

Medication Abortion: Overview of Research & Policy in the United States

Key Points for Policymakers

Medication abortion (also called medical abortion) is a safe method of abortion available for the past 15 years in the United States. In the US, a woman who has a medication abortion generally takes two medications: mifepristone, which halts the pregnancy by initiating the breakdown of the endometrium, followed by misoprostol, which leads to contractions and emptying of the uterus.

In 2000, Mifeprex© (the brand name for mifepristone) was approved in the United States for use in medication abortion, following years of approved use in Europe. Misoprostol had been previously approved in the US for other uses. The US Food and Drug Administration (FDA) has not approved any other abortion drugs besides Mifeprex. The Mifeprex approval came with requirements that affect both patients and providers, and that are far more specific than typical requirements for prescription drugs. The product label indicates procedures, including doses and timing, for mifepristone prescribers to follow; these were based on the regimen used during the drug's pre-approval clinical trials in the 1980s and 1990s.

Researchers have studied the safety and efficacy of Mifeprex, as well as the medication abortion process as a whole, both around the world and in the US. Their findings reveal that the protocol set out in the FDA Mifeprex label does not reflect current practice for safe and effective medication abortion and label revisions are needed.

In December 2015, the Jacobs Institute of Women's Health published a white paper summarizing the scientific evidence related to the current medication abortion process and the potential changes to the process that could make it even safer and more accessible for patients. The full white paper also identifies policy considerations and directions for future research. This overview document summarizes key information for policymakers from that white paper. The full paper, including additional detail about research to support the information included in this summary, is available at <http://bit.ly/1Or54En>.

OVERVIEW OF MEDICATION ABORTION

In 2011, nearly 240,000 medication abortions were performed in the US, out of 1.06 million total abortions. Since Mifeprex was approved in 2000, medication abortion has accounted for a growing share of US abortions, increasing from 14% of non-hospital procedures in 2005 to 23% in 2011. Ninety percent of clinics that provide abortion care offered medication abortions in 2011, and 17% of all non-hospital abortion providers offered only medication abortions (Jones & Jerman, 2014).

The cost of a medication abortion is generally similar to the cost of a surgical abortion, at comparable gestations; in 2011 and 2012, the median charge was \$500 for a medication abortion and \$495 for a surgical abortion (Jerman & Jones, 2014).

Safety and Efficacy. Medication abortion is a safe and effective process.

The CDC began collecting data on mortality from medication abortion in 1997 and noted no deaths among over 6,000 women using mifepristone during clinical trials (Beal, 2007). Since approval, mifepristone’s safety record has remained strong overall; the mortality rate for medication abortion is approximately 1 per 100,000, which is slightly higher than the mortality rate for surgical abortion but significantly lower than the maternal mortality rate for women bringing their pregnancies to term (9.8 per 100,000) (Beal, 2007).

After taking both mifepristone and misoprostol, women can expect heavy bleeding and cramping. In rare situations, some women need to seek medical attention to address very severe bleeding and cramping, infection, or the failure to terminate the pregnancy.

Studies of medication abortion find that between 95% and 98% of cases result in complete termination of the pregnancy. These outcomes may vary slightly depending on the exact regimen used but are similar to success rates for surgical abortion (Bartz & Goldberg, 2009).

FDA Approval of Mifeprex: Conditions of Approval and the Drug Label. Mifepristone was first approved for use in France in 1988 (Jones & Henshaw, 2002). In the US, Danco Laboratories, LLC first submitted Mifeprex for FDA approval in 1996, after a long delay and opposition by anti-abortion advocates and policy-makers. The approval process took approximately four years and included three review cycles (GAO, 2008).

As part of the approval conditions established in 1996, physicians who intend to offer medication abortion must sign a prescriber’s agreement and must meet certain criteria, including the ability to manage complications (GAO, 2008). Patients must also sign a patient agreement before they can receive the medications. Additionally, the FDA-approved Mifeprex label specifies that it is only for pregnancies of up to 49 days gestation, and that providers may determine pregnancy duration from menstrual history and clinical exam, with an ultrasound used if gestational duration is uncertain or ectopic pregnancy is suspected (FDA, 2005).

The label specifies that treatment requires three office visits and that “Mifeprex may be administered only in a clinic, medical office, or hospital, by or under the supervision of a physician.” On the first visit, the patient would sign the patient agreement and receive a 600 mg oral dose of Mifeprex. On the second visit two days later, she would take 400 µg of misoprostol orally. On the third visit approximately 14 days after the first one, she would return for a follow-up visit at which complete termination of the pregnancy is confirmed by clinical examination or ultrasound (FDA, 2005). In states that require a waiting period between a first visit and the initiation of medication abortion, following the FDA label’s protocol requires four visits.

