

World's only super-database for pharmaceutical use during pregnancy

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Should a woman prescribed antidepressants continue taking them while pregnant? The question is fraught—her health and that of her unborn child is at stake. Yet research to help her and her doctor make that decision is incomplete.

The problem, says epidemiologist Anick Bérard, is that medical researchers must exclude [pregnant women](#) from [drug trials](#) to protect their babies. Whether it's antidepressants, antibiotics or anti-migraine medications, "this potentially means that pregnant women have less evidence-based treatment than men and non-pregnant women," she says.

Bérard, a professor in the faculty of pharmacy at the Université de Montréal, aims to change that. She has built a super-database called the [Quebec Pregnancy Cohort \(QPC\)](#) that has already yielded crucial insights into drug use and health outcomes for both mothers and children.

The QPC links four databases containing information on pregnancies of women covered by Quebec's provincial prescription drug insurance starting in 1997. It represents one-third of women of child-bearing age in the province.

The QPC is one of few such databases, and the only one to contain precise gestational ages. This means researchers can match drug exposures to stages of pregnancy.

"Timing is pivotal," says Bérard. "Every week of pregnancy produces something different. At six to nine weeks of gestation for example, the heart is formed."

But the province's databases were built to help government keep track of payments to doctors and pharmacists, not to analyze drug use outcomes.

And so Bérard and her team have painstakingly validated the data in the QPC. For example, a particular database code may mean a woman was prescribed a drug, but it does not reveal whether she took it. So the team went back to women in the databases to ask if they indeed took the [drug](#), and whether they did so as prescribed.

Codes for birth defects were similarly validated. If it indicated a child was born with a heart defect, researchers cross-checked with hospital and medical records.

"When we study drugs and the risk of certain birth defects, we know it's a real risk," explains Bérard.

In 2005, Health Canada asked her to look into emerging research showing links between pregnant women taking an antidepressant called Paxil and heart defects in their babies.

In 2007, her team published a study based on QPC data showing that Paxil indeed increases the risk of [heart defects](#), helping shape guidelines in Canada and the U.S. on the treatment of depression during pregnancy.

Other users of the QPC have included the U.S. Food and Drug Administration, international universities and pharmaceutical companies.

Provided by University of Montreal

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