

No Touch Medication Abortion Protocol

Overview (of the evidence, states may have tighter restrictions)

- The maximum **gestational age is 77 days**.¹
- The **mifepristone dosage is 200 milligrams** (one pill). The FDA label states that the mifepristone must be **"dispensed"** by the clinician but does not specify how that is done or where the pill should be taken – which allows option for mail and home administration. Verbal consent can be documented by the clinician in the EMR.
- **Mucosal misoprostol 800 mcg administration** has better efficacy over oral. This administration can be buccal, vaginal or sublingual and, if it is assumed the routes are all bioequivalent, can be 6 to 72 hours after the mifepristone. For 9 to 11 weeks, a second dose of misoprostol should be given for use 4 hours after the first.
- First follow-up occurs one day after misoprostol use to assure the adequate cramping and bleeding occurred. The urine pregnancy tests to assure completion are done after 3-4 weeks and a communication from the patient that it was negative is ideal.
- The **prescriber can be any prescribing clinician**, including advanced practice clinicians.

No Touch Process

The primary provider should counsel the patient by phone or video chat about pregnancy options (and contraception if desired). Patients who choose medication abortion can then be counseled about the process. Patient information sheets can be emailed, faxed, or sent through patient portals.

Initial Assessment – Discussion of Home Medication Abortion

Counseling

1. Options counseling: It is preferable in many locations during this epidemic that the patient choose a medication abortion over a procedure if 11 weeks or less. Advise that medication abortion has a failure rate (i.e. ongoing pregnancy) of about 0.4-3%.²

Medication abortion is non-invasive, avoids surgical and anesthetic risk, and can occur very early in pregnancy. It has been perceived by many patients to be more natural, and allows more privacy and control.

2. Review of expected effects: Bleeding and cramping (usually heavier than with menses) are expected. Diarrhea and other gastrointestinal side effects are common.

¹ Dzuba, Ilana G., et al. "A non-inferiority study of outpatient mifepristone-misoprostol medical abortion at 64–70 days and 71–77 days of gestation." *Contraception* (2020).

² National Abortion Federation. Clinical Policy Guidelines, updated 2020

There is a very small risk of prolonged bleeding requiring an aspiration abortion or MVA. The patient should be instructed in how much bleeding would be considered excessive and when to call the clinician (more than 2 soaked pads per hour for two hours in a row).

3. Adherence to protocol: Explain to the patient the process and the importance of finishing the medication abortion protocol. Studies have shown that serious bleeding can occur if only the mifepristone is taken and not the misoprostol.

Compliance with State Requirements

Many states have specific requirements affecting abortion. Most of these laws apply both to medication and aspiration abortion. Providers must comply with mandatory waiting periods, parental notification, gestational age limits, and department of health reporting as required. To find out more about these regulations, consult www.reproductiverights.org/.

Medical History

1. Confirm that patient has done a home urine pregnancy test.
2. Rule out contraindications:
 - IUD in place (may be removed by patient³ or provider prior to medication abortion)
 - Allergy to prostaglandins or mifepristone
 - Chronic renal failure
 - Long-term systemic corticosteroid therapy
 - Hemorrhagic disorders
 - Concurrent anticoagulant therapy (excluding aspirin)
3. Ensure that the patient has access to a telephone and agrees to a follow-up call 24 hours after the misoprostol administration.
4. Obtain gestational dating. If patient is uncertain about last menstrual period (LMP), has irregular menstrual cycles, or clinician is concerned about ectopic pregnancy (risk factors include history of previous ectopic pregnancy, vaginal bleeding since LMP, adnexal pain, IUD in place, history of tubal surgery, and history of treatment for PID), an ultrasound will need to be obtained. Ultrasound examination should also be performed if the LMP places the pregnancy at >11 weeks (77 days). If last menstrual

³ Foster, Diana Greene, et al. "Interest in and experience with IUD self-removal." *Contraception* 90.1 (2014): 54-59.

period was >70 days and <77 days, ordering an ultrasound is at the discretion of the clinician. If ultrasound is not indicated, gestational dating should be done by LMP.^{4,5,6}

5. Discuss Rh status if pregnancy >8 weeks. If patient is Rh negative, recommend offering Rh immunoglobulin (50mcg dose). If patient is Rh unknown, recommend ordering Rh typing with discussion of Rh immunoglobulin if Rh negative. If patient known to be Rh positive, no labs necessary.⁷

Review the required provider/patient agreement and the consent form. This can be done verbally, via a screen where patient can see the forms, or by giving the patient a paper copy of the consent forms. Obtain either verbal or written consent (there may be different requirements by state).

