CNA HealthPro

An Informed Consent Primer

During our dental risk management seminars, we often see exasperated looks on dentists' faces when the topic turns to informed consent. Their faces seem to ask why they should bother to use valuable chair time to talk about the proposed treatment or ask for an acknowledging signature. After all, they've practiced their entire careers without incident, without ever formalizing the informed consent process or using a written consent document.

Although some dentists may consider the informed consent process burdensome and time consuming, it does have a number of positive risk management effects. The informed consent discussion represents the first step in managing the patient's expectations for treatment outcomes and reducing the possibility of a misunderstanding. Patients who have an understanding of the risks of treatment will be less likely to institute a malpractice claim if one of the described risks actually occurs. Additionally, chart documentation of the informed consent process provides the best defense against patient allegations that they were inadequately informed about the proposed treatment, the treatment options available, or the potential for injury. Furthermore, a patient alleging a claim based upon "lack of informed consent" must prove that informed consent was not given. Good communication and documentation by the dentist will increase that burden and act as a deterrent to allegations of a lack of informed consent.

Many claims of professional negligence are accompanied by an allegation of a lack of informed consent. In such an action, the patient may allege that the dentist was negligent in not properly educating the patient. Moreover, if the patient had known in advance of the treatment or procedure that a bad result was possible, he or she would have withheld consent.

It is uncommon for a claim to solely allege lack of informed consent, without other claimed damages. In many instances, we find that the dentist met the standard of care in the delivery of services, yet the patient felt wronged in some way, usually due to a lack of communication. In today's consumerist environment, the informed consent process assumes greater importance as a vehicle for patient education, doctor-patient communication, and sound risk management.

What is it?

Informed consent represents the exclusive right for patients to determine what is done to their bodies. In the United States, it has developed primarily over the past century from the legal concept of battery, which is the unauthorized touching of another person. Through the years, numerous legal cases have affirmed the health care provider's duty to obtain a patient's informed consent before treating.

Informed consent is the process through which a patient is provided sufficient information to make an informed, reasoned decision regarding the proposed treatment. All states require that a patient provide a dentist with his or her informed consent before each evaluation or treatment is started. The consent must be given without coercion or fraud, based upon the patient's reasonable understanding of what will take place.

The informed consent process involves two main components. They are the discussion, including disclosure and patient education, and the documentation in the patient record, which often includes the use of written informed consent forms.

Except in an emergency situation, whenever you ignore the wishes of a patient and proceed with treatment without the necessary consent, you may be subject to malpractice litigation. Litigation may ensue notwithstanding your professional opinion that treatment was in the best interest of the patient. You may also have committed the criminal offense of battery.

Most patients have a reasonable idea of some dental procedures that occur during routine examination or treatment. Thus, patients imply their permission to have work done when they visit an office for routine care. Implied consent, however, has severe limits as a legal defense. Dentistry is a highly technical profession, and patients often have a limited understanding of the procedures to which they have assented. The law employs the concept of informed consent to protect patients from making uninformed decisions about their welfare.

We encourage dentists to consider the informed consent process an educational experience, with the patient as the student and the dentist as the teacher. Although staff members, brochures, and electronic equipment can assist in educating the patient, the ultimate responsibility for ensuring the patient is informed rests with the dentist.

Disclosure and discussion

Informed consent is a process, not a specific document. The process requires a verbal component regardless of whether a written form is used. As such, a patient can give an oral informed consent. An exclusively oral informed consent is valid in most jurisdictions. However, individual state requirements govern in this area. The goal of informed consent is the same whether you have an entirely oral discussion or couple it with a written form: the patient must have an adequate understanding of the proposed treatment to provide you with the consent necessary to begin treatment.

Your diagnosis and treatment plan should serve as the framework for your informed consent discussion with the patient. The information provided as a basis for informed consent will differ based on the complexity of treatment and on the degree of risk presented by the proposed treatment. For example, the information for an orthognathic surgery consent should, therefore, be significantly more detailed than for a facial composite discussion. Treatments which are within the general understanding of the patient, either through past experience or general knowledge, require a less detailed explanation.

