INFORMED CONSENT – MORE THAN A PIECE OF PAPER

The informed consent to treatment process, commonly referred to as "informed consent," is often misunderstood to be merely an administrative form or document that a patient signs attesting that he consents to a given course of treatment. Informed consent is actually *an on-going communication process involving the physician and the patient* that requires that the patient be educated on the proposed treatment options, demonstrate an understanding of the proposed treatment options, and either consent to or refuse a specific treatment option. This article will examine briefly the basis underlying the informed consent process, as well as the practical application of this process.

Basis of the Informed Consent Process

Physicians have both ethical and legal obligations to obtain a patient's informed consent prior to treatment. The ethical obligation may be found in the *American Medical Association's Code of Medical Ethics* Opinion 10: Fundamental Elements of the Patient- Physician Relationship and Opinion 8.08: Informed Consent. The legal obligation is found in state law, both statutory and common law. The specific legal obligations will vary from jurisdiction to jurisdiction.

These obligations also promote good clinical care in that they cause patients to be actively involved in making treatment decisions. In addition, these obligations are consistent with good risk management practice as they compel the physician and the patient to assume shared responsibility for the outcome of treatment.

The Functions of the Informed Consent Process

The informed consent process fulfills a number of important functions. Each of these functions supports quality patient care, and thus helps reduce potential professional liability risks.

Functions of the Informed Consent Process

- It supports the patient's decision-making process.
- It promotes the patient's self-determination.
- It promotes physician-patient communication.
- It shares the burden of responsibility for treatment with the patient.
- It supports a fair and reasonable explanation of the proposed treatment.
- It helps to ensure that the patient has reasonable expectations regarding outcomes.

- It avoids allegations of battery, fraud, negligence, and duress against the physician.

Practical Application of the Informed Consent Process

In practice, the informed consent process can be broken down into five relatively obvious steps:

1. Determine who may legally consent
2. Physician-patient discussion
3. Patient decision
4. Documentation
5. Periodic re-evaluation

1. Determine who may legally consent

The first step is to determine who has the legal authority to give consent to the patient's treatment. This authority will rest with an adult patient who is competent to make treatment decisions. For those patients determined to be legally incompetent (e.g., minors), the physician must get informed consent from a legally recognized substitute decision-maker.

2. Physician-patient discussion

Once the physician has determined who can legally consent to treatment, the physician can proceed with the discussion of treatment recommendations and their attendant risks and benefits.

3. Patient decision

After discussing all relevant issues, patients can either decide to proceed with treatment or refuse treatment. As mentioned earlier, patients do have the right to refuse treatment, even if the physician disagrees with that decision, but the decision to forego treatment must be an informed one.

4. Documentation

As with all aspects of treatment, the informed consent process should be documented.

Signed forms can play a role in the documentation of informed consent, but they cannot replace the physician-patient discussion. Nevertheless, incorporating a signed form into the overall process may be valuable for two reasons. First, the formality of the procedure may force a patient to focus on what he is consenting to and, thus, make it less likely that he will later believe that he was not adequately informed. Second, the signed form supports the assertion that the consent process took place and establishes at least some of what was disclosed. The signed form along with the physician's entry in the record documenting the informed consent discussion will be beneficial to the physician should any malpractice litigation allege consent issues.

The disadvantage of using forms derives from the difficulty in knowing what information to include. If the content of the form is too broad, then a patient could allege that certain pieces of material information were withheld by the psychiatrist. On the other hand, if the form is very specific in listing all of the possible complications, any complication not listed could be presumed to have not been disclosed. Again, the best documentation is the entry in the record outlining the physician-patient discussion. Physicians may wish to contact personal counsel for the review or drafting of consent forms; hospitals and community clinics may also be resources for forms that can be adapted to private practice. Consent forms should be reviewed and updated periodically.

Occasionally, a statute will specify that a written consent form must be used. If so, the benefits and protections of the statute will attach only if the statutory form is followed.

