

ISSUE BRIEF, MARCH 2019

Abortion Pill "Reversal": Where's the Evidence?

Between 2015 and 2019, legislators in at least fourteen states have introduced bills that would require clinicians to inform patients during pre-abortion counseling that the abortion pill can be "reversed" if a woman were to change her mind after taking it. This is despite the fact that medication abortion is safe and that the vast majority of women who choose abortion do not regret their decision. So-called abortion "reversal" bills have been passed into law and implemented in four states as of 2019: Arkansas, Idaho, South Dakota, and Utah.

What is abortion pill "reversal"?

Abortion pill "reversal" is an experimental treatment developed by Dr. George Delgado that involves administering repeated doses of progesterone after a patient has taken mifepristone in order to attempt to stop the abortion process.^{1,2} Mifepristone is the first of two drugs used for medication abortion: it works to block progesterone, known as the "pregnancy hormone," which causes the pregnancy to detach from the uterine lining. The unproven hypothesis behind abortion pill "reversal" is that the progesterone will counteract the effect of the mifepristone.

Is abortion pill "reversal" effective?

If a woman decides that she no longer wants to have an abortion after taking mifepristone, she can simply not take the second drug in the abortion regimen, misoprostol. By not taking the second pill, there is a reasonable chance (25% or higher) that the pregnancy will continue on its own. There is no

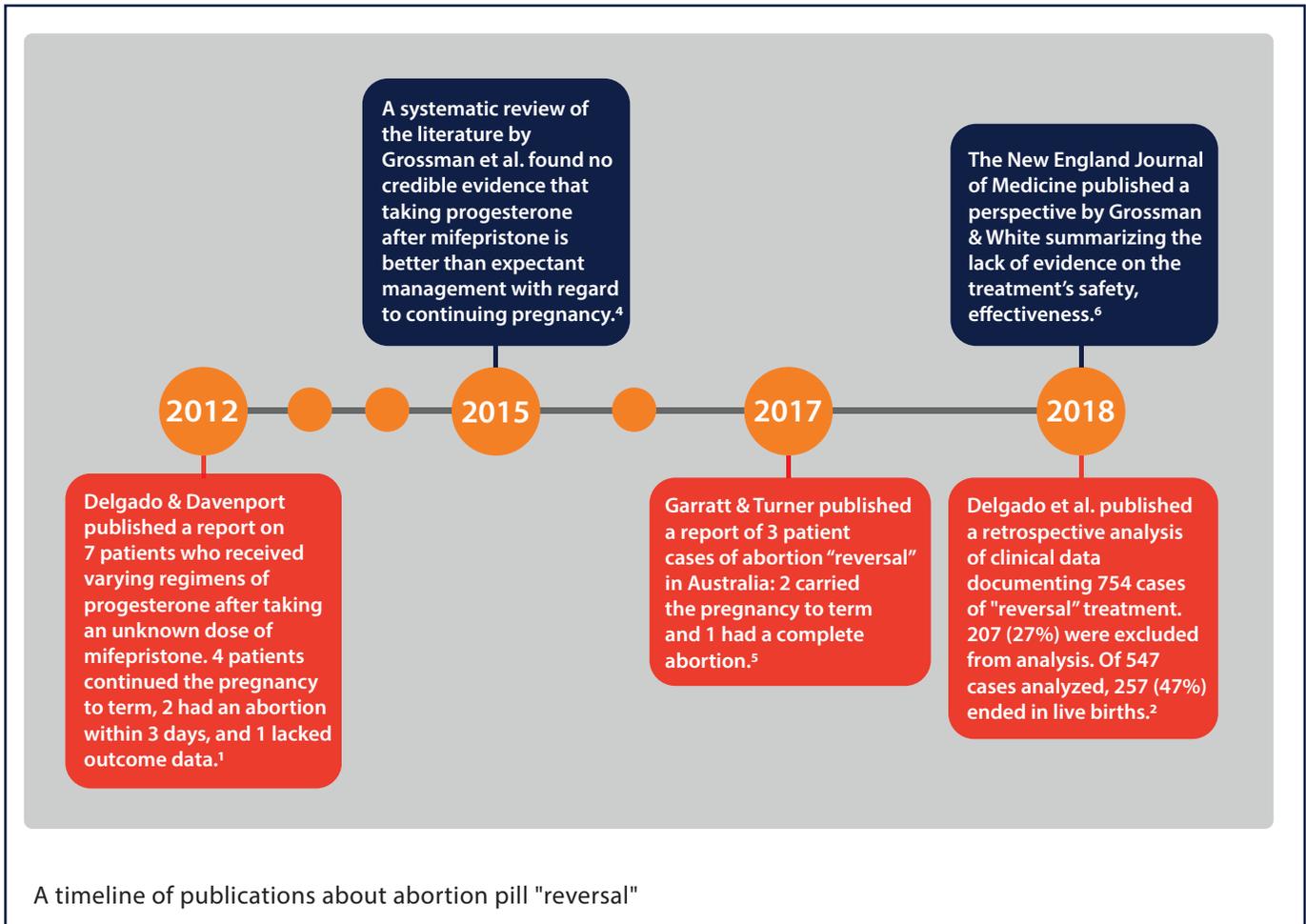
evidence that progesterone treatment increases the chance of the pregnancy continuing.

