

Commentary

# Reaching women where they are: eliminating the initial in-person medical abortion visit<sup>☆</sup>

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## Abstract

The requirement that every woman desiring medical abortion must come in person to a clinical facility to obtain the drugs is a substantial barrier for many women. To eliminate this requirement in the United States, two key components of the standard initial visit would need to be restructured. First, alternatives to ultrasound and pelvic exam would need to be identified for ensuring that gestational age is within the limit for safe and effective treatment. This is probably feasible: for example, data from a large study suggest that in selected patients menstrual history is highly sensitive for this purpose. Second, the Food and Drug Administration would need to remove the medically unwarranted restriction on distribution of mifepristone. These two changes could allow provision of the service by a broader range of providers in nontraditional venues or even by telemedicine. Such options could have profound benefits in reducing cost and expanding access to abortion. © 2015 Elsevier Inc. All rights reserved.

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The development of medical abortion with mifepristone and misoprostol was an important breakthrough in public health in part because it had the potential to offer a safe, effective and private way to terminate an unwanted pregnancy in settings where skilled surgeons were unavailable. Research over the past decade has focused on evaluating approaches to “demedicalize” the procedure. Consequently, we now have compelling evidence that nonphysician providers can effectively offer the service [1], that women can safely take both drugs at home [2,3], and that with simple tools, women can verify abortion completeness without having to come to a clinic [4–6]. These

practices have considerable logistical advantages for both women and providers.

Universally, medical abortion protocols still require that each patient must present in person to a clinical facility to obtain the service. In the United States, this visit typically includes multiple procedures: the provider counsels and instructs the patient to ensure that she understands the procedure; performs an ultrasound or pelvic examination to confirm the existence, duration and location of the pregnancy; ensures that she has no medical contraindications; determines her Rh type and administers Rh(D) immune globulin if she is Rh-negative; dispenses the abortifacient drugs; provides associated medications such as analgesics; and arranges follow-up. This required visit can be a major barrier to access, particularly in settings with a limited distribution of abortion providers. Even for women who live near an abortion facility, the visit may be expensive and inconvenient. Developing approaches to allow women to obtain medical abortion without a clinic visit is thus a

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Table 1  
Contraindications listed in FDA-approved mifepristone label.

<ul style="list-style-type: none"> <li>• Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass</li> <li>• Intrauterine device in place</li> <li>• Chronic adrenal failure</li> <li>• Concurrent long-term corticosteroid therapy</li> <li>• History of allergy to mifepristone, misoprostol or other prostaglandin</li> <li>• Hemorrhagic disorders or concurrent anticoagulant therapy</li> <li>• Inherited porphyrias</li> </ul>
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worthy goal. We propose here that this goal is feasible, at least for selected women.

Certainly many elements of the initial visit do not require a clinical venue. Counseling and instruction, for example, is performed by speaking with the patient and using written materials. Mifepristone and misoprostol have few contraindications (Table 1), most of which are detectable solely by history; measurement of vital signs, general physical examination and laboratory tests such as hemoglobin or tests for sexually transmitted infections, although commonly performed, are unnecessary for assessing medical abortion eligibility. Pregnancy itself can be diagnosed with a home urine pregnancy test. Many abortion patients know their Rh type, or they could get a test at a commercial laboratory. Management of women who are Rh-negative would need consideration as Rh(D) immune globulin is generally available only in clinical settings. Notably, an evidence base supporting the need for this treatment in women having first trimester abortion is lacking [7]. Regardless, this prophylaxis is not needed by the 85% of US women who are Rh-positive.

