

AT A GLANCE

How Vaccine Safety is Monitored in Ontario

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Introduction

A robust vaccine safety monitoring system is essential to ensure that vaccines we use are safe. Vaccines are held to an exceptionally high standard of safety as they are given to prevent illness in otherwise healthy individuals. Ensuring the safety of vaccines is also critical for sustaining public confidence in vaccines as vaccine hesitancy and the erosion of vaccine confidence threaten the success of immunization programs around the world.^{1,2} In 2019, the World Health Organization identified vaccine hesitancy as one of the top ten threats to global health.³ Thus, communicating how vaccine safety is monitored and demonstrating the safety profile of vaccines are key factors in maintaining public confidence in vaccines.

This document provides an overview of vaccine safety monitoring in Ontario and its integration within the broader Canadian system. It is intended for public health professionals and health care providers who report adverse events following immunization (e.g., physicians, nurse practitioners, nurses, and pharmacists).

Vaccine Pharmacovigilance

Vaccine pharmacovigilance is defined as the science and activities related to the detection, assessment, understanding, and communication of adverse events following immunization (AEFIs), as well as the prevention of untoward effects of the vaccine or immunization.² Pharmacovigilance activities are important throughout the lifecycle of a vaccine product.

An adverse event following immunization (AEFI) is an unwanted or unexpected health event that happens after someone receives a vaccine.² An AEFI may be an expected event (i.e., listed in product monograph) or an unexpected event. It can be any unfavourable or unintended sign, laboratory finding, symptom, or disease. An AEFI may or may not be caused by the vaccine.

The safety of vaccines is carefully monitored, beginning early in product development and continuing for as long as a vaccine is used. Although vaccines typically undergo about 10 years of research and development before they are considered for approval, not all potential adverse events can be identified during pre-market testing.^{2,4} Because clinical trials involve relatively small, select populations over short periods, some adverse events only emerge when vaccines are used on a larger scale in varied populations over time. Ongoing pharmacovigilance after approval is essential to ensure continued safety.

Vaccine Safety System in Canada

Canada has a robust vaccine safety system.⁵ Vaccines undergo rigorous testing for safety, efficacy, and quality through non-clinical and clinical trials before they are authorized for use in Canada. After authorization, post-market vaccine safety surveillance at the national level is a shared responsibility between two federal government departments: Health Canada and the Public Health Agency of Canada (PHAC).⁶ Health Canada oversees vaccine manufacturers' obligations for post-market safety monitoring and reporting as well as their regulatory oversight role for safety, quality, and effectiveness. PHAC, in collaboration with the provinces and territories, monitors and reports on AEFIs at the national level primarily through the management of the Canadian Adverse Event Following Immunization Surveillance System (CAEFISS). CAEFISS is a federal, provincial, and territorial (FPT) public health post-market vaccine safety surveillance system that allows for national monitoring of vaccine safety.⁷ AEFIs reported to FPT public health authorities are routinely submitted to CAEFISS.

Vaccine Safety Surveillance in Ontario

In Ontario, vaccine safety surveillance is carried out through a coordinated system involving health care providers (HCP), public health units (PHU), Public Health Ontario (PHO), and the Ministry of Health (MOH). See Figure 1 for their roles and responsibilities within the Ontario vaccine safety surveillance system.

The objectives of vaccine safety (AEFI) surveillance in Ontario include:

- Identifying and investigating serious or unexpected occurrences of AEFIs, particularly for new vaccines
- Detecting and investigating safety signals (e.g., lot specific problems),
- Estimating provincial rates of reported AEFI by vaccine
- Reporting to stakeholders on the safety of publicly funded vaccines in Ontario
- Maintaining public confidence in vaccine programs

Key Vaccine Safety Surveillance Methods in Ontario

Successful vaccine safety surveillance and monitoring employs multiple complementary systems to improve signal detection and signal confirmation. In Ontario these methods include:

1. **Passive vaccine safety surveillance:** Also known as spontaneous reporting, it relies on unsolicited individual AEFI reports from HCPs and the public.^{8,9} It is the primary method for vaccine safety surveillance in Ontario (see [AEFI reporting in Ontario](#)).
2. **Active vaccine safety surveillance:** Involves proactively searching for AEFIs in health records or eliciting symptoms and health events from individuals following vaccination. Active surveillance may provide rapid information on AEFIs in the early stages of a vaccine campaign.
 - Ontario participates in the Canadian National Vaccine Safety Network (CANVAS), which is part of the Canadian Immunization Research Network (CIRN). CANVAS elicits participant-centred reporting via web surveys to identify any AEFIs that prevent daily activities or require medical attention for select immunization programs.
3. **Special studies:** Studies conducted in response to signal detection or serious AEFIs, or to collect additional information from those who have experienced serious AEFIs, as rare events may need a large database with significant representation of groups at highest risk.