EVIDENCE-BASED PROTOCOLS FOR MEDICATION ABORTION

US providers began adopting evidence-based regimens that varied from the FDA label soon after the agency approved Mifeprex. These variations – technically considered “off-label” – do not adhere to all the specifications of the FDA label but are supported by substantial evidence. (Describing these variations as “evidence-based” is not meant to suggest that the FDA label is

not based on evidence; rather, it serves to distinguish between the FDA-approved regimen and the off-label regimens, which do not currently have FDA approval but do have a substantial evidence base from more recent studies conducted after Mifeprex's approval.)

Different Dosage. The use of 200 mg of mifepristone, rather than the 600 mg specified in the FDA label, is recommended by the World Health Organization, the American College of Obstetricians and Gynecologists (ACOG), the Society of Family Planning, and the Planned Parenthood Federation of America (Cleland & Smith, 2015). A 2014 ACOG practice bulletin notes that regimens using 200 mg of mifepristone “have similar efficacy and lower costs” than those involving 600 mg. It also states, “Based on efficacy and the adverse effect profile, evidence-based protocols for medical abortion are superior to the FDA-approved regimen” (Committee on Practice Bulletins—Gynecology and the Society of Family Planning, 2014). The use of 800 µg of misoprostol, rather than the 400 µg in the FDA label, is also common (Committee on Practice Bulletins—Gynecology and the Society of Family Planning, 2014).

Shorter Time Intervals Between Medications. The FDA label specifies that the interval between administration of the two drugs should be 48 hours, but evidence demonstrates shorter intervals are safe and effective. A 2010 systematic review and meta-analysis of the time interval between administration of mifepristone and misoprostol found no statistically significant differences in overall efficacy between intervals as long as 72 hours and as short as 8. There was a trend toward a lower success rate when dosing intervals were shorter than 8 hours (Wedisinghe & Elsandabesee, 2010). Allowing women to determine the interval within that range that is best for them improves flexibility for patients and clinicians.

Different Route of Administration of Misoprostol. Misoprostol can be taken orally (swallowed), buccally (held in the cheek to dissolve), sublingually (held under the tongue to dissolve), or vaginally (manually inserted into the vagina). The route of administration influences how the drug is metabolized and the peak concentration it can reach in the bloodstream. The FDA-approved label specifies oral administration. However, clinical trials found that oral and buccal administration are similarly effective for pregnancies of up to 49 days (Winikoff et al., 2008), and buccal and sublingual routes are equally effective in women with pregnancies of up to 63 days (Chai, Wong, & Ho, 2013).

Longer Gestational Limits. While the FDA label specifies that medication abortions may be performed for pregnancies of up to 49 days since the last menstrual period, several large studies demonstrate the safety and efficacy of the evidence-based protocol for gestations of up to 70 days (Abbas, Chong, & Raymond, 2015; Bracken et al., 2014; Sanhueza Smith et al., 2015; Winikoff et al., 2012).

Home Use of Misoprostol. The FDA label specifies that women should return to their providers to receive misoprostol in person, but large studies have evaluated different protocols in which the provider gives a woman the misoprostol to take at home. These confirmed high rates of safety and efficacy for home use (Cleland et al., 2013; Gatter, Cleland, & Nucatola, 2015).

Non-Physician Providers. The FDA label requires that mifepristone be administered “by or under the supervision of a physician” (FDA, 2005). Attorneys general and health departments in some states have interpreted this clause as allowing mid-level providers (MLPs) such as nurse practitioners (NPs), certified nurse-midwives (CNMs), and physician assistants (PAs) to provide medication abortion; one state, California, has passed a law specifically authorizing MLPs to provide medication abortions (Samora & Leslie, 2007; Weitz et al., 2013). MLPs, also referred to as advanced-practice clinicians, are increasingly involved in medication abortions in Denmark, France, Great Britain, and Sweden; in the US at some clinics, MLPs handle the entire medication abortion process (Yarnall, Swica, & Winikoff, 2009).

Medication abortions result in similar safety and efficacy profiles for both MLPs and physicians (Barnard et al., 2015). Ensuring that MLPs have the legal authority and training to provide medication abortions can increase access to safe abortion services in areas with few physicians, such as rural areas where advanced practice clinicians but not obstetricians or gynecologists are located (Foster et al., 2015; Taylor, Safriet, & Weitz, 2009). It can also enhance the cost-effectiveness of abortion care and allow providers to offer services to more women (Yarnall, Swica, & Winikoff, 2009).

