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Original Research Article

Federal, state, and institutional barriers to the expansion of medication and telemedicine abortion services in Ohio, Kentucky, and West Virginia during the COVID-19 pandemic



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ABSTRACT

Objectives: We aimed to characterize the combined impact of federal, state, and institutional policies on barriers to expanding medication and telemedicine abortion care delivery during the COVID-19 pandemic in the abortion-restrictive states of Ohio, Kentucky, and West Virginia.

Study Design: We analyzed 4 state policies, 2 COVID-related state executive orders, and clinic-level survey data on medication abortion provision from fourteen abortion facilities in Ohio, Kentucky, and West Virginia from December 2019 to December 2020. We calculated the percent of medication abortions provided at these facilities during the study period by state, to assess changes in medication abortion use during the pandemic.

Results: We ascertained that COVID-19-executive orders in Ohio and West Virginia that limited procedural abortion in Spring 2020 coincided with an increase in the overall number and proportion of medication abortions in this region, peaking at 1613 medication abortions (70%) in April 2020. Ohio and West Virginia, which had executive orders limiting procedural abortion, saw relatively greater increases in April compared to Kentucky. Despite temporary lifting of the mifepristone REMS, prepandemic regulations banning telemedicine abortion in Kentucky and West Virginia and requiring in-person clinic visits for medication abortion distribution in Ohio limited clinics' ability to adapt to offer medication abortion by mail.

Conclusions: Our findings illustrate how restrictive medication and telemedicine abortion policies in Ohio, Kentucky, and West Virginia created additional obstacles for patients seeking medication abortion during the pandemic. Permanently lifting federal regulations on in-clinic distribution of mifepristone would only advantage abortion seekers in states without restrictive telehealth and medication abortion policies. State policies that limit access to comprehensive abortion services should be central in larger efforts toward dismantling barriers that impinge upon reproductive autonomy.

Implication Statement: We find that abolishing the REMS on mifepristone would not be enough to expand access to patients in abortion-restrictive states with telemedicine and medication abortion laws. While the REMS is a barrier, it represents one of several hindrances to the expansion of telemedicine abortion distribution across the United States.

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1. Introduction

Abortion through medication has been increasingly utilized in the United States (US) since mifepristone was approved by the US Food and Drug Administration (FDA) in 2000, from 29% of all abor-

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tions in 2014 to 39% of all abortions in 2017 [1]. Because medication abortion can be safely administered outside of clinic settings, it is particularly amenable to telemedicine practices, whereby patients speak with a clinician over a video or audio call but do not see them in person. For example, groups in the United States such as Aid Access [2] and the TelAbortion research study protocol¹ provide virtual consultations and then distribute medication abortion pills to eligible patients by mail. Telemedicine abortion care can ameliorate transportation and financial burdens associated with inperson visit(s) for abortion counseling and medication administration [3]. Calls for the expansion of telemedicine abortion preceded the COVID-19 pandemic, with findings from a 2019 study arguing that, "in settings where abortion is legally restricted and availability of safe abortion services may be very limited, if available at all, high-quality telemedicine services undoubtedly improve access" [4].

However, use of medication abortion in the US is complicated by federal and state regulations regarding both the management of the medicine itself and its delivery by telemedicine. A federal Risk Evaluation and Mitigation Strategy (REMS) had been initiated through the FDA Amendments Act of 2007 [5], replacing an older requirement (Subpart (H)), requiring that the medication abortion drug mifepristone only be ordered, prescribed, and dispensed in a clinical setting by a certified provider [6]. In July 2020, in response to the pressures on the medical system created by the pandemic, a federal court ruled that the FDA could not enforce the REMS in-person dispensing requirements for the duration of the pandemic [7]. The REMS suspension allowed some abortion providers to offer medication abortion by mail, aligning with pandemic stay-at-home orders, social distancing guidelines, and the preservation of personal protective equipment for clinic personnel [7]. The Supreme Court halted this temporary loosening of the REMS in January 2021 [8], requiring certified providers to return to in-person dispensing despite the continuing public health crisis. Following this decision, the FDA's Center for Drug Evaluation and Research (CDER) reviewed the American College of Obstetricians and Gynecologists' concerns about the mifepristone REMS inperson dispensing requirements, and concluded in April 2021 that provided the other REMS Program requirements are met, mifepristone can be distributed through the mail under the supervision of a certified provider for the duration of the COVID-19 public health emergency [9].

