EDITORIAL

# Reinvent Motherisk to keep mothers and babies from harm

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This spring, Canada's Motherisk program shut its doors and permanently disconnected its helplines, disappointing the millions of Canadian patients and clinicians who had relied on its services since 1985.[1] At its peak, Motherisk provided evidence-informed counselling on drug safety in pregnancy and breastfeeding to tens of thousands of callers per year and conducted large-scale laboratory and clinical research on maternal–fetal toxicity. The loss of Motherisk has exposed a major public health and research void that is neither quickly nor easily reconciled. Although finding an immediate replacement for Motherisk is not feasible, reinventing a reputable and modernized clinical and research program in reproductive drug safety should be a national priority.

The ideal of a "normal pregnancy" free from illness and medications is at odds with reality. Twenty percent of pregnant women have chronic illnesses, and many others will develop pregnancy-related conditions.[2] Over the past 30 years, the prevalence of prescription drug use in pregnancy has increased by nearly 70%.[3] More than 90% of pregnant women will use at least 1 prescription or over-the-counter drug during pregnancy, and about half of breastfeeding women will continue to use prescription medications.[3,4]

For these women, a failure to provide appropriate access to information on drug safety is irresponsible and dangerous. Two possible outcomes may arise in the absence of timely information and expert counselling. First, women may continue drugs that could result in preventable harm to their children. Second — the more common and likely scenario — is that mothers may unnecessarily stop drugs for fear of harm to the baby. This could leave both mother and baby at risk of harm from untreated medical and psychiatric conditions during conception planning, throughout the duration of pregnancy, and into the postpartum period. None of these outcomes are acceptable.

In addition, major knowledge and research gaps remain in drug safety during pregnancy and breastfeeding.[4] Alarmingly, only 10% of drugs approved by the US Food and Drug Administration since 1980 have adequate data to determine an accurate teratogenic risk, and the time for determination of this risk is often decades.[5] Furthermore, most clinical recommendations for drug safety in breastfeeding are not based on lactation-specific data, and less than 2% are based on strong data.[4] Research in this area continues to rely heavily on observational data, as pregnant and breastfeeding women have been systematically excluded from clinical trials.[4,6] Motherisk was once a trusted source of knowledge in the field, maintaining extensive databases of drug-safety evidence in response to calls received by its helpline — this valuable information is now unavailable.

The closure of Motherisk followed the program's loss of credibility and external funding amid allegations of research misconduct involving its former director, Dr. Gideon Koren, who also oversaw the disgraced Motherisk Drug Testing Laboratory.[1] Given the fractured trust, it is essential that any reinvented program have the necessary oversights to ensure responsible conduct. This could be achieved by affiliation with an established research institute, and with federal support to guarantee financial independence from industry.

A reinvented program should also be modernized and aligned with the expanding complexities associated with providing perinatal care. We envision a national and interprofessional collaborative effort among clinical and research experts in reproductive drug safety; front-line providers in primary care and obstetrics; and health care organizations and specialty societies, including in family medicine, obstetrics and gynecology, nursing, midwifery, internal medicine, pediatrics and other relevant disciplines. The evidence-based counselling services should be complemented by open access and searchable databases to adapt to how patients and physicians may prefer to access information. Federal support would also mandate more patient and public involvement to ensure the program is meeting the most relevant needs of Canadians.

For now, several resources for pregnant and breastfeeding women exist outside of Canada: MotherToBaby, Best Use of Medicines in Pregnancy (BUMPS) and the Drugs and Lactation Database (LactMed). However, these are temporary fixes and cannot sustain a growing demand for timely access to drug-safety information for Canadian women and their health care providers. Canada prides itself on having some of the best indicators of maternal and child health in the world. We must reinvest in a clinical and research program focused on reproductive drug safety to ensure that Canadian women are fully supported in pregnancy and their babies can have healthy starts to life.



 

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**Competing interests:** Jonathan Zipursky completed clinical training at Motherisk as part of his fellowship in clinical pharmacology and toxicology at the University of Toronto. See www.cmaj.ca/site/misc/cmaj_staff.xhtml for Erin Russell and Nathan Stall.

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