

1 COMMENTARY

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

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

34 Word count: 2256

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

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

39

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

## 42 1. INTRODUCTION

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

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

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

## 83 2. PATIENT SELECTION

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

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

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

101 and Gynecologists (ACOG) and the Society for Family Planning[17] as well as  
102 the mifepristone label approved by the US Food and Drug Administration in  
103 2016 specify a 70-day limit. In response to the pandemic, ACOG has recently  
104 issued a statement acknowledging that LMP-based gestational dating without  
105 ultrasound is acceptable, although no specific GA limit was specified.[18]

106 Regardless of the precise GA limit selected, use of the no-test approach will  
107 inevitably result in treatment of some fraction of patients whose true GAs  
108 exceed 77 days. Data from studies that compared LMP-based GA estimates  
109 to ultrasound-based estimates suggest that this fraction tends to be higher in  
110 patient populations that include more patients with advanced GA[19,20] and  
111 that it may be reduced by decreasing the LMP-based GA cutoff.[19]

112 Reassuringly, the largest study, which was conducted in the United States in  
113 2005-2007,[21] found that only 31 (1%) of 3,012 MA patients who were  
114 certain that their LMPs had started  $\leq 77$  days prior had GAs  $> 77$  days by  
115 ultrasound examination. Furthermore, international studies that included  
116 nearly two thousand patients treated with mifepristone and one or more  
117 misoprostol doses at 13-24 weeks of gestation reported efficacy and safety  
118 similar to that expected in earlier gestation:  $> 93\%$  of patients aborted  
119 without further intervention, 0.7-4% required transfusion, and no patient  
120 required hysterectomy or died.[22] Therefore, we expect that serious  
121 adverse health consequences of GA underestimation based on LMP will be  
122 rare. Nevertheless, clinicians using the no-test approach to MA should have a  
123 plan for managing or referring patients who may need a second trimester  
124 procedure to complete the abortion.

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

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

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

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

### 156 3. RH TYPING AND OTHER PRE-TREATMENT LABORATORY TESTING

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

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

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

#### 172 4. TREATMENT REGIMEN

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

#### 185 5. SCHEDULED FOLLOW-UP

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

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

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

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



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

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

## 230 6. COUNSELING

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

## 246 7. CONCLUSION

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

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

## 262 ACKNOWLEDGEMENTS

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

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438  
439



440 **Figure 1. Sample Protocol for No-Test Medication Abortion**

441

442 **PURPOSE**

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

447

448 **CRITERIA**

- 449 • Pregnancy confirmed by patient report of urine or serum test or prior ultrasound  
450 • Last menstrual period started  $\leq 77$  days before anticipated date of mifepristone ingestion  
451 • Certain of last menstrual period onset date  $\pm 1$  week  
452 • None of the following symptoms or risk factors for ectopic pregnancy:  
453     o Vaginal bleeding or spotting within the past week  
454     o Unilateral pelvic pain or significant bilateral pelvic pain within the past week  
455     o Prior ectopic pregnancy  
456     o Prior permanent contraception or other tubal surgery  
457     o IUD in uterus at conception or currently  
458 • None of the following contraindications to medication abortion, assessed by history:  
459     o Hemorrhagic disorder or concurrent anticoagulant therapy  
460     o Chronic adrenal failure  
461     o Concurrent long-term systemic corticosteroid therapy  
462     o Inherited porphyria  
463     o Allergy to mifepristone, misoprostol, or other prostaglandin  
464 • No strong preference for pre-treatment ultrasound, pelvic examination or laboratory tests

465

466 **RH TYPING AND ADMINISTRATION OF ANTI-D IMMUNOGLOBULIN**

- 467 • Not needed if the gestational age on the anticipated mifepristone ingestion date will be  
468  $< 70$  days or if the patient reports positive Rh type, wants no future children, or declines  
469 anti-D immunoglobulin.  
470 • Should be considered for women not meeting above criteria

471

472 **TREATMENT**

473 Provide the following:

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

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

484

485 **FOLLOW-UP**

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

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

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

499 **1. Call your abortion provider if:**

- 500  You vomit within the first 30 minutes after taking mifepristone.
- 501  You have a fever of 100.4°F or higher more than 24 hours after you  
502 take the misoprostol.
- 503  One week after taking misoprostol, you have any of the following:
- 504       o You have not had cramping and bleeding heavier than a period.
- 505       o Your bleeding is not getting lighter.
- 506       o You do not feel that you passed the pregnancy.
- 507       o Your pregnancy symptoms (such as nausea and breast  
508 tenderness) are not resolving.
- 509  At any time, you have any of the following:
- 510       o An increase in pain/cramps or bleeding more than 24 hours after  
511 taking misoprostol.
- 512       o Severe pain or cramps that don't get better with pain medicine,  
513 rest, or heating pads.
- 514       o Enough bleeding to soak 2 maxi pads an hour for more than 2  
515 hours.
- 516       o Dizziness or vomiting lasting more than 2 hours.
- 517       o Weakness, nausea, or diarrhea lasting more than 24 hours.
- 518 **2. Perform one urine pregnancy test 4 weeks after taking misoprostol (not**  
519 **earlier). **Call your abortion provider if the result is positive or****  
520 **invalid.** Use the second test if instructed to do so by your abortion  
521 provider.
- 522