## 2020

## CLINICAL POLICY GUIDELINES FOR ABORTION CARE



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NATIONAL ABORTION FEDERATION



# 2020 Clinical Policy Guidelines for Abortion Care

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The National Abortion Federation is the professional association of abortion providers. Our mission is to unite, represent, serve, and support abortion providers in delivering patient-centered, evidence-based care.

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#### INTRODUCTION

The National Abortion Federation's (NAF) mission is to unite, represent, serve, and support abortion providers in delivering patient-centered, evidence-based care. 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.(1) NAF's programs make it possible for women to obtain the highest quality abortion care.

Like its precursors, the 2020 edition of NAF's *Clinical Policy Guidelines for Abortion Care* (CPGs) serve to provide guidance for facilities to use in establishing their clinical policies. The CPGs are developed by consensus, based on rigorous review of the relevant medical literature and patient outcomes.(2-6) These guidelines are intended to provide parameters to ensure that patients have access to the highest quality abortion care.

NAF's *Clinical Policy Guidelines* were first published in 1996 and have been revised annually since then. Since inception, they have been based on the methodology described by David Eddy, MD, in *A Manual for Assessing Health Practices and Designing Practice Policies: The Explicit Approach*.(7) 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. Since 2018, we have incorporated the Institute of Medicine's recommendations.(8)

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 policies according to their intended flexibility: standards, recommendations, and options:

- 1) **STANDARDS** are intended to be applied in virtually all cases. Deviations will be rare and difficult to justify.
- 2) RECOMMENDATIONS are steering in nature. They do not have the force of standards, but when not adhered to, there should be documented, rational clinical justification. They allow some latitude in clinical management.
- 3) **OPTIONS** are neutral with respect to a treatment choice. They merely note that different interventions are available, and that different people make different choices. They may contribute to the educational process, and they require no justification.

NAF's *Clinical Policy Guidelines for Abortion Care* include a list of references for each section and include discussion material for clarification when appropriate. These guidelines are meant to be living documents, subject to revision as new medical evidence becomes available.

Medline was searched monthly on Pubmed. An automated search using the following terms was created and checked monthly:

((((abortion induced [MeSH Major Topic]) OR mifepristone) OR medical abortion) OR (dilation and evacuation)) OR uterine aspiration.

The search was limited to clinical trials, case reports, comparative studies, reviews, meta-analysis, systematic review, and guidelines in humans from January 1, 2018. The search run on December 12, 2019, yielded 374 results. In addition, abstracts from major conferences, references in articles, and related non-abortion searches (for example, in analgesia and sedation) were run.

Studies were included that addressed CPG topics and either changed, updated, or substantially added support to a current recommendation. Studies were excluded that were not relevant, had poor methodology or inconclusive results, or did not substantially add to a current recommendation.

Eighteen new studies were included in the 2020 CPGs because they changed one or more statements or substantially improved the level of evidence supporting a current statement. Changes to each policy statement were drafted by NAF's Medical Director, Alice Mark, MD, MSc, based on the included papers. These papers were reviewed by the NAF Clinical Policy Committee and changes to each policy statement were edited and approved by the entire committee. A synthesis of how the new study altered the existing policy statement will be available in an online module.

#### NAF 2019 Clinical Policy Committee members:

Sarah Prager, MD, MAS; Chair Sue Carlisle, MD, PhD Lorie Chaiten, JD Vicki Cowart Angel M. Foster, DPhil, MD, AM Melissa Grant Daniel Grossman, MD Suzanne Morris, MD Lisa Perriera, MD, MPH Rolanda Ryan, RN, MHSA Ann Schutt-Ainé, MD Elizabeth Talmont, MSN, NP Cristina Villarreal Velásquez Katie Watson, JD Beverly Winikoff, MD, MPH

In 2020, the term "medical abortion" was replaced with "medication abortion" to reflect the fact that all abortions, whether aspiration abortion, dilation and evacuation, or medication abortion are medical procedures, and the term "medication abortion" more accurately reflects the process of taking medications to induce abortion.(9)

Note: The *Clinical Policy Guidelines for Abortion Care* 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 law 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.

- 1. Field M, Lohr KE. Guidelines for Clinical Practice: From Development to Use. Washington, DC: National Academy Press; 1992.
- 2. Eddy D. Clinical decision making: from theory to practice. Designing a practice policy. Standards, guidelines, and options. JAMA. 1990;263(22):3077, 3081, 3084. (http://www.ncbi.nlm.nih.gov/pubmed/2342221)
- 3. Hadorn DC, McCormick K, Diokno A. An annotated algorithm approach to clinical guideline development. JAMA. 1992;267(24):3311-4. (https://www.ncbi.nlm.nih.gov/pubmed/1597913)
- Woolf SH. Practice guidelines: a new reality in medicine. II. Methods of developing guidelines. Arch Intern Med. 1992;152(5):946-52. (http://www.ncbi.nlm.nih.gov/pubmed/1580720)
- 5. Walker RD, Howard MO, Lambert MD, Suchinsky R. Medical practice guidelines. West J Med. 1994;161(1):39-44. (https://www.ncbi.nlm.nih.gov/pubmed/7941505)
- 6. James B. Implementing practice guidelines through clinical quality improvement. Front Health Serv Manage. 1993;10(1):3-37; discussion 54-6. (<a href="http://www.ncbi.nlm.nih.gov/pubmed/10127902">http://www.ncbi.nlm.nih.gov/pubmed/10127902</a>)
- 7. Eddy D. A Manual for Assessing Health Practice and Designing Practice Policies: The Explicit Approach. Philadelphia: American College of Physicians; 1992.
- 8. Graham R, Mancher M, Wolman DM, Greenfield S, Steinberg E, Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. Clinical practice guidelines we can trust. Washington, DC: Institute of Medicine, 2011. (http://nap.edu/13058)
- 9. Weitz TA, Foster A, Ellertson C, Grossman D, Stewart FH. "Medical" and "surgical" abortion: rethinking the modifiers. Contraception. 2004;69(1):77-8. (<a href="http://dx.doi.org/10.1016/j.contraception.2003.08.017">http://dx.doi.org/10.1016/j.contraception.2003.08.017</a>)

#### **Notes on Formatting**

As presented here, standards, recommendations, and options are hierarchical in nature. It is therefore expected that clinical practices will favor the highest level of guidance available on a given point. 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 section, <u>Standards</u> are numbered consecutively starting with the section number with the standard to the right of a decimal. For example, the first standard in Section 1 will be Standard 1.1.

Recommendations are also numbered consecutively within each main subject heading, with numbers that are placed to the right of a second decimal point. Where a recommendation follows 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 1.1.1). 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 1.0.1).

The consecutive numbers denoting <u>Options</u> within each main subject heading are placed to the right of the third decimal point. Where an option follows a preceding standard or recommendation, it is indented below that standard or recommendation and the numbers identifying that option will be found to the right of a third decimal point added to the end of the standard or recommendation (e.g., Option 1.1.0.1 or Option 1.1.1.1). Where the option stands alone and is not related to a specific standard or recommendation, it is not indented in its placement on the page, and zeros will be placed in the position for the standard and recommendation (e.g., Option 1.0.0.1).

