Informed Consent: More than Just a Piece of Paper
New Informed consent forms are available at dds4dds.com. Learn about the changes made to make the forms more consistent, concise, and patient-friendly.
By: Michael J. Stronczek, DDS

Alphabet Soup: Regulatory Basics Related to LEP and ADA
With the growth in disparity in health care literacy levels and the ever-expanding gap between the abled and disabled, the need for a DDS to know the LEP and ADA regulations is at an all time high.
By: Lolade Mitchell MSN, MPH, RN

A Case of “He Said She Said”
This closed claim summary demonstrates the potential consequences that could result from poor documentation and failing to use a procedure specific informed consent form.
By: Sharde Woods, RDH

LEP and ADA Frequently Asked Questions
Additional information on LEP and ADA regulations in the form of FAQs are offered to provide additional guidance on how to comply.

Compliance with state and federal regulations can seem like a daunting task for many dental practices. This issue reviews the Americans with Disabilities Act (ADA), including the considerations for Limited English Proficiency (LEP) patients.
Informed Consent: More Than Just a Piece of Paper

Michael J. Stronczek, DDS

If you have attended our live risk management seminar, or have read this newsletter before, you should be acutely aware that informed consent is more than just the patient signing a piece of paper. Do not, however, downplay the consent forms, as we believe the form is an important part of the treatment process. For that reason, Fortress offers policyholders a library of consent forms you can use in your practice.

Revised Fortress Informed Consent Forms

As mentioned in our last issue, new and revised informed consent forms have been posted to the Fortress website. While it was a huge undertaking, a regular review of systems and best practices is just good risk management. Our goal was to make the forms more consistent, concise, and patient-friendly. The complete library is available to you at dds4dds.com. Here is a summary of the changes of which you should be aware:

- Forty-nine new procedure specific consent forms, patient education sheets and clinical & office documents, are now available to our policyholders.
- The Fortress Risk Management Committee and select legal counsel vetted the changes for clinical and legal considerations.
- Consent forms are available as Word documents to allow for editing and customization to accommodate the your preferences.
- Considerations were taken to accommodate the range of dental practices and patients including consent forms specific to:
  - general dentistry and specialties such as endodontics, orthodontics, and periodontal therapy;
  - minor patients, with verbiage directed at the patient’s parent/legal guardian instead of the patient directly; and
  - advanced anesthesia, surgical extractions, implants, and oral pathology.

Overall, we believe the changes will make the process easier for you and your patients, especially if you have, or will be, transitioning to electronic informed consents.

The Informed Consent Process

It is difficult to talk about informed consent without putting it in its proper context. In addition to the patient signing the form, we stress in our risk management education that the discussion with the patient and subsequent documentation of the discussion is just as important, if not more so. This process seems to take on a life of its own at times. With that in mind, let’s get down to some basic concepts about informed consent.

The dentist’s responsibility is actually quite straightforward. The dentist must develop and communicate a treatment plan specific to each individual patient. Each patient can have multiple treatment plans, each having its own merit. The informed consent discussion includes a review...
of the benefits and possible complications that can occur from each planned procedure. This should be a blunt and truthful discussion. It is important to have excellent communication skills to effectively communicate with patients. Additionally, since patients have different levels of knowledge and understanding, you as a dentist, must do your best to speak at the intellectual level of each patient. The best possible treatment plan, regardless of cost, should be the focus of the conversation, but alternative treatments need to be mentioned as well. The patient should be given the opportunity to discuss their treatment openly and ask questions. At the end of the day, the patient (and/or their family) must choose to have the procedure done based on the information they received. This is the essence of the informed consent conversation.