The doctrine of informed consent requires that the patient be given sufficient information about, and consider, three main components, which you are required to disclose and discuss with the patient. They are:

- the *nature* of the proposed treatment,
- any reasonable *alternatives*, and
- the *risks* and potential complications of the proposed treatment.

Information pertinent to the *nature* of the proposed treatment should explain why your diagnosis justifies the *need* for treatment, as well as an explanation of the anticipated *benefits*. State your diagnosis and indicate why you chose the treatment over other options.

An approximation of the *prognosis* of the treatment is required. No dental provider can, or should, promise a specific prognosis to a patient. Indicate the prognosis in general terms such as excellent, good, fair, or poor. Give the prognosis for the “big picture,” not simply for the procedure at hand, as the patient has a right to consider all pertinent information when determining a course of treatment. More extensive discussions with the patient about any treatment recommendation with only a fair prognosis would help the patient make a more informed decision. Treating patients with a poor prognosis is a risky proposition and should be avoided. Keep in mind that predictive analyses such as model surgery and computer-altered photos may create patient expectations that exceed the final case result.

Advise the patient of an approximate *cost* of the treatment, and estimate the *time* involved. Cost isn't part of the informed consent doctrine, per se, but more patients will make treatment decisions based on finances than on any other single factor. Therefore, the expenses should be included in the discussion. Be certain to update the patient whenever there is a change in cost, time or prognosis.

> A patient also must be informed of and understand the *alternatives* to the recommended treatment. This includes the alternative of forgoing treatment, when appropriate. Also, whenever the proposed treatment falls within what a specialist would normally perform in that specialty, the alternative of specialty referral should be offered

You are not ordinarily required to list every available alternative procedure. However, the alternatives must contain those procedures most relevant to specific patients and their oral and overall health conditions. The alternatives presented are usually those that have a better prognosis, are less costly, involve less time, require less follow-up care, or are less irreversible. Patients should be told why the recommended treatments are preferred over the alternatives. Patients should understand at what point in the treatment certain alternatives will no longer be available.

Lastly, the patient's treatment decision should consider the *risks* and potential complications of treatment. You are required to inform the patient of the foreseeable, material risks of the recommended treatment – those which have a reasonable likelihood of occurring and about which a reasonable person would be assumed to take an interest. We also recommend that you advise the patient of the risks of refusing the recommended treatment. As with the discussion of alternative treatments, the list of potential risks need not be all-inclusive, but should be pertinent to the patient's oral and overall health. Concentrate on risks that are likely to occur, such as swelling after an extraction or root sensitivity after scaling, or those with high severity, such as post-operative infections, tooth loss, and paresthesia.

Throughout the informed consent discussion, the patient should be given every opportunity to ask questions. Your duty is to answer the questions as clearly and completely as possible and to confirm that the patient understands your replies.

"Informed"

To be considered "informed," the patient must be given enough information upon which to base a decision *and* understand that information. One way to gauge both your level of disclosure and the sufficiency of the patient's understanding is to see if the patient is able to pass a "quiz" about the proposed treatment by answering three basic questions that relate to the main components of informed consent. Ask the patient:

1. What treatment is proposed and why has it been recommended?

2. What other choices do you have?

3. What bad things might happen as a result of (or lack of) the proposed treatment?

The next step is for the patient to state his desire to either pursue or decline the proposed treatment. The patient has a legal right to decline your treatment recommendation and refuse care. If this occurs, you must explain to the patient the consequences and foreseeable risks of refusing treatment. Also ask about the patient's reasons for refusing care. If the patient states, or if it appears, that the refusal is due to a lack of understanding, re-explain your rationale for the procedure or treatment, emphasizing the probable consequences of the refusal.

Discussion suggestions

Lawyers and judges have noted that *how* something is said is just as important as *what* is said. We recommend that the treating dentist lead the informed consent discussion when obtaining informed consent.

