phones while they wait (which can be disruptive to other patients). Providing wireless Internet allows waiting patients to work, communicate with friends and family, or just play. (To avoid hackers, work with a reputable technology company to set up a secure wireless network specifically for your patients' use.)

Children's entertainment. Provide used children's books in good condition; shop a consignment sale at least once a year to replenish your supply. Go further by offering visual treats, such as a model train suspended from the ceiling, with a button on the wall for children to start the train. Put a carnival mirror on the wall. Turtles in a tank are another great entertainment option.

Art. Perhaps some of your staff or patients are painters, photographers, quilters, etc., who would like to display their works on your walls. Place school projects by the children of staff and physicians or hold a photography contest for staff – or patients – to enter. In addition to showcasing local talent, your reception area will be decorated for free or at a very low cost.

Faces. Photographs of the physicians, providers, and staff with some professional and personal information can help establish a "personal" relationship between patients and your practice. Ask your physicians, providers, and staff to bring in baby pictures – of themselves. A display of your baby pictures will provide significant entertainment.

Marketing. Since you'll have your patients' undivided attention for at least a few minutes in the reception area, use the opportunity to promote your practice's services and provide helpful knowledge to patients. Display a PowerPoint presentation (a good one with high-quality photos and other images) on a large flat screen monitor in the reception area. Slides can discuss the benefits of your website or patient portal, practice policies, new services, and new clinicians or staff. Intersperse the marketing with displays of patient education and community resources.

In today's web-linked world of instant answers, online shopping, and one-day deliveries, managing patients' perspectives about your practice becomes ever-more important. Tending to the quality of your patients' wait can give them a reason to come back and recommend your practice to friends and family. As the old saying goes, it's the little things that count.

[1] *"2017 Survey of Physician Appointment Wait Times and Medicare and Medicaid Acceptance Rates."* *Merritt-Hawkins*

CMS Final Rule - Omnibus Burden Reduction

By Elizabeth Woodcock, MBA, FACMPE, CPC

On September 26, the Centers for Medicare & Medicaid Services released a Final Rule titled "Omnibus Burden Reduction." While the rule focuses on processes within health care facilities, a multitude of these changes will impact physicians practicing there. To highlight a few areas, CMS ruled:

1. Portable x-ray services can be ordered in writing, by telephone, or by electronic methods; the requirements for technician training is reduced.
2. Hospitals can reduce their requirements regarding pre-surgical assessments such that an outpatient visit can be used in lieu of a comprehensive H&P in certain circumstances.
3. Advanced practice providers can document progress notes in psychiatric hospitals.
4. Community health centers will be under policy review every two years, instead of annually.
5. Ambulatory surgery centers are no longer required to ensure that physicians have hospital admitting privileges, replacing the requirement with an "effective" transfer procedure.

These are only a handful of the revisions announced by CMS as part of the government's "Patients over Paperwork" initiative. For more information, read CMS' press release.