#### 1. WHO CAN PROVIDE ABORTIONS

**Policy Statement:** Abortion is a safe procedure when provided by qualified practitioners.(1) The vast majority of abortions, including uterine aspiration, dilation and evacuation, and medication abortion after the first trimester, can be safely provided in medical offices or freestanding clinics.(2) Telemedicine can be safely used in abortion care, including medication abortion and informed consent.(3, 4)

- <u>Standard 1.1.</u> Abortion will be provided by licensed\* practitioners. This category is intended to include physicians from various specialties as well as nurse midwives, nurse practitioners, physician assistants, registered nurses, and other health professionals.(5)
  - Recommendation 1.1.1. Documentation specifying privileges in accordance with each practitioner's scope of practice should be maintained.
  - Recommendation 1.1.2. Hospital admitting privileges are not needed to provide safe abortion care.(2, 6)
- Standard 1.2. All practitioners providing abortions must have received training to competency in abortion care, including the prevention, recognition, and management of complications.
- Standard 1.3. All staff members providing patient services must have appropriate training, for example, in ultrasound, counseling, sedation, laboratory, infection control, and other patient-related services.
- Standard 1.4. Appropriate referrals must be available for patients who cannot be cared for by a practitioner at your facility.<sup>†</sup>

- 1. Zane S, Creanga AA, Berg CJ, Pazol K, Suchdev DB, Jamieson DJ, et al. Abortion-related mortality in the united states: 1998–2010. Obstet Gynecol. 2015;126(2):258-65. (http://dx.doi.org/10.1097/aog.00000000000000045)
- 2. Roberts SCM, Upadhyay UD, Liu G, Kerns JL, Ba D, Beam N, et al. Association of facility type with procedural-related morbidities and adverse events among patients

<sup>\*</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, Mexico, and Colombia.

<sup>†</sup>This may include the NAF Referral Line.

- undergoing induced abortions. JAMA. 2018;319(24):2497-506. (http://dx.doi.org/10.1001/jama.2018.7675)
- 3. Fok WK, Mark A. Abortion through telemedicine. Curr Opin Obstet Gynecol. 2018;30(6):394-9. (http://dx.doi.org/10.1097/GCO.0000000000000498)
- Grossman D, Grindlay K. Safety of medical abortion provided through telemedicine compared with in person. Obstet Gynecol. 2017;130(4):778-82. (http://dx.doi.org/10.1097/AOG.0000000000002212)
- 5. Weitz TA, Taylor D, Desai S, Upadhyay UD, Waldman J, Battistelli MF, et al. Safety of aspiration abortion performed by nurse practitioners, certified nurse midwives, and physician assistants under a california legal waiver. Am J Public Health. 2013;103(3):454-61. (http://dx.doi.org/10.2105/ajph.2012.301159)
- 6. Jatlaoui TC, Boutot ME, Mandel MG, Whiteman MK, Ti A, Petersen E, et al. Abortion Surveillance United States, 2015. MMWR Surveill Summ. 2018;67(13):1-45. (http://dx.doi.org/10.15585/mmwr.ss6713a1)

#### 2. Patient Education, Counseling, And Informed Consent

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

#### **Informed Consent**

### Standard 2.1.

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

Option 2.1.0.1. Information may be provided either on an individual basis or in group sessions.

#### Standard 2.2.

Documentation must show that the patient affirms that she understands the abortion process and its alternatives, the potential risks and benefits, and that her decision is voluntary. Although other risks may be addressed, at a minimum, the following risks must be included (1-5):

- (1) Hemorrhage
- (2) Infection
- (3) Continuing pregnancy
- (4) Death.

For abortion procedures (uterine aspiration or dilation and evacuation), the additional risks must be included:

- (5) Perforation
- Damage to organs including hysterectomy.

#### **Patient Education and Counseling**

- Standard 2.3. Each patient must have a private opportunity to discuss the abortion.(6-10)
- A patient must undergo the abortion as expeditiously as possible in Standard 2.4. accordance with good medical practice.
- Standard 2.5. Information about aftercare and contraception must be available to patients at the facility.
  - Recommendation 2.5.1. The importance of contacting the facility for any concerns should be emphasized.

Recommendation 2.5.2. Evidence-based guidelines for contraceptive counseling should be followed.(11)

Standard 2.6. All reasonable precautions must be taken to ensure the patient's confidentiality.

Recommendation 2.6.1. The patient should be informed of the communication

of information to any third party.

Recommendation 2.6.2. A discussion should take place about which

individuals or agencies may receive communications regarding services. This discussion should include confidentiality implications of using insurance or

governmental health care coverage.

**Discussion:** Informed consent and abortion counseling are two different processes. The goal of informed consent is to assure that the patient's decision is voluntary and informed. Patient education and counseling includes a discussion of the feelings and concerns expressed by the patient, which may include help with decision-making and contraceptive choices, values clarification, or referral to other professionals. A referral to community services should be available if that becomes necessary or the needs of the patient are outside the scope of training of clinic staff.

Where abortion is safe and legal, the risk of death overall is less than 1 per 100,000 abortions. (4, 5, 12) Pregnancy-related deaths are significantly higher. (13, 14)

Risks of pregnancy-related death by country (14)

Country	Maternal mortality ratio*		
Canada	7		
United States	17		
Mexico	38		
Colombia	64		

<sup>\*</sup>deaths per 100,000 live births

- Achilles SL, Reeves MF. Prevention of infection after induced abortion: SFP Guideline 20102. Contraception. 2011;83(4):295-309. (<a href="http://dx.doi.org/10.1016/j.contraception.2010.11.006">http://dx.doi.org/10.1016/j.contraception.2010.11.006</a>)

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- 7. Baker A, Beresford T. Informed consent, patient education, and counseling. In: Paul M, Lichtenberg ES, Borgatta L, Grimes DA, Stubblefield PG, Creinin MD, editors. Management of Unintended and Abnormal Pregnancy: Comprehensive Abortion Care. Oxford: Wiley-Blackwell; 2009. p. 48-62.
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- Gold RB, Nash E. State abortion counseling policies and the fundamental principles of informed consent. Guttmacher Policy Review. 2007;10(4):6-13. (<a href="http://www.guttmacher.org/pubs/gpr/10/4/gpr100406.html">http://www.guttmacher.org/pubs/gpr/10/4/gpr100406.html</a>)
- 10. Baker A. Abortion and Options Counseling: A Comprehensive Reference. Granite City: Hope Clinic for Women; 1995.
- 11. Curtis KM, Tepper NK, Jatlaoui TC, Berry-Bibee E, Horton LG, Zapata LB, et al. U.S. Medical eligibility criteria for contraceptive use, 2016. MMWR. 2016;65(3):1-104. (https://www.cdc.gov/mmwr/volumes/65/rr/rr6503a1.htm)
- 12. Jatlaoui TC, Boutot ME, Mandel MG, Whiteman MK, Ti A, Petersen E, et al. Abortion surveillance United States, 2015. MMWR Surveill Summ. 2018;67(13):1-45. (http://dx.doi.org/10.15585/mmwr.ss6713a1)
- 13. Creanga AA, Syverson C, Seed K, Callaghan WM. Pregnancy-related mortality in the United States, 2011-2013. Obstet Gynecol. 2017;130(2):366-73. (http://dx.doi.org/10.1097/AOG.00000000000002114)
- 14. World Health Organization, World Bank Group, UNICEF, United Nations Population Fund. Trends in Maternal Mortality: 1990 to 2015. Geneva: 2015. (<a href="http://www.who.int/reproductivehealth/publications/monitoring/maternal-mortality-2015/en/">http://www.who.int/reproductivehealth/publications/monitoring/maternal-mortality-2015/en/</a>)

#### 3. INFECTION PREVENTION AND CONTROL

**Policy Statement:** Patients and health care personnel are at risk for exposure to blood borne pathogens and other potentially infectious material. Infectious material may be transmitted to patients when proper engineering\* and work-practice controls,† which reduce exposure, are not followed. Proper handling of chemicals and other materials needed for proper disinfection is important to prevent harm to staff. Prevention and treatment of infection will reduce post-abortion morbidity.

