2014 CLINICAL POLICY GUIDELINES

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NATIONAL ABORTION FEDERATION

2014 Clinical Policy Guidelines

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National Abortion Federation *Clinical Policy Guidelines* can be accessed on the Internet at www.guidelines.gov.

The National Abortion Federation is the professional association of abortion providers in the Americas. Our mission is to ensure safe, legal, and accessible abortion care, which promotes health and justice for women.

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Introduction

The mission of the National Abortion Federation (NAF) is to ensure safe, legal, and accessible abortion care, which promotes health and justice for women. An important part of this work is to develop and maintain evidence-based guidelines and standards as well as to educate providers in the latest technologies and techniques. NAF's programs make it possible for women to receive the highest quality abortion care.

Like its precursors, the 2014 edition of NAF's *Clinical Policy Guidelines* (CPGs) establishes clinical policy guidelines, which are developed by consensus, based on rigorous review of the relevant medical literature and known patient outcomes. These guidelines are intended to provide a basis for ongoing quality assurance, help reduce unnecessary care and costs, help protect providers in malpractice suits, provide ongoing medical education, and encourage research.

NAF's *Clinical Policy Guidelines*, first published in 1996 and revised annually, are based on the methodology described by David Eddy, MD, in *A Manual for Assessing Health Practices and Designing Practice Policies: The Explicit Approach.* Clinical policy guidelines are defined as a systematically developed series of statements which assist practitioners and patients in making decisions about appropriate health care. They represent an attempt to distill a large body of medical knowledge into a convenient and readily usable format.

When the outcomes of an intervention are known, practitioner choices are limited. But when the outcomes of an intervention are uncertain or variable, and/or when patients' preferences for those outcomes are uncertain or variable, practitioners must be given flexibility to tailor a policy to individual cases. This is addressed by having three types of practice policies according to their intended flexibility: standards, recommendations, and options.

1) **STANDARDS** are intended to be applied in virtually all cases. Deviations will be rare and difficult to justify.

2) **RECOMMENDATIONS** are steering in nature. They do not have the force of standards, but when not adhered to, there should be documented, rational clinical justification. They allow some latitude in clinical management.

3) **OPTIONS** are neutral with respect to a treatment choice. They merely note that different interventions are available and that different people make different choices. They may contribute to the educational process, and they require no justification.

NAF's *Clinical Policy Guidelines* include a list of bibliographic and cited references for each section when appropriate, and include discussion material in more controversial areas. These guidelines are meant to be living documents, subject to revision every year as new medical evidence becomes available.

Note: The *Clinical Policy Guidelines* are not intended to educate members regarding legal and regulatory issues which may affect abortion practice. It is expected that administrators, staff, and clinicians will be aware of pertinent local, state/provincial/territorial, and national legislation as well as the requirements and limitations of their individual duties and scope of professional practice. NAF provider members should ensure that all employees have access to appropriate resources for information and support.

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Notes on Formatting

As presented here, Standards, Recommendations, and Options are hierarchical in nature. It is therefore expected that clinical practices will favor the highest level of guidance available on a given point. In order to clarify the relationships of Recommendations and/or Options that are subordinate to higher level Standards and/or Recommendations, NAF's guidelines are numbered and formatted according to the following scheme:

Within each main subject heading, Standards are numbered consecutively (e.g., Standard 1).

Recommendations are also numbered consecutively within each main subject heading, with numbers that are placed in the first position to the right of a decimal point (e.g., Recommendation 0.1). Where a recommendation follows from or is related to a Standard, it is indented below the Standard and the number of that Standard will be found to the left of the decimal point (e.g., Recommendation 1.1). Where the recommendation stands alone and is not related to a specific Standard, it is not indented in its placement on the page, and there will be a zero in the position to the left of the decimal point (e.g., Recommendation 0.1).

The consecutive numbers denoting Options within each main subject heading are placed to the right of the second decimal point (e.g., Option 0.0.1). Where an option follows from or is related to a preceding Standard or Recommendation, it is indented below that Standard or Recommendation and the numbers identifying them will be found to the left of the decimal point and in the first position to the right of the decimal point respectively (e.g., Option 1.0.1 or Option 1.1.1, or Option 0.1.1). Where the Option stands alone and is not related to a specific Standard or Recommendation, it is not indented in its placement on the page, and there will be zeros in those positions (e.g., Option 0.0.1).

1. Who Can Provide Abortions

Policy Statement: Abortion is a safe procedure when provided by qualified practitioners.

Standard 1. Abortion will be provided by licensed* practitioners. This category is intended to include physicians from various specialties as well as nurse midwives, nurse practitioners, physician assistants, registered nurses, and other health professionals.

Recommendation 1.1. Documentation specifying privileges in accordance with each practitioner's scope of practice should be maintained.

Standard 2. All practitioners providing abortions must have received training to competency in abortion care, including the prevention, recognition, and management of complications.

Recommendation 2.1. Appropriate referrals should be available for patients who cannot be cared for by a practitioner at your facility.†

* The term "licensed" is used here to indicate that a person is lawfully entitled to practice their profession in the place in which the practice takes place. The laws are different throughout the United States, Canada, Mexico, and Colombia.

† This may include the NAF Referral Line.

2. Patient Education, Counseling, and Informed Consent

Policy Statement: Obtaining informed consent and assessing that the decision to have an abortion is made freely by the patient are essential parts of the abortion process.

Informed Consent

Standard 1. The practitioner must ensure that appropriate personnel have a discussion with the patient in which accurate information is provided about the procedure and its alternatives, and the potential risks and benefits. The patient must have the opportunity to have any questions answered to her satisfaction prior to intervention.

Option 1.0.1. Information may be provided either on an individual basis or in group sessions.

Standard 2. There must be documentation that the patient affirms that she understands the procedure and its alternatives, and the potential risks and benefits; and that her decision is voluntary.

Patient Education and Counseling

Standard 3. Each patient must have a private opportunity to discuss issues and concerns about her abortion.

Standard 4. A patient must undergo the abortion as expeditiously as possible in accordance with good medical practice.

