

September 13, 2004

The legal doctrine of informed consent relates to the information that should be given to a patient prior to the patient being deemed sufficiently informed to make a legally valid decision about dental treatment. Both patients and practicing dentists often misunderstand the concept.

Some dentists believe that if a patient refuses or declines dental radiographs but "signs off" on that refusal, the dentist is protected from any adverse consequences because he or she has the patient's consent. In fact, the dentist is at risk. Indeed, if a dentist determines that radiographs are necessary in a specific situation (ie, required by the applicable standard of care), a patient cannot legally consent to deviating from the standard of care and receiving substandard care. The courts have generally concluded that such purported consent is against public policy, as it would ostensibly provide legal protection to dentists for rendering substandard treatment and thereby potentially encourage such care, in addition to potentially put dental consumers at risk. Similarly, a patient cannot provide legally valid consent to a dentist placing crowns on periodontally involved teeth because, again, such would be a legal nullity and sanction substandard dental treatment. These are only 2 of many examples of what occurs in the dental office, and neither scenario constitutes an informed consent by the patient. A dentist confronting such a patient would be wise to decline treating, or to terminate, the dentist-patient relationship.

A dentist has the legal obligation to inform the patient of any proposed dental treatment, including any treatment options,

and the foreseeable risks associated with that treatment. For example, the extraction of an impacted third molar should include the foreseeable risks associated with such an extraction, in addition to the option of nonextraction and its attendant risks. If a patient opts for no treatment after affirmative treatment options and his or her risks have been explained, the patient assumes the risks for the deterioration of his or her dental condition and other potential adverse consequences. But in such a scenario the dentist is not rendering dental care that is below the standard of care.

Although there is generally no legal obligation to provide a patient with written treatment options and attendant risks, it is wise to do so. A written document can provide evidence both that the patient was given accurate and sufficient information relative to the treatment options and attendant risks and that the patient expressly selected a particular treatment option after reviewing all the information. Although such a written document does not in and of itself preclude a later claim alleging lack of informed consent, it certainly presents a significant degree of legal protection to the dental practitioner. Patients sometimes claim, especially after an adverse occurrence or less-than-ideal result, that they were not given information about the risks of treatment or the potential for a less-than-ideal treatment result. However, a copy of the consent form that has been signed by the patient can serve to refresh faulty patient recollections and deter malpractice actions.

Ultimately, to prevail on a claim alleging lack of informed consent, the patient must demon-

strate that he or she suffered an injury as a result of the occurrence of a risk associated with the dental procedure, and that he or she was not provided the required information about the reasonably foreseeable adverse sequelae. Most importantly, the patient must establish that if he or she had been provided the appropriate information about the foreseeable risk that actually materialized (eg, a lingual paresthesia associated with the removal of an impacted wisdom tooth), a reasonably prudent patient in the same situation would have declined to have the treatment rendered in the first place. Although there is no precise definition of what constitutes a "reasonably foreseeable risk," a dentist should disclose those risks associated with any procedure that are taught in dental schools or generally reflected in professional texts, treatises, and continuing education programs.

The American Academy of Implant Dentistry provides its members a sample informed consent for implant treatment on its website at [www.aaaid-implant.org](http://www.aaaid-implant.org). Some practitioners believe that the multiple risks delineated in the sample consent form could deter patients from receiving implant treatment. On the other hand, others believe it would be more prudent to risk losing an implant case rather than commence treatment on a patient who could later return to haunt the practitioner in malpractice litigation alleging lack of informed consent.

Frank R. Recker, DDS  
General Counsel for the  
American Academy of  
Implant Dentistry  
267 N Collier Boulevard  
Marco Island, FL 34145  
[recker@ddslaw.com](mailto:recker@ddslaw.com)

October 1, 2004

I enjoyed reading Dr Dennis Flanagan's article entitled, "Oral Triazolam Sedation in Implant Dentistry." The fact is that dental fear and anxiety remain pervasive throughout the public.<sup>1</sup> Oral premedication with triazolam is an effective and safe treatment adjunct for these patients and has become a popular means to increase tolerance of invasive dental procedures.