Abortion access in several US states was already limited before the pandemic [10], and disproportionately so for those in rural settings [11, 12]. A 2017 Guttmacher Institute study shows that restrictive state policies exacerbate persistent geographical disparities for rural abortion seekers, making "distance a significant barrier to accessing abortion care for the substantial minority who live farther away, and especially for economically disadvantaged women who make up the majority of abortion patients" [10]. Amidst the pandemic, some states – along with physicians and reproductive advocacy groups – have pushed to make telehealth for abortion more accessible [13], while abortion-restrictive states have continued to pass restrictive policies [14].

In this manuscript, we evaluate the combined impact of the REMS, state policies, and clinics' abortion provision practices on opportunities and barriers to expand access to medication and telemedicine abortion during the COVID-19 pandemic in Ohio, Kentucky, and West Virginia, abortion-restrictive states with significant rural areas. We characterize these three abortion-restrictive state contexts to illustrate how state and federal policies and institutional limitations interlock to limit the range of reproductive health care options available to abortion seekers in these states.

2. Methods

We used a mixed-methods approach and triangulated our findings to develop a nuanced understanding of the current accessibility and feasibility of expanding telemedicine abortion services under varied complex structures [15]. We analyzed state policies, state executive orders, and clinic-level survey data on medication abortion provision in this study. We sought to understand clinic-level barriers and opportunities that result from a dynamic federal and state regulatory landscape in Ohio, Kentucky, and West Virginia prior to and during the COVID-19 pandemic (December 2019–December 2020).

To assess policy and policy change, we searched for abortion bills and policies pertaining to distribution of medication abortion in Ohio, Kentucky, and West Virginia that were in effect in 2020. We reviewed enacted abortion laws, policy tracking resources, and reports compiled by organizations such as the Guttmacher Institute and NARAL, and executive actions pertaining to abortion care provision in these states during the COVID-19 pandemic. The search yielded 4 laws (2 in Ohio, 1 in Kentucky, and 1 in West Virginia), and 2 executive actions in Ohio and West Virginia. We analyzed these laws and policies for implications for provision of medication abortion during the pandemic. Laws that were currently enjoined (such as Ohio's 6-week ban) or not yet in effect (like Ohio's telemedicine abortion ban, which was poised to go into effect in 2021 but has since been blocked by a legal challenge) are not included in this analysis.

We also describe changes in medication abortion provision at 14 abortion facilities in Ohio, Kentucky, and West Virginia, from December 2019 through December 2020. This allows us to capture service delivery before and after COVID-19-related state regulations regarding abortion that were in effect in March and April 2020. We surveyed clinics monthly via an online questionnaire in which facility staff answered questions related to abortion service delivery and availability, including the number of abortions and distribution by method of abortion (procedural and medication) [16]. Survey data collection was approved by the Ohio State University and University of Cincinnati Institutional Review Boards. Based on data completeness and availability, we report on 14 of the 16 sites that offer medication abortion care in these 3 states, capturing more than three quarters of all medication abortions in this region. Sites from which we do not have data are excluded from the current analysis.

3. Results

3.1. Policy context

In March 2020, officials in Ohio and West Virginia issued executive orders requiring all elective surgeries to cease [17, 18]. State actors used these executive orders to deem procedural abortion an "elective," nonurgent procedure that could be delayed during the pandemic. The American College of Obstetricians and Gynecologists and other medical professional societies retorted that characterizing pregnancy termination as elective or non-urgent during the pandemic is inappropriate, as abortion is a time-sensitive procedure that generates additional risks when performed at a later gestational age [19]. Nevertheless, the Ohio and West Virginia executive orders were interpreted to require abortions before 10 weeks' gestation to be completed by medication abortion rather than procedural abortion whenever possible and unless contraindicated. Ohio abortion clinics successfully challenged the "elective surgery" designation for procedural abortion after 10 weeks, although limitations on procedural abortions before 10 weeks remained in place until the executive order was lifted on May 1, 2020 [20]. The West Virginia executive order remained in effect until it expired on April

¹ See for example, TelAbortion, US. https://telabortion.org/news

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30, 2020 [18]. During March and April 2020, these orders significantly curtailed access to procedural abortion in these two states, making medication abortion the most readily accessible method of abortion. While the State of Kentucky also issued an executive order halting nonemergent and nonurgent health care procedures in March 2020, procedural abortion provision was not subject to the order, falling under the definition of urgent healthcare that could risk serious or irreparable harm to the patient if delayed more than 30 days [21].