Now that we have reviewed the first part of the process, how do we confirm the discussion occurred? Thoroughly document your discussion with the patient in their chart. Additionally, include the signed, dated, and fully completed procedure-specific consent form. While this may seem redundant, Fortress, through its claim experience, emphasizes the importance of complete documentation of the informed consent process. After a patient files suit, a plaintiff’s attorney reviews your chart. Experience has shown that if there is a notation in the chart confirming the informed consent discussion occurred, and an informed consent form is signed, dated, and filled out completely and accurately, it will be difficult for the plaintiff’s attorney to argue the patient was uninformed of the possibility of a “material risk” occurring. We are often asked whether the consent form should be signed and witnessed. That is a great question, and one that will continue to be debated. At Fortress, we believe it is important for the patient and the dentist to sign and date these forms, thereby indicating that you and the patient have gone through the process. It is also important for your staff to witness your informed consent discussions. Your staff should be able to support the fact that the discussion happens with every patient.

As I stated earlier, mastering the informed consent process takes time and effort. We will continue to emphasize the necessity of completing the entire process for every patient, but we will also continue to research this process with the goal of making it easier for you, your staff, and your patients. Please take this to heart! It is important!
It is likely that you will experience the challenges of providing care to a patient with limited English proficiency (LEP) or a disability during your career. The U.S. Census Bureau estimates that approximately 25 million people in the United States have LEP, and an astounding 56.7 million people living in the United States have a disability. Who are these people? An individual with limited English proficiency is someone who does not speak English as their primary language and has a limited ability to read, speak, write or understand English. An individual with a “qualified disability” is a person who has a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having such an impairment.

According to the U.S. Department of Health & Human Services: Agency for Healthcare Research and Quality, individuals with LEP and/or a disability have a greater chance of experiencing an adverse event or patient safety issue than those individuals who speak English or do not have a qualified disability. As a result, a number of regulations have been enacted by the Civil Rights Division of the Department of Justice to prohibit discrimination, some of which impact the delivery of healthcare.

**Americans with Disabilities Act**

A patient's disability could impact the delivery of care in a dental office. The degree of impact is largely based on their respective disability. For example, patients with a physical disability, such as blindness, will present to the office with different challenges than those with a mental disability, such as alcoholism. In an attempt to ensure equal access to healthcare, irrespective of their presenting challenges, Titles II and III of the Americans with Disabilities Act (ADA) (an “equal opportunity” law for people with disabilities) established a clear mandate for “doctors, dentists and other health care providers, as well as all hospital programs and services” to eliminate discrimination against people with disabilities. Despite the regulations enacted by the ADA, patients with disabilities continue to experience discrimination with treatment and accessibility to health care. Three of the most prevalent issues related to access in the health care setting are (1) lack of effective communication, (2) lack of accessible equipment and services and (3) refusal of care.

**Communication**

According to the ADA, an office that interacts with hearing impaired patients or their family members is obligated to provide those patients or their family members with a method of communication, services, or aids needed to communicate effectively. Exchanging written notes, or utilizing forms and information sheets might be ideal for some situations with little interactive communication (e.g. filling out a medical history form). However, for more complex and interactive conversations (e.g. discussion of symptoms, diagnosis, treatment options, informed consent), providing and paying for a qualified sign language interpreter might be necessary. Video interpreting services may be an option, but the equipment must be in place and office staff must know how to operate it. The ADA prohibits requiring family members or other representatives to interpret for a person who is hearing impaired because of potential emotional involvement, confidentiality, and limited interpreting skills.
Equipment & Services
Under the ADA, failure or refusal to provide healthcare services to a patient with a “qualified”
disability is discriminatory. This may include failure to examine a patient thoroughly because of
an inability to transfer him or her to a dental table or chair, or refusal to perform an x-ray because
the patient cannot fit in the designated space. Ask yourself if your facility caters to those who
are wheelchair bound. Does your x-ray machine require patients to stand? If your office cannot
properly accommodate certain patients with physical disabilities, consider caring for them in a
local hospital that can accommodate them (if you have hospital privileges), or consider renting
the necessary equipment. Regardless of your ability to accommodate the patient, remember to
consider your level of comfort and expertise in treating the patient. It is important that an office
have a well-constructed plan in place for managing patients with physical disabilities.

