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Randomized trial assessing home use of two pregnancy tests for determining early medical abortion outcomes at 3, 7 and 14 days after mifepristone☆

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Abstract

Objective: To evaluate the accuracy, feasibility and acceptability of two urine pregnancy tests in assessing abortion outcomes at three time points after mifepristone administration.
Study design: This randomized trial enrolled women seeking early medical abortion at two hospitals in Vietnam. Investigators randomly allocated participants to at-home administration of a multilevel urine pregnancy test (MLPT) or a high sensitivity urine pregnancy test (HSPT) to assess their abortion outcomes. A baseline test was administered on the same day as mifepristone. Participants performed and interpreted results of pregnancy tests taken 3, 7 and 14 days after mifepristone. Ultrasound exam determined continuing pregnancy.
Results: Six hundred women enrolled, and 300 received each test. A percentage of 97.4 (584) had follow-up, of whom 13 women had continuing pregnancies. The specificity of MLPT at detecting absence of continuing pregnancy was 63.9%, 90.4% and 97.1% at study day 3, 7 and 14. The specificity of HSPT was 6.0%, 19.8% and 62.2%, respectively. The positive predictive value (PPV) of MLPT at detecting continuing pregnancy was 6.4% at day 3 and rose to 46.7% at day 14. In contrast, the PPV for HSPT was 2.2% at day 3 and rose to 6.5% at day 14. At all three time points, the sensitivity and negative predictive values for both tests were 100.0%. Most women found their assigned tests easy to use and would prefer future home follow-up with a pregnancy test.
Conclusions: The MLPT enables women to assess their abortion outcomes more reliably than with HSPT. With MLPT, women can know their outcomes as early as 3 days after mifepristone.
Implications: Medical abortion service delivery with an MLPT to obtain a baseline (preabortion) human chorionic gonadotropin (hCG) estimate and a second follow-up MLPT 1 to 2 weeks later can establish whether there has been a drop in hCG, signifying absence of a continuing pregnancy. Used this way, MLPTs can enable women to assess their abortion status outside of a clinic setting and without serum hCG testing and/or ultrasound.

Keywords: Semiquantitative pregnancy test; Multilevel pregnancy test; High sensitivity pregnancy test; Medical abortion; Task shifting; Task sharing

1. Introduction

For years, some providers and service delivery systems have sought to reduce or replace routine clinic-based follow-up visits after medical abortion using alternative means [1–4]. Researchers have assessed routine serum human chorionic gonadotropin (hCG) testing [5,6], telephone, text or Internet follow-up [7–12], home pregnancy testing using high and low sensitivity pregnancy tests (LSPTs) [7,9,10,12–14] and multilevel urine pregnancy tests (MLPTs) [15–18].

Home follow-up using commonly available, easy to use and low-cost urine pregnancy tests has had mixed results

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[7,10–12]. High sensitivity tests usually detect hCG of 25 mIU/ml or more, and low sensitivity tests usually detect hCG of either 1000 or 2000 mIU/ml or more. These tests can produce a high rate of false positive results when used 2 weeks after early medical abortion and are therefore largely unhelpful in reducing follow-up visits [14]. Serum hCG testing, although highly efficacious, also has drawbacks: it can be costly, requires a blood sample at a lab facility and results are not available right away.

Attempts to improve testing options for abortion follow-up prompted the development of MLPT, also known as *semiquantitative pregnancy tests*. Service delivery using an MLPT entails obtaining a baseline (preabortion) hCG estimate and a second, follow-up hCG estimate, typically 1 to 2 weeks later, to establish whether there has been a drop in hCG. The MLPT used in this study has accurately identified both absence and presence of continuing pregnancy when used for medical abortion follow-up at 1 and 2 weeks postmifepristone [15–18].

