



## Original research article

# TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States <sup>☆,☆☆,★,★★</sup>



Elizabeth Raymond <sup>a,\*</sup>, Erica Chong <sup>a,1</sup>, Beverly Winikoff <sup>a,1</sup>, Ingrida Platais <sup>a,1</sup>, Meighan Mary <sup>a,1</sup>, Tatyana Lotarevich <sup>a,1</sup>, Philicia W. Castillo <sup>b</sup>, Bliss Kaneshiro <sup>c</sup>, Mary Tschann <sup>c,d</sup>, Tiana Fontanilla <sup>c</sup>, Maureen Baldwin <sup>e</sup>, Ariela Schnyer <sup>e</sup>, Leah Coplon <sup>f</sup>, Nicole Mathieu <sup>f</sup>, Paula Bednarek <sup>e,g</sup>, Meghan Keady <sup>g</sup>, Esther Priegue <sup>h</sup>

<sup>a</sup> Gynuity Health Projects, 220 East 42nd Street New York, NY 10017

<sup>b</sup> Guttmacher Institute, 125 Maiden Lane, 7th Floor, New York, NY 10038, USA

<sup>c</sup> Department of Obstetrics, Gynecology, and Women's Health, University of Hawaii John A. Burns School of Medicine, 1319 Punahou Street, Suite 824, Honolulu, HI 96826

<sup>d</sup> Society of Family Planning, 225 South 17th Street, Suite 2709, Philadelphia, PA 19103-0046

<sup>e</sup> Oregon Health & Science University, 3181 SW Sam Jackson Park Road, UHN 50, Portland, OR 97239

<sup>f</sup> Maine Family Planning, PO Box 587, Augusta, ME 04332

<sup>g</sup> Planned Parenthood Columbia Willamette, 3727 NE Martin Luther King Jr. Blvd, Portland, OR 97212

<sup>h</sup> Choices Women's Medical Center, 147-32 Jamaica Ave, Jamaica, NY 11435

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## ABSTRACT

**Objectives:** To evaluate the safety, feasibility, and acceptability of a direct-to-patient telemedicine service that enabled people to obtain medical abortion without visiting an abortion provider in person.

**Study design:** We offered the service in five states. Each participant had a videoconference with a study clinician and had pre-treatment laboratory tests and ultrasound at facilities of her choice. If the participant was eligible for medical abortion, the clinician sent a package containing mifepristone, misoprostol, and instructions to her by mail. After taking the medications, the participant obtained follow-up tests and had a follow-up consultation with the clinician by telephone or videoconference to evaluate abortion completeness. The analysis was descriptive.

**Results:** Over 32 months, we conducted 433 study screenings and shipped 248 packages. The median interval between screening and mailing was 7 days (91st percentile 17 days), and no participant took the mifepristone at >>71 days of gestation. We ascertained abortion outcomes of 190/248 package recipients (77%): 177/190 (93%) had complete abortion without a procedure. Of the 217/248 package recipients who provided meaningful follow-up data (88%), one was hospitalized for postoperative seizure and another for excessive bleeding, and 27 had other unscheduled clinical encounters, 12 of which resulted in no treatment. A total of 159/248 participants who received packages (64%) completed satisfaction questionnaires at study exit; all were satisfied with the service.

**Conclusions:** This direct-to-patient telemedicine abortion service was safe, effective, efficient, and satisfactory. The model has the potential to increase abortion access by enhancing the reach of providers and by offering people a new option for obtaining care conveniently and privately.

☆ TelAbortion Project Team, 21 May 2019

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\* Corresponding author.

