Title

Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond

Authors

Raymond, Elizabeth

Grossman, Daniel

Mark, Alice

et al.

Publication Date

2023-12-13

Peer reviewed

COMMENTARY

No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond

Elizabeth G. Raymond, MD, MPH[a]; Daniel Grossman, MD[b]; Alice Mark, MD, MSc[c]; Ushma D. Upadhyay, PhD, MPH[b]; Gillian Dean, MD, MPH[d]; Mitchell D. Creinin, MD[e]; Leah Coplon, MPH, RN[f]; Jamila Perritt, MD, MPH[g]; Jessica M. Atrio, MD, MSc[h]; DeShawn Taylor, MD, MSc[i]; Marji Gold, MD[j]

[a.] Gynuity Health Projects, New York, NY, eraymond@gynuity.org
[b.] Advancing New Standards in Reproductive Health (ANSIRH), Bixby Center for Global Reproductive Health, Department of Obstetrics, Gynecology, and Reproductive Sciences, University of California San Francisco, Oakland, CA, Daniel.Grossman@ucsf.edu, Ushma.Upadhyay@ucsf.edu
[c.] National Abortion Federation, Washington DC, amark@prochoice.org
[d.] Planned Parenthood Federation of America, New York, NY, gillian.dean@ppfa.org
[e.] Department of Obstetrics and Gynecology, University of California, Davis; Sacramento, CA, mdcreinin@ucdavis.edu
[f.] Maine Family Planning, Augusta, ME, lcoplon@mainefamilyplanning.org
[g.] Reproductive Health and Family Planning Specialist, Washington DC, jamila.perritt@gmail.com
[h.] Society of Family Planning, Clinical Affairs Subcommittee and Department of Obstetrics and Gynecology, Montefiore Hospital and Albert Einstein College of Medicine, Bronx, NY, jatrio@montefiore.org
[i.] Department of Obstetrics and Gynecology, University of Arizona College of Medicine Phoenix, Arizona, d.taylor@desertstarfp.org
[j.] Department of Family and Social Medicine, Albert Einstein College of Medicine, Bronx, NY, mgold@montefiore.org

Corresponding Author: Elizabeth Raymond, MD, MPH, Gynuity Health Projects, 220 E 42nd St #710, New York, NY 10017, 201-448-1230, eraymond@gynuity.org

Financial support: This work was supported by an anonymous donor and BaSe Family Fund.

Word count: 2256

The findings and conclusions in this article are those of the authors and do not necessarily represent the views of Planned Parenthood Federation of America, Inc.

Declarations of interest: MDC is a consultant for Danco Laboratories.

Keywords: abortion, mifepristone, misoprostol, ultrasound, COVID-19, pandemic, telehealth

1. INTRODUCTION

The COVID-19 pandemic is acutely threatening access to essential health services, including abortion.[1] Across all fields of medicine, changes in practice models are occurring rapidly. For patients seeking abortion, urgent modifications of current protocols are needed to ensure that patients can continue to obtain this time-sensitive treatment while limiting transmission of infection by maintaining distance between and among patients and providers. Remote delivery of care, which has recently been endorsed by local, state, and federal authorities as a key epidemic control measure,[2] will be indispensable to accommodate patients and staff who are navigating quarantines, stay-at-home directives, lack of transportation, new family or work obligations, or other unavoidable circumstances that impede their ability to go in in person to a health facility.

Fortunately, medication abortion (MA) using mifepristone and misoprostol can address many of these challenges. At present, MA typically entails a visit to a clinician or facility that provides abortion where an ultrasound or pelvic examination and often blood tests are performed to evaluate eligibility before pills are dispensed. Many abortion providers require a follow-up ultrasound or blood test after treatment to confirm abortion completion. However, research and experience have demonstrated that these tests, which inherently involve physical contact between patient and health care worker, are usually unnecessary for safe and effective MA.[3-7] Indeed, over the past 15 years, international organizations have provided mifepristone and misoprostol by mail to tens of thousands of patients screened only by history.[8-11] A prospective study conducted in 2015-2016 in the United States, Mexico, and Moldova provided 406 MAs without screening ultrasound or pelvic examination.[12] No serious adverse events were reported that resulted from the omission of the tests, and participants were highly satisfied.