Standard 3.1. Proper engineering and work practice controls must be in place to reduce exposure of patient and staff to infectious agents. Clinics must protect employees and patients from being exposed to biohazardous material.(1)

Standard 3.2. Hands must be washed or disinfected before and after patient contact.(2-4)

Standard 3.3. Personal protective equipment must be provided to all staff.(1, 5-8)

Recommendation 3.3.1. New staff with potential exposure should have an initial training as part of orientation.

Recommendation 3.3.2. Periodic facility-level training should occur at least every three years.

Recommendation 3.3.3. Hepatitis B vaccine should be provided at no cost to the staff.

Standard 3.4. Exposure control plans must be established and followed.(5, 7, 9)

Recommendation 3.4.1. Post-exposure evaluation, prophylaxis, and follow-up should be available to exposed patients or staff for any potentially infectious agent, regardless of source.

Standard 3.5. All instruments coming into contact with patients must be properly cleaned and disinfected between patients.(10)

<u>Standard 3.6.</u> All instruments entering the uterus must be sterile.

Option 3.6.0.1. The cervix and vagina may be cleansed with a bactericidal agent though randomized trials have failed to show a benefit to this practice.(11)

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

<sup>&</sup>lt;sup>†</sup>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.

Standard 3.7. Tubing and manual uterine aspirators must be high-level disinfected or sterilized.(10) All tissue removed in the facility must be considered biohazardous Standard 3.8. and be handled, stored, and disposed of in a manner that minimizes the risk of exposure. A protocol for tissue handling, storage, and disposal must be in place. Standard 3.9. Sharps containers must be readily available. Standard 3.10. Routine antibiotic prophylaxis must be used for uterine aspiration and dilation and evacuation.(12, 13) Recommendation 3.10.1. All patients having uterine aspiration or dilation and evacuation should receive antibiotics preprocedure.(11, 14, 15) Recommendation 3.10.2. Prophylactic antibiotics should not be continued after the day of the procedure.(11, 14, 15) Antibiotics may be initiated at the time of insertion of Option 3.10.2.1. osmotic dilators. Option 3.10.2.2. Antibiotics are not required for patients choosing medication abortion.(16) Insufficient evidence exists to support routine antibiotic prophylaxis for medication abortion. Recommendation 3.10.3. Additional antibiotics are not recommended for endocarditis prophylaxis in patients with heart murmurs or other cardiac conditions.(13, 17, 18) Patients should be offered or referred for testing for Recommendation 3.10.4. chlamydia and gonorrhea according to local guidelines.(19) Testing should not delay the procedure. Empiric treatment of chlamydia may be considered for Option 3.10.4.1. patients with history, signs, or symptoms of current infection.

<u>Standard 3.11.</u> Diagnosed infection must be appropriately treated.

Recommendation 3.11.1. For documented infections of the reproductive tract, evidence-based regimens should be followed.(19)

**Discussion:** Regulatory agency policies (see references) may be helpful in developing exposure plans that protect personnel and patients from potentially infectious material. A sample exposure control plan can be found in the online learning resources at <a href="https://members.prochoice.org">https://members.prochoice.org</a>. Techniques for collection, labeling, and disposal of biohazardous material and for the processing of instruments are integral to any complete plan.

Expedited partner treatment may be considered for patients with a known diagnosis of a sexually transmitted infection.(20, 21)

- Centers for Disease Control and Prevention. Infection prevention checklist for outpatient settings: minimal expectations for safe care. 2015. (<a href="http://www.cdc.gov/hai/pdfs/guidelines/Ambulatory-Care+Checklist">http://www.cdc.gov/hai/pdfs/guidelines/Ambulatory-Care+Checklist</a> 508 11 2015.pdf)
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- 3. Centers for Disease Control and Prevention. Hand hygiene in healthcare settings [cited 2016]. Available from: <a href="http://www.cdc.gov/handhygiene/">http://www.cdc.gov/handhygiene/</a>.
- 4. World Health Organization. WHO guidelines on hand hygiene in health care. 2009. (http://apps.who.int/iris/bitstream/10665/44102/1/9789241597906\_eng.pdf)
- 5. Canadian Centre for Occupational Health and Safety. Universal precautions and routine practices. 2011. (<a href="http://www.ccohs.ca/oshanswers/prevention/universa.html">http://www.ccohs.ca/oshanswers/prevention/universa.html</a>)
- 6. Centers for Disease Control and Prevention. Bloodborne Infectious Diseases: HIV/AIDS, Hepatitis B, Hepatitis C. 2013. (www.cdc.gov/niosh/topics/bbp/)
- 7. Occupational Safety and Health Administration. Bloodborne pathogens and needlestick prevention [cited 2015]. Available from: <a href="https://www.osha.gov/SLTC/bloodbornepathogens/index.html">www.osha.gov/SLTC/bloodbornepathogens/index.html</a>.
- Ontario Hospital Association. Bloodborne diseases surveillance protocol for Ontario hospitals. 2018.
   (https://www.oha.com/Documents/Blood%20Borne%20Diseases%20Protocol%20(Novembe r%202018).pdf)
- Occupational Safety and Health Administration. Standard 1910.1030: Bloodborne pathogens. 2001. (www.osha.gov/pls/oshaweb/owadisp.show document?p table=STANDARDS&p id=10051)
- 10. Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee.
  Guideline for disinfection and sterilization in healthcare facilities. Center for Disease Control & Prevention, 2008. (http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection Nov 2008.pdf)

- 11. Achilles SL, Reeves MF. Prevention of infection after induced abortion: SFP Guideline 20102. Contraception. 2011;83(4):295-309. (http://dx.doi.org/10.1016/j.contraception.2010.11.006)
- 12. Sawaya GF, Grady D, Kerlikowske K, Grimes DA. Antibiotics at the time of induced abortion: the case for universal prophylaxis based on a meta-analysis. Obstet Gynecol. 1996;87(5 Pt 2):884-90. (http://www.ncbi.nlm.nih.gov/pubmed/8677129)
- 13. Van Eyk N, van Schalkwyk J. Antibiotic prophylaxis in gynaecologic procedures. J Obstet Gynaecol Canada. 2012;34(4):382-91. (<a href="http://sogc.org/guidelines/antibiotic-prophylaxis-in-gynaecologic-procedures/">http://sogc.org/guidelines/antibiotic-prophylaxis-in-gynaecologic-procedures/</a>)
- Levallois P, Rioux JE. Prophylactic antibiotics for suction curettage abortion: results of a clinical controlled trial. Am J Obstet Gynecol. 1988;158(1):100-5. (<a href="http://www.ncbi.nlm.nih.gov/pubmed/3276193">http://www.ncbi.nlm.nih.gov/pubmed/3276193</a>)
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- 17. Guiahi M, Davis A. First-trimester abortion in women with medical conditions: SFP Guideline 20122. Contraception. 2012;86(6):622-30. (<a href="http://dx.doi.org/10.1016/j.contraception.2012.09.001">http://dx.doi.org/10.1016/j.contraception.2012.09.001</a>)
- Wilson W, Taubert KA, Gewitz M, Lockhart PB, Baddour LM, Levison M, et al. Prevention of infective endocarditis: guidelines from the American Heart Association. Circulation. 2007;116(15):1736-54. (http://dx.doi.org/10.1161/CIRCULATIONAHA.106.183095)
- Centers for Disease Control and Prevention. Sexually transmitted diseases treatment guidelines, 2015. MMWR. 2015;64(3):1-137. (<a href="http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm">http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm</a>)
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#### 4. LABORATORY PRACTICE

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

- Standard 4.1. Rh status testing must be offered to all patients with unknown Rh status over 56 days from the last menstrual period.
  - Recommendation 4.1.1. Below 56 days from the last menstrual period, patients and providers may forego Rh testing and anti-D immune globulin for patients who are Rh negative.(2-5)
- Standard 4.2. Rh status or an informed waiver declining Rh testing must be documented in all patients over 56 days from the last menstrual period.
  - Recommendation 4.2.1. This documentation may be obtained by on-site testing, outside source, or self-report.
  - Recommendation 4.2.2. Additional testing for either sensitization or other antibodies is not required in patients undergoing pregnancy termination, including testing for Du ("weak D").
- Standard 4.3. Rh immune globulin administration must be offered to patients known to be Rh negative (-) who are over 56 days. If Rh immune globulin is not administered in the facility, other arrangements for administration must be documented.
  - Recommendation 4.3.1. A patient who declines Rh immune globulin should sign an informed waiver.
- Standard 4.4. Anemia and the risk of bleeding must be evaluated.(6)
  - Recommendation 4.4.1. Hemoglobin or hematocrit testing should be readily available.
  - Recommendation 4.4.2. Prior to uterine aspiration and medication abortion in the first trimester, hemoglobin/hematocrit and other laboratory evaluation should be done as indicated by medical history and patient symptoms. Routine hemoglobin or hematocrit has not been shown to improve outcomes.

