Dentist Spotlight: Informed Consent and Refusal

Dentist's Advantage, in collaboration with CNA, has published our Dental Professional Liability Claim Report: 3rd Edition (3rd Edition Report). It includes statistical data and case scenarios from CNA closed claim files, as well as risk management recommendations designed to help dentists reduce their malpractice exposures and improve patient safety.

You may access the complete 3rd Edition Report, and additional Risk Control Spotlights, at: www.dentists-advantage.com/dentalclaimreport.

This Dental Spotlight focuses on our analysis and risk recommendations regarding one of the most significant topics in the 3rd Edition Report: **Informed Consent and Refusal**.

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.

Informed consent is the process through which a patient is provided sufficient information to make an informed, reasoned decision regarding the proposed treatment or procedure. The consent must be given without coercion or fraud, based upon the patient's reasonable understanding of what will take place.

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. By pursuing the treatment, you also may have committed battery.

Informed consent is the process through which a patient is provided sufficient information to make an informed, reasoned decision regarding the proposed treatment or procedure.

We encourage dentists to consider the informed consent process as 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 dentist bears ultimate responsibility for informing the patient.

The informed consent process involves two main components:

- Discussion, including disclosure and patient education
- Documentation in the patient record, which often includes the use of a written informed consent form

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 understand the risks of treatment will be less likely to institute a malpractice claim if one of the described risks occurs. In addition, healthcare information record documentation of the informed consent process provides the best defense against a patient's allegation that he or she was inadequately informed about the proposed treatment, the treatment options available, or the potential for injury.

Informed Consent 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. Exclusively oral informed consent is valid in most jurisdictions. However, a number of states require written informed consent. As a practical matter, a written informed consent form memorializes and, thus, documents that the consent protocol was implemented.

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 upon the complexity of treatment and its associated risks.

Components of Informed Consent

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

1. Nature of the proposed treatment

The discussion regarding nature of the proposed treatment should include the:

- necessity for treatment
- anticipated benefits of treatment
- prognosis of treatment
- time involved
- cost involved

The nature of the proposed treatment should explain why your diagnosis justifies the need for treatment. State your diagnosis and indicate the benefits of your recommended treatment, including comparison with other treatment options.

An approximation of the prognosis of the treatment is required. No dental provider can, or should, promise a specific prognosis or healthcare outcome to a patient. Indicate the prognosis in general terms such as excellent, good, fair, or poor. Consider the "big picture," not simply for the prognosis for the procedure at hand, as the patient has a right to consider all information important to their decision.

Advise the patient of an approximate cost of the treatment, and estimate the time involved. Always update the patient whenever there is a change in cost, time or prognosis.

Financial issues are the most common reason claims are instituted against dentists. Patients who believe they were not provided full disclosure of the fees in advance often feel deceived. The lack of full fee disclosure may be perceived as a "bait and switch" tactic to lure them into a costly commitment. Clearly, these perceptions may damage the dentist-patient relationship, as well as the patient's oral health in circumstances in which the patient cannot afford to continue with care.

Therefore, we recommend that dentists disclose the cost of the informed treatment decision at hand (e.g., root canal treatment (RCT) vs. extraction), as well as the approximate charges to complete the various treatment alternatives available (e.g., the cost for restoring a tooth after RCT). By fully disclosing the fees, you minimize the likelihood of a financial misunderstanding that leads to frustration for both you and the patient.

2. Alternatives to the proposed treatment

The discussion of the reasonable alternatives to the proposed treatment should include the following:

- when the proposed treatment falls within what a specialist would customarily perform in that specialty, the alternative of specialty referral should be offered
- the alternative of no treatment, when appropriate

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. In many cases, the preferred option with the best prognosis may also be more costly and invasive. Ensure that you also present acceptable options that are less costly, involve less time, require less follow-up care, or are less irreversible. Patients should be told why the recommended treatments are preferable to the alternative options. Patients should understand at what point in the treatment certain alternatives will no longer be available.