To assist abortion providers with the current crisis, we present a sample protocol (Figure 1) for providing a "no-test" MA that includes recommendations for patient selection, Rh status evaluation and management, the treatment regimen, and follow-up. Although FDA-imposed restrictions on mifepristone dispensing may require patients to present to the abortion provider or facility to obtain the drug,[13] this protocol would enable every other part of the MA process to be implemented without any in-person encounter. The protocol is intended to serve as a guidance; abortion providers should use clinical judgment when adapting it for their practice settings and patient populations. Below we summarize the data that we considered in developing this protocol and our rationales for and comments on selected provisions.

2. PATIENT SELECTION

The three key goals of clinical evaluation before MA are (1) to confirm that the gestational age (GA) is within accepted limits for effective and safe outpatient treatment, (2) to exclude ectopic pregnancy, and (3) to establish that the patient has no other contraindications to MA.

The sample no-test MA protocol specifies an upper GA limit of 77 days as estimated from the first day of the last menstrual period (LMP). The LMP-based GA should be ≤77 days on the day of mifepristone ingestion, which may be later than the day the drug is dispensed if the patient plans to take the pills home for later use or if the medication is mailed or dispensed to a patient intermediary. The patient should be certain within one week of the LMP onset date.

We chose a 77-day limit because recent data have indicated that outpatient MA is safe and effective through that GA[14,15] and because this limit is consistent with current guidelines of the National Abortion Federation[16] and Planned Parenthood Federation of America (personal communication, Gillian Dean, MD, MPH, Planned Parenthood Federation of America). We note, though, that 2014 guidelines issued by the American College of Obstetricians

and Gynecologists (ACOG) and the Society for Family Planning[17] as well as the mifepristone label approved by the US Food and Drug Administration in 2016 specify a 70-day limit. In response to the pandemic, ACOG has recently issued a statement acknowledging that LMP-based gestational dating without ultrasound is acceptable, although no specific GA limit was specified.[18]

Regardless of the precise GA limit selected, use of the no-test approach will inevitably result in treatment of some fraction of patients whose true GAs exceed 77 days. Data from studies that compared LMP-based GA estimates to ultrasound-based estimates suggest that this fraction tends to be higher in patient populations that include more patients with advanced GA[19,20] and that it may be reduced by decreasing the LMP-based GA cutoff.[19] Reassuringly, the largest study, which was conducted in the United States in 2005-2007,[21] found that only 31 (1%) of 3,012 MA patients who were certain that their LMPs had started ≤77 days prior had GAs >77 days by ultrasound examination. Furthermore, international studies that included nearly two thousand patients treated with mifepristone and one or more misoprostol doses at 13-24 weeks of gestation reported efficacy and safety similar to that expected in earlier gestation: >93% of patients aborted without further intervention, 0.7-4% required transfusion, and no patient required hysterectomy or died.[22] Therefore, we expect that serious adverse health consequences of GA underestimation based on LMP will be rare. Nevertheless, clinicians using the no-test approach to MA should have a plan for managing or referring patients who may need a second trimester procedure to complete the abortion.

When assessing GA, providers may incorporate other historical information reported by the patient that, for simplicity, we do not mention in the sample protocol but that may indicate that the GA is greater than the proposed limit. For example, a patient who reports a positive pregnancy test >7 weeks before presentation is unlikely to have a GA of ≤77 days. The sample protocol does not exclude patients who report menstrual irregularity or

recent use of hormonal contraceptives. Although these conditions may signal ovulatory dysfunction, we expect that they would more likely lead to overestimation of GA than to underestimation, which is the primary concern for MA eligibility, and excluding patients with these conditions may therefore unnecessarily limit access by eligible patients.

MA with mifepristone and misoprostol is contraindicated in patients with ectopic pregnancy not because the drugs are dangerous for such patients but because the regimen is not a proven treatment for this condition. The sample no-test protocol excludes patients with significant symptoms of or risk factors for ectopic pregnancy; recent vaginal bleeding or pelvic pain, prior permanent contraception, prior ectopic pregnancy, or intrauterine device in place at conception.[23,24] We do not exclude patients who report prior pelvic inflammatory disease because unconfirmed diagnoses of this condition are associated with only a mildly increased risk.[24] We recognize that the listed criteria will not identify every patient with ectopic pregnancy; an estimated half of all patients with this condition have no risk factors.[25] However, published and emerging data suggest that the incidence of ectopic pregnancy among patients seeking MA is very low, <1%.[26,27] Moreover, substantial data[28-32] and current clinical MA guidelines[16,33] support treatment of patients in whom ectopic pregnancy has not been definitively excluded because the condition can be detected and managed afterwards. Thus, this aspect of the protocol is consistent with the standard of care.

