

Technical Data Notes

Vaccine safety surveillance tool

Introduction

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. In addition, AEFI surveillance provides important information to support and inform immunization program planning and evaluation.

In Ontario, the [Health Protection and Promotion Act, RSO 1990, c. H.7, Section 38](#) mandates reporting of AEFIs by registered nurses, pharmacists and physicians, although others may voluntarily report an AEFI to their local public health unit (PHU). The PHUs investigate and report AEFIs according to [provincial surveillance definitions](#) using the integrated Public Health Information System (iPHIS), the electronic reporting system for reportable diseases and AEFIs in Ontario. 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 to PHO from the Ministry of Health and Long-Term Care (MOHLTC) on January 1, 2012.

AEFI data included in this tool were extracted from iPHIS on May 11, 2018. Data presented here include AEFIs reported following vaccines administered between 2012 and 2017. It is important to note that this tool describes adverse events that were temporally associated and not necessarily causally linked to vaccines. For provincial surveillance reporting, an adverse event must occur after receiving the vaccine and must meet the [provincial AEFI surveillance definitions \(see Adverse Events below\)](#). This does not mean that the adverse event was caused by the vaccine.

For more detailed information on vaccine safety surveillance in Ontario including annual reports (in PDF format), please see PHO's [vaccine safety webpage](#). For a detailed description of the methods used for the analysis of AEFI surveillance data, please see the [Technical Annex of the Annual Report on Vaccine Safety in Ontario](#).

Vaccine safety surveillance tool

Trends

Temporal trends in the number of AEFI reports and reporting rate are assessed by year of vaccine administration. AEFI reports include only those with a confirmed case classification in iPHIS and at least one vaccine associated with the report. Note that the use of the word “confirmed” relates to the surveillance case definition only, and does not mean that the vaccine caused the AEFI. See [Appendix B \(Adverse Events Following Immunization\)](#) of the Ontario Public Health Standards, Infectious Diseases Protocol, 2016 for provincial AEFI surveillance definitions.

Calculating AEFI reporting rates

AEFI reporting rates are calculated using both doses distributed and population-based denominators, depending on the purpose and the availability of information. Doses distributed enables a more accurate comparison of AEFI reporting rates across geographic areas by taking into account the differences in vaccine distribution. However, dose distribution data are not available within specific demographic groups (e.g., age, sex). Therefore, population-based rates are used for calculating reporting rates within specific demographic groups (e.g., age group, sex).

Population-based reporting rates are calculated using the number of AEFI reports received by year of vaccine administration within a specific demographic group (e.g., age, sex and geography) divided by the annual population of the same demographic group. Population data are received from IntelliHEALTH Ontario via the MOHLTC and include estimates for 2012 to 2016 and projections for 2017 (extracted October 19 and 24, 2017, respectively). Reporting rates are expressed as the number of AEFI reports for every 100,000 population. In the Vaccine safety surveillance tool, population-based AEFI reporting rates are presented in the [Trends](#), [Age and sex](#), and [Map](#) sections.

Dose-based reporting rates are calculated using the number of vaccine-specific AEFI reports by year within a geographic region (e.g., all of Ontario or within a PHU) divided by the annual net number of vaccine doses distributed within the specified geographic region. Net doses distributed is used as a proxy for doses administered and are estimated using vaccine distribution data extracted from Panorama, which is the provincial information system for vaccine supply management. The number of net doses distributed are calculated by subtracting the number of wasted and reusable vaccines returned to the Ontario Government Pharmacy and Medical Supply Service (OGPMSS) from the gross number of vaccines distributed in a given year. Reporting rates are expressed as the number of AEFI reports for every 100,000 vaccine doses distributed. In the Vaccine safety surveillance tool, dose-based AEFI reporting rates are presented in the [influenza vaccine](#) section of the Map and the [Vaccine](#) section.

For additional information on AEFI reporting rates, please see the [Annual Report on Vaccine Safety in Ontario](#) and the [Technical Annex](#).

Reporting rates are not incidence rates. 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 age-specific analysis but are included in the 'all ages' category, 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 sex-specific analysis but are included in the 'all sexes' category, and indicated in footnotes where relevant.

Map

PHU-specific reporting rates are grouped into four categories using quartiles (ie 25th, 50th, 75th percentiles) specific to each year and vaccine category.

All vaccines

The reporting rate includes AEFIs reported following any vaccine administered in a given year. The population includes people of all ages.

School-based vaccines

The reporting rate includes AEFIs reported following vaccines that are routinely administered by PHUs to adolescents in school-based settings. These vaccines include Men-C-ACWY, HB, and HPV4; HPV9 replaced HPV4 in 2017. The population only includes adolescents between 11 and 17 years of age.

