No-Test Chemical Abortion Provision: Can it be Justified?

Ingrid Skop, M.D.
Previous Reports:

Jameson Taylor, Ph.D., *Using Tax Policy to Fund Pro-Life Objectives: Case Study in Mississippi*, On Point Series 79
Robert Marshall, M.A., *We the People Say No: The Democratic Demise of the ERA*, On Point Series 76
Amanda Stirone Mansfield, J.D., *Alternatives to Abortion Programs: Support for Mothers and Families*, On Point Series 74
Jeanneane Maxon, J.D., *Continued Attempts to Regulate Pro-Life Pregnancy Help Centers Amount to ‘Lipstick on a Pig’*, On Point Series 73
Susan Wills, J.D., L.L.M., Kathi Aultman, M.D., *Does Banning Abortions After 15 Weeks Make Any Sense?*, On Point Series 68

The full text of this publication can be found at: https://lozierinstitute.org/no-test-chemical-abortion-provision-can-it-be-justified

Comments and information requests can be directed to:

Charlotte Lozier Institute
2800 Shirlington Rd, Suite 1200
Arlington, VA 22206
E-mail: info@lozierinstitute.org
Ph. 202-223-8073 /www.lozierinstitute.org

The views expressed in this paper are attributable to the author and do not necessarily represent the position of the Charlotte Lozier Institute. Nothing in the content of this paper is intended to support or oppose the progress of any bill before any legislative body.
Despite their verbal commitment to safe abortion provision, abortion advocates are advancing a dangerous strategy. The U.S. Food and Drug Administration (FDA) requirements for in-person medical evaluation prior to medical abortion pill provision have been permanently removed. Researchers associated with abortion advocacy organizations recently published a study in the prestigious *Journal of The American Medical Association Internal Medicine*, “Outcomes and Safety of History-Based Screening for Medication Abortion” that supposedly demonstrated the safety of this “hands-off” approach. Many undocumented assumptions have been made to portray unsupervised, “self-managed” medical abortion as safe. These erroneous conclusions will, in fact, cause the procedure to become more dangerous for a woman seeking abortion, and will be addressed below.

The principal authors, Dr. Ushma Upadhyay and Dr. Elizabeth Raymond, performed a retrospective cohort study of 3779 women seeking medical abortions (more accurately termed “chemical abortions” because these pills lack the healing properties usually associated with medication). The abortions were provided through fourteen U.S. abortion clinics and did not include the standard pre-abortion ultrasound or physical exam. The article’s summary reported that 2/3 (66.4%) received their chemical abortion pills in person and 1/3 (33.6%) received the pills through the mail. Although they reported that some follow-up data was available on 3/4 (74.8%) of the women, abortion outcomes were only known on less than 2/3 (63.4%), placing the study conclusions in doubt.

Twelve (0.5%) women had major abortion related adverse events (defined as hospital admission, blood transfusion, major surgery, including laparotomy and laparoscopy for ectopic pregnancy, or death). Four (0.22%) were treated for previously undiagnosed ectopic pregnancies. Nine (0.4%) were retrospectively noted to have taken chemical abortion pills past the approved gestational age limits, including one who delivered a stillborn fetus of approximately 33 weeks gestation at home. According to the authors’ assessment, overall effectiveness was 94.8% (95.4% when distributed in-person and 93.3% when mailed). They optimistically assumed similar successful outcomes for the 1/3 of women for whom the abortion outcomes were unknown.

It is important to note that abortion advocates frame their statistics in terms of “effectiveness” or “abortion completion” rates rather than “abortion failure” rates. A chemical abortion was determined to have failed if the patient required a surgery or additional medications, was treated for a previously undiagnosed ectopic pregnancy, or if the medication failed to kill the fetus (which happened in 1.7%). While 95% success sounds reassuring (after all, one would be pleased with a child who consistently received

---

an A grade of 95%), when the statistic is presented in terms of failure, with one in twenty (5%) of women requiring unexpected surgery, then it sounds more concerning.

