

Original research article

## Feasibility of telephone follow-up after medical abortion<sup>☆</sup>

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### Abstract

**Background:** This study was conducted to assess the feasibility of using telephone calls combined with high-sensitivity urine pregnancy testing as a primary method of follow-up after medical abortion.

**Methods:** We enrolled 139 women up to 63 days of gestation to receive mifepristone 200 mg orally and misoprostol 800 mcg vaginally or buccally, per their choice. Participants were contacted by phone one week after mifepristone administration and interviewed using standardized questions. If the subject or clinician thought the pregnancy was not expelled, the subject returned for an ultrasound examination. Otherwise, subjects performed high-sensitivity home urine pregnancy testing 30 days after the mifepristone and were called within 3 days of the test. Those with positive pregnancy tests returned for an ultrasound examination. Those with negative tests required no further follow-up.

**Results:** Six of the 139 (4.3%, 95% CI 1.6–9.1%) subjects presented prior to Phone Call 1 for an in-person visit. All 133 (100%, 95% CI 97.8–100%) subjects eligible for their first telephone follow-up were contacted. Eight of the 133 (6.1%, 95% CI 2.6–11.5%) women were asked to return for evaluation and all did so (100%, 95% CI 63.1–100%). Eight of the 133 women eligible for the 30 day phone call presented for an interim visit prior to the call. After 30 days, 116 of the 117 (99.1%, 95% CI 97.5–100%) eligible subjects were contacted. One subject was not reached for the day 30 phone call. Twenty-seven of the 116 (23.3%, 95% CI 15.6–31.0%) subjects had a positive pregnancy test and required follow-up. Two of these subjects (7.4%, 95% CI 1.0–24.2%) did not return for in-person follow-up. Two of the 116 (1.7%, 95% CI 0.2–6.1%) subjects had inconclusive pregnancy tests and were asked to return for follow-up. One of these subjects (50%, 95% CI 1.2–98.7%) did not return. Complete follow-up was achieved in 135 of the 139 subjects (97.1%, 95% CI 94.3–99.9%). None of the 26 women evaluated for a positive or inconclusive pregnancy test had a gestational sac or continuing pregnancy.

**Conclusion:** Telephone follow-up combined with urine pregnancy testing after medical abortion is a feasible alternative to routine ultrasonography or serial serum hCG measurements.

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**Keywords:** Medical abortion; Telephone follow-up; Urine pregnancy test; Mifepristone; Misoprostol

### 1. Introduction

The Food and Drug Administration guidelines for medical abortion with mifepristone and misoprostol recom-

mend a pelvic examination approximately 14 days after medication administration to evaluate for complete expulsion and assess for complications [1]. Several studies have attempted to expedite follow-up after medical abortion through the use of vaginal ultrasonography [2,3], serial serum human chorionic gonadotropin (hCG) levels [4] and high- or low-sensitivity urine pregnancy testing [5].

With vaginal ultrasonography, investigators in the United States demonstrated that the follow-up examination can occur within the first week after treatment and accurately predicts clinical outcome [6]. The majority of clinicians providing medical abortion in the United States

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confirm completion by vaginal ultrasound [7,8]. With serum  $\beta$ -hCG evaluations, levels drop 60–66% from pretreatment levels within 24 h after misoprostol administration [9,10], and 80% by Days 6–18 [4]. Low levels of circulating  $\beta$ -hCG, however, can persist for a month or longer [11,12]. More importantly, both ultrasonography and serum hCG testing incur costs and require the patient to follow-up in-person for an evaluation. With urine pregnancy testing, both high-sensitivity (detection threshold 25–50 mIU/mL hCG) and low-sensitivity urine pregnancy testing (detection threshold 2000 mIU/mL hCG) have been evaluated at 7 and 14 days following medical abortion treatment [5]. More than 60% of both types of tests were still positive at 2 weeks. Although urine testing could be performed at home, the clinical utility to confirm expulsion shortly after treatment is limited.

