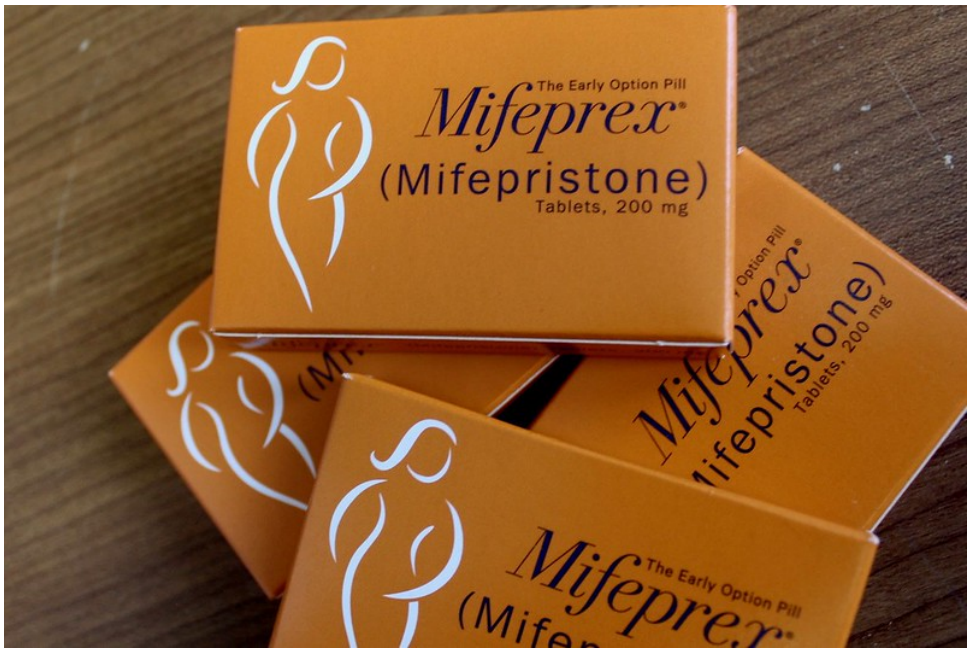
HEALTH, NATIONAL

No-Test Medication Abortion Increases Safety and Access During COVID-19

5/13/2020 by **CARRIE N. BAKER**



FEMINIST DAILY NEWS

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With increasing Taliban restrictions against

A new study proposes an innovative, no-test medication abortion protocol that would enable clinicians to safely administer medication abortion to patients without any preliminary tests or in-person encounters. (Robin Marty / Flickr)

Imagine a world where women could access safe and supported abortion health care without ever leaving their homes. In this world, after a phone call or video conference with a health care professional, women could receive the abortion pill in the mail, which they could take safely in the privacy of their own homes under the supervision of a clinician.

No invasive, time-consuming pelvic exams or blood tests. No state-mandated ultrasounds or waiting periods requiring multiple visits. No walking past lines of screaming anti-abortion protesters. No driving long distances, having to find and pay for child care, or taking time off from work. No exposure to COVID-19.

A recent study published in the medical journal *Contraception* offers a new way to make this world possible.

The study's ten authors—doctors and public health experts—propose an innovative, no-test medication abortion protocol that would enable clinicians to safely administer medication abortion to patients without any preliminary tests or in-person encounters. This would enable patients to access essential abortion health care while also social distancing.

Standard Protocol Requires Ultrasound, Blood Test and Follow-Up

The standard medical protocol for medication abortion currently requires two tests before the medication can be administered: an **ultrasound** to determine the gestational age of the pregnancy and a **blood test**.

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Gestational age is important because the U.S. Food and Drug Administration (FDA) restricts the use of medication abortion to the first 77 days of pregnancy.

The blood test determines whether the patient has an Rh negative blood type—in which case they may receive counseling and/or anti-D immunoglobulin treatment.

The study found that these tests are usually unnecessary for safe and effective medication abortion, noting that international organizations for the past 15 years have safely provided abortion pills by mail to tens of thousands of patients screened only by a brief medical review.

The study also cites research conducted in the United States, Mexico and Moldova where medical professionals provided medication abortion to 406 patients without a screening ultrasound or pelvic examination. No serious adverse events resulted from the omission of the tests, and participants were highly satisfied. In fact, in many European countries, medical standards do not recommend Rh testing for abortion or miscarriage in early pregnancy.

In addition to the preliminary tests, standard medical protocol requires a follow-up appointment to confirm the absence of a continuing pregnancy. The no-test protocol recommends a planned follow-up contact conducted by videoconference, telephone, patient portal, email or text, along with urine pregnancy tests that the patient purchases online or from a local pharmacy and performs at home.

ACOG issued guidance on March 30 stating that clinicians can perform an assessment, counseling and consent for medication abortion by video or telephone, and that an ultrasound and Rh testing is not necessary.

"As Providers, We Can Stand With [Women] in Partnership"

One of the study's co-authors, Dr. Jamila Perritt, told *Ms.* that her patients have responded very positively to the new protocol.

"Folks love it. They opt for it. Especially [women] who are confident about when their periods are." says Dr. Perritt. "Sixty-two percent of folks who have abortions already have children. Many already know their blood type. They can tell you. People are really good at self-screening. If we actually trust people, as providers we can stand with them in partnership, this is a really good way to take care of our community."

