2024CLINICAL POLICYGUIDELINES FORABORTION CARE



N A T I O N A L A B O R T I O N FEDERATION



2024 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 people to obtain the highest quality abortion care.

Like its precursors, the 2024 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 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 CPGs 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, and systematic reviews in humans from January 1, 2022. The search run on December 31, 2023, yielded 667 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.

Thirty-three new papers were included in the 2024 CPGs because they changed one or more statements, supported a new recommendation, or substantially improved the level of evidence supporting a current statement. Changes to each policy statement were drafted by NAF's Interim Medical Advisor, Alice Mark, MD, MSc, and Senior Director of Clinical Services, Reesa Roberts, PA-C, MSPA, 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 2022-2023 Clinical Policy Committee members:

Sarah Prager, MD, MAS; Chair Lorie Chaiten, JD Justin T. Diedrich, MD, MSCI Angel M. Foster, DPhil, MD, AM Tiffany Hailstorks, MD, MPH John C. Markley, MD, PhD Tram Nguyen, MHA/MBA Alisha Nord-Stewart, RN, BScN Lisa Perriera, MD, MPH Rolanda Ryan, RN, MHSA TaRhonda Slydell, BSN, MBA-HCA Maria Mercedes Vivas, MD, MPH Lin Fan Wang, MD Beverly Winikoff, MD, MPH Ying Zhang, MD, MPH <u>Note:</u> 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 laws 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.

<u>Commitment to diversity, inclusion, equity, and anti-racism:</u> Abortion is affected by structural, institutional, interpersonal, and individual-level racism that affects safety and quality of care, and degrades the abortion experience for many of those who seek it.(9,10) NAF holds itself accountable to anti-racist principles and endorses evidence-based clinical guidelines that are not a source of harm but promote health for people with historically marginalized identities, including but not limited to Black, Indigenous, and People of Color, lesbian, gay, bisexual, transgender, gender expansive, intersex, asexual and two spirit people, immigrants, refugees, people with limited financial resources, people with limited exposure to formal education, people who don't speak the dominant language, young people, people of all body sizes, and people with disabilities, chronic illness, or other conditions.

<u>A note about language:</u> NAF and our members understand and respect that not every person with the capacity for pregnancy identifies as a woman. We embrace and respect each individual's gender identity, expression, and experience, and desire to be inclusive and helpful to all who need information about abortion or support as providers. While we do make an effort to use gender-inclusive language (person/people/they/them/patient) in this document and our other materials, we do also use woman/women in some cases. We do so in order to acknowledge the long history of gender discrimination targeting women, the specialized health care that many of our members provide, and the need to be clear to various audiences.

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Notes on Formatting

As presented here, standards, recommendations, and options are hierarchical in nature. It is therefore expected that clinical practices will favor the highest level of guidance available on a given point. 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, **Standards** 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 included 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, 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 *Options* 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, 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 should be decriminalized. Abortion is a safe procedure when provided by qualified individuals.(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 to provide abortion care, including medication abortion provision, informed consent, and follow-up.(3, 4) People may manage all or part of an abortion on their own.(5, 6)

Standard 1.1

Abortion will be provided by trained providers. This category is intended to include physicians from various specialties as well as nurse midwives, nurse practitioners, physician assistants, registered nurses, other health professionals and community-based providers.(7)

Recommendation 1.1.1

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

Recommendation 1.1.2

Complex Family Planning accreditation or sub-specialty status are not necessary or required for the provision of safe abortion care.

Recommendation 1.1.3

Neither hospital admitting privileges nor transfer agreements are needed to provide safe abortion care.(2)

Recommendation 1.1.4

Community-based providers with appropriate training may safely provide care.(6, 8, 9)

Standard 1.2

People may manage all or part of an abortion on their own. People using self-managed abortion need access to evidence-based information, effective medications, and supportive services before, during, and after the abortion.

Recommendation 1.2.1

Don't engage in any behavior that criminalizes abortion or those who use it.

Standard 1.3

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

Recommendation 1.3.1

When making changes to clinical practice, consider values clarification for providers and staff to optimize patient-centered care.

Standard 1.4

All individuals providing ancillary services must have appropriate training, for example, in ultrasound, counseling, sedation, laboratory, infection control, and other services.

Standard 1.5

Appropriate referrals must be available for patients who cannot be cared for by an individual or facility.