Recommendation 4.4.3. Prior to administration of methotrexate, a complete

blood count (CBC) should be considered for patients

with history of blood dyscrasia.

Recommendation 4.4.4. Hemoglobin or hematocrit should be checked before

all abortions after the first trimester.

**Discussion:** Emerging epidemiologic and clinical evidence indicates that the risk of maternal-fetal hemorrhage caused by early abortion is negligible and Rh testing and provision of Rh immune globulin may not be necessary.(2) It is reasonable to forego Rh testing and anti-D immunoglobulin for women having any type of abortion before 56 days. Foregoing Rh testing and anti-D immunoglobulin for those using medication abortion before 70 days LMP may also be considered.

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

Moderate or asymptomatic anemia is rarely a reason to delay abortion care.

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#### 5. LIMITED SONOGRAPHY IN ABORTION CARE

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

- Staff members who perform ultrasound exams and clinicians who interpret those exams must either show documentation of proficiency or complete a program of training. Training must include a period of supervision. Documentation of this training must be maintained.
- Standard 5.2. A system of proficiency review must be in place for staff members who perform ultrasound exams and clinicians who interpret those exams.
- <u>Standard 5.3.</u> Patients must be informed of the purpose and limitations of the ultrasound exam in the abortion care setting.
- <u>Standard 5.4.</u> Patients must be informed of the sonographic diagnosis, including early pregnancy loss.(1, 2)
- Standard 5.5. The findings of all ultrasound exams and the interpretation of those findings must be documented in the medical record. This documentation must also include the name(s) of staff who performed and interpreted the exam.(3)
  - Recommendation 5.5.1. Ultrasound images should be included as part of the documentation, particularly for the purposes of proficiency review.
  - Recommendation 5.5.2. A standard form for documenting findings and interpretation should be used.
- <u>Standard 5.6.</u> A limited ultrasound exam must include the following:
  - a full scan of the uterus in both the transverse and longitudinal planes to confirm an intrauterine pregnancy;
  - (2) evaluation of embryo/fetal number;
  - (3) measurements to document gestational age;(4, 5)
  - (4) evaluation of pregnancy landmarks, such as yolk sac or the presence or absence of fetal/embryonic cardiac activity; and
  - (5) placental location in second trimester.

Recommendation 5.6.1. When clinically indicated, evaluation of other pelvic

structures (i.e., adnexal structures and the cul de sac) should be performed and documented or an appropriate referral should be made for further

evaluation.

Standard 5.7. When a patient with a prior uterine scar is found to have placenta

previa or a low anterior placenta, or when other placental abnormality is suspected, additional sonographic imaging should be performed

on-site or an appropriate referral made.(6-8)

Standard 5.8. Ultrasound equipment must be properly maintained.

<u>Standard 5.9.</u> All ultrasound transducers must be disinfected between patients.

**Discussion:** Resources for ultrasound training can be found in NAF's online learning resources on our members-only website at <a href="https://members.prochoice.org">https://members.prochoice.org</a>.

According to the American Institute of Ultrasound in Medicine (AIUM), in collaboration with the American College of Obstetrics and Gynecology and the American College of Radiology, a "limited ultrasound examination" is performed when a specific question requires investigation.(3, 9, 10)

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#### 6. EARLY MEDICATION ABORTION

**Policy Statement:** Medication abortion is a safe and effective method for early abortion.(1, 2) Adequate counseling and follow-up care will enhance its safety and acceptability. Providing medication abortion by telemedicine is a safe option.(3, 4)

<u>Standard 6.1.</u> Initial evaluation must include pertinent medical history.

Standard 6.2. The patient must be informed about the efficacy, side effects, and risks, including excessive bleeding, infection, and teratogenicity of the medications used.(5)

Recommendation 6.2.1. Breastfeeding is not a contraindication to medication abortion with mifepristone and misoprostol. Patients should be informed that breastfeeding can continue uninterrupted without concern for side effects in infants.(6, 7)

Option 6.2.1.1. As appropriate, patients may be informed that no evidence-based way to reverse mifepristone exists.(8)

Option 6.2.1.2. Not taking an evidence-based regimen of misoprostol after mifepristone may be associated with unusual bleeding, particularly after 49 days.(9)

<u>Standard 6.3.</u> The patient must be informed that a uterine aspiration may be necessary.

Standard 6.4. Patient instructions must include written and oral information about use of medications at home and symptoms of abortion complications.

Standard 6.5. 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 6.6.</u> Confirmation of pregnancy must be documented. Gestational age must be verified to be within the limits of the facility medication abortion protocol.

Recommendation 6.6.1.

If an ultrasound has been performed and an intrauterine gestation has not been confirmed, the medication abortion regimen should be offered concurrently with evaluation for pregnancy of unknown location, as outlined in CPG section 8 Management of Pregnancy of Uncertain Location.

<u>Standard 6.7.</u> IUDs must be removed prior to proceeding with medication abortion.

Recommendation 6.7.1. If an IUD cannot be removed without delaying the medication abortion, the patient should be offered a uterine aspiration.

<u>Standard 6.8.</u> An evidence-based medication abortion regimen must be used.

Recommendation 6.8.1. Where legally available and accessible, mifepristone and misoprostol should be used.(10-12)

Recommendation 6.8.2. A dose of 200 mg of mifepristone is recommended for combined mifepristone-misoprostol regimens.(2)

Option 6.8.2.1. Mifepristone may be taken outside the clinic setting.(13)

Recommendation 6.8.3. For medication abortion, oral mifepristone and vaginal, buccal, or sublingual misoprostol are recommended for gestations through 70 days.(14-19)

Recommendation 6.8.4. For medication abortion at 71 through 77 days, the regimen should include a second dose of misoprostol, 800 mcg, four hours after the first misoprostol dose.(20)

Recommendation 6.8.5. For medication abortion at 64-70 days, the regimen may include a second dose of misoprostol, 800 mcg, four hours after the first misoprostol dose.(21)

Recommendation 6.8.6. Where mifepristone is either not legally available or inaccessible, misoprostol-alone regimens may be offered.(22, 23)

Recommendation 6.8.7. When methotrexate and misoprostol are used, an evidence-based regimen oral or intramuscular methotrexate followed in three to five days with vaginal misoprostol is recommended for gestations up to 63 days.(2, 24)

Standard 6.9. Patient comfort level during the medication abortion process must be considered. Analgesia or other comfort measures must be discussed and offered as needed.

