

# Clinical Updates in Reproductive Health



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# Clinical Updates in Reproductive Health

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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

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# 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, girls', and pregnant people's 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 2023 update, we reviewed newly published literature related to follow-up care after medical abortion; cervical preparation before a procedural abortion; the use of telemedicine and other innovative service delivery mechanisms for abortion care; self-management of the component parts of medical abortion as well as the medical abortion process overall; and health worker roles in abortion care. We updated our recommendations accordingly. Additionally, we updated with supportive and informative data the sections on misoprostol quality, pain management, screening for ectopic pregnancy, recommended regimens for mifepristone and misoprostol and misoprostol used alone, the addition of letrozole to misoprostol-only medical abortion, home use of medical abortion pills, inducing fetal demise prior to abortion at or after 13 weeks, treatment for incomplete abortion and intrauterine demise, and postabortion contraception. We also reviewed newly published global guidelines for abortion care from the World Health Organization (2022) and others, and brought our recommendations into alignment whenever possible.

New for this edition of the *Clinical Updates*, we have incorporated tips for clinical practice into the recommendations for some topics. These tips are intended to help guide the implementation and operationalization of the recommendations contained in the *Clinical Updates*. Titled "In practice," these tips can be found in sections related to pain management, instrument processing, recommended medical abortion and postabortion care medication regimens, and contraception.

Similarly, we have incorporated links to a number of our clinical resources directly into the *Clinical Updates* topics where appropriate. These "resources" include clinical tools and job aids for clinicians, and, in a few cases, information to support self-managed abortion. The



resources are drawn from the evidence and recommendations contained in the *Clinical Updates in Reproductive Health*, and are found at the end of selected topics just before the references. Some of these online resources replace several of the items that were in the Appendices in previous editions, while others are new additions.

The online *Clinical Updates* ([www.ipas.org/clinicalupdates](http://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.

Finally, in recognition that people who identify as transgender, non-binary, gender-fluid, and additional gender identities can experience pregnancy and abortion, we have attempted to incorporate gender inclusive language in this revision of the *Clinical Updates in Reproductive Health*. Most available evidence about abortion care has been conducted in populations of cisgender women; where specific studies included in the *Clinical Updates in Reproductive Health* describe study participants as “women,” we also use the term “women” to be consistent with what is reported. In our discussions of abortion generally, and when referring to all the gender diverse individuals requiring abortion care, we use the terms “people,” “individuals,” “abortion seeker,” or other gender inclusive language.

## 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 searches 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 (Page et al., 2021; Stroup, Berlin, & Morton, 2000).

### Process for making recommendations

Ipas applies the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to its recommendation formation (Schunemann et al., 2013). 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 evi-

dence related to a specific clinical outcome 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. When assessing the quality of evidence, the following criteria are considered:

- 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 (Balslem 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 desirable consequences of a recommendation outweigh its undesirable 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 (Schunemann et al., 2013). 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 (Schunemann et al., 2013). 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 desirable and undesirable 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 regionally representative Clinical Advisory Group reviews all updates proposed by the writer and editor. New recommendations or substantially revised recommendations may undergo an internal peer review process. The revision process - including systematic search and 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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## 1 General recommendations for abortion care

# 1.1 Summary of recommended medical abortion regimens

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### Medical abortion with mifepristone and misoprostol

- **Before 13 weeks gestation:**
  - Mifepristone 200mg orally
  - Misoprostol 800mcg buccally, sublingually or vaginally 1-2 days after mifepristone. The dose of misoprostol can be repeated to achieve abortion success. After 9 weeks gestation, routinely using at least two doses of misoprostol, administered 3-4 hours apart, improves abortion success rates.
- **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
  - The median time to abortion is 6-10 hours after beginning misoprostol, although some individuals will require more time to successfully abort.

### Medical abortion with misoprostol only

- **Before 13 weeks gestation:**
  - Misoprostol 800mcg buccally, sublingually or vaginally every three hours until expulsion
  - Individuals undergoing misoprostol-only medical abortion outside of a health facility should be provided with 3-4 doses of misoprostol depending on the scenario.
- **At or after 13 weeks gestation (13-24 weeks):**
  - Misoprostol 400mcg buccally, sublingually or vaginally every three hours until fetal and placental expulsion. Vaginal dosing is more effective than other routes.
  - The average time to abortion is 10-15 hours after beginning misoprostol, although some individuals will require multiple days to successfully abort.

## Medical treatment for incomplete abortion, missed abortion or intra-uterine 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 buccally, sublingually or, in the absence of vaginal bleeding, vaginally
  - Missed abortion:
    - Misoprostol 800mcg buccally, sublingually or, in the absence of vaginal bleeding, 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 buccally, 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.

### Resources

<http://www.ipas.org/ClinicalResources>

Protocols for medical abortion (dosage card)

Mifepristone/Misoprostol Gestational Dating Wheels

Misoprostol Only Gestational Dating Wheels



## 1 General recommendations for abortion care

# 1.2 Uterine evacuation: Replace sharp curettage with aspiration or medications

---

### 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

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The World Health Organization (WHO) and the International Federation of Gynecology and Obstetrics (FIGO) recommend against the use of sharp curettage-including sharp curette 'checks' to complete the abortion-and state that vacuum aspiration or medication regimens should replace sharp curettage for uterine evacuation (FIGO, 2011; WHO, 2022). In places where no uterine evacuation services exist, vacuum aspiration and medical abortion should be introduced.

Multiple systematic reviews have shown that vacuum aspiration is as effective as sharp curettage in treating early incomplete and missed abortions, while reducing procedure time, blood loss and pain (Ghosh et al., 2021; Tuncalp, Gulmezoglu, & Souza, 2010), and it is feasible to introduce in settings using D&C (Kakinuma, et al 2020). 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 et al., 2015).

Multiple studies on induced abortion and postabortion care have shown that because vac-

uum aspiration can be performed in an outpatient setting by many different kinds of health care workers without general anaesthesia, the costs to both the health system and individuals are significantly less than sharp curettage (Benson, Okoh, KrennHrubec, Lazzarino, & Johnston, 2012; Choobun, Khanuengkitkong, & Pinjaroen, 2012; Farooq, Javed, Mumtaz, & Naveed, 2011; Johnston, Akhter, & Oliveras, 2012).

A 2021 network meta-analysis compared surgical uterine evacuation methods, including D&C, to medical management of early pregnancy loss, finding similar effectiveness for vacuum aspiration, D&C, and medical management (Ghosh et al., 2021). The safety and tolerability of medical regimens for uterine evacuation are well documented (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 tertiary 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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## 1 General recommendations for abortion care

# 1.3 Prophylactic antibiotics for vacuum aspiration and dilatation and evacuation

---

### 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.

### In practice

- When antibiotic prophylaxis is needed, a single dose of doxycycline (a tetracycline antibiotic) or metronidazole (a nitroimidazole antibiotic) are commonly used because of their efficacy, ease of oral administration, low cost, and low risk of allergic reaction

### Strength of recommendation

Strong

### Quality of evidence

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

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### 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 et al., 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, 2022), Society of Family Planning (Achilles & Reeves, 2011), American College of Obstetricians and Gynecologists (ACOG, 2018) and Royal College of Obstetricians and Gynaecologists (RCOG, 2022) recommend prophylactic antibiotics for all people 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 & Cherdchoogiat, 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 & Cherdchoogiat, 2012).

Giving prophylactic antibiotics is more effective than screening everyone presenting for abortion care and treating only those with evidence of infection (Levallois & Rioux, 1988). The inability to provide antibiotics should not limit access to abortion (WHO, 2022), 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; penicillins have also been shown to be effective but have more risk of allergy (Achilles & Reeves, 2011; O'Connell et al., 2008; WHO, 2022). 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.


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 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 et al., 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

Those at high risk should be screened for sexually transmitted infections in addition to receiving prophylactic antibiotics. Individuals 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, 2022; WHO, 2021). Partners of individuals with sexually transmitted infections also require treatment (WHO, 2016).

<b>Resources</b>	<a href="http://www.ipas.org/ClinicalResources">http://www.ipas.org/ClinicalResources</a>
<b>Recommendations for use of prophylactic antibiotics in safe abortion care (card)</b>	

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## 1 General recommendations for abortion care

# 1.4 Prophylactic antibiotics for medical abortion

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### Recommendation

- Routine use of antibiotics is not recommended for 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

Strong

### Quality of evidence

Very low

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### 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 et al., 2009; Henderson et al., 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 et al., 2002). One death from group A strep-

tococcus 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 et al., 2012). Given the large number of people 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 (2020), the Society of Family Planning (Achilles & Reeves, 2011), the Royal College of Obstetricians and Gynaecologists (2022) and the World Health Organization (WHO, 2022) do not recommend routine antibiotic use prior to medical abortion.

### **Therapeutic antibiotics**

Those at high risk should be screened for sexually transmitted infections. Individuals 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, 2022; WHO, 2021). Partners of individuals with sexually transmitted infections also require treatment (WHO, 2016).

#### **Resources**

<http://www.ipas.org/ClinicalResources>

**Recommendations for use of prophylactic antibiotics in safe abortion care (card)**



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## 1 General recommendations for abortion care

# 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

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### Definitions

*Contraindications:* People with any of these specific conditions 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:* For people with 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 individuals 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; Das et al., 2022; Hauseknecht, 2003; Tupek et al., 2022; Sahraei, Mirabzadeh, & Eshraghi, 2016; Schoen et al., 2014; Zhang et al., 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 et al., 1994).

*Chronic adrenal failure:* Mifepristone is a glucocorticoid receptor antagonist (Spitz & Bardin, 1993). Mifepristone blocks negative feedback mechanisms that control cortisol secretion. For those 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 people with adrenal insufficiency, but there is experimental and animal data to support the recommendation.*

## **Precautions**

*IUD in place:* A person 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 those 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 mini-

mize bleeding risk. Three case reports document misoprostol-induced acute coronary artery vasospasm, which in one case required coronary artery stent placement (Illa et al., 2010; Mazhar, Sultana, & Akram, 2018; Munoz-Franco et al., 2019). Whether to provide medical abortion to individuals 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. For those 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 people 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 people requiring systemic corticosteroids has not been studied as giving mifepristone risks asthma exacerbation. One review suggests using a high level of caution when giving mifepristone to such people 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 those 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 individuals with asthma who are not on long-term systemic steroids (Creinin & Gemzell Danielsson, 2009). *Quality of evidence: Very low*

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## 1 General recommendations for abortion care

# 1.6 Misoprostol product quality

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### 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

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### Manufacture and quality 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 stringent regulatory agencies (such as the European Medicines Agency or the United States Food and Drug Administration) or prequalified by WHO (WHO-PQ) conform to Good Manufacturing Practice and are of high quality (Hagen et al., 2020a).

Exposure to heat and humidity during manufacturing, packaging, shipping or storage may compromise the stability and quality of misoprostol (Cayman Chemical, 2012; Hagen et al., 2020a). Degradation decreases the effectiveness of misoprostol, leading to decreased success rates of medical abortion and unsuccessful treatment of incomplete abortion and postpartum hemorrhage.

Four studies have examined the quality of misoprostol products obtained from low- and middle-income countries. 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 per the International Pharmacopeia, meaning they contained between 90-100% of labeled content, and 40% were below specification, containing 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. A similar study in Malawi found 23 of 30 samples from health centers and pharmacies around the country met specification for misoprostol; all samples meeting specification were packaged in aluminum-aluminum blister packs (Hagen, Khuluza & Heide, 2020b). A systematic review and meta-analysis of the quality of medicines, including oxytocics, in low- and middle-income countries included these three studies and found that 39% of all misoprostol samples failed to meet specification (Torloni et al., 2020). A subsequent study assessed quality of misoprostol from health facilities in Rwanda (Bizimana et al., 2021), finding that 10 of the 25 misoprostol samples assessed (40%) did not meet specification. All substandard specimens derived from two brands.

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. Quality 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 et al., 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 (Hagen et al., 2020a). 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; Hagen et al., 2020a).

## 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](http://www.medab.org)) to assess the quality of products available in their setting (Hagen et al., 2020b). In some cases, providers may need to consult with one another to determine which local misoprostol brands are most effective.

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## 2 Pain management

# 2.1 Pain Management for medical abortion before 13 weeks gestation

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### Recommendation:

- Offer pain medication to all people 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: October 12, 2022**

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### 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). More than 75% of patients report resolution of pain by 12 hours after taking misoprostol, with reports increasing to 90% by 24 hours (Friedlander et al., 2022).



Patient characteristics associated with more pain include increasing gestational age, younger patient age, nulliparity, no previous vaginal deliveries, and history of dysmenorrhea (Dragoman et al., 2021; Kemppainen et al., 2020; Suhonen et al., 2011; Teal, Dempsey-Fanning, & Westhoff, 2007; Westhoff et al., 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; Reynolds-Wright, 2022).

## **Medications for pain management**

Two small randomized controlled trials indicate that ibuprofen is more effective than placebo (Avraham et al., 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). A three-armed randomized trial compared ibuprofen plus metoclopramide, tramadol, or placebo taken at the time of misoprostol administration and again 4 hours later; finding that ibuprofen plus metoclopramide and tramadol alleviated pain more effectively than the placebo, but did not result in clinically significant differences in participants' reported pain (Dragoman et al., 2021). 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 those who request them. One hospital-based study randomized women undergoing medical abortion into two groups: intravenous patient-controlled-analgesia for pain, or on-demand oral, intramuscular, or intravenous administration of oxycodone for pain (Kemppainen et al., 2022). Results show that most participants in both groups utilized opioid medication; those in the patient-controlled-analgesia group were more likely to characterize pain as mild or tolerable (21% compared to 6% in the on-demand group), although maximum reported pain was the same in both groups.

## **Non-pharmacologic pain management**

In one randomized trial, high frequency transcutaneous electrical nerve stimulation (80Hz TENS) applied to the abdomen and back when cramping began reduced women's abortion pain compared to placebo (Goldman et al., 2020). Another randomized trial found no benefit of auricular acupuncture or acupressure in improving medical abortion pain, when compared to placebo (Westhoff et al., 2021). Other non-pharmacologic pain management strategies for

medical abortion before 13 weeks gestation have not been the subject of comparative trials. However, experts recommend adjunctive non-pharmacologic measures to improve individual'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.

## Resources

<http://www.ipas.org/ClinicalResources>



**Appendix A: Pain medication table**

**Appendix B: Continuum of depth of sedation: Definition of general anesthesia and levels of sedation/analgesia**

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## 2 Pain management

# 2.2 Pain management for medical abortion at or after 13 weeks gestation

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### Recommendation:

- Offer pain medication to everyone 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: September 19, 2022**

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### 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 people required pain medication (Ashok et al., 2004; Gemzell-Danielsson & Östlund, 2000; Hamoda et al., 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

Limited evidence exists regarding the optimal pain medication regimen for medical abortion at or after 13 weeks gestation (Jackson & Kapp, 2020). 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 et al., 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. Those in the NSAID group had significantly lower pain scores at the time of abortion; however, nearly half of participants 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; World Health Organization [WHO], 2022).

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 et al., 2016; Winkler et al., 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.

### Resources

<http://www.ipas.org/ClinicalResources>

**Appendix A: Pain medication table**

**Appendix B: Continuum of depth of sedation: Definition of general anesthesia and levels of sedation/analgesia**



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## 2 Pain management

# 2.3 Pain management for vacuum aspiration

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### Recommendation

- A combination of paracervical block and preprocedure nonsteroidal anti-inflammatory drugs (NSAIDs) for pain management is recommended for all people.
- 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** recommended for pain management for routine vacuum aspiration procedures .

### In practice

- Pain management is recommended for all vacuum aspiration procedures, whether they are performed to induce abortion or for postabortion care.
- Clinicians consistently underestimate the amount of pain people experience during vacuum aspiration.

### Strength of recommendation

Strong

### Quality of evidence

High

**Last reviewed: October 12, 2022**

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### Pain during vacuum aspiration

Most people undergoing vacuum aspiration-whether for induced abortion (Borgatta & Nickinovich, 1997) or for postabortion care (Crouthamel et al., 2022; Gomez et al., 2004)-will experience pain. Preprocedure depression or emotional distress, or gestational age beyond 10 weeks, are associated with more pain during uterine aspiration (Allen et al., 2006; Belanger, Melzack, & Lauzon, 1989; Duros et al., 2018), while having a prior vaginal delivery is associ-

ated with less pain (Borgatta & Nickinovich, 1997). Clinicians consistently underestimate the amount of pain people experience during abortion (Oviedo et al., 2018; Singh et al., 2008; Tschann et al., 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 people (Renner et al., 2010; Royal College of Obstetricians and Gynaecologists [RCOG], 2022; World Health Organization [WHO], 2022). Intravenous sedation may also be offered (RCOG, 2022; WHO, 2022).