Pymar et al. [13] first evaluated history alone as a predictor of medical abortion completion. In 40 women undergoing medical abortion with mifepristone and misoprostol up to 49 days gestation, clinicians accurately predicted pregnancy expulsion 95% of the time based on history alone. This prediction was confirmed using transvaginal ultrasonography. The ability of history alone to accurately predict pregnancy expulsion was confirmed in a planned secondary analysis of a large medical abortion study [14]. In 931 women who attended a follow-up visit 1 week after medical abortion, the clinician and subject both felt the pregnancy had expelled 95% of the time. Vaginal ultrasound confirmed passage of the gestational sac in 99.1% of those subjects in which pregnancy expulsion was predicted.

Thus, it appears that the ability of history alone to predict expulsion of the gestational sac is 95% in women treated with an effective medical abortion regimen. The ability of history alone to predict complete medical abortion is higher than that seen with urine pregnancy testing. However, these assessments were made in a setting where in-person follow-up still occurred and ultrasonography was going to be performed regardless of the responses of the patient and clinician regarding expulsion. With proper education at the time of mifepristone administration, women may recognize and understand if expulsion has occurred. If clinicians can reliably assess medical abortion outcome without a physical examination or sonography, re-evaluation of guidelines for medical abortion follow-up care would be indicated. This study was designed to evaluate whether a system of early follow-up by telephone to triage who requires in-person evaluation in combination with self-administered high-sensitivity urine pregnancy testing at 30 days is an accurate and feasible alternative to current clinical practice. If telephone follow-up after medical abortion is a feasible option it has the potential to increase access to medical abortion, particularly for women that have to travel long distances for abortion services. As a secondary objective, we offered women the choice of vaginally or buccally administered misoprostol to assess

their preferences. Both options are widely used and are highly effective [2,15–17]. To our knowledge, no published studies have allowed women to choose the route of misoprostol administration.

## 2. Materials and methods

This prospective cohort study was performed at the University of Pittsburgh Center for Family Planning Research after receiving approval from the University of Pittsburgh Institutional Review Board. Healthy women 18 years old or older, up to 63 days of gestation, and desiring medical abortion were recruited from the community. Participants needed to be willing to comply with the visit schedules and undergo surgical abortion (suction curettage), if indicated. Potential subjects were excluded from the study if they were currently breastfeeding or had any of the following: no working telephone; a pregnancy with an intrauterine device in utero; ultrasound evidence of possible early pregnancy failure; a known clotting defect or receiving anticoagulants; a hemoglobin less than 10 g/dL; cardiovascular disease, including angina, arrhythmia, valvular disease, or cardiac failure; a contraindication to mifepristone, including adrenal disease or chronic systemic corticosteroid use; a contraindication to misoprostol, including glaucoma, sickle cell anemia, poorly controlled seizure disorder, allergy to prostaglandins; or had previously participated in this trial.

After obtaining written informed consent, the medical history and demographic information were reviewed. Subjects were asked to give every telephone number at which they could be contacted. They were asked to identify the telephone number they considered their primary telephone, and whether that telephone was a land line, a cellular telephone with a contract, or a prepaid cellular telephone (no contract). Subjects had blood drawn for hemoglobin and blood type, and underwent a pelvic examination and transvaginal ultrasonography to confirm gestational age of the pregnancy. The methods used to confirm gestational age have been previously described [15].

In accordance with the Pennsylvania Abortion Control Act, mifepristone administration was scheduled at least 24 h after abortion consent was obtained. Subjects were contacted between the screening visit and medication administration to confirm a working telephone number. A maximum of three attempts to contact the subjects at each telephone number was made. Women were excluded from the study if they could not be contacted.

On study Day 1, all subjects swallowed 200 mg of mifepristone. They were given the choice of self-administering 800 mcg of misoprostol vaginally or buccally. They were given an informational sheet which described the differences in timing and side effects between the two routes of administration based on the available literature (Appendix A) [16–18]. Women using vaginal misoprostol

were instructed to insert all four 200-mcg tablets as high up as possible into the vagina beginning anytime she chose up to 72 h after the mifepristone. Those selecting buccal misoprostol were instructed to place all four 200-mcg tablets in the buccal pouch (two on each side) from 24–72 h after use of the mifepristone and hold the tablets buccally for 30 min, after which the remaining tablets should be swallowed.

