


Informed Consent from a Historical, Societal, Ethical, Legal, and Practical Perspective

Lee M. Jameson, DDS,MS,FACP  & Sandra K. Al-Tarawneh, DDS,MS,FACP 

Department of Restorative Dentistry, College of Dentistry, University of Illinois at Chicago, Chicago, IL

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Correspondence

Lee M. Jameson, DDS, MS, FACP,
Department of Restorative Dentistry,
University of Illinois at Chicago, College of
Dentistry, 801 S. Paulina Street, Room 259,
Chicago, IL. E-mail: jamesonl@uic.edu

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Abstract

Informed consent is often perceived as a regulatory obligation without recognizing its educational potential in the dynamic provider/patient relationship. This article discusses the complex interaction of ethics, society, and law through a historical and practical perspective. The purpose is to provide general dentists and specialists with a comprehensive understanding of the complexity and practical dimensions of informed consent.

Healthcare professions tend to view informed consent as an obligatory prescription instead of a tool for educating patients. From this perspective, it is primarily an impersonal legal event document. As a process document, information integrated in the dialogue between the provider and patient over the course of the diagnosis and treatment creates a dynamic healthcare relationship.

Professionals are fiduciaries who place a patient's best interests above personal interests. This fiduciary relationship is based on the ethical principles of duty¹ and trust,² and begins with the process of informed consent at the diagnosis and treatment planning phase. This planning phase requires providing patients with a calculated prognosis of outcomes and expected longevity.

Informative and understandable communication is required for patients with complex dental needs. Therefore, the purpose of this article is for general dentists and specialists to have a comprehensive understanding of the ethical, societal, medical, legal, and practical dimensions of informed consent. The intent is to use a process-based consent in the establishment of a mutually respectful dialogue and relationship between patient and provider.

Discussion

Ethics and law

The process of informed consent is both an ethical³ and legal imperative. "Laws enforce the behavior we are expected to follow, while ethics suggests what we ought to follow, and helps us explore options to improve decision-making."⁴ In other words "law sets minimum standards of behavior while ethics sets maximum standards."⁵ Clear delineation between law and ethics is not always possible.⁴ There are many behaviors "that would be condemned as unethical are not prohibited by law."⁴

In general, the courts have determined how ethical principles translate into the requirements for how healthcare providers obtain a patient's consent for treatment.⁶ Consent from a legal perspective involves respecting the "bodily integrity of the individual."⁶ This dimension emanates from the philosophy of personal autonomy,⁷ defined as "an individual's capacity for self-determination or self-governance" or "the capacity to decide for oneself and pursue a course of action in one's life."⁸ The courts view the informed consent requirement for a healthcare provider as a requirement to disclose sufficient

information for the patient to make a “controlled decision before undergoing irreversible treatment.”^{6,9} A patient’s consent must be voluntary, meaning “no coercion or unfair persuasion and inducements”⁷ and can be withdrawn at any time.

The dentist-patient relationship² has several legal components based in law, one of which is to obtain the patient’s consent for treatment. Informed consent is a process of communication, comprehension, and understanding. It is not just a signature. Failure to obtain consent is considered a breach of duty, specifically battery.⁹ This component also requires the dentist to provide the patient with sufficient “information about their condition that allows them to choose among potential interventions, including the option of no treatment.”⁹ Without providing this information the dentist breaches their duty, resulting in potential negligence/carelessness.^{9,10}

However, a competent adult patient may choose informed refusal, and “decide to forego a recommended test or treatment.”⁹ Informed refusal⁹ occurs when a patient decides not to proceed with a test or treatment because, in the patient’s estimation, the risks outweigh the benefits. In turn, the provider does have the right to end the doctor-patient relationship if the informed refusal will cause the provider to be in breach of the standard of practice (state practice act) or standard care (tort case law). A procedure is unauthorized if performed without a patient’s consent, or if it exceeds the scope of the patient’s consent. Under civil tort law, negligence can be alleged if the practitioner performs the wrong procedure or treats the wrong anatomic location.⁹

By law, consent can be written or verbal. However, “verbal is not necessarily best practice.”⁶ Written consent should be obtained,⁹ giving the patient sufficient time to review, research, and deliberate before agreeing to the proposed treatment.⁶ There are only a few exceptions including a life-threatening event or trauma and an intervention to prevent mortality. In general, case law has deferred to the ability of the patient to understand (health literacy), including primary language in each element of the informed consent process. It is the ethical and legal responsibility of the provider to assure language and health literacy comprehension.