## **Local anesthesia**

A paracervical block given before dilating the cervix has been shown to decrease pain with dilation and uterine aspiration (Acmaaz et al., 2013; Renner et al., 2012; Renner et al., 2016). Paracervical block is a low-risk procedure that can be safely performed by many types of healthcare workers, including physicians, associate/advanced associate clinicians, nurses, traditional and complementary medicine professionals, and health workers who provide basic emergency obstetric care (Warriner et al., 2006; WHO, 2022). 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 (Acmaaz et al., 2013; Li et al., 2003). However, pre-procedure treatment with NSAIDs was found to decrease pain during and after the procedure in studies where participants also received paracervical block for pain relief (Renner et al., 2010; Romero, Turok, & Gilliam, 2008; Suprpto & Reed, 1984; Wiebe & Rawling, 1995); both oral and intramuscular NSAIDs are effective (Braaten et al., 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 et al., 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), while in another randomized trial, the addition of intravenous fentanyl to the same pain management regimen significantly improved procedural pain (Rawling & Weibe, 2001). Intranasal fentanyl, however, when added to ibuprofen and paracervical block, did not improve pain when compared to placebo (Moayedi et al., 2022). 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, 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). A subsequent trial compared preprocedure gabapentin to placebo amongst women having uterine aspiration under local anesthesia with paracervical block and oral ibuprofen and found no differences in intra-operative or postoperative pain scores (Hailstorks et al., 2020).

## **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 et al., 2009; Allen et al., 2006; Cansino et al., 2021; Wells, 1992; Wong et al., 2002). Intravenous administration of narcotics and anxiolytics is more effective than oral administration for pain during uterine aspiration (Allen et al., 2009). In people 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 (Cansino et al., 2021). 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; RCOG, 2022; WHO, 2022). 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 et al. 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

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 et al., 2016). Two subsequent randomized trials found no difference in reported pain between those receiving preprocedure music therapy (Belloeil et al., 2020), or 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). Two studies examining the use of auricular acupuncture, in combination with paracervical block and preprocedure NSAIDs, had conflicting results (Ndubisi et al., 2019; Oviedo et al., 2021). Additionally, a third trial combining auricular acupuncture with deep sedation did not find a clinically meaningful improvement in postprocedure pain in the intervention group (Zhu et al., 2022). The use of transcutaneous acupoint electrical stimulation (TEAS) 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). A single well designed randomized controlled trial examined high-frequency, high-intensity transcutaneous electrical nerve stimulation (TENS) as an alternative to intravenous sedation for aspiration pain relief up to 12 weeks gestation, finding TENS to be non-inferior to sedation (Lerma et al., 2021).

### Resources

<http://www.ipas.org/ClinicalResources>

**Appendix A: Pain medication table**

**Appendix B: Continuum of depth of sedation: Definition of general anesthesia and levels of sedation/analgesia**



## References

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## 2 Pain management

# 2.4 Pain management for dilatation and evacuation

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### 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

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### Pain during dilatation and evacuation

A longer duration of pregnancy at the time of abortion is associated with higher reported pain scores during dilatation and evacuation (D&E) (Dzuba et al., 2022). At later gestations, D&E requires more preoperative and operative cervical dilation, longer procedure times and deeper uterine manipulation.

### Methods of pain management

Comparative studies of pain management during D&E are largely lacking. Existing studies examine pain management during osmotic dilator placement before a D&E, the effect of adjuvant medications on post-procedure pain amongst people receiving general anesthesia or deep intravenous sedation, or focus instead on safety of pain management strategies during D&E. International consensus statements generally 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 [RCOG], 2022; World Health Organization [WHO], 2022).

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 et al., 1985; Castleman et al., 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, NSAIDs, paracervical block and intravenous sedation should be offered (Jackson & Kapp, 2020; RCOG, 2022; WHO, 2022).

## **Local anesthesia**

See section 2.5 Paracervical block.

## **Medications**

No studies assess the effectiveness of oral, intramuscular or intravenous pain medications during the D&E procedure. One study found that participants who received the intravenous NSAID ketorolac in combination with deep intravenous sedation or general anesthesia during their D&E procedure reported significantly lower pain post-procedure than those who did not receive the medication (Liu & Flink-Bochacki, 2021). These data must be interpreted with caution as the study was not designed to address this comparison, however, studies of vacuum aspiration have consistently found that pre-procedure administration of oral or intramuscular NSAIDs decreases pain during and after the procedure (Braaten et al., 2013; Renner et al., 2010; Romero, Turok, & Gilliam, 2008; Suprpto & Reed, 1984; Wiebe & Rawling, 1995).

## **Intravenous sedation**

Only one randomized trial has assessed the effectiveness of intravenous moderate sedation during D&E, finding that moderate sedation with fentanyl and midazolam was significantly more effective than inhaled nitrous oxide for pain management in women between 12-16 gestational weeks who also received preprocedure ibuprofen and paracervical block (Thaxton et al., 2018). Additional data from 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 et al., 2009; Allen et al., 2006; Wells, 1992; Wong et al., 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 et al., 2016; Wilson, Chen, & Creinin, 2009; Wiebe et al., 2013). Intravenous deep sedation with propofol and without intubation is safe and has few complications in the outpatient setting, without risk of pulmonary aspiration (Aksel et al., 2018; Dean et al., 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 (Cansino et al., 2021). The increased monitoring necessary to deliver intravenous seda-

tion 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 during the procedure, 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; RCOG, 2022; WHO, 2022). 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

Pain 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).

### Resources

<http://www.ipas.org/ClinicalResources>

Appendix A: Pain medication table

Appendix B: Continuum of depth of sedation: Definition of general anesthesia and levels of sedation/analgesia





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# 2.5 Paracervical block

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### 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.
- Many types of health care workers—including associate and advanced associate clinicians, nurses, midwives, traditional and complementary medicine professionals, auxiliary nurses and auxiliary nurse midwives—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.

### In practice

- Paracervical block should be used for uterine evacuation procedures performed for both induced abortion and postabortion care.

### Strength of recommendation

Strong

### Quality of evidence

High

**Last reviewed: October 7, 2022**

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## 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 et al., 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. Participants who received the paracervical block had less pain during dilation and aspiration compared to those who received the sham injection (Renner et al., 2012). Deeper injection of anesthetic (3cm) improves pain management compared to superficial (1.5cm) injection (Cetin, & Cetin, 1997; Renner et al., 2010). A subsequent randomized controlled trial found the addition of sodium bicarbonate (1mL of 8.4% sodium bicarbonate for every 10mL of anesthetic solution) to a paracervical block containing 1% lidocaine did not decrease pain scores at the time of injection or at cervical dilation when compared to lidocaine only (Chin et al., 2020). 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 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).

It is unclear if the volume of anesthetic administered influences pain relief; a randomized trial including 114 people having uterine aspiration found no difference in reported pain when people received a 40mL 0.5% lidocaine or a 20mL 1% lidocaine paracervical block (Crouthamel et al., 2022), while two observational studies with significant confounders showed that people who received a 20mL block reported lower pain scores than those who received a 10mL block (Allen et al. 2006; Wiebe, 1992). Providers should avoid inadvertent intravascular injection to limit potential dose-related lidocaine toxicity (Lau et al., 1999), and may prefer a two-point injection technique when using a smaller volume of anesthetic.

For people receiving deep 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 et al., 2002). When using general anesthesia, there is no additional benefit to administering paracervical block (Hall et al., 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 two randomized controlled trials assessing pain control during osmotic dilator placement before a D&E. One included 41 people and found significantly decreased pain during osmotic dilator placement when paracervical block was used (Soon et al., 2017). The other trial included 91 people and found that a smaller volume of anesthetic (12mL of 1% lidocaine) was noninferior to a larger volume (20mL of 1% lidocaine) in managing pain related to osmotic dilator placement (Shaw et al., 2021).

## 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 pain (Andersson et al., 2016; Winkler et al., 1997).

## Who can perform paracervical block

The World Health Organization (WHO) makes service delivery recommendations for the provision of uterine aspiration, which includes routine administration of paracervical block (WHO, 2022). Health workers with the skills to perform a transcervical procedure, and a bimanual pelvic examination to diagnose pregnancy and determine gestational age based on uterine size, can be trained to provide vacuum aspiration with paracervical block. WHO advises that uterine aspiration is within the scope of practice for specialty and general medical practitioners; and recommends the provision of vacuum aspiration by associate and advanced associate clinicians, midwives, and nurses based on moderate certainty evidence of safety and effectiveness. Traditional and complementary medical professionals are recommended to provide uterine aspiration based on low certainty evidence of safety and effectiveness, and WHO suggests that auxiliary nurses and auxiliary nurse midwives may be able to perform aspiration in settings where they provide basic emergency obstetric care (WHO, 2022). For more information about who can perform specific tasks related to abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

## Technique

More information on paracervical block technique can be found in the Paracervical block technique job aid, linked below.

## Resources

<http://www.ipas.org/ClinicalResources>

Appendix A: Pain medication table

Appendix B: Continuum of depth of sedation: Definition of general anesthesia and levels of sedation/analgesia

Paracervical Block Technique Job Aid

Abortion Care Videos – Ipas: How to do a Paracervical Block



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### 3 Recommendations for abortion before 13 weeks gestation

## 3.1 Adolescents: Safety and effectiveness

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### 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: September 19, 2022**

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### Adolescents and abortion

The World Health Organization (WHO) defines adolescents as individuals 10-19 years of age, and young people as 20-24 years of age. Adolescents face barriers to accessing safe abortion care and present for abortions at later gestational ages than adults (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 (Espinoza, Samandari, & Andersen, 2020; Fatusi et al., 2021; Keogh et al., 2021; Olukoya et al., 2001). The Guttmacher Institute estimates that in 2019, 5.7 million adolescents aged 15-19 living in low- and middle-income countries experienced pregnancies that ended in abortion, the majority of which were unsafe (Sully et al., 2020). Decreasing barriers to abortion services may particularly benefit adolescents and young people.

When adolescents receive safe abortion services, they experience fewer complications than do older people. 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 people 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, 2022).

### 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

A Finnish study compared the pain experience of 56 adolescents undergoing medical abortion to that of 76 adult women, finding that the pain experienced in both groups was similar, and that more than half of all participants experienced severe pain (Kemppainen et al., 2020). Despite this, satisfaction with care was high in both the adolescent and adult groups, with 90% of participants stating they would choose medical abortion again. In one small, non-comparative study of 28 adolescents aged 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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### 3 Recommendations for abortion before 13 weeks gestation

## 3.2 Gestational dating

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### Recommendation

- Gestational age must be assessed before provision of abortion services.
- For individuals confident of the dates of their last menstrual period (LMP), gestational age may be calculated using LMP alone.
- When there is clinically relevant uncertainty about pregnancy duration using LMP alone, gestational age should be assessed using estimated 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.

### In practice

- Bimanual examination is a routine step before intrauterine procedures and must be performed before all vacuum aspiration procedures, even when not indicated for gestational dating.

### Strength of recommendation

Strong

### Quality of evidence

Moderate

**Last reviewed: October 2, 2022**

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### Importance of gestational dating

The gestational age of the pregnancy will influence the method of abortion and whether the abortion can take place at home or should take place in a facility. There are multiple ways to assess gestational age, including LMP, clinical examination of uterine size, and ultra-

sound. The use of LMP, alone or in combination with a validated tool such as a pregnancy dating wheel or checklist, enables individuals to self-assess gestational age (World Health Organization [WHO], 2022). Ultrasound screening for ectopic pregnancy in symptom-free individuals without risk factors is not necessary before a medical abortion (WHO, 2022); the incidence of ectopic pregnancy is lower in abortion seekers than the general population (Duncan, Reynolds-Wright, & Cameron, 2022). See 3.3: *Recommendations for abortion before 13 weeks gestation: Screening for ectopic pregnancy* for more information.

## LMP alone

Most people can recall their LMP reasonably well regardless of their education and whether they usually record their LMP dates (Averbach et al., 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 et al., 2017; Schonberg et al., 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 LMP combined with bimanual examination 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.

Two prospective cohort studies reporting on the effectiveness of telemedicine for the provision of medical abortion during the COVID-19 pandemic utilized reported LMP alone to determine gestational age and medical abortion eligibility (Aiken et al., 2021; Reynolds-Wright et al., 2021). One study, from England, compared a cohort of 22,158 individuals who received a traditional medical abortion pre-pandemic, which included in-person assessment and routine ultrasound, to a cohort who received either a telemedicine abortion (if they had a low risk of ectopic pregnancy and their self-reported LMP was consistent with a gestational age of less than 10 weeks (n=18435)) or a traditional medical abortion if they did not meet these criteria (n=11549)(Aiken et al., 2021). Treatment success, serious adverse events and incidence of ectopic pregnancy did not differ between the two cohorts; 11 people (0.04%) in the telemedicine cohort were found to have a gestational age of greater than the expected 10 weeks; all were able to complete their abortion at home without incident. A smaller Scottish cohort study followed a similar telemedicine protocol, but included participants who were up to 12 weeks gestation by self-reported LMP (Reynolds-Wright et al., 2021). Of the 663 people included in the cohort, gestational age was determined using LMP alone in 79%; ultrasound was performed for uncertain gestational age in 14% and to confirm intrauter-

ine pregnancy in 5%. Complete abortion occurred in 98% of cases, and ongoing pregnancy occurred in less than 1% of women; 2.4% of women sought additional care but no serious adverse events were reported.

When asked to determine gestational age or medical abortion eligibility based on 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 et al., 2017); all three studies also evaluated participant'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%). A more recent US based study assessed the accuracy of 11 different questions for self-assessment of pregnancy duration compared to ultrasound measurements in a cohort of 1089 participants seeking abortion (Ralph et al., 2022). Using LMP alone, 84% of participants who were ineligible for medical abortion (using a 70-day cut off) accurately identified themselves as such; when asked instead if they were more than 10 weeks pregnant, the sensitivity rose to 91%.

### **LMP combined with bimanual examination**

Provider assessment based on 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 the accuracy of bimanual examination compared to ultrasound for gestational dating before 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 et al., 1986). A second study included 245 women and found that experienced providers using only bimanual examination 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).

## 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 et al., 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 et al., 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 et al., 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 (American College of Obstetricians and Gynecologists & the Society of Family Planning, 2020; Kaneshiro et al., 2011; Royal College of Obstetricians and Gynaecologists, 2022; WHO, 2022).

### Resources

<http://www.ipas.org/ClinicalResources>



Abortion Care Videos – Ipas: Dating a Pregnancy

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## 3 Recommendations for abortion before 13 weeks gestation

### 3.3 Screening for ectopic pregnancy

#### Recommendation

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

#### Strength of recommendation

Strong

#### Quality of evidence

Low

**Last reviewed: October 11, 2022**

#### Epidemiology

In both high and low resource settings, ectopic pregnancy rates range from less than 1% to 2% of pregnancies (Al Naimi et al., 2021; Anyanwu & Titilope, 2021; Berhe et al., 2021; Ghimire, 2020; Stulberg et al., 2013; Tao, Patel, & Hoover, 2016; Trabert et al., 2011; Webster et al., 2019), and are even lower in pregnant people seeking abortion (Aiken et al., 2021; Cleland et al., 2013; Duncan, Reynolds-Wright, & Cameron, 2022). Ectopic pregnancy accounts for 2.7% of pregnancy-related deaths in the United States (Creanga et al., 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 et al., 2006).

#### Risk factors

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

Risk factor	Risk of ectopic in the current pregnancy
Intrauterine device (IUD) in place	25-50%
Previous ectopic pregnancy	10-25%
History of tubal surgery, including sterilization	25-50%

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

Other risk factors include a history of infertility and assisted reproductive technology use, 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, Gas-kins et al., 2018; Olamijulo et al., 2020).

## Screening

Half of all ectopic pregnancies occur in people with no risk factors and with a benign clinical presentation in high-income countries (Stovall et al., 1990), whereas in low- and middle-in-come countries, people are more likely to present with acute clinical features, including he-modynamic instability (Olamijulo et al., 2020). Providers should screen 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 symptoms and signs of ectopic pregnancy found during history taking and phys-ical examination, such as an adnexal mass, pain on examination or vaginal bleeding.

Some people present for abortion care very early in pregnancy, before there is definitive ultrasound evidence of an intrauterine gestation. A 2020 systematic review, including three retrospective comparative cohort studies of 5,315 people seeking early medical or aspiration abortion, found that there was no increase in incidence of missed diagnosis of ectopic preg-nancy or incomplete abortion when abortion was initiated prior to ultrasound evidence of intrauterine pregnancy in women who did not have signs or symptoms of an ectopic preg-nancy (Schmidt-Hansen et al., 2020). Two subsequent small, retrospective cohort studies have confirmed that among people with very early pregnancies and no major ectopic preg-nancy risk factors, there is no increase in the diagnosis of a missed ectopic pregnancy when medical abortion was initiated before ultrasound evidence of pregnancy (Goldberg, et al., 2022; Jar-Allah et al., 2022).