Discussion: Values clarification is an essential part of hiring, training, and retaining abortion staff. Values clarification should be done routinely but particularly needs to be revisited if a clinic expands its services, increases gestational limits, if staff changes roles at clinic, or when new staff are hired. Resources for values clarification can be found on NAF's members-only website at https://members.prochoice.org in the Learning Lab.

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2. Patient Education, Informed Consent, and Counseling

Policy Statement: A person must give voluntary, informed consent prior to an abortion and express understanding. The goal of abortion education is to give people the knowledge they need to make an informed decision about whether to have an abortion and which type of procedure to choose.

Informed Consent

Standard 2.1

The practitioner must ensure that 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 their satisfaction prior to intervention.

Option 2.1.0.1

Information may be provided either on an individual basis, in group sessions, or with appropriate patient information materials, and can be done in person or remotely.(1)

Standard 2.2

Documentation must show that the patient affirms their decision to have an abortion, that their decision is voluntary, and that they are aware of the potential risks and benefits of the abortion procedure. Although other risks may be addressed, at a minimum, the following risks must be included (2-6):

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

Recommendation 2.2.1

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

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

Patient Education and Counseling

Standard 2.3

Each person must have a private opportunity to ask questions about the abortion.(7-9)

Standard 2.4

A person must undergo the abortion as expeditiously as possible in accordance with good medical practice.

Recommendation 2.4.1

Information about aftercare and contraception must be available. The importance of contacting the provider for any concerns should be emphasized.

Recommendation 2.4.2

Evidence-based guidelines for contraceptive counseling should be followed.(10)

Standard 2.5

All reasonable precautions must be taken to ensure confidentiality.

Recommendation 2.5.1

The person should be informed of the communication of information to any third party.

Recommendation 2.5.2

People need to know which individuals or agencies may receive communications regarding services. This information 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 person's decision is voluntary and informed, and that they understand the risks and benefits of the abortion procedure. 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. Although the large majority of people who present for abortion are sure of their decision, (8) 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.(5, 6, 11) Pregnancy-related deaths are significantly higher.(12)

| Risks of pregnancy-relate | d death by country, 2020 WHO dat | ta (12) | |
|---------------------------|----------------------------------|---------|--|
| Country | Maternal mortality ratio* | | |
| Canada | 11 | | |
| United States | 21 | _ | |
| Mexico | 59 | | |
| Colombia | 75 | - | |
| | | | |

*deaths per 100,000 live births

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3. Infection Prevention and Control

Policy Statement: Patients and health care personnel are at risk for exposure to blood borne pathogens, aerosol transmissible disease, 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)

^{*}Engineering control—available technology and devices that isolate or remove hazards from the workplace, such as puncture-resistant sharps disposal containers, needleless systems for withdrawing medications, and safer sharps devices.

[†]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, for example, prohibiting needle recapping.

Standard 3.6

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)

Standard 3.7

Tubing and manual uterine aspirators must be high-level disinfected or sterilized.(10)

Standard 3.8

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

Standard 3.9

Sharps containers must be readily available. Sharps containers must be made of rigid, puncture-resistant material, have a tight-fitting lid, and be labeled as hazardous material.

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 pre-procedure.(11, 14, 15)

Recommendation 3.10.2

Prophylactic antibiotics should not be continued after the day of the procedure.(11, 14, 15)

Option 3.10.2.1 Antibiotics may be initiated at the time of insertion of 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)

Recommendation 3.10.4

Patients should be offered or referred for testing for chlamydia and gonorrhea according to local guidelines.(19) Testing should not delay the procedure.

Option 3.10.4.1

Empiric treatment of chlamydia may be considered for patients with history, signs, or symptoms of current infection.

Standard 3.11

Diagnosed infection must be appropriately treated.

Recommendation 3.11.1

For documented infections of the reproductive tract, evidence-based regimens should be followed.(19, 20)

Discussion: Regulatory agency policies (see references) may be helpful in developing exposure plans that protect personnel and patients from potentially infectious material, including aerosol transmissible diseases. A sample exposure control plan can be found in the online learning resources on NAF's members-only site at https://members.prochoice.org. 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.(21, 22)

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4. Laboratory Practice

Policy Statement: Rh alloimmunization may jeopardize the health of a subsequent pregnancy.(1) There is no evidence that providing anti-D immunoglobulin in early pregnancy prevents alloimmunization and poor outcome in a subsequent pregnancy, however, it is recommended later in pregnancy.(2-7)

Standard 4.1

Rh status testing must be offered to all people with unknown Rh status over 12 weeks from the last menstrual period (LMP) and anti-D immune globulin must be offered to patients over 12 weeks who are Rh negative.

