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How to use the Informed Consent Materials

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A practical guide to informed consent for administrators, supervisors, and staff responsible for service delivery and for personnel providing direct care to clients.



Introduction

This booklet is a practical guide to informed consent for administrators, supervisors, and staff responsible for service delivery and for personnel providing direct care to clients. This information was developed to ensure that clients receiving fistula care give informed consent for procedures and/or surgeries (i.e., the primary surgery and any other that may become necessary in the course of the operation). Informed consent is especially important in fistula care services because many women who have lived with fistula have experienced a traumatic event and have become marginalized as a result of their injuries. Informed consent is a part of the healing process and shows respect for the woman. Women living with fistula have a right to safe services, including access to accurate information about their condition, about the range of treatment options, and about the variety of posttreatment outcomes. To ensure these clients' rights, we invite you to use this booklet as a reliable resource.

The informed consent booklet for fistula care contains three sections:

An overview of informed consent in fistula care	5
A suggested protocol for ensuring informed consent in fistula care	12
A sample informed consent form for use in fistula care services	13

This content is part of *Counseling the Obstetric Fistula Client: A Training Curriculum* and has been extracted to form a user-friendly pocket resource.

These informed consent materials for fistula care are intended to help sites providing fistula services, to establish a mechanism for ensuring the client's right to information for informed decision making, and to help the client actively participate in her health care. The materials can also be a resource for orienting staff and for refining supervisory tools to monitor this important element of quality of care.

Audiences for this material may include:

- Technical advisors, to facilitate implementation of informed consent
- Health policy makers, facility administrators, and supervisors
- Counselors and clinical providers (e.g., surgeons, midwives, or nurses)
- Community health personnel
- Tutors (in preservice training) and trainers (during in-service training)

Use by Technical Advisors, Policy Makers, Facility Administrators, and Supervisors

Administrators, supervisors, and other senior-level personnel should be sure to do the following:

- Review the three sections to become familiar with the content and process of informed consent for fistula care services.
- Identify appropriate stakeholders, including program counterparts, to introduce the materials and review them in relation to what is already in place in-country (where this exists).
- Determine what content should be incorporated into the informed consent overview, what steps should be included in the informed consent protocol, and what aspects of the informed consent form will be adapted into existing in-country materials and processes (or, whether the materials will be adopted in their entirety).
- Assist health policy makers to formulate and disseminate a policy statement regarding the updated or new informed consent protocol, materials, and form.
- Provide technical support to facility administrators to operationalize the new or updated informed consent protocol, materials, and form, including modifying supervisory tools to reflect the informed consent process.
- Provide technical support for orienting supervisors to the modified forms, as part of their orientation to the new or updated informed consent process, materials, and form.
- Provide technical support to supervisors and/or trainers to orient staff (facility and community) to the informed consent content, protocol, and form.
- Assist tutors and trainers to incorporate the approved informed consent content, protocols, and form into their preservice and in-service training curricula, respectively.



Use by Tutors and Trainers

Following incorporation of the informed consent content, protocols, and form into the preservice and in-service training curricula and activities, tutors and trainers will need to:

- Orient or train supervisors, counselors, and clinical providers to carry out their respective functions in support of informed consent.
- Provide postorientation/posttraining follow-up, to contribute to monitoring this quality of care element in fistula care service delivery.
- Adapt orientations/trainings based on posttraining follow-up findings that are related to training needs.
- Orient translators to the content of informed consent, to ensure accurate explanation of technical information in the language of the client.

Use by Counselors and Clinical Providers

Once the informed consent content, protocols, and form have been incorporated into service provision, counselors and clinical providers will need to:

- Carry out informed consent as outlined in the overview and the approved protocol, with each client being assessed and prepared for fistula care procedures and/or surgery.
- Document informed consent using the approved informed consent form and secure this documentation in the client's record.

Use by Community Health Personnel

Following the incorporation of informed consent processes into service provision, community health personnel will need to:

- Become familiar with the informed consent overview, to accurately present information to and answer questions from women, families, and communities.
- Share with women, families, and communities what to expect as part of the informed consent process when women present at sites for assessment and/or preparation for procedures and/or surgery.

This booklet is a practical guide for program managers responsible for facilitating service delivery and for personnel providing direct care. This information was developed to ensure that clients receiving fistula care give informed consent for procedures and/or surgeries (i.e., the primary surgery and any other that may become necessary in the course of the operation).

