



# 2013 Clinical Policy Guidelines

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

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#### National Abortion Federation

## 2013 CLINICAL POLICY GUIDELINES

## 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 2013 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 rigidly. They must be followed in virtually all cases. Exceptions 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 an alphabetic 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 three years or sooner if new medical evidence should become 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.

#### References:

- 1. Eddy, DM. Clinical decision making: From theory to practice. Designing a practice policy: Standards, guidelines, and options. *JAMA* 1990, 263:3077.
- 2. Eddy, DM. A Manual for Assessing Health Practices and Designing Practice Policies: The Explicit Approach. Philadelphia: American College of Physicians, 1992.
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- 10. Walker, RD, et al. Medical Practice Guidelines. West J Med 1994, 161: 39.
- 11. Woolf, SH. Practice Guidelines: A New Reality in Medicine. I. Recent Developments. *Arch Intern Med* 1990, 150: 1811.
- 12. Woolf, SH. Practice Guidelines: A New Reality in Medicine. II. Methods of Developing Guidelines. *Arch Intern Med* 1992, 152: 946.
- 13. Woolf, SH. Practice Guidelines: A New Reality in Medicine. III. Impact on Patient Care. *Arch Intern Med* 1993, 153: 2646.

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# A NOTE 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, <u>Standards</u> are numbered consecutively (e.g., Standard 1).

<u>Recommendations</u> 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 <u>Options</u> within each main subject heading are placed in the second position to the right of a decimal point (e.g., Option 0.01). 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 1.01 or Option 1.11, or Option 0.11). 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 0.01).

# WHO CAN PROVIDE ABORTIONS

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

- Standard 1: Abortion will be provided by licensed<sup>A</sup> 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.
  - <u>Recommendation 1.1</u>: If required by law, documentation specifying privileges in accordance with each practitioner's scope of practice should be maintained.
- <u>Standard 2</u>: All practitioners providing abortions must have received training to competency in abortion care, including the prevention, recognition, and management of complications.
- <u>Recommendation 0.1</u>: Appropriate referrals should be available for patients who cannot be cared for by a practitioner at your facility.<sup>B</sup>

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<sup>&</sup>lt;sup>A</sup> 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, and Mexico City.

<sup>&</sup>lt;sup>B</sup> This may include the NAF Referral Line.

## 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.

<u>Option 1.01</u>: Information may be provided either on an individual basis or in group sessions.

<u>Standard 2</u>: 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/OR COUNSELING

- <u>Standard 3</u>: Each patient must have a private opportunity to discuss issues and concerns about her abortion.
- <u>Standard 4</u>: A patient must undergo the abortion as expeditiously as possible in accordance with good medical practice.
- <u>Standard 5</u>: Information about clinical procedures, aftercare, and birth control must be available to patients at the facility.
- <u>Standard 6</u>: All reasonable precautions must be taken to ensure the patient's confidentiality.

**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, and to obtain legal permission for an abortion.

Patient Education and/or Counseling is 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.

When any third party is involved with payment for abortion, certain protected information will be given to that entity. Depending on applicable laws and regulations, the patient may need to be informed and authorization obtained for the communication of this information.

References:

- 1. Baker, A. *Abortion and Options Counseling: A Comprehensive Reference*. Granite City, Illinois: The Hope Clinic for Women, 1995.
- 2. 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.
- 3. Benson Gold, R. & Nash, E. State abortion counseling policies and the fundamental principles of informed consent, *Guttmacher Policy Review* 2007, 10(4), 8-13.
- 4. Needle, R. & Walker, L. *Abortion Counseling: A Clinician's Guide to Psychology, Legislation, Politics, and Competency.* Springer Publishing Co., 2008.

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## INFECTION PREVENTION

**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 eliminate exposure are not followed.<sup>A</sup>

<u>Standard 1:</u> Exposure control plans must be established and observed, in compliance with applicable local, state/provincial/territorial, and federal regulations.

**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. Clinics should protect employees and patients from being inadvertently exposed to biohazardous material. Personal protective equipment, annual training programs, and Hepatitis B vaccine should be provided at no cost to the staff. Post exposure evaluation, prophylaxis (when indicated), and follow-up should be offered to exposed patients or staff for any potentially infectious agent, regardless of source.

#### References:

- 1. Canadian Centre for Occupational Health and Safety. Universal Precautions and Routine Practices (2011). Available at: http://www.ccohs.ca/oshanswers/prevention/universa.html.
- Centers for Disease Control, U.S. Department of Health and Human Services (2003). Exposure to blood: What healthcare personnel need to know. Available at: http://www.cdc.gov/ncidod/dhqp/pdf/bbp/Exp\_to\_Blood.pdf.
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- 4. Claflin, N, Hayden, C (1998). National Association for Healthcare Quality Guide To Quality Management, Glenview, IL.
- Occupational Safety and Health Administration, U.S. Department of Labor (last reviewed 2011). Blood borne pathogens and needlestick prevention. Available at: http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

<sup>&</sup>lt;sup>A</sup> 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.

- 6. Occupational Safety and Health Administration, U.S. Department of Labor (2001; last amended April 2012) Standard 1910.1030: Blood borne Pathogens. Available at: http://www.osha.gov/pls/oshaweb/owadisp.show\_document?p\_table=STANDARDS&p\_id=10051.
- Ontario Hospital Association (2010). Blood-Borne Diseases Surveillance Protocol for Ontario Hospitals. Pub#206. Available at: http://www.oha.com/Services/HealthSafety/Documents/Blood%20Borne%20Diseases%20Protocol%20-%20Reviewed%20and%20Revised%20November%202012.pdf.
- Public Health Ontario. Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings (2010). Available at: http://www.oahpp.ca/resources/pidac-knowledge/.
- 9. Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force (2002). Guideline for Hand Hygiene in Health-Care Settings. 51(RR16); 1-44.

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## **Rh TESTING AND Rh IMMUNE GLOBULIN ADMINISTRATION**

Policy Statement: Rh alloimmunization may jeopardize the health of a subsequent pregnancy.

- <u>Standard 1:</u> Rh status must be documented in all women undergoing abortion.
  - a. This documentation may be obtained by on-site testing or outside medical source.
  - b. Du ("weak D") testing is not required. Testing for red blood cell antigens other than D (Rho) is not required.
  - <u>Option 1.01</u>: The use of approved slide/tube/spot methods is acceptable for onsite testing.
- <u>Standard 2:</u> Additional testing for either sensitization or other antibodies is not required in patients undergoing pregnancy termination.
- Standard 3: Rh immune globulin administration\* must be offered to Rh(-) women and documented.
- Standard 4: If Rh immune globulin is not administered in the facility, one of the following is required:
  - a. informed waiver signed by a patient who refuses Rh immune globulin; or
  - b. documentation of other arrangements for administration.

**Discussion:** There are as yet no data that support the safety of omitting the administration of Rh immune globulin 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.

\*For Rh(-) patients, Rh immune globulin is administered by standard intramuscular injection; some practitioners inject it into the cervix.

