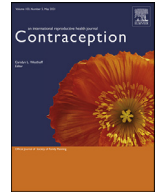




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The future of abortion is now: Mifepristone by mail and in-clinic abortion access in the United States

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ABSTRACT

The COVID-19 pandemic disrupted health care delivery in all aspects of medicine, including abortion care. For 6 months, the mifepristone Risk Evaluation and Mitigation Strategy (REMS) was temporarily blocked, allowing for the remote provision of medication abortion. Remote medication abortion may become a dominant model of care in the future, either through the formal health system or through self-sourced, self-managed abortion. Clinics already face pressure from falling abortion rates and excessive regulation and with a transition to remote abortion, may not be able to sustain services. Although remote medication abortion improves access for many, those who need or want in-clinic care such as people later in pregnancy, people for whom abortion at home is not safe or feasible, or people who are not eligible for medication abortion, will need comprehensive support to access safe and appropriate care. To understand how we may adapt to remote abortion without leaving people behind, we can look outside of the U.S. to become familiar with emerging and alternative models of abortion care.

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1. Introduction

Since the United States Food and Drug Administration (FDA) approved mifepristone more than 20 years ago, reproductive health advocates have concentrated efforts on broadening access to medication abortion. From changes in service delivery to expanding eligibility and pregnancy dating criteria, providers and advocates have developed care models that promote patient-centered use. Abortion provision that is timely, accessible, and convenient had been a long-held goal of providers, advocates, activists, and people seeking care.

The timeline for change was accelerated in 2020 as the COVID-19 pandemic not only exacerbated existing health inequities, but dramatically disrupted the delivery of all medical care, including abortion care. As providers scrambled to modify abortion services to incorporate public health protections, such as the limitation of in-person contact, researchers worked to develop evidence-based protocols for abortion that accommodated these guidelines, including eliminating lab testing and ultrasound. These practices have since been recommended by professional organizations and deployed in clinical services [1–3]. The temporary suspension of the

in-person dispensing requirement in the mifepristone Risk Evaluation and Mitigation Strategy (REMS) also permitted providers to dispense mifepristone and misoprostol through alternative means, such as the mail [4]. Online-only services supported by mail-order pharmacies started offering fully remote medication abortion care in the United States (U.S.).

Although the shifts have felt sudden to some, the pandemic simply accelerated long-term, evidence-based trends that have led to declining numbers of abortions performed in brick-and-mortar clinics. These shifts are likely to stay with us long after the pandemic has passed and may permanently alter the existing landscape of abortion care. In addition, even as the newly elected administration and Congress support reproductive rights, the prior administration leaves behind a federal judiciary that may prove dangerously hostile. We must prepare ourselves for changes in abortion access. To understand how we may adapt to change, we can look outside of the U.S. context to become familiar with emerging and alternative models of abortion care.

2. Abortion trends: Fewer abortions, with care shifting earlier in pregnancy

Over the last decade, the number of clinic-based abortions provided in the U.S. has declined. According to the Guttmacher Institute's periodic abortion provider census, from 2011 to 2017, the total number of reported abortions decreased 19% and the reported

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abortion rate dropped 20%, from 16.9 to 13.5 abortions per 1000 women ages 15 to 44 [5]. In addition, a higher proportion of abortions are being done earlier in pregnancy, with approximately one-third of all abortions now being provided less than 6 weeks [6]. For people under 9 weeks in pregnancy, half were medication abortion.

There are multiple factors that may be contributing to reduced abortion rates, including state-based restrictions and clinic closures and a rise in self-managed abortions that current surveillance systems do not capture. However, as abortion rates have been declining steadily, so have birth rates, indicating an overall drop in the pregnancy rate, the core driver of abortion [5]. Increased age at first intercourse, increased contraceptive use, improved access to and affordability of contraception, and increased use of more reliable contraceptive methods, including long-acting methods, have coincided with the change in pregnancy rates [7]. Notwithstanding court rulings that allow employers that assert “religious liberty” claim to deny their employees contraceptive coverage, the Affordable Care Act continues to provide contraceptive coverage for millions in the U.S. Recent evidence has also supported practices that expand access to pregnancy prevention methods, including immediate postpartum and postabortion contraception and increasing long-acting contraceptive access for adolescents and young people [8–10].