3. Foreseeable risks

The discussion of the foreseeable, material risks and potential complications of the proposed treatment should:

- define a foreseeable, material risk as one which has a reasonable likelihood of occurring and about which a reasonable person would be assumed to take an interest.
- advise the patient of the risks of refusing the recommended treatment

Similar to the discussion of alternative treatments, the list of potential risks need not be all-inclusive, but it should be pertinent to the patient's oral and overall health. Concentrate on risks likely to occur, such as swelling after an extraction or root sensitivity after scaling, or those with high severity, such as postoperative infections, tooth loss, and nerve injury/paresthesia.

To be considered "informed," the patient must be given sufficient information upon which to base a decision and understand that information. In order to assess the sufficiency of the patient's understanding, you may wish to determine whether the patient is able to pass a "quiz" about the proposed treatment by using the "teach-back" method. Ask the patient:

1. What treatment is proposed and why has it been recommended?
2. What other choices do you have?
3. What negative consequences may occur as a result of (or lack of) the proposed treatment?

The next step is for the patient to state their desire to either pursue or decline the proposed treatment. The patient has a legal right to decline your treatment recommendation and refuse care. (See the "Informed Refusal" section later in this piece for more information.)

Informed Consent Discussion Suggestions

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

- The oral discussion with the patient should be approached with empathy and reason and should be tailored to the needs of each individual.
- Use basic, uncomplicated language that the patient will understand. If you use technical terms, provide explanations. Limited oral health literacy is a significant barrier to effective informed consent discussions.
- Use brochures, pamphlets, models, educational DVDs and discussions with your staff to provide the patient with additional information about the proposed treatment.
- Give the patient every opportunity to ask questions. You should answer the questions as clearly and thoroughly as possible, and evaluate – and correct, if necessary – the patient's understanding of your replies.
- Where appropriate, 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.
- Secure the patient's informed consent at an appointment prior to the treatment visit whenever possible.
- Although staff members can assist in the informed consent process by helping to educate the patient, do not delegate the informed consent discussion to others. The patient must be given an opportunity to speak with, and ask questions of, the treating dentist before treatment begins.

Informed Consent Documentation

In dental professional liability litigation, the defendant dentist often must present documented (verbal, written, or recorded) evidence in court to prove that an informed consent discussion was conducted. There are two important elements to informed consent documentation:

- Verification that the discussion occurred, and
- Evidence that the patient understood and agreed to the treatment.

Whether supplied orally only or also in writing, receipt of the patient's informed consent must be documented in the patient record. A written description of the informed consent discussion, signed and dated by the patient, serves as the best evidence of this discussion. Typically, a pre-printed form that permits the dentist to insert patient-specific information, where appropriate, is used.

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. Your entry should include:

- What was discussed
- What questions were asked
- What answers were given
- Who was present, including staff and friends and/or family members of the patient
- What documents, brochures, or handouts were given to the patient and/or what patient information videos were viewed
- 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.

Although it may be efficient to write a simple progress note that includes the abbreviation "RPIC" for "received patient's informed consent," both a detailed progress note and a written customized document are preferable. A common progress note in dental records is "informed consent signed." This may be accurate, but it fails to document the required dentist-patient discussion.

Be aware that a cursory entry reading "risks, consequences, and alternatives were discussed" also has significant limitations. The dentist would still be required to explain in court the express discussion, without being able to refer to a comprehensive record of the specific points and topics covered.

Examples of customizing the progress note 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…").

Ultimately, if a "lack of informed consent" claim is 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. However, documentation of the informed consent discussion, as well as the patient's admitted understanding of the discussion, will aid in the defense of a "lack of informed consent" malpractice allegation.

Written Informed Consent Forms

Developing a Written Informed Consent Form

Written informed consent forms are used to supplement, but not replace, informed consent discussions. Most patients do not remember all that they were told during the informed consent discussion, making written forms a valuable reminder to both the patient and the dentist.

Written informed consent forms should:

- Use simple, plain language that the patient will understand.
- Specify the name of the dentist who will be providing care.
- Specify the name of the treatment(s), procedure(s), or test(s).
- Discuss the nature of the proposed treatment, its necessity and benefits, as well as the consequence of no treatment.
- List available alternative treatments to the recommended treatment.
- Discuss potential complications and general risks of the recommended treatment and any specific risks for this patient.
- Permit you to customize the form for each patient by using checklists and /or fill-in blanks.

Some dentists also include blank areas for patients to describe, in their own words, their understanding of the discussion. Written patient comments serve to verify that the patient has understood the information presented.