Even if the concept of "reversal" is biologically plausible, rigorous testing of the protocol should be required in order to determine whether it is effective and safe, and whether it is preferable to simply not taking the misoprostol. There are currently only three published case series on medication abortion reversal, each with significant limitations. None of the reports includes a comparison group or appropriate oversight by an ethics committee. Some patients in these case series had an ultrasound before receiving treatment, and only those with continuing pregnancies were given progesterone. Patients with a continuing pregnancy 1-2 days after mifepristone are much more likely to have a pregnancy that continues to term, so this pre-selection of patients inflates the success rate of "reversal" treatment.³ A systematic review of literature on the topic concluded in 2015 that there is no credible evidence that abortion

What is medication abortion?

Medication abortion (also known as the abortion pill) is safe, effective and preferred by many patients seeking an early abortion up to 10 weeks in pregnancy. Medication abortion involves two drugs, mifepristone and misoprostol, usually taken 24 to 48 hours apart. The mifepristone blocks the pregnancy hormone, progesterone, and the misoprostol causes a woman's body to expel the pregnancy. As of 2014, medication abortions account for nearly one-third of all abortions in the United States.

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"reversal" is better than simply not taking the second pill.⁴ A report that reanalyzed data from the most recent case series found no significant difference in continuing pregnancy after progesterone treatment compared to expectant management after mifepristone alone.⁶ The American College of Obstetricians and Gynecologists (ACOG) does not support the use of progesterone to "stop" a medication abortion because of a lack of scientific evidence.

In order to test clinical effectiveness and safety of an abortion pill "reversal" protocol, a randomized clinical trial is the most appropriate strategy – and this rigorous testing of a clinical protocol should occur before states consider laws that mandate counseling about that protocol. The US Food and Drug Administration (FDA) has not evaluated the treatment.

Does pre-abortion counseling on the possibility of "reversal" change women's decision-making?

State policies that require clinicians to counsel on abortion pill "reversal" assume that women who seek medication abortion are unsure of their decision to have an abortion. Research from ANSIRH shows that this is false.⁷ In the days after an abortion, the overwhelming majority of women report that it was the right decision.⁸ Only 0.004% of patients who took mifepristone between 2000 and 2012 ended up deciding to continue their pregnancies.⁴ States do not typically require clinicians to inform patients that they can reverse other common medical procedures, such as a vasectomy or tubal ligation – so why is it necessary for medication abortion?