Recommendation 4.1.1

Below 12 weeks from the last menstrual period, patients and providers may forego Rh testing and anti-D immune globulin for patients who are Rh negative.(2-7) This recommendation applies to both medication abortion and aspiration procedures.

Recommendation 4.1.2

If anti-D immune globulin is not administered in the facility, other arrangements for administration must be documented.

Recommendation 4.1.3

A person who is over 12 weeks LMP and declines Rh testing or anti-D immune globulin should sign an informed waiver.

Recommendation 4.1.4

Documentation of Rh status may be obtained by on-site testing, outside source, or self-report.

Recommendation 4.1.5

Additional testing for either sensitization or other antibodies is not required in patients undergoing pregnancy termination, including testing for Du ("weak D").

Standard 4.2

Anemia and the risk of bleeding must be evaluated.(8)

Recommendation 4.2.1

Hemoglobin or hematocrit testing should be readily available.

Recommendation 4.2.2

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 4.2.3

Hemoglobin or hematocrit should be checked before all abortions after the first trimester.

Discussion: 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 is not necessary.(2-7) There is no evidence to show that Rh testing and anti-D immune globulin is beneficial in the setting of early abortion, and added testing and treatment is a burden for many patients and providers. Therefore, it is reasonable to forego Rh testing and anti-D immunoglobulin for people having any type of abortion before 12 weeks LMP.

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.

Standard 5.1

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

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.

Standard 5.3

Patients must be informed of the purpose and limitations of the ultrasound exam in the abortion care setting.

Standard 5.4

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.

Standard 5.6

A limited ultrasound exam must include the following:

- 1) a full scan of the uterus in both the transverse and longitudinal planes to confirm an intrauterine pregnancy;
- 2) evaluation of 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 after 14 weeks, 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.

Standard 5.9

All ultrasound transducers must be disinfected between patients.

Discussion: Resources for ultrasound training can be found in the Learning Lab on NAF's members-only website at <u>https://members.prochoice.org</u>.

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) For most patients, testing before a medication abortion, including ultrasound, is not required.(5, 6) People can safely manage early medication abortion on their own.

Standard 6.1

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.(7)

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.(8, 9)

Option 6.2.1.1 As appropriate, patients may be informed that no evidence-based way to reverse mifepristone exists.(10)

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.(11)

Standard 6.3

The patient must be informed that a uterine aspiration may be necessary.

Standard 6.4

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

Standard 6.5

The provider must provide an emergency contact service on a 24-hour basis to assist with further care as needed.

Standard 6.6

Confirmation of pregnancy must be documented with a positive pregnancy test and/or ultrasound. Pregnancy dating 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 9 Management of Pregnancy of Uncertain Location.

Standard 6.7

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.

Standard 6.8

An evidence-based medication abortion regimen must be used.

Recommendation 6.8.1

Where legally available and accessible, mifepristone and misoprostol should be used.(12-14)

Recommendation 6.8.2

A dose of 200mg of mifepristone is recommended for combined mifepristonemisoprostol regimens.(2)

Option 6.8.2.1

Mifepristone may be taken outside the clinic setting.(15)

Recommendation 6.8.3

For medication abortion, oral mifepristone and vaginal, buccal, or sublingual misoprostol are recommended for gestations through 70 days.(16-21)

Recommendation 6.8.4

For medication abortion at 71 through 77 days, the regimen should include a second dose of misoprostol, 800mcg, four hours after the first misoprostol dose.(22)

Recommendation 6.8.5

For medication abortion at 64-70 days, the regimen may include a second dose of misoprostol, 800mcg, four hours after the first misoprostol dose.(23)

Recommendation 6.8.6

Where mifepristone is either not legally available or inaccessible, misoprostol-alone regimens or other evidence-based regimens may be offered.(24-27) See discussion for more information.

Standard 6.9

People can safely manage early medication abortion on their own.

Recommendation 6.9.1

People who self-manage abortion may need support from providers at different stages in the abortion process, including determining eligibility, understanding the regimen, accessing effective medications, and managing follow-up or complications.

Recommendation 6.9.2

People who self-manage abortion, along with those who support them through the process, should not be criminalized for their actions.