3. Accelerated change: Mailing medications from clinics and self-sourced, self-managed medication abortion

Before the COVID-19 pandemic, direct-to-patient medication abortion with mifepristone was only available in the U.S. to people enrolled in a research study [11]. The REMS specifies that mifepristone must be “dispensed to patients only in clinics, medical offices or hospitals, by or under the supervision of a certified prescriber.” [12] This language has been widely interpreted to mean that patients using mifepristone must physically enter the clinic setting to receive the medication, creating a substantial barrier to care.

Years of evidence from the U.S. and abroad shows that medication abortion provided remotely is as safe as in-person abortion [11,13,14]. During the pandemic, the British government issued emergency legal orders to allow for mifepristone use at home using a “no-test model.” A recent study of 52,142 people who were prescribed medication abortion both before and after the switch to a no-test model showed that, in comparison to the cohort who had “traditional” medication abortion with a clinic visit and ultrasound, those in the “telemedicine-hybrid” group who had a telemedicine consultation with no in-clinic visit and no ultrasound if eligible had equally effective and safe abortion outcomes with similarly low rates of major adverse events and ectopic pregnancy [15]. Of those in the “telemedicine-hybrid” cohort, 61% were fully remote with no need for ultrasound. People who were part of the telemedicine-hybrid cohort waited less time to get their appointments and could access abortion care earlier in pregnancy. Eleven people in the telemedicine-hybrid cohort who had an abortion were diagnosed with a more advanced pregnancy than the 10-week eligibility, and all of these completed the medication abortion at home with no further treatment.

In July 2020 in the U.S., a court temporarily blocked the in-person dispensing requirement in the REMS. Understanding the importance of safe, timely access to medication abortion, providers looked for opportunities to offer abortion completely remotely – using telemedicine for consultation, consent, and follow-up, and mailing medications from their offices or through a mail-order pharmacy. New online-only providers started offering services [16]. Other providers who were unable to transition completely to a telemedicine model also adopted evidence-based protocols that reduced other in-person requirements, including eliminating ul-

trasounds and removing unnecessary Rh testing and Rh-immune globulin for eligible patients [1,3,17].

Responding to a request for an emergency stay from the Trump administration, the Supreme Court reinstated the in-person dispensing requirement in the REMS in January 2021, despite the continued impact of COVID-19. Abortion advocates have asked the Biden administration to issue immediate nonenforcement guidance for the in-person dispensing requirement during the pandemic and direct the FDA to undertake a comprehensive reevaluation of the entire mifepristone REMS [18]. Although lifting the in-person dispensing requirement would help patients in some states, almost 20 states have laws that specifically restrict abortion by telemedicine and others have regulations that put telemedicine abortion out of reach [19]. Not surprisingly, states with telemedicine abortion bans also have the most restricted in-clinic access.

With legal paths to remote abortion unresolved, and in-clinic abortion often inaccessible, unacceptable, unavailable, or unaffordable, some people are accessing abortion outside the formal health system. Aid Access is one example of a web-based service that provides remote consultation and partners with an overseas pharmacy to ship abortion medications directly to people needing abortion care. From January 1, 2019 to April 11, 2020, Aid Access received 49,935 requests for abortion from U.S. residents [20]. From March 20 to April 11, 2020, in the early days of the pandemic, there was a 27% increase in requests. The volume of requests both before and during the pandemic shows how many people want fully remote telemedicine abortion care, regardless of whether it operates through the formal health system.