Recommendation 6.9.1. Non-steroidal anti-inflammatories such as ibuprofen should be offered over acetaminophen for pain control.(25)

Standard 6.10. Patients must be offered a follow-up assessment to confirm absence of ongoing pregnancy. Confirmation can be established by

ultrasonography, hCG testing, physical exam, or other evaluation in the office, by telephone, or electronic communication.(26-28)

Recommendation 6.10.1. Follow-up evaluation should be scheduled within 14 days after starting medication abortion.(2)

Recommendation 6.10.2. High-sensitivity urine hCG testing should not be checked within four weeks of medication abortion.(29-

32)

Option 6.10.2.1. Multi-level or low-sensitivity urine pregnancy tests may be used.(32-36)

Recommendation 6.10.3. Endometrial thickness should not be used to guide management after medication abortion.(37, 38)

Recommendation 6.10.4. Prolonged courses of misoprostol should not be given

routinely to improve success.(39, 40)

Option 6.10.4.1. Additional doses of misoprostol with or without

mifepristone may be given for persistent gestational

sac or continuing pregnancy.(41, 42)

<u>Standard 6.11.</u> Medications dispensed and prescribed must be documented.

**Discussion:** Medication abortion regimens and follow-up have evolved rapidly over the past decade and are likely to continue to improve.

The NAF recommended protocol for medication abortion up to 70 days gestation is 200mg mifepristone followed in 24 to 48 hours by 800mcg misoprostol buccally, vaginally, or sublingually. Vaginal misoprostol may be used if the time interval between mifepristone and misoprostol is shortened. More information on medication abortion regimens and follow-up may be found in NAF's online learning resources on <a href="https://members.prochoice.org">https://members.prochoice.org</a>.

Medication abortion later in pregnancy has increased efficacy rates when repeat doses of misoprostol are given. From 64-70 days, a second dose of misoprostol 800 mcg four hours after the first dose may be used. From 71 to 77 days, a second dose of misoprostol 800 mcg four hours after the first dose should be given (See Table 1).

Table 1: Efficacy of mifepristone 200 mg orally and misoprostol regimens by weeks (16, 20, 21, 43)

	(10, 20, 21, 10)	Overall efficacy	Ongoing pregnancy	
57-63 days gestation				
0	Misoprostol 800 mcg	93.5%	3.1%	
	buccal x 1 dose			
64-70 days gestation				
0	Misoprostol 800 mcg	92.3%	3.6%	
	buccal x 1 dose			
0	Misoprostol 800 mcg	99.6%	0.4%	
	buccal q 4 hours x 2			
	doses			
71-77 days gestation				
0	Misoprostol 800 mcg	86.7%	8.7%	
	buccal x 1 dose			
0	Misoprostol 800 mcg	97.6%	1.6%	
	buccal q 4 hours x 2			
	doses			

Mifepristone alone is not as effective as a combined regimen and has a higher risk of ongoing pregnancy. There is no high-quality evidence that progesterone given directly after mifepristone ingestion increases the rate of ongoing pregnancy compared to no intervention.(8) A recent small randomized controlled trial of progesterone vs. placebo after mifepristone was stopped early due to bleeding requiring intervention, especially in patients over 49 days gestation.(9) Laws that require abortion providers to discuss unproven methods to interrupt the abortion process with their patients are a violation of medical ethics in that they require providers to discuss an experimental treatment with no proven benefit.

There is no evidence that mifepristone exposure has a teratogenic effect on an ongoing pregnancy.(44) Misoprostol exposure early in pregnancy doubles the risk of causing major fetal malformations in a continuing pregnancy, from approximately 2% in cases with no exposure to 4% in cases of misoprostol exposure.(45) High-dose methotrexate exposure causes high rates of malformations or pregnancy loss.(46)

High-sensitivity pregnancy tests, such as those found in the pharmacy, typically detect hCG levels under 25-50 mIU/mL. These tests have a high rate of being positive for up to 30 days after a successful medication abortion.(30) Women should not take a high-sensitivity pregnancy test less than four weeks after medication abortion. Multi-level and low-sensitivity pregnancy tests, which detect hCG levels of 1000-2000 mIU/mL may be more accurate for medication abortion follow-up.(32-36)

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#### 7. FIRST-TRIMESTER ASPIRATION ABORTION

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

- Standard 7.1. Pertinent medical history must be obtained.
- <u>Standard 7.2.</u> Pregnancy must be confirmed, and gestational age must be assessed.
  - Recommendation 7.2.1. When gestational age cannot be reasonably determined by other means, ultrasonography should be used.
- <u>Standard 7.3.</u> Appropriate initial evaluation must be performed. Baseline blood pressure and pulse must be obtained for all patients.
  - Recommendation 7.3.1. Physical exam should be done as indicated by medical history and patient symptoms.
- <u>Standard 7.4.</u> The cervix should be appropriately dilated for the gestational age.
  - Recommendation 7.4.1. Cervical dilation may be achieved through the use of rigid cervical dilators. Tapered dilators such as Pratt or Denniston dilators are recommended over non-tapered dilators such as Hegar dilators.(1)
  - Recommendation 7.4.2. When cervical preparation with misoprostol is used, an evidence-based regimen should be followed.(2-5)
    - Option 7.4.2.1. The routine use of misoprostol before procedures may reduce rare complications but must be balanced against increased pain and other side effects for all patients.(5)
    - Option 7.4.2.2. Osmotic dilators may be considered when cervical dilation is expected to be difficult.(6)
- Standard 7.5. First-trimester abortion procedures must be performed by aspiration of the uterus, not by sharp curettage.(7-9)
  - Recommendation 7.5.1. Uterine aspiration is effective throughout the first trimester including prior to confirmation of a definitive intrauterine pregnancy on ultrasound.(10)
  - Recommendation 7.5.2. Sharp curettage should not be routinely used after uterine aspiration.

Recommendation 7.5.3. Uterotonics should not be used routinely after first-trimester uterine aspiration.(11)

**Discussion:** No evidence supports the routine use of sharp curettage or any uterotonic after first-trimester uterine aspiration.

Cervical preparation has limited effectiveness and is not needed before a routine first-trimester abortion. Its use must be balanced against the prolonged time in the facility, side effects, and patient satisfaction. If misoprostol is used for cervical preparation, an evidence-based regimen is misoprostol 400mcg buccally, vaginally, or sublingually, one to three hours prior to the abortion procedure.(4, 5)

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#### 8. Management of Pregnancy of Uncertain Location

**Policy Statement:** Many patients seek care very early in pregnancy before an intrauterine pregnancy can be visualized on ultrasound. When a patient has a positive pregnancy test and pregnancy of uncertain location, the most common diagnosis is an intrauterine pregnancy, but the possibility of ectopic pregnancy must be considered. For these patients, abortion care should be offered, and the patient must be followed to ensure that the pregnancy has ended. If abortion care is delayed allowing for visualization of pregnancy on ultrasound, the patient must be evaluated by a clinician, ectopic precautions must be given, and a plan for follow-up must be made.

- Standard 8.1. The patient must be evaluated by a clinician to assess for the risk of ectopic pregnancy in pregnancy of uncertain location.(1-3)
  - Recommendation 8.1.1. Evaluation should involve assessment of the history in combination with one or more of the following: physical exam, sonography, serial quantitative hCG, and/or uterine aspiration.(4)
  - Recommendation 8.1.2. Abortion care should be offered even if pregnancy location is uncertain.(5-7)
- <u>Standard 8.2.</u> Each facility must have a written protocol to evaluate pregnancy of uncertain location. All relevant staff at the site must be familiar with the protocol.
  - Recommendation 8.2.1. This protocol may include referrals as appropriate.
- All patients with a pregnancy of uncertain location must be informed of the options for evaluation and management. The symptoms and dangers associated with ectopic pregnancy, and a plan for when and how to seek emergency medical attention must be reviewed and documented.
  - Recommendation 8.3.1. Each facility should have a patient education handout describing ectopic warning signs and the medical record should reflect that the patient has received this handout.
- Standard 8.4. When a medication 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 hCG levels according to evidence-based regimens.