## Treatment for high-risk people

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 preg-nancy is to perform vacuum aspiration; presence of products of conception in the uterine aspirate confirms that the pregnancy was intrauterine. Individuals with suspicious signs and symptoms or a concerning physical exam should be diagnosed and treated as soon as possi-ble or transferred immediately to a facility that can manage ectopic pregnancy. Early diagno-sis and treatment of ectopic pregnancy can help preserve fertility and save lives.

## Post-procedure screening

For those undergoing vacuum aspiration, the aspirate should be strained and examined to confirm the presence of products of conception (see 3.4.4 Examining products of concep-tion). If products of conception are not seen, a diagnosis of ectopic pregnancy should be considered.

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### 3 Recommendations for abortion before 13 weeks gestation

## 3.4 Vacuum Aspiration

### 3.4.1 Safety and effectiveness

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#### 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: October 1, 2022**

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#### 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  $\leq 0.1\%$  of procedures; hospitalization was necessary in  $\leq 0.5\%$  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 et al., 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 et al., 2016; Mark et al., 2017).

## **Mortality**

In the United States, the mortality rate from all legal induced abortion between 2013-2018 was 0.41 deaths per 100,000 reported abortions; mortality rates disaggregated by abortion type or length of pregnancy are not available (Kortsmit et al., 2021). In comparison, during the period from 2007-2016 the mortality rate from live birth in the United States was 17 deaths per 100,000 live births (Creanga et al., 2017; Petersen et al., 2019). 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).

	<b>Upadhyay, 2015</b>	<b>Weitz, 2013</b>	<b>Jejeebhoy, 2011</b>	<b>Warriner, 2006</b>	<b>Hakim-Elahi, 1990</b>
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
<b>Total minor complication rate</b>	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%
<b>Total major complication rate</b>	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%

## Who can perform vacuum aspiration?

The World Health Organization (WHO) makes service delivery recommendations for the provision of uterine aspiration, which includes assessment of gestational age, cervical preparation if needed, the procedure itself, pain management including the provision of a paracervical block, and the assessment of procedure completeness through visual examination of the products of conception (WHO, 2022). Health workers with the skills to perform transcervical procedures and bimanual examinations to diagnose pregnancy and determine gestational age based on uterine size can be trained to perform vacuum aspiration. WHO advises that



uterine aspiration is within the scope of practice for specialty and general medical practitioners, and recommends the provision of vacuum aspiration by associate and advanced associate clinicians, midwives, and nurses based on moderate certainty evidence of safety and effectiveness. Traditional and complementary medicine professionals are recommended to provide uterine aspiration based on low certainty evidence of safety and effectiveness, and WHO suggests that auxiliary nurses and auxiliary nurse midwives may be able to perform aspiration in settings where they provide basic emergency obstetric care (WHO, 2022). For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

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### 3 Recommendations for abortion before 13 weeks gestation

## 3.4 Vacuum Aspiration

### 3.4.2 Cervical preparation

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#### Recommendation

- Cervical preparation is recommended routinely after 12 weeks gestation. Before 12 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;
  - Or mifepristone 200mg orally 1-2 days before the procedure.

#### Strength of recommendation

Strong

#### Quality of evidence

Moderate

**Last reviewed: October 7, 2022**

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#### 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 people given cervical preparation compared to those given placebo (Kapp et al., 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 et al., 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 those who were given misoprostol (O'Shea et al., 2020). For people at higher risk of complications during cervical dilation (young people, people 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 et al., 1985).

### **Side effects of cervical preparation**

In the largest randomized controlled trial of misoprostol for cervical preparation, 55% of participants 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 individuals must visit the clinic a day before the procedure 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). Patient 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 or mifepristone 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 et al., 2015; Saxena et al., 2008). Mifepristone given 24 hours prior to the abortion results in greater cervical dilation and less aspiration associated pain than misoprostol, but adds time and expense to the abortion procedure (Ashok, Flett, & Templeton, 2000; Hamdaoui et al., 2021; Kapp et al., 2010). Misoprostol and osmotic dilators have similar effectiveness, however the World Health Organization (WHO) recommends against the use of osmotic dilators for cervical priming before 12 weeks gestation due to the longer time to complete the procedure and reduced satisfaction among participants compared to misoprostol (Bartz, et al., 2013; Burnett, Corbett, & Gertenstein, 2005; Maclsaac et al., 1999; WHO, 2022).

### **Young people**

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 cervixes 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.

### **Who can perform cervical preparation with medications?**

WHO makes service delivery recommendations for the provision of uterine aspiration, which includes assessment of gestational age, cervical preparation if needed, the procedure itself, pain management including the provision of a paracervical block, and the assessment of procedure completeness through visual examination of the products of conception (WHO, 2022). WHO advises that provision of medication for cervical preparation is within the scope

of practice for specialty and general medical practitioners, and recommends the provision of cervical preparation medications by associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, and traditional and complementary medicine professionals based on expected competencies for these roles and low-certainty evidence of safety and effectiveness. Although there is no direct evidence, WHO suggests that community health workers, pharmacists and pharmacy workers can safely and effectively provide medications for cervical preparation based on expected competencies for these roles, adding that these health workers need to ensure continuity of care for the individual obtaining the medications prior to an abortion procedure (WHO, 2022). For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

<b>Resources</b>	<a href="http://www.ipas.org/ClinicalResources">http://www.ipas.org/ClinicalResources</a>
<b>Steps for performing manual vacuum aspiration using the Ipas MVA Plus® and EasyGrip® cannulae - Ipas</b>	

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### 3 Abortion before 13 weeks gestation

## 3.4 Vacuum Aspiration

### 3.4.3 Bimanual examination

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#### 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: September 22, 2022**

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#### Importance of bimanual examination

Bimanual examination is a routine step before intrauterine procedures recommended by the World Health Organization (WHO, 2022). 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

Uterine size can be assessed using bimanual examination. In cases where last menstrual period (LMP) is known, bimanual examination can confirm gestational age assessment based on LMP. When LMP is not certain, bimanual examination can offer an estimate of gestational age based on uterine size (See section 3.2 Recommendations for abortion before 13 weeks: Gestational dating). In cases of postabortion care, where some or all pregnancy tissue may have been expelled from the uterus, uterine size determined by bimanual examination should guide treatment. Medical regimens for abortion and postabortion care change based on the gestational age or uterine size. Techniques for vacuum aspiration and dilatation and evac-

uation, 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 et al., 1995; Mittal & Misra, 1985; Nathanson, 1972).

### Resources

<http://www.ipas.org/ClinicalResources>

#### Abortion Care Videos – Ipas: Dating a Pregnancy

Steps for performing manual vacuum aspiration using the Ipas MVA Plus® and EasyGrip® cannulae - Ipas



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### 3 Abortion before 13 weeks gestation

## 3.4 Vacuum Aspiration

### 3.4.4 Examining products of conception

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#### 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.

#### In practice

- To improve visualization, products of conception can be rinsed, floated in water, and viewed through a clear dish using a light source from underneath.
- If no products of conception are visible, or less tissue is seen than expected, further evaluation is required.

#### Strength of recommendation

Strong

#### Quality of evidence

Very Low

**Last reviewed: September 23, 2022**

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#### 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, 2022), the Royal College of Obstetricians and Gynaecologists (RCOG, 2022), and the National Abortion Federation (NAF, 2020). Presence of products of conception on visual inspection confirms that the pregnancy was intrauterine and is consistent with successful abortion (Westfall et al., 1998). If products of conception are not seen, the individual 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 expedites the diagnosis of ectopic pregnancy and decreases related morbidity and mortality (Goldstein, Danon, & Watson, 1994). In cases where abnor-



mal 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 et al., 2000; Paul et al., 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).

## Resources

<http://www.ipas.org/ClinicalResources>

**Abortion Care Videos – Ipas: Performing a Manual Vacuum Aspiration (“Inspect the Tissue” begins at 10:27 in this video)**

**Steps for performing manual vacuum aspiration using the Ipas MVA Plus® and EasyGrip® cannulae - Ipas**



## References

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### 3 Abortion before 13 weeks gestation

## 3.4 Vacuum Aspiration

### 3.4.5 Processing Ipas MVA Plus<sup>®</sup> and Ipas Single-Valve aspirators

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#### Recommendation

All Ipas multiple-use aspirators and adapters must be pre-soaked, rinsed or sprayed with water or enzymatic spray at the point-of-use, then cleaned and high-level disinfected or sterilized between patients.

#### In practice

Instruments processed using wet methods should be reprocessed daily.

**Last reviewed: September 23, 2022**

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#### Importance of correctly processing instruments

During use, the cylinder of the manual vacuum aspirator (MVA) fills with 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 as these may damage some medical instruments. Additionally, chlorine can be less effective when used before cleaning instruments in Step 2, and can lead to the development of antimicrobial resistance.

##### 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  Glutaraldehyde** soak for the time recommended by the manufacturer—most recommend 10 hours***  Sporox II solution soak for 6 hours***	Boil* the instruments for 20 minutes  Glutaraldehyde** soak for the time recommended by the manufacturer—recommendations range from 20-90 minutes***  Sporox II solution soak for 30 minutes***  0.5% chlorine solution soak for 20 minutes***
<p>* IPAS SINGLE-VALVE ASPIRATOR CANNOT BE BOILED OR AUTOCLAVED.</p> <p>** Because there are several glutaraldehyde products available with different recommendations for processing time, always follow the recommendations that come with your brand of glutaraldehyde.</p> <p>*** If chemical agents were used in processing, aspirator parts and adaptors (if used) should be thoroughly rinsed in clean, potable water (drinking water).</p>	

#### 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).

Resources	<a href="http://www.ipas.org/ClinicalResources">http://www.ipas.org/ClinicalResources</a>
<p>Processing the Ipas MVA Plus® Aspirator and Ipas EasyGrip® Cannulae (wall chart)</p> <p>Ipas MVA reprocessing videos – Ipas (available in English, French, Spanish and Arabic)</p> <p>Abortion Care Videos – Ipas: MVA Instrument Reprocessing</p>	

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### 3 Abortion before 13 weeks gestation

## 3.5 Medical abortion

### 3.5.1 Self-management

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#### Key information

- Individuals can safely and effectively self-manage medical abortion with either mifepristone and misoprostol, or misoprostol-only when they have accurate information, quality-assured medicines, and access to health services, if needed.

#### Quality of evidence

High

**Last reviewed: November 29, 2022**

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#### What is medical abortion self-management?

Self-management of medical abortion is the process by which an individual procures abortion medications (mifepristone and misoprostol, or misoprostol-only) and performs the component parts of their own abortion with or without support of a healthcare provider (World Health Organization [WHO], 2022b). While some individuals will prefer to manage all of the component parts of medical abortion outside of the health care system, others may choose to interact with trained health workers via traditional or innovative service delivery mechanisms as needed; importantly it is the individual who decides which aspects of care they will self-manage, and when and where to seek support (WHO, 2022a; WHO, 2022b). Barriers to clinical access, such as cost or inaccessibility of services, are the most commonly reported reason for self-managed abortion (Aiken, Starling, & Gomperts, 2021). While self-managed abortion has the potential to dramatically increase access to safe abortion, particularly in settings where access is limited (Jayaweera et al., 2021), individuals choose abortion self-management for many reasons. These reasons include more autonomy and control over the experience, possibility of greater comfort or privacy, and the ability to avoid stigma, discrimination, or other barriers associated with seeking care in a health facility (Aiken et al., 2018; Harries et al., 2021; Moseson et al., 2020a).

#### Self-management of medical abortion

Medical abortion before 13 weeks is a process that takes place over a period of hours to days, consisting of three components: (1) determining eligibility for medical abortion; (2) administration of abortion medicines and management of the abortion process; and (3) assessment of the success of the abortion. Abundant clinical evidence documents the ability of

pregnant people to safely and effectively perform each of these components. See 3.2: *Recommendations for abortion before 13 weeks: Gestational dating* and 3.3: *Recommendations for abortion before 13 weeks: Screening for ectopic pregnancy* for a summary of evidence supporting individuals' ability to self-assess their eligibility for medical abortion; see 3.5.6: *Recommendations for abortion before 13 weeks: Medical abortion: Home use of medications up to 12 weeks* for a summary of evidence supporting individuals' ability to self-administer abortion medications and manage the abortion process; and see 3.5.7: *Recommendations for abortion before 13 weeks: Medical abortion: Confirmation of success* for a summary of evidence supporting individuals' ability to self-assess the success of their abortion.

Many models of medical abortion self-management exist, depending on the extent that the formal health system, health workers, or other supportive services are involved in the process (Dragoman et al., 2022). Studies assessing self-management of the entire medical abortion process are understandably lacking, given the inherent difficulties in recruiting participants who have self-sourced and self-managed their abortion (Sorhaindo & Sedgh, 2020). However, a growing body of evidence documents the safety and effectiveness of various models of supported self-managed medical abortion. An example would be telemedicine abortion, where a health worker geographically separate from the abortion seeker facilitates a medical abortion. Telemedicine health workers could assess abortion eligibility based on history, provide medications for abortion seekers to use at home, and offer follow-up—can occur both within or outside of the formal health system, and may be synchronous or asynchronous (Endler et al., 2019 ; Raymond et al., 2020). Many cohort studies, including a large, prospective cohort study that compared outcomes between individuals receiving a traditional, in-person medical abortion (n=22,158) and those receiving a telemedicine abortion with no pre-abortion testing, examination or ultrasonography (n=18,435) (Aiken et al., 2021), confirm safety and effectiveness rates for telemedicine abortion that are comparable to traditional, in-clinic medical abortion (Aiken et al., 2022; Reynolds-Wright et al., 2021; Upadhyay, Koenig, & Meckstroth, 2021; Upadhyay et al., 2022). WHO recommends telemedicine as an alternative to in-person medical abortion care (WHO, 2022). In accompaniment models, trained non-clinical volunteers provide abortion seekers with evidence-based medical abortion information, guidance for obtaining medication abortion drugs and step-by-step instructions for their use, guidance assessing abortion success and warning signs of complications, and support during the abortion process when needed—these accompaniment groups work outside of the formal health care system in settings where abortion is highly restricted (Zurbriggen, Keefe-Oates, & Gerdts, 2018). Studies of abortion accompaniment have found abortion success rates for the combined mifepristone and misoprostol regimen that are comparable to in-clinic care (94%), and success rates for the misoprostol-only regimen (99%) that exceed those reported in clinical studies (Moseson et al., 2020b; Moseson et al., 2022). Two studies have documented the safety and effectiveness of misoprostol-only, self-managed abortion accessed through community-based distribution (Foster, Arnott, & Hobstetter, 2017; Foster et al., 2022). In these studies, lay or volunteer community health workers provided misoprostol and instructions for its use to individuals seeking abortion before 9 or 10 weeks gestation, based on their reported last menstrual period. In both studies, abortion success rates exceeded those seen in clinical misoprostol-only medical abortion studies (94-96%) with no serious adverse events recorded. One prospective cohort study conducted in Nigeria assessed success rates in pregnant individuals who purchased miso-

prostaglandin from drug sellers to self-manage their medical abortion (Stillman et al., 2020). Despite receiving inadequate information about the drugs, what to expect, or where and when to seek additional care, 94% of the sample reported a complete abortion without surgical intervention; one participant required a blood transfusion.

## Resources

<http://www.ipas.org/ClinicalResources>

[www.ipas.org/AbortionWithPills](http://www.ipas.org/AbortionWithPills)—Evidence-based resources on how to safely self-manage an abortion using pills

Abortion Care Videos for Women



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## **3.5 Medical abortion**

### **3.5.2 Risk of fetal malformations**

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#### **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 person has an ongoing pregnancy and decides not to terminate. Individuals 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: September 23, 2022**

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#### **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 et al., 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 the last menstrual period (LMP) and is not associated with anomalies following exposure after 13 weeks following an individual'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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## 3 Abortion before 13 weeks gestation

# 3.5 Medical abortion

## 3.5.3 Mifepristone and misoprostol: Recommended regimen

### Recommendation

- Mifepristone 200mg orally followed 1-2 days later by misoprostol 800mcg buccally, sublingually or vaginally. The dose of misoprostol can be repeated to achieve abortion success.
- After 9 weeks gestation, routinely using at least two doses of misoprostol, administered 3-4 hours apart, improves abortion success rates.
- A combined regimen of mifepristone and misoprostol is effective and safe with abortion success rates over 95%, continuing pregnancy rates around 2% and complication rates of 1-3%.

