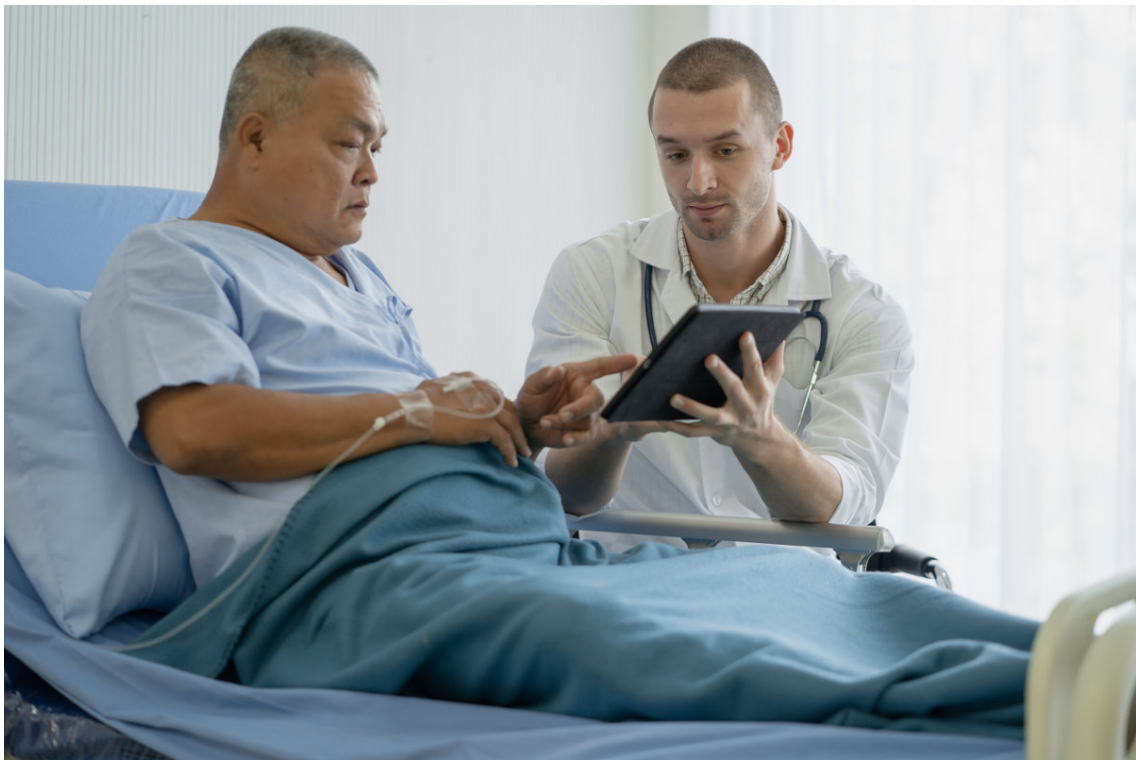
Informed Consent: Best Practices



By Jeffrey A. Woods, JD

This article is the second in a series of two; the first appeared last month and can be accessed here. In the previous article, we discussed important concepts of the informed consent process, including the need to document the discussion.

What are best practices when documenting consent? Documentation of the informed consent process should occur contemporaneously with the discussion and prior to the performance of a procedure. The practice of documenting the consent process **after** the fact (e.g. in an operative note) could be viewed as self-serving if there is an adverse event.

The most thorough informed consent process may be negated if there is no contemporaneous documentation to evidence that such a process took place. Poor or absent documentation forces a physician to testify from memory about an event which probably occurred several years earlier and negatively impacts his/her credibility as a result. Furthermore, poor or absent documentation may be a significant factor in the decision of a patient's attorney to pursue legal action in the first place. On the flip side, a well-documented and thorough informed consent may be the deciding factor for a

plaintiff's attorney not to pursue litigation at all.

Ideally, the informed consent discussion should be documented in both the patient's chart and in a separate consent form that is signed by the patient/representative. (If this discussion takes place in the office setting, it should be included within the office record.) Avoid generic forms. As an example – a hospital's boilerplate consent form typically does not include the risks unique to the patient and may not accurately reflect your discussion with the patient. In many cases we reviewed, the only documentation associated with the consent process was a boilerplate hospital surgical consent form, which did not reflect the details of the discussion during which surgeons outlined the risks. This made it difficult for the defense to argue that the particular surgical complication had been explained to, and was understood by, the patient prior to the procedure. Remember, it is the *discussion* that takes place between the physician and the patient (or patient's legal representative) that constitutes the basis for the consent to be informed. The consent form that is signed by the patient or representative is merely evidence memorializing that the discussion took place and the patient/representative understood the information discussed.

Some specialists do not always have the benefit of access to the patient's entire chart to document the informed consent discussion for their respective care, but, for example, in anesthesia, the content discussion should be documented in the pre-anesthesia record.

Since lack of informed consent is often an allegation in a malpractice lawsuit, let's review the specific documentation requirements of informed consent.