To fully understand the dangers of an unsupervised approach to chemical abortion, one needs to understand how chemical abortions have traditionally been administered, and how with a verbal sleight of hand, a much more dangerous approach is substituted. The chemical abortion pill regimen approved by the FDA consists of two components. The first, mifepristone (Mifeprex or RU486), blocks progesterone receptors to cut off hormonal support for the pregnancy, resulting in disruption of the placenta and causing embryonic or fetal death. The second, misoprostol (Cytotec), is taken 24-48 hours later to induce contractions to expel the dead baby and placenta.¹

Mifepristone is distributed in accordance with a Risk Evaluation and Mitigation Strategy (REMS), a safety strategy applied to medications that have potential serious risks associated with them. Mifepristone was initially only approved up to 49 days’ gestational age, the provider was registered after specific training, the chemical was only to be dispensed in certain healthcare settings, and the patients were to be informed of the risk of serious side effects. Mifepristone abortion providers were required to accurately determine gestational age, confirm an intrauterine location, and intervene surgically if needed (or have an arrangement with a provider who could perform that intervention).²

A supplemental application was approved by the FDA in 2016, which loosened these restrictions, extending use until 70 days’ gestational age, despite very few studies and much higher failure rates in later gestational ages.³ There was modification of the dose, timing, and route of administration. Abortionists were no longer required to report a complication unless it resulted in a woman’s death.⁴ Although U.S. abortion advocates reassure the public that chemical abortion is as safe as Tylenol or a shot of penicillin, they make these claims by analyzing non-mandatory complication reporting that is known to be incomplete, undoubtedly underestimating complications.⁵

---

² Danco Laboratories. Risk Evaluation Mitigation Strategy (REMS). NDA 020687 Mifeprex® (mifepristone) tablets, 200 mg; March 2016. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf.
It has long been the goal of the abortion industry to remove all restrictions on chemical abortions so that they can be obtained outside of the medical system and unregulated by the legal system. The removal of the FDA’s in-person requirement is a necessary key step toward reaching this goal. This transfers the responsibility for risk solely to women, allowing the abortion provider to end unborn lives from afar, leaving women abandoned and suffering complications alone.

Starting with the unproven assumption that women confronting an unintended pregnancy "need" to procure an abortion, several variables in this process must be questioned:

1. Are there advantages to a chemical abortion compared to a surgical abortion?
2. Should ease of access to abortion be a primary consideration, outweighing safety?
3. What are the advantages of pre-abortion testing?
4. What are the disadvantages of remote distribution?

One: There are distinct disadvantages of a chemical abortion compared to a surgical abortion.

Although recent abortion trends document a steady increase in chemical abortion as a percentage of all U.S. abortions\(^7\), this increase is driven by factors (such as lower product cost and decreased need for trained surgeons and surgical equipment) that benefit the abortion provider, but not the woman. A surgical abortion is faster and less likely to result in complications. The average woman undergoing a chemical abortion will bleed for nine to 16 days, and eight percent will bleed longer than a month. Almost all will experience side effects of labor-like cramping, heavy bleeding, nausea, vomiting, fever, chills, headache, diarrhea, and dizziness.\(^8\) A records-linkage study of more than 42,000 abortions documented four times as many complications after chemical (20%) than surgical abortions (5.6%). Hemorrhage (15.6 vs 2.1%) and incomplete abortion (6.7 vs 1.6%) were the most common complications, and almost 6% of the women undergoing chemical abortions required surgical completion.\(^9\)

The 2014 American College of Obstetricians and Gynecologists (ACOG) practice bulletin on medication abortion listed the following situations where chemical abortion has not been studied and may be dangerous: hemoglobin < 9.5 g/dL, severe liver, renal or respiratory disease or uncontrolled hypertension or cardiovascular disease. Additionally,


ACOG stated that women are not good candidates for chemical abortion if they are unable to adhere to care instructions, desire quick completion of the abortion, are not available for follow-up or cannot understand the instructions because of comprehension or language barriers. Despite no intervening studies documenting safety of chemical abortion for women suffering from these conditions, this advice was removed from the 2020 update bulletin, and the prior bulletin has been removed from the archives.