#### References:

- 1. ACOG practice bulletin. Prevention of Rh D alloimmunization. Number 4, May 1999. *Clinical management guidelines for obstetrician-gynecologists*. American College of Obstetrics and Gynecology.
- 2. Baskett, TF. Prevention of Rh alloimmunization: A cost-benefit analysis. Can Med Assoc J 1990, 142:337.
- 3. Bowman, J. The prevention of Rh immunization. Transfusion Med Rev 1988, 2:129.
- 4. Chavez, GFP. Epidemiology of Rh hemolytic disease of the newborn in the United States. *JAMA* 1991, 263:3270.

- 5. Commentary: Immunoprophylaxis for Rhesus disease Expensive but worth it. *Brit J Obstet Gynecol* 1991, 98:509.
- 6. Gibble, JW. Maternal immunity to red cell antigens and fetal transfusion. Cl Lab Med 1992, 12:553.
- 7. Jabara, S, Barnhart, K. Is Rh immune globulin needed in early first-trimester abortion? A review. *Am J Obstet Gynecol* 2003; 188 (3): 623-7. Review.
- 8. Roberts, H. The use of anti-D prophylaxis in the management of miscarriage in general practice. *Health Bull* 1991, 49:245.
- 9. Socol, M. Northwestern University Hospital, MFM. Personal communication.

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# LIMITED SONOGRAPHY IN ABORTION CARE

**Policy Statement:** Proper use of ultrasound can inform clinical decision-making and enhance the safety and efficacy of abortion care.

Standard 1: Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation that they have completed a program of training or must complete such a program developed by the facility. Training must include a period of direct supervision. Documentation of this training must be maintained. Following initial training, a system for evaluation of ongoing proficiency must be in place and documented.

<u>Option 1.01:</u> 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.<sup>5</sup>

- <u>Standard 2</u>: A system of clinical privileging must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams. This system must include periodic review and renewal of these privileges.
- <u>Standard 3:</u> Patients must be informed of the purpose and limitations of the ultrasound exam in the abortion care setting.

<u>Option 3.01</u>: This information may be provided in writing and the patient may be asked to sign a form acknowledging receipt of this information.

Standard 4: The findings of all ultrasound exams and the interpretation of those findings must be documented in the medical record. Photos or another method of storing the ultrasound images must be included as part of the documentation.<sup>3</sup> This documentation must also include the name(s) of the staff members who performed and interpreted the exam.

<u>Recommendation 4.1:</u> A standard form for documenting findings and interpretation should be used.

- Standard 5: In the first trimester, the ultrasound exam must include the following:
  - a. a full scan of the uterus in both the transverse and longitudinal planes;
  - b. measurements to document gestational age;
  - c. views to document the location of the pregnancy;
  - d. evaluation of fetal number; and
  - e. evaluation of the presence or absence of fetal cardiac activity.

agents.

	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.
	Recommendation 5.2:	Technology permitting both abdominal and transvaginal scanning should be available.
<u>Standard 6</u> :	<ul> <li>5: In the second trimester, the ultrasound exam must include the following:</li> <li>a. fetal measurements to document gestational age;</li> <li>b. views to document intrauterine location of the pregnancy;</li> <li>c. evaluation of fetal number;</li> <li>d. evaluation of the presence or absence of fetal cardiac activity; and</li> <li>e. placental localization.</li> </ul>	
	Recommendation 6.1:	When placenta previa is suspected in a patient with a prior uterine scar, or when other placental abnormality is suspected, a referral for further diagnostic imaging should be made.
<u>Standard 7</u> :	A procedure must be in place for further evaluation or referral of a patient in whom an intrauterine pregnancy has not been definitively identified or for whom an initial finding on the ultrasound may affect abortion management or future patient care.	
<u>Standard 8</u> :	Real-time ultrasound scanners must be used. Ultrasound equipment must be properly calibrated and maintained.	
<u>Standard 9</u> :	Ultrasound transducers must be disinfected between patients according to applicable infection control standards. <sup>4</sup> Adequate precautions must be taken to protect both staff members and patients from the potential toxicity of chemical	

**Discussion:** The use of ultrasound is not a requirement for the provision of first trimester abortion care. However, over the years, especially in higher resource settings, it has become widely used. Compliance with NAF standards for the use of limited ultrasound in abortion care will enhance the accuracy and reliability of ultrasound findings in this setting, thus improving the quality of care.

According to the American Institute of Ultrasound in Medicine (AIUM), in collaboration with the American College of Obstetrics and Gynecology (ACOG) and the American College of Radiology (ACR),<sup>3</sup> a "limited ultrasound examination" is performed when a specific question requires investigation. In addition to the determination of gestational age and location, limited

ultrasound examination may also be useful in intra-procedure and post-abortion care under certain circumstances.  $^{\rm A}$ 

References:

- 1. ACOG Practice Bulletin # 101, February 2009: Ultrasonography in Pregnancy. American College of Obstetrics and Gynecology.
- 2. AIUM Official Statement: Limited Obstetrical Ultrasound. Approved November 2009. American Institute of Ultrasound in Medicine.
- 3. AIUM Practice Guideline for the Performance of Obstetric Ultrasound Examinations. 2007. American Institute of Ultrasound in Medicine.
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- 5. Deutchman M, Reeves M, M Fjerstad et.al. Ultrasound in Abortion Care Training Program (CD-ROM and Workbook). 2007. Affiliates Risk Management Services, Inc.
- 6. Menihan, CM. *Limited Sonography in Obstetric and Gynecologic Triage*. Lippincott-Raven, Philadelphia, 1998.
- 7. Nursing Practice Competencies and Educational Guidelines for Limited Ultrasound Examinations in Obstetric and Gynecologic/Infertility Settings. 1993. Carol Ann Gorman, Chairperson. Association of Women's Health, Obstetric and Gynecologic and Neonatal Nursing.

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<sup>&</sup>lt;sup>A</sup> See guidelines for "Early Medical Abortion," "Second Trimester Abortion by D&E," and "Evaluation of Evacuated Uterine Contents."

# EARLY MEDICAL ABORTION

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

<u>Standard 1</u> :	Pertinent medical history must be obtained and documented.		
<u>Standard 2</u> :	Confirmation of pregnancy must be documented.		
<u>Standard 3:</u>	The patient must be informed about the efficacy, side effects, and risks, especially excessive bleeding and infection.		
<u>Standard 4</u> :	The patient must be informed of the need to ensure that she is no longer pregnant and of the teratogenicity associated with the medications to be used.		
<u>Standard 5:</u>	Patient instructions must include written and oral information about use of medications at home and symptoms of abortion complications.		
<u>Standard 6</u> :	The patient must be informed that a surgical abortion will be recommended if medical abortion fails and this must be documented.		
<u>Standard 7</u> :	The facility must provide an emergency contact service on a 24-hour basis and must offer or assure referral for uterine aspiration if indicated.		
<u>Standard 8</u> :	Gestational age must be verified and documented.		
	Recommendation 8.1: Ultrasonography, using a consistent and published table of fetal measurement, should be used to confirm and document gestational age when physical exam and LMP are substantially discordant.		
	Option 8.01: Ultrasonography may be used routinely.		
<u>Standard 9</u> :	If intrauterine gestation has not been confirmed by ultrasound, ectopic pregnancy		

Standard 9: If intrauterine gestation has not been confirmed by ultrasound, ectopic pregnancy must be considered. At a minimum, evaluation will include history and physical exam and may also require serology, sonography, and examination of uterine aspirate, as well as documented follow-up through either clinical resolution or transfer of care.<sup>A</sup>

<sup>&</sup>lt;sup>A</sup> See guidelines for "Management of Pregnancy of Uncertain Location."