### In practice

- A combined mifepristone and misoprostol regimen is more effective than misoprostol used alone, and is recommended for medical abortion before 13 weeks; where mifepristone is unavailable, the misoprostol-only regimen can be used.
- Additional doses of misoprostol can be used if bleeding, cramping, or pregnancy expulsion have not occurred, and at least 3 hours have passed since the previous misoprostol dose.

### Strength of recommendation

Strong

### Quality of evidence:

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

**Last reviewed: October 1, 2022**

## Background

Medical abortion success is defined as a complete abortion that needs no further intervention. A combined regimen of mifepristone and misoprostol is recommended for medical abortion as it is more effective than misoprostol alone (Abubeker et al., 2020; Blum et al., 2012; Kapp et al., 2019; Kulier et al., 2011; Ngoc et al., 2011; Raymond, Harrison, & Weaver, 2019; World Health Organization [WHO], 2022). Where mifepristone is unavailable, the misoprostol-only regimen may be used.

### 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 (Abubeker et al., 2020; Chen & Creinin, 2015; Kapp, Baldwin, & Rodriguez, 2018; Kulier et al., 2011; Raymond et al., 2012). A 2020 systematic review of medical abortion with 200mg mifepristone and 800mcg misoprostol up to 9 weeks gestation in low- and middle-income countries included 52 studies and found an average abortion success rate of 95% (Ferguson & Scott, 2020). Vaginal, buccal, and sublingual misoprostol are more effective than oral misoprostol (Kulier et al., 2011; Zhang et al., 2022). Buccal dosing (Middleton et al., 2005) and sublingual dosing (Tang et al., 2003; von Hertzen et al., 2010) have higher rates of gastrointestinal side effects than vaginal dosing (Zhang et al., 2022). 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 individual preferences or legal restrictions.

Simultaneous dosing of mifepristone and misoprostol for those 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 et al., 2011; Lohr et al., 2018; Schmidt-Hansen et al., 2022; Verma et al., 2017). 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).

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 ranging from 2.3-4.8%. 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 et al. 2019). Rates of complications observed during medical abortion with mifepristone and misoprostol up to nine weeks gestation is less than 1% (Cleland et al., 2013; Gatter, Cleland, & Nucatola, 2015; Goldstone, Walker, & Hawtin, 2017).

	<b>Goldstone, 2017</b>	<b>Cleland, 2013</b>	<b>Gatter, 2015</b>
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

## 9-11 weeks

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 a single dose of 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 a single dose of 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), and there were no differences in serious adverse events, such as hospital admissions or transfers, between the groups (0.7% and 0.5% respectively).

A prospective, open-label, non-inferiority trial compared the efficacy of a medical abortion regimen of 200mg mifepristone, followed by a single dose of 800mcg misoprostol, in 362 women at 64-70 days gestation to efficacy of the same regimen in 286 women from 71-77 days gestation (Dzuba et al., 2020b). The success rate was 92% in the 64-70 day group, with an ongoing pregnancy rate of 4%, compared to 87% and 9% in the 71-77 day group, respectively. A subsequent retrospective cohort study compared success rates when two doses of 800mcg misoprostol were taken at home, four hours apart, for pregnancies between 64-70 days and 71-77 days (Dzuba et al., 2020a). Although a high loss to follow up (25%) limits conclusions that can be drawn, investigators found abortion success rates improved to greater than 99% from 64-70 days, and 98% from 71-77 days. A 2019 systematic review of medical

abortion between 63 and 84 days gestation similarly concluded that abortion success rates are higher when routine, repeated doses of misoprostol are used, and when the vaginal route is used for misoprostol administration, compared to oral (Kapp et al., 2019). However, the review does not recommend a specific mifepristone and misoprostol regimen (Kapp et al., 2019).

## 11-13 weeks

One trial randomized 340 women with pregnancies up to 13 weeks to two groups: 1) 200mg mifepristone followed by either 800mcg vaginal, or 2) 600mcg sublingual misoprostol administration, followed by up to two additional doses of 400mcg sublingual or vaginal misoprostol every 3 hours (Hamoda et al., 2005). The overall success rate for this regimen was 95.8%. In both groups, most people required 2 doses of misoprostol to have a successful abortion; 3.4% of those in the vaginal group required surgical evacuation of the uterus, compared to 2.9% in the sublingual group. Those using misoprostol sublingually were more likely to experience side effects. A prospective cohort study (Lokeland et al., 2010), including 254 women with pregnancies between 63 and 90 days gestation, reported an abortion success rate of 91.7% and an ongoing pregnancy rate of less than 1% using a similar regimen of mifepristone followed by repeated doses of misoprostol. 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) and complication rates are around 3% (Hamoda et al., 2005).

## Who can provide medical abortion before 13 weeks gestation?

The World Health Organization (WHO) makes service delivery recommendations for the provision of medical abortion before 13 weeks gestation, which includes assessment of medical abortion eligibility (determining pregnancy duration and assessing for contraindications to abortion medications), administration of abortion medications, management of the abortion process, and assessment of abortion success (WHO, 2022). WHO advises that all cadres of health care workers (specialty and general medical practitioners, associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, traditional and complementary medicine professionals, pharmacists and pharmacy workers, and community health workers) can safely and effectively provide medical abortion with mifepristone and misoprostol or misoprostol-only based on a variety of evidence and the expected skills and knowledge for that type of health worker (WHO, 2022). WHO also recommends that the pregnant person can safely and effectively self-manage the medical abortion process, in whole or in part, when they have access to accurate information, quality assured medications including for pain management, the support of trained health care workers, and access to a health facility if needed (WHO, 2022). For more information about self-managed medical abortion, see *3.5.2: Recommendations for abortion before 13 weeks: Medical abortion self-management*. For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

## Resources

<http://www.ipas.org/ClinicalResources>



Protocols for medical abortion (dosage card)

Mifepristone/Misoprostol Gestational Dating Wheels

Abortion Care Videos – Ipas: Medical Abortion in Early Pregnancy

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### 3 Abortion before 13 weeks gestation

## 3.5 Medical abortion

### 3.5.4 Misoprostol only: Recommended regimen

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#### Recommendation

- Misoprostol 800mcg buccally, sublingually or vaginally every three hours until expulsion.
- A misoprostol-only regimen has success rates of 84-93%, with continuing pregnancy rates of 3-10% and complication rates of 1-4%.

#### In practice

- A combined mifepristone and misoprostol regimen is more effective than misoprostol used alone and is recommended for medical abortion before 13 weeks; where mifepristone is unavailable the misoprostol-only regimen can be used.
- Additional doses of misoprostol can be used if bleeding, cramping, or pregnancy expulsion have not occurred and at least 3 hours have passed since the previous misoprostol dose.
- Individuals undergoing misoprostol-only medical abortion outside of a health facility should be provided with 3-4 doses of misoprostol depending on the scenario. An extra dose of misoprostol, and information describing when to use additional doses, should be provided to be used if needed.

#### Strength of recommendation

Strong

#### Quality of evidence

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

**Last reviewed: October 1, 2022**

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#### Background

Medical abortion success is defined as a complete abortion that needs no further intervention. A combined regimen of mifepristone and misoprostol is recommended for medical abortion, as it is more effective than misoprostol alone (Abubeker et al., 2020; Blum et al., 2012; Kapp et al., 2019; Kulier et al., 2011; Ngoc et al., 2011; Raymond, Harrison, & Weaver, 2019; World Health Organization [WHO], 2022). Where mifepristone is unavailable, the misoprostol-only regimen may be used.

## Misoprostol-only abortion regimens

A 2019 systematic review assessed effectiveness of misoprostol alone by reviewing 42 studies where at least one group of participants received misoprostol alone to induce abortion. The misoprostol regimens differed across the included studies. The review, which included 12,829 women, found an overall abortion success rate of 78%. Twenty percent of participants underwent subsequent surgical uterine evacuation for any reason (Raymond et al., 2019); criteria to determine when surgical evacuation was required were heterogeneous across the included studies. The ongoing pregnancy rate, available for only half of those undergoing surgical uterine evacuation, was 6%. The largest randomized trial using the recommended misoprostol-only regimen of 3 doses of 800mcg of misoprostol by either the vaginal or sublingual route, included 2,046 participants with gestations of seven weeks or less (von Hertzen et al., 2007). Success of misoprostol-only abortion was 84%. A more recent study randomized 390 people with pregnancies up to 10 weeks of gestation to receive 3 doses of misoprostol 800mcg by either the buccal or sublingual route, with the option for an additional dose of misoprostol if the abortion was not complete at the time of follow up (Sheldon et al., 2019). At initial follow up, the ongoing pregnancy rate for both groups combined was 3%, and abortion success rate was 86%. After offering an additional dose of misoprostol to any participants who did not have a successful abortion, success rates increased to 93%. 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 et al., 1999; Carbonell Esteve et al., 1998, Carbonell et al., 2001). In studies that used the recommended misoprostol-only regimen or similar regimens, the rate of subsequent uterine aspiration for any reason ranges from 7-17%, with ongoing pregnancy rates of 3-10% (Carbonell et al., 1999; Carbonell et al., 2001; Sheldon et al., 2019; Velazco et al., 2000; von Hertzen et al., 2007).

Studies examining strategies to support safe and effective abortion outside the clinical setting, such as those exploring abortion accompaniment or community-based distribution of misoprostol for medical abortion self-management, have reported abortion success rates for misoprostol-only abortion that exceed those for facility based care (Moseson et al., 2020b). In the SAFE study, which documents effectiveness of abortion self-management with accompaniment support, 99% of the misoprostol-only users reported a successful abortion without surgical intervention (Moseson et al., 2022). Two studies have documented the safety and effectiveness of misoprostol-only, self-managed abortion, accessed through community-based distribution up to either 9 or 10 weeks gestation; abortion success rates were 94-96% with no serious adverse events recorded (Foster, Arnott, & Hobstetter, 2017; Foster et al., 2022). One prospective cohort study conducted in Nigeria assessed success rates in pregnant individuals who purchased misoprostol from drug sellers to self-manage their medical abortion (Stillman et al., 2020). Despite receiving inadequate information about the drugs, what to expect, or where and when to seek additional care, 94% of the sample reported a complete abortion without surgical intervention. Of the sample, one participant required a blood transfusion.

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). Systematic reviews from 2019 and 2022 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 et al., 2019; Zhang et al., 2022). 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). Participants in the sublingual group experienced more fever and chills than those in the buccal administration group.

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 et al., 2002; Kapp et al., 2018), higher initial doses of misoprostol (Raymond et al., 2019), non-oral routes of misoprostol administration (Kapp et al., 2018; Raymond et al., 2019; Zhang et al., 2022), and a longer time period before provider follow-up to confirm abortion success (Bugalho et al., 2000; Sheldon et al., 2019). However, individual's satisfaction decreases the longer the abortion process lasts (Ngai et al., 2000).

### **The addition of letrozole**

One high quality, randomized controlled trial has assessed if the addition of letrozole—a third generation aromatase inhibitor that decreases estrogen levels and leads to pregnancy loss—to a misoprostol-only regimen improves success of medical abortion up to 9 weeks gestation (Lee et al., 2011a). One hundred and sixty-eight participants were randomized to a three day course of letrozole (10mg orally each day followed, by a single dose of vaginal misoprostol on day three), or to placebo, followed by misoprostol. Complete abortion was more likely in the letrozole group (87%), than the placebo group (73%,  $p=0.021$ ); there were no statistically significant differences in continuing pregnancies between the two groups (8% compared to 11%,  $p=0.6$ ). An earlier pilot study conducted in 20 participants with gestations up to 9 weeks examined a two dose letrozole regimen (10mg orally for two days, followed by a single dose of 800mcg of misoprostol administered vaginally on day three), finding a lower success rate of 80% (Lee et al., 2011b). A subsequent pilot study, including 20 participants with gestations up to 9 weeks, found a higher abortion completion rate (95%), comparable to that seen with the mifepristone and misoprostol regimen, when a seven-day course of letrozole 10mg was administered before a single dose of misoprostol 800mcg vaginally on day 7 (Yeung et al., 2021).

One randomized controlled trial has examined the addition of letrozole to misoprostol compared to placebo and misoprostol in 46 participants with an average gestational age of 11 to 13 weeks (Javanmanesh, Kashanian, & Mirpangi, 2018). The letrozole group, which took 10mg of letrozole daily for three days, followed by repeated doses of sublingual misoprostol, had a 78% success rate, compared to 13% in the placebo group ( $p=0.0001$ ), with no differences in side effects and no complications reported. These findings must be interpreted with caution given the very low quality of the study, the small sample size, the discrepancy in

mean gestational age between the two groups ( $11.2 \pm 4$  weeks in the letrozole group compared to  $13.2 \pm 3$  weeks in the placebo group), and the markedly low success rate reported for the placebo group, which is not in alignment with other studies' reported success rates with misoprostol-only abortion regimens. Two additional randomized trials, conducted in participants with gestations after 13 weeks, have compared letrozole and misoprostol to placebo and misoprostol (Lee et al., 2011b; Naghshineh, Allame, & Farhat, 2015). Naghshineh, Allame, & Farhat (2015) included 121 participants with an average gestational age of 13 weeks, and found a significantly higher success rate in the group that took letrozole (10mg daily for three days prior to sublingual misoprostol)-77%-compared to placebo (43%,  $p < 0.0001$ ). Lee et al. (2011b) used a smaller dose of letrozole (7.5mg) and found no difference in complete abortion rates in a sample of 130 participants with an average gestational age of 15 weeks. In both of these studies, side effects were comparable between the two groups and no complications were reported. Two systematic reviews examining letrozole and misoprostol, compared to placebo and misoprostol-both of which included studies of second trimester abortion and one of which included a study using letrozole as a treatment for missed abortion-came to conflicting conclusions. Zhou et al. (2021), based on 4 heterogeneous randomized controlled trials including a total of 497 patients, found that complete abortion was more likely with the addition of letrozole (relative risk [RR]: 1.38, 95% Confidence Interval [CI]: 1.07, 1.78). Nash et al. (2018), based on 3 randomized controlled trials including 503 patients, found no statistically significant difference in abortion success between letrozole and misoprostol (74%), or placebo and misoprostol (56%, RR: 1.24, 95% CI: 0.92, 1.66).

Despite the limited evidence available to support its use, World Health Organization (WHO) has suggested that letrozole (10mg orally each day for three days), followed by misoprostol can be used for medical abortion before 12 weeks of gestation in settings where mifepristone is not available (WHO, 2022).

## Young people

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.

## Who can provide medical abortion before 13 weeks gestation?

The World Health Organization (WHO) makes service delivery recommendations for the provision of medical abortion before 13 weeks gestation, which includes assessment of medical abortion eligibility (determining pregnancy duration and assessing for contraindications to abortion medications), administration of abortion medications, management of the abortion process, and assessment of abortion success (WHO, 2022). WHO advises that all cadres of health care workers (specialty and general medical practitioners, associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, traditional and complementary medicine professionals, pharmacists and pharmacy workers, and community health workers) can safely and effectively provide medical abortion with mifepr-

stone and misoprostol or misoprostol-only based on a variety of evidence, and the expected skills and knowledge for that type of health worker (WHO, 2022). WHO also recommends that the pregnant person can safely and effectively self-manage the medical abortion process, in whole or in part, when they have access to accurate information, quality assured medications including for pain management, the support of trained health care workers, and access to a health facility, if needed (WHO, 2022). For more information about self-managed medical abortion, see *3.5.2: Recommendations for abortion before 13 weeks: Medical abortion self-management*. For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

<b>Resources</b>	<a href="http://www.ipas.org/ClinicalResources">http://www.ipas.org/ClinicalResources</a>
<p><b>Protocols for medical abortion (dosage card)</b> <b>Misoprostol-only Gestational Dating Wheels</b> <b>Abortion Care Videos – Ipas: Medical Abortion in Early Pregnancy</b></p>	
	

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### 3 Abortion before 13 weeks gestation

## 3.5 Medical abortion

### 3.5.5 Home use of medications up to 12 weeks gestation

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#### Recommendation

- Mifepristone can be taken in a facility or at home.
- Home use of misoprostol following mifepristone or in a misoprostol-only regimen may be offered up to 12 weeks gestation.
- After 12 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

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#### Mifepristone and misoprostol regimen

##### Home use of mifepristone

A South African trial randomized people seeking abortion at up to 9 weeks gestation to a standard medical abortion service delivery model where: 1) mifepristone was ingested in the health center (n=350) or, 2) a telemedicine model where mifepristone was taken at home (n=372) (Endler et al., 2022). The trial found no difference in rates of abortion success, adherence to medication regimen, safety, or satisfaction between groups (Endler et al., 2022). 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 et al. 2015) and Kazakhstan (Platais et al., 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. A population based cohort study conducted in Canada compared medical abortion safety outcomes before (n=7,269 medical abortions) and after (n=26,434 medical abortions) mifepristone became available for home use in that country, finding no difference in abortion safety outcomes (Schummers et al., 2022).