Refusal of Care
Based on laws outlined in the ADA, refusal to provide a patient care because he or she has HIV
is grounds for legal action. In Bragdon v. Abbott, “a case involving a dentist who refused to
provide even the most routine dental care to a patient with HIV”; the court ruled “a medical
provider may not refuse to treat by invoking the direct threat defense unless the risk of HIV
transmission is significant and based on objective evidence”. A similar group of patients who
might be refused care are those who utilize a service animal. According to the ADA, offices with
a “no pets” policy must ensure service animals are allowed into their facilities, and the patient’s
service animal is not isolated from any area the public or patients are allowed to go.

Limited English Proficiency
Communication challenges with LEP patients can include issues related to patient comprehension
of the condition of their oral cavity, the recommended treatment plan, procedural complications,
and pre or post-operative instructions, including how to prepare for a procedure, manage their
condition, and which symptoms should prompt follow up. Patients with LEP might provide an
office an inaccurate or incomplete dental/medical history, or may experience serious medication
errors related to a misunderstanding of instructions. These patients might also be recipients
of poor or inadequate informed consent as a result of their proficiency levels. Additional
communication tips can be found on page 6.

Although there is a vast amount of information that relates to healthcare regulations pertaining
to LEP and the ADA, knowledge of these nuances can be valuable to one’s professional
reputation, patient safety, and to protecting an office from claims of discrimination. Early, open-
communication with the patient might be the best ADA compliance tool used to help determine
the most reasonable accommodation.
## Recommendations To Ensure Effective Communication with LEP Patients

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<td>1</td>
<td>Provide a qualified interpreter(s) when communicating with an LEP patient. The interpreter must be able to (1) comprehend two languages as spoken and written (if the language has a script), (2) speak both of these languages, and (3) choose an expression in the target language that fully conveys and best matches the meaning of the source language.</td>
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<td>2</td>
<td>Refrain from using family members or friends as interpreters given their limited understanding of dentistry and their likelihood to not question the use of terminology that they and the patient do not understand. In addition, issues related to confidentiality may prevent patients from disclosing critical health information.</td>
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<td>3</td>
<td>Refrain from using non-qualified staff as interpreters. Refer to the above criteria to identify a qualified interpreter.</td>
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<td>4</td>
<td>Avoid the use of basic language skills to “get by”. A patient is at greater risk of encountering an adverse event when a clinician (dentist or his/her staff) with basic or intermediate foreign language skills attempts to manage a conversation without the use of a competent interpreter.</td>
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<td>5</td>
<td>Provide translated materials in the patient’s preferred language or, at a minimum, request the qualified interpreter interpret the written material that is not translated and sign as a witness.</td>
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<td>6</td>
<td>Use the “teach-back” method to confirm patient understanding. This is an effective way to confirm a patient’s comprehension of what is being explained to them. It requires he or she “teach-back” the information accurately.</td>
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<td>7</td>
<td>Recognize that a patient’s cultural beliefs and traditions might influence the dentist-patient encounter and impact the results of the care provided (i.e. minimized reports of pain, gender roles, authority deferment, etc).</td>
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The Background
A middle-aged man presented to the insured with a noncontributory health history and a chief complaint of chipped teeth due to clenching and grinding. The insured evaluated the patient’s dentition and determined a full mouth reconstruction, consisting of a combination of veneers and porcelain fused to metal crowns, was advised. The treatment plan was presented to the patient, a consent form was signed, and treatment commenced. Over the next year, temporary restorations were fabricated and eventually replaced with permanent veneers and crowns.

The patient returned on multiple occasions with several crowns in various stages of breakdown. The insured made multiple attempts to repair the broken restorations; however, the patient eventually discontinued care with the insured. The patient subsequently filed a complaint with the dental board and a lawsuit, alleging negligence, failure to recommend a nightguard, and lack of informed consent.

