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# Guidelines

## Informed Consent

### Self-determination is woven into the fabric of American society.

The history of American jurisprudence is replete with cases that addressed a citizen's rights to make decisions about his or her own health care. The preponderance of these rulings supported the premise that competent adults can determine the course of their own health care. This freedom is so inviolable that it also protects a patient's right to refuse care, even when refusal may cause injury or death.

Today most Americans know that they have the right to fully participate in their health care decisions. When interacting with physicians, dentists, or other health care providers, patients can (and should) ask questions and voice their concerns. Doctors understand that they must answer their patients' questions and address their concerns. Patients are also entitled to weigh various treatment options against their own cultural beliefs and value systems. Public policy proposes, and the courts affirm, that doctor and patient, together, must reach a consensus about the patient's condition and treatment plan. This partnership, called the doctor-patient relationship, is the foundation for good health care.

### The doctor-patient relationship is the foundation for informed decision-making.

Except in the most direct circumstances, the doctor-patient relationship must be established before a patient can commit to treatment. Its existence prevents miscommunication and gaps in the continuum of care. It establishes the doctor as advocate and advisor for the patient. It ensures that a clinically-trained expert will ensure that appropriate standards of care are met in all aspects of the patient's care.

Within the doctor-patient relationship, the physician or dentist uses his or her knowledge, skill, and experience to aid the patient. Within the doctor-patient relationship, the patient agrees to consult with and to be guided by the doctor's



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knowledge. Together, they identify the patient's health status and mutually agree on a course of action. This clinically-focused process is called informed decision-making.

The nature of informed decision-making assumes the patient's partnership and active participation in his or her health care. Outcomes-related research suggests that patients are more likely to have satisfactory results when they feel like partners in their care.

As partners, they are known to experience trusting and cooperative relationships with their doctors. Patients recover more quickly and suffer fewer setbacks or complications. Hospitalized patients go home sooner. Patients who feel like partners in their own care are more likely to follow home care instructions and, when surveyed, report greater levels of satisfaction with their overall health care experience. Not surprisingly, the clinical benefits of informed decision-making also include risk managements benefits--patients are less likely to initiate formal complaints or legal actions.

## Informed Consent formalizes (documents) the informed decision-making process.

Informed decision-making requires that several steps must take place before it can be determined that the patient is able to give his or her consent. Each of these steps builds on the other. Every time a doctor interacts with a patient in order to provide health care services, doctor and patient will hopefully reach an agreement. This agreement should be based on the doctor's sharing of information and advice with the patient. The patient then uses this information to decide which option/s to purse. When the treatment under discussion has significant risks, as medical care often does, this informed decision-making process is formalized and documented. Once this occurs, it can be said that the patient has given Informed Consent. In other words, the patient has been given sufficient information and has had his/her questions answered, and, as a result of the discussion, the doctor and patient have agreed on a treatment plan. Informed Consent is always documented in the patient's record and, in some instances, adequate Informed Consent will require the patient's signature on an Informed Consent agreement.

The doctor shares with the patient information about his or her current clinical status. The Informed Consent agreement formalizes the discussion. It clarifies the doctor's

role and participation in the patient's care. It should also clarify the patient's obligations within the recommended treatment. For very low risk interventions, the doctor may simply document the Informed Consent in the patient's record. For interventions that have higher risk, a signed document will likely be used. Regardless of the acuity of the patient's condition, the doctor's Informed Consent discussion with the patient will include:

- Diagnostic possibilities: which test/s, procedures are necessary to establish a diagnosis and a treatment plan.

- Final diagnosis and/or treatment options, including the doctor's rationale for these options.
- The risks/benefits associated with each treatment option, including possible limitations on the patient's quality of life that may result from the condition or treatment.

