Question

With regard to the government's response to adverse events following vaccination in relation to reproductive health (pregnancy, menstrual disorders, maternal outcomes): (a) does the Vaccine Injury Support Program, the Public Health Agency of Canada or Health Canada maintain any statistics on claims or medical reports submitted by pregnant persons (either who were pregnant at the time of vaccination or subsequently) whose alleged injury involves obstetric, fetal, neonatal, or reproductive outcomes (such as miscarriage, stillbirth, preterm birth, congenital anomalies, etc.), and, if so, what are the numbers, broken down by year, and how many such claims have been accepted or rejected; (b) does the Vaccine Injury Support Program or the Public Health Agency of Canada collect or monitor claims involving significant menstrual changes (heavy bleeding, amenorrhea, menstrual irregularities) temporally related to vaccination, and, if so, how many and what percentage of such claims have been accepted or declined; (c) if no such monitoring or claims exist in relation to (b), will the government commit to retrospective review of menstrual and reproductive adverse effects, and include them in an expanded Vaccine Injury Support Program mandate or bonus coverage; (d) what medical causality framework is used to adjudicate claims involving reproductive or menstrual injuries (what standard of evidence, what expert review, how is confounding risk handled); (e) has the government commissioned or examined any internal or external studies (Canadian or international) into vaccine-associated menstrual changes or adverse pregnancy outcomes that might inform eligibility, compensation policy, or claim adjudication guidelines, and, if so, what are the titles, findings, and government responses for each; and (f) does the government claim there is insufficient scientific evidence linking vaccination to menstrual or reproductive harm, and, if so, will it commit to funding a Canadian long-term cohort study or registry to monitor menstrual and reproductive outcomes post-vaccination (with transparent periodic reporting)?

Response

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Question number	Asked by	Date asked
Q-459	Tamara Jansen (Cloverdale—Langley City)	October 16, 2025

Presented by

Kevin Lamoureux

Parliamentary Secretary to the Leader of the Government in the House of Commons

Health Canada

Reply by: the Minister of Health

Name of Signatory: Signed by Maggie Chi

Reply

Public Health Agency of Canada

(a) does the Vaccine Injury Support Program, the Public Health Agency of Canada or Health Canada maintain any statistics on claims or medical reports submitted by pregnant persons (either who were pregnant at the time of vaccination or subsequently) whose alleged injury involves obstetric, fetal, neonatal, or reproductive outcomes (such as miscarriage, stillbirth, preterm birth, congenital anomalies, etc.), and, if so, what are the numbers, broken down by year, and how many such claims have been accepted or rejected?

Canada has a robust vaccine safety system that ensures vaccines are not made available unless they have been demonstrated to be safe and effective. After vaccines are made available, Health Canada works closely with provincial and territorial health authorities, the Public Health Agency of Canada, healthcare professionals, and vaccine manufacturers to gather and monitor safety data based on real-world use and results. Health Canada also reviews information from the scientific literature and international regulators. In the rare case when a safety issue is identified, Health Canada takes all appropriate action to protect the health and safety of Canadians by acting promptly to issue warnings, update the product monograph, change recommended use, or remove a product from the market.

Adverse effects are tracked and published on a number of Government of Canada websites, including the Canada Vigilance Program, the Canadian Adverse Events Following Immunization Surveillance System, and Reported side effects following COVID-19 vaccination in Canada. It is important to note that reports do not imply an established causal

relationship between a vaccine and an adverse event, only that an event occurred. This information is provided for the sake of full transparency, out of an abundance of caution. Any new or unusual adverse events, changes in trends, or changes in the severity of reactions trigger an investigation, including an in-depth medical review and risk assessment.

The evidence reviewed by the National Advisory Committee on Immunization to support public health recommendations for individuals who are pregnant or breastfeeding was presented in a 2022 National Advisory Committee on Immunization Statement and continues to be maintained in the Canadian Immunization Guide COVID-19 vaccines chapter. Based on this broader body of evidence, Health Canada and the Public Health Agency of Canada support the use of authorized COVID-19 vaccines during pregnancy and lactation. Observational studies have also shown that vaccination in pregnancy provides protection for infants under six months of age by reducing the risk of COVID-19–related hospitalization. Since 2020, the Canadian Adverse Events Following Immunization Surveillance System received only 85 reports of injuries involves obstetric, fetal, neonatal, or reproductive outcomes:

- 2020: 0
- 2021: 58
- 2022: 17
- 2023: 8
- 2024: 1
- 2025: 1

The Public Health Agency of Canada does not have access to data related to claims submitted to the Vaccine Injury Support Program. The Vaccine Injury Support Program is currently managed by a third-party administrator, which publishes program statistics at this website.