The medical contraindications in the sample protocol are those listed in the FDA-approved mifepristone label. Patient history is sufficient for assessing these conditions.

3. RH TYPING AND OTHER PRE-TREATMENT LABORATORY TESTING

Recent research has suggested that the risk of Rh sensitization after early abortion is negligible.[34-36] Consequently, the National Abortion Federation has concluded that forgoing Rh typing and administration of anti-D immunoglobulin is reasonable for Rh-negative patients having aspiration

abortion before 56 days of gestation and may be considered for all patients having MA at less than 70 days.[16,37] The sample protocol is consistent with this conclusion. In addition, it specifies that testing is unnecessary for patients who can report a Rh-positive blood type or who are certain that they want no future children after the planned abortion. Any patient may opt out of Rh typing; the recent statement from ACOG notes that Rh testing and RhD immunoglobulin administration should not be a barrier to the provision of medication abortion.[18]

Hemoglobin/hematocrit and other laboratory tests are not routinely needed before first-trimester abortion but may be performed as indicated by medical history and patient symptoms.[16]

4. TREATMENT REGIMEN

The sample protocol specifies that patients should receive a standard regimen of mifepristone 200 mg orally and misoprostol 800 mcg vaginally or buccally.[16] In addition, each patient should be provided with an extra dose of misoprostol 800 mcg. Those with estimated GA >63 days should be instructed to take this second misoprostol dose 4 hours after the first to improve effectiveness.[16,38] Patients with estimated GA <63 days may be instructed to take the second dose if no bleeding occurs within the first 24 hours after the first dose or to retain it for use if recommended by the provider. Alternatively, all patients may be told to take two misoprostol doses 4 hours apart. Although this specific regimen has not been studied, trials of repeated doses of misoprostol in the first and second trimester suggest that it will be safe.[39-43]

5. SCHEDULED FOLLOW-UP

The primary goals of follow-up are to confirm absence of continuing pregnancy, to detect ectopic pregnancies not diagnosed before treatment, and to identify complications that need evaluation and treatment. To accomplish these goals, the sample protocol relies on patient symptoms and

high sensitivity urine pregnancy tests (HSPTs) that the patient performs at home. This strategy has been validated in several studies,[44,45] is consistent with current MA guidelines for follow-up of patients who have documented intrauterine pregnancies,[16,17] and is increasingly used by MA providers.

The sample instruction sheet (Figure 2), which includes a list of symptoms that may need in-person evaluation, is derived from studies of symptoms used to assess outcomes in MA patients with intrauterine pregnancies documented by ultrasound[44-47] and from experience in managing patients with ectopic pregnancies. The instruction sheet directs patients to contact the abortion provider if specified symptoms occur or the HSPT result is positive. Research has shown that patients can safely use these tools on their own to recognize when follow-up is needed,[48,49] and indeed patient-controlled follow-up is widely used for MA follow-up by provider organizations in multiple European countries.[50-52] However, the sample no-test protocol recommends a planned follow-up contact with the provider one week after dispensing the abortifacient medications to confirm absence of symptoms of ongoing or undiagnosed ectopic pregnancy or other potential complications. This contact may be conducted by videoconference, telephone, patient portal, email, text, or other telehealth modalities.[53,54]

MA failures are often detectable based on symptoms alone.[6,44,47-49] Nevertheless, the sample no-test protocol recommends a HSPT 4 weeks after misoprostol use to confirm pregnancy termination. Available data indicate that 5-25% of HSPTs performed about a month after MA treatment produce positive results, nearly all of which are "false positives" in patients who no longer have viable pregnancies.[44,45] Therefore, the sample protocol recommends that two HSPTs be provided initially to each patient. The patient should be instructed to call the provider if the result of the initial 4-week test is positive. If the patient is asymptomatic, a repeat test one week later may be appropriate. If the patient has symptoms of ongoing or ectopic

pregnancy or the second HSPT result is positive, further evaluation is indicated. The specific procedures for this evaluation should address the patient's individual clinical situation and may include ultrasound, serial serum HCG levels, additional urine pregnancy testing, or aspiration and tissue examination.