Although you may have presented informed consent information thousands of times, it is probably the first time the patient is hearing it. “Dentalese” is often confusing, so use basic, uncomplicated language the patient will understand. If you use technical terms, provide explanations. Approach the discussion with empathy and reason, and give all participating parties every opportunity to ask questions. Present your need to obtain informed consent as a benefit to the patient. When patients are made aware that the discussion is for their own best interests, they will be more receptive and cooperative with the process.

There are many ways to inform and educate patients, including the use of CD-ROMs, pamphlets, professional or self-made videos, placards, and discussions with staff members. Regardless of what methods are used, it remains the ultimate responsibility of the treating dentist to ensure that the patient understands what has been presented and to answer any remaining questions. Always ask the patient, “Do you have any questions about the information you have been given or about the proposed treatment?”

When appropriate, it may be prudent to encourage the patient to have a family member present in the room during the informed consent discussion, both for emotional support and to assist in achieving an understanding of the information. At other times, it may be desirable for you to have a staff member present during the informed consent discussion to witness the conversation and make the patient feel more at ease.

When treating a minor, it is necessary to first obtain the informed consent of a parent or legal guardian prior to beginning treatment. A minor cannot consent to his or her own treatment unless legally declared emancipated by the court or determined to be emancipated pursuant to state law. In situations where the adult patient is legally incompetent or unable to understand his or her decision, obtain the consent of the legal guardian.

It is advisable to get the patient’s informed consent at a visit prior to the treatment visit whenever possible. Their return for treatment on the date of treatment is further validation of their desire to have the recommended treatment.

Finally, ask for the patient’s approval to perform your recommended treatment. And remember, any treatment rendered without the patient’s consent may result in allegations of battery or other charges.

Communication problems

If your patient cannot understand the informed consent process due to a foreign language or other barriers, it is likely that you cannot obtain the necessary *informed* consent. In such cases, invite the patient to bring a family member or friend to translate when needed. Thoroughly document who translated and what was said. Include the translator’s name, address, and telephone number in the body of your progress note for that day. If you routinely treat patients who speak the same foreign language, have your consent forms translated into that language to facilitate the informed consent process.

Informed consent documentation

In dental professional liability litigation, the defendant dentist often must present documented (verbal, written, tape recorded, etc.) evidence in court to prove that an informed consent discussion took place. There are two important elements to informed consent documentation: verification that the discussion took place and evidence the patient understands and agrees to the treatment procedure. Whether supplied orally or in writing, receipt of the patient’s informed consent must be documented in the patient record. This is best accomplished by a written description of the informed consent discussion which has been signed and dated by the patient. Typically, a pre-printed form that permits the dentist to fill in specific information where appropriate is utilized.

Regardless of whether a written informed consent form is used, the dentist should write a progress note that reflects the specific consent process for that patient. It should thoroughly describe what was discussed, what questions were asked, what answers were given, who was present (including friends

and/or family members of the patient), what documents, brochures, or handouts were given to the patient, and that informed consent was given by the patient.

Your level of documentation should correspond with your assessment of risk for the recommended treatment and your comfort level with both the patient and the procedure. While it is appropriate to write a simple progress note that includes the abbreviation “RPIC” for “received patient’s informed consent,” it is much better to have both a written customized document and a detailed progress note. Examples of customizing the entry to the patient include listing additional important information regarding alternatives and risks (“patient understands the possibility of numbness...”) and specific questions answered (“patient asked about possible swelling; I advised her that moderate swelling was likely…”).

Whenever adjunct aids are used, their use should be documented in the patient’s record. This can easily be done with abbreviations or short notations, such as “Pt. and mother viewed RCT tape #3” or “Pt. given implant pamphlet #12-B.” In this way, you can refer back to the tape or pamphlet if questions arise in the future. It also serves to document your education of the patient. Keep in mind that an informed consent form is also an excellent tool for educating patients.

Ultimately, should a “lack of informed consent” claim be heard in court, a jury will determine the adequacy of the informed consent. A signed form does not guarantee that the defendant dentist will win a case of this nature. But, documentation of the informed consent discussion and the patient’s admitted understanding of the discussion will aid the defense of a “lack of informed consent” malpractice action.