Clinical Updates in Reproductive Health

2020

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Ipas works globally to improve access to safe abortion and contraception so that every woman and girl can determine her own future. Across Africa, Asia and Latin America, we work with partners to make safe abortion and contraception widely available, to connect women with vital information so they can access safe services, and to advocate for safe, legal abortion.

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Clinical Updates in Reproductive Health

2020

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LIST OF ABBREVIATIONS

ACOG – American College of Obstetricians and Gynecologists
CI – confidence interval
D&E – dilatation and evacuation
FIGO – International Federation of Gynecology and Obstetrics
GRADE - Grading of Recommendations Assessment, Development and Evaluation
hCG – human chorionic gonadatropin
IM - intramuscular
IU – international units
IUD – intrauterine device
IV – intravenous
Kg - kilogram
LMP – last menstrual period
Mcg – microgram
Mg – milligram
MVA – manual vacuum aspirator
mL – milliliter
MOOSE - Meta-analysis of Observational Studies in Epidemiology
NSAID – Nonsteroidal anti-inflammatory drug
PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCOG – Royal College of Obstetricians and Gynaecologists
RR – relative risk
SC - subcutaneous
WHO – World Health Organization

TABLE OF CONTENTS

4. Recommendations for abortion at or after 13 weeks gestation

5. Postabortion care

Appendices

INTRODUCTION

Ipas's *Clinical Updates in Reproductive Health* contain up-to-date, evidence-based clinical recommendations on comprehensive abortion care, with new topics and resources added regularly. The *Clinical Updates in Reproductive Health* provide concise, easy-to-read information about abortion care, combining the latest evidence with lessons learned from health professionals globally to produce relevant clinical recommendations.

Who should use this resource

First published in 2013, the *Clinical Updates in Reproductive Health* were designed originally as an up-to-date, evidence-based clinical resource for Ipas staff. Over time, the publication has also been of use to:

- **clinicians** providing abortion care
- **clinical and public health professionals** working on patient care protocols in public health systems and the private sector
- **safe abortion advocates and policymakers** creating laws and policies that fulfill women's and girls' right to health

What's new in this revision

In this edition of the *Clinical Updates in Reproductive Health,* you will find updated, evidence-based recommendations on more than 40 abortion care topics. During the 2020 update, we reviewed newly published literature related to use of prophylactic antibiotics for postabortion care, pain management for medical abortion, timing of home use of medical abortion, and prevention of postabortion hemorrhage and updated our recommendations accordingly. Additionally, we updated with supportive and informative data the sections for misoprostol-only abortions before 13 weeks, effects and techniques for inducing fetal demise, and new data for cervical preparation prior to dilatation and evacuation (D&E). We also clarifed that the literature supports the use of paracervical block during procedures for postabortion care. Finally, we added a recommendation for a new topic on management of uterine perforation.

The online *Clinical Updates* (www.ipas.org/clinicalupdates) contains the recommendations included in this manual along with easy-to-use drop-down menus to help readers navigate quickly to the information they need. Both online and print/PDF editions are also available in Spanish, French and Portuguese.

We have also updated a number of our clinical tools and job aids, which are drawn from the evidence and recommendations contained in the *Clinical Updates in Reproductive Health,* and these are also available online at www.ipas.org/clinicalupdates.

MAKING IPAS RECOMMENDATIONS

Ipas strives to integrate the best scientific evidence into our clinical programs. This section documents the methodology Ipas uses to make its clinical recommendations.

Using evidence to support recommendations

Clinical recommendations are based on relevant published, peer-reviewed evidence. For each clinical topic contained in the *Clinical Updates in Reproductive Health,* we conduct systematic reviews of the literature using a methodology drawn from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines (Moher, Liberati, Tetzlaff, Altman, & the PRISMA Group, 2009; Stroup, Berlin, & Morton, 2000).

Process for making recommendations

Ipas applies the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to its recommendation formation (Guyatt et al., 2008b). The GRADE system provides a framework to evaluate the quality of the available evidence, and to translate that evidence into a context-appropriate recommendation. For every recommendation in the *Clinical Updates,* both the quality of evidence and the strength of the recommendation based on that evidence are reported.

Quality of evidence

Sources of clinical evidence range from well-designed large clinical studies that have minimized bias to uncontrolled clinical observations, case series or reports. When there is no available evidence, expert opinion may be used. In the GRADE system, the quality of evidence related to a specific clinical topic is defined as both the extent to which one can be confident that an estimate of effect is correct, and the extent to which the available evidence relates to the specific context in which it is being applied (Guyatt et al., 2008a). When assessing the quality of evidence, the following criteria are considered (Guyatt et al., 2008a):

- study design
- study limitations and the risk of bias
- consistency of the results across available studies
- precision of the results (wide or narrow confidence intervals)
- applicability with respect to populations, interventions and settings where the proposed intervention may be used
- likelihood of publication bias

Quality of evidence determinations are reported as follows (Balshem et al., 2011):

- A **high** grade: we are very confident that the true effect lies close to the estimate of the effect.
- A **moderate** grade: we are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- A **low** grade: confidence in the effect estimate is limited. The true effect may be substantially different from the estimate.
- A **very low** grade: we have very little confidence in the estimate of the effect. The true effect is likely to be substantially different from the estimate.

For example, randomized trials are initially given a high grade, while observational studies are initially labeled as low-quality.

Strength of recommendation

Strength of recommendation is defined as the extent to which one can be confident that the desireable consequences of a recommendation outweigh its undesireable consequences (Andrews et al., 2013). Desirable effects include improved health outcomes, less burden for providers and health systems, and cost savings. Undesirable effects include harm to patients, inconvenience or hassle, and increased resource use.

- **Strong** recommendations are made when the desirable effects of a recommended intervention clearly outweigh the undesirable effects (Guyatt et al., 2008b). Most informed people would make the recommended choice for an intervention (Andrews et al., 2013).
- **Weak** recommendations are made when evidence suggests that desirable effects of a recommended intervention probably outweigh the undesirable effects, but there are

small benefits or benefits that may not be worth the costs (Guyatt et al., 2008b). While most informed people would choose the recommended course of action, a substantial number would not (Andrews et al., 2013).

Can you have a strong recommendation based on low-quality evidence?

Answer: Yes. There are many factors that influence the strength of a recommendation.

For example, although there is limited evidence about bimanual examination prior to uterine aspiration, several factors increase the strength of the recommendation that bimanual examination should be performed by the clinician who will perform the procedure: 1) the potential benefit to patients, 2) the low risk of harm associated with bimanual examination, and 3) its low cost as well as potential savings when complications are avoided. All or almost all providers and women, when informed of the balance between desireable and undesireable effects, would choose to include a bimanual examination before uterine procedures.

Maintaining the Clinical Updates

The *Clinical Updates* are revised annually. The "last reviewed" date for each topic indicates all relevant published literature up to that date has been considered and included where appropriate. New topics and proposed revisions to the document come from end-users, a regionally representative Clinical Updates Advisory Group, and observations made during routine quality monitoring of clinical services in Ipas-supported programs. The Lead Writer, Medical Editor and Medical Director review all proposed updates. New recommendations or substantially revised recommendations may undergo an internal peer review process. The revision process—including systematic review of literature, documentation of the body of evidence, generation and revision of recommendations, and resultant changes to the *Clinical Updates in Reproductive Health*—is documented and archived.

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SUMMARY OF RECOMMENDED MEDICAL ABORTION REGIMENS

Medical abortion with mifepristone and misoprostol

- **Up to 10 weeks gestation (70 days since last menstrual period (LMP)):**
  - Mifepristone 200mg orally
  - Misoprostol 800mcg buccally, sublingually or vaginally 1-2 days after mifepristone
- **10-13 weeks gestation:**
  - Mifepristone 200mg orally
  - Misoprostol 600mcg sublingually or 800mcg vaginally 1-2 days after mifepristone, then misoprostol 400mcg sublingually or vaginally every three hours until expulsion
  - Alternatively, mifepristone 200mg orally followed 1-2 days later by misoprostol 800mcg buccally, sublingually or vaginally may be used. The dose of misoprostol may be repeated to achieve abortion success.
- **At or after 13 weeks gestation (13-24 weeks):**
  - Mifepristone 200mg orally
  - Misoprostol 400mcg buccally, sublingually or vaginally 1-2 days after mifepristone, then every three hours until fetal and placental expulsion
  - If the woman is stable and it is convenient for her to do so, providers should allow her at least four hours after fetal expulsion to expel the placenta.

Medical abortion with misoprostol only

- **Before 13 weeks gestation:**
  - Misoprostol 800mcg buccally, sublingually or vaginally every three hours until expulsion
- **At or after 13 weeks gestation (13-24 weeks):**
  - Misoprostol 400mcg sublingually or vaginally every three hours until fetal and placental expulsion. Vaginal dosing is more effective than sublingual dosing for nulliparous women
  - If the woman is stable and it is convenient for her to do so, providers should allow her at least four hours after fetal expulsion to expel the placenta

Medical treatment for incomplete abortion, missed abortion or intrauterine fetal demise (postabortion care)

- **Less than 13 weeks uterine size:**
  - Incomplete abortion:
    - Misoprostol 600mcg orally in a single dose or 400mcg in a single dose sublingually or, in the absence of vaginal bleeding, vaginally
  - Missed abortion:
    - Misoprostol 600mcg sublingually or, in the absence of vaginal bleeding, 800mcg vaginally every 3 hours until expulsion (generally 1-3 doses)

    - Where available, add pretreatment with mifepristone 200mg orally 1-2 days before misoprostol

- **13 weeks or larger uterine size:**
  - Incomplete abortion:
    - Misoprostol 400mcg buccally, sublingually or, in the absence of vaginal bleeding, vaginally every three hours until expulsion
  - Intrauterine fetal demise (up to 24 weeks):
    - Misoprostol 400mcg sublingually or, in the absence of vaginal bleeding, vaginally every 4-6 hours until expulsion. Where available, add pretreatment with mifepristone 200mg orally 1-2 days before misoprostol.

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UTERINE EVACUATION: REPLACE SHARP CURETTAGE WITH ASPIRATION OR MEDICATIONS

1.2

Recommendation

- Vacuum aspiration or medical abortion should replace sharp curettage (also known as dilatation and curettage [D&C]) for the treatment of abortion and postabortion care.

Strength of recommendation

Strong

Quality of evidence

Moderate

Last reviewed: December 2, 2019

The World Health Organization (WHO) and the International Federation of Gynecology and Obstetrics (FIGO) state that vacuum aspiration or medication regimens should replace sharp curettage (FIGO, 2011; WHO, 2012). In places where no uterine evacuation services exist, vacuum aspiration and medical abortion should be introduced.

A 2010 Cochrane review showed that vacuum aspiration is as effective as sharp curettage in treating incomplete abortion while reducing procedure time, blood loss and pain (Tuncalp, Gulmezoglu, & Souza, 2010). In a retrospective case series of 80,437 women seeking induced abortion, vacuum aspiration was associated with less than half the rate of major and minor complications compared to sharp curettage (Grimes, Schulz, Cates Jr, & Tyler Jr., 1976). A more recent series, including more than 100,000 abortion procedures, found that sharp curettage performed alone or in combination with vacuum aspiration was significantly more likely to be associated with complications, particularly incomplete abortion, than vacuum aspiration without curettage (Sekiguchi, Ikeda, Okamura, & Nakai, 2015).

Multiple studies on induced abortion and postabortion care have shown that because vacuum aspiration can be performed in an outpatient setting by physicians or midlevel providers without general anaesthesia, the costs to both the health system and women are significantly less (Benson, Okoh, KrennHrubec, Lazzarino, & Johnston, 2012; Choobun, Khanuengkitkong, & Pinjaroen, 2012; Farooq, Javed, Mumtaz, & Naveed, 2011; Johnston, Akhter, & Oliveras, 2012).

Although no trials exist comparing sharp curettage to medical management of induced, incomplete, or missed abortion, the safety and tolerability of medical regimens for uterine evacuation are well documented and appear as effective as vacuum aspiration in the management of incomplete abortion (Kulier et al., 2011; Neilson, Gyte, Hickey, Vazquez, & Dou, 2013).

The use of sharp curettage to manage incomplete or missed abortion may be associated with Asherman's syndrome (intrauterine adhesions). A retrospective review from one ter-

tiary care center reported on 884 women who underwent sharp curettage, manual vacuum aspiration or misoprostol for early pregnancy failure (Gilman Barber, Rhone, & Fluker, 2014). In follow-up, 1.2% of women managed with sharp curettage were found to have Asherman's syndrome (6 out of 483 women), while no cases were found in the 401 women managed by manual vacuum aspiration or misoprostol.

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PROPHYLACTIC ANTIBIOTICS FOR VACUUM ASPIRATION AND DILATATION AND EVACUATION

1.3

Recommendation

- Administer prophylactic antibiotics prior to vacuum aspiration and dilatation and evacuation (D&E).
- Where antibiotics are unavailable, uterine evacuation procedures should still be offered.
- Administer treatment doses of antibiotics to those with signs or symptoms of sexually transmitted infection; partners of individuals with sexually transmitted infections also require treatment. Treatment should not delay uterine evacuation.

Strength of recommendation

Strong

Quality of evidence

- Vacuum aspiration: High
- D&E: Very low
- Incomplete or missed abortion: Moderate

Last reviewed: December 2, 2019

Risk of infection

When objective measures are used to diagnose postabortion infection following vacuum aspiration performed before 13 weeks gestation, the infection rate ranges from 0.01-2.44% (Achilles & Reeves, 2011). In studies performed in the United States before routine use of antibiotic prophylaxis, reported rates of infection following D&E ranged from 0.8-1.6% (Achilles & Reeves, 2011).

Evidence for antibiotic prophylaxis

A Cochrane meta-analysis of 19 randomized controlled clinical trials showed that administration of prophylactic antibiotics at the time of vacuum aspiration for induced abortion before 13 weeks gestation significantly reduces the risk of infection (Low, Mueller, Van Vliet, & Kapp, 2012). Evidence to support use of prophylactic antibiotics before D&E is limited; however, because of the demonstrated benefit of prophylactic antibiotics before vacuum aspiration, the World Health Organization (WHO, 2014), Society of Family Planning (Achilles & Reeves, 2011), American College of Obstetricians and Gynecologists (ACOG, 2018) and Royal College of Obstetricians and Gynaecologists (RCOG, 2015) recommend prophylactic antibiotics for all women undergoing vacuum aspiration or D&E.

Five randomized trials have examined the use of prophylactic antibiotics before vacuum aspiration or curettage for incomplete or missed abortion (postabortion care) (Lissauer et al., 2019; Prieto, Eriksen, & Blanco, 1995; Ramin et al., 1995; Seeras, 1989; Titipant & Cherd-

choogieat, 2012). One large, multicountry randomized trial that examined currently recommended prophylactic antibiotics found that fewer women in the prophylactic antibiotic group developed postabortion infection than those in the placebo group when strict, international diagnostic criteria for pelvic infection were used (Lissauer et al., 2019; Serwadda, 2019). A secondary analysis of this study found that antibiotic prophylaxis is cost-effective, estimating that routine prophylaxis could save $8.5 million across the two regions of sub-Saharan Africa and South Asia (Goranitis et al., 2019). The four other studies found no statistically significant difference in postabortion infection rates between the groups that received antibiotic prophylaxis and those that received placebo or no treatment; however, these studies all suffered from serious methodologic flaws including small size, inadequate antibiotic dose or poor adherence to study protocol (Prieto, Eriksen, & Blanco, 1995; Ramin et al., 1995; Seeras, 1989; Titipant & Cherdchoogieat, 2012).

Giving prophylactic antibiotics is more effective than screening all women and treating only those with evidence of infection (Levallois & Rioux, 1988). The inability to provide antibiotics should not limit access to abortion (WHO, 2014), as the overall risk of infection with abortion procedures is very low.

Regimen

Many studies have examined antibiotic regimens for prophylaxis before abortion, but the ideal antibiotic, dose and timing has not been established (Achilles & Reeves, 2011; Low et al., 2012). Tetracyclines (doxycycline) and nitroimidazoles (metronidazole and tinidazole) are commonly used because of their efficacy, ease of oral administration, low cost and low risk of allergic reactions (Achilles & Reeves, 2011; O'Connell, Jones, Lichtenberg, & Paul, 2008). Although studies of abortion are limited (Caruso et al., 2008), evidence from the obstetric (Costantine et al., 2008), gynecologic (Mittendorf et al., 1993) and general surgery (Classen et al., 1992) literature supports the practice of giving antibiotics before the procedure to decrease the risk of infection. Antibiotic regimens do not need to be continued after the abortion procedure (Achilles & Reeves, 2011; Caruso, et al., 2008; Levallois & Rioux, 1988; Lichtenberg & Shott, 2003).

The following table lists regimens recommended by professional organizations based on clinical evidence and expert opinion.

Table 1.3.1. Propylactic antibiotic regimens

COMMON REGIMENS	RECOMMENDER
Doxycycline 200mg orally before the procedure *or* Azithromycin 500mg orally before the procedure *or* Metronidazole 500mg orally before the procedure	Planned Parenthood Federation of America (PPFA, 2016)
Doxycycline 200mg orally no more than 2 hours before the procedure *or* Azithromycin 500mg orally no more than 2 hours before the procedure	Royal College of Obstetricians and Gynaecologists (RCOG, 2015)
Doxycycline 200mg orally within 1 hour before procedure	American College of Obstetricians and Gynecologists (ACOG, 2018)

Antibiotics with osmotic dilators

Although not well studied, cervical preparation with osmotic dilators does not appear to increase the risk of infection (Fox & Krajewski, 2014; Jonasson, Larsson, Bygdeman, & Forsum, 1989). Some providers start antibiotics at the time of osmotic dilator placement, but there are no studies evaluating the benefit of this practice (White et al., 2018).

Therapeutic antibiotics

Women at high risk should be screened for sexually transmitted infections in addition to receiving prophylactic antibiotics. Women who have signs and symptoms of sexually transmitted infection should receive abortion services without delay and appropriate antibiotic treatment according to evidence-based regimens (WHO, 2014; WHO, 2005). Partners of women with sexually transmitted infections also require treatment (WHO, 2016).

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PROPHYLACTIC ANTIBIOTICS FOR MEDICAL ABORTION

1.4

Recommendation

- Routine use of antibiotics is not recommended for women undergoing medical abortion.
- Administer treatment doses of antibiotics to those with signs or symptoms of sexually transmitted infection. Partners of individuals with sexually transmitted infections also require treatment. Treatment should not delay medical abortion

Strength of recommendation

Weak

Quality of evidence

Very low

Last reviewed: December 2, 2019

Risk of infection

The overall risk of infection found in prospective studies of medical abortion using mifepristone and a prostaglandin before 13 weeks gestation is approximately 0.01-0.5% (Achilles & Reeves, 2011; Chen & Creinin, 2015; Upadhyay et. al, 2015). Serious infections requiring hospitalization are very uncommon, with rates in large retrospective studies from the United States ranging from 0.03% to 0.09% (Fjerstad, Trussell, Sivin, Lichtenberg, & Cullins, 2009; Henderson, Hwang, Harper, & Stewart, 2005).

Infection rates for medical abortion at or after 13 weeks gestation are more difficult to determine as fever is a common side effect of repeated doses of prostaglandin. Available data report infection rates of 1-3% following medical abortion at or after 13 weeks gestation (Achilles & Reeves, 2011).

Infectious mortality

Nine cases of fatal Clostridium sepsis occurred in North America following mifepristone and misoprostol medical abortion before 13 weeks gestation (Cohen et al., 2007; Fischer et al., 2005; Meites, Zane, & Gould, 2010; Sinave, Le Templier, Blouin, Leveille, & Deland, 2002). One death from group A streptococcus has been reported in Australia and one death from Clostridium sordelli has been reported in Portugal (Reis et al., 2011) in women who used mifepristone and misoprostol. The overall mortality rate from infection related to medical abortion remains very low at 0.58 per 100,000 medical abortions (Meites et al., 2010).

Prophylactic antibiotics

There have been no randomized controlled trials examining the effect of antibiotic prophylaxis on medical abortion outcomes (Achilles & Reeves, 2011; Low, Mueller, Van Vliet, & Kapp, 2012). Given the large number of women who would need to take antibiotics to

prevent a single infection, coupled with the expense and side effects of antibiotics, the American College of Obstetricians and Gynecologists (2014), the Society of Family Planning (Achilles & Reeves, 2011), the Royal College of Obstetricians and Gynaecologists (2015) and the World Health Organization (WHO, 2014) do not recommend routine antibiotic use prior to medical abortion.

Therapeutic antibiotics

Women at high risk should be screened for sexually transmitted infections. Women who have signs and symptoms of sexually transmitted infection should be provided abortion services without delay and receive appropriate antibiotic treatment according to evidence-based regimens (WHO, 2014; WHO, 2005). Partners of women with sexually transmitted infections also require treatment (WHO, 2016).

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1.5 MEDICAL ABORTION CONTRAINDICATIONS AND PRECAUTIONS

Recommendation

	MIFEPRISTONE AND MISOPROSTOL REGIMEN	MISOPROSTOL-ONLY REGIMEN
Contraindications	• Previous allergic reaction to mifepristone or misoprostol • Known or suspected ectopic pregnancy • Inherited porphyria • Chronic adrenal failure	• Previous allergic reaction to misoprostol • Known or suspected ectopic pregnancy
Precautions	• Intrauterine device (IUD) in place • Serious/unstable health problems, including but not limited to hemorrhagic disorders, heart disease and severe anemia • Severe uncontrolled asthma or long-term corticosteroid therapy	• IUD in place • Serious/unstable health problems, including but not limited to hemorrhagic disorders, heart disease and severe anemia

Strength of recommendation

Weak

Quality of evidence

Graded for each specific contraindication or precaution below

Last reviewed: December 5, 2019

Definitions

Contraindications: If a woman has any of these specific conditions, she should not be offered medical abortion with the specified regimen. Vacuum aspiration, dilatation and evacuation or treatment for ectopic pregnancy should be offered, as appropriate.

Precautions: If a woman has any of these specific conditions, medical abortion with the specified regimen may incur higher risks than normal. The risks, benefits and alternatives to medical abortion must be considered. Medical abortion provision to women with these conditions may require a higher degree of clinical judgment, skill and monitoring. Referral to a higher-level facility or alternative treatment may be appropriate.

Contraindications

Previous allergic reaction to one of the drugs involved: Allergic reactions have been reported after use of mifepristone and misoprostol (Bene et al., 2014; Cruz et al., 2009;

Hauseknecht, 2003; Sahraei, Mirabzadeh, & Eshraghi, 2016; Schoen, Campbell, Maratas, & Cheung, 2014; Zhang, Qian, Hong, & Lu, 2019). *Quality of evidence: High*

Known or suspected ectopic pregnancy: Mifepristone and misoprostol do not treat ectopic pregnancy and use of the medications may delay diagnosis and treatment of this life-threatening condition. *Quality of evidence: High*

Inherited porphyria: Porphyrias are rare metabolic disorders in which genetic mutations alter the body's generation of heme. Theoretically, mifepristone could exacerbate the manifestation of porphyria (Ventura, Cappellini, & Rochi, 2009). *Quality of evidence: Very low. No human studies exist, but animal models exhibit the effect of mifepristone* (Cable, Pepe, Donohue, Lambrecht, & Bonkovsky, 1994).

Chronic adrenal failure: Mifepristone is a glucocorticoid receptor antagonist (Spitz & Bardin, 1993). Mifepristone blocks negative feedback mechanisms that control cortisol secretion. In women with adrenal insufficiency on long-term corticosteroid therapy, mifepristone exposure may exacerbate the underlying condition (Sitruk-Ware & Spitz, 2003). *Quality of evidence: Very low. There are no data on mifepristone use in pregnant women with adrenal insufficiency, but there is experimental and animal data to support the recommendation.*

Precautions

IUD in place: A woman who is pregnant with an IUD is at significantly elevated risk of ectopic pregnancy (Barnhart, 2009) and must be evaluated for the presence of ectopic pregnancy. If the pregnancy is found to be intrauterine, the IUD should be removed before starting medical abortion due to the theoretical risk of uterine perforation from contractions during medical abortion and the potential risk of infection (Danco, 2016; Davey, 2006). *Quality of evidence: Very low. There are no studies to verify whether having an IUD in place poses actual risks during medical abortion.*

Serious medical problems: Medical abortion studies generally exclude women with severe anemia or serious medical problems (Christin-Maitre, Bouchard, & Spitz, 2000; Sitruk-Ware & Spitz, 2003). One case report (Hou, 2016) documents successful medical abortion in a patient with mild hemophilia; this patient received specialized, additional medication to minimize bleeding risk. Three case reports document misoprostol-induced acute coronary artery vasospasm, which in one case required coronary artery stent placement (Illa, Bennasar, Berge, Font, & Palacio, 2010; Mazhar, Sultana, & Akram, 2018; Munoz-Franco, Lacunza-Ruiz, Vazquez-Andres, & Rodriguez-Hernandez, 2019). Whether to provide medical abortion to women with medical conditions will depend on clinical judgment, monitoring and options available for safe abortion care. *Quality of evidence: Very low*

Severe uncontrolled asthma or long-term corticosteroid therapy: Mifepristone is a glucocorticoid receptor antagonist (Spitz & Bardin, 1993). Mifepristone blocks negative endocrine feedback mechanisms that control cortisol secretion. In women on long-term corticosteroid therapy for severe or uncontrolled asthma, mifepristone may exacerbate the underlying condition (Sitruk-Ware & Spitz, 2003). There are no direct studies of medical abortion among women on corticosteroid treatment, but one review suggested that increasing the dose of the steroid medications can counteract the cortisol blunting effect of mifepristone (Davey, 2006).

Medical abortion in asthmatic women requiring systemic corticosteroids has not been studied as giving mifepristone to such women risks asthma exacerbation. One review suggests using a high level of caution when giving mifepristone to such women and only doing so if the asthma is well-controlled (Davey, 2006). The glucocorticoid dose should be increased

for several days before and after mifepristone. Other experts recommend that women with severe, poorly controlled asthma who are on long-term corticosteroids not take mifepristone due to the life-threatening nature of acute asthma exacerbation (Christin-Maitre et al., 2000; Creinin & Gemzell Danielsson, 2009; Sitruk-Ware, 2006).

Inhaled corticosteroids for asthma are not systemically absorbed and are not a contraindication to mifepristone. Some experts recommend that mifepristone and misoprostol should be available to women with asthma who are not on long-term systemic steroids (Creinin & Gemzell Danielsson, 2009). *Quality of evidence: Very low*

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1.6 MISOPROSTOL PRODUCT QUALITY

Recommendation

- Providers should track medical abortion success rates to help ensure they are using an effective misoprostol product.
- Purchase misoprostol in double-aluminum blister packs, and keep the misoprostol in its original packaging; check the integrity of packaging before use. Avoid purchasing polyvinyl chloride [PVC] or polyvinylidene chloride [PVDC]/aluminum blister packs.
- Store misoprostol in a cool, dry place.

Strength of recommendation

Strong

Quality of evidence

Low

Last reviewed: December 5, 2019

Manufacture of misoprostol

Good Manufacturing Practice is a system for ensuring medications are consistently produced according to quality standards (World Health Organization [WHO], 2014). There are at least 30-40 manufacturers of misoprostol worldwide, and some manufacturers subcontract production of the drug, which makes the enforcement of Good Manufacturing Practice and the assurance of quality across all brands difficult (Hall & Tagontong, 2016). Misoprostol brands approved by the European Union or the United States Food and Drug Administration conform to Good Manufacturing Practice and are of high quality.

Exposure to heat and humidity during manufacturing, packaging, shipping or storage may compromise the quality of misoprostol (Cayman Chemical, 2012). Degradation decreases the effectiveness of misoprostol, leading to decreased success rates of medical abortion and unsuccessful treatment of incomplete abortion and postpartum hemorrhage.

A 2016 study analyzed 215 misoprostol samples from countries all over the world (Hall & Tagontong, 2016). When samples were tested for content and purity, 5% contained more misoprostol than expected (110-121% of labeled content, to allow for degradation), 55% were within specification (90-100% of labeled content), and 40% were below specification (less than 90% of labeled content). Of the 85 samples that were below specification, 14 contained no misoprostol at all. A 2018 study tested the quality of 166 misoprostol samples obtained from a variety of health care providers across Nigeria, ranging from federal medical centers and state hospitals to patent and proprietary medicine vendors (Anyakora et al., 2018). Although all samples passed a visual inspection, 34% did not meet specification as defined above.