Legal history

In English law, medical informed consent originated in 1767 in England, when the principles of self-determination and individual autonomy, were acknowledged by the courts.⁶ The legal case evolution through the years shows the progression of the requirements to provide the appropriate level of information. But, much remains in this complex intersecting of society, individual rights, law, and healthcare.⁶

1. 1767 – English law – Slater v. Baker and Stapleton⁷ – Surgery was performed without informing the patient. “...because the professional custom among surgeons was to obtain consent from their patients before beginning treatment, it was only fair to impose liability on a physician who failed to meet this standard of care.”⁶
2. 1917 – Schloendorff v. Society of New York Hospital – Justice Cardozo noted, “Every human being of adult years and sound mind has a right to determine what shall be done with his own body.”
3. 1932 – The T.J. Hooper – The court ruled, “If there is a practice that is reasonable but not universally ‘customary’ it may still be used as a measure of standard of care.”
4. 1934 – Garthe v. Ruppert – Started the process of defining standard of care. When someone does not follow a proven customary way of doing things then they have not met a required community standard. A jury was to decide if the deviation reached an unreasonable level.
5. 1955 – Hunt v. Bradshaw - North Carolina Supreme Court –The Plaintiff contended “the surgeon was not reasonably careful and diligent in making use of his knowledge, skill and ability, in advising the operation, ...”¹¹ The ruling stated that the “failure to explain surgical risks “may be considered a mistake on the part of the surgeon.”⁶
6. 1957 – Salgo v. Leland Stanford Junior University Board of Trustees⁷ – Stated a physician had an affirmative duty of disclosure. The ruling stated “a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed.”¹²
7. 1960 – Mitchel v. Robinson – The court said the duty of disclosure required the physician “to inform [the patient] generally of the possible serious collateral hazards.” In other words, possible bad results of a particular procedure. Courts have described these as side effects, collateral hazards, dangers, and perils – i.e., risks of the procedure.⁶
8. 1960 - Natanson v. Kline – This ruling went further than the Mitchel v. Robinson ruling. The court applied adequacy of information as a “professional community standard.” Furthermore, it specified “disclosure of the nature of the ailment, the nature of the proposed treatment, the probability of success, and the possible alternative treatments.”⁶
9. 1969 – Petterson v. Lynch – “... informed consent theory of liability shall be imposed upon dentists as well as physicians.”⁶
10. 1972 - Canterbury v. Spence – Court rejected “professional community standard” and adopted the “reasonable patient standard.” Established absolute right of individuals to self-determination in matters of health care.
11. 1974 – Helling v. Carey – During the appeals process, the Washington Supreme Court ruled that even if customary practice is followed, the physician could still be liable. Meaning, “if there is a practice that is reasonable but not universally ‘customary’ it may still be used as a measure of the standard of care.”¹¹ This ruling suggested the legal profession and the jury decides what is “reasonable” and “unreasonable.”
12. 1975 - Zeleznik v. Jewish Chronic Disease Hospital – “The physician’s obligation is to make reasonable disclosure of the available choices and the potential dangers, and the test of such reasonableness is for the jury to decide. The jury should not be bound by the conclusions of the medical community.”

13. 1975 - Mohr v. Williams – “The patient must be the final arbiter whether he will take his chance with the operation or take his chance of living without it.”
14. 1985 – Hall v. Hilbun – Helped to define standard of care.

Standards of care¹³

Medical malpractice falls under state civil tort law, specifically, negligence. Negligence is “the standard of conduct to which one must conform ...” In order for a plaintiff (typically a patient) to successfully file a lawsuit, four conditions must be present:

1. duty (there must be evidence of a sustained provider-patient relationship and evidence of a substantial medical condition),
2. breach of that duty¹² (not meeting the standard of care when a provider by omission or commission fails to meet what prudent individual with the knowledge, skills, and experience would do*),
3. harm, (there must be a permanent alteration of structure form or function), and
4. causation (the harm must be proximate in time and space to the act of omission or commission). Legal issues evolve as a result of court rulings since “Courts must determine, on a case-by-case basis, what information is significant and material on the particular case and what level of disclosure is necessary to satisfy” duty and breach of duty.¹⁴

*Note the adage that one is held to the level of a specialist regarding the definition of “knowledge, skills, and experience” varies state to state, therefore “standard of care” tends to vary state to state.

Prior to 1932, the standard of care was legally defined by the concept of ‘custom’ meaning the customary way of doing things. If a business followed, what other like businesses did in providing customer service, then that custom was considered reasonable. The 1932 ruling said that, if customer service could reasonably eliminate hazards “then this practice can be used to define the standard of care.”¹¹

In 1974, this legal ruling applied to the medical profession when the Washington State Supreme Court ruled against an ophthalmologist (i.e., *Helling v. Carey*) for not providing a tonometry test for a patient under 40 years of age, despite glaucoma being more prevalent in patients over 40. Both of these rulings suggested that the legal profession and the jury determines what is reasonable and unreasonable. In addition, these rulings prompted state legislatures to develop statutes defining standard of care. For example, the State of Washington defined professional negligence when a health care provider “failed to exercise that degree of care, skill, and learning expected of a reasonably prudent health care provider at that time in the profession or class to which he or she belongs, in the state of Washington, acting in the same or similar circumstances.”¹⁵

Court rulings have trended away from malpractice law toward general negligence law.¹ States have abandoned custom-based norms to a reasonable practitioner standard. Previously courts leaned towards customs-based standards whereby

traditional civil tort law “gives the medical profession ... the privilege,¹ which is usually emphatically denied to other groups, of setting their own legal standards of conduct, merely by adopting their own practices. Culturally, public faith in medicine is losing its ‘special’ standing as a “secular priesthood”¹ and continues to be perceived as more of a business/industry¹ than a healthcare profession.

