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Medication Abortion, Simplified: Addressing Research Challenges in Novel Models of
Abortion Care

by
Leah Ren-Ai Koenig

DISSERTATION

Submitted in partial satisfaction of the requirements for degree of
DOCTOR OF PHILOSOPHY

in

Epidemiology and Translational Science

in the

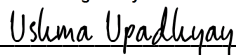
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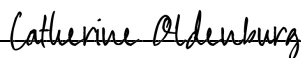


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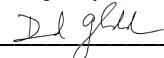
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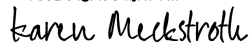
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Catherine Oldenburg



David Glidden

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Karen Meckstroth

Committee Members

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By

Leah Ren-Ai Koenig

Dedication

This dissertation is dedicated to my father, Michael Koenig, who devoted his career to understanding the health consequences of violence against women.

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Medication Abortion, Simplified: Addressing Research Challenges in Novel Models of Abortion Care

Leah Ren-Ai Koenig

Abstract

Since medication abortion was first introduced in the United States (U.S.) in 2000, studies have consistently shown that it is safe and effective. Approximately 5% of medication abortion patients require additional medical intervention to complete the abortion, and <1% experience a serious adverse event. Despite this evidence, policy challenges to the availability of medication abortion continue, often driven by purported safety concerns.

During the COVID-19 pandemic, the U.S. Food and Drug Administration (FDA) removed an in person dispensing requirement for the first drug in the medication abortion regimen, mifepristone. These changes allowed for remote provision of medication abortion, including telehealth models that involve dispensing of abortion medications by mail. Research demonstrates that telehealth can increase abortion access, promote patient-centered care, and save costs while maintaining safety and effectiveness.¹⁻⁷ However, these changes in clinical practice also introduce new challenges for researchers, including limited data sources and loss-to-follow-up. This dissertation investigates potential biases in research on the safety and effectiveness of simplified medication abortion care. It also offers recommendations for clinical practice, policy, and future research as these simplified models of abortion care expand, amid increasing state restrictions on abortion.

Paper 1 directly compares the safety and effectiveness of medication abortion provided with vs. without in-clinic screening tests (ultrasonography and pelvic exam) at 3 U.S. clinics. Paper 2 evaluates the impact of loss to follow-up on estimates of medication abortion safety and effectiveness by examining the outcomes of telehealth abortion patients who were difficult to reach for follow-up. Paper 3 examines the follow-up care trajectories of telehealth abortion patients, including the reasons, timing, and locations of follow-up visits.

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List of Abbreviations

β -hCG - Beta human chorionic gonadotropin

CHAT - California Home Abortion by Telehealth

CI - Confidence interval

OBGYN - Obstetrician-gynecologist

FDA - United States Food and Drug Administration

Chapter 1: Effectiveness and safety of medication abortion with vs. without screening ultrasonography or pelvic exam

1.1 Abstract

Background: Until the COVID-19 pandemic, medication abortion screening from clinics in the United States (U.S.) routinely involved ultrasonography or pelvic examination. Omitting screening tests expands abortion access by facilitating remote provision of medication abortion, which reduces travel, cost, and wait times. Remote medication abortion provision has become even more critical since the U.S. Supreme Court 2022 *Dobbs v. Jackson* decision. Despite evidence that medication abortion without in-clinic screening tests is safe and effective, screening ultrasound and pelvic examination remain common in clinical practice.

Objectives: In this cohort study, we compared the effectiveness and safety of medication abortion provided with and without in-person screening tests, specifically ultrasonography or pelvic examination.

Study Design: We conducted a retrospective cohort study of medication abortions provided as a part of regular clinical practice by 3 U.S. clinics from February 2020–January 2021. Clinics abstracted medical record data for all patients with gestations <77 days who had neither screening ultrasonography nor pelvic examination (“no-test” group) and a random sample who had either test (“screening test” group). Medically eligible patients were offered the choice between the two screening approaches. We imputed missing data and used inverse-probability-of-treatment-weighted logistic regression to compare abortion effectiveness (complete abortion without addi-

tional treatment), safety (abortions not involving major adverse events), emergency department visits, and abortions inadvertently provided beyond 77 days (a commonly used pregnancy duration limit for medication abortion) between study groups.

Results: We included 649 abortions with and 1,727 abortions without screening tests. Patients who obtained medication abortion without screening ultrasonography or pelvic examination had lower average pregnancy durations (48 vs. 50 days, $p<0.001$), were more likely to be White (43% vs. 32%, $p<0.001$), were less likely to reside in urban areas (78% vs. 83%, $p=0.004$), were more likely to receive abortion medications by mail (35% vs. 1%, $p<0.001$) and were more likely to pay out-of-pocket for abortion costs (62% vs. 55%, $p=0.002$). Abortion outcomes were documented for 72% of the screening test group and 58% of the no-test group ($p<0.001$). After imputing missing outcome data, we found similar effectiveness (95.3% vs. 93.4%, Risk Difference [RD]: -1.9% [95% CI: -6.9%, 3.1%]) and safety (99.8% vs. 98.7%, RD: -1.1% [95% CI: -2.9%, 0.7%]) between the screening test and no-test groups. Complete case analyses also found similar effectiveness (95.8% vs. 94.1%, RD: -1.7% [-4.4%, 1.1%]) and safety (100.0% vs. 99.2%, RD: -0.81% [-1.74%, 0.11%]) between study groups. Across both groups, 0.59% of abortions were found at follow-up to have been inadvertently provided at >77 days of gestation, and 4.0% involved an emergency department visit; these proportions did not differ by study group. Emergency department visits involving treatment were more common in the no-test group (2.1% vs. 0.39%, RD: 1.7% [95% CI: 0.1%, 3.3%]).

Conclusions: This study indicates that medication abortion care provided without screening ultrasonography or pelvic exam is comparably safe and effective to care with these screening tests, although loss to follow-up was high. Medication abortion should be routinely offered without screening ultrasonography or pelvic examination to eligible patients, even in in-person clinic settings.

1.2 Introduction

Since the approval of mifepristone in the United States (U.S.) in 2000, medication abortion was provided at medical facilities and was routinely preceded by ultrasonography or pelvic exam to assess pregnancy duration and confirm intrauterine pregnancy. However, in 2021, the U.S. Food and Drug Administration (FDA) lifted the in-person dispensing requirement for mifepristone, allowing for the expansion of abortion care models that omit these tests within the U.S. healthcare system. These models included remote consultation, mailing of medications, and pharmacy dispensing, provided by both brick-and-mortar facilities and telehealth platforms.^{8–11} In place of universal in-person screening tests, patients can be screened using medical history, including last menstrual period and risk factors for ectopic pregnancy.⁹ “No-test” medication abortion care has expanded since the 2022 U.S. Supreme Court *Dobbs v. Jackson Women’s Health Organization* decision that ended a constitutional protection for abortion.¹¹ However, protocols at in-person clinics have been slow to change, and many continue to require universal screening tests for medication abortion care.¹⁰ In addition to these clinical barriers to “no-test” medication abortion, 6 states where abortion remains legal have mandatory ultrasound laws. Studies of medication abortion provided without in-person screening tests have found high effectiveness and safety, however, most did not include comparison groups that received screening tests concurrently, in the same population.^{2, 3, 12–14} Only 3 small U.S. studies have directly compared medication abortions provided with and without these tests. They determined that both models were effective and safe.^{4, 5, 15} One found that patients in 2020 who did not have screening tests were more likely than those who obtained screening tests to receive procedural intervention and to have unplanned clinical encounters, though this difference did not persist into 2021.⁴ More research is needed to assess the comparability of these models of care to inform change in clinical practice. We previously published a retrospective case se-

ries study examining outcomes of medication abortion provided without ultrasonography or pelvic exam in 2020-2021.² While we found high effectiveness and safety, this study lacked a comparison group. To address this limitation, we subsequently collected data from 3 of the participating clinics for medication abortion patients who had screening tests during the same period. We aimed to compare the effectiveness and safety of the screening test and no-test medication abortion models.

1.3 Materials and Methods

1.3.1 Data

For this study, we drew data from a prior study of 3,779 no-test medication abortions provided without screening ultrasonography or pelvic exam by 14 clinics.² The participating clinics offered no-test medication abortion as an option to medically eligible patients. Medical eligibility for no-test abortion included a known first date of last menstrual period and absence of risk factors for ectopic pregnancy (e.g. sterilization, prior ectopic pregnancy, or intrauterine device in place, pelvic inflammatory disease). The present study includes the clinics in the original study that contributed more than 50 cases without screening ultrasonography or pelvic exam to the original study, provided medication abortions with and without these tests during the original study period, and were able to participate in continued research. We originally planned to abstract 1000 abortions across 7 clinics; however, only 3 clinics were ultimately able to participate in this study. We created a sampling frame stratified by the clinic and included all eligible patients between February 2020 and January 2021, allocated proportionally to the distribution in the original study. For the analysis, we included all abortions in the original study (all of which were provided without ultrasonography or pelvic exam) from these 3 clinics in which: the estimated pregnancy duration was <77 days (a common pregnancy duration limit among medication abortion providers¹⁶) at treatment; the

patient had not had a prior qualifying abortion during the study period; the abortion was not provided within the TelAbortion Study, a clinical trial on telehealth abortion (as we anticipated outcomes may have differed within the context of a clinical trial and outcomes of these patients were published previously);^{4, 12} and the patient took mifepristone, misoprostol, or both.² These cases constituted the “no-test” group. For comparison, we developed a “screening test” group comprised of patients who met the same criteria except that the patient had screening ultrasonography or pelvic exam. We selected screening test group cases using a random sequence until the target enrollment number was reached for each site. We selected screening test group cases using a random sequence until the target enrollment number was reached for each site. In both arms of the study, we included patients who obtained abortion medications in person and by mail from participating clinics. Trained study team members abstracted electronic medical record data into a standardized form in REDCap.^{Harris2009} This study was approved by the Allendale and University of Hawai‘i institutional review boards, which waived the need for patient informed consent given the retrospective medical record review study design. The study was also deemed exempt by the University of California, San Francisco institutional review board.

1.3.2 Measures

Outcomes were ascertained from all follow-up interactions (either remote interactions or in-person visits) documented in patients’ electronic medical records.

Effectiveness

We compared the proportion of medication abortions with known outcomes that were complete with 200 mg mifepristone and <1,600 mcg misoprostol without other intervention between study groups.

We used a threshold of 1,600 mcg misoprostol to reflect the maximum amount of misoprostol dispensed to patients at the time of treatment. We classified abortions as complete by test if the patient had a negative urine pregnancy test result, ultrasonography or pelvic examination showing no continuing pregnancy, an expected decline in serum beta human chorionic gonadotropin (β -hCG) level, a single posttreatment serum β -hCG value less than 500 mIU/mL $\geq$ 8 days after mifepristone dispensing, or clinician examination of fetus or fetal parts. Patients without a negative test were considered to have a complete abortion determined by history if their provider assessed symptoms as consistent with a complete abortion or reported no concern that additional evaluation or management was necessary. We considered patients not to have a complete abortion if they experienced an ultrasonography-confirmed continuing pregnancy at any point after initial treatment and/or an intervention to complete the abortion. Interventions included: 1) procedure such as an aspiration, 2) prescription of >200 mg mifepristone, >1,600 mcg misoprostol, or a uterotonic medication to complete the abortion, or 3) treatment for ectopic pregnancy.

Safety

We defined major adverse events as blood transfusion, major surgery, or hospital admission. We examined safety among patients who either had known outcomes and/or known major adverse events. Among this sample, we estimated the proportion of patients who did not experience a major adverse event.

Other outcomes

We also examined the proportion of patients who: were found at follow-up to have been treated at >77 days gestation, had emergency department visits, and had emergency department visits with treatment.

1.3.3 Analyses

We compared socio-demographic characteristics, obstetric history, abortion characteristics, and pregnancy duration by last menstrual period date, between the study groups using t-tests and Fisher's exact tests. We used multiple imputation by chained equations with 200 imputations to impute missing outcome and covariate data (for race or ethnicity and previous medication abortion), including patients' pre-treatment characteristics with no missing data (patient age, urbanicity, clinic, pregnancy duration, and whether mifepristone was dispensed in person or by mail) as independent variables in the imputation model. We first calculated proportions of each abortion outcome across the sample using bivariate logistic regression. We then used logistic regression with inverse-probability-of-treatment weighting to estimate risk differences (RD) comparing outcomes in each study group, and corresponding outcome proportions within each study group.¹⁷ We calculated weights using patient age, race or ethnicity, pregnancy duration, providing clinic, prior medication abortions, and mifepristone dispensing method. We calculated robust standard errors, using pseudo-observations to stabilize results in scenarios with rare outcomes.¹⁸ Then, we conducted unimputed (complete case) versions of the primary analyses. All analyses used StataMP version 18.0 (College Station, TX).

Sensitivity Analyses

First, we reconstructed our imputed analyses only among patients whose abortion medications were dispensed in person to account for the imbalance of mifepristone dispensing methods across the study groups and potential variation in outcomes by dispensing method. Second, we replicated the imputed analyses after excluding the clinic with the lowest follow-up (45%) to assess whether the primary results held in a sample with higher follow-up. Finally, we used two additional missing data approaches^{19, 20}—multiple imputation with a monotone-missing data pattern and inverse probability weighting—to assess the performance of our primary imputation approach.

1.4 Results

Our sample initially included 2,681 records. After applying our exclusion criteria, our analytic sample included 2,376 patients; 649 (27%) who obtained screening tests and 1,727 (73%) who did not obtain screening tests (**Figure 1**). Among those, 1,470 had known abortion outcomes, 466 (72%) in the screening test group and 1,004 (58%) in the no-test group ($p<0.001$). In **Figure A1**, we documented that abortion outcomes were more likely to be known in the screening test group within most strata of participant and abortion characteristics. Patient age was similar between the study groups (**Table 1.1**). Mean pregnancy duration determined by last menstrual period was slightly higher in the no-test group (50 days vs. 48 days, $p<0.001$). In the screening test group, nearly all (99%) obtained the mifepristone in person, while in the no-test group, 65% obtained the mifepristone in person and 35% obtained it by mail ($p<0.001$). A higher proportion of patients in the no-test group were White (43% vs. 32%, $p<0.001$), resided in rural areas (14% vs. 10%, $p=0.004$), and paid out-of-pocket for abortion costs (62% vs. 55%, $p=0.002$).

1.4.1 Effectiveness

In our imputed analyses, 93.4% (95% CI: 92.0%, 94.9%) of patients overall had a complete abortion without additional intervention (**Figure 2, Table 1.2**). Among those with complete abortions, we estimated that abortion outcomes were determined by history alone for 34% of those in the screening test group and 27% of those in the no-test group in our imputed analysis. Among the 6.6% of patients whose abortions were not complete without additional intervention, 4.0% had a procedure or aspiration, 2.5% obtained additional medications, 0.48% were treated for ectopic pregnancy, and 2.4% had a continuing pregnancy after initial treatment. Effectiveness (95.3% in the screening test group and 93.4% in the no-test group, RD: -1.9%, [95% CI: -6.9%, 3.1%]) and all other effectiveness outcomes were similar between the study groups (**Table 1.2**).

1.4.2 Safety

In our primary, imputed analyses, we found that 99.0% (95% CI: 98.2%, 99.7%) of patients did not experience a major adverse event (**Figure 2, Table 1.2**). Overall, the proportion of patients who experienced a major adverse event was 1.0% (95% CI: 0.3%, 1.7%); 0.19% in the screening test group and 1.3% in the no-test group, RD: 1.1% [95% CI: -0.6%, 2.8%]). All safety outcomes, including blood transfusion, major surgery, and hospital admission, were similar between the study groups.