## Standard 8.5. When an intrauterine pregnancy cannot be definitively seen on ultrasound, a clinician must review the patient's history, ultrasound images, and signs and symptoms of ectopic pregnancy. A clinician must discuss the risks and warning factors for ectopic pregnancy with the patient.

Option 8.5.0.1. hCG levels may be used to determine whether a patient is at elevated risk of ectopic pregnancy and needs immediate evaluation if abortion care is deferred.

#### Standard 8.6. Patient follow-up must continue until one of the following:

- (1) the diagnosis of ectopic pregnancy has been excluded;
- (2) clinical resolution of a pregnancy of uncertain location has been ensured; or
- (3) transfer of care to an appropriate provider has been made and documented.

## <u>Standard 8.7.</u> Patients experiencing symptoms suspicious for ectopic pregnancy must be evaluated emergently.

**Discussion:** A combination of clinical assessment, pelvic ultrasound, serum quantitative hCG, and/or examination of uterine aspirate is often needed to distinguish between an intrauterine and an ectopic pregnancy.(1) Although a gestational sac can usually be seen four to five weeks from LMP on transvaginal ultrasound, it may be confused with a pseudo-sac associated with an ectopic pregnancy.(8, 9) Although visualization of a yolk sac or embryo is needed to definitely confirm an intrauterine pregnancy on ultrasound,(10) the lack of visualization of these structures should not delay abortion care.

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 patients presenting for induced abortion.(5, 11)

Following aspiration abortion, if sufficient products of conception (POC) are not identified, one option for additional evaluation is the use of quantitative hCG testing. A baseline hCG can be obtained and a second hCG can be done in 24-48 hours. If there is a decrease of 50% or more, no further ectopic follow-up is necessary.(12-14) Otherwise, further evaluation should be initiated including consideration of ectopic pregnancy.

Similarly, following medication abortion, hCG can be used to rule out ectopic pregnancy while simultaneously evaluating success of the medication abortion.(15, 16)

For more information and protocols for management of pregnancy of uncertain location, please visit NAF's members-only website at <a href="https://members.prochoice.org">https://members.prochoice.org</a> and access the resources section of online learning.

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#### 9. ABORTION BY DILATION AND EVACUATION

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

- <u>Standard 9.1.</u> Pertinent medical history must be obtained, and relevant physical examination must be performed.
  - Recommendation 9.1.1. Obesity without comorbidities should not be used to restrict or delay access to D&E.(7-9)
- Standard 9.2. Gestational age must be verified by ultrasonography, using a consistent and published table of fetal measurements, prior to the termination of a pregnancy clinically estimated to be more than 14 weeks from LMP.
- Standard 9.3. The patient must be appropriately evaluated and prepared for the procedure.
  - Recommendation 9.3.1. Intravenous access should be established prior to evacuation.
  - Recommendation 9.3.2. When induced fetal demise is used, it should be provided through an evidence-based protocol.(10-16)
  - Recommendation 9.3.3. In a patient with a prior uterine scar, after appropriate evaluation to exclude placenta accreta spectrum, the patient may have a procedure in the outpatient setting.(17)
- Standard 9.4. When cervical preparation agents are used overnight or outside the facility, a plan for emergency care must be in place and communicated to the patient.
- Standard 9.5. Appropriate dilation of the cervix must be obtained gently and gradually.(18, 19)
  - Recommendation 9.5.1. Osmotic dilators, misoprostol, mifepristone, and/or other cervical preparation agents should be used to facilitate adequate dilation.(20-23)
  - Recommendation 9.5.2. Local anesthesia should be used for pain management with osmotic dilator placement.(24, 25)
  - Recommendation 9.5.3. An evidence-based regimen should be used for dosage, timing, and route of misoprostol.(23, 26-30)

Option 9.5.0.1. Synthetic osmotic dilators and/or misoprostol may be used for same-day cervical dilation.(26, 28, 29, 31)

<u>Standard 9.6.</u> All instruments entering uterine cavity must be sterile.

<u>Standard 9.7.</u> Evidence-based practices must be used to lower the risk of complications.

Recommendation 9.7.1. Intra-procedure ultrasonography should be used to aid in visualizing instruments, locating fetal parts, verifying an empty uterus, reducing the risk of uterine perforation, and shortening the procedure.(32-34)

Recommendation 9.7.2. Inhaled anesthesia should be avoided if possible due to the increased risk of hemorrhage.(35, 36)

Standard 9.8. Uterotonics must be available to aid in control of uterine bleeding.(17)

Option 9.8.0.1. An intra- or paracervical prophylactic vasoconstrictor can be used to reduce blood loss.(37)

**Discussion:** Cervical preparation before dilation and evacuation can be achieved with multiple agents either alone or in combination. Misoprostol is commonly used, with a dose of 400mcg supported by most studies.(38)

Induced fetal demise should be provided using an evidence-based regimen. A sample protocol for digoxin injection is available at <a href="https://members.prochoice.org">https://members.prochoice.org</a>. Intraamniotic or intrafetal digoxin may be used.(39, 40) Intracardiac potassium chloride or lidocaine may also be used.(11, 16, 41) Injections may be done either transabdominally or transvaginally.(42, 43) Cord transection may also be used.(44)

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#### 10. MEDICATION ABORTION AFTER THE FIRST TRIMESTER

**Policy Statement:** Medication abortion is a safe and effective method for termination of pregnancies beyond the first trimester when performed by trained clinicians in medical offices, freestanding clinics, ambulatory surgery centers, and hospitals. Induced fetal demise may be particularly important at later gestational ages.

- <u>Standard 10.1.</u> Pertinent medical history must be obtained, and relevant physical examination must be performed.
- Standard 10.2. Gestational age must be verified by ultrasonography, using a consistent and published table of fetal measurements, prior to the termination of a pregnancy clinically estimated to be more than 14 weeks from LMP.
- <u>Standard 10.3.</u> The patient must be appropriately evaluated and prepared.

Recommendation 10.3.1. Intravenous access should be established.

- <u>Standard 10.4.</u> Facilities must have a policy that addresses whether and when to induce fetal demise.
  - Recommendation 10.4.1. When induced fetal demise is used, it should be provided through a standard protocol.(1-6)
- <u>Standard 10.5.</u> Evidence-based regimens of medication abortion must be used.
  - Recommendation 10.5.1. Mifepristone 200 mg followed by misoprostol should be used, when available and feasible.(7-10)
    - Option 10.5.0.1. Misoprostol may also be used alone.(11)
    - Option 10.5.0.2. The initial dose of misoprostol may be more effective if administered vaginally than sublingually,(11) particularly in nulliparous patients.(12)
    - Option 10.5.0.3. Subsequent doses of 400 mcg misoprostol may be most effective when given every three to four hours and are effective by vaginal, buccal, or sublingual routes.(11)
    - Option 10.5.0.4. Oxytocin may be used according to a protocol.
    - Option 10.5.0.5. Osmotic dilators may be useful at later gestations.

Recommendation 10.5.2. Intraamniotic injection or instillation methods should be avoided as they are less effective and result in more complications than mifepristone-misoprostol or misoprostol-alone regimens.(13)

Standard 10.6. Once regular contractions have been confirmed, patients must be observed by health care staff trained to monitor contractions and expulsion, and who can recognize emergent situations.

<u>Standard 10.7.</u> A trained clinician must be available from initiation of induction until post-abortion discharge.

<u>Standard 10.8.</u> Access to surgical management or appropriate referral must be available if surgical intervention is required.

Standard 10.9. The facility and/or clinician should continue care of the patient until completion of the abortion or transfer of care to an appropriate provider is made.

**Discussion:** An interval of 24-48 hours between mifepristone and misoprostol shortens the time to completion after starting misoprostol.