Standard 6.10

Misoprostol with or without mifepristone can be used for management of pregnancy loss.

Recommendation 6.10.1

Mifepristone and misoprostol are more effective than misoprostol alone for patients with an anembryonic gestation or who have embryonic or fetal demise.(28, 29)

Standard 6.11

Analgesia or other comfort measures must be discussed and offered as needed.

Recommendation 6.11.1

Non-steroidal anti-inflammatories such as ibuprofen are more effective than acetaminophen for pain control.(30)

Recommendation 6.11.2

The risk of routine narcotic analgesics for pain management may outweigh the benefits.(31-33)

Standard 6.12

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 self-assessment.(34, 35)

Recommendation 6.12.1

For people who do not want further contact with the health care provider, selfassessment of abortion outcomes may be used.

Recommendation 6.12.2

High-sensitivity urine hCG testing should not be checked within four weeks of medication abortion.(36)

Option 6.12.2.1 Multi-level or low-sensitivity urine pregnancy tests may be used.(37-39)

Recommendation 6.12.3

Endometrial thickness should not be used to guide management after medication abortion.(41, 42)

Recommendation 6.12.4 Prolonged courses of misoprostol should not be given routinely to improve success.(43)

Option 6.12.4.1 Additional doses of misoprostol with or without mifepristone may be given for persistent gestational sac or continuing pregnancy.(29, 44)

Standard 6.13

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 Learning Lab on the members-only site at <u>https://members.prochoice.org</u>.

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 800mcg four hours after the first dose may be used. From 71 to 77 days, a second dose of misoprostol 800mcg four hours after the first dose should be given (See Table 1).

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.(10) 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.(11) 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.(46) 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.(47) High-dose methotrexate exposure increases the risk of malformations or pregnancy loss.(48)

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

Table 1: Efficacy of mifepristone 200mg orally and misoprostol regimens by weeks (18, 22, 23, 45)

If mifepristone is not available, misoprostol-only or other evidence-based regimens may be used. These regimens are all more effective when multiple doses of misoprostol are used. Prolonged follow-up may be required to reach the maximum efficacy without intervention. The efficacy of these regimens for very early pregnancy (that is, pregnancy of unknown location) and pregnancies in the later first trimester are not well studied. People who use these regimens need to understand their efficacy, side effects, and the potential exposure to known teratogens if the pregnancy continues.

Where mifepristone is not available, NAF recommends misoprostol, 800mcg sublingually every three hours for 3-4 doses for people <77 days LMP. An extra dose may be provided in case the patient has no bleeding or ongoing symptoms. Patient information, instructions, and a detailed sample protocol may be found on NAF's members-only site at https://members.prochoice.org.

When methotrexate and misoprostol are used, an evidence-based regimen of methotrexate 50mg oral or intramuscular followed in three to five days with misoprostol 800mcg vaginally may be used.(26, 49) Adding repeat doses of misoprostol is likely to improve the efficacy of this regimen.

When letrozole and misoprostol are used, the World Health Organization (WHO) regimen of letrozole 10mg daily by mouth x three days followed by misoprostol 800mcg sublingually on day four is recommended. Adding repeat doses of misoprostol is likely to improve the efficacy of this regimen.(50)

High-sensitivity pregnancy tests, such as those found in the pharmacy, typically detect hCG levels under 25-50mIU/mL. People should not take a high-sensitivity pregnancy

test less than four weeks after medication abortion. At four weeks, approximately 20% of people with a successful medication abortion will still have a positive pregnancy test.(36) Providers should be aware that delayed assessment of completion could result in the discovery of an ongoing pregnancy in the second trimester.

If pregnancy loss is diagnosed for a patient presenting for abortion, this must be disclosed to the patient. Patients with pregnancy loss who choose medication management should be offered mifepristone pretreatment prior to misoprostol unless there is evidence the expulsion is actively underway, in which case mifepristone is unlikely to provide additional benefit. Providers can use the same medication regimen for early pregnancy loss as they would with abortion at a similar gestational age. There is limited data that misoprostol may be optimally effective 7-20 hours post mifepristone pre-treatment for early pregnancy loss, and waiting 24 hours may not have added benefit.(51)

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7. Providing Abortion Medications Without a Positive Pregnancy Test

Policy Statement: Providers can prescribe and dispense abortion medications for patients who are at risk for pregnancy for future use (advance provision) or for use in the setting of suspected, but not confirmed, pregnancy (menstrual regulation or "missed period pills"). Once the patient either confirms or suspects they are pregnant and uses medication abortion, the guidelines in CPG 6 for Early Medication Abortion apply.

