Emerging Advances and Existing Barriers for Medication Abortion

TAYLOR FREEBURG, MD'22; MEGHNA NANDI, MD'21; ANDREA ARENA, MD

The COVID-19 pandemic has magnified existing barriers to abortion access including cost, limited appointments, and transportation.[1] Notably, these barriers likely had a disproportionate impact on people of low-income backgrounds and communities of color, who were more likely to face economic hardship during the pandemic. In response to these barriers and the increasing use of telemedicine, abortion providers have developed new methods for medication abortion care delivery to limit in-person contact and increase accessibility. As these new options for abortion care delivery emerged, some states have responded with increasingly restrictive legislation to limit abortion access. In this commentary, we discuss emerging options for medication abortion delivery and remaining barriers to access.

Reducing barriers through medication abortion

Medication abortion, achieved by administering Mifepristone and then Misoprostol, is a safe, effective abortion option that circumvents barriers to procedural abortion including in-person contact and limited providers with the required skillset. Currently, medication abortion is approved by the U.S. Drug and Food Administration (FDA) up to 70 days gestational age. Since the FDA-approved medication abortion in 2000, its use has grown, with nearly half of abortions at nine weeks gestation or less being medication abortions nationally in 2018.[2] The expected effects of medication abortion are heavy bleeding and cramping as the uterine contents are expelled over several days. If a medication abortion does not remove all fetal tissue, a secondary aspiration procedure may be necessary (6.2% of patients in a nationwide study).[3] Medication abortion is a generally safe, effective alternative to procedural abortion, especially for earlier gestations.

Restrictions on medical abortion

Despite the ease of use and pressing need, medication abortion has historically been limited by federal regulations. Mifepristone is tightly regulated under the Risk Evaluation and Mitigation Strategy (REMS) mandated by the FDA, even though the safety of Mifepristone is well established.[4] Mifepristone is easy to use and has well-established dosing protocols, unlike many medications that are not under REMS and require close monitoring or titrating, such as Warfarin and Valproic Acid. Although REMS is intended to minimize harms, the policy creates barriers to Mifepristone access since the drug cannot be dispensed at pharmacies. To prescribe Mifepristone, physicians must register with a distributor, stock the drug in their office, and provide a medication guide and agreement to the patient. Though the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Family Physicians (AAFP) have long called for removal of the Mifepristone REMS classification; the pandemic brought renewed attention to the issue, in part because in-person visits put patients and providers at risk for COVID-19.[5,6] In April 2021, the FDA temporarily suspended the REMS requirement that Mifepristone must be dispensed in a clinic, medical office, or hospital. This new policy follows a legal battle which began in May 2020, when the American Civil Liberties Union (ACLU) filed a lawsuit against the FDA on behalf of the ACOG which challenged the validity of REMS. Notably, the District Court of Maryland had previously blocked the REMS measure in July 2020 and Mifepristone remained free from REMS jurisdiction until January 2021, when the U.S. Supreme Court reinstated the regulations.[7,8] The temporary relaxation of the Mifepristone REMS is linked to the development of teleabortion clinics and increased options for patients to fill Mifepristone prescriptions that have transformed medication abortion delivery.

Telemedicine and abortion

The temporary suspension of the REMS has enabled opportunities to deliver medication abortion care that capitalizes on the accelerated use of telehealth. The Reproductive Health Access Project has developed a "no-touch" medication abortion protocol that outlines an approach where a patient is evaluated by video or phone and gestational age is determined by last menstrual period rather than in-person ultrasound.[9] In the first three months of the pandemic, one study surveying independent abortion providers found that 71% of providers moved to telehealth for follow-up and 41% for consultation.[10] Digital abortion clinics such as Hey Jane and TelAbortion that offer telehealth visits and then ship abortion pills to patients also emerged in the past year.[11,12]

Even prior to the pandemic, there was abundant global evidence supporting telemedicine for medication abortion. The findings from these studies suggest that rates of completion and complications of first-trimester medication abortions through telemedicine are similar to those following medication abortions started in the clinic.[13] One observational study from the United Kingdom followed outcomes of 663 patients who completed medication abortion at home through a telemedicine program without routine ultrasound. These patients had high rates of abortion completion and low rates of complications, similar to studies of patients who had ultrasounds and took Mifepristone in a clinical setting. Although pre-abortion ultrasound was not used routinely, in one-fifth of the patients, imaging was deemed necessary for cases in which gestational age was uncertain or to confirm location of pregnancy.[14] These findings are in line with the National Abortion Federation guidelines, which state that ultrasound is not required for first-trimester abortion care, but may be used inform clinical decision-making when gestational age cannot be determined by other means.[15]

Ongoing challenges facing medical abortion

The challenges of this past year have increased barriers to abortion access and thereby cast heightened scrutiny to current federal and state restrictions for medication abortion. The temporary suspension of REMS along with the increased use of telehealth nationally has created opportunities for increased flexibility and privacy for patients seeking medication abortion. These changes address barriers such as limited appointments and transportation; however, ongoing challenges to abortion access remain. People of low-income backgrounds may not have access to a computer to participate in telehealth or stable housing to endure the several days of heavy bleeding associated with medication abortion. Furthermore, the cost of a medication abortion can be prohibitive especially considering that RI's Medicaid program does not cover abortion except in cases of rape, incest, or life endangerment. In RI nearly 1 in 3 residents have public insurance and therefore cannot use their health insurance for an abortion. Currently there is proposed legislation at the state level, the Equality in Abortion Coverage Act, which would expand abortion coverage to government employees and users of Medicaid. It is currently being held in both chambers, and it is imperative for the medical community to throw their support behind these changes.[16]

