

Guideline on Informed Consent

Originating Council

Council on Clinical Affairs

Review Council

Council on Clinical Affairs

Adopted

2005

Revised

2009

Purpose

The American Academy of Pediatric Dentistry recognizes that informed consent is essential in the delivery of health care. The informed consent process allows the patient or the custodial parent or, in the case of minors, legal guardian to participate in and retain autonomy over the health care received. Informed consent also may decrease the practitioner's liability from claims associated with miscommunication. This guideline reflects that informed consent is governed by the statutes and case laws of individual states and that oral care providers should review applicable state law and regulations.

Methods

This revision included a systematic literature search of the MEDLINE/Pubmed electronic database using the following parameters: Terms: "informed consent", "pediatric consent", "pediatric informed consent", and "consent"; Fields: all fields; Limits: within the last 10 years, humans, English, review of legal cases. One hundred seven articles matched these criteria. Papers for review were chosen from this list and from references within selected articles. When data did not appear sufficient or were inconclusive, recommendations were based upon expert and/or consensus opinion by experienced researchers and legal practitioners.

Background

Informed consent is the process of providing the patient or, in the case of a minor or incompetent adult, the custodial parent or legal guardian with relevant information regarding diagnosis and treatment needs so that an educated decision regarding treatment can be made by the patient or custodial parent/legal guardian. The American Dental Association's Principles of Ethics states "the dentist should inform the patient of the proposed treatment, and any reasonable alternatives, in a manner that allows the patient to become involved in treatment decisions."¹

State laws and court decisions determine the criteria for informed consent.² In 1914, a New York state court ruled that "every human being of adult years and sound mind has a right to determine what shall be done with his own body...."³ Al-

though most cases have involved other health professionals, oral health care providers should follow the rulings established by these cases. Ruling from the Supreme Court of North Dakota found that laws pertaining to a physician's duty to obtain informed consent also pertained to dentists.⁴ As court rulings and laws differ in each state, it is difficult to develop an inclusive guideline.

The law generally has several criteria for selecting information to provide to a patient/parent/guardian as part of an informed consent. Some states follow a patient-oriented standard—that information which a reasonably prudent patient in same or similar circumstances would wish to know.^{5,6} Other states follow a practitioner-oriented standard—that information which a health care provider, practicing within the standard of care, would reasonably provide to a patient in the same circumstances.^{5,7} A hybrid approach, combining the patient-oriented and practitioner-oriented standards, is followed by some states.^{5,7} Whichever standard a state applies, the treating practitioner must disclose information that he/she considers material to the patient's decision-making process and provide a warning of death or serious bodily injury where that is a known risk of the procedure.^{2,5,8} The informed consent process generally excludes adverse consequences associated with a simple procedure if the risk of occurrence is considered remote and when such circumstances commonly are understood by the profession to be so.

It generally is understood that the person granting consent is the patient of the age of majority. Patients under the age of majority or adults with diminished mental capacity should have treatment consent obtained from a parent or legal guardian.^{2,5} The adult accompanying the pediatric patient may not be a legal guardian allowed by law to consent to medical procedures. Examples of this include a grandparent, stepparent, noncustodial parent in instances of divorce, babysitter, or friend of the family. A child in foster care or a ward of the state may be accompanied by a caretaker who may or may not be allowed to consent to medical procedures, according to individual state law. It is advisable that the oral health care provider obtain a copy of court orders appointing a guardian to verify who is authorized to consent for medical treatment for the patient.² One option

to consider is obtaining a parent/guardian's authorization via a consent by proxy or power of attorney agreement for any other individual to make dental treatment decisions for a child.⁹ In situations where individuals other than the parent/guardian regularly bring the child to the dental office, this can help eliminate doubt as to whether such individual has the legal authority to provide informed consent. Practitioners, however, should consult their own attorney in deciding whether to utilize such a form in their own practice.

Written consent is required by some states before treatment of a patient.^{2,5} Even if not mandated by state law, written consent is advisable as it may decrease the liability from miscommunication. A patient's or parent/guardian's signing a consent form should not preclude a thorough discussion. Studies have shown that even when seemingly adequate information has been presented to patients, their ability to fully understand the information may be limited.¹⁰⁻¹¹ Supplements such as informational booklets or videos may be helpful to the patient or custodial parent or legal guardian in understanding a proposed procedure. The oral discussion between provider and patient, not the completion of a form, is the important issue of informed consent. The consent form should document the oral discussion of the proposed therapy, including risks, benefits, and possible alternative therapy.

When a form is utilized, it is best to use simple words and phrases, avoiding technical terms, so that it may be easily understood. A modified or customized consent form is preferred over a standard form and should be in a format that is readily understandable to a lay person.¹² Overly broad statements such as "any and all treatment deemed necessary..." or "all treatment which the doctor in his/her best medical judgment deems necessary, including but not limited to..." should be avoided. Courts have determined it to be so broad and un-specific that it does not satisfy the duty of informed consent. Informed consent discussion, when possible, should occur on a day separate from the treatment and the practitioner should avoid downplaying the risks involved with the proposed therapy. Items appearing on a consent form should include:

1. name and date of birth of pediatric patient;
2. name, relationship to patient, and legal basis for adult to consent on behalf of minor;
3. description of specific treatment in simple terms;
4. alternatives to treatment;
5. potential adverse sequelae specific to the procedure;
6. an area for the patient or parent/guardian to indicate all questions have been answered;
7. signature lines for the dentist, parent or legal guardian, and a witness.

Consent forms should be procedure specific, with multiple forms likely to be used. For example, risks associated with restorative procedure will differ from those associated with an extraction. Separate forms, or separate areas outlining each procedure on the same form, would be necessary to accurately advise the patient regarding each procedure. Consent for sedation or behavior guidance techniques such as protective

stabilization (ie, immobilization) should be obtained separately from consent for other procedures. Consent may need to be updated or changed accordingly as changes in treatment plans occur. For example, a primary tooth originally planned for pulp therapy is determined to be nonrestorable at the time of treatment. Consent will need to be updated to reflect the change in treatment.

Recommendations

Informed consent is the process of providing the patient or, in the case of a minor or incompetent adult, the custodial parent or legal guardian with relevant information regarding diagnosis and treatment needs so that an educated decision regarding treatment can be made by the patient or custodial parent or legal guardian. Statutes and case law of individual states govern informed consent. Some states allow oral discussions, which should be documented in the medical record, while others may require written consent. Oral health practitioners should review applicable state laws to determine their level of compliance. Consent forms should be procedure specific, utilize simple terms, and avoid overly broad statements.

When a practitioner utilizes an "informed consent" form, the following should be included:

1. name and date of birth of pediatric patient;
2. name and relationship to the pediatric patient/legal basis on which the person is consenting on behalf of the patient;
3. description of the procedure in simple terms;
4. disclosure of known adverse risk(s) of the proposed treatment specific to that procedure;
5. professionally-recognized or evidence-based alternative treatment(s) to recommended therapy and risk(s);
6. place for custodial parent or legal guardian to indicate that all questions have been asked and adequately answered;
7. places for signatures of the custodial parent or legal guardian, dentist, and an office staff member as a witness.

References

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