Standard 7.1

Prior to prescribing and dispensing medication, the patient must be evaluated, either inperson or remotely, and eligibility for medication abortion must be confirmed.

Standard 7.2

The patient needs to be informed about the appropriate time to take medications in relationship to their pregnancy dating, the efficacy, side effects, and risks of medication abortion. They must be instructed on how to use the medications and symptoms of abortion complications.

Recommendation 7.2.1

The patient can contact the provider once they decide to use medications to review dating, eligibility, the medication abortion process, and follow-up.

Recommendation 7.2.2

The provider must offer a follow-up assessment for those who decide to take the medications and want further assessment.

Discussion: Advance provision or "missed period pills" may be acceptable to people who want medication abortion on hand, but there is, as yet, little evidence to show how frequently pills dispensed in this manner are used, and the efficacy and safety of this mode of abortion provision.(1-4)

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8. Procedural Abortion by Aspiration Alone

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

Standard 8.1

Pertinent medical history must be obtained.

Standard 8.2

Pregnancy must be confirmed, and gestational age must be assessed.

Recommendation 8.2.1

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

Standard 8.3

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

Recommendation 8.3.1

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

Recommendation 8.3.2

Weight and/or BMI alone are not contraindications to procedural abortion.

Standard 8.4

The cervix should be appropriately dilated for the gestational age.

Recommendation 8.4.1

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 8.4.2

When cervical preparation with misoprostol is used, an evidence-based regimen should be followed.(2-5)

Option 8.4.2.1

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 8.4.2.2

Osmotic dilators may be considered when cervical dilation is expected to be difficult.(6)

Standard 8.5

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

Recommendation 8.5.1

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

Recommendation 8.5.2

Sharp curettage should not be routinely used after uterine aspiration.

Recommendation 8.5.3

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 firsttrimester 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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9. 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.(1, 2) 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 9.1

The patient must be evaluated by a clinician to assess for the risk of ectopic pregnancy in pregnancy of uncertain location.(3-5)

Recommendation 9.1.1

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.(6)

Recommendation 9.1.2

Abortion care should be offered even if pregnancy location is uncertain.(7-9)

Standard 9.2

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 9.2.1

This protocol may include referrals as appropriate.

Standard 9.3

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

Recommendation 9.3.1

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 9.4

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 serum beta-hCG levels according to evidence-based regimens.

Recommendation 9.4.1

Where it is not possible to follow serial serum beta-hCG levels, urine pregnancy testing may be used.(10)

Standard 9.5

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 9.5.0.1

Serum beta-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 9.6

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.

Standard 9.7

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

Discussion: Treatment of pregnancy of uncertain location is not the same as "no-test" abortion. Pregnancy of uncertain location describes a situation in which an ultrasound is performed, and an intrauterine pregnancy is not visualized. "No-test abortion" describes a situation in which a patient has a certain or estimated last menstrual period, is otherwise eligible for abortion care, and ultrasound is not used prior to abortion.(11, 12)

Although the majority of patients who present with a low-risk pregnancy of uncertain location (that is, known early LMP, no history of ectopic pregnancy or significant risk factors, no signs and symptoms of ectopic pregnancy) will have an intrauterine pregnancy, ectopic pregnancy is more common in patients with a pregnancy of uncertain location compared to the general population of abortion seekers and needs to be assessed as the abortion proceeds. Providing abortion care to patients with pregnancy of uncertain location will decrease the time to definitive diagnosis of ectopic while at the same time providing most patients with a successful abortion.(1, 2) Abortion care, along with a combination of clinical assessment, pelvic ultrasound, serum quantitative hCG, urine hCG, and/or examination of uterine aspirate can be used to distinguish between an intrauterine and an ectopic pregnancy.(3)

Following medication abortion, hCG can be used to rule out ectopic pregnancy while simultaneously evaluating success of the medication abortion.(1, 2) When medication

abortion is initiated and no pregnancy is visible on ultrasound, patients should understand that the risk of ectopic pregnancy may be higher than the general population of abortion seekers, and the risk of medication abortion failure is higher. As such, followup is essential.