In order to ensure that the patient has been given sufficient information with which to make an informed decision as to the course of his/her medical treatment, the following should generally be discussed and documented in the medical record:

- Details of the nature of the patient's illness and diagnosis
- Indications for the proposed treatment plan, procedure, or medication, as well as the anticipated prognosis
- A description of the proposed treatment or procedure, including medication that will be prescribed, and its purpose
- The probable outcome, particularly if it is difficult to predict, and the patient's expected post-procedure/treatment course
- Potential modifications or extensions of the treatment or procedure
- The possible benefits of having the procedure
- The most likely and severe risks and side effects of the procedure and treatment or medication, preceded by a general inclusive statement, such as "including but not limited to"
- A statement about unexpected complications/additional medical procedures
- Reasonable alternative methods of treatment or no treatment, including the risks, benefits, and the prognosis associated with each alternative or with no treatment
- Notification of experimental or investigational procedures

For additional specifics to include, SVMIC policyholders and staff with a Vantage account may refer the following document: Sample Informed Consent Form.

Regardless of whether the office uses a paper-based medical record or an electronic health record (EHR), the informed consent process should be documented either through a consent form or through a detailed note in the medical record. Both forms of documentation should reflect all of the pertinent information given to the patient, specify what supplemental information was given, and indicate that the patient was given the opportunity to ask questions and have them answered. The name of a witness (if any) to the consent process should also be recorded on the consent form or in the medical record, and written documentation should be made as soon as possible after verbal consent is given. It is a good idea to have a place on the consent form for the patient to sign, preceded by a statement that he/she understands the information given, has been given the opportunity to ask questions and has had all questions answered, and consents to the medical intervention. Documentation of the consent process in the medical record should be noted by the practitioner as well. In an electronic system, this may require that the forms be printed and then scanned after signing, or that the system allow for an electronic authentication process to be employed by the patient.

Avoid the use of summary statements such as “The patient was advised of the potential risks/complications of the operation and alternatives.” Instead, note at least some of the actual risks, complications, and alternatives discussed with the patient. For example, a better entry would state that “information regarding the risks, complications and alternatives was discussed with the patient and/or family, including but not limited to…”, followed by the specific information discussed and any questions asked by the patient.

While the most serious risks for a procedure may be rare, it’s important to include those in your discussion and documentation as well. Juries may factor in the patient’s willingness to undergo surgery, which could potentially result in infection, bleeding, injuries to adjacent organs, and death when weighing the patient’s allegation that they would not have undergone a procedure if they had known about the complication of something more minor.

If using an EHR, the use of automated reminders or prompts might be employed so that when a procedure is scheduled, the practitioner is alerted to complete an informed consent discussion and the appropriate resources are made available for printing at that time. In addition, the prompt could include electronic links to the educational material that may be given to the patient as well as the appropriate consent form. Some EHRs may also include a pre-programmed default, which would document that the material was given to the patient, that a full discussion of the potential risks, benefits, and alternatives of the proposed medications or treatment took place, and that the patient gave full consent. However, if this default language does not include the details of the conversation, such as the specific risks and benefits that were discussed, the physician may need to add this information to the documentation.

Informed Refusal

The concept of informed refusal is the flip side of informed consent. Informed refusal acknowledges that every competent patient has the right to refuse a recommended test, procedure or treatment but requires the physician or healthcare provider to inform the patient of the risks of that refusal.

While most people are more familiar with the concept of informed consent, informed refusal is not an unusual allegation in medical malpractice litigation. In order to successfully defend against an allegation of informed refusal, there should be documented evidence that the patient was provided sufficient information regarding the risks of forgoing treatment. Both informed consent and informed refusal are predicated upon the notion that a patient is entitled to all information necessary to make an informed choice. Patients benefit from these discussions by becoming more knowledgeable about the recommended treatment and more vested in his or her own healthcare. Physicians benefit because informed patients tend to have more realistic expectations and are less likely to sue for malpractice even when faced with a less than optimal outcome.

If a provider encounters a competent patient who refuses recommended testing or treatment, rather than simply noting the patient's refusal, try the following steps:

- Ask about the reasons for refusal
- If it appears the refusal is due to a lack of understanding, re-explain the rationale for the procedure or treatment in lay terms, emphasizing the probable consequences of refusal.
- Document the patient's refusal and reasons for such; emphasize that the patient understood the risks of refusing the recommended care
- Try also to obtain the patient's signature on an "informed refusal" form (SVMIC policyholders and staff with a Vantage account may download a sample of a general informed refusal form here: **Sample Informed Refusal Form**). By using a refusal form, the patient may better appreciate the potentially serious consequences of his or her decision. If the patient refuses to sign the form, the documentation in the record regarding any discussion(s) with the patient, his or her reasons for refusing the care and his or her refusal to sign the form will suffice.
- If the patient was referred to the physician as a consult, the physician must be sure to document the previously-listed information in a letter to the referring physician

Thorough documentation of the informed consent/informed refusal discussion may very well prove to be the defining factor of a successful defense. Certainly, anytime there is an invasive procedure, anesthesia/sedation, treatment, testing, medication or injection that presents a risk of bleeding, infection, burns, fainting, severe adverse reaction, damage to adjacent structures/tissue, blindness, paralysis, loss of organ or death, informed consent should be obtained and documented. This is best done by providing the appropriate information for the patient or representative to make an informed decision, thoroughly documenting that discussion in the chart and, if possible, having a procedure-specific written consent form signed.

The contents of The Sentinel are intended for educational/informational purposes only and do not constitute legal advice. Policyholders are urged to consult with their personal attorney for legal advice, as specific legal requirements may vary from state to state and/or change over time.