Informed Consent When Using Artificial Intelligence

Dentists that currently either use or plan to use AI may wish to consider adopting the risk mitigation strategies listed below, in order to minimize liability exposures.

- **Review and revise informed consent forms** to ensure that they address the uses of AI technology in your practice. Consider specific, purpose based disclosure and whether use affects clinical care, rather than a blanket statement that "this practice uses AI."
- **Explain that such systems depend upon a steady flow of patient data** and indicate the risk of privacy breaches and invalid or biased conclusions.
- **Obtain written consent from patients for the use of their anonymized data** in training AI algorithms and explain that they have the right to request to erase any personal data from AI systems.

Suggested Dental Procedures for Using a Written Informed Consent Form

We recommend written informed consent forms for procedures with high claim frequency, a significant risk of injury, and those having the potential for patient misunderstanding. The informed consent protocol should be implemented for various procedures, including but not limited to, procedures such as:

- Extractions
- Root canal treatment
- Crown and bridge
- Implants (both placement and restoration)
- Surgery involving incision and flap reflection (perio, endo, preprosthetic, etc.)
- Pediatric dentistry, including behavior management
- Cosmetic dentistry
- Orthodontics
- Temporomandibular dysfunction (TMD) treatment
- Sedation or general anesthesia (use a separate consent form)

We also recommend that you employ a written informed consent form with patients who may present an increased risk, perhaps due to an argumentative nature or forgetfulness. Always retain written consent forms in the healthcare information record and provide a copy to the patient.

Dental Professional Liability Spotlights

In the months ahead, please access the Dentist's Advantage Prevention and Education Web page to download the report and Spotlights on key risk topics:

- Protecting Your License
- Informed Consent and Refusal
- Patient Termination and Referral
- Procedural Sedation
- Crowns and Bridges

Case Study: Informed Consent

Facts:

A 50-year-old male patient in good health with an unremarkable medical history sought care from a general practitioner (GP). The patient presented with pain in tooth #20, which had previously undergone a root canal. The GP referred him to an endodontist, who recommended extraction due to a crack in the tooth root and advised the patient to consult the GP for replacement options. An implant-supported crown represented the most conservative treatment, and the patient consented.

The GP took a periapical radiograph and decided on a 10mm implant, with an estimated 2-3 mm of bone between the implant and the mental nerve. On the days following extraction and implant placement, the patient reported numbness of the lower lip and chin. The GP was confident of their implant placement but agreed to remove it to err on the side of safety. The GP also prescribed methylprednisolone.

The patient's symptoms improved over several weeks, but he sought a second opinion from another GP, who referred him to an oral surgeon. Both dentists found no issue with the implant procedure, and the surgeon advised the patient that continuing to monitor the tooth was appropriate due to his improving symptoms.

Six months after the implant procedure, the patient sued the original GP alleging negligent implant placement, inadequate informed consent, and a failure to refer for implant therapy. The patient sought $250,000 in damages for permanent nerve injury, future medical expenses, pain and suffering, and mental anguish.

Defense:

Review of the patient record showed meticulous implant planning and due diligence by the GP. Pre-treatment cone beam computed tomography (CBCT) imaging would have strengthened the defense, but experts agreed that this was not a breach of the standard of care. Unfortunately, the written informed consent document was missing from the patient's records.

However, the dentist's informed consent process was well-documented in office procedures and other patient records. His process always included a progress note about the doctor-patient consent discussion, in addition to the use of consent forms. Although the progress note did not include the full details of the written consent form, the documentation supported that a valid informed consent was obtained.

The patient's symptoms had improved by approximately 75 percent at the time of his deposition, based on an independent clinical assessment. Defense experts agreed that mental nerve block local anesthesia may have caused post-procedure paresthesia. With improving symptoms, experts believed that a full recovery was still possible.

The dentist's quick action to assess the patient and remove the implant were very important to the defense. These activities met the standard of care and allowed for comparison as symptoms improved over time. Furthermore, the CBCT taken by the oral surgeon provided evidence that implant placement had not encroached on the mental nerve.

The jury eventually returned a judgement for the defense. Legal and other claim expenses totaled approximately $115,000.