Legal theory evolves through lawsuits that are supposed to add more certainty and clarity to each specific law category. Recent cases suggest a healthcare provider must use “minimally sound judgement and render minimally competent care.”¹¹ A 1995 ruling stated, “Negligence may not be inferred from a bad result. Our law says that a physician is not an insurer of health,¹ and a physician is not required to guarantee results.”^{1,11} Thus, it is prudent as a dentist to know the standards of care for the state they practice in and what are the current court rulings on informed consent.

The dentist/patient relationship places a responsibility of duty on the dentist. The duty of sufficient disclosure is informed consent law that originated from medical malpractice. Usually, there are two components of a malpractice claim: (1) departure from standard of care resulting in a proximate material injury and (2) failure to secure sufficient informed consent information.¹⁶ Informed consent is rarely the sole basis for a dental related lawsuit. An exception is in the *Roybal v. Bell* ruling involving “alleged failure to obtain informed consent in connection with an apicoectomy on tooth #20 resulting in pain and paresthesia.”¹⁷ The plaintiff claimed the dentist “failed to advise her adequately”¹⁷ and that she could have had the tooth extracted instead of her choice of an apicoectomy to retain the tooth. Summary judgment was granted to the defendant but was reversed to the plaintiff upon appeal.¹⁷

The appeal ruling refers to Twerski and Cohen’s¹⁸ article that focused on the adequacy of information to make an intelligent choice in reference to treatment and invasive diagnostic procedures. They criticize the *Canterbury v. Spence* ruling (“reasonable patient” standard) as a confluence of the standards of disclosure and causation. In other words, the courts would have to determine hypothetical patient decisions using a hypothetical decision-making process, i.e., would a patient choose a different course of action based on additional risk disclosure? Thus, providers would be liable for all outcomes not expected because of inadequate information. They appropriately reasoned that the complexity and variability of human decision-making could not accurately predict, “how people perceive and process information for close-call decisions.”¹⁸ Simple things like how you frame treatment outcome data will affect a patient’s decision to accept or forgo invasive treatment. They recommended moving away from personal injury to valuing process rights with greater patient involvement in the treatment dialogue process, thereby enhancing the dentist/patient relationship.

*Chinn v. Firorucci*¹⁹ is a dental malpractice case dealing with negligence, standard of care, and informed consent. The plaintiff claimed breach of standard of care in misdiagnosis, i.e. negligent diagnosis and negligence in performing extraction of two wisdom teeth and failure to promptly refer to a neurosurgeon. Post operatively the patient experienced bleeding, numbness, and sinus pain. All resolved in several weeks except the lower left numbness (i.e. permanent damage to the inferior alveolar

nerve). The lower court ruled in favor of the plaintiff and ruled that the signed informed consent documents and the discussions the patient had with the defendant were inadmissible evidence. The defendant appealed to the Virginia Supreme Court for admission of the informed consent documents and discussions as evidence. The Court reaffirmed the lower court decision that the documents and discussion were inadmissible as evidence because they were “neither relevant nor material to the issue of standard of care.”¹⁹ The plaintiff’s choice to proceed was based on the defendant’s recommendation of surgery and misdiagnosis of decay when the upper wisdom tooth was fused to the bone with signs of benign resorption. Further, the court said a patient may consent to the risks of surgery but the patient is “not consenting to negligent diagnosis and negligence care.”¹⁹

Evidence-based dental practice

Inherent in applying standards of care for dentistry is the decision of treatment or no treatment²⁰ when considering irreversible treatment. In some situations a shortened dental arch, e.g. remaining anterior teeth in addition to first and second premolars, may be sufficient.²⁰ Treatment goals should include providing “the most conservative procedure possible that is in the patient’s best interest,”²¹ controlling disease progression, and preservation of existing oral structures.²⁰ The next consideration is what evidence can justify a particular treatment?