Standard 5. Information about aftercare and contraception must be available to patients at the facility.

Standard 6. All reasonable precautions must be taken to ensure the patient's confidentiality.

Recommendation 6.0. The patient should be informed of the communication of information to any third party such as for payment for an abortion.

Discussion: Informed consent and abortion counseling are two different processes. The goal of informed consent is to assure that the patient's decision is voluntary and informed. Patient education and counseling includes a discussion of the feelings and concerns expressed by the patient, which may include help with decision-making and contraceptive choices, values

clarification, or referral to other professionals. A referral to community services should be available if that becomes necessary or the needs of the patient are outside the scope of training of clinic staff.

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3. Baker, A, *et al*. Informed Consent, Counseling and Patient Education. In Paul, M. *et al.* (Eds.), *A Clinician's Guide to Medical and Surgical Abortion.* Philadelphia: Churchill Livingstone, 1999.

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3. Infection Prevention and Control

Policy Statement: Health care personnel and their patients are at risk for exposure to blood borne pathogens and other potentially infectious material. Infectious material may be transmitted to patients when proper engineering* and work practice controls,† which reduce exposure are not followed.

Standard 1. Proper engineering and work practice controls should be in place to reduce exposure of patient and staff to infectious materials. Clinics should protect employees and patients from being exposed to biohazardous material.

- Recommendation 1.1. Personal protective equipment and training programs should be provided to all staff. New staff with potential exposure should have an initial training as part of orientation. Periodic facility-level training should occur at least every three years.
- Recommendation 1.2. Hepatitis B vaccine should be provided at no cost to the staff.

Standard 2. Exposure control plans must be established and followed.

- Recommendation 2.1. Post exposure evaluation, prophylaxis, and follow-up should be available to exposed patients or staff for any potentially infectious agent, regardless of source.

Standard 3. All surgically removed tissue must be considered biohazardous and be handled, stored, and disposed of in a manner that minimizes the risk of exposure. A protocol for tissue handling, storage, and disposal must be in place

Discussion: Regulatory agency policies (see references) may be helpful in developing exposure plans that protect personnel and patients from potentially infectious material. Proper techniques for collection, labeling, and disposal of biohazardous material and for the processing of instruments are integral to any complete plan.

* Engineering control—available technology and devices that isolate or remove hazards from the work place, such as puncture-resistant sharps disposal containers.

† Work practice control—an alteration in the way a task is performed that reduces the likelihood that an employee will be exposed to blood or other potentially infectious materials.

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4. Rh Testing and Rh Immunoglobulin Administration

Policy Statement: Rh alloimmunization may jeopardize the health of a subsequent pregnancy.(1-8)

Standard 1. Rh status testing must be offered to all women undergoing first-trimester abortion.

Standard 2. Rh status must be documented in all women undergoing second-trimester abortion.

- Recommendation 2.1. This documentation may be obtained by on-site testing or outside source, or self-report.
- Recommendation 2.2. Informed waiver should be signed by a patient who declines Rh testing and is unaware of her RH status.
- Recommendation 2.3. Additional testing for either sensitization or other antibodies is not required in patients undergoing pregnancy termination, including testing for Du ("weak D").

Standard 3. Rh immunoglobulin administration must be offered to Rh(-) women.

Standard 4. If Rh immunoglobulin is not administered in the facility, one of the following is required:
(a) Informed waiver signed by a patient who declines Rh immunoglobulin; or
(b) Documentation of other arrangements for administration.

Discussion: No data supports the administration of Rh immunoglobulin in very early pregnancies (less than eight weeks), or that indicate any harm associated with its administration. Until/unless such data is available, the NAF Rh testing standards must be applied to pregnancies of any gestation.

The use of approved slide/tube/spot methods is acceptable for on-site Rh testing.

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5. Limited Sonography in Abortion Care

Policy Statement: The use of ultrasound is not a requirement for the provision of first-trimester abortion care. Proper use of ultrasound may inform clinical decision-making in abortion care.

Standard 1. Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation of proficiency or complete a program of training. Training must include a period of supervision. Documentation of this training must be maintained.

Option 1.1.1. The *Ultrasound Training in Abortion Care* CD-ROM developed by ARMS, NAF, and CAPS is a good resource for training and may be utilized as part of a training program.(1)

Standard 2. A system of proficiency review must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams.

Standard 3. Patients must be informed of the purpose and limitations of the ultrasound exam in the abortion care setting. Patients must be informed of the sonographic diagnosis, including early pregnancy failure.(2, 3)

Standard 4. The findings of all ultrasound exams and the interpretation of those findings must be documented in the medical record. This documentation must also include the name(s) of staff who performed and interpreted the exam.

Recommendation 4.1. Ultrasound images should be included as part of the documentation, particularly for the purposes of proficiency review.(4)

Recommendation 4.2. A standard form for documenting findings and interpretation should be used.

Standard 5. A limited first-trimester ultrasound exam must include the following:
(1) A full scan of the uterus in both the transverse and longitudinal planes to confirm an intrauterine pregnancy;
(2) Evaluation of pregnancy number;
(3) Measurements to document gestational age; and
(4) Evaluation of pregnancy landmarks, such as yolk sac or the presence or absence of fetal/embryonic cardiac activity.

Recommendation 5.1. When clinically indicated, evaluation of other pelvic structures (i.e., adnexal structures and the cul de sac) should be performed and documented or an appropriate referral should be made for further evaluation.

Standard 6. A limited second-trimester ultrasound exam must include the following:

(1) Views to document intrauterine location of the pregnancy;
(2) Evaluation of fetal number;
(3) Fetal measurements to document gestational age;
(4) Evaluation of fetal cardiac activity; and
(5) Placental location.

Recommendation 6.2. When placenta previa is suspected or a low anterior placenta is identified in a patient with a prior uterine scar, or when other placental abnormality is suspected, further diagnostic imaging should be performed or an appropriate referral made.

Standard 7. Ultrasound equipment must be properly maintained.

Standard 8. Ultrasound transducers must be disinfected between patients.