Three factors influence misoprostol integrity:

- impact of moisture at all stages from production to patient
- manufacture and quality of the active pharmaceutical ingredient
- packaging

Clinic use and storage

Even misoprostol manufactured in high-quality conditions and packaged well can degrade if it is shipped or stored in conditions that expose it to heat or humidity for prolonged periods of time. Misoprostol is stable when stored properly in room temperature conditions (25°C and 60% humidity). There have not been large field studies on the stability of misoprostol when stored in tropical climates, but laboratory studies have shown that misoprostol is less stable when exposed to moisture or heat (Chu, Wang, Pang, & Rogers, 2007; WHO, 2009).

Misoprostol packaged in double-aluminum blister packs (aluminum on top and bottom) retains the most active ingredient; after one year, 100% of pills packaged in plastic and single-aluminum blister packs will degrade, compared to 28% of misoprostol packaged in double-aluminum blister packs (Hall & Tagontong, 2016). The integrity of the double-aluminum blister packs must be preserved to maintain drug potency. If the packaging is inadvertently opened or perforated, even in normal room-temperature conditions, the tablets' potency degrades within 48 hours and continues to degrade over time (Berard et al., 2014).

Quality assurance

If providers notice a decrease in medical abortion success rates from expected baseline, they should stop using the current lot of misoprostol and start a new lot. Providers should contact the pill vendor or manufacturer to ensure that there are no recalls of the affected lot. Providers should consult the Medical Abortion Commodities Database (www.medab.org) to assess the quality of products available in their setting. In some cases, providers may need to consult with one another to determine which local misoprostol brands are most effective. Store misoprostol in dry conditions at temperatures at or below 25°C (77°F) (Pfizer, 2016).

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PAIN MANAGEMENT FOR MEDICAL ABORTION BEFORE 13 WEEKS GESTATION

2.1

Recommendation

- Offer pain medication to all women undergoing medical abortion.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended either prophylactically or at the time cramping begins.
- Non-pharmacologic pain management measures may be helpful.
- Narcotic analgesics have not been demonstrated to be effective in relieving pain during the medical abortion process and are not recommended for routine use.
- Paracetamol should not be used unless an allergy or contraindication to NSAIDs exists.

Strength of recommendation

Strong

Quality of evidence

Low

Last reviewed: January 13, 2020

Pain during medical abortion before 13 weeks gestation

Pain is the most commonly reported side effect of medical abortion (Fiala et al., 2014). In one study of 6,755 women using medical abortion up to 63 days gestation, 78.4% reported moderate or severe pain and cramping (Goldstone, Michelson, & Williamson, 2012). Similarly, a 2006 systematic review of five large British and American case series of analgesia use during medical abortion concluded that 75% of women experience pain severe enough to require narcotic analgesia (Penney, 2006). A qualitative study of women's experience with medical abortion pain in Nepal, South Africa and Vietnam found that women described pain as stronger than what they experienced during menstruation and manifested in four distinct patterns: minimal or no pain; brief intense pain, typically right before expulsion; intermittent pain, similar to contractions; and constant pain for one or several hours (Grossman et al., 2019). Pain typically peaks 2.5 to 4 hours after misoprostol use and lasts around one hour (Colwill et al., 2019). Patient characteristics associated with more pain include increasing gestational age, younger patient age, nulliparity, no previous vaginal deliveries, and history of dysmenorrhea (Suhonen, Tikka, Kivinen, & Kauppila, 2011; Teal, Dempsey-Fanning, & Westhoff, 2007; Westhoff, Dasmahapatra, Winikoff, & Clarke, 2000).

There are few trials assessing effectiveness of pain management strategies during medical abortion before 13 weeks gestation. Neither pain nor its treatment are systematically reported in clinical trials of medical abortion; where these data are reported, multiple regimens and treatment protocols have been used, rendering them difficult to compare (Fiala et al., 2014; Fiala et al, 2019; Jackson & Kapp, 2011).

Medications for pain management

Two small randomized controlled trials indicate that ibuprofen is more effective than placebo (Avraham, Gat, Duvdevani, Haas, & Frenkel, 2012) or acetaminophen (Livshits et al., 2009) in relieving medical abortion pain in women with pregnancies of less than seven weeks gestation. Pre-treatment with ibuprofen is no better for pain management than treatment once cramping starts (Raymond et al., 2013). In women with pregnancies up to 10 weeks gestation, one randomized controlled trial found that pregabalin (a gamma-aminobutyric acid analog) did not decrease maximum pain scores when taken at the time of misoprostol administration; however, women who received pregabalin were less likely to require ibuprofen or narcotic pain medication and more likely to report satisfaction with analgesia than women who received the placebo (Friedlander et al., 2018). One randomized trial found no difference in the amount or duration of pain experienced by women receiving an oral opioid medication (oxycodone) to manage medical abortion pain, compared to placebo (Colwill et al., 2019). Study authors concluded that while providing routine opioid medications is unnecessary, it is reasonable to provide four or fewer oxycodone tablets to women who request them.

Non-pharmacologic pain management

There are no comparative trials evaluating the benefit of non-pharmacologic pain management strategies for medical abortion before 13 weeks gestation. However, experts recommend adjunctive non-pharmacologic measures to improve women's comfort during a medical abortion, including thorough education about expected pain and bleeding (Teal, Dempsey-Fanning, & Westhoff, 2007), a supportive environment and application of a heating pad or hot water bottle to the lower abdomen (Akin, et al., 2001). These modalities are to be employed in addition to—not as substitutes for—pain medications.

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2.2 PAIN MANAGEMENT FOR MEDICAL ABORTION AT OR AFTER 13 WEEKS GESTATION

Recommendation:

- Offer pain medication to all women undergoing medical abortion.
- Nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended and should be initiated with misoprostol.
- Narcotic analgesics and anxiolytics should be offered in addition to NSAIDs.
- Non-pharmacologic pain management measures may be helpful.
- Regional anesthesia and patient-controlled anesthesia may be offered where available.

Strength of recommendation

Strong

Quality of evidence

Very Low

Last reviewed: December 5, 2019

Pain during medical abortion at or after 13 weeks gestation

In multiple cohort studies of medical abortion using prostaglandin E1 analogues (misoprostol, gemeprost) at or after 13 weeks gestation, most women required pain medication (Ashok, Templeton, Wagaarachchi, & Flett, 2004; Gemzell-Danielsson & Östlund, 2000; Hamoda, Ashok, Flett, & Templeton, 2004; Rose, Shand, & Simmons, 2006). Advanced gestational age, higher number of misoprostol doses and longer induction-to-abortion interval are associated with increased pain during medical abortion (Hamoda et al., 2004; Louie et al., 2017). Pain rarely starts after taking mifepristone. Cramping pain generally starts after initiating misoprostol and typically peaks with expulsion (Mentula, Kalso, & Heikinheimo, 2014).

Medications for pain management

Little evidence exists regarding the optimal pain medication regimen for medical abortion at or after 13 weeks gestation (Jackson & Kapp, 2011). One randomized trial of 74 women at or after 13 weeks gestation undergoing abortion with mifepristone and misoprostol prophylactically treated patients with either an NSAID (diclofenac) or with paracetamol plus codeine at the time of misoprostol administration. There was no difference in reported pain between the two groups, but NSAID pretreatment reduced the need for subsequent intravenous opiates (Fiala, Swahn, Stephansson, & Gemzell-Danielsson, 2005). A second trial randomized 54 women undergoing abortion between 14-24 weeks gestation to receive the NSAID celecoxib or a placebo at the time of misoprostol administration. Women in the NSAID group had significantly lower pain scores at the time of abortion; however, nearly half of women in

both groups reported severe pain and there was no difference in use of additional analgesia between the two groups (Tintara, Voradithi, & Choobun, 2018).

In the largest available cohort study, 1,002 women at or after 13 weeks gestation undergoing abortion with mifepristone and misoprostol were offered a combination of oral and parenteral narcotic analgesics and NSAIDs to manage pain (Ashok et al., 2004). Study authors reported the proportion of women who used no analgesia (18%), and those who used paracetamol plus dihydrocodone (70%), parenteral morphine (7%) or NSAIDs (5%) for pain relief; women's pain or satisfaction with pain management was not reported. Ipas recommends a combination regimen involving prophylactic NSAIDs given at the time of misoprostol, plus oral and/or parenteral narcotic analgesics (Edelman & Mark, 2017). Regional (epidural) and patient-controlled anesthesia are safe and effective methods of pain management. They may be offered if the requisite personnel, monitoring and equipment are available, (Maggiore et al., 2016;Smith et al., 2016).

Two small studies examining use of paracervical block during medical abortion at or after 13 weeks gestation found no improvement in women's pain with this modality (Andersson, Benson, Christensson, & Gemzell-Danielsson, 2016; Winkler, Wolters, Funk, & Rath, 1997).

Non-pharmacologic pain management

There are no comparative trials evaluating the benefit of non-pharmacologic pain management strategies for medical abortion at or after 13 weeks gestation. However, experts recommend adjunctive non-pharmacologic measures to improve women's comfort during a medical abortion, including thorough education about expected pain and bleeding, a supportive environment and application of a heating pad or hot water bottle to the lower abdomen (Akin et al., 2001). These modalities are to be employed in addition to—not as substitutes for—pain medications.

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PAIN MANAGEMENT FOR VACUUM ASPIRATION

2.3

Recommendation

- A combination of paracervical block and preprocedure nonsteroidal anti-inflammatory drugs (NSAIDs) for pain management is recommended for all women.
- Additional measures such as narcotic analgesics, anxiolytics and non-pharmacologic pain management measures may be helpful.
- Intravenous sedation, where available, may be offered.
- Paracetamol is not effective for vacuum aspiration pain management.
- General anesthesia is not routinely recommended for vacuum aspiration pain management.

Strength of recommendation

Strong

Quality of evidence

Moderate

Last reviewed: December 6, 2019

Pain during vacuum aspiration

Most women undergoing vacuum aspiration will experience pain (Borgatta & Nickinovich, 1997). Preprocedure depression or emotional distress, or gestational age beyond 10 weeks, are associated with more pain during uterine aspiration (Allen, Kumar, Fitzmaurice, Lifford, & Goldberg, 2006; Belanger, Melzack, & Lauzon, 1989; Duros et al., 2018), while having a prior vaginal delivery is associated with less pain (Borgatta & Nickinovich, 1997). Clinicians consistently underestimate the amount of pain women experience during abortion (Oviedo, Ohly, Guerrero, & Castano, 2018; Singh et al., 2008; Tschann, Salcedo, Soon, & Kaneshiro, 2018).

Methods of pain management

For vacuum aspiration before 13 weeks gestation, a combination of paracervical block with local anesthesia, analgesics, and non-pharmacologic measures typically provides pain relief for most women (World Health Organization, 2014; Renner, Jensen, Nichols, & Edelman, 2010). Intravenous sedation may also be offered.

Local anesthesia

A paracervical block given before dilating the cervix has been shown to decrease pain with dilation and uterine aspiration (Acmaz, Aksoy, Ozoglu, Aksoy, & Albayrak, 2013; Renner, Nichols, Jensen, Li, & Edelman, 2012; Renner et al., 2016). Paracervical block is a low-risk procedure that can be safely performed by physicians and midlevel providers (Warriner et al., 2006). For further information, see section 2.5 Paracervical block.

Medications

Two small studies examining use of oral NSAIDs alone for vacuum aspiration pain found no benefit (Acmaz et al., 2013; Li, Wong, Chan, & Ho, 2003). However, pre-procedure treatment with NSAIDs was found to decrease pain during and after the procedure in studies where women also received paracervical block for pain relief (Renner et al., 2010; Romero, Turok, & Gilliam, 2008; Suprapto & Reed, 1984; Wiebe & Rawling, 1995); both oral and intramuscular NSAIDs are effective (Braaten, Hurwitz, Fortin & Goldberg, 2013). There are no studies assessing the additional benefit of NSAIDs when moderate intravenous sedation is used for pain relief; based on findings from three small randomized trials, it is unclear if NSAIDs provide additional benefit when deeper levels of intravenous sedation are used (Khazin et al., 2011; Lowenstein et al., 2006; Roche, Li, James, Fechner, & Tilak, 2012).

The benefit of narcotic analgesics in alleviating vacuum aspiration pain is unclear. In one randomized controlled trial, the addition of oral hydrocodone-acetaminophen to a pain management regimen of paracervical block, ibuprofen and lorazepam did not improve pain during uterine aspiration when compared to placebo (Micks et al., 2012). In another randomized trial, the addition of intravenous fentanyl to the same pain management regimen significantly improved procedural pain (Rawling & Weibe, 2001). Two randomized trials showed that oral and rectal NSAIDs are more effective than tramadol in alleviating postprocedure pain (Lowenstein et al., 2006; Romero et al., 2008); however, a third randomized trial showed that rectal tramadol was more effective than NSAIDs (Khazin et al., 2011).

Anxiolytics such as lorazepam or midazolam decrease anxiety related to the procedure and cause amnesia for some women, but do not affect pain scores (Allen, et al., 2006; Bayer et al., 2015; Wiebe, Podhradsky, & Dijak, 2003).

Only one study has assessed effectiveness of pretreatment with paracetamol on pain during uterine aspiration performed without paracervical block, finding no difference between the paracetamol group and control group (Acmaz et al., 2013). In two studies where women also received deep sedation or general anesthesia, paracetamol did not improve post-procedure pain (Cade & Ashley, 1993; Lowenstein et al., 2006).

One randomized trial compared the effect of preprocedure gabapentin to placebo in women who also received oral lorazepam, ibuprofen, oxycodone and acetaminophen and found no difference in pain scores between the two groups (Gray et al., 2019).

Intravenous sedation

Intravenous sedation using a combination of narcotics and anxiolytics is an effective means of pain control and improves satisfaction with the abortion procedure (Allen, Fitzmaurice, Lifford, Lasic, & Goldberg, 2009; Allen et al., 2006; Wells, 1992; Wong, Ng, Ngai, & Ho, 2002). Intravenous administration of narcotics and anxiolytics is more effective than oral administration for pain during uterine aspiration (Allen et al., 2009). In women who receive sedation for pain management, it is unclear if there is additional benefit in administering a paracervical block (Kan, Ng, & Ho, 2004; Renner et al., 2010; Wong et al., 2002). When delivered by trained staff and with appropriate monitoring, intravenous sedation is safe. A 2017 retrospective cohort study which included more than 20,000 normal weight, overweight and obese women who received intravenous sedation for vacuum aspiration found that the rate of any anesthesia-related adverse event was very low (0.2%) (Horwitz et al., 2018). However, providing intravenous sedation increases the expense, complexity and potential risks of an abortion procedure and requires a trained provider with equipment for patient monitoring.

The increased monitoring necessary to deliver intravenous sedation safely requires facility investments in training and equipment. For further information regarding the definition of levels of sedation, including general anesthesia, see Appendix B (Continuum of depth of sedation: Definition of general anesthesia and levels of sedation/analgesia).

General anesthesia

Although effective for pain control, general anesthesia increases the expense, complexity and potential risks associated with abortion and is not recommended for routine procedures (Atrash, Cheek, & Hogue, 1988; Bartlett et al., 2004; Royal College of Obstetricians and Gynaecologists, 2015). When using general anesthesia it is unclear whether preprocedure administration of pain medication affects postprocedure pain (Ali, Shamim, & Chughtai, 2015; Liu et al., 2005; Mustafa-Mikhail et al., 2017), and there is no additional benefit to using a paracervical block (Hall, Ekblom, Persson, & Irestedt, 1997; Renner et al., 2010). For further information regarding the definition of levels of sedation, including general anesthesia, see Appendix B (Continuum of depth of sedation: Definition of general anesthesia and levels of sedation/analgesia).

Non-pharmacologic pain management

A 2018 randomized controlled trial examining the use of auricular acupuncture in combination with paracervical block and preprocedure NSAIDs found that women in the intervention group reported significantly less pain and anxiety when compared to women receiving a placebo or usual care (Ndubisi, Danvers, Gold, Morrow, & Westhoff, 2019). The use of transcutaneous acupoint electrical stimulation as a means to modulate abortion pain is an area of active research, but no recommendations can be drawn from existing studies (Feng et al., 2016; Wang et al., 2018).

Medications and paracervical block should be supplemented with supportive techniques to decrease pain and anxiety (Allen & Singh, 2018). Helpful approaches include educating the patient about what to expect during the procedure; conducting the procedure in a clean and private setting with supportive staff; providing verbal support; using gentle and efficient technique; and applying a heating pad or hot water bottle to the lower abdomen in the recovery room (Akin et al., 2001). A 2016 systematic review of non-pharmacological adjunctive therapies to manage pain included studies of hypnosis, aromatherapy, music, relaxation and imagery exercises and use of doulas. While the review found that none of the interventions showed a statistically significant reduction in pain or anxiety, women rated non-pharmacological interventions highly and recommend their use, particularly those that include dedicated support people (Tschann, Salcedo, & Kaneshiro, 2016; Wilson, Gurney, Sammel, & Schreiber, 2016). A later randomized trial found no difference in reported pain between women receiving an adjunctive nonpharmacologic pain management strategy of their choosing (ambient music, guided imagery meditation or focused breathing, among others) and women receiving standard care (Tschann et al, 2018).

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PAIN MANAGEMENT FOR DILATATION AND EVACUATION

2.4

Recommendation

- A combination of paracervical block, nonsteroidal anti-inflammatory drugs (NSAIDs) and narcotic analgesics, with or without anxiolytics, is recommended.
- Intravenous sedation, where available, should be offered.
- The increased risks of general anesthesia must be weighed against the benefits

Strength of recommendation

Strong

Quality of evidence

Very Low

Last reviewed: December 5, 2019

Pain during dilatation and evacuation

There is a lack of published evidence regarding the level of pain women experience during D&E, but experts generally agree that abortion procedures become more painful as pregnancy advances. At later gestations, D&E requires more preoperative and operative cervical dilation, longer procedure times and deeper uterine manipulation.

Methods of pain management

Specific studies of pain control during D&E are lacking, and an optimal regimen for pain management has not been established. Studies focus instead on safety of pain management strategies during D&E; and rather than optimizing pain control, most international consensus statements focus on the minimum amount of anesthesia at which a D&E can be performed to ensure access at lower-level facilities (Royal College of Obstetricians and Gynaecologists, 2015; World Health Organization, 2014).

In studies reporting on D&E programs, pain management usually consists of intravenous sedation with a combination of narcotics and anxiolytics, and a paracervical block (Altman, Stubblefield, Schlam, Loberfeld, & Osathanondh, 1985; Castleman, Oanh, Hyman, Thuy, & Blumenthal, 2006; Jacot et al., 1993). Ipas recommends a combination of paracervical block, NSAIDs and narcotic analgesics, with or without anxiolytics (Edelman & Kapp, 2017). Where available, paracervical block with intravenous sedation should be offered.

Local anesthesia

See section 2.5 Paracervical block.

Medications

No studies assess the effectiveness of oral, intramuscular or intravenous pain medications during D&E. However, studies of vacuum aspiration have found that pre-procedure administration of oral or intramuscular NSAIDs decreases women's pain during and after the procedure (Braaten, Hurwitz, Fortin & Goldberg, 2013; Renner, Jensen, Nichols, & Edelman, 2010; Romero, Turok, & Gilliam, 2008; Suprapto & Reed, 1984; Wiebe & Rawling, 1995).

Intravenous sedation

No studies assess the effectiveness of intravenous sedation for pain control during D&E. However, studies of vacuum aspiration have found that intravenous sedation using a combination of narcotics and anxiolytics is an effective means of pain control and improves satisfaction with the abortion procedure (Allen, Fitzmaurice, Lifford, Lasic, & Goldberg, 2009; Allen, Kumar, Fitzmaurice, Lifford, & Goldberg, 2006; Wells, 1992; Wong, Ng, Ngai, & Ho, 2002). Studies that have assessed safety of intravenous sedation with fentanyl and midazolam in combination with paracervical block during D&E have found rates of major procedure-related complications of less than 1% (Racek, Chen, & Creinin, 2010), and no additional anesthesia-related adverse events (Gokhale, Lappen, Waters, & Perriera, 2016; Wilson, Chen, & Creinin, 2009; Wiebe, Byczko, Kaczorowski, & McLane, 2013). Intravenous deep sedation with propofol and without intubation is safe and has few complications in the outpatient setting, and no patients experience pulmonary aspiration (Aksel et al., 2018; Dean, Jacobs, Goldstein, Gervitz & Paul, 2011; Gokhale et al., 2016; Mancuso et al., 2017).

Providing intravenous sedation increases the expense, complexity and potential risks of an abortion procedure; and it requires a trained provider with equipment for patient monitoring. The increased monitoring necessary to deliver intravenous sedation safely requires facility investments in personnel, training and equipment. For further information regarding the definition of levels of sedation, including general anesthesia, see Appendix B (Continuum of depth of sedation: Definition of general anesthesia and levels of sedation/analgesia).

General anesthesia

Although effective for pain control, general anesthesia increases the expense, complexity and potential risks associated with abortion and is not recommended for routine procedures (Atrash, Cheek, & Hogue, 1988; Bartlett et al., 2004; MacKay, Schulz, & Grimes, 1985; WHO, 2014). For further information regarding the definition of levels of sedation, including general anesthesia, see Appendix B (Continuum of depth of sedation: Definition of general anesthesia and levels of sedation/analgesia).

Non-pharmacologic pain management

Medications and paracervical block should be supplemented with supportive techniques to decrease pain and anxiety. Helpful approaches may include educating the patient about what to expect during the procedure; conducting the procedure in a clean and private setting with supportive staff; providing verbal support; using gentle and efficient technique; and applying a heating pad or hot water bottle to the lower abdomen in the recovery room (Akin et al., 2001).

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PARACERVICAL BLOCK

2.5

Recommendation

- Paracervical block with local anesthetic is an effective method of pain management and should be a part of all vacuum aspiration, osmotic dilator placement and dilatation and evacuation (D&E) procedures.
- Midlevel providers can safely and effectively provide paracervical anesthesia.
- Paracervical block is not effective for managing pain associated with fetal expulsion during medical abortion at or after 13 weeks gestation.
- A paracervical block composed of 20mL of 1% lidocaine, injected to a depth of 3cm is recommended. If 1% lidocaine is unavailable, 10mL of 2% lidocaine may be substituted, although evidence supporting the use of 2% lidocaine is sparse. Either a two-point or a four-point paracervical injection technique should be used. Where available and where staff have been trained to do so, sodium bicarbonate (1mL of 8.4% sodium bicarbonate for every 10mL of anesthetic solution) may be added to the paracervical block.

Strength of recommendation

Strong

Quality of evidence

Moderate

Last reviewed: January 13, 2020

Local anesthesia for pain management

Vacuum aspiration

A 2013 systematic review evaluating paracervical block for gynecologic procedures requiring cervical dilation, including aspiration abortion before 13 weeks and uterine evacuation for incomplete abortion, found that paracervical block reduced pain during cervical dilation and uterine interventions, although not post-procedure pain, when compared to placebo or no anesthesia (Tangsiriwatthana, Sangkomkamhang, Lumbiganon, & Laopaiboon, 2013). In the highest-quality study available on the use of paracervical block during vacuum aspiration, 120 women undergoing abortion before 11 weeks gestation were randomized to receive either a paracervical block – containing 20mL of 1% lidocaine buffered with sodium bicarbonate and injected to a depth of three centimeters at four paracervical points – or a sham injection where a capped needle was touched to the cervicovaginal junction to mimic administration of paracervical block. Women who received the paracervical block had less pain during dilation and aspiration compared to women who received the sham injection (Renner, Nichols, Jensen, Li, & Edelman, 2012). Deeper injection of anesthetic (3cm) improves pain management compared to superficial (1.5cm) injection (Cetin, & Cetin, 1997; Renner, Jensen, Nichols, & Edelman, 2010). Adding sodium bicarbonate (1mL of 8.4% sodium bicarbonate for every 10mL of anesthetic solution) to lidocaine decreased pain during paracervical

block injection in one study (Wiebe & Rawling, 1995), and during cervical dilation in another (Wiebe, 1992); however differences in reported pain between groups in each of these studies were small. Adding sodium bicarbonate increases the cost and complexity of using a paracervical block. Furthermore, it is unclear whether a four-point injection technique is superior to a two-point injection technique. In one randomized trial, a four-point technique was superior to a two-point technique, however differences in women's pain were small (Renner et al., 2016). In a different randomized trial, no differences in pain were found between two- and four-point techniques (Glantz & Shomento, 2001). A waiting period between injection and cervical dilation is not necessary, as it does not improve pain control (Phair, Jensen, & Nichols, 2002; Renner et al., 2016; Wiebe & Rawling, 1995).

There are no trials that directly compare a block composed of 20mL of 1% lidocaine to one that contains 10mL of 2% lidocaine during abortion. It is unclear if the volume of anesthetic administered influences pain relief; two studies show that women who received a 20mL block reported lower pain scores than those who received a 10mL block (Allen, Kumar, Fitzmaurice, Lifford, & Goldberg, 2006; Wiebe, 1992). However, confounding factors such as different doses of anesthetic and different injection techniques between study groups may have influenced the outcome. When using a paracervical block composed of 10mL of 2% lidocaine, providers should avoid inadvertent intravascular injection to limit potential dose-related lidocaine toxicity (Lau, Lo, Tam, & Yuen, 1999); furthermore, they should consider the two-point injection technique rather than the four-point technique.

In women who receive sedation for pain management, it is unclear if there is additional benefit to administering paracervical block (Kan, Ng, & Ho, 2004; Renner et al., 2010; Wells, 1992; Wong, Ng, Ngai, & Ho, 2002). When women receive general anesthesia, there is no additional benefit to administering paracervical block (Hall, Ekblom, Persson, & Irestedt, 1997; Renner et al., 2010).

Dilatation and evacuation

No studies have evaluated paracervical block for pain management during D&E procedures without concomitant sedation or anesthesia. One randomized trial has examined paracervical block use during D&E when women also received deep sedation or general anesthesia; the addition of paracervical block did not improve postoperative pain (Lazenby, Fogelson, & Aeby, 2009). The recommendation to perform paracervical block for D&E has been extrapolated from data from vacuum aspiration studies and one randomized controlled trial of 41 women undergoing D&E which found significantly decreased pain during osmotic dilator placement when paracervical block was used (Soon, Tschann, Salcedo, Stevens, Ahn, & Kaneshiro, 2017).

Medical abortion

No studies evaluate use of paracervical block for pain management during medical abortion before 13 weeks gestation. Two studies examining use of paracervical block during medical abortion at or after 13 weeks found no improvement in women's pain (Andersson, Benson, Christensson, & Gemzell-Danielsson, 2016; Winkler, Wolters, Funk, & Rath, 1997).

Midlevel providers

In an international, randomized multi-center study examining 2,894 procedures, midlevel providers had similar complication rates as physicians when performing vacuum aspiration with paracervical block (Warriner et al., 2006). The midlevel providers experienced no complications related to use of paracervical block.

Technique

More information on paracervical block technique can be found in Appendix C: Paracervical block technique job aid.

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ADOLESCENTS: SAFETY AND EFFECTIVENESS

3.1

Recommendation

- Vacuum aspiration and medical abortion are safe and effective for adolescents and should be offered as methods of induced abortion.
- Cervical preparation before vacuum aspiration should be considered for adolescents.
- Adolescents should be able to access safe abortion services without delay.

Strength of recommendation

Strong

Quality of evidence

Moderate

Last reviewed: January 6, 2020

Adolescents and abortion

The World Health Organization (WHO) defines adolescents as individuals 10-19 years of age, and young women as 20-24 years of age. Adolescents face barriers to accessing safe abortion care and present for abortions at later gestational ages than adult women (Jatlaoui et al., 2017; Sowmini, 2013). Adolescents are at increased risk of complications of unsafe abortion due to delays in seeking and receiving care, seeking care from unskilled providers and not accessing services when complications arise (Olukoya, Kaya, Ferguson, & AbouZahr, 2001); WHO estimates that three million girls aged 15 to 19 undergo unsafe abortions annually (WHO, 2014a). Decreasing barriers to abortion services may particularly benefit adolescents and young women.

When adolescents receive safe abortion services, they experience fewer complications than do older women. In a large United States-based retrospective cohort study which captured all complications within six weeks of 54,911 surgical and medical abortions, adolescents experienced the lowest rate of abortion-related complications—1.5%—of any age group (Upadhyay et al., 2015). Results were not stratified by method of uterine evacuation, trimester or type of complication.

Vacuum aspiration

Effectiveness

Success rates for vacuum aspiration have not been disaggregated by age. In studies reporting data for adolescent and older women together, rates of incomplete and failed abortion were less than 1% (Upadhyay et al., 2015; Warriner et al., 2006; Weitz et al., 2013). A 2014 systematic review, which included 25 randomized and observational trials documenting abortion care for adolescent and young women concluded that abortion, including vacuum

aspiration, is safe and effective although specific effectiveness rates were not reported (Renner, de Guzman, & Brahmi, 2014).