<u>Standard 10</u>: Combined regimens are more effective than prostaglandin alone. Where mifepristone is available, an evidence-based mifepristone/misoprostol regimen must be used.<sup>B</sup>

Recommendation 10.1:	When mifepristone and vaginal, buccal, or sublingual misoprostol are used, the regimen is recommended for gestations up to 70 days. <sup>2, 9, 16, 24</sup>
Recommendation 10.2:	When mifepristone and oral misoprostol are used, the regimen is recommended for gestations up to 56 days. <sup>24</sup>
Recommendation 10.3:	Where mifepristone is not available and methotrexate and misoprostol are used, a regimen using vaginal, buccal, or sublingual misoprostol is recommended for gestations up to 63 days. <sup>1</sup>
Recommendation 10.4:	Where neither mifepristone or methotrexate are available and misoprostol alone is used, a regimen using vaginal, buccal, or sublingual misoprostol is recommended for gestations up to 63 days. <sup>1,11,12</sup>

Standard 11: Patient comfort level during the abortion procedure must be considered.

<u>Option 11.01</u>: Analgesia or other comfort measures may be used as needed unless there are contraindications.

<u>Standard 12</u>: Completion of the abortion must be documented by ultrasonography, hCG testing, or by clinical means. If the patient has failed to follow-up as planned, clinic staff must document attempts to reach the patient to ensure the abortion is complete. All attempts to contact the patient (phone calls and letters) must be documented in the patient's medical record.

<u>Recommendation 12.1</u>: Ultrasonography should be used to evaluate completion of the abortion when expected bleeding does not occur after medications.

Option 12.01: Ultrasonography may be used routinely.

Standard 13: Rh immune globulin must be offered in accordance with Rh Guidelines.<sup>c</sup>

<sup>&</sup>lt;sup>B</sup> Abortifacients must only be used within established regimens under protocols which have been shown to be acceptable, safe, and efficacious in published clinical research. See NAF's *Protocol for Mifepristone /Misoprostol in Early Medical Abortion* for further resources.

<sup>&</sup>lt;sup>c</sup> See guidelines for "Rh Testing and Rh Immune Globulin Administration."

Standard 14: *Clinical Policy Guidelines* Standards 6, 7, and 8 for Post-Procedure Care must be followed.<sup>D</sup>

Recommendation 0.1:	Either hematocrit or hemoglobin screening should be obtained in women with a history of significant anemia or specific indication.
Recommendation 0.2:	A complete blood count (CBC) should be considered for women receiving methotrexate.
Recommendation 0.3:	Vital signs (e.g., blood pressure, pulse, and temperature) and physical exam should be done as indicated by medical history and patient symptoms.

**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. On the other hand, medical abortion is less effective than surgical abortion (90-98% versus 99% or greater). It also takes longer and may require more office visits.

Extensive research has established the safety and efficacy of mifepristone combined with misoprostol for early pregnancy termination. Methotrexate and misoprostol have also been found to be effective and are used in some services where mifepristone is not available. While misoprostol alone is inferior to combined methods for termination of pregnancy,<sup>1, 11, 12</sup> in areas where mifepristone or methotrexate are not available, it may be an acceptable alternative.<sup>18</sup>

Mifepristone is administered orally. Original trials involved a 600 mg dose, but an abundance of research indicates that 200 mg provides comparable efficacy. The best studied methotrexate regimen involves 50 mg/m<sup>2</sup> (body surface area) given intramuscularly, the same dose used in treating early unruptured ectopic pregnancy. Research also indicates acceptable efficacy when methotrexate is administered orally in doses of 25-50 mg.<sup>5</sup>

Information has also evolved on the types, doses, and routes of administration of the prostaglandin agents used in medical abortion regimens. Currently, misoprostol is the favored agent because it is efficacious, inexpensive, stable without refrigeration, and already FDA-approved for other indications.

Buccal administration of misoprostol has a similar physiological effect on the uterus as vaginal administration and is similarly highly effective for medical abortion. Sublingual administration of misoprostol is also highly effective for medical abortion with mifepristone, but is associated with a higher frequency of chills. One large retrospective study suggests that a change of route from vaginal to buccal administration of misoprostol after mifepristone was associated with a reduced incidence of serious infection, although absolute risk is extremely low.<sup>8</sup> The effectiveness of

<sup>&</sup>lt;sup>D</sup> See guidelines for "Post-Procedure Care."

medical abortion declines very gradually with advancing gestational age. This decline is more evident with oral administration of misoprostol.<sup>17, 24</sup>

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- 1. Aldrich T, Winikoff B. Does methotrexate confer a significant advantage over misoprostol alone for early medical abortion? A retrospective analysis of 8678 abortions. *BJOG* 2007 May; 114(5):555-62.
- 2. Boersma AA, Meyboom-de Jong B and Kleiverda G. Mifepristone followed by home administration of buccal misoprostol for medical abortion up to 70 days of amenorrhoea in a general practice in Curaçao. *Eur J Contraception and Repro Health Care* 2011; 16: 61-66.
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## FIRST TRIMESTER SURGICAL ABORTION

**Policy Statement:** Legal abortion is one of the safest surgical procedures. The following guidelines enhance this safety.

#### PRE-PROCEDURE

- <u>Standard 1</u>: Pertinent medical history must be obtained and documented.
- <u>Standard 2</u>: Confirmation of pregnancy must be documented.
- <u>Standard 3</u>: Gestational age must be verified and documented.
  - <u>Option 3.01</u>: Ultrasonography, using a consistent and published table of fetal measurements can be of clinical value in verifying intrauterine pregnancy and gestational age.
- <u>Standard 4</u>: If intrauterine gestation has not been confirmed by ultrasound, providers should adhere to the guidelines for "Management of Pregnancy of Uncertain Location."
- <u>Standard 5:</u> Baseline blood pressure and pulse must be obtained for all patients.
- <u>Recommendation 0.1</u>: Hemoglobin or hematocrit and physical exam should be done as indicated by medical history and patient symptoms.<sup>A</sup>
- <u>Standard 6:</u> Pain control options must be discussed with the patient.

#### PROCEDURE

- <u>Standard 7</u>: Patient comfort during the procedure must be monitored. Analgesia or other comfort measures must be offered when needed.<sup>B</sup>
- Standard 8: All instruments entering the uterine cavity must be sterile.

<u>Option 8.01</u>: The vagina may be cleansed with a bacteriocidal agent.

<sup>&</sup>lt;sup>A</sup> By establishing a balance sheet of risks, costs, and outcomes, it was discovered that a pre-procedure Hct was of relatively questionable value statistically in preventing morbidity and mortality in a healthy woman in the first trimester with no history of anemia or major disease process.<sup>1</sup>

<sup>&</sup>lt;sup>B</sup> See guidelines for "Analgesia and Sedation."