Discussion: According to the American Institute of Ultrasound in Medicine (AIUM), in collaboration with the American College of Obstetrics and Gynecology and the American College of Radiology, a "limited ultrasound examination" is performed when a specific question requires investigation.(4-6)

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4. American Institute of Ultrasound in Medicine. AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations. Laurel, MD: American Institute of Ultrasound in Medicine, 2007.

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6. Early Medical Abortion

Policy Statement: Medical induction is an effective method for early abortion.(1-8) Adequate counseling and follow-up care will enhance its safety and acceptability.

Standard 1. Initial evaluation must include pertinent medical history.

- Recommendation 1.1. Baseline vital signs (e.g., blood pressure, pulse) should be done.
- Recommendation 1.2. Either hematocrit or hemoglobin screening should be obtained in women with a history of significant anemia or specific indication.
- Recommendation 1.3. A complete blood count (CBC) should be considered for women receiving methotrexate.

Standard 2. The patient must be informed about the efficacy, side effects, and risks, especially excessive bleeding and infection.

Standard 3. The patient must be informed of the need to ensure the success of the abortion and of the teratogenicity associated with the medications to be used.

Standard 4. The patient must be informed that a uterine aspiration will be recommended if medical abortion fails.

Standard 5. Patient instructions must include written and oral information about use of medications at home and symptoms of abortion complications.

Standard 6. The facility must provide an emergency contact service on a 24-hour basis and must offer or assure referral for uterine aspiration if indicated.

Standard 7. Confirmation of pregnancy must be documented. Gestational age must be verified to be within the limit of the facility medical abortion protocol.

Standard 8. If an ultrasound has been performed and an intrauterine gestation has not been confirmed, ectopic pregnancy must be considered. Additional evaluation should follow a protocol as outlined in CPG 8. Management of Pregnancy of Uncertain Location. Starting the medical abortion regimen does not need to be delayed.

Standard 9. Combined mifepristone/misoprostol regimens are more effective than misoprostol alone or methotrexate and misoprostol. An evidence-based medical abortion regimen must be used.(9-11)

Recommendation 9.1. Where mifepristone is available, a combined mifepristone-misoprostol regimen should be used. (1-7, 12-14)

Option 9.1.1. If a misoprostol-alone or methotrexate-misoprostol regimen is offered when mifepristone is available, full information on the differences between the chosen regimen and mifepristone-misoprostol regimens should be addressed with the patient and informed consent obtained.

Recommendation 9.2. A dose of 200 mg of mifepristone is recommended for combined mifepristone-misoprostol regimen.(7, 11)

Recommendation 9.3. When mifepristone and vaginal, buccal, or sublingual misoprostol are used, the regimen is recommended for gestations up to 70 days.(15, 16)

Recommendation 9.4. When mifepristone and oral misoprostol are used, the regimen is recommended for gestations up to 56 days.(17)

Recommendation 9.5. A regimen of misoprostol alone may be used by vaginal, buccal, or sublingual routes for gestations up to 63 days.(9-11, 18-22)

Recommendation 9.6: When methotrexate and misoprostol are used, an evidence-based regimen using vaginal, buccal, or sublingual misoprostol is recommended for gestations up to 63 days.(7, 23-25)

Standard 10. Patient comfort level during the medical abortion process must be considered.

Recommendation 10.1. Analgesia or other comfort measures should be discussed and offered as needed unless there are contraindications. Ibuprofen is more effective than acetaminophen for pain control.(26-28)

Standard 11. Success of the medical abortion must be assessed by ultrasonography, hCG testing, or by clinical means in the office or by telephone. If the patient has failed to follow-up as planned, clinic staff must document attempts to reach the patient. All attempts to contact the patient (phone calls and letters) must be documented in the patient's medical record.(29-31)

Recommendation 11.1. Follow-up evaluation should be scheduled for 7-14 days after starting medical abortion.(7)

Recommendation 11.2. High-sensitivity urine hCG testing should not be checked within three weeks of medical abortion.(32, 33)

Recommendation 11.3. Ultrasonography or hCG levels should be used to evaluate completion of the abortion when expected bleeding does not occur after medications.

Recommendation 11.4. Endometrial thickness alone should not be used to guide management after medical abortion.(34, 35)

Discussion: Many patients prefer pharmacological methods of terminating early pregnancies rather than suction curettage. Medical abortion has several advantages for patients. It avoids surgery and anesthesia and offers women more active participation and control over the abortion process.

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7. First-Trimester Surgical Abortion

Policy Statement: Induced abortion is one of the safest surgical procedures. The following guidelines are intended to outline procedures that maximize this safety.

Standard 1. Pertinent medical history must be obtained.

Standard 2. Pregnancy must be confirmed and gestational age must be assessed.

Recommendation 2.1. When gestational age cannot be reasonably determined by other means, ultrasonography should be used.

Option 2.1.1. Ultrasonography, can verify an intrauterine pregnancy and determine gestational age, using a consistent and published table of fetal measurements.(1, 2)

Standard 3. Appropriate initial evaluation must be performed. Baseline blood pressure and pulse must be obtained for all patients.

Recommendation 3.1. Physical exam should be done as indicated by medical history and patient symptoms.

Recommendation 3.2. Hemoglobin/hematocrit and other laboratory evaluation should be done as indicated by medical history and patient symptoms. However, routine hemoglobin or hemacrit has not been shown to be helpful.

Standard 4. All instruments entering the uterine cavity must be sterile.

Option 4.1.1. The vagina may be cleansed with a bacteriocidal agent though randomized trials have failed to show a benefit to this practice.(3)

Standard 5. The cervix should be appropriately dilated for the gestational age.

Recommendation 5.1. Cervical dilation may be achieved through the use of rigid cervical dilators. Tapered dilators such as Pratt or Denniston dilators are recommended over non-tapered dilators such as Hegar dilators.(4)

Option 5.1.1. The routine use of 400 mcg misoprostol before procedures may reduce rare complications but must be balanced against increased pain and other side effects for all patients.(5) Doses higher than 400 mcg are not recommended.

