Drug combination for women suffering miscarriages is cost-effective

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A pretreatment medication for women who suffer miscarriages—called

mifepristone—is not only more clinically effective when combined with the standard of care drug, but also more cost effective, according to researchers at the Perelman School of Medicine at the University of Pennsylvania. A new economic analysis found the average health care cost for a woman to receive mifepristone with the standard miscarriage drug misoprostol was roughly equal to the cost for a woman to receive only misoprostol, while the costs, from a societal perspective, for mifepristone plus misoprostol was about $1,000 less than misoprostol alone. Researchers published their findings this month in *JAMA Network Open*.

"Strict federal regulations and concerns over the high cost of mifepristone have made it harder for some women with early pregnancy loss to gain access to the drug through their providers," said study lead author Courtney A. Schreiber, MD, MPH, chief of the division of Family Planning and an associate professor of Obstetrics and Gynecology at Penn. "Showing this regimen's economic value is one important piece to help lower a barrier for patients seeking a safe and more comfortable closure to a painful experience. Physicians, payers, and health systems should be encouraged by these findings."

Schreiber is also the director of Penn's PEACE Program, which provides access to compassionate care for women and couples seeking family planning care and management of early pregnancy complications.

Each year in the United States, approximately one million women have miscarriages. When the body does not expel the pregnancy tissue on its own—the final part of a miscarriage—women need to undergo a surgical procedure or take the drug misoprostol. However, misoprostol does not always work, and many women who use it are still left with no option but to undergo an invasive procedure they wished to avoid, prolonging an already physically and emotionally difficult situation.

A landmark 2018 study in the *New England Journal of Medicine*, also led by Schreiber, showed that combining misoprostol with mifepristone more reliably completed the miscarriage, known as gestational sac expulsion, and reduced the need for surgical intervention, when compared to misoprostol alone.

Mifepristone is a highly regulated medication because it is also used with misoprostol to induce abortion in early pregnancy, which has limited its access for women. At present, the U.S. Food and Drug Administration requires that the drug be dispensed only in registered hospitals, clinics, and doctor's offices, but not in retail pharmacies. Providers in the U.S. may also be hesitant to use mifepristone due to its average cost of $90 per 200 mg pill. Misoprostol can cost less than one dollar.

For this study, researchers investigated both the clinical and cost effectiveness of the drug regimens in 300 women enrolled in a clinical trial between 2014 and 2017. They found that the treatment success rate for women who received the combination of drugs was 83.8 percent, while the success rate for patients who received only misoprostol was 67.7 percent.

To analyze the cost-effectiveness, the researchers collected economic data of the cost of miscarriage care from the health care and societal perspectives from the same 300 women. They compared the incremental cost per quality-adjusted life year (QALY) gained—essentially a measure of years of "perfect" health—as well as the cost per complete gestational sac expulsion between the two regimens. That evaluation assesses the value of a medical intervention based on cost and the number of years it would add to a patient's life.

Health care costs included those incurred by payers and participants for the therapies and for early pregnancy loss-related health care costs after one month, using average Medicare reimbursement rates or published

hospital prices. Costs from the societal perspective included the time costs to patients receiving care, transportation costs, lost wages, and other costs, all based on the 2018 dollar.

From the health care sector perspective, the mean cost per patient was similar among the two groups: $697 for those receiving mifepristone and misoprostol versus $691 for those receiving misoprostol alone after one month. From the societal perspective, the mean costs per patient were $3,846 for mifepristone and $4,846 misoprostol alone—a $1,000 difference.

The mifepristone pretreatment group had an incremental cost-effectiveness ratio of $4,225 per QALY gained in comparison to misoprostol alone, the researchers found. Interventions below the $100,000 to $150,000 threshold are considered cost effective in the United States, the researchers report. The authors also found that if mifepristone's cost increased from $90 up to close to $300 per dose, it would still remain cost effective.

The cost-effectiveness of misoprostol alone may be diminished because of its higher failure rate, resulting in a prolonged treatment course with multiple doses of medication or ultimately in surgical management, which would increase both time and costs.

"The findings further underscore the importance for mifepristone to be made widely available for physicians to prescribe and for insurers to cover it, so women with early pregnancy loss have expanded options," Schreiber said.

More information: Divyah Nagendra et al. Cost-effectiveness of Mifepristone Pretreatment for the Medical Management of Nonviable Early Pregnancy, *JAMA Network Open* (2020). DOI: 10.1001/jamanetworkopen.2020.1594

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