<u>Recommendation 0.2</u>: The cervix should be dilated gently and gradually.

- <u>Option 0.21</u>: Cervical dilation may be facilitated through the use of osmotic dilators or misoprostol, particularly in adolescents or women at risk for cervical stenosis.
- <u>Option 0.22</u>: Difficult cervical dilation at very early gestational age (less than seven weeks) may be facilitated by delaying the procedure. Alternatively medical abortion can be offered.<sup>C</sup>
- Standard 9: Completion of the procedure must be verified and documented.<sup>D</sup>
  - <u>Option 9.01:</u> Intra-operative ultrasonography can be of value to locate fetal parts and aid in their extraction, to help verify an empty uterus, and to help verify an intact uterus.
- Standard 10: Rh immune globulin must be offered per Rh policy guidelines.<sup>E</sup>

#### Standard 11: Clinical Policy Guidelines for Post-Procedure Care must be followed.<sup>F</sup>

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<sup>&</sup>lt;sup>c</sup> See guidelines for "Early Medical Abortion."

<sup>&</sup>lt;sup>D</sup> See guidelines for "Evaluation of Evacuated Uterine Contents."

<sup>&</sup>lt;sup>E</sup> See guidelines for "Rh Testing and Rh Immune Globulin Administration."

<sup>&</sup>lt;sup>F</sup> See guidelines for "Post-Procedure Care."

## 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 and physical exam must be evaluated in order to assess for the risk of ectopic implantation in early pregnancy. Certain signs and symptoms, such as vaginal bleeding and/or pelvic pain, should alert providers to the importance of following policies and procedures for ruling out ectopic pregnancy.

<u>Option 1.01</u>: In addition to physical exam, evaluation may include:

- a. sonography;
- b. uterine aspiration; and
- c. serial quantitative hCGs.
- <u>Recommendation 1.1</u>: Each provider site should have a written protocol to evaluate ectopic pregnancy.
  - <u>Option 1.11:</u> Clinical algorithms for the evaluation of possible ectopic pregnancy may be useful in developing practice protocols.<sup>4, 10, 11</sup>
- <u>Recommendation 1.2:</u> All relevant staff at the site should be familiar with the protocol.
- <u>Standard 2</u>: The patient must be evaluated for ectopic pregnancy if:
  - a. transvaginal ultrasonography shows no intra-uterine pregnancy and serum quantitative hCG exceeds 2000 mIU/ml;<sup> $\Lambda$ </sup> or
  - b. abdominal ultrasonography shows no intra-uterine pregnancy and serum quantitative hCG exceeds 3600 mIU/ml; or
  - c. a suspicious adnexal mass is found on ultrasound or pelvic exam; or
  - d. no pre-abortion sonography demonstrating an IUP has been performed, and there is minimal or no bleeding in response to abortifacient medications OR there are no products of conception identified in the uterine aspirate.<sup>B</sup>

<sup>&</sup>lt;sup>A</sup> All hCG values used in this document are based on the Third International Standard (originally referred to as the First International Reference Preparation).

<sup>&</sup>lt;sup>B</sup> Intrauterine gestation is confirmed when an ultrasound demonstrates a gestational sac with a yolk sac or when chorionic villi are identified in the uterine aspirate. Sonographic or tissue confirmation of an intrauterine pregnancy makes concurrent ectopic pregnancy extremely unlikely in naturally conceived pregnancies (1/4,000 - 1/8,000).<sup>4-6</sup>

Standard 3: All patients with a pregnancy of uncertain location must be informed about the possibility of ectopic pregnancy, the symptoms and dangers associated with ectopic pregnancy, and have a plan for when and how to seek emergency medical attention. This should be documented in the medical record.

<u>Recommendation 3.1</u>: Each provider site should have a patient education handout describing ectopic warning signs and the medical record should reflect that the patient has received this handout.

- <u>Standard 4</u>: The patient must not be released from follow-up care until either:
  - a. the diagnosis of ectopic pregnancy has been excluded;
  - b. clinical resolution of a possible ectopic pregnancy has been ensured; or
  - c. transfer of care to an appropriate provider has been made and documented.
- <u>Standard 5</u>: Patients experiencing symptoms suspicious for rupturing ectopic pregnancy should be emergently evaluated for possible surgical management.

<u>Standard 6</u>: If either 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 BhCG levels according to evidence-based regimens.<sup>c</sup>

**Discussion:** A combination of clinical assessment, pelvic ultrasound, serum quantitative hCG, and examination of uterine aspirate is often needed to distinguish between an early intrauterine gestation, a miscarriage, and an ectopic pregnancy.<sup>6</sup> With 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 4 to 5 weeks from LMP on transvaginal ultrasound, it may be confused with a pseudo-sac associated with an ectopic pregnancy.<sup>1</sup> Visualization of a yolk sac or embryo is therefore needed to definitely confirm an intrauterine pregnancy on ultrasound.

From seven to 20% of women with a pregnancy of uncertain location are subsequently found to have an ectopic pregnancy and approximately 25-50% of women with ectopic pregnancies initially present with pregnancy of uncertain location.<sup>1</sup> 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.<sup>3,5</sup>

<sup>&</sup>lt;sup>c</sup> See guidelines for "Evaluation of Evacuated Uterine Contents."

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## SECOND TRIMESTER ABORTION BY D&E

**Policy Statement:** Second trimester<sup>A</sup> abortion by dilation and evacuation (D&E) is a safe outpatient surgical procedure when performed by appropriately trained clinicians in medical offices, freestanding clinics, and ambulatory surgery centers.

#### PRE-PROCEDURE

<u>Standard 1</u> :	Pertinent	medical history must be obtained and documented.
<u>Recommenda</u>	<u>tion 0.1</u> :	A patient with a suspected or actual placenta previa and prior uterine scarring should be evaluated for placental abnormality, such as accreta.
<u>Recommenda</u>	tion 0.2:	Physical examination should be done as indicated by medical history and patient symptoms.
Recommenda	<u>tion 0.3</u> :	A pre-operative Hgb or Hct should be done.
<u>Standard 2</u> :	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 LMP.	
Option 0.01:	In later see	cond trimester abortions, intra-amniotic or intra-fetal injection may be

# given to cause fetal demise in utero prior to abortion (see Discussion).

## PROCEDURE

Standard 3: Patient comfort level during the abortion procedure must be addressed.<sup>B</sup>

<u>Recommendation 3.1</u>: Analgesic or other comfort measures should be offered unless there are contraindications. Such measures should be based on the woman's needs and the medical context.

<u>Standard 4</u>: Appropriate dilation of the cervix must be obtained.

<u>Recommendation 4.1</u>: Dilation should be achieved gently and gradually.

<sup>&</sup>lt;sup>A</sup> For the purposes of these guidelines, second trimester begins at approximately 14 weeks LMP. (Cunningham, FG, *et al. Williams' Obstetrics; 22nd Ed.* Columbus OH: McGraw-Hill Inc., 2005: Chapter 4).