Many studies presumably documenting the safety of remote chemical abortion provision have abysmal follow-up rates (frequently 20-40% of woman have unknown outcomes). Women who suffer complications often present in distress to an emergency room rather than returning to the abortion provider, and it cannot be assumed that those for whom data are unknown have had successful chemical abortions.

Many women suffer from anemia due to iron deficiency from poor nutrition or heavy periods, or inherited disorders such as sickle cell anemia, sickle cell trait, or thalassemia. These women are likely to have a baseline hemoglobin below the 9.5 g/dL cutoff, but most remote abortion protocols do not screen for these disorders (and certainly remote provision without labs has no way of detecting a woman’s hemoglobin). The extreme blood loss that can occur with a chemical abortion may bring an anemic patient perilously close to hemodynamic compromise (the inability for her compromised blood supply to adequately sustain her body).

Additionally, other known risk factors increase the likelihood of failed chemical abortion: older maternal age, advanced pregnancy, multiple prior deliveries, prior miscarriages, and prior induced abortions. Counseling women about additional risk might compel them to choose a surgical abortion instead, or perhaps if they were thoroughly counseled about all potential risks of abortion, they might choose to continue their pregnancies. It is likely that a remote abortion provider may fail to counsel a woman on options other than abortion. Even in-person abortion provision seems to be deficient in this vital element of informed consent. Planned Parenthood’s annual report documents

that 96% of their pregnancy outcome services are abortion, demonstrating the clear inadequacy of options counseling by many abortionists.\textsuperscript{13}

\textbf{Two: Convenience should not trump safety.}

Inequality of abortion access is frequently mentioned as an important reason for providing chemical abortion pills by telemedicine and mail order distribution to women who live remote from abortion clinics. Yet, the approximately one in twenty women who suffer a failed chemical abortion must have access to emergency care that is often far away, leaving them to suffer disproportionately. These women are frightened, and often hemorrhaging. They may require hospital admission for immediate surgery, blood transfusion, or intravenous antibiotics. They may overwhelm the emergency rooms and blood banking systems that are already overstressed due to the Covid-19 pandemic. Sadly, “women’s health advocates” who insist upon easily accessible abortion rarely devote similar concern to the lack of obstetric care and delivery facilities for women in rural locations who desire to safely give birth to their children (even though these women must travel to a provider 10-14 times during the average prenatal time period compared to one or two visits for women seeking abortion).

\textbf{Three: Pre-abortion testing improves safety for a woman.}

\textbf{A. Patient determination of gestational age is frequently incorrect}

Although the assumption is made that a woman will be able to accurately calculate gestational age based on a last menstrual period (LMP) calculator, clinical experience suggests otherwise. Increasing obesity in the American patient population has led to a high incidence of polycystic ovarian syndrome causing irregular menses. Sometimes a woman will have implantation bleeding which she assumes is a normal period even though she is already pregnant. Thus, it is a frequent occurrence for a woman to underestimate gestational age by a month or more. One study found almost 15% of women were in error by more than two weeks when calculating gestational age by LMP.\textsuperscript{14} Numerous studies have documented that ultrasound dating is more accurate than recollection of last menstrual period.\textsuperscript{15}

A meta-analysis of over 33,000 chemical abortions revealed that failures requiring surgical completion steadily increase as gestational age increases. Less than 2 percent


(1.9%) failed at < 7 weeks, 3.3% failed between 7-8 weeks, 4.8% failed between 8-9 weeks, and 6.9% failed between 9-10 weeks. Another meta-analysis of over 45,000 chemical abortions revealed an overall failure rate of 4.8% with the risk of failure much higher at gestational ages greater than 8 weeks.

If a woman miscalculates her gestational age and has entered the second trimester when she ingests mifepristone and misoprostol, the likelihood that she will require surgery increases dramatically. A records-linkage study of over 18,000 women comparing first-trimester to second-trimester chemical abortions found 38.5% of second-trimester abortions required surgical completion (versus 7.9% in the first trimester). Additionally, 4% of the later abortions were complicated by infections (versus 1.9% of the earlier ones).

