

Access to Medication Abortion Care: What We Learned During the COVID-19 Public Health Emergency

What is medication abortion care and how safe is it?

Medication abortion care is a safe and effective FDA-approved medication regimen for ending an early pregnancy. It is a non-invasive abortion option that is approved for use up to 10 weeks in pregnancy.¹

- The medication abortion regimen involves two different pills. One pill, called mifepristone, is taken first and then pills, called misoprostol, are taken 24-48 hours later.
- A growing proportion of women who end their pregnancies are using medication abortion care. In 2017, 4in-10 women seeking abortion chose this method.²
 - An overwhelming majority of women who choose medication abortion care are satisfied with the method. One study found that 97% of women would recommend the method to a friend.³

Since the FDA approved medication abortion care in 2000, it has been used by more than 4 million people in the U.S. It has a well-documented safety record, demonstrated in real-world use and more than 100 research publications.

- The National Academy of Science, Engineering, and Medicine (NASEM) conducted a systematic review of medication abortion care. Of nearly 34,000 medication abortions, NASEM found an overall effectiveness rate of 96.7% for gestations up to 63 days (9 weeks).⁴
- Medication abortion care is incredibly safe and effective, with a more than 99% safety rate.⁵

Why isn't medication abortion care available to anyone who wants a safe, early, and non-invasive option to end a pregnancy?

Although proven to be safe and effective, federal and state regulations have long restricted patient access to medication abortion care.

- As a result of FDA restrictions imposed more than 20 years ago, those currently seeking medication abortion
 care can only go to certain health care providers or health centers that have agreed to pre-purchase the
 medication ahead of time essentially acting as doctor and pharmacist.
- While the FDA has temporarily suspended its requirement that patients travel in-person to receive medication abortion care during the pandemic, providers are still limited in their willingness to offer medication abortion care.⁶
 - A recent survey of OB/GYNs found that 72% reported having a patient who wanted or needed an abortion in the last year, but only 24% provide abortion services. Of those not providing abortion services, 28% said they would start offering medication abortion care if distribution restrictions were changed.⁷
- In addition to federal regulations, 19 states ban the use of telehealth (the use of electronic information and telecommunications technologies to support or provide medical care when the patient and clinician are not in the same location for medication abortion care) or require the prescribing healthcare provider to be physically present when medication abortion is dispensed, which effectively bans telehealth.^{8,9}
 - State restrictions on abortion including waiting period laws, staffing and facility requirements, and billing and reimbursement restrictions – also apply to medication abortion care.
- Bans on insurance coverage for abortion, including under Medicaid, limit access and disproportionately
 impact those who already face significant barriers to receiving quality care, such as people working to make
 ends meet, immigrants, young people, and women of color.
- One study found that severe restrictions on Medicaid coverage of abortion forces 1 in 4 low-income women who seek abortion to carry an unwanted pregnancy to term.¹⁰

¹ The National Academies of Sciences, Engineering, and Medicine (NASEM). The Safety and Quality of Abortion Care in the United States. March 2018.

² Guttmacher Institute. Evidence you can use: medication abortion. November 2019.

³ Hollander, D. Most abortion patients view their experience favorably, but medical abortion gets a higher rating than surgical. Perspectives on Sexual & Reproductive Health. October 2000.

⁴ National Academies of Sciences, Engineering, and Medicine (NASEM). The Safety and Quality of Abortion Care in the United States. March 2018.

⁵ Advancing New Standards in Reproductive Health. Safety and effectiveness of first-trimester medication abortion in the United States. May 2021.

⁶ U.S. Food and Drug Administration. Questions and answers on Mifeprex. April 2021.

⁷ Grossman, D., Grindlay, K., Altshuler, A., & Schulkin, J. <u>Induced abortion provision among a national sample of obstetrician-gynecologists</u>. *Journal of Obstetrics & Gynecology*. March 2019.

⁸ Department of Health and Human Services. What is Telehealth. May 2021.

⁹ Guttmacher Institute. <u>State laws and policies: medication abortion</u>. December 2020.

¹⁰ Henshaw, S., Joyce, T., Dennis, A., Finer, L., Blanchard, K. Restrictions on Medicaid funding for abortions: a literature review. Guttmacher Institute. July 2009.

Changes to medication abortion care service delivery during the public health emergency have the potential to benefit women and should be made permanent.

