Informed Consent – What is the Best Practice?

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Sentara®

Informed Consent

Informed consent is a prevalent part of healthcare. This process involves the communications between a patient and health care provider (usually a physician) that result in the patient's understanding and authorization or agreement to undergo a specific medical intervention. The informed has a reputation of being confusing, vague, and inconsistent. So, what is the best practice?

Which Health Care Provider Should Obtain Informed Consent

WHO?

- **Which Health Care Provider should obtain Informed Consent?**
  - The general rule is that informed consent should be obtained by a practitioner.
    - "Practitioner" means a health care provider. This includes many different types of providers. *See* Va. Administrative Code 18 VAC 85-20-28; *See* Va. Code § 8.01-581.1.
  - The proper practitioner to obtain informed consent in each specific case should be one who has knowledge of the patient, symptoms, diagnosis(es), and treatment(s) and the practitioner who can adequately answer the patient's questions.

What Kind of Patients Can Give Informed Consent?

What kind of patients can give Informed Consent?

- **Adults**
  - **Adult patients are presumed to be capable of making an informed decision regarding their own health care. See Virginia Code § 54.1-2983.2.**
- **Minors**
  - **If the patient is a minor, then the following can give consent:**
    - **Patient's parent(s) or guardian(s);**
    - **Judge;**
    - **Director of local Social Services/ Director of Department of Corrections/ Principal Executive Officer of the state institution;**
    - **Any person standing in loco parentis, "in place of a parent"; or**
    - **A conservator or custodian for his ward or other charge under disability. See Virginia Code § 54.1-2969(A); See Virginia Code § 54.1-2969(B).**
  - **If the patient is a minor and delay in medical treatment may adversely affect the minor's recovery, no informed consent is required unless the minor is 14 years of age or older and is physically capable of giving consent. See Virginia Code § 54.1-2969(C).**
  - **If the patient is a minor, under the age of 18, the minor shall be deemed an adult for the purposes of consenting to services regarding the following:**
    - **Venereal disease or any infectious or contagious disease;**
    - **Birth control, pregnancy, or family planning;**
    - **Outpatient care, treatment, or rehabilitation for substance abuse;**
    - **Outpatient care, treatment, or rehabilitation for mental illness or emotional disturbance;**
    - **Sexual sterilization for a minor who is or has been married;**
    - **A pregnant minor for the sole purpose of consenting surgical and medical treatment relating to the delivery; or**
    - **Physical evidence recovery kit examination. See Virginia Code § 54.1-2969(E-G). See Virginia Code § 54.1-2970.1.**

Incapacitated or Incompetent

Incapacitated or incompetent

- Whenever a person is determined to be incapable of making an informed decision and (i) has not made an advance directive or (ii) has made an advance directive that does not indicate his wishes with respect to the health care at issue the consent may be obtained in this specific order of priority:
  - A guardian for the patient;
  - The patient's spouse except where divorced;
  - An adult child of the patient;
  - A parent of the patient;
  - An adult sibling of the patient; or
  - Any other relative of the patient in the descending order of blood relationship; or
  - Any adult, except anyone currently involved in the care of the patient, who has concern for the patient and is familiar with the patient's religious beliefs and basic values and preferences. See Va. Code § 54.1-2986.

Any Special Rules for Emergency Treatment?

Any special rules for emergency treatment?

- Where delay in treatment might adversely affect recovery, informed consent is not required to provide surgical or medical treatment when two physicians state in writing that they have made a good faith effort to explain the necessary treatment to the individual and that delay in treatment might adversely affect recovery. *See* Va. Code § 54.1-2970.

What Steps are Required for Informed Consent?

HOW?

- **What steps are required for Informed Consent?**
  - Obtaining informed consent is two-fold.
    - First, the patient and health care provider must engage in a conversation regarding the practitioner's medical diagnoses, prognosis, treatment(s), risks and outcomes, and alternative treatment options.
      - The practitioner shall present such information regarding the patient's care to the patient in understandable terms and encourage participation in the decisions regarding the patient's care. See Virginia Administrative Code 18 VAC 85-20-28.
    - Second, patient must sign the informed consent documentation memorializing the informed consent conversation. This is more than just a signature.
- **Which is better; paper or electronic consent?**
  - The informed consent documentation can be paper or electronic.
  - The type of documentation is immaterial, so long as the executed informed consent form contains at least the following items:
    - Name of patient, and when applicable, patient's legally authorized representative;
    - Name of the practitioner, institution, or organization;
    - Description of the medical treatment(s) specific to each treatment;
    - Name of the practitioner(s) performing the medical treatment, including both primary and secondary practitioner(s) involved in the performing of the medical intervention;
    - Patient's signature or their authorized representative's signature;
    - Date and time consent is obtained;
    - Statement that medical treatment(s), risks, and alternatives were explained to the patient or authorized representative;
    - Name and signature of practitioner who explained the medical intervention to the patient or authorized representative; and
    - Signature of individual witnessing the consent discussions and signatures.

Common Questions

- **How long is an executed informed consent document valid?**
  - Refer to Sentara Procedure- INFORMED CONSENT; 1/1/2015 (Revision: 8/15/2023).
  - The signed Consent Form will be valid for **60 days** from date of signature, unless:
    - Is revoked by the patient prior to the end of such period;
    - The patient no longer has the capacity to make medical decisions on or about the date of the procedure and/or treatment for which the consent was provided;
    - The patient has had a change in his/her medical condition.
- **Are Providers required to make a note in the patient chart regarding consent?**
  - Health care providers may make note of the informed consent conversation and documentation in the patient's health record or chart.
    - This step is not required by law but is encouraged for additional recordation.
- **Can Providers use abbreviations on the informed consent documentation?**
  - The use of abbreviations is not advised for the informed consent form that is signed by the Patient.
    - The use of abbreviations on the informed consent documentation that is signed by the Patient may lead to confusion after the fact regarding what was discussed as a part of the informed consent discussion.
  - However, in the Practitioner's note, the use of abbreviations is supported as standard practice.

When is a Consent Needed?

- **What kind of treatment requires informed consent?**
  - Informed consent must be obtained for the following treatments:
    - Surgery or any invasive procedure;
    - Anesthesia; or
    - Prescription or administration of opioids. *See* Virginia Administrative Code 18 VAC 85-20-28; Virginia Administrative Code 18 VAC 85-20-28; Virginia Administrative Code 18 VAC 85-20-320; Virginia Administrative Code 18 VAC 85-20-350; Virginia Administrative Code 18 VAC 85-21-90.
- **Can I obtain informed consent after treatment?**
  - Informed consent must be obtained before the treatment has begun.
  - Informed consent should be obtained within a reasonable time before treatment to ensure the patient understands and acknowledges the importance of the surgery, procedure or treatment, the risks and alternatives.
- **What happens if treatment is delayed?**
  - If the treatment is delayed, informed consent must be re-obtained to ensure the patient's understanding and wishes remain in conformity with the treatment.
  - General practice rule is if the necessary treatment exceeds the previously consented to treatment plan, either in time or in substance, a new informed consent conversation and documentation is required.

Is Informed Consent required for add-on treatments?

- Informed consent conversation and documentation may include the indication for potential add-on procedures based upon what the physician finds after the primary treatment has begun.
- A secondary informed consent is not required where the original informed consent included the potential need for the add-on procedure, including a conversation regarding the risks and alternatives.

Informed Consent Procedure

Policy: (compliance360.com)

Link is housed on Sentara, Wavenet, Policies and Procedures