<sup>&</sup>lt;sup>B</sup> See guidelines for "Analgesia and Sedation."

- <u>Recommendation 4.2</u>: Osmotic dilators, misoprostol, and/or other cervical ripening agents should be used to facilitate adequate dilation.
- <u>Standard 5:</u> When osmotic dilators, misoprostol, and/or other cervical ripening agents are used, a plan for emergency care prior to the scheduled procedure must be in place and communicated to the patient.

<u>Recommendation 0.4</u>: IV access should be established prior to evacuation.

- <u>Standard 6</u>: All instruments entering uterine cavity must be sterile.
- <u>Standard 7:</u> Uterotonics must be available to aid in control of uterine bleeding.
- <u>Option 0.02</u>: Prophylactic vasopressin may be used intracervically or paracervically to reduce blood loss.
- <u>Option 0.03</u>: Intra-operative ultrasonography can be of value to locate fetal parts and aid in their extraction, to aid in verifying an empty uterus, and to aid in diagnosis of uterine perforation.

#### **POST-PROCEDURE**

- <u>Standard 8</u>: Completion of the procedure must be verified and documented by the operator.<sup>c</sup>
- Standard 9: Clinical Policy Guidelines for Post-Procedure Care must be followed.
- <u>Option 0.04</u>: Uterotonic agents may be prescribed at discharge.

**Discussion**: Second trimester procedures comprise approximately 10% of abortions in the United States today. The dilation and evacuation procedure requires special training, techniques, and equipment appropriate for gestational age. Dilation and evacuation (D&E) is now the predominant second trimester abortion procedure in the United States.

Clinicians who provide second trimester D&E procedures should provide the safest procedure possible for their patients. The United States Supreme Court has upheld a law banning some abortion procedures. Although the law does not require the use of fetocidal injections, some providers may choose to use them in order to avoid violating the law.

<sup>&</sup>lt;sup>c</sup> See guidelines for "Evaluation of Evacuated Uterine Contents."

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 practice.

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## SECOND TRIMESTER ABORTION BY MEDICAL INDUCTION

**Policy Statement:** When performed in appropriate clinical settings by trained clinicians with appropriate medications, medical induction is a safe and effective method for termination of pregnancies beyond the first trimester.<sup>A</sup> As gestational age increases, complications and risks increase.

- Standard 1:Personnel capable of surgical management and the necessary equipment must be<br/>available until post-abortion discharge. If surgical intervention is required, the<br/>NAF *Clinical Policy Guidelines* for Second Trimester Abortion by D&E must be<br/>followed.
- <u>Standard 2</u>: A clinician must be available for emergency care from initiation of cervical pretreatment until post-abortion discharge.
- <u>Standard 3</u>: Medical history must be obtained and physical examination performed as indicated by patient history and symptoms. These must be documented.
- <u>Standard 4</u>: Gestational age must be verified by ultrasonography prior to the termination of a pregnancy clinically estimated to be more than 14 weeks LMP.<sup>B</sup>
- <u>Recommendation 0.1:</u> When abnormal placentation<sup>5</sup> is suspected, diagnostic imaging should be obtained.
- <u>Recommendation 0.2</u>: A pre-abortion Hgb or Hct should be done.
- <u>Standard 5</u>: Patient comfort level during the abortion procedure must be addressed, and analgesia and other comfort measures offered. Such measures should be based on the woman's needs and the medical context.<sup>C</sup>
- <u>Option 0.02</u>: Pretreatment with mifepristone 24-48 hours prior to misoprostol has been shown to reduce the induction-to-abortion interval (see Discussion).
- <u>Option 0.03</u>: In later second trimester abortions, intra-amniotic or intra-fetal injection may be given to cause fetal demise in utero (see Discussion).
- Option 0.04: Prostaglandins and/or oxytocin may be used to induce labor.

<sup>&</sup>lt;sup>A</sup> For the purposes of these guidelines, second trimester begins at approximately 14 weeks LMP. (Cunningham, FG, *et al. Williams' Obstetrics; 22nd Ed.* Columbus OH: McGraw-Hill, Inc., 2005: Chapter 4).

<sup>&</sup>lt;sup>B</sup> See guidelines for "Limited Sonography in Abortion Care."

<sup>&</sup>lt;sup>c</sup> See guidelines for "Analgesia and Sedation."

- <u>Standard 6</u>: Patients receiving prostaglandins or other priming and induction agents must be advised that administration of these medications may precipitate rapid onset of uterine contractions and expulsion.
- <u>Standard 7</u>: Patients must be given detailed instructions for how to contact the health care facility. Patients must also be given detailed instructions on how to proceed when signs of labor are noted, including a plan for management of unscheduled feto-placental expulsion and recognition of related complications.
- <u>Standard 8</u>: Once regular contractions have been confirmed, patients must be observed by a health care worker trained to monitor contractions and expulsion, and who can recognize emergent situations.

<u>Recommendation 0.3</u>: IV access should be established prior to expulsion.

- Standard 9: Completion of the procedure must be verified and documented by the responsible clinician.<sup>D</sup>
- Standard 10: Uterotonics should be available to aid in control of uterine bleeding.

Standard 11: Clinical Policy Guidelines for Post-Procedure Care must be followed.<sup>E</sup>

<u>Recommendation 0.4</u>: Evidence-based medication regimens should be used.

- <u>Option 0.41</u>: Pretreatment with mifepristone 24-48 hours prior to misoprostol should be used to reduce the induction-to-abortion interval (see Discussion).
- <u>Option 0.42</u>: In later second trimester abortions, intra-amniotic or intra-fetal injection may be given to cause fetal demise in utero (see Discussion).
- <u>Option 0.43</u>: Prostaglandins and/or oxytocin may be used to induce contractions.

**Discussion:** In the setting of second trimester induction abortion, cervical preparation, drug regimens, a history of a scarred uterus, and issues of fetocidal injections are important clinical and pragmatic considerations. With respect to cervical preparation and related drug regimens, osmotic or mechanical dilators, prostaglandins, and/or mifepristone have all been used to achieve cervical preparation for induction and expulsion.

<sup>&</sup>lt;sup>D</sup> See guidelines for "Evaluation of Evacuated Uterine Contents."

<sup>&</sup>lt;sup>E</sup> See guidelines for "Post-Procedure Care."

Current published data provide support for the use of 200 mg oral mifepristone, followed 24-48 hours later by repeated doses of 200-400 $\mu$ g misoprostol every three hours by the sublingual or buccal routes. Thereafter, 400  $\mu$ g oral, vaginal misoprostol may be utilized to a maximum of five doses.<sup>4,6,14</sup>

There is no evidence that the use of misoprostol increases the risk of uterine rupture in a previously scarred uterus in the second trimester compared to other induction agents. While the risk of uterine rupture during second trimester induction in a woman with a scarred uterus is unknown, there is a recognized risk at term and there have been case reports in the second trimester. At term, women with placenta previa and uterine scarring—especially multiple or vertical cesarean scars— are at increased risk for the rare occurrence of placenta accreta.<sup>5</sup>

In light of the relevant medical and legal context in which the abortion takes place, intra-fetal or intra-amniotic injection may be used to cause fetal demise in utero in later second trimester procedures. In addition to the references below, NAF Members may look to the *NAF Clinical Practice Bulletin for Digoxin Administration* for further information.