Safety

A large, prospective, United States multi-center cohort study of 164,000 women undergoing legal abortion, 50,000 of whom were adolescents, found that mortality and major morbidity were lower in adolescents compared to older women (Cates Jr., Schulz, & Grimes, 1983). The mortality rate was 1.3 per 100,000 in women under 20 years old compared to 2.2 per 100,000 in women age 20 and older. Serious adverse events including major surgery, hemorrhage requiring transfusion, and uterine perforation were less common in those under age 20. However, age of 17 years or younger was associated with higher rates of cervical injury, even after controlling for nulliparity (5.5 per 1000 compared to 1.7 per 1000 in women aged 30 years and older, relative risk 1.9, 95% CI 1.2, 2.9) (Cates et al., 1983; Renner et al., 2014; Schulz, Grimes, & Cates, 1983). To reduce this risk, cervical preparation before vacuum aspiration should be considered for adolescents (Allen & Goldberg, 2016; WHO, 2014b).

Acceptability

Age-stratified data on acceptability of vacuum aspiration among adolescents are lacking (Renner et al., 2014).

Medical abortion

Effectiveness

Clinical trials and cohort studies have shown that young women have similar (Haimov-Kochman et al., 2007; Heikinheimo, Leminen, & Suhonen, 2007) or increased (Niinimäki et al., 2011; Shannon et al., 2006) success rates when using mifepristone and misoprostol for medical abortion compared to older women. A large Finnish population-based retrospective cohort study that compared 3,024 adolescents to 24,006 adult women up to 20 weeks gestational age found the risk of surgical evacuation following medical abortion was significantly lower in adolescents (Niinimäki et al., 2011).

In a prospective cohort that included young women, the success rate of misoprostol-only medical abortion was the same for young and older women (Bugalho et al., 1996). Two prospective cohort studies of misoprostol-only abortion have enrolled only adolescents; efficacy in both studies was equivalent to that reported in trials of adult women (Carbonell et al., 2001; Velazco et al., 2000).

Safety

The Finnish population-based retrospective cohort study referenced above found that complication rates after medical abortion among adolescents were similar to or lower than those of older women, even when controlling for nulliparity. In this study, adolescents had a significantly lower incidence of hemorrhage, incomplete abortion, and need for surgical evacuation. Postabortion infection occurred at similar rates among adolescents and older women, despite adolescents' higher rates of chlamydia infection in the population (Niinimäki, et al., 2011). In studies of misoprostol-only medical abortion that include adolescents, adolescents do not experience higher rates of adverse outcomes than adult women (Carbonell et al., 2001; Velazco et al., 2000).

Acceptability

In one small, non-comparative study of 28 adolescents age 14-17 using mifepristone and misoprostol medical abortion, 96% found medical abortion acceptable and 79% reported satisfaction with the procedure by four weeks of follow-up (Phelps, Schaff, & Fielding, 2001).

Subsequent perinatal outcomes

Three studies have examined perinatal outcomes in pregnancies in adolescent and young women who have had a previous abortion—a United States-based retrospective cohort study comparing 654 nulliparous adolescent deliveries to 102 adolescent deliveries with a prior abortion (van Veen, Haeri, & Baker, 2015), a German retrospective cohort including 7,845 nulliparous adolescent deliveries and 211 adolescent deliveries with one prior induced abortion (Reime, Schucking, & Wenzlaff, 2008) and a Hong Kong case-control study comparing 118 adolescent deliveries with one or more prior abortions to 118 age- and parity-matched controls (Lao & Ho, 1998). The American and Hong Kong studies found no difference in adverse perinatal outcomes between study groups. After adjusting for confounding factors, the German study found an increased risk of very low birthweight infants among adolescents who had a previous abortion. Method of abortion and whether preoperative cervical preparation was undertaken was not specified in any of these studies.

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MIDLEVEL PROVIDERS: SAFETY AND EFFECTIVENESS

Key Information:

- Many cadres of trained health workers can provide vacuum aspiration and medical abortion before 13 weeks gestation as safely and effectively as physicians.

Quality of evidence

High

Last reviewed: January 6, 2020

Who is a midlevel provider?

"Midlevel provider" is a general term used to describe multiple cadres of trained health-care providers such as nurses, nurse midwives, clinical officers, advanced practice clinicians, and physician assistants. Expanding the abortion provider base to include midlevel providers increases access to safe abortion and postabortion care.

Vacuum aspiration

A 2015 systematic review compiled data from five studies, one randomized controlled trial and four cohort studies, that compared provision of aspiration abortion by midlevel providers to that by doctors (Barnard, Kim, Park, & Ngo, 2015). Included studies were from India, South Africa, the United States and Vietnam. Combined data found no difference in the overall risk of complications between physicians and non-physician providers (relative risk [RR] 1.36, 95% CI 0.86, 2.14). When examining risk of incomplete abortion separately, observational data (three studies including 13,715 women) indicated an increased risk of incomplete abortion when performed by midlevel providers (RR 2.25, 95% CI 1.38, 3.68) (Goldman, Occhuito, Peterson, Zapka, & Palmer, 2004; Jejeebhoy et al., 2011; Weitz et al., 2013); this increased risk was not observed in randomized controlled trial data (one study, 2789 women, RR 2.97, 95% CI 0.21, 41.82) (Warriner et al., 2006). One study showed that vacuum aspiration performed by midlevel providers was as acceptable to women as services provided by physicians (Jejeebhoy et al., 2011).

The World Health Organization (WHO) states that non-specialist doctors, associate and advanced associate clinicians, midwives and nurses can be trained to perform vacuum aspiration for induced abortion (WHO, 2015). In settings where there are established mechanisms to include auxiliary nurses and auxiliary nurse midwives in basic emergency obstetric care or postabortion care, these cadres can also perform vacuum aspiration. Where doctors of complementary medicine participate in other tasks related to maternal and reproductive health, they can also perform vacuum aspiration. WHO recommends against provision of vacuum aspiration by pharmacists, pharmacy workers or lay health providers.

Medical abortion

A 2017 systematic review and meta-analysis comparing medical abortion provision by midlevel providers and doctors (Sjostrom, Dragoman, Fonhus, Ganatra, & Gemzell-Danielsson, 2017) included three randomized controlled trials, reporting outcomes for 3,670 women from Mexico, Nepal and Sweden. Midlevel providers in the included studies were nurses, auxiliary nurse midwives, ayurvedic (traditional) physicians and midwives. The review found that effectiveness, measured as rate of complete pregnancy termination, was equivalent between the physician and non-physician groups (RR 1.0, 95% CI 0.99, 1.02). Across all included studies, only one serious adverse event—heavy bleeding requiring uterine aspiration—was recorded. Authors concluded that although the rarity of such events limits the ability to statistically analyze their likelihood based on provider type, the overall low rate was reassuring. Women consistently rate medical abortion provided by midlevel providers as highly acceptable (Kopp Kallner et al., 2014; Olavarrieta et al., 2015; Tamang et al., 2017).

WHO states that, in addition to specialist and non-specialist doctors, associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives can be trained to provide medical abortion. Where doctors of complementary medicine participate in other tasks related to maternal and reproductive health, they can also provide medical abortion. For pharmacists or lay health workers, WHO recommends that the provision of medical abortion subtasks, specifically assessing women's eligibility for medical abortion, administering the medications and managing the process and common side-effects, and assessing abortion success and the need for clinic-based follow-up occur only within the context of rigorous research. WHO recommends against the provision of medical abortion by pharmacy workers (2015).

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3.3 GESTATIONAL DATING

Recommendation

- Gestational age should be assessed before provision of abortion services.
- Gestational age should be calculated using a woman's last menstrual period (LMP) combined with bimanual examination; ultrasound may be useful when gestational age is unclear or there is a discrepancy between the two estimates.
- Routine use of ultrasound for gestational age determination is not necessary.

Strength of recommendation

Strong

Quality of evidence

Moderate

Last reviewed: January 6, 2020

Importance of gestational age assessment

Gestational age must be assessed before safe abortion care to determine appropriate method of uterine evacuation and medication regimen. If a provider is unable to assess gestational age through the combination of last menstrual period (LMP), history and bimanual examination, a more experienced clinician should perform a bimanual examination or the patient should undergo an ultrasound.

LMP combined with bimanual examination

Provider assessment based on women's reported LMP combined with bimanual examination is an accurate means of determining gestational age prior to abortion (Bracken et al., 2011; Fielding, Schaff, & Nam, 2002; Kaneshiro et al., 2011). The two largest trials comparing use of LMP and bimanual examination to ultrasound prior to medical abortion up to 9 weeks gestation found that fewer than 2% of the nearly 5,000 women included would have been inappropriately offered medical abortion beyond gestational age limits if LMP and bimanual examination were relied upon to determine pregnancy duration (Bracken et al., 2011; Fielding et al., 2002).

Two small cohort studies have examined accuracy of bimanual examination compared to ultrasound for gestational dating prior to vacuum aspiration (Kulier & Kapp, 2011). In one study of 120 women, 81% of gestational age determinations made with provider assessment were concordant with ultrasound and an additional 13% were within two weeks of ultrasound estimates (Fakih, Barnea, Yarkoni, & DeCherney, 1986). A second study included 245 women and found that experienced providers using bimanual examination only to assess gestational age were within two weeks of ultrasound estimates 92% of the time, while inexperienced providers were within two weeks only 75% of the time (Nichols, Morgan, & Jensen, 2002).

LMP alone

Most women recall theirLMP reasonably well regardless of their education and whether they usually record their LMP dates (Averbach, Puri, Blum, & Rocca, 2018; Harper, Ellertson & Winikoff, 2002; Wegienka & Baird, 2005). Several studies report the accuracy of LMP alone to determine gestational age compared to ultrasound prior to medical abortion (Blanchard et al., 2007; Bracken et al., 2011; Constant, Harries, Moodley, & Myer, 2017; Schonberg, Wang, Bennet, Gold, & Jackson, 2014). Two studies included a combined total of 833 women; both found that 12% of women eligible for medical abortion based on their LMP were beyond gestational age limits as determined by ultrasound dating (Blanchard et al., 2007; Constant et al., 2017). However, in the largest available study only 3.3% of 4,257 women fell into this group when a 63-day cut off value for medical abortion eligibility was used; even fewer women (1.2%) determined to be eligible by LMP were beyond 70 days gestation (Bracken et al., 2011). This study also examined the accuracy of provider assessment of pregnancy duration using both LMP and bimanual examination (see above) and found that, when this method of gestational dating was used, the rate of women who were incorrectly determined to be eligible for medical abortion decreased from 3.3% to 1.6%. A study of 660 women seeking medical abortion in Nepal compared gestational age determined by LMP to LMP plus bimanual examination without comparison to ultrasound (Averbach et al., 2018). Investigators found high agreement (99%) between the two gestational age measurements. Few women in this study (6%) reported a pregnancy duration beyond the legal limit for medical abortion in Nepal (63 days gestation), and study authors note that due to cultural practices related to menstruation, women in Nepal may be more aware of their cycles than women in other settings.

Although generally able to recall their LMP, when asked to determine gestational age or medical abortion eligibility based on that LMP, a minority of women's assessments disagree with those of their providers. Three studies have compared gestational age determinations made using LMP to those determined by provider assessment (Andersen et al., 2017; Ellertson et al., 2000; Shellenberg, Antobam, Griffin, Edelman, & Voetagbe, 2017); all three studies also evaluated women's ability to self-determine their eligibility for medical abortion based on their LMP. In the earliest of these studies (Ellertson et al., 2000), 10% of the 173 women in India who used a worksheet and their LMP to determine gestational age believed they were eligible for medical abortion, while providers determined that their pregnancies were beyond the 56-day cut off. In Nepal, 13% of 3,091 women who used their LMP and a modified gestational dating wheel to determine their medical abortion eligibility, using a 63-day cut off, were incorrect when compared to providers' assessments (Andersen et al., 2017). Finally, in Ghana, 770 women used a modified gestational dating wheel and LMP to determine if their pregnancy was before or after 13 weeks gestation (Shellenberg et al., 2017); when compared to provider assessment, 3.6% of women incorrectly believed their pregnancies were less than 13 weeks. Of these women, one pregnancy was 13 weeks (0.1% of 770), 15 were 14 weeks (1.9%), seven were 16 weeks (0.9%), two were 18 weeks and 22 weeks (0.3% each) and one was 28 weeks (0.1%).

Ultrasound

Ultrasound has an inherent margin of error of 3-5 days before 12 weeks gestation; this margin of error increases as the pregnancy advances (Hadlock, Shah, Kanon, & Lindsey, 1992). In studies conducted in low-resource settings– such as India, Nepal, Vietnam and Tunisia – lack of ultrasound availability has not had an impact on the success or safety of abortion (Coyaji et al., 2001; Mundle, Elul, Anand, Kalyanwala, & Ughade, 2007; Ngoc et al., 1999; Warriner et al., 2011). Ultrasound can be helpful to establish pregnancy duration when it cannot be estimated by other methods, to confirm an intrauterine pregnancy and to identify uterine malformations (Clark, Gold, Grossman, & Winikoff, 2007; Kulier & Kapp, 2011). Dependence

on routine ultrasound for gestational age determination can limit access to safe abortion services and is not necessary for accurate assessment of pregnancy duration (Kaneshiro, Edelman, Sneeringer, & Gómez Ponce de León, 2011; Royal College of Obstetricians and Gynaecologists [RCOG], 2015; World Health Organization [WHO], 2014).

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3.4

3. Recommendations for abortion before 13 weeks gestation

SCREENING FOR ECTOPIC PREGNANCY

Recommendation

- Diagnosis of an ectopic pregnancy should be excluded in women who have a concerning history or examination.

Strength of recommendation

Strong

Quality of evidence

Low

Last reviewed: January 7, 2020

Epidemiology

Data are scant from low resource settings regarding rates of ectopic pregnancy; in the United States, reported rates range from 1-2% of pregnancies (Stulberg, Cain, Dahlquist, & Lauderdale, 2013; Tao, Patel, & Hoover, 2016; Trabert, Holt, Yu, Van den Eeden, & Scholes, 2011). Ectopic pregnancy accounts for 2.7% of pregnancy-related deaths in the United States (Creanga, Syverson, Seed, & Callaghan, 2017). Ectopic pregnancy accounts for approximately 1% of pregnancy-related deaths in low resource settings where other causes of maternal death are more prevalent (Khan, Wojdyla, Say, Gulmezoglu, & Van Look, 2006).

Risk factors

Factors with the highest associated risk of ectopic pregnancy in pregnant women are:

RISK FACTOR	RISK OF ECTOPIC IN THE CURRENT PREGNANCY
Previous ectopic pregnancy	10-25%
History of tubal surgery, including sterilization	25-50%
Intrauterine device (IUD) in place	25-50%

(American College of Obstetricians and Gynecologists [ACOG], 2018; Ankum, Mol, Van der Veen, & Bossuyt, 1996; Barnhart, 2009; Gaskins et al., 2018; Jacob, Kalder, & Kostev, 2017)

Other risk factors include a history of infertility and assisted reproductive technology, a history of pelvic infections, multiple partners, early age at first intercourse, early age at first oral contraceptive use and smoking. (ACOG, 2018; Ankum et al., 1996; Barnhart, 2009, Gaskins et al., 2018).

Screening

Half of all ectopic pregnancies occur in women with no risk factors and with a benign clinical presentation (Stovall, Kellerman, Ling, & Buster, 1990). Providers should screen women for

ectopic pregnancy risk factors during the history and physical examination including relevant history, such as previous ectopic pregnancy, tubal ligation, tubal surgery or an IUD in place. Screening should also include signs of ectopic pregnancy found during physical examination, such as an adnexal mass, pain on examination or vaginal bleeding.

Treatment for high-risk women

Ultrasound and serial hCG testing are often used to help assess pregnancy location (Fields & Hathaway, 2017). In some cases, the most expeditious way to confirm an intrauterine pregnancy is to perform vacuum aspiration; presence of products of conception in the uterine aspirate confirms that it was intrauterine. A woman with suspicious signs and symptoms or a concerning physical exam should be diagnosed and treated as soon as possible or transferred immediately to a facility that can manage ectopic pregnancy. Early diagnosis and treatment of ectopic pregnancy can help preserve fertility and save women's lives.

Post-procedure screening

For women undergoing vacuum aspiration, the aspirate should be strained and examined to confirm the presence of products of conception (see 3.5.4 Examining products of conception). If products of conception are not seen, a diagnosis of ectopic pregnancy should be considered.

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3.5 VACUUM ASPIRATION
3.5.1 SAFETY AND EFFECTIVENESS

Key information

- Vacuum aspiration is effective and safe, with success rates over 98% and major complication rates under 1%.

Quality of evidence

High

Last reviewed: January 28, 2020

Effectiveness

A successful vacuum aspiration requires no further intervention to evacuate the uterus. In a large United States-based observational study of 11,487 first-trimester aspiration abortions done by physicians, nurse practitioners, certified nurse midwives and physicians assistants, the need for repeat aspiration due to incomplete abortion was 0.28% and ongoing pregnancy was 0.16% (Weitz et al., 2013).

Safety

A 2015 systematic review analyzed 57 studies reporting data for 337,460 aspiration abortions performed before 14 weeks gestation in North America, Western Europe, Scandinavia and Australia/New Zealand (White, Carroll, & Grossman, 2015). Major complications requiring intervention (such as hemorrhage requiring transfusion or perforation necessitating repair) occurred in ≤ 0.1% of procedures; hospitalization was necessary in ≤ 0.5% of cases. Studies looking at different cadres of providers (physician assistants, nurses, nurse midwives, etc.) in other settings have had similar results (Hakim-Elahi, Tovell, & Burnhill, 1990; Jejeebhoy et al., 2011; Warriner et al., 2006; Weitz et al., 2013). In two studies that compared newly trained midlevel providers to experienced physician providers (Jejeebhoy et al., 2011; Weitz et al., 2013), there were no observed differences in abortion success or complication rates.

A retrospective cohort study conducted in the United States compared rates of procedural complications during outpatient aspiration abortion through 13 weeks and six days gestation in women with at least one medical comorbidity (diabetes, hypertension, obesity, HIV, epilepsy, asthma, thyroid disease and bleeding/clotting disorders) to women without comorbidities. The overall rate of complications—which included uterine perforation, blood loss greater than 100mL, cervical laceration and retained products of conception that required reaspiration—was 2.9%; there was no difference between the two groups (Guiahi, Schiller, Sheeder, & Teal, 2015). Two retrospective cohort studies, that together included 5,288 aspiration abortion procedures performed before 13 weeks gestation, found no differences in complication rates between obese, overweight, and normal weight women (Benson, Micks, Ingalls, & Prager, 2016; Mark et al., 2017).

Mortality

In the United States, the mortality rate from legal induced abortion between 2008-2013 was 0.62 deaths per 100,000 reported abortions; mortality rates disaggregated by abortion type or length of pregnancy are not available (Jatlaoui et al., 2017). In comparison, during the period from 2011-2013 the mortality rate from live birth in the United States was 17 deaths per 100,000 live births (Creanga, Syverson, Seed & Callaghan, 2017). A secondary data analysis that compared mortality rates associated with live birth to those from legal induced abortion in the United States found that the risk of death from childbirth was 14-fold higher than the risk of death from abortion (Raymond & Grimes, 2012). In the 2015 systematic review about the safety of vacuum aspiration in multiple countries referenced above, no deaths were reported (White et al., 2015).

Table 3.5.1. Vacuum aspiration complication rates, by study

	UPADHYAY, 2015	WEITZ, 2013	JEJEEBHOY, 2011	WARRINER, 2006	HAKIM-ELAHI, 1990
Number of women included	34,744	11,487	897	2,789	170,000
Location	USA	USA	India	South Africa and Vietnam	USA
Provider type	Not specified	Experienced physicians and newly trained nurse practitioners, certified nurse midwives and physician assistants	Newly trained physicians and nurses	Experienced physicians, midwives and doctor-assistants	Experienced physicians
Time period	2009-2010	2007- 2011	2009-2010	2003-2004	1971-1987
Total minor complication rate	**1.1%**	**1.3%**	**1% (all reported as incomplete abortion)**	**1%**	**0.85%**
Incomplete abortion	0.33%	0.3%	1%	0.9%	Not reported (0.35% re-aspiration rate)
Ongoing pregnancy	0.04%	0.16%	Not reported	Not reported	0%
Minor infection	0.27%	0.12%	Not reported	0.1%	0.5%
Total major complication rate	**0.16%**	**0.05%** **(6 complications: 2 perforations, 3 infections and 1 hemorrhage)**	**0.12%** **(1 complication: 1 high fever)**	**0%**	**0.07% (hospitalizations for perforation, ectopic pregnancy, hemorrhage, sepsis or incomplete abortion)**
Death	**0%**	**0%**	**0%**	**0%**	**0%**

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VACUUM ASPIRATION
3.5.2 CERVICAL PREPARATION

3.5

Recommendation

- Cervical preparation is recommended routinely after 12-14 weeks gestation. Before 12-14 weeks gestation, cervical preparation may be considered, but should not be routinely used.
- Recommended methods for cervical preparation include:
  - Misoprostol 400mcg sublingually 1-3 hours before the procedure.
  - Misoprostol 400mcg vaginally or buccally 3 hours before the procedure.
  - Osmotic dilators placed in the cervix 6-24 hours before the procedure.
  - Mifepristone 200mg orally 1-2 days before the procedure.

Strength of recommendation

Strong

Quality of evidence

Moderate

Last reviewed: January 9, 2020

Benefits of cervical preparation

A meta-analysis of 51 randomized controlled clinical trials of cervical preparation through 13 weeks gestation found that procedure time was shorter with cervical preparation but there were no differences in serious complications, such as cervical laceration or uterine perforation, in women given cervical preparation compared to those given placebo (Kapp, Lohr, Ngo, & Hayes, 2010). In the largest multicenter randomized controlled trial, which included 4,972 women given either misoprostol 400mcg vaginally or placebo three hours before a vacuum aspiration, there was no difference in the rates of cervical laceration, perforation or infection between the two groups (Meirik, Huong, Piaggio, Bergel, & von Hertzen, 2012). However, a significant decrease in the risk of incomplete abortion was observed in those who received misoprostol for cervical preparation (<1%) compared to the placebo group (2%), but side effects were more frequent for women who were given misoprostol. For women at higher risk of complications during cervical dilation (young women, women with cervical abnormalities or prior cervical surgery) or for inexperienced providers, there may be a benefit from cervical preparation before 12-14 weeks gestation (Allen & Goldberg, 2016; Grimes, Schulz, & Cates, 1984; Kaunitz, Rovira, Grimes, & Schulz, 1985).

Side effects of cervical preparation

In the largest randomized controlled trial of misoprostol for cervical preparation, 55% of women who took misoprostol complained of pre-procedure abdominal pain and 37% had

vaginal bleeding, compared to 22% and 7% in the placebo group (Meirik et al., 2012). In addition, cervical preparation adds cost, complexity and time to an abortion, as women must visit the clinic a day before the procedure to have osmotic dilators placed or to receive mifepristone, or must wait in the health center for misoprostol to take effect. Because abortion before 13 weeks gestation is very safe, the gestational age at which the benefit of routine cervical preparation outweighs the side-effects is not known (Kapp et al., 2010). Women's satisfaction with cervical preparation has not been systematically studied in randomized controlled trials but is an important consideration for quality of care and service delivery (Kapp et al., 2010).

Choice of methods

The choice of misoprostol, mifepristone or osmotic dilators for cervical preparation depends on availability, expense, convenience and preference. Sublingual misoprostol has superior effectiveness but more gastrointestinal side effects than vaginal misoprostol (Kapp et al., 2010; Saav, Kopp Kallner, Fiala, & Gemzell-Danielsson, 2015; Saxena, Sarda, Salhan, & Nanda, 2008). Mifepristone given 24 hours prior to the abortion is superior to misoprostol but adds time and expense to the abortion procedure (Ashok, Flett, & Templeton, 2000; Kapp et al., 2010). Misoprostol and osmotic dilators have similar effectiveness but dilator placement is associated with increased pain, increased time to procedure and reduced satisfaction for women (Bartz, et al., 2013; Burnett, Corbett, & Gertenstein, 2005; MacIsaac, Grossman, Balistreri, & Darney, 1999).

Young women

Adolescents may benefit from cervical preparation due to their increased risk of cervical injury during abortion (Allen & Goldberg, 2016; Schulz et al., 1983). This risk is independent of nulliparity (Meirik et al., 2014); adolescents have physiologically immature cervices that may be more difficult to dilate regardless of obstetric history (Allen & Goldberg, 2016; Schulz et al., 1983). There are no clinical trials examining the use of cervical preparation in this patient population.

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3.5 VACUUM ASPIRATION
3.5.3 BIMANUAL EXAMINATION

Recommendation

- Bimanual examination must be performed before any procedure in which instruments are being placed in the uterus, such as vacuum aspiration or intrauterine device insertion.
- The bimanual examination must be performed by the clinician doing the procedure.

Strength of recommendation

Strong

Quality of evidence

Very Low

Last reviewed: January 9, 2020

Importance of bimanual examination

Bimanual examination is a routine step before intrauterine procedures recommended by the World Health Organization (WHO, 2014). It provides information about the client's comfort, pregnancy status, gestational age, presence of infection, anatomic abnormalities and uterine position, all of which affect management of intrauterine procedures. Ultrasound can additionally be performed but is not a replacement for bimanual examination before intrauterine procedures.

Determining uterine size

Bimanual examination, when paired with a woman's last menstrual period, enables accurate gestational age assessment (See section 3.3 Recommendations for abortion before 13 weeks: Gestational dating). Medical regimens for abortion and postabortion care change based on the gestational age or uterine size. Techniques for vacuum aspiration and dilatation and evacuation, including instrument choice and need for cervical preparation, depend on accurate knowledge of uterine size.

Determining uterine position

The position of the uterus in the pelvis, orientation of the fundus to the cervix and firmness of the uterus are best determined with bimanual examination. Knowledge of uterine position assists providers in avoiding complications, particularly perforation, during procedures (Chen, Lai, Lee, & Leong, 1995; Mittal & Misra, 1985; Nathanson, 1972).

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3.5 VACUUM ASPIRATION
3.5.4 EXAMINING PRODUCTS OF CONCEPTION

Recommendation

- Clinicians performing vacuum aspiration must inspect products of conception immediately after vacuum aspiration.
- Sending products of conception for routine histopathology evaluation is not recommended.

Strength of recommendation

Strong

Quality of evidence

Very Low

Last reviewed: January 10, 2020

Visual inspection of products of conception

Visual inspection of products of conception is a routine step in vacuum aspiration as recommended by the World Health Organization (WHO, 2014), the Royal College of Obstetricians and Gynaecologists (RCOG, 2015), and the National Abortion Federation (NAF, 2017). Presence of products of conception on visual inspection confirms that the pregnancy was intrauterine and is consistent with successful abortion (Westfall, Sophocles, Burggraf, & Ellis, 1998). If products of conception are not seen, a woman should not leave the facility until plans are made to follow local guidelines to exclude the diagnosis of ectopic pregnancy. Immediate examination of the products of conception expedite the diagnosis of ectopic pregnancy and decrease related morbidity and mortality (Goldstein, Danon, & Watson, 1994). In cases where abnormal pathology is suspected, such as molar pregnancy, histopathology may be used in addition to visual inspection.

Sending products of conception for routine histopathology exam does not affect clinical outcomes and increases the cost of abortion (Heath, Chadwick, Cooke, Manek, & MacKenzie, 2000; Paul, Lackie, Mitchell, Rogers, & Fox, 2002).

Instructions for visually inspecting products of conception are in Ipas's *Woman-Centered Comprehensive Abortion Care Reference Guide, 2nd edition,* page 177 (Ipas, 2013).

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3.5 VACUUM ASPIRATION
3.5.5 PROCESSING IPAS MVA PLUS® AND IPAS SINGLE-VALVE ASPIRATORS

Recommendation

- All Ipas multiple-use aspirators and adapters must be soaked, cleaned and high-level disinfected or sterilized between patients.

Last reviewed: January 10, 2020

Importance of correctly processing instruments

During use, the cylinder of the manual vacuum aspirator (MVA) fills with the patient's blood. There is a potential risk that contaminants from a previous patient could be introduced to a new patient if the MVA is not appropriately processed (sterilized or high-level disinfected) between each use.

Steps

Step 1: Point-of-use preparation

After use, do not let the device dry. Presoak, rinse or spray the device with water or enzymatic spray. Do not use chlorine or saline.

Step 2: Cleaning

Disassemble aspirator and adaptor (if used) and clean with warm water and detergent using a soft brush.

Step 3: Sterilization or high-level disinfection

All aspirators and adaptors must be sterilized or high-level disinfected after use.

