

U.S. studies on medication abortion without in-person clinician dispensing of mifepristone

Key points

- The Food and Drug Administration (FDA) imposed a Risk Evaluation and Mitigation Strategy (REMS) for mifepristone that requires the drug to be dispensed only in a clinic, medical office, or hospital.
- The FDA suspended the in-person dispensing requirement during the COVID-19 public health emergency, and FDA is reviewing evidence to inform its permanent policy regarding mifepristone dispensing.
- Four studies, each with more than 100 participants, have been published on medication abortion provided without in-person clinician dispensing of mifepristone in the United States (U.S.).
- In all four studies, the effectiveness of the medication abortion was high, and serious adverse events were uncommon. These metrics of effectiveness and safety were similar to what has been reported in prior studies of medication abortion when mifepristone was dispensed in person by a clinician.
- This evidence indicates that the in-person dispensing requirement of the REMS is not necessary to ensure medication abortion effectiveness or safety.

Background

- Studies of medication abortion up through 10 weeks' gestation with mifepristone dispensed in person by a clinician have found an overall effectiveness of 97.4%,¹ and a prevalence of serious adverse events (SAEs)[†] of less than 0.5% of patients.^{1,2}
- Since 2000, the FDA has mandated that mifepristone be dispensed in person only at healthcare facilities. This is codified in the drug's Risk Evaluation and Mitigation Strategy (REMS).³
- In April 2021, the FDA suspended the in-person dispensing requirement for mifepristone for the remainder of the COVID-19 public health emergency,⁴ and it has announced that it is reviewing the evidence to inform its policy after the emergency ends.
- A large study from the United Kingdom found that telehealth provision of medication abortion that involved mailing the medications was safe and effective.⁵
- In this issue brief, we summarize the published results of U.S. studies of medication abortion that did not involve a clinician dispensing mifepristone in a clinic, medical office, or hospital.

Research conducted on the safety and effectiveness of medication abortion without in-person clinician dispensing:

- In September 2021, we conducted a systematic review of published studies examining outcomes when mifepristone was not dispensed in person by a clinician in a clinic, medical office, or hospital in the U.S. (see [Methods section](#)). Four publications met our inclusion criteria for this review:[‡]

1. Chong et al.⁷ describes results from a direct-to-patient telemedicine abortion service. Study participants obtained screening tests as necessary (ultrasound, pelvic exam, blood tests)[§] and had a videoconference with a study clinician to confirm eligibility. Study sites mailed mifepristone and misoprostol to the participant's preferred address. The study took place between 2016-2020 and had abortion outcome data for 1,157 abortions (13.8% loss to follow-up).
 2. In a study by Grossman et al.,⁸ participants were assessed by a clinician in person for eligibility and dispensed mifepristone and misoprostol at a nearby brick-and-mortar pharmacy. The study took place between 2018-2020 and had abortion outcome data for 260 participants (1.5% loss to follow-up).
 3. In a second study by Grossman et al.,⁹ clinicians dispensed mifepristone and misoprostol via mail-order pharmacy to participants after an in-person eligibility assessment. The paper is an interim analysis of an ongoing study and includes abortion outcome data for 224 participants recruited in 2020-2021 (5.5% loss to follow-up).
 4. Upadhyay et al.¹⁰ describes the safety and effectiveness of an online, telehealth medication abortion model that includes mail-order pharmacy dispensing of mifepristone and misoprostol following an online screening (with ultrasound or virtual telehealth consult as needed).^{*} This retrospective analysis of patients receiving care in 2020-2021 includes abortion outcome data for 110 participants (22.0% loss to follow-up).
- As shown in Table 1, the effectiveness of medication abortion ranged from 93% to 97%. The pooled estimate of effectiveness was 95.7% (95% CI: 94.4% - 97.0%) (Figure 1).
 - There were no deaths in any of the studies. Other serious adverse events, which included hospitalization, blood transfusion, or surgery (not including uterine evacuation), were uncommon and ranged from zero to 0.9% (Table 1).

Implications

- Four recent, U.S.-based studies demonstrate that medication abortion provided without in-person dispensing of mifepristone is effective and safe, with findings similar to studies of medication abortion provided with in-person clinician dispensing.¹
- These findings, as well as data from other countries,⁵ indicate that the in-person dispensing requirement of the REMS is not necessary to ensure medication abortion effectiveness or safety. These data support the permanent removal of the in-person dispensing requirement for mifepristone.