E-mail addresses: [eraymond@gynuity.org](mailto:eraymond@gynuity.org) (E. Raymond), [echong@gynuity.org](mailto:echong@gynuity.org) (E. Chong), [bwinihoff@gynuity.org](mailto:bwinihoff@gynuity.org) (B. Winikoff), [iplatais@gynuity.org](mailto:iplatais@gynuity.org) (I. Platais), [mtarnagada@gynuity.org](mailto:mtarnagada@gynuity.org) (M. Mary), [tlotarevich@gynuity.org](mailto:tlotarevich@gynuity.org) (T. Lotarevich), [pcastillo@guttmacher.org](mailto:pcastillo@guttmacher.org) (P.W. Castillo), [blissk@hawaii.edu](mailto:blissk@hawaii.edu) (B. Kaneshiro), [mtschann@societyfp.org](mailto:mtschann@societyfp.org) (M. Tschann), [tianamf@hawaii.edu](mailto:tianamf@hawaii.edu) (T. Fontanilla), [schaum@ohsu.edu](mailto:schaum@ohsu.edu) (M. Baldwin), [schnyer@ohsu.edu](mailto:schnyer@ohsu.edu) (A. Schnyer), [lcoplon@mainefamilyplanning.org](mailto:lcoplon@mainefamilyplanning.org) (L. Coplon), [nmathieu@mainefamilyplanning.org](mailto:nmathieu@mainefamilyplanning.org) (N. Mathieu), [paula.bednarek@ppcw.org](mailto:paula.bednarek@ppcw.org) (P. Bednarek), [meghan.keady@ppcw.org](mailto:meghan.keady@ppcw.org) (M. Keady), [epriegue@choicesmedical.com](mailto:epriegue@choicesmedical.com) (E. Priegue).

<sup>1</sup> Tel.: +12,124,481,230.

*Implications:* Provision of medical abortion by direct-to-patient telemedicine and mail has the potential to increase abortion access by increasing the reach of providers and by offering people the option of obtaining abortion care without an in-person visit to an abortion provider.

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## 1. Introduction

Access to abortion is limited for many people in the United States. The number of clinics providing this service declined by 6% between 2011 and 2014 [1], and in 2017, 27 cities with populations of 50,000 or more had no abortion clinic within a 100 mile radius [2]. Even people who live near a clinic may have difficulty attending in person due to scheduling conflicts, long wait times for appointments, the high cost of travel, child care, and lost wages [3], concerns about confidentiality, and anticipated harassment at clinics [4].

In response to this problem, we launched the TelAbortion Project in 2016 to provide medical abortion using telemedicine. Unlike other telemedicine abortion services in our country [5–7], the TelAbortion model does not require the patient to present in person to a facility that provides abortion: rather, she obtains screening tests at laboratories and radiology offices and then communicates with the abortion provider by videoconference. If she is eligible for treatment, the provider dispenses the abortion medications by mail [8]. This direct-to-patient approach has been successfully instituted in international settings [9–15] but has been inhibited in the United States because the restriction on mifepristone distribution imposed by the Food and Drug Administration (FDA) is interpreted as prohibiting mailing [16]. Consequently, we implemented TelAbortion as a research study conducted under an Investigational New Drug application. The specific goals of the study are to assess the safety, acceptability, and feasibility of the service. Here, we provide data from the first 32 months of the project.

## 2. Methods

To date, the project has been conducted at five institutions: Choices Women's Medical Center in New York, the University of Hawaii (UH), Oregon Health & Science University (OHSU), Maine Family Planning (MFP), and Planned Parenthood Columbia Willamette (PPCW) in Oregon. These sites initiated enrollment in the order listed over 25 months. Choices stopped recruitment in mid-2017 due to slow accrual; the other sites are still enrolling. Each institution offered TelAbortions to people in its home state, and OHSU and MFP also served Washington and New York, respectively. We selected the six study states after confirming that they had no laws prohibiting the service.

We publicized the study using multiple approaches, including a study website ([www.telabortion.org](http://www.telabortion.org)), outreach to clinicians, media reports, Google advertising, and strategically placed posters and pamphlets. In addition, sites provided information about the study to people contacting them for abortion appointments.

