
Self-Managed Abortion Statement

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BACKGROUND

Physicians for Reproductive Health (Physicians) unites the medical community and concerned supporters. Together in 2009, the Physicians Board conducted a rigorous review of the science to create an institutional policy statement on self-administration. However, the position recommended then only examined using misoprostol alone as an abortifacient to self-induce in the U.S. Based on the evidence then, the Board's 2009 position on self-administered abortion was the following:

“Misoprostol alone is less effective than combination drug regimens for termination of pregnancy, and the safety of self-administered misoprostol outside a medical setting is unclear, especially after the first trimester. Therefore, Physicians does not advocate for use of a self-administered misoprostol regimen where more effective, safer methods are available.

In circumstances where abortion access is severely restricted, self-administration of misoprostol may be reasonable as a less harmful alternative to the morbidity and mortality associated with illegal, clandestine abortion by other means.

Physicians should continue to assure as its first priority that all women have access to the safest, state-of-the-art care for reproductive health and abortion services, so that women do not resort to less effective or less safe means of family planning.”

The purpose of this paper is to provide the Physicians Board with an up-to-date review of the medical and scientific evidence since 2009, in order to make recommendations regarding on what terms our organization should engage in advocacy around self-managed abortion.

Despite continued legal protection under *Roe v. Wade*, access to abortion services remains an ongoing challenge in the US, especially in light of the current political climate that is increasingly hostile to abortion at both state and federal levels. According to the Guttmacher Institute, ninety percent of all U.S. counties lacked a clinic that provides in 2014, and 39% of women of reproductive age lived in those counties.² In Texas alone, following the passage of H.B.2, the number of clinics decreased by more than half, and there was an increase in the number of women who were forced to travel out of state in order to obtain abortion care.^{3,4}

The technical legality of abortion does not guarantee access and some individuals prefer to avoid interaction with medical professionals due to stigma, fear of deportation, distrust of the medical system, previous negative experience, and other factors. For this reason, access to mifepristone and misoprostol⁵ for self-induction of abortion has been proposed as a solution by advocacy groups like Women on Web, Self-Induced Abortion Legal Team, and Women Help Women.⁶

There is not much literature for review in the U.S. on self-induced abortion with the FDA approved regimen of mifepristone and misoprostol; however, some international studies have confirmed the safety and efficacy of self-administered mifepristone and misoprostol abortion without compromise in patient satisfaction. That much of the available evidence is from international studies is likely a result of a lack of legal protection, less-developed healthcare infrastructure, and/or strong cultural stigma. These factors result in people seeking abortion care outside of a regulated standard of care model, and serve as a driver for research and innovation to establish channels for safe abortion care where it isn't

currently available due to illegality or medical infrastructure issues. In the U.S., there is comparatively limited evidence that self-administered medication abortion without the involvement of a healthcare provider is safe and feasible.

This paper presents the domestic and international data on self-induction with medication abortion. In considering Physicians' position on self-administered abortion, we posit that the areas in the U.S. where abortion access is very restrictive closely resemble countries where abortion is either illegal and/or where there are strict abortion laws or bans.

Medication Abortion Timeline

Medication abortion was initially “discovered” by women in Brazil who used off-label misoprostol for induction of late menses.⁷ Misoprostol is a prostaglandin analogue that was FDA-approved in 1989 for the prevention and treatment of peptic ulcers. It has many off-label uses, including treatment of postpartum hemorrhage, management of failed pregnancy, and induction of labor. In the setting of medication abortion, misoprostol causes uterine contractions that help expel the pregnancy.

Mifepristone, also known as RU-486, is a medication that blocks the action of the hormone progesterone. Progesterone is needed to sustain a pregnancy. In the U.S., mifepristone is used in combination with misoprostol for induction of medication abortion.