## Which treatments/tests should trigger Informed Consent?

Even though two medical or dental practices may be located in the same vicinity and even though the practitioners involved may have similar credentials and training, the elaboration of a formal Informed Consent policy may vary between practices. Each doctor/group of doctors should agree on their own Informed Consent policy—and each of the doctors within the group should abide by the various procedures that address the policy. Regardless of how streamlined or how elaborate the Informed Consent program is, physicians need to know that the formal elements of Informed Consent, as listed above, cannot be delegated—neither to another doctor, nor to ancillary staff. The nature of the doctor-patient relationship requires that Informed Consent must be obtained by the physician who will provide the patient's care.

Every practice should be able to identify a list of the treatments or procedures commonly performed by the practitioners within the group. These services will likely comprise the basis for the practice's Informed Consent system. When deciding which risks and benefits should be discussed, each physician/group of physicians should establish a formalized policy that takes into account several important factors:

- The societal expectation that a patient has a right to participate in his or her own health care decisions.

- State statutes that formalize Informed Consent requirements. Some states are very specific about which procedures require formal consent, while other states' statutes may be vague about the issue. State medical and dental associations are generally knowledgeable about local requirements. Hospital risk management departments may be able to help doctors develop systems that are consistent with the hospital's own Consent policies and procedures (although a hospital's Informed Consent document does NOT substitute for the doctor's own document).

- Tests/procedures/treatments most often provided by the practice. Once these have been identified, specialty-specific standards, e.g., recommendations from professional associations can be reviewed to ensure that Informed Consent protocols are consistent with standards for similar practices.

- Credentialing institutions' (e.g., JCAHO) or hospital association policies (e.g., AHA guidelines), designed to ensure consistency in the Informed Consent are followed for specific clinical interventions.

- The practice should formalize each doctor's acknowledgement that it is the non-delegable duty of each physician/dentist to participate in patients' informed decision-making consultations—and to ensure that formalized Informed Consent protocols are implemented on behalf of patients.

- The risks most frequently associated with a particular treatment option, regardless of how temporary or insignificant, i.e., pain, infection, loss of blood, etc. Significant risks that are known to occur with that particular treatment option, even though they may occur only rarely.

- Risks/consequences that may occur if the patient doesn't comply with the accepted treatment plan.

- Risks/consequences that may occur if the patient refuses all care.

- Business-related procedures that will ensure the participation and compliance of all members of the practice, as their job description relates to the Informed Consent process, including:
  - Policy development and sign-off by all physicians/dentists.
  - Procedure steps, including job description ownership.
  - Written reference materials that will provide guidance and consistency for each phase of implementation.
  - Training, in-service-updates, and methods for addressing non-compliance.
  - Periodic review and updates of all written policies and procedures.

## Doctor and staff formulate the practice's Informed Consent policy and procedures.

Once the practice has established a policy that addresses the elements of informed decision-making, it should formalize the various steps that each clinician will use to obtain Informed Consent. Several important steps should be included.

- Patient education is an important element of informed decision-making. It ensures that the patient understands his situation, his options, and his challenges. Just as in any educational process, the "student" must be able to ask questions—and the "teacher" must not only allow but should actively encourage the patient's questions.

  In many instances, the exchange of information and ideas identifies misunderstandings or unrealistic expectations that are critical to the success of the treatment. It is not only the patient who may have unrealistic expectations. The doctor, either physician or dentist, may also make "assumptions" about what might comprise an adequate outcome. Unless doctor and patient are agreed about the rationale behind the treatment and the anticipated outcome, the patient's surprise may trigger a legal action. The time to fine-tune unrealistic expectations, is during the informed decision-making phase of planning.

  Written materials, models, pictures, and even videos provide options that help patients visualize and understand the explanations provided by doctors. Written materials reinforce the educational messages imparted. They also memorialize the consultative and educational aspects of the Informed Consent process. Even

something as simple as a sketch drawn by the doctor in the patient's chart, and used to illustrate or explain a clinical issue to a patient, has proven effective in supporting a doctor's contention that the patient did indeed receive the necessary information.

