

ISSUE BRIEF, AUGUST 2016

Safety and effectiveness of first-trimester medication abortion in the United States

Quick facts about medication abortion:

- Medication abortion is extremely safe.
- Serious adverse events occur in less than one-third of one percent of medication abortions.
- Medication abortion is highly effective, with a success rate over 95 percent.
- Telemedicine, self-administration, and provision by non-physician clinicians have been shown to be safe, effective, and acceptable.

Since mifepristone was first approved in 2000, state legislatures have passed a number of laws that restrict access to medication abortion. These include limitations on the types of providers that can offer medication abortion, whether medication abortion can be provided through telemedicine, and home self-administration, as well as requirements that providers use the U.S. FDA (Food and Drug Administration)-approved regimen for medication abortion, which was outdated until a March 2016 update.

Overview of medication abortion

Medication abortion is also known as medical abortion, the abortion pill, or RU486. It involves the use of two types of medications: mifepristone, which blocks progesterone needed for a pregnancy to continue, and misoprostol, which causes uterine contractions and the cervix to open to induce an abortion. Medication abortions comprise an estimated 23% of all nonhospital abortions in the US.¹ While the mifepristone is generally provided in a clinic setting and the misoprostol is provided to the patient to be taken at home, evidence shows that home administration of both mifepristone and misoprostol is safe, effective, and acceptable. Allowing patients to take one or both medications at home can accommodate personal schedules and circumstances and improve efficiency in the healthcare system.^{2,3}

Additionally, follow-up evaluation to rule out ongoing pregnancy is important, but may not require a clinic visit.⁴

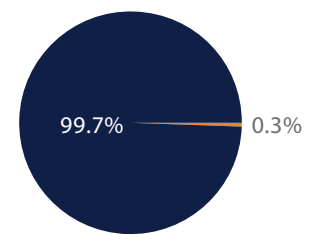
The 2016 FDA-approved regimen for medication abortion is highly safe and effective up to 10 weeks of pregnancy; different medication abortion regimens are effective later in pregnancy. Most people having a medication abortion will experience heavy bleeding and cramping. Side effects can include nausea, vomiting, diarrhea, headache, dizziness, and fever, but these are generally tolerable and resolve without medical treatment.⁴⁻⁸

Research findings on medication abortion safety and effectiveness

Medication abortion is extremely safe.

- Serious adverse events—cases requiring blood transfusion, surgery, or hospital admission—are rare with medication abortion. Multiple studies have found that such events occur in less than 0.5% of medication abortions in the United States.^{5,9-12}

- ANSIRH researchers analyzed data for 11,319 medication abortions in the California Medicaid system. This study was unique in that it captured all health care claims up to six weeks after the abortion at any clinical site, including emergency rooms and hospitals, and immediate and delayed adverse events. The study found that only 0.3% of medication abortions had a serious adverse event.⁹



- Sometimes a medication abortion is not effective and the abortion is incomplete. Some studies consider such unsuccessful abortions as adverse events, but these are usually not serious, rarely requiring blood transfusion, surgery, or hospital admission (see “Medication abortion is highly effective,” next page).
- Medication abortion is safer than many common drugs in the US, including acetaminophen (Tylenol) or sildenafil (Viagra).^{13,14}

For more information about this research and other ANSIRH work, please visit www.ansirh.org.

Medication abortion is highly effective.

- The success rate of medication abortion is 95% or higher for pregnancies up to 10 weeks.^{6,9,11}
- Additional treatments that may be required are repeat doses of mifepristone *and* misoprostol, additional doses of misoprostol, or in-clinic vacuum aspiration.
- ANSIRH research found that among 11,319 medication abortions, 5% required the use of an in-clinic vacuum aspiration procedure or additional medications to complete the abortion.⁹
- Medication abortion is slightly less effective in pregnancies at higher gestations.^{6,11}

Research continues to expand the provision of medication abortion

- After a 2011 Ohio law restricted medication abortion to the original FDA regimen, women had three times the odds of requiring additional medical treatments to complete the abortions, compared to women receiving the evidence-based regimen pre-law.¹⁵
- The FDA updated the regimen for medication abortion in March 2016 to be consistent with evidence-based standards of maximum gestational age, mifepristone and misoprostol dosage, misoprostol timing and location, and follow-up period.¹⁶ See Table 1, below.
- Telemedicine can make medication abortion more accessible by reducing barriers of distance to a provider, transportation, and affordability.^{17,18} Currently 18 states prohibit telemedicine for medication abortion.¹⁹
- Thirty-seven states mandate that a physician must administer the pills for a medication abortion.¹⁹ However, research has demonstrated that medication abortion can be administered safely by trained health professionals, such as physician assistants, nurse practitioners, certified nurse midwives and other advanced practice clinicians, which may improve access to medication abortion services.²⁰

