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Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics☆

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Abstract

Objectives: In 2000, the United States' Food and Drug Administration (FDA) approved mifepristone for medication abortion. In this article, we explore how the Risk Evaluation and Mitigation Strategy (REMS) criteria for mifepristone specifically impede family physicians' ability to provide medication abortion in primary care settings.

Study design: We conducted 56 qualitative interviews with a national sample of family physicians across the US who were not opposed to abortion. We examined how the REMS criteria for mifepristone impact family physicians' ability to provide medication abortion.

Results: Of the 56 interviews conducted, 23 participants (41%) raised the REMS criteria as a barrier to providing medication abortion in primary care. These participants reported the REMS added a layer of bureaucratic complexity that made it difficult for family physicians to navigate, even when trained, to provide abortion care. These family physicians described 2 predominant ways the REMS impede their ability to provide medication abortion: (1) The REMS require substantial involvement of clinic administration, who can be unsupportive; (2) The complexity of navigating the REMS results in physicians and clinic administration in primary care viewing

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medication abortion as not worth the effort, since it is only a small component of services offered in primary care.

Conclusion: Removing the REMS could simplify integration of medication abortion into primary care, which could meet patient preferences, improve access, and reduce abortion stigma. The FDA's revised REMS criteria may ease administrative burden but will likely maintain key barriers to integrating medication abortion into family physicians' practice.

Implications: Our study highlights that the REMS criteria are barriers to family physicians' ability to integrate medication abortion into their primary care practices. The FDA's removal of in person dispensing criteria may provide some impetus for trained family physicians to integrate medication abortion into their scope of practice but the revised REMS criteria maintain key barriers to broader adoption.

Keywords

Family medicine; Medication abortion; Mifepristone; Primary care; REMS

1. Introduction

In 2000, the United States Food and Drug Administration (FDA) approved mifepristone for medication abortion. A growing proportion of patients in the United States choose medication abortion instead of an in-office instrumentation procedure: in 2018, medication abortion made up 39% of abortions, up from 23% in 2014 [1–3]. Since only 11% of counties in the United States have a clinician who provides abortion care, many advocates hoped that the availability of mifepristone would allow primary care clinicians to integrate abortion services into their practices [4,5]. Unfortunately, this expansion into primary care has not occurred: more than twenty years later most abortions still take place in specialized abortion clinics, with only 1% of abortions taking place in a physician's office [5].

Family physicians are primary care physicians who provide broad scope of care across the life course, including reproductive health services. Provision of medication abortions by family physicians presents a unique opportunity to enhance access to patient-centered medication abortion care [6]. Further, having family physicians integrate medication abortion into their practice has the potential to destigmatize abortion for patients and providers by normalizing it as a routine part of full-spectrum care [4, 7]. Family physicians make up the majority of primary care physicians in the United States and provide care in many counties where there is no access to other health care services [8, 9]. Medication abortion care aligns with family medicine values related to meeting patients' needs for comprehensive care [4, 6, 10, 11]. Prior research demonstrates that family physicians who provide abortion services have low complication rates and that some patients prefer to have an abortion with their primary care provider [12–16].

While substantial efforts to expand abortion training for family physicians have been implemented, this has not resulted in substantial numbers of abortions being provided in primary care settings [17–19]. Several studies have outlined barriers that limit the integration of abortion into primary care, even among trained clinicians. These include

state laws, health system restrictions, and liability insurance [10, 17, 18, 20, 21]. An additional consideration for family physicians wishing to provide mifepristone to their patients is the FDA's stringent Risk Evaluation and Mitigation Strategies (REMS) [22, 23]. The REMS criteria for mifepristone includes a formal certification process, which determines that a provider can accurately date a pregnancy, diagnose an ectopic pregnancy, and provide surgical intervention or referral for any complication. Furthermore, the REMS require that each patient sign a Patient Agreement Form. While in December 2021, the FDA announced a critical decision to remove the REMS in person dispensing requirement, the FDA maintained 2 key provisions of the REMS: (1) Providers (and now pharmacies) must receive certification from the manufacturer of mifepristone to prescribe and dispense mifepristone, and (2) patients still must sign a Patient Agreement Form for mifepristone use [24].