Public health surveillance of AEFIs in Ontario

Mandatory Reporting of AEFIs

In Ontario, public health surveillance of AEFIs relies on HCPs, vaccine recipients, or their caregivers to report AEFIs to their local PHU (i.e., passive surveillance). See Figure 2 for an overview of the flow of AEFI reporting in Ontario.

The Health Protection and Promotion Act (HPPA), s. 38.3 mandates all HCPs who administer immunizations (e.g., physicians, nurse practitioners, nurses, pharmacists, or other regulated health professionals in Ontario) to report AEFIs to the local medical officer of health where the professional services are provided.¹⁰ The Ministry of Health is responsible for provincial public health legislation and standards, which enable the reporting and collection of information required for provincial surveillance.

The [Ontario AEFI Reporting Form](#) should be used by HCPs to report AEFIs to their local PHUs. PHUs may also use the form to record AEFI information reported to them. The form is designed to capture the information required for provincial vaccine safety surveillance and for complete and accurate data entry into the provincial electronic reporting system.

Public Health Unit Reporting and Data Entry

Once the local PHU receive an initial report of an AEFI, the PHU investigates, assesses, and documents the reports according to provincial surveillance guidelines outlined in the [Infectious Disease Protocol](#) (Appendix 1) of the Ontario Public Health Standards.¹¹ Complete and timely data entry of reports that meet the provincial case definition in the integrated Public Health Information System (iPHIS), the provincial electronic reporting system for diseases of public health significance and AEFIs, is critical to effectively monitor vaccine safety. New AEFI reports must be entered by the PHU into iPHIS within five business days of receipt of an AEFI report. Data entry should follow the guidelines outlined in the iPHIS User Guide: Adverse events following immunization. Any adverse events following products outside the scope of provincial surveillance should be reported to Health Canada using the [Side Effect Reporting Form](#).

Provincial AEFI Surveillance and Analysis

In Ontario, PHO uses AEFI surveillance data to conduct provincial vaccine safety surveillance, support publicly funded immunization program planning and evaluation and to inform communication about the safety of vaccines administered in Ontario. PHO routinely analyzes and monitors the data to identify and investigate serious or unexpected occurrences of AEFIs and to examine trends over time. Potential vaccine safety issues that may warrant further assessment or action are investigated.

Vaccine safety data are reported to immunization stakeholders and published [online](#) annually. PHO also produces ad hoc vaccine safety reports following enhanced surveillance and contributes to the national vaccine surveillance system. the national vaccine surveillance system.

Figure 1: Roles and Responsibilities Within the Ontario Vaccine Safety Surveillance System



Vaccine recipient, parents/caregivers, health care providers (HCPs)

- Vaccine recipients and/or parents/caregivers report AEFIs to their HCPs or local PHUs
- HCPs are required by law to report AEFIs to their local PHU and to inform vaccine recipients of the importance of reporting a potential AEFI



Local public health units

- Receive, assess, and investigate AEFI reports received
- Document AEFIs into provincial electronic reporting system, following provincial surveillance guidelines
- Provide information, support, and recommendations for HCPs and individuals experiencing AEFIs