1.4.3 Other outcomes

In the primary imputed analysis, 4.0% (95% CI: 2.8%, 5.1%) of patients had an emergency department visit following their treatment, 3.9% in the screening test group and 4.5% in the no-test group (RD: 0.56% [95% CI: -4.01%, 5.13%]). We estimated that 1.7% of the sample had emer-

gency department visits that involved treatment (40% of all emergency department visits involved treatment, 16% of emergency department visits in the screening test group and 45% of emergency department visits in the no-test group). Emergency department visits involving treatment were less common in the screening test group (0.39%) than the no-test group (2.1%, RD: 1.7% [95% CI: 0.1%, 3.3%]). Across the sample, one patient, who was in the no-test group, was found by follow-up ultrasonography to have been treated at 89 days. This patient had a continuing pregnancy after initial treatment treated with an abortion procedure at 101 days of gestation.

1.4.4 Complete case analyses

In our complete case analyses (**Table S1.1**), 94.4% of patients overall had a complete abortion without additional intervention and 99.5% did not experience a major adverse event. All outcomes were similar between the two study groups, however, patients in the screening test group were less likely to be prescribed additional medications compared to the no-test group (0.59% vs. 2.1%, RD: 1.5% [95% CI: 0.1%, 2.9%]). Emergency department visits involving treatment were less common in the screening test group compared to the no-test group (0% vs. 1.7%, RD: 1.7% [95% CI: 0.6%, 2.7%]).

1.4.5 Sensitivity analyses

In the first sensitivity analysis that restricted our imputed analysis only to patients who obtained their abortion medications in person, we estimated that 95.6% of patients overall had a complete abortion without additional intervention, 99.3% did not experience a major adverse event, and no outcomes differed by study group (**Table S1.2**).

In the second sensitivity analysis, we excluded the one clinic with very low follow-up, after which

follow-up was 76% in each group ($p=0.942$). In this analysis, we estimated 96.2% of patients overall had a complete abortion without additional intervention, 99.3% did not experience a major adverse event, and no outcomes differed by study group (**Table S1.3**).

Accounting for missing abortion outcome data using two additional approaches yielded results consistent with the primary imputed analysis (**Tables S1.4 and S1.5**).

1.5 Comment

1.5.1 Principal Findings

In this study, we found that medication abortion provided without screening ultrasonography or pelvic exam was comparably effective and safe to medication abortion with those tests. We estimated that 93.4% of all abortions were complete without additional intervention, and 99.0% were not followed by a major adverse event. Even after imputing missing abortion outcome data, these outcomes did not differ by study group.

1.5.2 Results in the context of what is known

The effectiveness and safety estimates in this study are comparable to evidence on medication abortion with^{21–24} and without^{3, 13, 14, 25} screening ultrasonography or pelvic exam in the published literature. Like prior direct comparisons of medication abortion provided with vs. without these in-person screening tests, our study found few differences in effectiveness and safety.^{4, 5, 15} This analysis is the largest study to our knowledge to make this comparison and applied rigorous statistical methods to minimize bias.

We observed differences in the characteristics of patients who obtained medication abortion care with and without screening tests in this study. No-test patients were more likely to pay for abortion costs, perhaps because no-test abortions can be less costly or because telehealth abortions are less likely to be covered by insurance.^{26, 27} Other differences, including no-test patients being more likely to reside in rural areas and receive abortion medications by mail, highlight potential benefits of omitting in-person screening tests. Echoing other studies, patients in the no-test group were more likely to be White than those in the screening test group.^{4, 7} Less medicalized models of care may be less likely to reach or interest patients of color.

In the complete case analyses, patients in the no-test group were more likely than those in the screening test group to be treated with additional medications. This may be attributed to a growing reliance on medications, such as additional misoprostol, to treat potential complications, especially for patients who obtained their abortion care remotely and may face greater barriers to returning to the clinic.

The proportion of patients who had emergency department visits did not differ between study groups and was comparable to prior studies.^{3, 4, 15, 24, 25} Emergency department visits involving treatment were more common in the no-test group, though absolute risks in both groups were low and risk differences were small. No-test patients may have been more likely to reside further from the providing clinic and, therefore, may have been more likely to visit an emergency department for concerns necessitating in-person evaluation instead of the clinic. During emergency department visits, clinicians may have also been more likely to provide treatment if the patient did not have an in-person screening test due to concerns about incomplete abortion or ectopic pregnancy, at least initially when this model of care first became available. As no-test medication abortion providers gain more experience and refine care protocols, more recent data may not demonstrate

this difference.³ One study that compared these models across 18 months in 2020-2021 found that higher risk of procedural intervention and unplanned in-person follow-up visits found initially among no-test patients resolved over time.⁴

1.5.3 Clinical implications

Although remote provision of medication abortion has increased, many providers require in-clinic screening tests before in-clinic medication abortion. Based on our findings and the weight of the evidence provided by other studies, we recommend that clinicians can safely offer medication abortion without in-person screening tests to all eligible patients, even in facilities with capacity for ultrasonography. Clinicians can rely on similar criteria, which include patient history to establish gestation and evaluate risk of ectopic pregnancy, to screen patients for no-test medication abortion eligibility. An update to the mifepristone label that clarifies FDA's position that in-person pre-abortion tests are not necessary²⁸ for all patients could accelerate the transition to this efficient, patient-centered model of abortion care.

1.5.4 Research implications

Future research can investigate how benefits and drawbacks of no-test models vary across patient populations to tailor services to underserved patients, including those in places where abortion is legally restricted. Loss to follow-up after medication abortion is likely increasing due to the expansion of less medicalized abortion models,¹¹ shifts in clinical guidelines away from universal follow-up,¹⁶ and the risks associated with re-contacting clinics for patients residing in states with abortion bans. While follow-up is not clinically necessary, high degrees of loss to follow-up in research can exacerbate risks of selection bias and undermine the credibility of results. Researchers should investigate how to minimize and address loss to follow-up, including methods to ensure

ascertainment of complications and analytic techniques to address missing data.

1.5.5 Strengths and limitations

This study is the largest to date to compare medication abortion provided with and without screening ultrasonography or pelvic exam, and the study groups were treated concurrently at the same clinics. Our results were consistent across several specifications of the analysis, all of which use robust methods to account for potential selection and confounding bias, supporting the credibility of our conclusions.

A major limitation is the high degree of loss to follow-up, particularly in the no-test group (42%). We addressed this using multiple imputation, which assumes that abortion outcomes of lost to follow-up patients can be estimated based on patients' pretreatment characteristics. This assumption may be questionable, as post-treatment factors, including recognition of a treatment failure or adverse event, can affect whether patients re-contacting the clinic. However, effectiveness in the no-test group appeared higher both in our complete case analysis and in the analysis that omitted data from the site with the highest loss to follow-up (which resulted in 76% follow-up in both study groups), suggesting that our primary results may be conservative.

A second limitation is that complete abortion was determined by history alone in one-third of patients with that outcome. History-based outcome assessment is used clinically but has not yet been rigorously validated.^{29, 30} If some patients determined by history to have complete abortions actually had ongoing pregnancies or subsequent interventions to complete the abortion, our analysis may overestimate effectiveness.

Third, because this study was a retrospective analysis of clinical data, some outcomes may have

been underestimated since they were not assessed prospectively or systematically. Fourth, we lacked patient-level data reflecting the reasons why patients received each screening approach, though clinic protocols were to offer no-test medication abortion to medically eligible patients. While we used inverse-probability-of-treatment weighting to address confounding, the electronic medical records contained limited patient and abortion characteristics, potentially resulting in residual confounding.

1.5.6 Conclusions

Since the 2022 *Dobbs* Supreme Court decision led to 12 states banning abortion, remote models of abortion care have become essential to meeting abortion demand where it remains legal and to reducing wait times in surge states. As of June 2024, 1 in 5 U.S. abortions are provided by telehealth,¹¹ demonstrating that no-test medication abortion can be delivered on a wide scale. Our study indicates that the mandatory ultrasonography requirements in 6 states where abortion remains legal³¹ are not evidence-based. Screening ultrasonography and pelvic examination can incur unnecessary costs, delay care, and be invasive. Expanding no-test medication abortion can increase access to abortion care without compromising effectiveness or safety.

1.6 Tables

Table 1.1. Characteristics of study sample with and without screening tests (N=2376)

	Screening test group (n=649) n (%)	No-test group (n=1727) n (%)	p-value ^a
Age at mifepristone provision, mean + SD	27.5 ± 6.4	28.0 ± 6.2	0.070
12-18 years	17 (2.6)	30 (1.7)	0.250
18-24 years	226 (34.8)	540 (31.3)	
25-29 years	172 (26.5)	485 (28.1)	
30-34 years	128 (19.7)	380 (22.0)	
35-47 years	106 (16.3)	292 (16.9)	
Pregnancy duration by last menstrual period, mean + SD	50.2 ± 11.3	48.3 ± 10.0	<0.001
11-42 days	172 (26.5)	531 (30.7)	<0.001
43-56 days	289 (44.5)	828 (47.9)	
57-63 days	95 (14.6)	222 (12.9)	
64-70 days	61 (9.4)	114 (6.6)	
70-77 days	32 (4.9)	32 (1.9)	
Race or Ethnicity			
American Indian, Native American, or Alaska Native	12 (1.8)	18 (1.0)	<0.001
Asian, Native Hawaiian, Pacific Islander	63 (9.7)	141 (8.2)	
Black	208 (32.0)	518 (30.0)	
Latinx	39 (6.0)	179 (10.4)	
White	205 (31.6)	734 (42.5)	
Multiple or another race or ethnicity	70 (10.8)	43 (2.5)	
Unknown	52 (8.0)	94 (5.4)	
Residence			
Urban	540 (83.2)	1339 (77.5)	0.004
Suburban	39 (6.0)	151 (8.7)	
Rural	66 (10.2)	233 (13.5)	
Unknown	4 (0.6)	4 (0.2)	
Previous medication abortion			
No previous medication abortion	456 (70.3)	1283 (74.3)	0.054
Any previous medication abortion	117 (18.0)	294 (17.0)	
Unknown	76 (11.7)	150 (8.7)	
Method of mifepristone dispensing			
In person	643 (99.1)	1131 (65.5)	<0.001
Mailed	6 (0.9)	596 (34.5)	
Out-of-pocket contribution for abortion cost			
No out-of-pocket contribution	293 (45.1)	659 (38.2)	0.002
Any out-of-pocket contribution	356 (54.9)	1068 (61.8)	
Clinic			
Clinic A	50 (7.7)	135 (7.8)	0.974
Clinic B	299 (46.1)	786 (45.5)	
Clinic C	300 (46.2)	806 (46.7)	
Abortion outcome known			
Abortion outcome unknown	183 (28.2)	723 (41.9)	<0.001
Abortion outcome known	466 (71.8)	1004 (58.1)	

^a - p-value derived from Fisher's exact tests

Table 1.2. Outcomes after medication abortion with and without screening tests estimated from imputed, inverse-probability-of-treatment weighted logistic regression (n=2376)

	Estimated proportion (95% CI)				p-value
	Overall (n=2376)	Screening test group (n=649)	No-test group (n=1727)	Risk difference (95% CI)	
Effectiveness					
Complete abortion without intervention †	93.4 (92.0, 94.9)	95.3 (90.6, 100.0)	93.4 (91.7, 95.0)	-1.9 (-6.9, 3.1)	0.447
Intervention or continuing pregnancy*	6.6 (5.1, 8.0)	4.4 (0.1, 8.6)	6.7 (5.1, 8.3)	2.3 (-2.3, 6.9)	0.326
Aspiration or other procedure	4.0 (2.9, 5.1)	2.3 (0.0, 5.0)	4.3 (3.0, 5.6)	2.0 (-1.0, 5.0)	0.193
Prescribed >1,600 mcg misoprostol, mifepristone, or other medications	2.5 (1.5, 3.5)	1.3 (0.0, 4.7)	2.7 (1.5, 3.8)	1.3 (-2.3, 5.0)	0.478
Suspected or confirmed ectopic pregnancy	0.48 (0.00, 1.14)	0.37 (0.00, 1.94)	0.50 (0.00, 1.29)	0.13 (-1.56, 1.83)	0.879
Confirmed continuing pregnancy	2.4 (1.5, 3.4)	2.2 (0.0, 5.7)	2.1 (1.1, 3.1)	-0.08 (-3.74, 3.58)	0.967
Safety					
No Major abortion-related adverse event	99.0 (98.2, 99.7)	99.8 (98.2, 100.0)	98.7 (97.8, 99.6)	-1.1 (-2.9, 0.7)	0.234
Major abortion-related adverse event*	1.0 (0.3, 1.7)	0.19 (0.00, 1.59)	1.3 (0.4, 2.2)	1.1 (-0.6, 2.8)	0.198
Blood transfusion	0.89 (0.19, 1.59)	0.18 (0.00, 1.58)	1.1 (0.3, 2.0)	0.93 (-0.73, 2.59)	0.269
Major surgery, including surgical treatment of ectopic pregnancy	0.55 (0.00, 1.28)	0.15 (0.00, 0.73)	0.61 (0.00, 1.44)	0.46 (-0.49, 1.42)	0.339
Hospital Admission	0.78 (0.11, 1.46)	0.17 (0.00, 1.25)	0.96 (0.14, 1.79)	0.80 (-0.58, 2.17)	0.255
Other outcomes					
Pregnancies treated >77 days	0.43 (0.00, 1.08)	0.18 (0.00, 0.81)	0.50 (0.00, 1.30)	0.32 (-0.66, 1.30)	0.519
Emergency Department visit	4.0 (2.8, 5.1)	3.9 (0.0, 8.3)	4.5 (3.1, 5.9)	0.56 (-4.01, 5.13)	0.810
Emergency Department visit with treatment	1.7 (0.8, 2.6)	0.39 (0.00, 1.61)	2.1 (1.0, 3.2)	1.7 (0.1, 3.3)	0.038

†We estimated that 34% of complete abortions in the screening test group and 27% of complete abortions in the no-test group were determined by history alone

* Categories are not mutually exclusive

Inverse-probability-of-treatment weights include patient age, duration of pregnancy, race or ethnicity, urbanicity, prior medication abortion, method of mifepristone dispensing, and providing clinic

Overall estimates draw from bivariate logistic regression models, while group-specific estimates and risk differences draw from inverse-probability-of-treatment-weighted logistic regression models.