### Home use of misoprostol up to 70 days

Two systematic reviews have confirmed the safety and effectiveness of misoprostol taken at home as part of a mifepristone-misoprostol regimen up to nine (Gambir et al., 2020) and 10 weeks gestation (Schmidt-Hansen et al., 2020). In Gambir et al. (2020), an examination of 19 prospective studies—three randomized controlled trials and 16 nonrandomized comparative trials including 11,576 people up to 63 days gestation—found that complete abortion rates and adverse event rates were the same for home- and facility-based misoprostol use. Women found home use as acceptable as clinic use. Schmidt-Hansen et al. (2020) compared the safety and effectiveness of home-based misoprostol for abortions up to 9 weeks gestation to those beyond 9 weeks, reported in 6 prospective and retrospective cohort studies including 3,381 people. The review found no difference in complete abortion rates or adverse events, confirming the safety and efficacy of home use of misoprostol up to 10 weeks. Since these reviews, a number of prospective and retrospective cohort studies have reported on the safety and effectiveness of telemedicine for the provision of medical abortion. In the largest prospective study, from the United Kingdom, 52,142 women who used misoprostol at home for abortions up to 70 days gestation, and reported a complete abortion rate greater than 98% and serious complication rate of less than 1% (Aiken et al., 2021). Several smaller prospective and retrospective cohort studies evaluating the safety and effectiveness of telemedicine abortion provision with home use of misoprostol have similar findings (Chong et al., 2021; Pena et al., 2022; Reynolds-Wright et al., 2021; Upadhyay, Koenig, & Meckstroth, 2021; Upadhyay et al., 2022). The Royal College of Obstetricians and Gynaecologists (RCOG, 2019) and the American College of Obstetricians and Gynecologists (ACOG, 2020) recommend offering home use of misoprostol up to 70 days gestation.

### Home use of misoprostol from 10-13 weeks

The upper gestational limit where misoprostol may be safely used at home has not been well-established. A non-inferiority trial compared the effectiveness of a medical abortion regimen of 200mg mifepristone followed by a single dose of 800mcg buccal misoprostol taken at home 24-48 hours later among women with pregnancies of 64-70 days to those with pregnancies of 71-77 days (Dzuba et al., 2020b). Investigators found a success rate of 92% in the earlier gestational age group compared to 87% in the later group, and significantly more ongoing pregnancies in the later group (9% compared to 4%), suggesting that additional doses of misoprostol are needed at gestations of more than 70 days. A subsequent retrospective cohort study compared success rates when two doses of misoprostol 800mcg were taken at home, four hours apart, for pregnancies between 64-70 days and 71-77 days

(Dzuba et al., 2020a). Although a high loss to follow up (25%) limits conclusions that can be drawn, investigators found abortion success rates of greater than 99% and 98%, respectively. 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, where study participants self-administered a single dose of misoprostol 800mcg vaginally, followed by up to four additional doses of 400mcg if bleeding did not occur (Larsson, & Ronnberg, 2019). Success rates were 96% and 94%, with no difference in incomplete abortion, excessive bleeding, or surgical intervention. An additional retrospective cohort study where women self-administered two doses of misoprostol 800mcg at home for medical abortions up to 77 days found a similar success rate (96%) (Kerestes et al., 2021). A prospective cohort study from Scotland that reported on the safety and efficacy of telemedicine for mifepristone and misoprostol medical abortion during the COVID-19 pandemic included women with gestations up to 12 weeks (Reynolds-Wright et al., 2021). Of the 663 people included in the study, only 21 (3%) had gestations between 10 and 12 weeks. Almost all women (98%) had a successful abortion; there were nine abortion failures (1.4%), only one of which occurred after 10 weeks. There are no comparative data regarding home use of misoprostol as part of a combined regimen after 11 weeks gestation. Despite this, the World Health Organization (WHO) recommends that pregnant people can self-manage the three component parts of the medical abortion process—self-assessment for eligibility, self-administration of abortion medicines and management of the abortion process, and self-assessment of the success of the abortion—up to 12 weeks gestation, when they have access to a source of accurate information and to a health-care provider, if needed (WHO, 2022).

## **Misoprostol-only regimen**

Although no studies have directly compared safety and effectiveness of home use of misoprostol in a misoprostol-only regimen to health facility use, a number of studies provide evidence to support the safety and effectiveness of misoprostol taken at home for medical abortion. Several randomized studies with misoprostol-only arms (Blum et al., 2012; Ngoc et al., 2011; Sheldon et al., 2019) and several prospective cohort studies of misoprostol-only medical abortion up to 9 (Carbonell, Valera, Velazco, Fernandez, & Sanchez, 1997; Velazco et al., 2000), or between 9-12 gestational weeks (Carbonell et al., 2001), have allowed participants to self-administer misoprostol at home without an effect on safety or medical abortion success. Studies examining strategies to support safe and effective abortion outside the clinical setting, such as those exploring abortion accompaniment or community-based distribution of misoprostol for medical abortion self-management, have reported abortion success rates for misoprostol-only abortion that exceed those for facility based care (Moseson et al., 2020b). In the SAFE study, which documents effectiveness of abortion self-management with accompaniment support, 99% of the misoprostol-only users reported a successful abortion without surgical intervention (Moseson et al., 2022). Two studies have documented the safety and effectiveness of misoprostol-only, self-managed abortion accessed through community-based distribution up to either 9 or 10 weeks gestation; abortion success rates were 94-96% with no serious adverse events recorded (Foster, Arnott, & Hobstetter, 2017; Foster et al., 2022). One prospective cohort study conducted in Nigeria assessed success rates in pregnant individuals who purchased misoprostol from drug sellers to self-manage their medical abortion (Stillman et al., 2020). Despite receiving inadequate

information about the drugs, what to expect, or where and when to seek additional care, 94% of the sample reported a complete abortion without surgical intervention. Of the sample, one participant required a blood transfusion.

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### 3 Abortion before 13 weeks gestation

## 3.5 Medical abortion

### 3.5.6 Confirmation of success

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#### Recommendation

- Most people undergoing medical abortion with a recommended medication regimen will have a successful abortion; routine follow-up is not required.
- 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.

#### In practice

- Individuals undergoing medical abortion should be given adequate information about when to seek additional care for a possible complication. This includes:
  - Heavy bleeding or soaking through more than 2 sanitary pads an hour for 2 hours in a row;
  - Fever or flu-like illness developing more than 24 hours after using misoprostol;
  - Severe or worsening pain, including pain which could indicate an undiagnosed ectopic pregnancy;
  - Unusual or foul-smelling vaginal discharge.
- Individuals undergoing medical abortion should be given adequate information about signs and symptoms that might indicate an ongoing pregnancy for which clients should seek medical attention, including:
  - Experiencing no bleeding or only spotting in the 24 hours after using misoprostol;
  - Continuing to feel pregnant 1 week after using abortion medications.
- Urine pregnancy tests may still have a positive result up to 4 weeks after a successful medical abortion.

#### Strength of recommendation

Strong

#### Quality of evidence

Moderate

**Last reviewed: October 19, 2022**

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## 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 et al., 2012). The World Health Organization (WHO) states that routine follow-up after medical abortion with mifepristone and misoprostol is not required (2022), advising instead that individuals should be adequately informed about symptoms of ongoing pregnancy and other medical reasons to return for follow-up such as prolonged heavy bleeding, no bleeding at all with medical management of abortion, pain not relieved by medication, or fever. Multiple strategies have been examined to confirm a successful medical abortion and identify rare ongoing pregnancies when using the mifepristone and misoprostol regimen.

### Self-assessment based on symptoms

Evidence indicates that individuals can accurately determine when their mifepristone and misoprostol medical abortion is successful—that is, whether pregnancy expulsion has occurred. In studies comparing self-assessments of expulsion based on symptoms to those made by clinicians (Cameron et al., 2015; Clark et al., 2010; Perriera et al., 2010; Rossi, Creinin, & Meyn, 2004) and by ultrasound (Rossi et al., 2004), self-assessment has 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 the client's 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 et al., 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 et al., 2007; Dayananda et al., 2013; Fiala et al., 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 person 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) due to hcg levels that remain elevated for at least 18 days after a medical abortion (Cameron et al., 2012; Clark et al., 2010; Godfrey et al., 2007; Perriera et al., 2010; Raymond et al., 2021). In a case series including 258 people with successful medical abortions who performed a high-sensitivity pregnancy test four weeks after taking mifepristone, 19% had a false positive result (Raymond et al., 2021). A number of studies have examined use of low-sensitivity (Cameron et al., 2012, Cameron et al., 2015; Constant et al., 2017; Iyengar et al., 2015; Michie & Cameron, 2014) and semi-quantitative or multi-level (Anger et al., 2019; Chong et al., 2020; Opegaard et al., 2015; Raymond et al., 2017; Raymond et al., 2018b) 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. One small trial randomized 88 participants with pregnancies of less than 63 days to independently use a low-sensitivity or a multi-level pregnancy test to determine medical abortion success, finding that individuals could correctly use and accurately interpret the results of these tests (Fok et al., 2021). A 2018 systematic review assessed the accuracy of using low-sensitivity pregnancy testing to identify ongoing pregnancy after medical abortion (Raymond, Shocket, & Bracken, 2018a), finding that a positive or invalid low-sensitivity pregnancy test had only moderate sensitivity for detecting ongoing pregnancy. A subsequent diagnostic accuracy study found that a low-sensitivity pregnancy test performed two weeks after mifepristone administration correctly identified all continuing pregnancies in a cohort of 558 people between 64 and 70 days gestation; the false positive rate was 15% (Whitehouse, Shocket, & Lohr, 2022). 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 people can successfully perform the tests themselves at home (Raymond et al., 2017). Multi-level pregnancy tests measure the approximate concentration of urinary hcg; a decline in hcg concentration between a test performed immediately before and one to two weeks after medical abortion indicates abortion success. Because hcg levels naturally fall in the late first trimester, multilevel pregnancy tests can only be used in the early first trimester (Chong, et al., 2020).

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 et al., 2019; Schmidt-Hansen et al., 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-assessment and clinic follow-up groups.



## **Medical abortion with misoprostol only**

The WHO states that routine follow-up after medical abortion with misoprostol alone is not required (2022), advising instead that individuals should be adequately informed about symptoms of ongoing pregnancy and other medical reasons to return for follow-up such as prolonged heavy bleeding, no bleeding at all with medical management of abortion, pain not relieved by medication, or fever. 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), more people using misoprostol alone for their medical abortion will require additional care than those using the combined mifepristone and misoprostol regimen.

## **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 serum or urine pregnancy testing to rule out an ongoing pregnancy.

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### 3 Abortion before 13 weeks gestation

## 3.5 Medical abortion

### 3.5.7 Ultrasound findings at follow-up

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#### 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: October 2, 2022**

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#### Background

Ultrasound is not necessary to provide abortion care (World Health Organization [WHO], 2022) 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*

A 2021 systematic scoping review, which included 79 randomized controlled trials and 169 observational studies, examined criteria for diagnosing retained products of conception following induced or spontaneous abortion before 14 weeks gestation, finding that although most studies utilized ultrasound, there was little diagnostic accuracy of this method (Hamel et al., 2021). 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 et al., 2004; Markovitch et al., 2006; Parashar et al., 2007; Rørbye, Nørgaard, & Nilas, 2004; Tzeng et al., 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 et al., 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 (Chen & Creinin, 2015; 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). If a woman chooses a second dose of misoprostol, she must be followed to see if it is successful.

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## 4 Abortion at or after 13 weeks gestation

# 4.1 Who has abortions at 13 weeks or later?

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### Key information

People 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 people.

### Quality of evidence

Low

**Last reviewed: October 11, 2022**

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### 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., 2019; Loeber & Wijssen, 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 individuals needing postabortion care present at or after 13 weeks gestation. (African Population and Health Research Center et al., 2013; Fetters et al., 2008; Gebreselassie et al., 2010).

### Why do people need abortions at 13 weeks and later?

*Young age:* Young people are disproportionately likely to seek abortion at or after 13 weeks (Espinoza, Samandari, & Andersen, 2022). In the United States, 23.7% of those younger than age 15 and 12.4% of adolescents ages 15-19 seeking abortion care do so after 13 weeks gestation (Jatlaoui et al., 2019). 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 studies in Ethiopia, India, Kenya, 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; Ushie et al., 2018).

*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. Poor understanding and awareness of fertility and pregnancy signs and symptoms affects individual recognition of pregnancy (Somefun, Harries, & Constant, 2021), particularly among young people (Espinoza, Samandari, & Andersen, 2020). 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 et al., 2019; Drey et al., 2006; Foster, Gould, & Biggs, 2021; Foster & Kimport, 2013; Gallo & Nghia, 2007; Harries et al., 2007; Ingham et al., 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 decision making 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 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 care-seeking (Waddington, Hahn, & Reid, 2015).

*Financial and logistical barriers:* Poverty (Goyal et al., 2020; Sium et al., 2022; Usta et al., 2008), immigrant status (Gonzalez-Rabago et al., 2017; Loeber & Wijzen, 2008), rural residence (Bonnen et al., 2014; Ushie et al., 2018), unemployment (Gonzalez, Quast, & Venanzi, 2019; Van de Velde et al., 2019), and lack of health insurance (Raidoo et al., 2020) are risk factors for presentation for abortion care at or after 13 weeks gestation. 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 (Goyal et al., 2020; Sium et al., 2021; White et al., 2021). In one case-control study of women presenting for abortion at over 20 weeks gestation were much more likely than those with 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 & Wijzen, 2008).

*Fetal indications:* Prenatal 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 (Edling, Lindstrom, & Bergman, 2021; Lyus et al., 2013).

*Maternal indications:* Medical conditions that worsen during the course of pregnancy or a new condition arising in pregnancy may endanger the life or health of the pregnant person (Kiver, Altmann, Kamhieh-Milz, & Weichert, 2019). Severe preeclampsia or preterm prema-



ture rupture of membranes may require termination of pregnancy to save pregnant person'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). Adolescents and young people, particularly those aged 10-14 years, are more likely to have a pregnancy due to rape, incest or transactional sex, and to subsequently present later in pregnancy for abortion (Espinoza, Samandari, & Andersen, 2020).

*Failed abortion:* Although failures are rare, those 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 a delay in care-seeking (Marlow et al., 2014).

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## 4 Abortion at or after 13 weeks gestation

# 4.2 Comparing methods

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### Key information

- Dilatation and evacuation (D&E) and medical abortion with mifepristone and misoprostol or misoprostol only are safe and effective methods of abortion.
- 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.

### In practice

Individuals should be offered a choice of methods when both D&E and medical abortion are available.

### Quality of evidence

Moderate

**Last reviewed: September 29, 2022**

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### Comparison of methods

#### Safety

In the largest randomized trial comparing methods of abortion at or after 13 weeks gestation, 58 women with gestations between 13-20 weeks received D&E and 52 received medical abortion with mifepristone and misoprostol (Kelly et al., 2010). Overall rates of complications were the same in the two groups (12%), although the types of complications differed. Five participants in the medical arm required uterine evacuation for retained products of conception and one suffered bleeding requiring transfusion; only one person 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 those randomized to medical abortion had more bleeding and pain and found the abortion process less acceptable than those 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). A prospective, nonrandomized trial, in which abortion seekers between 13-20

weeks chose their method of uterine evacuation, included 219 medical abortion and 60 D&E participants and found no difference in complication rates between the two groups (Tufa et al., 2021). However, nine patients (4%) in the medical arm required additional intervention to complete the abortion (Tufa et al., 2021).

The largest available retrospective cohort study comes from Nepal and included 2,294 women at or after 13 weeks gestation; 595 underwent D&E and 1,701 had a medical abortion (Kapp et al., 2020). Complications were rare overall (<1% for D&E, 1.4% for medical abortion), mostly consisting of hemorrhage, amongst both groups. In smaller retrospective cohort studies, people 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 people who had D&E; the rate of major adverse events including infection, transfusion, hysterectomy and death did not differ between the two methods (Auntry et al., 2002; Bryant et al., 2011; Sonalkar et al., 2017). A small retrospective cohort study comparing people undergoing medical abortion (n=77) or D&E (n=41) for IUFD between 13-24 weeks found similar rates of complications in both groups (19% and 17% respectively), although 2 patients in the medical abortion group (3%) experienced a major complication (McLaren et al., 2022).

