Informed Consent

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Abstract

Informed consent, essential in the delivery of health care, is the process by which a health care practitioner provides relevant information about diagnosis and treatment needs to a patient so the patient can make a voluntary and educated decision to pursue or refuse care. For minors, unless the patient is emancipated, parents (as defined within this document) are authorized to provide or decline permission for treatment. Adults with intellectual disabilities may either require consent by a guardian or, if states allow, use a supported decision-making process. Dentists must inform patients/parents about oral health conditions observed and the nature, risks, and benefits of recommended and alternative treatments, including no treatment. While young children do not possess the cognitive ability to participate in the informed consent discussion, older children and adolescents can participate and assent to care. Dental providers are encouraged to familiarize themselves with the laws and regulations in their state concerning informed consent in health care to include teledentistry. Although laws may differ, obtaining consent in writing before commencing treatment is recommended as it may reduce liability due to miscommunication. Guidance regarding written consent forms and the use of translation services is included. The key component of obtaining informed consent is the discussion between the dental provider and patient/parent.

This document was developed through a collaborative effort of the American Academy of Pediatric Dentistry Councils on Clinical Affairs and Scientific Affairs to offer updated information and guidance in obtaining informed consent for pediatric oral health care.

KEYWORDS: INFORMED CONSENT; CONSENT FORMS, INFORMED CONSENT FORMS; INFORMED CONSENT BY MINORS; DOCUMENT, INFORMED CONSENT

Purpose

The American Academy of Pediatric Dentistry (**AAPD**) recognizes that informed consent is essential in the delivery of health care. The informed consent process allows the patient or, in the case of minors, the parent* to participate in and retain autonomy over the health care received. Informed consent will help decrease the practitioner's liability from claims associated with miscommunication. Informed consent is governed by the statutes and case laws of individual states; oral health care providers should review the applicable laws and regulations of their state.

Methods

Recommendations on informed consent were originally developed by the Council on Clinical Affairs, adopted in 2005[1], and last revised in 2019.[2] This revision included a literature search of the PubMed/MEDLINE database using the terms: *informed consent*, *pediatric consent*, *pediatric informed consent*, *consent*, *informed refusal*, *cultural background informed consent*, *linguistic background informed consent*, and *interpreters informed consent*; fields: all; limits: within the last 10 years, humans, English, review of legal cases. Three hundred thirty-one 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 by which a health care provider gives relevant information concerning diagnosis and treatment needs to a patient so that the patient can make a voluntary, educated decision to accept or refuse treatment. Minor children are legally unable to give informed consent, and intellectually-disabled adults may lack capacity to give consent. Parents are

ABBREVIATIONS

AAPD: American Academy of Pediatric Dentistry. **ADA:** American Dental Association. **SDM:** Supported decision-making.

* *In all AAPD oral health care policies and clinical recommendations, the term "parent" has a broad meaning encompassing:*

1. *a natural/biological or adoptive father or mother of a child with full parental legal rights,*
2. *a person recognized by state statute to have full parental legal rights,*
3. *a parent who in the case of divorce has been awarded legal custody of a child,*
4. *a person appointed by a court to be the legal guardian of a minor child,*
5. *a person appointed by a court to be the guardian for an incapacitated adult,*
6. *a person appointed by a court to have limited legal rights to make health care decisions for a ward, or*
7. *a foster parent (a noncustodial parent caring for a child without parental support or protection who was placed by local welfare services or a court order).*

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authorized to grant or decline permission for treatment, with assent or agreement from the child or incompetent adult whenever possible.[3-6] All requirements of informed consent apply when the parent is acting on behalf of the child.[3,5] Supported decision-making (**SDM**) is an emerging concept related to individuals with disabilities as an alternative to guardianship.[7] In SDM, individuals with disabilities retain decision-making capability but consult with trusted advisors of their choosing to make informed decisions. Several states have enacted legislation recognizing such less restrictive alternatives to guardianship for adults with disabilities.[8]

Informed consent involves both ethical and legal obligations of the health care provider to the patient. Informed consent is the conversation during which the dentist "provides information to patients/parents about the dental health problems the dentist observes, the nature of any proposed treatment, the potential benefits and risks associated with that treatment, any alternatives to the treatment proposed, and the potential risks and benefits of alternative treatments, including no treatment."[9] By assessing the patient's/parent's understanding following the informed consent discussion, the practitioner can identify any confusion about the proposed treatment and clarify misconceptions before consent is granted.[6,10] Informed consent is not a document; it is a process and discussion that educates the patient.[9]