After a screening consultation with a study coordinator by telephone, each interested person had a "TelEvaluation" by videoconference with a study clinician who provided standard pre-abortion counseling and explained the study procedures, including expected costs. The participant signed the study informed consent form and other documents electronically using commercially available secure software. The clinician recorded relevant demographic and medical information. If the participant had not already had an ultrasound and Rh typing, the clinician assisted her in identifying facilities where she could conveniently obtain those tests and have the results sent to the study clinician. The participant and the clinician agreed on a plan for evaluating abortion outcome using ultrasound, serum HCG tests before and after mifepristone ingestion, or urine pregnancy test.

A person was eligible for medical abortion through the study if she was located in a project state where the study clinician was licensed, if she had no contraindications to medical abortion (intrauterine device in place, chronic adrenal failure, long-term corticosteroid therapy, allergy to mifepristone, misoprostol or other prostaglandin, hemorrhagic disorder, current use of anticoagulant therapy, or inherited porphyria), if her ultrasound showed an intrauterine pregnancy, and if the clinician judged that she would be able to receive and take the mifepristone at  $\leq 70$  days of gestation. Choices excluded people with negative Rh blood type because of concerns about ensuring provision of Rh immune globulin. OHSU and PPCW excluded people  $\ll 18$  years old and UH excluded people  $\ll 14$  years old.

If the participant was eligible and wished to continue with the abortion, the site sent to her by overnight or regular tracked mail a package containing one tablet of mifepristone 200 mg and eight tablets of misoprostol 200 mcg. Analgesics, antibiotics, anti-emetics, and contraceptives were included or prescribed at the discretion of the site clinician. The package also included an instruction sheet that described how to use the medications, expected symptoms and side effects, the follow-up plan, and emergency procedures. The abortifacient regimen was mifepristone 200 mg followed by misoprostol 800 mcg within 48 h administered buccally or vaginally per accepted practices at the sites. The participant was instructed to take the other four misoprostol tablets if no bleeding occurred within 24 h.

The site scheduled a follow-up contact with the study clinician for 7–14 days after the package was mailed. At this contact, the clinician interviewed the participant to assess symptoms, adverse events, and other relevant information. If further care was indicated, the clinician referred her to an appropriate facility. If a participant had not had the planned follow-up tests by 3–4 weeks after mifepristone ingestion, the clinician instructed her to obtain and perform a home urine pregnancy test. Once the clinician determined that the abortion was complete (i.e., she needed no further care related to the abortion), staff administered a satisfaction questionnaire by telephone.

Throughout the study, participants or their insurance were responsible for paying for tests and treatments obtained outside the study site. Initially, the study paid for all care and medications provided directly by the study sites; once we had gained some experience with the service, we amended the protocol to require that participants or their insurance pay standard charges for these services. Because sites initiated enrollment at different times, this amendment affected some participants at UH and all at MFP and PPCW; it was not implemented at Choices or at OHSU as of this analysis. Each participant at every site received \$50 after completing the exit interview.

We initially planned to enroll a total of 50 participants, a number determined by funding considerations. When additional support became available we continued the project to obtain more generalizable data.

Sites sent paper data forms to Gynuity Health Projects for entry into a central database. The analysis was descriptive. We counted each enrollment as an independent participant. We defined an adverse event as serious if it was fatal, life-threatening or resulted in hospitalization, transfusion, or significant disability. An unplanned clinical encounter was any visit to a clinician that was not planned before the study package was mailed. We defined meaningful follow-up as ascertainment of ingestion of abortion medications, abortion outcome, or unplanned clinical encounters.

The UH Office of Research Compliance Human Studies Program, OHSU Institutional Review Board, and Advarra Institutional Review

Board all approved the protocol. We registered the study at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT02513043).

