Chemical Abortion and Abortion Pill Reversal in 2023
Impacts on the Patient and the APR Treatment Team

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Medical Abortion Procedures

A. Eligibility—FDA approved up to 10 weeks estimated gestational age (EGA)—70 days after LMP.

B. Prevalence—53.4% of all abortions in 2020 (51% were ≤ 9 weeks gestation, 2.5% were > 9 weeks' gestation).[1]

C. Access—CDC removed the requirement for dispensing mifepristone in certain health care settings (clinics, medical offices, hospitals) — "in-person dispensing requirement" on 12/16/2021.[2] The REMS modification was approved on 1/3/2023.
   1. Can be written by a certified prescriber and dispensed by a certified pharmacy or under the supervision of a supervised prescriber.
   2. Prescriptions can be mailed via certified prescribers or pharmacies in addition to in-person.
   3. FDA does not "recommend" buying mifepristone online outside of the REMS program.

D. Access to Mifepristone (first medication in the protocol)
   1. REMS. The FDA lists Mifepristone on REMS (Risk Evaluation and Mitigation Strategy. REMS is for medications with serious safety concerns to ensure benefits outweigh risks—62 currently.
   2. Additionally, there are Elements to Assure Safe Use (ETASU). It is only given in specific settings; prescribers must hold a certified agreement with the manufacturer confirming assessment throughout the pregnancy, diagnose ectopic pregnancies, provide surgical abortion in the case of an incomplete abortion, and have a patient signed Patient Agreement form before dispensing the drug.[3]
   3. There are calls to remove it from REMS.[4]

E. Medications Used
   1. Mifepristone (Mifeprex and an approved generic as of April 2019) blocks progesterone's action, which is needed for the developing embryo.
   2. Misoprostol causes softening of the cervix and uterine contractions.
   3. Methotrexate (not often used) will stop the process of implantation.

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[1] Abortion Surveillance—United States, 2020. http://dx.doi.org/10.15585/mmwr.ss7110a1 Accessed 6/25/2023

[2] Questions and Answers on Mifeprex https://fda.gov/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex Accessed 6/25/2023

[3] Kaiser Family Foundation. "Abortion." https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/. Accessed 3/9/2021

[4] Henney JE and Gayle HD. Time to Reevaluate US Mifepristone Restrictions. N Engl J Med, Aug 15, 2019, 381(7):597-8.

F. Medical Abortion Eligibility Criteria
   1. Up to 70 days EGA (10 weeks after last menstrual period—LMP)
   2. No ectopic pregnancy suspected, no IUD, and specific other medical exclusions.
   3. Ability to follow instructions and follow-up contact.

G. Additional requirements:
   Require pregnancy confirmation by clinical evaluation or ultrasound. There is no requirement for viability confirmation, assessment for suspected anemia, or blood type (Rh testing). It is suggested that these be waived for telehealth visits.[5] However, in an ACOG document on Early Pregnancy Loss, Rh testing is still recommended to be considered in early pregnancy loss, especially later in the first trimester.[6][7]

H. Timing of Mifepristone Abortion Protocol
   Mifepristone 200 mg as a single dose, followed by misoprostol 800 mcg as a single dose 24-48 hours later.

I. Risks of Medical Abortion
   Gastrointestinal, headache/dizziness, fever/chills/sweats, heavy bleeding, need for emergency D&C, need for surgical evaluation for incomplete abortion, continuing pregnancy, and infection.

ABORTION PILL REVERSAL

A. Network of over 1300 health care providers (physicians, NPs, PAs, and pregnancy centers) in a variety of settings[8]
B. To access: abortionpillreversal.com—gets patient in contact with a nurse who takes information and relays it to a provider who contacts the patient to start treatment.

Method of Action

A. Mifepristone binds to progesterone receptors in the uterus, where the placenta develops. If progesterone cannot reach the receptors, the placenta breaks down, the cervix softens, and contractions occur.
B. Progesterone is given if the second medication (misoprostol) has not been taken. Large doses can outcompete the mifepristone, more progesterone to the placenta and the pregnancy.

How well does it work?

