

2010 **CLINICAL
POLICY
GUIDELINES**



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NATIONAL
ABORTION
FEDERATION



2010 Clinical Policy Guidelines

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National Abortion Federation Clinical Policy Guidelines can be accessed on the Internet at
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The National Abortion Federation is the professional association of abortion providers in the United States and Canada. Our mission is to ensure safe, legal, and accessible abortion care to promote health and justice for women.

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National Abortion Federation

2010 CLINICAL POLICY GUIDELINES

INTRODUCTION

The mission of the National Abortion Federation (NAF) is to ensure safe, legal and accessible abortion care to promote 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 2010 edition of NAF's *Clinical Policy Guidelines* 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* includes an alphabetic list of bibliographic and cited references for each section when appropriate, and includes 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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6. Hayward, RS, *et al*. Users' guide to the medical literature VIII: How to use clinical practice guidelines; A. Are the recommendations valid? *JAMA*, 1995, 274:570.
7. James, BC. Implementing Practice Guidelines through Clinical Quality Improvement. *Frontiers of Health Services Management*, 1993, 10: 1.
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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.

rev. December 2007

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, 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 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 SHOULD PERFORM ABORTIONS

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

Standard 1: Abortion must be performed by licensed physicians or licensed / certified / registered midlevel clinicians trained in the provision of abortion care, in accordance with state law.

Standard 2: All personnel performing abortions must receive training in the performance of abortions and in the prevention, recognition and management of complications.

Recommendation 0.1: When advanced practice clinicians such as physician assistants, nurse practitioners or certified nurse midwives perform abortions, medical protocols should be in place that adhere to the clinician's scope of practice permitted by state law.

Recommendation 0.2: Appropriate referrals should be available for patients who cannot be cared for at your facility.

rev. December 2008

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 clinician must ensure that accurate information is provided regarding the risks, benefits, and possible complications of abortion.

Option 1.01: This 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; the potential risks, benefits, and possible complications; that her decision is uncoerced; and that she is prepared to have an abortion.

PATIENT EDUCATION AND/OR COUNSELING

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

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

Standard 5: Information about clinical procedures, aftercare and birth control must be available to patients at the facility.

Standard 6: 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 woman'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 woman 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 woman are outside the scope of training of clinic staff.

Confidentiality might become an issue when third-party payers are involved. It is important to inform the patient that by billing her insurance company, she is giving the authority to release information to that company.

References:

1. Baker, A. *Abortion and Options Counseling: A Comprehensive Reference*. Granite City, Illinois: The Hope Clinic for Women, 1995.

2. Benson Gold, R. & Nash, E. State abortion counseling policies and the fundamental principles of informed consent, *Guttmacher Policy Review*, 2007, 10(4), 8-13.
3. Needle, R. & Walker, L. *Abortion Counseling: A Clinician's Guide to Psychology, Legislation, Politics, and Competency*. Springer Publishing Co., 2008.
4. 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.

rev. December 2007

INFECTON CONTROL

Policy Statement: Healthcare personnel and their patients are at risk for exposure to bloodborne 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.^A

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

Discussion: Regulatory agency policies (OSHA, CCOHS, etc.) may be helpful in developing exposure plans which protect personnel and patients from potentially infectious material. Proper techniques for collection, labeling and disposal of biohazardous material are integral to any complete exposure plan. Clinics should protect employees and patients inadvertently exposed to biohazardous material by providing provision of personal protective equipment, hepatitis B vaccine, postexposure evaluation, prophylaxis (when indicated), followup, and annual training programs at no cost to employees or exposed patients.

References:

1. 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
2. Clafin, N, Hayden, C (1998). *National Association for Healthcare Quality Guide To Quality Management*, Glenview, IL.
3. Occupational Safety and Health Administration, U.S. Department of Labor (last reviewed 2007). Bloodborne pathogens and needlestick prevention. Available at: <http://www.osha.gov/SLTC/bloodbornepathogens/index.html>
4. Occupational Safety and Health Administration, U.S. Department of Labor (2001; last amended 2006) Standard 1910.1030: Bloodborne Pathogens. Available at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
5. 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.

^A 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

Rh TESTING AND Rh IMMUNE GLOBULIN ADMINISTRATION

Policy Statement: Rh alloimmunization is a significant health risk to Rh(-) women undergoing abortion.

Standard 1: 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 testing is not required.

Standard 2: Rh immune globulin administration must be offered to Rh(-) women and documented.

Standard 3: 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;
b. documentation of other arrangements for administration.

Discussion: 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. 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.
3. Baskett, TF. Prevention of Rh alloimmunization: A cost-benefit analysis. *Can. Med. Assoc. J.*, 1990, 142:337.
4. Bowman, J. *The prevention of Rh immunization. Transfusion Med. Rev.*, 1988, 2:129.
5. Chavez, GFP. Epidemiology of Rh hemolytic disease of the newborn in the United States. *JAMA*, 1991, 263:3270.
6. Commentary: Immunoprophylaxis for Rhesus disease - Expensive but worth it. *Brit. J. Obstet. Gynecol.*, 1991, 98:509.
7. Gibble, JW. Maternal immunity to red cell antigens and fetal transfusion. *Cl. Lab. Med.*, 1992, 12:553.
8. Roberts, H. The use of anti-D prophylaxis in the management of miscarriage in general practice. *Health Bull.*, 1991, 49:245.

rev. December 2008

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.

Standard 1: Pertinent medical history must be obtained and documented.

Standard 2: Confirmation of pregnancy must be documented.