For more information and protocols for management of pregnancy of uncertain location, as well as information on diagnosis of early pregnancy on ultrasound, please visit NAF's members-only website at <u>https://members.prochoice.org</u> and access the Learning Lab.

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10. Procedural 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)

Standard 10.1

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

Recommendation 10.1.1

Weight and/or BMI alone are not contraindications to D&E.(7-9)

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.

Standard 10.3

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

Recommendation 10.3.1

Intravenous access should be established prior to evacuation.

Recommendation 10.3.2

When induced fetal demise is used, it should be provided through an evidence-based protocol.(10-16)

Recommendation 10.3.3

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)

Recommendation 10.3.4

Patients should be given anticipatory guidance on breast symptoms after later abortion or pregnancy loss.

Option 10.3.4.1

Cabergoline, 1mg orally x one dose may be used immediately after the procedure to reduce breast symptoms and lactation for those who want it.(18)

Standard 10.4

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 10.5

Appropriate dilation of the cervix must be obtained gently and gradually.(19, 20)

Recommendation 10.5.1

Osmotic dilators, misoprostol, mifepristone, transcervical catheter, and/or other cervical preparation agents should be used to facilitate adequate dilation.(21-25)

Recommendation 10.5.2

Local anesthesia should be used for pain management with osmotic dilator placement.(26, 27)

Recommendation 10.5.3

An evidence-based regimen should be used for dosage, timing, and route of misoprostol.(22-24, 28-32)

Option 10.5.0.1

Synthetic osmotic dilators or a foley/Cook catheter and/or misoprostol may be used for same-day cervical dilation.(25, 28, 30, 33)

Standard 10.6

All instruments entering the uterine cavity must be sterile.

Standard 10.7

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

Recommendation 10.7.1

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.(34-36)

Recommendation 10.7.2

Inhaled anesthesia should be avoided if possible due to the increased risk of hemorrhage.(37, 38)

Standard 10.8

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

Option 10.8.0.1

An intra- or paracervical prophylactic vasoconstrictor can be used to reduce blood loss.(39)

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.(40)

Induced fetal demise should be provided using an evidence-based regimen. A sample protocol for digoxin injection is available on the NAF members-only site at <u>https://members.prochoice.org</u>. Intraamniotic or intrafetal digoxin may be used.(41, 42) Intracardiac potassium chloride or lidocaine may also be used.(11, 16, 43) Injections may be done either transabdominally or transvaginally.(44, 45) Cord transection may also be used.(46)

Prophylactic use of methergine for prevention of postabortion hemorrhage is not recommended.(47) Prophylactic pitocin for procedures between 18-24 weeks gestation may be considered.(49)

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11. 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.

Standard 11.1

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

Standard 11.2

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 11.3

The patient must be appropriately evaluated and prepared.

Recommendation 11.3.1

Intravenous access should be established.

Recommendation 11.3.2

Patients should be given anticipatory guidance on breast symptoms after later abortion or pregnancy loss.

Option 11.3.2.1

Cabergoline, 1mg orally x one dose may be used immediately after the abortion to reduce breast symptoms and lactation for those who want it.(1)

Standard 11.4

Facilities must have a policy that addresses whether and when to induce fetal demise.

Recommendation 11.4.1

When induced fetal demise is used, it should be provided through a standard protocol.(2-9)

Standard 11.5

Evidence-based regimens of medication abortion must be used.

Recommendation 11.5.1

Mifepristone 200mg followed in 24 to 48 hours by repeat doses of misoprostol should be used, when available and feasible.(10-13)

Option 11.5.1.1 Simultaneous or short interval administration of mifepristone and repeat doses of misoprostol may also be used.(14)

Option 11.5.1.2 Repeat dosing of misoprostol may also be used alone.(15)

Option 11.5.1.3 Oxytocin may be used according to a protocol.

Option 11.5.1.4 Osmotic dilators may be useful at later gestations.(16-18)

Recommendation 11.5.2

Intraamniotic injection or instillation methods should be avoided as they are less effective and result in more complications than mifepristone-misoprostol or misoprostolalone regimens.(19)

Standard 11.6

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.

Standard 11.7

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

Standard 11.8

Access to surgical management or appropriate referral must be available if surgical intervention is required.

