Clinical Practice Guideline: **Informed Consent**

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Product: **Specialty**

GUIDELINES

American Specialty Health – Specialty (ASH) recognizes that patient informed consent to intervention is one of the most important ethical and legal issues impacting health care professional clinical practice. Because legal standards for informed consent vary among different jurisdictions, it is vital for practitioners to consult with their attorney, malpractice carrier, licensing board, state statutes, case law and CMS (Medicare) to determine the depth and breadth of the information required in an appropriate informed consent process. Informed consent is an ongoing process of communication between a patient and health care practitioner that results in the patient becoming educated about the intervention, its pros and cons and alternatives and then deciding whether to authorize or agree to undergo a specific clinical intervention(s). The standards for informed consent require a health care practitioner to provide all the information to a patient that a reasonable, prudent health care practitioner would provide and that a reasonable, prudent patient or guardian would wish to know prior to deciding about, approving, and undergoing an evaluation or treatment intervention.

Practitioner Responsibility

Prior to performing any evaluation or treatment intervention, the responsible health care practitioner should disclose to the patient enough information to enable the patient to make an informed decision about whether to accept or reject the proposed evaluation or treatment intervention. Informed consent requires that a patient have a full understanding about that to which he or she has consented. An authorization from a patient who does not understand what they are consenting to is not considered informed consent.

Delegating Informed Consent

In general, it is the responsibility of the health care practitioner performing the evaluation or treatment intervention(s) to obtain the necessary informed consent. Subject to regulatory requirements, if the practitioner chooses to delegate this function to another member of the health care team, the designee must be qualified to explain and answer questions about any aspect of the intervention to the patient.

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Types of Informed Consent

Implied Consent

The basis of consent which is implied either by the words or the behavior of the patient or by the circumstances under which care is given. When there is doubt about the acceptability of implied consent, it is preferable the consent be expressed, either orally or in writing.

Expressed Consent

Expressed consent must be oral and written and documented in the patient's medical record.

General Documentation Guidelines Regarding Informed Consent

Be sure that the form(s) are readable, detailed, and procedure specific (as opposed to generic). The consent should be, at a minimum, countersigned by the person obtaining the consent. Document the discussion in the patient's medical record and, if used, on the informed consent document itself. If the discussion took place in a language other than English, document the language used, and the name and relationship of any interpreter.

Specific questions or concerns raised by the patient should also be documented, along with the answers. Document any materials the patient was given or shown explaining the evaluation or treatment intervention. Examples include a copy of a procedure-specific consent form, pamphlets, brochures, videos or other educational materials. It is important to document the oral communication process in the progress note and file a copy of the signed form, if used, in the patient's records. This documentation may include:

- Met face to face with the patient;
- Reviewed each of the components listed above with the patient;
- The information reviewed is contained within the informed consent form;
- The patient was competent and understood the information; and
- The patient voluntarily signed the associated informed consent form.

Elements of Informed Consent

For patient consent for any evaluation or treatment intervention to be sufficient, the following items are typically required. These include but are not limited to:

- Differential diagnosis and pertinent evaluative findings;
- Nature of the evaluation or treatment intervention;
- Material (decisional) risks of serious harm, side effects, complications, and consequences associated with the evaluation or treatment intervention (i.e., indications and contraindications);
- Expected benefits/goals and anticipated outcome(s) associated with the proposed evaluation or treatment intervention;
- Referrals, reasonable alternatives, and the associated risks/benefits to these reasonable alternatives to the proposed evaluation or treatment intervention

(regardless of their cost or the extent to which these options are covered by health insurance);

- Consequences and potential risks of no evaluation or treatment intervention and/or refusal to complete a recommended referral;
- An affirmation that the patient reasonably understands the discussion and is legally and mentally competent to make the decision; and
- The voluntary decision by the patient to undergo the recommended evaluation or treatment intervention.

Other Elements of Informed Consent

Understanding

It is important to realize that understandability includes the ability to comprehend the language used and, if applicable, the use of assistive devices (e.g., eyeglasses/hearing aids). If the patient has limited literacy skills, all discussions and forms should be completed in the patient's preferred language or a language with which the patient is sufficiently familiar to be able to understand the information. In instances where a language barrier cannot be overcome between the health care practitioner and patient, then informed consent should be given through an appropriate interpreter. State regulations should be checked for recommendations on use of interpreters in a health care setting. Written forms must be at a readability level that follows appropriate health literacy guidelines for the patient population.

Competency

The individual must have decision-making capability, that is, they must have the ability to understand the nature and consequences of the evaluation or treatment intervention that they are being asked to undergo. The general rule is that a person is presumed to be competent unless there is a valid reason to believe otherwise. If the patient is incompetent for any reason, then consent must be obtained from a legally designated alternate individual.

Voluntariness

Patients must always be free to consent to or refuse any evaluation or treatment intervention and be free of any suggestion of duress or coercion. Consent obtained under any suggestion of compulsion either by the actions or words of the health care practitioner or others may not constitute consent and therefore be successfully challenged.

Minor Patients

A minor is typically defined as someone who has not yet reached the age of majority which, in most states, is anyone under 18 years of age. There may be exceptions to this definition of majority depending on the state, the procedure, and regulations regarding emancipated minors. In cases where the patient is a minor, the patient's parent, legal guardian, or conservator must provide the consent.

Exceptions to Obtaining Informed Consent

It is imperative that the health care practitioner understand that the following exceptions to obtaining informed consent should also be documented:

- Public Health Emergencies
  (e.g., in the case of an epidemic disease, such as tuberculosis)
- Medical Emergencies
  (e.g., the patient is not able to give consent due to incapacitation from a medical emergency)

Failure to Obtain Informed Consent

Failure on the part of the health care practitioner to obtain a patient's informed consent prior to any evaluation or treatment intervention may be considered a form of professional negligence and may constitute delivery of substandard care. Potential legal consequences (lawsuit) and risks of not obtaining informed consent (e.g., charges of assault/battery) need to be considered by the health care practitioner.

Informed Refusals

In the event that a patient refuses an evaluation or treatment intervention, the health care practitioner still has the same obligations of disclosure as when obtaining consent, that is, disclosure of the risk to be accepted. The health care practitioner must explain to the patient, in an objective fashion without creating a perception of coercion, the expected consequences of refusing the evaluation or treatment intervention. All of the same elements of informed consent identified above need to be discussed and documented, in addition to the patient's voluntary refusal to undergo the recommended evaluation or treatment intervention(s). Such documentation would then constitute legally *informed refusal.*

Being aware of and providing informed consent as appropriate benefits the practitioner and respects the patient's autonomy and right to make an informed decision about their care.

Use of Non-Evidence-Based Procedures

ASH practitioners agree not to use procedures or modalities that ASH has determined are not widely accepted as Evidence-Based* without first providing the member with a copy of the applicable ASH Clinical Practice Guideline, where available via ASHLink; notifying the member in advance and in writing of the clinical effectiveness and safety of the procedure or modality; and obtaining the member's written consent prior to performing the procedure or modality.

*Evidence-Based means that the health service (i) is supported by clinically relevant scientific information which can be used to inform the diagnosis or treatment of a patient that meets industry standard research quality criteria; (ii) is adopted as credible by an ASH clinical peer review committee; and (iii) has been published in an acceptable peer-reviewed clinical science resource and includes, but is not limited to, the techniques and procedures

identified by ASH clinical peer review committee as documented in the ASH clinical policies and clinical practice guidelines.

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