As always, it is incumbent upon each clinician to be aware of the laws pertinent to their clinical practice.

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# ANALGESIA AND SEDATION

**Policy Statement:** Anxiolysis, analgesia, or anesthesia should be provided during abortion procedures for any patient in which the benefits outweigh the risks.

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. Whether it be local anesthesia, oral analgesia, or procedural sedation, it is the degree of CNS depression rather than any type of modality *per se* that is the basis for the establishment of NAF guidelines.

NOTE: These guidelines do not address the use of deep or general anesthesia except to identify appropriate providers of such care, who are expected to follow their professional standards in the delivery of anesthesia services.

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

It is recognized that patient comfort and reduced anxiety are not dependent only on pharmacologic measures, but are significantly affected by patient counseling and by a supportive staff. It is also recognized that there is a wide range of alternative modalities (such as acupuncture, yoga, hypnosis) that are helpful for many 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**<sup>A</sup>

1. <u>Local Anesthesia</u> - 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, this almost always signifies paracervical block.

<sup>&</sup>lt;sup>A</sup> 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. <u>Minimal Sedation (Anxiolysis)</u> 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. <u>Moderate Sedation/Analgesia ("Conscious Sedation")</u> 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.
- 4. <u>Deep Sedation/Analgesia</u> 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. <u>General Anesthesia</u> 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<sup>\*\*</sup> patients whose level of sedation becomes deeper than initially intended.

\* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

\*\* 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.

## PERSONNEL AND MONITORING

<u>Standard 1</u>: 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.

<u>Recommendation 1.1</u>: Documentation of this education should include precautions relevant to transient mental impairment.

- <u>Standard 2</u>: The supervising practitioner must be immediately available when sedation is administered.
- <u>Standard 3</u>: 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.
- <u>Standard 4:</u> The potential need for IV access must be considered prior to administering any level of sedation.

<u>Recommendation 4.1</u>: When more than minimal sedation is intended, IV access should be maintained.

<u>Standard 5</u>: 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 5.1:	Pulse oximetry should be available to enhance this monitoring.
Recommendation 5.2:	The patient should be checked frequently for verbal responsiveness.
Recommendation 5.3:	For patients in ASA P-3, P-4, and P-5 provision of care by an anesthesia professional should be considered. (see ASA "Physical Status Definition" in this document).

- Standard 6: 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 if the patient's responsiveness has declined from baseline and must be prepared to provide respiratory support.<sup>B</sup>
- <u>Standard 7</u>: The practitioner administering **deep sedation** or **general anesthesia** must not be the practitioner performing the abortion.
- <u>Standard 8</u>: The practitioner administering **deep sedation** or **general anesthesia** must be certified according to applicable regulations and adhere to established professional standards of care.
- Standard 9: N2O/O2 must be self-administered by the patient.

<sup>&</sup>lt;sup>B</sup> See guidelines for "Emergency Procedures for Facilities that Offer/Provide Minimal Sedation."

<u>Standard 10</u>: The provision of N2O/O2 must follow guidelines for patient monitoring, which are consistent with Standards 7 and 8 above, and requires dedicated monitoring personnel.

<u>Standard 11</u>: Equipment for the delivery of N2O/O2 must:

- a. provide a concentration of N2O of no more than 70% inspired;
- b. provide a maximum of 100% and minimum of 30% O2 conc.; and
- c. be checked and calibrated regularly.

Recommendation 11.1:	Equipment for the delivery of N2O/O2 should be outfitted with an oxygen analyzer.
Recommendation 11.2:	Due to the potential for occupational exposure, room or personnel monitoring for levels of gases should be conducted (see Discussion below).

FACILITIES AND EQUIPMENT: See guidelines for "Emergency Procedures for Facilities that Offer/Provide Minimal Sedation."

## **DISCUSSION:**

ON THE USE OF PULSE OXIMETRY - There have been no trials evaluating the benefit of pulse oximetry to young women undergoing outpatient abortion, who only rarely have respiratory or hemodynamic compromise. Given the low risk of morbidity and mortality associated with this procedure it is unlikely that there will be studies large enough to assess pulse oximetry on the basis of outcomes. The major correlation with prolonged oxygen desaturation is advancing age and cardiovascular function deficits; however, the use of pulse oximetry has become the standard of care for any patient who has received medication which alters the level of consciousness or the respiratory drive.

ON THE USE OF N2O/O2 - 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. Attention must be paid to the level of sedation provided and the clinician must be prepared to recognize and care for changes in these levels. Occupational exposure to N2O has been associated with increased risks of neurologic impairment, spontaneous abortion, subfertility, and hepatic and renal disease. Although there is no OSHA standard for N2O, NIOSH recommends that airborne levels of N2O be kept below 25 ppm (1995) through well-designed scavenger systems and other engineering controls, equipment maintenance, exposure monitoring, and safe work practices.

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- 6. Council on Scientific Affairs, American Medical Association. The use of pulse oximetry during conscious sedation. *JAMA* 1993, 270:1463.
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# ANALGESIA AND SEDATION

#### American Society of Anesthesiologists

#### CONTINUUM OF DEPTHS OF SEDATION: DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA<sup>c</sup>

#### Committee of Origin: Quality Management and Departmental Administration (Approved by the ASA House of Delegates 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

\*\* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

<sup>&</sup>lt;sup>c</sup> 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.

# ANALGESIA AND SEDATION

American Society of Anesthesiologists

## PHYSICAL STATUS DEFINITION<sup>D</sup>

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.

<sup>&</sup>lt;sup>D</sup> ASA Relative Value Guide. 2012. Reprinted with permission of the American Society of Anesthesiologists; 520 N. Northwest Highway; Park Ridge, Illinois 60068-2573.

# USE OF ANTIBIOTICS IN ABORTION

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

Recommendation 0.1:	All women should receive antibiotics at the time of surgical abortion.
Option 0.01: Antibiotics	s may be given to women choosing medical abortion.
Recommendation 0.2:	Empiric treatment of Chlamydia should be considered for patients at high risk for pre-existing infection. <sup>A</sup>
Recommendation 0.3:	For documented infections of the reproductive tract, CDC guidelines should be followed. <sup>3</sup>
Option 0.02: Antibiotics	s may be initiated at the time of insertion of osmotic dilators.

Option 0.03: Patients with non-cardiac prostheses may be given peri-procedure antibiotics.<sup>B</sup>

**Discussion**: Our review of the literature supports universal antibiotic treatment of all women undergoing surgical abortion. There is one large retrospective analysis, which supports the use of antibiotics in medical abortion.<sup>5</sup>

#### References:

- 1. Advisory Statement: Antibiotic prophylaxis for dental patients with total joint replacements. *Journal of the American Dental Association* 2003, 134:895.
- 2. Blackwell, AL. Health gains from screening for infection of the lower genital tract in women attending for termination of pregnancy. *Lancet* 1993, 342:206.
- 3. Centers for Disease Control and Prevention. STD Treatment Guidelines (2010) MMWR 59 (no. RR-12).

e. history of pelvic inflammatory disease.