Standard 3: The patient must be informed about the efficacy, side effects, and risks, especially excessive bleeding and infection.

Standard 4: 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.

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

Recommendation 5.1: Written instructions should be given to all patients.

Standard 6: The patient must be informed that a surgical abortion will be recommended if medical abortion fails and this must be documented.

Standard 7: 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 8: 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.

Standard 9: When a patient with a positive pregnancy test presents with vaginal bleeding and/or pelvic pain, ectopic pregnancy must be considered.

Option 9.01: Evaluation may include:

- a. sonography;
- b. uterine aspiration;
- c. serial quantitative hCGs.

Recommendation 9.1: Each provider site should have a written protocol to evaluate ectopic pregnancy.

Option 9.11: Clinical algorithms for the evaluation of possible ectopic pregnancy may be useful in developing practice protocols.^{3, 7, 8}

Recommendation 9.2: All relevant staff at the site should be familiar with the protocol.

Recommendation 9.3: Patients with a positive pregnancy test in whom the pregnancy cannot be localized should be advised that an ectopic pregnancy cannot be ruled out.

Recommendation 9.4: Each provider site should have a patient education handout describing ectopic warning signs and documentation that the patient has received this handout.

Standard 10: The patient must be evaluated for ectopic pregnancy if:

- transvaginal ultrasonography shows no intra-uterine pregnancy and serum quantitative hCG exceeds 2000 mIU/ml; ^A or
- abdominal ultrasonography shows no intra-uterine pregnancy and serum quantitative hCG exceeds 3600 mIU/ml; or
- a suspicious adnexal mass is found on ultrasound or pelvic exam; or
- no pre-abortion sonography demonstrating an IUP has been performed, and there is minimal or no bleeding in response to medications.

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

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

Standard 12: 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.

Recommendation 12.1: 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 ^B

Recommendation 0.1: When mifepristone^C and vaginal, buccal or sublingual misoprostol are used, the regimen is recommended for gestations up to 63 days. ^{5,9}

Recommendation 0.2: When mifepristone^C and oral misoprostol are used, the regimen is recommended for gestations up to 56 days.

Recommendation 0.3: Where mifepristone is not available and methotrexate and misoprostol are used, the regimen is recommended for gestations up to 63 days. ¹

^A All hCG values used in this document are based on the Third International Standard (originally referred to as the First International Reference Preparation).

^B See *Clinical Policy Guidelines* on Rh Testing and Rh Immune Globulin Administration.

^C 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.

Recommendation 0.4: Where mifepristone is not available and misoprostol are used, the regimen is recommended for gestations up to 63 days. Combined regimens are more effective than prostaglandin alone.¹

Recommendation 0.5: Hct or Hgb should be obtained in women with a history of significant anemia.^D

Recommendation 0.6: 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 methotrexate or mifepristone combined with misoprostol for early pregnancy termination. However, medical methods are still evolving. Investigators continue to explore various pharmacologic agents, dosing regimens, routes of administration, the length of gestation during which they can be used, and the ideal protocols for their use.

Mifepristone is administered orally. Original trials involved a 600 mg dose, but further research indicates that 200 mg provides comparable overall efficacy. The best studied methotrexate regimen involves 50 mg/m² (body surface area) given intramuscularly, the same dose used in treating early unruptured ectopic pregnancy. One study found comparable efficacy using a standard 75 mg dose IM, but the results require confirmation. Research also indicates acceptable efficacy when methotrexate is administered orally in doses of 25-50 mg.

Information is also evolving on the types, doses, and routes of administration of the prostaglandin agents used in medical abortion regimens. Highly effective agents used in early European regimens included gemeprost and sulprostone, although the latter was discontinued due to adverse cardiovascular effects. These prostaglandins are not available in the United States. Currently, misoprostol is the favored agent because it is efficacious, cheap, 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 to 63 days gestation. Sublingual administration of misoprostol is also highly effective for medical abortion with mifepristone to 63 days gestation. Both buccal and sublingual administrations of misoprostol are 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 low.² The effectiveness of medical abortion declines with advancing gestational age.

Whereas the major U.S. medical abortion trials used transvaginal sonography routinely for gestational age assessment and follow-up, the extensive French experience relied more on clinical evaluation and hCG

^D By establishing a balance sheet of risks, costs and outcomes, it was discovered that a pre-operative 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.

monitoring, reserving sonography for cases of uncertain dating or outcome. Sonography avoids underestimation of gestational age, helps confirm complete abortion, and assists in the diagnosis of ectopic pregnancy. However, no randomized trials have been performed to assess the effects of sonography or clinical evaluation on medical abortion outcomes.

These Clinical Policy Guidelines include recommendations for gestational age limits in accordance with the most current evidence-based research.

Pharmacological induction of abortion provides an important alternative to surgical abortion in some circumstances. For example, medical methods may succeed when congenital uterine anomalies or fibroids limit surgical access to the gestational sac. Use of misoprostol may also avoid surgery in cases of incomplete spontaneous abortion.

