The public health aim of surveillance of adverse events following immunization (AEFIs) in Ontario is early detection and timely response to real or perceived vaccine safety issues, to lessen any impact on the health of individuals and immunization programs. In addition, AEFI surveillance provides important information to support and inform immunization program planning and evaluation.

In Ontario, AEFI reports originate from health care providers, vaccine recipients or their caregivers. The Health Protection and Promotion Act, R.S.O. 1990, c. H.7, Section 38 mandates reporting of AEFIs by registered nurses, pharmacists and physicians. Required AEFI data are subsequently reported by public health units (PHUs) to the province through integrated Public Health Information System (iPHIS). Public Health Ontario (PHO) conducts provincial surveillance of AEFIs and provides advice and support to local PHUs in the investigation and management of AEFI reports. This role was transferred from the Ministry of Health & Long-Term Care (MOHLTC) on January 1, 2012.

The source for AEFI data in this interactive tool is iPHIS, the electronic reporting system for reportable diseases and AEFIs in Ontario. AEFI data included in this tool were extracted from iPHIS on May 1, 2016. Data presented here include AEFIs reported following vaccines administered from 2012 to 2015. Some limited comparison for overall trends is also made to AEFIs reported following vaccines administered in 2011, however these data are excluded from further analysis (i.e., by vaccine) due to data quality issues.

For more detailed information on vaccine safety surveillance in Ontario including previous annual reports (in PDF format), please see PHO’s vaccine safety webpage.

Trends

Trends in the number of AEFIs and reporting rate are summarized by year of vaccine administration. AEFI counts include only those with a confirmed case classification in iPHIS. Confirmed AEFIs are defined in Appendix B (Adverse Events Following Immunization) of the Ontario Public Health Standards, Infectious Diseases Protocol, 2016. Note, the use of the word “confirmed” relates to surveillance case definitions only, and does not infer causality.
Calculating AEFI reporting rates
Annual AEFI reporting rates are calculated using the number of AEFI reports by year of vaccine administration divided by the annual Ontario population. Population data are received from Statistics Canada via the MOHLTC and include estimates for 2012-14 (as of November 18, 2015) and projections for 2015 (as of March 13, 2015).

Reporting rates are not incidence rates
Please note: Reporting rates are calculated to assess trends over time and compare to other jurisdictions; they should not be interpreted as incidence rates. A higher overall reporting rate does not necessarily suggest a vaccine safety concern; rather, it is an indicator of a robust passive vaccine safety surveillance system. The quantity of reports contributes to establishing a clear historical baseline that can be used to identify future vaccine safety signals.

Age and Sex

Age
Age categories for analysis are based on key age milestones within the provincial immunization schedule (<1 year, 1-3 years, 4-10 years, 11-17 years, 18-64 years, 65+ years). AEFI reports with unknown age are excluded from analysis which is categorized by age and indicated in footnotes where relevant.

Sex
Gender is completed in iPHIS by PHUs based on the reported gender of the client. For analysis purposes, gender is used as a proxy for biological sex. AEFI reports with unknown or unspecified gender are excluded from analysis which is categorized by sex and indicated in footnotes where relevant.

Map

Shaded map categories are defined using the provincial AEFI reporting rate as a benchmark. The higher two categories are at or above the 2015 provincial reporting rate and the lower two are below this rate. PHU-specific reporting rates are calculated using the number of AEFI reports by year of vaccine administration within a specific PHU divided by the annual PHU population. Population data is received from Statistics Canada via the MOHLTC and include estimates for 2012-14 (as of November 18, 2015) and projections for 2015 (as of March 13, 2015).

Reporting rates are not incidence rates
Please note: Reporting rates are calculated to assess trends over time and compare to other jurisdictions; they should not be interpreted as incidence rates. A higher overall reporting rate does not necessarily suggest a vaccine safety concern; rather, it is an indicator of a robust
passive vaccine safety surveillance system. The quantity of reports contributes to establishing a clear historical baseline that can be used to identify future vaccine safety signals.

**Vaccines**

The term “vaccine” refers to a generic active immunizing agent and may include one or more vaccine products (e.g., “influenza vaccine” refers to all influenza vaccine products). Each AEFI report pertains to one individual who received one or more vaccines administered on the same day. Therefore the total number of vaccine-specific AEFIs can exceed the number of individual AEFI reports. Vaccines are grouped and presented according to the [Publicly Funded Immunization Schedules for Ontario](https://www.gov.on.ca/eng/health/Vaccines/Schedules/).

Vaccine-specific reporting rates are calculated using the number of AEFI reports for a vaccine by year of vaccine administration divided by net vaccine doses distributed (adjusted for wasted and returned reusable vaccine). Reporting rates are expressed as the number of AEFI reports for every 100,000 vaccine doses distributed. Vaccine distribution data are provided by the MOHLTC. Vaccine specific reporting rates for travel and high risk vaccines are not calculated due to unknown vaccine distribution within the private market.

Serious AEFIs are defined using the WHO standard definition: an AEFI that results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or in a congenital anomaly/birth defect.

**Adverse Events**

Adverse events are grouped according to [provincial surveillance definitions and categories](https://www.gov.on.ca/eng/health/Vaccines/Schedules/). Each AEFI report pertains to one individual who may have experienced one or more specific adverse events after receipt of one or more vaccines. Therefore the total number of adverse events can exceed the number of individual AEFI reports.
General limitations of AEFI surveillance

General limitations of AEFI surveillance data presented here are similar to other passive AEFI surveillance systems. These include inconsistent quality and completeness of AEFI reports, and reporting bias including under-reporting, particularly for mild or common reportable events, as well as stimulated (elevated) reporting which can occur in response to media coverage and subsequently increased public awareness. Additionally, the provincial AEFI surveillance system does not include an unimmunized group for comparison, therefore determining whether immunization is associated with an increased risk of a specific adverse event is not possible; further study would be required.

Suggested citations

Citation for tool overall


Source statement for a graph:

Generic citation format

Author. Interactive tool name: Specific title as it appears on the graph [Internet]. Toronto, ON: Queen’s Printer for Ontario; Year [cited date].

Example


Notes

It is important to include a cited date in order to transparently reflect the currency of the data. URLs are not included for graphs because the URLs will only re-produce the default view, not the specific selections made to generate a particular graph.
Source statement for a map:

Generic citation format

Author. Interactive tool name: Specific title as it appears on the map [Internet]. Toronto, ON: Queen's Printer for Ontario; Year [cited date].

Example


Notes

It is important to include a cited date in order to transparently reflect the currency of the data. URLs are not included for graphs because the URLs will only re-produce the default view, not the specific selections made to generate a particular graph.

Source statement for downloaded data:

Generic citation format

Data source as extracted and/or received by author. Interactive tool name: Specific title as it appears on the source graph or map [Internet]. Toronto, ON: Queen’s Printer for Ontario; Year [cited date].

Example

Source: Data sources as extracted and/or received by Ontario Agency for Health Protection and Promotion (Public Health Ontario). Vaccine Safety Surveillance: Number of AEFI reports and reporting rate by age group and sex, Ontario, 2013 [Internet]. Toronto, ON: Queen’s Printer for Ontario; 2017 [cited 2017 May 17].

Notes

It is important to include a cited date in order to transparently reflect the currency of the data. The details about the data sources are available in the Trends, Map, and Vaccines, section of this document.