4. Anticipated effects: In-clinic abortion gives way to remote abortion

Ninety-five percent of reported abortion care in the U.S. is offered in freestanding clinics, which face increasing scrutiny and unnecessary regulation [21]. Clinics are susceptible to regulations that hostile state actors design to close doors (Targeted Regulation of Abortion Providers or TRAP laws), are subject to intense protests and violence, and operate on very slim margins [22]. As in-clinic abortion numbers and rates have decreased and state regulations have burdened abortion-providing facilities to the breaking point, clinics have closed. The number of abortion clinics declined by 7% between 2014 and 2017, with clinics disproportionately closing in the South and Midwest [21]. In addition, the pandemic caused temporary clinic closures as antiabortion politicians deemed abortion a “nonessential” service. Although court challenges to the pandemic closures were successful and clinics reopened, previous and repetitive attempts to restrict access through the legal system have led to permanent closures in the past [23].

Despite the Democratic administration and Senate, the Trump administration’s appointments to the federal courts may prove fatal to legal abortion access in hostile states. That the Supreme Court lifted the injunction on the in-person dispensing requirement for mifepristone on January 12, 2021, the same day that saw 4,400 COVID-19 deaths in the U.S., suggests a readiness to support abortion restrictions that flout evidence, in a direct rebuke to human rights [24]. The change in the courts may allow many states to make abortion, which is already so difficult to access, unavailable in the years to come.

While technological innovation in clinical care delivery may provide increased access for many, it may also present challenges for those seeking in-clinic care. In 2017, the average price of a first-trimester medication abortion supplied in clinic was USD551 [25]. In comparison, online-only services are generally priced at USD250 or less. Even if clinics can offer both in-clinic and remote abortion care, their remote service may need to be less expensive. People seeking abortion often pay out of pocket and are likely

to go with a less costly remote option, even if an in-clinic abortion is available. In addition, some people may prefer the privacy and convenience of remote care. Clinics that only offer early abortion will encounter stiff competition from remote providers. Clinics that provide early and later care may need a higher volume of in-clinic early abortion care to support them so that they can provide later care. As remote services increase, some brick-and-mortar clinics may be unable to sustain their current business models. They will either adapt by curtailing hours and staff or considering new clinical services to offer (for example, general gynecology, gender-affirming care, remote abortion evaluation, or follow-up) or they will close.

5. Unanticipated effects: Reduced choice and disproportionate burdens

The removal of the REMS would improve access to care for some people. In states that allow full remote medication abortion, eligible people who are early in pregnancy with good access to phone, internet, and a safe and private place to take the medications and pass the pregnancy may find telemedicine abortion safer, easier, and more convenient. Remote abortion can reduce logistical barriers for people who are distant from in-person clinics and financial hurdles when in-clinic abortion is not affordable. Although abortion is legal throughout the country, in many parts of the U.S., it is not accessible. Mississippi, North Dakota, South Dakota, and West Virginia have only one operating abortion clinic. In Minot, North Dakota, a pregnant person will need to drive 232 miles to their nearest clinic in Fargo. Remote or telemedicine abortion has the potential to open access to many who could not make their way to in-clinic care.

However, some people will still want or need in-clinic care. Medication abortion may be more difficult to conceal from an unsupportive or abusive partner or parent than an in-clinic abortion. Some may not be medically eligible for medication abortion. Some may prefer an aspiration procedure to medication abortion. Some, especially people who are young and people living on low incomes, may not have access to the reliable phone, internet, and mailing address needed to coordinate remote care. Some may not have access to the necessary support to manage an abortion on their own or a safe space to pass the pregnancy.