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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. Fjerstad, M, Trussell, J, Sivin, I, Lichtenberg, ES, & Cullins, V. *New England Journal of Medicine*, 2009, 361(2):145.
3. Gracia CR, Barnhart KT. Diagnosing ectopic pregnancy: Decision analysis comparing six strategies. *Obstet Gynecol*. 2001 Mar; 97(3):464-70.
4. Paul, M & Creinin, MD (Eds). Supplement on Medical Abortion. *Am J Ob Gyn*, 2000, 183:S1-S94.
5. Raghavan S, Comendant R, Digol I, Ungureanu S, Friptu V, Bracken H, Winikoff B. Two-pill regimens of misoprostol after mifepristone medical abortion through 63 days' gestational age: a randomized controlled trial of sublingual and oral misoprostol. *Contraception*. 2009 Feb;79(2):84-90.
6. Shannon, C, Wiebe, E, Jacot, F, Guilbert, E, Dunn, S, Sheldon, W, Winikoff, B. Regimens of misoprostol with mifepristone for early medical abortion: A randomised trial. *BJOG* 2006; 113:621–628.
7. Speroff, L, Fritz, MA (2005). Ectopic pregnancy. In *Clinical Gynecologic Endocrinology and Infertility*, 7th ed., pp. 1275–1302. Philadelphia: Lippincott Williams and Wilkins.
8. Stovall, TG, Ling, FW, Buster, JE. Nonsurgical diagnosis and treatment of tubal pregnancy. *Fertility and Sterility* 1990; 54; 537-538. Algorithm adapted by the University of Tennessee Medical Center and reproduced in Paul, M, et al (Eds.), *A Clinician's Guide to Medical and Surgical Abortion*. Philadelphia: Churchill Livingstone, 1999:163.
9. Winikoff B, Dzuba IG, Creinin MD, Crowden WA, Goldberg AB, Gonzales J, Howe M, Moskowitz J, Prine L, Shannon CS. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. *Obstet Gynecol*. 2008 Dec;112(6):1303-10

rev. October 2009

FIRST TRIMESTER SURGICAL ABORTION

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

PRE-OPERATIVE PROCEDURE

Standard 1: Pertinent medical history must be obtained and documented.

Standard 2: Confirmation of pregnancy must be documented.

Standard 3: Gestational age must be verified and documented.

Option 3.01: Ultrasonography, using a consistent and published table of fetal measurements can be of clinical value in verifying intra-uterine pregnancy and gestational age.

Standard 4: The patient must be evaluated for ectopic pregnancy if:

- transvaginal ultrasonography shows no intra-uterine pregnancy and serum quantitative hCG exceeds 2000 mIU/ml;^A or
- abdominal ultrasonography shows no intra-uterine pregnancy and serum quantitative hCG exceeds 3600 mIU/ml;
- a suspicious adnexal mass is found on ultrasound or pelvic exam.

Standard 5: When a patient with a positive pregnancy test presents with vaginal bleeding and/or pelvic pain, ectopic pregnancy must be considered.

Option 5.01: Evaluation may include:

- sonography;
- uterine aspiration;
- serial quantitative hCGs.

Recommendation 5.1: Each provider site should have a written protocol to evaluate ectopic pregnancy.

Option 5.11: Clinical algorithms for the evaluation of possible ectopic pregnancy may be useful in developing practice protocols.^{1,2,3}

Recommendation 5.2: All relevant staff at the site should be familiar with the protocol.

Recommendation 5.3: Patients with a positive pregnancy test in whom the pregnancy cannot be localized should be advised that an ectopic pregnancy cannot be ruled-out.

Recommendation 5.4: Each provider site should have a patient education handout describing ectopic warning signs and documentation that the patient has received this handout.

Recommendation 0.1: Hct or Hgb should be obtained in women with a history of significant anemia.^A

^AAll hCG values used in this document are based on the Third International Standard (originally referred to as the First International Reference Preparation).

Recommendation 0.2: Vital signs (e.g. blood pressure, pulse and temperature) and physical exam should be done as indicated by medical history and patient symptoms.

OPERATIVE PROCEDURE

Standard 6: Patient comfort level during the procedure must be considered.

Recommendation 6.1: Analgesic or other comfort measures should be offered unless there are contraindications.^B

Standard 7: All instruments entering the uterine cavity must be sterile.

Option 0.01: The vagina may be cleansed with a bacteriocidal agent.

Option 0.02: Intra-operative ultrasonography can be of value to locate fetal parts and aid in their extraction, to verify an empty uterus, and to verify an intact uterus.

Recommendation 0.3: The cervix should be dilated gently and gradually.

Option 0.31: Adequate dilation may be achieved by osmotic dilators or misoprostol.

Option 0.32: At very early gestational age, cervical dilation may be facilitated by delaying the procedure.

POST-OPERATIVE PROCEDURE

Standard 8: Completion of the procedure must be verified and documented.^C

Standard 9: Rh immune globulin must be offered per Rh policy guidelines.^D

Standard 10: Clinical Policy Guidelines for Post-Operative Care must be followed.^E

References:

1. Stovall, TG, Ling, FW, Buster, JE. Nonsurgical diagnosis and treatment of tubal pregnancy. *Fertility and Sterility* 1990;54: 537-538. Algorithm adapted by the University of Tennessee Medical Center and reproduced in Paul, M, *et al.* (Eds.), *A Clinician's Guide to Medical and Surgical Abortion*. Philadelphia: Churchill Livingstone, 1999:163.
2. Speroff L, Fritz MA (2005). Ectopic pregnancy. In *Clinical Gynecologic Endocrinology and Infertility*, 7th ed., pp. 1275–1302. Philadelphia: Lippincott Williams and Wilkins.
3. Gracia CR, Barnhart KT. Diagnosing ectopic pregnancy: decision analysis comparing six strategies. *Obstet Gynecol.* 2001 Mar; 97(3):464-70.

rev. December 2008

^A By establishing a balance sheet of risks, costs and outcomes, it was discovered that a pre-operative 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.

^B See *Clinical Policy Guidelines* on Anesthesia.

