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INFORMED CONSENT
What you need to know

Informed consent is the process by which a fully informed individual (patient/client) can participate in choices about his or her health care. It originates from the legal and ethical right the patient has to direct what happens to his/her body and from the ethical duty of the healthcare practitioner (e.g., physician, chiropractor) to involve the patient in his/her health care.

Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and healthcare provider that results in the patient's authorization or agreement to undergo a specific medical treatment or intervention.

Consent

This is permission obtained from a patient or client to perform a specific test or procedure. Consent is required before most invasive procedures are performed and before a patient is admitted to a research study.

Disclosure of Information

For consent to treatment to be considered valid, it must be an “informed” consent. The patient must have been given an adequate explanation about the nature of the proposed investigation or treatment and its anticipated outcome as well as the significant risks involved and alternatives available. The information must be such as will allow the patient to reach an informed decision. In situations where the patient is not mentally capable, the discussion must take place with the substitute decision maker.

The obligation to obtain informed consent must always rest with the healthcare practitioner (not a delegated representative) who is to carry out the treatment or investigative procedure, and who has the knowledge and experience to provide adequate explanations to the patient.

Although obtaining a valid consent from patients has always involved explanations about the general nature of the proposed treatment and its anticipated effect, the adequacy of these explanations has been and continues to be challenged in courts of law. The adequacy of consent explanations is judged by the "reasonable patient" standard, or what a reasonable patient in the particular patient's circumstances would have expected to hear before consenting.

Recent legal judgments repeatedly refer to the need to disclose "material" risks to patients. Generally speaking, the more frequent the risk, the greater the obligation to discuss it beforehand. Further, even uncommon risks that carry with it serious consequences such paralysis or death of great potential seriousness should be regarded as “material” and disclosed.

Documentation

It is important that the communication process itself be documented. Good documentation can serve as evidence in a court of the law that the process indeed took place. A consent document is the most common form of documenting informed consent, but it is not a substitute for discussion. Documentation of consent is evidence that the client has agreed to the intervention but does not prove the consent was informed or valid and may not preclude a patient from asserting that the actual disclosure did not include risks that the patient unfortunately discovered after treatment.

Risk Management To Do's

Review your informed consent process to ensure:

- The practitioner performing the intervention/treatment obtains the informed consent
- All "material" risks are being disclosed to patient/client
- A consent form is used to document that the discussion has taken place
- The consent form is used as an outline for discussion with patients (e.g. to ensure that all key information about risks and benefits is presented)