Standard 11.9

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: Evidence-based regimens for later medication abortion are difficult to compare. Mifepristone increases the efficacy and decreases the total time and doses needed for misoprostol to cause pregnancy expulsion. Misoprostol dosing can be repeated until expulsion with no limit on the number of doses. For abortion over 12 weeks LMP, the WHO recommends a regimen of mifepristone 200mg orally followed in one to two days by misoprostol, 400mcg buccally, vaginally, or sublingually every four hours until pregnancy expulsion.(20) The dosage of misoprostol may be adjusted as the pregnancy progresses or with previous cesarean section; however, when those adjustments need to be made is not well established. 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.(21) The risks should be balanced with alternative procedures for later abortion.

Caution should be used with osmotic dilators in the second trimester as they may prolong the induction time.(16-18)

Induced fetal demise should be provided using an evidence-based regimen. A sample protocol for digoxin injection is available on NAF's members-only site at <u>https://members.prochoice.org</u>. Intraamniotic or intrafetal digoxin may be used.(22) Intracardiac potassium chloride or lidocaine may also be used.(7-9) Injections may be done either transabdominally or transvaginally.(23)

Uterine curettage or aspiration should not routinely be performed.

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12. 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.

Implicit and explicit bias causes providers to undertreat pain for specific populations, including Black, Indigenous, and people of color, and people with substance use disorders.(1-3) All people seeking abortion care are entitled to adequate pain management.

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 for Gastrointestinal Endoscopy (ASGE), 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(4)

- 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. <u>Moderate Sedation/Analgesia</u> 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.

Standard 12.1

Pain control options must be discussed with the patient.

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

Standard 12.2

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 12.2.1

Documentation should include precautions relevant to transient mental impairment.

Option 12.2.0.1

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

Standard 12.3

Levels of sedation depend on the patient response, not the route of drug administration. Oral anxiolytics and analgesics given in combination can cause moderate sedation for some patients.

Standard 12.4

The amount of anesthesia given depends on the desired level of sedation and the individual patient response. Patient characteristics such as age, race, parity, body size, weight, or current or past substance use disorder, and use of medication for opioid use disorder should not be used to limit appropriate anesthesia and analgesia.

Standard 12.5

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

Recommendation 12.5.1

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 12.5.2

For patients receiving moderate sedation who are not at increased risk of aspiration, time from last meal should not limit access to abortion care.(5-7)

Recommendation 12.5.3

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.(8, 9)

Standard 12.6

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

Standard 12.7

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

Standard 12.8

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.(9, 10)

Standard 12.9

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 12.10

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

Recommendation 12.10.1

When more than minimal sedation is intended, intravenous access should be maintained at least until discharge criteria are met.

Standard 12.11

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

Standard 12.12

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

Recommendation 12.12.1

The patient should be checked frequently for verbal responsiveness.

Standard 12.13

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.(9)

Moderate Sedation

Standard 12.14

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.(11-13)

Recommendation 12.14.1

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.

Option 12.14.1.1

A regimen that includes ketamine may be used as an alternative or in conjunction with opioids for moderate sedation. Please see discussion for more information.(14)

| Drug | Usual initial dose | Max initial dose | Usual incremental Dose | Max incremental Dose |
|---|-----------------------|---------------------|------------------------------|----------------------------|
| Fentanyl | 50-100mcg | 200mcg | 50-100mcg | 100mcg |
| Midazolam | 1-3mg | 4mg | 1-2mg | 2mg |
| Ketamine (when used with fentanyl) | 10mg | 20mg | 10mg | 20mg |
| Ketamine (when used without fentanyl) | 20mg | 20mg | 10mg | 20mg |

Standard 12.15

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

Standard 12.16

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

Standard 12.17

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

Recommendation 12.17.1

For deep sedation and general anesthesia, the following should be monitored: continuous pulse oximetry, intermittent blood pressure, and respiration, either by measuring end-tidal CO₂ or clinical observation.

Recommendation 12.17.2

The capability to monitor temperature should be available.

Standard 12.18

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 12.19

The practitioner administering deep sedation or general anesthesia must adhere to established professional standards of care.(15)

Nitrous Oxide

Standard 12.20

N₂O must be self-administered by the patient or by a qualified anesthesia provider.

Recommendation 12.20.1

N₂O may be an alternative to local or oral sedation but is less effective for pain management than moderate intravenous sedation.(16, 17)

Standard 12.21

If not self-administered, the provision of N_2O must follow guidelines for patient monitoring for moderate sedation.