A. The latest review of cases from the hotline was published in 2018[9]
B. The overall rate of reversal was 48%.
C. The highest rate of reversal was in two subgroups.
   1. Progesterone IM initially or exclusively 64% successful
   2. Progesterone oral high dose to end of first trimester 68% successful

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[5] Raymond EG, Grossman D, Mark A, et al. Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond. Contraception. 2020;101(6):361-366. doi:10.1016/j.contraception.2020.04.005

[6] ACOG Practice Bulletin: Early Pregnancy Loss. Published Nov 2018. https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss Accessed 6/25/2023

[7] Practice Bulletin No. 181: Prevention of Rh D Alloimmunization, Obstetrics & Gynecology: August 2017 - Volume 130 - Issue 2 - p e57-e70 doi: 10.1097/AOG.0000000000002232

[8] https://www.heartbeatinternational.org/images/ImpactReports/APRN_Impact_Report_2022.pdf Accessed 6/25/2023

[9] Delgado G, Condly SJ, Davenport M, Tinnakornsrisuphap T, Mack J, Khauv V, Zhou PS. A Case Study Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone. Issues Law Med, Spring 2018, 33(1): 21-31.

What is the rate of continuing pregnancy if misoprostol is not taken but no progesterone?

In studies where mifepristone alone was taken without misoprostol, the highest survival, 23% using a single 200 mcg dose, now in the FDA protocol. The 2018 study used 25% to look statistically at survival.

Does mifepristone harm the embryo?

ACOG Bulletin on Medication Abortion up to 70 Days of Gestation[10] states that no evidence exists for the teratogenic effect of mifepristone.

BUT—misoprostol and methotrexate can cause birth defects.

What is the track record of progesterone in pregnancy?

It has been used safely in pregnancy for over 50 years. American Society of Reproductive Medicine states no long-term risks when used in pregnancy. The current FDA classification in pregnancy is P2 "Benefits are likely to exceed the risk."

Are the APR survivors at increased risk for birth defects?

No, the rate was 2.7% in the 2018 study, compared favorably to the general population rate of 3%.

What is required of the patient?

A. The patient is willing to see the doctor as soon as possible for an exam, ultrasound, and labs.
B. The oral regimen is easiest to start quickly (even before seeing the doctor) and costs reasonable.

What about Methotrexate? Can it be reversed?

Information, at this point, is anecdotal. A physician who has attempted is only aware of six successes. He knows two were born with a missing toe on each foot. The one he cared for was the only known defect, but the data is small and incomplete.

Methotrexate can cause birth defects—careful consent and documentation are needed. The protocol is available through APR to providers.

HOW DOES THIS IMPACT PATIENTS?
WHAT ABOUT THE HOTLINE PROVIDERS/PREGNANCY MEDICAL CLINICS?

For patients—access to medication abortion is easier than ever. They can obtain pills without seeing a physician in person, without verification of intrauterine pregnancy or gestational age, without Rh testing, and without knowing whether consent is being forced or pills being hoarded to give women without consent, hiding potential sex trafficking, sexual assault, and sexual activity among minors.

For APR Network providers/pregnancy centers—women may be starting medication abortions without verification of intrauterine pregnancy, so hotline patients may not have had their pregnancy verified as an IUP making early ultrasound access a must. Will women contact your center asking to verify that their abortion was complete by ultrasound?

[10] American College of Obstetricians and Gynecologists Practice Bulletin, Medication Abortion Up to 70 Days of Gestation, October 2020.

EMOTIONAL WEIGHT OF ABORTION REVERSAL FOR APR Network PATIENTS, APR Network PROVIDERS, AND PREGNANCY CENTERS— "the agony and the ecstasy."

The "agony"

--women calling the hotline and then not answering the providers when they call back, or not showing up for the ultrasound, or returning texts

--failures—roughly 1/3 fail. They can fail abruptly after a reassuring ultrasound when they're at a more advanced gestational age that would normally do better. The patients need to be supported, but so do the teams. For the patients, referral to pregnancy loss resources (but do they fit into the existing categories very well?) For the teams, utilize prayer hotlines, debriefings afterward, and strong prayer life.

The "ecstasy"

- helping women in moments of tremendous need

- ability to walk with them, spiritual sharing, staying with them through the pregnancy

- sometimes, they stay in touch for years!

In EITHER case (if the reversal attempt is successful or unfortunately fails), we should remember that we are God's hands and feet here and are asked to be faithful and provide the best care we can.