Mifepristone and Misoprostol for Miscarriage Management Care

Miscarriage in early pregnancy is common and can increase health risks for people who do not receive proper medical care.

- 16% of known pregnancies end in miscarriage. Estimates for confirmed and unconfirmed pregnancies is nearly 25%.[1]
- Most miscarriages occur early in the first trimester before the 12th week of pregnancy.[2]
- When the body does not expel all of the pregnancy tissue on its own, it is called an incomplete miscarriage. People experiencing an incomplete miscarriage need proper medical intervention to decrease risks of hemorrhage, sepsis, and death.[3]
- Miscarriage affects people of every age, race, ethnicity, and socioeconomic status, but is more common among groups negatively impacted by societal dynamics of power and oppression, such as pregnant people who are Black, have low incomes, or are exposed to environmental pollutants.

People experiencing an incomplete miscarriage can choose from three evidence-based care options.

- Miscarriage management strategies include: 1) expectant management, where no interventions are initiated but patients are actively monitored as part of a 'wait and see' approach; 2) medication management, where medications – mifepristone followed by misoprostol – are prescribed to help the body start or complete the miscarriage process; and 3) a procedure to end the pregnancy.[4]
    - Historically, misoprostol used alone has been the standard for medication management of miscarriage. But a growing body of evidence demonstrates that mifepristone used in combination with misoprostol is safe and more effective than misoprostol alone.[5,6,7]
    - Of note, both the medication option and the procedure option are the same for miscarriage as they are for abortion care.

Patient choice and shared decision-making are important to ensure quality, evidence-based care.

- Because expectant management can take up to 8 weeks, some patients prefer the medication or a procedure, which can allow a person to complete their miscarriage within a few hours or days of initiating treatment.

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[1] Quenby, S., et al. Miscarriage matters: the epidemiological, physical, psychological, and economic costs of early pregnancy loss. *Lancet*. 2021.
Wang, X., et al. Conception, early pregnancy loss, and time to clinical pregnancy: a population-based prospective study. *Fertility and Sterility*. 2003.

[2] Ibid.

[3] Goldberg, A.B., et al. Management of unintended and abnormal pregnancy: comprehensive abortion care. *Wiley*. 2009.

[4] American College of Obstetricians and Gynecology. ACOG Practice Bulletin No. 200: Early Pregnancy Loss. *Obstetrics and Gynecology*. 2018.

[5] Schreiber, C.A., et al. Mifepristone pretreatment for the medical management of early pregnancy loss. *New England Journal of Medicine*. 2018.

[6] Chu, J.J., et al. Mifepristone and misoprostol versus misoprostol alone for the management of missed miscarriage (MifeMiso): a randomised, double-blind, placebo-controlled trial. *Lancet*. 2020.

[7] Clinical guidelines from the American College of Obstetricians and Gynecologists advise that "[t]he addition of a dose of mifepristone (200 mg orally) 24 hours before misoprostol administration may significantly improve treatment efficacy." American College of Obstetricians and Gynecology. ACOG Practice Bulletin No. 200: Early Pregnancy Loss. *Obstetrics and Gynecology*. 2018.

- Research shows people who experienced miscarriage expressed a strong preference for informed choice among multiple options rather than being prescribed a single option by their health care team.[8]
- Clinical guidelines from the American College of Obstetricians and Gynecologists advise providers to engage patients in a shared decision-making process that centers patient choice.[9]

Regulators and policymakers should follow the science and remove unnecessary and harmful restrictions that limit who can use mifepristone for miscarriage management care.

- **FDA can take steps to add miscarriage to the mifepristone drug label.**
  - Mifepristone is currently only labeled for use in abortion care. While health care providers can typically prescribe medication "off label," FDA has put restrictions on who can prescribe and dispense mifepristone. These regulations, known as a Risk Evaluation Mitigation Strategy (REMS), require providers and pharmacies to become certified to prescribe and/or dispense mifepristone.
    - This means most people experiencing miscarriage cannot go to their own health care provider for a consultation and prescription and have that prescription filled by a local pharmacist.
  - In October 2022, 49 medical associations, research institutions, and patients support and advocacy organizations filed a citizen petition with the FDA urging the agency to add an indication for miscarriage care to the mifepristone drug label based on the robust scientific evidence in support of mifepristone's safe and effective use for miscarriage care.[10]
- **FDA can also eliminate outdated restrictions on who can prescribe and dispense mifepristone.**
  - The mifepristone REMS unnecessarily burden access to safe miscarriage and abortion care and disproportionately harm communities of color and people living with low incomes.[11]
  - When Canada allowed mifepristone to be prescribed and dispensed like any other drug, there was no difference in complications or serious adverse events.[12]
  - Data in the U.S. also show that pharmacists can safely and effectively dispense mifepristone.[13]
- **Finally, state lawmakers should repeal legislation that bans or severely limits access to an FDA-approved drug as this denies patients experiencing miscarriage access to the most effective, time-sensitive treatment.[14]**

Bottom line: Ensuring access to mifepristone as part of evidence-based miscarriage management care ensures that patients can get the safest and most effective treatments regardless of geographic location, race, ethnicity, and socioeconomic status.

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[8] Wallace, R., et al. "Every person's just different": women's experiences with counseling for early pregnancy loss management. *Women's Health Issues*. 2017.

[9] American College of Obstetricians and Gynecology. ACOG Practice Bulletin No. 200: Early Pregnancy Loss. *Obstetrics and Gynecology*. 2018.

[10] American College of Obstetricians and Gynecology, et. al. Citizen Petition to FDA. 2022.

[11] Thompson, A., et al. The disproportionate burdens of the mifepristone REMS - Contraception. *Contraception*. 2021.

[12] Schummers, L., et al. Abortion Safety and Use with Normally Prescribed Mifepristone in Canada. *New England Journal of Medicine*. 2022.

[13] Grossman, D., et al. Medication Abortion With Pharmacist Dispensing of Mifepristone. *Obstetrics and Gynecology*. 2021.

[14] Kaiser Family Foundation. Understanding Pregnancy Loss in the Context of Abortion Restrictions and Fetal Harm Laws. 2019.