1.7 Figures

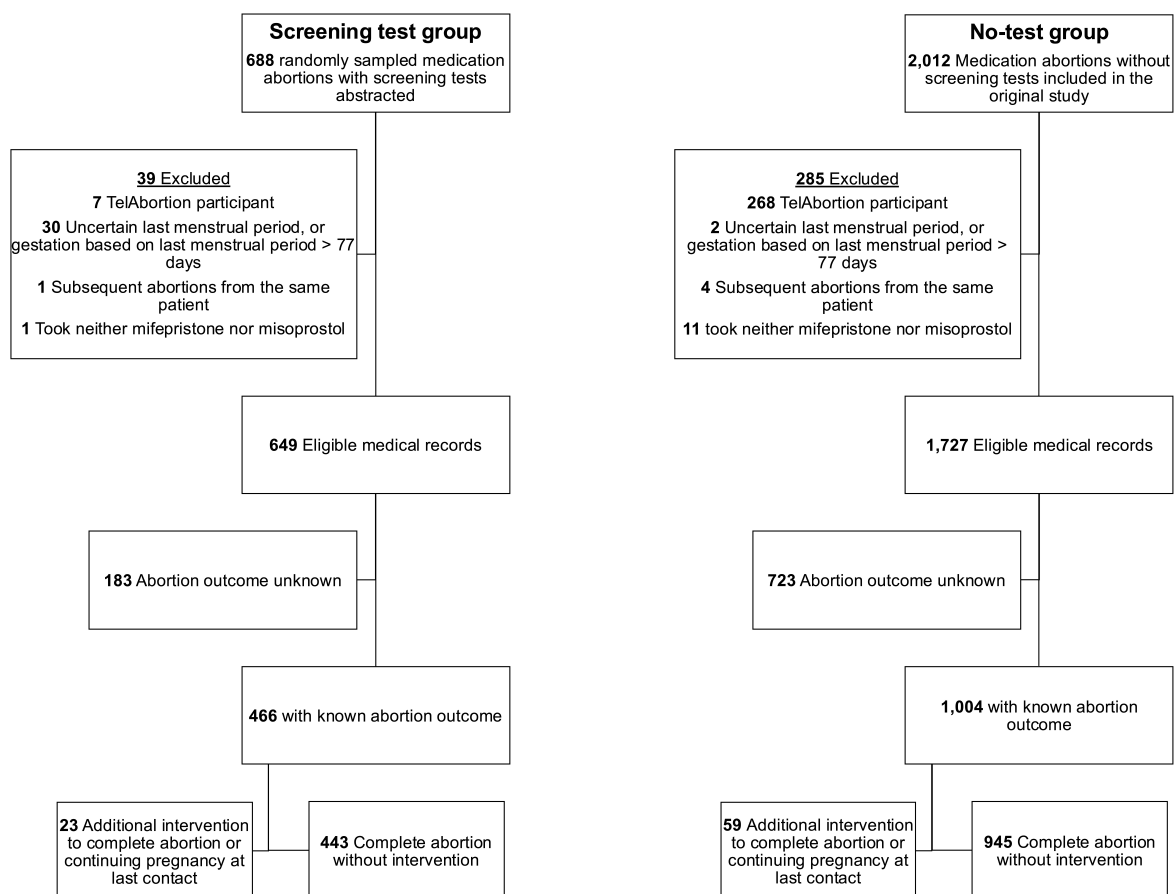


Figure 1.1. Study sample and inclusion criteria flowchart

1.8 Supplementary Material

Table S1.1. Complete case estimates of outcomes after medication abortion with and without screening tests estimated from unimputed, inverse-probability-of-treatment weighted logistic regression (n=1470)

	N	Overall (n=1470) Estimated proportion (95% CI)	N	Screening test group (n=466) Estimated proportion (95% CI)	N	No-test group (n=1004) Estimated proportion (95% CI)	Risk difference (95% CI)	p-value
Effectiveness								
Complete abortion without intervention†	1388	94.4 (93.2, 95.6)	443	95.8 (93.7, 97.9)	945	94.1 (92.3, 95.9)	-1.7 (-4.4, 1.1)	0.235
Intervention or continuing pregnancy*	82	5.6 (4.4, 6.8)	23	4.2 (2.1, 6.3)	59	5.9 (4.1, 7.7)	1.7 (-1.1, 4.4)	0.235
Aspiration or other procedure	52	3.5 (2.6, 4.5)	12	2.5 (0.8, 4.2)	40	3.6 (2.4, 4.9)	1.1 (-1.0, 3.2)	0.293
Prescribed >1,600 mcg misoprostol, mifepristone, or other medications	26	1.8 (1.1, 2.4)	6	0.59 (0.00, 1.40)	20	2.1 (0.9, 3.2)	1.5 (0.1, 2.9)	0.040
Suspected or confirmed ectopic pregnancy	2	0.14 (0.00, 0.32)	1	0.10 (0.00, 0.73)	1	0.09 (0.00, 0.35)	0.00 (-0.68, 0.68)	0.996
Confirmed continuing pregnancy	28	1.9 (1.2, 2.6)	11	1.9 (0.5, 3.4)	17	1.7 (0.7, 2.7)	-0.26 (-2.02, 1.51)	0.777
Safety								
No Major abortion-related adverse event	1462	99.5 (99.1, 99.8)	466	100.0 (99.4, 100.0)	996	99.2 (98.5, 99.9)	-0.81 (-1.74, 0.11)	0.084
Major abortion-related adverse event*	8	0.54 (0.17, 0.92)	0	0.00 (0.00, 0.60)	8	0.81 (0.11, 1.52)	0.81 (-0.11, 1.74)	0.084
Blood transfusion	6	0.41 (0.08, 0.73)	0	0.00 (0.00, 0.60)	6	0.63 (0.00, 1.28)	0.63 (-0.26, 1.52)	0.165
Major surgery, including surgical treatment of ectopic pregnancy	2	0.14 (0.00, 0.32)	0	0.00 (0.00, 0.60)	2	0.17 (0.00, 0.47)	0.17 (-0.50, 0.84)	0.619
Hospital Admission	5	0.34 (0.04, 0.64)	0	0.00 (0.00, 0.60)	5	0.60 (0.00, 1.23)	0.60 (-0.27, 1.47)	0.179
Other outcomes								
Pregnancies treated >77 days gestation	1	0.07 (0.00, 0.20)	0	0.00 (0.00, 0.60)	1	0.09 (0.00, 0.34)	0.09 (-0.56, 0.74)	0.789
Emergency Department visit‡	51	3.5 (2.5, 4.4)	10	2.7 (0.2, 5.2)	41	4.2 (2.8, 5.6)	1.5 (-1.4, 4.4)	0.312
Emergency Department visit with treatment‡	19	1.3 (0.7, 1.9)	1	0.00 (0.00, 0.59)	18	1.7 (0.8, 2.6)	1.7 (0.6, 2.7)	0.002

†35% of complete abortions in the screening test group and 28% of complete abortions in the no-test group were determined by history alone.

* Categories are not mutually exclusive

‡Denominator is n=468 in the screening test group and n=1006 in the no-test group

Inverse-probability-of-treatment weights include patient age, duration of pregnancy, race or ethnicity, urbanicity, prior medication abortion, method of mifepristone dispensing, and providing clinic.

Overall estimates draw from bivariate logistic regression models, while group-specific estimates and risk differences draw from inverse-probability-of-treatment-weighted logistic regression models.

Table S1.2. Outcomes after medication abortion with and without screening tests among patients who obtained mifepristone in person estimated from imputed, inverse-probability-of-treatment weighted logistic regression (n=1774)

	Overall (n=1774)	Screening test group (n=643)	No-test group (n=1131)	Risk difference (95% CI)	p-value
	Estimated proportion (95% CI)				
Effectiveness					
Complete abortion without intervention †	95.6 (94.4, 96.7)	95.3 (93.2, 97.4)	95.5 (93.9, 97.1)	0.20 (-2.49, 2.88)	0.885
Intervention or continuing pregnancy*	4.4 (3.3, 5.6)	4.7 (2.6, 6.9)	4.5 (2.9, 6.1)	-0.23 (-2.88, 2.43)	0.868
Aspiration or other procedure	3.1 (2.1, 4.1)	2.6 (1.0, 4.3)	3.5 (2.1, 4.9)	0.83 (-1.37, 3.03)	0.458
Prescribed >1,600 mcg misoprostol, mifepristone, or other medications	1.2 (0.6, 1.9)	1.2 (0.0, 2.3)	1.4 (0.3, 2.4)	0.18 (-1.35, 1.72)	0.813
Suspected or confirmed ectopic pregnancy	0.45 (-0.07, 0.97)	0.44 (0.00, 1.41)	0.45 (-0.29, 1.19)	0.01 (-1.17, 1.19)	0.987
Safety					
No Major abortion-related adverse event	1.8 (1.0, 2.5)	2.4 (0.8, 4.0)	1.3 (0.4, 2.3)	-1.1 (-2.9, 0.8)	0.263
Major abortion-related adverse event*	99.3 (98.8, 99.9)	99.8 (99.2, 100.5)	99.0 (98.0, 99.9)	-0.86 (-2.01, 0.30)	0.145
Blood transfusion	0.64 (0.11, 1.17)	0.20 (0.00, 0.94)	0.99 (0.07, 1.92)	0.79 (-0.38, 1.97)	0.185
Major surgery, including surgical treatment of ectopic pregnancy	0.51 (0.00, 1.03)	0.20 (0.00, 0.93)	0.81 (-0.06, 1.68)	0.61 (-0.49, 1.72)	0.278
Hospital Admission	0.38 (-0.14, 0.90)	0.28 (0.00, 1.19)	0.48 (-0.30, 1.26)	0.20 (-0.97, 1.37)	0.732
Other outcomes					
Pregnancies treated >77 days gestation	0.39 (-0.13, 0.90)	0.28 (0.00, 1.15)	0.47 (-0.27, 1.21)	0.19 (-0.92, 1.30)	0.735
Emergency Department visit	2.9 (2.0, 3.9)	1.9 (0.5, 3.3)	3.7 (2.3, 5.2)	1.8 (-0.2, 3.8)	0.074
Emergency Department visit with treatment	1.2 (0.5, 1.8)	0.42 (0.00, 1.34)	1.7 (0.7, 2.8)	1.3 (-0.1, 2.7)	0.066

†We estimated that 21% of complete abortions in the screening test group and 32% of complete abortions in the no-test group were determined by history alone.

* Categories are not mutually exclusive.

Inverse-probability-of-treatment weights include patient age, duration of pregnancy, race or ethnicity, urbanicity, prior medication abortion, method of mifepristone dispensing, and providing clinic.

Overall estimates draw from bivariate logistic regression models, while group-specific estimates and risk differences draw from inverse-probability-of-treatment-weighted logistic regression models.

Table S1.3. Outcomes after medication abortion with and without screening tests among patients at 2 of the 3 included clinics with 74% or higher follow-up estimated from imputed, inverse-probability-of-treatment weighted logistic regression (n=1291)

	Overall (n=1291)	Screening test group (n=350) Estimated proportion (95% CI)	No-test group (n=941)	Risk difference (95% CI)	p-value
Effectiveness					
Complete abortion without intervention†	96.2 (94.9, 97.4)	95.5 (92.8, 98.1)	96.3 (94.8, 97.7)	0.83 (-2.20, 3.87)	0.591
Intervention or continuing pregnancy*	3.8 (2.5, 5.0)	4.3 (1.7, 6.9)	3.7 (2.2, 5.1)	-0.67 (-3.64, 2.29)	0.657
Aspiration or other procedure	3.0 (1.8, 4.1)	2.6 (0.5, 4.7)	3.2 (1.8, 4.6)	0.63 (-1.91, 3.17)	0.627
Prescribed >1,600 mcg misoprostol, mifepristone, or other medications	0.81 (0.16, 1.46)	0.81 (0.00, 2.13)	0.83 (0.04, 1.63)	0.02 (-1.50, 1.55)	0.975
Suspected or confirmed ectopic pregnancy	0.38 (0.00, 0.97)	0.28 (0.00, 1.49)	0.41 (0.00, 1.11)	0.14 (-1.24, 1.52)	0.846
Confirmed continuing pregnancy	1.4 (0.6, 2.2)	1.8 (0.0, 3.6)	1.2 (0.3, 2.2)	-0.54 (-2.62, 1.54)	0.609
Safety					
No Major abortion-related adverse event	99.3 (98.6, 99.9)	99.7 (98.6, 100.8)	99.1 (98.2, 99.9)	-0.61 (-1.98, 0.75)	0.379
Major abortion-related adverse event*	0.66 (0.03, 1.28)	0.21 (0.00, 1.22)	0.84 (0.03, 1.66)	0.63 (-0.64, 1.90)	0.332
Blood transfusion	0.50 (0.00, 1.07)	0.30 (0.00, 1.43)	0.60 (0.00, 1.33)	0.30 (-1.04, 1.64)	0.663
Major surgery, including surgical treatment of ectopic pregnancy	0.38 (0.00, 0.97)	0.28 (0.00, 1.49)	0.41 (0.00, 1.11)	0.14 (-1.24, 1.52)	0.846
Hospital Admission	0.47 (0.00, 1.04)	0.26 (0.00, 1.38)	0.53 (0.00, 1.24)	0.27 (-1.02, 1.57)	0.682
Other outcomes					
Pregnancies treated >77 days gestation	0.39 (0.00, 0.98)	0.28 (0.00, 1.45)	0.42 (0.00, 1.12)	0.15 (-1.19, 1.48)	0.830
Emergency Department visit	2.9 (1.8, 4.0)	2.1 (0.2, 3.9)	3.4 (2.0, 4.8)	1.3 (-1.0, 3.6)	0.262
Emergency Department visit involving treatment	1.4 (0.6, 2.1)	0.75 (0.00, 2.14)	1.7 (0.7, 2.7)	0.93 (-0.80, 2.66)	0.291

†We estimated that 33% of complete abortions in the screening test group and 29% of complete abortions in the no-test group were determined by history alone.

* Categories are not mutually exclusive.

Inverse-probability-of-treatment weights include patient age, duration of pregnancy, race or ethnicity, urbanicity, prior medication abortion, method of mifepristone dispensing, and providing clinic.

Overall estimates draw from bivariate logistic regression models, while group-specific estimates and risk differences draw from inverse-probability-of-treatment-weighted logistic regression models.

Table S1.4. Outcomes after medication abortion with and without screening tests. Estimates are drawn from inverse-probability-of-treatment weighted logistic regression using inverse-probability-of-censoring weights to account for missing data (n=1248)

	Overall (n=1248)	Screening test group (n=374) Estimated proportion (95% CI)	No-test group (n=874)	Risk difference (95% CI)	p-value
Effectiveness					
Complete abortion without intervention†	93.9 (92.3, 95.4)	96.1 (94.1, 98.0)	93.8 (92.0, 95.6)	-1.3 (-4.1, 1.4)	0.341
Intervention or continuing pregnancy*	6.1 (4.6, 7.7)	3.9 (2.0, 5.9)	6.2 (4.4, 8.0)	1.3 (-1.4, 4.1)	0.341
Aspiration or other procedure	4.0 (2.7, 5.3)	2.5 (0.9, 4.1)	3.9 (2.6, 5.3)	0.92 (-1.18, 3.02)	0.391
Prescribed >1,600 mcg misoprostol, mifepristone, or other medications	2.0 (1.1, 2.9)	0.73 (0.00, 1.52)	2.3 (1.1, 3.5)	1.2 (-0.2, 2.6)	0.088
Suspected or confirmed ectopic pregnancy	0.29 (0.00, 0.61)	0.39 (0.00, 1.00)	0.18 (0.00, 0.42)	-0.23 (-0.97, 0.51)	0.538
Confirmed continuing pregnancy	2.2 (1.3, 3.2)	1.8 (0.6, 3.1)	1.9 (0.9, 2.9)	-0.36 (-2.10, 1.38)	0.686
Safety					
No Major abortion-related adverse event	99.4 (98.9, 99.8)	99.7 (99.1, 100.0)	99.1 (98.4, 99.8)	-0.55 (-1.52, 0.41)	0.259
Major abortion-related adverse event*	0.64 (0.17, 1.11)	0.30 (0.00, 0.88)	0.90 (0.18, 1.62)	0.55 (-0.41, 1.52)	0.259
Blood transfusion	0.53 (0.08, 0.98)	0.30 (0.00, 0.88)	0.72 (0.05, 1.40)	0.35 (-0.57, 1.27)	0.458
Major surgery, including surgical treatment of ectopic pregnancy	0.33 (0.00, 0.69)	0.30 (0.00, 0.88)	0.28 (0.00, 0.60)	-0.04 (-0.77, 0.68)	0.912
Hospital Admission	0.59 (0.13, 1.06)	0.30 (0.00, 0.88)	0.71 (0.10, 1.32)	0.40 (-0.51, 1.32)	0.390
Other outcomes					
Pregnancies treated >77 days gestation	0.24 (0.00, 0.54)	0.30 (0.00, 0.88)	0.17 (0.00, 0.40)	-0.13 (-0.83, 0.57)	0.719
Emergency Department visit	3.7 (2.5, 5.0)	3.2 (0.3, 6.0)	4.7 (3.1, 6.4)	0.79 (-2.54, 4.12)	0.644
Emergency Department visit with treatment	1.3 (0.6, 1.9)	0.30 (0.00, 0.87)	1.8 (0.8, 2.7)	1.3 (0.2, 2.4)	0.022

* Categories are not mutually exclusive.