### 3. Results

Between May 2016 and December 2018 (79 site-months), we conducted 433 screenings (Fig. 1), including three with people who had enrolled in a prior pregnancy. Most screened people (187; 43%) had learned about the study from the study clinic itself through the clinic's website or appointments personnel; the rest were referred by other providers, internet searches, the study website, media articles, or friends. Of the 433 people, 363 (84%) scheduled TelEvaluations with study clinicians. Most (322; 89%) cited speed, convenience, lack of local options, or cost as reasons for interest, including 47 (13%) who specifically mentioned cost. Seventy-eight (21%) said that they wanted privacy or to avoid harassment.

A total of 165 people (38%) either declined to schedule TelEvaluations or did not present for the appointment. We ascertained reasons from 98 (59%). The most common were concerns about the logistics or time involved (46%), the decision to have a medical abortion (18%), or cost (14%); 23% were ineligible for medical abortion through the study. In Hawaii, implementation of the protocol amendment for billing had no apparent effect on uptake of TelEvaluations over time.

The 268 participants who had TelEvaluations were diverse (Table 1). In the continental states, 52% of participants lived ≥50 miles from their study site, and 29% lived ≥150 miles distant. Of 59 participants enrolled by OHSU, 27 (46%) lived in Washington state, and one of the 30 participants enrolled by MFP lived in New York. In Hawaii, >60% of participants lived on an island without an abortion clinic.

We sent study packages to 248 (93%) of the 268 participants who had TelEvaluations (Fig. 1). Of the other 20, seven miscarried shortly

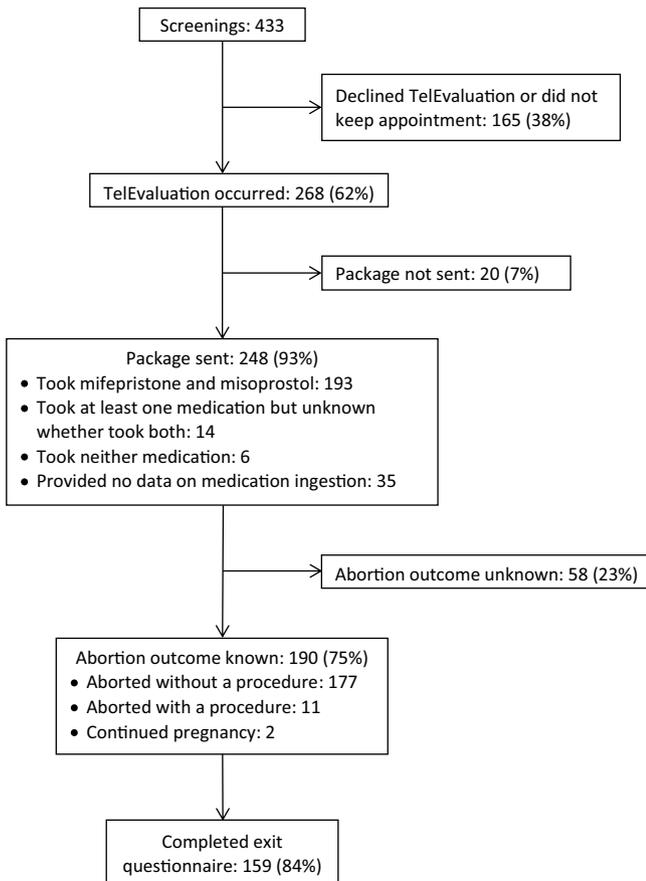
after their TelEvaluations, three decided against abortion, two would not have received the package by 70 days of gestation, seven had other reasons, and one did not provide a reason.

The characteristics of the 248 participants who were sent packages were similar to those of the screened population (Table 1). All met eligibility criteria, and all received the package sent. Of the 207 participants (83%) who reported having taken at least one abortifacient medication (Fig. 1), 187 reported the date of ingestion of mifepristone; all of these participants took that medication on or before 70 days of gestation except two who took it at 71 days.