B. Failure to diagnose an ectopic pregnancy is a serious and sometimes deadly medical error.

Ultrasound is considered the gold standard for diagnosis of an ectopic pregnancy. Omitting ultrasound will increase the likelihood of failing to make the diagnosis. Mifepristone exerts its effects on the uterine lining, so when an embryo is implanted in another location, the chemical abortion regimen has no effect. Continued growth may cause a Fallopian tube to rupture, or cause bleeding if the embryo is implanted on another vascular organ. Catastrophic hemorrhage in these situations sometimes leads to maternal deaths.

The American College of Obstetricians and Gynecologists’ (ACOG) website lists many risk factors for ectopic pregnancies: previous pelvic or abdominal surgery, sexually transmitted infections, pelvic inflammatory disease, endometriosis, cigarette smoking, age older than 35 years, history of infertility, and use of artificial reproductive technology. Yet the website also states that half of women with ectopic pregnancies do not have any of these risk factors, so it cannot be ruled out merely by history.

---

ACOG’s practice bulletin on ectopic pregnancy states, “Tubal ectopic pregnancy in an unstable patient is a medical emergency that requires prompt surgical intervention.” The matter-of-fact way this study reports four missed ectopic pregnancy diagnoses demonstrates that they are starkly unconcerned about the time-limited need to make this diagnosis. Although ectopic implantations occur in only 2% of recognized pregnancies, they account for up to 13% of maternal deaths.

A woman who experiences ectopic warning symptoms, such as pain or bleeding, while undergoing a chemical abortion may be less likely to report them to a health care provider, because she has been warned to expect these symptoms as a sign that the abortion drugs are working. A woman is 30% more likely to die from an ectopic while undergoing an abortion than if she had an ectopic but had not sought an abortion. A case report describes one such woman who was found unconscious with 1.3 liters of blood in her abdomen.

C. Standard recommendations about anti-D immunoglobulin (Rhogam) are ignored.

This article mentions that four of the fourteen clinics did not provide Rh screening prior to providing chemical abortion pills. Yet, ACOG’s practice bulletin on alloimmunization states, “Rh D immune globulin should be given to Rh D-negative women who have a pregnancy termination, either medical or surgical.” Additionally, the 2014 ACOG practice bulletin on medication abortion states, “Rh testing is standard of care in the United States, and Rh immunoglobulin should be administered if indicated.” Surprisingly, the 2020 updated practice bulletin on medication abortion repeats the statement, “Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated.” Yet, paradoxically, the next sentence recommends, “in situations where Rh testing and Rh D immunoglobulin administration is not available or would significantly delay medication abortion, shared decision making is recommended so that patients can make an informed choice about their care.” Thus,
without any additional evidence, this pro-abortion organization relaxed their own standards to allow remote abortion without Rh testing or Rhogam administration.

A review on alloimmunization demonstrated that nearly all medical societies recommend Rh D immune globulin in Rh-negative women undergoing abortion, because termination of pregnancy may lead to transplacental hemorrhage.Isoimmunization has been documented to occur with exposure to as little as 0.1 ml of fetal blood, and it is estimated that fetal blood volume is 0.33 ml at eight weeks’ gestation. Risk of isoimmunization in Rh-negative women after first-trimester surgical abortion appears to be 4.6% without Rh D immune globulin but no studies are available examining the risk after chemical abortion. Nonetheless, a pilot study of only 28 women is used as the basis for removing the Rhogam recommendations by the National Abortion Federation.

The consequence of failing to prevent anti-D alloimmunization is great in a subsequent pregnancy. Fourteen percent of untreated, affected infants are stillborn, and one half of liveborn untreated infants suffer neonatal death or brain injury. Treatment is difficult and invasive, often requiring repeated in-utero transfusions to counteract severe fetal anemia. Approximately 15% of the U.S. population is at risk, and current recommendations of providing anti-D immunoglobulin to at-risk women have reduced the risk of alloimmunization from 13-16% to 0.14 to 0.2%. The recommendation of abortion advocates to forego the standard intervention of Rh D immune globulin has the potential to result in catastrophic complications in future pregnancies.