Health care providers and researchers have learned how telehealth can improve patient care and ensure safety by minimizing in-person consultations and eliminating medically unnecessary testing.

- Research shows that using telehealth to provide medication abortion care is equally as safe and effective as an in-person visit and could enable patients to access abortion care earlier in their pregnancy. 11
 - A UK study shows that remote models result in clinical outcomes that are equivalent to in-person care, however, access to medication abortion care is better under the remote model with waiting times significantly reduced.¹²
 - The U.S.-based TelAbortion study confirmed providing medication abortion through telemedicine and mailed medication is safe and effective. Among nearly 1,400 abortions provided this way, 95% were completed without a procedure and 99% experienced no serious adverse events.¹³
- By eliminating medically unnecessary tests, patients can receive the same safe and effective medication abortion care virtually while still having 24/7 access to a health care provider throughout the process for support or to answer questions.
 - This approach improves access to care by eliminating unnecessary obstacles while also protecting patients and providers from potential exposure during a pandemic.¹⁴

Given the extensive data and real-world experience demonstrating that medication abortion care is safe and effective, FDA should provide more options to patients to receive the prescribed medication beyond the context of the COVID-19 pandemic.

- Women should be able to have medication abortion prescribed by their health care provider and then be able to receive their medications in the way that makes the most sense for them, whether that is at a health center, their local pharmacy, or delivered to their home.
 - Patients would continue to receive thorough instructions from a health care professional about how to use the medication and would have 24/7 access to call with any questions about side effects or other concerns.
 - This option would allow more women to receive the medication from their own health care provider, and allow rural women to receive the medication closer to home.

Medical societies and public health experts are calling on FDA to reevaluate restrictions on medication abortion care, especially in light of the COVID-19 pandemic.

- Former FDA Commissioner, Dr. Jane Heeney: "We have safety data from millions of women in the U.S. from the last 20 years, as well as all of the data from other countries that show using this product is safe—using it at home seems not to increase your risks [of complications] at all. I think because of the pandemic it's more imperative to look at it because of the access issues, and because it's an essential medicine for women's health."
- American College of Obstetricians and Gynecologists (ACOG), et al: Abortion is an essential component of
 comprehensive health care. It is also a time-sensitive service for which a delay of several weeks, or in some
 cases days, may increase the risks or potentially make it completely inaccessible. The consequences of
 being unable to obtain an abortion profoundly impact a person's life, health, and well-being. The American
 College of Obstetricians and Gynecologists [et al] do not support COVID-19 responses that cancel or delay
 abortion procedures.
- American College of Obstetricians and Gynecologists (ACOG): The current U.S. Food and Drug
 Administration (FDA) Risk Evaluation and Mitigation Strategy (REMS) and Elements to Assure Safe Use
 (ETASU) requirements for Mifeprex® (mifepristone, 200 mg) are outdated and substantially limit access to
 this safe, effective medication. Therefore, ACOG urges the removal of the REMS and ETASU for Mifeprex®.
- American Medical Association (AMA): Resolved that our American Medical Association support efforts
 urging the Food and Drug Administration to lift the Risk Evaluation and Mitigation Strategy on mifepristone.

D. Grossman D, K. Grindlay. Safety of Medical Abortion Provided Through Telemedicine Compared with In Person. Journal of Obstetrics & Gynecology. October 2017.
 Aiken, A., Lohr, P., Lord, J., Ghosh, N., & Starling, J. <u>Effectiveness</u>, <u>safety and acceptability of no-test medical abortion provided via telemedicine: a national cohort study.</u>
 British Journal of Obstetrics & Gynecology. February 2021.

¹³ Chong, E., Shochet, T., Raymond, E., Platais, I., Ánger, H.A., Raidoo, S., Soon, R., Grant, M.S., Haskell, S., Tocce, K., Baldwin M.K., Boraas, C.M., Bednarek, P.H., Banks, J., Coplon, L., Thompson, F., Priegue, E., Winikoff, B. <u>Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic. Confracention. March 2021</u>

COVID-19 pandemic. Contraception. March 2021.

¹⁴ Fulcher, I. R., Neill, S., Bharadwa, S., Goldberg, A. B., & Janiak, E. State and federal abortion restrictions increase risk of COVID-19 exposure by mandating unnecessary clinic visits. Contraception. December 2020.