[†]A fifth study by Kerestes et al. was identified (see reference 6); however, the majority of participants in this analysis who received medications by mail (56 of 75) were also included in the paper by Chong et al. Due to the small number of unduplicated participants, we did not include data from the Kerestes paper in this brief. [§]75% of enrollments had a pre-abortion ultrasound.

^{*}17% of cases where abortion outcome was known had a pre-abortion ultrasound, either because the patient sought the ultrasound themselves or the telehealth service referred the patient.

[†]SAEs included death, hospitalization, surgery (not including uterine evacuation), and blood transfusion.

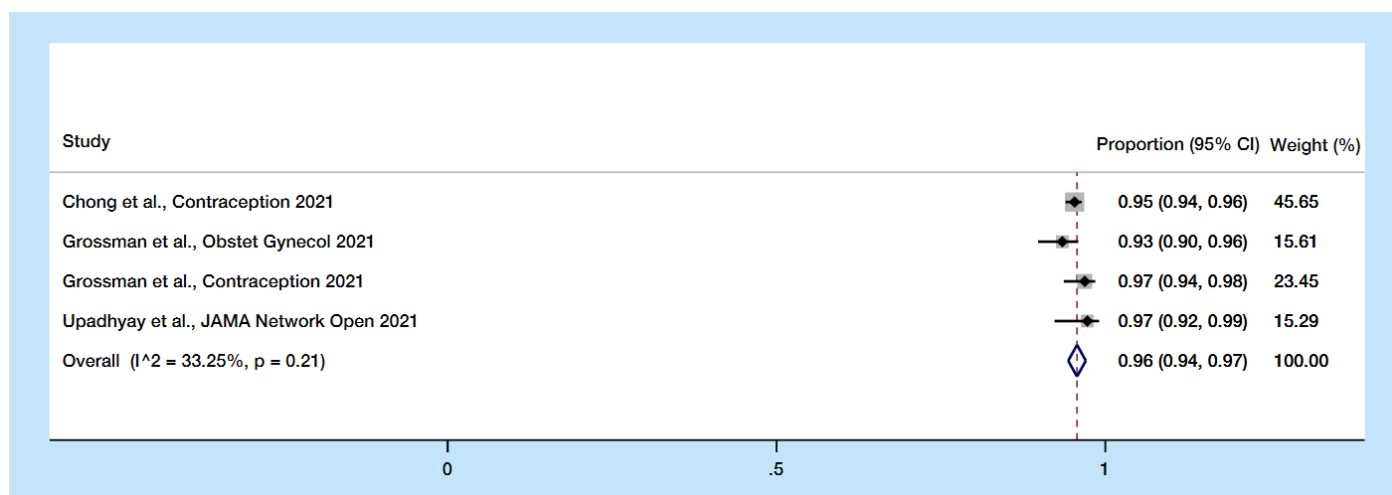
Table 1. Abortion outcome data on effectiveness and serious adverse events among cases for which outcome was known

Study	Abortion outcome known	Abortion complete with medications alone			Abortion not complete with medications alone*		Serious adverse events†		
	N	n	Proportion	95% CI	n	%	n	Proportion	95% CI
Chong et al., <i>Contraception</i> 2021	1157	1103	95.3%	94.0% - 96.5%	54	4.7%	9	0.8%	0.3% - 1.5%
Grossman et al., <i>Obstet Gynecol</i> 2021	260	243	93.5%	89.7% - 96.1%	17	6.5%	0	0	-
Grossman et al., <i>Contraception</i> 2021	224	217	96.9%	93.7% - 98.7%	7	3.1%	2	0.9%	0.1% - 3.2%
Upadhyay et al., <i>JAMA Network Open</i> 2021	110	107	97.3%	92.2% - 99.4%	3	2.7%	0	0	-

*Includes those who had ongoing pregnancies or who had vacuum aspiration, dilation & curettage (D&C), or procedural abortion for any reason.

†Serious adverse events related to medication abortion included death, hospitalization, surgery (not including uterine evacuation), and blood transfusion

Figure 1. Forest plot of the proportion with complete abortion with medications alone, by study and overall



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