Evidence-based dental practice is a “balanced mix of science, clinical expertise and patient needs, to optimize patient care.”^{22,23} However, dentistry lacks standardization regarding definitions of outcomes.²⁴ Dentistry, like medicine is not a pure science, meaning not all answers are available²³ and treatment uncertainties occur frequently. For many patient situations, there is limited or no available evidence other than anecdotal or clinical experience. This cannot prevent one from making a treatment decision.²³ Tooth prognosis and prosthetic level data is available in the literature.^{20,25–28} There are many articles in the periodontics literature^{27–29} on tooth prognosis and a few from the prosthodontic literature.^{20,25,30–32} However, with the success of dental implants, teeth are being removed on the assumption that implants are better than natural teeth. Levin’s systematic review found that “implant survival rates do not exceed those of compromised but adequately treated and maintained teeth.”²⁶ Before extracting asymptomatic teeth, a thorough prognostic risk assessment should be done and explained to the patient.³³ Edentulating a patient has long-term oral health implications.

Zygomatic dental implants have been used to rehabilitate patients with severe atrophic maxillae or oncologic defects.³⁴ While more zygomatic implants are available, they are still a relatively new implant solution. Therefore, what data is available should be shared^{35,36} with patients as to complications^{37,38} and survival rates for this type of implant.

The levels of evidence grading system of the *Journal of Evidence-Based Dental Practice*³⁹ is a valuable tool for assessing the quality of evidence in the literature.^{40,41} Using this knowledge in combination with the American College of Prosthodontists Diagnostic Prosthodontic Index⁴², tooth level prognosis^{25,27,29} and a decision matrix⁴³ can be developed to

inform the patient of the risks, level of evidence and prognosis of their treatment options.

Prognosis, risks, outcomes, and uncertainties

Prognostic factors are “any intrinsic or extrinsic characteristic associated with a likely outcome of a condition.”⁴⁴ Risk factors are characteristics associated with the, “initiation of a condition or a disease.”⁴⁴ Risk factors and prognostic factors are similar but do not necessarily have the same predictive capability. Risk factors typically have low predictive probabilities since appearance of an event may take a long time while prognostic factors are associated with frequent events.⁴⁴ Prognostic and risk factors involve dimensions of uncertainty that “creates difficult challenges for clinicians and patients.”^{45,46} Predicting treatment outcomes is not an exact science due to these uncertainties. Clinicians have the responsibility to inform patients of uncertainties that apply to their situation. Also, patients should understand that unexpected outcomes are not necessarily a result of deviation from standard of care.¹⁰

Dentists have a duty to provide patients with, “the most objective available knowledge and data relative to the prognoses”⁴⁴ of dental therapies. This also applies to patients who decide not to be treated. Evidence-based “prognostic values should reflect the potentials of different dental therapies under optimal conditions.”⁴⁴ Biological or technical problems can occur, but the incidence of adverse events in dentistry is low.⁴⁴

Requirements for informed consent

There are three basic types of informed consent: implied, verbal, and written. Implied consent is suggested by a patient’s actions,⁴⁷ for example, in emergency situations. Use verbal consent for routine treatment such as diagnostic procedures and prophylaxis. Written consent is used for extensive intervention, such as use of anesthesia or conscious sedation, irreversible/invasive restorative procedures, surgical procedures, and administering medications with known high risks.⁴⁸

A signed document does not tell us if the patient fully understands³ everything in a consent form.¹⁵ Also, a signed document does not “constitute actual consent”¹⁵ or prove that consent occurred. According to English law, true consent requires that a patient: (1) have capacity,⁷ (2) have sufficient information, (3) have understood this information, and (4) give consent without duress.¹⁵ Consent is a moral, ethical, and professional duty.¹⁵

While jurisdictions vary from state to state, a Pennsylvania Supreme Court overturned a lower court by rejecting “the defendant’s assertion that disclosures by a physician’s subordinate to a patient regarding treatment satisfies the duty of informed consent.”^{49,50} The patient was diagnosed with a nonmalignant brain tumor that recurred and was affecting the patient’s eyesight and impinging on the carotid artery. The neurosurgeon warned of possible damage to the carotid artery and the optic nerve, but the patient did not make a decision at their face-to-face meeting. Two months later the patient met the neurosurgeon’s physician’s assistant to review the medical history, complete a physical examination, and discuss the surgery. During the surgery, the carotid artery was perforated resulting in

partial blindness, hemorrhage, stroke, and brain injury. At trial the patient could not remember being informed about the relative risks of the surgery. The court ruled in the physician's favor and the patient appealed to the Pennsylvania Supreme Court which ruled "a physician cannot rely upon a subordinate to disclose the information required to obtain informed consent."⁵⁰ They reasoned, "Without direct dialogue and a two-way exchange between the physician and patient, the physician cannot be confident that the patient comprehends the risks, benefits, likelihood of success, and alternatives."⁵⁰ The take away from this case is not to allow office management issues to restrict proper provider/patient interactions and communication.⁵⁰

Ensuring a high level of communication between patients and dentist requires robust dialogue between provider and patient. The dentist must provide sufficient information with transparent documentation⁶ and in a language the patient can understand.⁵¹ Informed consent should be a process, not prescriptive or at an administrative level,¹⁵ but individualized for each patient's "calculation of the best course of action."^{14,52}

Errors of understanding occur too often during the consent process⁷ because a patient's capacity to comprehend is challenged by the overwhelming amount of information. The more time taken interacting with patients during treatment presentations, the more patients can increase their rational capacity to understand and comprehend.¹⁵ If done accurately and thoroughly, these interactive patient sessions generate a mutual understanding⁷ that elevates the dentist/patient relationship to a healthcare partnership.