† 35% of complete abortions in the screening test group and 28% of complete abortions in the no-test group were determined by history alone.

Inverse-probability-of-treatment weights include patient age, duration of pregnancy, race or ethnicity, urbanicity, prior medication abortion, method of mifepristone dispensing, and providing clinic.

Overall estimates draw from bivariate logistic regression models, while group-specific estimates and risk differences draw from inverse-probability-of-treatment-weighted logistic regression models.

Table S1.5. Outcomes after medication abortion with and without screening tests. Estimates are drawn from imputed logistic regression using monotone data imputation to account for missing data (n=2376)

	Overall (n=2376)	Screening test group (n=649)	No-test group (n=1727)	Risk difference (95% CI)	p-value
	Estimated proportion (95% CI)				
Effectiveness					
Complete abortion without intervention	93.4 (91.8, 95.1)	94.6 (88.2, 100.0)	93.6 (91.7, 95.4)	-1.0 (-7.7, 5.6)	0.756
Intervention or continuing pregnancy*	6.6 (4.9, 8.2)	5.4 (0.0, 11.6)	6.5 (4.6, 8.4)	1.1 (-5.4, 7.6)	0.739
Aspiration or other procedure	4.2 (2.8, 5.5)	3.2 (0.0, 7.9)	4.2 (2.7, 5.8)	1.00 (-3.93, 5.92)	0.691
Prescribed >1,600 mcg misoprostol, mifepristone, or other medications	2.6 (1.4, 3.7)	1.3 (0.0, 4.8)	2.7 (1.4, 4.1)	1.5 (-2.3, 5.2)	0.441
Suspected or confirmed ectopic pregnancy	0.74 (0.00, 1.66)	0.76 (0.00, 3.18)	0.70 (0.00, 1.74)	-0.06 (-2.53, 2.40)	0.960
Confirmed continuing pregnancy	2.6 (1.5, 3.7)	3.0 (0.0, 8.2)	2.2 (1.0, 3.4)	-0.76 (-6.06, 4.54)	0.779
Safety					
No Major abortion-related adverse event	98.9 (98.0, 99.8)	99.6 (97.3, 101.8)	98.6 (97.5, 99.7)	-0.92 (-3.45, 1.60)	0.473
Major abortion-related adverse event*	1.1 (0.3, 2.0)	0.43 (0.00, 2.29)	1.4 (0.3, 2.5)	0.96 (-1.15, 3.08)	0.370
Blood transfusion	1.0 (0.1, 1.9)	0.45 (0.00, 2.62)	1.2 (0.1, 2.3)	0.76 (-1.59, 3.10)	0.527
Major surgery, including surgical treatment of ectopic pregnancy	0.73 (0.00, 1.56)	0.50 (0.00, 2.88)	0.77 (0.00, 1.73)	0.28 (-2.25, 2.81)	0.830
Hospital Admission	1.1 (0.2, 1.9)	0.51 (0.00, 2.62)	1.3 (0.2, 2.3)	0.76 (-1.53, 3.04)	0.516
Other outcome					
Pregnancies treated >77 days gestation	0.63 (0.00, 1.51)	0.48 (0.00, 2.65)	0.69 (0.00, 1.73)	0.20 (-2.10, 2.51)	0.863
Emergency Department visit	4.1 (2.8, 5.4)	4.1 (0.0, 9.4)	4.7 (3.1, 6.2)	0.53 (-4.90, 5.95)	0.849
Emergency Department visit with treatment	1.8 (0.8, 2.8)	0.33 (0.00, 2.16)	2.2 (1.0, 3.4)	1.9 (-0.3, 4.1)	0.090

†We estimated that 30% of complete abortions in the screening test group and 27% of complete abortions in the no-test group were determined by history alone.

* Categories are not mutually exclusive.

Inverse-probability-of-treatment weights include patient age, duration of pregnancy, race or ethnicity, urbanicity, prior medication abortion, method of mifepristone provision, and providing clinic.

Models included robust standard errors.

Overall estimates draw from bivariate logistic regression models, while group-specific estimates and risk differences draw from inverse-probability-of-treatment-weighted logistic regression models.

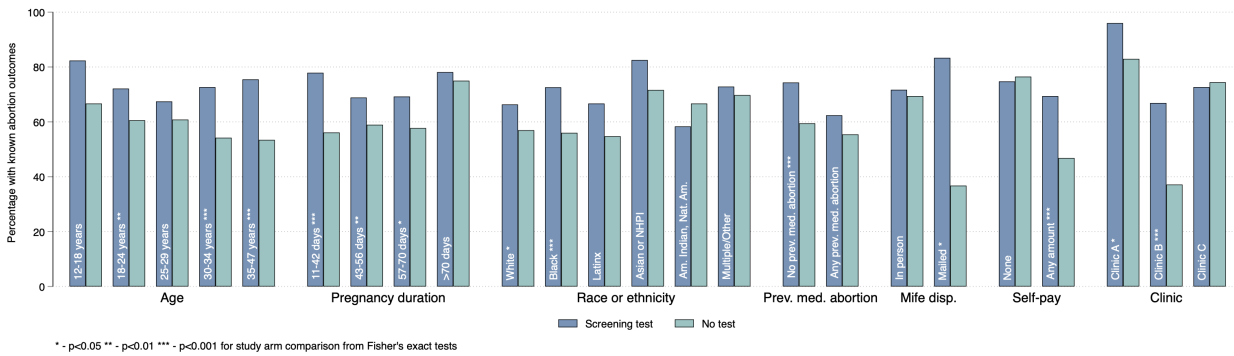


Figure S1.1. Sample proportion with known abortion outcomes, by study group and sample characteristics

Chapter 2: The impact of loss to follow-up on estimates of medication abortion effectiveness and safety

2.1 Abstract

Objectives: While medication abortion is effective and safe, many patients do not complete clinical follow-up. The impact of loss to follow-up on understanding of medication abortion outcomes is not understood and has great clinical and policy relevance.

Methods: We examined abortion outcomes among telehealth abortion patients in 2021–2022. We defined follow-up groups based on whether patients reported outcomes to their provider (clinical follow-up), completed outcomes via survey outreach (research follow-up), or were lost to follow-up. We compared follow-up group characteristics, calculated effectiveness (abortions completed without further intervention) and safety (absence of serious adverse events), and assessed differences between follow-up groups using logistic regression.

Results: Among 1,600 patients, 62% were reached through clinical follow-up, 29% through research follow-up efforts, and 8% remained lost to follow-up. The lost to follow-up group was more likely to have had a prior abortion and less likely to be college-educated. Effectiveness (96.5% vs. 96.9%, Risk Difference [RD]: 0.4%, [95% CI: -1.8%, 2.6%]) and safety (99.0% vs. 99.2%, RD: 0.2%, [95% CI: -1.0%, 1.4%]) were similar between clinical and research follow-up groups.

Conclusions: After accounting for loss to follow-up, medication abortion remains highly safe and effective.

2.2 Introduction

In over 100 studies since its approval in the United States (U.S.) in 2000, medication abortion has been found to be extremely safe and effective.^{13, 21, 32} In the U.S., the regimen is typically provided until 77 days of pregnancy and most commonly involves the drugs mifepristone and misoprostol. Consistently, 95%–98% of medication abortions have been found to be complete without additional intervention, and fewer than 1% involve a serious adverse event.^{13, 21, 32}

However, the effectiveness and safety of medication abortion remain contested in the policy arena. The 2024 U.S. Supreme Court case *Alliance for Hippocratic Medicine vs. Food and Drug Administration* questioned the continued availability of medication abortion based on purported concerns about its safety.²⁸ While the Supreme Court dismissed this case in June 2024, the decision did not prevent future restrictions on the availability of medication abortion, and some states have begun to classify abortion medications as controlled dangerous substances.³³

In the U.S., most abortion providers require medication abortion patients to complete follow-up interactions over several weeks after obtaining abortion medications. Follow-up protocols commonly include remote interactions to report an assessment of symptoms of a complete abortion one week after taking the medications and a home urine pregnancy test 2–4 weeks after taking the medications.⁹ The primary purpose of follow-up is to monitor for serious adverse events or the need for additional intervention to complete the abortion, such as additional medications or an aspiration procedure.^{16, 34} However, typically, up to 50% of medication abortion patients do not complete follow-up.^{12, 35–38} This loss to follow-up may be attributed to abortion stigma or a preference for greater privacy.^{39–41} Some experts posit that loss to follow-up can be attributed to the high effectiveness and safety of the medication abortion regimen, wherein patients who do not

experience complications may not feel obligated to re-contact their provider.³⁴ After 12 states have banned abortion completely,⁴² the digital trace involved with completing follow-up may pose risk of criminalization to patients residing in those states.

In 2020, direct-to-patient telehealth abortion became available on a wide scale for the first time within the U.S. healthcare system.⁴³ Telehealth abortion now constitutes 20% of U.S. abortions.¹¹ With telehealth abortion, patients first complete remote screening for medical eligibility with a licensed provider and then receive abortion medications by mail. Patients then administer the medications, pass the pregnancy, and complete remote follow-up from home or another location.⁹ Some evidence suggests that loss to follow-up may be higher after telehealth than after in-clinic care.^{2, 44}

To date, nearly all analyses of medication abortion safety and effectiveness do not engage with the potential selection effect of loss to follow-up; thus, estimates of these outcomes could be biased. Existing studies may overestimate medication abortion effectiveness and safety if lost-to-follow-up patients experience more complications than those who complete abortion follow-up. Alternatively, studies may underestimate these outcomes if patients who are lost to follow-up experience fewer complications than those who do complete follow-up. However, limited evidence suggests that loss to follow-up after medication abortion may not substantially impact research on these outcomes.^{24, 45} A 2015 study leveraging Medicaid claims data from California, which by design had no loss to follow-up, found that medication abortion safety was similar to estimates found in studies with loss to follow-up.²⁴ However, this study did not examine effectiveness and did not reflect more recent changes to the FDA protocol expanding its gestational limit or changes to the abortion environment, including the introduction of telehealth for abortion.^{46, 47}

Therefore, this study aims to examine the abortion outcomes of medication abortion patients who were difficult to reach for follow-up and evaluate whether they differ from those who initially completed follow-up.

2.3 Methods

2.3.1 Data Source

For this study, we used data from the California Home Abortion by Telehealth (CHAT) Study. Data were collected in 2021–2022 from patients of 3 virtual clinics (telehealth-only abortion providers) who were mailed medications in 20 U.S. states and Washington, D.C. The CHAT Study included two data sources: electronic medical record data and linked survey responses. We collected anonymized electronic medical record data for consecutive abortions from April 2021–January 2022. A subset of these patients (32% of invited participants) enrolled in a series of 3 surveys and were included in the sample for this study. The first survey was conducted at the time of their abortion intake, the second after 3-7 days, and the final survey after 4 weeks. The first survey collected participant background information, including sociodemographic characteristics, abortion characteristics, and obstetric history. Both follow-up surveys assessed adverse events using standard questions asked in clinical follow-up (i.e., receipt of any medical care or treatments after taking abortion medications), and participants received \$50 after completing all 3 surveys. The sample for this study was comprised of the survey participants.

2.3.2 Measures

We classified participants into 1 of 3 follow-up groups. The "clinical follow-up" group completed clinical follow-up to report abortion outcome information to the virtual clinic. We defined clinical

follow-up as having any of the following documented in the electronic medical record data: a complete abortion determined by the virtual clinic provider with at least 28 days of follow-up, a continuing pregnancy, a treatment to complete the abortion, or a serious adverse event. We used this definition to emulate the group whose outcomes clinicians would observe without further research outreach. The “research follow-up” group did not complete clinical follow-up but did complete a follow-up survey at least 28 days after abortion intake to report abortion outcomes. We also included patients in the research follow-up group if they completed clinical abortion follow-up but reported a continuing pregnancy, treatment to complete the abortion, or serious adverse event in the survey data but not the electronic medical record data. The final group was “lost to follow-up,” having never completed clinical or survey follow-up.

The abortion outcomes of interest for this study were composite measures of abortion effectiveness and safety.³ Abortion effectiveness was defined as the proportion of abortions that were complete without additional intervention (defined as >200 mg mifepristone, >1,600 mcg misoprostol, other uterotonic medication to complete the abortion, aspiration, other procedure, or treatment for ectopic pregnancy) or without a suspected or confirmed continuing pregnancy. Safety was estimated using the proportion of abortions that were not followed by an abortion-related major adverse event (overnight hospitalization, blood transfusion, or major surgery).

2.3.3 Analysis

We compared the distribution of participant characteristics by follow-up group using Fisher’s exact tests. We also used Fisher’s exact tests to compare differences in patients’ reasons for using telehealth reported in the baseline survey by their follow-up group.

We calculated effectiveness and safety using two approaches. We conducted a “naïve” complete

case analysis using only data from the clinical follow-up group. Then, we incorporated the outcomes of the research follow-up group (“informed” analysis), using multiple imputation by chained equations with 200 replications to impute missing covariate data and outcome data for the lost to follow-up group. Imputation models included pre-treatment participant and abortion characteristics, including patient characteristics, obstetric history, abortion characteristics, and two reported reasons for using telehealth (privacy and cost). We used inverse-probability-of-treatment weighted logistic regression to calculate risk differences in effectiveness and safety outcomes between the standard and research follow-up groups after imputing missing covariate data and outcome data for the lost to follow-up group.¹⁷ From each logistic regression, we used marginal estimates to calculate estimated proportions of effectiveness and safety outcomes.⁴⁸ Analyses were conducted using Stata version 18.0 (College Station, TX).

We adjusted our logistic regression models for participant and abortion characteristics measured from the baseline survey that we theorized to be associated with both the follow-up group and abortion outcomes. These factors included categorical measures of participant age; pregnancy duration determined by the first date of the participant’s last menstrual period or screening ultrasonography; urban, suburban, or rural residence; educational attainment; financial support for the abortion; participant race or ethnicity; and providing virtual clinic. We also included binary measures reflecting any prior births and any prior abortions.

2.3.4 Sensitivity analyses

To assess the robustness of our primary analysis of differential abortion outcomes in the lost-to-follow-up group, we used pattern-mixture modeling. This technique simulates results across scenarios of abortion outcomes among participants who were lost to follow-up to examine the

potential impact of the remaining loss to follow-up on the overall effectiveness and safety estimates.