Drawing on a national set of qualitative interviews with family physicians, in this article we examine how the REMS for mifepristone specifically impede family physicians' ability to provide medication abortion in primary care settings.

2. Methods

This study draws on interviews with family physicians performed with the primary goal of exploring how family medicine values can be leveraged to encourage family physicians to integrate medication abortion into primary care settings to improve abortion access. Given the geographic variation in abortion access across the United States, we focused on recruiting participants from diverse geographies and with a broad range of experiences. We used a multipronged recruitment approach that included recruiting participants from national conferences and from national listservs. In addition, we (CD, SM, LM, SR) used professional networks to purposively sample family physicians from states with more hostile abortion policies, as well as to identify family physicians who had successfully integrated abortion services into primary care or had experience in leadership in family medicine.

Inclusion criteria for this study included being either a new career family physician or a family medicine thought leader. These criteria were based on the desire to focus on the perspectives of those with insights into the ongoing evolution of family medicine practice patterns. We defined new career family physicians as those who completed a family medicine residency in the United States within the previous 10 years. Thought leaders included experts in the field of family medicine with experience motivating other family physicians to expand their scope, or family physicians specifically with experience related to abortion integration into family medicine. The study team directly asked thought leaders to participate in the study.

The study team screened participants in the primary study for eligibility over the phone or in person with an initial eligibility survey, and excluded individuals who self-identified as opposing abortion, based on their responses to: "Are you personally opposed to people getting abortions?" The research team met regularly to review transcripts and discuss findings. During the recruitment process, we also used purposive sampling to speak to individuals who successfully integrated medication abortion into primary care. Once the

team established that the themes related to the initial research question and aims reached saturation, by noting similar themes and responses during interviews, recruitment for the primary study ended.

2.1. Data collection

We developed an interview guide for the primary study with input from the research team including family physicians, educators, advocates, a social and behavioral scientist, and a communications specialist. Interview questions covered key components of the Theory of Planned Behavior, a well-described and frequently used approach to understanding influences on behavior change with attention to social norms, attitudes, perceived control, and intentions [25]. The research team iterated the interview guide based on participant feedback and themes that arose from interviews. Data for this analysis primarily came from responses to the following interview questions: “What factors do you think most contribute to you not providing medication abortion?” (asked only of those not providing medication abortion in a primary care setting) and, “What do you think are the main reasons why more family physicians don’t provide medication abortion?”

Research staff (CD, EF, SW) obtained oral informed consent and participants completed surveys with questions about demographics, training, and clinical experience ahead of the interviews. Three team members (CD, EF, SW), trained in qualitative interview methods and with experience working in reproductive health, conducted the interviews. Two UCSF research staff (EF, SW) conducted most of the interviews with new career family physicians and all interviews with thought leaders. Both self-identify as white women who led projects within the Person-Centered Reproductive Health Program. They are not family physicians or clinicians and therefore studying up in this setting based on clinical hierarchy. CD, a UCSF faculty member and practicing family physician, conducted 4 new career family physician interviews. CD identifies as a white woman. While CD brings extensive research expertise on reproductive health and family medicine, she did not know any of the providers interviewed and related to them as a peer.

Interviews took place either in person or virtually over video conferencing software and lasted 60 to 75 minutes. We audio-recorded all interviews. We compensated participants for their time with $100 gift cards. The UCSF Institutional Review Board approved this study.

2.2. Analysis

We used a HIPAA-compliant professional transcription service to transcribe verbatim and de-identify all transcripts. A team member (RK, CP, IS, SW) reviewed transcripts to ensure accuracy. Research team members (KH, IS, SW) read transcripts, discussed impressions with the entire study team, and developed a preliminary codebook based on components of the Theory of Planned Behavior.

