Brief Report: Exploring Patient and Provider Comfort and Expectations around Mifepristone Pharmacy Dispensing

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2/2023

BACKGROUND

For both miscarriage care and early abortion, the combination of mifepristone and misoprostol is most often recommended; mifepristone is taken first, followed by misoprostol. Misoprostol can also be taken alone, though it is slightly less effective.

Since its approval in 2000, mifepristone has been subject to requirements under the FDA's Risk Evaluation and Mitigation Strategy (REMS) program. Components of the mifepristone REMS program included provider registration with drug manufacturers, specific patient agreement forms, and dispensing directly by prescribers rather than from retail pharmacies, among other things. These regulations have proven burdensome to providers and create challenges for patient access. As a result of the COVID-19 pandemic health emergency, a federal court had enjoined some Food and Drug Administration (FDA) restrictions on mifepristone, allowing mifepristone to be mailed to patients.

After formal review prompted by a lawsuit filed by the American College of Obstetricians and Gynecologists, the FDA permanently lifted this requirement and established a pathway whereby "certified pharmacies" might dispense mifepristone directly to patients in brick-and-mortar stores. Just this month, the FDA gave final approval to certification plans proposed by the pharmaceutical companies that distribute mifepristone.

Large pharmacy retailers such as CVS and Walgreens have announced that they will seek certification to dispense mifepristone.

At the same time, the pandemic also prompted many providers to turn to telemedicine services, including for abortion care. Clinicians have implemented rapid innovations to reduce the need for in-person medication abortion visits and many patients can now receive abortion counseling virtually, with pills mailed to their location. With the latest change from the FDA, patients could now conduct a virtual visit anywhere in a state where abortion is legal and then pick up their prescription medication from a nearby certified pharmacy.

2000
FDA approves Mifepristone

2011
FDA applies REMS to Mifepristone

2017
Chelius vs. Azur. ACLU filed a a lawsuit arguing that REMS placed an undue burden an people seeking abortion in Hawai'i

2020
ACOG vs FDA ACLU filed a lawsuit against the FDA due to access restrictions from COVID.

2021
FDA changed REMS ruling

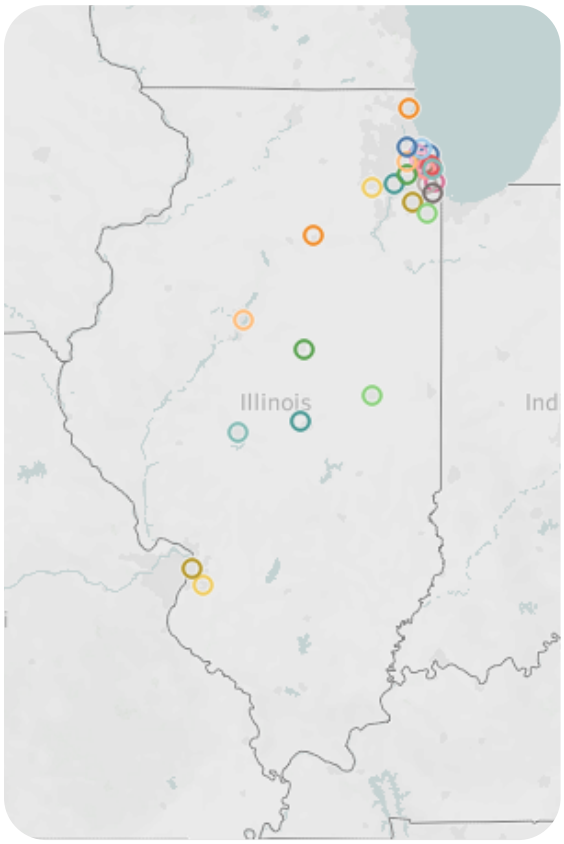
2022
Roe V Wade Overturned

2023
Pharmacies allowed to dispense Mife

However, at the same time these changes have taken place, the U.S. Supreme Court overturned Roe v. Wade and state restrictions on abortion have spread. Where some states now have no abortion providers, others have explored creative ways to expand access and provide care to those traveling from restricted states. These efforts have included expanding the number of abortion providers in "surge" states to meet the growing demand. Leveraging the role of community-based providers and, now pharmacists, may help meet the needs of those facing ever greater barriers to care.