Patients receiving a no-test MA may remain at risk for having ectopic pregnancy until a negative HSPT result is obtained. Therefore, vigilant attention on the part of both provider and patients to symptoms such as increased pelvic or abdominal pain, continued vaginal bleeding, or dizziness is imperative.

6. COUNSELING

Patients requesting a no-test MA should receive standard pre-abortion counseling about pregnancy options, the risks and benefits of MA, expected results, side effects, and warning signs. In addition, each patient should be explicitly informed that LMP-based dating may underestimate GA, in which case efficacy may be lower than expected, bleeding and cramping may be heavier, and, rarely, fetal tissue may be visible. Moreover, patients should understand that without ultrasound, ectopic pregnancy will not be definitively excluded before treatment. To increase the chance of abortion success and reduce the time to diagnosis of ectopic pregnancy or MA complications, patients should be advised to diligently follow all instructions provided. However, patients should also be advised that serious adverse events of no-test abortion are expected to be rare and that side effects of MA can often be managed remotely. To avoid unnecessary infectious exposure during a pandemic as well as excess cost and inconvenience, patients should contact the abortion provider before seeking in-person care.

7. CONCLUSION

Although the COVID-19 crisis prompted the development of this sample protocol, we recognize that the pandemic is only one of many longstanding,

serious impediments to abortion access in the United States. Omitting unnecessary use of ultrasound, examination, and laboratory tests before MA can reduce barriers to this essential service by decreasing cost and enhancing convenience and comfort. The no-test approach can enable provision of abortion in new venues and by new categories of providers, and it can facilitate new service delivery models, such as synchronous or asynchronous telehealth, stationary or mobile "mini-clinics", pill pick-up arrangements, or dispensing via lockboxes or, potentially, by mail.[7,54] If the no-test strategy results in earlier treatment, it may increase MA success rates.[14,43,55] Details of the no-test MA protocol will certainly need to be revised as new evidence emerges, but we anticipate that this approach to providing the service will continue to be beneficial for both patients and abortion providers even after the current epidemic resolves.

ACKNOWLEDGEMENTS

We are grateful to Patricia Lohr, MD, MPH, British Pregnancy Advisory Service, and Alisa Goldberg, MD, MPH, Planned Parenthood League of Massachusetts, for invaluable advice and information.

REFERENCES

[1] American College of Obstetricians and Gynecologists. Joint Statement on Abortion Access During the COVID-19 Outbreak. 2020 [cited 2020 March 18]; Available from: https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak.

[2] Robeznieks A. Key changes made to telehealth guidelines to boost COVID-19 care. 2020 [cited 2020 29 March]; Available from: https://www.ama-assn.org/delivering-care/public-health/key-changes-made-telehealth-guidelines-boost-covid-19-care.

[3] Raymond EG, Grossman D, Wiebe E, Winikoff B. Reaching women where they are: eliminating the initial in-person medical abortion visit. Contraception 2015;92:190-3.

[4] Kapp N, Grossman D, Jackson E, Castleman L, Brahmi D. A research agenda for moving early medical pregnancy termination over the counter. BJOG 2017;124:1646-52.

[5] Ellertson C, Elul B, Winikoff B. Can women use medical abortion without medical supervision? Reprod Health Matters 1997;9:149-61.

[6] Harper C, Ellertson C, Winikoff B. Could American women use mifepristone-misoprostol pills safely with less medical supervision? Contraception 2002;65:133-42.

[7] Raymond E, Chong E, Winikoff B, et al. TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States. Contraception 2019;100:173-7.

[8] Aiken ARA, Digol I, Trussell J, Gomperts R. Self reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland. Bmj 2017;357:j2011.

[9] Gomperts RJ, Jelinska K, Davies S, Gemzell-Danielsson K, Kleiverda G. Using telemedicine for termination of pregnancy with mifepristone and misoprostol in settings where there is no access to safe services. BJOG 2008;115:1171-5; discussion 5-8.

[10] Gomperts R, Petow SA, Jelinska K, Steen L, Gemzell-Danielsson K, Kleiverda G. Regional differences in surgical intervention following medical termination of pregnancy provided by telemedicine. Acta Obstet Gynecol Scand 2012;91:226-31.

[11] Endler M, Beets L, Gemzell Danielsson K, Gomperts R. Safety and acceptability of medical abortion through telemedicine after 9 weeks of gestation: a population-based cohort study. BJOG 2019;126:609-18.