Consent mandates the provider to inform the patient about their diagnosis, refer them when indicated, and initiate treatment once the patient approves by signing the consent agreement.

Requirements of informed consent:

1. The nature of the chief complaint/condition.
2. Outline the proposed treatment and procedures employed.
3. Prognosis - probability of success and risks of negative consequences (i.e. risks and benefits).
4. Any material risks or dangers associated with necessary follow-up care.
5. Any reasonable alternative treatment options and associated risks and benefits.
6. Risks and consequences of having no treatment as well as any benefits.⁷

General recommendations

1. Use a process-based consent that is individualized to the specific conditions and patient needs. This will promote a relationship of understanding and mutual respect.
2. "Provide the most conservative procedure possible that is in the patient's best interest."²¹
3. Refer patients when necessary.
4. Use appropriate radiographic imaging to aid diagnosis, planning, and treatment, for example, full-mouth radiographs, panoramic, CBCT (with the appropriate field of view), etc.

5. Thoroughly document the condition of each natural tooth and use prognostic criteria to determine potential long-term survival of natural teeth.^{24,26}
6. Communicate informed consent using language patients can understand.^{7,51}
7. Provide a sufficient amount of time for patients to make an intelligent decision about their condition, prognosis, and proposed treatment.
8. Continually provide an opportunity for patients to ask questions and have them answered.
9. Outline the treatment sequence and estimated time to complete treatment.
10. Provide patients with estimated costs, as well as the cost of treatment options.
11. Establish an individualized recall program; educate patients on the self-care involved with the care and maintenance of their prosthodontic treatment.
12. Reserve the right to change the diagnosis and treatment plan due to unforeseen circumstances.
13. Offer no guarantees of treatment outcomes⁵³ except one; guarantee to do the best to provide dental care and guarantee that without home maintenance care and a regular professional recall program, prosthesis failure will most likely occur.
14. Document all interactions with patients, including phone calls, emails, text messages, written notes, etc.
15. For complex treatment plans, encourage patients to get second opinions.
16. Educate office staff on the basic principles of informed consent and emphasize the critical nature of communication.
17. Carry adequate malpractice insurance.
18. Be familiar with the 2020 American College of Prosthodontists' Parameters of Care⁵⁵ including the 21 Parameters of Prosthodontics and their respective, (1) indications, (2) therapeutic goals, (3) risk factors affecting clinical assessment, and the three specialty performance assessment criteria, (1) standards of care, (2) favorable outcomes and (3) known risks and complications.

Process-based informed consent

From the patient perspective, consent educates them about their oral health condition and helps them make rational decisions while recognizing "their right to participate and respects their dignity and autonomy."^{54,56} A form is not informed consent. It "occurs when a patient and provider discuss their oral condition and choose an intervention together, a process that may take place in one sitting or over the course of several encounters."⁴³ It is a shared decision⁴³ that is part of the dynamic dentist-patient model of communication.⁵⁴

The value of informed consent is in the implementation. Preston and Sheppard's⁵⁷ prescient discussion of a confirmation of understanding letter as a follow-up to a face-to-face patient treatment planning meeting, closely approximates the principles of process-based informed consent. Their conclusion sums up the goals, "The patient confirmation letter should be viewed as an opportunity to inform and educate the patient rather than

regarded as a legal necessity...⁵⁷ Informed consent as a legal doctrine must disclose all material information in regards to a patient's ability to decide whether to "undergo or forego a proposed treatment or diagnostic procedure."⁵⁸ Values and goals are the ethical perspective of informed consent with the intent to promote provider/patient collaboration in the development and evaluation of treatment options.⁵⁸ Lidz et al⁵⁸ recognized two informed consent models: the traditional event model that views consent as a procedure and the process model that integrates information into the "continuing dialogue between the [dentist] and the patient that is the routine part of diagnosis and treatment."

"Informed consent is an integral part of the therapeutic alliance,"⁵⁴ that should be the structural basis of the information/communication relationship between provider and patient. It is an active and continual relationship process aimed at the crucial diagnostic/therapeutic decision aspect of provider care. This is process-based informed consent as opposed to the typical event (procedure)-based boilerplate document.