^C See *Clinical Policy Guidelines* on Evaluation of Evacuated Uterine Contents.

^D See *Clinical Policy Guidelines* on Rh Testing and Rh Immune Globulin Administration.

^E See *Clinical Policy Guidelines* on Post-Operative Care.

SECOND TRIMESTER ABORTION BY D&E

Policy Statement: Second trimester^A 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. As gestational age increases, complications and risks increase.

PRE-OPERATIVE PROCEDURES

Standard 1: Pertinent medical history must be obtained and documented.

Recommendation 0.1: A patient with a suspected or actual placenta previa and prior uterine scarring may be evaluated for placenta previa.²

Recommendation 0.2: Physical examination should be done as indicated by medical history and patient symptoms.

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 LMP.

Recommendation 0.3: A preoperative Hgb or Hct should be done.

OPERATIVE PROCEDURE

Standard 3: Patient comfort level during the abortion procedure must be considered.

Recommendation 3.1: Analgesic or other comfort measures should be offered unless there are contraindications.^B

Standard 4: Appropriate dilation of the cervix must be obtained.

Recommendation 4.1: Dilation should be achieved gently and gradually.

Recommendation 4.2: Osmotic dilators and/or misoprostol should be used to facilitate adequate dilation.

Standard 5: When osmotic dilators, misoprostol, and/or other cervical ripening agents are used, a physician must be available for emergency care prior to the scheduled procedure.

Option 0.01: In later second trimester abortions, intra-amniotic or intra-fetal injection may be given to cause fetal demise in utero. (See *Discussion*).

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

Recommendation 0.4: Uterotonics should be available to aid in control of uterine bleeding.

^A 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)

^B See Clinical Policy Guidelines on Anesthesia.

Option 0.02: Vasopressin may be used intracervically or paracervically to reduce blood loss.^{3, 7, 9-11}

Option 0.03: Intra-operative ultrasonography can be of value to locate fetal parts and aid in their extraction, to verify an empty uterus, and to verify an intact uterus.

Recommendation 0.5: IV access may be established prior to evacuation.

POST-OPERATIVE PROCEDURE

Standard 7: Completion of the procedure must be verified and documented by the operator.^A

Standard 8: Clinical Policy Guidelines for Post-Operative Care must be followed.^B

Option 0.04: 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 is now the predominant second trimester procedure.

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

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 second trimester abortion procedures. Although the law does not require the use of fetocidal injections, some providers may choose to use fetocidal injections in order to avoid violating the law. 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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^A See Clinical Policy Guidelines on Evaluation of Evacuated Uterine Contents.

^B See Clinical Policy Guidelines on Post-Operative Care.

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SECOND TRIMESTER ABORTION BY MEDICAL INDUCTION

Policy Statement: Medical induction is a safe and effective method for termination of pregnancies beyond the first trimester^A in appropriate clinical settings by trained clinicians. As gestational age increases, complications and risks increase.

Standard 1: Personnel capable of surgical management and the necessary equipment, including a clinician who can perform a timely curettage for retained placenta or bleeding, must be available until post-abortion discharge. The NAF *Clinical Policy Guidelines for Second Trimester Abortion by D&E* (pp.15-18 of this document) will be relevant when surgical intervention is indicated.

Standard 2: A clinician must be available for emergency care from initiation of cervical pretreatment until post-abortion discharge.

Standard 3: Pertinent medical history must be obtained and documented.

Recommendation 0.1: Physical examination should be done as indicated by medical history and patient symptoms.

Standard 4: 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.

Recommendation 0.2: A patient with a suspected or actual placenta previa and prior uterine scarring should be evaluated for other placental abnormalities.⁴

Recommendation 0.3: A pre-abortion Hgb or Hct should be done.

Standard 5: Patient comfort level during the abortion procedure must be considered.

Recommendation 5.1: Analgesic or other comfort measures should be offered unless there are contraindications.^B

Option 0.02: Pretreatment with mifepristone 24-48h prior to misoprostol has been shown to reduce the induction-to-abortion interval. (See *Discussion*).

Option 0.03: 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.

Standard 6: Patients must be advised that administration of prostaglandins for priming or induction may precipitate rapid onset of uterine contractions and expulsion.

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

^B See *Clinical Policy Guidelines* on Anesthesia.

Standard 7: 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 delivery and recognition of related complications.

Standard 8: Once regular contractions have been confirmed, patients must be observed by a health care worker trained to monitor contractions and expulsion.

Recommendation 0.4: IV access should be established prior to expulsion.

Standard 9: Completion of the procedure must be verified and documented by the operator.^C

Recommendation 0.5: Uterotonics should be available to aid in control of uterine bleeding.

Standard 10: Clinical Policy Guidelines for Post-Operative Care must be followed.

Option 0.04: Uterotonic agents may be prescribed at discharge.

Standard 11: Patients suspected of having any type of post-abortion complication must be evaluated by a trained clinician.

Discussion: Osmotic or mechanical dilators, prostaglandins, and/or mifepristone have been used to achieve cervical preparation for induction and expulsion. Current data support use of the following regimens:

200 mg oral mifepristone, followed 36-48 hours later by 600-800µg vaginal misoprostol. Thereafter, 400 µg oral or vaginal misoprostol may be utilized every three hours to a maximum of five doses.^{1, 7, 10}

Good evidence also supports use of 400 µg vaginal misoprostol every six hours until delivery.⁵

Rates of retained placenta related to medical induction abortion have been reported to occur at widely varying rates (between 13-15%). Uterotonics or surgical intervention may be necessary to complete the procedure.