Option 5.1.2. Misoprostol and/or osmotic dilators may be considered when cervical dilation is expected to be difficult.(6)

Standard 6. First-trimester surgical abortion must be performed by aspiration of the uterus, not by sharp curettage.(7-9)

Recommendation 6.1. Uterine aspiration is effective throughout the first trimester including prior to confirmation of a definitive intrauterine pregnancy on ultrasound.(10)

Standard 7. The procedure and all medications given must be documented.

Standard 8. Termination of pregnancy must be confirmed prior to the woman leaving the facility or further evaluation must be initiated.

Recommendation 8.1. Evacuated uterine contents should be examined before the woman leaves the facility.

Recommendation 8.2. In first-trimester terminations, flotation of tissue with backlighting should be used to identify products of conception, including gestational sac.

Option 8.2.1. Sending the evacuated uterine contents for additional pathological examination is not required.(11)

Standard 9. When insufficient tissue or incomplete products of conception are obtained, the patient must be re-evaluated.

Recommendation 9.1. Re-aspiration, serial quantitative hCG, and/or ultrasonographic examination should be considered.

Standard 10. If insufficient tissue is present after adequate patient evaluation, ectopic pregnancy must be considered, and the patient must be informed of symptoms and dangers of ectopic pregnancy.

Recommendation 10.1. If the uterine cavity is determined to be empty, serial quantitative hCG tests should be measured.(12-14)

Discussion: One option for additional evaluation if sufficient POC are not identified is the use of serum quantitative hCG testing. A baseline hCG can be drawn and a second hCG can be done in 24-48 hours. If there is a decrease of 50% or more, no further ectopic follow up is necessary.(14-16) Otherwise, further evaluation should be initiated including consideration of ectopic pregnancy.

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8. Management of Pregnancy of Uncertain Location

Policy Statement: The early identification of ectopic pregnancy will reduce morbidity related to rupture and increase the likelihood of successful non-surgical management.

Standard 1. The patient's medical history must be evaluated in order to assess for the risk of ectopic implantation in early pregnancy. Certain signs and symptoms, such as vaginal bleeding, pelvic pain, and/or failure to identify a definitive intrauterine pregnancy, should alert providers to the importance of following policies and procedures for ruling out ectopic pregnancy.(1-3)

Recommendation 1.1. In these cases, evaluation should involve assessment of the history in combination with one or more of the following: physical exam, sonography, serial quantitative hCGs, and/or uterine aspiration.(4)

Recommendation 1.2. Failure to identify a definite intrauterine pregnancy should not delay abortion care at early gestations.(5-7)

Standard 2. Each facility must have a written protocol to evaluate ectopic pregnancy. All relevant staff at the site must be familiar with the protocol.

Recommendation 2.1. This protocol may include referrals as appropriate.

Option 2.1.1. Posting a clinical algorithm for the evaluation of possible ectopic pregnancy may be useful.(4, 8)

Standard 3. All patients with a pregnancy of uncertain location must be informed of the options for evaluation and management. The symptoms and dangers associated with ectopic pregnancy, and a plan for when and how to seek emergency medical attention must be reviewed and documented.

Recommendation 3.1. Each facility should have a patient education handout describing ectopic warning signs and the medical record should reflect that the patient has received this handout.

Standard 4. When a medical or aspiration abortion is initiated for a patient with a pregnancy of uncertain location, resolution of the pregnancy must be verified and documented. This may be demonstrated by either the examination of aspirated tissue or by following serial beta-hCG levels according to evidence-based regimens.

Standard 5. Patient follow-up must continue until one of the following:
(1) the diagnosis of ectopic pregnancy has been excluded;
(2) clinical resolution of a possible ectopic pregnancy has been ensured; or
(3) transfer of care to an appropriate provider has been made and documented.

Standard 6. Patients experiencing symptoms suspicious for ruptured ectopic pregnancy must be evaluated emergently.

Discussion: A combination of clinical assessment, pelvic ultrasound, serum quantitative hCG, and/or examination of uterine aspirate is often needed to distinguish between an early intrauterine gestation, a miscarriage, and an ectopic pregnancy.(1) With normal early gestations, pre-procedure ultrasound may fail to identify an intrauterine pregnancy, leaving the clinician uncertain about the viability and location of the pregnancy. Although a gestational sac can usually be seen four to five weeks from LMP on transvaginal ultrasound, it may be confused with a pseudo-sac associated with an ectopic pregnancy.(9, 10) Although visualization of a yolk sac or embryo is needed to definitely confirm an intrauterine pregnancy on ultrasound,(11) the lack of visualization of these structures should not delay abortion care.

In the emergency department, from 7 to 20% of women with a pregnancy of uncertain location are subsequently found to have an ectopic pregnancy.(9) Although it is an important cause of pregnancy-related morbidity and mortality, ectopic implantation has been reported to occur in less than 1% of pregnancies in women presenting for induced abortion.(5, 12)

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9. Abortion by Dilation and Evacuation

Policy Statement: Abortion by dilation and evacuation (D&E) after 14 weeks from LMP is a safe outpatient surgical procedure when performed by appropriately trained clinicians in medical offices, freestanding clinics, ambulatory surgery centers, and hospitals.(1-6)

Standard 1. Pertinent medical history must be obtained and relevant physical examination must be performed.

Standard 2. Gestational age must be verified by ultrasonography, using a consistent and published table of fetal measurements, prior to the termination of a pregnancy clinically estimated to be more than 14 weeks from LMP.

Standard 3. The patient must be appropriately evaluated and prepared for the procedure.

- Recommendation 3.1. A pre-procedure hemoglobin or hematocrit should be checked.
- Recommendation 3.2. Intravenous access should be established prior to evacuation.
- Recommendation 3.3. When feticidal injections are employed, they should be provided through a standard protocol.(7-14)
  - Option 3.3.1. Intra-amniotic or intra-fetal injection of digoxin may be administered either transabdominally or transvaginally to cause fetal demise.(15-17)
  - Option 3.3.2. Intracardiac potassium chloride may be used to cause fetal demise.(14)

Standard 4. When osmotic dilators, misoprostol, and/or other cervical ripening agents are used, a plan for emergency care prior to the evacuation procedure must be in place and communicated to the patient.