STERILIZATION OPTIONS	HIGH-LEVEL DISINFECTION OPTIONS
Steam autoclave* instruments at 121°C (250°F) with a pressure of 106kPa (15lbs/in2) for 30 minutes	Boil* the instruments for 20 minutes
Glutaraldehyde** soak for the time recommended by the manufacturer—most recommend 10 hours***	Glutaraldehyde** soak for the time recommended by the manufacturer—recommendations range from 20-90 minutes***
Sporox II* solution soak for 6 hours***	Sporox II* solution soak for 30 minutes***
	0.5% chlorine solution soak for 20 minutes***

* IPAS SINGLE-VALVE ASPIRATOR CANNOT BE BOILED OR AUTOCLAVED.

** Because there are several glutaraldehyde products available with different recommendations for processing time, always follow the recommendations that come with your brand of glutaraldehyde.

*** If chemical agents were used in processing, aspirator parts and adaptors (if used) should be thoroughly rinsed in clean, potable water (drinking water).

Step 4: Store appropriately or use immediately

Aspirators and adapters may be dried, the O-ring lubricated and the device reassembled and stored in a clean dry area until use. The aspirator does not need to remain high-level disinfected or sterilized at the time of use and can be placed in a clean area or stored according to local standards.

Instruments processed by wet methods should be reprocessed daily.

These validated methods of instrument processing do not negatively affect the MVA for at least 25 reuse cycles (Powell & Kapp, 2019). Detailed information on MVA processing and other processing options are in Ipas's *Woman-centered comprehensive abortion care: Reference manual, 2nd edition,* page 150 (Ipas, 2013).

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3.6 MEDICAL ABORTION
3.6.1 SAFETY AND EFFECTIVENESS

Key information

- A combined regimen of mifepristone and misoprostol is effective and safe with success rates over 95%, continuing pregnancy rates of less than 2% and complication rates of less than 1% up to 10 weeks gestation.
- Between 10 and 13 weeks, the success rate of mifepristone combined with misoprostol is over 95%, with a continuing pregnancy rate of less than 2% and complication rate of 3%.
- A combined regimen of mifepristone and misoprostol is recommended for medical abortion; where mifepristone is not available, the misoprostol-only regimen may be used.
- A misoprostol-only regimen has lower success rates of about 80-85%, with continuing pregnancy rates of 3-10% and complication rates of 1-4% up to 13 weeks gestation.

Quality of evidence

High

Last reviewed: January 10, 2020

Background

A combined regimen of mifepristone and misoprostol is recommended for medical abortion as it is more effective than misoprostol only (Blum et al., 2012; Kapp, Eckersberger, Lavelanet, & Rodriguez, 2018; Kulier et al., 2011; Ngoc et al., 2011; Raymond, Harrison, & Weaver, 2019; World Health Organization [WHO], 2018). Where mifepristone is unavailable, the misoprostol-only regimen may be used.

Mifepristone and misoprostol

Effectiveness

Medical abortion success is defined as a complete abortion that needs no further intervention. A 2015 systematic review reported data from 20 studies that included a total of 33,846 women undergoing medical abortion with mifepristone and buccal misoprostol through 70 days gestation (Chen & Creinin, 2015). The overall success rate was 96.6% and the continuing pregnancy rate was 0.8% Two prospective cohort studies have examined mifepristone combined with either 400mcg or 600mcg of sublingual misoprostol through 70 days gestation, finding success rates of 93-99% and ongoing pregnancy rates of less than 2% (Bracken et al., 2014; Platais, Tsereteli, Grebennikova, Lotarevich, & Winikoff, 2016). One prospective cohort study has examined mifepristone combined with vaginal misoprostol from 63-70 days gestation, finding a success rate of 95% (Gouk et al., 1999).

Between 10 and 13 weeks gestation only one available study, a retrospective cohort study of 1,076 women, has used the currently recommended regimen of 200mg mifepristone followed 36-48 hours later by misoprostol (800mcg vaginally or 600mcg sublingually), and then repeated doses of 400mcg misoprostol vaginally or sublingually every three hours for two additional doses (Hamoda, Ashok, Flett, & Templeton, 2005). The success rate for this regimen was 95.8%, with an ongoing pregnancy rate of 1.5%. A smaller prospective cohort study which included 254 women used a similar regimen and reported a success rate of 91.7% and an ongoing pregnancy rate of less than 1% (Lokeland et al., 2010).

Three large cohort studies, including a total of 260,256 women who had mifepristone and misoprostol medical abortions up to nine weeks gestation (Cleland et al., 2013; Gatter, Cleland, & Nucatola, 2015; Goldstone, Walker, & Hawtin, 2017), found rates of incomplete abortion treated with uterine aspiration of 2.3-4.8%. Between 10 and 13 weeks, reported rates of uterine aspiration for any reason range from 4-8% (Hamoda et al., 2005; Lokeland et al., 2010). A Danish cohort study which included 86,437 mifepristone and misoprostol medical abortions before nine weeks concluded that increasing gestational age was most strongly associated with requiring surgical intervention (Meaidi, Friedrich, Gerds, & Lidegaard, 2019).

Safety

In the three cohort studies referenced above, rates of complications observed during medical abortion with mifepristone and misoprostol up to nine weeks gestation were less than 1% (Cleland et al., 2013; Gatter, Cleland, & Nucatola, 2015; Goldstone, Walker, & Hawtin, 2017). Between 10 and 13 weeks gestation, complication rates are around 3% (Hamoda et al., 2005). A large retrospective cohort study of 11,319 first-trimester medical abortions evaluated all complications from abortions provided in the state of California in the United States from 2009-2010 (Upadhyay et al., 2015). Researchers assessed complications arising at the time of the abortion, as well as complications diagnosed when patients sought additional care from sites other than the site where the abortion was provided, such as emergency departments. The overall rate of complications during the six weeks following medical abortion was 5.2%; only 0.3% were major complications—defined as requiring hospitalization, surgery or blood transfusion. Complications included incomplete abortion (0.87%), failed abortion (0.13%), hemorrhage (0.14%), infection (0.23%) and undetermined/other (3.82%).

Table 3.6.1. Medical abortion complications, by study

	GOLDSTONE, 2017	CLELAND, 2013	GATTER, 2015
Number of women included	13,078	233,805	13,373
Gestational age	≤ 63 days	≤ 63 days	≤ 63 days
Location/organization	MSI Australia	Planned Parenthood USA	Planned Parenthood USA
Time period	2013-2015	2009-2010	2006-2011
Incomplete abortion requiring aspiration	4.84%	Not reported	2.3%
Unrecognized ectopic pregnancy	Not reported	0.007%	Not reported
Ongoing pregnancy	0.76%	0.5%	0.5%
Transfusion	0.13%	0.05%	0.03%
Infection	0.11%	0.02%	0.01%
Death	<0.01% (1 death from pneumonia, likely unrelated)	0.0004% (1 death from unrecognized ectopic pregnancy)	No deaths

Misoprostol only

Safety and effectiveness data for medical abortion with misoprostol only are more limited. Large retrospective case series documenting success and complication rates are not available. Disparate regimens, gestational age ranges, timeframes to measure abortion success and reporting of complications makes comparison of success and complication rates across studies of misoprostol-only medical abortion difficult.

Effectiveness

The largest randomized trial using the recommended misoprostol-only regimen, repeated doses of 800mcg of misoprostol by either the vaginal or sublingual route, included 2,046 women with gestations of seven weeks or less (von Hertzen et al., 2007). Success of misoprostol-only abortion was 84%. Smaller studies using similar regimens have reported success rates of 92% for gestations up to eight weeks (Fekih, 2010), 89-91% up to nine weeks (Salakos et al., 2005; Velazco et al., 2000), and from 84-87% from 9-13 weeks (Carbonell, Varela, Velazco, Tanda & Sanchez, 1999; Carbonell Esteve et al., 1998, Carbonell et al., 2001). A 2019 systematic review assessed effectiveness of misoprostol alone by reviewing 42 studies where at least one group of women received misoprostol alone to induce abortion; however, the misoprostol regimens differed across the studies. The review, which included 12,829 women, found an overall abortion success rate of 78%; 20% underwent subsequent surgical uterine evacuation for any reason (Raymond et al, 2019). Criteria to determine when surgical evacuation was required were heterogeneous across the studies. The ongoing pregnancy rate, available for only half of the women undergoing surgical uterine evacuation, was 6%. In studies that used the recommended misoprostol-only regimen or similar regimens, the rate of subsequent uterine aspiration for any reason ranges from 12-17%, with ongoing pregnancy rates of 3-10% (Carbonell et al., 1999; Carbonell et al., 2001; Velazco et al., 2000; von Hertzen et al., 2007).

In general, higher rates of success with misoprostol-only regimens are associated with a gestational age of less than 7 weeks (von Hertzen et al., 2007; Zikopoulos et al., 2002), higher number of repeat doses of misoprostol (Carbonell et al., 1999; Jain, Dutton, Harwood, Meckstroth, & Mishell, 2002), higher initial doses of misoprostol (Raymond et al, 2019), non-oral routes of misoprostol administration (Raymond et al., 2019), and a longer time period before provider follow-up to confirm abortion success (Bugalho, Mocumbi, Faundes, & David, 2000). However, women's satisfaction decreases the longer the abortion process lasts (Ngai, Tang, Chan, & Ho, 2000).

Safety

Complications are infrequently reported: bleeding requiring aspiration occurs in 1-4% of women (Velazco et al., 2000; Salakos et al., 2005; Carbonell et al., 1999; Carbonell Esteve et al., 1998), transfusion is required in less than 1% of women (von Hertzen, et al., 2007; Carbonell et al., 1999), and infection is reported in 1-4% of women (Velazco et al., 2000; Carbonell et al., 2001; von Hertzen et al., 2007; Carbonell et al., 1999).

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MEDICAL ABORTION
3.6.2 RISK OF FETAL MALFORMATIONS

3.6

Recommendation

- Exposure to mifepristone alone has not been shown to cause fetal malformations. Exposure to misoprostol is associated with a small increased risk of malformations if the woman has an ongoing pregnancy and decides not to terminate. Women with an ongoing pregnancy after using misoprostol should be counseled about the risk if they choose to continue the pregnancy.

Strength of recommendation

Strong

Quality of evidence

- Mifepristone: Very low
- Misoprostol: Very low

Last reviewed: January 10, 2020

Background

The expected rate of fetal malformations in the general population is approximately 3% (Dolk, Loane, & Garne, 2010). Exposure to certain medications, infections, radiation or drugs of abuse during embryonic or fetal development may result in an increased risk of malformations if the pregnancy continues.

Mifepristone

Data on continuing pregnancy after mifepristone exposure without misoprostol are limited. The largest prospective study of 46 women continuing a pregnancy after mifepristone resulted in eight miscarriages and, in the pregnancies that continued, two major malformations (5.3%). Neither malformation was thought to be related to mifepristone exposure but may have been a result of other medical conditions (Bernard et al., 2013).

Misoprostol

Case reports, cohort studies (da Silva Dal Pizzol et al., 2005; Vauzelle, Beghin, Cournot, & Elefant, 2013) and case-control studies (da Silva Dal Pizzol, Knop, & Mengue, 2006) show that the incidence of malformations peaks if misoprostol is used between 5-8 weeks after a woman's last menstrual period (LMP) and is not associated with anomalies following exposure after 13 weeks following a woman's LMP (Philip, Shannon, & Winikoff, 2002). The most typical malformations associated with misoprostol use are Möbius sequence, a rare disorder of cranial nerve palsies associated with limb anomalies and craniofacial defects, and terminal transverse limb defects (da Silva Dal Pizzol, et al., 2006). Although not clearly established,

the proposed mechanism is vascular disruption from uterine contractions leading to disordered fetal development (Gonzalez et al., 2005; Shepard, 1995).

A systematic review of four case-control studies with 4,899 cases of congenital anomalies and 5,742 controls showed an increased rate of misoprostol exposure in cases with anomalies (da Silva Dal Pizzol, et al., 2006). Misoprostol exposure was 25 times more likely in cases with Möbius sequence and 12 times more likely in cases with terminal transverse limb defects. In a cohort of 183 women exposed to misoprostol during the first 12 weeks of pregnancy, the major malformation rate was 5.5%; half of these were consistent with misoprostol malformation patterns (Auffret et al., 2016). However, a prospective follow-up study comparing women who used misoprostol before 12 weeks of pregnancy to women who used antihistamines did not find a statistically significant difference in the rate of fetal malformations, although three malformations (2%) in the misoprostol group were consistent with misoprostol-related anomalies (Vauzelle, et al., 2013).

Although the rate of misoprostol exposure is higher in children born with characteristic defects such as Möbius sequence, the anomalies are so rare that the overall risk is low that a woman who takes misoprostol before 13 weeks gestation and carries a pregnancy to term will have a child born with a malformation related to misoprostol exposure. The risk of fetal malformation related to misoprostol exposure is less than 10 per 1,000 exposures (Philip, et al., 2002).

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MEDICAL ABORTION
3.6.3 MIFEPRISTONE AND MISOPROSTOL: RECOMMENDED REGIMEN

3.6

Recommendation

- **Up to 10 weeks gestation (70 days since last menstrual period (LMP)):** Mifepristone 200mg orally followed 1-2 days later by misoprostol 800mcg buccally, sublingually or vaginally.
- **10-13 weeks gestation:** Following mifepristone, women typically require two doses of misoprostol for a successful abortion.
  - Mifepristone 200mg orally followed 1-2 days later by either misoprostol 600mcg sublingually or 800mcg vaginally, then 400mcg sublingually or vaginally every three hours until expulsion.
  - Alternatively, mifepristone 200mg orally followed 1-2 days later by misoprostol 800mcg buccally, sublingually or vaginally may be used; the dose of misoprostol may be repeated to achieve abortion success.

Strength of recommendation

Strong

Quality of evidence

- Up to 10 weeks gestation: High
- 10-13 weeks gestation: Low

Last reviewed: January 10, 2020

Up to nine weeks (63 days since LMP)

Multiple randomized controlled clinical trials have shown that the combination of mifepristone and misoprostol is an effective medical abortion regimen with success rates ranging from 95-98% up to nine weeks gestation (Chen & Creinin, 2015; Kapp, Baldwin, & Rodriguez, 2018; Kulier et al., 2011; Raymond, Shannon, Weaver, & Winikoff, 2012). Vaginal, buccal and sublingual misoprostol are more effective than oral misoprostol (Kulier et al., 2011). Buccal dosing (Middleton et al., 2005) and sublingual dosing (Tang, Chan, Ng, Lee, & Ho, 2003; von Hertzen et al., 2010) have higher rates of gastrointestinal side effects than vaginal dosing. Sublingual dosing is associated with more side effects than buccal dosing (Chai, Wong, & Ho, 2013). Decreasing the sublingual misoprostol dose to 400mcg decreased side effects but increased the rates of incomplete abortion and ongoing pregnancy (Bracken et al., 2014; Raghavan et al., 2013; von Hertzen et al., 2010); therefore, the recommended dose of sublingual misoprostol remains 800mcg. Buccal or sublingual dosing may be preferred over vaginal dosing to accommodate women's preferences or legal restrictions.

Simultaneous dosing of mifepristone and misoprostol in women with gestations up to 63 days has demonstrated a success rate of approximately 95%, compared to 97-98% when misoprostol is used 24-48 hours after mifepristone (Creinin et al., 2007; Goel, Mittal, Taneja, Singal, & Attri, 2011; Lohr, Starling, Scott, & Aiken, 2018). Although this method is slightly less effective, it may be preferable in certain settings, such as where home use of medical abortion drugs is restricted (Lohr et al., 2018).

9-10 weeks (64-70 days since LMP)

A 2015 review reports data from five comparative studies including 801 women with gestations between 64-70 days and 1,163 with gestations from 57-63 days (Abbas, Chong, & Raymond, 2015). In four studies, women received 200mg mifepristone followed by 800mcg buccal misoprostol (Boersma, Meyboom-de Jong, & Kleiverda, 2011; Pena et al., 2014; Sanhueza Smith et al., 2015; Winikoff et al., 2012) and in one study, women received mifepristone and 400mcg sublingual misoprostol (Bracken et al., 2014). There was no difference in success rates between the two gestational groups (93.9% at 57-63 days compared to 92.3% at 64-70 days). Further, there were no differences in serious adverse events, such as hospital admissions or transfers, between the groups (0.7% and 0.5% respectively). One observational study included in the review reported an abortion success rate of 94.5% from 9-10 weeks when women used a regimen of mifepristone followed by 800mcg of vaginal misoprostol (Gouk et al., 1999). Additional studies published since this review using sublingual (Platais, Tsereteli, Grebennikova, Lotarevich, & Winikoff, 2016) or buccal misoprostol (Tan et al., 2018) after mifepristone have shown similar success rates for the gestational age range from 9-10 weeks.

10-13 weeks

A retrospective cohort study of 1,076 women showed that a combination of 200mg mifepristone followed 36-48 hours later by misoprostol (800mcg vaginally or 600mcg sublingually), and then repeated doses of 400mcg misoprostol vaginally or sublingually every three hours for two additional doses is safe and effective between 9-13 weeks (Hamoda, Ashok, Flett, & Templeton, 2005). All women took misoprostol in the health facility. The success rate for this regimen was high at 95.8%, with a low rate of serious adverse events. A smaller trial randomized 211 women with pregnancies between 9-13 weeks to either the vaginal or sublingual route of misoprostol administration described above; all women received pretreatment with mifepristone (Hamoda, Ashok, Flett, & Templeton, 2005a). In both groups, women typically required 2 doses of misoprostol to have a successful abortion; 3.4% of women in the vaginal group required surgical evacuation of the uterus, compared to 2.9% in the sublingual group. Women in the sublingual group were more likely to experience side effects. A prospective cohort study (Lokeland et al., 2010) including 254 women reported an abortion success rate of 91.7% using a similar regimen. A small prospective cohort study examined effectiveness of mifepristone 200mg orally followed 36-48 hours later by misoprostol 800mcg vaginally as a single dose (Gouk et al., 1999), and found a success rate of 95% among 126 women with pregnancies between 70-83 days. A 2018 systematic review of medical abortion in the late first trimester concluded that abortion success rates are higher when routine, repeated doses of misoprostol are used and when the vaginal route is used over oral administration (Kapp, Eckersberger, Lavelanet, & Rodriguez, 2018).

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MEDICAL ABORTION
3.6.4 MISOPROSTOL ONLY: RECOMMENDED REGIMEN

3.6

Recommended regimen before 13 weeks gestation

- Misoprostol 800mcg buccally, sublingually or vaginally every three hours until expulsion.

Strength of recommendation

Strong

Quality of evidence

- Up to nine weeks gestation: Moderate
- 9-13 weeks gestation: Low

Last reviewed: January 10, 2020

Misoprostol-only abortion up to 9 weeks

The only multicenter randomized controlled trial to compare different misoprostol-only dosing intervals showed that complete abortion rates are equivalent when misoprostol is given vaginally every 3-12 hours or sublingually every three hours for three doses. Sublingual dosing had a higher incidence of side effects than vaginal dosing (von Hertzen et al., 2007). A 2018 systematic review summarizing data on effectiveness of misoprostol alone for medical abortion found that vaginal, buccal and sublingual administration result in similar rates of surgical intervention, while oral administration resulted in significantly more (Raymond, Harrison, & Weaver, 2019). A trial that randomized women with pregnancies up to 10 weeks to either buccal or sublingual misoprostol (800mcg every three hours for three doses) found that sublingual administration led to significantly fewer continuing pregnancies at follow-up, 1.1% compared with 5.5% (Sheldon et al., 2019). Women in the sublingual group experienced more fever and chills than women in the buccal administration group.

Misoprostol-only abortion between 9-13 weeks

There is scant evidence upon which to recommend an appropriate misoprostol-only regimen between 9-13 weeks. Findings from comparative trials indicate that vaginal and sublingual dosing have similar efficacy and are superior to oral dosing (Ganguly et al., 2010; Van Bogaert & Misra, 2010). Several small cohort studies confirm the effectiveness of the both the vaginal and sublingual routes, and also confirm increased success when multiple doses of misoprostol are used (Carbonell Esteve et al., 1998; Carbonell et al., 1999; Carbonell et al., 2001; Grapsas et al., 2008; Kapp, Eckersberger, Lavelanet, & Rodriquez, 2018; Tang, Miao, Lee, & Ho, 2002). There is strong evidence in randomized controlled trials of misoprostol-only regimens that support using a vaginal dosing interval of every three hours for gestations over 13 weeks (von Hertzen et al., 2009). Extrapolating from the evidence supporting repeat doses of sublingual or vaginal misoprostol at gestations both below nine and above

13 weeks, the evidence-based regimen recommended for gestations below nine weeks may be used for gestations between 9-13 weeks.

Young women

Safety and effectiveness of misoprostol-only abortion has been demonstrated in adolescents with pregnancies up to nine weeks gestation (Velazco et al., 2000) and between 9-12 weeks gestation (Carbonell et al., 2001). Success rates of misoprostol-only abortion in young women are similar to those seen in studies of older women.

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MEDICAL ABORTION
3.6.5 HOME USE OF MEDICATIONS UP TO 11 WEEKS GESTATION

3.6

Recommendation

- Women may take mifepristone in a facility or at home.
- Home use of misoprostol following mifepristone or in a misoprostol-only regimen may be offered up to 11 weeks gestation.
- After 11 weeks gestation, misoprostol should be used in a facility.

Strength of recommendation

Strong

Quality of evidence

- Up to 70 days gestation: Moderate
- Over 70 days gestation: Very low

Last reviewed: January 10, 2020

Mifepristone and misoprostol regimen

Traditionally, providers have given mifepristone to women in a facility to start the abortion process. Then 1-2 days later, women may take misoprostol in a health facility, their own home or another safe location. Because of women's individual preferences for privacy, support and timing, they should have options about the location of mifepristone and misoprostol use.

Home use of mifepristone

Two prospective, non-randomized multicenter cohort studies conducted in the United States, which together included 701 women, showed that between a third and a half of women offered home or facility use of mifepristone chose home use (Chong et al., 2015; Swica et al., 2012). Women who used mifepristone at home were highly satisfied and had similar success rates and need for telephone or emergency room support as women who took mifepristone in the clinic. In similar studies conducted in Azerbaijan (Louie et al., 2014), Nepal (Conkling, Karki, Tuladhar, Bracken, & Winikoff, 2015) and Kazakhstan (Platais, Tsereteli, Grebennikova, Lotarevich, & Winikoff, 2016), 74%, 72% and 64% of women, respectively, chose home use. The most commonly cited reasons for the choice to take mifepristone at home were flexibility, ability to schedule abortion around duties, partner's presence and a more private experience. Abortion success rates were the same in the home use and clinic use groups. When a woman chooses home use of mifepristone, she should take it within one week of the clinic visit at which she received the prescription or medication, provided her pregnancy does not exceed 11 weeks at that time.

Home use of misoprostol up to 70 days

A systematic review of nine prospective comparative cohort studies including 4,522 women up to 56 days gestation showed that complete abortion rates and adverse event rates were the same for home- and facility-based misoprostol use (Ngo, Park, Shakur, & Free, 2011) as part of a mifepristone-misoprostol regimen. Women found home use as acceptable as clinic use. A non-randomized comparative trial including 731 rural and urban Indian women up to 63 days gestation found no difference in abortion success or adverse events between home and facility administration of misoprostol (Iyengar et al., 2016). Large observational studies up to 59 days (Fjerstad et al., 2009) and 63 days (Gatter, Cleland, & Nucatola, 2015; Goldstone, Walker, & Hawtin, 2017; Lokeland, Iversen, Engeland, Okland, & Bjorge, 2014; Louie et al., 2014; Raghavan et al., 2013) also confirmed the safety and effectiveness of home use of misoprostol. The Royal College of Obstetricians and Gynaecologists (RCOG, 2015) recommends home use of misoprostol up to 63 days gestation. The World Health Organization (WHO) suggests that when women have access to a source of accurate information and to a health care provider, they can self-manage the abortion process up to 12 weeks gestation. The WHO also calls for rigorous research to establish the safety, efficacy and acceptability of medical abortion in the outpatient setting for pregnancy from 9-12 weeks gestation (WHO, 2015; WHO, 2018).

A multicenter study of 729 women in the United States comparing a single dose of buccal misoprostol 800mcg at home from 57-63 days and from 64-70 days as part of a mifepristone-misoprostol regimen showed no difference between the groups in success rates, ongoing pregnancy or adverse events (Winikoff et al., 2012). A prospective, open-label trial conducted in India, Georgia, Tunisia and Ukraine compared outcomes of 703 women who received mifepristone followed by 400mcg of sublingual misoprostol in the home for pregnancies of 57-63 days or 64-70 days gestation (Bracken et al., 2014). Success rates and ongoing pregnancy rates did not differ between groups, although women in the later gestational age group were more likely to receive an additional dose of misoprostol or require intervention for bleeding. Additional smaller studies have shown similar results (Boersma, Meyboom-de Jong, & Kleiverda, 2011; Platais et al., 2016; Tan et al., 2018). The American College of Obstetricians and Gynecologists (ACOG, 2014) and the National Abortion Federation (NAF, 2017) recommend offering home use of misoprostol up to 70 days gestation.

Home use of misoprostol from 10-13 weeks

One small retrospective cohort study compared safety and effectiveness of home use of misoprostol for medical abortion at gestational age 57-63 days to home use from 64-76 days (Larsson, & Ronnberg, 2019). Women received mifepristone in the health center then returned home where 36-48h later they self-administered a single dose of misoprostol 800mcg vaginally, followed by up to four additional doses of 400mcg if bleeding did not occur. Success rates were 96% and 94% in the earlier and later gestational groups, although more women in the later group had an ongoing pregnancy (one versus four). There was no difference in incomplete abortion, excessive bleeding, surgical intervention or unscheduled return visits between groups. There are no comparative or prospective data regarding home use of misoprostol as part of a combined regimen after 11 weeks gestation.

Misoprostol-only regimen

No studies have directly compared safety and effectiveness of home use of misoprostol in a misoprostol-only regimen to health facility use. However, several studies with misoprostol-only arms have allowed women to self-administer the medication at home up to nine weeks gestation without an effect on safety or medical abortion success (Blum et al., 2012; Ngoc et al., 2011). Additionally, three small prospective cohort studies of misoprostol-only abortion conducted in Cuba allowed home use of medication up to 9 (Carbonell, Valera,

Velazco, Fernandez, & Sanchez, 1997; Velazco et al., 2000), or between 9-12 gestational weeks (Carbonell et al., 2001) without an effect on safety or success. Two studies that enrolled only adolescents (Carbonell et al., 2001; Velazco et al., 2000) found higher rates of nausea and vomiting than observed in studies with adult women.

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MEDICAL ABORTION
3.6.6 CONFIRMATION OF SUCCESS

3.6

Recommendation

- Most women undergoing abortion with a combined regimen of mifepristone and misoprostol have a successful abortion; routine follow-up is not required.
- Women using a misoprostol-only regimen for medical abortion need follow-up with a clinician to ensure the abortion was successful.
- Providers may perform a clinical assessment to assist in the confirmation of successful abortion.
- Ultrasound or other testing is needed only in cases where the diagnosis is unclear.

Strength of recommendation

Strong

Quality of evidence

Moderate

Last reviewed: January 10, 2020

Medical abortion with mifepristone and misoprostol

The success rate of mifepristone followed by misoprostol for medical abortion up to 10 weeks gestation is over 95%, with ongoing pregnancy rates of less than 2% (Chen & Creinin, 2015; Kulier et al., 2011; Raymond, Shannon, Weaver, & Winikoff, 2012). The World Health Organization (WHO) states that routine follow-up after medical abortion with mifepristone and misoprostol is not required (2014). Multiple strategies have been examined to confirm a successful medical abortion and identify rare ongoing pregnancies when using the mifepristone and misoprostol regimen.

Women's assessment of successful abortion

Evidence indicates that women can accurately determine when their mifepristone and misoprostol medical abortion is successful—that is, whether pregnancy expulsion has occurred. In studies comparing women's assessments of expulsion based on their symptoms to those made by clinicians (Cameron, Glasier, Johnstone, Dewart, & Campbell, 2015; Clark et al., 2010; Perriera et al., 2010; Rossi, Creinin, & Meyn, 2004) and by ultrasound (Rossi et al., 2004), women have repeatedly proven to be nearly as accurate as both.

Clinical assessment

Providers may help confirm successful mifepristone and misoprostol abortion at a follow-up visit by reviewing a patient history and performing a bimanual exam, if indicated. In studies

comparing clinical assessment to ultrasound (Rossi et al., 2004; Pymar, Creinin, & Schwartz, 2001), clinicians determined pregnancy expulsion with high levels of accuracy.

Ultrasound

Ultrasound can be used to confirm successful abortion but is not necessary and can add to the cost and complexity of medical abortion, particularly where providers are inexperienced in reading post-medical abortion ultrasound (Kaneshiro, Edelman, Sneeringer, & Gómez Ponce de León, 2011). Ultrasound is helpful in cases where there is doubt about the presence of an ongoing pregnancy.