Here Is What Happened
The patient was given several documents to review and sign at the new patient exam, including an informed consent form for dental treatment. The consent form said in part that, the patient promised to hold the office “harmless” in the event of any less than satisfactory results. No specific risk factors, benefits or alternatives were mentioned in the form, or documented in the chart. The insured attributed the failure of the patient’s restorative work to a combination of material failure, the patient’s parafunctional habit of clenching/grinding, and malocclusion. The patient stated in his complaint to the dental board that he was told at consultation that the full mouth reconstruction would correct his malocclusion and that he could discontinue the use of a nightguard after treatment was completed. In contrast, the insured stated that she advised the patient that the prosthetics were not guaranteed for life and that the use of a nightguard would need to be continued indefinitely. However, this information was not included in the informed consent form, nor was it documented in the patient’s chart. The case eventually went to mediation and was settled out of court.

Analysis
Informed consent is the process by which the treating healthcare provider discloses appropriate information to a competent patient, so that the patient may make a voluntary choice to accept or refuse treatment. While informed consent can effectively occur verbally, all information discussed, including possible complications and necessary homecare requirements, should be thoroughly documented in the patient’s chart. In order for informed consent to be effective, however, it must be used in conjunction with good clinical practice.

The Benefits of Using Procedure Specific Consent Forms:
- Ensures that all risks, benefits and alternatives are discussed with every patient
- Requires a patient’s signature to acknowledge receipt of the information
- Can assist in the defense of a claim when consent is an issue
Limited English Proficiency (LEP) FAQs
Frequently Asked Questions Regarding Limited English Proficiency Regulations

Who decides whether interpretation is needed?
The patient determines if he or she has limited English proficiency (read, write, and speak). The doctor in consultation with the patient or patient’s representative determines what strategies are needed to communicate effectively. Documentation of this conversation and the resultant use of or refusal of an interpreter should be recorded in the health record.

Can an appointment be rescheduled if an interpreter is not available?
Yes, in many cases. If the case is emergent, you might need to employ an alternative solution. A delay should not take place if the delay would reasonably deny the patient access to quality care. Consider language line services when in a time crunch. They typically have 24 hour services available.

Can the patient be asked to bring in a family member?
Family members or friends should not be used unless the patient chooses and only after you advise the patient of your obligation to provide him or her with the interpreting service at no cost. Family members may not have the appropriate skills to convey complicated health care information and the patient may not wish to disclose his or her personal information to a family member.

Do you have to use an interpreter selected by the patient?
No, you can require the patient use a qualified interpreter of your choice. The key word being “qualified” (check with your local hospital or local public office to find one).

Who pays for the interpreter?
You CANNOT charge the patient for interpreter services. Some forms of insurance offer reimbursement for interpretation services.

Americans With Disabilities Act (ADA) FAQs
Frequently Asked Questions Regarding Americans With Disabilities Act Regulations

What are some examples of ADA qualified disabilities?
Among others, AIDS, and its symptoms; alcoholism; asthma; blindness or other visual impairments; cancer; cerebral palsy; depression; diabetes, epilepsy; hearing or speech impairments; heart disease; migraine headaches; multiple sclerosis; muscular dystrophy; orthopedic impairments; paralysis; complications from pregnancy; thyroid gland disorders; tuberculosis; loss of body parts.

What are some examples of conditions that are not qualified “disabilities”?
The common cold or the flu, a sprained joint, minor and non-chronic gastrointestinal disorders, a broken bone that is expected to heal completely, compulsive gambling, pregnancy, old age, lack of education, poor judgment, bisexuality, or homosexuality. A person currently engaging in the illegal use of drugs is not considered an individual with a disability. This refers both to the illegal use of unlawful drugs such as cocaine as well as prescription drugs.
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