Risk Management Analysis and Recommendations:

- Meticulous and well-documented treatment planning shows due diligence in preparing for and executing treatment.
- Document your custom and practice for informed consent in an office policy/procedure, including the use of progress notes to confirm doctor-patient consent discussions.

Informed Refusal

An informed refusal is essentially the opposite of an informed consent in that the patient has said "no" to the procedure instead of "yes." The information presented to the patient is the same for both processes, until the patient declines the recommendation. From that moment, the dentist is required to provide more information to the patient.

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.

Numerous malpractice lawsuits have been filed against healthcare providers by patients who asserted that, upon suffering a serious injury after refusing care, they did not fully understand the potential consequences of such refusal. In a typical situation, a patient contends that the healthcare provider was negligent in not fully disclosing the risks of treatment refusal. Coupled with this allegation is the patient's assertion that he or she would have consented to the procedure or treatment if the risks of refusal had been properly and comprehensively explained by the healthcare provider.

Informed Refusal Options

A patient who has refused your treatment recommendation presents you with two choices. You can:

- Continue to treat the patient – within the outline of the parameters listed below
- Dismiss the patient from your practice due to noncompliance

There is no right or wrong decision, simply a matter of preference. Your decision may vary from patient to patient, depending upon your risk assessment for continuing to treat each individual.

Each choice presents some level of risk to your practice. If you decide to continue treating, you risk the possibility that the patient's condition or treatment recommendations may not be adequately evaluated or documented. If you decide to dismiss the patient, you risk alienating them and spreading their ill will to other patients. Your decision will be based on a myriad of factors, including the quality and longevity of your dentist-patient relationship, the nature and urgency of the recommended treatment, and the overall impact on your practice.

Continuing Duties

The dentist who retains the refusing patient in their practice and continues with care must be aware of several additional duties relating to the patient's informed refusal. These duties are imposed in addition to the informed refusal discussion.

They include:

- A continued duty to examine and diagnose the patient's condition for the duration of the dentist-patient relationship and as long as the patient continues to refuse treatment
- A continued duty to inform the patient about the condition and its associated risks while the dentist-patient relationship exists, the condition exists, and the patient continues to refuse treatment
- A heightened duty to tell the patient how treatment refusal may affect future treatment options, other oral/body structures and/or overall health

The failure to meet these obligations has resulted in numerous failure to diagnose and failure to inform allegations. A positive trend has developed inasmuch as fewer of these allegations have arisen in recent years.

Documentation of Informed Refusal

Refusals of care represent an increased liability risk and require greater diligence on your part to manage that risk. The most effective technique is to comprehensively document the informed refusal process. Criteria for documenting informed refusals are similar to, but go beyond, those for informed consent. Following a discussion of the consequences, we strongly recommend a comprehensive progress note as well as the use of a written form documenting the refusal.

Your progress note should document:

- Who was present
- The treatment discussed
- The educational documents, brochures, handouts, or presentations given to or viewed by the patient
- The questions asked and answers given by both parties
- The patient's refusal of the recommended care
- That the patient was informed of the risks of not following your recommendations (list the specific risks you stated)
- The patient's reasons for refusal
- That the consequences of refusal were re-explained and the patient continued to refuse the recommended treatment. Emphasize that the patient understood the risks of refusing care.

Using an informed refusal form

As noted, we also encourage the use of an informed refusal form. Few patients remember all that they were told during the informed consent/refusal discussion, making written forms a valuable reminder to both the patient and the dentist. A written form also helps manage patient expectations, provides further documentation of the disclosure of information, and helps to deter negligence claims alleging a lack of informed consent or informed refusal.

Complete the form, paying special attention to the section titled "Risks of Not Having the Recommended Treatment." Then ask the patient to sign it. Some patients will change their minds and agree to treatment when presented with a written document and an insistence on their signature. Although the documentation process is not necessarily designed to persuade patients into accepting treatment, these individuals will ultimately benefit from receiving the proper care.

Finally, note the refusal of care in the progress note for any visit during which you discuss the issue with your patient, notwithstanding that the time period between visits was brief.

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Special Issues in Informed Consent

Consent for Minors

As a general rule, consent for treatment offered by an unemancipated minor is not valid. The informed consent of a parent or legal guardian must be obtained before treatment is rendered. Adult siblings, grandparents, and other adult caretakers are not legally authorized to provide consent unless they have been granted legal guardianship by the court.