Serum pregnancy testing

Serum pregnancy testing has been used as an alternative to ultrasound to diagnose an ongoing pregnancy following mifepristone and misoprostol and compares favorably to ultrasound in reducing interventions at the time of follow-up (Clark, Panton, Hann, & Gold, 2007; Dayananda, Maurer, Fortin, & Goldberg, 2013; Fiala, Safar, Bygdeman, & Gemzell-Danielsson, 2003). Serum pregnancy testing is most useful when a pre-treatment hCG has been obtained for comparison; hCG declines by more than 90% seven days after mifepristone is administered in the case of a successful medical abortion (Pocius et al., 2016). A serum hCG level below 900 IU 14-21 days after early (<63 days gestation) medical abortion excludes ongoing pregnancy (Le Lous et al., 2018).

Urine pregnancy testing

A negative urine pregnancy test is reassuring that an abortion has been successful. Rarely, however, a pregnancy test is negative but a woman is still pregnant (false negative). Both high-sensitivity and low-sensitivity urine pregnancy tests can have positive results even when the medical abortion has been successful (false positive) (Cameron, Glasier, Dewart, Johnstone, & Burnside, 2012; Clark et al., 2010; Godfrey, Anderson, Fielding, Meyn, & Creinin, 2007; Perriera et al., 2010). A number of studies have examined use of low-sensitivity (Cameron et al., 2012, Cameron et al., 2015; Constant, Harries, Daskilewicz, Myer, & Gemzell-Danielsson, 2017; Iyengar et al., 2015; Michie & Cameron, 2014) and semi-quantitative or multi-level (Anger et al., 2019; Oppegaard et al., 2015; Raymond et al., 2017a; Raymond et al., 2017b) urine pregnancy tests, often in combination with a symptom checklist, to confirm a successful abortion or identify an ongoing pregnancy without returning for follow-up. A 2018 systematic review assessed the accuracy of using low-sensitivity pregnancy testing to identify ongoing pregnancy after medical abortion (Raymond, Shocket, & Bracken, 2018a); it found that a positive or invalid low-sensitivity pregnancy test had only moderate sensitivity for detecting ongoing pregnancy. A 2017 meta-analysis, which included seven studies that examined use of multi-level pregnancy tests to confirm abortion success when using the combined regimen up to 9 weeks gestation, found that the tests identified all continuing pregnancies (21 out of 1,599 participants, 1.3%) and that most women can successfully perform the tests themselves at home (Raymond et al., 2017a).

Two systematic reviews in 2019 compared outcomes for women who self-assessed medical abortion success at home using a low-sensitivity or semi-quantitative urine pregnancy test in combination with a pictorial instruction sheet, symptom checklist or no checklist, to women who received routine clinic follow- up (Baiju, Acharya, D'Antonio, & Berg, 2019; Schmidt-Hansen, Cameron, Lohr, & Hasler, 2019). Both reviews included four studies and more than 5,000 women and agreed that there were no differences in successful abortion, ongoing pregnancy, need for surgical intervention, or incidence of infection or hemorrhage between self-assesment and clinic follow-up groups. However, a 2018 prospective cohort study found that 14% of women, when directed to use a symptom analysis and multi-level pregnancy test to determine abortion success, failed to implement these measures correctly,

although none of the women had an ongoing pregnancy or serious adverse event (Raymond et al., 2018b).

Medical abortion with misoprostol only

Due to the lower success rate (80-85%) and higher rate of ongoing pregnancy following misoprostol-only medical abortion before 13 weeks gestation (von Hertzen et al., 2007), WHO recommends routine clinic follow-up for all women undergoing medical abortion with misoprostol only to ensure success of the abortion (WHO, 2014).

Follow-up assessment

There are no studies examining different strategies to determine abortion success when using the misoprostol-only regimen. Possible follow-up strategies, extrapolated from studies about the combined regimen (detailed above) and programmatic data, include a history and physical examination, bimanual examination, ultrasound and/or a serum or urine pregnancy testing to rule out an ongoing pregnancy.

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MEDICAL ABORTION
3.6.7 ULTRASOUND FINDINGS AT FOLLOW-UP

3.6

Recommendation

- If clinicians choose to use ultrasound for medical abortion follow-up, the only ultrasound finding that requires intervention is an ongoing viable pregnancy.

Strength of recommendation

Strong

Quality of evidence

Low

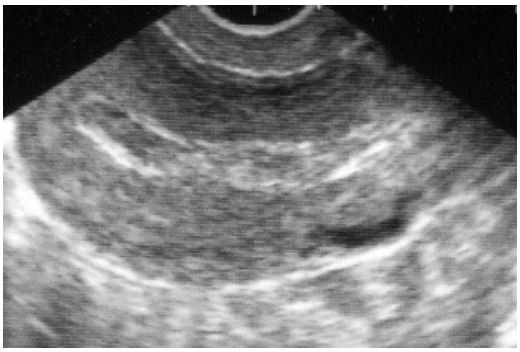
Last reviewed: January 10, 2020

Background

Ultrasound is not necessary to provide abortion care (World Health Organization [WHO], 2014) but may be common in some settings. Ultrasound for follow-up after medical abortion has diagnostic limitations. Except for the case of an ongoing viable pregnancy, intervention after a medical abortion should be based on clinical symptoms and not ultrasound findings.

Ultrasound findings at follow-up

Endometrial thickening: After a successful medical abortion, endometrial thickness varies and can be associated with a complex or heterogeneous appearance.



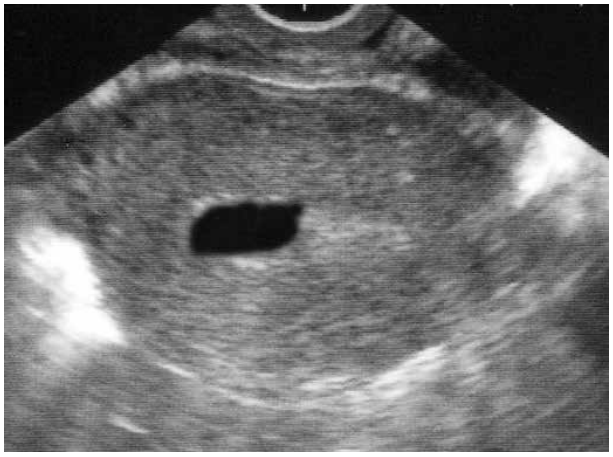
Endometrial thickening

Courtesy of Mary Fjerstad

Multiple retrospective and prospective cohort studies have shown that endometrial thickness ranges widely in women after medical abortion, with significant overlap between women with successful and failed medical abortion (Cowett, Cohen, Lichtenberg, & Stika, 2004; Markovitch, Tepper, Klein, Fishman, & Aviram, 2006; Parashar, Iversen, Midbøe, Myking, & Bjørge, 2007; Rørbye, Nørgaard, & Nilas, 2004; Tzeng, Hwang, Au, & Chien, 2013).

In a pooled analysis of 2,208 women one week after medical abortion, after women with a persistent gestational sac were excluded, the average endometrial thickness was 10.9mm in women who did not require more intervention and 14.5mm in 30 women who did require intervention (Reeves, Fox, Lohr, & Creinin, 2009). Although the average endometrial thickness in women who require intervention tends to be higher, because of the range and overlap between successful and unsuccessful abortion, no study has found that there is a thickness above which a diagnosis of unsuccessful medical abortion can be made. The decision to intervene should be made on clinical signs and symptoms, such as ongoing or heavy bleeding, rather than on ultrasound findings.

Persistent gestational sac: A persistent gestational sac, in which the sac is present but there is no viable embryonic tissue, occurs in less than 1% of medical abortions with the recommended mifepristone and misoprostol regimen (Creinin et al., 2004; Creinin et al., 2007; Winikoff et al., 2008). A persistent gestational sac is not a viable pregnancy and may be managed with aspiration, a second dose of misoprostol or expectant management according to a woman's preference. In a study of women with a persistent gestational sac within 11 days of medical abortion, a second dose of misoprostol was found to lead to expulsion in 69% of women (Reeves, Kudva, & Creinin, 2008).



Persistent gestational sac

Courtesy of Mary Fjerstad

Ongoing viable pregnancy: An ongoing pregnancy, in which a growing sac and/or embryo with cardiac activity are present, occurs in less than 1% of medical abortions with the recommended mifepristone and misoprostol regimen (Von Hertzen et al., 2009; Winikoff et al., 2008). Some women will be able to identify this outcome without ultrasound due to lack of bleeding or continued pregnancy symptoms. A woman with an ongoing pregnancy should be offered uterine evacuation as soon as possible with either vacuum aspiration or a second dose of misoprostol, depending on gestational age and local context. The success rate of misoprostol after failed medical abortion is 36% (Reeves et al., 2008; WHO, 2014). If a woman chooses a second dose of misoprostol, she must be followed to see if it is successful.

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4.1 WHO HAS ABORTIONS AT 13 WEEKS OR LATER?

Key information

- Women who present for abortion at 13 weeks of pregnancy or later are more likely than those who present at earlier gestations to be young or a victim of violence, have detected their pregnancy later, feel ambivalent about the abortion decision, and/or have financial and logistical barriers to care. Additionally, medical or fetal indications for an abortion may not be apparent until after 13 weeks. Reasons for presenting at or after 13 weeks gestation appear similar across countries and cultures and disproportionately affect underserved women.

Quality of evidence

Low

Last reviewed: January 10, 2020

Epidemiology of abortion at 13 weeks and later

While abortions at or after 13 weeks gestation comprise a minority (around 10-15%) of the total abortions worldwide, they are responsible for the majority of serious abortion-related complications (Harris & Grossman, 2011; Jatlaoui et al., 2017; Loeber & Wijsen, 2008). In more restrictive settings, or where safe abortion access is limited, presentation at or after 13 weeks gestation for postabortion care is more common. In Cambodia 17%, in Ethiopia 38%, and in Kenya 41% of women needing postabortion care present at or after 13 weeks gestation. (African Population and Health Research Center, Ministry of Health Kenya, Ipas Kenya, & Guttmacher Institute, 2013; Fetters, Vonthanak, Picardo, & Rathavy, 2008; Gebreselassie et al., 2010).

Why do women need abortions at 13 weeks and later?

Young age: Young women are disproportionately likely to seek abortion at or after 13 weeks. In the United States, 22.6% of girls younger than age 15 and 12.5% of adolescents ages 15-19 seeking abortion care do so after 13 weeks gestation (Jatlaoui et al., 2017). In Mexico City, adolescents comprised 9% of all women seeking abortion from 2007-2015; yet, they accounted for 13% of women seeking abortion beyond 12 weeks gestation (Saavedra-Avendano et al., 2018). Smaller case-control and cohort studies in Ethiopia, India, Nepal, Singapore and the United States have found young age to be a risk factor for later presentation (Bonnen, Tuijje, & Rasch, 2014; Foster & Kimport, 2013; Lim, Wong, Yong, & Singh, 2012; Sowmini, 2013).

Late detection of pregnancy: A common risk factor in all studies for presenting for abortion at or after 13 weeks is late recognition of pregnancy. Absence of pregnancy signs and symptoms, menstrual irregularity, contraceptive use, or amenorrhea after recent pregnancy can mask physical signs of pregnancy and delay pregnancy diagnosis (Constant, Kluge, Harries, & Grossman, 2019; Drey et al., 2006; Foster & Kimport, 2013; Gallo & Nghia, 2007; Harries, Orner, Gabriel, & Mitchell, 2007; Ingham, Lee, Clements, & Stone, 2008; Jones & Jerman,

2017; Purcell et al., 2014). In one case-control study in the United States, women who sought abortion after 20 weeks were much more likely to have been eight weeks pregnant or more at the time they discovered they were pregnant (68%), compared to women who had abortions before 13 weeks gestation (12%) (Foster & Kimport, 2013).

Ambivalence and/or difficulty with abortion decision: Women's decisionmaking may be delayed due to social pressures, fears, religious attitudes and changes in relationship status. Changes in circumstance (such as abandonment by partner) cause some women to seek an abortion after initially planning to continue the pregnancy (Foster & Kimport, 2013; Gallo & Nghia, 2007; Harries et al., 2007). Discouraging family and friends may also delay a woman seeking care (Waddington, Hahn, & Reid, 2015).

Financial and logistical barriers: Unemployment and lack of insurance are risk factors for presentation at 13 weeks or later, according to studies conducted in the United States (Gonzalez, Quast, & Venanzi, 2019). Globally, poverty (Usta, Mitchell, Gebreselassie, Brookman-Amissah, & Kwizera, 2008), immigrant status (Gonzalez-Rabago, Rodriguez-Alvarez, Borrell, & Martin, 2017; Loeber & Wijsen, 2008) and rural residence (Bonnen et al., 2014; Ushie, Izugbara, Mutua, & Kabiru, 2018) are additional risk factors. Delays may be related to raising enough money to cover the cost of the procedure, particularly as procedures later in gestation are more expensive (Foster & Kimport, 2013; Kiley, Yee, Niemi, Feinglass, & Simon, 2010). Abortions at or after 13 weeks gestation are provided at a limited number of facilities and travel logistics present difficulties for many. In one case-control study of women presenting for abortion at over 20 weeks gestation, women were much more likely than those in earlier gestations to have travelled over three hours to access care (Foster & Kimport, 2013). Clients at 13 weeks gestation or later may be referred by other providers or have trouble finding a provider before finally accessing care (Drey et al., 2006; Harries et al., 2007). Women may also need to travel out of their own country to access legal abortion after 13 weeks (Cameron et al., 2016; Loeber & Wijsen, 2008).

Fetal indications: Diagnosis of fetal anomalies typically occurs after the first 12 weeks of pregnancy, and women may make the decision to terminate pregnancy based on the diagnosis (Lyus, Robson, Parsons, Fisher, & Cameron, 2013).

Maternal indications: A woman may have a medical condition that worsens through the course of pregnancy or a new condition may arise in pregnancy that endangers her life or health. Severe preeclampsia or preterm premature rupture of membranes may require termination of pregnancy to save a woman's life (American College of Obstetricians and Gynecologists, 2015).

Victims of violence: Victims of violence have a higher risk of late presentation (Colarossi & Dean, 2014; Perry et al., 2015).

Failed abortion: Although failures are rare, women who experience an ongoing pregnancy after an abortion before 13 weeks may not discover they are still pregnant until after 13 weeks gestation (Gallo & Nghia, 2007).

Cultural beliefs: In rare cases there are local beliefs that having an abortion at 13 weeks or later is safer than the first 12 weeks of pregnancy, thus causing women to delay care (Marlow et al., 2014).

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4.2 COMPARING METHODS

Key information

- Dilatation and evacuation (D&E) and medical abortion with mifepristone and misoprostol or misoprostol only are safe and effective methods of abortion.
- Women should be offered a choice of methods when both D&E and medical abortion are available.
- Medical abortion has a higher rate of retained products of conception, failed abortion and minor adverse events.
- D&E requires a trained, experienced provider and specialized equipment.

Quality of evidence

Moderate

Last reviewed: January 6, 2020

Comparison of methods

In retrospective cohort studies, women with gestations 13-24 weeks who had medical abortions had an increased rate of failed abortion and retained products of conception with a need for further intervention compared to women who had D&E (Autry, Hayes, Jacobson, & Kirby, 2002; Bryant, Grimes, Garrett, & Stuart, 2011; Sonalkar, Ogden, Tran, & Chen, 2017). However, the rate of major adverse events including infection, transfusion, hysterectomy and death does not differ between the two methods.

The largest trial comparing methods randomized 122 women with gestations between 13-20 weeks to D&E or medical abortion with mifepristone and misoprostol (Kelly, Suddes, Howel, Hewison, & Robson, 2010). Overall rates of complications were similar in the two groups, although the types of complications differed. Five women in the medical arm required uterine evacuation for retained products of conception and one suffered bleeding requiring transfusion; only one woman in the surgical arm required repeat uterine evacuation, one suffered a cervical laceration, and five had hemorrhage that did not require transfusion. A statistically significant proportion of women randomized to medical abortion had more bleeding and pain and found the abortion process less acceptable than women who had D&E. A pilot randomized trial of 18 women with gestations between 14-19 weeks comparing D&E and medical abortion with mifepristone and misoprostol found a higher rate of adverse events, specifically retained placenta and fever, in women undergoing medical abortion, although none were serious (Grimes, Smith, & Witham, 2004).

In published studies of medical abortion compared to D&E, rates of intervention for medical abortion may be artificially high because failure was defined as no expulsion within 24 hours (Bryant et al., 2011) and retained placenta was diagnosed after two hours (Grimes et al., 2004). In practice, more time may be allowed for successful medical abortion to occur.

The importance of choice

In settings where both D&E and medical abortion are available, if a woman is a candidate for either procedure, she should be offered a choice. Both randomized trials referenced above (Kelly et al., 2010; Grimes, et al., 2004) had difficulty with recruitment due to women's strong preferences for one method-generally D&E-over the other. For women, the choice of abortion procedure is an intensely personal one (Kerns et al., 2018)—some women prefer the speed and predictability of D&E, while others prefer a more "labor-like" process with an intact fetus (Kelly et al., 2010; Kerns et al., 2012). To choose the abortion procedure that best facilitates their coping, women women need adequate information regarding the two abortion methods and the ability to make their decision autonomously (Kerns et al., 2018).

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4.3 GESTATIONAL DATING

Recommendation

- Gestational age should be calculated using a woman's last menstrual period (LMP) combined with physical examination.
- Routine use of ultrasound for gestational age determination is not necessary.

Strength of recommendation

Strong

Quality of evidence

Very low

Last reviewed: January 6, 2020

Importance of accurate gestational dating

Errors in gestational dating can increase the risks associated with abortion. If gestational age is underestimated prior to dilatation and evacuation (D&E), providers may not have the experience and equipment to complete the procedure safely. Accurate assessment of gestational age enables providers to determine whether the facility is equipped to provide the requested service and refer to another facility if necessary.

Dating

Gestational age assessment using bimanual examination and women's LMP is well established during prenatal care, as is the use of ultrasound. No trials have compared the accuracy of different methods of gestational dating prior to abortion at or after 13 weeks, and a 2011 systematic review aimed at determining if preabortion ultrasound affected the safety or efficacy of abortion procedures both before and after 13 weeks found no relevant studies (Kulier & Kapp, 2011). In the United States, virtually all providers use ultrasound for gestational age assessment after 12 weeks gestation, but data are lacking from other country contexts (O'Connell et al., 2018).

Prior to medical abortion, gestational age can be estimated using the first day of a woman's LMP and a physical examination that includes bimanual and abdominal examination (Nautiyal, Mukherjee, Perhar, & Banerjee, 2015; Ngoc et al., 2011; Royal College of Obstetricians and Gynaecologists [RCOG], 2015; World Health Organization [WHO], 2014). Measuring fundal height, as in routine obstetric care, can provide additional information as the pregnancy advances (Pugh et al., 2018). Ultrasound can be used to confirm gestational age if the LMP and clinical examination are discordant or if there is uncertainty about gestational age but is not required prior to medical abortion.

In published studies of D&E, including reports of implementation of D&E programs (Castleman, Oanh, Hyman, Thuy, & Blumenthal, 2006; Jacot et al., 1993), ultrasound has been

routinely used to establish or confirm gestational age prior to D&E. However, one published report (Altman, Stubblefield, Schlam, Loberfeld, & Osanthanondh, 1985), unpublished programmatic data (A. Edelman, personal communication, January 12, 2018) and expert opinion support use of LMP and physical examination for gestational age assessment, with use of ultrasound as needed (RCOG, 2015; WHO, 2014). If ultrasound is used, biparietal diameter is a simple and accurate method to confirm gestational age (Goldstein & Reeves, 2009). A femur length measurement can be used to confirm the biparietal diameter or used if there are technical difficulties in obtaining a biparietal measurement.

Women who present with fetal demise, incomplete abortion or for postabortion care may have discordant LMP dates and uterine size; they should be treated according to uterine size (RCOG, 2016; WHO, 2018).

After the abortion, clinicians can confirm gestational age by comparing actual fetal measurements (fetal foot length) to the expected gestational age (Drey, Kang, McFarland, & Darney, 2005; Mokkarala, Creinin, Wilson, Yee, & Hou, 2020). This comparison provides feedback regarding the accuracy of pre-procedure dating estimates. Pregnancy dating tools, such as fetal measurements, are included in Ipas's *Dilatation & Evacuation (D&E) Reference Guide: Induced Abortion and Postabortion Care at or After 13 Weeks Gestation,* page 38 (2017), and *Medical Abortion Reference Guide: Induced Abortion and Postabortion Care at or After 13 Weeks Gestation,* page 30 (2017).

Identification of fetal sex with ultrasound

After 14 weeks gestation ultrasonographic visualization of the male penis or female labial folds can be used to determine fetal sex in approximately 90% of gestations (Gelaw & Bisrat, 2011; Meagher & Davidson, 1996; Watson, 1999; Whitlow, Lazanakis & Economides, 1999).

Before 14 weeks, male and female genitals are similar in size and appearance on ultrasound (Feldman & Smith, 1975) and sex determination must instead be made by identification and evaluation of the genital tubercle (a protuberance on the lower ventral wall of the embryo that eventually becomes the penis or clitoris), (Efrat, Akinfewa, & Nicolaides, 1999). A 2013 review of studies determining fetal sex through ultrasonographic evaluation of the genital tubercle (Colmant, Morin-Surroca, Fuchs, Fernandez, & Senat, 2013) found that sex determination via this method was unreliable below 12 weeks gestation. Findings published since the review have been similar (Gonzalez Ballano, Saviron Cornudella, Puertas, & Luis, 2015; Lubusky, Studnickova, Skrivanek, Vomackova, & Prochazka, 2012; Manzanares, Benitez, Naveiro-Fuentes, Lopez-Criado & Sanchez-Gila, 2016).

Regardless of the method employed to determine fetal sex, accuracy improves with increasing gestational age (Elejalde, Elejalde, & Heitman, 1985; Colmant et al., 2013) and skill of the ultrasonographer (Lubusky et al., 2012). Unfavorable fetal position and a woman's body habitus may limit the ability to determine fetal sex regardless of gestational age or ultrasonographer skill (Behrendt, Foy, Center, & Durnwald, 2012; Efrat, Perri, Ramati, Tugendreich, & Meizner, 2006; Elejalde et al., 1985).

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4.4 INDUCED FETAL DEMISE

Recommendation

- Induced fetal demise prior to medical abortion or dilatation and evacuation (D&E) at or after 13 weeks gestation does not increase the safety of abortion. However, there may be legal, facility or social reasons for inducing preprocedure fetal demise.

Strength of recommendation

Strong

Quality of evidence

Low

Last reviewed: January 12, 2020

Background

Some providers may induce fetal demise before medical abortion or D&E at or after 13 weeks gestation for a variety of reasons. Patients, providers or staff may prefer that fetal demise occurs before an abortion procedure (Jackson, Teplin, Drey, Thomas, & Darney, 2001) or it may be dictated by the facility's practices. Additionally, induced fetal demise is one way to prevent transient fetal survival following a medical abortion.

Safety and benefit of inducing fetal demise

A retrospective cohort study comparing women with digoxin injection prior to D&E with historical controls who did not receive digoxin showed an increase in complications, including more hospital admissions, extramural deliveries and infections in women who received digoxin (Dean et al., 2012). One case series including nearly 5,000 D&E abortions after digoxin injection found rates of extramural deliveries (0.3%) and infection (0.04%) that authors concluded were acceptably low (Steward, Melamed, Kim, Nucatola, & Gatter, 2012). A retrospective cohort study comparing women who underwent fetal intracardiac potassium chloride injection before D&E to women who did not undergo the additional procedure found that while procedure duration was decreased by 3.5 minutes when fetal demise was induced, there was an increase in women's pain and in the incidence of uterine atony (Lohr, Parsons, Taylor, & Morroni, 2018).

Two retrospective comparative cohort studies measured the effect of intracardiac potassium chloride on induction-to-abortion interval when administered before medical abortion. In one study with a gestational age range of 17-28 weeks, the induction-to-abortion interval was significantly shorter in women who received the injection (15 hours) compared to those who did not (19.9 hours) (Akkurt et al., 2018). A similar study among women with a mean gestational age of 21 weeks found no difference in time-to-abortion between those with pre-procedure potassium chloride for feticide (35 hours) versus those without (32 hours) (Sik, et al.).

Technique

Fetal demise can be achieved prior to abortion at or after 13 weeks by injecting potassium chloride directly into the fetal heart or digoxin into the fetus or amniotic fluid.

Potassium chloride: Potassium chloride injection requires skill in ultrasound guidance techniques and has more potential risk due to the possibility of maternal intravascular injection which can cause cardiac arrest (Borgatta & Kapp, 2011; Coke, Baschat, Mighty, & Malinow, 2004). It is not recommended in a low-resource setting.

Digoxin: Digoxin is injected either transabdominally or transvaginally (Tocce, Sheeder, Edwards, & Teal, 2013) 1-2 days before the planned abortion procedure.

In a pharmacokinetic study of eight women between 19-23 weeks who had intra-amniotic injection of digoxin 1mg prior to D&E, maternal serum digoxin levels were in the low therapeutic range and were not associated with cardiac changes (Drey, Thomas, Benowitz, Goldschlager, & Darney, 2000). A pilot randomized trial of intra-amniotic or intra-fetal digoxin at doses of 1mg or 1.5mg showed an overall rate of fetal demise of 87% with no difference in effectiveness based on the dose or route of administration (Nucatola, Roth, & Gatter, 2010). In a prospective cohort study of 59 women undergoing termination of pregnancy between-21-30 weeks, digoxin 2mg administered intra-amniotically resulted in fetal demise for more than 90% of cases, with no adverse maternal effects (Sharvit, et al., 2018).

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FOLLOW-UP

4.5

Recommendation

- Routine follow-up care is not necessary unless desired by the woman or necessary for her chosen contraceptive method.
- At the time of the abortion, clients should receive adequate information regarding post-abortion care and warning signs.

Strength of recommendation

Weak

Quality of evidence

Very low

Last reviewed: January 12, 2020

Follow-up

There is no scientific data to demonstrate that routine follow-up is beneficial after abortion at or after 13 weeks. In addition, there is no evidence to suggest that a pelvic examination is beneficial in an asymptomatic woman if she does return for a routine follow-up visit.

Quality of evidence

Very low. The recommendation is based on expert opinion (World Health Organization [WHO], 2014).

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4.6 DILATATION AND EVACUATION
4.6.1 CERVICAL PREPARATION

Recommendation

- Routine preoperative cervical preparation is recommended before dilatation and evacuation (D&E).
- Osmotic dilators, misoprostol and mifepristone are options for cervical preparation. The choice depends on availability, expense, gestational age and timing of the procedure.

Strength of recommendation

Strong

Quality of evidence

High

Last reviewed: January 9, 2020

Background

Cervical preparation prior to D&E reduces the risk of procedure-related complications (Fox & Krajewski, 2014; Peterson, Berry, Grace, & Gulbranson, 1983). There is limited data to suggest the best method of cervical preparation before D&E because the trials that exist have heterogeneous comparisons, proxy outcomes for adverse events, small sample sizes, and include few women with pregnancies over 20 weeks (Ralph & Shulman, 2019). Available trials typically show differences in cervical dilation or procedure times, however they do not include enough participants to show differences in rare but more serious outcomes such as cervical or uterine injuries or inability to complete the procedure (Newmann et al., 2010). Choice of method of cervical preparation is often limited by supply availability, especially in low-resource settings.

Table 4.6.1. Cervical preparation methods

METHOD	DOSING	NOTE
Osmotic dilators (laminaria or synthetic osmotic dilators)	6-24 hours prior to procedure	Synthetic osmotic dilators may be used the day of the D&E
Misoprostol	400mcg buccally or vaginally 3 hours prior to procedure	May be used as a single agent up to 18 weeks, very limited data to support use as a single agent over 18-20 weeks May be combined with osmotic dilators or mifepristone May be repeated as needed

METHOD	DOSING	NOTE
Mifepristone	200mg orally 24-48 hours prior to procedure	Limited data support use as a single agent up to 18 weeks Often used prior to misoprostol

Osmotic dilators

Numerous cohort studies have demonstrated that osmotic dilators are safe, effective and do not increase infectious morbidity (Bryman, Granberg, & Norström, 1988; Fox & Krajewski, 2014; Jonasson, Larsson, Bygdeman, & Forsum, 1989; Peterson et al., 1983). A Cochrane meta-analysis of cervical preparation before D&E between 14-24 weeks gestation showed that overnight osmotic dilators provide better cervical dilation when compared to prostaglandins, and decreased procedure time between 13-16 weeks gestation (Newmann et al., 2010). In one randomized controlled trial, synthetic dilators and laminaria worked equally well (Newmann et al., 2014). Decisions about the number and timing of dilators to place should be individualized and take into consideration the type of dilator and its size, the gestational age of the pregnancy, parity and cervical compliance, and the provider's experience (Fox & Krajewski, 2014; Newmann, Dalve-Endres, & Drey, 2008). Administration of paracervical block prior to dilator insertion eases the discomfort of dilator placement for women (Soon et al., 2017).