References

- Jones RK, Jerman J. Abortion incidence and service availability in the United States, 2011. *Perspect Sex Reprod Health*. Mar 2014;46(1):3-14.
- Swica Y, Chong E, Middleton T, Prine L, Gold M, Schreiber CA, Winikoff B. Acceptability of home use of mifepristone for medical abortion. *Contraception*. Jul 2013;88(1):122-127.
- Chong E, Frye LJ, Castle J, Dean G, Kuehl L, Winikoff B. A prospective, non-randomized study of home use of mifepristone for medical abortion in the U.S. *Contraception*. Sep 2015;92(3):215-219.
- American College of Obstetricians and Gynecologists. Practice bulletin no. 143: medical management of first-trimester abortion. Mar 2014.
- Gatter M, Cleland K, Nucatola DL. Efficacy and safety of medical abortion using mifepristone and buccal misoprostol through 63 days. *Contraception*. Apr 2015;91(4):269-273.
- Winikoff B, Dzuba IG, Chong E, Goldberg AB, Lichtenberg ES, Ball C, Dean G, Sacks D, Crowden WA, Swica Y. Extending outpatient medical abortion services through 70 days of gestational age. *Obstet Gynecol*. Nov 2012;120(5):1070-1076.
- Winikoff B, Dzuba IG, Creinin MD, Crowden WA, Goldberg AB, Gonzales J, Howe M, Moskowitz J, Prine L, Shannon CS. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. *Obstet Gynecol*. Dec 2008;112(6):1303-1310.
- WHO. *Clinical Practice Handbook for Safe Abortion*. Geneva: World Health Organization; 2014.
- Upadhyay UD, Desai S, Zlidar V, Weitz TA, Grossman D, Anderson P, Taylor D. Incidence of emergency department visits and complications after abortion. *Obstet Gynecol*. Jan 2015;125(1):175-183.
- Cleland K, Creinin MD, Nucatola D, Nshom M, Trussell J. Significant adverse events and outcomes after medical abortion. *Obstet Gynecol*. Jan 2013;121(1):166-171.
- Raymond EG, Shannon C, Weaver MA, Winikoff B. First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. *Contraception*. Jan 2013;87(1):26-37.
- Ireland LD, Gatter M, Chen AY. Medical compared with surgical abortion for effective pregnancy termination in the first trimester. *Obstet Gynecol*. Jul 2015;126(1):22-28.
- Ostapowicz G, Fontana RJ, Schiodt FV, Larson A, Davern TJ, Han SH, McCashland TM, Shakil AO, Hay JE, Hynan L, Crippin JS, Blei AT, Samuel G, Reisch J, Lee WM. Results of a prospective study of acute liver failure at 17 tertiary care centers in the United States. *Annals of Internal Medicine*. Dec 17 2002;137(12):947-954.
- Mitka M. Some men who take Viagra die—why? *JAMA*. Feb 2 2000;283(5):590, 593.
- Upadhyay UD, Johns NE, Combellick SL, Kohn JE, Keder LM, Roberts SCM. Comparison of outcomes before and after Ohio's law mandating use of the FDA-approved protocol for medication abortion: a retrospective cohort study. *PLOS Med*. 2016;13(8).
- FDA. Mifeprex (mifepristone) Information—Postmarket Drug Safety Information for Patients and Providers. 2016.
- Grossman D, Grindlay K, Buchacker T, Lane K, Blanchard K. Effectiveness and acceptability of medical abortion provided through telemedicine. *Obstet Gynecol*. Aug 2011;118(2 Pt 1):296-303.
- Grossman DA, Grindlay K, Buchacker T, Potter JE, Schertmann CP. Changes in service delivery patterns after introduction of telemedicine provision of medical abortion in Iowa. *American Journal of Public Health*. Jan 2013;103(1):73-78.
- Guttmacher Institute. *State Policies in Brief: Medication Abortion*. New York: Guttmacher Institute; April 1 2016.
- Berer M. Provision of abortion by mid-level providers: international policy, practice and perspectives. *Bulletin of the World Health Organization*. Jan 2009;87(1):58-63.

Table 1. Comparison of 2000 and 2016 FDA-approved regimens for medication abortion

	2000 FDA-approved regimen	2016 FDA-approved regimen
Maximum gestation	7 weeks of pregnancy	10 weeks of pregnancy
Mifepristone dose	600 mg orally in office	200 mg orally in office
Misoprostol dose	400 µg orally (2 tablets)	800 µg vaginally or buccally* (4 tablets)
Misoprostol timing	48 hours after mifepristone	6–72 hours after mifepristone
Misoprostol location	In clinic	At home
Follow-up visit	14 days after mifepristone	5–14 days after mifepristone
Minimum number of office visits†	3	1

Source: U.S. Food and Drug Administration

* Buccal administration involves placing two tablets of 200 µg misoprostol in each cheek (total of 4 tablets) for 30 minutes

† Depending on state requirements, additional counseling visits may be required before the abortion appointment