

FOCUS ON

How vaccine safety is monitored in Canada

Introduction

Vaccine safety monitoring is an essential component of an effective immunization program spanning all phases of the vaccine product life cycle from development, to market authorization, administration and post-marketing surveillance.¹ In Canada, vaccines are highly regulated. They are thoroughly reviewed for efficacy and safety prior to being authorized for use and are continually monitored to ensure their safety. As vaccines for the novel Coronavirus Disease 2019 (COVID-19) are authorized for use in Canada, vaccine safety surveillance will be critical for the ongoing monitoring of these new vaccines.

This Focus On provides an overview of the vaccine safety surveillance landscape in Canada and Ontario, highlighting how local, provincial and federal vaccine safety systems work together to ensure vaccines authorized for use in Canada remain safe and effective throughout the product life cycle.

Vaccine safety surveillance in Canada

In Canada, post-marketing surveillance is a shared responsibility between Health Canada, vaccine manufacturers, the Public Health Agency of Canada (PHAC), provinces and territories, as well as local public health authorities. PHAC and Health Canada coordinate post-marketing vaccine safety surveillance nationally, while provinces and territories coordinate surveillance of adverse events following immunization (AEFIs) occurring within their jurisdiction in collaboration with local partners.

Following the approval of a new vaccine, post-marketing surveillance is initiated to ensure the ongoing monitoring of safety on a larger scale, throughout implementation of a vaccine program.¹ Individual reports of AEFIs represent an important source of data because they have the potential to identify previously unrecognized or rare AEFIs or an increase in frequency or severity of known AEFIs, which can be further evaluated.²

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of a vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.¹

AEFIs reported to provincial and territorial public health authorities are sent to the Canadian Adverse Event Following Immunization Surveillance System (CAEFISS), maintained by PHAC. Reports of AEFIs made directly to vaccine manufacturers are sent to Health Canada. CAEFISS is a collaborative post-marketing surveillance system that continuously monitors the safety of vaccines in Canada through active and passive (spontaneous) reporting processes, with the following objectives:

- Identify increases in the frequency or severity of previously identified vaccine-related reactions;

- Identify previously unknown adverse events that could possibly be related to a vaccine;
- Identify areas that require further investigation and/or research; and
- Provide timely information on AEFI reporting profiles that can help inform immunization-related decisions.³

Active surveillance is another component of the vaccine safety surveillance system that involves proactively soliciting adverse events from vaccine recipients or searching adverse events in clinical or administrative records.¹ In Canada, two key active surveillance programs for vaccine safety include: the [Immunization Monitoring Program ACTIVE \(IMPACT\)](#),⁴ which is a paediatric, hospital-based network administered by the Canadian Paediatric Society and the [Canadian Vaccine Safety \(CANVAS\) Network](#),⁵ a national network of sites across Canada that conducts active vaccine safety surveillance during implementation of immunization campaigns (e.g. annual influenza vaccine).

AEFI reporting in Ontario

The public health aim of surveillance of AEFIs in Ontario is early detection and timely response to real or perceived vaccine safety issues. In Ontario, passive vaccine safety surveillance relies on reporting of AEFIs by health care providers, vaccine recipients or their caregivers to their local public health unit (PHU). Reporting of AEFIs for all immunizing agents available for use in Canada is mandated for health care providers who administer immunizations under Section 38 of the Health Protection and Promotion Act (HPPA) and Regulation 569.⁶ The [Ontario AEFI reporting form](#) is used by health care providers to submit AEFI reports to the PHU.⁷

AEFI reports received by PHUs are investigated, assessed and documented in the provincial surveillance system. Public Health Ontario (PHO) conducts provincial surveillance of AEFIs and transmits data to PHAC for inclusion in CAEFISS. As COVID-19 vaccine programs are implemented in Ontario, enhanced surveillance will be completed on a frequent basis to review and monitor reported AEFIs and ensure the ongoing safety of these new vaccines.

Vaccine safety resources

The following are some key trusted resources to support public health and health care provider communication about the vaccine safety surveillance system:

- [Canadian Adverse Events Following Immunization Surveillance System \(CAEFISS\)](#)³
Public Health Agency of Canada
- [Canadian Immunization Guide Part 2: Vaccine Safety](#)¹
Public Health Agency of Canada
- [Canada's Eight-Component Vaccine Safety System: A Primer for Health Care Workers](#)⁸
Canadian Paediatric Society
- [Vaccine Safety](#)⁹
Public Health Ontario
- [Adverse Event Following Immunization Reporting for Health Care Providers in Ontario](#)¹⁰
Public Health Ontario

- [Vaccine Safety Surveillance Tool](#)¹¹
Public Health Ontario

Conclusion

Comprehensive surveillance of vaccine safety is critical to the success of immunization programs. As COVID-19 vaccines are authorized for use in Canada, Ontario is working with federal/provincial/territorial partners to conduct post-marketing surveillance to monitor the safety of these new vaccines. Coordinated efforts to ensure timely and ongoing reporting of AEFIs from public health authorities, and the broader health care system is essential to identify early vaccine safety signals, and maintain public confidence in Ontario's vaccine programs.

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<https://www.publichealthontario.ca/-/media/documents/f/2018/factsheet-aefi-healthcare-providers.pdf?la=en>

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