- The patient's values will necessarily be a part of any treatment decision. It is important that the doctor seek to identify these beliefs when engaging the patient in a discussion about needed care. For example, a patient may refuse care (or refuse to authorize care for a dependant) for religious reasons. In these circumstances, the doctor needs to have a plan of action. Courts have varied in their decisions related to refusal of care for religious reasons. It would be wise to know, perhaps through contact with the state or local medical society, how local courts have tended to rule. It would be wise to ensure that, in the case of children or incompetent adults, the doctor has verified which party/parties are legally authorized to give consent. The doctor has the right to demand to see a court order that specifies, for example, which parent has exclusive custody or which child is the authorized health care representative for an elderly parent. When a dispute arises over life-saving care and whether or not consent will be given, the doctor needs to focus on documentation of the various steps taken to educate the patient/custodian; to ensure authenticity of the health care power-of-attorney, and to be aware of which resources should be utilized in order to defuse the situation. Resources include: patient advocates, hospital internal neutrals (dispute resolution experts), risk managers, ethics committees, chaplains, and legal advisors. As a last resort, judicial involvement may become necessary.

- Informed Consent should always be documented. Depending on the level of risk involved, state regulations, professional and specialty guidelines, and the local standards, the documentation may be as simple as the doctor writing a statement in the patient's chart that says:

  *Have discussed treatment options with X, including the benefits and most common risks associated with each option. X has been encouraged to ask questions, and these have been answered to his/her satisfaction. X says that s/he understands the information we have discussed. S/he has asked questions and acknowledges that s/he understands the answers to the questions. X has elected (_____TREATMENT _____) and agrees to cooperate with and participate in this treatment.*

Even when the clinical care provided is within acceptable standards, defense attorneys find it more difficult to fight for a doctor when the patient's record is devoid of any Informed Consent documentation. In some cases, a brief note, entered contemporaneously with the doctor's meeting with the patient, has sufficed if it covered the basics of Informed Consent.

However, depending on the circumstances, doctors may want patients to participate in a more formalized Informed Consent meeting. When the information to be imparted is very technical, when the risk to the patient is significant, and when the treatment plan may be varied and lengthy, doctors will often opt for a formal signed document.

Hopefully, the more formal procedures encourage patients to consider the risks inherent in treatment. And, if well-written, the document will also force the patient to consider the possible injury that may occur if the patient does not abide by his obligation to comply with the treatment plan. While the written Informed Consent agreement should be designed for the patient's benefit, and this is its primary function, it does provide legal protection for the doctor and many practices opt for the formal agreements for cautionary rather than for clinical reasons.

- For some medical/dental specialties, professional associations may offer Informed Consent templates. While these can be useful in understanding the basics of the process, doctors should feel free to edit these forms to ensure that they address the needs of the patient demographics of the doctor's practice. In some instances, templates make little attempt to educate the patient; their focus is obviously on diverting liability. This type of form may, of itself, antagonize the patient. Potential Informed Consent documents should be assessed for their educational value first, for their legal protections second.

- Another factor that should be considered in the use of a written Informed Consent document is that it should not be used as a cost estimate for service. This usually in medical practices whose patients are uninsured and the physicians' well-meaning attempt to explain the financial aspects of care, may give the mistaken impression that the doctor is focused on being paid—rather then on educating the patient. This type of Informed Consent is also frequently used by dentists who may inadvertently

try to combine the patient's acceptance of a treatment plan as the patient's agreement to pay for treatment. Both are perfectly legitimate, but they are separate processes, designed to accomplish separate goals, and they should be implemented separately—and certainly not on the same document.

