Title

It Is Time to Change the Standard of Medication Abortion

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Invited Commentary

It Is Time to Change the Standard of Medication Abortion

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Before prescribing medication abortion, clinicians have been compelled to perform a pelvic examination or ultrasonography for gestational dating to adhere to the requirements of the US Food and Drug Administration (FDA) Risk Evaluation and Mitigation System (REMS) program for dispensing mifepristone. These examinations require an in-person clinic visit, which can be logistically burdensome and limit access to care. In this issue of *JAMA Internal Medicine*, Upadhyay et al[1] provide evidence that medication abortion using mifepristone and misoprostol is safe and effective for pregnancy termination without requiring an in-person clinical evaluation. These data should reassure clinicians and FDA evaluators that allowing history-based screening in lieu of in-person examinations is appropriate and evidence based.

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This report is particularly timely given the FDA's recently completed review of the Mifepristone REMS Program. On December 20, 2021, the FDA sent a letter to the plaintiffs in a case the American Civil Liberties Union filed in 2017 (*Chelius v Becerra*) on behalf of a Hawaiian doctor and health care associations, which argued that the FDA restricted access to abortion care with no medical basis by requiring in-person dispensing of mifepristone. Based on the available data, the FDA decided to remove the requirement for in-person dispensing of mifepristone.[2-5] This does not change current practice because the FDA had previously removed the in-person dispensing requirement during the COVID-19 public health emergency. While this decision eliminates the in-person dispensing requirement permanently, it does not adjust additional requirements for the patient agreement and the specialized clinician certification, which the FDA left in place. Moreover, the new rules added an additional restriction requiring certification of the pharmacies meant to dispense mifepristone. There are no data that we could find that these certifications of patients, clinicians, and pharmacies adds clinical benefit to an already safe and effective medication with limited contraindications and adverse effects. Moreover, the FDA's action will not affect existing state-level restrictions on access to medication abortion that are already in place. As a result, communities that already face difficulty accessing medication abortion remain vulnerable to medically unnecessary restrictions.

The study by Upadhyay et al[1] provides evidence collected before and during the COVID-19 pandemic in the US that supports a shift in the practice for initiating medication abortion to one that uses history-based screening and remote prescribing. The authors present data from a retrospective cohort study of 3779 medication abortions dispensed either in

person or by mail through 14 clinics that provide abortion care in diverse settings. Of these, 2825 (74.5%) had follow-up data available, and 2397 (63.4%) had abortion outcome data available. The adjusted effectiveness (defined as a binary measure of complete abortion after initial treatment without subsequent known intervention) among those with follow-up data was 94.5% (95% CI, 92.9%-96.1%) and did not differ by method of dispensation (in person or via mail). Among women with follow-up data, 0.39% had a major abortion-related adverse outcome, defined as requiring a blood transfusion, surgery, or hospital admission, and this rate also did not differ significantly based on method of dispensation. Given the low complication risk associated with medication abortion overall, it is unlikely that participants for whom additional abortion outcome data were not available experienced a substantially higher rate of complications.

These data are consistent with prior studies examining the safety and efficacy of medication abortion using protocols that mandated in-person evaluation. In these studies, efficacy was about 94% and adverse outcomes were uncommon, including surgical evacuation for reasons other than ongoing pregnancy (1.8%-4.2% of patients), blood transfusion (0.03%-0.6%), and infection (0.01%-0.5%).[6] Studies of telemedicine and out-of-clinic abortion care further demonstrate the efficacy and safety of medication abortion without prior examinations. Among 18 435 people who received medication abortion between April and June 2020 in a study based in the UK, abortion without in-person examination or assessment demonstrated slightly higher effectiveness compared with in-person care (99.2% vs 98.1%; $P < .001$), and the rate of serious adverse events was similar in the traditional in-person model with ultrasonography and the telemedicine-hybrid model without ultrasonography (0.02% vs 0.04%; $P = .56$).[4] In a study of 961 pregnant people in which trained laypersons, not physicians, supported pregnancy termination with medications without in-person examinations or tests, 93.8% of those who used the mifepristone/misoprostol regimen and were less than 90 days estimated gestational age experienced a complete abortion without surgical intervention.[7] These findings demonstrating the safety and efficacy of medication abortion with or without mandated in-person evaluation align with our own experience dispensing mifepristone and misoprostol in person before, and remotely during, the COVID-19 pandemic.

Many clinician providers of abortion services in the US already support moving toward a model that eliminates in-person requirements. During 2019 to 2020, Karlin et al[8] interviewed 40 clinician providers of abortion services from 24 states in the US about their level of comfort in supporting medication abortion without in-person contact with a medical clinician. During a baseline interview in March 2019, clinicians acknowledged that evidence already supported a less medicalized model of abortion care, including eliminating ultrasonography and laboratory work. Half of the clinicians felt that medication abortion was so safe that they supported terminating pregnancy without direct clinician assessment and evaluation—for example, by shifting medications to over-the-counter, providing medications prior to pregnancy ("advance provision"), or providing support by laypersons as described above. In surveys conducted after clinicians experienced models of care that did not require in-person evaluations during the COVID-19 pandemic, almost all became supportive of less burdensome care models, noting their direct observation of the safety and effectiveness of medications, as well as alignment with their own values as physicians around person-centered care.

The Institute of Medicine has identified 6 domains of health care quality, which include care that is safe, effective, patient centered, timely, efficient, and equitable. The findings reported by Upadhyay et al[1] provide reassurance of the safety and effectiveness of medication abortion using a history-based assessment tool, allowing us to move forward with a model of care that meets the highest standards of quality care while ensuring access. Given the evidence, it is our professional duty to recognize, reassess, and eliminate medically unnecessary barriers to care. Shifting to medication abortion that prioritizes these domains is essential to address inequities in outcomes for communities that have been marginalized. In doing so, we have the potential to address ongoing concerns regarding inequities in access to abortion care—inequities that are more likely to affect individuals with difficulty accessing care and those who have experienced stigma or trauma while accessing care, including communities of color, those living on low incomes and in rural communities, young people, and lesbian, gay, bisexual, transgender, queer, and other sexual and gender minority individuals.

Removing the medically unnecessary REMS restrictions and changing the standard protocol for a medication abortion will make care more timely, efficient, patient centered, and equitable by removing the barrier of access to a physical clinic. It also has the potential to support the expansion of the workforce of abortion care clinicians. As reported by Strasser et al[9] in this issue of *JAMA Internal Medicine*, the US abortion care workforce includes only 3550 abortion service clinicians. According to the Centers for Disease Control and Prevention, this limited workforce provided legal induced abortions for 629 898 people in the US seeking abortion care in 2019.[10] The number of clinicians who provide abortions can be increased by removing the requirement for clinicians to sign the REMS and through educating clinicians about the safety and efficacy of medication abortion that does not require in-person assessment. Researchers, clinician providers of abortion services, and experts are leading the way toward a less burdensome, evidence-based model of medication abortion care delivery. Hopefully, regulators will also follow the evidence and prioritize our collective principles of quality health care delivery.

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