Establishment of this empowerment⁴³ process between patient/provider requires both parties to work at clarification of values, expectations, and illness attitudes⁵⁸ to a mutually agreeable working level. This "mutual monitoring"⁵⁸ is continual through the diagnosis, treatment, and follow-up care. Establishing this mutually respectfully dialogue and relationship aligns all communicative efforts and prioritizes therapeutic efforts to individual and realistic outcomes. This complex provider/patient process "promotes better patient satisfaction, compliance and treatment outcomes."⁵⁶

The authors propose a generalized process-based outline for establishing process-based consent to supplement your comprehensive diagnostic data collection and treatment proposals. Templates tend to revert to event/procedure forms so understand that these are suggestions that should be modified to suit individual provider's style/preferences and additional statements that address the patient's condition and circumstances.

Affirmation of Understanding and Commitment to Personal Oral Health Care

1. Declaration of purpose – State diagnostic and therapeutic goals.
2. Confirmation of understanding – Verify patient participation in the decision process to the level necessary for understanding the certainties/uncertainties and what can and cannot be done in dealing with them.
3. Expected benefits – Are the expected benefits of treatment mutually agreeable by the clinician and patient?
4. Understanding biomaterials, procedures and positive long-term outcomes – Provide reasonable and understandable information about the properties and limitations of the biomaterials used in the diagnostic and therapeutic processes.
5. Risk disclosure – Discuss the reasonable and probable risks anticipated and possible means to mitigate them if they occur.
6. Acknowledgement of responsibilities – Establish a mutually agreeable patient commitment to their general

and oral health, with emphasis on how their compliance affects long-term positive treatment outcomes.

7. Disclaimers – Do not provide warranties or assurances of outcomes, provide a warning of unforeseen circumstances that affects predictability of outcomes allowing the provider to reserve the right to alter the diagnosis and treatment plan, request consent for photographic and radiographic documentation, and provide the patient with the option to revoke their consent at any time in writing.
8. Attestation – Affirmation that all questions have been answered, the patient will adhere to all patient instructions, there has been enough time to review all the information discussed, the patient gives timely notification of changes in address, phone numbers, medications, health, hospitalizations, and certifies consent to the chosen treatments.
9. Dated Signatures – Allow for space at the end of the consent form for the provider and patient signatures including date signed.

Some helpful guidelines: "be reasonable, readable and flexible when writing consent documents, prioritize pain control and comfort for the patient during and after procedures and delivery of prostheses, promote process-based dialogue, clarify issues that may arise, use evidence-based data to support decisional dialogue and recognize that a small number of patients exhibit behaviors that prevent establishment of trust and mutually respect with providers and should not be engaged in treatment."⁵⁹

Conclusion

Informed consent is a complex process involving a dynamic interaction of society, ethics, individual rights, law, and healthcare. Court rulings help advance certainty, clarification, and understanding to this process for the benefit of the public. It is imperative that general dentists and specialists stay vigilant and up-to-date with current informed consent rulings. Promoting provider/patient collaboration in the treatment decision process improves communication and understanding. Making the dentist/patient relationship a healthcare partnership can improve quality of care.

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Contributing editors: Clark M. Stanford, DDS, PhD, MHA, UIC Distinguished Professor and Dean, University of Illinois at Chicago, Chicago, Illinois, USA; Leila Ahmadian, DDS, MS, FACP, Department of Restorative Dentistry, College of Dentistry, University of Illinois at Chicago, Chicago, Illinois, USA; David Shonberg, DDS, MPH, FACP, Department of Restorative Dentistry, College of Dentistry, University of Illinois at Chicago, Chicago, Illinois, USA

Legal Content Reviewer: Richard Monahan, DDS, MS, JD, Department Head, Oral Medicine and Diagnostic Sciences and Director of Radiology, College of Dentistry, University of Illinois at Chicago, Chicago, Illinois, USA