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

### Subsequent perinatal outcomes

A Finnish register-based study of first-time mothers compared incidence of adverse birth outcomes among those with no history of previous abortion (364,392 women), those with past history of a medical or surgical abortion at 12 weeks gestation or less (46,589 women), and those with history of a medical or surgical abortion at greater than 12 weeks (7,709 women) (KC, Gissler, & Klemetti, 2020). Investigators found that the risk of any subsequent adverse birth outcome was small, but that risk is higher with increasing gestational age at the time of induced abortion. Women undergoing a later medical abortion had a 1.4 fold increased risk of both preterm birth and low birthweight compared to those having an earlier medical abortion. Women who had a late surgical abortion had a 2.6 fold and 1.5 fold increased risk of extremely preterm birth and very low birthweight compared with women who had an earlier surgical abortion.

### The importance of choice

The characteristics of medical abortion and D&E vary widely; in settings where both abortion methods are available and a person is a candidate for either, they should be offered a choice of abortion method. The choice of abortion procedure is an intensely personal one (Kerns et al., 2018)—some 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). Acceptability and satisfaction with the abortion process is highest when each individual can choose to receive their preferred method (Kapp & Lohr, 2020). Both randomized trials referenced above (Kelly et al., 2010; Grimes et al., 2004) had difficulty with recruitment due to participants’ strong preferences for one method—generally D&E—over the other. In the most recent of these studies, 100% of those randomized to D&E reported they would choose it again compared with only 53% of those randomized to medical abortion (Kelly et al., 2010). To choose the abortion procedure that best facilitates their coping, people 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 Abortion at or after 13 weeks gestation

### 4.3 Gestational dating

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#### Recommendation

- Gestational age should be calculated using a person'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

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#### 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 LMP is well established during prenatal care, as is the use of ultrasound. No prospective trials have compared the accuracy of different methods of gestational dating prior to abortion at or after 13 weeks, however, in a retrospective cohort of 2,223 women undergoing abortion at or after 13 weeks gestation in Nepal, gestational age assessed by measuring fetal foot length after pregnancy expulsion was highly correlated with ultrasonography (81%), physical exam (77%) and LMP (72%) assessments (Kapp et al., 2020). 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.

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 et al., 2015; Ngoc et al., 2011; Royal College of Obstetricians and Gynaecologists [RCOG], 2022a; World Health Organization [WHO], 2022). 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 et al., 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 et al., 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, 2022a; WHO, 2022). 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.

People 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, 2022b; WHO, 2022).

After the abortion, clinicians can confirm gestational age by comparing actual fetal measurements (fetal foot length) to the expected gestational age (Drey et al., 2005; Mokkarala et al., 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).



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## 4 Abortion at or after 13 weeks gestation

# 4.4 Induced fetal demise

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### 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: September 29, 2022**

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### Background

Some providers may induce fetal demise before medical abortion or D&E at or after 13 weeks gestation for a variety of reasons. Clients, providers or staff may prefer that fetal demise occurs before an abortion procedure (Jackson et al., 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 people who received an intrauterine 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 the group 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 et al., 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 et al., 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., 2019).

## Technique

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

*Potassium chloride/xylocaine:* Potassium chloride or xylocaine 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 et al., 2004; Maurice et al., 2019). In one retrospective cohort study including 80 people with pregnancies between 21 and 27 weeks gestation, the administration of intracardiac xylocaine resulted in fetal demise in 95% of pregnancies with no serious adverse events, although two participants developed side effects attributed to the injection (Tolu et al., 2020).

*Digoxin:* Digoxin is injected either transabdominally or transvaginally (Tocce et al., 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 et al., 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). In one retrospective cohort study including 49 people undergoing medical abortion between 20-27 weeks, digoxin 1mg administered intra-amniotically resulted in fetal demise in 90% of cases. Two participants expelled the pregnancy outside of the hospital (Tufa, et al., 2020).

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## 4 Abortion at or after 13 weeks gestation

### 4.5 Follow-up

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#### Recommendation

- Routine follow-up care is not necessary unless desired by the individual or necessary for their 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: September 24, 2022**

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#### Follow-up

There is no scientific data to demonstrate that routine follow-up is beneficial after uncomplicated abortion at or after 13 weeks. In addition, there is no evidence to suggest that a pelvic examination is beneficial in an asymptomatic person that does return for a routine follow-up visit. Those undergoing abortion at or after 13 weeks should be adequately informed about medical reasons to return for follow-up, and should receive appropriate supplies and information to meet contraceptive needs.

#### Quality of evidence

Very low. The recommendation is based on expert opinion (Royal College of Obstetricians and Gynaecologists, 2022; World Health Organization [WHO], 2022).

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# 4.6 Dilatation and evacuation

## 4.6.1 Cervical preparation

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### 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: November 1, 2022**

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### Background

Cervical preparation prior to D&E reduces the risk of procedure-related complications (Fox & Krajewski, 2014; Peterson et al., 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 individuals 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 (O’Shea et al., 2021). Choice of method of cervical preparation is often limited by supply availability, especially in low-resource settings.

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
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

Osmotic dilators are safe, effective and do not increase infectious morbidity (Bryman, Granberg, & Norström, 1988; Fox & Krajewski, 2014; Jonasson et al., 1989; Peterson et al., 1983). A 2021 systematic review and meta-analysis of cervical preparation before D&E between 14-24 weeks gestation showed that cervical priming regimens that included osmotic dilators provided better cervical dilation and reduced procedure difficulty when compared to regimens that did not include dilators; but dilator regimens were also associated with decreased patient satisfaction (O’Shea et al., 2021). In one randomized controlled trial, synthetic dilators placed on the day of D&E resulted in less initial cervical dilation and required more mechanical dilation than overnight laminaria, although there were no differences in procedure duration or complications between the two groups (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; Diedrich, Drey, & Newmann, 2020).

People experience pain both during dilator placement and overnight as dilators expand in the cervix; pain typically peaks two hours after dilator placement (Creinin et al., 2020; Liu & Flink-Bochacki, 2020; Nagendra et al., 2020) and does not differ by type of dilator used (Liu & Flink-Bochacki, 2020). In randomized controlled trials, provider-administration of paracervical block (Shaw et al., 2021; Soon et al., 2017) or self-administration of 2% lidocaine gel (Schivone et al., 2019) prior to osmotic dilator insertion eases the discomfort of dilator placement and use of non-steroidal anti-inflammatory medications (NSAIDs) decreases the experience of cramping pain for the hours following insertion until procedure, compared to oral opioids (Nagendra et al., 2020).

## Misoprostol

Misoprostol is inexpensive, safe (Nucatola et al., 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 et al., 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, those 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 patients often preferred misoprostol to dilators (Goldberg et al., 2005). Misoprostol may be given to individuals 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 found that adjuvant misoprostol did not significantly decrease procedure time or the need for initial dilation (Cahill et al., 2019). Overall complication rates were low in all three studies and did not differ significantly by treatment group, however in all studies side effects were greater among those using misoprostol (Cahill et al., 2019; Drey et al., 2013; Edelman et al., 2006; Goldberg et al., 2015). The Royal College of Obstetricians and Gynaecologists and the Society of Family Planning recommend against adjuvant misoprostol for patients who received uncomplicated dilator insertions the day prior to D&E (Diedrich, Drey, & Newmann, 2020; O’Shea et al., 2021), while the World Health Organization (WHO) recommends adding an adjuvant medication (misoprostol, mifepristone, or both) to osmotic dilators for D&E at or after 19 weeks (WHO, 2022).

Two small prospective randomized trials have examined adding misoprostol to dilators for same-day D&E (Borras et al., 2016; Kim et al., 2022). Investigators ended both studies early—one due to difficulty recruiting participants (Kim et al., 2022) and the other due to an unexpectedly high rate of complications, specifically serious cervical lacerations, in participants over 19 weeks gestation who received dilators alone for cervical preparation (Borras et al., 2016).

## 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 (Bor-gatta et al., 2012). Study participants who had cervical preparation with osmotic dilators had



a slightly shorter procedure time and greater dilation compared to those 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 placed the day prior to procedure) found no difference in procedure time between the two treatment groups (Paris et al., 2019). When asked, most participants who received mifepristone preferred it, while most who received 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 et al., 2016), and while administration of mifepristone 2 days prior to misoprostol resulted in improved cervical dilation in one study, the rate of preprocedure fetal expulsion 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 to 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.

### **Who can perform cervical preparation before D&E?**

WHO makes service delivery recommendations for the provision of D&E, which includes assessment of gestational age, cervical preparation, the procedure itself, pain management including the provision of a paracervical block, and the assessment of procedure completeness through visual examination of the products of conception (WHO, 2022). WHO advises that provision of medication for cervical preparation is within the scope of practice of specialty and general medical practitioners; and recommends the provision of cervical preparation medications by associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, and traditional and complementary medicine professionals, based on expected competencies for these roles and low-certainty evidence of safety and effectiveness. Although there is insufficient direct evidence, WHO suggests that community health workers, pharmacists and pharmacy workers can safely and effectively provide medications for cervical preparation based on expected competencies for these roles, adding that these health workers need to ensure continuity of care for the individual obtaining the medications before an abortion procedure (WHO, 2022). WHO advises that cervical preparation with osmotic dilators is within the scope of practice of specialty and general medical practitioners, and recommends the placement of osmotic dilators by associate and advanced associate clinicians, based on indirect evidence and the expected com-

petencies for these health worker roles. Although there is insufficient direct evidence, WHO recommends that midwives, nurses, auxiliary nurses and auxiliary nurse midwives can perform transcervical procedures-including osmotic dilator placement-based on the expected competencies for these roles. For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

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## 4 Abortion at or after 13 weeks gestation

# 4.7 Medical abortion

## 4.7.1 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.
- The combined regimen is safe and effective, with fetal expulsion rates of over 90% at 24 hours and major complication rates around 1%.
- The median time to abortion is 6-10 hours after beginning misoprostol, although some individuals will require more time to successfully abort.

### In practice

- A combined mifepristone and misoprostol regimen is more effective than misoprostol used alone, and is recommended for medical abortion at or after 13 weeks; where mifepristone is unavailable the misoprostol-only regimen can be used.
- If the individual is stable and it is convenient to do so, providers should allow 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: September 29, 2022**

### 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], 2022). Mifepristone combined with misoprostol has a consis-

tently shorter induction-to-abortion interval and higher expulsion rate at 15 (Ngoc et al., 2011), 24 (Constant et al., 2016; Shay et al., 2021) and 48 hours when compared to misoprostol alone (Dabash et al., 2015).

## **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 individuals continue misoprostol until expulsion with no cut off time, 99% of people eventually have a successful abortion (Ashok et al., 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; Prodan et al., 2019; Shaw et al., 2013). The induction-to-abortion interval is longer in nulliparous people, older people, and those 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 et al., 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 et al., 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 more recent but smaller prospective cohort study of mifepristone and misoprostol abortion between 13-18 gestational weeks conducted in Nepal, 35 out of 230 women required placental removal (15%) and three women experienced hemorrhage, for a serious adverse event rate of 1.3% (Blum et al., 2019). 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).

### 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 et al., 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). A 2020 systematic review which included three randomized controlled trials, two of which were included in the Shaw, 2013 review, found no significant differences in the induction-to-abortion interval or successful abortion rate when misoprostol was started one day, or two days, after mifepristone (Wu et al., 2021). 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 et al., 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 et al., 2000).

*Number of doses:* A prospective cohort study of 120 people 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 people between 13-22 weeks, 90% required five or fewer doses of misoprostol (Platais et al., 2019).

## **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 fetocidal 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 those managed expectantly during this time frame.

## **Who can provide medical abortion at or after 13 weeks gestation?**

The World Health Organization (WHO) makes service delivery recommendations for the provision of medical abortion at or after 13 weeks gestation, which includes assessment of medical abortion eligibility (determining pregnancy duration and assessing for contraindications to abortion medications), administration of abortion medications, management of the abortion process, and assessment of abortion success (WHO, 2022). WHO recommends the provision of medical abortion at or after 13 weeks by specialty and general medical practitioners, and suggests that in contexts where established and easy access to appropriate

surgical backup and other infrastructure necessary to address possible complications exists, associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, and traditional and complementary medicine professionals can also safely and effectively provide this service based on the expected competencies for these health workers (WHO, 2022). For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

<b>Resources</b>	<a href="http://www.ipas.org/ClinicalResources">http://www.ipas.org/ClinicalResources</a>
Protocols for medical abortion (dosage card)	



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## 4 Abortion at or after 13 weeks gestation

# 4.7 Medical abortion

## 4.7.2 Misoprostol only: Recommended regimen

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### Recommended regimen for 13-24 weeks gestation

- Misoprostol 400mcg buccally, sublingually or vaginally every three hours until fetal and placental expulsion. Vaginal dosing is more effective than other routes.
- Misoprostol-only medical abortion is safe and effective, with fetal expulsion rates of 72-91% at 24 hours and major complication rates of less than 1%.
- The average time to abortion is 10-15 hours after beginning misoprostol, although some individuals will require multiple days to successfully abort.

### In practice

- A combined mifepristone and misoprostol regimen is more effective than misoprostol used alone and is recommended for medical abortion at or after 13 weeks; where mifepristone is unavailable the misoprostol-only regimen can be used.
- If the individual is stable and it is convenient to do so, providers should allow 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: September 29, 2022**

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### 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], 2022).

## 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 et al., 2008; Tang et al., 2004), and fetal and placental expulsion rates of 62-64% at 24 hours and 79-82% at 48 hours (Bhattacharjee et al., 2008).

### Induction-to-abortion interval

In the von Hertzen trial, 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 (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 et al., 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).

## Routes of misoprostol administration

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 et al., 2008; Koh et al., 2017; Tang et al., 2004; von Hertzen et al., 2009). A 400mcg dose vaginally is more effective than a 200mcg dose (Koh et al., 2017).

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.

One trial randomized 130 women to misoprostol 400mcg every three hours either vaginally or buccally. Those 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 et al., 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.

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 et al., 2015).

### **Placental expulsion**

One retrospective cohort study measured intervention rates for placental removal in 233 women receiving a fetocidal 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 those 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 people with pregnancies over 20 weeks gestation.

### **Who can provide medical abortion at or after 13 weeks gestation?**

The World Health Organization (WHO) makes service delivery recommendations for the provision of medical abortion at or after 13 weeks gestation, which includes assessment of medical abortion eligibility (determining pregnancy duration and assessing for contraindications to abortion medications), administration of abortion medications, management of the abortion process, and assessment of abortion success (WHO, 2022). WHO recommends the provision of medical abortion at or after 13 weeks by specialty and general medical practitioners, and suggests that in contexts where established and easy access to appropriate

surgical backup and other infrastructure necessary to address possible complications exists, associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, and traditional and complementary medicine professionals can also safely and effectively provide this service based on the expected competencies for these health workers (WHO, 2022). For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

<b>Resources</b>	<a href="http://www.ipas.org/ClinicalResources">http://www.ipas.org/ClinicalResources</a>
Protocols for medical abortion (dosage card)	

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## 4 Abortion at or after 13 weeks gestation

# 4.7 Medical abortion

### 4.7.3 Presence of uterine scar: Recommended regimen

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#### 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.

#### Strength of recommendation

Weak

#### Quality of evidence

Very Low

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#### Risk of uterine rupture with medical abortion

Uterine rupture has been reported during medical abortion at or after 13 weeks gestation in people with and without a uterine scar. The risk of uterine rupture for anyone undergoing a medical abortion at or after 13 weeks gestation is very rare, occurring in fewer than 1 in 1,000 people (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 (Küçük-göz 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 one experienced rupture (Torriente, Steinberg, & Joubert, 2017).

One single-center prospective study of 250 women undergoing uterine evacuation for fetal demise using a low-dose misoprostol regimen included 95 participants with a uterine scar (Shakir, 2022). Those with gestations between 13-17 weeks received 100mcg of misoprostol vaginally every six hours for 24 hours, and between 18-24 weeks received 50mcg of misoprostol. No ruptures occurred, however only 67% had completely aborted after 24 hours.

### **Regimen for women with a uterine scar**

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

Expert opinion supports:

- No change in medical abortion regimen for people 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; Küçüköz 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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## 5 Postabortion care

# 5.1 Treatment of incomplete and missed abortion for less than 13 weeks uterine size

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### Recommendation

- Medical methods or vacuum aspiration may be offered for treatment of incomplete or missed abortion.
- Recommended medication regimen:
  - **Incomplete abortion:** Misoprostol 600mcg orally in a single dose or 400mcg in a single dose buccally, sublingually or, in the absence of vaginal bleeding, vaginally.
  - **Missed abortion:** Misoprostol 800mcg buccally, sublingually or, in the absence of vaginal bleeding, vaginally every three hours until pregnancy expulsion (generally 1-3 doses). Where available, add pretreatment with mifepristone 200mg orally 1-2 days before misoprostol.

### In practice

- Uterine size, not gestational age, should be used to determine treatment for postabortion care.