[12] Raymond EG, Tan YL, Comendant R, et al. Simplified medical abortion screening: a demonstration project. Contraception 2018;97:292-6.

[13] Raymond EG, Blanchard K, Blumenthal PD, et al. Sixteen Years of Overregulation: Time to Unburden Mifeprex. N Engl J Med 2017;376:790-4.

[14] Dzuba IG, Chong E, Hannum C, et al. A non-inferiority study of outpatient mifepristone-misoprostol medical abortion at 64-70 days and 71-77 days of gestation. Contraception 2020.

[15] Kapp N, Eckersberger E, Lavelanet A, Rodriguez MI. Medical abortion in the late first trimester: a systematic review. Contraception 2019;99:77-86.

[16] National Abortion Federation. Clinical Policy Guidelines. Washington DC: National Abortion Federation2020.

[17] American College of Obstetricians and Gynecologists. Practice Bulletin No. 143: Medical management of first-trimester abortion. Obstet Gynecol 2014;123:676-92.

[18] American College of Obstetricians and Gynecologists. COVID-19 FAQs for Obstetrician–Gynecologists, Gynecology. [cited 2020 30 March]; Available from: https://www.acog.org/en/clinical-information/physician-faqs/COVID19-FAQs-for-Ob-Gyns-Gynecology.

[19] Raymond EG, Bracken H. Early medical abortion without prior ultrasound. Contraception 2015;92:212-4.

[20] Constant D, Harries J, Moodley J, Myer L. Accuracy of gestational age estimation from last menstrual period among women seeking abortion in South Africa, with a view to task sharing: a mixed methods study. Reprod Health 2017;14:100.

[21] Bracken H, Clark W, Lichtenberg ES, et al. Alternatives to routine ultrasound for eligibility assessment prior to early termination of pregnancy with mifepristone-misoprostol. BJOG : an international journal of obstetrics and gynaecology 2011;118:17-23.

[22] Harris LH, Grossman D. Complications of Unsafe and Self-Managed Abortion. N Engl J Med 2020;382:1029-40.

[23] Barnhart KT. Clinical practice. Ectopic pregnancy. N Engl J Med 2009;361:379-87.

[24] Ankum WM, Mol BW, Van der Veen F, Bossuyt PM. Risk factors for ectopic pregnancy: a meta-analysis. Fertil Steril 1996;65:1093-9.

[25] Marion LL, Meeks GR. Ectopic pregnancy: History, incidence, epidemiology, and risk factors. Clin Obstet Gynecol 2012;55:376-86.
[26] Foster DG, Higgins JA, Karasek D, Ma S, Grossman D. Attitudes toward unprotected intercourse and risk of pregnancy among women seeking abortion. Womens Health Issues 2012;22:e149-55.
[27] Ulmann A, Silvestre L, Chemama L, et al. Medical termination of early pregnancy with mifepristone (RU 486) followed by a prostaglandin analogue. Study in 16,369 women. Acta Obstet Gynecol Scand 1992;71:278-83.
[28] Goldstone P, Michelson J, Williamson E. Effectiveness of early medical abortion using low-dose mifepristone and buccal misoprostol in women with no defined intrauterine gestational sac. Contraception 2013;87:855-8.
[29] Schaff EA, Fielding SL, Eisinger S, Stadalius L. Mifepristone and misoprostol for early abortion when no gestational sac is present. Contraception 2001;63:251-4.
[30] Heller R, Cameron S. Termination of pregnancy at very early gestation without visible yolk sac on ultrasound. J Fam Plann Reprod Health Care 2015;41:90-5.
[31] Bizjak I, Fiala C, Berggren L, et al. Efficacy and safety of very early medical termination of pregnancy: a cohort study. BJOG : an international journal of obstetrics and gynaecology 2017;124:1993-9.
[32] Li CL, Chen DJ, Song LP, et al. Effectiveness and Safety of Lower Doses of Mifepristone Combined With Misoprostol for the Termination of Ultra-Early Pregnancy: A Dose-Ranging Randomized Controlled Trial. Reproductive sciences 2015;22:706-11.
[33] Planned Parenthood Federation of America. Medical Standards and Guidelines. New York: Planned Parenthood Federation of America; 2018.
[34] Horvath S, Tsao P, Huang ZY, et al. The concentration of fetal red blood cells in first-trimester pregnant women undergoing uterine aspiration is

below the calculated threshold for Rh sensitization. Contraception 2020.