**Table 1**

Characteristics of TelAbortion study participants who had TelEvaluations, received study packages, and had known abortion outcomes

	Had TelEvaluation N=268		Received study package N=248		Had known abortion outcome N=190	
	n	%	n	%	n	%
<b>Study site</b>						
Choices Women's Medical Center	6	2%	4	2%	4	2%
University of Hawaii	161	60%	151	61%	115	62%
Oregon Health & Science University	59	22%	54	22%	43	23%
Maine Family Planning	30	11%	27	11%	17	9%
Planned Parenthood Columbia Willamette	12	4%	12	5%	6	5%
<b>Age</b>						
15–24 years	66	25%	63	25%	48	25%
25–34 years	144	54%	135	54%	105	55%
35–45 years	58	22%	50	20%	33	19%
<b>Highest level of education completed</b>						
Less than HS	10	4%	8	3%	2	1%
HS/GED	64	24%	61	25%	47	25%
More than HS	174	65%	160	65%	127	67%
Missing	20	7%	19	8%	14	7%
<b>Number of previous pregnancies</b>						
0	67	25%	62	25%	52	27%
1	64	24%	60	24%	42	22%
≥ 2	137	51%	126	51%	96	51%
<b>Number of previous medical abortions</b>						
0	226	84%	211	85%	165	87%
1	35	13%	33	13%	22	12%
≥ 2	6	2%	4	2%	3	2%
missing	1	0.4%	0	0	0	0
<b>Rh type</b>						
pos	244	91%	232	94%	178	94%
neg	18	7%	16	6%	12	6%
unknown	6	2%	0	0	0	0
<b>Gestational age at TelEvaluation</b>						
26–35 days	26	10%	26	10%	20	11%
36–63 days	208	78%	202	81%	157	83%
64–69 days	22	8%	20	8%	13	7%
missing	12	4%	0	0	0	0
<b>State of residence</b>						
Hawaii	161	60%	151	61%	117	62%
Oregon	44	16%	41	17%	32	17%
Washington	27	10%	25	10%	20	11%
Maine	29	11%	26	10%	16	9%
New York	7	3%	5	2%	5	3%
<b>Distance of residence from provider (OR, WA, ME, NY)</b>						
1–9 mi	15	14%	14	14%	12	16%
10–49 mi	36	34%	34	35%	22	30%
50–99 mi	15	14%	12	12%	9	12%
100–149 mi	10	9%	9	9%	8	11%
≥ 150 mi	31	29%	28	29%	22	30%
<b>Hawaiian island of residence</b>						
Oahu	52	32%	49	32%	39	33%
Hawaii	59	37%	53	35%	40	34%
Maui, Molokai, or Lanai	4	2%	4	3%	3	3%
Kauai or Niihau	46	29%	45	30%	35	30%
<b>Study paid for services provided by study site</b>						
yes	141	53%	128	52%	100	53%
no	127	47%	120	48%	90	47%



**Fig. 1.** Flow of participants through TelAbortion study\*.

We were unable to ascertain abortion outcomes for 58 package recipients (23%), and two participants decided to continue their pregnancies and did not take the mifepristone. Of the other 188, 177 (94%), including the three who had previously enrolled, aborted completely without a procedure. All but four of these 177 reported having taken at least one abortifacient medication. Tests used in assessment of completeness included ultrasound in 86 participants (49%), 80% decline in serum HCG concentration in 58 (33%), and urine pregnancy tests in 36 (20%). Five participants (3%) were assessed using only other means. Eleven participants (6%) had uterine evacuation procedures, of whom two had not taken the mifepristone, four had ongoing pregnancies after mifepristone ingestion as reported by the provider, and five had bleeding and/or incomplete abortions.

Eleven of the 16 Rh-negative participants who received packages obtained Rh immune globulin, three opted out of this prophylaxis before package shipment, one did not keep an appointment made for her to receive it, and one did not provide relevant information.