Autonomy over health care decisions is a patient's right. Relevant case law describes the doctrine of informed consent as "every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a [doctor] who performs an operation without his patient's consent commits an assault for which he is liable in damages."[11] Additional case law states that "the law on physician's duties to their patients also applies to dentists, and the law on a physician's duty to obtain informed consent from a patient… will likewise apply to a dentist."[12] Although the laws concerning informed consent are different in each state, the above examples demonstrate the importance for dentists to obtain informed consent regardless of where they practice.[3]

Some states follow a patient-oriented standard—that information which a reasonably prudent patient/parent in same or similar circumstances would wish to know.[13,14(pp494-497)] 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/parent in the same circumstances.[14(pp494-497),15] A hybrid approach, combining the patient-oriented and practitioner-oriented standards, is followed by some states.[14(pp494-497),15] Finally, a subjective person standard requires the practitioner to give information that the particular patient in question would want to know.[6,13]

Regardless of the state's informed consent standard, a practitioner is legally and ethically obligated to disclose information that he considers material to the patient's/parent's decision-making process and provide a warning of death or serious bodily injury where that is a known risk of the procedure.[14(pp493-494),16] 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.

The American Dental Association's (**ADA**) *Principles of Ethics and Code of Professional Conduct* recommends that dentists provide information "in a manner that allows the patient to become involved in treatment decisions."[17] Dental health care providers have the opportunity to guide and support pediatric patients to become involved in their own health care. Young children lack the cognitive ability to participate in the informed consent discussion, but older children and adolescents who have gained experience as dental patients may be included. Providing information to the patient in an age-appropriate manner aids the practitioners when seeking assent (agreement) from the patient.[18,19] By allowing the child to participate in health care discussions and informing the patient of the process of informed consent, not merely obtaining permission for a procedure, the dentist helps the patient in developing autonomy. Although the child can be involved, the parent is the individual giving consent, and the parent is the individual who decides to accept or refuse treatment. In general, either parent alone may consent to treatment for a minor; court orders, however, may dictate otherwise. Emancipated minors, for example, do not require parental permission and assume responsibility for their health care.[20]

The adult accompanying the pediatric patient may not be a legal guardian authorized by law to consent to medical procedures. Examples of such an adult 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 authorized to consent to medical procedures, according to individual state law. Obtaining a copy of court orders appointing a guardian can help verify who is authorized to consent for medical treatment for the patient.[19] One option to consider is obtaining a parent's authorization via a consent by proxy or power of attorney agreement for any other individual to make dental treatment decisions for a child.[14(pg498),19] In situations where individuals other than the parent 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. Consultation with an attorney is advised when deciding whether to utilize such a proxy or power of attorney form. Another option for obtaining authorization for treatment is a telephone conversation with the parent.[19,21] The parent is presented with all elements of informed consent followed by documentation in the patient's chart.[19,21] Having a witness both confirm and document telephone consent is advisable.

Informed consent regarding teledentistry has been evolving with technology for many years.[22,23] The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)/coronavirus disease 2019 (COVID-19) pandemic increased use of telemedicine and teledentistry.[24] A randomized-controlled trial of informed

consent conversations compared telemedicine-based video encounters with face-to-face interactions and found that telemedicine is as effective as in-person communications for informed consent conversations, with no differences in patient comprehension or understanding.[25] If patient privacy regulations are followed, video-based platforms can be used for health care discussions necessary to obtain informed consent.

Written consent is required by most states before treatment of a patient.[14(p498)] Even if not mandated by state law, written consent is advisable as the best way to decrease the liability from miscommunication.[21] A patient's or parent's signing a consent form does not preclude a thorough discussion. Studies have shown that even when seemingly adequate information has been presented to patients/parents, their ability to fully understand the information may be limited.[10,13] Cultural and linguistic backgrounds of patients and their families may affect how information is conveyed and understood; ensuring that information is available in culturally- and linguistically-competent formats can help parents in the decision-making process.[26]