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 women with scarred uteri 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 accrete.⁴

In light of the relevant medical and legal context in which the abortion takes place, the use of intra-fetal and intra-amniotic injection to cause fetal demise in utero may be beneficial in later second trimester procedures. In addition to the references below, NAF Members may link 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.

^C See *Clinical Policy Guidelines* on Evaluation of Evacuated Uterine Contents.

References:

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ANESTHESIA

Policy Statement: The use of anesthesia, analgesia or anxiolysis should be used to provide comfort during abortion procedures for any patient in which the benefits outweigh the risks.

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, this almost always signifies paracervical block.
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, and ventilatory and cardiovascular functions are unaffected. †
3. Moderate Sedation/Analgesia (“Conscious Sedation”) - 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.
* Monitored Anesthesia Care does not describe the continuum of depth of sedation, rather it describes “a specific anesthesia service in which an anesthesiologist has been requested to participate in the care of a patient undergoing a diagnostic or therapeutic procedure.”
** Reflex withdrawal from a painful stimulus is NOT considered a purposeful response. †
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. †
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 a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (“Conscious Sedation”) should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

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

*** Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner 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. It is not appropriate to continue the procedure at an unintended level of sedation. †

† “ Excerpted from **Contiuum of Depth Sedation: Definition of General Anesthesia and levels of Sedation Anesthesia, 2009** of the American Society of Anesthesiologists. A copy of the the full text can be obtained from ASA, 520 N. Northwest Highway, Park Ridge, Illinois, 60068-2573”

PERSONNEL AND MONITORING

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 of this education should include precautions relevant to transient mental impairment.

Standard 2: When minimal, moderate, deep sedation or general anesthesia are used, monitoring of the patient's level of consciousness must be documented.

Standard 3: When local anesthesia, minimal, moderate, deep sedation or general anesthesia is used, the practitioner responsible for the treatment of the patient and/or the administration of drugs for sedation must be appropriately trained.

Standard 4: When moderate sedation is used, a person other than the clinician, trained to monitor appropriate physiological parameters, must be present.

Recommendation 4.1: During moderate sedation the patient should be checked frequently for verbal responses.

Standard 5: The personnel administering moderate sedation must recognize that moderate sedation may lead to deep sedation with hypoventilation and be prepared to provide respiratory support.^A

Standard 6: The supervising practitioner must be immediately available when moderate sedation is administered.

Standard 7: When moderate sedation is used, monitoring must be of a degree which can be expected to detect the respiratory, cardiovascular, and neurological effects of the drugs being used.

Recommendation 7.01: Pulse oximetry should be used to enhance this monitoring.

Recommendation 0.1: During moderate sedation or local anesthesia, IV access should be maintained for patients in ASA P-3, P-4, and P-5. (See *page 28 of this document*).

Recommendation 0.2: When moderate sedation is used, IV access should be maintained.

Standard 8: The practitioner administering deep sedation or general anesthesia must be certified according to applicable regulations.

Standard 9: The practitioner administering deep sedation or general anesthesia must not be the practitioner performing the abortion.

Standard 10: For deep sedation and general anesthesia, the patient's oxygenation, ventilation and circulation must be continually evaluated as prescribed in the ASA Standards for Basic Anesthetic Monitoring. (See *pages 29–31 of this document*).

Recommendation 10.1: Temperature monitoring equipment should be available

^A See *Clinical Policy Guidelines* on Emergency Procedures.

Standard 11: When deep sedation or general anesthesia is used, IV access must be maintained according to ASA guidelines.

Standard 12: The use of N2O/O2 must be self-administered by the patient.

Standard 13: The use of N2O/O2 must follow guidelines for at least moderate sedation.

Standard 14: 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.;
- c) be outfitted with an O2 analyzer;
- d) be checked and calibrated regularly.

FACILITIES AND EQUIPMENT: See Emergency Procedures guideline.

Discussion: ON THE USE OF ANESTHESIA IN GENERAL - All medications used in anesthesia 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 delivered primarily in hospital settings and to patients varying widely in age and general health.

The promulgation of guidelines for the delivery and monitoring of anesthesia care issued by organizations such as the American Society of Anesthesiologists (ASA), the American Dental Society of Anesthesiologists (ADSA), American Society of Gastrointestinal Endoscopists and others have clarified many of the issues related to anesthesia care. Whether it be local anesthesia, intravenous sedation, or general inhalation analgesia/anesthesia, it is the degree of CNS depression rather than any type of modality *per se* that is the basis for establishment of NAF guidelines. Levels of sedation are not completely distinct, but merge one with the next - each level of deeper sedation requires an increased level of care and monitoring. These levels of sedation are defined elsewhere.

NAF guidelines specifically address the use of conventional anesthesia. 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, however, is on the monitoring necessary for the safe and effective use of pharmacologic methods generally used in outpatient abortion facilities.

ON THE USE OF PULSE OXIMETRY - There have been no trials on 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 - 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. The use of an oxygen analyzer allows the practitioner to monitor the concentration of inspired oxygen and is essential to the safe provision of nitrous oxide anesthesia. 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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ANESTHESIA

American Society of Anesthesiologists

CONTINUUM OF DEPTHS OF SEDATION: DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA^A

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)

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

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

^A “Excerpted from *Continuum of Depth of Sedation, Definitions of General Anesthesia and Levels of Sedation/Analgesia*. 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.”

ANESTHESIA

American Society of Anesthesiologists

Physical Status Definition^A

To avoid confusion as to the basis upon which the Department of Anesthesiology classifies physical status in operative patients, the following represents the official American Society of Anesthesiologists classification.

