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ACR PRACTICE GUIDELINE ON INFORMED CONSENT FOR IMAGE-GUIDED PROCEDURES

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Prudent and ethical medical practice requires close communication between the patient and the physician. The patient and, when appropriate, the family must have every opportunity to understand the treatment or procedure the patient is to receive, to have all questions answered, and to fully consent to the treatments and procedures. The degree of disclosure required for a valid consent varies from state to state, but there are two generally recognized legal standards. The first is measured by what a reasonable physician in his/her professional judgment believes is appropriate to disclose to the patients. The degree of disclosure depends on perceptions of the physician in each case. The second legal standard is based on what a reasonable patient would want to know in the same or similar circumstances. The legal trend is towards “the reasonable patient standard,” which usually requires greater and more detailed disclosure of information.

Informed consent is a process and not the simple act of signing a formal document. However, consent forms serve to document the physician’s discussion with the

patient, and by his/her signature a patient indicates that he/she understands and consents to the treatments and procedures that will be performed. Informed consent with appropriate documentation shall follow institutional policies and procedures and comply with applicable state law.

II. INDICATIONS

Informed consent and appropriate documentation should be obtained for, but not limited to, the following procedures:

1. Many invasive procedures requiring the insertion of needles, catheters, or any incisional procedures.

2. Moderate or "conscious" sedation.

Because of the documented low incidence of adverse events resulting from intravenous injection of contrast media, it may be exempted from the need for informed consent, but this decision should be based on state law and institutional policy, departmental policy, and local community practice.

III. QUALIFICATIONS OF PERSONNEL

The physician or healthcare provider who oversees or obtains informed consent should be familiar with the elements of informed consent, as well as the nature of the procedure being proposed, the risks of the procedure, the expected benefits of the procedure, and the alternatives to it.

IV. RESPONSIBILITIES OF PERSONNEL

In all cases requiring informed consent, it is the physician or healthcare provider performing the procedure, or other qualified personnel assisting the physician, who should talk with the patient, explain the procedure, answer all questions, and arrange for appropriate documentation of informed consent. This documentation might take the form of an executed consent form, videotape, or adequate documentation in the patient's medical record.

A consent form given to the patient by personnel unfamiliar with the procedure is not a substitute for a face-to-face discussion of the procedure between the physician or other qualified person and the patient, especially if the patient has unanswered questions about the procedure. If a person other than the one who is to perform the procedure obtains consent, the person performing the procedure shares the responsibility for the satisfactory completion of the consent.

Significant risks of the procedure, benefits, and alternative procedures that might be available must be explained to the patient.

Consent should allow the patient the opportunity to ask questions and discuss the procedure and should not be obtained in a coercive manner.

In institutions where department policy or legal advice based on state law requires informed consent for intravenous injections of contrast agents, ACR policy approves the obtaining of informed consent and injection of the contrast medium by technologists and nurses who are qualified to do so[1], but the patient has the absolute right to discuss the procedure with the radiologist if he/she requests it before signing a consent form.

V. SPECIFICATIONS AND DOCUMENTATION

Informed consent and appropriate documentation shall be obtained prior to the initiation of any procedure that is likely to expose the patient to any significant risks and potential complications.

A. Protocol for Informed Consent for Elective Procedures

1. Before the proposed procedure is performed, the following will be explained to the patient:
   a. The purpose and nature of the procedure or treatment.
   b. The method by which the procedure or treatment will be performed.
   c. The risks, complications, and expected benefits or effects of such procedure or treatment.
   d. The risk of not accepting the procedure.
   e. Any alternatives and their risks and benefits.
   f. The right to refuse to consent.

2. After the above items are explained and the physician or health care provider is satisfied that the patient understands the procedure and its possible consequences, the informed consent is appropriately documented. This is most commonly done by having the patient sign a consent form.

[1]The American College of Radiology approves of injection of contrast material and diagnostic levels of radiopharmaceuticals by certified and/or licensed radiologic technologists and radiologic nurses under the direction of a radiologist or his or her physician designee who is personally and immediately available, if the practice is in compliance with institutional and state regulations. There must be prior written approval by the medical director of the radiology department/service of such individuals; such approval process having followed established policies and procedures and the radiologic technologists and radiologic nurses who have been so approved maintain documentation of continuing medical education related to the materials being injected and to the procedures being performed. 1987, 1997 (Res. 1-H)

3. The name of the person (or practice group) performing the procedure must appear on the consent form prior to the signature by the patient.

4. Documentation: A note should appear in the medical record that a discussion was held with the patient and that informed consent was obtained. The note should also include the date and time of the discussion, the content of the discussion, and an evaluation of the patient's understanding and response to information provided. A copy of the consent form(s), if used, should be placed in the record. A copy of any written informational materials given to the patient may also be included in the record.

5. Since the patient must be able to understand the risks at the time he/she gives consent, medications that affect the sensorium should be kept at a minimum and ideally not given to the patient less than 4 hours prior to the patient's giving consent.

6. State statutes should be known and followed with regard to consent of those under legal age within that state. In states with "emancipated minor" and "mature minor" statutes, it may be not only wise but legally required, to discuss the procedure with the minor patient, even in those situations where consent will be given by a parent or a legal guardian.

7. Telephone consent: If consent is sought from the patient's health care representative, legally appointed guardian, or family member who cannot be physically present to sign the consent form before the procedure, informed consent by telephone may be obtained. The discussion should be documented on the consent form with a note that the consent was obtained by telephone. In such cases it is advisable to have the discussion witnessed by a second hospital staff member who signs the form as a witness.

B. Protocol for Informed Consent for Emergency Procedures

This protocol defines the scope of the emergency exception to the informed consent requirement when a patient needs immediate medical care and is unable to give informed consent.

1. When a delay in treatment would jeopardize the health of a patient, and the patient is unable to give informed consent, an exception to the requirement for obtaining informed consent from the patient is made.

2. If the patient is unable to consent and has a legally authorized representative who is available to consent, the treating physician shall obtain the informed consent of the representative.

3. When informed consent cannot be obtained from the patient or from his/her legally authorized representative, the physician treating the patient should determine the immediacy of the need for treatment.

    a. A physician may provide any treatment or perform any procedure immediately required to prevent serious disability or death or to alleviate great pain and suffering.
    b. During the course of an operation or a procedure, a physician may perform any procedure that becomes necessary because of a condition discovered or arising during the operation or the procedure that presents an immediate threat to the life or the health of the patient.

4. The emergency exception to the requirement of informed consent does not extend to a conscious, competent adult patient, otherwise able to give his/her own informed consent, who has refused to consent to a treatment or a procedure.

5. The need for immediate treatment is documented in the patient's medical record. Documentation includes all information establishing the nature, immediacy, and magnitude of the problem, and the impossibility of obtaining consent under the circumstances. Any consulting physicians should enter their findings and recommendations in the record. All notes should show the date and time that the determinations were made.

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