Two researchers (IS, SW) double coded an initial set of transcripts using NVivo 12 to assess inter-coder agreement, clarify codes, and resolve disagreements. Through this iterative process the research team revised the codebook. Three members of the study team (CP, NR, SW) coded approximately equal number of transcripts and met regularly to achieve consensus on coding and resolve any discrepancies.

We took a deductive-inductive content analysis approach and used memos to identify broad themes [26]. After coding a transcript, the study team drafted a memo to document and describe impressions of the interview. Over the course of the coding process, memos became more structured to highlight key domains. The team regularly met to discuss memos and major themes derived from the transcripts. Based on these analyses, researchers clarified the central attitudes and factors shaping family physicians' perspectives on providing medication abortion. Participants independently raised REMS as a topic that influenced their ability to provide medication abortion or integrate medication abortion into primary care. This paper focuses on a secondary analysis of family physicians' experience and knowledge of the REMS.

3. Results

We interviewed 56 family physicians (see Table 1). A plurality of participants received abortion training (n = 37, 66%) but most did not currently provide medication abortions (n = 39, 70%). Sixteen interviewees (29%) did not receive abortion training and did not provide abortions. Of the physicians that provided abortions 7 offered abortions in the primary care setting where they have a continuity practice with patients, with the remaining providing abortions in specialized reproductive health settings.

Of the 56 family physicians interviewed, 23 (41%) either named or described the REMS criteria as a barrier to providing medication abortion. Participants who mentioned the REMS represented all regions of the country and worked in states with abortion policies that ranged from supportive to hostile. Both thought leaders and new career family physicians raised the REMS criteria as a barrier. Most family physicians who mentioned the REMS criteria received abortion training (n = 20, 87%).

Family physicians who raised the REMS criteria described 2 predominant ways the REMS impede their ability to provide medication abortion within primary care: (1) The REMS require substantial involvement of clinic administration, who can be unsupportive; (2) The complexity of navigating the REMS results in physicians and clinic administration in primary care viewing medication abortion as not worth the effort, since it is only a small component of services offered in primary care.

3.1. Administrative interference

Participants discussed the REMS criteria as transforming the decision to provide mifepristone from being one between a physician and patient, to involving multiple levels of administration. Participants described to us how dispensing mifepristone requires that their clinics register, install a lockbox on site to stock medication, and have specific systems in place for ordering. These requirements meant that clinic administration must approve the process. As 1 participant who provided medication abortion only at a reproductive health clinic explained, "The only other huge hurdle, which would be wonderful if it could get overturned, it would be the REMS… You just have to sign some papers and have it on-site, but it does, you know, add another level of bureaucracy that we need to overcome to be able to stock the pill in our office" (Early career, northeast, abortion provider). As this participant

went on to explain, the REMS criteria not only require providers' training but specifically their clinic's backing.

You really do need [the] support of your administration before you could do it, especially with all the regulations that are required. It's the fact that mifepristone has the REMS criteria, and it's not easy to - you can't just prescribe it. Um, it has to be given to the person in person, so you have to stock it in your clinic, and there's just - those hurdles kind of keep a lot of providers from doing it (Early career, northeast, abortion provider).

The need to navigate regulations and logistics as a result of the REMs meant participants with unsupportive clinic leadership were unable to provide, even if there were no religious or other formal limitations on abortion provision. As another participant explained to us, "You're at the whim of the place that you practice and if the person in charge of your clinic doesn't feel like providing or purchasing mifepristone is important or profitable, then you just don't do it" (Early career, west, abortion provider). Another participant echoed this sentiment: "If you don't have a local champion, you don't have someone who's willing to put the time and effort into it, it's hard to do, right. It's easy for me to prescribe like antibiotics, but it's not so easy for me to prescribe mifepristone 'cause of all the stuff around it" (Early career, northeast, abortion provider).