CLASSIFICATION OF PHYSICAL STATUS

P-1 - A normal health 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.

^A *ASA Relative Value Guide*. 2009. Reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

ANESTHESIA

American Society of Anesthesiologists

Standards for Basic Anesthetic Monitoring^A

(Approved by the ASA House of Delegates October 21, 1986, and
last amended on October 25, 2005)

These standards apply to all anesthesia care although, in emergency circumstances, appropriate life support measures take precedence. These standards may be exceeded at any time based on the judgment of the responsible anesthesiologist. They are intended to encourage quality patient care, but observing them cannot guarantee any specific patient outcome. They are subject to revision from time to time, as warranted by the evolution of technology and practice. They apply to all general anesthetics, regional anesthetics and monitored anesthesia care. This set of standards addresses only the issue of basic anesthetic monitoring, which is one component of anesthesia care. In certain rare or unusual circumstances, 1) some of these methods of monitoring may be clinically impractical, and 2) appropriate use of the described monitoring methods may fail to detect untoward clinical developments. Brief interruptions of continual monitoring may be unavoidable. *Under extenuating circumstances, the responsible anesthesiologist may waive the requirements marked with an asterisk (*); it is recommended that when this is done, it should be so stated (including the reasons) in a note in the patient's medical record.* These standards are not intended for application to the care of the obstetrical patient in labor or in the conduct of pain management.

†Note that “continual” is defined as “repeated regularly and frequently in steady rapid succession” whereas “continuous” means “prolonged without any interruption at any time.”

STANDARD I: Qualified anesthesia personnel shall be present in the room throughout the conduct of all general anesthetics, regional anesthetics and monitored anesthesia care.

OBJECTIVE: Because of the rapid changes in patient status during anesthesia, qualified anesthesia personnel shall be continuously present to monitor the patient and provide anesthesia care. In the event there is a direct known hazard, e.g., radiation, to the anesthesia personnel which might require intermittent remote observation of the patient, some provision for monitoring the patient must be made. In the event that an emergency requires the temporary absence of the person primarily responsible for the anesthetic, the best judgment of the anesthesiologist will be exercised in comparing the emergency with the anesthetized patient's condition and in the selection of the person left responsible for the anesthetic during the temporary absence.

STANDARD II: During all anesthetics, the patient's oxygenation, ventilation, circulation and temperature shall be continually evaluated.

OXYGENATION

OBJECTIVE: To ensure adequate oxygen concentration in the inspired gas and the blood during all anesthetics.

METHODS:

^A *Standards for Basic Anesthetic Monitoring*, 2005. Reprinted with permission of the American Society of Anesthesiologists, 520 N. Northwest Highway, Park Ridge, Illinois 60068-2573.

- 1) Inspired gas: During every administration of general anesthesia using an anesthesia machine, the concentration of oxygen in the patient breathing system shall be measured by an oxygen analyzer with a low oxygen concentration limit alarm in use.*
- 2) Blood oxygenation: During all anesthetics, a quantitative method of assessing oxygenation such as pulse oximetry shall be employed.* When the pulse oximeter is utilized, the variable pitch tones and the low threshold alarm shall be audible to the anesthesiologist or the anesthesia care team personnel. Adequate illumination and exposure of the patient is necessary to assess color.*

VENTILATION

OBJECTIVE: To ensure adequate ventilation of the patient during all anesthetics.

METHODS:

- 1) Every patient receiving general anesthesia shall have the adequacy of ventilation continually evaluated. Qualitative clinical signs such as chest excursion, observation of the reservoir breathing bag and auscultation of breath sounds are useful. Continual monitoring for the presence of expired carbon dioxide shall be performed unless invalidated by the nature of the patient, procedure or equipment. Quantitative monitoring of the volume of expired gas is strongly encouraged.*
- 2) When an endotracheal tube or laryngeal mask is inserted, its correct positioning must be verified by clinical assessment and by identification of carbon dioxide in the expired gas. Continual end-tidal carbon dioxide analysis, in use from the time of endotracheal tube/laryngeal mask placement, until extubation/removal or initiating transfer to a post-operative care location, shall be performed using a quantitative method such as capnography, capnometry or mass spectroscopy.* When capnography or capnometry is utilized the end tidal CO₂ alarm shall be audible to the anesthesiologist or the anesthesia team personnel.*
- 3) When ventilation is controlled by a mechanical ventilator, there shall be in continuous use a device that is capable of detecting disconnection of components of the breathing system. The device must give an audible signal when its alarm threshold is exceeded.
- 4) During regional anesthesia and monitored anesthesia care, the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs/ and or monitoring for the presence of exhaled carbon dioxide.

CIRCULATION

OBJECTIVE: To ensure the adequacy of the patient's circulatory function during all anesthetics.

METHODS:

- 1) Every patient receiving anesthesia shall have the electrocardiogram continuously displayed from the beginning of anesthesia until preparing to leave the anesthetizing location.*
- 2) Every patient receiving anesthesia shall have arterial blood pressure and heart rate determined and evaluated at least every five minutes.*
- 3) Every patient receiving general anesthesia shall have, in addition to the above, circulatory function continually evaluated by at least one of the following: palpation of a pulse, auscultation of heart sounds, monitoring of a tracing of intra-arterial pressure, ultrasound peripheral pulse monitoring, or pulse plethysmography or oximetry.

BODY TEMPERATURE

OBJECTIVE: To aid in the maintenance of appropriate body temperature during all anesthetics.