A total of 217 participants had meaningful follow-up after package shipment. Two of these (1%) reported serious adverse events. One was hospitalized because of a seizure after an aspiration performed for bleeding. The second was hospitalized because of severe anemia (hemoglobin of 6.3 g/dl) 7 days after mifepristone ingestion at 56 days of gestation; she was diagnosed with complete abortion but received a transfusion. We judged that neither event would have been averted had the abortion medications been provided in person. Sixteen other participants (7%) attended an emergency department or urgent care center: 14 for bleeding and/or pain, one for dizziness, and one to get Rh immune globulin. Two of these 16 participants had aspirations, one had products of conception manually removed from her cervical os, three received medication for pain and/or nausea, one was treated for a urinary tract infection, and the other nine received no medical treatment. Eleven participants (5%) had clinic or office visits: eight had outpatient aspirations, and three had no reported medical treatment. All 29 participants reported having taken at least one abortifacient medication except one who miscarried without taking it, one who decided to have a uterine evacuation procedure, one who decided to continue the pregnancy, and two who did not provide data on medication ingestion. The proportion of participants with any unscheduled encounter was significantly more common among participants who lived  $\geq 50$  miles from the providing study site than among participants who lived closer (18% vs. 6%;  $p=.01$ ).

Implementation of the service was efficient (Table 2). The median duration of TelEvaluations as recorded in 180 cases was 24 min (range 8–70 min). Nearly all packages (91%) were mailed within 17 days after the participant's initial contact with the study site (median 7 days). Of the 177 participants who had complete medical abortion without a procedure, more than half had their last evaluation test within 17 days after the package was mailed.

The 159 participants who completed the satisfaction questionnaire were highly satisfied with the service (Table 3). The most valued aspects of the service cited by respondents were convenience (77%), privacy (45%), and communication with the study staff (39%). The most disliked aspect of the service, cited by 21%, was inconvenience.

**Table 2**  
Intervals between events in TelAbortion process.

	N	Days			
		Minimum	Median	90th percentile	Maximum
Screening to TelEvaluation	248	0	3	8	25
TelEvaluation to package shipment	248	0	2	11	35
Package shipment to package delivery	248	0	1	2	8
Package shipment to mifepristone ingestion*	187	1	2	6	12
Package shipment to final follow-up test†	166	1	16	41	127
Package shipment to exit questionnaire	159	7	24	67	280

† Among participants who aborted without a procedure; excludes 11 for whom date of final follow-up test was unavailable.

\* Excludes 19 participants who reported having taken mifepristone but did not provide a date of ingestion.

**Table 3**  
Acceptability of TelAbortion to study participants at exit interview.

	N=159	
	n	%
Satisfaction		
Very satisfactory	127	80%
Satisfactory	32	20%
Satisfaction with speaking to provider remotely		
Very satisfactory	135	85%
Satisfactory	22	14%
Unsatisfactory	0	
Very unsatisfactory	1	1%
Don't know	1	1%
Experience getting pre abortion tests		
Easy or very easy	135	85%
Difficult or very difficult	22	14%
Missing	2	1%
Future preference		
TelAbortion	136	86%
In-person abortion	16	10%
No preference	7	4%
Would recommend TelAbortion to a friend		
Yes	152	96%
No	3	2%
Maybe	4	3%

#### 4. Discussion

The TelAbortion Project is the first reported effort in the US to enable people to obtain abortion legally without an in-person visit to an abortion provider. The project has been highly successful. Participants received treatment appropriately and efficiently. Of participants with follow-up, 94% had complete abortion without a procedure, comparable to success rates of medical abortion provided in person [17]. No serious adverse events occurred that would have been avoided by an initial in-person encounter. All participants were satisfied with the service.