OUR RESEARCH

Given these changes in the policy landscape, we conducted research to understand and support successful, patient-centered implementation of pharmacy-dispensed mifepristone. We have gathered insight from pharmacists across the country on their readiness to provide mifepristone along with recommendations to improve comfort and capacity to dispense the medication. We also held workshops with individuals who sought abortion or supported someone seeking abortion to understand their preferences and concerns around pharmacy dispensing. Here we summarize preliminary findings to help guide community-based providers and pharmacists engage in patient-centered medication abortion provision.



Abortion Providers by Zip Code

SCOPE OF PROBLEM

The changing of REMS requirements has the potential to change the accessibility of abortion care. For instance, Illinois has 31 physical locations which provide abortion care, the majority of these clinics are clustered in urban and suburban locations.
Further, there are 5 strictly online abortion providers licensed to administer abortion care in Illinois. This leaves those living in rural areas or far away from clinics with an increased time and financial burden in accessing care. These REMS mitigations coupled with Illinois's telemedicine abortion policies have the potential to increase access and decrease inequity with abortion care. However, as pharmacists have never been allowed to dispense Mifepristone until now, pharmacists and patients alike may have concerns and questions about this novel process.

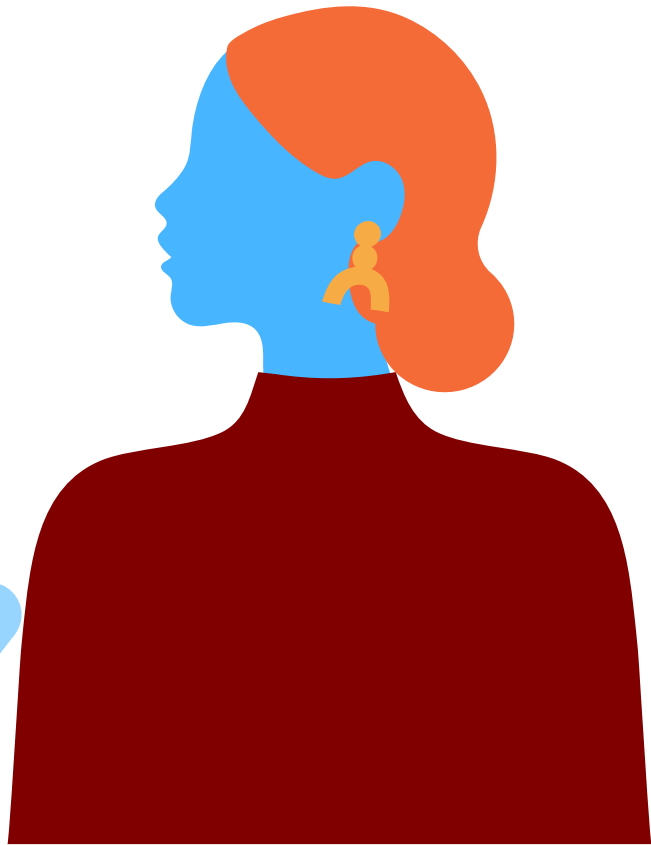
PRELIMINARY FINDINGS

We conducted interviews to explore the readiness of pharmacists to dispense mifepristone should the REMS regulations allow pharmacy dispensing. We conducted interviews by phone or zoom with 21 pharmacists in 9 states between June and December of 2021 to explore their knowledge about misoprostol and mifepristone, their comfort with dispensing both medications, and to explore resources needed to dispense mifepristone. All interviews were recorded, transcribed, verified and coded using Dedoose. We identified key themes through content analysis

We found that pharmacists are ready and able to fill prescriptions for mifepristone with minimal training. Almost all participants felt comfortable dispensing mifepristone following minimal additional training (e.g., webinar, one-pager, in-person). Most stated that their coworkers and employers would support pharmacy dispensing. Pharmacists saw themselves as "medication experts;" who have the skills and resources to learn about new medications quickly.