METHODS: Every patient receiving anesthesia shall have temperature monitored when clinically significant changes in body temperature are intended, anticipated or suspected.

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 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.^A

Recommendation 0.3: For documented infections of the reproductive tract, CDC guidelines should be followed.³

Option 0.02: Antibiotics may be initiated at the time of insertion of osmotic dilators.

Option 0.03: Patients with non-cardiac prostheses may be given peri-operative antibiotics.^B

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.⁵

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^A 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;
- e. history of pelvic inflammatory disease.

^B "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/immunosuppressed patients, 3. Patients with comorbidities (previous joint infections, malnourishment, hemophilia, HIV infected, Insulin-dependent type-1 diabetes, malignancy)] of experiencing hematogenous total joint infections."¹

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8. Larsson, PG, *et al.* Incidence of pelvic inflammatory disease after first-trimester legal abortion in women with bacterial vaginosis after treatment with metronidazole: A double-blind randomized study. *Am. J. Obstet. Gynecol.* 1992, 166:100.
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15. Sawaya, GF & Grimes, DA. Preventing postabortal infection. *Contemp. Obstet. Gynecol.*, 1994, 15:53.

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PRE-OPERATIVE ENDOCARDITIS PROPHYLAXIS AT THE TIME OF SURGICAL ABORTION

Policy Statement: Endocarditis is a potential risk of surgical procedures.

Standard 1: The AHA no longer recommends that patients with mitral valve prolapse *with or without a murmur* be given antibiotics prior to the procedure.

Option 0.01: Patients with a prosthetic heart valve, previous bacterial endocarditis or surgically repaired congenital heart defect with prosthetic material or device are at increased risk of bacterial endocarditis and may be given pre-operative prophylactic antibiotics on the recommendation of their cardiologist or primary care provider.

Discussion: In 2007 the AHA revised its endocarditis prophylaxis recommendations. The statements below are quotations from those recommendations.

“Antibiotic prophylaxis solely to prevent infective endocarditis is not recommended for GU or GI tract procedures, including diagnostic esophagogastroduodenoscopy or colonoscopy (Class III, LOE B). This is in contrast to previous AHA guidelines that listed GI or GU tract procedures for which IE prophylaxis was recommended and those for which prophylaxis was not recommended.”

“The cases of IE temporally associated with a GI or GU tract procedure are anecdotal, with either a single or very small number of cases reported. No published data demonstrate a conclusive link between procedures of the GI or GU tract and the development of IE. Moreover, no studies exist that demonstrate that the administration of antimicrobial prophylaxis prevents IE in association with procedures performed on the GI or GU tract.”

“Patients with infections of the GI or GU tract may have intermittent or sustained enterococcal bacteremia. For patients with the conditions listed in Table 3 (1. Prosthetic cardiac valve or prosthetic material used for cardiac valve repair, 2. Previous IE, 3. Completely repaired congenital heart defect with prosthetic material or device, whether placed by surgery or by catheter intervention, during the first 6 months after the procedure, 4. Cardiac transplantation recipients who develop cardiac valvulopathy) who have an established GI or GU tract infection or for those who receive antibiotic therapy to prevent wound infection or sepsis associated with a GI or GU tract procedure, it may be reasonable that the antibiotic regimen include an agent active against enterococci, such as penicillin, ampicillin, piperacillin, or vancomycin (Class IIb, LOE B); however, no published studies demonstrate that such therapy would prevent enterococcal IE.”

References:

1. Wilson, W, *et al.* Prevention of infective endocarditis: guidelines from the American Heart Association: a guideline from the American Heart Association Rheumatic Fever, Endocarditis, and Kawasaki Disease Committee, Council on Cardiovascular Disease in the Young, and the Council on Clinical Cardiology, Council on Cardiovascular Surgery and Anesthesia, and the Quality of Care and Outcomes Research Interdisciplinary Working Group., *Circulation*, 2007, 116:1736-1754, p.1748-1749.

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-OPERATIVE BLEEDING

Recommendation 0.1: An ectopic pregnancy or spontaneous abortion should be considered.

PERI-OPERATIVE BLEEDING

Standard 1: 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.^A

Option 1.21: Ultrasonography may be useful to determine whether the uterus is empty and to detect occult bleeding.

Option 1.22: 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 1.23: When atony is suspected, uterine massage and uterotonics^B may be useful.

Option 1.24: When coagulopathy is suspected, blood may be drawn for coagulation parameters and transfusion of blood or blood products may be necessary.

Recommendation 0.2: 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;
- e) prepare for transfer to a hospital facility if necessary.^C

Standard 2: 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.^C

^A See *Clinical Policy Guidelines* on Complications: Perforation

^B methergine (intracervical or IM); oxytocin (intracervical, IM, or IV); prostaglandins (e.g. Prostin, intracervical or IM)

^C See *Clinical Policy Guidelines* on Emergency Procedures

DELAYED BLEEDING

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

Discussion: Excessive bleeding in the peri-operative and in the post-operative 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, 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);
- d) none of the above.

Postoperatively, the following measures may be used for treatment of postabortion 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);
- 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.^E

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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^D Saturation of more than one pad per hour for more than three hours.

^E See *Clinical Policy Guidelines on Complications: Perforation*.

COMPLICATIONS: PERFORATION

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

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.

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.

Option 2.04: 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.

Recommendation 2.1: If a perforation occurs and *the pregnancy has been disrupted*, the abortion should be completed as soon as feasible.

Option 2.05: The uterine evacuation may be completed under direct ultrasonography.

Option 2.06: The abortion may be completed under laparoscopic visualization.