### Strength of recommendation

Strong

### Quality of evidence

Moderate

**Last reviewed: October 14, 2022**

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### Incomplete abortion

A 2021 systematic review and network meta-analysis examining methods for managing miscarriage before 13 weeks gestation included 26 randomized trials reporting on 5,735 women who were treated for incomplete abortion (Ghosh et al., 2021). Suction aspiration (RR 1.19, 95% confidence interval [CI] 1.09, 1.31) and misoprostol therapy (RR 1.14, 95%CI 1.03, 1.25) were slightly more effective than expectant management or placebo in achieving abortion completion, however success rates were similar for all management strategies. Reported completion rates range from 52-85% for expectant management, 80-99% for treatment

with misoprostol, and 91-100% for surgical treatment (Kim et al., 2017). Oral, sublingual and vaginal misoprostol show similar efficacy and side effect profiles; lengthening the time to follow-up assessment increases the success of misoprostol treatment (Kim et al., 2017).

## Missed abortion

A 2021 systematic review and network meta-analysis examining methods for managing miscarriage before 13 weeks gestation included 16 randomized trials reporting on 4,397 women who were treated for missed abortion (Ghosh et al., 2021). Suction aspiration (RR 2.43, 95%CI 1.69, 3.49), mifepristone plus misoprostol (RR 1.82, 95%CI 1.28, 2.58) and misoprostol alone (RR 1.67, 95%CI 1.18, 2.37) were all more effective in achieving a complete abortion than expectant management or placebo treatment. Three randomized controlled trials found that people with a missed abortion who received pretreatment with mifepristone before receiving misoprostol were more likely to successfully complete their abortion than those 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 (Sinha et al., 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). A third study of mifepristone or placebo, followed 48 hours later by misoprostol 800mcg, demonstrated successful expulsion in 83% and 76% of the 696 women in the trial, respectively, at seven days post-mifepristone (Chu et al., 2020). A meta-analysis, which included these three studies and one additional study accounting for 1,143 women, found a benefit for the addition of mifepristone in resolving missed abortion (RR 1.15, 95% CI 1.01-1.30) (Chu et al., 2020). In a prospective cohort study, risk of failure following mifepristone and misoprostol for missed abortion was increased among people with a uterine size of greater than nine weeks gestation (Ehrnsten et al., 2019). Despite the relatively high cost of mifepristone, two studies from the United States and one from the United Kingdom have shown that use of a combined mifepristone and misoprostol regimen for treatment of missed abortion is cost-effective, particularly in settings where surgical evacuation of the uterus is performed in an operating theater (Berkley, Greene, & Wittenberger, 2020; Nagen-dra et al., 2020; Okeke Ogwulu et al., 2021).

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 et al., 2017). A single dose of misoprostol 800mcg vaginally results in successful uterine evacuation in 76 to 93% of women (Fernlund et al., 2017; Mizrachi et al., 2017; Ngoc et al., 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 re-

ported an increase in abortion success when an additional dose of misoprostol is administered 24 (Barcelo et al., 2012; Graziosi et al., 2004; Muffley, Stitely, & Gherman, 2002), 48 (Lyra et al., 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 et al., 2003; Tang et al., 2006). No studies have evaluated single doses of sublingual misoprostol for treatment of missed abortion.

### **Who can provide postabortion care for individuals with a uterine size less than 13 weeks gestation?**

The World Health Organization (WHO) makes service delivery recommendations for the provision of postabortion care for individuals with a uterine size of less than 13 weeks gestation (WHO, 2022). Health workers with the skills to perform transcervical procedures, and a bimanual examination to diagnose pregnancy and determine gestational age based on uterine size, can be trained to perform vacuum aspiration for postabortion care. WHO advises that uterine aspiration is within the scope of practice for specialty and general medical practitioners, and recommends the provision of vacuum aspiration by associate and advanced associate clinicians, midwives, and nurses based on moderate certainty evidence of safety and effectiveness. Traditional and complementary medicine professionals are recommended to provide uterine aspiration based on low certainty evidence of safety and effectiveness, and WHO suggests that auxiliary nurses and auxiliary nurse midwives may be able to perform aspiration in settings where they provide basic emergency obstetric care (WHO, 2022). WHO advises that all cadres of health care workers (specialty and general medical practitioners, associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, traditional and complementary medicine professionals, pharmacists and pharmacy workers, and community health workers) can safely and effectively provide medical management of uncomplicated incomplete abortion and missed abortion, based on a variety of evidence and the expected skills and knowledge for that type of health worker (WHO, 2022). For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

#### **Resources**

<http://www.ipas.org/ClinicalResources>

**Protocols for medical abortion (dosage card)**

**Abortion Care Videos – Ipas: Caring for a Woman with a Miscarriage**



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# 5.2 Treatment of incomplete abortion and intrauterine fetal demise for 13 weeks or larger uterine size

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### Recommendation

- Medical methods or dilatation and evacuation (D&E) may be offered for treatment of incomplete abortion or intrauterine fetal demise.
- Recommended medication regimen:
  - **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 buccally, 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.

### In practice

- Uterine size, not gestational age, should be used to determine treatment for postabortion care.

### Strength of recommendation

Strong

### Quality of evidence

Low

**Last reviewed: October 16, 2022**

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### 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 people needing postabortion care present at or after 13 weeks gestation (Ministry of Health of Kenya, Ipas, & Guttmacher Institute, 2013). Individuals 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 et al., 2007). Pretreatment with mifepristone 1-2 days before misoprostol increases rates of abortion success within 24 hours and reduces the time to fetal expulsion (Allanson et al., 2021; Bracken et al., 2020; 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 post-abortion care at or after 13 weeks. D&E can be offered for postabortion care where skilled providers and supportive facilities exist (World Health Organization [WHO], 2022).

## Who can provide postabortion care for individuals with a uterine size of 13 weeks gestation or larger?

WHO makes service delivery recommendations for the provision of postabortion care for individuals with a uterine size of 13 weeks gestation or larger (WHO, 2022). WHO advises that D&E is within the scope of practice of specialty medical practitioners, and recommends provision of D&E by generalist medical practitioners based on expected competencies for that role. WHO suggests that in settings where established mechanisms exist to include associate and advanced associate clinicians, midwives, and traditional and complementary medicine professions in other tasks related to maternal and reproductive health care, they can safely and effectively provide D&E, based on expected skills and knowledge for these health worker roles. WHO recommends the provision of medical management of IUFD by specialty and general medical practitioners, and suggests that in contexts where established and easy access to appropriate surgical backup and other infrastructure necessary to address possible complications exists, associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, and traditional and complementary medicine professionals can also safely and effectively provide this service, based on the expected competencies for these health workers (WHO, 2022). For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.



## Protocols for medical abortion (dosage card)

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# 5.3 Postabortion contraception: When and what type

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### 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 person 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.

### In practice:

- 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.
- Satisfaction with contraceptive services/uptake amongst medical abortion clients is greater when contraception is initiated at the same time as mifepristone.

### Strength of recommendation

Strong

### Quality of evidence

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

**Last reviewed: November 1, 2022**

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## Fertility return

Following induced abortion at less than 13 weeks gestation, ovulation typically resumes within three to four weeks; however, some people can ovulate in as little as eight days (Boyd & Holmstrom, 1972; Lahteenmaki & Luukkainen, 1978; Schreiber et al., 2010; Stoddard & Eisenberg, 2011). At least 85% of people 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 et al., 1979). Given the rapid return to fertility, all people who wish to begin contraception should receive their preferred method at the time of their abortion. If the preferred method is not available, a referral should be provided and, if desired, an interim method (World Health Organization [WHO], 2014b).

## Safety and acceptability of postabortion contraception

For adults, 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 adolescents: Depot medroxyprogesterone acetate (DMPA) injection is classified by WHO as a category two for those under 18 years of age, due to concerns about effects on bone mineral density. Sterilization may be performed on young people, 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 et al., 1994; Cameron et al., 2012; Kilander et al., 2016; Korjamo, Mentula, & Heikinheimo, 2017; Langston, Joslin-Rohr, & Westhoff, 2014; Peipert et al., 2012; Pohjoranta et al., 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 et al., 2017; Rocca et al., 2018). A systematic review and meta-analysis of randomized controlled trials has demonstrated significantly higher rates of patient satisfaction with imme-

diate start (day of mifepristone) of implants and injectables compared with a delayed start (Schmidt-Hansen et al., 2020).

## 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 (Kim et al., 2021; WHO, 2015; WHO, 2022). Fertility awareness-based methods may be initiated once the person 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 (Kim et al., 2021; WHO, 2015; WHO, 2022). IUDs may be inserted and sterilization performed as soon as it is reasonably certain that the person is no longer pregnant (WHO, 2014a; WHO, 2022).

A person's immediate need for reliable contraception after abortion, coupled with the reduced uptake of contraception when provision is delayed, strongly supports the recommendation to start contraceptive methods immediately (WHO, 2022).

## 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 significantly 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. A 2022 systematic review, which included these three studies, concluded that provision of progestin-releasing implants, concurrently with abortifacients, has little or no negative impact on medical abortion success, and decreases subsequent unintended pregnancy (Sothornwit et al., 2022).

WHO recommends that generalist and specialist medical practitioners, associate and advance associate clinicians, midwives, and nurses can safely and effectively insert and remove subdermal implants. WHO suggests that in contexts with established health system mechanisms to include traditional and complementary medicine professionals in other tasks relat-

ed to maternal and reproductive health, and where training in implant removal is given along with training in insertion, these health workers can insert and remove implants. Auxiliary nurses and auxiliary nurse midwives can insert and remove implants in the context of targeted monitoring and evaluation, and community health workers can insert and remove implants in the context of rigorous research. For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

*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 et al., 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%); a 2021 systematic review suggests that those choosing DMPA initiation on the same day as mifepristone should be informed of the slightly increased risk of ongoing pregnancy (Kim et al., 2021). 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 et al., 2016). Women report high satisfaction with same-day administration of progestin-only contraceptives (Raymond et al., 2016a).

WHO recommends that generalist and specialist medical practitioners, associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, traditional and complementary medicine professionals, pharmacists, pharmacy workers, community health workers, and the individual using the progestin-only injection can safely and effectively administer this type of contraception. For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

*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 (Kim et al., 2021). 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 et al., 1999; Tang et al., 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 et al., 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).

## **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. 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). Two systematic reviews of randomized comparative trials (Cavallaro et al., 2020; Nelson et al., 2022) found that contraceptive counseling and provision at the time of abortion increases contraceptive use, although some individuals may prefer not to discuss contraception in depth at the time of their abortion visit, particularly if they already know what postabortion contraceptive method they want (Cansino et al., 2018). 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 et al., 2017; Benson et al., 2016). A recent systematic review examining contraceptive preferences included four studies among people seeking abortion services (Dam et al., 2022). Ease of use and effectiveness were important features of preferred contraceptive methods, as were cost, familiarity with the method, presence of hormones, and side effects, among others.

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## 5.4 Postabortion IUD use: Safety and timing

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### Recommendation

- When an individual 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 an individual chooses an IUD following medical abortion, it should be placed when it is reasonably certain they are no longer pregnant.

### Strength of recommendation

Strong

### Quality of evidence

High

**Last reviewed: October 7, 2022**

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### 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 et al., 1994; Cameron et al., 2012; Korjamo, Mentula & Heikinheimo, 2017b; Langston, Joslin-Rohr, & Westhoff, 2014; Peipert, Madden, Allsworth, & Secura, 2012; Pohjoranta et al., 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 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 the individual is no longer pregnant (WHO, 2022). IUDs placed within 5-10 days of a successful medical abortion have low rates of expulsion, high continuation rates (Betstadt et al., 2011; Sääv, Stephansson, & Gemzell-Danielsson, 2012) and lower pregnancy rates than delayed insertion (Pohjoranta et al., 2017; Saav et al., 2012; Shimoni et al., 2011). A systematic review of three randomized trials found no differences between early and delayed insertion after abortion at gestations less than nine weeks, and higher rates of expulsion, continuation and uptake after immediate compared to delayed insertion at 9–12 weeks of gestation (Schmidt-Hansen et al., 2020). 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 those 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 et al., 2009).

A 2022 study that randomized 114 people seeking medical abortion between 17 and 20 weeks gestation to receive either an immediate postabortion copper IUD, or placement three weeks later, found that many more people in the immediate group were using an IUD after 6 weeks (56%, compared to 19%), despite a significantly higher expulsion rate in the immediate group (32%, compared to 7%) (Constant et al., 2022). A smaller study randomized 57 people to immediate or delayed hormonal IUD placement following medical abortion between 12 and 20 weeks gestation. and 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 et al., 2015). An IUD may be placed following fetal and placental expulsion.

## Young people

The IUD for people 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 et al., 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 et al., 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).

## Who can insert and remove IUDs?

WHO makes service delivery recommendations for the provision of IUDs (WHO, 2022), recommending that IUD insertion and removal is within the scope of practice of specialty and generalist medical practitioners, associate and advance associate clinicians, nurses, midwives, and auxiliary nurse midwives, based on expected skills and knowledge for these health worker roles. WHO suggests that in settings where established mechanisms exist to include traditional and complementary medicine professions in other tasks related to maternal and reproductive health care, they can safely and effectively insert and remove IUDs, and that auxiliary nurses can insert and remove IUDs in the context of research. For further information about health worker roles in abortion care, see *Appendix C: World Health Organization recommendations for health worker roles in abortion care*.

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# 5.5 Postabortion hemorrhage: Prevention and management

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### Recommendation

- Clinicians should consider measures to prevent or prepare for increased bleeding in individuals 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 person for signs of shock.

### Strength of recommendation

Strong

### Quality of evidence

Low

**Last reviewed: September 28, 2022**

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### 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; Kerns et al., 2019; 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 individuals 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, fetal death, obesity, increased maternal

age, and placenta previa or accreta (Kerns & Steinauer, 2018; Kerns et al., 2019; 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 et al., 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). Methylergonovine, a medicine commonly administered prophylactically to prevent excessive bleeding after D&E, was found to increase, rather than decrease, bleeding when administered prophylactically immediately after D&E at 20-24 weeks (Kerns, et al., 2021).

## Diagnosis

When postabortion hemorrhage is suspected, clinicians should take a rapid, systematic approach to assessment and treatment. 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.



## Uterotonic medications and dosages.\*

Medication	Dosage
Methylergonovine	0.2mg intramuscularly or intracervically; can be repeated every 2-4 hours. Avoid in people with hypertension
Misoprostol	800mcg buccally or sublingually
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, 2020).

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 they remains stable after the balloon or gauze is removed, the patient 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, 2022). 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. Individuals at risk of shock require intravenous line placement, supplemental oxygen, fluid resuscitation and replacement of blood products as indicated.

## Who can provide initial management of non-life-threatening postabortion hemorrhage?

The World Health Organization (WHO) makes service delivery recommendations for the initial management of postabortion hemorrhage, which includes recognizing the complication, stabilizing the person, and providing intravenous fluids prior to referral to an appropriate health worker or facility (WHO, 2022). WHO recommends that specialty and generalist medical practitioners, associate and advanced associate clinicians, midwives, nurses, auxiliary nurses and auxiliary nurse midwives, and traditional and complementary medicine professionals can provide this care based on their established scope of practice or expected knowledge and skills for the health worker role (WHO, 2022). For further information about health worker roles in abortion care, see Appendix C: World Health Organization recommendations for health worker roles in abortion care.

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# 5.6 Managing uterine perforation

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### Recommendation

- Anyone with suspected uterine perforation, even if asymptomatic, should be informed of the complication and their clinical status should be observed.
  - If stable, individuals 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.
- Anyone 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: September 28, 2022**

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### 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 1,000 induced abortion procedures (Kerns & Steinauer, 2013; Pridmore & Chambers, 1999). This frequency increases with advancing gestational age and when performed by less experienced providers (ACOG, 2013).