Because of the restrictions around mifepristone, some participants characterized the REMS criteria as "a stop sign" (Early career, south, not abortion provider) and "the absolute biggest barrier" (Early career, south, not abortion provider) to providing medication abortion. One family physician trained in medication abortion felt unable to provide specifically because of the REMS. "Unfortunately, there's just so much more red tape… I would be doing it in a heartbeat if I could prescribe mifepristone, and my patient could pick it up at a commercial pharmacy, but she can't because of the way it's regulated by the FDA" (Early career, south, not abortion provider).

Even among family physicians who do provide abortions, several felt that the complexity required to implement medication abortion steered their colleagues away from adopting it into their scope of practice.

I think number 1 is the restrictions on mifepristone. That's a huge 1 because - because there are so many restrictions, it scares people into thinking that they can't do medication abortions. So even though you may - there may be a lot of physicians out there who agree with medication abortion and would, you know, in theory would do it, there's so many restrictions and barriers to doing it, I think it really turns people off (Early career, midwest, abortion provider).

One of the thought leaders we interviewed who provides medication abortion emphasized the barrier the REMS criteria pose for most family physicians.

I think the REMS is a huge factor. It's because the access to the medication is restricted and you have to order it and stock it in your health center. You have to get a lot of other people's approval before - you know, you can't just write a prescription… So, you know, you have to go to a pharmacy and therapeutics committee or the Director of Nursing has to approve it or

the CEO has to approve it or the Medical Director has to approve it, or all of those people have to approve it. And there's bound to be somebody in there who doesn't like the idea (Though leader, northeast, abortion provider).

3.2. Medication abortion as only a small part of primary healthcare

The REMS criteria impose the same restrictions on all clinical practices and prescribers, regardless of abortion volume. A number of participants mentioned that because a family medicine clinic might only care for patients choosing a medication abortion a few times a month (or even year), this low volume served as justification for leadership as to why they should not pursue approval to dispense mifepristone. In short, clinic leadership, and at times participants themselves, felt that the effort required to stock and dispense mifepristone outweigh the benefits of providing the service. As 1 participant explained, "Many primary care clinics think, oh, if our volume is low, like why bother going through all of this headache to be able to provide the service when, you know, we have maybe like 4 a week or something like that" (Early career south, not abortion provider).

Multiple participants highlighted how the REMS' disproportionately impacts clinics with low abortion volume. One participant we spoke with received training in medication abortion during residency, but she did not provide in her current practice. The REMS criteria determined where medication abortion took place in her organization as a mifepristone lockbox was only provided to the ob/gyn department. She explained, [F] or Mifeprex specifically, there's a multitude of restrictions that make it logistically incredibly challenging, depending on how many patients actually need it… The really irritating thing about it is they got exactly what they wanted by passing that, right? Which is that… you make a logistical barrier so high that providers who completely support it ideologically just don't feel that it's worth the time… While I wholly support it [mifepristone] being available, I can also see how, in terms of the use of time, like me like training and signing off every provider. And like making sure this med is stocked. And making sure there's lockboxes. And like all of this stuff. Uh, is an enormous burden relative to the number of patients whose lives it would improve (Early career, west, not abortion provider).

4. Discussion

In a United States sample of family physicians, we found that the REMS on mifepristone creates a barrier to some family physicians' ability to provide medication abortion in their primary care clinics, with many interviewees sharing without prompting that the REMS prevented them from providing medication abortion. While these criteria are not the only barriers family physicians hoping to provide medication abortion encounter [27], the REMS do pose specific challenges for family physicians. Furthermore, given mifepristone's safety record, the need for the REMS (even in its revised form) has been questioned [22, 28, 29]. Our findings add to growing research documenting the negative impact of the REMS on primary care practitioners' ability to provide medication abortions [23, 30]. In their study of primary care physicians and administrators in Illinois, Calloway and colleagues characterize the REMS as the "linchpin of a cycle of stigmatization that continues to keep mifepristone out of primary care practice" [30]. As family physicians make up the majority of primary

care physicians in the United States, our study adds to this literature by characterizing how this key group of physicians experience the REMS criteria and suggests that fully removing the REMS from mifepristone would be an important facilitator of efforts to broaden medication abortion access.