The proportion of participants who visited a hospital, emergency department, or urgent care center for abortion-related problems (8%) was higher than the proportion of 4% recently reported in an analysis of nearly 11,319 medical abortion patients in California [18]. Of note, our participants lived much farther from the abortion provider than did the California patients ( $\geq 100$  miles: 38% in our continental states vs. 2.5% in California [19]), which has been associated with higher use of emergency departments following treatment [20]. In our study, half of these encounters did not entail any medical treatment. Their incidence could possibly be reduced by stronger encouragement to contact the TelAbortion provider for advice before seeking unplanned in-person care.

More than half of the participants lived more than 150 miles from the project sites or on a Hawaiian island without an abortion clinic, suggesting that the TelAbortion option filled an evident need. We were surprised to find, though, that many participants lived quite close: 14% of participants in the four continental states lived less than 10 miles from the site and nearly half within 50 miles. Most of our participants cited convenience or privacy as key reasons for interest in TelAbortion;

some specifically mentioned difficulties with scheduling and the importance of having the abortion quickly. Remote provision of the service is well suited to address these issues.

We encountered several challenges in implementing the service. Ensuring that people across entire states are aware of the service requires outreach beyond routine local advertising. Identifying facilities where people can conveniently get pre-abortion tests and retrieving results can be time-consuming. Establishing billing processes for off-label use of mifepristone has been complicated. Connecting people with local sources of Rh immune globulin is also problematic. We expect that these issues will resolve as the service expands.

Our data have some limitations. Most of our participants came from Hawaii, which has unique access barriers due to the absence of abortion providers on most of its islands. We did not ascertain abortion outcomes for 23% of participants treated; our estimates of the proportion with medical abortion failure or complications may thus be underestimated. Interest in TelAbortion may have been influenced by the financial support and compensation provided by the study. Notably, though, at the UH site, which was the only site in this analysis that enrolled people before and after we instituted billing for the service, we found no evidence of a decrease in uptake of or satisfaction with TelAbortion.

We believe that the TelAbortion model has the potential to substantially increase access to abortion in the United States by increasing the reach of providers and by offering a safe and legal option for obtaining the service outside of an established clinical setting. Currently, the FDA's restriction on distribution of mifepristone appears to preclude implementation of TelAbortion except in the context of a research study. However, this restriction is medically unwarranted [16], and advocates are working to convince FDA to withdraw it [21]. Meanwhile, we intend to continue to offer TelAbortion through an expanded study to evaluate its benefits, risks, feasibility, and acceptability in a more diverse population. We plan to examine the potential for simplifications of the study procedures to decrease cost and further enhance convenience, and we hope to explore the potential for the TelAbortion model to reduce out-of-pocket costs, particularly for people who have no insurance coverage for abortion but do have coverage for the required screening and follow-up tests performed outside a facility that provides abortion. We anticipate that our data will ultimately be useful for supporting policy advances at both state and federal levels.

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**Supplemental Table**

Abortion outcome by gestational age on day of mifepristone ingestion, among participants who were sent study packages and provided date of mifepristone ingestion\*

	Gestational age on day of mifepristone ingestion						
	≤35 days N=3 n (%)	36-42 days N=12 n (%)	43-49 days N=37 n (%)	50-56 days N=46 n (%)	57-63 days N=45 n (%)	64-70 days N=42 n (%)	71 days N=2 n (%)
Aborted without procedure	3 (100%)	10 (100%)	32 (91%)	43 (98%)	39 (95%)	33 (97%)	2 (100%)
Aborted with procedure for ongoing pregnancy	0	0	1 (3%)	1 (2%)	1 (2%)	1 (3%)	0
Aborted with procedure for bleeding or incomplete abortion	0	0	2 (6%)	0	1 (2%)	0	0
Abortion outcome missing	0	2	2	2	4	8	0

\* Table excludes 6 participants who received study packages but did not take mifepristone, 19 who took mifepristone but did not provide a date of ingestion, and 36 who provided no data on mifepristone ingestion. Percents exclude women with missing abortion outcomes.

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