In contrast to executive orders that encouraged utilization of medication abortion, existing state laws impinged upon innovative provision of medication abortion during the pandemic. In Ohio, only physicians can prescribe abortion inducing drugs [22, 23]. Since 2005, Ohio has required abortion providers to complete inperson state-mandated counseling and to provide patients with copies of materials published from the state Department of Health 24 hours prior to performing or inducing an abortion [24]. In 2011, an Ohio law went into effect prohibiting off-label use of mifepristone [25]; while the 2016 labeling changes allowed Ohio-licensed physicians to prescribe mifepristone at evidence-based dosages, Ohio law still required that mifepristone be dispensed at a clinic as required by the REMS and the labeling. These Ohio laws - the law that requires physicians to administer mifepristone in a clinical setting in line with FDA's labeling of mifepristone combined with the 24-hour waiting period law that requires at least 2 clinic visits - made it impossible for Ohio abortion providers to transition to postal delivery of medication abortion during the pandemic [26].

In Ohio, legal restrictions result in patients having to travel to a clinic twice, first for preabortion counseling and second to obtain mifepristone and a prescription for misoprostol [24], while neighboring states Kentucky and West Virginia have laws that explicitly prohibit medication abortion distribution through telehealth services. Kentucky and West Virginia both banned telemedicine abortion in 2018 [27, 28]. Despite the lifting of the elective surgery bans in Ohio and West Virginia in April 2020 and the temporary loosening of the mifepristone REMS in July 2020, state laws governing medication abortion and telemedicine abortion remained in effect in Ohio, Kentucky, and West Virginia throughout 2020, barring patients from receiving medication abortion by mail.

3.2. Clinic survey findings

Across Ohio, Kentucky, and West Virginia there are 16 abortion facilities that provide medication abortion, 15 of which are located in urban areas [29]. Fourteen of these facilities, 13 of which are in urban areas, completed monthly surveys offering data on abortion provision from December 2019 to December 2020. Among the fourteen facilities included in this analysis, nine provide both medication and procedural abortion services and one provides medication abortion only. One of these clinics began offering services in March 2020, and is included in analyses from March 2020 onward. Four additional facilities provide medication abortion via clinic-toclinic telehealth only, wherein patients go to a health care facility for their second-day appointment to meet via videoconferencing with the physician who is located in another clinic and to obtain mifepristone. Three of these facilities began dispensing mifepristone via clinic-to-clinic telehealth before the study period began, and the fourth site began dispensing mifepristone in January 2020, and is excluded from the December 2019 analyses.

Overall, abortion facilities in these three states averaged approximately 893 medication abortions per month, ranging from 629 in December 2019 to 1613 in April 2020 (Table 1). Coinciding with state executive orders issued during the COVID-19 pandemic, the number of medication abortions hit a sharp peak of 1613 in April, accounting for 70% of all abortions provided at these four-

teen facilities that month. This value drops to 1052 by May, returning close to prepandemic rates by June.

Absolute numbers of medication abortions varied widely by state (averaging 40 per month in West Virginia, 170 per month in Kentucky, and 683 per month in Ohio), but the relative proportion of medication abortions peaked in April for all 3 (Fig. 1). Notably, this peak is most stark for Ohio (72%, compared to 40% average) and West Virginia (87%, compared to 49% average); Kentucky sees only a slight increase (55%, compared to 50% average). The one rural clinic in our sample, which dispenses mifepristone via a clinicto-clinic telehealth appointments, reported fewer medication abortion appointments after the declaration of the public health emergency, averaging 5.7 appointments per month before the pandemic (December 2019 through February 2020), and 1.6 per month from March 2020 through December 2020. In the face of facilities' ongoing inability to take advantage of the loosening of REMS regulations, we do not see major changes in medication abortion provision at clinics in Ohio, Kentucky, and West Virginia after the July 2020 court ruling.

4. Discussion

Findings from our policy review illustrate how restrictive medication and telemedicine abortion policies in Ohio, Kentucky, and West Virginia created obstacles for patients seeking a medication abortion during the first 10 months of the COVID-19 pandemic. Kentucky and West Virginia's requirements that mifepristone be administered in the presence of a clinician, and Ohio regulations that limit dispensing medication abortion pills to a clinical setting, hindered medication abortion distribution by mail. Mail distribution could benefit abortion seekers throughout and after the COVID-19 pandemic and especially for those for whom a visit to a clinic is not easily attainable. Our assessment of state policies that temporarily denied and continue to limit access to comprehensive abortion services during the pandemic should inform the larger effort toward dismantling the interwound barriers and impingement upon urban and rural people's reproductive autonomy.