All subjects were given a prescription for 20 tablets of codeine (30 mg) or oxycodone (5 mg). They were instructed to take ibuprofen 800 mg or acetaminophen 1000 mg initially for pain and to add the narcotic medication as needed. Rh-immune globulin was given to all Rh-negative subjects. Sure-Vue™ urine pregnancy tests (Fisher HealthCare, Houston, TX) (sensitivity 25 mIU/mL) with instructions were given to all subjects, and all received contraception counseling. Women choosing oral, transdermal or vaginal hormonal contraception were given a prescription, and those choosing injectable, implantable or intrauterine contraception were given referral information. Subjects were given written instructions regarding pain medication use and bleeding parameters. Women were advised to contact the research office if they had any questions or if they experienced vaginal bleeding exceeding two soaked sanitary pads per hour for 2 consecutive hours, fever greater than 100°F, or other severe side effects.

Subjects were scheduled to be called by a clinician on study Day 8 ( $\pm 2$  days), 7 days after taking mifepristone. Up to three attempts at each telephone number were made to contact subjects. The subjects were asked how and when they used the misoprostol, and to provide a general description of what happened after using the misoprostol. In addition, they were asked a standardized set of questions for the clinician to use to assess for expulsion:

1. Did you have cramping and bleeding heavier than a period?
2. Did you pass clots or tissue?
3. What was the highest number of pads you soaked per hour?
4. Do you still feel pregnant now?
5. Do you think you passed the pregnancy?

If the subject or the clinician did not think the pregnancy had passed, the subject was asked to return to the research office within 7 days. An endovaginal ultrasound was performed to determine if the gestational sac was present within the uterus. If the gestational sac was absent, the subject was considered to have completed the study, and she was instructed to begin her contraceptive method or to schedule an appointment for intrauterine or implantable contraception. Women who wanted injectable contraception received the injection at that visit. If the gestational sac was present without a continuing pregnancy, she was given the option of an additional dose of vaginal misoprostol or

dilation and curettage (D&C). If she chose an additional dose of misoprostol, she returned in one week for another ultrasound. A D&C was recommended for all women with a continuing pregnancy, defined as embryonic cardiac motion on ultrasound.

If both the clinician and the subject believed that the pregnancy had passed, the subject was instructed to begin her contraceptive method if applicable, or to schedule an appointment for injectable, implantable, or intrauterine contraception. The subject was told to perform the provided urine pregnancy test on study Day 30. She was told that she would be called within 3 days of taking the test, and the date and approximate time was scheduled. She was instructed to call at any time with problems or concerns.

All eligible participants were contacted by telephone as scheduled; if not initially reached, at least three attempts were made. The medical abortion was considered complete in participants with a negative urine pregnancy test, and no return visit was needed. Participants with a positive urine pregnancy test were scheduled for a return visit within 7 days of the telephone call. At the return visit, the urine pregnancy test was repeated with the Sure-Vue™ high sensitivity (sensitivity 25 mIU/mL) and the Clarity™ low sensitivity (Diagnostic Test Group, Boca Raton, FL, USA) (sensitivity 2000 mIU/mL) test. An endovaginal ultrasound was performed and the abortion considered complete in those subjects without a gestational sac visualized on ultrasound. If a gestational sac was present, the subject was offered an additional dose of misoprostol or D&C. Those subjects desiring an additional dose of misoprostol returned in one week for an ultrasound. The medical abortion was considered complete in those subjects choosing D&C. A D&C was recommended for all women with a continuing pregnancy.

At the final contact, either by telephone or in-person, subjects were asked if they would have preferred to take the misoprostol by a different route. The number of phone calls and length of the phone call each subject made to the research office was documented to gain insight into the amount of additional administrative time telephone follow-up may require.