We also held two speculative design workshops with potential patients to better understand concerns and questions that arise around the REMS mitigations. While the decrease in REMS requirements helps to lessen overall abortion exceptionalism, those seeking abortion care through a pharmacy may now need to navigate the typical challenges of our healthcare system.

> "I'm really curious about attitudes of pharmacists, and how that would impact accessibility. I just feel like I've had questions from pharmacists about medications that I'm taking that are pretty benign, but somehow pharmacists like to be pretty nosy about stuff. And so I can only imagine the opportunities that would come up with this. And if that's something that you all have thought about in terms of that being a huge barrier, especially for places that don't have a lot of pharmacy options, like how that would play out"



As we sought to identify tools and resources that would be helpful in supporting pharmacy dispensing of mifepristone (in person and by mail), we wanted to hear from those directly supporting abortion access and obtaining abortions about their preferences. To do this, we collaborated with leaders of the Chicago Abortion Fund and used human-centered design methods to explore preferred consumer experiences for obtaining mifepristone to be used for medication abortion care from a pharmacy.

Themes that arose in our workshop centered around: the logistics of obtaining mifepristone at a pharmacy or via mail order, actual use of the medication and follow-up care, payment challenges, and navigating privacy concerns.

Each of these themes related to participants' desire to have clearer communication between themselves, their clinician, and the pharmacist when navigating this process. We also found that participants had preferences on who they preferred to receive information from, depending on the issue (pharmacist or abortion provider/prescriber).

We also documented themes around the participatory design methodology we used. We found that using human centered design methods was an essential mechanism to engage, discuss, and share stories, concerns, and questions about changing access to abortion care in the United States. This research methodology created both a safe de-stigmatizing space for participants to discuss their abortion experiences and elevated participants voices and lived experiences.

RECCOMENDATIONS

The modified REMS mitigations have the potential to both increase access as well as confusion around abortion access. Our findings indicate that alongside the existing patient-oriented medication abortion resources, there is a need for resources specific to pharmacy pick-up and mailed delivery, and a corresponding need for clinician and pharmacist resources to best educate patients on what to expect. Ci3 located 9 toolkits and resources that provide information to provider and patients which answer many of the concerns and questions that participants identified around pharmacist dispersal of mifepristone. (Table Next Page)

Already Developed Resources		
Organization	**Audience**	**Toolkit Name**
UW Medicine: https://familymedicine.uw.edu/accessdelivered/	Provider	Provider Toolkit
Birth Control Pharmacist: https://birthcontrolpharmacist.com/resources/	Pharmacist	Pharmacy Forms and Guides
Reproductive Health Access Project: https://www.reproductiveaccess.org/resource/toolkit-integrating-abortion-primary-care/	Provider	Toolkit for Integrating Abortion into Primary Care
Reproductive Health Access Project: https://www.reproductiveaccess.org/resource/medication-abortion-coding/	Provider	Toolkit for Coding Medication Abortion
Reproductive Health Access Project: https://www.reproductiveaccess.org/resource/mab-patientinfo-previsit/	Patient	Abortion Pill Info to Read Prior to Phone Visit
Reproductive Health Access Project: https://www.reproductiveaccess.org/resource/sams-medication-abortion-zine/	Patient	Sam's Medication Abortion Zine
IPAS: https://www.ipas.org/resource/clinical-mentoring-and-provider-support-for-abortion-related-care/	Provider	Clinical Mentoring and Provider Support for Abortion-Related Care
How to Use Abortion Pill.Org: https://www.howtouseabortionpill.org/howto/	Patient	How to use the abortion pill
M+A Hotline: https://www.mahotline.org/	Patient	M+A Hotline (and chat)