The relaxation of REMS and expansion of telehealth have increased access to medication abortions; however, increasingly restrictive legislation makes decreasing barriers to abortion particularly urgent. Recently Texas passed a new law, one of several across the US banning abortions at six weeks gestation, only two weeks after the first missed period, before most individuals know they are pregnant. Texas' new law includes an unusual twist in that it allows any individual to sue people who "aid or abet" an abortion patient. A coalition of abortion providers filed a federal lawsuit to challenge this new law before it takes effect on September 1st.[17] In this increasingly restrictive and punitive climate, medication abortion, especially through a primary care office or telemedicine, provides a point of access. ❖

References

1. Bayefsky MJ, Bartz D, Watson KL. Abortion during the Covid-19 Pandemic - Ensuring Access to an Essential Health Service. N Engl J Med. 2020;382(19):e47. doi:10.1056/NEJMp2008006
2. Kortsmit K, Jatlaoui TC, Mandel MG, et al. Abortion Surveillance – United States, 2018. MMWR Surveill Summ. 2020; 69(7):1-29. doi:10.15585/mmwr.ss6907a1
3. Meaidi A, Friedrich S, Gerds TA, Lidegaard O. Risk factors for surgical intervention of early medical abortion. Am J Obstet Gynecol. 2019;220(5):478.e1-478.e15. doi:10.1016/j.ajog.2019.02.014
4. Raymond EG, Blanchard K, Blumenthal PD, Cleland K, Foster AM, Gold M, Grossman D, Pendergast MK, Westhoff CL, Winikoff B. Sixteen Years of Overregulation: Time to Unburden Mifeprex. N Engl J Med. 2017 Feb 23;376(8):790-794. doi: 10.1056/NEJMsb1612526. PMID: 28225670.
5. Improving Access to Mifepristone for Reproductive Health Indications. ACOG. 2018 June. https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications
6. Munger M. Letter to FDA on REMS Requirements for Mifepristone. AAFP. 2019 June 20. https://www-aafp.org.AAFP/documents/advocacy/prevention/women/LT-FDA-Mifepristone REMS-062019.pdf
7. American College of Obstetricians and Gynecologists v. U.S. Food and Drug Administration. Civil action no. TDC-20-1320 (D. MD. 2020).
8. American College of Obstetricians and Gynecologists v. U.S. Food and Drug Administration. No. 20A34. 592 U.S. (2021).
9. No Touch Medication Abortion Protocol. Reproductive Health Access Project. 2020 March 26. Accessed 2021 March 16. https://www.reproductiveaccess.org/resource/no-touch-mab-protocol/
10. Upadhyay UD, Schroeder R, Roberts SCM. Adoption of no-test and telehealth medication abortion care among independent abortion providers in response to COVID-19. Contracept X. 2020;2:100049. doi:10.1016/j.conx.2020.100049
11. Hey Jane. Accessed 2021 January 10. https://www.heyjane.co/.
12. TelAbortion. Accessed 2021 January 10. https://www.telabortion.org.
13. Endler M, Lavelanet A, Cleeve A, Ganatra B, Gomperts R, Gemzell-Danielsson K. Telemedicine for medical abortion: a systematic review. BJOG. 2019;126(9):1094-1102. doi:10.1111/1471-0528.15684
14. Reynolds-Wright JJ, Johnstone A, McCabe K, Evans E, Cameron S. Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic [published online ahead of print, 2021 Feb 4]. BMJ Sex Reprod Health. 2021;bmjsrh-2020-200976. doi: 10.1136/bmjsrh-2020-200976
15. Clinical Policy Guidelines for Abortion Care. National Abortion Federation. 2020. https://prochoice.org/providers/quality-standards/
16. Valverde B, Cano S, Goldin G, Mack T, Sosnowski, Euer D, Acosta J, Kallman M, Coyne C, Pearson R. Equality in Abortion Coverage Act. State of RI General Assembly. 2021; LC000764. http://webserver.rilin.state.ri.us/BillText/BillText21/SenateText21/S0267.pdf
17. Dias E. Lawsuit Takes Aim at Citizen-Enforced Texas Abortion Law. The New York Times. 2021 July 13. Accessed 2021 July 16. https://www.nytimes.com/2021/07/13/us/texas-abortion-lawsuit.html

Acknowledgments

We thank Dr. Daria Szkwarko, Dr. Rebecca Allen, and Dr. Edward Feller for their insightful discussions of this topic.

Authors

Taylor Freeburg, MD'22, Warren Alpert Medical School of Brown University, Providence, RI.

Meghna Nandi, MD-ScM'21, Primary Care-Population Medicine Program, Warren Alpert Medical School of Brown University, Providence, RI.

Andrea Arena, MD, Clinical Assistant Professor of Family Medicine, Warren Alpert Medical School of Brown University, Providence, RI.

Disclaimer

The views expressed herein are those of the authors and do not necessarily reflect the views of the Warren Alpert Medical School of Brown University.

Funding

None

Correspondence

Taylor Freeburg, MD'22
Brown University
Box G-9999
Providence, RI 02912
taylor_freeburg@brown.edu