First available in France and China in the 1980s, mifepristone was approved by the Food and Drug Administration after many years of evaluation in 2000 under the brand name Mifeprex[®]. Misoprostol, (brand name Cytotec[®]) had been available in the U.S. since 1988 to prevent gastric ulcers in persons taking non-steroidal anti-inflammatory drugs (NSAIDs) like ibuprofen. In the early 1990s, clinicians began using misoprostol off label for labor induction.⁸ In 2002, the FDA updated the label for Cytotec[®] to specify that the contraindication to use in pregnancy refers specifically to pregnant patients taking it for the prevention of gastric ulcers, in order to warn against accidental use in pregnant women but allow for evidence-based off-label uses related to pregnancy. Furthermore, the FDA also created a new “Labor and Delivery” section of the label that acknowledged its use for cervical ripening, labor induction, and for treatment of serious postpartum hemorrhage in the presence of uterine atony.⁹

The original FDA label reflected the protocol used in U.S. clinical trials, but did not take into account subsequent studies. The 2000 FDA label approved mifepristone for use in medication abortion up to 49 days since last menstrual period (LMP). The approved regimen specified 600mg oral mifepristone on day 1 and 400 µg oral misoprostol on day 3, both to be administered in a healthcare facility. Mifepristone was originally approved under Subpart H of FDA regulations which enabled FDA to establish a restricted distribution system.¹⁰ This restricted distribution system is applied when the agency feels that a drug with demonstrated efficacy can only be used safely if additional post-marketing restrictions are put in place. Subpart H was invoked late in the process and after an approval letter had been issued. Today the restricted distribution system is part of the Risk Evaluation and Mitigation Strategy (REMS), which was started in 2007 and requires manufacturers to develop a strategy for certain drugs to “ensure that the benefits of a drug or biological product outweigh its risks”.¹¹ Mifepristone is one of approximately 70 drugs that require this additional level of regulation, and individual REMS plans vary from drug to drug.¹¹

For mifepristone, the REMS stipulates that only qualified healthcare providers may order and distribute; it is not available through pharmacies; providers must register and sign a provider agreement, and patients must sign a patient agreement.

In November 2004 and July 2005, the FDA label for mifepristone was revised to include information about infection and sepsis, vaginal bleeding, and ectopic pregnancy. There were six deaths from

clostridium infections in women who had taken mifepristone and vaginal misoprostol and one death from an ectopic pregnancy.¹⁰ However, no causal relationship was established between the clostridium infections and medication abortion.

In 2016, the FDA label was again updated to reflect years of study that had occurred since the original U.S. clinical trials. The current label, for use up to 70 days LMP, specifies a dose of 200mg oral mifepristone on day 1 and 24-48 hours later a dose of 800 mcg buccal misoprostol at a location appropriate for the patient.⁵ The REMS remains in place although it has been clarified to allow advanced practice clinicians authorized by state law to provide abortion to obtain mifepristone.¹¹ The outstanding safety record of mifepristone and the extensive research conducted in the U.S. and elsewhere has shown that the REMS restrictions are not necessary to assure safe use.¹²⁻¹⁵

Safety of Self-Administered Medication Abortion

In both international- and U.S.-based studies, success and complication rates of self-administration of both mifepristone and misoprostol have been shown almost universally to be no different from healthcare facility administration.¹²⁻¹⁵ This is also true for a meta-analysis of prospective cohort studies of healthcare facility-administered mifepristone with self-administration of misoprostol regimens in Vietnam, Tunisia, Albania, France, India, Nepal, and Turkey involving 4,522 patients (3,478 home users and 1,044 clinic users) that found no difference in success rates or complication rates.¹⁶ A 2008 French study noted higher rates of surgical intervention for home administration of both medications, but almost 25% of patients were lost to follow up, and the study authors suggest that the climate in which the study was conducted was inclined to surgical intervention.¹⁷

Patient Acceptability of Self-Administered Medication Abortion

Self-administration of both mifepristone and misoprostol proves appealing to many women. In one Scottish study, a quarter of women report they would have chosen self-administered abortion had it been an option.¹⁸ Approximately 50-75% of patients in all studies of self-administered versus healthcare facility abortion elected self-use and between 92-99% of those who self-administered the medication would choose self-administration again. Women repeatedly cite the appeal of autonomy, control, scheduling, privacy, and having access to the comforts of home with supportive friends and/or family members as the most compelling advantages of undergoing home abortion.^{12-15,19,20} Indeed, abortion providers in both international and domestic studies would recommend self-administration to between 84-95% of patients seeking medical abortion.^{13,15,20}

Increasing Access and Reducing Stigma

Shifting the abortion venue out of the medical facility offers autonomy, privacy, and convenience. This benefit is of significant value at a time when there is a demonstrable increase in protests and clinic violence.²¹

Obstacles to Implementation of Self-Administered Medication Abortion in the U.S.