Although most people seek abortion early in pregnancy, 9% of abortions in the U.S. are provided for people over 13 weeks [6]. Because most remote or telemedicine abortion services provide care through 10 or 11 weeks from the first day of the last menstrual period, those needing abortions later in pregnancy rely on clinic-based care. Inequities in access to later care have disparate impacts. The need for later abortion care stems from an array of individual, systemic, and structural factors including structural racism, economic injustice, and inequities in access to quality, comprehensive, reproductive health care. Compared to people seeking early abortions, those who need abortions later in pregnancy are more likely to be living on low incomes and/or living in circumstances with less access to abortion care. Financial barriers, logistical challenges, and the experience of interpersonal violence all contribute to the need to access abortion care later in pregnancy [26–28].

Clinic closures will make it even more difficult for those seeking later care to find a provider. Travel distances, expenses, and time away from home will all increase. For some, the burden will be too high, and they will be forced to remain pregnant against their will. Others may self-manage later abortions, which carries potential legal and medical risks. When abortion care is more difficult to access, those who need in-clinic care will need not just the clinical service, but wrap-around, comprehensive support just to get in the door. They will need help finding providers, negotiating childcare and time off work, raising funds, traveling to a

procedure, and obtaining food and housing for the duration of the procedure. People who manage later abortion on their own need economic, social, emotional, and legal support in addition to clinical care before, during, or after the abortion itself.

6. Lessons from deregulating mifepristone: Shifting abortion care from clinics and throughout the health system

Looking to Canada may reveal one model of abortion in the U.S. in years to come. In 2015, Health Canada approved the mifepristone/misoprostol regimen under the brand name Mifegymiso for early abortion in Canada, and uptake of the method by providers and people seeking abortion care has been rapid. Prior to mifepristone's introduction, medication abortion (with methotrexate and misoprostol) accounted for 8.4% of all abortions provided by Canadian members of the National Abortion Federation (NAF) [29]. By the end of 2018, 25.6% of abortions provided by Canadian NAF members used medication and providers were offering medication abortion in all provinces and the Yukon Territory.

When initially approved by Health Canada, the mifepristone/misoprostol regimen was limited to people less than 49 days from the last menstrual period, required the use of ultrasound, and required providers to be certified and register with the distributor. Changes that took 20 years in the U.S. happened rapidly in Canada. Over the last 5 years, Canada expanded eligibility to 63 days, allowed certified prescribers, including nurse practitioners, to prescribe, removed certifications requirements, permitted pharmacy dispensing, and eliminated ultrasound requirements. Most provincial and federal health insurance programs now cover medication abortion. During the pandemic, the federal government's reaffirmation that abortion is an essential health service allowed for quick adoption of no test protocols and remote consultation at the onset of the COVID-19 pandemic [30].

The deregulation of mifepristone has expanded the pool of abortion providers by allowing primary care clinicians to offer medication abortion [31,32]. Telemedicine services combined with pharmacy dispensing of the drugs enabled early abortion care in rural areas where there had previously been limited access. These changes have certainly had implications for freestanding clinics. Many are trying to identify ways to change or expand their services to account for the shift toward community-based medication abortion providers. Unlike in the U.S. context, most provincial and federal insurance programs cover both medication and procedural abortion care. Financial assistance is available to patients who cannot find appropriate services within their own province or territory. As a result, there remains a safety net for people who need to travel if medication abortion is not a viable option.

The Canadian system is an example of one way forward for U.S. states that have supportive legislation, policies, insurance coverage, and provider networks to both promote and adapt to change, should the REMS be removed. States like California, Illinois, Massachusetts, and New York may see an increase in online-only providers or community-based providers prescribing from pharmacies, with resulting changes in in-clinic abortion, but have some of the systems in place to adapt to the needs of people seeking abortion care. These shifts may result in clinic closure, leading people who need in-clinic care to travel further. Most importantly, supportive states use state-based funds to cover abortion for people living on low incomes, a safety net if care in clinics becomes scarce [33]. This funding needs to be more inclusive of care in later pregnancy, including reimbursements to providers for costlier or hospital-based procedures and support for travel and logistics.