Caution should be used with osmotic dilators in the second trimester as they may prolong the induction time.(8, 14-16)

Induced fetal demise should be provided using an evidence-based regimen. A sample protocol for digoxin injection is available at <a href="https://members.prochoice.org">https://members.prochoice.org</a>. Intraamniotic or intrafetal digoxin may be used.(17, 18) Intracardiac potassium chloride or lidocaine may also be used.(6, 19, 20) Injections may be done either transabdominally or transvaginally.(21, 22)

Uterine curettage or aspiration should not routinely be performed.

The risk of uterine rupture during later medication abortion with misoprostol may be significantly increased for patients with two or more previous cesarean sections, however, the absolute risk remains low.(23) The risks should be balanced with alternative procedures for later abortion.

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## 11. ANALGESIA AND SEDATION

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

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

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

The promulgation of guidelines for the delivery and monitoring of anesthesia care issued by organizations such as the American Society of Anesthesiologists (ASA), 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.

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

# **Definitions** (1)

- 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, local anesthesia almost always involves a paracervical block.
- 2. <u>Minimal Sedation (Anxiolysis)</u> A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical

- coordination may be impaired, airway reflexes, ventilatory, and cardiovascular functions are unaffected.
- 3. Moderate Sedation/Analgesia A drug-induced depression of consciousness during which patients respond purposefully\* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained but may be impaired. This level of sedation was previously referred to as "Conscious Sedation." However, this term is no longer recommended.
- 4. <u>Deep Sedation/Analgesia</u> 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> A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

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

<u>Standard 11.1.</u> Pain control options must be discussed with the patient.

Standard 11.2. 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 11.2.1. Documentation should include precautions relevant to transient mental impairment.

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<sup>\*</sup>Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

- Option 11.2.0.1. An informed consent form specific for analgesia and sedation may be used.
- <u>Standard 11.3.</u> Prior to moderate sedation, a pre-sedation evaluation of the patient must take place.
  - Recommendation 11.3.1. Evaluation should include a relevant history and review of systems; medication review; targeted exam of the heart, lung, and airway as indicated by the patient's history and review of systems; and baseline vital signs.
  - Recommendation 11.3.2. For patients receiving moderate sedation who are not at increased risk of aspiration, time from last meal should not limit access to abortion care.(2-4)
  - Recommendation 11.3.3. A reduced level of sedation, an alternate abortion procedure, or provision of care by an anesthesia professional should be considered for patients with an atypical airway assessment or ASA Physical Status Classification 3 or greater.(5, 6)
- Standard 11.4. No additional evaluation is needed prior to paracervical block and/or NSAID administration.
- Standard 11.5. The supervising practitioner must be immediately available when sedation is administered.
- Standard 11.6. 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, with approval by the medical director or their designee.(6, 7)
- Standard 11.7. To administer moderate sedation, a provider must have the following: licensure as appropriate, basic airway skills, the ability to monitor and effectively rescue patients in an emergency, and the ability to screen patients appropriately for sedation.
- Standard 11.8. The potential need for intravenous access must be considered prior to administering any level of sedation.
  - Recommendation 11.8.1. When more than minimal sedation is intended, intravenous access should be maintained at least until discharge criteria are met (Standard 12.5).
- <u>Standard 11.9.</u> Pulse oximetry, with appropriate alarms, must be employed when moderate or deeper levels of sedation are used.

- Standard 11.10. 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.
  - <u>Recommendation 11.10.1.</u> The patient should be checked frequently for verbal responsiveness.
- Standard 11.11. When moderate sedation or deeper is provided, a person other than the clinician performing the procedure, and who is trained to monitor appropriate physiological parameters, must be present. This person must not be performing duties other than monitoring the patient.(6)

#### **Moderate Sedation**

- Standard 11.12. When moderate sedation is intended, sedation medication must be started at a reasonable low dose and titrated as needed, based on individual circumstances, such as weight and drug tolerance.(8-10)
  - Recommendation 11.12.1. The following table should be used for guidance for these commonly used drugs when used for moderate sedation. Similar ranges of other opioids and benzodiazepines may be used.

Drug	Usual initial dose	Max initial dose	Usual incremental Dose	Max incremental Dose
Fentanyl	50-100 mcg	200 mcg	50-100 mcg	100 mcg
Midazolam	1-3 mg	4 mg	1-2 mg	2 mg

Standard 11.13. When moderate sedation is administered, at least one individual with documented airway skills must be present in the procedure room.

## **Deep Sedation or General Anesthesia**

- <u>Standard 11.14.</u> Supplemental oxygen must be used with deep sedation and general anesthesia.
- <u>Standard 11.15.</u> The practitioner administering deep sedation or general anesthesia must not be the practitioner performing the abortion.
  - Recommendation 11.15.1. For deep sedation and general anesthesia, the following should be monitored: continuous pulse oximetry, intermittent blood pressure, and respiration,

either by measuring end-tidal CO<sub>2</sub> or clinical observation.

- Recommendation 11.15.2. The capability to monitor temperature should be available.
- Standard 11.16. Any individual responsible for administering, supervising, or monitoring a patient receiving any level of sedation must have current, health care provider level basic life support (BLS) certification.
- Standard 11.17. The practitioner administering deep sedation or general anesthesia must adhere to established professional standards of care.(11)

## Nitrous Oxide

- Standard 11.18. N<sub>2</sub>O must be self-administered by the patient or by a qualified anesthesia provider.
  - Recommendation 11.18.1. N<sub>2</sub>O may be an alternative to local or oral sedation but is less effective for pain management than moderate intravenous sedation.(12,13)
- Standard 11.19. If not self-administered, the provision of N<sub>2</sub>O must follow guidelines for patient monitoring for moderate sedation.
- Standard 11.20. Equipment for the delivery of N<sub>2</sub>O/O<sub>2</sub> must:
  - (1) provide a concentration of N<sub>2</sub>O of no more than 70% inspired;
  - (2) provide a minimum of 30% O<sub>2</sub>; and
  - (3) be checked and calibrated regularly.
  - Recommendation 11.20.1. The concentration of nitrous oxide should not routinely exceed 50% in the absence of qualified anesthesia personnel.
  - Recommendation 11.20.2. Equipment for the delivery of N<sub>2</sub>O/O<sub>2</sub> should include an oxygen analyzer.
  - Recommendation 11.20.3. Due to the potential for occupational exposure, room or personnel monitoring for levels of N<sub>2</sub>O should be conducted.

## **Emergency Equipment**

- Standard 11.21. Functioning equipment and current medications must be available onsite to handle medical emergencies and must include: an oxygen delivery system, oral airways, epinephrine, and antihistamines.
- Standard 11.22. In settings where benzodiazepines and opioids are used, appropriate antagonists, bronchodilators, and bag-valve masks capable of delivering supplemental oxygen must be available.
  - Recommendation 11.22.1. Facilities should have a specified area for emergency equipment, which includes oxygen, medications, and supplies. A protocol and time schedule for checking equipment and removing expired medications must be in place.
- Standard 11.23. In settings where deep sedation and general anesthesia are used, it is expected that providers maintain the appropriate medication and equipment required for an anesthesia emergency.

Recommendation 11.23.1. A defibrillator should be available.