Federal Laws: Risk Evaluation Mitigation Strategy (REMS) that affects mifepristone availability

When the FDA approved mifepristone for use in the U.S., it was mandated to fall under REMS, requiring it to be dispensed in the medical facility (see medication abortion timeline above).

State Laws

Currently 18 states require that the clinician providing a medication abortion be present during the procedure, effectively banning telemedicine abortion and/or abortion by mail.²

Estimating gestational age

In the U.S., ultrasound dating is often standard clinical practice, but studies indicate the vast majority of the time, women can estimate their own gestational age accurately. A 2015 Raymond and Bracken review of two U.S. and one U.K. study showed that of 2,681 women in the largest study who were certain that their LMPs began no more than 56 days prior, only 16 (0.6%) were >70 days by ultrasound.

Two smaller studies showed higher rates (7.8%, 12%) of gestational age >70 days when women thought they were earlier gestation based on LMP.²² Two international studies demonstrated that 9 out of 10 women can estimate their gestational age based on LMP accurately enough to safely use mifepristone-misoprostol.^{23,24} There are promising technologies such as smartphone apps that could serve as adjuncts to LMP dating, but further research is needed to determine if these are consistently reliable enough to produce favorable clinical outcomes.²⁵

Rh status

In developing countries, Rh testing is not performed because Rh immune globulin is not widely available; therefore, Rh testing is not a requirement of the WHO clinical practice guidelines for safe early abortion.^{26,27} For the U.S. and other higher-income countries with access to Rh testing and immune globulin, the National Abortion Federation, the American Congress of Obstetricians and Gynecologists, and the Royal College of Obstetricians and Gynaecologists all recommend Rh testing and administration of Rh immune globulin as indicated.²⁸⁻³⁰ All three professional groups acknowledge the paucity of data to demonstrate that the risk of alloimmunization in early medication abortion is high enough to warrant Rh immune globulin administration. However, in light of the potentially severe complications from Rh alloimmunization and the relatively low cost of and risk from Rh testing and prophylaxis, they have chosen to err on the side of caution and administer Rh immune globulin if the patient is Rh negative.

Ectopic pregnancy evaluation

Although the incidence of ectopic gestation in women seeking induced abortion has been reported at less than 1%, a rate significantly lower than the 1.6-2.4% rate among pregnant women in the general population, ectopic pregnancy remains a significant cause of pregnancy-related morbidity and mortality.³¹⁻³³ NAF's clinical policy guidelines direct that every patient must be evaluated for ectopic gestation by a review of history as well as at least one of the following: physical exam, ultrasound, serial quantitative bhCG, or uterine aspiration.³⁰ Patients undergoing in-clinic medical abortion are typically evaluated in this manner, but a patient who is self-administering medication abortion bypasses these standards of care. There are no studies evaluating outcomes for patients who have self-administered medication abortion and were subsequently found to have an ectopic gestation.

Management and Oversight of Complications

The complication rate of self-administration of mifepristone and misoprostol is low, and comparable to that of healthcare facility administration.¹²⁻¹⁶ Some studies that have examined self-administration address the problem of how to treat complications by requiring that participants live within a specified distance from a healthcare facility to attend to issues such as hemorrhage and infection; this does little to improve access in rural areas or for women who seek to self-administer without clinician interaction or outside of a study protocol. In order to avoid legal consequences and/or stigma in places where abortion is illegal or subject to strong social prohibitions, Women on Waves recommends that patients

report to healthcare providers that they are undergoing a miscarriage, which has an identical clinical presentation and requires the same treatment, instead of revealing they utilized medications to induce an abortion.

Patient self-selection and label comprehension

A 2017 article in *BJOG: An International Journal of Obstetrics and Gynaecology* by Kapp et al highlighted the lack of evidence to demonstrate that women are able to fully understand package labeling and determine if they are appropriate candidates for medication abortion, as they would need to do if medication abortion were available over the counter (OTC).²⁵ Although there are few true contraindications to medication abortion, there has been no research to determine if prospective users with medical contraindications such as bleeding disorders or liver disease can screen themselves prior to obtaining the medication. In the U.S., this may be especially significant for populations with low literacy, limited English proficiency, or lack of access to technology.