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 gestation

- 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 people 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 et al., 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 definitively 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 individual 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; Peterson et al., 1983; 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 individual 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 et al., 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 et al., 1995; Chen et al., 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. Patients 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 used 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 an individual'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	<ul style="list-style-type: none"> <li>• Pull back plunger before injecting to avoid intravascular injection</li> <li>• 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.</li> </ul>
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 people 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 people 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		<ul style="list-style-type: none"> <li>• Single dose IM ketorolac prior to surgery may reduce opioid use and postoperative pain (de Oliveira, 2012; Roche, 2011)</li> <li>• Do not use in women with active peptic ulcer disease, renal failure, breastfeeding or sensitivity to other NSAIDs</li> <li>• Breakthrough pain should be managed with narcotics rather than increasing ketorolac beyond the recommended doses</li> </ul>
Analgesic	Acetaminophen	Oral: 500-1,000mg 30-60 minutes before procedure	2-4 hours		<ul style="list-style-type: none"> <li>• Not a first-line pain medication for vacuum aspiration or medical abortion. May be used as an antipyretic</li> <li>• Liver toxicity from overdose (maximum dose = 4,000mg/day) is a risk</li> </ul>
Narcotic/analgesic combination	Acetaminophen 300mg + codeine 30mg	Oral: 1-2 tablets 1 hour before procedure	2-4 hours	Drowsiness; light-headedness; nausea and vomiting	<ul style="list-style-type: none"> <li>• Be aware of combining with other acetaminophen-containing products. Liver toxicity from overdose of acetaminophen (maximum dose=4,000 mg/day) is a risk.</li> </ul>
	Acetaminophen 500mg + hydrocodone 5mg	Oral: 1-2 tablets 1 hour before procedure	4-6 hours	Drowsiness; light-headedness; nausea and vomiting	<ul style="list-style-type: none"> <li>• Be aware of combining with other acetaminophen-containing products. Liver toxicity from overdose of acetaminophen (maximum dose=4,000 mg/day) is a risk.</li> </ul>
<b>Drug type</b>	<b>Generic drug name</b>	<b>Dose and timing</b>	<b>Half-life</b>	<b>Side effects</b>	<b>Comments</b>

Narcotic	Meperidine	<p>Oral: 100-150mg 30-60 minutes before procedure</p> <p>IV: 25-50mg 5-15 minutes prior to procedure</p> <p>IM/SC: 50-100mg 30-90 minutes prior to procedure</p>	2-4 hours	Drowsiness; light-headedness; nausea and vomiting; decreased breathing rate; loss of consciousness; hypotension; seizures	<ul style="list-style-type: none"> <li>• IM or SC administration preferred over IV</li> <li>• If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with naloxone (see Reversal agent for narcotic, below)</li> <li>• More rapid onset and shorter duration of action than morphine</li> <li>• Meperidine 300mg PO=Meperidine 75mg IV=morphine 10mg IV</li> </ul>
	Fentanyl	<p>IV: 50-100mcg immediately before procedure (may repeat every 5-10 minutes, not to exceed 250mcg)</p> <p>IM: 50-100mcg 30-60 minutes before procedure</p>	4 hours	Drowsiness; light-headedness; weakness; bradycardia; decreased breathing rate; loss of consciousness; hypotension; seizures	<ul style="list-style-type: none"> <li>• If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with naloxone (see end of chart)</li> <li>• More rapid onset and shorter duration of action than meperidine</li> <li>• Fentanyl 100mcg IV = morphine 10mg IV</li> <li>• Onset of action is 2-7 minutes when given IV</li> </ul>
	Tramadol	<p>IV/IM: 50-100mg 15-30 minutes before the procedure</p> <p>Oral/suppository: 50-100mg 60-90 minutes prior to the procedure</p>	6-8 hours	Drowsiness; light-headedness; sweating; weakness; fatigue; seizures	<ul style="list-style-type: none"> <li>• If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with naloxone (see Reversal agent for narcotic, below)</li> <li>• If using IV, inject slowly over 2-3 minutes</li> <li>• Less respiratory depression than morphine or meperidine</li> </ul>
<b>Drug type</b>	<b>Generic drug name</b>	<b>Dose and timing</b>	<b>Half-life</b>	<b>Side effects</b>	<b>Comments</b>

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	<ul style="list-style-type: none"> <li>If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with flumazenil (see Reversal agent for narcotic, below)</li> <li>Has a mild amnestic effect</li> <li>Onset of action is 1-22 minutes when given IV</li> </ul>
	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	<ul style="list-style-type: none"> <li>If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with flumazenil (see end of chart)</li> <li>Midazolam 2.5mg=diazepam 10mg</li> <li>Stronger amnestic effect than diazepam</li> <li>Onset of action is 1-5 minutes when given IV and 15-30 minutes when given IM</li> </ul>
	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	<ul style="list-style-type: none"> <li>If respiration is compromised, assist with breathing (airway management, oxygen and ambu bag) and reverse with flumazenil (see Reversal agent for narcotic, below)</li> <li>Amnestic effect</li> </ul>
Reversal agent for narcotic	Naloxone	IV/IM/SC: 0.4mg every 2 minutes until reversal is seen	1-1.5 hours		<ul style="list-style-type: none"> <li>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.</li> <li>Maintain airway and respirations while giving naloxone</li> </ul>

Drug type	Generic drug name	Dose and timing	Half-life	Side effects	Comments
Reversal agent for benzodiazepine	Flumazenil	IV: 0.2mg every minute until respirations return. Do not exceed 1mg	1 hour		<ul style="list-style-type: none"> <li>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.</li> <li>Maintain airway and respirations while giving flumazenil</li> </ul>
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	<ul style="list-style-type: none"> <li>There are no contraindications to epinephrine in the setting of anaphylaxis</li> <li>IM administration preferred</li> <li>Consider giving methylprednisolone 125mg IV</li> <li>Support respiration. If wheezing is present, inhaler may be helpful</li> <li>Immediate intubation if evidence of impending airway obstruction</li> </ul>

## References

De Oliveira, G. S., Agarwal, D., & Benzon, H. T. (2012). Perioperative single dose ketorolac to prevent postoperative pain: a meta-analysis of randomized trials. *Anesthesia & Analgesia*, 114(2), 424-433.

Roche, N. E., Li, D., James, D., Fechner, A., & Tilak, V. (2011). The effect of perioperative ketorolac on pain control in pregnancy termination. *Contraception*, 85(3), 299-303.

# 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-sedation-analgesia> on 03/17/2020. (reprinted with permission)

	<b>Minimal sedation anxiolysis</b>	<b>Moderate sedation/ analgesia ("conscious sedation")</b>	<b>Deep sedation/ analgesia</b>	<b>General anesthesia</b>
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)<sup>1</sup>

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

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

**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.

# Appendix C: World Health Organization recommendations for health worker roles in abortion care

In their Abortion Care Guideline (2022), the World Health Organization (WHO) provides evidence-based guidance on how to involve a wider range of health workers and pregnant people themselves in the provision or self-management of abortion care, in order to “encourage optimization of the available health workforce, address health system shortages of specialized health-care professionals, reduce costs and improve affordability, improve equity and equality in access to health care and increase the acceptability of health services for those who need them.” The recommendations made by WHO are intended for all resource settings, refer to a range of types of health workers who can safely, effectively and satisfactorily perform some or all of the specific abortion-related tasks. It is assumed that any health worker discussed has the basic training required of that type of health worker and that they will have received the appropriate task-specific training and information prior to performing that task.

Recommendation	Individual/ Self	Community health workers	Pharmacy workers	Pharmacists	Traditional/ Complementary medicine professionals	Auxiliary nurses/ Auxiliary nurse midwives	Nurses	Midwives	Associate/ Advanced associate clinicians	Generalist/ Specialist medical practitioners
Provision of information on abortion care	NR	Recommend	Suggest (1)	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend
Provision of abortion counselling	NR	Recommend	Suggest (2)	Suggest (2)	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend
Cervical priming with medication prior to surgical abortion at any gestational age	NR	Suggest (3)	Suggest (3)	Suggest (3)	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend
Vacuum aspiration for induced abortion at < 14 weeks*	NR	Recommend against	Recommend against	Recommend against	Recommend	Suggest (4)	Recommend	Recommend	Recommend	Recommend
Medical management of induced abortion at gestational ages < 12 weeks	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend
Cervical priming with osmotic dilators prior to D&E at gestational ages ≥ 12 weeks	NR	Recommend against	Recommend against	Recommend against	Suggest (3)	Recommend	Recommend	Recommend	Recommend	Recommend
D&E for surgical abortion at gestational ages ≥ 14 weeks	NR	Recommend against	Recommend against	Recommend against	Suggest (5)	Recommend against	Recommend against	Suggest (5)	Suggest (5)	Recommend

Recommendation	Individual/ Self	Community health workers	Pharmacy workers	Pharmacists	Traditional/ Complementary medicine professionals	Auxiliary nurses/ Auxiliary nurse midwives	Nurses	Midwives	Associate/ Advanced associate clinicians	Generalist/ Specialist medical practitioners
Medical management of induced abortion at gestational ages $\geq$ 12 weeks	NR	Recommend against	Recommend against	Recommend against	Suggest (6)	Suggest (6)	Suggest (6)	Suggest (6)	Suggest (6)	Recommend
Vacuum aspiration for management of uncomplicated incomplete abortion at gestational ages $<$ 14 weeks	NR	Recommend against	Recommend against	Recommend against	Recommend	Suggest (4)	Recommend	Recommend	Recommend	Recommend
Medical management of uncomplicated incomplete abortion with misoprostol at gestational ages $<$ 14 weeks	NR	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend
Medical management of intrauterine fetal demise at gestational ages $\geq$ 14 to $\leq$ 28 weeks	NR	Recommend against	Recommend against	Recommend against	Suggest (6)	Suggest (6)	Suggest (6)	Suggest (6)	Suggest (6)	Recommend
Insertion and removal of intrauterine devices (IUDs)	NR	Recommend against	Recommend against	Recommend against	Suggest (5)	Suggest (7)/ Recommend	Recommend	Recommend	Recommend	Recommend
Insertion and removal of implants	NR	Suggest (7)	Recommend against	Recommend against	Suggest (5)	Suggest (8)	Recommend	Recommend	Recommend	Recommend
Administration of injectable contraceptives	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend
Tubal ligation	NR	Recommend against	Recommend against	Recommend against	Recommend against	Recommend against	Suggest (7)	Suggest (7)	Recommend	Recommend
Initial management of non-life-threatening post-abortion hemorrhage or infection	NR	Recommend against	Recommend against	Recommend against	Recommend	Recommend	Recommend	Recommend	Recommend	Recommend

NR=no recommendation made

Suggest: A weak recommendation in favor of the intervention, requiring additional wording to qualify the recommendation, specifying the conditions of use

Recommend: A strong recommendation in favor of the intervention



\*The provision of vacuum aspiration includes the assessment of gestational age, cervical preparation (if needed), the actual procedure, pain management including administration of a paracervical block and assessment of abortion completeness through visual inspection of products of conception.

- (1) Condition: In contexts where the pharmacy worker is under the direct supervision of a pharmacist and there is access or referral to appropriate health services
- (2) Condition: Both medical and surgical abortion counselling is provided and there is access or referral to appropriate health services should the client choose a surgical abortion method
- (3) Condition: Health worker ensures continuity of care from the time of cervical priming to the abortion procedure
- (4) Condition: In contexts where established health system mechanisms involve these health workers in providing other basic emergency obstetric care
- (5) Condition: In contexts where established health system mechanisms involve these health workers in other tasks related to maternal and reproductive health
- (6) Condition: In contexts where access to appropriate surgical backup and proper infrastructure is available to address incomplete abortion or other complications
- (7) Condition: In the context of rigorous research.
- (8) Condition: In the contest of targeted monitoring and evaluation

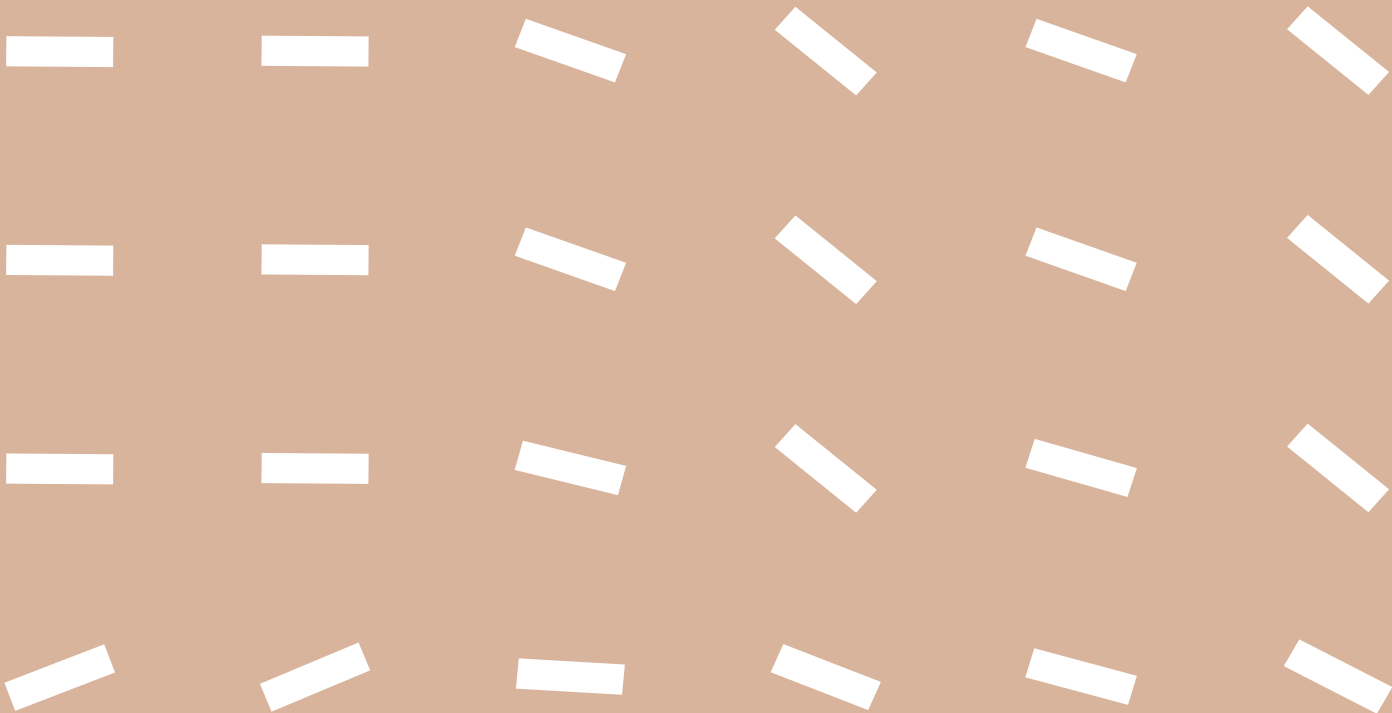
Adapted from World Health Organization. (2022). *Abortion care guideline*. Geneva: World Health Organization and World Health Organization. (2015). *Health worker roles in providing safe abortion care and post-abortion contraception*. Geneva: World Health Organization.

## World Health Organization definition of health worker categories and roles

Category	Description of qualifications and tasks
Community health worker	A person who performs functions related to health-care delivery/information provision and has been trained in some way in the context of the task, but has received no formal professional or paraprofessional certificate or tertiary education degree.
Pharmacy worker	Technicians and assistants who perform a variety of tasks associated with dispensing medicinal products under the guidance of a pharmacist. They inventory, prepare and store medications and other pharmaceutical compounds and supplies, and may dispense medicines and drugs to clients and instruct on their use as prescribed by health professionals. Technicians typically receive two or three years of training in a pharmaceutical school, with an award not equivalent to a university degree. Assistants have usually also been through two or three years of secondary school, with a subsequent period of on-the-job training or apprenticeship.
Pharmacist	A health-care practitioner who dispenses medicinal products. A pharmacist can counsel on the proper use and adverse effects of drugs and medicines following prescriptions issued by medical doctors/health-care professionals. Education includes university-level training in theoretical and practical pharmacy, pharmaceutical chemistry or a related field.
Traditional and complementary medicine professionals	A professional of traditional and complementary systems of medicine (non-allopathic physician) whose training includes a four- or five-year university degree that teaches human anatomy, physiology, management of normal labor and the pharmacology of modern medicines used in obstetrics and gynecology, in addition to their systems of medicine.
Auxiliary nurse midwife and auxiliary nurse	An auxiliary nurse is someone trained in basic nursing skills, but not in nursing decision making. An auxiliary nurse midwife has basic nursing skills and some midwifery competencies but is not fully qualified as a midwife. The duration of training may vary from a few months up to three years. A period of on-the-job training may be included, and this is sometimes formalized in apprenticeships.
Nurse	A person who has been legally authorized (registered) to practice after examination by a state board of nurse examiners or similar regulatory authority. Education includes three or more years in nursing school, and leads to a university or postgraduate university degree or the equivalent.
Midwife	A person who has been registered by a state midwifery or similar regulatory authority and has been trained in the essential competencies for midwifery practice. Training typically lasts three or more years in nursing or midwifery school, and leads to a university degree or the equivalent. A registered midwife has the full range of midwifery skills, which include abortion.
Advanced associate clinician and associate clinician	A professional clinician with basic competencies to diagnose and manage common medical and surgical conditions, and also to perform some types of surgery. Training generally requires three or four years post-secondary education in an established higher education institution. The clinician is registered and their practice is regulated by a national or subnational regulatory authority.
Generalist medical practitioner	A medical doctor who holds a university-level degree in basic medical education but does not have a specialization in obstetrics and gynecology.
Specialist medical practitioner	A medical doctor with postgraduate clinical training and specialization in obstetrics and gynecology.

Adapted from World Health Organization. (2022). *Abortion care guideline*. Geneva: World Health Organization.

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