The elimination of unnecessary medical tests would likely decrease the cost of abortion health care and increase access, says Dr. Perritt.

Ultrasound machines can cost providers $30,000—at the low end. If states mandate ultrasounds or standard medical protocols recommend them, doctors cannot provide abortion care without making this sizable investment.

Similarly, standard Rh testing increases the cost of abortion—since, in order to be able to perform the testing, providers have to be part of a system of regulation and inspection by health departments. This can burdensome for a private practice.

"Because of the way that medication abortion is restricted, part of the cost of medication abortion includes mandated ultrasounds, blood work and follow-up appointments," says Dr. Perritt. "If based on this protocol, we are able to show that this

medication is safe and effective and works really well, then the hope will be that the cost will go down."

There are of course other barriers—like the fact that 18 states currently require the prescribing clinician be physically present while medication abortion is dispensed, and that 14 states require that abortion providers perform an ultrasound on each woman seeking an abortion. But these requirements are not medically necessary.

FDA Restrictions on Mifepristone Another Barrier

While the no-test protocol is an important step toward increasing access to medication abortion, another important step is to eliminate FDA restrictions on the abortion pill mifepristone.

When initially approved by the FDA, anti-abortion forces blocked easy access to mifepristone (the abortion pill) by convincing the FDA to issue a restricted approval under what was called at the time Subpart H regulations, the precursor to the FDA's Risk Evaluation and Mitigation Strategy (REMS)—a drug safety program that allows the FDA to restrict the circulation of certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.

Under the REMS program, mifepristone must be dispensed by a clinic, medical office or hospital under the supervision of a healthcare provider registered with the drug manufacturer.

Additionally, patients must sign a "Patient Agreement" form confirming that they received counseling on the risks associated with the medication.

The requirement to appear on a registry with the drug manufacturer may discourage some providers from offering medication abortion for fear of becoming a target of anti-abortion protesters.

“There are more complications and deaths associated with Tylenol than mifepristone,” says Dr. Perritt. “If we are looking at it truly based on safety, then the argument doesn’t hold water.”

In fact, the abortion pill is six times safer than Viagra—yet the FDA allows men to receive this pill by mail.

While the no-test protocol is an important step toward increasing access to medication abortion, another important step is to eliminate FDA restrictions on the abortion pill mifepristone. (Robin Marty / Flickr)

Pressure is building on the FDA to remove the REMS restriction on the abortion pill. Attorneys general in 21 states recently signed an open letter to the FDA demanding the removal of these restrictions in order to make abortion more accessible during COVID-19.

Taking another approach, Francine Coeytaux and Elisa Wells of Plan C are challenging the consensus understanding of the REMS restriction that the pill cannot be mailed to patients. They argue that providers may distribute mifepristone by mail. Coeytaux and Wells have been working with doctors across the country to register with the manufacturers of the pill. Dozens of

doctors have signed up and several have already started shipping the pills or plan to do so soon.

"Most U.S. providers have taken the REMS to mean that mifepristone cannot be mailed," Wells told the New York Times. "We disagree. We think providers have clear latitude to 'dispense' the drug from their offices and then ship it to patients, and we're hearing from more and more of our colleagues who see it the same way."

Telemedicine Abortion

Elimination of the FDA restriction combined with the no-test medication abortion protocol would open up the possibility of telemedicine abortion—where health care providers supervise the use of abortion pills via videoconferencing or telephone consultations and send the medication to patients through the mail.

In fact, telemedicine abortion is already available in thirteen states under a research exception to the REMS requirement. Since 2016, the organization Gynuity has operated a research study on telemedicine abortion called TelAbortion, which allows clinicians participating in the study to provide medication abortion care by videoconference and mail mifepristone.

The study is currently running in 13 states: Hawaii, Washington, Oregon, New Mexico, Colorado, Georgia, New York, Maine, Iowa, Minnesota, Illinois, Maryland and Montana.

However, patients are still required to make an in-patient visit to obtain an ultrasound under the REMS program. But recent FDA COVID-19 guidance for testing relating to REMS drugs provides some flexibility in whether doctors must do these the ultrasound, stating that health care providers should "use their best medical judgment in weighing the benefits and risks of continuing treatment in the absence of laboratory testing and imaging studies."

"This is a move toward a broader goal," Dr. Perritt told *Ms.* "This medication is safe. People know how to take it on their own. We should trust people to care for themselves in the way that they see best. And the evidence supports it. My hope is that this no-test protocol is an early step to broadening access."

TAGGED: ABORTION ACCESS, ABORTION PILLS, ABORTION PROVIDERS, ANTI-ABORTION LAWS, COVID-19

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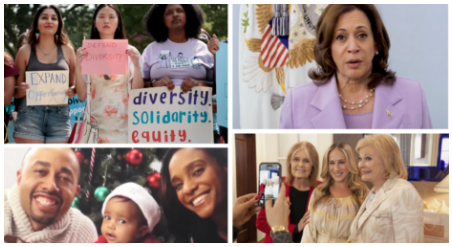

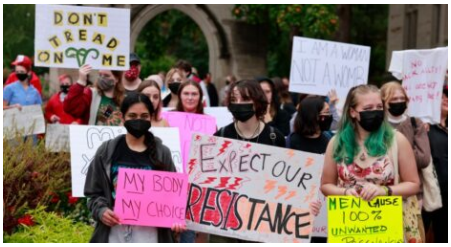

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