**Discussion:** The time of last food intake does not increase the risk of moderate sedation.(2-4)

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

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#### 12. Post-Procedure Care

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

- Standard 12.1. Patients who want contraception must receive their chosen method immediately following an abortion or appropriate referral should be made.
  - Recommendation 12.1.1. When desired by the patient, intrauterine contraception or contraceptive implants should be initiated immediately after first-trimester uterine evacuation or second-trimester D&E.(1-3)
  - Recommendation 12.1.2. When desired by the patient after medication abortion, intrauterine contraception should be initiated as soon as expulsion of the pregnancy is confirmed.(4-6)
  - Recommendation 12.1.3. When desired by the patient, contraceptive implants should be initiated on the day of mifepristone administration for medication abortion.(7-10)
    - Option 12.1.3.1. Depot Medroxyprogesterone acetate (Depo-Provera®) may be given at the time of mifepristone with appropriate counseling.(10-12)
- Standard 12.2. All patients receiving more than minimal sedation or in the second trimester must be continuously observed during the recovery period by a health care worker trained in post-procedure care.
- Standard 12.3. Patients who received moderate or deeper sedation must be monitored until determined to be no longer at risk for hemodynamic instability or respiratory depression.
  - Recommendation 12.3.1. A pulse oximeter with alarms should be used until the patient is alert and ambulatory.
- <u>Standard 12.4.</u> A clinician must remain in the facility until all patients are medically stable.
- Standard 12.5. 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 12.6. The patient must be given oral and written instructions outlining what to expect post-procedure, self-care, and signs and symptoms of complications.
  - Recommendation 12.6.1. Patients who receive sedation should have access to this information prior to the administration of medication.
- Standard 12.7. The facility must provide an emergency contact service on a 24-hour basis, where calls are triaged in accordance with written policies. A recorded message alone is unacceptable.
- Standard 12.8. Any non-clinician involved with first-call triage must be trained to take a post-abortion health history and follow clear written guidelines indicating when immediate consultation with a clinician is indicated.
- Standard 12.9. Any patient who gives a history suggestive of a post-procedure complication must have access to a clinician. The facility must establish a pathway for physician referral if indicated.
  - Recommendation 12.9.1. Uterotonic agents should be given as indicated and not on a routine basis. When used, an evidence-based regimen should be followed.
    - Option 12.9.1.1. Routine post-procedure follow-up is not required. Clinicians may offer a visit for patients who would like one.(13, 14)

**Discussion:** A recent study shows that Depot Medroxyprogesterone acetate (DMPA) (Depo-Provera®) given on the day of mifepristone may increase the risk of continuing pregnancy but does not increase the risk of needing aspiration to complete the abortion compared to when it is given at a follow-up visit.(12) Patient satisfaction is higher with immediate DMPA, but six-month use rates and pregnancy rates are the same due to high rates of discontinuation. If a woman understands the potential risk of ongoing pregnancy, DMPA may be offered and given at the time of mifepristone. DMPA given in the 24-48 hours after mifepristone, on the day of misoprostol, does not affect the rate of continuing pregnancy.(15)

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#### 13. EVALUATION OF EVACUATED UTERINE CONTENTS

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

- Standard 13.1. Termination of pregnancy must be confirmed prior to the patient leaving the facility or further evaluation must be initiated.
  - Recommendation 13.1.1. Evacuated uterine contents should be examined before the patient leaves the facility.
  - Recommendation 13.1.2. In first-trimester terminations, flotation of tissue should be used to identify products of conception, including gestational sac.
    - Option 13.1.2.1. Backlighting of tissue may be useful.
    - Option 13.1.2.2. Sending the evacuated uterine contents for additional pathological examination is not required.(1, 2)
- Standard 13.2. In the first trimester, when insufficient tissue or incomplete products of conception are obtained, the patient must be reevaluated.
  - Re-aspiration, serial quantitative hCG, and/or ultrasonographic examination should be considered.(3-5)
  - Recommendation 13.2.2. Ectopic pregnancy should be considered.
- Standard 13.3. After the first trimester, examination of the uterine contents must be performed to identify the placenta and all major fetal parts.
  - Recommendation 13.3.1. If the above are not identified, ultrasonographic evaluation and uterine exploration under ultrasound guidance should be considered.
  - Recommendation 13.3.2. The facility and/or clinician should continue care of the patient until completion of the abortion or transfer of care to an appropriate provider is made.

**Discussion:** One option for additional evaluation if sufficient POC are not identified is the use of serum quantitative hCG tests. A baseline hCG can be drawn and a second hCG can be done in 24-48 hours. If there is a decrease of 50% or more, no further ectopic follow-up is necessary. Otherwise, further evaluation should be initiated including consideration of ectopic pregnancy. In this situation, Section 8 (Management of Pregnancy of Uncertain Location) may be useful.

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#### 14. EMERGENCY PROCEDURES

**Policy Statement:** Appropriate management of abortion emergencies reduces morbidity and mortality. Hemorrhage can be one of the most serious immediate complications of an abortion procedure. Early recognition of the source of bleeding can reduce morbidity and mortality. Uterine perforation is a complication of abortion that can lead to significant morbidity. Morbidity is related to site of perforation, instrumentation, and gestational age.

- Standard 14.1. Protocols for the management of medical emergencies must be in place. These protocols must include indications for emergency transport and written, readily available directions for contacting external emergency assistance (e.g., an ambulance).
  - Recommendation 14.1.1. Protocols for the following topics should be in place: bleeding, perforation, respiratory arrest/depression, anaphylaxis, and emergency transfer.
  - Recommendation 14.1.2. Staff should review protocols annually.
    - Option 14.1.2.1. Annual drills of the emergency protocols are encouraged.
  - Recommendation 14.1.3. 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 14.2.</u> All staff must know their appropriate roles in the management of medical emergencies.
- <u>Standard 14.3.</u> Emergency supplies must be in known, appropriate locations and regularly updated.
- Standard 14.4. When abortion procedures are being performed, at least one medical staff member with health care provider level basic life support (BLS) training must be present.
  - Recommendation 14.4.1. All medical staff providing direct patient care should have current health care provider level BLS certification.

# Standard 14.5. All facilities must have a protocol for the management of acute hemorrhage.(1) This protocol must address the following items:

- (1) establishment of intravenous access;
- (2) administration of uterotonics;
- (3) evaluation of the cause and/or source of bleeding; and
- (4) criteria for hospital transfer.

# Standard 14.6. The facility must have at least two uterotonics and/or mechanical methods of controlling bleeding.

# <u>Standard 14.7.</u> If a perforation occurs or is suspected, even if the patient is asymptomatic, a protocol must address the following items:

- (1) establishment of intravenous access;
- (2) additional observation;
- (3) plan for follow-up including plans for completing the abortion if needed; and
- (4) criteria for transfer to a hospital such as the following:
  - (i) intra-abdominal viscera are detected in the uterine cavity, cervix, vagina, suction tubing, or on tissue examination;
  - (ii) fetal parts are detected in the abdominal cavity;
  - (iii) expanding intra-abdominal or retroperitoneal hematoma is detected; or
  - (iv) hemodynamic instability is present.

# Recommendation 14.7.1. If the procedure is completed after a suspected perforation, uterine evacuation should be performed under direct ultrasound guidance or laparoscopic visualization.(2, 3)

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

The following measures may be used for treatment of post-abortion hemorrhage:

- a. uterine massage;
- b. methylergonovine (Methergine);
- c. oxytocin (Pitocin);
- d. vasopressin (Vasostrict);
- e. misoprostol (Cytotec);
- f. carboprost tromethamine (Hemabate);
- g. intrauterine pressure using a Foley or Bakri balloon or vaginal pack; or
- h. uterine re-aspiration.

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. The patient may need immediate transfer to manage these conditions.

Perforations are often occult and may be difficult to identify.(4-6) If a perforation is suspected, it is safest to proceed as if there has been a perforation.

In the first trimester, perforations are often asymptomatic and self-healing. (7, 8) Most perforations are midline and/or fundal in location. (9) If they occur before suction, these usually can be managed with observation and close follow-up. (8) A lateral perforation may involve uterine blood vessels and, if so, will be more significant.

In the second trimester, even an asymptomatic perforation may warrant transfer to a hospital for evaluation depending on the instrumentation involved.(10, 11) There may be more significant morbidity due to increased uterine blood flow and the use of larger grasping instruments.

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