The primary outcome of the study was successful follow-up per study protocol, defined as successful contact with subjects and in-person follow-up for those women asked to return to the office. For sample size estimation, we considered a 90% follow-up rate to be acceptable for this initial study of feasibility. To ensure a 95% confidence interval of no more than 5% (a lower 95% confidence interval of 85%), 139 subjects would be required with an alpha of .05 and beta of .2. We assumed that approximately 10% of subjects that screened for the study would not enroll, yielding a final sample estimate of 157 subjects. Statistical analysis was performed using Stata 10 (Stata, College Station, TX, USA; [www.stata.com](http://www.stata.com)). Descriptive statistics and comparisons were calculated using chi-square and Fisher's Exact tests. The sensitivity, specificity, positive

and negative predictive value of the phone screen to predict pregnancy expulsion was calculated.

### 3. Results

Between March and October 2008, 157 subjects were screened and 139 subjects were enrolled in the study. Of the 18 screen failures only 2 subjects (11%, 95% CI 13.8–34.7%) were withdrawn because they did not have a working telephone. The remainder decided to continue the pregnancy, had hemoglobin levels less than 10 mg/dL or did not return to receive medications after screening. The characteristics of enrolled subjects are listed in Table 1.

Fig. 1 depicts the flow of the study. Six subjects returned to the office prior to Phone Call 1 for an interim visit and were not eligible for the first scheduled telephone call. All (100%, 95% CI 97.2–100.0) of the remaining 133 subjects were reached by telephone as scheduled, and all 8 subjects who were asked to return for a visit for unsure expulsion did so.

Table 1  
Subject characteristics;  $n=139$ , data presented as  $n$  (%) or median (range)

Age, years	25 (18–41)
Marital status	
Single	119 (85.6)
Married	10 (7.2)
Divorced or separated	10 (7.2)
Race	
White	60 (43.2)
Black	71 (51.1)
Other	8 (5.8)
Prior vaginal delivery	78 (56.1)
Prior cesarean delivery	27 (19.4)
Prior surgical abortion	54 (38.9)
Prior medical abortion	18 (13.0)
Income in dollars/year	
<10,000	33 (23.7)
10,000–20,000	37 (26.6)
20,000–30,000	33 (23.7)
>30,000	36 (25.8)
Education	
Less than high school	16 (11.5)
Completed high school	48 (34.5)
Some college or trade school	57 (41.1)
College or more	18 (13.0)
Telephone service	
Home phone	23 (16.6)
Cell phone with contract	70 (50.4)
Pre-paid cell phone <sup>a</sup>	46 (33.1)
Gestational age at time of medical abortion (days)	
≤35	1 (0.7)
35–42	14 (10.1)
43–49	50 (36.0)
50–56	65 (46.8)
57–63	9 (6.5)

<sup>a</sup> A cellular telephone without an annual contract and minutes can be added to the phone as needed.

Eight subjects had an interim visit prior to Phone Call 2. Of the 117 subjects eligible to be contacted for the second scheduled phone call, 99.1% (95% CI 95.3–100.0) were contacted, with only one subject lost to follow-up. The pregnancy test results were negative in 87 (75%, 95% CI 66.1–82.6) women; 27 (23.3%, 95% CI 16.0–32.0) had a positive test, and 2 (1.7%, 95% CI 0.2–6.1) had problems reading the test. These latter 29 subjects all denied any ongoing pregnancy symptoms but, per protocol, were asked to return for an in-person visit. Of the 26 subjects that presented for this visit, none had a retained gestational sac or required D&C. The manufacturer of the Clarity™ low-sensitivity test discontinued production during the study, and only the first 15 subjects who returned after Phone Call 2 received the low-sensitivity test. Only one of the 15 was positive (6.7%, 95% CI 0.2–31.9). The repeat high-sensitivity pregnancy test was still positive in 21 subjects (80.8%, 95% CI 60.6–93.4). Of subjects completing Phone Call 2, 19.5% (95% CI 12.6–28.0) would have preferred to return for an ultrasound one week after medication to confirm pregnancy expulsion.