The study was approved by the University of California, San Francisco institutional review board (20-32951).

2.4 Results

Results Our initial sample included 1,632 participants who were dispensed medications and enrolled in the study surveys. After excluding 32 participants who ultimately did not take their prescribed abortion medications, our analytic sample included 1,600 participants. Across the sample, 999 (62%) participants completed the final survey without receiving reminders and were in the clinical follow-up group. An additional 463 participants (29%) were reached through survey outreach, among whom 9 (2% of the research follow-up group) completed clinical follow-up but reported a complication in the survey data that was not documented in the electronic medical record data. Finally, the 135 (8%) participants who never completed clinical follow-up or the final survey comprised the lost follow-up group.

We examined differences in the distribution of follow-up groups by participant and abortion characteristics (**Table 2.1**), finding that participants who had a prior abortion and those who had completed less education were more likely to be lost to follow-up. We also noted variations in follow-up between the providing clinics. When we examined participants' reasons for using telehealth, we found that participants who used telehealth because they liked the mission of the virtual clinic, wanted a more private abortion experience, wanted to have an abortion as soon as possible, were more comfortable at home, and because they wanted to avoid protestors were less likely to be lost to follow-up (**Figure S2.1**). Participants who used telehealth because they were unsure where else

to get an abortion or because they had COVID-19-related concerns were more to be reached in clinical follow-up.

We used two approaches to examine the impact of including participants who were difficult to reach to ascertain their abortion outcomes (**Table 2.2**). Among the clinical follow-up group, “naïve” unadjusted complete case estimates were 96.5% for effectiveness and 99.1% for safety. After incorporating outcomes from both the standard and research follow-up groups and imputing missing outcomes for the lost to follow-up group, effectiveness was 96.7%, and safety was 99.1%

We compared the effectiveness and safety between the two follow-up groups in imputed, inverse-probability of-treatment weighted logistic regression models (**Table 2.2**). We found lower but not significantly different estimates of effectiveness (96.5% vs. 96.9%, adjusted Risk Difference [aRD]: 0.41% [95% CI: -1.8%, 2.6%]) and safety (99.0% vs. 99.2%, aRD: 0.20% [95% CI: -1.0%, 1.4%]) between the standard and research follow-up groups.

Using pattern-mixture modeling to assess the robustness of our findings to different outcome patterns among the 8% of participants who were lost to follow-up (**Figure S2.2**), we found that our results would be robust to a variety of scenarios of outcomes among the lost to follow-up group. Even under an extreme scenario in which the odds of complications were 10 times higher in the lost-to-follow-up group, across the sample, abortion effectiveness would be 94.9%, and safety would be 98.7%.

2.5 Discussion

Since medication abortion care has been available, questions have persisted about the outcomes of abortion patients who do not return to the clinic for follow-up. This study suggests that the

outcomes of patients who do not complete medication abortion follow-up are similar to patients who do complete follow-up. These results are consistent with the published literature on medication abortion effectiveness and safety, including a large study leveraging claims data with no loss to follow-up,²⁴ and with a bias analysis examining the effectiveness of self-managed medication abortion.⁴⁹ Taken together, our results suggest that existing research examining the effectiveness and safety of the abortion regimen is likely largely unbiased.

We found patterns in the characteristics of patients who do and do not complete follow-up. Patients who had lower levels of education and those who had a prior abortion were less likely to complete follow-up, findings that are consistent with prior studies on this topic.⁴⁵ Patients who had had prior abortions may feel more comfortable self-assessing their abortion outcomes. Meanwhile, those who have completed less education may have lower levels of digital connectedness or may have more competing demands on their time that make completing follow-up challenging.

In examining differences in follow-up by patients' reported reasons for using telehealth, we found that patients whose reasons suggested a preference for the telehealth model (e.g., preference for more privacy, liking the virtual clinic mission, being more comfortable at home, and avoiding protesters) were more likely to complete follow-up. Meanwhile, those who reported reasons that suggested limited access to in-clinic abortion (e.g., uncertainty about where to get an abortion) were less likely to follow up. These results highlight factors that can shape patients' tendency to follow up, which may include whether the abortion care they received aligned with their preferences. However, we found that these differences in patient and abortion characteristics did not translate into different abortion outcomes among patients who are difficult to reach for follow-up.

Now that abortion is banned in 12 states and severely restricted in more, patients obtaining medica-

tion abortion care who reside in states with bans may be less likely to complete abortion follow-up due to risk of criminalization. Given these considerations, providers should customize follow-up protocols to meet the needs of their patients. Clinicians should also consider the merits of a shift to models that rely on patients' self-screening for concerning outcomes, which has been shown to have predictive validity^{30, 50} and may be preferable for some patients. As of 2024, the National Abortion Federation medication abortion guidelines now recommend offering but not requiring routine follow-up and also endorse patient self-assessment of completion.¹⁶

This study has several limitations. The sample used in this study was relatively small considering the rare nature of adverse events after medication abortion. There is a possibility that small cell sizes are obscuring differences that would be observable in a larger sample. However, the differences in effectiveness between patients who did and did not complete clinical follow-up that we detected were extremely small in magnitude and are unlikely to be clinically significant. Some characteristics that were not captured in this data may differ between the clinical and research follow-up groups, such as patients' propensity to seek medical care. The factors that drive loss to follow-up in these telehealth abortion models may differ from 1) models that require patients to return to the clinic physically and 2) contexts where abortion is restricted. Therefore, the generalizability of these findings to those settings may be limited.

In recent years, efforts to restrict access to abortion, and medication abortion specifically, have intensified. Legal threats to medication abortion are often based on safety concerns. This analysis leverages robust statistical and epidemiologic methods to examine the abortion outcomes of patients who do not complete abortion follow-up. This study also sheds light on the outcomes of patients often overlooked by traditional data collection and analytic approaches. It demonstrates that medication abortion is likely as effective and safe as the prior literature suggests.

2.6 Tables

Table S1.1. Sample description overall and by follow-up group

N	Overall 1,600 Column %	Clinical follow-up 999 Row %	Research follow-up 463 Row %	Lost to follow-up 135 Row %	p-value ^a
Patient age at abortion intake			Row %		
<25 years	28%	65%	26%	9%	0.49
25-29 years	26%	59%	32%	9%	
30-34 years	25%	61%	31%	8%	
>34 years	20%	65%	26%	8%	
Pregnancy duration at abortion intake					
<35 days	29%	65%	29%	7%	0.41
35 - 49 days	55%	62%	30%	9%	
50 - 62 days	14%	61%	28%	11%	
63 - 70 days	2%	69%	19%	12%	
Residence					
Suburban or Rural	9%	61%	29%	10%	0.80
Urban	91%	63%	29%	8%	
Race or ethnicity					
Non-Hispanic white	53%	64%	28%	9%	0.40
Non-Hispanic Black or African American	9%	57%	37%	6%	
Hispanic or Latinx	13%	66%	24%	10%	
American Indian, Alaska Native, Middle Eastern, North African, or Multiracial	15%	59%	33%	8%	
Asian, Native Hawaiian, or Pacific Islander	7%	67%	24%	10%	
Unknown	4%	59%	35%	6%	
Any financial support from abortion fund					
No	78%	62%	29%	8%	0.84
Yes	22%	63%	28%	9%	
Had confirmatory pre-abortion ultrasonography					
No pre-abortion ultrasonography	89%	63%	29%	8%	1.00
Had pre-abortion ultrasonography	11%	62%	29%	9%	
Prior abortion					
No prior abortion	60%	66%	27%	7%	0.01
1 or more prior abortions	40%	58%	31%	10%	
Unknown	0%	100%	0%	0%	
Prior births					
No	50%	66%	26%	8%	0.08
Yes	35%	59%	32%	9%	
Unknown	14%	61%	31%	8%	
Education level					
High school or less	17%	58%	30%	12%	0.02
Some college, some technical school, or associate’s degree	41%	61%	30%	9%	
Completed 4-year degree or more	42%	66%	27%	7%	
Clinic					
Clinic A	34%	51%	41%	8%	<0.01
Clinic B	34%	76%	9%	14%	
Clinic C	31%	60%	37%	3%	

^a – p-values calculated from Fisher's exact tests

Table S1.2. Comparison of uninformed and informed analytic strategies examining medication abortion effectiveness and safety.

		Analysis	Estimated Proportion (95% CI)
Overall ^a			
Effectiveness		Naïve (n=999)	96.5 (95.4, 97.6)
		Informed (n=1,600)	96.7 (95.7, 97.6)
Safety		Naïve (n=999)	99.1 (98.5, 99.7)
		Informed (n=1,600)	99.1 (98.6, 99.6)
Comparison ^b			
Effectiveness	Clinical follow-up group (n=999)		96.8 (95.7, 97.9)
	Research follow-up group (n=466)		96.3 (93.3, 98.3)
	Risk difference		-0.48 (-2.8, 1.8)
Safety	Clinical follow-up group (n=999)		99.0 (98.3, 99.6)
	Research follow-up group (n=466)		99.2 (98.2, 100.0)
	Risk difference		0.20 (-1.0, 1.4)

^a - Estimated proportions and corresponding 95% confidence intervals (CI) for the overall sample are marginal estimates drawn from unadjusted logistic regression models.

^b - Estimated proportions and corresponding 95% CIs for comparisons are marginal estimates drawn from logistic regression models with inverse-probability-of-treatment weights. Imputation models included patient age, pregnancy duration, whether the patient had a screening ultrasound, providing clinic, abortion funding, urban residence, model of telehealth care, and reasons for using telehealth abortion.

2.7 Figures

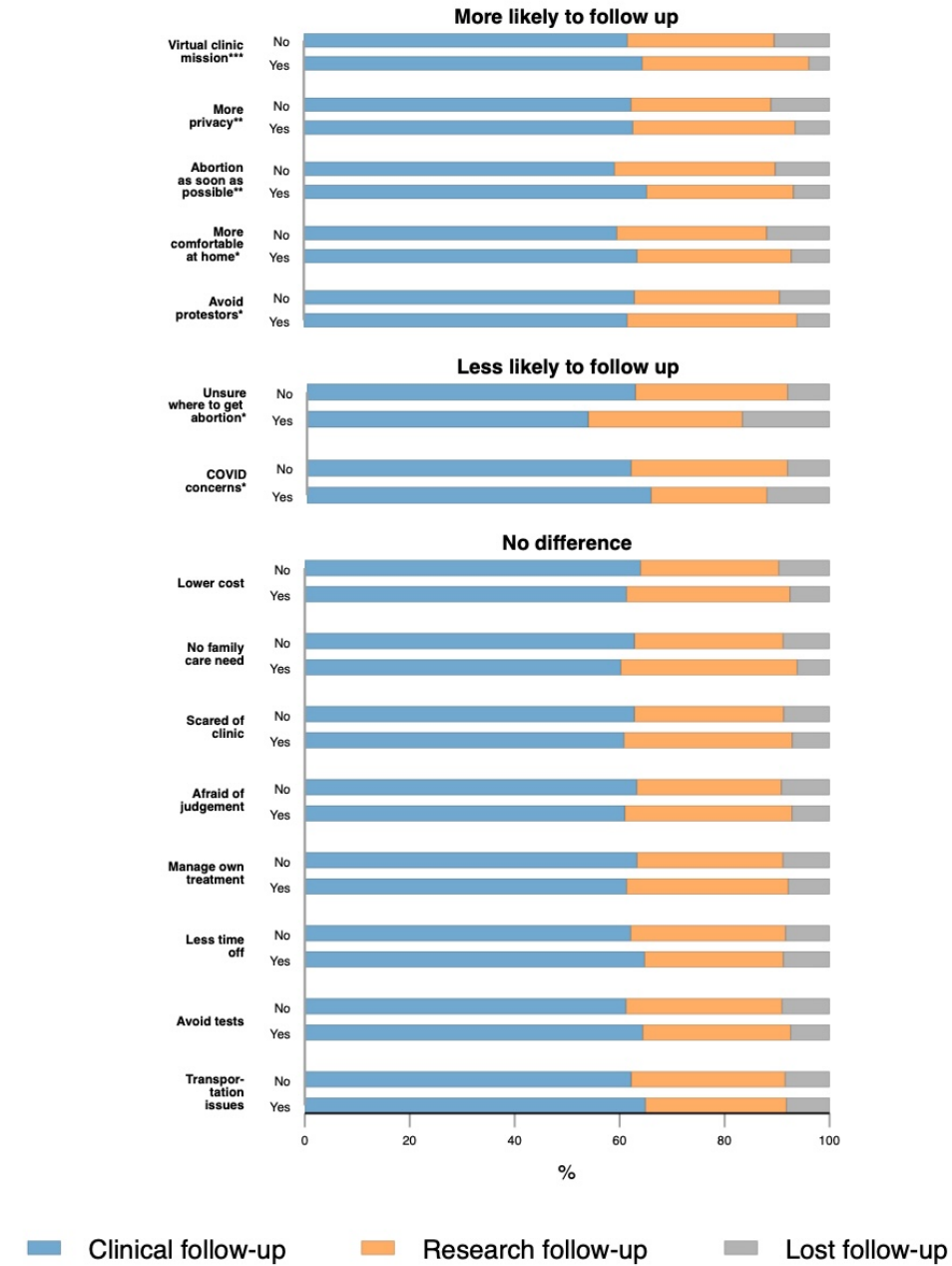


Figure S2.1. Distribution of reasons for using telehealth for abortion by follow-up group (n=1,600)

2.8 Supplementary Material

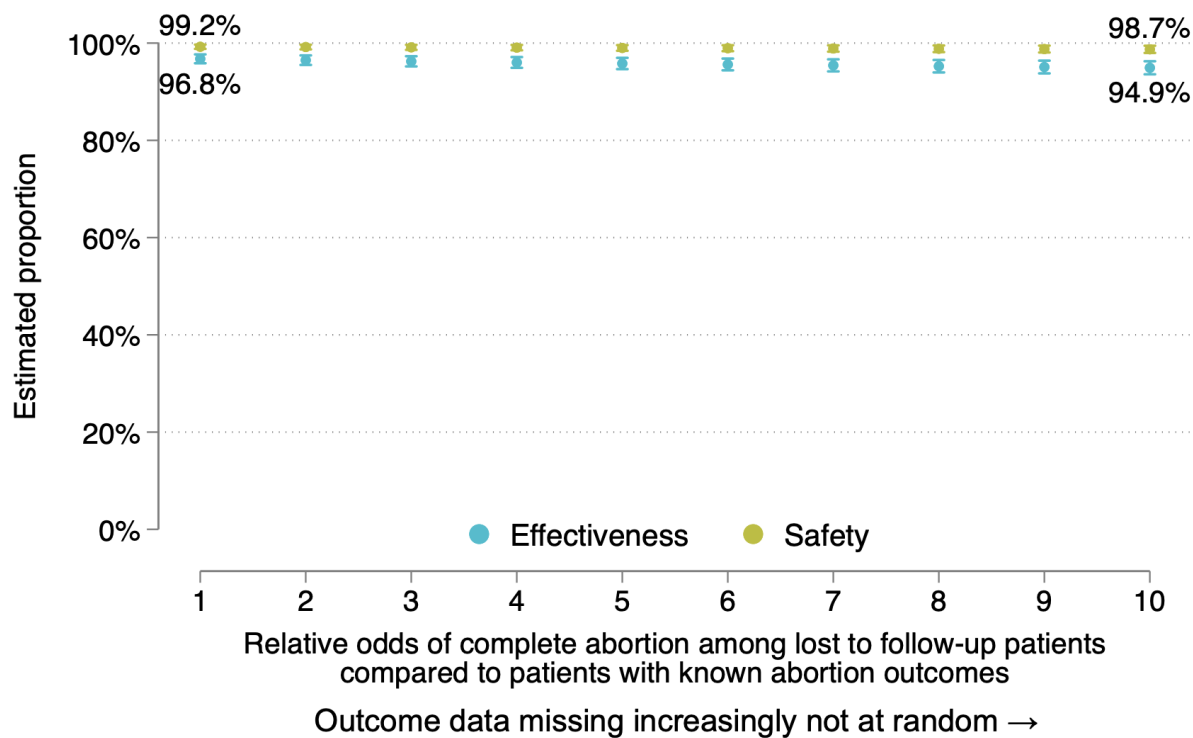


Figure S2.2. Pattern Mixture-Modeling Analyses Examining Missing-Not-At-Random Outcome Scenarios (n=1,600)

Chapter 3: Processes of follow-up care and adverse event diagnoses after telehealth abortion: a cohort study, 2021-2022

3.1 Abstract

Introduction: Telehealth abortion has expanded; however, little is known about how telehealth patients obtain follow-up care. We described patients' follow-up trajectories. Among patients treated for adverse events, we aimed to describe the timing and processes of diagnoses and treatment.