Fistula is a condition that few like to talk about, and the women living with fistula frequently feel shame at their constant leaking and odor. As a result, they often hide themselves or they are forced to live in isolation from their communities—sometimes even from their families. Because of the stigma and misunderstanding associated with this condition, women living with fistula are vulnerable to abuse and poverty, have limitations in caring for themselves and others, and may not have had access to education. Counseling women with these challenges requires openness, compassion, a willingness to simplify complex terms and concepts, and a genuine desire to make the woman feel welcome. Women living with fistula have a right to safe services, including access to accurate information about their condition, the range of treatment options, and the variety of posttreatment outcomes. Women living with fistula have a right to be treated with respect, dignity, and consideration. Within these characteristics for quality, informed consent is a key element of care.

Informed consent is the communication between a client and a provider, using simple language, terms, and visual aids that the client understands, intended to confirm that the client has made an informed and voluntary choice to use or receive a medical method, procedure, or surgery. Informed consent can only be obtained after the client has been given adequate and relevant information, in language and terms s/he understands, about the nature of the condition, the causes, and the medical procedure; the procedure's associated risks and benefits; and other alternatives. Voluntary consent cannot be obtained by means of special inducement (incentive or disincentive), force, fraud, deceit, duress, bias, or other forms of coercion or misrepresentation—including unwarranted deferral or repeated postponement of surgery.

The fact that the client signs a consent form does not necessarily mean that the person requests the procedure with full knowledge of the facts.

Informed Consent Process

Informed consent is one component of the counseling process designed to safeguard the client's right to make an informed decision. Documenting informed consent ensures that this process has occurred and that the health care facility is complying with legal requirements.

Counseling is the process by which service providers help ensure that a client makes an informed and well-considered decision about the fistula treatment procedure(s). **Counseling is defined** as a two-way communication process of helping clients make informed and voluntary decisions about their individual care. Counseling occurs one-to-one and involves the client and the provider; it may also include the client's partner or another support person whom the client has requested to be present. Through counseling, providers:

- Give information that the client needs to make a fully informed decision about fistula-related treatment.
- Determine whether the client understands the consequences of her own decision and is comfortable with it.

Counseling is the process; an informed decision is the intended outcome.

Five Elements of Informed Consent

1. Treatment options. Describe the treatment options in general terms; briefly describe the procedure indicated for the client; discuss whether that particular procedure can be carried out within the facility or whether the client will have to be referred; describe the costs associated with the treatment (e.g., transportation, follow-up visits, etc.).

2. Procedure details. Describe in understandable details, using language the client understands and visual aids that the client can follow, the type of surgery or procedure to be performed; discuss whether it will be one or potentially multiple surgeries; include the anesthesia to be used; describe the benefits of the procedure; provide a brief mention of the risks; explain pain management, the anticipated postoperative course, and follow-up, including the need for sexual abstinence for a time and family planning use afterwards; and discuss the possibility of residual postoperative side effects.

3. Associated risks. Provide understandable details of the risks associated with any surgical procedure (e.g., complications, bleeding, infection, and death) and the risks associated with fistula repair (e.g., damage to nearby organs). Inform the client that she may experience infertility, which may or may not be a result of the surgery.

4. Potential outcomes. Inform the client that she will no longer have leaking and associated discomfort once the test-of-cure assessment indicates the absence of leaking. Fertility may become an issue to address before complete healing takes place; therefore, the client will need to protect the repair by observing a period of abstinence, by using family planning, and by obtaining antenatal care and delivering by cesarean section from a skilled provider. In a few cases, the vagina may narrow after repair and the woman may experience pain when she has sex (dyspareunia) with a partner; this may require further care, and in a few cases the couple will have to adjust to coping with it. For clients who have completed their childbearing, family planning should be used to prevent unintended pregnancy. For some women, fertility may not return after the repair and they may not be able to have children.

If the repair procedure does not work, other options will need to be explained to the client before obtaining her consent for these procedures. However, as with any surgical procedures, symptoms may not resolve; the client and family members will need to be guided in ways to cope with the condition.

5. Options to decide for or against the procedure. If the client decides to have the procedure, confirm her understanding of the procedure, the benefits, the risks, the potential outcomes, and the need for a period of abstinence followed by use of family planning for a period of time postrepair. If the client decides not to have the procedure, confirm that she understood the description of the procedure and understands available options. Assure the client that she will not lose any health benefits that she received before and that she can still have the repair any time she changes her mind. Assess what other health care needs the client may have and refer her to the appropriate resources when available.