Two components of the standard initial medical abortion visit would have to be restructured in order to facilitate medical abortion without an in-person clinical encounter. The first is the ultrasound and pelvic exam, which are used primarily to estimate gestational age (GA) and are generally impracticable outside a clinical facility. But GA can be estimated in other ways. Many pregnant women know when they had sex, when they stopped using contraception and when their last menstrual period began. For these women, such historical information may reliably indicate whether GA is below the limit for outpatient medical abortion, which recent data indicate is safe and effective through at least 70 days of gestation [8–11]. Indeed, a recent study of 4257 women seeking medical abortion at 10 clinics across the United States found that menstrual history alone can be highly accurate for this purpose: if women who were certain that their last menstrual periods had started within the prior 8 weeks (56 days) had been permitted to forgo ultrasound and pelvic exam, nearly two thirds of the total patients could have avoided these tests, and only 0.6% of that group would have received treatment beyond the evidence-based limit [12,13].

Quantitative serum human chorionic gonadotropin (HCG) testing may provide further reassurance that a patient's GA is not above the limit. HCG production rises in the first trimester of pregnancy and then falls and plateaus

[14]. It seems possible that a concentration cutoff could be identified that in combination with menstrual history could identify a pregnancy of less than 70 days. If so, a woman who is eligible by history and who wants medical abortion without a clinic visit could be sent to a local laboratory to obtain an HCG titer, and a result below the cutoff would confirm that her GA is within the limit for the procedure. Research to refine this idea and test its feasibility would be useful.

Performing an ultrasound or exam on every patient requesting a medical abortion to identify a small proportion with advanced gestation is arguably unwarranted. As the efficacy of medical abortion decreases with GA, one risk of missing such a patient is continuing pregnancy; however, if the failed abortion is recognized promptly, the consequences would be minimal. Alternatively, the abortifacient drugs may work, resulting in a later abortion at home. Although data are scant, serious harm from such an event seems unlikely. One published study included 136 women treated with a standard outpatient mifepristone and misoprostol regimen at 70–83 days; of these women, more than 90% had complete abortion without surgical intervention, and only one had a serious complication (bleeding treated with transfusion) [15]. The risks of home abortion are higher even later in pregnancy but are still considered acceptable in some circumstances; for example, patients having second trimester surgical abortion are commonly pretreated with digoxin [16] despite the small possibility of extramural expulsion [17].

Some abortion providers rely on pretreatment ultrasound to exclude ectopic pregnancy. Although mifepristone and misoprostol clearly do not cause this condition and have no known effect on its clinical course, providers are concerned about missing the opportunity to make the diagnosis. In addition, some of the expected side effects of the abortifacient drugs overlap with and thus may obscure the symptoms of ectopic pregnancy. However, although in the United States, about 2% of all pregnancies are ectopic [18], the prevalence is about an order of magnitude lower in medical abortion patients. In the US study cited above, only 0.2% of patients presenting for treatment had this condition [12], and in an earlier, even larger study of more than 16,200 women in France, the proportion was 0.1% [19]. Moreover, mandating that all abortion patients be screened for ectopic pregnancy is inconsistent with other screening standards. For example, women planning to continue their pregnancies are not advised to have early ultrasounds to confirm pregnancy location despite their much greater risk of ectopic gestation. Testing for other conditions that are not directly related to abortion, such as cervical dysplasia or sexually transmitted infections, is not obligatory before medical abortion. Guidelines on medical abortion produced by the American College of Obstetricians and Gynecologists, the Royal College of Obstetricians and Gynaecologists, and the World Health Organization specifically note that ultrasound to rule out ectopic pregnancy is unnecessary in women without risk factors or symptoms [20,21].

Possibly the most important concern with omitting pretreatment ultrasound or exam is the risk that since these

tests are currently standard, an abortion provider who does not perform them could face a malpractice suit if an adverse event occurs. However, standards of care can be changed, and meanwhile, this problem could be mitigated with counseling and documented consent from the patient. Ultimately, under the ethical principle of autonomy, the properly informed patient herself should make the final decisions regarding her care [22].