Telemedicine. In the years since Mifeprex was approved in the United States, the use of telemedicine has grown significantly; today, approximately 10 million patients receive telemedicine services in the US each year. In 2008, the Iowa clinic network Planned Parenthood of the Heartland began offering medication abortion by telemedicine at clinic sites not staffed by physicians. A study comparing telemedicine patients and face-to-face patients in Iowa found that the two methods had equivalent success rates and few adverse events (Grossman, Grindlay, Buchacker, et al., 2011). A study of data on all abortions in the state during the two years before and two years after the telemedicine option was introduced found that clinic patients had an increased odds of obtaining either form of abortion before 13 weeks’ gestation (Grossman et al., 2013), and interviews with abortion patients and clinic staff found that many who chose telemedicine abortions did so because they could visit a closer facility and initiate an abortion more quickly (Grindlay, Lane, & Grossman, 2013).

REGIMEN VARIATIONS IN PRACTICE AND IN RESEARCH

Where there is robust evidence of safety and efficacy, some variations in the medication abortion regimen are already common among abortion providers. Ongoing research into other regimen variations aims to identify practices that can provide women with improved access to safe and effective abortion care while accommodating their preferences and safeguarding their privacy and dignity.

The evidence-based protocols most common in current clinical practice involve 200 mg of Mifeprex (rather than 600 mg) (Cleland & Smith, 2015) followed by 800 µg of misoprostol that women take at home rather than in a provider’s office (Clark, Gold, et al., 2007; Cleland et al., 2013; Wiegerinck et al., 2008). The interval between mifepristone and misoprostol dosage and

the route of administration may also vary – e.g., a woman may take misoprostol buccally and may do so one day after mifepristone rather than two.

Providers may also offer medication abortions later in pregnancies, with most providers currently using 63 days as the cutoff where permitted by state law (Jones & Jerman, 2014). Depending on state laws, medication abortions may be performed by mid-level providers

Home use of misoprostol, which eliminates the second of the three visits specified in the FDA label, is also common (Clark, Gold, et al., 2007; Cleland et al., 2013; Wiegerinck et al., 2008), and researchers are exploring ways to simplify or eliminate the initial visit and follow-up visit to further reduce barriers (Chong et al., 2015; Gold & Chong, 2015; Swica et al., 2013).

Provision of medication abortions via telemedicine or by providers not currently offering the service would improve access in areas where it is currently limited. Some advocates also suggest the safe and informed use of misoprostol alone for women who lack access to abortions with the mifepristone-misoprostol combination. While misoprostol alone is less effective than the two-drug combination, its efficacy is still high, and this regimen is used extensively in other countries where mifepristone is unavailable.

Reducing barriers to medication abortion can allow more women to receive abortion services early in their pregnancies, when risks are lowest, and may also lower costs and improve efficiency. However, several current and proposed policies create barriers to the adoption of evidence-based practices that improve access.

STATE-LEVEL MEDICATION ABORTION POLICIES

The number and type of restrictive abortion policies have been increasing over the last several years. These policies can affect one or more aspects of the medication abortion process, including the type of provider allowed to provide medication abortion, the exact protocol that must be followed, and the communication between a clinician and a patient.

Protocol and Clinician Restrictions. As of September 2015, 38 states allow only licensed physicians to provide medication abortion,¹ and 18 states require that the clinician be physically present for the medication abortion process (Guttmacher Institute, 2015b). These restrictions prohibit mid-level providers, such as physician assistants, nurse practitioners, and certified nurse midwives, from prescribing Mifeprex, despite significant evidence that these advanced practice clinicians can safely and effectively provide the same quality of care as physicians. Three states require medication abortion to be provided according to the FDA label, prohibiting any deviation from the protocol currently described in the FDA label, unless FDA approves a label change – or unless a state’s law specifies that certain variations are allowed.

¹ 38 states also allow only licensed physicians to provide surgical abortion. The states only limiting a single type of abortion are New Jersey (limits only surgical abortions) and Colorado (limits only medication abortions).

The cost of the abortion can be higher when clinics must use the higher doses of Mifeprex in the FDA protocol (the drug is not available in generic form), must pay for physician services rather than those of a MLP (who is typically compensated at a lower rate than a physician), and must see women for at least three visits (four visits in those states that also require an additional waiting period).

Telemedicine Restrictions. Some restrictions, such as those requiring the physician to be physically present, effectively prohibit the use of telemedicine for the medication abortion process. The telemedicine option may become increasingly important if more clinics providing abortion are required to close due to additional state laws designed to reduce abortion availability. Where it is not prohibited, telemedicine can present a promising option for women in rural or other health professional shortage areas, where travelling to a clinic for multiple visits may require days off from work or even overnight stays hundreds of miles from home.

