

ISSUE BRIEF, AUGUST 2016

Impact of Ohio's law mandating use of the FDA-approved protocol for medication abortion

Key points:

- In 2011, an Ohio law went into effect requiring the use of an outdated FDA protocol for provision of medication abortion.
- Women who had medication abortions after the law were three times more likely to require abortion.
- The law change in Ohio restricted medical practice to a protocol that did not result in

In 2011, an Ohio law took effect mandating the use of the outdated Food and Drug Administration (FDA)approved protocol for medication abortion. This restriction prohibited the use of the evidence-based regimen for medication abortion that was the accepted standard of care. At equivalent gestations, evidence-based regimens had higher effectiveness rates than the outdated FDAapproved regimen.¹⁻⁴ In March 2016, the FDA approved a revised label for mifepristone (brand name: Mifeprex), one of the drugs used for medication abortion.⁵ This change brings the FDA protocol in line with the current evidence.

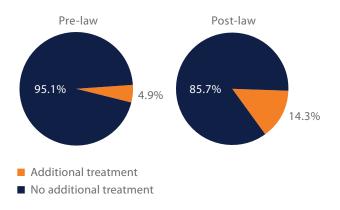
Researchers at ANSIRH sought to understand whether the 2011 law change had any impact on outcomes for 2,783 medication abortions performed less than 49 days from last menstrual period at four health facilities/ clinics providing medication abortion in Ohio. This study compared the need for additional medical treatments to complete the abortion, the experience of side effects, and the rate of medication abortion versus aspiration abortion in Ohio pre- and post-law.⁶

ANSIRH research findings on the effect of the law

Post-law, more women required additional medical treatments to complete the abortion.

- Women who had medication abortions in the post-law period had three times the odds of requiring at least one additional treatment compared to women in the pre-law period.
- The proportion of women requiring additional treatments (most commonly an additional misoprostol dose or aspiration abortion procedure) increased from 4.9% in the pre-law period to 14.3% in the post-law period.
- The rate of incomplete or possible incomplete abortion was significantly higher post-law (3.2% vs. 1.1% pre-law).
- Significantly more women in the post-law period had two or more additional follow-up visits to complete their care (6.2% vs. 4.2% pre-law).

Percent of medication abortions requiring additional treatments



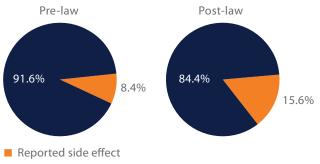
For more information about this research and other ANSIRH work, please visit www.ansirh.org.



Post-law, more women experienced side effects.

- Side effects were significantly more likely among women after the law change, with **15.6%** reporting at least one side effect in the post-law period, compared to **8.4%** pre-law.
- The most common side effect women experienced was nausea/vomiting, which significantly increased from the pre-law period (4.5% pre-law and 9.5% post-law).

Percent of medication abortions reporting at least one side effect



Did not report side effect

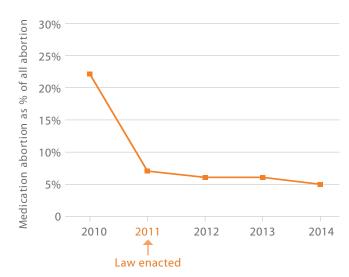
The law led to a major decline in medication abortion in the state.

- There was an 80% decline in medication abortion in Ohio between 2010 and 2014, while non-medication abortions stayed constant over the same time period.
- The proportion of medication abortions among all abortions provided declined from 22% before the law went into effect to 5% in 2014. This goes against the national trend that sees medication abortions increasing in most other states.

Conclusions

Through research and clinical experience, physicians, other clinicians, and women's health experts have determined the best regimens for medication abortion with optimal dosage and timing. Evidence-based regimens for medication abortion have been shown to maximize effectiveness and minimize side effects.

Although the FDA has now updated the regimen for medication abortion to bring it in line with the current



evidence, it too will eventually become out of date. These results from Ohio suggest that women may not experience better health outcomes when legislatures decide how medicine should be practiced; rather, such interference can force healthcare providers to provide care that falls below the accepted standard of care. By mandating adherence to an outdated protocol, doctors in Ohio were forced to treat women with a medication protocol that did not have any added benefit to women's health.

References

- ¹ World Health Organization Task Force on Post-ovulatory Methods of Fertility Regulation, Comparison of two doses of mifepristone in combination with misoprostol for early medical abortion: a randomised trial. BJOG, 2000. 107(4): p. 524-30.
- ² Spitz, I.M., C.W. Bardin, L. Benton, and A. Robbins, Early pregnancy termination with mifepristone and misoprostol in the United States. N Engl J Med, 1998. 338(18): p. 1241-7.
- ³ American College of Obstetricians and Gynecologists, Practice bulletin no. 143: medical management of first-trimester abortion. Obstet Gynecol, 2014. 123(3): p. 676-92.
- ⁴ Winikoff, B., I.G. Dzuba, M.D. Creinin, W.A. Crowden, A.B. Goldberg, J. Gonzales, M. Howe, J. Moskowitz, L. Prine, and C.S. Shannon, Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. Obstet Gynecol, 2008. 112(6): p. 1303-10.
- ⁵ U.S. Food and Drug Administration, Postmarket Drug Safety Information for Patients and Providers: Mifeprex (mifepristone) Information, 2016.
- ⁶ Upadhyay, U.D., N.E. Johns, S.L. Combellick, J.E. Kohn, L.M. Keder, and S.C.M. Roberts, Comparison of Outcomes before and after Ohio's Law Mandating Use of the FDA-Approved Protocol for Medication Abortion: A Retrospective Cohort Study. PLOS Med, 2016. 13(8).

Declines in medication abortion in four Ohio clinics (2010-14)