Responsibility for Informed Consent

The director or administrator of the fistula care facility is responsible for ensuring that informed consent is obtained and documented for every client who undergoes fistula repair. These senior personnel are responsible for ensuring that:

- A written protocol on informed consent is available to project staff.
- Staff responsible for counseling and documenting informed consent are appropriately trained.
- An adequate supply of the approved informed consent form is available.
- Adherence to informed consent procedures and principles is monitored regularly.
- The informed consent procedures at the service site comply with policies and procedures agreed upon with the national or international funding agencies, if any.

Informed consent can be obtained and documented by counselors, clinical officers, nurses or midwives, physicians, or administrative staff or volunteers after they have been successfully trained in how to obtain and document informed consent. However, the primary responsibility for ensuring that informed consent has been obtained is with the operating provider. The operating provider should also be the person accepting referrals from the staff when clients' questions or unresolved clinical issues arise.

Note: *In some settings, administrative or nonmedical personnel may begin the counseling process, and the physician obtains and documents the client's informed consent. The person who obtains the informed consent after the counseling process has been started must be trained to assess whether the client's knowledge is complete and the decision is informed.*

Informed consent should be obtained and documented before the procedure; documentation is made after the counseling process and **after** the person conducting the counseling determines that the decision has been made with full understanding of the facts.

Informed consent should be obtained by following the Five Elements for Informed Consent protocol (pages 6–7) and by reading the entire informed consent form aloud to the client. If the client can read, she should have a form to read along with the counselor. If the client cannot read, a witness should have a form to read along with the counselor. If the witness also cannot read, s/he should at least be present when the form is read aloud to the client. After asking if the client understands the information on the form and if she requests the procedure, the counselor must then obtain the required signature or marks.

The informed consent form and the entire counseling process should be communicated in a language and in terms understood by the client. In settings where clients speak many different languages, staff responsible for counseling should speak the language that most of the clients use, so that the largest number may be served. Where counseling staff do not speak the client's language, an interpreter should be available to ensure that the client understands the informed consent counseling. (This interpreter should be oriented to the philosophy and language of informed consent, to help ensure consistency and quality of care.)

Informed consent forms should be available in the most common language and, to the extent possible, in other languages.

- For clients who can read and write, the informed consent form must be signed by the client and the operating physician* or her/his designated assistant.
- For clients who cannot read or write, the informed consent form must be signed by the client using a thumbprint or mark and by the operating physician* or her/his designated assistant. In such cases, it is advisable for the client to have a witness (e.g., a support person of her choosing) present during counseling, to ensure recollection of information. The witness should also sign the consent form in the designated area.

Each signature must be dated, and the date of each signature must be before or on the day of the surgery.

*The operating physician or her/his designated assistant signs the consent form to indicate that s/he has verified the client's signature, thumbprint, or mark and has established that the fistula repair client understands and agrees to undergo the surgery.

Management and Supervision of Informed Consent Compliance

The informed consent form should be part of the client's medical-surgical record and must be kept on file at the service delivery site for at least 5 years or whatever the national/medico-legal guidelines call for—whichever is longer.

The director or administrator of the facility is ultimately responsible for ensuring compliance with informed consent policies and procedures. Responsibility may be delegated to supervisors of staff implementing informed consent procedures. Compliance should be verified by chart review, observation of informed consent counseling, and interviews with clients as part of quarterly or biannual medical monitoring.

Chart Review

Informed consent forms should be audited regularly; such audits should not be announced beforehand. The person conducting the review should have direct access to all records and should select the ones to be examined.

Objective review of the forms should be guided by use of the following questions:

- Are staff members using the approved informed consent form?
- Does the form being used comply with the program's guidelines?
- Is there an informed consent form on file for each client who has undergone fistula repair procedures?
- Is the form correctly signed and dated?



The reviewer should look for the following indications that standard informed consent procedures are not being followed:

- The client's signatures on a number of forms are dissimilar (indicating possible forgery).
- The handwriting of the various signatures on a number of forms looks similar (indicating possible forgery).
- There are missing client, witness, or provider signatures.
- A signature appears on the form, even though it is inappropriate to the setting (i.e. there is a script signature from someone who cannot read or write).

Observing Informed Consent Counseling

Observation of informed consent counseling should be a part of the quality improvement monitoring process on-site. Immediately before counseling, staff should obtain the client's permission for the observation. The supervisor should verify that staff members are following informed consent policies and procedures. If deficiencies are noted, the supervisor should determine if the staff have copies of the informed consent protocol and are familiar with it. Where necessary, staff should be coached or retrained.