Required Counseling on “Reversal.” In addition to restricting the ways in which providers can offer medication abortion, some states have introduced or passed legislation mandating that providers tell patients it may be possible to reverse a medication abortion after they have taken the initial dose of drugs. The claim is that, if a woman is treated with progesterone after taking mifepristone and before taking misoprostol, she might halt the abortion process and allow her pregnancy to continue.

Progesterone is a naturally occurring hormone, and synthetic versions of it are used during pregnancy for several established and tested clinical purposes. These include prevention of preterm birth and supplementing other hormones used in assisted reproductive technologies (Grossman, White, Harris, et al., 2015). However, there is virtually no credible evidence to support the claim that progesterone can reverse a medication abortion. A recent systematic literature review found only one article that examined the question of medication abortion reversal, and its methods are highly flawed. In more rigorous studies of taking mifepristone alone (but not taking either misoprostol or progesterone), the proportions of participants with continuing pregnancies ranged from 8-46% (Grossman, White, Harris, et al., 2015). This finding is important to mention because women who had no additional intervention after taking mifepristone (e.g., no progesterone) may have been likely to *continue* their pregnancies in nearly half of all cases. Thus, these continuing pregnancies seen by women who did take progesterone cannot be assumed to be due to *reversing* the effects of mifepristone, as claimed by the original study authors.

Yet, despite the lack of an evidence base, both Arizona and Arkansas have enacted laws requiring that women receive information on reversing abortion (HB 1578), and legislators in Louisiana have announced their intention to introduce similar bills (Resnick, 2015; Wilson, 2015). The Arizona law has been temporarily enjoined because of a pending lawsuit filed in federal court (Guttmacher Institute, 2015a).

Looking forward, there are clear needs for ongoing research and policy change to ensure that women benefit from the best available information and high-quality medical care.

Directions for Future Research. Significant evidence exists on multiple ways to improve medication abortion services, from dosage and timing of each drug to new directions for follow-up care. However, some gaps in the research persist, including provision by MLPs in the US and identification of the most effective alternatives to multiple in-person visits. Information about methods and outcomes of attempted self-induced abortion will be especially important as more state-level abortion restrictions take effect. Additionally, research into these restrictions will be essential for documenting the impacts on access, costs, other hardships, and the health for women who seek both medication and surgical abortions. Further research is also needed to explore the impact that medication abortion has had on access to abortion care more generally. The number of abortion providers has declined in recent years, as has the abortion rate. How has availability of medication abortion interacted with other developments, such as new legal restrictions on abortion care broadly, to affect these trends? Do extensive label requirements (provider agreement, rigid protocol, etc.) pose a challenge for uptake among providers and decisions by patients?

Advocacy for Label Change. Informed by the robust body of evidence regarding the safety and efficacy of mifepristone, reproductive health advocates are making a case that current FDA restrictions on distribution of the drug make medication abortion far more complicated and heavily medicalized in the United States than is necessary to ensure the health and safety of women using the drug. They argue that the drug regimen outlined on the US mifepristone label actually serves as a barrier to providing the highest standard of medication abortion care to women and have begun to call on FDA to update the mifepristone label to reflect the current evidence. Additionally, they are urging FDA to eliminate unnecessary regulatory barriers so that medication abortion can be provided in the ways that are safest, most effective, and most responsive to women's needs.

Specifically, advocates support updating the mifepristone dose on the drug label to 200 mg, which has been shown to be the safest, most effective dose (Cleland & Smith, 2015). They also call for the label to state that mifepristone has been shown to be effective when used up to 70 days gestation instead of the 49 days on the label today (Abbas, Chong, & Raymond, 2015). They point out that the label specification that patients make three office visits and complete extensive follow up imposes unnecessary medical costs as well as logistical burdens on women seeking medication abortions (Cleland & Smith, 2015; Raymond, Grossman, et al., 2015). Furthermore, they argue that FDA should eliminate mifepristone's Risk Evaluation and Mitigation Strategy (REMS) and the associated Elements to Assure Safe Use (ETASU), which were established based on the regimen used in the clinical trials the agency reviewed at the time of the drug's approval.

To comply with the ETASU, a provider has to sign a special prescriber agreement with the drug distributor and have each potential user of mifepristone sign a patient agreement stating that she will take the drug according to the regimen on the label. The ETASU also restricts the location where the drug can be administered to medical facilities, limiting dispensation to medical facilities. Advocates contend there is strong evidence that these requirements are not commensurate with mifepristone's risks and that they create unnecessary barriers to patient access to the drug (Cleland & Smith, 2015).

Without those medically unsupported regulatory hurdles, a wider range of providers would be able to offer medication abortion, potentially increasing access for women who are currently not able to obtain abortion care.

For more details on policy barriers and evidence-based medication abortion regimens, download the complete white paper at <http://bit.ly/1Or54En>.

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