"They made it clear that they had to say [abortion reversal] was possible, but also made it clear that medically it would be a bad decision. It did not affect the way I felt about my decision."

–Arkansas medication abortion patient

In Arkansas, following the passage of an abortion "reversal" bill in 2015, clinicians must counsel all medication abortion patients about the possibility to "reverse the effects of the abortion if the pregnant woman changes her mind." We recently conducted a survey with abortion patients recruited at a clinic in Arkansas to explore their perspectives on services. Among 16 patients who had undergone a medication abortion in Arkansas since the "reversal" law was implemented, only one woman reported that the counseling "somewhat" changed the way she felt about her decision to have an abortion. Nevertheless, she completed her medication abortion, said she would recommend it to others, and indicated that if she needed a future abortion she would "definitely" choose it. These limited data suggest that mandated "reversal" counseling has little effect on patients' decision-making around abortion. Instead, laws requiring 'reversal' counseling likely serve more to burden providers and confuse patients than to assist women.

Where is the evidence?

Fourteen states have introduced abortion "reversal" bills since 2015 and four (Arkansas, Idaho, South Dakota, and Utah) have implemented abortion "reversal" laws – all before evidence has been established on the effectiveness of the treatment. The California Board of Registered Nursing even approved a course on the procedure for continuing education credit – meaning nurses in the state can choose to learn about the unproven protocol alongside legitimate topics.

Other states have successfully warded off the adoption of mandated counseling on abortion "reversal." In Arizona, Planned Parenthood challenged a law in federal court, and the law was later repealed by the legislature. Bills introduced in California, Colorado, Georgia, and North Carolina failed to pass, and the Indiana Senate stopped a bill that had been passed by the House. When legislatures examine the treatment from a scientific perspective, its shortcomings become clear. After the Louisiana Department of Health conducted an investigation into the effectiveness of "reversal" at the state legislature's request, they concluded that "there is insufficient evidence to suggest that there is a sound method to reverse a medication-induced abortion."⁹ Rigorous evidence demonstrating the safety and effectiveness of abortion "reversal" is essential before clinicians in any state should be required to counsel their patients about the treatment.

References

1. Delgado G & Davenport ML. Progesterone use to reverse the effects of mifepristone. December 2012. *Ann Pharmacother*, 46(12): 1723-1723.
2. Delgado G, Condly SJ, Davenport M, et al. A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone. April 2018. *Issues Law Med*, 33(1): 21-31.
3. McLemore, MR. Explained: So-called "Abortion Reversal." March 2018. Retrieved from <https://innovating-education.org/2018/03/explained-so-called-abortion-reversal/>
4. Grossman D, White K, Harris L, et al. Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a systematic review. September 2015. *Contraception*, 92: 206-11.
5. Garratt D & Turner JV. Progesterone for preventing pregnancy termination after initiation of medical abortion with mifepristone. December 2017. *Eur J Contracept Reprod Health Care*, 22(6): 472-475.
6. Grossman D and White K. Abortion "Reversal" – Legislating Without Evidence. October 2018. *N Engl J Med*, 379(16): 1491-1493.
7. Ralph LJ, Foster DG, Kimport K, Turok D, Roberts SCM. Measuring decisional certainty among women seeking abortion. March 2017. *Contraception*, 95(3):269-78.
8. Rocca C, Kimport K, Gould H, Foster DG. Women's emotions one week after receiving or being denied an abortion in the United States. September 2013. *Perspect Sex Reprod Health*, 45(3):122-31.
9. Louisiana Department of Health, Bureau of Family Health. Legislative Report on 2016 House Concurrent Resolution (HCR) 87: Study Related to Whether the Effects of an Abortion Induced with Drugs or Chemicals Can Be Reversed. Authors: Daphne Robinson and Amy Zapata. April 12 2017. <http://ldh.la.gov/assets/docs/LegisReports/HCR87RS20161.pdf>