7. Lessons from restricted settings: Supported self-sourced, self-managed medication abortion

Suppose other states that do not support remote abortion throughout the South and Midwest also continue to have declining access to in-clinic abortion. In that case, self-sourced, self-managed medication abortion may become a dominant model. In restricted environments globally, support networks have grown around self-sourced abortion to ensure that people have the help they need to access safe, evidence-based medication abortion. Harm reduction programs [34,35], community-based distribution programs [36,37], safe abortion hotlines and telemedicine services [38], and accompaniment models [39] are some examples of abortion support outside the health system.

Hotlines and global telemedicine services have been used worldwide to promote the safe use of medication abortion in restricted settings. Hotlines have been sponsored by feminist groups, clinical providers, and nongovernmental organizations [40–42] and offer evidence-based information and support; some also provide medications. Global telemedicine services, such as Women on Web and Women Help Women, provide online consultations and send medication abortion drugs through the mail to those seeking care [38].

For those needing later care, accompaniment joins people having an abortion either in-person or virtually with an experienced supporter. In an analysis of 318 case records from people 13 to 24 weeks who used mifepristone and misoprostol outside the health system plus the accompaniment model in Argentina, Chile, and Ecuador, 76% of people successfully completed the abortion on their own. One-third of people were seen in the health system during their care [39]. Ultimately, over 95% of abortions were completed successfully. Accompaniment combines evidence-based protocols and supportive care to manage abortion successfully, including later abortion, when the health system refuses. Although accompaniment has been described where abortion is restricted, if declining access to in-clinic abortion means that people later in pregnancy cannot access in-clinic care, accompaniment may be a route for accessing supported care when in-clinic care is not obtainable.

All of these support systems also exist within the U.S. If/When/How's Repro Legal Helpline, the M&A hotline, Plan C, Aid Access, Self-managed Abortion, Safe and Supported (SASS), abortion Facebook groups and subreddits, and auntie networks and abortion funds provide pills, funding, transportation, information, emotional support, and evidence-based care to people who need an abortion. Although accessible to all in the U.S., many of these resources are explicitly aimed at those who have self-sourced abortion medications and need the social, legal, and clinical support to help them manage the abortion process.

When people manage abortion outside the health system, either in restrictive settings or with new modes of remote abortion care provided through the formal health system, some will still present to the health system before, during, or after a medication abortion. The decline of abortion clinics means that people may present to settings, like religiously affiliated hospital emergency departments, that are unaccustomed or unfriendly to people who have had an abortion and do not understand their needs. People who seek care will need accurate, respectful, evidence-based care that does not put them at risk of unnecessary procedures, reporting, arrest, and prosecution [43]. If state-based restrictions become even more punitive, ensuring their safety, along with those who care for them, is an urgent priority.

Conclusion

The COVID-19 pandemic accelerated changes in the delivery of abortion care that have already been underway for some time. Instead of these changes rolling out systematically and slowly, the urgency of ensuring access to abortion care during a public health crisis means they have occurred rapidly, over days, weeks, and months. When the pandemic ends, many of the changes will become permanent. With a change in the U.S. political landscape, re-evaluation and removal of the medically unnecessary REMS may finally occur. Also, we may see further disruption from unfavorable, restrictive legislation. The removal of the REMS will increase legal, remote abortion care in states with favorable abortion laws. It may distribute early medication abortion care away from specialized abortion clinics and into online services or community health settings where a provider can prescribe abortion medication at a pharmacy. In those states where removal of the REMS does not impact care, because they already ban remote abortion, further restrictions will push more people toward self-sourced, self-managed abortion.

No matter what happens, the current system of in-clinic abortion will likely change radically. Although the future may make abortion more accessible for many, it may further reduce access for those who currently experience the most barriers to care. As providers, advocates, activists, and people who seek abortion, we need to seek alternative models of abortion care and understand how they impact people seeking care and providers, prepare for the future, and consider the trade-offs that will come if most abortion is provided remotely.

Declaration of Competing Interest

The authors declare no conflict of interest.

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