Determine if the patient can be mailed the pills or if picking them up is the only option.
If mailing is an option: the mifepristone 200-milligram tablet and 4 to 8 tablets of misoprostol should be put into envelopes and mailed to the patient's home or preferred address. If possible, a urine pregnancy test for the follow up testing should be mailed as well, with the take home instructions and a copy of the consent.

Buccal administration: The patient will administer four 200-microgram misoprostol tablets, holding two in each cheek for 30 minutes and then swallowing them with a drink, at a convenient time 24-48 hours after taking mifepristone.⁸

Vaginal administration: The patient will place four 200-microgram misoprostol tablets in the vagina 6 – 72 hours after taking the mifepristone. The patient will then lie down for 30 minutes. If the tablets fall out after 30 minutes, they can be discarded.⁹

Sublingual administration: Four 200-microgram misoprostol tablets are placed under the tongue 24 hours after taking the mifepristone. They are allowed to dissolve for 30 minutes and then the remains are swallowed with a drink.¹⁰

⁴ Bracken, H., et al. "Alternatives to routine ultrasound for eligibility assessment prior to early termination of pregnancy with mifepristone–misoprostol." *BJOG: An International Journal of Obstetrics & Gynaecology* 118.1 (2011): 17-23.

⁵ Raymond, Elizabeth G., et al. "Simplified medical abortion screening: a demonstration project." *Contraception* 97.4 (2018): 292-296.

⁶ Royal College of Obstetricians & Gynecologists. "Coronavirus (COVID-19) infection and abortion care." Version 1: published March 21, 2020.

⁷ National Abortion Federation. *Clinical Policy Guidelines* 2020.

⁸ Chen, Melissa J., and Mitchell D. Creinin. "Mifepristone with buccal misoprostol for medical abortion: a systematic review." *Obstetrics & Gynecology* 126.1 (2015): 12-21.

⁹ Schaff EA, Fielding SL, Westhoff C, Ellertson C, Eisinger SH, Stadius LS, et al. Vaginal misoprostol administered 1, 2, or 3 days after mifepristone for early medical abortion: A randomized trial. *JAMA* 2000;284:1948-53.

If pregnancy is at 63-77 days, a second dose of misoprostol is recommended to increase efficacy. This should be utilized four hours after first dose of misoprostol.

Advise patient on use of pain medications: Prescriptions for acetaminophen with a narcotic and/or Ibuprofen 800 milligrams should be offered to the patient. Patients should be encouraged to fill the prescription/s in advance and to have the pain medications on hand to be taken as needed.

Make sure patient knows how to reach clinician on-call. An information sheet with instructions about how to call or page the provider should be sent with the pills to each patient, and the information should be reviewed during the counseling to be sure they understand. **The clinician should call the patient to assure that bleeding happened within 24 hours of using the misoprostol**, and a plan should be made for an urgent ultrasound if this did not happen. If the patient had the expected cramping and bleeding and now feels not pregnant anymore, the clinician and patient should make a plan for a home urine pregnancy test in 3-4 weeks.^{11,12} If that test is positive, the test can be repeated in one week or an ultrasound can be gotten urgently, depending upon the history and symptoms.

Review plans for post-abortion contraception: Patients who choose combination hormonal contraceptives (oral, patch, ring) may begin the method as soon as the next day or on the most convenient day after taking misoprostol – even if bleeding persists. Depo may be prescribed for subcutaneous use. The implant or IUD insertion can take place at a follow-up visit if desired and a bridge method can be prescribed until that time. Patients may begin to have vaginal sex with barrier contraception after 72 hours. Patients who choose tubal ligation should be referred as appropriate to avoid delays, with a bridge method for the wait time.

Further follow-up

Patients should be instructed to call or return if bleeding persists beyond 4 weeks or becomes heavy again.

¹⁰ Von Hertzen, H., et al. "Misoprostol dose and route after mifepristone for early medical abortion: a randomised controlled noninferiority trial." *BJOG: An International Journal of Obstetrics & Gynaecology* 117.10 (2010): 1186-1196.

¹¹ Perriera LK, Reeves MF, Chen BA, Hohmann HL, Hayes J, Creinin MD. Feasibility of telephone follow-up after medical abortion. *Contraception*. 2010;81(2):143-9.

¹² Chen MJ, Rounds KC, Creinin MD, Casino C, Hou MY. Comparing office and telephone follow-up after medical abortion. *Contraception*. 2016;94(2):122-126.