Successful follow-up per study protocol was achieved in 97.1% (95% CI 92.8–99.2) of subjects. A total of four subjects did not complete all follow-up (2.9%, 95% CI .08–7.2). One subject was never contacted by Phone Call 2, two subjects had a positive pregnancy test and one had an inconclusive test. None of these three returned for the in-person visit. Of the 135 women who completed follow-up, 64.4% (95% CI 55.8–72.5) never required an in-person visit.

Eight (6.7%, 95% CI 3.1–12.3%) D&C procedures were performed. Fig. 1 outlines the indications for the D&C procedures. Three subjects were diagnosed with a pelvic infection (2.2%, 95% CI 0.5–6.4%), with one requiring hospital admission and intravenous antibiotics. Two subjects (1.4%, 95% CI 0.2–5.2%) required blood transfusion for symptomatic anemia, one of whom underwent a D&C for bleeding. There were 4 continuing pregnancies (3.0%, 95% CI 0.8–7.4%); one was diagnosed prior to Phone Call 1, two were diagnosed at the follow-up visit after Phone Call 1, and the fourth was diagnosed at an interim visit prior to Phone Call 2.

The prediction by the subject and clinician that the pregnancy had been expelled had a sensitivity of 95.9%, specificity of 50.0%, positive predictive value of 97.5%, and negative predictive value of 37.5%. For this calculation, medical abortion was considered complete if there was ultrasound confirmation of pregnancy expulsion, or a negative high-sensitivity pregnancy test at Day 30. There were 129 subjects included in this analysis; the four subjects lost to follow-up were not included. The number of subjects without follow-up was too low to assess variables (such as type of telephone service or level of education) that were predictive of no follow-up. Fifty-two (37.4%, 95% CI 29.3–46.0) women contacted the research office for unscheduled calls; 57.6% (95% CI 43.2–71.2) called only once, while 42.3% (95% CI 28.7–56.8) called two or more times. The