References

- Peter P: The quiet demise of deference to custom: malpractice law at the millenium. *Wash & Lee L Rev* 2000;57:163
- Parmar B, Kelly D, Stephens D: Ethical and Professional Standards Study Session 1. CFA Institute (Chartered Financial Analyst). 2018
- Ezekiel E, Laufer D, Joffe S: The Ethics of Informed Consent. 2017. At: <https://medium.com/lantern-searchlight-informed-consent/the-ethics-of-informed-consent-f18749ef4fe6>. Accessed 6/23/2021
- Schwartz M: *Business Ethics: An Ethical Decision-Making Approach*, Chapter 2. 1st Edition. Wiley-Blackwell. 2017
- Tsahuridu E: Why ethics and law are not the same thing. *Ethics Leadership* 2015. At: <https://www.intheblack.com/articles/2015/04/01/why-ethics-and-law-are-not-the-same-thing>. Accessed 6/23/2021
- Berg JW, Appelbaum P, Lidz C, et al: *Informed Consent – Legal Theory and Clinical Practice* (ed 2). USA, Oxford University Press, 2001
- Emanuel E: *Informed Consent*. Holland-Frei Cancer Medicine (ed 6). BC Decker Inc. Bookshelf ID : NBK12636; 2003
- Dryden J: *Internet Encyclopedia of Philosophy – A Peer-Reviewed Academic Resource*. At: <https://iep.utm.edu/autonomy/>. 2020. Accessed 6/23/2021
- Wagner Jr RF, Torres A, Proper S: Informed consent and informed refusal. *Dermatol Surg* 1995;21:555-559
- Wright M: *Risk Management; Prevention of Medical Errors in the Dental Practice*. Academy of Dental Learning & OSHA Training, 2011
- Moffett P, Gregory M: The standard of care: legal history and definitions: the bad and good news. *West J Emerg Med* 2011;12:109-112
- Hunt v Bradshaw JUSTIA US law.1955 at <https://law.justia.com/cases/north-carolina/supreme-court/1955/746-1.html>. Accessed 6/23/2021
- Graskemper JP: The standard of care in dentistry: where did it come from? How has it evolved? *J Am Dent Assoc* 2004;135:1449-1455
- Walter P: The doctrine of informed consent: to inform or not to inform? *St John's Law Rev* 1997;71:543
- Washington Practice Series TM: *Negligence-General Health Care Provider*. 2019 at [https://govt.westlaw.com/wciji/Document/I2c8ca45ee10d11dab058a118868d70a9?viewType=FullText&originationContext=documenttoc&transitionType=DocumentItem&contextData=\(sc.Default\)](https://govt.westlaw.com/wciji/Document/I2c8ca45ee10d11dab058a118868d70a9?viewType=FullText&originationContext=documenttoc&transitionType=DocumentItem&contextData=(sc.Default)) Accessed 6/23/2021
- Shor JA, Ryan MD: *Defending a Lack of Informed Consent Claim in Mini-Dental Implant Surgery*. Defense practice update. Martin Clearwater Bell LLP, 2010, 1-4, Summer
- Roybal A, Bell G, 1989: At: <https://casetext.com/case/roybal-v-bell> and <https://law.justia.com/cases/wyoming/supreme-court/1989/122342.html>. Accessed: 11/8/2021
- Cohen NB, Twerski AD: Informed decision-making the law of torts: the myth of justiciable causation. *Univ Illinois Law Rev* 1988;607-665
- Chinn VF: 2014. At: <http://docplayer.net/3058206-Richard-d-fiorucci-et-al-opinion-by-v-record-no-131869-justice-elizabeth-a-mcclanahan-october-31-2014-stephen-chinn.html>. Accessed: 11/8/2021
- Rich B, Goldstein GR: New paradigms in prosthodontic treatment planning: a literature review. *J Prosthet Dent* 2002; 88:208-214
- Neuman L: Standard of care in dentistry. *Inside Dentist* 2008;4. www.aegisdentalnetwork.com/id/2008/10/standard-of-care-in-dentistry. Accessed 5/13/2021
- Dhar V: Evidence-based dentistry: an overview. *Contemp Clin Dent* 2016;7:293-294
- Mulimani P: Evidence-based practice and the evidence pyramid: a 21st century orthodontic. *Am J Orthod Dentofacial Orthop* 2017;152:1-8
- Patel D, O'Brien T, Petrie A, et al: A systematic review of outcome measurements and quality of studies evaluating fixed. *J Prosthodont*, 2014;23:421-433
- Samet N, Jotkowitz A: Classification and prognosis evaluation of individual teeth—a comprehensive approach. *Quintessence Int* 2009;40:377-387
- Levin L, Halperin-Sternfeld M: Tooth preservation or implant placement: a systematic review of long-term tooth and implant survival rates. *J Am Dent Assoc* 2013;144:1119-1133
- Perlish M: A systematic approach to the interpretation of tooth mobility and its clinical implications. *Dent Clin North Am* 1980;24:177-193
- Moghaddam AS, Radafshar G, Taramsari M, et al: Long-term survival rate of teeth receiving multidisciplinary endodontic, periodontal and prosthodontic treatments. *J Oral Rehabil* 2014;41:236-242
- Nunn ME, Fan J, Su X: Development of prognostic indicators using classification and regression trees for survival. *Periodontol* 2000 2012. 2012;58:134-142
- Juloski J, Radovic I, Goracci C, et al: The ferrule effect: a literature review. *J Endod* 2012;38:11-19
- Osorio-Vélez L-S: Individual prognosis of abutment teeth. *Rev Fac Odontol Univ Antioq* 2015;27:197-215 <https://doi.org/10.17533/udea.rfo.v27n1a10>
- Tada S, Ikebe K, Matsuda K-I, et al: Multifactorial risk assessment for survival of abutments of removable partial dentures based on practice-based longitudinal study. *J Dent* 2013;41:1175-1180
- American College of Prosthodontists: Extraction of asymptomatic natural teeth to facilitate prosthodontic treatment. American College of Prosthodontists Position Statement. 2016 at <https://www.prosthodontics.org/about-acp/position-statement-extractions-of-asymptomatic-natural-teeth-to-facilitate-prosthodontic-treatment/>. Accessed 6/23/2021
- Hackett S, El-Wazani B, Butterworth C: Zygomatic implant-based rehabilitation for patients with maxillary and mid-facial oncology defects: a review. *Oral Dis* 2021;27:27-41
- Gracher A, Boaventura de Moura M, da Silv Peres P, et al: Full arch rehabilitation in patients with atrophic upper jaws with zygomatic implants. A systematic review. *Int J Impl Dent* 2021;7:1-9
- Miglierança RM, Irschlinger AL, Peñarrocha-Diago M, et al: History of zygomatic implants: a systematic review and meta-analysis. *Dent Oral Craniofac Res* 2019;5:3-9
- Reychler H, Olszewski R: Intracerebral penetration of a zygomatic dental implant and consequent therapeutic dilemmas: case report. *Int J Oral Maxillofacial Implants* 2010;25:416-418
- Molinero-Mourelle P, Baca-Gonzalez L, Gao B, et al: Surgical complications in zygomatic implants: a systematic review. *Med Oral Pathol Oral Cir Bucal* 2016;21:e751-e757
- Statement of Purpose/Levels of Evidence. *J Evid Based Dent Pract* 2021;21:1-3 [https://doi.org/10.1016/S1532-3382\(21\)00147-0](https://doi.org/10.1016/S1532-3382(21)00147-0)
- Sadaf D: How to apply evidence-based principles in clinical dentistry. *J Multidiscip Healthc* 2019;12:131-136