Interviewing Clients

Client interviews may be conducted during the time between when informed consent is documented and when surgery is performed. The objective is to verify that the client was informed fully (consistent with the elements of informed consent). The interview should be conducted using an established list of questions and within a reasonable time after counseling, to minimize the potential for the client to have forgotten information.

Adapted from: Butta, P. 1988. Informed consent and voluntary sterilization: An implementation guide for program managers. New York: Association for Voluntary Surgical Contraception.

FISTULA CARE: INFORMED CONSENT PROTOCOL

- Set up a counseling area that can provide auditory and visual privacy.
- Collect job and visual aids that will be used during the counseling session, including the informed consent forms.
- Put the woman at ease and ask what she knows about her condition and the fistula treatment that is being proposed.
- Correct any misinformation and fill in any knowledge gaps.
- If the woman will have a specific fistula procedure or surgery, conduct the informed consent counseling using simple language to cover the **Five Elements**:
 - Provide general information about fistula and fistula treatment, including procedures and surgeries, using visual aids to illustrate what you are saying.
 - Describe in detail the specific procedures or surgery that will be carried out, and provide information on anesthesia, benefits, risks, pain management, postoperative course, and follow-up, including abstinence, family planning, and the woman's need to protect herself from becoming infected with HIV and other sexually transmitted infections.
 - Communicate the associated risks of any surgical procedure (complications, bleeding, infection, and death) and any risks specific to fistula repair (damage to nearby organs).
 - Explain the procedure's range of outcomes in terms of no longer having leaking, soiling, or both; its potential effect on sexual relations, and the possibility of experiencing pain with sexual intercourse (in a few cases); and the fact that future desired fertility cannot be guaranteed. Explain the possibility that additional surgery may be needed during or after the repair, as well as the possibility of continued leaking or soiling.
 - Inform the woman that she can choose to decide for or against the procedure, that she can decide not to have the procedure without penalty or loss of benefits, and that she may have the repair if she changes her mind.

- Ask the woman what clarifying questions she has, and reply to these.
- Confirm the woman's understanding by asking her to explain in her own words what will be done and what are the risks, the possible outcomes, the potential impact on sexual relations and future fertility, the chance that additional surgery will be needed, and the options to not have the surgery or to have it at a later time.
- Introduce the Informed Consent form and read through it. If the woman agrees to the procedure, follow the instructions on the form for obtaining her signature (and that of a witness, for women who cannot read or write).
- Document the informed consent counseling in the client record.
- Insert the signed form into the client record.
- Inform the operating physician or her/his designate so that s/he signs the same form.
- Follow the facility's general preoperative protocols.



FISTULA CARE: INFORMED CONSENT FORM

Instructions: Read through the form with the client and print the client's full name in the space provided on the first line below. Ask the client to put her initials in the space provided before each number after she has read the statement. After the client has read or heard the statement, ask her to put either her initials, fingerprint, or other agreed-upon mark on the signature line. Follow the instructions for the signature of a witness. Ask the physician or her/his designate to sign this form before preoperative preparations begin.

I, _____, (client's name) the signed, request that a fistula repair surgery be performed on my person.

I make this request of my own free, informed will, without having been forced, pressured, or given any special inducements. I understand the following:

- 1. The procedure to be performed on me is a surgical procedure, the details of which have been explained to my understanding.
- 2. This surgical procedure involves risks of complications such as bleeding, injury to other organs, and infection, including death.
- 3. This procedure offers the benefits of eliminating the fistula and its associated symptoms of leaking, soiling, or both.
- 4. No surgical procedure can be guaranteed to work 100% on all people; there is a potential for symptoms to continue; there also may be a need for additional surgery, or additional surgery may not be an option.
- 5. This surgical procedure will not guarantee future desired fertility.
- 6. The outcomes of this surgical procedure include a period of abstinence (3–6 months postrepair), followed by the use of family planning for a period of time before I can attempt to conceive.
- 7. I can decide against the procedure at any time before the operation is performed (and no medical, health, or other benefits or services will be withheld from me as a result).

Date

Signature or mark of the client

Date

Signature of attending physician/delegated assistant

If the client cannot read, a witness of the client's choosing, and speaking the same language, must sign the following declaration:

Date

Signature of attending physician/delegated assistant