(b) does the Vaccine Injury Support Program or the Public Health Agency of Canada collect or monitor claims involving significant menstrual changes (heavy bleeding, amenorrhea, menstrual irregularities) temporally related to vaccination, and, if so, how many and what percentage of such claims have been accepted or declined?

Since 2020, the Canadian Adverse Events Following Immunization Surveillance System received 928 claims of adverse events related to menstrual changes, broken down as follows:

- 2020: 0
- 2021: 556
- 2022: 264
- 2023: 97
- 2024: 9
- 2025: 2

The Public Health Agency of Canada does not have access to data related to claims submitted to the Vaccine Injury Support Program. The Vaccine Injury Support Program is currently managed by a third-party administrator, which publishes program statistics at this website.

(c) if no such monitoring or claims exist in relation to (b), will the government commit to retrospective review of menstrual and reproductive adverse effects, and include them in an expanded Vaccine Injury Support Program mandate or bonus coverage

The Government of Canada monitors vaccine safety through established post-market surveillance systems and reviews all emerging scientific evidence related to vaccine safety, including menstrual and reproductive outcomes.

(d) what medical causality framework is used to adjudicate claims involving reproductive or menstrual injuries (what standard of evidence, what expert review, how is confounding risk handled)?

Claims submitted to the Vaccine Injury Support Program are reviewed and adjudicated by the third-party administrator currently managing the program. The Public Health Agency of Canada is not involved in the process. Note that the Government of Canada will take over management of the Vaccine Injury Support Program as of April 1, 2026.

However, there is no evidence to support any claims of menstrual or reproductive harms suggested in the question. Available evidence from reputable sources does not demonstrate any increased risks from vaccination such as heavy menstrual bleeding, miscarriage, preterm birth, or other pregnancy-related complications

(e) has the government commissioned or examined any internal or external studies (Canadian or international) into vaccine-associated menstrual changes or adverse pregnancy outcomes that might inform eligibility, compensation policy, or claim adjudication guidelines, and, if so, what are the titles, findings, and government responses for each?

Available studies and safety assessments do not show the menstrual or reproductive harms described in the question, nor do they identify increased risks such as heavy menstrual bleeding, miscarriage, preterm birth, or other pregnancy-related complications. Health Canada continues to monitor the safety of all vaccines marketed in Canada through the review of post-market safety information from a variety of sources, including reports of adverse events following immunization, the scientific literature, manufacturers and international regulators.

Following reports of heavy menstrual bleeding following vaccination with the Comirnaty and Spikevax COVID-19 vaccines, Health Canada conducted a post-marketing safety review that included a comprehensive analysis of international and domestic literature as well as post-marketing adverse event information. The review found limited evidence to conclude that vaccination with Comirnaty or Spikevax COVID-19 vaccines increased the risk of heavy menstrual bleeding, and that any changes to menstrual cycles were temporary and resolved within 1 to 2 menstrual cycles. The review also found no evidence that vaccines increased the risk of having a miscarriage, preterm birth, or other pregnancy complications, and no evidence of increased risk for adverse events in breastfeeding individuals or breastfed newborns/infants following maternal vaccination with these vaccines. A summary of the review was published in the July 2023 edition of the Health Product Infowatch. The findings from this review are consistent with those of other international regulators of medicines on the same subjects.

The Public Health Agency of Canada, through the Canadian Institutes for Health Research, funded a Canadian National Vaccine Safety network survey of pregnant individuals, and through the COVID-19 Immunity Task Force, funded multiple studies in pregnant individuals. Details on their research and results can be found at the Geographic, priority population, Indigenous & 2SLBGTQ+ - COVID-19 Immunity Task Force website.

Canadian studies have included:

- Canadian Surveillance of COVID-19 in Pregnancy
- Canadian Population Serological Survey Using Antenatal Serum Samples
- Canadian COVID-19 Vaccine Registry for Pregnant & Lactating Individuals
- COVID-19 vaccination in pregnancy: A province-wide epidemiological assessment of safety and effectiveness using the Better Outcomes Registry & Network Ontario Registry

- Sadarangani, M et al. (2022). Safety of COVID-19 vaccines in pregnancy: A Canadian National Vaccine Safety network cohort study.

There is a Canadian COVID-19 Vaccine Registry for Pregnant and Lactating Individuals, hosted at the University of British Columbia and funded by the Public Health Agency of Canada, which was tasked with assessing the safety and effectiveness of COVID-19 vaccines in pregnant and breastfeeding persons. The study includes follow-up surveys on infant outcomes at 6 months after delivery and child outcomes at 12 months after delivery, capturing information about infant and child development and health.