Standard 5. Appropriate dilation of the cervix must be obtained gently and gradually.(18, 19)

- Recommendation 5.1. Osmotic dilators, misoprostol, and/or other cervical ripening agents should be used to facilitate adequate dilation.
  - Option 5.1.1. Dilapan and/or misoprostol may be used for same-day cervical dilation.(20-22)

Standard 6. All instruments entering uterine cavity must be sterile.

Standard 7. Evidence-based practices must be used to lower the risk of complications.

Recommendation 7.1. Intra-procedure ultrasonography should be used to aid in visualizing instruments, locating fetal parts, verifying an empty uterus, reducing the risk of uterine perforation, and shortening the procedure.(23-25)

Recommendation 7.2. Inhaled anesthesia should be avoided if possible due to the increased risk of hemorrhage.(26, 27)

Standard 8. Uterotonics must be available to aid in control of uterine bleeding.(28)

Recommendation 8.1. Prophylactic vasopressin should be used intracervically or paracervically to reduce blood loss.(29)

Standard 9. Examination of the uterine contents must be performed to identify the placenta and all major fetal parts.

Recommendation 9.1. If the above are not identified, ultrasonographic evaluation and uterine exploration under ultrasound guidance should be considered.

Recommendation 9.2. The facility and/or clinician should continue care of the patient until completion of the abortion or transfer of care to an appropriate provider is made.

Discussion: Clinicians must tailor surgical techniques to suit individual circumstances mindful of current legal implications and the need to maintain patient safety. As always, it is incumbent upon each clinician to be aware of the laws pertinent to their clinical practices.

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10. Second-Trimester Induction Abortion

Policy Statement: Medical induction abortion is a safe and effective method for termination of pregnancies beyond the first trimester when performed by trained clinicians in medical offices, freestanding clinics, ambulatory surgery centers, and hospitals.

Standard 1. Pertinent medical history must be obtained and relevant physical examination must be performed.

Standard 2. Gestational age must be verified by ultrasonography, using a consistent and published table of fetal measurements, prior to the termination of a pregnancy clinically estimated to be more than 14 weeks from LMP.

Standard 3. The patient must be appropriately evaluated and prepared for the procedure.

- Recommendation 3.1. A pre-procedure hemoglobin or hematocrit should be checked.
- Recommendation 3.2. Intravenous access should be established prior to induction.
- Recommendation 3.3. When feticidal injections are employed, they should be provided through a standard protocol.(1-7)
  - Option 3.3.1. Intra-amniotic or intra-fetal injection of digoxin may be administered either transabdominally or transvaginally to cause fetal demise.(8-10)
  - Option 3.3.2. Intracardiac potassium chloride may be used to cause fetal demise.(7)

Standard 4. Evidence-based regimens of medical induction must be used.

- Recommendation 4.1. Mifepristone 200 mg followed by misoprostol should be used, when available and feasible.(11-14)
  - Option 4.1.1. Misoprostol may also be used alone.(15)
  - Option 4.1.2. The initial dose of misoprostol may be more effective if administered vaginally,(15) particularly in nulliparous women.(16)
  - Option 4.1.3. Subsequent doses of 400 mcg misoprostol may be most effective when given every three to four hours and are equally effective by vaginal, buccal, or sublingual routes.(15)
  - Option 4.1.4. Oxytocin may be used as an adjunctive agent to induce labor or alone when misoprostol is contraindicated.

Recommendation 4.2. Osmotic dilators should not be used as they do not shorten the induction time but increase pain.(12, 17-19)

Recommendation 4.3. Intraamniotic injection or instillation methods should be avoided as they are less effective and result in more complications than mifepristone-misoprstol or misoprostol-alone regimens.(20)

Standard 5. Once regular contractions have been confirmed, patients must be observed by health care staff trained to monitor contractions and expulsion, and who can recognize emergent situations.

Standard 6. A trained clinician must be available from initiation of induction until post-abortion discharge.

Standard 7. Access to surgical management or appropriate referral must be available in the event that surgical intervention is required.

Standard 8. Uterotonics must be available to aid in control of uterine bleeding.

Standard 9. Examination of the uterine contents must be performed to identify the placenta and all major fetal parts.

Recommendation 9.1. If the above are not identified, ultrasonographic evaluation and (repeat) uterine exploration under ultrasound guidance should be considered.

Recommendation 9.2. The facility and/or clinician should continue care of the patient until completion of the abortion or transfer of care to an appropriate provider is made.

Discussion: Numerous studies have found that the use of misoprostol does not increase the risk of uterine rupture in a previously scarred uterus in the second trimester compared to other induction agents, even with three or more prior Cesarean deliveries.(21) The risk of uterine rupture during second-trimester induction in women with a scarred uterus is roughly 0.3%, and is not higher than among women without a prior Cesarean delivery.(22)

Clinicians must tailor surgical techniques to suit individual circumstances mindful of current legal implications and the need to maintain patient safety. As always, it is incumbent upon each clinician to be aware of the laws pertinent to their clinical practices.

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11. Analgesia and Sedation

Policy Statement: Anxiolysis, analgesia, or anesthesia should be provided during abortion procedures for any patient for whom the benefits outweigh the risks, with the aim of providing the appropriate level of analgesia and sedation required for each patient's needs. Patients should be involved in a shared decision-making process about pain control and sedation during the procedure.(1-14)

ON THE USE OF SEDATION IN GENERAL - All medications used in procedural sedation have the potential for serious risk. This risk may be reduced to a minimum by adherence to established practice guidelines. Guidelines developed by other organizations concern themselves with anesthesia and sedation delivered primarily in hospital settings and to patients varying widely in age and general health. Regardless of the drug or route of administration, the degree of central nervous system (CNS) depression is the basis for the NAF guidelines.