<sup>B</sup> "The statement concludes that antibiotic prophylaxis is not indicated for dental patients with pins, plates, or screws, nor is it routinely indicated for most dental patients with total joint replacements. However it is advisable to consider premedication in a small number of patients who may be at potential increased risk [1. All patients during first two years following joint replacement; 2. Immunocompromised/immunosuppresed patients; and 3. Patients with comorbidities (previous joint infections, malnourishment, hemophilia, HIV-infected, Insulin-dependent type-1 diabetes, malignancy)] of experiencing hematogenous total joint infections."<sup>1</sup>

<sup>&</sup>lt;sup>A</sup> Patients at high risk for Chlamydia are defined as those with any of the following:

a. age 25 or under;

b. new or multiple sexual partners;

c. mucopurulent discharge;

d. presence of any STD; or

- 4. Darj, E, *et al.* The prophylactic effect of doxycycline on postoperative infection rate after first-trimester abortion. *Obstet Gynecol* 1987, 70:755.
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- 7. Hakim-Elahi, E & Tovell, H. Complications of first-trimester abortion: A report of 170,000 cases. *Obstet Gynecol* 1990, 76:129.
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- 14. Sawaya, GF, *et al.* Antibiotics at the time of induced abortion: The case for universal prophylaxis based on a meta-analysis. *Obstet Gynecol* 1996, 87:884.
- 15. Sawaya, GF & Grimes, DA. Preventing postabortal infection. Contemp Obstet Gynecol 1994, 15:53.

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## **COMPLICATIONS: BLEEDING**

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

#### PRE-PROCEDURE BLEEDING

<u>Recommendation 0.1</u>: An ectopic pregnancy or spontaneous abortion should be considered.

#### PERI-PROCEDURE BLEEDING

<u>Standard 1</u>: When there is excessive bleeding, the provider must institute measures to identify the etiology of the bleeding and control it.

Recommendation 1.1:	IV access should be established.	
Recommendation 1.2:	The provider should consider incomplete procedure, atony, fibroids, lacerations, perforations, placenta accreta, cervical or cornual pregnancy, and coagulopathy. <sup>A</sup>	
Option 1.2	1: Ultrasonography may be useful to determine whether the uterus is empty and to detect occult bleeding.	
Option 1.2	2: When a cervical bleeding source is suspected, hemostasis may be achieved by compressing the cervix at the lateral fornices with ring forceps or placing a suture.	
Option 1.2	<u>3</u> : When atony is suspected, uterine massage and uterotonics <sup>B</sup> may be useful.	
Option 1.2	4: When coagulopathy is suspected, blood may be drawn for coagulation parameters and transfusion blood or blood products may be necessary.	

<sup>&</sup>lt;sup>A</sup> See guidelines for "Complications: Perforation."

<sup>&</sup>lt;sup>B</sup> methergine (intracervical or IM); oxytocin (intracervical, IM, or IV); prostaglandins (e.g. prostin, intracervical, or IM)

<u>Recommendation 0.2</u>: When excessive bleeding continues, the following measures should be instituted:

- a. monitor and document blood pressure, pulse, clinical status;
- b. uterotonics;
- c. maintain IV access;
- d. initiate appropriate volume replacement; and
- e. prepare for transfer to a hospital facility if necessary.<sup>c</sup>
- <u>Standard 2</u>: The patient must be transferred to a hospital facility when the bleeding does not respond to therapeutic measures or when the patient is hemodynamically unstable.<sup>C</sup>

#### DELAYED BLEEDING

<u>Standard 3</u>: When a patient reports excessive bleeding<sup>D</sup> after discharge from the abortion facility, she must be evaluated by that facility or an emergency contact service.

**Discussion**: Excessive bleeding in the peri-procedure and in the post-procedure period is almost always due to uterine atony, often complicated 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.

Many clinicians give uterotonics and vasoconstrictors as a preventive measure. Although there are data to support the routine use of vasopressin in the paracervical block, there is little evidence in the literature for other routine prophylactic strategies. However, experienced clinicians have found the following regimens useful:

In the paracervical block:

- a. 2-6 units of vasopressin;
- b. 4-8 units of oxytocin (e.g., 10 units in 50 cc of lidocaine, using 20 cc of the lidocaine for the block, or 4 units total dose);
- c. epinephrine (20 cc of 1:200,000 in lidocaine, equivalent to 0.1 cc of 1:1,000); or
- d. none of the above.

<sup>&</sup>lt;sup>c</sup> See guidelines for "Emergency Procedures for Facilities that Offer/Provide Minimal Sedation."

<sup>&</sup>lt;sup>D</sup> Saturation of more than one pad per hour for more than three hours.

Post-procedure, the following measures may be used for treatment of post-abortion hemorrhage:

- a. methergine 0.2mg po, IM, intracervical, or IV;
- b. oxytocin 10units IM or 10-40 units IV;
- c. misoprostol 800-1000mcg pr or 800mcg sl (has been used for PPH);
- d. hemabate 0.25mcg IM;
- e. intrauterine pressure (e.g., Foley or Bakri balloon, or pack); or
- f. 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.<sup>E</sup>

References:

1. Hakim-Elahi, E. & Tovell, H. Complications of first-trimester abortion: A report of 170,000 cases. *Obstet Gynecol* 1990, 76:129.

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<sup>&</sup>lt;sup>E</sup> See guidelines for "Complications: Perforation."

# **COMPLICATIONS: PERFORATION**

**Policy Statement:** Uterine perforation is a complication of abortion that can lead to significant morbidity.

- <u>Standard 1</u>: If, in the clinician's judgment, an instrument passes farther than expected, then uterine perforation must be considered.
- <u>Standard 2</u>: If a perforation occurs, even if the patient is asymptomatic, close observation and follow-up must be done.
  - Option 2.01: Antibiotic coverage may be instituted.
  - Option 2.02: Uterotonics may be administered.
  - Option 2.03: The patient may be transferred to a hospital.
  - <u>Option 2.04:</u> If a perforation occurs and *the pregnancy has not been disrupted*, the completion of the procedure may occur immediately, after a delay, or by referral to another provider.
  - <u>Recommendation 2.1</u>: If a perforation occurs and *the pregnancy has been disrupted*, the abortion should be completed as soon as feasible.
  - <u>Option 2.05</u>: The uterine evacuation may be completed under direct ultrasonography.
  - <u>Option 2.06</u>: The abortion may be completed under laparoscopic visualization.
- <u>Standard 3</u>: 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.
- <u>Standard 4</u>: When uterine perforation is suspected and the cannula has been inserted into the uterine cavity, suction must be released immediately before the cannula is withdrawn.

**Discussion**: Perforations may be difficult to identify correctly. When a perforation is suspected, it is safest to proceed as if there has been a perforation until that possibility has been excluded.

Most perforations are midline and/or fundal in location, especially in the first trimester. Perforations are often occult and usually do not present a problem. In second trimester abortions there is an increased risk of serious perforations because the myometrium is more vascular and less resistant to damage by larger instruments. Lateral perforations are more likely to damage uterine vascularity. Perforations are more likely to occur in the following situations:

- a. marked uterine anteflexion or retroflexion;
- b. cervical internal os stenosis requiring more force to dilate;
- c. uterine abnormalities; and
- d. difficult and prolonged uterine evacuation.