Nevertheless, dentists too frequently accept the consent of the adult party who brought the child rather than defer until the proper consent can be obtained.

If you are presented with an unemancipated minor, unaccompanied by a parent or legal guardian, the following steps can help to minimize potential conflict and reduce liability risks:

- First, make a professional judgment as to whether any delay in treatment will be detrimental to the minor patient's dental or systemic health. Ask yourself whether it is in the patient's best interest to proceed with the treatment immediately, or whether treatment can wait until a parent or legal guardian can be contacted.
- Next, make a reasonable effort to contact the parent or legal guardian. To that end, patient healthcare information records must include current contact information, including cellular telephone numbers. Ensure that all attempts to contact a parent or guardian are documented.
- If you cannot reach a parent or guardian, defer routine treatment or, if necessary, palliate the patient's condition until a parent or guardian's informed consent can be obtained.
- Generally, it is acceptable to intervene without parental consent when immediate intervention is imperative due to traumatic injury or other emergent conditions.

If an unaccompanied minor child presents for an appointment for simple or routine treatment that has already been discussed and consented to by the parent or guardian, it is permissible to proceed with treatment. Ensure that you do not perform any treatment transcending the limitations of the prior consent.

Although you may have obtained consent, certain appointments may arise when the planned treatment is complex and you wish to have a parent accompany the child. You may institute an office policy that requires a parent to be present for treatment to proceed. If you implement such a policy, clearly inform parents that their presence will be necessary at that time.

Children of divorced parents

Obtaining informed consent from one parent is adequate. However, it is essential that the parent granting consent be legally authorized to do so. Divorces can be highly contentious, such that some divorce decrees stipulate that a non-custodial parent is stripped of parental rights. If a natural parent lacks parental rights, that individual is precluded from granting consent on behalf of his or her child.

The right to legally grant consent for a minor child is independent of any financial obligations or arrangements that may have been made during divorce proceedings. Consequently, the parent paying your fees may or may not be legally authorized to grant consent. In the best interest of the minor patient, discuss and probe these issues, as necessary, before treatment begins to effectively mitigate miscommunication risks.

Decision Making, Consent, and Mental Capacity

As the number of older Americans continues to grow, dentists will encounter an increasing number of dental, medical, ethical and legal questions when treating mentally incapacitated patients and those with impaired mental capacity due to aging or disease. This issue also pertains to patients of any age where mental capacity issues arise.

Healthcare decisions, including informed consents and refusals, are valid solely when patients have the capacity to comprehend and consent to treatment – and patient capacity can be difficult to assess.

There are several basic tenets that a dentist should consider when capacity is at issue:

1. All adult patients are assumed to be capable of consent unless proven otherwise.
2. Only a court can officially designate someone as legally incapacitated.
3. Evidence of a good faith effort by the dentist to determine capacity will assist a dentist if the capacity issue arises after initiation of treatment.
4. There is no standard procedure that a dentist can utilize to evaluate and unequivocally prove capacity.

However, there is information that can assist the dentist. A 1982 report issued by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research continues to offer excellent guidance in this area. The report on the ethical and legal implications of informed consent included a three-pronged test for decision-making ability. According to this study, to be considered to have the requisite capacity, the patient must:

- Possess a set of values and goals
- Be able to communicate and understand information
- Have the ability to reason and deliberate about choices

Even in situations when the patient is of sound mind, the patient's spouse, siblings and/or children may insert themselves into the informed consent process and attempt to override the patient's wishes and demand specific treatment. In these circumstances, you may choose to provide the patient with written information regarding treatment options, as well as a written informed consent form, and suggest that the parties discuss the matter further before proceeding with treatment.

Informed consent is more than a form or formality. It is a cornerstone of the relationship between dentists and patients. By implementing a sound informed consent and refusal process, dentists and dental practices help ensure that patients are consulted, their questions answered, and their rights and dignity respected, thus minimizing the possibility of subsequent complaints and litigation.

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For more information, you can read CNA and Dentist's Advantage full report, *Dental Professional Liability Claim Report: 3rd Edition.* www.dentists-advantage.com/dentalclaimreport

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