These guidelines do not address the use of deep sedation or general anesthesia except to identify basic monitoring practices and appropriate providers of such care, who are expected to follow their professional standards in the delivery of anesthesia services. It is expected that those individuals providing deep sedation or general anesthesia will have appropriate emergency medication and equipment in place to ensure the safe care of a patient in the event of an anesthesia complication.

The promulgation of guidelines for the delivery and monitoring of anesthesia care issued by organizations such as the American Society of Anesthesiologists (ASA)(15), the Canadian Anesthesiologists' Society (CSA)(16), the American Dental Society of Anesthesiologists (ADSA), American Society of Gastrointestinal Endoscopists, and others have clarified many of the issues related to anesthesia care.

Patient comfort and reduced anxiety are significantly affected by patient counseling and by the presence of family, friends, and supportive staff, and are not solely dependent on pharmacologic measures. Alternative modalities (such as relaxation techniques, acupuncture, hypnosis) may be helpful for some patients. The focus of NAF guidelines for analgesia and sedation, however, is on the safe provision of pharmacologic methods generally used in outpatient abortion facilities.

Definitions*

1. Local Anesthesia - Elimination or reduction of sensation, especially pain, in one part of the body by topical application or local injection of a drug. In the context of abortion practice, local anesthesia almost always involves a paracervical block.

*Based on *Continuum of Depth Sedation: Definition of General Anesthesia and levels of Sedation/Anesthesia*, 2009, of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA; 520 N. Northwest Highway; Park Ridge, Illinois 60068-2573.

2. Minimal Sedation (Anxiolysis) - is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, ventilatory, and cardiovascular functions are unaffected.

3. Moderate Sedation/Analgesia - is a drug-induced depression of consciousness during which patients respond purposefully[†] to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained but may be impaired. This level of sedation was previously referred to as "Conscious Sedation". However this term is no longer recommended.

4. Deep Sedation/Analgesia - is a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained but may be impaired.

5. General Anesthesia - is a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce any level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Rescue corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia, and hypotension) and returns the patient to the originally intended level of sedation.

Standard 1. When minimal, moderate, deep sedation, or general anesthesia is to be given, patients must be given information about the risks, benefits, and side effects of the medications to be used.

Recommendation 1.1. Documentation should include precautions relevant to transient mental impairment.

Option 1.1.1. An informed consent form specific for analgesia and sedation may be used.

[†] Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

Standard 2. Prior to moderate sedation, a pre-sedation evaluation of the patient must take place.

Recommendation 2.1. Evaluation should include a relevant history and review of systems; medication review; targeted exam of the heart, lung, and airway; baseline vital signs; and last food intake.

Recommendation 2.2. A reduced level of sedation, an alternate abortion procedure, or provision of care by an anesthesia professional should be considered for patients with an atypical airway assessment or ASA P-3 or greater (see ASA "**Physical Status Definition**" in this document).

Standard 3. No additional evaluation is needed prior to paracervical block and/or NSAID administration.

Standard 4. The supervising practitioner must be immediately available when sedation is administered.

Standard 5. When local anesthesia or sedation is provided, the practitioner responsible for the treatment of the patient and/or the administration of drugs must be appropriately trained.

Recommendation 5.1. Moderate sedation proficiency should include the following: appropriate licensure, basic airway skills, the ability to monitor and effectively rescue patients in an emergency, the ability to screen patients appropriately for sedation, and documented pharmacology knowledge for both sedation medications and their reversal agents, if applicable.

Standard 6. The potential need for intravenous access must be considered prior to administering any level of sedation.

Recommendation 6.1. When more than minimal sedation is intended, intravenous access should be maintained.

Standard 7. Pulse oximetry, with appropriate alarms, must be employed when moderate or deeper levels of sedation are used.

Standard 8. When sedation is provided, monitoring must be adequate to detect the respiratory, cardiovascular, and neurological effects of the drugs being administered, and this monitoring must be documented.

Recommendation 8.1. The patient should be checked frequently for verbal responsiveness.

Recommendation 8.2. Monitoring for deep sedation and general anesthesia should be supplemented by continuous pulse monitoring or electrocardiography and monitoring of respiration, such as measuring end-tidal CO_2.

Standard 9. Supplemental oxygen must be used with deep sedation and general anesthesia.

Standard 10. When moderate sedation or deeper is provided, a person other than the clinician performing the procedure, and who is trained to monitor appropriate physiological parameters, must be present. This person must not be performing duties other than monitoring the patient.

Standard 11. The practitioner administering **deep sedation** or **general anesthesia** must not be the practitioner performing the abortion.

Standard 12. Any individual responsible for administering, supervising, or monitoring a patient receiving any level of sedation must have current, health care provider level basic life support (BLS) certification.

Standard 13. When moderate sedation is administered, there should be at least one individual with documented airway skills in the procedure room.

Standard 14. The practitioner administering **deep sedation** or **general anesthesia** must adhere to established professional standards of care.

Standard 15. N_2O must be self-administered by the patient or by a qualified anesthesia provider.

Standard 16. The provision of N_2O must follow guidelines for patient monitoring for moderate sedation.

Standard 17. Equipment for the delivery of N_2O/O_2 must:
(a) provide a concentration of N_2O of no more than 70% inspired;
(b) provide a minimum of 30% O_2; and
(c) be checked and calibrated regularly.

Recommendation 17.1. The concentration of nitrous oxide should not routinely exceed 50% in the absence of qualified anesthesia personnel.

Recommendation 17.2. Equipment for the delivery of N_2O/O_2 should include an oxygen analyzer.

Recommendation 17.3. Due to the potential for occupational exposure, room or personnel monitoring for levels of N_20 should be conducted.

Standard 18. Functioning equipment and current medications must be available on-site to handle medical emergencies and must include: an oxygen delivery system, oral airways, epinephrine, and antihistamines.

Standard 19. In settings where benzodiazepines and opioids are used, appropriate antagonists, bronchodilators, and bag-valve masks capable of delivering supplemental oxygen must be available.