As hCG levels decrease by about 70% within 24 h after misoprostol administration for early medical abortion [19,20], we posited that the MLPT might work for medical abortion follow-up as early as 2 days after misoprostol. A shorter process is generally preferable to women, and home use of MLPT could enable women to assess abortion outcomes themselves without needing a routine clinic follow-up visit.

This study sought to evaluate whether hCG trends could be monitored at home using an MLPT as early as 3 days after mifepristone.

2. Materials and methods

Between June 14, 2013 and February 14, 2014, women seeking early medical abortion at two hospitals in Vietnam were randomized to home follow-up with either a multilevel pregnancy test or a high sensitivity pregnancy test (HSPT). The institutional ethical review boards at both of the study hospitals approved this study; the trial is registered at clinical trials.gov as NCT01856777.

Eligibility criteria included gestational age ≤63 days and provision of signed informed consent. All women received ultrasound prior to enrollment per standard practice at the study sites. Gestational age limits were in accordance with national guidelines: women ≤63 days were eligible at the tertiary facility (Hung Vuong Tertiary Hospital in Ho Chi Minh City), and those ≤49 days were eligible at the regional hospital (HocMon Regional General Hospital in the periphery of Ho Chi Minh City). Other criteria included being literate, willing to use up to three home pregnancy tests and to return to the clinic. After documenting eligibility and consent, a trained study nurse opened the next sequentially numbered envelope containing the study group allocation.

Study nurses counseled the women and explained how to use and interpret the assigned pregnancy test. Participants then performed a baseline test on their own at the clinic after enrollment. After completing the baseline pregnancy test, each participant received one 200-mg mifepristone tablet to swallow immediately. Women received four 200-mcg misoprostol tablets to administer buccally the next day at home and three pregnancy tests per their study group to take at home at 3, 7 and 14 days after mifepristone. Women also received written and pictorial test instructions and a home diary for recording and interpreting results and abortion symptoms. The diary cards were returned to the study staff at follow-up visits. If immediate follow-up was not indicated as described below, women were instructed to return 2 weeks after mifepristone.

Women in both groups were asked to use the home test on study days 3, 7 and 14 and record results. Women in the MLPT group whose tests showed either a decrease or increase in hCG after using the test were instructed to return for clinic follow-up immediately. If hCG levels were unchanged, women were instructed to wait and administer the next scheduled pregnancy test. Women in the HSPT group with negative results (hCG<25 mIU/mL) were instructed to return for clinic follow-up immediately. Women who returned before day 14 and were found to no longer have a continuing pregnancy were exited from the study.

In all cases, abortion outcome, including absence of a continuing pregnancy, was verified using transvaginal ultrasound and clinical exam within 14 days of mifepristone. If ultrasound evidence of continuing pregnancy (defined as continued embryonic/sac growth or continuing fetal cardiac activity) was identified, immediate additional care was provided. All other women who sought care due to uncertainty about their abortion status were given reassurance and additional counseling.

Women who withdrew consent were given appropriate care and exited the study. If a participant did not return for clinic follow-up, study staff made at least three attempts to reach her by phone. During the exit interview, participants answered questions about the feasibility and acceptability of using the assigned pregnancy test on their own at home.

The MLPT used was the dBest hCG urine panel test® (AmeriTek, Seattle WA, USA) [15–18]. Participants were instructed to dip the test into a urine sample and stir it for at least 10 s to saturate the strips. They were told to place the test on a flat surface and read the result approximately 15 min later. The HSPT used was a locally available dipstick (Quickstick one-step hCG Pregnancy Test®, Phamatech, San Diego, CA, USA) that showed a "yes" response if hCG was >25 mIU/mL. Participants were instructed to dip the panel into a urine sample and read the result 5 min later.

Staff at Gynuity Health Projects in New York who were not directly involved in the study prepared the randomization. Randomization was stratified by study site using blocks of ten to ensure equal distribution in the two groups. Allocation was concealed until time of assignment when the provider opened the next consecutively numbered opaque envelope.