Follow-up

Follow-up care to confirm complete medication abortion can vary. Currently utilized approaches include ultrasound to look for persistent gestational sac, interval urine pregnancy test, or serial serum beta-hcg testing. Semi-quantitative urine pregnancy tests have shown promise in research studies in detecting ongoing pregnancy up to 63 days gestation, but not later in pregnancy. These tests are not yet commercially available.^{34–36}

Another concern related to follow-up is that medication abortion with misoprostol alone results in significantly higher rates of continuing pregnancy than the combination mifepristone and misoprostol regimen, and greater need for additional medication or surgical intervention.³⁷ Any effort to make misoprostol-only medication abortion more widely available as an alternative to combination therapy must address this issue and balance a possible increase in adverse outcomes. Adverse outcomes include continued pregnancy, need for additional intervention that might require travel or incur cost, unintended contact with the healthcare system, and possible legal consequences.

Ethics of Self-Administered Medication Abortion

Patient autonomy

Autonomy is the right of a competent adult to make informed choices about his or her medical care and to his or her body. Thorough counseling, informed consent and shared decision-making are vital to support patient autonomy. If the risks associated with self-administration of mifepristone and misoprostol can be adequately mitigated, the principle of autonomy supports the idea that the patient should be given the choice about when and where they desire to initiate their abortion process.

A 2012 Swedish qualitative study of 24 women (and 13 of their male partners) who received home mifepristone and vaginal misoprostol revealed themes of both autonomy and independence being important to the patient's desire to have a self-administered medication abortion than a medication abortion in a healthcare facility.³⁸

Independence is defined as desire to be treated with empathy and respect, to receive adequate information and societal support.

Patient autonomy is also related to the right to privacy and control when receiving healthcare services. Because abortion provision is heavily scrutinized by the media, regulatory agencies, and legal entities, healthcare providers may feel anxiety about increased patient privacy in the setting of self-administered medication abortion due to fear of negative outcomes and the possible legal or social consequences.

However, improved patient autonomy is critical to populations that have inadequate access to healthcare services. For example, Jessica González-Rojas, Executive Director of the National Latina Institute for Reproductive Health has stated “Distance, cost, language barriers, and immigration checkpoints are just some of the obstacles that may keep Latinas from accessing an abortion clinic. We need to expand access to a broader range of abortion options in order for our communities to regain control over their health and lives.”¹

Provider Non-Maleficence

The provider has an obligation to ensure that proper protocols are in place to facilitate safe self-administered medication abortion. It has been established that morbidity and mortality from abortion is higher in countries with restrictions on access to safe abortion.

Harm reduction models must be considered for women who live in areas with limited abortion access as they may resort to unsafe self-induced abortion strategies. In the U.S., a 2016 Texas-based study reported that while self-induction is relatively rare, there is some evidence that rates have gone up following the closure of clinics after the passage of H.B.2.³⁹ H.B.2 was a “TRAP” (Targeted Regulation of Abortion Providers) law that included provisions to require abortion facilities to operate as ambulatory surgical centers and mandate that all physicians providing abortion services must have hospital admitting privileges within 30 miles of the clinic where they provide abortions. H.B.2 resulted in the closure of more than half of the abortion clinics in Texas.⁴⁰ A 2010 study found that while most women who attempted to self-induce did so with herbs, misoprostol, or other medications, some women used potentially more harmful methods like alcohol and cocaine.⁴¹ There are several documented programs from which examples can be drawn.⁴²

1. Women on Waves: a Dutch organization that supports women’s right to information and access to safe abortion in places where it is illegal and maintains the Safe Abortion Hotline. The group provides accurate information about law, methods and risks intended to be disseminated by healthcare providers and by women in a grassroots fashion; 7 Latin American and Asian countries such as Uruguay and Bangladesh utilize this service.⁴³

2. Needle Exchange Programs/HIV pre-exposure prophylaxis (PrEP): intended to reduce HIV and hepatitis transmission with intravenous drug use and unprotected intercourse.

