Informed Consent

Informed consent is one of the foundations underlying the work of all physicians. It originates in long held beliefs about the right to control and govern one's own body and how it is treated. It has roots in ethics, religion, philosophy, law and medicine. It is often misunderstood and a concept and is always at risk of being presumed by hurried clinicians who think they know more or better for a patient.

The most frequent intervention by physicians for the treatment of disease is the prescription of medications. However nothing that we do in life is free of risk. As a matter of duty, a physician is required to provide informed consent to a patient when rendering treatment. Informed consent includes a discussion of the potential benefits, risks, treatment alternatives and course without treatment. It must be voluntary, non-coerced, and informed, that is to say the patient must have the capacity to understand the information, be allowed to ask questions, and to understand the provided answers. This process can be more complicated in the geriatric setting due to the potential of a person's limited cognitive abilities which result in the possibility of gaining informed consent from proxies to allow substituted judgment by guardians or interpretations from pre-prepared documents (e.g. living wills) about what the patient would have wanted if competent. It has been estimated that more than half of patients with mild to moderate dementia will lack the capacity for making therapeutic decisions with limitations arising out of multiple factors such as limited vocabulary, the varying levels of complexity associated with different medical interventions, sensory limitations, and co-morbid acute and chronic medical conditions (e.g. delirium). It should also be remembered that other

medical conditions frequently found in a geriatric population besides clearly identified dementia can also affect executive function/capacity such as hypertension, strokes, chronic obstructive pulmonary disease, and diabetes.

Informed consent is an ongoing discussion and not simply a signed document in a patient file. The patient or guardian must understands her right to come back at any time for more information and the doctor understands her duty to inform the patient of new information regarding treatment should it be significant and become available. In the clinical realm, this ongoing dialogue tends to focus on the choice of medication and the potential side effects of a specific medication or class of medications. A unique challenge which may occur in a geriatric patient is the ongoing use of a longstanding medications, such as a benzodiazepine or tricyclic antidepressant, which was appropriate when the patient was younger, but might now be "contraindicated" due to the changing tolerability/side effect profile as the patient ages. The patient needs to be informed of these concerns, even though it is a medicine the patient has been on and "knows".

In psychiatry it is especially important to discuss and document the potential benefits, which may or may not be apparent to the lay person. Theoretically, when psychiatric medications are working at their best, the patient should appear "normal" or at least stabilized. This often leads patients and families to wonder if the medicines "are working" (e.g. are providing any benefit), if the medications are really responsible for improvement, are still needed, or if better outcomes can be obtained with different

medication. Unfortunately many times it is only when a medicine is tapered or discontinued that the true benefits can be fully appreciated in hindsight.

Documenting informed consent

What to include. View informed consent as an ongoing discussion, not a document that needs to be put into a chart to comply with some legal mandate. Documenting informed consent may be as simple as going through the process and then including pertinent points in the medical record. The following is an example of a medical record entry, to document an initial informed consent discussion:

"I have explained to the patient the reasons for prescribing the above medication, the expected benefits and potential side effects, the treatment alternatives and possible risks and benefits of the alternatives, and the expected course w/o treatment. The patient asked appropriate questions and appeared to understand the answers. (I discussed off-label use.) I provided information from the manufacturer (or some other source). The patient has decided to try this medication and to be followed."

Caveats. Avoid "cutting and pasting" the identical language for each informed consent discussion into each medical record. Make your discussion and its documentation reflect each patient's individualized treatment plan. If you use a preprinted informed consent/medications side-effect form (as required by many institutions and clinics), consider entering a personalized note into the progress notes as needed, such as when:

- you prescribe medications with high risk for serious side effects
- you use off-label prescribing that is not customary

- a patient needs extra assistance in following the treatment plan.

The formality of the procedure helps a patient focus on the consent process, making it less likely that he/she will later believe he/she was not adequately informed. The signed form supports the assertion that the consent process took place and establishes at least some of what was disclosed. The signed form and the clinician's entry in the record documenting the informed consent discussion will be beneficial should malpractice litigation allege consent issues.

Preprinted forms. A disadvantage of using preprinted forms is the difficulty in knowing what information to include. If the form's content is very broad, then important information may not be disclosed. If the form is very specific and attempts to list all of possible complications, one could presume that any complication not listed was not disclosed. Thus, if you incorporate an informed consent form into your practice:

- include all significant and material risks on the form
- state on the form that the risks "include, but are not limited to" those listed on the form
- have thorough informed consent discussions with patients
- enter into the medical record your discussion and a copy of the form signed by the patient.

What to disclose. Clinicians often struggle with how much information to disclose to patients. In general, include what a reasonable person would need to know to make an informed decision. A practical way to think about this is to ask yourself the following questions:

- What information would I want a physician to disclose to my loved one (parent, child, spouse, etc.) if I was not present and my loved one needed to give consent to a treatment recommendation?
- Is this information of the type that a reasonable person could say: "I wouldn't have consented if the doctor had told me that"? If you think so, then provide this information to your patient.

Patient resources. Medication information sheets can enhance informed consent and patients' understanding and retention of information about medications you prescribe. The FDA's Web site offers printable patient education sheets on almost every medication as well as medication guides, and other information. Many manufacturers also offer patient education information at their Web sites, via pharmaceutical representatives, and as part of the package insert.