The study sought to document and compare the performance and acceptability of using MLPT and HSPT at home to identify continuing pregnancy at 3, 7 and 14 days after mifepristone. The sample size estimates were based on evidence from prior studies on the performance of MLPT and HSPT on days 7 and 14 [4,16,17]. We assumed that the test specificity at each time point would be 75% (MLPT) versus 10% (HSPT) on day 3, 99% (MLPT) versus 25% (HSPT) on day 7 and 99% (MLPT) versus 35% (HSPT) on day 14. We sought a total of 12 continuing pregnancies. Using evidence from five randomized trials that included 97 continuing pregnancies among 3702 cases of medical abortion conducted in Vietnam [16–17,21–23], we assumed the rate of continuing pregnancy would be 2%. Therefore we enrolled 600 women (300 per group).

Data entry and analysis were performed using Statistical Package for the Social Sciences 15.0 and Stata SE 12.1. The study investigators entered and cleaned the data in Vietnam. Analysis and findings are reported according to the CONSORT guidelines [24]. Group differences were assessed using Pearson's chi-square for categorical variables. p-values <0.05 were considered statistically significant. For both tests, we calculated sensitivity (for MLPT: proportion with continuing pregnancies whose test results showed stable or increasing hCG; for HSPT: proportion with continuing pregnancies who obtained a yes in the follow-up test), specificity (for MLPT: proportion with absence of continuing pregnancy whose test results showed declining hCG; for HSPT: proportion with absence of continuing pregnancy who obtained a "no" in the follow-up test), positive predictive value (PPV — for MLPT: proportion with stable or increasing hCG who had a continuing pregnancy, for HSPT: proportion with a yes result in the follow-up test who had a continuing pregnancy) and negative predictive value (NPV — for MLPT: proportion with declining hCG who had no continuing pregnancy, for HSPT: proportion with a "no" result in the follow-up test who had no continuing pregnancy). For calculations of test accuracy, we included cumulative results for all women who used at least one at-home follow-up test. We excluded 63 participants (MLPT = 9, HSPT = 54) who did not use a test on the designated day and had received a false positive (e.g., for the MLPT group, no ongoing pregnancy after a stable or rising hCG) from the analyses shown in Table 2 and Fig. 2.

3. Results

Fig. 1 shows participant flow; 16 participants (2.6%) were lost to follow-up. Table 1 summarizes the background and clinical outcomes of the 600 study participants. There were no discernable differences in background characteristics or abortion outcomes between the two study groups. All known outcomes were ascertained at clinic visits, women with unknown outcomes are listed as lost to follow-up. None of those lost to follow-up were seen in other departments of the study hospitals for abortion-related care.

Thirteen women (7 = MLPT, 6 = HSPT) presented with continuing pregnancy during the study period. Twelve of these women enrolled with a gestational age ≤ 49 days. Of the seven women with ongoing pregnancies in the MLPT group, one presented after using her first follow-up test on study day 3 with a stable hCG reading of $\geq 10{,}000$ mIU/mL. Five women presented after using a second test on day 7 due to stable or increasing hCG (and/or concerns about pregnancy symptoms), and one presented on day 14 after consecutive readings of ≥ 500 mIU/mL at baseline and study days 3 and 7 and a reading of ≥ 2000 mIU/mL at study day 14.

Among the six women with ongoing pregnancy assigned to HSPT, three presented after they used their home pregnancy test on day 7 due to concern about the test result and/or pregnancy symptoms and the remaining three presented on study day 14 per study protocol.