Early childhood vaccines

The reporting rate includes AEFIs reported following routine vaccines that are predominantly administered by primary health care providers to infants and young children. These vaccines include DTaP-IPV-Hib, Rot-1, Pneu-C-13, MMR, Men-C-C, and Var. The population only includes children under four years of age.

Influenza vaccine

The reporting rate includes AEFIs reported following influenza vaccine administered in a given year. The population includes people of all ages. For influenza vaccine, the reporting rate is calculated using both population and doses distributed.

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 refers to an individual who received one or more vaccines administered on the same day. Therefore the total number of vaccine-specific AEFI reports can exceed the number of individual AEFI reports within a given year. For each vaccine, the number of AEFI reports is the total of both serious ([see below](#)) and non-serious AEFI reports. Vaccines are grouped according to the [Publicly Funded Immunization Schedules for Ontario](#). Vaccine-specific reporting rates for high-risk publicly funded, travel, and non-publicly funded vaccines are not calculated due to unknown vaccine distribution within the private market.

Vaccine categories

Vaccines are grouped into categories based on the recommended age to receive the vaccine according to the [Publicly Funded Immunization Schedules for Ontario](#). Infant and childhood vaccines include those that are routinely administered to children 10 years of age and younger; adolescent vaccines include those that are routinely administered to adolescents between 11 and 17 years of age; and adult vaccines include those that are routinely administered to adults 18 years of age and older.

Serious AEFIs

Serious AEFIs are defined using the World Health Organization (WHO) standard definition: an AEFI that results in death, is life-threatening, requires in-patient hospitalization or prolongs an existing hospitalization, results in persistent or significant disability/incapacity, or in a congenital anomaly/birth

defect.^{1,2} Due to data limitations in iPHIS and the relatively brief follow-up period of AEFIs reported in Ontario, AEFIs that meet the serious definition typically have an in-patient hospitalization or are reported to have died. In-patient hospitalization is defined as having a hospitalization recorded in iPHIS with a discharge date that is at least one day following the admission date.

Adverse Events

Each AEFI report refers to an individual who experienced at least one adverse event after receiving one or more vaccine on the same day. An adverse event refers to an event which is temporally associated with receipt of vaccine and meets the corresponding event-specific provincial surveillance definition. These definitions are outlined in [Appendix B \(Adverse Events Following Immunization\)](#) of the Ontario Public Health Standards, Infectious Diseases Protocol, 2016. Adverse events are presented both individually and within event categories, based on the [provincial surveillance definitions and categories](#). As an AEFI report may contain multiple adverse events, the total number of adverse events can exceed the number of individual AEFI reports reported in a given year. In addition, if an AEFI report contains more than one adverse event within the same event category, they are counted only once in the category total. Therefore, the total number of adverse events within a category may not equal to the category total. Percent of all AEFI reports is calculated by dividing the number of event or category-specific AEFI reports by the total number of AEFI reports with at least one adverse event reported in a given year.

General limitations of AEFI surveillance

General limitations of the 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. Causality assessment is not part of the passive AEFI surveillance process. 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

¹ International Conference on Harmonisation Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH harmonised tripartite guideline. Clinical safety data management: definitions and standards for expedited reporting. E2A [Internet]. Geneva: International Conference on Harmonisation; 1994 [cited 2018 Aug 20]. Available from:

ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2A/Step4/E2A_Guideline.pdf

² International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH harmonized tripartite guideline. Post-approval safety data management: definitions and standards for expedited reporting. E2D [Internet]. Geneva: International Conference on Harmonisation; 2003 [cited 2018 Aug 20]. Available from:

ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2D/Step4/E2D_Guideline.pdf

possible; further study would be required. For more details, please see the the [Technical Annex of the Annual Report on Vaccine Safety in Ontario](#).

Suggested citations

Citation for tool overall

Ontario Agency for Health Protection and Promotion (Public Health Ontario). Vaccine safety surveillance [Internet]. Toronto, ON: Queen's Printer for Ontario; 2018 [cited 2018 Nov 15]. Available from: <http://www.publichealthontario.ca/en/DataAndAnalytics/pages/aefi.aspx>

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

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Vaccine safety surveillance: number of AEFI reports and AEFI reporting rate in Ontario, 2012-17 [Internet]. Toronto, ON: Queen's Printer for Ontario; 2018 [cited 2018 Nov 15].

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

Source: Ontario Agency for Health Protection and Promotion (Public Health Ontario). Vaccine safety surveillance: reporting rate of AEFIs in Ontario – all vaccines, 2017 [Internet]. Toronto, ON: Queen’s Printer for Ontario; 2018 [cited 2018 Nov 15].

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 map.

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 in Ontario, 2017 [Internet]. Toronto, ON: Queen’s Printer for Ontario; 2018 [cited 2018 Nov 15].

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.