Methods: We analyzed data from a cohort of virtual clinic telehealth abortion patients in 2021–2022. We categorized follow-up trajectories based on whether patients obtained treatment or in-person care. Among patients who received additional treatment to complete the abortion or a serious adverse event, we described whether concerns were first raised during or outside of scheduled follow-up and the time to treatment.

Results: Among 4,613 abortions with follow-up contact, 82% (n=3797) required no follow-up care or treatment, 12% (n=558) obtained remote follow-up care, and 5% (n= 247) had any in-person follow-up care. Overall, 2% (n=87) of abortions involved additional treatment, among which concerns were first raised during scheduled follow-up visits in 26% (n=23). The median time from mifepristone administration to treatment was 23 days (Interquartile Range: 12, 31); however, this interval ranged widely (1–93 days).

Conclusions: Most telehealth abortion patients do not seek either remote or in-person follow-up

care. When adverse events occur, most patients initiate follow-up care to raise concerns and obtain treatment expeditiously. While these results suggest that many patients do not require routine follow-up, some may prefer the reassurance of scheduled interactions. Instead of routine follow-up, providers should consider adopting flexible, patient-led follow-up protocols, which may be more patient-centered, cost-effective, and carry less criminal risk for patients in states with abortion bans.

3.2 Introduction

Telehealth abortion care first became widely available in the United States (U.S.) after regulatory changes in 2020–2021 first allowed patients to obtain abortion medications from a clinician without traveling to a clinic. This abortion model involves virtual consultations with a clinician to assess medical eligibility and dispensing of the abortion medications, typically mifepristone and misoprostol, by mail. After the medications are delivered, the patient administers the medications, passes the pregnancy, and completes routine follow-up interactions remotely. Since 2020, new virtual clinics that provide telehealth without brick-and-mortar medical facilities have opened and expanded.^{26, 51} This model of care now accounts for 1 in 5 abortions within the U.S. healthcare system.¹¹

Medication abortion care is extremely safe and effective, with research demonstrating that 2–5% of patients typically require treatment beyond the initially prescribed medications to complete the abortion, and <1% experience a serious adverse event.^{13, 21, 24, 32} After medication abortion, patients who do not experience adverse events may have uncertainty about the symptoms they experience,^{52, 53} and some prefer the definitiveness of an in-clinic ultrasound or blood test to confirm they have passed the pregnancy.^{6, 54} After a complete medication abortion, home urine

pregnancy tests can still show positive results for several weeks due to lingering elevated levels of beta human chorionic gonadotropin (β -hCG) in the urine.⁵⁵ Therefore, patients may also seek in-person follow-up care to confirm the result of a home urine pregnancy test. Typically, 2-5% of medication abortion patients visit an emergency department for abortion-related reasons after their medication abortion,^{2, 4, 24, 25} and about half of these visits do not involve any treatment.⁵⁶ However, to date, research investigating follow-up visits after medication abortion has focused primarily on emergency department visits and draws from a period when medication abortion care protocols required patients to return physically to a clinic.

Given that telehealth abortion is newly available on a wide scale in the U.S., little is known about patients' processes of obtaining follow-up care after virtual clinic telehealth abortion care when there is no brick-and-mortar facility for patients to go to. In addition, there is limited research that explores how adverse events are identified, diagnosed, and treated in this newer abortion care model, and the degree to which virtual clinic providers are involved in this follow-up care. In a previous paper, we reported the safety and effectiveness of telehealth abortion among these data.³ This study aims to provide an in-depth analysis of patients' patterns of seeking follow-up care after telehealth abortion using data from a cohort who obtained telehealth abortion in 2021-2022. Among the subset of patients who obtained treatment for an adverse event after telehealth abortion, we also sought to document the timing and process of diagnoses and treatment.

3.3 Methods

3.3.1 Data Source

We used data from the California Home Abortion by Telehealth (CHAT) Study, a cohort study of telehealth abortions in 2021-2022. Participants in the CHAT Study included patients who obtained medication abortion care from one of 3 virtual clinics, and medications were mailed to 20 states and Washington, D.C.

In the participating clinic's telehealth abortion protocols, patients underwent screening based on self-reported medical history and were referred for ultrasonography to verify medical eligibility if needed. If eligible, patients were mailed medications from a mail-order pharmacy. Subsequently, virtual clinic staff conducted two remote scheduled follow-up interactions; the first within a week of medication dispensing to confirm medication administration and screen for abnormal symptoms, and the second at about 4 weeks to collect results of a home urine pregnancy test. During each scheduled follow-up, virtual clinic staff collected information about subsequent in-person care received. Patients were also able to contact the virtual clinic with questions at any time during the follow-up period by text, email or phone.

CHAT Study data included anonymized electronic health record data for patients served from April 2021–January 2022, comprised of both structured fields and clinical notes. This data included structured fields for patient and abortion characteristics, the locations of follow-up care, and interventions provided beyond initial treatment. We used regular expression processing and manual review to extract the timing and process of adverse events from the clinical note fields. For these variables (process and timing of adverse event diagnoses), two authors (L.R.K. and L.P.)

independently coded outcomes.

All patients of the virtual clinics served between June 2021 and January 2022 were invited to participate in a series of 3 surveys, which were administered directly after abortion intake, at 1 week, and at 4 weeks. The two follow-up surveys collected information about follow-up care and treatments obtained. In total, 32% of invited patients enrolled in the surveys. We supplemented reports of treatments provided and of timing, location, and dates of follow-up care from linked survey data for a subset of 1,600 patients to include all available information about follow-up care.

3.3.2 Measures

Follow-up care trajectories

We followed published criteria to classify post-abortion incidents and treatments.¹⁹ We examined electronic health record data and survey responses to classify all cases with any follow-up contact after medications were dispensed into follow-up trajectories. Among abortion with follow-up consultation or treatment from the virtual clinic but no in-clinic care, we grouped abortions into 4 groups: 1) Complete abortions with no follow-up consultation or care, 2) those with follow-up care or reassurance from the virtual clinic, without any treatment provided, 3) abortions managed with over-the-counter treatment or additional doses of the initially dispensed misoprostol, 4) additional medications prescribed or dispensed. Among the remaining sample with any in-person follow-up care, we classified abortions into 4 groups: 1) in-person visits without treatment (“observation only”), 2) treatment provided with no intervention to complete the abortion or serious adverse event, 3) confirmed continuing pregnancies without further documented treatment, or 4) those involving an intervention to complete the abortion or serious adverse event.

Treatments

We defined treatments as any medication prescribed or intervention performed after administration of the initial medication abortion regimen, including additional mifepristone, misoprostol, or other uterotonic medications to complete the abortion; aspiration or other abortion procedure; treatment for ectopic pregnancy; surgery; blood transfusion; intravenous fluids; antibiotics; or pain medication.

Adverse events

We defined adverse events as either interventions to complete the abortion or to treat serious adverse events. We considered abortions to involve interventions to complete the abortion as those with prescription of ≥ 200 mg mifepristone, prescription of $\geq 1,600$ mcg misoprostol, prescription of other uterotonic medications, aspiration or another abortion procedure, or treatment for ectopic pregnancy. We defined serious adverse events as surgery, hospitalization, or blood transfusion.

Location of in-person follow-up visits

We examined all in-person follow-up visits reported in either the electronic health record data or in the surveys. Among these visits, we classified the location of each follow-up visit as occurring at 1) a primary care provider or obstetrician-gynecologist (OBGYN), 2) an emergency department or hospital, 3) an abortion clinic, 4) an urgent care center, 5) an imaging center, or 6) an unknown facility type.

Reasons for in-person follow-up visits

Among in-person visits, we classified reasons for in-person visits into the following categories: 1) to confirm the abortion outcome, 2) to initiate contraception, 3) for reasons unrelated to the abortion, 4) for heavy or prolonged bleeding, 5) due to a positive pregnancy test, 6) for ongoing pregnancy symptoms, 7) for concerns related to an infection, 8) for severe or prolonged pain, 9) for concerns related to ectopic pregnancy, 10) syncope, 11) to obtain Rhesus Immunoglobulin, and 12) for severe or prolonged vomiting. We allowed multiple reasons to apply to each abortion to reflect that some abortions involved multiple in-person follow-up visits, and some visits were motivated by multiple reasons.

Process of adverse event identification

Among the abortions that involved any additional treatment provided by the virtual clinic or in-person care, we examined the proportion with concerns first raised during vs. outside of scheduled follow-up with the telehealth provider. Patients were classified as having adverse events with concerns first raised outside of scheduled follow-up if the patient initiated contact with the provider to report a concern or sought in-person care without first consulting the telehealth provider.

Timing of adverse event identification

Among the abortions that involved additional in-person treatments for adverse events, we examined the timing of abortion complications by identifying the following dates: 1) the date of mifepristone administration, 2) the date of the first documented concern about a potential adverse event, 3)

the date of diagnosis of the complication, and 4) the date of treatment. We imputed missing date values using the midpoint of the plausible interval of events and used these dates to calculate three intervals of interest: the number of days from mifepristone administration to first documented concern, the days from first documented concern to diagnosis, and the days from diagnosis to treatment.

3.3.3 Analysis

We used descriptive statistics, including frequencies and percentages, to describe follow-up care trajectories, locations of in-person follow-up care, and the process of adverse event identification (whether the first documented concern about an adverse event was in a scheduled follow-up interaction or outside of these interactions). Among the abortions that involved treatment to complete the abortion or for serious adverse events, we constructed and visualized sequences of the overall time to treatment and its component intervals. We then estimated the median duration and corresponding inter-quartile range for the overall and component intervals.

After imputing missing data using multiple imputation by chained equations, we conducted a series of bivariate logistic regression analyses to identify participant factors (age, race or ethnicity, urbanicity, pregnancy duration, and prior abortion) associated with obtaining in-person follow-up care. After describing the differences between the survey and clinical samples, we replicated this analysis in a sensitivity analysis among the survey participants to examine associations between a wider range of participant factors (listed above, as well as food insecurity and health insurance) and in person care.

All analyses were conducted with Stata MP version 18.0. Research activities were approved by the University of California, San Francisco Institutional Review Board (20-32951).

3.4 Results

Our original sample included 6,154 records for abortions provided by the participating clinics during the study period (**Figure 1**). After excluding 120 records in which the patient did not take the dispensed medications, our analytic sample included 6,034 abortions. Among this sample, 24% (n=1,421) of abortions had no contact after the abortion medications were dispensed, leaving 4,613 abortions with follow-up.

Across the analytic sample, patients on average were 29 years old and had pregnancy durations of 5 weeks and 5 days (**Table 1**). Most (90%) resided in urban areas, were White (41%), and did not have pre-abortion screening ultrasonography (92%). Among those with known abortion and birth history, most reported having no prior abortion (67%) and approximately half reported having no prior birth (52%). Compared to patients who did not enroll in additional research surveys (**Table 3.A1**), the survey sample was younger (29 vs. 30 years, $p<0.01$) and more likely to: be White (53% vs. 37%, $p<0.001$), have received abortion funding (22% vs. 13%, $p<0.001$), and to have obtained pre-abortion screening ultrasonography (11% vs. 7%, $p<0.001$). Among those with known obstetric history, survey participants were more likely to have had a prior abortion (40% vs. 30%, $p<0.001$) and less likely to have had a prior birth (41% vs. 51%, $p<0.001$).

Among abortions with any follow-up, 82% (n=3,796) had complete abortions without follow-up consultation or treatment outside of scheduled follow-up (**Figure 1**). Among the remaining 817 abortions with any additional follow-up consultation, 77% (n=627) obtained follow-up assurance or treatment from the virtual clinic without an in-person visit. Within this group, 62% (n=324) had a consultation or reassurance from the virtual clinic, 12% (n=68) were treated with an over-the-counter treatment or with more of the initially dispensed misoprostol, (n=9) were dispensed

additional medications, and 25% had an unknown abortion outcome (n=140). Among the 247 abortions that involved any in-person follow-up care, 53% (n=136) had in-person visits with no treatment, 18% (n=46) obtained treatment but did not experience an adverse event, 2% had a confirmed continuing pregnancy without further known intervention, and 29% (n=76) were treated for an adverse event.

We next examined the patient and abortion characteristics associated with obtaining any in-person follow-up care (**Figure 2**). Patients who obtained in-person follow-up care were largely similar to those who did not. However, patients who obtained pre-abortion ultrasonography were more likely to obtain in-person follow-up care (13% vs. 5%, $p<0.001$). When we examined the same associations among the survey subsample, we found that participants with lower pregnancy durations, those who did not obtain screening ultrasonography, and who were uninsured were less likely to obtain in-person follow-up care (**Figure 3.A1**).

When we describe the locations of in-person care, we found that 43% (n=110) of abortions with in-person follow-up care involved visits to a primary care provider or OBGYN, 32% (n=82) to an emergency department or hospital, 18% (n=47) to an abortion clinic. Fewer abortions involved visits to urgent care (4%, n=11) and imaging (2%, n=4) facilities (**Figure 3**). In addition, 19% of abortions with in-person visits involved visits to an unknown type of provider. The most common reason for seeking in-person care was to confirm the abortion outcome (33% of in-person visits, n=84), followed by concerns about prolonged or heavy bleeding (24%, n=62), and a positive pregnancy test (16%, n=41, **Figure 4**).

Among the 87 abortions that involved an adverse event, 74% (n=64) were first identified outside of scheduled follow-up interactions with the virtual clinic, either in interactions where patients

contacted the virtual clinic, or the patient sought follow-up care themselves. Overall, the median time from mifepristone administration to treatment was 23 days (Inter-quartile range [IQR]: 12, 31) (**Figure 5**). The median component interval lengths were 14 days (IQR: 6, 23) from mifepristone administration to report of first concern, 0 days (IQR: CI: 0, 8) from report of first concern to diagnosis, and 0 days (IQR: 0, 2) from diagnosis to treatment.

