

## Active Surveillance & Canadian multi-province Cohorts of Pregnant Women and Children

### Summary

- The CAMCCO infrastructure leads to fast-track, valid and reproducible real-world evidence for decision making, and clinical practice guidelines, including identifying serious events associated with gestational medication
- CAMCCO can be used as the foundation of a range of perinatal/child/maternal health studies and allow for long term follow-up into adulthood (lifespan approach)
- CAMCCO is one of the largest and most representative longitudinal cohorts of pregnancies, mothers, and children worldwide.
- CAMCCO results comparing descriptive baseline rates of gestational medication use, prematurity, low birth weight (LBW), multiplicity, and major congenital malformations between Quebec, Manitoba, Saskatchewan, and Alberta produced comparable rates and are also like estimates from Statistics Canada, increasing the validity of the four CAMCCO cohorts

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### What is the current situation?

Large national administrative databases or registries have been increasingly used in the field of perinatal pharmacoepidemiology, recognizing the importance of large size longitudinal pregnancy/child cohorts. Building new pregnancy/children cohorts using existing health care data takes many months or even years because several databases need to be linked, and variables need to be operationalized, coded, and harmonized to give valid answers. This lengthy process can draw out, and often prevent valuable research. Pregnant women are systematically excluded from most of the clinical trials before a drug is approved for post-marketing use, even though at least 50% of pregnant women take medications. Having standardized cohorts ready to be used will expedite investigations and allow for near real-time queries that have the potential for a more significant impact on patient care.

### What was the aim of the study?

- To develop a provincial mother-child longitudinal, population-based cohorts in Canada (QC, ON, MB, SK, AB, BC)
- To develop standardized and harmonized tools to identify pregnancy/child cohorts adequately and similarly with longitudinal follow-up
- To put in place a common repository
- To conduct a systematic review of active surveillance methodologies and perform pilot studies on active surveillance using the Canadian Healthcare system data and other types of data that may inform pharmacovigilance in Canada.

### How was the study conducted?

The Canadian Mother-Child Cohort Active Surveillance Initiative (CAMCCO) is a sentinel system for safety signals related to drug exposures during pregnancy in Canada. The CAMCCO infrastructure leverages provincial health and sociodemographic databases to harmonize provincial mother-child cohorts with longitudinal follow-up of mothers and children. Pregnant women are identified in the databases by a prenatal visit, or a therapeutic procedure related to pregnancy. Women are followed from the beginning of pregnancy (first day of the last menstrual period), until the end of pregnancy. The status of the newborn is obtained via the birth/death database or by linking the mother-child hospital patient charts. Given the status of the available databases linked within CAMCCO, women are treated and followed prospectively as part of the usual health care management during and after pregnancy. Children are similarly followed after birth. CAMCCO developed standardized and harmonized diagnosis and medication codes, programming coding, SAS algorithms, common data model that enables database linkages, follow-up, and identification of variables in a similar manner across provinces, establishing common protocols at the provincial level. Aggregate measures are available in the CAMCCO secure repository for perinatal surveillance. The CAMCCO secure website is also used for sharing of algorithms and programming codes among team members during collaborative projects across provinces for harmonization purpose

### What did the study find?

- CAMCCO includes approximately 4 million Canadian pregnancies and 3 million children with up to 23 years of follow-up (1998-2021)
- Study with four CAMCCO provincial cohorts demonstrated reliability in the harmonization procedures
- Digitized health data may help researchers and care providers understand the risk-benefit ratios related to gestational medication use, as well as province-specific trends

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