Similarly, physical (eg, auditory) or mental/cognitive limitations can impact communication and understanding. The patient's self-assessed ability to communicate can provide guidance to accommodations needed for informed consent before any treatment. Some adults with intellectual disabilities, in accordance with state statues or case law, may utilize an individual or team of their choosing to assist in SDM. Other patients may require access to translation services (eg, in person, by telephone, by subscription to a language line) and sign language services in order to fully understand information being conveyed about their health care.[3,26] Practitioners who receive federal funding, as well as those in a significant number of states, are mandated to provide these services at no cost to the patient.[3] Translation apps have not yet shown sufficient accuracy in the health care setting to be considered a substitute for professional interpreters for informed consent.[27,28] Supplements such as informational booklets, videos, or models may be helpful to the patient in understanding a proposed procedure. The oral discussion between provider and patient, not the completion of a form, is the essential element of informed consent. A written consent form can then be used to document the oral discussion of the proposed therapy, including risks, benefits, and possible alternative therapy, as well as no treatment.[5,18,26]

Informed refusal occurs when the patient/parent refuses the proposed and alternative treatments.[21] The dentist must inform the patient/parent about the consequences of not accepting the proposed treatment. The ADA recommends that informed refusal be documented in the chart and that the practitioner should attempt to obtain an informed refusal signed by the parent for retention in the patient record.[14(pp498-499),29] An informed refusal, however, does not release the dentist from the responsibility of providing a standard of care.[29] If the dentist believes the informed refusal violates proper standards of care, a second opinion can be recommended[29] and/or the patient may be dismissed from the practice. If dental neglect is suspected, health care providers are obligated to report such to the appropriate authorities.[30]

When a consent form is used, simple words and phrases support better understanding during the decision-making process. A modified or customized form that is readily understandable to a lay person is preferred over a standard form.[5,21,26,29] 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…" have been determined by courts to be so broad and unspecific that they do not satisfy the duty of informed consent.[10] Having the informed consent discussion occur on a day separate from the treatment and avoiding downplaying the risks involved with the proposed therapy contribute to the decision-making process.[10] Items that should appear on a consent form are listed under **Recommendations**.

Separate procedure-specific informed consent and informed refusal forms, or separate areas outlining each procedure on the same form, would be necessary to accurately advise the patient/parent and increase understanding when multiple procedures are planned.[9] For example, risks associated with restorative procedures will differ from those associated with an extraction. In addition, separate detailed written consent forms for sedation, general anesthesia, or behavior guidance techniques such as protective stabilization (ie, immobilization) increase the parent's/patient's awareness of the procedures and their associated significant risks. Certain consents (eg, sedation, general anesthesia) may only be valid for specific timeframes and need to be updated accordingly. This information can be obtained from the state dental board or specific institution (eg, hospital, surgical center). Further, consent may need to be updated or changed accordingly as changes in treatment plans occur. For example, when 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. Depending on state laws, this update may be in oral or written form.

Recommendations

Informed consent is the process of providing the patient with relevant information regarding diagnosis and treatment needs so that an educated decision regarding treatment can be made by the patient. In the case of a minor or intellectually disabled adult, the parent gives informed permission with assent or agreement sought from the patient whenever possible. Emancipated minors can provide consent independently, and some states allow less-restrictive alternatives to guardianship (eg, supported decision-making) for patients with intellectual disabilities. Practitioners should be aware of and comply with such court orders and state statutes.

The oral discussion between provider and patient or parent, not the completion of a form, is the critical component of informed consent. A written consent form serves as documentation of the consent process and is required by most states.

Other states require only that the oral discussion be documented in the patient record. Dentists should be aware of the cultural and linguistic backgrounds of their patients and families, as well as their mental and physical limitations, and take care to ensure that information is available in culturally- and linguistically-competent formats to help patients and parents in the decision-making process. Translation apps should not be considered a substitute for professional interpreters during the informed consent process.

Statutes and case law of individual states govern informed 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. Legal name and date of birth of patient
2. Legal name and relationship to the pediatric patient/legal basis on which the person is granting permission on behalf of the patient
3. Patient's diagnosis
4. Nature and purpose of the proposed treatment in simple terms
5. Potential benefits and risks associated with that treatment in simple terms
6. Professionally-recognized or evidence-based alternative treatment – including no treatment – to recommended therapy and risk(s) of each treatment modality in simple terms
7. Place for the parent to indicate that all questions have been asked and adequately answered
8. Places for signatures of the parent, dentist, and an office staff member as a witness

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