DOCUMENTATION OF INFORMED CONSENT: WHEN SHOULD USE OF A FORM BE CONSIDERED

The informed consent is an important communication process between the patient and the psychiatrist. Patients should always receive and understand the following basic information: the nature of the proposed treatment, the risks and benefits of the proposed treatment, alternatives to the proposed treatment, the risks and benefits of alternative treatments, and the risks and benefits of doing nothing.

As with all aspects of treatment, the informed consent process should be documented. Without a written record of the informed consent discussion, in the event there is later a conflict regarding consent, it may be difficult to prove that the appropriate information was disclosed and that the patient understood the ramifications of his or her decision. Or in other words, that the patient's consent was truly *informed.* A written record of the process is the best evidence that the standard of care was met.

With some aspects of patient care (such as prescribing practices) being subjected to greater scrutiny, psychiatrists may be wondering if they should have patients sign a consent form as proof that the informed consent process took place. In considering this, psychiatrists should keep in mind that the use of a signed form may not be necessary in all cases and also that there are several methods for documenting consent.

Options for Documenting Informed Consent

Verbal consent documented only in the record

If only verbal consent is obtained, the psychiatrist should write an entry in the record indicating what the patient was told, the patient's understanding of the disclosure, and the patient's consent to treatment. Psychiatrists may want to personalize the entry in the record with specific issues and/or questions addressed with the particular patient. As discussed below, documentation in the chart of verbal consent alone may or may not be sufficient depending on the nature of the treatment being discussed.

Consent documented only by a form

Signed forms can play a role in the documentation of informed consent, *but they cannot replace the psychiatrist-patient discussion*. Moreover, a form merely stating that consent was obtained may not be sufficient. It may be necessary to document more details of the informed consent discussion.

Consent documented in the record *and* on a form

Optimal documentation of the informed consent process would consist of a thorough informed consent discussion documented on a signed consent form (perhaps incorporating patient information sheets, as discussed below), along with a brief entry in the patient record. However, this may not be necessary in all cases, particularly if the treatment being discussed is low risk.

Advantages and Disadvantages of Using a Consent Form

Advantages of incorporating a signed form into the consent process

Enhanced communication: The primary purpose of informed consent discussions is to help patients understand the treatment being contemplated. Using a consent form as a basis for your consent discussions, and personalizing the form by adding specific issues discussed with that particular patient, may enhance the patient's understanding as well as demonstrate that informed consent was obtained.

Patients' focus on consent: The formality of the process may force a patient to focus on what he/she is consenting to, making it less likely that he/she will later believe that the informed consent was not adequate.

Proof of consent: The signed form supports the assertion that the consent process took place and establishes at least some of what was disclosed. Also, under some states' laws, having the patient sign an informed consent form may create a rebuttable presumption that a patient's written consent is an informed consent. For example, Indiana's code provision 16-36-1.5-7 (*Rebuttable presumption of informed consent*) states the following:

> "Sec. 7. If a patient's written consent is:
>
> (1) signed by the patient or the patient's authorized representative;
>
> (2) witnessed by an individual who is at least eighteen (18) years of age; and
>
> (3) explained, orally or in the written consent, to the patient or the patient's authorized representative before a treatment, procedure, examination or test; a rebuttable presumption is created that the consent is an informed consent."

Disadvantages of incorporating a signed form into the consent process

The disadvantages of using consent forms derive from the difficulty in knowing what information to include. If the content of the form is non-specific, 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.

Considerations for Determining Whether A Form Should Be Utilized as Part of the Informed Consent Process

Use of an informed consent form may be required by law

Jurisdictions vary with regard to the standards required for the documentation of informed consent. Federal and state laws (statutes and regulations) may require that the patient sign an informed consent form for various clinical activities. For example, federal laws related to **clinical research** require that the subject's written informed consent be documented. And, under some states' laws, patients undergoing **ECT** are required to sign informed consent documents. Some states require written informed consent to be obtained from patients, including from parents of minors, prior to prescribing **psychotropic medications.** If a statute specifies that a written consent form must be used, the benefits and protections of the statute will attach only if the statutory form is followed.