Misoprostol

Misoprostol is inexpensive, safe (Nucatola, Roth, Saulsberry, & Gatter, 2008), and more readily available than osmotic dilators in many low-resource settings. Misoprostol may be used alone for cervical preparation prior to D&E up to 20 weeks gestation (Fox & Krajewski, 2014; O'Connell, Jones, Lichtenberg, & Paul, 2008; Shakir-Reese et al., 2019); there is limited data to support use of misoprostol as a single agent after 18 weeks (Maurer, Jacobson, & Turok, 2013; Shakir-Reese et al., 2019). In studies comparing osmotic dilators to misoprostol, dilators provided more cervical dilation (Goldberg et al., 2005; Sagiv et al., 2015; Shakir-Reese et al., 2019). However, women who received misoprostol for cervical preparation were able to have their procedures safely completed on the same day (Bartz et al., 2013; Goldberg et al., 2005; Sagiv et al., 2015), and women often preferred misoprostol to dilators (Goldberg et al., 2005). Misoprostol may be given to women with a prior cesarean delivery, as uterine rupture is rare (Fox & Krajewski, 2014). A study of same-day use of osmotic dilators plus adjunctive 400mcg misoprostol versus only misoprostol 4-6 hours prior to D&E up to 20 weeks gestation resulted in comparable D&E procedure times between the two groups, although the osmotic dilator plus misoprostol group had significantly greater dilation at D&E initiation (Shakir-Reese et al., 2019). Because placing osmotic dilators takes more time than was saved by having greater baseline dilation, the overall procedure time (placing osmotic dilators plus D&E procedure) was longer by 3.2 minutes in the osmotic dilator plus misoprostol group.

Misoprostol plus osmotic dilators

A meta-analysis of three randomized controlled trials of misoprostol versus placebo added to overnight laminaria at gestational ages greater than 16 weeks demonstrated a tendency toward improved baseline cervical dilation and decreased operating time by an average of 1.5 minutes (Cahill, Henkel, Shaw & Shaw, 2019); however, neither finding was statistically significant in the weighted analysis, with significant heterogeneity between studies. Overall complication rates were low in all three studies and did not differ significantly by treatment group (Cahill, Henkel, Shaw & Shaw, 2019: Drey et al., 2013; Edelman, Buckmaster, Goetsch, Nichols, & Jensen, 2006; Goldberg et al., 2015). In all studies, side effects were greater among women using misoprostol.

One small prospective randomized trial has examined adding misoprostol to dilators for same-day D&E (Borras et al., 2016). Investigators ended this study early due to an unexpectedly high rate of complications—specifically serious cervical lacerations—in women over 19 weeks gestation who received dilators alone for cervical preparation.

Mifepristone

One randomized trial of 50 women between 14-16 weeks gestation compared mifepristone as a single agent to dilators, both administered the day prior to the abortion procedure (Borgatta et al., 2012). Women who had cervical preparation with osmotic dilators had a slightly shorter procedure time and greater dilation compared to women given mifepristone, but women had less pain with mifepristone and strongly preferred it. A second randomized trial of 49 women between 15-18 weeks gestation with similar design (single-agent mifepristone compared with osmotic dilators the day prior to procedure) found no difference in procedure time between the two treatment groups (Paris, et al, 2019). When asked, most women who had the mifepristone preferred it, while most who had osmotic dilators reported that they would have preferred a different treatment option for cervical priming.

In studies examining the use of mifepristone in combination with misoprostol, same-day administration of mifepristone plus misoprostol is no better than misoprostol alone (Casey, Ye, Perritt, Moreno-Ruiz, & Reeves, 2016), and while administration of mifepristone 2 days prior to misoprostol resulted in improved cervical dilation in one study, the rate of preprocedure fetal expulsions was also increased (Carbonell et al., 2007). When compared to overnight dilators plus misoprostol, mifepristone administered the day prior to the abortion plus same-day misoprostol is less effective (Shaw et al., 2017).

Mifepristone plus osmotic dilators

Two randomized trials have assessed the addition of mifepristone when women received overnight osmotic dilators plus misoprostol for cervical preparation; neither study showed additional benefit with mifepristone (Shaw et al., 2017; Shaw et al., 2015). A third randomized trial compared overnight dilators alone, overnight dilators plus misoprostol, and overnight dilators plus mifepristone (Goldberg et al., 2015), and found that procedure times were no different between the three groups, although providers reported that procedures between 19-24 weeks gestation were easier in the dilators plus mifepristone group.

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MEDICAL ABORTION
4.7.1 SAFETY AND EFFECTIVENESS

4.7

Key information

- A combined regimen with mifepristone and misoprostol is recommended over a misoprostol-only regimen for medical abortion at or after 13 weeks gestation.
- The combined regimen is safe and effective, with fetal expulsion rates of over 90% at 24 hours, median induction-to-abortion time of 6-10 hours and major complication rates of less than 1%.
- Where mifepristone is not available, misoprostol-only medical abortion is safe and effective, with fetal expulsion rates of 72-91% at 24 hours, average induction-to-abortion time of around 10-15 hours and major complication rates of less than 1%.

Quality of evidence

High

Last reviewed: January 30, 2020

Combined regimen with mifepristone and misoprostol

Expulsion rates

Studies using the recommended regimen of mifepristone and misoprostol show fetal expulsion rates of 94% at 24 hours and 97% at 48 hours (Abbas et al., 2016), and fetal and placental expulsion rates of 88% at 24 hours and 92% at 48 hours (Dabash et al., 2015). When women continue misoprostol until expulsion with no cut off time, 99% of women eventually have a successful abortion (Ashok, Templeton, Wagaarachchi, & Flett, 2004; Louie et al., 2017).

Induction-to-abortion interval

In studies using the recommended mifepristone and misoprostol regimen, the median times to fetal expulsion were from 6-10 hours, with a wide range of times until complete expulsion (Abbas et al., 2016; Dabash et al, 2015; Louie et al., 2017; Ngoc et al., 2011; Shaw, Topp, Shaw, & Blumenthal, 2013; Prodan et al, 2019). The induction-to-abortion interval is longer in nulliparous women, older women and women with pregnancies at a later gestational age (Abbas et al., 2016; Ashok et al., 2004; Dabash et al., 2015; Louie et al., 2017; Platais et al., 2019). The addition of mifepristone to a misoprostol medical abortion regimen consistently reduces the induction-to-abortion interval (Constant et al., 2016; Dabash et al., 2015; Kapp, Borgatta, Stubblefield, Vragovic, & Moreno, 2007; Ngoc et al., 2011; Prodan et al., 2019).

Complication rates

The rate of major complications from mifepristone and misoprostol medical abortion at or after 13 weeks gestation is low, although minor complications—such as needing a procedure for bleeding or retained products of conception—are more frequent than for dilatation

and evacuation (Autry, Hayes, Jacobson, & Kirby, 2002). The largest related cohort study of medical abortion with mifepristone and misoprostol included 1,002 women between 13-21 weeks gestation (Ashok et al., 2004). Eighty-one women (8.1%) needed a uterine evacuation procedure, the majority of which were needed for retained placenta; only two women needed an evacuation to terminate the pregnancy. In this study, serious complications such as hemorrhage, blood transfusion or unanticipated surgery occurred in eight women (less than 1%). In a 2017 cohort study in which 120 women between 13-22 weeks gestation received mifepristone followed by unlimited dosing of misoprostol until fetal and placental expulsion, 99% of women evacuated the uterus without any additional intervention (Louie et al., 2017). No serious adverse events were reported in this study and only one woman failed to abort with the combined regimen.

In a meta-analysis of data from medical abortion studies at or after 13 weeks gestation using either the combined regimen or a misoprostol-only regimen, the overall rate of uterine rupture was 0.08%, with a rate of 0.28% in women with a previous cesarean section (Goyal, 2009).

Subsequent perinatal outcomes

A Finnish register-based study of women who had a medical abortion up to 12 weeks gestation (3,427 women) or between 12-20 weeks gestation (416 women) compared incidence of several outcomes in subsequent pregnancies—preterm birth, low birth weight, small-for-gestational-age infants and placental complications (Mannisto et al., 2014). No differences were observed between the two groups, suggesting medical abortion at or after 13 weeks does not increase risk of these outcomes in subsequent pregnancies compared to earlier medical abortion.

Misoprostol-only regimen

Expulsion rates

The largest international randomized controlled trial of medical abortion at or after 13 weeks gestation with the recommended vaginal or sublingual misoprostol-only regimen included 681 women between 13-20 weeks gestation (von Hertzen et al., 2009). The fetal expulsion rate was 84.8% at 24 hours and 94.3% at 48 hours. Smaller randomized trials using vaginal or sublingual misoprostol every three hours showed fetal expulsion rates of 72-91% at 24 hours and 91-95% at 48 hours (Bhattacharjee, Saha, Ghoshroy, Bhowmik, & Barui, 2008; Tang, Lau, Chan, & Ho, 2004), and fetal and placental expulsion rates of 62-64% at 24 hours and 79-82% at 48 hours (Bhattacharjee et al., 2008). In nulliparous women, vaginal misoprostol has higher expulsion rates than sublingual misoprostol (von Hertzen et al., 2009).

Induction-to-abortion interval

In the von Hertzen trial cited above, the median time to fetal expulsion was 12 hours (range 4.1-61.8 hours), with parous women having faster induction-to-abortion times than nulliparous women (von Hertzen et al., 2009). In smaller randomized trials, time to expulsion ranges from 10-15 hours (Bhattacharjee et al., 2008; Tang et al., 2004). Lengthening the dosing interval of misoprostol from every three to every six hours increases the induction-to-abortion time (Wong, Ngai, Yeo, Tang, & Ho, 2000).

Complication rates

The rate of major complications from misoprostol-only abortion at or after 13 weeks is low. In the trial cited above, 12 adverse events (0.02%) were reported; 10 women required blood transfusions (von Hertzen et al., 2009).

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4.7 MEDICAL ABORTION
4.7.2 MIFEPRISTONE AND MISOPROSTOL: RECOMMENDED REGIMEN

Recommended regimen for 13-24 weeks gestation

- Mifepristone 200mg orally followed 1-2 days later by misoprostol 400mcg buccally, sublingually or vaginally every three hours until fetal and placental expulsion.
- If the woman is stable and it is convenient for her to do so, providers should allow her at least four hours after fetal expulsion to expel the placenta before intervening.

Strength of recommendation

Strong

Quality of evidence

- Up to 20 weeks gestation: Moderate
- 21-24 weeks gestation: Low

Last reviewed: January 30, 2020

Background

Mifepristone combined with misoprostol is the preferred regimen for medical abortion at or after 13 weeks gestation, as it is highly efficacious, resulting in a short induction-to-abortion interval with an excellent safety profile (Borgatta & Kapp, 2011; Wildschut et al., 2011; World Health Organization [WHO], 2018). Mifepristone combined with misoprostol has a consistently shorter induction-to-abortion interval and higher expulsion rate at 15 (Ngoc et al., 2011), 24 (Constant et al., 2016) and 48 hours when compared to misoprostol alone (Dabash et al., 2015).

Mifepristone timing

A 2013 systematic review evaluating the effect of dosing interval between mifepristone and misoprostol on induction-to-abortion interval included 20 randomized controlled trials and nine observational studies (Shaw, Topp, Shaw, & Blumenthal, 2013). Based on the results of three randomized controlled trials, the review found that when mifepristone was given 12-24 hours before misoprostol, the induction-to-abortion interval was slightly longer (median 7.3 hours, range 7 to 8.5) than when mifepristone was administered 36 to 48 hours before misoprostol initiation (6.8 hours, range 6.3 to 7.2), but the abortion rate at 12 and 24 hours was the same (Shaw et al., 2013). In studies examining simultaneous administration of mifepristone and misoprostol, median expulsion times in the simultaneous group ranged from 10 to 13 hours, compared to 5 to 8 hours in women who waited 24 to 36 hours between mifepristone and misoprostol; however, rates of expulsion at 48 hours were equivalent in the two groups (Abbas et al., 2016; Chai et al., 2009).

Misoprostol loading dose

Although an early, large case series used an initial loading dose of vaginal misoprostol (Ashok, Templeton, Wagaarachchi & Flett, 2004), a more recent small, randomized controlled trial assigned 77 women to receive a loading dose of misoprostol vaginally (600mcg, followed by 400mcg every six hours) and 80 women to receive a no-loading dose regimen (400mcg every six hours) (Pongsatha & Tongsong, 2014). Median induction-to-abortion intervals and rates of complete abortion at 24 and 48 hours did not differ between groups, but the loading dose group suffered significantly more misoprostol-related side effects. Recent clinical trials that did not use loading doses of misoprostol showed average induction-to-abortion intervals of 8-10 hours and similar or better success rates as studies with loading doses (Abbas et al., 2016; Dabash et al., 2015; Louie et al., 2017; Ngoc et al., 2011). Therefore, a high initial dose of misoprostol appears to confer no benefit on expulsion times.

Misoprostol dosing

Route: In clinical trials of medical abortion at or after 13 weeks, misoprostol 400mcg vaginally or sublingually has higher success and shorter induction-to-abortion intervals than oral dosing (Dickinson, Jennings & Doherty, 2014; Tang, Chang, Kan & Ho, 2005). Buccal misoprostol has not been directly compared to other routes in a combined regimen for medical abortion at or after 13 weeks, but has similar efficacy as other routes of administration in abortion before 13 weeks (Kulier et al., 2011; Raymond, Shannon, Weaver, & Winikoff, 2013). Studies that use buccal misoprostol as part of a combined mifepristone-misoprostol regimen show an average induction-to-abortion interval of 8-10 hours (Abbas et al., 2016; Dabash, 2015; Louie et al, 2017; Ngoc et al., 2011; Blum et al., 2019).

Dose: Misoprostol 400mcg has higher expulsion rates, shorter induction-to-abortion intervals and similar side effects compared to 200mcg, regardless of route of administration (Brouns, van Wely, Burger, & van Wijngaarden, 2010; Shaw et al., 2013).

Timing: In one randomized trial examining two regimens of misoprostol-only medical abortion at or after 13 weeks gestation, the induction-to-abortion interval was shorter and the expulsion rate at 24 hours was higher when misoprostol was given every three hours compared to every six hours; rates of adverse events were similar (Wong, Ngai, Yeo, Tang, & Ho, 2000).

Number of doses: A prospective cohort study of 120 women between 13 and 22 weeks gestation who received mifepristone followed 24 hours later by misoprostol 400mcg buccally every 3 hours until fetal and placental expulsion reported a complete abortion rate of 99% without additional intervention (Louie et al., 2017). The median number of misoprostol doses necessary was four (range 2 to 6) and no adverse events were reported. In a similar prospective study of 306 women between 13-22 weeks, 90.2% required five or fewer doses of misoprostol (Platais et al., 2019).

Quality of evidence: The recommendation is based on multiple randomized clinical trials and a Cochrane meta-analysis comparing different mifepristone and misoprostol doses, dosing intervals and routes of administration in the second trimester (Wildschut et al., 2011). Most randomized controlled trials of medical abortion at or after 13 weeks do not include women with pregnancies greater than 21 weeks gestation.

Placental expulsion

In a prospective study of women between 13-18 weeks gestation utilizing mifepristone and misoprostol, most women expelled the fetus and placenta at about the same time, with a

median time between fetal and placental expulsion of 15 minutes (range 0-4.5 hours) and 15.5% requiring a manual removal of the placenta (Blum et al., 2019). One retrospective cohort study measured intervention rates for placental removal in 233 women receiving a feticidal agent and repeated doses of misoprostol to induce abortion for pregnancies between 18-23 weeks gestation (Green et al., 2007). Following fetal expulsion, the placenta was allowed to expel spontaneously; operative intervention was performed only for excessive bleeding following fetal expulsion or to expedite hospital discharge after a minimum of four hours had elapsed since fetal expulsion. The overall intervention rate for retained placenta was 6%, and most removals were to expedite discharge. The study found no increase in morbidity for women managed expectantly during this time frame.

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4.7 MEDICAL ABORTION
4.7.3 MISOPROSTOL ONLY: RECOMMENDED REGIMEN

Recommended regimen for 13-24 weeks gestation

- Misoprostol 400mcg sublingually or vaginally every three hours until fetal and placental expulsion. Vaginal dosing is more effective than sublingual dosing for nulliparous women.
- If the woman is stable and it is convenient for her to do so, providers should allow her at least four hours after fetal expulsion to expel the placenta before intervening.

Strength of recommendation

Strong

Quality of evidence

- Up to 20 weeks gestation: Moderate
- 20-24 weeks gestation: Low

Last reviewed: January 30, 2020

Background

A combination regimen with mifepristone and misoprostol has shorter induction-to-abortion intervals and higher success rates than misoprostol only for medical abortion at or after 13 weeks gestation (Wildschut et al., 2011). If mifepristone is not available, a misoprostol-only regimen with dosing every three hours is an acceptable alternative (Wildschut et al., 2011; World Health Organization [WHO], 2018).

Vaginal route

In randomized controlled clinical trials, misoprostol 400mcg vaginally every three hours is associated with a median induction-to-abortion interval of 10-15 hours and a 48-hour successful abortion rate of 90-95% (Bhattacharjee, Saha, Ghoshroy, Bhowmik, & Barui, 2008; Koh et al., 2017; Tang, Lau, Chan, & Ho, 2004; von Hertzen et al., 2009). A 400mcg dose vaginally is more effective than a 200mcg dose (Koh et al., 2017).

Sublingual route

In a meta-analysis of 1,178 women from three randomized controlled trials, misoprostol 400mcg sublingually is similar (Bhattacharjee et al., 2008) or slightly inferior to vaginal dosing when given every three hours (Tang et al., 2004; von Hertzen et al., 2009; Wildschut et al., 2011). In the trials that showed reduced efficacy, the difference was driven by an inferior response to sublingual misoprostol in nulliparous women only. Of note: all of these studies found that women prefer the sublingual route to vaginal administration by health care workers.

Other routes

Buccal route: One trial randomized 130 women to misoprostol 400mcg every three hours either vaginally or buccally. Women in the vaginal group had a shorter mean induction-to-fetal expulsion interval (25 compared to 40 hours, p=0.001) and higher rates of fetal expulsion at both 24 hours (63% compared to 42%, p=0.014) and 48 hours (91% compared to 68%, p=0.001) (Al & Yapca, 2015). A smaller trial of 64 women showed buccal misoprostol was as effective as vaginal; however, all of the women received an initial loading dose of misoprostol 400mcg vaginally and were randomized to 200mcg buccally or vaginally every six hours thereafter (Ellis, Kapp, Vragpvoc, & Borgatta, 2010). Finally, a trial including a cohort of 60 women who received misoprostol 400mcg buccally every three hours until fetal and placental expulsion found a complete abortion rate of 71% at 48 hours (Dabash et al., 2015). Based on these studies, vaginal and sublingual administration appear to be superior to buccal misoprostol dosing in this gestational age range.

Oral route: In multiple randomized clinical trials, oral dosing has been shown to be less effective with longer time-to-abortion intervals than vaginal or sublingual dosing (Akoury et al., 2004; Bebbington et al., 2002; Behrashi & Mahdian, 2008; Nautiyal, Mukherjee, Perhar, & Banerjee, 2015).

Dosing interval

In one randomized trial that examined two different regimens of vaginal misoprostol, lengthening the dosing interval from every three to every six hours decreases the efficacy of medical abortion (Wong, Ngai, Yeo, Tang, & Ho, 2000).

Placental expulsion

One retrospective cohort study measured intervention rates for placental removal in 233 women receiving a feticidal agent and repeated doses of misoprostol to induce abortion for pregnancies between 18-23 weeks gestation (Green et al., 2007). Following fetal expulsion, the placenta was allowed to expel spontaneously; operative intervention was performed only for excessive bleeding following fetal expulsion or to expedite hospital discharge after a minimum of four hours had elapsed since fetal expulsion. The overall intervention rate for retained placenta was 6%, and most removals were to expedite discharge. The study found no increase in morbidity for women managed expectantly during this time frame.

Quality of evidence

The recommendation is based on multiple randomized clinical trials and a Cochrane meta-analysis comparing different misoprostol doses, dosing intervals and routes of administration at or after 13 weeks gestation (Wildschut et al., 2011). This body of evidence is limited by the fact that most randomized controlled trials of medical abortion do not include women with pregnancies over 20 weeks gestation.

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MEDICAL ABORTION
4.7.4 PRESENCE OF UTERINE SCAR: RECOMMENDED REGIMEN

4.7

Recommendation

- **Less than 22-24 weeks gestation with one uterine scar:** No changes to recommended regimens necessary.
- **More than 22-24 weeks gestation with one uterine scar or 13-24 weeks gestation with more than one uterine scar:** Consider decreasing the misoprostol dose with or without lengthening the misoprostol dosing interval. There is insufficient evidence to know if this impacts the risk of uterine rupture in these women.

Strength of recommendation

Weak

Quality of evidence

Very Low

Last reviewed: February 7, 2020

Risk of uterine rupture with medical abortion

Uterine rupture has been reported during medical abortion at or after 13 weeks gestation in women with and without a uterine scar. The risk of uterine rupture for any woman undergoing a medical abortion at or after 13 weeks gestation is very rare, occurring in fewer than 1 in 1,000 women (Goyal, 2009). In a meta-analysis of 16 studies of 3,556 women undergoing medical abortion at or after 13 weeks gestation with combined or misoprostol-only regimens, three women suffered uterine rupture resulting in a rate of 0.28% with a previous cesarean section and 0.04% without (Goyal, 2009).

One single-center retrospective review of 279 women undergoing abortion between 14-26 weeks included 60 women with one and 26 women with more than one uterine scar (Küçükgöz Güleç et al., 2013). Women received misoprostol 200mcg vaginally every four hours; three had a uterine rupture. In another retrospective review of 263 women between 12-24 weeks undergoing misoprostol-only abortion, 48 had one and 29 had more than one scar; one rupture was observed in a woman with three prior cesarean sections who received a misoprostol regimen of 200mcg sublingually every three hours (Cetin et al., 2016). A third retrospective review included 231 women with one and 37 women with two prior cesarean deliveries, and used a regimen of 800mcg of misoprostol as a loading dose followed by 200mcg every two hours for three doses; no women experienced rupture (Torriente, Steinberg, & Joubert, 2017).

Regimen for women with a uterine scar

Due to the rarity of uterine rupture in women with a previous scar, no clear guidance can be obtained from the published literature (Borgatta & Kapp, 2011; Daponte, Nzewenga, Dimopoulos, & Guidozzi, 2006; Daskalakis et al., 2004; Dickinson, 2005; Morris et al., 2017).

Expert opinion supports:

- No change in medical abortion regimen for women with one uterine scar whose gestation is less than 22-24 weeks.
- After 22-24 weeks gestation with a single uterine scar or 13-24 weeks gestation with more than one uterine scar:
    - Consider decreasing the dose of misoprostol with or without lengthening the dosing interval (Ho et al., 2007; Küçükgöz Güleç et al., 2013).

There is insufficient evidence to know if changing the dosing regimen will decrease the risk of uterine rupture.

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TREATMENT OF INCOMPLETE AND MISSED ABORTION: RECOMMENDED MEDICATION REGIMEN FOR LESS THAN 13 WEEKS UTERINE SIZE

5.1

Recommendation

- **Incomplete abortion:** Misoprostol 600mcg orally in a single dose or 400mcg in a single dose sublingually or, in the absence of vaginal bleeding, vaginally.
- **Missed abortion:** Misoprostol 600mcg sublingually or, in the absence of vaginal bleeding, 800mcg vaginally every three hours until pregnancy expulsion (generally 1-3 doses). Where available, add pretreatment with mifepristone 200mg orally 1-2 days before misoprostol.

Strength of recommendation

Strong

Quality of evidence

Moderate

Last reviewed: February 7, 2020

Incomplete abortion

In a Cochrane review of 24 studies which included 5,577 women presenting with incomplete abortion under 13 weeks, management with misoprostol was as effective as expectant care to complete the abortion (relative risk [RR] 1.23, 95% confidence interval [CI] 0.72, 2.10), and was less effective than surgical treatment (RR 0.96, 95% CI 0.94, 0.98); success rates were high for all management strategies (Kim et al., 2017). Completion rates were 52-85% for expectant management, 80-99% for treatment with misoprostol, and 91-100% for surgical treatment (Kim et al., 2017). In the analysis, oral, sublingual and vaginal misoprostol showed similar efficacy and side effect profiles; lengthening the time to follow-up assessment increased the success of misoprostol treatment. A randomized controlled trial comparing a single dose of misoprostol to MVA demonstrated higher success of MVA for abortion completion (RR 0.84, 95% CI 0.77-0.92)(Ibeyemi, Ijaiya & Adesina, 2019).

Missed abortion

A 2017 systematic review and network meta-analysis of misoprostol management of missed abortion, which included 18 studies reporting on 1,802 women, concluded that misoprostol 800mcg vaginally or 600mcg sublingually are the most effective treatments (Wu, Marwah, Wang, Wang & Chen, 2017). A single dose of misoprostol 800mcg vaginally results in successful uterine evacuation in 76 to 93% of women (Fernlund, Jokubkiene, Sladkevicius, & Valentin, 2017; Mizrachi et al., 2017; Ngoc, Blum, Westheimer, Quan, & Winikoff, 2004). In two studies, when women were managed expectantly over seven days after a single dose of misoprostol, their abortion success rates increased over time (Ngoc et al., 2004) up to 88%

at seven days compared with 72% at four days (Mizrachi, et al, 2019). Although a number of studies have reported an increase in abortion success when an additional dose of misoprostol is administered 24 (Barcelo et al., 2012; Graziosi, Mol, Ankum, & Bruinse, 2004; Muffley, Stitely, & Gherman, 2002), 48 (Lyra, Cavaco-Gomes, Moucho, & Montenegro, 2017) or 72 hours after the initial dose (Gilles et al., 2004; Zhang et al., 2005), it has been unclear whether this is due to the additional medication or the increased time to evaluation. A 2017 trial which randomized women to receive a single dose of misoprostol 800mcg vaginally, or to receive an additional dose of misoprostol after four days, found that both groups had nearly identical success rates after seven days: 77 and 76% respectively (Mizrachi et al., 2017).

Misoprostol 600mcg sublingually repeated every three hours following the initial dose for a maximum of two more doses achieves abortion success rates of 88-92% (Tang, Lau, Ng, Lee, & Ho, 2003; Tang et al., 2006). No studies have evaluated single doses of sublingual misoprostol for treatment of missed abortion.

Two randomized controlled trials published in 2018, found that women with missed abortion who received pretreatment with mifepristone before receiving misoprostol were more likely to successfully complete their abortion than women who received misoprostol only. In Schreiber et al. (2018), women received either mifepristone followed 24 hours later by a single dose of 800mcg misoprostol vaginally or misoprostol with no pretreatment. Abortion success, determined the day after misoprostol was used, was 84% in the mifepristone group compared to 67% in the misoprostol-only group. In another study in the same year (Sinha, Suneja, Guleria, Aggarwal & Waid, 2018), women received either mifepristone or placebo, followed 48 hours later by identical multidose regimens of misoprostol. Abortion success rates were 87% and 58% respectively; more women in the mifepristone group than in the placebo group expelled the pregnancy after a single misoprostol dose (66% compared to 11%, respectively) and had a significantly shorter induction to abortion interval (4.7 hours compared to 8 hours, respectively). In a prospective cohort study, risk of failure following mifepristone and misoprostol for missed abortion was increased among women with uterine size of less than nine weeks gestation (Ehrnsten, Altman, Ljungblad, & Kopp, 2019).

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5.2 TREATMENT OF INCOMPLETE ABORTION AND INTRAUTERINE DEMISE: RECOMMENDED MEDICATION REGIMEN FOR 13 WEEKS OR LARGER UTERINE SIZE

Recommendation

- **Incomplete abortion:** Misoprostol 400mcg buccally, sublingually or, in the absence of vaginal bleeding, vaginally every three hours until expulsion.
- **Intrauterine fetal demise (up to 24 weeks):** Misoprostol 400mcg sublingually or, in the absence of vaginal bleeding, vaginally every 4-6 hours until expulsion. Where available, add pretreatment with mifepristone 200mg orally 1-2 days before misoprostol.
- Where skilled providers and supportive facilities exist, dilatation and evacuation (D&E) may be offered.