From survey results, we find a meaningful increase in the proportion of medication abortions provided by abortion facilities in Ohio and West Virginia in April 2020 after state executive orders were issued deeming procedural abortion elective and therefore unavailable in many circumstances. Kentucky saw a slight increase as well, but it was not as stark. As a whole, the range in the proportion of medication abortions across the study period (32%–70%) is somewhat higher than annual values seen in recent years; for example, in 2018 approximately 33% of abortions across these 3 states were medication abortions [30]. While medication abortion is increasingly utilized for a variety of reasons, the peak observed in April suggests that the increase in this month was due to state executive orders limiting procedural abortion care. The peak is particularly notable given the different policy landscapes of these three states: Ohio and West Virginia enacted state executive orders in March and April, respectively, limiting procedural abortions, resulting in a meaningful increase in medication abortion, whereas Kentucky's executive order did not halt procedural abortion and the proportion of medication abortions increased only slightly.

Furthermore, the relative increase in medication abortion during April specifically demonstrates how clinics adapted to meet their patients' abortion care needs while state executive orders limited their ability to provide procedural abortion care. However, the public health emergency necessitated other changes in health care delivery, which may have limited clinics' capacity to innovate in the use of telehealth and schedule appointments beyond the period of state executive orders. For instance, while the intention of clinic-to-clinic telehealth appointments to dispense mifepristone is to increase the availability of medication abortion appointment

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Table 1Number of medication abortions, total abortions, and percent of medication abortions out of total abortions provided at fourteen abortion facilities in Ohio, Kentucky, and West Virginia (December 2019–December 2020)

Year	Month	All Abortions				Medication Abortions			
		Overall	Kentucky	Ohio	West Virginia	Overall	Kentucky	Ohio	West Virginia
2019	December	1824	285	1457	82	629 (34%)	130 (46%)	460 (32%)	39 (48%)
2020	January	2258	366	1788	104	733 (32%)	157 (43%)	534 (30%)	42 (40%)
2020	February	2048	340	1610	98	722 (35%)	167 (49%)	509 (32%)	46 (47%)
2020	March	2150	362	1700	88	788 (37%)	169 (47%)	586 (34%)	33 (38%)
2020	April	2306	359	1917	30	1613 (70%)	199 (55%)	1388 (72%)	26 (87%)
2020	May	2281	359	1826	96	1052 (46%)	185 (52%)	817 (45%)	50 (52%)
2020	June	2085	322	1677	86	856 (41%)	162 (50%)	649 (39%)	45 (52%)
2020	July	2151	343	1753	55	876 (41%)	175 (51%)	681 (39%)	20 (36%)
2020	August	1949	364	1526	59	713 (37%)	182 (50%)	500 (33%)	31 (53%)
2020	September	2113	309	1698	106	888 (42%)	165 (53%)	676 (40%)	47 (44%)
2020	October	2176	365	1736	75	941 (43%)	196 (54%)	701 (40%)	44 (59%)
2020	November	1912	284	1540	88	879 (46%)	151 (53%)	681 (44%)	47 (53%)
2020	December	2137	331	1714	92	919 (43%)	173 (52%)	692 (40%)	54 (59%)
TOTAL		27390	4389	21942	1059	11609 (42%)	2211 (50%)	8874 (40%)	524 (49%)
AVERAGE		2107	338	1688	81	893 (42%)	170 (50%)	683 (40%)	40 (49%)

Note: Percent of medication abortion in parentheses.

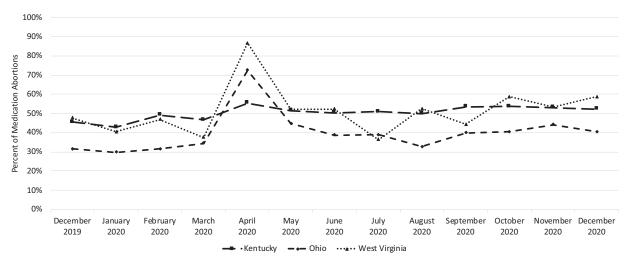


Fig. 1. Percent of medication abortions provided at fourteen abortion facilities in Ohio, Kentucky, and West Virginia, disaggregated by state (December 2019–December 2020).