3.5 Discussion

While telehealth abortion has grown considerably since its introduction in the U.S., concerns remain that patients may lack access to necessary in-person clinical support during the process.^{20–22} In this study, we found that most (84%) virtual clinic telehealth abortion patients do not require any follow-up care, either from their virtual clinic or from an in-person provider. However, it is important that the small proportion of patients who do obtain in-person follow-up care have a safe and supportive source of in-person follow-up care. During the abortion intake process, telehealth providers should work with patients to identify a plan for obtaining in-person care, should the need arise. This is of particular importance for patients residing in states that restrict abortion access to minimize criminal risk.

We found that most in-person visits were not for emergency situations and, instead, most commonly, were for reassurance. Prior research has documented that 50% of emergency department visits do not involve any treatment.⁵⁶ This study contributes novel evidence to the question of follow-up care after medication abortion by evaluating a broader range of post-abortion visits, and by describing the reasons motivating these visits. Patients seek in-person care after telehealth abortion for a range of reasons, and a small proportion of these visits involve adverse events. We also found that 2% of the sample were treated with additional medications by the virtual clinic. This finding

aligns with evidence that medications are comparably effective to procedures in treating incomplete abortion, and highlights that some post-abortion concerns can be managed remotely by telehealth providers.⁵⁷

Among those who ultimately experienced an adverse event, most patients first raised a concern outside of a scheduled follow-up, suggesting that patients can commonly recognize adverse events outside of the structure of scheduled follow-up visits. These findings suggest that this patient population may benefit from a shift towards more flexible follow-up protocols. Nearly 20 years ago, procedural abortion follow-up protocols shifted from a universal routine follow-up visit with ultrasound to a less involved follow-up model, with patients contacting providers as needed with any concerning symptoms.⁵⁸ These shifts were driven by evidence and justified by low rates of adverse events, a reduction in costs, and providers' confidence in the ability of patients to identify circumstances in which they require additional care. Routine medication abortion follow-up is no longer universally required in abortion care guidelines,³⁴ can lead to unnecessary tests and interventions,⁵⁹ and may not be patient-centered for those who prefer to self-assess symptoms.⁵⁴

We found that the characteristics of patients who obtained in-person follow-up care were largely similar to patients who did not obtain follow-up care. However, patients who obtained in-person follow-up care were more likely to have obtained pre-abortion ultrasonography. This may indicate that patients have an existing relationship with a healthcare provider. Alternatively, this finding may highlight a tendency towards health-seeking behavior, as patients who are anxious about the abortion process or otherwise prefer the definitiveness of tests like ultrasonography may be more likely to seek both screening and follow-up in-person care to confirm completion. Additionally, White patients were more likely to have obtained in-person follow-up care than the overall sample, highlighting racial and ethnic inequities in access to healthcare.

Patients who obtained in-person follow-up care were most likely to visit their primary care provider or OBGYN. This finding may be explained by the relative advantage of this sample; virtual clinic telehealth abortion patients were more likely to be White and older compared to the general population of abortion patients.⁶⁰ Therefore, they may be more likely to have health insurance and to have an established relationship with a primary care provider or OBGYN. As virtual clinic telehealth abortion expands, more patients may not have a physical clinic location to return to. Primary care providers and OBGYNs who do not routinely provide medication abortion care may require additional training to evaluate and treat telehealth abortion patients to correctly identify adverse events and avoid unnecessary treatments. Telehealth abortion providers should be cognizant of additional costs that patients who seek in-person medical care may incur, and counsel patients accordingly during intake.

These findings demonstrate that adverse events after telehealth abortion are typically treated within about 3 weeks. The interval between medication administration and treatment appears to be driven by the time elapsed between mifepristone administration and the report of first concern (about 2 weeks). Once a concern is raised, patients typically obtain diagnoses and treatment quickly, often on the same day. However, the amount of time it took for adverse events to be treated ranged widely between patients, suggesting that there may not be universally optimal times for scheduling follow-up to identify adverse events.

A shift towards flexible medication abortion follow-up protocols would also introduce new challenges for researchers. Evidence from telehealth abortion care in other healthcare systems that involve follow-up only as needed has found comparable safety and effectiveness to models with routine follow-up care.¹ However, the U.S. health system is fragmented, leaving many abortion patients un- or under-insured or without a primary care provider.⁶¹ Loss to follow-up may increase with

the expansion of de-medicalized models of medication abortion care. Additionally, as telehealth abortion provision to patients residing in ban states increases,¹¹ the digital trace of completing abortion follow-up could pose risk of criminalization for some patients. Researchers should expand the use of strategies to address missing data, such as imputation and bias analysis, to examine the potential selection effect of lost to follow-up.

This study leverages a large, prospective dataset to provide an in-depth analysis of how patients obtain follow-up care and treatment after telehealth abortion. However, about one-quarter of the sample did not respond to the clinic after the abortion, which may have led to selection bias in our findings. Specifically, some patients may have opted not to re-contact the clinic if they were experiencing concerning symptoms and instead sought in-person care without notifying their virtual clinic provider. However, remote follow-up procedures are becoming more common, even for in-clinic medication abortion models, and these findings may be reflective of what providers are seeing among their medication abortion patients. In addition, the proportion of patients who did not participate in the routine follow-up contact also suggests that a sizable group prefer not to involve the virtual clinic in their follow-up, and instead prefer to self-assess their abortion outcome without involving the virtual clinic or visit an in-clinic provider if they think follow-up is needed. While we leveraged a large sample, adverse events were rare, resulting in a small sample within which to examine adverse events. In some cases, detailed information, particularly about the timing of various steps in the adverse event diagnosis process, was limited. We attempted to account for this by using the median of the plausible interval. However, this likely introduced some degree of misclassification into our description of these intervals, which we expect would be random.

3.5.1 Conclusion

This study demonstrates that most telehealth abortion patients do not seek either in-person or virtual follow-up care after a medication abortion. However, some patients may prefer the reassurance of routine follow-up interactions. These results suggest that providers should consider adopting a flexible, patient-led follow-up protocol, which may be more patient-centered, cost-effective, and carry lower criminal risk for patients residing in states with abortion bans who obtain telehealth abortion under shield laws.

3.6 Tables

Table S2.1. Sample patient and abortion characteristics

N		6,034 n (%)
Patient age at abortion intake	Mean $\pm$ SD, years	29.7 $\pm$ 6.5
	<25 years	1491 (24.7%)
	25-29 years	1505 (24.9%)
	30-34 years	1587 (26.3%)
	>34 years	1451 (24.0%)
Pregnancy duration at abortion intake	Mean $\pm$ SD, days	40 $\pm$ 9.4
	<35 days	1732 (28.7%)
	35 - 49 days	3356 (55.6%)
	50 - 62 days	820 (13.6%)
	63 - 70 days	122 (2.0%)
	Unknown	4 (0.1%)
Residence	Suburban or Rural	600 (9.9%)
	Urban	5434 (90.1%)
Race or ethnicity	American Indian, Alaska Native, Middle Eastern, North African, or Multiracial	450 (7.5%)
	Asian, Native Hawaiian, or Pacific Islander	271 (4.5%)
	Non-Hispanic Black or African American	413 (6.8%)
	Hispanic or Latinx	339 (5.6%)
	Non-Hispanic white	2491 (41.3%)
	Unknown	2070 (34.3%)
	No	5112 (84.7%)
Abortion funding	Yes	922 (15.3%)
Had confirmatory pre-abortion ultrasonography	No pre-abortion ultrasonography	5548 (91.9%)
	Had pre-abortion ultrasonography	486 (8.1%)
Prior abortion	No prior abortion	3053 (50.6%)
	Any prior abortions	1523 (25.2%)
	Unknown	1458 (24.2%)
Prior births	No prior birth	2325 (38.5%)
	Any prior births	2144 (35.5%)
	Unknown	1565 (25.9%)

3.7 Figures

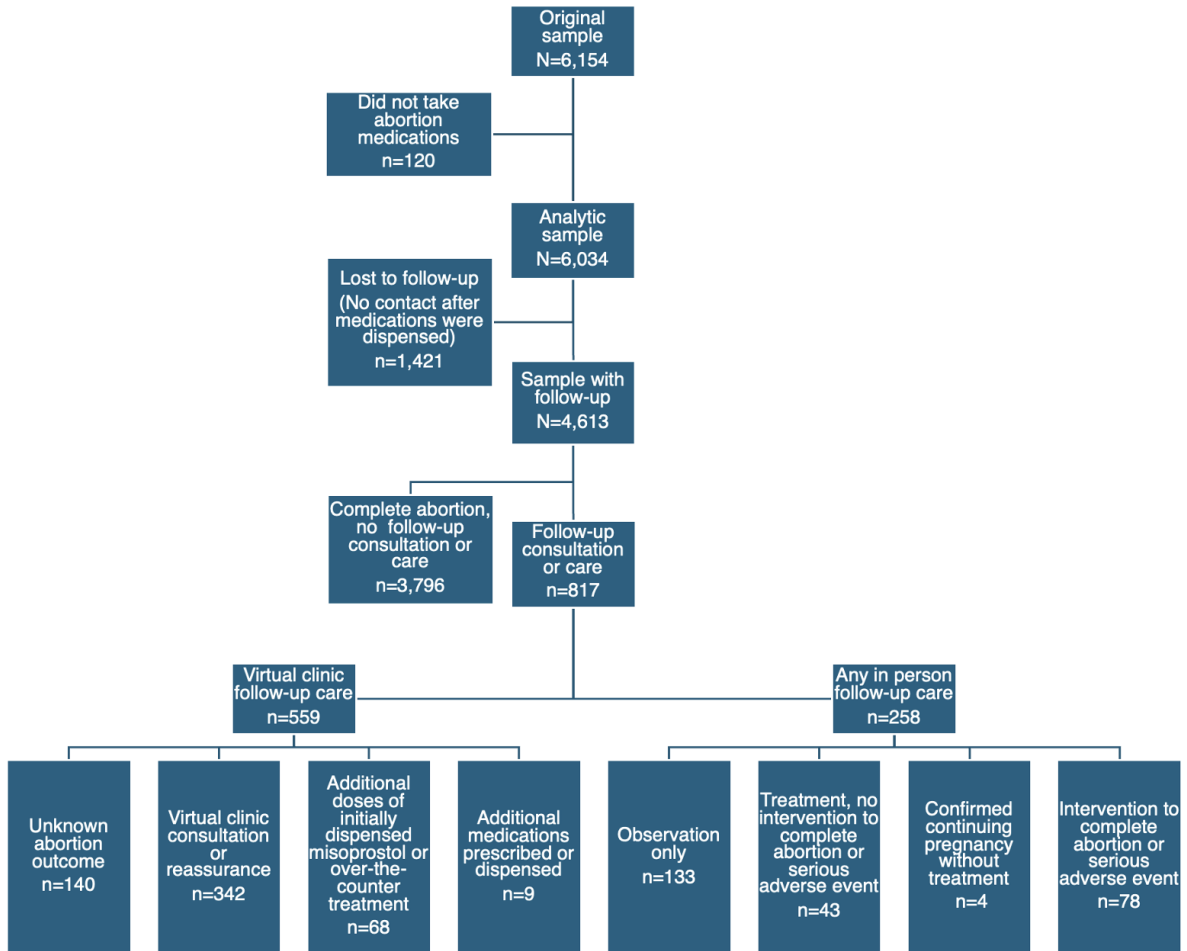


Figure 3.1. Follow-up trajectories after telehealth abortion

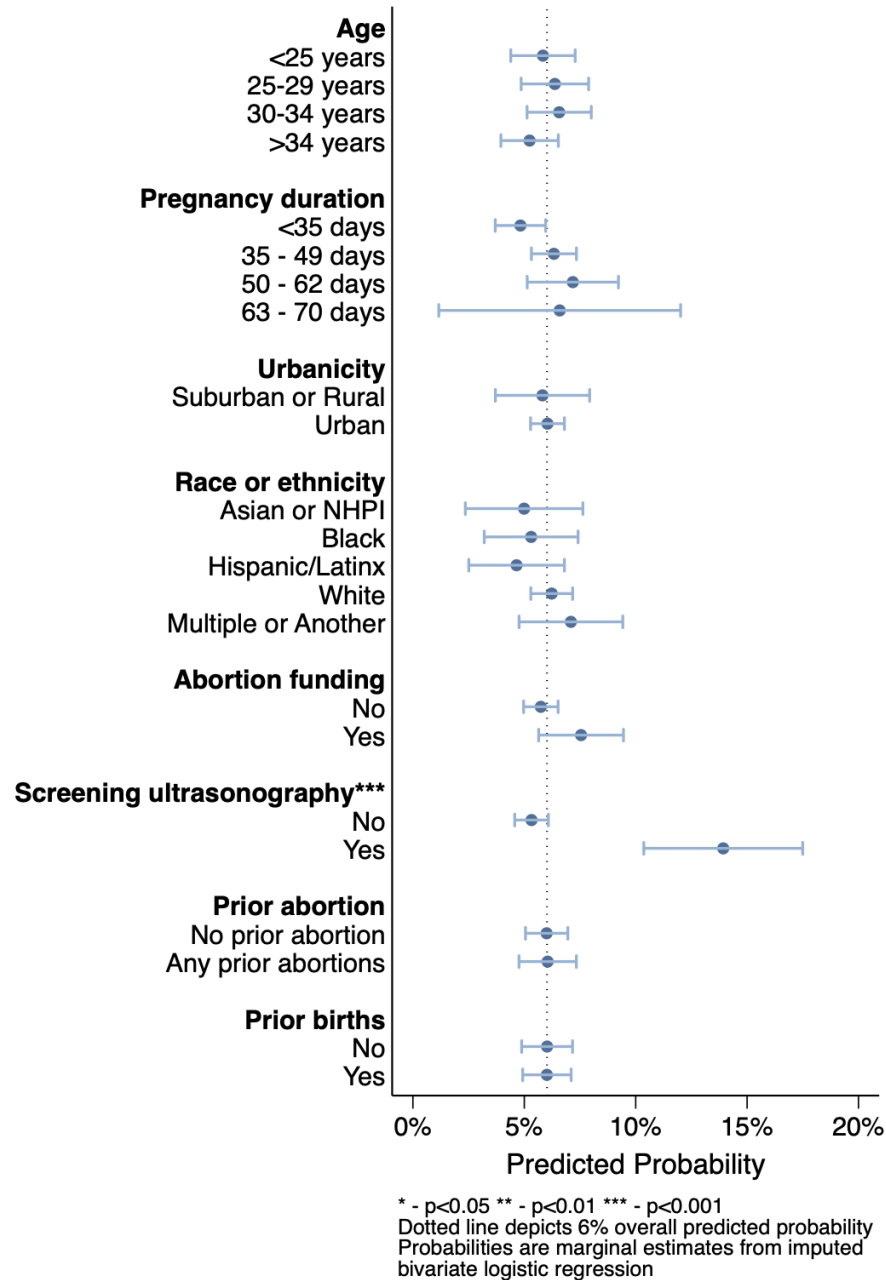
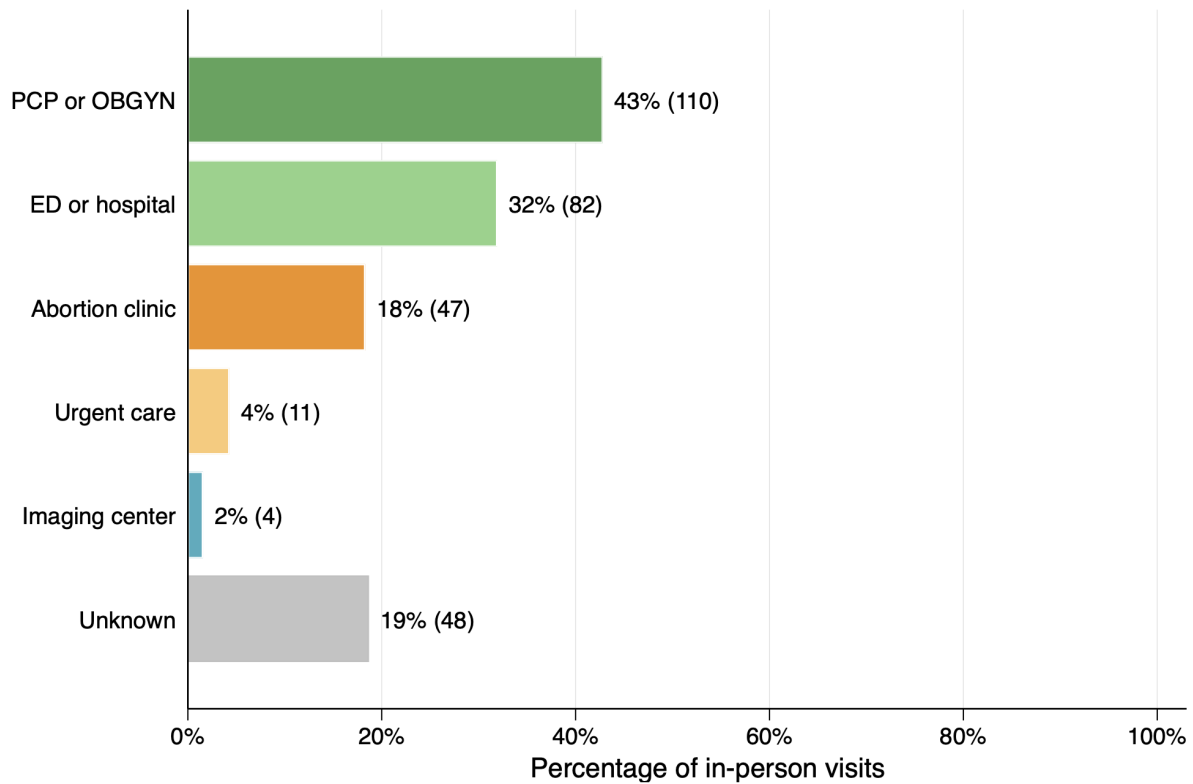