[35] Hollenbach SJ, Cochran M, Harrington A. "Provoked" feto-maternal hemorrhage may represent insensible cell exchange in pregnancies from 6 to 22 weeks gestational age. Contraception 2019;100:142-6.

[36] Wiebe ER, Campbell M, Aiken ARA, Albert A. Can we safely stop testing for Rh status and immunizing Rh-negative women having early abortions? A comparison of Rh alloimmunization in Canada and the Netherlands. Contraception: X 2019;1.

[37] Mark A, Foster AM, Grossman D, et al. Foregoing Rh testing and anti-D immunoglobulin for women presenting for early abortion: a recommendation from the National Abortion Federation's Clinical Policies Committee. Contraception 2019;99:265-6.

[38] Castillo P SP, Lugo Hernández EM, Castañeda Vivar JJ, Bousiéguez M, Dzuba IG. . Does a repeat dose of 800 mcg misoprostol following mifepristone improve outcomes in the later first trimester? A retrospective chart review in Mexico City. . Annual Meeting of the National Abortion Federation; Montreal, Canada2017.

[39] Raymond EG, Shannon C, Weaver MA, Winikoff B. First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. Contraception 2013;87:26-37.

[40] Abbas DF, Blum J, Ngoc NT, et al. Simultaneous Administration Compared With a 24-Hour Mifepristone-Misoprostol Interval in Second-Trimester Abortion: A Randomized Controlled Trial. Obstet Gynecol 2016;128:1077-83.

[41] Ashok PW, Templeton A, Wagaarachchi PT, Flett GM. Midtrimester medical termination of pregnancy: a review of 1002 consecutive cases. Contraception 2004;69:51-8.

[42] Hyland P, Raymond EG, Chong E. A direct-to-patient telemedicine abortion service in Australia: Retrospective analysis of the first 18 months. Aust N Z J Obstet Gynaecol 2018;58:335-40.

[43] Chen MJ, Creinin MD. Mifepristone with buccal misoprostol for medical abortion: a systematic review. Obstet Gynecol 2015;126:12-21.

[44] Perriera LK, Reeves MF, Chen BA, Hohmann HL, Hayes J, Creinin MD. Feasibility of telephone follow-up after medical abortion. Contraception 2010;81:143-9.

[45] Chen MJ, Rounds KM, Creinin MD, Cansino C, Hou MY. Comparing office and telephone follow-up after medical abortion. Contraception 2016.

[46] Clark W, Bracken H, Tanenhaus J, Schweikert S, Lichtenberg ES, Winikoff B. Alternatives to a routine follow-up visit for early medical abortion. Obstet Gynecol 2010;115:264-72.

[47] Jackson AV, Dayananda I, Fortin JM, Fitzmaurice G, Goldberg AB. Can women accurately assess the outcome of medical abortion based on symptoms alone? Contraception 2012;85:192-7.

[48] Raymond EG, Tan YL, Grant M, et al. Self-assessment of medical abortion outcome using symptoms and home pregnancy testing. Contraception 2018;97:324-8.

[49] Raymond EG, Shochet T, Bracken H. Low Sensitivity Urine Pregnancy Testing to Assess Medical Abortion Outcome: A Systematic Review. Contraception 2018.

[50] Millar SL, Cameron ST. Comparison of two low-sensitivity urine pregnancy tests for confirming the success of early medical abortion. The journal of family planning and reproductive health care 2017.

[51] Cameron ST, Glasier A, Johnstone A, Dewart H, Campbell A. Can women determine the success of early medical termination of pregnancy themselves? Contraception 2015;91:6-11.

[52] Hsia JK, Lohr PA, Taylor J, Creinin MD. Medical abortion with mifepristone and vaginal misoprostol between 64 and 70days' gestation. Contraception 2019;100:178-81.

[53] Endler M, Lavelanet A, Cleeve A, Ganatra B, Gomperts R, Gemzell-Danielsson K. Telemedicine for medical abortion: a systematic review. BJOG 2019.

[54] Upadhyay UD, Grossman D. Telemedicine for medication abortion. Contraception 2019;100:351-3.

[55] Abbas D, Chong E, Raymond EG. Outpatient medical abortion is safe and effective through 70 days gestation. Contraception 2015;92:197-9.