5. Periodic re-evaluation

As an on-going, continuous process, informed consent should be periodically re-evaluated to ensure that it remains relevant and meaningful. Re-evaluation can also be prompted by events such as changes in the patient's clinical needs, developments in the risks and benefits of the current treatment, or the appearance of new treatment options.

The Physician's Duty to Disclose

In general, the physician should disclose the following information.

Informed Consent Disclosure

1. The nature of the proposed treatment
2. The risks and benefits of the proposed treatment
3. The alternatives to the proposed treatment
4. The risks and benefits of the alternative treatments
5. The risks and benefits of doing nothing

Ideally, the disclosure discussion should be conducted by the physician personally, not delegated to a staff member. Furthermore, the physician should never rely solely on brochures, pamphlets, etc., to disclose information to the patient, although such materials can be used to supplement the person-to-person discussions.

1. The nature of the proposed treatment

The physician should provide a fair and reasonable explanation of the proposed treatment and why she is recommending it.

2. The risks and benefits of the proposed treatment

The physician should discuss the risks and benefits of the proposed treatment. This is an invaluable opportunity to

educate the patient about what to expect from treatment. Patients with realistic expectations for treatment may be less dissatisfied with actual treatment results and, therefore, more likely to stay involved with treatment and less likely to sue over poor outcomes.

3. The alternatives to the proposed treatment

The physician should also discuss alternative treatment options that might help the patient, even if the physician cannot or will not provide those alternatives herself, they may involve more risks, or would not be covered by the patient's insurance/

4. The risks and benefits of the alternative treatments

As with the proposed treatment, patients should be educated about what to expect from alternative treatment options.

5. The risks and benefits of doing nothing

The patient has the right to refuse treatment, even if the physician disagrees with that decision, but, as with consent, the decision to forego treatment must be informed. It is imperative, therefore, that patients be educated about the possible consequences of doing nothing.

Exceptions to Current Informed Consent Requirements

Under certain circumstances, obtaining consent is not legally necessary. There are four main exceptions to the informed consent requirement: 1) emergencies, 2) legal mandate, 3) waiver, and 4) therapeutic privilege.

Four Exceptions to Informed Consent

1. Emergencies
2. Legal mandate
3. Waiver
4. Therapeutic privilege

1. Emergencies

Where there is a true emergency (i.e., where the patient's life is in danger) and the physician cannot obtain consent from the patient or the patient's legally authorized representative, the physician may take appropriate action to save the patient's life. Once it is possible to obtain consent, it should be obtained. The documentation should describe the emergency, as well as the physician's decision-making process.

2.Legal Mandate

Treatment without consent, or over the patient's objection, may be legally required by court order or by statute.

3. Waivers

Theoretically, patients may choose to waive their right to informed consent. However, physicians should be extremely hesitant to rely on such waivers, as the waiving of legal rights is a highly contentious practice, especially within a vulnerable population like psychiatric patients. Physicians should always consult with personal counsel or a professional liability risk manager before relying on a waiver. If patients are merely reluctant to discuss treatment options, the physician must still attempt to have an informed consent discussion.

4. Therapeutic privilege

Traditionally, physicians have possessed a qualified therapeutic privilege allowing them to withhold information in situations in which complete disclosure would have a significantly detrimental effect on the patient. However, as stated in American Medical Association Ethics Opinion 8.08, "social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy." As with waivers, physicians should be extremely hesitant to rely on therapeutic privilege and should always consult with personal counsel or a professional liability risk manager before doing so.

In Conclusion

Informed consent should be approached as a communication process involving the physician and the patient or authorized decision-maker. Certain basic principles underlie this process and dictate the types of information that should be disclosed in order for the patient to make as informed a decision as possible. There are limited exceptions to informed consent; however, the best risk management advice is to *always* obtain informed consent prior to providing treatment.

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