Recommendation 19.1. Facilities should have a specified area for emergency equipment which includes oxygen, medications, and supplies. A protocol and time schedule for checking equipment and removing expired medications must be in place.

Recommendation 19.2. An automatic external defibrillator (AED) should be available.

Standard 20. In settings where deep sedation and general anesthesia are used, it is expected that providers maintain the appropriate medication and equipment required for an anesthesia emergency.

DISCUSSION: ON THE USE OF N_2O/O_2 - Nitrous oxide has a long history of use for analgesia and sedation, as well as an excellent safety record in the hands of both anesthesiologists and non-anesthesiologists. Occupational exposure to N_2O has been associated with increased risks of neurologic impairment, spontaneous abortion, subfertility, and hepatic and renal disease. Recommendations for safe use of nitrous oxide can be found in the reference section. In addition to employing adequate ventilation and scavenger systems, it is also recommended to deliver 100% oxygen to the patient for five minutes before removing the mask. This will purge the system, and the patient, of any residual nitrous oxide. Occupational exposure can be monitored by asking staff members to wear personal dosimetry badges or by placing an infrared spectrophotometer in the room. Although there is no OSHA standard for N_2O, NIOSH recommends that airborne levels of N_2O be kept below 25 ppm (1995) through well-designed scavenger systems and other engineering controls, equipment maintenance, exposure monitoring, and safe work practices.

American Society of Anesthesiologists

Continuum of Depths of Sedation:
DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA[‡]

Committee of Origin: Quality Management and Departmental Administration
(Approved by the ASA on October 27, 2004, and amended on October 21, 2009)

	Minimal Sedation/ Anxiolysis	Moderate Sedation/ Analgesia "Conscious Sedation"	Deep Sedation/ Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful response to verbal or tactile stimulation[§]	Purposeful response following repeated or painful stimulation[§]	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

[‡] Excerpted from *Continuum of Depth of Sedation, Definitions of General Anesthesia and Levels of Sedation/Analgesia.* 2009, reprinted with the permission of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA; 520 N. Northwest Highway; Park Ridge, Illinois 60068-2573.
[§] Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

American Society of Anesthesiologists

Physical Status Definition**

The following represents the American Society of Anesthesiologists classification and should be used in evaluation of patients.

CLASSIFICATION OF PHYSICAL STATUS

P-1 - A normal healthy patient.
P-2 - A patient with mild systemic disease.
P-3 - A patient with severe systemic disease.
P-4 - A patient with severe systemic disease that is a constant threat to life.
P-5 - A moribund patient who is not expected to survive without the operation.
P-6 - A declared brain-dead patient whose organs are being removed for donor purposes.

** *ASA Relative Value Guide*. 2012. Reprinted with permission of the American Society of Anesthesiologists; 520 N. Northwest Highway; Park Ridge, Illinois 60068-2573.

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12. Use of Antibiotics in Abortion

Policy Statement: Prevention and treatment of infection will reduce post-abortion morbidity.

Standard 1. Routine antibiotic prophylaxis must be used for surgical abortion.

- Recommendation 1.1. All women having surgical abortions should receive antibiotics pre-procedure.(1-3)
  - Option 1.1.1. For surgical abortions, antibiotics can be given post-procedure when giving antibiotics pre-procedure is not feasible.(4)
  - Option 1.1.2. Antibiotics may be initiated at the time of insertion of osmotic dilators.
  - Option 1.1.3. Antibiotics may be given to women choosing medical abortion.(5) Insufficient evidence exists to support routine antibiotic prophylaxis for medical abortion.
- Recommendation 1.2. Women at high risk for Chlamydia, gonorrhea, or other sexually transmitted infections should be offered testing.(6)
  - Option 1.2.1. Empiric treatment of Chlamydia may be considered for patients at high risk for pre-existing infection.

Standard 2. Diagnosed infection must be appropriately treated.

- Recommendation 2.1. For documented infections of the reproductive tract, evidence-based regimens should be followed.(6)

Discussion: The literature supports universal antibiotic prophylaxis for surgical abortion.(7) Only one large cohort analysis addresses the use of antibiotics in medical abortion.(5, 8)

References:

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13. Complications: Bleeding

Policy Statement: One of the most serious immediate complications of an abortion procedure is hemorrhage. Early recognition of the source of bleeding can reduce morbidity and mortality.

Standard 1. All facilities must have a protocol for the management of acute hemorrhage.(1)

Standard 2. The following items must be included in the protocol:
(1) Establishment of intravenous access;
(2) Administration of uterotonics;
(3) Evaluation of the cause and/or source of bleeding;
(4) Defined staff roles;
(5) Emergency supplies that will be readily available; and
(6) Methods for conducting a hospital transfer, if the bleeding does not respond to therapeutic measures or if the patient is hemodynamically unstable.

Recommendation 2.2. The following items should be considered:
(1) Ultrasonography to determine whether the uterus is empty.
(2) When atony is suspected, uterine massage and uterotonics may be useful.
(3) When coagulopathy is suspected, blood may be drawn for coagulation parameters and transfusion of blood or blood products may be necessary.
(4) Appropriate disclosure of events to the patient.

Standard 3. The facility must have at least two uterotonics and/or mechanical methods of controlling bleeding.

Discussion: Excessive bleeding during the procedure and in the post-procedure period is almost always due to uterine atony, often caused by incomplete emptying of the uterus. Therefore, the most important initial efforts should be directed at assuring complete evacuation of the uterus and at increasing uterine tone through uterotonics.

Problems arise when bleeding is ignored or its severity underestimated. Clinicians must always remember to do the simple things when confronted with a developing bleeding problem: continue assessment of the blood loss, measure and record blood pressure and pulse frequently, and assure intravenous access.

Post-procedure, the following measures may be used for treatment of post-abortion hemorrhage:
a. methergine;
b. oxytocin;
c. misoprostol;
d. carboprost tromethamine (Hemabate); or
e. intrauterine pressure using a Foley or Bakri balloon or vaginal pack.

When bleeding continues after assurance of complete uterine emptying and when there are no visible cervical or vaginal lacerations, the clinician must consider other complications such as perforation, coagulopathy, or placenta accreta.

