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Analysis of Medication Abortion Risk and the FDA report "Mifepristone US Post-Marketing Adverse Events Summary through 12/31/2024"

Summary

The Food and Drug Administration (FDA) report "Mifepristone US Post-Marketing Adverse Events Summary through 12/31/2024" includes adverse events associated with the use of mifepristone, regardless of their likelihood of being causally linked to the abortion.[1] Over 7.5 million people in the US have used medication abortion with mifepristone and misoprostol since mifepristone 200 mg was first approved by the US Food and Drug Administration (FDA) in 2000. Since then, the safety of the treatment has been reaffirmed by rigorous research that supplements monitoring data from the FDA.

Understanding medication abortion complications as published by the Food and Drug Administration (FDA)

As of December 2024, the FDA reports that 36 people, out of approximately 7.5 million, have died after taking mifepristone for medication abortion. However, as the FDA notes, the adverse events "cannot with certainty be causally attributed to mifepristone because of information gaps about patient health status, clinical management of the patient, concurrent drug use, and other possible medical or surgical treatments and conditions." Among these 36 deaths:

- 22 cases are probably or possibly related to the abortion, including:
  - 10 cases of Clostridium-related sepsis
  - 2 cases of sepsis with negative blood cultures
  - 1 case of sepsis without blood culture data
  - 2 cases of possible or confirmed delayed onset toxic shock-like syndrome
  - 1 case of septic shock due to necrotizing fasciitis
  - 1 case of hemorrhage
  - 2 cases of ruptured ectopic pregnancy
  - 1 case of probable anaphylactic medication reaction
  - 2 cases where the cause of death was unclear
- 14 cases appear to be unrelated to the abortion, including:
  - 7 cases of drug or substance use, intoxication, and/or overdose
  - 3 cases of confirmed or suspected homicide
  - 2 cases of suicide
  - 1 natural death due to severe pulmonary emphysema
  - 1 case of bilateral pulmonary thromboembolism

Based on this, the overall mortality rate associated with medication abortion is 0.48 deaths per 100,000 medication abortions (36 deaths/7.5 million medication abortion cases). This mortality rate is similar to that reported for abortion overall (0.7 deaths per 100,000 procedures).[2] If only the cases

that appear to be related to the abortion are included, the mortality rate is 0.29 deaths per 100,000 medication abortions (22/7.5 million medication abortion cases).

Because it is mandatory to report any death among someone who used mifepristone and because the US Centers for Disease Control and Prevention has had an active surveillance program to monitor abortion-related deaths,[2] these reports capture information about all possible deaths related to medication abortion.

The FDA also published the number of cases of hospitalization and other complications (some already counted in the hospitalization cases) reported to them among women using medication abortion. However, unlike for deaths, there is no active surveillance program, so this report should not be considered as conclusive. We do know that serious complications are rare with medication abortion. The most rigorous study of medication abortion safety included data from 11,319 Medi-Cal patients in California.[3] In this study, only 35 (0.31%) had a major complication, defined as hospitalization, blood transfusion, or surgery.

Other reports and FDA approvals highlight the safety of medication abortion

The FDA conducted a rigorous review of research from the United States and other countries to assess the safety profile before it approved mifepristone in 2000. The safety of medication abortion has been highlighted repeatedly since then:

- In 2016, the FDA approved an updated label for mifepristone that allowed for using medication abortion later in pregnancy (up to 10 weeks from last menstrual period) and simplified the drug regimen. It also removed the requirement that all serious adverse events be reported to the agency and now only requires that deaths be reported.[4]
- In 2018, the US Government Accountability Office published a report that evaluated the process that FDA used when it updated the mifepristone label. The report concluded that the agency used its standard review process to incorporate the best available evidence into the updated label.[5]
- In 2018, the National Academies of Sciences, Engineering, and Medicine released a report that highlighted the safety and effectiveness of medication abortion.[6]
- In 2019, the FDA approved a generic of mifepristone for medication abortion, which gave the agency another opportunity to review the safety of the treatment.[4]
- In 2021, the FDA issued permanent modifications to the mifepristone Risk Evaluation and Mitigation Strategy (REMS), removing the in-person dispensing requirement and enabling certified pharmacies to dispense mifepristone, including by mail.[4]