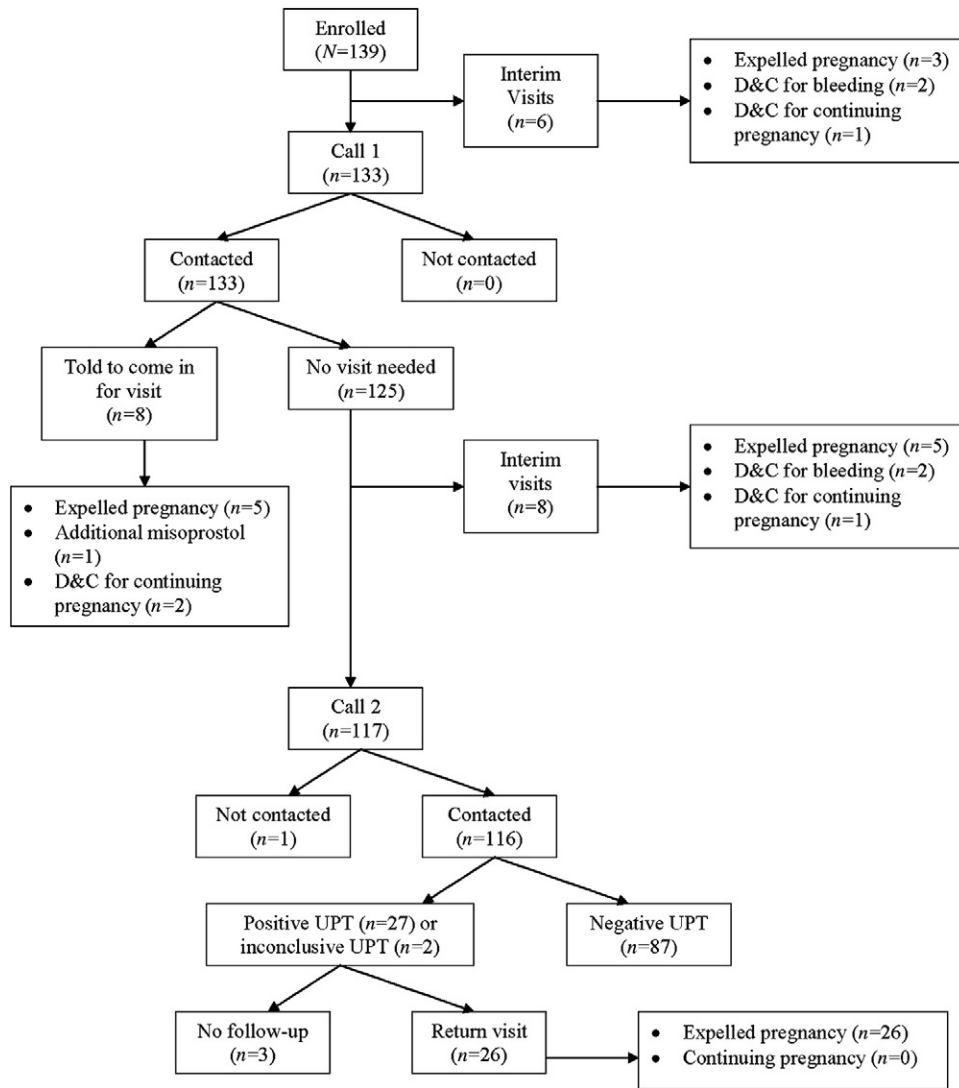


Fig. 1. Study flow. Call 1 scheduled 7±2 days after mifepristone use. Call 2 scheduled within 3 days of Day 30 pregnancy test. UPT, urine pregnancy test.

maximum number of phone calls by one subject was six calls. The mean length of each phone call was 2.5 min (95% CI 1.7–3.3, range 2–27 min).

Almost all women (94.2%, 95% CI 89.0–97.4%) chose vaginal misoprostol, with 74% using misoprostol within 6 h of mifepristone administration (Table 2). Only six women chose buccal misoprostol. When asked at the end of the study

if they would choose to take misoprostol the same way, 96.4% (95% CI 91.8–98.8) of subjects would choose the same misoprostol route.

#### 4. Discussion

The primary aim of our study was to determine if it is possible to reach women by telephone, and based on a standardized set of questions, determine if an in-person visit is indicated. The intention of these standardized questions is to predict pregnancy expulsion so as to make appropriate recommendations to women about whether or not they should return to the office. In reality, the goal is to ensure that this method of follow-up avoided missing any continuing pregnancies by the final follow-up 30 days after treatment. Only 3% of women did not follow all instructions for follow-up. Given that complete loss to follow-up rates is at least 2%

Table 2  
Timing of misoprostol use (n, %)

Time since mifepristone (h)	Vaginal misoprostol n=127	Buccal misoprostol n=6
0–<2	32 (25.2)	0
2–<4	46 (36.2)	0
4–<6	16 (12.6)	0
6–<12	14 (11.0)	0
12–<24	9 (7.1)	0
≥24	10 (7.9)	6

in studies and clinical practice [19,20], our data show that it is very feasible to use the telephone as a primary method of follow-up after medical abortion.

The high sensitivity and positive predictive value of the standardized question set are reassuring such that when the clinician and subject both believe the pregnancy has passed, they are almost always correct. These results are not unlike those found in previous studies when questions have been used to assess medical abortion success [13,14]. This study was not powered to detect which questions were most predictive of pregnancy expulsion, and this information may warrant additional research. Importantly, all women who did not require a return visit after the phone screen but had problems such as bleeding or continuing pregnancy symptoms presented to the office on their own.

A prior evaluation of high-sensitivity urine pregnancy testing used the test within 2 weeks of treatment to confirm pregnancy expulsion [5], essentially using high and low-sensitivity urine pregnancy tests as a screening tool to diagnose successful medical abortion. In our study, we were using medical history as the screening tool, not the high-sensitivity urine pregnancy test. We only used the pregnancy test to rule out continuing pregnancies. While 25% of the high-sensitivity urine pregnancy tests were positive or inconclusive, none of those subjects that followed up for a positive pregnancy test had a continuing pregnancy. All four subjects with a continuing pregnancy presented on their own to the office prior to Phone Call 2, with only one continuing pregnancy being diagnosed between Phone Call 1 and Phone Call 2. While performing the urine pregnancy test 4 weeks after medication administration increases the number of women that must return for evaluation, it ensures that continuing pregnancies are diagnosed and that a D&C can be performed within the first trimester. We selected high-sensitivity urine pregnancy tests because they are available over the counter. If this method of follow-up is adopted, women could theoretically purchase their urine pregnancy tests in the pharmacy after receiving medical abortion medications.