Strength of recommendation

Strong

Quality of evidence

Low

Last reviewed: February 11, 2020

Background

The majority of postabortion care research and programs focus on women with uterine size less than 13 weeks (Ipas, 2013). However, where unsafe abortion is prevalent, as many as 40% of women needing postabortion care present at or after 13 weeks gestation (Ministry of Health of Kenya, Ipas, & Guttmacher Institute, 2013). Women may present with incomplete abortion, retained placenta, fetal demise or ruptured membranes, all of which require uterine evacuation.

Medical regimens

Evidence is limited to suggest the optimal medical regimen for postabortion care at or after 13 weeks uterine size, but systematic reviews of the literature suggests that at least 200mcg vaginally, sublingually or buccally given every six hours is effective (Bracken et al., 2014; Mark, Borgatta, & Edelman, 2015). Two trials that randomized women to treatment with 200mcg or 400mcg of vaginal misoprostol found that the higher dose of misoprostol resulted in higher expulsion rates at 24 and 48 hours (Dickinson & Evans, 2002; Eslamian, Gosili, Jamal, & Alyassin, 2007; World Health Organization [WHO], 2018). Pretreatment with mifepristone 1-2 days before misoprostol increases rates of abortion success within 24 hours and reduces the time to fetal expulsion (Chaudhuri & Datta, 2015; Panda & Singh, 2013). A systematic review of medical treatment for intrauterine fetal demise found when the dose of 400mcg was administered every four hours, it was more effective with lower rates of adverse

events when compared with other doses; however, no direct comparisons exist to inform whether four hours is indeed the ideal interval (Cleeve, Fonhus & Lavelanet, 2019).

D&E

No studies have compared medical management versus vacuum aspiration or D&E for postabortion care at or after 13 weeks. D&E can be offered to women for postabortion care where skilled providers and supportive facilities exist (WHO, 2014).

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5.3 POSTABORTION CONTRACEPTION: WHEN AND WHAT TYPE

Recommendation

- Following vacuum aspiration or dilatation and evacuation (D&E), hormonal and non-hormonal contraception, including intrauterine device (IUD) placement and female sterilization, may be initiated immediately.
- Hormonal methods, including pills, patches, rings, injectables and implants may be started on the day of the first pill of medical abortion. IUD placement and female sterilization should be performed when it is reasonably certain the woman is no longer pregnant.
- Male sterilization (vasectomy) is safe and effective and can be performed at any time.
- Long-acting contraceptive methods have higher continuation rates and lower pregnancy rates compared to short-acting methods.
- People, including adolescents, should be able to choose whether to use a contraceptive method, and to select their preferred method, based on accurate contraceptive information and their personal needs and preferences.

Strength of recommendation

Strong

Quality of evidence

- IUDs and combined oral contraceptives: High
- Implants: Moderate
- Other methods: Low to Moderate

Last reviewed: January 12, 2020

Fertility return

Following induced abortion at less than 13 weeks gestation, women will typically ovulate within three to four weeks, however women can ovulate in as little as eight days (Boyd & Holmstrom, 1972; Lahteenmaki & Luukkainen, 1978; Schreiber, Sober, Ratcliffe, & Creinin, 2010; Stoddard & Eisenberg, 2011). At least 85% of women will ovulate before their first menses (Boyd & Holmstrom, 1972; Lahteenmaki & Luukkainen, 1978; Cameron & Baird, 1988). There is no difference in time to ovulation following medical abortion compared to vacuum aspiration (Cameron & Baird, 1988).

Data for return to fertility after abortion performed at or after 13 weeks gestation are limited. One study with only nine participants found that 66% ovulated within 21 days (Marrs, Kletzky, Howard, & Mishell, 1979). Given the rapid return to fertility, all women who wish to begin contraception should receive their preferred method at the time of their abortion. If a woman's preferred method is not available, she should be provided a referral and, if desired, an interim method (World Health Organization [WHO], 2014b).

Safety and acceptability of postabortion contraception

For adult women, WHO's 2015 *Medical Eligibility Criteria for Contraceptive Use* (WHO, 2015) classifies all contraceptive methods as category one, or safe for immediate use, following first-trimester uncomplicated abortion; recommendations do not differ based on the type of abortion. Female sterilization is classified as acceptable after an uncomplicated abortion.

Similarly, the *Medical Eligibility Criteria for Contraceptive Use* (WHO, 2015) classifies all contraceptive methods as category one, or safe for immediate use, following uncomplicated second-trimester abortion—except IUDs. Due to an increased risk of expulsion when used after abortion at or after 13 weeks gestation, IUDs are classified as category two, meaning the advantages of using the method generally outweigh the risks. Female sterilization is classified as acceptable after an uncomplicated abortion at or after 13 weeks gestation.

Two of these recommendations differ for adolescent women: Depot medroxyprogesterone acetate (DMPA) injection is classified by WHO as a category two for women under 18 years of age, due to concerns about effects on bone mineral density. Sterilization may be performed on young women, but special precautions may need to be taken due to the increased risk of regret (WHO, 2015).

In comparison to short-acting methods, long-acting methods of contraception such as implants and IUDs have higher continuation rates and lower pregnancy and abortion rates (Blumenthal, Wilson, Remsburg, Cullins & Huggins, 1994; Cameron et al., 2012; Kilander et al., 2016; Korjamo, Mentula, & Heikinheimo, 2017; Langston, Joslin-Rohr, & Westhoff, 2014; Peipert, Madden, Allsworth, & Secura, 2012; Pohjoranta, Mentual, Gissler, Suhonen, & Heikinheimo, 2015; Roberts, Silva, & Xu, 2010; Rose, Garrett, & Stanley, 2015). Uptake of long-acting methods is higher after surgical abortion as compared with medical abortion (Laursen, Stumbras, Lewnar, & Haider, 2017; Rocca et al., 2018).

Contraceptive start

Following vacuum aspiration, D&E or medical abortion where pregnancy expulsion occurs in a facility, all hormonal and nonhormonal contraceptive methods, including IUD insertion and female sterilization, may be initiated immediately (WHO, 2015; WHO, 2018). Fertility awareness-based methods may be initiated once a woman has had at least one postabortion menses. Male sterilization (vasectomy) may be performed at any time.

For medical abortion where pregnancy expulsion is expected to occur at home, most forms of contraception (including pills, injectables and implants) may be started with the first pill of the medical abortion if there are no medical contraindications (WHO, 2015; WHO, 2018). IUDs may be inserted and sterilization performed as soon as it is reasonably certain that a woman is no longer pregnant (WHO, 2014a; WHO, 2018).

Evidence related to specific contraceptive methods

IUDs: See section 5.4 Postabortion IUD use: Safety and timing.

Progestin-only subdermal implants: Two randomized non-inferiority trials conducted in women undergoing medical abortion before 13 weeks gestation (Hognert et al., 2016; Raymond et al., 2016b) have demonstrated that abortion success rates are the same in women receiving a contraceptive implant on the day they receive mifepristone compared to delayed placement. In both studies, insertion rates were higher for women receiving their implant on the day they received mifepristone. One study (Hognert et al., 2016) reported a signifi-

cantly higher pregnancy rate in the delayed insertion group at follow-up six months after the abortion (3.8% compared to 0.8%). An additional study randomized women undergoing D&E to either delayed or immediate implant insertion (Cowett et al., 2018). Fewer than half of women in the delayed group had their implant inserted, compared to 100% in the immediate group.

Progestin-only injection: A study of 132 women using DMPA immediately after aspiration abortion reported no serious adverse events but low method continuation rates (22%) at one year and high repeat pregnancy rates (Goldberg, Cardenas, Hubbard, & Darney, 2002). One randomized, controlled non-inferiority trial (Raymond et al., 2016a) comparing 220 women undergoing medical abortion up to 75 days gestation who received intramuscular DMPA on the day of mifepristone to 226 women who did not found similar rates of surgical intervention for any reason after medical abortion (6.4% and 5.3%, respectively) and pregnancy rates at six months after the intervention (2.3% and 3.2% respectively). However, ongoing pregnancy as a reason for medical abortion failure in the DMPA injection group was significantly higher (3.6% vs 0.9%). Smaller retrospective cohort studies have found no differences in medical abortion success rates or ongoing pregnancy rates in women who start progestin-only injections on the same day as mifepristone administration (Douthwaite et al., 2016; Park, Robinson, Wessels, Turner, & Geller, 2016). Women report high satisfaction with same-day administration of progestin-only contraceptives (Raymond et al., 2016a)

Combined oral contraceptives (COCs): A review of seven studies including 1,739 women demonstrated no serious adverse events using COCs immediately after aspiration or medical abortion before 13 weeks gestation (Gaffield, Kapp, & Ravi, 2009). Additionally, women who used COCs immediately demonstrate similar bleeding patterns to women using no contraception, and less bleeding than copper IUD users. Two randomized controlled trials of COCs compared to placebo started immediately after medical abortion up to 49 or 63 days gestation showed that pills do not have a significant effect on the efficacy of medical abortion or the quantity or duration of blood loss (Tang, Gao, Cheng, Lee, & Ho, 1999; Tang, Xu, Cheng, Lee, & Ho, 2002).

Combined vaginal ring: A cohort study of 81 women who placed a vaginal ring one week after aspiration or medical abortion before 13 weeks gestation showed no serious adverse events or infections (Fine, Tryggestad, Meyers, & Sangi-Haghpeykar, 2007).

Combined contraceptive patch: A trial of 298 women randomized to either immediate post-abortion start or delayed start the Sunday after an abortion showed no difference in continuation rates at two and six months. In the 53% of women who could be contacted at six months, half had stopped using the contraceptive patch (Steinauer et al., 2014).

Quality of evidence

Because of the demonstrated safety of contraception after vacuum aspiration and medical abortion before 13 weeks, the 2015 *Medical Eligibility Criteria for Contraceptive Use* categorizes the immediate initiation of hormonal injections, implants, combined hormonal contraception (pills, patches and rings) and progestin-only pills as category one, or safe for use (WHO, 2015).

With the exception of IUD use following D&E, the immediate use of most methods of contraception have not been adequately studied following D&E or medical abortion at or after 13 weeks gestation. The 2015 *Medical Eligibility Criteria for Contraceptive Use* recommendations do not differ based on type of abortion performed, whether medical or D&E. A woman's immediate need for reliable contraception after abortion, coupled with the re-

duced uptake of contraception when provision is delayed, strongly supports the recommendation to start contraceptive methods immediately.

Informed decision making

WHO recommends that sexual and reproductive health services, including contraceptive services, be delivered in a way that ensures fully informed decision-making, respects dignity, autonomy, privacy and confidentiality, and is sensitive to individuals' needs and perspectives (WHO, 2014b). People should be able to choose or refuse contraception based on their personal needs and preferences. Evidence-based, comprehensive contraceptive information, non-directive contraceptive counseling and support should be accessible for all people, including adolescents, so that patients are able to make an informed decision. In one US study, a majority of women preferred not to discuss contraception in depth at the time of their abortion visit, most commonly because they already knew what postabortion contraceptive method they wanted (Cansino et al., 2018). Ideally a range of contraceptive methods should be available, appropriate referrals for methods not available on site should be offered, and these services should be integrated with abortion and postabortion care (Baynes et al., 2019; WHO, 2014b). When contraception is delivered at the time of abortion and a wide range of contraceptive commodities is available, contraceptive uptake in postabortion patients can be as high as 73%, including among young women (Benson, Andersen, Healy, & Brahmi, 2017; Benson et al., 2016).

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5.4 POSTABORTION IUD USE: SAFETY AND TIMING

Recommendation

- When a woman chooses an intrauterine contraceptive device (IUD), it should be placed immediately following a successful, uncomplicated vacuum aspiration or dilatation and evacuation (D&E) abortion.
- When a woman chooses an IUD following medical abortion, it should be placed when it is reasonably certain she is no longer pregnant.

Strength of recommendation

Strong

Quality of evidence

High

Last reviewed: January 12, 2020

IUD placement after abortion before 13 weeks gestation

The World Health Organization's (WHO) 2015 *Medical Eligibility Criteria for Contraceptive Use* classifies IUDs as category one, or safe for immediate use, following first-trimester abortion; recommendations do not differ based on type of abortion.

In comparison to short-acting methods, long-acting reversible methods of contraception such as implants and IUDs have higher continuation rates and lower pregnancy and abortion rates (Blumenthal, Wilson, Remsburg, Cullins, & Huggins, 1994; Cameron et al., 2012; Korjamo, Mentula & Heikinheimo, 2017b; Langston, Joslin-Rohr, & Westhoff, 2014; Peipert, Madden, Allsworth, & Secura, 2012; Pohjoranta, Mentula, Gissler, Suhonen, & Heikinheimo, 2015; Roberts, Silva, & Xu, 2010). A 2014 Cochrane review of 12 trials including 7,119 women concluded that IUD insertion following vacuum aspiration and D&E is safe and practical (Okusanya, Oduwole, & Effa, 2014). The review found no differences in serious adverse events, such as infection or perforation, between immediate and delayed insertion. A 2011 trial randomized 575 women to immediate or delayed IUD insertion after uterine aspiration before 12 weeks (Bednarek et al., 2011). Although rates of IUD expulsion were slightly higher following immediate postabortion insertion (5% compared to 2.7%), women assigned to the delayed insertion group were significantly less likely to receive an IUD (75% compared to 100% in the immediate group) and more likely to have a subsequent pregnancy (five women compared to none). A historical cohort study compared immediate postprocedure IUD insertion performed by midlevel providers to physicians, and found no difference in adverse outcomes between the two groups (Patil et al., 2016).

Following a medical abortion before 13 weeks gestation, IUDs may be placed as soon as it is reasonably certain that a woman is no longer pregnant (WHO, 2014; WHO, 2018). IUDs placed within 5-10 days of a successful medical abortion have low rates of expulsion, high continuation rates (Betstadt, Turok, Kapp, Feng, & Borgatta, 2011; Sääv, Stephansson, &

Gemzell-Danielsson, 2012) and lower pregnancy rates than delayed insertion (Pohjoranta, Suhonen, Mentula, & Heikinheimo, 2017; Saav et al., 2012; Shimoni, Davis, Ramos, Rosario, & Westhoff, 2011). Uptake of IUDs is higher after surgical abortion as compared to medical abortion, despite similar contraceptive choices and desires (Fang, Sheeder, & Teal, 2018; Rocca et al., 2018).

IUD placement after abortion at or after 13 weeks gestation

The WHO *Medical Eligibility Criteria for Contraceptive Use* (2015) classifies IUD use following uncomplicated second-trimester abortion as category two, meaning the advantages of using the method outweigh risks, due to an increased risk of IUD expulsion. The Cochrane review of immediate postabortion insertion of IUDs following an abortion procedure referenced above concluded that although expulsion rates may be higher with immediate placement, continuation is higher with no increase in complications (Okusanya et al., 2014). In two randomized controlled trials of immediate versus delayed IUD placement after D&E, rates of IUD use were significantly higher with immediate insertion, without an increase in infection or complication rates (Cremer et al., 2011; Hohmann et al., 2012). Expulsion rates for women who had immediate insertion in both studies were low (3.1% and 6.8%) and were not different from delayed insertion. Notably, in both studies, about half of women randomized to delayed insertion did not return to have the IUD inserted. Requiring a follow-up visit for IUD insertion is a significant barrier to obtaining the IUD (Stanek, Bednarek, Nichols, Jensen, & Edelman, 2009).

The only available study of IUD placement immediately following medical abortion at or after 13 weeks gestation found that insertion is feasible and safe, however the study was underpowered to assess rate of expulsions (Korjamo, Mentula, & Heikinheimo, 2017a; Korjamo et al., 2017b).The WHO *Medical Eligibility Criteria for Contraceptive Use* (2015) recommendations for IUD use after second-trimester abortion do not differ based on the type of abortion performed, whether medical or surgical. Although not directly translatable, the evidence from post-partum IUD insertion is reassuring (Lopez, Bernholc, Hubacher, Stuart, & Van Vliet, 2015). An IUD may be placed following fetal and placental expulsion.

Young women

The IUD for women under the age of 20 is classified by WHO as category two, in which the benefits generally outweigh the risks (WHO, 2015). A large, US-based, prospective cohort study which examined pregnancy, birth and abortion rates in women provided all birth control methods at no cost included 1,056 women under the age of 20 and found that 62% of young women chose a long acting reversible contraceptive method—either the IUD (22%) or implant (40%)—compared to 71% of older women (Mestad et al., 2011). Continuation rates at 12 and 24 months were the same among older and younger women (Birgisson, Zhao, Secura, Madden & Peipert, 2015). Pregnancy, birth and induced abortion rates among the young women in the study were reduced by 75% compared to national averages (Secura et al., 2014).

A large 2017 systematic review and meta-analysis exploring risk factors for repeat pregnancies among teens, which included 26 studies reporting on more than 160,000 adolescent women, found that use of long acting reversible contraceptives exerted a significant protective effect, along with improved educational attainment and school continuation (Maravilla, Betts, Couto e Cruz, & Alati, 2017).

A 2017 systematic review examining risk of adverse outcomes in young women using the IUD found no differences in rates of perforation, contraceptive failure, pelvic inflammatory disease, or heavy bleeding in women younger than 25 compared to older women; rates of

IUD expulsion were slightly higher in young women (Jatlaoui, Riley, & Curtis, 2017). IUDs do not increase young women's risk of infertility (Grimes, 2000), and women's fertility returns to baseline rates rapidly following IUD removal (Hov, Skjeldestad, & Hilstad, 2007).

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5.5 POSTABORTION HEMORRHAGE: PREVENTION AND MANAGEMENT

Recommendation

- Clinicians should consider measures to prevent or prepare for increased bleeding in women who are at high risk for hemorrhage and are undergoing abortion.
- Hemorrhage caused by atony may be treated with uterine massage, uterotonic medications, re-aspiration, tamponade or surgery.
- Closely monitor hemorrhaging woman for signs of shock.

Strength of recommendation

Strong

Quality of evidence

Low

Last reviewed: January 16, 2020

Epidemiology

The Society for Family Planning defines postabortion hemorrhage as excessive bleeding that requires a clinical response such as transfusion or hospital admission, and/or bleeding in excess of 500mL (Kerns & Steinauer, 2013). Hemorrhage after induced abortion is rare, occurring in 0-3 per 1,000 cases following medical abortion up to 9 weeks gestation or vacuum aspiration before 13 weeks gestation, and 0.9-10 per 1,000 cases following uterine evacuation at or after 13 weeks gestation (Kerns & Steinauer, 2013; Upadhyay et al., 2014). Causes of bleeding include placenta previa or accreta, uterine atony, retained products of conception, cervical or vaginal laceration, uterine injury, and coagulopathy (Kerns & Steinauer, 2013; Perriera, Arslan, & Masch, 2017).

Prevention

All women presenting for abortion care should be asked about aspects of their medical history associated with increased risk for bleeding. That includes a review of obstetric complications, especially hemorrhage, having had two or more cesarean deliveries, a bleeding disorder, gestational age of more than 20 weeks, obesity, increased maternal age, and placenta previa or accreta (Kerns & Steinauer, 2018; Whitehouse et al., 2017). Providers may consider measures to prevent or prepare for increased bleeding—such as assessing a preabortion hemoglobin or hematocrit, ensuring uterotonic medications are readily available, preparing for possible transfusion, or referral to a higher-level facility—although there is little evidence to guide practice (Kerns & Steinauer, 2018). In one randomized trial, addition of four units of vasopressin to a preprocedure paracervical block significantly decreased blood loss during dilatation and evacuation procedures and reduced the incidence of postabortion hemorrhage when compared to placebo (Schulz, Grimes, & Christensen, 1985). This effect

was larger at later gestational ages. Administration of prophylactic oxytocin or syntocinon (five or 10 units) has not been shown to decrease postprocedure bleeding following first-trimester vacuum aspiration in a clinically meaningful way (Nygaard, Valbo, Heide, & Kresovic, 2010; Ali & Smith, 1996). When administered prior to dilatation and evacuation (D&E) procedures performed between 18-24 weeks, 30 units of oxytocin decreased blood loss and the incidence of hemorrhage compared to placebo (Whitehouse et al., 2019).

Diagnosis

When postabortion hemorrhage is suspected, clinicians should take a rapid, systematic approach to assessing and treating women. Initial assessment includes inspection of the cervix for laceration, bimanual examination to assess for uterine atony and tenderness, and uterine aspiration or ultrasound examination to evaluate for retained products of conception or blood.

Management

Cervical lacerations may be treated with direct pressure with gauze or ring forceps, application of topical clotting agents (silver nitrate or ferric subsulfate solution), or by placing absorbable sutures.

Uterine atony requires a rapid, sequential response starting with uterine massage, followed by uterotonics, re-aspiration, uterine tamponade and finally surgical measures. Clinicians should move quickly to the next step if bleeding is not controlled. When uterotonic medications are used, additional or repeat doses may be used if bleeding does not improve after the first dose.

Table 5.5.1. Uterotonic medications and dosages*

MEDICATION	DOSAGE
Methylergonovine	0.2mg intramuscularly or intracervically; can be repeated every 2-4 hours. Avoid in women with hypertension
Misoprostol	800mcg sublingually or rectally
Oxytocin	10-40 units per 500-1000mL fluid intravenously or 10 units intramuscularly
Intrauterine tamponade	Sterile gauze or 30-75mL Foley catheter balloon, condom catheter or obstetric balloon placed in uterus

*Extrapolated from postpartum data (American College of Obstetricians and Gynecologists, 2017; Kerns & Steinauer, 2013; Mavrides et al., 2016; Morris et al., 2017; Prata & Weidert, 2016; World Health Organization, 2012).

If tamponade is used to stop bleeding, the Foley balloon, obstetric balloon, gauze or inflated condom catheter should be left in place for several hours while the patient is observed. If the woman remains stable after the balloon or gauze is removed, she may be discharged.

When bleeding continues after assurance of complete uterine evacuation and no visible lacerations, providers must consider other complications, such as perforation, coagulopathy or placenta accreta (National Abortion Federation, 2017). If coagulopathy, such as disseminated intravascular coagulation, is present, blood products may be required. Surgical measures including hysterectomy, uterine compression sutures, uterine artery ligation or uterine artery embolization can be performed for severe bleeding that cannot be controlled by other measures. Providers at health centers without available operating theaters or expertise should have clear protocols for resuscitation and transfer to a higher level of care. Women

at risk of shock require intravenous line placement, supplemental oxygen, fluid resuscitation and replacement of blood products as indicated.

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MANAGING UTERINE PERFORATION

5.6

Recommendation

- Any woman with suspected uterine perforation, even if asymptomatic, should be informed of the complication and her clinical status should be observed
  - — If stable, women should be told warning signs for when to seek emergency care, if needed, and have a plan for follow-up before discharge from a health center
  - — If unstable or worsening clinical status is noted, transfer to tertiary-level facility for further management
- Any woman with a known uterine perforation with evidence of bowel injury should be transferred to tertiary-level facility for further management

Strength of recommendation

Strong

Quality of evidence

Low

Last reviewed: January 24, 2020

Epidemiology

Uterine perforation at the time of vacuum aspiration is a rare but potentially serious complication, estimated to occur in between 0.1-3 per 1000 induced abortion procedures (Kerns & Steinauer, 2013; Pridmore & Chambers, 1999). This frequency increases with advancing gestational age and when performed by less experienced providers (ACOG, 2019).

Factors that may increase the risk for uterine perforation at time of surgical abortion (Shakir & Diab, 2013; Obed & Wilson, 1999; Grimes, et al., 2006):

- Uterine position—retroverted, acutely anteverted or retroflexed
- Infection
- Multiparity
- Multiple gestations
- Advanced gestational age
- Inadequate cervical preparation
- Difficult cervical dilation
- Uterine anomalies or cavity distorted by fibroids
- Previous cervical/uterine surgery, including cesarean section
- Provider inexperience

- Presentation for postabortion care (after unsafe abortion procedure)

Uterine perforation can occur at almost any step of the abortion process as instruments pass into the uterus. Additionally, perforation may occur from a foreign object or implement used to perform an unsafe abortion.

The location of the perforation can be anywhere in the uterus, although the midline anterior or posterior surface of the fundus is the most common (Sharma, Malhotra & Pundir, 2003). Uterine perforation often goes undetected and resolves without the need for intervention for women who have procedures before 13 weeks (Kaali, Szigetvari & Bartfai, 1989; Sharma, Malhotra & Pundir, 2003). For example, perforation with a small, blunt instrument in the fundus is likely to cause no problems, heal quickly, and need no additional management. Lateral uterine perforations are rare, but are particularly concerning, given the proximity of the branches of the uterine artery and risk for serious bleeding (Berek & Stubblefield, 1979).

Diagnosis

A provider should suspect uterine perforation when a sudden loss of resistance occurs during cervical dilation or vacuum aspiration, allowing an instrument to pass well beyond the expected length of the uterus. If available, ultrasound may be a helpful diagnostic aid (Coughlin, Sparks, Chase & Smith, 2013; Crosfil & Hughes, 2006; Gakhal & Levy, 2009; Shalev, Ben-Ami & Zuckerman, 1986; Skolnick, Katz & Lancet, 1982).

Uterine perforation can be visualized during laparoscopy and laparotomy. A provider does not need to definitely diagnose a perforation if the patient is stable and the concern for intra-abdominal injury is low. If a provider sees yellow fatty tissue in the uterine aspirate, their suspicion for uterine perforation and bowel injury should be high and the woman should be referred for immediate surgical management whether stable or not. Prompt recognition and management of injury to abdominopelvic viscera (bowel, bladder, blood vessels, etc.) resulting from uterine perforation is necessary to avoid serious complications (Obed & Wilson, 1999; Amarin & Badria, 2005).

Management

In many cases, providers can manage uncomplicated uterine perforation before 13 weeks gestation conservatively by observing for any changes in clinical status (Moburg, 1976; Freiman & Wulff, 1977; Grimes, Schultz & Cates, 1984; Mittal & Misra, 1985; Chen, Lai, Lee & Leong, 1995; Lindell & Flam, 1995; Pridmore & Chambers, 1999). Providers should have a higher level of suspicion for intra-abdominal injury when a perforation occurs during an abortion at or after 13 weeks or during dilation and evacuation; these patients should be promptly referred for further evaluation as additional treatment may be warranted (Darney, Atkinson & Hirabayashi, 1990).

If there is concern for damage to abdominopelvic viscera, including bowel, but the woman is stable, and the experience and equipment are available, then laparoscopy is the investigative method of choice. With obvious bowel damage or herniation through the uterine defect, excessive bleeding, or hemodynamic instability, immediate laparotomy may be preferable (Lauersen & Birnbaum, 1973; Grimes, Schultz & Cates, 1984; Chen, Lai, Lee & Leong, 1995; Lindell & Flam, 1995; Kumar & Rao, 1998; Obed & Wilson, 1999). If the abortion was not completed, the uterus should be evacuated under direct visualization at the time of laparoscopy or laparotomy (Lauersen & Birnbaum, 1973; Goldschmitt, Elchalal, Dgani, Zalel & Matzkel, 1995; Chen, Lai, Lee & Leong, 1995). No evidence is available to support the safety or effectiveness of medical management to complete uterine evacuation immediately following suspected or confirmed uterine perforation.

Providers at health centers without available operating theaters or expertise should have clear protocols for resuscitation and transfer to a higher level of care. Women at risk of shock require intravenous line placement, supplemental oxygen, fluid resuscitation and replacement of blood products as indicated.

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APPENDIX A: PAIN MEDICATION TABLE

The medications listed in the table below are commonly used for pain management during vacuum aspiration and dilatation and evacuation. Many other options exist. This table does not cover general anesthetic agents.

Both anxiolytics and narcotics may cause respiratory depression, especially when they are used together. Accordingly, lower doses should be used when they are together than when they are used separately. When medications are given intravenously immediately before a procedure they should be given slowly and intermittently by a specially trained provider. Problematic side effects can be avoided by repeated small intravenous doses that are titrated to a woman's level of pain and sedation. The peak analgesic effect should occur during the procedure to avoid excessive postprocedure sedation.

Even clinicians using lighter sedation analgesia must be able to manage respiratory arrest, in the unlikely event that an unintentional overdose should occur. Providers should be trained in airway management and cardiopulmonary resuscitation. Resuscitative equipment and appropriate antagonist drugs (naloxone and flumazenil) should be available.

Disclaimer: This resource is designed to be a supplemental resource for clinicians and is NOT intended to serve as a replacement for drug label information or clinical judgment that accounts for patients' and facilities' unique circumstances.

Last reviewed: February 10, 2018

DRUG TYPE	GENERIC DRUG NAME	DOSE AND TIMING	HALF-LIFE	SIDE EFFECTS	COMMENTS
Local anesthetic *See section 2.5 Paracervical block*	Lidocaine	20ml of 1% solution or 10mL of 2% solution in a paracervical block not to exceed 4.5mg/kg	60-90 minutes	Ringing in ears; dizziness; numbness in lips, mouth and tongue; metallic taste Extremely rare: Seizures	• Pull back plunger before injecting to avoid intravascular injection • Allergic reaction is very rare. Reactions that do occur may be due to preservatives in multi-dose vials. Preservative-free lidocaine allergy is extremely rare.