D. Not all “telemedicine” protocols are equal.

Many studies that claim to document the safety of remote chemical abortion provision continue to implement standard pre-abortion screening including physical exam, ultrasound and labs. They merely differ in whether the chemical abortion pills are provided to the woman by mail or through a local pharmacy instead of in-person. Sometimes they confusingly include hybrid groups which include both pre-screened and unscreened groups. They also often contain large groups of women for whom follow-up is unknown. Yet, these studies are often dishonestly cited as proof that lack of screening is safe.

Four: Remote distribution fails to consider or screen for reproductive coercion:

Current FDA regulations require a woman seeking abortion to consume the mifepristone in the presence of the abortionist. One reason for this limitation is to make sure a woman has been counseled and desires the abortion. Potential for misuse and coercion is high when there is no way to verify who is consuming the drug and whether she is doing so willingly.

ACOG and the National Abortion Federation have documented that women seeking abortions are at risk for reproductive coercion defined as “partner using threats and coercion to enforce his will about the pregnancy outcome,” but these abortion-promoting organizations ignore the opportunity for sex traffickers, domestic abusers, and men who do not want to become fathers to surreptitiously give abortion pills to women when these drugs can be easily obtained by anyone.32

It has been documented that many women experiencing sex trafficking have been forced into multiple abortions. Interaction with the health care system is an opportunity for these women to be identified and helped, but ready availability of chemical abortion pills to their abusers will remove this opportunity for intervention.33
Though reversed by Parliament, the government of England had ended its approval of chemical abortion “pills by post” when it became aware of the frequent issue of domestic abuse. 70% of public commenters were concerned that remote provision would have a negative impact on the safety of women seeking abortion, particularly the “risk of women being coerced into an abortion when they are not physically being seen in a service.” This concern seemed to be validated when a BBC poll documented that 15% of respondents said they experienced pressure to terminate a pregnancy when they did not want to, and 3% experienced being given something to cause an abortion without their consent.34

Remote distribution fails to account for transit time and condition of the pills on arrival. An undecided woman may decide not to take the pills when they finally arrive (which could be days or weeks after ordering), but then change her mind again and take them later, when the risk of failure is much higher. A study on obtaining abortion pills from international distributors found that no prescription or clinical information was required, the pills averaged two weeks to arrive, analysis of the drugs demonstrated that some misoprostol pills contained only 15 percent of the advertised amount, often the packages arrived damaged, and no instructions were contained in any of the packages.35 A small Indian study examining the feasibility of providing chemical abortion pills over the counter found that 27% of forty women consumed the pills past the recommended gestational age cutoff, with 17% consuming them more than three weeks past the cutoff. This resulted in excessive hemorrhage in 77% of the women, surgical evacuation in 68%, severe anemia requiring transfusion in 12%, and 5% presenting in hemodynamic shock.36

Can the authors’ conclusions be substantiated?

The pro-abortion authors of this study concluded, “Given the high effectiveness and very low risks associated with omitting in-person tests and using history-based screening alone, no-test medication abortion can offer substantial benefits to clinicians and patients and is consistent with the principle of patient-centered care.”

I hope the foregoing discussion will convince the observer who cares for the well-being of women seeking abortion to answer with an emphatic “no”! Effectiveness is not high, as at least one in twenty women will experience failed chemical abortions requiring surgical completion. Risks are not low, as failure to perform in-person testing will increase failures due to underestimation of gestational ages, will fail to diagnose life-threatening ectopic pregnancies, and will cause missed opportunities to prevent Rh isoimmunization by foregoing standard-of-care Rh testing and administration of Rhogam.

34 Bbc.com/news/newsbeat-60646285
While these recommendations may benefit abortion providers by removing barriers to selling abortions, they certainly do not support “patient-centered care”, which above all else should prioritize the health and safety of the woman seeking abortion!

_Ingrid Skop, M.D. is Senior Fellow and Director of Medical Affairs with the Charlotte Lozier Institute._