Some women in both groups presented and had no ongoing pregnancy. These women had returned early for an unscheduled visit mainly due to anxiety about their test results. In the MLPT group, five (1.7%) women returned due to results that were stable (i.e., not decreasing) in successive tests. In the HSPT group, 56 (19.3%) women returned due to a false positive test result. These women were given reassurance and instructions to use the next pregnancy test at home per the study protocol. Women with persistent nonviable pregnancy or sac (MLPT = 10, HSPT = 9) were treated with either vacuum aspiration ($n = 10$) or additional misoprostol ($n = 9$). One woman with gestational age 42 days in the HSPT group had an ectopic pregnancy identified at an unscheduled visit. She took her first home pregnancy test on study day 3 obtaining a positive result and presented for an unscheduled visit a few days later due to abdominal pain and bleeding. She subsequently had surgery for ruptured ectopic pregnancy.

The performance of each test in identifying abortion outcomes (continuing pregnancy or absence of continuing pregnancy) is summarized in Tables 2 and 3. Both tests had 100% sensitivity and NPV at all three time points. There were notable differences, however, in specificity both between groups and over time, demonstrating large variations at each time point in favor of MLPT. The PPV was low at each time point, particularly at study days 3 and 7, due to the large number of false positives in both groups.

Fig. 2 shows the proportion of women for whom clinic-based follow-up would be recommended at each time point based on their test results. There were large differences in need for follow-up between the two study groups at each time point with the MLPT enabling two thirds of women to avoid clinic follow-up after study day 3.

Participant views are summarized in Table 4. The vast majority in both groups found their respective tests easy to use and would select home follow-up with a pregnancy test for managing future abortion follow-up. There were no significant differences between study groups in any acceptability measures.