There are numerous published scientific literature on the safety of vaccines administered to pregnant women and people. The Public Health Agency of Canada and Health Canada continue to monitor the safety and effectiveness of all authorized vaccines in pregnant individuals in collaboration with provinces, territories, and manufacturers. Health Canada also works closely with international regulatory partners to rapidly share emerging safety information, evidence, and analysis. This commitment to ongoing transparency provides Canadians with information to make informed decisions.

(f) does the government claim there is insufficient scientific evidence linking vaccination to menstrual or reproductive harm, and, if so, will it commit to funding a Canadian long-term cohort study or registry to monitor menstrual and reproductive outcomes post-vaccination (with transparent periodic reporting)?

The claims being made in this question are incorrect.

The evidence reviewed to date does not show a causal association between vaccination and menstrual or reproductive harm. Findings from a safety review completed by Health Canada found no scientific or medical evidence that vaccination with mRNA COVID-19 vaccines increases the risk of heavy menstrual bleeding. Similarly, Health Canada's review of the use of mRNA COVID-19 vaccines during pregnancy and breastfeeding found no evidence that vaccination with Comirnaty or Spikevax increases the risk of having a miscarriage, preterm birth or other pregnancy complications. In addition, no increased risk for adverse events in breastfeeding individuals and breastfed newborns/infants was observed following maternal vaccination. For more information, you may visit the Health Product Infowatch document.

Canada has a robust and well-established vaccine safety surveillance system involving Health Canada, the Public Health Agency of Canada, provinces and territories, and vaccine manufacturers. Health Canada continues to monitor the safety of COVID-19 vaccines approved in Canada to help ensure that the benefits continue to outweigh the risks for all groups of individuals, including pregnant and lactating women. The safety profile of these products are monitored by reviewing information from the scientific literature, manufacturers, and information shared by international regulators.

In addition, as part of the monitoring for all COVID-19 vaccines authorized in Canada, the market authorization holders assess outcomes in pregnancy and breastfeeding women including outcomes in breastfed infants and toddlers as a result of exposure to vaccinated mothers or their breastmilk as part of ongoing and completed pharmacovigilance activities. Results from these pharmacovigilance studies are submitted to and reviewed by Health Canada regularly. To date, there are no signals identified. Health Canada will take appropriate action should new safety information become available. This may include communicating new risks to Canadians and healthcare professionals or changing the recommended use of the drug product.

The beneficial effects of immunization during pregnancy for the pregnant person and/or fetus, as well as the newborn infant, have been well documented. Vaccination during pregnancy protects pregnant women and pregnant individuals from vaccine-preventable diseases that may otherwise be acquired and be transmitted to the fetus or infant. In addition, protective antibodies can be transferred to the fetus through the placenta, resulting in increased infant protection in the early postnatal period.

In Canada, vaccines that are recommended for pregnant persons have been reviewed for use by the National Advisory Committee on Immunization, an external advisory body that provides independent, expert advice to the Public Health

Agency of Canada on the use of authorized vaccines in Canada. The Committee recommends vaccines for use in pregnant and breastfeeding individuals where there is sufficient evidence that the benefits outweigh any potential risks, based on the continuous review of global vaccine safety surveillance, vaccine effectiveness, and vaccine safety studies, as well as Canadian epidemiology. Non-live vaccines administered in pregnancy have a good safety profile. No causal association to menstrual or reproductive harm has been identified with vaccines authorized for use in Canada.

There are no published data indicating that currently authorized non-live vaccines are harmful to an embryo or fetus. Currently, there are no published data confirming a causal relationship between any authorized non-live vaccine and pregnancy-specific adverse outcomes.

By contrast, both Canadian and United States data show an increased risk of preterm birth associated with SARS-CoV-2 infection in pregnancy. Preterm birth is linked to an increased incidence of diseases and long-term health complications.

Menstrual cycle irregularities are common during the reproductive years, independent of vaccination, particularly at the beginning and towards the end of the reproductive years. Additionally, stress, infections, and medications commonly cause changes in cycle length, duration, and heaviness of bleeding. There are published studies that suggest there could be an increased risk of mild, subtle changes to menstrual cycles that resolve quickly following COVID-19 vaccination, which might include prolonged bleeding, changes in cycle length, and increased pain. However, there were conflicting findings between studies, and multiple sources of bias. Health Canada and the Public Health Agency of Canada continue to review reports of menstrual irregularities following COVID-19 vaccination, as well as international studies on this issue.