Figure 3.2. Factors associated with obtaining in-person follow-up care after telehealth abortion (n=6,034)



*note: some patients had >1 visit, locations are not mutually exclusive

Figure 3.3. Locations of in-person visits after telehealth abortion (n=257)

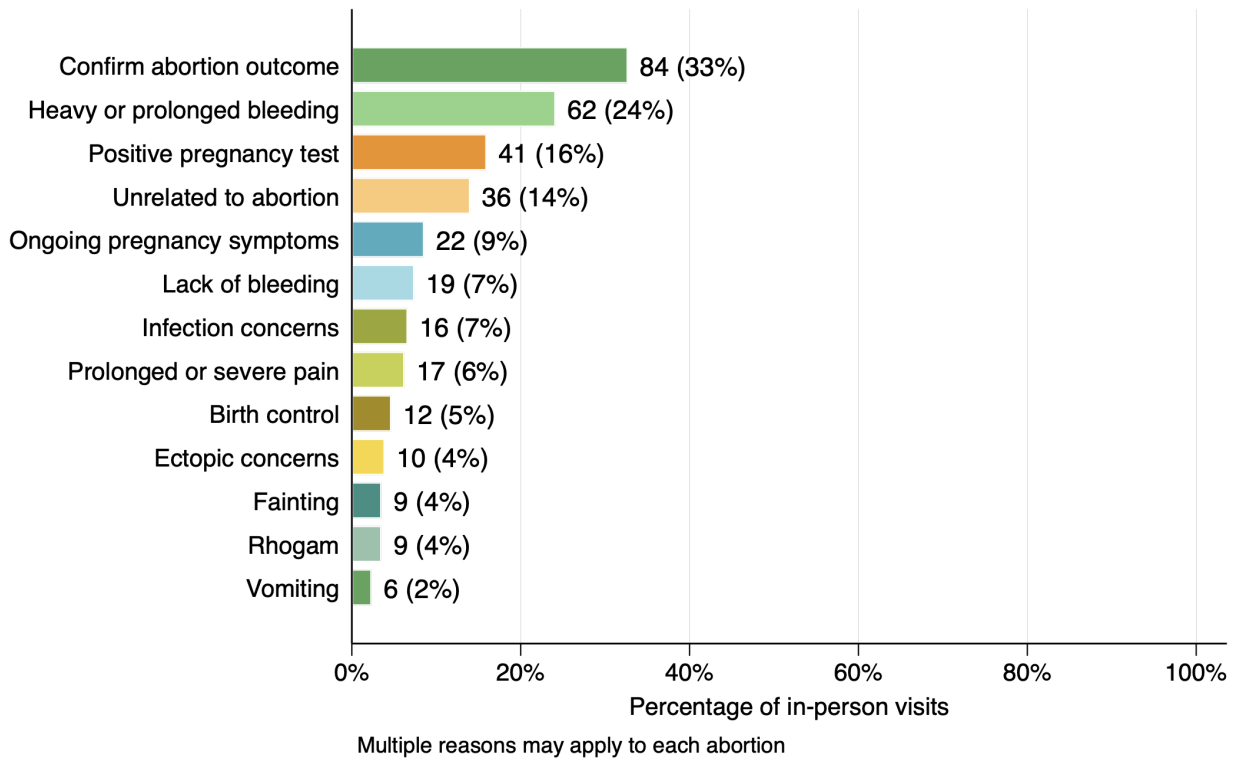


Figure 3.4. Reasons for in-person visits after telehealth abortion (n=257)

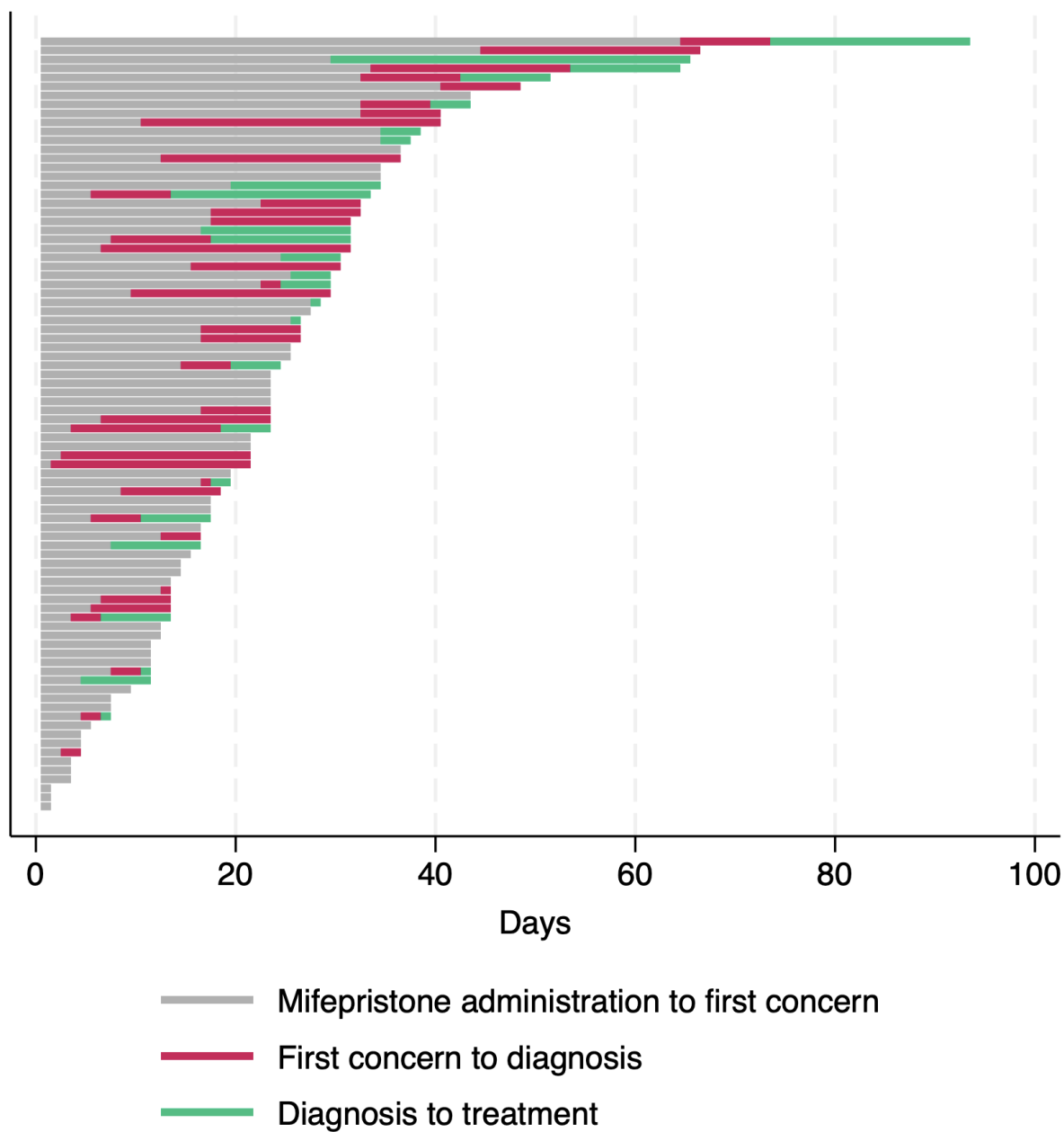


Figure 3.5. Time to adverse event diagnoses among telehealth abortion patients with in-person treatments for adverse events (n=87)

3.8 Supplementary Material

Table S3.1. Comparison of sample characteristics between patients who did and did not participate in survey research (n=6,034)

		Did not participate in surveys	Participated in surveys	p-value ^a
N		4421	1613	
		Mean (SD)		
Age in years		30 (7)	29 (6)	<0.001
Pregnancy duration in days		40 (9)	40 (9)	0.25
		N (column %)		
Urban/Rural	Suburban or Rural	451 (10.2%)	149 (9.2%)	0.28
	Urban	3970 (89.8%)	1464 (90.8%)	
Race/Ethnicity	Non-Hispanic White	1643 (37.2%)	848 (52.6%)	<0.001
	Non-Hispanic Black or African American	265 (6.0%)	148 (9.2%)	
	Hispanic or Latinx	136 (3.1%)	203 (12.6%)	
	American Indian, Alaska Native, Middle Eastern, North African, or Multiracial	211 (4.8%)	239 (14.8%)	
	Asian, Native Hawaiian, or Pacific Islander	165 (3.7%)	106 (6.6%)	
	Unknown	2001 (45.3%)	69 (4.3%)	
Received abortion funding	No	3849 (87.1%)	1263 (78.3%)	<0.001
	Yes	572 (12.9%)	350 (21.7%)	
Had confirmatory pre-abortion ultrasonography	No	4112 (93.0%)	1436 (89.0%)	<0.001
	Yes	309 (7.0%)	177 (11.0%)	
Prior abortion	None	2085 (47.2%)	968 (60.0%)	<0.001
	Any prior abortions	881 (19.9%)	642 (39.8%)	
	Unknown	1455 (32.9%)	3 (0.2%)	
Prior births	No	1513 (34.2%)	812 (50.3%)	<0.001
	Any prior births	1574 (35.6%)	570 (35.3%)	
	Unknown	1334 (30.2%)	231 (14.3%)	

^a - p-values are derived from Fisher's exact tests

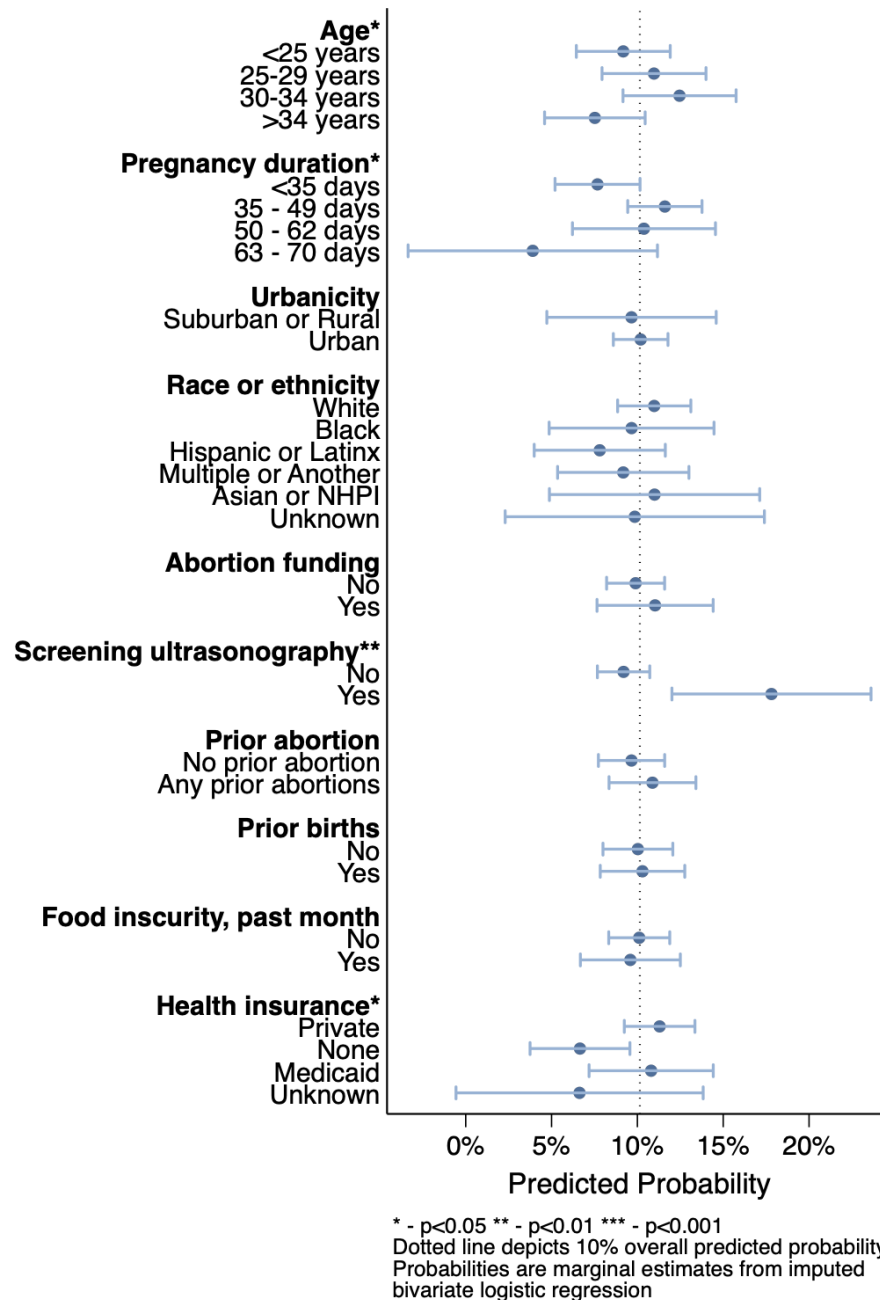


Figure S3.1. Factors associated with obtaining in-person follow-up care after telehealth abortion among survey participants (n=1,600)

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