References:

1. Kerns J, Steinauer J. Management of postabortion hemorrhage: SFP Guideline 20131. Contraception. 2013;87(3):331-42.

14. Complications: Perforation

Policy Statement: Uterine perforation is a complication of abortion that can lead to significant morbidity. Morbidity is related to site of perforation, instrumentation, and gestational age.

Standard 1. If, in the clinician's judgment, an instrument passes farther than expected, then uterine perforation must be considered.

Standard 2. If a perforation occurs, even if the patient is asymptomatic, close observation and follow-up must be done, according to the facility's established protocol.

Recommendation 2.1. The following interventions should be considered.

Option 2.1.1. Antibiotic coverage may be instituted.

Option 2.1.2. Uterotonics may be administered.

Option 2.1.3. The patient may be transferred to a hospital.

Recommendation 2.2. If a perforation occurs and the pregnancy has been disrupted, the abortion procedure should be completed as soon as feasible.

Option 2.2.1. If a perforation occurs and *the pregnancy has not been disrupted*, the procedure may be completed immediately, after a delay, or by referral to another provider.

Option 2.2.2. The uterine evacuation may be completed under direct ultrasound guidance or laparoscopic visualization.(1, 2)

Standard 3. The patient must be hospitalized for definitive care if:

(a) intra-abdominal viscera are detected in the uterine cavity, cervix, vagina, suction tubing, or on tissue examination;

(b) fetal parts are detected in the abdominal cavity;

(c) expanding intra-abdominal or retroperitoneal hematoma is detected; or

(d) hemodynamic instability is present.

Discussion: Perforations are often occult and may be difficult to identify.(3-5) If a perforation is suspected, it is safest to proceed as if there has been a perforation.

In the first trimester, perforations are often asymptomatic and self-healing.(6, 7) Most perforations are midline and/or fundal in location.(8) If they occur before suction, these usually

can be managed with observation and close follow-up.(7) A lateral perforation may involve uterine blood vessels and, if so, will be more significant.

In the second trimester, even an asymptomatic perforation may warrant transfer to a hospital for evaluation depending on the instrumentation involved.(9, 10) There may be more significant morbidity due to increased uterine blood flow, a thinner myometrium, and the damage possible with the use of larger grasping instruments.

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15. Post-Procedure Care

Policy Statement: Appropriate and accessible post-procedure and follow-up care is essential to patients' wellbeing.

Standard 1. All patients must be continuously observed during the recovery period by a health care worker trained in post-procedure care.

Standard 2. Patients who received sedation or exhibit signs of instability should remain in the care of an appropriately trained individual until no longer at risk for hemodynamic instability or respiratory depression.

Standard 3. A clinician must remain in the facility until all patients are medically stable.

Standard 4. The following criteria must be documented prior to discharge: the patient must be ambulatory with a stable blood pressure and pulse, and bleeding and pain must be controlled.

Standard 5. The patient must be given oral and written instructions outlining what to expect post-procedure, self-care, and signs and symptoms of complications.

Recommendation 5.1. Patients who receive sedation should have access to this information prior to the administration of medication.

Standard 6. The facility must provide an emergency contact service on a 24-hour basis, where calls are triaged in accordance with written policies. A recorded message alone is unacceptable.

Standard 7. Any non-clinician involved with first-call triage must be trained to take a post-abortion health history and follow clear written guidelines indicating when immediate consultation with a clinician is indicated.

Standard 8. Any patient who gives a history suggestive of a post-procedure complication must have access to a clinician. The facility must establish a pathway for physician referral if indicated.

16. Emergency Procedures

Policy Statement: Appropriate management of abortion emergencies reduces morbidity and mortality.

Standard 1. When abortion procedures are being performed, at least one medical staff member with health care provider level basic life support (BLS) training must be present.

Recommendation 1.1. All medical staff providing direct patient care should have current health care provider level BLS certification

Standard 2. Protocols for the management of medical emergencies must be in place. These protocols must include indications for emergency transport and written, readily available directions for contacting external emergency assistance (e.g., an ambulance).

Recommendation 2.1. Protocols to address the following topics should be in place: bleeding, perforation, respiratory arrest/depression, anaphylaxis, and emergency transfer.

Recommendation 2.2. Protocols should be reviewed annually by staff.

Recommendation 2.3. All staff should know their appropriate roles in the management of medical emergencies.

Option 2.3.1. Annual drills of the emergency protocols are encouraged.

Recommendation 2.4. Clinics should consider developing a transfer agreement with a hospital outlining the means of communication and transport and the protocol for emergent transfer of care.

17. Evaluation of Evacuated Uterine Contents

Policy Statement: Identification of appropriate products of conception following evacuation abortion procedures confirms termination of an intrauterine pregnancy.

Standard 1. Termination of pregnancy must be confirmed prior to the woman leaving the facility or further evaluation must be initiated.

- Recommendation 1.1. Evacuated uterine contents should be examined before the woman leaves the facility.
- Recommendation 1.2. In first-trimester terminations, flotation of tissue with backlighting should be used to identify products of conception, including gestational sac.
  - Option 1.2.1. Sending the evacuated uterine contents for additional pathological examination is not required.(1)

Standard 2. When insufficient tissue or incomplete products of conception are obtained, the patient must be re-evaluated.

- Recommendation 2.1. Re-aspiration, serial quantitative hCG, and/or ultrasonographic examination should be considered.

Standard 3. If insufficient tissue is present after adequate patient evaluation, ectopic pregnancy must be considered, and the patient must be informed of symptoms and dangers of ectopic pregnancy.

- Recommendation 3.1. If the uterine cavity is determined to be empty, serial quantitative hCG tests should be measured.(2-4)

Discussion: One option for additional evaluation if sufficient POC are not identified is the use of serum quantitative hCG tests. A baseline hCG can be drawn and a second hCG can be done in 24-48 hours. If there is a decrease of 50% or more, no further ectopic follow up is necessary. Otherwise, further evaluation should be initiated including consideration of ectopic pregnancy.

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