Understanding risk

Unfortunately, pregnancy can be risky, and birthing people are also at risk of dying if they choose to continue their pregnancy to term. In 2021, the national pregnancy-related mortality ratio (which includes abortion-related mortality) was 33.2 deaths per 100,000 live births, and it was even higher for Black women and birthing people at 69.3 deaths per 100,000 live births.[7] The mortality rate for those known to have had a live-born infant is 8.8 per 100,000 live births,[8] which is about 14 times higher than the mortality rate associated with medication abortion.

Other medications that are commonly administered in outpatient settings also have risks, including a small risk of death. Penicillin causes a fatal anaphylactic reaction at a rate of 2 deaths per 100,000 patients administered the drug.[9] Phosphodiesterase type-5 inhibitors, which are used for erectile dysfunction and include Viagra, have a fatality rate of 4 deaths per 100,000 users.[10] These risks are several times higher than the risk of death with medication abortion. Acetaminophen (Tylenol) overdose is the most common cause of acute liver failure in the US and accounts for over 300 deaths annually.[11] [12]

Conclusion

Medication abortion with mifepristone and misoprostol is very safe and effective. The safety profile is similar to that of vacuum aspiration abortion, and medication abortion is safer than continuing a pregnancy to term or using other common medications.

References

1. US Food and Drug Administration. Mifepristone US Post-Marketing Adverse Events Summary through 12/31/2024. Available at: https://www.fda.gov/media/185245/download [Accessed May 25, 2025].
2. Zane S, Creanga AA, Berg, CJ, Pazol K, Suchdev DB, Jamieson DJ, Callaghan WM. Abortion-Related Mortality in the United States: 1998-2010. Obstet Gynecol 2015;126(2):258-65.
3. Upadhyay ED, Desai S, Zlidar V, Weitz TA, Grossman D, Anderson P, Taylor D. Incidence of emergency department visits and complications after abortion. Obstet Gynecol 2015;125(1):175-83.
4. US Food and Drug Administration. Questions and Answers on Mifeprex. Available at: https://www.fda.gov/drugs/drug-safety-and-availability [Accessed March 25, 2025].
5. United States Government Accountability Office Report to Congressional Requesters, Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. March 2018. Available at: https://www.gao.gov/assets/gao-18-292.pdf [Accessed March 25, 2025].
6. National Academies of Sciences, Engineering, and Medicine. The Safety and Quality of Abortion Care in the United States. Available at: http:// www.nationalacademies.org/hmd/Reports/2018/the-safety-and-quality- of-abortion-care-in-the-unitedstates.aspx [Accessed March 25, 2025].
7. Pregnancy Mortality Surveillance System, US Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/maternal-mortality/php/pregnancy-mortality-surveillance/index.html [Accessed May 12, 2025].
8. Raymond EG, Grimes DA. The comparative safety of legal induced abortion and childbirth in the United States. Obstet Gynecol 2012;119(2 Pt 1):215.
9. Neugut AI, Ghatak AT, Miller RL. Anaphylaxis in the United States: an investigation into its epidemiology. Arch Intern Med 2001;161(1):15-21.
10. Lowe G, Costabile RA. 10-Year analysis of adverse event reports to the Food and Drug Administration for phosphodiesterase type-5 inhibitors. J Sex Med 2012;9(1):265-70.
11. Min J, Osborne V, Kowalski A, Prosperi M. Reported Adverse Events with Painkillers: Data Mining of the US Food and Drug Administration Adverse Events Reporting System. Drug Saf 2018;41(3):313-320.
12. Chidiac AS, Buckley NA, Noghrehchi F, Cairns R. Paracetamol (acetaminophen) overdose and hepatotoxicity: mechanism, treatment, prevention measures, and estimates of burden of disease. Expert Opin Drug Metab Toxicol. 2023 Jan-Jun;19(5):297-317.