ANSIRH
ADVANCING NEW STANDARDS IN REPRODUCTIVE HEALTH

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Pharmacist dispensing of mifepristone for medication abortion in the United States

Our research shows pharmacist dispensing of mifepristone is feasible, highly satisfactory to patients, and comparably safe and effective as in-person dispensing of mifepristone.

Key points

- **Medication abortion (MA)—a regimen of two medications, mifepristone and misoprostol—is very safe and effective.**
- **In the United States (US), Food and Drug Administration (FDA) regulations have long required that mifepristone only be dispensed in person at healthcare facilities, not at pharmacies. This poses a barrier to patient access to MA.**
- **Pharmacy dispensing of mifepristone could potentially double the number of MA providers in the US, with the largest possible increases in the Midwest and South.**
- **Our research supports calls by medical associations and clinicians for the FDA to permanently remove the in-person dispensing requirement for mifepristone.**

Background

- More than four million people in the US have used mifepristone for medication abortion since its approval by the FDA in 2000* with very rare incidence of serious adverse events.[1-4]
- Since 2000, the FDA has mandated that mifepristone be dispensed in person only at healthcare facilities, barring pharmacists from dispensing mifepristone for medication abortion. This is codified in the drug's Risk Evaluation and Mitigation Strategy (REMS).[8]
- Physicians who otherwise would offer medication abortion have been prevented from doing so by the REMS in-person dispensing requirement.[9] Particularly for clinicians who might have a small number of patients who need MA, stocking the medication can be logistically complicated.
- Pharmacists safely dispense mifepristone for medication abortion in other countries, including Australia and Canada.[10-12]

*In the US, the FDA-approved regimen for MA consists of mifepristone (200 mg), followed 24-48 hours later by misoprostol (800 mcg), administered buccally.[5] When used up to 10 weeks' gestation, this regimen is more than 95% effective at terminating pregnancy.[6-7]

Research findings

ANSIRH has studied the pharmacist-dispensing model of MA service delivery in the U.S. Our evidence indicates:

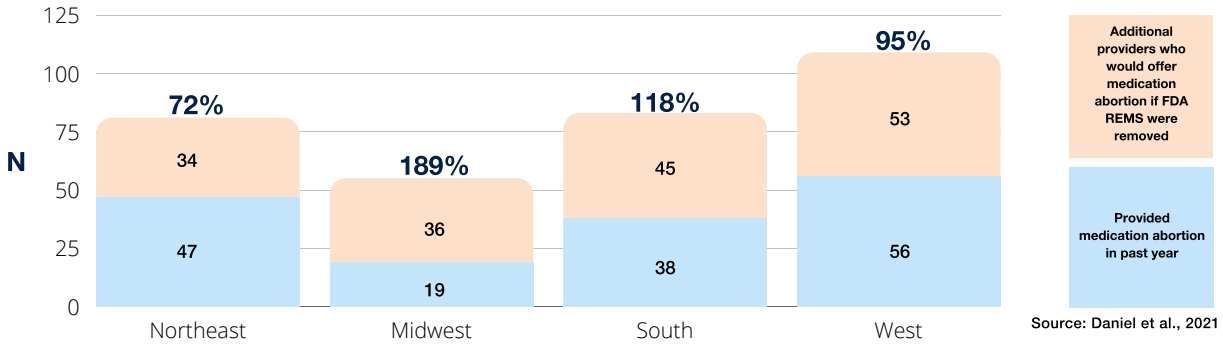
Physicians would be more likely to offer MA

- In 2017, we surveyed 655 obstetrician-gynecologists (ob-gyns) nationwide, assessing whether and why they did or did not provide abortion care. Among those who did not offer medication abortion, the cost and logistics of stocking mifepristone at clinical facilities was a significant barrier.[9]
- Of ob-gyns who did not already offer MA, 24% reported that they would do so if they could write a prescription for mifepristone rather than having to dispense it directly.[13] Patients would then obtain the medication from a pharmacy, as they do for other comparably safe medications.
- Based on this survey, we estimate that the number of ob-gyns providing MA would double if the in-person dispensing requirement were lifted. The increases in providers would be largest in the Midwest and South, regions that currently have limited abortion access.[13] (See figure below.)

Pharmacist dispensing of MA is safe and effective

- We studied more than 260 patients who were prescribed mifepristone and misoprostol for MA by a healthcare provider and then picked up their medications at a nearby pharmacy, with standard follow-up care from their provider afterward.[14]
- The vast majority (93%) of patients had a complete abortion. Very few had any complications (1.5%), of which none were serious or related to pharmacist dispensing.[14]
- These safety and effectiveness outcomes are very similar to those of MA with in-clinic dispensing of mifepristone.[6-7,15]

Potential percentage increase in ob-gyns offering MA if FDA REMS were removed



Source: Daniel et al., 2021

Our research supports calls by medical associations[17] and clinicians[18] for the FDA to permanently end the REMS for mifepristone. Doing so could significantly increase the number of providers offering medication abortion, especially in areas where abortion care is currently limited.

Patients are satisfied with pharmacist dispensing

- In the same study, most patients (91%) were satisfied with receiving their medications at the pharmacy. In particular, they valued having more control over the timing of their abortion process, because they could take the mifepristone at home rather than in the clinic.[14]
- Most patients (96%) were satisfied with their treatment by pharmacy staff.[14]
- More than 90% of patients supported pharmacist dispensing of mifepristone.[14]

Pharmacists dispensing is feasible to implement

- To explore the model's feasibility, we studied pharmacists' perspectives on dispensing mifepristone, in six pharmacies in California and Washington state. Only 6% of invited pharmacists declined to participate in training or refused to dispense mifepristone.[16]
- While the vast majority (91%) of pharmacists anticipated that they would experience challenges with mifepristone dispensing, only 33% reported experiencing challenges in the follow-up survey.[16]
- At the end of the study, 83% of respondents were satisfied with pharmacist dispensing of mifepristone.[16]

Pharmacists need training on medication abortion

- As part of this study, we provided participating pharmacists with a one-hour training covering mechanism of action, indications, safety, and effectiveness of the MA regimen.
- Prior to the training, pharmacists had limited clinical and regulatory knowledge of MA. After the training, MA knowledge increased, particularly on topics most relevant for dispensing, including dosing, contraindications, efficacy, and safety.[16]

Implications

- Our research supports calls by medical associations[17] and clinicians[18] for the FDA to permanently end the REMS for mifepristone. Doing so could significantly increase the number of providers offering MA, especially in areas where abortion care is currently limited.
- If pharmacist dispensing becomes available, high quality training and educational outreach for pharmacists will be necessary to make the model successful. Training should also address relevant legal statutes and pharmacists' obligation to refer to a willing dispenser in the case of pharmacist refusals.
- We are currently evaluating mail-order pharmacy dispensing of mifepristone, a model with important potential in areas where few pharmacists agree to stock mifepristone or fill prescriptions.

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