3. Uruguay’s Iniciativas Sanitarias program: Started in 2001 in one hospital where 47% of maternal deaths were due to unsafe abortion, and expanded nationally in 2006, the program is credited with a decrease in unsafe abortion-related morbidity and mortality. The program sought to reframe unsafe abortion as a public health issue (rather than a moral one) and was modeled after harm reduction programs that aimed to reduce HIV transmission. The goal was to connect women with confidential evaluation and referral services without technically offering “medical advice,” and offer both pre- and post-abortion assessment in order to reduce the likelihood of complications.⁴⁴

Provider Beneficence

Healthcare facilities and their providers should ensure that changes in provision of medication abortion positively impact the patient’s experience. The current literature supports high patient satisfaction with self-administration of medication abortion.

Justice

Access to abortion services is currently not distributed equally both geographically and in terms of ability to pay. There is also a legitimate concern about medical liability should there be a serious complication after self-administered medication abortion. Would the abortion provider that facilitated a

self-induced abortion be subject to prosecution and found in violation of the law? If this is the case, and a provider is barred from practice or jailed, then access to abortion for other women in that area may be negatively impacted.

Conclusion

Unanswered questions remain about several important considerations regarding the feasibility of self-administered medication abortion in the U.S.:

Can gestational age be reliably determined without ultrasound or a clinician exam? Is Rh testing and prophylaxis necessary (especially in the first trimester)? Can women determine if they have contraindications to medication abortion? Can ectopic gestation be reliably excluded without contact with a clinician or laboratory? In the event that emergency care is necessary, will women who have self-administered medication abortion be able to seek care without fear of prosecution?

What legal protections must be in place for both patients who have self-abortion and providers who might assist patients in obtaining medications for self-abortion? What constitutes appropriate follow-up to detect and manage ongoing pregnancy? Do women know when to seek emergency care?

What are the ethical considerations in advocating for a misoprostol-only versus mifepristone and misoprostol medication abortion, given the significantly higher rates of failure and need for additional intervention with misoprostol alone? At what point does access to abortion become so prohibitively difficult as to justify advocating for wider availability of the less effective misoprostol-only regimen? Does a commitment to patient autonomy and privacy compel providers to advocate for a woman's right to choose a less effective medication abortion regimen as long as she is informed of the risks and benefits?

Aside from the above questions, review of the current literature is supportive of the safety of self-administered mifepristone and misoprostol, with or without the use of telemedicine to interface with a physician. Self-administered medication abortion is as safe, effective and acceptable to patients and providers as healthcare facility-based medication administration.

Feasibility of forgoing routine ultrasound/clinician exam for gestational age evaluation, ability of women to self-screen for contraindications, and the logistics of Rh testing and prophylaxis in the U.S. remain to be studied.

Recommendations

1. We affirm that pregnant people seeking abortion deserve the care that will best meet their needs. A Reproductive Justice framework calls on us to consider ways to help expand safe options for accessing abortion care, whether that care involves a clinician or whether it occurs outside the medical system, by the patients themselves.

2. No person should be subject to legal action for decisions they make about ending a pregnancy. Physicians for Reproductive Health continues to unequivocally oppose efforts to criminalize self-administered abortion, including people who seek self-administered abortion and those who, in good faith, assist people seeking abortion. [This is a reaffirmation of the Board's position on criminalization in the 2009 statement.](#)

3. We reaffirm that in order to reduce morbidity and mortality from unsafe abortion, harm reduction programs using self-administered misoprostol alone or mifepristone and misoprostol (where available) should be readily available in situations where safe abortion is prohibitively difficult to obtain. Harm

reduction programs must exist in tandem with legislative and other advocacy efforts to ensure that no woman is forced to go outside of the medical system for abortion care.

4. We acknowledge that there are unanswered medical questions, including how best to determine gestational age, Rh status and whether prophylaxis is needed in the first trimester, what constitutes appropriate follow up, and what mechanisms would need to be in place to ensure adequate emergency care in the rare case of a complication. We support research efforts to address these questions, whether in or outside of the current clinical model.

5. We recognize that discussions about self-administered medication abortion are already happening in the reproductive health/rights/justice community and will likely receive increasing media and public attention. Physicians is well-positioned to be a leading reproductive health advocacy voice to shift the cultural dialogue about safe self-administered medication abortion.

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