Figure 1. Sample Protocol for No-Test Medication Abortion

PURPOSE

To enable safe and effective provision of medication abortion without a mandatory pre-treatment ultrasound, pelvic examination or laboratory tests when medically appropriate, given that these tests may be significant barriers to access and, in the setting of a pandemic, may increase transmission of infection to patients and health care workers.

CRITERIA

- Pregnancy confirmed by patient report of urine or serum test or prior ultrasound
- Last menstrual period started ≤77 days before anticipated date of mifepristone ingestion
- Certain of last menstrual period onset date ± 1 week
- None of the following symptoms or risk factors for ectopic pregnancy:
    - Vaginal bleeding or spotting within the past week
    - Unilateral pelvic pain or significant bilateral pelvic pain within the past week
    - Prior ectopic pregnancy
    - Prior permanent contraception or other tubal surgery
    - IUD in uterus at conception or currently
- None of the following contraindications to medication abortion, assessed by history:
    - Hemorrhagic disorder or concurrent anticoagulant therapy
    - Chronic adrenal failure
    - Concurrent long-term systemic corticosteroid therapy
    - Inherited porphyria
    - Allergy to mifepristone, misoprostol, or other prostaglandin
- No strong preference for pre-treatment ultrasound, pelvic examination or laboratory tests

RH TYPING AND ADMINISTRATION OF ANTI-D IMMUNOGLOBULIN

- Not needed if the gestational age on the anticipated mifepristone ingestion date will be <70 days or if the patient reports positive Rh type, wants no future children, or declines anti-D immunoglobulin.
- Should be considered for women not meeting above criteria

TREATMENT

Provide the following:

- Mifepristone 200 mg orally
- Misoprostol 800 mcg x 2
- Analgesics, antiemetics per health facility protocol
- Patient instruction sheet and health facility emergency contact information
- Two high sensitivity pregnancy tests (HSPTs)

The patient should take mifepristone 200 mg orally followed by misoprostol 800 mcg buccally or vaginally 24-48 hours later. Patients with estimated GA >63 days should take a second dose of misoprostol 800 mcg 4 hours after the first. Patients with estimated GA ≤63 days should take the second dose if no bleeding occurs within the first 24 hours after the first misoprostol dose or if instructed to take it by a clinician. Review the instruction sheet with the patient.

FOLLOW-UP

1. Plan a follow-up contact with the patient one week after dispensing treatment.
2. If the patient reports indicators of continuing or ectopic pregnancy (e.g., any of the symptoms on the instruction sheet), evaluate with ultrasound or serum HCGs.
3. Otherwise, instruct the patient to perform the first HSPT 4 weeks after taking misoprostol (not earlier) and to contact the abortion provider if the result is positive.
4. If the patient has indicators of continuing or ectopic pregnancy, evaluate with ultrasound or serum HCGs
5. If the first HSPT result is positive but the patient has no such indicators, instruct the patient to perform the second HSPT in 1 week.

6. If second HSPT result is also positive, evaluate with ultrasound, serum HCGs, additional urine testing, or uterine aspiration.

Figure 2. Sample Instructions for Patients Receiving No-Test Abortion

1. **Call your abortion provider** if:
   - ☐ You vomit within the first 30 minutes after taking mifepristone.
   - ☐ You have a fever of 100.4°F or higher more than 24 hours after you take the misoprostol.
   - ☐ One week after taking misoprostol, you have any of the following:
     - o You have not had cramping and bleeding heavier than a period.
     - o Your bleeding is not getting lighter.
     - o You do not feel that you passed the pregnancy.
     - o Your pregnancy symptoms (such as nausea and breast tenderness) are not resolving.
   - ☐ At any time, you have any of the following:
     - o An increase in pain/cramps or bleeding more than 24 hours after taking misoprostol.
     - o Severe pain or cramps that don't get better with pain medicine, rest, or heating pads.
     - o Enough bleeding to soak 2 maxi pads an hour for more than 2 hours.
     - o Dizziness or vomiting lasting more than 2 hours.
     - o Weakness, nausea, or diarrhea lasting more than 24 hours.
2. Perform one urine pregnancy test 4 weeks after taking misoprostol (not earlier). **Call your abortion provider if the result is positive or invalid**. Use the second test if instructed to do so by your abortion provider.