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.

Standard 4: 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:

- 1) marked uterine anteversion or retroversion;
- 2) cervical internal os stenosis requiring more force to dilate;
- 3) uterine abnormalities;

4) difficult and prolonged uterine evacuation.

Uterine perforation is likely if:

- 1) an instrument extends without resistance further into the uterine cavity than expected;
- 2) the patient experiences more than the expected amount of pain during the procedure;
- 3) the patient experiences inordinate and persistent pain in the immediate recovery period.

Several factors may help prevent perforations:

- 1) accurate assessment of gestational age;
- 2) accurate assessment of uterine position;
- 3) straightening the axis of the uterus; and
- 4) cervical preparation beyond the first trimester;^A

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.
3. Elchalal, *et al.* Ultrasound-directed diagnosis and treatment of pelvic hematoma after therapeutic abortion. *J Clin.Ultrasound*, 1993, 21:55.
4. Freiman, SM & Wulff, GJ Jr. Management of uterine perforation following elective abortion. *J Obstet.Gyn.*, 1977, 50:647.
5. Kaali, SG, *et al.* The frequency and management of uterine perforations during first-trimester abortions. *Am.J.Obstet.Gyn.*, 1989, 161:406.
6. Lajinian, S, *et al.* Sonographic appearance of suspected iatrogenic uterine perforation. *J Reprod.Med.*, 1994, 39:911.
7. Lauersen, NH & Birnbaum, S. Laparoscopy as a diagnostic and therapeutic technique in uterine perforations during first-trimester abortions. *Am.J Obstet.Gyn.*, 1973, 117:522.
8. White, MK, *et al.* A case-control study of uterine perforations documented at laparoscopy. *Am.J.Obstet.Gyn.*, 1977, 129:623.

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^A See *Clinical Policy Guidelines Second Trimester Abortion* by D&E.

POST-OPERATIVE CARE

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

Standard 1: Completion of the abortion must be verified and documented.^A

Standard 2: Rh immune globulin must be offered in accordance with Rh guidelines.^B

Standard 3: All patients must be observed during the recovery period by a health care worker trained in post-operative care.

Standard 4: A clinician must remain in the facility until all patients are medically stable.^C

Standard 5: 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 6: The patient must be given instructions outlining the signs and symptoms of post-anesthesia effects and post-operative complications.

Recommendation 6.1: Written instructions should be given to all patients.

Standard 7: The facility must provide an emergency contact service on a 24-hour basis where calls are triaged in accordance with applicable regulations. The facility must assure physician referral if indicated.

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^A See Clinical Policy Guidelines on Evaluation of Evacuated Uterine Contents.

^B See Clinical Policy Guidelines on Rh Testing and Rh Immune Globulin Administration.

^C 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.

Standard 1: Completion of abortion must be confirmed prior to the woman leaving the facility.

- A. When a fetal pole is not seen with pre-procedure ultrasound, evacuated uterine contents must be examined before the woman leaves the facility.
- B. In other cases either tissue exam or ultrasound must be used to confirm evacuation.

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 1.01: Pathological examination of evacuated uterine contents is not required.

Standard 2: 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.^A

Standard 3: If insufficient tissue is present after adequate patient evaluation, a protocol to rule out ectopic pregnancy must be followed, 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.

Standard 4: 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.¹

Recommendation 4.2: 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.

^A Sensitive urine pregnancy test is positive at 25 MIU of β -hCG.

Standard 5: 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. Crenin, MD. Change in serum beta-human chorionic gonadotropin after abortion with methotrexate and misoprostol. *Am J Obstet Gyn.*, 1996 Feb; 174(2):776-8.

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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.

Standard 1: All surgically removed tissue must be considered biohazardous and be handled, stored and disposed of in accordance with applicable local, state, and federal regulations. A proper protocol for tissue handling, storage and disposal must be in place.

Standard 2: Adequate engineering and work practice controls for handling potentially infectious materials must be observed.^A

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^A 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

Policy Statement: Optimal management of abortion emergencies reduces morbidity.

Standard 1: Functioning equipment and current medications must be available on site to handle medical emergencies and must include: an oxygen delivery system, oral airways, uterotonics, and epinephrine.

Recommendation 1.1: Facilities should have a specified area for emergency equipment to include oxygen, medications, and supplies.

Recommendation 1.2: Protocols should be in place to ensure ongoing training of staff in the use of emergency equipment, the management of emergencies and the indications for emergency transport.

Recommendation 1.3: Medications should include IV crystalloids, and, in clinics using IV sedation, appropriate antagonists.

Recommendation 1.4: Clinics should consider developing an inter-site transfer agreement with a hospital outlining the means of communication and transport, and the protocol for emergent transfer of care.

Standard 2: When abortion procedures are being performed, a current CPR-certified staff member must be available on-site for emergency care.

Recommendation 2.1: All medical staff should have current CPR certification.

Option 0.1: The following supplies may be used:

<u>Type of Emergency</u>	<u>Prevention, Treatment</u>
1. Anaphylaxis	Corticosteroids, epinephrine
2. Allergic reactions	Diphenhydramine (Benadryl), epinephrine, albuterol inhalers
3. Respiratory arrest	Oxygen, suction, ambu bag, airways
4. Hemorrhage, shock	IV crystalloid (normal saline or Ringers Lactate), uterotonics, compression balloon (Bakri or Foley)
5. Cardiac arrest	CPR, AED
6. Seizure	Diazepam (Valium), midazolam (Versed)
7. Respiratory depression	Pulseoximeter, oxygen

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