In all medical abortion studies and in clinical practice, some women are lost to follow-up. The percentage of women with incomplete follow-up in our study was similar to the percentage of women that do not follow-up with the standard medical abortion follow-up protocol. It is impossible to know which women undergoing medical abortion will have a continuing pregnancy and/or will be lost to follow-up. Our data indicate that women with a continuing pregnancy develop pregnancy symptoms and schedule a follow-up visit.

Our 3% continuing pregnancy rate is somewhat higher than the 0–1% cited in other medical abortion studies [16,18,21]. Unlike these other trials, we did not allow an additional dose of misoprostol for subjects with continuing pregnancies. One of the four continuing pregnancies was diagnosed before Day 7 in a subject who presented for worsening pregnancy symptoms. It is still possible that she may have aborted prior to Phone Call 1 had she not had the D&C. All of the subjects with continuing pregnancies used

vaginal misoprostol within 3 h of the mifepristone, and three of the four subjects had a gestation of 61 days. These factors may have contributed to the high continuing pregnancy rate.

This is the first published study that allowed women to select which route of misoprostol administration they would prefer. Women overwhelmingly chose vaginal misoprostol. While we did not specifically ask the reason they chose this route, 91.4% of subjects choosing the vaginal route used the misoprostol within 24 h after mifepristone administration. We infer that the ability to use the misoprostol sooner and thereby complete the medical abortion sooner is the reason the vaginal route of misoprostol was selected. While familiarity with a route can also be a contributing factor, only 13% of women had experienced a prior medical abortion, so this reason is unlikely in this case. Although some investigators have implied that women prefer an oral route, our findings suggest that, when all factors are considered, women may prefer the route that allows them to complete the abortion as quickly as possible [3].

We have found that telephone screening in combination with high-sensitivity urine pregnancy testing is feasible and believe that this method of medical abortion follow-up can be offered as an alternative to in-person evaluations for select patients. In our study, only one third of the subjects were required to return for a visit. Some women will feel more comfortable having a return visit and confirming pregnancy expulsion, while others find this additional visit inconvenient and would prefer telephone follow-up. Still, continued quality assessment will be required if such a program is implemented to determine if our findings are generalizable to other providers and settings. We are confident based on our data that women are very self-aware, and if they are having symptoms or problems after a medical abortion, they will return to the office for a visit despite the type of follow-up. This method of medical abortion follow-up provides women with more choices.

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## Appendix A. MEDICAL ABORTION with MIFEPRISTONE and MISOPROSTOL

### Comparing misoprostol use options

Buccal=between your cheek and gums

Vaginal=in your vagina

	Buccal	Vaginal
MIFEPRISTONE	Swallow the tablet right away in the doctor's office	Swallow the tablet right away in the doctor's office

## Appendix A (continued)

	Buccal	Vaginal
How you will use the MISOPROSTOL	Place all 4 of the tablets between your cheek and gum and allow them to dissolve for 30 minutes. After that time, you should swallow the rest of the tablets.	Place all 4 tablets in vagina
When you can use MISOPROSTOL	1-3 days later (whatever time works best for you)	Any time after you use the mifepristone, up to 3 days later (whatever time works best for you)
Where you will use the MISOPROSTOL	At home	In the office if you insert the pills immediately. At home if you use the pills later.
Chance of side effects	Nausea: 8 in 10 Vomiting: 5 in 10 Diarrhea: 4 in 10	Nausea: 4 in 10 Vomiting: 3 in 10 Diarrhea: 3 in 10
Likelihood of needing pain medication	Moderate to high	Moderate to high
Chance of needing a surgical abortion (because medicines didn't work)	4 out of 100	3 out of 100

Based on information from:

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