41. Brignardello-Petersen RA, Carrasco-Labra A, Booth HA, et al: A practical approach to evidence-based dentistry: how to search for evidence to inform clinical decisions. *JADA* 2014; 145:1262-1266
42. American College of Prosthodontics. Prosthodontic Diagnostic Index. <https://www.prosthodontics.org/acp-publications/parameters-of-care/>
43. Whitney SM, McGuire AL, McCullough LB: A typology of shared decision making, informed consent, and simple consent. *Ann Intern Med* 2004;140:54-60
44. Jokstad A. Chapter 6. Prognosis and evidence based prosthodontics. The Scandinavian Approach. In *A Textbook of Removable Prosthodontics*. Copenhagen, Munksgaard Denmark, 2012, pp. 85-99
45. Berger L, Bleichrodt H, Eekhoudt L: Treatment decisions under ambiguity. *J Health Econ* 2013;32:559-569
46. Han PKJ, Klein WMP, Arora NK: Varieties of uncertainty in health care: a conceptual taxonomy. *Med Decis Making* 2011; 31:828-838
47. Nunez K. How does informed consent differ from implied consent? Healthline 2019. At: <https://www.healthline.com/health/informed-consent>. Accessed 6/23/2021
48. Kara H, Gambhir RS, Singh S, et al: Informed consent: corner stone in ethical medical and dental practice. *J Fam Med Prim Care* 2014;3:68-71
49. Shinal v Toms. Google Scholar. 2017 At: https://scholar.google.com/scholar_case?case=4383380347487734123&hl=en&as_sdt=6&as_vis=1&oi=scholarr. Accessed: 11/8/2021
50. Shand JP, Watson C: Delegation of physician responsibility in obtaining informed consent. *J Am Acad of Psych Law, Legal Digest* 2018;46:254-256
51. Ebell MH, Siwek J, Weiss BD, et al: Simplifying the language of evidence to improve patient care. *J Fam Pract* 2004;53:111-120
52. Shokrollahi K: Request for treatment: the evolution of consent. *Ann R Coll Surg Engl* 2010;92:93-100
53. Lucero Dental Group Dental Office Informed Consent. <https://c1-preview.prosites.com/55207/wy/docs/DENTAL%20OFFICE%20INFORMED%20CONSENT%20-%20Copy.pdf> Accessed 11/18/2021
54. Recchia V, Dodaro A, Braga L: Event-based versus process-based informed consent to address scientific evidence and uncertainties in ionizing medical imaging. *Insights Imaging* 2013;4:647-653
55. American College of Prosthodontics. Parameters of Care for the Specialty of Prosthodontics. *J Prosthodont* 2020;29:3-147. <https://doi.org/10.1111/jopr.13176>
56. Lidz CW: Research on informed consent: unexpected impacts. *Am Sociol* 1996;27:90-94
57. Preston JD, Sheppard GA: Confirmation letter: information and protection. *Int J Prosthodont* 1988;1:143-148
58. Lidz CW, Appelbaum P, Meisel A: Two models of implementing informed consent. *Arch Intern Med* 1988; 148:1385-1389
59. Seidberg BH: Intersecting areas of law and dentistry: part 1. *Orthodontic Practice* 2020; <https://orthopracticeus.com/articles/intersecting-areas-of-law-and-dentistry-part-1/>