If use of a form is not required by law, psychiatrists have discretion

If use of a consent form is not required by law, psychiatrists can use their own judgment in deciding whether or not to incorporate forms into the informed consent process. The appropriateness of a form may be decided on an individual basis, depending in part on the risks associated with the treatment being discussed. For example, informed consent documentation for psychotherapy patients may be very different than consent documentation for patients considering ECT. Basically, the more risks associated with the treatment, the more consideration should be given to incorporating a form into the informed consent process. When choosing whether or not to utilize a signed informed consent form, psychiatrists may want to consider the following:

Does your state medical board recommend, in policies or guidelines, that written consent be obtained from the patient? In addition to promulgating laws (regulations), your state medical board may also issue guidelines or policy statements relating to informed consent. Psychiatrists should be aware of any such board statements, as they may be indicative of the standard of care.

Is the use of a consent form recommended by authoritative treatment guidelines? Clinical treatment guidelines, developed by authoritative organizations, may also be evidence of the applicable standard of care.

Is the recommended treatment ECT? It is a good risk management strategy to use a consent form for ECT, even if not required by law to do so, because of the prevalence of misinformation about the risks and benefits of this procedure.

Are medications with known serious side effects (such as tardive dyskinesia, lithium toxicity, neuroleptic malignant syndrome, SJS, etc.) being recommended? When medications are recommended that can cause significant injury to patients, psychiatrists may want to enhance the documentation of informed consent by including a signed form. By doing so, the psychiatrist may be able to more effectively communicate the seriousness of the known side effects of the medication to the patient. The form can also be used to document the monitoring that will be required if the medication is prescribed.

Is an off-label use of medication being recommended? Off-label use of medications is a widespread and well-accepted part of medical practice and is not, in and of itself, a professional liability risk. Off-label uses range from those that are clearly controversial to those that are considered the established standard of care. Some typical off-label uses include prescribing a medication for a condition not indicated on its FDA-approved label, prescribing at a different dosage than indicated, or prescribing for a different patient population (for example, much prescribing for children is off-label). Education about the nature and risks of the off-label use is a critical part of the informed consent process. Since malpractice allegations related to off-label use of drugs could include insufficient informed consent, psychiatrists may want to expand their consent documentation by incorporating an informed consent form and/or a patient information sheet for the particular medication.

Is the recommended treatment considered controversial, such as experimental or complementary and alternative? For some specific clinical practices, documentation of the informed consent can be crucial in litigation. If a psychiatrist proposes a type of treatment or treatment modality whose application or validity may be controversial, or if complementary and alternative treatments are recommended, then the information disclosed may need to be expanded and a very specific written consent should be obtained. The additional information should include the scientific basis for the treatment, if it is considered the standard of care, and why more conventional therapies are not being used. Without these extra measures, it may be easy for a plaintiff to allege that he/she did not understand the risks and potential outcomes and never would have given consent if he/she had understood. Moreover, it may be difficult to find an expert witness to support the care provided.

If You Incorporate Signed Consent Forms Into Your Informed Consent Process

Do not rely on the forms as a substitute for the informed consent discussion

Having a patient sign a consent form does not constitute informed consent. Signed forms can play an important role in the documentation of informed consent, but they cannot replace the informed consent discussion between the patient and the psychiatrist.

Consider incorporating patient information handouts, such as medication information sheets

Psychiatrists may wish to use patient information handouts in combination with the consent form. For example, the FDA has developed medication guides which are available through their website, www.fda.gov.

When using patient information handouts, do not rely exclusively on brochures, pamphlets, or articles to provide information about the treatment, and never assume that patients possess information which you have not provided. Discuss treatments with patients personally and give them a reasonable amount of time to digest the information and respond. They should be given every opportunity to ask questions, but the information disclosed should not be based solely on their questions.

Consent forms must be tailored to meet patient needs and must be kept up-to-date

The consent forms and all patient handouts should be easily understandable by patients and should be reviewed and updated periodically.

Retain copies in the record

- Copies of informed consent forms, written instructions, and educational information provided to the patient should also be kept in the patient's record.

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