Easing restrictions on abortion pill greatly improved access to care in Canada

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Removing restrictions on how mifepristone—the medical abortion drug—can be prescribed and dispensed in Canada greatly improved access to abortion, especially in rural communities across the country.

That's one of the key findings of new University of British Columbia-led research published today in the *Annals of Family Medicine*.

"Access to family planning health services has long been inadequate and inequitable in Canada," said Sarah Munro, the study's lead author and an assistant professor in the department of obstetrics and gynaecology in the UBC faculty of medicine. "The approval of mifepristone helped reduce these inequities, but it may not have been successful if Health Canada had not removed many of the early restrictions required in how the drug could be prescribed and dispensed."

In Canada, mifepristone is packaged together with the drug misoprotol. Together, they are marketed as mifegymiso, a combination product containing both drugs that are taken in sequence for the medical termination of a pregnancy.

For the study, the researchers worked closely with Health Canada, the Society of Obstetricians and Gynaecologists of Canada, the College of Family Physicians of Canada, the College of Physicians and Surgeons and the College of Pharmacists—both nationally and in provinces and territories across Canada—using the findings to help advance Canada's medical abortion policies to improve abortion access and equity in Canada.

The researchers say the findings may be relevant to other nations experiencing challenges with access to family planning services, as Canada was the first country in the world to implement evidence-based deregulation of all supplemental restrictions on dispensing and administration of mifepristone.

Early regulations made access to mifepristone complicated

Access to abortion in Canada has been historically inequitable, with few options for drug-induced abortion—the preferred method for ending a pregnancy during the first trimester in the United States and many European nations.

A potential solution appeared in 2015 when Health Canada approved mifepristone, the medical abortion drug considered to be the international standard. But with many dispensing and administration restrictions accompanying its approval at first, concerns arose that the drug's availability may not improve access to abortion care as hoped.

The initial requirements included:

- Physicians must observe the patient taking the medication
- Prescribers must take mandatory training
- Patients must sign a manufacturer consent form
- Only physicians, not pharmacists, can dispense the drug directly to the patient
- Prescribers must register with the manufacturer
- Mandatory ultrasound before prescribing
- Medication could only be used up to seven weeks of pregnancy (rather than nine weeks, which is the standard outside of Canada)

During the course of the study, Health Canada removed these restrictions on the drug.

However, the researchers found that shifting regulations during mifepristone's first year of availability created confusion for health care providers that persisted even after the drug was deregulated.

Shifting regulations created confusion for prescribers

For the study, the researchers sought to understand the perceptions of barriers to mifepristone in primary care during its first two years of availability in Canada.

They interviewed 90 people—55 health care providers and 35 stakeholders—involved in the planning and provision of abortion services across Canada.

"Throughout the interviews, health care providers told us the initial restrictions on how mifepristone could be prescribed and dispensed made the drug more complicated than it needed to be, which in turn limited access for patients," said Munro. "The requirement for ultrasound, for example, made it challenging for clinicians in remote or rural areas where access to timely ultrasound was challenging."

Health care providers were unanimous in their criticism of the initial requirement that they would need to observe the patient taking the drug, stating that they couldn't think of a legitimate safety reason for the requirement. A number of participants also still misbelieved that they had to observe their patients take the drug, even though this requirement was removed early on.

Overall, however, the researchers found that health care providers held strong perceptions that mifepristone was the new standard of care for medical abortion in Canada and within the scope of primary care practice.

Research offers lessons for U.S. approach to mifepristone

The researchers say their findings have important implications for other countries experiencing challenges with access to family planning services, such as the United States.

Many of the restrictions on mifepristone that Health Canada has repealed are still mandated nationwide in the U.S. For example, pharmacists there cannot dispense the drug directly to patients, prescribers must be registered with the drug distributor, and patients must sign a mandated consent form.

"Our research found that Canadian physicians perceived that these elements would not enhance safety, but rather would discourage physicians from prescribing the drug and would in turn limit access to abortion," said Dr. Wendy Norman, the study's senior author and associate professor in the UBC department of family practice. "Canada's experience of deregulating mifepristone might be useful for countries like the U.S. to bring the drug label in line with current international practice and evidence."

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