Standard 12.22

Equipment for the delivery of N_2O/O_2 must:

- 1) provide a concentration of N_2O of no more than 70% inspired;
- 2) provide a minimum of 30% O₂; and
- 3) be checked and calibrated regularly.

Recommendation 12.22.1

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

Recommendation 12.22.2

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

Recommendation 12.22.3

Due to the potential for occupational exposure, room or personnel monitoring for levels of N_2O should be conducted.

Emergency Equipment

Standard 12.23

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

Standard 12.24

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

Recommendation 12.24.1

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 12.25

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 12.25.1

A defibrillator should be available.

Discussion: The time of last food intake does not increase the risk of moderate sedation.(4-7)

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.

Ketamine offers an alternative or addition to opioid containing regimens for intravenous moderate sedation. Ketamine is effective in patients with opioid use disorder, allows

clinicians to use a lower dose of opioids in combined regimens, and has a reduced risk of respiratory depression.(14, 18) Ketamine, whether used alone or with an opioid, needs to be combined with a benzodiazepine to prevent adverse side effects, particularly dysphoria and hallucinations. When ketamine is used without an opioid, a higher or repeated dose of benzodiazepine may be required to prevent hallucinations.

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13. Post-Procedure Care

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

Standard 13.1

Patients who want contraception must receive their chosen method immediately following an abortion or appropriate referral should be made.

Recommendation 13.1.1

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 13.1.2

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 13.1.3

When desired by the patient, contraceptive implants should be initiated on the day of mifepristone administration for medication abortion.(7-10)

Option 13.1.3.1

Depot Medroxyprogesterone acetate (Depo-Provera®) may be given at the time of mifepristone with appropriate counseling.(10-12)

Recommendation 13.1.4

Emergency contraception should be discussed and either dispensed or prescribed to patients who want it.

Standard 13.2

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 13.3

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 13.3.1

A pulse oximeter with alarms should be used until the patient is alert and ambulatory.

Standard 13.4

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

Standard 13.5

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 13.6

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

Recommendation 13.6.1

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

Standard 13.7

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 13.8

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 13.9

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 13.9.1

Uterotonic agents should be given as indicated and not on a routine basis. When used, an evidence-based regimen should be followed.

Option 13.9.1.1

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 patient 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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14. 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 14.1

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

Recommendation 14.1.1 Evacuated uterine contents should be examined before the patient leaves the facility.

Recommendation 14.1.2

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

Option 14.1.2.1 Backlighting of tissue may be useful.

Option 14.1.2.2 Sending the evacuated uterine contents for additional pathological examination is not required.(1, 2)

Standard 14.2

In the first trimester, when insufficient tissue or incomplete products of conception are obtained, the patient must be reevaluated.

Recommendation 14.2.1

Re-aspiration, serial quantitative hCG, and/or ultrasonographic examination should be considered.(3-5)

Recommendation 14.2.2 Ectopic pregnancy should be considered.

Standard 14.3

After the first trimester, examination of the uterine contents must be performed to identify the placenta and all major fetal parts.

Recommendation 14.3.1

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

Recommendation 14.3.2

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 9 (Management of Pregnancy of Uncertain Location) may be useful.

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15. 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 15.1

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 15.1.1

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

Recommendation 15.1.2

Staff should review protocols annually.

Option 15.1.2.1 Annual drills of the emergency protocols are encouraged.

Recommendation 15.1.3

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.

Standard 15.2

All staff must know their appropriate roles in the management of medical emergencies.

Standard 15.3

Emergency supplies must be in known, appropriate locations and regularly updated.

Standard 15.4

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 15.4.1

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

Standard 15.5

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 15.6

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

Standard 15.7

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:
 - 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.

Recommendation 15.7.1

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:

- 1) uterine massage;
- 2) methylergonovine (Methergine);
- 3) oxytocin (Pitocin);
- 4) vasopressin (Vasostrict);
- 5) misoprostol (Cytotec);
- 6) carboprost tromethamine (Hemabate);

- 7) Tranexamic acid;(4)
- 8) intrauterine pressure using a Foley or Bakri balloon or vaginal pack; or
- 9) 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.(5-7) 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.(8, 9) Most perforations are midline and/or fundal in location.(10) If they occur before suction, these usually can be managed with observation and close follow-up.(9) 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.(11, 12) There may be more significant morbidity due to increased uterine blood flow and the use of larger grasping instruments.

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