While our study took place prior to the FDA's decision to partially revise the REMS, our research provides insights into how this decision may impact United States family physicians' ability to provide medication abortion. The FDA's removal of the in person dispensing provision may encourage family physicians whose clinical site previously did not support the provision of medication abortion to provide medication abortion. This group of family physicians, who made up the majority of our sample, could now prescribe mifepristone directly to a certified pharmacy. The removal of the in person dispensing means that much of the administrative and clinic barriers and complexity that study participants described may be more easily overcome.

Nonetheless, the physicians we interviewed still encountered a range of barriers to provide medication abortions that the revised REMS will not alleviate. For example, the certification requirement for providers, and now pharmacies, may continue to serve as a gatekeeper for some providers. The ongoing requirement for patients to sign a Patient Agreement Form may also limit the ability of family physicians to provide medication abortion, especially since having this form on site and incorporating it into medical records requires the involvement of clinical administrators. To our knowledge, there is no existing evidence that supports maintaining this requirement or how this form impacts clinicians' ability to integrate or provide medication abortion. Beyond the REMS restrictions, family physicians will continue to experience additional barriers, including the restriction on provision of abortion in Federally Qualified Health Centers because of the Hyde Amendment and state-level restrictions on telemedicine for abortion care.

The experience of the Canadian health care system with mifepristone expansion into primary care provides useful insights into the potential impacts of fully removing the REMS criteria [33]. In 2015, mifepristone was approved by Health Canada for medication abortion. The initial Risk Management Plan, similar to the FDA's REMS, instituted by Health Canada limited the availability and accessibility to medication abortion by limiting gestational age at the time of abortion to 7 weeks, requiring an ultrasound prior to dispensing, requiring providers to register with the manufacturer, and only allowing providers to dispense medications [34]. However, through the efforts of advocacy groups and regional professional organizations, Canada decreased regulations, including eliminating the ultrasound requirement and allowing pharmacists to directly dispense to patients. A study in Ottawa documented that after these changes, participants experienced shorter wait times and an increase in medication abortion access [35]. It is important to note, however, that these decreased regulations occurred alongside other influences on medication abortion access and provision, including government financing of abortion care and trainings conducted by the Canadian Academy of Family Physicians and the National Abortion Federation Canada.

In the United States, models such as *ExPAND Mifepristone* demonstrate that learning collaborations that provide evidence-based knowledge on the clinical use of mifepristone

and expertise on best practices to navigate the administrative logistics are important aspects of reducing logistical and psychological barriers to abortion provision in primary settings [30]. In addition, recent models of online provision of medication abortion by family physicians provide encouraging direction for expanding care [31,32]. These broad efforts will likely be necessary, alongside the full elimination of the REMS, to reduce stigma and optimize provision of medication abortion in primary care settings.

Because abortion restrictions vary across the United States, 1 of the strengths of our study is our geographically diverse sample of family physicians working in different practice settings. Our interview methodology allowed physicians to share in depth experiences with abortion provision that may not be captured in survey data. Nonetheless, our study does have limitations that are important for consideration when interpreting our findings. First, as with all qualitative studies, the small and not inherently representative sample limits the generalizability of our findings. While we did not necessarily seek to recruit abortion trained physicians who are not providing abortion care, our sample did have more individuals who received abortion training, which does not reflect the broader family medicine community. In addition, our study design was not aimed to explore REMS specifically or the role of REMS in relationship to other barriers. As a result, we may not have fully elucidated experiences related to REMs from our participants, and our ability to compare barriers or explore the role of REMS for participants who did not bring up this topic is limited. Nonetheless we believe that the emphasis many participants placed on the impacts of the REMS criteria on their practice highlights its role in shaping abortion provision.