opportunities to patients and to decrease the distance patients need to travel to receive mifepristone, the only facilities that offered clinic-to-clinic telehealth appointments to dispense mifepristone during our study period were already doing so before the pandemic began. Further, the rural health center in our sample reported dispensing medication abortion to 30 patients in 2020, while the state reported that it served 50 patients in 2019 [31]. This decline in medication abortions suggests that patient volume was lower at the rural facility during the pandemic, perhaps due to constraints imposed by the executive order, but also because of pandemic-related constraints on clinic scheduling protocols (e.g., maintaining adequate distance between individuals in the clinic and conserving personal protective equipment used in family planning and sexual health care).

If federal regulations and state law had permitted, dispensing medication abortion by mail may have been a more appealing option for patients and abortion facilities for the duration of the pandemic. Indeed, state officials in Ohio encouraged telehealth otherwise wherever possible [14] except for abortion care, highlighting the continued treatment of abortion as exceptional and something out of the norm of health care provision [32]. Additionally, we see no continued elevation in medication abortion use during the period subsequent to the emergency orders, during which the REMS on mifepristone was temporarily removed from July 2020 through

the end of our study period; this is not surprising, given the inability of these states to take advantage of the temporary lifting of the REMS in-person dispensing requirement due to state laws governing the distribution of medication abortion. Use of medication abortion care by mail during the study period of March-December 2020 would have been particularly beneficial for promoting contactless administration of mifepristone, given the dramatically increased use of medication abortion in these states in Spring 2020 and abortion facilities' continued need to limit person-to-person contact and preserve personal protective equipment throughout the pandemic [16]. While the FDA modified the REMS in-person distribution requirements in April 2021 for the duration of the pandemic, this will not benefit abortion seekers who reside in states with additional telemedicine and medication abortion distribution requirements [9]. Permanently lifting the REMS on mifepristone - during and outside of a pandemic - would alleviate transportation and additional costs attributed to mandatory in-clinic consultation and administration to obtain mifepristone and may allow clinics to utilize alternative distribution methods that would benefit abortion seekers in rural settings. However, our findings demonstrate that permanently lifting the REMS would only advantage some abortion seekers, but not those who live under restrictive state telemedicine and medication abortion policies such as those seen in Ohio, Kentucky, and West Virginia.

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Abortion seekers who live in both urban and rural areas in abortion-restrictive states such as Ohio, Kentucky, and West Virginia could only benefit from permanent changes to the mifepristone REMS and FDA labeling if state laws governing the distribution of medication abortion were also changed. Such regulatory changes could particularly advantage people experiencing structural oppression, such as those who are poor, low income, people of color, and geographically distant [33]. Yet even if the REMS were lifted, state laws would continue to limit abortion accessibility because of their hostility to abortion [34] and because of the limited number of facilities that even offer abortion services, most of which are not easily accessible for those who reside in rural areas [11]. Both restrictive regulations and geographical locations of clinics compound "abortion care churn," or the clinic-level instability and uncertainty that affect the accessibility of a full range of abortion services in a particular geographic area [35].

At the outset of the COVID-19 pandemic in the United States in 2020, abortion seekers increasingly sought medication abortion by mail [2]. An uptick in medication abortion requests to organizations like Aid Access suggest that pandemic-related abortion regulations led people to seek alternatives to clinic-based abortion care, but the current study can only speak to changes in clinical care. Future research should compare utilization of medication abortion and telemedicine abortion in more and less abortion restrictive states, assess changes in family planning care provision during the pandemic, and capture rates of interstate travel of abortion seekers to states that were less restrictive than Ohio, Kentucky, and West Virginia during the COVID-19 pandemic.

The COVID-19 pandemic has highlighted the entangled obstacles federal, state, and institutional barriers continue to impose on pregnant people's ability to obtain abortions. Eliminating in-person clinic visit requirements, telemedicine bans, and FDA-labeling requirements for medication abortion would alleviate some existing barriers to abortion care, with some arguing that "remote access will be the only way during this crisis and beyond to ensure that vulnerable rural women are able to access care" [36]. While the effects the pandemic has had on people's ability to obtain an abortion will not fully be understood until vital statistics are available on abortion and birth rates for 2020 by patient state of residence to enable comparison to rates in previous years, amending telemedicine and medication abortion policies in the meantime could alleviate significant barriers towards the actualization of reproductive freedom for the duration of this pandemic and beyond.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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