In the United States, the second issue that would need to be addressed to allow medical abortion without an initial in-person clinical visit is the dispensing of the mifepristone to the patient. The US Food and Drug Administration (FDA) currently requires that mifepristone be distributed to patients only in clinics, medical offices, and hospitals by healthcare providers who have signed a Prescriber's Agreement. This requirement, which was established when the drug was approved in 2000, has no medical justification. Because the pharmacologic action of mifepristone does not occur until several hours after ingestion, the location where the drug is dispensed is entirely irrelevant to patient safety: patients receiving the drug in an office may take it elsewhere, and they are nearly always elsewhere before any adverse effect could occur. Since in evidence-based practice, each patient receives only a single 200-mg tablet sufficient for her own abortion, redistribution of the drug is not a concern. The Prescriber's Agreement is an unenforceable and unenforced self-certification, and in any case, it is unnecessary for a drug that is as safe and simple to use as mifepristone. Certainly other drugs that are much more dangerous than mifepristone and have greater abuse potential are safely distributed by standard prescription at pharmacies. Fortunately, this problem is easily resolvable: FDA can amend its requirements.

Addressing these two issues could have prompt and profound benefits for provision of medical abortion even within clinical settings. Without ultrasound and exam, the cost of the procedure would be reduced. Minimizing the time that the clinician or ultrasound technician spends with each patient could enable abortion facilities to serve more women effectively. Abortion could be offered by a broader range of providers and in nontraditional places, since training in pelvic exam and ultrasound and the requisite equipment for performing these procedures would not be needed. Allowing mifepristone to be obtained from pharmacies would eliminate the need for clinics to stock the drug, which can be time consuming and expensive.

More importantly, these changes would also enable provision of medical abortion to at least some women entirely remotely — that is, by telemedicine. Telemedicine abortion is currently available in a few US states; an evaluation of a program in Iowa suggested that it increased the number of clinics that provided the service and enhanced accessibility, particularly to women living in remote areas [23,24]. However, the existing domestic programs all require that the patient be present in a facility that stocks mifepristone and that has a preestablished relationship with a remote abortion provider. These requirements limit the potential of these programs to reach large numbers of women.

A more inclusive approach would be a direct-to-consumer telemedicine model that patients could access from their homes. At least two such services are already in place in other countries. Women on Web is an Internet-based program based in the Netherlands that makes medical abortion available to women in countries with restricted abortion access [25]. To use this service, a woman enters information into an on-line form. If specified eligibility criteria are met, the program mails the pills to the patient. Since 2006, the service has provided medical abortion to about 45,000 women (R. Gomperts, personal communication).

A direct-to-consumer telemedicine abortion service was also recently initiated in Canada [26]. Each patient communicates with the abortion provider from her home using a popular Internet-based videoconference platform. She is directed to a laboratory for a quantitative serum HCG test; ultrasound is not required if the concentration is <5000 mIU/ml. The service mails or prescribes the abortifacient drugs to eligible patients. In this service, follow-up is also done remotely: abortion completeness is assessed by a decline in quantitative serum HCG concentration, and if in person treatment is judged to be required, it is arranged by the service. To date, 30 patients have been treated through this service, of whom one was lost to follow-up, one had surgical completion of the abortion, one decided to continue the pregnancy and the rest had successful medical abortions. None had any significant complications.

Recently in the United States, access to abortion has become increasingly limited. Many women, particularly in rural areas, travel exceedingly far to obtain this service [27]. Abortion itself is costly — a 2014 survey of members of the National Abortion Federation found an average charge of more than \$500 (V. Saporta, personal communication) — and the additional expenses incurred for travel, childcare and lost wages may be substantial [28]. In addition, harassment of patients by protesters is common: in a 2011 national survey, 53% of abortion providers reported picketing at least 20 times a year, and 28% reported that this picketing involved physical contact or blocking of patients [29]. These barriers, as well as the profound stigma currently associated with abortion, impair women's ability and willingness to attend abortion clinics. The consequences may be serious: some women may delay the procedure, which increases clinical risk, and some may even forgo the procedure altogether, resulting in unwanted births.

Eliminating the in-person visit and providing medical abortion by telemedicine has great potential to alleviate these problems. By enabling women to obtain abortions more promptly and by making them available to some women who currently cannot access them at all, telemedicine could benefit women's health and lives. It is an option that should be urgently explored.

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