Mifepristone's approval in 2000 did not significantly improve abortion access through integration into primary care, and our interviews demonstrate the role that the REMS criteria played in this failure. The FDA's decision to revise the REMS on mifepristone has been long overdue, yet it does not go far enough. By keeping key components of the REMS in place, the FDA maintains an exceptionality to abortion services and may continue to keep abortion outside the scope of routine medical care. By permanently, and fully, removing the REMS on mifepristone family physicians and other primary care providers could more easily incorporate medication abortion into their scope of practice and integrate medication abortion into primary care settings. Such changes can better honor patient preferences for where abortion services are offered, reduce abortion stigma for providers and patients, and finally improve abortion access for millions across the United States.

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Abbreviations:

REMS	Risk Evaluation and Mitigation Strategies

FDA	Food and Drug Administration

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Table 1

Participants' demographics and abortion training and provision

Gender	**Total participants *N* = 56 (%)**	**Mentioned REMS *N* = 23 (%)**
Female	43 (77)	19 (83)
Male	12 (21)	4 (17)
Non-binary/third gender	1 (2)	0
Race		
American Indian/Alaska Native	0	0
Asian	9 (16)	2 (9)
Black or African American	5 (9)	1 (4)
Native Hawaiian/Pacific Islander	1 (2)	0
White	35 (63)	18 (78)
Other	6 (11)	2 (9)
Ethnicity		
Hispanic or Latino/a/x	3 (5)	0
Non-Hispanic or Latino/a/x	53 (95)	23 (100)
Age (years)		
≤30	1 (2)	0
31–40	45 (80)	18 (78)
41–50	5 (9)	1 (4)
51–60	4 (7)	3 (13)
> 60	1 (2)	1 (4)
Regions of the U.S.[a]		
West	23 (41)	8 (35)
South	13 (23)	5 (22)
Midwest	6 (11)	2 (9)
Northeast	14 (25)	8 (35)
State Abortion Policy Landscape[b]		
Hostile	20 (36)	7 (30)
Neutral	4 (7)	3 (13)
Supportive	30 (54)	11 (48)

Gender	Total participants *N* = 56 (%)	Mentioned REMS *N* = 23 (%)
N/A	2 (4)	2 (9)
Approximate distance between provider's clinical setting and nearest abortion clinic[c] (miles)		
< 5	32 (57)	19 (83)
5–25	15 (27)	2 (9)
26–50	4 (7)	1 (4)
> 50	4 (7)	1 (4)
Unknown	1 (2)	0
Abortion Training		
Aspiration and medication abortion	35 (63)	19 (83)
Only aspiration abortion	3 (5)	1 (4)
Only medication abortion	2 (4)	0
Neither aspiration or medication abortion	16 (29)	3 (13)
Abortion services provided since graduating residency		
Aspiration and medication abortion	16 (29)	12 (52)
Only aspiration abortion	0	0
Only medication abortion	5 (9)	3 (13)
Neither aspiration or medication abortion	35 (63)	8 (35)
Current medication abortion provision		
Currently provides medication abortion	17 (30)	14 (61)
Does not currently provide medication abortion	39 (70)	9 (39)
Setting of current abortion provision		
Primary care	5 (9)	3 (13)
Reproductive health clinic	10 (18)	9 (39)
Primary care and reproductive health clinic	2 (4)	2 (9)
N/A (Does not provide abortion care)	39 (70)	9 (39)

[a] U.S. Census Bureau, Census Regions and Divisions of the United States, 2013.

[b] Nash E, State Abortion Policy Landscape: From Hostile to Supportive, Guttmacher Institute, 2019. *State categories were based on laws in effect as of July 1, 2020. N/A refers to areas where a state policy landscape was not available*. https://www.guttmacher.org/article/2019/08/state-abortion-policy-landscape-hostile-supportive

[c] ANSIRH, Abortion Facility Database, University of California, San Francisco, 2019. *Distance was calculated using the zip code of the clinic where the provider works and the address of the closest clinic that offers abortion care in the ANSIRH Facility Database. If a provider works at multiple sites, the zip code of the furthest clinic from an abortion clinic was used*. https://www.ansirh.org/abortion-facility-database