Public Health Ontario: Vaccine safety team

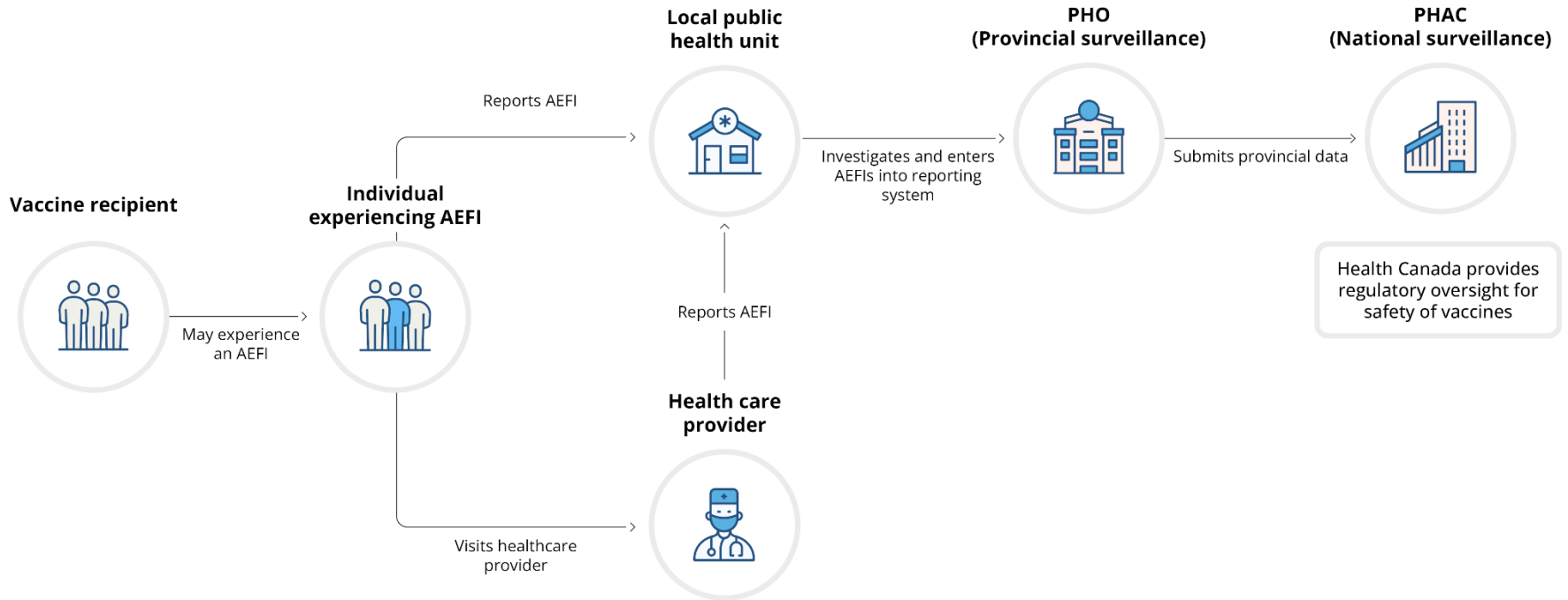
- Conducts ongoing provincial surveillance of AEFIs
- Provides support, training, and advice to PHUs
- Provides resources for HCPs
- Participates in the national surveillance system



Ministry of Health

- Implements immunization legislation, standards, and policy
- Manages vaccine supply, inventory, and logistics

Figure 2: Flow of AEFI reports in Ontario



Vaccine Safety Resources

- [PHO AEFI reporting form](#): The form is designed to capture the information needed for provincial vaccine safety surveillance and for complete and accurate iPHIS data entry. Use is highly recommended, though not required, for initial reporting of AEFI information—either by health professionals reporting AEFIs to their local PHU or by PHUs recording AEFI information reported to them.
- [Adverse Event Following Immunization Reporting for Health Care Providers in Ontario](#): Information for health care providers on how to report adverse events following immunization (AEFI).
- [Infectious Diseases Protocol Appendix 1: Adverse Events Following Immunization \(AEFIS\)](#): Provides provincial surveillance case definitions and public health management for AEFIs.
- [iPHIS User Guide: Adverse Events Following Immunization \(AEFIs\)](#): Outlines for PHUs the standardized data entry procedures and requirements for AEFIs in the integrated Public Health Information System (iPHIS). It highlights data fields in iPHIS that are required for provincial vaccine safety surveillance.
- [PHO Vaccine Safety Team](#): Provides PHU consultation on individual AEFIs, including AEFI reporting requirements.
- [Immunization Data Tool](#): An interactive online tool which provides comprehensive vaccine safety surveillance data collected from AEFIs from 2015 to 2025.
- [Canadian Adverse Events Following Immunization Surveillance System \(CAEFISS\)](#): CAEFISS is a federal, provincial and territorial (FPT) public health post-market vaccine safety surveillance system managed by PHAC that includes passive (spontaneous reports from FPTs), active, and enhanced surveillance data.
- [Canadian Immunization Guide: Part 2. Vaccine safety](#): Provides comprehensive information for healthcare providers on monitoring and managing adverse events after immunization (AEFIs), including guidelines for recognizing and treating anaphylaxis, understanding contraindications, and reporting safety data.
- [Special Immunization Clinic \(SIC\)](#): Provides expertise in the clinical care of patients who have experienced AEFIs and potential contraindications to immunization, and those who have medical conditions that may affect their response to immunization. The network is comprised of a national team of expert clinicians (e.g. infectious disease specialists, allergists) with an interest in vaccine safety. Physicians may refer their patients with an AEFI to a SIC in their area.
- [Vaccine Impact Assistance Program \(VIAP\)](#): The VIAP provides support to people in Canada who have been assessed as having been seriously and permanently injured as a result of receiving a Health Canada-authorized vaccine.
- [Managing Adverse Events Following Immunization: Resource for Public Health](#): Developed by the Special Immunization Clinic (SIC) Network Investigators, this document provides an overview of AEFIs seen at the Canadian SICs and support Medical Officers of Health (MOHs) and other public health officials in reviewing AEFI reports. It aims to guide decision-making regarding the continuation of immunization and the need for specialist referral.
- [Ontario Public Health Unit Locations](#)

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