Study finds physicians support pharmacy dispensing to expand access to medication abortion

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In a new study published online in spring 2021 and in the July issue of the journal *Contraception*, University of Chicago Medicine investigators and colleagues interviewed primary care providers in Illinois about their interest in providing medication abortion care and found that lifting FDA restrictions on mifepristone to allow pharmacy dispensing could normalize medication abortion, facilitate its use in primary care facilities, and address disparities in reproductive health access.

"Mifepristone is used in combination with misoprostol to end early pregnancies, during the first trimester," said senior author Debra Stulberg, MD, MAPP, Chair of the Department of Family Medicine at the UChicago Medicine. "The two-drug regimen is safe and highly effective, but access is limited by a strict Risk Evaluation and Mitigation Strategy (REMS) that prohibits pharmacy dispensing of mifepristone."

Together with students at UChicago and collaborators at Harvard Medical School, Stulberg interviewed 19 primary care providers and administrators, including family medicine physicians, nurse practitioners, certified nurse midwives and clinical directors.

In describing barriers and facilitators to providing medication abortion care in their practices, participants expressed strong support for removal of the mifepristone REMS to align medication abortion care with evidence-based practice.

"In interviews, study participants described how the restrictions around mifepristone contribute to the stigmatization of abortion care," said first author Kayla Rasmussen, a medical student at the Pritzker School of Medicine. "For example, one of the midwives we spoke to expressed that having a drug that can only be prescribed if you are 'a special someone,' it makes mifepristone seem like a mysterious thing. Since it can't be readily prescribed, it feels very restricted and specialized."

This sentiment was shared by multiple participants, who expressed hope that lifting the mifepristone REMS would shift perceptions of some colleagues and organizational leaders that abortion care requires a specialty referral to instead embrace it as an integral component of comprehensive primary care. Normalizing medication abortion would align practice with current scientific evidence of its safety, while making care more accessible for patients who face barriers to getting to an abortion clinic.

"Providers shared that allowing pharmacy dispensing of mifepristone would reduce the logistical barriers toward accessing medication abortion and allow clinicians to provide care remotely, via telemedicine," said Elizabeth Janiak, ScD, an assistant professor at Harvard Medical

School. "Expanding these services could reduce geographic disparities in abortion access and increase patient autonomy over where and how to receive care, whether it be for an abortion or a miscarriage."

The research team also wrote a related commentary, published in the same issue of *Contraception*, to explain in more depth how the REMS restrictions perpetuate the stigmatization of mifepristone use in primary care.

"The REMS creates the false perception that mifepristone is difficult to use, which leads to institutions feeling afraid to stock or use the medication," said Danielle Calloway, an undergraduate student at UChicago and lead author on the commentary. "When institutions create barriers that prevent their providers from integrating mifepristone into their care practices, it affects access to not only early abortions, but also early pregnancy loss management, which uses the same medications."

The team seeks to highlight the importance of promoting equitable access to abortion care, especially during the COVID-19 pandemic, which made it difficult for many patients to receive in-person medical care.

"Leading medical organizations, including the American College of Obstetricians and Gynecologists (ACOG) and American Academy of Family Physicians, have long supported removal of the mifepristone REMS," said Stulberg. "In 2020, ACOG sued the FDA over these restrictions, resulting in a temporary suspension of the in-person requirements for the duration of the pandemic. While providers can now mail mifepristone to patients, pharmacy dispensing is still prohibited, despite evidence supporting the safety and efficacy of mifepristone. This means that patients have to wait for someone to send them the medication, rather than being able to pick it up as soon as possible after it's been prescribed."

While study participants acknowledged further challenges that will remain to be addressed if the mifepristone REMS is lifted, such as pharmacist refusal to dispense the drug, these were not perceived as justifications for the restriction of abortion care. "Our study adds to the growing body of evidence that the current policy barriers to providing mifepristone cause more harm to patients than good," said Stulberg. "Primary care clinicians can help ensure equitable access to safe, effective abortion care, but the REMS restrictions make it unnecessarily hard."

In response to this growing body of evidence and the ongoing litigation, on Friday, May 7, the FDA announced that the agency will undertake a full review of the mifepristone REMS by the end of calendar year 2021. "This research makes it clear that the REMS unjustly restricts abortion provision without any tradeoffs in patient safety or efficacy," said Rasmussen. "It's time to reevaluate the basis for these restrictions and expand equitable access to abortion care."

More information: Kayla N. Rasmussen et al, Expanding access to medication abortion through pharmacy dispensing of mifepristone: Primary care perspectives from Illinois, *Contraception* (2021). DOI: 10.1016/j.contraception.2021.03.022

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