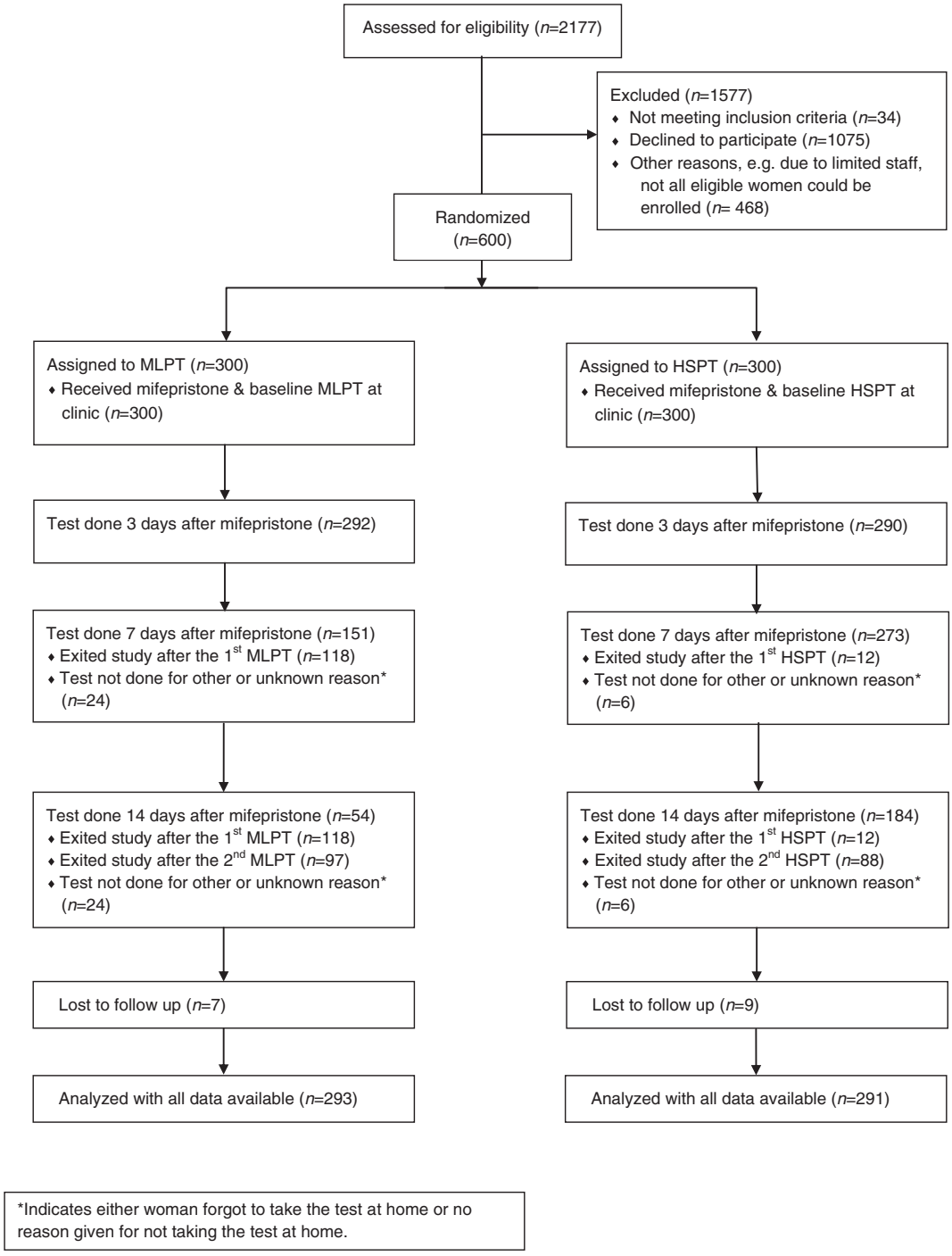

Fig. 1. Consort flow chart.

4. Discussion

Given the extremely high efficacy of early medical abortion, most women do not need clinic follow-up to confirm absence of continuing pregnancy. Our data show that most women can ascertain their abortion outcome at home using a simple MLPT. This advance in medical abortion service delivery could eliminate the need for standard follow-up with ultrasound and/or serum hCG, both of which are costly to women and health care systems. Using MLPTs, more than half of women will know within 3 days that their pregnancy has ended. Seven days after mifepristone, 90% of women can confirm absence of evolving pregnancy with the urine test; a small percentage may not receive that confirmation until day 14. In terms of service delivery, there are advantages and disadvantages to

Table 1
Study participant characteristics and clinical outcomes.

	MLPT $n=300$	HSPT $n=300$
Mean age in years ± SD (range)	30±6 (17–45)	29±6 (17–46)
Educational attainment: *n* (%)		
Primary (1–5 years)	15 (5.0)	22 (7.3)
Secondary (6–12 years)	203 (67.7)	202 (67.3)
University or higher	82 (27.3)	76 (2.0)
Parity: *n* (%)		
0	77 (25.7)	86 (28.7)
1	89 (29.7)	92 (30.7)
2	116 (38.7)	105 (35.0)
3+	18 (6.0)	17 (5.7)
Mean gestational age in days ± SD (range)	42±5 (30–61)	42±6 (30–63)
Prior abortion: *n* (%)	135 (45.0)	117 (39.0)
Baseline hCG range (mIU/mL): *n* (%)		
<25 (0–24)*	0	
≥25 (25–99)	0	
≥100 (100–499)	2 (0.7)	N/A
≥500 (500–1999)	106 (36.2)	
≥2000 (2000–9999)	107 (36.5)	
>10,000	78 (26.6)	
Outcome of medical abortion: *n* (%)		
Complete	276 (94.2)	275 (94.5)
Continuing pregnancy	7 (2.4)	6 (2.1)
Persistent nonviable pregnancy or sac^	10 (3.4)	9 (3.1)
Surgery for ectopic pregnancy	0	1 (0.3)
Lost to follow-up	7 (*2.3*)	9 (*3.0*)

MLPT denotes multilevel pregnancy test; SD, standard deviation.
Percentages have been rounded.
N/A is for data not available as the HSPT does not present hCG values using these ranges. All baseline hCG values for HSPT were positive (≥25 mIU/mL).
** Each MLPT result reflects a range of possible hCG values, as specified in parentheses.
^ Includes 3 women classified as incomplete abortion and 7 classified as missed abortion. All were managed with either uterine evacuation ($n=10$) or additional misoprostol ($n=9$).

