Policy

The client’s written informed voluntary consent to receive family planning program services must be obtained prior to the client receiving any clinical services. (8.0) In addition, if a client chooses a prescription method of contraception, written informed consent, specific to the contraceptive method, must be signed before the prescription contraceptive method is provided. (8.1)

Standards

1. Informed consent is an educational process. The consent form documents the educational process. This process includes a mutual sharing of information between the clinician and the client to facilitate the client’s autonomy in the process of making ongoing choices (ACOG, Committee Opinion #439).

2. Consent forms must be written in a language understood by the client or translated and witnessed by an interpreter. (8.1)

3. All consent forms should contain a statement that the client has been counseled, provided with the appropriate informational material, and understands the content of both. (8.1)

4. To provide informed consent for contraception, the client must receive information on the means by which the method prevents conception; effectiveness; benefits and risks; explicit instruction on how the method is used for effective contraception; when the method becomes effective and when an interim or back-up method is required, if appropriate; potential side effects, complications, discontinuation issues; danger signs of the contraceptive method chosen; and schedule for continuing care. (8.1)

5. Specific education and consent forms for the contraceptive method provided must be part of the project’s service plan. The method-specific consent form should be renewed and updated when there is a major change in the client’s health status or a change to a different prescriptive contraceptive method. (8.1)

6. The counseling and consent process for permanent contraception must assure that the client’s decision to undergo sterilization is completely voluntary and made with full knowledge of the permanence, risks, and benefits associated with female and male sterilization procedures. Federal sterilization regulations, which address informed consent requirements, must be complied with when a sterilization procedure is performed or arrange for by the project. (8.4)

7. Informed refusal is a fundamental component of the informed consent process. The subsequent election by the client to forgo an intervention that has been recommended by the provider constitutes informed refusal. (ACOG, Committee Opinion #306).

8. The client shall be informed of program policies that describe informed consent and the right to refuse services. Counseling must include information about the possible health risks associated with declining or delaying preventive screening tests or procedures (8.3). If a client chooses to decline or refuse a service, such refusal shall be evidenced by the client’s signature on the refusal form[s] (8.3).
The client has the right to refuse any laboratory exam. If the exam is one which is required by good medical practice as a prerequisite for a particular procedure or the prescription of a particular medication, the client shall be informed that the procedure cannot be performed or the prescription provided in the absence of the laboratory exam (8.3).

9. The signed informed consent form or release form when a test, service, or consultation will not be obtained as recommended must be a part of the client’s record. (8.1; 10.3)

**Procedure**

1. Provide information to the client that assists them in understanding that informed choice and informed consent or refusal is a serious process for ensuring voluntary, clearly understood medical care. This specialized aspect of client education is the highest priority of all educational tasks in the health care setting.

2. Incorporate educational considerations for consent into your encounter process. Adults and adolescents best learn, and make considered decisions, under the following circumstances:
   - In the absence of threat
   - When information seems relevant
   - When teaching takes cultural factors into account
   - When the learning process is interactive
   - When having a chance to ask and receive answers to questions
   - When the information is age appropriate

3. Inform all clients about their complete range of options and allow them to choose freely. Once a client chooses a course of action, give full disclosure about their choice. *Only when these two steps have been completed can the client provide an informed and documented consent to care.*

4. Ensure that the client sufficiently understands all reasonable alternatives and determine whether the client is competent to consent to the chosen medication, device, or procedure. The basic criteria for competence to consent include:
   - Is the client capable of understanding the proposed treatment, alternatives, and risks?
   - Is the client capable of making rationale decisions?

5. Evaluate learning and comprehension by having the client say *in their own words* what they have learned.

6. If the client’s competence is difficult to evaluate, or you have any doubt regarding a client’s competence to consent, consult with other professionals to determine the appropriate course of action. Document your consultation in the client’s record.

7. When informed consent by the client is impossible, a legally identified surrogate may represent the client (ACOG, Committee Opinion #439).

8. For contraceptive method informed consent, use Department of Health and Human Services regulations for guidance. Informed consent comprises seven basic elements (“BRAIDED”):
   - Benefits of the method
   - Risks of the method (all major risks, all common minor risks, and related uncertainties and unanswered questions); be sure to include consequences of method failure
   - Alternatives to the method (including abstinence and no method)
   - Inquiries about the method are the client’s right and responsibility
   - Decision to withdraw from using the method without penalty is the client’s right at any time
   - Explanation of the method is owed the client, in a format that is understandable to the client
Documentation that the caregiver has ensured understanding of each of the preceding six points, usually by use of a consent form

9. Review and complete the written consent and / or refusal form(s)* with client and witness signatures.

   * “MFHS Consent for Provision of Services and / or Supplies”
   * “Release When Test / Service / Consultation Will Not Be Obtained As Recommended”

10. Inform the client that the consent and / or refusal form(s) become a permanent part of their medical record.

11. Provide every client with written information specific to the contraceptive method voluntarily selected by and provided to that client.

Resources

- Program Guidelines …for Family Planning Services, OPA, 2001
- “Informed Consent”, ACOG Committee Opinion #439, August 2009
- “Informed Refusal”, ACOG Committee Opinion #306, December 2004

Document History

- 2008
- September 2003