ACG GI Practice Toolbox

Reviewing and Updating the Informed Consent Process in your Practice

AUTHORS:

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INTRODUCTION:

Beyond its obvious medical-legal ramifications, INFORMED CONSENT (IC) is a critical part of good patient communication and documentation. The principles of IC can be applied to procedures, treatments and the prescription of high risk medications. It is also more than a document. Informed consent is a process by which patients can accept or reject "health care treatments" in an informed and voluntary manner. Practices should periodically review the processes and the documents related to informed consent. This toolbox provides a useful framework to accomplish this important project.

TOPIC OVERVIEW:

Obtaining IC is a process that allows the provider to discuss risks and benefits of the proposed treatment. The "IC form" documents that discussion. As a rule, the consent process should not be delegated, and the performing provider should take full responsibility to provide the necessary information to the consenting patient. Simple and appropriate language is key. The provider should use words the patient understands to review the intervention being proposed, the indications for it, expected outcomes (including the possibility of incomplete or failed procedures), known risks and complications and any additional risks specific to that patient. Alternative treatments should also be reviewed especially if the patient declines consent. Consent for procedures should include discussions of the risks of sedation or additional interventions being provided. In all of this, a two-way conversation is optimal, always allowing time to hear and respond to questions from the patient and family. The documentation of the discussion should become a permanent part of the medical record.

INFORMED CONSENT REQUIREMENTS:

Informed consent documents are typically developed in response to state and local regulatory requirements. In addition, CMS CoPs (conditions of participation for ASC) and hospitals have their own requirements. We recommend against the use of consent forms provided by pharmaceutical companies or device manufacturers. Significant state to state variations in the informed consent process exist. There are also institutional interpretations of those laws that

need to be considered. Consult your legal team and malpractice provider to assist you in including all the required elements pertinent to your state.

If handouts or videos are used in the process, one should document in the patient's chart that the patient viewed/received them. Using a common format, develop a form for each procedure incorporating large font and simple language. The provider performing the test and the patient (or appropriate designee) should sign and date the form.

SPECIFIC ELEMENTS OF INFORMED CONSENT FOR GI PRACTICE:

1. What interventions should be consented?
    - Operative or invasive procedures
    - Percutaneous procedures traversing into an organ
    - High risk (risks that the patient would consider important) diagnostic or therapeutic interventions
    - Intravascular insertion of instruments (excluding peripheral IVs)
    - General, deep, or moderate sedation
    - Receipt of blood or blood products

2. What treatments or medications should be considered for a modified consent?
    - Drugs with black box warnings from the FDA (i.e., metoclopramide, obeticholic acid) or drugs with mandated consents (Isotretinoin)
    - Drugs with potentially serious side effects (i.e., biologics)

3. Who must give consent?
    - Any person 18 years or older who is mentally competent
    - If a person is judged to be incompetent (unable to understand the risks, benefits, and alternatives to the proposed Health Care Treatment) consent can be obtained from the following:
        - Court appointed guardian
        - Spouse
        - Adult Child
        - Parent
        - Adult Sibling
        - Next closest relative by blood or adoption
    - Utilize the services of an interpreter if the patient does not speak English and family member or friend accompanying the patient does not speak English and follow local policies and guidelines, regarding interpreters
    - In case of an emergency, and if none of the above persons is available, emergent consent may be obtained from two physicians, but this may vary from state to state and hospital/facility/health care system, depending on specific laws and regulations

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4. Who can obtain informed consent?
    - The provider who is supervising or performing the Health Care Treatment
    - Physicians can obtain consent for all treatments requiring IC for which they are credentialed
    - APPs may obtain IC for procedures in which they have been trained and for which they are credentialed

5. What key elements are included in the consent?
    - The intervention or treatment being proposed
    - The expected outcomes (including incomplete or failed procedure if possible)
    - The known risks, benefits, standard alternatives, and risks specific to the patient
    - The type and options of sedation provided

KEY CONCEPTS:

1. Remember simple and appropriate language
    a. Simple and clear wording is crucial.
    b. Use 12-point font or larger
    c. Use bullet points instead of paragraphs
    d. Place development date on your forms and review intermittently to keep up to date
2. Use educational language and keep legal jargon to minimum
3. Review all consents you are using now and update to include information and ideas in this kit
4. If trainees are performing the procedure this should be included in the discussion and document
5. For medications consider a modified consent as all elements will not be needed. Consider using the FDA medication guides and document they were given to the patient. (https://www.fda.gov/drugs/drugsafety/ucm594941.htm)
6. If treatment or procedure is not accepted, document refusal and discussion of alternatives and prognosis

RESOURCES:

1. Websites: CMS.gov [CMS Conditions of Participation for Hospitals: 42C>F>R> 482.24.C(2)(v).482.51(b)(2),482.13(B)(2)]; Your state Dept. of Health website ; FDA https://www.fda.gov/drugs/drugsafety/ucm594941.htm
2. Organizations: Your state Department of Health; Your malpractice carrier; [for Mississippi we use Medical Assurance Company of Mississippi (MACM)]
3. The Joint Commission Accreditation Hospital Standards: RI.01.03.01 The honors the patient's right to give or withhold informed consent Elements of Performance 1-7,9,11-12
4. Informed consent for GI Endoscopy. *Gastroinest Endosc* 2007; 66(2): 213-17.

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