In my reading of Dr Flanagan's article, I did find an area that seems contrary to published research on triazolam. It is stated on page 94, in the middle column, that azithromycin should not be given concomitantly with triazolam because this may cause "increased plasma concentration, and, therefore, increased clinical effects."<sup>2</sup> Although the inhibitory effects of erythromycin and clarithromycin on CYP 3A4 cannot be disputed, it has clearly been documented that azithromycin has no effects on the kinetics and dynamics of triazolam.<sup>3</sup> Greenblatt et al<sup>4</sup> state, "Coadministration of azithromycin had no significant effect on any of the pharmacokinetic variables for triazolam." Furthermore, the package insert for Zithromax (Pfizer) states that no dosage adjustment is needed when azithromycin is coadministered with triazolam.<sup>5</sup>

I feel that as the number of dentists utilizing triazolam (or other CYP 3A4 substrates like midazolam or alprazolam) increases, it is important to clarify the reaction between triazolam and azithromycin. Because a patient may have a penicillin allergy and cannot take a cephalosporin because of cross-allergy and may also be intolerant to clindamycin, azithromycin may

be a last resort for antibiotic prophylaxis. Azithromycin is the logical choice for these patients while still being safe to use together with triazolam.

#### REFERENCES

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Jason H. Goodchild, DMD  
Director, Division of Oral  
Diagnosis  
New Jersey Dental School  
110 Bergen Street, Room D-860  
Newark, NJ 07103  
goodchjh@umdnj.edu

October 5, 2004

I thank Dr Goodchild for his interest and thoughtful comment about my article concerning the coadministration of triazolam with azithromycin.<sup>1</sup> This coadministration is not well defined in the literature. Biotransformation of these drugs is performed by the hepatic or intestinal cytochromes P450, the mixed-function oxidase system. CYP 3A4 is within this system and is responsible for action on triazolam. Several references lump all the macrolides together and warn of potentiation by inhibiting the oxidative

biotransformation by CYP 3A4 of triazolam in coadministration.

Macrolides inhibit CYP 3A4 by being transformed into nitrosoalkanes that, with iron, form an inactive CYP 3A4 complex, thus inhibiting biotransformation and increasing the plasma concentrations and prolonging the half-life of triazolam. This reaction produces most of the interactions by macrolides. However, azithromycin may be an exception. Westphal<sup>2</sup> cites Greenblatt et al,<sup>3</sup> saying that azithromycin is a weak inhibitor of triazolam biotransformation, whereas erythromycin and clarithromycin are potent inhibitors and azithromycin produces "no effect on the kinetics or dynamics of triazolam." Pai et al<sup>4</sup> agree that azithromycin produces "few clinically significant interactions with any agent cleared through the cytochrome P450 enzyme system."

However, Drug Facts and Comparisons<sup>5</sup> and Mosby's Drug Consult<sup>6</sup> specifically mention azithromycin as contraindicated for coadministration with triazolam. The websites accessmednet.com and efactsonline.com also specifically mention azithromycin. (These references do not list citations.) There is also a question that arises about the in vitro method of drug investigation. There are uncertainties regarding nonspecific microsomal binding, solvent effects on enzyme activity, and estimations of enzyme-available inhibitor concentrations.<sup>7</sup> Because this issue is not well defined, I chose to state in my article that "macrolide antibiotics (such as erythromycin and azithromycin) ... may cause increased plasma concentration" and to include the category macrolides in the contraindicated column in the table.

Dr Goodchild's concern is well founded; however, the co-

administration of triazolam and azithromycin is not well defined and needs elucidation. Therefore, the practitioner should be aware of potential interactions and be prepared for such.

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Dennis Flanagan, DDS  
1671 West Main Street  
Willimantic, CT 06225  
dffdds@charter.net