Table 3
Cumulative test accuracy in identifying continuing pregnancy by 14 days of mifepristone administration.

		Ongoing pregnancy	
		Ø	+
MLPT	Ø	268	0
	(e.g., decreasing) +	17	7
	(e.g., stable or increasing)		
		Ø	+
HSPT	Ø	144	0
	+	141	6

Note: For each woman, the results used were those of last test taken.

the earliest, day three, confirmation, given that some women will receive potentially worrisome false positive results. For some women and systems, this will pose a barrier, and the more reliable 7-day follow-up may be preferable. For others, having peace of mind and closure within a few days is a perceived advantage, one that women and services may prefer.

In this study, we confirmed that HSPT is an unreliable predictor of absence of continuing pregnancy. In settings where HSPT is the only accessible test, our study indicates that it will ascertain absence of continuing pregnancy for 60% of women 2 weeks after mifepristone. This result is higher than previous reports using HSPT (14). With HSPT follow-up, it is unlikely that providers will miss a continuing pregnancy; however, service delivery improvements, such as shortened time until known abortion outcome and reduced number of (unnecessary) clinic-based follow-up visits would not occur.

LSPTs are not commercially available in Vietnam, and we did not assess this alternative strategy, although such tests are an option for medical abortion follow-up (9,10,12,25). Recent research using an LSPT that reads positive with an hCG of at least 1000 mIU/mL resulted in three ongoing pregnancies detected in the second trimester [25]. Two of the seven women with continuing pregnancies in our trial exhibited endline hCG readings of ≤2000 mIU/mL and might not have been signaled for follow-up if they had used an LSPT. In settings with strict upper gestational age limits for legal abortion, ongoing pregnancy needs be identified as early as possible in order to offer women

Table 2
Cumulative test accuracy in identifying continuing pregnancy at 3, 7 and 14 days of medical abortion.

	MLPT			HSPT		
	Day 3 ($n=292$)	Day 7 ($n=288$)	Day 14 ($n=283$)	Day 3 ($n=290$)	Day 7 ($n=284$)	Day 14 ($n=236$)
Sensitivity	100.0 (59.0–100.0)	100.0 (59.0–100.0)	100.0 (59.0–100.0)	100.0 (54.1–100.0)	100.0 (54.1–100.0)	100.0 (29.2–100.0)
Specificity	63.9 (58.0–69.4)	90.4 (86.3–93.6)	97.1 (94.4–98.7)	6.0 (3.5–9.4)	19.8 (15.3–25.0)	62.2 (55.6–68.5)
PPV	6.4 (2.6–12.7)	20.6 (0.9–37.9)	46.7 (21.3–73.4)	2.2 (0.8–4.7)	2.6 (1.0–5.6)	6.5 (2.4–13.5)
NPV	100.0 (98.0–100.0)	100.0 (98.6–100.0)	100.0 (98.6–100.0)	100.0 (80.5–100.0)	100.0 (93.5–100.0)	100.0 (97.5–100.0)

Data are % (95% confidence interval).
MLPT denotes semiquantitative pregnancy test.
Sensitivity was defined as the proportion of those with continuing pregnancies who obtained positive test results.
Specificity was defined as the proportion of those with absence of continuing pregnancy who obtained negative test results. *PPV* was defined as the proportion of those with positive test results who had a continuing pregnancy. *NPV* was defined as the proportion of those with negative test results who had no continuing pregnancy.