- The doctor cannot delegate his/her obligation to engage in the informed decision-making discussion with the patient. Neither can the actual formalization of Consent be delegated. However, in many practices, appropriately-trained staff can provide some levels of education--but only after a diagnosis has been rendered and discussed with the patient. Staff can also support the educational aspects of Informed Consent in a number of additional ways:

  - Staff can ensure that the patient actually does understand information that was imparted by the doctor. Sometimes patients forget or do not understand information that the doctor shared with them. Staff can subtly follow up with patients, before they leave the office, to identify misunderstandings. Depending on the question and the staffer's level of authority, the question can be answered or the doctor can be notified that the patient has unanswered questions.

  - Regardless of which approach is used, the staff must encourage and support the patient's need for additional information/clarification and it is critical that the doctor not show signs of impatience—however warranted. It's important to focus on the benefits of this approach when asking the doctors and staff to implement a process that may indeed ask for a greater investment of time.

    Sometimes data can be the convincing element. Example: For one month the practice should count the number of phone calls that come into the office from patients who: a) forgot instructions; b) don't understand a medication regiment; c) don't remember the next step in their care; d) need additional information about a referral, test result, etc. By measuring the number of calls and the amount of time that staff and doctors invest in answering them, the value of in-office screening for questions becomes clearer.

    An additional example of data gathering might put a slightly different focus on the same question. During the same month, each doctor should monitor the

number of return phone calls that could have been prevented by adequate instructions, questions answered, etc. By thinking about that front-end investment of minutes, and comparing it to the number of additional steps that must be made when the initial opportunity is lost, the practice may actually find it can save time overall—a certain benefit to staff. By eliminating a number of end-of-the-day call backs as well as a couple of late evening phone calls, the doctors may also be convinced.

- Staff can be additionally helpful because many patients do not perceive them as authority figures. The classic "white coat hypertension" is a legitimate indicator of some patients' level of intimidation, regardless of how benign the doctor! Staff can reinforce the educational message in a say the patient can recall. And, because patients may be more comfortable asking questions or revealing their "ignorance" to a staff member, the misunderstanding can be dealt with at the earliest possible moment.

- Staff are also invaluable at noting and documenting all non-compliance. The success of Informed Consent relies on both parties fulfilling their part of the agreement. In many instances, the doctor fulfills her/his role, but doesn't do a very good job of documenting the steps taken on the patient's behalf. At the same time, the doctor may also neglect to document patient non-compliance. In either scenario, the doctor may be criticized, even though the care provided may have been exemplary; it was the documentation that was problematic. Staff should abide by a formal protocol that ensures the documentation of:

    - All statements of non-compliance, especially if the patient makes joking reference or dismissive comments that indicate s/he has no intention of following through with a commitment.
    - All missed/skipped appointments should be promptly noted in the patient's record—and a specified time frame should be used to follow up in order to: discover why the patient did not keep the appointment and to reschedule.
    - All cancelled appointments—again, with attempts made to reschedule at the time the patient cancels.
    - All failure to follow through on recommended treatment, especially tests, specialty consults, etc. Wherever possible, systems should be

used to ensure communication and feedback to/from referring doctors and specialists. Staff can play a major role in keeping patients "honest" about these important health care steps.

## Conclusion.

The importance of Informed Consent cannot be underestimated in American health care. Patients have a right to information that will help them make wise decisions and participate in their treatment. Informed Consent should also ensure that patients understand and acknowledge their agreement to participate in and cooperate with the treatment plan that they and their doctors have devised.

Depending on the doctor's type of medical practice, depending on the demographics of patients the doctor treats, and depending on the geographic location in which the doctor practices, the Informed Consent system used within a particular practice may be fairly streamlined or rather elaborate. Medical Protective has historically avoided providing template Informed Consent forms because one size does not fit all. That said, however, any medical practice can obtain feedback on Informed Consent forms, advice about drafting them, resources for factoring in the important clinical information that only doctors should determine, and other myriad elements that go into an effective Informed Consent program. The Clinical Risk Management Department offers the services of risk management experts who can be reached by calling 800/4MEDPRO.





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