Uterine perforation is likely if:

- a. an instrument extends without resistance further into the uterine cavity than expected;
- b. the patient experiences more than the expected amount of pain during the procedure; or
- c. the patient experiences inordinate and persistent pain in the immediate recovery period.

Several factors may help prevent perforations:

- a. accurate assessment of gestational age;
- b. accurate assessment of uterine position;
- c. straightening the axis of the uterus; and
- d. cervical preparation beyond the first trimester.<sup>A</sup>

#### References:

- 1. Cervical preparation for second-trimester surgical abortion prior to 20 weeks of gestation. *Contraception* 2007, 76:486.
- 2. Cervical preparation for surgical abortion from 20-24 weeks' gestation. *Contraception* 2008, 77:308.
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<sup>&</sup>lt;sup>A</sup> See guidelines for "Second Trimester Abortion by D&E."

# **POST-PROCEDURE CARE**

Policy Statement: Most serious abortion complications are detectable in the immediate postprocedure period. Appropriate and accessible follow-up care is essential to patients' well-being.

<u>Standard 1</u> :	Rh immune globulin must be offered in accordance with Rh guidelines. <sup>A</sup>
<u>Standard 2</u> :	All patients must be observed during the recovery period by a health care worker trained in post-procedure care.
<u>Standard 3</u> :	A clinician must remain in the facility until all patients are medically stable. <sup>B</sup>
<u>Standard 4</u> :	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.
<u>Standard 5</u> :	The patient must be given oral and written instructions outlining what to expect post-procedure, self-care, and signs and symptoms of complications.
<u>Standard 6</u> :	The facility must provide an emergency contact service on a 24-hour basis, where calls are triaged in accordance with written policies and which conform to applicable regulations. A recorded message alone is unacceptable.
<u>Standard 7:</u>	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.
<u>Standard 8:</u>	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

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referral if indicated.

<sup>&</sup>lt;sup>A</sup> See guidelines for "Rh Testing and Rh Immune Globulin Administration." <sup>B</sup> Clinician is defined as a physician, nurse practitioner, physician assistant, or nurse midwife.

## EVALUATION OF EVACUATED UTERINE CONTENTS

**Policy Statement:** Complete removal and identification of products of conception help prevent complications of abortion.

<u>Standard 1</u> :	Completion of abortion must be confirmed prior to the woman leaving the facility.				
	<ul><li>a. When a fetal pole is not seen with pre-procedure ultrasound, evacuated uterine contents must be examined before the woman leaves the facility.</li><li>b. In other cases either tissue exam or ultrasound must be used to confirm evacuation.</li></ul>				
	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.			
	<u>Option 1.01</u> : Pathological examination of evacuated uterine contents is not required.				
<u>Standard 2</u> :	When insufficient tissue or incomplete products of conception are obtained, or ultrasound findings unclear, the patient must be reevaluated.				
	Recommendation 2.1:	Follow-up pelvic ultrasonographic examination should be considered.			
	Recommendation 2.2:	Resuctioning should be considered.			
	Recommendation 2.3:	Serial quantitative hCG or sensitive urine pregnancy tests should be considered. <sup>A</sup>			
<u>Standard 3</u> :	If insufficient tissue is produced out ectopic pregnancy may symptoms and dangers of the symptoms and dangers of the symptoms are symptoms and the symptoms are symptoms and the symptoms are symptoms a	resent after adequate patient evaluation, a protocol to rule nust be followed, and the patient must be informed of of ectopic pregnancy.			

<sup>&</sup>lt;u>Recommendation 3.1</u>: If the uterine cavity is determined to be empty, serial quantitative hCG tests should be measured.

 $<sup>^{\</sup>scriptscriptstyle A}$  Sensitive urine pregnancy test is positive at 25 MIU of  $\beta\text{-hCG}.$ 

<u>Standard 4</u>: The patient must not be released from follow-up care until the diagnosis of ectopic pregnancy has been excluded or an appropriate referral has been documented.

Recommendation 4.1:	A 48-hour post-procedure serum quantitative hCG test
	should be done. If there is a decrease of 50% or more,
	no further ectopic follow up is necessary. <sup>1</sup>

- <u>Recommendation 4.2</u>: If 48-hour post-procedure serum quantitative hCG testing shows no change, or a subnormal increase in value, ectopic pregnancy evaluation and definitive treatment should be instituted and documented, or a referral made and documented.
- <u>Standard 5</u>: In second trimester abortions, placenta and all major fetal parts must be removed from the uterus.

Recommendation 5.1:	If the above are not identified, ultrasonographic evaluation and repeat uterine exploration under ultrasound guidance should be considered.
Recommendation 5.2:	The clinician should continue care of the patient until completion of the abortion has been determined.

#### References:

1. Creinin, MD. Change in serum beta-human chorionic gonadotropin after abortion with methotrexate and misoprostol. *Am J Obstet Gynecol* 1996 Feb; 174(2):776-8.

rev. October 2009

## FETAL TISSUE HANDLING, STORAGE, AND DISPOSAL

**Policy Statement:** The improper handling, storage, and disposal of tissue can lead to spread of infectious disease, and can increase the risk of theft or misplacement of tissue. Because of the possible infectious nature of tissue removed during the abortion procedure, guidelines for proper fetal tissue handling, storage, and disposal are established.

- <u>Standard 1:</u> All surgically removed tissue must be considered biohazardous and be handled, stored, and disposed of in accordance with applicable governmental regulations. A proper protocol for tissue handling, storage, and disposal must be in place.
- <u>Standard 2:</u> Adequate engineering and work practice controls for handling potentially infectious materials must be observed.<sup>A</sup>

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<sup>&</sup>lt;sup>A</sup> 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.

## EMERGENCY PROCEDURES FOR FACILITIES THAT OFFER/PROVIDE MINIMAL SEDATION<sup>A</sup>

Policy Statement: Optimal management of abortion emergencies reduces morbidity.

<u>Standard 1</u>: When abortion procedures are being performed, a current health care provider level BLS-certified staff member trained and certified to the level equivalent to AHA health care provider level must be available on-site.

<u>Recommendation 1.1</u>: All medical staff should have current health care provider level BLS certification.

<u>Standard 2</u>: Functioning equipment and current medications must be available on-site to handle medical emergencies and must include: an oxygen delivery system; oral airways; uterotonics; vasopressors, including epinephrine; and antihistamines.

<u>Recommendation 2.1:</u> 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.

Standard 3: 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 (i.e., an ambulance).

Recommendation 3.1:	All staff should know their appropriate roles in the management of medical emergencies.
Recommendation 3.2:	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.

<u>Standard 4</u>: In settings where benzodiazepines and opioids are used, appropriate antagonists, bronchodilators, and ambu bags must be available.

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<sup>&</sup>lt;sup>A</sup> Where moderate or greater sedation is provided, a provider capable of handling associated emergencies must be present. See guidelines for "Analgesia and Sedation."