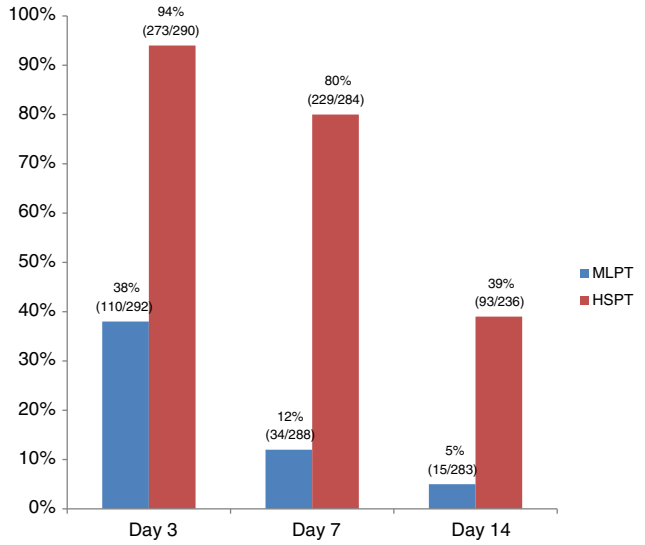

Fig. 2. Proportion of women for whom clinic-based follow-up would be recommended at study days 3, 7 and 14 days using standard follow-up protocols. Notes: Recommendation for follow-up was defined as indication of stable or increasing hCG when comparing the current test with the prior test result (MLPT), or a positive current test result (HSPT) or days 7 and 14; we assumed that all women who did not take a test on the designated day but received an accurate result in a previous test would have obtained the same result on the subsequent day.

additional care within the limits of the law. MLPT may offer such a possibility.

This study has some limitations. For instance, our protocol discussed study days as the number of days post mifepristone; however, the critical issue for hCG testing in early medical abortion is the number of days post misoprostol, given that the decline in hCG begins after taking misoprostol [19,20]. In our study, misoprostol was administered 24 h after mifepristone, allowing earlier assessment of abortion status. In settings where misoprostol is used 48 h later, MLPT follow-up may work better at different time points. We need more data to better understand options for the timing of MLPT follow-up. Further, although the protocol allowed for participation among women with gestations up to 63 days, the majority had gestations under 49 days. Finally, because the main value of an MLPT in early abortion follow-up is its ability to detect absence of continuing pregnancy, future research should consider including this endpoint as a primary outcome.

The ease with which women were able to use and interpret this MLPT opens a range of home and/or virtual follow-up options where clinic access to abortion care is limited [8]. This strategy also creates an enabling environment for task sharing in early medical abortion care [26]. Further research will contribute to efforts to further simplify service delivery models suitable to a range of environments. The test used in this study is not widely available, and its potential cost is unknown. The potential of MLPTs for medical abortion follow-up can only be realized once these tests are commercially available at minimal cost in settings worldwide.

Table 4
Participant views of at-home pregnancy test for medical abortion follow-up: % (*n*).

	MLPT group *n*=293	HSPT group *n*=291	p-value
Ease of use of test at home			
Very easy or easy	291 (99.3)	291 (100.0)	0.369
Neither easy nor difficult	1(0.3)	0	
Difficult or not very difficult	1 (0.3)	0	
Acceptability of time required to use test at home			
Very acceptable or acceptable	291 (99.3)	287 (98.6)	0.407
No opinion	2 (0.7)	4 (1.4)	
Unacceptable or very unacceptable	0	0	
Preferred location for managing abortion follow-up in future			
At clinic	28 (9.6)	25 (8.6)	0.286
At home with pregnancy test	257 (87.7)	263 (90.4)	
No preference	8 (2.7)	3 (1.0)	

Pearson chi-square for tests of differences between groups.

Contributors

JB, BW, PB and NTNN contributed to design of the original research. NTNN, NTBN and LVT were responsible for data collection. WS conducted the data analysis. JB and WS drafted the manuscript. All authors (JB, WS, NTNN, BW, PB, NTBN, LVT, RM) contributed to the interpretation of results.

Declaration of interests

We declare no competing interests. The anonymous donor that supported this study provided no infrastructure funding independent of research funding.

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