DRUG TYPE	GENERIC DRUG NAME	DOSE AND TIMING	HALF-LIFE	SIDE EFFECTS	COMMENTS
Nonsteroidal anti-inflammatory drug (NSAID)	Ibuprofen	Oral: 400-800mg 1 hour before the procedure	2 hours	Possible gastrointestinal upset	Do not use in women with active peptic ulcer disease or renal failure
	Naproxen	Oral: 500mg 1 hour before the procedure	12-17 hours	Possible gastrointestinal upset	Do not use in women with active peptic ulcer disease or renal failure
	Ketorolac	Oral: 20mg 1 hour before procedure IV: 30mg over at least 15 seconds 30-60 minutes before procedure IM: 60mg 30-60 minutes before procedure For women less than 50kg, all doses should be halved	4-6 hours		• Single dose IM ketorolac prior to surgery may reduce opioid use and postoperative pain (de Oliveira, 2012; Roche, 2011) • Do not use in women with active peptic ulcer disease, renal failure, breastfeeding or sensitivity to other NSAIDs • Breakthrough pain should be managed with narcotics rather than increasing ketorolac beyond the recommended doses
Analgesic	Acetaminophen	Oral: 500-1,000mg 30-60 minutes before procedure	2-4 hours		• Not a first-line pain medication for vacuum aspiration or medical abortion. May be used as an antipyretic. • Liver toxicity from overdose (maximum dose=4,000mg/day) is a risk
Narcotic/ analgesic combination	Acetaminophen 300mg + codeine 30mg	Oral: 1-2 tablets 1 hour before procedure	2-4 hours	Drowsiness; light-headedness; nausea and vomiting	• Be aware of combining with other acetaminophen-containing products. Liver toxicity from overdose of acetaminophen (maximum dose=4,000 mg/day) is a risk.
	Acetaminophen 500mg + hydrocodone 5mg	Oral: 1-2 tablets 1 hour before procedure	4-6 hours	Drowsiness; light-headedness; nausea and vomiting	• Be aware of combining with other acetaminophen-containing products. Liver toxicity from overdose of acetaminophen (maximum dose=4,000 mg/day) is a risk.

DRUG TYPE	GENERIC DRUG NAME	DOSE AND TIMING	HALF-LIFE	SIDE EFFECTS	COMMENTS
Narcotic	Meperidine	Oral: 100-150mg 30-60 minutes before procedure IV: 25-50mg 5-15 minutes prior to procedure IM/SC: 50-100mg 30-90 minutes prior to procedure	2-4 hours	Drowsiness; light-headedness; nausea and vomiting; decreased breathing rate; loss of consciousness; hypotension; seizures	• IM or SC administration preferred over IV • If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with naloxone (see end of chart) • More rapid onset and shorter duration of action than morphine • Meperidine 300mg PO=Meperidine 75mg IV=morphine 10mg IV
	Fentanyl	IV: 50-100mcg immediately before procedure (may repeat every 5-10 minutes, not to exceed 250mcg) IM: 50-100mcg 30-60 minutes before procedure	4 hours	Drowsiness; light-headedness; weakness; bradycardia; decreased breathing rate; loss of consciousness; hypotension; seizures	• If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with naloxone (see *Reversal agent for narcotic,* below) • More rapid onset and shorter duration of action than meperidine • Fentanyl 100mcg IV=morphine 10mg IV • Onset of action is 2-7 minutes when given IV
	Tramadol	IV/IM: 50-100mg 15-30 minutes before the procedure Oral/suppository: 50-100mg 60-90 minutes prior to the procedure	6-8 hours	Drowsiness; light-headedness; sweating; weakness; fatigue; seizures	• If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with naloxone (see end of chart) • If using IV, inject slowly over 2-3 minutes • Less respiratory depression than morphine or meperidine

DRUG TYPE	GENERIC DRUG NAME	DOSE AND TIMING	HALF-LIFE	SIDE EFFECTS	COMMENTS
Anxiolytic (Benzodiazepine)	Diazepam	Oral: 5-10mg 1 hour before procedure IV: 2-5mg 20 minutes before procedure	30-60 hours	Blurred vision; dizziness; disorientation; pain and redness on injection; decreased breathing rate; loss of consciousness	• If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with flumazenil (see *Reversal agent for benzodiazepine*, below) • Has a mild amnestic effect • Onset of action is 1-22 minutes when given IV
	Midazolam	IV: 1-2mg immediately before the procedure, then 0.5-1mg IV every 5 minutes as needed, not to exceed 5mg IM: 0.07-0.08mg/kg or about 5mg up to 1 hour before procedure	2.5 hours	Blurred vision; dizziness; disorientation; CNS and respiratory depression	• If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with flumazenil (see *Reversal agent for benzodiazepine*, below) • Midazolam 2.5mg= diazepam 10mg • Stronger amnestic effect than diazepam • Onset of action is 1-5 minutes when given IV and 15-30 minutes when given IM
	Lorazepam	Oral: 1-2mg 30-60 minutes before procedure IV: 2mg given over 1 minute 15-20 minutes before the procedure IM: 0.05mg/kg up to a maximum of 4mg within 2 hours before the procedure	14 hours	Blurred vision; dizziness; disorientation; decreased breathing rate; loss of consciousness	• If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with flumazenil (see *Reversal agent for benzodiazepine*, below) • Amnestic effect

DRUG TYPE	GENERIC DRUG NAME	DOSE AND TIMING	HALF-LIFE	SIDE EFFECTS	COMMENTS
Reversal agent for narcotic	Naloxone	IV/IM/SC: 0.4mg every 2 minutes until reversal is seen	1-1.5 hours		• Naloxone's duration of action is 1 hour and may wear off before the narcotic. Therefore, patients treated with naloxone must be monitored closely for several hours. • Maintain airway and respirations while giving naloxone
Reversal agent for benzodiazepine	Flumazenil	IV: 0.2mg every minute until respirations return. Do not exceed 1mg	1 hour		• Flumazenil's duration of action is 1 hour and may wear off before the benzodiazepine. Therefore, patients treated with flumazenil must be monitored closely for several hours. In the event of overdose with narcotic and benzodiazepine, reverse the narcotic first with naloxone and use flumazenil subsequently if needed. • Maintain airway and respirations while giving flumazenil
Treatment for hypersensitivity reaction/anaphylaxis	Epinephrine	IM/SC: 0.2-0.5mg every 5 to 15 minutes IV: 0.1mg diluted with 10mL of saline administered over 5 to 10 minutes	1 minute	Tachycardia; palpitations; nausea; diaphoresis; dizziness; anxiety	• There are no contraindications to epinephrine in the setting of anaphylaxis • IM administration preferred • Consider giving methylprednisolone 125mg IV • Support respiration. If wheezing is present, inhaler may be helpful • Immediate intubation if evidence of impending airway obstruction

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APPENDIX B: CONTINUUM OF DEPTH OF SEDATION: DEFINITION OF GENERAL ANESTHESIA AND LEVELS OF SEDATION/ANALGESIA

American Society of Anesthesiologists, Committee of Origin: Quality management and departmental administration (approved by the ASA House of Delegates on October 13, 1999 and last amended on October 23, 2019). Accessed at: https://www.asahq.org/standards-and-guidelines/continuum-of-depth-of-sedation-definition-of-general-anesthesia-and-levels-of-sedationanalgesia on 03/17/2020. (reprinted with permission)

	MINIMAL SEDATION ANXIOLYSIS	MODERATE SEDATION/ ANALGESIA ("CONSCIOUS SEDATION")	DEEP SEDATION/ ANALGESIA	GENERAL ANESTHESIA
Responsiveness	Normal response to verbal stimulation	Purposeful** response to verbal or tactile stimulation	Purposeful** response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

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

Moderate sedation/analgesia ("conscious sedation") is a drug-induced depression of consciousness during which patients respond purposefully** to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

*Monitored Anesthesia Care ("MAC") does not describe the continuum of depth of sedation, rather it describes "a specific anesthesia service performed by a qualified anesthesia provider, for a diagnostic or therapeutic procedure." Indications for monitored anesthesia care include "the need for deeper levels of analgesia and sedation than can be provided by moderate sedation (including potential conversion to a general or regional anesthetic." (American Society of Anesthesiologists, 2018).

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

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

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

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue*** patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia ("Conscious Sedation") should be able to rescue*** patients who enter a state of Deep Sedation/Analgesia, while those administering of Deep Sedation/Analgesia should be able to rescue*** patients who enter a state of General Anesthesia.

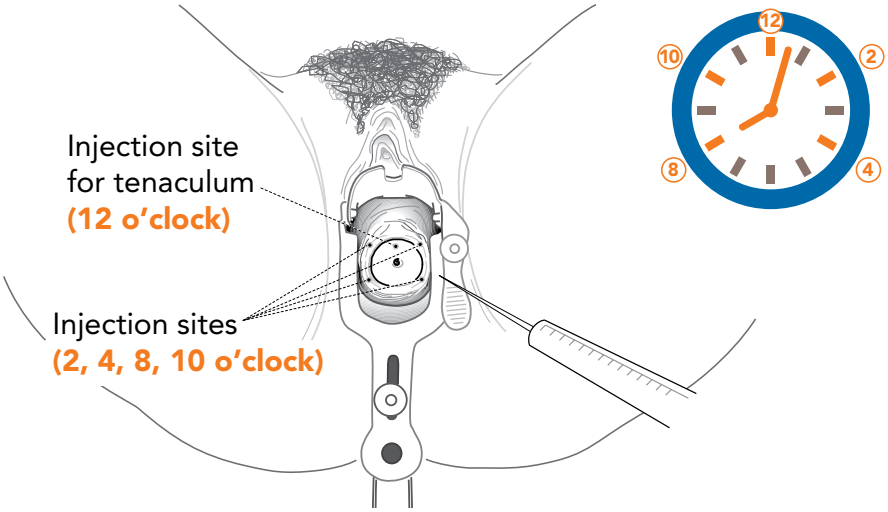
**Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

***Rescue of a patient from a deeper level of sedation than intended is an intervention by a practitioner proficient in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation (such as hypoventilation, hypoxia and hypotension) and returns the patient to the originally intended level of sedation. It is not appropriate to continue the procedure at an unintended level of sedation.

American Society of Anesthesiologists. (2018). *Position on Monitored Anesthesia Care.* Last amended on October 17, 2018.

APPENDIX C: PARACERVICAL BLOCK JOB AID

PARACERVICAL BLOCK TECHNIQUE



1. **Prepare lidocaine syringe using 20mL of 1% lidocaine and a 3cm (1in) needle.**
2. **Place the speculum and perform cervical antiseptic prep.**
3. **Inject 2mL of lidocaine superficially into the anterior lip of the cervix where the tenaculum will be placed (12 o'clock).**
4. **Grasp cervix with the tenaculum at 12 o'clock.**
5. **Inject remaining lidocaine in equal amounts at the cervicovaginal junction, at 2, 4, 8 and 10 o'clock.**
6. **Begin procedure without delay.**

PRACTICE TIPS

- Do not exceed the lidocaine maximum dose of 4.5mg/kg or 200mg total.
- If 1% lidocaine is unavailable, 10mL of 2% may be substituted. A two-point paracervical block technique (injecting at 4 and 8 o'clock) may be used.
- Where available, and where staff have been trained to do so, sodium bicarbonate may be added to the paracervical block (1mL of sodium bicarbonate for every 10mL of anesthetic solution).
- Deep injection of lidocaine (3cm or 1in) provides more effective pain relief than superficial injection.
- Aspirate before injecting to prevent intravascular injection.
- Possible side effects seen with intravascular injection include peri-oral tingling, tinnitus, metallic taste, dizziness or irregular/slow pulse.
- Midlevel providers trained to provide paracervical block demonstrate similar safety and efficacy as physicians.
- Serious adverse events related to paracervical block are rare.

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APPENDIX D: PROCESSING THE IPAS MVA PLUS® ASPIRATOR AND IPAS EASYGRIP® CANNULAE WALL CHART

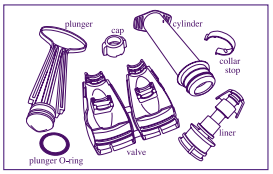
Processing the Ipas MVA Plus® Aspirator and Ipas EasyGrip® Cannulae

The following options are consistent with best practices regarding reuse of the Ipas MVA Plus Aspirator and Ipas EasyGrip Cannulae.
Use care when developing site protocols regarding the processing of instruments.
Chemicals or processing methods other than the ones listed here may cause damage.

Basics of Infection Prevention

- Wash hands immediately before and after every patient contact.
- Consider **all** blood and body fluids from **all** patients to be potentially infectious.
- Use personal protective barriers (gloves, gowns, face protection, shoes) when contact with blood or other body fluids is expected.
- Avoid accidental skin punctures; use care when handling needles.
- Use *No-Touch Technique:* The tip of the cannula, or the tip of any other instrument that enters the uterus, should never touch nonsterile surfaces (including the vaginal walls) prior to insertion.

1 Point-of-Use Preparation



Immediately following the procedure, all Ipas MVA Plus Aspirators and Ipas EasyGrip Cannulae that will be reused should be kept wet until cleaning. Presoak, rinse or spray device with water or enzymatic spray. Do not use chlorine or saline.

CAUTION: Aspirators and cannulae are not safe to handle with bare hands until cleaned.

2 Clean and Disassemble Instruments

- Wear gloves and face protection. Clean all instrument surfaces thoroughly in warm water and preferably detergent—not soap.
- Disassemble the aspirator by pulling the cylinder out of the valve. Remove the cap by pressing down the cap-release tabs with one hand and pulling off the cap with the other hand.
- Open the hinged valve by pulling open the clasp. Place the right thumb alongside the right valve button and the left thumb on the valve latch. With the left thumb, pull up and to the left on the valve latch while pushing down and out on the valve body with the right thumb. Remove the valve liner.
- Disengage the collar stop by sliding it sideways under the retaining clip, or remove the collar stop completely.
- Pull the plunger completely out of the cylinder. Displace plunger O-ring by squeezing its sides and rolling it into the groove below.
- Instruments must be completely clean before further processing. If tissue is trapped in the tip of a cannula, flush water through the cannulae repeatedly or use a cotton- tipped probe, soft brush or soft cloth to gently remove material. If unable to remove blood or tissue during cleaning despite repeated attempts, discard the instrument.

CAUTION: Do not use any pointed or sharp objects to clean the valve parts or to move the O-ring. This could cause damage and prevent the aspirator from maintaining a vacuum.

3 Processing Options

The Ipas MVA aspirator does not directly touch the woman's body. However, when it is used, the cylinder fills with blood. There is the potential risk that some contaminants from a previous woman could be introduced to another woman if the MVA aspirator is not fully processed (soaked, cleaned and sterilized or high-level disinfected) between each use. Therefore, after cleaning, the Ipas MVA Plus must undergo high-level disinfection or sterilization between patients to remove contaminants. Once processed, the aspirator may be kept in a clean container. Aspirators must be completely disassembled for all processing methods. Ipas EasyGrip Cannulae require high-level disinfection or sterilization before re-use and must be high-level disinfected or sterile when inserted into the uterus. Chemical processing agents are hazardous substances. When processing instruments, take necessary precautions, such as using personal protective equipment. Refer to the manufacturer's safety instructions to establish safe use.

For optimal infection prevention, items should be processed using a method that provides the highest level of effectiveness. **Use one of the following methods,** listed in order of descreasing effectiveness:

Sterilize

- Steam autoclave in linen or paper for 30 minutes at 121°C (250°F) and 106kPa (15lbs./in²). DO NOT USE OTHER AUTOCLAVE SETTINGS, SPECIFICALLY DO NOT USE HIGHER SETTINGS ("FLASH AUTOCLAVING"). Lay package flat in the autoclave to avoid bending the cannulae.
- Soak completely immersed in 2% glutaraldehyde solution (Cidex® or equivalent) for the time recommended by the manufacturer—most recommend 10 hours.
- Soak completely immersed in Sporox® II solution for 6 hours.

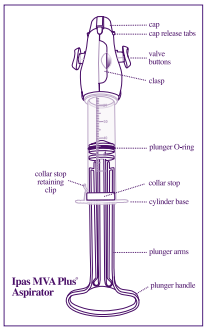
High-Level Disinfect

- Boil in water for 20 minutes. Grasping hot cannulae may cause flattening. Let water cool before removing cannulae and handle by the adapter/base.
- Soak completely immersed in a 0.5% chlorine solution for 20 minutes. Change chlorine solution daily or sooner if solution becomes cloudy.
- Soak completely immersed in 2% glutaraldehyde solution (Cidex® or equivalent) for the time recommended by the manufacturer—recommendations range from 20–90 minutes.
- Soak completely immersed in Sporox® II solution for 30 minutes.

After Processing MVA Instruments

- If chemical agents were used in processing, Ipas EasyGrip Cannulae are to be thoroughly rinsed with either boiled water (for instruments that were high-level disinfected) or sterile water (if instrument was sterilized) after processing. Ipas MVA Plus Aspirator parts can be thoroughly rinsed in clean potable water (drinking water).

4 Store Appropriately or Use Immediately



Storage

- Aspirators and adapters may be dried, the O-ring lubricated and the device reassembled and stored in a clean, dry area until use. The aspirator does not need to remain high-level disinfected or sterilized at the time of use and can be placed in a clean area or stored according to local standards.
- Cannulae must remain sterile or high-level disinfected until next use. Store cannulae in either sterile or high-level disinfected containers to preserve the level at which they were processed. Handle cannulae by the base ends.
- Instruments processed by wet methods should be reprocessed daily.

Assembly and Use

- Before use, reassemble, lubricate and check vacuum capability of the aspirator.
- Place the valve liner in position inside the valve by aligning the internal ridges. Close the valve until it snaps in place. Snap the cap onto the end of the valve. Push the cylinder into the base of the valve without twisting.
- Place the plunger O-ring in the groove at the end of the plunger and lubricate it by spreading one drop of lubricant around the O-ring with a fingertip. Silicone or other non-petroleum-based lubricants can be used. Squeeze the plunger arms and insert the plunger fully into the cylinder. Move the plunger in and out to lubricate the cylinder. Insert the tabs of the collar stop into the holes in the cylinder.
- Check vacuum by pushing the buttons down until they lock, and pulling the plunger back until the plunger arms lock. Leave in this position for two to three minutes, then release buttons. A rush of air indicates that the aspirator maintained the vacuum.
- If you do not hear the rush of air, remove the plunger. Check the plunger O-ring and instrument for foreign particles and cracks. If the aspirator still loses vacuum, it should be discarded.

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PROPLUS-E19

APPENDIX E: PROTOCOLS FOR MEDICAL ABORTION POCKET CARD

PROTOCOLS FOR MEDICAL ABORTION

Medical abortion with mifepristone and misoprostol

Up to 10 weeks gestation (70 days since last menstrual period (LMP)):

- Mifepristone 200mg orally
- Misoprostol 800mcg buccally, sublingually or vaginally 1-2 days after mifepristone

10-13 weeks gestation:

- Mifepristone 200mg orally
- Misoprostol 600mcg sublingually or 800mcg vaginally 1-2 days after mifepristone, then misoprostol 400mcg sublingually or vaginally every three hours until expulsion
- Alternatively, mifepristone 200mg orally followed 1-2 days later by misoprostol 800mcg buccally, sublingually or vaginally may be used. The dose of misoprostol may be repeated to achieve abortion success.

At or after 13 weeks gestation (13-24 weeks):

- Mifepristone 200mg orally
- Misoprostol 400mcg buccally, sublingually or vaginally 1-2 days after mifepristone, then every three hours until fetal and placental expulsion
- If the woman is stable and it is convenient for her to do so, providers should allow her at least four hours after fetal expulsion to expel the placenta.

Medical abortion with misoprostol only

Before 13 weeks gestation:

- Misoprostol 800mcg buccally, sublingually or vaginally every three hours until expulsion

At or after 13 weeks gestation (13-24 weeks):

- Misoprostol 400mcg sublingually or vaginally every three hours until fetal and placental expulsion. Vaginal dosing is more effective than sublingual dosing for nulliparous women
- If the woman is stable and it is convenient for her to do so, providers should allow her at least four hours after fetal expulsion to expel the placenta

Medical treatment for incomplete abortion, missed abortion, or intrauterine fetal demise (postabortion care)

Less than 13 weeks uterine size:

- Incomplete abortion
  - Misoprostol 600mcg orally in a single dose or 400mcg in a single dose sublingually or, in the absence of vaginal bleeding, vaginally
- Missed abortion
  - Misoprostol 600mcg sublingually or, in the absence of vaginal bleeding, 800mcg vaginally every 3 hours until expulsion (generally 1-3 doses)
  - Where available, add pretreatment with mifepristone 200mg orally 1-2 days before misoprostol

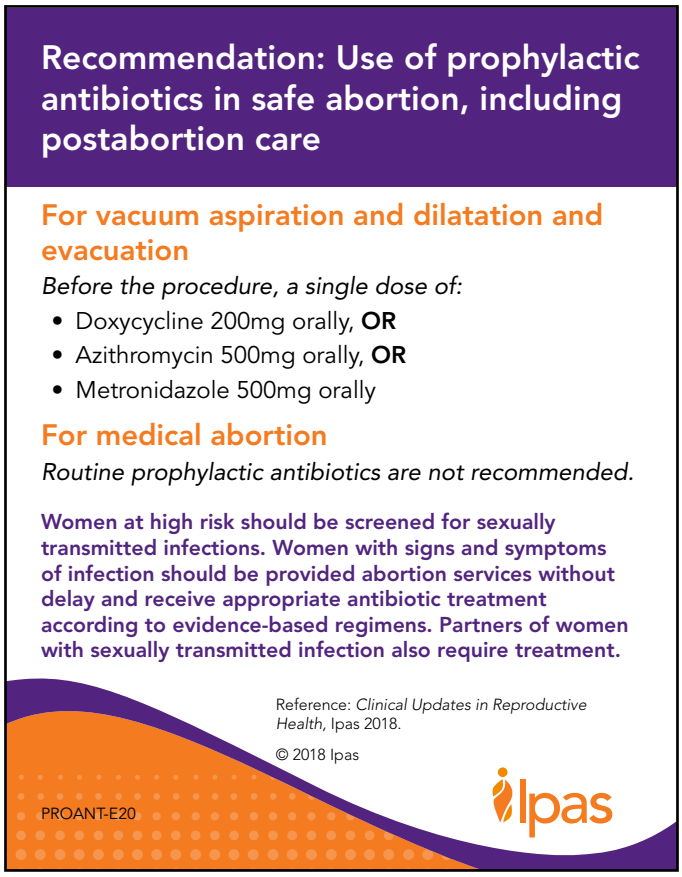
13 weeks or larger uterine size:

- Incomplete abortion
  - Misoprostol 400mcg buccally, sublingually or, in the absence of vaginal bleeding, vaginally every three hours until expulsion
- Intrauterine fetal demise (up to 24 weeks):
  - Misoprostol 400mcg sublingually or, in the absence of vaginal bleeding, vaginally every 4-6 hours until expulsion.
  - Where available, add pretreatment with mifepristone 200mg orally 1-2 days before misoprostol.

Citation: Ipas Clinical Updates in Reproductive Health 2019.
www.ipas.org/clinicalupdates; www.ipas.org/actualizacionesclinicas; www.ipas.org/actualitescliniques

MADOSCARD-E19

APPENDIX F: RECOMMENDATION: USE OF PROPHYLACTIC ANTIBIOTICS IN SAFE ABORTION, INCLUDING POSTABORTION CARE, POCKET CARD



Recommendation: Use of prophylactic antibiotics in safe abortion, including postabortion care

For vacuum aspiration and dilatation and evacuation

Before the procedure, a single dose of:

- Doxycycline 200mg orally, **OR**
- Azithromycin 500mg orally, **OR**
- Metronidazole 500mg orally

For medical abortion

Routine prophylactic antibiotics are not recommended.

Women at high risk should be screened for sexually transmitted infections. Women with signs and symptoms of infection should be provided abortion services without delay and receive appropriate antibiotic treatment according to evidence-based regimens. Partners of women with sexually transmitted infection also require treatment.

Reference: *Clinical Updates in Reproductive Health*, Ipas 2018.

PROANT-E20

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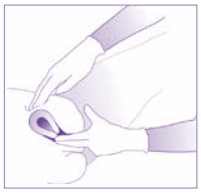
APPENDIX G: STEPS FOR PERFORMING MANUAL VACUUM ASPIRATION WALL CHART

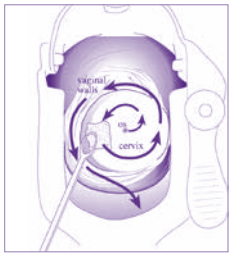
Steps for Performing Manual Vacuum Aspiration (MVA) Using the Ipas MVA Plus® and Ipas EasyGrip® Cannulae

Step One: Prepare the Patient



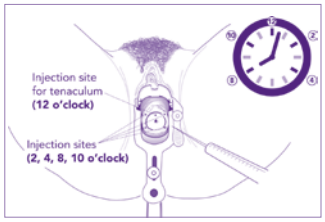
- Administer pain medication before the procedure to have maximum effect when the procedure begins.
- Give prophylactic antibiotics to all women, or therapeutic antibiotics if indicated.
- Ask the woman to empty her bladder.
- Conduct a bimanual exam to confirm uterine size and position.
- Insert speculum and observe for signs of infection, bleeding or incomplete abortion.

Step Two: Perform Cervical Antiseptic Prep



- Use antiseptic-soaked sponge to clean cervical os. Start at os and spiral outward without retracing areas. Repeat until os has been completely covered by antiseptic.

Step Three: Perform Paracervical Block

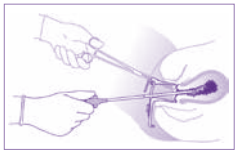


- Paracervical block is required prior to MVA.
- Perform paracervical block with 20cc of 1% lidocaine, or 10cc of 2% lidocaine. Inject a small amount of lidocaine (1-2cc) into the cervix at the tenaculum site (12 o'clock). Inject the remaining lidocaine in equal amounts at the cervicovaginal junction at 2, 4, 8 and 10 o'clock. Always aspirate before injecting to prevent intravascular injection of lidocaine.

Step Four: Dilate Cervix

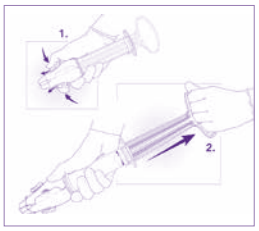
- Observe no-touch technique when dilating the cervix and during aspiration. Instruments that enter the uterine cavity should not touch your gloved hands, the patient's skin, the woman's vaginal walls, or unsterile parts of the instrument tray before entering the cervix.
- Use mechanical dilators or progressively larger cannulae to gently dilate the cervix to the right size.

Step Five: Insert Cannula



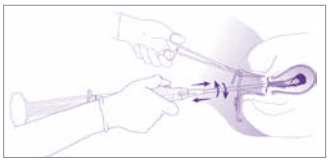
- While applying traction to the tenaculum, insert cannula through the cervix, just past the os and into the uterine cavity.
- Do not insert the cannula forcefully.

Step Six: Prepare the Aspirator



- Position the plunger all the way inside the cylinder.
- Have collar stop in place with tabs in the cylinder holes.
- Push valve buttons down and forward until they lock (1).
- Pull plunger back until arms snap outward and catch on cylinder base (2).

Step Seven: Suction Uterine Contents



- Attach the prepared aspirator to the cannula.
- Release the vacuum by pressing both buttons.
- Evacuate the contents of the uterus by gently and slowly rotating the cannula 180° in each direction, using an in-and-out motion.
- When the procedure is finished, depress the buttons and disconnect the cannula from the aspirator. Alternatively, withdraw the cannula and aspirator without depressing the buttons.

Signs that indicate the uterus is empty:

- Red or pink foam without tissue is seen passing through the cannula.
- A gritty sensation is felt as the cannula passes over the surface of the evacuated uterus.
- The uterus contracts around or grips the cannula.
- The patient complains of cramping or pain, indicating that the uterus is contracting.

Step Eight: Inspect Tissue

- Empty the contents of the aspirator into a container.
- Strain material, float in water or vinegar and view with a light from beneath.
- Inspect tissue for products of conception, complete evacuation and molar pregnancy.
- If inspection is inconclusive, reaspiration or other evaluation may be necessary.

Step Nine: Perform Any Concurrent Procedures

- When procedure is complete, proceed with contraception or other procedures, such as IUD insertion or cervical tear repair.

Step Ten: Immediately After the Procedure

- Reassure the woman that the procedure is finished.
- Ensure she is escorted to the recovery area.
- Immediately process or discard all instruments, according to local protocols.

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